MINUTES – SPRING 2008 MEETING
U.S. ARMY ABERDEEN PROVING GROUND, MD

Wednesday April 16, 2008

Morning Session

Mike Brisson offered opening remarks.
Donna Doganiero welcomed us to Aberdeen on behalf of CHPMM. She thought we had an excellent agenda and welcomed the dialogue on this as an emerging contaminant.
Housekeeping items were covered: ABIH points sign up roster was available with Dave Weitzman. During roundtables, speakers were requested to repeat the questions so remote listeners could be sure to hear the question.
Mike indicated that secretary John McKinney had resigned from the committee for work and personal reasons, and that secretarial duties would be split into thirds: Steve Jahn to take on recording of proceedings; Dave Weitzman to take on management of the membership roster; and Melecita Archuleta to be webmaster.

Speakers:
Dr. Lisa Maier gave a review talk on the immunology and sensitization mechanisms associated with beryllium disease. Members are referred to her slide presentation.

Questions #1(Mark Hoover, NIOSH):
Is it ionic beryllium or particulate beryllium that leads to sensitization?
Answer: We are not sure. This is the IH (exposure measurement) and medical interface to understanding the disease.

Comment from Mike McCawley: mostly soluble beryllium exposures show no evidence of disease. If something attached to particles that modified the body system, it may serve us as a model.

Question #2 (Paul Wambach, DOE-HQ HSS):
What other autoimmune disease targets are in antibodies blocking in vivo testing?
Answer: It is hypothesized that HDLPD (?) is one, while another is to investigate antibodies for T Cell initiation. The problem is that there would be downstream consequences of systemic response (the cure would be worse than the disease).

Dr. Anoop Agrawal presented his company's work on Fluorescence Analyzer Automation. Members are referred to his slide presentation.

Roundtable #1: Beryllium Oxide Digestion/Extraction and Particle Size
Participants included Tom Oatts (Y-12 Lab), Anoop Agrawal (Berylliant), Mark Hoover (NIOSH), Greg Turk (NIST), Mike Winchester (NIST) and Larissa Welch (Y-12 Lab).

Background: Much of the need of the beryllium affected community within DOE centered on availability of a NIST traceable standard for use by the lab community. What was needed was a Standard Reference Material (SRM) for beryllium oxide (BeO). DOE and NIOSH jointly approached NIST, and NNSA provided funding. A Scope of Work was generated in 2006. Early on it was recognized that BeO posed unique risks with respect to powder handling operations. The SRM was finally created and approved in April 2008.

Greg Turk proposed that others prepare digestions and send solutions of BeO. The material is highly aggregated at 200 nanometers, and is bottled according to NIST Specs. Sample prep kits were provided to Clayton (Bureau Veritas), SRS, Y-12, and NETL. All the labs supported the testing regiment for use of the SRM as a replacement PAT material. Tom Oatts indicated two approaches can be used: the sulfuric acid method currently employed or an alternative with ammonium bifluoride. Mark Hoover commented that material characterization for use in analysis would be prudent. Beryllium or beryllium copper is easily solubilized. Silicates and oxides are much harder. Particle sizing is important to support the relationships with disease. There in one should do sequential digestions.
Question: why was the IRE (need definition) changed from scandium to manganese?
Answer: solution with fluoride caused precipitation. Mike Winchester proposed the change.
Question (Steve Jahn): What enhanced hazard awareness for those personnel doing the actual handling of the beryllium oxide powders was employed by NIST?
Answer: The NIST Certificate of Analysis (COA) was reasonably equivalent to a material safety data sheet. A separate MSDS is under development for release with the sale of the standard.
Comment: Melecita Archuleta proposed that those familiar with the idiosyncrasies around beryllium powder handling help NIST underscore the level of detailed handling procedures needed for a NEW user.
Question (Geoff Braybrooke): Has Nanotechnology group within NIOSH established any SOPs for powder handling that might have application here?
Answer (Mark Hoover): No. It is under consideration, with a proposal to do storage in suspension (solution) to minimize contact.
Comment: Tom Oatts indicated that use of suspension in the submicrogram level essentially means doing serial dilutions. This works very well for beryllium oxide. Larissa Welch indicated that she knows via Beryllium PAT rounds that vendors are interested in a spiking program to minimize handling of BeO powders.
UOX1877 is the SRM under NIST. A new production lot could be used if needed to match production runs.
Question (Paul Wambach): Were soils characterized to confirm SRM as silicates. Anoop Agrawal responded no they did not.
Question (George Fulton): Any experience by the panel around soils generated samples with the sulfuric acid method? Tom Oatts indicated yes at Y-12. They experience poor recoveries at SRM values (80% recovery at submicrogram levels).
Question (Melecita Archuleta): Regarding the second set of SRM screens with ammonium bisulfate; error bands are very tight, is there other additional data? Tom Oatts

indicated yes there is. Oil contaminated standards, other interferences, and several wiping media were also tested. Always got good recoveries. Primarily this was due to the smaller number of steps in the sequence, which excludes additional opportunities for error. Mike Winchester commented that mean values were dead on to certified values.
Question (Mike McCawley): Regarding beryllium oxide as a ceramic, any thought for a ceramic SRM due to unique characteristics of binders? Any thought for a ceramic SRM to drive safe handling practices (in other words make the SRM of a ceramic form)? Larissa replied that those can be placed on a priority list for funding.
Question (Mike Brisson): At its inception, the concept for a BeO SRM was to put it out there and run through all the labs to check all digestion methods. Were all the lab methods validated through SRM development? Do we want to prioritize efforts at other methods with this SRM? Or with other SRMs? Greg Turk responded that users set SRM development priority. Larissa Welch indicated that an AIHA validation study around SRM will get confirmation of all methods validated. A recommendation from the study for accreditation is to address total beryllium versus soluble beryllium. Mike Brisson also indicated that the Analytical Accreditation Board of AIHA is leaning towards Beryllium Oxide as a Proficiency testing target.

