Building a Sustainable BSL-2 Lab Biosafety Program in Low-Resource Countries: Success in the Republic of Georgia

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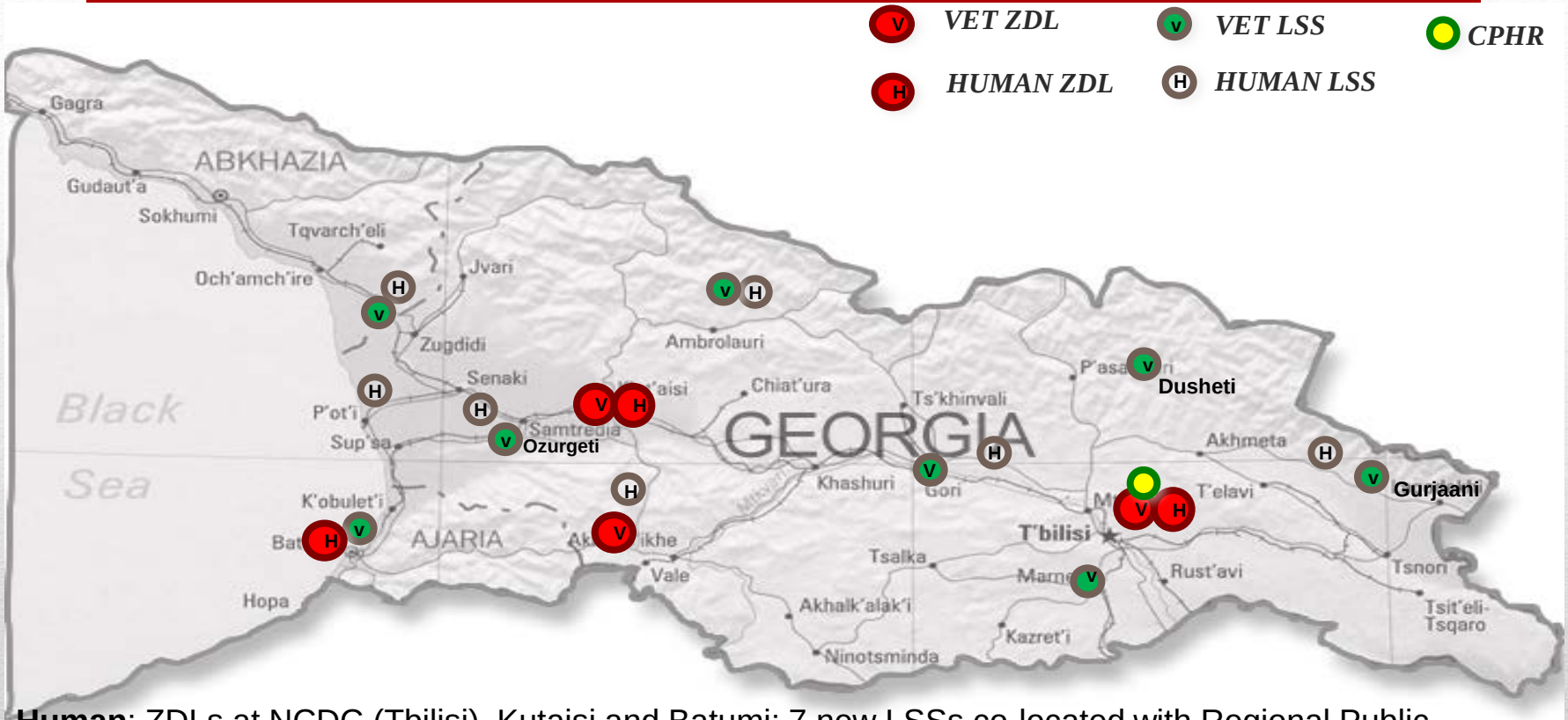
Pathogen Surveillance Network in Georgia

- Establish a surveillance network for early detection of pathogens and disease; extremely dangerous pathogens (EDPs)
- Build and staff modern diagnostic laboratories;
- Train and equip lab staff to detect, investigate, diagnose, and confirm human and veterinary EDP outbreaks.
- Establish written procedures & manuals to be followed.

