REGULATORY CONTROL AT THE CONSTRUCTION STAGE OF A RADIOPHARMACEUTICALS PRODUCTION FACILITY WITH CYCLOTRON IN THE CONTEXT OF COVID-19 PANDEMIC

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Abstract

Inspections and regulatory processes at the construction stage of a radiopharmaceuticals production facility with cyclotron have certain particularities that distinguish them from the processes related to other stages of the life of a facility. Particularly, the construction of a concrete shielding of great thickness, such as a non-self-shielded cyclotron vault, requires a set of specific controls by the regulatory body for the purpose of avoiding construction failures that could ultimately affect the safety conditions during the operational phase.

Due to the pandemic COVID-19 restrictions, the Nuclear Regulatory Authority, through the 'Class I Particle Accelerators Control Department', implemented alternative forms to develop the regulatory tasks associated to a facility denominated 'Cyclotron- Radiopharmacy Laboratory' from Oulton Institute located in Córdoba City, Province of Córdoba, Argentina, during the construction stage that had satisfactory results.

1. INTRODUCTION

The regulatory framework established by the Nuclear Regulatory Authority of Argentina (ARN) determines four stages for the authorization process of a radiopharmaceutical production facility with cyclotron; since it is classified as a Class I facility: construction, commissioning, operation and decommissioning [1]. This scheme of authorization stages is in line with the IAEA recommendations as the state of art for this type of facilities. In such way, in Argentina, the development of the construction stage of a cyclotron - radiopharmacy facility requires an authorization from the regulatory body [2].

This construction stage includes not only the development of civil works, but also the assembly of equipment and components of the facility. The documentation submitted by the applicant to get this authorization has to cover the following topics: facility layout, flow of materials and personnel, shielding design, ventilation system design, radiological impact on workers and the public, etc.[3]

The 'Class I Particle Accelerators Control Sector' of ARN did a detailed analysis of these documents in order to verify that all the radiation safety aspects were properly considered. In March 2020, the ARN granted the authorization of construction to begin the civil work of the facility 'Cyclotron - Radiopharmacy Laboratory' from Oulton Institute located in Córdoba City, Province of Córdoba, Argentina.

Regulatory inspections are a valuable instrument for verifying compliance with the conditions under which the authorization of construction is granted. Furthermore, since March 2020, the Government of Argentina has stablished restrictions to the circulation due to the sanitary emergency that was declared in view of the new coronavirus COVID-19, which affected the development of on-site regulatory tasks.

2. CRITERIA

There are a series of considerations that have to be taken into account in order to verify the conditions stipulated during the design phase, concerning radiation protection of workers, the public and the environment are being followed.

During the construction stage, a large proportion of the regulatory controls are intended to check that some criteria related to the cyclotron vault are followed, such as:

1. A cyclotron vault must be a monolithic structure; this is achieved by a one single cast of concrete or, in case it was not technically possible, by another technical solution that guarantee the shielding capacity of the vault.
2. Formwork and shoring systems must not reduce the shielding capacity; these elements remain inside the structure after the concrete curing decreasing the shielding capacity, so they should be replaced by heavy extern shoring systems.
3. Assembly of ducts ins and outs to the vault must avoid the leakage of neutrons; 90-degree bends over the three cardinal axes are necessary to be placed.
4. Future decommissioning tasks must be foreseen; the adoption of concrete blocks that work as a 'sacrificial' layer that facilitate the future dismantling works of the vault.

The compliance of these criteria has been a challenge for the licensee. Some of these criteria could be applied and others presented some difficulties (that are described below) that made necessary to apply innovative technical solutions.

1. A cyclotron vault must be a monolithic structure,

It was informed to ARN that there was no available concrete supply in Córdoba city to complete one single cast at once. Thus, it was necessary to plan several concrete casts to erect the vault in layers of concrete. A construction through layers of concrete can produce deficiencies in the contact surfaces that could affect the shielding capacity of the vault and the consequent risk of radiation leakages. After a discussion with the facility manager, it was agreed to insert a double wooden frame inside the steel armor, along the perimeter of the vault. A short time after the pour of concrete of the layer is finished, the wooden frame would be retired to produce 'steps' that avoid interface plans between the layers of concrete.

