IC Pre-Inspection Packet Checklist – LSRTIS Information and Preparation

The order of the information listed below is <u>not</u> in priority order. Each report or search should be considered as part of the preparation for inspection or as information required while on inspection. LSRTIS/Mail Log (LSRTIS/ML) is a powerful information tool and as we continue to use LSRTIS/ML, we will find better ways to search and sort information for the purposes of inspection.

The information can be put in a pdf or Excel format. The information may be printed or saved on the computer for use during the inspection. While we also can retrieve this information while at the firms using our hotspot, there may be times in which there is equipment issues – so don't be left without any preparation material, carry a hardcopy or save to your desktop.

1. Establishment Mgmt
LSRTIS > Licensing > Establishment Mgmt
  Enter: Est. #
  Export Profile

This provides overarching information about the firm.
- Portal Enabled
- Mail Address
- All Sites (for multi-site firms, including inactive)
- Active USDA Employee Assignments
- Reasons for Establishment License Reissue
- Mergers/Purchases

It can be long since it also lists active employees for the establishment.

2. Establishment Sites (for site you are inspecting)
LSRTIS > Licensing > Establishment Sites
  Enter: Est. #
    Status > Active
    Pick "In State" if applicable to the inspection

This provides more site specific information, including the telephone number for the site. Please note the Min Years Between Inspections and the Max Years Between Inspections. If your inspection indicates a change to this inspection interval is needed, please inform Section Leader, Inspection, when you return with the reason why.

3. Establishment Employees (List of APHIS Form 2007 on File with CVB)
LSRTIS > Licensing > Establishment Employees
  Enter: Est. #
    Site City or State (or both or neither)
    Click on "Only Active Employees"
    Click on "Only Active Employees for Establishment"

The Excel spreadsheet is more beneficial for this listing as it is searchable on your computer, but the pdf is cleaner. Currently, the pdf does not include the eauth user name.

4. Labels

LSRTIS > Licensing > Labels Search
>> Enter: Est. #
>>> Label Status: Active
>>> Click on "Only Active Licenses"
>>>> – note, this excludes any products in prelicensing
>> NOTE: Trade names are on this list.

Pay special attention to extended labels with expiration dates.
As a part of the pre-inspection preparation, you may want to run the report without choosing a Label Status and indicating an expiration date for the last two years (or since the last inspection). Auditing the "use" or inventory of these inactive/expired labels may be a good way to test label control.

5. Product Licenses

LSRTIS > Licensing > Product Licenses
>> Enter: Est. #
>>> License Status: Active
>> NOTE: Repeat this step with License Status as "Prelicense" and "FDA-EREA."

For this report, the Excel spreadsheet has much more useable information.
When conducting pre-inspection preparation, note the following:

- Conditional Licenses will have an expiration date under "License Expiration Date."
  - Are they continuing to make a diligent effort towards full licensure?
  - Recently Policy, Evaluation, and Licensing (PEL) has not automatically been re-issuing conditional licenses, especially when a fully licensed product has been licensed by another firm.
- Chose at least one Biotech product for auditing, if possible.
- If the date is not filled out in the "Expiration Dating Verification Date" column, this may be a good product to review why. There may be many blanks, so choose a product that has a high volume of released doses.
- Products containing FFM product are clearly listed. Use this to trace back to the FFM
- Combination packages are listed on this spreadsheet – encourage review of packaging for these products – this may include review of Section V testing for bacterins used as diluents.

6. Master Seeds

LSRTIS > Licensing > Master Seeds
>> Enter: Est. #
>>> Status: Active Inventory

7. Master Cells

LSRTIS > Licensing > Master Cells
>> Enter: Est. #
>>> Status: Active Inventory

For both Master Seeds and Master Cells, using the date listed in "Approval Date(s)" column can provide you information on newly approved seeds and cells. This may be a good place to ensure the inventory is correct (near the beginning of use).

Another search option is entering the regulatory status as "Disapproved." You may have to research why as this is not always clear in the Seed or Cell record. Knowing where this "disapproved" inventory is and its use may show control in the prelicensing functions.

8. Licensing Plan
LSRTIS > Licensing > Licensing Plans
> Enter: Est. #
> License Status: Prelicensing

The licensing plan is a useful tool. It lists parent product (if applicable), seeds and cells, risk analysis (if applicable), manufacturing process, Efficacy/Kit Sensitivity-Specificity, Safety/Kit field trial, Testing, Prelicensing Serials, and Other. The applicable ML are listed. The Reviewer Synopsis can also be helpful. While we can get this information from the ML, the Licensing Plan has it all in one place.

