

Tri-Valley CAREs

Communities Against a Radioactive Environment

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Secretary Janet Napolitano
Department of Homeland Security
U.S. Department of Homeland Security
Washington, DC 20528

Dear Ms. Napolitano,

We write you to suggest major revisions and additions be made to “*Planning Guidance for Recovery Following Biological Incidents.*” (Hereinafter “the Guidance”). Our membership has deep concerns regarding the response, decontamination and clean-up (“clearance-goals”) described in the Guidance. As a community that is home to a high containment BSL-3 facility our concern stems from the initially severe health impacts that could result, not only from an accidental or intentional release of deadly pathogens from the local BSL-3, but from the long-lasting and wide-spread health impacts that could arise from the slow, unorganized and incomplete decontamination and clean-up process described in the Guidance.

Exposures of harmful pathogenic organisms to the employees of a high containment lab or to the public as a result of an accidental or intentional act would be a terrible tragedy. In fact, we have already experienced such a tragedy originating from a high containment laboratory. In 2001, Dr. Bruce Ivins, an employee at the United States Army’s Fort Detrick Medical Research Institute for Infectious Diseases, reportedly used a deadly strain of anthrax obtained from his workplace in a biological attack on federal government employees. In her testimony before the Senate Subcommittee on Terrorism and Homeland Security, GAO Managing Director Nancy Kingsbury spoke about the findings of their Report to Congressional Requesters on High Containment Laboratories. She related that “this incident (at Fort Detrick) highlighted two lessons: (1) An ill-intentioned insider can pose a risk not only by passing on confidential information but also by removing dangerous material from a high-containment laboratory, and (2) it is impossible to have completely effective inventory control of biological material with currently available technologies.” *GAO-09-1045T*, pg. 3. Additionally, her testimony stressed that “(l)aboratory operators, in collaboration with regulators, need to develop and work through potential failure scenarios and use that information to develop and put in place mechanisms to challenge procedures, systems and equipment to ensure continuing effectiveness.” *Id.*

In light of the GAO’s concerns, the Guidelines not only glaringly fail to create any oversight for limiting the availability of bioagents or biotoxins, but also fail to create any oversight measures for high containment labs in advance of a catastrophe. While we realize this guidance is intended to address the recovery from a biological incident no matter the location, surely recovery would be more adequately responded to at a high containment biolab (where an incident is most likely to originate and occur) if guidance were provided both to prevent an incident

and to take precautionary measures (for example design suggestions, security training, personnel training, local law enforcement training, and equipment and facility maintenance suggestions). This kind of guidance should be added.¹

Dealing with Scientific Uncertainty

The Guidance repeatedly points to the existence of scientific uncertainty in the area of biological agent research (“There is no consensus-based methodology for evaluating human risks specifically posed by environmental exposures to biological agents and there are no established cleanup goals after biological attacks.” *Guidance* at 24.) Thus, determining viability for many pathogens or activity of a biotoxin is exceedingly difficult. In most cases, the ultimate viability test is the ability to cause an infection or toxic effect in a suitable animal or cell culture. And further, the Guidance specifically goes to great lengths to describe the level of scientific uncertainty in determining the infectious doses for harmful bio agents, (or even a universally accepted definition for the term “infectious dose”). However, it explains that “infectious dose may be useful to roughly predict illness in exposed individuals and to serve as a rationale for setting initial clearance goals” (aka- a clean up standard for a particular release). *Guidance* at 27. The Guidance relies on its extensive description of scientific uncertainties to justify its multi-factored Optimization Approach to response and clean-up.²

In sum, the Optimization Approach creates a clean-up standard that will “reduce exposure levels as low as is reasonable while considering potential future land uses, technical feasibility, costs and cost effectiveness, and public acceptability.”³ After careful review of this vague, “flexible” Optimization Approach as set out in the Guidance, it is clear to us that it is simply an unacceptable way of dealing with the clean-up of deadly virulent biological pathogens. In fact, it provides very little actual guidance to responding agencies at all. In our estimation, the scientific uncertainty, referred to in the Guidance, that exists with respect to the infectious dose, human risk, and clean-up goals resulting from “real life” situations arising outside the “perfect” parameters of the conditions under which decontamination conditions are reported, provides a rationale for nothing short of using the most precautionary, most stringent, and most health protective response and clean-up standards when addressing a biological contaminant release. Deciding instead, that scientific uncertainty as to the risk of a harm caused by a specific bioagent supports an approach that advocates for conducting time consuming future land use, risk, cost, and public acceptability analyses to determine what a “reasonable” clean up level when public health is clearly at risk, throws caution (and concern for the public) to the wind. Traditionally, scientific uncertainty and risk management guidelines both favor prevention, yet that subject is scantily considered in this draft guidance.

To knowingly allow even one infectious dose of a contagious pathogen in the environment could still lead to an outbreak of grave proportions. The agencies that respond and clean up after a biological contaminant release will have a responsibility to protect the public from exposure to harm. In the response to the 2001 attacks with *B. anthracis* spores, the overall criterion for success of the decontamination process was “no growth” on any clearance environmental sample processed by culture. Providing there is not a local natural background of the pathogen, ‘no growth on any sample’ should be the clearance standard applied to all biological agent releases regardless of “potential future land uses, technical feasibility, costs and cost effectiveness.” The burden of proof for any variance from that standard should be very high and response, decontamination and clean up efforts should begin based on the ‘no growth on any sample’ standard without waiting for time consuming studies to reach completion that might urge a lower standard.

