# Biological Materials Questions - Monkey Pox

Data used in this based on information provided from the Public Health Agency of Canada[[1]](#footnote-1) and supplemented by fact sheets produced by Sandia National Laboratories. All values range from 0 to 1, with 1 reflecting the greatest value and 0 the lowest.

## Likelihood of Infection Following Exposure

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| Question (English) | Question (French) | Answer and Value [[2]](#footnote-2) |
| **Likelihood of Infection (Probabilité d’une infection)** | | |
| Biological agents have unique properties which can influence the likelihood of an infection following an exposure and the consequences of disease in the event on an infection.  For likelihood of infection, the primary drivers are the routes of infection and the infectious dose. The specific infectious dose (or ID50) is not as important as understanding if the ID50 is very low (under 1000). For agents with a very low ID50, the potential for an exposure to cause an infection is notably higher than for agents with a higher ID50. | | |
| Can this agent cause disease in humans? *Yes* Can this agent cause disease in animals? *Yes, but, not agricultural animals – only impacts rodents and non-human* primates) | | |
| A1.       Is this agent known to cause infection via inhalation (to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract)? | (A1) L’agent peut-il provoquer une infection par inhalation chez l’humain / chez un hôte animal (infection par gouttelettes ou noyaux de condensation infiltrés dans les voies respiratoires supérieures et inférieures) en laboratoire? | Yes (Value 1) |
| A1a. Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (A1a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain / chez un hôte animal? | Unknown (Value 1) |
| A2.       Is this agent known to cause infection via percutaneous exposure (to cause infection through compromised skin or direct injection into the blood stream)? | (A2) L’agent peut-il provoquer une infection par voie percutanée chez l’humain / chez un hôte animal (infection par lésion cutanée ou par injection directe dans le sang) en laboratoire? | Yes (Value 1) |
| A2a. Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (A2a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain / chez un hôte animal? | Unknown (Value 1) |
| A3.       Is this agent known to cause infection via direct contact (to cause infection through the mucosal membranes)? | (A3) L’agent peut-il provoquer une infection par contact direct chez l’humain / chez un hôte animal (infection par contact des muqueuses) en laboratoire? | Yes (Value 1) |
| A3a. Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (A3a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain / chez un hôte animal? | Unknown (Value 1) |
| A4.       Is this agent known to cause infection via ingestion (to cause infection via contact with the gastrointestinal tract)? | (A4) L’agent peut-il provoquer une infection par ingestion chez l’humain / chez un hôte animal (infection par contact avec le tube digestif) en laboratoire? | No (Value 0) |
| A4a. Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (A4a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain/ chez un hôte animal? | No (Value 0) |

The likelihood of infection following an exposure is based on each different route (which reflects a binary value for possible infection via each route) is 1 for Inhalation, Contact, and Percutaneous exposure, and a 0 for Ingestion. This is true for humans and animals (non-human primates and rodents).

## Attractiveness of the Material for Malicious Use

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| Question (English) | Questions (French) | Answer and Value |
| **Utility of the material** | | |
| L1.       What type of material will be used in this procedure? |  | *For this example, we will focus on diagnostic samples (Value of .25)* |
| 1.       What is general population’s knowledge or awareness of this agent as related to biological weapons or bio-crime? | (1) Quelles sont les connaissances de la population générale concernant l’agent et son potentiel comme arme biologique ou à des fins criminelles ? | This biological agent has been in the news but not related to use as a biological weapon or linked to criminal activities (Value of 0) |
| 2.       What will the level of social impact (public panic, rioting, people being unwilling to go out and work, fear of additional incidents) of the disease caused by this agent occurring in the country? |  | With this biological agent in the news, there has been witnessed fear and social impacts (although likely muted due to COVID) (Value of 0.1) |
| **Production** | | |
| 3.       What is the level of microbiological skill required to grow a suitable quantity (to meet the malicious objective) of this agent? | Quel est le degré de compétences en microbiologie nécessaire pour cultiver un volume considérable de l’agent (répondant å un objectif malveillant) | Production of a suitable quantity of this agent requires advanced technical skills (Value of .25) – can be challenging, but the technical skills are not novel, just require experience |
| 4.       What is the general accessibility of production equipment required to produce this agent? | Quel est le risque que l’agent soit produit dans une installation clandestine? | Production equipment can be acquired or fabricated (Value of .75) – not easily acquired, but not abnormal for more laboratories |
| 5.       What are the storage requirements for this agent? | Quelles sont les exigences en matière d’entreposage pour cet agent une fois produit ?? | Agent is stable when dried  (Value of 0.30) |
| **Dissemination** | | |
| 6.       Is this agent known to cause infection via inhalation (to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract)? | (6) L’agent peut-il provoquer une infection par inhalation chez l’humain / chez un hôte animal (infection par gouttelettes ou noyaux de condensation infiltrés dans les voies respiratoires supérieures et inférieures) en laboratoire? | Yes (Value 1) |
| 6a.       Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (6a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain / chez un hôte animal? | Unknown (Value 1) |
| 7.       Is this agent known to cause infection via percutaneous exposure (to cause infection through compromised skin or direct injection into the blood stream)? | (7) L’agent peut-il provoquer une infection par voie percutanée chez l’humain / chez un hôte animal (infection par lésion cutanée ou par injection directe dans le sang) en laboratoire? | Yes (Value 1) |
| 7a.       Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (7a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain / chez un hôte animal? | Unknown (Value 1) |
| 8.       Is this agent known to cause infection via direct contact (to cause infection through the mucosal membranes)? | (8) L’agent peut-il provoquer une infection par contact direct chez l’humain / chez un hôte animal (infection par contact des muqueuses) en laboratoire? | Yes (Value 1) |
| 8a.       Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (8a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain / chez un hôte animal? | Unknown (Value 1) |
| 9.       Is this agent known to cause infection via ingestion (to cause infection via contact with the gastrointestinal tract)? | (9) L’agent peut-il provoquer une infection par ingestion chez l’humain / chez un hôte animal (infection par contact avec le tube digestif) en laboratoire? | No (Value 0) |
| 9a.       Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (9a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue chez l’humain/ chez un hôte animal? | No (Value 0) |
| 10.   Is this agent known to cause infection via vector-borne transmission (to cause infection by direct mucosal membrane contact or percutaneous exposure from a vector (e.g., arthropod))? | (10) L’agent peut-il provoquer une infection par transmission vectorielle (infection par contact direct des muqueuses ou exposition percutanée à un vecteur (ex. arthropode))? | No (Value 0) |
| 10a.       Is the infectious dose (ID50) of this agent for this route less than 1000 or unknown? | (10a) La dose infectieuse (ID50) de l’agent par cette voie  est-elle inférieure à 1000 ou inconnue? | No (Value 0) |
| 11.   What is this agent’s stability outside of a host? | (11) L’agent est-il stable en dehors de l’hôte? | Agent is stable for days  (Value of 0.30) |
| 12.   Can host to host transmission be used as a dissemination pathway to execute an attack? | (12) La transmission d’hôte à hôte peut-elle être utilisée comme voie de diffusion pour réaliser un attentat? | Yes (Value 1) |

