

Regulation Aspects for a Radioisotope Production Installation in Brazil

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Abstract : The Brazilian Nuclear Energy Commission (CNEN) is the main manufacturer of radiopharmaceuticals in Brazil. The Nuclear Engineering Institute (IEN), located at Rio de Janeiro, is one of its main centers of research and production, attending public and private hospitals in the state. This radiopharmaceutical production is used in diagnostic and therapy procedures and allows one and a half million nuclear medicine procedures annually. Despite this, the country is not self-sufficient to meet national demand, creating the need for importation and consequent dependence on other countries. However, IEN facilities were designed in the 60's, and today its structure is inadequate in relation to the good manufacturing practices established by sanitary regulator (ANVISA) and radiological protection leading to the need for a new project. In order to adapt and increase production in the country, a new plant will be built and integrated to the existing facilities with a new 30 MeV Cyclotron that is actually in project detailing process. Thus, it is proposed to survey current CNEN and ANVISA standards for radiopharmaceutical production facilities, as well as the radiological protection analysis of each area of the plant, following good manufacturing practices recommendations adopted nationally besides licensing exigencies for radioactive facilities. In this way, the main requirements for proper operation, equipment location, building materials, area classification, and maintenance program have been implemented. The access controls, interlocks, segregation zones and pass-through boxes integrated into the project were also analyzed. As a result, IEN will in future have the flexibility to produce all necessary radioisotopes for nuclear medicine application, more efficiently by simultaneously bombarding two targets, allowing the simultaneous production of two different radioisotopes, minimizing radiation exposure and saving operating costs.

Keywords : cyclotron, legislation, norms, production, radiopharmaceuticals

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