CADTH

Canadian Medical Imaging Inventory Service Report

The Implementation Considerations of PET-CT

Context

The utilization of PET-CT has grown around the world and this growth is expected to continue.[1] The expanded use of PET-CT is largely attributed to the role it plays in informing the staging of cancers and influencing treatment and management strategies.[2-4] Increasingly, PET-CT is being used for the diagnosis of other clinical indications, such as cardiology, neurology, and infectious disease.[3] Publicly funded oncology indications also continue to expand[4] and the introduction of new radiopharmaceuticals has further fuelled the use of PET-CT.[4]

The rising demand for PET-CT services has increased wait times for patients, and there are concerns that Canada may have fewer PET-CT units than are needed to meet demand.[4] When compared to other Organisation for Economic Co-operation and Development countries, Canada ranked 21 out of 33 countries on number of PET-CT or PET units, with 1.5 units per million population.[3] Similarly, Canada ranks 16 out of 25 on the volume of PET-CT exams, at 3.3 scans per 1,000 population.[3]

PET-CT imaging requires the use of radiopharmaceuticals that are injected into patients to produce a radioactive signal that is detectable with a PET-CT unit. The production of radiopharmaceuticals requires a particle accelerator known as a cyclotron,[5] and, because of the short half-life of radiopharmaceuticals, cyclotrons must be located close to PET-CT sites.[6]

Although there are no international benchmarks or recommendations related to the optimal number of imaging units per million population, having an inadequate number of units to meet the increasing demand can challenge accessibility of PET-CT procedures (e.g., resulting in long wait times, even for urgent cases). At the same time, the availability of too many PET-CT units can lead to overuse, or too few patients per PET-CT site. To avoid excess capacity or unnecessary usage, the procurement of a PET-CT unit at the facility level must be considered within the context of initial capital investment (including equipment, technology, and construction), service delivery, and allocation of human and financial resources.[7]

As jurisdictions consider enhancing capacity to accommodate the increased demand for PET-CT,[8-11] decision-makers may seek guidance on the key strategic and implementation considerations necessary to maximize value from health care resources.

Objective

The purpose of this report is to provide Canadian decision-makers with a summary of strategic and implementation-related considerations for setting up a new or replacement PET-CT unit and/or a cyclotron. The information included in this report is intended to help optimize equipment use and health care sustainability while also considering current capacity and future patient requirements.

About This Document

This document summarizes information identified through the Canadian Medical Imaging Inventory[4] and a limited literature search.

PET-CT

Strategic Considerations

The need for a PET-CT unit must be identified within the context of alignment with national and/or provincial or regional health care policies and goals.[1,12] An assessment of needs that considers future use, as well as an audit of existing equipment, can help determine the demand for medical imaging tools and provide a basis for project objectives.[12] It is also important to consider the overarching goals and priorities of the health care facility where the PET-CT unit will be placed, as this can help guide the planning process.[12]

The Atomic Energy Agency (IAEA) recommends setting up a multidisciplinary task force (e.g., with representatives from nuclear medicine, clinical oncology, and epidemiology) to guide the development of conceptual and technical objectives of the intended PET-CT unit, in addition to a project proposal.[1] As well as providing justification for the procurement of new equipment, the proposal should outline project guidelines, potential implementation issues and solutions, cost and time estimates, and potential financial sources.[1] A feasibility study can help guide decision-making by providing evidence to justify the investment, a comprehensive understanding of the resources required for successful implementation, and information on short- and long-term implications of setting up a PET-CT service.[1,12]

Early internal and external stakeholder engagement is recommended to gather information on technical factors and solutions to issues unique to clinical needs and operations, such as clinical indications applicable for PET-CT imaging, important patient considerations, staff requirements, and equipment location considerations.[1,12] Pre-market consultation with potential suppliers can provide insight on PET-CT specifications and the appropriate procurement approach.[1,12]

Long-term planning is key. The space allocated for the facility and resourcing of radiopharmaceuticals should consider expected volume for patients and the variety of services that will or may be provided in the future, including potential new clinical indications and procedures beyond diagnostics.[1,3,13] If possible, space should be allocated for growth to accommodate expanded demand as, once constructed, a PET-CT facility can be difficult to modify, especially if authorization is required from regulatory bodies.[1,4,14]

Costs

PET-CT scans can help save health care costs by avoiding unnecessary imaging tests, biopsies, or treatments, and allowing for quicker diagnosis and access to treatment.[2] However, a facility requires a considerable amount of capital to set up and operate.[15] A cost analysis may help assess whether installing and operating a PET-CT centre is financially viable. The World Bank recommends a fit-for-purpose approach, which takes into consideration evaluation of relevant costs and benefits, risks, and non-price attributes.[12] Total expenditure should factor in capital and operational outlay, including costs related to purchase, installation, construction, operations, maintenance over the unit's lifetime, and disposal.[12]

Initial capital costs consist of the unit's purchase, related equipment, installation, and construction overheads. The cost of installing a PET-CT unit is around $7 million; approximately $3 million for the PET-CT unit and $4 million for construction and installation.[16] Construction costs vary and can be difficult to estimate as they are dependent on the project complexity, project schedule, location of the equipment, and equipment requirements.[17,18]

If a cyclotron is required, costs can double. The cost of building a cyclotron facility can range from $2.5 million to $6 .6 million.[5,17] Currently, a new cyclotron and radiopharmaceutical facility planned for Calgary has an estimated cost of $18 million.[19] The broad range of costs is in part due to the level of investment made into creating cutting-edge research facilities for the development of new radiopharmaceuticals and radioisotopes.

Operational expenditure includes salaries, radiopharmaceuticals, equipment maintenance, and other overheads, which can vary between facilities. Some factors that may impact operational costs include number of scans, how radiopharmaceuticals are obtained, staff, maintenance arrangements, software, and training.[3,12,20] Estimated annual operating costs of CA$1.4 million to CA$2 million per year can be anticipated.[17] Operational and maintenance expenditure typically make up 10% of capital costs per year.[1] Some factors that may affect the overall financial outlay include:[12]

- volume of patients being scanned
- how radiotracers are obtained (e.g., purchased offsite versus produced onsite, transportation costs)
- number of staff needed (e.g., more staff may be needed if more patients are expected) and how they are paid (e.g., annual salary versus fee-for-service)[20]
- maintenance arrangements (e.g., internal versus external maintenance teams)[3,20]
- software costs (e.g., for radiology peer review software, dose history tracking)[21,22]
- training costs.

When planning to purchase a PET-CT unit, it is recommended that information on when the equipment was developed is considered, as well as information on how long the newly purchased PET-CT scanner's hardware, software, and service support will continue to be developed, supported, and upgraded by the manufacturer.[23] Newer models of equipment are often released during the time it takes to set up and operationalize an imaging system, which can lead to imaging hardware that is less current than supportive software that is purchased at a later date. Procurers should make themselves aware of the updates that will be provided with the original purchase and those that will have additional costs. They should also understand which hardware and software are optional, how long they will be available, and at what cost.[23] Certain software may not be necessary for all centres; for example, dose history tracking may be more useful for research or for patients who are expected to have multiple scans due to their specific indication, and in some situations it may be more appropriate to spend that money on other dose-reduction approaches.[22]

Conducting a cost analysis may help to assess whether installing and operating a PET-CT centre is financially viable. Within the cost analysis, the previously discussed expenditures can be considered, along with the expected frequency of scans per day or week, based on factors like demand, PET-CT capabilities, and estimated unit life expectancy.[12] Additionally, hidden costs that may be easily overlooked, such as those related to security, insurance, and environmental impact should also be considered in the analysis.[12]

Table 1: Cost Analysis Considerations for Purchase of Medical Imaging Devices[12]

Cost category	Type of cost	Additional details
Initial purchase costs	Purchase price	Including accessory items and customization, if needed
	Duties and taxes	As part of equipment purchase
	Delivery and transportation	Includes freight, foreign, and exchange costs, as well as transit insurance
	Installation	Includes installation, facilitating necessary access, and integrating and calibrating the unit onsite
	Integration	Includes integrating and interfacing the equipment with existing systems and other equipment
	Facility modification	Costs associated with accommodating the scanner and equipment, as well as any costs related to the removal of old equipment
	Initial training	Includes trainer fees, course material, engineer fees, engineering and technical support, training fees, and service manuals
	Initial licence	Operating costs related to licensing for equipment or software
	Trade-in	Discounts or allowances provided by the supplier for equipment trade-ins
Leasing costs	Lease payments, residual lease payments	Includes annual leasing costs for the equipment and any lump sum residual at the end of the term (if applicable)
Maintenance costs	Maintenance agreement(s)	Includes costs related to any third-party or original equipment manufacturer agreements for routine maintenance of the equipment
	Scheduled and preventive maintenance	Includes costs for in-house maintenance and/or maintenance contracts with external providers to ensure equipment is in safe working order
	Decontamination and waste disposal	Costs associated with cleaning, sterilizing, disinfecting, decontaminating, and disposing of hazardous waste (i.e., radioactive chemicals)
	Service and repairs that fall outside of a maintenance agreement	Includes costs not covered by maintenance agreements
	Spare parts	Costs necessary for upkeep
	Other maintenance	Other maintenance costs that arise

