Brain Computer Interface Export Controls Conference

February 16-17, 2023

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Welcome

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Opening Remarks

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Matthew S.Borman
Deputy Assistant Secretary of Commerce for Export Administration

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Patient Advocacy and the Need for BCI

Access to Emerging Assistive Technology allows future innovations to increase Quality of life for families living with ALS

Blair Casey
Executive Director, Team Gleason Foundation

www.TeamGleason.org

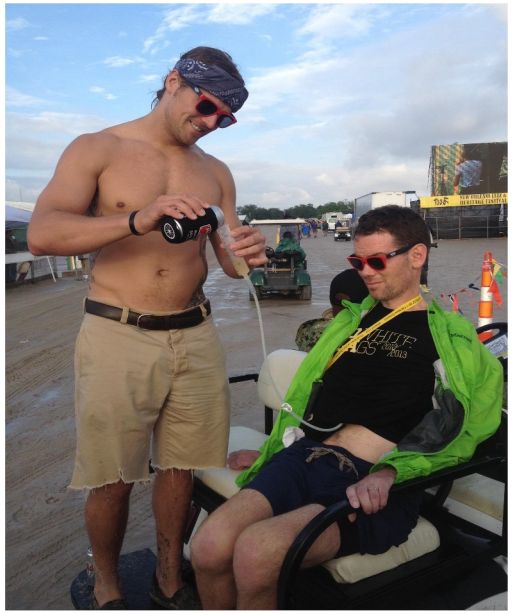
“I want to be honest with you... I am very scared and frustrated.”

- Steve Gleason

37
TEAM
GLEASON

STEVE GLEASON


2009/12/28




Team Gleason
Michael C. Hebert / New Orleans Saints


DEFEND
TEAM GLEASON


Team Gleason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TEAM
GLEASON

What is ALS?

• Every 90 minutes someone is diagnosed with ALS, and every 90 minutes someone loses their battle to this fatal disease.

• The average life span after diagnosis is 2-5 years.

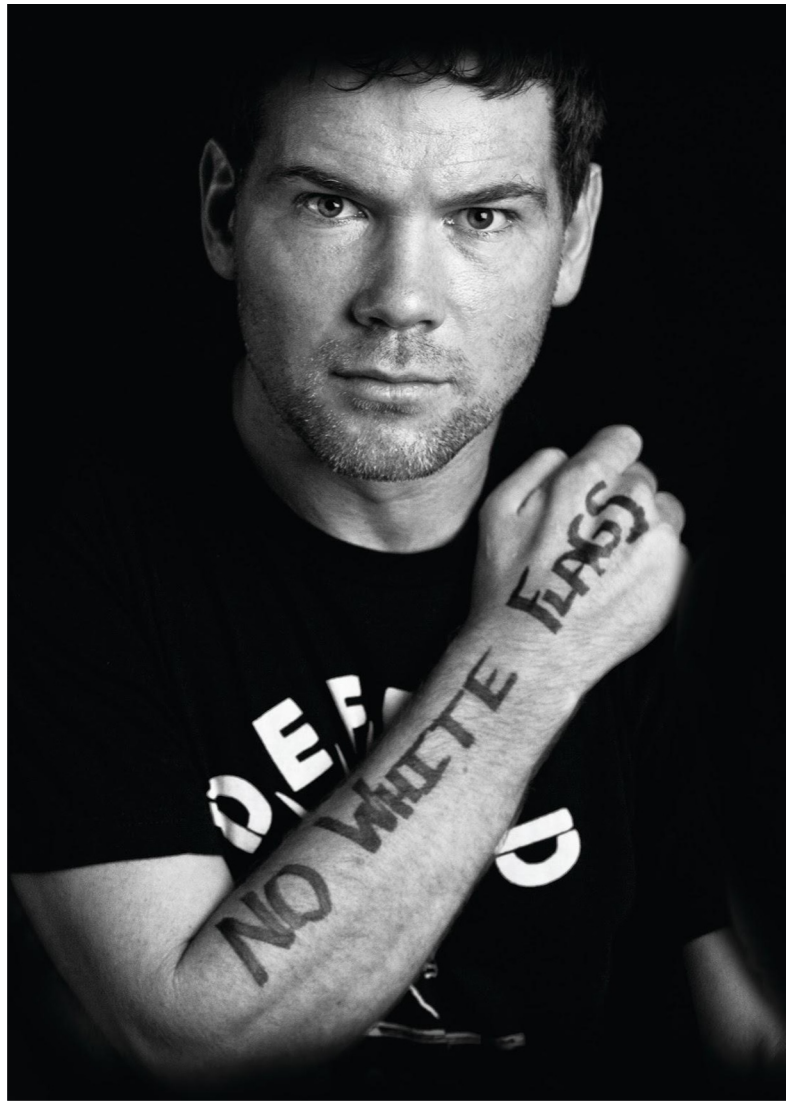
• Living with ALS can cost more than $200,000 per year above and beyond what is covered by insurance.

“ALS is a MOTHER#@$%ER!”

- Michel Varisco Gleason

Team Gleason Foundation Formed in October 2011.

- Provide leading edge technology, equipment and services.
- Provide and document extraordinary life adventures to raise awareness toward ALS to ultimately find a cure.



“Until There is a Cure for ALS, Technology is the Cure.”

- Steve Gleason

Team Gleason's Mission

To improve life for people living with ALS by providing essential, innovative technology and equipment to enhance their quality of life.

Advancements in Technology Improve the Quality of Life.

Improving the Quality of Life Through Innovation & Partnerships

Team Gleason's Equipment & Technology Program Services are a Necessity

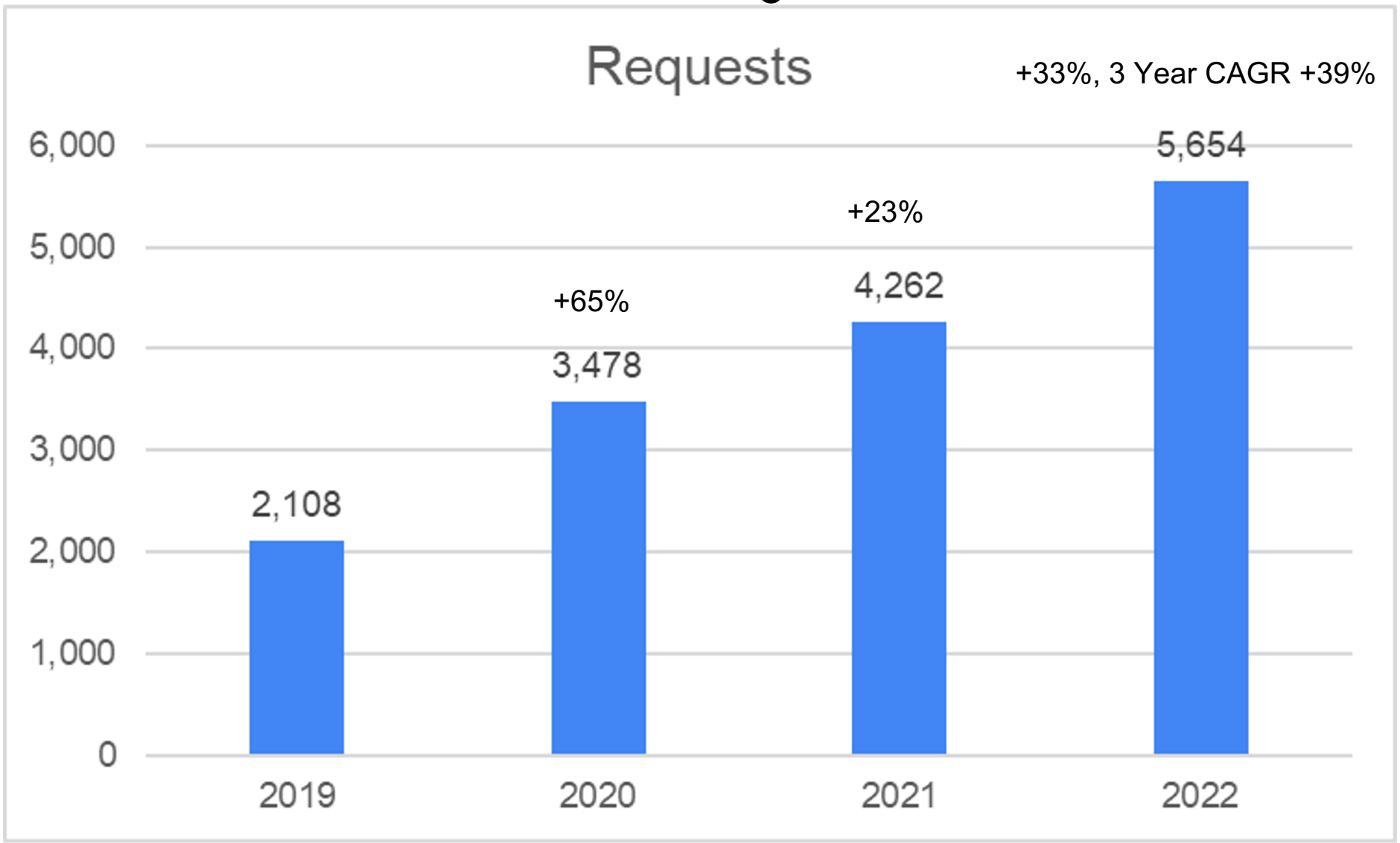
- Mobility
- Home Automation
- Communication
- Innovation
- Adventures

Team Gleason Milestones

- Provided over $30 million in technology, equipment, and adventures in all 50 states and Puerto Rico.
- Led the charge to pass 2 laws that ensure access to communication devices.
    - Steve Gleason Act
    - Steve Gleason Enduring Voices Act
- Partnered with Microsoft, Google, Comcast, Neuralink, Synchron, Quantum, Permobil, Numotion, Acapella, Tolt Technologies and others to advance R&D in communication and mobility.
- Steve received the Congressional Gold Medal in January 2020 and continues to push boundaries for people with ALS and other neurodegenerative diseases.
- 500 requests for program services each month

Team Gleason Staff

Team Gleason's program services have Increased significantly since 2019



Team Gleason's objective is to triple the patients served by 2027

Reaching 70-90% of U.S. ALS population

Reaching the uncounted, underserved

Team Gleason's Technology Advisory Committee

Jay Beavers
Assistive Technologies Engineer

Bernice You
Business Strategy Microsoft

Mark Francisco
Engineering Fellow with Comcast's Customer Experience Product Group

Monica Sampson PhD, CCC-SLP
Senior Director, Health Care Services (ASHA)

Casa Hannon
Innovation Evangelist, Stanford Graduate School of Business

Shanqing Cai
Senior Software Engineer Tools and Infrastructure, Google

Blair Casey
Team Gleason Executive Director

Bob MacDonald
Technical Program Manager, Google

Michael Brenner
Chief research scientist at Google Research, Professor of Applied Mathematics, and Professor of Physics at Harvard University

Mira Shah
User Experience Researcher, Speech Language Pathologist

John Costello MA, CCC-SLP
Director of the Augmentative Communication Programs and the Jay S. Fishman, ALS Augmentative Communication Program, Boston Children's Hospital

