

**Airborne Infectious Disease – Laboratories
Cal/OSHA Advisory Meeting
January 14, 2005, Oakland CA**

Chairs: Bob Nakamura, Deborah Gold, Senior Industrial Hygienists, Cal/OSHA

Janice Prudhomme, Department of Health Services, Occupational Health Branch
Janet Macher, Department of Health Services, Environmental Health Laboratory Branch
Sonia Rosenberger, University of California, Berkeley
Jennifer McNary, Department of Health Services, Environmental Health and Safety
Ken Smith, Department of Health Services, Environmental Health and Safety
Rupali Das, Department of Health Services, Occupational Health Branch

Summary of key points

1. Participants agreed that a laboratory section in the standard would allow it to address this specific environment, and would be helpful in gaining compliance with biosafety practices. Participants described some of their experience and knowledge regarding laboratory infectious disease hazards.
2. Participants agreed that the standard should require a biosafety plan with identification of the person responsible for implementation. Generally, their facilities have plans and biosafety officers or, in health care settings, infection control personnel.
3. Participants agreed that the standard should include labs based on procedures. There should be some exceptions possible from the standard based on risk analysis.
4. The CDC publications, Biosafety in Microbiological and Biomedical Laboratories, and Primary Containment for Biohazards, as well as guidelines published by the American Biosafety Association and other jurisdictions provide good guidance. However, there are some problems in the standard simply requiring institutions to follow BMBL recommendations.
5. The standard should address risk assessment, containment, personal protective equipment and other control measures, medical surveillance vaccination and treatment, training and emergency procedures.

Detailed Minutes

Deborah Gold opened the meeting at 9:15, thanking people for coming, and explained that the purpose of this meeting is to discuss a laboratory section for the potential airborne infectious disease standard. The general questions for the day are:

1. What should be done in terms of following established guidelines and what is the actual practice now?
2. What threshold should there be for defining a laboratory (setting the scope)?
3. Should the standard refer to the BMBL? If not, what reference should be used for the standard?

Laboratory hazards

Ken Smith asked if the intent is to revise Cal/OSHA's biosafety cabinet standard [Title 8, California Code of Regulations, Section 5154.2]. D. Gold said it is possible that these discussions may result in a proposal to update or amend this section. She suggested that the first topic of discussion be if there a need for a laboratory section for this standard. Janet Macher asked if there were many employee complaints. D. Gold replied that the Division did receive complaints, sometimes indirectly. Rupali Das described the exposure at the Children's Hospital Oakland Research Institute (CHORI) where laboratory workers were unintentionally exposed to live anthrax. They had been following the internal IRB, but the material was not handled in a hood, because they thought it was non-pathogenic. The problem occurred because the spores had not been inactivated.

Janice Prudhomme said that there have been many brucellosis cases, including at MDL [Microbial Disease Lab]. There are definitely gaps in infection control or biosafety procedures in laboratories. She suggested integrating requirements to fill the gap so that it merges with other required training. J. Macher said that currently, too much is left up to the institution; there is no uniform requirement. R. Das said that there had been infections in laboratory workers at the Veterans Administration in Palo Alto and in the Stanislaus County Public Health Laboratory. K. Smith asked if there was parallel Federal activity to this rulemaking, and D. Gold and R. Nakamura said that they were not aware of any current effort at the federal level.

Jennifer McNary said that there is value in regulations. At Kaiser, the regulations give EH&S some teeth. The BMBL is well accepted, but it is also a minimum standard – they look to the World Health Organization and Canadian standards as more protective. Sometimes people resist safety protocols, saying that the BMBL doesn't require it. Sonia Rosenberger said that they intentionally left guidelines subjective so that there could be some room for interpretation and application. The Canadian standard is unique, they actually go out and approve an institution's program. The National Institutes of Health guidelines are very similar to CDC, but if you get NIH funding, the recommendations become mandatory. A person will come out and inspect the facility. The NIH guidelines will apply to all laboratories in the institution, even the ones not directly funded by them. D. Gold said in her experience, the subcontractors who furnish materials to NIH contractors are not inspected, and some of these are pretty marginal operations. R. Das said that in the anthrax case, they thought it was killed anthrax that they were sent.

