

Medical Physics Department: framework, objective and perspectives

2 December 2022

Overview

1. Department of medical physics: aim and objectives
2. Department of medical physics: legal framework
3. Upcoming legislative initiatives
4. Questions

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Aim and objectives

What is medical physics?

2013/59/EURATOM

Acting or giving advice on matters relating to radiation physics applied to medical exposure

Medical exposure = exposure of patient, carers and comforters, participants in screening, volunteers in clinical studies

The medical physics expert takes responsibility for dosimetry, including physical measurements for evaluation of the dose delivered to the patient and other individuals subject to medical exposure, give advice on medical radiological equipment, and contribute in particular to the following:

- optimisation of the radiation protection of medical exposures
- the definition and performance of quality assurance
- acceptance testing
- the preparation of technical specifications and installation design
- the surveillance of the medical radiological installations
- the analysis (potential) accidental or unintended medical exposures
- the selection of equipment required to perform radiation protection measurements
- the training of practitioners and other staff in relevant aspects of radiation protection

Aim and objectives

Why a department?

- Empowerment of the “exploitant” concerning medical physics
- Recognising medical physics as a vital part of modern medicine
 - necessary resources to enable real and qualitative implementation of medical physics
- Strengthen role, coordination and visibility of medical physics at hospital level
 - multidisciplinary and integrated approach to (new) medical technologies and projects
 - single point of contact for external communication, e.g. with FANC
 - single point of contact for internal communication and procedures, e.g. with the health physics department, procurement department, technical department, etc.
 - framework external recognised medical physics experts

Overview

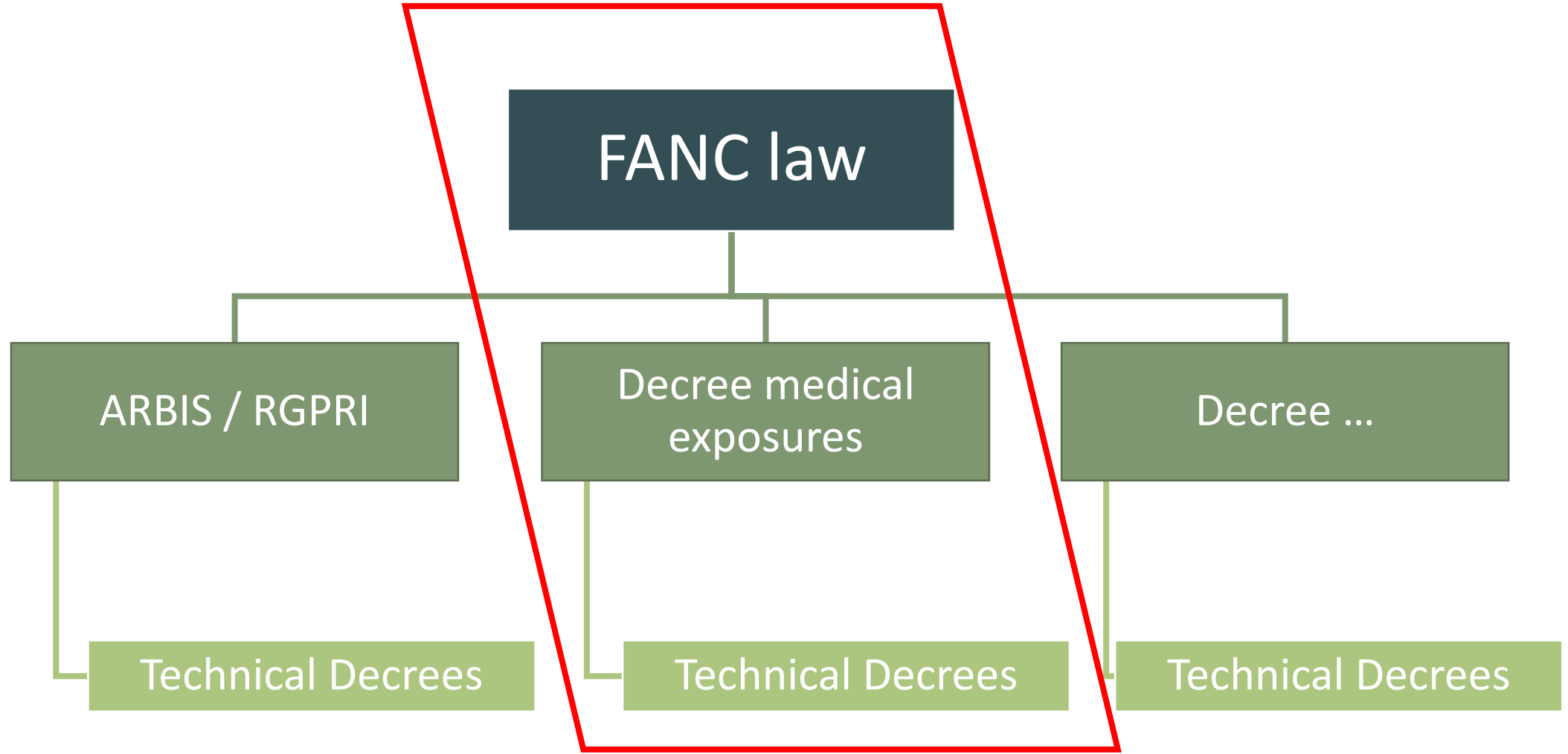
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Legal framework

