

# CRITICAL REAGENTS PROGRAM (CRP)

## SECURITY CLASSIFICATION GUIDE

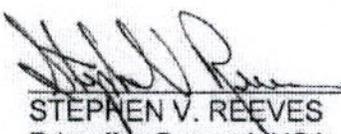
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This guide supersedes the previously issued guide dated October 28, 2004 and supplements AR 380-86, "Classification of Former Chemical Warfare, Chemical and Biological Defense, and Nuclear, Biological, Chemical Contamination Survivability Information," dated June 22, 2005.

Distribution authorized to the DoD and U.S. DoD contractors only. Other requests shall be referred to the Joint Project Manager for Chemical and Biological Medical Systems (JPM-CBMS), 64 Thomas Johnson Drive, Frederick, MD 21702-5041.

## **SECTION 1, GENERAL INSTRUCTIONS**

- 1.1. Purpose. To provide instructions and guidance on the classification of information and material derived from the Critical Reagents Program (CRP) using an unclassified identification of the effort.

This document does not offer guidance on measures to ensure program security; security measures will be addressed in the CRP Program Protection Plan (PPP).

- 1.2. Scope. This guide applies to classification of the CRP products and concerns research, development, test, and evaluation (RDT&E), and the procurement of chemical and biological defense materials for purposes not prohibited by biological weapons arms control agreement(s), and applies to all government and industrial activities involved in the CRP effort.

- 1.3. Authority. This guide is issued under authority of Presidential Decision Directive 39, Executive Order (EO) 12958 as amended, "Classified National Security Information," Information Security Oversight Office, National Archives and Records Administration "Classified National Security Information Directive No. 1", Department of Defense (DoD) 5200.1-R, "Information Security Program". Classification of information involved in Chemical Biological (CB) defense and CB detection systems is governed by, and is in accordance with (IAW), Army Regulation (AR) 380-86, "Classification of Former Chemical Warfare, Chemical and Biological Defense, and Nuclear, Biological, Chemical Contamination Survivability Information."

This guide constitutes classification authority, and may be cited as the basis for classification, regrading, or declassification of information and materials involved in the CRP effort. Changes in classification required by application of this guide shall be made immediately. Information identified as classified in this guide is classified by the Division Chief for Chemical, Biological, Radiological, and Nuclear/Military Police Systems, Office of the U.S. Army Deputy Chief of Staff for Programs.

- 1.4. The Office of Primary Responsibility (OPR). This guide is issued by and all inquiries concerning content and interpretation should be addressed to:

Joint Project Manager for Chemical and Biological Medical Systems  
64 Thomas Johnson Drive  
Frederick, MD 21702-5041

- 1.5. Summary of Changes. The major change within this guide is the use of agent codes. The CRP now distributes products that are coded (e.g. XY) and uncoded (e.g. anthrax). The correlation of agent to code remains classified **SECRET**, and steps have been taken to ensure that coded and uncoded products cannot be compared to reveal the codes. By keeping the agent to code correlation classified **SECRET**, historical data under the coded system is not compromised. At the initiation of the program in 1997, only the capability to identify four threat agents existed and coding was instituted to prevent disclosure of which agents could or could not be identified with DoD detection assays. Today, the CRP has the

capability to detect over 20 agents. New assays are being added each year. Because of this increased capability, and the requirement to provide products to first responders, CRP assays can now be ordered by Biological Warfare Agent (BWA) name.