Cost category	Type of cost	Additional details
Operating costs	Staffing	Salary and other costs related to staffing
	Accreditation and certification	Costs related to certifications and compliance audits, and professional standards
	Supplies and consumables	Costs for items used in operating the equipment
	Ongoing training	Costs for ongoing training for operating and maintaining equipment
	Facilities and infrastructure	Includes costs for any rented space
	Software upgrades	Costs of software upgrades to operate and maintain equipment
	Utilities	Estimate of energy costs associated with operating the equipment
	Insurance	Insurance of the equipment
	Licences	Costs associated with required licences
	Other operating	Other operating costs that arise
Repair costs	Repairs and unscheduled maintenance	Unanticipated costs necessary to maintain effective and safe working order of the equipment (this may be limited if a service contract exists)
	Upgrades and refurbishments	Costs associated with ensuring equipment is in accordance with statutory or manufacturer requirements
	Spare parts and accessories	Includes costs such as monitor cables
	Other repair	Other repair costs that arise
Downtime costs	Planned maintenance – additional	Includes costs related to planned outages
	Unplanned outages –additional	Includes costs related to unplanned outages
	Unplanned outages – lost revenue	Lost revenue due to unplanned outages
End-of-life disposal costs	Decommissioning or deconstruction	Costs related to decommissioning, removal from service, and safe disposal requirements
	Cost of transportation of equipment	Transport from the health care facility
	Disposal	Includes costs related to the safe disposal of any hazardous disposal
Disposal income	Resale or salvage value of equipment, parts, and operational items	The forecasted value of the item's resale or those related to salvage of equipment, parts, and/or operational items (consumables) at the end of the equipment's life

Location

Decisions on the geographic placement of a PET-CT unit may depend on several factors. Some commonly considered factors include:[20]

- Accessibility: It may be most practical to build a facility where it can be easily accessed by staff and the majority of patients with PET-CT indications. Other factors to consider include the increasing demand in use, the absence of a nearby PET-CT unit, and access to those who live in rural areas.[24-26]
- Availability of needed medical and support personnel: If a site is placed in an area with limited qualified personnel (e.g., rural areas) it may be more challenging to hire staff to operate the centre.
- Research personnel: As a PET-CT centre can benefit from research projects (e.g., clinical trials), it may be of interest to link the centre to an academic institution with research capacity in related fields (e.g., nuclear medicine, oncology).
- Access to a reliable supply of radiopharmaceuticals: The IAEA recommends that a PET-CT unit should be located within 4 hours of the production unit of radiopharmaceuticals (based on the half-life of fluorodeoxyglucose F 18 [^{18}F-FDG], which is approximately 2 hours).[1] If this is not possible, a cyclotron may be needed.
- Other environmental factors: A site's vibration environment, electromagnetic interference, and power quality may also affect the performance of some systems.[18] If applicable to the new unit, the site should be tested to determine if it meets manufacturer requirements; otherwise, appropriate corrections to the site will be needed.[18]

Within a health care facility, a PET-CT suite is typically located within a nuclear medicine department.[26] Locating the facility in this setting provides advantages such as saved space (as many rooms can be shared with other nuclear medicine imaging equipment, such as single-photon emission computed tomography) and staff (including radiologists who are already trained in the use of radiopharmaceuticals and radiation protection, which allows for more frequent rotation of duties, thus minimizing individual radiation exposure).[1] PET-CT units can also be placed in medical imaging departments, or in a comprehensive cancer centre.[26] Given that 80% of exam volume are for oncologic purposes,[3] a PET-CT unit located in a centre with a very large oncology caseload can operate very efficiently. In contrast, a tertiary health care centre can improve access for patient from other nearby facilities and accommodate the growing demand in exams for non-oncologic indications.[1] A tertiary centre also allows for easy access for patients, as well as to emergency services.[1,20] Furthermore, referring physicians often include cancer specialists who practice in tertiary care settings, so placing the PET-CT suite nearby helps allow PET-CT experts to easily communicate with and provide education to referring physicians.[1,20]

A standalone centre outside of a hospital is possible, such as an outpatient clinic, and may allow for improved access for patients who do not live near a hospital.[1] However, procedures must be developed in advance so staff can act quickly in emergency situations (e.g., a rare but potentially fatal allergic reaction to the radiopharmaceutical).[1] Since the introduction of specialized pre-clinical PET-CT scanners that are appropriate for research purposes but not for clinical uses, installing PET-CT units in non-clinical facilities to be used for both research studies and clinical purposes is no longer considered viable.[1]

PET-CT facilities that can accommodate pediatric patients may require extra services, such as equipment and staff needed for anesthesia or sedation (to limit movement during the scan). A scanner in a pediatric hospital reduces the need for children to be transported to another site for a PET-CT scan.[20] However, the number of pediatric patients who need PET-CT is likely to be limited,[14] and placing a unit in a specialist pediatric centre may not be feasible in Canada.

Models of Service Delivery

Hub and Satellite Approach

The IAEA and the Royal College of Radiologists in the UK recommend the hub and satellite system for service delivery.[1,14] Hubs have at least one PET-CT unit, a cyclotron, an adequate number of trained health care personnel, and are typically located near tertiary care facilities. They are used as training centres and provide support to a nearby satellite PET-CT facility. Satellite (static or mobile) PET-CT facilities are dependent on hubs for clinical expertise and the production of radiopharmaceuticals.[14]

Service delivery through the hub and satellite approach allows sites to benefit from expertise, while ensuring local access to a PET-CT scans and radiopharmaceuticals.[14] This approach may support efficiencies and increases production capacity by providing a supply of radiopharmaceuticals to numerous scanners, while splitting the cost of equipment and personnel between sites.[14] The timely and reliable delivery of radiopharmaceuticals to satellites should be considered, keeping in mind unexpected complications such as high traffic, specific delivery requirements, and weather conditions.[1]

Mobile PET-CT

Mobile or portable scanners are enclosed in a mobile trailer that can be deployed to different sites or be used in centres when equipment is out of service.[27,28] Mobile imaging may reduce disparities and inequalities in health care delivery.[27] Patients living in rural settings and patients who are too sick or have limited mobility can benefit from the decreased travel burden offered by mobile imaging.[27] Mobile imaging can also help reduce wait-lists, introduce flexibility to accommodate scheduling requirements, and provide relief in emergency situations (e.g., broken hospital equipment and site renovations). When planning for mobile PET-CT operations, the potential sites where the equipment will travel to will require sufficient room for the unit to be moved to, set up and taken down, in addition to the shielding requirements.[28,29] Mandatory safety, regulatory, grounding, and water requirements must be met.[29] It is recommended that each mobile site is fully integrated to the imaging services at local hospitals or a hub,[14,27] and that there is a secure electricity supply.[14,29] Other considerations include modality-specific requirements specific to each location (e.g., waiting facilities, toilets, disposal arrangements), in addition to the staff and training, and costs associated with structure and servicing to support the mobile delivery of services.[14,27,28]

Some disadvantages of a mobile unit include patient discomfort, poor staff retention, and increased costs due to transportation and servicing of mobile units.[14,27] Currently, there are no publicly funded mobile PET-CT units operating in Canada.[3]

Timelines

The implementation process involves many steps, and timing and outcomes may be challenging to predict due to factors like changes in regulatory requirements, and the availability of consultants and construction services.[3,20] The length of time to review and approve a PET-CT designation at a new site can vary between 1 year and 3 years.[3] This variation may be the results of program alignment, credentialing processes, or funding sources.[3] Overall, it can take between 3 years and 5 years from project conception to a fully operational centre, though timelines will vary depending on local circumstances.[1]

Developing a preliminary project plan and schedule can help identify a "first use" date, the processes that need to be incorporated into the project schedule (e.g., inspections), and help account for potential zoning changes and activities that are at high risk for delays (e.g., acquiring permits).[18]

Regulatory and Licensing Requirements

Early engagement with a consultant can help ensure compliance to regulatory and licensing requirements, including obtaining governmental approval, construction and delivery permits, and meeting radioisotope regulations.[18,26] It is important to note that certain authorizations need to be renewed periodically.[1]

The Canadian Nuclear Safety Commission (CNSC) requires a licence for the use, storage, possession, production, import, export, and service of nuclear substances and devices.[20,30] The use of nuclear substances and devices for diagnostic nuclear medicine is considered a medium risk activity; however, other activities that can be performed at PET-CT facilities (e.g., radiopharmaceutical studies) may require a high-risk licence.[30] Details of the proposed activities and locations associated with the use of nuclear substances and devices, management structure, and radiation safety program policies and procedures are required in the application.[30] Other specific requirements vary depending on the proposed licence activities. The CNSC states that the application can take up to 80 business days to process.[30]

Radiation Safety

It is estimated that 60% of radiation exposure is a result of the technologist handling the radioactive materials and 40% is the result of close contact with patients.[31] Overall, the main sources of radiation exposure include unshielded radiopharmaceuticals (during preparation and dispensing), patients after radiopharmaceutical administration, toilets used by patients who void radioactive urine, sealed calibration sources, and an active PET-CT scanner, particularly the CT component.[1,32]

Radiation Safety Program Policies and Procedures

The CNSC requires that all radiation safety programs be documented with detailed policies and procedures. To meet regulatory requirements, the "as low as reasonably achievable" principles for radiation dose must be implemented through the management and control of work practices, personnel training and qualification, control of occupational and public exposure to radiation, and planning for emergency situations.[30,33] As well, procedures to directly monitor the workplace to ascertain and record exposure are required.[30] It is recommended that the magnitude and location of radiation sources are directly monitored (e.g., ring dosimeters), as this can inform optimization practices and staff training, and ensure that levels are within regulatory limits.[31,34,35]

Provincial and territorial authorities are responsible for workplace health and safety through radiation protection programs or through occupational health bodies.[36] These authorities may have regulatory powers, or play an advisory or service role in support of other regulatory bodies;[36] hence, it is important to consider how provincial or territorial requirements can impact the facility's safety policies and procedures.

