**Session IV: Discussion of NSABB Preliminary Findings and Draft Recommendations**

**Panelist remarks:** Beth Willis mcbeth@mac.com

Good morning. I am Beth Willis, with Frederick Citizens for Bio-lab Safety, Frederick MD. I am here to speak to some of the perspectives of communities in these proceedings and to say something about many members of the general public who are deeply engaged in the issues we are discussing here.

Since 2004, I have worked with the Frederick Community and with a nation-wide coalition of communities living in proximity to BSL-3 and 4 laboratories. We have worked to bring a public perspective and concerns about health and safety and containment laboratories to policy makers and to Congress. Until a few months ago I served as Chair of the Containment Laboratory Community Advisory Committee (CLCAC) in Frederick MD, which is home to the National Interagency Biodefense Campus. The CLCAC is joint committee appointed by the elected officials of both Frederick City and the County.
(http://www.cityoffrederick.com/index.aspx?NID=127)

It is new, and important for a member of the public to be included on a panel such as this.

In my experience, community advocates who have engaged with these issues have worked hard to overcome significant technical barriers in order to understand the health and safety implications for their communities of all types of biological research of concern. Some of us are scientists; some are just highly motivated. We have to work through the technical detail to discern the bottom line safety impact for our communities. We have seen a great many of the specific safety concerns we have raised over the years play out in reports of safety and oversight lapses.

We submitted detailed comments to the Office of Science and Technology Policy on Dual Use Research of Concern policy and Gain of Function research in 2013, and in 2015 on Select Agent Regulation. We have recommended a structure of independent oversight, based upon other existing federal programs. These documents are germane to the issues under discussion at this meeting, and are available. What we say in these papers is not so very different from what others in this room have been speaking about.

All of us here have spent two days discussing complex matters with no easy answers.

There does not yet appear to be scientific consensus on how to proceed. That is striking when considering the potential consequences of conducting GOF research of concern. Funding risky GOF research in the absence of scientific consensus about safety does get the public's attention. As does the repeated references at this meeting to conflict of interest within the system.

So, I am here to speak for the application of common sense and wisdom as you grapple with all of this. I'm here to speak for putting your money where your words are and building out from where you are today by developing and implementing specific, robust, transparent and replicable decision-making and oversight processes that the public can have confidence in.

At this meeting, I heard the beginning of a reordering of the historically unbalanced balance of power between large institutions and public concerns. I saw some reordering of the balance of decision-making criteria from the strictly scientific and technical to what I hope will be the application of an equal measure of ethical and public health values.

I would propose that doing so will provide us all with some measure of protection from the risks of technical hubris. Human history is littered with the unintended consequences of technical hubris committed in the name of progress and national security.

There are a few bottom line points that jump out for this member of the public, points that also apply to DURC, select agent, and other research of concern. I hope these points will inform whatever final recommendations comes from the NSABB:

**1. Getting specific and actionable.** The report speaks broadly to many concerns raised by the public over the years. The task is to now move from the principles in this paper to that, which is actionable, funded and consistently required. From a community perspective, the usefulness of these ideas is in the detail and in funding.

It costs money to implement the good oversight, public communication and engagement and other concepts contained in the report, funding well beyond what is currently occurring. Implementing the recommendations that enhance public safety needs to be as much a part of doing business as any other aspect of the research. Otherwise all that we are discussing will be empty words and unfunded mandates. GOF research of concern projects that can't afford to implement such requirements should not be funded. I don't know why we are here unless this is a guiding principle.

Additionally, this "total cost of doing business" for GOF of concern makes such research more costly than less risky research. That should also be a factor when deciding what to fund in the context of the country's overall research priorities in an era of limited research funding.

**2. Making the transparency objectives real.** The working paper includes a greater and welcome emphasis upon transparency and principles of public communication and engagement than community advocates have seen in the past.

Last October, the White House issued a memo with numerous recommendations about BSAT research, emphasizing specific aspects of transparency, inventory control, accident and mishap reporting and other important matters, including evaluating the amount of such research that should be conducted. I would think these recommendations should explicitly inform the NSABB GOF effort.

