The auditor should not consider the Supplement to be “safe harbor” for identifying audit procedures to apply in a particular engagement, but the auditor should be prepared to justify departures from the suggested procedures. The auditor can consider the Supplement a “safe harbor” for identification of compliance requirements to be tested if the auditor performs reasonable procedures to ensure that the requirements in the Supplement are current. The grantor agency may elect to review audit working papers to determine that audit tests are adequate.

I. PROGRAM OBJECTIVES

The objectives of the National Immunization Program are focused on achieving the Healthy People 2020 Objectives which include the following immunization objectives: (1) Reducing indigenous cases of vaccine-preventable diseases (VPDs) to zero cases of diphtheria and tetanus among people aged 25 and younger; zero cases of polio, measles, rubella, and congenital rubella syndrome among people of all ages; 500 cases of mumps among people of all ages; and, 1,000 cases of pertussis among people of all ages by the year 2020; (2) ensure that 90% of children
complete by age 2 the vaccine series recommended by the Advisory Committee on Immunization Practices (ACIP); (3) Increase immunization levels for pneumococcal and influenza to at least 60 percent among non-institutionalized high-risk populations as defined by the ACIP.

The Immunization Grants are administered to assist States and communities in establishing and maintaining preventive health service programs to immunize individuals against vaccine-preventable diseases. (Authorization: Public Health Service Act, Section 317, 42 U.S.C. 247b)

The Omnibus Budget Reconciliation Act (OBRA) created the Vaccines for Children (VFC) program as Section 1928 of the Social Security Act Title XIX. The creation of this program (in October 1, 1994) marks the first time private providers could receive publicly purchased vaccine. (Authorization OBRA 1993, Social Security Act, Title XIX, Section 1928, 42 U.S.C. 1396s)

II. PROGRAM PROCEDURES

To achieve these objectives, Centers for Disease Control and Prevention (CDC) has identified the following areas of activity for programmatic emphasis: (1) improvements in the quality and quantity of vaccination-delivery services; (2) reduction in vaccine cost as a barrier for needy parents; (3) increases in community participation, education and partnerships; (4) improvements in monitoring of disease and vaccine coverage; (5) improvements in vaccines and vaccine use.

The Secretary of the Department of Health and Human Services (HHS) allocates funds to a State upon submission of an application by a State and approval of that application. The application must include a State plan for meeting the program objectives and must (1) include annual program objectives for each of the specified program components; (2) be based on CDC’s Immunization Program Performance Guidelines; (3) address methods of operation, including specific action steps to achieve the related objectives; (4) include a detailed budget and budget justification for each program component; (5) have a description of the State’s total vaccine needs by individual vaccine with funding allocation needs specified among 317, VFC and other funding sources.

The Department provides vaccines required by law (and other selected vaccines recommended by the ACIP) to public and private health care providers in accordance with 10A NCAC 41A .0401 and 10A NCAC 41A .0502 which are outlined below in the requirements section.

The Immunization Grants are administered by the North Carolina Department of Health and Human, Services, Division of Public Health, Women’s and Children’s Health Section, Immunization Branch, 1917 Mail Service Center, Raleigh, North Carolina, 27699-1917.

III. COMPLIANCE REQUIREMENTS

A. ACTIVITIES ALLOWED OR UNALLOWED

1. Federal Immunization funding must be spent only for immunization programs. Subrecipients/vaccine providers will impose no charge for the cost of vaccine (Authorization: Provider Agreement).

2. Subrecipients/vaccine providers will not deny administration of a federally procured vaccine to a child because the child’s parent/guardian is unable to pay the administration fee (Authorization: Provider Agreement).
3. Provide all vaccines needed during a visit unless a specific contraindication exists to one or more of the vaccines (Authorization: Provider Agreement)

4. Impose no condition as a prerequisite to receiving vaccine (Authorization: Provider Agreement and 10A NCAC 41A .0502)

5. Report all adverse vaccine reactions through the Vaccine Adverse Event Reporting System (VAERS) (Authorization: Provider Agreement and 10A NCAC 41A .0502)

6. Provide the latest edition of the applicable of the Vaccine Information Statement (VIS) to the parent, guardian, or person standing in loco parentis for each dose of vaccine administered; document this action within the patient’s permanent medical record; retain the documentation for a period of 10 years following the end of the calendar year in which the vaccine dose was administered, or for 10 years following the recipient’s age of majority, whichever is longer; upon request, furnish copies of the documentation to the local health department or the Department. Keep a record of the vaccine manufacturer, lot number, and date of administration for each dose of vaccine administered (Authorization: Provider Agreement and 10A NCAC 41A .0401)

