

**Cal/OSHA Advisory Meeting
Occupational Exposure to Antineoplastic Drugs
Tuesday, June 17, 2014
Oakland, CA**

Welcome: Juliann Sum, Acting Chief
Meeting Chairs: Grace Delizo, Bob Nakamura, Steve Smith
Notes: Peter Scholz, Mike Horowitz

MEETING ATTENDEES

<u>NAME</u>	<u>AFFILIATION</u>
Catherine Jansen	Kaiser Permanente
Thomas Connor	NIOSH
Janice Dang	Board of Pharmacy
Ed Ochi	San Francisco General Hospital
Kaila Benton-Vitz	U.C. Davis Medical Center
Angeles G. Price	Kaiser Permanente, Vallejo
Shelley Carry	Kaiser Permanente
Kate Durand	SFDPH/Laguna Honda
Janine Gundel	Kaiser Permanente
Megan Maddox	CA Pharmacists Association
Taylor Devens	Laguna Honda Hospital
Grace Daun	San Jose Kaiser Permanente
Nancy E. Lewis, RN	UCDHS, Sacramento
Patti Palmer, RN, MS	AOCNS, UCDHS Sacramento
Suzanne McClelland	Highland Hospital
Gail Blanchard-Saiger	Cal. Hospital Association
Hormozan Sarajhian	Kaiser Medical Center
Kari Frank	Kaiser Medical Center
Tracie Kirtz	ICU Medical, Inc.
Mike Van Fleet	Becton Dickinson
Devon Trower	U.C. Davis Adult Infusion Center. UCDCMC
Susan Reed	Adventist Health
Deborah Bolton	Santa Clara Oncology
Dorothy Wigmore	Worksafe
Sue Downing	DVM, Animal Specialty & Emergency Center
Vickie Wells	SFDPH
Luci Power	
Ricky Brecut	Epic-Care
Brad Ekstrand	Cal-Cancer-Care
Precious Rivera	Kaiser Santa Clara

Piera Wong	SF General Hospital
Bev Hart-Inkster	Alta Bates Summit Cancer Center
John Griffith	McKesson Specialty Health
David Ford	Noteware Government Relations
Kimberly Rosenberger	Service Employees International Union (SEIU)
Jennifer McNary	California Department of Public Health OHB/HESIS
Florence Toy	San Francisco General Hospital
Jocelyn Tom	University of California, San Francisco
Julie Vaday	Kaiser Permanente

Juliann Sum, Acting Chief Thanked everyone for coming. AB 1202 requires us to get your input. This process is really important and we are very excited to get your input. We recognize there are issues to hash out early on, including the scope of the standard. We are fortunate to have Dr. Connor here from NIOSH to give us an overview of the NIOSH Guidelines.

Steve Smith explained that the purpose of the meeting was to seek advice from the public, industries, workers, and experts on how to formulate a regulation addressing occupational exposures to antineoplastic drugs. Smith explained that the California legislature, by passing AB 1202, required Cal/OSHA to conduct a public comment period and public hearing. Additional handouts, Smith said, included a copy of AB 1202 and notes from the Center for Disease Control on hazardous drugs and from the NIOSH guidelines. Currently, without a specific regulation on antineoplastic drugs, Cal/OSHA would address a complaint or accident involving exposure to these drugs by applying existing regulations. These regulations include Injury and Illness Prevention Program (8CCR 3203), access to exposure records (8CCR 3204), proper personal protective devices (8CCR 3380 and following), lab hoods and biosafety cabinets (8CCR 5154.1 and 5154.2), and hazard communication (8CCR 5194).

In answer to the question, “What is the time frame?” **Steve Smith** said the legislature had not set a time limit for adoption of a regulation. However, once the preliminary advisory meeting stage is over and the process advances to the formal rulemaking stage, the California Administrative Procedures Act prescribes a one year time frame. Pre-formal rulemaking advisory meetings help streamline the process. The Division anticipates a second advisory meeting, and possibly a third, if necessary, so formal rulemaking should take place in 2015. Smith then introduced Dr. Connor, summarizing his long history of studying exposures to hazardous drugs, first at the University of Texas and currently at NIOSH.

Dr. Connor showed a PowerPoint presentation which summarized the history of NIOSH work on hazardous drugs in healthcare settings as well as the efforts of such organizations as the U.S. Pharmacopeial Convention (USP), a scientific nonprofit organization that sets consensus standards on safe handling of hazardous drugs such as USP 797 and USP 800. In its guidelines, NIOSH maintains a list of three categories of hazardous drugs that is updated every two years. Since the list was first adopted in 2004, there have been more than three hundred scientific studies on hazardous drugs published. The categories of hazardous drugs on the list are antineoplastic drugs, non-antineoplastic drugs, and drugs with reproductive effects. The updated list for 2014 is currently undergoing public review prior to its final adoption soon.

Shelley Carry asked if the updated list will include appropriate precautions for the three categories. Washington State in adopting its rule attempted to include an algorithm on precautions to use with different categories of drugs but struggled in getting this concept to work.

Dr. Connor said NIOSH has had a lot of stakeholder feedback on precautions. Initially when the guidelines were first adopted the focus was primarily on injectables, as most antineoplastic drugs at that time were in this class of drugs. But there has been dramatic change since that time. We do have guidance for the different categories. At the end of the list we have created a table, a matrix, for safe handling that we hope will be helpful to those handling these drugs. We have done this differently than Washington State, whose algorithm is difficult to follow because it attempts to give guidance for endless scenarios. But we are trying to provide additional guidance. You have in your handouts a bibliography of everything that has been published on this subject

Suzanne McClelland asked when the 2014 NIOSH Alert update is coming; only the 2012 recommendations are available on the NIOSH website.

Dr. Connor said the 2014 update should be available on the website in the next few weeks.

David Ford asked if NIOSH had interactions with the drug manufacturers beyond reading the package inserts.

Dr. Connor said there is some. Informal representatives from two pharmaceutical companies sit on the NIOSH hazardous drug panel. These two correspond with a pharmaceutical industry health and safety working group that meets a couple of times a year. We do get manufacturer feedback, asking questions about why a drug is listed and so forth.

Kaila Benton-Vitz asked about the scope of what is covered in the legislation by the term "health care", which seemed broad. Would a researcher injecting a mouse with a small dose of an antineoplastic drug be included?

Dr. Connor said the preamble of the NIOSH Alert lists work that should be covered, and work with investigational drugs should be handled as hazardous unless there is information to the contrary.

Steve Smith introduced the next agenda item: the requirements of the Assembly Bill 1202. **Grace Delizo** noted that a copy of the bill is in the handout package. As to scope, the bill states health care facilities, regardless of setting, are covered. In the Alert, as Dr. Connor said, research labs are covered and the Alert states that veterinary care practices and retail pharmacies are covered as well. In preparing for this meeting, we've tried to reach out to all these stakeholders to hear how you are currently handling hazardous drugs and how feasible the controls in this alert and the updates would be for you. Typical health care facilities we are looking at are hospitals that may routinely use antineoplastic drugs following the NIOSH recommendations, and also settings like oncology clinics or home health care agencies that may not currently be following all the recommendations of the NIOSH updates. We'd like to invite everyone to make comments with regard to whether there should be consideration given with regard to the scope of the standard. Reading from Assembly Bill 1202's text in the handout, the Board is directed to adopt a regulation covering the handling of antineoplastic drugs in all health care settings. The bill requires the standard to be consistent with and not exceed recommendations adopted by NIOSH. There is also a provision that updates to the NIOSH Alert are to be included in a regulation. As Juliann Sum mentioned, we are seeking input from hospitals, practicing physicians (including oncology), and organizations representing health care personnel including registered nurses, pharmacists, and other stakeholders. At this time we invite comment from all health care settings but are hoping to get input from pharmacies, labs, and veterinarians.

