Audits and Reference Slips for IC Documents

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Source Documents: CVB-SOP-0032, *Processing Serial Records*, and CVB-SOP-0048, *Export Documents and Certificates of Licensing and Inspection*

Specialists, Biologics Compliance Assistants (BCA), and Export Document Examiners (EDE) may attach reference slips to outgoing documents or audit documents back prior to completion. The documents included in these processes are:

- Veterinary Biologics Production and Test Report (APHIS Form 2008s and 2008a)
- Official Export Certificate for Animal Biological Products (APHIS Form 2017)
- Certificate of Licensing and Inspection (APHIS Forms 2046, 2046-S, 2047, and 2047-S)
- Attestations (GMP-Like certificates)
- Ingredients of Animal Origin (Certificates indicating policies of ingredients of animal origin)
- Request for information on Record Audits. Refer to CVB-SOP-5116, Section 6.3 on the procedure for record audits.

A reference slip is used to communicate information back to the submitter without interfering with the completion of the record. There are <u>two reasons that are most likely</u> used for a reference slip.

Reason for Reference	Example of When to Use	2008s	Certificates
Action	OP should be updated per letter from Reviewer	Yes	Yes
For Information	To clarify expectations	Yes	Yes

There are many other reasons listed in the drop down but should not be used as a reference slip for APHIS Form 2008s or Export Documentation.

An Audit stops the IC process. There may be many reasons a document process is interrupted.

Reason for Audit	2008s	Certificates
Expired Reference	Yes	No
Inadvertent NCAH Portal entry	Yes	No
Incomplete Form	Yes	Yes
Information Does Not Reflect OP	Yes	Yes
Invalid Establishment	Yes	Yes
Invalid Expiration Date	Yes	Yes - 2017s only
Invalid Product Number	Yes	Yes
Previously Released by APHIS	Yes	Maybe
Product Under Regulatory Action	Yes	Yes
Request for Data	Yes	Yes
Serial not Released by APHIS	Yes	Yes - 2017s only

A. Reference Slips

A reference slip may be initiated by any Inspection and Compliance (IC) Program employee to communicate specific information back to the submitter. A reference slip does not stop the IC process and the record is processed.

1. Reference slips can be added to APHIS Form 2008s at each tab in the Serial Action Sheet (except for Product Manager Review and Miscellaneous). It is found on the tab for each Action. If there is already a reference slip, the area will be blank.

2. Reference slips can be added to Export documents for a specific record at any action during the review and finalization process. The reference slip is found on the individual certificate record.

3. Reference slips (for both types of documents) are filled out in LSRTIS.

   a. Reason for reference slip – select from drop down

Reason for Reference	Example of When to Use
Action	OP should be updated per letter from Reviewer
For Information	To clarify expectations

   b. Signature (automatic)
   c. Establishment Address – select from drop down or you can choose to add Free Form Address – if you add Free Form Address, enter information in Address Line 1, 2, and 3 (as needed) and City, State, Zip

d. Establishment Employee – select from drop down or you can choose to add Free Form Employee Name – if you add Free Form Employee Name, enter Employee Name. The employee chosen may be the submitter or the Liaison.
e. Remarks should include the specific information for the reason a reference slip is being created.
f. Click on Create Reference Slip

4. Return to Firm

a. If the record will be returned via the NCAH Portal, no further action is needed.
b. If the records will be returned hard copy (note – all export documents are currently returned hard copy) follow the following instructions:

For APHIS Form 2008s

i. Under the Attachment category, choose the Reference Slip hyperlink.
ii. Open the attachment as a pdf and print.
iii. The document should be signed (wet signature).
iv. Return the reference slip with the hard copy APHIS Form 2008

For Certificates

v. Print and sign a copy of the reference slip and attach it to the certificate.

5. Since reference slips may be added at any step and this does not stop the process, the submission must be moved forward through the system.

B. Audits

Audits may be created by the Specialist, BCA, or EDE. Once an audit is created, the audit should be signed by the person who initiated the audit. The authority to audit at each action is based on why the audit is being done. Some audits created by the BCA or EDE must be reviewed by the Specialist or Export Manager prior to finalization.

1. Authorities

Reason for Audit	BCA/EDE	Specialist/Export Manager
Expired Reference	Yes	Yes
Inadvertent NCAH Portal entry	Yes	Yes
Incomplete Form	Yes	Yes
Invalid Establishment	Yes	Yes
Invalid Expiration Date	Yes	Yes
Invalid Product Number	Yes	Yes
Previously Released/Processed by APHIS	Yes	Yes
Serial not Released by APHIS	Yes	Yes
Product Under Regulatory Action	No	Yes
Request for Data	No	Yes
Info Does Not Reflect OP	No – should go to the Specialist	Yes

2. Examples of Audit Reasons for APHIS Form 2008s

BCA/EDE Examples:

a. The form is incomplete or used the APHIS Form 2008 for the second page instead of the APHIS Form 2008a.
b. The attached test summary identification does not match the information submitted via the NCAH Portal (i.e Wrong Serial Number, Product Code, or fill date).
c. Incorrect information – (i.e. - Doses on attachment does not match the portal entry.)
d. Serial is expired
e. Attached Test Data File is not “flattened”.

