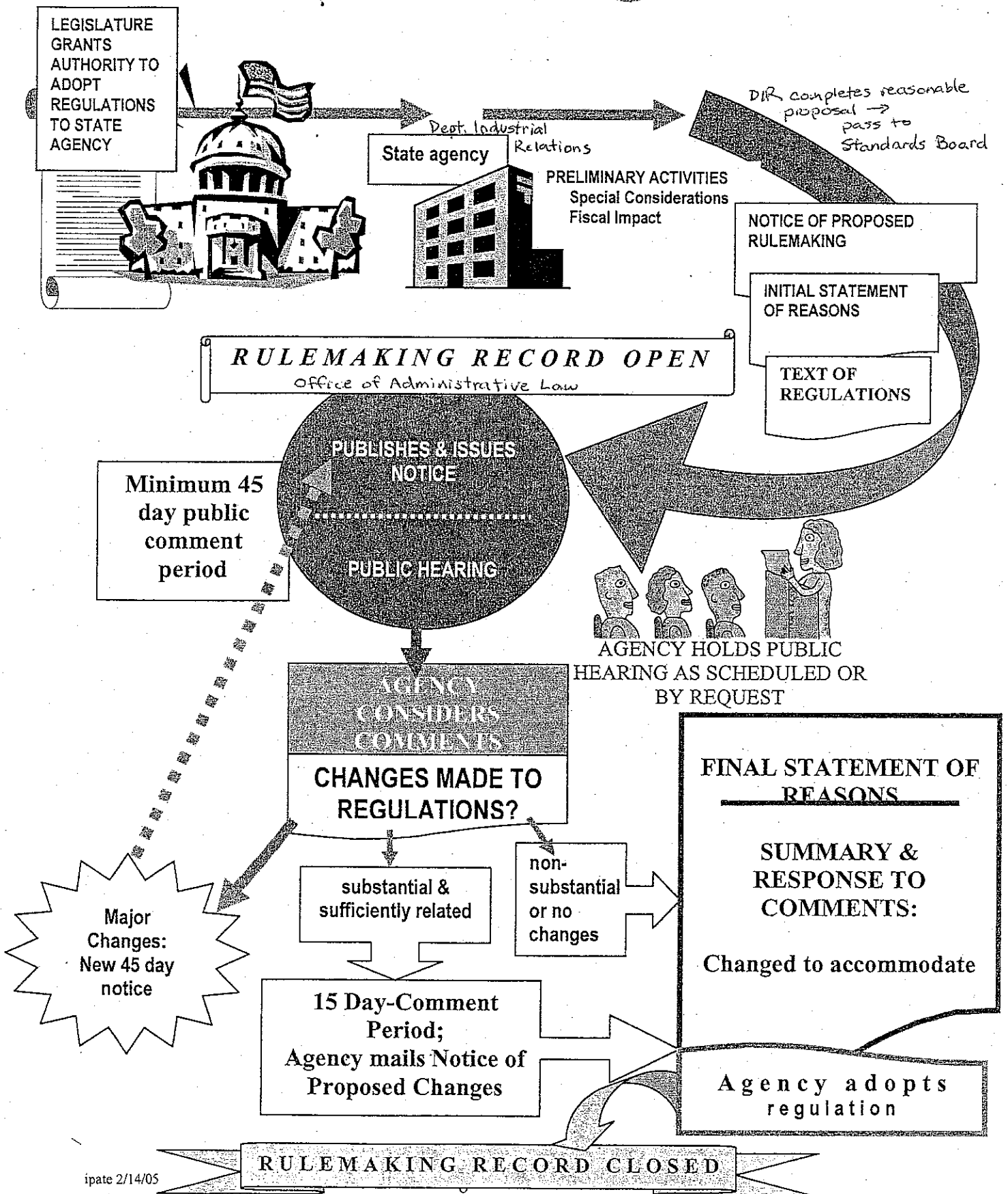


# The Rulemaking Process



## Current Status:

The "reasonable proposal" is being drafted by DIR staff in a process co-chaired by Deborah Gold and Bob Nakamura (Senior Industrial Hygienists). An initial meeting with an Advisory group was held in Oakland on July 24, 2004. Based on discussion, a draft for the Airborne Infectious Disease Standard was developed for the second meeting of the Advisory Group on 11-5-04. Three other sub-groups have been formed to ensure more complete input: Laboratories (met January 14, 2005 in Oakland), Corrections, jails, and law enforcement (met January 18, 2005 in Oakland), and Non-traditional settings; homeless shelters, EMS, home health, etc. (met on March 16, 2005 in Oakland). Based on comments gathered in these sessions, a new draft will be developed and circulated. Each group will be re-convened over the following months for further review. Meetings may be convened in southern California if timing, interest, and resources permit. Membership of any other groups is voluntary and welcomed. A final draft Standard is expected by late 2005 or early 2006.