I also note that initial efforts by media outlets to obtain information based upon the White House Memo have not been highly successful. This is to observe that achieving the transparency we all speak of will take significant additional commitment by the US Government.

With regard to making funding decisions, the public should also be informed of the decision-making process, and, among other things:

- Who approved the research.

- The identified risks and for whom.
  By that I mean questions of environmental justice, not just globally but within specific minority and disadvantaged populations in this country. Others discussed this extensively at this meeting.

- The criteria for deciding if the risk is too great.
  That criteria has not been defined. What constitutes too great a risk has not been defined.

- Who decided that the risk analysis was sufficient.

- And, of course, what has been done to mitigate the risks.

- The independent oversight that gives the public evidence that all of this has been properly conducted

**3. This report is candid about challenges and the limitations of risk benefit analyses** and the importance of a good balance of public health and ethical factors in making funding decisions. This idea is also new and welcome in the experience of communities living in proximity to containment laboratories. Acknowledging the reality that risk analyses have their limitations and uncertainties allows for that application of wisdom and common sense.

The report also suggests a number of ways to engage the public in meaningful ways throughout the life cycle of projects, some of it pre-decisional. Those who are at-risk need to be a part of the decision-making process. Engaging with the public should be required and assistance provided to make it so. Assistance might include a clearinghouse of ways this is being done, or could be done paired with technical assistance to laboratories and communities so they can develop locally effective goals and approaches.

**4. The scope needs to expand beyond NIH funded research.** Yes I understand the scope of the NSABB. But communities expect the US Government to be responsible for ensuring that safety mechanisms are in place. We are not so concerned with the details of Departmental scope. Research of concern in proximity to our communities comes from a great many more DOD, other federal, and private funding sources than NIH, some of which currently have no federal oversight. It is time to finally address this issue, which has been under discussion for years now.

**5. Long-term independent oversight is the lynchpin of these recommendations.** If risky research is to be funded, an adequately funded independent oversight system that covers the current oversight gaps also needs to be funded.

Laboratory safety and oversight failures have been in the news regularly in 2015, and for many years prior. Congressional testimony has not been reassuring. We've heard in some detail about the ways in which the system does not appear to be working well, with systemic institutional safety failures and inadequate safety cultures in more than a few federal and other laboratories. How can this overall situation with high containment laboratory safety in the nation not be high on the list of concerns when considering GOF research of concern?

It would be fair to conclude that the science we are discussing and the associated containment laboratory industry is young. There are a vast number of new laboratories and new researchers. Competition for money and career advancement is fierce. There is tension among these pressures and safety. Decisions to conduct risky research must acknowledge and find ways to address this reality. Time and

again we see that financial, mission and institutional pressures can negatively impact safety.

**6. The public is looking for a clear authority structure that governs the full scope of risky research.** We need an authority structure empowered to make health and safety decisions for the public good. Acting on behalf of public health and safety is a core function of government. That clear authority structure does not now exist, and the diffuse and overlapping authorities currently in place don't seem to adequately serve either science or the public.

Of course there is research that should not be conducted. Yes, we need both federal and institutional oversight. The public is looking for evidence of an effective and well functioning process that engenders confidence in both decision-making and the conduct of this work.

I am available to discuss approaches to engaging the public.

The following documents were mentioned during the panel discussion and are appended here as reference.

- Statement to the OSTP Listening Session on Select Agent Regulations on Science, Technology and National Security
- Comments on 2013 Office of Science and Technology Policy Proposed Policy on Dual Use Research of Concern
- Proposal for Establishing a Bio-Safety Facilities Safety Board

**Statement to the OSTP Listening Session on Select Agent Regulations on Science, Technology and National Security**

February 17, 2015

**From:** Beth Willis, Chair, Containment Laboratory Community Advisory Committee (CLCAC), Frederick, MD http://www.cityoffrederick.com/index.aspx?NID=127

and representing the National Coalition of Concerned Communities

To my knowledge this is the first time that members of the public who represent community concerns have been included in such a meeting. Communities are a vital part of this conversation and of the safety strategy.