- 1.6. Classification Challenges. All users of this guide are encouraged to assist in improving and maintaining the currency and adequacy of this guide. If the security classifications contained in this guide impose requirements that are impractical, challenged, or outmoded, completely documented and justified recommendations should be made through appropriate channels to the OPR. Pending final decision by the Original Classification Authority (OCA), items of information under review shall be handled at the current approved classification level.
- 1.7. Reproduction, Extraction and Dissemination. The Army is responsible, as Executive Agent and OCA, for the Chemical and Biological Defense Program. By extension of EO 12958, as amended, this guide applies to all government and industrial activities involved in the CRP effort. Changes in classification required by application of this guide will be implemented immediately. Authority is granted to make reproductions and take extracts or selected portions of this guide for application by government and industrial activities involved in the CRP effort. Supplementation of this guidance is prohibited without prior approval of the OPR and OCA. This classification guide will be reviewed every two years. Information is classified IAW Sections 3 and 4 of this guide and is consistent with EO 12958, as amended, and Original Classification Guidance contained in AR 380-86.
- 1.8. Public Release. Automatic release of information deemed unclassified in this guide is not authorized. Proposed public disclosure of unclassified information regarding the CRP effort shall be addressed through appropriate channels to the OPR for approval. Doctrinal and technical publications dealing with chemical and biological defense have restricted (U.S. Government only) distribution. Public release of unclassified chemical and biological defense doctrinal and technical publication materials requires coordination/approval through the U.S. Army Public Affairs Office. Such information is releasable to commercial firms under contract to the government IAW Federal Acquisition Regulations and where the government organization Contracting Officer Representative (COR) certifies a need to know.
- 1.9. Foreign Disclosure. Any disclosure to foreign officials of information classified by this guide shall be IAW procedures set forth in DoD 5200.1-R, Appendix 8 and international memoranda of understanding/agreement. If a country with which the DoD has entered into a reciprocal agreement, memorandum of understanding or offset arrangement expresses an interest in this effort, a foreign disclosure review shall be conducted prior to issuance of a solicitation.

## 1.10. Definitions.

Biological Defense	A generic term applied to all research efforts and material development related to protecting and defending U.S. forces against an adversary's employment of biological agents, munitions, or weapon systems.
Confidential (C)	Information, the unauthorized disclosure of which reasonably could be expected to cause damage to the national security that the original classification authority is able to identify or describe.
Confirmation Testing	Laboratory analyses performed to confirm or verify with high confidence a preliminary or screening test.
Countermeasures	That form of military science that, by employment of devices and/or techniques, has as its objective the impairment of the operational effectiveness of enemy activity. May also include anything that effectively negates an adversary's ability to exploit vulnerabilities.
Declassification	The determination that classified information no longer requires, in the interest of national security, any degree of protection against unauthorized disclosure, together with a removal or cancellation of the classification designation.
Derivative classification	A determination that information is in substance the same as information currently classified and the application of classification markings.
For Official Use Only (FOUO)	Information that has not been given a security classification pursuant to the criteria of an Executive Order, but which may be withheld from the public because disclosure would cause a foreseeable harm to an interest protected by one of more Freedom of Information Act (FOIA) Exemptions 2 through 9.
Secret (S)	Information, the unauthorized disclosure of which reasonably could be expected to cause serious damage to the national security that the original classification authority is able to identify or describe.
Unclassified (U)	Information which does not require the application of security safeguards, but the disclosure of which may be subject to control for other reasons. Unclassified information is approved for release to the public; except when designated FOUO.

## **SECTION 2, OVERALL EFFORT**

- 2.1. **Goals, Mission and Purpose.** The goals, mission and purpose of the CRP are Unclassified; however, certain information, and the process in which material is developed to arrive at the CRP end products, may be classified.
- 2.2. The CRP's charter is to provide the highest quality biological detection reagents for the nation, to standardize procedures and training, and to support ongoing efforts for optimization and transition of new technologies for homeland defense. The CRP supports the Warfighter by meeting the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD) customers' biological defense requirements. It is also a national resource for the biological defense community, supports domestic preparedness (DP)/homeland defense (HLD) or counter terrorist operations by Other Government Agencies (OGAs).
- 2.3. The CRP and its products comprise a key element of biological warfare (BW) agent detection, identification, confirmation and characterization. The CRP is capable of providing detection end items as completed environmental biological detection assays. Additionally, it provides foundation resources, such as raw ingredients, used in building assays. The CRP is both a supporting program to biological defense detection systems and a provider of stand-alone detection, identification and sampling products.
- 2.4. **CRP Detection Products.** The CRP detection products include coded and uncoded hand held immunochromatographic assays (HHA), polymerase chain reaction (PCR) assays, electrochemiluminescent (ECL) assays, and DoD Biological Sampling Kits.
- 2.5. **Constructive Classification.** If at least three specific pieces of unclassified information which would lead a reasonable and prudent person to deduct that this information (if made available to adversaries) would probably cause serious damage to the national security if released, then this compilation of information should be classified **SECRET**.