Shelley Carry asked if operations like Walgreens that have a pharmacist are covered, is this really a health care setting? Sometimes for healthcare settings, we may have facilities that are separate from the medical center, such as an automatic refill center; would that be considered a health care setting? What is the definition of health care setting?

Steve Smith said that's what we are seeking advice on. Those are some of the issues. "Regardless of setting" broadens it out to a lot of items: pharmacies, retail, distribution home health care and other settings.

Grace Daun said that since there are more oral chemo drugs being approved that can be used at home, I'm thinking that the family member caregivers in the home environment are exposed. So I'm thinking that the scope of the standard needs to be expanded to family members too.

Grace Delizo asked Grace Daun if she was saying the scope should include home health care, as discussed in the Alert. Grace Daun said "yes."

Debbie Bolton, Good Samaritan Hospital, San Jose, and a member of the San Jose Chapter of Society of Oncology Nurses, said that a number of retail pharmacies were now creating clinics in which treatments and infusions are actively being administered. So we need to expand the definition of retail pharmacies, or maybe come up with a different phrasing for care settings to include that type of environment. It's not just Walmart; we are seeing this at CVS and a variety of others.

Grace Delizo said that the Division's bill analysis proposed to look at defining "health care settings" which is different than the definition of "health care facilities" in Health and Safety Code 1250.

Janice Dang, Board of Pharmacy, said pharmaceutical suppliers, such as wholesalers supplying drugs to pharmacies, should be included in the definition.

Grace Delizo asked if wholesalers manipulated the drugs.

Janice Dang said that the Board of Pharmacy currently does not have law that tells suppliers how to package drugs for shipping to the pharmacy or hospital. Wholesalers get the drugs from the manufacturers and ship to their hospital or retail pharmacy customers. While there is no California law currently, USP 800 has recommendations on packaging. The wholesalers maintain the manufacturers' packaging; they may breakout the smaller packages from the manufacturer if there are, for example, 20 containers, but they won't break it out to the tablet level from their original manufacturer packaging. So what is sent to the retail pharmacy is in original manufacturer's packaging. Some, but not all wholesale distributors will put the containers in a plastic bag that will alert the customer that the bag contains chemotherapy or other toxic drugs.

Debbie Bolton, continuing discussion of pharmacy distribution, said that when she reviewed procedures at her hospital she found they will receive bulk packaging of different drugs alongside the chemo drugs in the same container, and they are not labeled separately. I really think that needs to be identified, more specified. In another area, under labs, we have patients now in all different sorts of communities who get their labs drawn, either at the hospital or retail settings, after they leave the doctor's office. What precautions are going to be set up? How are the lab clinicians going to get educated so they can protect themselves from exposure?

Nancy Lewis asked if this bill addresses prisons where inmates were undergoing cancer treatments. Also, she asked, if it addressed those who handle chemotherapy waste-- the housekeepers. It seems like there is a lot of education that needs to happen.

Grace Delizo said the following topic on the agenda would deal with what types of occupations and operations are covered by the regulation, and that Lewis' comments would be considered to be made under that topic.

Ed Ochi said, regarding the bulk distribution chain, that there are issues with medications being intermixed with other medications without any warnings on the exterior of packages. We have distributors that send these things themselves. Recently there has been new awareness that even with intact packages there can be contamination of the outside of vials. This external contamination should be handled somewhere on the bulk distribution side rather than each of us having to deal with it on the receiving side.

Grace Delizo asked Janice Dang if the Pharmacy Board had any rules regarding the issue of external contamination that Ed Ochi had raised. **Janice Dang** said there is no current specific state rule for wholesaler shipments and she wasn't aware of a federal regulation either. She agreed that mixed shipments of drugs without distinct warnings do occur. Some of the larger wholesale distributors will alert you with the packaging or appropriate warning labeling, but for the majority of smaller wholesalers, we do not see that happen.

Debbie Bolton said that within facilities you have people who are transporting the drugs, whether they are in the manufacturer's containers or whether the drugs have been reconstituted for distribution and are being transported from one part of a facility to another inside the building, or to another building. I think we have to look at who is handling the drugs in that process.

Suzanne McClelland said ASHP (American Society of Health-System Pharmacists) and USP 797 both have guidelines about handling received medications. One of them is that when you receive medications from a supplier, you are supposed to take them out and try to wipe them off because you don't know what has happened. Also, when compounding drugs, you wipe off your product, especially if it is chemo or hazardous, and you put it in a bag to contain contamination. So ASHP and 797 have guidance outlined already.

Dr. Connor said the NIOSH and CDC get many calls to their hotlines. One call concerned a distribution center employee who had opened a container that was filled with broken vials of 5-fluorouracil and inhaled a large quantity of the drug, immediately causing vomiting. So certainly distribution centers need to be considered. We hear many horror stories. We published a paper in 2005 showing that the outside of vials shipped from manufacturers are typically contaminated with the drug in the containers. This is an issue that needs to be addressed. I have a question about USP 800 which deals with hazardous drugs, while AB 1202 deals only with antineoplastic drugs. If the California Pharmacy Board enforces USP 800, which requirement will have to be addressed; who will trump who here?

Steve Smith said that you don't have to trump each other; agencies can work together. Again the overarching focus of Cal/OSHA is on workers, while the Board of Pharmacy has the broader mandate of public protection—not just the workers but more importantly the patients and downstream users of those pharmaceuticals. We try to work together, not trump each other.

Janice Dang said the Board of Pharmacy enforces California law. We use USP 797 as guidance but don't enforce it or issue violations for something that is in USP 797. However there is some California law that corresponds with USP 797. Currently the Board has a subcommittee for compounding that is reviewing USP 797, looking at the gaps between our law and 797 to see if additional law should be adopted that mirrors a little more of USP 797. Just to make it clear, we use USP 797 and probably will use USP 800 as a guideline, but what we enforce is California law.

Grace Delizo asked Janice Dang to elaborate on a fact discussed in a prior conversation regarding pharmacies that are certified that do follow USP guidelines.

Janice Dang agreed that many accrediting organizations like the Joint Commission, and other accrediting organizations, as part of their standards, have adopted USP 797. So because an accrediting organization has required them to be USP 797 compliant, some pharmacies are. That is what you are referring to.

Debbie Bolton said a lot of the settings we are now talking about don't have pharmacies. That's an area we have to consider. For example, you may have nurses—or doctors—reconstituting hazardous and antineoplastic drugs. A lot of the structures that they are in are not in a position to support following a lot of the Joint Commission, Pharmacy Board or other organization's recommendations. Because the Pharmacy Board and other bodies have not exactly been reaching out and overseeing these settings, they may not comply with safe handling procedures.

Grace Delizo asked Debbie Bolton to clarify what settings outside of the hospital she was referring to.

Debbie Bolton said small office practices and clinics, home health care, adult day care. And also the ability to recognize what they are doing; they may not realize the precautions that are necessary.

Steve Smith said we want the employees of the pharmacies protected. The bill talks about us not exceeding the NIOSH guidelines, which specifically excludes manufacturers. So the bill limits us to the rest of the pharmaceutical chain: compounders, distributors, retail-- all the other people in the pharmaceutical chain except for the manufacturers. Does anyone have a reading of the bill or a recommendation other than that?

Grace Delizo asked if there were any comments from veterinarians on preparation and administration of antineoplastic drugs in the veterinary setting.

