DEVELOPMENT AND APPLICATION OF INDICATORS FOR THE ASSESSMENT OF RADIATION SAFETY SYSTEMS IN RADIOPHARMACEUTICALS PRODUCTION FACILITIES WITH CYCLOTRON

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Abstract

The 'Class I Particle Accelerators Control Sector' of the Nuclear Regulatory Authority developed a tool that helps perform safety assessments of radiopharmaceuticals production facilities with cyclotrons. This tool was designed for the evaluation of safety systems implementation at the facilities and for monitoring the application of radiation safety standards in facilities that are currently operating. The paper presents indicators regarding safety systems considering the guidelines described in the document 'Criterios para el licenciamiento y requisitos de inspección en instalaciones con ciclotrones para producción de radioisótopos utilizados en aplicaciones e investigaciones médicas' (2013) from Foro Iberoamericano de Organismos Reguladores Radiológicos y Nucleares [1]. These indicators are intended to measure the level of adequacy of each facility compared to what is recommended in the referenced document. The indicators were collected and presented in an organized way using spreadsheets and graphics which makes easier its display and allows its interpretation depending on different criteria such as the type of safety system or type of facility. Finally, the follow up of these indicators was done from 2018 to 2021 and a tendency to improvement was detected as a consequence of the update of procedures and also due to the implementation of new safety systems. Moreover, through this tool, the Nuclear Regulatory Authority could monitor indirectly the success of the regulatory functions in the increase of the level of intrinsic safety at cyclotron facilities.

1. INTRODUCTION

Radiopharmaceuticals production facilities with cyclotron have to implement radiation safety systems in order to control and mitigate not only external exposure risks due to gamma and neutron fields generated during the cyclotron operation and the radioisotope production, but also internal exposure and surface contamination that may occur while working with unsealed sources.

Safety systems have to be prioritized in the features planned in the design of the facility and can be complemented with operational procedures with the purpose of ensuring the protection of workers, the public and the environment.

The design of these systems depend on different factors such as the equipment, for example, whether the cyclotron is self-shielded or not; the production processes that are carried out; the radioisotopes produced; etc. In addition, normal operational situations as well as incidents and accidents need to be considered during the design of this type of facilities.

The 'Class I Particle Accelerators Control Sector' of the Nuclear Regulatory Authority is the sector in charge of the regulatory control of radiopharmaceuticals production facilities with cyclotrons. The sector detected the need of a tool that helped perform safety assessments, particularly for the evaluation of safety systems implementation and the application of radiation safety standards at the facilities under regulatory control.

For its development, the document 'Criterios para el licenciamiento y requisitos de inspección en instalaciones con ciclotrones para producción de radioisótopos utilizados en aplicaciones e investigaciones médicas' (2013) [1] from Foro Iberoamericano de Organismos Reguladores Radiológicos y Nucleares was taken

as the primal reference, considering the guidelines presented there for interlocks, alarms, manual safety systems, plans and records. This document was chosen because it was considered the most representative of the state of the art concerning radiation safety in this type of facilities when the tool was developed.

In the paper, the conditions at cyclotron facilities that are in operation stage from Argentina are analysed. There are currently five facilities in operation stage, two of which have self-shielded cyclotrons, and the main radiopharmaceutical produced in the country is FDG.

The result of the analysis is presented using indicators that were developed by the 'Class I Particle Accelerators Control Sector'. The indicators are intended to measure the level of adequacy of each facility compared to what is recommended in the referenced document. They are collected and presented in an organized way using a spreadsheet and graphics which makes easier its display and allows its interpretation depending on different criteria such as the type of safety system or type of facility.

2. METHODS

The indicators were developed following the guidelines in [1]. For the purpose of the paper, they were divided in three categories: plans, safety systems (which includes interlocks, manual systems and alarms), and records. Each category consists of a list of requirements that are expected to be fulfilled by the cyclotrons facilities.

— Plans.
  - Site and location;
  - Facility layout, rooms function and distribution;
  - Location of cyclotron, hot cells and transfer lines;
  - Communication between rooms;
  - Flow of personnel and materials;
  - Room classification;
  - Identification and location of safety equipment and monitors;
  - Air flow and differential pressure in hot cells and rooms;
  - Constructive plans, indicating materials, shielding width, ventilation, electrical and other ducts, and filters.

