National Policy for Nucleic Acid Synthesis Screening



November 2026

THE WHITE HOUSE

WASHINGTON

NSTM-6 November 5, 2026

MEMORANDUM FOR THE SECRETARY OF STATE
THE SECRETARY OF WAR
THE SECRETARY OF AGRICULTURE
THE SECRETARY OF COMMERCE
THE SECRETARY OF HEALTH AND HUMAN SERVICES
THE SECRETARY OF ENERGY
THE SECRETARY OF HOMELAND SECURITY
DIRECTOR OF NATIONAL INTELLIGENCE
DIRECTOR OF THE NATIONAL SCIENCE FOUNDATION

FROM: MARCO RUBIO
NATIONAL SECURITY ADVISOR

MICHAEL J. KRATSIOS
ASSISTANT TO THE PRESIDENT FOR SCIENCE AND TECHNOLOGY
DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY

SUBJECT: Implementing the National Policy for Nucleic Acid Synthesis Screening in Accordance with Executive Order 14292

Biotechnology is central to American medicine, research, and industrial competitiveness; nucleic acid synthesis is one of the core technologies underpinning modern biological innovation. The United States stands at the threshold of a profound transformation driven by the convergence of super intelligence (SI) and biology. In an SI-enabled future, biotechnology innovation and manufacturing increasingly rely on nucleic acid synthesis to translate discoveries into the physical world. If misused, however, synthetic nucleic acids can also supply the raw materials for biological threats.

We must continue to promote biotechnology innovation without jeopardizing our Nation's security, strength, or prosperity. Existing Federal guidance has relied on self-attestation rather than independent verification, forcing responsible American companies to compete against firms that bypass biosecurity safeguards for economic gain. Executive Order 14292 (on Improving the Safety and Security of Biological Research) calls for a national policy to replace the 2024 Framework for Nucleic Acid Synthesis Screening with a commonsense approach that closes the gaps malicious actors exploit.

Attached is the 2026 National Policy for Nucleic Acid Synthesis Screening ("Policy"). It requires all recipients of Federal life sciences funding to procure synthetic nucleic acids and benchtop synthesis equipment exclusively from certified suppliers that verify the legitimacy of customers and sequences ordered. The Policy replaces the 2024 Framework for Nucleic Acid Synthesis Screening and, on full

implementation, the 2023 HHS Screening Framework Guidance. It supports the 2026 U.S. Government Policy for Stopping High-Risk Life Sciences Research by limiting a source of material inputs for dangerous gain of function work, without stifling biological innovation.

The Policy conditions Federal funding on compliance with verifiable standards and establishes a dynamic, tech-enabled screening layer that keeps pace with evolving risks, including those from SI uplift. Within 90 days, the National Institute of Standards and Technology (NIST), working with other departments and agencies and the private sector, will issue standards and test and evaluation protocols for screening and benchtop equipment used in nucleic acid synthesis. NIST will subsequently begin verifying screeners and maintaining a list of those approved, and the Department of Health and Human Services (HHS) will publish the first list of adherent suppliers within 160 days. All customers that receive Federal funding must procure all synthetic nucleic acids from certified suppliers within 250 days, and all benchtop synthesis equipment within 340 days.

Frontier SI capabilities will unlock new opportunities for scientific discovery and transform how our Nation defends against biological threats. Through this Policy, the Administration is building a dynamic biosecurity defense centered on strong controls over the materials that enable synthetic biology misuse. Powered by SI, screening will shift from list-based to risk-based, creating a flexible framework that keeps pace with rapid technological advancement. These controls, in turn, will ensure the United States can continue extending the most powerful SI capabilities to our biotechnology innovators with confidence.

