

Good Laboratory Practices (Criteria and Applications)

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What It Is....

Good Laboratory Practices (GLP) ?

- Set of criteria that describes good practices for non-clinical lab studies that support research or marketing approvals of commercially regulated products.
- Including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products.

Good Laboratory Practices (GLP)

- International Standardized Management System
- US Food and Drug Administration
 - Administers program for USA
 - Other countries have similar programs
- GLP compliance assures the:
 - Quality and Integrity of the Safety Data filed under the US Federal Food, Drug, and Cosmetic Act, of the US Public Health Service Act.



Good Laboratory Practices (GLP)

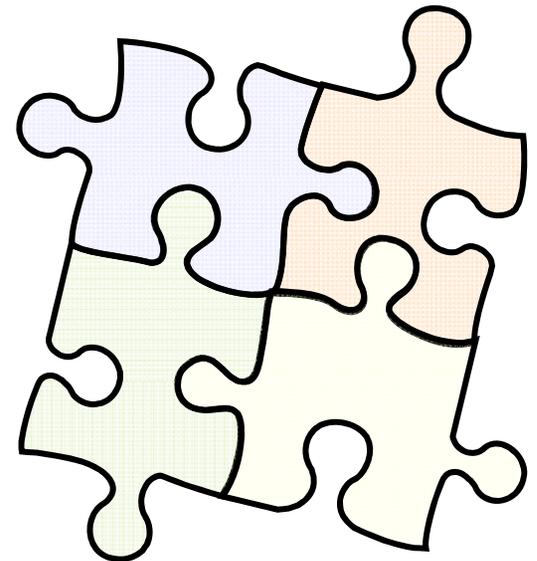
US Regulation (21 CFR 58):

TITLE 21: FOOD AND DRUGS

CHAPTER-I: FOOD AND DRUG ADMINISTRATION,
US DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER-A: GENERAL

PART-58: GOOD LABORATORY PRACTICE FOR
NON-CLINICAL LABORATORY STUDIES



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

- Subpart A--General Provisions
 - § 58.1 - Scope.
 - § 58.3 - Definitions.
 - § 58.10 - Applicability
 - § 58.15 - Inspection of a testing facility.



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart B--Organization and Personnel

- § 58.29 – Personnel (Appropriately qualified personnel)
- § 58.31 - Testing facility management.
 - Adequate resources
 - Appropriate procedures for: Test protocol development, Test methods, Data analysis, Report development, Sanitation, Health precautions, Clothing,
- § 58.33 - Study Director (Appropriately qualified).
- § 58.35 - Quality assurance unit.



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart C--Facilities

- § 58.41 – General
 - **Suitable size, construction, segregation**
- § 58.43 - Animal care facilities.
- § 58.45 - Animal supply facilities.
- § 58.47 - Facilities for handling test and control articles.
 - **Test & control products maintained in a secure area**
- § 58.49 - Laboratory operation areas.
- § 58.51 - Specimen and data storage facilities.



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

- Subpart D--Equipment
 - § 58.61 - Equipment design.
 - Appropriately designed, Adequate thru-put capacity, Appropriately located
 - § 58.63 - Maintenance and calibration of equipment.
 - Routinely maintained & calibrate
- Subpart E--Testing Facilities Operation
 - § 58.81 - Standard operating procedures.
 - § 58.83 - Reagents and solutions.
 - § 58.90 - Animal care.



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies :

Subpart E--Testing Facilities Operation

- § 58.81 - Standard operating procedures.
 - Collection & ID of specimens
 - Histopathology
 - Data handling, storage & retrieval
 - Equipment maintenance & calibration
 - Transfer, proper placement & ID of animals

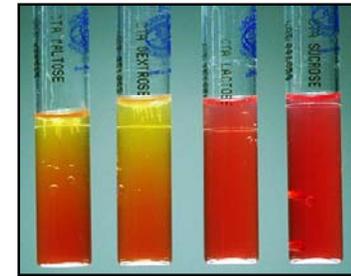


Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies :

