Annex G
(informative)

G.1 Biosafety Consultation Prior to BSC Purchase

A biosafety officer or qualified safety professional should be consulted prior to a BSC purchase. Some institutions have biosafety cabinet purchases approved by the biosafety officer or qualified safety professional after consultation with the user, architect and engineer. Biosafety officers or qualified safety professionals that perform this function should have training and field experience that includes methods used to control biohazards and knowledge of the design, application, and testing of biosafety cabinets.

Issues that may be considered include:
- Risk analysis,
- Proper location of BSCs within laboratories,
- Canopy connection to building exhaust system,
- Location of bag-in bag-out HEPA filter housings and magnehelic gauges,
- Laboratory ventilation and air exchange rates, and
- Placement of laboratory mechanical supply and exhaust diffusers.

G.2 Risk Assessment Procedure

G.2.1 Factors associated with worker's risk of exposure;
- Worker's work activity; diagnostic, research or production scale,
- Worker's proficiency, attitude and safety awareness, and
- Worker's age, sex, pregnancy, race, immune status and medications.

G.2.2 Agent/pathogen/recombinant’s factors associated with risk of disease or injury;
- Virulence,
- Infectious dose,
- Route of infection (portal of entry),
- Toxigenicity,
- Agent's host range,
- Availability of effective preventive measures, and
- Availability of effective treatment.

G.2.3 Risk assessments encompass four main elements;
- Hazard identification,
- Exposure assessment,
- Dose-response assessment,
- Risk characterization, and
- Risk management (job analysis)\(^1\).


G.2.4 Risk assessment team members include the;
- Investigator/Scientist,
- Laboratory staff,
- Animal care staff when appropriate,
- Animal veterinarian when appropriate, and
- Occupational health & biosafety professionals.
G.2.5 Risk assessment hazards considered:
- Animal hazards,
- Agent/pathogen/recombinant hazards,
- Chemical hazards, and
- Radiological hazards.

G.2.6 Risk management plan includes:
- Biosafety containment level assignment to the facility and microbiological practices,
- Safety equipment,
- Engineering controls,
- Personal protective equipment,
- Work practices – Standard Operating Procedures (SOPs),
- Emergency procedures,
- Work schedule – calendar, and
- Investigation protocols that include all risk management plans.

G.2.7 Investigation protocol review includes:
- Committee (IBC/IRB/IACUC) review, as appropriate,
- Meetings with workers to discuss approved protocols,
- Training,
- Dry runs without agent/pathogen/recombinant, and
- Regular audits.

G.2.8 Risk Management Analysis Table:

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Data Collection</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent Identity</td>
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</tr>
<tr>
<td>Known, classified</td>
<td>Agent summary statement</td>
<td>Decrease&lt;==&gt;Increase</td>
</tr>
<tr>
<td>Suspected, classified</td>
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<td>&lt;==&gt;</td>
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<tr>
<td>Known, unclassified</td>
<td>Disease Information</td>
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<tr>
<td>Unknown</td>
<td>Disease Information</td>
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<tr>
<td>Agent Transmission</td>
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<td>Aerosol potential</td>
<td>Tissue procedure</td>
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<tr>
<td>(Sample/activity)</td>
<td>Culture procedure</td>
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<tr>
<td></td>
<td>Concentration procedure</td>
<td>=========&gt;&gt;</td>
</tr>
<tr>
<td></td>
<td>Animal/non-shedder</td>
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</tr>
<tr>
<td></td>
<td>Animal/shedder</td>
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</tr>
<tr>
<td>Infectious route</td>
<td>Respiratory</td>
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<tr>
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<tr>
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</tr>
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<td>Immune globulin</td>
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<tr>
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<td>Antivirals</td>
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<tr>
<td>Treatment</td>
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<td>=========&gt;&gt;</td>
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<tr>
<td></td>
<td>Other</td>
<td>&lt;&lt;&lt;&lt;&lt;</td>
</tr>
<tr>
<td>Other Factors</td>
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</tr>
<tr>
<td></td>
<td>Poultry pathogen</td>
<td>=&gt;&gt;&gt;&gt;</td>
</tr>
</tbody>
</table>


G.3 Purchasing and installing a biosafety cabinet

G.3.1 Biosafety cabinets (BSCs) come in two standard widths, 4 foot and 6 foot. These are the inside, work area dimensions, not the outside dimensions. BSCs generally take up 5 or 7 feet of bench space, depending on whether they are 4 or 6 foot cabinets. Also available are 3 and 5-foot cabinets.