7. Screen all patients 0-18 years of age to determine the VFC eligibility and retain such information for a period of 3 years following the date the vaccine was administered. Document the VFC status on the first visit and when VFC eligibility changes (Authorization: Provider Agreement)

8. Submit an Annual Provider Profile on forms approved by the Immunization Branch (Authorization: Provider Agreement)

9. Ensure a vaccine disaster recovery plan is completed, posted, and read by current and new staff (Authorization: Provider Agreement)

10. Store vaccine on hand according to the most recent UCVDP Minimum Required Vaccine Ordering, Handling, and Storage procedures (Authorization: Provider Agreement)

11. Return all spoiled or expired vaccine to the Immunization Branch (Authorization: Provider Agreement)

B. ALLOWABLE COSTS/COST PRINCIPLES

All grantees that expend State funds (including federal funds passed through the NC Department of Health and Human Services) are required to comply with the cost principles described in the NC Administrative Code at 09 NCAC 03M .0201.

C. CASH MANAGEMENT

This is a requirement in the OMB Circular A-133 federal supplement. However, the State retains responsibility for this requirement and thus chooses not to pass it along to any of its subrecipients.
E. ELIGIBILITY

Children 0-18 years of age and younger are eligible to receive State supplied vaccines at no charge. Eligible agencies have been determined to be local and/or district health departments who have signed a consolidated contract and agreed to the terms of the contract addenda. Detail for VFC eligibility can be found in Module M-2 and Appendix A-3 of the Vaccines for Children (VFC) Operations Guide dated August 2007 (PL 103-66), U. S. Department of Health and Human Services, Public Health Service, CDC.

H. PERIOD OF AVAILABILITY OF FEDERAL FUNDS

All funds to local entities are allocated through NC Division of Public Health Consolidated Agreement for the SFY July 1, 2010 – June 30, 2011.

Per the January 2007 Health and Human Services Grants Policy Statement (page 78), “when a recipient enters into a service-type contract in which the term is not concurrent with the budget period of the award, the recipient may charge the costs of the contract to the budget period in which the contract is executed even though some of the services will be performed in a succeeding period if the following conditions are met:

- The awarding office has been made aware of this situation either at the time of application or through post-award notification.
- The project has been recommended for a project period extending beyond the current year of support. The recipient has a legal commitment to continue the contract for its full term.”

I. PROCUREMENT AND SUSPENSION AND DEBARMENT

All grantees that expend federal funds (received either directly from a federal agency or passed through the NC Department of Health and Human Services) are required to conform to federal agency codifications of the grants management common rule accessible on the internet at http://www.whitehouse.gov/omb/grants/chart.html.

All grantees that expend federal funds (received either directly from a federal agency or passed through the NC Department of Health and Human Services) are required to comply with the procurement standards described in the North Carolina General Statutes and the North Carolina Administrative Code, which are identified in the North Carolina Agency publishing manual accessible on the internet at: http://www.doastate.nc.us/pandc/agpurman.htm#p6.

Nongovernmental subrecipients shall maintain written Procurement policies that are followed in procuring the goods and services required to administer the program.

J. PROGRAM INCOME

This is a requirement in the OMB Circular A-133 federal supplement. However, the State retains responsibility for this requirement and thus chooses not to pass it along to any of its subrecipients.
L. REPORTING

Subrecipients must report electronically by the 10th day of each month immunization data from the population served by the local department. This data includes name, date of birth, social security (if available), vaccine given and dose number.

N. SPECIAL TESTS AND PROVISIONS

Conflicts of Interest and Certification Regarding No Overdue Tax Debts

All non-State entities (except those entities subject to the audit and other reporting requirements of the Local Government Commission) that receive, use or expend State funds (including federal funds passed through the NC Department of Health and Human Services) are subject to the financial reporting requirements of G. S. 143C-6-23 for fiscal years beginning on or after July 1, 2007. These requirements include the submission of a Notarized Conflict of Interest Policy (see G. S. 143C-6-23(b)) and a written statement (if applicable) completed by the grantee's board of directors or other governing body that the entity does not have any overdue tax debts as defined by G. S. 105-243.1 at the federal, State or local level (see G. S. 143C-6-23(c)). All non-State entities that provide State funding to a non-State entity (except any non-State entity subject to the audit and other reporting requirements of the Local Government Commission) must hold the sub-grantee accountable for the legal and appropriate expenditure of those State grant funds.