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Belgian class II nuclear facilities such as irradiators and accelerators: Regulatory Body attention points and operating experience feedback

The aim of this paper is to present the Regulatory Body attention points and the operating experience feedback from Belgian "class IIA" facilities such as industrial and research irradiators, bulk radionuclides producers and conditioners. Reinforcement of the nuclear safety and radiation protection has been promoted by the Federal Agency for Nuclear Control (FANC) since 2009. This paper is clearly a continuation of the former paper [1] presenting the evolution in the regulatory framework relative to the creation of Bel V, the subsidiary of the FANC, and to the new "class IIA" covering heavy installations such as those mentioned above. Some lessons learnt are extracted from the operating experience feedback based on the events declared to the authorities. Even though a real willingness to meet the new safety requirements is observed among the "class IIA" licensees, promoting the safety culture, the nuclear safety and radiation protection remains an endless challenge for the Regulatory Body.

Wichtige Punkte der Regulierungsbehörde und Feedback aus der Betriebserfahrung zu belgischen class-II-Nuklearanlagen wie Bestrahlungsanlagen und Beschleunigern. *In diesem Beitrag sind sowohl Rückschlüsse aus Betriebserfahrungen als auch Punkte, die von der Regulierungsbehörde mit besonderer Aufmerksamkeit bei belgischen Nuklearanlagen der Klasse II wie industriellen und Forschungs-Bestrahlungsanlagen, Radionukliderzeugern und Aufbereitungsanlagen beobachtet wurden, zusammengestellt. Seit 2009 wird von der Federal Agency for Nuclear Control (FANC) eine Verstärkung der nuklearen Sicherheit und des Strahlenschutzes gefördert. Dieser Beitrag präsentiert die Entwicklung der regulatorischen Rahmenbedingungen seit der Bildung von BelV, einer Tochterfirma der FANC und der Einführung der neuen Klasse IIA, die die o. g. Anlagen umfasst. Dabei werden Lehren aus der Betriebserfahrung mit meldepflichtigen Ereignissen erläutert. Auch wenn eine große Bereitschaft bei den Klasse IIA-Lizenznehmern beobachtet werden kann, den neuen Sicherheitsanforderungen gerecht zu werden, bleibt es weiterhin eine große Herausforderung für die Aufsichtsbehörde die Sicherheitskultur und den Strahlenschutz zu fördern.*

1 Introduction

This paper is a continuation of the former paper presented during the 2012 Brussels Eurosafe forum entitled "Recent evolution in the regulatory framework of the Belgian class II nuclear installations such as irradiators and accelerators" [1].

The evolution in the regulatory framework presented in this former paper was related to two different aspects. Firstly, in order to fulfil a Representatives Chamber requirement [2], it was decided to create the subsidiary Bel V by notarial act on September 7th, 2007. This subsidiary acts as the Technical Safety Organization (TSO) of the Belgian Federal Agency for Nuclear Control (FANC). Secondly, the Belgian Representatives Chamber [2] underlined the heterogeneity of the class II installations as defined in the 20/07/2001 Royal Decree [3], the regulatory framework dealing with the radiation protection of the population, the workers and the environment. On the one hand, we could 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 could find in the same category nuclear medicine services or laboratories handling for instance 50 MBq ^{131}I or 5 GBq of ^{3}H in unsealed form [3]. Consequently, the FANC decided to reform the facility classification by creating a subgroup including the "heavy" class II installations, the so called "class IIA" facilities.

The following facilities were included in this:

- the facilities producing and conditioning radioisotopes from irradiated fissile substances;
- the particles accelerators used in research or in the frame of radioisotopes production, and the facilities producing and testing particles accelerators. The electronic microscopes are excluded,
- the irradiators for the sterilization of foodstuffs, medical material, equipped with a source of activity higher than 100 TBq. The irradiators and linear accelerators 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 presented in Table 1.

Table 1. Numbers and nature of the "Class IIA" facilities

"Class IIA" licensees containing:	13
Industrial irradiators	2
Research irradiators	3
Cyclotrons	12
Cyclotrons awaiting dismantling	5
Bulk radioisotopes conditioning	1
Cyclotron suppliers	1

New stringent conditions were imposed by the FANC for the "class IIA" facilities:

- to organize an internal Health Physics Department;
- to write and apply:
  - a Safety Analysis Report (SAR) on the basis of the FANC note 009–176 [4];
  - a modifications management procedure on the basis of the FANC note 009–177 [5];
  - a procedure dealing with events declaration to the authorities based on the FANC note 009–174 [6];
- 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 [7] for all the requirements and $ 2.1 of the present paper.

2 Regulatory body attention points about the "class IIA" facilities

This chapter is dedicated to the main attention points of the Belgian Regulatory Body relative to the "class IIA" facilities.

2.1 Recording the radioactive gaseous effluents releases – Reporting to the authorities

2.1.1 Regulatory context

As already mentioned, the 20/07/2001 Royal Decree (RD) [3] constitutes the Belgian regulatory framework dealing with the radiation protection of the population, the workers and the environment. In particular, the regulatory criteria relative to the routine radioactive gaseous effluents treatment and releases are prescribed in article 36 of the 20/07/2001 Royal Decree [3].

Table H2 from the appendix III of the RD [3] imposes – for each radionuclide – a concentration limit at the emission point which must be respected to allow the radioactive gaseous effluent release into the atmosphere. Derogation to these concentration limits may be authorised by the FANC providing that the limits proposed by the licensee do not lead to an unacceptable dose to the most exposed population. This dose constraint defined by the FANC amounts to a fraction of the effective dose limit for the public (1 mSv/year).

