Chapter 35

BASIC REQUIREMENTS OF NUCLEAR MEDICINE SERVICES

Based on an IAEA document by E.H. Belcher

Introduction

Technological progress in nuclear medicine continues, not always to the immediate advantage of the developing world. The capital expense, operational demands and maintenance requirements of ever more complex equipment, the consequent need for highly trained staff, the necessity to assure regular supplies of costly radioactive materials, all present problems to which compromise or alternative solutions must often be sought.

This Chapter constitutes an attempt to define the basic requirements for the practice of nuclear medicine with respect to staff, equipment, accommodation, supplies and supporting services with particular reference to the needs of institutions in developing countries.

Nuclear medicine has been defined as embracing all applications of unsealed radioactive materials in diagnosis or treatment of disease or in medical research [1]. This definition includes not only procedures for clinical diagnosis and in vivo investigation and radiation therapy, but also radioimmunoassay and related procedures - radioassay procedures - for clinical diagnosis and in vitro investigation. It also includes a multitude of procedures and applications in medical research which, while of great potentiality to developing countries, fall outside the scope of this Chapter.

There are strong reasons for the close co-ordination, if not the integration, of all such applications, whether in vivo or in vitro, within a medical institution. Such co-ordination is prerequisite not only to ensure that proper facilities and equipment are available for the procedures to be carried out and at the same time to avoid wasteful duplication, but also to provide necessary infrastructure for the reception, preparation, quality control and dispensing of radioactive materials, including radiopharmaceuticals, the safe handling and safe disposal of radioactive wastes and the maintenance and quality control of equipment. The reasons are stronger with regard to institutions in developing countries, where the scale of work may be limited. It should be emphasized in this connection that nuclear medicine is a collaborative discipline involving not only the skills of the clinician but also those of the medical engineer, medical physicist and radiopharmacist.

It has, however, to be recognized that radioassay procedures in vitro have more in common with clinical laboratory procedures in general, especially those of clinical chemistry, than with other nuclear medicine procedures. More radioassays are performed in conjunction with clinical chemistry procedures; others have replaced such procedures or have counterpart assays in clinical chemistry - for example enzyme assays and fluorescence assays - which differ from them only in so far as a non-radioactive label is used in place of the radioactive one and which may be preferred to them on grounds of convenience. It is important for these reasons that a radioassay laboratory, whatever its administrative status, have close connections

not only with any nuclear medicine service in the institution concerned but also with other clinical laboratories there, which may provide further necessary infrastructure, for example in relation to the collection or reception of blood and other specimens. A radioassay laboratory should in any case be set apart from areas where nuclear medicine procedures are conducted in vivo, because of the need to avoid the radioactive contamination which could result from the higher levels of radioactivity used therein.

FACILITIES FOR NUCLEAR MEDICINE PROCEDURES IN VIVO

General remarks

As regards procedures for clinical diagnosis and investigation in vivo, a distinction may be made between non-imaging and imaging procedures. Non-imaging procedures still constitute a significant, though declining, part of the work of nuclear medicine services - for example in relation to haematology. At the present time, however, the emphasis in such services, at least in advanced countries, is on static or dynamic radionuclide imaging by scintillation cameras for the most part with $^{99}Tc^{m}$ labelled radiopharmaceuticals.

The widespread introduction of scintillation cameras in developing countries is still hindered by the capital cost, operational demands and maintenance requirements of these instruments, as well as by restrictions in the use of $^{99}Tc^{m}$ labelled radiopharmaceuticals due to the costs of these generators and their short useful life and the further costs of radiopharmaceutical preparation kits.

The rectilinear scanner, as a moderately-priced and relatively robust imaging instrument, had offered a partial solution to these problems and was at least useful for brain, liver and thyroid imaging. Unlike the scintillation camera, it is well adapted to work with Indium labelled radiopharmaceuticals, the use of which is attractive in some localities because of the long useful life of ^{113}In generators. Unfortunately, the manufacture of the scanner has now been mostly discontinued.

The purchase of new rectilinear scanners and of spare parts for existing ones is thus increasingly difficult. Because of this and in view of the wider possibilities for static and dynamic imaging with the scintillation camera, the rectilinear scanner seems no longer a generally appropriate instrument on which to base imaging procedures in a new nuclear medicine service, although many such instruments remain in efficient use, mostly in the developing countries.

