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Hot Cell Technologies in Radiopharma

5 Radiopharmaceutical Engineering Challenges

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Hot Cells are critical components in the production of radiopharmaceuticals, providing a controlled environment for handling radioactive materials safely.

As the demand for radiopharmaceuticals grows, so does the need for advanced Hot Cell technologies.

Here we look at 5 engineering challenges in Radiopharmaceutical manufacturing.

Scitech has been at the forefront of delivering pioneering solutions to address the challenges associated with Hot Cell engineering for 20 years, positioning itself as a leader in this field.

Our aim? To instil unwavering confidence in our clients through excellence in design.

Further information: Radio Pharma

Radiopharmaceutical facility design & construction - Scitech

Image Credit Radiopharmaceutical Research Centre Horia Hulubei National Institute

Scitech's driving purpose is to to provide clients with Radiopharma production lines that are designed with unparalleled precision and excellence.

With an impressive heritage in Radiopharma, that includes creating a hot lab with 7 hot cells within the site of the world's first PET scan for diagnostics in 2003-2005 and the first commercial line for an alpha emitting isotope in 2010-2012 and a few more since, Scitech has some impressive credentials.

We work globally with a wide range of radiopharmaceutical research and manufacturing organisations, with settings including healthcare (hospitals), research and commercial radioisotope and radiopharmaceutical manufacturers.

