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Education and Outreach in the Life Sciences - Qualitative Analysis Report

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October 2008

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Pacific Northwest National Laboratory
Richland, Washington 99352

Contents

1.0 Introduction

Rapid developments in biotechnology and the life sciences bring significant benefits, but also create new security challenges. In recent years, members of the scientific and security policy communities have raised concerns about the potential for misuse of knowledge, tools, and techniques for purposes of bioterrorism. Such research is sometimes called "dual-use" research because, although the research is intended for beneficial purposes only, it could be misapplied. The role of scientists, institutions, scientific societies, and the government is critical in fostering an environment that enhances both the scientific enterprise and national security.

In 2004, the U.S. government established the National Science Advisory Board on Biosecurity (NSABB) under the auspices of the National Institutes of Health to contemplate the possibility and impact of greater oversight for life sciences research to prevent or mitigate deliberate misuse. Similarly, the U.S. Department of Energy (DOE) is considering how to respond to emerging issues of concern related to dual-use. Other Federal agencies are planning to issue further guidelines and considering additional policies regarding responsible scientific research. Discussion sessions on this topic were also conducted by PNNL for the DOE's Office of International Regimes and Agreements (NA-243) at nine of the national laboratories in Fall 2006.

The DOE's National Nuclear Security Agency (NNSA) asked Pacific Northwest National Laboratory (PNNL) to consider the role of individual scientists in upholding safety and security. The views of scientists were identified as being a critical component of this policy process. Therefore, scientists, managers, and representatives of Institutional Biosafety Committees (IBCs) at the national labs were invited to participate in a brief survey that was designed to:

- Evaluate the function of the 2006 outreach and education seminars that were conducted by the U.S. DOE.
- Assess the opinions of scientists about potential future mechanisms to address dual-use concerns in the life sciences community.
- Gather data on scientists' attitudes toward potential security risks from agricultural, public health, and biomedical research.
- Give scientists a voice in the policy-making process.

In addition, three focus groups were conducted with scientists, managers, and IBC representatives to discuss some of the questions related to education, outreach, and codes of conduct in further detail and gather additional input on biosecurity and dual-use awareness at the laboratories. The overall purpose of this process was to identify concerns related to these topics and to gather suggestions for creating an environment where both the scientific enterprise and national security are enhanced.

The information gathered through the survey and focus groups will be instrumental in informing the U.S. position at the Biological Weapons Convention (BWC) Experts' Group meeting in August 2008, as well as to move toward a sustainable mechanism for biosecurity education and awareness. It will also guide DOE action in developing educational tools that will help promote a laboratory culture of responsibility.

2.0 Methods

The PNNL Project Director sent an e-mail invitation to individuals who participated in the 2006 training and other points of contact at each of the national laboratories (N=202). Of these, 173 were delivered and 29 were returned undeliverable. This e-mail introduced the purpose of the focus groups and invited individuals to participate. Separate times were established for managers, scientists, and IBC representatives. Each of these groups was offered a choice of times, and the date and time that was convenient for the majority of individual participants was selected for each of the three groups.

Additional follow-up e-mails were sent to points of contact at each of the laboratories to encourage participation. The following table summarizes the final focus group participation.

Focus Group Type	Date	# of Participants	Labs Represented
Scientists	June 11, 2008	5	Brookhaven, Los Alamos, Oak Ridge, PNNL
Managers	June 12, 2008	5	Idaho, Los Alamos, NREL, PNNL
IBC representatives	June 18, 2008	5	Berkeley, Los Alamos, Oak Ridge, Sandia

In addition, comments provided by three individuals who were not available to attend the IBC focus group were integrated into the analysis.

3.0 Results

Results of the focus groups are presented below. We begin by describing the apparent level of awareness of dual-use risk and the perceived need for increased awareness and/or training. Next, we describe concerns raised by participants regarding current developments related to dual-use guidelines, education and awareness training, and codes of conduct. Finally, we present participants' perceptions of the usefulness of training materials as well as recommendations for the format and delivery of these materials. A copy of the focus group moderator's guide used to conduct these groups is found in Appendix A.

3.1 Awareness of Dual-Use Risk

Focus group participants were asked about their awareness of dual-use risk and the risk they perceived in the work they conducted themselves or in their own workgroup (Section 3.1.1). Respondents were also asked for their opinions as to what constitutes being a "responsible scientist" when dual use is a possibility (Section 3.1.2). Finally, they were asked for their perspectives on groups (Section 3.1.3) or scientific disciplines (Section 3.1.4) that may require a heightened level of awareness.

3.1.1 Current Level of Awareness

The current level of awareness varies among individuals in differnet areas of the life sciences. Individuals perceived to have the greatest awareness of the issues were generally seen as those who worked with select agents or pathogens and also those with higher levels of security clearance. In addition, those working for national security clients such as the Department of Homeland Security were also seen as having higher levels of awareness. The reasons for that higher awareness were related to both

considerations of higher risk for dual use associated with that type of research, as well as increased regulations and procedures in place for individuals conducting projects in those areas. This was a common perception across all three groups.

