



The University of Tennessee Biosafety Program:

Policy Development: Purpose, Scope & Applicability

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Biosafety: What Is It?

- Specialized branch of industrial hygiene
 - Origins in the 1950s
- Risk assessment-driven practices used to safeguard people and the environment from biological hazards:
 - Lab design/engineering controls
 - Prudent practices
 - Administrative policies:
 - Documented procedures
 - Training
 - Personal protective equipment



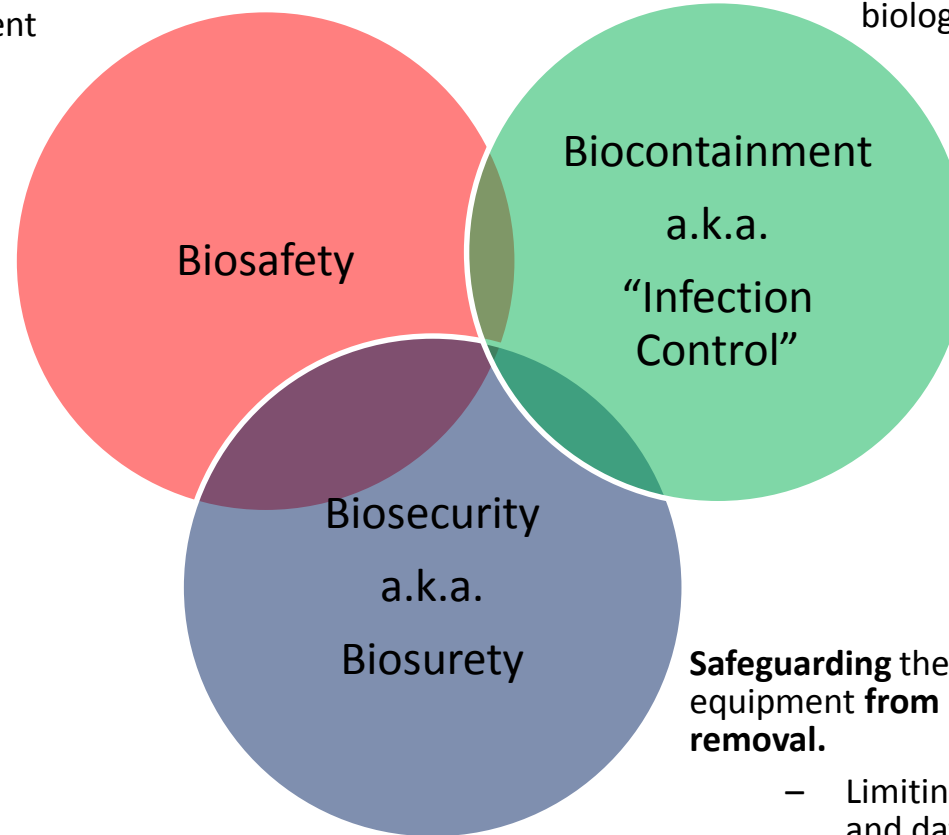
Minimizing potential hazards: Safety, Containment, and Security

Those practices used to **safeguard workers** from infectious agents and the habitants of the environment from accidental releases and/or unwanted disease.

Administrative policies:

- SOPs
- Training

Biocontainment strategies



The **prevention of the inadvertent release or spread** of biological agents/materials:

- Work practices:
 - Personal protective equipment
 - Standard Operating Procedures
- Engineering controls
- Lab design

Safeguarding the facility, agents, data and equipment **from misuse or unauthorized removal.**

- Limiting access to sensitive areas and data to only those necessary and approved
- Preventing disruption of research and other laboratory work due to natural and unnatural acts.



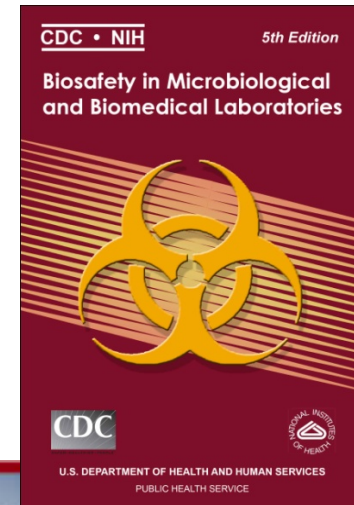
UTK Biosafety: A Brief History

- **NIH precedent:**
 - Formation of the Recombinant DNA Advisory Committee (RAC) in 1974;
 - Release of the first policies governing rDNA in 1976: *NIH Guidelines for Research Involving Recombinant DNA Molecules* (“NIH Guidelines”)
 - *Laboratory Safety Monograph* published in 1978
- **UT Biohazard Safety Committee formed in 1977:**
 - Review all research proposals for use of biohazards in research;
 - Review, inspect, monitor all individuals & facilities using biohazards
- **Biosafety Office established in 2004:**
 - Develop comprehensive biosafety program to assist/complement IBC

