



BIOSAFETY AND BIOSECURITY IN GEORGIA: NEW CHALLENGES

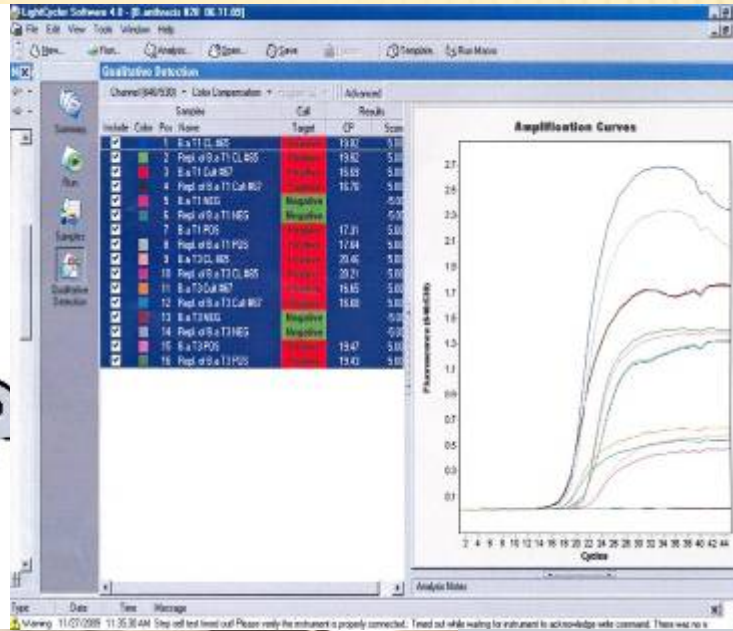
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The risk of infectious disease resulting from a laboratory's accidental release of a pathogen or from the use of biological weapons is real and growing!



Overcoming Global Risks



BIOSAFETY/BIOSECURITY – CROSS-CUTTING, ESSENTIAL ELEMENTS OF HEALTH SECURITY AND BIOLOGICAL NON-PROLIFERATION

| | WHO IHRs (2005) | BWC | UNSCR 1540 |
|---|--|--|--|
| Applicability: | All 192 UN Member States | 163 States Parties | All 192 UN Member States |
| Purpose: | “to prevent, protect, protect against, control and provide a public health response to the international spread of disease...” | To prohibit the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons | To prohibit non-State actors from developing, acquiring, manufacturing, possessing, transporting, transferring or using nuclear, chemical or biological weapons and their delivery systems. |
| Requirements: | 8 core capacities “to detect, assess, notify, and report events” [Laboratory core capacity includes biosafety / biosecurity] | Any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, retention, transfer or use of biological weapons | Domestic controls to prevent the proliferation of nuclear, chemical and biological weapons, their means of delivery, and related materials |
| Entry into force: | 15 June 2007 | 26 March 1975 | 28 April 2004 |
| Mandated reporting / where / when: | Status of implementation / WHO / <i>“As soon as possible but no later than five years from entry into force ...”</i> | None* “CBM voluntary reporting / BWC ISU/ every year by 15 April | Status of implementation / 1540 Committee / <i>“without delay”</i> |



Biosafety / Biosecurity



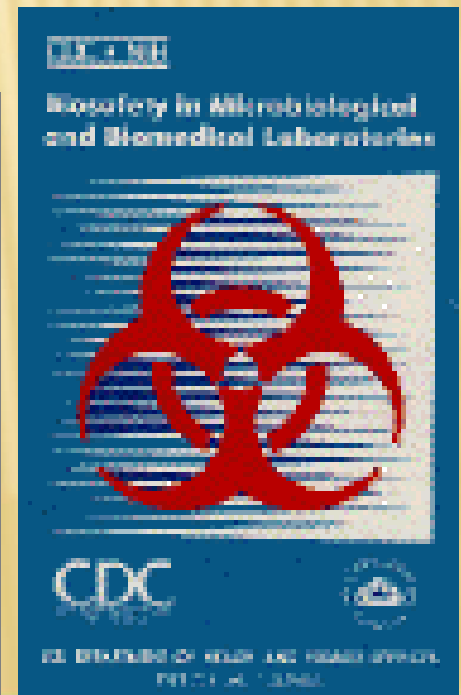
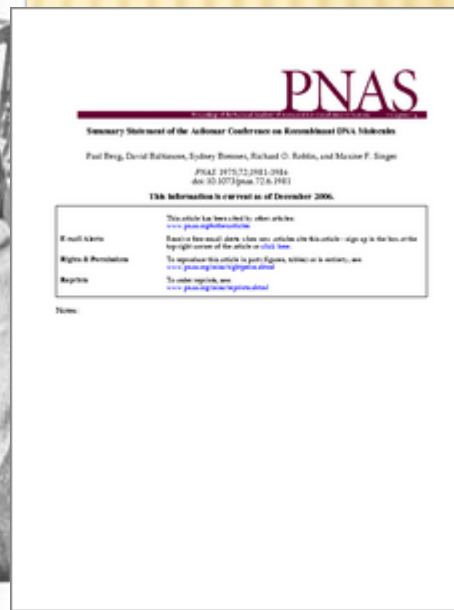
20 Indicators for Annual Reporting to WHA

