

2012 Academy Seminar -
Thessaloniki, Greece

**Storage and transportation of
pharmacy compounded drugs**

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Barbara Wimmer,

barbara.wimmer@gespag.at

Conflict of interest:

- nothing to disclose

1.

- Receipt of goods

2.

- Transportation into storage rooms

3.

- Storage

4.

- Compounding of the drugs
- Transportation to final users/wards

1.

- Receipt of Goods

2.

- Transportation into storage rooms

3.

- Storage

4.

- Compounding of the drugs
- Transportation to final users/wards

1. Receipt of goods

(flow of material is defined via SOPs)

How can we make sure nothing is transferred into our cleanrooms that is inappropriate?

Receipt of goods

- Delivery of defined material (drugs, solvents and consumables)

Inspection for

- Correctness and
- Integrity
- Sterile products: Certificate (batch)

... Documentation

1.

- Receipt of goods

2.

- Transportation into storage rooms

3.

- Storage

4.

- Compounding of the drugs
- Transportation to final users/wards

2. Transportation into storage rooms

- Storage
(ensure appropriate storage conditions)
- Unpacking
- Flow of material: SOPs

1.

- Receipt of goods

2.

- Transportation into storage rooms

3.

- Storage

4.

- Compounding of the drugs
- Transportation to final users/wards

3. Refrigerator defect or breakdown

- **In-house building control system** (surveillance of the refrigerators, temperature, pressure differences...)
- **Deviation** (rise out of defined ranges of e.g. refrigerators, cleanroom area): **Alarm**, doorkeeper of the hospital gets an alert and calls pharmacy
- If breakdown outside of office hours of the pharmacy: doorkeeper of the hospital alerts engineers, SOPs for emergencies available with the doorkeeper
- Plan where goods are going to be transferred
- Documentation of the deviation

Displays of pressure differences and temperatures within the different parts of the cleanroom area as pass-throughs, storage rooms and locks.



1.

- Receipt of goods

2.

- Transportation into storage rooms

3.

- Storage

4.

- Compounding of the drugs
- Transportation to final users/wards

4. Compounding of the drugs

- Transportation protocol
- Transportation to the wards/final users
(in-house or to external hospitals)

Implementation of compounding of cytotoxic drugs into pharmacy premises

Transportation logistics of in-house pick up and delivery service

- Analysis of established routes and procedures
- Analysis of needs of end-user (=supplied wards)
- Definition of requirements of end-user
- Definition of new routes and timetables for the pick-up and delivery service

Transportation

Transportation had to be validated

External transportation:

- Ratified contract with the transportation company and the pharmacy
- Time within the span as defined in qualification of transportation boxes