LAWS

**Royal
Decrees**

**FANC
decrees**



Terminology

EN	NL	FR
	Exploitant <i>de persoon aan wie de exploitatievergunning werd verleend (elke natuurlijke of rechtspersoon die verantwoordelijk is voor de inrichting onderhevig aan de vergunnings- of aangifteplicht overeenkomstig de bepalingen die voortvloeien uit artikel 17 uit de FANC-wet)</i>	Exploitant <i>la personne à qui l'autorisation d'exploitation a été délivrée (toute personne physique ou morale qui assume la responsabilité de l'établissement devant faire l'objet d'une autorisation ou d'une déclaration conformément aux dispositions découlant de l'article 17 du loi AFCN)</i>
Establishment	Inrichting	Etablissement
Entitled person	Gemachtigde <i>de persoon aan wie de practicus de praktische aspecten van medisch-radiologische handelingen kan delegeren krachtens de nationale voorschriften die van toepassing zijn</i>	Personne habilitée <i>la personne à laquelle le praticien peut déléguer les aspects pratiques des pratiques radiologiques médicales, conformément aux prescriptions nationales en vigueur</i>
Practitioner	Practicus <i>(tand)arts die bevoegd is om de medische verantwoordelijkheid te dragen voor een individuele medische blootstelling of blootstelling bij niet-medische beeldvorming met medisch-radiologische uitrustingen in overeenstemming met nationale wettelijke en reglementaire bepalingen</i>	Praticien <i>un médecin/dentiste habilité à assumer la responsabilité médicale d'une exposition médicale individuelle ou d'une exposition à des fins d'imagerie non médicale avec des équipements radiologiques médicaux, conformément aux dispositions légales et réglementaires nationales</i>
Health physics	Fysische controle	Contrôle physique

Legal framework

Who is concerned?

Each “exploitant” of a establishment with medical radiological equipment has to install a medical physics department (FANC law)

*This department is responsible for the **organisation of the medical radiation physics** in the establishment, including identification of resources needed to fulfil the regulatory requirements set by the type of the establishment and the objectives of the establishment in the field of medical radiation physics*

Exemption for establishments of class III without CT and/or without interventional radiology

Deadlines (decree on medical exposures):

- Establishments that apply radiotherapy applications:
1/10/2021 (postponed due to COVID, originally 20/2/2021)
- Other: **20/02/2023**

Legal framework

The department

- The organisation and resources of the Medical Physics Department depend on
 - the specific areas of activity
 - on the technical equipment and its complexity
 - on the number of treatments and examinations and their complexity,
 - on patient safety, quality and risk management activities
 - where appropriate, on teaching and research activities at the facility.
- The department has a department head
- The “exploitant” must provide its medical radiation physics department with all resources, information and documents necessary to carry out its mission.

