



# FRAMEWORK FOR NUCLEIC ACID SYNTHESIS SCREENING

*A product of the*  
FAST TRACK ACTION COMMITTEE ON  
SYNTHETIC NUCLEIC ACID PROCUREMENT SCREENING  
*of the*  
NATIONAL SCIENCE AND TECHNOLOGY COUNCIL

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## **About the National Science and Technology Council**

The National Science and Technology Council (NSTC) is the principal means by which the Executive Branch coordinates science and technology policy across the diverse entities that make up the Federal research and development enterprise. A primary objective of the NSTC is to ensure that science and technology policy decisions and programs are consistent with the President's stated goals. The NSTC prepares research and development strategies that are coordinated across Federal agencies aimed at accomplishing multiple national goals. The work of the NSTC is organized under committees that oversee subcommittees and working groups focused on different aspects of science and technology. More information is available at <http://www.whitehouse.gov/ostp/nstc>.

## **About the Office of Science and Technology Policy**

The Office of Science and Technology Policy (OSTP) was established by the National Science and Technology Policy, Organization, and Priorities Act of 1976 to provide the President and others within the Executive Office of the President with advice on the scientific, engineering, and technological aspects of the economy, national security, homeland security, health, foreign relations, the environment, and the technological recovery and use of resources, among other topics. OSTP leads interagency science and technology policy coordination efforts, assists the Office of Management and Budget with an annual review and analysis of Federal research and development in budgets, and serves as a source of scientific and technological analysis and judgment for the President with respect to major policies, plans, and programs of the Federal Government. More information is available at <http://www.whitehouse.gov/ostp>.

## **About the Fast Track Action Committee on Synthetic Nucleic Acid Procurement Screening**

The NSTC established this Fast Track Action Subcommittee in 2023 to develop a framework for nucleic acid synthesis screening, pursuant to Section 4.4(b)(i) of [Executive Order 14110 of October 23, 2023, “Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.”](#)

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## Abbreviations and Acronyms

|              |  |
|--------------|--|
| <b>APNSA</b> | Assistant to the President for National Security Affairs |
| <b>BSAT</b>  | Biological Select Agents and Toxins                      |
| <b>CCL</b>   | Commerce Control List                                    |
| <b>CISA</b>  | Cybersecurity and Infrastructure Security Agency         |
| <b>CRO</b>   | Contract Research Organization                           |
| <b>FSAP</b>  | Federal Select Agent Program                             |
| <b>FBI</b>   | Federal Bureau of Investigation                          |
| <b>HHS</b>   | Department of Health and Human Services                  |
| <b>NSTC</b>  | National Science and Technology Council                  |
| <b>NIST</b>  | National Institute of Standards and Technology           |
| <b>ORCID</b> | Open Researcher and Contributor ID                       |
| <b>OSTP</b>  | Office of Science and Technology Policy                  |
| <b>SOC</b>   | Sequence of Concern                                      |
| <b>WMD</b>   | Weapons of Mass Destruction                              |

## I. INTRODUCTION

In October 2023, President Biden issued a landmark [Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence](#) (“Executive Order”). In section 4.4(b), the Executive Order directs the federal government to reduce the risks of misuse of synthetic nucleic acids and improve associated biosecurity measures. The Executive Order requires that OSTP develop a framework to encourage providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms. As the building blocks for life, nucleic acids underpin much of research and development in the life sciences, thereby serving as a critical control point allowing industry to ensure beneficial usage and minimize the risk of misuse.

This framework outlines a unified process for screening purchases of synthetic nucleic acids and benchtop nucleic acid synthesis equipment. While the framework will be incorporated into requirements for recipients of federal research funding, including through domestic and international funding documents, broader use of the framework is encouraged. This approach guides providers of synthetic nucleic acids (“Providers”) and manufacturers of benchtop nucleic acid synthesis equipment (“Manufacturers”) to screen purchase orders to identify sequences of concern (SOCs) and assess customer legitimacy.

In support of this framework, as directed by section 4.4.(b)(ii) of the Executive Order, the National Institute of Standards and Technology (NIST) will engage with industry and relevant stakeholders to further develop and refine specifications for effective nucleic acid synthesis procurement screening; best practices for managing SOC databases to support such screening; technical implementation guides for effective screening; and conformity-assessment best practices and mechanisms.

