

Performance Evaluation of IVC Systems

- Part 2: Evaluation Criteria -

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For the most reliable and economic operation of IVC systems possible, not only is the standard of technical quality crucial, but also the straightforward operation and handling of the system as well as the compatibility and interoperability of all the different components. For this reason, the following criteria were compiled with the intention of assisting the user in the evaluation of IVC systems.

The points listed herein can, however, only serve as an orientation for the appraisal of IVC systems. They do not replace a critical review by the operator/user in regard to the intended use (for instance, positive product protection or bio-containment, whereby protection against allergens is also included). Ultimately, the meaning and importance of each single criterion depends on the concrete, individual application. For effective selection of a suitable system, the most exact definition of the **purpose** for which an IVC is intended is, therefore, a decisive factor. The different systems available on the market have different strong and weak points. Which system is most suitable for a particular case is determined, apart from the quality of the IVC system, above all by its purpose. Consequently, it is urgently recommended that the suitability for the intended application is checked on IVC systems currently in operation (rack plus matching ventilation system). For certain application areas (for instance, Safety Level 2 (S2) and higher according to GenTSV regulations or Council Directive 90/219/EEC and Council Directive 98/81/EC), regulatory requirements must be fulfilled (**approval and confirmation by the authorities required!**) It is, therefore, recommended to apply to the relevant authorities for approval in advance of purchasing an IVC system.

This list also includes points (for instance, space requirements, consideration of technical tools and equipment already installed, such as cleaning systems, autoclaves etc.) that are not determined by the IVC system itself, but depend on the circumstances of each individual location and application. To ensure optimum operation of an IVC in a given animal facility, it is **essential** to tailor the system to **meet the distinctive requirements of the particular facility**, as these cannot be influenced by the manufacturer of the system. For this reason, these points have been included in the list, although they do not relate directly to the IVC systems themselves.

For the air supply of the animals, it should actually be irrelevant how the air is supplied to the racks and exhaust air extracted: whether by decentralized ventilation units, such as are offered by the manufacturers of such systems, or a centralized air supply & exhaust system. However, the air supply method is an integral component of the complete system and, thus, essential for an appraisal of the system by the individual user. For this reason, the air supply means and method have also been integrated into this practice-oriented (from the user's point of view) checklist.

We would explicitly draw attention to the fact that the criteria presented in this list cannot be fulfilled by the manufacturer without financial consequences. The housing of small rodents in IVC systems for this and other reasons (for instance, increased personnel costs, increased maintenance for the additional technical equipment – ventilation units, sterile workbenches – etc.) incurs greater costs than “open-cage housing”. However, IVC systems are much more cheaper than the housing of small rodents in isolators.