S. Rosenberger said that in the absence of a good work culture, it is useful to have regulation. For them, it is usually a funding issue. D. Gold noted that medical professionals have said that the bloodborne pathogens regulations had a large impact in changing work practices and controls.

Scope

J. Macher asked whether the laboratory part of the airborne infectious disease standard should apply only to live agents, or whether it should apply to toxins or fragments. R. Das said that at Children's they had thought the anthrax wasn't live, and technically it was not live. J. Macher asked if you can render an agent non-viable, could you move to lesser precautions? R. Das said that at Children's the receiving institution didn't do tests to confirm that the anthrax wasn't viable. J. Macher asked if there is any infectious risk from fragments. S. Rosenberger said there is a "tat" [transactivator

protein] associated with HIV but this is unusual, and is not normally a problem. Tests for infectivity are unique to the microorganism.

R. Das said that Children's had received, stored and then used the anthrax spores. She said she wasn't sure whether testing would have detected that they were viable. S. Rosenberger said that testing should have been able to pick up that they were viable. The select agent rules (regarding shipping and handling of certain agents) only cover viable agents. Janet Macher suggested that the standard should address agents that were infectious, not fragments or non-viable agents that were allergenic. There was general agreement with this.

D. Gold then asked what kinds of laboratories should be included, clinical, production, or research? J. Macher suggested adding public health laboratories. J. McNary asked what differentiated a public health laboratory. K. Smith said these laboratories oversee clinical labs. J. Macher said that public health laboratory is a distinct category, and there is a certified public health microbiologist classification. A clinical lab is directly linked to patient care. J. McNary asked if the standard meant to include academic or teaching laboratories. S. Rosenberger said that at UC they generally don't distinguish between academic/teaching and research labs. D. Gold asked about whether there were some labs, such as high school biology labs, that should be excluded because the agents were of such little risk. S. Rosenberger said that UC Davis had been asked about controls for work on recombinant DNA in a high school project and J. Macher agreed that issues sometimes arose with special projects such as science fair projects.

K. Smith said that some drinking water can be pretty infectious – they are now starting to use biosafety cabinets in their labs. J. Macher said that in drinking water testing, they were generally looking for a non-infectious indicator organism. K. Smith said that the sample may contain coliform, and no one knows what type until it's cultured. J. Macher said that water testing in a lab is pretty contained, they do grow it, but they don't spread it on plates, or centrifuge it. Maybe the standard should address processes. S. Rosenberger agreed that the focus should be on processes rather than the type of facility. D. Gold and R. Nakamura said that they would look into the type of processes involved in drinking water and sewage treatment laboratories. J. Macher said that in water laboratories they are looking for marker organisms, but there is a possibility of inhaling vibrio. R. Das said that there has been some interest in drinking water in terms of bioterrorism.

D. Gold asked what processes the standard should address. S. Rosenberger said that in her experience, skilled lab personnel do not generate aerosols when dispensing, it depends upon their work practices. Activities that do generate aerosols include centrifuging, inoculation, pipetting and mixing, blending, grinding, sonication, and aspirating from a vessel with a higher pressure. J. McNary added opening a vial that may have higher pressure, and opening vacutainer tubes. S. Rosenberger said they ask people not to open vacutainer tubes, but many people agreed that tubes are opened. K. Smith said that aerosols are created when you snap a vial open. R. Das said that plating can create an aerosol, and mentioned the practice of "sniffing." S. Rosenberger and J. Macher discussed that some microbiology classes still teach the practice of sniffing. Sniffing gives you an idea of what's present. They still run the objective tests to identify. But certain organisms have characteristic odors. S. Rosenberger said there has been some transmission of meningitis by sniffing, and J. Prudhomme said that Brucella may have been transmitted that way.

