

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 8981**

**OFFERED BY MS . McClain Delaney (MD)**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

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

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

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

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

11           (2) by redesignating paragraphs (22) through  
12       (32) as paragraphs (23) through (33), respectively;  
13       and

14           (3) by inserting after paragraph (21) the fol-  
15       lowing new paragraph:

16           “(22) perform research to facilitate and support  
17       the development of a voluntary, consensus-based set  
18       of technical standards, guidelines, best practices,

1 methodologies, procedures, and processes for engi-  
2 neering biology, biomanufacturing, biotechnology,  
3 and biometrology;”.

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

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

9 (2) by inserting after section 35 (15 U.S.C.  
10 278t) the following new section:

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

12 “(a) IN GENERAL.—The Secretary, acting through  
13 the Director, shall establish a program of measurement  
14 research for engineering biology, biomanufacturing, and  
15 biotechnology (in this section referred to as the ‘bio-  
16 metrology laboratory program’).

17 “(b) PURPOSES.—The purposes of the biometrology  
18 laboratory program are the following:

19 “(1) To enable innovation and industrial com-  
20 petitiveness in engineering biology, biomanufac-  
21 turing, and biotechnology.

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

24 “(3) To support the safe, secure, and respon-  
25 sible development and application of biological tech-

1       nologies across sectors to support economic and na-  
2       tional security.

3       “(c) ACTIVITIES.—In carrying out the biometrology  
4       laboratory program, the Director shall carry out the fol-  
5       lowing:

6               “(1) Support basic measurement science and  
7       technology research for engineering biology, bio-  
8       manufacturing, and biotechnology to advance the  
9       following:

10               “(A) Measurement technologies to support  
11       foundational understanding of the mechanisms  
12       of conversion of DNA information into cellular  
13       function.

14               “(B) Technologies for measurement of bio-  
15       molecular components and related systems used  
16       for engineering biology, biomanufacturing, and  
17       biotechnology, including biomolecular compo-  
18       nents and related systems pertinent to commer-  
19       cial scale and distributed manufacturing of  
20       products.

21               “(C) Tools, technical standards, guidelines,  
22       best practices, methodologies, procedures, and  
23       processes for biological data.

1           “(D) Life cycle and sustainability assess-  
2           ments of engineering biology, biomanufacturing,  
3           and biotechnology products.

4           “(E) The development of technical stand-  
5           ards, guidelines, best practices, methodologies,  
6           procedures, and processes that can inform and  
7           address biorisk, biosafety, and biosecurity con-  
8           cerns.

9           “(F) Other areas of measurement science  
10          and technology research determined by the Di-  
11          rector to be critical to the development and de-  
12          ployment of biometrology.

13          “(2) Inform and expand the development of  
14          measurements infrastructure needed to develop tech-  
15          nical standards to establish interoperability and fa-  
16          cilitate commercial development of the following:

17               “(A) Biometrology technology.

18               “(B) Engineering biology, biomanufac-  
19               turing, and biotechnology.

20          “(3) Seek to convene representatives of indus-  
21          try, institutions of higher education, nonprofit orga-  
22          nizations, Federal laboratories, and other Federal  
23          agencies engaged in engineering biology, biomanu-  
24          facturing, and biotechnology research and develop-  
25          ment to develop coordinated technical roadmaps for

1 authoritative measurement of the molecular compo-  
2 nents of the cell.

3 “(4) Provide access to user facilities with ad-  
4 vanced or unique equipment, services, materials, and  
5 other resources to industry, institutions of higher  
6 education, nonprofit organizations, and Federal,  
7 State, and Tribal government agencies to perform  
8 research and testing.

9 “(5) Establish or expand, as appropriate, col-  
10 laborative partnerships or consortia with other Fed-  
11 eral agencies engaged in engineering biology, bio-  
12 manufacturing, and biotechnology research and de-  
13 velopment, institutions of higher education, Federal  
14 laboratories, and industry to advance engineering bi-  
15 ology, biomanufacturing, and biotechnology applica-  
16 tions.

17 “(6) Support graduate and postgraduate re-  
18 search and training in biometrology, biomanufac-  
19 turing, and engineering biology.

20 “(7) Establish and periodically update, as ap-  
21 propriate, common definitions and terminology per-  
22 taining to engineering biology, biomanufacturing,  
23 biotechnology, and the bioeconomy, and maintain a  
24 publicly available lexicon of such definitions and ter-  
25 minology.

1           “(8) Support extramural research, as appro-  
2           priate, that helps the Institute in advancing meas-  
3           urement science, standards, and guidelines for bio-  
4           metrology, engineering biology, biomanufacturing,  
5           and biotechnology.

6           “(9) In coordination with the heads of relevant  
7           Federal agencies, as appropriate, identify where  
8           technical standards, standardized assessments, or  
9           other governance pathways are needed to manage  
10          risks and support the commercialization of novel en-  
11          gineering biology, biomanufacturing, and bio-  
12          technology.

13          “(d) ENGINEERING BIOLOGY FOUNDRY.—In car-  
14          rying out the biometrology laboratory program, and in  
15          partnership with industry, institutions of higher edu-  
16          cation, and nonprofit organizations, the Director shall  
17          support the development of engineering biology related  
18          foundries to improve measurement assurance and make  
19          the engineering of living measurement systems more pre-  
20          dictable, scalable, and routine.

21          “(e) OUTREACH.—In carrying out the activities  
22          under subsection (c), the Director shall seek input from  
23          other Federal agencies, institutions of higher education,  
24          nonprofit organizations, and industry, on an ongoing  
25          basis, to help inform research and development priorities,

1 including through workshops and other multistakeholder  
2 activities.

