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## Certification Data Collection Instructions for Data Collectors

Note: The database sample used for certification will contain records from the "cohort of interest". The cohort of interest is the cohort containing children born during the 3-month period ending 1 year prior to the site visit. For example, if the certification site visit for your registry is scheduled for January 1, 2003, then the cohort of interest will be all children born from October 1, 2001-December 31, 2001.

For each standard where database information is requested, the sample will always be drawn from the cohort of interest. Historical data<sup>1</sup> should be omitted from the sample. Personally identifiable information should be masked in the records collected.

Any required fields that are null, empty, or which contain "unknown" or "filler" data (non-relevant data entered to force the computer past a required field) shall be considered "non-valued". Required fields containing plausible data shall be considered "valued."

All queries required by the review shall be run in a production environment and shall include in the report output, those records which contain non-valued or invalid data. Any summary statistics generated by the query shall be adequate for the reviewer to determine the percentage of records containing non-valued or invalid data.

The parameters for all queries required by the review shall be accessible to the reviewer. A printed listing of the report parameters is requested for each query.

### **Standard #1**

#### **Electronically store data on all NVAC-approved core data elements**

1. Prior to the site visit, review the database sample, which lists the required fields.
  - Review birth dates to ensure that the cohort falls within the requested range.
  - Determine the method(s) used to populate fields when data is unknown or unavailable.
  - Review data to see that it looks valid; e.g., containing a range of plausible birth dates, vaccines, and vaccine manufacturers.
2. If using the preferred method for certifying this function, ask the registry to generate a frequency distribution report showing the percent of completion for each required field for all of the records in the sample. The registry should use the template provided. Request the query parameters and verify that the query

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<sup>1</sup> Historical data: Immunizations given prior to the implementation date of the registry, or immunization data captured from a secondary data source (i.e., data reported from a source other than the current immunization provider).

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parameters properly differentiate between valued and non-valued data. For example, a query which would count a field containing the string "unavailable" as being 'completed' would not be acceptable. Check whether the frequency distribution report shows that 25% of each required field is valued. If any required field is less than 25% valued, then this standard has not been met.

3. For the purpose of the pilot site visits, if it is not possible for the registry to generate a frequency distribution, then the database sample will be processed by NIP's statistical analysis branch following the site visit.

## **Standard #2**

### **Establish a registry record within 6 weeks of birth for each newborn child born in the catchment area**

1. Prior to the site visit, review the database sample that lists the birth date and registry entry date for each child in the cohort of interest.
  - Review birth dates to ensure that the cohort falls within the requested range.
  - Review to see if non-valued data is included.
  - Review the validity of the data; e.g., a variety of plausible birth dates
2. Observe the generation of a query and collect a copy of the resulting report, showing the birth date and registry entry date for each child in the cohort of interest. The query should include columns listing the birth date and registry entry date; and the difference between the two dates stated in days. If the report showing the difference between the birth date and the registry entry date does not show that for 90% of the records submitted, a registry record was established within 6 weeks of birth for each newborn child in the sample, then this standard has not been met.

***Note: An alternative method to calculate this percentage may be proposed by the registry and accepted by the reviewers. If an alternative is proposed, reviewers should confirm that the method is acceptable with Systems Development Branch (SDB) staff before accepting.***

## **Standard #3**

### **Enable access to and retrieval of immunization information in the registry at the time of encounter**

1. Randomly select 10 records from the sample requested under Standard #2, and ask the registry to retrieve the immunization records for these children at the selected provider site(s). The response for the records retrieved should identify each specific child in the request and include their current immunization status. If less than 90% of the immunization records are retrieved, then this standard has not been met.

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3. Observe and document the method of information retrieval and the proportion of patients successfully retrieved. The access methods may include electronic, phone, fax, etc.
4. Collect any forms used for record retrieval and copies of screen prints for records retrieved. For records retrieved, mask any personally identifiable information.

