License Processing for Biological Exports

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Department of Commerce Export Controls

- Dual-use biological material
  - subject to BIS regulatory jurisdiction
  - predominantly commercial/academic uses
  - could also be used in military applications
  - Listed in Export Administration Regulations (EAR) by Export Control Classification Number (ECCN)
  - Commerce Control List (CCL)
- May require export license
- Other Controls to consider – USML (CAT XIV), OFAC

Department of Commerce Export Controls

- Part 732 of the Export Administration Regulations (EAR) – Steps for using the EAR
  - What is the item
  - Where is it going (what country)
  - Who will use it (ultimate consignee, end users)
  - What will they do with it (end use)
  - What else do the recipients do (red flags)
- Supplements 1 -3 of Part 732 of the EAR
  - Decision Tree for export license
  - Decision Tree for subject to the EAR
  - Know your Customer Guidance

Biological Agents and Toxins

- 1C351 and 1C354
  - Human, Animal and Plant Pathogens Australia Group (AG) controlled -
  - Select Agents not on the AG list are also controlled
  - Select Agent (SA) exempt strains ARE controlled for export
- 1C353
  - Genetic Elements for controlled agents/toxins
  - Genetically Modified controlled organisms
- 1C991
  - Vaccines if licensed or Investigational New Drug (IND)
  - Medical toxins
- EAR99
  - Killed pathogens with destroyed genetic elements
  - Technology for vaccine production

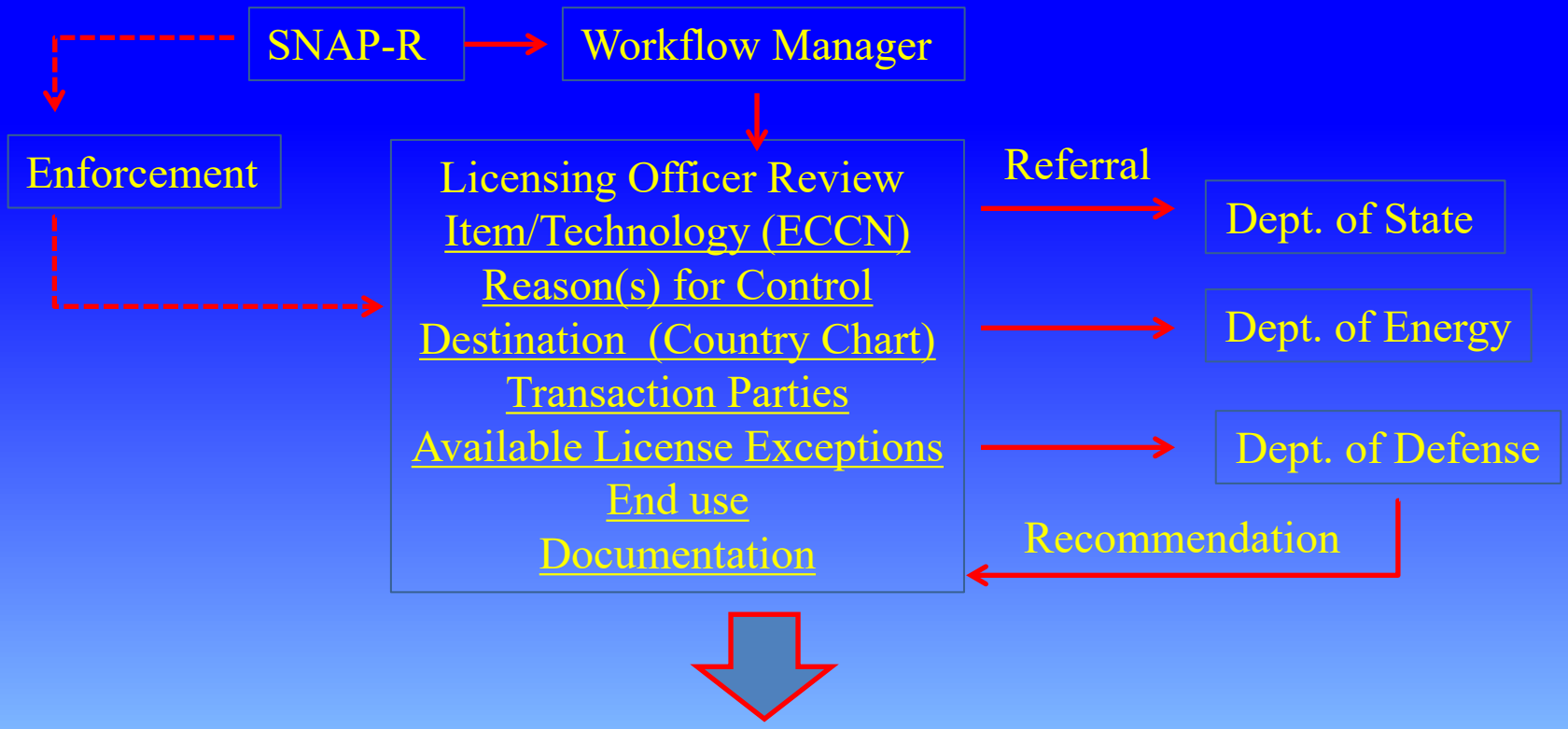
Genetic Element Exports

- Chimeric Viruses- controlled if
  - Based on a controlled virus
  - Has controlled virus element in non-controlled virus
- Plasmids - controlled if
  - Promoter present
  - Complete gene or Viral Particle
  - Replication competent
- DNA– not controlled if
  - Certified non-infective and chemically treated to be non-recoverable

