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

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Abstract:
This paper presents the recent evolution in the regulatory framework of the Belgian class II nuclear facilities. It was decided to reassess the nuclear safety and radiation protection requirements in the "heavy" class II facilities such as irradiators and accelerators (new class IIA).

The added requirements for the class IIA facilities are based on some class I facilities requirements, for instance, an internal Health Physics Department and the writing up of a Safety Analysis Report.

Three years after the implementation of the Integrated strategy for Inspection and Surveillance, the regulatory body's first findings are presented. Several significant events reported during the period 2009 – 2012 are briefly discussed.

1 BELGIAN REGULATORY FRAMEWORK

The regulatory framework has been evolving these past five years.

Formerly, the Belgian Regulatory Body consisted in the Federal Agency for Nuclear Control (FANC) created by Law on April 14th, 1994 [1]. Some of its inspection missions were entrusted to three Licensed Bodies. In order to fulfil a Representatives Chamber requirement [4], it was decided to create by notarial act on September 7th, 2007 the subsidiary Bel V. This subsidiary acts as Technical Safety Organization (TSO) for the FANC and is also in charge of carrying out the surveillance of the Belgian nuclear installations. The staff and the missions of the different Licensed Bodies had to be transferred into the subsidiary. Until now, only one (formally AVN) has been transferred.

The radiation protection aspects of the workers, the population and the environment are regulated by the 20/07/2001 Royal Decree [2]. The nuclear safety prescriptions for the class I nuclear facilities are regulated by the 30/11/2011 Royal Decree [3].

2.1 2 SAFETY ASSESSMENT OF THE CLASS II FACILITIES

Classification of the authorized facilities

The requirements for the licensing of facilities are prescribed in the article 3 of the 20/07/2001 Royal Decree [2]. The facilities are categorized in four different classes depending on their specificities:

- Class I : nuclear reactors, facilities containing or handling fissile substances in quantities higher than half of the minimal critical mass, reprocessing plants of nuclear fuel, radioactive waste handling and treatment facilities and final disposals ;

- Class II : facilities producing and conditioning radioisotopes from irradiated fissile substances, particles accelerators, facilities containing fissile substances which are not considered as Class I, facilities where radioactive substances are used for medical or veterinary diagnosis or treatment, X-ray generators with nominal peak voltage higher than 200 kV, …
- Class III : facilities handling radioactive substances in quantities exceeding the exemption limits, X-ray generators not considered as Class II ;
- Class IV: facilities exempted of authorization.

The above-mentioned definition intends to show the large heterogeneity of facilities described under the Class II category. Indeed, these facilities range from industrial and research irradiators, cyclotrons used to produce radio-isotopes for nuclear medicine service, industrial X-rays installations, radiopharmaceutical or radiochemical bulk producers ...

The Sterigenics Accident, the trigger for the evolution of the regulatory framework

2.2 The objective of this paper is not to describe the accident in detail, nor its possible cause nor the safety improvements which were subsequently brought to the Sterigenics installations. However, this accident enjoined the authorities to reconsider the classification of the class II nuclear installations and the regulatory surveillance of some of them.

Sterigenics is an industrial irradiator located in the Fleurus industrial park, close to Charleroi. It is specialized in the sterilization of foodstuffs and medical devices. It is composed of two irradiation vaults shielding ^{60}Co sealed sources: 96 PBq ($2{,}6.10^6$ Ci) in Gammir I and 37 PBq (1.10^6 Ci) in Gammir II. During the irradiation, the sealed sources are raised from the pools where they are stored and shielded. Then huge gamma dose rates of several thousand Gy per hour are delivered.

The irradiation in Gammir II occurs in batches. The products awaiting treatment are placed in hanged up containers. These containers are introduced in the vault by a conveyer. The operator then checks the absence of other workers in the cell, actuates an inner switch and leaves the vault in order to command the closing of the door.