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
1.	IVC system as a complete functional unit	Rack filled with cages + air supply (via ventilation unit or central building ventilation)					
		How large is the cage capacity required by the specific project?					
1.1	Space requirements for the complete IVC system	Local requirements to be considered: Room, corridor, doorway, lock gate dimensions etc. must be taken into consideration (for instance, do the racks, ventilation units, sterile workbenches fit through all the doors, are the corridors wide enough to allow the racks and sterile workbenches to be turned around so that they can be pushed into the animal rooms etc.?).					
		Space requirements:					
		It must be ensured that the actual housing unit, in which the IVC system will be used, provides sufficient space to stock a limited supply of provisions and back-up material (spare cages in case water bottles leak etc., safety reserves in case of an autoclave break-down).					
1.2	Space requirements for reserve material, storage capacities	Does the area allow storage under clean (barrier) conditions to avoid contamination with pathogens or other unwanted microorganisms?					
		Are special containers / protective covers necessary to avoid contamination with pathogens or other unwanted microorganisms during storage? If so, number of containers / protective covers necessary?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
1.3	Transport of sterilized material (for instance cages, drinking bottles etc.) from the autoclave / sterilizer to the animal room(s) / storage area	Is the transport possible under clean (barrier) conditions to avoid contamination with pathogens or other unwanted microorganisms?					
		Are special containers / protective covers for the transport necessary to avoid microbiological contamination during transport? If so, number of containers / protective covers necessary?					
1.4	Is a technical description pertaining to the ventilation system provided?	In accordance with the Test Instructions in Part 1.					
1.5	Is a technical description pertaining to noise / vibration factors provided?	In accordance with the Test Instructions in Part 1.					
1.6	Has documentation been supplied that the ventilation-caused parameters of the delivered systems were calibrated in the manufacturing plant?						
1.7	Is it intended to carry out functional measurements subsequent to installation of the system on site?						
1.8	Is this IVC system also available for other cage sizes?	For possible purchases or applications at a later date.					
1.9	Is straightforward, user-friendly operation of the system under daily working conditions assured?	The system is generally operated by animal care and scientific staff, i.e. by non-technical users.					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
1.9.1	<ul style="list-style-type: none"> ➤ Is it possible to handle the cage racks without tools? - Connection / disconnection of rack and ventilation unit - I.e. connection / disconnection of racks with / from each other - I.e. connection / disconnection of ventilation unit and room exhaust extraction system 	<p>It should be possible to carry out the changing of racks and ventilation units simply and without using tools; ideally, one person should be able to do this on their own (member of animal care staff, i.e. non-technical user). This function must remain intact even after years of usage (for instance, in spite of material fatigue of connecting pieces made of plastics). In this context, it is to be noted that different materials show a wide range of resistance not only to cleaning, disinfection and sterilization processes but also to aging. Parts subject to wear and tear must be easily replaceable.</p>					
1.9.2	➤ Rack mobility	Are the racks easy to push and turn: weight (empty and filled with cages), wheel diameter, dimensions, danger of falling over etc.?					
		Can they be effortlessly moved over or through impediments such as doorway thresholds, cleaning systems, autoclaves etc.?					
		Can they be moved by one person (preferably)?					
1.9.3	➤ Ventilation unit mobility (for mobile designs)	Are they easy to push and turn: weight (empty and with cages), wheel diameters, dimensions, danger of falling over etc.?					
		Can they be effortlessly moved over or through impediments such as doorway thresholds, cleaning systems, autoclaves etc.?					
		Can they be moved by one person (preferably)?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
				Yes	No		
	Main criteria	Detailed comments, notes and specific questions					
1.9.4	➤ Mobility of connected ventilation units and corresponding racks	Is mobility sufficient to allow room cleaning?					
		If the ventilation unit is connected to the air exhaust system of the room / building, is mobility still adequate?					
1.10	Finishing	Are the joints and seams of the stainless steel parts welded in their entirety?					
		Are hollow spaces that cannot be accessed for cleaning, disinfecting and sterilizing purposes completely and permanently sealed?					
		Are there any sharp corners or edges (→ risk of injury for staff and animals)?					
1.11	Wheels / castors	Can they be autoclaved?					
		Are the wheels/castors fitted with brakes?					
		Are the brakes easy to reach for locking/releasing purposes?					
		Is there any risk of injury? For instance, due to wheels/castors protruding from below the rack frame (danger of ankle injuries) or when releasing the brakes?					
1.12	Resistance of all materials used in regard to:						
1.12.1	➤ Mechanical strain	Is mechanical stability good?					
1.12.2	➤ Detergents and disinfectants	See Point 6: "Hygiene".					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
1.12.3	➤ Sterilization methods	See Point 6: "Hygiene".					
1.13	How does light intensity in the cages (<u>based on</u> : 450 Lux at a height of 1 meter in the room) change at different positions within the rack?	Are there any differences between the different rack shelf levels?					
		Are there differences between inner (rack center) and outer (rack sides) rack positions?					
		Caution must be exercised when filling a rack with different-sized cages, for instance: Type II and Type II long.					
1.14	Measuring cage for determining the Air exchange rate in the cage and the pressure differential between cage interior and holding room	Is such a measuring cage commercially available?					
		Information on how cage functions: see ventilation system description in Part 1, Test Instructions.					
		Is the measuring cage easy to handle (by animal care staff, i.e. non-technical users)?					
1.15	Is maintenance of the system straightforward?	For instance in regard to ventilation unit, filter changing, general technology. (See also Point 8.1: "Service – Maintenance").					
2.	Ventilation unit (decentralized air supply)						
2.1	Is a technical description pertaining to the ventilation system provided?						
2.2	Can several racks be connected to one ventilation unit?	If so, how many? (Refer to manufacturer's system manual or instructions!)					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
2.3	Can the outgoing air of the ventilation unit be connected to the central exhaust system of the building?						
2.4	How high is the pressure differential between the cage interior and the room outside the cage in positive pressure mode?	Manufacturer's specifications: (See also Part 1, Test Instructions: Point 4.1.3).					
2.5	How high is the pressure differential between the cage interior and the room outside the cage in negative pressure mode?	Manufacturer's specifications: (See also Part 1, Test Instructions: Point 4.1.3).					
2.6	How is it ensured that the pressure differential prescribed by the manufacturer is constantly maintained, or that a reversal of the pressure modes cannot ensue?	Manufacturer's specifications: (See also Test Instructions in Part 1, Point 4.2.2.2).					
2.7	Can the operating mode - negative or positive pressure (cage interior to room outside the cage) - of the system be selected as required?						
2.7.1	➤ To do this, is any modification of the system required?	If so, what modifications are required?					
2.8	Is there an independent ventilation unit that is separate from the rack?						
2.9	Is the ventilation unit integrated into the rack?						