## Key Issues from the Non-traditional settings Sub-committee (March 16, 2005; 9am -3pm)

- \* 1. **Scope** – Who should this standard apply to and how to decide? HCWs in facilities, in home health, in clinics, labs. Correctional workers. Shelter workers. Refugee workers. Social service workers. Anyone in the home of high-risk clients? Only health and social services? How is a line drawn?
2. **Education** – EMS and shelter groups did not know TB basics; reporting, how to get training, what a TB program does, how to write an Exposure Control Plan. Key groups that perhaps should be included in our State/local education and training plans?
3. **Communication** – How to develop systems to identify EMS responders, shelter staff, home health workers who have had significant exposure to a reported case. Was a major concern for these groups. Vice versa...how do they know to report suspects to TB programs? Do we have 24/7 assistance/information for these types of groups in our communities?
4. **Focus on "pre-planning"** – High-risk agencies need to work with local health departments more closely to know what to do and how to do it.
5. **HIPAA** – There was a great deal of confusion. Most felt that HIPAA precluded telling responders about any medical conditions, even that the facility suspected TB. For example, shelters did not know that they could tell a responding EMT that they thought (or knew) a resident had TB.
- \* 6. **What other airborne diseases should be covered in the Standard**, and how might requirements be different? Current list of 6 diseases that CalOSHA is considering for the Standard comes from the CDC: TB, SARS, monkey pox, smallpox, measles, varicella.

## Cal/OSHA Airborne Infectious Disease Advisory Meeting

September 28, 2005

Los Angeles, CA

### Purpose

Discussion of September 28, 2005 revised draft of Airborne Infectious Disease Standard to prepare a document for the Standards Board. This is the start of the Rule-Making process. The meeting was led by CalOSHA staff (industrial hygienists) and included a range of participants including infection control practitioners, law enforcement, emergency services, laboratorians, and public health representatives.

### More information/copies of the most recent standard/minutes of meetings

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### Key discussion items

1. Scope – Who should be covered by the standard? Input is especially sought for defining what type of community-based workers should be included. Current language: “In home health care services and in other community-based services in which there is an elevated potential for occupational exposure to Significant Respiratory Infectious Disease (SRID)”
2. SRID – Which respiratory agents should be included? Currently proposed to cover TB, measles, varicella, smallpox, monkeypox, SARS, anthrax spores.
3. There was agreement to ensure language for LTBI testing permits use of new techniques (Interferon gamma release assays, etc)
4. Fit-testing for respirators – How best to balance federal requirements for annual fit-testing with cost and practicality. New language introduces concept that core staff can be required to have annual fit-testing and “surge” staff can be fit-tested as needed. New language implies powered air purifying respirators are preferable to N95s (Some evidence they are more effective at reducing risk? They don’t require fit-testing. Johns Hopkin’s study shows PAPRs may be more cost-effective?) There was much discussion and participants did not support PAPR use.
5. Communication between providers about exposure incidents should be enhanced. This was discussed at previous meetings and identified as a key concern. Discussion included issues such as HIPAA (does not preclude communication but is misunderstood); How are ambulance providers notified if TB is diagnosed in a transported patient?; How are home health agencies notified if TB is diagnosed in one of their clients; Who is responsible for such notifications?; etc.
6. What is the definition of an “exposure incident?” Who decides what significant exposure is? An exposure incident triggers employer responsibility for follow-up, thus it is an important concept. (I suggested that the health department should be included in defining “exposure incidents” and follow-up recommendations. Other counties wondered if that would place too much demand on local health departments. There was general agreement that involvement was desirable for TB, but might be different for other types of respiratory agents?)
7. Technical issues – How and how often should negative pressure rooms be tested? Daily? Can an alarm system reliably notify of malfunction?
8. Can employees be compelled to have post-exposure evaluation? Pre-exposure vaccination? If not, what is an employer’s liability for subsequent disease? How can an employer ensure employees wear respirators?

## CalOSHA Airborne Infectious Disease Standard Advisory group

### History:

In a 1994 rulemaking process, CalOSHA developed a TB Standard. Coincidentally, OSHA started their own rule-making process, which resulted in CalOSHA waiting for federal OSHA to develop the national standard. Thus, the 1994 CalOSHA Standard became an "interim" Standard awaiting final OSHA direction. In 2003, OSHA suspended their rule-making process for a separate overall TB infection control standard, but decided to put TB "respirator" issues under an existing General Respiratory Standard. The federal General Respiratory Standard changed requirements for the use of respirators for TB in two ways 1. Requires an initial medical exam for persons who must wear respirators, 2. Requires annual fit-testing and training for all persons who must wear respirators (in addition to the initial testing and training). CalOSHA had to adopt these requirements for TB respiratory protection, since they need to be at least as stringent as federal OSHA.

The health care industry in CA vigorously opposed these added requirements and asked CalOSHA to mitigate this OSHA rule. Thus, California re-initiated their rule-making process in mid-2004. In addition, CalOSHA was asked to broaden the TB Standard to include other respiratory agents. Thus, the Standard under consideration is entitled "Airborne Infectious Disease".

### Other developments:

The 2005 CDC Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings was released for public comment in December 2004 and comments were received until February 4, 2005. These will update the 1994 Guidelines.

In December 2004 OSHA announced Congressional action (part of the omnibus spending bill) that restricted OSHA's enforcement of the respiratory standard as it applied to TB through September 30, 2005. The restriction provided that no federal funds or State matching funds could be used to administer or enforce annual fit testing. CalOSHA notified Technical staff in January 2005. All activities related to this part of the Standard must be funded with 100% State funds.

### Rulemaking Process:

CalOSHA (Department of Industrial Relations, DIR) staff writes a "reasonable proposal" for the Standard under consideration. This moves to the CalOSHA Standards Board. Once approved, it moves to the Office of Administrative Law. Once approved, the proposed Standard is published and open to a minimum 45-day public comment period (public hearings). If there are no substantive comments, the Standard is adopted. Minor changes require another 15-day comment period. Major changes require another 45-day comment period.