Dave Wietzman asked if it is a reasonable outline of strategy approaching particle sizing for an SRM as 50 micron. Mark Hoover indicated that work with Brush Wellman, using NIOSH facilities for such work would be prudent. He stated that the practical question for laboratories will be application of an appropriate sample analysis protocol. A follow up question was asked: Will the labs be expected to develop a material specific protocol? Will they do it? Mark Hoover responded that the labs might have to only harvest a few large particles sizes, turning such analysis into one that is cost prohibitive. 20 grams of size selective sources going to a round robin might work, but it would deviate from the NIST protocol.

Anoop Agrawal offered that priority for further activities should be towards spiked filters because of their inherent safety performance against powder handling. Comment made that a 100 micron particle has a mass of 0.7 micrograms! Others offered that more toxic materials may be particle size dependant (smaller particle size to deeper lung penetration for an example), and that this runs counter to analysis of total mass.

Tom Oatts commented that the digestion protocol is best supported as moving BeO from a natural material form (powder in this case) to solution. Kevin Ashley stated regarding wipes and large particles, the easiest way to investigate and compare a method of evaluation is versus the reference method. ASTM and NIOSH should not worry about larger particles.

AFTERNOON

Mike McCawley reviewed the Research Needs Subcommittee listing for priority of review. Please refer to Mike's presentation attached. He was pleased to report that several actually had been worked, but there was still significant needs. He proposed that all participants would consider drafting a paragraph describing the importance of remaining or new items for the benefit of others reviewing the listing, and supporting a

rank ordering process to be established by the subcommittee. Mike then opened the floor for questions.

Question (Mark Hoover): Does the Subcommittee seek priority on the master list as well as new thoughts or items that others feel should be added? And what expectation is set on how to close an item out from the Research Needs listing? Mike indicated any and all items would be considered for the continuing use of the listing. Closure should be by way of a position paper or some peer reviewed journal articles.

Question (Mike Brisson): Past practice was subcommittee breakouts twice a year. Now conference calls are happening once a month. This offers cross pollination to other subcommittees. Maybe one rep from each other committee should sit on research needs subcommittee? Don Harvey responded that he felt it was part of subcommittee chairpersons responsibility to submit such needs to the committee.

Question (Dr. Lisa Maier): Could other groups not so intimately involved in BSHC dealings get copies of the research needs listing for input? Mike McCawley says absolutely. Dr. Maier and her peers will be using in the space of the med/epi committee.

Mike Brisson introduced Dr. Rominder Suri. He is with the Emerging Compounds of Concern Initiative, a cooperative arrangement between Villanova and The New Jersey Institute of Technology. Their focus area for targeting research needs are the DOD, DOE, NASA and industry. Executive Order 13423 established University Collaborative Research Centers. Economic interests and national laboratories can participate. His organization is seeking seed funding; DOD has signed up with an initial commitment of $35,000. He presented a slide presentation on the targeted research capabilities at NJIT.

Question #1: Any DOE contacts yet for sponsoring dollars? No.
Question #2: Any other work with other National Science Foundation (NSF) Members such as the University of Massachusetts? He is aware of their capabilities and would explore such collaborative efforts as made sense. Nothing currently on line.
Question #3: Don Harvey asked what aspect of the University is supporting mission that could aid the beryllium research causes? What resources could they focus on the problem: medical? Engineering? Other? Response indicated that NJIT would focus on engineering and science applications.

BHSC Discussions

Mike discussed committee operations. He is hopeful that an operational BHSC website will be up and running shortly. Symposium planning is going well and possibly funds will be left over. BHSC is looking for EFCOG assistance.

Two new ASTM Standards are in the works directly from BHSC efforts: ICP Mass Spec measurements (D-7439); and separation of beryllium by column extraction (D-7441).

Committee Breakout Sessions

Please refer to the subcommittee minutes reproduced in this report.

Thursday April 17th, 2008

Discussion of the NIOSH Alert

Steve Jahn on behalf of the CBD Prevention Committee spoke on considerations for improvements to the NIOSH Alert. He was joined by one of the authors, Christine R. Schuler for the discussion.

Prior to the BHSC meeting, a small group of interested parties collected on a telephone conference call and discussed the intentions and issues surrounding a draft of the NIOSH Alert. See **Attachment 1** for a copy of those notes. Ms. Schuler was very clear that all comments need to be submitted through the formal mechanism on the NIOSH website for disposition. See **Attachment 2** for Ms. Schuler's slides.

Following her presentation, comments and questions were offered by the participants.