Other scientists working in the life sciences in the national laboratories – for example, those working with organisms at BSL-2 level or below, those who worked on NIH-funded projects, and those who conducted more "fundamental" or basic science research – were seen as generally aware of the potential for dual use or misuse of research, but were not driven by this consideration in conducting their own work. As one manager noted, *"If you had somebody that's really focused on understanding an environmental organism that's related to biomediation, their head is in that space. It's not necessarily focused on how somebody could use the research they're doing and applying it to a biothreat agent."* It was also stated that " scientists may be intellectually aware of dual-use issues, but they do not necessarily connect these issues to their research on a day-to-day basis." Reasons for this lower level of awareness were generally seen as due to the lower level of potential for dual use inherent in the research and the belief that you cannot guard against all possible risk. General awareness was driven by cases where research methods and/or results were published in scientific or popular media rather than by examples from scientists' own work. Scientists in particular believed that while *"there is always the potential for misuse,"* there are safety measures in place to mitigate these risks. Most scientists do not see security as a central focus of their work.

Scientists also made this distinction about the risks inherent in their own work. Those working below BSL-2 tended to see their own research as having *"minimal"* risk related to dual use. A few mentioned the potential for misuse, but did not feel that it could be a widespread use. Those working with select agents or pathogens felt that risks may exist, but these were mitigated by following safety practices, legal guidelines, and client requirements regarding information sharing. Scientists in this category required permits to obtain certain organisms, had institutional- and client-level review procedures for dual-use considerations, and (depending on the client), limited distribution and publication of some research.

Across focus groups, the lowest general level of awareness was considered to be in individuals working in the academic sector, while scientists working in the national laboratories were considered to have a generally high level of awareness. . University researchers were seen as having fewer regulations placed on the types of work they could conduct. Participants across the focus groups also noted that publications are a significant driver of academic research, and that academic researchers would resist dual-use reviews or other activities that could be a potential hindrance to publication.

3.1.2 Being a "Responsible Scientist" When Dual-Use Considerations Exist

Focus group participants believed that there was a "shared responsibility system" in the national laboratories. A number of individuals and organizations reviews are responsible for safety and security, including the Principal Investigator (PI) who reviews the research direction, project managers and line managers that approve of proposals, the Institutional Biosafety Committee (and biosafety officer), Institutional Review Boards (IRBs) that consider legal and regulatory requirements, and the authorized derivative classifer (ADC). When considering classification prior to release of research methods or findings, the ADC has a responsibility to consider dual use.These and other institutional controls help ensure that inappropriate material is not released or inappropriate research planned.

In project planning, managers believed it was the role of the PI to understand the potential for dual use in the project and modify experiments to mitigate the potential risk. However, it was noted that the PI should also have the project reviewed by the IBC to assess potential dual-use risk, and obtain approval to proceed with the research, rather than making an independent determination. Additionally, the Scientist group

thought that PIs have a responsibility to use common sense and not disclose inappropriate information, even to other scientists during discussions or at scientific conferences.

Scientists in particular believed that their institution had a responsibility to set up clear policies and procedures to assist them in understanding where the line was in pursuing research with dual-use potential. Most believed that their institutions had adequate protections in place and that the majority of researchers were responsible and would not release inappropriate materials. However, managers warned about over-reliance by PIs and others in the laboratory on the organizational systems, reviews, and protections that are in place. It was considered that there was potential for high variability in assessing dual-use risk, and that reviewers may need reminders to conduct their reviews based on dual-use considerations. This perspective is given credence by the view of one IBC member, who noted that other than for select agent work, *"I don't even think that we consider dual use even in IBC meetings, unless it's really so obvious. Everybody understands that in any laboratory, in any facility, any protocol can be misused or abused if the intention is there. That's a given in life sciences…"* A significant challenge is that there is no clear line that delineates research of concern. Some research clearly has high-risk; some clearly has low risk. However, the majority of research falls somewhere in the middle – where that research has clear benefit, but could be misused by an individual with malicious intent – and so it is difficult to identify the risk posed from that research.

Managers noted that gaps that may stem from variability in individual judgement are mitigated by defense-in-depth -- having redundant systems for review by individuals and committees.

A further example of defense-in-depth is in safeguards, based on editorial board policies for reviewers and submitters to consider dual-use considerations, that have been built into the publication system However, participants admit that these procedures are sometimes inadequate and allow for some publications that one IBC member *"wondered how they got through the review gauntlet without somebody raising a red flag."*

A significant minority of individuals in each group believed that there should not be excessive restrictions on sharing information and publications due to dual-use considerations except for the most extreme examples. Several related reasons for this view were put forth:

- Research is happening on an international basis outside of the national security system and cannot be stopped.
- Much of the potential dual-use research also has beneficial aims.
- It is better to use technological solutions to keep ahead of the risk rather than assuming that the release of information can be prevented.
- A nuclear model for nonproliferation is inadequate to the life sciences because there are so many "gray areas" where there is a potential for misuse, but also the potential for great advances.
- Restricting publication just leads to the duplication of effort by other credible laboratories and a waste of resources.

