



Hot Cells

Client: Hull University (HU)

Aims and objectives

To design, manufacture and install shielded hot cells to be used within a preclinical facility, dealing with research into positron emitting isotopes (non-GMP) at Hull University.



Shielded Facilities

Cyclife EDF Group - Subsidiaries



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The client

Hull University has a reputation for world-class multi-disciplinary research that drives forward improvements to healthcare and the wellbeing of society as a whole. Research facilities include a spectacular, new £28 million Health Campus, a PET Research Centre and the Daisy Research Laboratories at Hull's Castle Hill Hospital.

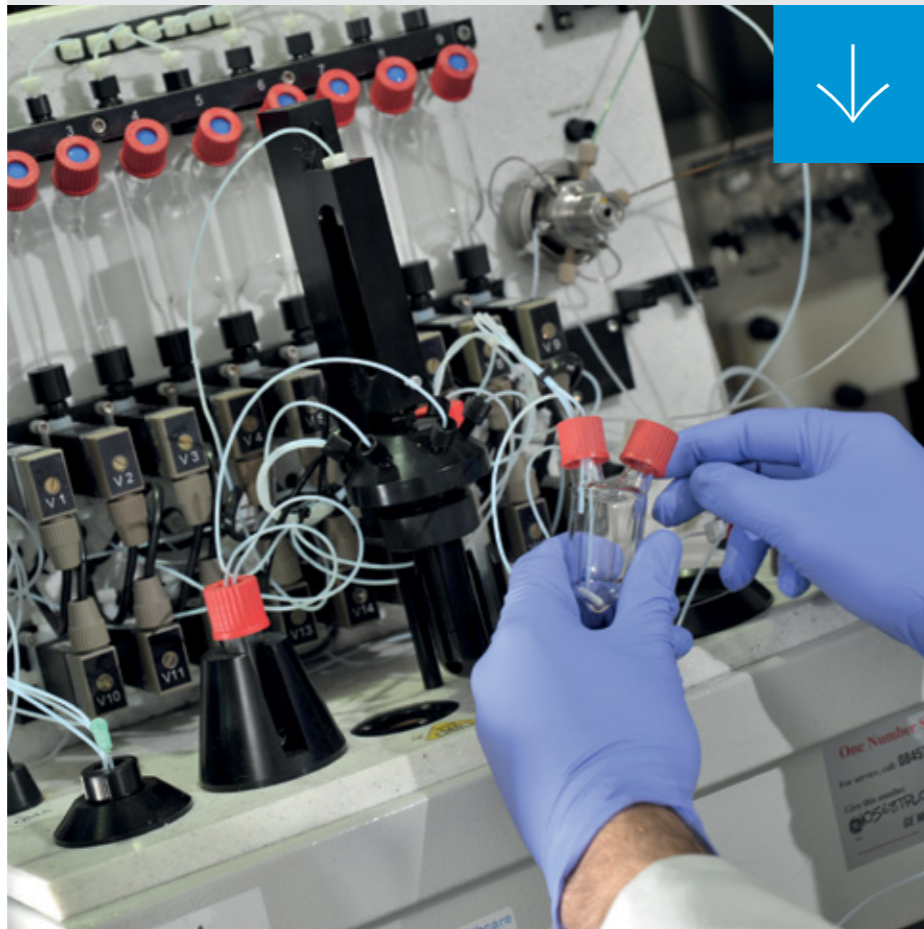
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Project overview

These Cyclife Aquila Hull University (HU) shielded hot cells are used within a preclinical facility, dealing with research into positron emitting isotopes (non-GMP).

This facility includes a low-power cyclotron, hot cells for isotope dispensing, shielded fumehoods and preclinical scanning facilities across two floors in a new extension to an existing biomedical science research building.

The facility uses both internally and externally produced isotopes (delivery from other commercial and research cyclotron sites). Synthesis of radiotracers is carried out using commercial synthesis units and bespoke microfluidic systems.



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Full specification

The hot cells are used for the manufacture of fluoride-18, carbon-11 and other radiopharmaceutical compounds incorporating metal and iodine isotopes. These two hot cells are arranged side-by-side with a service hatch to allow transfer between cells. Each hot cell contains an automated process rig. Under bench space is provided for equipment storage, including for example, the electrical cabinet and cooling unit associated with Eckert and Ziegler Modular lab device.

The Cyclife Aquila HU system includes compliance, performance, coordination, integration, design, detailing, engineering, fabrication, manufacture, assembly, shipping, supply, delivery, off-loading, rigging, hoisting, on-site transportation, positioning, alignment, fixing, installation, interconnection, living, testing, commissioning, calibration, demonstration, certification, client training, documentation and bringing to readiness for the intended use of its entire works.

This includes, but is not necessarily limited to:

- Hot Cells
- Electrical cabinets
- Control cabinets
- Other ancillary components and equipment
- Interconnecting cable containment, pipe supports,
- Cabling, piping, glanding, termination.



