

URS Cabinets Clothes (in sluices for “clean clothes”)

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Cabinets have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Dimensions: as large as possible, see drawings for location and available space.	B		
2.2	Tilted top-plate to avoid allocation of dirt.	A		
2.3	Doors that give easy access.	A		
2.4	Floor based cabinets on wheels to move for easy cleaning below and behind cabinets or shielded feed to avoid dirt traps. The vendor should give suggestions.	B		
2.5	Materials: The vendor should give suggestions for suitable materials.	B		
2.6	Door handles that are easy to use and clean.	B		
3.0	“Specific for this equipment”			
3.1	Solid racks inside the cabinets.	B		
3.2	Racks should be height adjustable in three to five centimeter increments.	B		
4.0	Others			
4.1	The vendor has to provide a manual that is easy to understand.	A		
4.2	The manual has to be in English and if possible Norwegian language.	B		
4.3	The vendor has to perform a test of function of each cabinet before delivery.	A		
4.4	The vendor has to perform a test of function of each cabinet on site.	A		
4.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			
6.1	The supplier should provide adequate training for both maintenance and operation of cabinets.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
7.3	The vendor has to test the equipment on site and document function as described.	B		

7.4	Localization: see drawings of the facility	B		
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A = minimal requirements
B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Cabinets Clothes (in sluices for “unclean clothes”)

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Cabinets have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Dimensions: as large as possible, see drawings for location and available space.	B		
2.2	Tilted top-plate to avoid allocation of dirt.	A		
2.3	Doors that give easy access.	A		
2.4	Floor based cabinets on wheels to move for easy cleaning below and behind cabinets or shielded feed to avoid dirt traps. The vendor should give suggestions.	B		
2.5	Materials: The vendor should give suggestions for suitable materials.	B		
2.6	Door handles that are easy to use and clean.	B		
3.0	“Specific for this equipment”			
3.1	Clothes rail for clothes hangers.			
3.2	Solid racks inside the cabinets above the clothes rail.	B		
3.3	Racks should be height adjustable in three to five centimeter increments.	B		
4.0	Others			
4.1	The vendor has to provide a manual that is easy to understand.	A		
4.2	The manual has to be in English and if possible Norwegian language.	B		
4.3	The vendor has to perform a test of function of each cabinet before delivery.	A		
4.4	The vendor has to perform a test of function of each cabinet on site.	A		
4.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			
6.1	The supplier should provide adequate training for both maintenance and operation of cabinets.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		

7.3	The vendor has to test the equipment on site and document function as described.	B		
7.4	Localization: see drawings of the facility	B		

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Explanation Initials

Initials	Name	Signature

URS Cabinets Consumables

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Cabinets have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Dimensions: as large as possible, see drawings for location and available space.	B		
2.2	Tilted top-plate to avoid allocation of dirt.	A		
2.3	Doors that give easy access.	A		
2.4	Floor based cabinets on wheels to move for easy cleaning below and behind cabinets or shielded feed to avoid dirt traps. The vendor should give suggestions.	B		
2.5	Materials: The vendor should give suggestions for suitable materials.	B		
2.6	Door handles that are easy to use and clean.	B		
3.0	“Specific for this equipment”			
3.1	Solid racks inside the cabinets.	B		
3.2	Racks should be height adjustable in three to five centimeter increments.	B		
4.0	Others			
4.1	The vendor has to provide a manual that is easy to understand.	A		
4.2	The manual has to be in English and if possible Norwegian language.	B		
4.3	The vendor has to perform a test of function of each cabinet before delivery.	A		
4.4	The vendor has to perform a test of function of each cabinet on site.	A		
4.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			
6.1	The supplier should provide adequate training for both maintenance and operation of cabinets.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
7.3	The vendor has to test the equipment on site and document function as described.	B		

7.4	Localization: see drawings of the facility	B		
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Explanation Initials

Initials	Name	Signature

URS Cabinets Valuables

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Cabinets have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for sluices in cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Space for up to 20 compartments, sized 30x30x40 cm (HxBxD). Supplier should advise on details.	B		
2.2	Compartments should be lockable. Describe different possibilities of integrated and external locks.	B		
2.3	Floor based on wheels for easy movement to clean beneath and behind. Or wall mounted. Vendor should describe possible solutions.	B		
2.4	Materials: The vendor should give suggestions for suitable materials.	B		
3.0	Others			
3.1	The vendor has to provide a manual that is easy to understand.	A		
3.2	The manual has to be in English and if possible Norwegian language.	B		
3.3	The vendor has to perform a test of function of each cabinet before delivery.	A		
3.4	The vendor has to perform a test of function of each cabinet on site.	A		
3.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
4.0	Demands for documentation and equipment			
4.1	The supplier should provide adequate system management documentation.	A		
5.0	Training			
5.1	The supplier should provide adequate training for both maintenance and operation.	A		
6.0	Localization and installation			
6.1	The vendor has to remove and dispose of the wrapping.	B		
6.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
6.3	The vendor has to test the equipment on site and document function as described.	B		
6.4	Localization: see drawings of the facility	B		

