

- 政治運動家（「反中絶運動」の右翼活動家）
- 薬物中毒／アルコール中毒／精神障害者
- 不満を持つ従業員／学生の不満分子
- テロリスト／人種差別主義者（国内および国際的）

これらの人々が、次の者である可能性に注意：

- 部内者
- 部外者
- 両方（共謀）

D. 脆弱性評価の一部が次の面に関する統合評価となる：

- どのような弱点が付け込まれ、それぞれの研究所の資産の損失、損傷、危機、または崩壊に結び付く可能性があるか？
- 施設の設置場所：脅威レベルの高い地域にあるか、施設には接近しやすいか、他の建物との近接具合や、警察など対応施設、車両で接近できる道路への近さはどうか？
- どのようにして敵対者が侵入することができるか、あるいは他の方法で目的を達することができるか：強引な侵入、秘密裏の侵入（部内者との共謀の場合）、許可を得た侵入（部内者）、部内者に対する強要、同伴者なしの侵入、時間外まで潜伏、放火、陽動作戦など？
- 次のものを評価して、物理的セキュリティシステムに関するその現場独自の要件を決定する：
  - 物理面（つまり、境界柵、建物の構造と配置、施設の配置、連絡道路、対応車両と装備）。
  - 技術面（つまり、既存の物理的セキュリティシステムと装置、通信、配電および警報通達基盤、照明）。
  - 運用面（つまり、職員、運用の概念）。

E. リスクの評価には、次のものを含む、または考慮する：

- 敵対者の動機／目的（欲望、復讐、妨害、社会不安、破壊活動、自尊心、機会、国への危害、プロパガンダ、窃盗、認知された権利、不明な理由）。
- 敵対者の知識、能力、熱意、技能、および「内部」から援助を獲得する可能性のレベル。
- 任務の目標と価値への、損失、損傷、危機、または崩壊による影響の深刻さに従って、資産の優先順位を決定する。
- その資産に対する最も現実的な脅威を選択する。
- その資産の最も現実的な脆弱性を選択する。

- 発生の可能性を決定する。この可能性は、資産の脆弱性や資産に対する脅威と相関する。

F. 対策の選択肢。

- 何もしない。
- 既存のセキュリティの改良、増強、または置換を行う。
- 運用の考え方を改変する。
- 職員の再訓練または再装備を行う。
- より安全な場所に資産を移転する。
- 物理的セキュリティ目標を再評価する。

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2006年3月



## Emergency Preparedness: “Biological Agents”

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### 1. Introduction

Despite a greater awareness of biosafety and biocontainment practices, handling infectious microorganisms remains a source of infection, and even mortality, among laboratory workers. Incidents of secondary transmission of disease to the public at large, which may be due to possible contamination of the environment or personnel, are also occurring. There is a steady increase in both the number of laboratories handling pathogens and in the number of scientists wishing to work with new or exotic strains for further study. Laboratory workers can minimize the risks associated with work involving these infectious agents through the application of appropriate biosafety and containment principles and practices. Increasing demands are also being placed on regulatory authorities to ensure that such pathogens are handled in a safe and secure manner.

National Ministries of Health are encouraged to establish a centre of expertise for biosafety and biocontainment, to ensure effective, evidence-based biosafety interventions through regulatory control, surveillance, applied research and timely dissemination of information. The goal and expected outcome of the Centre's programs is a reduction in the risks of occupationally acquired infection, environmental contamination and disease transmission to the public.

The strategies that should be employed by the biosafety centre of expertise to achieve this goal include:

- X regulating the importation and use of human pathogens
- X providing biocontainment and biosafety standards and guidelines
- X ensuring compliance to these standards and appropriate biological containment
- X conducting surveillance and applied research projects to develop evidence-based biosafety guidelines
- X liaising with other government departments, standard setting associations, national committees and organizations
- X building the national biosafety capacity through information dissemination and training

## 2. Office of Laboratory Security

Canada's national centre for biosafety, the Office of Laboratory Security (OLS), was established within Health Canada in 1980. Strengthening its ability to protect the health and safety of Canadians, the Government of Canada has delivered on its commitment to establish a new Public Health Agency of Canada and appoint a new Chief Public Health Officer, Dr. David Butler-Jones. The creation of the Public Health Agency of Canada marks the beginning of a new approach to federal leadership and collaboration with provinces and territories on public health and responds to a consensus from the provinces, public health experts and concerned citizens on the need for federal leadership on public health to be consolidated in a public agency. As a result of the creation of the Public Health Agency of Canada, the Office of Laboratory Security is now part of this new agency.

