

*Research Compliance Conference  
6-June-2017*

# The Federal What...?

## Using the FSG as Organizing Principles for a Research Compliance Office

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## Many of us think and work in regulatory silos

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- It's not necessarily a bad thing
  - Regulations governing our areas of responsibility are complex and require specialized training and experience to operationalize correctly
- How do we know we have covered all the bases with our SOPs?
  - Accreditation programs offer guidance for human and animal research
- What about the regulatory areas that do not have accreditation programs?
  - Is there is higher order set of principles that can guide development and implementation of SOPs for the various silos?

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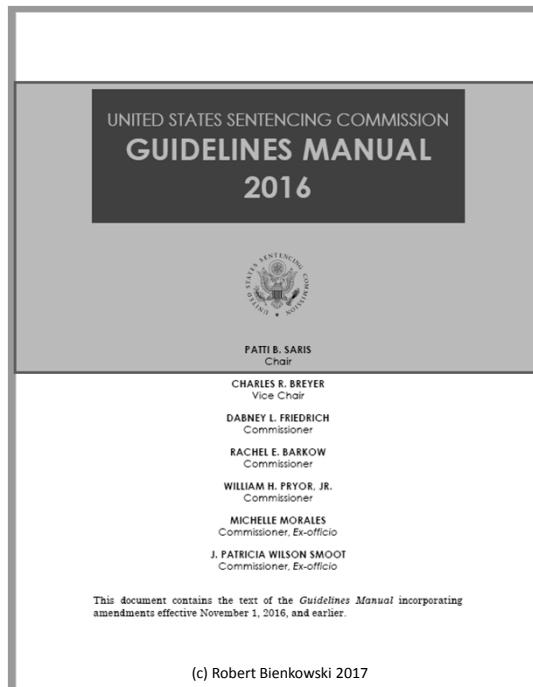
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# Objectives

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1. Propose a modified version of the Federal Sentencing Guidelines (*mFSG*) as organizing principles for an Office of Research Compliance.
2. Illustrate how the standards of the major research compliance accrediting bodies (AAHRPP and AAALAC) map onto the *mFSG*.
3. Illustrate how the *mFSG* can guide development of institutional standards for other research compliance areas such as the IBC, Controlled Substances, and Export Control.

But first, some background about the FSGs.



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## Is it relevant?

*Its principal purpose is to establish sentencing policies and practices for the federal criminal justice system that will assure the ends of justice by promulgating detailed guidelines prescribing the appropriate sentences for offenders convicted of federal crimes.*

# FSG

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**Original**

Due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the law ... minimally require the following:

The organization shall establish standards and procedures to prevent and detect criminal conduct.

**Modified**

Due diligence and the promotion of an organizational culture that encourages ethical conduct and a commitment to compliance with the regulations ... minimally require the following:

The organization shall establish standards and procedures to prevent and detect noncompliant conduct.

# Turning Prison Stripes into Pin Stripes

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*The Federal Sentencing Guidelines* are often restated in more positive terms as *7 Elements of an Effective Corporate Compliance Program*

## Working Version of the 7 Elements

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1. Establish Policies, Procedures and Controls
2. Exercise Effective Compliance and Ethics Oversight
3. ~~Exercise Due Diligence to Avoid Delegation of Authority to Unethical Individuals~~  
Ensure that Individuals in Positions of Responsibility are Properly Trained and Vetted
4. Communicate and Educate Employees on Compliance and Ethics Programs
5. Monitor and Audit Compliance and Ethics Programs for Effectiveness
6. Ensure Consistent Enforcement and Discipline of Violations
7. Respond Appropriately to Incidents and Take Steps to Prevent Future Incidents

