Status Report and Future Plan for Molecular Imaging Center (I-One) Facility

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1. Abstract:

The radiopharmaceuticals production and imaging facility is known as I-One at King Abdul-Aziz University in the western region of Saudi Arabia. Started the first production in 2018. We will discuss the facility features, considering the university's existence, where some basic research and training in different aspects of cyclotron operation and radiopharmaceutical production.

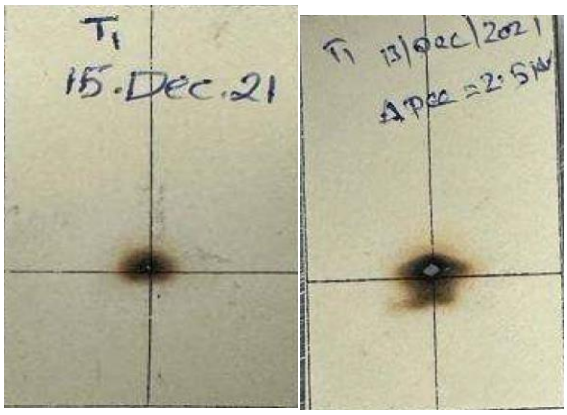
Key words:

Fluorodeoxyglucose, Sodium fluoride, Prostate-specific membrane antigen, Positron emission chromatography, High performed liquid chromatography, Gas chromatography, Tin layer chromatography, Portable Test System, international atomic energy agency, good manufacturing practice, Heating - Validation and air conditioning,

2. Introduction:

According to IAEA,[1] the facility's layout should have planning to achieve the intended product quality and safety, and a manufacturing facility's design and layout must be adequate. Additionally, it is important to recognize that each facility will have its own unique characteristics depending on a variety of variables, such as any applicable national or international legislation and standards, the availability of resources, and the nature of the project. Aspects of facility architecture and layout also differ greatly between member states. For more details, the non-controlled area is the entrance to a facility with access restrictions, the offices, the cleaning facilities, the bathrooms, and the warehouses for materials while the controlled area that needs to be managed to guarantee GMP or radiation protection are included in the restricted area. Furthermore, cleanroom Production must take place in a controlled atmosphere to provide product quality control and conformity with GMP rules for pharmaceutical manufacturing, which may be accomplished in a suitably built cleanroom. Controlled access for both people and materials and the purity of the air inside the room are two aspects of the cleanroom's particular construction requirements. Layouts and air handling equipment that is appropriately constructed help to accomplish both qualities (HVAC). Other considerations, floors, walls and ceilings, doors and windows, benches, waste disposal sink, drainage pipes, ventilation and containment, and radioactive storage facilities these structural and auxiliary elements demand meticulous care.

Several studies used PETtrace 800 cyclotrons for medical applications.[2–4] The PETtrace 800 central component is a compact, well-proven negative ion cyclotron with a vertical mid-plane that includes both protons and deuterons for optimum versatility and reduced-cost radioisotope synthesis.[5]



Here we see a paper burn test , which show the beam location and profile when it hit the target

3. Molecular imaging center (I-One):

I-One facility is the first cyclotron in the western region of Saudi Arabia. Building started in 2013 in King Abdul Aziz University. First Beam has been performed on Oct 2017. April 2019, I-One center started to distribution the radiotracer production under special consideration. Despite that the nearest cyclotron is more than 1000 Km away in Riyadh city, I-One is the first and only center of its kind in the Kingdom of Saudi Arabia which specialized in both the production of radioactive isotopes and offers positron emission tomography scanning services. Moreover, I-One follows the highest standards of quality and good manufacturing for the building, quality management system, and productions that have been manufactured such as 18F-FDG, 18F-NaF, and 18F-PSMA. The conducted of first bone examination in the western region using 18F-NaF was performed in early 2022 besides the main and common radiotracer 18F-FDG which is used for oncology, cardiology, and neurological examinations.

3.1. The I-one facilities:

The facility covers an area of 8000.00 m^2, where 1200 m^2 is for cyclotron and radiopharmaceutical production (Figure 2). The facility is near the university's gate 2 for easy access to radiopharmaceutical distribution. The production department involves duplicated shielded rooms for any future investments. The radiopharmaceuticals quality control room is substantial to accommodate more equipment in the future. The center facilities are following the highest standers and measurements. The controlled area includes:

- ***Cyclotron section:***

The section contains four rooms which are the shielding vault housing of the cyclotron, the service room, the control room, and the power supply room. The cyclotron vault provides shields against ionizing radiation. Typically, strong steel is used to construct the vault. Also, an offer additional bunker to a self-shielded cyclotron is available.

