



Export Controls Compliance

Overview of U.S. Export Controls Compliance

Why is Export Controls Compliance Critical?

- Adverse publicity
- Civil and criminal penalties (including imprisonment)
- Legal costs
- Disruption of business
- Exporting is a privilege, not a right

Agencies Regulating Export Activities

- Department of Commerce, Bureau of Industry and Security (BIS)
 - Dual-use goods
- Department of State, Directorate of Defense Trade Controls (DDTC)
 - Defense articles and services, brokering

Penalties

- Administrative Penalties
 - Up to greater of \$368,136 or twice the value of the transaction for each violation
 - Can be multiple charges per violation
- Criminal Penalties
 - Up to \$1,000,000 and/or up to 20 years in prison
 - Criminal liability provided for anyone who “willfully conspires to commit, or aids or abets in the commission of” an unlawful act described in the statute – personal liability may arise

BIS

- Authorized to regulate exports by the Export Administration Act of 1979
- Implements authority through the Export Administration Regulations (EAR)
- Enforces prohibitions on trade with certain countries/entities/individuals
- Implements Commerce Control List (CCL)
- Regulations at 15 CFR 730-774
- www.bis.doc.gov



What is an Export Shipment?

- What types of items are covered?
 - Commodities of U.S. Origin and Foreign Products in the U.S. or incorporating more than a *de minimis* amount of U.S. components or technology
 - Technology
 - Software
- What types of transactions are covered?
 - Direct Export
 - Re-Export of EAR items
 - Deemed Export

Direct Export

- Goods shipped directly from the U.S. to the ultimate destination
- Mode of transportation does not matter, includes:
 - Mail
 - Email
 - Electronic submission, including website posting
 - Services, e.g., installation of equipment, servicing, seminars, lectures, bidding
 - Oral communication
 - Employment

Re-Export

- Shipment or transshipment of goods subject to the EAR from one foreign country to another
- Release of technology or software subject to the EAR to a foreign national outside of the U.S.
- Principle of extra-territoriality (U.S. law follows U.S. products, technology and software wherever they go, assuming they are subject to the EAR)
- Need to advise and possibly control foreign agents, distributors, warehouses and partners

Deemed Export

- Defined as the release of technology or source code subject to the EAR to a foreign national in the U.S.
- Such a release is deemed to be an export to the home country or countries of the foreign national
- Must be taken into consideration when hiring foreign nationals or providing technology to visiting foreign nationals at your facility
- Must coordinate with Human Resources Dept.

Who is a Foreign National for Deemed Exports?

- Foreign nationals include all but the following:
 - U.S. citizens
 - Permanent residents (Green Card)
 - Protected individuals (e.g., political refugees and political asylum holders)
- Deemed export licensing policy based on most recently established legal permanent residence/citizenship.

What is Covered by Deemed Exports?

- Many types of technology and source code are not subject to the EAR and thus outside the scope of the deemed export rule.
- Includes information subject to the exclusive jurisdiction of another federal agency, but also technology which is in the public domain such as technology resulting from fundamental research.

Technology Subject to EAR

- “Technology,” as used in the EAR, refers to specific information required for the development, production, use, operation, installation, maintenance, repair, overhaul, or refurbishing of specific products.
- “Required” technology refers exclusively to that portion of the technology that is specifically responsible for achieving or exceeding controlled performance levels, characteristics or functions.



“Development”

- “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, layouts.

“Production”

- “Production” means all production stages, such as:
 - product engineering,
 - manufacture,
 - integration,
 - assembly (mounting),
 - inspection,
 - testing,
 - quality assurance.

“Use”

- Allowing a foreign national to use equipment is not a deemed export
- Deemed exports occur when technology subject to the EAR is actually transferred to the foreign national
- “Use” defined in regulations as technology for the (1) operation, (2) installation (including on-site installation), (3) maintenance (checking), (4) repair, (5) overhaul and (6) refurbishing.
- All six elements must be present.

