

**OCCUPATIONAL SAFETY  
AND HEALTH STANDARDS BOARD**

2520 Venture Oaks, Suite 350  
Sacramento, CA 95833  
(916) 274-5721  
FAX (916) 274-5743  
[www.dir.ca.gov/oshsb](http://www.dir.ca.gov/oshsb)

**FINAL STATEMENT OF REASONS**

## CALIFORNIA CODE OF REGULATIONS

TITLE 8: Division 1, Chapter 4, Subchapter 7, Group 16, Article 109, New Section 5199  
of the General Industry Safety Orders

Aerosol Transmissible Diseases**MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM  
THE 45-DAY PUBLIC COMMENT PERIOD**

There are no modifications to the information contained in the Initial Statement of Reasons (ISOR) except for the following substantive, and/or sufficiently related modifications that are the result of public comments and Board staff evaluation.

This proposed rulemaking action contains nonsubstantive, editorial, reformatting of subsections, and grammatical revisions. These nonsubstantive revisions are not all discussed. In addition to these nonsubstantive revisions, the following actions are proposed:

Contents

This subsection as originally noticed, used the term “surveillance” to describe the set of medical services that would be provided to an employee with occupational exposure as a preventive measure, or to an employee who has had an exposure incident. However, these services are not all included within the common language use of the term “surveillance.” Therefore, a modification is proposed to the list of Contents for subsection (h), and at several other places in the proposal, to replace the term “medical surveillance” with the term “medical services.” The term “surveillance” will be used only to identify the program to look for and record tuberculosis infection among exposed employees.

Subsection (a)(1)

This subsection, as originally noticed, listed public health services as one of the categories of health care services that were within the scope of coverage, but did not describe to which public health services the standard applied. A modification is proposed to move subsection (a)(1)(A)6 Public Health Services to become subsection (a)(1)(D). The new listing includes language that more accurately describes the scope of public health services meant to be covered by this standard. This change resulted in the renumbering of the following subsections (A)7-10 to (A)6-9, and (a)(1)(D)-(H) to (E)-(I). The purpose and necessity for this is to better define this category of services.

Subsection (a)(1)(C)

This subsection, as originally noticed, identified police services when reasonably anticipated to be provided to cases or suspected cases of aerosol transmissible diseases. A modification is

proposed to more specifically identify those police services to which this standard will apply. The purpose and necessity is to better define this category of services.

Subsection (a)(1)(I)

This subsection, as originally noticed was subsection (a)(1)(H) and identified maintenance, renovation and service or repair operations involving air handling systems or equipment or building areas that may reasonably be anticipated to be contaminated with aerosol transmissible pathogens. Comments to the Board noted that this could be construed very widely to apply to air handling systems in any building, whereas the actual intent was to focus on systems that are directly connected to rooms or areas where individuals who are symptomatic or have an ATD are isolated or treated. A modification is proposed to clarify that this subsection applies to air handling systems that serve airborne infection isolation rooms or areas, and to ventilation systems such as laboratory hoods that are used to contain infectious aerosols. The purpose and necessity for this change is to provide greater clarity as to what activities are included within the scope of this standard.

Subsection (a)(2)(A)

This subsection as originally noticed excluded from the scope of this standard dental offices that screened patients for ATDs and did not perform dental procedures on those patients. Several commenters stated that this exclusion did not provide a mechanism to ensure that the screening procedures would be carried out, and that employees would be trained in those procedures. A modification is proposed to add the phrase “The Injury and Illness Prevention Program includes a written” before the phrase “procedure” to clarify that the screening procedures are to be included in the Injury and Illness Prevention Program. A further modification is proposed to add the requirement that “Employees have been trained in the screening procedure in accordance with Section 3203.” The purpose and necessity of these modifications is to provide a mechanism to ensure that dental offices who wish to come under this exemption will provide the screening and training necessary to ensure that employees are not unreasonably exposed to ATDs.

Commenters were also concerned that a physician may not be able to determine whether a given dental procedure posed a transmission risk when performed on an individual who had an ATD. As a result, the last requirement of this subsection has been modified to state that once an individual has been screened as being a potential ATD case, dental procedures would not be performed unless a physician determined that the person did not have an ATD. The purpose and necessity of this modification is to ensure that dental procedures, which are capable of aerosolizing infectious pathogens, are not performed on persons with a transmissible disease.

Subsection (a)(2)(B)

This subsection as originally noticed excluded from the scope of this standard outpatient medical specialty offices whose policy is not to diagnose or treat ATDs, if the office did not perform aerosol-generating procedures on ATD cases or suspected cases and the employer had a screening procedure to identify and refer those patients for further medical evaluation to an appropriate medical provider. Several commenters stated that this exclusion did not provide a mechanism to ensure that the screening procedures would be carried out, and that employees

would be trained in those procedures. A modification is proposed to add the phrase “The Injury and Illness Prevention Program includes” before the word “written” to clarify that the screening procedures be included in the Injury and Illness Prevention Program. A further modification is proposed to add the requirement that “Employees have been trained in the screening procedure in accordance with Section 3203.” The purpose and necessity of these modifications is to provide a mechanism to ensure that medical specialty offices who wish to come under this exemption will provide the screening and training necessary to ensure that employees are not unreasonably exposed to ATDs and to clarify what conditions must be met by outpatient medical specialty practices that are not intended to be covered by the standard.

Subsection (a)(3)(A)3

A modification is proposed to clarify that the persons to whom referring employers do not intend to provide services beyond first aid, initial treatment and screening or referral, are those persons who are cases or suspected AirID cases.

Subsection (a)(4)

The proposal as noticed used the term “medical surveillance and management” to refer to certain protective medical services that would be provided to an employee. This term has been changed to “medical services,” which encompasses all of the functions referred to by the previous wording. The necessity and purpose of this modification is to reflect that the medical services required by this section are not all included within the common language meaning of “surveillance.” This is consistent with the change described above for the list of “Contents”.

Subsection (b) Definition of “Aerosol Transmissible Disease or Pathogen”

The proposal as noticed defined this term as a disease or pathogen for which airborne or droplet precautions are “recommended.” The term “recommended” is changed to “required” to be consistent with the text of this section.

Subsection (b) Definition of “Case”

A formatting modification is proposed for the definition of case to clarify that it refers to either of two conditions.

Subsection (b) Definition of “CTCA”

A modification is proposed to define the term CTCA, to mean California Tuberculosis Controllers Association (CTCA). The purpose and necessity of this is to identify the organization of local tuberculosis controllers that issues consensus guidelines regarding case identification, treatment, management, and prevention of tuberculosis in California.

Subsection (b) Definition of “Emergency medical services”

A modification is proposed to define the term “emergency medical services,” to mean medical care provided by certified emergency medical technicians or licensed paramedics, as defined by Title 22. The purpose and necessity of this is to clarify the scope of this section and to be consistent with other regulations.

Subsection (b) Definition of “Epidemiology and Prevention of Vaccine-Preventable Diseases.”

A new definition is proposed to identify the reference for recommendations for vaccine-preventable diseases. This definition is necessary in order to establish the national public health reference for vaccine preventable diseases.

Subsection (b) Definition of “Exposure incident”

A modification is proposed for the definition of the term “exposure incident” to include the instances where an employee is exposed to an area or equipment that has been contaminated with infectious ATD material without the control measures required by this section.

Subsection (b) Definition of “Health care worker”

As originally noticed, subsection (b) had a definition for health care worker that included employees in the category of service which was consistent with the scope. A modification for the term “health care worker” is proposed to include employees in public health operations as identified in the modified subsection (a)(1)(D). This change is necessary for consistency.

Subsection (b) Definition of “M. Tuberculosis”

As originally noticed, *M. tuberculosis* was defined as the bacterium that causes tuberculosis. A modification of this definition is proposed to use this term to refer to *M. Tuberculosis* complex, which includes four Mycobacterium species which cause tuberculosis disease in humans, and to which public health recommendations regarding tuberculosis apply. These organisms are: *M. tuberculosis*, *M. bovis*, *M. Africanum*, and *M. microti*. The necessity and purpose of this modification is to ensure that protective measures are taken to prevent tuberculosis transmission to employees covered by this standard.

Subsection (b) New Definition of “Medical specialty practice”

In response to several comments this term has been defined as a medical practice other than primary care, general practice, or family medicine.

Subsection (b) Definition of “Occupational Exposure”

As originally noticed, the definition of occupational exposure used the term “at-risk” populations, in order to explain what work activities would involve occupational exposure. The term “at-risk” was not defined. A modification is proposed to change this term to “facilities identified in subsection (a)(1)(E),” the renumbered subsection that refers to homeless shelters, correctional facilities and drug treatment programs. This modification is made in the interest of clarity of the proposed definition.

Subsection (b) Definition of “Public health guidelines”

A new definition is proposed to define “public health guidelines” to mean, for tuberculosis, certain guidelines published by the CTCA and/or California Department of Public Health (CDPH), and for vaccine preventable diseases, to mean Epidemiology and Prevention of Vaccine-Preventable Diseases. These documents are incorporated by reference. For other diseases, “public health guidelines” is defined to mean recommendations of the local health officer or CDPH that are provided under the authority of the California Health and Safety Code

or Title 17 of the California Cod of regulations. The purpose and necessity of this definition is to identify the medical guidelines that are to be used in providing medical services to employees.

Subsection (b) Definition of “Referring employer”

In the original proposal, the definition section for referring employer did not specifically exclude acute care hospitals. A modification is proposed to clearly state that general acute care hospitals are not referring employers. This is necessary to provide clarity.

Subsection (b) Definition of “Reportable aerosol transmissible disease (RATD)”

A modification is proposed to define an RATD as being a disease that both meets the definition of an aerosol transmissible disease and is reportable in accordance with Title 17. This modification is proposed for clarity.

Subsection (b) Definition of “Screening (health care provider)”

In the original proposal, the definition of this term included the statement that screening does not include diagnostic tests. A modification is proposed to change the statement to reflect that screening does not include high hazard procedures. The purpose and necessity of this modification is to recognize that non-aerosol generating tests are often conducted in primary care facilities and do not unreasonably expose employees to the risk of contracting an ATD.

Subsection (b) Definition of “Screening (non health care provider)”

In the original proposal, the definition of this term included the statement that screening does not include diagnostic tests. A modification is proposed to change the statement to reflect that screening does not include high hazard procedures. The purpose and necessity of this modification is to recognize that non-aerosol generating tests do not unreasonably expose employees to the risk of contracting an ATD.

Subsection (b) Definition of “Susceptible person”

In the original proposal, the definition for susceptible person was based on a determination by a PLHCP using “CDC or CDPH” guidelines. A modification is proposed to change this reference to “applicable public health guidelines,” which is defined in terms of specific documents incorporated by reference. This modification is necessary to clarify the sources of this information.

Subsection (c)(1)

As originally noticed, subsection (c)(1) required the program administrator to implement and maintain infection control procedures. A modification is proposed to require that these procedures be in writing and be available at the worksite. The purpose and necessity for this modification is to ensure that employees and supervisors will be able to refer to the procedures when necessary, and to be consistent with Section 3203. A modification is also proposed to require that these procedures identify the job categories in which employees have occupational exposure. The purpose and necessity of this modification is to ensure that employees and supervisors know which employees are included in the plan. A further modification is included which requires that the infection control procedures include the procedures for the cleaning and

disinfection of the work area, vehicles and equipment that may pose an infection hazard to employees. The purpose and necessity for this modification is to ensure that the employer's infection control procedures include the means of disinfection, in order to prevent indirect transmission of aerosol transmissible pathogens.

Subsection (c)(3)(B)

As originally noticed the minimum set of screening requirements for non health care providers required referral for persons who have a "persistent" cough. A modification is proposed to change this to require a referral for persons who have a "cough for more than three weeks." The purpose and necessity of this change is to be consistent with the screening criteria in Appendix F. Also as originally noticed the screening requirements included referral for a person who exhibited signs and symptoms of influenza-like illness outside of the period in which seasonal influenza typically occurs. A modification is proposed to require referral based on influenza-like symptoms that persist for more than two weeks at any time during the year, since that would indicate that the person might have an ATD other than seasonal influenza. The purpose and necessity of this modification is to conform with current public health recommendations for the screening of people in settings such as homeless shelters and drug treatment programs.

Note to subsection (c)(3)

A modification is proposed to replace the term "procedure" with the term, "criteria." The purpose and necessity for this is to improve the clarity of the text.

Subsection (c)(4)

As originally noticed, this subsection required the employer to establish, implement and maintain effective procedures for communication with employees and other employers regarding the infectious diseases status of referred patients. A modification is proposed to include the local health officer in the parties with whom the employer will communicate. The purpose and necessity of this modification is to place the employer in communication with the local health officer, who under the Health and Safety Code has responsibility for public health issues in their jurisdiction, and can provide expert recommendations regarding communicable diseases.

Exception to subsection (c)(5)(C)

As originally noticed, condition ii of the exception required the employer to have written procedures that specified the conditions of operation. A modification is proposed to require that these procedures be implemented. The purpose and necessity of this modification is to ensure that employers who utilize this exception to the use of respirators when transporting cases and suspected cases in vehicles implement the written procedures.

Subsection (c)(7)

As originally noticed, this subsection required a referring employer to provide the initial and annual training to employees. A modification is proposed to require additional training if there are changes in the workplace or procedures that could affect the employee's exposure to aerosol transmissible pathogens. This is necessary to ensure that employees are informed in a timely

manner about new hazards or procedures, and therefore to be able to implement effective control measures.

Subsection (c)(7)(G)

As originally noticed, this subsection required the employer to include in the employee training, information about the medical services that would be available and the methods for reporting an exposure incident. A modification is proposed to include information about the employer's procedures for providing an exposed employee with post exposure follow-up services. This is needed to inform an employee about how the employer will provide testing, prophylaxis or other medical follow-up in the event of an exposure incident.

Subsection (c)(7)(I)

A modification is proposed to include the phrase "in accordance with subsection (c)(8)" to clarify what is meant by the requirement of this subsection that employees be trained in how they can participate in reviewing the effectiveness of the employer's infection control procedures.

Subsection (c)(7)(J)

As originally noticed, this subsection required that employees be provided with an opportunity for interactive questions with the person conducting the training. A modification is proposed to address requirements when training is conducted by methods other than an in-person training session, such as computer or web-based training. In those circumstances, the modification would require that the employee be provided with an opportunity for interactive questions to be answered within 24 hours of the training by a knowledgeable person. This is necessary to provide employers with more flexibility in providing training to employees, especially in cases where an employer has more than a single work shift. This also allows for greater opportunities for employees to be trained during their normal work hours.

Subsection (c)(8)

A modification is proposed to clarify the language regarding the annual review of infection control procedures. Language is proposed that would require infection control procedures to be reviewed at least annually by the administrator and by employees regarding the effectiveness of the program in their respective work areas. This is necessary in order to clarify requirements to involve employees in the annual review of procedures.

Subsection (d)(2)(E)

As originally noticed, this subsection required that an employer identify methods of implementation of the Exposure Control Plan (Plan) and to list them for each type or group of tasks, operations, or work areas in which occupational exposures occur. A modification is proposed to remove the words "type or group of tasks," in response to comments that this element could be interpreted to require that the plan be overly detailed, and would not provide useful information. It is proposed to specifically identify "cleaning and decontamination procedures" as among the measures that must be included. This change is necessary to ensure that the employer includes appropriate cleaning and disinfection methods to prevent indirect methods of transmitting aerosol transmissible pathogens (ATPs).

Subsection (d)(2)(F)

As originally noticed, this subsection described requirements for surge procedures, or for receiving of persons from the scene of a release of a biological agent. A modification is proposed to move this content to subsection (d)(2)(Q) in which all ATD plan requirements related to surge would be located. The purpose and necessity of this change is to recognize that response to these conditions must be coordinated with local and regional all-hazard response plans.

Subsection (d)(2)(M)

A modification is proposed to remove the phrase “surge situations” from language in this subsection regarding maintaining supplies of personal protective equipment. This issue is proposed to be addressed as part of the surge requirements in subsection (d)(2)(Q). The purpose and necessity for this change is to consolidate requirements for surge planning.

Subsection (d)(2)(P)

As originally noticed, this subsection required that the ATD Exposure Control Plan include procedures to involve employees in the review of the ATD Plan. In response to comments, a modification is proposed to use more precise language to address these requirements. This is necessary to ensure that employers, plan administrators and employees understand how employees can effectively participate in the review of the plan.

Subsection (d)(3)

As originally noticed, this subsection required an annual review of the Plan by the program administrator and employees in the affected work area. In response to comments, a modification is proposed to add the sentence that “Deficiencies found shall be corrected.” This is necessary to ensure that deficiencies found in infection control procedures are corrected, in order to reduce the risk to employees of contracting an ATD.

Subsection (d)(4)

This subsection in its original form did not reference time limits and other issues in regards to accessing the Plan. A modification is proposed to require that these records be made available in accordance with subsection (j)(4), which addresses access to various records under this standard.

Subsection (e)(1)(A)

As originally noticed, this subsection required the implementation of work practices to control transmission of ATDs via airborne, droplet and contact routes. A new phrase is added to require implementation of these measures in accordance with Appendix A and in accordance with the Guideline for Isolation Precautions where it is not addressed in Appendix A. The need to apply contact precautions to certain patients, for example, are not addressed in Appendix A, but are addressed in the Guideline for Isolation. The necessity and purpose of this change is to clarify that it is appropriate precautions that must be taken for each disease, and to reference Appendix A, which distinguishes between diseases requiring droplet precautions and diseases requiring airborne infection isolation. Contact precautions may or may not be required for these diseases, and those recommendations are listed in the referenced document. Also, the note to this

subsection, as originally noticed, provided examples of work practice controls. In response to comments, references to personal and respiratory protective equipment were removed from the note, to clarify what is meant by work practices as compared to personal or respiratory protective equipment.

#### Subsection (e)(3)

As originally noticed, this subsection was written to apply to contract or temporary employees who may “incur” occupational exposure. This was intended to apply to employees at the facility who would perform work such as patient care, or maintenance of engineering controls for high hazard procedures or airborne infection isolation areas. In response to comments, a modification is proposed to clarify that the contractors who are required to be informed are the ones who have employees who can “be reasonably anticipated to have occupational exposure.”

#### Subsection (e)(5)(B)1

As originally noticed, subsection (e)(5)(B) was constructed to differentiate the transfer process within a facility as opposed to a transfer from one facility to another. However there may be times in which even large health care facilities may not have sufficient airborne isolation facilities to accommodate the patient load. These incidents would likely require more than five hours to rectify, and might require transferring patients elsewhere. Therefore, a modification is proposed to allow employers who are not able to provide an appropriate transfer within their facility to follow the same procedure that is proposed for facilities that will routinely make transfers. The change is intended to allow an employer the same flexibility when providing an appropriate placement to another facility as established in (e)(5)(B)2.

#### Subsection (e)(5)(B)2

As originally noticed, this subsection contained a list of five activities that an employer must perform if an employer does not transfer a patient requiring airborne infection isolation within the timeframe provided. The language has been restructured to state explicitly that each activity must be performed. The purpose and necessity for this change is clarity within the text. (References to this exception in other subsections have also been changed.)

#### Subsection (e)(5)(B)2.e

As originally noticed, this subsection required respirator use by a susceptible employee who entered a room or area in which a person awaiting transfer to another facility is housed due to the unavailability of appropriate isolation facilities. A modification is proposed to remove the term “susceptible,” since all people are considered susceptible to tuberculosis, the most prevalent disease requiring airborne infection isolation. For vaccine-preventable diseases, it may be difficult to determine, particularly in a short timeframe, whether even a vaccinated individual is immune. An additional modification is proposed to require the use of appropriate personal protective equipment in addition to respiratory protection in this circumstance. This is necessary to ensure that employees are protected against droplet or contact transmission, where needed.

#### Exceptions to subsection (e)(5)(B)

As originally noticed, exceptions were provided to the requirements for timely transfers of patients requiring airborne infection isolation to other facilities that were contained in subsections (e)(5)(B)2. These exceptions pertained to situations in which either there was a medical reason that prevented transfer of a patient, or in which it was not feasible to provide AII due to infection with a novel or unknown pathogen. This exception has been retitled to reflect that the exception would apply to transfers within a facility, as well as to transfers outside of a facility. The purpose and necessity of this modification is to ensure that within facility transfers are provided with the same options as transfers between facilities.

Subsection (e)(5)(C)

As originally noticed, this subsection required that high hazard procedures are to be performed in airborne infection isolation rooms or areas. It did not address the issue of what protective measures would be required for other employees who might be assigned to work in that area during the procedures. Generally, employees not involved in performing the high hazard procedure should be excluded from the area, however, that is not always possible. Therefore a modification is proposed to clarify that in high hazard procedure areas, individuals who are not directly involved in conducting the procedure must also be using the respiratory and protective equipment that is required for the employees performing the procedure. This is to assure that bystanders are not exposed to aerosols generated by these procedures without appropriate personal protective equipment.

A modification to the Exception to this subsection is also proposed to assure that when high hazard procedures are not conducted in an AII room or area, employees working in the area where the procedure is performed must also use personal protective equipment (as well as respiratory protection). This is necessary to reduce the risk to these employees of contracting an ATD.

Subsection (e)(5)(D)4.

A modification is proposed to add the words “exhaust or recirculation” to describe those filters that must be maintained, inspected and performance monitored in regards to use in AII rooms or areas. This modification is proposed to clarify that filters that are not part of controlling exposure to ATPs are not subject to this requirement.

Subsection (e)(5)(D)9.

A modification is proposed, in response to comments, to add the phrase “Table 1 in” in the referenced tuberculosis (TB) guideline, to clarify the method of determining when employees may enter a previously occupied AIIR without respiratory protection.

Subsection (f)(2) and (f)(3)

As originally noticed, subsection (f)(2) required an employer with a laboratory facility to implement feasible engineering and work practice controls, as well as the use of appropriate personal protective devices in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL) reference. A modification is proposed to clarify that the employer’s biological safety officer is to perform a risk assessment consistent with Section II of the BMBL

for procedures involving ATPs-L, in order to determine what safe practices are necessary for the agent/procedure. This subsection would further require the biosafety officer to record this determination in the biosafety plan. The previous language from subsection (f)(2) was renumbered to subsection (f)(3). An additional modification to the language in renumbered subsection (f)(3) is proposed to require the employer to utilize the findings of the risk assessment as the basis for implementing feasible engineering and work practice controls. These modifications are made to more clearly require an appropriate risk assessment, and to require that control measures will be based on that assessment. The necessity and purpose of the changes are to ensure that the employer evaluates the potential exposure to a specific organism and process, and applies appropriate controls on a case-by-case basis.

#### Subsections (f)(4) and (f)(5)

Subsections (f)(3) and (f)(4), as numbered in the original proposal, are renumbered to subsections (f)(4) and (f)(5) respectively, due to the insertion of new subsection (f)(2).

#### Subsection (f)(4)(K)

As originally noticed (as subsection (f)(3)(K)), this subsection referred to medical surveillance and directed employers to use recommendations from the CDC or CDPH. A modification is proposed to change the wording to medical “services” and “applicable public health guidelines.” The purpose and necessity for the changes are explained above.

#### Subsection (g)(3)(A)

This subsection as originally noticed required the employer to provide a higher level of respiratory protection if one is recommended by the CDC or CDPH. A modification is proposed to require employers to provide a higher level of respiratory protection if the employer’s evaluation of respiratory hazards determines that a higher level is necessary. The purpose and necessity for the change is to recognize the employer’s obligation to assess whether a given level of respiratory protection is sufficient, and to be consistent with Section 5144.

#### Subsection (g)(3)(B)

This subsection originally limited the type of respirator to be used for performing high hazard procedures to a Powered Air Purifying Respirator (PAPR). A modification is proposed to allow the use of respiratory protective equipment that provides equivalent protection. The purpose and necessity for this is to allow an employer more flexibility in providing an appropriate respirator. The phrase “and to employees who perform high hazard procedures” is also inserted before the words “on cadavers” for clarity.

Exception 1 to subsection (g)(3)(B) is proposed to apply to situations where a high hazard procedure is performed by placing the patient within an enclosure that is equipped with local exhaust ventilation that effectively removes the aerosols generated by the procedure. The exception would allow the employees performing the procedure, and not within the enclosure, to use a respirator that is not as protective as a PAPR but otherwise meets the requirements of section (g)(3)(A). The purpose and necessity for this is to allow more flexibility in respirator selection where the risk has been reduced due to the use of an effective engineering control.

Exception 2 to subsection (g)(3)(B) is proposed to permit the use of a P100 respirator instead of a PAPR by paramedics and other emergency medical personnel in field operations. This is necessary to provide the most effective level of protection to these employees in which PAPR use may not be feasible.

New subsection (g)(3)(C)

New subsection (g)(3)(C) is proposed to clarify the required process for respirator selection in a laboratory operation. The proposed modification to subsection (f)(2) requires a risk assessment. This new subsection requires that the risk assessment be used for selecting respiratory protection. The purpose and necessity for this change is to make the two requirements consistent and clear.

Subsection (g)(4)

A modification is proposed that states that the employer is to provide a respirator that is selected in accordance with subsection (g)(3) and Section 5144. The purpose and necessity for this is to ensure that appropriate respirators are selected.

Subsection (g)(4)(D)

As originally noticed, this subsection required that respirators be used when an employee works in an area occupied by an AirID case or suspected case and during decontamination procedures. A modification is proposed to also require that respirators be used as required by (e)(5)(D)9, which specifies respirator use until the area has been sufficiently ventilated. The purpose and necessity for this change is to provide consistency and clarity within the text of the proposal.

Subsection (g)(4)(F)

As originally noticed, this subsection required the use of respirators when aerosol-generating procedures were performed on cadavers suspected or confirmed as being infected with airborne infectious pathogens. A modification is proposed to change this to cadavers suspected or confirmed as being infected with aerosol transmissible pathogens. The purpose and necessity for this is to be consistent with subsection (g)(3)(B). Respirator use is also necessary because aerosol-generating procedures performed on cadavers may create airborne infectious aerosols that would not be created through the respiratory secretions of living patients and therefore all aerosol transmissible pathogens may create a risk that must be protected against through the use of respirators.

Subsection (g)(4)(H)

As originally noticed, this subsection required the use of respirators when an employee transports an AirID case or suspected case in an enclosed vehicle or within the facility when that individual is not masked. A modification is proposed to clarify this language, to mean that respirator use is required during transport if the patient is not masked, whether the transport is in a vehicle or within the facility. The purpose and necessity of this modification is clarity. A change is also proposed in the exception to subsection (g)(4)(H) to clarify that the employer's written procedures required in condition ii of the exception must be implemented.

Exception to subsection (g)(6)(B)3

As originally noticed, this exception allowed employers to increase the interval for fit testing of respirators that are not being used for high hazard procedures, to no more than two years until January 1, 2014. A modification is proposed to exclude respirators used to protect against laboratory-generated aerosols from this exception. The purpose of this modification is to clarify that when a respirator is required based on a risk assessment performed in accordance with subsection (f)(2), an annual fit-test is required. Another modification to this exception would require that when employers do not provide an annual fit-test, the employer must instead provide a respirator fit-test screening that includes the information in Appendix G. The purpose of this modification is to actively solicit from employees information that would require an additional fit-test. The purpose and necessity for this is to identify employees who need an additional fit-test, and to provide additional information to employees during the interval between fit-tests.

Subsection (h) Medical Services

A modification is proposed to change the title of this subsection from Medical Surveillance to Medical Services. The purpose and necessity for the change is to avoid confusion with the common language use of the term "surveillance." This change in terminology is used throughout this subsection.

Subsection (h)(1)

A modification is proposed to revise the reference to CDC and CDPH recommendations to the term now defined in subsection (b), "public health guidelines." This revision is made throughout this subsection, and is for the purpose of clarifying the hierarchy of public health recommendations to be used. Also, as originally noticed, this subsection required that medical services be in accordance with recommendations for the type of work setting. A modification has been proposed to add the phrase "and disease." This is necessary because recommendations may differ both based on the type of work setting and the type of disease.

Subsection (h)(2)

A modification is proposed to change the term "medical surveillance provisions" to "medical services," as discussed above, to be consistent with the common use of the term "medical surveillance." Similarly, the term "public health guidelines" has been substituted for the phrase "as recommended by the CDC and/or CDPH" as discussed above. Additionally, the term "tests" has been added to clarify that the medical services required by this section include tests. The purpose and necessity for these changes is to provide clarity and consistency within the text.

Subsection (h)(3)

A modification is proposed to replace the term “surveillance” with the term “assessment” to refer to testing and other procedures that are used to identify individuals with latent tuberculosis infection. The purpose and necessity for this change is to be consistent with the common language use of the term “surveillance.”

Subsection (h)(5)

As originally noticed this subsection required that employees in laboratory operations be provided with vaccines in accordance with CDC and CDPH recommendations for the specific laboratory operation. A modification is proposed to change this reference to the BMBL, which recommends provision of applicable commercially available vaccines for certain pathogens. The purpose and necessity of this modification is to clarify which vaccines must be offered to laboratory employees based on their occupational exposure.

Subsection (h)(5)(A)

As originally noticed this subsection required employers to provide recommended vaccinations to employees within 10 working days of receiving the training required in subsection (i). A modification is proposed to also include the training referenced in subsection (c), which is the section requiring training for employees of referring employers. This modification is necessary in order to clarify that employees of referring employers are to be provided with vaccines within the timeframe included in this subsection.

Subsection (h)(5)(B)

As originally noticed, this subsection required employers to provide additional vaccinations when recommended by the CDPH or CDC. A modification is proposed to change this to additional vaccine doses. The purpose and necessity of this modification is to make this subsection consistent with subsection (5), and Appendix E, which contains those vaccines that are required to be provided to health care workers. However, at times public health authorities may determine that a “booster” or additional vaccine dose is required, and this subsection has been changed to reflect this situation.

Subsection (h)(5)(C)

As originally noticed, this subsection restricted the employer from making employee participation in a prescreening program a prerequisite for receiving a vaccination. A modification is proposed to clarify that this refers to serology, and not to the typical screening provided for vaccinations, such as inquiries regarding allergies. The purpose and necessity for this is to clarify that prescreening procedures, unless recommended by public health guidelines, may not be made a condition to provision of vaccine.

Subsection (h)(5)(D)

As originally noticed, this subsection required an employer to make a vaccination available to an employee who had previously declined to receive it. A modification is proposed to specify that

this request is to be written. The purpose and necessity for this is to make this process consistent with the declination process, which involves a written format.

#### Subsection (h)(5)(E)

As originally noticed, this subsection referred to the declination statement in Appendix C for vaccines other than seasonal influenza. A modification is proposed to change this reference to Appendix C1. The purpose and necessity for this modification is to clarify which of the two statements in Appendix C apply to these vaccinations.

#### New Subsection (h)(5)(F)

A new subsection (F) is proposed to specify the information that the PLHCP who administers the vaccination to employees is to provide to the employer. These specific items are:

1. The employee's name and identifier.
2. The date of the vaccine dose or determination of immunity.
3. Whether the employee is immune to the disease and whether there are any specific restrictions on the employee's exposure or ability to receive the vaccine.
4. Whether an additional dose is required and if so, the date the additional vaccination dose should be provided.

The purpose and necessity for this is to assure that the relevant and necessary information for the vaccination and infection control is conveyed to the employer, and that other personal medical information is not revealed.

#### Subsection (h)(5) Exception

As originally noticed, this exception did not require an employer to inform employees of the projected availability date of a vaccine that has not been available. It also required an employer to investigate the availability with suppliers every ten working days. Modifications are proposed to require the employer to inform the employees when the vaccine is expected to be available and to extend the time period for the employer to repeat the inquiries to once every 60 calendar days. The purpose and necessity for the first change is to assure that employees will know when to expect to be able to receive a vaccination. The second change is needed because a ten-day cycle for investigating vaccine availability may be unrealistically short for changes in vaccine availability.

#### Subsection (h)(6)(A)

As originally noticed, this subsection required the employer who determined that a person was an RATD case or suspected case to report the case to the local health officer; to determine, to the extent that information was available from the employer's records, whether employees of other employers may have been exposed to the patient; and to notify that employer. A modification is proposed to this subsection to restructure it, and to identify that the responsibility to report to the local health officer may be met by the diagnosing health care provider or by the employer of the provider. This change is made to be consistent with reporting requirements in Title 17.

Subsection (h)(6)(B)

As originally noticed, this subsection required that an employer report an RATD case or suspected case to the local health officer within 24 hours of identification. The reporting employer was also required to determine from its records whether employees of other employers were exposed to the case or suspected case, and to notify those employers within the same timeframe. As discussed under subsection (h)(6)(A), the requirement to report to the local health officer has been separated from the requirement to identify employers of employees who may have been exposed to the patient. Subsection (h)(6)(B) has been modified to require the employer in the facility, service or operation that originated the report to the local health officer to determine, to the extent information is available in its records, which employers may have had employees who were exposed to the patient and to notify them. In response to comments received, the timeframe required for this notification has been changed to permit more flexibility based on the specific nature of the disease, but no longer than 72 hours after the report to the local health officer. The purpose and necessity for this modification is to assure that the process is consistent with the change to subsection (h)(6)(A) as to the parties who make the report, and to allow for the different medical requirements that apply to preventing or mitigating a specific disease. A maximum of 72 hours is permitted for notification in order to permit an accurate investigation by the notified employer of the employees who may have been exposed. Also, a sentence has been added to require that the employer not provide the identity of the source patient to notified employers. The purpose and necessity of this addition is to be consistent with other portions of this standard, and other legal requirements regarding medical confidentiality.