9. List of APHIS Form 2008s (2008s) Received
LSRTIS > Reports & Searching > APHIS 2008 Search

This search can be done in several ways to target specific information or use the Excel spreadsheet to sort for specific information.

> ### Serials Signed by Specialist
> Enter: Est. #
> > With an Action of: APHIS 2008 Signed by Specialist
> > > NOTE: Can be left blank to see all serials submitted.
> > Action Timestamp: From date of last inspection to today

> ### Missing Serials – found because there is a 2008 but no samples
> Enter: Est. #
> > Click "Has No Samples"
> > Serial Status: Active
> > Action Timestamp: From date of last inspection to today

Reminder – 2008s submitted for Reprocess & Retest are not expected to have samples. Also, if the firm uses sequential numbering to assign serial numbers, you may be able to see this in a listing and ask about any missing numbers.

> ### Release Requirements
> > Enter: Est. #
> > Click "Release Criteria Required?"
> > Action Timestamp: From date of last inspection to today

This is helpful to ensure they are meeting the expectation related to marketing release. Check and see if the completion date was done to double check the firm's compliance.

10. Unsatisfactory or Unmarketable Serials
LSRTIS > Reports & Searching > APHIS 2008 Search
        Enter: Est. #
        APHIS Disposition: Test Completed UNSATISFACTORY and/or
                            Other – UNSATISFACTORY Based on Firm's
                            Results
                            and/or Other – Serial NOT RELEASED FOR
                            MARKET
        Action Timestamp: From date of last inspection to today

This search should be used as preparation tool. Reminder, most serials initially marked as not to be marketed have additional history, and the disposition may be changed based on additional information. All serials in these categories should be researched prior to the inspection.
REMINDER – Serials marked "Tests Completed Unsatisfactory" and in some cases the other two dispositions above may require CVB to observe the destruction.

11. Internal Doses Report (this is only a pdf report)
LSRTIS > Reports & Searching > Reports > Internal Doses Produced
        Enter: Est. #
        Enter From Date: Date of Last Inspection
        Enter To Date: Today's Date
        Click on PDF

This report lists the number of serials and doses released to the marketplace per product code. It also shows which products have had serials destroyed by the firm. It should be used in preparing for serial audits of specific products. It is advised to audit a product which is produced often and also a product that is not prepared as often. It is best not to choose the same product codes as audited in previous inspections unless there were significant issues.

12. Most Recent Release Date
LSRTIS > Reports & Searching > Reports > Most Recent Serial Release Date by Firm
        Enter: Est. #
        Status: Active

This information can be used to look for inactive products (products not released in the last 5 years). But if a serial of an active license has not been released in LSRTIS (since November 2011), this product code will not show on this report. It is a deficiency in this report that is scheduled to be fixed by April 2017. Also, the report is a pdf and does not sort by any discernable means. In its current state, it is not the most useful report but has nuggets of information. It can be used to ensure annual outline of production (OP) reviews are being done even for product that has not been recently released.

13. Serials Received – another way to search for information listed under #9 and #10
LSRTIS > Serial Release > Serial Search
> Enter: Est. #
> With an Action of: Aphis 2008 Logged In
> Action Timestamp: From date of last inspection to today

This will give you a complete listing of 2008s submitted to CVB for review and processing. You may want to sort Active vs. Complete.

14. Samples
LSRTIS > Sample Processing > Sample Search
> **Missing Serials – Sample submitted but no corresponding 2008**
> Enter: Est. #
> Click "Has No APHIS 2008?"
> Action Timestamp: From date of last inspection to today

This can be a great area to find issues, including on-going process deviations. There are times a sample is submitted prior to the full QA review or there are issues with testing. These are highlighted by this listing. Be aware of the date received as samples recently received may have been submitted in accordance with concurrent testing and there are no issues. The flag is samples received 2-3 months (or more) from the date the report is run if testing does not include a lengthy animal test.

> **Sample Submission Issues**
> Enter: Est. #
> Click "Was Rejected?"
> Action Timestamp: From date of last inspection to today

This may be an indication of lack of control or if the firm has requested samples be rejected, there may be a larger issue.

