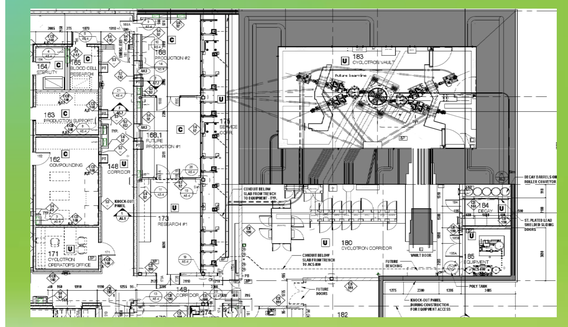
PLANNING CONSIDERATIONS FOR RADIOISOTOPE PRODUCTION CYCLOTRON PROJECTS REGULATORY FEEDBACK

Mandate

The Canadian Nuclear Safety Commission regulates the use of nuclear energy and materials to protect health, safety, security and the environment in Canada. Its mandate includes the oversight of particle accelerators. The CNSC regulates the full life cycle of such facilities, with regulatory oversight though construction, commissioning, operation, and decommissioning activities.

Planning for Safety

Experience has shown that prudent design with careful consideration of safety at the very early stage of the project as well as along with the evolution of the project is vital to the overall safe operation of the facility. Deficiencies in the design are often difficult to fix or costly



LAYOUT AND SPACE

A radioisotope production cyclotron facility is more than merely a vault to host the machine and a control room. The footprint needed for the processing and servicing areas is large. For medical institutions which are often located in dense urban areas, the available space is an issue. The layout should allow to host all the required equipment and to permit the implementation of all contamination controls. Also, it should allow easy and safe movement of the workers and materials within the facility and to and from the facility.

WORKLOAD PROJECTION AND MAXIMUM PRODUCTION CAPACITY

Nowadays, there are many cyclotron designs available commercially with increasing beam currents and energy. For conventional isotope supply such as PET isotopes, the machine beam current doesn't need to be very high. A single target machine with 150 µA beam current on target would probably be sufficient to supply a reasonably large demographic area. The research programs associated with new projects are often less defined in the beginning and the needs for beam current, the number of beamlines, and hours of operation, are hard to predict.
The safety implications are two folds; first, the proponent should establish a safety envelop for the maximum parameters they want to design the facility against. This safety envelope will be used to design the shielding required for the target areas and/or the cyclotron bunker. It will also, define the maximum radioactivity that will be present in the target which must be confined at all time. This is used to assess the consequences of target failures and any release to the facility or the environment in case of an accident.
Second; since in practice, the urgency and needs is what drives the progress of the project, it often happens that the proponent is keen on proceeding with a partial operation of the facility such as the clinical isotope part but is not ready for the more advanced research on other parts of the facility. The CNSC may permit approval of the project in phases, i.e., allowing limited operation of the facility. However, this requires a rigorous quality assurance program and change control to clearly define the various phases of the project and what is allowed and what is not allowed at any given time.

SHIELDING PENETRATIONS

Cyclotron bunkers are normally built with thick concrete walls. Penetrations are needed for various purposes such as product transfer, electrical, control, cooling water circuits and ventilation. Also, the facility may have under the floor service channels passing through walls. Penetrations present weak points in the shielding. Normally, they are positioned so as to avoid direct eye sight from the radiation source to the area outside being protected and to minimize leakage of radiation especially neutrons. Efforts are made to minimize the diameter or the cross section of the penetrations as much as practically possible.
Shielding calculations may be performed using empirical formulae or Monte Carlo simulations. The latter provides better estimates for the radiation fields outside the shielded bunker. Details about the penetrations should be used for the shielding estimates. This is to avoid having to potentially have to add more shielding after the fact and the space has been allocated or the walls already built. Add-on shielding, to reduce the leakage from penetrations, could take valuable space in the work area; it would make access to certain areas impractical and might constitute tripping hazard.

