

Meeting on Procurement of Laboratory Items

**Jointly organized by
AIDS Medicines and Diagnostics
Service and Essential Health
Technologies**

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Technical specifications for TB laboratories

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Technical Specifications for Quality Equipment

Covering the needs for **equipment, consumables** and **chemicals** of all TB laboratory activities

➤ **Microscopy**

➤ **Culture - with subsections on**

1. Culture (decontamination/inoculation)

2. Media kitchen

3. DST

4. Molecular Tests

➤ **Detailed specifications on selected items**

Additional considerations

- **Climate** (temperature, humidity, rainy seasons, thunder-storms...)
- **Seismological instabilities**
- **Accessibility of laboratory**
- **Infrastructure** (uninterrupted supply with **clean** water under sufficient **pressure**, uninterrupted supply with electricity of constant voltage, gas supply ...)
- **Laboratory**: Preparedness and condition?

AC Mains Power (Power fluctuations)

- **Spikes**, pulses of high voltage and current usually lasting less than a second (e.g. lightning); multi-outlet power strips with filter of good quality
- **Surges** and **sags**, periods of less severe too high or too low voltage lasting from seconds to few minutes. Laboratory equipment is usually designed to tolerate $\pm 15\%$ of operating voltage; else a voltage stabilizer will be needed
- **Brownouts**, longer sag, lasting minutes or hours
- **Blackouts**, periods of (nearly) zero voltage; UPS or Generator
- **Check for proper grounding at entrance of electricity and plugs**

Detailed Specifications

Pos.	ITEMS AND MAIN SPECIFICATIONS	No of Items	Detailed Specification
1	Binocular Bright Field Microscope	30	Yes
2	Microscope slides , lime soda glass with SiO ₂ : 72 - 74 %, Al ₂ O ₃ : 1 – 1,9 %, Fe ₂ O ₃ : 0.09 – 0.1 %, size 76 x 24 mm, thickness 1.0-1.2 mm according to ISO 8037/1, cleaned and degreased, straight edges and corners, cellophanized (tropical packing, paper in-between) (a box size of 50 is used for calculation; but does not matter much, and should be adjusted when different (e.g. 72 for Chinese packing)	4000	
2a	Alternatively , microscope slides as described in position 2, but with frosted end, 20mm, both sides	4000	
2b	Alternatively , microscope slides as described in position 2a, but edges grinded 90°	4000	

Detailed Specifications (Continued)

NAME OF EQUIPMENT: XXXXXXXXXX		CODE NUMBER YYYYY
Tender specifications		<i>Bidder's Specification</i>
Quantity	<i>MANUFACTURER:</i>	
	<i>Type / Model:</i>	
	<i>Country of Origin:</i>	
Description of function and use:		

Detailed Specifications

All technical specifications on:

- Mechanical, electrical, optical requirements
- Size and structure of the equipment, including special design features
- Materials (and e.g. coating for anticorrosion, its layers, thickness or its heat stability, resistance to disinfectants and so on) to be used for construction
- Accepted noise level
- Minimal light intensity at working area
- Connections (e.g. for electricity, gas, test systems and so on) for additional equipment to be used for work or maintenance/ certification test systems
- Other specific properties

Detailed Specifications (Continued)

Electric needs:

- **Supply voltage:** 230 \pm 10V AC, 50 Hz, European plug** or for USA, Canada, Brazil, Japan 110 \pm 10V AC, 60/50 Hz
- **Consumption:** xyz W
- Conform to electrical safety IEC-60601-1
- Protection class: EN 60529/or country specific
- Circuit radio interference free in accordance with EN 55 014/ or country specific norms

Detailed Specifications (Continued)

- **Accessories**
- **Spare Parts**
- **GLP** : documentations
- **Manufacturer's Certificate** (at least ISO 9001)
- **Quality and Safety standards** met by the product, have to be listed
- **Operation/Maintenance/Service** manuals, at least one set, in... language(s)
- **Warranty**
- **Standard Maintenance Tools**
- **Installation and Maintenance**
- **Packing data**