This framework incorporates and supplements portions of the [Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids](#), U.S. Department of Health and Human Services, October 2023, and its accompanying Companion Guide (collectively, “2023 HHS Guidance”).

As described in Section II, federal funding agencies will, as appropriate and consistent with applicable law, require that procurement of synthetic nucleic acids and benchtop nucleic acid synthesis equipment using federal life sciences funding be conducted through Providers and Manufacturers that adhere to this framework. To adhere to this framework, Providers and Manufacturers should take the following six actions for such procurement, consistent with the 2023 HHS Guidance and the Executive Order section 4.4(b)(iii):

- 1) Attest to implementing this screening framework through a statement that either is posted on a public website or provided to the federally funded customer and federal funding agency upon request;
- 2) Screen purchase orders for synthetic nucleic acids to identify SOCs;
- 3) Screen customers submitting purchase orders of synthetic nucleic acids with SOCs, and purchase orders of benchtop nucleic acid synthesis equipment, to verify legitimacy;

- 4) Report potentially illegitimate purchase orders of synthetic nucleic acids involving SOCs or of benchtop nucleic acid synthesis equipment;
- 5) Retain records relating to purchase orders for synthetic nucleic acids and benchtop nucleic acid synthesis equipment; and
- 6) Take steps to ensure cybersecurity and information security.

### **II. ROLE OF FEDERAL FUNDING AGENCIES**

The Executive Order requires that all agencies that fund life sciences research will, as appropriate and consistent with applicable law, establish that, as a requirement of funding, synthetic nucleic acid procurement for federally funded research is conducted through Providers or Manufacturers that adhere to the framework.<sup>1</sup> This requirement will take effect for all purchases of synthetic nucleic acids and benchtop nucleic synthesis equipment that take place on or after April 26, 2025.

Federal funding agencies will establish these requirements under statutory and regulatory authorities applicable to them, such as through terms and conditions of awards. Federal funding agencies will work with the Assistant to the President for National Security Affairs (APNSA) and the Director of OSTP to coordinate the process of reviewing such funding requirements to facilitate consistency in implementation of the framework across funding agencies.

This framework complements existing federal statutes, regulations, and policies, and does not supersede any federal statutory or regulatory authority. Nothing in this framework impairs or otherwise affects the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals. In rare cases, federal funding agencies may encounter circumstances that require an exception to this framework. The heads of federal funding agencies may issue exceptions to the requirements in this framework on a case-by-case basis when needed to address health or national security priorities, in consultation with the Director of OSTP and the Federal Bureau of Investigation.

### **III. SCOPE**

This framework applies to federally funded life sciences research involving the procurement of all types of synthetic nucleic acids – including but not limited to DNA and RNA, whether single- or double-stranded, as well as whole organism genomes (e.g., viruses, bacteria) – containing any synthetic SOC. It also applies to federally funded life sciences research involving the procurement of any benchtop equipment capable of synthesizing nucleic acids.

This framework applies to the distribution by Providers of synthetic nucleic acids, including by biofoundries, cloud labs, institutions with core nucleic acid synthesis facilities, and contract research organizations (CROs) or laboratories with integrated nucleic acid synthesis capabilities. This framework also applies to the distribution by Manufacturers of benchtop equipment to synthesize

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<sup>1</sup> See Section 4.4(b)(iii), Executive Order. This includes research funded or sponsored by grants, contracts, cooperative agreements, and other agreements and transactions.

nucleic acids. To be adherent to this framework, Providers and Manufacturers should also ensure the framework is followed when a third-party vendor or other intermediary is involved.