Lewis White, Mechanical Engineering Team Leader

5 Radiopharmaceutical Engineering Challenges

01

Containment & Sterility

02

Radiation Shielding

03

Ergonomics

04

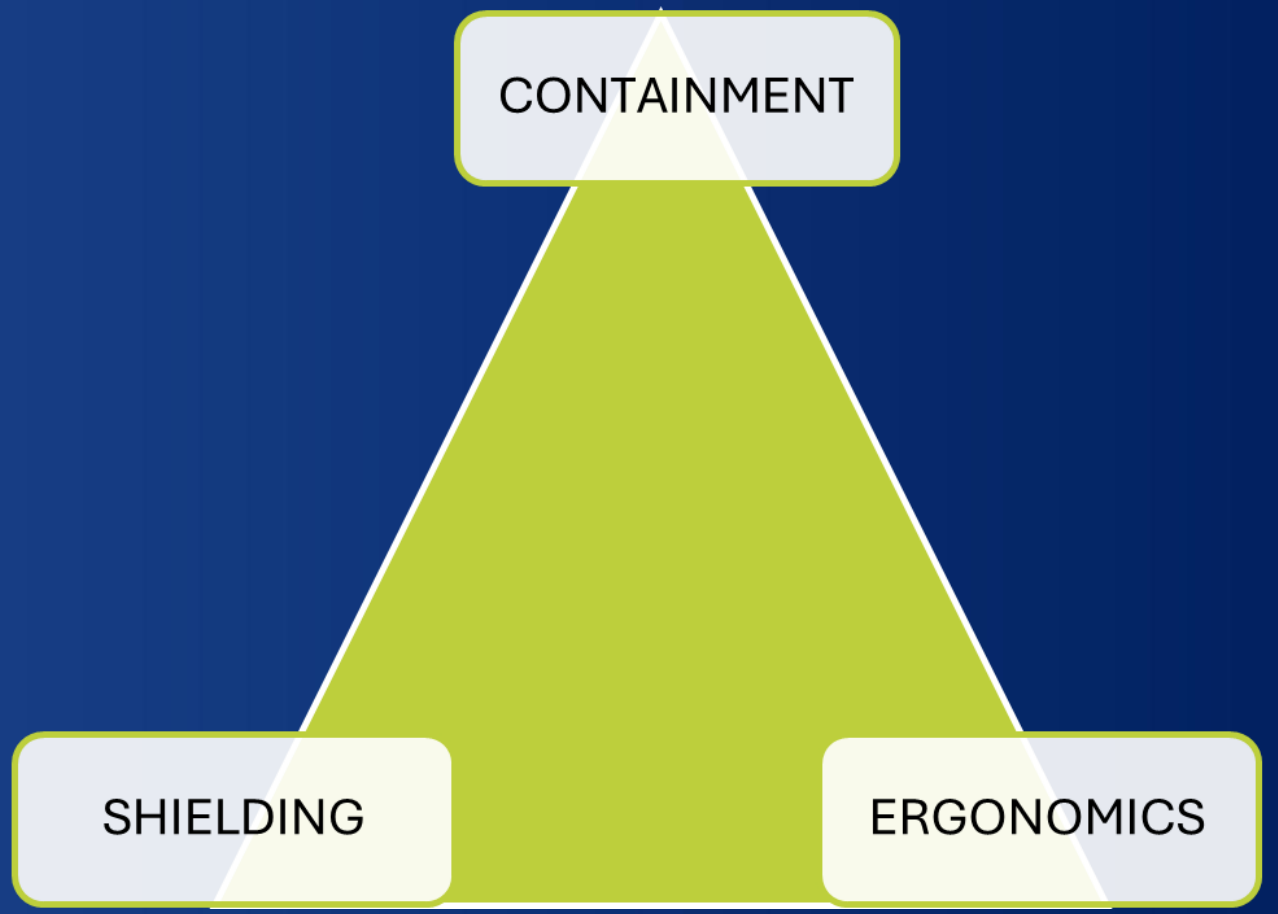
Gas Abatement Systems

05

Maintenance

*Of the three essential requirements, it is the ergonomics that generally suffer because **Containment** and **Shielding** safety must dominate.*

Engineering for nuclear containment and safety - the “wicked triangle”



Containment & Sterility

01

Materials used must maintain their integrity overtime.

Maintaining a controlled environment that prevents the escape of radioactive materials and ensures the sterility of the products being handled is paramount. This requires careful selection of materials and robust construction techniques.

Challenges occur as radiopharmaceutical activities necessitate radiological safety (negative pressure containments) and GMP activities necessitate product safety (positive pressure containments).

Adhering to stringent regulatory standards for radiation protection and pharmaceutical manufacturing, such as those set by the EU and US Nuclear Regulatory Authorities, adds another layer of complexity.

- Rigorous testing plays a key role with compliance with standards such as ISO 10648, which dictate minimal volume loss and effective containment.
- VPHP sterilisation requires precise control over parameters like concentration, exposure time, humidity, and temperature.
- HEPA filters and BIBO mechanisms must be regularly maintained to function correctly.
- Rapid Transfer Ports (RTPs) and pre-chambers involves meticulous design to safely transfer materials in and out of Hot Cells without compromising containment.
- Shielding designs incorporate materials up to 300mm thick.

Hot Cell at the Saskatchewan Centre for Cyclotron Sciences

Key factors for containment & sterility:

1. Sophisticated ventilation systems; HEPA filters and BIBO (Bag-In/Bag-Out)
2. Chevron lead bricks & stainless-steel containment structures
3. Rapid Transfer Ports (RTPs) and Vapor Phase Hydrogen Peroxide (VPHP) sterilisation systems

Radiation Shielding

02

Image credit Eckert & Ziegler Medical

Shielding in Hot Cells is essential to protect operators from harmful radiation.

Primary challenge is to provide adequate protection without compromising operational efficiency.

Making sure the shielding does not impede the operator's ability to work efficiently and comfortably is a delicate balance that requires thoughtful layouts.

Image credit Comecer

Key factors for Radiation Shielding:

1. Materials must be precisely engineered to block radiation effectively
2. Designs must incorporate air gaps and other features to prevent radiation "shine lines," - potential pathways for radiation leakage.

Ergonomics

03

It is the ergonomics that generally suffer when looking at Hot Cell design.

Operators should be able to work safely and efficiently without undue strain or discomfort.