J. McNary asked about veterinary and animal laboratories? The BMBL and the NIH have guidelines for animal laboratories, and there are biosafety levels for animal labs [ABSL 1, 2, or 3]. Participants thought that most veterinarians should not come under the standard, but facilities with animal laboratories in which infectious agents are present probably should depending on the agents. This generally would not include meat or poultry testing labs. D. Gold noted that there has been a special order for UCSF for many years regarding Q-fever. K. Smith noted that the state runs tests on sentinel chickens for west Nile virus. S. Rosenberger said that this involves testing of blood in the laboratory. J. Macher said that there are clinical and research labs looking at zoonotic diseases.

Participants then discussed pathology labs in hospitals and coroners' offices. J. McNary said that both the autopsy area and the area where specimens are analyzed are called the path lab. There was general agreement that the specimen analysis area should be included as a laboratory, while the autopsy area should come under the general part of the standard. K. Smith noted that a doctor in the army got a TB infection of the bone while doing an autopsy.

J. Macher said that research labs may intentionally generate aerosols of agents, so the standard should include the creation of aerosols. Any aerosol generating procedure should be included, even if the agent is RG1 [Risk Group 1]. S. Rosenberger said that a lot of agents are not listed in the BMBL, but may actually affect a subpopulation. Controls should probably be based on procedures, but what about an agent that is only a plant pathogen. D. Gold asked whether it would be appropriate to create an exception where there is a known agent that is well characterized and isn't pathogenic. K. Smith said there would need to be a training element. J. McNary asked if this would be covered by a risk assessment of the process and agent. J. Macher said that should include a literature search on the pathogen, particularly for those not listed in the BMBL. D. Gold said that how the standard could address this issue would depend on whether it generally required following the BMBL recommendations, or whether the standard specified certain requirements, such as requiring a biosafety cabinet (BSC) unless the agent can be shown to not be a hazard using alternate controls.

Biosafety cabinets, BMBL, and Biosafety Plan

K. Smith noted that his facility had some problems with BSC units that were not properly interlocked with the general ventilation system. If the exhaust fan in a room drops out, the supply fan should shut off also, in order to avoid positive pressurization. All fans should stop if the BSC fan stops, if there is a hard ducted fan, to avoid circulating air from the BSC. You need to watch for bad design and installation and there should be a maintenance schedule. D. Gold said that there may be more on maintenance in the CDC "green book," their publication on primary containment. S. Rosenberger said that a lot of BSC manufacturers have interlocks, and that everyone has problems with B2 cabinets. J. McNary suggested referencing the CDC publication on primary containment, and also requiring commissioning of building systems. K. Smith said that a CDC group had come through his facility, and had a list of requirements that had not been met.

J. Macher said that the standard also needed to address warning signs and posting. K. Smith said that in his facility, the BSL 3 laboratories have been temporarily downgraded to BSL 2. A lot had to do with ventilation. Also a recently installed BSC had a design flaw creating a leak at the plenum so that dirty air leaked out the front. J. McNary said that the NuAire had a positive pressure plenum

and a gasket had failed. The BSC had passed certification, but a microbiologist used soap bubbles to demonstrate the air flow. They have now created a negative pressure plenum. J. McNary noted that the National Sanitation Foundation publication 49 requires testing of positive pressure plenums, and that Title 8, Section 5154.2 refers to that. D. Gold pointed out that because it is recommendation in a note, it is not an enforceable requirement. Annual velocity testing is required under section 5143, which is specifically mentioned in the standard. She suggested that people review Cal/OSHA's BSC standard (Section 5154.2) to see if there is a need for updating or changing it, and let B. Nakamura or D. Gold know.

D. Gold asked if there were any problems in referencing the BMBL. A participant asked about referencing other standards, such as the Canadian standard. D. Gold said it was more likely that a standard could reference a CDC publication, but if there are specific problems with the BMBL, or something that needs strengthening, we should discuss it. S. Rosenberger said that the BMBL requires wearing goggles with contact lenses, which is unnecessary and cumbersome. Lab facility guidelines are left subjective for a reason, so you should be cautious about making them into requirements. K. Smith said it should prohibit using a non-filtered hood in place of a BSC. There are still a lot of fume hoods in biology labs.