Susan Downing said that her practice, specializing in veterinarian oncology in Los Angeles, was at one end of the spectrum of safety and training. Her practice utilizes a biosafety cabinet, personal protective equipment and extensive training. But for the majority of veterinary practices, the only protective procedure is to keep antineoplastic pharmaceuticals on a separate shelf or maybe in a separate container; most have no biosafety cabinet or specific personal protection for antineoplastic drug administration. The costs of such equipment for such a small-scale use may be prohibitive. There is definitely room for a lot more education. The difference is that our practice specializes in treating cancer. We administer 8 to 12 chemotherapy treatments per day, as opposed to one or two per month. Part of the nature of a specialty practice is that we pass on the costs of having the specialized materials and equipment to our clients. In contrast, a lot of general practice veterinarians are trying to save their clients some money, although possibly at the expense of personal protection. **Grace Delizo** asked about the use of closed system transfer devices; **Sue Downing** said these were comparable to tools used in human practice.

Dr. Connor said NIOSH developed a document on veterinary medicine dispensation of antineoplastic drugs—mostly to small animals, but also chemotherapy to horses. When they defecate or urinate animals can spread the contamination by the drugs. Some drugs are inactive when they go into the body and they are metabolized to and excreted in an active form. Then they are excreted in the active form. Some drugs are active when ingested and pass through the body unchanged. One recommendation we had for veterinary teaching hospitals was to have a color-coding for animals receiving chemotherapy so that it could be known for which animals precautions had to be taken in handling them or their excretions. When the animals go home to the family members, the animals continue to excrete chemo drugs, sometimes in fairly high concentrations. Unfortunately, many veterinary hospitals are way behind in adopting proper precautions. They really need a lot of education, and more guidance in this area.

Steve Smith reminded the audience that the mandate was to develop a regulation regardless of health care environment, regardless of setting. But it's a little doubtful we can consider a veterinarian as a traditional health care setting. It is certainly health care for animals but it is a little bit of a stretch to think the legislative intent was for us to go into the veterinarian area. We did invite veterinarians to the meeting, and we are not shutting out the possibility of regulating veterinary applications, especially since the NIOSH guidelines do apply to them and its precautions are recommended for veterinarians. But we do understand that it is a whole different occupational setting there.

Catherine Jansen said that veterinary workers were still employees who are exposed and they do need to be included in the regulation. Skilled nursing facilities, rehab facilities, and hospice should also be included.

Susan Downing said it would be an impactful burden for some veterinary practices to follow some of the NIOSH guidelines; now some have no precautions other than regular gloves.

Steve Smith deferred a question about surface testing for drug residues and housekeeper exposure to later in the agenda.

Debbie Bolton said that chemotherapy drug potency could continue for 48 hours after the last dosage. She wondered if any thought had been given to communication to the mortuary regarding autopsies and similar situations, when the patient died while receiving chemotherapy. There needs to be education and precautions available to this population of employees.

Patty Palmer said she had given chemotherapy treatments for 40 years, beginning long before there was any guidance for personal protection or any concern about her exposure. The argument was made that protecting her was a burden on the health care system; it took a long time. She had experienced more exposure than anybody in her hospital would in their lives. Veterinary workers should be protected, and not have to be exposed for years, as she had been.

Shelley Carry said that one thing about the bill that struck her regarding scope, is the restriction to antineoplastics, even though there are other drugs, with different toxicities, that are on the NIOSH list, and that are equally as hazardous as antineoplastics. What is the background history for this restriction? Is there a possibility to expand it beyond antineoplastics?

Luci Power was involved in the effort to get AB 1202 passed. Part of getting a bill through the process is trying to circumvent your competition, the naysayers. In Washington State, because of the large number of hazardous drugs on the NIOSH list which impact retail pharmacies, the pharmacies and pharmacy unions objected to passage of a law there. We faced the same issue and alignment of opponents in

California. We proponents realized that the inclusion of all hazardous drugs within the scope of the bill would ensure its defeat. Restricting the scope to antineoplastics got the bill passed. I'm hoping that ultimately the list of covered drugs will expand the way the NIOSH list has expanded. But to be stopped dead would get us nowhere.

Steve Smith reminded people that he had already pointed to a number of general application standards that apply today to the use of all hazardous drugs, that would require the protection of employees. Even if a drug doesn't fall on the antineoplastic or hazardous drugs NIOSH list, there are still protections.

Dorothy Wigmore said antineoplastics were one of the first hazards she learned about when she started doing health and safety 30 years ago. If the regulation has to be restricted to antineoplastics, let's get on with it, but let's ensure that everyone who falls under the broad rubric of health care gets covered. Be creative and go as far as you can towards protecting all exposed to antineoplastics. We've known this for years. The outcomes, the things that can happen from exposure, are huge burdens, not just to the individuals, but also to their employers and to society at large. Ask "What does the problem cost?" not just the cost of fixing things. Most often the problem cost far outweighs the cost of fixing it. Be creative, do as much as you can.

John Griffith, a pharmacist for McKesson Specialty Health, said that one of the things that derailed the Washington State regulation was its requirements that would have had retail pharmacists, when counting out 30 coated tablets, have to gown up and do the work in biosafety cabinets, which made no sense. I hope that this rulemaking focuses on the hazard assessment made by the pharmacist, because this was not the focus initially of the Washington State rulemaking. Also, with regard to USP 800, the proposal and recommendation has been made that packages and containers be cleaned at the manufacturer, rather than at the recipient wholesale level. This would decrease the risk. McKesson Specialty Health has responded to this aspect of the USP 800 recommendation by placing containers of antineoplastic and hazardous drugs in plastic bags that are clearly labeled, warning of their contents. Unlike competitors McKesson ships hazardous and non-hazardous drugs separately, in separate packages. There is no regulation requiring this, but there should be. To reduce risk, we recommend that you make this procedure guidance or law.

Dr. Connor said he appreciated the comment. As the situation has evolved and we recognize more oral and other drugs as hazardous, NIOSH has tried to respond to stakeholder feedback and include these as separate guidance in its recommendations. Hopefully the 2014 guidance will be more user-friendly. Unfortunately Washington State began its rulemaking process with our earlier, undifferentiated list. Washington State may make changes based upon the new NIOSH guidance when it comes out soon.

John Griffith said, in regard to the Washington State effort, birth control such as Depo-Provera, which was on the original 2004 NIOSH list, pharmacists administering it in the retail setting were to wear full PPE (full gown, gloves, and splashguard) not just when drawing it out but also when administering the product, even though the risk was extremely small. [Depo-Provera is a progesterone contraceptive in aqueous solution administered by syringe via intramuscular injection-ed.] This requirement in the Washington State regulation would also have affected all settings, including Planned Parenthood sites administering the drug. The pharmacy and other stakeholders had not been consulted. Hopefully the 2014 NIOSH list will address this discrepancy.

Steve Smith said one other item under scope is labs. We've talked about clinical labs, but the NIOSH guidelines discuss research labs. Many research labs are in universities, and are not health care, per se.

We've had one comment from a university that said it didn't see a need to include research labs in this regulation. Are there any comments on this issue?

Dorothy Wigmore said she had one person's name to mention when she hears that university labs should be excluded: Sheri Sangji. She died in a university lab because safety wasn't taken seriously. Universities should be reminded of their responsibilities. I've been on a university health and safety committee. I know how many hazards there are in those kinds of places. If universities are asking for exemptions, they are on another planet.

Devon Trower said that she didn't work directly with labs, but UC Davis Infusion Center does work with hazardous drugs. One is a drug in clinical trials. Some lab workers take the trial participant's biological samples, and the person in charge of this was very concerned with potential exposure and how to protect themselves. So I think it is important to include this type of exposure in the regulation.

Debbie Bolton said another area is Operating Room and radiation techs who are now giving a lot of drugs directly.

