

Welcome

**Biotechnology Quality Management
Support (BQMS) Program
&
Confidential Business Information
(CBI)**

Webinar

March 29, 2018



Speakers

- Chessa Huff-Woodard Esq., Branch Chief, Policy Program and International Collaborations Group
- Rochelle Langley, PhD, BQMS Manager, Policy, Program and International Collaborations Group
- Cindy Eck, Document Control Officer, Team Lead for BRS Communications Group



Agenda

1. Webinar Objectives
2. BQMS Program Overview
3. Confidential Business Information (CBI)
4. CBI Examples in Document Submissions



Learning Objectives

The participants will be able to describe:

1. BQMS Program in general
2. Confidential Business Information (CBI)
3. Use of CBI



Biotechnology Quality Management Support Program (BQMS)

Rochelle Langley, PhD

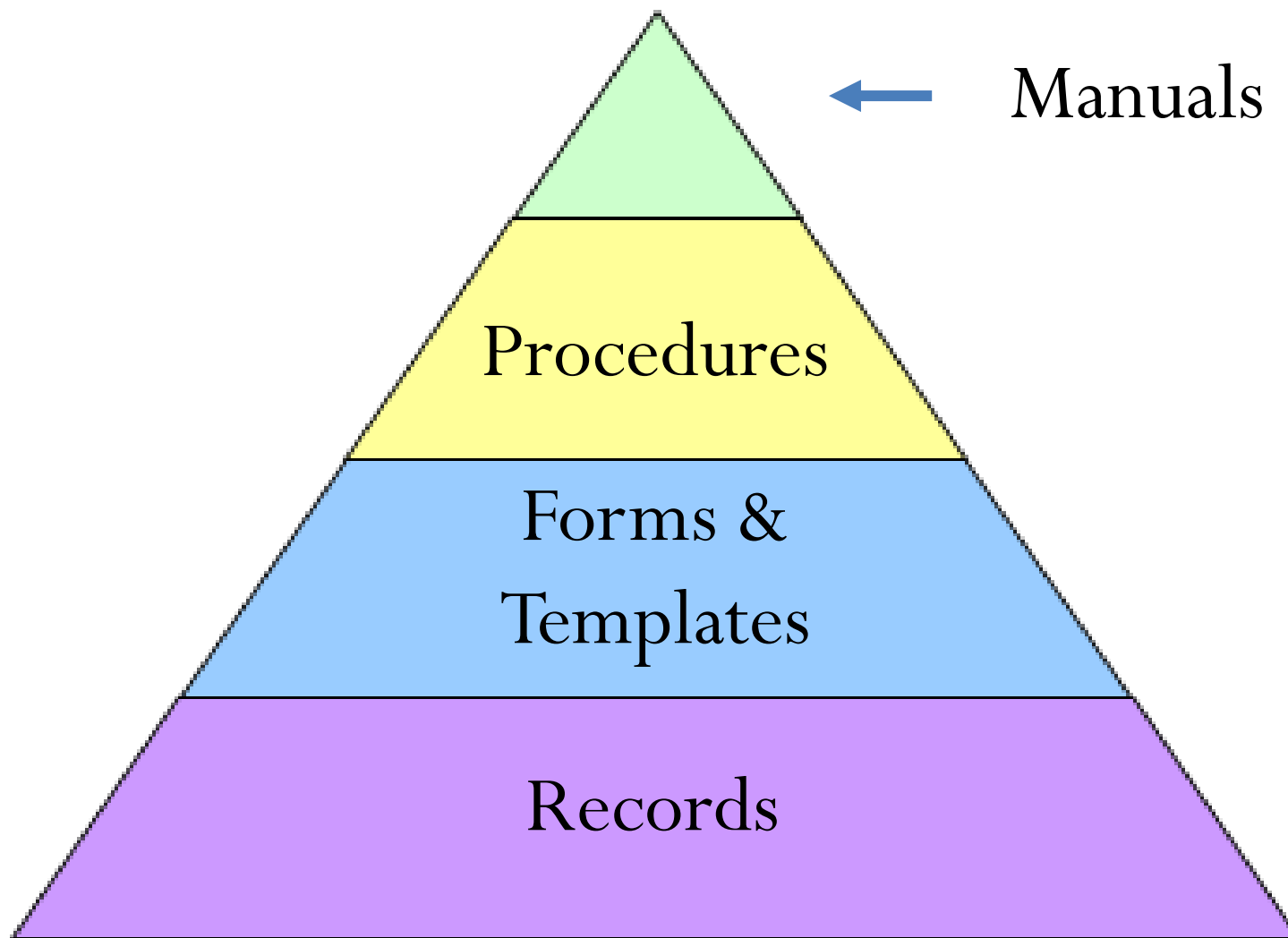


Biotechnology Quality Management Support Program

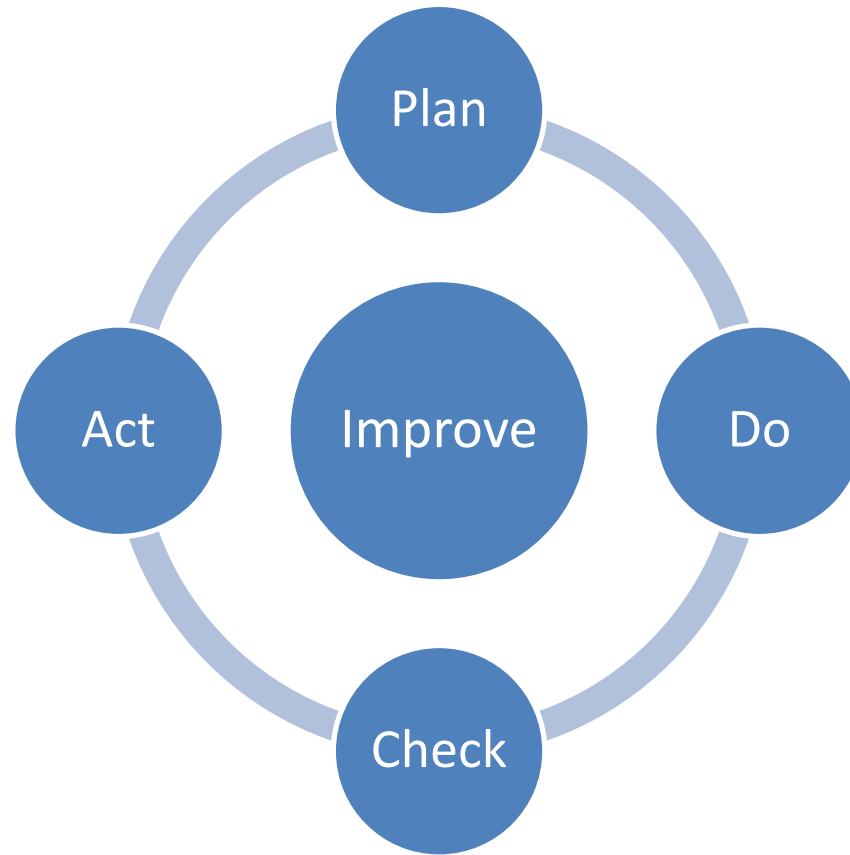
- Supports compliance with 7 CFR 340
- Voluntary program
- Accessible to ALL organizations
- Online resources found on our BRS website
- Targeted training from BRS



Quality Management System (QMS)

