NIOSH-126

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To: NIOSH Docket Office (CDC)
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Subject: Comments regarding Docket Number 126: NIOSH/Emergency Preparedness and Response Research Portfolio Town Hall Meeting, Tuesday March 25, 2008

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My written "Town Hall Meeting" comments, which I respectfully submit to NIOSH as an independent and unaffiliated technical analyst, are focused on the specific context of responder- preparedness for an "anthrax incident" type of bioterrorism response and recovery operation guided predominantly by indoor environmental surface-testing for dispersed "bio-threat agent" contamination detection and assessment. But the ideas expressed may have more general applications to civil society's responses to and recoveries from other kinds of "homeland security events" or to industrial accidents, which likewise involve indoor, initially-airborne dispersals of finely-particulate CBRN "threat- agents", such as what transpired in 2001-4 following the U.S. mail-borne anthrax attacks and their associated multifocal anthrax-disease outbreaks of 2001.

While I am most concerned about the welfare of civil stakeholders and of the Nation generally in the wake of any such future CBRN- involved incident, I shall focus my remarks as requested, primarily but not exclusively on the "safety and health of emergency responders".

> Give your opinion about the top three goals needed to improve the
> safety and health of emergency responders. Discuss why these are the
> top goals. Address any obstacles in achieving these goals.
> Talk about how research can help the nation address the top goals that
> you have identified. Provide a couple of examples of research ideas
> for each of your top goals identified.

My offered opinions focus on the following three operational issues, each intended to improve national preparedness for employing effective environmental surface-testing procedures in actual practice, during responses to bioterrorism events:

(A) Unmet needs (as disclosed) for operational "positive controls" to support validations of specified microbiological surface- testing methods, as well as to enable the routine quality assurance of proficiency training and of actual on-scene practices of various indoor environmental surface-testing procedures.

(B) A need to employ visualizable "threat-agent" contamination simulants during proficiency training of responder personnel in manual procedures for on-site environmental-testing, and for remediation of indoor-contaminated facilities.

(C) A notional PPEE "trade-off": a need to reduce responders' reliance upon costly, personally-debilitating and ergonomically- burdensome "Level A" personal protective equipment ensembles (PPEE), by introducing an alternative reliance on less costly and less-restrictive Level B/C PPEE, combined for acceptable safety with efficient threat-agent removal plus non-lethal inactivation, along with medical prophylaxis and continuing surveillance.

(A) Microbiological surface-test method "positive controls".

Routinely-applied "positive controls" are fundamental and arguably indispensible to the effective development, credible science-based validation and quality-assured execution in training and in actual practice, of any test-method whether environmental, clinical or industrial in nature. This need is almost universally understood, and is generally satisfied as a matter of "sound science" -- but all recognized environmental surface-testing practices for indoor "anthrax detection"_/1 appear to be noteworthy and unfortunate post-"9/11" exceptions to this methodological rule (as disclosed).

On-site responders as well as the stake-holding public could be adversely affected by uncontrolled and possibly false-negative environmental tests, as such tests might lead to erroneous clearances of facilities or portions of facilities as being contamination-free "cold zones", or as being contaminated at only tolerably-low levels of estimated potential occupational exposure, according to microbial risk assessments based on unreliable surface-contamination data (especially, "false- negatives").

Also, absent well-controlled and reliable surface-testing capabilities, detailed planning for the remediation of facilities may not be accomplished with any credible assurance of predictable success, and may result in otherwise-avoidable, costly and hazardous exposures of responder personnel to unnecessary, misdirected or ineffectual facility-testing and remediation operations.

As evidenced during the nation's 2001-4 "anthrax incident" response, environmental surface-testing was undertaken to meet numerous important needs in bioterrorism crisis- and consequence-management, i.e., either:
"initial" sampling to initially detect or else to "rule out" indoor facility contaminations;
"characterization" sampling to qualitatively or quantitatively assess spatial distributions and bioburden extents of confirmed indoor contaminations, including the localizations of any threat-agent contamination "hot spots" on-site, in order to inform facility remediation stategies as well as to guide early demarcations of "hot-zone"/"cold-zone" boundaries, and for forensic reconstructions of threat-agent dispersal events; and "verification" or "clearance"
sampling to evaluate post-remediation results (e.g., "log kill"
impacts) of any applied facility decontamination procedures (e.g., sporacidal surface-treatments, or extensive zonal fumigations) to support stakeholders' decision-making about facility clearances for reoccupancy.

