

INTEGRATION OF INTERNAL DESIGN MANAGEMENT AND REQUIREMENTS FOR MEDICAL CYCLOTRON FACILITIES

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Abstract

A new era of technology in nuclear medicine has begun utilizing radioisotopes produced by medical cyclotron (e.g. F-18). Such cyclotrons are designed mainly for the purpose of introducing short lived radionuclides in nuclear medicine (e.g. PET methodology). A facility of hot cells is assigned to receive the radionuclides (F-18) to prepare the pharmaceuticals (e.g. FDG). For the interest of radiation control and safety engineering features have to be satisfied in the self-protected facility structure to match the required, set safe limits, design. Accordingly, the present work is performed to develop the main principles of workplace design for integration of requirements and radiological regulatory aspects to mitigate and reduce hazardous risks of abnormal events during operation.

Introduction

Considering the plans and arrangements for managing safety, and the preliminary design features, it is expected that the construction of the proposed radiation Facility, will not result in the introduction of any significant risks, that must be taken into account in deciding whether to issue a facility license. The content of this work is based on the following assumptions. The cyclotron facility is mainly used for radionuclide and radiopharmaceutical production. And the facility is operated in a regulated environment complying with the IAEA guidelines. Some of the factors that must be considered in project planning include assessing:

- The realistic need for facility of cyclotron produced radionuclides.
- What are the project mission and goals?
- What size and type of cyclotron is needed for this facility?

The accelerated particles, may lead to activation of materials around the target and create residual radioactivity. Although, the radioactive isotopes produced due to neutron activation are generally of short half-lives, their accumulated activity should be considered while handling the shielding materials, in particular the components near to the target that are likely to get activated to significant levels should be optimized.

CLASSIFICATION OF CYCLOTRON FACILITIES

The designer concludes that based on the application the facility may be constructed without undue risk to the health and safety of the people and the environment. The designer recommends that; the design details of facility construction are license as-built. Then the Act defines a controlled facility as either a nuclear installation or a prescribed radiation facility. The design principles considered in the design of the facility. The PSAR adopts the fundamental safety objective of the IAEA Safety Fundamentals (SF-1) which is to protect people and the environment from the harmful effects of ionizing radiation. The design safety objectives during normal operation of the facility are:

- Minimization of hazards wherever possible through design, job organization, work procedures and instructions and staff training and competence
- ALARA principle to all operations and seek to continuously improve safety through monitoring and the measurement of safety performance.

The design has incorporated multiple layers of barriers and redundancy and diversity for safe operation of the facility such as physical barriers to confine radioactive materials- containment, ventilation etc.

The facility description includes the location of the facility, the layout and main components comprising the facility.

In general, cyclotron facilities shall be made up of three clearly separated areas (zones):

- (1) Non-controlled area, which houses the offices for the staff, storage rooms and restrooms.

(2) Controlled area, which is built and classified according to the local regulations and international recommendations as an area for work with open radioactive sources. The cyclotron with its utilities, the radionuclide production and quality control laboratories and rooms for temporary storage of radioactive waste shall be all within the controlled area.

(3) Clean rooms within the controlled area, which are used for the production of radiopharmaceuticals.

The following sections provide examples of the facilities the space requirements will be taken as indicative only (i.e. minimum functionally required space for normal operation).

In the design phase care should be taken that the local architectural, ergonomic, safety (for example fire protection, mechanical, electrical and compressed gas safety) and regulatory (e.g. radiation protection and GMP) aspects of facility design are strictly followed.

Layout Assessment and Approval

The appropriate design and layout of a manufacturing facility is an essential requirement in achieving the desired product quality and safety. The medical cyclotrons are located either in the hospital premises or in the industrial area. The first stage of process is, assess the suitability of the site as in accordance with the seismic condition, history of earthquakes in the region, proximity to a capable fault, flooding potential, ground water level, and soil composition, height from the sea level, geo-hydrology, approach road, and the type of occupancy. It should be ensured that there should be no residential or public premises within a radius of 30 m from the site. The geological and soil characteristics are important from the point of view of induced soil activity and supporting heavy structures. Further, presence of any materials dumps, and storage of inflammable and toxic substances in the vicinity are also considered.

