### Summary of Proposed Changes to FMD-76 Version 4

<table>
<thead>
<tr>
<th>Section</th>
<th>Proposed Change(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Scope</strong></td>
<td>Removed tissue residue from the list of program areas covered by this FMD since it is no longer a contracted inspection program</td>
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</table>
| **3. Responsibilities** | C. Removed District Director role since all State Liaisons are now aligned with HAF Program Divisions  
E. Added reference to State Liaison role as Division Technical Advisor, to align with the contract SOW  
G & H. Added Project Manager role to reflect changes in OP related to management of contracts. Contracting Officer Representative (COR) role is now held by Office of Management  
I. Changed title of Program Manager DPIA to Audit Program Manager to reduce the confusion with new Project Manager role assigned to DPIA staff |
| **4. Background** | Added a description of changes from May 2015 revision of FMD to present, to document the history and reasons for the document changes. |
| **5. References** | Added new SOP-000115 Management of ORA State Contract Inspection Process |
| **6. Procedures** | 6.2 Auditor Qualifications-removed list of Human Food and Animal Food specialized training courses. Added a statement to follow OTED and contract requirements, eliminating need to update FMD each time courses and prerequisite courses change.  
6.3 State Implementation of the Audit Program: Phases II and III-added clarification that the Appendix H, State Implementation Agreement and Year end Evaluation, must be signed by the FDA Director and the Director of the state inspection program, and submitted with the state’s contract proposal prior to award of the contract, to align with language in the contract SOW  
6.3.2 FDA Verification Audits-clarified section language describing audit rate requirements and what counts as a verification audit, addressing feedback that section is confusing  
6.3.3 Verification Audit Failure-clarified section language describing verification audit failure, addressing feedback that section is confusing  
6.4 Audit Rates-section renamed to Audit Requirements and Table 1 changed to reflect change to Egg Program (described in Section 6.5.3)  
6.4.2 Audit Selection-Added Preventive Control program area to the list of areas to be audited  
6.5.2 Human and Animal Food Verification Audits-clarified section language, addressing feedback that section is confusing  
6.5.3 Egg, Medical Device, and Other Applicable State Inspection Programs-Added the option for Divisions to choose to perform an audit instead of Joint Audit Inspection for the Egg Program only. Instructions for how to complete the audit are included.  
6.8.1.C. Individual Inspector Performance Deficiencies-added clarifying sentence: “The state inspector or state auditor cannot return to performing inspections or audits until all of these steps are completed and passed.”  
6.8.2 Program Performance Deficiencies |
1. changed definition of “Needs Improvement” for a single performance factor. Previously it was defined as four or more “needs improvement” ratings in a single performance factor. Added “OR a score of less than 80% conformance in a single performance factor” “The Program Division will determine which performance measure will be used at the beginning of the contract period of performance.” This provides an option for larger programs (20 or more audits) because the 4 or more NI requirement is more advantageous to smaller programs (less than 20 audits).

2. Changed the overall audit performance rating from 90% to 80% to align this audit program with the regulatory program standards audit requirement.

6.9 Process for Contract Modifications for program and Performance Deficiencies-Revised section to include OM role in contract modification process

9. Supporting Documents

Appendix B FDA-3610 form-added questions covering audits of Limited Scope and Modified Preventive Controls inspections
Appendix B1 Guidance for Completing the Contract Audit Form-added examples of “Needs Improvement” for new section
Appendix C Animal Food Safety Inspection Audit Form
1. Renamed to “Animal Food Safety Inspection Audit Form”
2. Added new section covering AFRPS inspections
3. Revised wording of some questions to reflect changes in regulation
Appendix C.1 Guidance for Completing the Animal Food Safety Inspection Audit Form-updated questions to agree with audit form
Appendix D Guidance for Conducting Joint Audit Inspections, Verification Audits for State Auditors, and Joint Inspections
1. Removed tissue residue audits since they are no longer contracted work
2. Added description of findings that would warrant a “Needs Improvement” rating
Appendix H State Implementation Agreement and Yearend Evaluation
1. Planned Resources-clarified the state personnel who could become qualified auditors
2. Section I. Contact Information-updated FDA and state contact information to agree with contract SOW
3. Section IV. & V. Planned and Completed Audits-minor changes to form information requested
Appendix I Request for Audit Reduction-updated to reflect changes to audit requirement from percentage of total contract inspections to inspector audit of 2 audits in 36 months