The attractiveness for malicious use of Monkey Pox is a .5 which reflects a possibility for use toward humans or animals, but only with a moderate level of attractiveness.

## Consequence of Infection

Blue are human only, grey are animal only, white are used in both human and animal calculations.

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| Question (English) | Questions (French) | Answer and Value |
| **Morbidity (Morbidité)** | | |
| 1.       What is the duration of illness in a normal healthy human host? | (1) Quelle est la durée de la maladie (durée moyenne des signes cliniques d’une infection) chez un hôte humain normal? | Weeks to Months (Value 0.75) |
| 2.       What is the severity of illness in a normal healthy human host? | (2) Quel est le degré de gravité de la maladie (gravité moyenne entre l’absence de signes de la maladie et l’hospitalisation en état critique) chez un hôte humain normal? | Moderate signs of Diseases – able to function but in a limited capacity (e.g., bed rest) (Value 0.50) |
| 3.       What is the duration of infection in a normal healthy human host? | (3) Quelle est la durée d’une infection (durée pendant laquelle l’hôte est infecté par l’organisme) chez un hôte humain normal? | Host infected (able to transmit to others) for weeks (Value 0.50) |
| 4.       Does this disease cause any long-term conditions in a normal healthy human host? | (4) La maladie provoque-t-elle des conditions à long terme (séquelles) chez un hôte humain normal? | Minor scars witnessed (value .05) |
| **Mortality** | | |
| 5.       What is the frequency of death (mortality rate) in humans caused by this disease? | (5) Avec quelle fréquence la maladie provoque-t-elle le décès chez l’humain dans une population définie pendant un intervalle spécifique (taux de mortalité)? | Mortality rate 1 to 10% (typically in children) (Value 0.25) |
| **Animal Impact (Animale)** | | |
| 6.       If the agent infects animals, what is the expected morbidity rate to a naïve but otherwise healthy animal population? | (6) Si l’agent infecte des animaux, quelle est la morbidité attendue pour une population animale naïve mais autrement saine? | Virtual none (value 0) |
| 7.       What species of animals can this agent infect? | (7) Quelles espèces d’animaux peuvent être infectées par cet agent? | Does not impact a species of agricultural importance (Value 0.25) |
| 8.       What is the disease impact on the general population? |  | Minimal (Value 0) |
| **Socioeconomic (Conséquences socioéconomiques)** | | |
| 9.    What is the economic impact of an outbreak of this agent to the country? | (9) Quel serait l’impact de la maladie sur la population générale?  Tenir compte de l’immunité collective, des niveaux de vaccination, des populations immunodéprimées, etc. | With this biological agent in the news, there has been witnessed fear and social impacts (although likely muted due to COVID) (Value of 0.1) |
| 10.   Is this agent endemic in the country? | (10) Quelle est l’incidence économique d’une flambée de cet agent dans le pays? | Witnessed in multiple regions (Value of 0.25) |
| 11.   Are there active eradication/control programs of this agent in the country? | (11) L’agent est-il endémique au pays? | No current eradication efforts (Value of 0) |
| 12.   Are clinical signs strong indicators of disease present? (For example, diseases that cause sudden death or diseases with obvious signs will be detected faster.) | (12) Existe-t-il des programmes en cours pour éradiquer cet agent dans le pays? | Minimal consequences (Value of 0.1) |
| **Mitigation Measures (Conséquences des mesures d’atténuation)** | | |
| 13.   Are effective diagnostic tests available in the country for humans? | (13) Des tests de diagnostic efficaces existent-ils pour les humains ? | Yes (Value of 1) |
| 14.   Are effective post exposure treatments (including immuno-globulin, vaccines and anti-microbials) available in the country for humans? | (14) Les traitements après exposition existent-ils pour les humains (y compris les vaccins d’immunoglobuline et antimicrobiens)? | Supportive care only (Value of .5) |
| 15.   Are preventative measures (vaccines) available in the country for humans? | (15) Des mesures préventives pour les humains existent-elles (vaccins) ? | Smallpox vaccine is 85% effective against monkey pox (Value 0.50) |