Requires a Biosafety Program that meets international standards and best practices but is also sustainable.



Human: ZDLs at NCDC (Tbilisi), Kutaisi and Batumi; 7 new LSSs co-located with Regional Public Health Centers.

Veterinary: ZDLs at LMA (Tbilisi), Kutaisi and Akhaltsikhe; 8 LSSs throughout Georgia

Capabilities of ZDLs and LSS's

BSL-2 rating,

Biosafety cabinets, fluorescent microscopes,

Sample receipt and preparation,

Bacteriology, Serology, Real-time PCR,

Waste Autoclave,

Incinerator

- BSL-2 rating
- Biosafety cabinets
- Sample receipt and preparation,
- Basic serology,
- Also basic bacteriology in H-LSS,
- Waste autoclave in H-LSS

BS&S Sustainment Goals

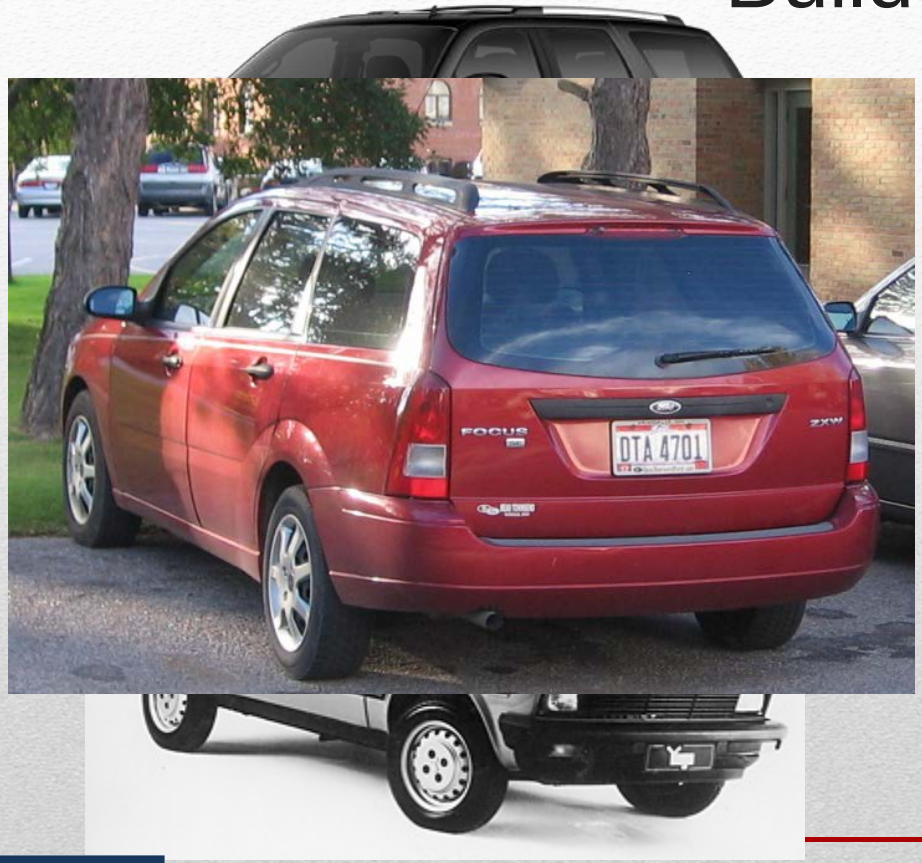
- Sustainment - Function of an effective, mature biosafety & biosecurity program used throughout Georgian network of surveillance labs.

- Sustainability – Ability to maintain program with reduced DTRA funding by Jan 2016. Funding, technical expertise, teaching & training, maintaining equipment & supplies, continued compliance.

