

Cal/OSHA Advisory Meeting
Occupational Exposure to Antineoplastic Drugs

Wednesday, October 28, 2015

10:00 a.m. – 3:45 p.m.

Oakland, California

Division Staff: Eric Berg, Steve Smith, Grace Delizo, Bob Nakamura, Valerie Royo

Meeting Attendees

<u>Name</u>	<u>Affiliation</u>
Ed Ochi	San Francisco General Hospital
Vickie Wells	San Francisco Department of Public Health
Mary Kochie, RN	Cal/OSHA Medical Unit
Sue Downing	Diplomate ACVIM Oncology
Kaila Benton-Vitz	UC Davis Medical Center
Deborah Bolton	HCA Good Samaritan
Benjamin Moskoff	UC Davis Medical Center
Greg Hurner	Carpenter Sievers
Katalin Olah, RN	Marshall Medical – Hematology/Oncology
Robert Kosnik	UC San Francisco
Brad Ekstrand	Association of Northern California Oncologists
Kathy Hughes	SEIU 121 RN
David Kernazitskas	Occupational Safety and Health Standards Board (OSHSB)
Kathy Pang	San Francisco General Hospital
Tracie Kirtz	ICU Medical, Inc
Catherine Jansen	Kaiser Permanente
Matt Carlson	UC San Francisco Medical Center
DeAnn McEwn, RN MSN	California Nurses Association
Jocelyn Tom	UC San Francisco
Steve Derman	Medishare, CIHC
Michele Knudson	Solano Hematology Oncology
Luci Power	Power Enterprises
Shelley Carry	Kaiser Permanente
John Griffith	McKesson Specialty Health
BJ Bartleson	California Hospital Association
Andrea Iannucci	UC Davis Medical Center
Tanja Monroe	UC Davis Medical Center
Kristie Elton	UC Office of the President
Jane Schroeder	California Nurses Association
Piera Wong	San Francisco General Hospital
Angeles G. Price	Kaiser Vallejo
Fred Noteware	
Cheryll Willin	Cancer Center of Santa Barbara
Kate Durand	San Francisco Department of Public Health – Laguna Honda Hospital
John Benton	
Jennifer McNary	California Department of Public Health
Tina Beam	Solano Hem/Onc
Corbin Bennett	Kaiser Permanente
Janice Dang	California State Board of Pharmacy

Welcome and Introductions by Bob Nakamura

This is the second meeting for advisory purposes on AB 1202 that requires the Standards Board to adopt a new regulation on incorporating NIOSH's antineoplastic drugs document. We are determining how to do that while creating a workable regulation. We would like assistance on specific issues as we go through them. We are trying to make our regulation consistent with other things that are happening concurrently. For example, the Board of Pharmacy is in the process of having advisory meetings as well, and we have to be aware of those as we don't want to create something that conflicts. We are also aware that many of you have to operate under United States Pharmacopeia (USP) standards, and that the USP 800 is about ready to go. Does anyone have any updates on that?

Luci Power: I am an expert panel member for USP 800. Unofficially what we've heard was that the electronic ballot had gone out to the entire expert committee, and USP 800 did pass.

Summary of the meeting on June 17, 2014 by Grace Delizo

Last meeting was on June 17 2014, and we were fortunate to have Dr. Connor, author of the NIOSH Alert and its updates and USP 800 expert panel member, present to our group. At the time of the presentation, the NIOSH 2014 List of Antineoplastic and Other Hazardous Drugs was in the process of being updated.

Since then, the 2014 list has come out, which has a table of suggested controls for different forms of drugs that we have used and incorporated into our draft. We added the list to the appendix. The table is also being updated as well for 2016, and it will get updated every couple of years.

We covered AB 1202 as well as the Labor Code which gives us the edict to come up with a standard that is consistent with but does not exceed the recommendations in the NIOSH Alert and its updates.

We discussed the type of program elements that we would like to see in the standard: inventory of antineoplastic drugs, hazard assessment, policy and procedures, training, and recordkeeping. These are all typical elements. We also had a discussion of NIOSH's detailed recommendations.

Rulemaking Process by Steve Smith

For those who may not be familiar with how we develop a regulation, there is a flowchart which depicts steps of typical rulemaking in the state of California. All agencies follow this process to develop regulations, and we are no different. We focus many activities upfront in the preliminary activities stage of rulemaking.

The advisory committee meeting process that we are going through is part of pre-rulemaking. The first box in the chart is the reasons why we are going into rulemaking. This particular regulation is because of legislation, AB 1202, which was enacted in 2013 which required the Standards Board to adopt a regulation. In order to do that, we wanted to solicit advice. That's why we have advisory committee meetings, and the first was held last year in 2014 as Grace has summarized. The minutes of that meeting are on the webpage along with the preliminary documents that we talked about at the meeting. Also included is the NIOSH guide link to that. The AB 1202 link is also available on our webpage.

After this advisory committee meeting, we will determine if there will be another meeting, and we will have a revised draft for that meeting. If we feel we are ready to move forward with rulemaking, our next step is then to draft supporting documents that go with the draft proposal, such as the Notice of proposed rulemaking, Initial Statement of Reasons, and also the impacts of the proposal. This is why it is important for us to get advice upfront of why some requirements are necessary or not necessary.

Once these documents are developed with the final draft proposal, we go to formal rulemaking, which is handled by the Standards Board. The Agency will issue a notice and hold the public hearing on this proposal. At that time, there will be another opportunity to provide formal comments with a 45-day comment period and a public hearing.

We will then consider the formal comments, finalize the proposal, and adopt the proposal. This flowchart goes through all the various options.

Discussion of the Draft Language by subsection by the meeting chairs

Scope & Application

Grace Delizo: The draft proposal is a 17-page document, and it is one of three handouts available. The scope states that this section applies to all healthcare settings where employees have an occupational exposure to antineoplastic drugs. "Healthcare settings" is defined in the Definitions section. Health care settings include pharmacies, hospitals, other healthcare institutions, patient treatment clinics, physicians' practices facilities, or veterinarians' offices where antineoplastic drugs are handled. The NIOSH Alert when published in 2004 addressed workers in healthcare settings, veterinary medicine, research labs, retail pharmacies, and home health care agencies. It specifically stated that it does not apply to workers in the drug manufacturing sector.

Questions/Comments:

Vickie Wells, City and County of San Francisco Department of Public Health: Do you intend the standard to apply to health care settings where the only exposure is distribution of oral (tablet or capsule, not liquid) antineoplastic drugs? This could be an issue in the future, particularly in jails.

Grace Delizo: If it is in the final dosage form, the guidance from the NIOSH chart was to dispense those with a pair of chemo gloves. What we found with tablets for those with trouble swallowing is that they crush them. Even coated tablets vary in their consistency so you might still have exposure dermally.

Vickie Wells: We need to be clear whether you're going to require facilities that only handle oral tablets and doesn't crush them, to adhere to all the requirements in this section.

Grace Delizo: We have not excluded that application.

Steve Smith: As we get into the control methods, there are varying amounts of controls depending on amount of handling and exposure.

Vickie Wells: We need to consider that some facilities fall into that category.

Debbie Bolton, HCA Good Samaritan: Regarding the discussion oral agents that might be cut or crushed: That is something that is not supposed to be done, so that needs to be considered as well.

Bob Kosnik, UCSF: What about the definition of home health care? The definition of a plan becomes a problem. Is it a plan for home health care or is it a plan for a home? How do you define the workplace for home health care? The definition needs clarification.

Steve Smith: The plan is meant for the institution that is sending that worker to that home.

Ed Ochi, San Francisco General Hospital: I do want to point out that home health care or jails, the standard will impact the people administrating the drugs, and also the different population taking care of those patients for 48 hours afterward. There isn't necessarily the same employer as those administrating the drugs. You need to plan for that scope of coverage.

