

MODULE 9 – Quality Assurance



<http://www.cdc.gov/vaccines/programs/vfc/default.htm>
<http://www.cdc.gov/vaccines/programs/cocasa/default.htm>

Introduction

The purpose of this module is to provide immunization programs at both the state and local level with information on the quality assurance requirements for the VFC program. All immunization grantees are required to conduct compliance site visits to all enrolled and active VFC providers in both public and private healthcare sectors. The review and evaluation of VFC provider practices involves the assessment of the verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the VFC program.

Compliance site visits help program staff determine the extent to which a provider site is in compliance with the requirements of the VFC program, including identifying potential issues with VFC accountability and determining whether VFC vaccines are being handled, stored, and administered in accordance with the laws and policies that govern the VFC program. Aggregated provider site visit results provide grantees with information on areas where providers are doing well or areas of non-compliance needing additional attention (e.g., policy change, training, education, etc.).

VFC Compliance Site Visits

The purpose of the VFC compliance site visit is to review records of children who are immunized through the VFC program and to evaluate the provider's recordkeeping, vaccine handling and storage procedures, and compliance with requirements of the VFC program. All immunization grantees are required to conduct compliance site visits to all enrolled and active VFC providers in both public and private healthcare sectors. VFC compliance site visits must include the administration of all questions in Section One of CDC's VFC Site Visit Questionnaire. During a VFC compliance site visit, the provider's compliance with requirements of the VFC program are evaluated by reviewing a sample of the records of children who are immunized through the VFC program, evaluating the provider's recordkeeping, vaccine handling and storage procedures, and responses to Section One of CDC's VFC Site Visit Questionnaire; to be considered a VFC compliance site visit, the visit must include the administration of all questions in Section One of CDC's VFC Site Visit Questionnaire.

Publication Date: August 2007

Revision Date: January 2011

VFC compliance site visits must include:

- Administration of the VFC Site Visit Questionnaire;
- Reviewing VFC eligibility screening procedures;
- Verifying the information in the provider profile;
- Monitoring VFC vaccine administration, storage and handling;
- Ensuring VFC program policies are being properly implemented;
- Providing feedback and, as necessary, implementing corrective actions and follow-up of identified problems.

Site visit minimums and selecting provider sites

As of January 2011, grantees are required to conduct VFC compliance site visits to at least 50% of their enrolled and active VFC providers annually, so that at least half of enrolled and active VFC providers are visited in one year and the remaining half the following year. The composition of the providers visited should be split between both public and private providers so that, at a minimum, grantees are conducting VFC compliance site visits to half of their public providers and half of their private providers annually. The compliance site visits to 50% of enrolled and active VFC providers is the minimum-level requirement and grantees that wish to conduct more compliance site visits are encouraged to do so.

Selecting the order in which to see providers in a given year is at the discretion of the grantee. Factors such as volume of vaccine orders, past non-compliance issues, reports of waste, complaints, or geographic location may influence decisions to prioritize the order of the visits made during the year.

Staff training and joint compliance site visits

Conducting quality compliance site visits begins with well-trained and competent reviewers. Reviewers conducting site visits are, at a minimum, required to participate in annual trainings sponsored by the grantee. The training should provide updates on program policies and additional education that prepares reviewers to conduct effective site visits and provide current and accurate information to clinic staff. Newly hired reviewers are required to shadow an experienced site visit reviewer on a VFC compliance site visit as part of their training. The experienced reviewer must have a thorough understanding of VFC program requirements and knowledge on conducting VFC compliance site visits in provider office settings. The VFC Coordinator (or qualified designee) is also required to accompany new reviewers on at least one VFC compliance site visit when the new reviewer begins conducting independent site visits. The VFC Coordinator (or qualified designee) should observe the reviewer's practices in conducting the compliance site visit and, if needed, provide guidance and suggestions to improve the quality of the visit conducted. A record or notes from the joint visit should be documented in the reviewer's training file.

VFC Coordinators are encouraged to conduct at least one joint VFC compliance site visit with each reviewer annually and document the joint visit in the reviewer's training file.