## **Standard #4**

### **Receive and process immunization information within *1 month* of vaccine administration**

1. Prior to the site visit, review the database sample showing the immunization records for each child in the cohort of interest
  - Review birth dates to ensure that the cohort falls within the requested range.
  - Review to see if filler data is included. If it appears that filler data is included, request and record the registry's explanation, and determine the proportion of required fields that are non-valued.
  - Determine the proportion of records that contain 100% valid and valued data
  - Review data to see that it looks valid; e.g., a variety of vaccine types and administration dates. If it appears that invalid data is included, request and record the registry's explanation, and determine the proportion of sample records containing invalid data.
2. Observe the generation and collect a copy of the report calculating the percentage of records that were processed within 1 month of vaccine administration. The report shall include columns listing the date of vaccine administration; the date of receipt of primary immunization information; and a column listing the difference between these dates, in days. Review the query parameters, and verify that the query adequately differentiates between valued and non-valued data for the required fields. Records containing invalid or non-valued data should be included in the report, and should be clearly flagged on the report listing. If the report calculating the percentage of records that were processed within 1 month of vaccine administration does not show that at least 90% of the primary immunization information was received and processed within 1 month of vaccine administration, then this standard has not been met.

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## **Standard #5**

### **Protect the confidentiality of health care information<sup>2</sup>**

For certification, a registry's **process** for implementing their privacy policy will be evaluated. A Confidentiality Working Group (CWG), to be formed by NIP, will evaluate the **content** of the privacy policy.

Until the CWG has been formed and standards for the content of the privacy policy established, the registry should submit a copy of their existing privacy policy for informational purposes only.

Certification that is awarded before this process is in place will be provisional.

## **Standard #6**

### **Ensure the security of health care information**

Prior to the site visit, review the written security plan and check to see that the plan addresses all the items listed below. During the onsite visit, interview registry staff and confirm with users and document how the items listed are executed.

#### **I. Administrative procedures**

**\_\_Security certification.** The registry must conduct a technical evaluation, performed by either internal or external staffs, to assess the extent to which its computer system and network design and implementation meets a pre-specified set of security requirements.

**\_\_Data transfer.** The registry should have a signed agreement with each partner<sup>3</sup> (e.g., researchers) with whom they electronically exchange data, agreeing to protect the integrity and confidentiality of the data exchanged.

**\_\_Contingency plan.** The registry should implement a routinely updated plan for responding to a system emergency. This plan may include performing backups, preparing critical facilities that can be used to facilitate continuity of operations in the event of an emergency, and recovering from disaster. The plan should address all of the following features:

- Applications and data criticality analysis
- Data backup plan
- Emergency mode operation plan
- Procedures for testing and revising written contingency plan
- Disaster recovery plan:

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<sup>2</sup> Health care information in this document refers to patient demographics, as well as medical conditions, care or services related to the health of the patient.

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The registry should have a written backup and recovery plan that provides for regular incremental and periodic full database backup. Backup media should be stored securely in a separate location. In addition, the registry should have a regularly tested (at least annually) disaster recovery plan.

**\_\_Information access management.** The registry should have documented policies and procedures for granting different levels of access to health care information that addresses all of the following features:

- Access authorization
- Access establishment
- Access modification

**\_\_Personnel security.** The registry should ensure that all personnel who have access to any individually identifiable information have the required authorization as well as all appropriate clearances. The registry should address all of the following features:

- Assure that operating and maintenance personnel have proper access authorization and supervision
- Establish personnel clearance procedures
- Maintain a record of access authorizations
- Establish and maintain personnel security policy/procedure
- Assure that system users receive security awareness training
- Establish termination procedures that include appropriate security measures, e.g.,
  - Change combination locks
  - Remove user from access lists
  - Remove user account(s)
  - Retrieve user keys, token or access cards

**\_\_Assign security responsibility.** The registry should have a practice established to manage and supervise the execution and use of security measures to protect data and manage and supervise the conduct of personnel in relation to the protection of data

**\_\_Security configuration management.** The registry should have measures, practices, and procedures for the security of information systems that can be coordinated and integrated with each other and other measures, practices and procedures of the organization established in order to create a coherent system of security. The registry should address all of the following features:

- Documentation of security system
- Review and test hardware/software installation and maintenance for security features
- Inventory hardware and software assets
- Conduct/implement security testing
- Conduct/implement virus checking

**\_\_Security incident procedures.** The registry should implement documented instructions for reporting security breaches that address all of the following features:

- Report procedures to document security incidents

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- Response procedures to be taken as a result of a security incident report