- 1.Laws, regulations, administrative requirements, policies or other government instruments in place are sufficient for implementation of obligations under the IHR.
- 2.A mechanism is established for the coordination of relevant sectors in the implementation of the IHR.
- 3.IHR National Focal Point (NFP) functions and operations are in place as defined by the IHR(2005).
- 4.Indicator-based routine surveillance includes an early warning function for the early detection of public health events.
- 5.Event-based surveillance is established.
- 6.Public health emergency response mechanisms are established.
- 7.Infection prevention and control (IPC) is established at national and hospital levels.
- 8.A multi-hazard National Public Health Emergency Preparedness and Response Plan has been developed.
- 9.Public health risks and resources are mapped.
- 10.Mechanisms for effective risk communication during a public health emergency are established.
- 11.Human resources are available to implement IHR core capacity requirements.
- 12.Laboratory services to test for priority health threats are available and accessible.
- 13.Laboratory biosafety and biosecurity practices are in place.
- 14.Effective surveillance is established at Points of Entry (PoE).
- 15.Effective response is established at PoE.
- 16.General obligations at PoE are fulfilled.
- 17.Mechanisms are established for detecting and responding to zoonoses and potential zoonoses.
- 18.Mechanisms are established for detecting and responding to foodborne disease and food contamination.
- 19.Mechanisms are established for detection, alert and response to chemical emergencies.
- 20.Mechanisms are established for detecting and responding to radiological and nuclear emergencies.

WHA Resolutions on Biosafety

- World Health Assembly resolution 55.16 (2002):
“Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health”
- World Health Assembly resolution 58.3 (2005):
“Prevention and control of the international spread of disease and public health risks”
- World Health Assembly resolution 58.29 (2005):
“Enhancement of laboratory biosafety”

After 1975 Asilomar Recombinant DNA Conference CDC and NIH encouraged the life science community to participate in a collaborative initiative to develop consensus guidelines to safeguard workers and the public health from hazards associated with the possession and use of human pathogens in microbiological and biomedical laboratories.



UNSC Resolution 1540 Matrix for Biological Weapons and Related Materials

- Measures to account for/secure production
- Measures to account for/secure use
- Measures to account for/secure storage
- Measures to account for/secure transport
- Regulations for physical protection of facilities/materials/transport
- Licensing/registration of facilities/persons handling biological materials
- Reliability check of personnel
- Measures to account for/secure/physically protect means of delivery
- Regulations for genetic engineering work
- Other legislation/regulations related to safety and security of biological materials

BWC IMPLEMENTATION IN GEORGIA

- ✘ Georgia state party to the BWC is legally obligated to implement the Article 1 prohibitions in its national legal jurisdiction
- ✘ Georgia has extensive legislative measures in place to ensure that all activities on its territory are treaty-compliant and that prohibited activities are deterred and detected and perpetrators punished

UN SECURITY COUNCIL RESOLUTION 1540

recognizes “the need to enhance coordination of efforts on national, sub-regional, regional, and international levels in order to strengthen a global response to this serious challenge and threat to international security.”

LEGISLATIVE BASIS

- ✘ The issues of export of conventional weapons and technologies related to them are regulated by the following laws:
 - + The Law of Georgia on Weapons;
 - + The Law of Georgia on Export and Import Control of Weapons, Military Equipment and Dual-Use Materials;
 - + The Law of Georgia on Basis of Issuing License and Permit for Production Activities.
- ✘ In addition to the above-mentioned laws, there are other legal acts and mechanisms, which form the core of the state regulation system of non-proliferation of weapons, in particular:
 - + Criminal Code of Georgia;
 - + Decree # 408 of the President of Georgia, dated September 22, 2002, on Certain Measures for Settlement of Issues on Export, Re-export and Transit of Dual-Use Materials Subject to Export Control;
 - + Decree # 424 of the President of Georgia, dated July 4, 1999, on Certain Measures for Export Control of Dual-Use Materials (Technologies, Equipment, Service).

