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(Original Signature of Member)

119<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R.** \_\_\_\_\_

To establish in the National Institute of Standards and Technology a program of measurement research for engineering biology, biomanufacturing, and biometrology, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mrs. McCLAIN DELANEY introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To establish in the National Institute of Standards and Technology a program of measurement research for engineering biology, biomanufacturing, and biometrology, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Standards and Calibra-  
5 tion for American Leadership in Engineering Biology Act”  
6 or the “SCALE Biology Act”.

1 **SEC. 2. NIST BIOMETROLOGY LABORATORY PROGRAM.**

2 (a) CERTAIN IMPLEMENTATION ACTIVITIES.—Sub-  
3 section (c) of section 2 of the National Institute of Stand-  
4 ards and Technology Act (15 U.S.C. 272) is amended—

5 (1) in the matter preceding paragraph (1), by  
6 inserting a comma after “Director”;

7 (2) by redesignating paragraphs (22) through  
8 (32) as paragraphs (23) through (33), respectively;  
9 and

10 (3) by inserting after paragraph (21) the fol-  
11 lowing new paragraph:

12 “(22) perform research to facilitate and support  
13 the development of a voluntary, consensus-based set  
14 of technical standards, guidelines, best practices,  
15 methodologies, procedures, and processes for engi-  
16 neering biology, biomanufacturing, biotechnology,  
17 and biometrology;”.

18 (b) BIOMETROLOGY LABORATORY PROGRAM.—The  
19 National Institute of Standards and Technology Act (15  
20 U.S.C. 271 et seq.) is amended—

21 (1) by redesignating section 36 (15 U.S.C. 271  
22 note) as section 37; and

23 (2) by inserting after section 35 (15 U.S.C.  
24 278t) the following new section:

1 **“SEC. 36. BIOMETROLOGY LABORATORY PROGRAM.**

2 “(a) IN GENERAL.—The Secretary, acting through  
3 the Director, shall establish a program of measurement  
4 research for engineering biology, biomanufacturing, and  
5 biotechnology (in this section referred to as the ‘bio-  
6 metrology laboratory program’.

7 “(b) PURPOSES.—The purposes of biometrology lab-  
8 oratory program are the following:

9 “(1) To enable innovation and industrial com-  
10 petitiveness in engineering biology, biomanufac-  
11 turing, and biotechnology.

12 “(2) To improve the accuracy, interoperability,  
13 and reliability of biological data and materials.

14 “(3) To support the safe, secure, and respon-  
15 sible development and application of biological tech-  
16 nologies across sectors to support economic and na-  
17 tional security.

18 “(c) ACTIVITIES.—In carrying out the biometrology  
19 laboratory program, the Director shall carry out the fol-  
20 lowing:

21 “(1) Support basic measurement science and  
22 technology research for engineering biology, bio-  
23 manufacturing, and biotechnology to advance the  
24 following:

25 “(A) Measurement technologies to support  
26 foundational understanding of the mechanisms

1 of conversion of DNA information into cellular  
2 function.

3 “(B) Technologies for measurement of bio-  
4 molecular components and related systems used  
5 for engineering biology, biomanufacturing, and  
6 biotechnology, including biomolecular compo-  
7 nents and related systems pertinent to commer-  
8 cial scale and distributed manufacturing of  
9 products.

10 “(C) Tools, technical standards, guidelines,  
11 best practices, methodologies, procedures, and  
12 processes for biological data.

13 “(D) Life cycle and sustainability assess-  
14 ments of engineering biology, biomanufacturing,  
15 and biotechnology products.

16 “(E) The development of technical stand-  
17 ards, guidelines, best practices, methodologies,  
18 procedures, and processes that can inform and  
19 address biorisk, biosafety, and biosecurity con-  
20 cerns.

21 “(F) Other areas of measurement science  
22 and technology research determined by the Di-  
23 rector to be critical to the development and de-  
24 ployment of biometrology.

1           “(2) Inform and expand the development of  
2           measurements infrastructure needed to develop tech-  
3           nical standards to establish interoperability and fa-  
4           cilitate commercial development of the following:

5                   “(A) Biometrology technology.

6                   “(B) Engineering biology, biomanufac-  
7           turing, and biotechnology.

8           “(3) Seek to convene representatives of indus-  
9           try, institutions of higher education, nonprofit orga-  
10          nizations, Federal laboratories, and other Federal  
11          agencies engaged in engineering biology, biomanu-  
12          facturing, and biotechnology research and develop-  
13          ment to develop coordinated technical roadmaps for  
14          authoritative measurement of the molecular compo-  
15          nents of the cell.

16           “(4) Provide access to user facilities with ad-  
17           vanced or unique equipment, services, materials, and  
18           other resources to industry, institutions of higher  
19           education, nonprofit organizations, and Federal,  
20           State, and Tribal government agencies to perform  
21           research and testing.

22           “(5) Establish or expand, as appropriate, col-  
23           laborative partnerships or consortia with other Fed-  
24           eral agencies engaged in engineering biology, bio-  
25           manufacturing, and biotechnology research and de-

1        velopment, institutions of higher education, Federal  
2        laboratories, and industry to advance engineering bi-  
3        ology, biomanufacturing, and biotechnology applica-  
4        tions.

