

# **Xymox**

## **Export Compliance Manual**

## EXPORT COMPLIANCE POLICY

Xymox Technologies, Inc., (Xymox or “the Company”) is committed to observing the highest ethical standards in all of its activities in all locations where the Company conducts operations. All Xymox employees and consultants are expected to comply with all laws that are applicable to the Company’s activities, and no actions may be taken to evade or avoid the application of these laws. In particular, it is the policy of the Company that all applicable Xymox employees must comply with U.S. export laws and regulations.

Exports of items, including technology or information, or in some case services, from the United States to foreign destinations are regulated by three primary sets of regulations: the Export Administration Regulations (“EAR”); the International Traffic in Arms Regulations (“ITAR”); and various regulations administered by the U.S. Department of Treasury’s Office of Foreign Asset Control (the “OFAC Regulations”). As discussed in this Export Compliance Manual, the regulations that currently apply to the Company are the ITAR, because the Company does not export dual-use goods, information, technology or software, and does not engage in export transactions that are likely to implicate the OFAC Regulations. The Company is monitoring its export activities, and if this should change will amend this Manual to include coverage of these regulations.

Failure to comply with the ITAR can result in serious consequences for the Company and its employees and consultants. Violations can result in substantial fines for the Company and can subject the Company and its employees and consultants to prosecution, criminal fines, and imprisonment. The Company will take all necessary disciplinary action, including termination of employment, for any violation of Xymox’s standards. The Company also will determine if disclosures to relevant U.S. Government agencies are required.

Every director, officer, and employee to whom this Export Compliance Manual is distributed must read and understand its content. If you have any questions concerning the applicability of U.S. export laws and regulations to a specific activity or would like to report a possible violation of U.S. export laws or regulations, please bring such concerns to the attention of Xymox’s Export Compliance Manager, **Bob Hartline**, who may be contacted by e-mail at **bhartline@xymox.com** or by telephone at **414-365-6169**.

## COMPLIANCE WITH THE ITAR

It is the Company's policy that all Company employees must comply with the laws and regulations that are administered by the U.S. Department of State's Directorate of Defense Trade Controls ("DDTC"), including the International Traffic in Arms Regulations ("ITAR").<sup>1</sup> The ITAR regulate the export and reexport of defense articles and defense services, and they also regulate the transmission of defense-related technical data to any foreign person, whether located in the United States or abroad. It is generally necessary to obtain authorization from DDTC to export or reexport defense articles, defense services, or controlled technical data, regardless of destination, unless one of the exemptions set forth under the ITAR applies. Accordingly, Company employees are required to consult with the Export Compliance Manager before exporting any defense-related items, services, or technical data.

### **I. Overview of the ITAR**

The ITAR govern exports and reexports of defense articles and defense services. Defense articles encompass both commodities and technical data that are used for military purposes.<sup>2</sup> Technical data includes information that is required for the design, development, production, manufacture, assembly, operation, repair, testing, maintenance, or modification of products and may take the form of blueprints, plans, diagrams, engineering designs, drawings, photographs, manuals, and instructions, among other things.<sup>3</sup> Defense services refer to the furnishing of assistance to foreign persons, whether in the United States or abroad, in the design, development, engineering, production, manufacture, assembly, operation, repair, testing, maintenance, modification, demilitarization, destruction, or processing of defense articles, and they also include furnishing technical data controlled under the ITAR to foreign persons whether in the United States or abroad.<sup>4</sup>

#### **A. Controlled Defense Articles, Defense Services, and Technical Data**

Defense articles, defense services, and technical data that are controlled under the ITAR are identified on the U.S. Munitions List ("USML").<sup>5</sup> There are twenty specific categories enumerated under the USML covering thousands of military-related items, and some categories of potential applicability to the Company include those pertaining to naval vessels (Category VI), military vehicles (Category VII), aircraft (Category VIII), military electronics (Category XI), and auxiliary military equipment (Category XIII). In addition, it should be noted that any items that are not specifically enumerated in any of the designated USML categories, but which have a substantial military utility and have been specifically

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<sup>1</sup> The International Traffic in Arms Regulations ("ITAR") are codified at 22 C.F.R. Parts 120–130.

<sup>2</sup> See ITAR § 120.6.

<sup>3</sup> See ITAR § 120.10.

<sup>4</sup> See ITAR § 120.9.