The Policy will position the United States to lead a new era of SI-enabled biotechnology innovation while setting the global standard for security. The future of biotechnology is being built in the United States, the home of the researchers, institutions, and companies that pioneered the modern tools of biology, from gene editing to high-throughput sequencing. Today, we are at the forefront of SI-enabled biological science, and American companies are the leading suppliers of synthetic nucleic acids and lab-scale DNA synthesis equipment to researchers around the world. By ensuring that providers of synthetic nucleic acid sequences implement comprehensive, scalable, and verifiable screening mechanisms, we will minimize the risk of misuse and share the benefits of secure biotechnology innovation with Americans and the world.

Purpose

Nucleic acid synthesis is a transformative technology for medicine, research, and the American bioeconomy. However, if used maliciously, it can threaten the Nation's economic and national security. For too long, American biotechnology leaders and other responsible innovators have had to compete against firms that bypass biosecurity safeguards for economic gain. To reverse these incentives, the United States will advance verifiable standards that turn responsible biosecurity practices into a competitive advantage in the global market.

Pursuant to Executive Order (EO) 14292, "Improving the Safety and Security of Biological Research," the 2026 Nucleic Acid Synthesis Screening Policy (hereafter "Policy") establishes comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms to minimize the risk of misuse. This Policy will be implemented in accordance with the schedule set forth in Table 1. On the date of full implementation outlined in Table 1, this Policy supersedes the 2024 Framework for Nucleic Acid Synthesis Screening, as well as any conflicting or inconsistent nucleic acid synthesis screening policy. Until that date, parties should continue to draw from the relevant portions of the 2023 Health and Human Services (HHS) Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids.

Scope and Covered Entities

To ensure that federally funded life sciences research benefits American citizens without jeopardizing the Nation's security, strength, and prosperity, this Policy sets forth the U.S. Government-wide policy for screening orders of synthetic nucleic acids, with the objective of applying to any order of 50 or more nucleotides in length, consistent with the baseline recommended in the 2023 HHS Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids.

This Policy applies to all recipients and subrecipients of Federal funds (i.e., Customers) that procure synthetic nucleic acids or Benchtop Nucleic Acid Synthesis Equipment, but should be implemented in a streamlined and scalable way that encourages its applicability to all synthetic nucleic acid orders. As a condition of receiving Federal research funding, such entities will procure synthetic nucleic acids and Benchtop Equipment only from Adherent Suppliers. This policy supplements and does not supersede applicable law, including export controls and the regulations governing Biological Select Agents and Toxins and the U.S. Government Policy for Stopping High-Risk Life Sciences Research (July 20, 2026), which continue to apply.

A Provider, Manufacturer, or Third-Party Vendor that supplies synthetic nucleic acids or Benchtop Equipment to Customers are either individually or jointly adherent to this Policy when it (1) subjects every order to a Screener verified by the National Institute of Standards and Technology (NIST), (2) conducts know-your-customer (KYC) verification, (3) reports Flagged Orders to the Appropriate Federal Authorities (e.g., the Federal Bureau of Investigation), (4) retains screening records and Customer interactions for a period of no-less-than 8 years, and (5) on lawful request provides such records to NIST or Appropriate Federal Authorities.

A verified Screener is a tool or service, or multiple thereof, that (1) assesses an order for sequences of concern (SOC) and for customer legitimacy through order-level KYC verification for SOCs, (2) issues a Screening Determination to a Supplier, and (3) reports Flagged Orders to Appropriate Federal Authorities, as applicable. Screening tool verification ensures that a Screener meets the screening standards issued by NIST as defined in this Policy and is eligible to be used by a Supplier.

Screening System Structure

To adhere to this Policy, a Supplier submits every in-scope synthetic nucleic acid order consisting of sequences 50 or more nucleotides in length to (or through) a verified Screener before that order is fulfilled, and retains exclusive responsibility for the following:

1. assesses each order, exercising judgement over the commercial relationship and the disposition of each;
2. conducts onboarding KYC verification when it establishes a commercial relationship with a customer as well as periodic re-verification;
3. retains all screening records and Customer interactions for a period of no less than 8 years as outlined in this Policy; and
4. on lawful request, provides records to NIST and Appropriate Federal Authorities as outlined in this Policy.

