Radiopharmacy Cleanrooms Planning and Design

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Scope of Presentation

- Initial planning considerations
- Key stages in the Design Development process
- ‘Steps’ for developing cleanroom layout
- Environmental requirements
- Internal fabric and fixtures

Initial planning considerations (1)

- Footprint/envelope
  - Floor area : sq m
  - Shape
  - Structural
- Project Costs — Include All - Facility, HVAC, Equipment plus Validation, professional fees, enabling works, backfilling, 'buying in' service ,relocation…..

Initial planning considerations (2)

- Project team – capabilities and capacity
- Knowledge, skills **and** experience
  - Engineers
  - Architects
  - Cleanroom designers
  - Cleanroom builders
  - Validation specialists
- Resources - backfilling

GMP Standards documents

- EU GMP (UK Rules and Guidance (Orange Guide) ...Annexe1 and 3…Sterile and Radiopharmacy
- BS EN ISO 14644 ….cleanrooms/spaces …
- Health Building Note HBN 14-01….Pharmacy facilities
- Health Technical Memorandum e.g. HTM 03- 01 ….Ventilation in healthcare premises

Standards/Guidance

- Document official standards in user specifications
- Some GMP elements not explicit, require interpretation/ clarification
- Refer to additional documents – PICS, Published design guidance
- Regulators i.e. MHRA, H&S, EA
- Future proofing

Design Development Stages

- User Requirement Specification(s) (URS) developed
- Bidders' design proposals evaluated
- Preferred cleanroom Contractor selected
- Contractors design proposals refined , accepted/contract sign off at fixed price
- Functional Design Specifications (FDS) developed
- Design Qualification (DQ)
- FDS refined, construction drawings accepted / signed off

User Requirement Specifications

- Fully loaded 1:50 room layout drawings
- Environmental Performance Standards
- Air handling Requirements
- Finish of clean room envelope/fixtures
- Individual items of Equipment and Fixtures
- Services – power, data, telecom …

User Requirement Specifications

Information provided by user must be accurate and sufficiently detailed to:

- Ensure hospital and bidders have a common understanding of requirements and constraints of project
- Ensure hospital requirements will be met
- Ensures cost comparisons between bidders' proposals are valid
- Ensures a high degree of price certainty

Activity Analysis

- Types of product/nature of materials to be handled
- Volume of anticipated demand/output
- Changes in ways of working
- The production process steps/ flow of materials
- Assess each step for hazards/risks exist to:

