DRAFT MEETING SUMMARY

12th Meeting of the Health Expert Advisory Committee (HEAC) for Permissible Exposure Limits for Airborne Contaminants in the Workplace California Code of Regulations, Title 8, Section 5155

June 23, 2010 Elihu Harris State Building 1515 Clay Street Oakland, California

HEAC Members

Michael Cooper, Exponent Corp. Will Forest, Santa Cruz County Public Health Services Agency Linda Morse (retired from Kaiser Permanente Occupational Medicine) Patrick Owens, Shell Oil Refinery, Martinez, CA James Unmack, Unmack Everett Environmental

Assisting Agency Staff

Dennis Shusterman, HESIS Kashyap Thakore, HESIS

Public and Interested Parties

Chuck Barton, Georgia-Pacific for American Forest and Paper Association Eric Brown, Southern California Edison Steve Derman, MediShare Marilyn Foster, American Association of Occupational Health Nurses Diana Graham, Keller & Heckman Law Firm Wendy Holt, Contract Services Administration Trust Fund / Alliance of Motion Picture and Television Producers Ron Hutton, Pacific Health and Safety Jim Kegebein, Kegebein Associates Dan Leacox, Greenberg Traurig Law Firm Paul Niemer, Sierra Pacific Industries Robert Preston, Lumber and Mill Employers Association Olivera Radovanovic, Unmack Everett Environmental Michael Smith, WorkSafe

DOSH

Bob Barish (meeting chair) Steve Smith (co-chair) Bob Nakamura Mike Horowitz

Preliminaries and Opening Remarks

Bob Barish welcomed attendees, reviewed the agenda items and tentative schedule for the meeting including planning items for future meetings and revision of the Priority List of Substances for PEL work. He noted that the agenda had listed a possible preliminary presentation on phthalates by HEAC member Howard Spielman but that this would be postponed because of his absence due to other commitments.

Following self-introductions Bob Barish asked if there were any comments on the minutes for the last HEAC meeting March 24, 2010. There were none.

Updated draft priority list for PEL work

The discussion of this topic was chaired by Steve Smith. He said the updated list passed out as a handout in the meeting reflects changes discussed since the last meeting on March 24 at which a preliminary draft of items to be added to Priority 1 was distributed, reflecting primarily new and revised ACGIH TLVs 2008 through 2010, as well as adjustments in the priority of a number of substances already in the list (Note: This handout can be found as attachment in the minutes of the March 24, 2010 HEAC meeting at the PEL Project website)

A copy of the updated draft priority list passed out at the June 23 meeting can be viewed by clicking on the icon immediately below (the icon may take several seconds to appear):



On this draft list pesticides with new or revised ACGIH TLVs are noted in bold red text. The California Department of Pesticide Regulation (DPR) is being consulted with respect to their view of the priority of the pesticides listed for possible PEL revision based on usage levels and cases of pesticide illness reported. More information on this will be available for a future meeting. Bob Barish noted that a number of the pesticides with ACGIH TLVs new or revised since 2000 are no longer registered for use in California and so appear in Priority 4 on the list.

Ron Hutton asked why acetonitrile was moved up to Priority 1 from Priority 3. Bob Barish responded that it appears that it is a widely used laboratory solvent and may be used in other solvent applications.

Ron Hutton suggested that with respect to substances that have passed through the HEAC and FAC processes at the top of the list (Priority "0" substances), it should be clarified what the HEAC and FAC recommendations were. Steve Smith expressed agreement with the suggestion (Note: The revised Priority list posted at the PEL Project website in July 2010 reflects this suggestion)

New substances for HEAC work

HEAC members present volunteered to take on the following substances from the draft Priority List with new or revised ACGIH TLVs:

Jim Unmack: aluminum, n-propyl alcohol Will Forest: 2-butoxyethyl acetate and acetonitrile Linda Morse: polyvinyl chloride particulate, Portland cement Patrick Owens: cyclohexane

(Note: HEAC members not in attendance have also volunteered for additional substances. A complete list of the substances currently being evaluated by HEAC members for new or revised PELs can be found on the current Substance Status List posted at the PEL Project website.)