The thick shielding materials and complex containment structures in Hot Cells create physical barriers that hinder visibility and accessibility, making it difficult for operators to perform precise tasks. Features such as adjustable windows and glove ports should be considered.

Working at the hot cell workface should be for as little time as possible. Layouts of the inside of the hot cell, therefore, need to enable manipulations to be as quick and efficient as possible, reducing the overall interface time.

Mock-ups and simulations are often used to optimise the design and identify potential ergonomic issues before the Hot Cells are built.

Key solutions:

1. Interfaces need to accommodate different operator heights and reach capabilities
2. Layout must minimise awkward postures and repetitive motions

Example of a bespoke Hot Cell arrangement mock-up to ensure positive outcomes from the design process.

In the spotlight – Gas Abatement Systems

04

Gas Abatement Systems are a hot topic now!

Designs must capture and neutralise radiotoxic gases before they are released into the environment.

Achieving efficient gas mitigation is a complex task, particularly with isotopes that emit highly radiotoxic gases like radon. Systems can be tailored to specific isotopes, guaranteeing they comply with regulatory standards.

- *Activated Carbon filtration*

An activated carbon system can be provided by a Hot Cell vendor that suits the technology of a heavy-duty frame, with suitable lead shielding and calculated volumes of activated carbon (charcoal) to provide the required DWELL time of the gas in contact with the carbon.

- *Delay / Decay Filtration*

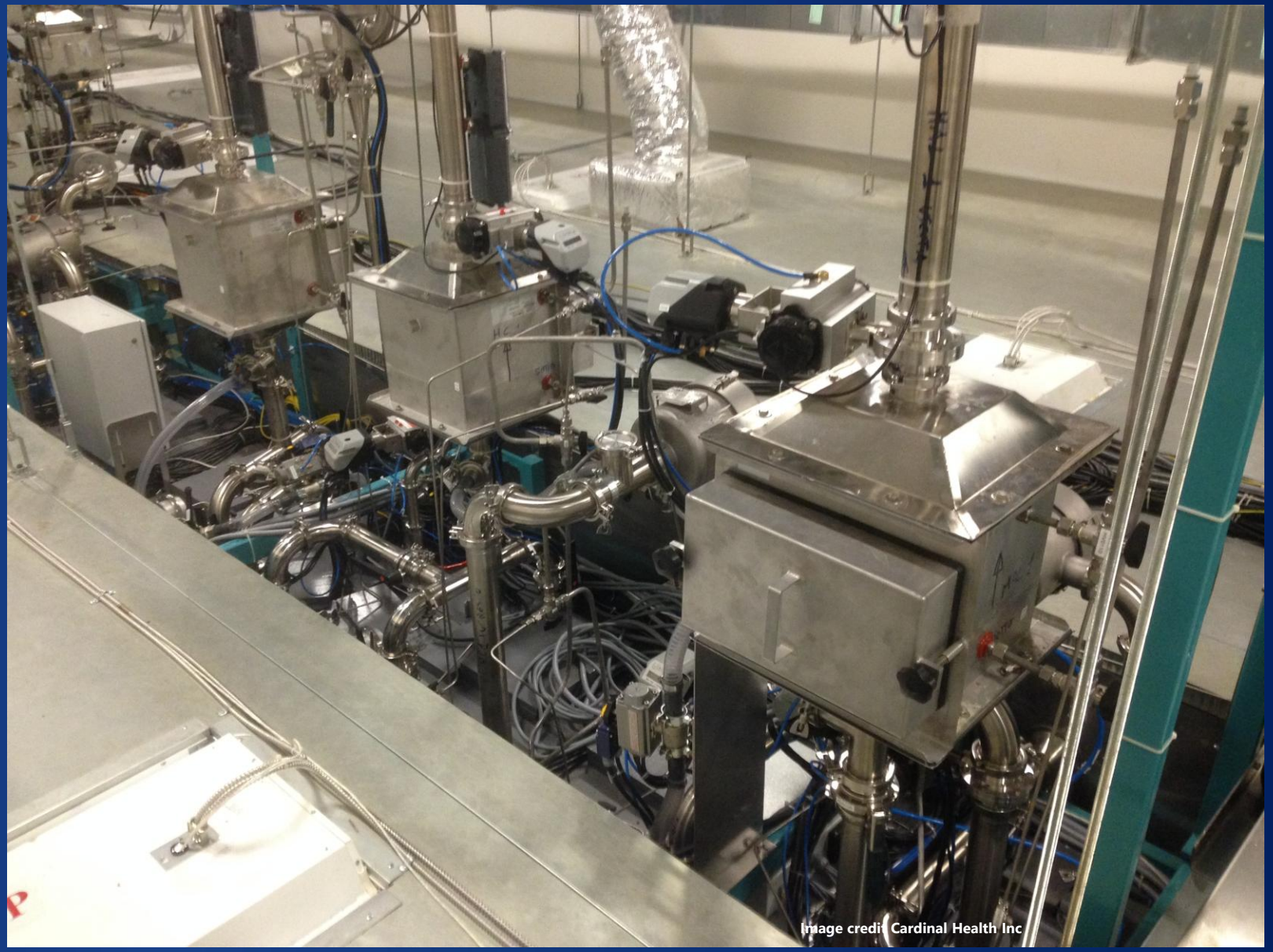
Delay/Decay systems are very simple and formed by steel or plastic ductwork that may be square or round in section. They work by greatly increasing the journey time of the gas from source to final stack discharge. This solution though can still cost up to £1M!