— Interlocks.
  - Last person buttons (for non-self-shielded cyclotrons);
  - Single key system;
  - Vault door interlock associated with the cyclotron operation; for self- shielded cyclotrons irradiation only possible when the self-shielding is closed.
  - Vault door interlock due to high dose rate and/or monitor failure;
  - Hot cells doors interlock due to high dose rate and/or monitor failure;
  - Interlock due to differential pressure loss in cyclotron vault and hot cells;
  - Radioactive material transfer between cyclotron and hot cells only allowed when the pressure level in the hot cell is adequate and the door is closed;
  - Irradiation conditioned to the liquid level in liquid self-shielded cyclotrons;
  - Self-shielding movements not allowed during radioactive material transfer is completed;
  - Leak tightness test of the target, transfer lines and synthesis modules for gas production before.

— Manual systems.
  - Emergency buttons;
  - Manual system for opening the vault door internally.

— Audible and visual alarms.
  - Cyclotron operational status;
  - High dose rate in area monitors;
  - Transfer of radioactive material between the cyclotron and hot cells;
  - Failures in ventilation systems (differential pressure loss);
  - Area monitors failure;
  - Opening of vault door, hot cell's doors or opening of self-shielding;
  - Level of discharges in chimney;
  - Increase in activity concentration in different rooms;

- Reduction of the liquid level of self-shielding;
- Temperature change in the cyclotron vault (for liquid self-shielded cyclotrons).

— Records.

- Staff and visitors access to the facility
- Discharges and estimation of public doses
- Occupational exposure (staff doses)
- Optimization program
- Radiological surveillance – monitoring
- Operational and production
- Radiological events and/or accidents reports
- Maintenance
- Radioactive waste
- Training
- Safety systems testing
- Calibration sources inventory and its calibration certificates
- List of radiological equipment
- Calibration certificates of radiological equipment
- Inspections and audits reports
- Packages, shipping and sales

Once these categories were established, it was necessary to perform a safety assessment in order to determine the level of adequacy for each category. The safety assessment was done mainly by reviewing the documentation and procedures of the facilities, such as: the safety report, operational procedures, maintenance procedures, monitoring reports, emergency preparedness and response plan, etc. The process of reviewing these documents is aimed also to verify the compliance to the requirements established in the regulation applicable to this type of facilities ([2], [3] and [4]). Other relevant information could also be obtained by other means, for example, during regulatory inspections.

By doing this assessment, it could be determined whether a requirement was fully, partially or not fulfilled. With the aim of having a numerical representation, it was arbitrarily assigned a value of '2' for those requirements that were fully met; for those that were partially met, a value of '1'; and for those that were not met, a value of '0'.

Afterwards, the percentage of adequacy was calculated considering the total points obtained. For this calculation, it was also taken into account the type of facility, as there are requirements that apply only in certain cases. For example, some interlocks may not be needed if the cyclotron is self-shielded whereas others are only applicable in those cases. Moreover, some safety systems are related to liquid self-shielded cyclotrons.

The results of the assessments were collected using a spreadsheet in which the indicators were calculated. A sample of the spreadsheet is shown in Fig. 1. For the purpose of the paper, the facilities were named *A*, *B*, *C*, *D* and *E*.

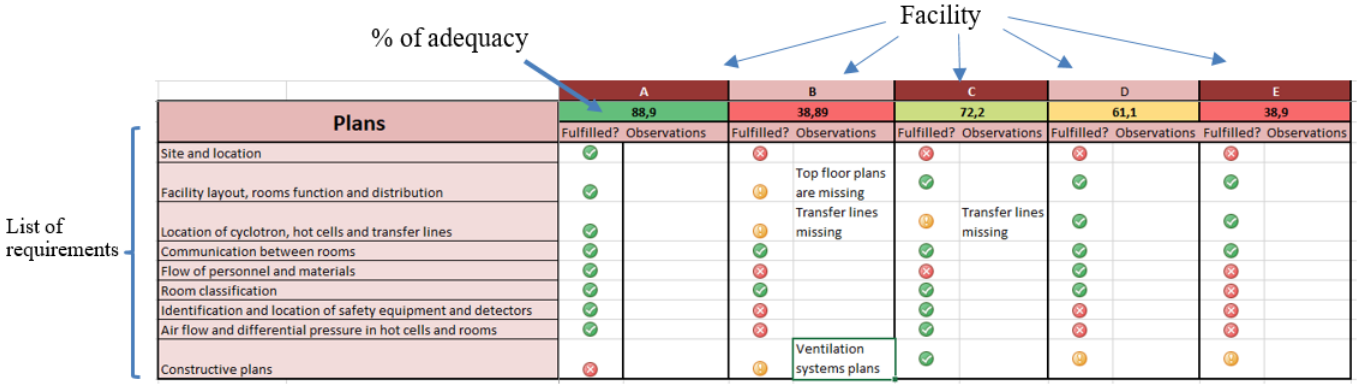

FIG. 1. Sample table with the result of safety assessments.