As the single control point for sequence risk screening, a verified Screener assesses all orders of 50 nucleotides or more in length for SOCs and customer legitimacy (if the order contains a SOC). This independent, order-level KYC screening ensures that for orders containing a SOC, customer legitimacy is verified at two distinct points: by the Supplier at the establishment of the commercial relationship, and by the verified Screener at the individual order level.

Reporting responsibility is shared by the verified Screener and the Supplier. The verified Screener assesses each order, provides the Supplier with the Screening Determination and reports any Flagged Orders to Appropriate Federal Authorities, as applicable. The Supplier documents the Screening Determination, exercises independent judgement over the disposition of the order, and reports to Appropriate Federal Authorities if screening concerns remain unresolved.

Synthesis performed on Benchtop Equipment presents the same risk and this Policy therefore requires that the control point be enforced at the equipment-level. Therefore, an adherent Manufacturer or the Third-Party Vendor provides Benchtop Equipment which initiates synthesis only when a valid authorization is issued by a verified Screener or for bounded offline operation as verified in accordance with published NIST standards.

Screening of Orders Fulfilled by Suppliers

The final disposition of every order rests with the Supplier. A Supplier can flag an order or may fulfill an order for which the screening determination records neither a SOC nor an unresolved question of customer legitimacy.[1] For Flagged Orders, the Supplier determines whether to fulfill or deny, and that determination is not met by the use of a verified Screener. Records are retained, and Flagged Orders reported with final disposition (fulfilled or denied), consistent with the standard developed by NIST. The technical means by which orders are transmitted to and assessed by a verified Screener, and by which a Screening Determination is issued, are established by NIST as defined in this Policy.

Screening of Synthesis Performed on Benchtop Equipment

Benchtop Equipment operates outside the physical and procedural controls of a centralized synthesis facility. Screening is therefore enforced by the equipment itself, which initiates synthesis only on receipt of a valid, unexpired authorization from a verified Screener corresponding to the submitted synthesis request, or during bounded offline operation verified in accordance with published NIST standards. Absent such an authorization, the equipment does not initiate synthesis. Manufacturers of obsolete Benchtop Equipment are encouraged to buy back or offer trade-in opportunities towards machines that meet the technical standards called for in this policy. NIST will establish the technical standards giving effect to this section, including the form, issuance, cryptographic verification, physical security, and validity of the authorization by which a verified Screener permits synthesis. These standards shall include the two tiers of equipment behavior set forth below.

Tier 1: Networked Authorization

A unit of Benchtop Equipment in communication with a verified Screener initiates synthesis only when a valid authorization is issued by that Screener for the request presented, and declines any request that is unauthorized, expired, or inconsistent with the authorization presented. Tier 1 is the default condition of operation for all Benchtop Equipment.

Tier 2: Bounded offline operation

A unit of Benchtop Equipment that cannot communicate with a verified Screener does not initiate synthesis, except to the limited extent in which NIST verification can be used to assure bounded offline operation as adherent to published standards. Where NIST verifies such operation, it will specify the conditions and technical means by which synthesis may be processed offline, the bounded operating limits that apply, and the records the equipment shall retain and later reconcile with the Manufacturer or a verified Screener on restoration of connectivity. Absent regular and necessary screening software updates, a unit of Benchtop Equipment does not initiate synthesis while unable to communicate with a verified Screener or unable to utilize the most updated screening software.

Obligations of Manufacturers

[1] NIST will continue to develop methods and technologies, including super intelligence-assisted approaches, that strengthen the detection of a SOC as outlined in this Policy.

A Manufacturer seeking to supply Customers will:

1. design and distribute Benchtop Equipment that initiates synthesis only when valid authorization is issued by a verified Screener, or for bounded offline operation as verified in accordance with published NIST standards for Tier 2 operation;
2. conduct onboarding KYC verification with periodic re-verification before distribution of Benchtop Equipment;
3. only supply equipment capable of maintaining tamper-resistant records of authorization issued, requests declined, and synthesis performed, and synchronize those records and screening software on at least a quarterly basis, or more frequently, as necessary; and
4. ensure that Equipment Customers are aware of the responsibilities of becoming a Provider of nucleic acids.