Items Not Subject to EAR

- Information and “software” that:
 - Are published, as described in §734.7;
 - Arise during, or result from, fundamental research, as described in §734.8;
 - Are released by instruction in a catalog course or associated teaching laboratory of an academic institution;
 - Appear in patents or open (published) patent applications available from or at any patent office, unless covered by an invention secrecy order, or are otherwise patent information as described in §734.10;
 - Are non-proprietary system descriptions; or
 - Are telemetry data as defined in Note 2 to Category 9, Product Group E (see supplement no. 1 to part 774 of the EAR).

ECCN and CCL

- The U.S. Commerce Control List (CCL) is broken into 10 Categories 0 – 9 (see Supplement No. 1 to part 774 of the EAR).
- Key in determining export license requirement is whether item, technology or source code has a specific Export Control Classification Number (ECCN).
- ECCN: alpha-numeric code, e.g., 5A992, that describes the item and indicates licensing requirements and reasons for control. Listed in CCL.

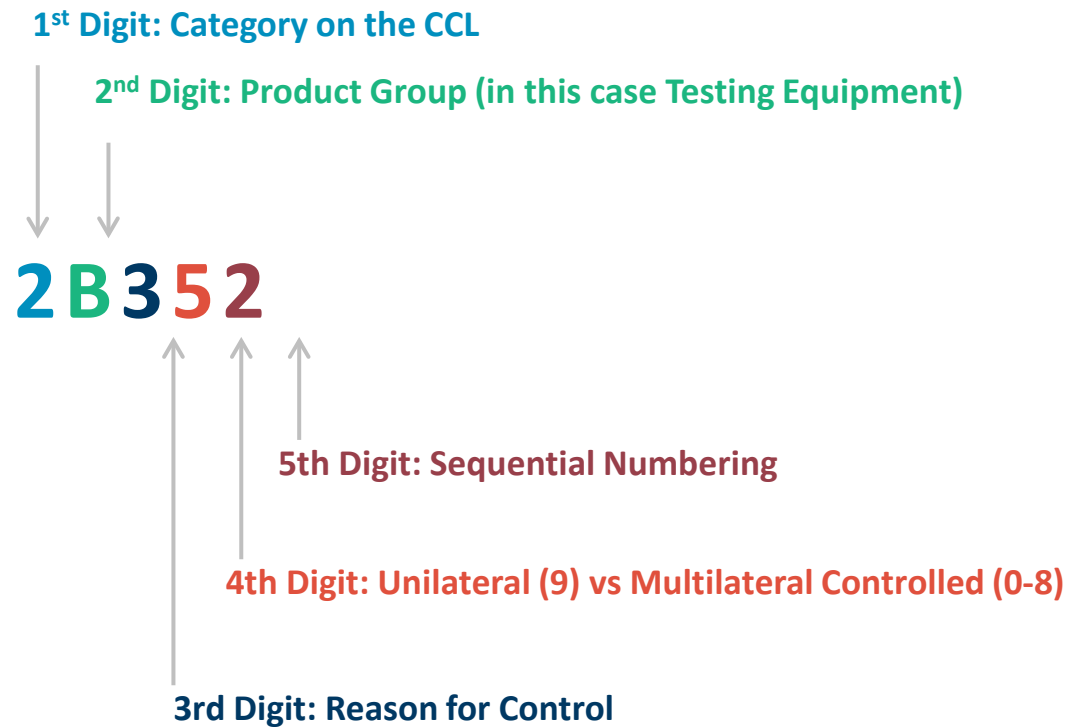
ECCN and CCL

- CCL Categories
 - 0=Nuclear materials, facilities and equipment (and miscellaneous items)
 - 1=Materials, Chemicals, Microorganisms and Toxins
 - 2=Materials Processing
 - 3=Electronics
 - 4=Computers
 - 5=Part 1: Telecommunications and Part 2: Information Security
 - 6=Sensors and Lasers
 - 7=Navigation and Avionics
 - 8=Marine
 - 9=Aerospace and Propulsion

ECCN and CCL

- Five Product Groups
 - A. End Items, Equipment, Accessories, Attachments, Parts, Components, and Systems
 - B. Test, Inspection, and Production Equipment
 - C. Materials
 - D. Software
 - E. Technology

ECCN and CCL



such as chemical plants, rather than those used for batch-mode operation in laboratories.