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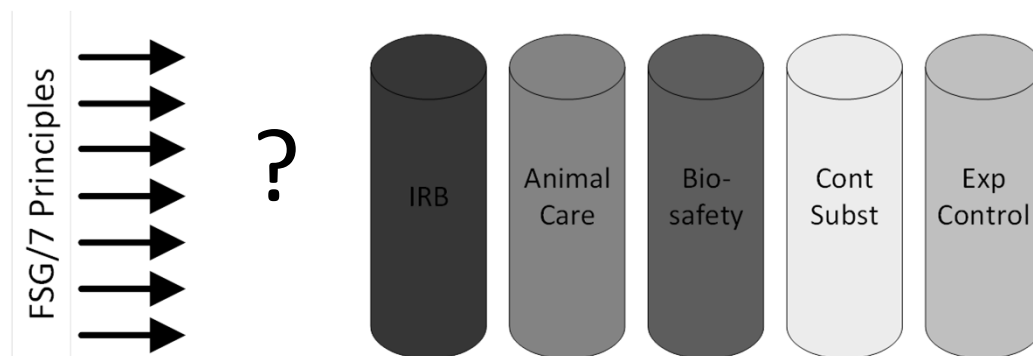
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## Can the *m*FSG Confederates the Silos?

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Typical ORC Areas (Silos) of Responsibilities



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## Accreditation Standards

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- Accreditation standards for research involving human subjects and animals are detailed tools for evaluating research compliance programs at universities and medical institutions.
  - They should be used even when there is no immediate intent to pursue accreditation
- The accrediting bodies are:
  - Association for Accreditation of Human Research Protection Programs (AAHRPP)
  - Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)

### AAHRPP Evaluation Instrument for Accreditation

- 75 Elements organized into
  - 15 Standards, which are grouped into
    - 3 Domains
      - Institutional
      - Review Unit (IRB)
      - Investigator

### AAALAC Program Description for accreditation

- 59 Elements organized into
  - 17 Topic areas, which are grouped into
    - 4 Domains
      - I. Animal Care and Use Program
      - II. Animal Environment, Housing and Management
      - III. Veterinary Care
      - IV. Physical Plant

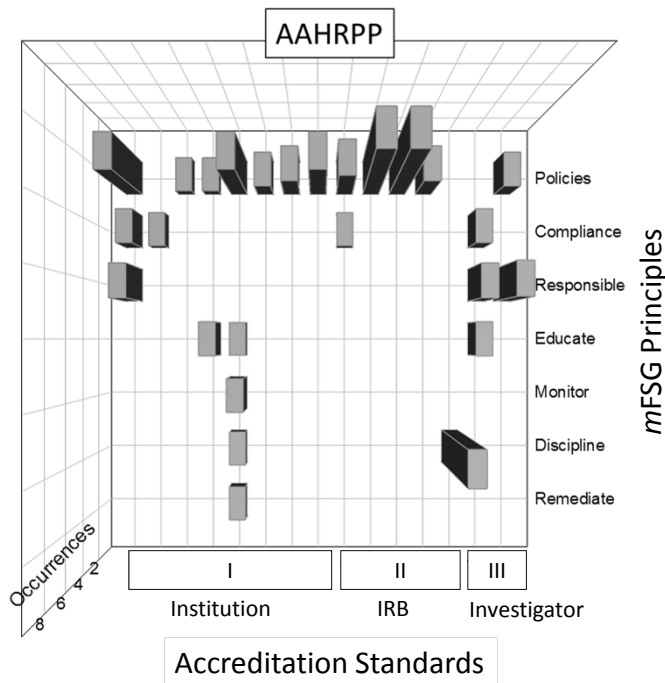
# Methodology

- Each Element was “coded” according to which of the 7 principles was addressed
  - It was expected that several elements would be coded for more than one principle
- “Counts” were summarized at the “domain” level
- Limitation: Consistency in coding is a problem