Question #1(Paul Wambach): The alert makes it clear that liquid solutions offer risk of disease. Why?
Reply (Ms. Schuler): A skin sensitization mechanism is very plausible with such materials.
Comment (Mark Hoover): Concerns have been raised about aerosolization from dissolved materials in cutting oils.
Comment (Paul Wambach): The bubble was burst in AIHA 2007 publication that dealt with pickling tanks. [Directed to Marc Kolanz of Brush Wellman] Is the beryllium cited there oxide materials or was it in solution? Mark Kolanz replied that it was from beryllium in solution used in the process of electromarking.

Question #2 (Dave Weitzman): Does NIOSH intend to suggest sensitization from solutions through aerosolization?
Reply (Ms. Schuler): the main intent was to address dermal exposure paths.
Comment (Mark Hoover): consider placing the solutions risk statement in multiple locations in the Alert.
Comment (Dave Wietzman): beryllium oxide's slight solubility may contribute to longer retention in lung tissue versus shorter residence time for soluble forms of beryllium.
Comment (Mike McCawley): Soluble materials in the aluminum industry and any correlation with sensitization is still an open question. CBD from solutions would be a continuing exposure if one thinks through the logic of exposure from the perspective of an industrial hygienist watching an operator at a pickling tank.
Comment (Tom Oatts): From a laboratory perspective, there is clear demarcation of treatment of articles (traditional OSHA HazCom use of term) versus treatment of a submitted sample. Their lab is routinely handling (safely) 100 microgram to 100 milligram samples within solutions. This Alert blurs metals analysis under beryllium

controls with lab standard compliant (OSHA 29 CFR 1910.1450) performance in handling solutions. Steve Jahn echoed this sentiment regarding beryllium rule compliance versus R&D lab work under the lab standard (note that some sites include a lab activity in their CBDPP Implementation Plans while others use the scope definition of the rule to insulate themselves from including it).
Comment (Mark Hoover): The IG Review of nanoparticles did not find that special controls were needed, but instead nanoparticles in R&D were part of a broader "chemical suite" to be managed. Mark does not consider the alert to force others (Steve Jahn/Tom Oatts) into different management strategy that Steve/Tom had explained.
Comment (Christine Schuler): the alert is for a much broader industrial segment than the relatively highly informed population of DOD and DOE labs.
Question #3: Could NIOSH explain the difference between an Alert and a Criteria Document? If a new recommended exposure limit is proposed, then a criteria document is issued. An Alert is an invitation to the community to assist in gathering of data against standard practices.

Question #4 (Dr. Maier): she applauded the Alert initative by NIOSH authors, and agrees that disease is marked by inhalable beryllium that may only yield sensitization. Ms. Schuler requested that Dr. Maier please propose specific improvements to the alert, with particular intent to emphasize exposure avenues to both sensitization and disease.

Comment (Bob Immele, PNNL): From a diseased worker perspective, the Alert is a long time coming. It needs to be written to where most workers can understand it, but that should not mean that it is to be watered down. He indicated he will offer comments on the website. Dr. Schuler indicated she would be happy to receive them.

Question #5 (Dave Wietzman): Could Dr. Schuler please address inhalation of solutions as a risk factor to development of CBD?
Reply: Dr. Schuler indicated that processes handling beryllium as wet were not as great a concern, UNLESS they have become dry and can now be aerosolized.
Comment (Mike Van Dyke): From his studies, he cannot declare with any certainty that inhalations from aerosolized liquids will not lead to sensitization and disease; we simply do not know.
Comment (Mark Hoover): Would solubles that are quickly eliminated be sensitizer risks, CBD risks, or both? Rhetorical question….He also commented on CBD Prevention targeting risk communication beyond exposure management. Specifically he challenged all on how the Alert could help in preplanning as well as emergencies.
Comment (Mike Van Dyke): Can we say solubles offer no risk?
Reply (Mar Kolanz): CBD has come from solely soluble materials at Brush Wellman. So don't dismiss the questions. Solutions need to be managed under source controls similar to contamination management used for radiological work.
Comment (Hector Rodriguez, DOE NETL): Hector offered a caution on the broad omission of background beryllium levels. Those sources should be managed.
Marc Kolanz commented that his experiences indicate where ever you use it you will find it. Mark Hoover commented that regardless of source, if an agent caused an exposure you would manage it. Perhaps the Alert should consider a list of examples where those

forms would bridge into mandatory controls to manage exposures. Mark believes that fly ash risk is one that is managed not through DOE's rule, but through common industrial hygiene principles of control of dust, total metals contribution , etc. Finally, Gary Whitney commented on his experiences with background beryllium measurement and exposures. Typically a total high background dust loading is reached before any applicable beryllium criteria.

Charles Davis presented "Statistical Issues Arising in Facility Surveys for Beryllium". His presentation offered significant considerations for the treatment of data and a model for dealing with censored (mostly non-detects) data. Please refer to Charles presentation attached. Anyone reviewing it should recognize the need for statistical expertise in designing a campaign for sampling and decision making with respect to beryllium contamination levels.