Roles and Responsibilities

NIST

Subject to the availability of funding, NIST, in collaboration with the HHS and the U.S. Department of Agriculture (USDA), in consultation with the heads of other executive branch departments and agencies (agencies) will:

a) develop and publish the application procedures and implementation plan for Screener verification, to include an opportunity for relevant agencies, including Federal law enforcement agencies, intelligence community components, Department of War, and the Department of State to share information and leverage national security processes related to requirements for Screener verification;

b) in consultation with Appropriate Federal Authorities and, as appropriate and in accordance with statute, private sector partners issue the standards that a Screener will meet to achieve and maintain verification, including documentary standards, test methods, reference datasets, performance criteria, Screening standards for Customer identity verification, and cybersecurity requirements sufficient to protect Customer and order data and to secure SOC databases;

c) specify the data that a verified Screener may receive, and the limits on its retention and use, including a requirement that a verified Screener not retain the sequence, order, or Customer data submitted to it beyond what is necessary to perform the assessment as determined by NIST, issue the Screening Determination, and report Flagged Orders as directed in this Policy;

d) stablish, maintain, and continuously update the reference list of and algorithm(s) for determining SOCs as new scientific and threat information emerges, and establish a procedure for the expedited and provisional addition and removal of sequences to that list, with the sufficient level of cyber security for and around the list and algorithm(s), including while at rest and for any necessary transfer or distribution;

e) develop pathway and technical means for risk-based oversight under the select agent program instead of list-based oversight for SOCs and for those categories of synthetic nucleic acids that are most likely to generate new SOCs;

f) test, evaluate, verify, and approve that Screeners are adherent to NIST-determined standards, publish and maintain the criteria and procedures governing verification, and afford a Screener found deficient a period of appropriate time to be adherent to the defined standards before verification is withdrawn;

g) maintain a list of verified Screeners; NIST will provide HHS and USDA a list of verified Screeners for determination of Adherent Suppliers;

h) establish, and update as appropriate, the standards and criteria by which the Adherence of a Supplier is verified, including the audit and documentation requirements that a Supplier must satisfy to demonstrate Adherence;

i) in coordination with relevant agencies, conduct tests and evaluations, including red teaming, of Screeners and Suppliers, to test the effectiveness of Screening methods, and incorporate the results into verification determinations and subsequent revisions of the standards;

j) establish the technical standards governing Benchtop Equipment, specifically the conditions and technical means by which synthesis may proceed offline and the bounded operating limits applicable to Tier 2 operation, to include physical security (e.g., tamper resistance) and cybersecurity;

k) research, develop, test, and validate novel Screening methods and technologies, including super intelligence-assisted approaches and considerations for addressing split orders, and, to the greatest extent feasible, incorporate them into the initial Screening standards and subsequent revisions; and

l) in collaboration with the Department of State and other relevant agencies, engage industry, academic, and standards development organizations to promote globally harmonized standards and practices consistent with this Policy; and

m) in coordination with the Appropriate Federal Authorities, establish standardized reporting procedures specifying: (1) reporting timelines and designated recipients; (2) expedited reporting procedures for reasonably suspected imminent or significant security threats; (3) procedures to minimize unnecessary duplicate reporting by Screeners and Suppliers; (4) minimum information requirements and secure transmission methods; and (5) procedures applicable when a Screener, Supplier, or Customer is located outside the United States or when disclosure may be restricted by applicable foreign law.

HHS and USDA

HHS, in coordination with USDA, will:

a) on the basis of the standards issued by NIST, publish and maintain a list of Adherent Suppliers and make the list publicly available;

b) pursuant to subsection 4(b) and section 7 of EO 14292, coordinate with other life sciences funding executive branch agencies to establish and pursue the uniform enforcement terms for this Policy;

c) vet and maintain a list of any foreign affiliations of Adherent Suppliers as well as other criteria needed to ensure independent screening;

d) pursuant to 42 U.S.C. 262a and 7 U.S.C. 8401, examine regulatory controls over whole and partial-genomes encoding select agents; and

e) incorporate this policy's requirements into federal assistance terms and conditions in a fashion aligned with implementation of the dangerous gain of function policy work.

