

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

From: Jean Scholz [Jeans@ohanet.org]
Sent: Tuesday, July 01, 2008 1:43 PM
To: 'nioshdocketoffice@cdc.gov'
Cc: Carol Jacobson; 'dstock@aha.org'; Dragon, Karen E. (CDC/NIOSH/EID)
Subject: NIOSH Docket number 135
Attachments: SDOC1035.pdf; 7-1-08 niosh.doc

To Whom It May Concern:

This message is sent re: ***NIOSH Docket number 135, Notice of public meeting and availability for public comment (Vol. 73, No. 64). April 2, 2008.*** Please accept the attached comments and use them to improve the proposed study of hospital worker and employer safety practices.

If I can be of further assistance, please contact me at the Ohio Hospital Association.

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July 1, 2008

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

Re: NIOSH Docket number 135, Notice of public meeting and availability for public comment (Vol. 73, No. 64). April 2, 2008.

To Whom It May Concern:

On behalf of Ohio's hospitals and their employees and medical staff, we reiterate the concerns already expressed to you by the American Hospital Association (AHA) on NIOSH proposed national surveys of health care workers' safety and employer safety and health practices. A copy of the letter sent to you by AHA is attached for your reference.

Ohio hospitals employ over 250,000 health care workers and in Ohio, the health care workforce makes up about 10 percent of the total Ohio workforce. Therefore, the health and safety of Ohio's health care workforce is significant to our state and we share your intent to study the issues associated with their work. However, AHA's concerns are valid and their comprehensive comments should be carefully considered prior to embarking on any national survey. OHA requests your reconsideration of the strategy NIOSH will use to study and investigate workplace safety in hospitals.

OHA is committed to helping hospitals create environments that attract and retain employees. Safe workplaces are environments that attract and retain staff. OHA and the Industrial Commission of Ohio created the hospital Safety Campaign in January 1953. Ohio hospitals continue to have a strong commitment to reducing workplace injuries. OHA's Safety Campaign is a positive, win-win approach to the design of institution-based health and safety management policies, programs and resources. We would be happy to share more details about the Safety Campaign with you, and would be happy to help you redesign your efforts to advance any work place safety needs of healthcare professionals. We look forward to hearing from you.

Sincerely,

Jean Scholz

CC: Deb Stock, AHA
Carol Jacobson, OHA



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June 26, 2008

NIOSH Docket Office
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RE: NIOSH Docket number 135, Notice of public meeting and availability for public comment (Vol. 73, No. 64), April 2, 2008.

To Whom It May Concern:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the National Institute for Occupational Safety and Health's (NIOSH) proposed national surveys of health care workers' safety and employer safety and health practices.

As employers and as providers of health care, hospitals and health systems are committed to the health and safety of our caregivers and patients. Hospitals have long had in place policies, programs and resources that are designed to protect employees, and they strive to ensure that these protections are updated and kept relevant as new hazards emerge and best practices are defined.

NIOSH states that the overall objective of this project is to "describe the prevalence and distribution of important health and safety hazards and perceptions, work practices, and use of exposure controls from a health care worker perspective, and to describe institution-based health and safety management policies, programs and resources of health care establishments, from the perspective of the person responsible for employee health and safety." We agree that it is critical to have current and accurate data on the top health and safety issues facing caregivers. However, we have serious concerns about these surveys and the methodology that NIOSH proposes to use to obtain these data.



Problems with the pilot-testing of the questionnaires. NIOSH reports that it conducted a pilot-test of the surveys at two large medical centers to evaluate the establishment-based approach for implementing the employee survey, the preference for mode of response, response rates, and to validate the worker and management questionnaires. NIOSH further reports that the management questionnaire was validated at four hospitals that completed the surveys and permitted site visits to assess the accuracy of their response. However, no detail is provided in the background materials as to the type, location or size of these hospitals or whether they included the two large medical centers that also participated in the employee survey pilot test. Given the lack of detail in the background materials provided to the public, it is impossible to determine whether the pilot-testing was adequate and, therefore, whether the conclusions drawn from the pilot test can be used to support the content and conduct of the NIOSH surveys. Certainly, using just two large medical centers to validate the questionnaires would not lead to results that were representative of the different types of hospitals in the nation. In order to support the validity of the management survey in particular, it would be important to include several types of hospitals, such as a small rural or critical access hospital, and a medium-sized community hospital.

Problems with the length and complexity of the surveys. The management and health care worker surveys are extremely long, with complex questions, many of which contain multiple parts. We believe that completing them will take far longer than the time NIOSH estimates. NIOSH estimates that it will take 20 minutes to complete the core module of the worker survey, which is 25 pages long and contains 79 questions; and that the hazard modules, which include up to 42 questions, will take an average of seven minutes to complete. The agency estimates that it would take 45 to 50 minutes to complete the management survey, which is 50 pages long and contains 63 core questions, with 140 questions in the hazard modules. Further, many of the questions in the management survey would require significant research to determine the appropriate response.

Clearly, NIOSH has significantly underestimated the time it will take to complete the surveys. We are concerned that this level of burden will reduce the survey response rate, particularly in the management survey, and result in an inadequate and non-representative sample of respondents completing the survey. A significant response burden would fall on larger hospitals, which, because they generally offer a full range of services, would need to complete not only the core questions but most or all of the hazard modules.

Completing the management survey is a far more complicated task than completing the worker survey. Within a single hospital there will likely be a number of individuals, such as infection control, occupational health and safety/facility officers, who will be called on to complete various sections of the survey. Also, while many hospitals have on-site occupational health offices, health systems with multiple hospitals may not have such offices within each of their facilities. They would have to provide access to data to complete the survey from within their centralized occupational health departments. Still other facilities contract out the occupational health functions to a third party.

