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Background

The following tables provide a comparison of principles and business rules from three retired Modeling of Immunization Registry Operations Workgroup (MIROW) resources¹ with the updated principles and business rules in 2022 MIROW Data Quality Assurance in Immunization Information Systems. Rules that the workgroup decided were no longer accurate or applicable to this guide are marked as "retired".

Data Quality Assurance in Immunization Information Systems: Incoming Data

Principles

Previous	Current
P01 Consistency principle: The conditions (criteria) for validating data items should be the same regardless of how these data items have been reported to an IIS.	P07 - Consistent application of business rules
P02 Variable outcomes principle: When conditions (criteria) of a validation check are not satisfied, the resulting actions (e.g., accept, reject, research) may vary depending on the data item's source and the way data were reported.	Retired

¹ The resources were *Data Quality Assurance in Immunization Information Systems: Incoming Data, Data Quality Assurance in Immunization Information Systems: Selected Aspects, Lot Number Validation Best Practices Micro-Guide.* Please email info@immregistries.org to request the three archived documents

Previous	Current
 P03 Rejected data principle: When information is rejected by the IIS, the following actions should be taken: If batch, then log the error and notify submitter. If UI, then display an error message and offer the opportunity to correct 	Retired
P04 Internal consistency principle: Characteristics of the vaccination history should not contradict one another. This includes reported data as well as data already in the IIS.	P06 – Cross-field validation
P05 Accuracy principle: The data recorded in the IIS should match exactly what happens in a clinical encounter, whether or not it is clinically appropriate.	Retired covered by P10 – Accurately reflect vaccination event
P06 Appropriate vaccination principle: The vaccinations reported by a provider should be appropriate for the population served at the clinic.	Retired covered by BR168 – Submissions are appropriate for provider organization type
P07 Vital Records principle: Vital Records is the definitive source for date of birth and date of death.	P18 - Vital records
P08 Validation priority principle: The importance of validating a data item is related to the data item's significance in clinical decision making, public health assessments, and research.	P02 - Validation priority
P09 Maintain data integrity principle: Any modification of the data in the IIS should not violate the integrity of the existing data.	Retired
P10 ACIP recommendations principle: Deviations from ACIP recommendations and US licensure may indicate data quality problems.	P09 - Advisory Committee on Immunization Practices recommendations
P11 Timeliness principle: Data should be timely. Data should be reported and recorded in the IIS, as well as be available to users in a timely manner.	P03 - Timeliness
P12 Completeness principle: The information submitted to the IIS must contain the minimum/mandatory set of data items in order to be accepted by an IIS	P05 - Mandatory data elements
P13 Supremacy of medical records principle: Medical records are a more reliable source of immunization data than billing records.	P19 - Supremacy of medical records

Business Rules

Business rules BR101 through BR127 from the 2008 guide were reviewed and updated in 2013 Data Quality Assurance in Immunization Information Systems: Selected Aspects and are included with that set of business rules below.

Previous	Current
 BR128 Expected number of vaccination event record: A patient should not have more than: 50 vaccinations before 5 years of age 35 vaccinations before 2 years of age 70 vaccinations regardless of age 	BR140 - Expected number of vaccination event records
BR129 Recommended number of vaccine doses: A patient should not have more than 7 DTaP vaccinations by age 7.	BR141 - Recommended number of vaccine doses
BR130 Patient age within recommended range: Doses should not be recorded as given before the minimum patient age or after the maximum patient age for that particular vaccine.	BR125 - Patient age within recommended range
BR131 Minimum intervals for vaccination event records: Doses should not be recorded as given before the minimum interval has been met.	BR142 - Minimum intervals for vaccination event records
BR132 Number of vaccine doses in a vaccination encounter: A patient should not have more than 10 vaccinations per visit.	BR143 - Number of vaccine doses in a vaccination encounter

The table of business rules related to ranges and codes for selected individual data elements was summarized in the following updated rules:

- BR109 Standard value tables
- BR110 Valid calendar dates in a submission
- BR117 Vaccine type CVX
- BR122 Vaccine has vaccine product type
- BR127 Vaccination event dosage
- BR128 Approved vaccine administration method
- BR129 Lot number validation
- BR145 Allowed character for name
- BR146 Use official names
- BR147 Patient first name
- BR148 Patient first and last name two characters
- BR154 Complete address
- BR155 International address supported
- BR160 Medical record number not equal to Social Security number

Data Quality Assurance in Immunization Information Systems: Selected Aspects

MIROW guides no longer include general recommendations, so the seven general recommendations from the 2013 guide were retired.

