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Background

• Database of Existing Practice Standards
• Examination of Content
• Content of ISOPP Standard
• Writing of Standard Chapters
• Review of Chapters
• Final Draft

ISOPP Safe Handling Standard

Robert McLauchlan
ISOPP Standards Committee

ISOPP Membership

• China 6
• Japan 3
• Malaysia 58
• Macau 2
• Singapore 11
• Taiwan 1
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ISOPP Standard of Practice for the Safe Handling of Cytotoxics
1. Introduction and Definitions

Cytotoxic Drugs
- Agent with Specific Destructive Action on Certain Cells, may be Genotoxic, Oncogenic, Mutagenic, Teratogenic
- Therapeutic Agents Intended to treat Cancer, Highly Toxic, Carcinogenic
- Drugs that Can Inhibit Cell Growth, Result in Blockage of Cell Multiplication

Hazardous Drugs
- Carcinogenic, Mutagenic or Endanger Reproduction
- Liable to Cause Hypersensitivity
- Genotoxic, Carcinogenic, Teratogenic or Impair Fertility, Serious Organ Toxicity at Low Doses in Experimental Animals or Treated Patients

2. Transport of Cytotoxics

Transport of Cytotoxics
- External
  - Supply from Drug Manufacturers
  - Contamination Free Containers
  - Documentation of No External Contamination
  - Material Safety Data Sheets (MSDS)
  - Packaging, Labelling, Storage

Transport of Cytotoxics
- Internal
  - Transport of Commercial Product
  - Transport of Admixture
  - Packaging - Leaktight, Unbreakable
  - Labelling
  - Contact Details for Emergency
  - Availability of Spill Kit
  - No Detours within Institution
3. Personnel

- Pharmacy Personnel Only
- Exclusions
  - Illness, Family Planning, Abnormal Pathology Results
- Health Monitoring
- Facilities
- Hygiene

Personnel

- Staffing Levels
  - Expected Workload, Number of Preparations, Complexity
- Sufficient Work Breaks
- Documentation
- Education and Training

4. Education and Training

- Qualification for Preparation
  - Validation/Written Test/Checklist to Assess Technical Skills of Operator
  - Pharmacist / Technician
- Staff Undergoing Training
  - Direct and Active Supervision
- Hierarchy of Responsibility
  - Senior / Checking Technician

Education & Training

- Persons to be Educated / Trained
- Content of Courses
- Education Providers & Trainers
- Documentation
- Evaluation / Validation
- Re-Education / Re-Training
5. Hierarchy of Protection

1. Elimination/Substitution/Replacement
2. Isolation of Hazard/Source Containment
3A. Engineering Controls/Ventilation
3B. Administrative Controls/Organization
4. Personal Protective Equipment

6. Sterile Facilities

• Centralised Preparation
• Classification of Cleanroom
  - Particulate and Microbial Contamination
  - Access for Personnel and Products
• Pressure Differentials
• Monitoring of Facilities
  - Particulate, Microbial

Sterile Facilities

• Certification and Quality Assurance
  - Design, Installation, Operation, Performance
• Personal Protective Equipment (PPE)
  - Gowns
  - Masks
  - Gloves
  - Goggles

7. Containment Devices
Containment Devices

- Protection of Handler of Vial / Ampoule
- Protection of Nurse During Drug Administration
- Protection of Operator During Drug Preparation

Containment Devices

- Luer Lock Syringe / Attachments
- Wide Bore Needles
- Hydrophobic Venting Filter
- Chemospike
- All Steps in Preparation
- Contact Between Drug and Surroundings

Closed Systems

- Clear Differences Between Microbiological and Chemical Contamination
- NIOSH Closed System Drug Transfer Device
  - A Device that Mechanically Prohibits the Transfer of Environmental Contaminants into the System and the Escape of Hazardous Drug or Vapour Outside the System
- ISOPP - CONTAINMENT DEVICE

8. Ventilation Tools

Ventilation Tools

- Biological Safety Cabinet
  - Sterility of Product & Safety of Operator
  - Recirculation of Air 0% / 30% / 70%
  - Inclusion of Activated Carbon Filter (AUS)
  - Continuous Operation 24/7
  - Alarm for Insufficient Exhaust/Internal Aiflow
  - Validation 6-12/12
    - DOP, Air Speed, Smoke, KI Disc, Micro

Ventilation Tools

- Isolator
  - Positive Pressure Isolator
    - Protection of the Product
  - Negative Pressure Isolator
    - Protection of Operator / Environment
  - Continuous Operation 24/7
  - Sterile Internal Environment
  - Alarm for Insufficient Exhaust/Internal Aiflow

www.cdc.gov/niosh
Ventilation Tools

- Isolator
  - Transfer Systems
  - Immediate Surroundings
  - Validation 6-12/12
    - DOP, Leak, Airspeed, Micro, Sterilization