LEGISLATIVE BASIS (CONTINUED)

- ✘ The issues of WMDs and related technologies are regulated by the following provisions of the **Criminal Code of Georgia (pertain to Article I of BWC):**
- ✘ **In compliance with Article 406, the crime against the mankind consists in “production, purchase or sale of the chemical, biological or other weapons of mass destruction prohibited under the International Treaties that Georgia is party to” and shall carry legal consequences of imprisonment ranging from 8 to 15 years in length.**
 - + Prohibits Infringement of safety rules for handling microbiological or other biological agents and toxins
 - + Bans preparation, purchase, sale of BW
 - + Bans transportation of BW
 - + Bans export of WMD
 - + Bans use of WMD
- ✘ **Law of Export Control (pertains to Article III of BWC):**
 - + “Disease agents, their genetically altered forms, and fragments of genetical material which can be used for the creation of bacteriological (biological) and toxin weapons, control lists of which are established by international nonproliferation regimes’ subject to export control”
 - + **Illicit export of technology, scientific-technical information or service for the production of weapons of mass destruction or military equipment, their transportation, whereon special export control is imposed shall be punishable by fine or imprisonment ranging from 3 to 5 years in length.**

THE LAW OF GEORGIA ON GUARANTEES AND PROMOTION OF THE ACTIVITIES ON INVESTMENTS

- ✗ According to Article 9 of this Law, it is prohibited to invest in:
 - a) development, production and proliferation of **nuclear, bacteriological and chemical weapons**;
 - b) creation of testing areas for **nuclear, bacteriological, and chemical weapons**;
 - c) import of nuclear and toxic remains with a view to their burial or disposal;

AFTER ITS INDEPENDENCE, GEORGIA CONTINUED TO ABIDE BY THE OLD SOVIET REGULATIONS REGARDING THE HANDLING OF DANGEROUS PATHOGENS

- ✗ the Decree of the Ministry of Health of USSR “Concerning Rules of Registration, Containment, Handling and Transfer of Pathogenic Bacteria, Viruses, Rickettsia, Fungi, Protozoa and others, also Bacterial Toxins and Poisons of Biological Origin” approved by the Ministry of Health of USSR, 18.05.1979
- ✗ the “Instruction on Regime of Control of Epidemics while Working with Materials Infected or Suspected to be Infected with Causative Agents of Infectious Diseases of I-II Groups” approved by the Ministry of Health of USSR, 29.06.1978

LAW OF GEORGIA “ON HEALTH CARE” - (10.12.1997)

- ✗ Cl.70 – *“Providing safe for public health environment is responsibility of the State. The Ministry of Health of Georgia elaborates, approves sanitary - hygiene regulations and norms and controls their observance”;*
- ✗ Cl.72- *“Observance of sanitary - hygiene, sanitary-control regulations and measurements elaborated for avoiding negative effect of environment or other factors on public health, that are approved, is obligatory for any physical, or legal body in spite of its proprietary, organizational or legal form or departmental subordination”;*
- ✗ Cl. 77 – *“Import, export, containment, transfer and work with infectious diseases causative agents is allowed only under permission of the Ministry of Health of Georgia”.*

LAW OF GEORGIA “ON EXPORT CONTROL OF ARMAMENT, MILITARY TECHNIQUES AND PRODUCTS OF BILATERAL PURPOSE” (28.04.1998)

Cl.4d states:

- ✗ products undergoing export control include “Causative agents of diseases, their genetically modified forms and fragments of genetic materials that can be used for production of bacteriological (biological) and toxic weapons according to the list of international regimes of nonproliferation.”

LAW OF GEORGIA “ON PUBLIC HEALTH ”- (27.06.2007)

Chapter V - “*Providing Biosecurity/ Biosafety*”,

- ✘ Cl.16 - Providing Biosecurity/ Biosafety;
- ✘ Cl.17 - Limitation of Possession, Use, Transfer, Transportation and Destruction of Causative Agents of Especially dangerous Infections;
- ✘ Cl.18 - Destruction of Causative Agents of Especially dangerous Infections;
- ✘ Cl.19 – Import and export of Causative Agents of Especially dangerous Infections;
- ✘ Cl.20 – Functions of Sufficient Institutions working on Biosafety/Biosecurity;
- ✘ Cl.21 – Establishing Unique Laboratory System for Detection, Surveillance and Response on Causative Agents of Especially dangerous Infections.

BILATERAL AGREEMENTS

- ✘ Agreement Between Georgia and the USA on Cooperation in the Sphere of Prevention of Proliferation of WMDs and on Expansion of Relations in the Defence and Military Sphere;
- ✘ Agreement Between the State Department of State Border Defence of Georgia and the Department of Defence of the USA on Rendering Assistance in Establishment of System of Export Control For Prevention of Proliferation of WMDs in Georgia;
- ✘ Agreement Between the Government of Georgia and the Government of the USA on Insuring the Programme of Prevention of Terrorism;
- ✘ Agreement Between the Department of Defence of the United States of America and the Ministry of Defence of Georgia **On Cooperation in the Sphere of Prevention of Spread of Technologies, Pathogens and Information Related to Development of Biological Weapons.**

EFFECTIVE NATIONAL ACTION

- SUMMARY -

- ✗ Legislation and regulations
- ✗ Biosafety and Biosecurity
- ✗ Oversight of science
- ✗ Education and awareness
- ✗ Disease surveillance

**Natural
disease
outbreak**

**Unintended
consequences**

Accidents

Negligence

**Vandalism
/ sabotage**

**Deliberate
use of BW**



Thank you!

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