Principles

Previous	Current
P801 - Consistent provider organization management: IIS should be consistent in the approaches followed for Facility Identification Management.	P17 - Consistent provider organization management
P802 - Document approaches used: IIS should clearly document the approaches followed for Facility Identification Management.	Retired: Concept added into P17 - Consistent provider organization management

Business Rules

Previous	Current
BR101 - Vaccination Encounter Date must not be before Patient Date of Birth.	BR111 - Vaccination event date not before patient's date of birth
BR102 - Vaccination Encounter Date should not be after the Patient Date of Death.	BR114 - Vaccination event date not after patient's date of death
BR103 - Vaccination Encounter Date must be less than or equal to (before or the same as) the Submission Date.	BR113 - Submission not before vaccination event
BR104 - The minimum/mandatory set of data items for the Demographic- only submission includes: IIS-AO ID (Recorder) Patient Date of Birth Patient Name, First Patient Name, Last Birth Certificate Number Birth Facility (code, name, address) Gender	BR001 - Minimum/mandatory data elements

Previous	Current
BR105R1 - The minimum/mandatory set of data items for the "administered" Vaccination Event submission must include: • IIS-AO ID (Vaccinator/Recorder) • Patient Name, First • Patient Name, Last • Patient Date of Birth • Vaccination Encounter Date • Vaccine Type • Administered/Historical Indicator = "Administered" • Lot Number	BR001 - Minimum/mandatory data elements
BR105R2 - The minimum/mandatory set of data items for the "historical" Vaccination Event submission must include: • Patient Name, First • Patient Name, Last • Patient Date of Birth • Vaccination Encounter Date • Vaccine Type • Administered/Historical Indicator = "Historical"	BR001 - Minimum/mandatory data elements
BR106 – Retired in the 2013 guide The minimum/mandatory set of data items for the Electronic Medicaid/Billing Records must include: • Provider Organization Name/ID • Patient Name, First • Patient Name, Last • Patient Date of Birth • Vaccine Encounter Date • Vaccine Type	Not applicable because the rule was retired in 2013
BR107 - Every administered vaccine should be recorded as a single Vaccination Event.	BR120 - Combination vaccine reported as single vaccination event
BR108 - Vaccinations submitted via electronic data exchange to IIS that do not perform a manual review should appear in the IIS within 2 business days of the Submission Date. Vaccinations submitted via electronic data exchange to IIS that perform manual reviews should appear in the IIS within 2 weeks of the Submission Date.	BR162 - Review rejected submissions within five days
BR109 - Retired in the 2013 guide Vaccination Event reported by Provider assumed to be "Historical" until attested or proven otherwise.	Not applicable because the rule was retired in 2013