Legal framework

The department

- assure that the MPEs can act independently

The establishment of an medical physics department does not change the close collaboration of the recognised MPEs with the medical doctors and other members of the medical team for the benefit of the patient!

Remarks: There should be only one department with one head

The head of the department: who?

- A recognised medical physics expert (MPE), employee of the exploitant
- If exploitant has no MPE employed
 - employee with (minimal) training as determined in
 - article 85, § 2 **and** § 3 for class III establishments (= training entitled persons X-rays)
 - 85, § 2, § 3 **and** § 7 for class II establishments (training entitled persons X-rays + nucl. med.)
- The head depends directly on the “exploitant”
- Is protected against resignation based on tasks or decisions taken in a role as head of the department
- Coordinates and organises the proper execution of the task assigned to his department (this also includes procedures for when MPEs should intervene, on-call service, ...)

The head of the department: specific tasks

- For each equipment, system or process, guarantee that:
 - recognised experts in each of the relevant fields of competence (RT, NG, RX) are implicated
 - written clearance before clinical use, after acceptance and commissioning procedures medical physics
- Consults regularly with
 - The medical heads of concerned medical departments
 - The chief medical officer

Legal framework

The head of the department

Time use of the head

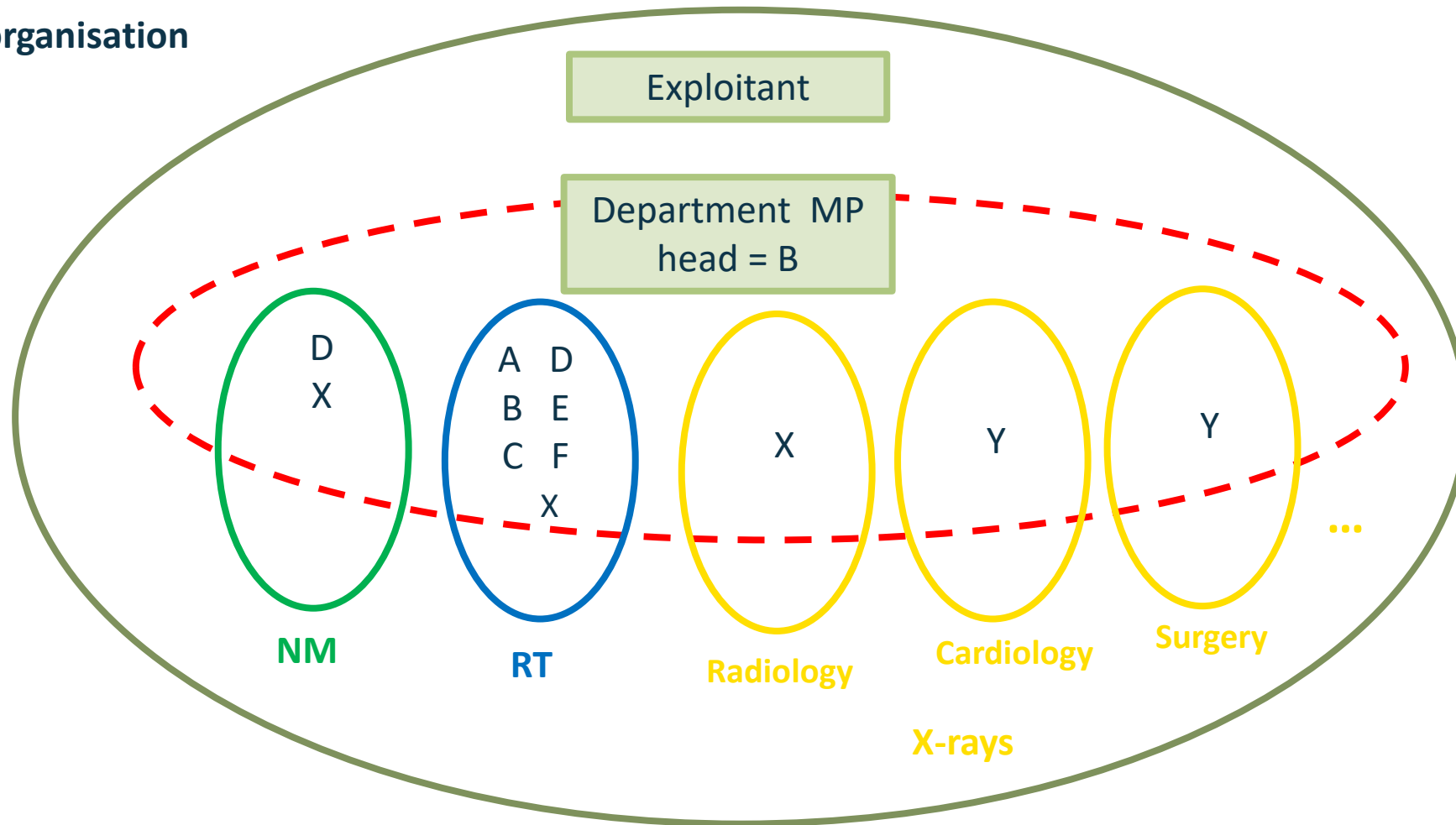
- No requirements for assignment as head, but this should be in line with the size of the department, the number of devices, any geographical distribution of sites, ...
- If MPE: min. 20% MPE assignment

