



APPENDIX C

Novel Viruses and Other Infectious Pandemics

This appendix to the Kryosphere Business Continuity Plan, in coordination with Kryosphere's Standard Operating procedures, is to be used for handling daily operations, health and safety of staff members, maintaining client stored material and possible facility quarantine or shut down in the event of an infectious health pandemic that inhibits the normal operations of the biorepository.

The term Novel virus refers to a virus not seen before. It can be a virus that is isolated from its reservoir or isolated as the result of spread to an animal or human host where the virus had not been identified before. It can be an emergent virus, one that represents a new strain, but it can also be an extant virus not previously identified. The virus also may come up just as the result of genetic makeup mutations under various causative factors and thus being unnoticed by humans.

Novel viruses such as a coronavirus, influenza or other highly contagious viruses or bacteria pose a potential risk to the normal daily operations of Kryosphere's biorepository and related services. Because of the uncertainty associated with a newly discovered organism (or even a known organism such as the "flu") and how it will impact the health and safety of the general population; it is imperative that even this plan be somewhat flexible and fluid in mitigating and handling situations as they evolve.

Kryosphere's Pandemic Plan includes the following components:

- A. Communications
- B. Workplace health & safety precautions
- C. Employee travel restrictions
- D. Alternate employee work plan
- E. Employee reporting of illness and exposure
- F. Monitoring employee exposure, health and mandatory medical evaluations, vaccinations and return to work
- G. Facility preparedness, quarantine and shutdown

PLAN ACTIVATION AND AUTHORITY

During the time of an actual pandemic outbreak that is threatening the U.S., Kryosphere Management will make all final decisions to raise the level from Preparedness to instituting alternate work plans or facility partial or full closure.

Three Levels of Response will be followed:

LEVEL	ACTIVATION CRITERIA
Preparedness Response	<ul style="list-style-type: none"> • Pandemic health concern affects the United States. • CDC recommendations.
Alternative Work Plan/Facility Slow Down	<ul style="list-style-type: none"> • Community has severe outbreak and exposure to employees is probable. • Recommendations from local health departments.
Facility Closure	<ul style="list-style-type: none"> • Exposure risk is very high. • Multiple employees infected resulting in loss of manpower. • Mandatory quarantine by local health departments.

EMPLOYEE REPORTING OF ILLNESS AND EXPOSURE

During the time of an actual or probable pandemic outbreak, the appropriate and timely reporting of employee illness is very important. Employees who are sick or have potentially been exposed to another infected person or traveled to an infected area should refrain from work until released by a medical professional.

Employees who have symptoms of acute respiratory illness are recommended to stay home and not come to work until they are free of fever (100.4° F [37.8° C] or greater using an oral thermometer), signs of a fever, and any other symptoms for at least 24 hours, without the use of fever-reducing or other symptom-altering medicines (e.g. cough suppressants). Employees should notify their Direct Manager and stay home if they are sick.

Any employee with a known exposure or illness to a novel virus or other contagious diseases will not be allowed to return without appropriate Return To Work authorization from their healthcare professional.

PREPAREDNESS RESPONSE

A. Communications

Ongoing communications from Kryosphere Management, as well as communications from employees regarding employee illness and/or exposure during the time of a potential or actual pandemic outbreak is paramount.

1. Kryosphere Management will make a formal announcement that the Company is now in PREPAREDNESS RESPONSE.
2. Kryosphere Management will monitor daily the latest communications and information released by the local health departments, city, state and federal governments, as well as the Center for Disease Control (CDC) during a possible or actual pandemic. Any relevant information will be communicated to all employees.
3. Kryosphere Management will also communicate to all employees any necessary changes to daily operations, work assignments or need for quarantine or facility closure.

4. Employees are required to report any know or probable exposure to a novel virus or other infectious disease as soon as possible in order to take appropriate precautions from exposing other employees.
5. Employees who are required to stay home because of illness or quarantine are expected to communicate daily with their direct manager to update them on their status and expected return to work date.

B. Workplace Health & Safety Precautions

1. Facility Disinfection and Contamination Prevention

- a. Daily Disinfection - Kryosphere SOP #200.009.X Kryosphere Facility Cleaning Program, should be followed each day. Quality approved disinfectants should be utilized to wipe down all work surfaces, equipment and instruments. Everyone can help to keep the environment germ-free by cleaning frequently touched surfaces and objects like doorknobs. Regularly cleaning surfaces and objects that are frequently touched is recommended.
- b. Personal Protective Equipment (PPE) – Kryosphere standard operating procedures for cleaning, material handling or transporting material require the use of personal protective equipment. Appropriate gloves, gowns, eye protection, and masks should always be worn when handling any biological or pharmaceutical material.