Its mission is to ensure effective, evidence-based biosafety interventions on a national basis through regulatory control, surveillance, applied research, and timely dissemination of information related to needs, priorities and strategies. The Office of Laboratory Security has the following functions:

### **Biosafety Division**

- ▶ develop and apply national biosafety policies and guidelines
- ▶ assess permit applications for importation of human pathogens
- ▶ issue permits for importation of human pathogens
- ▶ certify level 3 and 4 containment facilities
- ▶ offer consultative services to microbiological laboratories
- ▶ act as a resource centre by providing training services and information
- ▶ act as a WHO collaborating centre

### **Emergency and Bioterrorism Response Division**

- ▶ develop policies, procedures and guidelines for biosafety emergencies, threat reduction initiatives and biological proliferation prevention programs
- ▶ control and track the use of dangerous pathogens in Canada
- ▶ monitor the accidental release of biological materials from certified and non-certified facilities and the instances of laboratory-acquired infections
- ▶ effect the Emergency Response Assistance Plan (ERAP) for national transportation emergencies involving Risk Group 4 human pathogens
- ▶ effect a national plan for 24/7 on-scene responses to suspicious packages and other bioterrorism events

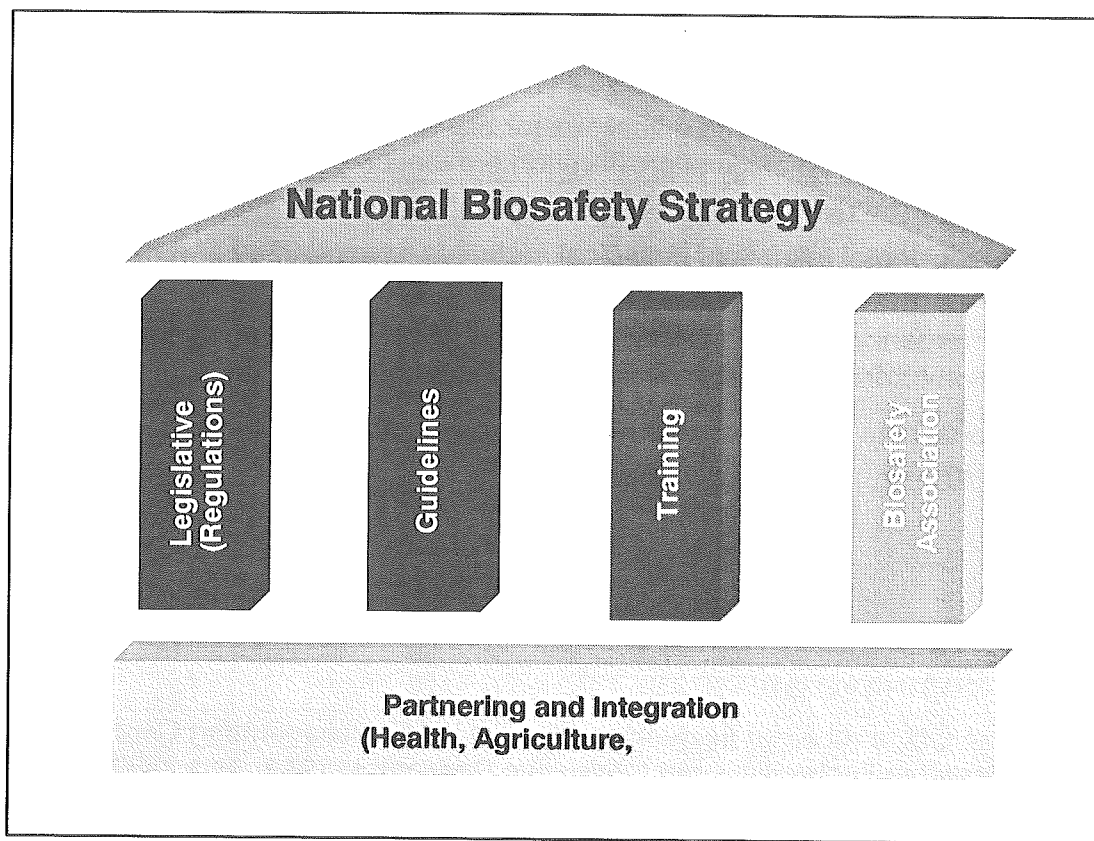


### **WHO Collaborating Centre on Biosafety Technology and Consultive Services**

The Office received its designation as a WHO Collaborating Centre in Biosafety Technology and Consultive Services in 1983. As a WHO collaborating centre, the Office provides guidelines and safety programs for microbiology laboratories worldwide including consultive services in biocontainment technology and biosafety, biosafety training, the dissemination of information, the provision of a biosafety resource centre, surveillance and applied biosafety research programs.

## **3. Establishing a National Biosafety Strategy**

Achieving a successful national biosafety strategy involves the partnering and integration of a number of key players including national health authorities, animal health authorities, and security authorities. Biosafety should ideally be incorporated within national public health security policies and programs. The four pillars of an effective strategy include enabling biosafety legislation, biosafety guidelines and standards, training, and the establishment of biosafety associations.



