

ILLINOIS DEPARTMENT OF PUBLIC HEALTH

State Of Illinois – National Electronic Disease Surveillance System

Illinois Department of Public Health

INEDSS

Manage Tuberculosis Business Rules

Version 1.6

Revision History

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| April 3, 2007 | 1.1 | Added Field validation rules | Mike Jadala |
| April 9, 2007 | 1.2 | Added Calculated field rules and Anatomic Site validations (Appendix1) | Mike Jadala |
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1 INTRODUCTION

1.1 Scope

1.2 References

1.3 Assumptions

Please see the [Assumptions](#) section for a detailed list of assumptions.

1.4 Overview

1.5 Open Issues

1.6 Notes

2 BUSINESS RULES

2.1 Fields validation rules

- General Illness
 - 'Age at Report' = (Date of Birth – Date LHD Received)
- TB Diagnostics
 - If 'TB Clinic (For CDPH only)' is answered, 'Jurisdiction' of Case must be 'Westside Center for Disease Control (CDPH)'.
 - If 'Jurisdiction' of Case is not 'Westside Center for Disease Control (CDPH)', then disable 'TB Clinic (For CDPH only)'.
 - If the 'State Case Number' from Admin Review page is not null, then disable the 'TB Clinic (for CDPH only)' field.
 - If 'If yes, year of previous diagnosis (ccyy)' or 'Was there more than one previous diagnosis?' is answered, then 'Previous Diagnosis of Tuberculosis' must be answered as 'Yes'.
 - If 'Previous Diagnosis of Tuberculosis' is not answered as 'Yes', then disable 'If yes, year of previous diagnosis (ccyy)' and 'Was there more than one previous diagnosis?'.
 - 'Where is the major site of disease?' must not have same value as 'Where is the additional site of disease?' except for 'Other'.
 - If 'Where is the additional site of disease?' and 'If other additional site, select additional site type' are not blank, then 'Where is the major site of disease?' cannot be selected as 'Miliary' or 'Site not stated' or blank.
 - If 'Where is the major site of disease?' is selected as 'Miliary' or 'Site not stated' or blank, disable 'Where is the additional site of disease?' and 'If other additional site, select additional site type'.
 - If 'If Microscopic exam test is positive, select site(s)' or 'If Culture of Tissue test is positive, select site(s)' have values, then 'Where is the major site of disease?' must not be selected as 'Site not stated' or blank.
 - If 'Where is the major site of disease?' is answered as 'Site not stated' or blank, disable 'If Microscopic exam test is positive, select site(s)' and 'If Culture of Tissue test is positive, select site(s)'.
 - If 'Where is the major site of disease?' is answered as 'Other', then 'If other major site, select other type' must have a value selected.
 - If 'Where is the additional site of disease?' is selected as 'Miliary', no other value can be selected.
 - If 'If other additional site, select additional site type' has a value, then 'Where is the additional site of disease?' must be selected as 'Other'.
 - If 'Where is the additional site of disease?' is not selected as 'Other', disable 'If other additional site, select additional site type'.

- If 'Where is the additional site of disease?' is selected as 'Other', then 'If other additional site, select additional site type' must have a value.
- 'If other additional site, select additional site type' must not have the same value selected as 'If other major site, select other type'.
- If 'Sputum Smear Test Date' has a value, then 'Sputum Smear Result' must be answered as 'Positive' or 'Negative' or 'Unknown'.
- If 'Sputum Smear Result' is not answered as 'Positive' or 'Negative' or 'Unknown', then disable 'Sputum Smear Test Date'.
- If 'Sputum Smear Result' is answered as 'Positive', then either 'Where is the major site of disease?' or 'Where is the additional site of disease?' must be selected as 'Pulmonary' or 'Pleural' or 'Lymphatic: Intrathoracic' or 'Miliary'

OR

either 'If other major site, select other type' or 'If other additional site, select additional site type' must be selected as 'Nose' or 'Accessory Sinus' or 'Nasopharynx' or 'Epiglottis and larynx' or 'Trachea'.