Technical Specifications for Quality Equipment

MICROSCOPY

Microscope light

Microscope fluorescence

Water distiller

Technical Specifications for Quality Equipment BIOSAFETY

BSC I

BSC II

UPS with battery for BSCs

Thermal anemometer

Atomizer aerosol generator

Particle counter for inspection of BSC

Dilution stage

Emergency spill-kit

FFP2/FFP3 respirators

Technical Specifications for Quality Equipment

CULTURE / DST

Freezer

Refrigerator

Centrifuge

Centrifuge tubes

Gas safety burner

Microincinerator

Hot air sterilizer

Electronic precision balance

Analytical balance

Autoclave

Incubator

pHmeter

Inspissator

Magnetic stirrer

Technical Specifications for Quality Equipment

MOLECULAR TOOLS

Microliter centrifuge

Thermocycler

Ultrasonic bath

PCR workstation

Reaction tubes

Electrophoresis power supply

Mini-shaker

Horizontal electrophoresis system

Thermoshaker

Micro-pipettes 0.5 - 10 ; 10 - 100; 100 - 1,000 μ l

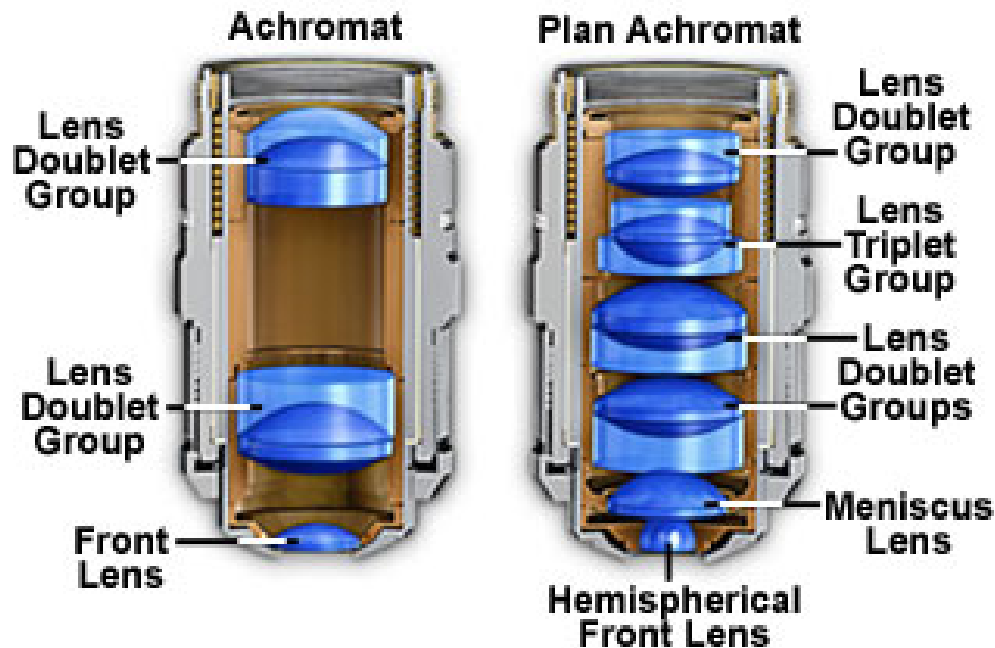
Microscope

- **Description of function and use**
- **Mechanical parts**
- **Optical parts**
- **Electrical parts**

Microscope (Continued)

Plan Achromat (corrected for field curvature, spherical and chromatic aberration) parfocal and parcentered infinity corrected objectives

Objective Correction for Field Curvature



Microscope

(Continued)

- All optical parts including objectives, eye pieces, lenses, prisms, should have **anti-reflex coating**
- The entire optical system must be “**anti-fungus**” treated (all components incl. fixation) with a warranty of **3** years
- Binocular, viewing angle 30° , tube rotateable through 360° . Inter-pupillary distance ranging from at least **50 – 75** mm,
- Eye pieces, paired, high quality, achromatic, 10x magnification, field number ≥ 18 , diopetre adjustment