Hormozan Sarajhian of Kaiser said that materials reaching his oncology pharmacy from stores were potentially contaminated. While safe for transport, the material after arrival in our setting may be a source of exposure.

Steve Smith said we'd get more in-depth on these items a little later. I think we have finished the scope issue, he said. We'll reconvene after lunch on the topic of the types of occupations and operations to be covered.

LUNCH BREAK

After the lunch break **Steve Smith** summarized the morning's activity. On the concept of scope, he said, there had been a lot of comments on the variety of health care settings that have occupational exposure to antineoplastic drugs including pharmaceutical settings, except for the manufacturer end because that setting is excluded from the NIOSH guidelines. Most lab settings, including research laboratories, where work is done with antineoplastics should be covered. The recommendation from the morning comments was for veterinarians with occupational exposure also to be included in the standard, consistent with NIOSH. We are still open to comments today or by submittal after the meeting on this question. On the second bullet item, we heard a lot of comments about the types of occupations and operations to be covered, including the preparation of the drugs, the administration, the housekeeping related to the drugs, the clinical lab, and handling of the waste stream part of the drug. If there are other comments related to these two topics, we can hear them now. Otherwise we'll go into the possible plan and program elements. These suggested elements were developed from the NIOSH guidelines and also from our pre-existing requirements such as the Injury and Illness Prevention Program. These are suggested elements. We'd like feedback on what elements you may already have in your programs dealing with antineoplastic drugs, and also on the minimum elements you envision should be put into a regulation.

Bob Nakamura reviewed the suggested elements and the likely effect including them would have on stakeholders. One thing that applies to all stakeholders already is the Injury and Illness Prevention Program. We'd like to compare what people are doing under their IIPP to the recommendations of the NIOSH Alert. So, looking at the elements of the Alert, does a written inventory of antineoplastic drugs

seem like something everyone does? How about in veterinary practices, is that tracked or well-recognized?

Sue Downing said that there is probably not a specific inventory in most general veterinary practices. Practices that deal with a lot of antineoplastic drug use, such as ours, keep a separate inventory list.

David Ford said one of the concerns about creating a list is how you would conceive of its use in the future. How could a practitioner become aware of a change to the list, if it changes as does the NIOSH list, as described this morning? How, for example, would one learn that a drug had been added to the list?

Bob Nakamura said that was an issue that we'd have to work out. There are some precedents, but this could be cumbersome. The NIOSH list is updated periodically, and probably this is something not all stakeholders are aware of. We need a mechanism for updating the list.

Shelley Carry said she had a similar thought. Most people would probably use the NIOSH list of antineoplastics. The challenge is going to be in between the years when the list is updated, as new drugs come on the market. What is the process that stakeholders will use to add these new drugs to their lists? UC Davis has a very robust process, with technical experts sitting at a table discussing all the drugs that come on the market. They determine whether the new drugs should be added to their list or not. But I would guess this capability is in the minority. A lot of organizations don't have the resources to update that list with the new drugs that come on the market.

Bob Nakamura said that we would not expect stakeholders to make that assessment on their own.

Dr. Connor said that NIOSH realizes the list is typically two years out-of-date. NIOSH recommends health care facilities and other users look at the drugs that are in use by their facility and assess new drugs on their own whenever they are added to their formulary. That is a possibility. But here we are only talking about antineoplastic drugs, and that makes it quite a bit easier. It is pretty clear-cut that when an antineoplastic drug comes into a facility, it should automatically go on the list.

Luci Power said in clarification that this worry comes from several existing documents. What it means is: 'What drugs are in your inventory?' -not: 'What drugs exist in the universe?' I know Kaiser has a system to evaluate bringing in new drugs. **Shelley Carry** agreed this was true. **Luci Power** said that for new antineoplastic drugs for oncology and other facilities, Kaiser's assessment system should determine that there should be special handling for new oncology drugs. So what needs to be on your list is only what is in your facility, not everything that is on the NIOSH list.

Janice Dang asked if the expectation for a community retail or chain-store pharmacy to also maintain a written inventory of the antineoplastic drugs they are going to carry?

Bob Nakamura said yes and no. Someone needs to know what is out there and what the employees are being exposed to. Depending on the type of facility—we've already heard about dispensing centers...

Janice Dang clarified she was talking about the regular retail pharmacy.

Bob Nakamura said that those people need to know what they are handling, and whether or not they have antineoplastic drugs. So far we don't have a very good picture of what kind of awareness those types of places have.

Janice Dang said that sometimes pharmacies will special order an antineoplastic drug for a physician. So if this drug is not already on their written inventory, they will have to add it?

Steve Smith said we are not saying this is required. We are asking for your advice. We want to know what people are doing now, what people think. The concept is: “Should this be part of the program, if they keep an inventory?”

Janice Dang said retail pharmacies, chain pharmacies—none of them keep an inventory. They order based upon whatever prescriptions come in and whatever their wholesaler has. In general they don’t know what they are going to get because they have people coming in with prescriptions all the time.

Bob Nakamura said that could be an issue in regard to occupational exposures.

Ed Ochi said that a hospital had, in addition to its standard formulary, certain specialty medications that come in. In a recent incident a patient already under treatment came in with specialty medication not in the hospital formulary. We had to continue this chemo treatment from that point. We wouldn’t expect this abnormal item drug to be on our inventory, but it caused staff concern and a lot of scrambling to deal with this one specialty patient. So the inventory requirement of a regulation has to be understanding and accepting of this type of situation.

Florence Toy said there are more and more specialty pharmacies coming out that are the assigned pharmacy to handle only one particular drug. Because there is only one place marketing it who is not the manufacturer, the hospital is more challenged when the drug is allowed in to treat a patient. The way this situation is evaluated may be fairly straight-forward, but sometimes it is not.

Steve Smith asked if such specialty drugs were on the NIOSH list, and the collective answer from Kaiser employees present was: “No, it is too new.” Steve said that typically in the regulatory arena we would regulate the list that NIOSH has, not drugs that may be placed on the NIOSH list later. We have an obligation as an agency to not proactively obligate you to abide by all future potential drugs that may be listed in the future. We would have to come back and revise the regulation to include the newer version of the list.

Bob Nakamura said that the next topic, hazard assessment, touches on how to deal with drugs not on the current NIOSH list.

Kate Durand said that you are implying the regulation will only apply to the NIOSH list of drugs, while what we have to do now is to look at the NIOSH list of drugs as well as consider any other drugs. I would hate to say that we don’t have to protect people because the drug isn’t on the list. So, what Ed is saying is: if we have to have an inventory it shouldn’t be restricted to what is on the NIOSH list, which we’ve already acknowledged is two years behind. We are obligated to protect from anything we deem hazardous, but as in the hazard communication standard, our inventory list may not include everything.

Bob Nakamura said we understand that.

Debbie Bolton said that in the world of oncology nursing, the Oncology Nursing Society has identified seven elements that are criteria for evaluating the hazardous drugs category. One criterion says that if it looks like and has similar properties to a hazardous drug, you treat it as if it has hazardous potential until you identify that it doesn’t. Because there are so many gray areas you haven’t dealt with yet, you have

to have some guidance out there for the one or two staff people that may end up with problems because they worked closely with such a drug.

Bob Nakamura reminded all that we were talking about a spectrum of stakeholders that range from hospitals to retail outlets. So not everyone is going to be able to do everything the same way or have the same assessment.

Vicky Wells suggested getting input from home health care on the inventory requirement, as how they would do an inventory and how useful the inventory would be in this setting. Conditions are different for home health care than for a hospital. In home health care, people are going out to homes where different doctors are prescribing for patients. Drugs prescribed changes; the patients visited changes. So I would just suggest getting specific input from home health care.

