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COWI AS

PLANNING AND CONSTRUCTION OF A NUCLEAR MEDICINE DEPARTMENT

AGENDA

- NUCLEAR MEDICINE DEPARTMENT
- REGULATIONS
- PIC/S PE 010-3
- HOSPITALS IN NORWAY
- AREA REQUIREMENTS
- PRODUCT PROTECTION
- PERSONNEL PROTECTION
- PRODUCT AND PERSONNEL PROTECTION

NUCLEAR MEDICINE DEPARTMENT



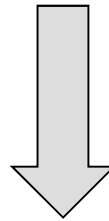
Medical use of open radioactive materials



REGULATIONS

- National legislation regarding:
 - medicine preparation
 - radiation
- ISO 14644: Cleanrooms and Associated Controlled Environments
- EU GMP
- PIC/S

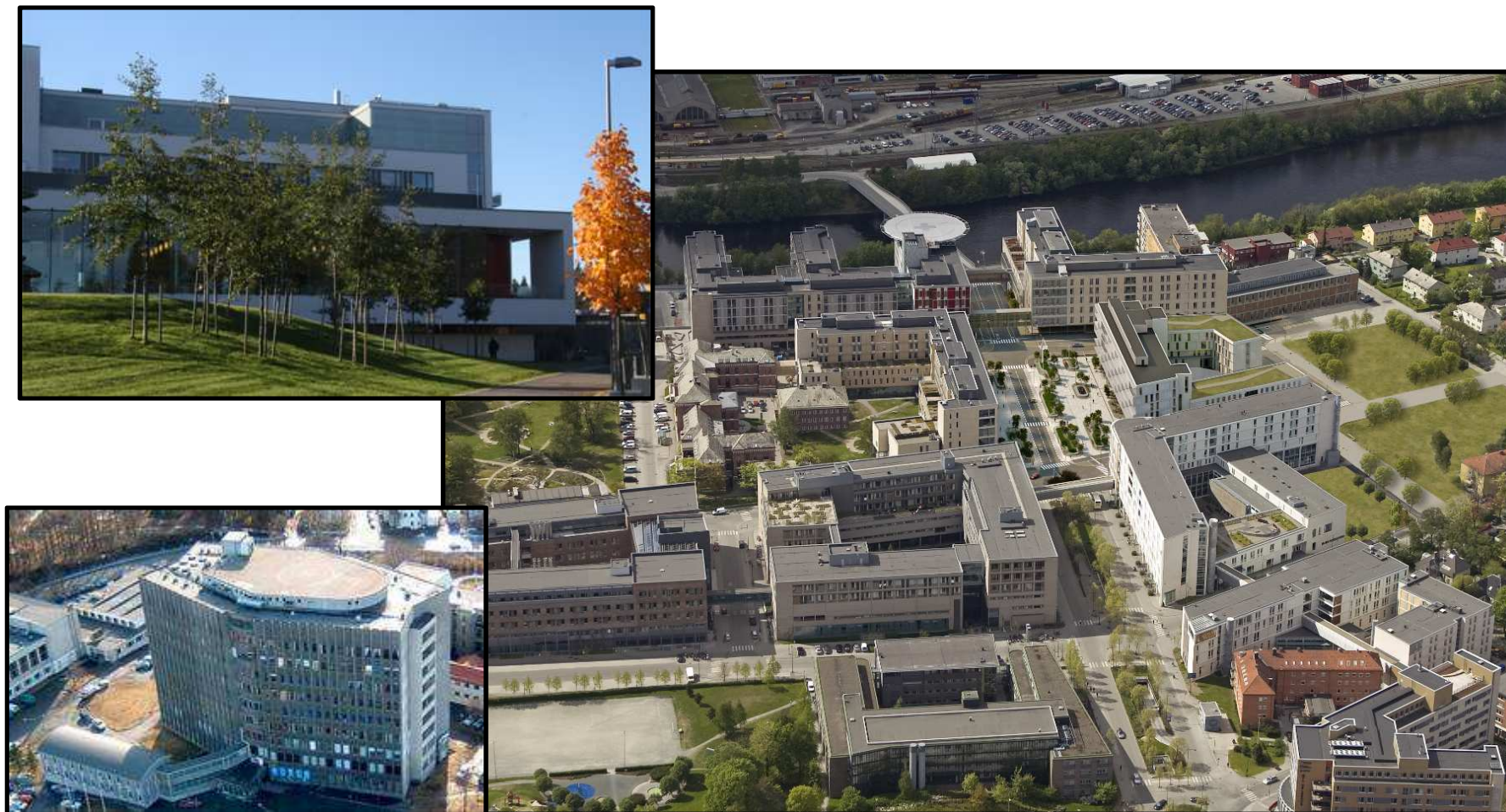
PIC/S GUIDE TO GOOD PRACTICES FOR THE PREPARATION OF MEDICINAL PRODUCTS IN HEALTHCARE ESTABLISHMENTS