Wood Dust

Linda Morse is the HEAC member evaluating wood dust and western red cedar. She said the main revisions to her draft assessment document from that discussed at the last HEAC meeting March 24 involve industrial hygiene issues, and may more appropriately be addressed by the Feasibility Advisory Committee (FAC). She said she looked at reports of levels of worker exposure to wood dust in the U.S. and Europe suggesting that they are generally near 1 mg/M³ measured as "total particulate." She said she had looked at the information on the Tulane study (see below) presented by Professor Roy Rando at the March 24, 2010 HEAC meeting.

Bob Barish introduced Chuck Barton representing the American Forest and Paper Association (AFPA). He noted that Chuck Barton had copies of the AFPA's latest letter to HEAC dated June 8, 2010, as well as several printed PowerPoint slides summarizing the letter and his comments. Chuck Barton summarized the four central points of this letter as follows:

1. That a PEL for wood dust expressed and measured as "inhalable" particulate is more stringent by a factor of between 2 and 3 than is a PEL based on "total" particulate, meaning that a PEL of 1 mg/M^3 inhalable particulate would be at least a 10-fold reduction from the current PEL of 5 mg/M^3 expressed as "total" particulate. Chuck Barton also noted that the AFPA letter points out the lack of availability of data to conduct a quantitative risk assessment for cancer from wood dust.

2. That with regard to health effects found and the significance of the loss of subject employees to medical follow-up in the study, the HEAC health assessment draft document for wood dust misinterprets the Tulane University study of wood dust exposures and disease sponsored by the Inter-Industry Wood Dust Coordinating Committee (*Glindmeyer et al., Am. J. Ind. Med, 51:595–609 (2008)*). He said that the Tulane study is probably the most comprehensive evaluation of the health effects of wood dust done to date and that it found no significant health effect correlated with exposure to "wood solids" (i.e. the nonvolatile constituents of wood).

3. Methodological issues with sampling for the "inhalable" fraction of airborne particulate with respect to Wood dust. He noted that the NIOSH Recommended Exposure Level (REL) for wood dust is 1 mg/M³ measured as "total" particulate, not "inhalable"

4. That the statement in the HEAC draft document that current industry exposure levels are at or near the TLV of 1 mg/M^3 inhalable particulate is not consistent with the data reported in the Tulane study where 65% of employee exposures measured were found to be above 1 mg/M^3 inhalable, and 37% above 2 mg/M^3 inhalable.

Linda Morse noted that the sinonasal cancer that has been attributed to wood dust in some human studies is a very rare cancer.

Brief discussion of the role of HEAC health assessment documents

There was a short discussion of the purpose, function, and context of the HEAC health assessment documents such as that done for wood dust by Linda Morse. Bob Barish said the current documents represent a formalization of the "summary documents" that were developed and discussed by committee members in previous years' rounds of PEL advisory committee work. Mike Cooper noted that in the last round of PEL work (2001 through 2004) in which he had been a committee member the primary purpose of those documents was to summarize very succinctly the reviewing member's recommended health-based PEL, although sometimes like the HEAC documents they did include extensive and detailed references and discussion of those. But he also said he thought the documents were intended to serve as the primary basis for the rulemaking documents. Bob Barish said that in his experience the minutes, along with the summary documents, had been the most important to informing the formal rulemaking process of the committee's deliberations and recommendations. Mike Cooper and Will Forest suggested that the goal of the health assessment documents is, or should be, to serve as documentation for the Standards Board to be able to rely on in their consideration of proposed PELs.

Bob Barish said that with the current more formalized process there are greater expectations of the detail that will be included in the health assessment documents and their posting on the project website before the meeting. He said it had been thought at the beginning of the process that they might be able to serve almost as templates for formal rulemaking documents like the Initial Statement of Reasons (ISOR). But since the health assessment documents are actually used in the HEAC primarily for the purpose of informing the meeting discussion, they don't always reflect the committee's final recommendation or all of the detailed discussion that led to it. He said it is the minutes that document the meeting discussion and recommendations. Bob Barish said it is the health assessment documents developed by HEAC members, combined with the HEAC meeting minutes where recommendations when made are always reflected, that serve as the fullest record of discussion and deliberation by the HEAC. Steve Smith added that writing the ISOR for formal

rulemaking requires Division staff to review the key articles in the HEAC assessment document, and sometimes others, and explain in a more focused way the rationale for the PEL being proposed.