Kathy Hughes, SEIU: We represent nurses in home health as well as those in the correctional facilities settings. I propose that within home health care, it would be the home health agency that is responsible for having plans and procedures in place. Obviously, there should also be patient education that goes along with that. They are already administering these drugs in the home and don't always do it with the full precautions. I've asked nurses at conferences how they distribute these, do they mix these at bedside and an alarming number raise their hands. I think home health, labs, and corrections should be spelled out and listed so that it's clear to everyone that they're not excluded, and that there are different control measures depending on the type of facility. Something needs to be in place to protect these workers.

Ed Ochi: If that approach is taken, you would need to add a hazard communication element similar to the aerosol transmissible diseases standard where you need to notify because you will have multiple employers dealing with the same care but different administration, depending on the drugs that are being administered within 48 hours or 7 days. It will not be the same people or same employer.

Bob Nakamura: We taking an operational approach to this, so these comments are very helpful in identifying the situations that we have to consider with this standard.

Shelley Carry, Kaiser Permanente: This seems to be regarding health care settings around the treatment of the patient, but we also happen to have distribution centers for drugs and automated refill centers. Would those be

included in the definition of a health care setting? These are not pharmacies but locations where drugs come into a distribution center and then distributed out, like a FedEx. There are boxes of drugs.

Bob Nakamura: In the last meeting, we heard of incidents where deliveries were damaged and workers were exposed when handling them. So we would include those. They would be covered, but we are not saying that we are going to have one program that applies to everybody.

Steve Smith: The standard is based on exposure. Are employees of distribution centers exposed in any way?

Shelley Carry: In some instances, drugs are delivered from the manufacturer to a distribution center, and what employees do is break down the boxes. The drugs are still actually in the boxes from the manufacturer, and these drugs are being sent out by carrier transport to our facilities, to our clinics, and to our hospitals. So these facilities aren't even connected to the hospitals. They are separate distribution centers, like warehouses. The definition seems to be very treatment centered or hospital- or clinic-centered. We are just seeking clarification to see if this standard extends beyond the campus of a hospital or clinic to a separate kind of facility that may not even have the same business classification code as a health care facility.

Janice Dang, Board of Pharmacy: What you are describing as a distribution center is what we would define as a wholesaler, so the question is: are we applying this the same way to a wholesaler.

Bob Nakamura: We are looking at this from the standpoint of occupational exposure, so distribution centers might at least need to have an emergency plan, how to clean up and who to contact to do it safely.

Debbie Bolton: There has been evidence-based research that indicates that products coming from the manufacturer and their packaging have been contaminated. So they're not clean (boxes) as you would think, so there does need to be something in place.

Cheryll Willin, Cancer Center of Santa Barbara: I have heard several times that this is based on exposure, but my understanding that this is based on the potential for exposure.

Bob Nakamura: The language we use is occupational exposure, but that includes the potential for exposure.

David Kernazitskas, Occupational Safety and Health Standards Board: Would it helpful to add a definition for exposure? Is there a threshold?

Steve Smith: We have included it under Definitions under O.

Kathy Pang, Clinical Pharmacist, San Francisco General Hospital: Antineoplastic drugs is a fairly broad category, and even in the NIOSH list, there are cytotoxic drugs that have been historically handled with extra care as well as targeted agents that are arguably less toxic or are hormonal manipulations. It is interesting that this covers both categories.

Bob Nakamura: We have to go by what NIOSH categorizes as antineoplastic drugs.

Steve Smith: There are more risks with certain drugs than others, and certain routes of exposures will be different. This is something that you would have to address in your planning, which we will get to. Just because a drug is on the list doesn't mean it's all equal. Levels of exposure and levels of risk have to be addressed.

Debbie Bolton: Within that context, you have to also include the employee, and that's where the variability is. You may have some level of risk related to a drug, but the one you don't have control over is the immunocompetence of the employee whether in an acute situation or over time.

Luci Power: If you have looked at USP 800 or NIOSH, the new designation is hazardous drugs and not antineoplastics. AB 1202 is specifically for antineoplastic drugs, not hazardous drugs. The purpose of this regulation of this designation should only be antineoplastic drugs. It becomes very difficult when you use a very broad list of drugs that are hazardous. Nobody is going to be happy with the list.

Andrea Iannucci, UC Davis Medical Center: Perhaps if an institution does develop their own hazardous guidelines within their own facilities that is more drug-specific, but may be different from NIOSH, would that be supported by this legislation?

Steve Smith: This is getting into the discussion of plans and control methods and how that affects various drugs and handling, so we will get to that question later.

Bob Kosnik: The language says "kills cancer cells." Does this refer to leukemic or anti-leukemic agents which, depending on solid or liquid tumor, may be considered cancer or not.

Luci Power: If you look at the general, broad list of the American Hospital Formulary Service, it says 10.00 equals antineoplastic agent. It might be best to use that. That could be how you narrow down the list.

Grace Delizo: There is a note that I wanted to point out under Scope & Application. This new section will not preclude the application of other regulations that we have, such as 3203 Injury and Illness Prevention Program or other orders. This regulation will cover antineoplastic drugs. Other non-antineoplastic hazardous drugs will be covered by our existing regulations.

Sue Downing, Diplomat ACVTM Oncology: Knowing that the NIOSH list is forever going to be updated, there are some drugs that aren't currently on this list that should be. There are certain drugs we use for dogs that aren't on this list.

Bob Nakamura: So there is a separate FDA review process?

Sue Downing: They are FDA approved for dogs, and it is a separate process than for humans.

Janice Dang: You would find all the FDA-approved human drugs in the "orange" book, and all the FDA-approved veterinary drugs in the "green" book. They still both go through an approval process, but veterinary drugs are not classified the same way as the ones for humans. Animal drugs are also very specific to the species of the animal. There are some drugs that appear in both books, but there are more drugs in the "green" book that are not fit for humans because they have higher toxicity for humans.

Definitions

Grace Delizo: Reviewed the antineoplastic drugs definition, we took the 2014 NIOSH list as we've mentioned and added that as Appendix A. Are there any comments on that?

Questions/Comments:

Debbie Bolton: Could the definition of cancer pathways be included in the Definitions? There is a whole line of agents that control and/or interfere with cancer cells.

Grace Delizo: As we go through the Definitions as well as the rest of the regulation, we have to be mindful that we are still bound to AB 1202 and must limit our regulation the NIOSH alert, updates, and guidance. That was the challenging part of doing this.

DeAnn McEwn, California Nurses Association: A lot of antineoplastic drugs are used clinically and not in acute care settings and in outpatient clinics to treat other conditions that are not defined as cancer. There should be consideration for the fact that hospitals need a plan for antineoplastic drug use for conditions that are not cancer in other units. There also has to be a workplace hazard analysis, proper personal protective equipment for other staff where the administration equipment needs to be kept and/or properly disposed of.

Janice Dang: The definition of "hazardous drug" is different from how we define it. They are antineoplastic, and we also allow the pharmacist-in-charge to also determine if it's hazardous.

Grace Delizo: Our definition was taken directly from the NIOSH definition.

Bob Kosnik: "Reasonably" is troublesome in the definition of "occupational exposure" to antineoplastic drugs. Is there any way to use a more specific word than "reasonably?" The ATD standard is more specific as they use "above-average."

Steve Smith: We will take a look into the ATD standard to see if it has better wording, and if there is language that you feel is better to use, please let us know. We use the same terminology that is used in other Title 8 regulations, which may not be as familiar to other agencies.

Bob Nakamura: In the ATD standard, we had to make a distinction between the general public and actual occupations with higher expectations of being exposed to diseases. Here, we are talking only of a select group of occupations that are dealing specifically with antineoplastic agents, and we are approaching this from the standpoint that it is expected who are handling these drugs and what they should be doing.

Kathy Hughes: A nursing assistant who does linen changes with patients receiving cancer treatment, but who doesn't mix or handle the medications, are still reasonably exposed. I like the language "reasonably anticipated." It is not always just a pharmacist handling these drugs or being exposed, and workers need to be protected knowing that there is exposure in those settings. When you are working within that healthcare setting, you can be "reasonably exposed."