The Data Reporting Task Force (DRTF) discussed white paper #2 on the use of uncensored data to understand how conclusions were arrived at. Charles Davis argued strongly to not censor data, but to use all of it available to serve the goals of acquiring it. Tom Oatts discussed the laboratory detection limits and reporting limits for beryllium samples as he had presented the information in March at the Chemical Lifecycle Management forum at DOE Headquarters.
Paul Wambach addressed policy considerations around the use of data. Consensus standards, where available, should be used. They should be created where necessary and currently lacking. The DOE Technical Standard that is planned can be written by any element within DOE and or industry. The initial one created by Dave Wietzman and Paul Wambach was assembled from other available resources, specifically:

A sampling element	MARISSUM
An analytical element	NIOSH Methods with Reporting Limits
A decision criteria	AIHA Manual on Exposure Strategy

The use of a 95% Confidence Limit around a 95%tile value (95/95) was established as an element of compliance. The DRTF has made great strides to build consensus on improvements to this initial decision process.
Gary Braybrooke has created a sampling matrix to address the use of censored data. It does not aid worker exposure evaluations, but perhaps trending could occur within data sets for use by the sampling and analysis community. Gary would appreciate comments on the matrix. The intent is to make a tool for use, but not a hammer for driving requirements.

DRTF White Paper # 2 and the Sampling Matrix are to go to the BHSC for the 3 week review.

Melecita Archuleta presented the latest revision of the paper to remove any opinion or conclusion on what should be done, but merely presents the issues and incongruities around metrics of lab analysis performance. She reminded everyone of the significant energy put into this by Gary Whitney at LANL who joined us by phone. Gary had created it as a communication tool that management had asked for.

Question #1 (Gary Braybrooke): it appears that increasing uncertainty (error bandwidth) appears below the criteria use in reporting. Charles Davis replied that this is a misperception, and it is fueled by the widespread use of MDLs as defined by EPA protocol. Absolute uncertainty occurs when the standard deviation is at a zero value. Lab analysts think in terms for *relative* uncertainty. Melecita commented that Reporting Limits come from precision and accuracy decisions within a method; below the RL there is no commitment on the validity of the method (i.e. the precision and accuracy criteria are not assured) which means it cannot be used.

Question # 2 (Paul Wambach): Theoretically, the distribution of noise around a zero value is comparable to the distribution of beryllium data near zero. There does not exist a good theoretical basis for distribution assumptions in this region. Charles Davis commented that it appears his model does do it. It is philosophically justified, but it is not necessarily very easy to do empirically. His generated model data plot matches a real data plot saturated with non-detect values. He further stated that all should be cautioned that the purpose of your data acquisition is not the only utility for that data. You can go back and employ it in other ways for other hypotheses so long as the criteria in assumptions are maintained.

Question #4 (George Fulton): George inquired of the DRTF if any were familiar with the National Bureau of Standards (NBS) Experimental Statistics text by Neutrella and their statement therein (paraphrased as) "Variability changes at the extremes of the calibration curve." ? Charles Davis replied that anytime a line is fitted to data, uncertainty is greater at the extremes (slope of the line comes into play). The quoted statement assumes a constant Standard Deviation, which may or may not be the case. George replied that he recommended the DRTF look at that citation with respect to white paper #2.

Question #5 (Larissa Welch): Larissa requested clarification on Instrument Detection Limits from Method Detection Limits if using data at the IDL. Charles Davis indicated that if for the purposes of 95% Confidence Intervals at an Upper Tolerance Limit less than the criterion one should employ the MDL. Any consideration for treatment of data that is not validated is still an open question, but it should not be confused as detects versus non-detects; the latter should not be considered as a discussion of valid versus invalid data.

In closing Melecita commented that the DRTF is trying to establish the constraints of model deployment.

ABSRACT PRESENTATIONS

Marc Kolanz presented the latest DVD training guide that Brush Wellman has developed. It is completely interactive, and to date they have issued approximately 8000 to downstream users of Brush Wellman products: their own operations, as well as manufacturers, vendors, etc. Anyone can sign up to receive a copy at Brush Wellman's website, www.brushwellman.com

Marc Kolanz presented a review of the Small Business initiative within OSHA. It is a relatively new requirement from the Office of Management and Budget, allowing small business to have input to regulatory development. The SBREFA Report was issued January of 2008. The proposed rule date is in question, probably a 2009 date. PEL being explored is from 0.1 to 2.0 micrograms /m3. Medical surveillance provisions are included for skin as well as inhalation exposures to powders and dusts. However, no medical removal provisions (MRP) as found in other OSHA vertical standards are proposed. Surface contamination is proposed as low as practical. Surveillance obligations of monitoring occur on a 3 month frequency if above the PEL, or on 6 month frequency if above the AL. Review panel findings included concern over cost of engineering controls, costs of exposure assessment, and broadly the economics of the proposal with respect to competitiveness.
Question #1 (Dr. Maier): Is there a medical education component in the proposal? Marc indicated no.
Question #2 (Burney Hook, SRS): are there any exemptions for those working to the OSHA 1910.1450 Lab Standard? Don Harvey replied that the option of lab standard application rests with the operator and his/her evaluation.

Caroline Mueller of the University of Montreal presented an Inhalation Toxicology Study and specifically analysis of the worker protection program created around the animal study being done. Specifically she explored the methodology for clean up of the operational environment during and following inhalation exposures to mice.