Joel Moffat
Principal Product Manager and Customer Experience Lead for Comcast's Accessibility Team

Phil Green
Team Gleason Board Member, ALS Advocate

Google Microsoft COMCAST TOLT TECHNOLOGIES Google Cloud

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Innovation and Technology Council
(The International Alliance of ALS/MND Associations)

Blair Casey

Chair, Innovation and Technology Council

Team Gleason Executive Director

Richard Cave

Speech and Language Therapist - Google Research

Jarnail Chudge

Design and Innovation Architect in the Enable Group, Microsoft Technology + Research

John Costello MA, CCC-SLP

Director of the Augmentative Communication Programs and the Jay S. Fishman, ALS Augmentative Communication Program, Boston Children's Hospital

Sara Feldman PT, DPT, ATP

Clinical Liaison for the ALS Hope Foundation

Mike Gardner

C-Suite Executive

Phil Green

Team Gleason Board Member, ALS Advocate

Tammy Moore

CEO of the ALS Society of Canada

Stuart Moss

Head of IT Innovation & Group IT Sustainability Lead

INTERNATIONAL ALLIANCE OF ALS/MND ASSOCIATIONS

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Team Gleason A-TEAM Advisory Committee
The Accessible Technology Enhancements Advisory Members
pALS pursuing affordable technology solutions

Daniel Vance
Team Gleason
Lead Technology
& Equipment
Specialist

John Otto Knoke
Guatemala City, Guatamalla

Kevin Rowland
Cincinnati, OH

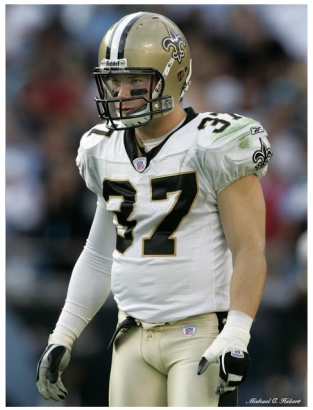
Andrew Miller
Lincoln University, PA

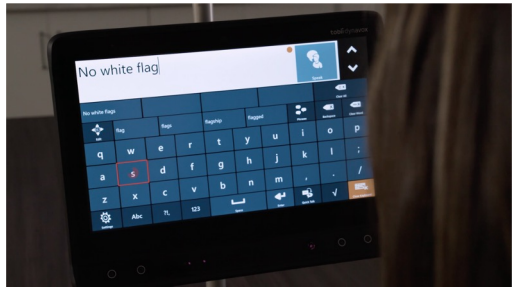
Shawn Sexton
Boston, MA

Jay Smith
Austin, TX

Phil Green
Temecula, CA

Steve Kowalski
Boston, MA





Steve Gleason's Journey

>2010
Pre-ALS Diagnosis

2011
Diagnosed With ALS
Speech to Text

2012
Wheelchair

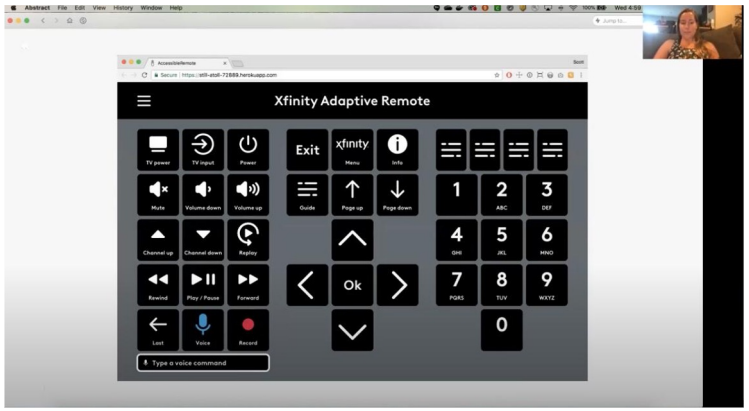
2013
Eye Gaze

2014
Ventilator

2015
Eye Driving Technology

2019
Automation

Today



Without the continuation of innovative solutions like:

- Ability Drive
- Non standard speech recognition
- Accessible environmental controls
- BCI

The **quality of life** for those living with ALS will remain unchanged.

Team Gleason understands why people living with ALS need more.

- More connectivity.
- More access.
- More independence.
- More options

Current and future partnerships-

Collaborate despite the natural competitive landscape

Team Gleason is unique

Because we built strong relationships and trust with the ALS community.

We're open to partnerships that help evolve our services and enhance quality of life.

Will you commit so people like...

Jay Rink
Lived 2.5 years with ALS

Arthur Saran
Lived 3.5 years with ALS

Brett Gleason
Lived 2 years with ALS

Doug Rushton
Lived 3 years with ALS

Hayley Steffen
Lived 2 years with ALS

Scott Matzka
Lived 5 years with ALS

Dwight Clark
Lived 2.5 years with ALS

Stephen Hawking
Lived 55 years with ALS

Maxine Benton
Diagnosed 2015

Jay Quinlan
Diagnosed 2016

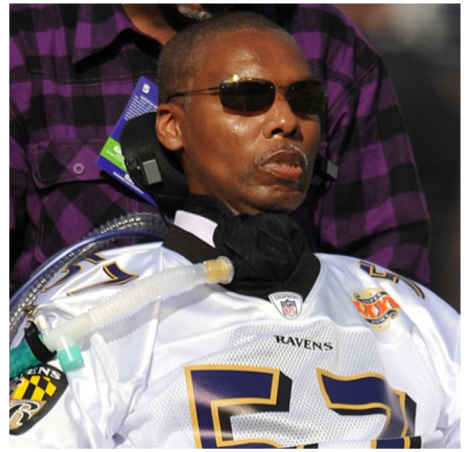
Troy Drouant
Diagnosed 2016

Steve Sailing
Diagnosed 2006

Kennedy Arney
Diagnosed 2018

Jason Becker
Diagnosed 1989

Andy Kates
Diagnosed 2017



OJ Brigance
Diagnosed 2007

Blair Casey
Executive Director
www.TeamGleason.org

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Export Control 101

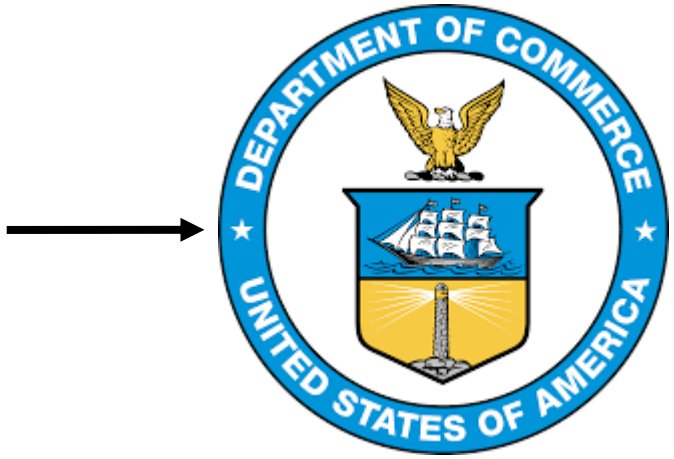
Introduction to Export Control and the Intangible Technology section by Dept of Commerce

Emerging & Foundational Technology Controls
(Section 1758 Technology Controls)
An Overview

Tongele N. Tongele, Ph.D.
Emerging Technology
Office of Technology Transfer
Bureau of Industry and Security
US Department of Commerce

Export Control Reform Act (ECRA)

U.S. Congress: *Export Control Reform Act* (*ECRA*) of 2018



Section 1758 of ECRA: Commerce to establish appropriate controls on the export, reexport, or transfer (in-country) of emerging and foundational technologies essential to the national security of the United States

Advance Notice of Proposed Rulemaking (ANPRM)

- November of 2018: Emerging Technology ANPRM.
- Seeking public comments on criteria for identifying emerging technologies.
- Universities, industries, government and private research laboratories, science and technology organizations and associations, private individuals, etc., contributed comments.
- The ANPRM identified 14 general areas/categories of science/technology for review for potential emerging technologies that may arise and may be determined to be essential to the national security of the United States.

The 14 Technology Categories Listing (ANPRM)

(1) Biotechnology
(2) Artificial intelligence (AI) and machine learning technology
(3) Position, Navigation, and Timing (PNT) technology
(4) Microprocessor technology
(5) Advanced computing technology
(6) Data analytics technology
(7) Quantum information and sensing technology
(8) Logistics technology
(9) Additive manufacturing.
(10) Robotics
(11) Brain-computer interfaces
(12) Hypersonics
(13) Advanced Materials
(14) Advanced surveillance technologies

Each Category Has Subfields/Subsets

Take, for example, the category of **Brain-Computer Interfaces**:

(i) Neural-controlled interfaces;

(ii) Mind-machine interfaces;

(iii) Direct neural interfaces; or

(iv) Brain-machine interfaces.

AI Subfields/Subsets

Another category: **Artificial intelligence (AI) and machine learning technology**

(i) Neural networks and deep learning (*e.g.,* brain modelling, time series prediction, classification);

(ii) Evolution and genetic computation (*e.g.,* genetic algorithms, genetic programming);

(iii) Reinforcement learning.

(iv) Computer vision (*e.g.,* object recognition, image understanding);

(v) Expert systems (*e.g.,* decision support systems, teaching systems);

(vi) Speech and audio processing (*e.g.,* speech recognition and production);

(vii) Natural language processing (*e.g.,* machine translation);

(viii) Planning (*e.g.,* scheduling, game playing);

(ix) Audio and video manipulation technologies (*e.g.,* voice cloning, deepfakes);

(x) AI cloud technologies; or

(xi) AI chipsets.

What Is (to be) Controlled Under Section 1758 of ECRA ?

- NOT the 14 technology categories, NOR the subsets/subfields of each category.
- So, what is controlled or to be controlled?
  - There are those that believe that the United States should control more, unilaterally, and faster.
  - Others believe the United States should take a hands-off approach, or else risk all innovation.
- BIS' approach is based on:
  - national security (responsibilities): rigorous identification of the national security and foreign policy risks associated with technologies being considered for control.
  - methodical learning about and understanding technologies' development stages and readiness for commercialization (export).
- Section 1758 controls must be specific items (hardware, software, technical information), described with specific parameters, and with specific reasons for control.

From Emerging and Foundational Technologies to Section 1758 Technologies

- Why is BIS now using section 1758 technologies or section 1758 controls instead of emerging and foundation technologies or emerging and foundational controls?
  - Neither Section 1758 nor any other section of ECRA defines the terms “emerging technology” or “foundational technology.”
  - ECRA does not provide guidance on how to differentiate between “emerging technology” and “foundational technology.”
  - ECRA does not mandate that BIS defines either term nor does ECRA require that either of the two categories be treated differently from the other.

Section 1758 Technologies

- On 05/23/2022 : proposed rule for “Controls on Certain Marine Toxins” (87 FR 31195).
  - The four marine toxins (brevetoxin, gonyautoxin, nodularin and palytoxin) addressed in this proposed rule are naturally occurring and are not necessarily considered, by themselves, to be “emerging” technologies. Consequently, they could be evaluated as “foundational,” rather than “emerging” technologies. However, novel synthesis methods and equipment can now be used to easily isolate and purify these toxins to make them (“emerging technology”?) more usable for biological weapons purposes than in the past.
- This proposed rule demonstrates some of the difficulties in attempting to draw meaningful and functional distinctions between “emerging” and “foundational” technologies.