- If 'Sputum Culture Test Date' has a value, then 'Sputum Culture Result' must be answered as 'Positive' or 'Negative' or 'Unknown'.
- If 'Sputum Culture Result' is not answered as 'Positive' or 'Negative' or 'Unknown', then disable 'Sputum Culture Test Date'.
- If 'Sputum Culture Result' is answered as 'Positive', then either 'Where is the major site of disease?' or 'Where is the additional site of disease?' must be selected as 'Pulmonary' or 'Pleural' or 'Lymphatic: Intrathoracic' or 'Miliary'

OR

either 'If other major site, select other type' or 'If other additional site, select additional site type' must be selected as 'Nose' or 'Accessory Sinus' or 'Nasopharynx' or 'Epiglottis and larynx' or 'Trachea'.

- If 'Sputum Culture Result' is answered as 'Positive', then 'Reason Therapy Stopped' on Follow Up Report 2 must not be answered as 'Not TB'.
- If 'Sputum Culture Result' is answered as 'Negative' or 'Not Done' or 'Unknown', then 'Sputum Culture Conversion Documented' on Follow Up Report 2 must not be answered as 'Yes'. This rule is subsumed by the [rule on Follow up Report 2](#).
- If 'If Microscopic exam test is positive, select site(s)' is answered, then 'Microscopic Exam of Tissue and Other Body Fluids Result' must be answered as 'Positive'.
- If 'Microscopic Exam of Tissue and Other Body Fluids Result' is not answered as 'Positive', then disable 'If Microscopic exam test is positive, select site(s)'.
- If 'Microscopic Exam Test Date' has a value, then 'Microscopic Exam of Tissue and Other Body Fluids Result' must be answered as 'Positive' or 'Negative' or 'Unknown'.
- If 'Microscopic Exam of Tissue and Other Body Fluids Result' is not answered as 'Positive' or 'Negative' or 'Unknown', then disable 'Microscopic Exam Test Date'.
- See [Appendix 1](#) for validations tying 'Where is the major site of disease?' and 'Where is the additional site of disease?' to 'If Microscopic exam test is positive, select site', 'If Culture of

Tissue test is positive, select site' and 'If Nucleic Acid Amplification Test is positive, select site'.

- If 'If Culture of Tissue test is positive, select site(s)' is answered, then 'Culture of Tissue and Other Body Fluids Result' must be answered as 'Positive'.
- If 'Culture of Tissue and Other Body Fluids Result' is not answered as 'Positive', then disable 'If Culture of Tissue test is positive, select site(s)'.
- If 'Culture of Tissue Test Date' has a value, then 'Culture of Tissue and Other Body Fluids Result' must be answered as 'Positive' or 'Negative' or 'Unknown'.
- If 'Culture of Tissue and Other Body Fluids Result' is not answered as 'Positive' or 'Negative' or 'Unknown', then disable 'Culture of Tissue Test Date'.
- If 'Reason Therapy Stopped' on Follow Up Report 2 is answered as 'Not TB', then 'Culture of Tissue and Other Body Fluids Result' cannot be answered as 'Positive'.
- If 'If Nucleic Acid Amplification test is positive, select site(s)' is answered, then 'Nucleic Acid Amplification Test Result' must be answered as 'Positive'.
- If 'Nucleic Acid Amplification Test Result' is not answered as 'Positive', then disable 'If Nucleic Acid Amplification test is positive, select site(s)'.
- If 'Nucleic Acid Amplification Test Collection Date' is answered, then 'Nucleic Acid Amplification Test Result' must be answered as 'Positive' or 'Negative' or 'Unknown'.
- If 'Nucleic Acid Amplification Test Result' is not answered as 'Positive' or 'Negative' or 'Unknown', then disable 'Nucleic Acid Amplification Test Collection Date'.
- If 'If abnormal, select the abnormality' or 'If abnormal, select the condition' has a value, then 'Chest X-Ray Result' must be selected as 'Abnormal'.
- If 'Chest X-Ray Result' is not selected as 'Abnormal', then disable 'If abnormal, select the abnormality' and 'If abnormal, select the condition'.
- If 'Date of Chest X-Ray' has a value, then 'Chest X-Ray Result' must be answered as 'Normal' or 'Abnormal' or 'Unknown'.
- If 'Chest X-Ray Result' is not answered as 'Normal' or 'Abnormal' or 'Unknown', then disable 'Date of Chest X-Ray'.
- If 'Tuberculin Skin Test Date' has a value, then 'Tuberculin (Mantoux) Skin Test at Diagnosis result' must be answered as 'Positive' or 'Negative' or 'Unknown'.
- If 'Tuberculin (Mantoux) Skin Test at Diagnosis result' is not answered as 'Positive' or 'Negative' or 'Unknown', then disable 'Tuberculin Skin Test Date'.
- If 'mm. of Induration' is >9 and <99, then 'Tuberculin (Mantoux) Skin Test at Diagnosis result' must be answered as 'Positive'.
- If 'mm. of Induration' is <5, then 'Tuberculin (Mantoux) Skin Test at Diagnosis result' must be answered as 'Negative'.
- If 'mm. of Induration' is >4 and <10 or equal to 99, then 'Tuberculin (Mantoux) Skin Test at Diagnosis result' must be answered as 'Positive' or 'Negative'.
- If 'Blood Test Type' or 'Blood Test Date' has a value, then 'Blood Test Result' must be answered as 'Positive' or 'Negative' or 'Unknown'.