For reasons already indicated, an integrated service is essential to the efficient conduct of nuclear medicine procedures in vivo. None the less, the interrelations of radionuclide imaging and other imaging modalities, among them angiography, ultrasonography (US), computed tomography (CT) and magnetic resonance imaging (MRI) should be appreciated and the competing claims of the latter given due recognition. CT and MRI remain outside the

reach of most institutions in developing countries. US, on the other hand, is in widespread use and, moreover, may now be preferred for imaging certain organs - for example, liver and thyroid.

For these reasons, it may be convenient to locate facilities for radionuclide imaging adjacent to other imaging facilities in the institution concerned, so that the results obtained by different modalities may be more readily compared and also so that some of the necessary infrastructure - for example, in relation to the reception of patients and darkroom facilities - may be shared.

Radiation therapy

Radiation therapy with unsealed radioactive materials is likely to be limited to the use of ^{131}I in the treatment of thyrotoxicosis and thyroid cancer and the use of ^{32}P in the treatment of polycythemia vera. Use of ^{131}I-MIBG for neuroblastoma is gaining acceptance now. Specific monoclonal antibodies labelled with an appropriate radionuclide is looming on the horizon as a therapeutic possibility.

Any nuclear medicine service undertaking clinical diagnosis and investigation in vivo may also practice these applications. However, the relatively large activities which they employ necessitate some special measures for the protection of the staff and the general public against radiation hazards. These measures should include the segregation of the patients undergoing therapy, the instruction of nursing staff in their management,the containment of radioactive contamination and the storage of radioactive wastes to allow appropriate radioactive decay before disposal.

CATEGORIES OF NUCLEAR MEDICINE SERVICE

Three categories of nuclear medicine service for which different facilities are needed may be considered, viz.:

Category 1: Performing non-imaging procedures for clinical diagnosis and investigation in vivo.

Category 2: As Category 1, but also performing static imaging procedures with preparation of relevant radiopharmaceuticals.

Category 3: As Category 2, but also performing dynamic imaging procedures with preparation of relevant radiopharmaceuticals.

An additional Category may be considered to designate those laboratories which undertake radioisotope therapy. The radioiodine therapy of thyroid cancer needs special additional features.

Category 1 functions may be adequate if the service relates particularly to another specialty. In general, however, services should be established at least in Category 2. The eventual upgrading of a proportion of Category 2 services to Category 3 may be foreseen. Such upgrading implies the interfacing of a computer for digital data processing to an existing scintillation camera. However, interfacing a new computer with an old gamma camera may be difficult if such an upgrading is undertaken after a lapse of many years. If sufficient capital funds are available there are distinct advantages in starting a nuclear medicine service as a Category 3 service.

In a locality with several nuclear medicine services, the establishment of a centralized radiopharmacy for the preparation and distribution of radiopharmaceuticals is clearly advantageous, above all in relation to the use of $^{99}Tc^{m}$. This may be done within an existing service or independently - for example, in the laboratories of a national atomic energy authority.

Basic requirements of Category 1, 2 and 3 services as regards staff, accommodation, equipment, supplies and supporting services will now be presented. The details given in these respects are representative only and should be modified to accord with the particular circumstances of any one service.

REQUIREMENTS FOR A CATEGORY 1 SERVICE

Staff

Staff requirements for a Category 1 service depend on both its functions and its workload. A modest service may be operated by 1-2 professionals plus 1-2 technicians, all employed full-time, with secretarial and other support as appropriate.

The professionals should be physicians and may be specialists in nuclear medicine or in some other specialty to which the service particularly relates. In the former case, they should have received comprehensive training in nuclear medicine extending over at least one or two years. In the latter, they should have received training in nuclear medicine as related to their own specialty extending over at least six months. More specialized training should be provided according to needs as the work of the service expands.

The technicians should already have clinical or medical laboratory experience - for example, in diagnostic radiology or clinical chemistry - in which case their specialized training can be given in the service itself.

One member of the staff should be designated as Radiological Health and Safety Officer [2] to the service, with the responsibility to ensure safe handling of radioactive materials and safe disposal of radioactive wastes.