Bob Nakamura said we had been hoping the home health care industry would have shown up.

Dr. Connor said individuals from home health care had participated in the NIOSH committee working on the Alert. In the latest revision, almost all of the injectable antineoplastics have handling guidelines. Recently the FDA has provided only the OSHA website, with a link to NIOSH, for handling guidance. But the package inserts always have this guidance for most antineoplastic drugs.

Bob Nakamura said this was a useful comment in the discussion on how useful the inventory requirement might be.

Kari Frank, Kaiser Medical asked if this list is expected to be separate from the inventory list required by the hazard communication standard? Or could it be rolled into the same program?

Bob Nakamura said it would be rolled into the hazard communication list, but it depended on how you educate the people who are going to be exposed to it.

Debbie Bolton said their pharmacy had created a list of hazardous drugs and antineoplastic agents on their intranet for staff availability. It will be updated when new drugs are received or when NIOSH releases updated recommendations. We are also working with our pharmacy so that on the charts on in-patients there will be a 'pop-up' listing special safe handling procedures to be implemented. These provisions address all settings in our system. We have other tools in place to notify people about the precautions that should be taken.

Florence Toy said her question was: what do you do for non-formulary drugs? Everyone is supposed to have a formulary, but when you have a non-formulary drug come in that I may know requires precautions, but others don't. I don't know if I can get that message out to the nursing staff on my shift that this is a cancer medication requiring specific precautions. Or if I do get that message out on my shift, but the information isn't transmitted from shift to shift. That is the challenge we have at San Francisco General.

Bob Nakamura said that is a problem beyond inventory. It is more like a problem of hazard assessment and training. We will have to consider this concern in the course of discussing these other items.

Kate Durand said that as she listens, she is beginning to think that maybe there shouldn't be an inventory requirement, since it doesn't apply to hazardous drugs in general. It is pretty clear what's antineoplastic and what is not. Maybe the regulation doesn't need an inventory requirement. Couldn't

we just say the program applies to all antineoplastics and not list them, given the issues that some facilities are going to have doing that?

Bob Nakamura asked how you would convey that information about which thing is which, if you don't have an inventory.

Kate Durand said she would say by labeling. There are other ways you can convey that drugs have to be handled in a certain way. I'm just saying that maybe the regulation doesn't need to require people to have a list, and the facility can say all antineoplastics will be handled in a certain way.

Bob Nakamura said there needs to be a process of knowing what you are getting in, and what people are using. That could be an inventory in itself.

Kate Durand said home health care and things like that can't have a list of all the antineoplastics necessarily that they are going to be exposed to. I'm saying that rather than have a list of specific drugs, you just have policies and procedures you follow when handling antineoplastics.

Bob Nakamura asked who is going to tell the employees that they are getting an antineoplastic drug to use.

Voice from back of room said that is what the training and the rest of the standard is about.

Bob Nakamura asked if the information is to come from the manufacturer, the distributor? Or is everyone supposed to know what the list is, or what?

Ed Ochi said a possible alternate method is the State of Washington requirement that hospitals use a sort of control banding whereupon when a drug is input into the hospital you are supposed to be screening the various drugs-- whether it is hazardous or antineoplastic. They use an algorithm in the form of a flow chart that places each drug in one of six categories. You don't actually need a list of what you have with this method; you have the category that a given drug is assigned to. So any time you see a new drug, you don't have to put it on the list, which half the people aren't going to consider anyway. You have the take-away that this is a "Class I" or this is a "Class II" drug. With each of the associated classes you have specific controls. You don't have an inventory; you have a classification for each drug. This may be a more rapid method than trying to modify and maintain an up-to-date list.

Bob Nakamura said that at some point an institution needs to know what is coming into their facility and is being used. You are not saying institutions don't need to do that? (Ochi, others: no they didn't mean that.)

Kate Durand said that they were just saying that maintaining an up-to-date list in a lot of settings was difficult, so maintaining an up-to-date list perhaps should not be a requirement of the standard.

Patti Palmer said there is a difference between the end user and the dispenser of a drug. In a hospital, the pharmacy is going to be keeping the list, not the nurses administering the drug. The same thing with home health care. Home health care providers don't inventory drugs. They go pick them up at a pharmacy and take them to the home. They are the end users, and I don't think the inventory requirement should apply to them as long as the pharmacy where they get the drug was keeping the inventory and then labeling them appropriately. In a hospital, you don't expect the nurses administering the drugs to have the inventory in their hands; it is housed in pharmacy where the drugs

are coming from. It is the same in the out-patient world; the list is not going to be maintained by the end user.

Bob Nakamura said let's move on to hazard assessments. What are people doing now, so far as incoming material and how it is being used?

Patti Palmer said at UC Davis there is an oncology subcommittee of the pharmacy and therapeutics committee that reviews all drugs that come into the formulary. It makes recommendations to the larger committee that then decides which go on the hazardous drug list.

Luci Power said the bullet points are too detailed. For hazard assessment, the NIOSH Alert includes work practices, working environment, and not just the drug. For written inventory, the goal is to figure out what drug you physically have, because in most cases it is the tech without a degree or toxicology experience who is doing the work. So all they know is the little sticker, the hazard label, which says use gloves, do something. I think hazard identification as well as the inventory goes towards making sure that items that come into the workplace are identified as requiring some kind of special handling.

Bob Nakamura said that brings up the idea of evaluating what the end user is exposed to. Any comments on that?

Debbie Bolton said a number of facilities are subcontracting housekeeping/environmental services, so these people may not be employees of the hospital in these settings. So these other employers will have to be made aware of the requirements of the regulations on drugs that apply to their employees.

Devon Trower said it is hard to classify some newer clinical trial drugs coming into the clinical setting, as to whether they are antineoplastic.

Bob Nakamura said we will be forced to rely upon the NIOSH list according to the law. But what we want to see is that every employer has a process for assessing the hazard to which their employees are exposed, and coming up with appropriate procedures and personal protective equipment, or engineering controls to protect them. That's our basic requirement.

Taylor Devens said he had been part of a team that worked with new clinical drugs, new specialty drugs. As far as doing a hazard assessment, all we had was the package insert and a Google search which provided only information similar to information on other monoclonal antibodies that I have seen. All we did was put a sticker on it.

Bob Nakamura said in the absence of anything else, whatever works.

Vicky Wells asked for clarification on whether the standard would only apply to the NIOSH list which NIOSH is telling us is always two years out of date. Is that what you are saying?

Bob Nakamura said: No, I'm saying we are going by the list that NIOSH comes up with, and the updates.

Vicky Wells asked if an experimental drug being used in a clinical trial, but that is not yet on the NIOSH list-- is that drug going to be regulated by this standard?

Bob Nakamura said technically we can't do that because it is not on the list.

Vicky Wells said: So, in other words your intent is to only regulate the drugs that are on the NIOSH list?

Bob Nakamura said: I think that is what we are limited to. I didn't say that was our intent. When I say we are limited to something, that means that our legislative authority says we should do at least this. It doesn't prevent us from doing more; it does prevent us from doing less. So we are here to decide if we should expand the envelope that NIOSH has. What we are talking about now is the drugs on the NIOSH list and the ones that will be listed in the future. But until they are listed I don't know that we could issue a citation based upon something that is not on the list.

Debbie Bolton said that from a practitioner's perspective, if I am dealing with a research drug, there are going to be side effects for my patient, and I'm at greater risk. So common sense tells me that until I have further information, I should treat this drug as if I am at risk for the same side effects. My recommendation is that the standard should have a generic statement that would say that.

Dr. Connor said the NIOSH Alert states that for an investigational drug without hazard information, until the information becomes available, the drug should be treated as hazardous.