Subpart E--Testing Facilities Operation

- § 58.83 - Reagents and solutions.
 - Adequate labeling
 - Identity
 - Concentration
 - Storage requirements
 - Expiration date



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies :

Subpart E--Testing Facilities Operation

- § 58.90 - Animal care.
 - Animal room prep
 - Receipt, ID, storage, handling, mixing & sampling of test & control articles
 - Lab test, Test system observations
 - Handling of moribund or dead animals
 - Necropsy or postmortem exams of animals



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart F--Test and Control Articles

- § 58.105 - Test and control article characterization.
 - Adequate characterization
- § 58.107 - Test and control article handling.
 - Proper receipt, storage, distribution
- § 58.113 - Mixtures of articles with carriers.
 - When mixed with a carrier, adequate methods to confirm
 - Mixture uniformity
 - Article concentration
 - Article stability

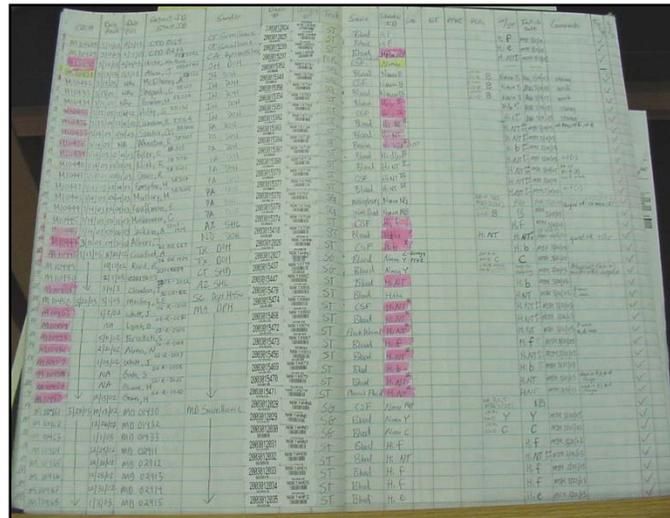


Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart G--Protocol for and Conduct

- § 58.120 - Protocol.
 - Written, approved protocol indicating test objectives & methods
 - Standard data capture/recording requirements
 - Legibility
 - Permanence
 - Accountability
 - Changes



Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart G--Protocol for and Conduct (continued)

- § 58.130 - Conduct of study (Implementation).
 - Written, approved protocol indicating test objectives & methods
 - Study conducted in accordance with protocol
 - Study monitoring to confirm protocol compliance
 - Appropriate labeling of specimens by test system, study, nature & collection date
 - Records of gross findings from postmortems available to pathologist for specimen histopathology

Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart H-I [Reserved]

Subpart J--Records and Reports

- § 58.185 - Reporting of laboratory study results.
 - **Final report of results**
- § 58.190 - Storage and retrieval of records and data.
 - **Study records & data methodically archived to facilitate expedient retrieval**
 - **Protocols, Study documents, Raw data, Specimens**
 - **QA inspections**
 - **Personnel training & qualifications**
 - **Calibration & maintenance records**

Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart J--Records and Reports

- § 58.195 - Retention of records.
 - **≥ 2 yr after FDA marketing clearance**
 - **≥ 5 yr after data submitted to FDA in support of marketing application**
 - **≥ 2 yr after Sponsor decision not to proceed with marketing application**
 - **Wet specimens hold as long as viable**
 - **Records transferable with written FDA notification**

Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart K--Disqualification of Testing Facilities

- [§ 58.200](#) - Purpose.
- [§ 58.202](#) - Grounds for disqualification.
 - **Failure to comply with regulations**
 - **Non-compliance adversely affects study validity**
 - **Previous regulatory actions have been unsuccessful in modifying facility operations**
- [§ 58.204](#) - Notice of and opportunity for hearing on proposed disqualification.
- [§ 58.206](#) - Final order on disqualification.

Good Laboratory Practices (GLP)

21 CFR 58 – GLP for Non-clinical Laboratory Studies:

Subpart K--Disqualification of Testing Facilities (continued):

§ 58.210 - Actions upon disqualification.