  Product quality
  Personnel
  Environment

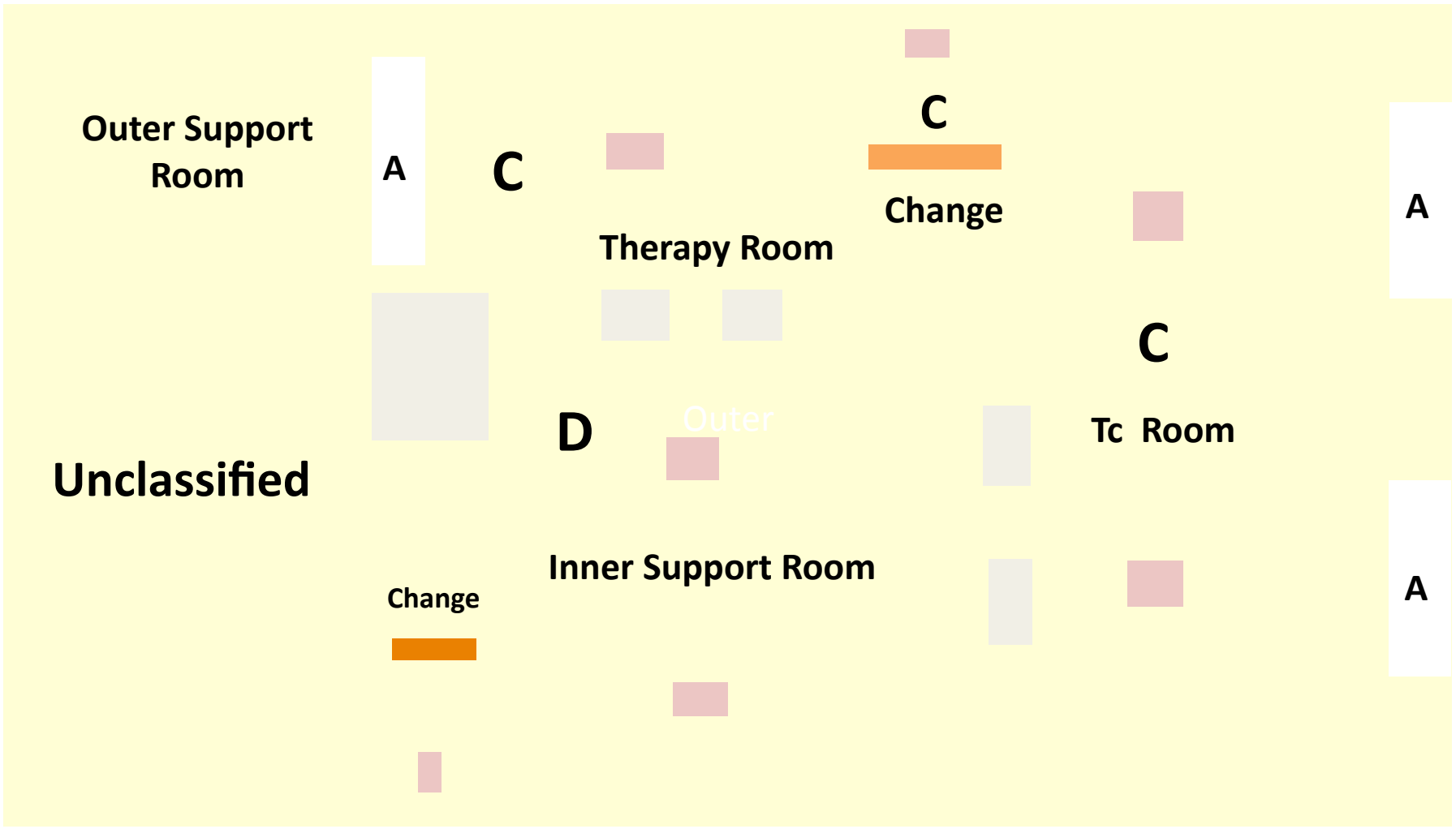
- (Hazards include: Microbial, Cross contamination, Radiation, Product mix-ups, manual handling …..)

Developing Cleanroom layout (1)

- Identify which activities require clean environment
- Determine which EU GMP grades are appropriate for each of these activities
- Identify the number of individual/dedicated clean rooms/workstations required
- Identify room adjacencies –essential/desirable/ contra-indicated.

Developing Room layout (2)