Classified cleanrooms

Dedicated rooms for blood products
and radiopharmaceuticals

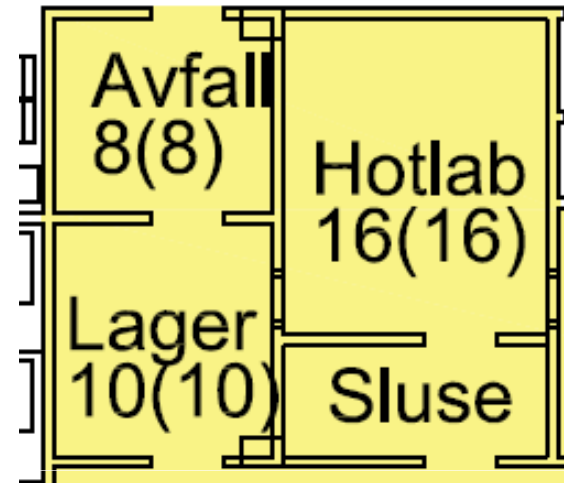
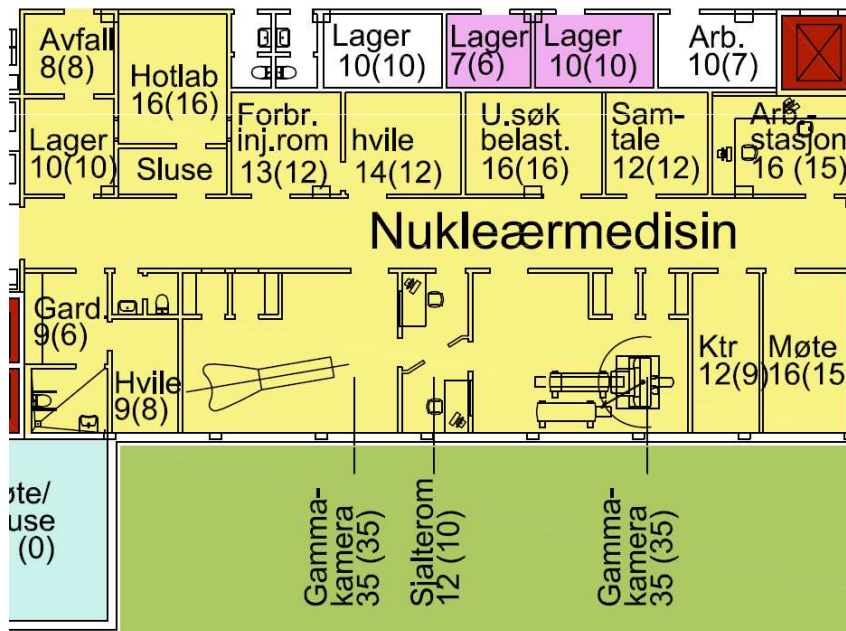
HOSPITALS IN NORWAY



