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Important Export Control Considerations for the Life Sciences Industry

August 28, 2024

Training Topics

- Overview of Export Compliance
- Exports under the ITAR and EAR
  - With emphasis on medical devices and pharmaceuticals
- Compliance Strategies
- Sanctions and FCPA

What is Export Compliance?

A critical component of the U.S. national security strategy is the organized control of goods and services that, in the wrong hands, would harm U.S. national security interests or frustrate our international objectives/priorities.

Several laws and regulations limit the ability of U.S. persons to export or provide such goods and services without prior governmental approval.

Export Compliance is simply the practice of properly complying with such laws and regulations.

The export compliance regulations we will focus on today are the International Traffic in Arms Regulations ("**ITAR**") and the Export Administration Regulations ("**EAR**").

Overview of Export Regulations

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What is the ITAR?

- The ITAR controls the temporary and permanent export and temporary import of "**defense articles**" (e.g., military equipment), technical data related to defense articles, and **defense services**.

- The ITAR prohibits the temporary and permanent export of defense articles, technical data, and defense services from the U.S. abroad or to a foreign person/entity, unless the export is authorized by license, or an exemption applies.

- Generally, goods to be exported to foreign customers within the life sciences industry (e.g., medical devices and pharmaceuticals) are NOT controlled under the ITAR.

22 C.F.R. Part 120-130

What is the EAR?

- The Export Administration Regulations ("**EAR**") are U.S. regulations that control the export of "dual-use" items (i.e., articles that have both a military and a commercial application) and information related to such items ("**Technology**").

- The EAR prohibits the temporary and permanent export of certain dual-use items and **Technology** from the United States to certain countries and certain foreign nationals, unless the export is authorized by a license, or an EAR exemption applies.

15 C.F.R. Part 730 *et. seq.*

Which Dual-Use Items are Regulated?

- The EAR regulates those commercial and dual-use items found on the Commerce Control List ("**CCL**").

- The CCL consists of **ten categories**:
  1) Nuclear Materials, Facilities, and Equipment (and Miscellaneous Items)
  2) Special Materials and Related Equipment, Chemicals, and Microorganisms, and Toxins
  3) Materials Processing
  4) Electronics
  5) Computers
  6) Telecommunications and Information Security
  7) Sensors and Lasers
  8) Navigation and Avionics
  9) Marine
  10) Aerospace and Propulsion

- Each category is further divided into **five product groups**:
  1) Systems, Equipment, and Components
  2) Test, Inspection, and Production Equipment
  3) Material
  4) Software
  5) Technology

What is the EAR99 Designation?

- If an item falls under the jurisdiction of BIS but is not listed on the CCL, then it is designated as "**EAR99**."

- EAR99 items typically do not require an export license.

- **However**, before exporting an EAR99 item (i) to an embargoed or sanctioned country; (ii) to a party of concern; or (iii) in support of a prohibited end use, an exporter may be required to obtain a license.

What Constitutes "Technology" Under the EAR?

- Under the EAR, technical information relating to controlled dual-use items AND the communication of such technical information are both characterized as "**Technology**."

  - "**Technology**" is defined in EAR Part 772 as "[i]nformation necessary for the 'development,' 'production,' **'use,'** operation, installation, maintenance, repair, overhaul, or refurbishing (or other terms specified in ECCNs on the CCL that control 'technology') of an item."

    - **NOTE**: "'Technology' may be in any tangible or intangible form, such as written or oral communications, blueprints, drawings, photographs, plans, diagrams, models, formulae, tables, engineering designs and specifications, computer-aided design files, manuals or documentation, electronic media or information revealed through visual inspection[.]"
    - "Use" includes all of the following activities: operation, installation (including on-site installation), maintenance (checking), repair, overhaul and refurbishing.

Key Concepts: EAR

- If hardware is not ITAR controlled, it will always be EAR controlled, even if it's "EAR99."
- Exports of EAR99 items may still require a license depending on the destination and end user.
- Classification analyses take time and careful consideration of all potential options on the CCL. Just because a product is not obviously listed, does not mean it is not controlled.
- While the EAR contains many license exceptions, it does not mean the products can be shipped without any oversight.

Exporting from the U.S.

