

COMPLETING THE INITIAL APPENDIX H FOR THE UPCOMING CONTRACT PERIOD

Considerations When Completing the Initial Form

Ensure you are utilizing the most current version by accessing the form at the bottom of the HFP OIFSS [FDA Contracts Webpage](#). When completing the initial Appendix H and collecting signatures, ensure that there are no settings in effect such as “lock document after signing.”

The Appendix H is the signed agreement between the inspectorate division and the state (contractor). The Appendix H documents the agreed plans for auditing state contractors conducting contract inspections on behalf of the inspectorate division.

Completing Section II. Contract Information

Enter the contract period of performance dates. For “Audit Phase” consider the following:

- Phase I: Currently Not Applicable
- Phase II: Check “Phase II”
- Phase III: Check “Phase III”

Completing Section IV. Planned and Completed Audits

For the purposes of the Audit Program (specifically), the terms “contract audit,” “training audit,” and “verification audit” are not synonymous.

- **Contract Audit:** The audit of an inspector conducting a contract inspection
- **Training Audit:** A contract audit where an auditor trainee observes the auditor conducting a contract audit for the purposes of preparing for a verification audit
- **Verification Audit:** The audit of an auditor performing a contract audit of an inspector conducting a contract inspection
- **Joint Inspection:** An inspection conducted jointly by an FDA investigator and a state inspector for training purposes (this is not necessarily exclusive for initial or onboard training)

Breakdown of Section IV by Row

1. Number of inspectors performing contract work under the contract for that year
2. Number of contract audits (see terms listed in section above)
3. Number of training audits, regardless of the parties leading the activities (i.e. FDA & State)
4. Number of *initial* verification audits completed by the state
5. Number of verification audits completed by state for previously established auditors

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6. Number of verification audits completed by FDA for previously established auditors
7. Number of contract audits completed by inspectorate division (see terms listed in the section above)
8. Number of contract audits completed by state agency (see terms listed in the section above)
9. Number of joint inspections completed by inspectorate division (this would not include a contract inspection and must be specified in the contract as allowable)
10. Number of *contract audits* rated as acceptable
11. Number of *contract audits* rated as needs improvement

Completion of the Initial Form

It is recommended that the Appendix H be a direct result of workplanning efforts. The form should be initially drafted by the division based on discussions and agreement with the state agency. All auditors working under contract for the year must be listed in the appropriate Section V (and be reflected accurately in the CAT Tool Master Member Lists). Once signed by the program division, the form will be signed by the state and submitted with their contract proposal. The State Liaison will email the initial form to contractaudits@fda.hhs.gov prior to the award of the contract.

The program division is responsible to complete the End of Year Form, including the completed number of audits (“Planned” and “Completed” columns do not need to match), and to route to the state once the yearend evaluation is completed and discussed with the state agency. The State Liaison will route to the Office of Domestic Partnerships (contractaudits@fda.hhs.gov) within 30 days from the end of the contract period of performance.

COMPLETING THE END OF YEAR APPENDIX H FOR THE PREVIOUS CONTRACT PERIOD

When Able to Edit Form

If the finalized/signed initial Appendix H **can be edited** within Adobe Acrobat:

- Update the “Completed*” audits column to demonstrate actual audit activities conducted and by which party.
- The names of auditors that actually worked on the contract should be updated to reflect all state auditors performing contract audit work for the division during that contract period of performance.
- Complete Section “VII. YEAREND EVALUATION,” the date the evaluation was discussed between the Program Division and state agency, and the names and titles of those that participated in the discussion.
- Save as a separate file, please include “EOY” in the file name, complete any other steps necessary and route accordingly.

When Form is Locked

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If the finalized/signed initial Appendix H *is locked and will not allow direct editing* to the file:

- Select “Print” from the File menu.
- Print to PDF.
- Utilize “Add Text” tool and select each area you need to update and add the necessary language.
- Once complete, save as a separate file, please include “EOY” in the file name, complete any other steps necessary and route accordingly.