Previous	Current
BR110 - Retired in the 2013 guide VFC-eligible children should have the manufacturer and lot number reported with Vaccination Event.	Not applicable because the rule was retired in 2013
BR111 - Adverse reactions reported on administered vaccines should be identified for tracking and provider follow-up.	Retired
BR112 - The percentage of Vaccination Event Submissions from Vital Records with hepatitis B birth doses should be within an expected threshold level (to be determined by each IIS).	BR164 - Hepatitis B birth dose
BR113 - If the IIS-AO (Vaccinator) is a "specific," (e.g., pediatric) practice, the currently administered vaccinations should match a pattern in similar practices.	BR168 - Submissions are appropriate for provider organization type
BR114 - Vaccination Encounter Date should not be the same as the Patient Date of Birth unless it is on the list of vaccines recommended for administration on the date of birth, e.g., Hep B.	BR116 - Vaccination event date for birth vaccine types
BR115 - For administered Vaccination Event submissions, Submission Date should be within 14 days of Vaccination Encounter Date.	BR106 - Administered initial submission
BR116 - Trade Name, Manufacturer, CVX Code, CPT Code, and Vaccine Type should not contradict one another.	Retired. Covered by BR126 - Vaccine information should be consistent
BR117 - The same patient should not receive the same antigen more than once in a single day.	BR144 - Same antigen on same day
BR118 - Vaccination Encounter Date should not be after the lot number expiration date.	BR115 - Vaccination event date not after lot number expiration date
BR119 - Route and Site should not contradict each other for a given Vaccine Type and Patient's age.	BR128 - Approved vaccine administration method
BR120 - Vaccination Encounter Date should be within the Vaccine Product License Date range: after the Vaccine Product License Begin Date and before the Vaccine Product License End Date.	BR133 - Vaccine product license
BR121 - Administered vaccinations should have specific Vaccine Types, e.g., Hib PRP-OMP; unspecified vaccine types, e.g., Hib, UF (unspecified formulation), are not appropriate.	BR118 - Specified formulation for administered

Previous	Current
BR122 - A patient's eligibility for a public program (e.g., VFC program, state program) should be consistent with the administered vaccine dose's designation for a stock type (e.g., public, private).	BR135 - Consistent vaccine eligibility
BR123 - The volume of reporting from the Vital Records feed should be within an expected threshold level (to be determined by each IIS).	BR165 - Vital records submissions
BR124 - The percentage of Vaccination Events in which the responsible party name is the same as the patient name should be within an expected threshold level (to be determined by each IIS).	Retired
BR125 - The percentage of rejected Vaccination Events submissions in a Combined Submission should be within an expected threshold level.	BR166 - Rejected vaccination event submission
BR126 - An administered vaccine should not have a medical contraindication for a patient.	Retired
BR127 - Hepatitis B birth doses from the Vital Records feed should be reported within an agreed-upon timeframe.	BR107 - Vaccination event submission of hepatitis B birth dose
BR801 - Conduct a pre-certification process: IIS should conduct a pre-certification process in order for the IIS-AO system to submit data to the IIS via Electronic Data Exchange	BR101 - Authorized provider organization
BR802 - Maintain IIS-AO DQA profile: IIS should identify and maintain baseline (IIS-AO DQA Profile) data for comparison later. Measures for this baseline data may include (not an exhaustive list): • Frequency of submissions • Content of data • Volume of Vaccination Events • Volume of Demographic events • Method of reporting • EHR vendor	BR102 - Establish provider organization profile
BR803 - Review the submission reports: The IIS should review the submission logs for error trends on a daily basis.	BR163 - Review the submission reports
BR804 - Track participants in the submittal chain: Vaccination Event Submission for "administered" Vaccination Events must have the Vaccinator, Recorder, and Submitter(s) IIS-AO ID.	Retired: Included in BR001 - Minimum/mandatory data elements

Previous	Current
BR805 - All Submitters should be identified: All Submitters in the submission chain should be identified.	Retired: Changed to P21 - Complete chain of submitting organizations
BR806 - Track Recorder IIS-AO: For Vaccination Event Submissions, the IIS-AO that enters information into the IIS-AO system or IIS Direct UI should be tracked as the Recorder IIS-AO ID.	Retired: Included in BR001 - Minimum/mandatory data elements
BR807 - Track status for all submissions: Status (i.e., accepted, accepted with errors, rejected, etc.) and Status Date should be tracked for all Vaccination Event Submissions.	Retired: Covered by BR161 - Record submission errors and submission status
BR808 - Include Vaccine Administrator and Vaccine Prescriber in the submission: Vaccine Administrator and Vaccine Prescriber should be included in the Vaccination Event Submission.	BR138 - Include vaccine administrator and vaccine prescriber in the submission
BR809 - Record submission errors and submission status: IIS should record error and reason for error of a Vaccination Event Submission and Demographic-only Submission.	BR161 - Record submission errors and submission status
BR810 - Maintain unique medical record numbers for IIS-AO patients: During the pre-certification process, the IIS should review with a Submitter the process to be followed to ensure that they maintain unique medical record numbers for patients.	BR159 - Educate on use of medical record numbers
BR811 - IIS-AO IDs must be unique: All IIS-AO IDs must be unique and must never be reused.	BR173 - IIS-AO IDs should be unique
BR812 - IIS-AO IDs should not embed information about the IIS-AO: IIS-AO IDs should not embed information about the IIS-AO.	BR174 - IIS-AO IDs should not embed information about the IIS-AO
BR813 - User must be associated with IIS-AO: A User who is submitting and/or retrieving data from the IIS must be associated with the IIS-AO that is responsible for those records.	Retired
BR814 - Maintain both legal and common names for an IIS-AO: An IIS should maintain both legal and common names for an IIS-AO.	BR176 - Maintain both legal and common names for an IIS-AO