| 16.   Are effective diagnostic tests available in the country for animals? | (16) Des tests de diagnostic efficaces existent-ils pour les animaux? | No (Value of 0) |
| 17.   Are effective post exposure treatments (including immuno-globulin, vaccines and anti-microbials) available in the country for animals? | (17) Les traitements après exposition existent-ils pour les animaux (dont les vaccins d’immunoglobuline et antimicrobiens)? | No (Value of 0) |
| 18.   Are preventative measures (vaccines) available in the country for animals? | (18) Des mesures préventives pour les animaux existent-elles (vaccins) | No (Value of 0) |
| 19.   Are secondary consequence measures feasible in the country for animal populations? | (19) Existe-t-il des mesures concernant les conséquences secondaires chez les populations animales? | No (Value of 0) |
| **Secondary Transmission (Exposition secondaire)** | | |
| **Transmission (Contagiosité)** | | |
| 20.   How easily does this agent transmit between human hosts? | (20) L’agent est-il facilement transmissible entre hôtes humains? | Yes, human to human has been witnessed (Value of 0.75 |
| 21.   How easily does this agent transmit from animal to human hosts? | (21) L’agent est-il facilement transmissible d’un hôte animal à un hôte humain? | Yes, primarily via bites or contact with blood (Value of 0.75) |
| 22.   How easily does this agent transmit from human to animal hosts? | (22) L’agent est-il facilement transmissible d’un hôte humain à un hôte animal? | Not witnessed, but possible (Value .05) |
| 23.   How easily does this agent transmit between animal hosts? | (23) L’agent est-il facilement transmissible entre hôtes animaux? | Yes, in close proximity (Value .5) |
| **Routes (Voies d’exposition naturelles)** | | |
| 24.   Is this agent known to cause infection via inhalation (to cause infection via droplets or droplet nuclei that have entered the upper or lower respiratory tract) in the natural environment? | (24) L’agent peut-il provoquer une infection par inhalation (infection par gouttelettes ou noyaux de condensation infiltrés dans les voies respiratoires supérieures et inférieures) dans le milieu naturel? | Yes (Value 1) |
| 25.   Is this agent known to cause infection via percutaneous exposure (to cause infection through compromised skin or direct injection into the blood stream) in the natural environment? | (25) L’agent peut-il provoquer une infection par voie percutanée (infection par lésion cutanée ou par injection directe dans le sang) dans le milieu naturel? | Yes (Value 1) |
| 26.   Is this agent known to cause infection via direct contact (to cause infection through the mucosal membranes) in the natural environment? | (26) L’agent peut-il provoquer une infection par contact direct (infection par contact des muqueuses) dans le milieu naturel? | Yes (Value 1) |
| 27.   Is this agent known to cause infection via ingestion (to cause infection via contact with the gastrointestinal tract) in the natural environment? | (27) L’agent peut-il provoquer une infection par ingestion (infection par contact avec le tube digestif) dans le milieu naturel? | Yes (Value 1) |
| 28.   Is this agent known to cause infection via vector-borne transmission (to cause infection by direct mucosal membrane contact or percutaneous exposure from a vector (e.g., arthropod))? | (28) L’agent peut-il provoquer une infection par transmission vectorielle (infection par contact direct avec les membranes muqueuses ou par exposition percutanée provenant d’un vecteur (ex. arthropode))? | No (Value 0) |
| 29.   Is this agent known to cause infection via vertical transmission (to cause infection from mother to fetus in the womb or via ingestion of infected breast milk)? | (29) L’agent peut-il provoquer une infection par   transmission verticale (infection de la mère au fétus dans le ventre ou par ingestion de lait maternel infecté)? | No (Value 0) |
| 30.   Is this agent known to cause infection via sexual transmission (to cause infection through sexual contact including intercourse)? | (30) L’agent peut-il provoquer une infection par transmission sexuelle (infection par contact au cours de rapports sexuels)? | No (Value 0) |

