Documenting the FSA

- Use appropriate FSA tools in PHIS
- If Word version needed, obtain from Advanced EIAO SharePoint site to ensure current version
- Do not keep notes outside tools as they may be evidence
Noncompliance

- Noncompliance observed during the FSA will always be documented in the FSA report.
- Additionally, noncompliance will be documented in either an NR or it may be included in an enforcement letter (NOIE or NOS).

Example:
- EIAO determines the establishment failed to identify a step in the flow chart.
- This is regulatory noncompliance, but it may not pose an immediate health risk.
- It would be prudent to complete the assessment process to determine how the matter should be addressed (NR or part of an enforcement letter if other noncompliance exists).

If additional noncompliance is observed during the FSA and an NOIE is warranted:
- The NOIE documents noncompliance findings supporting the proposed action.
- Other noncompliances that are not in support of the NOIE would be documented on NRs.
- All enforcement letters and NRs are presented to the establishment at the exit meeting.
Noncompliance

- If no enforcement is warranted, any noncompliance would be documented on NRs.

- Work with the FLS and IPP to assure NRs are presented at the exit meeting.

Noncompliance

- FSIS must first stop the practice and take a RCA immediately if an establishment is:
  - shipping or producing adulterated product,
  - operating without a HACCP plan
  - treating animals inhumanely
  - engaging in any other type of noncompliance that supports taking action under the Rules of Practice

- A NR should be issued to the plant ASAP

Noncompliance

- For immediate enforcement, correlate with the IPP, the FLS, and the District Office.

- If a suspension without notice is warranted, the NR can serve as a basis to support the action.

- The Food Safety Assessment can be completed later during the enforcement process.
Noncompliance

- Anytime noncompliance is observed, it is important to bring it to the establishment’s attention and discuss it as soon as possible.

Noncompliance

- Whenever noncompliance is discussed with the establishment:
  - Document what was discussed, including when the discussion took place and who was present.
  - The written summary can be part of the FSA or a separate memorandum for the record.
  - It is important in the administrative record to support that noncompliance was brought to the establishment’s attention in a timely manner.

Noncompliance

- When notified of noncompliance that is not part of an enforcement action:
  - The establishment may take action to bring themselves back into compliance
  - An NR will still be documented and presented at the exit meeting

- This is why it is important to document that the establishment was notified, in the FSA or in an MOI.
Noncompliance
- NRs are fundamental “building blocks” to effective enforcement.
- They assure establishments have been provided the opportunity to correct situations before enforcement becomes necessary.

Noncompliance
- EIAO should reiterate with inspection team importance of documenting noncompliance, associating NRs, and building a case
- Being able to show history of multiple, recurring noncompliances is an important factor to support issuing a NOIE
- When suspending the assignment of inspectors without notice, documentation must exist to support action is warranted.

Follow-up
- Work with FLS to determine whether noncompliances require a follow-up
- Document need for follow-up in General Tool
- Contact the FLS within 30 days of the exit meeting to determine status of the NR