Therefore, the FANC may allow specific radioactive effluents limits with respect to the ALARA principle, taking into account technical factors such as the best available technology, good practices, and also economic and societal aspects.

2.1.2 Findings about the radioactive gaseous effluents releases from radiotracers production

Positron Emission Tomography (PET) is a powerful nuclear medicine imaging technique able to early diagnose and follow the treatment of many diseases, including cancers. This technique requires the injection in the patient of radio-pharmaceuticals labelled with positron emitting radionuclides.

^{18}F and ^{11}C positron emitters are daily used in radiolabelling for PET tracers. These short lived radionuclides are produced by a cyclotron and inserted in biomolecules during a synthesis process performed in shielded cells. During the transfer from the cyclotron target to the shielded cells and mostly during the synthesis, volatile radioactive components are produced and, without mitigating actions, can routinely be spread in the shielded cell and in the ventilation system of the facility.

During the FANC inspections of the cyclotron facilities producing positron emitting radionuclides, two facts were identified:

- these "class IIA" facilities are not able to respect the H2 table limits for their radioactive gaseous effluents releases (for example, instantaneous limit of 2100 Bq/m^3 for ^{18}F);
- these facilities could improve the treatment and the monitoring of their radioactive gaseous effluents.

2.1.3 FANC actions in order to resolve the observations about cyclotron gaseous effluents treatment

In 2010, the FANC organised an assessment programme of the radioactive gaseous effluents releases for each facility producing PET radiolabelled molecules.

The objective of this campaign was to determine:

- the extension of the radioactive gaseous effluents releases with or without effluents treatment;
- the effluents treatment efficiency (mainly filtration and effluent collection in order to benefit from the decay of the short-lived β+ emitters);
- the gaseous effluents radiation monitoring efficiency;
- practical releases limits based on the efficiency of the effluents treatment systems, on the existing facilities design and on the ALARA principle.

The conclusions of this campaign allowed the FANC to define standard authorisation conditions for this facility category [7]:

a. the total β+ activity (^{15}O, ^{13}N, ^{11}C, ^{18}F) excluded, the radioactive gaseous effluents releases may not exceed the concentration limits at the emission point prescribed in the table H2 from the appendix III of 20/07/2001 RD [3];
b. the annual effective dose to the individual from the reference group must be lower than 200 μSv for all the radioactive gaseous effluents releases;
c. the total β+ release (^{15}O, ^{13}N, ^{11}C, ^{18}F) during 12 consecutive months must be lower than 1,85 TBq (50 Ci);
d. the total β+ release during 12 consecutive months must respect the following conditions:
   - maximum release of 3 % of the produced activity for the range from 0 to 18,5 TBq (500 Ci), i.e. a maximum of 555 GBq (15 Ci) for this range;
   - maximum release of 1 % of the produced activity for the range from 18,5 TBq (500 Ci) to 111 TBq (3000 Ci), i.e. a maximum of 925 GBq (25 Ci) for this range;
   - maximum release of 0,5 % of the produced activity for the range from 111 TBq (3000 Ci) to 185 TBq

(5000 Ci), i.e. a maximum de 370 GBq (10 Ci) for this range;

e. The daily total β+ release must be lower than 18,5 GBq (500 mCi);
f. A monthly report on the radioactive gaseous effluents releases is delivered to the FANC;
g. An annual report on the radioactive gaseous effluents releases and the population dose assessment is delivered to the FANC.

Some lessons learnt on the radioactive gaseous effluents treatment will be presented in § 3.2.2 of the present paper.

2.2 Radioactive solid waste management

The competence related to radioactive waste management is shared among two different authorities. On the one hand, the Belgian Agency for Management of Radioactive Waste and Enriched Fissile materials (ONDRAF/NIRAS) is competent for:

- the drawing-up of the radioactive waste inventory as well as the facilities and sites containing radioactive substances inventory [12];
- the writing-up of radioactive waste acceptance criteria and the verification of their correct implementation by the licensees;
- the accreditation of waste processes treatment and waste treatment facilities;
- the long term management of the radioactive wastes [8].

On the other hand, the FANC mission is to promote the effective protection of the population, the workers and the environment against the dangers of ionising radiations. The FANC has to ensure that the radioactive waste management is performed in compliance with the Belgian safety regulations. In practice, the FANC has to verify that this process does not lead to excessive doses to the workers or the population, due to an inappropriate waste management system.

The FANC inspections and Bel V controls highlighted that the radioactive waste transfer from the licensees to the Belgian Agency for Radioactive Waste and Enriched Fissile materials (ONDRAF/NIRAS) was not always optimal. Indeed, in some facilities, the radioactive wastes were accumulated in the storage rooms.

The FANC organised in collaboration with the ONDRAF/NIRAS and Belgoprocess, the ONDRAF/NIRAS technical subsidiary, a cross inspections campaign in the Belgian "class IIA" and I facilities (NPPs, research centres, fuel assemblies producer, radionuclides producer, ...).

The main conclusions related to the "class IIA" facilities are presented below:

- the definition of a radioactive waste has to be clarified:
  - criteria relative to the assessment of a potential future use of the radioactive substance are necessary in order to avoid accumulation of material in controlled areas;
- several "class IIA" licensees appoint the radioactive waste characterisation andmanagement to another licensee better equipped to perform these activities. Nevertheless,it is important to note that the waste producer remains accountable for its waste;
- some licensees can be tempted to keep radioactive waste during long periods of time inorder to let the activity decay and hopefully reach the clearance criteria.

A better understanding of the radioactive waste management in the facilities was the main result of this campaign. Opportunities for improvement were defined for the licensees and for the Regulatory Body.