#### IV. DEFINITIONS

The 2023 HHS Guidance provides definitions for the following terms, which are reproduced or adapted here:

Table 1: Basic Definitions Used in the Framework for Nucleic Acid Synthesis Screening

| Term                                      | Definition  |
|---|---|
| Benchtop nucleic acid synthesis equipment | Benchtop nucleic acid synthesis equipment sold by Manufacturers that is intended to be used to synthesize nucleic acids for use within a research laboratory or within an institution. While this nucleic acid synthesis equipment may not be small enough to be placed on a benchtop (e.g., it sits on the laboratory floor), it is still considered benchtop equipment if it is sold with the intent that it will be used by researchers individually or in a core facility in an institution.  |
| Customer                                  | The individual or entity (such as an institution) that orders or requests synthetic nucleic acids from a Provider, or that purchases nucleic acid synthesis equipment from a Manufacturer.  |
| Manufacturer                              | An entity that produces and distributes benchtop equipment for synthesizing nucleic acids. Manufacturers may provide equipment to a customer or third-party vendor.   |
| Provider                                  | An entity that synthesizes and distributes synthetic nucleic acids. Providers may provide nucleic acids to a customer or third-party vendor. A Provider is understood to be synthesizing and distributing nucleic acids as a transactional service, rather than as a research scientist collaborating with a colleague.   |
| Sequence of Concern (SOC)                 | At the time of this framework’s issuance, a nucleotide sequence or its corresponding amino acid sequence that is a Best Match to a sequence of federally regulated agents (i.e., the Biological Select Agents and Toxins List (BSAT), or the Commerce Control List (CCL)), except when the sequence is also found in an unregulated organism or toxin. As of and after October 13, 2026, this definition will include sequences known to contribute to pathogenicity or toxicity, even when not derived from or encoding regulated biological agents (see Screening Framework below). |

## FRAMEWORK FOR NUCLEIC ACID SYNTHESIS SCREENING

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| Synthetic nucleic acids subject to screening | At a minimum, DNA or RNA, single- or double-stranded, 200 nucleotides (including the corresponding amino acid sequence, if applicable) or longer should be screened for SOCs. As of October 13, 2026, this screening window will be decreased to 50 nucleotides, and Providers should implement screening mechanisms that detect the potential for shorter nucleotides to be assembled into SOCs when multiple synthetic nucleic acids are ordered by the same customer in a bulk order or for multiple orders over time (see Screening Framework below). |
| Third-party vendor                           | An entity that orders synthetic nucleic acids from Providers and distributes them or their constructs, with or without reformulation. Also, an entity that orders benchtop equipment for synthesizing nucleic acids from Manufacturers and distributes them.  |
| Verifying legitimacy                         | Review of information that would allow Providers and Manufacturers to authenticate the recipient of synthetic nucleic acids containing SOCs or benchtop nucleic acid synthesis equipment as a legitimate member of the scientific community.  |

This framework additionally specifies that the term Provider includes the following non-traditional types of providers:

Table 2: Definitions of Non-Traditional Providers of Synthetic Nucleic Acids

| <b>Non-Traditional Types of Providers</b> | <b>Definition</b>   |
|---|---|
| Biofoundry                                | A centralized facility that provides a high degree of automation and infrastructure to support the engineering and scalable manufacturing of biological systems including nucleic acid sequences or that utilizes biological systems to produce molecules and nucleic acid sequences.   |
| Cloud Lab                                 | A highly automated research laboratory possessing a diversity of analytical and synthesis capabilities across the life sciences and that can be remotely operated by specifying experimental protocols via software.  |
| Core Facility / Academic Core Facility    | An institution-based capability that either facilitates orders to third parties or that has in-house equipment intended to provide services to faculty and research staff at that university or others and not otherwise to customers from the general public (e.g., the ability to create nucleic acid sequences <i>de novo</i> from benchtop synthesizers). |

|                                      |   |
|--------------------------------------|---|
| Contract Research Organization (CRO) | An organization that provides research and development services to companies in the life sciences, typically related to clinical trials and drug-development. |
|--------------------------------------|---|

## V. SCREENING FRAMEWORK

To adhere to this screening framework, Providers and Manufacturers should meet the following criteria:

**1) Attest to implementing this screening framework through a statement that is either posted on a public website or provided to the federally funded customer and federal funding agency upon request**

As indicated above, per the requirements of the Executive Order, federal funding agencies will require that procurement of synthetic nucleic acids and benchtop nucleic acid synthesis equipment using federal life sciences funding be conducted through Providers and Manufacturers that attest to adhering to this screening framework. To adhere to this framework, a Provider and Manufacturer should either post on a public webpage a statement that self-attests to following each of the criteria in this framework, or provide such a statement to the federally funded customer and the federal funding agency upon request.