The impact of the disease to a human reflects a value of .4 (some impact to individuals and society of presence of the disease) and a .2 for animals (minimal impact). For animals (non-human primates and rodents) the consequences are closer to .2, this reflects the impacted species having less social impact.

## Risks of infection assuming exposure

The relative risks of infection assuming an exposure associated with Monkey Pox are presented below in the two scatter plots (one reflecting risks toward human (figure 1) and the other animals (figure 2) – non-human primates and rodents). From these relative risk plots, Monkey Pox – if there is an exposure - is a moderate risk via inhalation, contact, or percutaneous exposure for humans and a low risk for animals. Monkey Pox is not an ingestion risk for either. Its security risk is also low.

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| Figure 1 Human Risks associated with Money Pox | Figure 2 Animal risks associated with Monkey Pox |

# Laboratory Procedures

For this example, we are going to focus on diagnosis of Monkey Pox via viral isolation. No animals are used in this procedure.

Any work with infectious material increases the potential for an exposure. This includes indirect exposures such as the infectious material being on a hand, which is transferred to the eyes, mouth, nose, or potentially to another individual. Any work with infectious material has the potential to cause a spill or splash potentially causing an exposure via contact, ingestion, or inhalation.

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| Question (English) | Questions (French) | Answer and Value |
| 1.       What type of material will be used in this procedure? | (1) Quel type de matières sera utilisé pour cette procédure (si la procédure utilise des matières biologiques purifiées et des échantillons de diagnostic, choisir l’option matières purifiées) | Diagnostic samples (Value .25) |
| 2.       What is the greatest volume of material existing at one time in the procedure? | (2) Quel volume maximal de matières sera présent à tout moment pour cette procédure? | Small volume, but more than microliter since growing in cell culture (Value .25) |
| 3.       What is the potential for aerosols to be generated as a byproduct of this procedure? (E.g., pipetting, sonication, etc.)? | (3) Quel est le risque d’une libération d’aérosols comme sous-produit de cette procédure? (ex. pipetage, sonification, etc.)? | Minimal potential for aerosol, mostly pipetting and some centrifuging (Value 0.1) |
| 4.       Are aerosolization experiments being conducted as part of this procedure? | (4) L’aérosolisation est-t-elle utilisée dans les procédures d’expérimentation? | No aerosolization work (Value .01) |
| 5.       What is the amount of sharps used in the procedure? | (5) Quelle est la quantité d’objets tranchants utilisée pour cette procédure? | Sharps not readily in use other that tips from micropipettes (Value .1) |
| 6.       What is the amount of breakable material or items with sharp edges in this laboratory? | (6) Quelle est la quantité de matières cassables ou d’objets tranchants utilisée dans ce laboratoire? | Very little breakable material in the lab (Value .25) |
| 7.       What is the potential and extent of a splash or spill in this procedure? | (7) Quel est le risque et l’étendue d’une éclaboussure ou d’un déversement pour cette procédure? | There is a potential for a spill or a splash (Value .5) |

## Risk of exposure and subsequent infection

The relative risks of exposure and infection of Monkey Pox based on the defined laboratory procedures without including any mitigation are presented below. The first (figure 3) reflects the risks to those working in the laboratory and to humans in the community. The second (figure 4) reflects the risks to animal populations – non-human primates and rodents – also outside the laboratory. For humans, the consequences of disease are slightly higher in the community than for those in the laboratory to reflect the wider potential individuals in the community, such as children or others with lower immunities. By adding in the potential for exposure based on the procedure to just considering infection with an exposure, you can see a reduction in the relative risk.

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| Figure 3 Human Risks Associated with Diagnosis of Monkey Pox | Figure 4Animal Risks Associated with Diagnosis of Monkey Pox |

# Effectiveness of BioSafety and BioSECURITY Mitigation Measures

For this example, the facility and specific laboratory will be defined mirroring an academic containment laboratory. The following table reflects the general measures used in the analysis and specifics will be reflected in the answers to the questions below. The provided summary of the facilities safety and security system should not be considered a listing of required or desirable measures, but simply provided to help users better understand software.

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| The laboratory’s safety system | The laboratory’s security system |
| * Substantive management oversight and performance-management system in place * Documented, structured risk assessments   + Mitigation measures (e.g., containment, PPE, waste handling, training) defined specifically by the risk assessments   + There is active safety training for all with laboratory access * Containment system   + BSC     - validated, documented procedures for use, cleaning, and maintenance   + Directional airflow     - validated, documented procedures for use, cleaning, and maintenance * PPE   + Gloves     - Nitrile Single Pair used for all procedures     - Specific training (including donning and doffing and storage), validated and documented procedures for use and disposal   + Gowns     - Gowns or lab coats are always worn over street clothes     - Specific training (including donning and doffing and storage), validated and documented procedures for use and disposal   + Shoes     - Persons must wear closed-toed shoes * Waste   + Decontaminated in lab (validated and documented procedures)   + Sharps housed in puncture resistant container, autoclaved, then incinerated * Area   + Surfaces solid, all watertight * Cleaning procedures validated and documented | * Substantive management oversight and performance-management system in place * Documented, structured risk assessments   + Security processes and procedures defined specifically by the risk assessments   + Physical security elements designed and implemented based on the risk assessment   + There is active security training for all those with access to the laboratory * Facility protection layers   + The outer perimeter is defined as the building housing the laboratory   + Doors are only locked after hours and weekend   + The laboratory itself has a double door for entry, the outer door is locked with a manual key, the inner door is not locked, there are no functional windows in the laboratory   + The freezer where isolates are stored in locked with a manual key * Detection and Response   + The building has door alarms and motion sensors which are active after hour with an attached sounder to alert guards   + The laboratory has motion sensors which are active after hours with an attached sounder to alert guards * Access Control Management   + Keys are managed by the laboratory principal research, who assigns and tracks keys to both the building, laboratory, and freezer   + Keys and access are given to students with approved research to be conducted within the laboratory, approvals are granted by the university’s safety committee   + Laboratory staff cleans laboratory themselves and escorts guests and maintenance personal * Material Control   + Isolates are tracked in an electronic inventory system that is maintained by the university’s information technology center   + Materials in the laboratory are considered ‘owned’ by the approved researcher and their responsibility for transfer or destruction following completion of the experiment * Research information is protected as proprietary until release for publication, but no other informational processes exist |

