Entry and Primary Review of Export Documents (APHIS Form 2017 and Certificates of Licensing and Inspection)

Export Document Examiner

A. Receipt of Export Documents from Licensee/Permittee/Distributor:

Hard Copy Submissions:

1. Apply (stamp) date received to cover letters and to the <u>back</u> of APHIS Forms 2017. Certificates of Licensing and Inspection (CLIs) do not receive the date received stamp.

2. A cover letter does not always accompany an export document; however, a cover letter is preferable. The cover letter may include additional information or explain requests, such as the use of an original licensing date.

Portal Submissions:

1. Submissions are entered by designated firm personnel via the NCAH Portal.

2. The submissions may also include cover letters, air bills, and additional instructions. NOTE: The use of the original licensing date is not eligible for Portal submissions.

B. The Export Module in LSRTIS can be found under IC – Exports Tab

1. Hard copy submissions - Most fields are auto fill, so in many cases you can start typing and it automatically completes the field or provides options in the form of a drop down. Select correct information from the drop down list.

2. Portal submissions – The Portal user conducts this step. Portal submissions will have a Y and hard copy submissions will have an N.

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C. Create LSRTIS Record (hard copy submissions only)

1. Go to Export Module in LSRTIS, under IC heading (red circle)

2. Click on Create Certificate (yellow highlight)
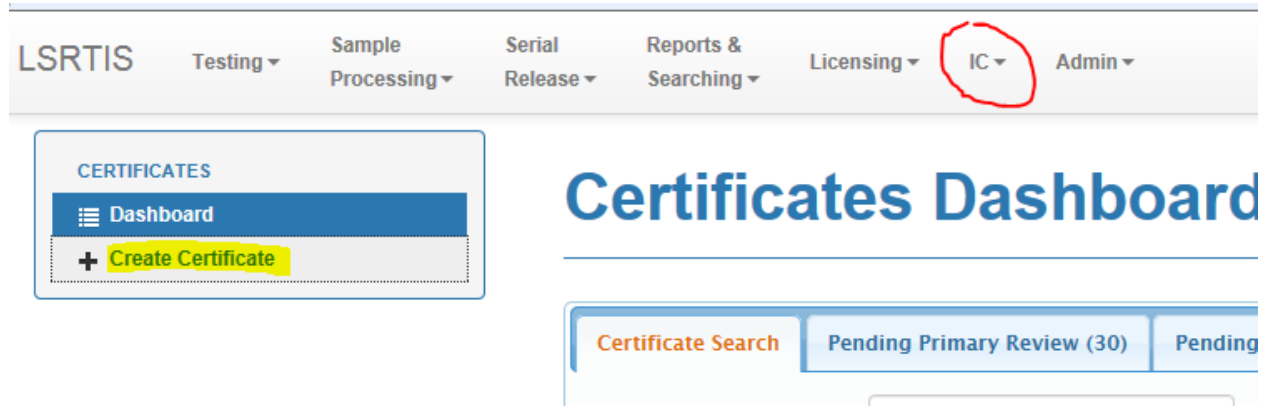
3. Enter Information (* required fields)
   a. Establishment * – this is the assigned establishment number of the manufacturer of the product or serial
   b. Submitting Establishment (if different) – distributors or other manufacturers can submit APHIS Forms 2017 for serials they are going to export
   b. Establishment Site * – if a specific site is designated on the export document, choose that site in the drop down. If not, choose the main site where production occurs.
   c. Type (Certificate type) * – See current version of **ICSOP0044**, *Export Certificates and Certificates of Licensing and Inspection*, for definitions of certificate types
      i. 16-4
      ii. APHIS Form 2017
      iii. APHIS Form 2046
      iv. APHIS Form 2046-S
      v. APHIS Form 2047
      vi. APHIS Form 2047-S
      vii. Attestation
      viii. Attestation (Spanish)
      ix. Ingredients of Animal Origin Statement
      x. Ingredients of Animal Origin Statement (Spanish)
   d. Date Received*
   e. Destination Country – if listed
   f. Certificates Requested (not applicable for APHIS Form 2017s)
   g. Products
      i. The True Name will populate automatically after entering Product Code.
      ii. Select the trade name provided if available.

        iii.   APHIS Form 2017 – several products and serials may listed. Add the information for each certificate by clicking on +Add.

        iv.   APHIS Form 2046, APHIS Form 2046-S – several products may be listed. Add the information for each certificate by clicking on +Add.

        v.   APHIS Form 2047, APHIS Form 2047-S – only one product may be listed.

        vi.   Attestation or Ingredients of Animal Origin Statement
- No products are listed
- Submit as a separate document

Not appended to a Certificate of Licensing and Inspection (CLI).

4. Visually review information – corrections can be made at this time if the data is incorrect. *Note: Establishment Number" and "Type" cannot be edited after you click on Create.*

5. If data is correct, Click on "✓Create."

6. Date and initial cover letter by the received date stamp after export documents have been entered into LSRTIS

D. Primary Review

1. Certificate Records are found in LRSTIS – Exports, Pending Primary Review tab.

2. If a data entry error from a hard copy submission is noted in LSRTIS – it can be corrected at this point. Portal submissions with data entry errors should be audited.
   a. Click "Edit" at the bottom of the page.
   b. Correct any fields with errors.
   c. Verify information is correct.
   d. Click "Update"

e.   Cancel can be used to exit the editing interface without saving changes. If the data entry error is the Establishment Number or the type of certificate, you must submit a system admin request. Guidance is provided at PIMSSOP0008.