Accommodation

Accommodation requirements for a Category 1 service depend on its functions and workload. There should be a simple radiopharmacy for the dispensing of radiopharmaceuticals, with corresponding storage facilities. There should be a laboratory for radioactivity measurements in vitro. There should be a clinic for the administration of radiopharmaceuticals and for radioactivity measurements in vivo. There should be waiting rooms for patients.

There should also be office accommodation for staff and for the keeping of records. Separation of the various functions is imperative.

In general, a radiopharmacy area of 10 m^2, a laboratory area of 10 m^2, a clinic area of 25 m^2, and an office area of 10 m^2.

The radiopharmacy should meet the requirements of Type B working places for handling radioactive materials [2] and those of a simple clean Room for pharmaceutical operations [3]. Special facilities for the disposal of liquid radioactive wastes are not normally required, provided that the effluent is discharged to a main sewer, but attention should be paid to the national regulations in this regard, which differ greatly from country to country.

A well-ventilated fume hood to provide protection against airborne radioactive contamination during dispensing operations is a desirable facility, and an essential one if radiation therapy with unsealed radioactive materials is to be practised. The latter would also require special storage facilities for radioactive wastes.

The laboratory and clinic should meet the requirements of Type C working places for handling radio-active materials [2]. Again, special facilities for the disposal of liquid radioactive wastes are not normally required, provided that the effluent is discharged to a main sewer, but attention should be paid to the national regulations in this regard.

The radiopharmacy and laboratory should have ample workbenches, strong enough to carry lead bricks for radiation shielding, as well as centrifuges, electronic equipment and similar items. There should be adequate space for free-standing items such as refrigerators and appropriate facilities for the storage of radioactive materials, radioactive wastes, reagents and supplies. Electricity and water services should be liberally available. Air conditioning is an essential requirement in tropical climates.

In the clinic, electricity and water services should also be liberally available. Air conditioning is again an essential requirement in tropical climates. Chairs, couches, tables and other furniture should be provided as appropriate, likewise in the waiting rooms and offices.

A separate power line fed directly from the final step-down transformer in the institution and a separate earth line are desirable for electronic equipment. Outlets of these should be

available in the radiopharmacy, laboratory and clinic as appropriate, so that an independent conditioned power supply may be provided for each major equipment.

Equipment and supplies

Equipment requirements for a Category 1 service are dictated by the particular procedures to be carried out. Major items of electronic equipment normally needed are a probe scintillation counting system for radioactivity measurements in vivo, a manual well-type scintillation counting system for measurements in vitro, a radionuclide "dose" calibrator and two or more portable radioactivity monitors. There should be the means to provide conditioned power supplies for this equipment. Appropriate radiation sources should be available for equipment quality control.

Thyroid ^{131}I uptake measurements would require a single-probe system for radioactivity measurements in vivo, with scaler output; this could also be used for studies of red cell destruction processes with ^{51}Cr or ferrokinetic studies with ^{59}Fe. Renography with ^{131}I would require at least a double probe system, with ratemeter-recorder output. If on the other hand, no procedures based on radioactivity measurements in vivo are foreseen, the probe system can be omitted. A heavy workload involving the manual well-type system for measurements in vitro would justify the eventual provision of an automatic system for such measurements. The manual system could then be retained as a standby. A trustworthy radionuclide "dose" calibrator is indispensable; so also are portable radioactivity monitors.

There should be a refrigerator, clinical centrifuge with accessories, mini-autoclave and drying oven for glassware; there should be shielded devices for the handling, dispensing and storage of radioactive materials and initial supplies of laboratory glass and plastic ware, disposable gloves, disposable syringes and needles etc.

The total cost of these items may be estimated at US $ 40,000, depending on the type of probe scintillation counting system required.

Running costs in respect of radiopharmaceuticals in a Category 1 service vary widely according to the particular procedures carried out. It is important in planning any new service to obtain assurances that such costs will be covered.

Supporting services.

An efficient and fast mechanism for the reception of radioactive materials and other supplies is indispensable to the smooth operation of any nuclear medicine service. Delays in importation should above all be avoided. If such a mechanism does not already exist when a service is being established, one should be put into effect. Facilities for the maintenance and repair of electronic equipment should also be assured.

Measures for the protection of staff against radiation hazards must be enforced [4]. Film badges or other devices should be provided to monitor external radiation exposure. Regular

checks for possible internal radioactive contamination - for example, thyroid ^{131}I uptake - should be conducted.

