



Inspections of x-ray equipment at Danish public hospitals 2013 - 2015

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Danish legislation

- Sundhedsstyrelsens bekendtgørelse nr. 975 af 16. december 1998 om medicinsk røntgenanlæg til undersøgelse af patienter
- Every single x-ray equipment has to be registered in a database maintained by NIRP
- Responsibility of X-ray equipment is divided between a named radiologist and physicist
- If a department has more than one piece of equipment the department needs to implement a quality assurance system

Traditional inspection of the quality assurance system

- Inspection of the quality assurance system of a department is quite cumbersome with several interviews and a review of the overall system
- It usually takes a few days and only a fraction of the equipment is inspected visually
- In 2009 and 2010 only one department yearly at a public hospital was inspected.
- The personnel at the hospitals was certainly interested in more inspections and visibility by NIRP

Technical inspection of the medical physicist 1/2

- New strategy for public hospitals:
- Follow one physicist through every single piece of equipment for which he or she is responsible
- The responsibilities of a medical physicist includes room shielding, equipment optimization, lead shielding, training of personnel, dose monitoring, quality control
- The way the responsibilities of the physicist is entrusted to other personnel is very different between the 5 different Danish hospital regions and further down to hospital units

Technical inspection of the medical physicist 2/2

- The observations made will have an indirect effect on the quality assurance system
- Some observations such as procedure clarifications will even have a direct effect on the quality system

Performing the inspection

1/3

- All public departments covered from January 2013 till May 2015
Except the two minor hospitals already visited in 2009-10
- The physicist would receive a 2 month notice for the visit with suggested dates and duration by NIRP
- The physicist had the responsibility to plan the visit
- Inspections always included 2 persons and lasted from 1 day to 1 week

Performing the inspection

2/3

- Included an interview with the physicist
- 'Random' check of several controls
 - Chosen to represent different equipment types
 - Equipment with previous known difficulties
 - Equipment at departments traditionally having little contact with an x-ray department.
- Included some equipment at the hospitals that has no requirement of supervision by a physicist such as dental and pathological equipment
- The physicist was encouraged to let personnel know of the inspection so they could ask NIRP what ever questions they liked during our visits

Performing the inspection

3/3

- 13 physicists visited covering all equipment in Denmark excluding some PET/SPECT-CTs
- Nearly 1200 pieces of equipment at almost 250 departments at more than 70 places inspected.
- Demands collected departmentwise
- A few severe demands out of the scope of the physicist send directly to hospital direction
- Some general observations regarding controls performed by a company sent to company

Places visited



Typical observations and demands

1/3

- Equipment:
 - Unregistered
 - Moved
 - Room/shielding not as on drawing submitted to NIRP
 - Responsible radiologist changed

- Lacking documentation

- Apron checks not systemized

- Audit of quality system not performed

- Education and dose surveillance of staff assisting in fluoroscopy

Typical observations and demands

2/3

- Constancy test not performed or does not contain enough information to show that requirements are fulfilled

- Requirements to a control document specified.

The following minimum information shall be contained:

- Apparatus, room and hospital
- Date of performed control
- Measured data
- Reference data with tolerances
- Information of person performing check
- Evaluation of the control (ok/not ok)
- Space to write comments or corrective actions
- All above points shall appear systematically and organized to give an overview of the shape of the equipment and the regularity of performed checks and that operating condition are observed

Typical observations and demands

3/3

- Shielding of operating position (mammography screening)
- Visibility of patient from operating position
- Lead aprons, gloves and gonadal protection missing or not accessible
- Patient dose optimization
- Procedure clarifications

Actions

- Several immediate prohibitions for using equipment due to
 - Lacking registration
 - lacking documentation
 - Documentation showing requirements not fulfilled
- Requirements for diagnostic monitors not up to date
 - A working group has been established (NIRP initiative)
- Clarification on what to be measured for mammo equipment
 - A working group has been established (physicists initiative)
- Operators of bone mineral scanners need education (both for medical and research applications)
 - Emphasized a newly made set of less demanding requirement to operators as opposed to a be a fully educated radiographer

Letters to Companies

- Controls stating that equipment is not functioning
- Controls stating that equipment is functioning – but in fact not
- General errors appears in control template even after company has been notified
- General problem with equipment type
 - Adjusting the way dose response is calculated
- Initial quality control to be performed at address of permanent location
- Controls not covering all required aspects (typical AEC)

Curiosities

- Gardeners unsure working outside building containing PET/CT
- Mineral bone scanning of personnel during education
- Physicist not having access to documents in database due to firewalls between access points at different hospitals
- Room height very low. Not all projections could be performed with a FFD of minimum 1 m.
- Radioactivity sign used improperly to signal “Stay out”
- Changes of environment with respect to existing examination room
 - Adding new building next to room
 - Adding rehabilitation facilities on lawn outside room

Outcome and lessons learned

- Physicists have been positive towards the concept
- Physicist perform a substantial amount of work
- The inspection gives an overall view of the condition at the hospital as opposed to a thorough inspection of a single department
- Database up to date and information extended compared to old DB from before 2012
- Ready to focus on some new aspects
 - quality assurance system
 - diagnostic monitors
 - mammography controls