Factors Affecting Sustainability of BS&S

- Cost to maintain BS&S program that is built
- Technical capabilities to run the BS&S program
- Level of bio risk changes with sustainment?
- Which standards to use and degree of compliance?
- Lack of operational practice with EDPs; few samples come to lab
- Supply limitations; inventory control; expired items
- Training capabilities; future BSOs
- Biosecurity levels that can be sustained
- Field Biosafety considerations vs laboratory

Build to What Level?



- Best that money can buy?
- Or cut back to bare necessities?
- Best to build to what is needed and can be maintained by new “owners”

Basis for Biosafety Manuals & SOPs

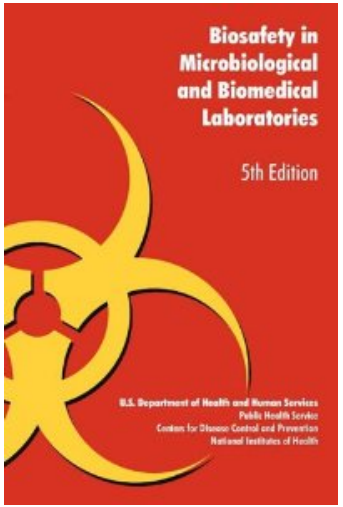
Example of safety centrifuges

BIOLOGICAL RISK ASSESSMENT
Safety equipment such as BSC, centrifuge safety cups, and sealed rotors are used to provide a high degree of protection for the laboratory worker from exposure to microbial aerosols and droplets. The safety characteristics of modern centrifuges are only effective if the equipment is operated properly.

PRINCIPLES OF BIOSAFETY
An example of another primary barrier is the safety centrifuge cup, an enclosed container designed to prevent aerosols from being released during centrifugation. To minimize aerosol hazards, containment controls such as BSCs or centrifuge cups must be used when handling infectious agents.

Proper use also in BSL-2 Practices, Agent Summaries, Appendix A and I.

BMBL can be used



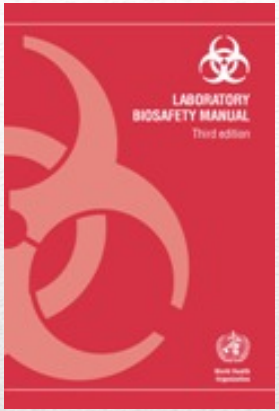
Template for Biosafety Manuals & SOPs

Example of safety centrifuges

LAB TECHNIQUES -- Use of centrifuges

- Centrifuges should be operated according to the manufacturer's instructions.
- Centrifuges should be placed on bench so workers can see into the bowl.
- Centrifuge tubes and specimen containers for use in the centrifuge should be made of plastic and should be inspected for defects before use.
- Tubes and specimen containers should always be screw-capped for centrifugation.
- The buckets must be loaded, sealed and opened in a biological safety cabinet.
- Buckets should be paired by weight and, with tubes in place, correctly balanced.
- Distilled water or 70% alcohol should be used for balancing empty buckets.
- Sealable centrifuge buckets must be used for microorganisms in Risk Groups 3 & 4.
- Do not overload angle-headed centrifuge rotors as they might leak.
- The interior of the centrifuge bowl should be inspected daily for staining or soiling.
- Centrifuge rotors and buckets should be inspected daily for corrosion and cracks.
- Buckets, rotors and centrifuge bowls should be decontaminated after each use.
- After use, buckets should be stored in an inverted position to drain the balancing fluid.

WHO is better



EMERGENCY PROCEDURES FOR LABS
Breakage of tubes inside sealable buckets.
All sealed centrifuge buckets should be loaded and unloaded in a biological safety cabinet. If breakage is suspected within the safety cup, the safety cap should be loosened and the bucket disinfected.