Type I facility

This facility (Fig. 1) is designed to produce FDG. For this purpose, a 9–19 MeV cyclotron is adequate. If the volume of planned production is low (or if FDG is used only locally) a small 9–11 MeV cyclotron could be sufficient. There is a single product being made and, therefore, the layout is relatively simple. There will be a small number of employees at this facility, thus there is only one personnel airlock for entering the controlled area. The cyclotron in this example is an unshielded one. Alternatively, one may place a self-shielded cyclotron within the same footprint of the presented shielding vault into a lightly shielded room. The doses can be passed out of the synthesis area to the packaging area for distribution and for QC through a material airlock. There is a convenient service corridor behind the hot cells, which might be omitted if not required by the particular design of hot cells. The hot cells are located as close to the cyclotron vault as possible, for keeping the transfer lines as short as possible. This suggested floor plan has a 400 m² footprint. The HVAC system of the facility can be conveniently placed on the roof of the building, adding an additional ~30 m² to the total space requirements.

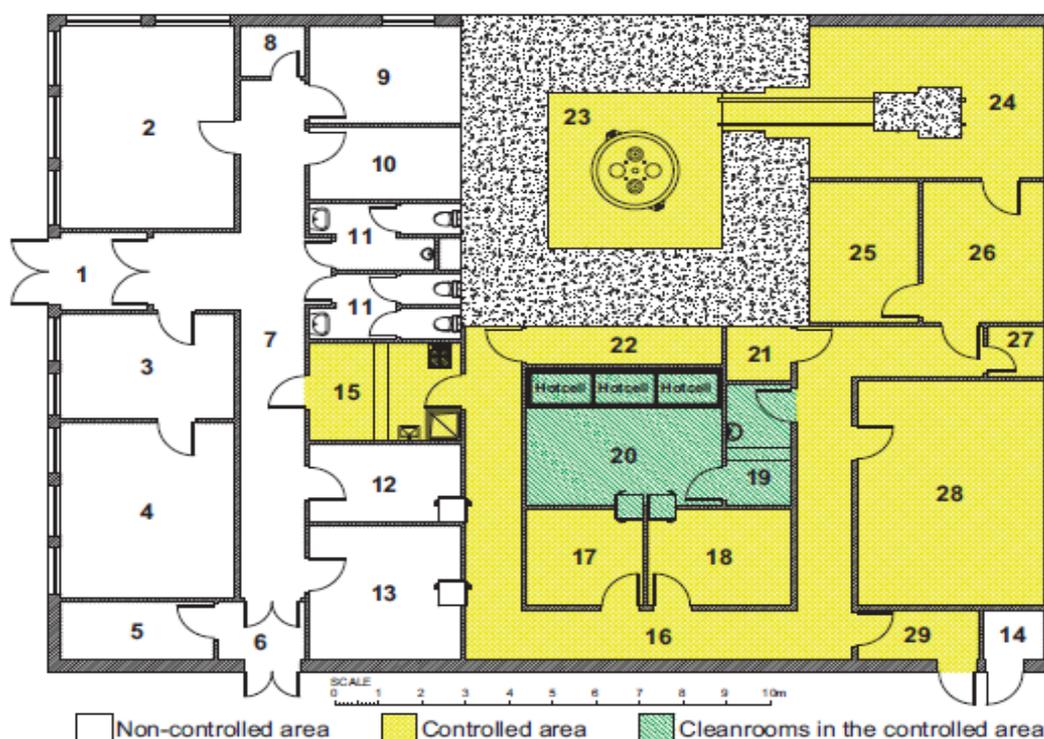


FIG..2. Simple FDG radiopharmaceutical production and distribution centre (type I facility). The numbers in the figure are explained in Table 6.1.