To adhere to this framework, the Provider or Manufacturer should (i) ensure that the attestation is signed by an individual with the authority to respond on behalf of the organization; (ii) provide point of contact information; (iii) update the attestation by January 1st of each year, or more frequently if point-of-contact information changes; and (iv) expressly commit in the attestation that, if they cease to adhere to the framework, they will notify, within 72 hours, any federally funded customers and federal funding agencies to which they previously submitted an attestation.

Following the release of this framework, OSTP anticipates coordinating development of a standardized template statement that Providers and Manufacturers may use for this purpose, if they wish.

**2) Screen purchase orders for synthetic nucleic acids to identify any sequences of concern (SOCs)**

To adhere to this screening framework, a Provider screens purchase orders for synthetic nucleic acids to identify any SOC pursuant to the 2023 HHS Guidance. All nucleotide sequences or corresponding amino acid sequences that are Best Matches to a sequence of federally regulated agents – i.e., the Biological Select Agents and Toxins (BSAT) list or, for international orders, the Commerce Control List (CCL)<sup>2</sup> – are SOC, except when the sequence is identical to a sequence found in an unregulated organism or toxin.<sup>3</sup>

<sup>2</sup> A Best Match approach, or equivalent screening mechanism, should identify scattered mutations which no longer make the screening window an exact match for a SOC. Nucleic acid sequence that encode proteins should be screened across all applicable reading frames (i.e., 3 for single-stranded nucleic acids and 6 for double-stranded nucleic acids).

<sup>3</sup> Synthetic nucleic acids containing a screening window that is a Best Match to a BSAT agent or – for international orders – a CCL agent contain a SOC if the window is a Best Match to a window from a regulated agent but is not an equivalent match

Notwithstanding the above, Providers may still be adherent to the Framework if they identify “exempted sequences” that qualify as SOCs but pose no known pathogenic or toxicity risk. Providers are not required to verify customer legitimacy for such exempted sequences, as described in the following section. To adhere to the Framework, Providers should only exempt sequences from genes from non-viral agents with functions that cannot reasonably be construed as contributing to pathogenicity or toxicity (e.g., sequences from genes that encode bacterial or fungal DNA gyrase, ribosomal RNA, or hexokinase). Exempted SOCs should not include any sequences from federally regulated viruses. In addition, the exempted SOCs should not include sequences that could restore or enhance the virulence of an attenuated excluded strain of a regulated agent on the BSAT list. Providers should refer to the Export Administration Regulations, administered by the Department of Commerce, Bureau of Industry and Security, to determine if a SOC requires a license for export. Providers may also contact the Export Counseling Division of the Office of Exporter Services (ECDOEXS@bis.doc.gov) for additional information.

Synthetic nucleic acids should be screened over each 200 nucleotide window within their sequences for SOCs (see below for changes that will take effect on October 13, 2026).<sup>4,5</sup> Providers or Manufacturers conducting this screening may determine which commercial services, open source solutions, or in-house developed algorithms and software systems to use to make this determination. Where available, standards from the National Institute of Standards and Technology (NIST) should be applied to determine that the mechanism used by each entity is sufficient.

To adhere to this screening framework on and after October 13, 2026 (three years after the 2023 HHS Guidance was issued), Providers should implement the following additional practices. First, Providers should reduce the size of the screening window and screen each 50 nucleotide window for SOCs.<sup>6</sup> Second, Providers should apply screening methods that detect the potential for shorter nucleotide sequences to be assembled into SOCs when multiple synthetic nucleic acids are ordered by the same customer in a bulk order or in multiple orders over time.<sup>7</sup> Third, Providers should make efforts to implement a mechanism to screen additional SOCs known to contribute to pathogenicity or toxicity,

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to a window from an unregulated agent. For instance, nucleotides 96942 – 97156 from horsepox virus (DQ792504) are identical to nucleotides 76415 – 76629 from variola virus (NC\_001611.1) and windows over this region of the variola virus genome are not SOCs under this definition.

<sup>4</sup> Screening should take place over each 66 amino acid and/or 200 nucleotide window. The screening should be applied across all applicable reading frames for nucleotide sequences that encode proteins (i.e., 3 for single-stranded nucleic acids and 6 for double-stranded nucleic acids).