...appropriate temperature

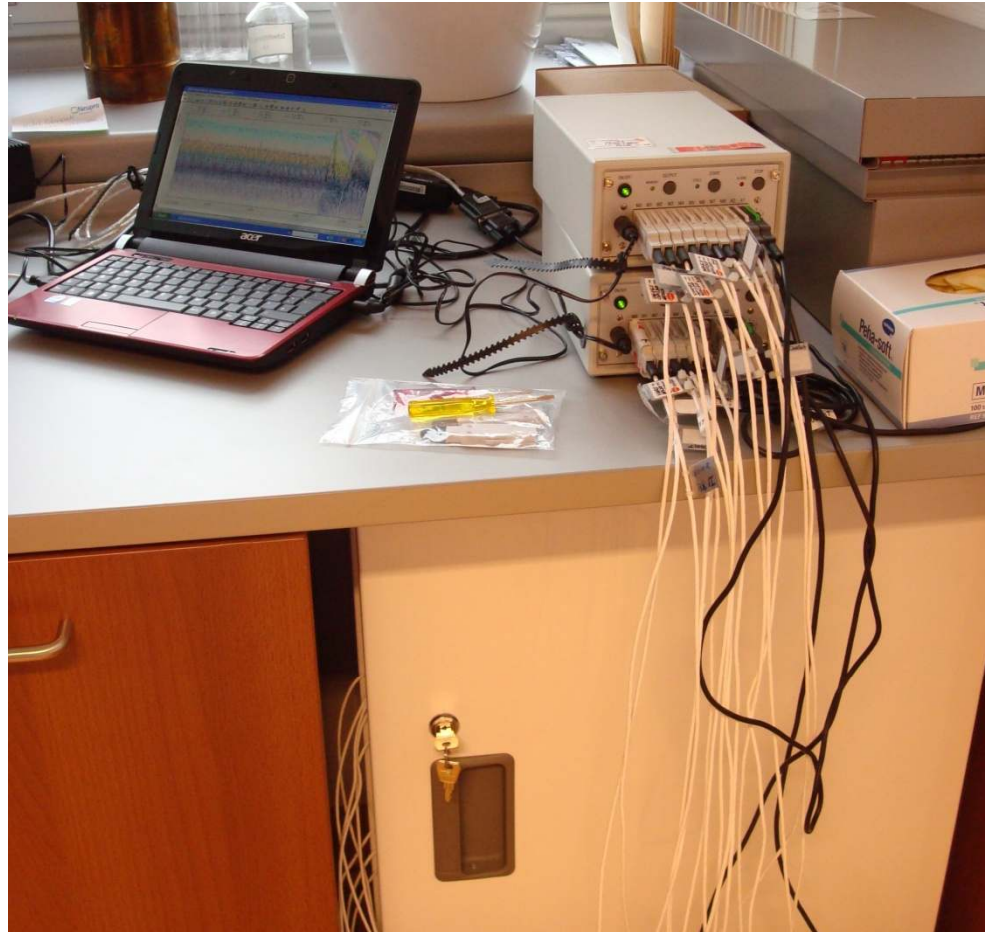
Equipment

On the basis of risk analyses the following documents were generated

- User requirement specification (to describe the required functions of the device)
- Design specification
- Plan and subsequent report of qualification of the refrigerators and the boxes for transportation