The concerns of communities regarding high containment BSAT research conducted in our neighborhoods do not fit neatly into the topical structure of today's meeting or within the box of Select Agent Regulation. I invite everyone to think outside of the box, and the walls and fences of the laboratories when considering the public. There are many actions that need to be taken at a federal level in order to start including the public in the safety plan.

Supporting information and earlier submissions to OSTP and other federal decision-makers are attached.

The broad themes are: reduce the number of labs, greatly improve transparency and accountability, and guarantee community rights. We need to be able to reconcile the concerns of both researchers and communities.

1. Communities support proposed actions discussed in the August 16, 2014 memo Enhancing Biosafety and Biosecurity in the United States and the 12/16/14 FACT Sheet: Biosafety and Biosecurity in the United States. Making specific improvements to inventory control, training, culture of safety etc. are very important. But we highlight the following: taking a step back to evaluate the size, scope, purpose, risks and benefits of the entire BSAT program.

    a. <u>Formally addressing the number of BSL-3 and 4 laboratories now operating and planned.</u> This is of central importance and has been spoken of by many, including Dr. Frieden of the CDC.

    Our communities have been subjected to decisions about risk made by others, and at the same time our voices have been excluded. This has been done for what has been a significant growth industry since the anthrax letters of 2001, and in the absence of a rigorous national assessment of need and capacity to manage oversight effectively. (see attached open letters)

Open, formal, timely action on this, independent of vested interests, is long overdue and needs to occur on the near horizon. Yes, what is the minimal number of labs required? And even more to the point what are the requirements goals and objectives that need to be met, and how to they reconcile with available resources when considering other vital public health research needs?

We agree with the July 2014 editorial in the *Annals of Internal Medicine* which states "…greatly limiting the number of BSL-3 and BSL-4 laboratories would probably better enable us to ensure their safety. We must contain the terror within."

b. Confusion of authorities. Communities are well aware of the confusing and labyrinthine regulatory system that disperses executive, congressional and academic/corporate interests and authorities. The public also lives with that every day as we struggle to obtain safety information and work with the many players who operate and regulate labs in our neighborhoods. In particular, we are concerned by the apparent lack of federal authority to compel safety review actions in private and academic BSAT labs. We are deeply concerned about the lack of federal authority with regard to decisions about the efficacy and safety of some experiments. (see attached comments on DURC policy which largely applies to all BSAT research)

2. Why does the public matter? While this question may appear self evident, we do not find evidence of the public's important role reflected in policies or procedures. Here are a few reasons why the public is important in this conversation:

    a. Protection of the public's welfare is a core government function
    a. Lack of public trust can and has derailed projects
    b. Lack of public trust can negatively impact science over the long-term
    c. It can also harm reputations of both institutions and individuals
    d. Public engagement is a key part of the safety plan
    e. Scientific and government debates about the public's welfare won't work without the public's voice
    f. That public voice needs to be independent of the financial and professional interests of researchers and research institutions
    g. We live in a democracy

3. Transparency

    a. Public transparency about safety and safety performance is essential.

b. Lack of transparency results in profound public distrust, whether or not it is warranted.

c. Public transparency about safety throughout a facility's life cycle is important, from planning through decommissioning. The NEPA process is a limited and inadequate communication tool and clearly does not apply to every BSAT lab.

d. Fact-based safety performance information is most important. People most want to know how well equipment, lab designs, policies, procedures and training are actually working. People consistently state that they want fact-based evidence of safe performance.

e. Current federal law and regulation makes it very difficult to impossible for the public to obtain fact-based safety performance information. The public's right to know about safety is not guaranteed by law or public policy. It is impossible to obtain information about safety performance at academic and private BSAT labs. The public is not allowed to even know of their existence in our communities.

f. Currently federal policy consistently invokes national security in order to deny public access to a very wide swath of information. This effectively trumps public health and safety concerns making them subservient to anything labeled national security.

g. Each of the many government entities conducting or funding BSAT research has different cultures, rules, and chains of authority and transparency policies. This creates an extreme and highly tangled burden on communities seeking information.

h. This industry and federal regulators have not yet adopted standards for what safety information should be made publicly available, despite numerous recommendations about this made by the ABSA, the 2009 Transfederal Task Force, the journal *Nature* last July, those who testified before the House Energy and Commerce Committee last summer, and many others.