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
2.9.1	➤ If so, are oscillations and vibrations transferred from ventilation unit to rack?	If so, what details in this respect are available? (See also description of acoustic parameters, Part 1, Test Instructions, Point 7.2).					
2.10	Mobility of racks and ventilation units	See Points 1.9.2, 1.9.3 and 1.9.4..					
2.11	Sound levels	Is a technical description pertaining to noise/vibration factors provided? (See also Test Instructions in Part 1, Point 7).					
		If so, which values are given?					
2.12	Survival span of animals in the case of ventilation unit failure, depending on animal species and housing density	Are manufacturer's specifications available? If so, which values are given?					
		Are measurement results for the development of the carbon dioxide (CO ₂) and ammonia (NH ₃) content available? If so, which values are given?					
		<u>Note:</u> If no "emergency filter" is installed in the cage hood or no filter hood is used, the following applies: the longer the survival spans of the animals, the less "airtight" the system (high percentage of leakage)!					
2.13	Filters						
2.13.1	➤ HEPA filters (in air supply and exhaust extraction ducts)	Are manufacturer's specifications for filter quality available? If so, what are they? (See also Test Instructions in Part 1, Point 6).					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
2.13.2	➤ Location of HEPA filters (in air supply and exhaust extraction ducts)	In the case of decentralized ventilation, are the filters housed in the ventilation unit?					
		In the case of centralized ventilation, are the filters housed in the “connection box” of the building ventilation system in the animal room?					
		Are they mounted on the cage rack (at the tube connecting points of the rack)?					
		Are they fitted into the cage hood?					
2.13.3	➤ Changing the HEPA filter in the air supply duct	Does the manufacturer recommend changing intervals/service life? If so, how long are they?					
		If a filter needs to be replaced, is this indicated in some way? (See also Point 5.7.4: “Control and safety functions”).					
		Is the filter changing complicated, time-consuming?					
		Is a tool required to replace the filter?					
		HEPA filters should only be replaced by trained staff to ensure correct functioning.					
2.13.4	➤ Changing the HEPA filter in the exhaust extraction duct	Does the manufacturer recommend changing intervals/service life? If so, how long are they?					
		If a filter needs to be replaced, is this indicated in some way? (See also Point 5.7.5: “Control and safety functions”).					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		Is the filter changing complicated, time-consuming?					
		Is a tool required to replace the filter?					
		HEPA filters should only be replaced by trained staff to ensure correct functioning.					
2.13.5	➤ Monitoring the HEPA filters	Is a monitoring system for the HEPA filters installed? (See also Points 5.7.4 and 5.7.5: “Control and safety functions”).					
2.13.6	➤ Coarse dust filters (in the air supply and exhaust extraction ducts)	Are manufacturer’s specifications on filter quality available? If so, what are they? (See also Test Instructions, Part 1, Point 6)					
2.13.7	➤ Location of coarse dust filters (in the air supply and exhaust extraction ducts)	In the case of decentralized ventilation, are the filters housed in the ventilation unit?					
		In the case of centralized ventilation, are the filters housed in the “connection box” of the building ventilation system in the animal room?					
		Are they mounted on the cage rack (at the pipe unions of the rack)?					
		Are they fitted into the cage hood?					
2.13.8	➤ Changing the coarse dust filter in the air supply duct at the ventilation unit	Does the manufacturer recommend changing intervals/service life? If so, how long are they?					
		As a rule, this filter must be replaced or cleaned frequently (depending on installation location and system). (See above: manufacturer’s specifications on changing intervals).					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		Is changing easy to carry out?					
		Is changing possible without using a tool?					
		Can changing be carried out by one person (animal care staff, i.e. non-technical users)?					
		Are the coarse dust filters easy to clean and can they be reused several times?					
		Are the coarse dust filters autoclavable?					
2.13.9	➤ Changing the coarse dust filter in the exhaust extraction duct at the ventilation unit	Does the manufacturer recommend changing intervals/service life? If so, how long are they?					
		As a rule, this filter must be replaced or cleaned frequently (depending on installation location and system). (See above: manufacturer's specifications on changing intervals).					
		Is changing easy to carry out?					
		Is changing possible without using a tool?					
		Can changing be carried out by one person (animal care staff, i.e. non-technical users)?					