2.3 Dismantling of unused facilities

In the short term, the dismantling of some unused facilities or installations should be investigated. Indeed, some cyclotrons have been at a standstill for several years without any future industrial prospect. Dismantling projects have to be examined and approved by the FANC and the ONDRAF/NIRAS. This issue will not be treated in this paper. However the FANC and Bel V are currently working on the development of a common strategy about nuclear facilities dismantling.

2.4 Promoting safety culture

As defined in the IAEA INSAG 4, the safety is "*that assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance*" (see § 6 of [9]). It is obvious that this definition can be extended to other nuclear facilities.

In the last years, analysis of the human and organisational factors (HOF) has become a key issue of the nuclear safety. As mentioned by experts in HOF, "*the organisations at risk are first of all human systems*" [10].

The increasing interest for the safety culture led Bel V and FANC to develop a Safety Culture Observations Tool. This tool is used by the Regulatory Body to improve the detection and the reporting of positive or negative indicators of safety culture in the facilities' organisations and in the attitude and behaviour of their staff [11].

Since 2013, safety culture observations have been collected in a structured way by the FANC inspectors and the Bel V controllers in the class I facilities such as nuclear reactors, facilities containing or handling fissile substances in quantities higher than half of the minimal critical mass, radioactive waste handling and treatment facilities.

These observations are analysed in order to detect good practices as well as weaknesses in the licensees' safety culture.

A similar approach has been performed in the "class IIA" facilities since 2014. Until now, the number of collected observations is not sufficient to allow a representative analysis of the safety culture in the "class IIA" facilities. Indeed, the frequency of the contacts with the licensees is not so high than with the class I facilities.

Developing the safety culture observation in the "class IIA" facilities consists certainly in an opportunity for improvement. Indeed, the following chapter covering the operating experience feedback will demonstrate that human behaviour is frequently involved in the events related to nuclear safety and radiation protection.

3 Operating experience feedback 2009–2015

The class II(A) and III licensees have to declare to the authorities the events related to nuclear safety and radiation protection. The FANC requirements for this reporting are described in the note 009–174 rev. 0 [6].

Aiming to produce the most representative picture of the causes of events reported by the "class IIA" facilities between 2009 and 2015, the present study includes the first ten or so

events described in the previous paper on the Belgian regulatory framework evolution [1].

Some difficulties were encountered during this analysis. A positive remark relies on the fact that the number of reported events is relatively small: 39 events on the period 2009–2015. However this low events number constitutes a hindrance to perform any statistical study on the identified causes of events. Moreover, as previously stated, the "class IIA" covers very different types of facilities. Industrial irradiators, cyclotrons or bulk radionuclides producers present specific challenges in terms of nuclear safety and radiation protection. Therefore, the study requires evaluating separately each group of "class IIA" facilities, decreasing further the number of observations per group and their statistical significance.

It is important to note that, apart from one event that occurred in a cyclotron facility, no event led to the exceedance of the annual effective dose limit for the population (1 mSv) or the effective dose limit on 12 consecutive months for the workers (20 mSv).

3.1 Events in industrial and research irradiators

This analysis focused on this specific group of "class IIA" facilities as the lethal or severe irradiation exposure risks do exist in these facilities. Indeed, the high γ dose rate of several thousand Gy per hour delivered by the 94 PBq ^{60}Co sources (2.5×10^6 Ci) used in a Belgian industrial irradiator is able to deliver a lethal dose in a fraction of second.

Eight events were reported to the Belgian authorities between 2009 and 2015:

- unauthorised by-pass of safety systems or layers (four events);
- the blockage of sources in unsafe position (one event);
- the incorrect transition from a degraded mode to a normal mode when reloading;
- a start of fire (one event);
- unintentional release of potentially contaminated liquid effluent (one event).

3.1.1 By-pass of safety systems or layers in industrial and research irradiators

Fortunately, these four events did not lead to staff exposure to irradiation. Two of the safety system or layer by-pass incidents occurred in the industrial irradiators facility where safety was deeply reassessed after the actual accidental exposure of an operator in 2006 [1]. Indeed, the potential interference of the vault door opening system on the source driving mechanism – the most probable cause of the irradiation accident that occurred in 2006 – was eliminated by a clear separation of the two hydraulic systems (door and source mechanisms). In fact, when the sources are in a safe position, the mechanical system lifting the sources is physically blocked in order to prevent any unintentional sources lifting. These first two events are presented below:

- *Preparation of an irradiation cycle while absence of check that no operator was present in the 29 PBq ^{60}Co irradiator vault* (7/5/2009, INES 2):
  - The batch mode irradiator being in the safe mode (consignment of the machine), one maintenance technician announced to the operator that he was entering the vault in order to perform some measurements. Approximately fifteen minutes later, the operator forgot the potential presence of the maintenance technician in the cell and began the door locking procedure without checking the absence of staff inside the vault. Fortunately, the technician heard the door closing and actuated the stop contact interrupting the door locking procedure and therefore prohibiting the irradiation start.
  - No irradiation of the maintenance technician occurred.
  - The causes of the event are:
    - Non-compliance with the irradiation procedure, requiring the absence verification of staff members in the vault before shutting the cell door;
    - the irradiator consignment/deconsignment procedure did not foresee two simultaneous activities taking place at the same time: one operator preparing the next irradiation and the other entering the vault to perform some maintenance activities.
  - The design was improved, among others, by adding in front of the vault entrance asensitive carpet and an optical barrier in order to decrease the number of entries in thevault when it is not necessary to actuate the inner switch.
- *Entering the irradiator vault while avoiding the actuation of the sensitive carpet and theoptical barrier in order to save tens of seconds, the time necessary to actuate the inner switch* (12/01/2011, INES 0):
  - When no entrance in the vault is detected by the sensitive carpet or by the optical barrier placed in front of the vault door, the actuation of the inner switch is not required. In order to save a few tens of seconds, an operator entered the vault while deliberately avoiding the two presence detection systems. This by-pass led the operator to enter the vault without the need to actuate the inner switch in order to start a new irradiation procedure. This event was notified to the internal Health Physics Department who then reported directly to its upper management as well as the authorities.
  - No irradiation of the operator occurred.
  - This by-pass of the procedure constituted a clear violation.
  - The entrance design was modified in order to prevent such an acrobatics. A thorough effort to increase the operators' awareness was granted by the Health Physics Department as well as the facility management. Working procedures were adapted.