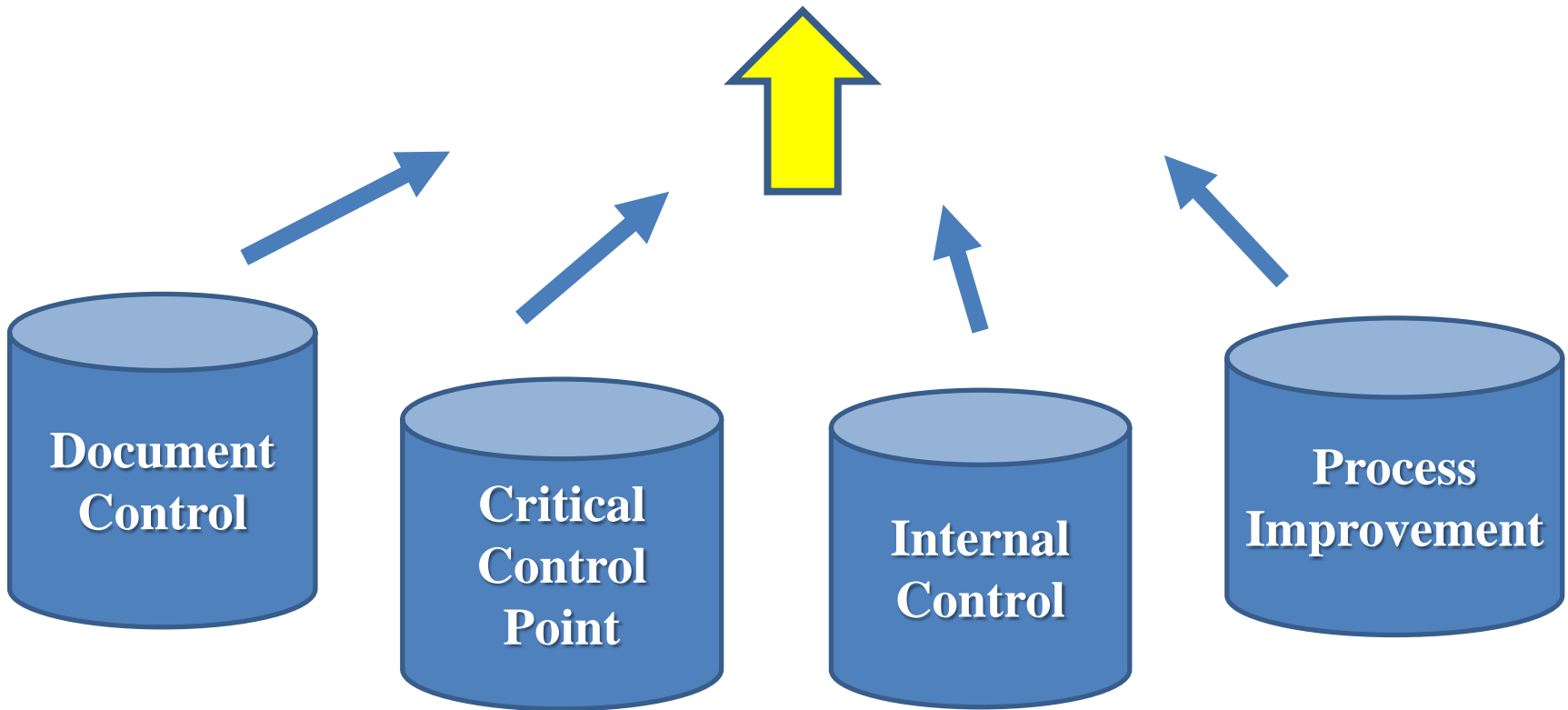


Quality Management System Cycle



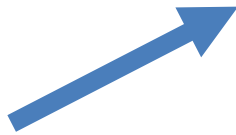
BQMS Program

Your Unique BQMS



BQMS Program

Your Unique BQMS



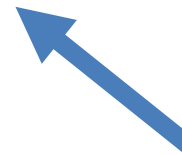
Document control

Record Control

BQMS Program

Your Unique BQMS

1. Site Selection Planning
2. Storage
3. Transport, Movement, and Import
4. Environmental Release Planning and Monitoring
5. Post-harvest Handling and Transfer
6. Devitalization and Final Disposition
7. Potential Regulatory Compliance Incidents
8. Reporting Form for Potential Regulatory Compliance Incidents