Items:

- a. Designed for continuous operation and usable for the detection of chemical warfare agents or chemicals controlled by 1C350 at concentrations of less than 0.3mg/m³; *or*
- b. Designed for the detection of cholinesterase-inhibiting activity.

2B352 Equipment capable of use in handling biological materials, as follows (see List of Items Controlled).

License Requirements

Reason for Control: CB, AT

<i>Control(s)</i>	<i>Country Chart (See Supp. No. 1 to part 738)</i>
CB applies to entire entry	CB Column 2
AT applies to entire entry	AT Column 1

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

LVS: N/A
GBS: N/A

List of Items Controlled

Related Controls: See ECCNs 1A004 and 1A995 for protective equipment that is not covered by this entry. Also see ECCN 9A120 for controls on certain “UAV” systems designed or modified to dispense an aerosol and capable of carrying elements of a payload in the form of a particulate or liquid, other than fuel “parts” or “components” of

such vehicles, of a volume greater than 20 liters.

Related Definitions: (1) “Lighter than air vehicles” – balloons and airships that rely on hot air or on lighter-than-air gases, such as helium or hydrogen, for their lift. (2) “UAVs” – Unmanned Aerial Vehicles. (3) ‘VMD’ – Volume Median Diameter.

Items:

- a. Containment facilities and related equipment, as follows:
 - a.1. Complete containment facilities at P3 or P4 containment level.

Technical Note to 2B352.a.1: P3 or P4 (BL3, BL4, L3, L4) containment levels are as specified in the WHO Laboratory Biosafety Manual (3rd edition, Geneva, 2004).

- a.2. Equipment designed for fixed installation in containment facilities specified in paragraph a.1 of this ECCN, as follows:

- a.2.a. Double-door pass-through decontamination autoclaves;
- a.2.b. Breathing air suit decontamination showers;
- a.2.c. Mechanical-seal or inflatable-seal walkthrough doors.

- b. Fermenters and components as follows:

- b.1. Fermenters capable of cultivation of micro-organisms or of live cells for the production of viruses or toxins, without the propagation of aerosols, having a total internal volume of 20 liters or greater.

- b.2. Components designed for such



ECCN and CCL

- Can self-classify, rely on third party experts, or request a ruling (CCATS) from BIS.
- If item falls under BIS jurisdiction but is not identified by a specific ECCN, it is EAR99.
- EAR99 items generally consist of low-technology consumer goods and do not require a license in many situations.
- However, may need a license to export EAR99 item to embargoed country, end-user of concern, or for prohibited end-use.



Commerce Country Chart

- Based on the proposed export destination and the Reason for Control that applies to the ECCN of the product proposed for export, the exporter can then consult the “Commerce Country Chart” and determine whether a license will be required.
- Unless a license exception applies, which would be governed by the ECCN of the product, then the exporter will need to apply for a license.

Commerce Country Chart

Reason for Control

Countries	Chemical & Biological Weapons			Nuclear Nonproliferation		National Security		Missile Tech	Regional Stability		Firearms Convention	Crime Control			Anti-Terrorism	
	CB 1	CB 2	CB 3	NP 1	NP 2	NS 1	NS 2	MT 1	RS 1	RS 2	FC 1	CC 1	CC 2	CC 3	AT 1	AT 2
	Brunei	X	X		X		X	X	X	X	X		X		X	
Bulgaria ³	X					X		X	X							
Burkina Faso	X	X		X		X	X	X	X	X		X		X		
Burma	X	X	X	X		X	X	X	X	X		X		X		
Burundi	X	X		X		X	X	X	X	X		X		X		
Cambodia	X	X		X		X	X	X	X	X		X	X			
Cameroon	X	X		X		X	X	X	X	X		X		X		
Canada	X										X					
Cape Verde	X	X		X		X	X	X	X	X		X		X		
Central African Republic	X	X		X		X	X	X	X	X		X		X		
Chad	X	X		X		X	X	X	X	X		X		X		
Chile	X	X		X		X	X	X	X	X	X	X		X		
China	X	X	X	X	X	X	X	X	X	X		X		X		

Export License Application

- If item is subject to EAR and requires a license, can register and submit export license through BIS on-line system called SNAP-R (Simplified Network Application Process – Redesign), accessible at www.snapr.bis.doc.gov.
- An exporter applies for access to the system and receives a Company ID (CIN) and a pin to fill out export applications electronically
- The licensing division reviews all export licenses for proliferation or security concerns.