AREA REQUIREMENTS – HOTLAB AREA

STEP 1 - PROGRAMMED AREA

- changing room: 4 m²
- laboratory: 10 m²
- storage room: 10 m²

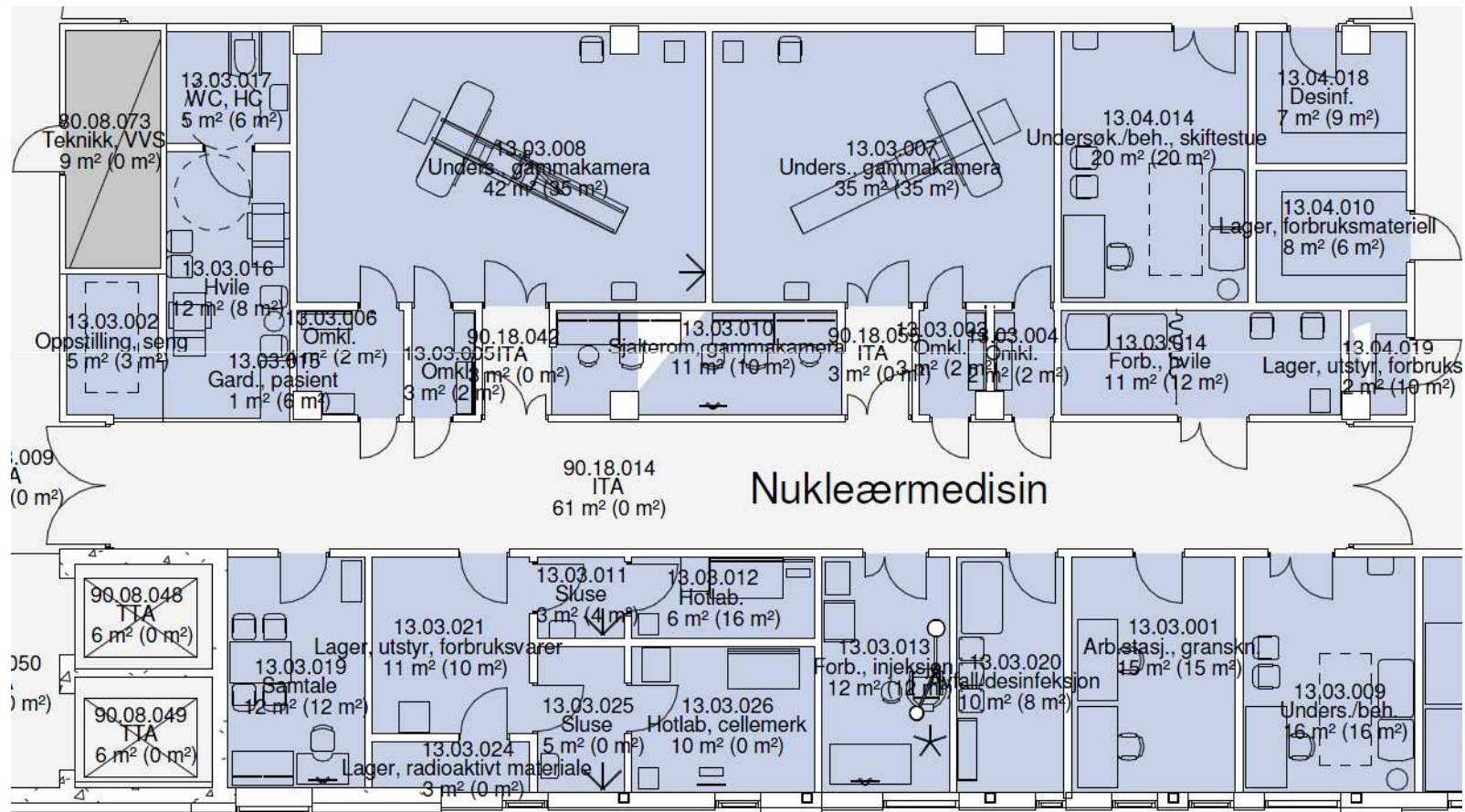


Classified cleanrooms ?

Dedicated rooms for blood products and radiopharmaceuticals ?

AREA REQUIREMENTS – HOTLAB AREA

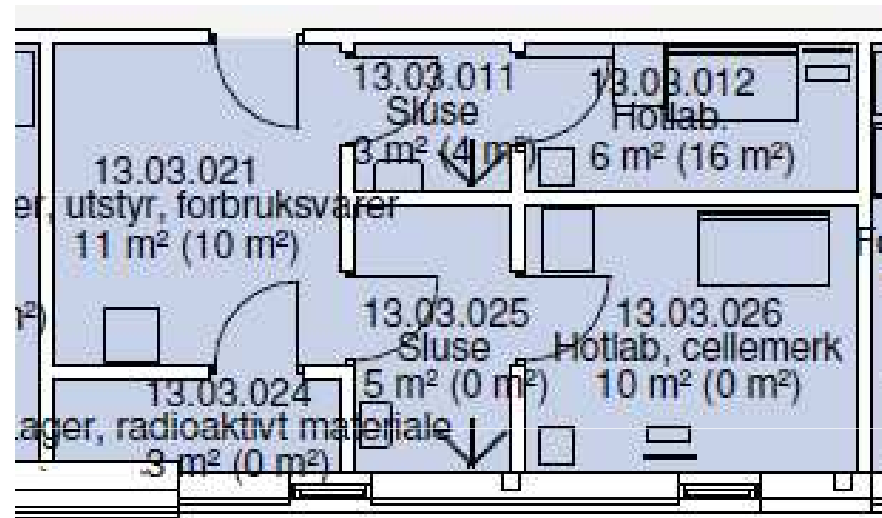
STEP 2 – TWO SEPARATE LABORATORIES



AREA REQUIREMENTS – HOTLAB AREA

PLANNED AREA

-changing room 1:	3 m ²
-laboratory 1:	6 m ²
-changing room 2:	5 m ²
-laboratory 2:	10 m ²
-storage room:	11 m ²