Recommended procedures to minimize exposure to staff include:

- decreasing time spent near radioactive patients by monitoring patients with video cameras and performing some procedures before radiopharmaceutical administration[37]
- using remote or automated dispensing and injection systems[31,35]
- regular maintenance of the PET-CT unit to improve radiation protection[31]
- placing the thyroid uptake probes and scintillation away from rooms used by PET patients[37]
- moving radioactive patients to protected areas away from staff and other patients[37]

- limiting the number of patients receiving PET-ST scans to ensure exposure does not exceed limits (although difficult to estimate, some recommendations for maximum patients per year range from 2,400 to 4,300, though more patients may be seen with lower doses [e.g., with newer PET-CT scanners that allow for lower doses] or with more staff on rotating shifts)[31]
- maintain or upgrade PET-CT scanners (e.g., newer scanners allow for lower doses)[31]
- staff education and suitable local shielding (e.g., stock vials, syringes, waste).[31,34,35]

In Canada, numerous radiation protection initiatives at the federal, provincial and local levels have been developed. However, not all initiatives are implemented, and adherence may vary from province to province, facility to facility, and in some instances from department to department.[38] This lack of adherence may, in part, be due to a lack of education and training opportunities, and poor dissemination of available information.[38]

Replacing a PET-CT Scanner

Every institution or authority should have a plan for replacing medical imaging equipment that considers site-specific factors (e.g., clinical programs, staffing, budgets) and evidence (e.g., health technology assessments) that shows that PET-CT is the optimal modality for imaging specifical clinical indications.[25,39,23] In Canada, the most common reasons to replace or upgrade existing equipment are equipment age, end of manufacturer support, and equipment failure.[3]

In accordance with life cycle guidance from the Canadian Association of Radiologists, imaging modalities should be considered for replacement after 10 years of use, and should not exceed 15 years.[39,23] However, device utilization impacts the aging process and should be taken into consideration when assessing equipment performance.[23] According to the Canadian Association of Radiologists, life expectancy based on use follows these general guidelines:[23,39]

- high utilization (24 hours, 5 days per week; or 750 8-hour shifts per year; or > 6,000 exams per year) is 8 years
- medium utilization (16 hours, 5 days per week; or 500 8-hour shifts per year; or 3,000 to 6,000 exams per year) is 10 years
- low utilization (8 hours, 5 days per week; or 250 8-hour shifts per year; or < 3,000 exams per year) is 12 years.

Another approach that can help evaluate the lifespan of medical equipment is to follow the guidelines set out by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry. It recommends that at least 60% of equipment is less than 5 years old, which is considered state-of-the-art technology with potential upgrades.[42,39] Equipment between 6 and 10 years old is fit for use but requires a replacement strategy.[42] Devices in this category should be no more than 50% of installed equipment. Finally, no more than 10% of equipment should be older than 10 years old.[42]

Other factors that can influence a medical imaging device's life expectancy include the extent of equipment maintenance, the availability of replacement parts, and the equipment's efficiency.[23,39] Older PET-CT scanners are at high risk of breakdown and require more maintenance, which delays diagnosis and treatment, and increases operating costs.[39,43] From a financial standpoint, the cost benefit, the residual value of older equipment for trade-in, and the disposal and installation costs associated with replacing the technology should be considered.[12,39]

Replacing PET-CT units may also be considered within the context of technology advances that have led to significant improvements, including lower radiation exposure to patients and staff, clearer images, and faster acquisition times.[4,39]

Equipment Considerations

Several specifications influence a PET-CT unit's imaging quality, such as spatial resolution, sensitivity, noise, scattered radiations, and contrast.[12] These parameters are interdependent, and if one parameter is improved, one or more of the others may be compromised.[12] High detector performance is particularly essential for facilities planning to use radiopharmaceuticals with very short half-lives.[12] Experts also recommend higher slice counts, preferably at least 16 or more slices.[12]

Most PET-CT suites only have one scanner, though the IAEA recommends planning for more than one per facility to increase efficiency and allow for smoother patient service.[1] Having 2 PET-CT units use less than twice the amount of radiopharmaceuticals of one unit, reducing the cost per patient dose; it also allows for more efficient use of staff, and can help navigate planned downtime or unexpected breakdowns (e.g., the functioning scanner can be used for high-priority procedures, or operate extended hours).[1] While more scans may lead to increased radiation exposure for staff, proper use of shielding, and safety procedures and policies can help manage radiation concerns.[1]

Information on relevant service and upgrade support provided by the manufacturer, and the use of these services, as well as information on additional costs and relevant hardware and software availability, should be obtained in writing before procurement.[23] The most commonly used equipment servicing methods at sites with PET-CT units in Canada are via full vendor support at 63% followed by third-party support at 18% of all use.[3] Certain software may not be necessary for all centres: dose tracking software may be more useful in the research setting or for patients who are expected to have multiple scans.[22]

Supporting Technological Requirements

Some technological requirements that allow for communications for PET-CT units are needed. These include telephone equipment and services, broadband (high-speed internet) connectivity, and network connectivity.[18] Other systems may require consideration at the building stage; for example, closed-circuit television for patient viewing and security surveillance, voice and data outlets, and conferencing facilities.[18] Stable internet is needed for patient booking and appointment systems, PET-CT unit calibration and installation, and to handle patient and clinical information systems. Newer PET-CT systems must also support picture and archiving communication systems.[3]

Site and Construction Considerations

Human Resources

Planning

Identifying experienced team members and starting team meetings early in the site preparation process can help avoid delays and additional costs.[18] A project team should include senior management, a project manager, an architectural and engineering firm, a construction team, an information technology representative, system users, and other personnel who have an impact on project implementation.[18] For example, a nuclear medicine physicist should be involved in preparing bid specifications and evaluating vendor quotations, in addition to working with physicians to determine equipment needs, ensure radiation protection, and perform maintenance.[1] Ideally, an individual with experience and background in medical facility construction should be responsible for managing the entire project, including the planning stages.[44]

Design and Construction

The design team develops the floor plan that considers the functions to be performed in all areas, the flow of patients and staff, radiation protection measures, building codes, and regulation requirements.[1,18] The design team should include the facility director, physicians,

architects, engineers, radiation protection experts, and equipment vendors.[1] The design team is also responsible for coordinating project plan reviews and any necessary follow up with local departments.[18] An architectural or engineering design team with experience in the medical field and site preparation for diagnostic imaging systems may help to avoid some issues that might occur with an inexperienced team.[18]

Infrastructure Considerations

Some general site considerations include:[18,26]

- a structural assessment to ensure structural support for the equipment and shielding[26] (PET-CT units can weigh approximately 3 tons, so the room containing the scanner and delivery path must meet weight-bearing capacity, and extra supports may be needed, especially in seismic areas[1,44])
- foundation design (e.g., to address concerns like vibrations)
- level flooring for equipment positioning and patient safety
- mechanical and electrical infrastructure to meet the power, cooling, heating, ventilation, and air-conditioning requirements for the PET-CT unit, including ventilation for heat-generating equipment and extraction for the hot labs; related items may include uninterruptable power supply; provision for cable support trays; recessed cable ducts in the floors, walls, and ceilings; and large electrical cable trays (which may impact room space)
- appropriate ceiling heights (should be at least 3 meters for ceiling tube mount installations)
- accessibility (e.g., for people in wheelchairs, those using mobility aids, people with other disabilities, and bariatric patients)
- ergonomics (e.g., height of desks and benches to ensure comfort for staff)
- door sizes to allow for trolley and bed access, where needed, and for equipment access.

