SHIELDED ITM - GALLIUM FLOW CABINET

(Or other products that has to be lifted)

Our starting point was:

- To produce a working space with a laminar flow cabinet with a integrated place for 2 Tc-Generators, a dose calibrator, a lifting place for an ITG – Gallium generator incl. eluting place and a waste separation unit incl. 2 moveable lead windows.

- Good Manufacturing Process.
  1. The European harmonized standards: **EN 12469, CEN EN 475; CEN EN 1281-CENELEC EN 60601-1 und 60601-1-1:** CEN EN 46001 and 46002 (CEN = European Norm Institute) PIC'S 2014

  2. Acc the standard: DIN 12950, till part 10 (for Microbiological and Biotechnical work, demands and certifications.)

SAFETY CABINET CLASS II for the use of Tc-99M & Gallium-68
(**Biological safety Cabinet**)

acc. EN 12469
Dim. working area chamber: 1910 mm x 660mm x 680mm (w x d x h)
Outside dim+/-: 2005mm x 890mm x 2.550mm (w x d x h) by **50mm Pb** lead shielding
Material: - complete inside stainless steel 3.16
Standard: - 2 x glass window, arranged to slide vertically
                - alarm system for air-mistakes inside working area
                - see technical information

Most essential qualities

- guaranteed current of air over the whole working area
- a guaranteed depression up to the pressure-chamber caused by leaving out an inlet-filter
- by building in an extra stainless air-gauze, an absolute equal air-flow is guaranteed.
- Main- (HEPA) and exhaust-filters will be choked equally.
  In case of normal B-lab. use renewing of the filters has to take place after min. 5 years.
- I is a recirculation-cabinet: 70% of the air circulates and 30% outlet resp. inlet
- Continuous under pressure measurement
- Lead shielding on right-, left-, under & backside **50mm** up till the filter high.
- aerosols, caused by the eluting will be sucked off immediately
- building in of a 1 x 2 litre waste-container, shielded with **50** mm lead.
  Material   : steel powder coated
- building-in and mounting of 1 x dose calibrator incl. ionisation-chamber incl back wall display. Lead shielding of Ionisation chamber is **50**mm
- 1 x moveable lead glass 350mm x 500mm, Pb-**30mm** 511 keV 1 x moveable lead glass 350mm x 500mm, Pb-**5mm** 140 keV
- Incl. 1 x laboratory chair
- Total weight incl. cabinet: **4.600 kilo**
  (point pressure is lower <8 kilo/cm²)
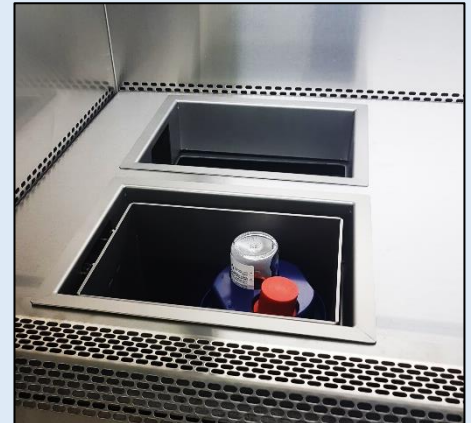
- On the **left side** is a stainless steel drawer built in for the storing/eluting of 2 pce Tc-Generators. (System is exactly the same as the Technetium drawer system.)
Lead drawer has all **around 50mm lead shielding.**

- On the **right side** is a stainless steel Block of 50mm lead surrounded with stainless steel AISI 3.16 to lift the complete Ga-68 unit and to take care that all labelling activities are under GMP conditions.

Please look also at separate video

Double moveable lead glass. The right of has 30mm Pb equivalent

Option 1.1 Active Carbon - Iodine filter.

This filter has to be placed between the exhaust of the laminar flow cabinet and for example the exhaust- air back into the room or into the house ventilation system
Complete housing stainless steel. The filters are made from aluminium and can be changed easily.
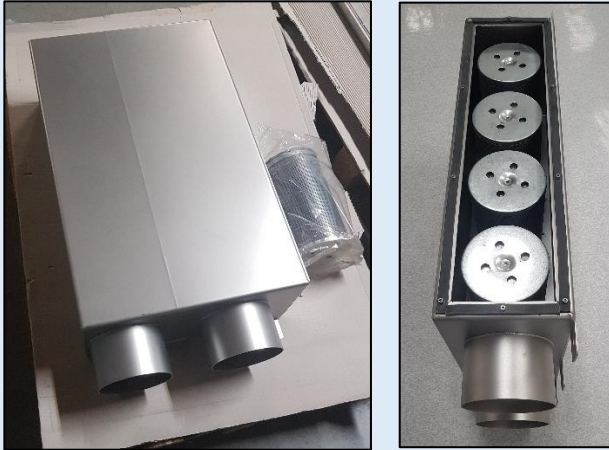
Option 1.2 Pharmacy cabinet

These furniture cabinets are specially made to place in all syringes boxes and all digital equipment, (Computer, printer, disposables etc…..)

Option 1.3 Waste separation.
This cabinet is standing next to the cabinet.
Material partly steel powder coated. The higher part is a Standard cupboard and the lower part is completely surrounded with **25mm** lead shielding.
Inside there is place for 2 x 60 litre containers for plastics & non plastics or glass & non glass products waste.
You can separate the waste directly from the working area inside the cabinet to the waste system. It is also possible that you place 4 x 30 litre containers instead of 2 x 60 lit.
The containers are standing on a sliding screen.
Inside material complete stainless steel.

Option 1.4 Dose calibrator Isomed 2010
 consisting of:
- mini-PC-system (or micro-tower)
- Windows-software licence
- dose calibrator-software ISOMED 2010 with special quality check acc. to DIN
- integrated database with measuring value storage
- Measuring chamber, complete well-type ionization chamber with 4 mm lead
  shielding, incl. electrometer amplifier, type 638200
- sample holder / vial and syringe dipper
- Operation manual Supplied with English software and product documentation
- Cable length from chamber to device: 2.5 meters
- Display 19" monitor build in on the back side of the cabinet (working area)

Option 1.4.1 Test source Cs-137 5MBq with storage box

 Please note that a test source is <u>necessary for periodical quality check</u> according
 to EN 61303.
 Only a Cs-137 test source can be used (5 MBq).
 If you already have such a source, MED is pleased to help by entering the test source
 data into the system (e.g. by phone, e-mail or team viewer).

 We can only supply if the user has to confirm that he has a handling and stock
 licence!

Option 1.4.2 Numeric keyboard with integrated touch-pad, for operation inside
box complete closed keyboard. (GMP) and is for every type of glove, workable.

- rechargeable
- no cables inside cabinet
- complete flat, 10mm thick   .

Option 1.4.3. Printer für Isomed
 Typ Label printer Seiko SLP 440 or equivalent, incl. 10 rolls of paper

  For more info please look at website (chapter measurement)

Option 1.4.4. Software Venus
Radiopharmaceutical Management.
Software for Software for administration , documentation and balancing of produced
Radiopharmaceuticals , As. detailed software description Venus

Interface link (HL7)
e.g. to RIS- or KIS-systems, incl. HL7-module s. detailed software description
Basic price, excl. house inline project-specific adaption**.**

Adaptation/integration into your house RIS system
We are depending on the house RIS, if they are willing
to give the information/data free, so we can connect..

Training (only software … Special skill training)
3 x working day

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