Table 1 Brief description of rooms of a type 1 facility Presented in fig. 1

Room No.	Function	Classification	Area (m ²)	No. of air changes (h ⁻¹)	Room pressure (Pa)	
1	Entrance for the personnel	Non – Controlled area	4	—	—	
2-4	Staff offices		50	—	—	
5	Quarantine storage room		5	—	—	
6	Material entrance		3	—	—	
7	Corridor		24	—	—	
8	Janitorial room		2	—	—	
9	Kitchen		9	—	—	
10	Data centre (archive)		7	—	—	
11	Toilets		12	—	—	
12	Storage room for transport containers		7	—	—	
13	Storage room for released raw materials		12	—	—	
14	Storage room for technical gases		2	—	—	
15	Personnel airlock for entering the controlled area		Controlled area	9	5-10	-5
16	Corridor			34	5-10	-10
17	Preparatory laboratory	7		5-10	-10	
18	Packing room	8		5-10	-10	
19	Personnel airlock for entering the clean room	5		10-20	+5	

Room No.	Function	Classification	Area (m ²)	No. of air changes (h ⁻¹)	Room pressure (Pa)
20	Radiopharmaceutical production laboratory	Controlled area	16	10-20	+20
21	Storage for radioactive waste, recalled products and retention samples		3	5-10	-25
22	Service corridor for hot cells		5	5-10	-25
23	Shielding vault for the cyclotron		64 (16 internal)	10-20	-60
24	Service room		21	10-20	-30
25	Power supply room		9	10-20	-30
26	Control room for the cyclotron		10	5-10	-10
27	Janitorial room		2	5-10	-10
28	QC laboratory		25	5-10	-10
29	Material airlock/emergency exit		4	5-10	-5

Type II facility

This facility is designed to produce a range of common radiopharmaceuticals based on short lived positron emitters (11C, 13N, 15O and 18F). For this purpose, a 9–19 MeV cyclotron is adequate. If the volume of planned production is low, a small 9–11 MeV cyclotron could be sufficient. There are multiple products being made and, therefore, the layout

is a bit more complex and the overall size of the facility is also larger than that of a Type I facility. There will be more employees at this facility; however, one personnel airlock for entering the controlled area should be generally sufficient. The cyclotron in this example is an unshielded one. Alternatively, one may place a self-shielded cyclotron within the same footprint of the presented shielding vault. Dispensing, sterile preparation and synthesis boxes are all in clean rooms separated from the rest of the facility by a personnel airlock. There are two separate clean rooms for radiopharmaceutical production, in order to reduce the congestion of material flow and personnel traffic in the clean rooms. The raw materials and synthesizer kits are entering the clean area through a material airlock, from a preparatory laboratory. The doses can be passed out of the clean rooms to the packaging area for distribution and for QC through a material airlock. There is a convenient service corridor behind the hot cells, which might be omitted if not required by the particular design of hot cells. The hot cells are located as close to the cyclotron vault as possible, for keeping the transfer lines as short as possible. This suggested floor plan has a 450 m² footprint. The HVAC system of the facility can be conveniently placed on the roof of the building, adding additional ~35 m² to the total space requirements.

Type III facility

This facility is designed to produce a range of common radiopharmaceuticals based on short lived positron emitters (11C, 13N, 15O and 18F) this facility provides for the production of long lived positron emitting radionuclides and for the preparation of various radiotracers for research purposes used locally or to be distributed to other research centers. For this purpose, a 13–19 MeV cyclotron is adequate and the installation of a variable energy cyclotron would be advantageous. There are multiple products being made combined with research activities, therefore, the layout is more complex and the overall size of the facility is also larger than that of a Type II facility.

There will be a large number of employees at this facility, thus two personnel airlocks for entering the controlled area should be provided (separated male and female airlocks). The cyclotron in this example is an unshielded one, equipped with a short external beam line at whose end a solid target station might be installed. The dose dispensing, sterile preparation and synthesis boxes are all in clean rooms separated from the rest of the facility by a personnel airlock.

There are two separate clean rooms for short-lived radiopharmaceutical production, in order to reduce the congestion of material flow and personnel traffic in the clean rooms. The raw materials and elements of the kits are entering the clean area through a material airlock, from a preparatory laboratory. The doses can be passed out of the clean rooms to the packaging area for distribution and for QC through a material airlock. There is a separate hot laboratory housing hot cells and shielded hoods for processing the irradiated solid targets, separation of radionuclides from the target material. There is a convenient service corridor behind the hot cells, which might be omitted if not required by the particular design of hot cells. The hot cells are located as close to the cyclotron vault as possible, for keeping the transfer lines as short as possible. There are two separate QC laboratories (separating the QC of radiopharmaceuticals based on short lived radionuclides from those of longer lived radionuclides). There is an additional research laboratory, which might be used for cell studies, or for housing a micro-PET. There is also a small workshop for maintaining and modifying targets and other research equipment (for instance modules under development). This suggested floor plan has a 700 m² footprint. The HVAC system of the facility can be conveniently placed on the roof of the building, adding additional ~40 m² to the total space requirements.