## **SECTION 3, CRITICAL ELEMENTS**

Biological warfare agent identification provided by CRP products is accomplished via wet chemistry technology. Current biological detection sensors use reagents and immunoassays as consumables in this process. CRP products are furnished to detection programs and fielded systems through the JPEO-CBD. The reagents/assays are designed to identify specific BW agents. Subsequently, disclosure of critical elements within reagents/assay production have the following instructions:

- 3.1. The sequences and target specificities of the probes, as well as the target nucleic acid sequences, are classified **SECRET**, declassify 25 years from the original classification decision (per AR 380-86, Table 2, Para 3b.). Detailed information relating to the structural characteristics of those targets could allow adversaries to genetically engineer BW agents that could no longer be detected with our current reagents and equipment.

- 3.2. Discussion of the Limits of Detection of the end item products in relation to the agents the DoD is able to detect is considered Unclassified **FOUO** (per DoD Directive 5400.7-R, Exemption 7).
- 3.3. Biological Detection sensors, in themselves, may not be classified, but they may contain agent CRP reagents/assays. Therefore, loss of an operational sensor to theft should be considered a compromise of Unclassified **FOUO** (per DoD Directive 5400.7-R, Exemption 7) information.
- 3.4. Loss of assay stocks (in-transit or maintained on-hand for replacement of sensor consumables) to theft should be considered a compromise of Unclassified **FOUO** (per DoD Directive 5400.7-R, Exemption 7) information.
- 3.5. System waste (e.g., used and unused assays) must be treated as Unclassified **FOUO** (per DoD Directive 5400.7-R, Exemption 7) waste unless destroyed by burning or treated with a decontaminant which renders the waste unreadable to analyses for intelligence exploitation. CRP assay materials are treated with a decontaminating solution prior to disposal.
- 3.6. Reagent manufacturing entails use of government owned/furnished information or material (GFI or GFM). Specific nucleic acid sequence information will be handled as **SECRET**, declassify 25 years from the original classification decision (per AR 380-86, Table 2 Para 3b). Additional detail on how coded and uncoded assays are manufactured and shipped will be included in the PPP.
- 3.7. The prime vendor will, upon reagent manufacture completion, ship the material to CRP conformance testing laboratories before release to the DoD end user. The conformance data generated by the CRP conformance testing laboratories will be in an uncoded format and will be handled as Unclassified **FOUO** (per DoD Directive 5400.7-R, Exemption 7).
- 3.8. Agent Codes
  - 3.8.1. Code List. The BWA to Agent Code Correlation list is classified **SECRET**, declassify 25 years from the original classification decision (per AR 380-86, Table 2, Para 1.). The list uses one or two letter codes to identify specific BWA that can be detected and identified by CRP products.
  - 3.8.2. Coded Assays. Codes will continue to be used in place of agent names (for example a test kit may be labeled XX instead of ricin toxin). Limits of detection (LOD), a list of targets that detection kits are manufactured for, QA/QC data for test kits and antibody performance data can be associated with a coded product and the information is treated as Unclassified **FOUO** (per DoD Directive 5400.7-R, Exemption 7). However, associating performance data with codes should be avoided and codes reserved for reports referring to fielding and deployments of biological defense systems only. Codes are not to be tied to performance data in order to bypass the need to classify test reports as **SECRET** when such a classification is appropriate. The intention of coding assays is to conceal the

