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A Military Tool For Pharma Vulnerability Assessment – The CARVER + Shock Technique

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Following the terror attacks of Sept. 11, 2001, the U.S. Department of Homeland Security issued *Presidential Directive 7: Critical Infrastructure Identification, Prioritization, and Protection* to establish a national policy for federal departments and agencies to identify and prioritize critical infrastructure and to protect them from terrorist attacks.

The directive's goal is to protect critical infrastructure, including agriculture and food; public health and healthcare; drinking

water and water treatment systems; energy, including the production, refining, storage, and distribution of oil, gas, and electric power, except for commercial nuclear power facilities; banking and finance; national monuments and icons; and the defense industrial base.



In addition to acts of terrorism, other nefarious events such as illegal, falsified, intentionally contaminated, and/or counterfeit products also threaten the supply chain and can impact critical infrastructure and disrupt the flow of pharmaceuticals.

CARVER + Shock is a vulnerability assessment tool that can help manufacturers of medicinal products protect their products from deliberate contamination. CARVER was originally developed by the U.S. military to identify areas within critical or military infrastructure that could be vulnerable to an attack, while at the same time minimizing the risk to the attacking force. The CARVER + Shock technique can be applied to raw/starting materials, production, distribution, and commercial and retail sales.

CARVER is an acronym for the following six attributes:

- **Criticality** – measure of public health and economic impacts of an attack

- **Accessibility** – ability to physically access and egress from target
- **Recuperability** – ability of system to recover from an attack
- **Vulnerability** – ease of accomplishing attack
- **Effect** – amount of direct loss from an attack as measured by loss in production
- **Recognizability** – ease of identifying target

A seventh attribute, **Shock**, adds the combined health, economic, and psychological impacts of an attack.

The application of the CARVER + Shock technique includes five steps:

1. Establish the parameters
2. Assemble the experts
3. Detail the supply chain
4. Assign the scores
5. Apply what has been learned

CARVER & Shock Scoring

The FDA's *Carver + Shock Primer, An Overview Of The Carver Plus Shock Method For Food Sector Vulnerability Assessments* provides the following definitions and scoring criteria for completing a vulnerability assessment.

Criticality

A target is critical when introduction of threat agents into food at this location would have significant health or economic impact.

Criticality Criteria	Scale
Loss of over 10,000 lives OR loss of more than \$100 billion. (Note: if looking on a company level, loss of >90 % of the total economic value for which you are concerned*)	9 – 10
Loss of life is between 1,000 and 10,000 OR loss of between \$10 billion and \$100 billion. (Note: if looking on a company level, loss of between 61% and 90% of the total economic value for which you are concerned*)	7 – 8
Loss of life between 100 and 1,000 OR loss of between \$1 billion and \$10 billion (Note: if looking on a company level, loss of between 31% and 60% of the total economic value for which you are concerned*)	5 – 6
Loss of life less than 100 OR loss of between \$100 million and \$1 billion (Note: if looking on a company level, loss of between 10% and 30% of the total economic value for which you are concerned*)	3 – 4
No loss of life OR loss of less than \$100 million (Note: if looking on a company level, loss of <10% of the total economic value for which you are concerned*)	1 – 2
*The total economic value for which you are concerned depends on your perspective. For example, for a company this could be the percent of a single facility's gross revenues, or percentage of a company's gross revenues lost from the effect on a single product line. Likewise, a state could evaluate the effect of the economic loss caused by an attack of a facility or farm by the proportion of the state's economy contributed by that commodity.	

Accessibility

A target is accessible when an attacker can reach the target to conduct the attack and egress the target undetected. Accessibility is the openness of the target to the threat. This measure is independent of the probability of successful introduction of threat agents.

Accessibility Criteria	Scale
Easily Accessible (e.g., target is outside building and no perimeter fence). Limited physical or human barriers or observation. Attacker has relatively unlimited access to the target. Attack can be carried out using medium or large volumes of contaminant without undue concern of detection. Multiple sources of information concerning the facility and the target are easily available.	9 – 10
Accessible (e.g., target is inside building, but in unsecured part of facility). Human observation and physical barriers limited. Attacker has access to the target for an hour or less. Attack can be carried out with moderate to large volumes of contaminant but requires the use of stealth. Only limited specific information is available on the facility and the target.	7 – 8
Partially Accessible (e.g., inside building, but in a relatively unsecured, but busy, part of facility). Under constant possible human observation. Some physical barriers may be present. Contaminant must be disguised, and time limitations are significant. Only general, non-specific information is available on the facility and the target.	5 – 6
Hardly Accessible (e.g., inside building in a secured part of facility). Human observation and physical barriers with an established means of detection. Access generally restricted to operators or authorized persons. Contaminant must be disguised, and time limitations are extreme. Limited general information available on the facility and the target.	3 – 4
Not Accessible. Physical barriers, alarms, and human observation. Defined means of intervention in place. Attacker can access target for less than 5 minutes with all equipment carried in pockets. No useful publicly available information concerning the target.	1 – 2

Recuperability

A target’s recuperability is measured in the time it will take for the specific facility to recover productivity.

Recuperability Criteria	Scale
> 1 year	9 – 10
6 months to 1 year	7 – 8
3-6 months	5 – 6
1-3 months	3 – 4
< 1 month	1 – 2

Vulnerability

A measure of the ease with which threat agents can be introduced in quantities sufficient to achieve the attacker’s purpose once the target has been reached. Vulnerability is determined both by the characteristics of the target and the characteristics of the surrounding environment. It is also important to consider what interventions are already in place that might thwart an attack.