Return to discussion of wood dust

Will Forest said that generally in the past when there has been discussion of whether a PEL should be based on "inhalable" or "total" particulate, it had not been decided how to meaningfully translate exposure measurement results based on "total" particulate sampling into exposures as "inhalable." Will Forest said he didn't agree with trying to extrapolate from one kind of sampling to another as ACGIH did for wood dust.

Bob Barish said that the majority of research shows that for a wide range of substances and operations the "inhalable" particulate samplers generally collect 2 to 3 times as much particulate mass as the "total" particulate samplers. Ron Hutton noted that it is the nature of the operation and the size distribution of particulate being generated that determines the ratio of "inhalable" to "total" in particular situations and so he agreed with Will Forest that it's difficult to meaningfully extrapolate from one to the other in developing a PEL.

Jim Unmack noted that in the TLV document for wood dust ACGIH reviewed a number of studies of wood-working and milling operations and found ratios of "inhalable" to "total" particulate in side-by-side air sampling to range from 1.2 to 4.2. He noted that the TLV document for wood dust said that a ratio of 2.5 had been used to interpret studies with exposure measurements based on "total" particulate sampling.

Linda Morse said that in most of the studies of health effects of wood dust, including most of those cited in the TLV Documentation for wood dust, worker exposure was measured using "total" particulate samplers.

Bob Barish said that at the last HEAC meeting it had been pointed out that one of the graphs presented by Professor Rando from Tulane had suggested that a "respirable" particulate standard of 0.2 mg/M³ might be highly feasible as a PEL. Bob Barish noted also that Professor Rando had said that the only statistically significant finding of health effects in the Tulane study was for the respirable fraction of "residual particulate matter," not wood solids. He said it had also been suggested that a PEL based on "respirable" particulate would, in theory, be the most appropriate to prevent the effects on pulmonary function on which the TLV is based.

Linda Morse disagreed with the suggestion that respirable particulate was necessarily the most appropriate standard for prevention of decreased pulmonary function, and she also noted that other effects the TLV was intended to address at least qualitatively were in the head and upper respiratory system as would be addressed especially by the inhalable fraction and to a lesser degree by the "total" particulate fraction. Mike Cooper said it did not appear there were very many studies assessing the health effects of the respirable fraction of wood dust. Will Forest said the PEL should be expressed in terms of the particulate fraction measured in the bulk of the health effects studies which is "total" particulate.

Ron Hutton said that in the consideration of wood dust by the HEAC there had been no suggestions made for an exposure standard based on respirable particulate. He said that the particle size-selective devices required to collect respirable and inhalable particulate, the industrial hygiene air sampling can be more difficult to conduct.

Bob Barish said that the discussion among HEAC members appeared to be moving toward a health-based PEL recommendation for wood dust based on measurement of "total" particulate. Will Forest suggested setting the recommended PEL based on the NOAEL with use of a safety factor.

Linda Morse said her review of the health effects studies suggested a LOAEL of about 5 mg/M^3 total particulate. Bob Barish said that several of the studies cited in the TLV document had suggested 2 mg/M^3 as a possible NOAEL. Chuck Barton said that based on its experience with sampling and monitoring of employee health Georgia-Pacific's experience suggested a NOAEL of 5 mg/M^3 which is the current Cal/OSHA PEL. He said this was consistent with the findings for wood solids in the Tulane study.

Linda Morse said that workers are never exposed just to wood solids but to the entire mixture of solids and the residual matter measured separately in the Tulane study. She said that in light of this fact it did not seem appropriate to base the PEL on the NOAEL based on the effects, or lack thereof, for wood solids alone. Will Forest agreed, saying that the PEL should cover wood dust as workers are actually exposed to it in the workplace.

Will Forest said that a LOAEL of 5 mg/M³ based on human exposure studies suggested by Linda Morse would normally translate into a PEL recommendation of 0.5 mg/M³ [NOTE: On reviewing the draft minutes, Will Forest said he had intended to say that a LOAEL of 5 mg/M³ would normally translate into a NOAEL of 0.5 mg/M³ (based on a default LOAEL-to-NOAEL uncertainty factor of 10), which would require a PEL recommendation lower than 0.5 mg/M³ to account for intraspecies variation.] But he said he did not oppose sending a PEL recommendation of 1 mg/M³ total particulate to the FAC recognizing that the variable nature of wood dust makes it difficult to clearly establish the pulmonary NOAEL. [NOTE: On reviewing the draft minutes, Will Forest also noted that because sinonasal cancer is a rare cancer, the additional risk attributable to exposure to wood dust at 1 mg/M³ is likely to be less than 1 in 1,000.]