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- If 'Blood Test Result' is not answered as 'Positive' or 'Negative' or 'Unknown', then disable 'Blood Test Type' and 'Blood Test Date'.
 - Epidemiologic Data
 - 'Date of Arrival (if foreign born)' must be on or before 'Count Date'.
 - 'Date of Arrival (if foreign born)' must be on or before 'Date LHD Received'.
 - If 'Date of Arrival (if foreign born)' is answered, then 'Country of Origin' must be answered as any value other than 'blank' and 'United States'.
 - If 'Country of Origin' is answered as 'blank' or 'United States', disable 'Date of Arrival (if foreign born)'.
 - If 'If positive HIV status, what is it based on?' is answered, then 'HIV Status' must be answered as 'Positive'.
 - If 'HIV Status' is not answered as 'Positive', then disable 'If positive HIV status, what is it based on?'.
 - If either one of 'Was the patient resident of a correctional facility at the time of diagnosis?' or 'Was the patient a resident of a long term care facility at time of diagnosis?' is answered as 'Yes', then the other must be answered as 'No'.
 - If 'If yes, select correctional facility' is answered, then 'Was the patient resident of a correctional facility at the time of diagnosis?' must be answered as 'Yes'.
 - If 'Was the patient resident of a correctional facility at the time of diagnosis?' is not answered as 'Yes', then disable 'If yes, select correctional facility'.
 - If 'Was the patient a resident of a long term care facility at time of diagnosis?' is answered as 'Yes', then 'If yes, select correctional facility' must be blank.
 - If either one of 'If yes, select correctional facility' and 'If yes, select long-term care facility' is not blank, then the other must be blank.
 - If 'If yes, select long-term care facility' is answered, then 'Was the patient a resident of a long term care facility at time of diagnosis?' must be answered as 'Yes'.
 - If 'Was the patient a resident of a long term care facility at time of diagnosis?' is not answered as 'Yes', then disable 'If yes, select long-term care facility'.
 - If 'Was the patient resident of a correctional facility at the time of diagnosis?' is answered as 'Yes', then 'If yes, select long-term care facility' must be blank.
 - For 'Patient Occupation (Check all that apply within the past 24 months)', if 'Unknown' is selected, then no other value can be selected and vice versa.
 - For 'Patient Occupation (Check all that apply within the past 24 months)', if 'Not Employed with the past 24 months' is selected, then no other value can be selected and vice versa.
 - For 'Additional TB Risk Factors', if 'Unknown' is selected, then no other value can be selected and vice versa.
 - Follow up Report 1
 - If the Calculated Variable **'Culture Positive'** is **'No'**, then disable access to the page 'Follow up Report 1' and display a message 'Patient is not Culture Positive and therefore Follow up Report 1 is not required'.