## Safety System Effectiveness

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| Safety System Effectiveness (English) |  | Answer and Value |
| **Engineering Controls** | | |
| Overall measures to ensure engineering controls are maintained, certified (or validated), trained on and operating procedures verified, helps to ensure the equipment is working as designed and offering the appropriate level of protection. | | |
| 1.1 Are there procedures in place for preventative equipment maintenance to reduce/eliminate accidents or equipment failure, which meet defined best practices? These would include equipment calibration, validation, certification, etc. |  | Maintenance defined for equipment, which includes documentation. (Value = 1) |
| 1.2 What is the implemented process for the decontamination of equipment prior to maintenance? |  | Maintenance defined for equipment does not specifically include decontamination. (Value = 0) |
| Primary containment reduces the potential for an aerosol release during a procedure; likewise, biosafety cabinet or other isolators reduce exposure potentials in the same manner. Building ventilation and directional airflow reduce the potential for an aerosol release to the environment. | | |
| 1.3 Are Biosafety cabinets used in this procedure? | Les enceintes de biosécurité (BSC) sont- elles utilisées pour la procédure ? | Yes, and there exist validated, documented procedures for use, cleaning, and maintenance (Value = 1) |
| 1.4 Is all the equipment used in this procedure with a potential to generate infectious aerosols (e.g. centrifuge, vortexer, sonicator) isolated or sealed in a manner to prevent aerosol escape (e.g. sealed rotor cups, equipment in BSC or in a biobubble, etc) prior to use? | L’équipement utilisé pour cette procédure ayant le potentiel de produire des aérosols infectieux (ex. une centrifugeuse, un agitateur-mélangeur à vortex, un appareil sonique) est-il isolé ou scellé de manière à éviter les échappées d’aérosols (ex. une roue à auguets scellée, équipement en BSC ou en biobubble, etc.) avant son utilisation? | Yes, and there exist validated, documented procedures for use, cleaning, and maintenance (Value = 1) |
| 1.5 Are other forms of Primary Containment used in this procedure? | D’autres formes de confinement primaire sont-elles en vigueur pour cette procédure? | Yes, and there exist validated, documented procedures for use, cleaning, and maintenance (Value = 1) |
| 1.6 Are measures in place to reduce infectious aerosols exiting the laboratory? (Ventilation / HVAC) | Les modalités sont-elles en place pour éviter les échappées d’aérosols à l’extérieur du laboratoire? | Direction airflow via duct work, but not HEPA filtered (Value = .75) |
| Waste handling equipment (autoclaves, incinerators, effluent treatment systems, etc.) reduce the potential for a contact (and potentially ingestion) exposure within the laboratory by reducing the amount of infectious material in the laboratory, but more specifically reduce the potential for a release to the environment. | | |
| 1.7 How is liquid waste (effluent) handled? | Comment les déchets liquides (les effluents) sont ils traités? | There is no process for capturing liquid waste in this laboratory, liquid leaves laboratory untreated (Value = 0) |
| 1.8 How easy are the surfaces in the laboratory to decontaminate? |  | Surfaces are solid and airtight and cleaned with validated procedures (Value = 1) |
| 1.9 How is contaminated waste stored in the laboratory? |  | Waste is decontaminated in lab (validated and documented procedures) (Value =1) |
| Puncture resistant containers for sharp or potentially sharp waste also reduce the potential for a contact or percutaneous exposure to individuals within the laboratory and to the environment. | | |
| 1.10 How is sharp waste handled? | Comment les déchets tranchants sont-ils traités? | Sharps housed in puncture resistant container, autoclaved, then incinerated (Value .75) |
| **Administrative Controls** | | |
| Starting with management commitment to safety, administrative controls reduce the potential of exposure by enabling better work practices, incident management, and create a responsible safety culture. Administrative controls can reduce the potential for an exposure to an individual in the laboratory and to the environment.  Administrative controls include implementation of good laboratory practices, practices and procedures to reduce generation of aerosols, proper hand washing techniques, proper inventory management, proper sharps handling, proper spill response procedures, larger incident response procedures, and waste storage and handling. These measures reduce the potential for exposure via all routes. | | |
| 2.1 Does the institution have defined roles and responsibilities for biosafety? | L’institution a-t-elle défini les rôles et les responsabilités relatives à la biosécurité ? | Yes (Value = 1) |
| 2.2 Has the institution made a commitment to safety? | L’installation s’est-elle engagée envers la sécurité? | Yes (Value = 1) |
| 2.3 Does the institution have comprehensive biosafety documentation? | L’institution a-t-elle une documentation complète en matière de biosécurité? | Yes (Value = 1) |
| 2.4 Does the institution conduct biosafety drills or exercises? | L’institution mène-t-elle des exercices ou des simulations relatives à la biosécurité? | Drills are not formalized, but more random (Value = 0.3) |
| 2.5 Does the institution periodically review the biosafety program? | L’institution passe-t-elle périodiquement en revue le programme relatif à la biosécurité? | Yes (Value = 1) |
| 2.6 Are all biological agents in this laboratory inventoried? | Tous les agents biologiques de ce laboratoire sont-ils inventoriés? | No, inventory is really ad hoc (Value = .1) |
| 2.7 Is there a shipping and receiving program in place at this laboratory? | Un programme d’expédition et de réception existe-t-il dans ce laboratoire? | Not formalized so very limited (Value =.25) |