Regulations, Standards, Guidelines



Department of Environment

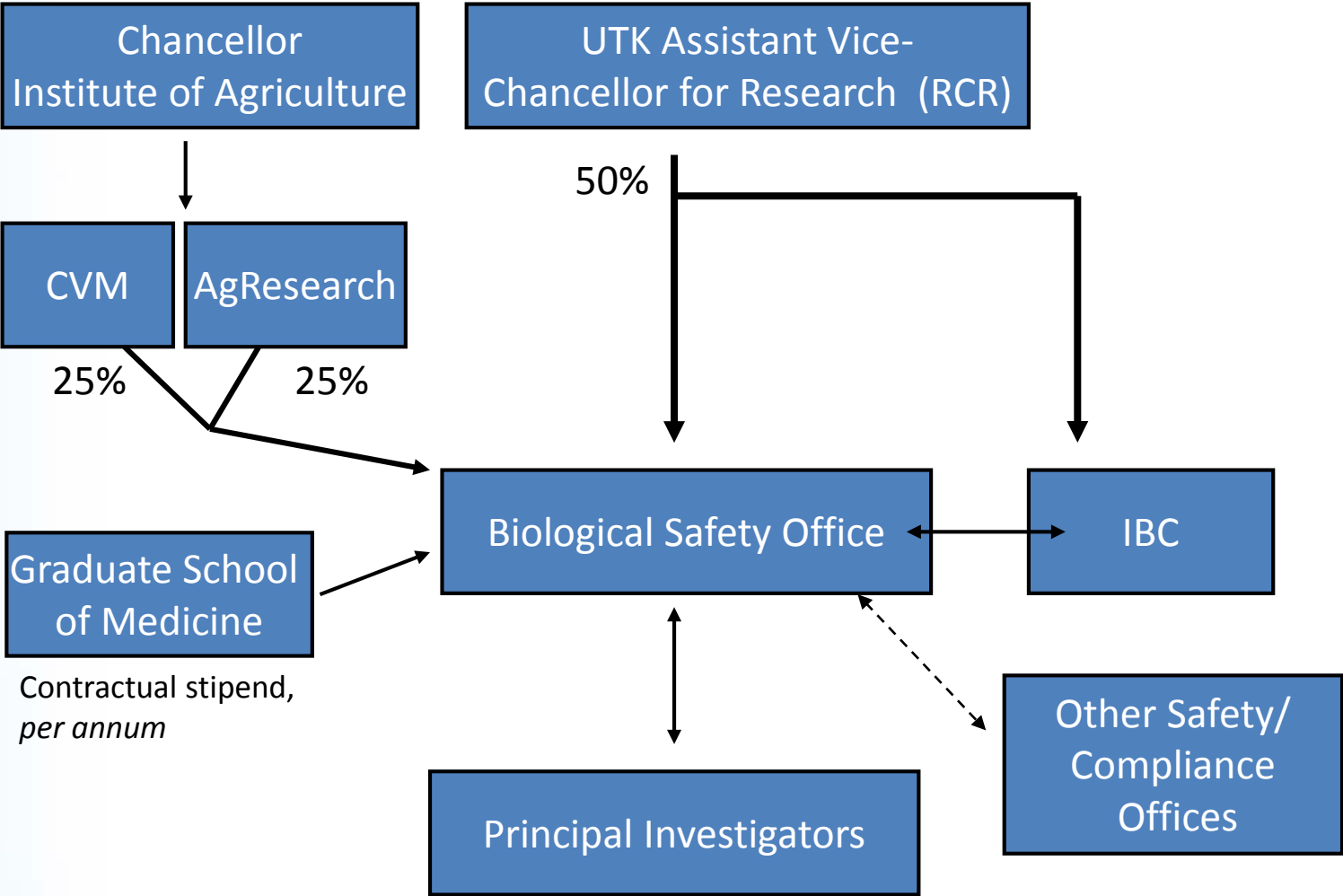




The Current Biosafety Program

- The Biosafety Program for the UT-Knoxville area campuses consists of:
 - **The Institutional Biosafety Committee (IBC)**
 - Consists of 16 voting members; 4 non-voting *ex officio* members
 - Voting representation:
 - 12 academic departments;
 - 4 UTK; 4 AgResearch; 4 CVM; 1 GSM;
 - 3 non-affiliated representatives (public health)
 - **The Biosafety Office**
 - Full time Biosafety Officer & Biosafety Specialist
 - ½ -time Administrative Support Assistant
 - (Occupational Health Nurse)

Organizational Chart





Current Purview of the IBC:

- Review/approval of recombinant DNA research protocols (**NIH obligation**):
 - Routine experiments; requirements dependent on risk:
 - Covered low risk experiments declared to IBC upon initiation
 - Higher risk experiments (e.g. Risk Group 2 agents as hosts; recombinant microbes in animals) must be approved **prior** to beginning the experiment
 - Development of transgenic plants or animals
 - Dual use research of concern (DURC)



IBC Purview (cont.):

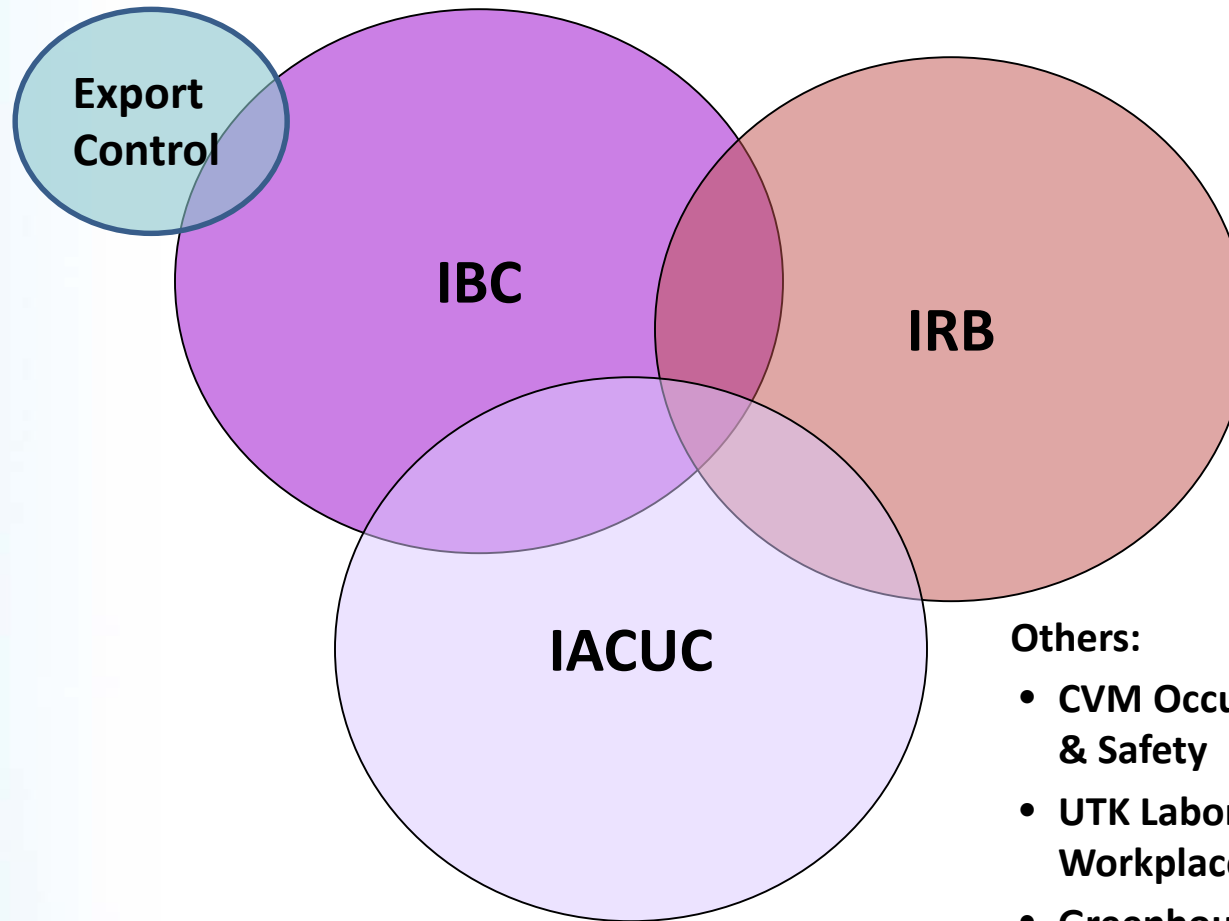
- Review/approval of research involving agents infectious to humans, animals, and plants:
 - Capable of causing disease in immunocompetent humans
 - Special containment/practices (animal/plant pathogens)
 - Select Agents
- Biological toxins (select agents; e.g. ricin, saxitoxin, etc.)
- Human and nonhuman primate blood, tissues (cell lines), and body fluids
- Nanoparticles conjugated to biological effectors
- Poisonous plants or venomous animals