Steve Smith clarified that Dr. Connor was saying the NIOSH guidelines go beyond the list. He conceded that the legislation stated that the regulation should not exceed the NIOSH guidelines, but we were clarifying that the guidelines go beyond just those drugs listed.

Bob Nakamura asked for a discussion on engineering controls and work practice controls. Let's start with: are engineering controls routinely being used for antineoplastics and hazardous drugs? Ventilation, like biosafety cabinets or ESBs?

Shelly Carry said that ventilation controls are used for just antineoplastics. Her sense is that they probably are using controls for antineoplastic drugs on the list. But for other drugs on the list, this is probably a gray area.

Bob Nakamura said we need a sense of what is happening and asked if everyone makes a sharp distinction between a hazardous drug and an antineoplastic?

Catherine Jansen said that especially private practices in the community, such as rehab centers, are not using engineering controls. They may be crushing oral antineoplastics outside of a biosafety cabinet.

Bob Nakamura said sometimes with other standards we've heard that some employees are rushed to do things, so they have to use what is available. So is it a question of availability or rushing, or both?

Catherine Jansen said both.

Janice Dang said what the Board of Pharmacy sees hospitals with compounding, or in-home health care, or a compounding pharmacy...if they are compounding chemo drugs, we require them to compound in a biological safety hood. The problem that we have is with the possibility of a requirement that they have a segregated area for compounding. So there will be an issue if the USP standard comes out. Right now we have the sterile room with a biosafety cabinet and the horizontal laminar flow hood all in the same room; they are not segregated. When it comes to dispensing in a retail pharmacy where the chemotherapy drugs are in capsules, I'm not aware of any community pharmacy that does not do compounding, that just does dispensing. And I'm not aware of any such pharmacy that has a biological safety hood for chemo drugs. We are not talking about compounding creams or ointments or injectables. We are talking about a regular chain store or community pharmacy that just does dispensing.

Ed Ochi said he encouraged people to be cognizant of existing facilities, and that you don't push the state of the art too far. For example, with USP 797--and we have an older facility. In order to meet those requirements --and we are doing compounding without biological safety hoods-- we have to of course use isolators for that. That's good from both the product protective and employee protective standpoints. A lot of biosafety cabinets are ergonomic nightmares; San Francisco General had a lot of injuries of pharmacy staff even though tasks were rotated. So you have to be careful to not create additional problems with controls that might be required.

John Griffith said working with community oncology partners he sees many levels of engineering controls-- from negative-pressure rooms containing primary engineering devices such as biological safety cabinets that have external ventilation, as opposed to biological safety cabinets placed within a hallway of an administration area, or within a physician's office in a facility. This covers the range of low and medium-level risk situations addressed by USP 797. USP 800 seems to impose a negative pressure room to start with the unpacking of the box in which the drug arrives. I have not seen a facility in California that meets that standard. In my travels I have seen many different levels of utilization of engineering controls. Some are older facilities for which it would be extremely burdensome, and would cost hundreds of thousands of dollars, to reverse engineer them—which is very different from primary containment such as a barrier isolator or a glove box. This should be taken into account.

Hormozan Sarajhian said at Highland Hospital they use barrier curtains to meet the requirement to separate the laminar flow hoods from the biological safety cabinets. We have very old building ventilation. We were able to obtain HEPA filters with fans for two thousand dollars. We put in a drop ceiling. So there are so many things you can do without spending a million dollars. We've been doing a gap analysis of our hospital facility. Things like pneumatic tubing delivery of hazardous and antineoplastic drugs are not allowed because of the possibility of a disaster. We've got special cases in which we transport them. We've been educating our patients about how to interact with the clinical pharmacist on how the patient can dispose of these things between hazardous and antineoplastic drugs when they get home. So doing a gap analysis of your facility is the place to start. We do use the NIOSH list. There are things like Selenium Sulfide are on the list that you have to dispose of. Start from what is specific to your facility.

Brad Ekstrand said speaking as a practicing oncologist, from the oncology society's perspective, we have members who have very small practices for whom instituting some of the safety measures being discussed would add significant administrative and financial burdens on their practices. The trend in oncology is that small group practices with one or two practitioners are being absorbed into larger medical groups which would be more likely to have the financial wherewithal to have biological safety cabinets and appropriate ventilation. Reading the NIOSH guidelines, I would encourage you to be very specific about what meets them and what doesn't. For example, the guidelines say you should make sure storage areas should have "sufficient" ventilation. I don't know what that means; I would like more specifics in the guidelines about what the threshold is for compliance. It is hard for practitioners to assess the financial burdens of compliance unless the specific requirements for ventilation are known. I would like to know if it is NIOSH's position that one really can't practice oncology safely without a biological safety cabinet. Is it correct that there is no alternative?

Dr. Connor said basically we adhere to the hierarchy of industrial hygiene controls: engineering, administrative work practices and PPE. That is the NIOSH recommendation. While NIOSH's recommendation has not been that strong a statement, I think USP 800's recommendation will be a strong statement. I think it explicitly states you must have certain things to handle hazardous drugs. I

understand the concern about small offices and practices. One anecdote: we get a lot of calls at NIOSH. One caller was a nurse in a one-doctor office. The doctor asked the nurse to go to the other end of the building to prepare the chemotherapy. The office did not have a biosafety cabinet and the doctor and his wife were trying to have a baby, and he did not want to be exposed to chemotherapy drugs. Many big facilities do have the money to put in engineering controls, clean rooms, and so forth. Smaller clinics do have the concern that they may not have the capabilities to do it. But, analogous to that, would you send out policemen or firemen without the proper PPE?

Sue Downing had a question about dispensing as a veterinarian. Are we talking about transportation? Reconstitution? Filling a syringe? That has a lot of ramification in my world, and we are not even talking about monoclonal antibodies yet. My colleagues in remote locations, their clients would have to travel two or three hours, with their beloved pet, in order to obtain specialty medicine. Should these people in essence be denied access to these drugs because of protection requirements for personnel? Or is there a low-usage, low-frequency exception in the standard that would allow remote practitioners relief from some of the strict protective requirements?

Janice Dang said that the Board of Pharmacy requires that any pharmacy that does compounding must have a master formula indicating the equipment that is to be used. So if a drug has to be compounded in a biological safety hood it would be included in this master formula.

Luci Power said she had reviewed thousands of anecdotal reports and published studies. Unfortunately, all the studies that look for drugs indicate one vial of vincristine, or one syringe, one small methotrexate dose, pounding tablets in a mortar and pestle, administering drugs and having the line come loose, a spill on the floor, is enough to cause a problem. There is no place that they have looked for drugs and not found them. Several recent studies have found drugs on elevator buttons when the elevator was between the pharmacy in the basement and oncology on an upper floor. Those buttons are not restricted to oncology personnel or restricted to patients or staff. I'm not unsympathetic, but saying "I can't treat you," is necessary sometimes because the health hazards, the reproductive risks, to employees and patients are well-known and too high to ignore.

Bob Nakamura asked if there were standard work practices that people follow.

Shelly Carry said there is some outdated data, or not a lot of data, on the half-life of these drugs as they go through the body. So I'm thinking about when housekeepers have to pick up the waste streams or change the linens, most people are using a standard 48 hour precaution—wearing gloves, things like that. Is there data that suggests 48 hours is too conservative; should the period be longer, or shorter?

Dr. Connor said the last publication on that was 1992 or 1993. Some of the drugs are still being excreted four or five days later. The oncology nursing society has a large table listing the duration for excretion of each of these drugs. NIOSH generally says 48 hours to be safe. If you look at the half-life, most of the drugs have been excreted within 48 hours, but it is difficult to get information on specific drugs. I've been trying to work with the author of that original paper to look at the excretion rate for some of the newer drugs, but we have not been able to get to it.