Publication Date: August 2007

Revision Date: January 2011

Joining reviewers on VFC compliance site visits is one means to observe reviewer practices and behaviors during a compliance site visit in order to assess site visit skills, make suggestions or corrective actions for improvement, and learn of techniques the reviewer may be using that could be valuable for others. The goal of the joint site visit is to make observations and recommendations that will ultimately improve the quality of the visits conducted by assessing a site visit reviewer's behaviors and practices. A sample supervisory site visit tool shared by a grantee is located in Appendix 6.

Preparing for the site visit

Reviewing previous site visits

Prior to conducting a compliance site visit, reviewers should prepare by reviewing past site visit data, if available. Information on past site visits, planned or conducted follow-up, or other contacts made with the provider site can provide the reviewer a basis to help identify areas in which to focus attention during the visit. Particular attention should be paid to past non-compliance resulting in corrective actions in order to note whether behavior changes or compliance to other requirements were sustained. Vaccine wastage or expired vaccine reports should also be reviewed to detect unusual patterns or problems that need to be addressed during the site visit.

Reviewing the fraud and abuse database and excluded provider list

Fraud and abuse database

Grantees are required to maintain a database to monitor fraud and abuse allegations that include the date of the allegation, source of allegation, actions taken, and outcomes. Additional information regarding the development and maintenance of the database can be found in Module 10 of this *VFC Operations Guide*. In preparation for the compliance site visit, the grantee maintained fraud and abuse database must be checked to see if the provider to be visited was involved in past allegations and the outcomes of any allegations. The reviewer can use the information found on past allegations to help inform or focus the site visit and must address any re-lapses of non-compliance found during the site visit.

Excluded provider list

The Department of Health and Human Services (HHS), Office of Inspector General (OIG) established a program to exclude certain providers from participating in Federally-funded health care programs and maintains a list of those excluded on the "*List of Excluded Individuals/Entities*." The basis for exclusion includes program-related fraud, patient abuse, licensing board actions, and default on Health Education Assistance Loans. The list can be accessed at: <http://oig.hhs.gov/fraud/exclusions.asp>.

The list must be reviewed at the provider site's initial enrollment into the VFC program and subsequently reviewed on a monthly basis for all provider sites. Grantees may check a state database for excluded providers in addition to the HHS OIG list, but not in place of the list. Persons on the "*List of Excluded Individuals/Entities*" are not allowed to participate in the VFC program; a VFC-enrolled provider site that has a person employed

Publication Date: August 2007

Revision Date: January 2011

on the excluded provider list must be terminated from the VFC program. The state Medicaid Agency must be notified of the termination. Additionally, excluded providers cannot participate in the program indirectly, such as providing services under a non-excluded VFC provider. A non-excluded VFC provider that employs or contracts with a provider who is an excluded provider cannot seek payment on behalf of the excluded provider. In such circumstances, the non-excluded provider employing or contracting with the excluded provider is not able to participate in the VFC program. Additional information is available in the *Special Advisory Bulletin on the Effect of an Exclusion* located at: http://oig.hhs.gov/fraud/alerts/effect_of_exclusion.asp. Please refer to Module 10, Fraud and Abuse, of this *VFC Operations Guide* for further guidance.

Preparing the provider site

Just as grantees prepare for the compliance site visit, it is useful for providers to be informed about their upcoming visit and what to expect. Preparing the office in advance will improve the efficiency of the site visit by making the most of the limited time available during the visit. Provider sites should be provided with general information about the upcoming compliance site visit in order to help them understand what to expect and the items they will need to have available for the reviewer. Provider site staff involved in the site visit should be prepared to accurately answer and demonstrate behaviors assessed in the questionnaire. Grantees may wish to send Section One questions 1-8 to the provider prior to the visit and ask that the responses be completed prior to the site visit. However, the complete questionnaire (Section One) in its entirety should not be provided to the clinic/practice in advance of the compliance site visit. The compliance site visit should give the reviewer a realistic picture of how the provider site is implementing the VFC program on a daily basis, and not one that is changed specifically for the site visit.