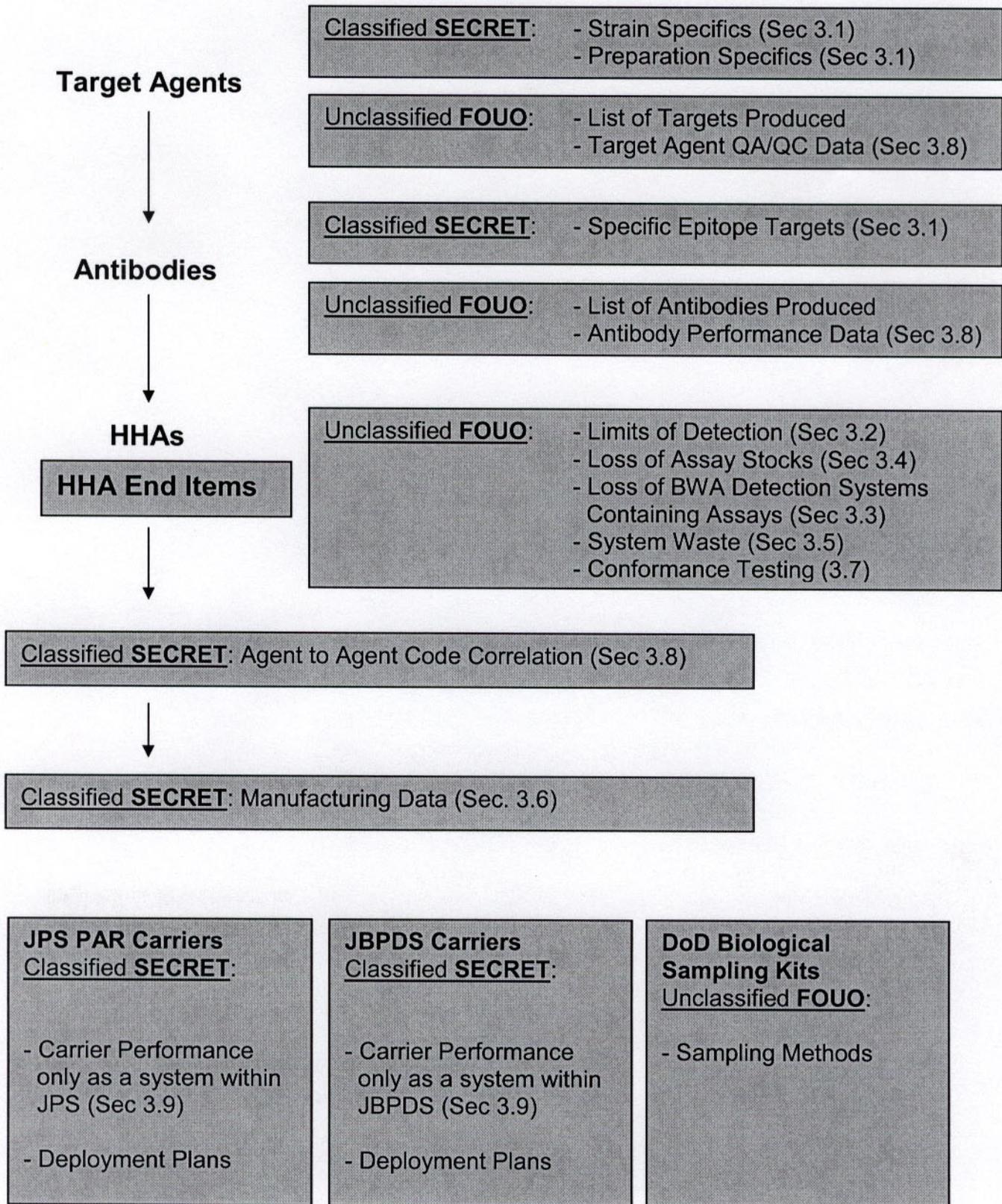
identity of the agents that a biological defense system is searching for or that a test kit will identify when it is used in an operational context. Unnecessarily associating performance data with codes in Unclassified **FOUO** documents creates the potential of disseminating data that could ultimately become **SECRET** in the event that the code list becomes compromised.

3.8.3. Uncoded assays. The intention of uncoded assays is to allow first responders and other personnel to use detection products when access to the classified decode list is not feasible. Uncoded assays will have the threat agent name clearly printed on the label (for example ricin toxin). Limits of detection (LOD), a list of targets that detection kits are manufactured for, QA/QC data for test kits and antibody performance data can be associated with an uncoded product and the information is treated as Unclassified **FOUO** (per DoD Directive 5400.7-R, Exemption 7). Personnel who have access to both coded and uncoded information shall take steps to prevent the mixing of data such that classified information is not inadvertently released.

