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Methodological guide to the implementation of a process for airborne surface disinfection applied to containment areas

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Introduction

Microbiology laboratories are nowadays subject to strict security constraints designed to protect workers, the public and the environment. In particular, public health concerns related to the toxicity of formaldehyde, used as an airborne surface-disinfection (ASD) agent, have led to the development of alternative processes whose use and efficacy are not always well controlled. Knowledge of the basic principles of ASD and broad user experience are of crucial importance for maintaining biosafety in laboratories. Consequently, ANSES's Committee for the Control of Laboratory Biorisks (CMRBL) decided to compile a guide on all the information available in this area that could help the user select an ASD process. Note that the disinfection techniques covered in this guide relate exclusively to automatic disinfection process , without human presence. This guide reviews the key principles of ASD use, presents the main applicable regulations and standards relating to it, and provides users with practical advice for implementing ASD.

General information on airborne surface-disinfection processes

With regard to the aims of this guide, ASD can be defined as "an operation with a temporary result that reduces contamination of inert environments or surfaces by micro-organisms to an acceptable level, depending on the objectives set by the risk assessment".

This operation is performed by means of an automatic process, whose active ingredients are chemical agents in gaseous or mist form. It is intended for disinfecting surfaces in a given volume, regardless of their orientation. Because of the toxicity of the disinfectants used, this type of process is essentially implemented in a laboratory, strictly in the absence of any human presence. This operation, which is especially vital to the operation of Biosafety Level 3 (BSL3) laboratories, is justified prior to periodic maintenance of the room, and also prior to moving a device outside the containment area, before *in situ* maintenance of a contaminated device or system, or after accidental release of infectious material.

European regulations

Products used for ASD are defined as "biocidal" products under the European Biocides Directive, 98/8/EC. The European Union has established a regulatory framework for the marketing of biocidal products to ensure a high level of protection for humans, animals and the environment. Since 1 September 2013, implementation of this Directive has been subject to Regulation (EU) no. 528/2012 of 22 May 2012, which consists of two steps:

- an assessment of biocidal active substances, that may or may not result in their inclusion on a European positive list;
- an assessment of products that contain the active substance(s), with a view to obtaining national or European marketing authorisation (MA) that meets common requirements at European level.

Among the 22 product types (PT) covered by the European regulation, in the scope targeted by this regulation, biocidal products used for ASD fall into category PT2. Full implementation of this regulation involves a transitional period that currently requires manufacturers to declare their products and processes to the Ministry of Ecology.

French regulations

The above-mentioned Biocides Directive has been transposed into French law in Articles R 522-1 to 522-47 of the French Environment Code. In addition, the Decree of 19 May 2004 defines the conditions relating to control of the marketing of biocidal active substances and marketing authorisation for biocidal products. The French National Agency for Medicines and Health Products Safety (ANSM) has been entrusted with monitoring the market for ASD processes in accordance with Article L.3114-1 of the French Public Health Code (CSP), which stipulates that "when it is necessary due to either the transmissible nature of infections of people being accommodated, treated or transported, or the risk factors for acquiring infections by people admitted to these premises or transported in these vehicles, biocidal products must be used to disinfect: 1) premises receiving or accommodating patients and those where medical, paramedical or veterinary treatments are given; 2) vehicles used for medical transport or for transporting bodies; 3) premises and vehicles exposed to the micro-organisms and toxins mentioned in Article L.5139-1 of the Public Health Code (Decree of 30 April 2012 establishing the list of micro-organisms and toxins)."

Since 2007, the French government has regularly published decrees leading to bans on biocidal substances. These bans must be linked to a given product type, and result in the suppliers withdrawing these products for a specific use. In fact, for the ASD processes covered by the ANSM's market surveillance, these bans now only concern the hospital sector. In addition, the user must choose from the products and processes that are on the market according to the specificities and constraints of the laboratory(ies) for which they are intended.

