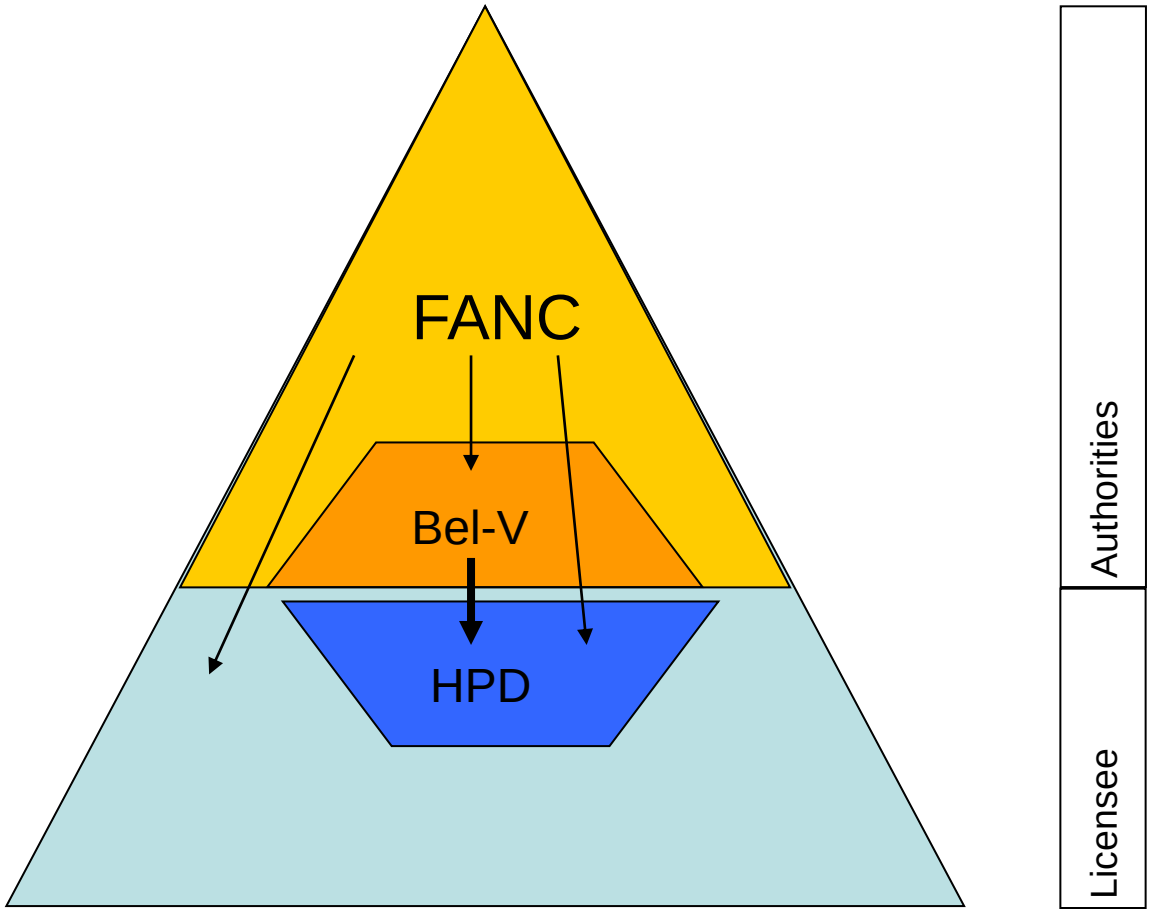
E. Minne, C. Peters, C. Mommaert, C. Kennes, G. Degreef, G. Cortenbosch,
F. Schmitz, M. Van haesendonck, H. Drymael (Bel V)
*P. Carlier (*Federal Agency for Nuclear Control)

Recent evolution in the regulatory framework of the Belgian class II nuclear installations such as irradiators and accelerators

Content

- The Belgian regulatory framework in a few words
- Brief description of the 2006 Sterigenics irradiation accident
- Safety assessment of the class II installations
- Refining the class II installation definition
- Improving the safety requirements in the class IIA installations
- First findings since 2009
- Lessons learned - Challenges

Belgian regulatory framework since 2008



Integrated strategy for Inspection and Surveillance (ICI)

The ICI objective is to explicit the Regulatory Body missions :

- The Federal Agency for Nuclear Control inspections :
  - guarantee the general surveillance of the Belgian nuclear sector ;
  - enable the assessment of the nuclear safety or Radiation Protection level for a given activity, and initiate some improvement actions if required ; …
- The Bel V surveillance :
  - guarantees that the Health Physics Department activities of each class IIA Licensee are in accordance with the regulation ;
  - reviews and analyses the licensee technical notes such as modification projects, procedures related to safety, INES rating, ...

2006 Sterigenics irradiation accident

- Evolution of the regulatory framework was in the air but this was the trigger to the improvement of the safety requirements of some installations.
- The lawsuit conclusions as well as the accident consequences are clearly out of scope.
- Sterigenics is a class II industrial irradiation facility composed of two vaults :
  - Gammir I : 96 PBq ^{60}Co (2,6 MCi) ;
  - Gammir II : 37 PBq ^{60}Co (1 MCi).
- Medical devices and foodstuffs sterilization.

2006 Sterigenics irradiation accident (2)

- In March 2006, a senior operator was called back on site following recurring high level radiation alarms on Gammir II.
- These alarms were considered as false by the operator.
- Believing the sources were in a safe position in the pool, he entered the vault in order to actuate the inner switch and to close the door.
- Blood analyses revealed an effective dose of 4,4 to 4,8 Gy.
- Fortunately, the operator was successfully treated in France.