§ 58.213 - Public disclosure of information regarding disqualification.

§ 58.215 - Alternative or additional actions to disqualification.

§ 58.217 - Suspension or termination of a testing facility by a sponsor.

§ 58.219 - Reinstatement of a disqualified testing facility.

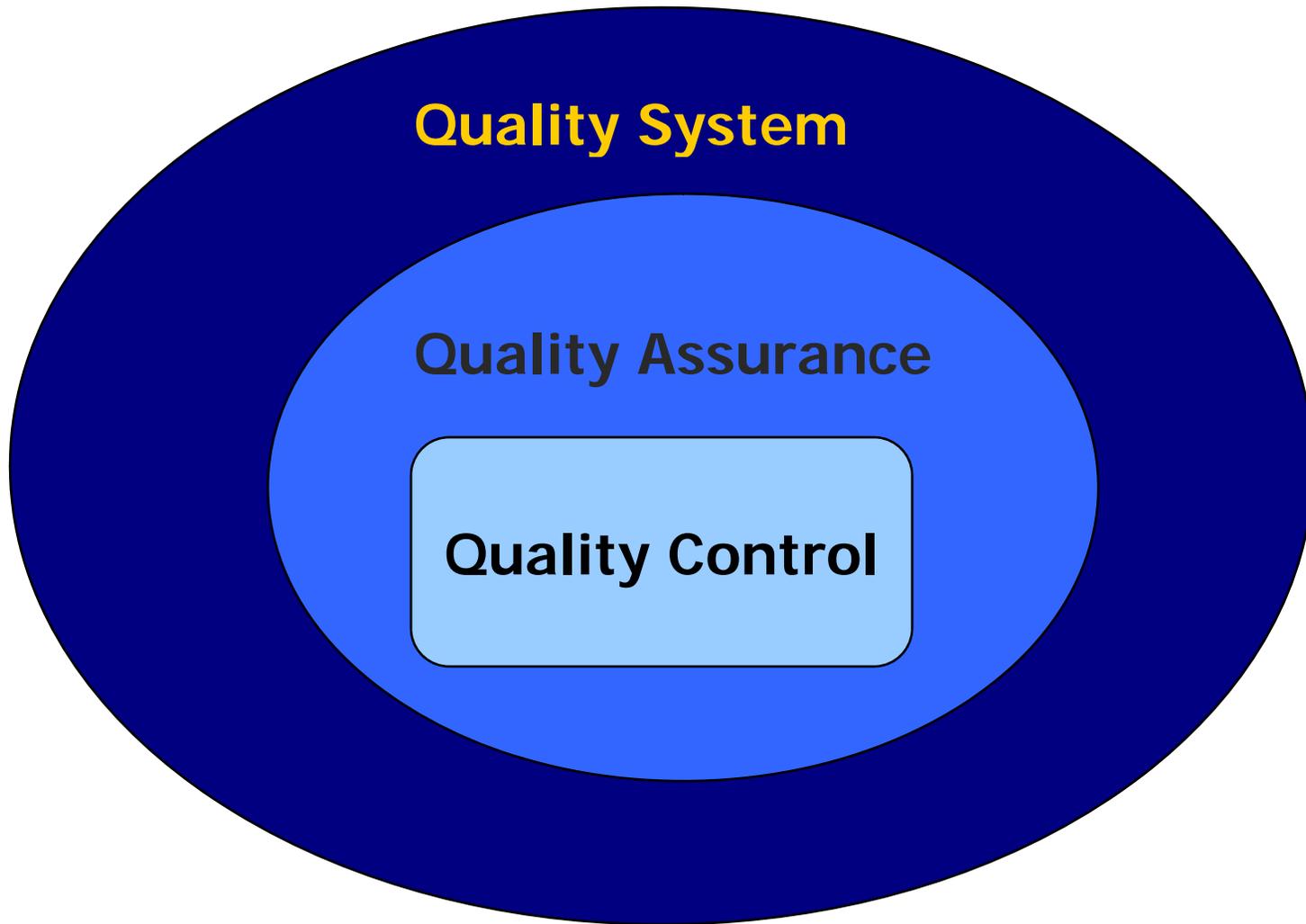
Good Laboratory Practices (GLP)