Steve Smith: The NIOSH guide that we are trying to be consistent with uses "may be exposed."

Shelley Carry: In industrial hygiene, duration of exposure, volume, frequency, the time, etc. are all looked at when figuring out what is reasonable exposure.

Luci Power: I think this is an issue we won't solve at this time. There is a group from Canada and British Columbia that was doing a great deal of research on actual exposure and defined 8 categories of exposure. The person who was most exposed in their study by urine sample and wipe sampling of the work area was the unit secretary. The dirtiest thing they found was the box cutter in the receiving area. There really isn't a good handle on who is exposed or who is reasonably exposed, but there is a need to be as vague as possible at this time because there is more research being done.

Bob Kosnik Regarding the definition of "supplemental engineering control," the language of the text includes secondary engineering controls, but there is no definition for that.

Grace Delizo: Thank you. We have language for containment primary engineering controls (C-PEC), but we didn't see in the NIOSH guide or its updates any specific language pertaining to containment secondary engineering controls (C-SEC, i.e. the room). Instead of having the C-PEC definition we can just refer to the biosafety cabinet or isolators.

Steve Smith: When we get into Control Methods, we may want to get into the discussion then.

Jennifer McNary, Occupational Health Branch, CDPH: If antineoplastic drugs are approved to be administered via aerosol, wouldn't a containment device fall under that?

Grace Delizo: It hasn't been discussed in the current guidance.

Luci Power: There are several documents available that discuss different definitions. Cal/OSHA should put a blanket statement addressing the fact that other documents are continuing to be updated. She completed the engineering control section of the new alert and submitted the third version to NIOSH. Previous versions looked too much like USP and she was told the NIOSH version can't look like USP. This will be a problem for writing regulations based on two documents that don't want to look like each other.

Janice Dang: In the Pharmacy Board regulations, we do not define secondary. We use "clean room" versus "clean area" versus "buffer area."

Grace Delizo: Are there other definitions that we need to add to this section?

Ed Ochi: In the draft standard, "large spill" is used several times, but there is no definition on how to identify what a large spill is. A "spill that exceeds capacity of a spill kit" is a flaky definition. You not only have to take into consideration the volume, but also the concentration of the material. You can also look at the time clock response measurement, but you would also have to take into consideration of when that time clock response starts.

Kathy Pang, San Francisco General Hospital: A secondary engineering control is more of a protection for patients receiving sterile products than it is protection for employees or workers.

Antineoplastic drugs safety and health plan (Plan)

Bob Nakamura: We will discuss the basic approach to control measures, and I'll preface by reviewing 3203, the Injury and Illness Prevention Program (IIPP). California requires that every employer has a plan to identify safety and health problems in the workplace and take appropriate precautions to protect their employees.

This includes control measures like ventilation, personal protective equipment (PPE), etc that will control the exposure or correct safety hazards. This also means providing training for employees so that they are aware of how to do what they have to do.

AB 1202 frames the requirements to use the approach of the IIPP. This has happened in several other regulations like workplace violence and safe patient handling. What that means is the framework of this proposed regulation is reflective of 3203.

When an employer has employees exposed to antineoplastic drugs, the employer has to identify who does it, what the drugs are, and the appropriate control measures. The first step is to have a plan, which most of you already have, but make part of the plan that will cover antineoplastic drugs. This is not a new concept.

We had issues during our first meeting of inventory where an employer has to identify the antineoplastic drugs in their inventory.

The employer also must do a hazard assessment which includes various elements, like identification of units, job

classifications, task and procedures, engineering work practice controls, PPE, and what they should be doing and how this is going to work out. This requires that what we have lately is that to ensure employees in these units that they're involved in making assessment with management.

Questions/Comments

Janice Dang: How is "unit" defined?

Bob Nakamura: A unit is essentially a work unit. The problem is everyone defines that differently. It could be based on specific operations or procedures or based on a work activity, like a pharmacy versus the shipping industry. We're talking about a unit in those terms.

Janice Dang: Do you mean like the primary work environment?

Bob Nakamura: We generally use the word "unit" in all of our health care regulations, and everyone seemed to be fine with it.

Vickie Wells: This works well in the hospital setting, but you may want to broaden it when you consider other health care settings.

Bob Nakamura: We appreciate any suggestions on the language.

Cheryll Willin: It sounds like "unit" refers to location, because the next part in the language says operations, so it could be interpreted as a location or environment and what happens there.

Kathy Hughes: I'm a little confused. When you refer to assessment by employees, do you mean hazard assessment? Employees would be part of that?

Bob Nakamura: Yes.

Kathy Hughes: The employees would have input on effectiveness of the controls?

Bob Nakamura: They could identify what things work and which things don't.

Kathy Hughes: In other regulations, it will say that the employees are part of developing the plan, doing the hazard identification assessment, reevaluating whether the plan is effective, so I just want to make sure that that it was clear that employees are having input on the controls and the effectiveness of controls. Nobody knows better than the people receiving it in the warehouse, distributing it in the pharmacy, mixing it or administering it. They know better than anyone else what is effective and what works and what doesn't, and how they're being exposed.

Shelley Carry: On D & E sections regarding evaluation and assessment, are there any thoughts of frequency? Will that be left to the employer?

Bob Nakamura: Our approach we are planning to take will be to take an initial evaluation and assessment, and then periodic.

Corbin Bennett, Kaiser Permanente: This is a general comment about the entire document. You use "shall" in your regulations, but USP uses "must." The recommendation would be to use "must." USP moved away from "shall" to "must" because there was a lot of confusion with the definition of "shall."

Eric Berg: We use "shall" to keep consistent with other Title 8 regulations.

Steve Smith: For our own regulatory audience, it is more consistent with Title 8. We'll take a look at USP.

David Kernazitskas: My concern is with section E regarding the assessment by employees. Is there an industrial hygienist in there, or is there a possibility that the employees would be exposed without them knowing? Does section E encourage explicitly enough that you need a professional to assess effectiveness of controls? An industrial hygienist could quantify effectiveness and air samples.

Bob Nakamura: We're not talking about employers who have access to an industrial hygienist such as home health agencies, veterinary clinics, or other settings that typically won't have access to a specific professional evaluation. We're not trying to spell out how exactly they have to do those evaluations.

David Kernazitskas: Can you say assessment by employer and employee?

Steve Smith: The employer is doing the assessment but must include employee input in the assessment, like how it's done with 3203. They can use an Industrial Hygienist if they have one.

Bob Nakamura: We can put that the employer shall conduct a hazard assessment.

Vickie Wells: The last paragraph states "assessment by employees," but what it seems what you really want is employees involved in the entire process. I'm not sure you can accomplish that by the way that E is currently

written. My second point is that not all employers have Industrial Hygienist on staff, but there are plenty of consulting firms in this state, including Cal/OSHA Consultation.

Jennifer McNary: I also have a similar concern on the evaluation of the control set. Perhaps it should be explicitly said that it should be a professional evaluation.

Bob Nakamura: We haven't been explicit in the past, but we can look at that. We can try to expand on some of these.

The next step for employers is to create policies and procedures for preparing, administering, and disposing of antineoplastic drugs; using and taking care of equipment to reduce exposure; cleaning and decontaminating areas; waste handling and disposal; spill control; medical surveillance and training. Are there any comments regarding this part?

Shelley Carry: Is it possible to add definitions for cleaning and decontamination? These could mean different things but are used interchangeably all the time. There are very different agents that you would use for cleaning than you would use for decontamination, so those are different processes. It would be helpful to have definitions spelled out.

Bob Nakamura: The problem is we have is that USP 800 is coming out, and the Pharmacy Board is also writing regulations. We're trying to get consistent information, and also trying to establish proper procedures for people to follow while wanting to minimize confusion between standards. We will need more input on how to define that distinction, and what kind of problems will be in various settings, especially with waste disposal. This is an open ended section.