Mike Cooper agreed that a PEL of 1 mg/M^3 total particulate based on non-allergic pulmonary effects would be a reasonable value for the HEAC to refer on to the FAC for review of feasibility and cost. There was general agreement to this among the other HEAC members present and that was the HEAC recommendation, 1 mg/M^3 total particulate measured gravimetrically.

Mike Cooper suggested, and there was general agreement, that the minutes of the discussion should reflect that the PEL recommendation is for wood "as used in commerce" or "as commercially available" to make clear it was not just for "wood solids" as had been separated out in the Tulane study.

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Benzyl chloride

Bob Barish said there had been no major changes to the draft document prepared by HEAC member Susan Ripple who was not able to attend this meeting due to a last minute commitment. He said that in consultation with Susan he had made some changes to highlight and clarify the units in the risk assessment calculation in the document and added reference to the OEHHA 2007 report on PELs with which it was consistent in its calculations of the cancer risk for benzyl chloride.

Mike Cooper noted a couple of typographical errors in the boxed conclusion and PEL recommendation summary in the document. Bob Barish said those would be corrected and the document reposted at the PELs Project website. Mike Cooper noted that the document format used by Susan Ripple for benzyl chloride was that used by the AIHA WEEL committee.

1,1,2,2-Tetrabromoethane

Bob Barish noted that, as detailed in the minutes for the March 24 HEAC meeting discussion, the outstanding issue on this substance was the uncertainty factors to be applied to the NOAEL identified in HEAC member Jim Unmack's assessment. However, before that discussion commenced, Mike Cooper asked Jim Unmack about his reference to NTP having found this substance to be "tumorigenic." Jim Unmack said he would look into this again and revise the document as needed.

Regarding the uncertainty factors he applied to reach a recommended PEL Will Forest asked Jim Unmack the basis for using an intraspecies uncertainty factor of 3. He said he understood the use of an interspecies uncertainty factor of 3 rather than the usual default factor of 10 because similar findings were observed in 5 different test animal species, but he didn't see a basis for a similar adjustment to the default factor for intraspecies uncertainty, i.e. variability in response between individual humans.

Jim Unmack said he thought that the similarity of findings with independent tests of 5 test animal species supported reduction in the value of the intraspecies uncertainty factor from the default of 10. But Will Forest noted that laboratory animals are deliberately bred for a minimum of inter-individual variation. Bob Barish asked Will Forest what could be examples of an acceptable basis for using an intraspecies uncertainty factor of less than 10. Will Forest responded that studies of health effects responses in humans could influence the intraspecies uncertainty factor chosen if there was confidence, for example, that there was not significant variation in metabolism of the substance. Will Forest said the scientific basis for the default value of 10 for intraspecies uncertainty is that a 10-fold variation in sensitivity between human individuals has been observed and is not uncommon.

Will Forest added further that the NOAEL value from the Hollingsworth study used in the draft health assessment document to reach the recommendation lasted only 100 days and so was really only subchronic, which would then necessitate application of an additional uncertainty factor. He said also that although the potential of this substance to cause cancer had not been fully established, the positive Ames test and structural similarity to other known carcinogens such as ethylene dibromide suggested it might be one as well and so he advocated erring on the side of caution in the PEL to be recommended by the HEAC.

Jim Unmack said that in light of the discussion, and his own concern with the toxicity of the chemical, he did not object to the recommendation of 0.03 ppm and would change the document to reflect this.

Patrick Owens noted that based on what is indicated in the document now there may be difficulty with measuring worker exposure down to this level. Jim Unmack said, as he'd indicated in his document, that use of an electron capture detector in the analytical method could bring the detection limit down well below 0.03 ppm. He said he would address the lab issue in his document revised for the discussion.