- **Identify number and types of links at room interfaces** – hatches, rooms, doors.
- **Prepare indicative room layout drawing**
- **Identify numbers and dimensions all floor occupying equipment/furniture/people**
- **Transfer to 'footprint' of architectural drawing**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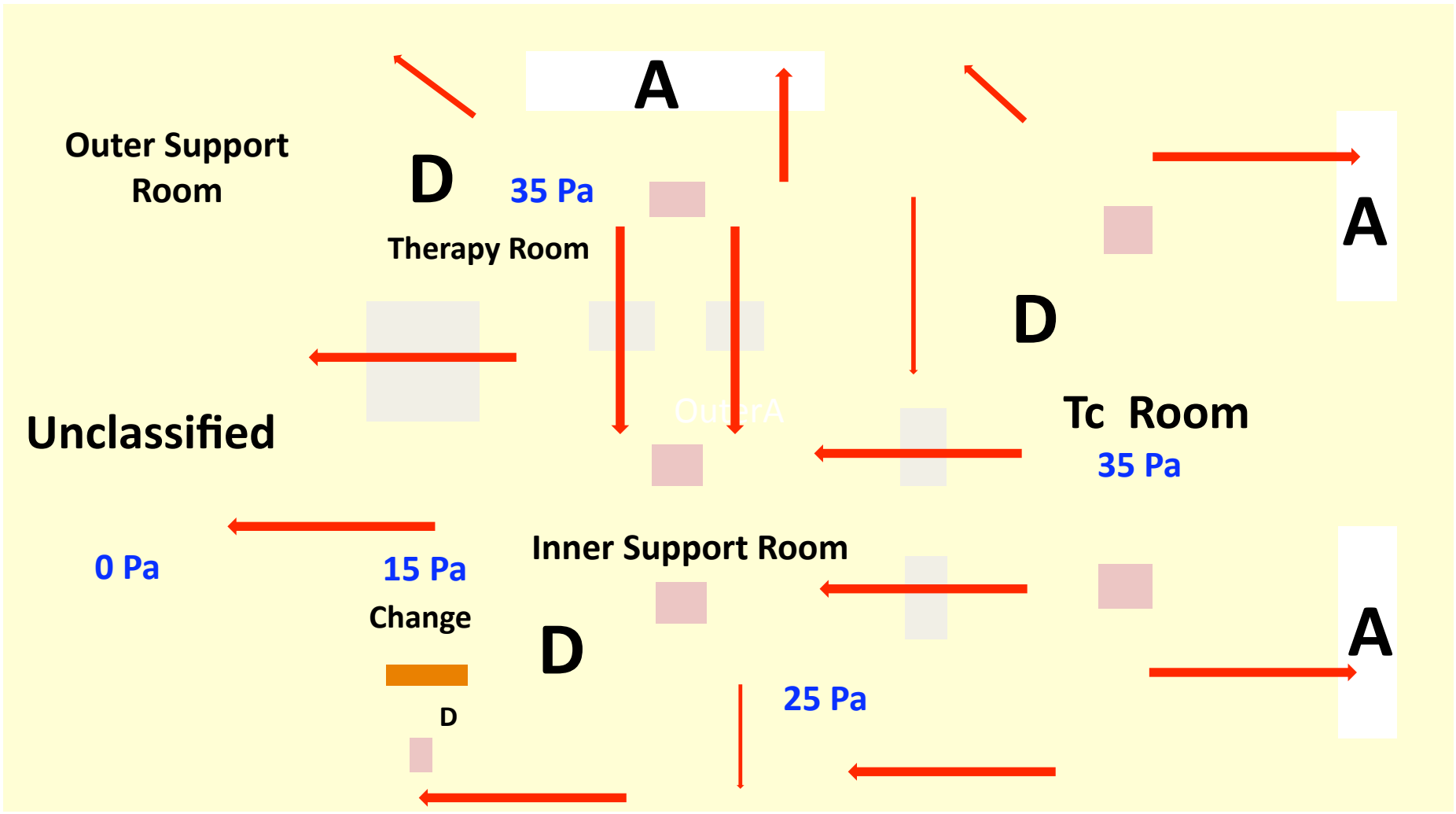
Developing Room layout (3)

- Add in sufficient circulation space – traffic pathways
- Sufficient space?
- Add emergency break out panels and vision panels
- Consider how to move equipment into/out of cleanrooms
- 1:50 Architectural drawings : reviewed and adjusted.
- Fully loaded 1:50 scaled Architectural drawing completed, checked and signed off