3.1.3 Perspectives on Who Should Be Aware

Managers and scientists relied on the IBC and ADCs to be aware of dual-use issues and thought that individual with these responsibilities needed to be explicitly aware of dual-use concerns. All the groups thought it would be valuable to provide some formal training on dual-use research of concern to IBC members. IBC participants also thought that additional awareness for IBC members would be valuable to

ensure that all members (especially new members) were fully cognizant of dual-use when reviewing projects. IBCs were further seen as having an important role to play in ensuring wide-spread education of scientists in the lab. IBC participants thought it would be helpful for project managers to be aware of these issues since they give final approval for proposals. Other audiences mentioned as needing additional awareness and education included: the public, students, foreign nationals, and technicians.

None of the groups saw a particular need to provide explicit training to junior scientists versus senior scientists on these issues. All groups saw that some senior scientists in their institutions were not aware of these issues and could use additional awareness, while some more junior scientists working on higher risk research might be aware already. However, as a caveat, several managers did think that additional experience could help junior scientists in determining what constituted a dual-use concern and what did not. In addition, some managers saw a need for increased awareness for scientists working on NIH-funded research versus those with national security clients who already have greater awareness.

3.1.4 Perspectives on Which Areas/Disciplines Should Be Aware

In terms of risk relating specifically to one scientific discipline or another, participants saw that life science work was becoming increasingly interdisciplinary. While experimental biologists may already have some level of awareness of these issues; additional awareness of dual-use concerns may be needed by, *inter alia*, mathematical modelers, physical modelers, material scientists, and those working in nanotechnology. As noted earlier, participants believed that awareness was critical for those who work in the area of select agents and biodefense countermeasures and detection – however a high level of awareness may already exist for these groups.

3.2 Need for Increased Awareness and/or Training

Participants were asked about factors that have influenced current levels of awareness in their laboratories, including changes in the level of awareness over time (Section 3.2.1), as well as their perceptions about additional training needs (Section 3.2.2).

3.2.1 Factors that Influence Current Levels of Awareness

Most groups were fairly evenly split between those who saw that awareness had increased in their laboratory in the last few years versus those who thought that awareness had not changed much recently. Factors accounting for increased awareness noted across the three groups are noted in Table 1. Drivers for increased awareness and discussion include: the training held by PNNL, issues in the news, (increased but now waning interest after 9/11 and the anthrax attacks), client-driven requirements for proposals or project review, and review of projects by IBCs.

As noted earlier, however, the level of awareness shown by different individuals depends on the types of research they conduct. Factors that contributed to lower levels of awareness included: working on research perceived as less risky, lack of consensus around what constitutes a dual-use concern, lack of technical expertise to be able to identify a dual-use issue, and lack of interest (particularly among academic researchers) who do not want publication restrictions. IBC members commented that one should not expect the same level of awareness between researchers working with select agents as researchers working with cancer, for example. Scientists also noted that, while increased IBC oversight occasions some restrictions on the types of work they can do, it generally only involves changes in the paperwork and planning requirements rather than the nature of the research itself.

Table 1. Factors that influence changes in awareness across focus groups

	Managers	IBC	Scientist
PNNL training/brown bag held in 2006	✓	✓	✓
Issues in the popular media or publications of concern	✓	✓	
Increased awareness after 9/11 and anthrax attack		✓	
Discussion around proposals with such requirements		✓	✓
Awareness due to client directive and regulations		✓	✓
Local incident of anthrax found at the laboratory		✓	
Awareness after creation of IBC			✓
Awareness due to teaching of classes on related topics			✓

3.2.2 Perceived Need for Additional Awareness and/or Training to Inform Scientists of Risks

Focus group participants were mixed in their perceptions of the need for additional awareness and/or training for scientists in the life sciences. IBC members and managers generally saw a value in additional awareness for most scientists. However, they saw this as generally working best through a tiered system that would offer introductory information to scientists working in less risky areas, and more extensive training for those conducting more risky research, such as with select agents. Those working with select agents may already have a level of basis awareness, so training should focus on specific topics or areas of interest, such as the Biological Weapons Convention, as well as on applied examples and case studies.

Scientists, on the other hand, were more mixed in their views about the need for further training or higher levels of awareness. Some thought that heightened awareness could be valuable for those who do not consider dual-use on a daily basis. However, others believe that sufficient information and protections are available to those who need them in the form of existing safety guidelines, and that additional awareness or formal training is not needed.