European and French standards

With regard to the claims declared by the manufacturers, in terms of efficacy, each product granted an MA must meet the requirements described in some or all of the following standards, taking into account, where appropriate, additional

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requirements according to their specificities. Examples include the following standards:
- NF EN 14348 for mycobactericidal activity;
- NF EN 14476 and NF EN 14675 for virucidal activity;
- EN 1650 and EN 1657 for fungicidal activity;
- EN 1276 and EN 1656 for bactericidal activity;

It should be noted that this list is not exhaustive and is constantly evolving. The Afnor website can be consulted for updated information. For the ASD processes targeted by this guide, the French standard NF T 72-281 (2009) proposes a method for determining bactericidal, fungicidal, yeasticidal and sporicidal activity for ASD processes. It applies to automatic and manual processes, non-pressurised (spray type) or pressurised (limited to 10 bars). In early 2011, this method was proposed at European level and discussions are underway on a future European standardisation by the European Committee for Standardization (CEN/TC 216: "Methods of airborne disinfection of surfaces - Determination of bactericidal, fungicidal, yeasticidal, sporicidal and virucidal activity"). As part of the next revision of the French NF T 72-281 Standard, a chapter on the determination of virucidal activity will be included.

Focus on the use of formaldehyde and its derivatives in ASD with regard to the regulations

The provisions of Decree No. 2001-97 of 1 February 2001 establishing the specific rules for the prevention of carcinogenic, mutagenic or reprotoxic (CMR) risks and amending the French Labour Code apply to formaldehyde and any preparation containing more than 0.1% of formaldehyde. The Decree of 13 July 2006 (amending the Decree of 5 January 1993 establishing the list of carcinogenic substances, preparations and processes within the meaning of the second paragraph of Article R.231-56 of the French Labour Code) includes formaldehyde. Although formaldehyde is still authorised under PT2, this French (and perhaps future European) position led to work being reinitiated on seeking alternatives to formaldehyde. In fact, formaldehyde is classified as a Group 1 carcinogen by the International Agency for Research on Cancer (IARC) and as a Category 3 carcinogen with the risk phrase R40 (*"Limited evidence of a carcinogenic effect"*) in the European classification.

Principles of airborne surface disinfection

ASD involves applying a biocidal product to surfaces, using air as the diffusion vector. The aim of this method is to disinfect surfaces (equipment, walls, floors) by emitting a biocidal product into the atmosphere using an automated dispersion device. It is important to emphasise that this process only applies to the disinfection of surfaces and cannot under any circumstances be applied to directly disinfect the air. The device should diffuse the biocidal product in such a way that it comes into contact with all the surfaces in the room to be disinfected. At least three types of dispersion device are currently available on the market and are based on the following processes:
- Nebulisation: droplet size is less than 5 *µm*;
- Spraying: droplet size ranges from 10 to 50 *µm*;
- Flash evaporation: the heated biocidal product (e.g. hydrogen peroxide) vaporises and is drawn by an airstream into the room to be disinfected.

The level of efficacy of the biocidal products will depend on the diffusion process that is selected. Consequently, the efficacy assessment, as well as the laboratory validation of a process, apply only to an inseparable "device/product" combination.

Preparation of the room

The preparation of the room to be disinfected is an important preliminary step that should not be neglected. Inadequate preparation could otherwise lead to non-compliant disinfection results or degradation of equipment. This phase includes:
- cleaning and bio-cleaning;
- protecting sensitive devices;
- opening doors and drawers in furniture;
- installing disinfection equipment;
- verifying that it is in working order;
- configuring the air handling unit (AHU);
- verifying that the room is sealed;
- positioning biological (BIs) and chemical indicators.

The various phases of ASD

An ASD cycle can theoretically be broken down into four successive phases that can be adapted as needed:
- **the pre-treatment phase** during which the correct environmental conditions (temperature and humidity) are obtained in the room to be disinfected, in order to optimise the efficacy of the treatment. This optional phase is dependent on the chosen process;
- **the phase of dispersion** of the disinfectant by the device in the room to be disinfected;
- **the phase of contact** between the product and the surfaces to be disinfected;
- **the aeration phase** intended to remove the disinfectant before operators can re-enter the room. Environmental verifications may be considered in order to better determine how long the room will be unavailable, for ensuring safety of personnel. The maximum exposure limits (MEL) for each product must be known.