- Dual-use items – subject to BIS regulatory jurisdiction
  - Predominantly commercial/academic uses
  - Could also be used in military applications
  - Listed in Export Administration Regulations (EAR) by Export Control Classification Number (ECCN)
  - Commerce Control List (CCL)
- May require export license
- Other Controls - USML, OFAC

How to obtain an ECCN

– There are three ways to obtain an ECCN:

1. Contact the manufacturer, as they may know the ECCN of the item;
2. Self-classify the item by reviewing the Commerce Control List (CCL); or
3. Submit an official commodity classification request to BIS electronically using SNAP-R (BIS' online platform)

Reasons for Control

- Multilateral controls (international regimes)
  - Australia Group for chemical and biological items and equipment
    - All states participating in the Australia Group are parties to the Chemical Weapon Convention (CWC) and the Biological Weapon Convention (BWC). See here: https://www.dfat.gov.au/publications/minisite/theaustraliagroupnet/site/en/
  - Wassenaar Arrangement for certain detection equipment associated with chemica and biological weapons
- Unilateral controls (US only)
  - Implemented independent of the above regimes to countries of concern to the US Government

What Might Need a License?

- Biological agents and genetic elements (1C351-4) (Australia Group list plus Select Agents)
- Vaccines (ECCN 1C991) (unilateral)
- Biological processing equipment (ECCN 2B352)
- Technology (Development, Production, Use) – ECCNs 1E001, 2E001, 2E002, 2E301
- Foreign worker in US facility (deemed export – see below slide)
- Re-export of U.S.-origin items from a foreign country see EAR 732.3(b)

Key Questions to Determine if License is Needed

- What is the ECCN of the item to be exported?
  - EAR99 means that it's okay to export to most destinations
  - Listed on Commerce Control List – might mean:
    - **License required**
    - No License Required (NLR)
    - License exception eligible
  - What is the destination country (or countries)?
- Who are the recipients and are they reliable?
  - Ultimate Consignee
  - End User
- End use – is it reasonable? Examples of **prohibited end-use** include restrictions on certain nuclear end-uses, use of products in weapons of mass destruction, and use of microprocessors for military end-use.

Not Controlled

- Electrophoresis apparatus
- Protein Sequencing apparatus
- Peptide synthesis apparatus
- DNA sequencing apparatus
- Oligonucleotide synthesis apparatus
- Consumer or medical protective gear – latex gloves, surgical masks, etc.
- Fundamental Research §734.8 & §734.11
  - Does not include government sponsored or proprietary research the results of which ordinarily are restricted for proprietary reasons or specific national security reasons as defined in §734.11(b)

Not Controlled, continued

- Pathogen or toxin not on CCL
- Gene fragments (must be whole gene with ORF)
- Chromosome fragments
- E. coli Nucleic acid sequences
- Unless sequence code for verotoxin

Technology for Controlled Items

- "Technology" takes the form of "technical data" or "technical assistance"
  - Tangible **or intangible** (e.g., source code or engineering drawings)
  - Deemed Exports (see below slide)
- Types of Technology controlled:
  - "Production", "Development", "Use"
  - Specific definitions found in Part 772

Technology NOT Subject to the EAR (734.3)

- "Publicly Available Technology and Software
- Already published or will be published (734.7)
- Arise during fundamental research (734.8)
- Educational (734.9)
- Included in certain patent applications (734.10)

Deemed Exports

- Export of controlled technology or source code
  - To a foreign national (except for green card holders, permanent residents, or protected persons
  - Inside the United States – See EAR 734.2(b)(3)
  - See EAR 734.2(b)(3)
  - http://www.bis.doc.gov/index.php/policy-guidance/deemed-exports

Foreign Government Requirements: Exporting Medical Devices to the EU

- The European Union (EU) is an important market for U.S. exporters in the healthcare sector.
- The U.S. exported over $20 billion in medical devices to the EU in 2018 (representing 38% of the total export market), and in the pharmaceuticals sector, U.S. exports to the EU totaled $36 billion.
- As the European Union (EU) does not have a Food and Drugs Administration (FDA), the task of harmonizing requirements and regulating medical devices is handled by the European Commission in close cooperation with Member States' Health Authorities.
- In the European Union (EU) medical devices must undergo a conformity assessment to demonstrate they meet legal requirements to ensure they are safe and perform as intended prior to being imported.