For each facility there are two columns: in the first one it is selected if the requirement is fully (green), partially (orange) or not fulfilled (red); in the second one, any other observation or comment can be added. The second column does not necessarily have to be completed, it is just to add further comments or additional information that could be useful.

The spreadsheet has also the option to save the indicator values in a different table with the date. This option has the purpose of recording the indicators over time so that it can be analysed the development of each facility.

3. RESULTS

The indicators were measured from 2018 to 2021, taking into consideration the list of requirements presented in section 2.

The following charts show the evolution of the indicators from 2018 to 2021 for facilities A to E. In Fig. 2 it can be observed the percentage of adequacy throughout the years regarding the plans listed in the previous section. It can be seen that, in general, all the facilities improved the information presented in their plans. It should be noted that *Facility E* was the one that had the biggest improvement, especially between 2020 and 2021, due to the update of their plans in the context of the process of authorization of an expansion of the facility.

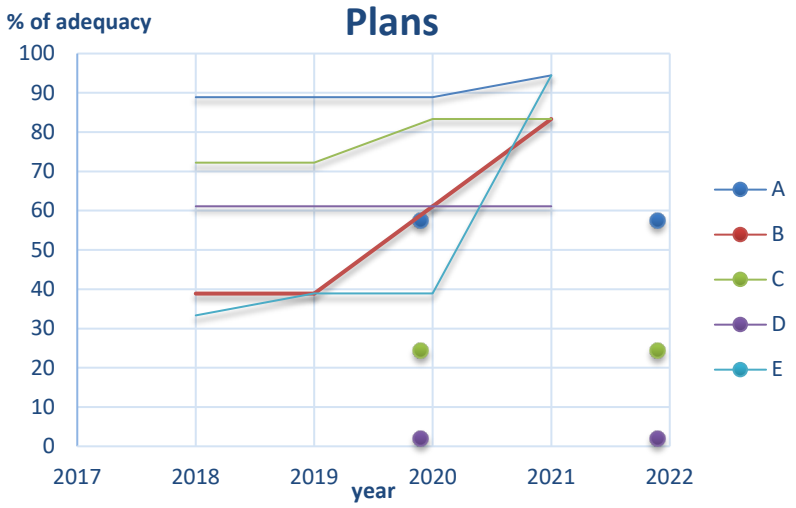

FIG. 2. Percentage of adequacy of plans for facilities A to E, from 2018 to 2021.

In Fig.3 it is showed the percentage of adequacy of safety systems (including interlocks, alarms and manual systems) over time. There are some points in which the percentage drops because, for example, a safety system was out of service due to failure of a radiation monitor. However, the general tendency is positive and whenever a problem with a safety system was detected, it was repaired or compensated in order to maintain or improve the level of safety.

Furthermore, it is observed that *Facility B* improved significantly its safety systems. One major improvement was the addition of a last person button, which is an extremely relevant interlock in a non-self-shielded cyclotron to assure that the vault is empty before irradiation and prevent accidents.

Figure 4 shows the evolution of the percentage of adequacy of records over time. It can be observed that in 2021 the level of adequacy is over 80% for all the facilities.

The results of the last assessment are shown in Fig.5. It can be observed that the general conditions are within an acceptable level of adequacy. Regarding safety systems, *Facility D* is the one with the least fulfilment with nearly 50% of adequacy because it does not have modern equipment in the radiopharmacy laboratory. However, the facility is in process of updating the laboratory and relevant improvements are expected in the upcoming year.

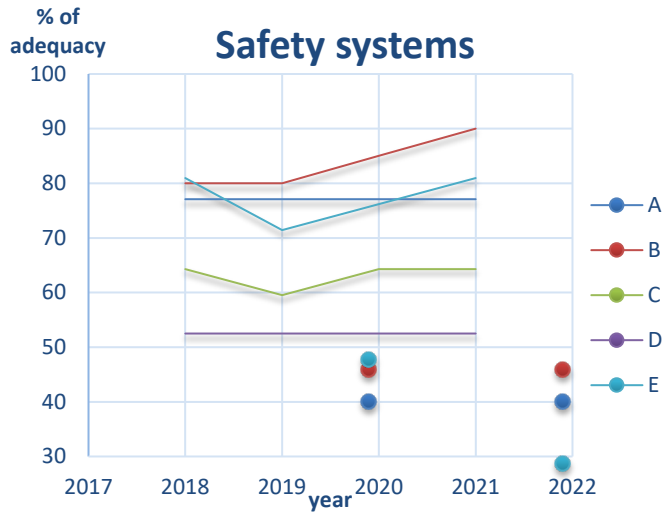

FIG. 3. Percentage of adequacy of safety systems for facilities A to E, from 2018 to 2021