Dispersion time, contact time and particle size of the disinfectant droplets

The dispersion and contact times for the biocidal product with the surfaces to be disinfected are parameters to be considered closely:
- dispersion time is the period needed to reach the target concentration of the product on the surface to be disinfected, in a given volume;
- the contact time of the product with the surfaces to be disinfected is the duration needed to achieve the expected biocidal efficacy.

The automated devices diffuse the biocidal products either as a gas or in the form of microdroplets. Concerning the size of these microdroplets, a relationship has been established with their settling times. The example given in **Table 1** concerns a room left undisturbed and clearly demonstrates that the smaller the droplets' diameter, the greater their stability in the air.

Table 1. Relationship between biocide droplet size and settling time

Droplet diameter	0,5 µm	1 µm	3 µm	10 µm	100 µm
Settling time	41 h	12 h	1.5 h	8 min	5 sec

It is also important to note that the particle size of the droplets is dependent on the viscosity of the products. Thus, for the same process, two products of different viscosity will produce droplets of different size. Finally, the efficacy of ASD is dependent on the stability in air of the biocidal product, which, in order to maintain its biocidal power, must remain chemically

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stable for a sufficiently long period. A trade-off must be found between the product's chemical stability to obtain optimal biocidal activity and its rapid post-disinfection degradation to prevent it persisting on surfaces, which is both hazardous to personnel and harmful to facilities. Therefore it is important to obtain precise information from the supplier of the process (device/product combination) about the size of the droplets, their propulsion speed in the air, or the maximum distance reached by these droplets under normal operation in a room left undisturbed, as well as the duration of the product's chemical stability.

Compatibility of the disinfectant with the materials

In a laboratory, the facilities and equipment are composed of a wide variety of materials. In addition, new equipment can be regularly introduced and new layouts arranged. It is important to ensure that the surfaces to be disinfected are compatible with the selected product. Therefore, it is necessary to obtain information from the manufacturer about the product's corrosive power and its compatibility with the target surfaces to be disinfected. This is because many of the available products are highly acidic and/or oxidising (**Table 2**). Given these characteristics, users should be aware that excessive condensation promotes the corrosion of many materials.

Authorisation of personnel and maintenance of the disinfection process

Laboratory operators need to be authorised to use, maintain and verify the disinfection process. Regarding the process, before it can be implemented, it is important to obtain precise information on its maintenance, upkeep and appropriate verifications. On some types of complex equipment, it may be necessary to establish a maintenance contract.

Criteria for selecting an ASD process

The ultimate objective when selecting an ASD process is to obtain microbicidal efficacy against the strains used in the laboratory. The microbicidal efficacy of the device/product combination should be assessed under the conditions of use specified by the manufacturer. This efficacy with regard to the known targets handled in the laboratory can be measured through biological indicators selected as being representative,