Microscope

(Continued)

- All objectives should be engraved with the following information:
 1. Name or code of the manufacturer
 2. Magnification and numerical aperture
 3. Sign: ∞
 4. 100 x objective with identification for immersion oil (word oil and/or colour code)
- For fluorescence microscopes objectives must be corrected for the use with **NO COVER GLASS (NCO)**

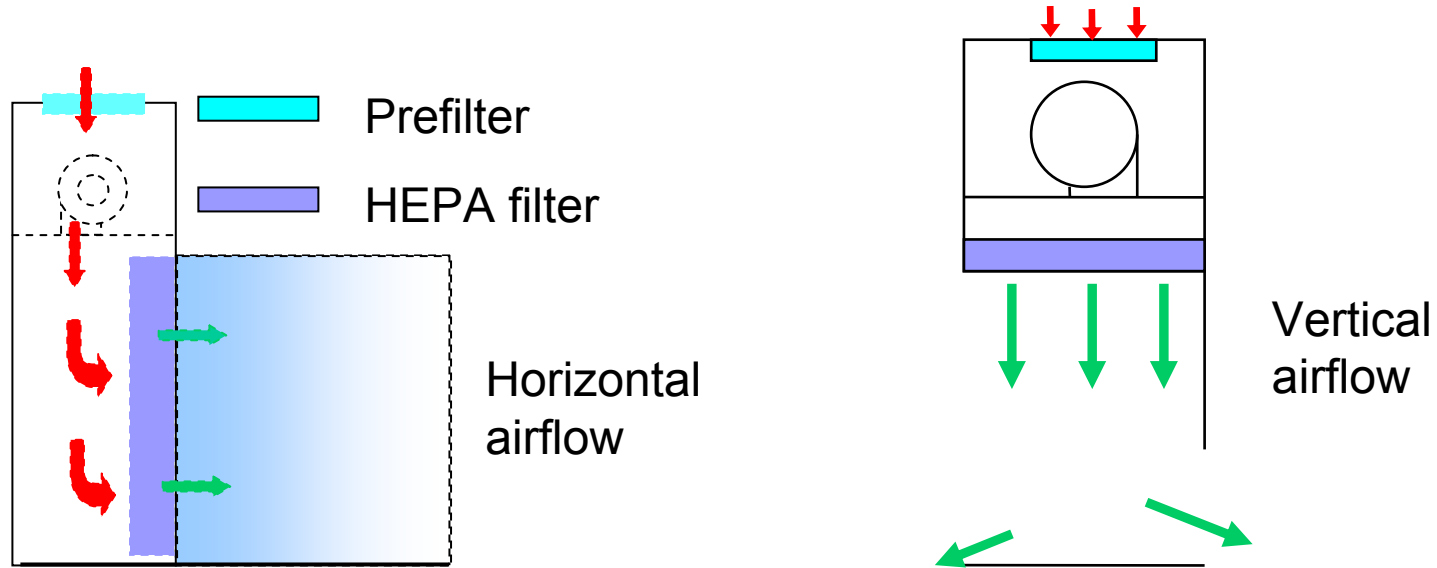
BSCs - Lessons learned

Terms like “Laminar Flow Hoods (Laminar Flow Units or Cabinets)” and

“Biological Safety Cabinets” are clearly defined.