Focus group participants observed that additional training may be valuable for the following groups:

- *Institutional Biosafety Committees.* IBCs could benefit from additional training to ensure that members (both old and new) are taking dual-use issues into consideration when conducting reviews. IBCs should also be made aware of changing regulations and guidelines in this field, such as codes of conduct and NSABB guidelines for dual-use research of concern. .
- *Trainees and interns.* These types of individuals are given training in proper laboratory procedures but are rarely provided with a broader rationale behind the work they are conducting. Giving them additional information about dual-use concerns may be a helpful building block as they complete their degrees and move into careers in science.
- *Security officers.* Security officers could play a greater role in preventing inappropriate release of information. However, most are trained in physical sciences and do not have the background to fully understand dual-use concerns in the life sciences.
- *Authorized Derivative Classifers.* As with IBCs, ADCs can serve as a valuable safety net to ensure that inappropriate content is not published. ADCs primarily review work for classification issues, so may need additional training on dual use; however, many will be knowledgeable about these issues.

- *Foreign nationals.* There are restrictions on the type of information and training that can be provided to foreign nationals (as opposed to U.S. citizens) in the national laboratories. In a security clearance environment, this puts restrictions on the amount of information that can be provided about dual use without revealing classified information.
- *Project managers and higher level managers.* These individuals have the responsibility for approving new proposals. It would be valuable for them to consider dual-use concerns as they review proposals.
- *Universities.* Universities may need education and training about the dual use risks of research. Academic researchers have a responsibility for training future researchers, yet they are in general less aware of dual-use issues than are researchers in the national laboratories. Introducing students to these concepts while still in school can reduce their learning curve as new researchers.

3.3 Concerns in Scientific Community Regarding Current Developments

Focus group participants expressed concerns about some of the current developments related to dual-use and biosecurity concerns. The National Science Advisory Board for Biosecurity (NSABB), a Federal advisory panel for NIH, is developing a sample code of conduct related to these types of issues. The document is fairly generally focused, and intended to be put forward as a sample code that organizations can adopt if desired, focus group participants had some reservations about putting forward such a document as well as future implications of the development of such a standard. This code is still in draft form.

A common theme across focus groups was that a *mandated* code of conduct or set of guidelines related to dual use would be negative. Depending on how such a code would be implemented, it would tend to impose unneeded and inappropriate regulations on many projects that do not warrant it and would tend to constrain science unnecessarily. As an IBC member noted, *"I think we are all concerned about stifling good science by mandating something that becomes too restrictive."*

Focus group participants had varying reactions to *voluntary* guidelines or codes of conduct. Some participants across groups believed that additional guidance and consensus about what constitutes dual use would be valuable as a clarification for researchers. If such guidance were included in RFPs, it would enable researchers to understand the review criteria by which dual-use concerns would be judged. Additional guidance would encourage greater consistency in identifying the types of research that constitute a dual-use concern versus those where dual use is not of great concern. Voluntary adherence to guidelines could be viewed as a competitive advantage for national laboratories versus university researchers if they were seen as adhering to a higher standard of conduct for certain types of research. Guidelines could also tend to engender a culture of responsibility.

While the all groups saw general benefit in voluntary guidelines, there was an almost universal concern that even voluntary standards could become a slippery slope that would lead to more restrictions in the form of additional policies, procedures, or training that would not be needed by all groups equally. Some theorized that such guidance could also eventually lead to increased regulations such as by the Department of Defense or NNSA and thus become a mandate. As one manager noted, *"The devil is in the details of implementation."* Scientists also were concerned about whether it would be possible to develop one set of standards that could adequately address all situations. A minority of scientists believed a code of conduct was not needed at all for the life sciences and for the national laboratories. These scientists

saw a more critical need for this in other science fields, such as chemistry, where the potential for misuse of research was perceived as greater or in other settings, such as universities.

3.4 Training Materials

Focus group participants were specifically asked for their opinions related to the development of training materials (Section 3.4.1), the format and content of such materials (Section 3.4.2), organizations that would be credible to develop such material (Section 3.4.3), and whether such materials would be used if they were made available (Section 3.4.4).

3.4.1 Usefulness of Training Materials Focusing on BWC, Dual-Use, and Scientific Ethics

As noted in Section 3.2.2, focus group participants found that additional training and materials related to the Biological Weapons Convention, dual-use, and scientific ethics could be useful for various groups in the laboratory. Across focus groups, participants agreed that the PNNL training conducted in 2006 was the only training they have received at the laboratory specifically focused on these topics. In terms of specific content, participants noted that they would like to see examples of what is considered dual use, that there should be opportunities for discussion and questions, that content should change over time so that it remains relevant to training participants, and that different types of complementary training may be needed for different types of staff.