Specialist Examples:

a. A test conclusion is listed as a No Test but is actually Inconclusive. (This may also be done via a reference slip.)
b. Validation criteria listed in the OP not included on the APHIS Form 2008.

3. Examples of Audit Reasons for Export Documents
   a. At primary review by the EDE
      i. The Export Certificate, (APHIS Form 2017), does not list the correct dose size or the document exceeds inventory released.
      ii. The serial listed on the Export Certificate (APHIS Form 2017) is not released.
      iii. The Export Certificate lists products from multiple establishments.
      iv. Inconsistent details from the header of pages of the submitted Certificate of Licensing and Inspection (different addresses and/or different codes).
      v. The Certificate of Licensing and Inspection submitted is two sided.
      vi. The product license listed on the Certificate of Licensing and Inspection is not active. Exceptions can be made for current inventory of firms participating in a merger. Discuss with Export Manager.

vii. Pages appended to the Certificate of Licensing and Inspection do not list the page x of y format, the product code, label number (when applicable) and/or establishment number.
viii. Incorrect/Unofficial form used.
ix. Firm employees signed the block for the certifying official.
x. True name is incorrect or is not presented as it is on the product license.

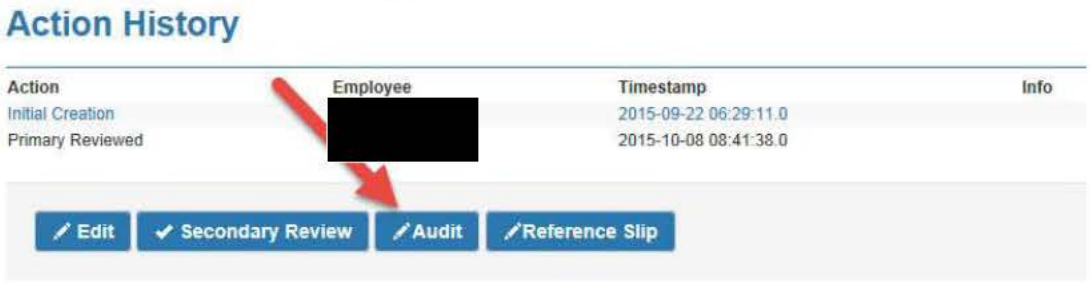
b. Example of Audit reasons by Export Manager during Secondary Review
i. Information other than country of destination next to the USDA Official signature block (Certificates of Licensing and Inspection) without prior authorization.
ii. The Export Certificate is from a product restricted to a specific recipient (FFM).
iii. The Export Certificate does not list the country destination.
iv. The discrepancy is verified by official hard-copy documents in the file room or on the CVB SharePoint site.
v. The gmp-like statement deviates from the examples provided or is not listed in the outline of production. The gmp-like statements which only reference the firm may be submitted as stand-alone documents.
vi. An APHIS Form 2008 was appended to the Certificate of Licensing and Inspection (APHIS Forms 2046, 2046-S, 2047, or 2047-S).
vii. Incorrect establishment or product license date used.
viii. The information submitted is not available on file.
ix. The information provided in special labels do not list the disclaimer.

4. Audit Process
a. Audits can be added to APHIS Form 2008s at each tab in the Serial Action Sheet (except for Product Manager Review and Misc.). It is found on the tab for each Action. If there is already an Audit, the area will be blank.

i. Choose the Audit Reason from the List of Values (LOVs) (mandatory field).
Note: The default for this field is "Expired Reference."
ii. Signature (automatically filled in by user logged in)
iii. Comments – free field text for the user to enter information that they want relayed back to the establishment – limit of 499 characters.
Note: This wording goes directly back to the manufacturer.
iv. Once audited, the Form 2008 will move to <u>BCA Ready for Approval.</u>
v. The system sends the Audit and APHIS Form 2008 back to the firm after the 2008 record is signed.

vi. If the 2008 was submitted hard copy, the audit should be printed and signed as well.

b. Audits can be added to Export documents for a specific record at any action during the review and finalization process.



i. Choose the product to audit – the list of product codes available will be in the drop down.

ii. Audit Reason from the List of Values (LOVs) (mandatory field).
Note: The default for this field is "Expired Reference."

iii. Signature (automatically filled in by user logged in)

iv. Comments – free field text for the user to enter information that they want relayed back to the establishment – limit of 499 characters.
Note: This wording goes directly back to the manufacturer.

v. Once audited, Certificate will have a finalize button at the bottom of the page. This action will finalize the certificate.

5. Return to Firm
   a. If the record will be returned via the NCAH Portal, no further action is needed, no hard copy is needed, but the Step 5.b.iii. must be followed.

b. If the records will be returned hard copy follow the following instructions:

For APHIS Form 2008s – under BCA Ready for Approval

i. Under the Audit Actions, open PDF and print
ii. Attach to hard copy APHIS Form 2008
iii. Move forward to Ready for Signature – have auditor physically and electronically sign the audit form.

For Certificates

i. Print and sign a copy of the audit slip and attach it to the certificate (Hard Copy Certificates.
ii. Update shipping information in LSRTIS.

If the submission was received through the NCAH Portal, finalize the certificate after the audit and "Update Shipping" by indicating "Portal" in the list of options.