Section 1758 Technologies

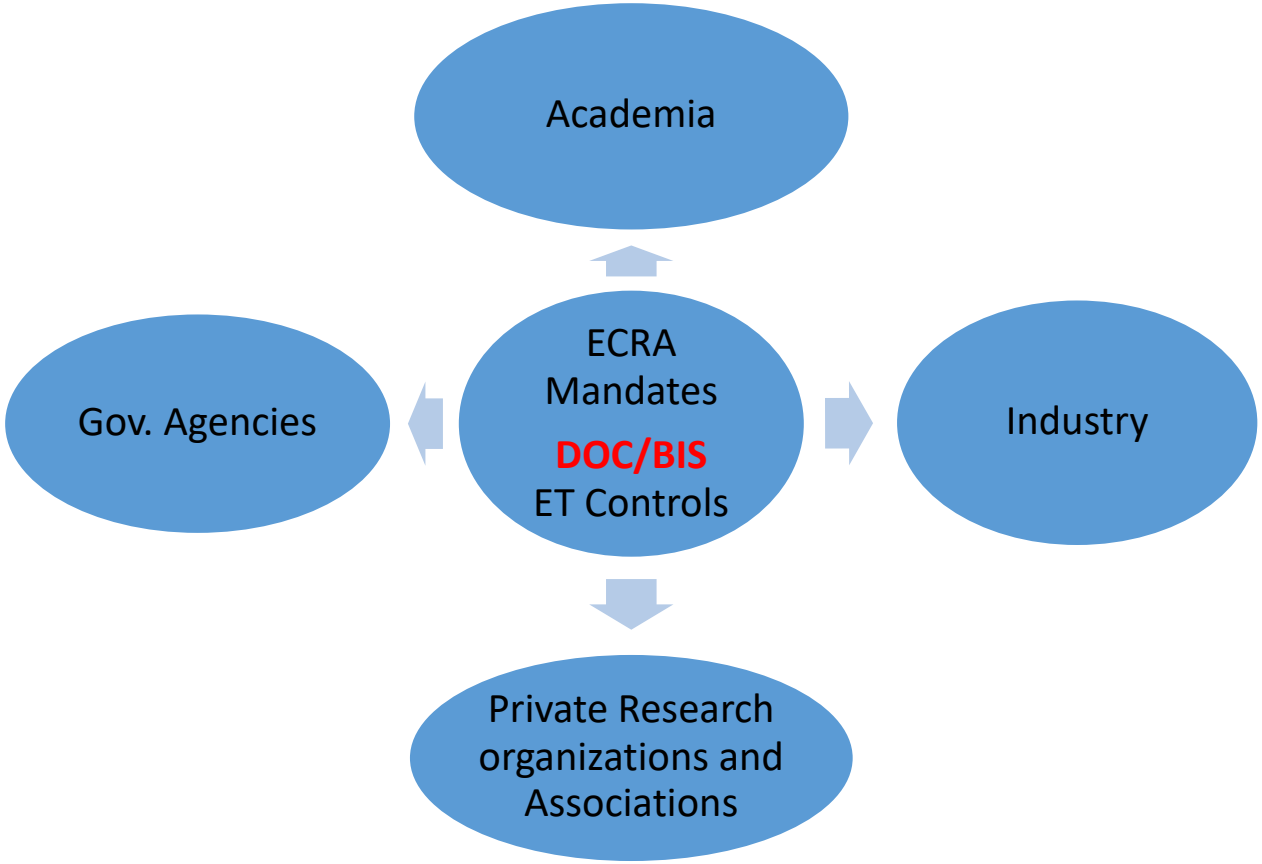
- BIS therefore opted to characterize all technologies identified pursuant to Section 1758 as “Section 1758 technologies” without drawing a distinction between “emerging” and/or “foundational” technologies
  - in consultation with its interagency partners, and
  - as a result of reviewing certain comments submitted in response to the November 19, 2018, Advance Notice of Proposed Rulemaking (ANPRM) and the August 27, 2020, ANPRM, which sought public comments on “emerging” and “foundational” technologies.

Section 1758 Controls

The process of establishing section 1758 control is same or like BIS' existing rulemaking process :

- identify and assess an item, discuss (the item) with technology developers and its interagency partners and Technical Advisory Committees (TACs),
- determine whether the item qualifies for control pursuant to section 1758 of ECRA,
- draft and publish a proposed rule in the form of a NOI (notice of inquiry) or an ANPRM (advance notice of proposed rulemaking) for feedback from the public,
- refine and take the proposed rule to multilateral export control regimes for discussions and adoption and, if agreed upon, then
- publish (it) in the *Federal Register* as an ECCN, with its specific parameters and reasons for control, and license requirements, and incorporate it in the Export Administration Regulations (EAR) for all to see and use.

Roadmap: BIS interaction with technology developers



BIS Working With Technology Developers

Will be able to:

- understand technology development stages,
- be able to identify pieces of technologies (gadget, hardware, software, technical information) that are mature enough for control,
- specify the implicated national security and the reason(s) for control,
- determine what level of control is appropriate to apply such that it does not hamper/hinder innovations.

Technology Developers Working With BIS

Will be able to :

- understand the essentials of export control regulations,
- properly classify technologies they develop by themselves, or submit to BIS a commodity classification request to have BIS classify the technologies for them,
- become equipped to determine
  - tools that may be subject to control and those that may not,
  - research that is fundamental and whose outcomes may not be subject to control,
  - research and research outcomes that may require certain control to certain countries,
  - when do foreign nationals need license to access certain technologies or research facilities in the US, and more.

The Essentials of Export Control Regulations

The Commerce Control List ("CCL")
Part 774, Supplement No. 1

- Contains lists of those items subject to the licensing authority of BIS
- Each entry is called an Export Control Classification Number ("ECCN")
- Most items are described in terms of their technical parameters

The Essentials of Export Control Regulations

Example of an Export Control Classification Number ("ECCN")

0A983 "Specially designed" implements of torture, including thumbscrews, thumbcuffs, fingercuffs, spiked batons, and "specially designed" "parts," "components" and "accessories," n.e.s.

License Requirements

Reason for Control: CC

Control(s)

CC applies to entire entry. A license is required for ALL destinations, regardless of end-use. Accordingly, a column specific to this control

does not appear on the Commerce Country Chart. (See part 742 of the EAR for additional information.)

List Based License Exceptions (See Part 740 for a description of all license exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Related Controls: N/A
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

Note to ECCN 0A983. *In this ECCN, "torture" has the meaning set forth in Section 2340(1) of Title 18, United States Code.*

How to Read an ECCN

Heading:

ECCN & Description

0A979 Police helmets and shields; and parts, n.e.s.

License Requirements

Reason for Control: CC

Control(s)	*Country Chart*
CC applies to entire entry	CC Column 1

License Exceptions

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Unit: $ value
Related Controls: N/A
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

How to Read an ECCN

0A979 Police helmets and shields; and parts, n.e.s.

License Requirements

Reason for Control: CC

Control(s)	*Country Chart*
CC applies to entire entry	CC Column 1

License Exceptions

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Unit: $ value
Related Controls: N/A
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

License Requirements:

Reasons for Control

How to Read an ECCN

0A979 Police helmets and shields; and parts, n.e.s.

License Requirements

Reason for Control: CC

Control(s)	*Country Chart*
CC applies to entire entry	CC Column 1

License Exceptions

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Unit: $ value
Related Controls: N/A
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

License Exceptions:

List-Based

How to Read an ECCN

List of Items Controlled:

Units

Related Controls

Related Definitions

Items

0A979 Police helmets and shields; and parts, n.e.s.

License Requirements

Reason for Control: CC

Control(s)	*Country Chart*
CC applies to entire entry	CC Column 1

License Exceptions

LVS: N/A
GBS: N/A
CIV: N/A

List of Items Controlled

Unit: $ value
Related Controls: N/A
Related Definitions: N/A
Items:

The list of items controlled is contained in the ECCN heading.

The Essentials of Export Control Regulations

What does the Export Control Classification Number ("ECCN") tell us?

- What items are controlled?
- Why BIS controls the item?
- Which destinations will require a license? (see Country Chart in Supp. 1 to part 738)
- What (if any) list-based license exception applies?

The Essentials of Export Control Regulations

The structure of an Export Control Classification Number ("ECCN")

0 A 983

0	**Category**
A	**Product Group**
983	**Type of Control**

The Essentials of Export Control Regulations

There are 10 Product Categories on the Commerce Control List (CCL)

0	Miscellaneous & Nuclear Materials
1	Materials, Chemicals, Microorganisms, and Toxins
2	Materials Processing
3	Electronics
4	Computers
5	Part 1-Telecommunication
5	Part 2-Information Security
6	Sensors & Lasers
7	Navigation & Avionics
8	Marine
9	Aerospace & Propulsion

The Essentials of Export Control Regulations

There are 5 Product Groups on the Commerce Control List (CCL)

A	Systems, Equipment & Components
B	Test, Inspection & Production Equipment
C	Materials
D	Software
E	Technology

The Essentials of Export Control Regulations

Types of Controls associated with ECCNs on the Commerce Control List (CCL)