Mice were exposed for 3 weeks to 250 microgram/cubic meters. The study duration was 12 weeks of preparations and 42 weeks duration, with effective total exposure durations to the lab staff of 54 weeks. Her assessment of exposures was through use of Dust Trak® and Cascade Impactors. Exposure Management during the study include the lab being set as a restricted zone, with ventilation controls exhausted to outside air through a HEPA filter. The room was retained at negative pressure. Six air changes per hour occurred. Dedicated PPE was donned and doffed in change rooms with a policy of no personal effects entering the work zones. Air samples were collected weekly from the testing chamber. BeLPT was collected from all workers prior to the work and monthly for the duration of worker involvement. They were also collected 6 months following cessation of the exposure. Study results are to be published soon; preliminary data shows neither real exposures nor incidence of sensitization.

Question #1: What cleaning agents were used for surface decontamination? Soapy water with three washes, and followed by a fourth was 24 hours later.
Question #2 (Mike McCawley): What caused the high reading presented in the data table within the INTOX test chamber? They believe it was the result of poor practices around the inhalation chamber and hypothesize contamination migration into the space from the delivery system.
Question #3 (Hector Rodriquez, NETL) Any consideration of HEPA filter testing to verify atmosphere contamination? No. How were technicians sampled for contamination? Wipe sampling of hands.

Mike Van Dyke presented his doctoral work covering a variety of projects over the past 4 years. Recall that Antigen Presenting Cells ("Glutamic Acid 69") are probably involved in the mechanism of sensitization and disease in workers. There has been only one study examining exposure levels and Glutamic Acid 69 . As a result Mike created a research project around this issue.

He defined exposed populations associated with BeS and CBD. A case controlled study was conducted involving 100 cases of Beryllium sensitization and disease. 3 sites were studied based upon availability: Rocky Flats, Y-12, and Southeast Precision Machine. He collected work histories via questionnaire and available sampling data from each site. Former workers were included, with controls matched by decade of hire. Please refer to Mike's presentation for details, he expects to complete his PhD in late 2008 and will be publishing this information.

Question #1 (Dave Wietzman): Any air sampling conducted? No.
Question #2 (Marc Kolanz): Has a real sampling campaign yet been formulated going forward? No.

Data Reporting Task Force White Paper on Wall Deposits

Martin Harper introduced this paper. Wall Deposits are a significant issue in total sample available for analysis. Here are the salient issues:

1. Understanding what constitutes a sample.
2. Significance of particulate collecting on the walls of the sample.
3. Cost of implementing a change to current analytical methods.
4. Data comparability should a change be adopted.

Melecita Archuleta strongly believes that as a community of concerned experts in these matters, we have an obligation to act. We (BHSC/Sampling and Analysis Subcommittee) are at a cross roads, with these options:

1. Tackle the problem or not.
2. Step forward to look at the data or create the data, then analyze it.
3. Act on what is learned to the appropriate parties (OSHA, NIOSH, DOE)

Discussion
Mike McCawley commented that best of all worlds is an analysis separating filter capture from wall capture as it would be tied to particle size and hence lung deposition/ skin penetration issues. He recognizes the increase in cost and time of analysis.
Kevin Ashley commented that a combined result is available with current extraction techniques and feels discrimination of wall from filter is less pertinent.
Melecita Archuleta offered that her major recommendation is to call for everyone to dig out the data that all say is out there, and bring it to the table for analysis.
Kevin Ashley made the argument that epidemiologically relevant data is ideally found with the aerosol scientists, and recommended we work to be sure we are capturing the size fraction that has health relevance. Mike Brisson indicated that this was the thrust of the Johnson conference on particles held last summer in Vermont. Those aerosol

scientists are in agreement as to the target. Mike McCawley felt strongly we could not pursue this angle without understanding the particle size issue with respect to disease, and reminded all that the BHSC cannot make recommendations.

Marc Kolanz, Steve Jahn, and Mark Hoover all praised the raising of our collective consciousness with respect to these issues by the work of the DRTF. Mark Hoover recommended that the DRTF establish what we want to gather for data (factors around wall deposits contribution to sample result, particle size relationship for response to an exposure) and put it out seeking the data.

Paul Wambach reminded all that we should be leading, not stepping aside. The DRTF paper on this issue should also capture what the rest of the world is doing (if not already captured in the paper).

Kent Kerr asked George Fulton (since LLNL is the only lab routinely capturing wall deposits today in beryllium air sample analysis) how they are treating their data against the PEL and TLV criteria? And are they content with being more conservative? George indicated they handle it straight as we all do: results vs. limit. No futher comparison. As to contentment, it appears it was not a decision the contractor made alone nor willingly, but were told to do.

George further commented that this position paper supports comments to the pending OSHA rulemaking.
Mike McCawley requested that the SAS provide bullet points and one or two priority items for research needs. It appears the underlying issue is what equals a sample? Research and validation are needed. And the significance of these issues towards exposure measures is the real goal.
John Bishop (USNavy) offered that the Navy would like to champion improvements, but is concerned with comparability to historical data and the costs of implementation.
Tom Oatts commented that during his recent AIHA Accreditation audit he was asked if the analysis steps included wiping of cassette walls. As director he said no and asked if AIHA Lab Accreditation Committee had a position on the matter. The question was unanswered.

