REGULATORY FRAMEWORK ADOPTED BY THE NUCLEAR REGULATORY AUTHORITY OF ARGENTINA FOR THE LICENSING OF THE ARGENTINE CENTER OF PROTON THERAPY AND PROGRESS ACHIEVED

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Abstract

The Argentine public health system is currently carrying out the project of the Argentine Proton Therapy Center (CeArP), being the first in the region to incorporate high-energy proton beams for cancer treatment. This center is designed to have two treatment rooms and a Research and Development laboratory, provided with a 230MeV proton beam generated by a cyclotron. This project represents a challenge for the regulatory body, the Nuclear Regulatory Authority of Argentina (ARN), as it does not have a specific regulatory framework or staff with prior experience in this technology. The paper summarizes the activities conducted by the ARN during the CeArP licensing process, describes the regulatory approach adopted and the implemented steps to strengthen its capacities. Finally, the milestones achieved so far, the lessons learned and future plans are presented in the paper, as well as the challenges caused by COVID-19 pandemic that led to adapting de regulatory process with remote collaborative work to analyze the documentation.

1. INTRODUCTION

In 2016, the National Commission of Atomic Energy (CNEA) notified to the Nuclear Regulatory Authority of Argentina (ARN) the plan to carry out the project of the Argentine Proton Therapy Center (CeArP). The original project included a treatment room and a Research and Development laboratory, provided with a 230MeV proton beam generated by a cyclotron. Despite pauses in the project that delayed construction, progress continued and modifications were implemented, adding one more treatment room to the original design. The placement has been defined in Buenos Aires City, in a strategic zone, next to the Oncology Institute “Dr. Angel H. Roffo” and the “Nuclear Medicine Center Foundation (FCDN)”.

This center would be the first in Latin-America with this type of technology, representing a challenge not only for the entity in charge to operate the facility, but also on the regulatory side. During this time ARN had to work improving their technical capabilities to deal with this new technology properly. Furthermore, the regulatory framework of ARN had to be adapted to carry out the regulatory processes in a proper way.

Finally, in February 2021, the Responsible Entity presented the documentation formalizing the beginning of the licensing process of the facility.

2. REGULATORY APPROACH

The ARN is facing this regulatory endeavour working on different strategies. Since the beginning of the project, the development of technical capabilities of the personnel has been a priority. Furthermore, adapting the regulatory framework and different organizational aspects in order to facilitate the licensing processes to a new technology has been a great challenge.

2.1. Training

Since ARN was notified of the Argentine Proton Therapy Center (CeArP) project in 2016, efforts are being made by the regulatory body to further develop the technical capabilities of its human resources, through the participation of members of the evaluation group in technical meetings, workshops, specializations studies, collaboration projects with other regulatory bodies and internal training sessions related to proton therapy, among others.

2.1.1. Participation in technical meetings, workshops

ARN has encouraged the participation of the personnel in technical meetings and workshops; events as a technical meeting in the University of Philadelphia that took place in 2016 with the vendor of the center, or the 1st Argentine Workshop of Proton Therapy in 2019.

2.1.2. Specialization Studies

Most of the members of the evaluation group have completed the IAEA funded Specialization Course in Radiological Protection and Safety of Radiation Sources. Moreover, one member chose the licensing of a proton therapy center as the final project for the Specialization.

Additionally, another member embarked on master's studies through a Fulbright scholarship in the United States, at the University of Florida, which houses an active proton therapy center. He was able to take different courses on various topics relevant to the licensing of the center and participate in the Penn Radiation Oncology, "Fifth Annual course in Proton Therapy", in November 2018.

2.1.3. Internal training sessions

A comprehensive reading of IAEA-TECDOC 1891 was performed; the document was distributed among the personnel for its reading and study after its publication in January 2020. A session was organized to discuss the most relevant topics of the document.