Also, there are many variations in the types of positions responsible for the areas being addressed in the survey, making it more difficult to identify those to whom the survey should be targeted. These factors will make it difficult to ensure that the survey gets to the right individual(s) within hospitals and increase the likelihood that surveys could be lost in the system, hurting the response rate and jeopardizing accuracy for the management survey.

Problems with survey questions. While NIOSH claims to be seeking comments on the content of the survey questionnaires, its background materials note that the survey questionnaires have already been pilot tested in two large medical centers. The agency states that "the content of the questionnaires has been fairly well-defined" and "minor revisions will be made...prior to use in this study." The AHA has serious concerns about many of the questions in the survey, which we describe in attached detailed comments. However, NIOSH implies that it does not intend to correct or remove the problems, errors and inconsistencies in the survey instruments and instead is seeking input only in an attempt to identify other issues for possible inclusion in these already long and burdensome questionnaires. We urge NIOSH to reconsider this decision and be open to making substantive changes to the content of the surveys.

Our greatest concerns relate to statements, especially those to which the worker is asked to respond, that are presented as factual or imply a best practice, but which do not have solid supporting evidence. In our attached detailed comments, we identify those questions that do not have a proper basis in evidence and recommend that they be removed or changed. Additionally we are concerned that many questions, especially those referring to the use of personal protective equipment, have inadequate response options. As a result, respondents cannot answer in a way that accurately describes their health and safety practices. Our detailed comments also address these concerns. Unless NIOSH ensures that its questions describe practices that are truly supported by scientific evidence and allow responses that reflect actual health and safety practices, the survey results will be misleading and identify gaps that are not relevant to worker health and safety.

Concerns about the methodology for conducting the surveys. For the worker survey, NIOSH indicates that it will use a "population-based" approach to gather hazard surveillance data from health care workers by partnering with various labor unions and professional associations that will send survey information to their membership. These organizations will either directly e-mail their members with a link to the survey or promote the survey to members via various avenues of communication and direct them to a Web site where they can complete the survey. This results in a "convenience" survey sample of workers who are members of the partnering labor unions and professional associations and who have access to the Internet. To maximize response rates, NIOSH proposes to award workers who complete the survey with a \$10 on-line gift certificate.

The AHA has serious concerns about this approach. As stated in NIOSH's background materials, the disadvantages associated with the use of a convenience sampling approach include the problem of a non-representative sample of the total population of workers and sampling bias. The use of labor unions to market the survey further magnifies this problem because within

health care, labor unions are concentrated in certain areas of the country and therefore the workers that unions such as the Service Employee's International Union (SEIU) will be able to reach will skew the sample and move it further away from being nationally representative. We recommend that NIOSH continue to reach out to other organizations that may have a more appropriate balance of geography among their membership to help ensure a more nationally representative health care worker survey sample. We also support NIOSH's intention to modify the survey to include questions regarding characteristics of the worker's place of employment (i.e., type and size) and professional association or labor union affiliation; this will help researchers determine whether the survey results are nationally representative.

For the management questionnaire, NIOSH proposes to use an "establishment-based" approach from which a size-stratified random sample of hospitals will be drawn. Contact will be made with each hospital to obtain the name and e-mail address of the person primarily responsible for employee occupational health and a series of survey related e-mails will be sent. While we believe that this approach has a better chance of resulting in a nationally representative sample of respondents, we have a number of concerns and questions about how NIOSH proposes to conduct the management survey.

First, NIOSH indicates that the sample of hospitals it will draw will be size-stratified by the number of employees (1-19; 20-449; 500+). The AHA recommends that NIOSH not finalize this sampling framework, but instead use the more typical hospital research sampling framework that is based on bed size, geographic region and type of facility.

We also are concerned that the stark differences in the approaches used to conduct the two surveys will make it appear, incorrectly, that hospitals are indifferent to the health and safety of their workers. As noted above, due to the lengthy and complex management questionnaire, we believe that there will be a low response rate, resulting in an inadequate and non-representative respondent population. While the worker questionnaire is also lengthy, workers will be provided with a financial incentive, a \$10 gift certificate, to complete the survey.

Further, the worker questionnaire, being primarily based on worker's perceptions and opinions, and being loaded with questions that are not evidence-based, is far more subjective than the management questionnaire, which is largely based on concrete management practices.

There is no way to validate the results of the worker questionnaire because it includes no information that could link a worker to his or her place of employment. By contrast, NIOSH has indicated that it will validate some samples of the management questionnaire responses via site visits.

For these reasons, we recommend that NIOSH reconsider its methodology for administering the health care worker survey. Instead of utilizing a convenience sample, NIOSH should evaluate how it could develop a statistical sampling approach that would more accurately represent the populations of workers it would like to survey. NIOSH also should consider developing a methodology to validate the worker questionnaire results, perhaps by linking the responses from

NIOSH Docket Office
June 26, 2008
Page 5 of 5

workers within a single institution and/or through comparing the worker responses to the responses from a validated management questionnaire from the health care facilities in which they are employed.