		Evaluation Criteria		Correct/existing		Not applicable	Not known
				Yes	No		
	Main criteria	Detailed comments, notes and specific questions					
		<p>In the case of infection experiments, genetic laboratory research (S2 and higher) as well as similar applications (for instance, quarantine), it must be ensured that contamination-free filter changing (work safety, environmental protection) can be carried out. ⇒ Is this possibility provided for?</p>					
3.	Cage rack: Matching of cage and rack						
3.1	Distance between the individual cages in the rack (beside each other, above / below each other)	(See also Point 5: "Control and safety functions").					
		Is enough clearance provided between the cages to ensure that they can be easily taken from the rack and pushed back into it?					
3.2	How is the functional unit of cage and hood connected to the air ducts of the rack?	Via air supply and extraction valves protruding into the cage hood?					
		Via air supply and/or extraction valves/outlets mounted on the edge of the cage hood?					
		Via air supply and extraction valves protruding into the cage base?					
		Via air supply and/or extraction valves/outlets mounted on the edge of the cage base?					
		From behind?					
		From above?					
		Is the exhaust air extracted above an integrated coarse dust filter in the cage hood?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		Is there a different type of construction than described above? If so, what is it?					
		Is the connection "airtight"?					
		Are the cage and its hood well anchored in the correct position?					
		Is a permanently high level of functional reliability guaranteed even if the cages are frequently removed and replaced (no material fatigue)?					
		Is the whole system easy to handle?					
3.3	Control function to monitor correct position of cage in rack	Is there an audible or palpable indication for the correct position of the cage in the rack?					
		Is there a visual control method (for instance, color marking on the rack for the correct positioning of the cage, or a colored control lamp)?					
		Is there a different type of control system than described above?					
		If so, which?					
3.4	Are the air supply and exhaust extraction ends of the hood clearly and unmistakably indicated?	For hood to cage fitting (hood fits only in one direction onto the cage or the correct position is unmistakably marked)?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		For hood to rack fitting (hood fits only in one direction into rack or the correct position is unmistakably marked)?					
		Ideally, the cage should fit into the rack (respective the hood onto the cage) only in the correct orientation , so that the opening for the air inlet respective air outlet in the cage is always the same one.					
3.5	Construction of the air supply and exhaust extraction valves for the individual cages in the rack	Can the bedding dust come into direct contact with the opening for the air inlet respective air outlet?					
3.6	How are air inlet and outlet openings in the hood or cage constructed?	Flat (rectangular, broad opening)?					
		Valve-type lead-through opening (round, small opening)?					
		Is there a risk of contamination whenever the closed cage is removed from the rack (lead-through openings for the air supply and extraction valves: filter, shutter or unprotected openings)?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
3.7	Ventilation of, and extraction of humidity from the cage	<p>Is the standard value between 45 and 60 % for relative humidity at a room temperature of 22°C +/- 2°C (expert group advising the Council of Europe on revision of the European convention ETS123) maintained even at maximum housing density?</p> <p>Adequate temperature and humidity must be guaranteed by appropriate conditioning of the ambient air. Ideally, the humidity that develops inside the cage should be extracted so effectively by the IVC system that the relative humidity prevailing in the animal room is also present inside the cages (measurement in cages required).</p>					
3.8	Ergonomic considerations in daily practice	Can the cages be easily drawn out from and pushed into the racks (i.e. with little effort)?					
		Are the lower cage levels easy to access and attend to?					
		Are the highest cage levels easy to access and attend to?					
4.	Matching of Cage – wire lid – cage hood - bottle						