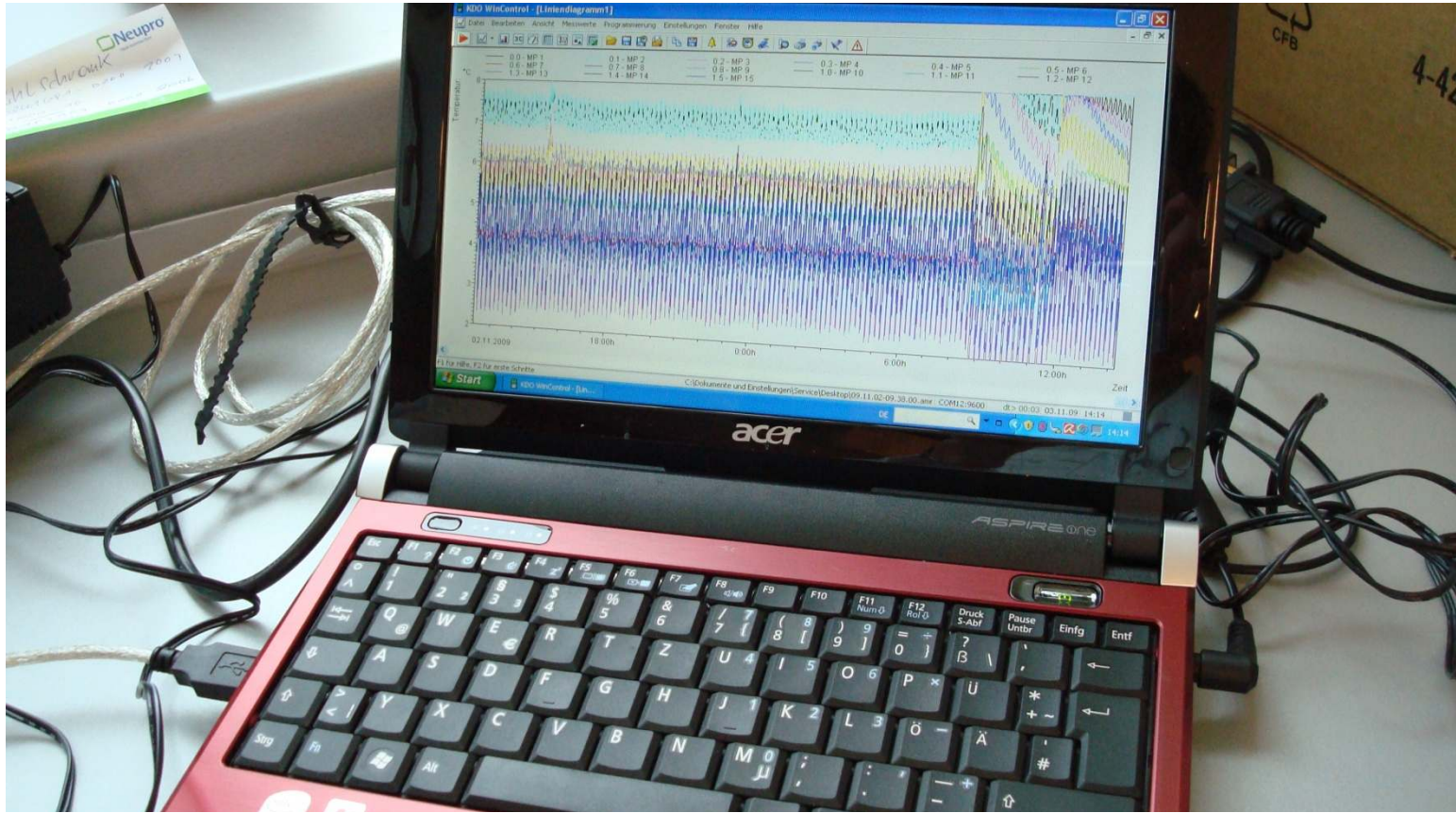
Qualification of equipment

- Definition of the number and positions of the measuring equipment
- Qualification of the refrigerators and the transportation boxes via temperature sensors and data loggers
- Adherence to appropriate and consistent temperature
- Worst case scenarios



Equipment qualification (refrigerator)

Temperature detectors are placed on defined positions



Equipment qualification (refrigerator)