2. Employee Responsibilities

- a. Stay home when you are sick. Staying home when ill prevents the spread of infections to others.
- b. Use good respiratory etiquette and hand hygiene in all community settings, including homes, childcare facilities, schools, workplaces, and other places where people gather. Cover your coughs and sneezes with a tissue and put the used tissue in a waste basket. If you don't have a tissue, cough or sneeze into your upper sleeve, not your hands.
- c. Wash your hands often and thoroughly with soap and water for at least 20 seconds (sing happy birthday to yourself twice) or use an alcohol-based hand sanitizer (with at least 60-95% alcohol).
- d. Avoid touching your eyes, nose or mouth: Germs are often spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth.
- e. Avoid large crowds and assemblies.
- f. Practice other good health habits: Clean and disinfect frequently touched surfaces at home, work or school, especially when someone is ill. Get plenty of sleep, be physically active, manage your stress, drink plenty of fluids, and eat nutritious food.
- g. Regularly disinfect your cell phone.

- h. Stay appropriate distance from other people to prevent airborne droplet contamination.
- i. If a family member you live with is diagnosed or suspected of being infected by a novel virus or other contagious disease; you should notify your direct Manager before coming to work.

C. Facility Preparation

1. Adequate Supplies
 - a. Inventory and order additional personal protective equipment,
 - b. Surface disinfectants and alcohol-based hand sanitizers.
2. Top off gases and fuels
 - a. Ensure liquid nitrogen bulk tank is filled,
 - b. Generator fuel tanks should be topped off. These par levels should be maintained throughout the Preparedness Response Phase.
3. Essential Vendors – communicate with vendors regarding essential supplies required for dry ice, liquid nitrogen and generator fuel.
4. Training – ensure all staff all trained on the appropriate use of PPE and facility cleaning.
5. External Temperature Monitoring – continue weekly testing of the facility EMS temperature monitoring and alert system.
6. Communicate with Kryosphere customers regarding Kryosphere’s preparedness.

ALTERNATIVE WORK PLAN/FACILITY SLOW DOWN

This phase of the plan will be implemented when the pandemic begins to affect the general population of our community and employee exposure is high or imminent. Action steps taken during this phase are to prevent the entire workforce from infecting each other that could potentially lead to further quarantine or facility shutdown.

A. Communications

Frequency of communications to employees and clients should increase to daily. This should include the current status of operations, number of employees exposed, and any additional action(s) being taken to prevent employee exposure, as well as the safeguarding of client material.

B. Employee Travel Restrictions

Employees will be restricted from traveling outside of Kryosphere Headquarters for work or conferences during the period of Alternative Work Plan or Facility Slow Down. This includes

traveling to any area of high virus outbreak or know significant risk areas. Once Kryosphere reaches this level of response, it has been recommended and/or mandated by the local health department and CDC to avoid all travel.

C. Workplace Health & Safety Precautions

1. Daily Disinfection - Disinfection of all surfaces, equipment, telephones, computers, etc. should be increased to multiple times a day using facility-approved disinfectants.
2. Personal Protection Equipment – PPE should always be worn when handling or transferring any client material, during cleaning procedures, as well as if an exposed co-worker is detected until all surfaces and the location have been decontaminated.
3. Visitor Restriction – To limit exposure, all visitors to Kryosphere will be restricted during the time of the Alternative Work Plan or Facility Slow Down. This will be communicated via email to all current clients, as well as signage it to be placed on all entrances by Kryosphere Management.
4. Employee Responsibilities
 - a. Employees should be continuously monitoring and following all communications and directions from Kryosphere Management.
 - b. Monitor health status of self and family members
 - c. Report any illness of self or family members to Kryosphere Management prior to arriving at facility. Based upon the situation, employee may be told to stay home to prevent exposing other co-workers.

D. Facility Preparation

1. Notify all clients that Kryosphere is operating on an Alternative Work Plan to protect the health and safety of employees. During this time, transfers in and out of material to Kryosphere will be halted. This will aid in limiting any further potential exposure to the employees and the facility.
2. All critical remote systems (EMS alert monitoring, remote CCTV, IT back-ups and security systems should all be tested to ensure functionality in the event that a sudden facility shutdown requires remote monitoring of facility.
3. Employee Health Status should be determined each day by Management to ensure adequate coverage to maintain basic facility operations.
4. Weekly testing of the EMS and generators should continue.

