Baxa Corporation

# NIOSH Alert Summary

## Technical Paper

Preventing Occupational Exposures
to Antineoplastics and Other Hazardous
Drugs in Health Care Settings

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## Introduction

On March 25, 2004 the National Institute for Occupational Safety and Health (NIOSH) released a comprehensive analysis and description of specific suggestions entitled "Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Health Care Settings". This landmark effort resulted from the collaboration of physicians, nurses, pharmacists and scientific experts.

Contributions to the Alert were made also by members of the NIOSH Hazardous Drug Safe Handling working group, which included members of the pharmaceutical industry, government and other interested groups. Agencies and organizations represented in that working group are listed in Appendix C of the report.

The Alert details the measures that have been implemented in the past to protect employees, building the case for what hasn't worked and what is needed to improve safety in the future. This technical paper summarizes the more critical observations and suggestions within the Alert. For a one-page employer summary of the health care worker issues, visit www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165sum.pdf.

## Alert Overview

The review process for this Alert took several years and produced a number of drafts. NIOSH released an electronic copy of the 93-page draft document in March. They followed with the release of the final print version, 54 pages in length, in September. Copies are available at *www.cdc.gov/niosh/docs/2004-165/*. The Alert applies to any workers handling hazardous drugs, such as pharmacy and nursing personnel, but also researchers and shipping and receiving personnel. The purpose of the Alert is summarized in the Foreword:

*Healthcare workers who prepare or administer hazardous drugs or who work in areas where these drugs are used may be exposed to these agents in air or on work surfaces, contaminated clothing, medical equipment, patient excreta, and other surfaces. Studies have associated workplace exposures to hazardous drugs with health effects such as skin rashes and adverse reproductive outcomes (including infertility, spontaneous abortions, and congenital malformations) and possibly leukemia and other cancers. The health risk is influenced by the extent of the exposure and the potency and toxicity of the hazardous drug. To provide workers with the greatest protection, employers should (1) implement necessary administrative and engineering controls and (2) assure that workers use sound procedures for handling hazardous drugs and proper protective equipment. (page iii)*

The Alert begins with the following notice:

> ***Warning!***
> *Working with or near hazardous drugs in health care settings may cause skin rashes, infertility, miscarriage, birth defects, and possibly leukemia or other cancers.*

The remainder of the Alert discusses the risks to healthcare workers involved in handling antineoplastic and dangerous drugs. It contains many suggestions to employees, and their employers, of appropriate measures for protecting their health. More than 150 references support the Alert's statements with solid scientific evidence. In addition, the Alert includes five case reports of workers who suffered adverse health effects after exposure to antineoplastic drugs.

## Using Closed Systems

The NIOSH Alert mentions the use of closed systems several times:

- *Develop workplace procedures for using and maintaining all equipment that functions to reduce exposure – such as ventilated cabinets, closed-system drug-transfer devices, needleless systems, and PPE.* (page 11)
- *Store and transport hazardous drugs in closed containers that minimize the risk of breakage.* (page 12)
- *Use devices such as closed-system drug-transfer devices, glovebags, and needle-less systems for added protection:* (page 13 – 14)
  - *Use these closed-system devices inside a ventilated cabinet whenever possible to transfer hazardous drugs from primary packaging (such as vials) to dosing equipment (such as infusion bags, bottles, or pumps). Closed systems limit the potential for generating aerosols and exposing workers to sharps. Evidence documents a decrease in drug contaminants inside a Class II BSC when a closed-system transfer device is used...*
- *Administer drugs safely by using protective medical devices (such as needleless and closed systems) and techniques such as priming of IV tubing by pharmacy personnel inside a ventilated cabinet or priming in-line with nondrug solutions.* (page 14)

## Exposure to Hazardous Drugs

In addition to highlighting the overall issue of environmental and personnel contamination, the Alert notes that exposure to hazardous drugs may occur to both clinical and non-clinical workers throughout the drug's life cycle – from manufacture, to transport, to usage, to disposal. Specific conditions for exposure from inhalation, skin contact, ingestion or injection include: (pages 3 - 4)

