Johns Hopkins Bloomberg School of Public Health | Center for Health Security

Providers: 6 Key Actions for Compliance

Most of the language in this document comes directly from the *US Framework for Nucleic Acid Synthesis Screening* (Framework) and reformatted for ease of use. See the Appendix for more information.

In order to be able to sell nucleic acid sequences to federally funded entities, Providers must comply with the Framework. To do so, Providers need to take the following 6 actions, summarized here with more detail beginning on the next page:

Action 1

Attest to implementing the Framework through a statement that either is posted on a public website or provided to both the federally funded customer and federal funding agency.

Action 2

Screen purchase orders for synthetic nucleic acids to identify sequences of concern (SOCs).

Action 3

Screen customers who submit purchase orders of synthetic nucleic acids with SOCs to verify legitimacy.

Action 4

Report potentially illegitimate purchase orders of synthetic nucleic acids involving SOCs.

Action 5

Retain records relating to purchase orders for synthetic nucleic acids.

Action 6

Take steps to ensure cybersecurity and information security.

Providers: 6 Key Actions for Compliance

Action 1: Attest to implementing the Framework through a statement that either is posted on a public website or provided to both the federally funded customer and federal funding agency.

- To adhere to the Framework:
  - ensure that the attestation is signed by an individual with the authority to respond on behalf of the organization;
  - provide point-of-contact information;
  - update the attestation by January 1st of each year, or more frequently if point-of-contact information changes; and
  - expressly commit in the attestation that, if Providers 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.
- Here is a sample version (developed by the Johns Hopkins Center for Health Security based on the University of California attestation form) that can be adapted by Providers for individual purposes: **Sample Attestation Form**

Action 2: Screen purchase orders for synthetic nucleic acids to identify sequences of concern (SOCs).

- **Before October 13, 2026:**
  - A Provider must screen 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—ie, the Biological Select Agents and Toxins (BSAT) list or, for international orders, the Commerce Control List (CCL)—are SOCs, *except when the sequence is identical to a sequence found in an unregulated organism or toxin*.
  - Orders of 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).
  - Providers 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.
  - 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. Providers should only exempt sequences from genes from non-viral agents with functions that cannot reasonably be construed as contributing to pathogenicity or toxicity (eg, 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.

- Please see the Framework for more details.
- Please see our non-exhaustive **list of available screening companies and tools**.

- **On or After October 13, 2026:**
  - Reduce the size of the screening window and screen each 50 nucleotide window for SOCs.
  - 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.
  - Make efforts to implement a mechanism to screen additional SOCs known to contribute to pathogenicity or toxicity, even when not derived from or encoding regulated biological agents.
    - 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.
  - Providers 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 they should undertake efforts to measure the effectiveness of this new screening criteria and improve screening over time.
  - Please see the Framework for more details.
  - Please see our non-exhaustive **list of available screening companies and tools**.

Action 3: Screen customers who submit purchase orders of synthetic nucleic acids with SOCs to verify legitimacy.

- Assess customer risk by following the 2023 HHS Guidance and industry standard "know your customer" practices. 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.
- Develop and implement a process to assess the legitimacy of orders that have been identified by the sequence screening protocol as containing an SOC. The legitimacy of an order is determined by verifying the legitimacy of both the individual customer placing the order and their institution.
- Confirm the legitimacy of the individual customer by ensuring that the person (or customer) placing an order has no red flags, is affiliated with a legitimate institution, and has a legitimate need for using synthetic nucleic acids.
- 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, and ensuring there are no red flags.
- At minimum, include a field or mechanism in ordering systems where customers can self-identify that an order contains an SOC. When an order does contain an SOC, Providers

should also include a mechanism for customers to provide information that is useful for verifying the customer's legitimacy.

- 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.

Action 4: Report potentially illegitimate purchase orders of synthetic nucleic acids involving SOCs.

- Develop criteria to determine when not to fill an order, based on the Framework and as informed by the results of sequence and/or customer screening. In such cases:
  - Follow the 2023 HHS Guidance and report flagged orders to relevant authorities, including, where appropriate, to the WMD coordinator at the nearest FBI Field Office or through the FBI's general hotline (1-800-CALL-FBI [1-800-225-5324]).
  - If there is suspicion that customers may be attempting to violate federal export control laws, (eg, Export Administration Regulations), Providers are encouraged to report such violations to the US Department of Commerce Bureau of Industry and Security or by calling its Enforcement Hotline (1-800-424-2980).
- Cyber incidents can be reported to the Cybersecurity Infrastructure Security Agency of the US Department of Homeland Security under the Cyber Incident Reporting for Critical Infrastructure Act.

Action 5: Retain records relating to purchase orders for synthetic nucleic acids.

- Follow the 2023 HHS Guidance.
- Retain for at least 3 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.

Action 6: Take steps to ensure cybersecurity and information security.

- Follow the practices outlined in the 2023 HHS Guidance regarding cybersecurity, information security, and securing SOC databases.
- As part of screening protocols, Providers may consult SOC databases developed internally or externally.
- Providers 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.
- Take appropriate measures to protect customers' identities and proprietary information.
- Closely examine the security of their supply chains, following NIST SP 800-161 Rev. 1.
- If there is suspicion of a network intrusion, data breach, or ransomware attack, contact the nearest FBI Field Office, per instructions given above.
- Please see the Framework for more details.

APPENDIX: Definitions

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

Table 1: Basic Definitions Used in the Framework for Nucleic Acid Synthesis Screening (adapted to include only the definitions relevant for Providers)

Term	Definition
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.
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 (ie, 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.
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.
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.

Providers: 6 Key Actions for Compliance

The 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

Non-Traditional Types of Providers	Definition
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 (eg, the ability to create nucleic acid sequences de novo 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.

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