000-099 – National Security

100-199 – Missile Technology

200-299 – Nuclear Nonproliferation

300-399 – Chemical and Biological

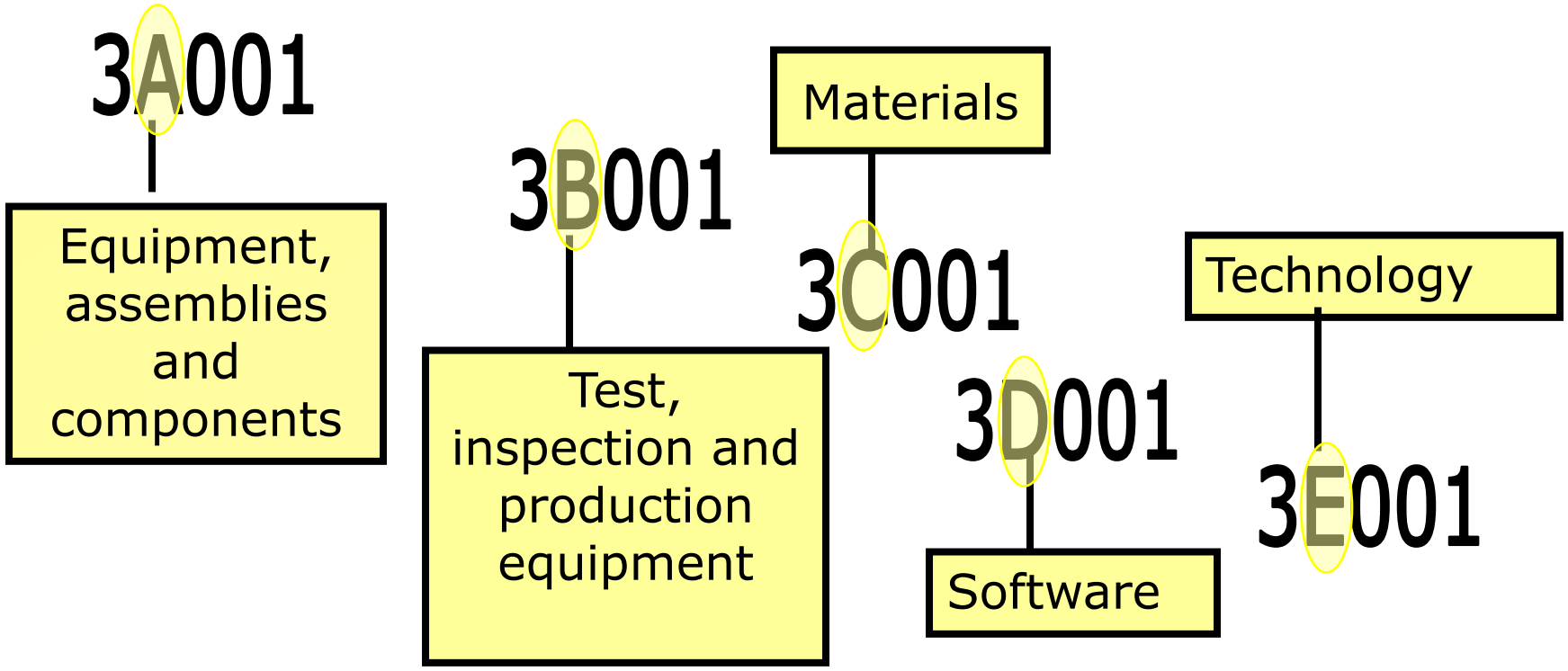
500-599 – National Security or Foreign Policy

600-699 – Wassenaar Arrangement Munitions List (WAML)
or former U.S. Munitions List (USML)

900-999 – Anti-terrorism, Crime Control, Regional Stability, Short Supply, UN Sanctions, etc.

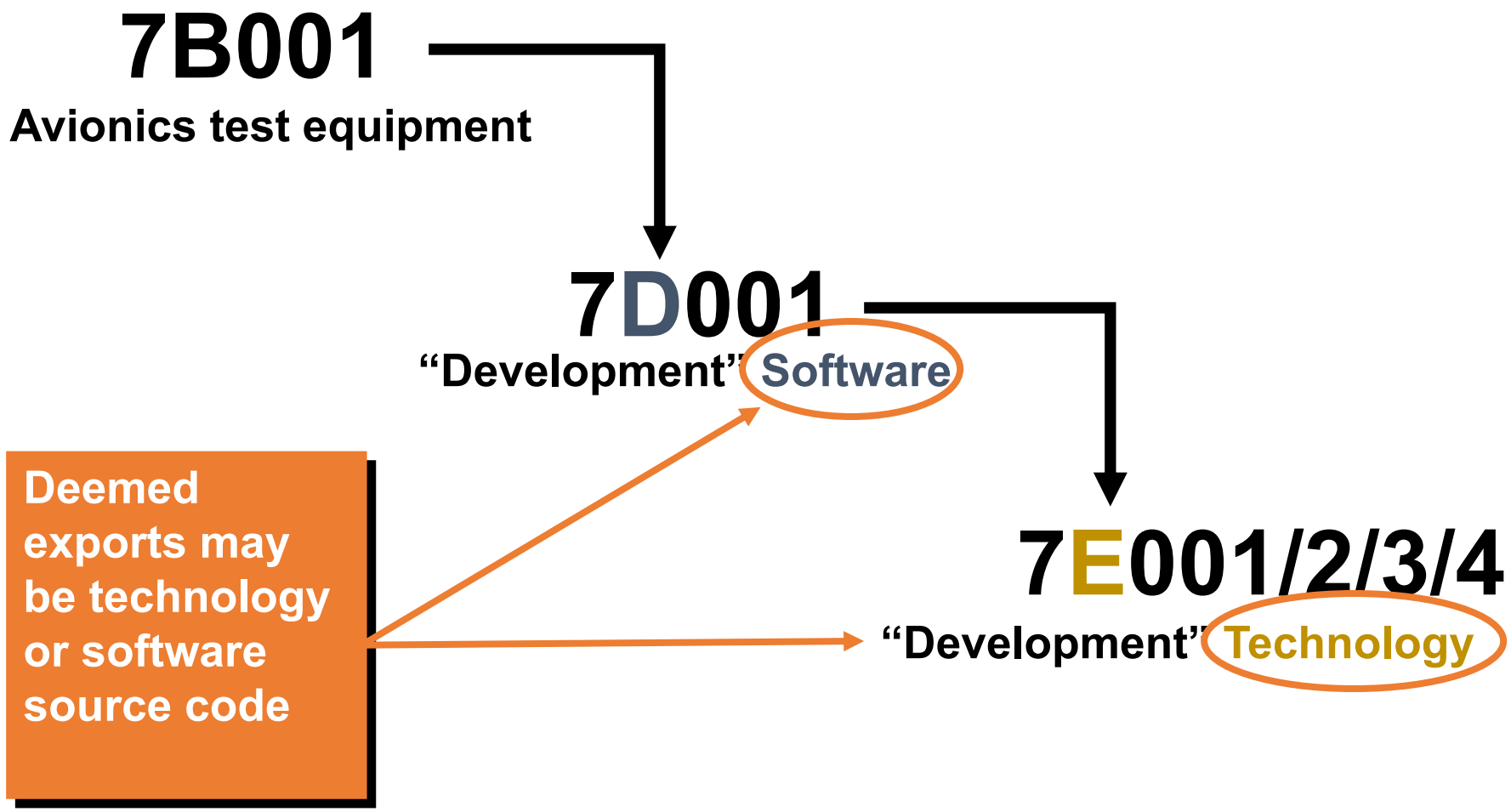
The Essentials of Export Control Regulations

Related items are often grouped in ECCN series on the (CCL)



The Essentials of Export Control Regulations

Export (A,B,C,D,E) and Deemed Export (only D and E)



The Essentials of Export Control Regulations

Export and Deemed Export

- **Export** means an actual shipment or transmission of items out of the United States.
  - sending or taking of an item out of the United States, in any manner;
  - Reexport means an actual shipment or transmission of items subject to the EAR from one foreign country to another foreign country.

- **Deemed Export** means a release of technology or source code to a foreign national in the United States or abroad Considered to be an export to that person's most recent country of citizenship or permanent residency Does not apply to U.S. citizens, individuals granted permanent resident status, protected individuals
  - Release outside the United States is a deemed reexport. ''Technology'' and ''software'' are ''released'' through:

  (1) Visual or other inspection by a foreign person of items that reveals ''technology'' or source code subject to the EAR to a foreign person; or

  (2) Oral or written exchanges with a foreign person of ''technology'' or source code in the United States or abroad.

The Essentials of Export Control Regulations

Where to Find Section 1758 Controls ?

- There is no special section in the EAR where section 1758 controls are enumerated/listed.
- A section 1758 controls is/can be:
  - A modification of an existing ECCN (Export Control Classification Number),
  - A new paragraph or subparagraph added to an existing control (ECCN), or
  - A new controls (ECCN)
- Section 1758 controls and other controls are all enumerated on the Commerce Control List (CCL), in the Supplement No.1 to Part 774 of the EAR.

The Essentials of Export Control Regulations

Examples of Section 1758 Controls

1) ECCN 3A001.b.3.f (certain microwave transistors, a major component of wideband semiconductors)
2) ECCN 3D005 (continuity of operation software)
3) ECCN 5A002.a.4 (postquantum cryptographic algorithms)
4) ECCN 6A001.a.1.b.1; .a.2; .a.2.a; .a.2.a.6 (underwater transducers designed to operate as hydrophones)
5) ECCN 9A004.g (aircraft specially designed or modified to be air-launch platforms)

Note:
2) is a new ECCN, 5) is a paragraph, 1), 3) and 4) are subparagraphs of existing ECCNs.

The Essentials of Export Control Regulations

What About the Export of Medical Devices ?

- For exporter guidance, BIS posted on its website the “BIS List of EAR99 Medical Devices” (see https://www.bis.doc.gov/index.php/documents/product-guidance/711-bis-list-of-ear99-medical-devices/file)
- The posting states that “One-year specific license applications must be submitted to the Office of Foreign Assets Control (OFAC) for export or reexport to Iran or Sudan” of these medical devices classified as EAR99.
  - An item is designated as EAR99 when it is subject to the Export Administration Regulations (EAR) but is not anywhere specified (enumerated) in any category in the Commerce Control List (CCL).
  - The Office of Foreign Assets Control ("OFAC") of the US Department of the Treasury administers and enforces economic and trade sanctions based on US foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, those engaged in activities related to the proliferation of weapons of mass destruction, and other threats to the national security, foreign policy or economy of the United States.

The Essentials of Export Control Regulations

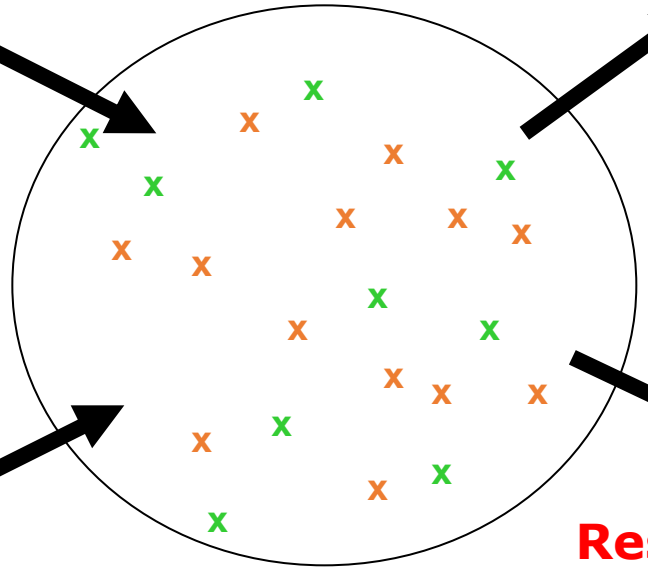
What About Research and Development ?

Publicly available technologies
(Not Subject to the EAR)

Results of research published: (e.g., Fundamental Research)
(Not Subject to the EAR)

INPUT

OUTPUT



Preexisting Export Controlled Technologies
(Subject to the EAR)

Results of research withheld from publication
(Subject to the EAR)

The Essentials of Export Control Regulations

How to Classify ECCNs?

When Tech developers work with BIS, they'll :

- properly classify technologies they develop by themselves, or
- submit to BIS a commodity classification request to have BIS classify the technologies for them,
- become equipped to determine
  - tools that may be subject to control and those that may not,
  - research that is fundamental and whose outcomes may not be subject to control,
  - research and research outcomes that may require certain control to certain countries,
  - when do foreign nationals need license to access certain technologies or research facilities in the US (deemed export).

