



Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Inspection - On Site Sampler Training and Portal Submission

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ON SITE INSPECTION SAMPLER TRAINING

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Purpose

Review expectations regarding the procedures of sample collection, identification, and submission of biological samples for testing by the Center for Veterinary Biologics (CVB), and the handling and storage of Animal and Plant Health Inspection Service (APHIS) reserve samples at licensed establishments.

Authorizations

9CFR 113.3 and VSM 800.59

- Authorized Government Samplers
 - *Personnel designated and trained to select, submit and retain samples required by the Center for Veterinary Biologics (CVB)*
 - *Individual authorized for sampling by the CVB - Inspection and Compliance (CVB-IC)*
 - *Samples may also be selected by an APHIS Employee*
- A sampler cannot perform sampler duties until authorized by CVB-IC
 - *Even if trained by an Establishment Employee or CVB Representative*

Authorized Government Sampler Requirements

- APHIS Form 2007 must be submitted to CVB-IC
 - *Include request for sampling authorization*
 - *Include training documentation or statement indicating the employee has been trained by a person familiar with sampling procedures according to 9 CFR 113.3 and VSM 800.59*
- The Authorized Government Sampler must be located at a site on the establishment license.
- They are responsible for the chain of custody of the samples – from selection through submission or retention

Imported Product Samples

- Each Shipment to the United States should be accompanied by a new sample submission.
 - *Each Sample Submission will receive a new Sample Code*
 - *Foreign Manufacturer Must Ship samples to the U.S. Permittee*
 - *The U.S. Permittee will be the authorized Sampler to submit to the CVB*
 - *The Foreign Manufacturer may be trained as Samplers to select samplers if :*
 - There are authorized samplers at the quarantine site in the United States.
 - The sampler at the U.S. quarantine site must be located at the quarantine site (on licensed premises)

Samples Required

- Market Release [9 CFR 113.3(a)]
- Support Product Licensure [9 CFR 113.3.(c)]
 - *Prelicensing Serials*
 - *Master Seeds, Master Cells*
- Support Changes to Outline of Production [9 CFR 113.3.(c)]
- Support Technology Transfers – either as part of a merger or sublicensing situation
 - *Each licensee and permittee shall furnish representative samples (in representative containers) of each serial or subserial of a biological product manufactured in the United States or imported as part of the market release process--9CFR113.3*

Final container Representative Sample

- The entire serial or subserial should be presented for sampling.
- Sampling should include all container sizes of the same serial in representative proportions.
- Samples should be selected from several containers or trays in order to obtain samples that represent different time periods of the filling process or different locations in the lyophilizer.
- Selection made using a plan involving judgement factors (random selection not typically used for biologics sampling).

Other Types of Representative Samples

- **Bulk Samples - as prescribed in 9 CFR 113.3 (a)(1) and (3)**
 - *Bulk samples should only be submitted if approved or requested by the CVB.*
 - The entire serial should be presented for sampling.
 - The identity of the bulk should be verified by checking tags, labels, or other markings on the tank or container in which the bulk product is held.
 - Agitators or mixers in the tanks or containers should be in operation for enough time to ensure the product is completely mixed and uniform.
- **Serum Samples – used for host animal potency tests, see VSM 800.79**
 - *Submit samples if needed for confirmatory testing.*
 - Submit only with an APHIS Form 2020.
 - Do NOT submit through NCAH Portal
- **Panel Members – used for Section V testing**
 - Submit only with an APHIS Form 2020.
 - Do NOT submit through NCAH Portal

Clarification of VSM 800.59, Section III.B.1. – Selection versus Submission

- The number of samples selected for each pre-release serial/subserial is specified in 9 CFR 113.3(b) or in the Outline of Production

This is the number of samples to be taken by the authorized sampler - remember to also account for the number of reserve samples required

- A subset of at least two containers or a sufficient quantity of containers to conduct a potency test are selected and submitted to CVB.
- If no additional samples are requested by CVB, upon market release the remaining submission samples selected may be returned to salable inventory – proper internal documentation should be maintained but no need to submit an APHIS 2008 for an inventory correction

Reduced sample submission is a privilege and if there are regulatory concerns, this privilege may be suspended.

Sample Identification/Labels

1. Establishment/Permit Name
2. Establishment/ Permit Number
3. True name of the product (may use abbreviations)
4. Serial or Subserial number
5. Volume of contents
6. Number of doses or tests or volume
7. Expiration date (If available)
8. Product code
9. Red check mark if the ingredients include thimerosal. (For appropriate disposal by APHIS)

Sample Submission Information

(NCAH Portal or APHIS Form 2020)

- If more than one sample size is submitted, use the smallest volume for entry
- However, multiple dose sizes submitted should be entered into the Remark Section.
- If the volume is less than 1 unit, round the number up to 1. If the volume is not a whole number, but is greater than 1 (i.e. 10.5 mL), round down to the nearest whole number.
- **Container Type – Doses, mLs, Units.**
 - *For diagnostic test kits, use units.*
 - *For Bulk or FFMs, use mL*
 - *Most others will use Doses*