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Technical requirements & scope

The Aquila HU cells include the following features:

- **Portholes**
2 per hot cell with detachable mechanical arms/ manipulators that can be switched with gauntlets to also allow for hand/ forceps operations. The portholes are provided with shield doors.
- **Doors**
Hot cell door is a hinged swing opening mechanism.
- **Electrical Power**
Electrical power points in hot cells allow for operation of synthesis unit and pumps (~6 per cell).
- **Shielding**
The cells are provided with lead shielding for the following amounts of activity to be used; 20 GBq of C-11 or 30 GBq of F-18. The cells are free of shine paths/short paths and are tested independently after installation. The cells include

shielding from the floor up to the main compartments, for the delivery tubing into the cells (of sufficient thickness for rapid delivery of the activity into the cell). A lead glass viewing window - minimum size 250mm x 250mm is included.

- **Dimensions**
The compartment size is nominally: width 1200 mm x height 650 mm x depth 750 mm.
- **HVAC/Ventilation**
The cells are capable of operation to ISO 14644 Class 7 (Class C) under GMP conditions but delivered to an appropriate standard for preclinical work only. Cells operate at -60Pa. The cell depression is provided by exhaust fans in the facility. No fans are provided with the cells. Inlet and outlet filtration is to be provided on the hot cells

Inlet: Prefilter, HEPA, Outlet: HEPA. These are to be provided with the facility for DOP testing Separate carbon filters are not be provided.

The cells are leak tight to ISO 10648-2 class 3 in accordance with ISO 11933-4 Table A3), equivalent to <1% v/v per hour.

Regular maintenance and leak testing is provided. Visual indication of the hot cell pressure is provided via a magnahelic gauge mounted in the facia, and alarm lights for pressure good/bad.

- **MOC/Finish**
The cell is lead shielded, with clean finish stainless steel lining. The material of construction is stainless steel (bright/polished). All internal and external corners are smooth radius for easy cleaning. A retractable floor within the hot cell is provided to enable easy access to all parts of any equipment inside.

The external finish is stainless steel, polished.

- **Lighting**

The hot cell includes internal lighting, - 1000 lux, externally switched with suitable maintenance access to replace the bulbs.

- **Process Connections**

Both hot cells feature a delivery system for transfer of fluorine-18 and carbon-11 to the hot cells from the cyclotron. The hot cells allow for shielding from the floor to the hot cell,

This includes:

- One line (1/16" polymeric) into the cell from the fluoride target.
- One line (1/16" S/S) into the cell from the carbon-11 target (gas).
- These are provided for on a transit plate through the wall/floor of the cell. This transit plate is leak tight to preserve the cell integrity.
- Transit plate includes 4 off 1/16" Swagelok bulkhead connections. The lines from the cyclotron shall terminate at these Swagelok connectors.
- The transit plate is also includes a 1/4" Swagelok bulkhead for connection to a Scavenge system.
- For active vents from process module; equipped with connection to a waste drum or delay system in the cyclotron room.

The Aquila HU cells include the following features:

- **Data/Comms Connections**

Transits are provided for data & control cabling between the process equipment inside the cell and the controls outside the cell. Separate 'spare' lemo-type transits for future are provided.

- **Utility Connections**

Is provided for 4 gases (hydrogen, nitrogen, argon, compressed air). The cells also provide for the delivery of 4 gases (unspecified) from lecture bottles mounted outside the hot cell and piped in. Each of the 8 gas lines are provided with a pressure regulator, gauge and ball valve mounted on the hot cell facia for isolation as part of the hot cell scope. MOC of pipes and valve - stainless steel.

- Compressed Air - 1/4"
- Helium - 1/8"
- Nitrogen - 1/8"
- Argon - 1/8"

- **Vial Transfer In/Out**

Provision is provided for the transfer out of the product in a shielded vial (6R or 10R), via a "post out" drawer. The design of this post-out system maintains the shielding and air pressure/classification integrity.

The product dispenses into a pair of vials which are installed prior to the run in lead carry pots mounted on actuators which are part of the hot cell. When

the dispensing is complete the needles are withdrawn from the vials and the vials dropped out of the cell on the rams.

The cells includes end-of-Synthesis sample delivery tray and suitable lead pots.

- **Dose Calibrator**

One hot cell includes an integrated dose calibrator mounted in the floor of the hot cell to measure radioactivity from the cyclotron supplied isotope. The dose calibrator (Capintec CRC-55tPET) is supplied and fitted within the cell.

- **Safety**

Controls and interlocks are provided as is required for safe operation. External monitoring of the in cell pressure is provided. Customer terminals are provided for door closed and pressure good for connection to a safety and local warning system. Fire extinguishing measures can be offered as an option (e.g. the option of a manually operated system for example CO₂ release into hot cell).

- **Radiation Detection**

The hot cells are provided with internal radiation detection with external visual alarm lights (red/green) to allow the operator to be aware of the status inside the cell. Door interlock is offered as an option.

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Summary

Aquila completed the design manufacture and installation of the hot cells including testing, training, maintenance and full engineering documentation, and operation & maintenance manuals.