D. Gold asked if BSCs should be specified as a minimum for aerosol generating procedures with infectious agents, or are there exceptions. S. Rosenberger said that there should be a definition of primary containment to include engineering controls, and maybe give examples. The BMBL includes more than engineering controls as primary containment. This is different than the approach in the bloodborne pathogens standard, where the specification of separate control measures makes it harder to apply. The standard should have a containment matrix. She suggested that it also define infectious agents. She does support using the BMBL. J. McNary noted that BMBL doesn't talk about respirators very much. J. Macher asked if the new BMBL would have more. S. Rosenberger said the new BMBL will not be going towards more prescriptive requirements.

J. McNary said that the standard should address emergency plans, identification of responsible individuals, personal protective equipment, and respirators. D. Gold summarized suggested elements of the lab part of the standard which would be based around a written plan, analogous to the chemical hygiene standard. These include identification of a biosafety officer and lines of authority, risk assessment, engineering controls, personal protective equipment, respirators, biosafety cabinets including when to use and maintenance, procedures for higher risk agents or activities, emergency plans, and where appropriate an interface with hazard communications or chemical hygiene plans. K. Smith said that DHS has an excellent biosafety officer, Heike Quinn, who has written many plans, and could be a good resource for this process. S. Rosenberger asked whether the plan could be for an institution as a whole, or for each lab. She suggested that there could be one biosafety officer, and a general plan, with specific procedures as necessary. J. McNary said she would like to see clear requirements for a biosafety officer, including that the person have oversight over labs, conducts risk assessment, and develops and implements a plan. S. Rosenberger suggested looking at the ABSA website for a definition. She didn't recommend specifying that the person be a certified biosafety professional, but that the person should have some minimum of experience and training.

S. Rosenberger noted that the NIH requires a biosafety committee to review BSL-2 and above work at institutions that it contracts with. She asked if there was a requirement like that in the chemical hygiene standard and D. Gold said there was not, but it could be part of the chemical hygiene plan. She asked whether facilities have biosafety staff. S. Rosenberger said that biosafety staff usually administer the committee, which is work, but the committee is also a lot of help, because they're the "stick" for enforcing the program, because they are peers. Usually the committee will include someone with good specific microbiology background, as well as an EH&S representative, and for NIH committees, a community representative. They always include appropriate subject matter experts. K. Smith said that in a hospital the biosafety staff would overlap with infection control. S. Rosenberger said that in a health care setting they would defer to infection control where there's an overlap with patient care. J. McNary said that a committee is important for reviewing changes in equipment or instrumentation, and that would also be the safety committee. You need a procedure for review by qualified people, and it is helpful if the committee is multi-disciplinary. She asked if a biosafety committee could meet requirements for a safety committee. D. Gold explained that there is no current requirement in California for health and safety committees, but employers can use them to meet communications requirements of the Injury and Illness Prevention Program. S. Rosenberger said that NIH has very formal committee requirements. She said that she likes language, similar to the bloodborne pathogens standard, about employee review of the program. It is good to let people know they can comment, but it's hard to document that the process has occurred. S. Rosenberger suggested contacting BSAFE.

D. Gold asked whether there was some size or type of laboratory that should be excluded from the standard. She asked if the standard should apply to a doctor's office with a centrifuge. Several people thought it should. There was some discussion that if they are centrifuging blood, the bloodborne pathogens standard would apply. D. Gold asked about collection of sputum. S. Rosenberger said that there are guidelines to prevent aerosolization. D. Gold asked about the CDC guidance for laboratories for SARS relating to aliquoting and dilution. Janet Macher suggested contacting the laboratory licensing section of the department of health services (Carol Glaser) for input on the definition of a laboratory.

Medical Surveillance

D. Gold asked if people followed recommendations in the BMBL regarding exclusion of certain people from higher BSL levels, such as the exclusion of pregnant women. People agreed that they did not. S. Rosenberger said that if they are working with lysteria or toxoplasma, they will post signs and prohibit entry for non-lab people. They will refer pregnant employees to an occupational medicine physician to evaluate their particular risk and precautions.