Temperature graphs were analysed



Annual check of the refrigerator

Loaded, data loggers



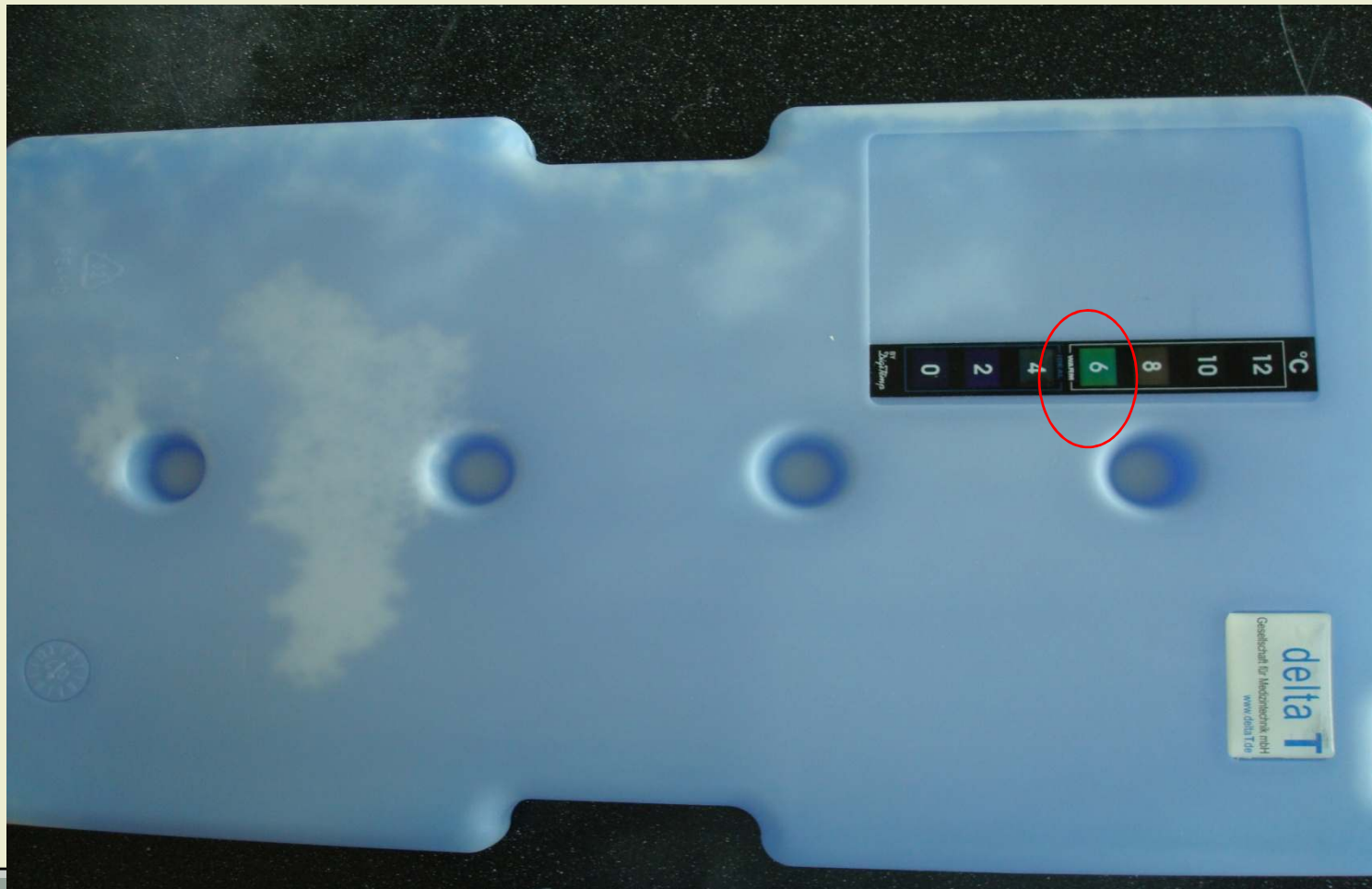
Annual check of the refrigerator

Without load, data loggers



Annual check of the refrigerator

Moderately loaded, data loggers



Cooling packs used in the transportation boxes

Cooling packs with temperature indicators

Eviter tout contact avec le produit

En cas de contact avec la peau ou les yeux, rincer abondamment avec de l'eau froide uniquement pendant au moins 10 minutes, puis consulter un médecin ou un ophtalmologue sans délai.

En cas de casse, ne pas toucher et contacter +.../.....

Les femmes enceintes ou qui allaitent ne doivent ni manipuler ni entrer en contact avec ces produits.



Avoid any contact with the product

In case of contact with the eyes and/or skin rinse thoroughly with cold water for at least 10 minutes and consult a doctor or ophthalmologist immediately.

In case of spillage or damage, do not touch and contact immediately +.../.....

Any contact with pregnant or breast-feeding women must be avoided.

Labelling of the transportation boxes

Source: ESOP recommendation for transport of highly potent drugs, the text must be written in the language spoken in the region



Transportation box

Safe disposal of spilt cytotoxics

Content **BERNER SpillKit^{Extra} XP** Protection



GB 12 0097

Personal Protective Equipment	
Cytostatic protective overall	✓
Cytostatic protective gloves	✓
Cytostatic protective overshoes	✓
Yellow protective gloves	✓
P3 protective mask	✓
Safety goggles	✓
Marking	
Marker pen + Warning sign	✓
Cleaning	
Absorbent wipes	✓
Wipes	✓
H ₂ O	✓
Scoop + Spatula	✓
Tongs	✓
Waste disposal bag 1 + 2	✓
2 ties	✓
Documentation	
Instructions for use	✓
Accident report	✓
Quick guide	✓