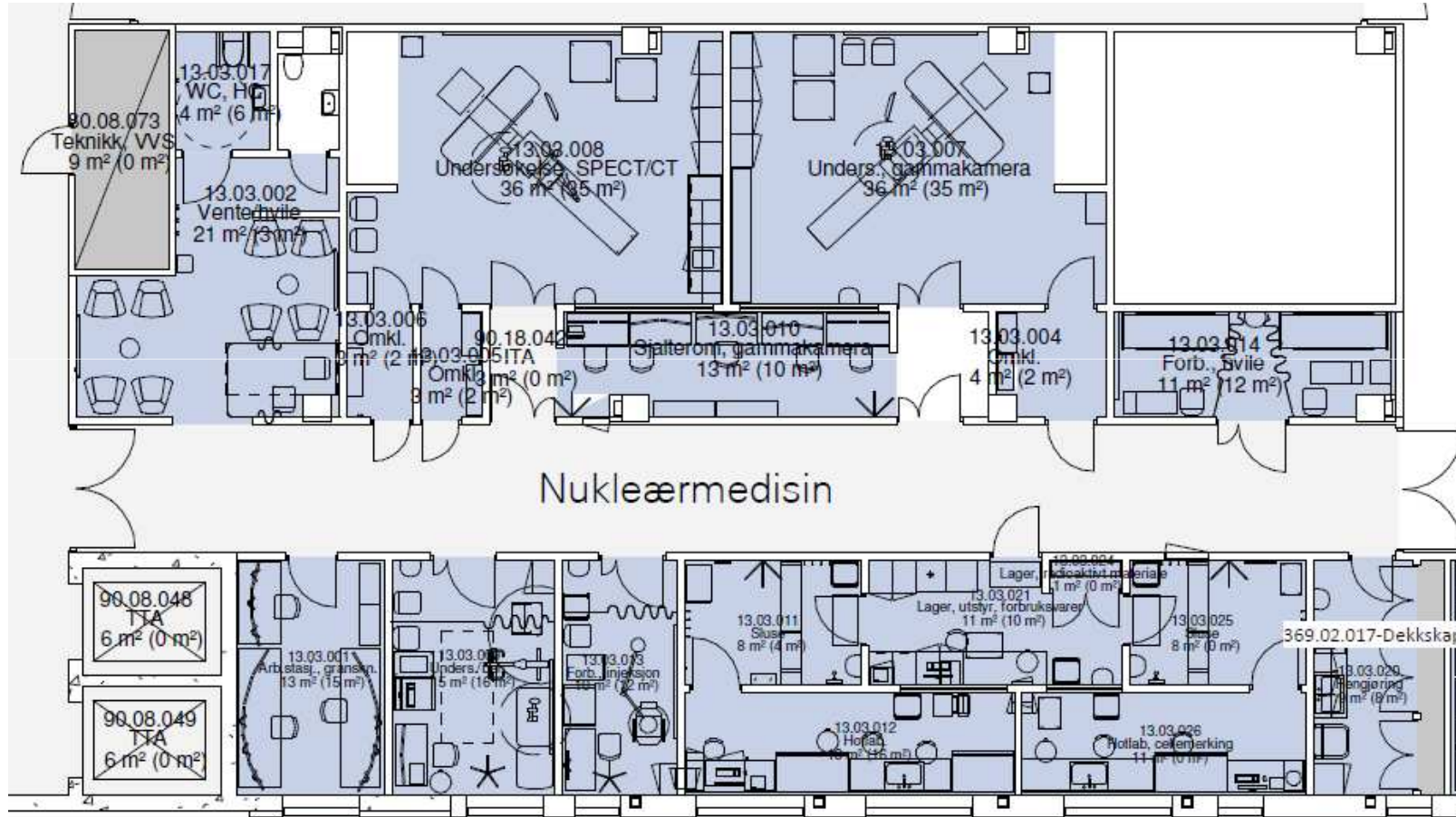


Classified cleanrooms ?

