WORKING ON DECISION MAKING AND STAKEHOLDER INVOLVEMENT IN THE ARGENTINE ADVISORY COUNCIL ON MEDICAL, INDUSTRIAL AND RESEARCH USES OF RADIOISOTOPES AND IONIZING RADIATION USES (CAAR)

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Summary

This paper summarizes the role of the “Advisory Council on Medical, Industrial and Research Uses of Radioisotopes and Ionizing Radiation Uses” (CAAR, according to its Spanish acronym) of the Argentine Nuclear Regulatory Authority (ARN), describing the routine activities related to evaluating compliance with the requirements associated with radiation protection accordingly the ARN policy and the proposals from the stakeholders related to new technologies that imply a review of the requirements in force.

Regulatory framework

The ARN has the mission to protect people and environment of the deleterious effects of ionizing radiations derived from nuclear activities in accordance with the provisions of the Nuclear Activity Act N° 24.804 [1] and its Regulatory Decree N°1390/98 [2].

The authorization process is one of the tasks among those performed by ARN for the different facilities and practices.

According to ARN, Class II facilities (facility or practice that only requires an operation license), the authorization processes are associated with the granting of individual license for the staff occupationally exposed.

ARN’s classification includes in the Class II: medical linear accelerators; tele-therapy; brachytherapy; nuclear medicine departments; self-shielded gamma irradiators; gamma radiography; mining and milling installations (not including mining tails disposal); nuclear installations without criticality potential; research and development in physical-chemical and biomedical areas and import, export, and storage of radioactive material. The total registered facilities for this class are around 2000.

Background

In Argentina, the first Advisory Council was established in 1958 in the National Atomic Energy Commission (CNEA) by the Decree 842/58: REGULATION FOR THE USE OF RADIOISOTOPES AND IONIZING RADIATIONS [3].
Nuclear regulatory activities in Argentina started in 1950. The education requirement to obtain a license for the use radionuclides in different applications, among them in Medicine, was the approval of the “Course of Methodology and Application of Radioisotopes” delivered by the National Atomic Energy Commission (CNEA).

There was a great evolution in the application of radioisotopes in medicine. Today, nuclear medicine is recognized as a medical specialty by the World Health Organization (WHO).

The increase of types of radioisotopes, imaging and treatment devices used in medicine determines a continue education and training to acquire new skills and knowledge, not only related to radioisotopes manipulation (i.e. radioprotection measures, radiobiology). Besides that, the pharmaceutical form of their administration, interaction with other treatments (pharmacokinetics bio-distribution, route of administration) and fundamentally regarding the clinical status of the patient: clinical management, co-morbidities, adverse effects produced by both: radioisotopes, radio-compounds or / transporting elements thereof, how to avoid these effects and occur as mitigate them.

In the same way, in the field of Radiotherapy, some special practices such as radiosurgery (Gamma-Knife and X-Knife), IMRT, Cyber-Knife or others that arise with new technological advances require the accreditation of specific training with programs subject to obtain the approval of the ARN.

The evolution of practices and technologies, mainly in medicine, constitute a challenge in the regulatory activities, so that, other relevant of CAAR job is the reviewing of syllabus of training courses for updating radiation protection of specialists in radiotherapy and nuclear medicine to assure an appropriate training and education in radiation protection of users.

The current CAAR’s structure was established in 2001 by the RESOLUTION ARN 28/01. It was established a rule procedure which was reviewed in 2019 in accordance with the provision in GSG-12: Organization, Management and Staffing of the Regulatory Body for Safety [4]:

4.38. The regulatory body may choose to give a formal structure to the processes by which expert opinion and advice are sought and provided. An effective advisory committee can provide a valuable service to the regulatory body by helping to ensure that policies and regulations are clear, practical and complete, and provide a good balance between the interests of authorized parties and the needs of the regulatory body and other interested parties.

Objectives

The objective of CAAR is advised to the Board of Directors of the ARN in the process of approval the applications of personal licenses for the use of ionizing radiation in medicine and industry (class II facilities with the exception of nuclear fuel cycle facilities, due to this is the task of the other ARN Council).

Their job is related to:

- Recommend the action to be taken on each application (approval or reject) for a new license or license renewal/modification.
- Advice on updating or proposing new requirements.
- Advice on education and the training and actualization programs that applicants must comply with.
- Analysis of other issues that may arise linked to individual license and formulation of relevant recommendations.
In this assessment of background and competencies, the CAAR works as a complementary instance advising directly to the ARN Board of Directors in accordance with the art 4.39 of GSG-12: Organization, Management and Staffing of the Regulatory Body for Safety [4]:

4.39. Advisory committees should report to the highest level of authority within the regulatory body...

Conformation

The CAAR is a team conformed by stakeholders and personnel from ARN.

The stakeholders are recognized experts from the following profile: physicians specialized in radiotherapy (2); physicians specialized in nuclear medicine (2); medical physicist specialized in radiotherapy (1); medical physicist specialized in nuclear medicine (1); industrial uses expert (1); radiopharmaceutical industry expert (1).

The participation of stakeholders provides transparency to the ARN licensing process, meanwhile through their expertise and knowledge they help ARN regarding the regulation of new radiopharmaceuticals and technologies in medicine or new industrial practice to develop coherent regulation for assuring the radiation protection of workers, publics and patients.

The personnel of ARN accomplish the role of President, Technical Secretary and Administrative Secretary of CAAR.

Both the stakeholders and ARN personnel are designed by the Board of Directors of the ARN.

In the accomplishment of their duties, all members of the Council may express their opinions with complete independence of their relationship with departments and organizations to which they belong. This is in accordance with the provisions in GSR Part 1 - Governmental, legal and regulatory framework for safety [5]:

4.18. The regulatory body may decide to give formal status to the processes by which it is provided with expert opinion and advice. If the establishment of advisory bodies, whether on a temporary or a permanent basis, is considered necessary, it is essential that such bodies provide independent advice, whether technical or non-technical in nature.

The Council meets monthly in the ARN headquarters and at this time all members, who signed a confidentiality form, are allowed to access to all user data, including files or records, educational programs under consideration, since they signed a confidentiality form, and any other documentation for assessment. CAAR proceeding of each meeting with the Council recommendations signed by the CAAR members are remitted to the Board of Directors for consideration.

Conclusions

The Advisory Council on Medical, Industrial and Research Uses of Radioisotopes and Ionizing Radiation (CAAR), according to its Spanish acronym) of the Argentine Nuclear Regulatory Authority (ARN) is a collegiate body, which main task consists of advising the Board of Directors directly regarding the granting of user licenses and all the issues associated with the assurance of radiation protection in practice. The commitment of the stakeholders contributing with their expertise and knowledge is a key in the process of licensing in Argentina.
The member’s expertise besides highest recognition in their specialty, determine a very qualify advice and it is a valuable complementary review in the ARN licensing process.

Finally, CAAR is an example of stakeholder commitment that contribute in regulatory decision making for affording greater confidence and quality to the process while providing greater transparency.

References

1. Argentine Nuclear Activity Act N° 24.804
2. Argentine Regulatory Decree N°1390/98
3. Argentine Decree 842/58: Regulation for the Use of Radioisotopes and Ionizing Radiations
5. IAEA GSR Part 1 - Governmental, legal and regulatory framework for safety