On Saturday March 11th, 2006, a senior operator was called back on site following recurring high level alarms on the Gammir II installation gamma monitors. However the installation was thought to be in shutdown state (with the sources in safe position, down in the pool). These alarms were considered as false by the operator. The door of the vault being open, he decided to enter in order to actuate the inner switch and to close the door. He did not respect the procedure set in place to enter in the cell as he did not carry any of the following mandatory items: personal passive dosimeter and dose rate meter.

In the following hours the first symptoms of an acute irradiation syndrome appeared (nausea) but the operator did not link them with his twenty seconds stay in the vault. His health started to seriously deteriorate in the two or three weeks after this event. Blood analyses revealed an effective dose of 4,4 to 4,8 Gy. Fortunately, the operator was successfully treated in a French hospital. [5]

The cause of the accident is not clearly demonstrated. The alarms operated correctly and no irradiation process was started. Possible pressure instability in the hydraulic system in charge of the raising of the sources out of the pool was suspected. This instability created unwanted rising of the sources, actuating the alarms. The root cause of this instability seems to be a modification of the hydraulic system which was not properly evaluated by the licensee [6].

This accident was classified on level 4 of the INES-scale.

Safety assessment campaign of the class II installations

2.3 In 2006 and 2007, the Federal Agency for the Nuclear Control, with the collaboration of the Licensed Bodies, has carried out an in-depth safety assessment of the class II installations presenting a potential risk of exposure to high dose rates. The class II installations were divided into three categories depending on the risk of high dose rate exposition:

- Priority 1 considered the facilities where :
  - a sealed source with an activity higher than 100 TBq is present ;
  - a dose rate of at least 100 mSv/h near the source is expected ;
  - the annual dose for the population (1 mSv) can be reached in a normal situation.

  Such facilities are :
  - cyclotrons producing medical radioisotopes ;
  - industrial irradiator(s) ;
  - radiotherapy departments ;
  - Industrial radiography using γ sources.

- Priority 2 considered the presence of :
  - accelerators for radiotherapy applications ;
  - X-ray generators with peak voltage higher than 200 kV ;
  - sealed sources with activity lower than 100 TBq for radiotherapy ;
  - container scanners such as used in ports.

- Priority 3 : presence of contamination risk for the persons and the environment :
  - medical radioisotopes storage ;
  - small irradiators (blood sterilization)

Since 2007, a particular attention is being paid to industrial radiography.
The Priority 3 installations and industrial radiography are not considered in this paper.

The first step of this campaign was a technical and administrative screening in order to verify the existence of:

- a documented safety analysis ;
- procedures identifying safeguard systems in normal operation ;
- procedures describing actions to be taken in abnormal or incidental situations ;
- procedures on the management of the installations modifications ;
- means applied to sensitize the workers to the risks (information and training).

The second step consisted in walk-down inspections in order to:

- verify the existing safety requirements ;
- remedy to potentially observed non-compliances to the rules ;
- formulate recommendations.

The results of this campaign were respectively summarized in two reports ([7] and [8]). In the 37 Priority 1 installations inspected, a few breaches were noticed (for instance, no procedure for modification approval by the Health Physics Department, no identification of sealed sources following the regulation, insufficient fire protection). Many of them were rapidly solved. Generally, safety awareness was observed at the licensee's. However, there was a need to formalize the risk management and the knowledge transfer [7].

The results in the 57 Priority 2 installations showed in some cases no or insufficient workers knowledge, lack of work procedures in normal or abnormal situation. The diversity of installations belonging to this group was underlined [8].

The different lessons learnt from this safety assessment campaign were summarized in a set of recommendations in order to organize the radiation protection in high dose rate installations [9].

3 CLASS II REGULATORY SURVEILLANCE EVOLUTION

As already mentioned, the heterogeneity of the former class II installations is apparent. We find in this category some industrial irradiators able to deliver lethal doses in fractions of seconds, radioisotopes producers handling or storing several hundreds of GBq of ^{18}F, or tens of TBq of ^{131}I or ^{133}Xe. On the other hand, we also find in this category nuclear medicine services or laboratories handling for instance 50 MBq ^{131}I or 5 GBq of ^{3}H in unsealed form [2].