G.3.2 Investigators should consult with a biosafety officer or qualified safety professional request a risk assessment of the proposed investigation to ensure that an appropriate BSC is used for the work. Purchase of NSF 49 listed Class II biosafety cabinets is recommended, but alternative containment equipment may be suggested for special tasks.

G.3.3 An external exhaust duct transition system, commonly called a canopy connection should be connected to Type A1 and A2 BSCs and are available from most BSC manufacturers. The canopy connection will capture the BSC exhaust, BSC latent heat and will also serve as the as the laboratory exhaust. Canopy connections may be waived when appropriate.

G.3.4 The investigator should notify building management to arrange for a feasibility assessment of laboratory alterations and BSC location can be completed. The investigator and biosafety officer or qualified safety professional should discuss the following points about the BSC and its delivery:

- Make sure all arrangements are planned in advance of the BSCs arrival,
- Get a written price quote for the entire package, including the BSC Model number, optional equipment, canopy exhaust connection, etc. Work out the details about shipping and delivery with the manufacturer’s representative at the time of purchase,
- Determine the costs for shipping and delivery because there may be additional costs depending on delivery location and level of difficulty,
- Make sure that the sales representative clarifies in writing what “shipping and delivery” includes; does delivery include moving the BSC from the receiving dock of your building to your laboratory and does delivery also include BSC set-up in the work area?
- There are options for moving BSCs from a loading dock to a laboratory, such as hiring moving contractors to uncrate and move the BSC,
- Make sure the corridor pathways are clear for delivery to the laboratory,
- Will the BSC fit through door jams?
- Will the BSC travel around sharp, narrow corridors and corners?
- Will the elevators in your building accommodate the BSC?
- Does the BSC have to be brought up steps?
- The moving contractor should be advised that the BSC should be lifted onto its stand or leg extensions (working position), because a hydraulic lift may be needed.

G.3.5 When the BSC arrives, inspect it carefully. Compare the invoice with the delivered equipment. Check for any damage or missing materials and report them immediately to the proper carrier and the BSC supplier regardless of how insignificant they may first appear. Be careful of sharp crating material and let the loading dock personnel help you check for damage.

G.3.6 Arrange for certification after the BSC is installed. Building operations personnel may be needed to connect the BSC to laboratory plumbing, electrical, and supply/exhaust air ventilation systems.

G.4 Moving a biosafety cabinet

G.4.1 It is a common practice to move BSCs to other locations within a laboratory or to other laboratories. Despite the apparent simplicity of the job, there are certain conditions that must be
met prior to moving this equipment. BSCs should not be moved without consultation with a biosafety officer or qualified safety professional.

G.4.2 Existing BSCs and ancillary equipment, such as canopy connection exhaust ducting, gas, electric and vacuum connections, should be cleared for maintenance by a biosafety officer or qualified safety professional prior to disassembly. Prior to a move, BSCs should be space decontaminated. After a BSC is moved, it should be certified according to applicable performance standards.

G.5 Recommended microbiological decontamination procedure

G.5.1 Space decontamination is mandatory when maintenance work, filter changes, and performance tests require access to any contaminated portion of the cabinet. All interior work surfaces and exposed interior surfaces should be decontaminated with a suitable surface disinfectant before certification tests are performed and before gaseous decontamination takes place. In addition, it may be desirable to perform gaseous decontamination of the entire cabinet before performing certification tests when the cabinet has been used with agents assigned to Biosafety Level 2, and is recommended when the cabinet has been used with an agent assigned to Biosafety Level 3. A safety and risk assessment of cabinets potentially contaminated with biological agents should be performed by a biosafety officer or qualified safety professional. Appropriate decontamination (space and/or surface) should be performed before BSCs are moved to another location. Additionally, after spills and splashes of research agents, contaminated surfaces should be suitably decontaminated.

G.5.2 Certification of Cabinet Decontamination

BSCs must be decontaminated prior to decommissioning and salvage, before physically moving the cabinet and whenever maintenance work or filter changes or performance tests require access to any contaminated portion of the cabinet.

Biological Decontamination:
Surface decontaminate accessible work surfaces with an appropriate disinfectant. Rinse work surfaces with water and then wipe dry. Use formaldehyde gas or an acceptable alternative space decontamination procedure to decontaminate the HEPA filters and cabinet interior spaces. Remove and discard all HEPA filters and any prefilters. Rinse work surfaces with water and wipe dry.

Chemical, Radiological, Oil, or Heavy Metal Decontamination:
Surface decontaminate accessible work surfaces with an appropriate disinfectant and/or cleaning agent wipe down. Use formaldehyde gas or an acceptable alternative space decontamination procedure if biological agents may be present. Rinse work surfaces with water and wipe dry. Remove and discard all HEPA filters and any prefilters.