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Explanation Initials

Initials	Name	Signature

URS Chairs

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Chairs have to have a smooth surface that is easy to clean.	A		
1.2	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
1.3	Seamless design with as few as possible joints to avoid dirt traps.	B		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Chairs have to be GMP compliant and suitable in a clean room environment.	A		
2.2	Material: The vendor has to describe and recommend alternatives.	B		
2.3	Working height: 35 to 50 cm at desks and LAF benches, 50 to 75 cm at high work benches.	B		
2.4	Chairs have to be height adaptable. The buffering system should contain particle reducing filters.	B		
2.5	Chairs have to be equipped with wheels, suited for a hard floor and not producing particles.	B		
2.6	Compact and space saving design.	B		
2.7	Washable and resistant to disinfectants.	A		
3.0	Others			
3.1	The vendor has to provide a manual that is easy to understand.	A		
3.2	The manual has to be in English and if possible Norwegian language.	B		
3.3	The vendor has to perform a test of function of each chair before delivery.	A		
3.4	The vendor has to perform a test of function of each chair on site.	A		
3.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
4.0	Demands for documentation and equipment			
4.1	The supplier should provide adequate management documentation.	A		
5.0	Training			
5.1	The supplier should provide adequate training for both maintenance and operation of the chairs.	A		
6.0	Localization and installation			
6.1	The vendor has to remove and dispose of the wrapping.	B		
6.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
6.3	The vendor has to test the equipment on site and document function as described.	B		
6.4	Localization: see drawings of the facility	B		

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Date, Signature Vendor

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Explanation Initials

Initials	Name	Signature

URS Desk height adjustable

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Desks have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	GMP compliant and suitable in a clean room environment.	A		
2.2	Material: steel or other suitable materials. The vendor has to describe and recommend alternatives.	B		
2.3	Working height: adjustable, around 70 to 100 cm.	B		
2.4	Depth and width of desks: when possible 80cm. Refer to drawings for placement, width and depth.	B		
2.5	On a suitable scaffold with wheels. The vendor has to describe and recommend alternatives.	B		
2.6	Desks have to fit in all areas described, see figures.	B		
2.7	Desks have to be equipped with drawer sections underneath, see figures of the facility for detailed location.	B		
2.8	Mechanical adjustment of height of desk. The vendor has to describe and recommend alternatives.	B		
3.0	Others			
3.1	The vendor has to provide a manual that is easy to understand.	A		
3.2	The manual has to be in English and if possible Norwegian language.	B		
3.3	The vendor has to perform a test of function of each desk before delivery.	A		
3.4	The vendor has to perform a test of function of each desk on site.	A		
3.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
4.0	Demands for documentation and equipment			
4.1	The supplier should provide adequate system management documentation.	A		
5.0	Training			
5.1	The supplier should provide adequate training for both maintenance and operation.	A		
6.0	Localization and installation			
6.1	The vendor has to remove and dispose of the wrapping.	B		
6.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
6.3	The vendor has to test the equipment on site and document function as described.	B		

6.4	Localization: see drawings of the facility	B		
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Explanation Initials

Initials	Name	Signature

URS Desk

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Desks have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	GMP compliant and suitable in a clean room environment.	A		
2.2	Material: steel or other suitable materials. The vendor has to describe and recommend alternatives.	B		
2.3	Working height: around 70 cm.	B		
2.4	Depth and width of desks: when possible 80cm. Refer to drawings for placement, width and depth.	B		
2.5	Mounted to the wall or on a suitable scaffold with wheels. The vendor has to describe and recommend alternatives.	B		
2.6	Desks have to fit in all areas described, see figures.	A		
2.7	Desks have to be equipped with drawer sections underneath, see figures of the facility for detailed location.	A		
3.0	Others			
3.1	The vendor has to provide a manual that is easy to understand.	A		
3.2	The manual has to be in English and if possible Norwegian language.	B		
3.3	The vendor has to perform a test of function of each desk before delivery.	A		
3.4	The vendor has to perform a test of function of each desk on site.	A		
3.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
4.0	Demands for documentation and equipment			
4.1	The supplier should provide adequate system management documentation.	A		
5.0	Training			
5.1	The supplier should provide adequate training for both maintenance and operation.	A		
6.0	Localization and installation			
6.1	The vendor has to remove and dispose of the wrapping.	B		
6.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
6.3	The vendor has to test the equipment on site and document function as described.	B		
6.4	Localization: see drawings of the facility	B		

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Explanation Initials

Initials	Name	Signature

URS Hanging Cabinets Consumables

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Cabinets have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Depth and width of cabinets: As big as possible. Refer to drawings for placement, width and depth.	B		
2.2	Hanging on the wall or stably standing on a work-bench or desk.	B		
2.3	Tilted top-plate to avoid allocation of dirt.	A		
2.4	Doors that give easy access.	A		
2.5	Door handles that are easy to use and clean.	B		
2.6	Materials: The vendor should give suggestions for suitable materials.	B		
3.0	“Specific for this equipment”			
3.1	Solid racks inside the cabinets.	B		
3.2	Racks should be height adjustable in three to five centimeter increments.	B		
4.0	Others			
4.1	The vendor has to provide a manual that is easy to understand.	A		
4.2	The manual has to be in English and if possible Norwegian language.	B		
4.3	The vendor has to perform a test of function of each cabinet before delivery.	A		
4.4	The vendor has to perform a test of function of each cabinet on site.	A		
4.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			
6.1	The supplier should provide adequate training for both maintenance and operation.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
7.3	The vendor has to test the equipment on site and document function as described.	B		

7.4	Localization: see drawings of the facility	B		
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Date, Signature Vendor