The Belgian Representatives Chamber underlined this fact and asked the FANC to reform this classification [4]. It was decided to create a sub-group with the “heavy” class II installations, the so called class IIA.

The class IIA installations

3.1 The following installations were included in this class:

- the facilities producing and conditioning radioisotopes from irradiated fissile substances;
- the particle accelerators used in research or in radioisotopes production, and the facilities producing and testing particle accelerators ;
- the irradiators for the sterilization of foodstuffs, medical material … equipped with a source of activity higher than 100 TBq. The irradiators fitted for patient treatment as well as irradiators with a source staying in all circumstances in its shielding are excluded ;
- the facilities conditioning radioisotopes in order to sell them in industrial quantities.

The number of class IIA licensees and equipment are divided as such :

3.2

Class IIA licensees containing :	13
Industrial irradiators	3
Research irradiators	6
Van de Graaff accelerators	3
Cyclotrons	13
Cyclotrons awaiting dismantling	3
Radioisotopes conditioning	1
Cyclotron constructor	1

New safety requirements for the class IIA installations

The regulatory body’s strategy for the new safety requirements has been presented to the stakeholders in November 2009. The idea was to incite the class IIA licensees to reach a higher safety level based on some requirements of the class I installations.

Since June 1th, 2009, the regulatory surveillance of these installations is carried out by FANC inspectors supported by Bel V (TSO). The frequency of the visits is minimum quarterly.

The new requirements for these class IIA licensees are:

- to preferably organize an internal Health Physics Department ;
- to write up :
  - a safety analysis report on the basis of the FANC note 009-176 [10]
  - a modifications management procedure on the basis of the FANC note 009-177 [11]
  - a procedure of events declaration to the authorities based on the FANC note 009-174 [12]
- to improve the radioactive gaseous effluents management (if applicable), and ;
- to declare to the authorities the radioactive gaseous effluents released by the cyclotrons producing β+ emitters (if applicable). See FANC note 011-001 [13].

The Integrated strategy for Inspection and Surveillance (ICI)

3.3 The ICI presents the FANC general strategy for inspection and surveillance. This strategy is defined for three years [14].

The missions of the regulatory body are divided as follows:

- the FANC inspections :
  - guarantee the general surveillance of the Belgian nuclear sector ;
  - allow the assessment of the nuclear safety or Radiation Protection level for a given activity, and initiate some improvement actions if required ;
  - allow the evaluation of the Belgian regulation adequacy ;
  - guarantee the police competence if required (enforcement).
- the Bel V surveillance :
  - guarantee that the Health Physics Department activities of each class IIA licensee are in accordance with the regulation ;
  - review and analyse the licensee technical notes such as modification projects, procedures related to safety, INES rating, ...

The main themes that will be examined for the 2012-2014 ICI are:

- nuclear safety and radiation protection ;
- respect of the licensee authorization ;
- radioactive releases surveillance ;
- follow-up of the action plans based on observations made during inspections and surveillance ;
- management of the sub-contracted workers ;
- equipment knowledge and safe usage ;
- fire protection ;
- the Safety Analysis Report.

4 FIRST FINDINGS

Three years after the new inspection strategy implementation, the regulatory body observes in general a real willingness from the licensees and their Health Physics Departments to meet the new nuclear safety and radiation protection requirements.

4.1 From these observations, several findings are described below.

Facility design

An important disparity is observed among each type of facility (irradiators or particles accelerators). This disparity is attributable to the licensees activities (research, radionuclides production, ...), the design period and to the licensee‘s choices.

It is evident from these disparities, that each facility is somewhat unique. To lay down a common rule for all these facilities requires some flexibility from the regulatory body.

Safety culture - Means

4.2 We observe that the effort to tend to the class I requirements requires a change in the safety culture of the licensees, of the workers and of the Health Physics Departments.
Indeed, an interrogative attitude is necessary to reassess the decisions made previously.

It is obvious that the licensees resources are not comparable with those of the class I installations. The staff is smaller, usually less than 10 or 20 persons. The financial means are also lower. The internal Health Physics department is considered as a luxury.
The reassessment leads to an unavoidable additional workload.

