

Nomination of CDR SAMPLE OFFICER, PHS#####, for the Outstanding Service Medal

CDR SAMPLE OFFICER is nominated for leading the development of national and international laboratory safety guidance in the 5th edition of ANONYMOUS DOCUMENT from DATE to DATE.

Background

Over the past two decades, ANONYMOUS DOCUMENT has become the consensus code of practice for biosafety in laboratories throughout the world. The ANONYMOUS DOCUMENT serves as the basis for biosafety regulation from the National Select Agent Program (impacting 450+ select agent registered entities in the U.S.). ANONYMOUS DOCUMENT guidance is also applied to the 190,000+ Food and Drug Administration Clinical Laboratory Improvement Amendments registered labs in the U.S. and the 700+ Association for the Assessment and Accreditation of Laboratory Animal Care registered facilities. ANONYMOUS DOCUMENT definitions for biosafety levels (BSL) form the design and operating standards for every biomedical laboratory in the U.S., including 15 operational or planned BSL-4 facilities, 500+ BSL-3 facilities, and countless academic, military, government, and private laboratories. Published in 1999, the 4th ANONYMOUS DOCUMENT edition was thoroughly out of date regarding biosecurity, select agents, and new biocontainment guidelines for emerging public health threats such as SARS and pandemic influenza. In response, CDR SAMPLE OFFICER led AGENCY efforts in the creation of new biosafety guidelines and oversaw complex negotiations with federal agencies and other partners for the ANONYMOUS DOCUMENT 5th edition.

Accomplishments and Impacts

Developing National Biosafety Policy: Beginning November 2005, CDR SAMPLE OFFICER led development of national biosafety policy for several new and existing sections of the 5th edition. He consulted with the nation's leading experts and recruited them to serve as subject matter experts. Based on lessons from earlier work at AGENCY (for which he received a Commendation Medal in DATE), CDR SAMPLE OFFICER reorganized and expanded the new chapters into new formats to increase ease of use and applied it to hundreds of newly characterized viral agents. He oversaw assembly of the arboviral and hemorrhagic fever (AHF) chapter, the agent summary statements for lymphocytic choriomeningitis virus and human herpesviruses, integrated pest management guidelines, and the arthropod containment guidelines. CDR SAMPLE OFFICER also directed efforts to engage research partners, scientific and regulatory agencies, and biosafety experts to reach consensus on contentious safety issues. He championed the effort to resolve critical infrastructure and safety issues created by outdated information in the old edition. For example, vaccines were required for working at BSL-2 with a variety of attenuated vaccine strains, including yellow fever virus and rift valley fever virus. Without these immunizations, work on these strains would need to be conducted in BSL-3 laboratories, or researchers would need respiratory protection and additional protective equipment. Recognizing serious problems in vaccine availability, CDR SAMPLE OFFICER drove an initiative to change these national recommendations based on a new risk assessment. **Impact:** Based on comments received to date, the new formats he developed are considered far superior to earlier editions, allowing critical safety information to be accessed far more efficiently. Hundreds of new and dangerous pathogens were added to the ANONYMOUS DOCUMENT through his efforts; e.g., >200 new emerging arboviruses were added to the AHF virus chapter (the largest within the ANONYMOUS DOCUMENT) which includes some of the world's most dangerous pathogens and select agents (Ebola virus, Marburg virus, etc.). For most, the guidance developed by CDR SAMPLE OFFICER represents the only published biosafety recommendations for these organisms. The new risk assessment he championed allows critical research to continue in more highly available BSL-2 space without costly and limited vaccinations and without peril to staff. Now that clear, updated guidance was available, the Select Agent programs of the AGENCY and USDA could now apply more fair, consistent, and effective standards in their inspection process, improving their programs for ensuring national security.

Leading Steering Committee AGENCY Representation: The effort to create the 5th edition ANONYMOUS DOCUMENT was overseen by a four member steering committee representing the AGENCY and the AGENCY. After coming to AGENCY, CDR SAMPLE OFFICER directed AGENCY representation on the committee and was responsible for the development and implementation of an unprecedented level of contribution and review in the 5th edition. The 5th edition is over 50% larger than the 4th edition and over 200 subject matter experts (SMEs) contributed to it. As the leading steering committee representative for the AGENCY, CDR SAMPLE OFFICER was responsible for representing the AGENCY in the review of hundreds of submissions for the new document and reaching consensus with subject matter experts, agencies, and other partners in the formulation of biosafety policy in the ANONYMOUS DOCUMENT. **Impact:** CDR SAMPLE OFFICER's leadership in the review process and his editorial contributions to the document allowed for a dramatic increase in consistency and clarity of the guidance in it, thus allowing for easier compliance and understanding of the guidelines. Every complex issue was resolved to the satisfaction of multiple government agencies. The safety and security of hundreds of thousands of laboratory employees and their surrounding communities were greatly enhanced through his efforts and leadership.

Resolving and Negotiating Inter- and Intra-Agency Differences: Glaring oversights and out-dated information (e.g., failure to take new select agent regulations into account) in previous editions led to significant differences in operations and design of laboratory facilities. CDR SAMPLE OFFICER directed AGENCY negotiations with AGENCY and USDA regarding consensus over significant differences in lab operation and design policy. Given these differences, the ANONYMOUS DOCUMENT faced unprecedented levels of review and approval. CDR SAMPLE OFFICER spearheaded the approval process by representing the entire Steering Committee (both AGENCY and AGENCY) in intra-AGENCY negotiations for AGENCY approval of the 5th edition. Representing AGENCY, AGENCY, and USDA, CDR SAMPLE OFFICER worked with AGENCY leadership to create and implement an multiple agency approval process, negotiated with AGENCY scientific and policy managers to resolve difficult biosafety policy issues with national implications, and obtained the first ever AGENCY level clearance in less than four weeks. His efforts encompassed over 30 meetings and conference calls and included negotiations with and obtaining approval from Center leaders, the AGENCY Office of the Scientific Director, and NIOSH. **Impact:** CDR SAMPLE OFFICER's leadership resulted in the rapid resolution of overlapping and conflicting rules and opinions of multiple agencies. Thus, the 5th edition, which was already delayed due to the scope of changes in it, was able to be released to the public faster. Faster release avoided millions of dollars of costly redesign and construction costs, especially in existing facilities requiring Select Agent program approval. For example, the AGENCY and AGENCY took different approaches in the design and construction of duct systems for BSL-4 labs. Each interpreted small phrases such as "dedicated systems" differently, resulting in very different facilities being constructed. Each agency was concerned that ANONYMOUS DOCUMENT language changes would result in failures to obtain clearance from the national select agent program to begin operations in already constructed buildings. This would result in large research facilities such as AGENCY's Emerging Infectious Diseases Building 18 either going unused or necessitating a rebuilding of the entire HVAC system. In this example, CDR SAMPLE OFFICER fashioned compromise language interpreting these systems, obtained approval from AGENCY, AGENCY, and USDA for the compromise, and then negotiated on behalf of these agencies with the AGENCY during the clearance process for the document.

Conclusion

CDR SAMPLE OFFICER' outstanding leadership and initiative impacted every microbiological, clinical, and biomedical research laboratory in the nation. The resultant biosafety and laboratory design guidance directly affected billions of dollars of construction and hundreds of thousands of laboratory employees. CDR SAMPLE OFFICER is fully deserving of recognition with an Outstanding Service Medal.