

Highlight from the 3 month-Training Courseon Radiopharmaceuticals in Sydney'99

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The 3 month-training course on **Radiopharmaceuticals**, under the fellowship of the International Atomic Energy Agency (IAEA), was carried out from February till April, 1999 in Sydney, Australia. The first three weeks were spent in Australian Nuclear Science and Technology Organisation (ANSTO), another 5 weeks in Department of Nuclear Medicine and Ultrasound of Westmead Hospital, and another 3 weeks at Liverpool Health Service. During the last week in Australia, the two conferences in Broome and Perth were attended.



In order to cope with several topics, the training was based on observation, discussion and reading. On the **Registration and Good Radiopharmaceuticals Aspect**, the institute whose product(s) will be administered into human via any route have to be registered with the Therapeutic Goods Administration (TGA), and the manufacturers must hold a license. There are 3 main categories for each product: Category I for a new product, Category II for abridged one, and Category III for the development of the registered product. For the Category I, 4 major parts have to be completed in sequence: basic information, chemistry pharmaceuticals, toxicology & pre-clinical

investigation done in animals, and clinical study in patients. The production of medical products has been standardised in the same pattern of European countries including U.K., and Nordic Group (Denmark, Finland, Iceland, Norway, and Sweden).



ANSTO, Lucas Height



Nuclear Medicine, Westmead Hospital.



Nuclear Medicine, Liverpool Health Service.

Production of Generators, Radioisotope Labelled Kits, and Pharmaceuticals:

This is aseptically performed in a clean environment to meet GMP (Good Manufacturing Practice) standards for the manufacture of sterile medicinal goods. Monitoring of the environment, equipment and operators are carried out before and after each production run. Operators carrying out these tasks are required to wear special, sterile and clean garments, if they use a clean room. Alternatively, a sterile cabinet class III, which needs to be fumigated periodically, can be used effectively. The



Production of pharmaceuticals in a clean room.

production of ^{99m}Tc -generator and some in-house pharmaceuticals were observed first hand.



A sterile cabinet class III in a room with filtered air coming in.

Three pharmaceuticals that cannot be produced as in-house kits according to the Registration Law are MAG 3 (Mallinckrodt), Ceretec (Amersham), and MIBI (Dupont). In this case, one vial of the drug will be reconstituted and then *split* into 5 fractions in a sterile cabinet class III or in a clean room.

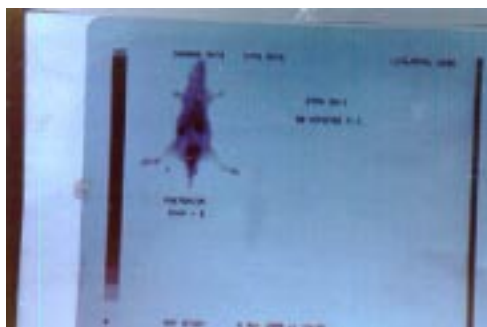


Either dispensing or splitting of pharmaceuticals is done in a sterile cabinet class III or in a clean room.

Quality Control:

The QC tests for all finished products are carried out to meet the approved specifications and test methods prior to releasing to end users. They include the tests for

sterility, pyrogen, pH, concentration of Sn^{2+} , radiolabelling (radiochemical purity), and biodistribution. The problem(s) found in any performance will be recorded in the Radiopharmaceuticals Complaints Book, and adverse reactions in the Adverse Reactions Book.



Biodistribution test using a rat.

White Blood Cell Labelling:

It is a common tool to detect infection. In Westmead Hospital, Liverpool Health Service, and some other places, the pharma-



Rotation of white blood cells labelled with $^{99\text{m}}\text{Tc}$ -colloid, done in a sterile cabinet class II.

ceuticals is produced in-house. Usually, the labelling will be carried out with great care and aseptic techniques in a sterile cabinet class II or III.



Nearly every step in the white blood cell labelling technique including centrifugation is done in a sterile cabinet.

Estimation of GFR:

To estimate the **GFR (Glomerular Filtration Rate)**, a technique with blood collection is used and recommended. After the injection of $^{99\text{m}}\text{Tc}$ -DTPA, blood collection is done at either 2 & 3 hours (Westmead) or 1.5 & 2.5 hours (Liverpool), then counted, and calculated for the GFR values via the programme in a computer. This method is claimed to be more accurate than that calculated by a γ -camera.

Others:

Other experiences fell on the observation of activities in a hot laboratory, iodination using ^{123}I or ^{131}I , ^{14}C -urea breath test, and



A stainless steel container with the hydrolic system for keeping various labelled compounds separately.



A Co-PET at Liverpool Health Service.



The production cells at the National Medical Cyclotron, Camperdown.

determination of red blood cell volume/ plasma volume/ total blood volume using ^{51}Cr , and Co-PET imaging using ^{18}F -FDG. The Educational Programme is held regularly - every week at Westmead and every fortnight period at Liverpool. Their staff or a guest speaker will present a talk on a medical/ scientific topic.

During these 3 month-course, there were good opportunities to have *a special visit* to the Reactor 'HIFAR'[#] (ANSTO, Lucas Height), the National Medical Cyclotron (ANSTO, Camperdown) and PET Unit (Royal Prince Alfred Hospital, RPAH, Camperdown). The ^{18}F -FDG from the National Medical Cyclotron is transported through the underground tube to the PET Unit, RPAH which is located on the opposite side of the street.



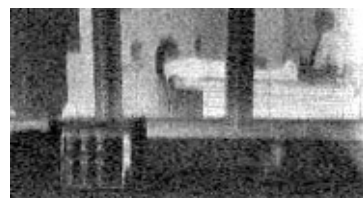
Royal Prince Alfred Hospital, located on the opposite of the street.



The National Medical Cyclotron Building, Camperdown.



^{18}F -FDG, Nuclear Medicine, RPAH.



PET Unit, Nuclear Medicine, RPAH.

[#] HIFAR = High Flux Australian Reactor

Before leaving Australia, the 2 day Pre-conference on 'Sports Medicine Imaging' held in Broome was attended and found that bone scanning is obviously helpful. Lastly, the attendance of the *Annual Scientific Meeting of the Australian & New Zealand Society of Nuclear Medicine (ANZSNM)* held in Perth was made. Their activities included Symposium, Workshop, Proffered Papers, Plenary Session, Awarded Papers, Concurrent Session, Meet the Experts, Poster Presentation, and Exhibition.

It was recognised that the systematic and well-planned work system has been established in every institute to reach the same and international standards. The laboratories are well-equipped with adequate facilities. Good documentation systems (for protocols, results, etc.) have also been introduced. In addition, their staffs are properly educated, experienced, and helpful. Thus, it is not exaggerated to say that the 3 month-training course on Radiopharmaceuticals in Sydney provides valuable and fruitful knowledge and experience.



Poster presentation at the Annual Scientific Meeting held by ANZSNM in Perth.



Booths at the Annual Scientific Meeting held by the ANZSNM in Perth.