3.8.4. Historical Documentation. Information that exists which was produced prior to the issuance of this security guidance will be held at their current classification level. Data generated from this point forward shall follow the guidance as written in section 3.

3.9. Assay/Carrier Performance in a system, on a specific site/installation, in a specific Area of Responsibility is classified **SECRET**, declassify 25 years from the original classification decision (per AR 380-86, Table 2, Para 3b.).

The following figures (3-1, 3-2, and 3-3) identify specific classification guidance for the components and end items of the CRP products:



- **SECRET**, declassify 25 years from original classification decision. Classifications per **AR 380-86, Table 2, Para 1, Table 2, Para 3b and Table 2, Para 3c.**
- **FOUO** Classifications per **DoD Directive 5400.7-R, Exemption 7.**

Figure 3-1 Hand Held Assay Classification Guidance

**Target Agents**

Classified SECRET: - Strain Specifics (Sec 3.1)  
- Preparation Specifics (Sec 3.1)

Unclassified FOUO: - List of Targets Produced  
- Target Agent QA/QC Data (Sec 3.8)

**Antibodies**

Classified SECRET: - Specific Epitope Targets (Sec 3.1)

Unclassified FOUO: - List of Antibody Types Produced  
(Sec 3.8)

**ECL MINItubes**

Unclassified FOUO: - Limits of Detection (Sec 3.2)  
- Loss of Assay Stocks (Sec 3.4)  
- Loss of BWA Detection Systems  
Containing Assays (Sec 3.3)  
- System Waste (Sec 3.5)  
- Conformance Testing (Sec 3.7)

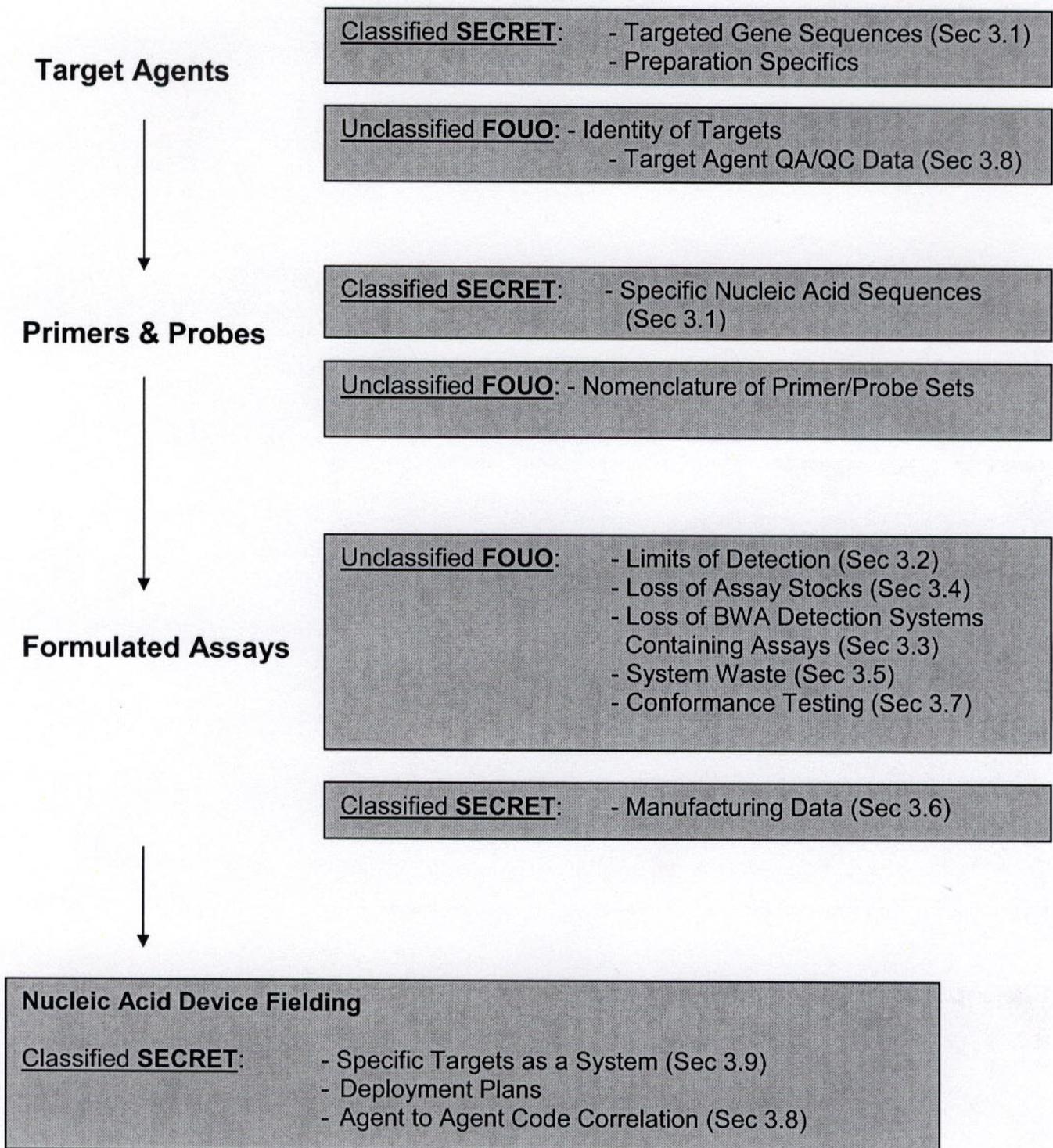
Classified SECRET: - Manufacturing Data (Sec. 3.6)