3.4.2 Best and Most Useful Format for Such Training Materials

Focus group participants did not have one consensus recommendation for the best format for training materials. Instead they noted several related types of training formats that might be valuable to institute in the national laboratories, as shown in Table 2. The two most frequently recommended formats were web-based training included in existing annual training, training as a stand-alone module or as a webinar and/or in-person sessions, such as through brown bags. Participants saw these as potentially complementary methods. Web-based training has broad reach and can serve to raise awareness. The amount of training or content of training could also be tiered to group needs. However, participants were concerned that it might have low impact and that it might not be equally effective for those less familiar with dual-use issues (such as trainees or some managers).

In-person trainings are seen as valuable to staff who need a more in-depth awareness of dual-use issues. They also serve as a forum for discussion and interaction around dual use. In-person trainings are seen as particularly valuable for training small groups that require specialized information, such as IBC members, ADCs, biosafety officers, and project managers. However, they could also be used for general training purposes. Potential barriers to this approach included the facts that it may not reach all staff that need it and that such trainings were logistically difficult to schedule.

Additional mechanisms to raise awareness were also mentioned by focus group participants. These included:

- *Brown Bags.* Incorporating dual use as a topic in an existing brown bag series for staff such as those conducted by the project manager or NIH officer.

- *Institutional Biosafety Committees.* Provide educational material to help IBCs educate scientists about dual-use concerns in their research and any future changes to requirements or policies.
- *Inclusion in Requests for Proposals (RFPs).* Inclusion of dual-use considerations in NIH-sponsored research was seen as a valuable way to bring these issues to greater prominence among researchers who are currently less aware.
- *Guidance websites.* Provide resources for staff to self-education. This could include directing staff to websites from existing groups such as NSABB.
- *Culture change.* Pursuing long-term cultural change where dual-use considerations are simply part of the way of doing business in the laboratory. The value of this concept was discussed in several groups. As one IBC member noted, *"To me, culture change means getting out of that mentality [of only doing what is required] to one where just as a normal course of doing business as a scientist I will consider these issues."*

Table 2. Training formats suggested by focus group participants

Training Format	Audience(s)	Potential Benefits	Potential Negatives	Managers	IBC	Scientists
Incorporated into existing annual web-based training (e.g., safety training, ethics training, newcomer orientation, etc.)	All relevant staff – content might be tiered by BSL level or other criteria; off-site staff; also appropriate for students/trainees	Existing requirement so it will be done; easy to incorporate additional information; broad reach	Staff don't retain information; quizzes for comprehension are generally easy to pass; not interactive; for ethics training this is offered to all staff not just those in the life sciences so it may not seem relevant to all.	✓	✓	✓
Stand-alone web-based module	Targeted to new staff or those who need more in-depth knowledge on the topic, such as IBC members	Possibility for more in-depth presentation of information; not everyone needs to receive it; content can be tailored to different groups; less resource-intensive than sending people to off-site training	Staff don't retain information; quizzes for comprehension are generally easy to pass; if voluntary, people will not complete it; logistic difficulty in knowing which staff have completed it and conveying information to the training coordinator; not interactive	✓	✓	✓
DVD presentation that takes participants through a dual-use scenario		Gaining consensus on the content would be a helpful clarification on what constitutes dual use		✓		
Brown Bag/ in-person sessions	Could be targeted to all relevant staff; Could be held for IBC members specifically; specific to managers; ADC; biosafety officer	Allows for discussion; encourages interaction around dual use; may be incorporated into an existing series of discussions and offered by on-site staff	Logistics difficult to coordinate; may not have a broad reach; could create difficulties if people with different clearance statuses are present	✓	✓	✓
Webinars	Could be targeted to all relevant staff	Seen as a good way to present information as well as provide a discussion forum; conducted to geographically dispersed population			✓	
Hands-on training	Students/interns	Helps to retain information; responsibility of PI or mentors to conduct; if they learn it as students they are prepared as new researchers	Trainees may lack context for dual-use training because they are focused on methods			✓

In discussing training content: participants across groups recommended case studies as useful content to include in a training session. They could be included in either web-based approaches or in-person sessions. Participants suggested giving both extreme examples as well as more borderline examples. One approach suggested was to have readers score an article that has been flagged as potentially problematic by NSABB or other Federal agencies for dual-use concerns and have a discussion about the issues raised. Other suggestions related to training content and how it is conveyed included:

- Ensure that both the positive aspects of dual-use research are discussed as well as the potential negatives of such research.
- Ensure that researchers understand why dual-use concerns are relevant to their work and what the impact of inappropriate disclosure is or could be.
- Ensure that the content has personal relevance to the researcher and is not repeated every year.
- IBCs need knowledge of what to look for in regards to dual use – including guidance in discerning which issues are really of concern.

3.4.3 Organizations Considered Appropriate to Develop and Deliver Such Training Materials

Focus group participants did not have strong opinions about which organizations could develop and deliver training material. They did, however, believe that it would be better to have centrally developed content that would be consistent across the national laboratories (or potentially even to university audiences) rather than having each institution independently develop content on this subject. Content developed and delivered by PNNL staff would be acceptable.