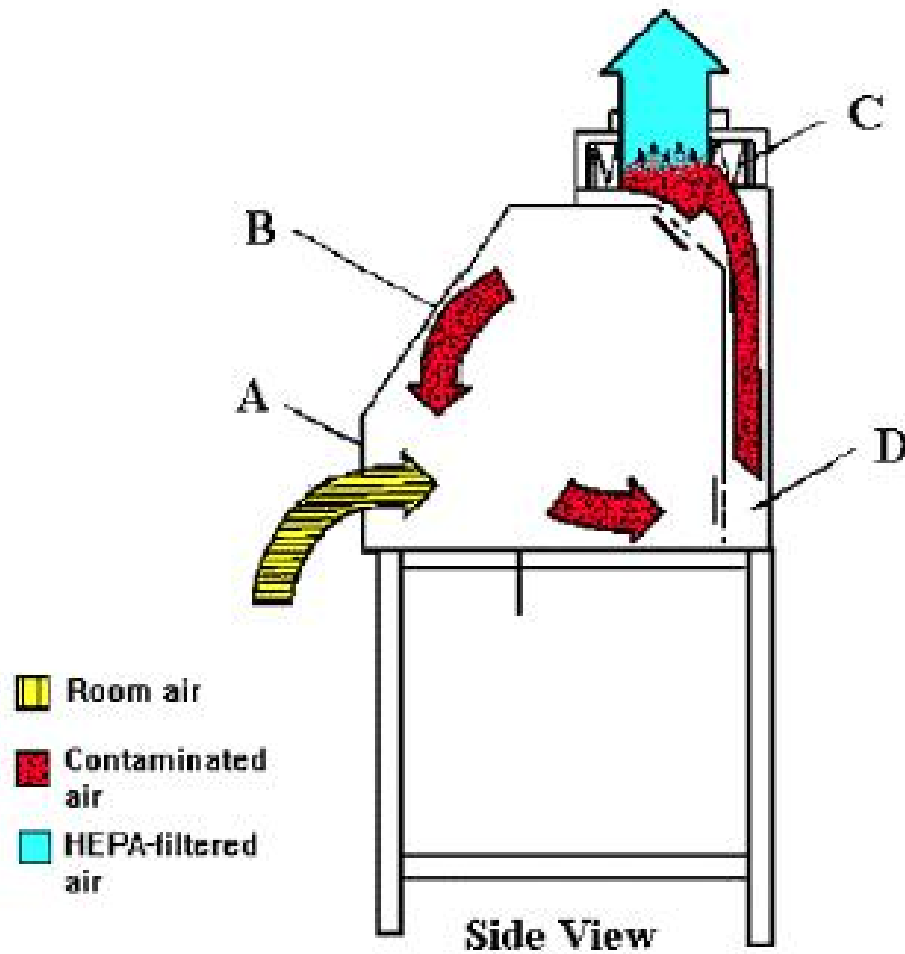
It is important to pay attention to their differences in design and use!

Laminar Flow Hoods



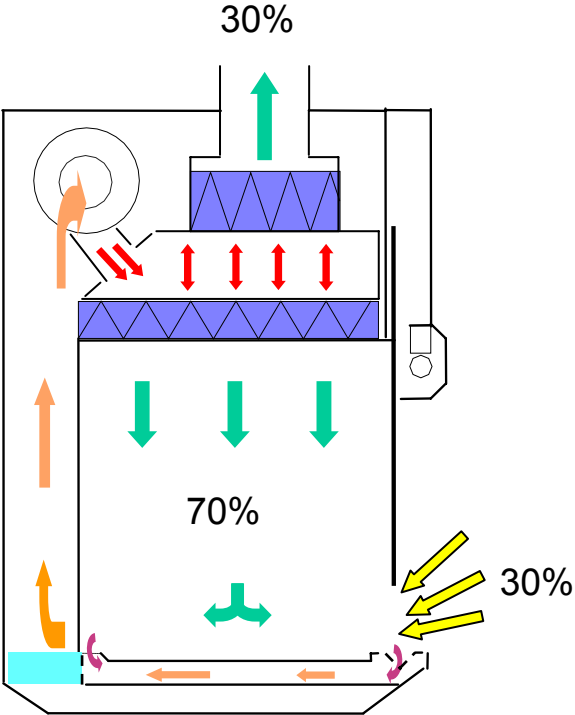
- Provide product protection only and **must not be used when working with any form of biohazard or chemical hazard**
- **Any potentially infectious aerosol that is created on the work bench will lead to exposure of the operator and the environment**
- Horizontal-flow clean-air bench are used for preparing culture media, cell cultures