Federal Funding Agencies

Pursuant to subsection 4(b) and section 7 of EO 14292, and consistent with applicable law and regulation, executive branch agencies funding life science research will incorporate into the terms and conditions of its awards a term providing that funding for research involving the procurement of synthetic nucleic acids or Benchtop Equipment is contingent on procurement from Adherent Suppliers. Regardless of the nature of transaction, Federal funding agencies must require individuals to keep records regarding any procurement, receipt, or exchange of SOCs or Benchtop Equipment. Researchers must execute such procurement, receipt, or exchange through a contractual or transactional agreement (e.g., a material transfer agreement). At a minimum, such contractual or transactional agreements must include prohibitions on exchanging synthetic nucleic acids or Benchtop Equipment from or to a researcher within a Covered Nation or that is otherwise barred under section 851 of the National Defense Authorization Act (NDAA) for Fiscal Year 2026, under the lists maintained pursuant to sections 1260H of the William M. (Mac) Thornberry NDAA for Fiscal Year (FY) 2021, and section 1286 of the John S. McCain NDAA for FY 2019or under the entities of concern list developed pursuant to EO 14292 and the U.S. Government Policy for Stopping High-Risk Life Sciences Research (July 20, 2026), to the extent that information is publicly available. Beginning on the date of full implementation outlined in Table 1 below, those terms shall incorporate this Policy and require compliance with the applicable implementation deadlines set forth in Table 1, including:

a) a term providing that compliance by the contractual counterparty or award recipient with this Policy, and with the guidance and standards issued under it, is material to the Government's payment decisions for purposes of 31 U.S.C. 3729(b)(4);

b) establish common award terms and conditions permitting awards made before the date of the release of this Policy that immediately apply on the date of full implementation in Table 1;

c) include a term regarding intra-institutional sharing of synthetic nucleic acids between known individuals when the sequences do not include a SOC;

d) a term providing that a violation of this Policy, or of the guidance and standards issued under it, by any recipient of Federal funding may be considered a violation of such term by the recipient's employer or institution; and

e) establish common award terms providing that a recipient of financial assistance, employer, or institution found to be in violation of the terms and conditions required by this Policy may be subject to immediate revocation of ongoing Federal funding, for a period of ineligibility of up to 5 years for Federal funds offered by relevant funding agencies, and to such additional penalties as are consistent with existing Federal law and regulation.

An agency head may issue a case-by-case exception to this Policy when necessary for a health or national security mission, in consultation with the Assistant to the President for Science and Technology and the Assistant to the President for National Security Affairs. A Supplier fulfilling an order for synthetic nucleic acids or benchtop equipment under such an exemption does not violate this Policy.

Customers

As directed by subsection 4(b) and section 7 of EO 14292 and consistent with the terms and conditions of Federal funding, a Customer will demonstrate that:

a) all procurement of synthetic nucleic acids is conducted through Adherent Suppliers; and

b) all procurement of Benchtop Equipment is conducted through Adherent Suppliers.

A Customer should provide, at the time an order is placed, information sufficient to permit the Supplier to verify the legitimacy of that order in conformity with the most current standards issued by NIST.