While the staff requirements given for a modest Category 1 service do not include medical physicists or radiopharmacists, support in medical physics and radiopharmacy is desirable, at least on an occasional basis. This may be possible to arrange from neighbouring services.

REQUIREMENTS FOR A CATEGORY 2 SERVICE.

It is assumed that the minimum equipment requirement for static imaging in a new Category 2 service should now be defined as a single scintillation camera and that such a Service may eventually be upgraded to Category 3 by interfacing a computer for digital data processing to this camera.

Staff

Staff requirements for a Category 2 service again depend on both its functions and its workload. Minimum requirements may be 2-3 professionals plus 3-4 technicians, with secretarial and other support as appropriate.

One of the professionals should be a physician with specialization in nuclear medicine, who has received comprehensive training in nuclear medicine extending over at least two years and is employed full-time in the service. Also available should be a medical physicist and a radiopharmacist. The former should have received post-graduate training in medical physics extending over at least one year; the latter should have received similar training in radiopharmacy. Their initial employment on a part-time basis may be adequate.

The technicians should already have medical laboratory experience- for example in diagnostic radiology or clinical chemistry- in which case their specialized training can be given in the service itself.

One member of the staff should again be designated as Radiological Health and Safety Officer [2] to the service, with the responsibility to ensure safe handling of radioactive materials and safe disposal of radioactive wastes.

Accommodation

Accommodation requirements for a Category 2 service also depend on its functions and workload. Additionally to that for a Category 1 service, accommodation is required to house the scintillation camera and to allow the preparation and/or dispensing of $^{99}Tc^{m}$-labelled and other radiopharmaceuticals according to needs. There should thus be a more extensive radiopharmacy for the preparation and dispensing of radiopharmaceuticals, with corresponding storage facilities. There should be a laboratory for radioactivity measurements

in vitro. There should be a clinic with separate rooms for clinical examination, for the administration of radiopharmaceuticals, radioactivity measurements in vivo and imaging procedures. There should be waiting rooms for patients. There should also be office accommodation for staff and the keeping of records. Separation of the various functions is again imperative.

In general, a radiopharmacy area 30 m^2, a laboratory area of 20 m^2 , a clinic area of 60 m^2, and a waiting room area of 20 m^2 and an office area of 20 m^2, totalling 150 m^2, should meet initial requirements. It is good policy when installing a scintillation camera for static imaging to allow space for the eventual addition of a computer and other facilities for dynamic imaging, since otherwise such upgrading may require relocation of the camera.

The different sections should meet the various requirements previously specified for a Category 1 service. A laminar-air-flow (LAF) work station in which radionuclide generators can be installed is an appropriate, if not essential, facility in the radiopharmacy.

Equipment and supplies

Equipment requirements for a Category 2 service are again dictated by the particular procedures to be carried out.The major items needed additional to those of a Category 1 service are the scintillation camera itself and accessories for its quality control and use, among them a formatter for multiple-view registration on X-ray film. The preparation and quality control of $^{99}Tc^{m}$ -labelled radiopharmaceuticals require some additional facilities in the radiopharmacy - a water bath, a microbalance, equipment for membrane filtration and sterility testing etc.

A trustworthy radionuclide "dose" calibrator is again indispensable; so also are portable radioactivity monitors. The total additional cost of these items may be estimated at US $ 175 000, depending on the model of scintillation camera selected.

Running costs in respect of radiopharmaceuticals in a Category 2 service vary widely according to the particular procedures carried out. The costs of Tc generators must be taken into account. An important issue is whether or not commercial radiopharmaceutical preparation kits are used. A considerable saving may result if locally prepared reagents or kits are used instead, but careful product quality control is then more than ever essential. It is important in planning any new service to obtain assurances that such costs will be covered.

Supporting services

Supporting services in respect of the reception of radioactive materials and other supplies, the maintenance and repair of electronic equipment and the protection of staff against radiation hazards are needed in a Category 2 service as in Category 1.

ADDITIONAL REQUIREMENTS FOR A CATEGORY 3 SERVICE

It is assumed that a Category 2 service may be upgraded to Category 3 by coupling a computer for digital data processing to an existing scintillation camera. The acquisition of an integrated scintillation camera/computer system in the first place would, of course, provide Category 3 facilities directly.