Included in Safety Checklist, Tables A4-1 and A4-2 (Hazards and Controls)

What Is Not Needed

NIH rDNA Guidelines

- No rDNA or GMO work being done

IATA Hazardous Goods Training

- In-country transport/lab-to-lab only

Select Agent Rules

- BPRP not practical; SAs not used

IACUC

- No animal research in network labs; inadequate facilities where animals are used.

Safety Engineered Sharps

Enhanced security measures

Sustainable Respiratory Protection

- Respiratory program is based on N95
- Medical exams – paid by Program year 1 and 2
- Supplied by Program
- Quantitative fit testing of N95
  - Cheap kits & supplies
  - Train BSOs to do fit test
  - Easy to keep records
  - No calibration, certification, maintenance
  - Easy to use & to re-supply

Sustainable Training

- Train to level that is needed and used
- Much practical, OTJ, and exercises
- Led by BSOs and Lab Supervisors
- Use supplies & equipment available to them
- Mentoring & small group discussions
- Easy-to-read and follow instructions

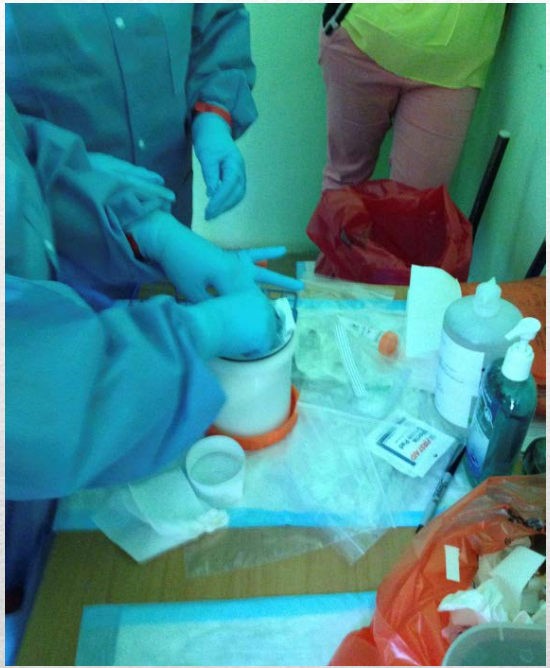
Sustainable Training

Practical exercises in lab and field to practice and hone skills. On-farm collection of samples; Receiving samples into BSL-2 lab; Bio spill cleanup.

Sustainable Training

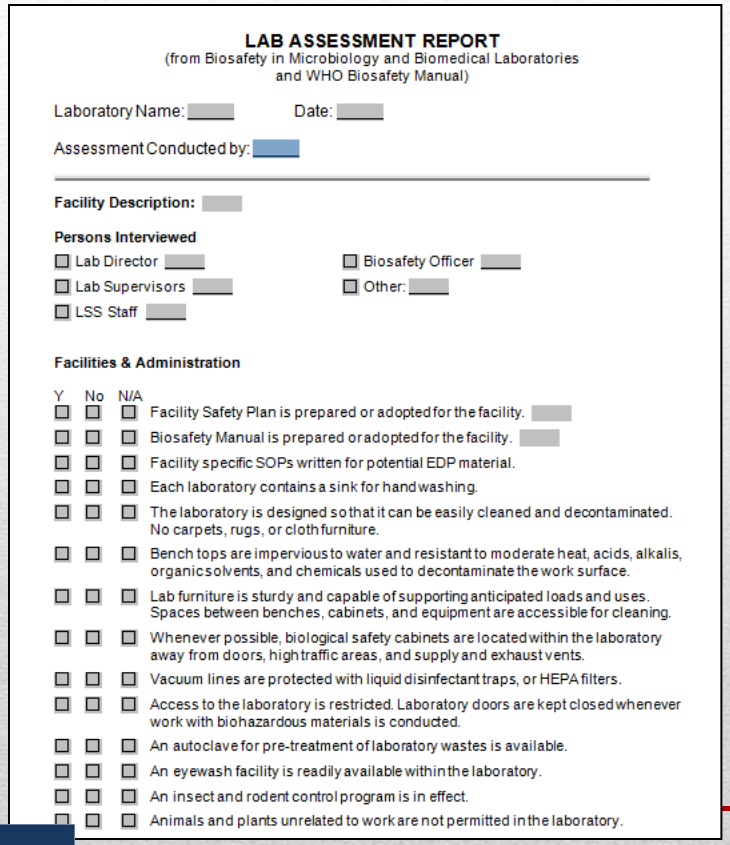
Classroom training for initial and refresher. BSOs do some of training. Train-the-Trainer classes scheduled for Georgians.