Foreign Government Requirements: Exporting Medical Devices to the EU, *cont.*

- US manufacturers can place a CE (Conformité Européenne) mark on a medical device once it has passed a conformity assessment.
- The conformity assessment usually involves an audit of the manufacturer's quality system and, depending on the type of device, a review of technical documentation from the manufacturer on the safety and performance of the device.
- EU Member States designate accredited notified bodies to conduct conformity assessments.
- Medicinal products may only be placed on the EU market when a marketing authorisation has been issued by the competent authorities of a Member State or by the European Medicines Agency.
- Only applicants established in the EU may be granted a marketing authorisation.
- The marketing authorisation holder is the person responsible for placing the medicinal product on the market.
- The application dossier must be submitted to the Agency and consists of administrative information and the necessary scientific documentation to demonstrate the quality, safety and efficacy of the medicinal product (results of physico-chemical, biological or microbiological tests, toxicological and pharmacological tests and clinical trials).
- The label, the package leaflet and the container also become part of the marketing authorisation, therefore they need to be approved.
- Marketing authorisations granted following this procedure are valid throughout the EU and are recorded in the European Register for medicinal products.

Exports Under the ITAR + EAR

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Requirements for Exporting Under the ITAR + EAR

- Generally speaking, unless an **exclusion** or an **exemption** applies, a U.S. person **MUST** obtain an export authorization from the U.S. government before exporting any **ITAR-controlled defense articles**, **CCL-controlled items**, **technical data**, **defense services**, or **technology**.

- This authorization comes in the form of a “license.”

- **NOTE**: Under the EAR, the precise destination of an export will invariably determine whether a license is required.
  - Restrictions vary from country to country and from item to item. The most restricted destinations are the embargoed countries and those countries designated by the Department of State as state sponsors of terrorism, including Cuba, Iran, North Korea, Sudan, and Syria.

But How Do I Know If I Am "Exporting" in the First Place?

Will there be . . .

– An **actual shipment or transmission** out of the U.S.?
  - Or the sending or taking of a defense article out of the U.S. in any manner?

Is there a . . .

– **Transfer of registration, control, or ownership** of any aircraft, vessel, or satellite subject to the ITAR by a U.S. person to a foreign person?

Will you . . .

– **Perform a defense service** on behalf of, or for the benefit of, a foreign person, whether in the United States or abroad?

Will you . . .

– **Release or otherwise transfer** a defense article to an embassy or to any of its agencies or subdivisions, such as a diplomatic mission or consulate, in the U.S.?

Will you . . .

– **Release technical data** in the U.S. to a foreign person?
  - Or allow visual or other inspection by foreign persons of a defense article that reveals technical data to a foreign person?
  - Or conduct oral or written exchanges with foreign persons of technical data in the U.S. or abroad?

This is an export under the ITAR!

This is a "deemed export" under the ITAR!

But How Do I Know if I Am "Exporting" in the First Place?, *cont.*

Will there be . . .

– An **actual shipment or transmission** out of the U.S.?
- Or the sending or taking of an EAR-controlled item out of the U.S. in any manner?

Is there a . . .

– **Transfer of a U.S. person's registration, control, or ownership of:**
- A **spacecraft** subject to the EAR that is not eligible for export under License Exception STA **or**
- Any other **spacecraft** subject to the EAR to a person in or a national of a **Country Group D:5** country?

Will you . . .

– **Release or otherwise transfer "Technology"** or source code (but not object code) to a foreign person in the U.S.?

This is an export under the EAR!

This is a "deemed export" under the EAR!