   The CLCAC, whose membership includes biosafety experts and safety metrics experts have also made numerous recommendations. (see attached) The public is in a no-win situation in the absence of federal policy. There are solutions that respect security and safety culture, but no action has been taken.

   We agree with the July 2014 editorial in *Nature* that authorities should require reporting of all serious accidents and near misses in

biocontainment labs. They go on to say "Timely incident reports should also be made available on public websites—as many nuclear regulators require of power plants—perhaps with an option for sharing details more-sensitive information confidentially."

i. Other industries with national security concerns have figured out ways to communicate safety performance to the public, even in situations involving highly technical information. The safety status of nuclear power plants is available online. Airline safety and accident records are available online. Citizens do not have to individually negotiate with each power plant or airline.

   But citizens DO have to individually negotiate with, make lengthy FOIA requests to or bring lawsuits to obtain safety information from any of the federal or 1500+ private/academic BSAT laboratories. These requests are all too often denied. This is an unacceptable situation for communities.

4. The impact of money on health and safety. Community concerns include:

   a. Sufficient money to keep safety, maintenance, adequate oversight and public engagement a first priority in an age of limited federal funding and competitive and profit-driven research. In the past year, safety and oversight failures have brought home this issue. Conversations with laboratory safety professionals, particularly in the smaller private labs have not been reassuring and reveal resource limitations, i.e. lack of money for adequate biosafety programs.

   b. There is particular concern about budgets for safety and maintenance over time, over the full life cycle of a facility.

   c. There is particular concern about the financial and professional drivers for research decisions trumping public interest. There is concern about inadequate legal authority and budgetary resources to conduct oversight of decision-making for risky experiments and the risk of unintended consequences stemming from technical and scientific hubris in the name of progress. (see attached)

   d. Engagement with the public costs time and money. It is not currently part of the cost of doing business and needs to be.

   e. It is important to distinguish among PR activities with local civic and business organizations, the terrific work some labs perform with schools etc., and the fraught efforts of communities to obtain factual information.

f. Laboratories impose financial burdens on communities, which are often dismissed. These include stretching medical resources, which may be entirely inadequate to address a laboratory-acquired infection, intentional malevolent release or more extensive public health event. There are financial burdens on hospitals, medical personnel, police, fire, first responder, public health and emergency management systems within communities. None of these public services are adequately compensated for the additional burden. Some communities are in financial distress and are already experiencing cuts to services. Some communities are not confident in the monitoring conducted by laboratories and feel obligated to invest in their own costly independent monitoring. Some communities have no medical personnel qualified to deal with the relevant pathogens, thus requiring a ramp up in training they are in no position to provide.

g. What is the federal responsibility to address these financial issues as a cost of building and operating or funding laboratories? This is also part of the cost of doing business that has not been addressed.

5. Community Roles and Rights. A short list of needed foundational actions:

a. Specific community concerns need to be included in industry standards for oversight and transparency. (see attached)

b. Legal and policy guarantees for community rights are essential. These rights include the right to information and the right to participation in decision-making that impacts the community. (see attached)

c. Accountability to the public on safety matters must be an embedded part of the cost of doing business.

d. Institutional structures that include public representation need to be the norm at every level, including mechanisms to ensure that information flows back to the public. Each community is unique with its own specific safety, geographical, demographic, and economic issues and concerns.

e. Barriers to community participation must be addressed and solutions institutionalized with commitment and resources. Barriers are technical, communication and a balance of power. Many members of the public are very well informed. But that takes more work than should be generally expected. The technical nature of this research creates a barrier for the public at large, which take time and effort to address.

f. The imbalance of power between research institutions and public interest needs to be reordered. In many locations there has been an adversarial relationship between large powerful institutions and communities that hold almost no power. This benefits no one.

g. There needs to be priority on public health, which includes actually addressing specific public concerns in communities.