Reference Documents & Links (www.fda.gov/cder)

21 CFR 58 – GLP for Non-clinical Laboratory Studies

- Div. of Scientific Investigations: Good Laboratory Practice
www.fda.gov/cder/Offices/DSI/goodLabPractice.htm
- BIMO Compliance Program Guidance 7348.808A: GLP Program
www.fda.gov/ora/compliance_ref/bimo/7348_808A/Default.htm

Systems Approach



Framework: Laboratory Quality Management (QMS) System

Organization

- Quality policy and Standards
- Sufficient resources
- Clearly defined roles and responsibilities
- A culture committed to quality

Personnel

- Human resource planning
- Hiring
- Retention
- Training
- Supervision
- Performance management

Equipment

- Selection
- Acquisition
- Installation
- Maintenance, service and repair
- Troubleshooting
- Disposition

Purchasing and Inventory

- Procurement
- Receiving
- Storage
- Inventory Management
- Record keeping

Process Control

- Standard operating procedures
- Specimen management
- Quality control

Documents and Records

- Standard forms
- Document approval
- Document distribution
- Document storage / retrieval
- Document destruction

Information Management

- Information flow
- Data collection and management
- Patient privacy and confidentiality
- Computer skills

Occurrence Management

- Written procedures for addressing errors
- Corrective actions
- Occurrence records
- Occurrence reporting

Assessment

- External quality assessment
 - Proficiency Testing
 - On-site evaluation
- Improvement measures
- Internal audits