In addition, participants noted that content developed by NSABB or NIH would be valuable to IBCs as supplementary guidance on how they should review dual-use concerns. In addition, ensuring that training materials were developed consistently with emerging NIH guidance would help staff to understand that the laboratories were in compliance and what the emerging scientific consensus was related to dual use and biosecurity considerations.

3.4.4 Likelihood That Materials Would Be Used If Developed

Focus group participants across groups thought that, if training were not mandatory in some way, then the likelihood individual researchers would self-educate would be used would be low. As one IBC member suggested, *"with all of the constraints on the investigators' time, they're not going to take it unless there really is a personal interest or a requirement to do so."* Suggestions for making it mandatory included including it in institutional requirements, such as a requirement of IBC review or in mandatory annual refresher trainings. Other suggestions included making it a requirement of funding from NIH rather than an institutional requirement similar to human subjects review certification requirements. The two types of requirements could also be tied, since if NIH makes it a requirement for scientists, then the institutions will have to find a way to comply.

4.0 Conclusions and Recommendations

4.1 Current Levels of Awareness

Based on the focus group responses, staff in the national laboratories have varying levels of awareness of dual-use and biosecurity considerations. A primary driver of awareness is the type of research conducted and whether it is considered to be of low risk or of high risk. While participants acknowledge the risks inherent in almost all types of life science research, in the absence of clear guidance and consensus in the scientific community about what actually constitutes dual-use research of concern, participants tend to be more concerned about security concerns in circumstances where the potential for dual use is clear cut (e.g., select agent research) and where regulations and protections are already in place. In most other circumstances, they tend to see dual-use considerations as of minor concern; in these cases, greater importance is placed on furthering science and sharing research.

4.2 Need for Increased Awareness

Focus group respondents identified a number of groups that could benefit from greater awareness of dual-use and biosecurity considerations and/or more training on more in-depth topics of related interest. Groups included scientists at the national laboratories, other individuals conducting research, including technicians and students; those involved in the review process, including IBCs, ADCs, biosafety officers, and managers; and the general public. The need for broader awareness of dual-use issues is highlighted by increased attention paid by Federal agencies as well as new guidance being developed by groups such as NSABB. With such changes on the way, scientists in the national laboratories and elsewhere who have not traditionally considered these issues may find increased awareness of dual-use and security issues both necessary and inevitable. They may also find that proactive early engagement facilitates cultural change and gives scientists a voice into the development of new guidelines.

In addition, focus group participants pointed out the challenges in identifying dual-use research of concern, and accurately assessing risk. They acknowledge that there is the potential for misuse of almost all life sciences research, but note that the uncertainties of scientific research make it difficult to characterize potential risks and benefits of conducting the science and publishing results. Thus, when the level of risk is unclear, participants tended to categorize it as a minimal, and pursue and publish research. Given this situation, focus group participants did see a need for additional guidance and clarity around what constitutes a dual-use concern. Increased awareness and training in this area seems both warranted and needed.

4.3 Concerns Related to Guidelines and Codes of Conduct

Focus group participants believed that mandated guidelines and codes of conduct related to dual use and biosecurity issues in the life sciences would be overly restrictive, burdensome, and unnecessary. Participants also noted that such guidelines would be difficult to enforce. Voluntary standards could help contribute needed clarity in this area and help raise awareness, but participants were also concerned that voluntary standard would drive regulations (which they view as negative). However, participants also recognized that if such regulations or guidelines were enacted, the laboratories would have to respond and react, and that new guidelines or future regulations would be a driver of awareness and a reason for scientists that have not been concerned about these issues to take notice. Additional guidance would be needed from NSABB/NIH/DOE regarding how a code of conduct and guidelines would be implemented and future implications they might have in the future.

4.4 Training Materials

Most participants were open to the idea of future training in this area with the preference that, for most staff, it be included in existing training rather than constituted as a separate requirement. They also preferred that the information or level of training be tiered so that those who are conducting "lower risk" work not have the same requirements as those conducting work with higher dual-use potential. They also saw benefit in more interactive forums tailored to various groups of staff to address more specialized issues. . A small minority of participants did not see any additional need for training on this topic.

Based on these results, we recommend a two-tiered approach to training that includes the development of content for inclusion in existing web-based annual training sessions for conduct on an individual level. We also recommend a more tailored webinar approach that can be customized for use with individuals across laboratories in various groups (e.g., IBCs, ADCs, managers, etc.).

However, regardless of the specific training approach selected, it is important to obtain management support, buy-in, and leadership. A clear message needs to be conveyed to staff at all levels as to why these are important issues, how it applies to their work, and how the institution views their level of responsibility related to this topic. Additionally, to implement a cultural change around dual use considerations and biosecurity issues will require leadership and commitment on the part of parent institution.