If such changes are not made, and if the responses to the worker and management surveys are determined not to be nationally representative (as NIOSH notes it expects will be the case with housekeeping staff), NIOSH should place the caveat in its public release that the results should not be used to make generalizations about entire populations, and that any associated conclusions run the risk of being false.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

Two Attachments

Attachment 1

AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS

OVERARCHING AREAS OF CONCERN

The American Hospital Association (AHA) has identified a number of issues and problems that are repeated throughout the health care worker and the management questionnaires. Revisions should be made throughout the survey in a consistent manner. These issues:

Use of personal protective equipment (PPE) excludes masks. The questions in the core questionnaires and modules consistently exclude masks from the definition of PPE. This is a major flaw in these surveys and the absence of questions regarding the use of masks prevents the collection of important information. Surgical masks remain important in health care settings for managing patients and facilities cannot always separate protection of patients or equipment from protection of the worker when care is being provided. There are circumstances where the use of masks is perfectly acceptable and consistent with Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) guidance. This would be the case, in locations involving biological agents, such as isolation rooms or around patients in "contact precautions;" when a worker preparing antineoplastic drugs uses a biological safety hood; where the sterility of equipment must be protected; and many other circumstances. The survey's consistent misrepresentation of what is acceptable PPE will undermine health care worker confidence that masks have value. By maintaining this position throughout the questionnaire, a systematic bias is introduced and valuable information on standard and appropriate practices is lost. The survey language's implication is that a respirator is required to protect the worker from any potential exposure. The questionnaires should be revised to list masks as an appropriate type of PPE.

Routine medical surveillance for workers. The management questionnaire consistently, and inaccurately, implies that routine medical surveillance of workers in the absence of a specific problem is a standard of practice. In fact, with the exception of skin testing for occupational exposure to tuberculosis and a very few other circumstances, most health care facilities do not routinely conduct medical surveillance. Instead, they have occupational health programs in place to which an employee would be referred if there is evidence of a problem related to perceived exposures in the workplace, such as a worker with shortness of breath or an allergic reaction. This concern about the assumption that routine medical surveillance is taking place applies to questions regarding exposure to antineoplastic agents (page 16, questions B10-B13A); ribavirin, pentamidine and tobramycin (pages 23-24, questions C8-C12); glutaraldehyde (page 28, questions D9-12A); ethylene oxide (page 35 and 36, questions E10-13A); and waste anesthetic gases (page 44, questions F9-F12A). These questions should be restated to inquire whether

testing is being conducted when problems are identified (e.g., worker with shortness of breath or allergic reaction.). For instance, they could ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace.

Use of back belts not supported by evidence. (See attached citations for back belts.)

Several of the questions in the worker core questionnaire refer to the use of back belts. The implication throughout is that this is expected behavior or policy, or standard of practice. Yet the literature is clear that back belts are not recommended. The National Institute for Occupational Safety and Health's (NIOSH) own major study published in the *Journal of the American Medical Association* in 1996 states, "There is a lack of scientific evidence that back belts work. Workers wearing back belts may attempt to lift more weight than they would have without a belt. A false sense of security may subject workers to greater risk of injury." Back or gait belts are referred to within the health care worker core questionnaire in questions 50, 52, 54 and 55 on pages 17-20. In the management survey, back belts are referred to on page 9, question A41 (Musculoskeletal Injury). These references to back belts should be removed from the questionnaires.

Natural rubber latex products. All references to powder-free natural rubber latex gloves and other natural rubber latex products should be changed to reflect the current availability of Food and Drug Administration (FDA) approved powder-free, low protein/allergen latex products. Powder-free, low protein/allergen natural rubber latex gloves are already widely used within health care facilities, and we expect that there will be other products on the market by the time these surveys are administered. Therefore, to avoid confusion among respondents, all such references should be cited as "powder-free and low protein/allergen" natural rubber latex gloves or products.

Within the health care worker questionnaire, the references to natural rubber latex gloves and other products that need to be changed are in:

- Core Module, page 20, question 57;
- Module B (Antineoplastics (Pharmacists, Pharmacy Techs)) pages B-6 through B8, questions 24 and 27; and
- Module C (Antineoplastics Agents Administration (Oncology Nurses)) page C-6 and C7, questions 24 and 26.

Within the management questionnaire, the references to natural latex rubber gloves and other products that need to be changed are in:

- Section A, Core Questions, Pages 10-11, Question 54-59; and
- Section B, Antineoplastic Agents, Page 20, Question B28, option (f).

HEALTH CARE WORKER QUESTIONNAIRE

CORE MODULE

Health & Safety Hazards Concerns

Page 3 Question 2 (j). In its example of an infectious agent, NIOSH selects only the airborne agent tuberculosis. We believe that contact transmission of infectious diseases is of equal, if not greater concern to health care workers. However, this would require that NIOSH include questions referring to masks as part of PPE, not just respirators. This is an issue that surfaces repeatedly in the management and worker (both core and individual hazard) modules and results in a built-in bias that will not permit collection of information on actual safe practices.

Page 12, Question 29: Safe Needle Devices – Universal Precautions. The term “Universal Precautions” should be replaced with “Standard Precautions,” the current terminology. Also, as there is increasing usage of non-needled syringes with luer locks to IV lines, which do not involve sharps at all. Please replace the word “syringes” with “syringes with needles” in the question, “do you handle syringes, scalpels or other sharp instruments...”

Page 14 Questions 39-40. This question asks about the frequency of handling soiled sheets, bedpans, etc. The follow-up Question 41 asks *only* if water-resistant gowns/gloves are always worn. There is no choice for responding that water-resistant gowns/gloves are worn most or some of the time, as is offered for other questions. Further, handling a soiled sheet or bedpan may not require a water-resistant gown and no option is given for any other types of protective or isolation gowns. The wording permits no other response.

Medical Evaluation

Page 21, Question 58. The question indicates that an evaluation “may include blood tests, and/or urine test.” Mentioning these sets an expectation that blood and urine testing are required without any reason and implies a standard of practice that does not exist.

MODULE A: AEROSOLIZED MEDICATIONS (RESPIRATORY THERAPISTS)

(See attached citations for aerosolized medication.)