New Note 2 to (h)(6)(B)

A new Note is proposed to explain the factors that should be considered in determining the timeframe for notifying other employers and conducting an exposure investigation. The purpose and necessity for this change is to provide an explanation for determining an appropriate timeframe for reporting an exposure incident.

Subsection (h)(6)(C)1

As originally noticed, this subsection required the employer to conduct an analysis of the exposure incident within 24 hours of becoming aware of the potential exposure. It is proposed to modify this time period to be a timeframe that is reasonable for the specific disease, as described in subsection (h)(6)(B), but no later than 72 hours after the employer's notification to the local health officer. The 72-hour maximum period would start with the receipt of notification from another employer or the local health officer, if the employer is not the reporting employer. Further modifications are proposed to replace the term "identification numbers" with "other employee identifier used in the workplace" to clarify that identification numbers need not be created for compliance with this subsection. Also, the term "CDC or CDPH guidelines" is proposed to be replaced with "public health guidelines," as explained above. A final modification is proposed to assure that the local health officer will have access to the exposure analysis upon request. The purpose and necessity for these modifications is to provide consistency within the text of the standard, and to assure that the local health officer, who is responsible for public health investigations, will have prompt access to information developed by the employer.

Subsection (h)(6)(C)2

As originally noticed, a timeframe of 48 hours was provided for notifying employees of their potential exposure after the employer became aware of the exposure. A modification is proposed, consistent with subsections (h)(6)(B) and (h)(6)(C)1, that provides that the notification occur within a timeframe that is reasonable for the specific disease, and no later than 96 hours from the employer becoming aware of the potential exposure. This modification is necessary to provide consistency within the text of the standard, and to establish a timeframe that will protect employees against developing disease and also provide for an effective exposure investigation.

Subsection (h)(6)(C)3

As originally noticed this subsection required the employer to provide a post-exposure evaluation to employees who had a significant exposure. A modification is proposed to add the word “medical” before evaluation. The purpose and necessity of this modification is to clarify that the evaluation required by this subsection is a medical evaluation.

Subsection (h)(6)(C)5

As originally noticed, a timeframe of 24 hours was provided for notifying other employers of potential exposures to their employees after the employer became aware of the exposure. A modification is proposed, consistent with subsections (h)(6)(B) and (h)(6)(C)1, that provides that the notification occur within a timeframe that is reasonable for the specific disease, and no later than 72 hours from the employer becoming aware of the potential exposure. This modification is necessary to provide consistency within the text of the standard, and to establish a timeframe that will protect employees against developing disease and also provide for an effective exposure investigation.

Subsection (h)(8)(B)

As originally noticed, this subsection authorized the PLHCP evaluating an employee to recommend precautionary removal for that employee. A modification is proposed to also authorize the local health officer to recommend precautionary removal. The purpose and necessity for this change is to be consistent with Title 17 of the California Code of Regulations, which provides this authority to the local health officer.

Subsection (h)(10)

As originally noticed, the vaccine declination statement was the influenza vaccine statement referred to in Appendix C. A modification is proposed to change the reference to the influenza vaccine declination statement to be appendix C2, to clarify which of the statements in Appendix C applied to seasonal influenza.

New Exception 2 to subsection (h)(10)

A new exception is proposed that would allow the employer to use an alternate influenza vaccine declination statement in lieu of the statement provided in Appendix C2 if the statement is acceptable to the CDPH as established by the Health and Safety Code Section 1288.7. The

purpose and necessity for this is to avoid unnecessary duplication in declination statements between the requirements of CDPH and this subsection.

Subsections (i)(3) and (i)(4)

The subsection that was originally noticed as subsection (i)(5) is proposed to be renumbered as subsection (i)(3). This subsection requires that training material be appropriate in content and vocabulary to the educational level, literacy and language of employees. The subsection previously numbered (i)(3), which contains the specific training elements, is proposed to be renumbered as (i)(4). The purpose and necessity for this change is to provide clarity in the text.

Subsection (i)(3)(M)

As originally noticed, subsection (i)(3)(M) required that training sessions include an opportunity for interactive questions and answers with the person conducting the training. As noted above, training requirements are now renumbered as subsection (i)(4). The requirements in previous subsection (i)(3)(M) have been relocated to subsection (i)(5), which addresses the issue of interactive questions and answers.

Subsection (i)(5)

As originally noticed, subsection (i)(4) required training to be conducted by a knowledgeable person. This subsection has been renumbered to (i)(5), and the language has been expanded to address situations where training is provided in a format other than an in-person training session, such as computer or web-based formats. In that case, interactive questions would be required to be answered by a knowledgeable person within 24 hours of the end of that session. The purpose and necessity for this is to provide an employer with more flexibility in providing training to employees, especially in cases where an employer has more than a single work shift. This new flexibility also increases the opportunity for employees to be trained during their normal work hours.

Subsection (j)(1)(B)1

As originally noticed this subsection required that the medical record contain the employee identification number. A modification is proposed to change this to “any other employee identifier used in the workplace.” This change is necessary to be consistent with the text of the standard, and to clarify that employers are not required to create an employee identification number to comply with this standard.

Subsection (j)(1)(B)2

As originally noticed, this subsection listed the information that the medical record must contain regarding vaccination status, which included medical records relevant to the employee’s ability to receive vaccination. A modification is proposed to reference the information provided by the PLHCP in new subsection (h)(5)(F). The purpose and necessity of this modification is to protect employee medical privacy, by ensuring that the record contains only the information the employer needs in regards to employee immunity to diseases. A modification is also proposed to include any vaccination record provided by the employee. The purpose and necessity of this

modification is to include in the record information for vaccines that the employee may have received from sources other than the employer's PLHCP.

Subsections (j)(1)(B)3, 4, and 5

As originally noticed, subsection (j)(1)(B)3 required that the record contain a copy of all results of examinations, medical testing and follow-up procedures as required by this section. Subsection (j)(1)(B)4 required that the record include the employer's copy of the PLHCP's written opinion as required by subsection (h)(9). A modification is proposed to change the language in subsection (j)(1)(B)3 to require the record to include a copy of all PLHCP written opinions required by this section, and the results of TB assessments. The purpose and necessity of this modification is the protection of the employee's medical privacy, by specifying that the employer's medical record only contain the specific information that is necessary for protecting the employee, and for controlling ATDs in the workplace. The modified language eliminates the subsection (j)(1)(B)4 as redundant, which results in the renumbering of the following subsection.

Subsection (j)(2)(A)3

As originally noticed, subsection (j)(2)(A)3 required the training record to include the names and qualifications of persons conducting the training. A modification is proposed to add that the record must include the names and qualifications of persons designated to respond to interactive questions. The purpose and necessity of this modification is to be consistent with the changes proposed to subsection (i)(5), which permits alternative training formats, and specifies that knowledgeable persons must be available to answer interactive questions.

New Subsection (j)(3)(B)

As noticed, this item originally addressed the records of vaccine unavailability. A modification is proposed to insert a new subsection addressing the records required for an exposure incident, and to renumber the succeeding subsections. The records required for an exposure incident are proposed to include: the date of the incident, the names and other employee identifiers of employees included in the exposure evaluation, the disease or pathogen to which employees may have been exposed, the name of the person who performed the exposure evaluation, the name of the local health officer and/or the PLHCP consulted, the date of the evaluation, and the date and contact information for any other employer who either notified the employer or was notified by the employer regarding potential exposure of their employees. This subsection would further require that the record be maintained in accordance with Section 3204 as an employee exposure record.

The purpose and necessity for this addition is to assure that an exposure incident involving a disease is recorded in a manner consistent with other employee exposures as provided in Section 3204.

Subsection (j)(3)(D)

As originally noticed, this subsection required that records of the unavailability of AII rooms or areas be retained for three years. A modification is added to specifically require that the record not contain a patient's individually identifiable medical information. The purpose and necessity

for this modification is to assure that the standard is consistent with state and federal laws protecting medical privacy.

Subsection (j)(3)(E)

As originally noticed, this subsection established requirements for records of decisions not to transfer a patient to another facility for AII for medical reasons. The subsection required that the record include certain items. A modification is proposed to specifically exclude a patient's individually identifiable medical information from this record. The purpose and necessity for this modification is to assure that the standard is consistent with state and federal laws protecting medical privacy.

Subsection (j)(3)(G)

As originally noticed, this subsection describes the records that are related to the respiratory protection program. A modification is proposed to add a requirement for employers who provide fit-test screening, in accordance with the exception to subsection (g)(6)(B)3, to retain records of this screening for two years. The purpose and necessity for this addition is to provide documentation of the employer's use of this provision, for use in evaluating the Plan, and for determination of compliance with this standard.

Subsection (j)(4)(A)

As originally noticed, this subsection requires that the employer provide access to all records, other than employee medical records more specifically dealt with by subsection (j)(4)(C) to the Chief of the Division of Occupational Safety and Health and NIOSH. A modification is proposed to add that the local health officer would have the same access. The purpose and necessity for this change is to clearly provide ready access to the local health officer in accordance with their authority under Title 17 of the California Code of Regulations.

Subsection (j)(4)(B)

As originally noticed, this subsection required that employee training records would be made available to the employee, employee representatives, the Chief and NIOSH. A modification is proposed to remove the Chief and NIOSH from this subsection, as their access is addressed in subsection (j)(4)(A). The purpose of this modification is for clarity. An additional modification is proposed to identify that the exposure control plan or biosafety plan, and other records of plan implementation, would be made available as employee exposure records, in accordance with Section 3204, to employees and their representatives. The purpose and necessity of this additional modification is to ensure that employees and their representatives have access to the information they need to fully participate in reviewing the plan, and to establish reasonable access procedures.

Subsection (j)(4)(C)

As noticed, this subsection addressed accessibility of employee medical records. A modification is proposed to include the local health officer among the entities who are to be provided these records in accordance with Section 3204. The purpose and necessity for this change is to provide prompt access to the local health officer in the investigation of infectious diseases.

#### Appendix A

This appendix, as originally noticed, contained a footnote to the effect that airborne precautions include droplet precautions. A modification is proposed to remove this footnote. This is necessary because the footnote is incorrect.

A change is proposed to the introductory language of this appendix to clarify that the provisions of the standard as a whole pertain to pathogens and diseases classified as either requiring airborne infection isolation or droplet precautions. However, provisions regarding airborne infection isolation or droplet precautions apply to those diseases or pathogens that are on the respective lists.

The appendix as originally noticed contains a list of diseases/pathogens. Non-substantive changes are proposed to harmonize the nomenclature for diseases with the nomenclature used in Appendix A of the referenced document, *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*. Parenthetical references to vaccinia and congenital rubella were removed for clarity. A Note is also proposed to be added to the listing for viral hemorrhagic fevers to the effect that airborne infection isolation and respirator use may be required for aerosol generating procedures. This Note is in response to comments, and is also necessary to reflect the notation in Appendix A of the referenced document.

#### Appendix B

The appendix, as originally noticed, contained a note directed at the employer that an employee who answered in the affirmative to certain questions need not be provided with a medical examination. Since the employer is not supposed to be reviewing the completed questionnaire (it is to remain confidential between the employee and the PLHCP) this Note is proposed to be modified to address the PLHCP.

#### Appendix C

This appendix, as originally noticed contained two vaccination declination statements. A modification is proposed to number the two statements as C1, the declination statement for vaccines other than seasonal influenza, and C2 the declination statement for the seasonal influenza vaccine. This is necessary for clarity in referring to the statements.

#### Appendix D

This appendix, as originally noticed, contained an introductory statement referring to pathogens requiring biosafety level (BSL) 3. A modification is proposed to change the introductory language to indicate that when materials containing listed pathogens are reasonably anticipated to be present in laboratory operations, the employer must perform a risk assessment and address appropriate control measures in the biosafety plan, in accordance with subsection (f). This modification is necessary to clarify that the presence of a pathogen on this list does not necessarily require that the laboratory implement BSL 3 control measures, and also to be consistent with the language of the proposed standard.

This appendix, as originally noticed listed Adenovirus as an Aerosol Transmissible Pathogen – Laboratory (ATP-L). A modification is proposed to include a parenthetical phrase indicating that only Adenovirus in clinical specimens and cultures and materials derived from clinical specimens is an ATP-L. This is necessary to clarify that this section does not apply to modified non-pathogenic strains used in various biotech applications.

This appendix, as originally noticed, contained the notation (HICPAC) after several listings. This notation has been removed for clarity.

This appendix, as originally noticed, did not contain the pathogen vaccinia virus. A modification is proposed to list vaccinia. This is necessary in order to prevent laboratory acquired vaccinia infections, by ensuring that a risk assessment is performed for vaccinia containing laboratory materials, and appropriate protective measures are utilized.

#### Appendix E

This appendix, as originally noticed, included a statement that immunity would be determined in consultation with current CDC and CDPH guidelines. A modification is proposed to indicate the specific source of these guidelines, Epidemiology and Prevention of Vaccine-Preventable Diseases, which is proposed to be incorporated into the standard by reference, and is the nationally recognized authority on this issue. This is necessary to indicate how physicians or other licensed health care providers will determine whether an employee needs a vaccine dose.

#### Appendix F

As originally proposed, the introductory statement contained information regarding screening procedures for work settings in which no health care providers are available. A modification is proposed, to include an instruction that employees be instructed in how clients' privacy will be maintained during the screening procedures. This is necessary in order to ensure that screening procedures will be effective and will be conducted in a manner to protect people's privacy rights.

#### Appendix G

A new appendix G is proposed, which would be required to be utilized by employers who adopt a fit-test interval longer than one year, in accordance with the exception proposed to subsection (g)(6)(B)3. This appendix informs employees of the importance of fit-testing and proper respirator use, and queries employees as to whether they have had (1) dental work, facial injury or facial surgery or (2) weight changes that may affect respirator fit. It also informs the employee that he or she can request an additional fit-test from the employer, and provides a space to indicate that request. Under any of these three conditions, the standard would require an additional fit-test. This is necessary to ensure that employees who have a longer automatic fit test interval are promptly provided with an additional fit test when a change occurs that would alter the facepiece fit.

Summary and Response to Oral and Written Comments:

Roger Richter, Senior Vice President Professional Services, California Hospital Association (CHA), oral comments and written comments dated August 21, 2008.

Comment #RR1: The commenter commended Division staff for convening the advisory committee meetings, and for their responsiveness during the process. The hospital industry is pleased that respirator fit-testing requirements are to be permitted to be biannual until 2014 for certain hospital workers and the industry believes that based upon risk assessment, that biannual fit-testing can provide for more than an equivalent level of worker safety.

Response: The Board appreciates the feedback on the advisory process, and the hospital industry's support for the temporary biennial fit-testing option for certain hospital workers.

Comment #RR2: The hospital industry is pleased with Appendix B, the Alternative Respirator Medical Evaluation and its succinct structuring of pertinent information.

Response: The Board thanks the CHA for its support of Appendix B.

Comment #RR3: For compliance purposes, the term, "controlled substance release," in Section 5199(a)(1)(B) as opposed to the term, "uncontrolled substance release," should be referenced to Section 5192 of Title 8.

Response: The proposed standard includes a reference to Section 5192 of Title 8 for the term "uncontrolled substance release." The definition of "uncontrolled release" in Section 5192 has been in use for fifteen years, and is the subject of federal and state interpretations. The term "controlled release" does not appear in the ATD standard or in Section 5192. As explained in the ISOR, the use of this term is to identify employees who may be exposed to persons arriving from the scene of an intentional or unintentional release of biological agents, and who may bring contaminants with them on their clothing or persons. Therefore the Board believes that no change is necessary.

Comment #RR4: The definition in subsection (a)(2)(B) for "outpatient medical specialty practices whose policy is not to diagnose or treat ATDs" is ambiguous; the definition would benefit from specificity on which types of outpatient services are included or excluded.

Response: A definition of "medical specialty practice" is proposed to be added to subsection (b). Subsection (a)(2)(B) exempts from this standard outpatient employers, whose operation fits within the definition of medical specialty practices, have a policy not to diagnose or treat ATDs, and implement effective screening procedures.

Comment #RR5: The definition of "exposure incident" in subsection (b) should also require an investigation of the exposure and then should require an evaluation only if this screening investigation indicates the need for an evaluation; this screening should include a reference to

the immunity of the exposed employee. Medically determined or documented immunity to the disease in question should mean that the exposed individual requires no additional follow-up.

Response: The Board agrees that the points raised in the comment are legitimate issues to be included in evaluation of exposure incidents, but believes that these issues are more properly addressed in the procedures for exposure incidents, included in subsection (h)(6), rather than in the definition. The purpose of the definition of an “exposure incident” is to clarify when an exposure investigation is to be initiated. Because determination of an individual employee’s immunity or need for medical follow-up is a medical issue, and involves confidential medical information, subsection (h)(6) separates the evaluation of exposure from the medical evaluation of the exposed employee. To clarify the difference between the exposure evaluation and medical evaluation, the term “medical” has been inserted into subsection (h)(6)(C)3.

Comment #RR6: The definition of “referring employer” in subsection (b) should clearly state that general acute care inpatient hospitals are not included.

Response: The definition has been changed by adding this sentence: “General acute care hospitals are not referring employers.”

Comment #RR7: Subsections (c)(4) and (e)(5)(B) regarding communication of disease status of referred patients to employees and other employers are problematic because of strict Health Insurance Portability and Accountability Act (HIPAA) and other confidentiality regulations. Communication and contact regarding some reportable diagnosed diseases, such as TB and measles, are handled by the health department.

Response: HIPAA and other confidentiality regulations were written so as not to pose obstacles to the protection of public health, and the provisions of these laws for health information privacy should be viewed from this context. The intent of the communication components of the ATD standard is to convey only that information necessary for post exposure evaluation and treatment. In addition, this proposal specifies that information should be communicated without communicating the name of the source patient. (A more complete discussion of California medical privacy requirements and HIPAA requirements is contained in several memos from DOSH staff attorney Allyce Kimerling in the rulemaking file). As to the second part of the comment, a change has been made to subsection (c)(4) to clarify the role of communication between the employer and the local public health officer.

Comment #RR8: Subsection (c)(7)(I) needs clarification on the extent of employee participation in reviewing the effectiveness of the employer’s procedures.

Response: Subsection (c)(7) lists the topic areas that referring employers must address in their training program. Subsection (c)(7)(I) is meant to train employees on how they can participate in the review of the employer’s infection control procedures. The review, and employee involvement in the review, is required by subsection (c)(8). Each employer’s review process will be different, but all are required to be effective. To clarify that this training element relates to the

requirement in subsection (c)(8), a modification is proposed to subsection (c)(7)(I) to reference the procedures in (c)(8). A modification is also proposed for subsection (c)(8) to provide more specific information on requirements for employee participation in the review of the employer's procedures.

Comment #RR9: Subsection (c)(7)(J) on training should recognize that for many modern forms of training such as computer-based training, the person conducting the training may not be immediately available for interactive questions and answers. It should be permissible for contact information to be provided for a knowledgeable person who can be contacted within 72 hours after the training is completed.

Response: The Board recognizes that it is not always practical to have in-person training sessions led by a knowledgeable trainer and that computer and other training methods are frequently used. The requirement for interactive questions and answers is intended to assure that the training content that is provided to employees is understood within the context of the specific work activities of the employees. The opportunity for interactive questions is also meant to prevent an employee from misunderstanding subsequent material in the training because the question was not answered. The requirement for interactive questions and answers is also intended to ensure that the employee can pose the question before the employee forgets to do so. Also, in group training sessions, a question one person asks may represent questions others may share, but not ask. On the other hand, permitting answers via e-mail, phone, an in-person discussion or other mechanism by a designated knowledgeable individual may provide more consistent answers. It may also provide a mechanism for collecting information the employer can use in revising training. In addition, some employees may feel more comfortable asking questions outside of a group setting. To balance these concerns, the Board has proposed a modification of subsection (i), to apply to situations in which training is not provided by a knowledgeable in-person trainer. This would permit a mechanism for interactive questions in which questions submitted would be answered by a knowledgeable person within 24 hours of the end of the session.

Comment #RR10: There is no value to the subsection (d)(2)(D) requirement for listing all assignments or tasks requiring personal or respiratory protection equipment ahead of time since the trigger for use of the protection is the identification of a patient with an airborne or droplet transmissible disease and rooms/areas are required to be posted with warnings to employees about required PPE. Training of employees to recognize these postings and the appropriate use of the PPE is the key activity, and these requirements are elsewhere in the standard. So identifying ahead of time each specific task employees could perform that might require PPE is not necessary.

Response: The requirement in the Exposure Control Plan (Plan) to list the tasks or assignments requiring the use of PPE or respirators is intended to identify what assignments or tasks would require their use rather than predetermining locations for their use. In a large institution, this may be done by units, or assignment categories (such as respiratory therapy), as appropriate. This requirement is intended to assure that the employer has assessed procedures and identified the

ones that would require personal protective equipment and/or respiratory protection, and recorded them in the Plan, so that the equipment and support activities such as training or fit-testing will be provided. This does not require the employer to restrict the use of rooms on the basis of periodic use of protective equipment, or to record each use of a room on that basis. This requirement would not preclude a procedure for posting a room for the type of protections that employees are to use. Consequently, the Board believes that a modification of this subsection is not necessary.

Comment #RR11: In most counties, adequate supply of personal protective equipment is under the control of the county public health officer for use in foreseeable emergencies and surge situations, so the requirement in subsection (d)(2)(M) for employers to ensure this adequacy of PPE supply should be limited to normal operations and an explanation of how the hospital links to the county plan.

Response: This requirement was intended to address how employers would plan to obtain supplies of essential equipment during normal operations, foreseeable emergencies, and surge situations, not necessarily to require employers to maintain excessive individual stockpiles. Some supplies need to be available on-hand, to cover normal operations and short-term emergencies that do not activate local or regional surge plans. The Board agrees that a prolonged surge situation may exceed the capacity of an individual employer's planning and resources, and acknowledges that some of this function has been delegated to local and regional planning agencies. The employer needs to assess how to cover an initial period before local or regional area surge supplies can be located and distributed, and how access to local and regional stockpiles will be accomplished. For this reason, requirements regarding surge in subsection (d) have all been relocated to subsection (d)(2)(Q) which would require that the plan explain how the employer will interact with the local and regional emergency plan.

Comment #RR12: Subsection (e)(1)(A) incorrectly directs employers to use the CDC TB Guidelines for determining airborne precautions for all diseases while these guidelines are specific to TB and do not reference other airborne communicable diseases. Instead, the following rewording is suggested, "Airborne, droplet, and contact precautions shall be in accordance with Guideline for Isolation Precautions. Airborne precautions specific to tuberculosis shall be in accordance with the Guideline for preventing TB."

Response: A modification to this subsection is proposed to require that control measures to minimize airborne, droplet or contact transmission of ATPs be adopted as necessary for the specific disease, pathogen or condition, and as listed in Appendix A, which identifies diseases requiring airborne infection isolation or droplet precautions. Droplet and contact precautions are described in the CDC Guideline for Isolation Precautions. However, this document references the Guideline for Preventing the Transmission of Mycobacterium Tuberculosis for further explanation of airborne infection isolation, and notes that the explanation of these controls may be applied to other diseases transmitted by the airborne route. For this reason, the standard refers to the TB publication to further describe airborne precautions.

Comment #RR13: Subsection (e)(3) is too vague about which contractors with temporary or contract employees it is necessary to provide information about infectious disease hazards, when in fact such information dissemination needs to be based on risk of exposure to these employees.

Response: A modification to the language of this subsection is proposed to require providing information to contractors whose employees may be “reasonably anticipated to have occupational exposure” to infectious disease hazards.

Comment #RR14: For consistency, subsection (e)(5)(D)4 should reference maintenance of High Efficiency Particulate Air (HEPA) filters associated with Ultraviolet Germicidal Irradiation (UVGI) systems to the Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings. CHA assumes this section refers to HEPA filtration of air from an AIIR that would enter a room receiving recycled air or HEPA filtration for exhaust air. CHA recommends replacing the first two sentences with “Engineering controls (including any HEPA filters for UVGI) shall be used, maintained, inspected and controlled in accordance with Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings.”

Response: The Board believes that it is important to specifically include the information on the maintenance of HEPA filters currently provided in subsection (e)(5)(D)4. These filters are used to provide supplemental air cleaning technology. UVGI is a separate form of air cleaning technology that is still undergoing considerable development and research. For this reason, the Board cannot, at this time, establish specific requirements for its use, but instead refers employers to the discussion of UVGI in the referenced guideline.

Comment #RR15: Health care laboratories that are certified by the College of American Pathologists (CAP) should be exempt from the requirements of subsection (f) because CAP certification addresses laboratory worker safety issues and provides equivalent protection.

Response: No requirement in subsection (f) is in conflict with the requirements for CAP certification. To the extent that meeting the requirements for CAP certification fulfills all the requirements of subsection (f), there would be no additional obligations upon health care laboratories. However, this subsection is necessary for all labs, CAP certified or not, in order to create enforceable requirements. Audits by certifying agents cannot be used in place of the Labor Code mandate for the Division to respond to complaints and accidents or for the Board’s responsibility to adopt regulations necessary to protect the health of employees.

Comment #RR16: Subsection (g)(3)(B) should read “The employer shall provide a respirator at least as effective as a powered air purifying respirator (PAPR)” because there may be other appropriate respirators available now, or in the future.

Response: A change has been made to the subsection allowing respirators providing equivalent protection to the PAPR.

Comment #RR17: For the examples of respirator use under subsection (g)(4), it should be emphasized that a N95 respirator be used.

Response: In subsection (g)(3)(A) the proposed standard clearly permits the use of an N95 respirator, where it will provide sufficient protection. In order to coordinate those requirements with subsection (g)(4), which specifies the circumstances in which respirator use is required, a phrase has been inserted into subsection (g)(4) stating that “a respirator, selected in accordance with subsection (g)(3) and Section 5144...” shall be used.

Comment #RR18: CHA supports the fit-testing requirements recommended in this policy and the exceptions that are part of the standard.

Response: The Board appreciates the support of CHA for the respirator fit-testing requirements of this standard.

Comment #RR19: Subsection (h) language should be consistent with workers compensation program language. Rollouts over a reasonable time period should be permitted for new employees and existing employees. CHA suggests a one-year phase in.

Response: Precautionary removal provisions of this subsection apply to a period when an exposed employee is not yet eligible for workers compensation benefits (i.e., during a possible incubation period of a disease when the employee is potentially infectious to others but is not sick), so language equivalence with the workers compensation program is not appropriate. Precautionary removal specifically does not apply to a period of time during which the employee is unable to work, other than for reasons of precautionary removal, such as when the employee is sick with an occupational illness. The implementation date of the vaccination requirements of this subsection is proposed to be extended by a year after the effective date of the regulation.

Comment #RR20: In the first sentence of subsection (h)(1), CHA recommends the term “medical surveillance” be replaced with the term “screening measures” to avoid conflict with the way the term surveillance is generally understood.

Response: Throughout the standard, the Board has substituted the term “medical services” for “medical surveillance,” except where the term is used to refer to the surveillance program for tuberculosis infection. The term “assessment” is used to refer to individual TB tests or other TB screening measures.

Comment #RR21: For subsection (h)(5)(D), if an employee declines a vaccination initially but later wants to accept it, the request needs to be in writing.

Response: The Board has made the requested change.

Comment #RR22: Subsection (h)(6)(B) establishes a 24 hour time period within which an analysis of an exposure incident must occur and a 48 hour time period within which to notify

employees who had significant exposure. The 24 hours should be changed to “a period of time which is prudent and reasonable” because often the exposure incident would be to a reportable disease for which the health department has jurisdiction and consequently the employer’s infection control and occupational health personnel must coordinate with the health department. Sometimes 48 hours is too long and sometimes it is not reasonable, largely because of weekends, so the standard should list exceptions. Specific time intervals shouldn’t be used unless the California Department of Health requires them.

Response: This subsection has been changed so that the timeframe within which the employer is to notify other employers and is to initiate an investigation to identify exposed employees is to be based on the timeframe necessary to provide appropriate intervention, but in no case shall it be later than 72 hours following the report to the local health officer. The issues affecting the appropriate timeframe include effective medical intervention to prevent disease or mitigate the disease course and measures to prevent further disease transmission. In addition, the timeframe must be short enough to initiate an effective investigation to identify exposed employees. A note to this subsection has been added to provide further clarification. For communicating about exposure incidents to exposed employees, the period is proposed to be lengthened to a maximum of 96 hours following employer awareness of the potential exposure. As the CHA suggested, variability in timeframe is necessary because sometimes 24 or 48 hours is unnecessarily short, and sometimes it is too long, depending on the disease. However, delays of more than a few days can adversely affect the success of investigations of exposure incidents, and may lead to the exclusion of some employees from post-exposure follow-up.

Comment #RR23: Appendix A’s linking via footnote #1 of Airborne Infectious Diseases/Pathogens of Airborne infection isolation including droplet precautions is incorrect. CHA recommends using the same List and same language as the most recent CDC Guidelines for Isolation Precautions (2007).

Response: The footnote in Appendix As has been removed. Additional changes have been made in Appendix A to make its nomenclature consistent with the published version of the referenced guidelines.

Comment #RR24: Most employees do not understand many of the technical terms for different types of respirator utilized in Appendix B. It would be beneficial if Cal/OSHA provided a diagram/definitions which health care facilities can access via Cal/OSHA’s website to educate workers.

Response: The Board thanks the CHA for the suggestion on increasing the useful information on respiratory protection terminology that should be added to the Division’s web site. The Division has indicated that it is preparing a number of educational materials and implementation aids to help employers if the proposal is adopted.

Meanwhile, some resources currently available on this subject, include:

Page 9 of the Division's publication, *Respiratory Protection in the Workplace* [[http://www.dir.ca.gov/dosh/dosh\\_publications/respiratory.pdf](http://www.dir.ca.gov/dosh/dosh_publications/respiratory.pdf)], includes a partial glossary of respirator terminology as does the Cal/OSHA respiratory protection standard 8CCR 5144 definition section [<http://www.dir.ca.gov/Title8/5144.html>]. The CDC and Federal OSHA also have useful materials, for example, *TB Respiratory Protection Program In Health Care Facilities* [<http://www.cdc.gov/niosh/99-143.html#step2>] and the OSHA Respirator Quick Card [<http://www.osha.gov/Publications/3280-10N-05-english-06-27-2007.html>]

Bill Kojola, Industrial Hygienist, American Federation of Labor and Congress of Industrial Organizations, by letter dated August 15, 2008.

Comment #BK1: The AFL-CIO is pleased that California is proposing a workplace standard to protect workers against aerosol transmissible diseases. The proposed standard takes the most effective approach, which is a comprehensive standard incorporating airborne and droplet exposures to a wide range of infectious agents.

Response: The Board thanks Mr. Kojola for his comments.

Comment #BK2: The exclusion for dental offices (a)(2)(A) makes sense where these offices do not perform dental procedures on known or suspected ATD cases. However the screening procedures need to be covered in order to ensure that employers implement them and train employees. Also, there is no evidence that physicians have the knowledge and experience to determine whether or not a given dental procedure performed on a patient identified through the screening procedures poses an ATD risk to employees under subsection (a)(2)(A)3. If procedures are to be performed on a patient with an ATD, the employees should be protected by the requirements of the standard.

Response: The Board agrees with the commenter that it is necessary to ensure that the screening procedures are implemented and that employees are trained. However inclusion of these operations under Section 5199 is not necessary to accomplish this purpose. Instead, language has been added to subsection (a)(2)(A) to ensure that screening procedures and training of employees will be accomplished in accordance with the Injury and Illness Prevention Program regulation, Section 3203.

The Board further agrees that a physician may not be able to determine whether a given dental procedure poses a risk of ATD transmission to dental employees. The proposed language has been changed to condition the exemption of a dental office from application of this standard on a policy of not performing dental procedures on patients who had been screened as potentially having a transmissible ATD, unless a physician determines that the patient does not have an ATD.

Comment #BK3: The exclusion for medical specialty practices in subsection (a)(2)(B) does not ensure that the screening procedures required by the exclusion will be conducted. Including

these workplaces within the scope of the standard is the only way to ensure that employers implement screening procedures and to ensure that employees are trained.

Response: The Board agrees with the commenter that it is necessary to ensure that medical specialty practices that do not come within the scope of this section conduct appropriate screening procedures. However, inclusion of these operations in Section 5199 is not necessary to accomplish this purpose. Instead, language has been added to subsection (a)(2)(B) to ensure that screening procedures and training of employees will be accomplished in accordance with the Injury and Illness Prevention Program regulation, Section 3203.

Comment #BK4: The commenter is pleased to see that California is proposing to include within the definition of Airborne Infectious Disease (AirID) "novel and unknown pathogens." The commenter believes that treating novel and unknown pathogens as potentially transmitted by airborne means is an appropriate precautionary approach and is necessary to protect exposed workers. The commenter also supports the note that explicitly includes pandemic influenza strains as novel pathogens.