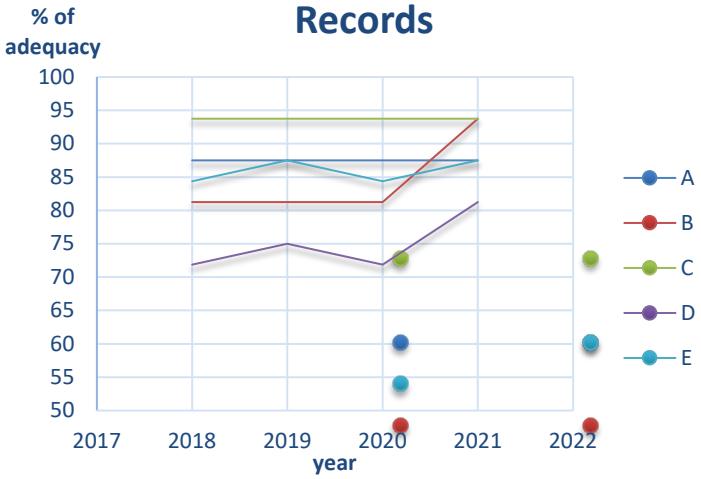

FIG. 4. Percentage of adequacy of records for facilities A to E, from 2018 to 2021.

When the implementation of a safety system is not available or it is not feasible, procedures have to be implemented with the objective of replacing temporarily the lack of the safety system. In this case, the requirement is classified as "partially met" for the indicator calculation, which corresponds to a value of "1".

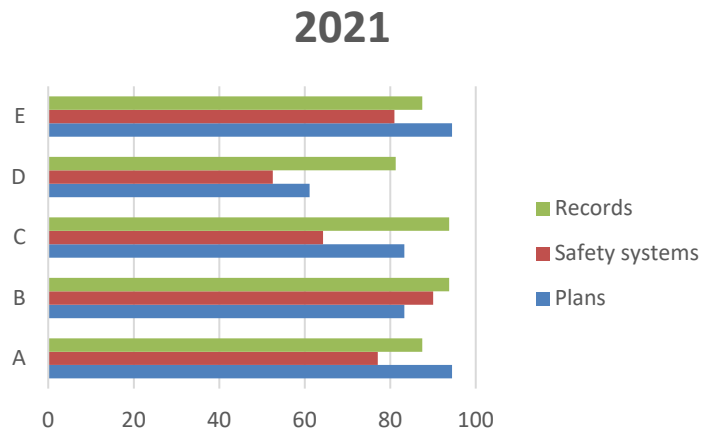

FIG. 5. Results in the 2021 for facilities A to E

4. CONCLUSIONS

Through the development and implementation of the tool presented in the paper, it was possible to not only measure but also to follow up over time the general safety conditions in radiopharmaceuticals production facilities with cyclotron.

In the first place, the indicators developed by the 'Class I Particle Accelerators Control Sector' proved to be useful, as it is a systematic way to measure the results of the safety assessments done by the regulatory body. It also allowed to record and to follow the evolution of the indicators throughout the years in a simplified way, because the spreadsheet is easy to update.

Furthermore, the indicators helped to detect which aspects had to be improved in the different facilities. In this regard, it could be observed that the general tendency was towards improvement in all three of the categories (plans, safety systems and records). Nonetheless, if a significant drop in the percentage of compliance happens to be detected, the regulatory body needs to take further actions to determine the causes and to assure the re-establishment of the previous safety conditions. In this way, the regulatory body can monitor indirectly the regulatory functions in the increase of the level of intrinsic safety at cyclotron facilities.

For the above mentioned reasons, performing safety assessments with the aid of this kind of tool is really valuable for the regulatory body, but it also has to assure that all the safety systems and records are implemented. Thus, this task has to be complemented with regulatory inspections in which it can be verified that safety systems are operating correctly and records are being completed. Additionally, the process of developing this instrument is really fruitful for safety inspectors because it leads them to study deeply the characteristics and safety aspects of the facilities under regulatory control.

It has to be noted that the results presented in the paper are limited to the facilities that are currently in operational stage in Argentina, but the same analysis can be applied to other stages of the life of a facility, such as construction, commissioning and decommissioning. In these cases, the list of requirements should be extended considering the particularities of each stage. It could also be developed an equivalent tool for other type of facilities.

Overall, it is important to highlight that the enforcement of new standards in facilities that are already constructed and have been operating for several years is not an easy task for the regulatory body. However, it is one of the main goals of the regulator to ensure that the safety conditions always tend to be better and stay aligned as much as possible with the state of the art for this type of facilities. Then, counting with a tool as the one presented in the paper is remarkably helpful to review the evolution of the safety conditions and to pursue said objective.

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