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AREA REQUIREMENTS – HOTLAB AREA

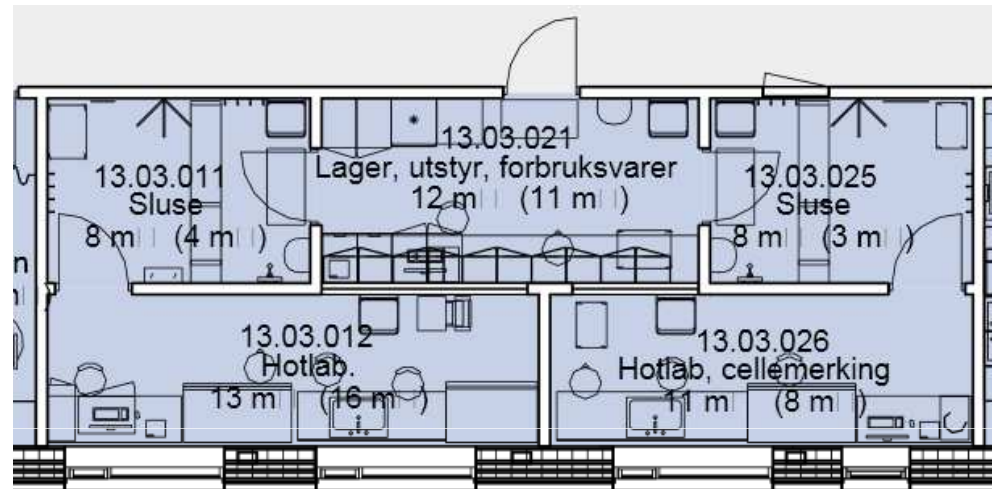
STEP 3 – FUNCTIONAL CLEANROOMS



AREA REQUIREMENTS – HOTLAB AREA

PLANNED AREA

- changing room 1: 8 m²
- laboratory 1: 13 m²
- changing room 2: 8 m²
- laboratory 2: 11 m²
- storage room: 12 m²

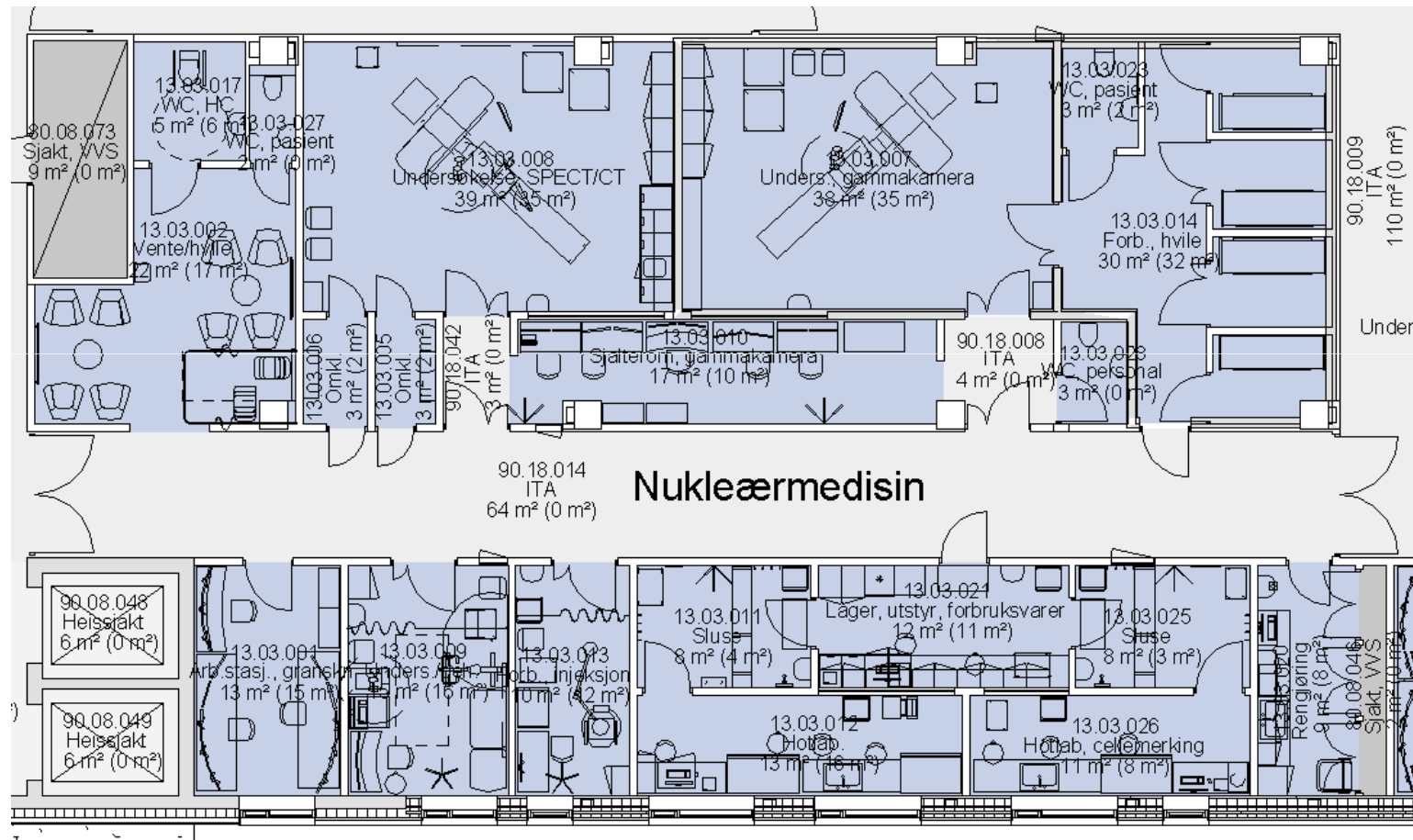


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AREA REQUIREMENTS – HOTLAB AREA