Response: The Board thanks Mr. Kojola for his support of the proposed standard.

Comment #BK5: The qualifying phrase in subsection (c)(5)(C) would limit the circumstances in which a referring employer would be required to provide employees with respiratory protection when entering a room or area in which a person is waiting for referral to those circumstances in which the person "is not compliant with source control procedures." This condition is vague and difficult to interpret, and is insufficiently protective of worker health. The commenter asked what the criteria are for determining if a person is compliant. The standard should include a requirement for the use of respiratory protection whenever a worker enters the room or area of a person awaiting referral, with no exception.

Response: The standard envisions that the main methods referring employers will use for controlling exposures to airborne infectious diseases are early identification of possible cases and limiting the amount of time potentially infectious individuals remain in the work place. Additional protection is afforded by separating the individual and providing ventilation, where feasible. The standard requires most employers to develop effective source control measures, including how people will be informed about those measures. These steps will result in increased compliance with source control measures. Training of supervisors and employees in source control measures which the standard requires will help them to determine whether a patient is compliant. Where the patient is non-compliant, respirators must be used if it is feasible. For employees in homeless shelters and other referring employer environments, the combination of the methods described above will substantially reduce risk without mandating the use of respirators in all situations.

Comment #BK6: To maximize the protection of employees who will enter areas where persons are awaiting referral, the standard should require that the referred person be provided with a procedure mask, as part of the source control measures.

Response: Source control measures, as recommended by the CDC, permit the use of masks or, as an alternative, tissues and hand hygiene materials to control respiratory secretions. In some circumstances a patient cannot use a mask. The proposal leaves it to the institution to determine the most effective means for controlling respiratory secretions in that setting. This determination would be reviewed annually, with the participation of employees.

Comment #BK7: The language in subsection (c)(6)(B) that would require that referring employers provide medical services in accordance with subsections (h)(6) through (h)(9) is too limited in requiring the services only for RATD cases or suspected cases. The commenter states that diseases reportable under Title 17 do not include avian influenza, SARS, monkey pox and novel and unknown pathogens. There is no scientific reason to exclude “unreportable” diseases from procedures for exposure incidents.

Response: Title 17, section 2500, requires reporting of human cases of avian influenza, and SARS. Title 17 is regularly reviewed by the state health department and local health officers to ensure that it is up-to-date. Monkey pox is an extremely rare disease in the U.S. Title 17 also requires reporting of the occurrence of any “unusual disease” and “outbreaks” of any disease. The Board believes that this sufficiently covers novel and unknown pathogens.

In creating this standard, the Division attempted to work within the current public health structure, which relies on the local health officer and the current system of communicable disease reporting. It is beyond the scope of the Board's authority to create a new mandate for local health officers.

Comment #BK8: The commenter supports the requirement in subsection (c)(7) that employees covered by this standard receive training at the time of initial assignment and at least annually thereafter. New language should be added requiring additional training when there are changes in the workplace or new information becomes available. It is important that workers have the new information as soon as possible.

Response: The Board agrees that changes in procedures or in the workplace that potentially affect employee exposures should require additional training, and language has been added to the proposed subsection.

Comment #BK9: Subsection (c)(7)(H), which requires training on vaccines, should be expanded to include training on treatment options such as antibiotics and antiviral drugs which may be used to protect workers after exposure incidents or as prophylaxis.

Response: The Board agrees that a requirement to provide information on how exposure incidents will be handled, which may include information on the use of prophylactic medications, should be included in the standard. Subsection (c)(7)(G) has been modified to include a requirement that employees be trained on the employer's procedures for providing employees with post-exposure evaluations. Providing information on vaccines is necessary to

ensure that employees choose to participate in vaccination programs, unless the vaccine is not appropriate for them. Information on specific use of antibiotic or antiviral therapies is more appropriately given, if necessary, when there is a specific exposure. The information should be provided by a knowledgeable PLHCP who can assess the employee's specific medical circumstances.

Comment #BK10: The development of an exposure control plan is a necessary and critical function of the standard. The proposal places responsibility for the development of the plan on the employer but is silent on the sources of information and expertise that the employer should seek out in preparing the plan. Frequently workers and their unions represent rich and useful sources of information, knowledge and input that can assist the employer and development of the plan. The commenter therefore recommends requiring that employers involve workers and their unions in developing the plan.

Response: The Board agrees that the exposure control plan is an important tool in controlling employee exposures to ATDs, and that workers and their unions are a valuable resource in developing such a plan. The proposal as written allows the employer to develop the plan in any way that is appropriate to the work place, which may include consultations with employees and their representatives. Since most facilities will be modifying an existing infection control plan to comply with this standard, a requirement that employers go back to the beginning in developing a plan may lead to unnecessary implementation delays. The proposal does include language requiring the employer to consult employees at least annually as to how the plan is implemented in their work areas. This consultation should provide a mechanism for employees to be involved in reviewing the plan and ensuring that it is effective.

Comment #BK11: The commenter supports the requirement in subsection (d)(3) for annual review of the plan by the program administrator and employees regarding the effectiveness of the plan in their work area. Additional language should specifically require employers to actually modify the plan based upon the findings and employee input obtained in the annual review. Also, the proposal should include a requirement that the plan be modified whenever there is new information or circumstances that significantly impact on the health and safety of workers.

Response: The Board agrees that employers should be required to act on findings of the annual review, and language has been added to this subsection to require that deficiencies found be corrected. The language in subsection (d)(2)(P) has also been revised to clarify that the procedures for involving employees in the review of the plan be effective. The Board does not agree that is necessary to require in subsection (d)(3) that the plan be reviewed whenever there is new information or circumstances that impact on employee exposure. The current performance language, which requires that the employer's plan contain effective procedures for review, permits the employer to review the plan as necessary. The requirement to review the plan at least annually does not prevent the employer, either on its own initiative or based on employee request, from reviewing the plan more frequently. In addition, subsection (d)(2)(J) requires that the plan include a procedure for evaluating exposure incidents and revising existing procedures to prevent further incidents.

Comment #BK12: The commenter supports the requirement in subsection (d)(4) that the exposure control plan be made available to employees and their representatives for examination and copying. The commenter supports adding a requirement establishing the maximum timeframe, preferably by the end of the next business day following a request. The commenter also suggests adding a requirement that the copy be provided to requesters at no cost to them.

Response: The Board agrees that the standard should incorporate a maximum timeframe for making the plan available. Language has been added to subsection (d)(4) and subsection (j)(4), the effect of which is to require the plan to be available for copying in accordance with Section 3204, which generally establishes a maximum timeframe of 15 days, and requires the employer to provide the first copy to a requestor at no charge, or to loan it to the requestor for copying.

Comment #BK13: The commenter supports the requirement in subsection (e)(1) to use feasible engineering and work practice controls to minimize exposure. Examples of engineering and work practice controls should be provided. Also subsection (e)(1)(A) should be rewritten to discuss types of engineering controls. The existing language relating to work practice controls should be placed in subsection (e)(1)(B). Existing subsections (e)(1)(B) and (e)(1)(C) would then be re-lettered. The personal protective equipment references should be removed from the context of the note about work practices currently attached to subsection (e)(1)(A). The commenter also suggests requiring personal protective equipment for employees who transport ATD cases or suspected cases.

Response: Subsection (e)(1) establishes a hierarchy of controls for ATP hazards. The primary methods of control are engineering controls and work practices. Although the commenter suggests separating engineering controls and work practices, particularly in the health care environment, these two methods of control work together. For example, early case identification and limiting contact with a potentially infectious patient is a work practice control, including placing the patient in a separate room or area. The separate room, and the ventilation provided to that room or area are engineering controls. For this reason, these two items are addressed together. When these control measures are not sufficient to control the hazards, then this section requires the use of personal protective equipment and respiratory protection. This hierarchy pertains to all operations, including transport of patients.

The purpose of subsection (e)(1)(A) is to reference two recognized sources of more specific information about airborne precautions and about droplet and contact precautions. The note is meant to give examples of work practice controls, and therefore the Board agrees with the commenter that the examples of using personal and respiratory protection should be removed, and the language of the note has been modified.

The purpose of subsection (e)(1)(B) is to address source control measures in the context of employers who are not referring employers. Source control, which consists of a combination of work practices and engineering controls, is currently strongly supported by the CDC and other public health and infection control practitioners.

Employers whose employees transport ATD cases and suspected cases, in facilities and in vehicles, are required to comply with the general requirements of subsection (e)(1), including providing appropriate personal protective equipment. The purpose of subsection (e)(1)(C) is to specifically address the use of engineering controls such as barriers and air handling systems in the context of vehicle use.

Comment #BK14: The term “susceptible” should be removed from proposed subsection (e)(5)(B)2.e. which requires respirator use by all “susceptible” employees who enter an AIIR room or area where AirID cases or suspected cases are housed. The commenter states that the term “susceptible” is undefined and should be removed to avoid confusion. All workers who enter the room or area should be provided with respiratory protection, as well as other forms of PPE.

Response: Although, the term susceptible is defined in subsection (b), the Board agrees that removal of the term “susceptible” from this subsection will prevent any confusion about whether an employee needs to use a respirator when entering an airborne infection isolation room. Most AIIR use is in conjunction with suspect or confirmed TB, to which all people are considered susceptible. In addition, since vaccines are not 100 percent effective, it is prudent to require respirator use for all AIIR.

Language has also been added requiring that employers provide appropriate personal protective equipment.

Comment #BK15: The commenter supports the requirement in the exception to subsection (e)(5)(C) that when high hazard procedures are performed outside of airborne infection isolation rooms or areas, that all employees working in the room or area where the procedure is performed use respiratory protection. The commenter believes that this requirement should also include all necessary PPE.

Response: The Board agrees that personal protective equipment must be provided to anyone in the area where a high hazard procedure is performed. Language has been added to require that persons not performing the procedure be excluded from the area where these procedures are being performed, unless the person is provided with the PPE and respiratory protection required for persons performing the procedure.

Comment #BK16: The commenter disagrees with subsection (g)(3)(A) which requires that the minimum level of respiratory protection provided under this standard be at least as effective as an N95 filtering facepiece respirator. The commenter believes that the minimum level of protection should be a P100 filtering facepiece respirator equipped with an elastomeric facepiece seal. The commenter provided several articles that he believes raise questions about the effectiveness of N95 filtering facepiece respirators in protecting employees against infectious aerosols. (See Lee, 2008, Balazy, 2006, and Eninger, 2008).

Response: The Division has reviewed the referenced articles. Although these articles raise some question regarding the exact protection factor provided by N95 respirators against some sizes of particles, many questions remain. For example, it is not known what size particle must be captured by the respirator filter in order to prevent infection, as many pathogens are presented in a droplet or droplet nuclei, rather than as a naked pathogen. At this time, the National Institute for Occupational Safety and Health and the Centers for Disease Control and Prevention, recommend the use of the N95 respirator. Studies have found that N95 respirators provide effective protection against a range of particle aerosols. (See, for example, Coffey 2004, Lawrence, 2006) In addition, the other control measures required by this standard, including limiting the amount of contact employees have with AirID cases and suspected cases, requiring the placement of AirID cases and suspected cases in specially ventilated rooms, and requiring additional controls for high hazard procedures provide a matrix of risk reduction measures that supplement the filtering capacity of respirators. Therefore the Board has not determined at this time that a higher level of respiratory protection is necessary, other than in the conditions specified in other portions of this standard.

Comment #BK17: The commenter supports the requirement in subsection (g)(3)(B) that a PAPR equipped with HEPA filters be provided to workers who perform high hazard procedures and work on cadavers. This requirement should be modified to permit the use of a respiratory protection device providing equivalent or better levels of protection, in order to permit the use of supplied air respirators or other respirators. Also, employers should be required to provide a PAPR to employees who have been determined to be medically incapable of wearing a filtering facepiece respirator but who are capable of wearing a PAPR.

Response: The Board agrees with the commenter that a respirator equivalent to a PAPR should be permitted, and language has been added to permit the use of respirators at least as effective as a PAPR with HEPA filters.

The issue of whether an employer should be required to provide a PAPR if a PLHCP determines that an employee cannot use an air-purifying respirator for medical reasons, but can use a PAPR, was discussed in the advisory meetings. Participants believed that while a PAPR may be a reasonable way to address a medical disqualification in some circumstances, it may not be appropriate, or it may not be feasible in others. For this reason, the Board does not think it is advisable to include a requirement in the standard that would apply to all circumstances. However, the Board notes that a PAPR when recommended by a PLHCP to address a medical issue, may be a reasonable and appropriate way to provide the employee with respiratory protection.

Comment #BK18: The commenter disagrees with the exception to subsection (g)(6)(B)3, that permits the repeat fit-testing interval to be increased to every two years until January 1, 2014, for employees who do not perform high hazard procedures. The commenter states that although the proposal mentions a NIOSH study that will provide information on appropriate fit-test intervals, there is no evidence available at this time that supports a fit-test interval longer than one year, and there is evidence that supports the requirement for annual fit-testing. Further, the commenter

cites several studies that show that a respirator that has passed a fit-test for an individual worker provides better protection than one that has not (Lee 2004, Coffey 2004, Lawrence 2006).

The commenter also cites evidence in the OSHA record supporting annual fit-testing, and a letter from NIOSH Director John Howard, supporting an annual fit-test interval. The commenter disagrees that the issue of cost to employers of annual fit-testing should be a reason to increase the fit-test interval, given the lack of scientific support for a longer interval. The commenter further states that this Cal/OSHA provision would be less effective than Federal OSHA.

Response: The Board agrees in part with this comment, and additional requirements pertaining to the biennial fit-test exception have been included in the proposed language. The Board agrees that initial and periodic respirator fit-testing are necessary to ensure that employees are issued respirators that can provide protection to the employee. The studies cited by the commenter do not actually address an appropriate fit-test interval. In the course of this rulemaking, the Division has received some evidence regarding fit-test intervals (Mendelsohn), and the relationship between training and fit-testing (MC Lee). Respirator fit-testing is currently an area of active research. The Board believes there is a need for scientific studies to determine how employees can be reliably provided with good-fitting respirators, including the reproducibility of fit-tests and the role of training in achieving a good fit.

This rulemaking proposal represents, in significant part, one manner in which the State of California is preparing for the threat of health care surge events, the most prominent example of which is the possibility of pandemic influenza.

The reality is that when a surge event arises, employees are called on to participate and do participate whether they are adequately protected or not from the consequences of exposure to the patients they care for. Therefore, it is in the interest of public health in general as well as the individual workers who will be involved in surge events to emphasize the kind of preparation needed to maintain employee health and safety during these events. Because respirator use is one of the most important forms of employee protection available in surges, maximizing the number of employees provided with fit-tested respirators is essential.

This requires identification, medical evaluation, training and fit-testing of all employees likely to need a respirator in the event of a surge. The temporary lengthening of the fit-test interval will have a direct and significant impact on the number of workers who can be maintained in a state of readiness at any given time and is essential to maximizing the preparedness of the health care industry to confront surge events. Without this lengthened interval, it is likely that significant numbers of employees who, under this proposal would be fit-tested and prepared for respirator use, will either not be provided a respirator in situations where one is necessary to protect the employee's health, or be provided a respirator without any fit-testing at all or any of the evaluation or training that go with fit-testing to assure that the respirator will protect them.

The language permitting a biennial fit-test for employees who do not perform high hazard procedures will sunset on January 1, 2014, requiring that by January 1, 2015, all respirator users have a fit-test within the previous 12 months.

In addition to this sunset language, the proposal has been amended to include a requirement that employers who provide biennial fit-tests provide fit-test screening during the year when a fit-test is not provided. This screening, included in Appendix G, explains the importance of proper respirator use and respirator fit, and describes conditions such as facial injury or surgery, major dental work, or significant weight change, that may change the fit of the respirator. Appendix G asks the employee to indicate if any of these conditions apply. In that case, the employer would be required to provide an additional fit-test. Appendix G also explains that an employee who wishes an additional fit-test will be provided one upon request.

The Board believes that the overall framework of the standard is the most effective approach to protecting employees from ATDs and that the standard, as proposed to permanently take effect, is at least as effective as existing federal requirements.

Comment #BK19: The commenter supports the activities required in subsections (h)(6)(A) and (h)(6)(B) in response to exposure incidents. These activities should not be restricted to diseases that are reportable under Title 17 of the California Code of Regulations, which the commenter states does not include avian influenza, SARS, monkeypox and novel or unknown pathogens. There is no scientific rationale for eliminating these diseases from requirements for exposure incidents.

Response: See response to comment #BK7.

Comment #BK20: The commenter believes that subsection (j)(4)(A) should include a requirement that employees and employee representatives be afforded access to all records, other than employee medical records, that are required to be maintained under this standard. Lack of access may hamper the ability of employees and their representatives to utilize their knowledge and expertise to advance safety and health measures in their workplace. The standard should include provisions establishing a deadline by which records are to be provided to a requester, such as by the end of the next business day. The records should be provided to employees and their representatives at no cost to them whenever they are requested.

Response: The Board agrees that access to records of program implementation, other than employee medical records, would enhance the ability of employees and their representatives to participate in reviewing and updating the employer's infection control procedures. The Board believes that Section 3204 establishes a reasonable framework for providing these records, including that the records be provided within 15 days of the request, and establishes a framework for either providing an initial copy of the record to the requester at no cost, or loaning the record for copying. Therefore language has been added to subsection (j)(4)(B) to require that access be provided to employees and their representatives in accordance with Section 3204.

Comment #BK21: A section should be added to address “housekeeping,” to include such issues as disposal of infectious waste and patient-care equipment, and environmental cleaning and disinfection.

Response: Housekeeping, as described in this comment is important to controlling infectious disease; and the proposal and existing standards include a number of requirements that address this issue. Proposed subsection (c)(1) requires referring employers to establish, implement and maintain effective infection control procedures, which was originally envisioned to include cleaning and disinfecting. In response to this and other comments, an additional sentence has been added to clarify that these procedures include cleaning and disinfection of work areas, vehicles, and equipment that may become contaminated with ATPs and pose an infection risk to employees. An addition has also been made to subsection (d)(2)(E) to specify that cleaning and decontamination must be included in the written Exposure Control Plan. Subsection (e)(2) requires non-referring employers to have effective decontamination and cleaning procedures for work areas. In laboratories, subsection (f)(4)(G) (formerly (f)(3)(G)), requires decontamination and disinfection procedures. Most employers within the scope of this standard are also within the scope of Section 5193, which contains specific housekeeping requirements to protect employees against contact with blood or other potentially infectious materials (OPIM). Additionally, Article 9 of Title 8 requires all employers to maintain workplaces in a clean and sanitary condition. Therefore, the Board does not believe there is a necessity to establish a separate housekeeping section in this proposal.

Comment #BK22: A subsection should be added regarding labels and signs to alert and warn employees about exposure potential related to equipment, objects, rooms or areas. This would assist in reducing exposure incidents and protecting workers from infection.

Response: The bloodborne pathogens standard, Section 5193, requires labeling of contaminated equipment and wastes, and the Board does not see a need to supplement this requirement in the proposed standard. In regards to the labeling or signage for areas in which there is a potential exposure, the Board believes there may be significant patient confidentiality issues in adopting a broad requirement for signage. Therefore, the proposed standard requires employers to include an effective means to communicate with employees regarding the infectious disease status of patients in the exposure control plan, or, in the case of referring employers, in their infection control procedures. These procedures must be reviewed at least annually with employees.

Annemarie Flood, President Elect, California Association of Professionals in Infection Control (APIC) Coordinating Council (CACC), electronic mail dated August 21, 2008.

Comment #AF1: CACC believes that the proposed requirement for the use of Powered Air Purifying Respirators (PAPRs) for high hazard procedures is not supported by existing data that demonstrates the existence of a hazard. CACC previously supplied Cal/OSHA with conversion rate data. There is also the concern that the PAPR because of the noise it produces, and the weight of the device, may interfere with patient and employee safety.

Response: Health care workers in California continue to experience TB conversions and develop active tuberculosis. A health care worker who contracts TB infection has an estimated ten percent risk of developing active TB during his or her lifetime, and for some individuals, this risk may be higher. To reduce this risk, many health care workers who develop infection are placed on antibiotic therapy that involves one or more drugs that may have significant side effects. During the advisory process, a nurse who contracted active TB as a result of an exposure in a LA area hospital, spoke about his experience working in an ICU, and the effect developing infectious TB had on his life. The California Labor Code requires the Board to adopt regulations that are necessary to protect employees against health and safety hazards. In 2007, over 2700 TB cases were reported through the public health system in California. Each reported case may expose dozens of health care workers to infection.

In addition, TB in California is increasingly likely to be drug resistant. The CDPH Report on Tuberculosis in California, 2007, states that the “*frequency of resistance to isoniazid (INH), one of the primary drugs used to treat TB, rose to 11 percent in 2007 (Table 45) from less than 10 percent in 2006 (Table 45). Among those with a prior episode of TB, the frequency of INH resistance was nearly 18 percent (Table 38). Where INH resistance exceeds four percent, the recommendation is to start all TB cases on an initial four drug regimen. In 2007, over 88 percent of cases began TB treatment with a four drug regimen (Table 26).*

*“California continues to report the largest number of multidrug resistant (MDR; resistant to at least isoniazid and rifampin) TB cases in the nation. Between 27 and 39 cases of MDR TB were reported per year in California between 2003 and 2007 (Table 43, Figure 13). During this five year period, MDR TB cases were reported in 25 (41 percent) of California’s 61 local health jurisdictions, including several rural and smaller health jurisdictions where experience in treating MDR TB may be limited. Although the overall proportion of MDR TB cases remains low (1.3 percent in 2007), the potential consequences of these deadly strains of TB to the patient and to the public can be costly in terms of human mortality, transmission of disease, and resource requirements. Three cases of the most severe form of drug resistance, termed extensively drug resistant TB (XDR TB) were reported between 2003-2007 (data not shown). XDR TB is defined by the World Health Organization as resistance to isoniazid and rifampin, as well as at least one fluoroquinolone and any of the second-line injectable agents, amikacin, kanamycin, or capreomycin.”*

As noted in the ISOR, the requirement for the use of PAPRs for high hazard procedures on AirID cases and suspected cases is based in part on the recommendations of the American College of Chest Physicians and the American Association for Bronchology. In addition, tuberculosis researchers have documented significant risk to health care providers during high hazard procedures. Some of this research is summarized in a communication from Kevin P. Fennelly, Transmission of Tuberculosis During Medical Procedures (Fennelly, 1997). In a 1998 article, Fennelly recommended the use of PAPRs during autopsies and bronchoscopies for TB, and stated, “Bronchoscopic procedures and autopsies on patients with possible tuberculosis have been associated with a high risk of transmission of tuberculosis and estimates of 250 to over 1000 infectious particles produced per hour.” He also summarized the successful experience

with PAPRs at National Jewish hospital, saying, “We have little difficulty in the use of only three of these units at our facility; this allows for use by a bronchoscopist and one or two assistants. These devices are quite comfortable for procedures, and patients seem to become accustomed to their use quite easily. In my opinion, PAPR hoods are the most sophisticated personal respiratory protective devices which are appropriate for health care settings.” (Fennelly, 1998)

The requirement to use PAPRs for high hazard procedures is not only based upon tuberculosis. Although there are no current reports of Severe Acute Respiratory Syndrome (SARS), during the SARS outbreak in 2002-2003, high hazard procedures were significantly associated with the development of disease in health care workers. A study of critical care nurses who were exposed to SARS patients in a Toronto hospital in March 2003, found that nurses who performed intubation and suctioning before intubation were at increased risk of developing SARS, and that two nurses who performed these procedures even though they used N95 respirators, contracted SARS (Loeb). Similarly, nine health care workers in Toronto in April 2003 who were exposed to a SARS patient who was intubated, developed illnesses consistent with the definition of a SARS probable case, and two developed atypical symptoms, despite the use of N95 respirators and the placement of the patient in an airborne infection isolation room (Ofner, 2003).

The requirement to use PAPRs is also based upon research showing that high hazard procedures may increase the generation of infectious aerosols substantially. In a study of aerosols emitted during voluntary coughing and coughing due to sputum induction, Fennelly found that one patient coughing as a result of sputum induction generated approximately 600 colony forming units (cfus) of multi-drug resistant TB bacteria during the 10-minute test (Fennelly, 2004).

N95 respirators are required to provide a protection factor of 10 to the user, when properly fitted and used. Several recent studies (see, for example, Lee, 2008) have indicated that, because of the size of test aerosol used and the method of filtration, that some of these respirators may provide somewhat less protection, with a 95<sup>th</sup> percentile protection factor around 8. But even at a factor of 10, it is clear that the potential of infection to workers exposed to high hazard procedures may considerably exceed the protection factor of an N95 respirator. Surgical masks provide virtually no protection against respirable aerosols.

The Board does acknowledge that although newer PAPR designs reduce the noise and weight of PAPRs intended for use in health care settings, there may be situations where employees cannot use PAPRs. Therefore, the proposed standard states that PAPR use is not required where that use would interfere in the successful performance of the task or tasks. This permits the employer and employees to make the final determination as to whether a PAPR can be used.

This notice also includes a proposed modification to the PAPR requirement. This modification would permit the use of other respirators (such as N95s) by employees during high hazard procedures, where the patient is placed in a booth or other ventilated enclosure and the employee remains outside of the enclosure. This would apply to booths or hoods used for sputum induction or administration of aerosolized medications.

Finally, it is up to the employer to determine which procedures are high hazard. For example the use of closed circuit devices, or devices with filtered output, may reduce the hazard associated with some procedures and therefore may reduce the level of respiratory protection that is needed.

Comment #AF2: CACC believes that the requirement to notify other employers regarding an exposure incident should be modified to reflect the specific incubation periods and other disease characteristics that each disease would have rather than the 24 hour period required for all incidents.

Response: See response to comment #RR22.

Comment #AF3: Footnote number 1 to Appendix A requires airborne precautions to include droplet precautions. We are not aware of any reference including such a requirement, as the mechanisms for transmission differ between airborne and droplet transmitted diseases.

Response: See response to comment #RR23.

Lawrence Gibbs, Associate Vice Provost, Environmental Health and Safety, Stanford University, by letter dated August 13, 2008.

Comment #LG1: Mr. Gibbs commented that the laboratory section should exempt biomedical research laboratories which operate under the guidelines of the National Institutes for Health (NIH), and conform to the recommendations in the BMBL. The NIH further requires institutions receiving federal grants and doing research on recombinant DNA to develop a biosafety committee that approves research protocols, conduct inspections and assure adequate training of laboratory personnel, and perform other functions necessary to assure a safe environment. Since the monetary sanctions that would follow from a failure to implement these requirements are far greater than Cal/OSHA penalties, such institutions already comply with these requirements and complying with the proposed standard would involve a duplicative effort that would be costly and time consuming. The proposed standard also applies a more conservative general risk characterization than is found in standard practice that would require more costly control measures that are not necessary.

Response: The Board notes that the Division and participants in the advisory process considered the recommendations of the BMBL, and in fact incorporated this document by reference. The intent of subsection (f) is to require employers to perform a risk assessment consistent with the BMBL and to implement control measures and a biosafety plan based on this risk assessment.

The commenter's belief that the proposed standard applies a more conservative general risk characterization may have come from an ambiguous introductory statement to Appendix D, which lists the pathogens for which risk assessments must be performed. This introductory statement has been changed, to reflect that inclusion on this list does not mandate biosafety level 3 (BSL-3) precautions. Rather, that determination is to be based on a risk assessment that

includes both the pathogen and the processes in which the materials are used. Also, a new subsection (f)(2) has been added to require that a risk assessment, in accordance with BMBL, be conducted. Similarly the requirement to implement engineering and work practice controls has been modified (renumbered subsection (f)(3)) to reflect that the engineering and work practice controls should be based on this risk assessment.

In regards to Mr. Gibbs' statement that the NIH contracting system obviates the need for Cal/OSHA regulation, the Board is aware that Cal/OSHA penalties may not be a significant financial disincentive to violations. However, Cal/OSHA regulations are necessary to ensure that employers, employees and other interested parties are aware of these requirements. The California Labor Code provides a mechanism by which employees can seek to get hazardous conditions in their work place corrected in a timely manner, and the responsibility of Cal/OSHA to protect employees cannot be delegated to a contract between the employer and a third party. Further, periodic contract audits do not serve the same function. In the Division's experience enforcing other regulations in laboratory environments, the existence of a contractual relationship with NIH or other federal agencies does not always ensure compliance with occupational safety and health standards.

The Board understands that as originally noticed, the proposal raised some concerns among researchers that there would be a substantial expansion of required control measures beyond those generally recognized. The modifications proposed should clarify that the standard would require risk assessments and control measures that comply with BMBL and NIH guidelines. The Board believes therefore, that this proposal will not create substantial additional costs and will not adversely impact on research in California. The Board also notes that the financial and human costs of laboratory acquired infections can be devastating, and may lead to the termination of the research grant or project.

Comment #LG2: The proposed standard imposes a few more stringent requirements that are unnecessary that would entail extra time and costs, exemplified by the requirement to verify that biological materials marked as non-pathogenic which are received by the laboratory from an outside source are indeed non-pathogenic.

Response: Several recent incidents illustrate the need for the requirement to verify the safety of a received biological material represented as containing an attenuated or non-pathogenic strain. For example, in 2004 researchers at Children's Hospital Oakland Research Institute received a suspension from a contractor that was represented as containing non-viable anthrax, which was injected into mice. The mice unexpectedly died, as did a subsequent group of mice. When the incident was investigated, the suspension was found to contain viable anthrax. The Morbidity and Mortality Weekly Report (MMWR) editorial comment stated, "Inactivated suspensions of *B. anthracis* should be cultured both at the preparing laboratory before shipment and at the research laboratory several days before use to ensure sterility." (Lucas, 2005). Similarly, samples containing the 1957 pandemic H2N2 influenza strain were mistakenly sent by a CDC contractor to laboratories in 18 countries. It is common practice in laboratories to handle incoming samples represented as being an attenuated or non-pathogenic strain at BSL-2, until the nature of the

sample has been verified. In addition, most establishments dealing with non-pathogenic strains have procedures for periodically validating that condition. For these reasons, the Board believes that a change to the proposed subsection is unnecessary.

Larry Wong, University of California Safety Manager, University of California Environmental Health and Safety Office of Risk Services, by letter dated August 21, 2008.

Comment #LW1: Proposed subsection (f) does not seem to allow a laboratory employer to assess the risks that are involved with the specific organism and type of task that is being utilized and determine the appropriate types of exposure controls that should be applied to that procedure. It is important for research facilities to be able to make an assessment of appropriate controls in accordance with the BMBL guidelines. Imposing the use of BSL3 controls for all the organisms listed in Appendix D would be unnecessary and would impose prohibitive costs on research grants and institutions.

Response: Subsection (f) and Appendix D as originally proposed were interpreted by a number of individuals as requiring BSL-3 control measures for all pathogens listed as ATP-L. However, this was not the intent of the proposed subsection, which was to require the biosafety officer to perform a risk assessment in accordance with the BMBL and establish appropriate control measures in the context of a biosafety plan. To ensure that this subsection is interpreted as intended, the introductory sentence to Appendix D is proposed to be modified to read: “This appendix contains a list of agents that, when reasonably anticipated to be present, require a laboratory to comply with Section 5199 for laboratory operations, by performing a risk assessment and establishing a biosafety plan that includes appropriate control measures as identified in the standard.”

Also, a new subsection (f)(2) specifically referencing a BMBL risk assessment has been added: “The biological safety officer shall perform a risk assessment in accordance with the methodology included in Section II of the BMBL for each agent and procedure involving the handling of ATPs-L and record the findings of the assessment in the Biosafety Plan.”

Finally, an additional phrase referencing the risk assessment in (f)(2) has been added to renumbered subsection (f)(3) regarding engineering and work practice controls.

The Board believes that this should remove any ambiguity and clearly direct employers as to the requirements of the subsection.

Comment #LW2: Regarding subsection (e)(1)(B) it will be difficult for an employer to show compliance with the implementation of source control measures if patients do not cooperate.

Response: This subsection does not require an employer to assure that a patient utilizes the source control measures that have been provided, but does require the employer to have made the measures available and to have ways to inform the patient of the need to make use of them.

The effectiveness of these measures should be assessed as part of the annual review of the program.

Comment #LW3: Regarding subsection (c)(7)(J), the employee training requirement to have a trainer available to answer questions during every training session is impractical when the training must be given for multiple shifts which cover a 24 hour workday and all seven days of the week. Live trainers are not available for all these shifts. Computerized training allows more flexible training scheduling and can be augmented by having questions submitted and answered by a knowledgeable trainer in a reasonable time.

Response: Modified language is proposed to address this concern, and permit training methods other than in-person traditional training sessions. This would require answers to questions be provided within 24 hours, if a knowledgeable training is not present during the training session. See response to comment RR#9 for further discussion.

Comment #LW4: In subsection (g)(3)(B), the language should be changed to permit the use of PAPRs or equivalent protection,” to allow the use of other respirators.

Response: The language of this subsection has been changed to permit the use of a respirator providing equivalent protection.