Section 1758 Controls: Work in Progress

- Section 1758 control, like all the EAR, is a work in progress
  - Technologies evolve: some become obsolete, new ones emerge.
  - Technology categories evolve: new ones appear, others dwindle in importance.
  - Section 1758 controls can only evolve with evolving technologies.
- Section 1758 control is and must be collaborative and inclusive
  - Nationally, working through interagency process.
  - Internationally, working with allies and partners and through multilateral export control regimes.
- Exchanges and sharing through conferences, seminars and workshops like this one feed into this work in progress.

Thank you

The information herein contained may not be taken as the official position of the Bureau of Industry and Security of the US Department of Commerce

Intangible Technology Transfer

BUREAU OF INDUSTRY AND SECURITY

Betty Lee, Ph.D.
Chemical and Biological Controls Division
Office of Non-Proliferation and Treaty Compliance

BCI Conference, Washington, DC Feb 16 and 17, 2023

Overview

- Authorities-Export Administration Regulations (EAR)
- ECRA (Export Control Reform Act)
- Intangible Technology Definitions
- Outreach / Training
- Summary

Export Administration Regulations (EAR)
15 CFR parts 730-774

- Controls "items"
  - "commodities"
  - "software"
  - "technology"
- Controls "exports", "reexports", and "transfers"
  - Including intangible transfers of software or technology
  - Exports include:
    - An actual shipment or transmission of items out of the United States
    - "Release" of technology or source code to a foreign person in the United States (deemed export)
- Controls activities of "U.S. persons" and some foreign persons

Export Control Reform Act (ECRA)of 2018

- Section 1758 of ECRA – "**Requirements to identify and control the export of emerging and foundational technologies."**
- Authorizes Commerce to establish ***appropriate controls, including interin controls,*** on the export, reexport, or transfer (in country) of emerging and foundational technologies.

“Subject to the EAR” EAR § 734.2

- “Subject to the EAR” means that the EAR are the applicable regulations
- An export or reexport of items “subject to the EAR” requires an authorization, unless designated “No License Required” (NLR)
  - “Subject to the EAR” does not automatically mean that a license is required
  - An authorization can be:
    - A license
    - A license exception

Intangible Technology Definitions

Definitions in “Technology” Controls (EAR 772.1)

- “**Development**” is related to all stages prior to serial production, such as: design, design research, design analyses, design concepts, assembly and testing of prototypes, pilot production schemes, design data, process of transforming design data into a product, configuration design, integration design, and layouts.
- “**Production**” means all production stages, such as: product engineering, manufacture, integration, assembly (mounting), inspection, testing, quality assurance.
- “**Use**” includes all of the following: operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing.
- The definition of “Use” differs for munitions items.

Intangible Technology cont.

Publicly Available Technology Not Subject to Export Controls (General Technology Note)

- Published (EAR 734.7)
- Fundamental Research (EAR 734.8)
- Patent Information (EAR 734.10)

Deemed Export and Re-Export

- Deemed Export (734.13): “Release” of technology or source code, subject to the EAR to a foreign national in the United States.

- Deemed Re-Export (734.14): “Release” of technology or source code, subject to the EAR to a foreign national in a third country.

How is the Release achieved?

- Visual inspection of U.S. origin equipment and facilities
- Oral exchanges of information in the U.S. or abroad
- Application of personal knowledge or technical experience acquired in the U.S. to situations that will benefit another country

Training

https://www.bis.doc.gov/index.php/compliance-a-training/export-administration-regulations-training/online-training-room

Contact Information

- Office of Exporter Services:

Washington, D.C.	Western Regional Office, Irvine, CA
Counseling: (202) 482-4811 e-mail: ECDOEXS@bis.doc.gov	Counseling: (949) 660-0144
	Northern California Branch, San Jose, CA
	Counseling: (408) 998-8806

- Encryption Help Line: (202) 482-0707
- Export Enforcement Hotline: 1-800-424-2980

www.bis.doc.gov www.trade.gov/consolidated-screening-list

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Part II: Neurotech Ethics & Dual Use

Neurotechnology & Ethics Guidance

Karen Rommelfanger, PhD
Institute of Neuroethics Think and Do Tank
director@instituteofneuroethics.org

Institute of Neuroethics
Think and Do Tank

Neuroethics

The brain is
biologically and culturally special.

The implications of brain interventions have implications that rival any other organ.

How might NT challenge-

- what it means to be human?
- what we consider “normal”?
- notions of privacy?

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Global landscape of neuroethics

Research Community

The Recommendation embodies nine principles:

1. **Promote responsible innovation in neurotechnology to address health challenges.**
2. **Prioritise assessing safety in the development and use of neurotechnology.**
3. **Promote the inclusivity of neurotechnology for health.**
4. **Foster scientific collaboration in neurotechnology innovation across countries, sectors, and disciplines.**
5. **Enable societal deliberation on neurotechnology.**
6. **Enable the capacity of oversight and advisory bodies to address novel issues in neurotechnology.**
7. **Safeguard personal brain data and other information gained through neurotechnology.**
8. **Promote cultures of stewardship and trust in neurotechnology across the public and private sector.**
9. **Anticipate and monitor the potential unintended use and/or misuse of neurotechnology.**

National-level proposals

Chile: Pioneering the protection of neurorights

GNS delegates et al, *Neuron*, 2018
Rommelfanger, Pustilnik, Salles, AAAS *Science Diplomacy*, 2022

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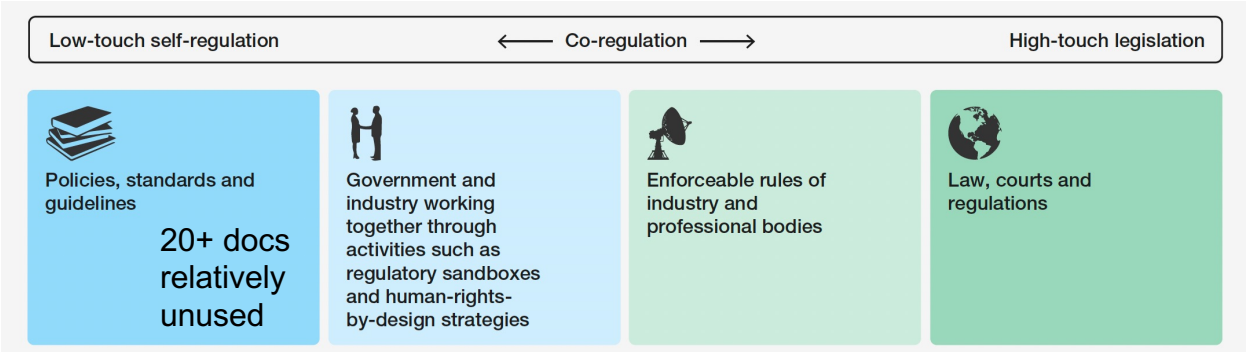
State of the art governance



Theme	Subtheme	Key topics
Safety and privacy	Safety and risk	Effectively assessing safety and risk Sensitive applications (e.g., military/dual use, malign use, manipulation) Particular sensitivity due to complexity and significance of the brain Particular sensitivity of using neurotechnologies with children
	Privacy	Effective informed consent for data use/privacy concerns Use of repurposed data or unexpected future uses Reidentification Control of data; user ability to amend or delete Cultural differences in the importance and meaning of privacy
Equity and justice	Equity and distributive justice	Equitable distribution of new technologies and therapeutics Equitable distribution of risks Diversity, inclusion, and avoidance of social/cultural bias in research Non-human animal research
	Discrimination and stigma	Protection from brain-data-based discrimination Pressure to use enhancements Definitions of "normal" and potential for stigma
Agency, autonomy, and identity	Consent	Meaningful informed consent Continuing consent when using technologies that may alter the mind
	Manipulation	Ability of neurotechnologies to manipulate people Limiting use in manipulative applications
	Human-ness	Integrity of person Regard for donors of, e.g., brain tissue Moral significance of synthetically created neural systems

Table 2: Key ethics concerns described in guidance documents.

IoNx Lab: O'Shaughnessy et al, 2023 in review

Individual guidance docs accessible at the
Neuroethics Guidance Repository: instituteofneuroethics.org

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Challenges

- Definitional scoping
- Jurisdiction of regulation, action
- Pacing problem

Opportunities

Now

- Self-governance tools
- Toolkits for regulators
- Working groups

Intermediate/Longer-term

- Standards
- International Agreements

Responsible NT as Sociotech Challenges
Robinson J, Rommelfanger KS…French J. et al, *Neuron*, 2022

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Thank you.

Karen Rommelfanger, PhD
Institute of Neuroethics Think and Do Tank
director@instituteofneuroethics.org

https://instituteofneuroethics.org

Public engagement with Terminus Dance: Step the Brain Along a Path

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Dual Use

Arleen Salles, MA, PhD

Export Controls for BCI Conference

Washington DC, February 17th 2023

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Dual Use: definitions

Concept controversial and contested

- Traditionally: binary understanding (civilian vs military uses)
- Research and technology that has the potential to have beneficial and harmful applications

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Human Brain Project

Human Brain Project

Support and develop multidisciplinary information and communication technology (ICT) for neuroscience research.

Achieve a more integrated understanding of the human brain, leading to medical and technological applications (Amunts et al. 2019).

Develop a research infrastructure that provides data, tools and computing facilities via six open-access platforms. Future sustainable research infrastructure: EBRAINS

Committed to addressing ethical and societal issues raised by research and applications

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The HBP and Responsible Dual Use

Human Brain Project

Ethics & Society

Opinion on 'Responsible Dual Use'

Political, Security, Intelligence and Military Research of Concern in Neuroscience and Neurotechnology

Areas of concern

Political applications
Security Applications
Intelligence Applications
Military Applications

Responsible Dual Use:

- Principles of Responsible Research and Innovation (RRI) used to identify 'dual use research of concern'
- **AREA** framework (Anticipate, Reflect, Engage, Act) allows the distinction between 'responsible' and 'irresponsible' systems of research and technological development
- Responsibility: encouraging reflection on potential social and ethical implications of research, promoting open discussion.

Aicardi C. et al 2018 Opinion on Responsible Dual Use, Political, Security, Intelligence and Military Research Of Concern in Neuroscience and Neurotechnology. https://sos-ch-dk-2.exo.io/public-website-production/filer_public/77/61/7761fdcd-b0a0-40a2-a6bd-904d68d52b87/opinion_dual_use_hbp_ethicssociety.pdf

SOME RECOMMENDATIONS FOR THE HBP

HBP Governance mandate to lead an HBP Working Group (created in 2018) to develop an action plan on dual use

- Examination of whether individual elements of the HBP that have no obvious dual-use implications on their own may present dual-use concerns in combination with others (key role for ethics rapporteurs)
- Access to and use of the HBP platforms should require users' explicit commitment to the principles of RRI in research, and to ensuring that their work will not be used in ways that threaten the peace, security, health and well-being of citizens (formal statement)
- Consideration of whether and on which conditions to partner with institutions and projects that receive military funding
- Development of an educational program concerning the political, security, intelligence and military uses of brain inspired research and development

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Our Approach: Responsible Research and Innovation

“an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation” (https://ec.europa.eu/programmes/horizon2020/en/h2020-section/responsible-research-innovation)

societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.