- ***Radiopharmaceutical production section:***

The area is divided into two sections. Section **1** includes the raw material warehouse and gowning room. However, section **2** includes the clean room where the radiolabeling synthesis takes place. For any future production plan, another empty room is available with its special features. The hot laboratory has advanced equipment for producing isotopes, including two dispenser modules Timotheo and Theodorico2. Timotheo can be dispensed manually for one vial by the manual arm, while Theodorico 2 can be dispensed robotically for more than 30 vials. Consequently, the ability to distribute to a wide variety of clients is present as shown in **Table.1**

Table.1the production parameters of ^{18}F.

Production parameters	
Number of installed targets	2
Max current on each target	65 uA
Production time	2.0 hours
^{18}F transfer time	3:15 min
Synthesis time	23 min
Max current on the probe	0.8 mA
Max current on foil	75.6 uA
Current on collimator	4.5-5.7 uA
Collimator / Target current	8%
Beam loss	< 2.5 %

- ***QC laboratory:***

The quality laboratory receives great attention and high monitoring to ensure that obtains a product that conforms to specifications and standards according to European Pharmacopeia by performing several tests. For example, HPIC determines the impurities in the final product. Besides that, GC is to measure residual solvents. Also, Gamma spectra, TLC, and endotoxin (PTS) are performed to ensure product's conforming to the standers. Moreover, sterility tests are performed after decay.

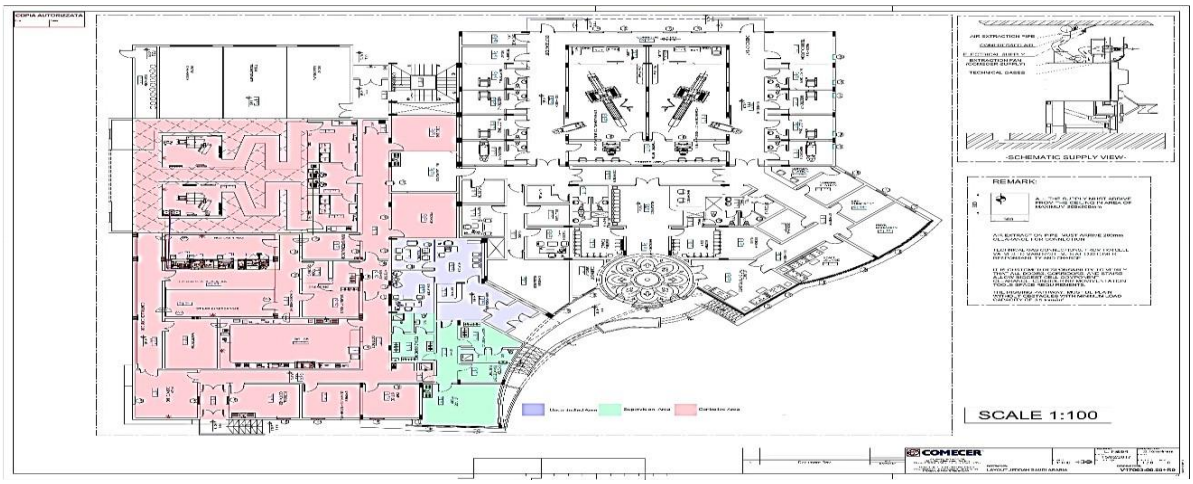


Figure 2: diagram for I-One facility imaging facility.

The colored area illustrated the production department, pink area is the controlled area where all production chain takes place, green illustrated the supervised area including the staff lounge, and purple illustrated the uncontrolled area.

4. Future aims:

- As an advanced center owned by King Abdulaziz University, I-One has the advantages of collaboration with university's research colleges for possible development of radio-pharmaceuticals production.
- Believing in the effective social role of community initiatives and contributions, I-One started a training program for both under graduated and graduated students.
- I-One center aims to provide consulting for different medical and pharmaceuticals facilities.

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