



Survey results on authorization process for interventional and fluoroscopy in Europe

Question to ERPAN
september 2014





Question from ASN to ERPAN

Context

In France, except for computed tomography, all electrical devices in the medical field are subject to registration. For electrical devices including conventional and interventional radiology there is no graded approach with regard to radiation protection for patients and workers exposed. The French Nuclear Safety Authority (ASN) is working on a revision of the authorization system

7 countries have answered

(Slovenia, Belgium, Switzerland, Romania, Norway, Greece, Ireland)

Questions 1 and 2

- What is subject to an authorization process for structures practicing interventional radiology and fluoroscopy ? (acts, equipments, facilities, departments, ..)
- License, registration ? Fixed or mobile ?





Question from ASN to ERPAN

Answer

For all countries :

All medical facilities that use equipment for interventional radiology and fluoroscopy are subject to licensing regardless if units are fixed or mobile=> either practice / facility or equipment (both for Slovenia)

- trade, installation and maintenance (manufacturers)
- practice of custody or use, commissioning/decommissioning (users)
- siting and construction (Romania)

All radiation emitting equipment has to be registered before use (Norway)



Question from ASN to ERPAN

Question

- Who is the holder of the license ?

Answer

A legal entity (hospital ..) or a person

A medical practitioner is also subject to licensing (Belgium)

In France, the holder is a physician with a specific qualification (interventional practitioner for interventional radiology or guided procedure)





Question from ASN to ERPAN

Question 4

- What is the duration of the license or registration ?

Answer

During (Years)	1	2	3	5	10	15
Number of countries = 8	1	1	2	2	3	1

Slovenia : up to 3 years when a new practice is introduced and up to 10 years for license extensions.

Belgium, 10 years for medial professional and 15 for the facility

Ireland :1, 2 or 3 years according to the services provided by the hospital

Question 5

- Is a graded approach implemented ?
- If yes, please provide a short description ?

Answer

Yes for all countries except Belgium

- Duration of the license (Ireland)
- Specific requirements : involvement of medical physicist, QA more frequent, diagnostic reference level for high dose range
- No special shielding for fluoroscopy examinations with mobile unit (Romania)
- More frequent inspections





Question from ASN to ERPAN

Question 5

- What are the prospects in the context of the implementation of the Euratom 2013/59 directive ?

Answer

A project for the transposition of the Euratom 2013/59 directive has been initiated for all countries. (Not so relevant in Norway)

Graded approach high dose/low dose and pediatric patients and screening (Slovenia), individual dosimetry dedicated to occupational exposure of the lens of eye (Romania), graded approach to authorisation in Ireland (IR and fluoroscopy will remain at licensing)