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Explanation Initials

Initials	Name	Signature

URS Intercom

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
1.2	Intercoms have to have a smooth surface that is easy to clean.	A		
1.3	Washable and resistant to disinfectants.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Talking from room to room, choose which room.	A		
2.2	Doorbell function	A		
2.3	Call with picture, camera at door bell side, monitor on recipient side.	B		
2.4	Build in the wall close to the doors. See drawings for location.	B		
2.5	Spare-parts and replacements have to be deliverable for 9 years in the future.	B		
2.6	Smooth surface that is easy to clean.	A		
2.7	Easy to handle also with clean room gowning and gloves.	B		
2.8	Touchscreen	B		
3.0	Electronic functions and controls			
3.1	See 2.0 Demands			
4.0	“Specific for this equipment”			
4.1	See 2.0 Demands			
5.0	Safety and alarms			
5.1	Connected to fire alarm system	B		
5.2	Panic button connected to main areas of EVF and Haukeland security	B		
6.0	Others			
6.1	The vendor has to provide a manual that is easy to understand.	A		
6.2	The manual has to be in English and if possible Norwegian language.	B		
6.3	The vendor has to perform a test of function of each intercom unit before delivery.	A		
6.4	The vendor has to perform a test of function of each intercom unit on site.	A		
6.5	The vendor has to perform a test of function for the whole intercom network on site.	A		
6.6	The vendor has to provide documentation of test and function of the delivered equipment.	A		
7.0	Demands for documentation and equipment			
7.1	The supplier should provide adequate system management documentation.	A		
8.0	Training			

8.1	The supplier should provide adequate training for both maintenance and operation.	A		
9.0	Interfaces			
9.1	Touchscreen	B		
9.6	Doorbell	A		
9.6	Camera			
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
10.3	The vendor has to test the equipment on site and document function as described.	B		

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Explanation Initials

Initials	Name	Signature

URS Laboratory Hand Sink

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Sinks have to have a smooth surface that is easy to clean.	A		
1.2	Sinks have to be equipped with faucet and basket drain.	A		
1.3	Warm and cold water with a mixing battery.	A		
1.4	The sinks should be CE labeled according to current directives and follow Norwegian laws and regulations.	A		
1.5	Sinks have to be safe to operate in a GMP environment (class C and D) according to current directives and follow Norwegian laws and regulations.	A		
1.6	Sinks have to be connected to drains that prohibit a spill back into the room. The supplier should give suggestions for such a system.	B		
1.7	Washable and resistant to disinfectants.	A		
1.8	Suitable for cleanrooms in air purity class D/C in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Sinks have to be delivered as a solid construction, build with lasting and enduring materials that can withstand long and demanding use. All surfaces, screws, bolts, connections and so on have to be maintenance free. Documentation by the manufacturer.	A		
2.2	Sinks have to be mounted to the wall.	B		
2.3	For placement of sinks see drawings.	B		
2.4	Material: steel or other suitable materials. The vendor has to describe and recommend alternatives.	B		
3.0	Electronic functions and controls			
3.1	Water flow has to be controlled automatically by a sensor.	B		
3.2	The sensor should be powered by electricity or batteries which are easy to exchange.	B		
4.0	“Specific for this equipment”			
4.1				
5.0	Safety and alarms			
5.1	Sinks should be equipped with a water sensor that detects leakage and stops water flow automatically and sends an alarm to the connected alarm system. The supplier should give suggestions for such a system.	B		
6.0	Others			
6.1	The vendor has to provide a manual that is easy to understand.	A		

6.2	The manual has to be in English and if possible Norwegian language.	B		
6.3	The vendor has to perform a test of function of each sink before delivery.	A		
6.4	The vendor has to perform a test of function of each sink on site.	A		
6.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
7.0	Demands for documentation and equipment			
7.1	The supplier should provide adequate system management documentation.	A		
8.0	Training			
8.1	The supplier should provide adequate training for both maintenance and operation.	A		
9.0	Localization and installation			
9.1	The vendor has to remove and dispose of the wrapping.	B		
9.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
9.3	The vendor has to test the equipment on site and document function as described.	B		
9.4	Localization: see drawings of the facility	B		

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Explanation Initials

Initials	Name	Signature

Laminar Air Flow (LAF) benches Class 2 for EFV

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	The LAF bench has to be constructed in a way that the air inside the bench under normal use is clean/sterile	A		
1.2	The LAF bench should have laminar air flow to protect the product in the best possible manner	A		
1.3	The air in the work zone has to be as clean as possible depending on the background of the cleanroom according to ISO 14644 - 1 (1999; Cleanrooms and Associated Controlled Environments and inform about the cleanroom class that is achieved during normal use).	B		
1.4	Suitable for placement inside cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
1.5	Documentation about testing has to be attached	B		
1.6	The LAF bench and/or parts of it have to be CE labelled according to current directives and follow Norwegian laws and regulations.	A		
1.7	It is highly desirable that the LAF bench produces as little as possible noise. The producer has to provide documentation of the noise measurements and how they were obtained.	B		
	The LAF bench should produce as little as possible particles that are released to the cleanroom environment. Documentation about particle release should be provided by the manufacturer.	B		
2.0	Demands about dimensions, function and mechanical setup			
2.1	The LAF bench has to be delivered as a solid construction, build with lasting and enduring materials that can withstand long and demanding use. All surfaces, screws, bolts, connections and so on have to be maintenance free. Documentation by the manufacturer.	B		
2.2	All connections, gaps and seams have to consist of enduring materials and be treated with anti-microbial surfaces. Documentation by the manufacturer.	B		
2.3	The LAF benches are to be placed in rooms with approx. 240cm height. There has to be enough space for access for maintenance and repair of components on the top of the bench. Description by the manufacturer.	B		
2.4	The LAF bench has to be delivered with a floor-stand that is very stable with welded or well-connected parts for the construction. The feet of the construction should contain wheels for easy movement. Description by the manufacturer, also of surface treatment.	B		
2.5	The LAF bench has to have a maximum width of 170cm. The working surface inside the bench is supposed to be according to the manufacturer's standards. Description by the manufacturer.	B		