BQMS Program

Your Unique BQMS



Internal
Control

Competency
Awareness

Management Review
Meeting Form

BQMS Program

Your Unique BQMS



Internal Audit

Corrective Actions

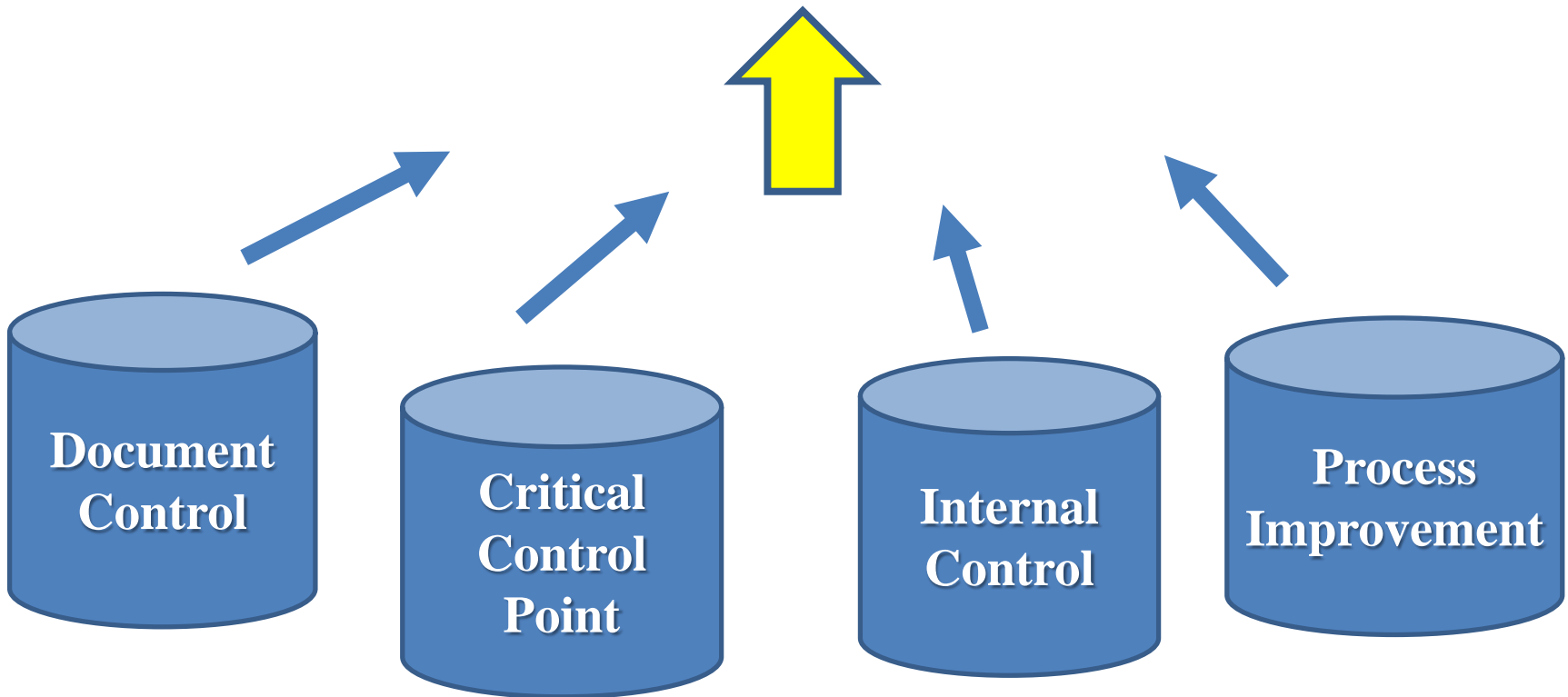
Preventive Actions

CARs and PARs Form



BQMS Program

Your Unique BQMS



Confidential Business Information (CBI) in Submissions to BRS

Cindy Eck

Document Control Officer

Team Lead, Communications Group



Give Attention to Records

The Federal Records Act of 1950
amended in 2014

E-Government Act of 2002
and other Laws & Regulations

36 CFR Parts 1220-1238

18 U.S. Code § 2071

18 U.S. Code § § 793, 794, & 798



Freedom of Information Act (FOIA)



Freedom of Information Act (FOIA)

- Anyone can request government records
- Practices and policies fall in line with 5 U.S.C § 552 FOIA
- All Federal Agencies receive CBI guidance/FOIA guidance through case law and the DoJ
- Familiarize yourself with these current court decisions:
<http://www.justice.gov/oip/courtdecisions/exemption4.html>



Freedom of Information Act (FOIA)

We want you to prepare your CBI justifications as though you were preparing them for release under the FOIA.

- The APHIS FOIA Office says your justification should tell us:
 - What each category of information reveals about your organization's business
 - How a competitor could use this information to cause your company competitive harm
 - The specific competitive harm (e.g., financial, research & development, etc.) that could result if the information is released



Confidential Business Information

- The term “CBI” is used for information that is protected from disclosure under section (b)(4) of the Freedom of Information Act (FOIA). This is sometimes referred to as “Exemption 4”.
- BRS allows permit, notification, petition applicants, and *Am I Regulated* inquirers to make a claim of CBI for documentation they send to us (voluntarily).



Confidential Business Information

- CBI includes TWO distinct categories of information:
 1. Commercial and financial information that is privileged or confidential
 2. Trade secrets



Commercial and Financial information



Exemption 4

Explained

- Exemption 4 is intended to protect the interests of both the government and **submitters** of information. The very existence of Exemption 4 encourages submitters to **voluntarily** furnish useful commercial & financial info to the government and provides the government with an assurance that required submissions will be reliable.



Exemption 4 Continued

- Exemption 4 also affords protection to those business submitters who are **required** to furnish commercial or financial information to the government by safeguarding them from the competitive disadvantages that could result from disclosure.



