

## **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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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 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. This 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.

The ARN is facing this challenge by strengthening its regulatory framework for licensing and processes oversight, to ensure that national and international standards are met. The licensing process is being implemented in stages, with construction, commissioning, operation and closure licenses. Facility personnel will be authorized through a mixed licensing scheme, combining the staff licensing applicable to Class I facilities with the one for obtaining individual permits that applies to Class II facilities. 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.

To carry out these regulatory endeavors, a multidisciplinary working group was formed, with strategic personnel with background in regulatory affairs in an attempt to leverage prior experience. Moreover, efforts are being made by the ARN to further develop the technical capabilities of the human resources. Finally, the milestones achieved so far, the lessons learned, and future plans are presented.

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