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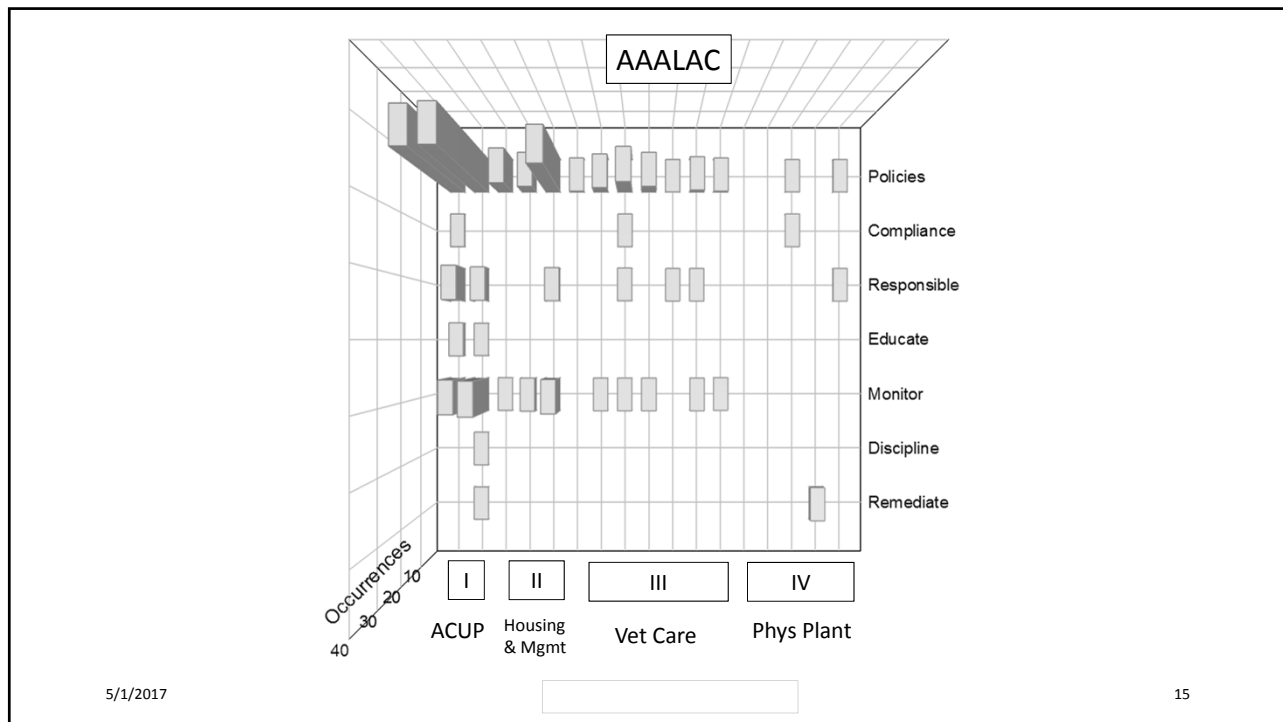
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## Working Conclusions

Analysis of a compliance program’s documentation should reveal:

- At least one “hit” for each principle
  - Absence of a reference to one of the principles is a red flag
- Heavy concentration on P1 (policies & procedures)
- Distribution of policies varies with the discipline.
  - But the distribution should “make sense”



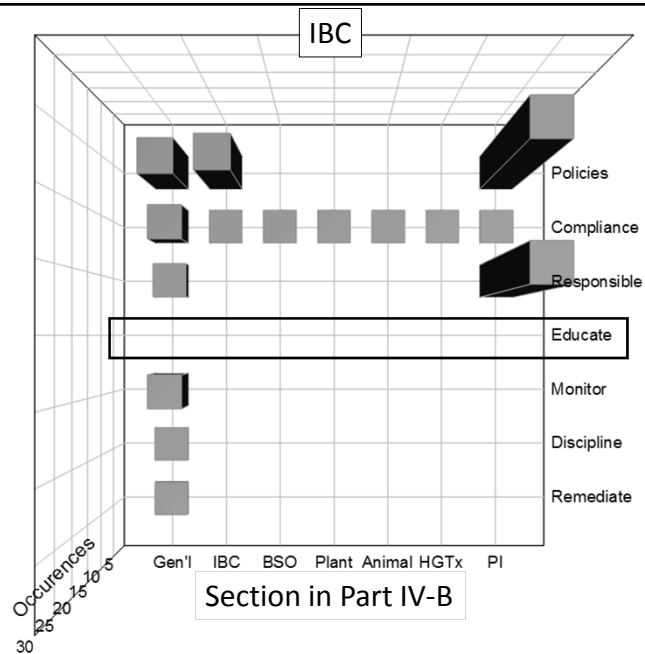
# IBC – Institutional Biosafety Committee

- No accreditation program
- Scope of oversight varies among institutions
  - Always includes recombinant molecules
  - May include infectious agents
- We started with *NIH Guidelines for research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*
  - Section IV Roles and Responsibilities
    - Section IV-B Responsibilities of the Institution