\_\_**Security management process.** The registry should have a process in place for the creation, administration, and oversight of policies to ensure the prevention, detection, containment, and correction of security breaches involving risk analysis and risk management. This process should address the following features:

- Risk analysis
- Risk management
- Sanction policies and procedures
- Security policy
- Regular review of systems activity logs and audit trails

\_\_**Training.** The registry should provide education concerning the vulnerabilities of the health information in the registry's possession and ways to ensure the protection of the information. Training may consist of the following features:

- Provide awareness training for all personnel (including management)
- Issue periodic security reminders
- Educate users concerning virus protection
- Educate users of importance of monitoring log-in success/failure and how to report discrepancies
- Educate users about password management

## II. **Physical safeguards**

\_\_**Facility access controls (limited access).** The registry should have documented policies and procedures to be followed to limit physical access to an entity while ensuring that properly authorized access is allowed. The registry should address the following features:

- Facility security plan
- Procedures for verifying access authorizations prior to physical access
- Maintenance records
- Need-to-know procedures for personnel access
- Sign-in for visitors and escort, if appropriate
- Testing and revision

\_\_**Policy/guideline on workstation use:** The registry should provide documented instructions/procedures delineating the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific computer terminal site or type of site, dependent upon the sensitivity of the information accessed from that site.

\_\_**Media controls.** The registry should have documented policies and procedures that govern the receipt and removal of hardware/software into and out of a facility. The registry should address the following features:

- Accountability (tracking mechanism)
- Data backup
- Data storage

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- Disposal
- Media reuse procedures

**\_\_Workstation security:** The registry should provide physical safeguards to eliminate or minimize the possibility of unauthorized access to information.

### III. Technical security services

**\_\_Access control:** The registry should address emergency access and a mechanism to restrict access

**\_\_Audit controls:** The registry should address mechanisms employed to record and examine system activity.

**\_\_Authorization control:** The registry should address a mechanism for obtaining consent for the use and disclosure of health information that may include one of the following implementation features:

- Role-based access
- User-based access

**\_\_Data authentication:** The registry should have corroboration that data has not been altered or destroyed in an unauthorized manner (e.g., use of check sum, message authentication code, digital signature)

**\_\_Entity authentication:** The registry should have corroboration that an entity is the one claimed including automatic log off (or equivalent) and unique user identifier. Registries should consider adding at least **one** of the following:

- Biometric identification
- Password
- Personal Identification Number (PIN)
- Telephone callback procedure
- Token

### IV. Technical security mechanisms

**\_\_Transmission security.** If the registry employs network communications, the security standards for technical security mechanisms should address integrity controls and message authentication and must implement encryption if Internet is used as a transmission media.

## **Standard #7**

### **Exchange immunization records using Health Level Seven (HL7) standards**

Evaluation methods for this standard are not complete. We hope to work out a method for testing HL7 capability when we meet with David Marotta next week. David is the contractor developing the HL7 communications tool for immunization registries.

1. Observe and document the registry's processing of a test data set of 40 HL7 records. The HL7 transaction types shall include the VXU and VXQ.

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2. Provide a set of test queries and immunization records and ask the registry to create test messages.
3. Request a printout of the messages processed.

## **Standard #8**

**Automatically determine the routine childhood immunization(s) needed, in compliance with current ACIP recommendations, when an individual presents for a scheduled immunization**

1. Prior to the site visit, the registry should download the CDC generated test cases from the NIP website. The registry should run these test cases through their algorithm and submit the results with their application for certification. If the registries algorithm does not score at 95% correct, and there is no documentation that state or local variances from the ACIP recommendations exist, then this standard has not been met.
2. If the registry did score at least 95% correct, then during the site visit, provide the registry with a subset of the CDC test cases to run through their algorithm. Record the percent of test cases correctly forecasted by their algorithm.
3. If variance from the ACIP recommendations are detected, and were not reported with the application for certification, document the registry's reason(s) and whether the variance was intentional. For example, if state requirements are different from the ACIP recommendations, document the differences and their rationale.
4. During the provider site visit(s), ask the provider to retrieve 10 patients' records, access this function, and show what vaccinations are due next. The patient's records may be a drawn from the sample of records used for Standard #3. Document how the provider gets this information.