During the planning stages, the manufacture can provide technical support, such as floor plans and a preinstallation manual, to ensure the needed infrastructure is accounted for in the design stage.[12] A generic design that can accommodate all equipment manufacturers should be used if equipment has not been chosen by initial design, which may have greater requirements to ensure it can meet any potential demands.[26]

Patient Comfort Considerations

Acoustics, natural lighting, and temperature can help achieve a comfortable environment for patients and staff.[26] Facilities should also ensure privacy for patients, especially in consult, uptake, and scanning rooms.[26]

Security Measures

The design of the PET-CT suite will need to prevent unauthorized access to areas of high-risk exposure to radioactivity (e.g., hot laboratory and hot store) and ensure security of radiopharmaceuticals and radioactive waste.[26] Security measures for radioactive materials are subject to radiation safety regulations, with measures including access control (e.g., reed switches, card readers, electric strike and magnetic locks), radioactive warning signs, closed-circuit television monitoring, and duress alarm buttons for staff in relevant and accessible areas.[26,35]

Size and Placement

The size of a PET-CT suite will depend on numerous factors, including the dimensions of the equipment, the amount of space needed for maintenance equipment, and the clinical service plan (i.e., the size and scope of the operation). Over the past 15 years, volume of PET-CT use

in Canada has exceeded initial expectations during its design stages, particularly in terms of injection sites and patient waiting areas.[4] Therefore, planning should consider current and expected volume for patients and services in the future, as well as potential new clinical indications and procedures beyond diagnosis.[1] As previously mentioned, modifications to accommodate growth post-construction can be difficult to accomplish due to required regulatory approval if additional space is needed. Consideration should also be given to the width and heights of corridors and doorways, and elevator size and capacity, so that equipment delivery is optimized.[18,44]

If located near or in a nuclear medicine unit, the effect of emitted radiation on other nearby nuclear medicine imaging modalities needs to be considered, as it can affect other units' imaging, correction floods, tuning, and calibration.[34] Anecdotal reports have indicated that it is very difficult to shield, and thus other nuclear medicine imaging modalities within the nuclear medicine department should be as far away from PET-CT scanners as possible.[34] Nuclear medicine services (e.g., intrinsic calibrations, tunes, high count floods) may need to be scheduled when there are no CT operations and no PET isotopes nearby.[34]

Layout

The creation of an architectural blueprint is recommended to avoid costly and time-consuming revisions post-planning. Size recommendations and layout and design considerations for specific rooms are provided in Appendix 2 .

This section will expand on how the layout can help minimize radiation exposure using 3 basic principles: distance, shielding, and time.[35] A proper layout design can help to minimize staff exposure and identify required shielding materials. Areas within a PET-CT facility are categorized as "hot" or "cold" areas. Rooms with low risk of exposure are known as the "cold" or "uncontrolled" areas (e.g., reception, waiting room), whereas rooms at high risk of exposure are described as "hot" or "controlled" areas (e.g., hot lab, uptake room).[1]

Distance

Hot and cold areas should be geographically separated, and using separate patient and staff corridors can also help to limit radiation exposure.[26] For example, cold areas with high occupancy and patient rest areas should be located as far as possible from the PET uptake and imaging rooms.[35,37] Furthermore, the layout should consider rapid and easy access for radiotracer deliveries and safe disposal of radioactive waste.[1] A special parking area for vehicles can help ensure safer delivery of isotopes and rapid access to the hot lab.

Shielding

While the layout can help reduce radiation exposure through distance, shielding will still be required because of the high levels of emitted radiation and because the patient is a constant source of radiation after radiopharmaceutical intake.[35,37] A radiation protection assessment will detail the type, location, and amount of radiation protection areas required according to final equipment selection, layout, and in relationship to other areas.[26] As radiation exposure can be affected by various factors, shielding requirements can differ across various rooms within the facility.[35,37,45] Factors affecting the amount of shielding required include:[37]

- the number of patients imaged per day and per week
- the radiopharmaceutical dosage per patient, which may vary between patients, or depend on the PET-CT unit, as newer machines have dose-reduction algorithms[31,4]
- the radiopharmaceutical used

- the length of time that patients remain in the facility (as the patient becomes a radioactive source after radiopharmaceutical administration)
- the location of the facility and general environment
- the construction materials used (e.g., concrete, lead, iron)
- regulatory limits for radiation exposure
- occupancy (the percentage of time an area is occupied by a person; for example, work areas, laboratories, and offices tend to have high or full occupancy, while corridors tend to have partial occupancy, and toilets and closets tend to have occasional occupancy); potential changes in occupancy should also be considered, such as how the area may be used in the future.[35]

All rooms used for imaging procedures need radiation shielding: scan room, injection room, hot labs, hot stores, and any rooms with hot patients.[26,37] A certified physicist or qualified expert can determine shielding requirements and is required to review plans for radiation protection to ensure local radiation and nuclear safety regulations are met.[18,40] Radiation requirements also need to be reassessed if the intended use of a room changes at any point, equipment is upgraded, or surrounding room occupancy (including those above or below) is altered.[26] The American Association of Physicists in Medicine recommends accounting for the shielding requirements of cold rooms above and below the PET-CT facility.[37] Further considerations should also be made for strategic placement of doors to avoid the high cost associated with the purchase of one with extensive shielding, in addition to ensuring that the floors can support the weight of extra shielding.[37,45]

A room that is shielded for PET is unlikely to need additional shielding for the CT component, though some exceptions exist; for example, if the distance between the radiation source to the area of concern is more than 3 metres, shielding required for PET radiation is minimal and CT shielding is the primary concern.[37]

Time

Radioactive waste may be held for a period of time to allow its radioactivity to diminish before it is safe for routine disposal; it is considered no longer radioactive after it has been appropriately shielded and has decayed to a safe level set by the regulatory authority.[26]

Non-Radiation Safety Considerations

Infection control measures should also be considered; this includes hand basins in scan rooms, uptake rooms, induction rooms, clean and dirty utility rooms, bed holding rooms (1 basin per 4 bed bays), corridors, and adjacent to the staff station.[26] Finishes should consider infection control and ease of cleaning, fire safety, and durability. All surfaces (e.g., floors, walls, bench tops, junctions) need to be waterproof and easy to clean; floors should be sealed and coved at the edges.[26] Medicated hand gel dispensers should also be considered and placed strategically in staff and patient circulation corridors.[26]

Additional Considerations if Working With an Existing Space

Building a PET-CT centre from scratch rather than using an existing facility (e.g., inside a nuclear medicine clinic) offers better choices for the most appropriate site design, distribution of activities, and whole facility size.[1] If working with an existing space, various modifications are likely required and may be expensive and complex (e.g., redesigning rooms, tearing down walls, adding shielding, rerouting the electrical supply and water pipes).[44]

Upgrades to picture and archiving communication systems and digital storage, and installing high-speed internet will be needed to accommodate the storage and dissemination requirements of PET-CT images, which have large file sizes.[46]

Considerations for Radiation Therapy Planning

If integrating PET-CT into radiation therapy planning, specific personnel training and hardware requirements will need to be considered.[47] Some PET-CT units produce attention correction-only CT scans; these are not sufficient for radiation therapy planning, which requires diagnostic-quality CT images.[47] If contrast-enhanced CT is used, specific tools like a pressure injector will be needed, and technologists will also require related training.[47] In addition, due to the risk of anaphylactic shock from use of contrast agents, staff must be properly trained and prepared in case of this emergency, with a physician covering this responsibility.[47] As therapy tables are flat, scans used for therapy planning must also be obtained on a flat surface; therapy pallets that fit over the curved PET-CT table can help achieve the image.[47] Other equipment that may be needed include stabilizing products, such as a 4-dimensional infrared patient alignment laser system (to assist correct patient positioning for the scans); stabilizing masks; bite blocks; and bean bags. Computer hardware must also be capable of integrating the images.[47] The use of PET-CT imaging for radiation therapy planning may lead to increased demand for PET-CT scans, which should be incorporated into planning.

Human Resources for PET-CT Procedures

Sufficient staffing is needed to ensure sustainable operation and development of PET-CT services.[14] Planning for staff should begin at an early stage, and should include identifying needed positions, providing necessary training, and ensuring there are enough staff to minimize radiation exposure levels to personnel.[1]

Diagnostic Imaging Physicians

A diagnostic imaging physician (or nuclear medicine physician) supervises patient care, management procedures, and clinical protocols, as well as oversees quality of services, supports and enforces quality assurance and control of equipment, and establishes clinical review and auditing processes.[1] When the PET-CT unit is initially set up, diagnostic imaging physicians may also need to dedicate time to establish the PET-CT program and participate in regulatory processes.[20]

Most jurisdictions in Canada only allow specialists to practice nuclear medicine, including PET-CT scanning, if they have had fellowship training in nuclear medicine from The Royal College of Physicians and Surgeons of Canada. Some provinces (Alberta and Manitoba) also have extra requirements for clinical interpretation of PET studies.[20] Additional training to handle radiopharmaceuticals, spills and contamination events, improve patient preparation, and enhance reporting criteria may be required.[4]

The IAEA states that the continuous presence of at least 1 medical doctor is required (i.e., at least 1 physician should be present for each shift).[1] However, the number of needed physicians will depend on various factors, such as the expected number of scans, clinical indications for scanner use, types of PET-CT investigations, human resource organization, and experience.[1,20]

In Canada, some nuclear medicine physicians have reported a potential shortage of replacement staff due to the upcoming retirement of a wave of nuclear medicine physicians and not enough trainees to replace them and meet increased demand.[4] This may be due, in part, to the minimal amount of training sites in Canada that offer accredited nuclear medicine residencies and fellowships.[4]

Technologists

Technologists contribute to preparing clinical examination protocols and performing patient examinations, and are also involved in routine calibration and quality control of scanners. The IAEA recommends that the number of technologists should be 2 to 3 times the number of physicians.[1] In most instances, 2 technologists will generally be required, though 1 may be acceptable if they have sufficient training and patient throughput is modest.[46] If patient throughput is high (i.e., more than 12 per day) and includes complex patients (e.g., inpatients, pediatric patients, radiation therapy planning patients), an additional technologist or patient assistant may be needed.[46] Additional considerations are also needed to account for holidays, sick leave, and minimizing radiation exposure.[20] To accommodate absences, technologists may rotate (e.g., at one PET-CT site in Canada, 8 technologists rotate through 3 days per week); nurses may also be involved in these duties and the rotation schedule.[20,46] Each province has its own legislation for who can operate X-ray emitting devices, including PET-CT units; this is typically an X-ray technologist. However, other technologists may have limited practice.[20] In Canada, a shortage of technologists trained in PET-CT imaging has been reported.[4]