Comment #LW5: In regards to subsection (d)(2)(D), the Exposure Control Plan should not be required to include a list of all tasks and assignments that require personal or respiratory protection because it will be very difficult to frequently update the information about which specific patients or rooms will require the use of protective equipment. It is better to have rooms posted with signs that designate for the employees which types of protection will be needed to work in a specific room.

Response: See response to comment #RR10.

Comment #LW6: Regarding subsection (d)(2)(N), the ECP should not be required to include a procedure for ensuring that there is an adequate supply of PPE and other equipment during emergency and surge situations. Under surge conditions, employers may not have access to supplies through the normal channels, or through prearranged vendor contracts and cannot ensure that the supplies will be accessible to them.

Response: The requirements for surge have been relocated to subsection (d)(2)(Q), and contain a reference to the local and regional emergency plan. For further discussion, see response to comment #RR11.

Comment #LW7: Regarding subsection (e)(3), the requirement to notify contractors who may have exposure to aerosol transmissible pathogens is phrased too loosely, so that it could be construed to include any contractor in the facility. The requirement should be applied only to

contractors who are expected to enter rooms under airborne or droplet precautions or perform work on equipment that can generate aerosolized ATPs.

Response: A modification is proposed to change the wording of this subsection to require notification of contractors whose employees may be “reasonably anticipated to have occupational exposure,” to infectious disease hazards. It is up to the Plan administrator to determine which tasks would involve occupational exposure.

Comment #LW8: Regarding subsection (c)(3), the requirement to transfer an AirID patient to an airborne infection isolation room within the facility within a five hour limit is too restrictive because many facilities do not have many extra AII rooms that could accommodate periodic fluctuations in patients who would require the transfer. The exceptions that are provided for transfers to another facility should be available for the internal situation as well.

Response: Subsection (c)(3) refers to transfers by referring employers to hospitals and other facilities that provide services to airborne infectious disease cases. The issue of a five-hour time limit was discussed extensively in the advisory meetings. It was on the basis of these discussions that the exceptions provided both in subsection (c)(3), and in subsection (e)(5)(B) were developed. It is important that transfers of infectious AirID cases be accomplished in a timely manner, as referring employers are not likely to have airborne infection isolation rooms, and may not have respiratory protection programs. A longer timeframe is provided for persons who initially present at the referring employer after 3:30 p.m. and if there is no facility available to transfer the person to. This subsection also refers to additional exceptions in subsection (e)(5)(B).

Subsection (e)(5)(B)1 addresses transfers within the facility. Modified language is proposed to require that when in-facility transfers are not performed within five hours, then a between facility transfer be provided. That would then bring into play all of the exceptions that apply to those transfers, which are included in (e)(5)(B)2. With the several exceptions included in the standard, the Board believes that a five-hour limit is reasonable, and is necessary to protect the health of employees.

Comment #LW9: Subsection (e)(5)(D)4 does not identify the type of filters that are included in the requirement. The subsection should also delete the phrase that requires corrections to be made “in a reasonable amount of time” to be consistent with the CDC guideline language which does not contain that phrase.

Response: A modification is proposed to insert the term “exhaust or recirculation” before “filter” in order to identify filters to which this requirement applies. The exhaust or recirculation side filters are directly involved in capturing infectious particles prior to release or recirculation of the air.

The maintenance of effective airborne infection isolation rooms is critical to controlling employee exposures to airborne infectious pathogens. If problems are not corrected in a

reasonable period of time, then infectious patients may not be able to be transferred to an AIIR, which increases the potential for employees to contract disease. The language that problems be corrected in a reasonable period of time is performance language, intended to ensure the availability of properly functioning AIIR. The Board does not agree that the language proposed by the commenter provides a better framework for addressing maintenance of engineering controls, such as HEPA filters, since it does not give as much notice to employers and employees regarding requirements for maintenance of these controls.

Comment #LW10: Regarding subsection (h)(5)(D), ten days is too short a time limit for providing vaccine to an employee who originally declined it. Also, this subsection should require that the employee make a written request for the vaccine.

Response: In order to clarify how vaccine will be provided to an employee who originally declined a vaccine, and then decided to accept the vaccine, a phrase has been added to this subsection to reference the provision of vaccine to subsection (h)(5)(A). The requirement to provide the vaccine within ten days is conditioned on the availability of the vaccine, as indicated by the exception to subsection (h)(5). Also, language has been added to require the provision of the vaccine after receipt of a written request. In reviewing the experience of enforcing a similar ten-day requirement for provision of hepatitis B vaccine under Section 5193, the Division has found that this requirement is generally practicable.

Comment #LW11: In regards to subsection (h)(6), the time limits of 24 hours for analyzing the exposure scenario of an exposure incident and the 48 hours allowed to make the notifications may not allow the employer enough time in practice. Further, the term “significant exposures” should be defined.

Response: In regards to the timeframes in subsection (h)(6), a modification is proposed to provide more flexibility for notifications, based upon the disease, and providing an outer limit to the time frames of 72 and 96 hours, respectively. See comment #RR22 for further discussion of this requirement.

Significant exposure is defined in subsection (b) to mean “an exposure to a source of ATPs or ATPs-L in which the circumstances of the exposure make the transmission of a disease sufficiently likely that the employee requires further evaluation by a PLHCP.” This performance definition is to be applied by an individual who (subsection (h)(6)(C)1) is “knowledgeable in the mechanisms of exposure to ATPs or ATPs-L.” The Board believes that this is an appropriate approach to addressing exposure incidents.

Comment #LW12: The Board should re-examine the content of the proposed Standard and condense the laboratory relevant sections into a separate appendix that connects the desired outcome of a safe and healthy laboratory workplace concomitantly with the available resource of the NIH, CDC as well as OSHA. This was done successfully with Bloodborne Pathogens.

Response: The proposal includes a separate section on laboratories (subsection (f)) and Appendix D, which provides a list of pathogens. Risk assessment is incorporated into subsection (f), as are the BMBL guidelines. This is similar to the structure of Section 5193, which addresses certain laboratory operations under subsection (e), while also applying certain requirements of the general standard to laboratory operations.

David Campbell, Ph.D., Chair, Institutional Biosafety Committee and Roberto Peccei, Ph.D., Vice-Chancellor of Research, University of California, Los Angeles, by electronic mail dated August 20, 2008.

Comment #DC1: UCLA strongly supports the comments submitted by Stanford University in regards to laboratory operations. The commenters believe that this standard would have a negative impact on the research community in California. The proposal is redundant with existing NIH requirements, and does not provide delineated risk assessment for each regulated agent and its use in the laboratory. Requirements are elevated to higher containment and practices without appropriate cause. For example, inclusion of adenovirus and retroviruses as pathogens requiring aerosol control or Biosafety Level 3, disregards that there are readily available avirulent or attenuated strains of these agents. These agents can be used for human gene therapy studies, and assigning aerosol control or BSL3 to such agents will impact studies and hinder research.

Response: Changes have been made to subsection (f) and Appendix D to clarify that inclusion of pathogens on the list in Appendix D triggers a risk assessment, and does not necessarily require BSL3 practices or containment. See response to comments #LW1, #LG1, and #LG2 for further discussion.

Donna Gerber, California Nurses Association and National Nurses Organizing Committee, by letter dated August 15, 2008, and Deanna Furman, Legislative and Community Advocate for the California Nurses Association (CNA), oral comments received at the August 21, 2008, Public Hearing.

Comment #DG1: The California Nurses Association supports strong regulations to protect health care workers and many areas of strength are evident in this regulatory package. There are numerous and increasing threats from emerging diseases and multiple drug resistant organisms that impact health care workers directly. The inclusion of the term novel and unknown pathogens is very important to protect the health care workforce from the currently unknown and as yet unidentified pathogens.

Response: The Board thanks the Ms. Gerber, Ms. Furman, and the CNA and NNOC for their comments.

Comment #DG2: In regards to Section 5144, it is important that the “fit test” for the respiratory protection equipment not be used under any circumstances to discriminate in the workplace or in the health care coverage the health care worker holds.

Response: Fit testing required by this standard (and Section 5144) is designed to ensure that the respirator fits the health care worker, and should not relate to the health status of the employee. Medical evaluations and fit tests are currently required for all employees using respirators, including health care workers, under Section 5144, and issues relating to protecting employees from discrimination in the workplace would not be affected by this proposal. As required by Section 5144, an employer is responsible to offer more than one respirator for use in the workplace, so that employees may be provided with a good fitting respirator.

Comment #DG3: The regulation should retain annual fit testing to assure compliance and worker protection, rather than biannual fit testing.

Response: The proposal includes an exception permitting biennial fit-testing for employees who do not perform high hazard procedures, which will sunset in 2014. The intent of this exception is to maximize the number of health care workers who are prepared to use respirators, by providing them with annual training and initial and periodic fit-testing. The modified proposal includes an additional requirement that employees of employers who only provide biennial fit-tests be annually surveyed to determine if they have had facial or weight changes that may effect respirator fit, or if they want an additional fit-test. The Board believes that this standard will protect health care workers against aerosol transmissible diseases while ensuring that health care organizations do not unduly restrict respirator use in order to conserve resources. Please see the response to comment #BK18 for additional response on this issue.

Comment #DG4: The commenter strongly supports the recommendation that employees performing high hazard procedures on suspected or confirmed airborne infectious disease cases be provided with the high level of protection provided by powered air purifying respirators (PAPR). All registered nurses, and other health care workers, should be trained in their use. Droplet precaution should be viewed as aerosol transmissible disease/pathogen as a practical matter.

Response: Aerosol generating procedures (high hazard procedures) may generate aerosol concentrations that are ten times or more higher than other patient care activities (Fennelly, 2004). For this reason, the proposal specifies a higher level of protection for these activities. It is up to the employer, with the input and review of employees, to determine which employees need to be trained for PAPR use, based on current assignment and foreseeable surge situations. Diseases requiring droplet precautions are included within the scope of the standard. However, based on current public health recommendations, they do not require airborne infection isolation.

Comment #DG5: This regulation should provide protection for exposure to animal diseases, such as *Mycobacterium bovis*, which can infect humans.

Response: The Board agrees that all human *Mycobacterium tuberculosis* complex infections should be included in this standard, and the proposal has been changed to clarify that the term *M. tuberculosis* means the complex, which includes *M. bovis*, *M. africanum*, and *M. microti*. Avian

influenza is also specifically included in Appendix A, as is SARS and monkey pox. If new aerosol transmissible zoonotic diseases emerge, they will be considered novel and unknown pathogens, and therefore addressed by the requirements of this standard. In regards to laboratories, Appendix D includes a number of zoonotic pathogens.

Comment #DG6: Clear, accurate, timely, and focused communication is important to preventing and ameliorating workplace problems, and is an important training element. All workforce sectors of health facilities should be held accountable for communication to protect employees, patients, families and their communities.

Response: The Board agrees that communication is necessary to protect employees from disease, and notes that there are a number of provisions in this proposal addressing communication.

Comment #DG7: The commenter is concerned that most of the employers within the scope of the standard would be considered referring employers, to whom only “minimal” requirements would apply. These employers do not provide services beyond first aid and initial treatment to patients requiring airborne infection isolation, as AirID suspect or confirmed cases. The commenter believes that the underlying assumptions for distinguishing between referring employers and other employers are faulty. “Individuals who have airborne transmissible disease (ATD) may not know they have it, or may not remember or report accurately their symptoms, including the severity and duration.” The commenter states, “The very high rate of uninsured and underinsured residents of California (many of whom are healthcare workers) means that a portion of the population who may seek health care in medical offices and clinics, homeless shelters, drug treatment programs, hospices, long-term care facilities, or are sent to jails, are, in fact infectious with an airborne transmissible disease.”

The commenter further states that health care workers in referring employer environments will be exposed to airborne transmissible diseases that require both droplet precautions and airborne infection isolation. An additional problem is the “disturbingly low” level of personal health literacy among the general public.

Response: The standard distinguishes between referring employers and employers who house, treat or otherwise manage AirID cases and suspected cases in order to ensure that patients who are infectious with diseases requiring airborne infection isolation are, in fact, appropriately isolated. Homeless shelters, drug treatment programs, and most primary care practices do not have airborne infection isolation rooms. Homeless shelters and drug treatment programs, and some correctional facilities and police operations do not have personnel who are trained in medically managing ATD cases. Therefore, the primary method of protecting workers in referring employer environments is early case recognition and prompt placement of those people requiring airborne infection isolation in an appropriate facility. For referring employers who do not have health care providers, the emphasis is on referring people who manifest certain easily recognized symptoms, as described in Appendix F, to health care providers.

In addition, source control measures such as separating the patient and providing a mask or tissues and hand hygiene materials, vaccination of health care workers, annual TB assessment, employee training, and procedures for exposure incidents will further reduce the risk to those employees.

Health care operations, such as home health care, which may be providing services to persons with infectious TB or other diseases requiring airborne infection isolation and are managed in a home or community setting, would not be considered referring employers.

Through ten advisory meetings, public health guidelines, research and the direct experience of health care workers and organizations were reviewed and discussed, in order to develop a proposal that could be implemented and provide protections that would reduce the risks to health care workers and other workers in high risk environments. Everyone who interacts with the public, students, customers, or other people runs the risk of exposure to infectious diseases. However, experience has shown that people who perform high hazard procedures, or who have prolonged or intense contact with infectious people are at higher risk.

The intent of creating the referring employer category is to require employers to have infection control procedures that are appropriate for the specific risks and exposures in their environments. These procedures may be very different in homeless shelters, where there may not be medical providers on-site, than they are in skilled nursing facilities or primary care offices and clinics.

Comment #DG8: The commenter believes that exempting dental offices and outpatient medical specialty offices from the standard if they screen patients for ATDs, refer those patients, and do not perform aerosol-generating procedures on those patients, is based on the faulty assumptions that underlie the referring employer category.

Response: The proposal is designed to address those workplaces at which employees are at higher risk than employees in other public contact operations. Aerosol generating dental procedures may transmit aerosol transmissible diseases, and dentists who perform these procedures on persons who have an ATD are covered by this standard. However, current dental practice guidelines advise dentists to screen patients for ATDs before performing procedures on them. The Board believes there is a necessity to ensure that employees are trained in screening procedures and that these procedures are implemented. Therefore, the proposal has been modified to require written screening procedures and training of employees in these procedures. See response to comments #BK2 and #BK3 for further discussion of these provisions.

Comment #DG9: The commenter is concerned regarding how worker protections are being integrated into the All Hazards Disaster Response of health care facilities, communities, regional and public health departments. How would it address alternate care sites, which will be staffed by health care providers and non-health care providers, and how would Appendix F apply? Also, it is essential that appropriate supplies be on hand for immediate use during a public health surge.

Response: Subsection (d)(2)(F) and (d)(2)(M) as first noticed by the Board contained requirements regarding surge planning. The revised proposal relocates these requirements to subsection (d)(2)(Q) which also references local and regional emergency plans. Subsection (i)(4)(L) also requires employees to be trained in the employer's surge plan.

Appendix F is meant to apply to situations in which health care providers are not available to perform screening.

Comment #DG10: The commenter states that in discussing costs and savings, the costs avoided from workers compensation claims, lost work time, and productivity losses to the employer, as well as employers of the employee's family, as well as the harm due to significant illnesses, disabilities and premature death, should be considered as potential savings due to the proposed standard.

Response: The Board has included projected savings related to vaccination and certain other provisions in the cost estimates of this proposal, and thanks the commenter for calling attention to the significant harm, as well as costs that result when an employee contracts an ATD.

Vickie L. Wells, CIH, CSP, Director, Occupational Safety and Health, City and County of San Francisco, by letter dated August 21, 2008, and oral comments received at the August 21, 2008, Public Hearing.

Comment #VW1: Many facilities that do not provide health care services do not have rooms or areas equipped with a separate ventilation system where a symptomatic individual can stay while awaiting transportation. It is not clear who can establish what is feasible for the establishment to do to provide such an area.

Response: The Board agrees that there will be facilities that are not equipped to provide areas with separate ventilation. The issue of feasibility has to be considered in light of the reasonableness requirements of Labor Code sections 6401 and 6403. A determination of feasibility requires a good faith effort on the part of employers to assess their capabilities and the level of risk. This determination may differ between employers, even in the same sector. For example, some homeless shelters are essentially a large area where cots or other temporary beds are placed. The most that can be feasibly done in that situation may be to place a possible ATD case in an area separated by as much distance as possible from where others are located. Other shelters may have a side room where a person can be placed. Similarly, some clinics may have an examination room or other room with a separate ventilation system, while others may not. A facility that frequently is in the position of temporarily housing individuals requiring referrals may need to put more resources into developing control measures than one that does not. Ultimately, the burden in this standard will lie on the Division to establish that a feasible method was not used.

Comment #VW2: The requirement in subsection (d)(2)(E) to list specific engineering controls and other specific protective measures for each task where occupational exposure may occur is

impossible because there are so many tasks in that category. Also, the protective measures to be taken would depend on the specific organism of concern.

Response: The purpose of this subsection is to address how facilities, services or operations will implement the requirements of this standard. The purpose of listing specific control measures is so that employees and employers can be aware of how ATD risks will be controlled in a specific operation. While it is true that some control measures are based on the specific pathogen, control measures must often be implemented before the actual disease agent has been identified.

The Board agrees with the comment to the extent that a requirement to list control measures by task or group of tasks may appear to require more detail than is necessary or practicable in a written plan. Therefore, modified language is proposed to remove the words “type or group of tasks,” leaving the requirement to apply to operations or work areas. The rest of this subsection explains that the Plan must include the applicable engineering controls and work practice controls, cleaning and decontamination procedures and personal protective equipment and respiratory protection, for an operation or work area. In developing the Plan, the employer should address operations or work areas, in a manner appropriate to the facility. For example, a hospital may choose to address all airborne infection isolation rooms in the facility as one type of operation, and may in addition state that when the patient in the room is a suspect or confirmed SARS case, that additional personal protective equipment must be used. The Board believes that with the modifications proposed, employers will be able to efficiently structure the Plan to provide the necessary guidance to supervisors and employees.

Comment #VW3: In regards to subsection (e)(5)(B)2.d, it is not within the current scope of duties for local health officers to recommend measures to use when an individual cannot be transferred to an airborne isolation room within 24 hours. This is not an appropriate task for a local health officer and this responsibility should not be assigned to the local health officer [LHO].

Response: Representatives of the California Conference of Local Health Officers were active during the advisory process. Division staff specifically queried the CCLHO on this issue in 2006, and again in response to your comment. These representatives indicated that the language in the standard in regards to the LHO is within the scope of their authority and duties (Iton). Further, this subsection does not assign to the LHO a responsibility to make recommendations, it only requires the facility to follow any recommendations made by the LHO to prevent further spread of disease.

Comment #VW4: Subsection (e)(5)(D)2 should require conformance with the 2005 CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Healthcare settings and adopt them by reference.

Response: The Board notes that this document is incorporated by reference in the definitions listing in subsection (b) of the proposed standard, and reference is made to this document in subsection (e)(1)(A). The purpose of specifically stating the ventilation requirements in this

subsection, which are consistent with the referenced document, is to provide clear notice to employers and employees of these requirements.

Comment #VW5: Subsection (e)(5)(D)3 should be revised to state: "Negative pressure shall be demonstrated by smoke tubes, other visual checks or equally effective methods daily while a room or area is in use for AII."

Response: The term "visual checks" has been used in CDC publications, however, the only method other than smoke trails that is mentioned is the use of strips of paper or other lightweight material that are attached near a ventilation intake or exhaust in a room and intended to move with the air movement into or out of the opening as a qualitative indication that the system is operating. These would not necessarily demonstrate negative pressure. However, the existing language allows for the use of equally effective means to smoke tubes, which would permit strips or other visual indications if they are effective. Consequently, the Board declines to make the recommended change.

Comment #VW6: In regards to subsection (e)(5)(D)9, the method for calculating 99.9% removal efficiency in the Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-care Settings is not straightforward. Cal/OSHA should include the calculation method in the standard or provide alternative methods. Also, evidence supporting the 99.9% standard should be provided before including this requirement in the standard.

Response: The requirement for requiring respirator use until the room has been sufficiently ventilated to provide a removal efficiency of 99.9% is included in the 2005 CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Healthcare settings, and was determined by the CDC to be necessary to protect employees against contracting tuberculosis. The document provides the method of calculating removal efficiency in Table 1. This table shows how many minutes it takes to achieve 99% and 99.9% removal of aerosols at specific rates of air changes per hour, which means how many times the total volume of air for a given room can be removed (and replaced) by the ventilation system installed in that room in the period of an hour. The Board agrees that the method of calculating air changes per hour based on volumetric air flow, which has been incorporated into CDC TB guidelines through many revisions, is not a precise calculation of removal efficiency, and an accurate determination of removal efficiency would require a much more complicated method of measurement. However, the Board believes that the method included in the CDC guideline is the most practicable approach to determining when respirator use can be discontinued. The phrase "Table 1" has been added to this subsection in order to clarify that this is the method to be used to calculate the time necessary for 99.9% removal.

Comment #VW7: Subsection (g)(4)(B) seems to include any patient with a droplet transmissible infection, or any of the infections listed in Appendix A. This should apply only to pathogens requiring airborne infection isolation. There is no scientific evidence of airborne transmission of diseases requiring only droplet precautions, such as pertussis, that would warrant this level of

protection. Also, is a PAPR required for nebulizer treatment of a patient with an extrapulmonary draining lesion?

Response: Subsection (g)(4)(B) only addresses provision of services for airborne infectious disease (AirID) cases and suspected cases. Further, a PAPR would only be required for high hazard procedures on an AirID case or suspected case (see subsection (g)(3)(B)). The proposal would not require a PAPR, or any respirator, for pertussis, although the employer may choose to require one. In regards to extrapulmonary tuberculosis, Appendix A of the Guideline for Infection Control in Healthcare Settings lists extrapulmonary tuberculosis, draining lesion as requiring airborne precautions.

Extrapulmonary, (draining lesion)	A,C	Discontinue precautions only when patient is improving clinically, and drainage has ceased or there are three consecutive negative cultures of continued drainage <sup>1025, 1026</sup> . Examine for evidence of active pulmonary tuberculosis
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This recommendation was discussed with the office of the CDPH Tuberculosis Control Branch. They indicated that there are very few cases (about one per year) of extrapulmonary TB with draining lesions that did not also have pulmonary TB. In addition to irrigation of extrapulmonary TB lesions, the recommendation for airborne infection isolation is based on the possibility that there is undetected pulmonary TB, as indicated in the comment section in the above box. In addition, the standard provides the employer with sufficient flexibility to identify whether administration of aerosolized medications to a patient that does not have pulmonary TB (or other AirID), is a high hazard procedure.

Comment #VW8: Appendix A should be clarified to indicate that extrapulmonary tuberculosis is on the airborne isolation list because of risks during irrigation procedures because currently only standard precautions are recommended by HICPAC/CDC for this condition. Are there any other diseases or conditions, such as a draining lesion in which potentially aerosolizing procedures may take place where airborne precautions would be recommended?

Response: Please see response to comment #VW7 regarding extrapulmonary TB. In regards to other diseases or conditions that may require airborne isolation for aerosol generating procedures, such as procedures involving multi-drug resistant organisms, employers should make that determination based on current public health guidelines.

Comment #VW9: Regarding Appendix A, to what specifically does “serious invasive disease” listed in droplet precautions refer?

Response: A formatting error in the Appendix separated this line from the line it referred to, which was Group A streptococcus. The reformatting of Appendix A in the modified draft, will list it under “Streptococcal disease (group A streptococcus).”

Comment #VW10: In Appendix A, for Viral hemorrhagic fevers, the following statement should be added, “Consider airborne precautions during aerosolizing procedures.”

Response: The Board agrees that this would be an appropriate statement to add to the text and proposes this addition as a modification to the appendix.

Comment #VW11: Appendix C should be amended to allow equivalent declination forms.

Response: Subsection (h)(10) requires employers to ensure that the declination statement contained in Appendix C2 be signed by employees who do not accept influenza vaccine. It does not require the use of a specific form. An exception to subsection (h)(10) permits the use of other influenza vaccination vaccine declination forms that are acceptable to the CDPH for licensed facilities.

Julie R. Jackson, CIH, CSP, Corporate Biosafety and Chemical Hygiene Officer, Corporate Quality, Environment, Health and Safety, Amgen Inc., by letter dated August 21, 2008.

Comment #JJ1: In regards to subsection (a)(2) it is unclear as to whether a walk-in onsite health clinic is exempted under this standard.

Response: The issue of whether a walk-in onsite health clinic is considered an outpatient medical specialty practice that does not diagnose or treat ATDs must be determined by each clinic. To come under the exemption, the walk-in clinic must also include screening procedures in the Injury and Illness Prevention Program. Other walk-in clinics would likely be referring employers. A definition has been added to subsection (b) to clarify what is meant by a medical specialty practice. The term outpatient facility refers to facilities in which patients are not housed.

Comment #JJ2: In regards to subsection (a)(3)(A), the statement that to be a referring employer, the facility, service or operation “must do or not do each of the following” is confusing.

Response: This subsection has been reworded for clarity.

Comment #JJ3: Regarding subsection (a)(1)(I), this section as worded could be read to broadly include a variety of building maintenance operations.

Response: The language of this subsection has been modified to indicate that it refers to those maintenance, renovation, service or repair operations that involve areas or equipment reasonably anticipated to be contaminated with ATPs or ATPs-L associated with AIIRs or areas in which AirID cases and suspected cases are housed, etc. It is meant to apply to operations in which an employee may be exposed indirectly to pathogens from a case or suspected case, or a laboratory material.

Comment #JJ4: Regarding subsection (b) the definition for AIIR should exclude the areas covered under the laboratory section.

Response: Subsection (a)(3)(B) identifies those subsections that apply to laboratories in which employees do not have direct contact with cases or suspected cases of ATDs or infected cadavers. Those subsections do not include subsection (e) which contains requirements for AIIR. Requirements for AIIR appropriately apply to laboratory operations in which there is direct patient contact, because the purpose of this engineering control is to prevent exposure to employees outside of the room or area.

Comment #JJ5: Subsection (f) does not but should support the risk based approach that is described in CDC's BMBL even though it is incorporated by reference. Also, laboratory facilities that do not receive government funding and are thus not obligated to maintain a Biosafety Committee nevertheless have an industry standard to perform a review of research with recombinant DNA and experiments with infectious agents prior to the initiation of experiments including a risk assessment with the principal investigator. Approval for the project may be granted after the risk assessment is performed.

Response: The Board agrees that risk assessment should be clearly included in subsection (f), and modifications have been made to the proposed standard to this effect. See response to comment #LW1 for more discussion on this issue.

Comment #JJ6: Appendix D of the proposed standard seems to impose more conservative characterizations to infectious agents that are commonly used throughout the research industry. Some of the organisms lack qualifiers, and others are more likely to be transmitted through percutaneous injuries. Some adenoviruses are used as a basis for gene therapy, and there should be a qualifier explaining when they are included. Appendix D does not account for the factors that would make lentiviruses or retroviruses less pathogenic such as rendering the virus replication deficient before use, thus preventing reproduction in the host as a disease.

Response: Appendix D, as originally noticed was compiled by participants from laboratories involved in the advisory process. It was derived from BMBL entries pertaining to pathogens that may require aerosol controls under some circumstances, and from pathogens identified by the Guideline for Isolation Precautions. Listing in Appendix D was only intended to trigger a requirement for risk assessment, not to specify BSL-3 precautions. However, the number of comments received on this issue have illustrated the need to clarify this language, and the language in subsection (f). Therefore, the introductory language in Appendix D has been modified to indicate that listing in Appendix D requires the biosafety officer to perform a risk assessment. In addition, a new subsection (f)(2) is proposed to specifically address risk assessment, and language is added to requirements for engineering and work practice controls (relocated to subsection (f)(3)) that references those controls to the risk assessment. Further Appendix D now contains an annotation to adenovirus that states that it applies only in clinical samples and culture and materials derived from clinical samples. These provisions permit the biosafety officer to determine the level of control measures necessary for modified virus strains. See responses to comments #LG1 and #LW1 for further discussion of this issue.

Comment #JJ7: Appendix A seems to exclude pathogens on the Droplet List from the requirements of the standard.

Response: The Board notes that Appendix A provides the list of aerosol transmissible diseases. Both diseases classified as requiring airborne infection isolation and diseases classified as droplet are covered by this standard. A modification is proposed to the introductory language of Appendix A to clarify that provisions of Section 5199 apply to both categories of diseases (airborne and droplet), but that airborne precautions only apply to those listed as “airborne.”

Comment #JJ8: The training requirements may be onerous and difficult to accomplish. The requirement to have a qualified instructor precludes the use of web based training. Secondly, it is onerous to individually identify staff annually who need to be trained. Thirdly, it is onerous to provide the epidemiology of each agent that may be present in laboratories.

Response: A number of comments were received regarding the need to address modes of training other than in-person sessions. For that reason, subsection (i) has been restructured to address how an opportunity for interactive questions will be provided if training is not provided in person by a knowledgeable trainer. For more details, please see comment #RR9 for further discussion.

The Board does not agree that it is difficult to identify staff who need training, and notes that there are many other annual training requirements such as respiratory protection and bloodborne pathogens. Annual training is particularly necessary because work practice controls are key to preventing exposure in a laboratory context. In regards to training on the “epidemiology” of each agent, there is no requirement in this proposal to that effect. Training is required to address a general explanation of ATDs including the signs and symptoms of ATDs that require further medical evaluation, and an explanation of the modes of transmission of ATPs or ATPs-L and applicable source control procedures.

Comment #JJ9: In regards to subsection (h)(5), vaccinations for laboratory employees, this may be a problem as it is not clearly stated that these vaccines are limited to commercially available vaccines.

Response: In order to clarify vaccine requirements, this subsection has been changed to refer vaccination requirements to the BMBL, which recommends commercially available vaccines.

Comment #JJ10: This standard duplicates some of the requirements of Section 3203, for example the biosafety plan duplicates requirements of Section 3203.

Response: The advisory process identified a need to more specifically address required control measures for aerosol transmissible diseases. The intent of a vertical standard such as this is to create a matrix of control measures. While it is true that Section 3203 requires a written safety and health program, it cannot be construed to require all of the specific elements that are necessary to building an effective biosafety plan or exposure control plan.

Comment #JJ11: There is no differentiation described for Biosafety Level 3 and aerosol droplet precautions. Consequently, it is unclear as to whether adenovirus may need to be manipulated at Biosafety Level 3. The wording of Appendix A implies that the standard is not applicable to the list of pathogens on the droplet precaution list.

Response: The precautions to be taken with any pathogen in a laboratory are based on the risk assessment performed by a biosafety officer, in accordance with the BMBL. The modified proposal contains a reworded introduction to the lists on Appendix A to clarify that the requirements of the proposed standard apply to all aerosol transmissible diseases, droplet and airborne, but that airborne infection isolation requirements only apply to diseases or pathogens classified as airborne.

Sean Barry, Campus Biological Safety Officer, Environmental Health and Safety Department, UC Davis, by oral comments at the August 21, 2008, Public Hearing.

Comment #SB1: Subsection (f) establishes a requirement that the University already meets. They are required to have an institutional biosafety committee to review all research, research labs, and research activities on all of the UC campuses, and that requirement has been in place with NIH since 1974. It was originally directed at recombinant DNA research in particular. The research involves microbes and pathogenic microbes and the committee is specifically charged with performing a risk assessment on every piece of research. The proposal as written does not allow space for risk assessment, and safety committees would feel that they were being second-guessed by the proposal.

Response: The Board notes that other comments received from laboratory operations made similar comments regarding the absence of a “risk-assessment” requirement. As explained in the response to #LW1, the Board proposes a modification to clarify this issue. Also the issue of potential redundancy of requirements is addressed in the response to comment #LG1.

Comment #SB2: Many institutions already have a committee review process for a safety assessment of proposed research. They have an institutional safety committee that evaluates the proposal and decides if an approval is appropriate or not. The researcher needs a use authorization from this committee in order to proceed with the experiment or process.

Response: Existing biosafety structures, such as biosafety committees, can be an important part of the employer’s biosafety plan, as required under this section. There is no contradiction between the guidelines to which the commenter refers, and requirements under this section. There is further discussion of this issue in the response to comment #LG1.

Comment #SB3: The list of pathogenic organisms in Appendix D does not seem to make allowance for the use of metaviral or genetically modified agents that are quite useful for all sorts of genetic investigations.

Response: Modifications are proposed to the introduction to Appendix D, and to subsection (f) to clarify the Board's intent that the employer perform a risk assessment based on recognized guidelines, which can take into account modifications of the agent. The specific listing of adenovirus has been modified to reflect that it only applies to clinical specimens and cultures and other materials derived from clinical specimens. Further discussion is included in the response to comments #LW1, #LG1 and #JJ6.

Donna Bennett, FNP, COHN-S, Employee Health Services, Lodi Memorial Hospital by electronic mail dated July 25, 2008.

Comment #DB1: Documented immunity by blood titers to the aerosol transmissible diseases should be included as an acceptable record in place of documentation of vaccination.