FOIA & BRS CBI

Submission Requirements

- Executive Order 12600
- FR- Vol. 52, No. 122/Thursday June 25, 1987
 - Pre-disclosure Notification Procedures for Confidential Commercial Information
 - Sections 1-10
- BRS' CBI Instruction Package



What BRS Typically Accepts as CBI

- Field Test Location Sites - cities, zip codes and descriptions (this does not include County and State Names)
- Acreage Location (descriptions, drawings, maps, addresses and gps) and quantities
- Literature references that point to gene/genotype and other area of the submission that is claimed as CBI
- Individuals who are connected to a field test site location
- Novel: methods, design protocols, devitalization methods
- Voluntary submission of self-certifying audit reports.



What BRS Does Not Consider CBI

- Any information found on the Web.
- Previously claimed CBI that is now publically available.



Submitting CBI Documentation must have a Justification

- A detailed justification statement should include:
 1. Active competition
 2. Substantial competitive harm or disadvantage would result from disclosure

Submitting a CBI Justification to BRS

Sample justification:

- Revealing genetic material (promoters, genes & terminators) is typically claimed as CBI.
- You would tell us how providing the phenotype description, phenotype, and genetic material inserted and/or the donors would compromise the time and expense spent in developing the technology to produce the desired trait. You would state that: this particular genetic combination is unique because the arrangement is novel and the genetic constructs are also unique.
Tell us HOW they are unique or novel.

Justifications Continued

- You would tell us: If this information was disclosed, replication by a competitor would cause the loss on many dollars in developing your technology.
- Furthermore, the competitors would have access to this technology for free at your expense.



Let's summarize:

Submitting CBI Documentation

If you claim CBI, you must:

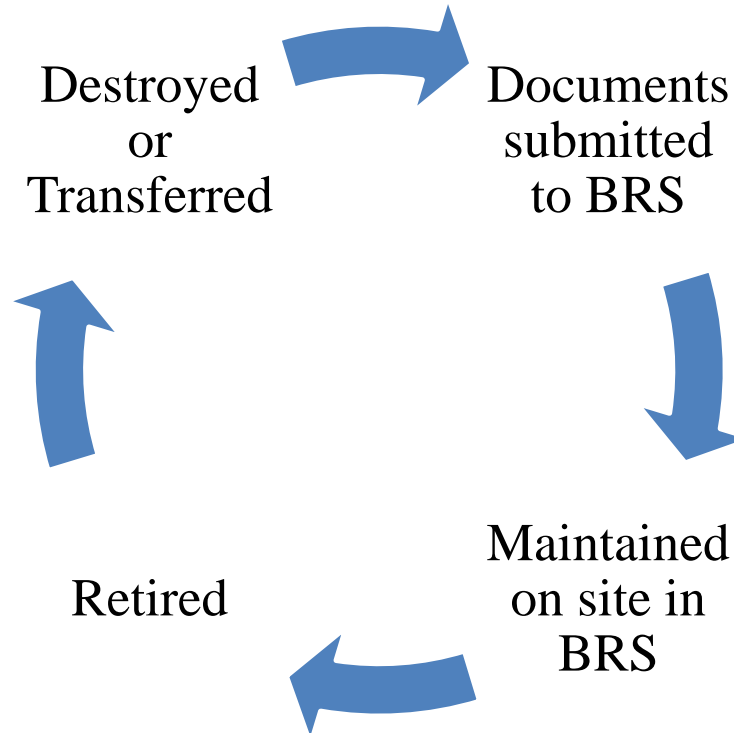
- Mark the document “Contains CBI” and
- Provide us a CBI-deleted copy.
- Provide us
 - A CBI justification and
 - Documentation using bracket formatting that we will discuss. READ our Regs 7 CFR 340 to know how to submit and how to mark up!



Practical Instructions when e-mailing CBI to BRS



Submitting CBI Documentation Full Life Cycle



How Does BRS Handle CBI Submissions?

- Officials and agents who receive, create, or handle CBI for BRS must prevent the unauthorized disclosure and maintain CBI under secure conditions while in their possession.
- Officials are responsible for ensuring the proper use of email to disseminate CBI and proper hardcopy handling of CBI.
- Officials and agents are responsible for maintaining the confidentiality of CBI as well as other documentation.

Authorized Employees

- Must have a demonstrated need to know CBI
- Must sign or certify the APHIS BRS confidentiality agreement
- Must be trained annually



We recommend some Practical Steps in Safeguarding YOUR CBI

- Confirm the name, office location, phone number, & email of your BRS contact.
- USDA requires officials and agents to place the following legal disclaimer on emails we send out. Let us know if you do not see this message from your sender:

“This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.”