<sup>5</sup> The U.S. Munitions List ("USML") is set forth under Part 121 of the ITAR.

designed or modified for military purposes, can be deemed to be controlled under the ITAR.<sup>6</sup> Examples of items that are controlled under the ITAR include motors for military vehicles, transmissions for naval vessels, and generators specially designed for the military. Products or technology that are incorporated into other downstream products may, in certain circumstances, be controlled as well, if they are intended for a military use. Technical data relating to such items also would be controlled. Company employees must contact Xymox's Export Compliance Manager prior to entering into any contract involving the U.S. Department of Defense ("DOD") or a U.S. defense contractor so that proper determinations can be made as to the extent to which work to be performed under such proposed contracts would be subject to ITAR controls and requirements.

## **B. Registration Requirements**

All U.S. companies that engage in manufacturing or exporting defense articles or furnishing defense services are required to register with DDTC.<sup>7</sup> To register, a company must submit to DDTC a Form DS-2032 (Statement of Registration), a document evidencing that it is authorized to do business in the United States (*e.g.*, State Incorporation Certificate or State Certificate of Good Standing), a required transmittal letter, and applicable registration fee.<sup>8</sup> Registrations must be renewed on an annual basis, and a renewal application must be submitted to DDTC at least 30 days prior to the expiration date.<sup>9</sup>

A registrant must notify DDTC of any material change to its Statement of Registration, such as a change in the senior management, the establishment, acquisition, or divestment of a subsidiary or foreign affiliate, or the dealing in an additional category of defense articles or services, and such notification must be provided to DDTC by registered mail within five days of the event.<sup>10</sup> Moreover, a registrant must notify DDTC by registered mail at least sixty days in advance of any intended sale or transfer of ownership or control to a foreign person.<sup>11</sup> As such, the Company's Chief Operating Officer ("COO") must provide timely notice to Xymox's Export Compliance Manager regarding any changes to senior management, any proposed acquisition or sale of a foreign subsidiary or affiliate, or any proposed sale or transfer to a foreign entity of ownership or control of the Company so that required notification can be provided to DDTC within the timeframes required under the ITAR. In addition, Company employees must contact Xymox's Export Compliance Manager prior to entering into any contract involving DOD or a U.S. defense contractor so that proper determinations can be made as to whether the Company needs to provide notification to DDTC regarding any material changes to the Company's Statement of Registration.

## **C. Licensing Requirements and Exceptions**

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<sup>6</sup> See ITAR § 120.3.

<sup>7</sup> See ITAR § 122.1.

<sup>8</sup> See ITAR §§ 122.2-122.3.

<sup>9</sup> See ITAR § 122.3.

<sup>10</sup> See ITAR § 122.4(a).

<sup>11</sup> See ITAR § 122.4(b).

Under the ITAR, the term “export” is broadly defined to actual shipments of defense articles, as well as disclosing (either orally or visually) or transferring technical data to a foreign person or entity, whether in the United States or abroad.<sup>12</sup> In practice, this means if technical data is provided or transferred to a non-U.S. person, including an employee of the Company, or if a non-U.S. person is allowed into an environment containing technical data subject to the ITAR, or given access to computerized databases that contain such data, the information is deemed to have been exported to that person’s home country. As such, unless an ITAR exemption can be used, it is imperative to obtain appropriate authorization from DDTC prior to: (1) the physical transfer of any defense article; (2) the physical disclosure of any controlled technical data to a foreign national; or (3) the exposure of a foreign national to any controlled technical data..

## 1. Licenses

Specific licenses can be obtained from DDTC that authorize the export of defense articles to foreign destinations. Such licenses typically are valid for a period of four years, and they authorize the export of a specified quantity or value of product to designated end-users or consignees. A license expires when the total authorized value or quantity of product has been shipped or when the date of expiration has been reached, whichever occurs first. Licenses frequently contain “proviso” (*i.e.*, limitations) that restrict their applicability.<sup>13</sup>

It also is possible to obtain specific licenses to permit the transfer of controlled technical data to foreign nationals that are employed by U.S. companies. The license authorizes the U.S. person to transfer technical data and perform limited defense services to the employee(s) on their products, and the license authorizes the foreign person to perform defense services on behalf of the U.S. company. The foreign person employed by a U.S. company does not have to reside in the U.S. to be considered an employee but may reside and perform the job duties outside the United States. If the foreign person is a full time regular employee, directly paid, insured, hired/fired and/or promoted exclusively by the U.S. company, the foreign person is deemed to be “employed” by the U.S. company. The U.S. company is liable to ensure the employee’s compliance with U.S. export laws and regulations regardless of where the employee currently resides. A license approved for foreign person employment will be valid only for a period of four years or until expiration of their authorized stay from U.S. Department of Homeland Security (“DHS”), whichever is shorter. If the foreign person employee resides outside the United States, the license will be valid for the standard validity of a license. In instances when the authorized stay is longer than four years, or the employee’s employment continues beyond the approved validity, the applicant must apply for a renewal of the license.<sup>14</sup>

Company employees wishing to export defense articles to any foreign entities must submit such requests to the Company’s Export Compliance Manager at least three months prior to the time when shipment is desired. Similarly, Company employees that are foreign nationals and wish to be granted access to

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<sup>12</sup> See ITAR § 120.17.

