

**Miller, Diane M. (CDC/NIOSH/EID)**

---

**From:** Justine Coffey [JCoffey@ashp.org]  
**Sent:** Wednesday, June 25, 2008 8:58 AM  
**To:** NIOSH Docket Office (CDC)  
**Subject:** 135 - NIOSH Healthcare Workers Survey  
**Attachments:** NIOSH Comments final.doc

Dear Sir/Madam:

Attached please find the American Society of Health-System Pharmacists' comments relating to the NIOSH proposed national survey of healthcare workers' safety.

If you could send me a confirmation that you received our comments, I would greatly appreciate it.

Thank you,  
Justine

Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs  
American Society of Health-System Pharmacists  
Government Affairs Division  
7272 Wisconsin Avenue  
Bethesda, MD 20814  
Phone: 301-664-8702  
Fax: 301-634-5802



June 25, 2008

NIOSH Docket Office  
Robert A. Taft Laboratories  
MS-C34  
4676 Columbia Parkway  
Cincinnati, Ohio 45226

**Re: NIOSH Docket No. 135 – Comments on the Proposed NIOSH Survey of  
Healthcare Workers' Safety and Health**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the proposed National Institute for Occupational Safety and Health (NIOSH) Survey of Healthcare Workers' Safety and Health. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

**General Comments**

ASHP is pleased that NIOSH is developing the health care workers' survey since the Society believes the survey will identify trends and areas for improving the processes health care workers are required to follow when handling hazardous materials and drug products. Although the information that NIOSH proposes to gather through the survey will be useful, ASHP is concerned that the complexity and length of the survey may limit participation. The Society recommends that NIOSH consult with survey experts to determine appropriate survey length and appropriate use and timing of reminders to obtain the best response rate.

Where possible, NIOSH should prioritize information requests to encourage broader survey participation. ASHP also suggests that NIOSH ask respondents to complete the survey in stages, and that administrator and worker surveys be staggered to alleviate the burden imposed at each site.

Additionally, each module in the survey lists the health care workers toward whom the module is directed. However, this proscriptive approach may preclude the possibility of obtaining data from other relevant practitioners. For example, many health care facilities

have established an operating room pharmacy, but NIOSH does not identify pharmacists and pharmacy technicians who practice in these settings and post surgical care areas as practitioners who should respond to Modules H and I.

Furthermore, the instructions for Module B indicate that pharmacists and pharmacy technicians are the primary respondents to the survey. However, nursing personnel also prepare hazardous drug products in outpatient clinics. ASHP therefore recommends the following alternative wording for Module B: "This module is directed toward individuals such as pharmacists, pharmacy technicians or nurses who prepare, mix, or compound hazardous drugs or antineoplastic agents."

Project Aim 3: Project Aim 3 of the Background information states: "Describe prevalence and distribution of worker exposures, health and safety perceptions and practices, and use of exposure controls and barriers to their use." ASHP recommends comparing employee reports of exposure with the number of incidents reported to employee health departments at those same institutions. This comparison should identify the extent to which incidents are under- or over-reported.

Hazardous Drug and Antineoplastic: The terms "hazardous drug" and "antineoplastic" are interchanged throughout the modules. ASHP recommends providing a comprehensive definition of these terms at the beginning of the survey, and maintaining consistent terminology throughout the modules. The Society is concerned that, without this consistency, specific mention of "antineoplastic agents" to the exclusion of other hazardous drugs (e.g., monoclonal antibodies, immunosuppressants, etc.) may result in respondents answering from a more limited perspective. ASHP recommends the following broader terminology: "Hazardous drugs (including oral, topical or injectable forms of cytotoxic or antineoplastic agents)." This is a critical change for the Core Module question 71, where respondents will self-select additional modules to complete.

Disposal of Hazardous Drugs: NIOSH should consider adding questions to the current survey, or developing a separate survey, to assess the disposal of hazardous drugs and materials. There has been significant recent coverage in the trade and lay press about the environmental impact of pharmaceutical waste, and wastes from hazardous drugs present an occupational hazard while they remain in the health care setting.

### **Worker Core Module**

General comment: In several places tobramycin is provided as an example, however it is unclear why this drug is listed since it is not defined as a hazardous drug product.

Question 1R: Following Question 1R, which assesses adequate staffing, ASHP recommends asking whether workers believe the construction or layout of their facilities is adequate to minimize hazardous exposures. For example, personally protective equipment located far away from the area where it is needed would discourage use.

Question 2J: It is unclear whether the intent of Question 2J is to assess exposure to infectious diseases. The use of the term “infectious diseases agents” could be misinterpreted as exposure to drugs used to treat infectious diseases. ASHP recommends revising this question to read: “Infectious diseases (e.g., tuberculosis).” Gene therapy could also be included as an example.

Question 2O: ASHP recommends changing the wording to “Excessive noise level.”

Question 3: ASHP recommends breaking out “Special Practitioners” into a distinct category, and naming that category “Other Health Care Professionals,” since pharmacists, dietitians, nutritionists, and others are unlikely to identify themselves as “Special Practitioners.” This new category could follow the “Nurses and Nursing Support Staff” category.