It is also critical to communicate to the provider site the items and locations the reviewer will need to access in order to efficiently conduct the site visit. In advance of the site visit, the provider site should be notified the reviewer will need access to:

- A space to work (and a power source if a laptop is used)
- Patient medical records to screen for patient eligibility. The provider site should be informed of the number of records to select and the protocol for selecting the records if the reviewer does not complete this task for the provider site.
- Current and past temperature logs and vaccine borrowing reports for the last 3 months or longer if issues are found.
- Clear access to the circuit breaker. The provider site should be informed that maintenance staff may need to be available during the site visit to gain access to the circuit breaker, if needed.
- Access to admitting and billing personnel to clarify screening and billing processes, if needed.
- Access to all vaccine storage units where VFC vaccine is maintained, both permanent and temporary storage units.
- Other items deemed necessary to review by the grantee.

Publication Date: August 2007

Revision Date: January 2011

Having provider site staff who will be involved in the site visit understand the needs and expectations of the site visit will increase the reviewer's ability to conduct an effective and successful visit in a timely manner.

The VFC Site Visit Questionnaire

The CDC VFC Site Visit Questionnaire is a tool used to determine a provider site's compliance with the federal requirements of the VFC program. The Questionnaire is reviewed and updated annually and is available in the Comprehensive Clinic Assessment Software Application (CoCASA). CDC requires all grantees to administer all high priority questions in Section One of the CDC VFC Site Visit Questionnaire as written. The Questionnaire and answer key to the high priority questions may also be found at: <http://www.cdc.gov/vaccines/programs/vfc/psv-questionnaire.htm>.

Persons conducting VFC compliance site visits must complete all the questions in Section One of the CDC VFC Site Visit Questionnaire. Questions identified with a red exclamation point (!) are considered high priority and corrective actions must be developed if the provider is not in compliance with any of these questions. Only Section One of the VFC Site Visit Questionnaire is required to be completed during a site visit; all other additional questions asked during the site visit are optional and at the discretion of the grantee. Section Two of the questionnaire includes optional questions related to the Standards of Pediatric and Adolescent Immunization Practices. Section Three of the questionnaire allows grantees to create custom questions specific to their programs (Section Three is only available in the CoCASA software application). Grantees choosing to ask additional optional questions beyond the required Section One questions must make sure the questions asked and information gained are used to improve the quality of the VFC program or provider site practices. If asked by CDC, the grantee must be able to demonstrate how this information is being collected and used in a standardized manner across the grantee's jurisdictional area.

Every grantee must develop a written protocol for provider compliance site visits that outlines procedures for:

- Selecting provider sites
- Conducting compliance site visits (including instruction on how to administer the VFC Site Visit Questionnaire)
- Reporting results from completed compliance site visits and post compliance site visit actions (follow-up activities).

All immunization grantees are required to conduct VFC compliance site visits to 50% of enrolled and active VFC provider sites annually.

Administering the Questionnaire

Understanding the intent of each question (and the associated federal requirement) in Section One of the questionnaire and successfully using interview and observation skills to complete the questionnaire are key elements to conducting quality site visits. Administering the questionnaire is more than reading the questions verbatim and

Publication Date: August 2007

Revision Date: January 2011

collecting the provider's responses. A successful visit involves assessing the verbal, written, and visual cues encountered during the visit to complete the questionnaire. The reviewer should engage in dialogue with provider staff to gain a full understanding of how VFC requirements are being met and to what degree; the reviewer should provide education and corrective actions when the provider site is not compliant with the high priority questions.

Each question in Section One of the CDC VFC Site Visit Questionnaire is linked to a federal requirement for the program. It is important for reviewers to understand all questions asked in Section One of the questionnaire and be comfortable in providing the correct guidance when provider sites are noncompliant with a question, especially for the high priority questions designated by the red "!".

Verifying the Provider Profile

Providers are required to submit an updated provider profile with the provider enrollment agreement annually to the grantee. The provider is required to estimate the number of children who will receive vaccinations at the provider site and the number of children expected to be VFC eligible. A copy of the provider profile is located in Appendix 2.