Type IV facility

This type of facility is designed for large scale commercial production and distribution of a wide range of SPECT and PET radiopharmaceuticals, leaving very limited space for research activities. It is based on a 30 MeV cyclotron with four beam lines and three types of target stations (two solid target stations, one ¹²⁴Xe gaseous target station for ¹²³I production and a target station with several targets for PET radionuclide production) placed in separate shielding vaults. The solid target station is

connected to a receiving hot cell by a rabbit target transport system. The non-controlled area of this facility would house the offices for the staff, meeting room, toilets, lounge, different storage areas, workshop, power supplies of the cyclotron and its control room, and utilities. The space requirements for the non-controlled area will depend on the number of staff and ergonomic requirements. In any case, it is wise to design the layout in such a way that the non-controlled area can be extended at a later time. The controlled area would consist of four blocks: (a) the cyclotron block with its utilities, beam lines and target stations; (b) the SPECT production block housing the hot laboratories needed for the production and quality control of SPECT radionuclides and radiopharmaceuticals; (c) the PET production block consisting of three clean rooms for the production of PET radiopharmaceuticals; and (d) utilities, including the active janitorial, temporary storage of solid and liquid waste, storage of recalled products and retained product samples.

The layout presented in outlines the design principles; the actual layout should take into account the radiopharmaceutical production programs of the particular facility. However, when designing such a facility, it is important to make the design in such a way that it can be easily extended in the future, for instance for the

implementation of research and development programs. It is also important to leave free access to the cyclotron vault, as it might be necessary to upgrade or even replace the cyclotron in the future. Typically, such facilities will have 2000–3000 m² footprints.

Type V facility

This type of facility is designed for large scale production of a wide range of SPECT and PET radiopharmaceuticals, as well as for extensive research basically in the field of radiopharmaceutical sciences, but it can be used for other types of research, for example, for radiation physics, chemistry and biology, modification and analysis of materials, etc. The radiopharmaceuticals produced in this facility. placed in separate shielding vaults. the facility would become much more complex, but the basic principles of its construction would have to be the same. The non-controlled area of this facility would house the offices for the staff, meeting room(s), toilets, lounge, inactive laboratories, different storage areas, workshop(s), power supplies of the cyclotron and its control room, various utilities, etc. The space requirements for the non-controlled area can be very different, depending on the number of permanent staff (extensive collaboration with a university or some large institute would demand less space on-site) and planned uses of the facility. In any case, it is wise to design the layout in such a way that the non-controlled area can be extended at a later time. The controlled area would consist of five blocks: (a) the cyclotron block with its utilities, beam lines and target stations; (b) the SPECT production block housing the hot laboratories needed for the production, quality control and research related to the SPECT radionuclides and radiopharmaceuticals. The layout presented in Fig. 5 outlines the design principles; the actual layouts should take into account the radiopharmaceutical production and research programs of the particular facility. However, when designing such a facility, it is important to make the design in such a way that it can be easily extended in the future. It is also important to leave free access to the cyclotron vault, as it might be necessary to upgrade or even replace the cyclotron in the future. Typically, such facilities will have footprints of several thousands of m².

Methodology Analysis of Design

Planning and Design of the Workplace

The planning and design of the workplace should ensure that planning and design take into account relevant codes and standards and international best practice to minimize the exposure to radiation. It is expected that appropriate engineering controls are in place to minimize the reliance on administrative controls.

The design features for engineering controls were assessed for the siting license and were found acceptable (R13/10687). Relevant standards and codes for the design of the engineering controls are referred to in relevant supporting documents provided with the construction license application.