The need for positive controls to avoid "false-negative" or otherwise- Inaccurate, misleading or unconvincing environmental surface-testing outcomes (as the historical record suggests did sometimes occur during the 2001-4 U.S. anthrax incident response_/2,3) has been recognized explicitly as a matter of Federal interagency "quality" testing policy_/4, as well as being a fundamental "best practice" in most technical science-based professions.

Yet "environmental" positive controls remain absent (as disclosed) for any of the known end-to-end procedures_/1,5 as were practiced for indoor surface-testing during the U.S. anthrax incident response, including specified procedures for on-scene "sampling" collection and for off-site transport and microbiological laboratory analyses of environmental (as distinguished from "clinical") specimens.

Without routinely-applicable positive controls, the functional efficacies or reliabilities of any environmental-testing methods under particular circumstances of operational applications, cannot be evaluated "scientifically".

Also, dependable quality assurance of any such "uncontrolled"
testing procedures cannot be accomplished in actual practice, with any convincing, science-based foundation for responder or stakeholder confidence in reported testing results -- especially for the kind of exclusively-negative testing-outcomes as were generally reported to have been obtained in the post-fumigation verification sampling performed in 2001-4 anthrax remediations.

Furthermore, the kind of "statistical" or "randomized" facility sampling capability (as distinguished from "targeted" sampling) which the U.S. Government Accountability Office has expressly advocated_/5,6, implies a kind of quantitatively dependable test- method performance which can only be designed into contingency testing procedures and quality-assured in actual practice, through routine application of suitable positive controls to complement the "negative controls" (i.e., sample "blanks") which have been employed for similar purposes of procedural quality-
assurance_/1,7 and which have apparently serve well in actual practice, to guard against indoor anthrax-detection "false- positive" testing-outcomes, attributable to collected-specimen
cross-contaminations._/8

Given the manifest importance of well-controlled environmental- testing practices, it is unclear why no such "environmental"
positive controls for, e.g., viable-anthrax detection procedures have yet been developed by any Federal agency (as disclosed) for routine contingency uses on-site, during the six-plus years since the 2001 U.S. anthrax incident's inception; but such a complete positive-controls "gap" appears in fact to be the case,

even today.

What is clear, is that without appropriate positive controls, there is no reasonable prospect for credible science-based validations (as the GAO has publicly urged be accomplished_/5,6) of any specified end-to-end surface-testing methods for indoor detection of dispersed fine-particulate anthrax threat-agents, nor for any scientifically-defensible claim of quality-assurance of any such uncontrolled test-method, when performed by responders either during their proficiency training, or in actual practice.

There does exist one arguably-suitable science-based model for a surface-testing positive-control system (see below). However, two kinds of obstacles may be confronted in the adaptation of that "legacy" microbiological positive-control approach to the unique circumstances of "anthrax incident" responses, or to other kinds of indoor-dispersed CBRN agent-involved homeland security events:
one obstacle involves the highly-variable nature of indoor environmental surfaces needing to be tested; another involves properties of the CBRN "threat agent" test-analytes themselves, which may affect surface-testing method recoveries idiosyncratically (i.e., differently from some "surrogates" which might be routinely- employed in positive controls).

Regarding the first obstacle, while it may never be practicable to simulate all possible "real world" test-surface characteristics in any positive-control approach, it does seem clearly feasible to specify a small series of representative surface-types (e.g., porous and non-porous, hard or soft, flat or irregular) and conditions (e.g., clean, dusty, or soiled) which can be uniformly replicated for purposes of test-method positive-control provisioning.

Regarding the second obstacle, the mechanical and biological properties of various "select agents" or more generally, CBRN agents presented in engineered "weapons grade" or other initially- particulate states and applied to test-surfaces either as airborne "fallout" or by other means of transfer (including by wet-suspension
surface-"seeding"_/) may introduce variations in test-analyte susceptibilities to sampling removal, or to subsequent separation by "extraction" procedures from collection media, which can adversely affect a surface test-method's overall analyte-recovery efficiency.