Janine Gundel from Kaiser, San Raphael said she didn't think they had very good work practices at all. Not just for housekeeping, but for other ancillary staff going into the patient's room --that could be radiology, or the lab. We don't have good education in place for the ancillary staff. So I really think this should be mandated for employees' protection. It can't just be the cursory annual review. It needs to be

more intensive than that, so people actually comprehend the risk of the work, and understand how they can reduce that risk. Definitely the ancillary staff has the least amount of training, support and knowledge.

Bob Nakamura asked if that training should include just notifying people when they are going into an environment that has an exposure potential? Or both?

Janine Gundel said we follow oncology nursing society standards and practices; these policies are in place for nursing staff, but nursing assistants and ancillary staff do not receive comprehensive training.

Bob Nakamura said there is a training issue, but also don't people know they are getting exposed to something? So, is there a need for a sign?

Janine Gundel said it is a dual issue.

Precious Rivera said that if you are lengthening or shortening the period during which precautions should be taken, make it the same for all drugs. It is already so hard for nurses to follow the different instructions for different drugs.

Deborah Bolton said drugs that have long half-lives should be addressed and so should the method of delivery, such as intra-arterially, since the method of delivery can affect how long the drug stays in the patient. In regard to education for RNs in our annual competency training, we review information and recommendations about handling precautions for new drugs. We've also incorporated this training into our CNA review, and also for our environmental services staff as well. We have signage on the door that records the date that administration of the hazardous drug starts, and also lists 48 hours after the last dose. So if something is administered orally, daily, then we have a list of all the precautions on the sign to be read by people entering the room.

Janice Dang said the Board has a requirement for competency training for pharmacies that compound. Prior to being permitted to work with a biosafety or laminar flow hood, the pharmacists and technicians have to demonstrate the competency to do so. In hospitals, we are finding that there is a lot of lack of training for housekeeping. For example, in cleaning the clean room, there is lack of knowledge on how they are supposed to be gowned, or dressed; what type of cleaners they are using; what type of procedures they are following to clean the area near the biosafety cabinet.

Deborah Bolton said that when we were looking at cleaning, some of the new language in the guidelines, disinfectant and decontamination, we did a surface decontamination study. It allowed us to in a more constructive way go to areas where we thought we were doing everything right and see the gaps. One of them was that an area that had been disinfected was not necessarily decontaminated.

Shelley Carry said it the use of terminology when you look at USP and NIOSH and OSHA struck her. This standard should be written with a consistent use of terminology. Different people use terms like 'disinfection', 'decontamination' and 'deactivation' the same way but actually they mean different things. Some people use 'disinfection' and 'decontamination' interchangeably. But actually they mean different things. 'Deactivation' means deactivating a drug. Isopropyl alcohol for USP is used extensively for disinfection but you can't use it for decontamination. So make those distinctions.

Bob Nakamura asked for comments about personal protective equipment. Earlier someone spoke about how expensive that could be. Any comments about that?

Angeles Price said outpatient nurses have complained that PPE is too bulky. There needs to be clarification in the guidelines about re-use of gowns. Is it one gown per patient, or one per shift? I have seen in some clinics the improper hanging of gowns leading to contamination of the walls and the nurses who reuse the gowns. How long you should use the gowns needs to be clarified. Some clinics treat 50 patients a day, so frequent changes of gowns could be very expensive, and also, waste containers would quickly fill.

Bob Nakamura asked for further comments about training. He also said that since this is an OSHA standard, something would have to be said about recordkeeping, i.e., injury and illness recording on the Log 300. In the safe patient handling regulation that is being considered; there have been instances of injury. So here we are talking about things like exposure incidents— if someone is exposed to an improper dosage of antineoplastic drugs, is that being recorded? We are talking about spills and exposures to employees.

Deborah Bolton said her facility does incident reports of spills. We call spill response “Code Orange” for which we have spill kits and have received training. We have policies and procedures to support this. Part of these policies and procedures is medical follow-up for exposed employees. This may include a visit to the emergency room for a wash, and availability of the SDS. Occupational Health follows up on the emergency room visit.

Catherine Jansen agreed with Deborah Bolton that, in the hospital and clinic settings, reporting is done. But she is not sure reporting is done in other settings.

Piera Wong said she is not sure how contaminated her workplace might be, or how often it should be cleaned. In terms of training, some of us used to teach the biotherapy and chemotherapy class. She wonders if the state or NIOSH could develop standardized training modules.

Bob Nakamura said that would have to be considered after we get a regulation.

Julie Vaday said Kaiser Santa Clara also has in-service training for nurses who have been given training all year, tracking if they have any reproductive health or other problems, working with the employee health staff. This recordkeeping is relatively new for us.

Bob Nakamura asked if there was anything else on recordkeeping.

Ed Ochi asked if Bob had in mind some sort of internal recordkeeping mechanism so that those who need to know within a facility are made aware of incidents involving a chemotherapy drug, or a system more in line with the standard log that you as an enforcement agency could come in and review. If the latter, I’d point out that it would have to be a lot stricter than the Log 300 requirements. There are very explicit rules about what needs to be recorded-- what is recordable or not. If you are looking for something where you are collecting data then you are going to have to have a lot of guidance. Because you will find that there is a lot of judgment--even when I review the internal reports, about what gets reported through our ‘unusual occurrence reporting system’ versus what I catch word-of-mouth. There is a lot of gradation there. An internal record reporting mechanism is one thing, but if you are talking about a centralized system that an outside agency may audit and review, than you will need a lot more strict guidance.

Bob Nakamura said Cal/OSHA bases a lot on exposure incidents, so we we’re considering something like that, but we don’t necessarily have to do that.

Ed Ochi said you would have to specify what you consider to be an exposure incident. For example, a broken vial versus a bloody contact.

Grace Delizo said a lot of what we've talked about is defining the scope, the kinds of occupations and operations to be covered, and what Bob has been bringing up are a lot of the potential program elements. It would be useful now to touch upon certain areas of the detailed NIOSH recommendations that we have not already covered. With regard to engineering controls, what about the closed system transfer devices?

Dr. Connor said there is literature that says closed system transfer devices do reduce contamination and exposure, although unfortunately they don't eliminate it. So NIOSH recommends these devices only be used inside engineering controls such as a biological safety cabinet. We do not recommend that they be used on a countertop by themselves. I got a call from someone at the Indian Health Services who was having to prepare chemotherapy in the middle of nowhere. In that situation, maybe a closed system transfer device would be applicable because there really isn't any other type of engineering control to use. If it is considered an engineering control. Probably it is. That is the only thing available to nursing. Pharmacy has means of isolation; they have robots, but nursing only has closed system devices.

Deborah Bolton pointed out that there are many different types of closed transfer system. But until there is more research to support the outcome that they are actually closed, it is still necessary to use PPE--such as a respirator when using a closed transfer system to, for example, reconstitute a chemotherapy drug where no biological safety cabinet is available.

Grace Delizo said, starting with page 10, let's go through some of the NIOSH recommendations. What about the use of chemotherapy gloves? Is that something you are using for administration? Are you using other types of gloves? Or are those gloves not being used?

Janine Gundel asked if chemotherapy glove could be defined because there were several kinds--the double short-cuffed glove and the double long-cuffed nitrile glove-- which are chemotherapy tested.

Grace Delizo said such gloves generally have the ASTM designation. They do talk about double gloving, but just in general, Cal/OSHA wanted to know if they were being used across industries and operations. Are you fully incorporating recommendations?

Janine Gundel said at her Kaiser facility they do use double thickness gloves for administration at the bedside. But what brand of nitrile is chemo-tested? I believe they are. And I think double-gloving is required, but not everyone knows that.