Process Improvement

- On-going data collection
- Improvement measures

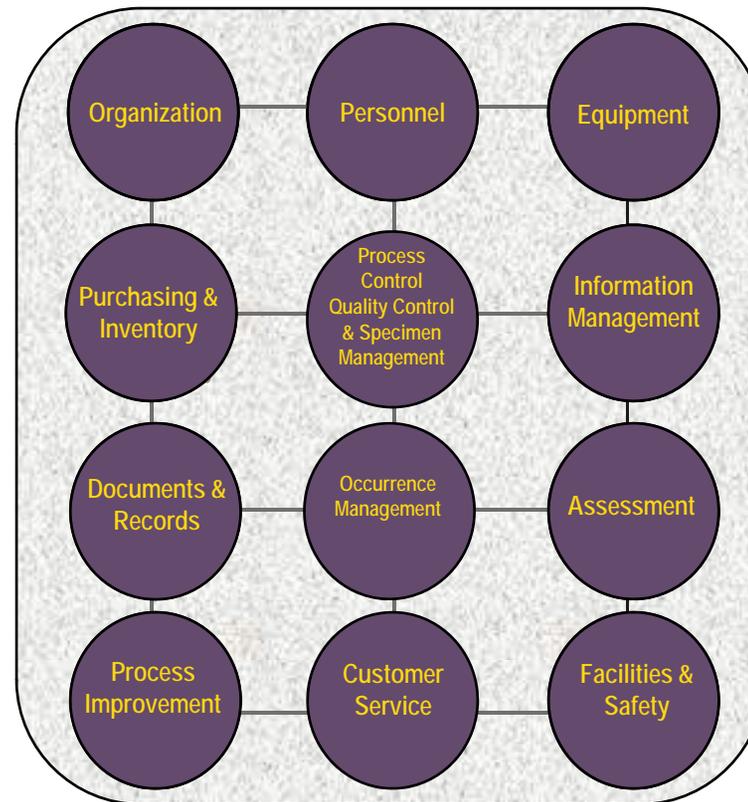
Customer Service

- Monitoring customer satisfaction
- Process improvement
- Records

Facilities and Safety

- Testing and storage areas
- Safety practices
- Safety procedures and records

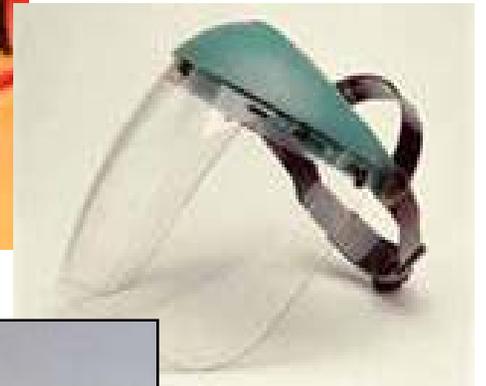
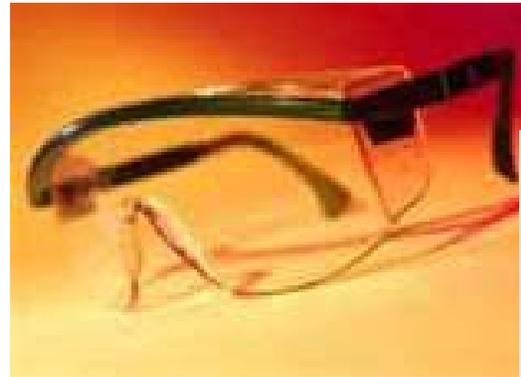
Framework for Implementing A Laboratory Quality System