Table 2. Example of biocidal products used for ASD

Product	Forms	Conditions of use	Advantages	Disadvantages
Formaldehyde	Liquid	3% to 10%	Broad spectrum of activity	Highly irritating, toxic, mutagenic, carcinogenic by inhalation
Formaldehyde	Gas	4 to 10 g/m3 18 - 22°C and 70% d'humidité	Broad spectrum of activity	
Glutaraldehyde	Liquid	2% Optimal pH: 8	Broad spectrum of activity	Irritant, toxic to the skin and respiratory tract. Activity greatly reduced in the presence of soiling.
Chlorine derivatives: Sodium hypochlorite, Sodium dichloroisocyanurate, Chloramine T	Liquid	Optimal pH: 6-7	Broad spectrum of activity	Aggressive. Toxic disinfection by-products. Activity reduced in the presence of soiling
Chlorine dioxide	Gas	Soluble in water	Broad spectrum of activity, Unlike hydrogen peroxide gas, it can tolerate a wide range of temperature and humidity	Produced *in situ*, corrosive
Peracetic acid	Liquid	Relatively unstable: decreases by 0.4% per month	Active at low concentrations in the presence of organic and inorganic soiling. Good candidate to destroy biofilms	Irritating to eyes and respiratory tract.
Hydrogen peroxide	Gas Liquid	Useable from 5 to about 35%. Relatively unstable.	In fumigation: faster and safer than formaldehyde. More stable than peracetic acid. Greater activity in the gas/liquid form	Depending on the procedure, may require humidity to be controlled at a low level. Some devices are expensive.

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in terms of resistance of the micro-organisms handled by the laboratory. These biological indicators can then be used to validate the ASD process.

Criteria of the device/product combination

The correspondence between the device's power to diffuse the biocidal product and the volumes to be treated must be assessed. The upper and lower limits to the volume that can be treated by the device must be specified by the supplier. The microbicidal efficacy must be assessed for the device/product combination, under the conditions of use specified by the manufacturer. For this reason, it is important to obtain from the manufacturer full test reports that must be consistent with the claims and conditions of application. If the manufacturer makes any technical changes to the device (e.g. changes to the nozzle, pump, etc.), it must provide updated test reports. In terms of performance, the minimum log10 reductions expected by the manufacturers, according to the NF T 72-281 (2009) Standard, must be greater than or equal to, respectively:

- 5 log for bactericidal activity;
- 4 log for fungicidal activity;
- 3 log for sporicidal activity;
- for virucidal activity, if the falls in titres from the other European standards are used, this is set at a minimum of 4.

In addition to these levels of requirements specified by the standards, each laboratory should consider whether to adapt these performance levels to the risks associated with the biological agents handled.

Laboratory criteria

The room may be more or less complex in shape and have a varying degree of partitioning. Furthermore, the internal space may differ greatly, not only from one room to another but also in the same room, from one period to another and thus from one disinfection operation to another. Consequently, during the initial validation of the ASD application conditions described in the next section, and then during successive disinfection operations, a review of rooms and equipment is recommended in order to determine any changes and assess their potential impact. To promote air circulation for better diffusion of the disinfectant in the most inaccessible areas, aeraulic disinfection bypasses and/or fans carefully positioned in the TWRs may be used. Users must be especially vigilant to the risk of diffusion outside the room to be treated, given the toxicity of the biocidal product.

Procedure for validating an ASD process

ASD must be systematically validated (biological qualification) to ensure the efficacy of the process. It must undergo an initial validation before being used routinely.

It is important that operators and managers of the operation be qualified to apply and verify ASD, and to decide whether it is compliant. As each laboratory has its own organisation and configuration, it is difficult to see how this phase could be standardised. Only the main principles will be presented here.

Initial validation procedure

Initial validation involves ensuring that ASD is suitable for the room and the activities concerned, and that it meets the requirements set. It is a prerequisite to allowing a containment laboratory to become operational, and guarantees that, when used routinely, the process will be optimal. Therefore, this procedure must be validated, documented and formalised. All the critical parameters (temperature, humidity, time, etc.) should be verified and if possible recorded continuously throughout the ASD. Any changes to the layout of the room must be assessed with a view to possibly reconsidering the initial validation procedure. The initial validation phase includes a detailed plan of the containment laboratory specifying:

- the choice of biological indicators (BIs);
- the plan for positioning BIs;
- the plan for positioning chemical indicators, if necessary and if available;
- the plan for positioning ASD devices and fans, if necessary.

Choice of biological indicators

The choice of BIs is crucial because it is proof of the microbicidal efficacy of the process implemented. Among the biological criteria for selecting these indicators, the following should be taken into account:

- the nature of the micro-organisms to be tested that will be used as BIs;
- the nature of the medium on which these test micro-organisms are deposited;
- the possible presence of interfering material.

