

Federal Select Agent Program Responsible Official (RO) Webinar Series, 2022

Complexity Scoring of Entities

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Previous Characterization of Entity Complexity

- Prompted by federal reviews of the Federal Select Agent Program (FSAP) in 2015 and 2016, Division of Select Agents and Toxin (DSAT) published a study in 2017 characterizing inspection departures.
- As part of this study, a complexity score was assigned to each entity that was inspected based on criteria such as registered biosafety levels, possession of Tier 1 select agents or toxins, work with animals, volumes of agent produced at one time, etc.

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Characterization of Departures from Regulatory Requirements Identified During Inspections Conducted by the US Federal Select Agent Program, 2014–15

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GAO Recommendation October 2017

- Government Accountability Office (GAO) issued a recommendation* to FSAP to align oversight to prioritize high-risk activities and entities.
 - To improve the ability to perform reviews, the CDC director of the Select Agent Program should work with APHIS to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities.
- **FSAP Response:** FSAP created an internal workgroup to update the published complexity system to include other high-risk variables.

* Recommendation 6 (<https://www.gao.gov/products/gao-18-145>)



Response to GAO Recommendation

- **Total Complexity Score is a combination of the Registration Score and the Compliance Score**
- **Registration Score**
 - Focused on similar categories as the 2017 publication, but further defined the categories and included other high-risk variables such as:
 - Tiering of work with animals (large animal, non-human primates, small animals)
 - Entity size based on the number of registered rooms, inactivation of select agents for future use
 - Focusing on risk groups of registered agents instead of biosafety level
- **Compliance Score**
 - Compliance Score was not a component of the 2017 complexity scoring system.
 - The compliance score is based on past compliance issues, such as suspensions, severe inspection observations, and issues resulting in corrective action plans.



Registration Score

- Most of the information used to generate the Registration Score is auto-populated from the information submitted in eFSAP in the Form 1.
- Registration Scores are also validated by the FSAP staff.

The screenshot shows a web form titled "Section 1 - Form 1 Data Completion" for the "UNIVERSITY OF SELECT AGENTS AND TOXINS". The form is divided into several sections:

- Entity Information:** Includes "Entity Application Number" (b516a8ed-d92a-e711-8168-005056936003) and "Current Registration Number" (20190502-151653).
- Entity Name:** "University of Select Agents and Toxins" (62 of 100 characters left).
- Physical Address:** "5550 Select Agent Road SE" (75 of 100 characters left).
- City:** "Decatur" (43 of 50 characters left).
- State:** "Georgia" (dropdown menu).
- Zip Code:** "30129-5505".
- Additional Physical Address(es):** "456 Select Agent Blvd, Decatur GA 30333" (961 of 1000 characters left).
- Type of Entity:** "Commercial - Profit" (dropdown menu).
- Entity Abstract:** A text area containing a paragraph about restriction endonucleases and genetic fingerprinting.



Breakdown of Registration Score

	Registration Score Variable	Point Value	Where to Find?
Agent/Size	Entity Size Score	0-30	Form 1, Section 6
	Possess	10	Form 1, Section 3
Possession Status	Storage only	0	Form 1, Section 6
	Risk Group 1/Plant Agents 1	0	Form 1, Section 3, NIH risk group score
	Risk Group 2/Plant Agents 2	10	Form 1, Section 3, NIH risk group score
	Risk Group 3/Plant Agents 3	20	Form 1, Section 3, NIH risk group score
	Risk group 4/Plant Agents 4	30	Form 1, Section 3, NIH risk group score
	SMPX, FMD, RIND	10	Form 1, Section 3, additive (such as registered for both FMD and Rinderpest)
	Tier 1	30	Form 1, Section 3
Work Practices	Large Animal (Based on caging)	30	Form 1, Section 7, Attachment C
	Non-human Primate	20	Form 1, Section 7, Attachment C
	Small Animal (Based on caging)	10	Form 1, Section 7, Attachment C
	Arthropod Containment Laboratory	10	Form 1, Section 7, Attachment E
	Plant Pathogens	10	Form 1, Section 7, Attachment D
	Aerosol Studies (Route of infection aerosol)	10	Form 1, Section 7
	Large Volume (~1-10 L at a time)	5	Form 1, Section 7
	Fermentation/Large Scale (Over 10 L)	10	Form 1, Section 7
	Approved for Restricted Experiment	10	Form 1, Section 7, Attachment B
	Inactivation for Future use	10	Form 1, Section 7, Attachment C or Work objective, POC Confirmed



Compliance Score

- Points not as defined as the Registration Score due to differences in severity.
- Compliance Score points are additive to the Registration Score.
- Points assigned by FSAP leadership.
- Length of time Compliance Points added to Registration Score depends on severity of issue and time to correct issue.

Compliance Score Variable	Increase Point Value
CAP	50-100
Partial Suspension/Immediate Action	5-50
Suspension	100
Action by FBI/OIG	5-50
Severe Inspection Observations	5-50



Use of Complexity Score

- Registration and Compliance scores are not visible to the entities but are kept by FSAP for internal use.
- The combination of the two scores is used for determining inspection frequency, inspection type (onsite, remote, or hybrid), length of inspection, and aid in determining inspection staffing requirements.
- The scores are also used to balance workloads among the POCs and teams.
- Some aspects and uses of these scores were on hold due to the COVID-19 pandemic, changes in our inspection process, and updates to the eFSAP information system.



Future Plans for Complexity Scores

- FSAP plans to update the Registration Score so that it changes depending on the current work being conducted at the entities.
- Other high-risk variables may be included, such as the inclusion of Gain-of-Function research or Dual Use Research of Concern with select agents.



Use of Complexity Score-Report Cards

- While the scores are not visible to the entities, the Registration Score is used to group entities into categories for inspection report cards and entities will know which category they are in.

Registration Score Range	Category
151+	Category 4 - Mega
80-150	Category 3 - High
50-79	Category 2 - Moderate
0-49	Category 1 - Low



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