<sup>5</sup> Screening over windows in synthetic nucleic acid orders will identify a SOC that has been appended onto a larger harmless sequence in an attempt to mask the SOC.

<sup>6</sup> Screening should take place over each 16 amino acid and/or 50 nucleotide window. The screening should be applied across all applicable reading frames for nucleotide sequences that encode proteins (i.e., 3 for single-stranded nucleic acids and 6 for double-stranded nucleic acids).

<sup>7</sup> In these cases, multiple synthetic nucleic acids should be considered in total using a short sequence alignment software package. If the resulting ungapped alignment of any constituents of a customer's order(s) is a Best Match to any SOC, and if these sequences are constructed to allow their ligation to form these SOCs (i.e., overlaps are present to support the construction of a larger nucleic acid sequence, which itself is a SOC), Providers or Manufacturers should consider those orders as containing SOCs.

even when not derived from or encoding regulated biological agents.<sup>8</sup> Providers and Manufacturers conducting screening may determine which commercial services, open-source solutions, or in-house developed algorithms and software systems to use to make this determination, and should undertake efforts to measure the effectiveness of this new screening criteria and improve screening over time. As part of ongoing review and updates to this framework, an OSTP-designated interagency group will assess the scientific state of the art before October 13, 2026 and recommend any updates to this framework if necessary.

The following criteria may inform which sequences should be designated as SOCs:

- Scientific evidence establishing that the sequence contributes to pathogenicity or toxicity in humans and animals.
- Degree to which this sequence is likely to be recognized as a candidate for misuse, based on the extent to which its function is widely known.
- Ease with which this sequence could be misused, for example through *de novo* assembly of a pathogen or insertion into a backbone.

To adhere to this screening framework on and after October 13, 2026, Manufacturers should integrate into benchtop nucleic acid synthesizers the capability to screen sequences for SOCs, meeting the standards as outlined in the 2023 HHS Guidance. As described in the 2023 HHS Guidance, this level of screening should be on par with the SOC screening best practices recommended for Providers in this framework, including screening against SOC databases, when available, that are updated regularly as new SOCs are identified as a required step before synthesizing the sequence, in a verifiable manner.<sup>9</sup> Following the release of this framework, NIST will support the development of technical standards<sup>10</sup> that will inform an OSTP-designated interagency group that will consider and recommend updates to this framework every two years, or as appropriate. This group will work to provide additional guidance, as needed, to support implementation of an expanded SOC definition prior to October 13, 2026. These updates will be informed by advances in the state of the art including:

- Scientific evidence of sequences contributing to pathogenicity.
- Improvements in ability to identify sequences that are functionally equivalent to SOCs.
- Advances in predictive modeling that allow for assessments of novel or unknown sequences.
- Algorithmic approaches for sequence screening that do not explicitly utilize a pathogen reference database or sequentially evaluate multiple reading frames.

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<sup>8</sup> Pathogenicity or toxicity that threatens human and animal health. SOCs include sequences for which a direct and harmful impact on a host has been verified based on published experimental data; and, where experimental data do not exist, based on homology to a sequence encoding a verified function.

<sup>9</sup> Here, verifiability means the ability to confirm that every prospective sequence has been screened for SOCs against an up-to-date database, and screening is up to date and performant; when users input sequences of concern, this is flagged and reported in real time; and attempts to tamper with the equipment to avoid screening are flagged and reported in real time.

<sup>10</sup> See Section 4.4(b)(ii), Executive Order.

### **3) Screen customers who submit purchase orders of synthetic nucleic acids with SOCs, and of benchtop nucleic acid synthesis equipment, to verify legitimacy**

To adhere to this screening framework, Providers and Manufacturers should assess customer risk by following the 2023 HHS Guidance and industry standard “know your customer” practices. As noted in the 2023 HHS Framework, this includes assessing customer identity for all orders, such as point-of-contact name, institution, address, and contact information, and verifying customer legitimacy for orders containing SOCs. Notwithstanding the previous sentence, the Provider may still be adherent to this Framework without verifying customer legitimacy for exempted SOCs as described in the preceding section.