The two other events related to a safety system by-pass occurred in a research irradiator containing three sources for a total activity of about 22 TBq ^{60}Co:

- *By-pass of door interlock in order to simplify the entrance procedure during calibration tests in a research Co-60 irradiator vault* (4/1/2011, INES 1).
  - The operator intentionally by-passed the interlock on the vault door in order to simplify its entrance procedure (avoiding the repetition of the relatively long door opening/closing process). After one irradiation, the operator along with 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 their legal passive dosimeters indicated that no significant effective dose was received by the operators.
  - Following an investigation, it appeared that one source had not returned in its safe position due to the partial blockage of one source lifting cable.
  - The following actions were performed:

  - improvement of the mechanical sources lifting system as well as its maintenance programme;
  - improvement of the source positions visualization and audio warning signals;
  - increasing the operators' awareness.
- *^{60}Co research irradiator kept working even though safety Programmable Logic Controller(PLC) was out of service. The by-pass of the safety system prevented stopping irradiationwhen the door was opened* (27/2/2014, INES 1):
  - The access to the irradiator control room was locked (with a key only available by the licensee). The irradiator manager opened this door to allow the Bel V controller to enter the control room.
    The access to the working irradiator is normally prevented by a mechanical interlock on the vault door. The irradiator emergency procedure states how to manually open the mechanical lock if required. As he performed this specific procedure, the Bel V controller noticed that the irradiator was still operating. Indeed, the interlock forcing the return of the sources in their safe position had been by-passed in order to irradiate in a degraded mode.
    The FANC obliged the licensee to stop the irradiation and forbid the realization of any other irradiation before a thorough safety reassessment.
  - No irradiation of the operator occurred.
  - The facility was restored in conformity with the installation description (SAR). Then, the approval of the FANC was granted to pursue the irradiator operation. Several procedures (as well as the SAR) were adapted to take into account the safety reassessment results. The safety PLC was repaired in compliance with safety requirements. The safety test programme was updated by the licensee.

The analysis process of the causes of events linked to a by-pass of a safety system or layer in irradiators, is described in this section.

For each of the four presented events, the detected causes could be categorised as a function of their nature, for example due to:

- the facility design;
- the lack of maintenance or a structure, system or component failure;
- a shortcoming in the documentation or an unsuitable procedure;
- a "slip or lapse" human error or a procedure violation.

Figure 1 shows the distribution of the detected causes for these events. It is obvious that a procedure violation was noticed in four cases. It brings up many questions to observe that there has been a voluntary action of one operator or one responsible to by-pass a safety system. Clearly, it must be noted that the routine activities can lead to less operator's focus or to operator's exasperation. The facility manager has to be aware of these phenomena. Another mechanism leading to the violation of procedures might be the stress to gain time or to guarantee the production. Also in this case, the message delivered by the manager and by the Health Physics Department is of first importance to avoid risky behaviours.

Nevertheless, it would be too simplistic to only point out at the operator's behaviour. It is obvious that these events have multiple causes. Indeed, we observe that the facility design, the licensee's organisation, the lack of maintenance on systems or a failure are also detected as causes of event. For both irradiation facilities, we notice that the sources driving mechanism has been deteriorating and that this degradation led to the blockage of the sources rack in an unsafe position, creating at-risk situations (see the following event).

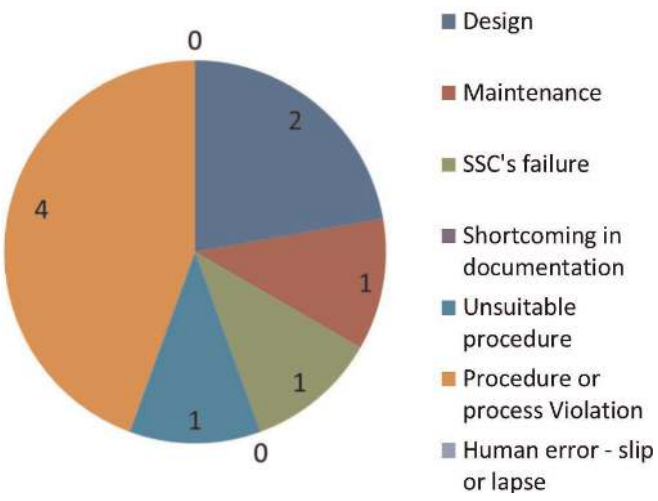

Fig. 1. Distribution of the identified events causes for the four incidents "Safety layer by-pass" that occurred at the Belgian industrial and research irradiators facilities (2009–2015)

3.1.2 Blockage of ^{60}Co sources in unsafe position due to the degradation of guiding cable

- *The ^{60}Co sources of an industrial irradiator remained in unsafe position consequently to a damaged sources guiding cable* (12/11/2014, INES 0):
  - No irradiation of operators occurred.
  - The possible causes of the degradation of one guiding cable are:
    - metal fatigue after two working decennia without replacement;
    - metal corrosion, maybe accelerated by the radiolysis of tape glue in contact with this cable.
  - Preventive replacement of all the cables is organised. Taking into account of externaloperating experience feedback about the impact of glue.

