

Compliance Today – June 2021 In shape for shipping out? Establishing an export compliance program

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Regardless of size, organizations that export items, services, or products listed on the Commerce Control List^[1] (CCL) are subject to Export Administration Regulations^[2] (EAR), which govern exportation from the US, reexportation from foreign countries, or the transfer of items from a person to a foreign country. Biological and technological research with a foreign national is subject to EAR, and certain countries, individuals, and organizations are subject to trade sanctions, embargoes, and other US restrictions. Healthcare businesses and research organizations, including health systems that conduct clinical research and trials and engage in foreign transactions, are subject to EAR and should implement an export compliance program (ECP)^[3] to help steer export decisions and navigate the waters of highly regulated and risky business transactions.

Research facilities are especially vulnerable to scrutiny since biological and technological research information is developed and disseminated throughout scientific communities. These facilities should ask themselves the following questions to determine whether they have plugged all the holes in their compliance programs:

- Do we have items, services, and product lines that potentially qualify as an export? If so, do we have an international or trade compliance expert to oversee and direct this area?
- Does my provider education program include topics such as sanctions, exclusions, and conflict disclosure with sanctioned individuals and countries, including how to recognize criminal tactics used by underground recruitment agencies?
- Do we have a policy governing international and trade transactions, and are we enforcing the procedures to comply with conflict-of-interest and nondisclosure requirements?
- Are we consistently conducting thorough and compliant investigations of licenses and certifications for all individuals and faculty?
- Do we properly vet visa applications and follow proper citizenship and immigrant worker permit requirements?

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