The successful development of operational positive-control systems for bioterrorism-response applications will require experimentally- substantiated consideration of such analyte-recovery interfering effects which can be reasonably anticipated or experimentally distinguished, based on "bioweapons" knowledge which may itself be Classified or otherwise restricted from public accessibility for reasons of national security. Operationally-reliable positive controls may well require some degree of acommodation to such idiosynchratic attributes of bonafide CBRN threat agents, by means of judicious selection and preparation of analyte-surrogate materials and of the means for their test-surface contamination, so as to be employable reproducibly and predictably in the working positive-control systems.

A seemingly-apt basis for routine positive-control provisioning (in the form of removable, "rinse-assay" testable surface- contaminated coupons or test-strips_/9-11) is suggested by the analogous and decades-long experiences of NASA-supporting "planetary quarantine" (now, "planetary protection") program microbiologists in their occasional, seemingly well-controlled performance of microbiological monitoring of select spacecraft- mission hardware surfaces for microbial contamination._/12,13 While the operational context of bioterrorism response and recovery operations support may be somewhat different, the relevancy of NASA's experience with positive controls for microbiological surface-testing procedures, seems to merit emulation. The NASA "planetary protection" paradigm suggests that working positive controls are indeed practicable to help regulate many if not all operational variables of the highly manual (i.e., non-automated) set of procedures involved in environmental surface-testing practice.

Two R&D ideas based on the notion that NASA's removable "intramural air" contaminated test-strip rinse-assay approach is indeed practical and adaptable to the bioterrorism-response surface-testing context, are:

(a) Devising and trial of non-toxic surrogate-analyte based portable surface-contaminating systems, as a means of presenting to responders and analysts a quantitatively determinate surface-loading (simulated "bioburden") upon representative on- scene surfaces, so that actual environmental samples can be collected and analyzed against predictable results. Following the NASA "test strip" paradigm, such a positive control system would notionally consist of a bell-jar type shroud applied to a

representative environmental surface, onto which several small sterile test-strip coupons are also pre-positioned. A metered puff of simulant-containing carrier powder would be applied through the shroud (cf. asthma-medication inhaler devices), and the resulting dry-dispersed dust-cloud allowed to settle out, undisturbed by air currents. The set of "fallout" exposed test strips would be collected individually for rinse-assay to determine reference averaged simulant surface-loading levels.
Portions of exposed "immovable" surface would also be sampled using swabs, wipes, vacuuming, etc. following identical end-to-end practices as would also be applied during the facility surface- sampling operation.

Depending on the analyte-simulant's properties, a range of operational factors affecting overall test-method recovery (e.g., stepwise efficiencies of analyte susrface-removal, transport attrition, extraction, and culture-based analysis) could be evaluated in this manner, with the yield-results credibly applicable to the bonafide surface-tests themselves.

For example, if some tested surfaces carried toxic residues of germicidal substances (as might be likely in previously-fumigated environments), or the specimen transport-container precautionary- disinfection procedures routinely employed introduced toxicants into the collected specimens_/14, then an otherwise-indeterminate viable-analyte attrition effect could be recognized by means of quantitative viability-assays (i.e., plate-counts of "colony forming units", CFU) of the positive-control sample's recovered simulant, provided that the simulant-mix included calibrated amounts of suitable viable bio-threat agent "surrogates" (e.g., non-pathogenic bacterial spores).

(b) Devising pre-loaded portable "contaminated" test- surfaces and evaluating their utility as on-scene positive controls.
While "indirect" and thus less convincing than the on-scene surface- contaminating system described above, the use of pre-loaded portable surrogate-contaminated surfaces (similar in appearance and handling to coated thin-layer chromatography plates) might be cost-effective and well worth evaluating, as part of a surface-testing positive- control system.

Such small surrogate-analyte bearing powder-coated "porta-surfaces"
laid down and sampled (by swabbing, wiping, vacuuming, etc.) at intervals within a contaminated facility, could help control for human factors (e.g., fatigue or carelessness) or for airborne environmental toxicants (e.g., introduced during specimen-bag disinfection, as discussed above) which could otherwise degrade on-scene "threat-agent" analyte recoveries surruptitiously.

(B) Visualizable threat-agent surrogate analytes.