Once the scope has been defined, with a vision of possible expansion in the future, the next logical step is designing a facility that will achieve these objectives. The facility design should encompass not only the physical requirement of space, but also be compatible with regulatory requirements of radiation safety and pharmaceutical manufacturing. Furthermore, integral parts of the facility design are the support services and amenities, including utilities, climate control and equipment. For example, radiopharmaceutical manufacturing necessitates using HEPA filters to ensure air quality conforming to GMP. Radiation protection on the other hand requires that the air released from the cyclotron facility is passed through filters for control of radioactive particulates. With the optimum combination of factors, a well-designed facility should serve for a long time.

Over time, laboratories invariably need to be reconfigured or expanded to meet changing research needs. Electrical and mechanical systems can be fed from a utility chase as illustrated in Fig. 1. This arrangement (module management) will allow easy extension without taking other laboratories off-line. Foundation walls can be extended beyond the end walls and expansion is possible without disrupting laboratory operations. Modular laboratory units can be used if they are flexible enough to adapt to new programs and requirements without major alterations or expense.

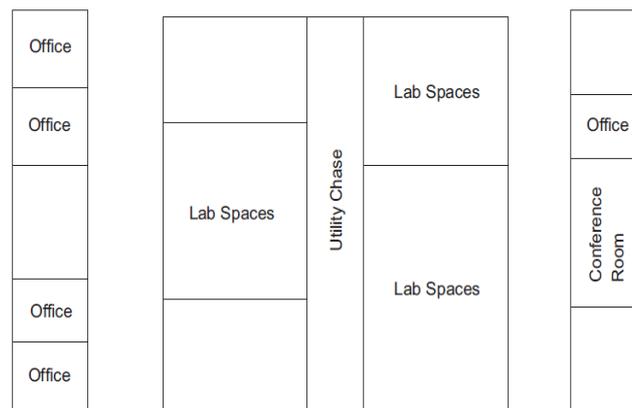


FIG. 1 Use of a central utility chase in a laboratory environment to simplify utility access and increase the efficient use of space.

Overall considerations

The Design for radiological safety ensures that the radiation exposure within the facility and due to any release of radioactive material from the facility is kept as low as reasonable achievable and below the prescribed limits (DC 80-82).

The facility design has considered the expected inventory in the facility and the processes and controls that will be in place to minimize exposure to operators, to the public and to the environment. The design has taken into account the ALARA objective of an annual effective dose of 20 μ Sv for the public and 2 mSv for occupational workers. notification levels for airborne discharges are set to achieve the ALARA objective for the public. The facility design will incorporate appropriate shielding, containment, ventilation systems, radiation monitoring devices and on-line monitoring system. The construction materials selected are easy to decontaminate and resistant to radiation damage.

There are several overall considerations in the design of a radioisotope production facility which are similar regardless of the type of facility.

Air flow. The air flow pattern in a facility is one of the most critical parameters to control airborne contamination. The air handling requirements for radiation protection and radiopharmaceutical manufacture are often at odds with one another. For example, to reduce the chance of the spread of contamination, the flow of air in a hood or hot cell should be away from the personnel and up the exhaust stack. In contrast, maintenance of pharmaceutical quality of the products requires air flow out of the hood, away from the product and towards the personnel. To prevent the spread of contamination, the air flow should always be designed so that the cyclotron vault is at the lowest pressure in the building, and the hot laboratories are at slightly higher pressure and the surrounding public areas are at the highest pressure.

On the other hand, the area where vials are prepared and product is dispensed is typically a clean room with specified air particle quality needs to be at higher pressure than its surroundings. This ensures that the 'dirty' air particles do not contaminate the product causing degradation of pharmaceutical quality. Furthermore, the area in immediate contact with the open product vials is the most critical and should be controlled for achieving the highest quality of air. An additional requirement for air flow is the number of air changes in unit time, particularly in the clean rooms and hot cells. From this discussion it should be clear that the air flow patterns must be engineered to accommodate these opposing requirements. If the air pressure gradient is in the direction of the hot laboratory, then some of this material may be drawn into the laboratory and may contaminate the samples being produced. In the case of PET radiotracers, the contamination could well be long lived material. The air flow should always be designed so that the cyclotron vault has the lowest pressure in the building and the hot laboratories are at slightly higher pressure. An ideal facility pressure gradient is shown in Fig. 3