2.1.4. Collaboration projects with other regulatory bodies

There is a collaboration project signed in 2021 between ARN and CNEN (the regulatory body of Brazil), where it was included the cooperation in 'Proton therapy and authorization processes in high energy cyclotrons'. Thus, exchange activities were programmed including remote virtual meetings and technical visits in Argentinian and Brazilian facilities. The authorization processes for facilities' personnel were also included in the agenda, which is in progress.

2.2. Regulatory framework

The Nuclear Regulatory Authority of Argentina (ARN) is the responsible of establish, develop and implement a regulatory regime for all nuclear activities carried out in Argentina. The national law Act 24.804, which came into force on April 25, 1997, gives to the ARN the power of dictate the country standards. The regulatory framework of the nuclear activity is sustained by 64 regulatory standards and 10 regulatory guides. It classifies the facilities as Class I, Class II and Class III considering the following criteria [1]:

- radiation sources in the facility or practice,
- environmental radiological impact,
- radiological consequences of potential exposures,
- the ocupational doses and,
- technological complexity.

From the Argentine regulatory framework, does not emerge a direct classification for a proton therapy facility. This classification is not trivial, since all the medical applications with accelerators are classified as Class II facilities and cyclotrons are generally considered Class I. But in this case, the facility was considered as one single element.

ARN has strengthened its regulatory framework for authorization and processes oversight, to ensure that national and international standards are met. For this purpose, ARN has defined some general guidelines related with the authorization processes of the facility and the regulatory task assignments.

2.2.1. Authorization process

The Argentine Proton Therapy Center (CeArP) was categorized as a Class I facility. This classification was defined using a graded approach, considering not only the radiological risk of its operation, but also the consequences of an incidental/accidental event and its technological complexity [3]. The authorization process is being implemented in four stages, with construction, commissioning, operation and decommissioning authorizations, as established by the ARN standards for Class I facilities and the recommendation of IAEA.

2.2.2. ARN Strategic plan

The authorization process of the Proton Therapy Center has been included as a priority in the ARN strategic plan for 2021-2025. In this manner, ARN reaffirms its commitment to radiation safety with the corresponding allocation of resources [5].

2.2.3. Creation of the Project

To carry out these regulatory endeavours, a multidisciplinary working group was formed by the ARN, with strategic personnel with background in regulatory affairs in an attempt to leverage prior experience. The creation of the 'Licensing Project of the Argentine Center of Proton Therapy' gives a formal structure, but taking into account that their members belong to different working areas of the ARN with their own responsibilities.

The 'Project' has its following objectives:

- Manage the licensing of the facility, until the eventual granting of the Operating License,
- Plan regulatory activities related to licensing,
- Generate the necessary communications with the Responsible Entity,
- Manage documentation related to licensing,
- Coordinate the necessary evaluations and give intervention to suitable personnel of the "Class I Particle Accelerators" sector and the "Radiotherapy and Brachytherapy" department, in addition to submitting requests for external evaluations to management, when necessary,
- Prepare the relevant reports

The 'Project' depends on the 'Radiation Safety, Safeguards and Security' Department of ARN and it is essentially formed by two sectors: "Class I Particle Accelerators Control" and "Radiotherapy and Brachytherapy". Two members of other ARN sectors with experience in safety assessments have been summoned to the working group, and to this day, it is composed of six members.

3. RESULTS

After several years of work, results are starting to be seen in each of the lines of action in which the ARN has advanced.

3.1. Training

The training activities carried out to date have given satisfactory results, being able to strengthen the capacities of the staff introducing themselves in the particularities of the proton therapy. In addition, the trainings have allowed the personnel of the two main sectors participant to be able to get involved in the regulatory aspects that derive from the other and thus increase the technical capacities of the group.

There are some other activities planned to be carried out soon, as the technical visits of experts and the development of knowledge exchange activities with other regulatory bodies with experience on authorization and inspection process of this technology.

3.2. Authorization processes

3.2.1. Facility

In February 2021, the Responsible Entity submitted to the ARN the Preliminary Safety Report required for granting the construction authorization, which has been evaluated by the working group of the 'Licensing Project of the Argentine Center of Proton Therapy'. Due to the COVID-19 restrictions, the regulatory processes needed to be adapted; in this way, the safety assessment of this documentation was realized remotely.