2.6	The rooms in the facility have limited areas. The depth of the LAF benches and their distance from the wall is crucial for the function of the room. It is important that the depth of the bench gives a good work environment and the distance of the back of the bench to the wall is as small as possible.	B		
2.7	The legs at the back of the LAF bench have to be indented to avoid a conflict with the cleaning edge of the lower wall, so that the back of the bench can be placed as close as possible to the wall. Description by the manufacturer.	B		
2.8	The LAF bench has to be delivered with a working height of around 90cm.	A		
2.9	Describe possibilities to adjust the legs of the LAF bench to guarantee the leveled placement of the bench even if the floor is uneven.	B		
2.10	The wheels on the legs of the LAF bench should be made of materials that do not wear on the floor. Description by the manufacturer.	B		
2.11	The LAF bench is delivered with the standard surface in stainless and acid resistant steel. The manufacturer has to provide documentation of the materials used and their properties.	B		
2.12	The design of the work area of the LAF bench has to facilitate easy cleaning and accessibility for maintenance. Smooth surfaces that can be easily cleaned and disinfected are important.	B		
2.13	It is important that the working area in the LAF bench is well illuminated and bright. Please describe possibilities for illumination and transparent walls of the bench.	B		
2.14	Integrated HEPA filters of the LAF bench have to filter all air that comes in contact with the product.	A		
2.15	The LAF bench has to be constructed in compliance with cGMP regulations.	A		
2.16	The LAF bench should have a function, either manually or automatically, to reduce ventilation speed when at rest to save the material from excess burden. Describe solutions.	B		
2.17	The LAF bench will be located in a room with limited space, possibly next to each other or other equipment or walls. It is important that service, repair and maintenance can be performed easily without major rearrangements in the room. Describe the need to access the LAF bench from the sides, back or top.	B		
2.18	In case the LAF bench has to be removed from a cleanroom it has to fit through the doors and corridors without changes of the building. An easy way to deconstruct the bench or transport upraised would be beneficial. Describe possible solutions.	B		
2.19	It is important that the LAF bench is equipped with an easily accessible control board and easy to use control panel.	A		

2.20	It is important that the LAF bench has a ledge at the opening that is as narrow as possible to ensure a comfortable working position for the operators. Describe solutions.	B		
2.21	The air out does not need a HEPA filter for protection of the outside environment.	B		
3.0	Electronic functions and controls			
3.1	The LAF bench has to be delivered with a cable and power-plug that is compatible with Norwegian regulations for 230V, 16A, power plug, circuit.	A		
3.2	The LAF bench has to have at least 2 power sockets inside the working area on the walls.	A		
3.3	The LAF bench has to be delivered with an integrated light source that delivers an evenly distributed illumination of about 1000 Lux evenly distributed over the whole working area.	A		
3.4	The LAF bench has to have a UV light source for sterilization of the work area. This UV light source has to be built in or easily to be used for sterilization after a work-shift. The UV light should not be a danger for personnel and equipment in close vicinity of the bench. Describe possible solutions.	B		
3.5	The LAF bench should have a monitor showing the performance of the ventilation in real time and the history of performance of the LAF bench. Describe solutions.	B		
4.0	Ventilation, air flow and more			
4.1	The LAF bench is part of the ventilation system in the room it is placed in.	A		
4.2	The LAF bench is not directly connected to the ventilation system. The air flow out of the bench is removed by the ventilation system. There is no direct connection between bench and ventilation system (“brudd avtrekk”).	B		
5.0	Safety and alarms			
5.1	The LAF bench has to be equipped with a system that gives a local alarm in case of deviation of the air flow rate in the work area. Other deviations can also trigger an alarm. Describe solutions, functions and adjustment possibilities.	B		
5.2	The LAF bench has to be equipped with an exit for external alarms (potential free alarm type (e. g. Boomerang) that can send a signal to a central alarm and function control.	A		
5.3	The LAF bench should be marked on both sides of the opening with the normal position of the sash in working position. The marks should be at the same height the sash stops automatically.	A		
6.0	Others			
6.1	The LAF bench has to be delivered with a quick guide for users in a special format, laminated in plastic. The guide should depict the airflow.	A		
6.2	The vendor has to check the equipment immediately after delivery and perform all necessary installations and check	B		

	for proper function of the units on site. Documentation of the installation.			
6.3	Prior to hand-over the vendor has to perform and document a complete test of all functions and alarm settings for all delivered units.	A		
7.0	Demands for documentation and equipment			
7.1	All units have to be CE labeled and a declaration of conformity has to be attached by the vendor.	A		
7.2	A certificate of compliance with cGMP standards for each unit has to be attached by the vendor.	A		
7.3	An attachment containing documentation/report for factory testing of each single unit, including certificates for the HEPA filters and other has to be provided by the vendor. The documentation from factory testing has to be traceable for each unit and has therefore to be attached to it or delivered in a way that mix-ups can be excluded. If parts of the documentation are missing or cannot be traced back for a unit, the unit will not be accepted.	A		
7.4	The vendor has to provide all results and reports from installation, final tuning and testing of the equipment.	A		
8.0	Training			
8.1	The users have to be trained by manufacturer/vendor in addition to the written manual.	A		
9.0	Interfaces			
9.1	The bench has to have the possibility to be connected to an external alarm system (e. g. Boomerang).	B		
9.2	The bench has to have the possibility to connect it to the environmental monitoring system of the facility.	B		
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to place the LAF bench on site without damaging the floor, walls or doors.	A		
10.3	The vendor has to test the equipment on site and document function as described.	B		
10.4	For localization and dimension of each LAF bench, see drawings of facility.	B		

A = minimal requirements

B = evaluation requirements

Dimensions: There will be three different sizes of LAF benches required (see schematics for placement):

- Small benches with approximately 80 to 90 cm working opening.
- Medium benches with approximately 120 cm working opening.
- Large benches with approximately 150 cm working opening.