Practical Steps Continued

- Only authorized officials and agents can handle your CBI
- Official and agents must return CBI documents to where they are controlled under our file plans. We place a file plan with our Agency's Records Officer, which is sent to the NARA annually.
- Remind attendees to treat all discussions as CBI



Practical Steps Continued

- Verify identity of participants on the call
- Conversation can be claimed as CBI – Tell us what is CBI
 - NOTE: telephone lines are **not** secure
- Meetings – We erase dry erase boards & collect materials at the end of meetings and refile according to our file plans



Destruction of CBI Material

- Memory sticks are crushed
- Disks are physically destroyed in a disk shredder
- Paper is shredded
- Typewriter ribbons are burned

Let's Go over one last Item

Confidential Business Information (CBI)

VS

Personal Identifiable Information (PII)

– Often confused



Personal Identifiable Information (PII)



Personal Identifiable Information Requirements

- Privacy Act of 1974
5 U.S.C. § 552a &
- FOIA's Exemption 6



General Document Preparation for Submission to BRS

**BRS User's Guide: General Document
Preparation Guidelines for Submission to BRS**



Preparing to Submit?

Know what we expect

- General Text Formatting
- Scientific Names and Terminology
- References
- Tables
- Figures
- Equations
- Sequence Data
- Color Printing Media Type and Number of Copies



Quick Guide to BRS Submissions

Documents submitted to BRS are primarily related to **four types of regulatory procedures** and **one non regulatory solution**:

- Permits for the introduction of regulated articles
- Notification of the introduction of regulated articles
- Petitions to determine nonregulated status of a regulated article
- Petition extensions
- Providing developers with a determination of whether their organism or product is regulated according to 7 CFR part 340



Permits & Notifications

e-Permits Submission Requirements

e-Permits System

- Brackets []
 - Applications
 - Supporting Documents
 - Compliance Reports/Reporting
 - Uploaded documents may need resubmission
 - Science Journals and the problem with brackets...



Design Protocol Submissions

Does your entire DP or SOP need to be claimed as CBI? Probably not.....



Petition & Extension Petition Submission Requirements

- [Guidance for New Users to the Petition Process](#)
- [Guidance for Submitting a Petition](#)
- [Guidance on Requests for Extensions of Non-Regulated Status](#)



Petition Submission Requirements

- [7 CFR 340.6](#)

The petitioner shall include copies of scientific literature, copies of unpublished studies, when available, and data from tests performed upon which to base a determination. The petition shall include all information set forth in paragraph (c) of 7 CFR 340.6. **If there are portions of the petition deemed to contain trade secret or confidential business information (CBI), each page of the petition containing such information should be marked “CBI Copy”.** In addition, those portions of the petition which are deemed “CBI” shall be so designated. The second copy shall have all such CBI deleted and shall have marked on each page where the CBI was deleted: “CBI Deleted.” **If a petition does not contain CBI, the first page of both copies shall be marked: “No CBI.”**

“Am I Regulated (AIR) Inquiry” Submission Requirements

[Am I Regulated Under 7 CFR part 340?](#)

AIRinquiry@aphis.usda.gov



Transferring a Permit or Notification?

- Permit/Notification number(s)
- New Owner Username (eAuthentication User ID)
- New Owner Name First, Middle (if any), Last
- New Owner Email
- New Owner Phone Number(s)
- Organization Name
- Previous Owner Name (submitter)
- Previous Owner Username (eAuthentication User ID) – if available, for verification purposes



Transferring a Permit or Notification?

Send to

Cynthia A. Eck

Document Control Officer

USDA APHIS BRS

4700 River Road, Unit 146,

Riverdale, MD 20737

You CAN email the signed company letterhead to:

Cynthia.a.eck@aphis.usda.gov



Compliance Report



Compliance Reporting Submission Requirements

- Planting ID - should not be CBI' d
- Location IDs - should not be CBI' d



How to Find More Information



Questions about CBI?

- Rochelle Langley – BQMS Quality Manager
- Cindy Eck – Document Control Officer

USDA/APHIS/BRS
Riverdale, MD

(301) 851-3906 or (301)851-3892

Rochelle.A.Langley@APHIS.USDA.GOV

Cynthia.A.Eck@APHIS.USDA.GOV



Closing Remarks