Environmental Requirements

- Air supply/filtration –dedicated, conditioned, HEPA filtered
- Room airflow patterns /distribution – high level in/low level out
- Air change rates - 15 -25 ach / Grades C-D
- Room recovery/clean up times - 15 -20 minutes
- Room Pressures/cascade/air flow, airlocks 10-15Pa
- Air extraction/Recirculation
- Air handling failure /spills - contingencies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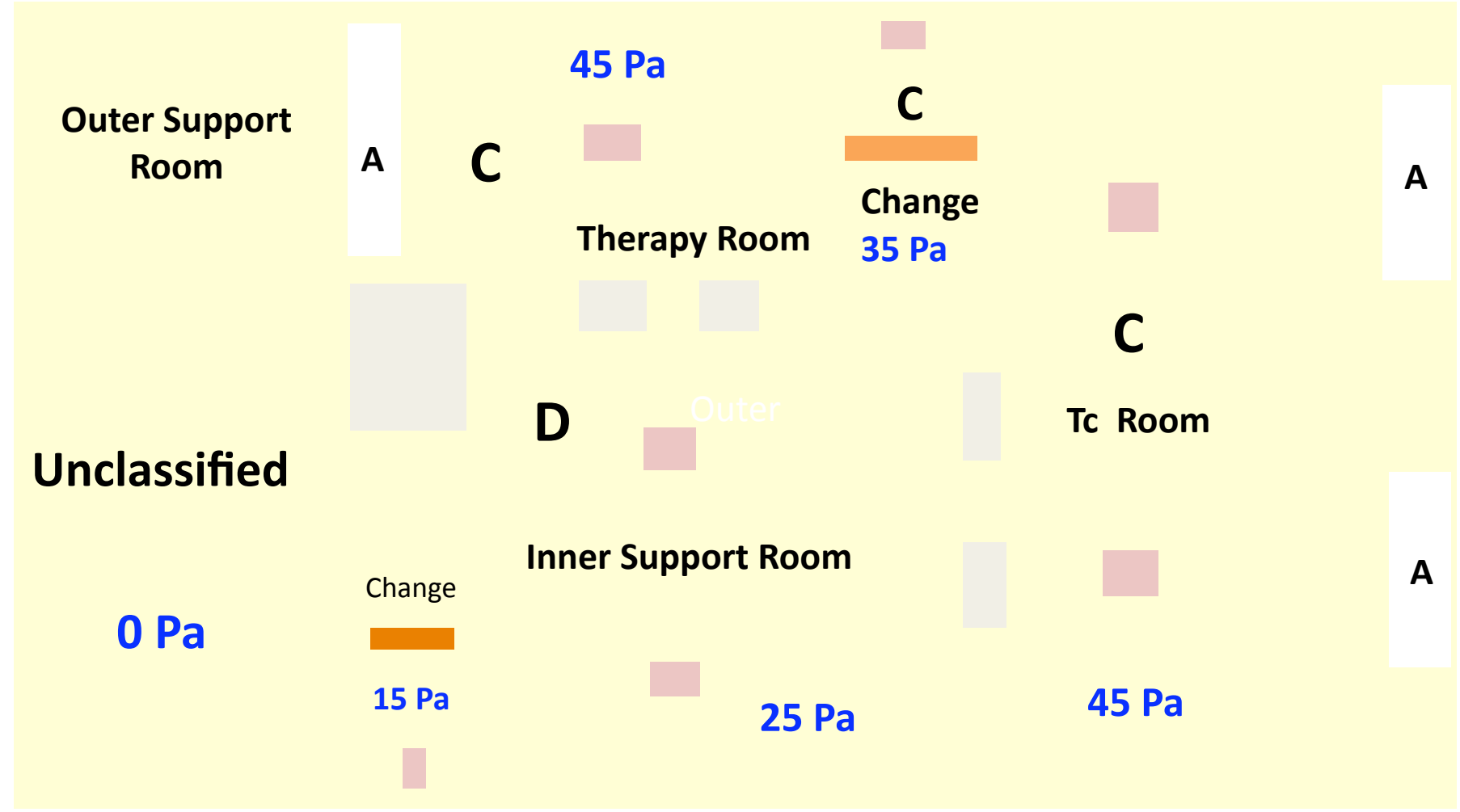
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D
Outer
Tc Room
Unclassified
Inner Support Room
A
Change
0 Pa
15 Pa
25 Pa
45 Pa

Cleanroom fabric and fixtures

- Materials of construction – smooth, continuous, impervious ,non-shedding, robust, chemically resistant
  316 S/S, Trespa, vinyl, GRP
- Minimise 'dust gathering' projecting ledges:
  flush fitting doors/VPs/ hatches/ power sockets
  No shelves ,racking or cupboards in Isolator room
- Minimise difficult to clean areas:
  corners coved, pipes/ducts, high ledges etc. boxed -in
- Ensure Integrity of fabric – all internal surfaces sealed especially floors, ceilings /penetrating fixtures e.g. lights, HEPA housings


144 A


Fire exit
EMERGENCY ESCAPE PANEL
PULL HANDLE TO REMOVE RETAINING STRIP
PUSH OUT PANEL


17
Non Sterile 2
121
Non Sterile 1


Fire exit
PUSH OUT PANEL
124
Solutions Room


exit
Assembly Area

Vinyl Finish Coving Corner Joins

Successful Design

- Team effort
- Full range of capabilities- knowledge, skills and experience
- Accurate and Detailed User Specifications