Clean room placement of LAF benches:

- 2 LAF benches in clean room class B.

- 1 LAF bench in clean room class C.
- 4 LAF benches in clean room class D. (2 in Production D “Minimal Manipulation”)

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Local Exhaust Ventilation LEV (punktavsug)

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	LEV have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Mounted to Wall or ceiling.	B		
2.2	Connected to/ integrated into the ventilation system of the room.	B		
2.3	Ability to remove particles and aerosols from the area below the LEV to maintain air-purity and protect operator.	A		
2.4	LAV should be equipped with a flexible hose to adapt area of suction to equipment.	B		
2.5	LAV should have a build in light source to illuminate the work area below.	B		
3.0	“Specific for this equipment”			
3.1				
4.0	Safety and alarms			
4.1	Air flow has to be monitored and an alarm has to be triggered in case of malfunctioning of LAV.	B		
5.0	Others			
5.1	The vendor has to provide a manual that is easy to understand.	A		
5.2	The manual has to be in English and if possible Norwegian language.	B		
5.3	The vendor has to perform a test of function of each LAV before delivery.	A		
5.4	The vendor has to perform a test of function of each LAV on site.	A		
5.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
6.0	Demands for documentation and equipment			
6.1	The supplier should provide adequate system management documentation.	A		
7.0	Training			
7.1	The supplier should provide adequate training for both maintenance and operation.	A		
8.0	Localization and installation			
8.1	The vendor has to remove and dispose of the wrapping.	B		

8.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
8.3	The vendor has to test the equipment on site and document function as described.	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Mirrors

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Mirrors have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for sluices in cleanrooms in air purity class C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Wall or door mounted.	B		
2.2	Large enough for self-inspection of gowning.	B		
2.3	Frameless mirrors.	A		
2.4	Backing plate that seals out moisture, eliminates germ traps.	B		
3.0	“Specific for this equipment”			
3.1				
4.0	Others			
3.1	The vendor has to provide a manual that is easy to understand.	A		
3.2	The manual has to be in English and if possible Norwegian language.	B		
3.3	The vendor has to perform an inspection of each mirror before delivery.	A		
3.4	The vendor has to perform an inspection of each mirror on site after installation.	A		
3.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			
6.1	The supplier should provide adequate training for both maintenance and operation.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
7.3	The vendor has to test the equipment on site and document function as described.	B		
7.4	Localization: see drawings of the facility	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS: Pass Boxes (PB)

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	PBs have to be constructed in a way that the air inside the PB under normal use is clean/sterile.	A		
1.2	PBs should have air flow/air shower to protect the content in the best possible manner during passing.	A		
1.3	Documentation about testing has to be attached	B		
1.4	PBs have to be CE labelled according to current directives and follow Norwegian laws and regulations.	A		
1.5	It is highly desirable that PBs produce as little noise as possible. The producer has to provide documentation of the noise measurements and how they were obtained.	B		
1.6	PBs should produce as little as possible particles that are released to the cleanroom environment (e. g. opening/closing doors). Documentation about particle release should be provided by the manufacturer.	B		
1.7	Suitable as sluices between cleanrooms with air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	PBs have to be delivered as a solid construction, build with lasting and enduring materials that can withstand long and demanding use. All surfaces, screws, bolts, connections and so on have to be maintenance free. Documentation by the manufacturer.	B		
2.2	All connections, gaps and seams have to consist of enduring materials and be treated with anti-microbial surfaces. Documentation by the manufacturer.	B		
2.3	All surfaces inside the PBs should be in stainless steel and easy to clean and disinfect and resistant to all common disinfectants.	B		
2.4	PBs have to be integrated into the wall system and air tight towards neighboring rooms.	A		
2.5	The placement between rooms is shown in the drawings. The biggest part of the PBs should be strategically localized to areas with more space. Describe solutions.	B		
2.6	Easy cleaning and sterilization of the inside and the outside of the PBs has to be possible and considered during planning and construction.	A		
2.7	The size of the inside of the PBs has to be big enough for their purposes, but small enough to conserve space in the confined size of the rooms and hallways. The minimal size should be big enough to transfer a tube or bag with patient cells between rooms. The maximum size should be sufficient to transfer large amounts of consumables or large plastic bags containing waste. Describe solutions.	B		

2.8	PBs have to maintain a GMP compliant cleanroom environment and have to be part of the ventilation system with HEPA filtered air. Describe how PBs can be connected to the ventilation system.	B		
2.9	All PBs have to be equipped with interlock doors that can be only opened at one side at a time and after closing are blocked until the environment inside the PB is adjusted to the environment with the highest GMP class connected by the PBs.	A		
2.10	The PBs have to have a visual system indicating that the environmental conditions inside the PB are stable and that doors can be opened.	A		
2.11	The interlock doors of all PBs should have a big glass window to inspect the content of the PB and the room on the other side. The doors, windows and seams between frame and window have to be easy to clean.	A		
2.12	The PBs have to be monitored by the environmental control system	A		
2.13	Alarm: external at hospital.	A		
3.0	Electronic functions and controls			
3.1	PBs have to be delivered with a cable and power-plug that is compatible with Norwegian regulations for 230V, 16A, power plug, circuit.	A		
3.2	PBs have to be delivered with an integrated light source that delivers an evenly distributed illumination.	A		
3.3	PBs have to have a UV light source for sterilization of the pass through area. This UV light source has to be built in for sterilization. The UV light should not be a danger for personnel and equipment in close vicinity of the PB. Describe possible solutions.	B		
3.4	The PBs have to have a control panel showing the status of the interlock doors and pressure and airflow inside the box.	B		
4.0	Ventilation			
4.1	The PBs are part of the ventilation system and can be regarded as a separate room with a GMP classified environment.	A		
5.0	Safety and alarms			
5.1	PBs to be equipped with an exit for external alarms (potential free alarm type (e. g. Boomerang) that can send a signal to a central alarm and function control.	A		
6.0	Others			
6.1	PBs have to be delivered with a quick guide for users in a special format, laminated in plastic. The guide should depict the use of the interlock doors.	A		
6.2	The vendor has to check the equipment immediately after delivery and perform all necessary installations and check for proper function of the units on site. Documentation of the installation.	B		

