DC | HEALTH

District of Columbia Department of Health **Vital Event Audits, Site Visits, and Enforcement Actions**		**PROCEDURE 1126.000** Implementing Office: Center for Policy Planning and Evaluation/Vital Records Division Training Required: Yes Originally Issued: JUN 15 2022 Revised/Reviewed:
Approved by: LaQuandra S. Nesbitt MD, MPH; Agency Director	**Review by Legal Counsel:** Phillip Husband, Esq.; General Counsel	**Effective Date:** JUN 15 2022 **Valid Through Date:** JUN 19 2025

I. Authority	Reorganization Plan No. 4 of 1996; Mayor's Order 1997-42; DC Official Code Chapter 2A §7-231.
II. Reason for the Policy	The District of Columbia Vital Records Division (DCVRD or "the Division") within the Center for Policy Planning and Evaluation (CPPE) is responsible for issuing birth, death, and fetal death records for such events occurring in the District of Columbia. DCVRD relies upon a range of community partners to provide accurate and timely data to accomplish its mandates. Protocols are necessary to standard processes to reinforce data quality, address data quality deficiencies, and facilitate enforcement actions through compiling evidence to support those actions. Further, these protocols are also required to evaluate the effectiveness of DCVRD practice, and identify areas for continuous improvement.
III. Applicability	This SOP shall apply to all employees, contract employees, vendors, volunteers, and student interns working within DCVRD. These individuals are collectively referred to herein as "employees" or "DCVRD employees."
IV. Policy Statement	Vital event audits (VEAs), site visits, and enforcement actions are part of the portfolio of DCVRD. The State Vital Records Registrar ("the Registrar") is the accountable manager for all tasks assigned to DCVRD.

	VEAs, site visits and enforcement actions are the responsibility of the Code Enforcement and Compliance Unit (CCEU). They are responsible for conducting and documenting the VEA/Site visit. CCEU will conduct a VEA for each medical facility and funeral home in the District of Columbia on a quarterly basis to ensure compliance of all vital events, including whether they have been reported to DCVRD and identify any potential data quality issues or lagged reporting. The CCEU Supervisor may direct an ad hoc VEA for any facility for any reason. The Registrar, or designee, has the discretion to order a site visit announced or unannounced any reason, including a precipitating issue identified with a vital event. A VEA consists of an electronic audit of all of the following data sources for the review period, as applicable: 1. The Statement of Deficiencies (SOD) from the most recent VEA or site visit at that facility if one is available; 2. All notices of infraction for enforcement actions taken within the current fiscal year, if available; 3. The Registered Vital Events Reports and Code Enforcement Reports for all vital events occurring in the District of Columbia at the facility for the review period. This report is prepared by the Data Management and Analysis Division within CPPE (DMAD); 4. The Open Action Reports for all vital events occurring at the facility for the review period; 5. Complaint or registration issues for the facility under review documented by the Customer Service and Certification Operations Unit (CSCO) and/or Registration and Policy Unit of DCVRD (RPU); 6. The Corrections/Amendments Log for the facility. The log will be sorted by corrections/amendments initiated by the facility, and those initiated by customers; 7. A list of any issues or concerns about the facility's data quality. The Compliance and Code Enforcement Unit may consult with the Supervisory Statistician, or designee, to make this list more comprehensive; 8. A list of authorized users, including all system actions taken during the review period; and

9. The facility's current user list of the Electronic Birth Registration System (EBRS), Electronic Death Registration System (EDRS), and/or Electronic Fetal Loss System (EFLS).

CCEU will utilize the compiled documentation to generate a list of cases for thorough examination during the VEA or site visit.

CCEU will debrief the appropriate facility staff before concluding the onsite portion of the VEA/site visit.

If applicable, a written SOD is to be submitted to the Compliance and Code Enforcement Supervisor within five (5) business days of concluding the onsite portion of the VEA/site visit, and to the Registrar for approval within ten (10) business days of concluding VEA/site visit. Each item tagged in the SOD must include a specific code/regulation citation, and the evidence for the facility having been in violation.

The facility shall be given ten (10) business days to respond to the SOD with a corrective action plan. Any response received must be appended to the original document. Specifically, CCEU will request that the corrective action plan:

1. State exactly how the deficient practice has been or will be corrected. A general statement indicating that compliance has been achieved or will be achieved is not acceptable.
2. Identify the nature of the corrective action, and how the corrective action will address the concerns identified in the investigative findings.
3. Identify what systematic changes will be made to ensure that the deficient practice will not recur and how the facility will monitor its corrective action to ensure that the deficient practice is corrected. (i.e., what quality assurance program will be put into place?).
4. Specify the position of the staff person(s) who will be responsible for monitoring corrective action and the quality assurance mechanisms.

In addition to the SOD, the CCEU shall prepare an internal document summarizing all findings and debrief the Compliance and Code Enforcement Supervisor. This internal document will be submitted to the Registrar. Recommendations for policy changes,