To adhere to this screening framework, Providers should develop and implement a process to assess the legitimacy of orders that have been identified by the sequence screening protocol as containing a SOC. The legitimacy of an order is determined by verifying the legitimacy of both the individual customer placing the order and their institution.

To adhere to this screening framework, Providers and Manufacturers should confirm the legitimacy of the individual customer by ensuring that the person (or customer) placing an order has no red flags,<sup>11</sup> is affiliated with a legitimate institution, and has a legitimate need for using synthetic nucleic acids.

To adhere to this screening framework, Providers and Manufacturers should confirm the legitimacy of the institution by verifying its legal standing and that it has a life sciences-oriented mission and purpose, or uses synthetic nucleic acids for other relevant applications,<sup>12</sup> and ensuring there are no red flags.<sup>13</sup>

To adhere to this screening framework, at a minimum, Providers should include a field or mechanism in their ordering system where customers can self-identify that an order contains a SOC. When an order does contain a SOC, Providers should also include a mechanism for customers to provide information that will be useful for verifying the customer’s legitimacy.<sup>14</sup> In addition, Providers should ask customers if they are the end user for the SOCs or if the order will be passed along to a third party(s), in which case the legitimacy of the third party(s) should also be assessed.

To adhere to this screening framework, Manufacturers should develop and implement a process to assess the legitimacy of orders for their equipment, such as through verified user accounts. As stated above, the legitimacy of an order is determined by verifying the legitimacy of both the individual

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<sup>11</sup> As defined in the 2023 HHS Guidance including its Companion Guide.

<sup>12</sup> Such as DNA storage or other emerging applications of synthetic biology.

<sup>13</sup> As defined in the 2023 HHS Guidance and discussed in its Companion Guide.

<sup>14</sup> While other types of information may also be useful for verifying customers’ legitimacy—as determined by individual Providers and Manufacturers—a mechanism for providing at least the following information should be included: proposed end user of the order, institutional or corporate affiliation (if applicable), the name of a biosafety officer (if available), documentation of internal review and approval of the research, evidence provided by the recipient’s Responsible Official that the recipient is registered with the Federal Select Agent Program (FSAP) or Statement by Ultimate Consignee and Purchaser (i.e., a completed BIS-711 form, if applicable), other evidence of a legitimate research or training program (e.g., publication history, researcher persistent identifiers such as ORCID, business licenses, grant numbers, research plan) or other legitimate use (e.g., diagnostic test development or manufacture). While all these types of information are not likely needed to verify individual instances of legitimacy, the opportunity to provide all of them should be included in ordering materials.

customer placing the order and their institution—which should include verification that the institution will cooperate in ensuring that benchtop synthesizers are only accessed by legitimate end users. Manufacturers should implement mechanisms to track legitimate use of their equipment, including when it is potentially transferred to a new user during the lifecycle of these equipment. Ensuring that benchtop nucleic acid synthesis equipment is only sold to legitimate customers and end users in this context also includes ensuring that proprietary and sole-use reagents for their benchtop synthesizers<sup>15</sup> are only sold to legitimate customers and end users, even if they were not screened for legitimacy when initially obtaining their benchtop nucleic acid synthesizer (e.g., if they acquired their equipment prior to the time this framework comes into effect).

#### **4) Report potentially illegitimate purchase orders of synthetic nucleic acids involving SOCs or of benchtop nucleic acid synthesis equipment**

To adhere to this screening framework, Providers and Manufacturers should develop criteria to determine when not to fill an order, based on this framework and as informed by the results of sequence and/or customer screening. In such cases, Providers and Manufacturers should follow the 2023 HHS Guidance and report flagged orders to relevant authorities, including, where appropriate, to an FBI Field Office. There are [56 FBI Field Offices](#) across the United States and Puerto Rico. Each FBI Field Office has a WMD Coordinator. Providers can identify FBI Field Offices using the above link. Flagged orders can be reported to a Field Office or through FBI’s general hotline for reporting suspicious WMD-related activity, 855-TELL-FBI (855-835-5324). Providers and Manufacturers may contact the WMD Coordinator at their respective Field Office to establish a relationship even before a flagged order occurs.