Biological Processing Equipment

a. BSL3 and 4 facilities
b. Fermenters and components
c. Centrifugal separators
d. Cross Flow Filtration equipment and components
e. Sterilizable freeze drying equipment
f. Spray Drying equipment
g. Protective and Containment equipment
h. Aerosol inhalation equipment
i. Spraying or Fogging systems and components
j. Nucleic Acid Assemblers and synthesizers

License Application Review



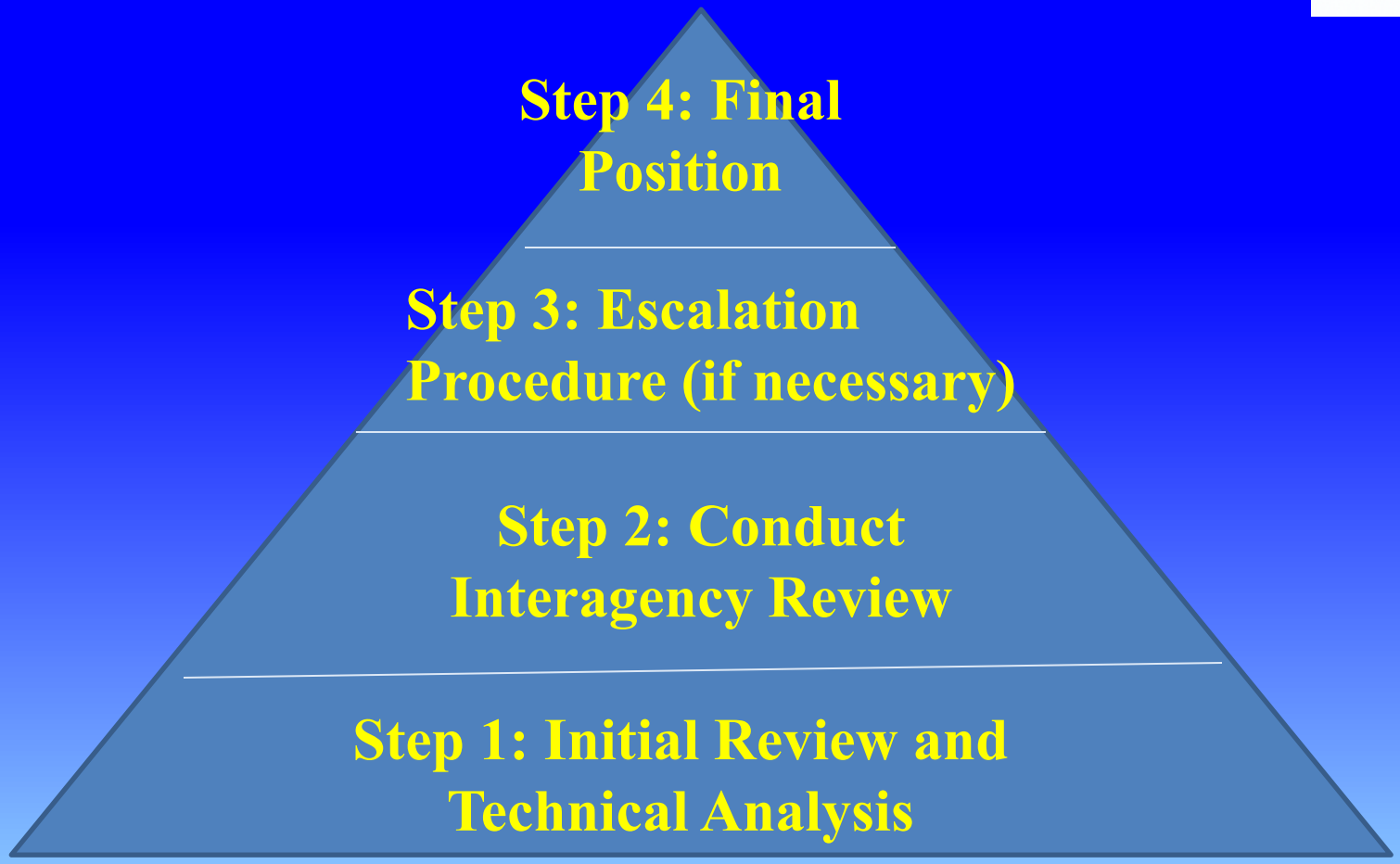
Initial Review and Technical Analysis § 750.4(c)

- Contact applicant for additional information
- Verify classification
- RWA – Return application if license not required
- Refer to other agencies if required
- HWA – Hold without action
- Approve or notify of intent to deny

Interagency Review § 750.4(d)

- Review by other agencies or interagency groups
  - State, Defense, Energy, Justice
  - MTEC, SNEC, The Shield
- Recommendation by reviewing agencies
  - Must provide regulatory basis for denials
  - If no response within 30 days, agency deemed to have no objection to BIS decision

License Review Process



Commodity Classifications

- Requests are submitted electronically via SNAPR
- Check the BIS and OFAC lists for common medical equipment
- Technical Specifications
- Description of items-Model numbers, use
- Maximum of six items per request

Summary

- Biological Exports of Organisms, Toxins and Genetic Elements
- Biological Processing Equipment
- Licensing Process
- Commodity Classifications

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