

items.<sup>16</sup> In the event that a company, entity, or person on the list appears to match that of a customer or other recipient, additional due diligence should be conducted before proceeding. There may be a strict export prohibition, a requirement for seeking a license application, or other evaluation of the Customer or other recipient necessary to ensure it does not result in an activity prohibited by any U.S. export regulations, or other restrictions. Before fulfilling the order, to ensure full compliance with all the terms and conditions of the restrictions placed on the parties on this list, the Provider must check the official publication of restricted parties in the **Federal Register**.

#### **VII. Following Up With the U.S. Government in Cases Where Malintent is Suspected by Providers, Third-Party Vendors, or Manufacturers**

If sequence or Customer screening raises concerns that are not alleviated through follow-up screening, Providers, Third-Party Vendors, and Manufacturers should not fulfill the order and are strongly encouraged to contact their nearest FBI Field Office's WMD Coordinator. Institutions are encouraged to work with their Principal Users and End Users to help them understand that only individuals with legitimate, *bona fide*, and peaceful purpose should obtain synthetic nucleic acids containing SOC's.

#### **VIII. Records Retention**

The *Guidance* recommends that Providers, Third-Party Vendors, and Manufacturers retain the following types of records for at least three years, and longer (e.g., eight years) if this does not pose an undue burden on their operations:

- Records of Customer orders including the following information: Customer information (point-of contact name, organization, address, email, and phone number), order sequence information (nucleotide sequences ordered, vector used), and order information (date placed and shipped, shipping address, receiver name);
- Records of protocols for sequence screening and for determining whether a sequence hit qualifies as a SOC;
- Records of screening documentation of all hits, even if the order was deemed acceptable;
- Records of any follow-up screening, even if the order was ultimately filled; and

- The ultimate disposition of any SOC orders, with documentation of reasoning for final decision (fulfill versus deny).

#### **IX. Periodic Review, Evaluation, and Improvement of This Guidance**

This *Guidance* addresses biosecurity risks that have emerged in a dynamic and rapidly developing technological landscape. It is likely that new risks will emerge and that new technological approaches will also appear to address them. As such, this *Guidance* encourages the further development of mechanisms to detect SOC's and screening strategies for sequences that contribute directly to pathogenicity and toxicity. For instance, strategies may be used by malicious Customers to obfuscate SOC's, including engineering pathogenic or toxic proteins with completely novel sequences. In such cases, synthetic nucleic acid orders may contain 50 nt windows that are not a match to any known sequence. Although there are likely legitimate explanations for orders of sequences with no matches in existing databases (e.g., nucleic acids ordered to populate microarrays or to store digital information), in such cases, it may be possible to use predictive bioinformatic algorithms to screen sequences that are not a match to any known sequences to determine if they could produce proteins that are structurally and functionally identical to SOC's. This *Guidance* encourages Providers to continue to develop these methods to best ensure the safety and security of the synthetic nucleic acid research enterprise.

This *Guidance* will be periodically revisited, including by soliciting stakeholder input, and feedback is encouraged from the nucleic acid synthesis industry as well as from their customers as they implement the *Guidance*. Furthermore, implementation of this *Guidance* will be supported through the publication of a Companion Guide.

**Dawn O'Connell,**

*Assistant Secretary for Preparedness and Response.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Biomedical Advanced Research and Development Authority Industry Day 2023**

**AGENCY:** Administration for Strategic Preparedness and Response (ASPR),

Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Biomedical Advanced Research and Development Authority (BARDA) annually hosts BARDA Industry Day (BID), a two-day conference with industry and our government partners to share BARDA's goals and objectives, increase awareness of U.S. government medical countermeasure (MCM) priorities, and facilitate collaboration between public and private sectors within the health security space. This year, BARDA plans to discuss implementation efforts for our *2022–2026 Strategic Plan*, which focuses on strengthening the health security of the nation, embracing lessons learned from the COVID–19 pandemic, incorporating new avenues of promising research and development, and addressing the imperative for MCMs that are safe, effective, and widely accessible.

**DATES:** BID 2023 will be a hybrid event, held from Monday, November 13–Tuesday, November 14, 2023. The meeting will begin each day at 9 a.m. Eastern Standard Time.

**ADDRESSES:** This meeting is open to the public. Register here: <https://medicalcountermeasures.gov/barda/barda-industry-day-2023/>.

**FOR FURTHER INFORMATION CONTACT:** Ezinne N. Ebi, Biomedical Advanced Research & Development Authority (BARDA), [ezinne.ebi@hhs.gov](mailto:ezinne.ebi@hhs.gov), (202) 989–5539.

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public by videocast as indicated below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should

<sup>16</sup> <https://www.trade.gov/consolidated-screening-list>.