Basic Packaging & Transport



Simple triple-pack packaging for transport to other labs in work vehicles. Minimal labeling with good chain-of-custody control and documents.

Sustainable Inspections & Op Reviews



LAB ASSESSMENT REPORT
(from Biosafety in Microbiology and Biomedical Laboratories and WHO Biosafety Manual)

Laboratory Name: _____ Date: _____

Assessment Conducted by: _____

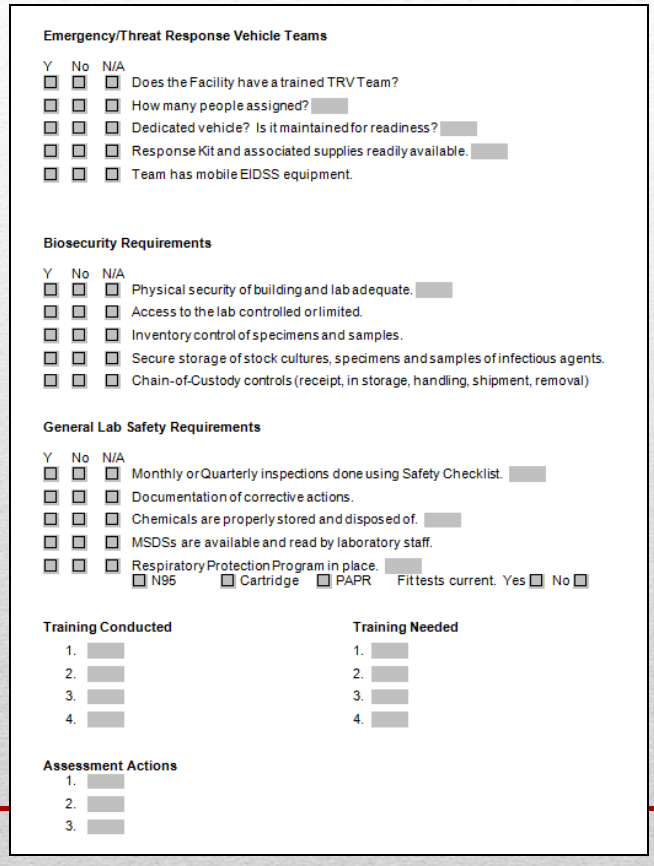
Facility Description: _____

Persons Interviewed

- ☐ Lab Director _____
- ☐ Biosafety Officer _____
- ☐ Lab Supervisors _____
- ☐ Other: _____
- ☐ LSS Staff _____

Facilities & Administration

Y	No	N/A	
☐	☐	☐	Facility Safety Plan is prepared or adopted for the facility.
☐	☐	☐	Biosafety Manual is prepared or adopted for the facility.
☐	☐	☐	Facility specific SOPs written for potential EDP material.
☐	☐	☐	Each laboratory contains a sink for hand washing.
☐	☐	☐	The laboratory is designed so that it can be easily cleaned and decontaminated. No carpets, rugs, or cloth furniture.
☐	☐	☐	Bench tops are impervious to water and resistant to moderate heat, acids, alkalis, organic solvents, and chemicals used to decontaminate the work surface.
☐	☐	☐	Lab furniture is sturdy and capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
☐	☐	☐	Whenever possible, biological safety cabinets are located within the laboratory away from doors, high traffic areas, and supply and exhaust vents.
☐	☐	☐	Vacuum lines are protected with liquid disinfectant traps, or HEPA filters.
☐	☐	☐	Access to the laboratory is restricted. Laboratory doors are kept closed whenever work with biohazardous materials is conducted.
☐	☐	☐	An autoclave for pre-treatment of laboratory wastes is available.
☐	☐	☐	An eyewash facility is readily available within the laboratory.
☐	☐	☐	An insect and rodent control program is in effect.
☐	☐	☐	Animals and plants unrelated to work are not permitted in the laboratory.



