Justification of Medical Exposure in Diagnostic Imaging

Mobile and portable X-ray devices
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Mobile and portable X-ray devices special problems

1. by the design;
   - used in hospitals, clinics

2. or any X-ray device
   - on the vehicle
Mobile and portable X-ray devices: special problems

Mobile X-ray devices:

- used in hospitals, clinics:
  - it's not possible to take a patient to the radiology department
  - in operating theaters (several applications – cardiology, urology, surgery, neurosurgery etc.)
  - in emergency units
Mobile and portable X-ray devices
special problems

„Mobile“ - X-ray on the vehicle:

- CT machines on trailers:
  - reconstruction of old CT rooms
  - remote areas – go to a patient??
  - developing countries
Mobile and portable X-ray devices special problems

„Mobile“ - X-ray on the vehicle:

- **Angiography** on trucks (full angiography equipment)
  - „Rental“ service for small hospitals/clinics:
    - not enough patients
    - distant areas
Mobile and portable X-ray devices special problems

„Mobile“ - X-ray on the vehicle:

- Radiography
  - C-arms driven from one hospital to another – e.g. monitoring lithotripsy procedures

- Mammography on vehicles
  - screening? in order to be available in the whole country
Mobile and portable X-ray devices: special problems

Portable X-ray devices:
- Primarily designed and intended to be used in specific cases:
  - nursing homes, private homes
  - correctional facilities
  - military field clinics, hospitals
- In general - where the X-ray machine must be brought to a patient
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Portable X-ray devices:
- In majority - radiography and dental devices
  - **Advantage**: light, easy to carry, to transport
  - **Disadvantage**: appropriate quality of the examination is a question, image quality, dose to the staff and public, ...
Mobile and portable X-ray devices special problems

The utilization of mobile and portable X-ray devices are subject to authorization

Should be the same as for fixed X-ray installations
Mobile and portable X-ray devices special problems

Common approach is to restrict the utilization of mobile and portable devices only to the justified cases
Mobile and portable X-ray devices special problems

- But should be the **specific license** for the "**practice on a wheel**"?
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**Justification**: the same approach as for “standards radiological procedure”

- **General** – medical uses of radiation
- **Generic** – medical procedure (such as value of a mammography as a practice)
- **Specific** – (procedure/patient) – to take into account particular issues
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Justification:

- Specific – (procedure/patient) – taking into account particular issues:
  - Why? (why it is not possible to use standard examination procedure on “fixed“ devices)?
  - Who is referral practitioner in these cases? (agreement whit general practitioners, agreement with clinics/hospitals,...)?
  - What about self referral
  - For whom it is intended (category of patients – homes for old or disabled individuals, poor access to radiology department,...)?
  - Who then justify the procedure (radiologist?, also in case of “angiography on trucks“)?
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Justification - cont.:

- **Who** assess the condition during the examination (radiation protection issues - staff/patient/public)?
- Mobile X-ray devices - sometimes **used by other professionals** (operating rooms)
- **Is there enough staff** to perform the examination properly?
- Is the staff **satisfactory trained**?
- Has the staff **enough experience**?
- How to **inform patient** and how to obtain the patient **consent**?
- **Who finally** has the patient files? – (passed back to general practitioners, clinics, patient?)
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Optimization

- Is QC performed and is it appropriate?
- Does transport have influence on quality of the functioning of the device (velocity, rattling, dust..)?
- Is it necessary to perform some kind of test after long hours driving?
- Who is capable to perform and evaluate the test if anybody?
- What about the shielding issues – trucks – are they assessed/approved?
Specific example of licensing of portable X-ray dental devices

- Primarily intended to be used only in specific cases – not for a routine examination of patients (hurricane – „Catherina“, forensic exam.,....)
- But the characteristics of the device would allow to use it more frequently
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Request to use it routinely - the main reasons:

- to save expenses (device could be shared by several doctors e.g. price of the device, maintenance, servicing and regular QC check,..)
- easy to handle, fast examination, good image quality
- type approved – and „commonly“ used in European countries (importer declared)
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Process of justification:

- General – yes – medical exposure
- Generic – yes - value of dental X-ray examination – but this could be a question, the device was primarily intended to be used only in specific cases

Device is type approved as a medical device – and has a **CE certification (?)**

Negotiation with the **Czech Dental Chamber**– mutual agreement
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In the justification process the applicant has to explain why this device he needs

- Acceptable reasons are:
  - It is allowed to use it only if there is not possible to install fixed device
  - For specific cases:
    - examination of patient in the facilities for old patients, homes for pensioners,
    - private homes if patient could not be moved to the dentist
    - the dentist has more offices in distant areas

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Specific requirements for the device have to be fulfilled:

- device is equipped with appropriate holder of image receptor - to assure the fixed distance focus – skin and proper focusing
- security of the device has to be ensured
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Quality of radiation protection has to be at least the same as for the procedure with a standard intraoral device proved by the evidence of optimization which includes:

- Monitoring of the workplace
  scattered radiation to be measured at the points – hands, eyes, chest, gonads and where other individuals could be present during the exposure.
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Additional requirements:
- on **acceptance test** and **constancy tests** to assure the minimal requested exposure time (0.2 s)
- to **image receptor**
  - only digital
  - sensitivity of the imaging system