The construction project of the vault that was presented by the facility to ARN is illustrated in figure 1.

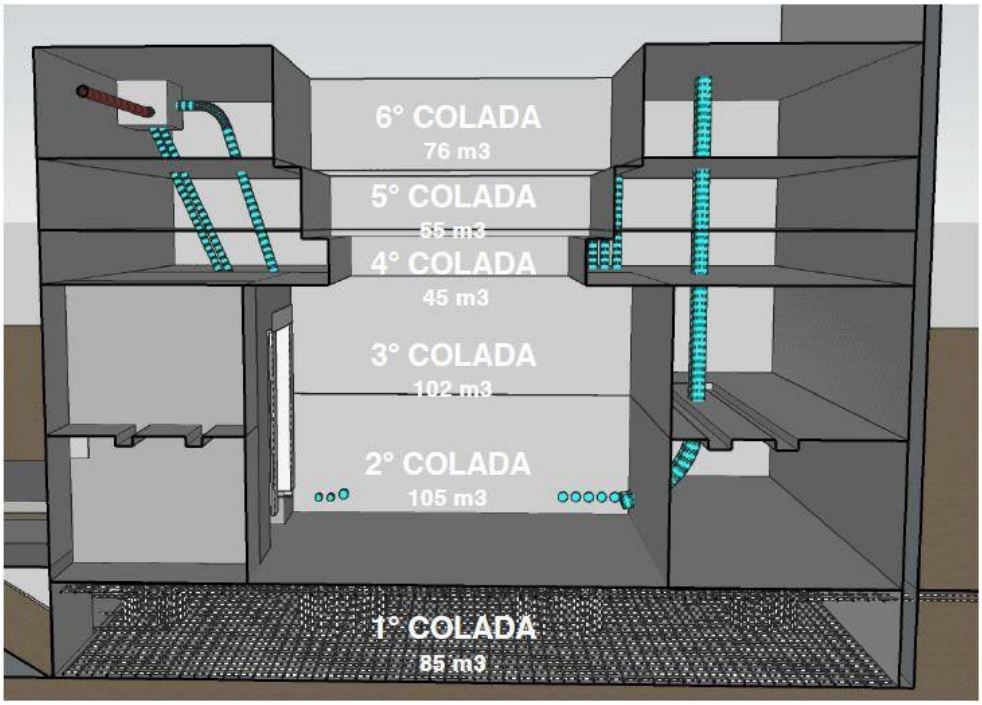

FIG. 1. Vault project with the concrete cast in six layers

The ARN analyzed that plan and suggested to modify the height of the layers n°2 and 3, because the interface surface between those layers matched the proton acceleration plan of the cyclotron and its targets. (*See FIG. 2*)