### ***Legislative Mandate***

The International community has recognized and addressed the importance of proactively decreasing the risk of accidental or deliberate release of dangerous pathogens by implementing biosafety and biosecurity legislation.

Such legislation should generally consider the following elements:

- a list of dangerous pathogens where anyone in possession must register with the national health authority;
- a list of the most dangerous pathogens where the possession and use of which would be restricted to laboratories certified by the national health authority;
- enhanced security requirements for laboratories handling all dangerous pathogens; both in terms of containment and selected laboratory personnel;
- reporting requirements to the national health authority concerning anyone in possession, or with potential access to the most dangerous pathogens;

- issuance of import permits;
- Consultation with and inspection, certification and re-certification of containment laboratories;
- Compliance and enforcement activities;
- Collaboration with the animal health authorities on permits/inspections involving pathogens that infect both humans and animals; and
- Liaison with security authorities for security screening of personnel with access to dangerous human pathogens.

The legislative authority with respect to biosafety of dangerous pathogens within Canada resides with: the Human Pathogen Importation Regulations (HPIR) under the Department of Health Act (DHA) for human pathogens; the Health of Animals Act and Regulations for animal pathogens and the Plant Protection Act and Regulations for plant pathogens. The latter two pieces of legislation are administered by the Canadian Food Inspection Agency (CFIA). The HPIR are administered by the Office of Laboratory Security, within the Public Health Agency of Canada (PHAC).

The HPIR require that an importer must obtain an import permit to import risk group 2, 3 or 4 human pathogens into Canada. Subsequent transfer of risk group 3 or 4 human pathogens requires permission from our office as well. A condition of permit issuance requires the importing facility to meet the Laboratory Biosafety Guidelines, 3<sup>rd</sup> edition, 2004 (LBG). For containment level 3 and 4 facilities, using risk group 3 or 4 human pathogens, the facility must be certified, by the OLS, as meeting the guidelines. This certification process requires submission of all pertinent Standard Operating Procedures (SOPs) specific to the human pathogens the facility wishes to be certified to use, a review of the physical (electrical, mechanical, facility design) aspects of the facility and finishes with a site visit by the OLS inspection staff. Once all conditions of the LBG have been met, a certification letter is issued.

## ***Guidelines***

Countries are encouraged to develop national guidelines for the safe handling of pathogenic microorganisms in laboratories within their geographical borders. Since 1983, many countries have used the guidance provided in the World Health Organization's *Laboratory Biosafety Manual* to develop such codes of practice. A third edition of the manual was published in 2005.

The Office of Laboratory Security has also recently published the 3<sup>rd</sup> edition of the Public Health Agency of Canada's **Laboratory Biosafety Guidelines**. Since publication of the 2<sup>nd</sup> edition in 1996, adherence to the *Guidelines* has become mandatory for many laboratories handling human pathogens in Canada. This 3<sup>rd</sup> edition was updated to



reflect current biosafety and biocontainment principles and practices. The document was written with a performance-based approach, which not only accommodates contemporary state-of-the-art technologies and ever-changing approaches to achieving containment but provides simple and sensible solutions as well. Performance-based guidelines define the end-result desired rather than providing detailed solutions to containment design.

The construction of cost-effective containment facilities is essential for countries and regions for developing networks of laboratories to respond to incidents of disease outbreaks and bioterrorism. Biocontainment research leading to cost-effective solutions is urgently needed to fill the existing gaps in containment knowledge. Such research will also generate scientifically sound containment measures that can be incorporated into evidence-based national biosafety guidelines. In this way, the real risks of biohazards can be mitigated instead of perceived risks of the spread of pathogens from containment facilities.

### *Training*

The key to success of a national biosafety program is on-going consultation and training for laboratory clients. Guidance should be provided to microbiology laboratories on interpretation of the requirements of the national biosafety guidelines including the planning of containment facilities from start-up to certification. National biosafety centre's of excellence should provide timely biosafety information and solutions to problems in biosafety.

Training courses and workshops should be provided on an on-going basis to ensure continued biosafety awareness within the laboratory community. Biosafety specialists will also require security training that outlines physical facility security mechanisms, personnel screening issues and pathogen inventory systems.

The increase in containment facilities has, in turn, brought increased demand for biosafety practitioners to oversee these facilities, as well as increased demand for biosafety training for those who design, build and work in containment facilities (e.g. engineers, architects, contractors, laboratory workers, laboratory supervisors, maintenance personnel).

## ***Biosafety Associations***

Biosafety Associations comprise a network of individuals with interests in biosafety and provide a forum to:

- Promote biosafety
- Share biosafety knowledge
- Develop and exchange resources and guidelines
- Provide training seminars and workshops
- Advance biosafety as a scientific discipline
- Expanding biosafety awareness

These associations offer a unique opportunity for biosafety professionals to coordinate and develop a national biosafety forum for the sharing of information, development of common standards and collaboration in all aspects of biological safety.