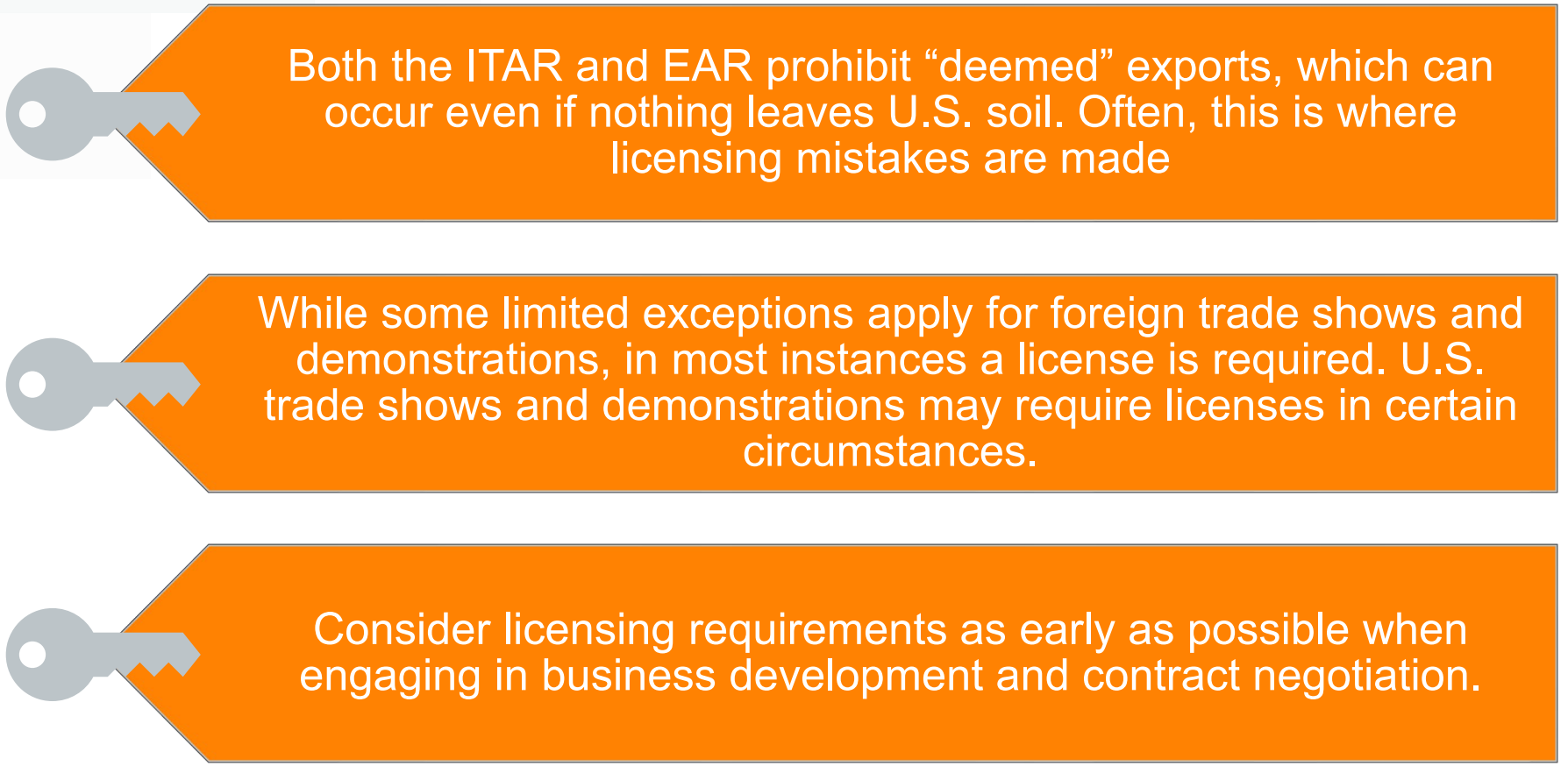
Types of Licenses Under the ITAR

1. **Manufacturer License and Exporter License**

2. **License via Agreement**
   - Technical Assistance Agreement - "An agreement (e.g., contract) for the **performance** of a defense service(s) or the **disclosure** of technical data" (22 C.F.R. § 120.22).
   - Manufacturing License Agreement - "An agreement (e.g., contract) whereby a U.S. person grants a foreign person an **authorization to manufacture defense articles abroad** and which involves or contemplates:
     - The export of technical data…or defense articles or the performance of a defense service; or
     - The use by the foreign person of technical data or defense articles previously exported by the U.S. person…" (22 C.F.R. § 120.21).
   - Distribution Agreement - "An agreement (e.g., a contract) to **establish a warehouse or distribution point abroad** for defense articles exported from the United States for subsequent distribution to entities in an approved sales territory…" (22 C.F.R. § 120.23).

3. **Broker License**

Key Concepts: Exports



The Foreign Corrupt Practices Act

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What is the FCPA?

In general terms, the Foreign Corrupt Practices Act ("**FCPA**") is a U.S. law prohibiting **corrupt payments** or **promises** for payments, **directly or indirectly**, to **foreign officials** in exchange for **preferential treatment**.

Who is Subject to the FCPA?

– "**U.S. persons**" (U.S. companies, U.S. citizens and permanent residents).
  - Applies to actions anywhere in the world, and NOT just in US territory.

– **Non-U.S. citizens** are ***ALSO*** subject to the FCPA under three circumstances:

1) If they work for a U.S. company, whether as an employee or as an agent;
2) If they directly, or indirectly, engage in any act in furtherance of a corrupt payment while having contact with U.S. territory; and

    - Examples of contact include:
      – Physically present in the U.S.;
      – Making or receiving phone calls that are routed through the U.S.;
      – Sending or receiving emails that transit a U.S.-based server; and
      – Making, arranging, or receiving wire transfers that transit the U.S. banking system.