Most technologists are trained in nuclear medicine and require additional training for PET-CT units, but there are limited programs in Canada that provide this training.[4] Generally, a 2-year technical degree or equivalent is required.[1] In Canada, nuclear medicine technologists complete a training program by the Canadian Association of Medical Radiation Technologists to obtain nuclear medicine certification; PET-CT imaging is part of the current curriculum, and distant continuing medical education is also available for technologists who were trained before PET-CT imaging was added to the curriculum.[20] Previous experience from a PET-CT site in one province indicated that sending nuclear medicine technologists on a 1 to 2 week preceptorship to a site that uses the same scanner they will use is a helpful experience.[20] Other specialized training may include on-the-job training, supervised training, extensive mechanical and electrical repairs, radionuclide production, radiation safety, and additional CT scanning training.[1,20] Technologists also require training to receive radiotracers, including radiation safety, Transport Canada regulations, quality assurance training, safe handling of radiopharmaceuticals, drawing up individual doses, and transport regulations for shipping empty containers back.[20]

Medical Physicists

Medical physicists provide support primarily related to ongoing quality assurance of technology and equipment performance.[1,20] Dedicated nuclear medicine medical physicists can generally also support the general nuclear medicine program or diagnostic imaging.[20]

The number of medical physicists needed will depend on various factors, including the number of patients, if therapy is undertaken, and the type of treatment performed.[1] In general, at least 1 dedicated medical physicist is required for the operation, support, and development of a basic PET-CTunit.[14] Human resource shortages are not widely considered an issue for medical physicists, although it may become a concern if more PET-CT units are installed or upgraded and more novel radioisotopes are approved.[4]

Nurses

Nurses specialized in nuclear medicine are also involved in PET-CT investigations, particularly in the management and care of patients (e.g., placing IV cannulas and administering pharmaceuticals).[1] They are also involved in preparing protocols and checking operation of other services in the hospital (e.g., transportation).[1] The number of nurses is typically estimated as 2 to 3 times the number of physicians.[1]

Radiation Safety Officer

A radiation safety officer is primarily involved in ensuring radiation safety practices are adopted.[48] The radiation safety officer also delivers supervised training.[48] All nuclear medicine departments have radiation safety officers, as required by the CNSC, and the educational training and practical experience required will depend on their responsibilities and the magnitude, complexity, or diversity of the use of nuclear substances.[30] An assessment will also be needed to determine if the current number of radiation assessment officers is adequate to manage a new PET-CT suite; factors to consider may include the amount of dedicated time needed and required skillsets for PET-CT scans.[30]

Other Positions

Support personnel are required for managerial, administrative, and logistic duties, such as electronic diagnosis and repair, and quality management.[1] Some staff may perform multiple functions, with the exception of quality control: this person should be independent from production operations or must have sole oversight of these duties.[1]

A dedicated position to handle regulatory and clinical trial enrolment is also recommended. Ideally, this person may be a health care worker with experience in clinical trials and Health Canada's clinical trial application process for FDG (e.g., research nurses, allied health professionals).[20] This position will be particularly important if novel radiopharmaceuticals are considered for use due to the regulatory specifications. A qualified person with formal training in good manufacturing practices (GMP) and at least 2 years of practical experience working in an authorized GMP-licensed facility involved in radiopharmaceuticals may also be needed.[1]

Staff may be needed to conduct PET-CT maintenance, though it is also possible for maintenance to be conducted by the manufacturer or a different external team.[20]

A summary of the suggested minimal staff needed for a PET-CT scanner in effective full-time equivalents is presented in Table 2 . Some general considerations may include strategies to hire and train staff who may require additional onsite training, as well as how to improve recruitment and retention for certain areas (e.g., providing sponsoring programs for students).[20]

Table 2: Summary of Suggested Minimal Operational Staffing Levels for Effective Full-Time Equivalents[20]

Staffing	FTE for PET-CT	FTE for cyclotron
Medical director or diagnostic imaging physician	0.20 (assuming sufficient administrative, regulatory, and clinical research supports)	NA
NM physician	2 to 3	NA
Radiochemist or radiopharmacist	May be needed early on only to validate stability of imported radiotracers	1.0
NM technologist	2.4	2.4
Medical physicist	< 1.0	1.0
Radiation safety officer	< 1.0	< 1.0
Clinical trials or research coordinator	1	NA
Equipment service	< 1.0	< 1.0

Staffing	FTE for PET-CT	FTE for cyclotron
Clerical	< 1.0	< 1.0
Housekeeping	< 1.0	< 1.0
Facility maintenance	< 1.0	< 1.0
Management, finance, human resources support	Allocated support relative to current infrastructure	Allocated support relative to current infrastructure
Regulatory consultant(s)	Significant resources from beginning until full regulatory approval	Significant resources from beginning until full regulatory approval

FTE = full-time equivalent; NA = not applicable; NM = nuclear medicine.

Other Human Resource Considerations

Staff at risk of accidental radiation exposure should take a radiation protection course recognized or approved by the relevant regulatory body of the area they live in. The course may be integrated into professional education, as long as it meets training criteria set by the regulatory body.[1] Other positions (e.g., nurses, maintenance, engineering, and cleaning staff) may not require accreditation, but should have some instruction on radiation protection.[1]

When setting up a PET-CT facility, establishing training programs may help to encourage staff recruitment and continuing education.[20] Ideally, PET-CT sites should be training centres and time should be allocated into the job plans of those conducting the training.[14] Adequate facilities, funding, and study leave to conduct adequate training at all levels are needed.[14] Developing e-learning modules may help expand PET-CT expertise.[14]

Radiopharmaceutical Production and Security

The production of radiopharmaceuticals requires a particle accelerator known as a cyclotron. Radioisotopes are created in the cyclotron and converted into radiopharmaceuticals using chemistry techniques. Some issues related to radiopharmaceuticals to consider in advance when setting up a new PET-CT unit may include:[14]

- Which radiopharmaceuticals will be needed, and what is the expected level of demand?
- How will they be obtained: purchased from offsite, or produced onsite?
- What will be done if the offsite supplier or onsite cyclotron has unexpected downtime? Alternative sources should be identified.
- What staff need to be hired, and what additional training may be needed?

Purchasing Radiopharmaceuticals

Due to the high costs associated with purchasing and operating cyclotrons, many facilities choose to purchase radiopharmaceuticals offsite.[12] In fact, only a third of PET-CT sites in Canada have access to a local cyclotron.[3] Some factors to consider when planning for radiopharmaceutical supplies include schedules, costs, receipt of products, alternative suppliers, responsibility for training matters and legal transport requirements, and penalties for failure to supply.[14]

Radiopharmaceuticals are delivered by road or air via commercial flights.[3] To ensure timely delivery, logistical details of the delivery process should be settled early in the planning process to determine the reliability of transporting isotopes within a 4 hour distance, including any potential delays.[1] Delays can render radiopharmaceuticals unusable due to their short half-life,

which results in last-minute exam cancellations and delayed treatment, which can lead to worse patient outcomes. A feasibility study that simulates regular delivery of radiopharmaceuticals twice a day from an available supply should be conducted to account for factors that differ across regions, such as weather, traffic, frequency of commercial flights, and special check-in requirements.[1] A feasibility study conducted by the PET-CT centre in Winnipeg found that 13% of radiopharmaceutical shipments arrived on time, 66% were late but did not impact patient appointments, 5% were late and required cancelling some appointments, and 10% led to all appointments being cancelled.[20]

Reductions in commercial flights, as was seen during the COVID-19 pandemic when travel restrictions led to reduced traffic volume, can hinder access to radiopharmaceuticals and drive up their costs.[49] The rescheduling of exams also takes administrative effort, and pushes back other patients' exams, which may cause anxiety and distress in patients as well as impact their health outcomes. To prevent the need to cancel or reschedule appointments, many hospitals order 2 or 3 times more than the volume of radiopharmaceuticals that are needed. This approach is expensive and should be considered when calculating operating costs. Finally, purchasing specific, lesser-used radiopharmaceuticals may be difficult. Some radiopharmaceuticals are only produced in specific provinces, and may be very difficult to access in non-producing provinces (e.g., due to short half-life and potential for transportation delays).