6.3	Prior to hand-over the vendor has to perform and document a complete test of all functions and alarm settings for all delivered units.	A		
7.0	Demands for documentation and equipment			
7.1	All units have to be CE labeled and a declaration of conformity has to be attached by the vendor.	A		
7.2	A certificate of compliance with cGMP standards for each unit has to be attached by the vendor.	A		
7.3	An attachment containing documentation/report for factory testing of each single unit, including certificates for the HEPA filters and others, has to be provided by the vendor. The documentation from factory testing has to be traceable for each unit and has therefore to be attached to it or delivered in a way that mix-ups can be excluded. If parts of the documentation are missing or cannot be traced back for a unit, the unit will not be accepted.	A		
7.4	The vendor has to provide all results and reports from installation, final tuning and testing of the equipment.	A		
8.0	Training			
8.1	The users have to be trained by manufacturer/vendor in addition to comprehensible written manual.	A		
9.0	Interfaces			
9.1	PBs have to have the possibility to be connected to an external alarm system (e. g. Boomerang).	A		
9.2	PBs have to have the possibility to connect it to the environmental monitoring system of the facility.	A		
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to install the PBs as indicated in the drawings.	A		

A = minimal requirements

B = evaluation requirements

There are different types of pass boxes required:

1. Between rooms with same clean room classification: no ventilation required. Only interlock doors and light.
2. Between rooms with different clean room classification: ventilation, interlock doors and light required. On the side with lower cleanroom class a sterile bench/ fume hood for disinfection of material before sluicing in is required.

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS PC Class C and B (to be installed but not procured/produced by vendor)

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	PCs have to be suitable for cleanrooms in air purity class C and B in accordance with DIN EN ISO 14644-1.	A		
1.2	PCs should be without ventilation to prevent interference with the ventilation system of the room.	B		
1.3	Smooth surface that is easy to clean	A		
1.4	Resistant to disinfectants.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Stand alone or client machines			
3.0	Electronic functions and controls			
3.1	OS: Windows 10	B		
3.2	PCs should be equipped with a clean room (class C/B) compatible keyboard or touch screen.	B		
3.3	PCs have to be compatible with the hospital network.	B		
3.4	PCs have to be connected with the clean room network/server.	A		
3.5	PCs have to be compatible with the environment monitoring system.	B		
3.6	PCs should have an input device (e. g. computer-mouse).	B		
3.7	PCs have to be equipped with a clean room (class B/C) compatible screen.	B		
4.0	“Specific for this equipment”			
4.1				
5.0	Safety and alarms			
5.1	PCs should be integrated in the environmental monitoring system.	B		
5.2	Backup system	B		
6.0	Others			
6.1	The vendor has to provide a manual that is easy to understand.	A		
6.2	The manual has to be in English and if possible Norwegian language.	B		
6.3	The vendor has to perform a test of function of each PC before delivery.	A		
6.4	The vendor has to perform a test of function of each PC on site.	A		
6.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
7.0	Demands for documentation and equipment			
7.1	The supplier should provide adequate system management documentation.	A		
8.0	Training			
8.1	The supplier should provide adequate training for both maintenance and operation to employees of the facility and the IT department of the hospital.	A		
9.0	Interfaces			
9.1	Central Alarm system hospital.	B		
9.2	Internet	B		

9.3	Server	B		
9.4	Environmental monitoring system	A		
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
10.3	The vendor has to test the equipment on site and document function as described.	B		
10.4	Localization: see drawings of the facility	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS PC Class D (to be installed but not procured/produced by vendor)

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	PCs have to be suitable for cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
1.2	PCs should be without ventilation to prevent interference with the ventilation system of the room.	B		
1.3	Smooth surface that is easy to clean	A		
1.4	Resistant to disinfectants.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1				
3.0	Electronic functions and controls			
3.1	OS: Windows 10	B		
3.2	PCs have to be compatible with the hospital network.	A		
3.3	PCs have to be connected with the clean room network.	A		
3.4	PCs have to be compatible with the environment monitoring system.	A		
3.5	PCs should have an input device (e. g. computer-mouse).	B		
3.6	PCs should be equipped with a clean room (class D) compatible keyboard.	B		
3.7	PCs have to be equipped with a clean room (class D) compatible screen.	B		
3.8	PCs have to have the standard connections to connect external equipment (e. g. printer, scanner, external memory).	A		
4.0	“Specific for this equipment”			
4.1				
5.0	Safety and alarms			
5.1	PCs should be integrated in the environmental monitoring system.	B		
5.2	Backup system	B		
6.0	Others			
6.1	The vendor has to provide a manual that is easy to understand.	A		
6.2	The manual has to be in English and if possible Norwegian language.	B		
6.3	The vendor has to perform a test of function of each step over bench before delivery.	A		
6.4	The vendor has to perform a test of function of each step over bench on site.	A		
6.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
7.0	Demands for documentation and equipment			
7.1	The supplier should provide adequate system management documentation.	A		