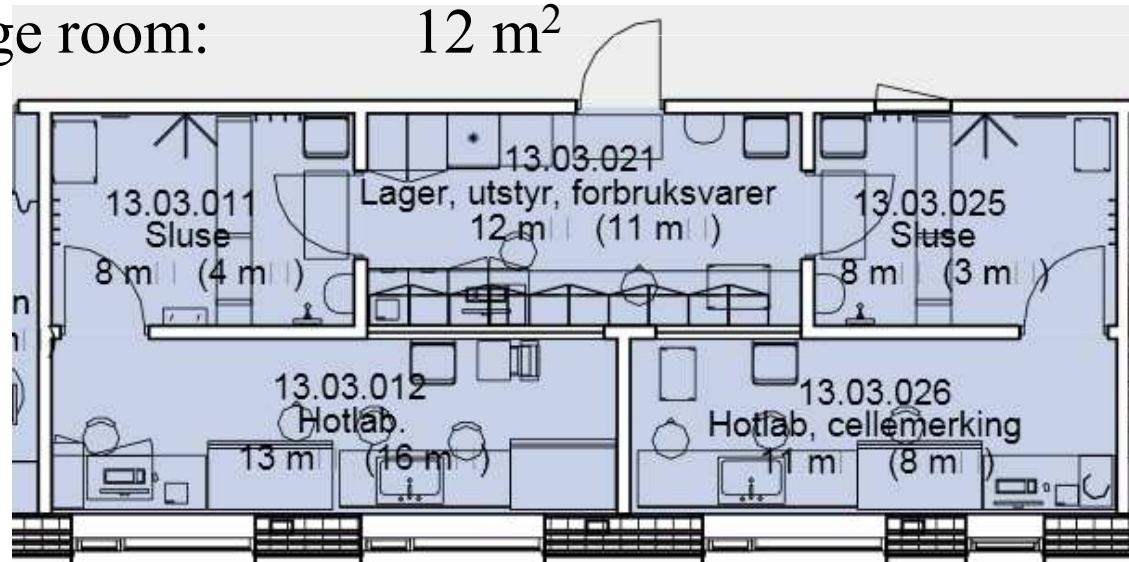
STEP 4 – FINAL LAYOUT



AREA REQUIREMENTS – HOTLAB AREA

PLANNED AREA

- changing room 1: 8 m²
- laboratory 1: 13 m²
- changing room 2: 8 m²
- laboratory 2: 11 m²
- storage room: 12 m²