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- If 'Was drug susceptibility testing done?' is answered as 'Yes', then at least one drug must be selected among 'Drugs – Susceptible' and 'Drugs – Resistant'.
 - If 'Was drug susceptibility testing done?' is answered as 'Yes', then the Calculated Variable '**Culture Positive**' must be 'Yes'.
 - If the Calculated Variable '**Culture Positive**' is 'No',, disable 'Was drug susceptibility testing done?'
 - If 'Was final drug susceptibility testing done?' on Follow up Report 2 is answered as 'Yes', then 'Was drug susceptibility testing done?' must be answered as 'Yes'.
 - If 'If yes, enter date first isolate collected for which drug susceptibility was done' is answered, then 'Was drug susceptibility testing done?' must be answered as 'Yes'.
 - If 'Was drug susceptibility testing done?' is not answered as 'Yes', then disable 'If yes, enter date first isolate collected for which drug susceptibility was done'.
 - If 'If yes, enter date final isolate collected for which drug susceptibility was done' on Follow up Report 2 is answered, then 'Was drug susceptibility testing done?' must be answered as 'Yes'.
 - If 'Was drug susceptibility testing done?' is not answered as 'Yes', then disable 'If yes, enter date final isolate collected for which drug susceptibility was done' on Follow Report 2.
 - If any 'Drugs' are selected under 'Final Susceptibility Results' on Follow up Report 2 page, then 'Was drug susceptibility testing done?' must be answered as 'Yes'.
 - If 'Was drug susceptibility testing done?' is not answered as 'Yes', then disable 'Drugs' fields under 'Final Susceptibility Results' on the Follow up Report 2 page.
 - If any 'Drugs' are selected under 'Susceptibility Results' on the Follow up Report 1 page, then 'Was drug susceptibility testing done?' must be answered as 'Yes'.
 - If 'Was drug susceptibility testing done?' is not answered as 'Yes', then disable 'Drugs' fields under 'Susceptibility Results' on Follow up Report 1 page.
 - 'If yes, enter date first isolate collected for which drug susceptibility was done' must be [greater than or equal to] 30 days before 'If yes, enter date final isolate collected for which drug susceptibility was done'.
 - If 'If yes, enter date first isolate collected for which drug susceptibility was done' is answered, then the Calculated Variable '**Culture Positive**' must be 'Yes'.
 - If the Calculated Variable '**Culture Positive**' is 'No', disable 'If yes, enter date first isolate collected for which drug susceptibility was done'
 - If any drugs are selected under 'Susceptibility Results' on the Follow up Report 1 page, then the Calculated Variable '**Culture Positive**' must be 'Yes'.
 - If the Calculated Variable '**Culture Positive**' is 'No', then disable fields under 'Susceptibility Results' on Follow up Report 1 page.
- Follow up Report 2
 - If the Calculated Variable '**Initial Drug Regimen**' is equal to '**No Drugs**', then disable access to the page 'Follow up Report 2' and display a message 'Patient did not start treatment and therefore Follow up Report 2 is not required'.
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- If 'Sputum Culture Result' is not answered as 'Positive', then disable 'Sputum Culture Conversion Documented'.
 - If 'Sputum Culture Conversion Documented' has a value, 'Sputum Culture Result' must be answered as 'Positive'.
 - If 'Was final drug susceptibility testing done?' is answered as 'Yes', then at least one drug must be selected among 'Drugs – Susceptible' and 'Drugs – Resistant'.
 - If 'If yes, date specimen collected on initial positive sputum culture' or 'If yes, date specimen collected on first consistently negative culture' is answered, then 'Sputum Culture Conversion Documented' must be answered as 'Yes'.
 - If 'Sputum Culture Conversion Documented' is not answered as 'Yes', then disable 'If yes, date specimen collected on initial positive sputum culture' and 'If yes, date specimen collected on first consistently negative culture'.
 - 'If yes, date specimen collected on initial positive sputum culture' must be on or before 'If yes, date specimen collected on first consistently negative culture'.
 - If 'If yes, date specimen collected on first consistently negative culture' has a value, then 'If yes, date specimen collected on initial positive sputum culture' must have a value.
 - If 'If no, specify reason for not documenting sputum culture conversion' is answered, then 'Sputum Culture Conversion Documented' must be answered as 'No'.
 - If 'Sputum Culture Conversion Documented' is not answered as 'No', then disable 'If no, specify reason for not documenting sputum culture conversion'.
 - If 'Sputum Culture Conversion Documented' is answered as 'No', then 'If no, specify reason for not documenting sputum culture conversion' must have a value.
 - 'If yes, date specimen collected on initial positive sputum culture' must be populated with the value entered for 'Sputum Culture Test Date' on TB Diagnostics page.
 - Implementation detail: If this field is populated as soon as 'Sputum Culture Test Date' is answered on TB Diagnostics page, the rule 'If yes, date specimen collected on initial positive sputum culture' or 'If yes, date specimen collected on first consistently negative culture' is answered, then 'Sputum Culture Conversion Documented' must be answered as 'Yes' will be violated. Therefore, this field will be populated only once the User answers the 'Sputum Culture Conversion Documented' as 'Yes'.
 - 'Date Therapy Stopped' must be populated with the latest date among all the 'Stop Date' fields entered for 'Drug Regimen' pages. This should be calculated only when 'Reason Therapy Stopped' has been selected and when 'Stop Date' on all Drug Regimen pages are answered.
 - 'Date Therapy Stopped' should be on or after 'Date Therapy Started'.
 - The number of weeks between 'Date Therapy Started' and 'Date Therapy Stopped' must not be less than 'Number of weeks of directly observed therapy'.
 - If 'Date Therapy Stopped' is answered, then at least one drug must be selected under the Treatments section.
 - If no Drugs are selected under 'Treatments' section, disable 'Date Therapy Stopped'.