SNAP- R

[ABOUT SNAP-R](#)
[BIS HOME](#)
[SNAP-R FAQ](#)
[LOGIN HELP](#)
[REGISTRATION HELP](#)
[NEW FEATURES!](#)
[STELA](#)
[CONTACT US](#)

WARNING WARNING WARNING WARNING WARNING WARNING WARNING

USE OF THIS SYSTEM IS RESTRICTED AND MONITORED !!!

You are accessing a U.S. Government information system, which includes: 1) this computer, 2) this computer network, 3) all computers connected to this network, and 4) all devices and storage media attached to this network or to a computer on this network. You understand and consent to the following: you may access this information system for authorized use only; you have no reasonable expectation of privacy regarding any communication of data transiting or stored on this information system; at any time and for any lawful Government purpose, the Government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system; and any communications or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

Unauthorized use of the system is prohibited and subject to criminal and civil penalties.

WARNING WARNING WARNING WARNING WARNING WARNING WARNING

Login to SNAP-R

Login ID [?](#)

Password [?](#)

CIN (Applicant ID) [?](#)

[Forgot Password/Login ID/CIN\(Applicant ID\)? \[?\]\(#\)](#)

[Register online for a SNAP-R account](#)

Privacy Act Statement

The Export Administration Act of 1979, as amended (50 U.S.C. app Sec 2401 et seq.), authorizes collection of this information. The primary use of this information is for the submission of:

- Export and Reexport License Applications,
- Commodity Classification Requests, and
- Agricultural License Exception Notifications

The information you provide may be disclosed, as a routine use:

- If the Department discovers a violation or potential violation of law or contract and may be referred to an appropriate agency, whether Federal, state, local or foreign, charged with the responsibility of investigating or prosecuting such violations or charges;
- To a Federal, state or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a Department decision concerning the assignment, hiring or retention of an individual, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit;
- To a Federal, state, local, or international agency, in response to its request, in connection with the assignment, hiring or retention of an individual, the issuance of a security clearance, the reporting of an investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter;
- In the course of presenting evidence to a court, magistrate or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations;
- To a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record;
- To the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular;
- To the Department of Justice in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552);
- To a contractor of the Department having need for the information in the performance of the contract, but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

Deemed Export License Application

- Comparable to applications for other technology, but must also include:
 - Detailed letter of explanation
 - Comprehensive bio/resume of foreign national
 - Personal background of foreign national, including visa status, family ties in U.S., etc.
 - Complete job description
 - Projected outcome of employment (e.g., becoming a U.S. citizen)
 - Safeguards established by application to restrict access to approved technology

Technology Safeguards

- Deemed export and technology export licenses often impose technology control requirements
- Often include the following essential elements:
 - Corporate commitment to export compliance
 - Physical security plan
 - Information security plan
 - Personnel screening procedures
 - Training and awareness program
 - Self evaluation program

China-Specific U.S. Export Controls

China Export Controls Framework

- Generally, licensing policy for the PRC is to approve items for civil end-use to civil end-users.
- In addition to the license requirements for items specified on the CCL, there are additional restrictions on items listed in Supplement No. 2 to Part 744 of the EAR if you have knowledge that those items are intended, entirely or in part, for a military end-user or end-use.
- In addition, a license is required for any item subject to the EAR if you have knowledge that the items are intended, entirely or in part, for a military-intelligence end-use or end-user (MIEU), or if a U.S. person, wherever located, is providing any “support” as defined in § 744.6(b) to an MIEU.