Because indoor environmental surface-sampling procedures shall remain highly or exclusively manual (i.e., non-automated) practices for the foreseeable future, and shall be exercised under widely- varying ambient environmental conditions, it is common-sensical that the on-scene responders and their supporting laboratarians alike may need to literally "see what they are doing" in order to attain and to sustain a reliable degree of proficiency in the performance of the susrface-sampling and analytical methods which they are taught and (infrequently) tasked to perform, in actual practice.

The U.S. "anthrax incident" taught that under most circumstances the "bio-threat agent" target of on-scene sampling effort proved to be a completely invisible analyte; and responder personnel assigned surface-sampling duties had no obvious sensory indication of how effectively they were performing their manual surface- testing specimen-collection tasks. Nor, presumably, did the supporting laboratarians have any obvious sensory means to monitor how well their handling of the received "environmental specimens"
did in fact succeed in separating and recovering whatever amount of micron-scale bio-threat agent analyte the samples presented to them for "rule out" analysis, actually contained.

Furthermore, following either surface-treatments or zonal fumigations of contaminated areas during facility remediations, some change in the distribution of surface-settled analyte might occur, e.g., due to effects of moisture or of elevated-humidity exposures. For example, fine-particulate analyte might accumulate in or around surface-irregularities on non-porous surfaces, or concentrate within the trails of condensate or surface-rinse drippings. Such altered analyte distributions might affect surface-removal efficiencies of sampling methods, and simulant visualization during the practice of such remediation activities for the purpose of "verification sampling" proficiency training, might help responders to adapt their sampling techniques appropriately to post-decontamination circumstances.

Under proficiency-training or field-exercise conditions, this problem might be surmountable rather easily, by the expedient of contaminating test-surfaces with simulant preparations which, in addition to some laboratory-determinable viable "bio-threat agent"
surrogate (e.g., non-pathogenic bacterial spores), also contain physically-similar fine-particulates (e.g., starch granules) which fluoresce (light-up) brilliantly under ultra-violet "blacklight"
illumination.

Responders-in-training could then practice their surface-sampling procedures, and by simply darkening the room and shining a UV black-light around it, could see for themselves how well they had done in removing the applied-simulant contamination from the sample coverage-areas of tested "contaminated" surfaces, and also see exactly where the removed simulant went, within (or beyond) the collected environmental specimen itself. In this manner, such operational variables as surface-applied pressure, degree of swab or wipe pre-moistening or drying-out, surface-coverage track- pattern thoroughness and specimen cross-contamination avoidance could be accurately monitored with confidence by trainees and by their supervising trainers (and by responders on-site, in actual practice), by means of immediate visual feed-back as to the effects of varying such elements of manual surface-sampling practice.

Similarly, laboratory technicians presented with "environmental specimens" which include varying burdens of "environmental matrix"
junk (i.e., of co-collected dusts and soils) could visually follow the success of their applied mechanical wet-extraction efforts (e.g., of brief vortexing) in separating the "analyte" (or at least, its "lit-up" constituent) from the internal volume and insoluble substance of the sample's fibrous collection media. In this manner, refractory mechanical entrapments or "sticky" adhesive bindings of the collected surface-contamination remaining within the extracted specimen (i.e., failing to be dispersed uniformly into the liquid- extract volume) could be recognized visually, perhaps leading to consistently-improved individual proficiency in the assigned extraction techniques, and even to technical improvements in the specified extraction-protocols themselves.

Obstacles to this "visualizable surrogate" approach may be trivial, or serious. If fluorescent particles are to be relied-upon, then the sampled location has to be completely darkened in order for the visual "tracer" to be seen by dark-adapted eyes; and this may prove to be an inconvenient or impracticable activity, in some training facilities or situations. Also, this approach necessarily imposes a delay between the manual action being performed (e.g., surface-sampling, or specimen-extraction), and the visualization of the completed activity's effect "in the dark".

A different expedient might be to add intensely-colored fine particles (e.g., colored photocopy-machine or laser-printer "toner" powder_/15) instead of or in addition to intensely-fluorescing particles, to the simulant mix; but the more immediate visual detection of these bright- light "chromophores" is likely to be much less sensitive and more subject to environmental interferences under normal lighting conditions, than is the observing of fine fluorescent particles in the dark.