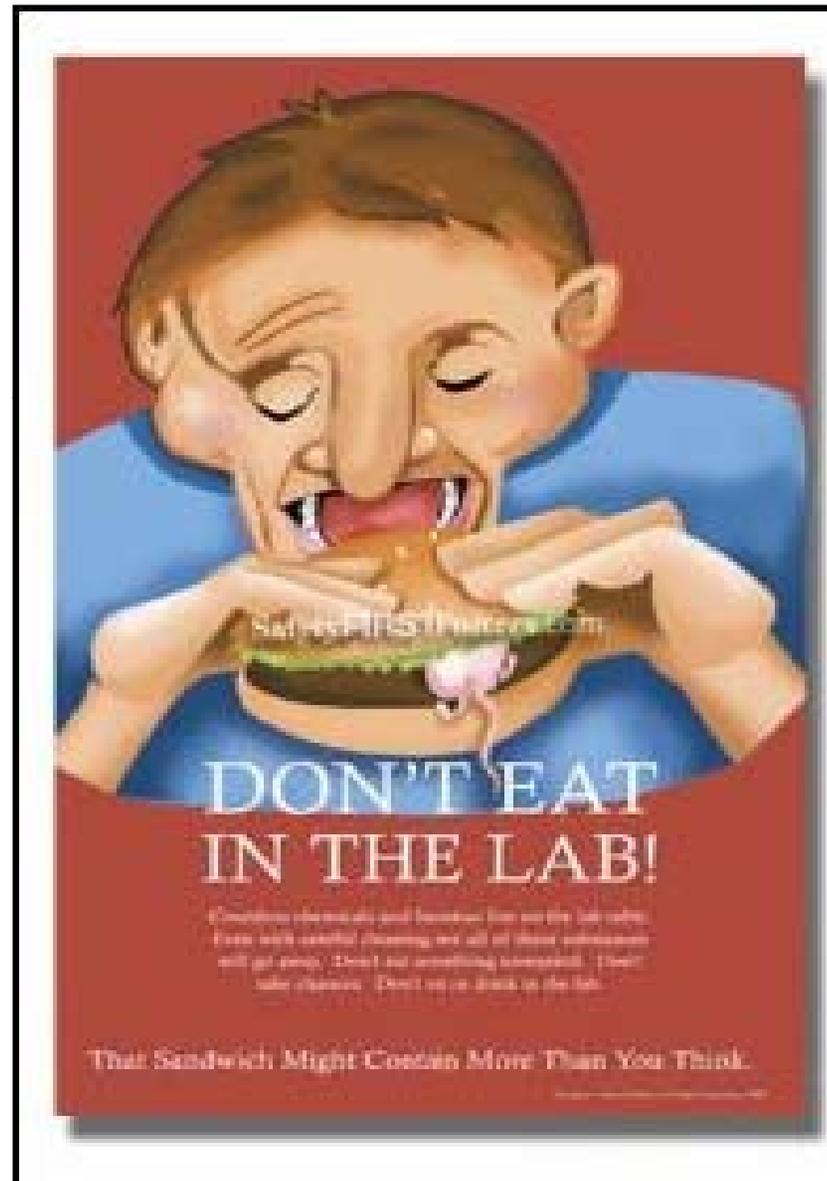
Similar and Different

- Good Laboratory Practices
 - Quality Management Systems
- VS.
- Good / Standard Microbiological Practices
 - Combination of practices and policies that
 - Protect the worker, product, processes and environment.

PPE Policies and SOPs



SafetyFirstPosters.com

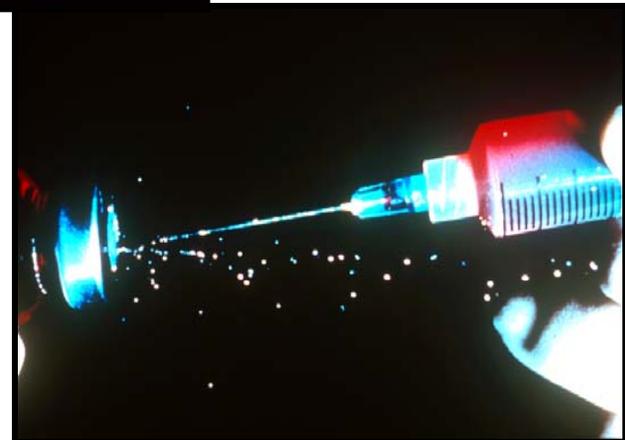


Use Proper Equipment & Techniques



No mouth pipetting

Standard Practices: Minimize Aerosols



Good Microbiological Practices:

Maintain a clean workspace and decontaminate daily with a disinfectant that is effective against the target organism



Sodium hypochlorite



70% Alcohol

Sharps Control and Disposal Policies



- Always use a proper leak proof container to dispose of sharp materials

Waste Management Program



Biological waste containers should always be labeled with a biohazard symbol



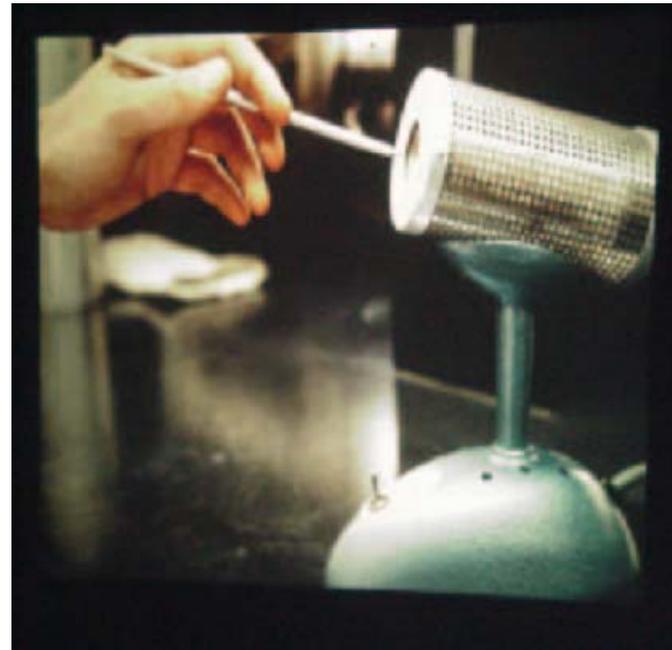


Any comments?