	system enhancements, or any applicable corrective action will be included. The Registrar shall determine the appropriate action to pursue based on the issues cited in the internal document. The Compliance and Code Enforcement Unit is responsible for a scheduled internal audit at least quarterly. The Compliance and Code Enforcement Supervisor may order an unscheduled internal audit for any reason. At a minimum, an internal audit will examine a sample of unregistered records, registrations, issuances, amendments, corrections, to establish if DCVRD employees have complied with: 1. Applicable federal and District law; 2. Applicable regulations; 3. Applicable DC Health standard operating procedures. The Compliance and Code Enforcement Unit will perform an internal audit of all memoranda of understanding, and data sharing agreements in DCVRD at least once annually to ensure those agreements comply with applicable federal and District law and regulations, and that data released outside of DCVRD is within the parameters of the applicable agreement. Included in this audit will be recommendations for revisions to those documents in the following fiscal year. A summary of findings will be compiled and submitted for review to the Compliance and Code Enforcement Supervisor within five (5) business days of concluding the audit and to the Registrar for approval within ten (10) business days of concluding the audit. The summary of findings submitted to the Registrar will include recommendations for correction of findings. These recommendations include, but are not limited to: 1. Software enhancements; 2. SOP creation or revision; 3. Suggested revisions to a vital records statute or regulation; 4. Employee training or re-training; 5. Revision of a memorandum of understanding; 6. Revision of a data sharing agreement; Any DCVRD employee in violation of any portion of this SOP may be subject to commensurate disciplinary action.

V. Definitions & Acronyms	**Corrective Action Plan-** A specific action for achieving compliance in response to deficiencies issued. **CPPE-** Center for Policy Planning and Evaluation **CSCO-** Customer Service and Certification Operations Unit of the DC Vital Records Division **DCVRD-** District of Columbia Vital Records Division **DMAD-** Data Management and Analysis Division **EBRS-** Electronic Birth Registration System **EDRS-** Electronic Death Registration System **EFLS-** Electronic Fetal Loss System **Enforcement action-** The imposition of a fine against an individual or entity per the legal authority granted to DCVRD under DC Code Chapter 2A § 7–231.28. **NICU-** Neonatal Intensive Care Unit **RPU-** Registration and Policy Unit of the DC Vital Records Division. **Site visit-** An onsite review of a medical facility or funeral home's vital event reporting. A site visit may be announced, or unannounced at the discretion of the Registrar or designee. **SOD-** Statement of Deficiencies. A report at the conclusion of an audit that summarizes each identified violation of a DC vital records statute or regulation. For each deficiency, the corresponding statute and/or regulation will be cited. **VEA-** Vital event audit. A comprehensive onsite review of a facility's vital event reporting. VEAs are routine, announced quarterly reviews for all hospitals and birthing facilities. **Vital event-** A birth, death, or fetal death occurring in the District of Columbia.

VI. Procedures	**Procedure A: Vital Event Audit** 1. The CCEU will review the Statement of Deficiencies from the most recent VEA, site visit, or enforcement action, if available. 2. The CCEU will obtain and review all required documentation pertaining to the facility being audited (see above). 3. The CCEU will review all documentation to identify cases with possible data quality issues. 4. The CCEU will generate a report of all vital events occurring at the facility during the review period. Any vital events identified in step 4 as a possible data quality issue will be flagged on the report. **Procedure B: Site Visit and Onsite Documentation Review** 1. The CCEU will schedule the visit to the facility (disregard if the visit is an unannounced site visit). 2. Once onsite, the CCEU will compare the facility vital event logs to the Vital Event Report to ensure all vital events at that facility in the reporting period have been registered. These logs include, at a minimum: a. The facility's labor and delivery log; b. The facility's Neonatal Intensive Care Unit (NICU) log; c. The facility's nursery log; d. The facility's morgue log; e. The facility's secure body release log; or f. The facility's emergency room log; 3. The CCEU field staff will conduct an exhaustive review of all cases identified as having possible data quality or lagged reporting issues.

4. The CCEU will request facility personnel provide access to the electronic health record for all flagged cases, and all unregistered vital events discovered in step 6, as applicable. This will include:

    a. The death summary notes;
    b. The birth summary notes;
    c. The patient's history and physical;

5. The CCEU field staff will review all flagged cases and unregistered vital events in the review period, noting all instances where the facility's internal record conflicts with that event's entry in EBRS/EDRS/EFLS.

6. The CCEU will prepare a list of cases where a data quality issue, lagged reporting, or any other instance of non-compliance was substantiated by the VEA and onsite review.

7. The CCEU will facilitate a wrap-up meeting with appropriate facility staff. The CCEU will share all high-level issues discovered during the VEA and onsite records review.

8. If applicable, the field staff will submit a statement of deficiencies to the facility's compliance officer, or other authorized individual, no later than thirty (30) calendar days after the review.

Procedure C: Statement of Deficiencies and Enforcement Action

1. The CCEU will draft a formal Statement of Deficiencies.

2. The CCEU will submit the preliminary statement of deficiencies to the CCEU Supervisor within five (5) business days of concluding the onsite portion of the VEA/site visit.

3. The CCEU Supervisor will submit the reviewed statement of deficiencies to the Registrar for approval within ten (10) business days of concluding the onsite portion of the VEA/site visit.

	4. The CCEU will submit a final statement of deficiencies to the facility's compliance officer no later than thirty (30) calendar days after concluding the onsite portion of the VEA/site visit. Included in this document will be the request for a corrective action plan from the facility within ten (10) business days of receipt. 5. The CCEU will monitor performance on each deficiency by generating weekly reports. 6. If the deficiency continues to occur, the CCEU Supervisor has the discretion to convene a meeting with facility staff to assess ongoing needs. The CCEU Supervisor has the discretion to offer additional technical assistance as necessary to alleviate the deficiency. 7. The CCEU Supervisor will refer facilities with repeat findings to the DC Health General Counsel with a recommendation for a referral to the applicable authority, e.g. the applicable Health Professional Licensing Board, or the Board of Funeral Directors at the DC Department of Consumer and Regulatory Affairs.
VII. Contacts	State Vital Records Registrar Compliance and Code Enforcement Unit Supervisor
VIII. Related Documents, Forms and Tools	None