2006 Sterigenics irradiation accident (3)

- The possible cause of the accident is an instability in the hydraulic system leading to unwanted rising of the sources.
- The root cause of this instability seems to be a modification of the hydraulic system :

  - not properly evaluated by the Licensee ;
  - not mentioned to the external Health Physics Dpt.

- After this accident, thorough reassessment of the facility, important safety improvement and operator‘s training effort.
- Trigger of the safety assessment of class II installations.

Authorized nuclear installations (RD 20/07/2001)

- Class I (NPP, ...), Class III, IV (out of scope)
- Class II :
  - facilities producing or conditioning radionuclides from irradiated fissile substances ;
  - particle accelerators ;
  - facilities containing high activity sources (irradiators, ...) ;
  - nuclear medicine ;
  - X-rays generators with nominal peak voltage > 200 kV ;
  - ...

Authorized class II facilities (RD 20/07/2001)

- Cla up :
  be ds,
  ar

2006 – 2007 Safety assessment in class II facilities

- The Federal Agency for the Nuclear Control and the Licensed Bodies carried out a safety assessment of the class II facilities.
- Three priority levels depending on the risk of high dose rate exposure :
  - Priority I : Cyclotrons producing medical radionuclides, industrial irradiators, ...
  - Priority II : radiotherapy, X-rays generators (V > 200 kV), ...
  - Priority III : medical radionuclides storage, small irradiators, ...
- Priority II and III are out ot scope of this presentation. Particular attention has been paid to industrial radiography.

New subclass IIA facilities

- Priority I results showed a few breaches generally rapidly solved.
- This led to create a IIA subclass covering the heavy class II:

Class IIA licensees : containing :	13
Industrial irradiators (>100 TBq)	3
Research irradiators	6
Van de Graaff accelerators	3
Cyclotrons	13
Cyclotrons awaiting dismantling	3
Radionuclides conditioning	1
Cyclotron constructor	1

New class IIA safety requirements

The class IIA Licensee has to :

- when possible, organize an internal Health Physics Dpt ;
- write up a safety analysis report ;
- formalize in procedures approved by HPD and Bel V :
  - the facility modifications management ;
  - the events declaration process to the authorities.

First findings about class IIA since 2009

- The facility design disparity due to :
  - the Licensee‘s activities (research, radionuclides production, ...)
  - the design periode ;
  - the Licensee’s choices ; …
- The safety culture and means :
  - an interrogative attitude is required from the Licensee, the workers and the Health Physics Department to reassess the decisions previously made;
  - the licensees resources are not comparable with those of the class I installations (internal HPD is a luxury, additional workload, ...).
- Real willingness to meet the new safety and RP requirements.

Significant events since 2009

- None of these events led to dose exceeding legal limit for the workers or the public
- In industrial / research irradiators :
  - procedure for entering irradiation vault not respected ;
  - **by-pass of the vault door interlock** ;
- In radionuclides producers :
  - **opening of a synthesis shielded cell containing high ^{18}F activity**
  - non-authorized physical by-pass of the door shielded cell interlock ;
  - Unintentional deactivation of a door interlock on a new shielded cell ;
  - Unintentional releases of radioactive gaseous effluents.

Significant events since 2009 (2)

- In a ^{60}Co research irradiator : By-pass of vault door interlock :
  - the operator bypassed the interlock of the vault door in order to simplify the entrance procedure (dose rate calibration) ;
  - after an irradiation, the operator and a subcontractor entered the chicane vault ;
  - they were warned by their electronic personal dosimeter (30 µSv/h) ;
  - No dose was recorded on the legal dosimeters.
- Cause : - incomplete return of the sources in safe position due to partial blocking of a source driving cable.
- Actions : - the driving mechanism was improved ;
  - the alarm logics was reviewed ;
  - increasing the operator‘s awareness.

Significant events since 2009 (3)

- In a radionuclides producer : opening of a synthesis shielded cell containing high ^{18}F activity :
  - during the synthesis of 74 GBq ^{18}F-compound (2 Ci), incomplete transfer of the activity in the synthesis module ;
  - to ensure the next production, the operator opened the cell door in order to replace the single use tubing system ;
  - he directly closed the door after actuation of his electronic personal dosimeter alarm ;
  - the production manager arrived at this moment and decided to stop.
- Causes : - absence of interlock on the cell door ;
  - rush to ensure a second production.
- Tubing kit defect notified. Procedure improved. Operator‘s awareness.

Recurring causes identified

From these events, we underline :

- inappropriate behaviour or mistakes ;
- pressure on the operators to gain time or to ensure on-time radiopharmaceutical delivery ;
- inadequate design of older installations with regards to the new RP or nuclear safety standards (absence of door interlock, poor gastightness, ...) ;
- insufficient knowledge on the safe use of new equipment.

Lessons learned - Challenges

From these observations, the RB promotes:

- the implementation of several layers to build the Defence in Depth ;
- the safety culture development in order to encourage a questioning attitude with regards to possible adverse consequences of choices and actions.

Some remaining challenges for the near future :

- Radioactive waste management is not always optimal ;
- Future dismantling of unused installations.

To summarize

- The heterogeneity of the authorized class II facilities led to define the subclass IIA (irradiators, particle accelerators, radionuclides producers, ...).
- Enhanced safety requirements were requested from these Licensees (internal HPD, SAR, approved procedures, ...).
- The FANC inspections and the Bel V surveillance show the real willingness of the Licensees, the workers and the HPD to meet these requirements.
- The collected significant events since 2009 did not lead to dose exceeding dose limits.
- The authorities intent to continuously promote the nuclear safety and the safety culture.

Thank you for your attention.

Do you have any question ?