R. Das said that medical surveillance should be developed in consultation with a physician. Some control measures depend on immunizations. At CHORI, people were not immunized, although people working at the manufacturer were. Employee health would like more jurisdiction over who to vaccinate, and would like to have individual specifications. An occupational health physician should evaluate the need for medical surveillance and vaccination based on the pathogen and the specific procedures and conditions in the lab.

K. Smith said that in his facility, personnel have specific inoculations for specific agents. Participants generally agreed that the BMBL has good recommendations for vaccination, and that they also follow recommendations from the Advisory Committee on Immunization Practices (ACIP). R. Das said that one of the problems at CHORI was that employee health was not aware of the research at the institute. Their system relied on information from the primary investigator. S. Rosenberger said there should be a system of medical surveillance for research. J. Macher asked if facilities were storing serum. S. Rosenberger said that it's only recommended for animal facilities, and those are the only people she knows who do it. In terms of following treatment recommendations by the CDC, R. Das said that some of these are reportable diseases, so the state DHS would also get involved. She suggested referring to DHS recommendations as well, and contacting Jon Rosenberg about this issue. J. Macher said the county health officer is also a good source of information. S. Rosenberger said that for BSL 3 or above, a physician should be involved in the program.

Respirators

D. Gold asked if respirators were being used in laboratories, and which types were used. J. Macher said that it was rare to require them. S. Rosenberger said that not all BSL 3 laboratories use respirators. J. McNary asked if it was more common for entry into areas with unknown or emerging pathogens. R. Das said MDL would use respirators in BSL3 when there was an equipment breakdown. BSL 3 containments should be adequate. J. McNary asked if the BSC provides adequate protection. She suggested using respirators for uncharacterized risk. K. Smith said that they use an N95 for TB. One person uses a powered air purifying respirator (PAPR) with an elastomeric facepiece. S. Rosenberger said that their TB lab uses respirators. Not all BSL 3 labs use respirators – it depends on the agent and the institution. K. Smith said the employer should provide respirators if requested; it could come under voluntary use, but be provided by the employer. He said that they fit-test employees if they want to be. J. McNary said that the provision of respirators in their facility comes under the respiratory protection program, not their biosafety plan. K. Smith said that some employers will say that since the respirator isn't needed, they won't provide it. J. McNary suggested listing the agents where the CDC recommends respirator use. S. Rosenberger said that respirators should be used in BSL 3 for aerosols.

D. Gold asked about respirators for emergency response. J. McNary said that an emergency is defined in part by where it occurs. Several participants agreed that a spill in BSL3 outside of a BSC would be an emergency that would require use of a respirator. BSL2 should not require a respirator to clean up. S. Rosenberger said that TB handled outside of a closed system and brucella are BSL 3. J. Macher said that they provide an N 95 for that purpose. S. Rosenberger said she cleaned up one spill using a fullfacepiece with a HEPA and organic vapor cartridge (for the disinfectant). J. McNary said that they have full facepiece PAPRs for emergencies. Risk can be minimized through other procedures, such as the recommended waiting times. Still, a risk of 5 percent with the N95 may not be acceptable. J. Macher said that risk assessments and waiting times involved certain assumptions that may not be substantiated. K. Smith said that the people in the terrorism unit advocate Level A for unknown spills, with a special room to receive specimens.

S. Rosenberger said that in spills outside of a cabinet in BSL3 laboratories, a risk assessment should consider factors such as the volumes spilled and the maximum titer. Some spills require special

agent cleaning, and asked if the standard would address BSL4. She said she couldn't make an argument for SCBAs, but there is a need to go beyond the N95. Several people agreed. Several participants discussed that a spill should be treated before it is touched to avoid creating an aerosol, but that the specifics of the spill effect the efficacy of disinfection, and that a spill may need to be absorbed and then treated. There is some discussion of spills in the MMWR.

Follow Up

Participants were asked to provide existing biosafety plans to D. Gold and B. Nakamura. They will work on some language for a laboratory section. People were asked to provide contact information for resource people, and to review the Biosafety Cabinet standard.