BSC I



BSC II A

Flow pattern









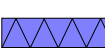
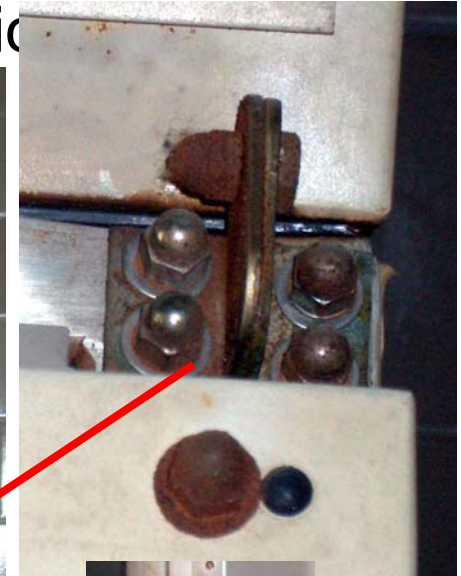
-  Inflow room air
-  Recirculation in the BSC
-  Pressure plenum
-  HEPA filtered air
-  Downflow 70%, Exhaust 30%
-  Prefilter
-  HEPA Filter

Table 3. Summary of biosafety level requirements

	BIOSAFETY LEVEL		
	1	2	3
Isolation ^a of laboratory	No	No	Yes
Room sealable for decontamination	No	No	Yes
Ventilation:			
— inward airflow	No	Desirable	Yes
— controlled ventilating system	No	Desirable	Yes
— HEPA-filtered air exhaust	No	No	Yes/No ^b
Double-door entry	No	No	Yes
Airlock	No	No	No
Airlock with shower	No	No	No
Anteroom	No	No	Yes
Anteroom with shower	No	No	Yes/No ^c
Effluent treatment	No	No	Yes/No ^c
Autoclave:			
— on site	No	Desirable	Yes
— in laboratory room	No	No	Desirable
— double-ended	No	No	Desirable
Biological safety cabinets	No	Desirable	Yes
Personnel safety monitoring capability ^d	No	No	Desirable

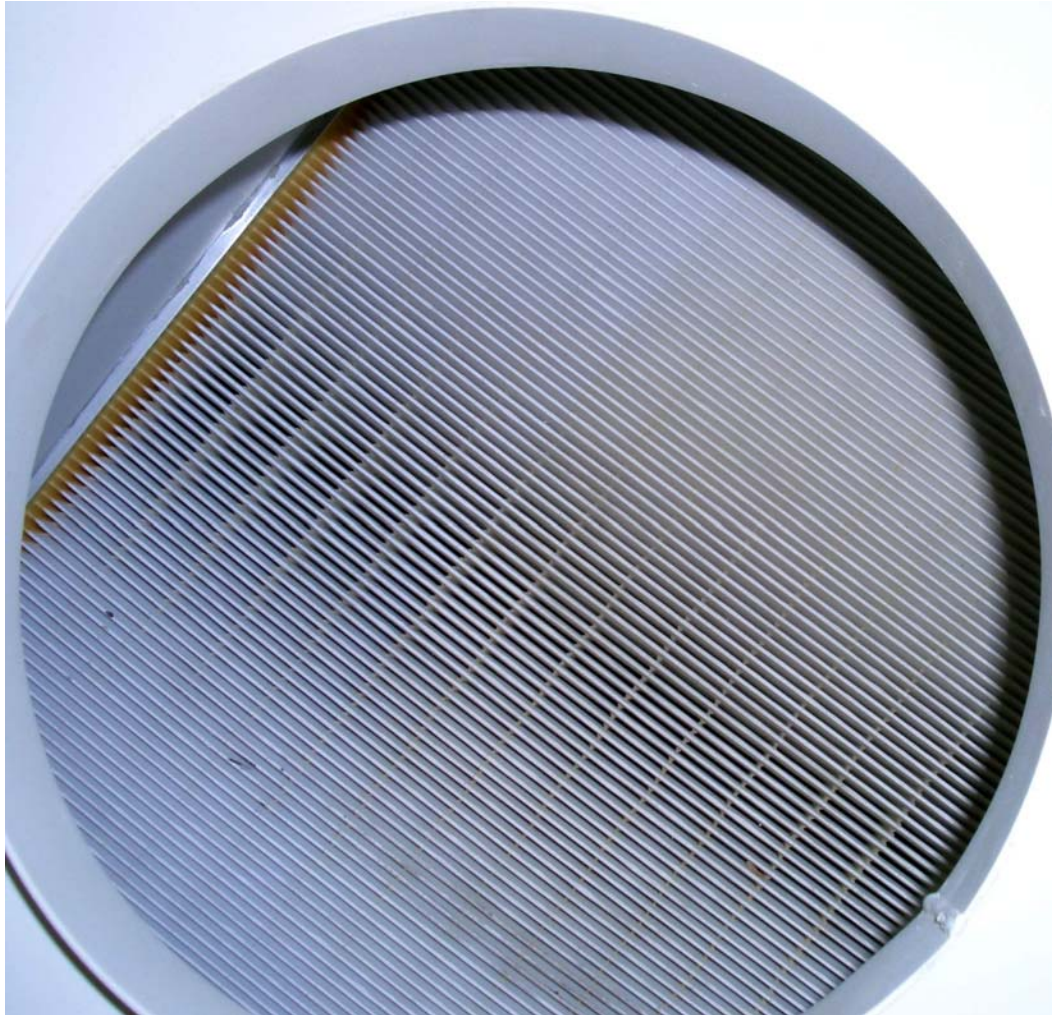
Findings: Three year old BSC class I, **No duct out!** no certification at all. No maintenance. No filter protection. No spare filter. 90 cm stand used in sitting position