8.0	Training			
8.1	The supplier should provide adequate training for both maintenance and operation to employees of the facility and the IT department of the hospital.	A		
9.0	Interfaces			
9.1	Central Alarm system hospital.	B		
9.2	Internet	B		
9.3	Server	B		
9.4	Environmental monitoring system	A		
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
10.3	The vendor has to test the equipment on site and document function as described.	B		
10.4	Localization: see drawings of the facility.	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Wire Shelves

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Shelves have to have a smooth surface that is easy to clean.	A		
1.2	Shelves have to be GMP compliant and suitable in a clean room environment according to current directives and follow Norwegian laws and regulations.	A		
1.3	Washable and resistant to disinfectants.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Height: As high as possible, so upper shelves can still be reached.	B		
2.2	Depth and width of shelves: As big as possible. Refer to drawings for placement, width and depth.	B		
2.3	Shelves should be placed on wheels or be constructed in a way that allows easy access for cleaning beneath and behind.	B		
2.4	Material: steel or other suitable materials. The vendor has to describe and recommend alternatives.	B		
2.5	Shelves should have wire shelving storage compartments.	B		
2.6	Shelves should be easily adjustable to vary height of storage compartment.	B		
3.0	“Specific for this equipment”			
3.1				
4.0	Others			
4.1	The vendor has to provide a manual that is easy to understand.	A		
4.2	The manual has to be in English and if possible Norwegian language.	B		
4.3	The vendor has to perform a test of function of each shelf before delivery.	A		
4.4	The vendor has to perform a test of function of each shelf on site.	A		
4.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			
6.1	The supplier should provide adequate training for both maintenance and operation.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		

7.3	The vendor has to test the equipment on site and document function as described.	B		
7.4	Localization: see drawings of the facility.	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Shoe Racks

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Shoe racks have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Room for up to 20 pairs of shoes.	B		
2.2	Wall mounted or integrated under Step over benches. Supplier should give alternatives.	B		
3.0	“Specific for this equipment”			
3.1				
4.0	Others			
4.1	The vendor has to provide a manual that is easy to understand.	A		
4.2	The manual has to be in English and if possible Norwegian language.	B		
4.3	The vendor has to perform a test of function of each shoe rack before delivery.	A		
4.4	The vendor has to perform a test of function of each shoe rack on site.	A		
4.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			
6.1	The supplier should provide adequate training for both maintenance and operation.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
7.3	The vendor has to test the equipment on site and document function as described.	B		
7.4	Localization: see drawings of the facility.	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Step Over Benches

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Step Over Benches have to have a smooth surface that is easy to clean.	A		
1.2	Suitable for sluices in cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
1.3	Washable and resistant to disinfectants.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Height: approximately 45 cm	B		
2.2	Width: approximately 30 cm	B		
2.3	Length: From wall to wall, see drawings for details	B		
2.4	Rounded edges to avoid dirt traps.	B		
3.0	Electronic functions and controls			
3.1	none			
4.0	“Specific for this equipment”			
4.1	Step over benches should have a hinge so they can be opened and give room to transport large equipment on the floor.	B		
4.2	Step over benches could contain integrated storage for shoes. Each side with access to shoes of the corresponding cleanroom class. Describe solutions.	B		
5.0	Safety and alarms			
5.1	No alarms			
6.0	Others			
6.1	The vendor has to provide a manual that is easy to understand.	A		
6.2	The manual has to be in English and if possible Norwegian language.	B		
6.3	The vendor has to perform a test of function of each step over bench before delivery.	A		
6.4	The vendor has to perform a test of function of each step over bench on site.	A		
6.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
7.0	Demands for documentation and equipment			
7.1	The supplier should provide adequate system management documentation.	A		
8.0	Training			
8.1	The supplier should provide adequate training for both maintenance and operation.	A		
9.0	Localization and installation			
9.1	The vendor has to remove and dispose of the wrapping.	B		
9.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		

9.3	The vendor has to test the equipment on site and document function as described.	B		
9.4	Localization: see drawings of the facility	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Clean room telephone Class C and B

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Suitable for cleanrooms in air purity class C/B in accordance with DIN EN ISO 14644-1.	A		
1.2	Telephones have to have a smooth surface that is easy to clean.	A		
1.3	Washable and resistant to disinfectants.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	IP telephone.	A		
2.2	Compatible with Helse Bergen system.	A		
3.0	Electronic functions and controls			
3.1	Can interact with intercom system.	B		
4.0	“Specific for this equipment”			
4.1	Wall mounted	B		
4.1	Programmable with speed dials to neighboring rooms, security desk at the hospital, external numbers.	B		
5.0	Safety and alarms			
5.1				
6.0	Others			
6.1	The vendor has to provide a manual that is easy to understand.	A		
6.2	The manual has to be in English and if possible Norwegian language.	B		
6.3	The vendor has to perform a test of function of each telephone before installation.	A		
6.4	The vendor has to perform a test of function of each telephone on site after installation.	A		
6.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
7.0	Demands for documentation and equipment			
7.1	The supplier should provide adequate system management documentation.	A		
8.0	Training			
8.1	The supplier should provide adequate training for both maintenance and operation of telephones.			
9.0	Interfaces			
9.1				
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
10.3	The vendor has to test the equipment on site and document function as described.	B		

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A = minimal requirements
B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Clean room telephone Class D