Response: Subsection (h)(5) would require employers to make the vaccine doses listed in Appendix E available to all susceptible health care workers. Susceptibility is to be determined in accordance with Epidemiology and Prevention of Vaccine-Preventable Diseases, published by the CDC. Titers are one method of determining immunity, however, depending on the disease, they may not always provide sufficient information. An employee who does not decline a vaccination will be provided with the vaccine by a PLHCP, who may determine that the employee is immune and does not need the vaccine. The standard, however, prohibits employers from requiring that employees participate in a serology screening as a condition of providing the vaccine. This is in order to prevent delay in providing a needed vaccine and to prevent employees from declining the vaccine because they do not wish to participate in a serology program for personal or religious reasons.

Comment #DB2: It is unclear why the annual fit testing requirement would be changed for six years to a biennial requirement and then changed back to annually. "It is not reasonable to fit test employees for a mask they will not be wearing. The N95s are disposable and therefore different every time they are used. If the employee is trained to do a fit check each time the mask is worn, they should not need refitting unless there is a change in facial structure or they are having problems. Annual fit testing is a monumental waste of man hours and creates unnecessary waste in landfills. I have 800 employees fit tested every year in addition to new hires. That is 800+ respirators that could have been used for a legitimate need to actually protect someone."

Response: Annual fit-testing is currently required by Section 5144. The Initial Statement of Reasons discussed the purpose of the exception, permitting a less frequent periodic fit-test interval until 2014. Periodic fit-testing is necessary because employees are not always aware of facial changes that influence respirator fit, and to reinforce the proposed use of respirators. For additional comment on respirator fit-testing please see comment #BK18.

Comment #DB3: The fit testing process is cumbersome and should be amended to reduce the amount of time it takes to perform. The test procedure should be altered to allow the tester to determine the employee's ability to taste/smell the test solution after the mask is tested, because in her experience most of the time the employee can detect the smell with one puff of the solution.

Response: The fit-test methods are required by Section 5144 and by the equivalent federal regulation 29 CFR 1910.134. They have been validated by extensive testing. The purpose of determining the taste threshold of the employee prior to the test, is that it is used to determine how much of the test agent is applied to the atmosphere outside of the respirator during testing. This is used to ensure that the respirator provides a sufficient level of protection. It should be noted that in addition to the taste agents used for N95 qualitative fit-tests, Section 5144 and this proposal permit the use of two quantitative methods.

Victoria Becker, RN, by letter dated August 4, 2008.

Comment #VB1: The commenter states that she is a registered nurse in California. She believes, based on her experience as a nurse, that it is very important that the Board adopt the proposed regulation. Currently, there are a lot of voluntary guidelines, but, unlike bloodborne pathogens there is no regulation that specifies what is necessary to protect employees. When she was working as a home health nurse, she was assigned to visit a TB patient who had recently been discharged from the hospital. The initial information she was provided indicated that the patient had been hospitalized for two weeks, and was not infectious, and that she didn't need any protective measures. But when she asked for documentation of his discharge, it turned out he had not been hospitalized for two weeks, he had not had three consecutive cleared sputums, and he was considered infectious. She then had to argue with her supervisor to get fit-tested for a respirator, and when they had trouble finding a respirator that fit, her supervisor tried to get her to do the visit with a respirator that had not passed the fit test. When she called Cal/OSHA, they said the employer is required to provide a fit-test if they require respirator use, but that Cal/OSHA might have trouble establishing that a respirator is required in a home health situation. Therefore it is important that this proposal requires the use of respirators in home health care operations.

Response: The Board thanks Ms. Becker for her comments and agrees that home health care operations belong within the scope of this standard.

Comment #VB2: This section should apply to people who work in all home care operations, including in-home support services. People requiring personal care may be immune-compromised, and latent TB may become infectious. The people who provide personal care generally do not have the knowledge to determine whether a patient may be infectious. Therefore, this standard should apply to all home care operations, not just home health care.

Response: See response to comment #MC2.

Comment #VB3: The communications provisions, and provisions for medical follow-up are very important. Home health nurses are often sent out to visit patients without adequate information about who may be present in the home with infectious diseases. It is important that employers be required to tell nurses about the patient's status as part of the initial assignment.

When nurses and other employees get exposed, they need to be provided with prompt and knowledgeable medical care.

Response: The Board thanks Ms. Becker for her support for these provisions.

William T. Fujioka, Chief Executive Officer, and Steven E. NyBlom, Manager, Risk Management Branch, County of Los Angeles, by electronic mail dated August 21, 2008.

Comment #WF1: The Initial Statement of Reasons (ISOR) does not include a cost/benefit explanation of the need for this regulation and does not accurately estimate the costs associated with implementing the various programs required by the regulation. The regulation would impose significant financial burden on local governments, in particular peace officer and firefighting agencies. For example, Section 5199 would require annual TB skin testing of all 60,000 peace officers in the state without any evidence of increasing TB rates among peace officers not assigned to correctional facilities.

Response: The Board disagrees with the statement that the ISOR does not adequately address the costs and benefits of the proposed regulation. The necessity for this regulation is discussed in general in the ISOR summary, and with great specificity the necessity and benefits are elaborated for more than 40 pages in the section of the ISOR titled *SPECIFIC PURPOSE AND FACTUAL BASIS OF PROPOSED ACTION*. Cost estimates begin on page 46 of the ISOR. Estimated costs for each proposed subsection of the regulation are discussed. Firefighters and peace officers would generally be considered employees of Referring Employers; costs for this type of employer are detailed from page 47 to page 49. The Board notes that many of the proposed requirements for jails and other correctional facilities are currently required by Titles 15 and 17 and therefore do not impose new costs. Tables in the ISOR illustrate that the cost for vaccinations is offset by savings from employees not having to take sick leave.

Finally, the comment that all of California's peace officers would have to be given the TB skin test is a misinterpretation of the regulation's requirements. The Board agrees that many peace officers are not occupationally exposed to aerosol transmitted diseases. "*Occupational exposure*" as defined in the definition section of the standard requires circumstances that elevate the risk of contracting any disease caused by ATPs or ATPs-L. Thus only some peace officers or firefighters would have to have the TB skin test: those who are reasonably anticipated to be exposed to a source of ATPs that is elevated above the exposure risk incurred by employees in public contact operations not included within the scope of the standard, such as retail clerks or public transit operators. Examples of peace officers who are likely to be included in the standard are those who work in correctional facilities or who transport or maintain in custody persons who are ATD cases or suspected cases. It is up to the employer to determine which officers have occupational exposure in the course of their duties.

Comment #WF2: The Standards Board needs to show that the targeted diseases are rising in incidence, while TB is in fact dropping in incidence.

Response: The Board disagrees that it is required to show an increase in TB or other targeted diseases in order to adopt a standard. The Board is required to adopt standards that are necessary to protect the health and safety of employees. Health care workers and other workers identified in this standard continue to have exposure to ATDs in the course of their work, and are additionally being prepared to deal with a potential outbreak of pandemic flu or other disease outbreak. The Initial Statement of Reasons contains the factual basis for this standard. Additional discussion is provided in response to comment #AF1.

Comment #WF3: Subsection (h)(6)(B) transfers the duties and responsibilities of the local public health officer to each employer, in essence requiring them to become public health investigators.

Response: Subsection (h)(6)(A) and (h)(6)(B) have been restructured to separate out the responsibility of health care providers or employers to report cases or suspected cases to the local health officer. Subsections (h)(6)(B) and (h)(6)(C) establish requirements for employers to conduct exposure investigations in relation to their employees and to communicate about potential exposure with other employers. This is not a transferring of duties from the local health officer. The LHO is responsible for community contact investigations which may overlap with the employer's responsibility to investigate workplace exposures, injuries and illnesses. A new sentence has been added to subsection (h)(6)(C) to require that the exposure investigation be provided to the LHO upon request.

Bonnie R. Kolesar, ARM, CCSA, Assistant Secretary, Office of Risk Management, California Department of Corrections and Rehabilitation (CDCR), by written comments dated August 20, 2008.

Comment #BRK1: CDCR disagrees with the assertion in the ISOR Informative Digest that the proposal will not result in significant costs to state agencies. There will be costs to assess whether current ATD control practices already mandated by other statutory and regulatory requirements are adequate to be compliant with Section 5199. There will be start-up, annual and on-going administrative costs associated with the vaccination program while the existing TB surveillance program has unresolved issues unrelated to Section 5199. The costs of Section 5199 compliance include training, record creation and data management. The cost balancing claim contained in the ISOR is questionable on two counts: 1) because CDCR does not receive Workers Compensation claims for influenza, there are no cost savings arising from an influenza vaccination program; and, 2) it would be difficult to figure out how to distribute any cost savings to the parts of our agency that would incur the vaccination program costs.

Response: Many requirements of Section 5199 are at least in part required by other standards, so the magnitude of costs will be in many cases less than required to initiate totally new programs because the costs will stem more from fine-tuning of existing programs. For example, the California Penal Code, Sections 6066-6009 require initial and annual or more frequent TB assessments for all correctional employees. Title 8, Section 3203 requires employers to evaluate

and address hazards in the workplace through training and hazard correction. Title 8 Section 14300 et seq require recording of TB conversions.

Like many employers in the private business sector that have recognized the benefits of having fewer employee sick days due to the flu, and due to the importance of maintaining a healthy population in correctional facilities, the CDCR itself in 2008 initiated an influenza vaccination program for correctional employees and inmates. Vaccinations other than influenza are only required to be provided to employees working within the health care operations in facilities operated by CDCR, not to all correctional employees. Many health care workers are already vaccinated for mumps, measles, rubella, and varicella. Boosters of tetanus, diphtheria and acellular pertussis vaccine are typically recommended to be provided every 10 years. As discussed in the ISOR, the cost of immunization is low relative to the cost of disease. Providing these vaccinations permits the employer to reduce the susceptibility of its workforce to these diseases, such as chicken pox, which appear sporadically, and to pertussis, which is a re-emerging disease.

The Board agrees that in most instances influenza is not a disease eligible for workers compensation benefits. The ISOR reference to workers compensation savings refers instead to other ATDs whose etiology can often be determined to be work related such as TB, chicken pox, and meningitis.

Comment #BRK2: The vaccination program raises issues of medical confidentiality, responsibility of adverse impacts of vaccinations, impingement on CDCR pre-employment vaccination requirements, and impact on public sector bargaining obligations.

Response: The issue of medical confidentiality is addressed through modified language that limits the information to be provided regarding vaccines and immunization to the employer by the PLHCP, in subsection (h)(5)(F). A one-year delay is proposed for implementation of vaccination requirements to allow employers to deal with administrative issues in providing the vaccines, and to minimize costs to employers. This will provide additional time to state agencies to integrate the vaccination program with other requirements.

Comment #BRK3: The CDCR's custody functions relating to inmate health care have been diverted to a receivership by the Federal courts; the Receiver's responsibilities and span of organizational control are intertwined with that of the CDCR but with independent authority. Therefore adoption of the relevant proposals should be postponed until the Board has received the Receivership's comments, if any.

Response: The Receivership has not indicated any objections to Section 5199 to date. Section 5199 applies to employee health and safety, not to the inmate health care responsibilities that are the purview of the Receiver. The requirements of this standard are consistent with general public health recommendations.

Barbara Materna, Ph.D., CIH, Chief, Occupational Health Branch, California Department of Public Health, by written and oral comments received at the August 21, 2008, Public Hearing.

Comment BM#1: The California Department of Health (CDPH) voices its strong support for the ATD standard, the promulgation of which is an important and necessary step to ensure that California's health care, laboratory, public health, correctional facility and other workers at risk for contracting aerosol transmissible diseases have enforceable protections and employers have clear direction. Over the past years the CDPH has responded to many situations involving workers who have contracted ATDs or have been potentially exposed to aerosol transmissible pathogens, including investigations involving brucellosis, exposure to live anthrax spores, TB, Q-fever, and seasonal influenza. It is now time for a comprehensive approach, and Cal/OSHA has conducted an extremely thorough and thoughtful advisory process to involve all potentially impacted stakeholders in the development of the proposed standard, identify current "best practices" in infection control and review the scientific basis for the prevention measures required. CDPH anticipates working closely with Cal/OSHA to support effective implementation of the standard after its adoption.

Response: The Board thanks Ms. Materna for her comments and recognizes the support the CDPH has provided to the Division in developing this standard.

Bill Taylor, CSP, Safety Manger, City of Anaheim Risk Management, by written comment dated August 15, 2008, and oral comment received at the August 21, 2008, Public Hearing.

Comment #BT1: In subsection (a), scope, correctional facilities are broadly incorporated, from the very large state prisons to the far smaller facilities like our City jail. Jail population, cell population, length of stay and the proximity of the inmates are key factors that must be evaluated to assess the true risk of transmission of an ATD in a correctional facility. At our City jail, each detainee is medically screened and referred out to a County jail or hospital as appropriate. While it would thus appear we should qualify as a "referring employer, under this regulation our detention facility staff is still mandated to comply with all of the other requirements of the regulation. The City of Anaheim proposes instead that correctional facilities that meet the following conditions would not be required to comply with the standard: screen detainees pursuant to the guidelines in Appendix F and house less than an average of 30 inmates with each inmate in residence for less than an average of 3 days.

Response: The City of Anaheim jail, as described by Mr. Taylor, fits the definition of a referring employer. Referring employers *do not* have to comply with all the requirements of the standard. As is made clear in subsection (a)(3), Application, a referring employer is required only to comply with the provisions of subsection (a), subsection (c), and subsection (j) and some parts of other subsections referenced in subsection (c). The Board does not agree with the proposal to exclude certain correctional facilities from the standard as this would leave correctional facility employees at risk of exposure to ATDs.

Comment #BT2: Subsection (a), by placing maintenance employees who perform routine HVAC work on facilities that house inmates in the same category as correctional officers, grossly overstates the risk maintenance employees have of acquiring an ATD. Maintenance operations on correctional facilities should not be covered by this standard if the facilities meet the conditions described in Comment #BT1.

Response: The reference in subsection (a) to maintenance operations involving air-handling systems has been changed to clarify that the air-handling systems addressed in the standard are those connecting to AII rooms or areas, or laboratory areas, or other areas reasonably anticipated to be contaminated with aerosol transmissible pathogens. It is then up to the employer to determine whether there is occupational exposure, and whether occupational exposure has been prevented through decontamination procedures. For example, an employee doing maintenance activities in an AIIR that is occupied by a patient with active tuberculosis would be considered to have occupational exposure. An employee doing the same maintenance activity when the room is no longer occupied and it has been decontaminated and ventilated, might not have occupational exposure.

The situation described in the comment, where a person is only held in the City Jail for a short period of time, might not create a situation where the air handling systems are considered a reasonable source of exposure to ATPs, particularly if maintenance activities do not take place within a short period of time after the person has left the area.

Comment #BT3: It is impractical to expect respiratory hygiene/cough etiquette recommendations to be followed with non-compliant detainees.

Response: The respiratory hygiene/cough etiquette requirement of subsection (c)(2) clearly states it is operative only to the extent reasonably practical. The Board expects that while it may be futile to insist that hostile, combative detainees use cough etiquette, many other detainees would comply with appropriate requests from correctional officers.

Comment #BT4: Police officers have only very limited exposures for short durations to arrested persons, so there is little chance for TB conversion. In fact, in the past five years we have not had a case when a police officer was exposed to an ATD and then tested positive for the disease. A Latent TB Infection (LTBI) surveillance program for our 400 police officers and 17 correctional officers would cost over \$20,000 annually, allowing an hour per test. Police service operations where personnel are classified as referring employers need not provide surveillance of LTBI infection.

Response: Whether or not an employee must be in an LTBI surveillance program is dependent upon whether or not the employee has occupational exposure to cases of or suspected cases of TB. A modification has been proposed to subsection (a)(1)(C) to further clarify which police services are included within the scope of the standard. In addition, an employer must determine which employees have occupational exposure as defined in subsection (b). In assessing employee exposure, an employer may, for example, identify those officers who perform higher

risk activities, such as screening of detainees for infectious diseases or transporting detainees needing medical care, as being the employees who have occupational exposure. The employees who are determined to be at increased risk are the only ones to whom medical services or other components of this standard must be provided.

Comment #BT5: In regard to the vaccination requirements of subsection (h)(5), not one City of Anaheim police officer or firefighter has contracted one of the listed ATDs via occupational exposure. Only influenza vaccination should be on the list, and administering the influenza vaccination will cost the city over \$20,000 annually.

Response: The only vaccine required by this standard for non health care workers is the influenza vaccine. As indicated in the ISOR, influenza vaccine is an extremely effective measure in preventing productivity loss and other costs associated with employee absenteeism. Further, the commenter estimated the employee time spent in receiving the vaccine to be one hour per employee. However, employers who sponsor flu vaccine clinics have indicated that the time an employee spends from start to finish, is typically less than 15 or 20 minutes, even when there is some waiting time. Employers may also choose to provide influenza vaccine through an employer-paid health plan, so long as the employee is not charged a co-payment, which is currently the case for many health plans. The ISOR contains additional discussion of influenza vaccination.

Elizabeth A. Treanor, Director, Phylmar Regulatory Roundtable, by written comments dated August 20, 2008, and oral comments received at the August 21, 2008, Public Hearing.

Comment #ET1: Phylmar Regulatory Roundtable (PRR) supports the exclusion from the standard of medical specialty practices that meet the specifications for exclusion contained in subsection (a)(2)(B) but believes further clarification is necessary. Many employers provide on-site occupational health clinics for employees. Occupational health clinics that meet the criteria for exclusion (i.e., have written screening procedures and refer employees to an appropriate medical provider), should be specifically mentioned in the subsection so there is no confusion in the general industry workplace about application of the subsection in the workplace. Based upon the number of queries received by PRR, the current language is not clear with respect to occupational health clinics. The subsection should begin, "Outpatient medical specialty practices, including employers on-site occupational health clinics..."

Response: A definition of medical specialty practice is proposed to be included in subsection (b), which would include any medical practice other than one that is primary care, general medicine or family practice. Further enumeration of the different types of medical specialties would be unwieldy and is unnecessary to understanding the application of this section. Each occupational health clinic, if it is not a primary care, general medicine, or family practice, will need to determine for itself whether it treats or diagnoses ATDs. If it does not, and it has screening procedures meeting the requirements of subsection (a)(2)(B), then it can come under this exemption. Additional discussion of this provision, as modified, is included in response to comment #BK3.

Comment #ET2: PRR recommends adding a new exception to subsection (a)(2) for voluntary or collateral duty first aid. Paramedic and emergency medical services are specifically included in the standard but voluntary and collateral duty first aid are not explicitly excluded. PRR has received a number of queries regarding the applicability of Section 5199 to employees who perform first aid, so we recommend the addition of a new exception to eliminate potential confusion.

Response: The ISOR states this standard was developed to address the risks to health care workers and workers in other high-risk environments due to exposure to aerosol transmissible pathogens, such as the agents which cause tuberculosis (TB). Unlike the bloodborne pathogens standard, which broadly applies wherever there is occupational exposure, this proposed standard only applies in the facilities, services and operations specifically identified. Incidental delivery of first aid outside of these identified environments is not included within the scope of this standard. *Paramedic* and *emergency medical services* are defined and regulated in California codes and do not include ancillary first aid providers. Therefore, it would be confusing to specifically exclude a group of employees who are not working within the scope of the proposed standard.

Kevin Bland, representing California Framing Contractors Association (CFCA), California Conference of Mason Contractor Associations (CCMCA), and Residential Contractors Association (RCA), Bo Bradley, Director of Safety, Health, and Regulatory Services, Associated General Contractors (AGC) of California, Bruce Wick, Director of Risk Management, California Professional Association of Specialty Contractors (CalPASC), by oral comments received at the August 21, 2008, Public Hearing.

Comment #KB1: Kevin Bland, Bo Bradley, and Bruce Wick stated that they support the comments prepared by Elizabeth Treanor.

Response: See responses #ET1 and #ET2.

Daniel C. Tappen, Supervising Industrial Hygienist, Occupational Health Program, Department of Environmental Health, County of San Diego, by written comment dated August 21, 2008.

Comment #DT1: The proposed regulation is not needed, as Section 3203, the Injury and Illness Prevention Program regulation, addresses the issues better than trying to incorporate a wide variety of infectious disease guidelines into a “one size fits all” regulation.

Response: The Board believes that the control of aerosol transmitted diseases is not addressed with sufficient specificity by Section 3203, when it comes to protecting workers in high risk environments such as health care, corrections, and other workplaces identified in this proposal. Section 5199 identifies which specific employer categories need to address this issue to protect employees and points employees to CDC and other sources of recognized recommendation for the handling of specific disease risk.

Comment #DT2: The definition in section (b) for aerosol transmissible disease as diseases or pathogens for which droplet or airborne precautions are *recommended* in Appendix A is confusing, as Appendix A, which is *mandatory*, states employers are required to follow Section 5199's protections. Also, please clarify if the referenced diseases apply to both the airborne disease pathogen list and the droplet precaution list.

Response: The introductory language of Appendix A has been modified to clarify, consistent with the definition, that both diseases identified as requiring droplet precautions and diseases requiring airborne infection isolation are included within the scope of this standard. In addition, the term "recommended" in the definition has been changed to "required."

Comment DT3: The term "*outpatient medical specialty practices*" in subsection (a)(2)(B) is not defined anywhere in the regulation.

Response: A definition of the term "medical specialty practice" is proposed to be included in this section. Please see comment #ET1 for further discussion.

Comment #DT4: Subsection (e)(5)(D) on ventilation rates for airborne infection isolation rooms is more restrictive than the more flexible CDC recommendations which only recommends 12 air changes per hour (ACH) if feasible. The flexibility of the CDC recommendations is especially important to older facilities for whom upgrading from 6 ACH to 12 ACH is particularly infeasible. The 6 ACH comes from ASHRAE and AIA criteria for isolation or treatment rooms, and there are no studies showing employees are at risk at the lower ACH. When this section discusses necessity for negative pressure to be maintained in AI rooms or areas, it does not specify the differential in pressure between the AI room and adjacent areas. The pressure differential is more significant for employee health than the ACH question. Currently, CDC's TB criteria recommend, but do not insist on,  $\geq 0.01$  inches water gauge, while older CDC numbers and the formerly proposed Fed/OSHA TB standard called for a 10% greater exhaust flow than supply flow to the AI room with a minimum of 50 CFM differential. This latter recommendation should be the minimum requirement in the ATD standard with  $\geq 0.01$  inches water gauge required if feasible.

Finally, this subsection of the proposed regulation calls for compliance with the CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings for hoods, booths, tents, etc. Reference to the CDC document here is confusing, as it appears Cal/OSHA is deviating from CDC recommendations for AI rooms but not for hoods, booths, etc. Again, using Section 3203 would be preferable.

Response: In regard to isolation rooms and in regard to hoods, booths, etc., this subsection *does* follow the CDC recommendations and it has the same flexibility, allowing for AIIR, no matter the age of the facility, to achieve the required ventilation rate in part through air cleaning technology, so long as 6 ACH are maintained. Both ACH and negative pressure are necessary to reduce the concentration of pathogens within the room and to protect persons located outside of

the room, since the negative pressure of these rooms may be overwhelmed by cross drafts and other air movements when doors to the rooms are opened, etc.

Generally, as stated explicitly in subsection (e)(1), all engineering controls are required to follow recommendations in the CDC TB guideline. The purpose of specifically enumerating the requirements for AIIR is to make clear which of the CDC recommendations are specifically incorporated. The proposal does not incorporate a specific negative pressure value because negative pressures as low as 0.01 or 0.001 in. of water gauge are difficult to measure accurately, and may not be meaningful. It is also not always possible to measure accurately a 50 cubic feet per minute (CFM) difference in supply and exhaust rates. There is no conflict between the provisions specifically adopted into the standard, and the general guidance provided by the referenced document.

See also the response to comment #RR14 regarding the relationship between the guideline and the standard.

Comment #DT5: Subsection (d)(2) on the ATD Exposure Control Plan does not mention the most important part of an Exposure Control Plan, *risk assessment*. Risk assessment allows for risk classification of employees so that appropriate control measures can be implemented based upon level of risk. It is through risk assessment that many of the requirements of subsection (d), such as the list of job classifications with ATD exposure, can be addressed. Is it correct that for respiratory protection, a low risk classification (at least by CDC TB guidelines) would fall under Cal/OSHA voluntary use criteria? Also, is it correct that the ATD Exposure Control Plan is not required for Referring Employers?

Response: The concept of “risk assessment” is incorporated into the definition of the term “occupational exposure,” defined as “exposure from work activity or working conditions that is reasonably anticipated to create an elevated risk of contracting any disease caused by ATPs or ATPs-L...” The additional text in this definition provides guidance to the employer in identifying who is to be included in the ATD plan. An ATD plan is not required for referring employers, instead there is a reduced requirement for infection control procedures in subsection (c).

The concept of “risk assessment” is also included in the definition of high-risk procedures. Again, guidance is given by the definition, but exposure control plan administrators must assess their operations to determine which procedures fall into this category.

California TB guidance has differed from the CDC document referenced by Mr. Tappen on several issues, including frequency of TB testing for health care workers, and discharge criteria. It is not correct that risk assessment in accordance with the CDC TB guidelines controls respirator use under this section. Respirator use is defined in subsection (g). A minimum list of activities for which respirator use is required are enumerated in subsection (g)(4). The employer may add to this list, based on their “risk assessment.” Whenever an employer requires respirator

use, that use is not considered voluntary under OSHA regulation 29 CFR 1910.134 or the California equivalent, Section 5144.

The concept of risk assessment has been incorporated for laboratory operations, for which there are specific procedural guidelines in the BMBL.

Comment #DT6: The standard should not be adopted, especially after only one public comment period. I disagree with the cost estimates—the standard will have a dramatic time/cost impact on employers. If the standard is adopted, there should be a long phase in period or distant implementation date to allow employers enough time to get all the pieces in place.

Response: Section 5199 is the result of a four-year advisory process with significant input from all stakeholder groups, including participation by San Diego County. The Board believes that there is a necessity to move forward as quickly as possible with this proposal, because preparation of the health care and public safety workforce for a health care surge event, such as pandemic influenza, is critical to the ability of our state to weather such a storm. In the meantime, California workers are exposed daily to TB, pertussis, and other infectious diseases. The implementation date of the standard's vaccination provisions is proposed to be extended for a full year, and the Board will consider other prolonged implementation periods for specific provisions of the standard. The commenter provided no specific information regarding potential cost impacts, and on review of the rulemaking file, the Board finds no basis to dispute the original analysis.

Mark Catlin, Industrial Hygienist, Bill Borwegen, Occupational Health and Safety Director, Service Employees International Union, by letter dated August 20, 2008, and oral comments provided by Mr. Catlin on August 21, 2008, at the Public Hearing.

Comment #MC1: The Service Employees International Union (SEIU) believes that it is important to protect workers against hazards posed by aerosol transmissible pathogens. The SEIU represents more than 700,000 workers in California, most of whom will gain some additional protection by the adoption of this proposal. They are pleased that California is proposing a standard to protect workers from ATDs, which takes a comprehensive approach to both airborne and droplet exposures, and covers a wide range of infectious agents.

Response: The Board thanks Mr. Catlin and Mr. Borwegen for their comments.

Comment #MC2: It is clear that home health care is included in the standard under subsection (a)(1)(A)5. The standard should also clearly include *home care* work. Home care workers provide assistance to frail elderly and disabled people in their homes, and the duties range from bathing them to preparing meals and administering medications. More than 400,000 Californians depend on home care to meet their most basic daily needs. These workers are already included as important resources in many pandemic flu preparedness plans to meet the surge in demand for home care expected either because of the flu itself or because people's support networks have become unavailable.

Response: Most people in this society are at some risk of contracting an ATD from the people around them. Employees whose work activities bring them into close or sustained contact with other people may have some increased risk. However, inclusion of work settings within the scope of this standard was based on experience and research showing that the environments and activities included in this standard contained sufficient increased risk beyond that of typical public contact occupations.

Home health care operations provide nursing and other services in a home setting to persons who have diseases, such as TB, or are immuno-compromised, that might otherwise be provided in a hospital or skilled nursing facility. For this reason, home health care operations have been included in this standard. Risks to home care workers were discussed in advisory meetings, as were risks to employees in non-health care facilities for persons needing long-term care (such as assisted living facilities). At this time, the Board has not received sufficient evidence of increased risk to these worker populations to require their inclusion in this proposal. Section 3203, Injury and Illness Prevention Program, provides a framework for employers not included in this standard to identify, evaluate and correct any infectious disease hazards that may exist in the work place.

Comment #MC3: The commenters are concerned with the exclusion of outpatient dental clinics or offices in subsection (a)(2)(A), if they meet certain criteria. These establishments need to be included in the standard in order to ensure that employees are trained and that patients are screened for ATDs. Also, there is no evidence that physicians have the knowledge and experience to determine whether or not a given dental procedure performed on a patient identified through the screening procedures does not pose an ATD risk to employees under subsection (a)(2)(A)3. If procedures are to be performed on a patient with an ATD, the employees should be protected by the requirements of the standard.

Response: See the response to comment #BK2.

Comment #MC4: The commenters believe that the exclusion for medical specialty practices in subsection (a)(2)(B) does not ensure that the screening procedures required by the exclusion will be conducted. Including these workplaces within the scope of the standard is the only way to ensure that employers implement screening procedures and to ensure that employees are trained.

Response: See the response to Comment #BK3.

Comment #MC5: The commenters are pleased to see that California is proposing to include within the definition of Airborne Infectious Disease (AirID) “novel and unknown pathogens.” Treating novel and unknown pathogens as potentially transmitted by airborne means is an appropriate precautionary approach that is necessary to protect exposed workers. The commenters also support the note that explicitly includes pandemic influenza strains as novel pathogens.

Response: The Board thanks Mr. Catlin and Mr. Borwegen for this comment.

Comment #MC6: The commenters support the definition of exposure incident, with the clarification that it includes situations in which the employee exposure is not in the presence of the individual with known or suspected disease – “for example a worker with proper PPE entering a vacated airborne infection isolation room before proper decontamination has occurred.”

Response: Language has been added to the definition of exposure incident to clarify that it includes exposure to a source of ATPs such as a contaminated room or air ducts.

Comment #MC7: The commenters believe that this standard should apply to home care workers. The commenters believe that either the definition of health care worker should be changed, or a new definition should be added to define home care workers.

Response: See response to comment #MC2.

Comment #MC8: The commenters object to the phrase in subsection(c)(5)(C) which would limit the circumstances in which a referring employer would be required to provide employees with respiratory protection when entering a room or area in which a person is waiting for referral, to those circumstances in which the person "is not compliant with source control procedures." This language is vague and difficult to interpret, and is insufficiently protective of worker health. What are the criteria for determining if a person is compliant? The standard should include a requirement for the use of respiratory protection whenever a worker enters the room or area of a person awaiting referral, with no exception.

Response: See response to comment #BK5.

Comment #MC9: The commenters believe that to maximize the protection of employees who will enter areas where persons are awaiting referral, the case or suspected case should require that the referral person be provided with a procedure mask, as part of the source control measures.

Response: See response to comment #BK6.

Comment #MC10: The language in subsection (c)(6)(B) that would require that referring employers provide medical services in accordance with subsections (h)(6) through (h)(9) is too limited in requiring the services only for RATD cases or suspected cases. The commenters state that diseases reportable under Title 17 do not include avian influenza, SARS, monkey pox and novel and unknown pathogens. There is no scientific reason to exclude “unreportable” diseases from procedures for exposure incidents.

Response: See response to comment #BK7.

Comment #MC11: The commenters support the requirement in subsection (c)(7) that employees covered by this standard receive training at the time of initial assignment and at least annually thereafter. New language should be added requiring additional training when there are changes in the workplace or new information becomes available. It is important that workers have the new information as soon as possible.

Response: The Board agrees that changes in procedures or in the workplace that potentially affect employee exposures should require additional training, and language has been added to the proposed subsection.

Comment #MC12: Subsection (c)(7)(H) which requires training on vaccines, should be expanded to include training on treatment options such as antibiotics and antiviral drugs which may be used to protect workers after exposure incidents, or as prophylaxis.

Response: See response to comment #BK9.

Comment #MC13: The development of an exposure control plan is a necessary and critical function of the standard. The proposal places responsibility for the development of the plan on the employer but is silent on the sources of information and expertise that the employer should seek out in preparing the plan. Frequently workers and their unions represent rich and useful sources of information, knowledge and input that can assist the employer and development of the plan. The commenters therefore recommend requiring that employers involve workers and their unions in developing the plan. The comment includes proposed language requiring the employer to develop a written plan of action regarding the implementation of employee participation, and to consult with non-managerial employees and their representatives.

Response: See response to comment #BK10.

Comment #MC14: The commenters suggest that the language from the Bloodborne Pathogens standard regarding review of the plan be incorporated into subsection (d)(3). In addition to reviewing and updating the plan annually, the language proposed by the commenters would require the plan to be reviewed and updated whenever necessary to reflect new information or circumstances that significantly affect occupational exposure, to reflect new or revised employee positions with occupational exposure, and to reflect changes in technology that eliminate or reduce exposure. The commenters also suggest requiring that the employer document annually the consideration and implementation of appropriate commercially available technology designed to eliminate or minimize occupational exposure.

Response: See response to Comment #BK11.

Comment #MC15: The commenters agree with subsection (d)(4) that the exposure control plan should be made available to employees and employee representatives for examination and copying. The proposal should include the language from the bloodborne pathogens standard that refers to the records access provision of Access to Employee Exposure and Medical Records.

