RAPID INSTALLATION AND START-UP OF A CYCLOTRON FOR MEDICAL USE

Fabio Colombo, Mario Matarrese, Edward Deutsch and Ferruccio Fazio
I.T.B.A. - C.N.R., Università di Milano, Istituto H San Raffaele, Milano, Italy

The practicability of clinical PET will depend largely upon the general availability of cyclotron produced isotopes. This in turn depends upon the ability of medical institutions to efficiently install cyclotrons while minimizing construction costs. The advent of self-shielded, compact cyclotrons dedicated to the production of medical isotopes makes possible efficient, cost-effective installations. We describe here the first Italian experience with the installation and start-up of a PET/Cyclotron facility based on a self-shielded, negative ion compact cyclotron.

An RDS-112, 11.2 MeV, negative ion cyclotron was ordered from CTI Corp. (Berkeley, CA) in August, 1987 (see Table I). The machine was delivered to Italy in April, 1988 and installed in an existing room of the Scientific Institute H San Raffaele (see Figure 1); the floor of this room was modified to support the weight of the cyclotron and its associated shielding. Modification of the room required 2 months, while the actual cyclotron installation required an additional 2 months. This cyclotron, and its associated "black box" production modules, provide clinicians with O-15 labelled O_2 (both bolus and continuous flow), CO_2, CO, H_2O and N-13 labelled NH_3, C-11 labelled CO and CO_2 and F-18 labelled fluoride and FDG (2-fluorodeoxyglucose). Acceptance testing of the cyclotron and all chemical production modules was finished in July, 1988, and the first human images obtained using N-13 ammonia and F-18 FDG were obtained in the same month. By June 1989, less than one year after acceptance of the cyclotron, 145 human studies had been accomplished despite 60 days of machine down time. The RDS-112 system can produce in a single run 200-300 mCi 18-F FDG, which is sufficient to supply several PET centers within a reasonable distribution radius. Routine operation and maintenance of the RDS-112 system requires 2 chemists and 2 technicians.

In order to ensure the proper operation of the production modules, the radiopharmaceuticals produced must be routinely subjected to chemical and radiochemical quality control procedures. Gases are analyzed by vapor phase chromatography, N-13 labelled ammonia is analyzed by high performance liquid chromatography (HPLC), while F-18 labelled FDG is analyzed by both thin-layer chromatography as well as by HPLC. During the first ten months of operation of the RDS-112 system, quality control of 31 N-13 NH_3 preparations and 91 F-18 FDG preparations showed average radiochemical purity of 99.3% and 98.0% respectively. Likewise, radiolabeled gases were consistently produced with 98.5% radiochemical purity.

In summary, our experience has shown that the self-shielded, negative ion RDS-112 compact cyclotron can be rapidly installed and brought into operation within an existing medical facility. Start-up difficulties and down time have been greater than anticipated, but not so great as to dampen our enthusiasm for the ultimate practicability of clinical PET.

Table 1

INSTALLATION TIME SCHEDULE

Order Placed	August	1987
Acceptance Test in the Factory	January	1988
Arrival at H.S. Raffaele Institute	April	1988
Installation Completed	May	1988
First N-13 Production	June	1988
First F-18 FDG Production	July	1988
Acceptance Test in the H.S. Raffaele Institute	July	1988

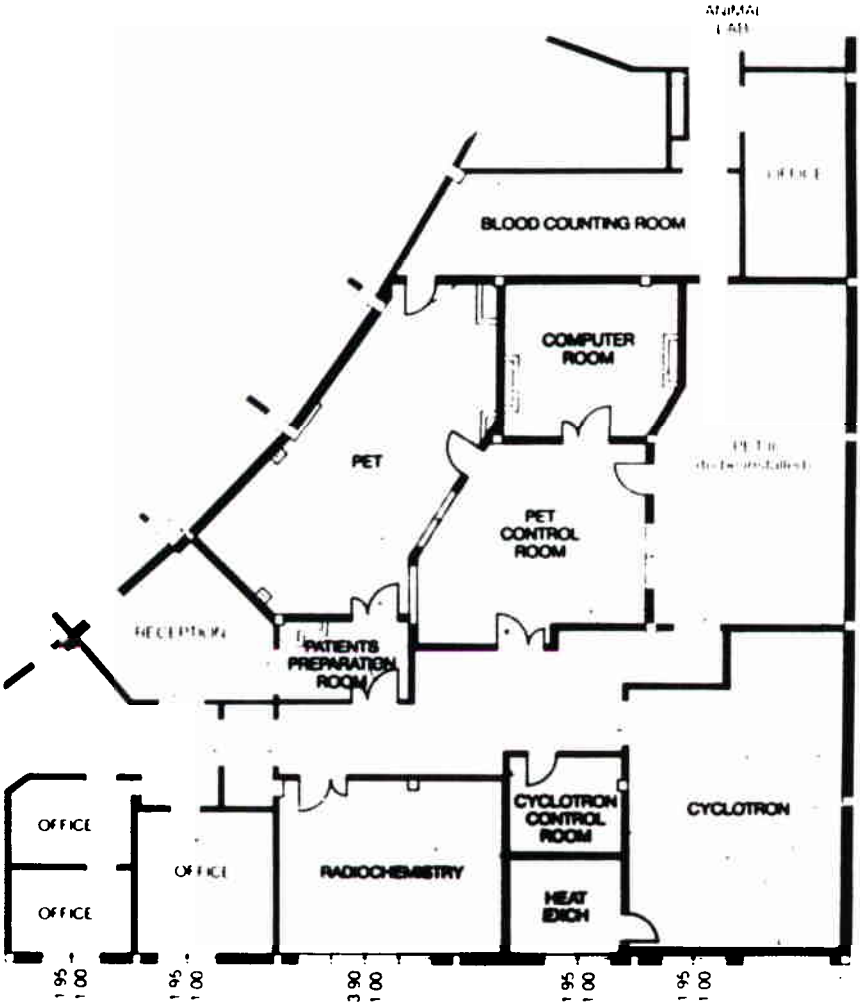

Figure 1
Map of PET/Cyclotron Facilities