6. Other

a. Communities have concerns about the adequacy of risk assessments in this industry. The National Research Council and others have verified these concerns.

b. There is concern that current biosecurity risks are not adequately communicated to all of the laboratories, particularly to the large number of private and academic labs sited throughout the country.

c. There are concerns about reports of extreme difficulty in diagnosing LAI's, when researchers are unaware they have been exposed and particularly with researchers in private and academic BSAT laboratories. How can this be addressed? This is a first line public health issue.

**Attachment 1. Examples of Safety Performance Information suggested/sought by the CLCAC and others:**

1. Executive summaries of regulatory and oversight reviews, such as from the CDC, USDA….

2. Listings posted of what external entities do oversight on what schedule.

3. Metrics related to 1) employee biosafety operational performance; 2) facility biosafety system maintenance and performance; and 3) biosecurity performance. Metrics should include both lagging indicators (e.g. performance outcomes), as well as leading indicators (e.g. precursor events, near-misses etc.).

4. For reported incidents:

    - Indicate threshold for an incident to be reportable to CDC and other agencies.

    - Indicate how many incidents were reportable to CDC and other agencies in specific time period.

5. Provide sample incident reports, so that community can better understand those evaluations. Better yet, provide the incident reports on all accidents and mishaps.

6. Post information on required corrective actions from oversight reports, and their closeout. Include issues of some consequence, not long lists of minor / administrative matters.

7. Provide information from Institutional Biosafety Committees, including

    - IBC rosters
    - Committee composition
    - Qualifications of all members
    - Agendas
    - Decisional documents
    - Electronic communication concerning the INC or its activities
    - Rules/Procedures under which the IBC operates
    - Written records
    - Processes
    - Meeting information
    - Minutes

**Attachment 2: Letter from Members of the Public to Congress on High Containment Laboratories, July 2014**

**Attachment 3: Comments on 2013 OSTP proposed policy on DURC, April 2013**. Comments are largely applicable to all BSAT research

**Attachment 4: Open Letter to Biodefense Decision-makers, from National Coalition of Concerned Communities, April 2012.**

**Attachment 5: Proposal for establishing a Bio-Safety Facilities Safety Board to address independent oversight issues.** First submitted to Members of Congress, by communities, in 2008

## Comments on

## 2013 Office of Science and Technology Policy Proposed Policy on

## Dual Use Research of Concern

The Office of Science and Technology Policy (OSTP) has requested public comment for its policy on Dual Use Research of Concern (DURC). The following comments reflect concerns from members of the public who live in proximity to laboratories across the U.S. where DURC is conducted.

We have particular concern about the adequacy of the DURC policy, given the March 2013 Government Accountability Office (GAO) report that cites lack of adequate federal oversight of high containment laboratories and the need for a comprehensive national assessment of research needs:
http://www.gao.gov/products/GAO-13-466R

This is coupled with the call for a moratorium on Gain of Function (GOF) research of all types, as published in Nature on March 27th: http://www.nature.com/news/h5n1-viral-engineering-dangers-will-not-go-away-1.12677

And the related concerns expressed by the Foundation for Vaccine Research (FVR), as further reported by the Center for Infectious Disease Research and Policy (CIDRAP):
http://www.cidrap.umn.edu/cidrap/content/influenza/avianflu/news/mar2913ethics.html

These recent reports and statement make clear the need for a DURC policy that ensures the engagement of communities, elected officials and a much broader scientific consensus when considering risk, and the appropriateness of DURC. While we understand that DURC and GOF research are not identical, they overlap and are interconnected issues.

We join the FVR in calling for a moratorium on such research until the safety and ethical issues are resolved.

This research occurs in laboratories in our communities. We were not consulted when decisions were made to conduct this research in our neighborhoods.