Key solutions for Gas Abatement:

1. Activated carbon filtration
2. Delay/decay systems
3. Bespoke engineered systems
4. Combinations of the above three

Maintenance

05



Regular maintenance is essential to ensure all systems continue to function correctly

Accessibility is a major challenge, as the thick shielding and intricate containment structures restrict access to critical components.

Avoid increased downtime and higher maintenance costs by designing for maintenance:-

- Ample roof space to allow access to components located at the top units, including ventilation systems and filters that need regular maintenance
- Placed in strategic locations access panels let maintenance personnel reach internal components without dismantling the entire unit
- Designing service corridors facilitates easier access for maintenance tasks
- Modular designs mean components can be easily swapped out quickly, such as modular ventilation units, filter housings, and shielding sections
- Sensible positioning of, and access for, equipment during detailed design

Image credit Cardinal Health Inc

Key benefits:

1. Continuous, safe operations
2. Minimised downtimes

Maintenance should also be planned for
Units should be designed with back up systems incorporated (e.g. duty / standby fans).
Any failure, therefore, won't mean emergency maintenance being needed.

The added Value

Scitech's expertise in Hot Cell engineering addresses the multifaceted challenges of radiopharmaceutical production.

By combining advanced shielding, containment, ergonomic design, and innovative gas abatement solutions, we ensure safe and efficient radiopharmaceutical manufacturing process.

As the industry evolves, Scitech remains committed to leading the way with cutting-edge technologies and comprehensive solutions, reinforcing its position as a leader in the field of pharma manufacturing.

Contact us if you have any questions or would like to discuss how we can help you with your Radiopharma project. info@scitech.com call 01483 270555

About Scitech.

20 YEARS track record in Pharmaceutical design and qualification:

1. Consultancy
2. Qualification and Validation
3. Design and Engineering
4. Construction
5. Commissioning

Scitech provides full project support through our in-house specialists, delivering a tailored and integrated service.

We focus on key client goals and objectives of safety, quality, environment, cost, and schedule.

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Lewis White | Mechanical Engineering Team Lead

Nicola Hale | Therapeutics Operations Director

Info@Scitech.com

+44 (0) 1483 270555

GODALMING | CARDIFF | MANCHESTER | ANTWERP | BREDA

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