Previous	Current
BR815 - Validate organizational and reporting structure periodically: IIS should proactively validate the current organizational and reporting structure for existing IIS-AOs on a quarterly basis.	BR177 - Validate organizational and reporting structure regularly
BR816 - Validate organizational and reporting structure on rejection: IIS should validate the current organizational and reporting structure when a submission gets rejected due to an invalid or unknown IIS-AO ID.	BR175 - Educate submitting organization to include all IIS-AO IDs
BR817 - Update IIS-AO when a structural change occurs: IIS-AO attributes and relationships should be updated, where necessary, any time a structural change occurs regarding one or more organizations and/or organizational sub-units.	Retired: Added as a comment in BR177 - Validate organizational and reporting structure regularly
BR818 – BR823: Six business rules from Data Quality Assurance in Immunization Information Systems: Selected Aspects were determined to be out-of-scope for this guide and would be better addressed in a future guide.	The original language for the six rules is provided in Appendix G.
BR824 - De-authorize IIS-AO if it dissolves: If an IIS-AO dissolves, it should be de-authorized in the IIS.	BR179 - Deauthorize IIS-AO if it dissolves
BR825 - De-authorize IIS-AO if it no longer plays any of IIS-AO roles: If an existing IIS-AO is no longer a Vaccinator, Submitter, Recorder, or Data Consumer, the IIS-AO must be deauthorized in the IIS.	BR180 - Deauthorize IIS-AO if it no longer plays any IIS-AO roles
BR826 - Do not de-authorize IIS-AO that is required to submit but not submitting: If a Vaccinator is required to submit to the IIS and is not submitting to the IIS, the IIS should not deauthorize the IIS-AO.	Retired: Covered by BR181 - Assess necessity to deauthorize IIS-AO that is not required to submit and is not submitting
BR827 - Assess necessity to de-authorize IIS-AO that is not required to submit and is not submitting: If a Vaccinator is not required to submit to the IIS and is not submitting to the IIS, the IIS should assess the necessity to de-authorize the IIS-AO.	BR181 - Assess necessity to deauthorize IIS-AO that is not required to submit and is not submitting

Micro-Guide: Lot Number Validation Best Practices Principles

Previous	Current
P01 - Reference a directory of known lot numbers: A directory of known lot numbers should be created, maintained, and referenced for lot number's validation purposes.	P23 - Reference a directory of known lot numbers
P02 - Reference a directory of manufacturer-specific coding schemes for lot numbers: A directory of manufacturer-specific coding schemes for lot numbers should be created, maintained, and referenced for lot number's validation purposes.	P24 - Reference a directory of manufacturer-specific coding schemes for lot numbers
P03 - Reference a directory of generic rules (for all manufacturers) for coding lot numbers: A directory of generic manufacturer rules for coding lot numbers should be created, maintained, and referenced for lot number validation purposes.	Retired
P04 - Maintain reliability of reference directories: Reference directories (directory of known lot numbers, directory of manufacturer- specific coding schemes, directory of generic manufacturer rules for coding lot numbers) should be periodically reviewed and reconfirmed as reliable reference sources for validating lot numbers.	P25 - Maintain reliability of reference directories