Another obstacle might be personnel time: responders and laboratarians alike are busy and their time is valuable, and the meticulous effort needed to effectively use visualizable "trace" surface-contamination simulants may be hard to gain very often, or at all, from the students or from their supervisory trainers. But if the benefit of prompt visual feedback is recognized to be an important part of reliable and quality- assured proficiency training in environmental surface-testing practices, then the extra efforts needed to widely introduce such a proficiency- training and quality-assurance refinement, ought to be attainable.

(C) PPEE trade-off

While the very concept of dispensing with Level A PPEE grade personal protection for CBRN-involved event responders may appear to be dangerous and even irresponsible to suggest, its merit (if practicable with sufficient safety) is worth some careful consideration.

A major problem with the Level A PPEE paradigm lies in its limited
"scalability": not only are the individual PPEE systems expensive and complicated to maintain and to use and recycle properly, but the numbers of prospective responder personnel proficiently-trained or trainable in their use are correspondingly limited in number. Furthermore, the "hot zone" sortie working-time and productive capabilities of PPEE-encumbered personnel are so restricted by the

protective equipment (e.g., due to the suits' rapid interior overheating, and to limited tactility), that both the number of event-associated hot-zones which can be simultaneously serviced, and the amount of manual labor which can be carefully accomplished within hot-zones, become seriously-limiting logistical factors involved in mounting scaled-up crisis- and consequence-management responses to homeland security events.

Should hundreds or even thousands of occupied urban structures become involved at-once as suspected or confirmed CBRN-dispersed "hot-zones", where will all of the PPEE-qualified personnel and their supporting materiel come from, as may be needed to do what needs to be done for effective civil response and recovery?

So, may there be a more widely-practicable "appropriate technology"
solution to the responder-protection challenge, specifically during bioterrorism response and recovery operations, e.g., following a large-scale "anthrax attack"?

I suggest consideration of reliance on PPEE less complex, expensive and ergonomically-restrictive then "Level A" ensembles, which might be employed with acceptable safety for responders whenever the following circumstances apply:

(i) when the "bio-threat agent"'s pathogenic identity is known, and also when reasonably effective prophylactic and therapeutic means exist (e.g., vaccines and antibiotics) with respect to that specific pathogen, which can be applied proactively to reduce risks of morbidity or mortality to agent-exposed responders, when combined with individual medical surveillance of responder personnel, following their "hot zone" deployed service; and

(ii) when some non-lethal means of threat-agent "inactivation"
can be shown to reduce substantially the biological infectivity (i.e., the microbial exposure risk) of responder-contaminating residues of the bio-threat agent involved in the dispersal event.

If these two conditions are met -- along with use of highly protective respirators and eye-protection -- then it may serve the public good to somewhat compromise the whole-body personal protection of responder personnel, in exchange for vastly increasing the potential numbers and individual capabilities of personnel who can be trained and be made available to respond quickly, in case a widespread bioterrorism event occurs.

A key consideration in this concept is the current or potential existence of highly efficient means of non-toxic threat-agent contamination-removal from responders as they exit the "hot zone", as distinguished from decontamination which involves some kind of germicidal substance (such as applied bleach solution) used in an attempt to kill any bio-agent present on the exposed clothing or body surfaces of the person being decontaminated.

It may be the case, that simple detergent solutions or even "windshield-washer" type wetting-agent fluids -- i.e., aqueous solutions having their surfactancy raised by additives such as low-toxicity alcohols -- in combination with use of misting pressure-washer type applicator devices, can do a highly-efficient job of removing most surface-settled threat-agent contaminants from the outer clothing and from the possibly-exposed body-parts of "hot-zone" exiting workers. Such rinse treatments may have to counter electrostatic attraction between threat-agent particles and PPEE equipment surfaces, in order to achieve highly efficient removal.

High-capacity filtration and recyling of the rinse-liquid at suitably-equipped "car wash" like decontamination stations might thusly support many orders of magnitude of removal of contaminating threat-agent particulates from the exiting responders, along with safely containing whatever is removed in the wash, e.g., pending its safely-germicidal treatment on- or off-site as bio-hazardous waste.