3 “(f) COORDINATION.—

4 “(1) FEDERAL DEPARTMENTS AND AGEN-  
5 CIES.—In carrying out the activities under sub-  
6 section (c), the Director shall coordinate with the  
7 heads of appropriate Federal departments and agen-  
8 cies, including the Executive Office of the President  
9 and the National Engineering Biology Research and  
10 Development Initiative established pursuant to sec-  
11 tion 10402 of the Research and Development, Com-  
12 petition, and Innovation Act (42 U.S.C. 19132).

13 “(2) MANUFACTURING USA PROGRAM.—The  
14 Director shall coordinate the activities carried out  
15 pursuant to subsection (c) with the Manufacturing  
16 USA Program, as the Director considers appro-  
17 priate, to support United States leadership in bio-  
18 manufacturing.

19 “(3) BIOMASS FEEDSTOCK UTILIZATION.—The  
20 Director, as practicable and appropriate, shall sup-  
21 port efforts relating to the coordination and develop-  
22 ment of biomass feedstock utilization with the Sec-  
23 retary of Energy and the Biomass Research and De-  
24 velopment Board established pursuant to section

1       9008 of the Farm Security and Rural Investment  
2       Act of 2002 (7 U.S.C. 8108).

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

7       “(h) REPORT.—Not later than three years after the  
8 date of the enactment of this section, the Director shall  
9 submit to the Committee on Science, Space, and Tech-  
10 nology of the House of Representatives and the Committee  
11 on Commerce, Science, and Transportation of the Senate,  
12 and make publicly available on the website of the Institute,  
13 a report regarding the implementation by the Institute of  
14 the biometrology laboratory program.

15       “(i) IMPLEMENTATION PLAN.—Not later than the  
16 end of the first fiscal year after the date of the enactment  
17 of this section, the Director shall submit to the Committee  
18 on Science, Space, and Technology and the Committee on  
19 Appropriations of the House of Representatives and the  
20 Committee on Commerce, Science, and Transportation  
21 and the Committee on Appropriations of the Senate, and  
22 make available on a public website of the Institute, a plan  
23 to carry out the biometrology laboratory program, includ-  
24 ing the following:



1           “(1) A plan for establishing the Biometrology  
2       Laboratory Program within the Institute as de-  
3       scribed by this section, including in relation to the  
4       Institute’s Material Measurement Laboratory and  
5       Physical Measurement Laboratory.

6           “(2) A plan of how the Institute will carry out  
7       the biometrology laboratory program’s activities  
8       under this section.

9           “(3) A plan of how to leverage existing Insti-  
10      tute infrastructure and expertise to drive inter-  
11      national cooperation for the advancement of vol-  
12      untary consensus standards.

13          “(4) A plan of how the Director will ensure the  
14      Institute will carry out the biometrology laboratory  
15      program’s activities safely and securely in compli-  
16      ance with existing law.

17      “(j) DEFINITIONS.—In this section:

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

22              “(A) Bioeconomy.

23              “(B) Biological data.

24              “(C) Biomanufacturing.

25              “(D) Biomass.

1 “(E) Biometrology.

2 “(F) Biorisk.

3 “(G) Biosafety.

4 “(H) Biosecurity.

5 “(I) Biotechnology.

6 “(J) Engineering biology.

7 “(2) ADDITIONAL TERMS.—

8 “(A) DIRECTOR.—The term ‘Director’  
9 means the Director of the National Institute of  
10 Standards and Technology.

11 “(B) INSTITUTE.—The term ‘Institute’  
12 means the National Institute of Standards and  
13 Technology.

14 “(C) INSTITUTION OF HIGHER EDU-  
15 CATION.—The term ‘institution of higher edu-  
16 cation’ has the meaning given such term in sec-  
17 tion 101(a) of the Higher Education Act of  
18 1965 (20 U.S.C. 1001(a)).

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

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

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

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

7           (a) REPEAL.—Section 10221 of the Research and  
8           Development, Competition, and Innovation Act (42 U.S.C.  
9           18931) is repealed, and the item relating to such section  
10          in the table of contents in sections 1 and 10000 for such  
11          Act is struck.

12          (b) DEFINITIONS.—

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

16                       (A) by striking paragraphs (4) and (6);  
17                       and

18                       (B) by redesignating—

19                               (i) paragraph (5) as paragraph (4);  
20                               and

21                               (ii) paragraphs (7) through (30) as  
22                               paragraphs (5) through (28), respectively.

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

1 (A) by redesignating paragraphs (1) and  
2 (2) as paragraphs (10) and (11), respectively;  
3 and

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

6 “(1) BIOECONOMY.—The term ‘bioeconomy’  
7 means the economic activity derived from the life  
8 sciences, particularly in the areas of biotechnology  
9 and biomanufacturing, including industries, prod-  
10 ucts, services, and the workforce.

11 “(2) BIOLOGICAL DATA.—The term ‘biological  
12 data’ means the information, including associated  
13 descriptors, derived from the structure, function, or  
14 process of a biological system(s) that is measured,  
15 collected, or aggregated for analysis.

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

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

23 “(5) BIORISK.—The term ‘biorisk’ means the  
24 effect of uncertainty expressed by the combination of  
25 the consequences and the associated likelihood of oc-

1 currence that a biological event will adversely affect  
2 the health of humans, nonhuman animals, or the en-  
3 vironment.

4 “(6) BIOSAFETY.—The term ‘biosafety’ means  
5 the practices, controls, and containment infrastruc-  
6 ture that reduce the risk of unintended exposure to,  
7 contamination with, release of, or harm from patho-  
8 gens, toxics, and biological materials.

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

15 “(8) BIOTECHNOLOGY.—The term ‘bio-  
16 technology’ means technology that applies to or is  
17 enabled by life sciences innovation or product devel-  
18 opment.

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