Sample Purpose (Type) APHIS Form 2020

All samples listed on an individual Form 2020 must have the SAME Purpose

- Routine (Concurrent Samples): When a manufacturer submits routine post-license samples to the CVB, they are eligible to be selected for confirmatory (check) testing.
- Retention Samples: CVB has requested the submission of the APHIS Reserve samples
- Master Seed – list the Special Test Request (STR) Authorization number in Block 16, Remarks
- Resubmission (Specify reason in Remarks): for additional samples submitted in response to CVB requests or other circumstance
- Cell Line – list the STR Authorization number in Block 16, Remarks
- Other (Specify in Remarks): Stock cultures, serums, or panel members (Specified in Block 16) These usually do not get sample codes assigned with APHIS.
- Prelicensing – includes both prelicensing and outline change samples. List the STR Authorization number in Remarks

NCAH Portal Submission

- See NCAH Portal User Guides
 - Guide 6, Submitting Routine Biologics Samples
 - Guide 7, Submitting Special Request Biologics Samples
 - Guide 8, How to Generate Packing Slips for Biological Samples
- Authorized sampler is responsible for:
 - *Entry of Biological Sample information*
 - *Print packing slips*
 - *Enclose packing slip with package of samples*
 - *Submit to CVB*
- Only an Authorized Sampler can search on sample submission

NCAH Portal Access

https://www.aphis.usda.gov/animal_health/vet_biologics/publications/2-PortalRoles.pdf

1. Firm must be Portal Enabled
2. Employee Must have Level 2 (Verified) E-Authentication with USDA
3. Must submit Employee's APHIS Form 2007 to the CVB with user name
4. APHIS Form 2007 Must have applicable Role selected (Sampler)


Shipment of Samples to CVB

- Samples must be adequately identified
 - *Sample identification much match the information listed on the APHIS Form 2020 or the NCAH Portal Packing Slip*
 - *If the sample and the Form 2020/packing slip do not match, this may result in destruction of the samples and a delay in market release of the serial*
- Samples should be packaged to withstand leakage of contents, pressure changes, or other conditions common to transportation of veterinary biologics
- Samples shipment should be maintained at the proper temperature, as listed on the label or Outline of Production

Shipment of samples to CVB is the responsibility of the licensee/permittee

Additional Samples Requested

- If the CVB requests additional samples to be submitted due to testing:
 - The Firm will receive an email at ENSR address with the following:

 **NCAH Portal Updates!**

The following Submissions have been updated by CVB in the NCAH Portal today:

Samples Open Request:

Sample Info	CVB Sample Code	Number Requested	
Product: 264853 - Serial #: 876888	pppp	7	Re-submit


Samples that have been received by the CVB greater than 60 days do not have information stored within the NCAH Portal, therefore, a status update will not be shown within the NCAH Portal. This email serves as the ONLY notification of this request. For more information, contact NCAH Sample Processing at 515-337-7212 or NCAH_Samples@aphis.usda.gov

[Click Here to view detailed information about these and other Submissions](#)

Additional Samples Requested... cont.

- Within the Portal Screen -- An Open Sample Request will Appear:

Biologics Samples 

Show 100  entries Search:

Submission Info	Site	Sample Code	Status	Submitter	Submission Date
Est: 999, Product: 264853, Serial #: 876888	125 1st Street, Ames, IA 50010	PPPP	Open Sample Request	Jeanette Watson	12/23/2019 info

Showing 1 to 1 of 1 entries

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- If Choosing “Resubmit Samples” option, the applicable information will Auto populate, with the exception of # samples
- Refer to Training Guides and Videos

CVB Sample Selection Period

- **7 Day Selection (Vaccines/Bacterins)**
 - *Samples logged on March 14 (Day 0)*
 - *Selection day begins March 15 (Day 1) through March 21 (Day 7)*
 - *The earliest possible consideration for release date is March 22*

- **3 Day Selection (Diagnostic Test Kits)**
 - *Samples logged on March 14 (Day 0)*
 - *Selection day begins March 15 (Day 1) through March 17 (Day 3)*
 - *The earliest possible consideration for release date is March 18*

Reserve (retention) Samples

9 CFR 113.3(e)

- Selected and maintained by an authorized sampler – including documented chain of custody
- Samples must be rendered Tamper Evident
- Samples Must be Authenticated – Initialed and Dated (By Authorized Sampler)
- Samples must be held in a special compartment set aside under refrigeration at the storage temperature recommended on the labels, until requested by the CVB.
- Samples must be maintained on licensed premise for 6 months past expiration date

These samples are held in reserve for the CVB and not for use by the firm. CVB may request submission of these samples for up to 6 months beyond the

expiration date as the serial.

Approved by: KGRABER
Date: 02 Feb 2021
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Expectations for an Authorized Sampler

- Sample Selection is representative of the whole process
- Sample identification is complete and accurate
- Samples are stored & handled appropriately [9 CFR 114.111]
 - *Includes APHIS reserve samples [9 CFR 113.3(e)]*
- Sample Submission Information complete and accurate
 - *NCAH Portal*
 - *APHIS Form 2020*
- Samples are adequately packaged and submitted to CVB

Sampler Responsibility

From VSM 800.59

“Negligent or deliberate disregard for proper sampling procedures, specified in 9 CFR 113.3, may be grounds for revocation or suspension of product and/or establishment licenses or permits.”

Sampling authorization can be suspended – if samples cannot be submitted, serials cannot be considered for market release