Issue: Engineering controls versus personal protective equipment (PPE) in handling aerosolized medications. Research studies detail the progress on the use of sealed or scavenger type systems that minimize risk and indicate that engineering controls and work practices are primary over respiratory protection. There also are options such as booths, enclosed hoods or negative pressure rooms, especially since pentamidine may be used on patients infected with tuberculosis. However the questions in the survey do not

recognize improved sealed delivery systems that offer more options and less reliance on PPE. This issue, raised below for ribavirin, also applies to the questions on pentamidine (pages A-4 and A-5, questions 20 and 21; page A-3, question 16) and tobramycin (page A-6, questions 28 and 29; page A-5, question 24).

- **Page A-3, Question 12.** This question offers only three options: sealed booth, partially enclosed hood/tent or no enclosure. There is no option related to a negative pressure room (possibly an isolation room). This option should be added to question 12.
- **Page A-3, Question 13.** In this question, use of a negative pressure room option should not be limited to an isolation room.
- **Page A-2, Question 8 and Page A-3, Question 13.** These questions begin to address the fact that the type of equipment used is a critical engineering control to minimize aerosols and deliver drug directly to a patient's lungs, but they do not address this directly or clearly. Distance from patient (within five feet) is made to appear to be more important than the seal of the medical device being used. There should be a statement added indicating that the best engineering control is a well-sealed drug delivery device.

Page A-10 Questions 38-41. Although respirators may be "reasonable" according to cited current studies, studies have not shown that masks or respirators are effective. Rather, engineering controls are critical, from the type of sealed device to the use of scavenging systems. The survey should make it clearer that cited study data supporting engineering controls take precedence over PPE. Exclusion of masks prevents a response that masks may be worn to protect the patient.

Page A-11, Question 41. "Did you wear booties to administer any of the above?" again puts more emphasis on PPE at the expense of other more effective controls. Further, there are no recommendations for booties to be used within the current OSHA Technical Manual nor in the "Guidelines for Controlling Occupational Exposure to Hazardous Drugs." (www.osha.gov/dts/osta/otm/otm_vi_2.html)

MODULE B: ANTINEOPLASTICS (PHARMACISTS, PHARMACY TECHS)

Page B-9, Questions 30-32A. These questions do not allow a response for masks, implying that they are not protective. However, the OSHA Technical Manual is clear that, as long as the worker uses a biological safety hood (an engineering control), a respirator is not required. Further, we recommend that the questions be modified to refer to the "appropriate use of respiratory protection," since many of these listed drugs are not aerosolized but rather they are liquids or tablets.

Page B-10 Question 33—Use of booties. We echo the comment identified under module A, question 41 for respiratory therapists. There are no OSHA recommendations for use of booties.

MODULE C: ANTINEOPLASTICS AGENTS ADMINISTRATION (ONCOLOGY NURSES)

This module contains no questions about respiratory protection or booties, yet many oncology nurses in clinics prepare these drugs in medication rooms and hoods and administer them directly to the patient. This again raises the question of why booties are included in other modules.

MODULE D: CHEMICAL STERILANTS

Page D-6, Question 27. STERRAD is mentioned here and used as an example of hydrogen peroxide but is not listed or used as an example in the management questionnaire or in the worker questionnaire module E. The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

Page D-7, Questions 33 and 34. This question does not permit a response involving the appropriate use of a mask. The implication is that respiratory protection of the worker is routinely required. However there are other protocols that require workers to wear masks; for example, in protocols for protecting sterile equipment. The inability to choose a mask as a response makes this question difficult to answer.

MODULE E: HIGH LEVEL DISINFECTANTS

Page E-1 and E-3 (Question 9). Why is STERRAD not listed here and used as an example of hydrogen peroxide, although it is listed in Worker Survey D? The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

Page E-3, Question 11. We recommend the addition of a third option as follows: "3. No local exhaust, but in a room with either good air dilution (six, 10, 12 air changes per hour) AND/OR a negative pressured room, in which the air is exhausted out of the room."

Pages E-7 and E-8, Questions 24-26A. These questions relate to the use of respiratory protection and do not permit a response involving the appropriate use of a mask. The implication is that a respirator is required to protect the worker from any of these chemicals, regardless of room ventilation or the use of local exhaust.

MODULE F: SURGICAL SMOKE (FROM LASERS OR ELECTROSURGERY DEVICES)

MODULE G: ANESTHETIC GASES (ADMINISTRATION)

MODULE H: ANESTHETIC GASES (BYSTANDERS WHO DO NOT ADMINISTER)

MODULE I: WASTE ANESTHETIC GASES (POST ANESTHESIA & SURGICAL RECOVERY)

(See attached citations for anesthetic gases, surgical smoke and laser plume.)

Pages F-6 to F-8, Questions 20-22A; Pages G-5 and G-6, Questions 27-29A; Pages H-4 and H-5, Questions 19-21A; and Pages I-2 and I-3, Questions 10-12A. The questions are misleading in that they do not reference any need for verifying functioning scavenger

systems or ensuring they are in good working order. While engineering controls are far more critical to worker protection, all the emphasis in this module is on respiratory protection. The questions imply that a respirator is required to protect workers from surgical/laser smoke, regardless of room ventilation or use of local exhaust. But the surgical suite is an area in which personnel would be wearing FDA-approved sterile surgical masks, worn to protect the patient, and appropriately relying on engineering controls such as scavenging system and use of filters to protect workers. OSHA, the agency that sets out regulations and guidance for worker safety, has made it clear that engineering controls and administrative/work practices are effective, and the data do not demonstrate the usefulness of respirators at this time.