Radiopharmaceutical Availability

While ^{18}F-FDG is the most commonly used PET-CT radiopharmaceutical, others have been developed and are used in research settings, such as ^{18}F-FDG prostate-specific membrane antigen-1007 (PSMA) and simultaneous gallium-68 prostate-specific membrane antigen for prostate cancer PSMA.[50] Many of these novel radiopharmaceuticals are not approved by Health Canada for clinical use, although they are allowed for clinical trials.[51]

While Canada has a strong reputation for clinical trials, health research, and use of evidence-based medicine, Canada's adoption of novel radiopharmaceuticals has been noted as a barrier to the efficient use of PET-CT services.[4]

Even if novel radiopharmaceuticals were to be approved, the expertise and infrastructure needed to manufacture and handle them may not be in place immediately.[4]

Supplier Monopoly

Over the past decade in Canada, poor economic viability and significant industry consolidation in radiopharmaceuticals may have led to the commercial monopoly of radiopharmaceutical production in some settings.[54] Dependency on a single supplier can impact radiopharmaceutical accessibility and innovation, which can have detrimental downstream effects to patients and the services provided by PET-CT facilities.[55,4] PET-CT facilities that are reliant on a single supplier have reported increased risk of service disruptions in the supply chain and limited redundancy when issues arise during production.[4] In such cases, the facilities might purchase products that are at a higher risk of loss in radioactivity from farther locations at a greater cost.[56] Suppliers with a monopoly on the radiopharmaceutical market can drive market prices and impose purchase limitations to customers (e.g., limiting doses per patient).[4,57]

Regulatory Considerations

A Heath Canada drug establishment licence is required for a facility to produce radiopharmaceuticals. In particular, Health Canada's Food and Drug Regulations require conformity to GMP.[58] The length of time it takes before a fully operational cyclotron receives a licence may vary, and may take up to 5 years.[59]

Cyclotrons

The production of radiopharmaceuticals requires a particle accelerator known as a cyclotron.[4] Some hospitals house their own cyclotrons and produce radiopharmaceuticals onsite. Other cyclotrons are privately owned and operated near PET-CT units and transport radiopharmaceuticals from their facility to hospitals in shielded containers and cases.[60] All cyclotrons require licensing through the CNSC and Health Canada.[4]

Current Capacity Challenges

Cyclotron capacity is noted as a potential factor that can limit the number of PET-CT exams that can be performed. PET-CT sites that rely on radiopharmaceuticals produced offsite must coordinate with external cyclotrons' production schedules. With expected increases in PET-CT exam volume, it is possible that existing cyclotrons may not have the capacity to meet demand as new PET-CT units are installed and more clinical indications are approved.[4]

Strategic Considerations

The need for a cyclotron must be assessed within the context of the facility's needs, circumstances, and program objectives and priorities.[1] The type of isotopes needed and space available should be determined to guide the planning process and ascertain whether a reliable external supply will be required.[1,61] Engaging a PET-CT task force and other stakeholders, including users, can help assess the feasibility and viability of purchasing and operating a cyclotron onsite, as well as inform on the type of cyclotron capabilities needed.[61]

The operating times of PET-CT units are closely tied to cyclotron supply operations.[3] The installation of a local cyclotron allows for a more predictable supply of radiopharmaceuticals, flexible scheduling, enhanced research capacity, reduced transportation costs, and lower purchase costs to account for losses due to short half-lives.[1,20,61] However, cyclotrons are more likely to be affected by downtime than PET-CT units, and are more complex to establish than a PET-CT suite.[1] Many tests, validation procedures, and licensing processes must be performed, which take time, and regular clinical production may take several years after all technology has been installed.[1] Some isotopes do not require a cyclotron and can be produced from generators (e.g., rubidium-82 chloride), requiring dedicated spaces for a laboratory (for processing) and quality assurance testing.[1]

Equipment Specifications

Cyclotron

Once the needs of the planned facility have been established, the most suitable cyclotron model with the features that meets the facility's needs can be selected.[1] Cyclotron models have varying specifications that impact their production yield, specifically, beam energy and beam current.[1,62] A single beam current of 150 μA (a unit for measuring electrical current) on target is considered sufficient to produce conventional PET isotopes in an area with a reasonably large population for PET-CT use.[62] Another feature that should be determined in the planning phases is whether the cyclotron is self-shielded or non-shielded. This can impact the design, shielding, and space

needed within the cyclotron facility.[61,62,63] It has been reported that some staff with knowledge and experience with cyclotrons may prefer unshielded cyclotron because self-shielded may slow down repairs and maintenance.[61]

If there is clinical interest in producing radiopharmaceuticals that are not routinely used, specialized systems may be required.[1]

Hot Cells

Hot cells are shielded enclosures that provide an environment to prepare radioactive isotopes. Most hot cells will have automated synthesis modules for the production of clinical radiopharmaceuticals.[1] They can have 2 independent modules or 2 modules in the same hot cell. In cases of synthesis failures, there will be lower radiation exposure in 2 shielded hot cells compared to one, where it needs to be opened to load a second module, or clean and prepare for another synthesis.[1] For facilities that have a single hot cell, cyclotron production may be limited to a single product per day.[4]

Maintenance

Similar to PET-CT units, equipment maintenance and service are important considerations for cyclotrons. Facility personnel with appropriate technical training can conduct routine maintenance work such as simple repairs or process changes, which may include valve check-ins and repairs. If facility personnel do not have appropriate training or time, a maintenance and service contract can be negotiated with the vendor, ideally during purchase negotiations.[1] It is suggested that a list of spare parts that may fail more frequently is obtained from the vendor to enable quick replacement.[1] Additionally, it is recommended to design a routine verification program to ensure all safety equipment and systems involved in radioisotope production (e.g., electrical safety, fire protection, drainage) are operating efficiently together.[62] Many of these systems may be designed and installed by different companies with varying knowledge of cyclotron facilities.[62]

Costs

Similar to a PET-CT facility, the costs of construction, maintenance, and staffing are important considerations for cyclotrons.[17] Some recent technological developments may help to reduce the costs of producing radiopharmaceuticals, including smaller and less expensive cyclotrons that are self-shielded, and automated radiochemistry systems.[12]

A cost-benefit analysis can ascertain whether setting up a new cyclotron facility is justified.[61] It is difficult to clearly determine in advance whether onsite production or purchasing from external vendors is more cost-effective: many costs are market-driven and unpredictable (e.g., labour and construction), and losses from unstable product (e.g., from travel delays) are also difficult to calculate.[20] A previously conducted analysis estimated cyclotron costs over 20 years from the health care institution's perspective, and generally found in-house production of ^{18}F-FDG to be more expensive than importing it.[20] However, it was also noted that this analysis may have underestimated costs related to external acquisition, and did not take into account costs from other perspectives (e.g., from patients');[20] as well, this analysis may not have considered future expanded use of equipment.[14]

Licence and Regulatory Requirements

CSNC considers cyclotrons as class II prescribed equipment and cyclotron facilities as nuclear facilities that require the following CSNC licences. The requirements listed may be independent of provincial and territorial regulations.

Class II Nuclear Facility License

There are 3 types of categories of class II nuclear facility licences: licence to construction, licence to operate, and licence to decommission. To obtain a licence to construct, control of the site the facility will operate in and compliance to regulatory requirements must be proven.[64] This licence does not authorize the possession of nuclear substances or the production of radiation.[64] There are 2 types of licences require to operate, one for the purpose of commissioning and the other for routine operation. The former is to determine the robustness of the facility's design.[64] The latter is required to use prescribed equipment for patient treatment and requires the applicant to demonstrate that equipment is functional and that staff are properly trained.[64] The licence to decommission is to ensure prescribed equipment will be dismantled properly and that radioactive substances will be handled and disposed of properly.[64]

Class II Prescribed Equipment Licence

To acquire a class II prescribed equipment licence, conditions of the class II nuclear facility licence must be met.[64] There are 2 types of licences: a licence to service and a licence to operate. To service the prescribed equipment, the 2 types of licences to service allow you to either have an in-house servicing staff or to contract servicing companies.[64] Both types of servicing routes require the correct expertise for maintenance, as well as training in radiation safety.[64] The licence to operate requires facilities to ensure staff are properly trained and to demonstrate measures in place to protect staff.[64]

Class II Prescribed Equipment Certification

Prescribed equipment must be certified by the CNSC before it can be used in Canada.[64] It is typical for vendors to apply for the certification; however, the licensee is responsible for ensuring the equipment is certified. The submission is used to determine if the equipment is safe for use with adequate safety measures and that design meets Canada's international obligations.[64]

Timelines

If it is established that a new cyclotron is needed, a general timeline for creating a cyclotron program may include:[20]

1. begin process for purchasing a cyclotron (e.g., determining needed space, electrical requirements)
2. cyclotron facility planning (estimated 9 to 12 months) and acquiring licences to construct the facility and use, operate, service, and decommission equipment
3. Health Canada considerations (e.g., whether using currently approved radiopharmaceuticals, if operating under another institution's clinical trial application)
4. human resource considerations (e.g., consultants for CNSC and Health Canada applications, facility director).