3.   Certificate of Licensing and Inspection

   a.   Print Product License Profile
      i.   Go into LSRTIS; click "Licensing" on the top of the page to open the submenu.
      ii. Click on "Product Licenses" to move to the Product License Search Page
      iii. Fill in the "Establishment Number" and "Product Code". Click "Search"
      iv. A list will be populated based on the information entered. Click "Show" in line with the correct information relating to the CLI. This will bring up the Product License page.
      v.   Click "Export Profile" to generate a PDF version.
      vi. Print the FIRST page of the generate PDF.

Note: Product License Info Sheets do not need to be created for attestations or ingredients of animal origin stand-alone statements.

   b.   Verify Establishment License Date and write this on the Product License Profile.
      i.   Go into LSRTIS; click "Licensing" on the top of the page to open the submenu
      ii. Click on "Establishment Mgmt" to move to the Product License Search Page
      iii. Fill in the "Establishment Number." Click "Search"
      iv. Click on "Show" and this will bring up the Establishment.
           The First Issue Date and Current Issue Date are both at the top of the page under Establishment Info. If the cover letter requested the original establishment license date, note this on the Product License Profile.

   c.   Verify product information on the certificate matches the Product License Profile. If they match, put a check mark next to the field. If they do not match, note the discrepancy. Check the following:
      i.   Establishment Number and Name
      ii. Product Code
      iii. True Name
      iv. Status (must be active)
      v.   Product License Date (Firms may request original licensure date.)
      vi. License Restrictions

   d.   Verify the proper form was used
      i.   "S" form versions (Spanish) should have a complete English translation.

    ii. APHIS Forms 2047 and 2047-S should only be used for product codes with restrictions. Only one product code may be used for these forms.

    iii. The true name of the product must be written as it appears on the product license. The Spanish true name must match a true name depicted in labels that are active and on file at the Center for Veterinary Biologics.

e. Check additional information that is not on the Product License Profile and note these additions on the Product License Profile. They may include the following:

    i. Trade Names – if not in LSRTIS, labels available on SharePoint may be used.

    ii. Product Labels – firm should supply the correct APHIS File Number – review against labels on Mail Log, SharePoint or in the file room.

    iii. Ingredients of Animal Origin Statement – as allowed for in the Outline or Production or template provided by the Center for Veterinary Biologics.

    iv. Statements regarding good manufacturing practices (Attestations)

    v. Compositions and/or formulations – write "formulations" on the Product License Profile

      o Compositions and/or formulations can be verified by comparing information to previously reviewed Export Documents.

      o These Export Documents are copied and placed in a Mock Book.

      o If the composition and/or formulation does not match the information in the Mock Book, annotate either the information does not match or there is no mock information.

    vi. Pages – If the certificate has appended pages, these must be numbered using the format "page X of Y." Portal submission attachments must be numbered starting with Page 2 of Y.

f. Once all the information has been reviewed Primary Review and is correct:

    i. Initial and date the top of the Product License Profile

    ii. Go to Pending Primary Review Tab in Certificates Dashboard

      o Search for the record

      o Click on Info and open the certificate record

      o Click on "√ Primary Review" to move record forward.

    iii. If there are no discrepancies, eliminate any unused space in Blocks 4-7, space on the left side of the APHIS signature block, and empty space of the appended page with a diagonal line from top-left to bottom right.

    iv. Provide hard copy of CLI and Product License Profile to Secondary Reviewer.

g. If the CLI is not complete or has incorrect information, the document may be audited. See most current version of **ICWI0075**, *Audits and Reference Slips for IC Documents*.

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4. Export Certificate (APHIS 2017)

   a. Go to Pending Primary Review Tab in Certificates Dashboard
      i. Search for the record
      ii. Click on Info and open the certificate record
      iii. Click on Serial Stat located at the end of the Product/Serial line for each serial – this brings up the serial status for each serial listed.

Licensing

Product/Serials

Product	True Name	Tradename	Serial	Number Of Containers	Size Of Containers	Doses Type	Most Recent Exp Date	
■	Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus	Newcastle LaSota	■	1000	1	Doses	12/23/2016	Serial Stat
	Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus	Newcastle LaSota		1000	1	Doses	04/28/2016	Serial Stat
	Newcastle Disease Vaccine, B1 Type, LaSota Strain, Live Virus	Newcastle LaSota		1000	1	Doses	07/24/2016	Serial Stat

   b. Review information on the APHIS Form 2017 against the information on the Serial Status
      i. Product Code (Block 3) and Name (True Name) of the product (Block 4) corresponds to the licensed product
         Trade Name can be listed in Block 4 – this can be verified through Labels scanned onto SharePoint File Room.
      ii. Serial has been released for market – *Note: An export certificate can NOT be issued if serial has not been released by APHIS.*
      iii. Container size/dose (Block 7)
      iv. Inventory – Compare the inventory remaining to ensure there are enough doses to be shipped under this export certificate. Previously issued exports are shown on the serial status.
      v. Expiration date (Block 8)
      vi. Establishment number (Block 9). If there are discrepancies, note them for the secondary reviewer or audit, finalize, and return the export certificate.

   c. If no discrepancies in hard copy submissions, eliminate unused space in Blocks 3-9 with a diagonal line from top-left to bottom-right (unused space between Blocks 3 through 9).

   d. Click on "√ Primary Review" to move record forward and provide hard copy to Secondary Reviewer.

   e. If the APHIS Form 2017 is not complete or has incorrect information, the document may be audited. See most current version of **ICWI0075.**