3.1.3 Incorrect transition between degraded mode and normal mode

- *Loading one industrial ^{60}Co irradiator after repairing the mechanical sources driving system without prior consignment* (16/11/2014, INES 2):
  - After the change of driving cables and the replacement of a defective valve, the unloaded lifting mechanism was successfully tested.
    Afterwards, the sources reloading was initiated until the Health Physics Department noticed that there had been no prior consignment of the irradiator. The operators directly evacuated the vault and the irradiator was properly consigned.
  - No irradiation of operators occurred.
  - The main cause of this event is:
    - the dispersion of responsibilities among the different actors: local operators, Health Physics Department and Corporate staff. Indeed, nobody was clearly appointed to perform the correct irradiator consignment after the tests in degraded mode.

- A Human and Organisational Factor analysis was performed by the licensee and led tothe definition of some corrective actions to be approved by Bel V (nomination of aproject leader, improvement of the degraded mode procedure, …).

3.1.4 Fire in an industrial irradiator

Only one fire related event was reported between 2009 and 2015. Working with a disk cutter produced hot particles close to one extraction shaft. Some hot particles were sucked into the ventilation system. As the inner surface of this extraction shaft was covered with dust, its ignition occurred in the ventilation system. Fire was rapidly extinguished. No degradation of the irradiator occurred. The ventilation system maintenance was improved. The work procedure was modified (stop and isolate the concerned ventilation circuit).

3.1.5 Unintentional release of potentially contaminated liquid effluents from an industrial irradiator

Only one event was reported to the authorities. Potentially contaminated water with ^{60}Co produced by the water treatment system of industrial irradiators is collected in a dedicated tank. A γ spectrometry measurement on a liquid effluent sample is required in order to confirm the respect of the liquid effluent release limit before authorising its release in the sewage net.

Unfortunately, the tank's plug was defective and water drained by gravity in the sewer without any prior analysis. Neither water level measurement nor alarming system was installed in the tank. Therefore, the operators were not alerted of this draining.

Some design improvements were realised on the tank. The draining is now performed while using a pump, avoiding the use of the plug. Tank water level monitoring has also been installed.

3.2 Events in bulk radionuclides producers facilities

This group of facilities covers a large range of activities, from synthesizing short-lived positron emitters labelled biomolecules, purifying and conditioning important ^{133}Xe activities or conditioning ^{192}Ir sealed sources in gammagraphy projectors.

During the considered period (2009–2015), twenty-one events in the radionuclides producing or conditioning facilities were reported to the authorities. Only the events likely to seriously impact the workers, the public or the environment will be described in this paper.

3.2.1 Safety system by-pass in radionuclides producers

This type of event is relevant due to the important activities manipulated during the processes.

Three events occurred in facilities producing PET tracers.

- *Opening of a synthesis shielded cell containing high ^{18}F activity (INES 0)*
  - The hot cells of this laboratory are not equipped with an interlock preventing the door opening when 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 generation of the radiolabelled molecule, the operator decided to perform 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. His electronic personal dosimeter alarm was actuated and the operator directly closed the cell. The production manager appeared 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 (single-use synthesis kit defect). The production procedure was improved. The operators' awareness was enhanced.
- *Non authorized physical by-pass of the door shielded cell interlock (INES 0)*
  - This event occurred in an accelerator facility producing ^{18}F and synthetizing 2-[^{18}F]-fluoro-2-deoxy-D-glucose (^{18}F-FDG).

  The shielded cells doors, the vault door and the liquid target valves are interlocked in order to prevent the risks of irradiation and contamination of the operators.
  - An unauthorized physical by-pass was placed by an operator in order to open the shielded cell door and fill the liquid target at the same time. The objective of this by-pass was to win a few minutes of the ^{18}F production time.
  - No irradiation or contamination of the staff occurred.
  - The following installation improvements were performed:
    - 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's safety;
    - the awareness of the staff was furthermore increased.
- *Unintentional deactivation of a door interlock on a new shielded cell*
  - This event occurred in a laboratory producing PET tracers used in medical imaging. In order to avoid the irradiation or contamination of the operator, the shielded cell door stays locked when 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 while performing the securities quarterly check.
  - No irradiation or contamination of the staff occurred.
  - The event cause is related to 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 when an interlocks by-pass can be applied, was written.

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

As explained in § 2.1.3 of this paper, the radioactive gaseous effluents releases from the producing β+ emitters facilities have to remain below the daily limit of 18,5 GBq total β+.