| 2.8 Are there standard operating procedures in place for unexpected or catastrophic incidents, including the release of or exposure to an infectious agent (e.g. Incident response plans)? | Existe-t-il des mesures pour l’entretien préventif de l’équipement afin de minimiser/éliminer le risque d’accidents ou de pannes d’équipement, qui répondent aux normes professionnelles? Telles que le calibrage de l’équipement, la validation, la certification, etc. | This laboratory has some procedures in place for incident response, but lacks oversight in implementation (Value = .5) |
| 2.9 Does this laboratory implement standard good laboratory practices for safety? | Ce laboratoire applique-t-il les meilleures pratiques normalisées pour la sécurité en laboratoire? | Yes (Value = 1) |
| 2.10 How are sharps handled in the laboratory? | Comment les objets tranchants sont-ils utilisés? | Sharps are rarely handled by hand (Value = 0.5) |
| 2.11 Does this laboratory have procedures in place for sharps handling to reduce/eliminate percutaneous exposure that meet defined best practices? | Ce laboratoire a-t-il des procédures en vigueur qui répondent aux meilleures pratiques normalisées pour la manipulation d’objets tranchants afin de réduire ou d’éliminer l’exposition percutanée ? | Yes (Value = 1) |
| 2.12 Does this laboratory have procedures in place for agent handling to reduce/eliminate aerosols? These procedures should meet defined best practices. | Ce laboratoire a-t-il des procédures en vigueur pour la manipulation d’agents afin de réduire ou d’éliminer la production d’aérosols? Ces procédures doivent répondre aux meilleures pratiques normalisées | Yes (Value = 1) |
| 2.13 Are absorbent materials used on the bench or BSC to contain spills and reduce splashing? | Des matériaux absorbants sont-ils utilisés sur le banc ou l’enceinte de biosécurité (BSC) pour confiner les déversements et réduire les éclaboussures? | Yes (Value = 1) |
| 2.14 After working with potentially contaminated material (cultures, infectious waste), how are objects that should not become contaminated (door handles, computer keyboards) handled? | Suite aux travaux avec des matières potentiellement contaminées (cultures, déchets infectieux), comment manipule-t-on les objets qui ne devraient pas être contaminés (poignées de porte, claviers d’ordinateur)? | Yes (Value = 1) |
| 2.15 Does this laboratory have procedures in place for spill response that meet defined best practices? | Ce laboratoire a-t-il des procédures en vigueur répondant aux meilleures pratiques normalisées pour une intervention en cas de déversement? | The lab has basic spill response procedures in place, but does not conduct validation exercises on these procedures (Value = 0.5) |
| 2.16 Does this laboratory have procedures in place for lab workers to reduce/eliminate contact exposure through broken skin, which meet defined best practices? | Ce laboratoire a-t-il des procédures en vigueur répondant aux meilleures pratiques définies pour les employés du laboratoire afin de minimiser ou éliminer le risque d’exposition par lésion cutanée? | Proper practices for reducing/eliminating contact exposure through broken skin exist, but are not taught, enforced, verified or documented (Value = .75) |
| 2.17 How frequently are hands washed? | Avec quelle fréquence les mains sont-elles lavées? | Hands are washed only when leaving the lab (Value = .75) |
| **Personal Protective Equipment** | | |
| Training for use of, maintenance of, storage of, and disposal of is required for PPE to be effective at reducing the risk of exposure. Proper donning and doffing procedures are also required. | | |
| 3.1 Is there a formal personal protective equipment (PPE) program in place? | Existe-t-il un programme officiel afférant à l’équipement de protection individuelle (PPE) | This laboratory has an active PPE program which includes, well-defined procedures for donning, doffing, storing, and maintaining PPE (Value = 1) |
| Gloves provide direct protection of the wearer of contact to the skin on the hands and indirect protection of the mouth, nose, and eyes due to better awareness by the wearer. Multiple gloves can reduce the potential of a percutaneous exposure minimally, puncture resistant or puncture proof gloves offer true reduction in percutaneous exposure. Lab coats or other coverings help to reduce the potential for contact to the skin and help prevent the transfer of infectious materials outside the laboratory. | | |
| 3.2 What types of gloves are used for this procedure? | Quel type de gants est utilisé pour cette procédure? | Single pair nitrile gloves (Value = .75) |
| 3.3 What type of protective clothing (PPE) is used in this laboratory? | Quel type de vêtements de protection (PPE) est porté dans le laboratoire? | Gowns or lab coats over street clothes (Value =.75) |
| 3.4 What types of gloves are in use while using sharps (e.g., needles, scalpels, etc) in this procedure? | Quel type de gants est utilisé dans la manipulation d‘objets tranchants (ex. seringues, scalpels, etc.) pour cette procédure? | Single pair of nitrile type gloves are typically worn while handling sharps (Value = 0) |
| Safety glasses or goggles reduce the potential for exposure to the eyes. Face shields provide protection to the eyes, mouth, and nose. Surgical masks provide protection to the mouth and nose. | | |
| 3.5 What type of protective eyewear is used in this laboratory? | Quel type of lunettes de protection est utilisé dans ce laboratoire? | None (Value = 0) |
| 3.6 Are face shields or masks worn for this procedure? | Un masque ou écran facial est-il utilisé pour cette procédure? | None (Value = 0) |
| Solid shoes protect the feet from contact exposure and provide barrier protection of physical hazards. Note feet often have compromised skin more often than hands. Laboratory dedicated shoes or shoes covered reduce the potential of transfer of infectious material outside the laboratory. | | |
| 3.7 What types of shoes are worn in the laboratory? | Quel type of chaussures est porté au laboratoire? | Persons must wear closed-toed shoes (Value =.25) |
| Respirators, which are fitted and certified, offer protection from an inhalation exposure. | | |
| 3.8 Is respiratory protection used in this procedure? (Surgical masks are not considered respiratory protection) | Une protection respiratoire est elle utilisée pour cette procédure? (les masques chirurgicaux ne sont pas considérés comme protection respiratoire) | No (Value = 0) |