<sup>13</sup> See ITAR Part 123.

<sup>14</sup> See ITAR § 124.1. See also (available at [https://www.pmdotc.state.gov/ddtc\\_public?id=ddtc\\_kb\\_article\\_page&sys\\_id=ddae5ed9db874c10d0a370131f961913](https://www.pmdotc.state.gov/ddtc_public?id=ddtc_kb_article_page&sys_id=ddae5ed9db874c10d0a370131f961913)).

controlled technical data for work-related purposes must provide such requests to the Export Compliance Manager at least three months prior to the time when access to the technical data is desired. Doing so will provide the Export Compliance Manager with sufficient time to work with the Company's Material Controls Department in order to prepare and submit the necessary license applications to DDTC and have them processed by DDTC. No export should occur until the license application has been approved. Care should also be taken to ensure that the conditions of the approval are met, and that there have been no changes that would bring the transaction out of the terms of the approval.

Even if a license is obtained from DDTC, the applicable Company employees must check DDTC's list of debarred parties ("Debarred Parties List") prior to export to ensure that the intended recipient of the defense article or the technical data has not been added to the List since the time that DDTC issued the export license to the Company. The Debarred Parties List can be accessed at <https://www.cbp.gov/trade/trade-community/programs-outreach/blocked-denied-debarred>.

## 2. Agreements

In addition to specific licenses, the ITAR provide for the use of agreements for the transmission of technical data. Agreements are generally used in situations in which the exporter anticipates the need for an unrestricted two-way exchange of technical data with a foreign person/entity within certain pre-determined technical parameters. The agreements are generally structured as commercial contracts for the exchange of technical data with mutual rights and obligations. The contracts are then approved by DDTC; thereafter exports of technical data may be made without individual licenses. Typical agreements may concern the design and development of foreign-origin equipment, the delivery of overseas maintenance or training support, technical studies or evaluations and the release of manufacturing data or production rights to foreign parties.

A Manufacturing License Agreement ("MLA") is an agreement whereby a U.S. person grants a foreign person an authorization to manufacture defense articles abroad. This agreement covers 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. An MLA is generally used when a company is teaching a foreign party how to manufacture an item. An MLA may also cover just the assembly of hardware abroad and no actual manufacturing, if the foreign party requires U.S.-origin manufacturing data to complete the assembly.<sup>15</sup>

A Technical Assistance Agreement ("TAA") is an agreement for the performance of a defense service or the disclosure of technical data, as opposed to an agreement granting a right or license to manufacture defense articles. Assembly of defense articles may be included in the TAA, provided production rights or manufacturing know-how are not conveyed. Should such rights be transferred, a Manufacturing License Agreement would be required. When the Company is required to provide a foreign national employee with technical training in order to perform a job function, a TAA must be prepared and submitted for approval before any information or training is provided.<sup>16</sup>

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<sup>15</sup> See ITAR § 120.21; see also ITAR Part 124.

<sup>16</sup> See ITAR § 120.22; see also ITAR Part 124.

A Distribution Agreement is an agreement or 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. Such agreements must be limited to unclassified defense articles, and they must contain conditions for special distribution, end-use, restrictions on re-exporting, and reporting.<sup>17</sup>

Company employees wishing to exchange controlled technical data with any foreign entities must submit such requests to the Company's Export Compliance Manager at least seven months prior to the time when such an exchange is desired. Doing so will provide the Export Compliance Manager with sufficient time to work with the Company's Material Controls Department to prepare and submit the proposed Agreement to DDTC and have it be processed by DDTC. No exchange of data should occur until it is confirmed with the Export Compliance manager that the DDTC approval is in place.

Even if an agreement is obtained from DDTC, the applicable Company employees must check DDTC's Debarred Parties List prior to export to ensure that the intended recipient of the technical data has not been added to the List since the time DDTC issued the agreement to the Company. The Debarred Parties List can be accessed at <https://www.cbp.gov/trade/trade-community/programs-outreach/blocked-denied-debarred>.

