

Improving the production of radioisotopes and radiopharmaceuticals in Chile

The challenge...

The Chilean Nuclear Energy Commission (CCHEN) plays a leading role in producing radiopharmaceuticals for nuclear medicine in Chile, benefiting patients in need of diagnostic and therapeutic treatment. National regulations for the pharmaceutical industry made a major upgrade of the 30 year old Radioisotopes Production Laboratory necessary. Old production cells had to be replaced, and new procedures to ensure the required pharmaceutical quality level and to attain the radiological protection of the operators, the general public, and the environment, had to be put in place.

The project...

The upgrade of the CCHEN laboratory was supported by an IAEA technical cooperation project, and was based on good manufacturing practices (GMP), incorporating tight specifications for air quality, control of personnel pathways, and optimization of radiological conditions and control.

Initially, the project considered providing two new hot cells for the production of radiopharmaceuticals, but after further analysis, it was decided that six new hot cells could be built if the funds were used differently. Mutually collaborative, fresh creative thinking led to an agreement with the national authorities that the cells could be manufactured in Chile, with expertise and some key components procured by the IAEA. CCHEN provided all the design and civil engineering works, as well as the materials and labour force needed to construct the 6 hot cells. This amounted to an estimated contribution of US\$ 2 326 000.

As well as expertise and key cell components, the TC project supported training of the personnel at facilities abroad, and introduced standardized operational procedures for production.



The laboratory under construction.



The laboratory after construction.

The impact...

By October 2014, Chile will be able to produce all the radioactive Iodine and activation ^{99m}Tc required by its national medical services, in line with pharmaceutical quality standards and under strict GMP standards. In addition, a larger number of patients can be treated more effectively and efficiently.

The innovative approach to funding the project not only allowed for the construction of the required number of hot cells and for compliance with GMP and radiation safety considerations, but also built capacity for the construction of hot cells within Chile. Chile can now act as a resource country for any other Member State in the region that might need such technology.

Technical cooperation project CHI/4/022: Modernizing the Radioisotope Production Laboratory of La Reina Nuclear Centre by Incorporating Advanced Concepts of Safety and Good Manufacturing Practices