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- If the Calculated Variable '**Culture Positive**' is '**Yes**', then 'Reason Therapy Stopped' cannot be answered as 'Not TB'.
 - If 'Reason Therapy Stopped' is answered, then at least one drug must be selected under the Treatments section.
 - If no Drugs are selected under 'Treatments' section, disable 'Reason Therapy Stopped'.
 - For 'Reason Therapy Extending over 12 months', if 'Unknown' is selected, then no other value can be selected and vice versa.
 - 'Type of Health Care Provider' derivation rule (Null value should not be treated as a selected value for purposes of evaluation)
 - For all 'Drug Regimen' pages, if the 'Type of Health Care Provider' field is answered as 'Health Department', populate the field on Follow up Report 2 with 'Health Department'.
 - For all 'Drug Regimen' pages, if the 'Type of Health Care Provider' field is answered as 'Private/Other', populate the field on Follow up Report 2 with 'Private/Other'.
 - For all 'Drug Regimen' pages, if the 'Type of Health Care Provider' field is answered as 'Both Health Department and Private/Other' at least onceOR
is answered as 'Health Department' at least once AND 'Private/Other' at least once, populate the field on Follow up Report 2 with 'Both Health Department and Private/Other'.
 - 'Directly Observed Therapy' derivation rule (Null value should not be treated as a selected value for purposes of evaluation)
 - For all 'Drug Regimen' pages, if the 'Directly Observed Therapy' field is answered as 'Unknown' at least once, populate 'Directly Observed Therapy' on Follow up Report 2 with 'Unknown'.
 - For all 'Drug Regimen' pages, if the 'Directly Observed Therapy' field is answered as 'No, Totally Self-Administered', populate the field on Follow up Report 2 with 'No, Totally Self-Administered'.
 - For all 'Drug Regimen' pages, if the 'Directly Observed Therapy' field is answered as 'Yes, Totally Directly Observed', populate the field on Follow up Report 2 with 'Yes, Totally Directly Observed'.
 - For all 'Drug Regimen' pages, if the 'Directly Observed Therapy' field is answered as 'Yes, Both Directly Observed and Self-Administered' at least onceOR
is answered as 'No, Totally Self-Administered' at least once AND 'Yes, Totally Directly Observed' at least once, populate the field on Follow up Report 2 with 'Yes, Both Directly Observed and Self-Administered'.
 - 'If yes, give site(s) of directly observed therapy' derivation rule (Null value should not be treated as a selected value for purposes of evaluation)
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- For all 'Drug Regimen' pages, if the 'If yes, give site(s) of directly observed therapy' field is answered as 'Unknown', populate the 'If yes, give site(s) of directly observed therapy' field on Follow up Report 2 with 'Unknown'.
- For all 'Drug Regimen' pages, if the 'If yes, give site(s) of directly observed therapy' field is answered as 'In Clinic or other Facility', populate the field on Follow up Report 2 with 'In Clinic or other Facility'.
- For all 'Drug Regimen' pages, if the 'If yes, give site(s) of directly observed therapy' field is answered as 'In the Field', populate the field on Follow up Report 2 with 'In the Field'.
- For all 'Drug Regimen' pages, if the 'If yes, give site(s) of directly observed therapy' field is answered as 'Both in Facility and in the Field' at least once