AREA REQUIREMENTS – HOTLAB AREA

PROGRAMMED AREA

-changing room:	4 m ²
-laboratory:	10 m ²
-storage room:	10 m ²

Total 24 m²

PLANNED AREA

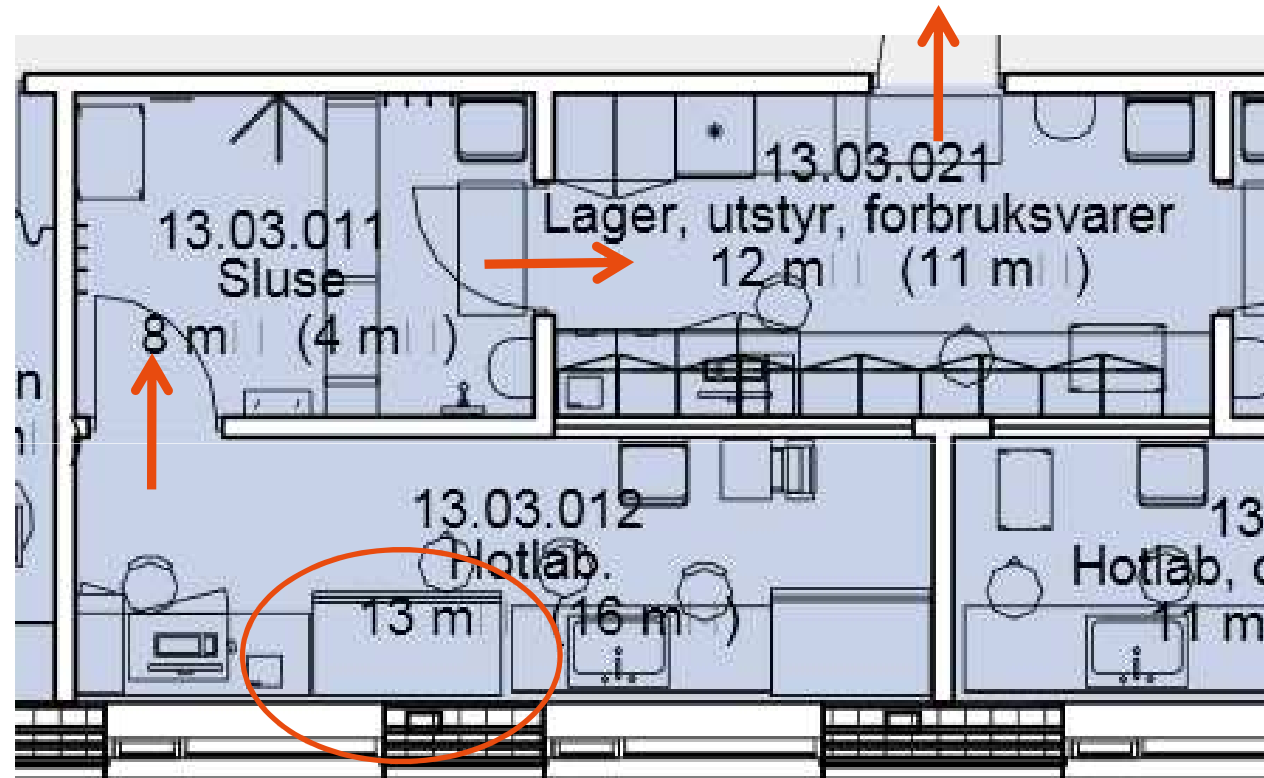
-changing room 1:	8 m ²
-laboratory 1:	13 m ²
-changing room 2:	8 m ²
-laboratory 2:	11 m ²
-storage room:	12 m ²