Emergency/Threat Response Vehicle Teams

Y	No	N/A	
☐	☐	☐	Does the Facility have a trained TRV Team?
☐	☐	☐	How many people assigned? _____
☐	☐	☐	Dedicated vehicle? Is it maintained for readiness? _____
☐	☐	☐	Response Kit and associated supplies readily available. _____
☐	☐	☐	Team has mobile EIDSS equipment.

Biosecurity Requirements

Y	No	N/A	
☐	☐	☐	Physical security of building and lab adequate. _____
☐	☐	☐	Access to the lab controlled or limited.
☐	☐	☐	Inventory control of specimens and samples.
☐	☐	☐	Secure storage of stock cultures, specimens and samples of infectious agents.
☐	☐	☐	Chain-of-Custody controls (receipt, in storage, handling, shipment, removal)

General Lab Safety Requirements

Y	No	N/A	
☐	☐	☐	Monthly or Quarterly inspections done using Safety Checklist. _____
☐	☐	☐	Documentation of corrective actions.
☐	☐	☐	Chemicals are properly stored and disposed of. _____
☐	☐	☐	MSDSs are available and read by laboratory staff.
☐	☐	☐	Respiratory Protection Program in place. _____ ☐ N95 ☐ Cartridge ☐ PAPR Fit tests current. Yes ☐ No ☐

Training Conducted

1. _____
2. _____
3. _____
4. _____

Training Needed

1. _____
2. _____
3. _____
4. _____

Assessment Actions

1. _____
2. _____
3. _____

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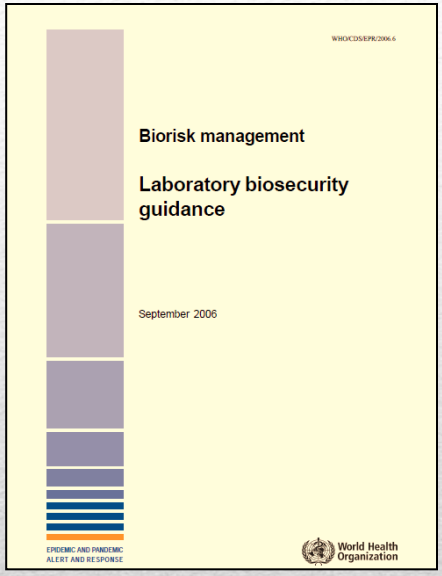
Sustainable Biosecurity



Start with older buildings & structures; conduct biosecurity risk assessment as to what is needed; do upgrades & improvements that improve and can be sustained. Based on WHO Guidance.

Sustainable Biosecurity

Physical door locks, keycard or keycode access to labs, perimeter fencing with locked gates, special fencing where needed.

Sustainable Stockroom & Supplies

Assist ZDL and LSS staff to prioritize needed supplies; organize stock room and shelves; identify and dispose of expired items; reorder what is needed.

Sustainable Field Biosafety

State Field Vets work with very little BS&S supplies; usually work alone so assist from farmer is necessary; expensive and impractical sharps container so use alternate that is always available & cheap.

Summary – BS&S Sustainment

- Cost effective
- Can be implemented & maintained
- Technology & skill set effective
- Sufficiently compliant with standards
  - Basic program and build from there
  - As resources become available
- Georgian BS&S involvement
  - Teaching, mentoring, assessments, etc