Appendix A

Focus Group Moderator Guide

INTRODUCTION **10 mins**

I would like to welcome you all and thank you for making time in your busy schedules to talk with us today. I am [Name] with Battelle [group/division]. My colleague [Name] from Battelle [group/division] is also on the line and will be taking notes today.

First, I'd like to give you a little background. In 2006, PNNL developed educational materials and conducted brown-bag seminars at nine of the national laboratories. These outreach and education seminars were designed to convey information and raise scientist awareness regarding the requirements of the Biological Weapons Convention, concerns regarding dual-use in the life sciences, and emerging discussions regarding codes of conduct.

We are now engaged in a follow-up process to:

- Determine what discussion has taken place in the labs related to the initial workshop, and gather additional feedback from laboratories.
- Discuss the best path forward for establishing a more wide-spread mechanism for education.
- Consider the appropriate best format for effective and widespread scientist education, and how best to integrate material into laboratory training systems.

To gather this data, we are conducting a survey and several focus groups with seminar participants and other laboratory POCs. Results will be used to qualitatively evaluate the function of the 2006 outreach and education seminars, and assess the value and need of future mechanisms to promote awareness and education of dual-use concerns in the life sciences.

I will be asking a series of questions about these topics. There are no right or wrong answers to these questions, just different points of view and different experiences. So don't be afraid to give your honest opinion or talk about an experience. It's important that we hear the range of ideas. Please feel free to agree or disagree with each other. That type of information is important to us. Also, you can choose not to respond to any question, and you may stop participating at any time. I will make sure that we stay focused on the topic. Also, I will keep the discussion moving so we can finish within the 2 hours we promised you.

We will be audiorecording our conversation today, but no names or identifying information will be included in the reports we prepare and the audio files will be deleted when analysis is complete, so please feel free to share your opinions.

I'd like to begin by asking everyone to introduce themselves by first name only, and tell us which scientific discipline you're in.

GENERAL **30 mins**

Thank you. Next, I'd like to ask you about biosecurity and possible risks to biosecurity.

Over the past several years, particularly following the terrorist attacks of September 11 and the subsequent anthrax attacks, there has been a growing concern that information and technology from life sciences research could be diverted for malicious purposes. The availability of materials, equipment, and technology to build, sustain, and advance offensive BW programs is growing with globalization of trade and research. The pervasiveness of biotechnology throughout the world increases the availability of agents and toxins, equipment, and expertise that could support a biological weapons program.

Because of increasing concerns, it is recognized that there needs to be increased awareness of biosecurity risks, dual-use experiments and technology, etc. The dual-use nature of life sciences makes it difficult to control BW-related materials in the same manner as nuclear materials (i.e. classification and export controls)

A few definitions:

Biosecurity: New biosecurity measures have been – and are being -- developed in order to mitigate security risks. While biosafety measures are designed to prevent accidental exposure to potentially harmful pathogens, biosecurity tries to prevent the theft or diversion of materials, technology, and information.

Dual-use: Dual use research is legitimate research that has the potential to be diverted to producing a WMD, threatening public health and national security. Dual use life sciences research can be applied in fundamental research, research in biodefense and biological countermeasures, and biological weapons.

Dual-use CASE STUDIES (AS NEEDED)

- **Recent report warning that Synthetic biology' may be misused for 'bioterrorism'.** "Scientists at the University of Nottingham have warned that 'synthetic biology' - a technique popular for its ability to create artificial life by engineering organisms - is at risk of damaging the ecosystem and being abused by terrorists. In a report, commissioned by the Biotechnology and Biological Sciences Research Council, the university researchers stress the need for new control and regulations on the use of synthetic biology, highlighting ethical and social concerns over the issue. They fear that synthetic biology may be misused to spread 'bioterrorism,' designing new organisms to be hostile to humans." **Scientists have used new DNA synthesis technologies and open-source access to DNA sequence information to synthesize genomes of several viruses and bacteria, including the 1918 flu virus and poliovirus, without access to the organism.**
- Mousepox IL-4 Experiments: Use the Australian experiments with the Mousepox virus as a case study. The research team was developing contraceptive vaccines for sterilising mice and rabbits without killing them. The researchers modified the mousepox virus by adding a gene for a natural immunosuppressant called IL-4, expecting this would boost antibody production. **Researchers inserted an IL4 gene into the virus expecting benign results; however, the mice died when treated with the vaccine strain.** The modified IL-4 seemed to switch off a key part of the immune system (cell-mediated

immune response), making the modified mousepox virus far more lethal than the unmodified version, and killing 60 per cent of vaccinated mice. This study provides a clear example of how genetic recombination is capable of creating a virus (or other pathogens) with genes that allow the pathogen to overcome host defense and to spread with little or no control.