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Safe disposal of spilled cytostatics

10-Point-Handling-Instructions (1)

1. Keep calm!

- Don't panic
- People before material decontamination
- Care for affected people immediately
- Take off contaminated clothing straight away
- Keep emergency and clean up "SpillKit" accessible



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Figure source: www.berner-international.de, April 2012

Safe disposal of spilled cytostatics

10-Point-Handling-Instructions (2)



2. Follow instructions!

- Adhere to workplace and material related operating instructions
- Proceed systematically in accordance with yearly briefing
- Cleanup only with trained staff
- Cleanup with two people

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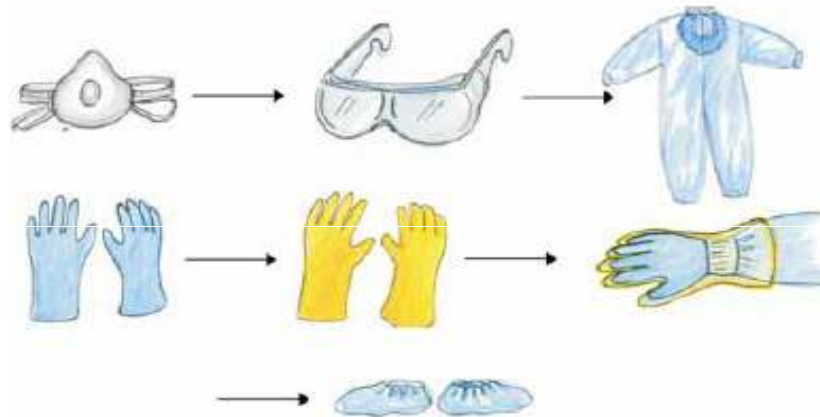
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Figure source: www.berner-international.de, April 2012

Safe disposal of spilled cytostatics

10-Point-Handling-Instructions (3)

3. Wear suitable PPE!



- Protect all people involved
- Respiratory mask, safety goggles, overall or gown, protective gloves, overshoes
- Important: Leak tight respiratory mask
- Note the size of protective clothing
- Gloves: No protection from broken glass

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Figure source: www.berner-international.de, April 2012

Safe disposal of spilled cytostatics 10-Point-Handling-Instructions (4)

4. Seal off and mark scene of accident!

- Block off easily accessible areas
- Widely mark scene of accident
- Protect cross-contamination: close windows and doors, stop people traffic, possibly switch off ventilation system in the laboratory
- Safety cabinet: venting system on