Response: The Board agrees with this comment, and language has been added to subsection (d)(4) and (j)(4) effectively referencing the record access provisions of Section 3204, Access to Employee Exposure and Medical Records.

Comment #MC16: The commenters support the requirement in subsection (e)(1) that employers use feasible engineering and work practice controls to minimize employee exposure. It would be useful to provide definitions and examples of engineering and work practice controls.

Response: The Board believes that this section establishes performance requirements for employers. Employers covered by this section may have very different operations, and it would be impossible for this standard to include examples from all of the different environments. The Board believes that these examples are more appropriately placed in educational materials to be developed by the Division to assist in the implementation of this standard.

Comment #MC17: The commenters suggest that subsection (e)(1)(A) be revised to clearly describe the hierarchy of controls used in occupational safety and health, and include a discussion of engineering controls for ATPs. The commenters included a reference to material available from the Areobiological Engineering/Architectural Engineering Department at Penn State University.

Response: Subsection (e)(1) clearly adopts a hierarchy of controls. In many operations under this standard, engineering and work practice controls are interwoven. For example, early case identification and limiting contact with a potentially infectious patient is a work practice control, including placing the patient in a separate room or area. The specifications for the ventilation to be provided to that room or area are engineering controls. Examples of control measures and references are more appropriately provided through educational material that will be developed to support implementation of the standard.

Comment #MC18: The term “susceptible” should be removed from proposed subsection (e)(5)(B)2.e. which requires respirator use by all “susceptible” employees who enter an AII room or area where AirID cases or suspected cases are housed. The commenters state that the term “susceptible” is undefined and should be removed to avoid confusion. All workers who enter the room or area should be provided with respiratory protection, as well as other forms of PPE.

Response: See response to Comment #BK14.

Comment #MC19: The commenter supports the requirement in the Exception to subsection (e)(5)(C) that when high hazard procedures are performed outside of airborne infection isolation rooms or areas, that all employees working in the room or area where the procedure is performed use respiratory protection. The commenter believes that this requirement should also include all necessary PPE.

Response: The Board agrees that personal protective equipment must be provided to anyone in the area where a high hazard procedure is performed. Language has been added to require that persons not performing the procedure be excluded from the area where these procedures are being performed, unless the person is provided with the PPE and respiratory protection required for persons performing the procedure.

Comment #MC20: The commenters disagree with subsection (g)(3)(A) which requires that the minimum level of respiratory protection provided under this standard be at least as effective as an N95 filtering facepiece respirator. The commenters believe that the minimum level of protection should be a P100 filtering facepiece respirator equipped with an elastomeric facepiece seal. The commenters referred to several articles that they believe raise questions about the effectiveness of N95 filtering facepiece respirators in protecting employees against infectious aerosols. (See Lee, et al 2008, Balazy et al 2006, and Eninger et al 2008).

Response: See response to comment #BK16.

Comment #MC21: The commenters support the requirement in subsection (g)(3)(B) that a PAPR equipped with HEPA filters be provided to workers who perform high hazard procedures and work on cadavers. This requirement should be modified to permit the use of a respiratory protection device providing equivalent or better levels of protection, in order to permit the use of supplied air respirators or other respirators. Also, employers should be required to provide a PAPR to employees who have been determined to be medically incapable of wearing a filtering facepiece respirator but who are capable of wearing a PAPR.

Response: See response to comment #BK17.

Comment #MC22: The commenters disagree with the Exception to subsection (g)(6)(B)3, that permits the repeat fit-testing interval to be increased to every two years until January 1, 2014, for employees who do not perform high hazard procedures. The commenters state that although the proposal mentions a NIOSH study that will provide information on appropriate fit-test intervals, there is no evidence available at this time that supports a fit-test interval longer than one year, and there is evidence that supports the requirement for annual fit testing. Further, the commenters cite several studies that show that a respirator that has passed a fit test for an individual worker provides better protection than one that has not (Lee 2004, Coffey 2004, Lawrence 2006).

The commenters also cite evidence in the OSHA record supporting annual fit-testing, and a letter from NIOSH Director John Howard, supporting an annual fit-test interval. The commenters disagree that the issue of cost to employers of annual fit-testing should be a reason to increase the fit-test interval, given the lack of scientific support for a longer interval. The commenters further state that this Cal/OSHA provision would be less effective than federal OSHA.

Response: See response to comment #BK18.

Comment #MC23: The commenters support the activities required in subsections (h)(6)(A) and (h)(6)(B) in response to exposure incidents. These activities should not be restricted to diseases that are reportable under Title 17 of the California Code of Regulations, which the commenter states does not include avian influenza, SARS, monkeypox and novel or unknown pathogens. There is no scientific rationale for eliminating these diseases from requirements for exposure incidents.

Response: See response to comment #BK19.

Comment #MC24: The commenters strongly support the training requirements in this proposal, including requirements that the training be done by a knowledgeable person, and that training material be appropriate in content and vocabulary to the education level, literacy and language of the employees, and that workers have an opportunity for interactive questions and answers with the person conducting the training. Similar training requirements that were in the OSHA Bloodborne Pathogens standard were important in reducing the rate of occupationally acquired Hepatitis B infection.

Response: The Board thanks the commenters for their support.

Comment #MC25: Subsection (j)(4)(A) should include a requirement that employees and employee representatives be afforded access to all records, other than employee medical records, that are required to be maintained under this standard. Lack of access may hamper the ability of employees and their representatives to utilize their knowledge and expertise to advance safety and health measures in their workplace. The standard should include provisions for access in accordance with the Access to Employee Exposure and Medical Records standard.

Response: The Board agrees that access to records of program implementation, other than employee medical records, would enhance the ability of employees and their representatives to participate in reviewing and updating the employer's infection control procedures. Section 3204, Access to Employee Exposure and Medical Records establishes a reasonable framework for providing these records. Therefore language has been added to subsection (j)(4)(B) to require that access be provided to employees and their representatives in accordance with Section 3204.

Comment #MC26: A section should be added to address "housekeeping," to include such issues as disposal of infectious waste and patient-care equipment, and environmental cleaning and disinfection.

Response: See response to comment #BK21.

Comment #MC27: A subsection should be added regarding labels and signs to alert and warn employees about exposure potential related to equipment, objects, rooms or areas. This would assist in reducing exposure incidents and protecting workers from infection.

Response: See response to comment #BK22.

Azita Mashayekhi, M.H.S., Industrial Hygienist, Safety and Health Department, The International Brotherhood of Teamsters, by letter dated August 21, 2008.

Comment #AM1: The International Brotherhood of Teamsters (IBT) represents 1.4 million workers in the United States and Canada, including thousands employed by the private sector and state and municipal governments in California, who are at increased risk of exposure to aerosol transmissible pathogens. These workers are employed in hospitals and other health care facilities and operations, correctional facilities, firefighters, and emergency responders, police services and laboratory workers. Adoption of an aerosol transmissible disease standard is necessary to ensure the mandate of the California Labor Code Section 6400 that “Every Employer shall furnish employment and a place of employment that is safe and healthful for the employees therein.” The IBT strongly supports the intent of the standard, to protect employees from exposure to infectious aerosols, such as the agents that cause tuberculosis and Severe Acute Respiratory Syndrome (SARS) and pertussis. The commenter is also reassured by the fact that the proposal was developed with the assistance of a broad spectrum of stakeholders.

Response: The Board thanks Ms. Mashayekhi for her comments.

Comment #AM2: The definition of “home health care” in subsection (a)(1)(A) should include home care work performed by personal attendants. Home care workers provide assistance to frail elderly and disabled people in their homes, and the duties range from bathing them to preparing meals and administering medications. More than 400,000 Californians depend on home care to meet their most basic daily needs. These workers are already included as important resources in many pandemic flu preparedness plans to meet the surge in demand for home care expected either because of the flu itself or because people’s support networks have become unavailable.

Response: See response to comment #MC2.

Comment #AM3: The commenter agrees with the definition of Airborne Infectious Disease (AirID) as it extends to a disease process caused by a novel or unknown pathogen. This definition addresses her concern that pandemic influenza virus may be transmitted via an airborne route, and the “confusion on the federal level surrounding the use of respirators versus facemasks during a pandemic.” It supports the IBT position in favor of mandatory workplace requirements for protecting health care, emergency response, and other workers during a pandemic influenza outbreak.

Response: The Board thanks the commenter for her support.

Comment #AM4: The phrase in subsection (c)(5)(C) would limit the circumstances in which a referring employer would be required to provide employees with respiratory protection when entering a room or area in which a person is waiting for referral, to those circumstances in which the person "is not compliant with source control procedures." This is vague and difficult to interpret, and is insufficiently protective of worker health. The commenter asked what the

criteria are for determining if a person is compliant. Entry into an area where a person who is a case or suspected case of AirID is located, even while awaiting referral, constitutes occupational exposure and an “elevated risk,” which necessitates ensuring that workers are protected from exposure, independent of whether the person is utilizing source control measures. Also, to maximize protection, the person awaiting referral should be provided with procedure or surgical masks. The standard should include a requirement for the use of respiratory protection whenever a worker enters the room or area of a person awaiting referral, with no exception.

Response: In regards to the first part of the comment, see the response to comment #BK5.

In regards to requiring procedure masks for persons awaiting referral, source control measures as recommended by the CDC and by advisory committee participants permit the use of masks or, as an alternative, tissues and hand hygiene materials to control respiratory secretions. There are some circumstances in which a patient cannot use a mask. The proposal leaves it to the institution to determine the most effective means for controlling respiratory secretions in that setting.

Comment #AM5: Subsection (c)(7) should include a requirement that additional training be provided when there are changes in the workplace or new information becomes available. The language used in Section 5193, Bloodborne Pathogens, provides a good model. It is important that workers have the new information as soon as possible.

Response: The Board agrees that changes in procedures or in the workplace that potentially affect employee exposures should require additional training, and language has been added to the proposed subsection.

Comment #AM6: Subsection (c)(7)(H) which requires training on vaccines, should be expanded to include training on treatment options such as antibiotics and antiviral drugs which may be used to protect workers after exposure incidents, or as prophylaxis.

Response: See response to comment #BK9.

Comment #AM7: The development of an exposure control plan is an essential component of the standard. The proposal places responsibility for the development of the plan on the employer but is silent on the sources of information and expertise that the employer should seek out in preparing the plan. Frequently workers and their unions represent rich and useful sources of information, knowledge and input that can assist the employer and development of the plan. The commenter therefore recommends requiring that employers involve workers and their unions in developing the plan, and suggests the following language:

“An employer, who is required to establish an Exposure Control Plan shall develop a written plan of action regarding the implementation of employee participation. The employer shall consult with non-managerial employees responsible for direct patient care who are potentially exposed to ATDs and ATPs and their representatives on the

identification, evaluation, and selection of effective engineering, work practice controls and personal protective equipment and shall document the consultation in the Exposure Control Plan. This participation shall include the required annual reviews of the plan.”

Response: See response to comment #BK10.

Comment #AM8: The commenter supports the requirement in subsection (d)(3) for annual review of the plan by the program administrator and employees regarding effectiveness of the plan in their work area. Additional language should specifically require employer to actually modify the plan based upon the findings and employee input obtained in the annual review. Also, the proposal should include a requirement that the plan be modified whenever there is new information or circumstances that significantly impact on the health and safety of workers.

Response: See response to comment #BK11.

Comment #AM9: The commenter supports the requirement in subsection (d)(4) that the exposure control plan be made available to employees and their representatives for examination and copying. The commenter supports adding a requirement establishing the maximum timeframe, preferably by the end of the next business day. The commenter also suggests adding a requirement that the copy be provided to requesters at no cost to them.

Response: See response to comment #BK12.

Comment #AM10: In regards to subsection (e)(1), a definition of engineering controls and work practice controls should be provided in order to clarify what is meant by each of these control measures. An appendix could accomplish this. Section (e)(1)(A) should not include the use of personal or respiratory protection in the note on work practices. The commenter also suggests requiring personal protective equipment for employees who transport ATD cases or suspected cases.

Response: See response to comment #BK13.

Comment #AM11: The term “susceptible” should be removed from proposed subsection (e)(5)(B)2.e. which requires respirator use by all “susceptible” employees who enter an AII room or area where AirID cases or suspected cases are housed. The commenter states that the term “susceptible” is undefined and should be removed to avoid confusion. All workers who enter the room or area should be provided with respiratory protection, as well as other forms of PPE.

Response: See response to comment #BK14.

Comment #AM12: The commenter supports the requirement in the Exception to subsection (e)(5)(C) that when high hazard procedures are performed outside of airborne infection isolation rooms or areas, that all employees working in the room or area where the procedure is performed

use respiratory protection. The commenter believes that this requirement should also include all necessary PPE.

Response: See response to comment #BK15.

Comment #AM13: Subsection (g)(3)(a) proposes that a respirator at least as effective as an N95 filtering facepiece respirator become the minimum level of respiratory protection under this standard. The commenter believes that the minimum level of respiratory protection should be an N100. The commenter referred to several articles that raise questions about the effectiveness of N95 filtering facepiece respirators in protecting employees against infectious aerosols. (See Lee, et al 2008, Balazy et al 2006, and Eninger et al 2008).

Response: See response to comment #BK16.

Comment #AM14: The commenter supports the requirement in subsection (g)(3)(B) that a PAPR equipped with HEPA filters be provided to workers who perform high hazard procedures and work on cadavers. This requirement should be modified to permit the use of a respiratory protection device providing equivalent or better levels of protection, in order to permit the use of supplied air respirators or other respirators. Also, employers should be required to provide a PAPR to employees who have been determined to be medically incapable of wearing a filtering facepiece respirator but who are capable of wearing a PAPR.

Response: See response to comment #BK17.

Comment #AM15: The proposed Exception to subsection (g)(6)(B)3 seeks to circumvent the requirement to conduct annual fit testing of respirators by permitting the repeat fit testing interval to be increased to every two years until January 1, 2014. The commenter states that despite possible studies by NIOSH related that may relate to fit testing intervals, there is no evidence that supports a two-year fit testing interval versus annual fit testing.

Response: See response to comment #BK18.

Comment #AM16: The commenter supports the activities required in subsections (h)(6)(A) and (h)(6)(B) in response to exposure incidents. These activities should not be restricted to diseases that are reportable under Title 17 of the California Code of Regulations, which the commenter states does not include avian influenza, SARS, monkey pox and novel or unknown pathogens. There is no scientific rationale for eliminating these diseases from requirements for exposure incidents.

Response: See response to comment #BK19.

Comment #AM17: The commenter believes that subsection (j)(4)(A) should include a requirement that employees and employee representatives be afforded access to all records, other than employee medical records, that are required to be maintained under this standard. Lack of

access may hamper the ability of employees and their representatives to utilize their knowledge and expertise to advance safety and health measures in their workplace. The standard should include provisions establishing a deadline by which records are to be provided to a requester, such as by the end of the next business day. The records should be provided to employees and their representatives at no cost to them whenever they are requested.

Response: See response to comment #BK20.

Comment #AM18: A section should be added to address “housekeeping,” to include such issues as disposal of infectious waste and patient-care equipment, and environmental cleaning and disinfection.

Response: See response to comment #BK21.

Comment #AM19: A subsection should be added regarding labels and signs to alert and warn employees about exposure potential related to equipment, objects, rooms or areas. This would assist in reducing exposure incidents and protecting workers from infection.

Response: See response to comment #BK22.

Danielle Lucido, Staff Attorney and Suzanne Murphy, Executive Director, Worksafe, by letter dated August 21, 2008.

Comment #DL1: Worksafe is a California-based non-profit organization dedicated to promoting occupational safety and health through education, training, technical and legal assistance and advocacy. They urge the adoption of Section 5199 with minor changes. A standard to protect workers against aerosol transmissible diseases is long overdue. Since the resurgence of tuberculosis in the 1980’s, OSHA and Cal/OSHA have relied on policies and procedures to piece together protective measures that have not been adequate to address tuberculosis. A standard is needed to address tuberculosis and other diseases, including the possibility of pandemic flu.

Response: The Board thanks Ms. Lucido and Ms. Murphy for their comments.

Comment #DL2: The proposal would require that the minimum level of respiratory protection would be an N95 respirator. Recent studies have found that existing N95 respirators, which partially rely on electrostatic charges to filter the air, may not provide enough protection for aerosols smaller than 0.3 microns, which is the size at which respirators are tested. There is also controversy about whether a filtering facepiece respirator is as effective as a respirator with a rigid plastic facepiece. Different types of germs have different infective doses, and remain viable for different periods of time in the air, and may be present in a broad size range of particles. The minimum level of respiratory protection under this standard should be provided via an N, P or R 100 filter, and if a powered air-purifying respirator is not used for high hazard procedures, then the minimum class of respirator should be an elastomeric facepiece respirator with an N, P or R 100 cartridge.

Response: See response to comment #BK16.

Comment #DL3: The commenters disagree with the exception to annual fit-testing permitted in subsection (g)(6)(B)3. In the absence of any evidence to the contrary, an annual fit-test is an appropriate interval.

Response: See response to comment #BK18.

Comment #DL4: Proposed Section 5199 [subsection (e)(1)(C)] only requires that employers *consider* the use of barriers or air handling systems in ambulances and other vehicles. Barriers and air handling systems should be *required* in ambulances. Emergency medical personnel provide life-saving treatment and transport to people who may have a variety of underlying illnesses, and deserve effective protection.

Response: Subsection (e)(1) requires employers to implement feasible engineering controls, which would include feasible barriers and ventilation systems. Subsection (e)(1)(C) was added as a result of discussion at advisory meetings, in which some participants reported that patient transport areas in ambulances may not be separate from the area where the driver is located. Participants also reported that patient transport areas may not be ventilated, or may not be adequately ventilated, and recent barrier designs may increase the problem. A number of practical issues were also raised regarding installation of partitions and ventilation systems in existing vehicles. For this reason, the proposal requires employers to look into the feasibility of implementing engineering controls in ambulances and other vehicles used for transporting AirID cases and suspected cases, and to document this assessment. This assessment is further required to be reviewed annually in accordance with subsection (d)(3). Subsection (e)(1)(C) enhances the requirement for employers to implement feasible engineering controls by requiring the employer to effectively annually assess the feasibility of their use. The Board believes that this is a reasonable approach to encouraging the use of barriers and ventilation systems.

Comment #DL5: The commenters support requirements that exposure be communicated to employees and other employers. Some of the proposed timeframes may be too long, and should be reconsidered and shortened, if possible. For example, if a worker were exposed to bacterial meningitis, that worker should be provided with antibiotics immediately.

Response: The proposed language has been changed to reflect the differences in the window necessary for initiating appropriate medical intervention, and to set a maximum timeframe for communication that is based on the need to start exposure investigations in a timely manner. A note has also been added to address different considerations for timely communication. See Comment #RR22 for further discussion.

Comment #DL6: The commenters support the requirement that powered air purifying respirators be used for high hazard procedures, they believe high hazard procedures should include suctioning.

Response: The definition of high hazard procedures in the standard includes some examples, however, the examples are not intended to be a complete list of all high hazard procedures. It is up to the employer, under subsection (d)(3)(C), to list high hazard procedures that are performed in the facility. This list is subject to review by the employer and employees.

Kevin White, California Professional Firefighters, by electronic mail dated August 19, 2008.

Comment #KW1: In reference to subsection (g)(3) California Professional Firefighters believes that an N95 respirator does not provide sufficient protection against infectious aerosols to firefighters and other emergency medical services personnel. Although an N95 respirator may be adequate in a hospital environment with other control measures, in a pre-hospital setting, it is never known what pathogen or route of exposure may be encountered. Therefore the highest level of PPE should be available, and CPF recommends mandating a minimum of a P-100 filtering facepiece respirator. The commenter provided several references. Further, a higher level of respiratory protection, including a full or half facepiece air purifying respirator (APR) or PAPR with HEPA filter/canister, should be available to all responders.

Response: Emergency medical services (EMS), such as paramedics, may be exposed to high concentrations of aerosols, particularly when performing high hazard procedures, or being exposed to aerosols generated by intubated patients. It is also possible that emergency medical procedures provided in the context of injuries and accidents may involve wet or oily environments that would compromise the integrity of N95 filter materials, or of the sealing surfaces of the respirator.

The standard as originally proposed required the use of PAPRs for high hazard procedures, unless it would interfere with the performance of the task, in which case a respirator at least as effective as an N95 would be required. However, in these emergency operations, it may not be feasible to provide a PAPR. Therefore, in order to address the potential for higher exposures in the EMS setting, the modified proposal contains a new exception to subsection (g)(3)(B) permitting the use of P100 respirators by paramedics performing high hazard procedures when PAPRs are not used.

Lauri Thrupp, MD, and Linda Dickey, RN, MPH, CIC, Assistant director, Epidemiology & Infection Prevention, UC Irvine Healthcare, by electronic mail dated August 21, 2008.

The commenter states that her comments pertain only to “sections dealing with aerosol-transmitted contagious diseases.” The commenter further states that she has separately forwarded specific wording changes, however, those suggestions have not been received.

Comment #LT1: The overall tone of the document seems laboriously aimed at prevention of transmission from patients with known or seriously suspect disease. It would be informative background information to include introductory comment emphasizing that it is the undiagnosed or unsuspected patient that may transmit. “Such patients [are] not in negative pressure rooms and not being handled with masks (surgical or N-95) that represents virtually all of the few cases of

occupational transmission that occur. We have had no problems with infection from our known patients in airborne precautions (without PAPRs).”

Response: The proposed standard includes several provisions that are meant to reduce exposures to persons who have not yet been identified, including requiring source control procedures, early identification of cases or suspected cases, and referral of those persons to appropriate facilities. Transmission has occurred in settings where patients were not appropriately isolated after manifesting symptoms consistent with tuberculosis, and some of these cases were discussed during the advisory process. However, transmission of airborne disease has also occurred from identified cases during high risk procedures, such as SARS transmission to nurses performing intubation and suctioning prior to intubation on identified potential SARS cases, using only surgical masks or N95 respirators. In addition there is also a published report of transmission of SARS to health care workers during bronchoscopy (Ofner). Dr. Catanzaro reported transmission of tuberculosis during bronchoscopy as well (Catanzaro).

For more discussion regarding the necessity for PAPRs, please see Comment #AF1.

Comment #LT2: The draft Section 5199 and Appendices bundles patients with diseases requiring airborne or droplet precautions as all subject to requirements including PAPRs for high risk procedures. The droplet group has long been handled with Standard Precautions plus surgical (“droplet”) masks and the commenter is not aware of any clinical evidence of failure of this procedure.

Response: Subsection (g)(3)(B) requires PAPRs in a clinical setting only for high hazard procedures on cases or suspected cases of airborne infectious diseases (AirIDs). PAPRs, and respiratory protection in general, is not required for diseases for which airborne infection isolation is not required. The standard requires PAPRs for aerosol generating procedures on cadavers because those procedures, such as the use of saws, create aerosols that would not normally result from coughing and other respiratory secretions from living people.

An incorrect footnote in Appendix A of the original proposal may have created some confusion between airborne and droplet precautions. This footnote has been removed in the modified draft.

For more discussion regarding the PAPRs please see Comment #AF1.

Comment #LT3: “The draft Section 5199’s definition of high risk procedures includes suctioning, administration of aerosol medication (e.g. albuterol), as well as bronchoscopy; with other paragraphs and definitions calling for PAPRS for these.”

Response: Procedures that increase employee exposures to infectious aerosols are considered high hazard procedures. Under this standard, employers would be required to determine whether a procedure is high hazard. The examples provided are those provided by the Centers for Disease Control and Prevention and other public health authorities, and were reviewed by the advisory committee at a number of meetings. The list is not meant to be exhaustive. A procedure is only

considered to be high hazard when it is performed on a case or suspected ATD case. PAPRs are only required for AirID cases. However, because high hazard procedures increase infectious aerosols, and may create an airborne exposure risk which would not be present under normal patient care circumstances, and because disease transmission, as noted by the commenter above often occurs before a final diagnosis is made, high hazard procedures are required to be conducted in an AII room or area. The standard requires employers to determine which high hazard procedures are performed in the institution and to provide appropriate control measures.

For more discussion regarding PAPRs please see comment #AF1.

Comment #LT4: The requirement for PAPRs is “vastly overstated.” Others supporting PAPRs have quoted the Johns Hopkins Hospital TB Control Plan of 2005 which called for PAPRs with airborne precautions. The commenter refers to a statement made to her by Dr. Trish Perl, Director of Infection Control and Epidemiology at Johns Hopkins “to the effect that they have found their PAPR program to be cumbersome, impractical and difficult to administer. Therefore they are at present in the process of significantly revising this point, and will likely go back to the N-95 or equivalent guideline.”

Response: The Johns Hopkins respiratory protection program has been revised and posted. It continues to maintain that the PAPR is the primary respirator used at Johns Hopkins. A modified RPP program was posted in September 2008, which states:

“The Johns Hopkins Hospital provides Respiratory Protection Devices (i.e., Powered Air Purifying Respirators (PAPRs) or Suitable Alternatives) for use by staff who have patient care/environmental responsibilities for patients on airborne precautions or patients who are receiving Ribovirin, for the protection of all staff, prevention of disease transmission, and to comply with external regulatory agency requirements.

“PAPRs are battery-powered systems that use a small HEPA filter unit to clean ambient air before it is delivered to the wearer. A PAPR system typically includes a blower/filter unit/battery pack (base unit), a headpiece, and a breathing tube that connects the base unit to the headpiece. Suitable alternative devices include N95 Respirators. While this policy refers primarily to PAPRs, it should be understood that suitable alternative devices may also be employed, based on the approval of HSE (Health, Safety, and Environment).”

It goes on to state that “The PAPR is the primary device available for use. N-95’s are used by staff who cannot use the PAPR for any reason.”

This proposed regulation is considerably more limited in requiring PAPR use than is the Johns Hopkins policy. PAPRs would not be required under the proposed standard for entry into airborne infection isolation rooms, for example. They are only required for the performance of high hazard procedures on AirID cases or suspected cases. Where this use would interfere in the performance of the task or tasks, a PAPR is not required by the proposed standard.

Please see response to comment #AF1 for further discussion of PAPRs.

Paul A. Schulte, Ph.D., Director, Education and Information Division, National Institute for Occupational Safety and Health, by letter dated August 14, 2008.

Comment #PS1: The commenter stated that the reference in the public notice to a planned NIOSH study concerning respirator fit-test intervals is potentially misleading. “The study is not designed to establish a scientifically validated periodicity for fit-testing of respirators. The study is designed to track changes in test subjects’ key facial dimensions and fit factors with designated respirator models and sizes at 6-month intervals over 3 years. NIOSH expects the data gathered in this study will provide insight into: (1) which facial dimension changes correlate with changes in respirator-to-face fit factors, and (2) the rate at which various key facial dimension vary over times. These detailed analyses will **not** support a scientifically based evaluation of the effectiveness of annual fit testing.”

Response: The Board thanks Dr. Schulte for providing this information. Len Welsh, Chief of the Division of Occupational Safety and Health, wrote to Dr. Schulte to request clarification of these comments (see Welsh letter dated 28 August 2008).

On October 17, 2008, Mr. Welsh received a response from Dr. Schulte, dated October 15, 2008. In this letter, Dr. Schulte stated that “On behalf of NIOSH, I would like to offer a clarification of the information you reference and an update on the status of the NIOSH study. Dr. Schulte explained that the NIOSH study cited has been “critically reviewed and significantly revised since the report by John Decker at your December 8, 2005 advisory meeting. The protocol and study objectives have undergone significant changes during the past three years of development, and the project has not been initiated.”

The inclusion of the correspondence between Dr. Shulte and Len Welsh in this record is intended to clarify the status of NIOSH research.

The Board believes there is still adequate reason to propose a date of January 1, 2014, for the termination of the exception permitting biennial fit-testing of some respirator users.

Response to Comments from Board Member Jonathan Frisch received at the August 21, 2008, Public Hearing:

Comment #JF1: In regards to subsection (g)(5) and Appendix B, that he would appreciate more information regarding why an alternative respirator questionnaire is necessary.

Response: In the course of the July 26, 2004, advisory meeting, several participants identified significant problems in the completion and review of the respirator questionnaire contained in Section 5144, Appendix C. Participants agreed that many of these questions would not be used by physicians and other licensed health care professionals (PLHCP) in determining whether an employee can use a filtering facepiece respirator or PAPR in typical health care operations.

Some participants reported that some employees objected to the detailed history questions (in the form of “have you ever had...”) as invasive of their privacy and objected to furnishing this information, since they did not perceive it as being directly relevant to their use of respirators in their current employment. Participants also indicated that having to re-do respirator medical evaluations using the questionnaire in Section 5144 Appendix C was creating a problem in meeting the implementation date of the section.

As a result, the Board adopted an emergency regulation on September 23, 2004, permitting the use of medical evaluations conducted prior to October 18, 2004, for filtering facepiece respirators used to protect employees against tuberculosis. On January 20, 2005, the Board adopted a permanent regulation to this effect. The questionnaires used in these evaluations were broadly used in health care and addressed the subjects in Section 5144, Appendix C.

Advisory meeting participants supported developing a questionnaire that would specifically address the questions that would prompt a further evaluation by a PLHCP. Several occupational health physicians, including physicians from the California Department of Health Services, reviewed the existing questions and forms, and determined that the content of proposed Appendix B was appropriate for assessing the ability of employees to use respirators in this context, and provided a medical screening equivalent to the screening provided by the questionnaire in Section 5144, Appendix C.

Finally, it should be mentioned that the evaluating PLHCP will have the final word on whether the information gathered by Appendix B is sufficient for them to make a determination regarding the individual employee’s ability to use a respirator. The PLHCP or the employer can still choose to use the questionnaire in Section 5144, Appendix C.

Comment #JF2: In regards to the exception to annual fit-test requirements proposed to subsection (g)(6)(B)3, Dr. Frisch asked if the Division could do anything to increase the protection provided to employees whose employers utilized the exception to provide biennial fit-tests instead of annual.

Response: An additional safeguard has been included to ensure that employees are provided with a good-fitting respirator. Both existing Section 5144, and proposed Section 5199 require additional fit-tests when an employee reports having certain facial changes such as surgery, dental work, or significant weight changes, and if an employee reports that he or she needs an additional fit test.

Mary Mendelsohn, of the Association of Professionals in Infection Control (APIC) worked with the California Hospital Association to survey hospitals in California and determine how many employees changed respirators as a result of an annual re-fit test. She found the number of employees needing a different respirator to be very low, and also found that a significant number of them would be predicted based on their answers to questions regarding facial changes. (See response to comment #BK18 and Mendelsohn letter)

For this reason, the proposal now includes Appendix G, which would be mandated for employees who are not provided an annual fit-test. This appendix contains respirator fit-test screening information, and asks whether there have been weight or facial changes, and also asks whether the employee is requesting an additional fit-test, even if the employee does not report weight or facial changes.

The Division believes that this Appendix provides an appropriate reminder to employees regarding the need for a respirator to fit them, and a means to detect those individuals who are in need of an additional fit-test.

Comment #JF3: Dr. Frisch asked if the Division could provide evidence supporting the use of N95 respirators against infectious aerosols.

Response: In 1995 NIOSH published a final rule that specifically identified N95 respirators as being appropriate for use against tuberculosis (60 FR 30335). This rulemaking was based on a significant record, including many scientific studies. NIOSH is the agency that has the primary responsibility for approving respirators, and OSHA and Cal/OSHA rules (29 CFR 1910.134, 8 CCR 5144) reference NIOSH approvals. Since that time there have been a number of studies addressing the appropriate assigned protection factors for N95 filtering facepiece respirators and their effectiveness against infectious aerosols. Qian et al, for example reported that N95 materials were very effective against aerosols in the size range of concern (Qian, 1998). Although the specific numbers have varied, it has generally been found that fit-tested N95 respirators provide a 5<sup>th</sup> percentile protection typically around 10, and always greater than five. For example, a recent NIOSH study (Duling, 2007) tested 15 models of N95 filtering facepiece respirators, 15 models of elastomeric facepiece respirators with N95 particle filters, and six models of surgical masks. All 15 models of N95 filtering facepiece respirators provided a simulated workplace protection factor 5<sup>th</sup> percentile value over 10 when the respirator had passed a fit-test using saccharine or the PortaCount Plus. Passing a fit-test using Bitrex did predict a lower 5<sup>th</sup> percentile value averaging 7.9.

The studies cited by Bill Kojola and other commenters (Lee, 2008, Balazy, 2006, and Eninger, 2008) raise concerns about whether some users will realize a protection factor of 10 in regards to certain particle sizes, with some N95 respirators. However, even the worst performing N95 respirator provided a 5<sup>th</sup> percentile APF greater than 5 for all particle sizes. The better performing N95 respirators provided a 5<sup>th</sup> percentile APF greater than 8 for all particle sizes, and the 25<sup>th</sup> percentile was considerably greater than 10. This study, if confirmed by other data, may indicate a need for NIOSH to amend the test procedures in 42 CFR Part 84, but the results of this study also clearly indicate that N95 respirators reduce risk to virtually all users.