Significant events since 2009

4.3 The following events demonstrate the need for a specific regulatory context (class IIA) put into place since 2009.

4.3.1 Events in industrial irradiators

4.3.1.1 Procedure for entering irradiation vault not respected

This event occurred in an irradiation facility.
In order to ensure that the operator checks the absence of a person in the vault before irradiation, the operator has to actuate the vault inner switch. To avoid the frequent entry in the irradiation cell, two person detection systems are placed at the entrance of the vault door (a presence mat reacting to the pressure and an optical barrier). When no detection occurs, the actuation of the inner switch is not required.

In order to save a few tens of seconds, an operator entered in the vault deliberately avoiding the two person detection systems. This permitted to start a new irradiation without actuating the inner switch. The internal Health Physics department was notified of this event and then reported directly to its upper management and to the authorities.

No irradiation of staff occurred. This misapplying of the procedure showed an irresponsible way to work.

A thorough effort to increase the operators’ awareness was consented by the Health Physics department.

4.3.1.2 Bypass of the vault door interlock

The ^{60}Co industrial irradiator of a Belgian university required a dose rate calibration at many specific positions in the irradiation zone. The total activity of the three ^{60}Co sources was around 22 TBq when this event occurred.

The operator bypassed the interlock on the vault door in order to simplify the entrance procedure (avoiding the repetition of the slow door opening / closing process). After the irradiation, the operator and a subcontractor entered the chicane vault. They were suddenly warned by their electronic personal dosimeters of an excessive dose rate (30 µSv/h). They immediately left the vault. The reading of the legal passive dosimeters showed no significant dose.

After analysis, it appeared that the return of the sources to a safe position was not complete due the partial blocking of one source driving cable.

The following actions were applied:

- improvement of the mechanical sources driving system and of the maintenance programme ;
- alarming logics improvement ;
- improvement of the source positions visualization and audio warning signals ;
- increasing the operators' awareness.

4.3.2 Events in radionuclides producers

4.3.2.1 Opening of a synthesis shielded cell containing high ^{18}F activity

The hot cells of this laboratory are not equipped with an interlock preventing the door opening if the inner dose rate is above a given threshold.

During the synthesis of 74 GBq ^{18}F-compound (2 Ci), the operator observed that only a fraction of the activity was correctly transferred into the synthesis module.
In order to ensure the production of the radiolabelled molecule, the operator decided to execute a second production, without referring to the production manager. He opened the shielded cell in order to restart the synthesis module by replacing the single use tubing system. The electronic personal dosimeter alarm was actuated and the operator directly closed the cell. The production manager happened to be present at this moment and directly decided to stop the production until the following day.

The operator's electronic dosimeter (Dosicard) showed a dose of 497 µSv. The reading of the passive dosimeter revealed an effective dose of 1 mSv.

The causes of this irradiation are the absence of a door interlock and the rush to ensure a second production without prior reflection about the location of the lost ^{18}F activity.

The origin of the activity loss was identified and notified to the supplier (one-use synthesis kit defect). The production procedure was improved. The operators' awareness was enhanced.

4.3.2.2 Non authorized physical by-pass of the door shielded cell interlock

This event occurred in an accelerator facility producing ^{18}F and synthetizing fluorodeoxyglucose (^{18}F-FDG).
The shielded cells doors, the vault door and the liquid target valves are interlocked in order to prevent the risk of irradiation or contamination of the operators.

An unauthorized physical by-pass was placed by an operator in order to open the shielded cell door and to fill the liquid target at the same time. The objective of this bypass was to save a few minutes on the ^{18}F production.

No irradiation or contamination of the staff occurred.

The following installation improvements were done:

- the electrical board including the switches commands is now less accessible in order to discourage this practice ;
- the interlocks logic was modified in order to facilitate the target maintenance and guarantee the operator safety ;
- the awareness of the staff was furthermore increased.

4.3.2.3 Unintentional deactivation of a door interlock on a new shielded cell

This event occurred in a laboratory producing radiolabelled molecules used in medical imaging. In order to avoid the irradiation or contamination of the operator, the shielded cell door stays closed if the dose rate inside the cell is higher than a given threshold.