Debbie Bolton: It's clear that this is covering transport, preparation and administration of antineoplastic drugs, but there isn't a definition of the handling of the patient or working with the patient. It talks about patient waste but we haven't clearly defined that, and it is not in the definitions.

Bob Nakamura: So your suggestion is that we need to amplify parts for patient waste and excreta? We would like input on what types would be worst.

Debbie Bolton: It's one thing to dispose, but care providers are exposed to incontinence. In terms of the plan, it doesn't identify terms of how to take care of patient on these drugs.

Bob Nakamura: We don't tell an employer what to do step by step because we're not addressing just hospitals. We have to consider all aspects of exposures that have to be dealt with. We won't go into specifics, but we are trying to have the employer identify what they need to do.

Debbie Bolton: In terms of PPE, between (C) and (D), I suggest adding another category for care of patient.

Kate Durand, San Francisco Department of Public Health – Laguna Honda Hospital: I suggest putting another category in (A) for caring for a patient on drugs. I'm not just talking about disposal of waste. At Laguna Honda, we do very little administration of chemo but we are taking care of patients who go out for chemo and then come back and we're changing their linens. Add that to A as another thing you need procedures for.

Steve Smith: So your suggestion is that we need to include in procedures how to deal with multi-employer worksites?

Kate Durand: Yes.

Vickie Wells: We need to be clear and careful. For outpatients out in the public, don't want to broaden it that far.

Steve Smith: This is just talking about multi-employer.

Kate Durand: It makes sense for home health. There are going to be different people administering the drug than taking care of the person.

Ed Ochi: When you look at these items under #3 within a hospital environment, you are talking about a non-monolithic program. For example, the preparation would be under pharmacy procedures. Administration would be a nursing procedure. Waste disposal would be handled under environmental care procedures. Do you really intend to have a plan spread out over different programs?

Steve Smith: We're trying to provide performance-oriented goals, whether it's done with 3203 or something separate. We understand that a variety of employers here are covered, so we must have flexibility to allow an employer to perform and meet these goals. We are not saying you need one monolithic document.

Cheryll Willin: As an analogy, when you visit different sites, the criteria for Quality Oncology Practice Initiative (QOPI) certification (oncology) is identified but the mechanism for how that happens at each site can be quite different. It depends on how places operate. It is possible to get that all done and point in the right direction.

Steve Smith: Thank you. Again, everyone has already been dealing with these drugs and have IIPP plans that address a lot of these elements already.

Kaila Benton-Vitz, UC Davis: To echo what Ed mentioned, the language says the plan may be incorporated into the IIPP, or may be maintained as a separate document, so you might say “maintained in separate documents.” The other comment I have is in the initial part where you have “a written inventory,” you might want to use the word, “list” as inventory implies that an amount might be in there, too. NIOSH also uses the word “list.”

Kathy Hughes: Regarding the earlier issue of caring for the patients receiving these drugs, the precautions for employee need to be addressed. I don’t see handling of lab specimens. There should also be a communication plan in place because patients are being treated in different places. It’s not in here, but good points were brought up.

Bob Nakamura: We appreciate the feedback. We started out with a draft which we knew we needed to amplify on certain issues.

Janice Dang: Under (3)(A) for detailed procedures, can we also add receiving and storing?

Steve Smith: We can use “handling” since receiving and storing is covered in that definition.

Break: 12:00 p.m. Meeting resumes: 1:00 p.m.

Methods of compliance

Bob Nakamura: We want employers to minimize exposures where occupational exposure exists. So this includes engineering controls, and we also have a table that talks about minimum control methods from NIOSH. Are there any comments?

Questions/Comments:

Shelley Carry: In the section for tablets and capsules in the table, it says “yes” for ventilated engineering controls. However, for respiratory protection, it states “yes, if not done in an engineering control, if not done in a control device.” If I’m to read this correctly, is it saying that in some situations where it might not be practical to do anything in a biological safety cabinet, like when a pharmacist compounds on the floor in the nurses station without a hood provided they have respiratory protection? When manipulating any type of drug, it is supposed to be done inside a hood. Here, it is giving you an out that it is recognized under some circumstances that it is not possible to perform that activity within an engineering control, and you can use respiratory protection instead of mixing inside of a hood.

Steve Smith: The example being given is for cutting or crushing a tablet or capsule. In situations where ventilation is not possible, respirators are being required. That is how it is being read, and that is how it is intended in the NIOSH guide.

John Griffith, McKesson Specialty Health: Regarding ventilated engineering controls, there is no definition within the use of biological safety cabinets for ventilation. This caused great turmoil within Washington State’s Hazardous Drug law for what type of ventilation is required if using a biological safety cabinet or a compounding aseptic containment isolator (CACI) that recirculates air versus partial or complete external ventilation?

Janice Dang: In the Pharmacy Board’s proposed draft, it will be required to be externally ventilated.

John Griffith: There are multiple hoods that have minimal external ventilation, but are felt to meet all design criteria, versus a 100% ventilation.

Janice Dang: We follow the USP 800, which says to use an external outside environment.

Steve Derman: We reviewed with some of our partners from NIOSH, and obviously a class 2 biological safety cabinet can be exhausted to the exterior. However, there are other designs for alternative ventilation controls, which are recirculated, but they use heavy-duty, HEPA-type filters and have been shown to be effective for particulate or aerosol when used properly. If clarification is needed, there is an ANSI standard that can be looked it.

Bob Nakamura: We need to verify what is said in USP 800.

John Griffith: So they will be harmonized regardless?

Steve Smith: At this point, we're soliciting advice, and we will look into it. The standard just talks of class 2, class 3 bio safety cabinets, and it doesn't specify how it is ventilated, but it has to comply with our standards.

John Griffith: I'm referring to ventilation control. It doesn't refer back to a definition.

Kate Durand: We need a definition.

Luci Power: After reviewing, I've found that this document refers to 5154.2, which is badly out of date. It still has 1 a type and 3 b types which have been changed at least 5 years ago. I don't know if you can promote to update that standard.

Janice Dang: Refers to Title 16 CCR 1735.6(e), for hazardous drug compounding. It shall be completed in an externally ventilated physically separate room with at least 30 air changes per hour, while maintaining negative air pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces. Each PEC in the room shall also be externally vented;

Ed Ochi: There is one consideration for compounding isolators. I can understand why you would want external ventilation, but what manufacturers are doing is recirculating 80% of the air. Even if you are calling it external ventilation, you're still recirculating air. When you periodically disinfect hoods where you're recirculating air, other contaminants go straight through HEPA filters. You could create other hazards like explosion or fire hazards.

Janice Dang: So this goes further on in the 1735.1. Compounding Definitions, under (f). It says that where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation.

Ed Ochi: That would also be referring to air exhausted out.

Janice Dang: It also says that this external venting shall be dedicated to one biological safety cabinet or CACI. Air within the CACI shall not be re-circulated nor turbulent.

Ed Ochi: So you're saying that it would be single pass? Ok.

Brad Ekstrand, Association of Northern California Oncologists: I value the opportunity to comment. I would like clarification on what the minimum standard is for biological safety cabinets. I would like the committee to keep in mind is that we represent small oncology practices, which includes rural areas. When you talk about creating standards, there are so many infrastructures and costs to implement especially if there is data to suggest that there is a less highly engineered way that may just be as good at minimizing employee risk. We must keep in mind the burden on all sizes of practices.

Janice Dang: The regulations that I've been talking of only apply to pharmacies. We don't have jurisdiction over physicians.

Brad Ekstrand: But these Cal/OSHA standards will, which is why I ask to consider being more consistent with NIOSH.

Steve Smith: We can also look at providing the minimum requirements per NIOSH, and we understand that pharmacies have more protective means that is equivalent or better and are sufficient. Pharmacies are complying with the Board of Pharmacy, which is just as protective if not more than.