MODULE J: HOUSEKEEPING OR ENVIRONMENTAL SERVICES STAFF

Page J-2, Questions 5 and 6; Page J-4, Question 12; Page J-4, Question 15. The manner in which these questions are presented is misleading. Question 5b (Safe clean-up procedures for spills of anti-cancer drugs) may be addressed in policies and procedures, but policies are likely to indicate that a spill team will do the initial clean-up and environmental services/housekeeping will only do the final clean-up. So the task in question 5b is not usually the responsibility of environmental services. For clarity, question 6 should be applied to each practice listed under question 5, since only choices (a) and (c) may apply. Policies and procedures are usually covered under training but often it indicates that a trained registered nurse, pharmacist or spill team will handle (b). We recommend that anti-cancer drugs should be included as a separate question. For question 12, we recommend that it first ask whether spills are pre-cleaned by a specialist for (a), (b), and (c). Then there should be questions asking whether they do the final cleanup after a spill of (a), (b) and (c). In question 15, we recommend that the question be asked separately for anti-cancer drugs, chemicals and bodily fluids.

Page J-3, Question 8. With regard to the list of quaternary ammonium compounds and phenols, the questionnaire should list all common brands if brand names are going to be used. Also, "oxidizers" is not a familiar term. We recommend using "low level disinfectants."

Pages J-4 and J-5, Questions 17-18. The questionnaire never asks about cleaning in locations involving biological agents, such as isolation rooms, or around patients in "contact precautions" where, in most cases, the use of masks is perfectly appropriate. This undermines confidence that masks have any value. By maintaining this position throughout the questionnaire so consistently, a systematic bias is introduced and valuable information on standard and appropriate practices is lost. The theme and implication for all modules is also that a respirator is required to protect the worker from any chemical, regardless of its concentration.

MANAGEMENT QUESTIONNAIRE

SECTION A. CORE QUESTIONS

Page 1, Question A4. The question should reference accreditation by the American Osteopathic Association (AOA) and any other organizations that have deemed status from the Centers for Medicare & Medicaid Services. Further, the question should be reworded to use the current name of The Joint Commission (TJC) and the parenthetically note "formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)."

Page 3, Question A14. The question should include options if the respondent is answering as a corporate headquarters for a multiple hospital system.

Page 12, Question A60, Respiratory Protection. In this question, masks are erroneously eliminated from consideration of respiratory protection.

SECTION B. ANTINEOPLASTIC AGENTS

Pages 15-16, Questions B8-B9A, Exposure Monitoring. These questions should be clarified as to whether the sampling/monitoring is done routinely versus as a result of spills. This blurs the difference between a standard of practice versus emphasis on prevention.

Page 16, Questions B10-B13A, Medical Surveillance. These questions should be clarified as to whether the medical surveillance is done routinely versus as a result of known exposures. For instance, they should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace (e.g., worker with shortness of breath or allergic reaction.)

Page 19, Question B27, Policies for Designated Spill Clean-Up Teams. This question appropriately refers to a spill team. This reinforces the problem in the Worker Questionnaire modules J (environmental services/housekeeping) in questions that do not ask if these staff perform a final cleanup after a spill team is engaged, resulting in a biased question for environmental services/housekeeping.

Page 20, Question B28. With regard to option (n), as in all other PPE questions, the option of surgical masks is not allowed, erroneously implying that respirators should always be used for antineoplastic agents. If NIOSH wishes to collect information on actual practice, then questions should be included regarding surgical masks.

SECTION C. AEROSOLIZED MEDICATIONS

(See attached citations on aerosolized medications)

Pages 22-23, Questions C6 and C7, Exposure Monitoring. These questions should be clarified as to whether the sampling/monitoring is done routinely versus as a result of spills. This blurs the difference between a standard of practice versus emphasis on prevention.

Pages 23-24, Questions C8-C12, Medical Surveillance. These questions imply that medical monitoring, including blood, urine and pulmonary function tests, should be done routinely for these medications. The data do not support these non-specific tests as a standard of practice for any one of these drugs. Studies have been done to determine risk but they do not include recommendations for routine medical surveillance.

Page 26, Question C14. In this question, masks are erroneously eliminated from consideration of respiratory protection.

SECTION D. GLUTARALDEHYDE AND OTHER HIGH LEVEL DISINFECTANTS (HLD)

STERRAD is not listed as an example of hydrogen peroxide in this section, although it is listed elsewhere in the Worker Survey D. The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

Page 27, Question D7. This question implies an expectation that air sampling should be done for all HLDs, whether or not engineering controls are in place (e.g., local exhaust). In addition, there are no questions on ensuring whether engineering controls are functioning properly.

Page 28, Questions D9-12A, Medical Surveillance. This question inaccurately implies that routine medical surveillance of workers, including pulmonary function or allergy sensitization testing, is a standard of practice. For instance, they should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to glutaraldehyde in the workplace (e.g., worker with shortness of breath or allergic reaction).

Page 32, Question D27(h), Policies for PPE. We reiterate our concern here that masks are not considered as PPE. This does not permit a response for practices that could legitimately involve the use of a mask. The implication is that respiratory protection of the worker is routinely required versus the wearing of a mask by the worker to protect the sterile equipment, as required by other protocols. This makes a response to this question difficult.

SECTION E. CHEMICAL STERILANTS

Pages 35 and 36, Questions E10-13A, Medical Surveillance. These questions inaccurately imply that routine medical surveillance is a standard of practice. Also, we do not understand why non-specific "blood tests" are listed. Instead, the question should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to ethylene oxide in the workplace.

Page 38, Question E21, PPE. We are concerned that, in this question, masks are not considered as PPE for exposure to any sterilants, posing potential confusion for respondents. Standard practice is mandatory and rigid engineering controls (e.g., for ethylene oxide) are required. Workers in these areas wear surgical masks to protect sterile equipment being processed, and this question makes it impossible to reflect actual practice, even if for other purposes.

SECTION F. ANESTHETIC GASES

(See attached citations for anesthetic gases, surgical smoke, laser plume.)

