

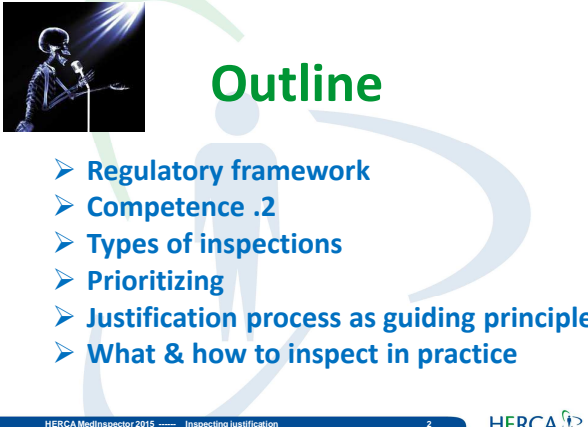
1st European Inspection Workshop
HERCA MedInspector 2015

Things to consider when inspecting justification

Lodewijk Van Bladel
FANC

FANC
federal agency for nuclear control

HERCA
Heads of the European Radiological protection Competent Authorities



Outline

- Regulatory framework
- Competence .2
- Types of inspections
- Prioritizing
- Justification process as guiding principle
- What & how to inspect in practice

HERCA MedInspector 2015 — Inspecting Justification 2 HERCA

Justification: Regulatory framework

- Eu Directives (Med, New BSS)
 - MS shall insure that the principle of justification is applied... and in particular all individual exposures are justified in advance....
 - The referrer and practitioner, as specified by MS, seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure
 - The referrer and the practitioner are involved, as specified by MS, in the justification process of individual medical exposures
 - Whenever practicable and prior to the exposure taking place, the practitioner and the referrer, as specified by MS, ensures that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters.....

HERCA MedInspector 2015 — Inspecting Justification 3 HERCA

Justification: Regulatory framework

- Eu Directives (Med, New BSS)
 - MS shall insure that the principle of justification is applied... and in particular all individual exposures are justified in advance....
 - The referrer and practitioner, as specified by MS, seek, where practicable, to obtain previous diagnostic information or medical records relevant to the planned exposure and consider these data to avoid unnecessary exposure
 - The referrer and the practitioner are involved, as specified by MS, in the justification process of individual medical exposures
 - Whenever practicable and prior to the exposure taking place, the practitioner and the referrer, as specified by MS, ensures that the patient or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the medical exposure. Similar information as well as relevant guidance shall be given to carers and comforters.....

HERCA MedInspector 2015 — Inspecting Justification 4 HERCA

Justification: Regulatory framework

- Eu Directives (Med, New BSS)
 - MS shall insure that referral guidelines, taking into account the radiation doses, are available to the referrers
 - MS shall insure that clinical audits are carried out in accordance with national procedures
 - MS shall ensure that training and recognition requirements, ..., for the practitioner, the medical physics expert and the individuals, to which practical aspects of procedures may be delegated, are met
 - MS shall encourage the introduction of a course on RPR in the basic curriculum of medical and dental schools
 - MS shall ensure that that the referrer and the practitioner, as appropriate, inquire, as specified by MS, whether the individual subject to medical exposure is pregnant or breastfeeding,...

HERCA MedInspector 2015 — Inspecting Justification 5 HERCA

Justification: Regulatory framework

- Eu Directives (Med, New BSS)
 - MS shall insure that referral guidelines, taking into account the radiation doses, are available to the referrers
 - MS shall insure that clinical audits are carried out in accordance with national procedures
 - MS shall ensure that training and recognition requirements, ..., for the practitioner, the medical physics expert and the individuals, to which practical aspects of procedures may be delegated, are met
 - MS shall encourage the introduction of a course on RPR in the basic curriculum of medical and dental schools
 - MS shall ensure that that the referrer and the practitioner, as appropriate, inquire, as specified by MS, whether the individual subject to medical exposure is pregnant or breastfeeding,...

HERCA MedInspector 2015 — Inspecting Justification 6 HERCA

Justification: Regulatory framework


- **Your national regulation**
 - The way the Directives relevant to medical applications are **transposed and implemented** in your country will set the framework for, and the borderlines of what you can inspect
 - Make sure that when you transpose the Directive(s) into national regulation, requirements are very clear and responsibilities unambiguously assigned, so that **compliance verification** becomes straightforward;

HERCA MedInspector 2015 — Inspecting justification 7 HERCA

Inspecting justification: a question of competence (.2)