Grantees are required to assess if the patient population estimate reported in the provider profile is a reasonable estimate that coincides with the provider site's vaccine ordering patterns. This requirement is reflected in the first high-priority question on the CDC Site Visit Questionnaire, "Are vaccine orders consistent with the most current provider profile?" Assessing the reasonableness of the population estimate reported on the provider profile could involve comparing the estimate to the birth cohort for your state or jurisdiction to see if the percentage of patients estimated to be seen relative to the birth cohort is an amount that appears to make sense for the community that the provider serves. Grantees can also assess the provider site's vaccine orders to determine if the ordering pattern is an appropriate amount for the estimated VFC-eligible patient population. For example, if the provider profile indicates the provider site estimates serving 100 eligible patients under one year of age over a twelve month period, the grantee could review the amount of DTaP doses ordered during the same period to see if it greatly exceeds or falls short of what a child under one would expect to receive over the course a year (3 doses per eligible child, 300 doses over a year, or 75 doses over a quarter). If the quantity of doses greatly exceeded or falls short of the expected number of doses to be used for the estimated population, the provider site should be queried to better understand the reasons for the differences or if the provider profile needs to be updated and/or the source of the estimate.

Another method to verify the provider profile could involve using doses administered data reported through a registry system. A comparison between the amount of vaccine ordered and the doses that provider site administered to eligible patients could help show whether doses ordered are being correctly administered to eligible populations, and whether the quantities ordered are appropriate amounts for the eligible populations estimated on the provider profile.

Screening for VFC Eligibility

The purpose of assessing provider site procedures for eligibility screening is to monitor whether providers are appropriately identifying eligible populations to receive VFC vaccine. Screening for VFC eligibility is the foundation of provider-level accountability. Screening children for eligibility at every visit is the only way to ensure that VFC vaccine is used only for VFC eligible patients. Consequently, provider sites must screen all children at every immunization visit. During a child's initial visit to the provider site, documentation of the child's eligibility category must be collected and then maintained on future visits. Verbal screening is sufficient for subsequent visits after initial documentation as long as the child's eligibility status has not changed; if the child's eligibility status changes, it must be documented. However, grantees have the discretion to require enrolled providers to document the VFC screening results at every immunization encounter even when the eligibility status is unchanged.

To assess provider sites screening practices, the grantee must have a written standardized protocol that all field staff follows that includes sample size, random records/charts selection, reviewing the records/charts and compiling results. CDC recommends a sequential-based review, which involves using the appointment schedule and selecting the last X (sample size) patients who were 0 through 18 years of age and were seen for immunizations. At a minimum, CDC requires at least 10 records/charts be reviewed for documentation of screening for VFC eligibility unless the provider has fewer than 10 patients from birth through 18 years of age. If a provider has 10 or fewer patients from birth through 18 years (both VFC and non-VFC eligible), charts for all 10 (or fewer) of those patients must be reviewed for documentation of screening for VFC eligibility. If a provider has 11 or more patients from birth through 18 years (both VFC and non-VFC eligible), the grantee has the option of determining the sample size. The number of records/charts reviewed can be based on the volume of patients seen from birth through 18 years by a provider. Appendix 6 contains sample instructions on how to conduct VFC eligibility screening by selecting a random sample of children within a practice. The protocol and methodology uses a sample size of 30 records/charts and discusses different methods for selecting the screening sample. The methods for pulling the sample can be used with different sample sizes (e.g., 10 records).

If a combination visit (VFC/AFIX) is being conducted, the records from the AFIX sample can be used to assess eligibility screening. If the AFIX sample does not contain at least 10 records, use the AFIX sample and systematically select additional records from the 0-18 years age group until the needed number of records for the eligibility screening sample is reached. Reviewing more than the minimum 10 records is at the grantees' discretion. Grantees must establish a standard number of charts to be reviewed for eligibility screening during all VFC compliance site visits. The sample must include both VFC and non-VFC eligible children. If a provider does not have the necessary number of records for children in the 0-18 years of age group, review all available charts.

Publication Date: August 2007

Revision Date: January 2011

The grantee may require the provider to use the CDC screening form (see Appendix 3), a grantee developed screening form that contains all data elements on the CDC form or a provider-specific method. If a grantee approves a provider-specific method, the screening documentation must include **all data** elements listed on the CDC screening form. The screening documentation must be standardized regardless of type of health record used (paper or electronic).