Staff

Additional staff may not be necessary if a Category 2 service is upgraded to Category 3; this depends on its existing staff and workload. However, at least one of the physicians with specialization in nuclear medicine should have undergone or should undergo training in the clinical applications of dynamic imaging procedures with scintillation camera/counter systems and a medical physicist or other professional with training in computer applications should be available.

Accommodation

Additional accommodation may not be necessary if a Category 2 service is upgraded to Category 3, provided that such upgrading was foreseen. Ample space should be available, however, for the computer itself and for necessary accessories.

Equipment and supplies

Additional equipment requirements if a Category 2 service is upgraded to Category 3 are the computer itself, its interface with the scintillation camera, accessories for its quality control and use, and various other accessories that may be necessary in dynamic imaging procedures. If the main applications are in cardiac function studies, the latter include a cardiac stress system and an electrocardiograph synchronizer. The computer should be supplied with the necessary software for a wide range of clinical applications. The total additional cost of these items may be estimated at US $ 100,000, depending on the model of computer selected.

Supporting services

Supporting services are needed in a Category 3 service as in Category 2.

In addition, a maintenance contract with the computer manufacturer's agents is desirable to assure adequate facilities for its maintenance and repair.

CHAPTER 35

FACILITIES FOR RADIOASSAY PROCEDURES IN VITRO

General remarks

Radioassay procedures are now the methods of choice for the measurement of most hormones, many vitamins and drugs and various indicators of specific diseases in blood and other specimens in vitro. Since they may be performed in a central laboratory on samples sent from external institutions, they find particular uses in developing countries. For many analytes, commercial assay kits are available and provide a means for laboratories with limited facilities and workloads to perform assays. They are, however, costly and their use may entail various inconveniences, for which reason assays based on acquired or locally prepared individual reagents are often to be preferred.

An important consideration is that the majority of radioassays are now based on the use of reagents labelled with ^{125}I. Requirements for radioactivity measurements are thereby greatly simplified.

Radioassays in general require a separation step for the separation of a liquid and a solid phase before radioactivity measurements. This separation is commonly effected by centrifugation; for certain assays the centrifuge should be refrigerated. A current development which seems likely to have important consequences, however, is the introduction of magnetic particulate material as the solid phase, whereby the separation is achieved simply by allowing the particles to sediment towards a permanent magnet placed below the tubes containing the reaction mixtures and then decanting the supernatant. If this becomes a standard practice, the need for a centrifuge in the separation step will vanish, with significant savings in equipment costs and labour.

CATEGORIES OF RADIOASSAY LABORATORY.

Two categories of radioassay laboratory for which different facilities are needed may be considered [5], viz:

Category 1: Performing assays with assay kits or acquired reagents.

Category 2: As Category 1, but also preparing ^{125}I-labelled assay reagents for internal use.

Category 1 laboratories should be the first to be established. Since assays may be performed in a central laboratory on samples sent from external institutions, it may be desirable that individual laboratories assume responsibility for different groups of assays - for example those for thyroid-related hormones - within a defined area. This may avoid much wasteful duplication. The eventual upgrading of a proportion of Category 1 laboratories to Category 2 may be foreseen.

In a locality with several radioassay laboratories, the establishment of higher category laboratories undertaking the preparation and distribution of assay reagents or kits and also performing external assay quality control is clearly advantageous.

Basic requirements of Category 1 and 2 services are given below. The details given are again representative only and should be modified to accord with the particular circumstances of any one laboratory.

REQUIREMENTS FOR A CATEGORY 1 LABORATORY.

Staff.

Staff requirements for a Category 1 laboratory depend primarily on its workload, increasing with the variety and number of the assays performed. Radioassay may be performed to a limited extent by a single person, either a professional or a technician, though a graduate in medicine should be responsible for the interpretation of the clinical results. Initial requirements for a modest laboratory providing a clinical service and assaying 100-200 samples per week are 1-2 Professionals plus 1-2 technicians, all employed full time, with secretarial and other support as appropriate.

The professionals may be graduates in medicine or science. If not already trained in radioassay, they should undergo preliminary instruction, preferably through a formal training course of a few weeks' duration followed by in-service training for 3-6 months in an established radioassay laboratory. If such training can be given locally, this should be done. More specialized training should be provided according to needs as the work of the laboratory extends.