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
4.1	Cage hoods with “emergency filters” (or also filter hoods)	<p><u>Advantages:</u> ⇒ A so-called “emergency filter” increases the survival span of the animals in the case of ventilation unit failure.</p> <p><u>Disadvantages:</u> ⇒ “Emergency filters” do not comply with the HEPA quality standard; consequently, they do not offer the same degree of airtightness and thus increases the risk of contamination in the case of ventilation unit failure. ⇒ Further potential fault sources are, for instance, the incorrect installation of the “emergency filter”.</p>					
		<p>The working group recommends avoiding the use of an “emergency filter” and compensating for the risk of ventilation unit failure by setting up an appropriate fault alarm system, an adequate store of changing units and a plan of remedial action for the case that a failure occurs. However, if a cage is not slotted correctly into its rack seating, this cannot be recognized by the fault detector of the alarm system. In such a case, survival of the animals could, on the one hand, be ensured by an “emergency filter”, on the other hand, however, this clearly demonstrates the significance of having some method of efficiently and simply controlling the correct seat of the cage in the rack (see Point 3.3).</p>					
4.1.1	➤ Is the IVC system available	only with “emergency filter” or filter hood?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		only without “emergency filter” or filter hood?					
		Optionally with or without “emergency filter” or filter hood, as required?					
4.2	Cage hoods with integrated coarse dust filters for exhaust extraction ducts	<p><u>Advantages:</u> This kind of system reduces the dust load that the exhaust extraction piping has to deal with, depending on the quality of the bedding material.</p> <p><u>Disadvantages:</u> The efficiency and cleaning or changing intervals of such systems depend on further factors (type, surface area, type of installation in cage hood). As the filter becomes more and more saturated by dust particles, and depending on the system, this can lead to a reduction of the ACH rates or a reversal of the pressure mode (for instance: positive pressure builds up inside the cage instead of the required negative pressure). Depending on the system in use (for instance, pressure-controlled systems), this may not be immediately recognizable by the user without the pressure mode being intentionally checked (for instance, with a smoke tube test)!</p>					
4.3	Is the IVC system compatible with the cages or cage bases of an existing system?	For instance, cages from the “open-cage” type for animal housing?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
4.4	Which materials have been used?	This point is required in order to evaluate the possible differences in the resistance of the materials to cleaning, disinfection and sterilization processes as well as to assess fitting irregularities after a prolonged period of service life that are due to material fatigue or wear.					
		Plastics?					
		Stainless steel?					
		Are magnets used in the system?					
		Have other materials been used? If so, what are they?					
		Do the system components made of different materials still fit well together, even after repeated cleaning and sterilization in an autoclave?					
		⇒ Has this been verified by tests?					
4.5	Number of parts of which a functional cage unit consists (for instance, cage with wire lid/food rack, cage hood, possibly with exhaust and emergency filters).	Depending on the system, the number of parts affects the following: ⇒ amount of work required to replace the cage, ⇒ amount of work required to clean the cage including accessories, ⇒ costs of changing worn-out parts.					

		Evaluation Criteria		Correct/existing		Not applicable	Not known	
				Yes	No			
		Main criteria	Detailed comments, notes and specific questions		Yes	No	Not applicable	Not known
			Number of parts used:					
4.6	Handling of the functional unit consisting of cage, wire lid, cage hood (possibly with exhaust and emergency filters) and drinking bottle.	Is the complete unit low in weight? Weight in kilograms: [Kg]						
		Is handling of the functional unit simple, i.e. can assembly/disassembly of the unit be carried out in a few straightforward steps (for instance, cage hood and/wire lid slideable etc.)?						
		Is handling of the functional unit or cage changing easily possible also under a sterile workbench ?						
		How long does it take to change a single cage? [Min]						
		Are there any sources for errors that could occur during handling of the functional unit?						
4.7	Stacking suitability of all components	Can the cages be stacked?						
		Can the cage hoods be stacked?						
		Can the wire lids be stacked?						
		Can the filter elements and frame holders for the coarse dust filter in the air supply duct/exhaust extraction duct of the cage hood be stacked?						