### 3. Exemptions

Certain exemptions exist that release an exporter from the licensing requirements of the ITAR. These exemptions are very narrow in scope, and there often are numerous requirements that must be satisfied before they can be used. Accordingly, Company employees must consult with Xymox's Export Compliance Manager to determine whether there may be any applicable exemptions that would eliminate the need for obtaining a license or agreement from DDTC.

## II. Penalties for Violations

Violations of the ITAR can result in sanctions being imposed by the Company on the employees involved, including termination of employment. In addition, such violations can result in significant civil and/or criminal penalties being imposed on the Company and on the responsible individuals, including civil penalties up to \$500,000 per violation and criminal penalties of up to \$1,000,000 and imprisonment for up to 10 years.

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<sup>17</sup> See ITAR § 120.23; see also ITAR Part 124.

### **III. Compliance Procedures and Training**

#### **A. Compliance Procedures**

It is the policy of Company to comply with the requirements of the ITAR. As discussed above, this necessitates that Company employees contact Xymox's Export Compliance Manager before entering into contract with the DOD or U.S. defense contractors.

Company employees wishing to export defense articles to any foreign entities must submit such requests to the Company's Export Compliance Manager at least three months prior to the time when shipment is desired. Similarly, Company employees that are foreign nationals and wish to be granted access to controlled technical data for work-related purposes must provide such requests to the Export Compliance Manager at least three months prior to the time when access to the technical data is desired. Doing so will permit the Export Compliance Manager with sufficient time to work with the Company's Material Controls Department in order to prepare and submit the necessary license applications to DDTC and have them processed by DDTC.

In addition, Company employees wishing to exchange controlled technical data with any foreign entities must submit such requests to the Company's Export Compliance Manager at least seven months prior to the time when such an exchange is anticipated. Such timing is necessary to permit the Export Compliance Manager with sufficient time to work with the Company's Material Controls Department in order to prepare and submit the proposed Agreement to DDTC and have it be processed by DDTC.

Even if a license or agreement is obtained from DDTC, the applicable Company employees must check DDTC's Debarred Parties List to ensure that the intended recipient of the defense article or the technical data has not been added to the List since the time that DDTC issued the license or agreement to the Company. The Debarred Parties List can be accessed at <https://www.cbp.gov/trade/trade-community/programs-outreach/blocked-denied-debarred>. They also must review the SDN List, which can be accessed at <https://home.treasury.gov/policy-issues/financial-sanctions/specially-designated-nationals-and-blocked-persons-list-sdn-human-readable-lists>, and the Denied Persons List, the Unverified List, and the Entity List, which are accessible at <http://www.bis.doc.gov/complianceand enforcement/liststocheck.htm>.

The Company will comply with the retention requirements for all records compiled and maintained in accordance with the ITAR. All documents required to be maintained under the ITAR must be retained for a minimum of five years, and as deemed necessary by Xymox's Export Compliance Manager, may be required to be retained for a longer duration, depending on the type of record.

The Export Compliance Manager will be responsible for coordinating and monitoring the Company's compliance with the ITAR. Among other things, the Export Compliance Manager will be responsible for:

- providing guidance to management and the different departments within the Company on ITAR compliance matters;
- monitoring legal and regulatory developments and best practices in the ITAR area;

- recommending changes to the Company's ITAR compliance procedures based on such developments;
- filing any required documents with DDTTC; and
- providing for training on ITAR issues.

#### **B. Technology Control**

Xymox developed four documents that address how technology is controlled at Xymox.

- Xymox Reference Document RF0090 ITAR IT Control Plan
- Xymox Work Instruction WI0327 ITAR Process
- Xymox Reference Document RF0077 ITAR Clean Desk Policy.
- Xymox Policy Document Res020, Employee Handbook (Building Security section)

#### **C. Training**

To promote awareness of the Company's obligations under the ITAR and to help employees understand their roles and responsibilities with respect to the ITAR, the Company will provide training on ITAR issues. All designated employees are required to participate in and complete the Company's general ITAR training program and will be provided refresher training on a periodic basis. New hires will receive ITAR compliance training during orientation, as appropriate. The Company will maintain records of training materials and attendance at training sessions.

# ACKNOWLEDGMENT OF RECEIPT

## Xymox Export Compliance Manual

Date: \_\_\_\_\_

I acknowledge that I have received a copy of the Xymox Export Compliance Manual. I recognize that it is a statement of the Company's policy and procedures regarding full compliance with the U.S. export laws and regulations, to which the Company is committed and to which I am expected to adhere during my employment with the Company. I further acknowledge and agree that I have read the Xymox Export Compliance Manual and will comply with the policy and procedures set forth in it, including my reporting obligations if I suspect or become aware of any violations of U.S. export laws and regulations.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (please print)