Continual education

- If MPE:
 - regular continuous education as MPE
 - of which 2h/3years specific training for heads (organized by FANC)
- If not MPE:
 - 10h every year
 - + 2h/3years specific training for heads (organized by FANC)

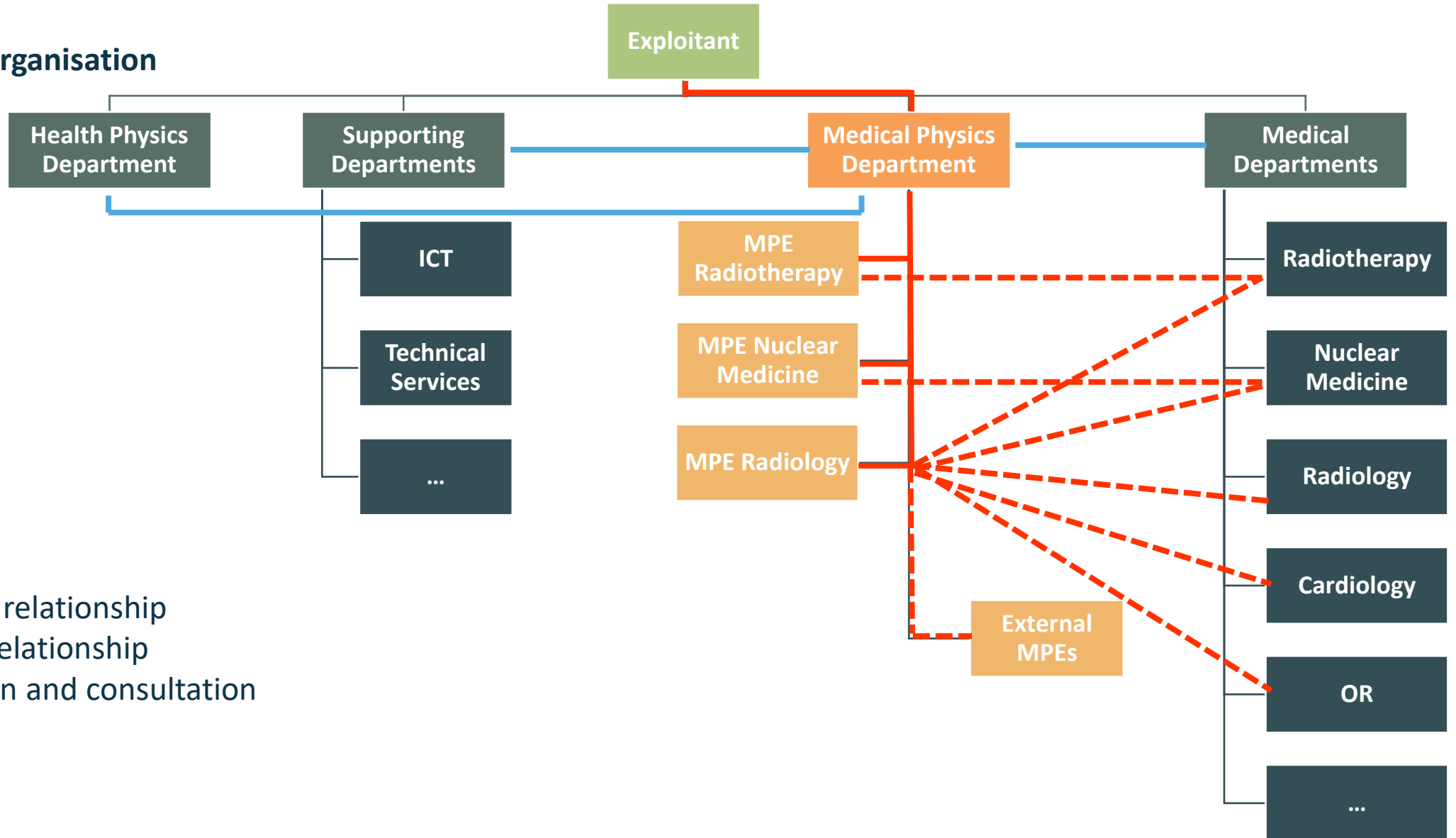
Legal framework




Practical organisation



Legal framework

Practical organisation



-  Hierarchical relationship
-  Functional relationship
-  Collaboration and consultation

Legal framework

Common/joint departments → Prior approval by FANC !

- At least one MPE is employee of the concerned establishments
- Head is an MPE
- Written agreement between the exploitants
 - Responsibilities MPEs and head
 - Time occupation MPEs and head

Point of attention: feasibility! This depends on

- *Number of establishments*
- *Numbers of devices*
- *Geographical location of the different sites*
- *Time allocation of the head*
- *Existing collaborations*
- ...

Legal framework

Verification by FANC?

- By default when application for a new license or adaptation of a license after the relevant deadlines (1/10/2021 or 20/2/2023)

→ be aware that this can be a blocking factor in the progress of the license application

Technical decree describing the modalities for the description of the organisation of medical physics in the application for the facility's operating licence. That description will have to describe a number of processes, relating to the achievement of certain tasks and regulatory requirements.

- Common/joint departments need prior approval!
- By inspection

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Upcoming legislative initiatives

Proposal for adaptation of the decree on medical exposures (ready for official advice)