The International Working Group was established to support and promote biosafety on a national and international level through collaboration among national and regional biosafety organizations worldwide. The Working Group is composed of representatives from national, and international organizations or groups with a recognized mandate in biosafety and includes representatives from:

- European Biological Safety Association (EBSA), [www.ebsa.be](http://www.ebsa.be)
- Asia Pacific Biosafety Association (APBA), [www.a-pba.org](http://www.a-pba.org)
- American Biological Safety Association (ABSA), [www.absa.org](http://www.absa.org)
- ABSA Canada, [www.absa-canada.org](http://www.absa-canada.org)
- Associacao Nacional de Biosseguranca, Brasil (ANBio), [www.anbio.org.br](http://www.anbio.org.br)
- Japanese Biosafety Association
- International Veterinary Biosafety Working Group (IVBWG), [www.ivbwg.org](http://www.ivbwg.org)
- International Level-4 Users Group
- Pharmaceutical Biosafety Group
- World Health Organization
- Pan American Health Organization
- Centres for Disease Control
- Other countries with a strong interest in creating a Biosafety Association (e.g. Russia)

## 4. Biosecurity

Today, facilities handling infectious agents need not only a biosafety program but also a biosecurity plan in place. While biosafety deals with all aspects of containment to prevent any exposure to and accidental release of pathogens, biosecurity is implemented to prevent the theft, misuse or intentional release of pathogens. Whether it be for the advancement of science or the diagnosis of agents causing disease or the misuse of these technologies, there is unfortunately a dual use potential in the nature of the work (i.e., procedures, equipment, etc.) that takes place with these agents.

As the planning and implementation of a biosecurity plan needs to be specific to the nature of each facility, the type of research and diagnostics conducted, and the local environment, a diverse working group needs to be involved. Consideration should be made to include scientific directors, principal investigators, laboratory workers, administrators, safety officers, security staff, maintenance staff, and law enforcement agencies where appropriate. Also, include the "Responsible Official" (RO) where one is designated. A Responsible Official is typically responsible for the development, training, and implementation of safety, security, and emergency response plans. As such, the RO is contacted with timely notice of any theft, loss or release of agents. This individual is involved in allowing only approved individuals to have access to agents and is involved in the transfer and transportation of agents from the facility. This person can assist with maintaining detailed records of information necessary to give a complete accounting of all activities related to pathogens.

A primary component to a biosecurity plan must be a detailed risk assessment . The biosecurity risk assessment should review and list the relevant assets, define the threats, outline the vulnerabilities, and determine the countermeasures or mitigation strategies specific for each facility. The biosecurity plan should then address the following factors: physical protection; personnel suitability/reliability; pathogen accountability; and related incident and emergency response.

### ***Physical Protection***

The physical protection risk assessment should include all levels of biosecurity review: perimeter security, facility security, laboratory security and agent specific security, and outline procedures for securing the area, e.g., card access, key pads, locks etc. All laboratories should adopt biosecurity practices to minimize opportunities for unauthorized entry into laboratories, animal and storage areas, as well as the unauthorized removal of infectious materials from their facility. Similarly, information security for data and electronic technology need to be addressed.

### ***Personnel Suitability/Reliability***

Background checks and security clearances may be required before employees are granted access to containment facilities. These factors should be considered as part of the local risk assessment process when developing a biosecurity plan. Photo identification badges for employees and temporary badges for escorted visitors can also be used to identify individuals with clearance to enter restricted areas. Procedures are needed for approving and granting visitors access to controlled areas. In this capacity the access to agents and storage facilities is limited to legitimate use/individuals only. Biosecurity training needs to be provided.

### ***Pathogen Accountability***

Pathogen accountability procedures should include inventory requirements for proper labelling, tracking of internal possession, inactivation and disposal of cultures after use, and transfers within and outside the facility. These inventory controls also assist in keeping track of pathogen storage locations and under whose responsibility the pathogens lie. Inventories must be updated regularly to include new additions as a result of diagnosis, verification of proficiency testing, or receipt from other locations as well as to remove agents after transfers or appropriate inactivation and disposal mechanisms have been used. The record keeping should include pathogen inventories, who has access to agents, who has access to areas where agents are stored or used, as well as transfer documents. A notification process for identifying, reporting, and remediating security problems, i.e., inventory discrepancy, equipment failure, breach of security, release of agents, etc., should be in place.

### ***Biosecurity Incident and Emergency Response***

A protocol for reporting and investigating security incidents e.g., missing infectious substances, unauthorized entry, should be addressed. A mechanism needs to be in place for the reporting and removal of unauthorized persons. Biosecurity incident and emergency plans should include response to intentional (bomb threats etc.), unintentional (accidental release) and natural events (power outages, severe weather). Training needs to be provided to all relevant personnel.