- **Overall concern:**

We represent citizen groups from many localities throughout the U.S. who have specific health, safety and environmental concerns about the presence of advanced biodefense laboratory research in our neighborhoods and cities**.** In each of our communities, we have found that environmental impacts and hazards associated

with these labs have not been analyzed with thoroughness, clarity and scientific rigor. Additionally, there has been inadequate community input to the planning and design of risk assessments, resulting in assessments that do not reflect community concerns. That concern is much greater as we consider risk assessments associated with DURC.

Transparency is a prerequisite for effective oversight, for establishing trust with communities and with others who may not trust the intentions of the United States. It is important in relation to Biological Weapons Convention. Yet the work conducted in U.S. biodefense labs is not transparent, and nothing in the proposed DURC policy suggests increasing transparency, even for unclassified research.

Despite great effort, community groups have been unable to obtain vital information about what is actually happening or planned for laboratories in our communities. Security concerns are used as an excuse to inappropriately restrict citizen access to reports of ongoing or planned studies. Freedom of Information Act requests about accidents and the minutes of Institutional Biosafety Committee meetings are routinely denied. We are concerned that nothing in the proposed DURC policy addresses these issues.

- **Defining acceptable risks.**

  "Low-probability" but "high-consequence" accidents that could result in a public health disaster in our communities are of great concern. Who decides what is an acceptable level of risk? Should an academic institution, a corporation, or a federal agency decide what is acceptable risk for the at-risk citizens?

  These high consequence, low probability events have a high probability of fatal outcome and require more isolation than what can be obtained in residential areas. Just because an event 'hasn't happened before' is not scientific reason for assuming that it is safe to proceed.

- **Poor research agenda oversight.**

  The research agenda of U.S. biodefense programs has also expanded greatly in the wake of the 2001 anthrax letters. Nothing in the proposed DURC policy addresses the question of who sets priorities for risky biodefense research.

  **Oversight of Research Proposals.** The 2012 policy and the 2013 proposed DURC policy update, speak to detailed procedures for submitting research plans, risk assessments and risk mitigation plans. Decision-making authority is alluded to but not made explicit.

  Given the extreme difficulty and confusion of authority and process in evidence from the international debate about ongoing H5N1 and other Gain

of Function (GOF) research, the undersigned members of the public believe it is imperative that there be a clear and open process by which decisions are made regarding the safety and appropriateness of proposed DURC. Important questions include:

a. Who exactly is authorized to decide if DURC is too risky?
b. By what criteria?
c. What is the scope of that authority?
d. Who is authorized to decide if the risk assessment and risk mitigation plan is adequate?
e. Who determines if the safety record of the researchers / institution warrants approval?

**Scope-** Does this policy extend to private labs? It needs to. That is not clear.

- **Transparency.**

Transparency is the key component to compliance with the Biological Weapons Convention, and is cited as critical by the GAO, the 2009 Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, and others.

**Yet transparency with communities is missing from this policy.**
Communities have the right to know about risk and risk mitigation for research being conducted in their midst. It is not acceptable to say that no information can be made public because public release of all information may not be appropriate from a security perspective. Increased secrecy breeds increased mistrust locally and abroad. Yes, the public should be told, for example, if H5N1 research or GOF research is being conducted locally.

The public should be told:

a. Who approved the research,
b. What, the risks are,
c. Who decided the risk analysis was sufficient,
d. What has been done to mitigate the risks,
e. How to provide input in a timely manner and how to track the ways in which their participation has been considered and influenced decisions.

This can all certainly be accomplished at an appropriate level of specificity to ensure that security concerns are not compromised.

- **Classified research**.

The policy appears to say that the remedy for research risks that are not adequately mitigated is to make the research classified. Making the research

classified makes it a secret; it does nothing to protect from accidental release, LAI's or malevolent intent. This approach decreases transparency. We find this solution to risks that cannot be mitigated appallingly inappropriate. Such research should be banned. The federal government should exert authority in ensuring it is banned.

- **Biological Weapons Convention (BWC)**

  How does this policy address BWC requirements? That is not clear.

