Program Coordinator Duties

The Program Coordinator, also known as PC, receives telephone calls from the public specifically to adverse event repots (AERs), firm questions, or general questions in regard to the CVB. The PC also is responsible for signing APHIS Form 2008s (Form 2008s) for market release and reviewing other Form 2008s. The PC also moderates the daily Specialist Meetings.

The PC is assigned on a weekly basis by the Product Specialist, but can be reassigned on a daily basis if needed. Changes to the assigned PC duty should be documented in the IC In/Out Board of the IC Calendar, but to enhance communication, the Specialist may inform the BCAs and the CVB Administration Unit. PC duty is covered Monday through Friday, 8 a.m. through 4 p.m.

I. Signing and Reviewing 2008s for Market Determination

1. See **ICSOP0010**, *Processing Serial Records*, for information on Serial Release processes.
2. Signing and Reviewing Form 2008s
   a. See **ICWI0058**, *Ready for Signature Action in LSRTIS (Specialist and BCA duties)*, for LSRTIS workflow.
   b. Priority for the PC is signing Form 2008s for market determination. This is usually done prior to 11 a.m. for Electronic Notification for Serial Release (ENSR) emails to be sent to the manufacturers. The second ENSR goes out at 3 p.m. daily as well.
3. Reviewing Form 2008s at Specialist Review
   a. See **ICWI0048**, *Specialist Review Action within LSRTIS*.
   b. Next priority is reviewing Form 2008s needing attention (i.e., those with "I" or "NT" conclusions in testing, or those with specific Firm Dispositions or comments). This occurs after the Form 2008s are entered and QA'd for entry requirements (usually after lunch).

II. Phone Calls from Outside the CVB

Phone calls should be documented and recorded in the PhoneLog module within LSRTIS. See the current version of **ICWI0238**, *Tracking Customer Service using LSRTIS Phone Log*, for instructions on documenting these.

1. Adverse Event Reports
   a. See **ICSOP0017**, *Receiving Adverse Event Reports at the Center for Veterinary Biologics*, for further information.
   Note: The URL for the AER worksheets is not current in Version 4 of this SOP.
   b. The employee can either take the report directly from the caller and enter the information directly into the AER Website, or
   c. The employee can direct the caller to the CVB Website. There is currently a shortened website URL for the AER landing page. See the Program

Information Management and Security (PIMS) Program Analyst, Amber Peterson, for this URL.

2. FOIA
   Callers wanting specifics on previous AERs or other Confidential Business Information (CBI) may have to request this information through the Freedom of Information Act (FOIA) staff. Questions can be directed to the CVB PIMS Section Leader or the caller can be directed to the APHIS FOIA Website. Remind the caller that the licensing information and studies performed are property of the manufacturers (if applicable), and the manufacturers will have the opportunity to review this information for redaction of Confidential Business Information (CBI) prior to release.

   Remember that information already shared on the CVB Website or label information is public knowledge and does not have to be directed to FOIA staff.

   Current contact:
   APHIS FOIA Contact Information
   Tonya Woods, FOIA Director
   Legislative and Public Affairs
   Freedom of Information Act
   4700 River Road, Unit 50
   Riverdale, MD 20737

   Phone: 301-851-4102
   Fax: 301-734 -5941
   Email: foia.officer@aphis.usda.gov

3. Requests for Licensing of a New Biologic Product
   a. The employee can direct the caller to the CVB Website under Veterinary Biologics/Licensing a Biologic. The caller may want to familiarize themselves with this information prior to speaking with PEL staff.
   b. If the caller has received this information previously, direct the caller to the PEL Staff Assistant or the PEL Section Leader.

4. 116.5 Notifications from Licensed Manufacturers
   a. Be sure to get the following information from the manufacturer:
      i. Product(s), serial(s), or fraction(s) involved
      ii. Time frame of event
      iii. Preliminary suspect event
      iv. Location of event (especially important if manufacturer has multiple sites)
      v. Manufacturer's actions (internal hold, voluntary stop sale, destruction of the serial(s), or any other action)

b. The employee provides the information to the Specialist assigned to the firm, if applicable, and to the Section Leader, Compliance, for concurrence on manufacturer's action.
c. If samples have been received and still within the 7 or 3 day at risk window for testing, provide the information to the Laboratory Vet/Micros, current Outlook group: [redacted].
d. Also, determine if testing has been initiated by the Laboratory (do a serial stat). Discuss with the Laboratory if they should stop testing or not.

5. Questions from Licensed Manufacturing
   a. Verbal releases: CVB does not routinely give out verbal releases due to the ENSR. Further information can be found in **ICWI0240**, *Receipt of "Electronic Submissions" from PEL APHIS Form 2007s and APHIS Form 2008*, regarding this type of notification.
   b. Other information regarding specific submission questions may be provided to firm personnel who have APHIS Form 2007s on file for such information. The employee should do their due diligence to assure the information can be provided. See a Section Leader or Manager for questions.
   c. Reagent Requests – send requests to the applicable laboratory.
      Inform the caller they may email the APHIS Form 2018 requests to the CVB@aphis.usda.gov mailbox; which will then be forwarded to the applicable laboratory.

6. Information not under CVB Jurisdiction – examples:
   a. Owners wanting to know what to do with animals possibly exposed to Rabies
      i. Inform the owner to contact their local or State Veterinarian
      ii. Consult with IC Management regarding specific responses
   b. Information regarding importation of non-biological products
      i. Inform the caller to contact National Import Export Services (NIES) – Previously NCIE
      ii. May direct the call to the ePermits Website via the CVB Import/Export Website
   c. Information regarding NVSL testing
      Inform the caller to contact the applicable NVSL laboratory (DVL, DBL, PL). Current contact phone numbers can be found at the NVSL SharePoint site/Contact Info for NVSL Testing (NVSL Disease List)/external list.

7. Media Inquiries
    a. Must be forwarded to LPA (Legislative and Public Affairs). APHIS LPA contacts are Joelle Hayden and Lyndsay Cole.

Joelle Hayden
Joelle.r.Hayden@aphis.usda.gov
(ph) 301 851-4040 // 301 919 7129

Lyndsay Cole
Lyndsay.m.cole@aphis.usda.gov
(ph) 970 494-7410 // 301 538 9213

III. Moderator of Specialist Meetings

1. The PC will moderate the Specialist Meetings, take notes, and consult with Section Leaders if employee absences warrant cancelling the meeting.