- **Formal aspect: competences legally assigned to you**
 - What are you supposed to do/must you do?
 - What are you allowed to do?
 - *Going round limitations, such as access to patient data:*
 - Operate within the law yourself!
 - anonymised data, help from third party (such as MD of professional society, health Ministry, Order of Medical doctors, Court order if need be)
- **E&T aspect: what are you “technically” able to do?**
 - Background: engineer? physicist? radiographer? MD? radiologist?
 - Specific E&T, experience, updates(CPD)
 - Personality and attitude


HERCA MedInspector 2015 — Inspecting justification 8 HERCA



Inspecting justification: Types of inspections

- **Pro-active inspection, announced**
- **Pro-active inspection, unannounced**
- **Reactive inspection**
- **Broad scope, general inspection vs specifically targeted**

HERCA MedInspector 2015 — Inspecting justification 9 HERCA



Inspecting justification: Prioritizing efforts

- **Rad risks/health benefit ratio = high**
 - Radiation **dose** considerations (individual/collective)
 - Vulnerability of **exposed subject** : paediatric patient, (possible) pregnancy
 - **Low probability of benefit** to the exposed subject: screening, IHA,....
- **System risks**
 - Anything “**new**”: department, equipment, procedure, people
 - **Time**: night, in particular during WE’s, holidays
 - **Risk-prone conditions**: self-presentation, self-referral, teleradiology, CDS , computerised order entry systems

HERCA MedInspector 2015 — Inspecting justification 10 HERCA

Justification process

- Follows **clinical logic**:
 - Easy for you, recognisable your from own experience
 - Easy for caregivers, “their” logic

IMPORTANT NOTICE: repartitioning of tasks may be different in your country from what is further described, could depend on the local setting...

➤ This process as **backbone** of your inspection



HERCA MedInspector 2015 — Inspecting justification 11



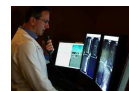
Justification process: part 1

- **Clinical information:**
 - antecedents (patient history) including imaging history
 - complaints/requests,....
 - Observations, signs and symptoms
- **Clinical question (s) :**
 - What do I want verified?
 - What am I thinking about?: diagnosis , ΔΔ,
 - What Δ do I want excluded?
- **Check clinical imaging guidelines (referral guidelines)**
- **Information of patient (and/or representative) on “ALL pro’s and con’s of radiological procedure”, then verify consent**
- **Referral containing a concise version of the above**

HERCA MedInspector 2015 — Inspecting justification 12

Justification process: part 2

- Appointment & reception
 - Right patient?
 - Check RIS, patient record for imaging history?
 - Request filled in properly?
 - Request guideline conformal?
 - Standard information delivered?
 - Possible pregnancy, breast feeding
- Radiographer:
 - Right patient? Right side?
 - Request clear, reasonable, guideline conformal?
 - Patient correctly informed and consenting?
 - Possible pregnancy, breast feeding
- Radiological practitioner
 - Final decision in all (esp. doubtful) situations:
 - Overall responsibility for QA & Auditing
 - Procedures, Staff E&T, repartitioning of tasks & responsibilities
 - Communication with referrer, feedback on appropriateness
 - Incident/accident management

HERCA MedInspector 2015 — Inspecting justification 13 HERCA

Inspection in practice


- Your regulatory authority's QA!
 - Recruitment, selection
 - Procedures for inspections
 - E&T, CPD of inspectors
 - experience exchange and feedback
 - "Customer" feedback: how did they experience our visit?
- Come prepared!
 - RP Regulations know the by heart and have them at hand
 - Don't waste time on things that can be checked in advance: licenses, authorisations, notifications,.... their website may be interesting
 - Clear focus: what exactly do I want to check?




HERCA MedInspector 2015 — Inspecting justification 14 HERCA

Inspection in practice (ctd.)

- Attitude & perspective
 - Inspection = intrusive, imposed, sanctions possible: don't expect them to love you coming! More so if unannounced, reactive
 - Respect clinical workflow as much as possible: do not immobilize the complete staff or department for the duration of your visit (unless something seriously wrong)
 - Respect general and also local rules and habits: privacy of patients, hygiene (such as in surgical ward!), hierarchy, language!
 - Respect the expertise of the inspected!
 - Look at the bigger picture: conditions in which health care provided!
 - Don't expect everything to be flawless: you will find infractions
 - You may also find things that are surprisingly good and may serve as an example to others (and to yourself)
 - Debrief locally when inspection finished, in front of those who are responsible "in fine": the good, the bad and the ugly
 - Opportunity to improve rather than reason to punish (PDCA) unless....



HERCA MedInspector 2015 — Inspecting justification 15 HERCA

Thank you for your attention




HERCA MedInspector 2015 — Inspecting justification 16 HERCA

QUESTIONS?



HERCA MedInspector 2015 — Inspecting justification 17 HERCA



HERCA MedInspector 2015 — Inspecting justification 18 HERCA