BSC MODEL Number _______ Serial Number ____________

1. Check each type of hazardous material that has been used or is contained in this equipment. If there has been no contamination, check "NONE" for each hazard.

2. List decontamination procedure and product used for decontamination

3. Indicate biosafety level of facility where cabinet was used:

BSL-1 ___ BSL-2 ___ BSL-3 ___ BSL-4 ___ Not applicable ___
4. Complete and sign the certification below,

<table>
<thead>
<tr>
<th>CONTAINED HAZARD (v)</th>
<th>DECONTAMINATION PROCEDURE</th>
<th>HAZARD TYPE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>BIOLOGICAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CHEMICAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>RADIOLOGICAL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OIL, HEAVY METAL (e.g., lead, mercury, or other hazardous material).</td>
</tr>
</tbody>
</table>

I hereby certify that this equipment has been decontaminated and thoroughly cleaned in accordance with the appropriate procedures (or that the equipment has not been used with any of the materials listed above).

________Signature of last user or biosafety officer __________ Date

________Name (PLEASE PRINT) __________ Title

________Room Number __________ Phone Number

G.5.3 In most instances where gas decontamination is necessary, the procedure described below utilizing depolymerized paraformaldehyde is used. Prior to decontamination with an alternative method (such as vaporous hydrogen peroxide [VHP]), cycle parameters and validation of those parameters must be developed for each model and size of BSC. Material compatibility in terms of degradation and absorption of an alternative decontaminant are critical for maintaining cabinet integrity and the time required for decontamination, respectively. Alternate methods are required in certain instances, e.g., slow disease viruses. The decontamination method should be determined by consultation between user and certification agency. When paraformaldehyde is used for gas decontamination, follow OSHA Regulations Code of Federal Regulations, Title 29, Formaldehyde-1910-1048, which addresses monitoring; posting of regulated areas; respirator selection, protection, and fit testing; medical surveillance; hazard communication and training; and recordkeeping. Automatic formaldehyde gas decontamination/neutralization may be used as a substitute to the following method provided that the manufacturer’s instructions have been followed.

CAUTION – All sources of hydrogen chloride must be removed from the cabinet before decontamination. Hydrogen chloride in the presence of formaldehyde, at ambient air conditions, will form the carcinogen Bis(chloromethyl)ether (BCME). Refer to NIOSH, Department of Health and Human Services (DHHS) reports in "Hazard Review of Bis(chloromethyl)ether (BCME)."

a) Calculate the total volume of the cabinet by multiplying the height, width, and depth.

b) Multiply the total volume of the cabinet by 0.30 g/ft³ (11 g/m³) of space to determine the gram weight of paraformaldehyde required [CHECK CONCENTRATION]. Determine the stoichiometric amount of NH₄HCO₃ or alternative to neutralize the resulting formaldehyde gas with ammonia gas. The ammonium bicarbonate should be weighed out so that it is 10%
greater than the weight of paraformaldehyde used for the decontamination to ensure completion of the reaction.

1 The information contained in this Annex is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI’s requirements for an ANS. Therefore, this Annex may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.


c) If the cabinet is equipped with an exhaust duct, this duct must be gas tight. This may be accomplished at the terminal end of the duct, or if present, at the damper located near the cabinet. If the exhaust duct is more than 10 ft (3 m) long, additional paraformaldehyde may be needed to compensate for the increased volume. If the cabinet exhausts into a recirculating building exhaust system, disconnect the cabinet from the building system and form a gas tight seal (plastic film and tape may be used).

d) If the cabinet exhaust air is discharged into the room, tape a plastic cover over and completely seal the exhaust port.

e) To provide for emergency evacuation of the formaldehyde and to allow removal of the neutralized formaldehyde following the decontamination and neutralization, a flexible hose can be pre-positioned close to the cabinet. This hose must be attached to a chemical fume hood or other exhaust suitable for the evacuation of toxic fumes.

f) Place a heating device, such as a commercially available electric frying pan or a remote formaldehyde generator/neutralizer, with the thermostat set at 450 to 475 °F (232 to 246 °C), on the work tray. The paraformaldehyde is spread evenly over the heating surface of the heating device.

   CAUTION – The auto-ignition temperature of paraformaldehyde is 572 °F (300 °C).

g) Place an additional heating device on the work tray for the neutralizing agent. The neutralizing agent (NH₄HCO₃ or equivalent) should be separated from the air in the cabinet until needed. Below are two examples of how this separation could be achieved.

