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

Manufacturers: 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, Manufacturers must comply with the Framework. To do so, Manufacturers 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 synthetic nucleic acids to identify sequences of concern (SOCs).

Action 3

Screen customers who submit purchase orders benchtop nucleic acid synthesis equipment to verify legitimacy.

Action 4

Report potentially illegitimate orders of synthetic nucleic acids involving SOCs or of benchtop nucleic acid synthesis equipment.

Action 5

Retain records relating to orders for synthetic nucleic acids and benchtop nucleic acid synthesis equipment.

Action 6

Take steps to ensure cybersecurity and information security.

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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.

- The White House Office of Science and Technology Policy (OSTP) anticipates coordinating development of a standardized template statement Manufacturers may use for this purpose, if they wish.
- 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 Manufacturers for individual purposes: **Sample Attestation Form**

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

- **On or After October 13, 2026:**
  - 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 the 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.
  - 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 for benchtop nucleic acid synthesis equipment to verify legitimacy.

- Assess customer risk by following the 2023 HHS Guidance and industry standard "know your customer" practices.
- 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.
- 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 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.
- 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.
- Ensure that proprietary and sole-use reagents for benchtop synthesizers 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 (eg, if they acquired their equipment prior to the time this framework comes into effect).

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Action 4: Report potentially illegitimate orders of synthetic nucleic acids involving SOCs or of benchtop nucleic acid synthesis equipment.

- 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, Manufacturers 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 orders for synthetic nucleic acids and benchtop nucleic acid synthesis equipment.

- 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, Manufacturers may consult SOC databases developed internally or externally.
- 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.
- Take appropriate measures to protect customers' identities and proprietary information.
- Closely examine the security of their supply chains, following NIST SP 800-161.
- If there is suspicion of a network intrusion, data breach, or ransomware attack, contact the nearest FBI Field Office, per instructions given above.
- Design benchtop nucleic acid synthesis equipment with security and safety in mind. Manufacturers are encouraged to adhere to the Cybersecurity and Infrastructure Security Agency's (CISA) Secure by Design principles, which are intended to encourage the design and manufacturing of products that reasonably protect against exploitation of product defects.
- 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 Manufacturers)

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 (eg, 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.
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.

Last updated August 2024