## **Standard #9**

**Automatically identify individuals due/late for immunization(s) to enable the production of reminder/recall notifications**

1. During the site visit, provide the registry with a subset of 10 test cases. Ask the registry to demonstrate the production of reminder/recall notifications.
2. Document whether the registry successfully identified individuals due or late for immunizations and generated reminder/recall notices. The reviewer should carefully document any variances.

## **Standard #10**

**Automatically produce immunization coverage reports by providers, age groups, and geographic areas**

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During the site visit, ask the registry to demonstrate the generation of immunization coverage reports for each:

- 4:3:1 coverage by individual provider/ provider site
- 4:3:1:3 coverage at 12-month age intervals (e.g. 0-11 months of age)
- 4:3:1:3:3 coverage by zip code

For each coverage report produced, collect the query definition and a copy of the report's output.

## **Standard #11**

### **Produce official immunization records**

During the provider site visit, observe an authorized user produce a copy of an individual's immunization history that serves as an official record. Collect a copy of the record with personally identifiable information blacked out. Record the time needed to perform this task, and describe the features of the report that identify it as an official record. Ask if the report has ever been known to have been falsified, or rejected by any entities as falsifiable. Document any history of falsification or rejection.

### **Standard #12 – Promote accuracy and completeness of registry data.**

1. Registry data accuracy will be measured using a two-step process. The first step will assess the sensitivity (percentage of test case duplicates identified as duplicates by the registry) and specificity (percentage of test cases non-duplicates identified as non-duplicates by the registry) of the registry's automated (pre-human intervention) de-duplication process using CDC's de-duplication test cases.

During the certification site visit, test cases will be downloaded from CDC's web site and processed by the registry. If the registry's automated process meets 90% sensitivity and 100% specificity, the second step will occur. Records of the cohort of children born during the 12-month period ending 1 year prior to the site visit will be assessed for duplicates using the registry's automated de-duplication algorithm. A duplicate rate of no more than 5% is required for certification.

2. Where possible, registry data completeness will be measured using the National Immunization Survey (NIS). The NIS provides ongoing national estimates of vaccination coverage among children 19-35 months of age living in the 50 states and 28 selected urban areas<sup>4</sup>. To collect vaccination data for

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<sup>4</sup> \*Jefferson County, Alabama; Maricopa County, Arizona; Los Angeles, San Diego County, and Santa Clara, California; District of Columbia (DC); Dade and Duval counties, Florida; Fulton/DeKalb County, Georgia; Chicago, Illinois; Marion County, Indiana; Orleans Parish, Louisiana; Baltimore, Maryland;

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children aged 19--35 months, NIS uses a random-digit--dialing sample of telephone numbers for each survey area. During the survey, parents are asked to allow access to immunization information from all of their child's immunization providers. These providers are then contacted and asked to check their records and provide this information to the survey team. Consent is also solicited to access the appropriate immunization registry for this information. Two measures of completeness will be calculated:

- 1) *Population completeness*: the percentage of consented children in the NIS sample with records with at least 2 immunizations in the registry, and
- 2) *Immunization history completeness*: for all consented children in the NIS who are also in the registry (with at least 2 immunizations recorded in the registry), the percentage of these children with registry immunization histories that include all vaccines identified in the NIS (i.e., same vaccine type and date recorded for all NIS vaccines identified).

NIS data quality comparisons will be conducted on an ongoing basis for registries throughout the U.S. Thus information on the registry's population completeness and immunization history completeness should be submitted with the certification application. 80% population completeness and 90% immunization history completeness will be required for certification. In areas where the NIS is not conducted (e.g., U.S. Territories), the alternate methodology below may be used to assess completeness.

3. Alternate methodology. Ask the registry to pull a sample of **10** immunization records from each provider site that you will visit. During the provider site visit, compare the registry data with that in the provider's records. Do the records match? If no, document any differences.

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Boston, Massachusetts; Detroit, Michigan; Newark, New Jersey; New York, New York; Cuyahoga and Franklin counties, Ohio; Philadelphia County, Pennsylvania; Davidson and Shelby counties, Tennessee; Bexar, Dallas, and El Paso counties, and Houston, Texas; King County, Washington; and Milwaukee County, Wisconsin.