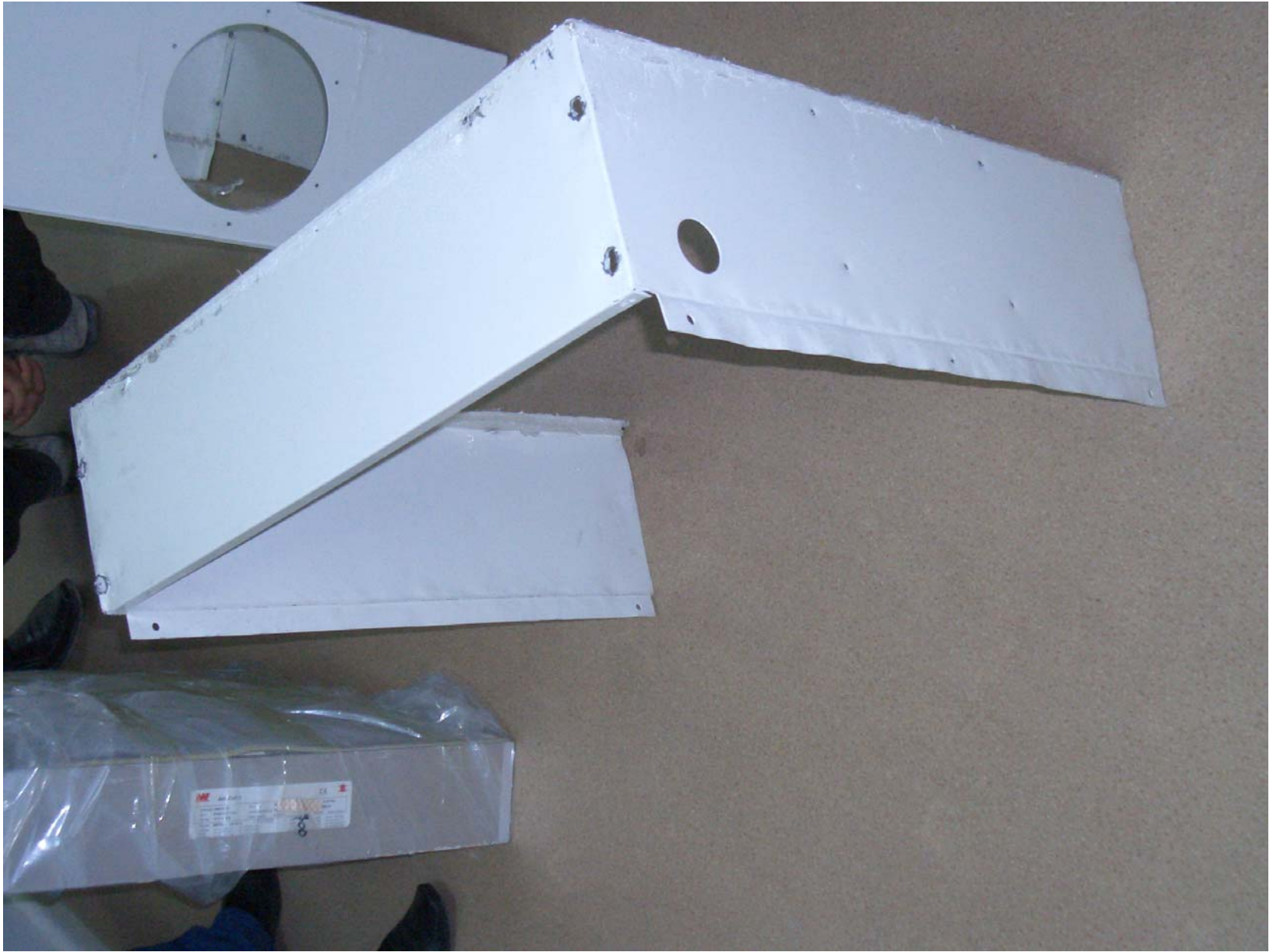


Consequences

- Ask for the country of origin
- Define material to be used e. g.
 - a) Inner housing stainless steel, 304 grading
 - b) Outer housing stainless steel, incl. screws/hinges or equivalent resistant galvanized (zinc-coated) sheet steel, subsequently powder coated and thermally hardened, (thickness min. 80 μm), resistant to disinfectants, chemicals used in a TB-lab and abrasion resistant. **Non rusting screws/hinges are unalterable (alcohol/HCl).**

Unprotected HEPA Filter





Consequences

Order:

- Grids and hoods from the company which produced the BSC
- Advice the local handicraft men not to alter any delivered device and to adjust their constructions to the delivered ones
- Port or stand for BSC
- Adjustable, disinfectable 5-wheel chair without armrest
- Plugs inside the BSC suited for equipment used inside
- Organise Initial On-site Testing before use and a service for maintenance and certification of BSCs





Consequences

Instruct local people about

- Location and power of extractor fan
- Cross section, design and length of air leading pipes
- Material, thickness and coating to be used for tubes
- Its fittings
- Electro installation, number of plugs, their location, including proper grounding
- Gas installation, including valves (if gas is used)

Three year old autoclave



Costs vs. Best Price

Warranty – Maintenance (Service contract)

Main questions to be addressed for highly technical equipment:

- What is the cost of maintenance per year of operation?
- Which spare parts does this service include?
- Has the supplier/company and/or manufacturer a service representative in the area or have they built up any other capacities or structures to respond adequately (within 14 days when difficulties with the equipment are reported)?
- If this is not fulfilled, it usually will be better to buy an equipment of highest quality with longer warranty or to pay for a prolonged warranty/service in advance.

Standard Tender Documents (Continued)

The Requirements

III.i	Specifications
III.ii	Drawings

Technical Specifications shall normally be fully descriptive and give the full requirements in respect of, but not limited to, the following

- (a) standard of materials and workmanship required;
- (b) details of all factory tests required (type and number);
- (c) details of all work required to achieve completion;
- (d) details of all precommissioning and commissioning activities to be performed by the contractor;
- (e) details of all functional guarantees required and liquidated damages to be applied in the event that such guarantees are not met.