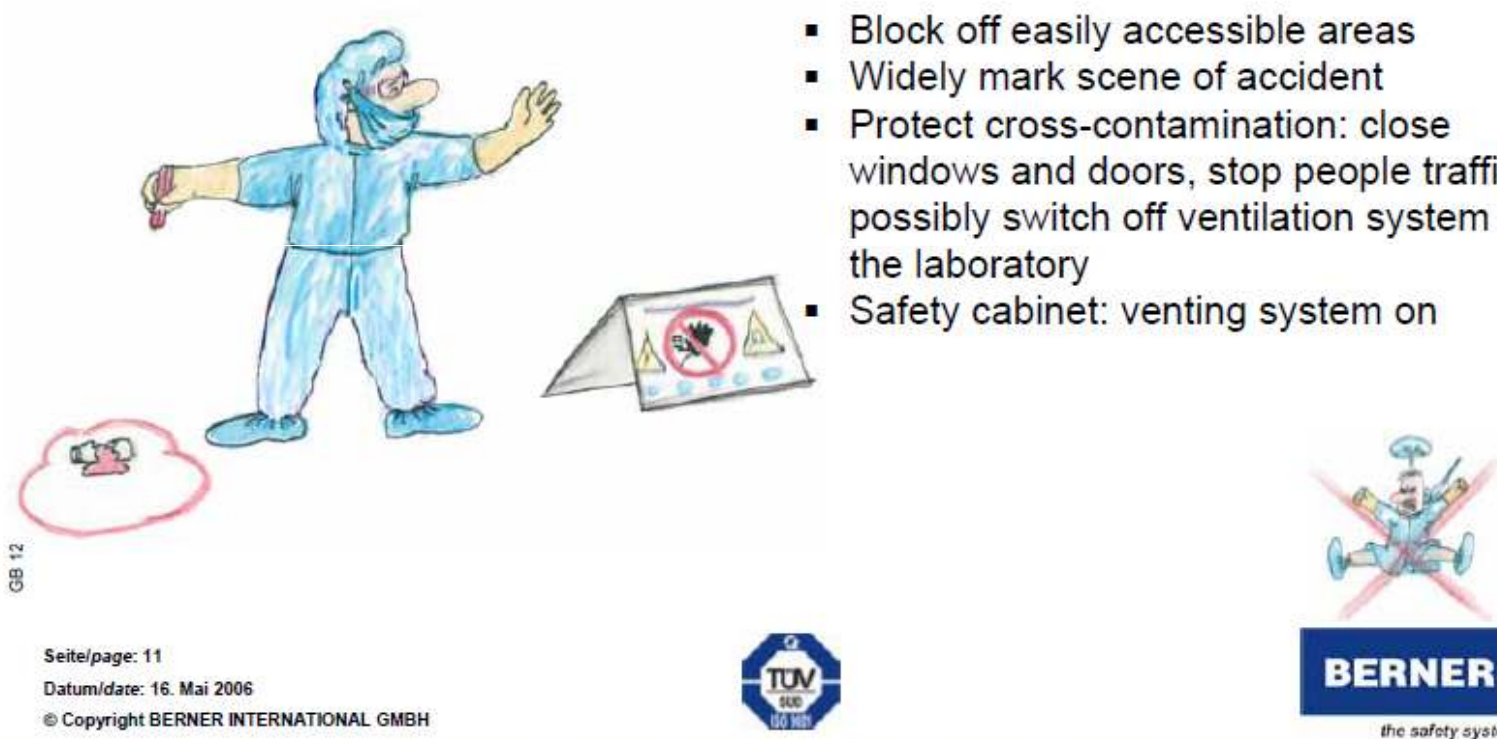


Figure source: www.berner-international.de, April 2012

Safe disposal of spilled cytostatics

10-Point-Handling-Instructions (5)

Liquid contamination



Powdery contamination



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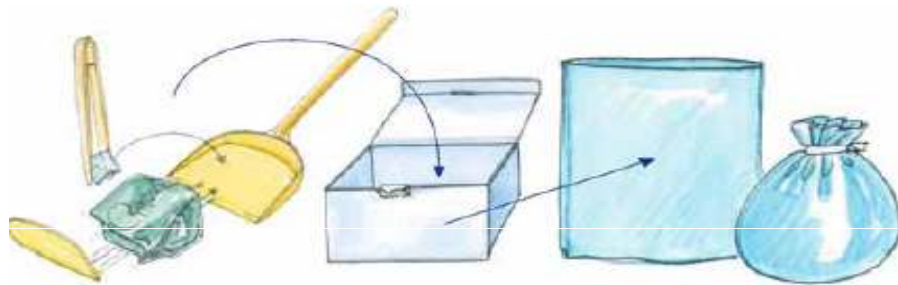
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5. Observe type of cleanup!