Patrick Owens noted that the substance is of low volatility and that the TLV is designated IFV ("inhalable fraction and vapor") and so the PEL should be expressed in terms of mg/M³. Jim Unmack said he thought that both inhalable fraction and vapor could be captured by placing an appropriate vapor sampling tube in line with an inhalable particulate sampler. Patrick Owens suggested skepticism about such an approach and also suggested the particulate fraction for the PEL be changed to "total" from "inhalable." Steve Smith noted that the PEL for glyoxal adopted in 2009 was based on "inhalable fraction and vapor." Steve Smith said DOSH would look into whether the NIOSH or other methods could be adapted for this and have it discussed when the substance is brought to a FAC meeting.

<u>Arsine gas</u>

Patrick Owens reported on revisions he had made to the document for arsine gas based on discussion at the last meeting, additional research he had done, as well as clarifying the central points of his assessment and the basis for his recommendation of a PEL of 0.005 ppm 8-hour TWA. He said he had looked at the EPA reference concentration for arsenic and had gotten help from HESIS and from Craig Steinmaus, an expert on arsenic risk in drinking water.

He said the central basis for his PEL recommendation being at the TLV of 0.005 were the findings of Landrigan referred to in the TLV documentation. He said the Landrigan study findings in an occupational setting of urinary arsenic levels associated with airborne levels of about 0.005 ppm as he recommended for the PEL, was associated with urinary arsenic levels of 50 ug/L which is a level ACGIH in its documentation states is below those found to be associated with chronic organ system changes due to absorption of arsenic. He noted that a cancer risk assessment for arsine based on arsenic absorption done by Craig Steinmaus suggested there could be a small increased risk of cancer at the TLV but that this did not account for the potentially short residence time of arsenic in the lung from arsine which might reduce the cancer risk, as was discussed at the March 24, 2010 HEAC meeting.

Dennis Shusterman said the assessment he had requested by Craig Steinmaus indicated a 16% excess cancer risk of 1.16 for lung cancer at a PEL of 0.005 ppm which then raises the question of not exceeding the goal of limiting the maximum excess risk from exposure to one excess cancer per 1000 exposed workers. He said that data from the NCI SEER Program (Surveillance, Epidemiology, and End Results, National Cancer Institute) indicated a baseline population rate for lung cancer of 0.5 cases/1000/year. He said there would be four excess cases if all arsine at 0.005 ppm was

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absorbed and processed as inorganic arsenic, but that the increased risk from arsine exposure among smokers cannot be distinguished from the background rate. Will Forest noted that the SEER data is for non-smokers while the background rate is 6% for smokers a greater than 10-fold risk differential from the lung cancer risk for non-smokers.

Will Forest said the high water solubility of arsine suggests that arsine converts readily to inorganic arsenic.

Steve Smith said he agreed with the approach that Patrick Owens had taken with his assessment and said that it's hard to disagree with the PEL he is recommending if it is based on prevention of urinary arsenic levels above those at which any health effects have been detected and that is at or near the population background level. He noted also with respect to coverage by the Cal/OSHA standard for inorganic arsenic (8 CCR 5214) that it contains a note specifically excluding its application to arsine.

Will Forest said arsine is very toxic and found as a gas He said this high toxicity means in all likelihood there will never be epidemiologic data available on its carcinogenicity, nor with chronic animal studies as the animals would be unlikely to survive long enough for development of cancer. In light of this Mike Cooper said he thought it would not be appropriate to set the PEL based on the possible carcinogenic effect of the arsenic. Will Forest responded that he thought arsine should probably be regulated as a carcinogen, but that there is no good evidence for it at the present time. He suggested it couldn't be regulated as a carcinogen unless there was information that it is metabolized the same as inorganic arsenic

Bob Barish asked if at this point there was general agreement on the PEL recommended by Patrick Owens of 0.005 ppm. Mike Cooper noted that the current value is .05 ppm and that many or most arsine gas monitoring detectors have been set to this level or may even be mandated to be set at that level by local toxic gas ordinances. Steve Smith said that could be looked into and taken up as an item by the FAC if necessary. Mike Cooper said part of the issue may be whether there are sensors available to detect down to 0.005 ppm.

It was suggested there appeared to be some consensus for a health-based recommendation 0.005 ppm ppm 8-hour TWA. Mike Cooper agreed but wanted the minutes to indicate that this PEL was based on non-cancer effects. Will Forest wanted to note that this PEL might not protect against cancer if arsine is as carcinogenic as arsenic, but others said the recommendation should be left at not being based on cancer. Patrick Owens said he would not be comfortable if the recommendation implies the proposed PEL is protective against cancer.