Another key consideration is the availability of non-lethal inactivation (complete or partial) of the pathogenic "threat" of bio-threat agents by some means which reduces the exposure risk to occupational workers from whatever contaminant residues fail to be removed during this removal-approach to personnel decontamination. Two ideas are suggested regarding anthrax specifically, which may apply also to other kinds of bio-threat agents, to some degree:

(a) forced germination-activation of "inert" bacterial endospores (the biological form in which "weaponized" anthrax would presumably be dispersed as a dry powder, so as to pose a high risk of

causing "inhalation anthrax" disease in humans), so as to quickly turn hardy spores into much more vulnerable, abortively-germinated and physiologically-activated "vegetative" cells; and/or

(b) humidity-mediated fine-particle adhesion, a process whereby fine-particulate threat agents could become entrapped or agglomerated into larger bodies, and thereby be rendered too large, even if re-aerosolized, to efficiently cause disease in humans by the airborne inhalational route.

Either or (preferably) both of these two novel approaches, if developed as practical "anthrax incident" remediation techniques, might greatly reduce the risks of subsequent human infection from any viable anthrax-spores which failed to be removed from responders'
clothing or body exteriors, and subsequently passed into their bodies by either inhalation or ingestion. The exposure-risk reduction value of these two approaches for other recognized bio-threat agents than anthrax, is probably much less, and would need individual evaluation.

Obstacles: Clearly Mother Nature or Science might not cooperate, and means of reducing residual microbial risks might not be found which suffice to justify reducing personal protection within hot zones.
Alternatively, even if the science is favorable, responders (or their insurance companies, and families) might not believe it, and may refuse to expose themselves to perceived dangers (more avoidable with Level A PPEE protection), on the strength of the promised alternatives.

But it must always be kept in mind that in the event of a large-scale bioterrorism attack, the welfare of civil society at large must be the authorities' primary consideration; and some increased "wartime" risk to responders may be justifiable (and acceptable) if balanced against increased capacity to serve the public, when the need is at its greatest.

Suggested experimental approaches:

(a) Study the role of rinse-liquid "surfactancy" in efficient removal of surface-settled bio-threat agent particulates from PPEE equipment and from exposed body surfaces of "hot zone" workers.

(b) Investigate forced anthrax-spore germination-activation approaches using low-molecular-weight activators_/16,17, seeking spray-treatment conditions which would be effective at the relatively low ambient temperatures of indoor environments. Perhaps even brief applications of "body temperature" warm-water sprays during decontamination procedures can provide sufficient time/temperature/ contact opportunity for some germination-inducer to be highly effective on bio-threat agent spores, thereby increasing their sensitivity to disinfectants and reducing their inhalational infectivity risk.

(c) Study of the "Whitfield-David effect"_/18-20 of progressive, humidity-mediated adhesion of fine dust-particles to surfaces, for its intentional application to fine-particulate bio-threat agent contaminated environments as a first-response threat-mitigation and/or decontamination-augmentation technique.
For example, a recently-reported airborne-particle "knockdown"
technique employing "co-polymer" sprays_/20 might be adapted to promote humidity-mediated adhesion processes so as to efficiently yield only enlarged threat-agent-bearing particulates, thereby reducing or (in the case of inhalation anthrax disease) possibly eliminating almost entirely the risk of subsequent human infection by the inhalational route._/21-23

> Discuss opportunities you see on the horizon that could lead to
> improvements in emergency responder safety and health.

Two current "non-medical" interagency activities now reportedly in progress, offer some potential for Federally-supported R&D initiatives leading to improved responder safety, specifically in the context of an "anthrax incident" response and recovery
scenario:

(a) the interagency "Environmental Anthrax Sampling Validation Working Group"_/23, apparently stood-up in response to the GAO's 2005 call for science-based validation of indoor anthrax-detection methods employed during the 2001-4 U.S.
anthrax incident response_/5,6, may eventually identify R&D "gaps" as obstacles to successful method-

validations, and then act to apply needed resources to the gaps' science-based resolution; and

(b) the "Interagency Biological Restoration Demonstration" (IBRD) program, is reportedly a "collaborative DoD (DTRA)/DHS (S&T) program aimed at improving restoration following a large-scale outdoor anthrax release"._/24 Depending on how cross-government coordination and funded R&D fares under this recently-initiated program, improved responder practices might result from its supported undertakings.