15. Inspection Action Items
LSRTIS > IC > Inspections
> Go to Pending Action Items Tab
> In Search Field, Type Est. #
Review these action items prior to the inspection.
If no action items are still pending:
> Go to Action Item Search
> Enter: Est #
> You can focus on the priority by selecting Serious or Less Serious

Review the action items that are pertinent to the site you are inspecting. Being aware of older action items is helpful in preparing for the current inspection.
ALWAYS read the last inspection report. Suggest reading the last two or three reports, if available.

16. Inspection Items to Consider
Mail > Search > Master Search
>> Enter: Est. #
>> Mail Log Tags: Inspection Items to Consider

The reports do provide a brief comment, but this search should be done in preparation for the inspection as you may need to talk to the CVB individual who tagged the ML item if it is not apparent what the concern is. Try to get as many specific details as possible as to what the issue may be or what is suspected. It may just be following up on a request made.
NOTE: general statements are not helpful for inspection purposes.

This will also be used as a method to follow up on VBI information as the Investigation and Compliance Specialist (ICS – Rick Dewald) will be tagging these Mail Logs.

17. Investigations
LSRTIS > IC > Investigations
>> Enter: Est. #
>> Click on "Is Not Closed?"

This list should be reviewed as a part of preparation for inspections. Additional information or assistance can be provided by the ICS – Rick Dewald. For closed investigations, the ICS will confirm inspection recommendations made in the Report of Investigation are noted as Inspection Items to Consider.

18. Exports

Issuance of export certificates is a service we provide. Perceived misuse of these certificates must be reviewed by the Inspection and Compliance Management Team (ICMT) prior to determining any violation. In most cases, the observation may be an item of concern. This tool is more to assist with an audit of a restricted license, labeling and/or distribution and provide some information regarding the use of export certificates. Below are several searches that can be used to determine compliance.

18.a. Export Documents Certified
LSRTIS > IC > Exports
>> Enter: Est. #
>> With an Action of: Finalized
>> Action Timestamp: From date of last inspection to today

The reports just provide a listing of type of certification [APHIS Form 2017 (2017) or Certificate of Licensing and Inspection (CLI)] and destination country. The reports do not provide product code or serial number, so this search should be used as a part of the pre-inspection preparation. Information regarding individual certificates on the LSRTIS screen do list type of certificate, products, and country. Using the "Show" button, you can see more details, such as serial numbers and doses for 2017s. This information can be used during an audit of distribution.

Go to the file room and review CLIs issued that include appended labels. Note the product code and country.

When at the firm, request distribution records for serials of product to that specific country. Review labeling records for one of the serials shipped to see what labels were used. While there is no restriction on only using the label appended to the CLI, we should understand why this label was submitted for certification and then NOT used. This is not a violation, but may be an item of concern or perhaps a control/communication issue.

18.b. Export Documents Audited
LSRTIS > IC > Exports
                Enter: Est. #
                With an Action of: Audited
                Action Timestamp: From date of last inspection to today

This can provide insight regarding control of review, both for the information on the export document and perhaps Outline review.

18.c. Export Documents for Product Licenses with an Export Distribution Restriction
Step 1 – LSRTIS > Licensing > Product Licenses
                Enter: Est. #
                License Status: Active
                Restriction: 46 – Export distribution….
Step 2 - LSRTIS > IC > Exports
                Enter: Est. #
                Product (as found above): Product Code
                Type: Aphis 2017
                With an Action of: Signed by Specialist
                Action Timestamp: From date of last inspection to today

This should provide a listing of some serials to review for compliance with the export distribution restriction. Any serials/inventory exported to other countries must have written authorization from the proper animal health official from the receiving country. This may be in the form of a registration or certificate from the receiving country.

18.d. Export Documents For Further Manufacture products
Step 1 – LSRTIS/Licensing > Product Licenses
                Enter: Est. #
                License Status: Active
                Restriction: 51- For Further Manufacture
Step 2 - LSRTIS > IC > Exports
                Enter: Est. #
                Product (as found above): Product Code
                Type: Aphis 2017
                With an Action of: Signed by Specialist
                Action Timestamp: From date of last inspection to today

This should provide a listing of serials to review for compliance with distribution of the FFM product. The Outline of Production Section VI lists acceptable recipients of the FFM product. Alternatively, PEL may have provided written authorization to export product to locations other than what is listed in the OP. This most likely is on a one-time basis.