Catherine Jansen, also from a Kaiser facility, said that from her experience giving trainings, people know what the standards say, and they know they have to double glove with gloves tested for the chemotherapy agent. But whether they double glove or not is another story. Wearing a single glove is consistent across California, however.

Deborah Bolton said she would agree that PPE use in chemotherapy is inconsistent. We also need to be cognizant that a manufacturer may market their product with the assumption that the glove has been chemo-tested, but they may not have used the ASTM process. At least for gloves there is a specific standard, but nothing has been set up for gowns. The current guidelines have recommended an impermeable gown. There have been some reports that these permeable gowns have been breached during chemotherapy administration. So the recommendation at our facility is that we use

impermeable gowns. With the new reports of permeation, people are beginning to follow the recommendation to use impermeable gowns.

Grace Delizo said that as with glove permeation charts, some gown material may be effective for some chemotherapy drugs, but permeable to others. I don't know if you are looking at that while performing your hazard assessments.

Ed Ochi said San Francisco uses chemo-tested gloves. A caveat about that is that if you look at the ASTM criteria for testing gloves, it actually tests only a narrow subset of the chemo agents out there, I think only 6 or 8 agents. You have to make sure that the tested gloves you use matches your chemo formulary. The problem I'm having is that our procurement department says the vendor says these are chemo-tested gloves, while I'm comparing our formulary against the glove testing profile for the best match against our formulary. Our materials management are challenging me for using gloves that may be twice as expensive as other gloves billed as chemo-tested. So you have to be very careful about this nomenclature of "chemo-tested." You have to see if what the glove was tested against actually matches your formulary.

Dr. Connor said he wrote most of the ASTM standard. We took the drugs that we knew were the most permeable—the worst actors. So we had seven required drugs and two optional drugs. We took a worst case scenario, assuming that if they protected against those drugs, they would be protected against pretty much all the other drugs out there. You just can't test every drug; the cost would be outrageous. The cost for the 'nine-drugs' testing of gloves is in the hundreds of thousands of dollars range. As far as chemotherapy gowns: what I have been noticing lately is that they are being tested to ASTM F739 which is less rigorous than the chemotherapy glove standard. They are using the drugs from the glove standard to test the gowns, but with less rigorous criteria. So more drugs are able to permeate the gowns using that standard.

Deborah Bolton said when her facility was researching gowns, they found that the current design of gowns doesn't provide the same areas of thickness of material that you would see in a glove. The closest design is actually the surgical gown like you would use in an OR. So that is what we went with until we can find another manufacturer. Good Samaritan is a national chain of 160 hospitals. We had to go to materials management and present a case for why we were recommending a gown that was out of contract. Fortunately we have been able to maintain support for use of this safer gown.

Ed Ochi said, on the subject of gowns and testing requirements, you have to be a little bit careful in writing the standard about specifying more than simply stating, "chemo-tested." We are having the same fight with contract versus non-contract gown suppliers. One is presenting us with ASTM F739 tested gowns (which I agree is an over-test, with only a different end-point than the glove test) while the other is offering D6978-tested which has a different end point. The first manufacturer says that's the incorrect test. Materials management is saying— "What are you doing to us?!" Really what we need is criteria for what the minimum has to be. You are going to have to be very explicit there or you will be leaving us at the mercy of our vendors.

Janice Dang said when it comes to hospitals, health care, and compounding pharmacies, the majority is complying with use of chemo-tested gloves, gowns, masks, and booties. However, when it comes to dispensing oral tablets and capsules that are chemo drugs, I do not believe that is the standard that they wear gloves while dispensing the tablets either in a community pharmacy or a hospital. I don't know about nurses administering methotrexate and tamoxifen...

Deborah Bolton said we were still not at the automatic stage yet, where nurses would automatically don gloves for this purpose. That is why an electronic popup is so valuable. For them it would be double gloves; we may even ask for a mask in some situations.

David Ford said medical surveillance should be discussed before the meeting ended, and Grace Delizo agreed.

Brad Ekstrand wanted to know what NIOSH envisioned the medical surveillance requirement to be. Representing oncologists and groups that have relatively small workforces, we would want to know if the regulation would require routine lab testing for techs and nurses and anyone else who works in the office. Would it involve asking those individuals to follow up with their own physicians?

Dr. Connor said NIOSH has really struggled with this. We have talked with many individuals in occupational medicine. Our recommendation is to do an annual health assessment and questionnaire—an annual reproductive health questionnaire for people who are at reproductive risk. Really, you can't do very much. We've talked about incident reports—maybe people who have had a needle stick with chemotherapy, or who have spilled chemotherapy drugs on themselves. For such individuals: do a follow-up, maybe laboratory work. We've gone back and forth on routine laboratory work, but while there may be some benefit from a pre-job and periodic evaluation, medical opinion differs on the value of this.

Kaila Benton-Vitz said she wanted to read a position statement by the UC Davis Occupational Employee Health Advisory Committee: "It has been suggested by OSHA that hospitals establish some medical surveillance program for healthcare workers routinely exposed to hazardous drugs. It is the consensus of the UCDOEHAC that such monitoring programs need not be essential for an effective screening program. Screening is best for a specific identifiable disease with a highly sensitive test where early and effective treatment exists to alter the natural course of that untreated disease. As such we do not recommend that the hospital establish such a program until such time as more specific and effective screening exists for hazardous drug monitoring. We instead endorse maximizing all exposure prevention, engineering and environmental controls as well as enforcing the use of personal protection equipment by workers working with antineoplastic drugs. We do support evaluations for any employee who experiences a significant unprotected exposure to a hazardous drug.

Shelley Carry said the Washington standard requires following the recommendations of the NIOSH Alert, but explicitly excluded medical surveillance. Dr. Connor, do you know why?

Dr. Connor said this is because NIOSH was in the process of updating the NIOSH Alert while Washington was adopting its standard, so they did not include medical surveillance.

Precious Rivera said as a former employee of the VA, she was involved in a spill. I still get routine labs every year.

Catherine Jansen said the bottom line was you still need to have the health assessment for employees who have had exposure even though we don't have a great way to cure any illness that might result from the exposure. If someone had an exposure, we need a way to record that.

Grace Delizo asked if what she was suggesting was that there was a need to establish a baseline following an exposure with a questionnaire?

Catherine Jansen replied affirmatively.

Ed Ochi asked if there were a medical surveillance component of the regulation, would there be a standardized questionnaire such as the one in the Aerosol Transmissible Disease Standard, or would it be up to each facility to develop their own questionnaire, procedure, or screening tool.

Grace Delizo said she would like to see a copy of the ONS Guidelines, because she understood there to be a questionnaire being used there that would be flexible enough for employers to incorporate the specific exposures that they would be trying to screen for.

Ed Ochi said: So you would be either incorporating by reference or bringing it into the standard?

Grace Delizo said that was something Cal/OSHA would be looking at.

Steve Smith said Cal/OSHA was looking for advice.

Ed Ochi recommended that Cal/OSHA adopt a standardized tool.

Grace Delizo said a lot of ground had been covered today, and a lot of input had been heard from stakeholders. We had a communication from SEIU earlier today, saying that they wanted more input from long term health care and similar institutions— those that may not be fully aware of the controls that are available now. So Cal/OSHA will be continuing to reach out to affected stakeholders. We anticipate having another meeting, probably in the fall. Hopefully at that meeting we will have a draft discussion document. You are all welcome to provide additional input to the website we provided. My email and Bob Nakamura's are on that web location as well. We appreciate all of you coming today, and also we appreciate Dr. Connor coming across the country to share this information. Dr. Connor's presentation and the minutes of this meeting will be posted on the website.