The development of a medical cyclotron program usually takes longer than a PET-CT imaging program, approximately 3 years to 5 years (compared to 1 year for PET-CT imaging); thus, unless the cyclotron is developed in advance, there will be a period where radiopharmaceuticals will need to be brought in from outside (likely at least 2 years), if this is possible.[20]

Ideally, the planning process for a cyclotron should begin early, and no later than the process for setting up a PET-CT scanner.[20] The first delivery of ^{18}F-FDG is expected to take 6 months to 1 year,[1] and is dependent on the number of documents and procedures that must be created and

established.[1] However, the length of time it takes before a fully operational cyclotron receives a drug establishment licence that approves the use of radiopharmaceuticals for clinical purposes may take up to 5 years.[59]

Similar to PET-CT imaging, it is likely that the program will need to be expanded over time, as demand grows and new radiopharmaceuticals are introduced.[1] Plans should consider how potential expansions can be facilitated. One method is to set up the cyclotron at the central core of the facility, and use other rooms around it as they are needed.[1]

Design and Construction Considerations

Radiation Safety

The same principles applied to developing a PET-CT site also apply to a cyclotron; namely, distance, shielding, and considerations for limiting radiation exposure, in addition to regulatory requirements. Careful design and security features can help to ensure safe operations of the cyclotron.[1,62]

Cyclotron rooms are typically built with concrete walls for the purpose of shielding. The extent of shielding depends on the type of cyclotron, the shielding material used, and if the cyclotron has a self-shield design.[65] Some self-shielded cyclotron should still be shielded because the self-shielding material may not fully reduce neutron and gamma activity to safe levels.[44] Unshielded cyclotrons require very thick concrete walls with a lengthy maze to reduce radiation exposure. Mazes are containment systems that safely hold any radioactive gases until they have decayed to non-radioactive elements.[44]

Penetrations to the shielding walls are needed for various purposes, including product transfer, electrical, control, cooling water circuits, and ventilation, in addition to under-floor service channels passing through the walls. Minimizing these penetrations can ensure protection and reduce the risk of radiation leaks.[62] Additional shielding is possible, but this can reduce the working space available. Penetrations should not provide a direct line of sight to the vault. [61,62]

A cyclotron facility requires ventilation for the cyclotron, as well as for processing hot cells and fume hoods because small but continuous airborne radioactive activity from the production of radioisotopes and during processing of hot cells can escape.[62] If any radioactive gas is detected in the facility exhaust system, airflow can be diverted into the containment system and the radioactive gases are held until no more radioactivity can be detected.[66] The design of the facility should also consider potential backflow. Additionally, analysis of the consequences of releases from failed targets and failed processing can guide what should be filtered or confined by ventilation systems.[62]

Overall Size and Location

It is crucial to ensure there is enough space to accommodate all required equipment and contamination control zones, while allowing staff to safely move through the cyclotron suite.[62] A suite, including a research laboratory, requires approximately 1,500 ft^2 to 2,500 ft^2 (approximately 139 m^2 to 232 m^2), though the size needed will depend on the type of cyclotron and amount of required shielding.[20,62] It should be located relatively close to the PET-CT suite to allow for easy and quick delivery of the radiopharmaceuticals, especially those with short half-lives. The cyclotron should also be far from areas with high traffic as it emits relatively high radiation levels.[20,44] The cyclotron should be installed on the lowest floor (ground floor or basement) due to the heavy weight of shielding and the magnet, which are approximately 35,000 lbs and 22,000 lbs, respectively.[44] The soil and underground condition must be assessed: if the water level is too shallow or there is a sewer running underneath, the area should be avoided or extra support materials are needed.[44]

Layout

The area required will depend on the radiopharmaceuticals that are being produced at the cyclotron and the functional requirements for the facility.

The main rooms in the controlled or hot areas include the cyclotron room, control room, and radiochemistry laboratory.[44] These rooms should have shielding and be adjacent to each other. Their minimum sizes will depend on equipment size and available space, though some guidance on minimum sizes have been provided.[1,44,67] Rooms and corridors in the controlled area also must consider the number of air changes per hour and required room pressure for safety purposes. Negative pressure is required to confine gaseous or aerosol discharge, but production requires positive pressure to prevent contamination.[67]

A summary of recommendations from the IAEA is provided in Table 3 . The International Health Facilities Guideline provides a similar recommendation for the size of the cyclotron room (80 m^2), though it suggests a larger size for the radiopharmaceutical laboratory (40 m^2) and less space for technical support and staff rooms (including staff amenities, changing rooms, and so forth; 20 m^2).[26]

Table 3: Space and Room Pressure Requirements for a Cyclotron's Controlled Area From the International Atomic Energy Association[1]

Room	Size (m^2)	Number of air changes per hour	Room pressure (Pa)
Personnel airlock for entering controlled area	10	5 to 10	−5
Corridor	40	5 to 10	−10
Preparatory laboratory	7	5 to 10	−10
Packing room	10	5 to 10	−10
Personnel airlock for entering clean room (GMP class C)	5	10 to 20	+5
Radiopharmaceutical production laboratory (GMP class C)	20	10 to 20	+20
Storage for radioactive waste, recalled products, retention samples	3	5 to 10	−25
Service corridor for hot cells	5	5 to 10	−25
Shielding vault for the cyclotron	80 (20 internal)	10 to 20	−60
Service room	20	10 to 20	−30
Power supply room	10	10 to 20	−30
Control room for the cyclotron	10	5 to 10	−10
Janitorial room	2	5 to 10	−10
Quality control (quality assurance) laboratory	25 to 30	5 to 10	−10
Material airlock and emergency exit	4	5 to 10	−5

GMP = good manufacturing practice.

Cyclotron Room

Cyclotron rooms vary in size (between 58 m^2 and 80 m^2), depending on the compactness of the medical cyclotrons.[1,26,44] If a separate cooling room is used, a minimum size of 10 ft by 10 ft is recommended, consisting of chillers with a heat exchange and deionizer water system to handle the heat generated by the cyclotron and power supply unit.

The room should also have a sink and floor drain and access to a power supply unit.[44] Entrance to the room should be monitored with an electronic alarm for security purposes.[44]

The IAEA also recommends installing a beam line on the cyclotron and having an area to process these targets.[1]

Control Room

The control room should be large enough to contain a workstation, printer, and other auxiliary terminals to operate the cyclotron.[44] It should have easy access to the cyclotron room with an alarm-monitored entrance.[44]

Radiochemistry and Radiopharmacy Laboratory

The laboratory manufactures sterile radiopharmaceuticals that have been produced in the cyclotron.[26] The size will depend on the scope of service and range of radiopharmaceuticals being manufactured. A recommended dimension is 400 sq ft, or approximately 40 m.[2,26,44] It should be adjacent to the cyclotron to easily transfer irradiated targets for processing and synthesis of radiopharmaceuticals.[44] Furthermore, the laboratory should meet all relevant local, provincial and federal requirements, standards and regulations, in order to obtain a license for processing unsealed radioactive materials.[1,26]

Space, equipment, and processes for quality management are needed. In general, a thin-layer chromatography scanner is used to determine the radiochemical identity and purity of radiopharmaceuticals, and high-pressure liquid chromatography equipment are used in parallel as they provide different but useful information. This equipment is used in routine daily quality control procedures.[68]

Packaging and Shipping Room

If there are plans to distribute products to other sites, a separate room for packaging and shipping, as well as office space for staff and records management will be needed.[1] Regulations will determine licensing and/or registration requirements before commercial distribution is granted.[1]

Human Resources Requirements

Staffing for a cyclotron will depend on the size of the program. At minimum, staff needed would likely include a cyclotron operator, radiopharmacist and/or radiochemist, and radiotechnologist.[20] Minimum staffing recommendations for operations are outlined in Table 2.

Cyclotron Operator

A cyclotron operator is responsible for daily routine operations, takes part in acceptance tests of equipment, and oversees calibration and quality control procedures such as preventive maintenance.[1,20] A cyclotron operator is often a technologists who receives additional PET-CT training, as well as a factory preceptorship from the manufacturer before the cyclotron is installed.[20] More operators will be needed if there is a high demand for cyclotron products.[20]

It may be challenging to find experienced operators in Canada, especially for specific cyclotron models.[20] It is anticipated that there may be a shortage of cyclotron operators in Canada as demand for new radiopharmaceuticals increase, particularly as many staff are trained in-house and losing 1 cyclotron operator can impact production.[4]

Radiopharmacists and Radiochemists

Radiotechnologists for a cyclotron can be nuclear medicine technologists, but it is not required.[20] Radiochemists and radiopharmacists are responsible for acceptance testing, routine calibration,

and quality control, including validation of pharmaceuticals purchased from an offsite unit.[20] Radiochemists and radiopharmacists generally require at least a diploma or degree in chemistry or equivalent.[1] Specialized training for radiotracer synthesis, laboratory operations, analytical chemistry, quality assurance, radiation safety, and other board-certified or required courses should be considered.[1] If both clinical and research programs are expected, it may be best to have both a radiopharmacist and a radiochemist.[20] Many radiopharmacists and radiochemists are trained in other occupations and require in-house, on-the-job training because there are not enough training programs in Canada for these positions.[4]

Radiotechnologists

Radiotechnologists for a cyclotron can be nuclear medicine technologists, but it is not required.[20] A GMP facility will need at least 2 additional radiotechnologists: 1 responsible for quality assurance and 1 responsible for production.[20] Radiotechnologists can also provide back-up to the other nuclear medicine technologists in the PET-CT centre, which can improve efficiencies. They must be able to operate the cyclotron, and conduct routine radiopharmaceutical production to cover for the cyclotron operator as needed.[20] Most technologists are trained in nuclear medicine and require additional training for PET-CT imaging, but there are limited programs in Canada that provide this training.[4]