5            “(6) Support graduate and postgraduate re-  
6        search and training in biometrology.

7            “(7) Establish and periodically update, as ap-  
8        propriate, common definitions and terminology per-  
9        taining to engineering biology, biomanufacturing,  
10       biotechnology, and the bioeconomy, and maintain a  
11       publicly available lexicon of such definitions and ter-  
12       minology.

13           “(8) Support extramural research, as appro-  
14       priate, that helps the Institute in advancing meas-  
15       urement science, standards, and guidelines for bio-  
16       metrology, engineering biology, biomanufacturing,  
17       and biotechnology.

18           “(9) In coordination with the heads of relevant  
19       Federal agencies, as appropriate, identify where  
20       technical standards, standardized assessments, or  
21       other governance pathways are needed to manage  
22       risks and support the commercialization of novel en-  
23       gineering biology, biomanufacturing, and bio-  
24       technology.

1       “(d) ENGINEERING BIOLOGY FOUNDRY.—In car-  
2 rying out the biometrology laboratory program, and in  
3 partnership with industry, institutions of higher edu-  
4 cation, and nonprofit organizations, the Director shall  
5 support the development of engineering biology related  
6 foundries to improve measurement assurance and make  
7 the engineering of living measurement systems more pred-  
8 icable, scalable, and routine.

9       “(e) OUTREACH.—In carrying out the activities  
10 under subsection (c), the Director shall seek input from  
11 other Federal agencies, institution of higher education,  
12 nonprofit organizations, and industry, on an ongoing  
13 basis, to help inform research and development priorities,  
14 including through workshops and other multistakeholder  
15 activities.

16       “(f) COORDINATION.—

17               “(1) FEDERAL DEPARTMENTS AND AGEN-  
18 CIES.—In carrying out the activities under sub-  
19 section (c), the Director shall coordinate with the  
20 heads of appropriate Federal departments and agen-  
21 cies, including the Executive Office of the President  
22 and the National Engineering Biology Research and  
23 Development Initiative established pursuant to sec-  
24 tion 10402 of the Research and Development, Com-  
25 petition, and Innovation Act (42 U.S.C. 19132).

1           “(2) MANUFACTURING USA PROGRAM.—The  
2           Director shall coordinate the activities carried out  
3           pursuant to subsection (c) with the Manufacturing  
4           USA Program, as the Director considers appro-  
5           priate, to support United States leadership in bio-  
6           manufacturing.

7           “(3) BIOMASS FEEDSTOCK UTILIZATION.—The  
8           Director, as practicable and appropriate, shall sup-  
9           port efforts relating to the coordination and develop-  
10          ment of biomass feedstock utilization with the Sec-  
11          retary of Energy and the Biomass Research and De-  
12          velopment Board established pursuant to section  
13          9008 of the Farm Security and Rural Investment  
14          Act of 2002 (7 U.S.C. 8108).

15          “(g) CONTROLS.—In carrying out the biometrology  
16          laboratory program, the Director shall ensure proper secu-  
17          rity controls are in place to protect sensitive information,  
18          as appropriate.

19          “(h) REPORT.—Not later than three years after the  
20          date of the enactment of this section, the Director shall  
21          submit to the Committee on Science, Space, and Tech-  
22          nology of the House of Representatives and the Committee  
23          on Commerce, Science, and Transportation of the Senate,  
24          and make publicly available on the website of the Institute,

1 a report regarding the implementation by the Institute of  
2 the biometrology laboratory program.

3 “(i) IMPLEMENTATION PLAN.—Not later than the  
4 end of the first fiscal year after the date of the enactment  
5 of this section, the Director shall submit to the Committee  
6 on Science, Space, and Technology and the Committee on  
7 Appropriations of the House of Representatives and the  
8 Committee on Commerce, Science, and Transportation  
9 and the Committee on Appropriations of the Senate, and  
10 make available on a public website of the Institute, a plan  
11 to carry out the biometrology laboratory program, includ-  
12 ing the following:

13 “(1) A plan for establishing the Biometrology  
14 Laboratory Program within the Institute as de-  
15 scribed by this section, including in relation to the  
16 Institute’s Material Measurement Lab and Physical  
17 Measurement Lab.

18 “(2) A plan of how the Institute will carry out  
19 the biometrology laboratory program’s activities  
20 under section.

21 “(3) A plan of how to leverage existing Insti-  
22 tute infrastructure and expertise to drive inter-  
23 national cooperation for the advancement of vol-  
24 untary consensus standards.

1       “(j) AUTHORIZATIONS.—There are authorized to be  
2 appropriated to the Director to carry out this section as  
3 follows:

4           “(1) \$55,000,000 for fiscal year 2026.

5           “(2) \$60,000,000 for fiscal year 2027.

6           “(3) \$70,000,000 for fiscal year 2028.

7           “(4) \$78,000,000 for fiscal year 2029.

8           “(5) \$85,000,000 for fiscal year 2030.