Minimize flames in BSC

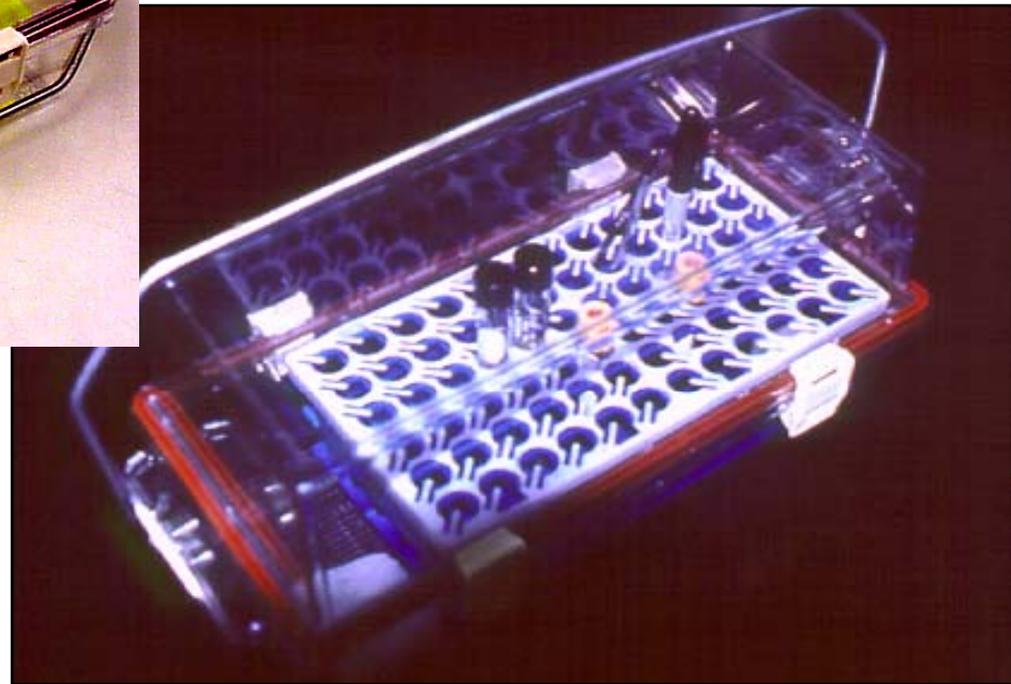
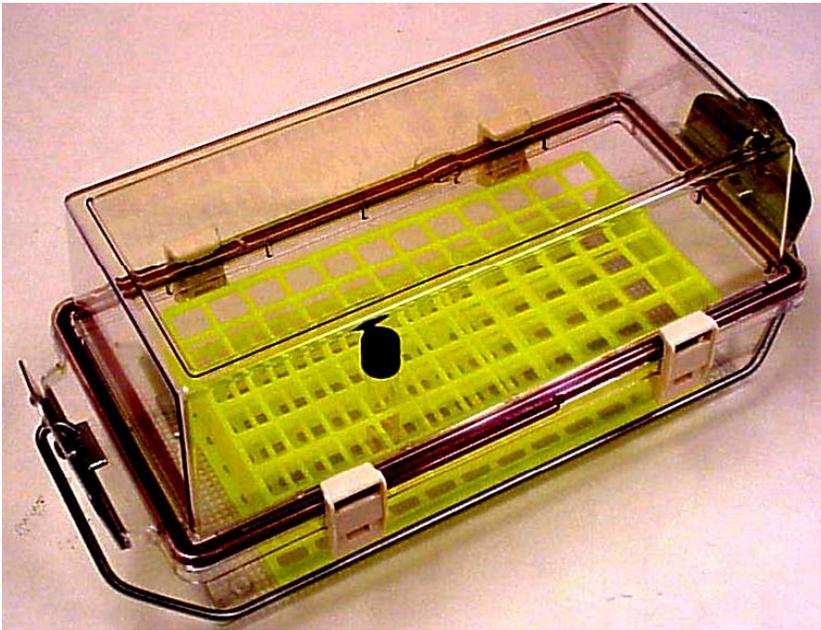
Bunsen burners

- Fire hazard
- Can damage HEPA
- Interferes with proper airflow
- Micro incinerator preferred





Transport of Materials (within the lab)



Hand Wash Policies & Procedures



Questions





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