In cases where Providers and Manufacturers suspect that customers may be attempting to violate federal export control laws, Providers and Manufacturers are encouraged to report such violations to the U.S. Department of Commerce Bureau of Industry and Security through its [website](#) or by calling the Enforcement Hotline at 800-424-2980. Cyber incidents [can be reported](#) to the Cybersecurity Infrastructure Security Agency of the U.S. Department of Homeland Security under the Cyber Incident Reporting for Critical Infrastructure Act.

#### **5) Retain records relating to purchase orders for synthetic nucleic acids and benchtop nucleic acid synthesis equipment**

To adhere to this screening framework, Providers and Manufacturers should follow the 2023 HHS Guidance and retain for at least three years all screening records, including flagged orders; customer screening interactions, including when the orders were deemed acceptable; documentation of further action taken in response to flagged orders; and rationale for decisions about the legitimacy of customers whose orders were flagged, including where orders contained SOCs. Retained records may help identify attempts to order components of SOCs from multiple entities for reassembly, and to

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<sup>15</sup> Reagents that can only be obtained from the manufacturer for their equipment and do not have common applications other than the operation of their equipment.

support industry-wide collaborations to identify such orders. Such efforts may become part of future adherence standards.

### **6) Take steps to ensure cybersecurity and information security**

To adhere to this screening framework, Providers and Manufacturers should follow the practices outlined in the 2023 HHS Guidance regarding cybersecurity, information security, and securing SOC databases. As part of screening protocols, Providers and Manufacturers may consult internally or externally developed SOC databases. SOC databases compiling sequences that have been experimentally determined to contribute to pathogenicity or toxicity from unregulated agents may pose potential biosecurity risks, including from entities with malign intent that may attempt to exfiltrate data for illicit purposes. Therefore, Providers and Manufacturers that develop or maintain a SOC database with information on sequences from unregulated agents or that aggregate information that could pose biosecurity risks should implement appropriate cybersecurity safeguards to protect the information in it, both in transit and at rest, consistent with relevant cybersecurity Executive Orders, standards, and frameworks.<sup>16,17,18,19,20</sup>

To adhere to this screening framework, Providers and Manufacturers should also take appropriate measures to protect their customers' identities and proprietary information.<sup>21</sup> In addition, it is recommended that Providers and Manufacturers closely examine the security of their supply chains, following NIST SP 800-161.

To adhere to this screening framework, Providers and Manufacturers that suspect they have been the victim of a network intrusion, data breach, or ransomware attack should contact their [FBI Field Office](#), per instructions given above.

To adhere to this screening framework, Manufacturers should design their benchtop nucleic acid synthesis equipment with security and safety in mind. Manufacturers are encouraged to adhere to the Cybersecurity and Infrastructure Security Agency's Secure by Design principles, which are intended to encourage the design and manufacturing of products that reasonably protect against exploitation of product defects.<sup>22</sup>

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<sup>16</sup> Standards should align with the Presidential Executive Order 14028 on Improving the Nation's Cybersecurity (issued May 12, 2021) and the Cybersecurity Enhancement Act of 2014.

<sup>17</sup> ISO/IEC 27032:2023 & ISA/IEC 62443

<sup>18</sup> <https://www.nist.gov/cyberframework>

<sup>19</sup> <https://www.nist.gov/cybersecurity>

<sup>20</sup> Database administrators should patch systems against known cybersecurity vulnerabilities, in particular patching within seven days vulnerabilities known to be actively used by threat actors, such as those vulnerabilities listed on the freely available [Known Exploited Vulnerabilities](#) list. Database systems should be developed and deployed such that common cybersecurity weaknesses, such as [improper neutralization of special elements or commands](#), are prevented systematically rather than remediated ad hoc.

<sup>21</sup> As such, digital ID management of all entities involved in synthetic nucleic acid procurement should comply with NIST SP 800-63

<sup>22</sup> Further actions that can demonstrate adherence to the principles are detailed in CISA's whitepaper entitled "[Shifting the Balance of Cybersecurity Risk: Principles and Approaches for Secure by Design Software](#)." Manufacturers are also encouraged to review the FDA document [Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions](#).

## **VI. UPDATING THE SCREENING FRAMEWORK**

This screening framework will be updated based on advances in technologies and screening mechanisms. OSTP will continue to explore additional ways to promote consistent screening practices and verification mechanisms, including through the use of independent audits, and will update this framework as necessary.