- **Institutional Procedures for DURC.**

  **We fully support** making procedures for reviewing DURC accessible to the public.

- **Role of a coherent federal oversight mechanism and decision-making process.**

  The fragmented federal approach to oversight and decision-making on matters of critical health and safety is apparent in this policy. In addition, this fragmented approach disenfranchises communities with concerns about the research being conducted in its midst. The recommendations in the 2013 GAO report are relevant here, and we specifically ask that the report be considered as part of our comment, along with the Nature article and the statement by the FVR cited earlier. Moreover, OSTP's assertion that oversight and needs assessments for research have been adequately addressed are not supported by this policy, even accounting for DURC being a subset of what the GAO was addressing.

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# Proposal for Establishing
# a Bio-Safety Facilities Safety Board (BFSB)

A Bio-Safety Facilities Safety Board (BFSB) would be authorized to assist Congress in public health and safety oversight of bio-safety facilities that work with select agents and other pathogens such as SARS, that represent a risk to public health. This board would be independent of agencies currently planning for and/or operating bio-safety facilities. The board would have access to all documentation dealing with safety and would conduct on site reviews as necessary to assure that there is no undue risk to the health and safety of the work force and the public. Findings and recommendations resulting from these reviews would be provided to Congress and the applicable executive branch agencies for appropriate action. BFSB reviews would seek public input and all findings and recommendations and the corrective plans would be available to the public.

Members of the board would be approved by Congress. The current National Science Advisory Board for Bio-security (NSABB) is not affected by this action and there is no intended overlap in responsibilities between these two entities. The BFSB would perform the same functions for Congress on oversight of bio-safety facilities as the Defense Nuclear Facility Safety Board established in 1988 does for the defense nuclear facilities.

**Background: The Defense Nuclear Facility Safety Board** (DNFSB) (http://www.dnfsb.gov/) was created by Congress rather swiftly in 1988, at the height of the Rocky Flats crisis. While circumstances are not identical to the bio-defense labs, there are a number of lessons to be learned from the nuclear weapons complex environmental and safety crises. It should also be noted that the Department of Homeland Security has endeavored to model the bio-defense lab system on the DOE National Laboratory system.

**An important point in parallel**: The safety and environmental disasters associated with the nuclear weapons complex came about at least in part because of a cold war political climate that valued swift progress in service of weapons production over safety. The resulting history of devastating environmental and human health consequences is well known, at Rocky Flats, Hanford, Paducah and many other locations around the country. Some of these sites are shockingly close to major population centers such as Denver and San Francisco.

The past thirteen years has found the nation in a similar political climate, with a similar safety culture with regard to the proliferation of laboratories conducting research and development (R & D) with bio-warfare pathogens. This culture is further complicated by the extraordinary private sector economic stakes involved in bio-defense R & D programs. Clearly a Bio- Safety Facilities Safety Board would need to provide oversight of academic and private sector facilities as well.

**How does the Defense Nuclear Facilities Safety Board function?** The DNFSB created a methodology for safety programs and safety reviews. It is empowered to make safety

recommendations that both Federal and contractor entities are required to respond to; corrective action is taken, including operational stand-down, if warranted.

The DNFSB reports to Congress quarterly. While no one mechanism can make the nuclear weapons facilities perfectly safe, the DNFSB has by all accounts significantly improved safety and oversight within the nuclear weapons complex. The DNFSB has also been used as the operating model for a number of other powerful boards providing oversight for other DOE programs and labs. The DNFSB includes scientists who also often work with the National Academy of Sciences.

**Relationship of a Bio-Safety Facilities Safety Board to the NSABB. The** National Science Advisory Board on Biosecurity (NSABB) has been in place for several years, but has a different charter from what is being proposed here. (http://www.biosecurityboard.gov/ ) The NSABB makes recommendations re: dual use research for all life science research. This does not appear to be an overlap. NSABB recommendations would presumably be used by the Bio-Defense Facilities Safety Board in conducting its reviews.

**In summary, the new Bio-Safety Facilities Safety Board would focus on:**

- evaluating and improving actual safety performance across all funding sources from all Federal agencies, and

- reporting to Congress and to the public.

- independent, transparent, safety oriented accountability by researchers, laboratories and funding agencies.

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