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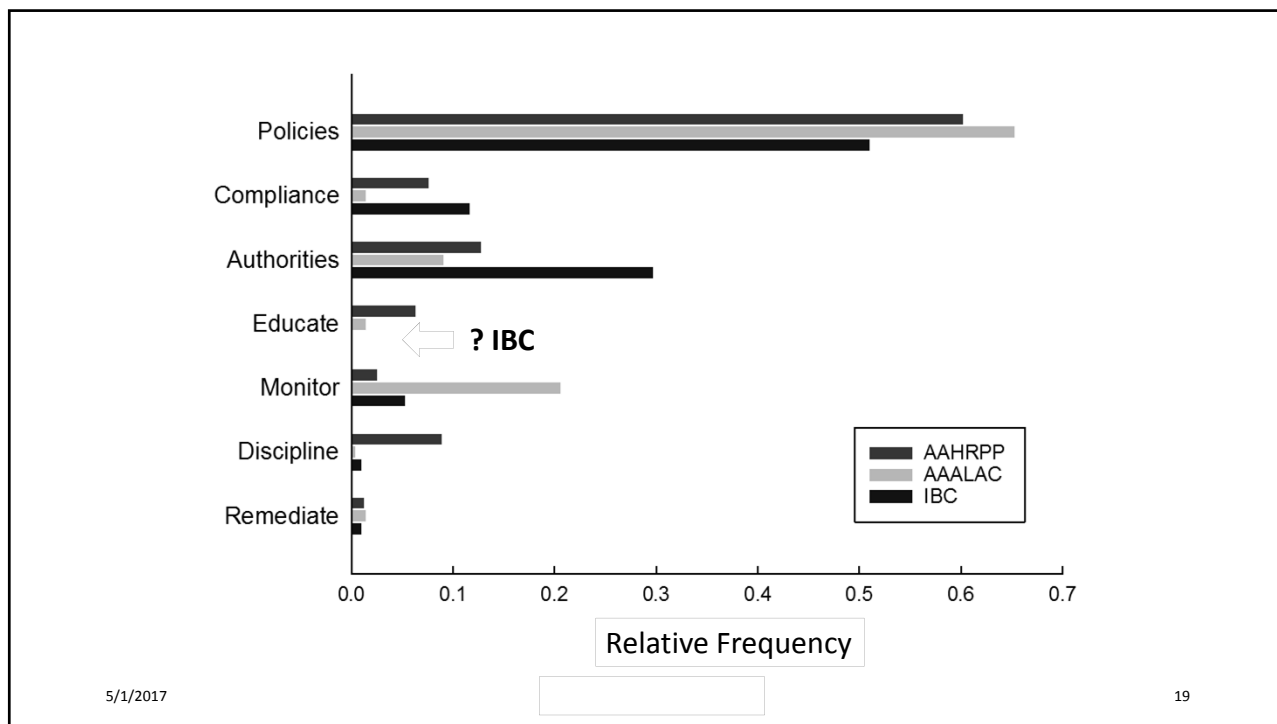
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## Concerns raised by our analysis

1. What does appropriate compliance and ethics education mean for working with recombinant materials?
2. Who is responsible for the education?

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# Controlled Substances in Research

Use of controlled substances in research presents several challenges to institutional oversight:

- Both state and federal government have jurisdiction
- Regulations refer only to individual users
  - there is no mention of an institutional official or of institutional responsibility.

**BUT INVESTIGATORS ARE AGENTS OF THE INSTITUTION, SO THE INSTITUTION MUST HAVE OVERSIGHT AUTHORITY**

Here is our initial approach

## Controlled Substances in Research

Central Michigan University has developed a policy for oversight of controlled substances used in research. The forms and guidance documents below have been designed to supplement the policy and to assist researchers with meeting specific regulatory requirements