Based on these responses, the safety system is 60 to 65% effective in reducing the potential for an exposure to individuals working in the laboratory and between 80 and 90% at reducing the potential for an exposure outside the lab. The following chart reflects the effectiveness for each route and the breakdown by type of mitigation measure (engineering controls, administrative controls, or PPE).

Figure Effectiveness of Biosafety System at Reducing Exposure

Combining the effectiveness of the mitigation system with the potential for an exposure from the laboratory procedure and the potential for infection from Monkey Pox, the following figures reflect the relative risk. In comparing these to the unmitigated results from Figure 3 & 4, you can see the impact of the mitigation measures at reducing the risks.

|  |  |
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| Figure 6 Human Risks Associated with Diagnosis of Monkey Pox | Figure 7Animal Risks Associated with Diagnosis of Monkey Pox |

## Security System Effectiveness

|  |  |  |
| --- | --- | --- |
| Security System Effectiveness (English) | Caractéristiques de Sûreté (French) | Answer and Value |
| **Security Culture (Gestion du Programme)** | | |
| 1.       Does the institution have defined roles and responsibilities for biosecurity? | L’institution a-t-elle défini les rôles et les responsabilités relatives à la biosûreté ? | Yes, part of the biorisk management process implemented at this facility (Value of 1) |
| 2.       Has the institution made a commitment to security? | L’installation s’est-elle engagée envers la sûreté? | Yes, part of the biorisk management process implemented at this facility (Value of 1) |
| 3.       Does the institution have comprehensive biosecurity documentation? | (40) L’institution a-t-elle une documentation complète en matière de biosûreté? | Yes, part of the biorisk management process implemented at this facility (Value of 1) |
| 4.       Does the institution conduct biosecurity drills or exercises? | L’institution mène-t-elle des exercices ou des simulations relatives à la biosûreté? | Yes, part of the biorisk management process implemented at this facility (Value of 1) |
| 5.       Does the institution periodically review the biosecurity program? | L’institution examine-t-elle périodiquement le programme relatif à la biosûreté? | Yes, part of the biorisk management process implemented at this facility (Value of 1) |
| **Physical security (Sûreté physique)** | | |
| 1.       What type (if any) of a perimeter security exists outside the building(s)? | Quel type de périmètre existe (ou non) autour du campus ou de l’installation ? | No, since open campus there are not specific perimeters outside of the building (Value of 0) |
| 2.       How many barriers exist between public areas and the biological agent? | Le bâtiment qui abrite l’agent possède-t-il un système de contrôle pour limiter l’accès? | There are two normally locked barriers (door and freezer) between the public and the isolates of anthrax (Value of .3) |
| 3.       Does the building housing the select biological agent or toxin limit access through a control system when the building is not occupied? | La salle qui abrite l’agent possède-t-elle un système de contrôle pour limiter l’accès? | Building has manual access controls (keys and locks) (Value of .5) |
| 4.       Does the room housing the select biological agent or toxin limit access through a control system when the room is not occupied? | Les zones où sont entreposées l’agent (congélateurs, collecte de cultures, etc.) possèdent-elles un système de contrôle pour limiter l’accès? | Room has manual access controls (keys and locks) (Value of .5) |
| 5.       Do the select biological agents or toxins storage areas (freezers, culture collection, etc.) limit access through a control system? | Des systèmes de détection d’intrusion existent-ils dans les zones où l’agent est  entreposé ou utilisé? | Storage areas have manual access controls (keys and locks) (Value of .5) |
| 6.       Are ALL individuals with access to the room, work areas, and any storage areas where select biological agents and toxins exist specifically approved for access? | Les alarmes sont-elles posées sur toutes les portes et fenêtres (ou autres points d’entrée)? | Procedural access restrictions exist and individuals with access have been registered and approved (Value of .5) |
| 7.       Do intrusion detection systems exist in the areas where select biological agent or toxins are used or stored? | Comment les alarmes sont-elles évaluées? | Local annunciation of alarms only (Value of .7) |
| 8.       Are ALL doors (or other potential entry points) covered by an intrusion detection system? | Comment répond-t-on à ces alarmes? | Control only on doors (Value of .7) |
| 9.       How are alarms assessed? | Quel type de périmètre existe (ou non) autour du campus ou de l’installation ? | Guards sent to assess alarms (Value of .45) |
| 10.   How are alarms responded to? | Le bâtiment qui abrite l’agent possède-t-il un système de contrôle pour limiter l’accès? | Onsite guard response and local law enforcement back-up (no formal MOUs between university and local law enforcement) (Value of .8) |
| **Personnel Reliability (Fiabilité du personnel)** | | |
| 1.       How are personnel vetted prior to allowing them unescorted access to the agent? | Comment s’effectue la vérification du personnel avant d’octroyer un accès à l’agent sans escorte? | Vetting includes only verification of credentials (education, prior employment) and references (Value of .2) |
| 2.       How are the personnel vetted who will not have direct access of the agent? | Comment s’effectue la vérification du personnel qui n’aura pas d’accès direct à l’agent ? | No vetting of personnel prior to granting access (Value of 0) |
| 3.       How are visitors and other individuals who have not been vetted escorted when accessing rooms with the biological agent or other materials? | Comment les gens sont-ils escortés? | Escorting requirements in place but not defined escort ratios (value of .45) |
| 4.       Are badges worn? | Des badges d’accréditation sont ils portés ? | No (value of 0) |
| 5.       Do badges indicate level of access allowed by the wearer? | Les badges indiquent-ils le niveau d’accès autorisé du porteur? | Badges not required or routinely worn or badges that are worn do not identify if badge belongs to person wearing it (Value of 0) |
| 6.       Does badge include a photo of the wearer (owner) and a time interval for when it is valid? | Le badge comprend-t-il une photo du porteur (propriétaire) et une durée de validité ? | Badges not required or routinely worn (Value of 0) |
| 7.       Are there procedures for returning badges or reporting lost badges? | Existe-t-il des procédures pour le retour des badges ou le signalement en cas de perte? | Badges not required or routinely worn or there are no formal badge procedures (Value of 0) |
| 8.       What is the level of biosecurity training provided? | Quel est le niveau de formation dispensé en matière de biosûreté? | Biosecurity training provided to all employees (Value of .7) |
| 9.       Do employee assistance programs exist? | Des programmes d’aide aux employés existent-ils? | Informal support network among personnel (Value of .2) |
| **Transport Security** | | |
