



United States Department of State

*Bureau of Political-Military Affairs
Directorate of Defense Trade Controls
Office of Defense Trade Controls Compliance
Compliance & Registration Division
Washington, D.C. 20522-0112*

April 2, 2008

ROBERT J. OWEN / VP / GENERAL MANAGER
CORETEC CLEVELAND, INC.
7 ASCOT PARKWAY
CUYAHOGA FALLS, OH 44223

EXPIRATION DATE: 03/31/2010

Reference: Manufacturer Registration Statement, Transmittal Letter and Fee Submission

Dear Mr. Owen:

The Office of Defense Trade Controls Compliance, Compliance and Registration Division (CRD), received your registration statement, transmittal letter and fee to register as a manufacturer. Our review is now completed. It expires on 03/31/2010.

Any person who engages in the United States in the business of either manufacturing or exporting defense articles or furnishing defense services is required to register and keep their registration current with this Office pursuant to the Arms Export Control Act (AECA) and the International Traffic in Arms Regulations (ITAR Part 122). Registration serves as a precondition to submitting an application for an export license or other approval from the Directorate of Defense Trade Controls (DDTC), or to use of export exemptions. This registration does not satisfy the requirements for registering as a broker pursuant to ITAR Part 129.

As you are the senior officer who has been empowered to sign the registration statement and transmittal letters, we ask you to confirm which key senior officer listed on the registration will oversee the export compliance program and be responsible for designating the full-time employees who will serve as "empowered officials" at their place of employment. We further request that you provide us with a list of qualified, full-time employees who will serve as "empowered officials" by name, position, business unit, phone and fax. Please provide this information by fax to the attention of Registration at (202) 261-8695. Please note that third parties (individuals who are not full-time employees, such as consultants, subcontractors or outside counsel, for example) cannot serve as "empowered officials." We also require that you provide information on how you ensure that foreign persons will not have access to defense articles without written authorization from the Directorate of Defense Trade Controls, as

required by ITAR Part 123, **within 30 days** to the attention of: Compliance and Registration Follow-Up.

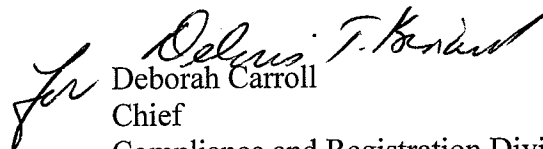
ITAR Section 122.5 requires you to maintain records concerning your registration and the manufacture, acquisition and disposition of defense articles; the provision of defense services; and information on political contributions, fees, or commissions furnished or obtained, as required by ITAR Part 130. Records maintained shall be available at all times for inspection and copying by this Office or by Customs officials. To maintain such records, managers, supervisors and employees need appropriate training on AECA and ITAR requirements and understand the individual and organizational ramifications for failure to comply. Ramifications may include shipment delay and/or shipment seizure by Customs and Border Protection, loss of export privileges, or criminal charges.

We refer you to our website for a copy of the ITAR and to keep abreast of changes to the regulations at <http://www.pmdtc.state.gov/>. The site also includes explanations of export licensing procedures, how to submit a license application, country sanctions, individuals/companies debarred by the Department of State and other export matters. The website also includes procedures for requesting a commodity jurisdiction determination (ITAR Section 120.4) should you have questions on whether an article, services or technical data is covered by the ITAR Part 121 (U.S. Munitions List).

Please include your registration code and the following statement on all Registration correspondence to this Office: "Under penalty according to federal law (22 CFR 127.2; 22 USC 2278; 18 USC 1001) I, [insert your name], as authorized by [name of company, if applicable] warrant the truth of the statements made herein." Again, your registration must be submitted at least thirty days prior to this new expiration date. Registration must be current to apply for export licenses or other approvals, or to use export exemptions. Current also means notifying this Office of any changes to your transmittal letters or material change in the information contained in your Registration Statement (ITAR Section 122.4).

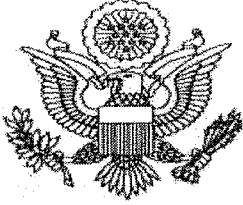
If you have any questions regarding registration, please contact us at (202) 663-2813 or (202) 663-2815.

Sincerely,

 Deborah Carroll
Chief

Compliance and Registration Division

Attachment:
Compliance Guide



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Guidelines for DDTC Registered Exporters/Manufacturers Compliance Program

Comprehensive operational compliance programs include manuals that articulate the processes to be followed in implementing the company program. Important elements of effective manuals and programs include:

Organization Structure

- Organizational charts.
- Description (and flow charts, if appropriate) of company's defense trade functions.
- Description of any management and control structures for implementing and tracking compliance with U.S. export controls (including names, titles, and principal responsibilities of key officers).

Corporate Commitment and Policy

- Directive by senior company management to comply with Arms Export Control Act (AECA) and the International Traffic in Arms Regulations (ITAR).
- Knowledge and understanding of when and how the AECA and ITAR affect the company with ITAR controlled items/technical data.
- Knowledge of corporate internal controls that have been established and implemented to ensure compliance with the AECA and ITAR.