E. Alternative Work Plan

To minimize cross-contamination and exposure to the entire workforce, Kryosphere will initiate a “team” system approach. All operations staff will be divided into two teams. Team A and Team B will not work in the Kryosphere facility at the same time. Employees should always continue to

practice excellent hand hygiene and avoid coming into contact with infected individuals during their time off.

Kryosphere Management will notify all employees of their Team Designation and the work schedule associated for the team. Every employee, regardless of assignment is to report in by 8:00 a.m. each day to the Kryosphere Director of Operations or designee.

The normal on-call technician process will continue and be adjusted by Kryosphere Management based upon current employee health and illness.

During this phase, all work will be confined to the Kryosphere Headquarters. Delivers, transfers and shipments will not occur.

FACILITY SHUTDOWN

This phase of the plan will be implemented only as a last resort when a substantial amount of the work force is either ill or has been quarantined by the local health facilities and the continual daily operations of Kryosphere cannot be carried out safely.

Kryosphere has the capability to continue cGMP storage throughout the time of a prolonged absence of personnel. All storage and refrigeration units are backed up with generator power in the event of a power failure, as well as an adequate number of qualified, “at temperature” freezers and refrigerators are always available as our standard backups. Continuous monitoring of the biorepository will occur in the same fashion as on weekends and extended holidays when no employees are present. Designated on-call personnel will remotely monitor all systems and respond in accordance with Kryosphere Emergency Response Standard Operating Procedures. In addition to the remote monitoring while the facility is closed; a physical walk through the facility will occur at least once a day by the designated on-call technician. The following remote monitoring systems are to be used throughout the time there is a facility closure:

- A. LabGuard 3D Environmental Monitoring System – utilized to monitor all Controlled Temperature Units and room temperatures and humidity.
- B. BSI Laboratory Inventory Management System
- C. Remote commercial power and generator monitoring
- D. Montitis – remote server monitoring
- E. Security systems
 - i. Building Burglar Alarm System
 - ii. CCTV system
 - iii. Honeywell badge card access system

A. Communications

Kryosphere Management will notify all employees and clients of a complete facility closure. During the closure, employees are expected to report to their Direct Manager daily to report on their

health status, ability to work and any abnormalities noted from the remote monitoring. Kryosphere will update clients at least every three (3) days of the status of the biorepository and the anticipated return to full operations.

B. Facility Closure Procedures

1. Kryosphere Management will notify all employees and clients of closure date and time.
2. Kryosphere Management will notify vendors of the facility closure.
3. The telephone system will be forwarded to Kryosphere Management.
4. Prior to closing the facility, all remote monitoring systems are to be tested a final time; including the monthly testing of the SIP communication server to ensure appropriate roll over between the land, cellular and voice over IP phone systems.
5. Director of Operations or designee is to provide to each employee a work from home schedule designating who and when each employee is responsible for monitoring the remote systems.
6. Each employee is to ensure they take their laptop computer home with them for the duration of the closure.
7. The designated monitoring on-call employee is to do the normal 12 a.m., 6 a.m., 12 p.m., 6 p.m. checks of the remote systems and review all temperatures and humidity.
8. The designated monitoring on-call employee is to physically come to the facility each day and walk the entire biorepository if they have not responded to another issue earlier in the day.
9. Any abnormality is to be reported immediately to the Director of Operations and Kryosphere Management.
10. Director of Operations will decide if the on-call employee or another employee is to physically come to the facility to address the issue. All Kryosphere Standard Operating Procedures for handling emergency situations should continue to be followed.
11. Weekly testing of the remote systems should continue to occur during the facility closure.

C. Reopening the Facility

1. Prior to reopening the facility, all surfaces, equipment, telephones, door handles are to be disinfected with the approved disinfectant.
2. Kryosphere Management will notify all employees and clients of the date and time facility is reopening.
3. A determination will be made by Kryosphere Management if the facility is being fully reopened or on an Alternative Work Plan.
4. Notify all vendors of reopening. Order new dry ice supply and other supplies as needed.

CONCLUSION OF EVENT

At the conclusion of the Alternative Work Plan or Facility Closure phase, a formal critique and evaluation of the process, including the items that went well, those that could be improved and other issues should be reviewed, documented and the plan is to be revised with this new information.