Radiation level gradient. In a similar fashion to the pressure gradient, there should also be a radiation field gradient. With the cyclotron turned off, the highest level of radiation will be around the target. The radioactivity from the targets will be transferred into the hot cells, processed and then transferred to the dispensing (radiopharmacy) and QC units. At each step along this path, the amount of radioactivity being handled is less. The ideal situation is when the facility is set up in such a way that the staff and materials follow this gradient and do not have to pass through a low radiation area on their way from one high radiation area to another. The entrance and exit to the facility should be through only one point. This point is where the transition is made from the radiation areas to the outside. This is where personal protective clothing will be put on and removed, and checking for contamination will be carried out. If there are

contamination areas within the facility, there should be a single entrance and exit to these areas as well, so that checking can be minimized. There should be multiple emergency exits in case of fire as is consistent with life safety codes, but they should not be used routinely. The ideal situation is illustrated in Fig. 3

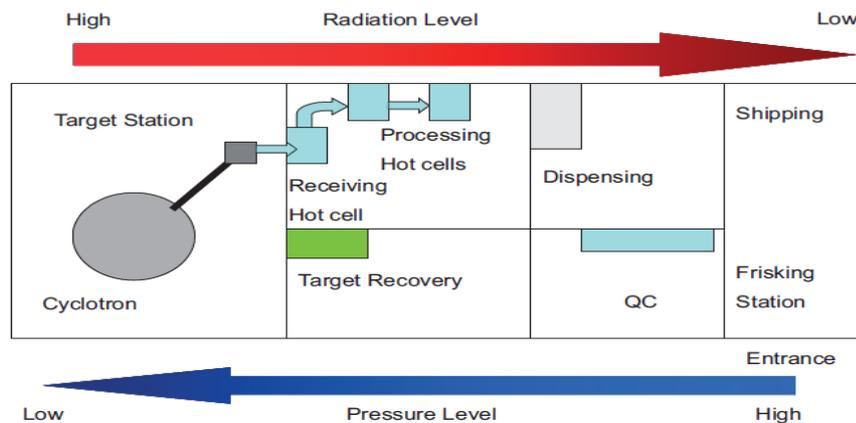


FIG. 3 Ideal pressure and radiation gradients in a cyclotron facility.

WorkflowThe flow of laboratory operations should be examined in the context of the entire facility. A great deal of consideration should be given to the workflow within the facility. It is important to minimize radiation exposure and to increase efficiency by providing a smooth flow to processing. This can be done by ensuring that the area for each step in the processing is in close proximity to the step before. Another approach is to use a shielded transport system for moving the dose along without human contact. A pass-through in a wall can be an effective means of moving material from one area to another, while minimizing the chance of the spread of contamination. Control of quality in the radiopharmaceuticals necessitates unidirectional workflow in order to reduce product contamination and mix-ups. Good work habits should be observed while in clean rooms to minimize the chance of product contamination.

Mazes versus doors. One of the considerations in the design of the facility is the use of a maze versus the use of shielding doors for entry into the cyclotron vault. Mazes make entry very simple, but require careful calculation as to the effectiveness of the radiation shielding. Several turns are required to minimize the neutron flux at the entrance of the maze. Another disadvantage is that mazes require the vault to have a larger footprint. As a result, the total cost of the concrete for this larger footprint will be increased. In sliding doors or whenever it is advantageous to reduce the thickness of doors or shields, barite concrete (concrete with added barium sulphate) may be used since it has higher density. Doors make the design of the vault simpler, but are costlier to build. It may also take longer to access the vault with a door than it does with a maze. There are many types of doors, including elevator type doors, which are sunk into the floor below the cyclotron vault; rotating doors; and sliding doors. Rotating doors may restrict the size of items that can be transferred to and from the cyclotron vault. Sliding doors seem to be the most common.

Concrete type. Concrete is invariably chosen as the practical construction material for permanent structures to shield accelerators. The concrete used to build the vault should contain specific proportion of water to help increase the concrete's neutron absorbing properties. The other important consideration is the activation of the concrete by the neutron or gamma flux from the cyclotron.

Short term activities come primarily from manganese-56, sodium-24, potassium-42, potassium-43 and iron-59. These decay away relatively quickly (half-lives ranging from 3 hours to 44 days), but do contribute to the radiation dose to the cyclotron workers doing maintenance, although it is usually small in comparison to the dose from the target components.