¹ The Guidance suggests the establishment of “A risk communication plan” to be “put in place before a biological incident occurs.” This plan would include “(p)re-planned messages (that) should anticipate necessary guidance for target audiences and should relay accurate information to address the public’s concern.” The guidance seems to create an inconsistency by directing the Joint Information Center (JIC) to create the risk communication plan *before* an incident, however, earlier the guidance states that the JIC would not be established until “immediately” *after* the occurrence of an incident. If the JIC is intended to be a centralized, permanent and separate governmental body, the Guidance should expressly state that this is so and provide more details as to the duties, scope of work, agency, location, and jurisdiction of the JIC.

² “Setting site specific clearance goals should be based on the results of the best possible risk assessment... (and) careful consideration of scientific uncertainties.....” *Guidance* pg. 62.

³ See *Guidance* pg. 62.

The use of PCR analysis followed by a culture seems a very cumbersome and time consuming approach in the face of a potential bioagent release. Bacterial culture analysis takes 24-48 hours, a significant period when dealing with contagious pathogens. Considerable harm to the public could result during this lag time. We wish to see acknowledgement of this in the Guidance and indications of any research into alternative assessment procedures that are less time consuming.

Public Participation

The opportunity for public participation in the Guidance should be ongoing. While it is important for the public to have input on this first draft, as the Guidance develops, both in response to the comments on this draft and in response to new science and technology, it is essential that public input on any changes or additions. Public stakeholders will have should have the ability to accept or reject the response, decontamination and clean up protocol in advance of an actual biological incident.

The Guidance provides extensive direction for how responding agencies should communicate with the public when a biological incident occurs. *Guidance, Basic Tenets of Crisis and Emergency Risk Communication*, pg. 87. The Guidance also provides ways for responsive agencies to involve the public in the response and clean up decision making process. The Guidance acknowledges that the local public could have extremely important input and/or concerns that could effect response, decontamination and clean up efforts. Additionally, it acknowledges that the public's concerns should be addressed. While we are pleased that the Guidance addresses public concern in the case of a biological incident, we would go further, asking that the public should be accurately informed as to what the response, decontamination and clean up plans are **before** they commence and given the opportunity to accept or reject those plans. There needs to be an indication as to exactly what kind of authority public stakeholders will have. In short, the Guidance needs to provide specific opportunities for public input (preferably through the Stakeholder Work Group), participation and acceptance at every juncture of the response, decontamination and clean up process.

Agency Jurisdiction

The Guidance provides that certain agencies that operate high containment laboratories, like the DOE and the DOD, have authority over the response, decontamination and clean up process in the event that there is a biological incident at their facility. There should be explicit guidelines for oversight by the CDC, HHS and EPA to ensure that these agencies are making sufficient response decontamination and clean up goals. At a minimum, these oversight capabilities should mirror the "go, no-go" authority that the EPA has at key junctures in the Superfund clean up process. We would like to see an outline with clear agency checks and balances in cases or in situations where DOE and/or DOD sites are involved.

Additionally, in the case of a biological incident at these DOE and DOD facilities, which agency has jurisdiction over the contamination if and when that contamination gets off site? Will the DOE or DOD continue to control the decision making process and the communication with the public?

Another concern of ours is that the secrecy surrounding any classified "bioweapons agent/ bio-defense" research installations may hamper detection and diagnosis of bioagents on the premises should a disaffected insider plan a release of such an agent. One example is that the BSL-3 at the DOE's Lawrence Livermore National Laboratory is part of a classified nuclear weapons facility. Guidance to address the possible tensions between the secrecy at some of these facilities and the needs for access and information of responding agencies to a biological incident should be created.

Biotoxins

The Guidance makes clear that, "(f)or biotoxins, the tools currently available for chemical risk assessment may be more relevant. Guidance such as the EPA's Exposure Factors Handbook (USEPA 1997), Risk Assessment Guidance for Superfund (RAGS) (USEPA 1989 and 1991), and other guidance for chemical risks and remediation

should serve as excellent resources for information on biotoxin remediation.” *Guidance* at 25. This piece of guidance causes us concern.

Suggesting that the EPA regulations for the clean up levels for hazardous materials would somehow be analogous to the clean up levels for biotoxins does not take into account the scientific realities of the wide variety of health hazards posed by different chemicals at different levels. The clean up levels for hazardous chemicals set in the cited EPA standards vary (in part) based on the health hazard posed by that chemical. The clean up level for one chemical contaminant cannot be used to substitute for the clean up level for another chemical, let alone a biotoxin.

If the Guidance is suggesting that biotoxins are analogous to chemicals in that there could be a fairly uniform clean up level (clearance level) established regardless of any site-specific issues, then the Guidance should propose that an agency, like the EPA or CDC, establish uniform clean up standards for biotoxins that include full public disclosure. Once created, these biotoxin standards should be officially adopted as guidance and responding agencies could be directed to use those standards rather than being directed to unrelated EPA Superfund clean-up standards for chemical contaminants. Additionally, follow up for assessment of illness arising from biotoxins needs to be strengthened. Fungal toxins can have deleterious consequences years after ingestion- an indication that longer term follow up should be detailed.

To summarize, we are concerned that the Guidance creates a response, decontamination and clean-up approach to a biological incident that is so cumbersome and vague that it will result in harm to the public. Additionally, it fails to adequately involve the public or create proper agency checks and balances to ensure that the response, decontamination and clean-up process take place properly and to a level that will avoid additional harm to the public or environment.

We look forward to your response to these concerns.

Sincerely,

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