9       “(k) DEFINITIONS.—In this section:

10           “(1) IN GENERAL.—The following terms have  
11 the meanings given such terms, respectively, in sec-  
12 tion 10401 of the Research and Development, Com-  
13 petition, and Innovation Act (42 U.S.C. 19131):

14           “(A) Bioeconomy.

15           “(B) Biological data.

16           “(C) Biomanufacturing.

17           “(D) Biomass.

18           “(E) Biometrology.

19           “(F) Biorisk.

20           “(G) Biosafety.

21           “(H) Biosecurity.

22           “(I) Biotechnology.

23           “(J) Engineering biology.

24       “(2) ADDITIONAL TERMS.—

1           “(A) DIRECTOR.—The term ‘Director’  
2 means the Director of the National Institute of  
3 Standards and Technology.

4           “(B) INSTITUTE.—The term ‘Institute’  
5 means the National Institute of Standards and  
6 Technology.

7           “(C) INSTITUTION OF HIGHER EDU-  
8 CATION.—The term ‘institution of higher edu-  
9 cation’ has the meaning given such term in sec-  
10 tion 101(a) of the Higher Education Act of  
11 1965 (20 U.S.C. 1001(a)).

12           “(D) NONPROFIT ORGANIZATION.—The  
13 term ‘nonprofit organization’ means an organi-  
14 zation described in section 501(c)(3) of the In-  
15 ternal Revenue Code of 1986 and exempt from  
16 tax under section 501(a) of such code.

17           “(E) SECRETARY.—The term ‘Secretary’  
18 means the Secretary of Commerce.

19           “(F) TECHNICAL STANDARD.—The term  
20 ‘technical standard’ has the meaning given such  
21 term in section 12(d)(5) of the National Tech-  
22 nology Transfer and Advancement Act of 1995  
23 (15 U.S.C. 272 note).”

1 **SEC. 3. TECHNICAL AND CONFORMING AMENDMENTS.**

2 (a) REPEAL.—Section 10221 of the Research and  
3 Development, Competition, and Innovation Act (42 U.S.C.  
4 18931) is repealed, and the item relating to such section  
5 in the table of contents in sections 1 and 10000 for such  
6 Act is struck.

7 (b) DEFINITIONS.—

8 (1) GLOBAL DEFINITIONS.—Section 10002 of  
9 the Research and Development, Competition, and  
10 Innovation Act (42 U.S.C. 18901) is amended—

11 (A) by striking paragraphs (4) and (6);

12 and

13 (B) by redesignating—

14 (i) paragraph (5) as paragraph (4);

15 and

16 (ii) paragraphs (7) through (30) as  
17 paragraphs (5) through (28), respectively.

18 (2) TITLE DEFINITIONS.—Section 10401 of the  
19 Research and Development, Competition, and Inno-  
20 vation Act (42 U.S.C. 19131) is amended—

21 (A) by redesignating paragraphs (1) and

22 (2) as paragraphs (10) and (11), respectively;

23 and

24 (B) by inserting before paragraph (10), as  
25 so redesignated, the following new paragraphs:

1           “(1) BIOECONOMY.—The term ‘bioeconomy’  
2 means the economic activity derived from the life  
3 sciences, particularly in the areas of biotechnology  
4 and biomanufacturing, including industries, prod-  
5 ucts, services, and the workforce.

6           “(2) BIOLOGICAL DATA.—The term ‘biological  
7 data’ means the information, including associated  
8 descriptors, derived from the structure, function, or  
9 process of a biological system(s) that is measured,  
10 collected, or aggregated for analysis.

11           “(3) BIOMANUFACTURING.—The term ‘bio-  
12 manufacturing’ means the use of biological systems,  
13 including the use of biomass as a feedstock, to  
14 produce commercially important goods and services.

15           “(4) BIOMASS.—The term ‘biomass’ means any  
16 material of biological origin that is available on a re-  
17 newable or recurring basis.

18           “(5) BIORISK.—The term ‘biorisk’ means the  
19 effect of uncertainty expressed by the combination of  
20 the consequences and the associated likelihood of oc-  
21 currence that a biological event will adversely affect  
22 the health of humans, nonhuman animals, or the en-  
23 vironment.

24           “(6) BIOSAFETY.—The term ‘biosafety’ means  
25 the practices, controls, and containment infrastruc-

1           ture that reduce the risk of unintended exposure to,  
2           contamination with, release of, or harm from patho-  
3           gens, toxics, and biological materials.

4           “(7) BIOSECURITY.—The term ‘biosecurity’  
5           means the security measures designed to prevent the  
6           loss, theft, misuse, diversion, unauthorized posses-  
7           sion or material introduction, or intentional release  
8           of pathogens, toxics, biological materials, and related  
9           information or technology.

10          “(8) BIOTECHNOLOGY.—The term ‘bio-  
11          technology’ means technology that applies to or is  
12          enabled by life sciences innovation or product devel-  
13          opment.

14          “(9) ENGINEERING BIOLOGY.—The term ‘engi-  
15          neering biology’ means the design, construction, or  
16          assembly of the components of living systems (such  
17          as genetics circuits, enzymes, or metabolic pathways)  
18          to achieve an intended function or outcome.”.