The technicians should already have medical laboratory experience - for example in clinical chemistry - in which case their specialized training can be given in the laboratory itself.

Accommodation.

Accommodation requirements for a Category 1 laboratory also depend primarily on its workload. If facilities for the collection or reception of blood and other specimens do not already exist elsewhere - for example in association with the clinical chemistry laboratory in the institution concerned - there should be a clinic for this purpose. There should be an assay section for the performance of assays. There should also be office accommodation for staff and for the keeping of records. While all these can in fact be provided in a single room of appropriate size, separation of the clinic and office from the laboratory functions is desirable. In general, a clinic area of 15 m^2 , an assay section area of 25 m^2 and an office area of 10 m^2, totalling 50 m^2, should meet Initial requirements for the laboratory designated. A more limited workload can be handled in a correspondingly smaller place. An expansion of 25 % during the first year and 15% per year thereafter should be foreseen.

For reasons given previously, the chosen location should be such that the laboratory can have close connections, not only with any nuclear medicine service in the institution concerned but also with other clinical laboratories there. The laboratory should in any case be set apart from areas where nuclear medicine procedures are conducted in vivo because of the need to avoid the radioactive contamination and increased radiation background which could result from the higher levels of radioactivity used in such procedures.

Depending on the clinical situation, it may be desirable to provide separate rooms for in-patients and out-patients from whom specimens are to be collected. In any case, careful design of @he clinic is necessary to minimize risks of infection. Electricity and water services should be available in this area. Chairs, couches, tables and other furniture should be provided here and in the offices as appropriate.

The assay section should meet the requirements of Type C working places for handling radioactive materials [2]. Special facilities for the disposal of liquid radioactive wastes are not normally required, provided that the effluent is discharged to a main sewer, but attention should be paid to the national regulations in this regard, which differ greatly from country to country.

The assay section should have ample workbenches, strong enough to carry centrifuges, water baths and similar items. There should be adequate space for free-standing items such as freezers and refrigerators, and appropriate facilities for the storage of reagents and supplies. It may be desirable to provide a separate room for equipment for radioactivity measurements and another for storage purposes. Electricity and water services should be liberally available. A standby power supply for the freezer is desirable. A separate power line fed directly from the final step-down transformer in the institution and a separate earth line are desirable for electronic equipment, so that a conditioned power supply may be provided. Air conditioning is an essential requirement in tropical climates.

Equipment and supplies.

Major items of equipment normally needed in a Category 1 laboratory are an automatic well-type scintillation counting system for ^{125}I measurements, a manual well-type counting system as a standby to the latter, one or more portable radioactivity monitors for ^{125}I measurements and a refrigerated centrifuge capable of accepting 100 or more assay tubes at a single loading. There should be the means to provide a conditioned power supply for the electronic equipment. A simulated ^{125}I radiation source should be available for calibration of the counting system. The automatic well-type counting system should incorporate facilities for data processing on-line. There should be additional facilities in the form of a simple personal computer for data processing.

There should be a refrigerator, freezer, clinical centrifuge, shaking water bath, magnetic stirrer, vortex mixer and interval timer; there should be single-delivery and repeating micropipettes with disposable tips, repeating dispensers and an initial supply of laboratory

glass and plastic ware, disposable syringes and needles, disposable assay tubes etc. The total cost of these items may be estimated at US $ 50,000.

Needs may be modified, however, in the case of a laboratory with limited workload. If only a few assay batches are to be handled per week, a second manual well-type counting system may be substituted for the automatic system. If appropriate, a non-refrigerated centrifuge may be substituted for the refrigerated one. Finally, if all assays to be performed utilize the magnetic separation technique or some other technique not involving centrifugation, this centrifuge may be omitted altogether. Such changes can reduce the total cost by more than half.

The laboratory should have access to an analytical balance and a pH meter. Ample supplies of deionized or distilled water and ice should be available.

Whereas assays for most analytes of importance in clinical diagnosis and investigation can be performed with the items listed, some call for additional facilities. Assays with ^{3}H-labelled reagents require a liquid scintillation counting system for radioactivity measurements. An initial supply of counting vials and liquid scintillator is then needed. Access to a tissue homogenizer and an ultracentrifuge is necessary for sample preparation in radioreceptor assays. It is not recommended, however, that such assays form part of the initial work of a Category 1 laboratory.