Page 42, Question F7 -F8A, Air Sampling. This question implies that routine air sampling should be conducted even though engineering controls are expected to be in place per other rules and regulations. The questionnaire never asks about whether engineering controls are working. Questions could address whether sampling is done to maintain environmental quality control with indirect impact on patients as well as workers.

Page 44, Questions F9-F12A, Medical Surveillance. This question inaccurately implies that routine medical surveillance is a standard of practice. Instead, it should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace.

Page 45, Question F14, PPE. We are concerned that masks are not considered part of PPE for exposure to any anesthetic, regardless of scavenging system. Further, with regard to OSHA recommendations for Waste Anesthetic gases, the only time respirators are considered is for spills. There are no questions in this questionnaire regarding PPE, including respiratory protection, during spills.

SECTION G. SURGICAL SMOKE

(See attached citations on anesthetic gases, surgical smoke, laser plume.)

Pages 46-47, Questions G4-G5A and G7, Air Sampling. This question implies that routine air sampling should be conducted even though engineering controls are expected to be in place per other rules and regulations. However, we are pleased that at least one engineering control is addressed; in question G7, where the question is whether smoke evacuation systems are inspected to prevent leaks.

Page 48, Question G9, PPE. We are concerned that in this question masks are not considered as PPE for exposure to smoke, posing potential confusion for respondents. Given the importance of scavenger system and use of FDA-approved sterile surgical masks for surgical procedures, this does not permit response that reflects actual practice in surgical procedures.

SECTION H. SPILL RESPONSE TEAM AND HOUSEKEEPING

Page 49, Questions H2-H5. We support the use of these questions, as we do in Section B, Antineoplastics. This appropriately refers to a spill team, but again this reinforces the problem in the Worker Questionnaire modules J (environmental services/housekeeping) in questions that do not ask if these staff perform a final cleanup after a spill team is engaged, resulting in a biased question for environmental services/housekeeping.

Page 50, Question H7, PPE. This question does not ask about cleaning in locations involving biological agents, such as isolation rooms or around patients in "contact precautions" where, in most cases, the use of masks is perfectly appropriate. This undermines confidence that masks have any value. This introduces a systematic bias and the loss of valuable information on standard and appropriate practices. The theme and implication here, as elsewhere in these surveys, is that a respirator is required to protect the worker from any chemical, regardless of its concentration.

Attachment 2

ANNOTATED CITATIONS

Back Belt

1. Martimo, KP, Verbeek J, Karppinen J, Furlan AD, Takala EP, Paul P, Kuijer FM, Jauhiainen M, Viikari-Juntura E. **Effect of training and lifting equipment for preventing back pain in lifting and handling: systematic review** *BMJ* 2008; 336;429-431; originally published online 31 Jan 2008.
Conclusion: There is no evidence to support use of advice or training in working techniques with or without lifting equipment for preventing back pain or consequent disability. The findings challenge current widespread practice of advising workers on correct lifting technique.
2. Martimo KP, Verbeek J, Karppinen J, Furlan AD, Kuijer PP, Viikari-Juntura E, Takala EP, Jauhiainen M. **Manual material handling advice and assistive devices for preventing and treating back pain in workers** *Cochrane Database Syst Rev.* 2007 Jul 18;(3):CD005958.
Conclusion: There is no evidence available from RCTs for the effectiveness of manual material handling advice and training or manual material handling assistive devices for treating back pain.
3. Ammendolia C, Kerr MS, Bombardier C. **Back belt use for prevention of occupational low back pain: a systematic review.** *J Manipulative Physiol Ther.* 2005 Feb;28(2):128-34.
Conclusion: Currently, because of conflicting evidence and the absence of high-quality trials, there is no conclusive evidence to support back belt use to prevent or reduce lost time from occupational low back pain.
4. Anon, **Recommendation statement from the Canadian Task Force on Preventive Health Care: Use of back belts to prevent occupational low-back pain,** *CMAJ,* 2003, Aug. 5, 2003; 169 (3).
Recommendation: The Canadian Task Force on Preventive Health Care concludes that the existing evidence is conflicting and does not allow the task force to make a recommendation for or against the use of back belts to either prevent occupational low-back pain or to reduce lost work time due to occupational low-back pain (Grade C recommendation).
5. Wassell JT, Gardner LI; Douglas, Landsittel P; et al. **A Prospective Study of Back Belts for Prevention of Back Pain and Injury** *JAMA.* 2000; 84(21):2727-2732
Conclusion: In the largest prospective cohort study of back belt use, adjusted for multiple individual risk factors, neither frequent back belt use nor a store policy

that required belt use was associated with reduced incidence of back injury claims or low back pain.

6. NIOSH Press Release – JAMA 2000 study.

Conclusion: In the largest study of its kind ever conducted, the CDC's NIOSH found no evidence that back belts reduce back injury or back pain for retail workers who lift or move merchandise, according to results published today in the *Journal of the American Medical Association (JAMA)* Dec. 6 2000 issue.

7. NIOSH- Back Belts Do They Prevent Injury? 1996 (online reviewed 1997) Pamphlet.

Conclusion: There is a lack of scientific evidence that back belts work. Workers wearing back belts may attempt to lift more weight than they would have without a belt. A false sense of security may subject workers to greater risk of injury.

Aerosolized Medication

1. Dimich-Ward H, Wymer ML, Chan-Yeung M. Respiratory health survey of respiratory therapists. *Chest* 2004;126:1048–1053 (full document).

Conclusion: The lowest ribavirin levels were measured when an additional aerosol containment tent was used or when ribavirin was administered through a ventilator, which is a closed system. On the other hand, reporting the use of a small particle aerosol delivery or ribavirin unit, which is exclusively used for ribavirin, was not associated with reported asthma or respiratory symptoms. If the ribavirin units had aerosol containment systems, this would be effective in reducing occupational exposures.