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		Can any other components be stacked? If so, which?					
4.8	Fastening: hood - cage	Are the fasteners easy to release and close (for instance: clamps)?					
		Are the fasteners susceptible to damage during routine handling (for instance: toggle latches that break off easily)?					
		Are the fasteners robust, i.e. would they withstand a fall of 120 cm (important, for instance, for infection experiments, genetic technique and similar applications)?					
4.9	Changing the coarse dust filter in the air supply duct/exhaust extraction duct of the cage hood (if installed)	Does the manufacturer recommend changing intervals/service life? If so, how long are they?					
		Is a visual assessment of the filter saturation possible with the cage still in the rack, i.e. can the cage remain in the rack to inspect the filter?					
		Is filter changing easy to carry out?					
		Is a tool required to carry out filter changing?					
		To carry out filter changing, must the animal care staff be particularly nimble-fingered?					
4.10	Changing the “emergency filter” in the hood or the filter in the filter hood (if installed)	Does the manufacturer recommend changing intervals/service life? If so, how long are they?					
		Is filter changing easy to carry out?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		Is a tool required to carry out filter changing?					
		To carry out filter changing, must the animal care staff be particularly nimble-fingered?					
4.11	Provision for attachment of cage cards	Are holders provided for the attachment of cage cards?					
		Does the position of the card restrict the line of vision into the cage for the purpose of monitoring the animals?					
		Does the card disturb when a cage is opened or replaced?					
		Can the cage card be easily attached?					
		Can the card easily fall off the cage?					
4.12	Risk of injury for staff and animals	Are there sharp edges or corners on which staff or animals could be injured?					
		Are there gaps (especially V-shaped gaps) in which body parts of the animals could become stuck?					
4.13	Drinking bottle volume	Is the drinking bottle volume sufficient to supply the cage at maximum housing density for one week (including 20 % reserve)?					
4.14	Location of drinking bottle	Is the bottle installed inside the cage? (This is important for infection experiments, genetic technique (S2 and higher) and similar applications.)					
		Is the bottle installed outside the cage (inside the rack dimensions)?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		Is the bottle installed on the outside of the cage (protruding from beyond the rack dimensions)?					
		In the case of an outside bottle, is there a risk of contamination with regard to the position of the lead-through opening (in the hood or in the cage) and the type of lead-through opening (silicone disc, shutter, unprotected opening) and location (dirt collector)?					
4.15	Changing of drinking bottle	Is the drinking bottle easily replaced (i.e. without effort)?					
		To replace the bottle, do the cages situated above have to be raised (if the bottle is mounted on the outside)?					
5.	Inspection and safety functions						
5.1	Animal supervision and monitoring with cages installed in rack	Is the line of vision into the cage restricted , for instance, by the hood, or (if applicable) by the emergency and coarse dust filter for the air supply/exhaust extraction mounted in the hood, the position or size of the cage card, insufficient clearance between the cage shelves (including uppermost, lowest cage levels) or in any other way?					
5.2	Control of content level of the drinking bottles	Can this control be easily carried out?					
5.3	Control of the feed quantity	Can this control be easily carried out?					
5.4	Securing the cage in the rack	Can the cage be securely and easily connected to the air supply and extraction vents?					
		Is there a mechanical catch to hold the cage in place?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
				Yes	No		
	Main criteria	Detailed comments, notes and specific questions					
		Is there a color marking or a control lamp installed?					
		Is there any other device to secure the cage in the rack? If so, what kind?					
5.5	Plug connections for power supply and fault alarm system	Are the plug connections easily connected and disconnected?					
		Do the plug connections have splash water protection to IP X4 or higher? Type of protective enclosure: (Required for room cleaning / disinfection.)					
		Can these plug connections be clearly and unmistakably assigned to their respective functions/devices (for instance, different plug systems, color markings etc.)?					
5.6	Labeling of all connections for air supply, electricity and controls	Are there separate labels for air supply and exhaust extraction ducts?					
		Is the connection for the power supply labeled accordingly?					
		Is the connection for the fault alarm system labeled accordingly?					
		Are there any further kinds of labeling? If so, what are they?					
5.7	Alarm system functions	The "IVC User" working group recommends the following fault alarm system to monitor the system functions and deliver fault alarms:					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
5.7.1	➤ Airflow volume	This factor is critical for the survival of the animals. Measuring method:					
5.7.2	➤ Pressure differential between cage interior and environment	Immission respective emission protection (positive product protection or bio-containment) Measuring method:					
5.7.3	➤ Power failure / voltage loss	Measuring method:					
5.7.4	➤ Monitoring system for the HEPA filter in the air supply duct	Is this achieved by means of monitoring the pressure? If so, which measuring method is used?					
		Is this achieved by means of monitoring time? If so, which measuring method is used?					
		The fault alarm indicating the necessity of a filter changing must be triggered well in advance of any problems occurring in the ventilation system (with respect to ACH rates, pressure modes). It must allow enough time to carry out a filter changing.					
5.7.5	➤ Monitoring system for the HEPA filter in the exhaust extraction duct	Is this achieved by means of monitoring the pressure? If so, which measuring method is used?					
		Is this achieved by means of monitoring time? If so, which measuring method is used?					
		The fault alarm indicating the necessity of a filter changing must be triggered well in advance of any problems occurring in the ventilation system (with respect to ACH rates, pressure modes). It must allow enough time to carry out a filter changing.					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
5.8	Type of fault messaging	The fault alarms should be indicated visually in the animal room (for instance, at the ventilation unit, or in the case of a centralized ventilation, at the corresponding connection box). Connection of the fault alarm system to the building control center should also be possible to allow the routing of fault alarms to a control center (computer-based data output) but also for documentation of faults.					
5.8.1	➤ Are the above parameters continuously monitored?						
5.8.2		In the case of decentralized air supply, is the visual monitoring device positioned on the ventilation unit?					
		In the case of centralized air supply, is the visual monitoring device positioned at the connection box?					
		Is a visual monitoring device positioned in any other location? If so, where?					
		In the case of a double-rack, can the visual monitoring device be read from both sides?					
5.8.3	➤ Is there an acoustical alarm device in the adjacent working area?	⇒ This fault alarm should usually be installed in the building and is therefore not a requirement to be fulfilled by the IVC manufacturer. ⇒ This fault alarm must be recognized by animal care staff even if there is no one in the animal room at that specific moment. ⇒ This fault alarm must not be located inside the animal room itself (due to the impact of the noise on the animals).					
5.8.4	➤ Is it possible to connect the respective fault alarm system to the building control center?						
5.8.5	➤ Is it possible to readout the fault alarm data on a computer?						
5.9	The following additional functions are helpful to ensure an error-free routine operation:						

