

Security and Anti-Terrorism Activities Assessment Questionnaire

(Applies to Product Liability applicants.

Also applies to Clinical Laboratories, Blood Banks, Tissue Banks and OPO's)

Name of Organization _____

Type of Business _____

Address _____

Phone Number _____

Name and Title of Person
Completing Form _____

PART A SAFETY/SECURITY

1. Does your organization have a written security plan? (If yes, please attach)
 Yes No
2. Do you have an individual(s) with designated responsibility for the management, enforcement and monitoring of the security plan?
 Yes No
3. Has your organization conducted a vulnerability assessment for security and terrorism threats?
 Yes No
4. Does your security plan address threats or acts of bioterrorism or product tampering?
 Yes No

If not, is there a separate plan that does? Yes No
5. Is access to your manufacturing or processing facility(ies) limited?
 Yes No
6. Does your organization perform mock exercises or scenarios in preparation for potential terrorist or product tampering situations (not including fire drills or evacuation drills)?
 Yes No

If yes, when was the last exercise? _____

PART B HIRING AND SCREENING/EMPLOYEE TRAINING

1. Do you perform background checks on all employees, including non-manufacturing staff (e.g., maintenance and administrative staff)?
 Yes No
2. Do you require all subcontractors providing on-site services to perform background checks on all of their employees?
 Yes No NA (no on-site subcontractors)
3. Do you provide training to employees on:
 - a. The security plan and potential security threats Yes No
If yes, how often? _____
 - b. Identification and prevention of terrorist threats? Yes No
If yes, how often? _____
 - c. Identification and prevention of product tampering? Yes No
If yes, how often? _____

PART C PRODUCT INTEGRITY (FOR PRODUCT LIABILITY APPLICANTS , TISSUE AND BLOOD BANKS, AND OPO'S ONLY. CLINICAL LABS – GO TO SECTION D)

1. Does your security plan address procedures and methods to reduce the risk of intentional product contamination or tampering during manufacturing or processing?
 Yes No
2. Are hazardous materials and chemicals stored in a secured setting with limited access?
 Yes No
3. Do you have methods or procedures within your quality control procedures to identify product contamination or tampering?
 Yes No
4. Do you have procedures to analyze and identify the source of a suspected contamination or tampering?
 Yes No
5. If you package your product(s) within your facility for end use, is the packaging tamper proof?
 Yes No NA (Do not package product for end use)
6. If product leaves your facility/control in mass volume, do you have specific methods or procedures to protect the product from contamination/tampering until the product is under the control of the intended recipient.
 Yes No NA (Do not ship product in mass volume)

7. Have you received any warning letters from the Food and Drug Administration within the past 3 years? If yes, please attach copies of the letters along with a summary of the remedies implemented.

Yes No

PART D CLINICAL LABORATORIES ONLY

1. Is your laboratory currently accredited by the College of American Pathology?
 Yes No

2. If not, do you perform proficiency testing using an external agency?
 Yes No

If Yes, identify the external agency: _____

3. Is your laboratory within the CDC Laboratory Response Network?
 Yes No

4. If not, are you providing any testing beyond what is appropriate for a Level A clinical laboratory (related to agents of bioterrorism)?
 Yes No

If yes, what testing are you providing? _____

Please make sure you have attached any plans, policies, procedures and other materials as requested above.

The person completing this form should sign below:

Name & Title Date