COOLING WATER CIRCUIT ACTIVITY

The design should look into the potential of activation of the water volume and devise a solution to prevent from exposing the workers to high radiation fields during the cyclotron running.
Predicting the level of water activation during operation under maximum operating parameters has some uncertainty. Proponents should apply conservative estimates for these components and either install or have provisions for implementing particular measures to reduce the radiation from cooling circuits outside the shielded bunker. This may include delay loops in the circuit in the exclusion area or special shielding for the heat exchanger area. In either case, space is needed to potentially accommodate such measures.

STORAGE OF ACTIVE COMPONENTS

The amount and the need for storage of active components vary between one machine and another. This is not only related to the workload and use of the machine but also to its design and the performance of the machine. So far, the number of machines installed and operating is not large enough to predict standard maintenance and servicing needs. Many components, especially targetry components, are prototypes or under testing and development.
It is possible that a storage location for activated components is rarely used. However, in the case to the contrary, when no shielded space is available in the original design, this becomes a safety concern. A location for storage far from bunker is not practical and might discourage the operators from safely storing the active components in the designated locations, leading to components being temporarily stored in an inappropriate area.
The cyclotron bunker and/or a target room might be attractive options for storing active components due to their proximity to the cyclotron and to the fact that the areas are shielded and rarely occupied. However, the potential high residual radiation fields in the target areas might be a negative factor due to the dose to the workers accessing the area. Having sufficient space to store the components underground or inside a shielded box is acceptable. Adding a storage container after the fact might reduce the work area or access around the target stations or the cyclotron, both of which are required for the safe use of the facility and traffic of workers.

MANAGEMENT OF RADIOACTIVE WASTE FROM CYCLOTRON AND PRO-CESSING LABS

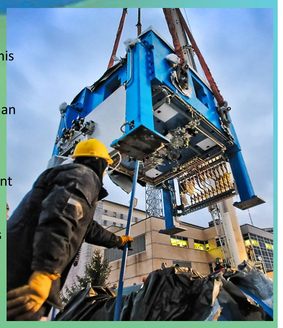
The procedural aspect of waste management is not necessarily finalized with hammering out all the details at the design phase. It is somehow dependent on the volume, nature and the activity of the potentially radioactive waste and the decay rate of the radioactivity processed. However, having sufficient space to store the waste safely in the proximity of the work area is important. An inappropriate waste storage location, whether for interim, i.e., during the processing, or for longer-term waste storage, is practically useless, since workers might use makeshifts instead. A storage location outside the work area is not recommended as it introduces unnecessary movements crossing the contamination zone barriers.

CONTAMINATION CONTROL ZONES AND HAND AND FOOT MONITORS

For an isotope production and processing cyclotron facility, the design of the zoning of the facility with regard to the susceptibility of contamination is a challenge. There are various considerations which are not all compatible. "Clean" rooms, or areas to meet the medical requirements, are normally inserted in the facility and present the heart of conventional medical radio tracer production such as FDG. Also, depending on the recent operation of the cyclotron and the isotopes produced including their half-lives, the needs for contamination control check at the exits vary.
It is expected that at the exit of a contamination control area that hand, foot and goods are checked clear of contamination. Also, all gloves, overshoes and lab coats removed must be kept at the check point of the contamination control area. If contamination is found on an item, there must be at provision to store the contaminated items safely and appropriately at the exit/check point.
Whether it is a handheld contamination detector, a full body or a hand and foot monitor, a minimum space is required to accommodate the setup and the "contamination control" station. When this is not fully taken into account at the design stage, the introduction of a contamination control check point is done on the expense of other operational requirements, such as corridors and access entrances. This could make the access and exit point to a contamination control zone crowded or narrow.
Finally, if the operator of the facility intends to operate the facility under various schemes where contamination hazards may be different, the design should allow for different access protocols for contamination control purposes with distinct and clear procedures for what is required at each case. More specifically, it is possible to define different exit paths or verification requirements depending on the mode of operation.

construction and commissioning project management

Most of the new projects for radioisotope production cyclotrons in Canada belong to medical or academic institutions. They often have little or no previous experience with this type of facility. The institutions should build the project team with enhanced knowledge and experience with or training on this special type of facility.
The radiation safety and regulatory resources required for such projects is much more than what is needed for other conventional facilities and licensing such as medical linacs or nuclear medicine applications. While in a case of a medical electron accelerator for instance, a medical physicist and radiation safety officer might be able to oversee the project from the regulatory and safety side, in the case of a cyclotron, it is usually different individuals or groups performing these two tasks. Coordination of the communications with the regulator and satisfying the regulatory requirements is an important task that should not be postponed until it might be too late for the project where design decisions have already been made.