Angeles G. Price, Kaiser Permanente: For oral liquid topical drugs under administration of oral liquid, you don't require eye protection unless patient receives via feeding tube. However, in the topical chart, it says "yes, if liquid that could splash." We are already talking about oral liquid drug, so why is that a no, and not a yes?

Bob Nakamura: The topical drug, and the one above it?

Angeles G. Price: Yes. For oral liquid, it says no eye protection, but for topical drug under administration, it says "yes, if liquid that could splash." All liquids have a potential for splashing, and yet for the oral liquid drug itself, it says no. Why isn't it a yes?

Bob Nakamura: We will have to look into that.

Kathy Pang: In terms of a nurse doing the administration, it does have the note that it would be required if the patient may resist. But if you have a compliant patient, would it be practical for nurses to be wearing eye protection every time?

Debbie Bolton: It should be yes because several things can happen. There was a case the other day where we didn't have a right connection for an NG tube, and there was splashing and resistance in the tube. It was oral.

Angeles G. Price: That is also an exception. My question is regarding a patient simply drinking. A patient can drop it, they can cough it up.

Steve Smith: This is exactly what we got from NIOSH, so we will ask them.

Ed Ochi: The table isn't uniform. In some cases, it requires safety glasses, and sometimes it doesn't. And there is this consistent requirement of protective gowns. However, once you're inside an isolator, are the gown and safety glasses really called for? If there is ergonomic stress, those things become a nightmare. The more you put on, you can have vision problems for the employees. In an isolator, do you really need that? There should be some credit given to those controls.

Steve Smith: For those kinds of things, there are caveats.

Ed Ochi: Those are only for respiratory protection.

Steve Smith: They are for respiratory protection and eye protection. Can you give examples of compounding a liquid in a controlled device that doesn't need gloves or a gown?

Ed Ochi: The gown itself depends on whether you are using a biological safety cabinet or an isolator. There is also the issue of double gloves. You already have gloves in the isolator itself and you're wearing another set of gloves so if you're counting those you're good. But otherwise, if you're talking about putting on two additional layers of gloves on the employee, they're never going to use their fingers.

Luci Power: I can address the use of gowns with an isolator. There is not a single published study in a peer-reviewed journal that shows that an isolator protects the person using it any better than a person using a biological safety cabinet. From a work practice point of view, you have to get to the isolator, you have to put things into the isolator, and there are at least five studies that show that vials from manufacturers are already dirty. Spills can happen at any place from the storage area to the isolator, and an isolator doesn't wash anything off. It only contains from the moment you are in the isolator. You need the gown for the stuff that goes into the isolator and the stuff that comes out of the isolator. So if you want to take the gown off and hang it on the corner, work in the isolator, come out and put the gown back on, the extra minutes are not worth it. If you're using a particular isolator and want the manufacturer to prove to you that nothing comes out of the isolator so you won't need to have a gown, see if they can publish it.

Janice Dang: The Board of Pharmacy's draft 1751.4. Facility and Equipment Standards for Sterile Compounding states that during the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile American Society for Testing and Materials (ASTM) D6978-05 standard gloves.

Ed Ochi: You have to look at separating tasks out in terms of PPE. It's not all continuous activity. Different tasks call for different levels of PPE.

Kathy Pang: You are dealing with employee safety and patient safety. For sterile compounding practicality, you'll already be gloved and gowned in the isolator. It's a different scenario for non-sterile compounding.

Ed Ochi: In unpackaging, you could be donning a full on chemo gown. You could potentially be using a different gown once you get to the isolator.

Kate Durand: When a person is exposed outside of an isolator, that person needs a gown. When you are in an isolator, you change gowns.

Steve Smith: Is it the same person? Are they really degowning after they've got all materials in the control device and then regowning when they take it out of the control device?

Janice Dang: In the USP 800, the draft suggests that when it comes to a tablet or capsule, this is left to your discretion on how you assess the hazard of that drug. The risk of exposure is considered based on the drug, and then you determine the type of containment you do. You have to assess each different drug.

Kathy Hughes: You have to consult with nurses who do this work on whether or not they're having the full level of protection while doing this work. There are different gowns depending on your tasks. Let's give them the higher level of protection because you're going to have to evaluate each drug and decide which gown you're going to use. It's part of the problem when NIOSH doesn't think you need eye protection when administering an

oral medication, but people are not being protected to the highest level. If NIOSH says to wear a gown to do this, then let's wear the gown to do this.

Luci Power: There is a footnote on the table for both liquids that says eye and respiratory protection are required if a patient may resist or if administered by a feeding tube. Is that sufficient?

Kathy Hughes: For me, yes.

Kate Durand: That doesn't address the person who drinks, but then coughs it out, which could happen involuntarily.

Shelley Carry: I would like to make modifications in wording to reduce undue burden for the testing of gloves and gowns. For the ASTM standard, they only require manufacturers to test 7 different drugs, and there are many that aren't tested, so it would not be reasonable to ask folks to get a glove for a drug that the manufacturer hasn't tested for. I suggest modifying language to say that gloves that have been chemo-approved per ASTM, as opposed to gloves for specific agents. For the gown, my understanding is that when it is required, there isn't a testing protocol for permeability of chemo drugs. That would be an undue burden to select a gown that hasn't been tested, so you might want to list the type of gowns you want them to wear, but it goes back to the question of chemo gowns versus isolation gowns. Strike out in B where it says "when required." Use something that's tested to resist permeability by antineoplastic drugs.

Luci Power: There are two ASTM standards. One is specific for gloves and the other is for any other type of material. The glove standard is specific for hand temperature, concentration and time exposure. If you just say they can use the ASTM standard, they'll use the other one and there's 10 to 100 fold difference between exposure using the two standards. It's best interest to not step back on that.

Shelley Carry: Leave in the ASTM testing for the glove standard, but take out that it has to be tested for a specific drug.

Ed Ochi: The theory behind the ASTM standard for gloves is that they chose the seven most aggressive that are most likely to permeate the gloves. Once you start asking for beyond the seven plus two that were tested, you will get resistance from the manufacturer. You are also going to be running into problems for protective gowns. We chose chemo gowns and got push back from the manufacturer we did not select, and said we were applying the glove standard to gowns. We are going to need something to work off of.

Steve Smith: The language says it'll change for the manufacturer's information on permeation.

Ed Ochi: The only recognized permeation for gowns is ASTM F739. It is generic but shouldn't be something you should be using. We recommend using the glove standard for gowns.

Luci Power: Manufacturers are using the F739 standard procedures but using the drug concentrations from 6978. However, the temperature and permeability of the gloves and gowns are not similar. This is not a problem that will be solved today, but the issue needs to be kept at the forefront.

Steve Smith: So the wording should be that the gown shall be appropriate to the drug that they're exposed to?

DeAnn McEwn: When you talk about resistance and permeation, there are standards (ASTM 1670-1671) that we need to look at as well.

Grace Delizo: If you have any language that you can suggest, we would like to have that.

Steve Smith: It looks like testing alone is not the right wording.

Debbie Bolton: Sterile gowns have gone through rigorous testing.

David Kernazitskas: Would "approved gown" work? Approved would mean by what your peers agree for common practice.

Ed Ochi: ASTM is not an approval process. It comes back with a numeric score, and that can't be used for approval.

David Kernazitskas: It'll just say that you're using PPE that's approved for this kind of use, where approved means whatever necessary regulatory agency or professionals all agree is acceptable.

Kate Durand: There is no gown that is perfect for every drug. You are using hundreds of drugs, and if you say that you need to use a gown that is appropriate for that specific drug, your staff will have to know which gown for which drug. That will get complicated and easy to mess up.

Steve Smith: You would have to use the most protective gown that covers more drugs.

Kate Durand: But there isn't one that is most protective, depending on the chemical compound.

Debbie Bolton: Perhaps remove the second sentence under protective clothing?

Steve Smith: The employer could've chosen the most protective gown that everyone is going to wear. Isn't that what it says?