My views expressed above are conditioned by long-standing science- based skepticisms and publicly-expressed critical concerns_/25,26 regarding the efficacy and apparent untrustworthiness of the several Federally-recognized but still-"unvalidated"_/5,6 and apparently ad hoc_/7,27 variants of end-to-end environmental surface-testing methods for indoor anthrax detection (as disclosed in their specified details) -- i.e., generally culture-based swab-rinse, wipe-rinse or "HEPA-vac" dry-vacuuming-rinse microbiological assays._/1,7

My concerns derive mainly from apparent test-procedure deviations from "legacy science" analogs in more than twenty distinguishible procedural attributes. The sum of these apparent disparities clearly challenges the currently-recognized methods' foundations in "sound science" for stakeholder and public confidence in the outcomes of environmental surface-testing activities as were reported during the course of the 2001-4 U.S. anthrax incident -- most especially, in the frequently-reported findings of "negative test results for [viable] anthrax", arguably because of inferred susceptibilities of each of the post-9/11 ad hoc test-methods to variable, insensitive or even false-negative testing-outcomes.

Apparently, little has changed (as disclosed) in the more than six years intervening to-date since the anthrax incident's inception in 2001, to merit any change in such critical views regarding the presumptive unreliability of each of these ad hoc surface-testing procedures, which apparently remain normative even today in the authoritative "interim" contingency technical guidance of Federal agencies._/7,27

>From such a critical "methodological" perspective, my comments offered to this Town Hall Meeting are intended to improve foundations for demonstrable effectiveness and greater cost- effective scalability of environmental surface-testing practices employed to guide on-scene responder technical-assessment and remediation operations supporting any future bio- (or CBRN-) terrorism-associated crisis or consequence management.

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_/1 Surface-testing practices identified in: National Response Team Technical Assistance for Anthrax Response, Interim-Final Draft. September 2002, Phase I Update November 2003. Updated issued July 2005 is available at URL: <http://www.nrt.org/Production/NRT/NRTWeb.nsf/AllAttachmentsByTitle/A-47AnthraxTAD/$File/Anthrax_TAD_72905.pdf>.

_/2 e.g., see: Sanderson W. et al. (2001) Evaluation of Bacillus anthracis Contamination inside the Brentwood Mail Processing and Distribution Center - District of Columbia, October 2001. December 21, 2001. Morb Mortal Wkly Rep 50(50):1129-1133. URL (accessed January 24, 2002): <http://www.cdc.gov/mmwr/PDF/wk/mm5050.pdf>. Also J Am Med Assoc 287(4):445-446, 2002.

_/3 U.S. POSTAL SERVICE: Better Guidance Is Needed to Improve Communication Should Anthrax Contamination Occur in the Future.

GAO-03-316. U.S. General Accounting Office (GAO), Washington DC, April 7, 2003. Available at URL: <http://www.gao.gov/new.items/d03316.pdf>.

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> ...Although screening data are used only for preliminary or intermediate
> decisions, the quality of the data is still very important. To ensure
> that screening data meet project quality objectives (PQOs), positive
> controls should be used to verify that the analysis will detect
> contaminants in samples when they are present. The purpose of using
> positive controls is to eliminate false negatives...

--- Source: Uniform Federal Policy for Quality Assurance Project Plans (UFP-QAPP), Part 2B Final Sec. 2-1. EPA/DoD/DOE Intergovernmental Data Quality Task Force (IDQTF), March 2005, URL: <www.epa.gov/swerffrr/pdf/qaqc_v1_0305.pdf>.

_/5 "Unvalidated" end-to-end stages of surface-testing procedures are illustrated schematically in Figure 1 in: ANTHRAX DETECTION: Agencies Need to Validate Sampling Activities in Order to Increase Confidence in Negative Results. GAO-05-251. U.S. Government Accountability Office, Washington DC, March 2005. Available at URL: <http://www.gao.gov/new.items/d05251.pdf>.

_/6 See also Figure 1 in: Rhodes K. Anthrax Detection: DHS Cannot Ensure That Sampling Activities Will Be Validated. Statement at the House Appropriations - Homeland Security (HS) Subcommittee hearing "Bioterrorism Preparedness and the Role of the Department of Homeland Security Chief Medical Officer", 110th Congress. GAO-07-687T, March 29, 2007. Available at URL: <http://www.gao.gov/new.items/d07687t.pdf>.