INTEGRATION OF EQUIPMENT SAFETY SYSTEMS WITH BUILDING SAFETY SYSTEMS

A radioisotope production cyclotron facility comprises several systems performing various monitoring and control functions. The cyclotron machine safety interlock proper is only a part of many other safety systems ensuring the safe operation of the facility. For instance, a plug type door for a cyclotron bunker is often controlled by its own operating, movement and interlock system. The nuclear ventilation system normally has its own back up, monitoring and control features which are part of the building monitoring. There are many other examples such as electrical safety, fire protection system, drainage or sump monitoring, target transfer systems, hot cell monitoring, as well as radiation monitoring systems. Each of these systems has one or more safety functions meaning that it monitors certain parameters and either alerts the operator or triggers an action like shutdown or diversion or switching to render the process safe.
Usually, these systems are designed and installed by different specialized companies or groups with varying degrees of familiarity with the other components of the overall facility. It is critical that these systems work together and communicate properly to achieve the desired functions. Designing, building and commissioning the interface between these systems requires particular attention from the part of the project management to ensure common understanding of each system input and output requirements.
As every system needs to be maintained and tested periodically, it is a good practice to design a periodic verification program covering all the involved systems and features of the facility and its auxiliary systems. Designing the facility with the notion of integration of safety is useful also for compliance verification purposes as the regulator requires the licensee assurance and verification that all work as intended without safety degradation.

NUCLEAR VENTILATION AND FILTRATION OPTIONS

In general, two streams of ventilation are required for a cyclotron facility for isotope production; one for the cyclotron and its targets and one for the processing hot cells and fume hoods. Routine operation generates airborne activity from air activation in the vault and target area near high intensity neutron fields. This represents a continuous, but often of limited concern, stream of small radioactive release to the facility stack. More of a concern is activity escaped during processing in the hot cells or from the targets during or after irradiation.
Some older designs have used delay tanks to slow releases until decay. Nowadays, more efficient filtration with charcoal filters is considered the norm. The filters could be close to the source or at the stack depending on the design choices and space limitations. New hot cell designs come with ventilation interlocks where ventilation stops when a detector at the exhaust of the hot cell detects a high level of airborne activity. In such situations, the hot cell air volume is open to an emergency system of storage tanks under negative pressure to suck the contaminated air volume.
If the processing side and the cyclotron side of the facility are to use the same stack, protection against backflow should be devised and analyzed during the original design and an upgrade to any leg of the nuclear ventilation system.
An analysis, at the design stage, of the consequences of releases from failed targets or processing should define the source term releases that should be filtered or confined by the ventilation protection systems.

STRATEGY FOR STAFFING AND TRAINING

The design and commissioning of the project as well as building the various components of the facility constitute an excellent opportunity to train staff for operation and safety functions to run the facility in the future. It is expected that the applicants document all design basis arguments and decisions during the progress of the project. This is usually mandated by their quality assurance programs. It is also required that all the facility defining safety parameters are documented as part of the licence application and will eventually be part of the licence requirements when a licence is issued.
It is strongly recommended that the applicant build the facility operation team right from the start of the project. This team will be involved in the regulatory interactions as well with the commissioning tests of the facility. Ideally, contracts with specialized companies to deliver and or install certain components of the facility should include training provisions. A long initial training period is often needed for new staff to get familiar with the operation and safety of the facility and to understand the logic behind the chosen design options. By introducing the new staff to the project prior to the operation and during the progress of the project, the above mentioned safety vulnerability can be eliminated.

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