- **Nanotechnology could also be used to deliver toxic agents maliciously.** For instance, one area has been in the advancement of aerosol delivery systems; these are now employed for vaccinations, drug therapy, recombinant proteins, and nucleotides.
- **Disposable lab equipment** (i.e. disposable bioreactors) can allow production of pathogenic material without a WMD "footprint"

Questions:

- US science has traditionally been seen as value-neutral – in your opinion, how aware are scientists of the dual use nature of much of biological research? *(Alternatively: Do you believe that the lack of awareness regarding the potential for dual-use of biological knowledge and materials creates a danger?)*

For clarification, if needed:

- Who is sufficiently aware? Who is not?

- How would you describe the biosecurity risks involved in the kind of work you do? Do you think that your work could be misused by a person or group who wanted to do harm?

For clarification, if needed:

- What is your perspective of the biosecurity risks associated with life sciences research more broadly? How much of a biosecurity risk is there, in your opinion?

- What does it mean to be a responsible scientist when there is a possibility that the products or knowledge you generate could be misused?

- What considerations do you make in releasing your research methodology or results to the public?

For clarification, if needed:

- How else do you address the risk posed by dual-use technologies?
- Are there any long-term ramifications that you consider?
- Do you consider whether there is a "dual" use or another possibly dangerous use for your research results or methodology?
- Do you believe that trying to control the dissemination of information can help deter misuse of life sciences work for biological weapons?

AWARENESS AND EDUCATION **30 mins**

The National Science Advisory Board for Biosecurity (NSABB), an advisory body to the USG, was tasked with proposing an oversight framework for the "identification, review, conduct, and communication of life sciences research with dual-use potential." NSABB advises HHS and NIH, as well as the heads of all federal departments and agencies that support life sciences research. **Part of this framework includes "considerations in developing a code of conduct for dual-use research in the life sciences", as well as recommendations for training in dual-use research.**

In 2006, PNNL conducted a series of seminars for the national labs; you may have participated in these seminars. These seminars focused on the BWC, Dual-use concerns, and the possibility that the US government might promulgate guidelines for developing "Codes of Conduct" in the life sciences.

Considering that NSABB developed guidelines will most likely be adopted by NIH and will therefore impact the national laboratories,

- What are your reactions to the general idea of a code of conduct? To dual-use guidelines? How might these affect the balance of promoting security and ensuring freedom of research?

- What types of needs do you see for increased awareness and education in some of the areas we've discussed, or mentioned by the NSABB group, that is, biosecurity, dual-use, codes of conduct?

- Has there been any increase in the overall awareness of biosecurity and dual-use concerns among your colleagues or within your organization over the past few years?

For clarification:

- What is the driver for increased awareness?
- Were the 2006 seminars helpful in raising awareness about the BWC, dual-use concerns, codes of conduct, and education and outreach?
- Alternatively: Would a seminar such as the one conducted in 2006 be helpful in raising awareness about the BWC, dual-use concerns, and codes of conduct?

TRAINING METHODS **20 mins**

Finally, I'd like to ask for your thoughts and recommendations related to tools for education and training, in light of the new guidelines being developed and promulgated.

- What critical gaps do you see in education and awareness that are not covered by existing guidance (including BMBL, IBCs, etc), for which additional training tools would be helpful in raising awareness of biosecurity concerns and dual-use risks?

- Assuming they were made available (and were free of charge), what types of tools would be most helpful for you in communicating this information to staff, other scientists, new hires, students and interns, etc.?
    - What types of tools would you find helpful as you mentor and communicate with interns and new hires?
    - What types of tools would be useful in maintaining awareness for scientists already in the laboratory system? For managers? For IBCs/IRBs, etc.?
    - What groups might benefit most from these tools?

If needed:
What format would be most useful and effective for these tools?

- Web-based
- Reference manual/book
- Materials for classroom training
- Seminars
- Others?

(IF Web-based tools are selected:)

- How should the tools be delivered?
- In conjunction with existing biosafety modules? Independently?
- To be incorporated into annual training?
- To be delivered to PIs and junior staff on a per-project basis

- Are there other means or mechanisms that could most effectively raise awareness regarding the dangers of dual-use materials and knowledge, either conjunctively or alternatively? (e.g., readings and acknowledgment required by client, magazines and journals, computer training, DVD video, staff brownbag discussions, practical exercises, etc.)

Ways and means: (IF it's appropriate:)

- How frequently should training/refresher courses be delivered?
- How would you suggest we have junior investigators participate in workshops, seminars, or other educational venues?
- Culture of responsibility: There has been some discussion about moving towards a "culture of responsibility". \Are there additional means that you would propose to promote such a culture of responsibility related to safety, security, and bioresponsibility?

CLOSING

Thank you so much for your thoughts and recommendations. Your input is very important to this process. Before we close, is there anything else you would like to share about this topic that we have not already covered?

Thanks again for participating today. Please let us know if you are interested in the analysis of these results.

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