2. Prober CG, MD; Walson PD, MD; Jones J. and the Committee on Infectious Diseases and Committee on Drugs **Technical Report: Precautions Regarding the Use of Aerosolized Antibiotics December.** *PEDIATRICS* 2000 Vol. 106 No. 6 December 2000.

Recommendation 8: To minimize microbial contamination of nebulizer equipment, centers should develop policies for aerosolized antibiotic use in the home, clinic, and inpatient facility. Such a policy should address barrier techniques, filters, exhaust, environmental contamination, disposal of unused product, and cleaning of nebulizers.

3. Shults RA, Baron S, Decker J, Deitchman SD, Connor JD. Health care worker exposure to aerosolized ribavirin: biological and air monitoring. Occup Environ Med. 1996 Mar;38(3):257-63. NIOSH.

Recommendation: Ventilators and other administration units that were enclosed by an aerosol containment tent produced significantly lower airborne ribavirin exposures than administration units without a containment tent did (range, < 2.5 to 78 micrograms/m³). *On the basis of this and other evaluations of airborne*

ribavirin concentrations, we recommend using aerosol containment systems with all types of ribavirin administration units except mechanical ventilators.

4. Mueller BA, Waldon VK. **Use of an in-house-built ribavirin aerosol evacuation system to control incidental employee exposure to ribavirin aerosol.** *J Clin Eng.* 1996 Jan-Feb;21(1):46-50.
- Conclusion:** Ongoing controversy regarding the hazards of exposure of healthcare workers to ribavirin aerosol led to the design and evaluation of a ribavirin aerosol evacuation system that scavenges the excess ribavirin. The results suggest that the system evaluated is an efficient and inexpensive means of reducing incidental employee exposure to ribavirin aerosol.
5. Balmes JR, Estacio PL, Quinlan P, Kelly T, Corkery K, Blanc P. **Respiratory effects of occupational exposure to aerosolized pentamidine.** *J Occup Environ Med.* 1995 Feb;37(2):145-50.
- Conclusion:** Pentamidine was not detected in the urine of any of the subjects. There were no significant increases in symptoms on days when AP was administered. There was no statistically significant difference in mean diurnal variation of peak expiratory flow rate on days when AP was administered. Methacholine inhalation challenge testing did not show a statistically significant mean change in airway responsiveness across the workweek. The ambient concentrations of pentamidine that we measured document that detectable occupational exposure to AP can occur in poorly ventilated treatment rooms. *We recommend that steps be taken to minimize health care worker exposure to AP.*
6. AARC Clinical Practice Guideline-Selection of a Device for Delivery of Aerosol to the Lung Parenchyma *Respir Care* 1994; 41(7):647-653.

Protocol Because the data regarding adverse health effects on the health-care worker and on those casually exposed are incomplete, the prudent course is to minimize exposure in all situations.(26).

Measures to reduce aerosol contamination of room air include:

- 6.5.2.1.1 discontinuing nebulization of medication while patient is not breathing the aerosol;
 - 6.5.2.1.2 ensuring that staff who administer medications understand risks inherent with the medication and procedures for safely disposing of hazardous wastes;
 - 6.5.2.1.3 screening of staff for adverse effects of exposure to aerosol medication;
 - 6.5.2.1.4 providing alternative assignments for those staff who are at high risk of adverse effects from exposure (eg, pregnant women or those with demonstrated sensitivity to the specific agent).
- 6.5.2.2 *Engineering controls:*
- 6.5.2.2.1 **Filters or filtered scavenger systems to remove aerosols that cannot be contained.**

6.5.2.2.2 Frequent air exchanges to dilute concentration of aerosol in room to eliminate 99% of aerosol before the next patient enters/ receives treatment in area.

6.5.2.2.3 Booths or stalls for sputum induction and aerosolized medication administration in areas in which multiple patients are treated. Booths or stalls should be designed to provide adequate air flow to draw aerosol and droplet nuclei from the patient and into an appropriate filtration system, with exhaust directed to an appropriate outside vent.

6.5.2.2.4 Handling of filters, nebulizers, and other contaminated components of the aerosol delivery system used with suspect agents (such as pentamidine and ribavirin) as hazardous waste.

6.5.2.3 Personal protection devices:

6.5.2.3.1 Personal protection devices should be used to reduce exposure *when engineering alternatives are not in place or are not adequate*. Use properly fitted respirators with adequate filtration *when exhaust flow cannot adequately remove aerosol particles.* (28)

6.5.2.3.2 Goggles, gloves, and gowns should be used as splatter shields and to reduce exposure to medication residues and body substances.

7. Kacmarek RM, Kratochvil J. **Evaluation of a double-enclosure double-vacuum unit scavenging system for ribavirin administration.** *Respir Care.* 1992 Jan;37(1):37-45.

Conclusions: Use of a double-enclosure, double-pump scavenging system and implementation of entry protocols ensure reduction of environmental ribavirin levels below recommended maximum levels during administration to spontaneously breathing patients. Use of expiratory filters adequately controls environmental ribavirin levels during mechanical ventilation.

8. Kacmarek RM **Care-giver protection from exposure to aerosolized pharmacologic agents Is it necessary?** *Chest* 1991;100:1104-1105 (full publication).

Conclusion: Pentamidine should be administered in a negative-pressure HFPA-filtered room with at least six exchanges per hour or with use of a booth or hood designed for scavenging the drug. Nebulizers should incorporate a hand control for aerosol production and exhalation filters.

9. Torres A Jr, Krilov LR, Jacobson JM, Kelly KJ, Havens PL. **Reduced environmental exposure to aerosolized ribavirin using a simple containment system.** *Pediatr Infect Dis J.* 1991 Mar;10(3):217-21.