Regarding the choice of micro-organism, the microbicidal activity of the device/product combination should ideally be tested on the micro-organisms actually used in the laboratory. However, some micro-organisms cannot be tested because of their high pathogenicity and/or for technical reasons (this is the case with viruses, for instance). In this case, a literature review is needed to find representative micro-organism(s) from among non-pathogenic representatives of the same family, or for reasons of safety, highly resistant micro-organisms should be chosen whose resistance covers that of a very wide range of micro-organisms. For information, suppliers typically recommend using *Geobacillus stearothermophilus* and *Bacillus atropheus* as BIs. These two micro-organisms have long been used to test sterilisation methods using moist or dry heat. However, the use of commercial BIs occasionally has certain disadvantages:

- the preparation method for commercial BIs (drying on medium from spore suspensions placed in aqueous or alcoholic solutions) is not always representative of the target micro-organisms (such as viruses) that may be included in complex environments (culture media, excretions, biological fluids, faeces, etc.) likely to interfere with the disinfectants and reduce their efficacy;
- following the ASD operation, when the strips containing these BIs are returned to culture, they may contain residual disinfectant likely to inhibit germination and growth of vegetative forms.

The chosen solution could then be for the laboratory to manufacture its own biological indicators. Regarding virucidal activity, the limits inherent to some BIs should be taken into account (varying loss of viral titre on drying, difficulty producing a sufficiently large viral stock, no cell line for production and titration of virus, etc.). Selection of biological indicators, whether they are commercial or in-house, must also take into account the nature of the medium for the micro-organisms: the medium on which the BI is deposited should not interfere with the disinfectant. The medium used is normally made of stainless steel, or glass or plexiglass slides. It should not promote excessive adsorption of the disinfectant, which could inhibit the culture of the BIs. The last parameter to be taken into account in the choice of BIs, which would enable the efficacy of the chosen ASD process to be validated, is the presence of interfering materials. Indeed, in some cases, such as in facilities

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holding large animals or autopsy rooms, the microbicidal activity should be tested in "dirty" conditions. This is because there is interference between disinfectants with high chemical reactivity (oxidants, aldehydes, peracids, quaternary ammonium, etc.) and various organic media that can contain micro-organisms. For this reason, it is necessary to deposit the BIs on a strip containing an organic medium representative of the organic materials (secretions, excretions, faeces, blood, etc.) of interest to the operator. Usually this means using semi-skimmed milk at 1/20 dilution, 1% albumin or 1% yeast extract.

Once the choice of BI has been made, the ASD will be validated by calculating the reduction factor in the microbial population. This reduction is assessed by comparison with a BI that has not been exposed to the decontaminant. When using dehydrated BIs, it should be noted that during drying, 1 to 3 log losses of titres are not uncommon. The media may contain residual disinfectant that must be neutralised to avoid inhibition of micro-organism growth or a toxic effect on the cell system. In the latter case, gel filtration could be considered. Ideally, the process should be carried out three times to ensure reproducibility of results and that the results from the BIs meet the established compliance criteria. When the results are unsatisfactory, an analysis should be carried out to determine why the BIs were not completely inactivated. The following questions should be asked: is it related to a failure of performance by the process or the way it was applied? Is it related to a difference in the resistance of the BIs from one batch to another?

Plan for positioning biological indicators

This must be established taking into account the volume of the room, its shape, available space, MSCs, incubators and refrigerators, levels, specific critical areas, etc. Indicators should be positioned horizontally and vertically, in such a way that both sides of the strip can come into contact with the biocide. They should be placed in the parts of the laboratory most inaccessible to the product.

Plan for positioning chemical indicators

Where available, chemical indicators for detecting the presence of the decontaminating product should be used and positioned in the least accessible places in order to detect any possible heterogeneity in the decontaminating treatment.