Kate Durand: It is not that there are levels for gowns. One gown might be permeable to one drug but more protective for others. So for every single drug you're using, you're going to have to choose a gown.

Ed Ochi: There is a very limited testing library for chemo agents. You're going to have to use the ASTM D6978, and accept that you're using a glove testing standard on gowns. There's very limited willingness to test gowns and gloves except against a very narrow suite of materials.

Vickie Wells: When an employer tries to contract out, it'll become onerous. If Cal/OSHA requires it, it'll be easier for us to require in our contracts. It'll help the employer's purchasing ability. There are going to be conflicts if not specified in the standard.

Kate Durand: This is regarding large spills (under respirators) in (d)(2)(D)4. There should be a better example. In (d)(2)(D)5., it says large spill if larger than a spill kit, but that will depend on the spill kit. There should be further clarification.

Ed Ochi: Regarding #5, are you suggesting full face respirators because of protection factor or eye protection? If it's for the protection factor, once you go over the protection factor of 10 you would need to quantitatively fit test those. What is the purpose for a full-face respirator?

Steve Smith: Our basis is NIOSH. They gave us the respiratory guide, and we are going by the minimum in the NIOSH standard.

Kathy Hughes: If the full-face piece is used for respiratory protection, they would need to be fit-tested as opposed to what?

Ed Ochi: If you want the full-face piece for a higher degree of protection, you would need to quantitatively fit-test a fairly large group of people.

Cheryll Willin: For items 2-5 regarding respirators, those should be condensed to one statement about the type of respirator to be used.

Steve Smith: Okay, we'll look into that.

Ed Ochi: On respiratory protection, I want to make sure that people in the room are aware that this is talking about donning a chemical cartridge respirator whenever you have a spill of any size. This is quite different from current nursing practices. For example, when you are administering a chemo agent and there's a spill, this is expecting staff to leave the area to don respirators while patient is dripping with the chemo agent. There will be pushback. I don't believe that staff will accept stepping away from the patient.

DeAnn McEwn: The issue here is a reasonable expectation that you can be exposed to that situation. We want to ensure that the appropriate PPE is made available to the nurse before you go into the room. If there is a reasonable expectation of a spill, there has to be a standard in place so that the employee can use their judgment with PPE made available in areas of reasonable expectation to exposure.

Sue Downing: Regarding fit-tested respiratory protection, respiratory protection is needed for veterinarians, but I don't know what a fit-tested respiratory protection is. Veterinarians don't use it, and I'm not sure how practical it is. When operating in a closed system with people who are trained in animal restraint, I'm not sure if it's necessary.

Kathy Hughes: How accessible is the respiratory protection and equipment during a spill? I won't leave my patient alone, so how readily available would these be?

Ed Ochi: In terms of spill kits, which do not include respiratory protection because those require fit testing, they are supposed to be at the site of administration in the same room. Within pharmacies, they are within high-risk areas. Even if the respirators are in the same room, it would take time to don it correctly. It would take 5-10 minutes to properly don a respirator, so how practical is respiratory protection in terms of spills? People may not comply because of patient safety.

Kate Durand: We don't distinguish in this section between things that are going on between administration and within pharmacy. This seems to be clear cut in pharmacy. We fit-test all our pharmacy techs. The pharmacy scenario isn't even addressed here. You should also define, or clarify, the definition of the kinds of spills and the

kinds of respirators.

Jennifer McNary: There needs to be language for when it is anticipated that an antineoplastic drug will be used as an aerosol.

Steve Smith: In the last row of the table, it talks about inhalation and requires respirators for powder/solution.

Ed Ochi: I don't know if any of the materials covered in Appendix A are administered as aerosol.

Jennifer McNary: It was reported by NIOSH. There was a drug under investigation.

Ed Ochi: On this list?

Steve Smith: It may be on others.

Grace Delizo: Going along with the idea of the hierarchy from engineering controls to work practice controls, we have basically taken some of these from existing NIOSH guidelines. Does anyone have comments under work practice controls on the receiving and storage section?

Kathy Pang: On page 8 #4. We have a closed system transfer device where we have a spike adaptor that goes into the IV bag. On the floor, the nurse primes the line with non-drug solution and then takes that line and spikes it into the spike adaptor and then gets access to the chemo drug. We're not priming inside the ventilated cabinet because we have isolators and there's not a lot of vertical space. Another reason we don't is because you are then bringing more things into a hood that contains contamination on top of more sterility issues. There are more points of entry for microbes to ingress, so in terms of practice, some of the closed-system drug-transfer devices (CSTDs) allow for priming outside but still safe administration for nursing staff.

Steve Smith: Isn't that mentioned here?

Kathy Pang: We are issuing bags with special spike adaptors so nurses are priming inside the patients' room with non-drug solution. Right now, the language says "not within a patient's room."

Vickie Wells: The language should probably be clearer to say that it's okay to do in the patient's room as long it's with a non-drug solution.

Steve Smith: We will look into that wording.

Kathy Hughes: When you're talking about the visual examinations for shipping container, you should be wearing PPE for this?

Steve Smith: I think the whole issue is supposed to be addressed in their plan.

Shelley Carry: There is verbiage in B and C where there needs more clarity around agents, frequency, and surfaces. Are we properly cleaning for sterility (alcohol wiping) or is it for deactivating drugs, which is using bleach?

Steve Smith: So this is the same issue that was mentioned previously about clean versus disinfect.

Cheryll Willin: You can use disinfectant or antiseptic for cleaning and decontamination for hazardous drugs.

Steve Smith: We will work on the language.

Corbin Bennett: Regarding priming and spiking inside the C-PEC, USP 800 line 511 states examples of protective techniques include spiking or priming of IV tubing in a C-PEC. Also under routine cleaning, it states to "clean work surfaces with the appropriate deactivating agent." Does that mean we need to deactivate before and after compounding activity? That would be a higher standard than USP 800.

Steve Smith: We will look at the NIOSH guide for that.

Kathy Hughes: It also says, "if available." Are there not deactivation agents available?

Steve Smith: We have it in there if NIOSH says it.

Ed Ochi: There are a few agents not prone to oxidation, so unless you want to get down into the weeds, you might want to be specific on what deactivating agent means.

Luci Power: It was mentioned previously, but deactivation, decontamination, disinfection, clean work surfaces, clean patient rooms, etc. all need to be defined.

Grace Delizo: I assume that work surfaces refer to work surfaces in patient rooms and administration areas, but we will find the language and clarify.

Cheryll Willin: I would like to address waste disposal. Our waste contractor and I are in deep discussions on what trace waste comprises and what bulk hazardous waste comprises and the proper disposal of them. Does the USP 800 go into that? What is everyone doing about bulk hazardous waste like within pharmacies?

Steve Smith: We don't regulate waste streams but exposures to waste. Cal EPA would be the one to regulate. We can address the issue of making sure employees handling this waste are properly protected.

Ed Ochi: Just for the record, I would like to have a definition on "large spill."

Angeles G. Price: On page 9 #14 at the end, it is very specific to animal body fluid wastes. What about human waste?

Steve Smith: So the suggestion is to not use the word "animal."

Debbie Bolton: We are disposing of this in our hazardous waste containers, so we're not double bagging. The container is locked and closed and disposed as one unit. The hazardous waste container is hard plastic.

Steve Smith: This has to do with bagging you use at the site of a spill before you put it into the container.

Debbie Bolton: It refers to waste disposal. It is impermeable.

Steve Smith: We will look at the language.

Catherine Jansen: I think we're talking more about trace waste versus bulk waste, which is disposed differently.

Medical surveillance

Questions/Comments

Kathy Hughes: Under item 1 where it says to do a questionnaire at the time of hire and periodically after, how often is "periodically?" Is it spelled out in NIOSH?

Steve Smith: No. But what is the practice?

Kathy Hughes: It seems like there should be a quantifier there.

Steve Smith: We are dealing with what NIOSH gave us, but we'll take a look at the language.