Post-Approval Monitoring

- Annual review of documentation
- Site visits:
 - Annual for IBC-approved BL-1 labs
 - Semiannual for IBC-approved BL-2 labs
 - Constructive process
- Ongoing monitoring:
 - OSP & TERA PAMS (UTK & UTIA)
 - MTAs
 - IACUC protocols
- Escalation procedures for noncompliance

Biosafety and Other Research Oversight Committees



Others:

- CVM Occupational Health & Safety
- UTK Laboratory & Workplace Safety
- Greenhouse Committee
- UTK Safety Committee
- Safety Directors



Biosafety Policy Summary:

- System Policy SA0450:
 - *The biological safety program of the University of Tennessee system shall comply with all existing state, federal and local codes, ordinances, laws and university policies relating to the transportation, use, generation, storage and disposal of whatever may be determined by those regulations to be biological hazards. The program shall be communicated and available to all departments and persons who may be in contact with these materials and/or subject to the requirements governing these materials*
- IBC Charter (2010) and operational standards have been developed and implemented to meet this objective




Biosafety Policy Summary (cont.) :

- Proposed general policy for UTK-area stakeholders:
 - Repackaging of IBC Charter/bylaws
 - Defines authority, scope, purview, and programmatic roles/responsibilities:
 - Reiteration of *NIH Guidelines* (DO, IBC, BSO, PI)
 - Additional provisions for assigning a Responsible Official for Select Agent use (currently N/A)
 - Establishes coordination/oversight with teaching and diagnostic (testing) laboratories via the “Laboratory Coordinator”
 - Already reviewed by IBC (approved) and UTK Laboratory Safety Committee (minor comments)




Biosafety Framework for Teaching Laboratories:

- Teaching labs covered in mission statement and bylaws of initial IBC Charter (1977), but dropped in 2005 restructure
 - Separation of research compliance from general safety objectives
 - Departmental determinations of curriculum and best practices
 - Informally monitored by BSO (risk-based)
- Task force assembled to review current status, assess needs, and make recommendations
 - Representatives from UTK, UTIA, & CVM
 - Impact assessment: research and academic interests



Biosafety Framework for Teaching Laboratories (cont.):

- Proposed framework defines a programmatic approach for verifying safety standards in teaching labs or other training exercises involving biological hazards
- Based on the American Society for Microbiology's *Guidelines for Biosafety in Teaching Laboratories* (2012)
 - Response to *Salmonella spp.* outbreak associated with teaching/diagnostic labs (2010)
 - Defines prudent practices in accordance with other well-established standards/guidelines
 - Focuses primarily on traditional wet lab settings; does not consider all types of experiential learning



Biosafety Framework for Teaching Laboratories (cont.):

- Roles/responsibilities:
 - Curriculum/objectives and materials still defined by departmental faculty;
 - Coordination/verification of safety approaches by LC and BSO (with IBC providing *ad hoc* expertise as necessary)
- Programmatic verification of:
 - Hazard identification/communication;
 - Training;
 - Personal protective equipment;
 - Medical evaluation recommendations;
 - Accidents, injuries & exposure reporting;
 - Inspections/verification & documentation.

Questions?



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