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Characteristics

Interactive process

Mutual responsiveness and joint reflection on the purpose of science and its outcomes

Discourse beyond a narrow construction of ethics simply as “applied ethics” or safety assessment

Legal, ethical and social issues should feed into the scientific research agenda

Development of reflection mechanisms for open discussion from the very beginning

Reconceptualization of the notion of responsibility

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Some Key Insights

Identification of research and technology of concern is not straight forward Moving beyond immediate risk assessment is key

Importance of awareness raising activities (targeted workshops) Revisiting notion of responsibility

Continuous reflection and dialogue

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The Road Ahead

Creation of diverse training and awareness raising activities (experimentation with various approaches)

- Goal: to enhance capacity to identify DU of concern and start the conversation

Creation of safe spaces where questions and concerns by different publics can be assessed

Experimentation, learning, dialogue

Routledge
Taylor & Francis Group

Journal of Responsible Innovation

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/tjri20

Experimentation, learning, and dialogue: an RRI-inspired approach to dual-use of concern

Inga Ulnicane, Tara Mahfoud & Arleen Salles

To cite this article: Inga Ulnicane, Tara Mahfoud & Arleen Salles (2022): Experimentation, learning, and dialogue: an RRI-inspired approach to dual-use of concern, Journal of Responsible Innovation, DOI: 10.1080/23299460.2022.2094071

To link to this article: https://doi.org/10.1080/23299460.2022.2094071

Published online: 18 Jul 2022.

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Thank you!

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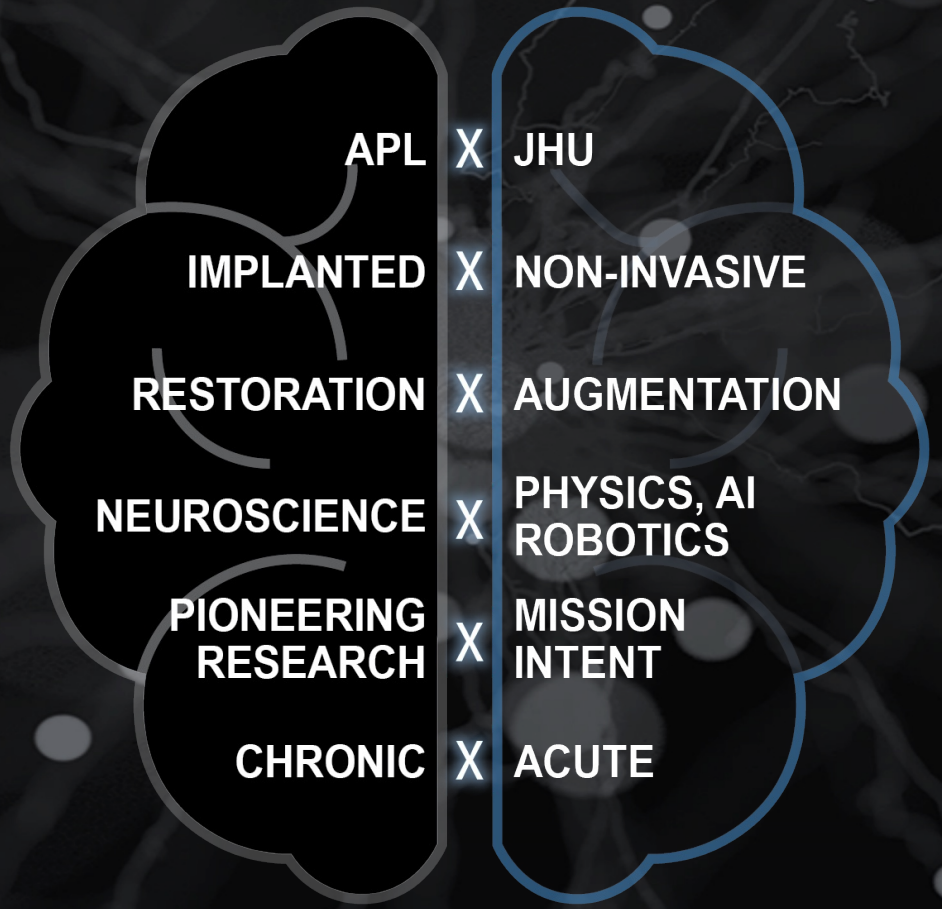
JOHNS HOPKINS
APPLIED PHYSICS LABORATORY

Brain-Computer Interface Technology

Comments for BIS

Mike Wolmetz, PhD
Program Manager
Human & Machine Intelligence
mike.wolmetz@jhuapl.edu



JHU/APL in Laurel, MD

Nation's oldest, largest University Affiliated Research Center (UARC)

Create *defining innovations* that ensure our nation's preeminence in the 21st century

Relevant topics not yet covered

- *Non-human* BCI
- *International* neuroethics landscape
- *Standard* performance metrics, *independent* validation
- *Mission pull* for BCI
- Role of AI (*beyond increasing BCI performance*)
- *Next-generation non-surgical* neurotechnologies

Democratize Restoration, Revolutionize Interfacing with Technology

- Invasive Brain-Computer Interface R&D is revolutionizing restoration of perception, communication and control for severely-impaired clinical populations
- Today's surgically-implanted devices are unlikely to scale, even for severely-impaired clinical populations
- As mixed reality and intelligent systems permeate both the battlefield and everyday life, our bodies will increasingly be the weakest link in sensing, communication, command and control
- *Next-generation non-surgical neurotechnologies* approaching implant resolutions will democratize assistive technologies, revolutionize interfacing with technology for all users, and may offer strategic advantages for national security applications

Anthropomorphic perception, communication & control

Beyond anthropomorphic perception, communication & control

AI/BCI shared perception, communication & control

Next-gen non-surgical interfaces

Hype vs. Technology Forecasting

Eléctronic 'Brain' Teaches Itself

The Navy last week demonstrated the embryo of an electronic computer named the Perceptron which, when completed in about a year, is expected to be the first non-living mechanism able to "perceive, recognize and identify its surroundings without human training or control." Navy officers demonstrating a preliminary form of the device in Washington said they hesitated to call it a machine because it is so much like a "human being without life."

Dr. Frank Rosenblatt, research psychologist at the Cornell Aeronautical Laboratory, Inc., Buffalo, N. Y., designer of the Perceptron, conducted the demonstration. The machine, he said, would be the first electronic device to think as the human brain. Like humans, Perceptron will make mistakes at first, "but it will grow wiser as it gains experience," he said.

recognize the difference between right and left, almost the way a child learns.

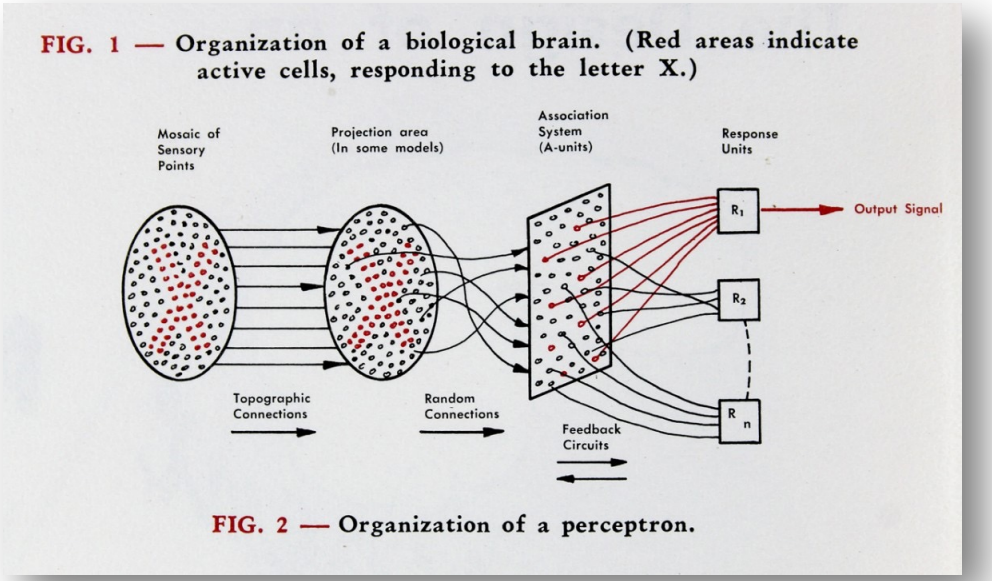
When fully developed, the Perceptron will be designed to remember images and information it has perceived itself, whereas ordinary computers remember only what is fed into them on punch cards or magnetic tape.

Later Perceptrons, Dr. Rosenblatt said, will be able to recognize people and call out their names. Printed pages, longhand letters and even speech commands are within its reach. Only one more step of development, a difficult step, he said, is needed for the device to hear speech in one language and instantly translate it to speech or writing in another language.