- *Reconstituting powdered or lyophilized drugs and further diluting either the reconstituted powder or concentrated liquid forms of hazardous drugs*
- *Expelling air from syringes filled with hazardous drugs*
- *Administering hazardous drugs by intramuscular, subcutaneous, or intravenous (IV) routes*
- *Contacting measurable levels of drugs present on drug vial exteriors, work surfaces, floors, and final drug products (bottles, bags, cassettes, and syringes)*
- *Generating aerosols during the administration of drugs, either by direct IV push or by IV infusion*
- *Priming the IV set with a drug-containing solution at the patient bedside (this procedure should be done in the pharmacy)*
- *Handling contaminated wastes generated at any step of the preparation or administration process*

- *Handling unused hazardous drugs or hazardous-drug-contaminated waste*
- *Decontaminating and cleaning drug preparation or clinical areas*

### Risks In Current Work Practice

The Alert also repeatedly documents evidence that workers are being exposed to hazardous drugs in and that they are experiencing serious health consequences despite current work practice guidelines:

- *Worker exposures have been assessed by studies of biological markers of exposure. No single biological marker has been found to be a good indicator of exposure to hazardous drugs or a good predictor of subsequent adverse health effects*... (page 5)
- *Sessink and Bos [1999] noted that 11 of 12 studies reported cyclophosphamide in the urine of health care workers tested, indicating continued exposure despite safety precautions*. (page 5)
- *When all the data are considered, the weight of the evidence associates hazardous drug exposures at work with increased genotoxicity*... (page 6)
- *Recent evidence summarized in this Alert documents that worker exposure to hazardous drugs is a persistent problem. Although most air-sampling studies have not demonstrated significant airborne concentrations of these drugs, the sampling methods used in the past have come into question...and may not be a good indicator of environmental contamination of the workplace. In all studies involving examination of surface wipe samples, researchers have determined that surface contamination of the workplace is common and widespread*. (page 10)

## Recommendations for Improvement

In addition to the references cited above, the Alert includes a number of specific, scientifically supported recommendations to improve employee safety in handling hazardous drugs:

- *Evaluate the workplace to identify and assess hazards before anyone begins work with hazardous drugs. As part of this evaluation, assess the following:...*
  - *Equipment (i.e., ventilated cabinets, closed-system drug transfer devices, glovebags, needleless systems and PPE)* (page 10)
- *Implement a program for safely handling hazardous drugs at work and review this program annually on the basis of the workplace evaluation. Establish work policies and procedures specific to the handling of hazardous drugs. These policies and procedures should address and define the following:...*(page 11)
  - *Detailed procedures for preparing, administering, and disposing of hazardous drugs*
- *Attach drug administration sets to the IV bag, and prime them before adding the drug to the bag.* (page 14)
- *Never remove tubing from an IV bag containing a hazardous drug.* (page 14)
- *Remove the IV bag and tubing intact when possible.* (page 14)
- *If you handle hazardous drugs, participate in medical surveillance programs provided at your workplace.* (page 18)

- *Monitor the urine of workers who handle hazardous drugs with a urine dipstick or a microscopic examination of the urine for blood...* (page 19)
- *Conduct environmental sampling and/or biological monitoring when exposure is suspected or symptoms have been noted.* (page 19)

## Closed-System Transfer Devices

Closed-system transfer devices were recognized in a 2002 research study for their success in improving on previous practices thought to be completely safe:

- *A U.S. investigation demonstrated that use of a closed-system device for 6 months reduced both the concentration of cyclophosphamide or ifosfamide in the urine of exposed health care workers and the percentage of samples containing these drugs..* (page 5)

A needle-safe, closed system supports the Alert's recommendations for safe handling. A key differentiation for closed-system transfer devices over chemo pins and venting devices is that it that they offer protection from drug reconstitution to handling and transport, through administration to disposal. Closed-system transfer devices have been demonstrated to dramatically reduce, or completely eliminate environmental and personal contamination in hazardous drug handling.

## Conclusion

The Alert concludes with two appendices containing considerable detailed information about the topic of hazardous drug handling:

- Appendix A discusses "Drugs Considered Hazardous." (page 31 - 40)
- Appendix B is a "Glossary of Terms and Abbreviations" that includes a primer on vertical flow hoods and other related topics. (page 41 – 46)

The NIOSH Alert on Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings is a major step toward making these processes safer for everyone involved. Needle-safe closed-system transfer devices offer documented capability for that enhanced safety.

Technical Information is available online at www.baxa.com/onlinehelp.