| 1.       What is the level of control at a facility of materials moving between laboratories or while in shipping/receiving areas? | Dans l’installation, quel est le niveau de contrôle des matières transportées d‘un laboratoire à l’autre ou dans la zone d’expédition et de réception ? | Agent not left outside of custody of authorized individual during transit unless secured but level of security is lower than how it is secured in storage (Value of .7) |
| 2.       What type of vetting is required for personnel transporting material within the facility? | Quelles sont les habilitations requises pour le personnel transportant les matières à l’intérieur de l’installation? | Facility personnel who have access to the materials during internal transport are vetted but to a lower degree than those who handle the agent in the laboratory (Value .45) |
| 3.       What type of administrative approvals is required for internal transport? | Quelles sortes d’autorisations administratives sont nécessaires pour le transport interne? | Pre-approval not required for internal transport, but transfer is documented in laboratory records (Value of .5) |
| 4.       What type of administrative approvals is required for external transport? | Quelles sortes d’autorisations administratives sont nécessaires pour le transport externe? | Pre-approval by a responsible individual at the facility required prior to shipping to external recipient (Value of .7) |
| 5.       What is the required security level for the receiving facility when sharing this agent? | Lorsque l’agent est partagé, quel est le niveau de sûreté exigé pour l’installation réceptionnaire? | Receiving facility has equivalent or better biosecurity (Value of .9) |
| 6.       How are agents packaged for external transport? | Comment les agents sont-ils emballés pour le transport externe? | Conforms to infectious substance shipping labeling requirements but does not identify the specific agent on the outside of the package. (Value of 1) |
| 7.       How are external carriers selected? | Comment les transporteurs externes sont-ils sélectionnés? | External carrier chosen has good reputation for security of commercial shipments (e.g. FedEx, DHL, Airborne Express) no knowledge of their security plan regarding biological materials.  (Value of .5) |
| **Material Control and Accountability (Contrôle matériel et responsabilisation)** | | |
| 1.       How does the facility determine which materials are subject to material control and accountability (MC&A) measures? | Comment l’installation détermine-t-elle les matières qui seront soumises aux mesures de contrôle matériel et de responsabilisation? (MC&R) | Individual PIs/lab owners make decisions about which materials require MC&A measures (Value of .2) |
| 2.       Which materials are inventoried? | Quelles matières sont inventoriées? | Seed stock inventory electronically managed (Value of .2) |
| 3.       What is the level of control of agents while in use (working stocks, infected animals, etc.)? | A quel degré de contrôle sont soumis les agents pendant leur utilisation (stock de travail, animaux infectés, etc.)? | No controls in place when materials are in use (Value of 0) |
| 4.       Are there clearly defined accountability roles and responsibilities? | Les rôles, les responsabilités et l’imputabilité sont-ils clairement définis? | PI aware of each agent used within their laboratory (Value of .45) |
| 5.       Are there clearly defined procedures for material control and accountability (MC&A)? | Les procédures sont-elles explicites pour le contrôle et la responsabilisation des matières  (MC&R)? | Some MC&A procedures are in place, but they are not comprehensive and/or are not fully implemented (Value of .45) |
| **Information Security (Sûreté de l’information)** | | |
| 1.       Has information which is considered sensitive been clearly identified, marked, and protected at a level equivalent to the risk of loss or release? | Les informations jugées sensibles ont-elles été clairement identifiées, marquées et protégées à un niveau équivalent du risque de perte ou de libération d’un agent? | No identification and classification of information in place (Value of 0) |
| 2.       Is information which is considered sensitive protected from release or loss? | Les informations jugées sensibles sont-elles protégées d’une perte ou d’une fuite? | Some information protection procedures are in place, but they are not comprehensive and/or are not fully implemented (Value of .5) |
| 3.       Are there clearly defined communication policies regarding sensitive information? | Existe-t-il des politiques clairement définies relatives à la communication d’informations sensibles? | Staff is trained on communication policies (Value of .5) |
| 4.       Are electronic critical infrastructure systems (including inventory databases, alarm control stations, access control systems, building monitoring systems, etc.) protected from attack? | L’infrastructure critique des systèmes électroniques est-elle protégée contre les attentats (y compris les bases de données de l’inventaire, les postes de contrôle d’alarmes, les systèmes de contrôle d'accès, les systèmes de surveillance de bâtiments, etc.) | Comprehensive IT security infrastructure in place or not applicable because no sensitive information is stored (Value of 1) – University IT |
| 5.       Are there clearly defined policies for public disclosure of information? | Existe-t-il des procédures clairement définies relatives à la divulgation d’information au public? | Some procedures/policies regarding public disclosure are in place but they are not comprehensive and/or are not fully implemented (Value of .45) |
| 6. Are electronic physical security systems (alarm control stations, access control systems, building monitoring systems, etc.) isolated from the public internet? | Les informations jugées sensibles ont-elles été clairement identifiées, marquées et protégées à un niveau équivalent du risque de perte ou de libération d’un agent? | Systems are on a private isolated network with no access from the internet or the general facility intranet (Value of 1) |

Based on these responses, the security system is just under 50% effective in reducing the potential someone without authorized access (an outsider) acquiring material from the laboratory and 55% effective at reducing the potential for someone with authorized access (an insider). The following chart reflects the effectiveness against each threat and the breakdown by type of mitigation measure.

Figure 8 Effectiveness of Biosafety System at Reducing Exposure

Combining the effectiveness of the mitigation system with the attractiveness of Monkey Pox for malicious use, the following figures reflect the relative risk. While the security system being ~50% effective seems limited, the system based on the risks associated with Monkey Pox, the overall risks as low to very low.

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| --- | --- |
| Figure 9 Human Security Risks Associated with Diagnosis of Monkey Pox | Figure 10Animal Security Risks Associated with Diagnosis of Monkey Pox |

1. https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/monkeypox-virus.html [↑](#footnote-ref-1)
2. I have the answer options in French also, but I wasn’t sure how best to include them here [↑](#footnote-ref-2)