A study of SARS among 43 critical care nurses in Toronto who were exposed to SARS patients found that 2 out of 16 nurses who consistently used N95 respirators contracted infection, as compared to 5/9 who used them inconsistently, yielding a relative risk of 0.22, p=0.06 (Loeb). This indicates that N95 use was protective. In addition, the activities that were found to be at

highest risk (intubation and suctioning before intubation) require a higher level of respiratory protection under this proposal.

A different but related issue is that the concept of “assigned protection factor” was developed in relation to chemical risk. For chemical exposures for which there is a threshold (non-carcinogens) the concept is that an exposure limit is determined, including some safety factor. The assigned protection factor then determines the maximum concentration in which the respirator can be used by multiplying the exposure limit by the assigned protection factor. (This is a simplification, and does not include issues such as cartridge capacity, etc.) Infectious aerosols differ, because for at least some pathogens, such as tuberculosis, the infectious dose may be contained in one droplet nuclei, and therefore, respirators and other controls are directed at reducing the risk that an infectious particle will be inhaled and deposited in a manner that will result in infection. One determinant of this risk is the protection factor of the respirator, but if the permitted dose is one pathogen containing droplet nuclei, there is no finite protection factor that will provide 100% protection if there are pathogens in the environment.

Comment #JF4: Dr. Frisch expressed a need to include non-medical home care in the standard.

Response: The issue of non-medical home care was discussed at advisory meetings. Neither meeting participants nor Division staff were able to discover evidence related to the risk of non-medical home care employees. These activities are similar to activities performed in assisted care living facilities, which are also not included in the standard.

The occupation of non-medical home care is undergoing considerable change and restructuring, such as the creation of In Home Support Services public agencies. The Division staff will continue to monitor this situation. In the mean time, employers who come within the scope of the Cal/OSHA authority are required to assess infectious disease risks in accordance with the Injury and Illness Prevention Program. For further discussion, please see response to comment #MC2.

Comment #JF5: Dr. Frisch was concerned about the exclusion of dental offices.

Response: The dental office exclusion is based on infection control guidelines in dental offices, published by the Centers for Disease Control and Prevention, and on the practical difficulties of performing procedures on patients with aerosol transmissible diseases. However, in response to comments from Dr. Frisch as well as public comments, the proposal now specifically requires employers to include the screening and employee training procedures in the IIPP, and also requires a physician to determine that a screened patient does not have an ATD prior to performing procedures. Unlike health care workers, dental workers are also not considered at increased risk for tuberculosis.

Comment #JF6: Dr. Frisch stated that the standard should include a requirement for cleaning and disinfection of the worksite for referring employers.

Response: A sentence containing this requirement has been added to subsection (c)(1).

Comment #JF7: Dr. Frisch stated that he is concerned that subsection (a)(1)(c) is not sufficiently specific about what is meant by police services. He is also concerned that the standard provide a consistent level of safety for police officers across the state, and not be swayed by individual departments that may have a stronger program than others.

Response: The language of subsection (a)(1)(C) has been modified to specifically address that the services covered are those that are provided during transport or detention of persons reasonably anticipated to be cases or suspected cases of aerosol transmissible diseases, and those services that are provided in conjunction with health care and public health operations. This is consistent with public health recommendations and the recommendations of participants in advisory meetings. Many departments currently provide N95 respirators for use by officers when there is a concern about tuberculosis or other airborne disease. The use of particulate respirators to protect against infectious diseases is included in the Model Respiratory Protection Program provided by the Commission on Police Officer Standards and Training (POST), which is a statewide reference, and was developed in cooperation with the Division. The Division intends to continue to work with local and state law enforcement in implementing this standard.

Comment #JF8: Dr. Frisch asked if there is there a way for this standard to apply to volunteer workers.

Response: Len Welsh addressed the jurisdictional issue during the course of the hearing to the effect that the Division has no jurisdiction over people who are actually volunteers in health care facilities, although there are many details involved in determining that status. As a practical matter, most health care institutions require that volunteer workers observe the same infection control procedures as paid workers, because that is necessary to prevent health care associated infections.

Comment #JF9: Dr. Frisch stated that the standard should address computer-based training and other training modalities.

Response: Language was added in subsection (c) and subsection (i) to address training that is not provided in person.

Comment #JF10: Dr. Frisch expressed concern about whether the communication requirements regarding the “hand-off” of patients are clear.

Response: Each employer is required to develop effective procedures for communicating with other employers regarding the infectious disease status of referred patients, and to establish a means to receive information as well. This issue was discussed at length in the advisory process. For example, it was suggested at one meeting that a sign be placed in the home of an ATD patient to inform home health workers or emergency responders that there was a case or suspected ATD case in the house. This idea was rejected for a number of reasons including confidentiality and social stigmatization. Also, different types of employers will have different

information to send and receive. The Division intends to provide guidance during the roll-out of this standard that will be more specific to different types of work operations.

Comment #JF11: Dr. Frisch said that the standard should clarify that a PLHCP cannot medically remove himself/herself.

Response: There are two types of conditions in which a PLHCP would recommend precautionary removal – (1) as a result of a medical evaluation due to a TB test conversion, or (2) as a result of a medical evaluation after an exposure incident. In both cases, the employer is choosing the medical provider who will evaluate the employee. The standard does provide that when an employer is acting as the evaluating health care professional, that the employee be informed that it can refuse to consent to receive medical services from the employer-health care provider. In that case, the employer must make arrangements for the employee to see another PLHCP. However, in no case does the standard permit a PLHCP to determine, in the absence of one of the triggering condition and an employer referral, that the PLHCP himself or herself should be medically removed. The only exception is for a self-employed PLHCP, as the Division has no jurisdiction over self-employed persons.

Comment #JF12: Dr. Frisch recommended that the standard address influenza during the shoulder months (the months immediately adjacent to the generally recognized influenza season).

Response: There are two references in the proposal to the influenza season. The first is in subsection (c)(3)(B) which requires the referral of patients who exhibit influenza-like symptoms outside of the months typically associated with seasonal influenza (November through February). As a result of this comment and others, a modification has been proposed to add a sentence clarifying that a client or patient exhibiting influenza-like symptoms for a period greater than two weeks should also be referred.

The second reference is to provision of influenza vaccine, in subsection (h)(10). The exception states that an employer need not provide the seasonal influenza vaccine outside of the period recommended by the CDC. This exception is triggered by the recognized season for administering influenza vaccine, which typically starts around September and ends in January or earlier. However, in any given year, this exception is flexible in terms of being based on the CDC recommended period for providing influenza vaccine.

Comment #JF13: Dr. Frisch expressed concerns about the costs to state agencies as discussed in the comments submitted by the California Department of Corrections and Rehabilitation (CDCR).

Response: Please see response to comment #BRK1 for discussion of CDCR costs.

Comment #JF14: Dr. Frisch expressed discomfort with the proposal's lack of a specific set of documents to be used as the threshold for adding covered diseases, pathogens or vaccinations to

be included in the proposal rather than any CDC or CDPH recommendation. Recommendations can take a variety of forms, and he expressed concern that the proposal should be more precise about what sort of notice is expected to be considered for adding diseases, pathogens or vaccinations to the lists in the Appendices.

Response: The list of diseases triggering inclusion in the standard is in Appendix A. Pathogens required to be addressed by a risk assessment are included in Appendix D. Similarly, the list of vaccinations required for health care workers is defined in Appendix E. Other than novel and unknown pathogens, such as SARS in 2002-2003, the list in Appendix A will only change through rulemaking. The list of reportable diseases is promulgated by the CDPH into Title 17, California Code of Regulations, under authority of the Health and Safety Code. Therefore notice will be provided to the public of additions of reportable diseases. Similarly, the list of Aerosol Transmissible Pathogens – Laboratory (appendix D) and required vaccinations (Appendix E) will only change through rulemaking.

A modification is proposed to subsection (b) and other subsections, defining a term “public health guidelines” and listing current versions of guidelines to be incorporated by reference, including a comprehensive list of tuberculosis guidelines issued by the California Tuberculosis Controllers Association and the CDPH, and the national reference for vaccine preventable diseases published by the CDC. For new diseases, or diseases not addressed in these guidelines, the proposed standard will rely on the recommendations issued by the local health officer and the CDPH based on their authority in Title 17. The Division will monitor newly issued guidelines and propose rulemaking to update referenced guidelines for medical services including the vaccinations listed in Appendix E. The Division will also propose rulemaking if it is necessary to add or remove diseases or pathogens from Appendix A or D.

#### MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE 15-DAY NOTICE OF PROPOSED MODIFICATIONS

No further modifications to the information contained in the Initial Statement of Reasons are proposed as a result of the 15-Day Notice of Proposed Modifications mailed on February 26, 2009, except for the following substantive, and/or sufficiently related modifications that are the result of Division staff evaluation.

##### Subsection (g)(3)(B)

An effective date of September 1, 2010, is proposed to provide employers whose employees perform high hazard procedures with additional time to implement this provision, including evaluation and purchase of any additional equipment, and provide training to employees who will use respirators for high hazard procedures.

##### Subsection (h)(5)

An effective date of September 1, 2010, is proposed to provide additional time for implementation of vaccine requirements for health care workers to employers so that they can assess their employees’ vaccination status and provide any necessary vaccine doses. This

extended implementation date does not apply to seasonal influenza vaccine, which is addressed by subsection (h)(10).

Summary and Response to Written Comments:

Roger Richter, Senior Vice President, Professional Services, California Hospital Association (CHA), by facsimile dated March 16, 2009

Comment #RR1: The California Hospital Association appreciates the leadership of the Board and Research and Standards staff in developing this proposal, and the thorough responses to the comments CHA raised regarding the proposal. CHA looks forward to working on the phased implementation of this standard.

Response: The Board thanks the CHA for this comment and their offer of assistance in implementation.

Ken Nishiyama Atha, Regional Administrator-Region IX, Occupational Safety and Health Administration, U.S. Department of Labor, by letter dated March 4, 2009

Comment #KNA1: OSHA's review of the proposed standard has determined that when fully implemented, it will be at least as effective as the federal standards in protecting employees from aerosol transmissible diseases. The commenter recognizes that employers affected by the standard will need to take significant actions, and that the Board has taken steps to mitigate the burden of initial implementation by permitting a biennial fit-test for employees who do not perform high hazard procedures. This provision will sunset in 2014, and require that by January 1, 2015, all respirator users have a fit-test within the previous 12 months. The purpose of the proposed biennial fit testing exception for a limited group of employees is to promote emergency response capability within California for health care surge events, and to decrease the initial burden of the standard on employers. During the interim period, Appendix G includes a requirement that employers who choose to provide biennial fit tests also provide additional fit-test screening during the year when a fit test is not provided, and to provide an additional fit test at the request of the employee. These added requirements are intended to provide effective alternative protection for employees covered by the temporary biennial fit-test exception. OSHA will continue to monitor this aspect of the proposed standard.

Response: The Board thanks the commenter for his comments and participation in the rulemaking process.

Danielle Lucido, Staff Attorney, Worksafe, by letter dated March 16, 2009

Comment #DL1: Worksafe urges the Board to adopt the proposed regulation, which creates a comprehensive standard to protect against the transmission of aerosol transmissible diseases in California. California's health care and emergency workers deserve the protection offered by this groundbreaking standard.

Response: The Board thanks the commenter for her support.

Mark Catlin, Industrial Hygienist, Bill Borwegen, Occupational Health and Safety Director, Service Employees International Union, by letter dated March 11, 2009

Comment #MC1: The Service Employees International Union (SEIU) supports the modified standard and urges its adoption as a final rule. The Aerosol Transmissible Diseases standard represents a broad and comprehensive approach for protecting workers against exposure to diseases. Taken as a whole, it is at least as effective as existing federal protections. If in the future federal OSHA issues a more protective standard, the commenters will expect the Board to modify this standard.

The SEIU believes this standard is particularly important because it provides protection for workers not only against known diseases such as tuberculosis, but also against novel or unknown aerosol transmissible diseases, such as pandemic influenza. No other standard in the United States provides this protection, and this standard is a vital step forward in protecting workers.

The SEIU has a long record of support for annual fit test requirements. Annual fit testing is important for ensuring a good fit of the respirator, and protecting workers from the inhalation of airborne hazards. This standard's exception to annual fit testing for workers who do not perform high hazard procedures will sunset on January 1, 2014, and then return to annual periodicity. The commenters support this phase-in requirement given that annual fit testing will be required for all respirator wearers after the sunset date. The SEIU also strongly supports the mandatory fit test screening provisions contained in Appendix G. These provisions strengthen the effectiveness of the use and fit of respiratory protection in the final standard. This appendix is mandatory when an annual fit test is not provided, and includes important requirements for workers to obtain a fit test whenever they experience facial changes that might impact the fit of their assigned respirators, or when they request to be given an additional fit test.

The commenters urge the Board to approve and adopt the modified proposal.

Response: The Board thanks the commenters for their support.

Bonnie R. Kolesar, ARM, CCSA, Assistant Secretary, Office of Risk Management, California Department of Corrections and Rehabilitation (CDCR), by electronic mail dated March 13, 2009

Comment #BRK1: Section (h)(6) requires employers to assume public health responsibilities. Some employers do not have the public health expertise to perform these functions. Subsection (h)(6)(A) requires employers to report cases or suspected cases of "reportable airborne infections" to the local health officer. Currently, reporting is required only by health care professionals. The proposed regulation extends that responsibility to employers. Non-medical employers do not have the medical knowledge to make a reasonable determination than an employee is a "suspected case" and should not be required to make such a report.

Response: As published in the notice of proposed modification (NPM) subsection (h)(6)(A) states that “A health care provider, or the employer of a health care provider ~~An employer~~ who determines that a person is an RATD case or suspected case shall ~~1. Report, or ensure that the health care provider reports,~~ the case to the local health officer, in accordance with Title 17.

This language clearly states that it is the health care provider or the employer of that provider who is required to ensure that the case or suspected case is reported to the local health officer (LHO). Participants in advisory meetings stated that in some cases the health care provider directly reports the case, and in other cases, the report may go through a hospital’s infection control department. This subsection is consistent with existing requirements in Title 17, and imposes no duty on non-medical employers to report cases or suspected cases. Health care provider is defined in this standard as it is defined in Title 17, to ensure consistency between these titles. It is reasonable to require an employer of a health care provider to ensure that the legal requirements regarding reporting communicable diseases to the LHO are met.

Subsection (b)(3)(B) states that where screening is provided by persons who are not health care providers, the result of the screening is to refer potential cases to a health care provider. The health care provider can then determine whether the patient meets the criteria of a case or suspected case, and report this information to the LHO as necessary. Employers who are not health care providers and do not employ health care providers are not required by this section to report communicable diseases to the LHO.

Comment #BRK2: Subsection (h)(6)(C) requires employers to conduct contact investigations and report suspected exposures to co-workers. Title 8 requires “investigation” of workplace illness and injuries. “Until now, in non-medical settings, covered illnesses have been limited to illnesses caused by toxic agents or environmental conditions. Attempting to expand employer responsibilities to include investigation of infectious disease blurs the line between traditional workplace investigations and public health contact investigations.”

Response: Occupational illnesses have traditionally included, and continue to include, infectious diseases, as well as diseases related to chemical or physical agents. For example, tuberculosis is specifically mentioned as a recordable illness in Title 8, Section 14311. The Division, and federal OSHA, have enforced requirements regarding TB recording and investigation of occupational illnesses in medical and non-medical environments, including correctional facilities. Diseases caused by bloodborne pathogens, whether in a medical setting, law enforcement, or even in a retail establishment in which there is occupational exposure, are also occupational illnesses that must be investigated. Federal OSHA record keeping requirements (and the equivalent California requirements) specifically address the recording of infectious diseases including tuberculosis whether the disease is contracted from a patient, client, detainee, co-worker, or other person in the workplace.

Federal and California record keeping regulations require employers to complete a form 301, “Injury and Illness Incident Report” for all recordable occupational injuries and illnesses. The

form contains space for more detailed information about the injured or ill employee, the physician or other health care professional who cared for the employee (if medical treatment was necessary), the treatment (if any) of the employee at an emergency room or hospital, and descriptive information telling what the employee was doing when injured or ill, how the incident occurred, the specific details of the injury or illness, and the object or substance that harmed the employee. Both the federal and state regulations provide procedures to maintain the privacy of the employee in recording certain types of cases, including tuberculosis.

The existing California regulation, Section 3203(a)(5), requires that the employer's Injury and Illness Prevention Program (IIPP) "Include a procedure to investigate occupational injury or occupational illness." Section 3203(a)(4) requires the IIPP to "(4) Include procedures for identifying and evaluating work place hazards including scheduled periodic inspections to identify unsafe conditions and work practices. Inspections shall be made to identify and evaluate hazards... (C) Whenever the employer is made aware of a new or previously unrecognized hazard." Section 3203(a)(3) requires that the IIPP "(3) Include a system for communicating with employees in a form readily understandable by all affected employees on matters relating to occupational safety and health, including provisions designed to encourage employees to inform the employer of hazards at the worksite without fear of reprisal." These existing regulations already require employers to investigate infectious diseases, and take appropriate actions. Proposed subsection 5199(h)(6)(C) clarifies how employers should investigate employee exposures to aerosol transmissible diseases.

The changes that were noticed in the NPM to subsection (h)(6)(C) that specifically state that the results of the employer's exposure investigation shall be made available to the local health officer upon request, will also help to clarify the relationship between the employer's investigation and the LHO.

Comment #BRK3: The Health and Safety Code Section 1-28 grants local health departments the authority to conduct contact investigations. The proposed regulation would require employers to assume that responsibility, and to inform co-workers that they may have been exposed to infectious diseases. These are public health functions and require specialized public health training. In many settings the determination of exposure requires professional medical expertise, and interpretation of medical information about both the suspected source and potentially exposed individual. Communications about possible disease exposures are very sensitive, and require specialized public health expertise. It is critical to assure that no information is provided to the exposed individual that would inadvertently reveal the identity of the suspected source of infection. Non-medical employers do not have the authority or expertise to perform these functions.

Response: The Board recognizes that the Health and Safety Code provides authority to the local health officers (LHO) in protecting the public's health against a broad range of health hazards, including toxic substances and infectious diseases. The proposed standard recognizes, and in many cases relies on, the role of the LHO. The Board recognizes that in practice, as well as in

this proposal, employers interact with local health department personnel to control infectious disease risks.

This authority of the LHO, however, does not relieve the Board of its responsibility as the “only agency in the state authorized to adopt occupational safety and health standards.” (Labor Code Section 142.3(a)(1)). Nor does it relieve each employer of its responsibility to “furnish employment and a place of employment that is safe and healthful for the employees therein,” (Labor Code Section 6400), and to “furnish and use safety devices and safeguards,” and to “adopt and use practices, means, methods, operations, and processes which are reasonably adequate to render such employment and place of employment safe and healthful.” (Labor Code Section 6401) The Labor Code further states that every “employer shall do every other thing reasonably necessary to protect the life, safety, and health of employees.” (Labor Code Section 6401)

The State of California operates a “state plan” under the federal Occupational Safety and Health Act, which requires every employer to furnish to each employee “employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.” California’s plan must be as effective as federal regulations.

Subsection (h)(6) distinguishes between an exposure investigation, the purpose of which is to determine which employees may have had an exposure that warrants medical follow-up, and medical services provided to those identified employees. The person performing the exposure investigation need not have medical information about exposed employees. If the investigation reveals that the employee was exposed to a source patient or material, then the employee is to be referred to a physician or other licensed health care professional (PLHCP) who can evaluate the susceptibility status of the employee, and other medical information, and provide appropriate medical follow-up. Subsection (h) requires that all medical services be provided in accordance with applicable public health guidelines. Subsection (h)(6)(C) requires that the analysis of the exposure scenario be conducted by an individual knowledgeable in the mechanisms of exposure. It further requires that this analysis be provided to the local health officer upon request. It is also foreseen that the employer may consult with the local health officer. These and other provisions provide an interface with the local health department.

In regards to confidentiality, subsection (b) defines individually identifiable medical information as “medical information that includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.” Subsection (h)(6) also contains protections regarding the identity of the source patient. For example, subsection (h)(2)(C) requires that all medical services be provided in a manner that ensures the confidentiality of employees and patients. It further specifies that test results and other information regarding exposure incidents and TB conversions be provided without providing the name of the source individual. Subsection (h)(6)(B) further requires that

the notifying employer not provide the identity of the source patient to other employers. Subsection (h)(9) limits the information that will be provided to the employer by the PLHCP who evaluates an employee, and further states that “all other findings or diagnoses shall remain confidential and not be included in the written report.” Subsection (j)(1)(C) addresses confidentiality of employee medical records, and subsection (j)(3)(B) further limits the records that can be made and retained regarding exposure incidents.

The Board further notes that employers in various environments maintain other confidential information about employees, including personnel information and information regarding occupational injuries and illnesses.

Comment #BRK4: The implementation of this regulation will be “prohibitively expensive.” CDCR employs 60,000 staff at 35 institutions/facilities and 44 camps. In order to provide the medical and public health services required by the standard, CDCR would need to establish a large occupational health network with a public health nurse and disease surveillance expert at 36 locations across the state, and cost over \$6,600,000 annually. First year costs for vaccination of employees for seasonal influenza, measles, mumps, rubella, tetanus, diphtheria, acellular pertussis and varicella zoster is anticipated to cost between \$1,500,000 and \$2,200,000. These costs are in addition to the costs for currently mandated programs. Although the ISOR estimates that the cost of the regulations will be offset by savings in compensation claims, lost work time, and productivity losses, the commenter does not know how the savings were calculated, and they may be insufficient to cover the increased costs associated with the proposed regulations. In addition, savings in terms of sick leave or reduced workers’ compensation will not necessarily be redirected to the costs of the program. The CDCR would need a budget change proposal for program costs and position authority.

Response: Only health care workers are covered by vaccination requirements for other than seasonal influenza. Most CDCR employees do not work in health care operations, and therefore are not subject to these requirements. At the Corrections and Law Enforcement advisory meetings, several participants stated that the mumps measles and rubella (MMR), varicella, and tetanus, diphtheria and acellular pertussis (Tdap) vaccines were provided to health care workers in correctional settings. The vaccination provisions of the proposal resulted in part from this discussion, as well as from the recommendations of the CDC and the Immunization Branch of the CDPH. Many health care workers are not considered to be susceptible to MMR or varicella, and need not be provided with vaccine. (Susceptibility is to be determined in accordance with the referenced CDC guidelines, and may be based on previous vaccinations or age.) This reduces the cost. One Tdap vaccine dose is required every ten years.

The CDCR has had several significant infectious disease outbreaks of varicella zoster (VZV, chicken pox) during recent years. Although VZV is generally a self-limiting illness, it can also lead to serious complications including pneumonia and encephalitis. It is particularly a risk for immune compromised people. Two doses of vaccine are recommended for susceptible health care workers. As stated in the Initial Statement of Reasons, the cost of the vaccine is estimated as \$142. In addition to the health risks posed by contracting this disease, exposure to VZV can cost

thousands of dollars of productivity and personnel costs to replace the employee during a period of quarantine or illness. Significant costs are also involved in treating the illness. VZV vaccination can therefore produce significant savings. Similar savings are realized through provision of MMR and Tdap to health care workers.

The commenter's statements fail to take into consideration the costs already being incurred as a result of prison health care improvements resulting from the federal receivership, including the announced establishment of a network of public health nurses, including nurses assigned to occupational health. CDCR is also currently implementing vaccination programs. For example, in 2008, seasonal influenza vaccine was offered to all inmates and facility staff (The Turnaround Lifeline January 6, 2009). The commenter also does not explain why the network that currently implements the annual TB screening, and responds to outbreaks such as varicella and influenza, would not be responsible for implementation of this proposal, which is consistent with existing state law requiring infection control programs in CDCR facilities, TB surveillance, and licensing of correctional health care facilities.

Infectious disease outbreaks are expensive. Employees that become ill need to be replaced, often at the cost of overtime. Procedures must be implemented to segregate sick inmates and provide appropriate care. Final reports on an influenza outbreak at a southern California prison in 2008 indicate that between 500 and 800 inmates became ill, 12 were hospitalized, and two died (KESQ). Public health authorities did not report employee illness, but an e-mail from CDCR indicated that approximately 40 employees became ill (Baumrind). The cost of temporarily replacing 40 employees (potentially including workers' compensation costs), isolating the prison, treating over 500 inmates, and hospitalizing 12 inmates are substantial.

The commenter states that the CDCR processes make it difficult to apply the savings realized due to the disease control measures required by this standard to the costs of implementing the program. However, these are still savings that the agency will realize. In addition, the Board believes that infection control activities that will be required under this standard are currently mandated by existing infection control requirements, both in law and as mandated by the federal courts.

Comment #BRK5: The portions of the proposal that apply to vaccinations should be approved. The portions of the regulation that relate to contact investigation and "public health surveillance" for infectious diseases should be eliminated.

Response: The Board appreciates the commenter's support for the vaccination provisions of this proposal. The proposed standard does not address "public health surveillance" for infectious diseases. It addresses the identification and correction of hazards in the workplace, including procedures for the control of diseases introduced into the workplace by patients, clients and others, and for the investigation of employee exposures and occupational illnesses. Please see comments #BRK1 and #BRK2 for further discussion of the relationship of occupational and public health in this context.

Bill Kojola, Industrial Hygienist, American Federation of Labor and Congress of Industrial Organizations, by letter dated March 10, 2009

Comment #BK1: The proposed standard as modified represents a broad and comprehensive approach for protecting workers against exposure to aerosol transmissible diseases, which, in totality when all of its provisions become final, will be at least as effective as existing federal regulations. The AFL-CIO supports its adoption as a final rule. If at some point federal OSHA issues a more protective standard, the commenter will expect Cal/OSHA to modify its standard so that it becomes at least as effective as any new federal standard.

The AFL-CIO believes California's standard is particularly important in its requirements to protect employees from novel or unknown aerosol transmissible diseases such as potential pandemic influenza. The California standard is unique in this respect and is a vital step forward in protecting workers in these circumstances.

The AFL-CIO has a long record of support for the requirement of annual respirator fit-testing, and believes annual fit testing is important for protecting workers. The commenter notes that the biennial fit test exception for non-high hazard procedures will sunset on January 1, 2014. The commenter supports the phase-in requirement for annual fit-testing, given that annual fit-testing will apply to all respirator users after the sunset date. The commenter also supports the fit test screening provisions in Appendix G, which includes important requirements for workers to obtain a fit test whenever they experience facial changes that might impact the fit of the respirators, and when employees request an additional fit test. This is critically important to protecting workers during the time period before annual fit testing becomes mandatory in all circumstances for employees who wear respirators.

The commenter urges the Board to adopt the modified proposal.

Response: The Board appreciates the commenters support for the proposed standard.

Rick Kreutzer, MD, Chief, Division of Environmental and Occupational Disease Control, California Department of Public Health, by letter dated March 13, 2009

Comment #RK1: Barbara Materna, Chief of the Occupational Health Branch testified on behalf of CDPH in support of the original version of the proposed standard at the August 21 hearing. Following the hearing, Dr. Materna compiled technical comments on the ATD standard from a number of CDPH staff in communicable disease, occupational health and laboratory science, and provided those comments to Division staff. Those comments were thoughtfully considered, and on the whole were satisfactorily addressed in the modifications in the present version. The CDPH enthusiastically supports the adoption of Title 8, Section 5199, which would make California the first state in the nation to enact a regulation that protects workers from aerosol transmissible diseases. Dr. Materna has already begun working with colleagues from Cal/OSHA and the University of California to develop an educational program that will assist employers in implementing these necessary protections.

Response: The Board thanks the commenter for his support, and thanks the CDPH for their assistance in developing this proposal.

Daniel Shipp, President, International Safety Equipment Association (ISEA), Arlington, VA, by letter dated March 10, 2009

Comment #DS1: The ISEA represents manufacturers and suppliers of personal protective equipment including over 90% of all NIOSH certified respirators in the US. The ISEA supports this rulemaking effort to address important issues related to the aerosol transmission of disease.

Response: The Board thanks the commenter for his support of the standard.

Comment #DS2: The commenter does not believe there should be an exception to annual fit testing. Permitting this exception is contrary to Federal OSHA regulations which require annual fit testing in accordance with 29 CFR 1910.134. Additionally, fit testing provides the employee with an opportunity to be trained and review the proper donning of the respirator. The commenter believes that annual fit testing should always be performed where respiratory protection is required to be worn by an employee.

Response: The exception to subsection (g)(6)(B)3, to which the commenter refers, was included in the original Notice of Proposed Rulemaking. The Notice of Proposed Modifications added two provisions limiting this exception. The first was to clarify that respirators used to protect employees against laboratory-generated aerosols were not subject to this exception. The second was to include an additional information requirement for employers who utilize this exception to perform biennial fit-testing during the period for which the exception is in effect. The information the employer is required to provide to affected employees includes information on the importance of respirator fit, and asks employees whether they meet any of the conditions that would require an additional fit test, including facial injuries or surgery, major dental work, and significant weight change. Employees will also be asked whether they want an additional fit test.

Please see comment #KNA1 for further discussion of federal equivalence.

Robert A. Weber, CIH, Manager, Technical Service and Regulatory Affairs, Occupational Health & Environmental Safety Division, 3M Company, by letter dated March 11, 2009

Comment #RW1: 3M is a major manufacturer and supplier of respiratory protective devices. In regard to the definition of “occupational exposure” in subsection (b) of the proposed regulation, the phrase “exposure range” requires further explication because a possible interpretation is that there is a safe, finite distance away from an exposure case such as three or six feet. This concept has not been proven for aerosol transmissible diseases. The separation between an area in which an employee has a high probability of encountering a disease-causing exposure level and an area in which there is a lower probability would be better defined by a physical barrier coupled with a control method such as ventilation or filtration than solely by distance.

Response: The definition to which the commenter refers was modified in response to comments to replace the term “at risk” populations with the phrase “populations served by facilities identified in subsection (a)(1)(E).” The phrase to which the commenter refers was not changed pursuant to the 15-day Notice, and therefore the comment may not be considered timely. However, the Board notes that the use of the term “exposure range” is not meant to indicate that distance is the only parameter to consider in determining whether a person has occupational exposure. It is given as an example of criteria that may be used. Building construction, barriers, ventilation, the nature of the pathogen, and the activities of the infectious individual and the employee, may well determine the risk to an employee in the vicinity. The purpose of defining the term “occupational exposure,” is to identify those employees who require protections defined in this standard.

Comment #RW2: Subsection (g)(3)(A) requires more protective levels of protection above the N95 respirator if the CDC or CDPH specifies a more protective level. The commenter believes that the CDC has not always been clear on what a more protective respirator is. For example a more protective respirator, as listed by the CDC, may be the “same type of respirator with a different filter “for example a half mask filtering facepiece or elastomeric respirator with an N95 filter vs. a similar respirator with an N100 filter. Both have the same Assigned Protection Factor (APF) of 10—meaning there is no difference in the minimum level of protection they provide—and hence one is not more protective than the other. This is logical, when one considers that most airborne contaminant penetration is through face seal leaks and not the filter. The APF should be used to identify the protection level of the respirator. Therefore the commenter suggests that the wording be changed to, “unless the CDC or CDPH specifies a respirator with a higher APF than an N95 filtering facepiece respirator, in which case the more protective respirator shall be provided.”

Response: It appears that this comment is not based upon the version of the standard presented in the Notice of Proposed Modification (NPM) because one of the changes published in the NPM was to remove the reference to CDC and CDPH. The language as noticed in the NPM was changed to “the employer is required to provide a more protective respirator when the “employer’s evaluation of respiratory hazards determines that a more protective level respirator is necessary.””

The Board does not agree that APF is the only appropriate criteria for assessing the protection provided by a respirator, although APF is an important factor. Environmental conditions, for example the presence of oil mists, require different types of filters for respirators having the same APF. The presence of other contaminants may require the use of a cartridge type respirator that has the same APF as the filtering facepiece respirator. Durability may also be a factor. OSHA recognizes a difference between types of half-facepiece respirators in the asbestos standard, which prohibits the use of filtering facepiece respirators for asbestos, for example 29 CFR 1926.1101(h)(3)(i)(A) (equivalent to Title 8, Section 1529(h)(3)(A)). Also, some studies cited by commenters (and summarized in the NPM) indicate that some N95 respirators may not actually provide a protection factor of 10 for biological aerosols. The National Institute for

Occupational Safety and Health (NIOSH) has nine types of approvals for particulate filters, which have different specifications, and recognize different levels of filter efficiency.

The APF approach was developed for protection against chemical contaminants for which there is an occupational exposure limit (OEL) to which exposure levels can be compared. The concentration of a contaminant in the environment is divided by the OEL, and the necessary protection factor is determined. With infectious aerosols, little is often known about the concentration in the environment, and little may be known about the infectious dose, which may vary based on the susceptibility of the individual and other conditions. Therefore public health and occupational health authorities make risk-based recommendations based on projected exposure scenarios.

The Board believes that, having established a minimum level of respiratory protection based on the type of exposures, the proposal takes a reasonable approach by requiring that the employer continue to evaluate the work environment and ensure that an appropriate level of respiratory protection is provided, as is currently required by 29 CFR 1910.134 and California's 8 CCR 5144.