3) If they help a U.S. entity/individual bribe a foreign official no matter where they are in the *world*.

Key Concepts: FCPA

Sanctions Compliance

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What are the Sanctions Lists?

For a variety of reasons relating to national security, law enforcement, and the protection of basic human rights, the U.S. government maintains "**sanctions**" on certain individuals, entities, and countries.

The objective of these sanctions is to economically isolate these individuals, entities, and countries, by generally prohibiting U.S. persons from conducting business, and trading, with them.

Each set of sanctions is memorialized in a "list," which U.S. individuals and companies can use to determine whether the party with which they want to conduct business/trade has been sanctioned.

OFAC's Specially Designated Nationals List

- The majority of sanctions are enforced by the Office of Foreign Assets Control ("**OFAC**") at the U.S. Department of the Treasury.

- OFAC publishes lists of individuals and companies owned or controlled by, or acting for or on behalf of, targeted countries. It also lists individuals, groups, and entities, such as terrorists and narcotics traffickers designated under programs that are not country-specific.
  - Collectively, these individuals and companies are called **"Specially Designated Nationals."**
  - Their assets are blocked and **U.S. persons are generally prohibited from dealing with them.**

Other OFAC Sanctions Programs

– Other non-SDN sanctions lists are captured in a consolidated set of data files called the "the Consolidated Sanctions List." This consolidated list includes:

1. **The List of Foreign Financial Institutions Subject to Part 561** - List of foreign financial institutions that knowingly violate the Iranian Financial Sanctions Regulations.

2. **The Foreign Sanctions Evaders List** - List of (a) foreign individuals and entities determined to have violated, attempted to violate, conspired to violate, or caused a violation of U.S. sanctions on Iran and Syria, or U.S. sanctions pertaining to non-proliferation or anti-terrorism; and (b) foreign persons who have facilitated deceptive transactions for or on behalf of persons subject to U.S. sanctions.

3. **The Sectoral Sanctions Identifications List** - List of entities in the Russian financial and energy sectors that have been sanctioned.

4. **List of Foreign Financial Institutions Subject to Correspondent Account or Payable** - Through Account Sanctions (CAPTA List) - List of foreign financial institutions subject to correspondent or payable-through account sanctions.

Other OFAC Sanctions Programs, *cont.*

– Other non-SDN sanctions lists are captured in a consolidated set of data files called the "the Consolidated Sanctions List." This consolidated list includes:

5. **Sectoral Sanctions Identifications (SSI) List** - List of persons operating in sectors of the Russian economy identified by the Secretary of the Treasury pursuant to Executive Order 13662.

6. **The Palestinian Legislative Council List** - List of individuals sanctioned on the basis that they are members of the Palestinian Legislative Council who were elected on the party slate of Hamas, or any other Foreign Terrorist Organization, Specially Designated Terrorist, or Specially Designated Global Terrorist.

7. **The Non-SDN Iranian Sanctions Act List** - List of persons determined to have made certain investments in Iran's energy sector or to have engaged in certain activities relating to Iran's refined petroleum sector.

Proscribed Parties

The Department of Commerce and Department of State maintain their own lists of proscribed parties:

Department of Commerce	Department of State
• **The Denied Parties List** - individuals and entities that have been denied export privileges. • **The Unverified List** - parties that are ineligible to receive items subject to the Export Administration Regulations by means of a license exception. • **The Entity List** – foreign parties that are prohibited from receiving some or all items subject to the EAR without a license. • **Military End User List** – foreign parties that are prohibited from receiving items described in Supplement No. 2 of Part 744 of the EAR without a license.	• **The Nonproliferation Sanctions List** - foreign individuals, private entities, and governments that have been sanctioned for engaging in proliferation activities. • **The AECA Debarred List** - entities and individuals that have been prohibited by the Department of State from participating directly or indirectly in the export of defense articles, including technical data and defense services.

Compliance Strategies

- Despite the breadth and complexity of the U.S. sanctions programs, complying with them is relatively straightforward.

- OFAC recommends using a risk-based approach based on a variety of factors including the company's size and sophistication, products and services, customers and counterparties, and geographic location.

- Each program should be predicated on and incorporate at least five essential components of compliance:

1. Management commitment;
2. Risk assessment;
3. Internal controls;
4. Testing and auditing; and
5. Training.

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