OR

is answered as 'In Clinic or other Facility' at least once AND 'In the Field' at least once, populate the field on Follow up Report 2 with 'Both in Facility and in the Field'.

- If 'If yes, give site or directly observed therapy' or 'Number of weeks of directly observed therapy' is answered, then 'Directly Observed Therapy' must be answered as either 'Yes, Totally Directly Observed' or 'Yes, Both Directly Observed and Self-Administered' .
 - If 'Directly Observed Therapy' is not answered as either 'Yes, Totally Directly Observed' or 'Yes, Both Directly Observed and Self-Administered', then disable 'If yes, give site or directly observed therapy' and 'Number of weeks of directly observed therapy'.
 - The value of 'Number of Weeks' from each Drug Regimen record where 'Directly Observed Therapy' is answered as either 'Yes, Totally Directly Observed' or 'Yes, Both Directly Observed and Self-Administered' should be summed up and used to populate 'Number of weeks of directly observed therapy'.
 - If 'Was drug susceptibility testing done?' on Follow up Report 1 is not answered as 'Yes', then 'Was final drug susceptibility testing done?' cannot be answered as 'Yes'.
 - If 'If yes, enter date final isolate collected for which drug susceptibility was done' is answered, then 'Was final drug susceptibility testing done?' must be answered as 'Yes'.
 - If 'Was final drug susceptibility testing done?' is not answered as 'Yes', then disable 'If yes, enter date final isolate collected for which drug susceptibility was done'.
 - If any 'Drugs' are selected under 'Final Susceptibility Results', then 'Was final drug susceptibility testing done?' must be answered as 'Yes'.
 - If 'Was final drug susceptibility testing done?' is not answered as 'Yes', then disable 'Drugs' fields under 'Final Susceptibility Results'.
- Treatments
 - Drug Regimen field on Header page
 - Take abbreviations for all the drugs selected on the Drug Regimen detail page and string them together separated by ', ' in the same order as they are listed on the 'Drug' drop down. E.g. INH, RIF, PZA
 - Display Hover help on 'Mouse over' for the Drug Regimen field expanding the abbreviations of drugs listed on the Treatments list page.

- Table for populating 'Drug Regimen' field for Header on Treatments list page.

| | |
|---------------------------|-------|
| Isoniazid | INH |
| Rifampin | RIF |
| Rifapentine | RPT |
| Pyrazinamide | PZA |
| Ethambutol | EMB |
| Streptomycin | SMN |
| Ethionamide | ETH |
| Kanamycin | KAN |
| Cycloserine | CYC |
| Capreomycin | CAP |
| Para-Amino Salicylic Acid | PAS |
| Amikacin | AMI |
| Rifabutin | RBT |
| Ciprofloxacin | CIP |
| Ofloxacin | OFL |
| Other Quinolones | OQU |
| Other | Other |