The long term activation of the concrete in the walls of the accelerator vault may become a problem during operation and a liability when it is time to decommission the facility. There is some information in the literature on the choice of concrete and how it may affect the walls of the vault. The use of scrap iron or iron rich minerals as shielding additives to vault concrete should be avoided because of the inevitable risk of the addition of cobalt and nickel, elements that after long term neutron bombardment will produce ^{60}Co .

Some practical steps to minimize activation of the permanent vault material during the planning and design stages are:

- Employ 'local shielding' around the target(s) to absorb neutrons before they can activate the vault walls.
- Employ a 'sacrificial' and easily disposable layer of wall material.
- Use informed judgement in selection of raw materials in concrete.

Portland cement is acceptable. Sedimentary aggregates are much preferred over igneous (volcanic) aggregates.

—Mix boron carbide into the concrete. Caution: Do not under any circumstances add boron in the form of borate ion (i.e. boric acid, borax) to fresh concrete as it will completely undermine the structural integrity of the material!

Work surfaces. There should be some work surfaces, either inside the vault or in an area immediately adjacent to the vault, that are set up for carrying out radioactive work. These surfaces are essential for the routine maintenance and repair work on the cyclotron. The work surfaces should be resistant to chemicals and solvents, smooth, and easy to clean. They should not generate dust.

Floor surface. The floor surface should be hard, washable, and smooth. The concrete surface should be painted or covered with an epoxy coating, so that there will be a minimum of dust collected and contamination can be removed.

Floor drains. The floor of the vault must contain drains for water. There will be hoses that break and, during maintenance, it is often necessary to remove water from the water lines. These drains are normally connected to the sanitary sewer system. They may also be tied into a hold up system, for the water to be checked for radioactivity, before it is released into the sanitary sewer system. The holdup system is preferable, but is not always possible.

Floor loading. The weight of a bare cyclotron is of the order of 15–25 t. The weight of the self-shielding system may be 85–100 t. The weight of the vault of a locally shielded cyclotron with 1.2 m thick concrete walls is approximately 300 t. The total weight of a self-shielded cyclotron is much less than an unshielded or locally shielded cyclotron, which must be installed in a vault with thick walls. The floor underneath the cyclotron and vault must be strong and thick enough to bear these weights. A floor thickness of 40–50 cm is typical for the self-shielded version of the cyclotron.

Shielding thickness. The thickness of the shielding around the cyclotron vault will depend on the type of cyclotron, the energy, types of particles, and the targets to be used. The main purpose of the shielding is to reduce the neutron flux during the operation of the machine. Any shielding that will reduce the neutron flux to an acceptable level will also reduce the gamma flux.

Air conditioning and humidity control. Much of the heat load of the cyclotron and associated equipment must be removed by the air conditioning system. The humidity in the room must be maintained low enough so that water will not condense on the cooling water lines. Typical requirements are for temperature control at $20^{\circ} \pm 2^{\circ}\text{C}$, with less than 2°C change/hour and a relative humidity which must not exceed 65%. The air in the cyclotron vault must be clean and free of dust.

Dust contamination. Dust in the vault can be a means of transport of radioactive contamination out of the vault and into other areas and, therefore, should be kept to a minimum. Dust can be kept to a minimum by using epoxy or other sealant on the floors and walls of the vault. This will minimize the number of small particles which flake off the concrete. The other fixtures in the vault should be made of rust resistant materials, and the exposed metal surfaces should be oiled to prevent corrosion if possible.

Control and utility access There will be a need to provide access to the cyclotron vault from the outside to accommodate power cables, control cables, and gas supply and water lines. These are brought into the vault either through wall penetrations or in trenches