9. Non Sterile Preparations

- Oral, Topical Formulations
- Conditions Similar to Parenteral Products
- Separate Room for this Purpose
- BSC Class I
- BSC Class IIIB2 May be Used
- Mixed Activity Not Recommended
- Dedicated Equipment for this Purpose

Non Sterile Preparations

- Orally, Topical Formulations
- Conditions Similar to Parenteral Products
- Separate Room for this Purpose
- BSC Class I
- BSC Class IIIB2 May be Used
- Mixed Activity Not Recommended
- Dedicated Equipment for this Purpose

10. Chemical Contamination

- Environment
  - Dermal and Inhalation Exposure
  - Surface Sampling and Air Sampling
- Surface Sampling
  - Detectable Concentration of Hazardous Drugs
    - BSC, Isolator, Floor, Counters, Treatment Areas
  - External Surfaces of Drug Vials

Chemical Contamination

- Air Sampling
  - Cyclophosphamide, Ifosfamide, 5-FU, Methotrexate
  - Actual Measured Concentrations Low
  - Occupational Exposure Levels in Pharmaceutical Industry (OELs)
  - Occupational Exposure Levels Not Possible in Hospital Pharmacy
11. Checking Procedures

- Clinical Checks, Preparation Checks, Validation
  - Clinical Checks
    - Chemotherapy Regimen, Patient Profile, BSA, Dose Calculation, Premeds, Lab Values
  - Preparation Checks
    - Assembly of Raw Materials, Preparation, Finished Product

Checking Procedures

- Validation
  - Product
    - Concentration/Volume, Microbiological, Physicochemical Stability
  - Cross Contamination
    - Operator Technique, Containment Devices
  - Computer Program
    - Accurate and Free of Error

12. Administration

- Careful Selection of Devices
- Nurses Exposed to Concentrated or Diluted Cytotoxic
- Use of PPE During Administration
- Disconnection Procedure Risky
- Advice on Oral / Topical Formulations
- Advice on Ambulatory Pumps

13. Cleaning Procedures
Cleaning Procedures

- Cleaning Ventilation Tool
- Cleaning Rooms
- Cleaning Equipment for Non Sterile Preparations
- PPE, Disinfectants and Detergents, Procedures and Frequencies
- Validation of Cleaning Procedures

14. Spills/Extravasation

Cytotoxic Spills

- Location of Spill
  - BSC/Isolator, Cleanroom/Anteroom, Storeroom, During Transport
- Content of Spill Kit
- Spill Clean Up Procedure
- Contamination of Staff / Patient
- Documentation and Reporting

Extravasation

- Multidisciplinary Institutional Policy
- Alert to Presence of Vesicant
- List of Vesicant Drugs
- Extravasation Kit
- Documentation and Reporting
  - Inclusion of Photograph of Site

15. Waste Handling

Handling Cytotoxic Waste

- Definitions of Cytotoxic Waste
- Multidisciplinary Institutional Policy
  - Segregation
  - Packaging
  - Collection
  - Storage
  - Transport
Handling Patient Excreta

- Precautions for Up to 7 Days
- Use of PPE
- Disposable Equipment where Possible
- Use of Toilet Facilities
- Contaminated Linen
- Incontinent Patients
- Inclusion of Excretion Rate Table

16. Laundry

Laundry

- Use of PPE where Appropriate
- Segregation of Contaminated Linen
- General Handling Recommendations
- Disposable Equipment where Possible
- Applicable to Hospital and Home

17. Alerting Staff

Alerting Staff

- Storage Facilities
- Reconstitution Facilities
- Transport
- Administration
- Waste
- Spills
- Home Care

18. Home Care
Chemotherapy in the Home
- Care by Nursing Staff
- Care by Patient or Relative
  - Reconstitution
  - Transport of Cytotoxics
  - Facilities Available - Washing, Toilets, Storage
  - Equipment Available - PPE, Spills
  - Transport
  - Detailed Written Patient Instructions

19. Risk Management
- Hazard Identification
- Exposure Assessment
- Exposure Control
- Work Organisation
- Medical Surveillance
- Early Therapeutic Intervention

Risk Management

20. Medicines Management
- Detailed Written Procedures
  - Drug Selection
  - Drug Purchasing
  - Stock Control
  - Reuse of Drugs
  - Partially Used Vials
  - Use of Unlicensed Drugs

21.Documentation
Documentation

- Staff
- Facilities
- Transport
- Incidents and Accidents
- Cleaning
- Workload
- Procedure Manual

Conclusion

Numerous Guidelines Exist Focusing on Limited Aspects of Practice
In General Good Consistency Between Documents
Differences Relatively Minor
Consensus Should Be Possible

ISOPP Gold Standard

Standard Encompassing Best Practice
- Occupational Health & Safety
- Use of Technology
- Education and Training
- Quality Use of Medicines
- Clinical Pharmacy

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