_/7 See: Comprehensive Procedures for Collecting Environmental Samples for Culturing Bacillus anthracis. Centers for Disease Control and Prevention, Atlanta and Cincinnati, April 25, 2002. URLs (accessed June 29, 2002): <http://www.bt.cdc.gov/Agent/Anthrax/environmental-sampling-apr2002.asp>; <http://www.bt.cdc.gov/Agent/Anthrax/environmental-sampling-apr2002.doc>; <http://www.bt.cdc.gov/Agent/Anthrax/environmental-sampling-apr2002.pdf>; and <http://www.cdc.gov/niosh/unp-envsamp.html>.

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Miller, Diane M. (CDC/NIOSH/EID)

From: Niemeier, Richard W. (CDC/NIOSH/EID)
Sent: Monday, March 31, 2008 9:16 AM
To: NIOSH Docket Office (CDC)
Cc: 'Lee, Sharon (CDPH-EHIB)'
Subject: FW: ICTW: NIOSH Emergency Preparedness and Response Seeks Comments - Docket 126

Thanks Sharon. I have forwarded the comment to the NIOSH Docket Office. Rick

-----Original Message-----
From: Lee, Sharon (CDPH-EHIB) [mailto:Sharon.Lee@cdph.ca.gov]
Sent: Wednesday, March 26, 2008 2:58 PM
To: Niemeier, Richard W. (CDC/NIOSH/EID)
Cc: Lee, Sharon (CDPH-EHIB)
Subject: FW: ICTW: NIOSH Emergency Preparedness and Response Seeks Comments - Docket 126

Rick, I had this comment back on the NIOSH goals review. I'm passing it on. Please let me know if the comments should be submitted somewhere else.
Thanks, Sharon

-----Original Message-----
From: Klein, David [mailto:David.Klein@dshs.state.tx.us]
Sent: Tue 3/25/2008 7:36 PM
To: Lee, Sharon (CDPH-EHIB)
Cc: rkobelski@cdc.gov
Subject: Re: ICTW: NIOSH Emergency Preparedness and Response Seeks Comments - Docket 126

I would like to see a chemical screen panel included for first reponders reasonably expected to have been in acute exposure to toxic chemicals

-----Original Message-----
From: Lee, Sharon (CDPH-EHIB) <Sharon.Lee@cdph.ca.gov>
Sent: Tue Mar 25 16:01:18 2008
Subject: ICTW: NIOSH Emergency Preparedness and Response Seeks Comments - Docket 126

Request to the ICTW for comments on NIOSH research portfolio. Thanks, Sharon

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From: Niemeier, Richard W. (CDC/NIOSH/EID) [mailto:rwn1@CDC.GOV]
Subject: NIOSH Emergency Preparedness and Response Seeks Comments - Docket 126

The NIOSH Office of Emergency Preparedness and Response (EPR) is requesting comments on the Research Portfolio. Comments may be provided to the NIOSH docket office (Docket 126) or at the NIOSH Office of Emergency Preparedness and Response public meeting on March 25 in Arlington, Virginia. More information is available on the EPR public town hall meeting at http://www.cdc.gov/niosh/programs/epr/townhall.html <http://www.cdc.gov/niosh/programs/epr/townhall.html>

As a stakeholder of NIOSH's efforts, you may be interested in commenting on the EPR Research Portfolio.

The mission of the NIOSH Emergency Preparedness and Response program is to advance research and collaborations to protect the health and safety of emergency response providers and recovery workers by preventing diseases, injuries, and fatalities in anticipation of and during response to natural and

man-made disasters and novel emergent events.

EPR has developed strategic goals to address important issues surrounding health and safety of emergency responders including: safety climate, personal protective equipment, engineering/technological interventions and controls, characterization/assessment of potential hazards, sub-group specific strategies, surveillance, environmental microbiology, and environmental and biological monitoring of terrorism agents.

Stakeholders are encouraged to review the EPR's strategic goals on the NIOSH website at http://www.cdc.gov/niosh/programs/epr/ <http://www.cdc.gov/niosh/programs/epr/> and provide feedback.

Specifically the EPR program is seeking:

- Your opinion about the top three goals needed to improve the safety and health of emergency workers.

- Comments to explain why these are the top goals. Address any obstacles in achieving these goals.

- Discuss how research can help the nation address the top goals you have identified. Provide examples of research ideas for each of the top goals you have identified.

- Discussion on opportunities you see on the horizon that could lead to improvements in emergency safety and health.