Examples of detail:

- ◆ **Citation of basic authorities (AECA, ITAR).**
- ◆ **Identification of authorized USG control body (Directorate of Defense Trade Controls ("DDTC")).**
- ◆ **Corporate policy to comply fully with all applicable US export control laws and regulations.**
- ◆ **Compliance as a matter for top management attention that needs adequate resources.**
- ◆ **Identification, duties, and authority of key persons (senior executives, empowered officials) for day-to-day export/import operations and compliance oversight.**
- ◆ **Corporate Export Administration organization chart.**

◆ **Operating Division Export Administration flow chart.**

Identification, Receipt and Tracking of ITAR Controlled Items/Technical Data

- Methodology used, **specifically tailored to corporate structure, organization, and functions**, to identify and account for ITAR controlled items/technical data the company handles (trace processing steps of ITAR controlled transactions from the time the company manufactures/receives the item to the time an item is shipped from the company – or in the case of a defense service when provided).

Examples of questions to be addressed:

- ◆ **Are appropriate employees familiar with the AECA and ITAR and related requirements, including handling export approvals with certain provisos and limitations?**
- ◆ **Are company employees notified of changes in U.S. export control restrictions, and are they provided accurate, reliable interpretation of U.S. export control restrictions?**
- ◆ **What US origin defense articles are manufactured/received by the firm and from whom? How identified and “tagged”?**
- ◆ **What US origin technical data related to defense articles are produced/received by the firm and from whom? How identified and “tagged”?**
- ◆ **What items are manufactured by the firm using US origin technical data? How identified and “tagged”?**
- ◆ **What items or articles are manufactured by the firm that incorporate US origin defense articles (components)? How identified and “tagged”?**
- ◆ **What kind of recordkeeping system does the company maintain that would allow for control of, and for retrieval of information on, US origin technical data and/or defense articles exported to the company?**

Re-Exports/Retransfers

- Procedures utilized to (a) obtain written State Department approval prior to the retransfer to a party not included in a State Department authorization of an item/technical data transferred or exported originally to the company, and (b) track the re-export or re-transfer (including placing parties on notice that the proposed transfers involve US origin products and labeling such products appropriately).
 - ◆ Procedure when an ITAR controlled item/technical data is transferred by the company to a foreign national employed at the company.
 - ◆ Procedure when an ITAR controlled item/technical data is transferred by the company to a foreign person within the U.S.
 - ◆ Procedure when ITAR controlled technical data or defense articles are transferred from the company to a foreign person outside of the U.S.
 - ◆ Procedure when an ITAR controlled item/technical data is to be used or transferred for an end-use not included in the State Department authorization.

Restricted/Prohibited Exports and Transfers

- Procedure for screening customers, carriers, and countries.
- Screening procedure for high-risk transactions to combat illegal exports/retransfers.
- Procedures to investigate any evidence of diversion or unauthorized use of US origin products.

Recordkeeping

- Description of record systems concerning US origin products.
- Procedures for maintaining records relating to US origin products for five years from the expiration of the State Department license or other approval.
- Regular internal review of files to ensure proper practices and procedures by persons reporting to top management. Internal Monitoring
- Perform audits periodically to ensure integrity of compliance program.
- Emphasis on validation of full export compliance, including adherence to license and other approval conditions.
- Measurement of effectiveness of day-to-day operations.
- Adopt procedure for highlighting any compliance areas that needs more attention.
- Report known or suspected violations to Corporate export administration office.
- Effective liaison and coordination with Ombudsman.ⁱ

Examples of detail:

- ◆ **Specific description of procedures (examination of organizational structure, reporting relationships, and individuals assigned to export/import controls process.**
- ◆ **Random document review and tracing of processes.**
- ◆ **Review of internal recordkeeping, communications, document transfer, maintenance and retention.**
- ◆ **Conclusion and report of violations to Corporate Export Administrator.**
- ◆ **Coordination with Ombudsman.***

Training

- Explanation of company training program on U. S. export control laws and regulations.
- Process to ensure education, training, and provision of guidance to all employees involved on exports (including those in departments such as Traffic, Marketing, Contracts, Security, Legal, Public Relations, Engineering, Executive Office). Violations and Penalties
- Procedures for notification of potential violations, including use of voluntary disclosure and Ombudsman to report any violation of the company's internal control program or U.S. export controls.
- Emphasis on importance of compliance (to avoid jeopardizing Corporate business and severe sanctions against the Corporation and responsible individuals).

- Description of AECA/ITAR penalties.
- Written statements and procedures to foster employee discipline (e.g., keying certain types of advancement to compliance understanding and implementation, and establishment of internal disciplinary measures).

ⁱ For companies seeking to prevent violations, the establishment of an Ombudsman is an optional step. The Ombudsman is meant to serve as a prominent source of confidential advice and information for a company's employees and assure that the company's ITAR controlled exports and transfers are being closely monitored and conducted according to the highest standards. The Ombudsman has two basic jobs:

- (a) initiate inquiries or investigations when an export control problem (suspected violations of the Arms Export Control Act or the International Traffic in Arms Regulations) is brought to or comes to his attention, with the aim of ensuring the issue is resolved in accordance with appropriate law and regulations; and
- (b) provide independent evaluations (reports) on overall implementation of the companies' compliance programs.