Biosecurity requirements for facilities handling infectious agents at containment levels 3 and 4 will generally be more stringent than those required in clinical and research containment level 2 laboratories. Recommendations on biosecurity practices (e.g., storage of pathogens, inventories, log books to record entry) and physical design security features (locks, restricted access) should be incorporated.

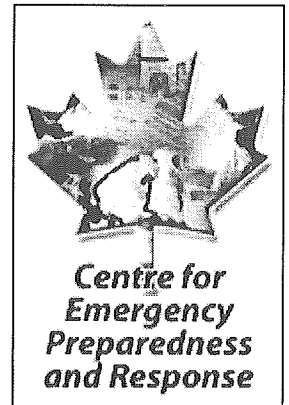
Expert advice from security and/or law enforcement experts should be sought in the development of threat assessments and security protocols specific to each facility. The threat assessment and security practices should be regularly reviewed and updated to reflect new threats that may be identified.

## **5. Emergency Preparedness and Response**

## ***Centre for Emergency Preparedness and Response***

The public look to their governments for protection from health risks. They expect their governments to be ready to deal with the possible health risks from:

- natural events and disasters such as floods, earthquakes, fires and highly dangerous infectious diseases; and
- accidents or criminal and terrorist acts involving explosives, chemicals, radioactive substances or biological threats.



Within Canada, all levels of government help to protect the health of Canadians from these threats as part of their efforts to promote health and prevent disease. Municipal governments respond to local emergencies. Provincial and territorial governments respond to emergencies within their borders, but may ask for federal government assistance if the emergency exceeds their resources. Local, provincial and territorial authorities do much of that work with federal government support from the Public Health Agency of Canada's **Centre for Emergency Preparedness and Response (CEPR)**.

The CEPR's bioterrorism and emergency response responsibilities include:

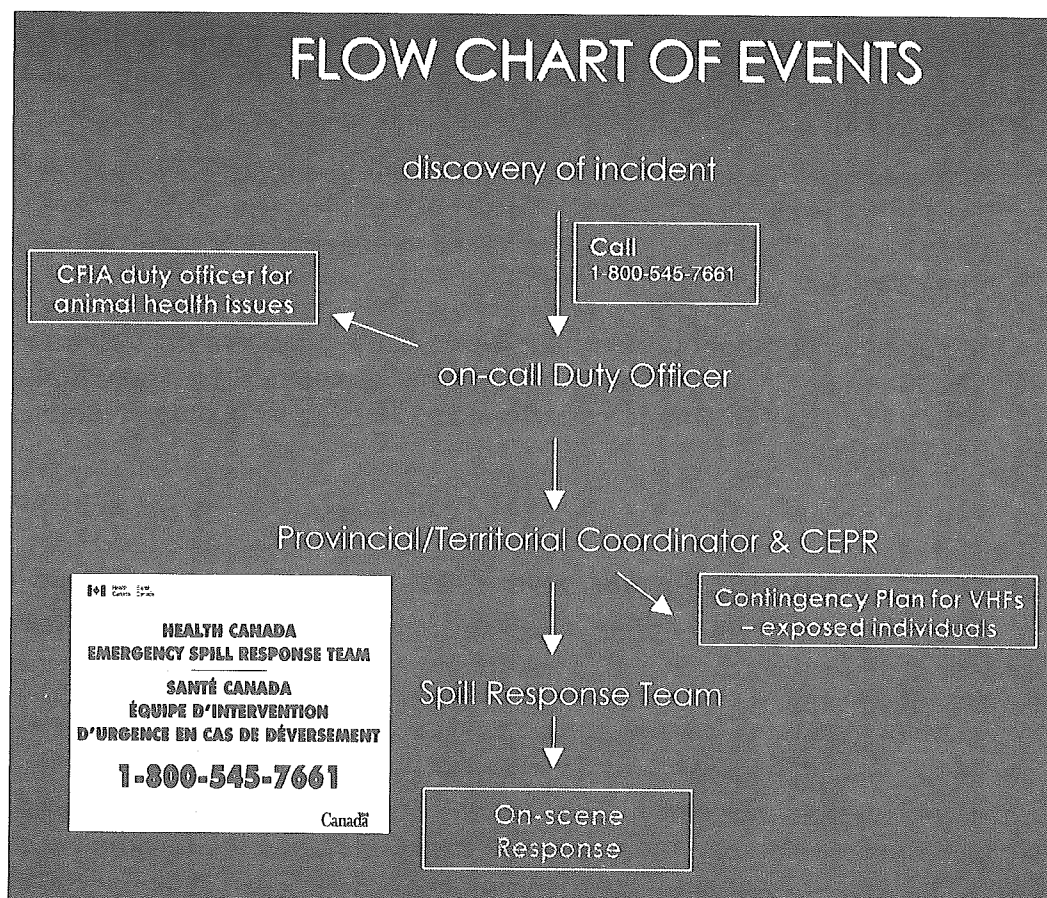
- developing and maintaining national emergency response plans, such as the National Smallpox Contingency Plan;
- managing the Quarantine Service, which enforces the Quarantine Act at Canadian border crossings and ports of entry;
- maintaining a deployable laboratory capacity, including mobile equipment, and Microbiological Emergency Response Teams ready to quickly deploy across Canada or abroad;
- acting as the focal point for Canada's National Emergency Response Assistance Plan for the transportation of Human Risk Group IV agents (e.g., ebola, marburg, nipah, crimean-congo hemorrhagic fever)
- monitoring disease outbreaks and global disease events through the Global Public Health Intelligence Network;
- managing the National Emergency Stockpile System, a \$330 million system that provides emergency medical supplies and pharmaceuticals quickly to provinces and territories when requested;