Kate Durand: My question has to do with this section which is really short and vague in comparison to the other Cal/OSHA standards. It is not specific on timeframe or type of testing to be done. There aren't phrases in there that Cal/OSHA usually includes about needing to be supervised by a licensed physician, or needing to keep medical information private or other protections used in medical surveillance. Health effects in this case may or may not be due to hazardous drugs, so what is private medical information in this case or part of medical surveillance that the employer is supposed to be tracking?

Brad Ekstrand: I am actually not surprised that this section is vague. This was our main concern a year ago as to the real purpose here, and how evidence-based this is. This entire section could just be removed. The issue on privacy between employer and employee, especially in terms of reproductive, is not quite clear. I'm not opposed to some amount of responsibilities in this area, but legislating health monitoring with employees is problematic. I'm curious as to how other stakeholders feel about this?

Steve Smith: The concept is that this talks very generally on medical surveillance being an element, but it does not go much further into it than that. What we are trying to provide is basic language that calls out a program and the importance of including a physician and the medical community with providing preventative guidance as far as a surveillance program. It leaves it to that physician the appropriateness of what that entails. We think it is a minimalistic medical program.

Brad Ekstrand: So for one of our member practices, you're saying the employer needs to have a workers health initiative where workers need to be given the opportunity to see a physician outside of practice?

Steve Smith: We cannot advise you on the conflicts of providing medical surveillance to your own employees, but yes medical surveillance should be offered to those employees, including a history and review of the employee's medical conditions and of the issues the types of drugs the employees are being exposed to. At that point, proper medical surveillance can be decided upon by the physician.

Brad Ekstrand: Who is the bill going to be under?

Steve Smith: The employer.

Brad Ekstrand: So we provide this to employees at no cost to employees?

Steve Smith: Yes. Our regulations with medical components to it, like the lead standard, asbestos, and even the respiratory standard, require medical screening. It has to be provided to the employee at your cost and on work time, and these records are to be available to the employees. At least for the respiratory protection standard, they do a medical questionnaire.

Vickie Wells: In most standards, like the lead standard, there are specific end points. This is very, very vague, and that makes it difficult. Maybe this is more appropriate to have something like ATD, where there is follow-up after acute exposure such as a spill. Someone has to give directions to the physician. You're also going to have the whole medical storage for 30 years. I'm not sure if I see a benefit to this section the way it is now.

Debbie Bolton: We're just in the process of implementing for the first time our program, and there are two levels. New employees get a letter where they may get exposed to hazardous locations, and then we provide them with a generic questionnaire based on the Oncology Nurses Society. Annually, they're asked to complete this electronically, and all new employees go through a physical exam as part of bringing someone in. Another piece is if someone is exposed, there is a follow-up and a focused exam in relationship to the drugs.

Catherine Jansen: Staff are given questionnaires and lists of hazardous drugs and symptoms that aren't explained. There is a separate step for when there is an exposure, and that is actually a lot more valuable than what is here.

Angeles G. Price: I recommend an initial questionnaire and then if exposed, there should be additional testing.

Steve Smith: Item 1 on this section tries to explain that, but we can work more on the wording.

Kathy Hughes: Employers, and even small employers to some degree, have a pre-employment process, such as getting vaccines and pre-employment physical exams. The language is vague, but I have a problem with it for a different reason. Health care is a predominantly female industry. We find within our members go to their doctors with something like Methicillin-resistant Staphylococcus aureus (MRSA) infection, doctors will say it's from the community and not from work. As a union representative, it is important that these people have health screenings so that employees are aware beforehand what they might have going into the job. In construction and other industries, if you get an illness or injury, you're going to assume it is work-related. We know we're dealing with chemotherapy drugs which can be cancer-causing to those administering. We have to have something in place. If something health-related happens in the future, employers will say that's not their fault, and that employees got it somewhere else. There are protections in place for other industries, so there has to be something in place to protect these health care workers.

Vickie Wells: Nothing in medical surveillance will provide support to workers trying to get workers compensation. The only reason to provide medical surveillance is the benefit in letting us know immediate exposure to something hazardous and remove those workers from exposure. I don't see that standard as doing this. We should look at the standard to ensure that does it actually provide protection to workers. What does it actually provide for them? You need to look at the burden for private physician offices that fall under the standard, home health care agencies, and health care groups that are not general acute care hospitals and don't have employee health care services in place.

Ed Ochi: I reviewed this section with our Medical Director from Occupational Health Services. The concern is that this section is excessively vague, so that unless you give some kind of baseline or criteria for what exams will be, your data is going to be all over the place. There won't be anything that you can compare from one group to another. Outside of the hospital settings, unless you give guidance, you'll get something minimal and different from what a hospital can provide. Nurses don't stay with the same employer. If we don't have a standardized data set, you won't have data that you'll be able to use. You're going to have to establish more structure. If it remains this vague, it shouldn't be in this standard.

Steve Smith: The point of medical surveillance is to include a physician as part of a way to help prevent or reduce exposures by including medical advice and medical awareness. All of these things are components of a prevention plan.

Ed Ochi: Realistically, that occurs when you have your own in-house occupational medical services. Occupational health service clinics are becoming rare, and you don't get true knowledge about what it is happening.

Steve Smith: You should rely on those physicians to be experienced professionals that are going to provide appropriate exams for those employees.

Kate Durand: Physicians aren't even mentioned in this section.

Steve Smith: Understood. It says "medical professionals."

Kathy Hughes: Maybe it doesn't play into workers compensation, but reality is the reason that the legislation passed and why we're working on a regulation is because not all employers are good players in the

chemotherapy game. They don't follow guidelines, and they're not protecting workers. If we don't have a baseline, there isn't any way to determine future cancer. If someone develops cancer, is there a way to back track that? The law says we have to follow NIOSH, and NIOSH says we have to have something in place.

Brad Ekstrand: I don't know that you have to keep records for 30 years or keep a yearly update for each employee. They will be on our payroll and there will be records there. I don't know what a separate mandated employee physical exam serves, or that separate medical records need to be kept somewhere. I don't know for what purpose. The reason that this is vague is that there is no data to suggest that any of this makes a difference and the committee should think strongly about whether this is meeting the goals.

Steve Smith: We are trying to structure something that is following NIOSH guidance that is preventative. We understand a workers' comp is there for issues after exposure, but we are trying to prevent that. NIOSH and we think there is some role that a medical professional can play in providing a baseline exam and a periodic follow-up as part of a prevention strategy.

Brad Ekstrand: A primary care physician would have a conversation with the employee.

Steve Smith: There might also be a questionnaire for personal risks factors and their personal history.

Brad Ekstrand: I don't know if that should be under the purview for the employer that says that you have to go out and get this information.

Steve Smith: As an employer, you should provide that to your employees to have that medical exam as far as a preventive program.

Kate Durand: In reality, most primary care doctors don't ask what you do for a living, and in the occupational health world, we wish they did. Also, not everybody goes to their primary care doctor on a regular basis. OSHA's perspective is to have employers provide employees with that opportunity to see someone trained in occupational health. In this case, for this standard, it is so unclear what information is supposed to be gathered, that there is no end point or marker that we're looking for. There aren't any specifics of that here.

Brad Ekstrand: I don't want to mandate anything where there is no evidence that it will help.

Steve Smith: Isn't providing a medical professional input part of an overall prevention program? For example, with the respirator standard, you have to provide an employee with a medical questionnaire and approval by a physician to wear that respirator. This is similar in that it doesn't give you an endpoint or require testing other than a questionnaire. We have a standard for people who work in labs, and there is a medical component in that standard that every person that works in chemical labs has the opportunity to be provided a medical consult. It also has a part for post exposure. This is about providing an opportunity. We can spell it out there for you.

Kate Durand: Currently, it's not saying you must provide an opportunity for a consult. It says they must provide a questionnaire.