Over the period 2009–2015, ten events about unintentional radioactive gaseous releases were declared to the FANC. Five of them led to releases (nearly) exceeding the daily release limit. These events are briefly mentioned below:

- *Release of 90 TBq ^{133}Xe during the purification process of this radio-isotope (authorised daily release limit of 91 TBq, INES 1).*
  - The purification column suddenly blocked during the process. The overpressure in the purification system generated the ^{133}Xe diffusion in the helium distribution line. A leak in a helium valve situated outside the hot cell occurred and ^{133}Xe diffused in the adjacent rooms.
  - The staff was evacuated from the controlled area. Electronic personal dosimeter of two operators measured respectively 296 µSv and 372 µSv. Internal contamination by inhalation was suspected.
  - The lack of maintenance of the ^{133}Xe purification system and the inadequate installation design are considered to constitute the causes of this event.
- *Release of 45,8 GBq 18F due to incorrectly connected vial on the synthesis module (INES0).*
  - The vial containing one reagent for the synthesis of ^{18}F biomarker was not correctly tightened. ^{18}F volatile component diffused in the hot cell and was dispersed into the ventilation system.
  - The operating procedure prescribes the verification of each connection on the synthesis module. The operator performed an incomplete check of the connectors.
  - The operator's awareness on procedures and good practices was enhanced.
- *Release of 31 GBq ^{11}C under the form of $^{11}CH_3I$ and $^{11}CO_2$ occurred during the synthesisof radiolabelled molecules (INES 0).*
  - The radioactive gaseous effluents are conventionally collected in a plastic bag in order to reduce the activity release while using 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 verification procedure did not clearly mention this bleed line.
  - The procedure has been adapted. The design was improved by adding a soda lime trap on the gaseous effluent line.
- *Release of 24,4 GBq ^{11}C occurred because of forgetting the placement of a gaseouseffluent collecting bag on the synthesis module (INES 0).*
  - ^{11}C was dispersed through the chimney.
  - A "slip or lapse" human error occurred.
  - The operator's awareness to respect the production check lists was enhanced. The possibility to add an electrical contact in order to warn the operators if the bag is missing was considered.
- *Release of 19 GBq ^{18}F due to leak of the collecting bag during FDG synthesis (INES 0).*
  - The gaseous effluent collecting bag was damaged by excessive wear.
  - Preventive replacement of the bag was decided.

  The five other events did not lead to releases exceeding the daily release limit. The causes of these releases are similar to the ones already mentioned.

  An analysis to detect the main causes of these ten events was performed. See Fig. 2.

  It is clearly observed that human error (mainly by lapse) and inadequate design constitute the most frequent causes of event. The lack of maintenance of some components is also frequently observed.

  Even though the number of events seems to be relatively important, the radiological impact on the workers and the population remained relatively low.

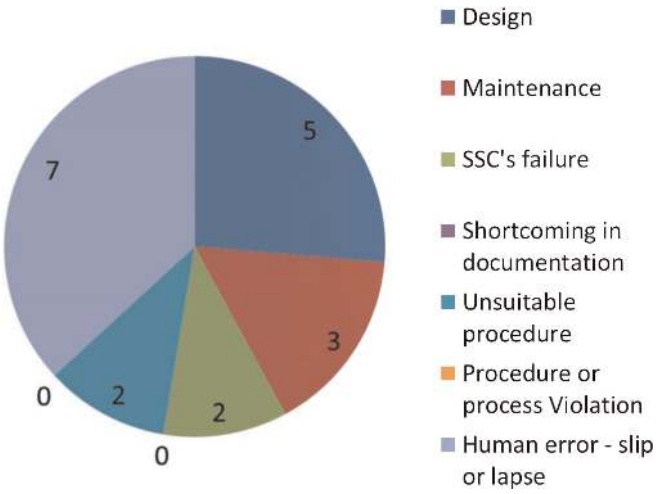

Fig. 2. Distribution of the identified causes for the ten events generating unintentional radioactive gaseous effluents releases declared by the Belgian radionuclides producers and conditioners facilities (2009–2015)

3.2.3 Other events that occurred in radionuclides producing and conditioning facilities

Eight other events were declared by the radionuclides producers or conditioners. The nature of these events is various and they were grouped in three types of events.

- *Loss of dynamic confinement. No respect of the pressure cascade.*
  - In the first event case, a gaseous nitrogen accumulation in a hot cell (due to an ice blocking filter) led to pressure disequilibrium. ^{123}I was dispersed in the controlled area and was released by the ventilation system to the chimney *(INES 0)*.

    One operator incorporated about 26200 Bq (internal effective dose estimated to 20 µSv).

    It was decided to perform, before the production, a nitrogen pressure verification as well as a blank test (without radioactivity).
  - The second event leading to pressure cascade inversion occurred in a facility awaiting decontamination. Ventilation was switched off by maintenance operators without prior notice to the Health Physics Department.

    No operators or controlled area contamination occurred.

    The staff training on the modification facility management procedure was improved. A licensee's note approved by the Health Physics Department was written to justify the ventilation stoppage.
- *Internal flooding of the controlled area due to drilling in water feedline when placing a laboratory shelf.*
  - The documentation on this water feedline was missing. Water flooded during about thirty minutes before finding the correct valve to switch off.

    No contamination occurred.

    The documentation on the structures, systems and components was improved.

- Five contaminations of operators, controlled area or shielded transport container occurred without significant increase of effective dose for the operators. Among them:
  - Two contaminations of operators occurred because the decontamination procedure did not clearly mention the frequency for this type of operation. Clarification of the procedure was performed. Training of the operators was enhanced.
  - The use of a "sealed" ^{137}Cs source in order to verify the calibration of a hands-feet monitor led to contamination in the controlled area and on one document found outside the controlled area.
    The thin film protecting the caesium deposit was damaged.
    The awareness of the radiation protection agent on good practices was enhanced. The damaged sealed source was discarded.

3.3 Events in accelerators (cyclotrons)

Ten events were declared to the regulatory authority by the cyclotrons facilities managers.