Virtual technical meetings were realized for this purpose, where technical discussion enriched the group work. Other ARN sectors have contributed to the evaluation working in specific topics. Technical reports with the safety assessment conclusions were made and circulated among the group.

At the moment, the experience of virtual work in safety assessment has been very positive for this working group. The work has been smooth and efficient, and it is expected to continue in this way with the evaluation of the remainder documentation that it is expected to come.

3.2.2. Staff

Facility personnel will be authorized through a mixed licensing scheme, combining the staff licensing process applicable to Class I facilities with the one for obtaining individual permits that applies to Class II facilities [6] [7]. This licensing scheme has been developed by applying a graded approach to existing ARN standards for staff licensing during the evaluation of the proposed organizational structure of the Proton Therapy Center. Emphasis will be placed on ensuring adequate education and training for all positions in the organization chart, as well as the application of an Integrated Safety Management System that includes a program for the promotion of a strong safety culture, according to ARN standards, in particular **AR 10.6.1** "Management System for Safety" and GSR Part 3 [8].

4. CONCLUSION

The efforts made by the ARN since the notification of the construction plan to assume the licensing of a new technology, such as proton therapy, are showing promising results.

On one hand, special efforts have been made to support and promote staff training. The ARN understood from the beginning that the training process must be continuous and once started, the skills of the personnel must be maintained and improved. From 2016 to date, several training activities have been completed with satisfactory results. It is planned to continue in this direction in the years to come.

On the other hand, it has been necessary to strengthen the regulatory framework in order to carry out the licensing process in accordance with national and international standards. For this reason, work is being done on the application of a graded approach both to the licensing of the facility itself and in the personnel licensing process, with visible progress.

To meet the aforementioned objectives, the development of an 'ad hoc' working group, with complementary backgrounds, can be considered an adequate decision. Proof of this is the work carried out, within the context of the restrictions due to the pandemic, delivering concrete results such the complete evaluation of the first version of the Preliminary Safety Report.

Finally, the ARN's commitment to safety and good practices has been demonstrated, which are not only expressed in documents such as the strategic plan, but also in regulatory actions and we hope to continue on this path.

REFERENCES

[1] Autoridad Regulatoria Nuclear, "Norma AR 10.1.1. - Norma Básica de Seguridad Radiológica - Revisión 4", (2019).
[2] Autoridad Regulatoria Nuclear, "Norma AR 0.0.1. - Licenciamiento de instalaciones Clase I - Revisión 2", (2002).
[3] Autoridad Regulatoria Nuclear, "Norma AR 5.1.1. - Exposición ocupacional en aceleradores de partículas Clase I - Revisión 1", (2002).
[4] Autoridad Regulatoria Nuclear, "Norma AR 5.7.1. - Cronograma de la documentación a presentar antes de la operación de un acelerador de partículas - Revisión 1", (2002).
[5] Autoridad Regulatoria Nuclear, "Plan Estratégico Institucional 2021-2025", (2021)
[6] Autoridad Regulatoria Nuclear, "Norma AR 0.11.1. - Licenciamiento de personal de instalaciones Clase I - Revisión 3", (2002).
[7] Autoridad Regulatoria Nuclear, "Norma AR 8.11.3. - Permisos individuales para especialistas y técnicos en física de la radioterapia - Revisión 0", (2006).
[8] Autoridad Regulatoria Nuclear, "Norma AR 10.6.1. - Sistema de gestión para la seguridad en las instalaciones y prácticas - Revisión 0", (2020).
[9] IAEA, TECDOC-1891 – "Regulatory Control of the Safety of Ion Radiotherapy Facilities", (2020) AAPM task group 224: Comprehensive proton therapy machine quality assurance, (2019)
[10] PTCOG Safety Group Report On Aspects of Safety in Particle Therapy – Version 2, (2016)
[11] Autoridad Regulatoria Nuclear, "Norma AR 8.2.2. - Operación de aceleradores lineales de uso médico - Revisión 1", (2002).