future legislation !

Most important proposal related to the organisation of the medical physics department

- Possibility to have deputy-head(s)
 - training requirements comparable to head
 - hierarchical line between MPE and head medical physics department cannot be interrupted by a non-MPE

→ *principle of deputy head is already allowed today under same conditions*
- Training for non-MPE head and deputy head
 - Related to the applications used in the establishment (or in case of a deputy head, the applications used in the concerning departments) and not to the class of the license
- Continuous education for MPE head
 - “regular” continuous education can be related to other domains than the domain of competence of the recognition of the MPE
- Extra clarification on hierarchical link between head and exploitant and MPE and head.

Upcoming legislative initiatives

Proposal for adaptation of the decree on medical exposures (ready for official advice)

future legislation !

Most important proposal related to the organisation of the medical physics department

- QC
 - Maximal interval between 2 full QC procedures (14 months)
 - Report of last full QC and possible follow-up visits of MPE remain with device upon sale
 - Verification of prohibitions related to medical physics
- Devices for external radiotherapy with a nominal radiation energy of more than 1 MeV should be subject to an external dosimetry audit before the first clinical use.
- FANC can
 - exempt certain types of brachytherapy from the attendance requirements of an MPE
 - determine a list of maintenance, modification or repair about which the recognised expert in medical physics must be informed

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