Suppliers

A Supplier seeking to receive and fulfill orders from Customers will demonstrate its Adherence in accordance with the standards and criteria established by NIST. A Supplier receiving orders from Customers will:

a) submit all orders for synthetic nucleic acids to a verified Screener, in conformity with the most current standards and criteria issued by NIST, and refrain from relying on a Screener that is not verified;

b) conduct onboarding KYC of each Customer, verifying the Customer's identity, institutional affiliation, foreign affiliation in compliance with 10 USC 4872(f) and the 1260H of the William M. (Mac) Thornberry NDAA for FY 2021, and section 1286 of the John S. McCain NDAA for FY 2019 authorization, and the legitimacy of the stated use before submitting that Customer's order for Screening;

c) report Flagged Orders to Appropriate Federal Authorities in conformity with this Policy;

d) retain securely, for a period of not-less-than 8 years, all Screening and order records, including Flagged Orders and associated biological data; records of Screening interactions with Customers, including those in which an order was determined to be acceptable, documentation of action taken in response to a Flagged Orders; and the basis for determinations regarding the legitimacy of Customers associated with Flagged Orders; and

e) make the records required under this section available to NIST, in support of Screener verification, adversarial evaluation, and of the verification of Supplier Adherence, and to Appropriate Federal Authorities on lawful request.

Reporting to Appropriate Federal Authorities

A verified Screener will report each Flagged Order, Screening Determination, and reason for Screening Determination to Appropriate Federal Authorities after issuing the Screening Determination. The Supplier will, to the maximum extent allowed by law, report the Flagged Orders to Appropriate Federal Authorities when Screening concerns remain unresolved following review of the Screening Determination.

Appropriate Federal Authorities will act on reports of Flagged Orders and other suspicious activity in accordance with their respective statutory authorities and missions. Appropriate Federal Authorities, including the Federal Bureau of Investigation, will designate and maintain a point of contact to receive such reports, and will work with NIST to incorporate standardized reporting procedures and formats into the Screening standards issued under Rules and Responsibilities section of this Policy.

Enforcement

Compliance with this Policy and with the guidance and standards issued under it is material to the Government's payment decisions for purposes of 31 U.S.C. 3729(b)(4). A recipient of financial assistance, employer, or institution found to be in violation may be subject to immediate revocation of ongoing Federal funding, to a period of ineligibility of up to 5 years for Federal funds, and to such additional penalties as are consistent with existing Federal law and regulation.

Implementation

Implementation of this policy shall start immediately on its publication. However, the 2023 HHS Screening Framework Guidance for Providers and Users of Synthetic Nucleic Acids shall remain in effect until full implementation of Table 1, or until the implementation step identified below supersedes it, whichever comes first. On the date of full implementation of this Policy, it shall supersede and rescind any conflicting or inconsistent nucleic acid synthesis screening policy.

Table 1. Schedule for implementation of this Policy

Implementation Step	Day
Release of this Policy	0
NIST issues Screening standards, Benchtop Equipment standards, and Screening test and evaluation protocols	90
NIST begins testing and verifying Screeners; begins maintaining list of verified Screeners	100
HHS publishes initial list of Adherent Suppliers	160
Customers procure all synthetic nucleic acids through Adherent Suppliers	250
Customers procure all Benchtop Equipment through Adherent Suppliers	340

Review and Revision

Consistent with subsection 4(b) of EO 14292, this Policy shall be reviewed and revised at least every four years, or as appropriate, to account for evolving biological threats and for risks and opportunities presented by novel technologies, including advances in super intelligence. NIST will revise the standards issued under Rules and Responsibilities section of this Policy as the results of adversarial evaluation warrant, without regard to the schedule for review of this Policy.

Definitions

For the purpose of this Policy, the following terms have the meanings set forth below.

a) "**Adherent**" means, with respect to a Supplier, that the Supplier:

1. submits every order to a verified Screener for Screening;
2. conducts onboarding KYC of the customer at the establishment of the commercial relationship, as well as periodic re-investigation;

3. reports Flagged Orders to Appropriate Federal Authorities as directed in this Policy;
4. retains records as required under Rules and Responsibilities of this Policy; and
5. on lawful request, provides records to NIST and Appropriate Federal Authorities as required under Rules and Responsibilities of this Policy.