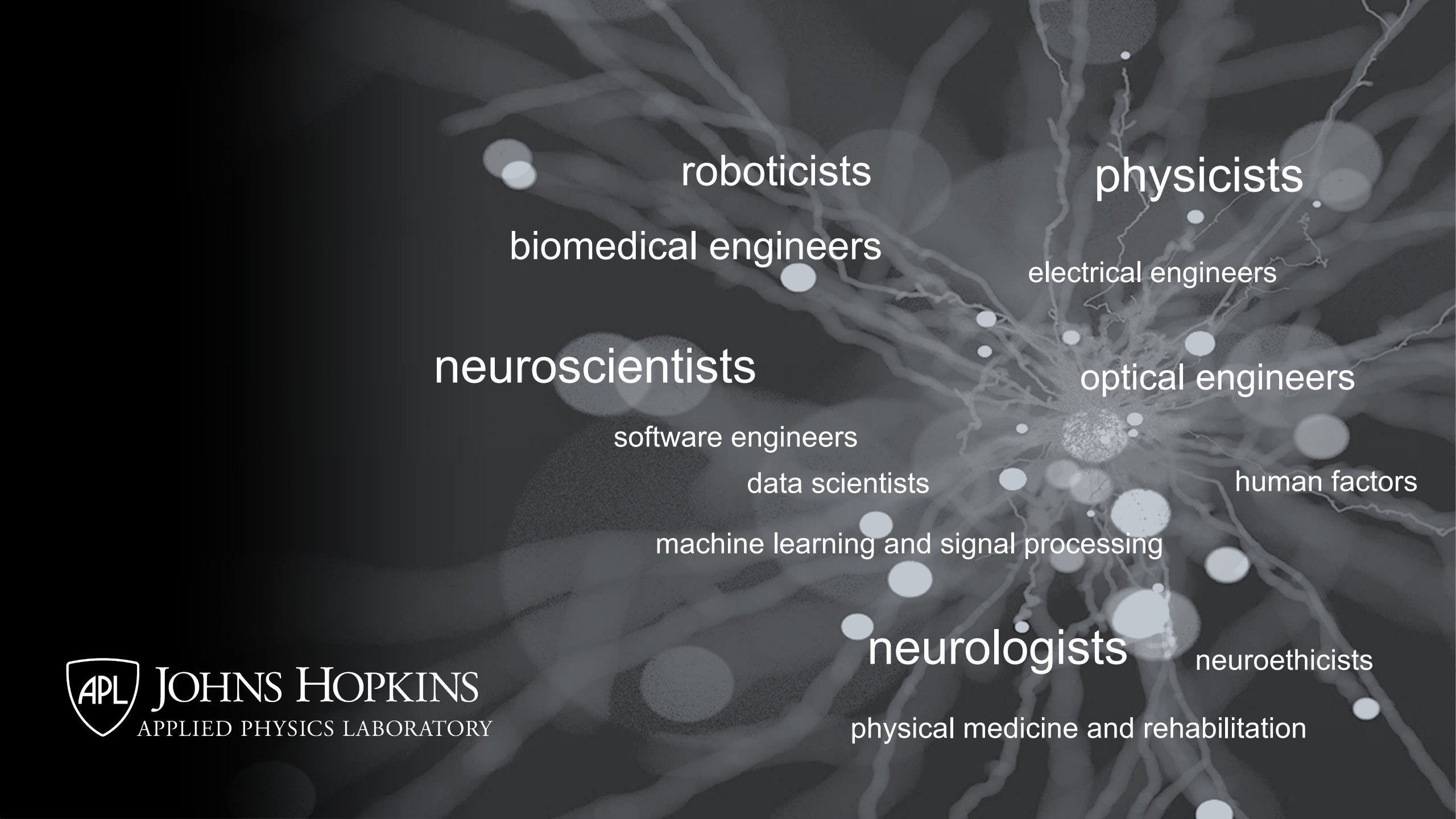
Self-Reproduction

In principle, Dr. Rosenblatt said, it would be possible to build Per-

NYTimes July 13, 1958, Section E, Page 9



Frank Rosenblatt, The Design of an Intelligent Automaton. Research Trends 6, no. 2 (1958), pp. 1-7.


roboticists
physicists
biomedical engineers
electrical engineers
neuroscientists
optical engineers
software engineers
data scientists
human factors
machine learning and signal processing
neurologists
neuroethicists
physical medicine and rehabilitation
APL
JOHNS HOPKINS
APPLIED PHYSICS LABORATORY

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Q&A

Karen Rommelfanger, Arleen Salles, and Mike Wolmetz

Brain Computer Interface Export Controls Conference

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Part III: Risk Mitigation Strategies

Existing Export Controls and BCIs

Lucille Nalbach Tournas, J.D., Institute of Neuroethics (IoNx)

Institute of Neuroethics
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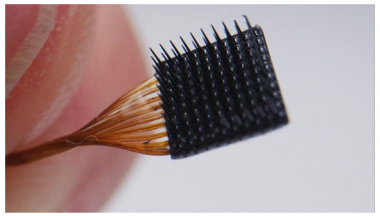
Brain Computer Interface



Hardware

Software

Data Surveillance

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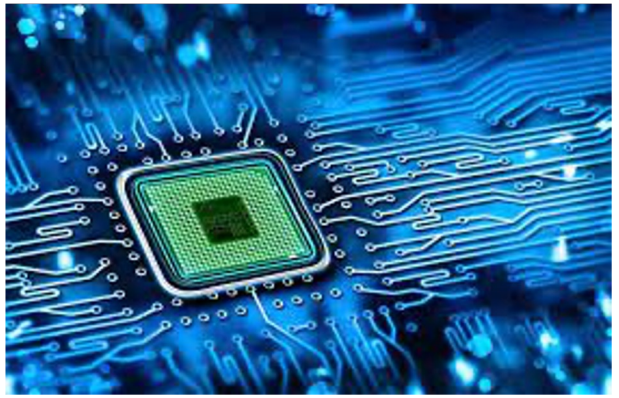
Existing Export Controls: Hardware



- October 2022 China **semiconductor technology (SME)**
  - Advanced computing semiconductor chips, tools, integrated circuits, expertise to make chips or produce China's own manufacturing equipment (SME)
  - April 9, 2021 BIS in its, Annual Threat Assessment of the U.S. Intelligence Community, acknowledged China's proliferation of nuclear arcenal and the significance of semiconductor technologies to deployment of WMDs.
- January 6, 2020, BIS published an interim final rule to add a new worldwide (minus Canada) unilateral export control on a type of **geospatial imagery**.
- U.S. export controls apply not only to U.S.-origin products, software, technology, but also to foreign-origin items that enter the United States before being exported again, and foreign-origin items that contain more than a de minimis amount (generally 25 percent) of controlled U.S. content.
  - https://www.bis.doc.gov/index.php/policy-guidance/deemed-exports/deemed-exports-faqs/faq/48-what-technologies-are-subject-to-the-commerce-department-controls

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Software

U.S.

U.S. Accuses Chinese Software Developer of Stealing Source Code

Xu Jiaqiang is scheduled to be arraigned Thursday

- Technical Data
- The sharing, shipping, transmission or transfer of almost all encryption software in either source code or object code is subject to US export regulations
  - Not just defense manufacturers, but all technology companies affected
  - Important when considering the significance of Global Supply Chains

CNN Exclusive: A single Iranian attack drone found to contain parts from more than a dozen US companies

By Natasha Bertrand

Updated 1:51 PM EST, Wed January 4, 2023

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Data and Surveillance

- Neither collected individual nor aggregate data is an easy fit in BIS definition of “commodities, software, or technology.”
- Executive Order 13873-gave advanced power to Commerce Secretary in managing supply chains. Can address risks related to foreign adversaries exploiting vulnerabilities in information and technology systems.
- Protecting Americans' Data From Foreign Surveillance Act of 2022 (Dead 1/3/23 118th Congress began)
    - This bill establishes certain export controls on personal data of U.S. nationals and individuals living in the United States. Among other requirements, the bill directs the Department of Commerce to identify categories of personal data that could be exploited by foreign governments and harm U.S. national security if exported, re-exported, or in-country transferred in a quantity that exceeds the threshold established by Commerce.
- TikTok testifying before Congress March 2023 about National Security Risk.
    - Platforms have started to respond in policy making
- In 2023 likely California, Colorado, Virginia, Utah and Connecticut Privacy Laws Changing or Coming into Effect

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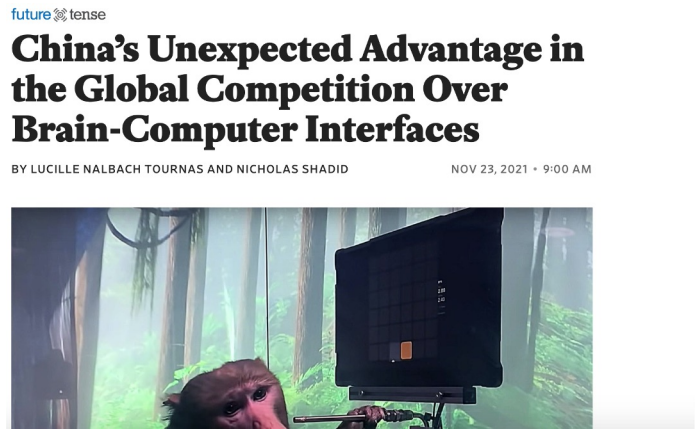
Foreign National Employment

Section 734.2(b)(ii) of the Export Administration Regulations (EAR) defines "export" to include a release of technology or software to a foreign national and considers such release to be a "deemed export" to the home country of the foreign national.

- Licenses are required for release of controlled technology or software to a foreign national only if a license is required for the export of such items to the home country, e.g. China highlevel software develpers
- In practice, prior to President Trump, granting of deemed licenses was almost never denied; there was a presumption of a grant.
    - After Trump, this was turned into a presumption of denial.
    - We are not fully aware where this will finalize under Biden

Technological Development

- Developers should be aware of both these export controls while in technical development, as well as the geopolitical landscape.
    - China Brain Project focuses heavily on BCIs and other neurotechnologies



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Look Forward

- There is a lot of opportunity for partnership to protect both US economic growth alongside national security interests.
- Developers can take a lead in here by understanding current rules, gaps that may exist, and increasing technological protectionism we are witnessing between the US and China.
- Institute of Neuroethics (IoNx)-Multi-disciplinary think and do tank
    - Our aim is to offer real time collaboration, translation, and strategies for neurotechnology development
    - Bridging the technology with its application with involves the complexity of domestic and international ethics, governance, laws, regulations, and policy.

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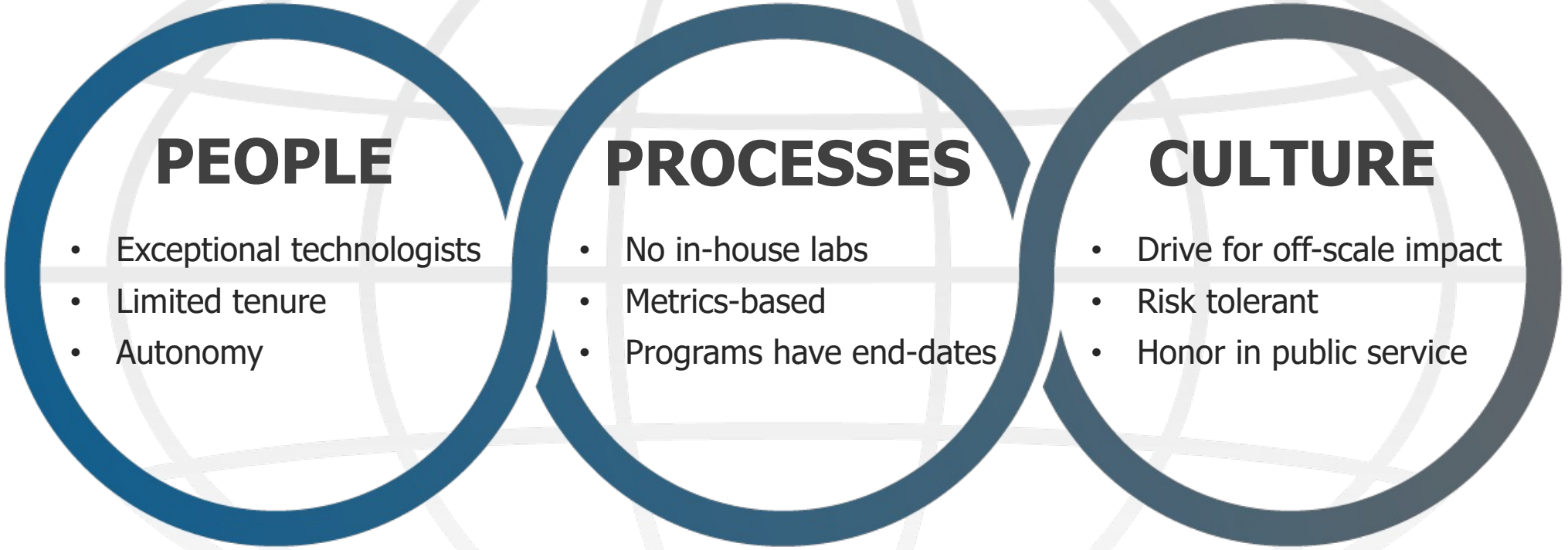
Defense Advanced Research Projects Agency: Biological Technologies Office

Dr. Joeanna C. Arthur
Program Manager, BTO
Joeanna.Arthur@darpa.mil

DARPA's not-so-secret formula to develop breakthrough technologies and capabilities for national security