- working with provinces, territories and local public health authorities to ensure that front-line health workers have the tools to deal with, identify, and diagnose an event requiring emergency medical supplies;
- establishing emergency medical response surge capacity, in the form of Health Emergency Response Teams, to assist provinces, territories and other jurisdictions, upon their request, in relieving the effects of medical and health major disasters; and
- managing an emergency operations centre that may be mobilized in response to calls for emergency assistance from provincial and territorial governments, from other parts of the Government of Canada as well as from other international health organizations.

### ***Emergency Response Assistance Plan***

Suspect cases of Risk Group 4 disease may present at any location in Canada. Management of these cases includes the shipment of diagnostic samples from hospitals and public health laboratories to the Public Health Agency of Canada's biosafety level 4 laboratory in Winnipeg, Manitoba. In the unlikely event of an accident involving such shipments in transit, an emergency response assistance plan (ERAP) was developed by the Office of Laboratory Security. The purpose of the plan is to protect the health and safety of immediate workers, the public, the transporter, and the environment when shipping Risk Group 4 agents. This ERAP provides for a "24/7" national coordinated response for such incidents, including spill containment and clean-up and the management of potentially exposed individuals.

# FLOW CHART OF EVENTS



On-call duty officers put the plan into motion, and each province/territory has a coordinator responsible for managing their team's response in the province in which the spill occurred. The plan is used as a guide to a coordinated response and to provide appropriate management should such an event occur. It outlines detailed protocols for mobilization of spill responders and logistics, spill remediation, equipment and training, and financial responsibility. Spill response teams are mobilized on-site with an emergency spill kit and appropriate personal protective equipment.

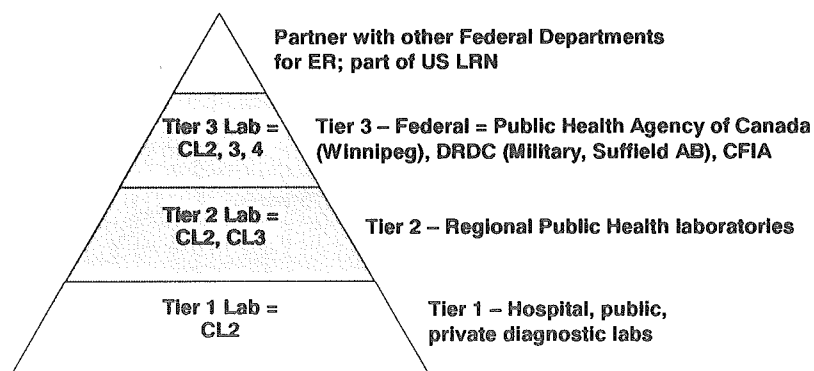
While designed specifically for incidents involving Risk Group 4 agents, the thirteen fully equipped and trained ERAP teams positioned across the country are also capable of responding to spills of infectious agents in Risk Groups 2 and 3. Further, because of a recent series of suspicious package events in Canada, several of these ERAP teams have expanded their role to provide laboratory assistance to law enforcement authorities and the first responder community for dealing with suspicious packages and bioterrorism events.

## Laboratory Support for Bioterrorism in Canada

The development of a laboratory network for responding to bioterrorism incidents enables the effective and efficient response to such threats. The benefits envisioned by such a network include a coordinated response, standardized laboratory procedures and greater consistency of results, earlier detection of events of concern and enhanced national capability for the detection of new and emerging diseases.