Comment #RW3: Subsection (g)(3)(B)'s requirements for utilization of a powered air purifying respirator (PAPR) with HEPA filter for high hazard procedures does not appropriately distinguish between types of PAPR, based on the type of inlet covering. Some PAPR's provide an APF of 1000, and some, including the loose-fitting facepiece type most commonly used in health care, provide an APF of 25. This section should specify the type of PAPR, or else should specify the APF required. The most popular PAPR in use in health care is, in fact, a loose-fitting face piece type with an APF of 25. The regulation does not distinguish between these two categories of PAPR. The standard should clearly state whether an APF of 25 or 1000 is to be required.

Response: The language of this subsection was changed in the NPM, to require that the employer provide a PAPR or an equivalent respirator for high hazard procedures. Equivalence is based on the respirator's ability to protect employees against the higher concentrations that are anticipated during high hazard procedures. This includes APFs; however, it also includes the context in which the procedure is performed, and what type of respirator can reasonably provide an appropriate level of protection. This subsection does permit the use of loose fitting facepiece PAPRs. The Board notes that as explained in the Initial Statement of Reasons and the NPM, these PAPRs have been used successfully in health care facilities to protect employees against diseases such as drug resistant tuberculosis.

This subsection specifically recognizes that respirators used in emergency response activities and that come under Section 5192 (Hazardous Waste and Emergency Response Operations), which is equivalent to 29 CFR 1910.120, must also meet the requirements of that standard.

For further discussion regarding assigned protection factors, please see response to comment #RW2.

Comment #RW4: The last sentence of subsection (g)(6)(A) refers to a “single use respirator” which is defined in 42CFR 84.2(bb) as a respirator that is entirely discarded after excessive resistance, sorbent exhaustion, or physical damage renders it unsuitable for use. Not all single use respirators would be acceptable for aerosol exposures, as many can be cleaned and disinfected using wipes, which Federal OSHA allows during fit testing. The commenter believes Cal/OSHA means a filtering facepiece respirator such as an N95 because these respirators cannot be cleaned and disinfected. Substitute “filtering facepiece” for “single use” in the sentence.

Response: This comment appears to be outside of the scope of the NPM. However, the Board notes that this subsection refers only to providing a new disposable respirator for fit-testing to each employee, as compared to requiring disinfection of facepieces between users for other respirators. This requirement to discard “single-use” respirators between individuals may apply to more than filtering facepiece respirators.

Comment #RW5: The Exception to subsection (g)(6)(B)3, as explained in the initial statement of reasons, permitting biennial fit-testing does not provide equivalent protections to the Federal OSHA respiratory protection standard. Recent studies demonstrate the importance of frequent fit testing, especially for new respirator users.

Response: This comment does not appear to respond to a change noticed in the NPM, and therefore no response is provided. The Board notes that the content of this comment was addressed in the NPM, particularly in response to comment #BK18, and changes in regards to this requirement as noticed in the NPM, are addressed in comments #DS2 and #KNA1.

Comment #RW6: The option in subsection (g)(5) to utilize an alternative medical questionnaire to the one in the respiratory protection standard is ambiguous in its application, lacks clarity, and is inadequately justified. From the Appendix B wording about affirmative answers to questions in Section 1 and question 6 in Section 2, it might suggest affirmative answers to the other questions require a medical examination. The following wording should be added to this subsection or to Appendix B: “The employer shall ensure that a medical examination is provided for an employee who gives a positive (yes) answer to questions 1-5 in Section 2 of the questionnaire in Appendix B.”

Response: This comment is not within the scope of the NPM, and therefore no response is provided. The justification for this requirement is contained in the Notice of Proposed Rulemaking.

Azita Mashayekhi, M.S., Industrial Hygienist, Safety and Health Department, The International Brotherhood of Teamsters, by facsimile dated March 13, 2009

Comment #AM1: The International Brotherhood of Teamsters (IBT) supports the modifications to the proposed standard and urges the Board to adopt this Standard. They look forward to participating and helping Cal/OSHA to implement this standard and review its effectiveness. The

IBT represents 1.4 million workers in the United States and Canada, including thousands employed by the private sector and State and municipal government in California, who are at increased risk of exposure to aerosol transmissible pathogens. These include workers employed in hospitals and other health care facilities and operations, correctional facilities, firefighters and emergency responders, police services and laboratories.

When fully implemented, this standard would be at least as effective as existing federal requirements. Should a federal standard that specifically and comprehensively addresses occupational exposure to aerosol transmissible disease become available, the IBT would expect Cal/OSHA to revisit the existing standard to ensure that it will remain as effective as OSHA's requirements.

The commenter supports the standard's intent to establish minimum requirements for controlling risks to health care workers and workers in other high-risk environments from exposure to infectious aerosols, which can cause diseases such as pandemic flu, tuberculosis, Severe Acute Respiratory Syndrome (SARS) and pertussis. Although IBT favors annual fit testing of respirators, as mandated by federal OSHA, they recognize that the exception that permits the repeat fit testing interval to be increased to every two years for workers who do not perform high hazard procedures will sunset on January 1, 2014. The IBT fully supports the addition of Appendix G which will clarify required training and strengthen the effectiveness of use and fit of respiratory protection in the final standard, during the period before annual fit testing goes into effect for all workers who wear respirators.

The IBT commends California for spearheading a standard that specifically and comprehensively addresses occupational exposure of thousands of workers, including many Teamster members to a wide range of aerosol transmissible diseases. The IBT looks forward to actively participating in the process of implementation and appraisal of this important standard.

Response: The Board thanks the commenter for her support and offer of help in implementing and evaluating the standard.

Bill Taylor, Legislative Committee Chairperson, Public Agency Safety Management Association (PASMA) South Chapter, by letter dated March 13, 2009

Comment #BT1: PASMA supports the comments submitted by William Fujioka and Steven E. NyBlom of the County of Los Angeles (submitted in response to the notice of proposed rulemaking), particularly in regards to the comment that the Board needs to show that the diseases that are addressed by the proposed standard are rising in incidence (comment #WF2 in the NPM dated February 26, 2009). Although the Board's response to the comment was in part that health care workers and other workers continue to experience TB conversions and develop active tuberculosis, it did not speak to other types of workers covered by the standard. The risk of these other workers has not been quantified. These other workers identified in the standard include police officers and firefighters, who are being treated as though they were health care workers. While it is true that they don't have to follow every requirement of the health care

workers, nonetheless, they are being classified and will be required to be treated in similar fashion, such as the requirements to include: training, annual vaccinations, and eventually annual fit-testing of N-95 respirators, and engineering and work practice controls.

PASMA is aware of no TB conversions among police officers within their agencies. The Board should exempt police officers from the routine TB testing in the standard.

Response: Several items addressed in this comment are beyond the scope of the Notice of Proposed Modification (NPM) and are therefore not addressed in this response. However, the NPM did include a change in the definition of police services that was intended to address the concern that the inclusion of police services was overly broad.

In the NPM, the Board modified the definition of police services that are included in the scope of this standard. The proposed standard includes “police services, provided during transport or detention of persons when reasonably anticipated to be provided to cases or suspected cases of aerosol transmissible diseases; and police services provided in conjunction with health care or public health operations.” This clarifies the types of police operations that are included in this standard. This statement of scope should be read together with the definition of “occupational exposure” to determine which police personnel are to be included within the employer’s ATD infection control procedures, and therefore provided with annual TB tests and seasonal influenza vaccine.

The definition of occupational exposure requires employers to include within their infection control procedures only those employees whose risk exceeds the risk in public contact operations that are not included within the standard. For example, a police officer or sheriff making traffic stops, conducting investigations, apprehending suspects, or directing traffic, may not have exposures that exceed those of other public contact operations, even if those activities may occasionally bring them into contact with a person who has an ATD. However, an officer who is regularly assigned to assist public health operations involving contact with ATD cases or suspected cases, whose primary assignment is within a correctional facility or health care facility (in areas in which there is contact with the facility population or patients), or who regularly transports detainees to hospital facilities for diagnosis or treatment of ATDs, probably does have occupational exposure.

In regards to TB testing, the Division held two advisory meetings specifically directed at law enforcement and corrections, as part of the ten meeting series leading to publication of the standard. At these meetings representatives of local police and sheriff’s departments indicated that while some do initial tests for latent tuberculosis infection (LTBI), they do not do annual LTBI testing on police personnel. Without active surveillance, the conversion rate among occupationally exposed law enforcement personnel is not known.

In regards to respirator use, participants in the advisory meetings indicated that most departments have prepared either all or some officers for respirator use, and the Division worked with the Police Officers Standard and Training (POST) Agency to develop a model respiratory protection

program. At the request of law enforcement agencies, the Division's Medical Unit reviewed the current POST physical and determined that passage of that physical can be used to meet the requirement for medical evaluation for respirator use. The Board also notes that the circumstances in which police officers are required to use respirators for protection against aerosol transmissible pathogens are those in which respirator use is currently required under Section 5144 and the equivalent federal regulation 29 CFR 1910.134.

Comment #BT2: The commenter's personal experience with flu shot administration for Anaheim city employees required an overall average of one hour per employee when accounting for administration of vaccine to all shifts, rescheduling missed appointments, and handling declination forms. This is more realistic than the Board's figure of 20 minutes per employee. The process will be a logistical problem for police and firefighters due to their multiple shifts, and mobility.

Response: The Board appreciates the commenter's sharing of his experience. The time required for administering flu shots may vary depending on the actual method of scheduling employees and providing the vaccinations. However, whether the time spent in vaccination is 20 or 60 minutes, that time is considerably less than the time lost by an employee who contracts influenza, and typically misses three or more days of work. Employees who contract influenza are also infection risks for other employees. During influenza outbreaks employers incur significant expenses in overtime and other costs in covering for sick employees. Further, only employees who have been determined to have occupational exposure are required to be provided with flu shots.

Comment #BT3: The commenter believes that it is unrealistic to provide only 15 days to comment on a standard as lengthy and complex as the proposed standard. It seems likely that some agencies have not had the time or resources to review the standard. The standard would have a significant and far-reaching impact on thousands of employees throughout the state. The commenter requests an extended comment period.

Response: The publication of this proposal was preceded by a public four-year advisory process, including 10 advisory meetings, two of which were specifically targeted for law enforcement and corrections. A 45-day notice of intended rulemaking was published in July 2008, and a public hearing was held on August 21, 2008. The NPM was issued in accordance with the Administrative Procedure Act.

Comment #BT4: The commenter believes that the responses to comment did not include a cost benefit analysis for the implementation of the proposed regulation, and there should be an acknowledgement that there will be a significant cost for all California police and firefighting departments. The commenter believes that there will be little increased protection from aerosol transmissible diseases if the standard is implemented.

Response: This comment is beyond the scope of the NPM, and no response is given. The Board has included within NPR and the NPM all cost and savings information available to it. As was

stated by several commenters to the NPR, the benefits to this standard primarily are to safeguarding the health of employees. The Board's mandate is to adopt regulations that will protect employees from hazards at work, and to ensure that employees' health is not jeopardized in the performance of their work.

LeAnna Williams, CSP, Department of Risk Management, County of San Bernardino, by facsimile dated March 14, 2009

Comment #LW1: Before issuing a respirator to employees, an employer must perform a hazard assessment for respiratory hazards. This is specified by Section 5144. Requests were made at the advisory meetings to provide scientific data to establish the need for the proposed standard. Studies to link the likelihood of contracting a disease with increased exposure to aerosols, such as a current NIOSH study, have not been performed. Such a hazard assessment is necessary before the county and professional agencies can implement the protective measures in the proposed standard.

Response: This comment is beyond the scope of the NPM. Studies and other information documenting the risk of aerosol transmissible diseases and the need for respiratory protection were presented at advisory meetings, and some of these studies were included in the documents relied on in the NPR. Others were added in the NPM dated February 27, 2009. The Centers for Disease Control and Prevention and other public health agencies recognize the necessity for respiratory protection to reduce the risk of infection with airborne infectious diseases. The NIOSH study on influenza is only the latest study to look at the airborne route for influenza. A number of other studies have documented that route. It should also be noted that seasonal influenza does not require airborne infection isolation under this standard.

Comment #LW2: San Bernardino County has the primary socioeconomic demographic for TB in California. In 2007 and 2008, there were 59 and 74 confirmed cases in the county, but no county personnel had exposure incidents or conversions.

Response: Please see response to comment #BT1 and #BT2.

Comment #LW3: The exception for police officers having a partition in vehicles to reduce the flow of air from the back seat passenger to the front seated officer(s) may be expensive; a cost estimate showed retrofitting one car would be \$1,000. Also, such a partition may conflict with side impact air bags which conflicts with the National Highway Safety Transportation requirement that takes effect in 2013.

Response: This comment is beyond the scope of the NPM, because no change to the exception was proposed in the NPM. The Board does note that this is an exception that a department may choose to utilize, and the effectiveness of this exception was tested in patrol cars currently in use by a local police department. (See the minutes of the May 31, 2006, advisory meeting for a discussion of the experiment demonstrating the efficacy of currently existing barriers.) The new motor vehicle regulations may result in changes in vehicles that are used to transport detainees.

Employers may continue to utilize this exception as it may apply to new types of vehicles. Departments can comply with this standard by providing respirators to officers transporting suspect or confirmed cases of airborne infectious diseases, such as tuberculosis.

Comment #LW4: The proposed standard would impact 8059 county employees, of which 4600 would require medical screening to use a respirator. Although county clinics can provide the screening, the clinics cannot provide all the vaccines required by the standard. The costs for these medical services would exceed \$2,000,000.

Response: This comment is beyond the scope of the NPM. However, the Board refers the commenter to comment #BT1 for discussion of coverage of this standard, determination of occupational exposure, application of vaccination provisions, and costs.

Comment #LW5: What would an employer be expected to do if an employee is not determined to be medically qualified to use a respirator?

Response: This comment is beyond the scope of the notice to which it was made (NPM1). NPM1 did not expand the conditions under which respirator use is required, and did not change the type of medical evaluation to be provided. Respirator use to protect employees against infectious aerosols is currently required under Section 5144, and the equivalent federal regulation 29 CFR 1910.134. These requirements include providing medical evaluation to employees who use respirators, in order to protect the health of those employees. Employers have several options in regards to employees who can not use a respirator, which include asking the evaluating PLHCP whether a different type of respirator might be suitable, or changing the employee's assignment in accordance with California law.

#### MODIFICATIONS AND RESPONSE TO COMMENTS RESULTING FROM THE SECOND 15-DAY NOTICE OF PROPOSED MODIFICATIONS

No further modifications to the information contained in the Initial Statement of Reasons are proposed as a result of the 15-Day Notice of Proposed Modifications mailed on April 3, 2009.

#### Summary and Response to Written Comments:

Bill Taylor, Legislative Committee Chairperson, Public Agency Safety Management Association (PASMA) South Chapter, by letter dated April 20, 2009

Comment #BT1: In the second Notice of Proposed Modification dated April 3, 2009, (NPM2), an effective date of September 1, 2010, was added to subsection (g)(3)(B) to provide employers whose employees perform high hazard procedures with additional time to implement requirements for higher levels of respiratory protection. This subsection included a previously noticed exception that permitted paramedics to use a P-100 respirator when performing high hazard procedures. The commenter believes that this requirement is not cost effective and is not justified. The commenter is not aware of any scientific studies that indicate that exposure to

airborne pathogens during high hazard operations are significantly affected by the use of a P-100 respirator as compared to an N-95 respirator. The commenter further states that “the average paramedic involved in a high hazard procedure such as an advanced airway adjunct is only around the patient for 90 seconds, because it should be performed in 30 seconds with no more than 3 attempts allowed.” The commenter further states that research shows that exposure to TB is defined as face to face contact for more than 10 minutes, or remaining in the same room with an infectious individual for more than 30 minutes without the use of a respirator mask.

The City of Anaheim fire department uses approximately “500-700 masks” each year. As purchased in a box of 20, N-95s cost approximately “\$1.25 per mask.” It is estimated that P-100 costs “range from \$5 to \$12.50” per mask. Assuming the highest cost for a P-100, then the additional cost for the city of Anaheim fire department would be \$7, 875. If this cost were extrapolated, it would add to the cost to fire departments in California by about \$787,500. If other emergency medical personnel are included, additional costs could exceed \$1,000,000 statewide.

Response: NPM2, to which the commenter responded, did not change the requirement to which he is responding, and therefore this comment may not be timely. The necessity to use higher levels of respiratory protection was addressed in the Notice of Proposed Rulemaking. The exception permitting paramedics to use P100 respirators in lieu of a PAPR was noticed in the Notice of Proposed Modifications dated February 26, 2009 (NPM1). The P100 is a less costly alternative than the PAPR for high hazard procedures, and also is less complicated to implement when performing high hazard procedures in field operations.

With some exceptions, the proposal requires the use of respirators other than N95 respirators when employees perform high hazard procedures, which are defined as “Procedures performed on a person who is a case or suspected case of an aerosol transmissible disease or on a specimen suspected of containing an ATP-L, in which the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens.” As explained in the Initial Statement of Reasons and in the response to comment #AF1 in NPM1, the reasons for this requirement are: high hazard procedures create higher concentrations of infectious aerosols; recent investigations have found that N95 respirators, while providing some level of protection against infectious aerosols may not provide the expected level of protection against infectious aerosols (see letter and attachments from Bill Kojola, dated August 13, 2009, and summarized in NPM1); the American Society for Bronchoscopy has recommended higher levels of respiratory protection for certain procedures and pathogens; and, in regards to paramedics, activities are often performed without the benefit of other control measures on patients who have not been fully assessed, and in environments that may physically degrade the respirator or degrade the level of filtration. The Board also notes that representatives of firefighters, emergency medical personnel, and paramedics, have indicated in advisory meetings and in response to the NPR (comment #KW1 in NPM1), that paramedics should have higher levels of respiratory protection available.

The introduction of an airway adjunct is not specifically identified in the standard as a high hazard procedure, and paramedics and emergency medical personnel may perform other aerosol generating activities. The proposal requires the employer to assess their operations and determine whether the procedures performed by employees are high hazard procedures. This determination should be reviewed as part of the review of the aerosol transmissible diseases exposure control plan, with the participation of employees.

The commenter cited certain recommendations regarding determination of exposure for the purpose of contact investigations regarding tuberculosis. The commenter stated the recommendations limited the definition of exposure to ten minutes of face to face contact. However, high hazard procedures create higher levels of aerosol than simple face to face contact. Further, some pathogens addressed by this standard are more easily transmitted than TB, and some are not. Other factors may influence transmission, including the specific strain of the pathogen and the susceptibility of the employee. The experience with SARS in Canada shows that health care workers, including paramedics and other emergency response personnel are at risk for contracting aerosol transmissible diseases through their work operations.

In regards to the additional cost information provided, the commenter does not state how many of the 500-700 respirators used by Anaheim firefighters and paramedics in the course of a year are for high hazard procedures performed on cases or suspected cases of airborne infectious diseases. These are the only uses for which a P100 respirator, PAPR, or equivalent respirator would be required. In addition, according to the commenter, the cost difference for a P100 as compared to an N95 respirator may be as little as \$3.75 per respirator, and at that price difference, the additional cost is considerably lower than the estimate provided. The commenter did not provide a justification for assuming that all fire departments in California use respirators as the City of Anaheim does, or assuming that all N95 respirators used by firefighters and paramedics in California are used to protect employees during high hazard procedures performed on cases or suspected cases of airborne infectious diseases. The Board therefore does not find that this comment should require revision of cost estimates provided in the NPR.

Comment #BT2: The second item in the NPM2 would change the effective date of the vaccination provisions for health care workers in subsection (h)(5) to September 1, 2010. The commenter understands that paramedics and emergency medical personnel would be classified as health care workers under this proposal, and that is not justified. The commenter referred to his comments submitted on August 15, 2008, summarized in NPM1, that providing these vaccines would cost the City of Anaheim \$17,488. In five years the City of Anaheim has not had a single report of any firefighter or paramedic contracting one of the diseases listed in Appendix E.

Response: The change in the NPM2 addressed only an extension of time for employers to ensure that health care workers were provided with the vaccines listed in Appendix E, so this comment goes beyond the scope of the noticed modification. This comment, as it pertained to whether firefighters should be considered health care workers, was addressed in NPM1, as comment #BT5. The Board notes that inclusion of paramedics and emergency medical personnel within

the classification of health care workers is consistent with public health guidelines, and with California law and regulation. For example, emergency medical personnel are included within the vaccination recommendations of public health agencies, such as “Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC), MMWR, December 26, 1997 / Vol. 46/ No. RR-18;1-42”, (listed in the Initial Statement of Reasons). This documents states, “Because of their contact with patients or infective material from patients, many health-care workers (HCWs)(e.g., physicians, nurses, **emergency medical personnel**, dental professionals and students, medical and nursing students, laboratory technicians, hospital volunteers, and administrative staff) are at risk for exposure to and possible transmission of vaccine-preventable diseases. Maintenance of immunity is therefore an essential part of prevention and infection control programs for HCWs.” (emphasis added)

Comment #BT3: The commenter is concerned that paramedics and emergency medical personnel are being classified as health care workers. The commenter has stated previously that the risk to other workers, such as firefighters and police officers has not been quantified, and they should not be treated as though they are. Even if not covered by all provisions of the standard, eventually firefighters, police officers and paramedics will have to be trained, provided with annual vaccinations, and eventually fit-tested annually for N-95 and P-100 respirators.

Response: This comment is not in response to a change noticed in the current notice (NPM2). In regards to the concerns raised regarding paramedics, and firefighters who perform these emergency medical functions, please see response to comments #BT1 and #BT2 above. In regards to other police and fire personnel, see the response to comments to NPM1 (letter from Bill Taylor dated March 13, 2009) response to comment #BT1.

Comment #BT4: The extensions of the compliance deadlines provided in NPM2 in regards to subsections (g)(3)(B) and (h)(5) would not negate any of the additional costs associated with compliance. The commenter continues to believe that 15 days is not sufficient time to comment on over 115 pages of written comments and 12 additional documents. Many in the regulated community may not have sufficient time or resources to comment on this regulation.

Response: The extensions were provided in response to employers’ statements that additional time would permit them to implement these provisions in an orderly and cost-effective manner, such as by screening health care workers regarding their vaccine status during their annual TB assessment. The formal rulemaking proposal was published in July 2008, after a four year advisory process, in which 10 meetings were held, and draft proposals and discussion items were additionally published on the internet and circulated by e-mail. The Board has complied with the Administrative Procedures Act in the publication of these notices, and has responded to all comments received.

Comment #BT5: The Board’s responses did not demonstrate that there was a cost-benefit analysis performed in regards to this proposal. The commenter estimates that the implementation of the P-100 and vaccination program for Paramedics and emergency medical personnel will

result in statewide costs of approximately \$3,000,000. This will exacerbate problems for police and fire departments in California, while providing a “very minimal increase” in the level of protection against airborne transmissible diseases for firefighters, police officers and correctional officers.

Response: As noted by the California Nurses Association in their comment to the NPR, by letter dated August 15, 2008 (summarized as comment #DG10 in NPM1), the evaluation of the fiscal impact of the proposed standard should include the costs avoided from workers compensation claims, lost work time, and productivity losses to the employer, as well as employers of the employee’s family, as well as the harm due to significant illnesses, disabilities and premature death. It is not possible, nor is it required, for the Board to balance the benefits of the health of employees against the cost to employers. However, the Board has made a diligent attempt to determine the costs and savings related to this proposal. An employee who contracts tuberculosis, particularly drug resistant tuberculosis, measles, varicella, meningitis, or other diseases addressed by this proposal sustains a significant health impairment, from which they may not fully recover. Employees who become ill also sustain economic losses. Their employers also sustain losses in productivity, and in the cost of replacing the employee, often through overtime, and in providing medical management for the employee.

In a health care emergency, such as the SARS outbreak in Canada, paramedics and emergency medical personnel were critical in providing care within the system. However, almost half of these employees were under quarantine at some point during the outbreak, due to uncontrolled exposure to infectious patients. Recognizing the key role played by emergency responders, Canadian authorities immediately implemented additional control measures to maintain this vital capacity.

Many of the protective measures in this proposal are already required by existing standards, such as medical evaluation, training, and fit-testing of employees who use respirators to protect against infectious disease. Please see response to comment #BT1 for additional specific response to the commenter’s cost statements.

The Board believes that this proposal, without creating undue costs, will provide significant protection to employees against both current and potential health threats, and will also create a framework that will help sustain critical services during an infectious disease outbreak or pandemic.

Ken Nishiyama Atha, Regional Administrator-Region IX, Occupational Safety and Health Administration, U.S. Department of Labor, by letter dated April 9, 2009

Comment #KNA1: The modifications proposed in the NPM2 do not alter our determination that the proposed standard, when fully implemented, will be at least as effective as the federal standards in protecting employees from aerosol transmissible diseases. The commenter recognizes that employers affected by the standard will need to take significant actions, and that the Board has taken steps to mitigate the burden of initial implementation by permitting a

biennial fit-test for employees who do not perform high hazard procedures. This provision will sunset in 2014, and require that by January 1, 2015, all respirator users have a fit-test within the previous 12 months. The purpose of the proposed biennial fit testing exception for a limited group of employees is to promote emergency response capability within California for health care surge events, and to decrease the initial burden of the standard on employers. During the interim period, Appendix G includes a requirement that employers who choose to provide biennial fit tests also provide additional fit-test screening during the year when a fit test is not provided, and to provide an additional fit test at the request of the employee. These added requirements are intended to provide effective alternative protection for employees covered by the temporary biennial fit-test exception. OSHA will continue to monitor this aspect of the proposed standard.

Response: The Board thanks the commenter for his comments and participation in the rulemaking process.

#### ADDITIONAL DOCUMENTS RELIED UPON

- Balazy A, Toivola M, Adhikari A, Sivasubramani K, Reponen T, and Grinshpun S. 2006. Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks? *Am J Infect Control* 34:51-57.
- Catanzaro A. Nosocomial Tuberculosis. *Am Rev Respir Dis.* 1982; 125:559-62.
- California Commission on Peace Officer Standards and Training. Model Respiratory Protection Program for Law Enforcement. May 2004.
- Coffey CC, et al. Fitting Characteristics of Eighteen N95 Filtering-Facepiece Respirators, *Journal of Occupational and Environmental Hygiene*, 1: 262–271, 2004.
- Duling, Matthew G. et al. Simulated Workplace Protection Factors for Half-Facepiece Respiratory Protective Devices. *Journal of Occupational and Environmental Hygiene*,4:6,420 – 431, 2007.
- Eninger RM, Honda T, Adhikari A, Heinonen-Tanski H, Reponen T, and Grinshpun S. 2008. Filter Performance of N99 and N95 Facepiece Respirators Against Viruses and Ultrafine Particles. *Ann Occup Hyg* 52:385-396.
- Fennelly, Kevin P. Transmission of Tuberculosis During Medical Procedures. *Clinical Infectious Diseases* 1997;25:1273-4.
- Fennelly, KP. The role of masks in preventing nosocomial transmission of tuberculosis. *The International Journal of Tuberculosis and Lung Disease*, Volume 2, Supplement 1, September 1998, pp. S103-S109(1).
- Fennelly, Kevin P. Cough-generated Aerosols of Mycobacterium tuberculosis A New Method to Study Infectiousness. *Am J Respir Crit Care Med* Vol 169. pp 604–609, 2004.
- Howard, John. Letter to Bill Borwegen and Bill Kojola dated July 9, 2007. (NIOSH Respirator Fit Test Letter).
- Iton, Anthony. Duties of the Local Health Officer. E-mail dated January 27, 2009.
- Johns Hopkins Safety Manual, Addendum A: Respiratory Protection Devices for Airborne Infectious Agents and Aerosolized Hazardous Drugs Protocol, 9/23/08.

- Lawrence RB et al. Comparison of Performance of Three Different Types of Respiratory Protection Devices. *Journal of Occupational and Environmental Hygiene*, 3: 465–474, September 2006.
- Lee K, Slavcev A, and Nicas M. 2004. Respiratory Protection Against *Mycobacterium tuberculosis*: Quantitative Fit Test Outcomes for Five Type N95 Filtering-Facepiece Respirators. *J Occup Environ Hyg* 1:22-28.
- Lee MC et al. Respirator-Fit Testing: Does It Ensure the Protection of Healthcare Workers Against Respirable Particles Carrying Pathogens? *Infection Control and Hospital Epidemiology*. December 2008, vol. 29, no. 12
- Lee, Shu-Ann et al. Respiratory Protection Provided by N95 Filtering Facepiece Respirators Against Airborne Dust and Microorganisms in Agricultural Farms. *Journal of Occupational and Environmental Hygiene*, 2: 577–585, 2005.
- Lee S, Grinshpun SA and Reponen T. Respiratory Performance Offered by N95 Respirators and Surgical Masks: Human Subject Evaluation with NaCl Aerosol Representing Bacterial and Viral Particle Size Range. *Ann Occup Hyg* 52:177-185, 2008.
- Loeb M et al. SARS among Critical Care Nurses, Toronto. *Emerging Infectious Diseases*, Vol. 10, No. 2, February 2004.
- Lucas A et al. Inadvertent Laboratory Exposure to *Bacillus anthracis* - California, 2004. *Morbidity and Mortality Weekly Report*, April 1, 2005 / 54(12);301-304.
- Mendelsohn, M. Letter to Deborah Gold dated September 29, 2008.
- Ofner M et al. Cluster of Severe Acute Respiratory Syndrome Cases Among Protected Health-Care Workers --- Toronto, Canada, April 2003. *Morbidity and Mortality Weekly Report (MMWR)*, May 16, 2003 / 52(19);433-436.
- Qian, Yinge et al. Performance of N95 Respirators: Filtration Efficiency for Airborne Microbial and Inert Particles. *American Industrial Hygiene Association Journal*; Feb 1998; 59, 2; ABI/INFORM Global pg. 128.
- Schulte P. Letter to Len Welsh dated October 15, 2008.
- Welsh, L. Letter to Paul Schulte dated August 28, 2008.

These documents are available for review during normal business hours at the Standards Board's Office located at 2520 Venture Oaks Way, Suite 350, Sacramento, CA.

ADDITIONAL DOCUMENTS RELIED UPON  
FOR SECOND NOTICE OF PROPOSED MODIFICATION

- The Turnaround Lifeline, Volume 2, Issue 1, January 6, 2009.
- KESQ, Prison Returns to Operations in Midst of Flu Outbreak, March 19, 2008.
- Nikki Baumrind, e-mail regarding Respiratory Outbreak at Chuckawalla SP in Blyth, dated March 10, 2008.

These documents are available for review during normal business hours at the Standards Board's Office located at the address listed above.

ADDITIONAL DOCUMENTS INCORPORATED BY REFERENCE

1. Epidemiology and Prevention of Vaccine-Preventable Diseases. Epidemiology and Prevention of Vaccine-Preventable Diseases. Centers for Disease Control and Prevention, Hamborsky J, McIntyre L, Wolfe S, eds. 10th ed. 2nd printing, including chapters from the 9<sup>th</sup> edition on Anthrax and Smallpox. Washington DC: Public Health Foundation, 2008, available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm>
2. The following public health guidelines available at: <http://www.ctca.org/guidelines/index.html>
  - (A) Guidelines for Tuberculosis (TB) Screening and Treatment of Patients with Chronic Kidney Disease (CKD), Patients Receiving Hemodialysis (HD), Patients Receiving Peritoneal Dialysis (PD), Patients Undergoing Renal Transplantation and Employees of Dialysis Facilities, May 18, 2007.
  - (B) Guidelines for the Treatment of Active Tuberculosis Disease, April 15, 2003 (under review) including related material: Summary of Differences Between 2003 California and National Tuberculosis Treatment Guidelines, 2004, Amendment to Joint CDHS/CTCA Guidelines for the Treatment of Active Tuberculosis Disease, May 12, 2006, Appendix 3 - Algorithm for MDR-TB Cases and Hospital Discharge, May 12, 2006.
  - (C) Targeted Testing and Treatment of Latent Tuberculosis Infection in Adults and Children, May 12, 2006.
  - (D) California Tuberculosis Controllers Association Position Statement: The Utilization of QuantiFERON – TB Gold in California, May 18, 2007.
  - (E) Guidelines for Mycobacteriology Services in California, April 11, 1997.
  - (F) Guidelines for the Placement or Return of Tuberculosis Patients into High Risk Housing, Work, Correctional, or In-Patient Settings, April 11, 1997.
  - (G) Contact Investigation Guidelines, November 12, 1998.
  - (H) Source Case Investigation Guidelines, April 27, 2001.
  - (I) Guidelines on Prevention and Control of Tuberculosis in California Long-Term Health Care Facilities, October 2005.
  - (J) Guidelines for Reporting Tuberculosis Suspects and Cases in California, October 1997.
  - (K) CTCA recommendations for serial TB testing of Health Care Workers (CA Licensing and Certification), September 23, 2008.

These documents are too cumbersome or impractical to publish in Title 8. Therefore, it is proposed to incorporate the documents by reference. Copies of these documents are available for review Monday through Friday from 8:00 a.m. to 4:30 p.m. at the address listed above.

#### DETERMINATION OF MANDATE

These standards do not impose a mandate on local agencies or school districts as indicated in the Initial Statement of Reasons.

#### ALTERNATIVES CONSIDERED

The Board invited interested persons to present statements or arguments with respect to alternatives to the proposed standard. No alternative considered by the Board would be more

effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the adopted action.