Running costs in respect of assay reagents in a Category 1 laboratory also depend on its workload but very much too on whether or not commercial kits are used. The prices of kits vary widely. Costs of assays with bulk reagents are likely to be several times less, however, but careful assay quality control is then more than ever essential. It is important in planning any Category 1 laboratory to obtain assurances that such costs will be covered.

Supporting services.

An efficient and fast mechanism for the reception of reagents and other supplies is indispensable to the smooth operation of a Category 1 laboratory. Delays in importation should above all be avoided. If such a mechanism does not already exist when a laboratory is being established, one should be put into effect. Facilities for the maintenance and repair of electronic equipment should also be assured.

ADDITIONAL REQUIREMENTS FOR A CATEGORY 2 LABORATORY

Staff

Additional staff may not be necessary if a Category 1 laboratory is upgraded to Category 2; this depends on its existing staff and workload. However, at least one member of the staff should have undergone or should undergo specialized training in the preparation of ^{125}I-labelled reagents.

One member of the staff should be designated as Radiological Health and Safety Officer [2] to the laboratory, with the responsibility to ensure safe handling of radioactive materials and safe disposal of radioactive wastes.

Accommodation

In addition to the accommodation of a Category 1 laboratory, a Category 2 laboratory should have a separate reagent preparation section comprising at least one room of 15 m^2 or more in which ^{125}I-labelled reagents can be prepared without risk of general radioactive contamination.

This section should meet the requirements of Type B working places for handling radioactive materials [2]. Special facilities for the disposal of liquid radioactive wastes are not normally required, provided that the effluent is discharged to a main sewer, but attention should again be paid to the national regulations in this regard, which differ greatly from country to country. A well-ventilated fume hood to provide protection against airborne radioactive contamination during labelling operations is an essential facility.

Like the assay section, the reagent preparation section should have ample workbenches strong enough to carry moderately heavy equipment. Electricity and water services should be liberally available. Outlets of a conditioned power supply should be provided for electronic equipment. Air conditioning is an essential requirement in tropical climates.

Equipment and supplies

Additional equipment requirements if a Category 1 laboratory is upgraded to Category 2 are a further manual well-type scintillation counter for ^{125}I measurements, a further portable radioactivity monitor for ^{125}I measurements, a further, small refrigerator and a fraction collector. There should also be an additional supply of laboratory glass and plastic ware, including items required in labelling with ^{125}I. These items are for use in the reagent preparation section and should he segregated from other equipment in the laboratory to avoid the spread of possible radioactive contamination. The total additional cost of these items may be estimated at US $ 15 000.

Running costs in respect of reagent preparation depend on workload. It is again important in planning any Category 2 laboratory to obtain assurances that such costs will be covered.

Supporting services

Supporting services in respect of the reception of reagents and other supplies and the maintenance and repair of electronic equipment are needed for a Category 2 as for a Category 1 laboratory.

Measures for the protection of staff against radiation hazards, particularly in the

preparation of ^{125}I-labelled reagents must be enforced [2]. Film badges or other devices should be provided to monitor external radiation exposure. Regular checks for possible internal radioactive contamination - for example, thyroid ^{125}I uptake - should be conducted. If nuclear medicine procedures in vivo are performed in the institution concerned, such services should in any case be available.

ASSISTANCE THROUGH IAEA TECHNICAL CO-OPERATION PROGRAMS

Assistance in projects aimed at the establishment of nuclear medicine services or radioimmunoassay laboratories in the categories considered may be available through IAEA technical co-operation programs. Such assistance may take the form of fellowships for the necessary specialized training of project staff, appropriate equipment for the initiation and development of the project and/or expert advice or assistance in its planning and execution. Relevant requests should be directed to national atomic energy authorities.

This Chapter is based on an IAEA document entitled " Basic requirements of nuclear medicine services" , prepared by E.H. Belcher, and presented at the International Symposium on "Nuclear Medicine in the developing countries" held at Vienna in 1985. Some of the financial estimates from the original text are revised to reflect the current prices. Few differences may be noted between this Chapter and other Chapters dealing with the same theme in this Handbook. These differences serve to emphasize that planning of a laboratory should be based on national guidelines and local facilities.

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