Dave Weitzman addressed the work of the Technical Standards Committee with ACGIH TLV comments. Inhalable TLV is a poor idea because of filter treatment creating the data that supports the exposure studies (those sample cassettes were not wiped). Tech Standards committee made a judgment that effectively matches this wall deposit issue. Mike Brisson asked the technical standards committee to retrospectively create the history of this issue. This document can be valuable to those commenting on the next ACGIH NIC for beryllium.

Mike Brisson closed the DRTF discussion with these two points:

- Put a disclaimer on the paper that it is not intended to provide advice (do that through other forums with the same information)
- And should be considered guidance towards building consensus.

Additionally, following publication of DRTF #2, another task group should be considered to the task of getting targeted data. Kevin Ashley reminded all that significant data has already been collected regarding filter retained materials versus wall borne materials. He asked if others consider that beryllium needs unique treatment in this regard. Mike McCawley responded that yes it did. This is based on particle sizing research data Mike published across various processes that yielded difference in distribution.

Subcommittee Reporting

CBD Prevention (now called Risk Communication)

In attendance:

Jim Jenkins, Y-12	Tom Ford, Y-12
George Fulton, LLNL	Tony Quinn, AWE
Lisa Barker, National Jewish	Steven Jahn, Savannah River Site
Iain Aldridge, AWE	Bob Immele (by proxy)

Discussion:

Those in attendance discussed beryllium management in the face of a conventional exposure management approach, using a threshold concept of an allowable exposure. Since the rule implementation at DOE sites, a hierarchy of controls logic has been in place for years, relying upon engineering processes to avoid airborne beryllium to the greatest extent possible. Those additional measures to reduce or avoid exposures altogether seem to lie in human behaviors and performance. Coupled with the NIOSH Alert discussion, and a "no threshold" / carcinogen concept, management attention should be focused on a "start clean, stay clean" process that is easily understood by the worker.

Following additional dialogue, these proposals were made for the future efforts of the committee:

1. Consider formation of an "IH Issues" subcommittee, to work on issues hand in hand with the research needs committee as follows:

   -aerosol properties related to risk of disease
   -method for skin surface exposure assessment
   -particle size distribution across operations (feeds the continuing analytical question)
   -relationship of surface contamination and health risk

2. Risk Communication to address the need for core training content that effectively educates workers, supervisors, managers, medical and human resource staffs across the entire spectrum of issues (such as what to expect from Belt results, counseling of employees, etc.) This one garnered unanimous support from those in attendance. Specific targets might be supervisors of sensitized workers, workers consenting to Belt tests (so they can get a sense of possible results and

consequences), work practices (Brush Wellman Video Trainer and the AWE worker training program).

3. Consideration of an Affected Worker's Voice subcommittee. Bob Immune's proposal includes the following:

A) A survey sent out to all the BeS and CBD patients gathering info in several key areas so that we can get an overall view of their needs and difficulties. With this info we could set up some common categories that we could look at making suggestions on improving. I think this should be followed up on a regular basis to see if improvements are taking place. Bob indicated he has several questions for a start to this survey.

B) Bob believes it would help the BHSC to have several (3 to 5) CBD patients from across the DOE complex to give insight and to help the committee see the whole puzzle. He would be willing to be one of these, but we need several to be affective.

C) A conference intended to support patients with BeS and CBD. Just as the International Beryllium Conferences help the different Doctors, Researchers, Industrial Hygienists, Program Managers, epidemiologists, etc. to learn what is new and what they need to do to be more proficient in their field. This same type of benefit could help affected workers in many areas such as:

-Deeper understanding of their illness and how it will affect them and their families.

-What type of medical providers are available to them, like NJMC, U of Penn., Home Nursing Care, Physical Therapist, Physiologist, etc.

-What governmental organization they have available to them, DOE, DOL, State L&I, Veterans Administration, etc.

-Education is the key to preventing Be exposures, being able to recognize hazards and prevent exposures.

-Equipment providers: Home health care providers, CPAP, O2 equipment, Nebulae's, walkers/wheel chairs, power carts, exercise equipment, etc.

-Better educated patients have less stress and a better understanding of the overall picture so they can share their information with their co-workers there by contributing to a safer work environment.

-Maybe not all affected workers from each contractor could attend, but if we could get 2 to 5 patients from each contractor across the DOE complex and maybe some from the private sector we could make a tremendous impact by sharing the info on all the patients.

-Developing a web site where all the info from the conference could be accessed by anyone.

D) Beryllium Training across the DOE complex varies dramatically. The different areas of training need to be standardized to some degree including: Beryllium Worker Training, Managers of Affected Workers, Affected Worker Training, etc.. Each site could add the material that they deem necessary. The Beryllium Worker Training has had the most development but training directed at Managers of Be Affected Workers and Training actually directed at Be Affected Workers has had very little attention. Bob has (in the last couple of months) started doing these two types of training for PNNL. He is working to develop all the necessary lesson plans, outlines, etc. for each of these trainings so they will become a permanent part of training at PNNL.

E) Risk Communication is very important especially to the patient. How we communicate with affected workers has the ability to enhance or mare their perception of what we are saying to them. Being able to give the correct information in compassionate caring method of communicating is a learned skill. Not all health care workers, managers, IH, affected workers have this skill but it could be taught and communications could be improved.