- *In spite of a possible failure of the Safety Programmable Logic Controller (PLC) of a cyclotron or in spite of a failure in the communication between the safety PLC and the cyclotron PC, the cyclotron starts running without any warning signal (17/11/204, INES 2).*
  - Preparing the cyclotron start up, the operator checks on the command PC all indicators related to the security status. He observes a message "Safety PLC not alive". However, the main security indicator is green: all safety interlocks are actuated. The operator decides to start the cyclotron but he observes that the γ probe measuring the ambient dose rate in the cyclotron vault is actuated. Normally it must be deactivated in order to be protected against radiation damages. He directly stops the cyclotron.
  - No irradiation of an operator occurred.
  - It seems that the communication between the safety PLC and the cyclotron PC was lost during several minutes. The licensee, his HPD and an informatics specialist tried to repeat this defect without any success. The worst case scenario would be the entrance of an operator in the vault without automatic stop of the cyclotron. Unfortunately, the real status of the vault door interlocks during this event remained unknown.
  - The licensee decided to place interlocks on the vault door connected with the electrical alimentation of the ion source in order to ensure that entering the vault will directly stop the cyclotron, without any intervention of the safety PLC.
- *By-pass of the cyclotron vault door interlock in order to allow cyclotron running indegraded mode. One operator entered the vault when cyclotron was potentially running(7/5/2015, INES 2).*
  - In order to perform neutrons measurement in the vault, the licensee decided to allow the cyclotron work in degraded mode (without prior approval of the HPD). Indeed, it was necessary to place a camera in the vault in order to read the results of the measuring equipment. The reading was realised by a student who remained outside the vault. Therefore, it was necessary to deactivate the interlock on the door in order to place the cable between the camera and its monitor outside the vault. The deactivation of the interlock was orally communicated to the present operators without any other indication on the vault door. An operator (who had not been warned as he was not working in the service that day) entered the vault during two minutes or so before going to the control room when he discovered that the cyclotron might have been running.
  - The operator did not wear any electronic personal dosimeter. A first dose evaluation led to an effective dose of 30 μSv. A conservative evaluation provided maximal effective doses of up to 700 to 1 500 μSv due to the neutrons and 40 μSv due to the γ emission.
  - The detected causes are:
    - the by-pass of the vault door interlock;
    - insufficient information was provided to the potentially implicated staff;
    - the operator did not wear any electronic personal dosimeter;
    - no clear warning that cyclotron was running in degraded mode: neither specific beacon nor physical barrier in front of the vault door.
  - Some improvements to the design are on-going: light indications modification, alarm ofgamma detector repeated in the hall, design modification to allow cable circulationunder the floor. The installation of an immaterial barrier in the vault chicane has alsobeen planned in order to stop the cyclotron when somebody enters.
- *Effective dose for two months of a cyclotron maintenance technician equals to 32 mSv, exceeding the dose limit of 20 mSv during 12 consecutive months (INES 2).*
  - The reading of a cyclotron maintenance operator legal dosimeter showed an effective dose of 32 mSv during a 2 months period, exceeding the legal limit of 20 mSv on 12 consecutive months. The HPD and the licensee tried to identify the cause of such an important dose. However, it seems unlikely that this dose could be received during the maintenance of the cyclotron. Indeed the HPD always performs a radiological survey before allowing the cyclotron maintenance. Measured dose rates and maintenance timing are incompatible with the effective dose of 32 mSv.
  - The operator effective dose during the last 5 years was 70 mSv. The Belgian regulation does not consider the average on five consecutive years of 100 mSv effective dose limit as proposed in the IAEA Radiation Protection Basic Safety Standards [13]. However, knowing the operator's experience and the radiological work conditions, the qualified physician and the HPD accepted that the operator continues to work in the controlled area on the condition that his effective dose per month remains lower than 500 μSv (or 6 mSv/12 months).
- *Three flooding events of the cyclotron vault due to infiltration of abundant rain watercoming from a bordering building construction.*
- *Two flooding events due to a defective secondary cooling water filter or bursting of asecondary cooling water line.*
- *Shooting on an empty liquid target until piercing of target back wall and havar sheet.*
  - Failure of the rheodyne valve that prevented the correct liquid target loading. Irradiation of an empty target led to piercing of the target back wall and the havar target window.
    Cooling water entered the He circuit. The degraded situation was not clearly identified by the licensee. In order to ensure the ^{18}F production, the licensee decided to irradiate on another target. The second irradiation

automatically stopped after 30 min. Indeed the water pressure in the He circuit generated overpressure on the titanium sheet between the vacuum chamber and the He circuit. The titanium sheet broke and approximately 20 litres of water were sucked into the cyclotron cavity.
  - No irradiation or contamination of the staff occurred. Small contamination of the intervention technicians was highlighted. Contamination of the cyclotron vault occurred (max ambient doserate in the vault 200 µSv/h).
  - Placement of "limit switch" on the rheodyne valve.
- *Release of 406 MBq ^{18}F through the chimney and dispersion of 130 GBq in the cyclotrondue to window target piercing.*

The identified causes of these ten events concerning cyclotrons are presented on Fig. 3. Inadequate design and structures, systems and components failures represent together two third of the causes of events.The procedure violation which consists in the placement of a by-pass on the vault door and the "slip or lapse" human errors are proportionally less abundant than those for the industrial and research irradiators (see § 3.1 of the present paper). The three external flooding of the radiopharmaceutical laboratories and the cyclotron due to abundant rainfall and infiltration from an adjacent building construction phase are particularly site specific events.

4 Discussion about operating experience feedback – Lessons learnt

A detailed analysis of the declared events by the licensees could be necessary to take advantage of any finding specific for each group of the "class IIA" facilities. The presented exercise could be usefully refined.

However, the aim of this paper is to highlight general messages about nuclear safety and radiation protection in the Belgian industrial and research irradiators, in the facilities producing and conditioning radionuclides and in the cyclotrons facilities.