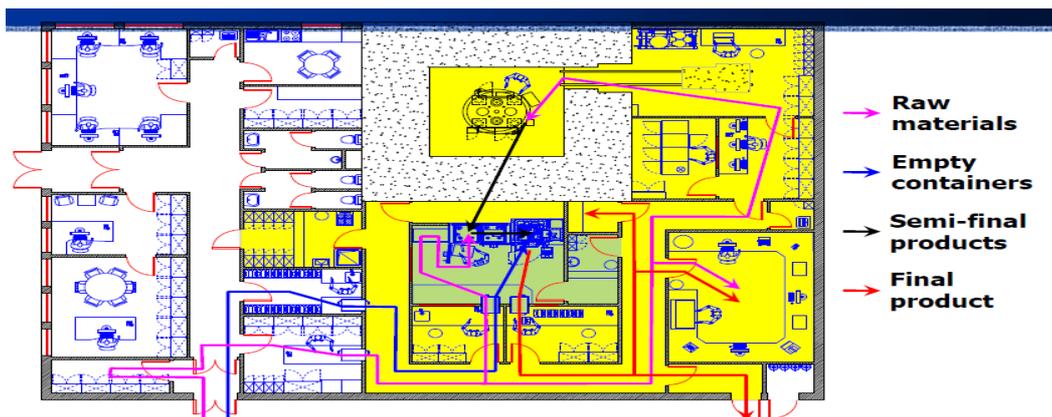


FIG.4 Examples of Material Flow and shielding wall penetrations designed to minimize line of sight radiation.

The number of penetrations of this type should be sufficient to carry all the cables, gas and water lines, etc., with at least 50% excess capacity to allow for additional cabling to be added in the future. One method is to embed a number of curved plastic pipes in the concrete wall during installation to act as conduits. The ducts through the wall should also allow for the voluminous ventilation ducts needed to exhaust the room air. Special attention should be paid to the routing of these wide cross-section openings. but if it is necessary to run more than one type of utility in a single trench, then they should be separated vertically with the water lines on the bottom and the electrical conduits or lines supported at least 3–4 cm above the bottom of the trench. The trenches should have drains to the sanitary sewer system to prevent water leaks from flooding the cyclotron vault.

FloorsThe floor of the controlled area should be covered with an easily cleanable surface such as a continuous sheet of PVC or linoleum at least 2.5 mm thick. The covering should be covered (extending up the wall) to a height of about 15 cm contiguous with the floor surface. All edges at the walls and between sheets should be sealed or welded to prevent seepage of spilled materials. As an alternative, an epoxy resin coating may provide an acceptable finish.

Walls and ceilingsThe walls and ceilings should generally be smooth and painted with a hard gloss or high quality waterproof vinyl emulsion to facilitate cleaning. The use of stippled surfaces or a paint finish applied to un-plastered concrete blocks is unacceptable. Paint-coated aluminum based sandwich-type plates used to build cleanrooms are ideal for building controlled areas as well. Joints between plates should be sealed with silicone type materials to facilitate cleaning. Service penetrations in walls and ceilings should be sealed and covered.

Doors and windowsWooden surfaces should be covered with plastic laminate material or painted with a good quality polyurethane gloss paint or varnish. Doors should be lockable to ensure safe keeping or to restrict access. A high level of security for a building and/or an entire site is preferable to securing an individual laboratory within a building. Windows that can be opened to the outside are not permitted in controlled areas. Windows which do not open are acceptable, but should generally be avoided on the external walls of controlled areas.

CONCLUDING

As stated in the introduction, the examples provided are derived from experience of various facilities in the world. The primary design purpose for the facility is to conform to the regulatory (radiological and pharmaceutical) requirements. The examples emphasize separation of areas according to functions, control of materials and people movements and fulfilment of regulatory requirements. Minimizing radiation exposure can and should be achieved by Every exposure must be justified the ALARA (As Low as Reasonably Achievable) principle must be implemented into the design of the facility. for that the facility should be designed and used in such a way that the

– Radiation dose received by the staff via internal and external radiation is within the permitted limits.

-Several thick concrete walls are built around the cyclotron and target stations.

The medical cyclotron shall be housed in a room with adequate shielding. Radiation areas and electrical high voltage areas need adequate isolation and access control. The design should incorporate safe cable routing, segregation of power and signal cables and provision of barriers to prevent fire. The design of the medical cyclotron and its associated facilities has to be approved by the Regulatory Body prior to its Preliminary Safety Analysis Report (PSAR) submission. However, the application describes relevant arrangements for radiation protection including principles of radiation protection, engineering controls considered in the design and radiation monitoring programs to be in place. The application for consent for layout and construction approval for medical cyclotron facility is given in (AERB/RSD/MCY/LCA). The safety analysis report PSAR for a medical cyclotron.

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