Vulnerability Criteria	Scale
Target characteristics allow for easy introduction of sufficient agents to achieve aim.	9 – 10
Target characteristics almost always allow for introduction of sufficient agents to achieve aim.	7 – 8
Target characteristics allow 30 to 60% probability that sufficient agents can be added to achieve aim.	5 – 6
Target characteristics allow moderate probability (10 to 30 %) that sufficient agents can be added to achieve aim.	3 – 4
Target characteristics allow low probability (less than 10%) that sufficient agents can be added to achieve aim.	1 – 2

Effect

Effect is a measure of the percentage of system productivity damaged by an attack at a single facility. Thus, effect is inversely related to the total number of facilities producing the same product.

Effect Criteria	Scale
Greater than 50% of the system’s production impacted	9 – 10
25-50% of the system’s production impacted	7 – 8
10-25% of the system’s production impacted	5 – 6
1-10% of the system’s production impacted	3 – 4
Less than 1% of system’s production impacted	1 – 2

Recognizability

A target’s recognizability is the degree to which it can be identified by an attacker without confusion with other targets or components.

Recognizability Criteria	Scale
The target is clearly recognizable and requires little or no training for recognition	9 – 10
The target is easily recognizable and requires only a small amount of training for recognition	7 – 8
The target is difficult to recognize or might be confused with other targets or target components and requires some training for recognition	5 – 6
The target is difficult to recognize. It is easily confused with other targets or components and requires extensive training for recognition	3 – 4
The target cannot be recognized under any conditions, except by experts	1 – 2

Shock

Shock is the final attribute considered in the methodology. Shock is the combined measure of the health, psychological, and collateral national economic impacts of a successful attack on the target system. Shock is considered on a national level. The psychological impact will be increased if there are a large number of deaths or the target has historical, cultural, religious, or other symbolic significance. Mass casualties are not required to achieve widespread economic loss or psychological damage. Collateral economic damage includes such items as decreased national economic activity, increased unemployment in collateral industries, etc. Psychological impact will be increased if victims are members of sensitive subpopulations such as children or the elderly.

Shock Criteria	Scale
Target has major historical, cultural, religious, or other symbolic importance. Loss of over 10,000 lives. Major impact on sensitive subpopulations, e.g., children or elderly. National economic impact more than \$100 billion.	9 – 10
Target has high historical, cultural, religious, or other symbolic importance. Loss of between 1,000 and 10,000 lives. Significant impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$10 billion and \$100 billion.	7 – 8
Target has moderate historical, cultural, religious, or other symbolic importance. Loss of life between 100 and 1,000. Moderate impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$1 billion and \$10 billion.	5 – 6
Target has little historical, cultural, religious, or other symbolic importance. Loss of life less than 100. Small impact on sensitive subpopulations, e.g., children or elderly. National economic impact between \$100 million and \$1 billion.	3 – 4
Target has no historical, cultural, religious, or other symbolic importance. Loss of life less than 10. No impact on sensitive subpopulations, e.g., children or elderly. National economic impact less than \$100 million.	1 – 2

Example

A drug manufacturer decided to perform a vulnerability assessment for its over-the-counter pharmaceutical product as part of its overall risk management program. The cross-functional team completed the vulnerability assessment and tabulated the results as follows:

TARGET (Nodes)	Criticality	Accessibility	Recuperability	Vulnerability	Effect	Recognizability	Shock	Overall Score
Starting material	5	7	2	7	1	5	2	29
Active pharmaceutical ingredient	5	2	2	3	3	5	2	22
Production facility	5	2	2	3	3	5	2	22
Transportation (finished goods)	5	8	2	6	3	3	2	29
Storage	5	5	2	5	1	3	2	23
Retail sales	5	7	2	4	2	7	2	29

The vulnerability assessment determined the greatest risks are associated with the starting materials, transportation of finished goods, and retail sales. These are the three areas where the organization will focus its resources to minimize the threat of nefarious events.

Mitigation Strategies

There are several strategies available for an organization to use to minimize the threat of a nefarious event, including but not limited to:

- Facility vulnerability assessments
- Physical security and access control
- Process design changes
- Penetration audits
- Supply chain assessment and monitoring
- Raw materials inspection
- Employee peer monitoring programs
- Awareness training

Conclusion

While the FDA’s primary focus for the CARVER & Shock technique has been the food supply, the concepts can be readily applied to medicinal products, including pharmaceuticals. Vulnerability assessments, like any other risk management documents, should be periodically reviewed for adequacy, changes, and effectiveness.

The discussion above focuses on using the Carver & Shock technique for identifying and deploying risk mitigation strategies throughout manufacturing and distribution. There are many more tools available to identify, analyze, mitigate, and monitor risk.

I cannot emphasize enough the importance documenting the tools and methods used. Best practice includes providing rationale for your organization's use of risk tools and activities. The requirements and risk management tools presented in this article can and should be utilized based upon industry practice, guidance documents, and regulatory requirements.

References:

1. *FDA Carver + Shock Primer, An Overview of the Carver Plus Shock Method for Food Sector Vulnerability Assessments*, 9/23/2009
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2. *FDA Vulnerability Assessments of Food Systems, Final Summary Report*, June 2009 – February 2012 <https://www.fda.gov/downloads/Food/FoodDefense/UCM317547.pdf>

About the Author:

Mark Allen Durivage has worked as a practitioner, educator, consultant, and author. He is managing principal consultant at Quality Systems Compliance LLC, an ASQ Fellow, and an SRE Fellow. He earned a B.A.S. in computer aided machining from Siena Heights University and an M.S. in quality management from Eastern Michigan University. He holds several certifications including CRE, CQE, CQA, CSQP, CSSBB, RAC (Global), and CTBS. He has written several books available through ASQ Quality Press, published articles in *Quality Progress*, and is a frequent contributor to Life Science Connect. Durivage resides in Lambertville, Michigan. Please feel free to email him at mark.durivage@qscompliance.com with any questions or comments.