Questions 29-33: Questions 34 and 35 assesses whether workers experienced a sharps injury from a non-sterile needle or device, meaning one not contaminated with drugs or biohazards. ASHP recommends making this same distinction for questions 29-33.

Question 41: ASHP recommends assessing the use of protective eyewear.

Question 54: Various levels of personal protective equipment may be worn during the day or week depending on the types of tasks performed. ASHP therefore suggests changing Question 54 to read: “During the past 7 calendar days, which of the following personal protective devices or equipment were you required to wear while performing specific tasks for your job?”

In Question 54, and throughout all modules, the term “respirators” is used. Health care professionals commonly refer to the respirator as an “N95 mask.” Therefore, ASHP recommends using more specific terminology, such as “Respirators or N95 mask (does not include surgical mask),” rather than simply using the term “respirators.”

Question 57: ASHP recommends adding a question after Question 57 that assesses the use of chemotherapy or nitrile gloves. Adherence to double gloving should also be assessed.

Questions 58 – 60: “Medical Surveillance” is commonly used for the testing defined in questions 58 through 60. This terminology should replace or supplement the current section title, “Medical Evaluation.”

Question 69: ASHP recommends adding Pharm.D as an example of a professional degree.

Question 71: Nurses sometimes prepare hazardous drugs in a clinic setting, which may not be perceived as “pharmacies.” ASHP recommends rewording this question as follows: “In your current job, do you prepare or mix oral, topical or injectable hazardous drugs or antineoplastic agents in a pharmacy, outpatient clinic, or pharmacy-like setting?”

### **Module B: Antineoplastic Agents (Pharmacists, Pharmacy Technicians)**

ASHP recommends that Module B be expanded to include questions that assess proper practices for staging, preparation, labeling, and decontamination (including spills and exposures). The following are examples of questions that should be addressed in the survey, and include areas where exposure and contamination may occur:

- Are drug vials wiped before placement in the biological safety cabinet?
- Are final products surfaces decontaminated prior to placement of labeling?
- Are gloves worn when moving vials to the product preparation area?
- Are gloves changed at least every 30 minutes during compounding procedures or when damaged or contaminated?
- Are gowns worn for no longer than 3 hours?

ASHP recommends developing these questions based on the practices described in ASHP Guidelines on Handling Hazardous Drugs, Appendices B, C, D, E, H, I ([http://www.ashp.org/s\\_ashp/docs/files/BP07/Prep\\_Gdl\\_HazDrugs.pdf](http://www.ashp.org/s_ashp/docs/files/BP07/Prep_Gdl_HazDrugs.pdf)). ASHP would be pleased to assist NIOSH in the development of these questions.

Several questions in this module ask respondents why they do not use personal protective equipment. It would be useful to add the following answer option: “Not recommended or required by the Food and Drug Administration (FDA) or manufacturer.”

Question 2: Following this question, ASHP recommends adding a question to assess whether respondents have received training on the principles and proper use of the biological safety cabinets and/or isolators.

Question 3: ASHP recommends deleting this question. While individual practice settings may “certify” their employee in product preparation and handling, there is no nationally recognized certification program for preparation of these products. At a minimum, option two should be deleted since the Pharmacy Technician Certification Exam is a knowledge-based exam that cannot assess the ability of personnel to *demonstrate* proper handling precautions for hazardous drugs.

Question 5: ASHP recommends assessing whether workers believe the facility’s policies and procedures are consistent with nationally recognized standards, including the ASHP Guidelines on Handling Hazardous Drugs and NIOSH’s Hazardous Drug Alert.

Question 6: ASHP recommends modifying “street clothing” to “unprotected street clothing.”

Question 8: ASHP recommends that the respondent not be limited to two write-in drugs.

Question 13: ASHP recommends adding option (d) “biologic safety cabinet” and option (e) “barrier isolator.”

Question 20: ASHP recommends adding an additional question following Question 20 assessing the number of spills that occurred inside the compounding area (biological safety cabinet or barrier isolator).

Question 24: ASHP recommends adding an additional question following Question 24 to assess adherence to recommendations to use inner and outer gloves.

Question 30: This question asks about the use of a respirator for product preparation. However, the question does not acknowledge that most hazardous drugs are prepared in a biological safety cabinet, which is ventilated and therefore does not require use of a respirator. This question may provide results that falsely indicate low use of respirators, when in fact respirators are not needed for this most common setting of product preparation.

The Society appreciates this opportunity to present its written comments on the proposed survey. Feel free to contact Cynthia Reilly, R.Ph., Director, Clinical Standards and Quality, Practice Standards and Quality Division, if you have any questions regarding our comments. She can be reached by telephone at 301-664-8664, or by e-mail at [creilly@ashp.org](mailto:creilly@ashp.org).

Sincerely,



Justine Coffey, JD, LLM  
Director, Federal Regulatory Affairs