Note that D and E on his list are essentially collected into our second proposal.

Conclusion:
With respect to a groundswell of support to move this subcommittee into a risk communication mode, as chair of the subcommittee I propose that we rename it the Risk Communication subcommittee.

A dedicated monthly call will be initiated in mid May. Agenda and starting documents to follow.

Technical Standard Subcommittee

Re-suspension of Particulate Beryllium.
The objective is to determine if there exists a meaningful and useful correlation between surface and air levels so that the health risk of a surface level can be better communicated by comparing its correlated air level to an inhalation exposure standard. Y-12 has a large number of wipe sample results and breathing zone (BZ) results for the IH technicians that took the wipe sample. They have 14,000-15, 000 wipe results and 283 IH tech BZ results for the January 2000 to June 2007 period. They asked their statisticians to analyze these data to determine if there exists a correlation between the wipe and BZ levels.

The statisticians so far have said they cannot provide statistically sound correlations but are re-analyzing the data. A member suggested that the Y-12 statisticians collaborate with the statisticians and others on the BHSC Data Reporting Task Force for ideas on additional approaches to analyzing these data, e.g., using uncensored wipe data instead of censoring the data that is less than the reporting limit and that comprises approximately 80% of the data set.

A very small number of BZ results were above the laboratory reporting limit and were obtained in inaccessible legacy facilities know to be relatively heavily contaminated. A member suggested that it may be useful to report on those levels as an empirical finding even if the statistical analysis of the data is fruitless. Another member pointed out that this type of empirical reporting can give a strong impression of a science-based conclusion when not actually supported by the science. The subcommittee will wait to see what additional statistical analysis provides before deciding on what to recommend concerning reporting on this effort.

Contamination Resulting from Clean Operations. The subcommittee held a discussion of the common situation in which machining operations on materials represented as not containing beryllium, but nonetheless contain small concentrations, up to around 100 parts per million, can generated sufficient surface levels of beryllium to exceed DOE's release criteria limit of 0.2μg/100 cm^2. Beryllium is ubiquitous in metals from manufacturing processes especially as a result of nearly universal metal recycling and suppliers do not bother to specify concentrations of impurities below around 100 parts per million. The subcommittee had no ideas for how to approach this issue at this time.

Closed-face Cassette (CFC) Wall Deposits and ACGIH Notice of Change for Beryllium. The subcommittee recognizes that its previous recommended position on Acid's intent to adopt a new TLV as inhalable beryllium may not be consistent with the information that will be in the Sampling and Analysis Subcommittee's (SAS) imminent white paper on including wall deposits in beryllium sample results. The Technical Practices subcommittee will monitor the wall deposits white paper and deliberate on a recommendation to amend the BHSC suggested comments to the ACGIH on this issue.

Research Needs Subcommittee
Attendees:

Mike McCawley, Chair
Rominder Suri, Villanova University
Don Harvey, DOE
Mike Van Dyke, National Jewish Hospital
Deanna Harkin, US Army

The subcommittee discussed the renewal of the Research Needs List. Other subcommittees will be providing research ideas as part of this meeting. Topics will be sought up through 11/15/08. The topics should have a paragraph accompanying them, explaining why the topic is important. The Research Needs Subcommittee will assemble all of the topics, review them, especially for redundancy and assemble a final list. That list will then be circulated to the BHSC for review, comment and prioritization.

The subcommittee is also asking for examples of work (such as project titles or journal citations) that has been done on the original set of Needs. This list of accomplished work will accompany the final version of the new list as a preamble.

Once the new Research List is finalized it will be as widely disseminated as possible (including all the National labs and universities). The plan is that the BHSC will seek project proposals addressing the Research Needs. The proposals will be requested in the format of an NIH R01 grant application. The proposals will be reviewed by an independent group of reviewers. The suggestion was made that the American Institute of Biological Sciences could be used as a review group. However, there is a cost associated with using that group. NIOSH was also suggested as a potential group of reviewers.

The reviewed proposals will thus be scored and a second round of review by the Subcommittee can be done to assure that the reviewed values seem appropriate. The highest scored proposals can be bound together for dissemination to groups that can seek funding for the proposals or fund the proposals themselves (including DOE, DoD, NIH, NASA, NIOSH).

Symposium

November 17th, 2008 in Albuquerque, NM. University of New Mexico is hosting for us. Call for abstracts to go out shortly. $300 for registration, with publication of proceedings by the Journal of Occupational and Environmental Health. Agenda planned as follows:

- Monday, surface sampling tutorial at the BHSC (Ashley, Braybrooke, Jahn AIHCE presentation)
-

Medical/Epidemiology Subcommittee

In attendance: Donna Cragle, Lisa Maier, Paul Wambach,
Lisa Barker, Steve Jahn

Group wants to increase perceived value of this subcommittee by creating a work product that will be useful to the medical staff at the DOE sites. For example: when a "cluster" or an as-yet-to-be specified number of new cases (hired after 2000) are identified, a standardized procedure for investigation of the sensitized individual(s) job history including exposure monitoring.

Group members continue to be concerned about new cases of sensitization being diagnosed in current workers, most hired after 2000.

A former SOMD has recommended to the group that a presentation from a researcher/epidemiologist reviewing past publications and and rates of BeS/CBD, etc. in current and former worker populations would be helpful and may engage the SOMD's.