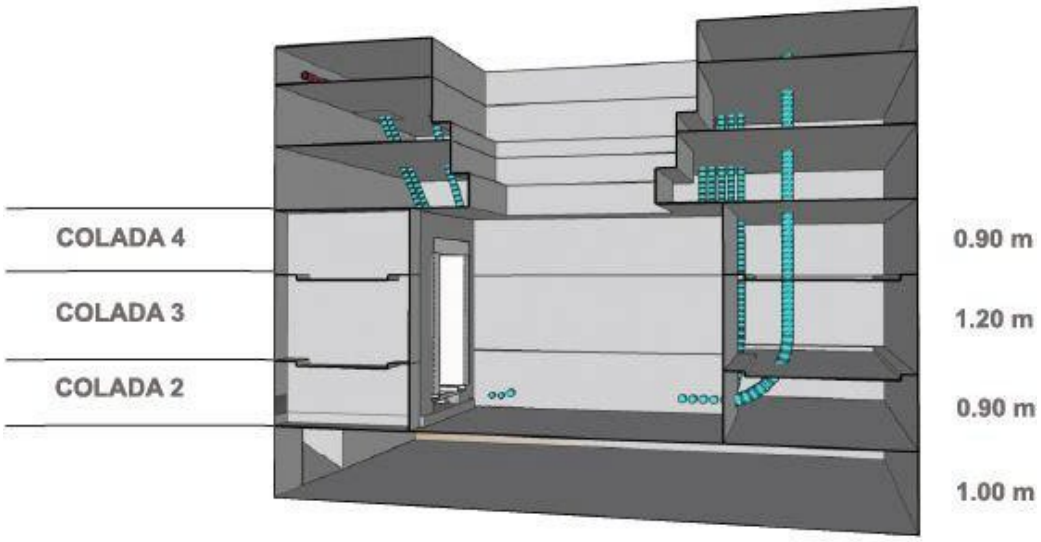

FIG. 2. Vault with the layers' height modified

In addition to this, it was requested to vibrate the concrete with appropriate equipment during the pouring, to prevent the generation of air bags inside the vault shielding.

2. Formwork and shoring systems must not reduce the shielding capacity,

It is common in civil constructions the use of metallic tensors to grew the resistance of the concrete containment during the pouring and simplify the formwork assembly. These tensors remain in the shielding structure and might produce possible radiation leakages due to metal corrosion. For this reason, it is requested to replace the use of tensors for extern shoring systems that have to be able to resist the concrete pressure.

Extern shoring systems were foresaw in this project and these criteria could be successfully complied through the adoption of different kinds of shoring systems. (*See FIG. 3*)

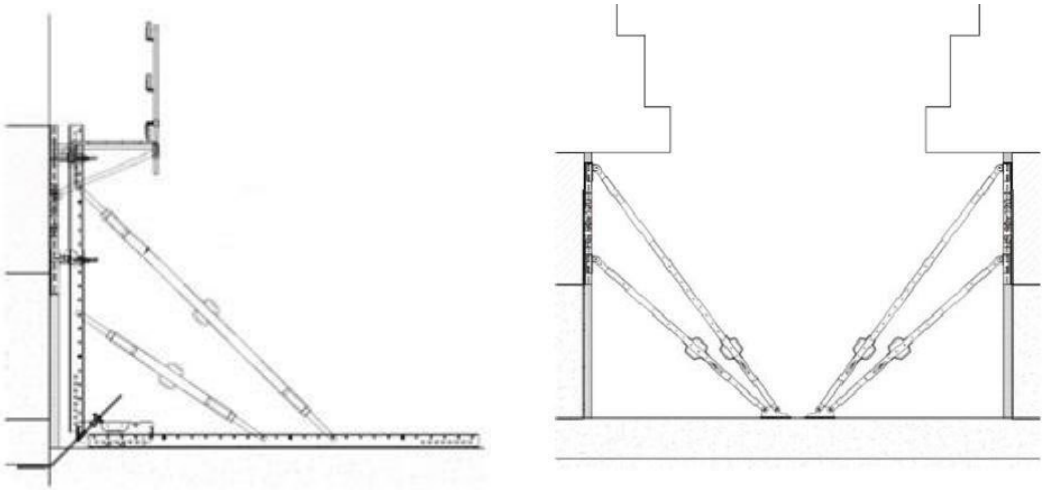

FIG. 3. Shoring systems

3. Assembly of ducts ins and outs to the vault must prevent the leakage of neutrons,

The route of ins and outs ducts to the vault that were presented in the ventilation system project, satisfies the requirements by adopting three 90-degree turns over the cardinal axes preventing neutron leakages. This can be observed in the next figure.