Patrick Owens said he would revise the assessment document for arsine to reflect the day's discussion.

Mike Cooper said he could help establish contact with local CUPA officials, and additional semiconductor industry groups in order to assess if they had concerns about the possible effect on toxic gas monitoring and other matters from a lowering of the PEL.

Gallium arsenide

Patrick Owens said the PEL he recommends, same as the TLV, is 0.0003 mg/M3 respirable particulate; He said it is based on the most sensitive health endpoint non-neoplastic pulmonary effects observed in rats in an NTP (2000) study. He noted this level should also protect against the carcinogenic effects of the arsenic seen at higher levels of exposure in the NTP study. or at least provide greater protection than the standard for arsenic at 8 CCR 5214 since the PEL would be substantially lower.

There was discussion of whether the pulmonary effects seen in rats in the NTP study was due to the arsenic or the gallium arsenide compound and whether there should be a separate PEL for gallium arsenide given the coverage currently provided by PEL and comprehensive standard for arsenic at 8 CCR 5214. Mike Cooper noted the potential problem in solar cell manufacturing, for example, if the PEL for gallium arsenide is lower than that for arsenic, but the air sampling method for gallium arsenide is based on analysis of arsenic. An employer could not distinguish between what might be arsenic from gallium arsenide and what might be from other sources if there are any.

Ron Hutton asked if lung hyperplasia was consistent with arsenic. Linda Morse said it can be a way point to lung cancer. Will Forest and Ron Hutton asked if there were any studies, such as by the TLV committee which assessed the differences in health effects between gallium arsenide and inorganic arsenic.

Bob Barish asked if there should be more work on the document to discuss this. Will Forest said he would be reassured if there was no other cancer assessment by EPA, OEHHA, or other government agency. Jim Unmack said the TLV committee wrote in the documentation that gallium arsenide dissociates in the body and the gallium component seems to be more active on the heme enzymes than the arsenic.

Patrick Owens said he couldn't answer the questions being raised in the meeting from the research he has done so far. Will Forest said that this should be reviewed more thoroughly, but he thought it likely there is no knowledge or study that differentiates gallium arsenide from arsenic in general. Patrick Owens noted that the TLV Documentation for gallium arsenide indicates that the assessment of Webb et al. had found that this arsenic compound was of higher toxicity than several others. Will Forest said that may or may not be an appropriate comparison for considering the PEL. He said further that if the risk basis for the PEL is based on arsenic itself, for cancer, then an exposure limit based on respirable particulate would not be appropriate.

There was discussion that if the basis was chosen to be non-neoplastic effects seen in test animals then an uncertainty factor of 3 rather than 10, yielding the TLV value of 0.0003 mg/M3 respirable particulate as the PEL recommendation could be appropriate. 1

Mike Cooper asked why a separate PEL for gallium arsenide was needed when it could be covered by the existing comprehensive standard for arsenic. Patrick Owens said a separate PEL at a lower level specifically for gallium arsenide was warranted based on the non-neoplastic effects seen in rats lungs that was the basis for the TLV.

Hydrogen sulfide

Patrick Owens gave a preliminary presentation on his research to this point on hydrogen sulfide which he had agreed to take on. He said that in human dosage studies there were findings of subclinical nasal effects with exposure at 5 ppm, but that animal data gives a NOAEL of 30 ppm. He noted the PEL TWA is currently at 10 ppm for respiratory effects.

Dennis Shusterman said the geometric mean for odor threshold is 8 ppb, far lower than the TLV and PEL. He said it was his impression that effects on pulmonary function are the focus of current research.

It was announced that, at the request of Patrick Owens' in light of his potential conflict of interest with being employed in petroleum refining where hydrogen sulfide can be present as a health and safety issue, HEAC member Mike Cooper would be taking over the work on this substance.

The meeting concluded at 3:15 p.m.

END



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CHAIRPERSONS Steve Smith / Bob Barish LOCATION Room 1304 1515 Clay Street, Oakland

NEW ATTENDEES: PLEASE BE SURE TO WRITE YOUR NAME, AFFILIATION, AND E-MAIL ADDRESS CLEARLY

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