Canada has developed a bioterrorism laboratory response network to facilitate early detection, prevention, and intervention concerning bioterrorism events. The network consists of a three tier collaborative effort:

### Canadian Laboratory Response Network (CLRN)



Model approved by CPHLN in 2001

CEPR/CPHLN

18

Tier 1 Lab BT Recognition Course

#### What a Tier 1 lab does:

- Performs routine testing on clinical specimens
- Performs additional testing to rule out suspect BT agents
- Forwards suspect organisms to Tier 2/3

#### What a Tier 2 lab does:

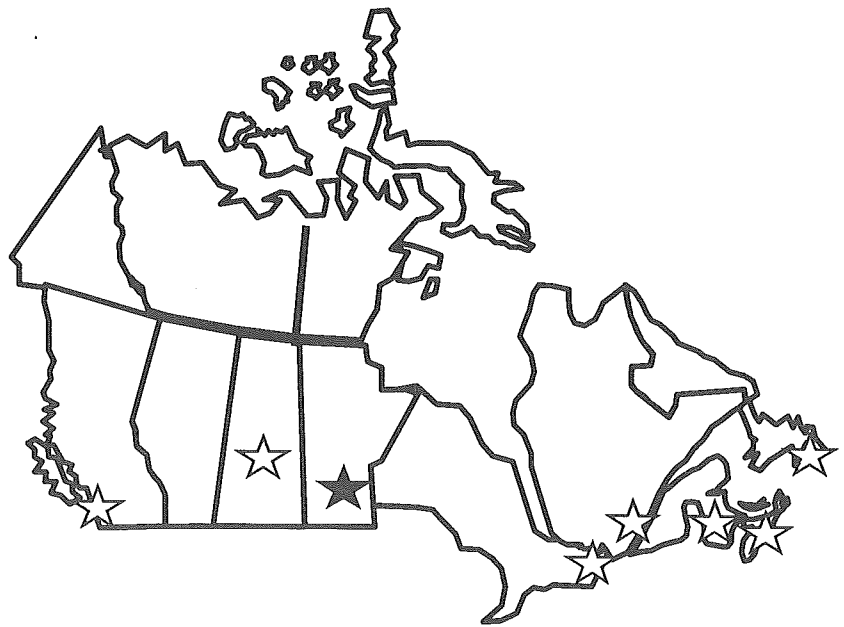
- Responsive 24/7, clinical material or isolated agent triaged by Tier 1 or directly, if suspicious



- Identify agent if possible; send to Tier 3 for further characterization
- Send material or agent recovered from specimen to Tier 3 lab if required, for definitive characterization and typing
- Use Chain of custody/careful evidence handling
- Report results to sender, MOH

**What a Tier 3 lab does:**

- Responsive 24/7, examine materials, agents or environmental specimens directly or triaged by Tier 1 or Tier 2; partner US LRN
- Use advanced diagnostic technologies
- Research and Development
- Provide secure environment for culture collections



☆ Tier 2 laboratories

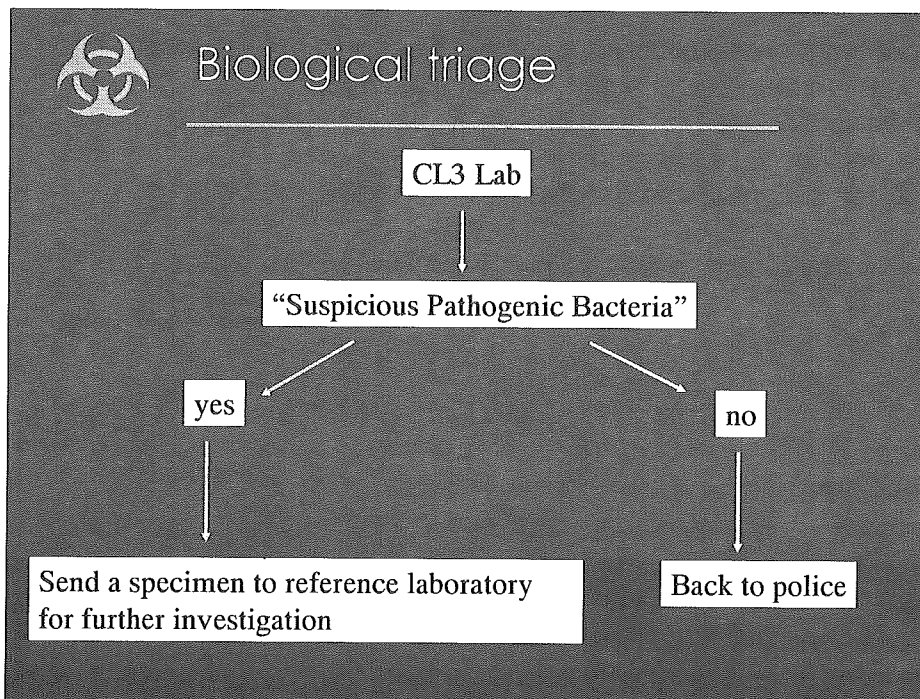
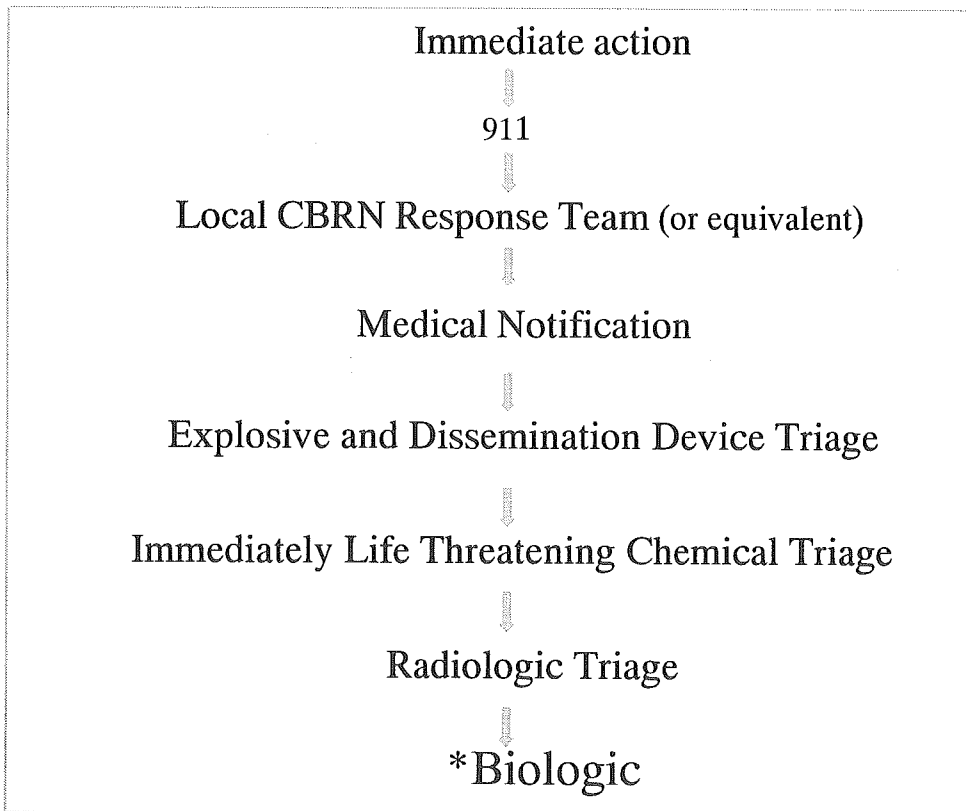
★ Tier 3 laboratories