We discussed the possibility of compiling a reading list of articles and information that will help a new person get up to speed on beryllium and beryllium exposure health effects. We could put those articles on a CD to distribute.

Data on single abnormal LPT's and outcome would be of interest for the group to analyze, both one and two abnormals by site would be analyzed/ PW is charged with reviewing this data by site and reporting back to the subcommittee/ full committee.

Also what is the "Standard" for SOMD's in dealing with this.

As industry continues to lower exposures, we predict that we will see less disease. Less disease is good and we need to continue to follow these workers with LPT surveillance to ensure. Group members also discussed the merits of testing when the prevalence of BeS falls below a certain rate. This rate is still to be determined.

Discussed with Steve Jahn about Med/Epi taking the BeS/CBD worker issues.

Research Needs: **Med/Epi Priorities**
(1) Develop and validate improved screening and diagnostic tests, including the identification of genetic factors that relate to risk.……in process, some funding, still lots of unanswered questions.
(2) Study the mechanism and risk factors (both personal and exposure-related) that affect the progression of sensitization to disease and the progression of mild disease to severe disease ……in process, some funding, still lots of unanswered questions.
(3) Explore opportunities for therapeutic interventions (pre-CBD) or specific therapies for CBD….. in process, some funding, still lots of unanswered questions.
(4) Determine the prevalence of sensitization and disease in the general population…..in process
(5) Cancer risk for Be exposed workers.
(5) Develop Tissue Repository – in process, 2nd year of three year collection.

Others on the list, in no order for us:

- Animal model
- Nationwide Be registry – NIOSH?
- In-vivo fate of Be
- Physiochemical properties of Be aerosols and health risk
- Skin, mucous membrane exposure

<u>Sampling & Analysis Subcommittee</u>
BHSC SAS Breakout Session
BHSC Meeting, 16-17 April 2008, Aberdeen Proving Ground, MD

Present:

Geoff Braybrooke, USACHPPM (Secretary)
Larissa Welch, BWXT Y-12
Charles Davis, EnviroStat
Amy Ekechukwu, SRS
Tom Oatts, BWXT Y-12
Marc Kolanz, Brush Wellman Inc.
Mark Hoover, NIOSH Morgantown
John Bishop, U.S. Navy
Natalie Phillips, Idaho National Lab

Anoop Agrawal, Berylliant Inc.
Dave Weitzman, DOE OWP

1. Draft White Paper on wall deposits in air sampling filter cassettes.

Melecita Archuleta, SAS Chair, had requested the SAS to review the bullet points in the Conclusions (possible topics that can be pursued to answer questions raised in this document) and identify 1 or 2 top priorities. Those present could not reach a consensus.

It was noted that "what constitutes a sample" is the key underlying issue. However, recovery of wall deposits must be validated for their inclusion in the sample to be meaningful. Likewise, the significance and influence of wall deposits must be understood.

Bishop said the Navy would like to champion the inclusion of wall deposits but needs to assess the impacts. His concerns are the possibility that wipes will introduce contaminants and increase variability, the problem of non-comparability with historical data, and how inclusion affects lab accreditation status.

Oatts noted that if dilution is increased to include a wipe, the reporting limit could actually rise.

At sites with generally low exposures, the cost of including wall deposits will be predominantly analytical costs. For other sites, it may predominantly be for compliance when previously-compliant areas are redefined as noncompliant.

There was concern about the effect of including wall deposits in samples on laboratory accreditation status. During a recent reaccreditation at Y-12, the auditor asked whether they wiped cassettes of metal particulate samples and added them to the sample. The auditor stated that AIHA had no position or requirement for this, but was just collecting the information.

It was agreed that there are few samples for which wall deposits have been compared to filter deposits, and that more are needed to determine the significance of the former. This could be combined with evaluation of wall deposit recovery methods. It was recommended that research begin with a small-scale protocol and identification of possible confounders and influences such as particulate size, humidity, static charges, flow rates, and matrix effects. Kolanz can arrange to collect general area samples in well-characterized areas at Brush Wellman facilities that are unlikely to include large particles.

The SAS agreed to submit several proposals to the Research Needs Subcommittee:

a. Identification and validation of methods to recover wall deposits. There are fully digestible inserts available (AccuCaps from SKC) and the French method for digestion inside the cassette, as well as OSHA's wipe method.

b. Further research on wipe sampling media and methods (to support proposal 2). This would continue the efforts discussed at the previous Symposium.

c. Study of the significance and influence of wall deposits as they relate to Be exposures.

d. Development of additional reference materials to validate existing and emerging S&A methods to support the proposals above. Suggested examples were a ceramic material and large (50 µg) BeO particulate.

Hoover asked how this White Paper could be distributed to the public. Kevin Ashley's column in the Journal of Occupational and Environmental Hygiene was suggested. Martin Harper had written on the subject of wall deposits in this column previously.

2. Additional research needs.

a. A laboratory round robin for validation of preparation of filters using the NIST SRM. AIHA wants this done before including these in the BePAT program. It was noted that some DOE labs cannot justify funding this work from existing lines of funding unless or until it is established that this would be required to maintain their accreditation.

3. Working Group updates.

These weren't discussed due to lack of time.