Steve Smith: Would it be more helpful to change the wording to "provide an opportunity?" It would be more consistent with language from our other standards, which says it is a provision. All of our standards say that you have to provide a pre-exposure opportunity. You also need to tell them the importance of medical exams. When you suggest that they should go to their own doctor, you are saying that they need to do it at their own time and at their own cost.

Kathy Hughes: The bill requires that the standard be consistent with and not exceed NIOSH recommendations. If you look at NIOSH, there is a whole page on medical surveillance, and refers to OSHA's technical manual, and recommends the Oncology Nursing Society. There are things in here that does what we need it to do, and NIOSH says we should do it. It needs to be workable for everybody, but I don't see how we can get out of not addressing medical surveillance. I don't like all of it either, but I don't want to eliminate it.

Cheryll Willin: What is the likelihood that Cal/OSHA can maintain a database of all this.

Steve Smith: We aren't asking for data.

Cheryll Willin: So if you don't have occupational health, and you are providing insurance to employee, and that employee has the right to see their primary care provider (PCP) on an age-appropriate maintenance schedule, we're assuming at that point, that PCP has the understanding of what surveillance is both needed and required. Is that correct?

Steve Smith: No. I think typically, health packages provided by employers are separate from the offer of this exam for medical surveillance. It is similar to how you would offer TB tests every year. You offer, but you don't

say you have to do go to your PCP to get it done, pay the co-pay and bring it back to us. The employer offers it to them, and that is the distinction. In OSHA standards, it is a provision that employers provide this at the cost of the employer. It does not obligate the employee to take employers up on that. That is the OSHA standard for the select things that require a medical. In this language, trying to make a barebones medical surveillance that doesn't require you to report to us or collect data, but you offer to the employee to go to the doctor that includes doing a questionnaire appropriate to these issues at-risk, and the doctor performs an evaluation that's appropriate for the exposures. That opportunity is there for that interface between the employee and the medical professional.

Kate Durand: The only thing that is missing is that the physician is supposed to provide an opinion to the employer. In this case, there is no opinion going back to the employer. If the physician sees somebody thinking of becoming pregnant and thinks that person should not be working with chemotherapy drugs, what is that physician supposed to do?

Steve Smith: The question is: what happens when a medical professional knows of an employee's work risks and says that it is inappropriate? You advise that patient of those risks. Would you give them a note to say not to go to work?

Brad Eckstrand: Isn't that part of patient privacy of the doctor giving the employee a medical opinion to not go to work because of the risks to that person?

Steve Smith: That is an outcome. We'll work on it.

Jennifer McNary: Occupational medical professionals are trained to write those recommendations. They can be contracted to spell out the kind of communication that would happen.

Steve Smith: I'm not sure enough occupational health professionals to do this kind of service.

Kathy Hughes: In privately-owned healthcare services, if an employee is injured on the job, who are they referred to?

Vickie Wells: That depends on the employer. The employer has options in the state of California. Employee health services may not be the same.

Kathy Hughes: But in privately-owned health care services, they wouldn't have their own employee health services. If those employees have work-related health issues, who do they choose to see?

Vickie Wells: Then the employer can tell the employee that they can go to whatever doctor they chose, and the employer would cover for that.

Ed Ochi: What was being verbally described earlier is different from medical surveillance. In medical surveillance, specific markers are being looked for. What is being discussed here is not that, it's medical counseling.

Steve Smith: All of you have good ideas, and if you can submit them to Grace and Bob, we can take another crack at this. We hear your ideas.

Andrea Iannucci, UC Davis Medical Center: I like the term "medical surveillance" because it is used everywhere. Language is better to be vague because it leaves this to the employers to handle as this is very controversial. Each institution or individual employer needs to determine what they need to do in their own facility. USP is similarly vague because there is no standard. If these were effective tools for identifying people at risk for cancer, we would probably be screening people. If someone who had been working with antineoplastics were to develop a symptom, you can't even go back and know with any certainty that this is related to their exposures. So it is better to be kept vague.

Steve Smith: We will take another look at this, so please provide us with the input that you want.

Training

Questions/Comments

Ed Ochi: You specifically reference in f 1(A) Handle antineoplastic drugs safely, including all Hazard Communication training requirements in accordance with section 5194. The drugs are specifically exempt from 5194 in paragraph B. If regulated by the FDA, they're out from that.

Steve Smith: They're out from the labeling part.

Ed Ochi: They're out from the safety data sheet requirement, too, which are key training elements. There is more confusion when you're looking at your label for pictograms, but your drugs don't have them.

Steve Smith: They don't, but are you saying they don't have a safety data sheet (SDS)?

Ed Ochi: They're exempt from that. Look back at the standard. Referencing the standard is not applicable here.

Steve Smith: We'll take a look at that.

Kathy Hughes: In recently published regulations, like for Safe Patient Handling and for the pending Workplace Violence, training incorporates interactive questions and answers. I would like to have training for this that is also interactive questions and answer, and the person providing the information should be a subject matter expert. There is specific language in prior regulations, and I ask that that also be included here.

Catherine Jansen, Kaiser Permanente: I would caution putting "whenever a new antineoplastic drug is introduced into the work area" because we have so many new drugs being developed all of the time, so we could be doing in-servicing quite often which would not be realistic in the work setting. Annual updates or something like that is much more likely to be followed than something that is done every time a new drug comes out. (Line 2 and line 4 of f).

Vickie Wells: If you say "new hazard," it might be more appropriate.

Catherine Jansen: It is not uncommon for us to provide training to staff if a new drug comes out, but doing a whole new training each time

Steve Smith: I'm assuming it's like hazcom where you can train around categories of hazards.

Ed Ochi: It's not phrased that way in the language though.

Steve Derman: The entire training component should, as close as possible, mirror the hazard communication standard itself, which includes annual training thereafter.

Jennifer McNary: Annual is more manageable than periodic from an employers' point of view.

Recordkeeping

Steve Smith: This is using standard verbiage. Any questions or comments?

Questions/Comments:

Vickie Wells: There isn't anything about retention of medical records. If you'll require medical surveillance, there should be something about medical records.

Steve Smith: We aren't requiring medical records to be given to you.

Vickie Wells: To be consistent with other standards, it should be included. Medical surveillance is no good without retention of medical records.

John Griffith, McKesson Specialty Health: What does "inspection" refer to?

Kathy Hughes: Is it part of establishing a plan when you do your hazard assessment?

Steve Smith: We'll take a look at it. We will see if it should be mentioned earlier on.

Kathy Hughes: You do have a hazard assessment under what a plan should include.

Additional issues to consider

Steve Smith: The last part of the standard is a reprint of the latest NIOSH guidance and a list of the drugs.

(Person didn't state name): What do you do when the list changes at NIOSH?

Steve Smith: As the list changes, we will do a follow-up rulemaking to update the list.

(Person didn't state name) Why include the list and not just reference it?

Steve Smith: We can do that. We thought it would be helpful to have here, but if you think it would be better to just reference it, I can only reference a list specific that has been published.

Vickie Wells: So they cannot reference something that says "the current NIOSH list." If they put a reference, it will still only refer to this particular list.

Steve Smith: The question is whether you want it as an Appendix or if everyone just wants pull this particular list from the internet. The problem for us is that sometimes the list disappears from the internet, and we've lost it.

Vickie Wells: It's better to include it with the standard.

Steve Smith: This also shows that this is the base list that we were using at the time of writing this standard. As we can, we will try to update to the current list.

Steve Smith: For the next steps, we have received your comments here today, and if you want to provide written comments before the end of November, please do so. Give us language that you think is appropriate, and give us ideas about what you think should or shouldn't be in here. We will take your comments into consideration and provide a revised draft.

(Same person who didn't state name): Do you weigh verbal comments differently from written comments?

Steve Smith: All comments are equal. During the advisory process, we appreciate any and all comments. Please send them to Grace Delizo or Bob Nakamura. Thank you very much.

Meeting adjourns at 3:45 p.m.