DEPARTMENT OF ENERGY
Financial Assistance Regulations

Date: November 22, 2024
No: FAL 2025-03

FINANCIAL ASSISTANCE LETTER

This Financial Assistance is issued under the authority of the Senior Procurement Executives of DOE and NNSA. It is intended for use by the procurement professionals of DOE, primarily Contracting and Grants Officers, and other officials of DOE that participate in the acquisition process. Other parties are welcome to its information, but definitive interpretation of its effect on DOE solicitations, Notice of Funding Opportunity Announcements, Awards, and other related procedures and actions may only be made by DOE Contracting and Grants Officers.

Subject: Implementation of the Framework for Nucleic Acid Synthesis Screening

References:
Executive Order 14110, Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

The White House Office of Science and Technology Policy (OSTP), Framework for Nucleic Acid Synthesis Screening

When is this Financial Assistance Letter (FAL) effective?

This FAL is effective upon issuance.

When does the FAL expire?

This FAL remains in effect until superseded or canceled.

Who is the intended audience?

Department of Energy (DOE) and National Nuclear Security Administration (NNSA) Contracting and Grants Officers. Any reference in this guidance to Contracting Officer (CO) should be understood to include Grants Officer (GO). Any reference in this guidance to the DOE should be understood to include the NNSA, unless otherwise indicated.

Who are the points of contact?

For DOE questions, contact the Contract and Financial Assistance Policy Division at DOE_OAPMPolicy@hq.doe.gov.

For NNSA questions, contact NNSA Office of Policy and Oversight Division, Policy & Oversight Branch (NA-PAS-111) at (505) 845-5639 or Reina.Serino@nnsa.doe.gov.

What is the purpose of this FAL?

The purpose of this FAL is to provide information and guidance regarding DOE's implementation of synthetic nucleic acids and benchtop nucleic synthesis equipment using federal life sciences funding.

What is the background information?

In October 2023, President Biden issued an 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 the Office of Science and Technology Policy (OSTP) develop a framework to encourage providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms.

The Executive Order further requires that all agencies that fund life sciences research will, as appropriate and consistent with applicable law, establish that, as a requirement of funding, federally funded research that uses synthetic nucleic acids and/or benchtop nucleic acid synthesis equipment is only being conducted through Providers and Manufacturers that adhere to the framework developed by OSTP.

What are the instructions/guidance of this FAL?

Sections

A. Applicability
B. Definitions
C. Implementation

A. Applicability

The FAL applies to all DOE and NNSA notice of funding opportunities (NOFOs), financial assistance agreements resulting from those NOFOs, and non-competitive financial assistance agreements– that are: 1) issued on or after the effective date of this FAL; and 2) encompass life sciences research and development (R&D) activities, or technical assistance to support life sciences R&D activities.

B. Definitions

Customer – as defined in the *Framework for Nucleic Acid Synthesis Screening*, is the individual or entity (such as an institution, principal users, end users, and third-party vendors) that orders or requests synthetic nucleic acids from a Provider, or that purchases nucleic acid synthesis equipment from a Manufacturer.

Provider —as defined in the *Framework for Nucleic Acid Synthesis Screening*, is 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.

Manufacturer — as defined in the *Framework for Nucleic Acid Synthesis Screening*, is an entity that produces and distributes benchtop equipment for synthesizing nucleic acids. Manufacturers may provide equipment to a customer or third-party vendor.

C. Implementation

Life Sciences R&D activities, or technical assistance to support life sciences R&D activities with synthetic nucleic acids of 200 nucleotides or more shall be implemented within 30 days of the effective date of this FAL, and for synthetic nucleic acids of 50 nucleotides or more by October 13, 2026. Grants Officers must:

1. Include the NOFO provision outlined in Attachment 1a for NOFOs that include life sciences research and development (R&D) activities, or technical assistance to support life sciences R&D activities.

2. Include the award term outlined in Attachment 1b for awards that include life sciences research and development (R&D) activities, or technical assistance to support life sciences R&D activities.

Attachment 1a

Language for Notices of Funding Opportunities

a. **Provision:** Grant Officers must include the following text in Award Administration for NOFOs that include life sciences R&D activities, or technical assistance to support life sciences R&D activities with synthetic nucleic acids – including but not limited to Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), whether single- or double-stranded, as well as whole organism genomes (e.g., viruses, bacteria), or the use of any benchtop equipment capable of synthesizing nucleic acids.

Framework for Nucleic Acid Synthesis Screening NOFO Language

Entities who receive an award under this funding opportunity are required to obtain synthetic nucleic acids or devices capable of synthesizing them – from Providers or Manufacturers that attest to implementing 2024 OSTP Framework for Nucleic Acid Synthesis Screening.

The attestation may be provided through: (1) a publicly posted statement (e.g., public website) or (2 directly to the Grants Officer and the prime recipient/subrecipient for subawards by the Provider or Manufacturer.

Flowdown of requirements to subrecipients. The prime recipient shall incorporate the substance of this term in its terms and conditions, including this paragraph, in all subawards in support of the award that may involve the procurement of synthetic nucleic acids and benchtop nucleic acid synthesis equipment.

Attachment 1b

Language for Award Term

b. **Term:** Grant Officers must include the following text in awards that include life sciences R&D activities, or technical assistance to support life sciences R&D activities with synthetic nucleic acids – including but not limited to Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), whether single- or double- stranded, as well as whole organism genomes (e.g., viruses, bacteria), or the use of any benchtop equipment capable of synthesizing nucleic acids.

Framework for Nucleic Acid Synthesis Screening Requirement

Entities conducting life sciences R&D activities, or technical assistance to support life sciences R&D activities awards issued after October 2024 with synthetic nucleic acids – including but not limited to Deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), whether single- or double-stranded, as well as whole organism genomes (e.g., viruses, bacteria), or the use of any benchtop equipment capable of synthesizing nucleic acids are required to obtain synthetic nucleic acids or devices capable of synthesizing them – from Providers or Manufacturers that attest to implementing 2024 OSTP Framework for Nucleic Acid Synthesis Screening.

The attestation may be provided through: (1) a publicly posted statement (e.g., public website) or (2) directly to the Grants Officer and the prime recipient/subrecipient for subawards by the Provider or Manufacturer. The Provider or Manufacturer must ensure that the attestation is signed by an individual with authority to respond on behalf of the organization.

Flowdown of requirements to subrecipients. The prime recipient shall incorporate the substance of this term in its terms and conditions, including this paragraph, in all subawards in support of the award that may involve the procurement of synthetic nucleic acids and benchtop nucleic acid synthesis equipment.