

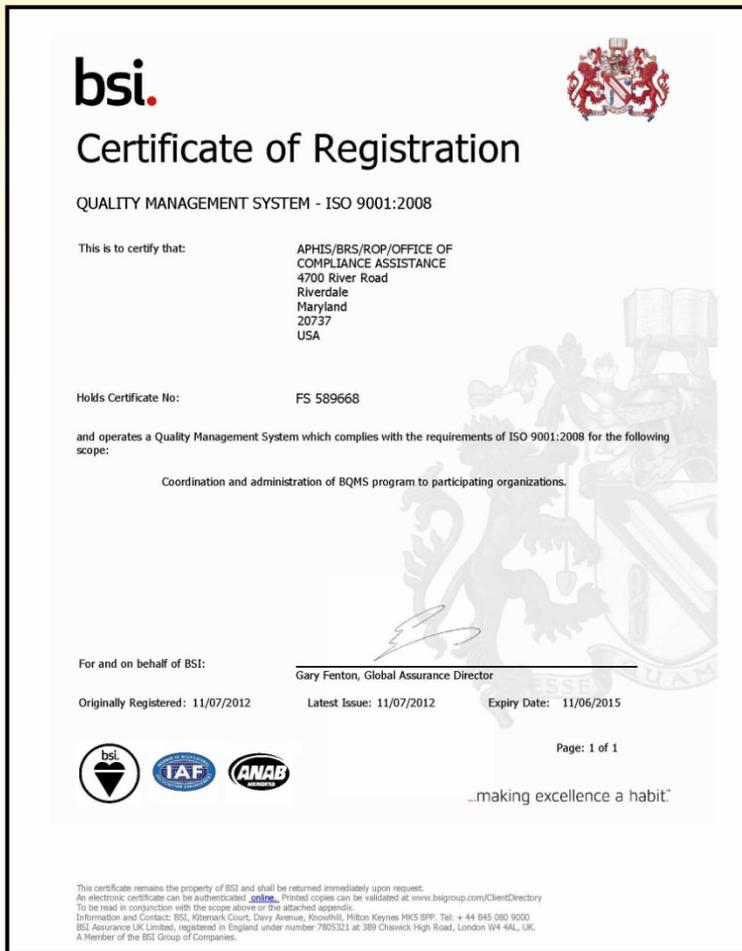


# **Office of Compliance Assistance 2012 Review**

**BRS Stakeholder Meeting  
December 5, 2012  
Samantha J. Simon**

# Office of Compliance Assistance

- November 7, 2012
- ISO 9001:2008
- Coordination and administration of BQMS Program to participating organizations



**bsi.** 

## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2008

This is to certify that: **APHIS/BRS/ROP/OFFICE OF COMPLIANCE ASSISTANCE**  
4700 River Road  
Riverdale  
Maryland  
20737  
USA

Holds Certificate No: **FS 589668**

and operates a Quality Management System which complies with the requirements of ISO 9001:2008 for the following scope:  
**Coordination and administration of BQMS program to participating organizations.**

For and on behalf of BSI:   
**Gary Fenton, Global Assurance Director**

Originally Registered: 11/07/2012    Latest Issue: 11/07/2012    Expiry Date: 11/06/2015

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To be read in conjunction with the scope above or the attached appendix.  
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# Biotechnology Quality Management System (BQMS) Program



- Objective: To help the regulated community- including academia and small businesses- develop management systems that enhance compliance with 7 CFR part 340
- 22 participants
  - 19 recognized
  - 2 in the process of being recognized
  - 1 on hold
- Large majority of release sites and acreage under the scope of a BQMS during FY 2012



# ETS-BQMS Partnership



- ETS-BQMS

- 5 audits conducted under the ETS-BQMS Memorandum of Understanding
- Cost savings to the Agency

- Auditor Training

- December 10-14 in Kansas City
- Partnership with ETS
- Internal and external auditors

# Templates for Permit and Notification Design Protocols



- May be used in the development of SOPs for the introduction of regulated articles
  - Address the operational controls for movements and environmental release processes
- Intended to facilitate the process and compliance with the requirements of 7 CFR part 340
- Do not need a BQMS



# Educational Workshops



- 5 workshops in FY 2012
  - AZ State Univ.; Univ. of MO (Columbia); Univ. of FL (Gainesville); NC A&T State Univ. (Greensboro); State Univ. of NY (Syracuse)
- Approximately 132 attendees
- Focus on academia and public researchers



# Educational Workshop Objectives

Knowledge of:

- Risk assessment application process
- Compliance inspection and enforcement processes
- Difference between permits and notifications
- Compliance assistance opportunities



# Educational Workshop Outcomes



- Positive feedback from participants
- Frequently Asked Questions
  - Application process and ePermits
  - Compliance to the regulations
  - Compliance inspection process
  - Compliance enforcement actions



# FY 2013 Compliance Assistance Activities



- Continue to focus on compliance assistance services
  - BQMS Program
  - Educational workshops
  
- Analysis of Data
  - 5 re-recognition audits
  - Are there trends?

# Office of Compliance Assistance

Questions?