Since the VFC requirement is to screen children at all immunization encounters (Module 3, *VFC Operations Guide*), anything less than full compliance (that is, identifying any chart that does not have documentation of screening) must be discussed with the provider and office staff and may require additional follow-up. If a provider site is not documenting the initial screening of all pediatric patients for VFC eligibility correctly, CDC's *Non-Compliance with VFC Provider Requirements Protocol* must be followed. After the initial documentation of VFC screening, CDC requires, at a minimum, verbal screening at all future immunization encounters; if a child's eligibility status changes, CDC requires documentation of the child's new eligibility status. Grantees have the discretion to require enrolled providers to physically document the VFC screening results at every immunization encounter even if the status is unchanged. Further discussion on screening practices and accountability is located in Modules 3 and 8 of this *VFC Operations Guide*.

Tips to understanding the Site Visit Questionnaire

The following are tips to understand select high-priority questions contained in Section One of the CDC VFC Site Visit Questionnaire:

- A. “Are vaccine orders consistent with most current provider profile?”**
- The purpose of this question is to verify the population estimates reported on the provider profile by confirming that the quantities of vaccine ordered are in the appropriate range to serve the VFC-eligible population the clinic reported on its provider profile. This cross-check will need to be conducted prior to the visit, and by staff at the grantee level with access to ordering information and the provider profiles. If this activity is done centrally and apart from the site visit questionnaire, responses to this question will need to be compiled and entered into the site visit questionnaire or compiled and reported in the annual VFC Management Survey.
- B. “What is the vaccine administration fee charged to non-Medicaid VFC eligible patients (uninsured, American Indian/Alaska Native, under-insured if vaccinated at FQHC/RHC)?”**
- Providers cannot charge more than the maximum regional charge for their state or territory for the non-Medicaid VFC-eligible patient. During the site visit, the provider site must be able to explain or demonstrate how much the practice charges for the administration fee for non-Medicaid VFC eligible patients.
- C. “Which of the following vaccines are NOT routinely administered in this clinic/practice?”**

- All VFC enrolled primary care providers should offer all ACIP-recommended vaccines. Specialty care providers (such as OB/GYNs, family planning clinics, pharmacies, and birthing hospitals) may be an exception and are allowed to offer select vaccines appropriate for the setting.

D. “When does this clinic/practice provide patients with copies of the Vaccine Information Statements (VIS) to keep?”

- Vaccine Information Statements should be offered at every immunization encounter prior to administration.

E. “When does the clinic/practice screen patients for VFC eligibility?”

- Screening of all children must occur at every immunization visit. Documentation of initial screening must be present in the patient record and the provider must document when change of eligibility occurs. Verbal screening is acceptable after the initial documentation. However, grantees have the discretion to require providers to document screening at all immunization encounters.

F. “Does this clinic/practice always notify the Immunization Program when publicly purchased vaccine has been involved in a cold chain failure, has expired or been wasted?”

- This question helps to identify sites with problem storage and handling practices. If expired vaccine is found in the storage unit and there was no indication the provider had notified the immunization program, this question must be documented as being noncompliant with a “No” response.

G. “Does the clinic/practice “borrow vaccine” between public stock and private stock?”

- Providers that care for VFC-eligible and privately insured children in non-universal purchase states must maintain two separate stocks of vaccines, one for privately insured children and another for VFC and/or state vaccine-eligible children. Borrowing between public and private stocks of vaccines is allowed, but must be a rare occurrence. CDC’s expectation is that VFC-enrolled providers maintain adequate stocks of vaccine to administer to both privately insured and VFC-eligible children. When a situation occurs which necessitates the borrowing of vaccine from VFC stock to administer to a non-VFC-eligible child or from private stock to administer to a VFC-eligible child, the VFC borrowing report must be completed.

Similar to temperature log forms, the bi-directional borrowing form must be maintained by the provider site and must be reviewed during VFC site visits. Grantees will review the borrowing report during site visits and use it to respond to the borrowing questions located in the VFC Site Visit Questionnaire.

A completed sample of the borrowing report and a blank borrowing report are located at the end of Module 3. Immunization grantees are required to report the incidence of borrowing in aggregate to CDC in the VFC Management Survey.

Please refer to Module 3 for additional guidance related to the borrowing of vaccine between public and private stocks.

H. “Does the clinic/practice have a written plan for vaccine management including the following (review for accurate content)...”