The operator unintentionally deactivated the door interlock of a new shielded cell. The deactivation was noticed by the health physics department a few weeks later during the securities quarterly check.

No irradiation or contamination of the staff occurred.

The event cause is the lack of knowledge about the new software managing the shielded cell.
The training of the operators was improved. A procedure describing the authorized situations in which to apply an interlocks bypass was written.

4.3.2.4 Unintentional releases of radioactive gaseous effluents near or above the authorized limits

These events were reported :

- release of 90 TBq ^{133}Xe during the purification process of this radio-isotope. The lack of maintenance and the inadequate installation design are considered to be the causes of this event ;
- the release of 31 GBq ^{11}C under the form of $^{11}CH_3I$ and $^{11}CO_2$ occured during the synthesis of radiolabelled molecules. The radioactive gaseous effluents are normally collected in plastic bags in order to reduce the activity release by radioactive decay. The incomplete closing of the collecting bag bleed line is the most probable cause of this release. The tightness of the synthesis module and the transfer lines was correctly checked by the operators. But the procedure did not clearly mention this bleed line. The procedure has been adapted ;
- the release of 45,8 GBq ^{18}F occurred after an incomplete check for correct tightness of the synthesis reactor. A human mistake was mentioned.

4.4

First conclusions on the basis of the internal REX

Some recurring causes of events can be identified :

- inappropriate behaviour or mistakes ;
- pressure on the operators to gain time or to ensure on-time radiopharmaceutical delivery. This can lead to intentionaly skip one safety layer (by-pass, procedure,...). The messages given by the top management and the health physics department are of primary importance in order to prevent such behaviour;
- inadequate design of ancient installations with regards to the new radiation protection or nuclear safety standards (absence of door cell interlock, ...) ;

- insufficient knowledge on the safe use of new equipments or installations ;

These observations lead the regulatory body to promote :

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

Challenges

Some important challenges remain and require the attention of the regulatory body :

4.5

- the correct radioactive waste management is of first importance. The RD 20/07/2001 already describes this correct management from a radiation protection point of view. However we observe that the radioactive waste transfer from the licensees to the Belgian Agency for Radioactive Waste and Enriched Fissile materials (ONDRAF / NIRAS) is not always optimal. To avoid the accumulation of waste by some licensees, the regulator has to find solutions to accelerate the transfer to ONDRAF/NIRAS ;
- in a relatively close future, the possible dismantling of some unused facilities or installations will be necessary. These projects have to be examined and approved by the Regulatory Body.

5 CONCLUSIONS

This paper presents the recent evolution in the regulatory framework of the Belgian class II nuclear facilities. The heterogeneity of this class II was underlined by the Belgian Authorities in 2007. It was decided to reassess the nuclear safety and radiation protection requirements in the “heavy” class II facilities such as irradiators and accelerators (class IIA).

The requirements for the class IIA facilities are based on some class I facilities requirements such as an internal Health Physics Department, the writing up of a Safety Analysis Report, the formalization of the facility modification management process and the event declaration to the authorities. The improvement of the gaseous radioactive effluents management for the accelerators producing β+ emitters was also required.

Three years after the implementation of the Integrated strategy for Inspection and Surveillance, the regulatory body has been observing in general a real willingness of the licensees to meet the new requirements.

During the period 2009 – 2012, some events were reported by the licensees such as the non-respect of a procedure for entering an irradiation vault, the use of an unauthorized interlock bypass or the opening of a synthesis shielded cell containing high ^{18}F activity. Fortunately, none of these events led to a dose higher than the effective dose limit for the workers (20 mSv on 12 consecutive months).

Some unintentional radioactive gaseous effluents releases higher than the authorized limits were reported. None of them led to a significant dose to the population.

These observations lead the regulator to promote the defence in depth and the safety culture development.

Two challenges require the attention of the regulatory body: the improvement of the radioactive waste transfer from some licensees to the ONDRAF as well as the examination and approval of future facilities dismantling projects.

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