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
5.9.1	➤ Time meter	Is a time meter installed?					
		Is a differentiation made between the HEPA filters in the air supply and exhaust extraction ducts?					
5.9.2	➤ Is it possible to automatically generate maintenance alert signals at predetermined operating intervals?	For instance, to indicate the necessity for changing the coarse dust filters, for cleaning the air ducts in the rack etc.					
5.9.3	➤ Operating panel						
5.9.3.1	➤ Are all the components labeled?						
5.9.3.2	➤ Are the display values easily readable?						
5.9.3.3	➤ Is the operating panel a monitor?	If so, the monitor could be a disturbing light source during the dark phases; therefore, it should be possible to switch it off during these phases.					
		Can the monitor be switched off?					
		Does it switch off automatically?					
5.10	Has an emergency response plan in case of ventilation failure been set up by the user?	For decentralized air supply: failure of one or more ventilation units For centralized air supply: failure of the building's central air supply system (see also Point 4.1)					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
6.	Hygienic aspects						
6.1	Cleaning of cage rack incl. accessories (connecting tubes and pipes, couplings etc. between racks and ventilation unit) as well as of cages and cage accessories	Are the surfaces smooth and, therefore, easy to clean?					
		Are angles, corners or surface roughness present that could make cleaning difficult?					
		Are there places in which detergent liquids (cleaning water) could collect?					
6.2	Resistance to common cleaning detergents and disinfectants (see also Point 4.4: "Which materials have been used?")	Acidic or alkaline detergents, detergents containing aldehydes, quarternary ammonium compounds, chlorine ions etc.					
		Are manufacturer's specifications provided? If so, what are they?					
		Has resistance to the cleaning substances routinely used in the specific animal facility been tested?					
6.3	Compatibility with the cleaning systems used in the animal facility	Is compatibility assured, in particular for the cage hoods, filter elements/frames of the coarse dust filters mounted in the air supply duct / exhaust extraction duct of the cage hood?					
		Are additional wash baskets or similar accessories required?					
		Is compatibility assured with respect to the rack dimensions (for instance, chamber size, door opening, thresholds etc.)?					
		Was a trial run carried out with sample components?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
6.4	Inspection and cleaning of the air ducts in the rack	Are closable apertures (caps, lids or similar) provided for visual inspections and cleaning purposes (e.g. for rinsing with a liquid the apertures must be large enough to accommodate standard hose adapters like 3/8 or 1/2 inch)?					
		Does it take a lot of time and effort to dismantle/disassemble the parts for cleaning purposes?					
6.5	Rack resistance, including accessories, to steam sterilization (autoclaving)	Are the racks heat resistant up to 121 °C?					
		Are the racks heat resistant up to 134 °C?					
		Are they resistant to high pressure and vacuum conditions?					
		Are manufacturer's specifications provided? If so, what are they?					
		Recommendation of the working group: <u>All the materials used in the IVC system, including all the connecting tubes and pipes, couplings etc., between the racks and the ventilation unit (except for the actual ventilation unit with its electronic components and HEPA filters) should be autoclavable.</u>					
6.6	Resistance of cages and cage accessories to steam sterilization (autoclaving)?	Are the cages and accessories heat resistant up to 121 °C?					
		Are the cages and accessories heat resistant up to 134 °C?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
				Yes	No		
	Main criteria	Detailed comments, notes and specific questions					
		Are they resistant to high pressure and vacuum conditions?					
		Are manufacturer's specifications provided? If so, what are they?					
		Recommendation of the working group: <u>All</u> the materials used in the IVC system, including all the connecting tubes and pipes, couplings etc., between the racks and the ventilation unit (except for the actual ventilation unit with its electronic components and HEPA filters) <u>should be autoclavable.</u>					
6.7	Resistance of cage racks, including accessories, to chemical sterilization (See also Point 4.4: "Which materials have been used?").	Are they resistant to hydrogen peroxide ((H ₂ O ₂))?					
		Are they resistant to formaldehyde (HCHO) (and possibly also to ammonia neutralization)?					
		Are manufacturer's specifications provided? If so, what are they?					