Entity List Additions

- In recent years, the additions of Chinese entities on the Entity List have been predicated upon a determination that:
 - Entities have been involved in prohibited military end use activities,
 - Entities have diverted EAR items to embargoed destinations,
 - Entities have enabled human rights violations in the Xinjiang Uyghur Autonomous Region (XUAR) or against people from that region, or
 - Entities have facilitated military activities in the South China Sea, amongst other reasons.
- Additions to the Entity List, and to some extent the Unverified List, are essentially blacklisted from doing business with the U.S. and can be devastating (see, e.g., Wuxi Biologics).

Validated End-User Program

- End-users in China can apply for the Validated End-User (VEU) program. Allows end-users who have an established track record of exclusive engagement in appropriate end-use activities to receive exports of specified items for civil end uses without the need for their suppliers to first obtain individual export or reexport licenses.
- Interested companies can apply by submitting a request for an advisory opinion to BIS, as described in Section 748.15 of the EAR.

Relevance to U.S. life sciences/biotechnology industry

- BIS, which administers U.S. “dual use” export controls, has steadily expanded export controls on emerging and foundational technologies, including biotechnology.
- BIS has highlighted biotechnology as an emerging technology essential to national security for potential additional export controls restrictions.
- Controls are established by modifying an existing ECCN, adding a new subparagraph to existing an ECCN, or adding new standalone ECCNs.
- Two new emerging biotechnology items are ECCN 2B352.b.2.b (single-use biological cultivation chambers with rigid walls), and ECCN 2D352 (software designed for nucleic acid assemblers and synthesizers).

Other Potential Areas with Licensing Requirements

- Biological agents and genetic elements (1C351-4)
- Vaccines (ECCN 1C991)
- Biological processing equipment (ECCN 2B352)
- Technology (Development, Production, Use technology under ECCNs 1E001, 2E001, 2E002, 2E301)
- Deemed exports and re-exports

General Compliance Best Practices

A Successful Compliance Program

- Requires:
 - Management Support
 - Coordination of Efforts
 - Communication Between Departments
 - Cooperation Between Departments
 - Written Procedures
 - Personnel Training
 - Robust Auditing

General Compliance Best Practices

- Pay heightened attention to red flag indicators and communicate red flag concerns internally.
- Obtain detailed information on credentials of customers to assess diversion risks.
- Communicate export controls classification and destination information to end-users and consignees on government and commercial export documentation.

General Compliance Best Practices

- Use information technology to the maximum extent feasible to augment KYC and other due-diligence measures in combating the threats of diversion and increase confidence that shipments will reach authorized end-users for authorized end-uses.

General Compliance Best Practices

- Develop comprehensive written policies addressing exports controls and sanctions compliance (an Internal Compliance Program or ICP).
- Identify one person who reports directly to senior management (Board, CEO, General Counsel, etc.), other than sales and marketing, who is responsible for the company's export controls and sanctions compliance program.

General Compliance Best Practices

- Ensure that all relevant personnel receive adequate training in export controls and sanctions compliance.
- Screen all parties to a proposed transaction against all government published control lists, including the Denied Parties List, Unverified List, Entity List, Specially Designated Nationals (SDN), Non-Proliferation Sanctions and Debarred List, and maintain a record of each screening.

Hosting a Foreign National

- Best Practice:
 - Foreign National Visitors Control
 - Need to Identify Citizenship of Visitors
 - Identify Product and Technology Classification
 - Control Access to Controlled Technology
 - Ensure Security of Electronic and Hard Copy Data
 - Designate Employee as Escort
 - Establish a Badge or Similar Visual Identification

Hosting a Foreign National

- Best Practice:
 - Foreign National Visitor Request Form
 - Establish Specific Request Form
 - Purpose of Visit
 - Obtain Foreign National's ID Information
 - Screen Foreign National
 - Will Export-Controlled Technology be Discussed?
 - Area of Building to be Visited
 - Identify Escort

Questions?

Matthew A. Bock, Esq., LCB

Partner

Bock Trade Law

53 State Street, Suite 500

Boston, MA 02109

Tel.: +1 (781) 272-7966

Email: mbock@bocktradelaw.com