Plan for positioning ASD devices and fans if necessary

This positioning plan should display the list of the devices used (name, serial numbers) to ensure that they are always positioned in the same place during routine ASD.

Routine checks

Each time ASD is implemented, it must undergo biological qualification. However, for routine use, it is no longer necessary to place the BIs in the most inaccessible places, they may be limited to critical areas where contamination is most common (handling areas, incubators, refrigerators, storage areas, areas of personnel traffic, etc.). This routine checking phase assumes that nothing has changed since the initial validation (no modification to the ASD process during upkeep or maintenance - no rearrangement of the room - no new micro-organisms handled in the laboratory, etc.). If this was not the case, the initial validation operation should be repeated. A fundamental point is verification of the compliance criteria for the disinfection cycle, which must be fully consistent with those used in the initial validation. This is why it is important that the temperature and humidity parameters be systematically recorded.

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Practical guidelines for the implementation of the ASD procedure

This section offers a set of practical guidelines for the implementation of ASD. This list, based on the experience and discussions of the CMRBL, is not exhaustive.

Preparatory phase

During the preparatory phase, entering and leaving the BSL3 area shall be in accordance with the usual work procedures.

Operations	Description	People involved
Tidying and removing clutter	Put all equipment away in its place, if possible in cupboards or drawers. Remove paper and cardboard as well as small consumables not wrapped in double packaging. Empty water baths.	Personnel with BSL3 authorisation and trained in disinfection
Sealing doors	Seal exterior doors (interlocking security doors for equipment and personnel) with adhesive tape, if they do not have inflatable seals, to prevent micro-leakage.	
Protecting equipment that must not be decontaminated	Use hermetic packaging to protect equipment that must not be decontaminated and that will therefore not be accessible while the laboratory is open (e.g. microscope, computer equipment, etc.). Tape the doors of chambers containing biological material to prevent access. If possible, lock these chambers with keys or protection bars.	
Preparing materials and equipment	*To enable the decontaminant to come into contact with all areas, open cupboards, drawers, furniture under lab benches (if empty), incubators, centrifuges, etc.* *If it is compatible with the decontaminant, switch on the containment equipment (MSC, insulators, ventilated cabinets, ventilated rack) to ensure that the product passes through the filters.* *If the containment equipment is not compatible with the decontaminant, consider disinfecting the filters separately.* *Please note that switching on the containment equipment may also have an adverse affect on the product's diffusion in the room.*	
Surface cleaning	Thoroughly clean all surfaces (lab benches, worktops, MSC, incubators, etc.) using the detergent/disinfectant normally used for cleaning surfaces in the laboratory.	
Waste disposal	Take out all of the waste bins (after tidying, removing clutter and cleaning) and autoclave them. Remove liquid waste (water from incubators, water baths, etc.) either by autoclaving (liquid cycle) or *via* the effluent treatment plant by pouring them in the sink.	Personnel with BSL3 authorisation and trained in the use of incubators
Putting up signs	Display a sign on freezers, refrigerators and non-decontaminated equipment: "Do not open/use". Display a sign at the laboratory entrance explaining that entry is prohibited during the disinfection phase.	Personnel with BSL3 authorisation and responsible for application of the disinfection procedure
Positioning biological and chemical indicators	Prepare the indicators and position them according to the validated procedure. The number of BIs will depend on the volume of the room to be disinfected (usually between 3 and 5 for 10 m^2).	
Putting ASD devices in place	Check beforehand that the ASD devices are in working order. The ASD devices should be positioned according to the volume to be treated and the available space in the room. If possible, arrange them so they are visible from the outside in order to be able to check their operation. Check that the volume of decontaminant is adequate for the disinfection cycle.	
Putting fans in place	If the laboratory is not equipped with a disinfection "bypass", use fans to improve the diffusion of the disinfectant: note that they must be arranged as validated and described in the disinfection procedure.	
Sealing the entrance door	Leave the area to be disinfected and tape the entrance door giving access to the area.	