Conclusion: To minimize the exposure of health care workers to aerosolized ribavirin, we designed a double tent containment system with circulating mist and suction applied between the tents and we evaluated the ability of this system to contain and evacuate aerosolized ribavirin. Though the risk to exposed health care workers is unknown, this system offers a simple way to decrease significantly occupational exposure to ribavirin.

10. Bradley JS Connor JD, Compogiannis LS, Eiger LL, **Exposure of Health Care Workers to Ribavirin during Therapy for Respiratory Syncytial Virus Infections, *Antimicrobial Agents and Chemotherapy, Apr. 1990***, p. 668-670 Vol. 34, No. 4 (Full publication).

Conclusion: These data confirm, in a clinical setting, that ribavirin concentrations in room air can be substantially lowered when the delivery of aerosol is accompanied by a system designed to remove and filter the aerosol during treatment. However, such devices may prove to be more effective if education for HCW includes specific instructions to stop the nebulizing airflow prior to opening the hood.

11. Montgomery AB, Corkery KJ, Brunette ER, Leoung GS, Waskin H, Debs RJ **Occupational exposure to aerosolized pentamidine. *Chest. 1990*** Aug;98(2):386-8.

Conclusion: The greater risk to health care workers is probably transmission of tuberculosis from undiagnosed cases, especially in populations with an increased incidence of tuberculosis.

12. Rodriguez WJ, Dang Bui RH, Connor JD, Kim HW, Brandt CD, Parrott RH, Burch B, Mace J. **Environmental Exposure of Primary Care Personnel to Ribavirin Aerosol When Supervising Treatment of Infants with Respiratory Syncytial Virus Infections** *ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, July 1987*, Vol. 31, No. 7 p. 1143-1146 (full publication).

Conclusion: The absence of detectable ribavirin in the erythrocytes of nurses participating in the study is reassuring. However, these negative data must be interpreted within their limitations. Finding neither detectable levels nor side effects with the sample size provides an approximate 84% probability of deriving the right conclusion. These data rule out any long-run risk rate higher than 16%, with 95% confidence or 5% limit of credibility (8). We should also note that the air exchange rates at the two institutions studied could have contributed to optimal environmental conditions. These factors should also be considered by those engaged in administering aerosol therapy.

13. OSHA Technical Manual for "Controlling Occupational Exposure to Hazardous Drugs. (www.osha.gov/dts/osta/otm/otm_vi_2.html)

Anesthetic Gases; Surgical Smoke; Laser Plume (laser or electro-surgical unit).

1. Alp E, Bijl D, Bleichrodt R, Hansson B, A, Voss. **Surgical smoke and infection control. *Journal of Hospital Infection, 2006*** Volume 62, Issue 1, Pages 1 - 5 E. (Full publication).

Conclusion: While higher quality filter masks and/or double masking may increase the filtration capability, a smoke evacuation device or filter placed near (2-5cm) the electrocautery blade or on endoscope valves offers additional (and necessary) safety for operating personnel and patients. Various studies demonstrated that specially designed masks (respirators) are still insufficient

barriers. Furthermore, leakage of the mask's seal to the face is another source of possible penetration. No studies have measured the effectiveness of these respirators. The degree to which they protect individuals from surgical smoke is not known and varies depending on the filtering efficiency of the different respirators.

2. OSHA Directorate for Technical Support; *Office of Science and Technical Assessment Anesthetic Gases: Guidelines for Workplace Exposures, 2000* Revised May 18, 2000.

Engineering controls such as an appropriate anesthetic gas scavenging system are the first line of defense and the preferred method of control to protect employees from exposure to anesthetic gases. An effective anesthetic gas scavenging system traps waste gases at the site of overflow from the breathing circuit and disposes of these gases to the outside atmosphere. HVAC system also contributes to the dilution and removal of waste gases not collected by the scavenging system or from other sources such as leaks in the anesthetic apparatus or improper work practices.

Administrative controls represent another approach for reducing worker exposure to waste gases other than through the use of engineering controls, work practices, or personal protective equipment.

Personal protective equipment should not be used as a substitute for engineering, work practice, and/or administrative controls in anesthetizing locations and PACUs. During clean-up and containment of spills of liquid anesthetic agents, personal protective equipment should be used in conjunction with engineering, work practice, and/or administrative controls. *Respirators, where needed, should be selected based on the anticipated contamination level.*

Operating Room. As a result of using appropriate anesthetic gas scavenging in ORs, the levels of contamination have been decreased.

PACU. A properly designed and operating dilution ventilation system should be relied upon to minimize waste anesthetic gas concentrations.

3. OSHA Hospital eTool-Surgical Suite Module,
www.osha.gov/SLTC/etools/hospital/index.html.

Anesthetic Gases: Recommendations Use appropriate anesthetic gas scavenging systems in Operating Rooms. Appropriate waste gas evacuation involves collecting and removing waste gases, detecting and correcting leaks, considering work practices, and effectively ventilating the room (Dorsch and Dorsch 1994).

4. OSHA Hospital eTool-Surgical Suite Module,
www.osha.gov/SLTC/etools/hospital/index.html.

- **Laser smoke:** During surgical procedures that use a laser or electro-surgical unit, the thermal destruction of tissue creates a smoke byproduct *Although there has been no documented transmission of infectious disease through surgical smoke*, the potential for generating infectious viral fragments, particularly following treatment of venereal warts, may exist.
- **Recommendation engineering controls and work practices:** *Use portable smoke evacuators and room suction systems. Install new filters and tubing before each procedure. Inspect smoke evacuator systems regularly to prevent possible leaks.* Use Universal Precautions as required by the OSHA Bloodborne Pathogens Standard [1910.1030(d)(1)].