**Institutional Policies & Procedures**

**Institutional Forms Based on Regulations**

**DEA Forms & Regs**

- [Oversight of Controlled Substances in Research](#)
- [Controlled Substances in Research Guidance for Registrants](#)
- [Controlled Substance Research Records-DEA Biennial Controlled Substance Inventory Form](#)
- [Controlled Substance Research Records: Diluted Solution Usage Log](#)
- [Controlled Substance Research Records: General Inventory Log](#)
- [Controlled Substance Research Records: Initial/Closing Inventory Log](#)
- [Controlled Substance Research Records: Multiple Dose Usage Log](#)
- [Controlled Substance Research Records-State of Michigan Annual Inventory Log](#)
- [DEA Biennial Controlled Substance Inventory Form: Appendix B7](#)
- [DEA Disposal of Controlled Substances](#)
- [DEA Disposal of Controlled Substances Final Rule 9-9-14](#)
- [DEA Registrant Record of Controlled Substances Destroyed: Form DEA-41](#)
- [Disposal Regulations: Registrant Fact Sheet](#)
- [Sample Standard Operating Procedures for Controlled Substances](#)
- [Use of Controlled Substances in Research Authorized Agent Log](#)
- [Use of Controlled Substances in Research Authorized Agent Screening Form](#)

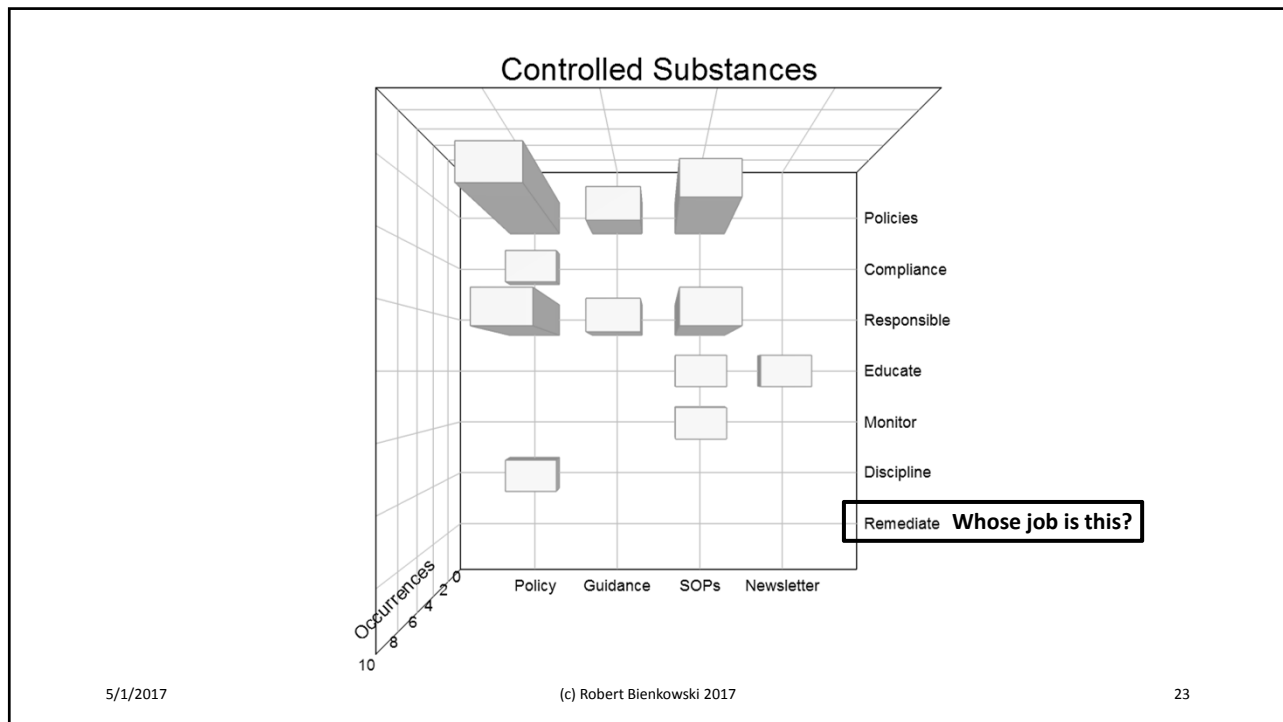
**Asserts Institutional Authority**

If you have questions about the content or intended use of any of the forms above,

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## Export Controls – In a nutshell

**If** you want to:

share *certain* kinds of information or send *certain* things to *certain* foreign persons, institutions or countries,

**then** you may need a **license** from the government.

>>*certain* means being on a **list**

## Three sets of regulations govern the lists

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**EAR** (Export Administration Regulations; Dept Commerce) deal with “dual use” items that have military and nonmilitary uses

**ITAR** (International Trafficking in Arms Regulations; Dept State) deal with things that have military uses

**OFAC** (Office of Foreign Assets Control; Dept Treasury) deals with persons, places such as companies or institutes, and countries that are restricted from receiving any exports without a license

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## Universities' Security Blanket - The Fundamental Research Exemption (FRE)

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Fundamental Research is "basic and applied research in science and engineering, the results of which are ordinarily published and shared broadly within the scientific community."