- Remove broken glass with scoop and sweeper or tongs
- Take up liquid contamination with wipes
- Remove powdery contamination with moist wipes
- Cleaning direction from outside to inside
- Do not use a hand brush

Figure source: www.berner-international.de, April 2012

Safe disposal of spilled cytostatics 10-Point-Handling-Instructions (6)



6. Waste into blue disposal bag!

- Broken glass in cardboard box
- Cardboard box, auxillary and cleaning implements in blue waste disposal bag
- Seal disposal bag
- Multi-stage cleaning of contaminated areas
- All articles: use once only

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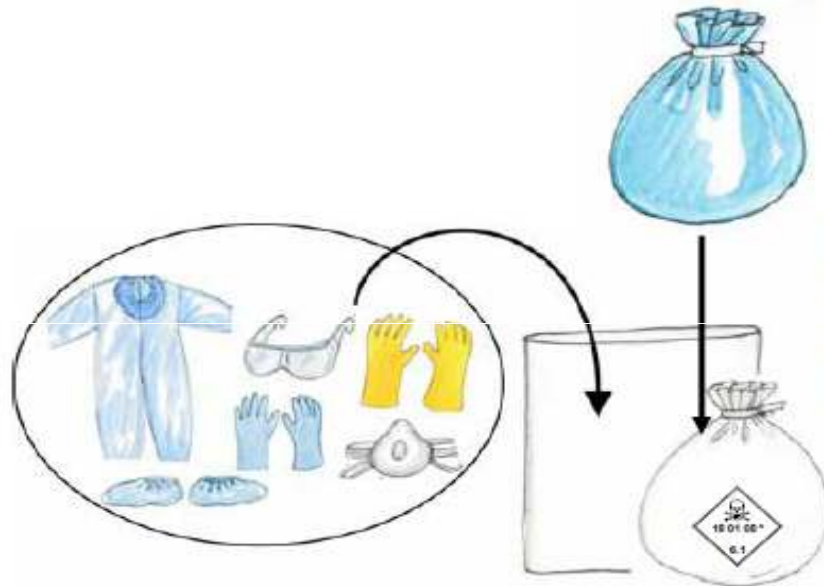
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Figure source: www.berner-international.de, April 2012

Safe disposal of spilled cytostatics

10-Point-Handling-Instructions (7)



7. Waste bag and PPE in hazardous waste disposal bag!

- Waste bag and protective clothing in the hazardous waste disposal bag
- Systematically remove PPE
- Attention: PPE could be contaminated
- Seal hazardous waste disposal bag
- Waste in need of special monitoring: European waste code: 18 01 08*

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Safe disposal of spilled cytostatics

10-point-handling-instructions (8)



8. Shower thoroughly!

- All people involved should clean themselves thoroughly

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Safe disposal of spilled cytostatics

10-Point-Handling-Instructions (9)



9. Visit a doctor!

- If necessary visit a doctor
- Essential in case of personal injury or contamination
- Document examination

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Safe disposal of spilled cytostatics

10-Point-Handling-Instructions (10)



10. Document incident!

- Write report
- For personal injuries entry in accident book and notice of accident
- Employer has duty of disclosure
- Notice of accident to employers liability insurance association, government safety organisation or staff association
- If necessary inform the occupational safety and company medical officer

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Pharmacy entrance

Transportation boxes are collected here

Good distribution practice (GDP)
ensures that the level of quality
determined by GMP is maintained
throughout the distribution
network, so that medicines are
distributed without any alteration of
their properties.

References

- Useful links:

http://www.gmp-compliance.org/eca_link_navigator.html

http://www.gmp-navigator.com/nav_guidelines.html

- ASHP American Society of Health system Pharmacists Guidelines on handling hazardous drugs, 2006.
- Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use, 1992.
- EU Guidelines to Good Manufacturing Practice, Medical Products for Human and Veterinary Use, Volume 4, Annex 1 Manufacture of Sterile Medicinal Products, 2008.
- ESOP recommendation for transport of highly potent drugs, 2008.
- Guidelines on good distribution practice of medicinal products for human use (94/C 63/03), Good distribution practices (GDP): practices as specified in the European Commission.
- ICH Q9 Quality risk management, 2005.
- QuapoS Quality standard for the oncology pharmacy service, 2009.
- Resolution CM/ResAP on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients, 2011.

Thank you very much for your
attention!

Source photos: Pharmacy LKH Steyr