Total 52 m²
+ technical areas

PRODUCT PROTECTION

Cleanroom
class D

Positive
pressure

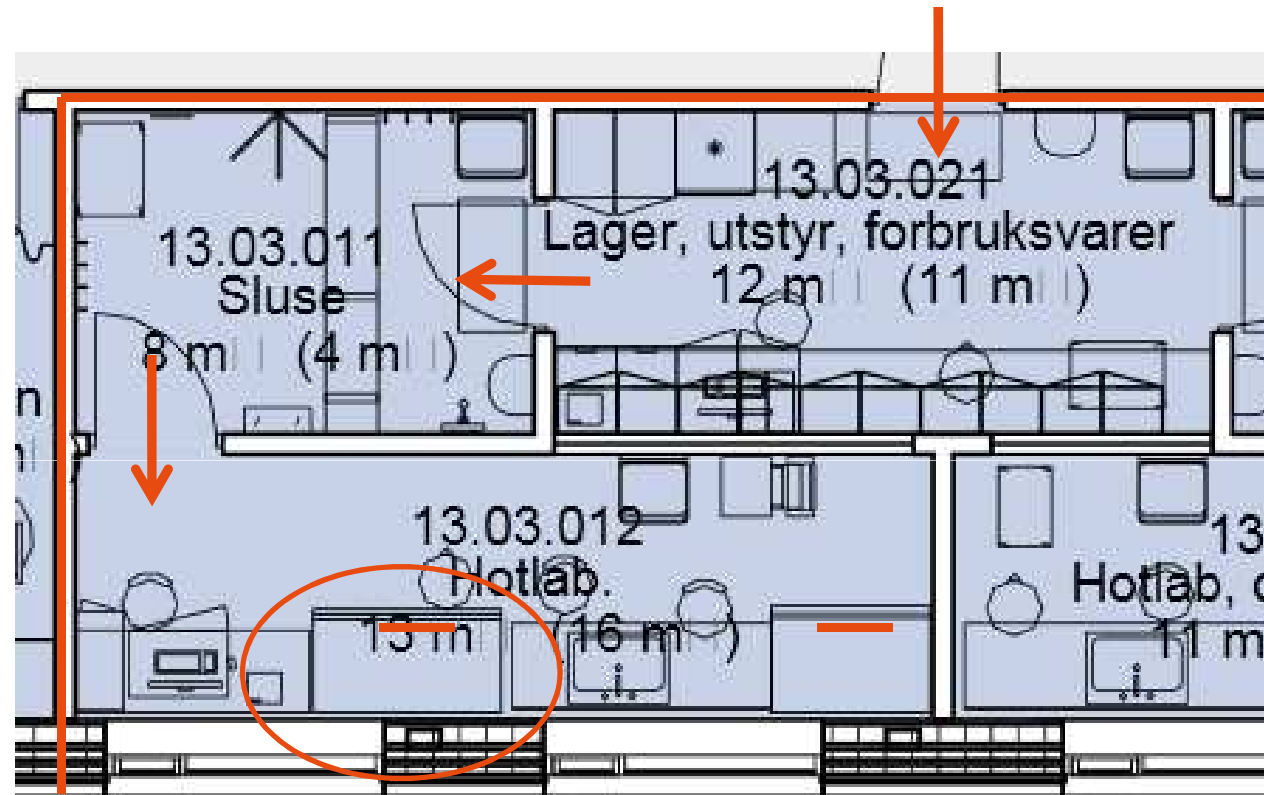


SAFETY CABINET CLASS 2

PERSONNEL PROTECTION

Lead
protection

Negative
pressure



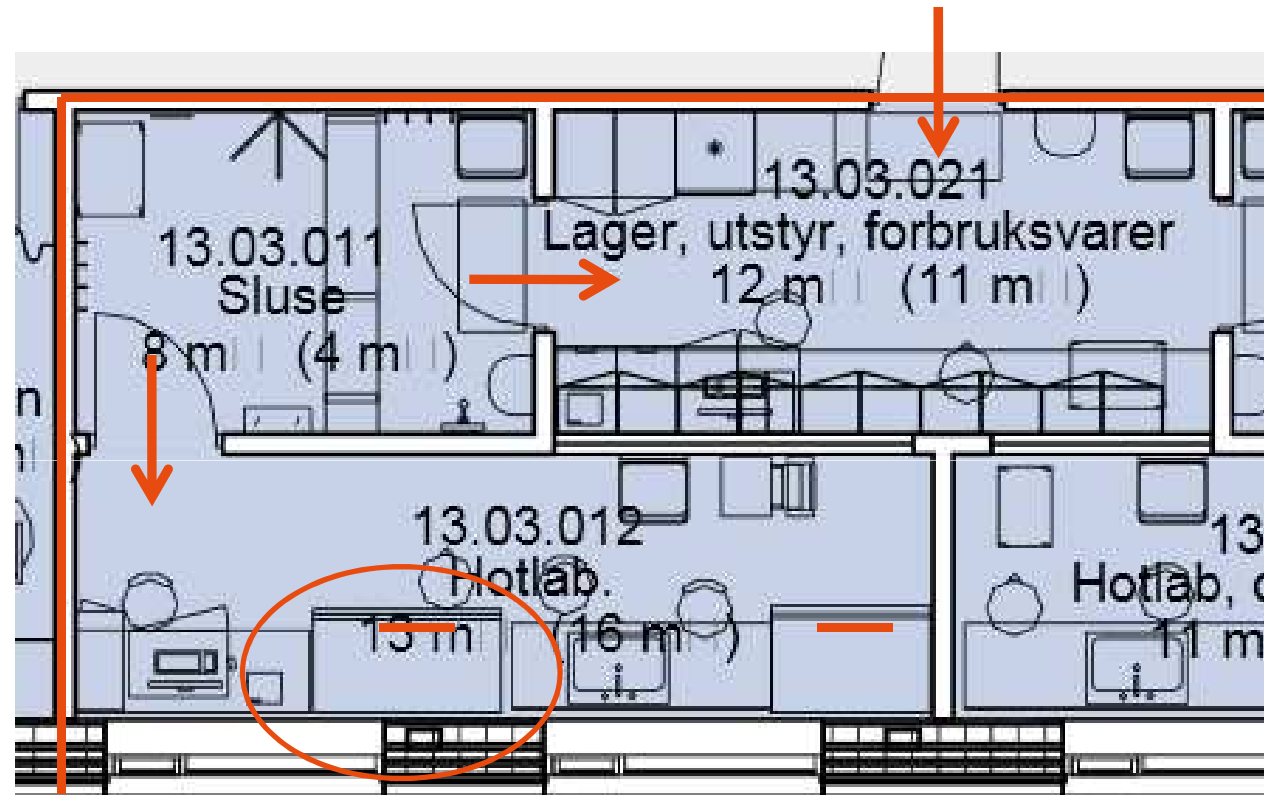
SAFETY CABINET CLASS 2

PRODUCT AND PERSONNEL PROTECTION

Cleanroom
class D

Negative
pressure

Lead
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SAFETY CABINET KL.2