## ***Responding to Suspicious Packages***

Centre for Emergency Preparedness and Response (CEPR) has developed general guidance procedures for responding to suspicious packages. The guidance is principally aimed at local response agencies that are involved in initial decisions around such episodes, e.g. fire, police, public health. It is essential that the local clinical and public health sectors are informed of the event by the CBRN team immediately.

The guiding principles in responding to such incidents are as follows:

- Assume the worst case scenario until ruled out;
- Gradually scale back as allowed by evidence/information;
- Critical decision-making/response must be local (with advice from “experts” if warranted);
- Use all available evidence/information to decide on the course of action
  - Presence of threatening note
  - Credibility of threat
  - Likely terrorist target
  - Presence of substance/powder
  - Recent history of similar packages
- There is to be no further exposure (e.g. initial handlers, emergency responders, transporters, laboratory personnel, environment);
- Scale of evacuation determined by first responders & building authorities;
- Determine contents expeditiously but safely. Priority is explosive → chemical agent → radiological agent → biological agent;
- Preserve forensic evidence;
- Identify potentially exposed persons;
- Assess need for decontamination of persons, work area, building; and
- Include local medical authorities in risk assessment for exposed persons.



## 6. Emerging Challenges

In today's new reality the considerations that guide what we do on a daily basis have changed dramatically, and the biological safety profession is no exception to this. Not only does the biosafety professional have to concern him/herself with keeping potentially dangerous pathogens in an environment that is safe and contained, but they now have to equally concern themselves with keeping potentially dangerous individuals out. These concerns can be further complicated by shrinking budgets, limited resources, and the threat of a potential pandemic looming around the corner. The responsibilities of today's biosafety professional require them to be all at once a scientist, an engineer, a security expert, and a teacher. In order for today's biosafety professionals to efficiently achieve their objectives it will be crucial that they develop and/or participate in an interrelated framework for responding to their new challenges. This should include: a highly focused and well-coordinated national, regional and international response; a high degree of collaboration among biosafety organizations on emerging issues; a global biosafety capacity; integration into global public health security; bringing forward innovative ideas, and finally working together.

Facing the challenges of an evolving world, biosafety professionals have had to become flexible and adaptable to the increasing demands on their profession. Multidisciplinary and integrated networks are now fundamental requirements of the profession. Building a global biosecurity capacity through an integrated network is an important concept that is driving biosafety professionals as they work to minimize the likelihood of a bioterrorist event and prepare for the eventuality of the next pandemic or emerging infectious disease. As the biosafety profession continues to respond to new challenges it will be crucial to build upon the interrelated framework it has established between its regional, national, and international organizations, as well as other agencies, and work together to come up with innovative ideas and solutions to the evolving challenges it will continue to face.