Research results generated during the course of conducting fundamental research are exempt from the requirements of export control laws and regulations.

<https://www.princeton.edu/orpa/compliance/export-controls/fundamental-research/>

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## Deemed Exports – The Land Mine of Export Control

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Release of controlled technology to a foreign person in the U.S. is "deemed" to be an export to the person's country of nationality.

Typical organizations using deemed export licenses include universities, high technology research and development institutions, bio-chemical firms, as well as the medical and computer sectors.

So, a professor giving a graduate seminar about her research on nanotubes that could be weaponized may be exporting information.

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## University Export Violations Related to Healthcare Research

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**University of Michigan** (2013) Mohamad Nazemzadeh, who was a Research Fellow in the Neurology Department at the time of his arrest, was prosecuted for sending a medical device to Iran.

**NYU School of Medicine** (2013) Three researchers were charged for sharing non-public information with Chinese companies about their work conducted through an NIH grant to develop MRI technologies.

**Texas Tech University** (2004) Professor Thomas Campbell Butler, MD, was sentenced to 2 years in prison for illegally exporting the *Yersinia pestis* (bacterium that causes human plague), which is a controlled item under the EAR and cannot be exported without export licenses.



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## Developing an Export Compliance Program

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1. Write and publish an export control compliance policy
2. Identify an office at the university in charge of export control training and compliance
  1. Conduct a needs analysis/risk assessment
  2. Establish SOPs
3. Determine who needs training, what level of training is required, and how frequently the training should be delivered
  1. whom to ask
  2. when to ask about export compliance
4. Monitor effectiveness of the program

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## We do not have to reinvent the wheel

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There are many resources available on the web:

- Basic information
- Training (including CITI)
- SOPs

Penn has a very good set of materials

They illustrate a unique challenge to developing a compliance program for export controls

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**Roles and Responsibilities for Export Controls at Penn**

PIs  
Research Staff  
ORS  
RAs  
BAs

	Ensure adequate resources	Identify issues	Resolve issues	Screen foreign nationals	Identify controlled items and applicable regulations	Classify items/activities within ECL	Licensing determinations	Apply for licenses	Training	Record keeping	Technology Control Plans	Security	Advise on issues	Point of Contact (external)
Senior University Management	X		X											
Senior School Administration	X		X									X		
Empowered Officials	X	X					X						X	X
Dir. Exp Comp	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Export Liaisons		X		X					X					
PIs		X		X	X	X			X	X	X	X		
Research Staff		X		X	X	X			X	X	X	X		
ORS		X		X					X	X				
RAs		X		X										
BAs		X			X					X				
Purchasing					X					X				
CTT				X		X								
OIP		X					X		X	X				
OGC							X						X	X
EHRS		X											X	
ISC												X		
Travel Services		X												

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## Challenge of Developing an XC Compliance Program

In contrast to compliance programs for “traditional research areas,” authorities and responsibilities for an Export Compliance Program are distributed among several university offices and entities that report to distinct Senior VPs:

- Provost
- Advancement
- Student Services
- Finance and Administrative Services
- General Counsel
- University Communications

It will be interesting to see how the *m*FSG map onto the SOPs!

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## Conclusions

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- The *mFSG* provide a consistent framework for determining whether a compliance program addresses all the major areas.
  - They set a minimum standard.
- We have found the *mFSG* useful in:
  - Highlighting where we have “holes in our programs.”
  - Developing policies for new areas of responsibilities.

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## Historical Note – Coming Full Circle

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- The AAHRPP Accreditation Standards were based on the *OIG Compliance Program Guidance for Hospitals\**
  - Federal Register / Vol. 63, No. 35 / Monday, February 23, 1998
- The *OIG* Guidance references the *FSG*

\*My thanks to Jeff Cooper for bringing this to my attention

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*Thank you!*

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