Other Positions

Additional staff will also be needed to address regulatory issues, including meeting requirements from the CNSC (licences for construction, service, commissioning, and operations) and Health Canada (clinical trial applications, new drug notice of compliance, GMP certification, and radiopharmaceutical compliance).[20] This can be carried out by an experienced project manager hired for a specific term, or by hired consultants. In either case, hiring should be done early in the planning process. Shortages for these support staff, particularly clinical trial coordinators, clerical staff, clinical trial nurses, and clinical trial technologists have been noted in Canada.[4] As well, there are staffing shortages with those familiar with regulatory affairs, requirements for approved and novel radiopharmaceuticals, and new drug submissions (e.g., Notice of Compliance, Drug Identification Number).[4]

Other Staff Considerations

As most of these positions lack training programs in Canada and often require in-house training, it can be difficult to find experienced staff; thus, losing one staff member can put an entire program in jeopardy.[4]

As with PET-CT units, setting up training programs and continuing education at a newly established cyclotron is recommended to help address current or anticipated human resource shortages, as well as to help ensure staff are kept up-to-date with training.[20] Staff may also need additional training to meet Health Canada's GMP standards for radiopharmaceutical production.[4] For sites that produce short-lived or uncommon radioisotopes, training for the production and use of these tracers may be especially beneficial.[4]

As all of these positions are facing shortages of experienced workers in some parts of Canada, steps to attract workers should be implemented early on in the planning process.[4]

Conclusion

Implementing a PET-CT program is a logistically complex and intricate endeavor that requires time, extensive planning, and significant expertise drawn from a wide range of disciplines. Stakeholder engagement along the entire pathway may help ensure that important steps and considerations are not overlooked.

It is likely that the clinical indications for PET-CT imaging will expand, as will new radiopharmaceuticals and the application of PET-CT imaging in radiotherapy planning. When considering new PET-CT imaging programs, decision-makers should plan for the anticipated expanded demand of PET-CT services. Failure to do so may result in new, state-of-the-art facilities being unable to optimally support patient volumes. Where possible, site planning should accommodate space for a second PET-CT unit that could be installed at a later date.

The decision around where to install a PET-CT unit should be influenced by the availability of a secure supply of radiopharmaceuticals. If a new cyclotron is required, planning should start early, ideally ahead of planning for the PET-CT suite. And, as with PET-CT imaging, future cyclotron needs should be considered, such as the adoption of newer radiopharmaceuticals that may be more complex to develop and additional space requirements.

Investment in the workforce through education and training opportunities will help to ensure that staffing shortages do not get in the way of delivering the best quality of care to patients. This can be achieved, at least in part, through the provision of mentorship and tailored education programs.

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Appendix 1: Footprint of a PET-CT Suite

Note that this appendix has not been copy-edited.

Table 4: Rooms Required and Minimum Recommended Sizes From the International Health Facility Guidelines and International Atomic Energy Association

	IHF guidelines[26]		IAEA
Room	Number needed	Minimum size (m^2)	Recommended size (m^2)
Entry/reception			
Reception	1	10	10 to 20
Waiting	2	10	16
Consult room	1	14	12
Office (2 persons, shared)	1	12	NR
Store (stationery/ photocopy)	1	8	5
Toilet – accessible	1	6	NR
Toilet – public	2	3	NR
Patient and imaging areas			
Patient bay – holding	2	10	NR
Uptake room	3	9	12 to 16
Uptake induction room	1	15	NR
PET-CT scanning room	1	50	35
Control room	1	8	NR
Computer equipment room	1	8	NR
Hot laboratory	1	8	NR
Hot store/waster disposal room	1	6	NR
Office – workstations, quality control	2	5.5	NR
Toilet – patient, hot	4	4	30 (includes all toilets and preparation rooms)
Support areas			
Bay – beverage	1	4	NR
Bay – emergency shower and eyewash	1	1	NR
Bay – handwashing, type B	1	1	NR
Bay – linen	1	2	NR
Bay – mobile equipment	1	4	NR
Bay – PPE	1	1.5	NR
Bay – resuscitation trolley	1	1.5	NR
Bay – wheelchair park	1	2	NR
Cleaner's room	1	6	NR
Clean utility/ medication	1	8	NR
Dirty utility	1	8	NR

	IHF guidelines[26]		IAEA
Staff station	1	10	NR
Store – equipment/ general	1	6	NR
Viewing and reporting (optional; 3 workstations)	1	12	NR
Staff areas			
Meeting room – may be shared with NM/MI	1	15	NR
Office – single person (e.g., manager, radiographer, physicist)	1	9	NR
Property bay – staff	2 (separate male and female)	2	NR
Staff room – may be shared with NM/MI	1	15	NR
Toilet – staff	2 (separate male and female)	3	NR

IAEA = International Atomic Energy Agency; IHF = International Health Facility; MI = medical imaging; NM = nuclear medicine; NR = not reported.

Appendix 2: PET-CT Planning and Layout Considerations

Note that this appendix has not been copy-edited.

Table 5: Planning and Layout Considerations

Room (recommended size)	Planning and layout considerations
Office area (400-600 square ft)[23] **Includes secretarial room (10-20m2) and waiting room(16m2)1**	• Far from the PET-CT to avoid exceeding regulatory exposure limits.[44] • Separate waiting areas from for patients entering via ambulatory services and patients waiting for beds[15] • Separate entrance for inpatients on beds and the medical imaging unit[26] • Separate female/family areas based on cultural requirements, if possible[26] • Seating options for people with varying mobility and bariatric patients • Play areas and areas to place strollers for pediatric sites[23] • Other potential rooms: storage room, administrative offices, reading/reporting room.
Consulting room (12 m^2)[1] **Where patients are interviewed, informed of the procedure, and physically examined, if necessary**	Must be equipped with a supply of oxygen gas for medical use and a vacuum for aspiration[1]
Support areas	Support rooms should be located near both the scanning and patient areas for convenience.[26] Support areas include:[1,26] • emergency shower and eyewash in case of chemical spills; should be easily accessible for patients and staff and located near all 'hot' areas • equipment storage • clean utility room and store (to store quality control phantoms, supplies, and so forth; 5 m2 should sufficient) • beverage bay to provide light refreshments for patients since they are required to fast • storage (e.g., linen, resuscitation trolley, wheelchairs, other equipment, sterile supplies) • staff station for supervision of uptake rooms and holding areas • an optional area for reviewing images and reporting • areas for teaching, research, and students
PET-CT suite (170 m^2 to 200 m^2)[1] **without a cyclotron**	

Room (recommended size)	Planning and layout considerations
Uptake room (9 m2)1 **Where patients receive the radiopharmaceutical intravenously and should be near the scanner with direct access to a shielded toilet1,26,35**	Can also be used the cool down room after scanning procedures. One report recommended 2 uptake rooms for 1 scanning room, assuming separate "cool down" rooms; if the same rooms are being used for before and after scanning, more rooms are needed.[26] Others have recommended 3-5 uptake (injection and preparation) rooms for each PET-CT scanner.[35,46] Should include:[1,26] • privacy screening to the doorway • a secure area to store patient belongings • a recliner chair or bed • doors that allow bed access • hand basin with paper towel and soap • services panel, including oxygen and suction outlets, call buttons (patient call, staff assist, emergency) • dimmable lighting to allow patient to rest • ceiling mounted examination light • lead shielded sharps and waste containers to hold radioactive waste • CCTV to monitor patients since they are alone in case of emergency; monitors should be in the control room and/or staff station • mobile lead screens may be used when administering radiopharmaceuticals

Room (recommended size)	Planning and layout considerations
Scanning room (35 m^2 to 50 m^2)[1]	• For scanners that are water cooled, extra space may also be needed for the water chiller.[1] • The room should fit the PET-CT gantry, table, power distribution unit, main disconnect, partial uninterruptible power supply, countertop with sink, and any peripherals needed by the technologist • An image reconstruction cabinet may also be needed.[18] Other scanning room provisions to consider include:[1,26] • patient service panel, including oxygen and suction outlets, call buttons (patient call, staff assist, emergency), and power outlets (at least 6) • closed-circuit TV cameras (CCTV) from several different directions to allow for patient observation (including at the head and foot of the PET-CT unit), as patients are alone in this room during the scanning process to limit radiation to staff[26] • communication system between the scanning room and control room (intercom, or speakers and microphones) • clock within patient's view • scrub basin for staff use with paper towels and soap • bench with cupboards and shelving for storage • manual handling items for assisting with patient transfers; note that hoists are not recommended, as they increase time needed for patient transfer and expose staff to radiation • mobile lead screens to help protect staff when positioning the patient • if the room is also being used for radiotherapy simulation, laser positioning lights are required
Control room (10' x 10')[23] **Where the console of the operation is installed**	Placed adjacent to the can room, with a glass viewing window to observe the patient[44]
Hot laboratory **Used for the receipt, delivery, storage, and dispensing/preparation of radiopharmaceuticals**	• accessible from a service corridor to allow for deliveries of radiopharmaceuticals, as well as to the uptake and scanning room.[44] • located with direct entry from the corridor and near the injection room (or uptake room, if that is where the injection is done).[1] A • decontamination kit should be stored to contain and clean up any radioactive spills.[26]
Hot store for waste disposal	Should be located near the exit (to remove waste when it is safe for disposal)[26,44]
Electronics room[44] (10' x 8')[44]	The electronics room is where all electrical units, connecting wires, and so forth are installed, and should also adjacent to the scan room.[44]

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