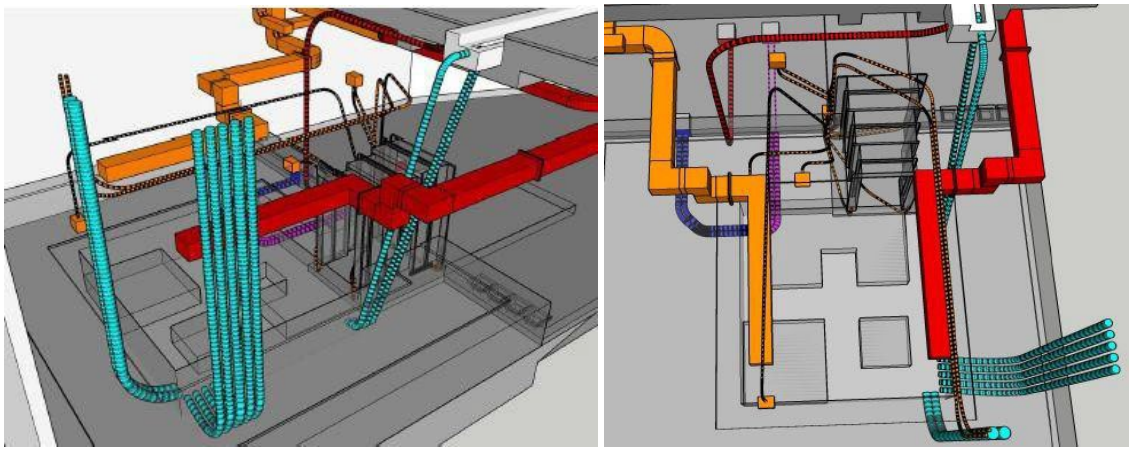

FIG. 4. Project of ins and outs ducts of ventilation system

4. Future decommissioning tasks must be foreseen.

ARN requested the facility to include a sacrificial layer in the vault project. The facility presented a project of concrete blocks with a particular design (*See FIG. 5*). This design of blocks to assemble allows the interior walls of the vault to be covered easily.

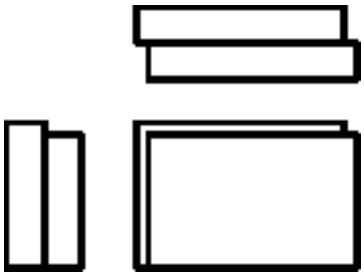

FIG. 5. Concrete blocks project for 'sacrificial' layer

Considering the expected use of local shielding for FDG production targets, the resulting concrete blocks thickness is 10 cm.

3. INSPECTIONS AND REGULATORY CONTROL

The development of inspections during the construction stage and especially prior to the pouring of the concrete, allows the regulatory body to verify whether the criteria described in the previous section have been considered.

The restrictions established due to the COVID-19 pandemic made it difficult to travel to Córdoba city to carry out on-site inspections. Thus, it was required to implement alternative solutions in order to continue with the regulatory control adequately. ARN adapted its regulatory processes incorporating the remote work, and to this extent, the 'Class I Particle Accelerators Sector' followed the execution of the civil works remotely by reviewing photographic reports that the facility sent to the ARN continually.

In this context, photographic records of the civil works were critical, and it was extremely important that workers in charge of taking these photos understood what needed to be depicted in them. For this purpose, a remote meeting between inspectors of ARN and the civil work staff was made. Inspectors of ARN clarified relevant concepts as well as answered questions and the staff could take great pictures of the civil work progress.

The following pictures show the fulfillment of the criteria, according to the approved project.

