A new approach for the implementation of the « generic » justification principle

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BSS - Article 55. 2.a :

“ **New types** of practices involving medical exposure are justified **in advance** before being **generally** adopted”

How to transpose this article in the French regulation?

A point on the « French » terminology (a “practice” is not “une pratique”)

- A “practice” is a “nuclear activity” (in French)
- “Medical practices” (in English) are included in “nuclear activities” (in French) :
  - Nuclear medicine
  - Radiotherapy
  - Radiology
  - Interventional imaging
  - Dental radiology
- “Une pratique médicale” (in French) : an examination, a treatment

BSS - Article 19.1 (justification level 1 for medical application)

“ New classes or types of practices (“nuclear activity”) resulting in exposure to ionizing radiation are justified ~~**in advance**~~ before being ~~**generally**~~ adopted”

Existing legislation :

- The definition of the justification principle for all nuclear activities : in the law since 2001 but updated in February 2016
- For medical applications, a general provision in the law, since 2001 : *“the use of IR on the human body is only permitted for treatment, diagnostic, biomedical research and screening (disease) ….* “Justification level 1”

In preparation, to transpose the BSS art.19.1, a general regulatory frame for all nuclear activities (industry, research, medical, transport …):

- A decree (draft), submitted to a public consultation, in September 2016

The decree (draft):

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- Elements for justification are under the responsibility of the “undertaking”
- **“Categories”** of “nuclear activities” will be defined by order, considering existing practices : definition of “categories” for the justification level 1 in the medical field will be needed
- Simplification :Elements for justification must be communicated to the regulatory authority, **only for new “nuclear activity” not included in a category**
- The information on clinical evaluation (BSS, art. 78.2) for new medical device to be considered

“Categories” of “nuclear activities” in the medical field : to be defined in 2017

First proposal, with reference to medical device or radiopharmaceutic :

- External radiotherapy (using accelerators)
- Stereotaxic radiotherapy (using accelerators or other technics)
- Brachytherapy (identification of sealed sources yet authorised : I125, …)
- Internal radiotherapy (identification of radionuclides yet authorised)
- Medical imaging in nuclear medicine (identification of radionuclides yet authorised)
- Medical imaging with CT
- Medical imaging in conventional radiology (with X Ray generators)
- Medical imaging in dental radiology (with X Ray generators)
- Interventional radiology or interventional imaging (the definition of “categories” seems to be difficult : *the reference to equipment is not sufficient, the types of exposure depend of the act and the number of act is high*
- …

The definition of categories should be also use for the classification between registration and licensing (BSS, art.27)

The generic justification (level 2)

" **New types** of practices involving medical exposure are justified **in advance** before being **generally** adopted"

The new general regulatory frame for all nuclear activities (nuclear, research, medical, transport…) not sufficient for the "generic justification" (level 2) of medical exposure :

- Since 2003, national guidelines ("good pratices"), prepared by medical societies and deemed to be issued by ASN, define for medical indications the recommended "type of examination/treatment"

- i.e. "the guide of good use of medical examinations" (GBU, 2013), and a new guide in radiotherapy (RECORAD, October 2016)

The French referral guidelines

GBU (2013): gives the most appropriate examination for a particular patient

- Inhalation of objects by children : Thoracic radiography is indicated
- Follow up of lymphoma : chest, abdomen and pelvis (CAP) scanner is indicated
- Aortic dissection : Magnetic Resonance Imaging (MRI) and CAP scanner are indicated
- Multiple sclerosis : MRI is indicated

RECORAD (2016) : gives the most appropriate radiation treatment for a particular patient

ex : for the breast, recommandations :

- depending on the type of initial surgery (lumpectomy / masectomy)
- on the total dose and dose per fraction (usual or hypofractionnated)
- on the target delineation
- on the technique to be used (conventional, modulated, with breath hold, intraoperative…)

The decree (draft) : the national guidelines will be prepared by medical societies **but approved by Health ministry** (reinforced the link with reimbursement)

The national guidelines : updated each 5/10 years, not appropriated for new act/examination resulting of the use of new technics.

A complementary approach for new technics/examination/treatment

(for the implementation of BSS - Article 55.2.a)

2 questions :

- How to deal with the justification of new types of examination (medical imaging) or of treatments (therapy) ? With (or not) a new technology ?
- How to avoid administrative burden before the implementation of a new technology, a new examination (i.e.with new radiopharmaceutical) …

A complementary “approach” for the implementation of BSS - Article 55.2.a

- Organizing a “watch” on new technics and on new examination or treatment : strong collaboration between medical societies, expert bodies and regulators at national level

- Identifying the “stakes “ from radiation protection point of view (patient, occupational and public exposure) and the needs in terms of research funding

- The decree (draft) : **possibility (depending of the stakes)** to issue a **regulatory decision to support the implementation** of a new technic/examination/treatment, during a transitory period :
  - To collect data related to benefit/risk ;
  - To state specific radiation protection rules, if needed.

- Organizing the evaluation of “justification” with an **expert committee**, at the end of the transitory period

- And updating national guidelines

Conclusion

The consultation on the decree is not at the end (caution)

After the publication :

1. To organize the collaboration between “stake holders” (with a new Expert committee)
2. To test the new approach : which will be the new technic “candidate for the new approach” ?

3. Probably in radiotherapy