- Providers must have written documentation for all eight required policies listed and the documentation must contain proper content. For the required content, please refer to Module 6 in this Guide. Grantees are strongly encouraged to develop policy templates for each of the eight areas that providers may customize by completing appropriate sections and dates. Please see the *Vaccine Storage and Handling Toolkit* (<http://www2a.cdc.gov/vaccines/ed/shtoolkit/>) section on *Storage and Handling Plans* and Appendix 5 for resources.

I. “Please identify the publication date for each of the VIS currently being used in this clinic/practice and check the appropriate status for each VIS.”

- During the year, updates to VIS forms periodically occur. Providers should have a process to frequently check for updated VIS forms on the CDC website (<http://www.cdc.gov/vaccines/pubs/vis>). The site visit questionnaire in CoCASA has a feature to allow users to change the dates of the VIS as needed.

J. “What type of storage units does this clinic/practice use to store varicella-containing vaccines and all other vaccines?”

- Dorm-style units and combined units with single doors are not acceptable as permanent vaccine storage units. Dorm-style units may be used on a limited basis to store VFC vaccine (but **never** varicella-containing vaccine) during clinic hours only.

K. “For each type of thermometer used by the clinic/practice, indicate if the thermometer is calibrated with certificate.”

- Units storing VFC vaccine must have a working calibrated thermometer inside each storage compartment. Each device is to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to NIST, or to another internationally recognized standards agency. A certificate of calibration accompanies thermometers that have undergone this calibration against a reference standard. If the program does not provide a calibrated thermometer with certificate of traceability and calibration to enrolled providers, the clinic/practice must be able to show the reviewer the appropriate documentation for the thermometer used by the clinic/practice.

A corrective action plan must be developed even if only one unit does not have a thermometer with a certificate of traceability and calibration. If any storage units contain multiple thermometers with and without required documentation, the clinic/practice staff must be instructed to use only the thermometer with proper

documentation of traceability and calibration to record the temperature on the log sheets.

L. “For each refrigerator and freezer, indicate how often temperatures are recorded.”

- Temperatures must be visually inspected and documented twice a day during clinic hours (a.m. & p.m.) on temperature logs and provider sites must document actions taken if the temperatures fall outside guidelines. Corrective actions must be developed if provider sites are documenting the temperature fewer than two times a day or if no documentation of action is provided for any temperature excursions outside allowable limits. If there is any period of time for which no temperatures are documented, additional research must be done by reviewers, including contacting utility companies to determine if any outages occurred during the time period.

Use of temperature monitoring systems that employ continuously recording data loggers with alarm systems are not a substitute for visually inspecting and documenting temperatures twice daily. Built in, automatic, alarmed thermometers have not proven to be error proof and in several cases have either not triggered the alarm, the alarm has been ignored by staff, the calibration was not current or the monitoring devices have proven inaccurate. A continuous data logger system can be a helpful tool to assess temperature ranges at past points in time, such as providing temperature information during past power outages to help determine the length of time vaccine may have been exposed to inappropriate temperatures. However, these systems cannot be a substitute for the visual inspection of temperature readings assessed with a calibrated thermometer twice daily and manual documentation of the temperature in a log.

M. “Are current temperatures within the guidelines according to the reviewer’s thermometer?”

- Reviewers are required to bring working calibrated thermometer to the provider site to assess the temperatures of storage units containing VFC vaccine.

N. “Is there a ‘Do Not Disconnect’ sign on the circuit breaker?”

- In advance of the site visit, provider sites should be informed the reviewer will need clear access to the circuit breaker. The reviewer needs to check that proper signage is posted to minimize the possibility the circuit breaker will be inadvertently switched off. The provider site may need to have facility management staff available to open the room where the circuit breaker is located and assure, in advance, that there is a clear path available to access the box.

If the reviewer encounters situations where the circuit breaker is not accessible due to debris or materials that may be blocking the circuit breaker or that would make it unsafe for staff to enter the room, the reviewer will need to provide corrective actions for the provider site to require that clear access to the circuit breaker is established. It is also incumbent upon the reviewer to determine

whether conditions to enter the room or to get to the circuit breaker are safe, especially if there is concern over an unusual location for the circuit breaker or debris that may be blocking the area. If a power failure were to occur, the provider site would likely need access to the circuit breaker to assess the problem. Circuit breakers that are not accessible or are unsafe to access are problems that providers are required to correct.