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
6.8	Resistance of the cages and cage accessories to chemical sterilization (See also Point 4.4: "Which materials have been used?").	Are they resistant to hydrogen peroxide (H ₂ O ₂)?					
		Are they resistant to formaldehyde (HCHO) (and possibly also to ammonia neutralization)?					
		Are manufacturer's specifications provided? If so, what are they?					
6.9	Compatibility of cage racks including accessories with the sterilizing units used in the animal facility	Do the cage racks and the accessories fit into the sterilizing units (for instance, chamber size, door openings, thresholds etc.)?					
6.10	Decontamination of the ventilation unit as a whole, including the air ducts (outside and inside, for instance, gas decontamination in a chamber)	Are manufacturer's recommendations provided (method, compounds, frequency)?					
		If so, what are they? Methods:					
		Compounds:					
		Frequency:					
Is decontamination with hydrogen peroxide (H ₂ O ₂) possible? If so, specify frequency:							

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
		Is decontamination with formaldehyde (HCHO) (and possibly ammonia neutralization) possible? If so, specify frequency:.....					
7.	Operating instructions						
7.1	Are operating instructions provided?						
7.2	Are the operating instructions written in the language of the staff operating / maintaining the IVC units?						
7.3	Are the operating instructions written clearly and coherently for good understanding?						
7.4	Do the operating instructions include graphics and the designations of the individual components?						
7.5	Do the operating instructions contain all the details and instructions required for operation of the system?	For instance, connection of the rack to the ventilation unit etc.					
7.6	Are the requisite safety instructions provided in the operating instructions?						

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
7.7	Do the operating instructions give details on installation and startup?	For instance, removing protective covers, closing caps and similar also from the interior of the ventilation units etc.					
7.8	Do the operating instructions provide explanations on manufacturer-specific points and characteristics?						
7.9	Details on the appropriate handling / operation of the system in the operating instructions	Are details given in written form?					
		Are details given on some kind of imaging (for instance, video, CD-ROM or similar)?					
7.10	Handling of the functional unit consisting of cage, wire lid, cage hood (possibly also with air supply / exhaust and emergency filters) and drinking bottle in the operating instructions (Also for the case of handling under a sterile workbench).	Are details given in written form?					
		Are details given on some kind of imaging medium (for instance, video, CD-ROM or similar)?					
7.11	Are details on the requisite maintenance measures provided in the operating instructions?						
7.12	Are details given on the requisite maintenance intervals?						

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
7.13	Is a description of filter changing enclosed with the operating instructions?	HEPA filters and coarse dust filters for the air supply and exhaust extraction ducts, coarse dust filter (if installed) for the air supply / exhaust extraction duct in the cage hood, "emergency filter" or filter hood (if installed) (see also the following points: 2.13.3, 2.13.4, 2.13.8, 2.13.9, 4.9 and 4.10).					
7.14	If there is a measuring cage for the determination of the ACH rates in the cage and the pressure differential between cage interior and room.	Is a description of the functionality provided?					
		Is a description of correct and proper operation provided?					
8.	Service – Maintenance						
8.1	Is maintenance of the system as a whole easy to perform?						
8.2	Is a long-term provision of spare parts guaranteed?	IVC systems are presently (still?) undergoing rapid change and development. Spare parts must, however, be available for many years subsequent to the initial purchase.					
8.3	Are spare parts lists provided?						
8.3.1	➤ Do these spare parts lists provide the specific ordering numbers?						
8.3.2	➤ Are details concerning the respective delivery times provided?						
8.3.3	➤ Is information given on which spare parts the user should store on site as reserves?						

		Evaluation Criteria		Correct/ existing		Not applicable	Not known
	Main criteria	Detailed comments, notes and specific questions		Yes	No		
8.3.4	➤ Are details provided on the service life of the parts subject to wear (for instance, air supply and exhaust extraction valves, closing latches for cage hoods etc.)?						
8.4	Instructions and training for animal care staff by the manufacturer	Is a practical demonstration / training course at the user's location offered?					
		Is this provided on some kind of imaging medium (for instance, video, CD-ROM or similar)?					
8.5	Standard operating procedures	Are these provided in written form?					
		Are these provided in electronic form?					
8.6	Is a maintenance agreement offered by the manufacturer, or is it possible to conclude such an agreement?						
8.7	Can service engineers be contacted if required?						
8.8	How quickly can a service engineer get to the customer's location?						
8.9	Is a 24-hour on-site service assured or possible?						
8.10	Is a 24-hour on-site service for public holidays and weekends assured or possible?						

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Norms / Instructions

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