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Suitable for cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
1.2	Telephones have to have a smooth surface that is easy to clean.	A		
1.3	Washable and resistant to disinfectants.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	IP telephone.	A		
2.2	Compatible with Helse Bergen system.	A		
3.0	Electronic functions and controls			
3.1	Can interact with intercom system.	B		
4.0	"Specific for this equipment"			
4.1				
5.0	Safety and alarms			
5.1				
6.0	Others			
6.1	The vendor has to provide a manual that is easy to understand.	A		
6.2	The manual has to be in English and if possible Norwegian language.	B		
6.3	The vendor has to perform a test of function of each telephone before installation.	A		
6.4	The vendor has to perform a test of function of each telephone on site after installation.	A		
6.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
7.0	Demands for documentation and equipment			
7.1	The supplier should provide adequate system management documentation.	A		
8.0	Training			
8.1	The supplier should provide adequate training for both maintenance and operation of telephones.			
9.0	Interfaces			
9.1				
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
10.3	The vendor has to test the equipment on site and document function as described.	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Trolley / Utility cart

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Trolleys have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	GMP compliant and suitable in a clean room environment.	A		
2.2	Material: steel or other suitable materials. The vendor has to describe and recommend alternatives.	B		
2.3	Working height: around 95 cm.	B		
2.4	Solid Two-Tier Shelves.	B		
2.5	Light duty casters for mobility. Wheels should have protection from shedding particles.	B		
2.4	Depth and width of trolleys: Width 40 to 65 cm, depth 60 to 90 cm.	B		
3.0	Others			
3.1	The vendor has to provide a manual that is easy to understand.	A		
3.2	The manual has to be in English and if possible Norwegian language.	B		
3.3	The vendor has to perform a test of function of each desk before delivery.	A		
3.4	The vendor has to perform a test of function of each desk on site.	A		
3.5	The vendor has to provide documentation of test and function of the delivered equipment.	A		
4.0	Demands for documentation and equipment			
4.1	The supplier should provide adequate system management documentation.	A		
5.0	Training			
5.1	The supplier should provide adequate training for both maintenance and operation.	A		
6.0	Localization and installation			
6.1	The vendor has to remove and dispose of the wrapping.	B		
6.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
6.3	The vendor has to test the equipment on site and document function as described.	B		
6.4	Localization: see drawings of the facility	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Wall-mounted Clothes hooks

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Washable and resistant to disinfectants.	A		
1.2	Suitable for cleanrooms in air purity class D in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	Four to ten single or connected hooks.	B		
2.2	To be mounted on the wall. Mounting should not result in gaps that collect dirt and can cause cross-contamination.	A		
2.3	Must tolerate the weight of jackets/lab-coats	A		
2.4	Material: stainless steel or other suitable material. The vendor should advise.	B		
6.0	Others			
6.1	The vendor has to perform a test of function of each Clothes hook before delivery.	A		
6.4	The vendor has to perform a test of function of each Clothes hook on site.	A		
6.5	The vendor has to provide documentation of test and function of the mounted Clothes hooks.	A		
10.0	Localization and installation			
10.1	The vendor has to remove and dispose of the wrapping.	B		
10.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
10.3	The vendor has to test the equipment on site and document function as described.	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature

URS Work Benches:

#		Priority	Accepted Y/N	Date and initials
1.0	Basic demands and standards			
1.1	Work benches have to have a smooth surface that is easy to clean.	A		
1.2	Washable and resistant to disinfectants.	A		
1.3	Suitable for cleanrooms in air purity class D/C/B in accordance with DIN EN ISO 14644-1.	A		
2.0	Demands about dimensions, function and mechanical setup			
2.1	GMP compliant and suitable in a clean room environment.	A		
2.2	Material: steel or other suitable materials. The vendor has to describe and recommend alternatives.	B		
2.3	Working height: approximately 90cm.	B		
2.4	Depth and width of benches: when possible 80cm. Refer to drawings for placement, width and depth.	B		
2.5	Mounted to the wall or on a suitable scaffold with wheels. The vendor has to describe and recommend alternatives.	B		
2.6	Work benches have to fit in all areas described, see figures.	B		
2.7	Work benches have to be equipped with drawer sections underneath, see figures.	B		
3.0	“Specific for this equipment”			
3.1	Storage cabinets on top possible.	B		
3.2	Storage cabinets or drawers under the work bench.	B		
3.3	Space for equipment under work bench, e. g. fridge, ultra-freezer, blood cabinet, wheel-cart.	B		
3.4	Hydraulic work bench to regulate height of work top some places. The vendor has to describe and recommend alternatives.	B		
4.0	Others			
4.1	The vendor has to provide a manual that is easy to understand.	A		
4.2	The manual has to be in English and if possible Norwegian language.	B		
4.3	The vendor has to perform a test of function of each work bench before delivery.	A		
4.4	The vendor has to perform a test of function of each work bench on site.	A		
4.5	The vendor has to provide documentation of test and function of the delivered equipment.	B		
5.0	Demands for documentation and equipment			
5.1	The supplier should provide adequate system management documentation.	A		
6.0	Training			

6.1	The supplier should provide adequate training for both maintenance and operation.	A		
7.0	Localization and installation			
7.1	The vendor has to remove and dispose of the wrapping.	B		
7.2	The vendor has to place the equipment on site without damaging the floor, walls or doors.	A		
7.3	The vendor has to test the equipment on site and document function as described.	B		
7.4	Localization: see drawings of the facility	B		

A = minimal requirements

B = evaluation requirements

Date, Signature Vendor

Date, Signature recipient

Explanation Initials

Initials	Name	Signature