**Electrochemiluminescent Assay Fieldings**

Classified SECRET: - Assay Performance as a System (Sec 3.9)  
- Deployment Plans  
- Agent to Agent Code Correlation (Sec 3.8)

- **SECRET**, declassify 25 years from the original classification decision. Classifications per **AR 380-86, Table 2, Para 1, Table 2, Para 3b and Table 2, Para 3c.**
- **FOUO** Classifications per **DoD Directive 5400.7-R, Exemption 7.**

**Figure 3-2 Electrochemiluminescent Assay Classification Guidance**



- **SECRET**, declassify 25 years from the original classification decision. Classifications per **AR 380-86, Table 2, Para 1, Table 2, Para 3b and Table 2, Para 3c.**
- **FOUO** Classifications per **DoD Directive 5400.7-R, Exemption 7.**

.Figure 3-3 Nucleic Acid Reagent Classification Guidance

## **SECTION 4, ADMINISTRATIVE DATA**

- 4.1. Security measures will be addressed in the Program Protection Plan (PPP) for the CRP. The PPP contains specific security procedures/countermeasures designed to prevent unauthorized intelligence collection or disclosure of Critical Program Information (CPI) during the acquisition process -- rendering the PPP a classified document. Unclassified security measures will also be found in doctrinal, training and technical manuals.

## **SECTION 5, ACRONYMS**

AOR	Area of Responsibility
AR	Army Regulation
BW	Biological Warfare
BWA	Biological Warfare Agents
COR	Contracting Officer Representative
CPI	Critical Program Information
CRP	Critical Reagents Program
EO	Executive Order
ECL	Electrochemiluminescent
FOIA	Freedom of Information Act
FOUO	For Official Use Only
GFI	Government Furnished Information
GFM	Government Furnished Material
HHA	Hand Held Assay
HLD	Homeland Defense
IAW	In Accordance With
JBPDS	Joint Biological Point Detection System
JPEO-CBD	Joint Program Executive Office for Chemical and Biological Defense
JPS	Joint Portal Shield
NBC	Nuclear Biological Chemical
OCA	Original Classification Authority
OGA	Other Government Agencies
OPR	Office of Primary Responsibility
OPSEC	Operations Security
PAR	Progressive Assay Reader
PCR	Polymerase Chain Reaction
PPP	Program Protection Plan
QA	Quality Assurance
QC	Quality Control