Disinfection phase

Once the operators are out of the room, the disinfection phase can begin. It is then necessary to switch off or bypass the ventilation system.

The ASD device will then operate for the time that was previously defined during the initial validation phase. When the contact time has elapsed, the ventilation system is restarted.

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Post-disinfection phase

At this stage, when entering the laboratory, the operator must wear the normal PPE.

Operations	Description	People involved
Ventilation time	Generally 2 to 5 hours but depends on the product and process used. It is preferable to speak of air renewal rate. Each decontaminant manufacturer provides guidance in Volume/h.	Personnel with BSL3 authorisation and responsible for the disinfection procedure
Verifying that there is no remaining disinfectant	Measurement of the residual concentration of the disinfectant in the air by means of test tubes and/or a measuring device. Measurement of the concentration of disinfectant must give a result consistent with the requirements of the product's safety data sheet.	
Verifying the efficacy of disinfection	Recover the BIs and culture them; this operation is performed in the BSL3 laboratory. Remove the stoppered test tubes after surface disinfection and incubate. Check BI growth in the tubes daily for at least 5 days.	
Validating the disinfection	Disinfection can be validated if the BIs most exposed to the disinfectant remain negative after the required culture time and the chemical indicators are positive.	
Disinfection certificate	Produce a disinfection certificate that can be given to all companies working in the BSL3 for inspections and maintenance.	Laboratory manager + person in charge of the facility and of risk management + Laboratory director
Authorisation to reopen the laboratory	Remove the signs prohibiting entry to the containment area.	Personnel with BSL3 and disinfection procedure authorisation

Protection and safety of personnel

Disinfection preparation phase	Description
Type of protection	Protection against biological risks: PPE normally used in the BSL3 laboratory.
Safety instructions	Put up the "disinfection in progress" signs. Follow the instructions relating to lone workers: a LWP system must be worn or mandatory presence of 2 people inside and one person outside who can intervene in an emergency.
Disinfection initiation phase	**Description**
Type of protection	To start the device: normal PPE but with a protective mask against chemical contamination fitted with a chemical filter suitable for the disinfectant used (e.g. single-cartridge gas mask with panoramic visor and chemical filter).
Safety instructions	Work in pairs monitored from the outside by at least one person who can intervene if necessary.
Disinfection verification phase	**Description**
Type of protection	PPE suitable for the biological risk and chemical mask suitable for the disinfectant used (see above).
Safety instructions	Work in pairs monitored from the outside by at least one person who can intervene if necessary.

Conclusion

Disinfection of surfaces in a containment laboratory is a complicated yet important operation, both for the safety of users and for the laboratory environment. It must be carried out meticulously and methodically, with the aim of achieving zero contamination risk. Given the many parameters involved in this operation, we have seen that there is no universal process or method. Only a very good knowledge of the situation of the laboratory concerned and its operation, along with the training of qualified personnel, will guarantee the success of the operation. Carrying out an ASD operation is relatively onerous and expensive. Therefore, once it has been validated, we recommend writing down the entire protocol in detail to ensure that the operation can easily be reproduced. Document traceability is important because it is often an aid to reconstruction of events in case of an incident.

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Definitions and acronyms

A3 animal housing: Biocontainment level 3 animal housing in accordance with the Decree of 16/07/2007

Aerosol: Suspension of solid or liquid particles in a gas with a negligible settling rate

Afnor: French Standards Institute

AHU: Air handling unit

ANSES: French Agency for Food, Environmental and Occupational Health & Safety

ANSM: French National Agency for Medicines and Health Products Safety

ASD - Airborne Surface Disinfection: operation with a temporary result that reduces contamination of inert environments or surfaces by micro-organisms to an acceptable level, depending on the objectives set by the risk assessment. This operation, performed by means of a process whose active ingredients are chemical agents in gaseous or mist form, is intended for disinfecting surfaces in a given volume, regardless of their orientation.

Automatic disinfection process: Process that diffuses a substance in gaseous or mist form, solid or liquid, from an emitting source, without human presence.