O. “Can the clinic/practice physically differentiate privately purchased vaccine from publicly purchased vaccine? To answer yes, clinic/practice must be able to demonstrate how this is done.”

- If providers see privately insured children, the clinic must have private stock vaccine. The only exception will be for universal states where the grantee supplies all vaccine for children in its jurisdiction.

P. “Upon checking the clinic/practice’s vaccine supply, did the reviewer find any unreported expired vaccine?”

- All VFC vaccine inventory in each storage unit must be checked for unreported expired vaccine. Random sampling of one or two containers of vaccine is not an acceptable method to answer this question.

Grantees are required to report the volume of publicly purchased (VFC, 317, and state) vaccine wasted by VFC-enrolled providers due to expiration and improper storage and handling. For additional information, please refer to Module 8, *Vaccine Accountability*, of this *VFC Operations Guide*.

A subset of the storage and handling questions require completing responses for storage units listed from one to five for each the refrigerator and freezer. Please note that if the provider site uses temporary storage units to store VFC vaccine during business hours, these temporary units must be assessed during the VFC compliance site visit as well as the permanent storage units. If the provider site has more than five total storage units for the refrigerator and/or freezer each (both temporary and permanent combined), reviewers need to use the tables to first document the non-compliant units for all the storage and handling questions containing tables. Notes and comments for all remaining units in excess of five are to be documented in the final corrective actions section, under the storage and handling area.

Feedback, Corrective Actions and Site Visit Follow-up

During or at the end of the VFC compliance site visit, reviewers should provide education to the provider site staff when non-compliant behaviors or practices are observed or encountered, in order to correct the situations. If the provider is found to be non-compliant with a high priority question (identified by a red “!”), corrective actions need to be documented at the end of Section One of the VFC Site Visit Questionnaire, along with next steps for follow-up and a timeframe. The *Non-compliance with VFC Provider Requirements Protocol (VFC Operations Guide, Module 10)* must be used when any high-priority question is answered incorrectly during a VFC compliance site visit.

Some issues of non-compliance can be corrected on-site with technical assistance and may not require further action. For example, during a site visit, a reviewer may have encountered an outdated VIS and lack of “Do not disconnect” signs next to the storage outlets. The reviewer can provide technical assistance during the visit to educate site staff on the importance and purpose of both requirements, and subsequently observe the provider site staff correct the problems during the review. In situations where education and corrective actions can be implemented during the site visit and the reviewer is confident the provider staff can maintain compliance with the requirement moving forward, no further action is needed. Other non-compliant issues encountered during the site visit for which further education and monitoring of behavior change or a referral of the case to an external agency is needed will require the use of the *Non-compliance with VFC Provider Requirements Protocol*. Please refer to Module 10 of this *VFC Operations Guide* for further guidance on use of the *Non-compliance with VFC Provider Requirements Protocol*.

Reporting Requirements

Grantees must have written plans and protocols for meeting CDC's annual reporting requirements. Detailed summary reports of provider site visits are submitted in the VFC Management Survey and should include findings from VFC-only visits, AFIX-only visits, and combined VFC/AFIX visits. Site visit definitions are located in Appendix 6.

If the VFC/AFIX Evaluation module of CoCASA is used, the software can be used to generate reports on VFC/AFIX core activities and responses to the Site Visit Questionnaire; these reports are used to complete the annual VFC Program Management Survey. For example, the VFC activity section of the VFC Management Survey asks the user to record the number of providers that answered each high-priority question incorrectly from the VFC Site Visit Questionnaire administered during every VFC compliance site visit. If information is entered into the VFC/AFIX module of CoCASA, the software can be used to produce a summary report that will aggregate the responses to the selected questions that grantees are required to report to CDC.

The VFC/AFIX Evaluation module of CoCASA is a helpful tool for organizing the VFC/AFIX site visit information and producing aggregate results. Use of this software is not required; however, if this software is not used, grantees must create their own system for collecting the data elements required to complete the VFC Management Survey.

This document can be found on the CDC website at:

<http://www.cdc.gov/vaccines/programs/vfc/downloads/vfc-op-guide/13-module-9.pdf>