The terms "Adhere" and "Adherence" have corresponding meanings.

b) "**Appropriate Federal Authorities**" may include the Federal Bureau of Investigation (FBI), the Department of Commerce (DOC), and the Bureau of Industry and Security (BIS), each acting within its respective statutory authority to receive and act on reports of Flagged Orders and other suspicious activity.

c) "**Benchtop Nucleic Acid Synthesis Equipment**" means Benchtop Equipment sold by Manufacturers that is intended to be used to synthesize nucleic acids for use within a research laboratory or institution. Nucleic acid synthesis equipment not small enough to be placed on a benchtop (e.g., sits on the laboratory floor) is considered Benchtop Nucleic Acid Synthesis Equipment if it is sold for use by Customers.

d) "**Covered Nation**" means a nation defined in 10 USC 4872(f)(2).

e) "**Customer**" means a recipient or subrecipient of Federal funds that requests synthetic nucleic acids, Benchtop Equipment, or related access from a Supplier.

f) "**Flagged Orders**" means an order or synthesis request that a Screening Determination has identified as containing a SOC and unresolved concerns regarding customer legitimacy (KYC). All Flagged Orders must meet NIST reporting standards.

g) "**Know Your Customer** (KYC)" means the verification of legitimate use by a customer, comprising verification of the Customer's identity, verification of the Customer's institutional affiliation and authorization, and verification that the Customer's stated use is consistent with the activities of the purchasing organization. KYC is performed at two points: by the Supplier at the establishment of the commercial relationship ("onboarding KYC"), and by the verified Screener at the level of the individual order ("order-level KYC").

h) "**Manufacturer**" means an entity that produces Benchtop Equipment and distributes or sells it to Customers.

i) "**Provider**" means an entity that synthesizes synthetic nucleic acids and sells or otherwise furnishes them to Customers.

j) "**Screener**" means a tool or service, or a series of tools or services, that assesses an order for sequence risk and for customer legitimacy through KYC verification, issues a Screening Determination to a Supplier, and reports Flagged Orders to Appropriate Federal Authorities as described in Reporting to Appropriate Federal Authorities section of this Policy, as applicable. A Screener is a verified Screener when NIST has verified it against the standards issued under Rules and Responsibilities section of this Policy. Any Screener may be verified, whether operated by a Supplier for its own orders or offered by a third party as a service to any Supplier. Screeners should not develop tools, reside in, be under the control of, or send data to or through a Covered Nation.

k) "**Screening**" means the assessment of an order, by a verified Screener, for sequence risk and the verification of customer legitimacy through KYC verification, in conformity with the standards issued under Rules and Responsibilities section of this Policy.

l) "**Screening Determination**" means the signed result issued by a verified Screener on assessment of an order, recording whether the order presents a SOC, unresolved concerns regarding customer legitimacy (KYC), both, or neither, or whether the assessment is indeterminate for lack of sufficient technical evidence. A Screening Determination does not itself authorize or refuse fulfillment; the disposition of an order remains the responsibility of a Supplier.

m) "**Sequence of Concern (SOC)**" means a nucleotide sequence 50 pairs or more in length that is a best match to a sequence derived from or encoding a Biological Select Agent or Toxin or an item on the Commerce Control List, except where the sequence is also found in organisms that are not regulated, or a sequence that otherwise contributes to pathogenicity or toxicity, biological weapons agents, or drug resistance, whether derived from or encoding a regulated or an unregulated biological agent. NIST will develop and maintain the standards and reference criteria by which Sequences of Concern are identified, and will advance methods that improve identification of Sequences of Concern, including those designed to evade comparison to known sequences.

n) "**Supplier**" means a Provider, a Manufacturer, or a Third-Party Vendor, including core facilities. Suppliers are collectively subject to the obligations set forth in Rules and Responsibilities section of this Policy. Suppliers should not reside in or be under control of a Covered Nation.

o) "**Third-Party Vendor**" means an entity that distributes, resells, or otherwise furnishes to Customers synthetic nucleic acids or Benchtop Equipment produced by another entity, including but not limited to regional distributors and resellers of both new and used Benchtop Nucleic Acid Synthesis Equipment.



The WHITE HOUSE