BI: Biological indicator

Biocide: Preparations containing one or more biocidal active substances presented in the form in which they are delivered to the user, and intended to destroy, deter, or render pests harmless, to prevent their action or to combat them in any other way, by chemical or biological action. A disinfectant used for ASD is a biocide.

Bio-cleaning: Operation that combines cleaning and disinfection

Biological agents: Micro-organisms, including those obtained by genetic engineering, cell culture and endoparasites, whether pathogenic or not.

Biological pathogens: Biological agents capable of causing infection, allergy or toxicity or otherwise constituting a risk to human health.

BSL3: Biological safety level for handling group 3 micro-organisms as defined by the Decree of 18 July 1994.

BSL3 laboratory: Biosafety level 3 containment laboratory

Chemical disinfection: according to the EN 15889-1 Standard: "action of one or more chemicals whose main aim is to be a microbicide".

CMR: Carcinogenic, mutagenic, reprotoxic

CMRBL: Comittee for the Control of Laboratory Biorisks

Contact time: Time required to reach the expected efficacy.

Containment: Series of technical measures and actions aimed at keeping a biological agent or other entity within a given space.

Containment area: Area built and used (and equipped with a suitable air treatment and filtration system) to prevent the external environment being contaminated by biological agents from this area.

Contaminant: Any particulate, molecular, non-particulate or biological entity likely to produce an adverse effect on a product, process, organism, or on the environment in general.

Contamination: Phenomenon of interaction by contact between two entities, one being the contaminant and the other the target, entailing disturbance of the target and whose consequences can be diluted over time.

CSP: French Public Health Code

Disinfection: Operation consisting in reducing the number of micro-organisms in or on an inert matrix, achieved by the irreversible action of a chemical or physical process on their structure or metabolism, at a level deemed acceptable for a defined objective.

According to the AFNOR NF T 72-101 Standard: disinfection is "an operation with a temporary result that can eliminate or kill micro-organisms and/or inactivate viruses carried by contaminated inert matrices, depending on the objectives set".

Disinfection bypass: Aeraulic system enabling closed-circuit laboratory ventilation

Dispersion: Dissemination of micro-droplets in the air.

Dispersion time: Time required to reach a defined concentration of the product in a given volume.

IARC: International Agency for Research on Cancer

ID_{50}: Dose infecting 50% of target tissues or species.

Inactivation: Partial or complete destruction of a given activity or destruction of a microbiological system.

Infected: Contaminated by foreign biological agents that can multiply in a matrix and may or may not reproduce there.

LWP: Lone worker protection

MA: Marketing authorisation

MEL: Maximum exposure limit

Micro-organism: Any microbiological entity, whether cellular or non-cellular, capable of reproducing or transferring genetic material

MSC - Microbiological safety cabinet: ventilated enclosure designed to protect the user and the environment from hazards related to aerosols when handling potentially hazardous and hazardous micro-organisms, with the air filtered before being released into the atmosphere.

Non-compliance: Non-fulfilment of a requirement

Procedure: Description of the operations to be carried out and precautions to be taken in an area, directly or indirectly related to the micro-organisms or toxins.

PPE: Personal protective equipment

Qualification of equipment, facilities, a room: Operation seeking to demonstrate that the equipment/facilities/room function properly and actually give the expected results.

PT2 - Product Type 2: Private and public health area disinfectants and other biocidal products

REACH: European Regulation on the registration, evaluation, authorisation and restriction of chemicals. It entered into force on 1 June 2007.

Risk: Probability of occurrence of a hazard causing harm and the degree of severity of this harm.

TWR - Technical Work Room: rooms in which samples, bodies and animals – which have been or are likely to be contaminated with biological pathogens – are handled, as well as rooms in which biological pathogens are intentionally handled.

Validation: Establishment of proof, in accordance with the principles of good manufacturing practices, that the implementation or use of any process, procedure, equipment, raw materials, packaging article or product, activity or system can actually achieve the desired results.