

119TH CONGRESS
2D SESSION

S. _____

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

IN THE SENATE OF THE UNITED STATES

Mr. BUDD (for himself and Ms. BLUNT ROCHESTER) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To establish in the National Institute of Standards and Technology a program of measurement research, 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.—Sec-
3 tion 2(c) of the National Institute of Standards and Tech-
4 nology Act (15 U.S.C. 272(c)) 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:

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:

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 support 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.—

10 “(1) IN GENERAL.—In carrying out the activi-
11 ties under subsection (c), the Director shall seek
12 input from other Federal agencies, institutions of
13 higher education, nonprofit organizations, industry,
14 and Manufacturing USA institutes with relevant ex-
15 perience, on an ongoing basis, to help inform re-
16 search and development priorities, including through
17 workshops and other multi-stakeholder activities.

18 “(2) INSTITUTIONS OF HIGHER EDUCATION.—
19 To promote the broadest participation in bio-
20 metrology research and ensure training outreach will
21 engage all types of institutions of higher education,
22 input sought under paragraph (1) shall include input
23 from minority-serving institutions, historically Black
24 colleges and universities, Tribal Colleges or Univer-
25 sities, and public institutions of higher education

1 that, according to data published by the National
2 Center for Science and Engineering Statistics, are
3 not, on average, among the top 100 institutions in
4 Federal research and development expenditures.

5 “(3) DEFINITIONS.—In this subsection:

6 “(A) HISTORICALLY BLACK COLLEGE AND
7 UNIVERSITY.—The term ‘historically Black col-
8 lege and university’ means a part B institution,
9 as defined in section 322 of the Higher Edu-
10 cation Act of 1965 (20 U.S.C. 1061).

11 “(B) MINORITY-SERVING INSTITUTION.—
12 The term ‘minority-serving institution’ means
13 an eligible institution under section 371(a) of
14 the Higher Education Act of 1965 (20 U.S.C.
15 1067q(a)).

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

21 “(D) TRIBAL COLLEGE OR UNIVERSITY.—
22 The term ‘Tribal College or University’ has the
23 meaning given that term in section 316 of the
24 Higher Education Act of 1965 (20 U.S.C.
25 1059c).

1 “(f) COORDINATION.—

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

11 “(2) MANUFACTURING USA PROGRAM.—The
12 Director shall coordinate the activities carried out
13 pursuant to subsection (c) with the Manufacturing
14 USA Program and, to the maximum extent prac-
15 ticable, leverage existing capabilities of Manufac-
16 turing USA institutes to support United States lead-
17 ership in biomanufacturing.

18 “(3) BIOMASS FEEDSTOCK UTILIZATION.—The
19 Director, as practicable and appropriate, shall sup-
20 port efforts relating to the coordination and develop-
21 ment of biomass feedstock utilization with the Sec-
22 retary of Energy and the Biomass Research and De-
23 velopment Board established pursuant to section
24 9008 of the Farm Security and Rural Investment
25 Act of 2002 (7 U.S.C. 8108).

1 “(g) RESEARCH SECURITY.—The activities author-
2 ized under this section shall be carried out in accordance
3 with the provision of subtitle D of title VI of the Research
4 and Development, Competition, and Innovation Act (42
5 U.S.C. 19231 et seq.) and section 223 of the William M.
6 (Mac) Thornberry National Defense Authorization Act for
7 Fiscal Year 2021 (42 U.S.C. 6605).

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

16 “(i) IMPLEMENTATION PLAN.—Not later than one
17 year after the date of the enactment of this section, the
18 Director shall submit to the Committee on Commerce,
19 Science, and Transportation and the Committee on Appro-
20 priations of the Senate and the Committee on Science,
21 Space, and Technology and the Committee on Appropria-
22 tions of the House of Representatives, and make available
23 on a public website of the Institute, a plan to carry out
24 the biometrology laboratory program, including the fol-
25 lowing:

1 “(1) A plan for establishing the biometrology
2 laboratory program within the Institute as described
3 in this section, including in relation to existing
4 measurement laboratories.

5 “(2) A plan for how the Institute will carry out
6 the activities of the biometrology laboratory pro-
7 gram.

8 “(3) A plan for how to leverage existing infra-
9 structure and expertise of the Institute to drive
10 international cooperation for the advancement of vol-
11 untary consensus standards.

12 “(j) DEFINITIONS.—In this section:

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

17 “(A) Biological data.

18 “(B) Biomanufacturing.

19 “(C) Biometrology.

20 “(D) Biorisk.

21 “(E) Biosecurity.

22 “(F) Engineering biology.

23 “(2) ADDITIONAL TERMS.—

24 “(A) BIOECONOMY.—The term ‘bio-
25 economy’ means the economic activity derived

1 from the life sciences, particularly in the areas
2 of biotechnology and biomanufacturing, includ-
3 ing industries, products, services, and the work-
4 force.

5 “(B) BIOMASS.—The term ‘biomass’
6 means any material of biological origin that is
7 available on a renewable or recurring basis.

8 “(C) BIOSAFETY.—The term ‘biosafety’
9 means the practices, controls, and containment
10 infrastructure that reduce the risk of unin-
11 tended exposure to, contamination with, release
12 of, or harm from pathogens, toxics, and biologi-
13 cal materials.

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

18 “(E) INSTITUTION OF HIGHER EDU-
19 CATION.—The term ‘institution of higher edu-
20 cation’ has the meaning given that term in sec-
21 tion 101(a) of the Higher Education Act of
22 1965 (20 U.S.C. 1001(a)).

23 “(F) MANUFACTURING USA INSTITUTE.—
24 The term ‘Manufacturing USA institute’ has
25 the meaning given that term in section 34(d).

1 “(G) NONPROFIT ORGANIZATION.—The
2 term ‘nonprofit organization’ means an organi-
3 zation described in section 501(c)(3) of the In-
4 ternal Revenue Code of 1986 and exempt from
5 tax under section 501(a) of such code.

6 “(H) TECHNICAL STANDARD.—The term
7 ‘technical standard’ has the meaning given that
8 term in section 12(d)(5) of the National Tech-
9 nology Transfer and Advancement Act of 1995
10 (15 U.S.C. 272 note).”.

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

12 (a) REPEAL.—Section 10221 of the Research and
13 Development, Competition, and Innovation Act (42 U.S.C.
14 18931) is repealed, and the item relating to such section
15 in the table of contents in sections 1 and 10000 for such
16 Act is struck.

17 (b) DEFINITIONS.—

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

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

22 and

23 (B) by redesignating—

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

25 and

1 (ii) paragraphs (7) through (30) as
2 paragraphs (5) through (28), respectively.

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

6 (A) by redesignating paragraphs (1) and
7 (2) as paragraphs (7) and (8), respectively; and

8 (B) by inserting before paragraph (7), as
9 so redesignated, the following new paragraphs:

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

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

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

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

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