

Idaho Technology Background

- Salt Lake City based biotech company
 - 18 years old company with 220 Employees
- Pathogen Detection Systems
 - Biological Warfare Agents, Anthrax
 - Common Infections, Influenza
- Export controlled products – focus on ITAR
 - Bio Defense items controlled by the ITAR
 - Some ‘civilian’ products are tainted by ITAR parts
 - Typically 10 open export licenses



ITI Export Compliance Program

Sell products and economically comply with regulations

- Compliance Improvement Effort
 - Audited our program, gaps identified
 - Process development
 - High level documents committing Management to compliance
 - Work instructions committing employees to functions
 - Company training program
 - Audit process to ensure compliance

ITI Export Compliance Program

- Components of Compliance Program
 - Processes for licensing and license management
 - Processes for product and materials handling
 - Processes for communication with technical data
 - Processes for development and jurisdiction determination
- Improvement Plan Results and Outcome
 - Focus efforts where needed
 - 6 months effort to arrive at 90/10 solution

Organization & Staffing

- Compliance team
 - Export Compliance Administrator
 - Empowered Officials, primary and alternate
 - Support from Quality Assurance, Operations
 - Compliance Council includes Company President
- For ITI, approximately 1 FTE
- Double licenses, need to add 0.5 FTE
 - Hidden costs – Technical support, Repairs and Returns, etc.

Jurisdiction & Classification

- Military based products are controlled
 - Goal: Avoid controls on non-military products
 - Commodity Jurisdiction requests not successful
 - Lesson learned:
 - Understand consequences of design decisions
 - Design commercial products first
 - Modify commercial products for controlled applications
- Classification becomes integrated activity
 - R&D, Management, Materials

Jurisdiction & Classification

- Design Controls required for products
 - Export control evaluation integrated in Design Process
 - R&D Project Managers work with EO to comply
 - R&D staff trained on a project-by-project basis
 - Redesign as needed to avoid tainting
- Release Process
 - Part and materials evaluation process
 - Vendor qualification for purchasing

License Management

- Processes and check lists for
 - License type or exemption determination
 - Application for licenses
 - Implementation of approved licenses
 - *System to check recipients of controlled products*
 - Information transferred along operations chain
- Processes for
 - Verification of appropriate use of licenses
 - Audit processes, particularly at time of shipment
 - Closing and evaluating files

Due Diligence

- Denied Party Screening
 - At quote
 - At export application
 - At shipping
 - At proof of delivery
 - All parties to transaction

Lessons

- Compliance
 - ITI has other regulatory compliance requirements
 - Export Control is just another requirement
 - Process planning is key
 - Cost of doing business
- Protect products
 - Export requirements should be part of Design phase

Contact

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