— A cyclotron vault must be a monolithic structure

FIG. 6. Wooden frame inside the armor previous the concrete cast

FIG. 7. Double wooden frame inside the armor

FIG. 8. The 'step' generated by the wooden frame

FIG. 9. A civil worker vibrating the concrete during the cast

— Formwork and shoring systems must not reduce the shielding capacity,

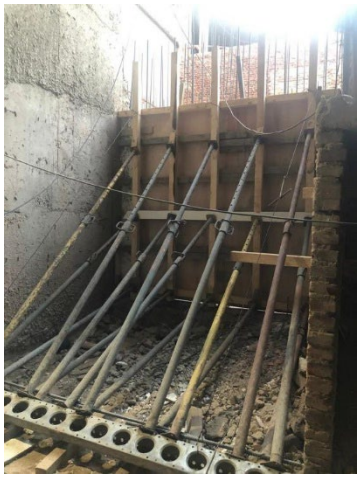

FIG. 10. Shoring system to extern vault wall

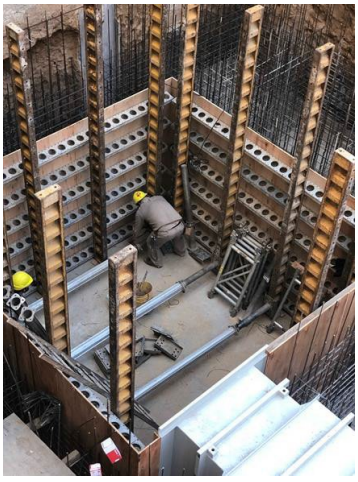

FIG. 11. Shoring system to intern vault wall

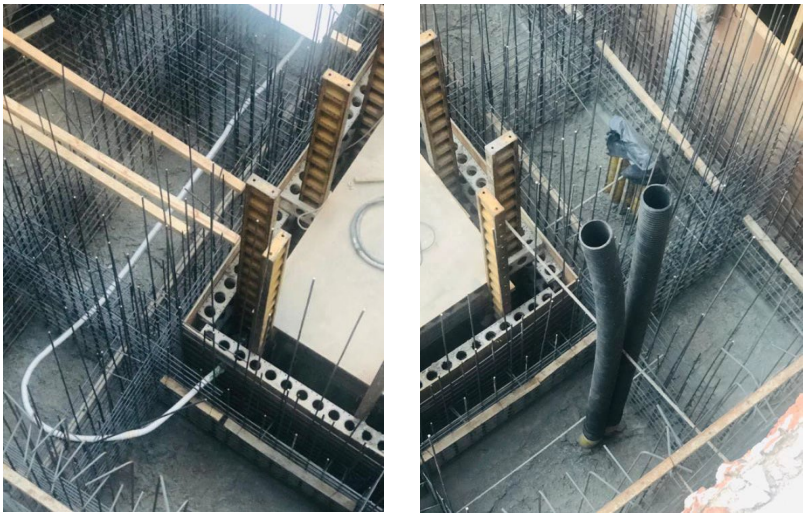

FIG. 12. Absence of intern metallic tensors

— Assembly of ducts ins and outs to the vault must prevent the leakage of neutrons,

FIG. 13. Ins and outs ventilation ducts from the vault

The proper assembly of ventilation ducts was verified by these pictures. In addition to this, the electrical cabling, water, gas and product supply tubing to and from the cyclotron were also properly placed on trenches in the vault floor, connecting to the underside of the cyclotron.

FIG. 14. General services piping

— Future decommissioning tasks must be foreseen.

FIG. 15. Concrete blocks for 'sacrificial' layer

The inner walls of the cyclotron vault were covered with concrete blocks as it was approved in the design phase. These concrete blocks were built on the construction site.

4. CONCLUSIONS

The objectives of the regulatory control during the vault construction were successfully fulfilled. The current criteria in the matter were properly considered and adapted according to the needs and the technical limitations, as it could be observed.

The Covid-19 restrictions forced inspections processes to be adapted and the results obtained by the 'Class I Particle Accelerators Sector' of ARN in the control of construction stage tasks have been very positive until now. The implementation of a remote meeting to exchange knowledge with not only the operators but also the civil work team has been a great decision in order to assure that the verification could be done properly, taking into account that some relevant aspects can be verified only during the concrete cast but not later.

The early participation of the regulatory bodies in the evaluation of the design projects and the fluid communication with the operators could demonstrate that streamlines the progress of the civil work.

Fortunately, a few months after the concrete cast, the restrictions were released and the inspectors of ARN could verify on site that the construction progress is in accordance with the approved project. However, it is valuable to consider that despite the fact that remote controls had satisfactory results, they do not replace on-site verifications; because the remote-control success relies strongly on an effective communication between the licensee and the regulatory body, which could not always be the case.

Currently, the construction authorization is still valid, and this stage continues by the assembly of the radiopharmacy systems and the radiological protection equipment. The cyclotron is already placed and also the hot cells of the radiopharmacy lab. In April of 2022, the external contractors are finishing their construction jobs and the commissioning authorization has been already requested to ARN.

ACKNOWLEDGEMENTS

A special recognition should be given to Oulton Institute authorities and to 'Cyclotron - Radiopharmacy Laboratory' staff who gave permission to show pictures of the work performed in the civil work of the facility.

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