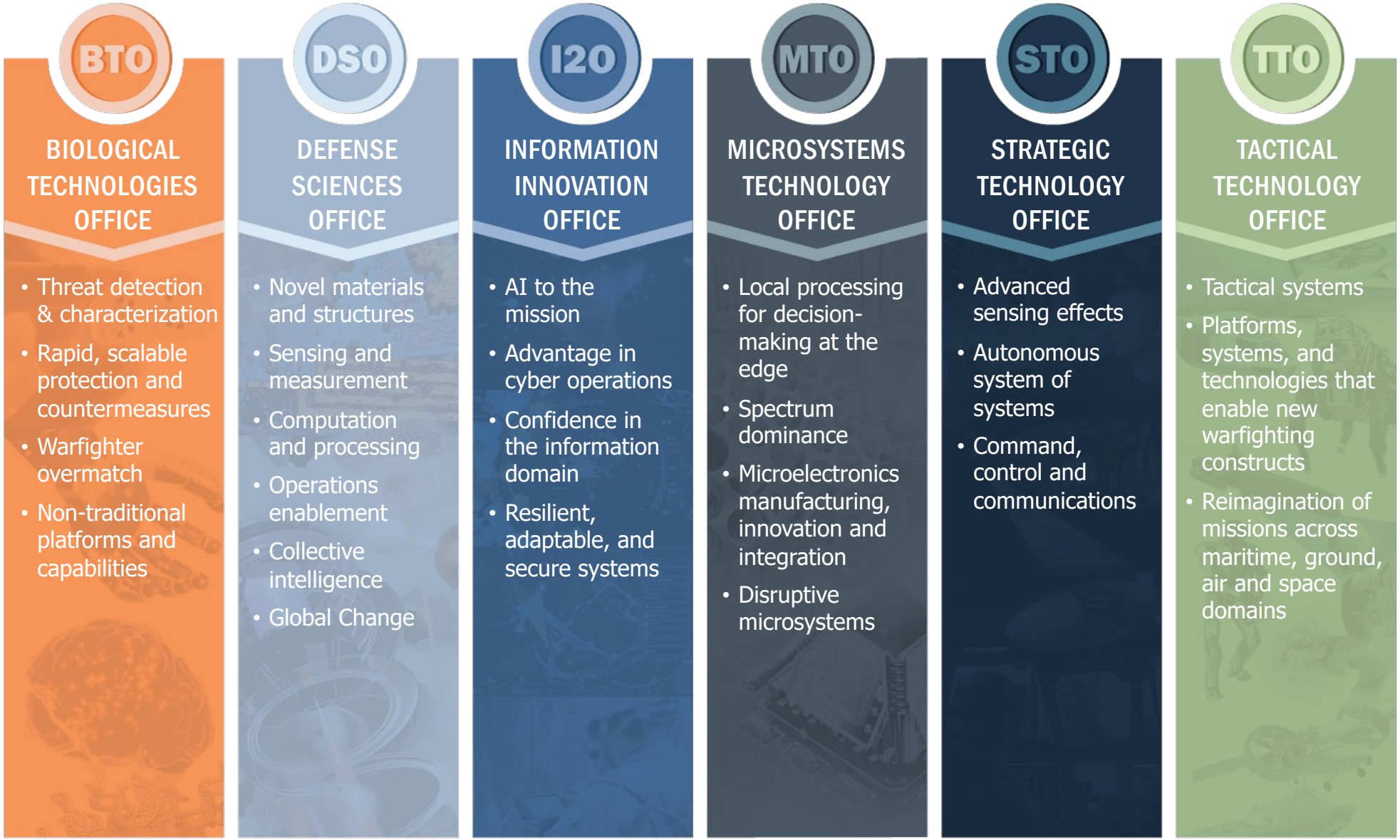
Role in the Department of Defense Science & Technology ecosystem

- **Create breakthrough, paradigm-shifting solutions.**
- **Accept and manage significant technology risk.**
- **Disrupt or massively accelerate technology roadmaps.**





DARPA technical offices



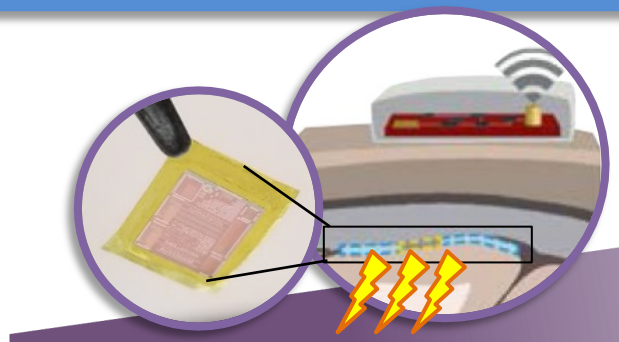
Harnessing Biology to Support the Warfighter

BTO develops capabilities that embrace the unique properties of biology to revolutionize how the United States defends the homeland and prepares and protects its Warfighters

(U)

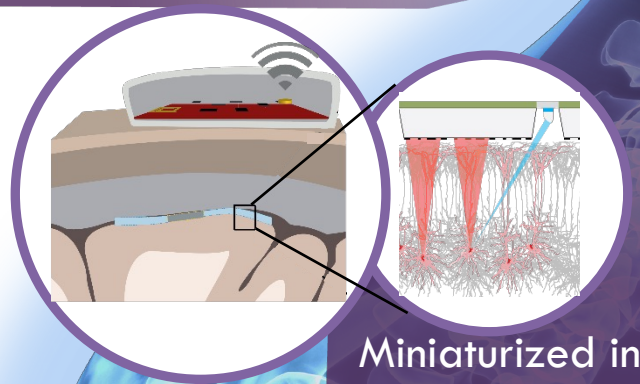
Neural Engineering System Design (NESD)

DoD Problem: Current implantable neural interfaces are not able to provide dense high-quality signals nor the bandwidth required to transfer data between the brain and electronics



Flexible surface electrodes with thousands to millions of contacts

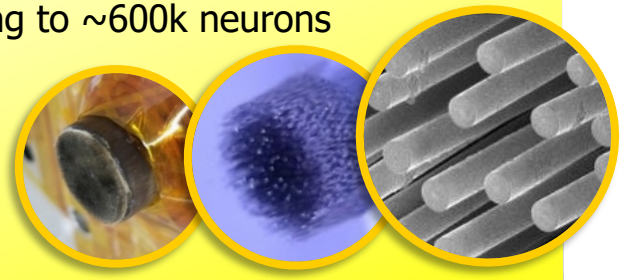
Vision:
1M Retinal ganglion cells



Miniaturized interfaces for optically reactive neurons

Adult human primary visual & auditory cortex:
one cubic millimeter contains ~50,000 neurons

Cochlear nerve:
~30k fibers
Connecting to ~600k neurons



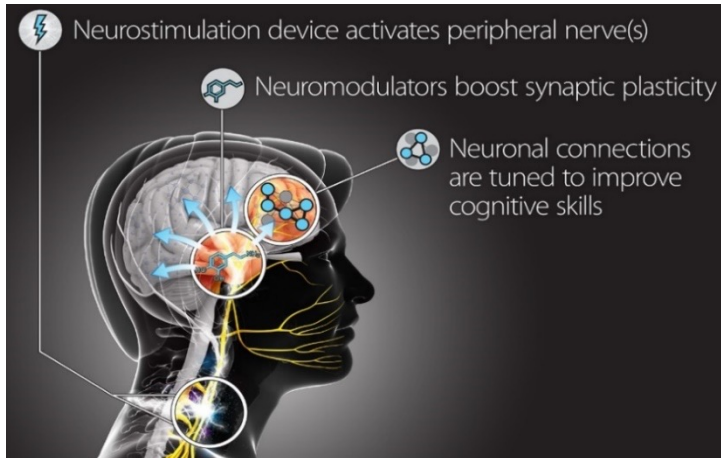
High density bundles of penetrating microelectrodes

Vision: Provide a revolutionary neural prosthetic solution to restore high-fidelity vision, hearing, and speech through a modular and scalable high-definition neural interface

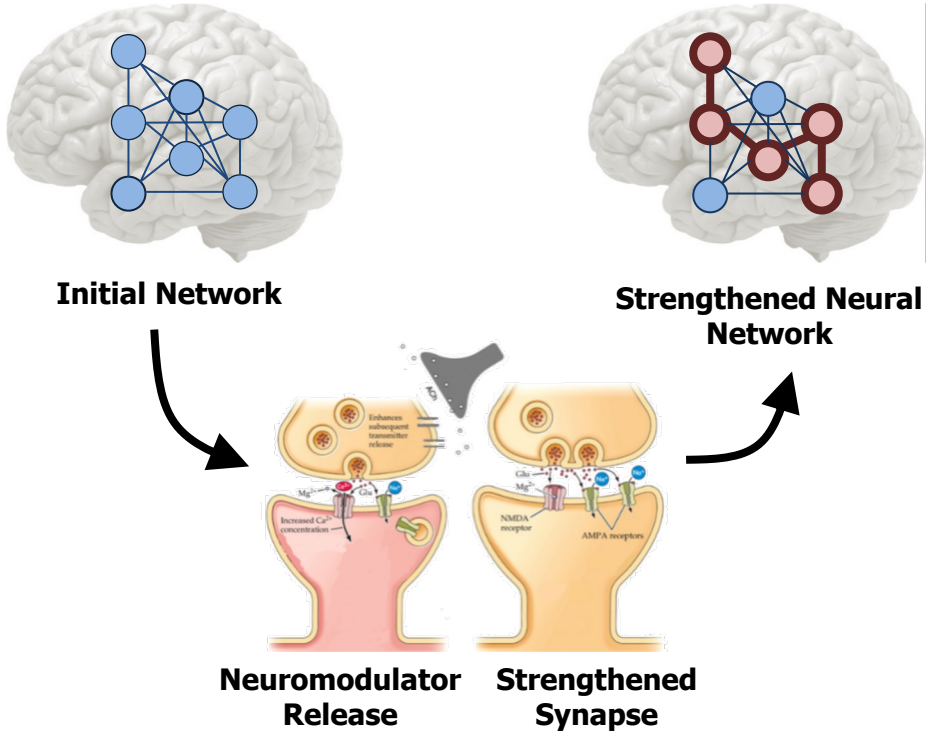
Targeted Neuroplasticity Training (TNT)

DoD Problem: Training personnel is time consuming and low yield. Demands of proficiency from various agencies suggest the need for accelerated training methods

Peripheral Nerve Stimulation Engages Neuromodulatory Circuitry



Training Protocols Engage Task-specific Brain Regions



Goal:

Train personnel **faster** & achieve **superior** cognitive abilities

Vision: Enhancing skill learning in healthy adults by using noninvasive peripheral neurostimulation to promote synaptic plasticity in the brain

www.darpa.mil

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Q&A

Joeanna Arthur and Lucille Tournas, Amanda Pustilnik

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Meeting Summary

Amanda Pustilnik
University of Maryland Law

Brain Computer Interface Export Controls Conference

February 16-17, 2023

Thank you for attending