The lessons learnt presented in this paper are certainly not "new". They are well known and applied in the class I facilities such as nuclear power plants. However the safety in the "class IIA" facilities could be reinforced by identifying the necessary corrective actions from these lessons learnt.

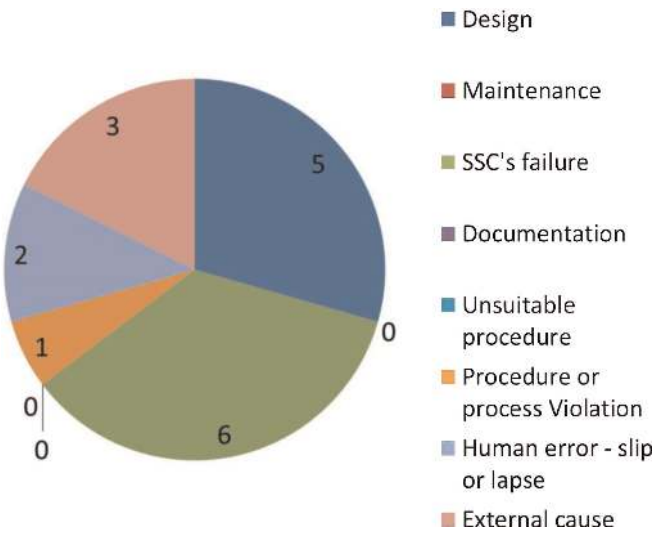

Fig. 3. Distribution of the identified causes for the ten events declared by the Belgian cyclotron facilities producing β+ emitters (2009–2015)

4.1 Facility and installation design

As already mentioned in the former paper [1], ancient installations are sometimes built with a weak design with regards to the new nuclear safety and radiation protection standards (for instance, the ventilation system, the absence of door cell interlock, ...).

Moreover, the documentation of some old systems or circuits is incomplete or missing. Modifications performed in the past were not always (sufficiently) documented. This incomplete written knowledge of the facility can lead to difficulties during the operational and post-operational phases of the facility.

4.2 Safety culture observations in the declared events

Analysis of the safety system by-pass events reported in § 3.1.1, § 3.2.1 and § 3.3 shows that the operators can be very inventive to circumvent interlocks in order to simplify their activities.

It is obvious that safety system by-pass is necessary to recover the facility in particular circumstances. The Regulatory Body pays specific attention to the fact that the use of by-pass has to be correctly analysed by the licensee's Health Physics Department and documented in an approved procedure (Operational Limits and Conditions should also be described in SAR).

Operator's behaviour can be a cause of event. On one hand, routine activities tend to lessen the operator's vigilance. On the other hand, (actual or supposed) pressure to gain time or ensure the production can lead to intentionally skip one or more safety layers.

The message given by the management and the Health Physics Department and the attention paid to the operator's supervision are of primary importance in order to prevent such behaviour [1].

It is impossible to develop nuclear safety and radiation protection without the staff's participation. Questioning attitude has to be encouraged in order to create favourable conditions allowing the staff's members to mention any anomaly or gap from a safe situation.

4.3 Lack of maintenance on systems important for safety

Safety analysis has to underline the safety functions and identify the structures, systems and components which ensure the safety functions.

Special effort to adequately maintain these SSC's is required.

4.4 Electronic personal dosimeter

The use of the electronic personal dosimeter should be strongly promoted. Indeed, correctly set and used, this equipment can be the last safety layer able to alarm and protect the operator from an irradiation.

5 Conclusions

This paper presents the significant events that occurred between 2009 and 2015 in the Belgian so-called "class IIA" facilities presenting a higher risk related to the ionising radia-

tions. These facilities are the industrial and research irradiators, the radionuclides producers and conditioners and the cyclotrons (see 20/07/2011 RD [3]).

The subsequent event causes analyses led to define some lessons learnt and to suggest some proposals for improvement for these facilities:

- the facility design has to integrate the recent nuclear safety and radiation protection standards;
- the systems description has to be sufficiently developed and correctly up-to-date after modification realisation;
- the safety culture has to be continuously reinforced. The operator's behaviour and self-discipline can be affected by the routine operation and/or by the pressure to ensure on time production. The management's as well as the HPD's messages are of primary importance to encourage the questioning attitude of the operators and to effectively promote the safety culture;
- the maintenance programme has to cover all parts of the systems important to safety which are subject to ageing;
- the use of the Electronic Personal Dosimeter should be strongly promoted.

In order to improve nuclear safety and radiation protection in the so-called "class IIA" facilities, it was decided to reinforce their safety requirements. Between 2009 and 2015, the Federal Agency for Nuclear Control (FANC) and Bel V paid attention, among others, to:

- the inspection and control programme performed by the Regulatory Body;
- the recording and reporting of the radioactive gaseous effluents releases from β+ emitters producing facilities;
- the radioactive waste management;
- the experience sharing with the licensees.

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Abbreviations

ALARA	As Low As Reasonably Achievable
FANC	Federal Agency for Nuclear Control (Belgium)
^{18}F-FDG	2-[^{18}F]-fluoro-2-deoxy-D-glucose
HOF	Human and Organisational Factors
HPD	Health Physics Department
IAEA	International Atomic Energy Agency
INES	International Nuclear and Radiological Event Scale
ONDRAF/NIRAS	Agency for Management of Radioactive Waste and Enriched Fissile Materials (Belgium)
PET	Positron Emission Tomography
PLC	Programmable Logic Controller
RD	Royal Decree
SAR	Safety Analysis Report
TSO	Technical Safety Organization

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