   – Example One: The NH₄HCO₃ or equivalent alternative is spread evenly over the heating surface of the heating device. The top of the device is covered with aluminum foil in such a way as to prevent the NH₄HCO₃ or alternative from reacting with the formaldehyde during the decontamination. The aluminum foil can be placed to allow the escape of ammonia gas when heated, or provision can be made to remove the aluminum foil remotely at the start of the neutralization phase. The removal technique must not allow unsafe levels of formaldehyde to escape the cabinet.

   – Example Two: The cabinet is sealed using plastic with gloves as an integral part of the sheet of plastic. The NH₄HCO₃ or equivalent alternative is placed in a sealed container inside the cabinet. At the neutralization phase, the person performing the decontamination reaches into the cabinet without breaking the seal by using the gloves. The NH₄HCO₃ or equivalent alternative is removed from the sealed container and spread evenly over the heating surface of the heating device. The heating device is energized and the NH₄HCO₃ or equivalent alternative is heated and releases ammonia.

h) Place a hot plate, a beaker of water, and temperature and humidity indicators on the cabinet work tray. Do not connect electrical cords to the internal cabinet electric supply.

i) Close the opening to the work area with heavy gauge plastic film and tape. Close all possible leak areas, such as the exit of electrical cords, around the window and the junction of the plastic film and cabinet.
j) Determine the temperature and humidity inside the cabinet.

k) The temperature should be 70 °F (21 °C) or higher, and humidity should be 60 to 85%. Use the hot plate to heat the beaker of water until the desired temperature and humidity are achieved.

l) Prior to depolymerizing the formaldehyde, access to the area or room around the cabinet must be restricted in accordance with applicable federal and state regulation and prudent safety practice. OSHA’s Standard on Occupational Exposure to Formaldehyde requires that areas where the airborne concentration of formaldehyde exceeds the Permissible Exposure Limits be established as a regulated area with signs and labels marking the area and access restricted to properly trained personnel. Applicable regulations must be reviewed and complied with.

m) Plug the cord of the heating device into an outlet not installed on the cabinet.

n) After 25% of the paraformaldehyde has depolymerized, turn on the cabinet blower(s) for 10 to 15 s. Repeat after 50%, 75%, and 100% of the paraformaldehyde has depolymerized. In cases where the cabinet blower is inoperative, circulation of air within the cabinet should be promoted with additional blowers or fans, or the time of decontamination should be extended beyond the times suggested in p) below.

o) Disconnect the hot plate and heating device used for the paraformaldehyde from the electrical outlets.

p) Allow the cabinet to stand for a minimum of 6 h, preferably overnight (12 h).

q) Prepare the neutralizing agent as previously established in step g) and energize the heating device containing the NH₄HCO₃ and the cabinet blower until the NH₄HCO₃ has dissipated. As with the paraformaldehyde, after 25% of the NH₄HCO₃ has depolymerized, turn on the cabinet blower(s) for 10 to 15 s. In cases where the cabinet blower is inoperative, circulation of air within the cabinet should be promoted with additional blowers or fans or the time of neutralization should be extended to a minimum of 6 h.

r) Let the cabinet stand for at least 1 h before opening seals.

s) If a flexible hose has been provided for the evacuation of the neutralized formaldehyde, slit the plastic covering the exhaust opening of the cabinet and seal the flexible hose to the opening. If the hose is working properly, the plastic covering the front opening of the cabinet should be sucked in. One or two small openings (approximately 6 x 6 in [15 x 15 cm]) are cut into the plastic covering the front opening of the cabinet to allow fresh air to enter the cabinet while the neutralized formaldehyde is being drawn out of the hose at the exhaust opening of the cabinet.

NOTE – Alternate removal procedures are acceptable provided that they allow for safe and effective removal of the formaldehyde gas.

G.6 Recommended HEPA Filter Disposal Procedures
G.6.1 HEPA filters that have been decontaminated are often burned in an incinerator. This disposal method is also effective for HEPA filters containing toxic chemicals. Factors to be considered when incinerating filters include, but are not limited to, composition of the waste to be burned, feed rate, combustion temperature and dwell time in the primary chamber.

G.6.2 HEPA fillers may be placed in heavy plastic bags, such as those used to bag-out filters from contaminated filter housings. The bagged filters can be chemically decontaminated in situ by cutting small holes in the bag and delivering disinfectant by inserting a garden-type spray through the hole and spraying the filter media. The holes can be sealed with duct tape and shipped to an incinerator or sanitary landfill. This chemical method may be appropriate for filters containing agents (i.e. toxic chemicals or prions) that can not be inactivated by the usual space decontamination procedures.

G.6.3 Decontaminated HEPA filters may be safety buried in a sanitary landfill because they no longer pose a hazard.