- 'Start Date' is required to save a Drug Regimen page.
- Every Drug Regimen record that has at least one 'Drug' field answered must have 'Body Weight' answered.
- 'Start Date' for a Drug Regimen cannot be before the 'Stop Date' of a previous regimen in a chronological order of Drug regimens by 'Start Date'.
- 'Stop Date' cannot be a future date.
- For each Drug Regimen record, 'Stop Date' has to be on or after 'Start Date'.
- If either one of 'Body Weight' or 'Units' is answered, the other field should also be answered.
- If 'Body Weight' is not entered, disable 'Units'
- If 'Dosage (in mg)' is answered, then its associated field 'Drug' must have been answered.
- If 'Drug' is not answered, then disable its associated field 'Dosage (in mg)'.
- Each 'Drug' can be selected only once on each Drug Regimen.
- If any of 'Frequency', 'Type of Health care provider', 'Directly Observed Therapy' and 'Number of Observed Doses' has a value, then one of the 'Drug' fields must have been answered.
- If no 'Drug' field is answered, then disable 'Frequency', 'Type of Health care provider', 'Directly Observed Therapy' and 'Number of Observed Doses'.

- If any 'Drug' field is answered, then 'Frequency', 'Type of Health care provider' and 'Directly Observed Therapy' are required.
- If 'If yes, give site of directly observed therapy' is answered, then 'Directly Observed Therapy' must be answered as either 'Yes, Totally Directly Observed' or 'Yes, Both Directly Observed and Self-Administered'
- If 'Directly Observed Therapy' is not answered as either 'Yes, Totally Directly Observed' or 'Yes, Both Directly Observed and Self-Administered', then disable 'If yes, give site of directly observed therapy'.
- If 'Number of Observed Doses' is answered as >0, then 'Directly Observed Therapy' must be answered as either 'Yes, Totally Directly Observed' or 'Yes, Both Directly Observed and Self-Administered'
- If 'Directly Observed Therapy' is not answered as either 'Yes, Totally Directly Observed' or 'Yes, Both Directly Observed and Self-Administered', then disable 'Number of Observed Doses'.
- Contact Page
 - If any Contact Information is added, then "Were close contacts identified for this case?" must be answered as 'Yes'.
 - If "Were close contacts identified for this case?" is not answered as 'Yes', then the User should not be able to add Contact Information.
 - Header fields mapping
 - Name – [First Name] [Last Name]
 - DOB – [DOB]
 - Distance – [Distance]
 - Signs & Symptoms – [Signs and Symptoms checklist complete?]
 - TB? – If 'Contact Evaluation' is answered as 'Active Disease', set 'TB?' to 'Yes'; If not set it to 'No'.
 - LTBI Rx – [Preventive Therapy Regimen] Use abbreviations for drugs (same as on treatments page).
 - Start Date – [Preventive Therapy Start Date]
 - End Date – [Preventive Therapy Stop Date]
 - Test Type – [Test Type] or [Other Test Type]
 - Test Date – [Specimen Collection Date/TST Placement Date]
 - Test Result – [Organism Identified] or [Other Organism Identified] or [Test Result] or [Other Test Result] or [Measured Result] [Units]
 - 'Age' or 'DOB' is required to save the Contact Detail page.
 - Age at Investigation = [Date Contact Investigation Initiated – DOB]
 - Dates relating to a Contact cannot be before the Contact's DOB and cannot be future dates.
 - 'Preventive Therapy Start Date' must be on or after 'Date Contact Investigation Initiated'.

- 'Preventive Therapy Stop Date' must be on or after 'Preventive Therapy Start Date'.
- If 'Preventive Therapy Start Date' or 'Preventive Therapy Regimen' or 'Preventive Therapy Stop Date' or 'Preventive Therapy Stop Reason' or 'Was the contact on Directly Observed Preventive Therapy?' is answered, then 'Contact Evaluation' must be answered as 'Not infected; preventive treatment started' or 'Latent Infection; preventive treatment started' or 'Positive skin test; active disease not ruled out'.
- If 'Contact Evaluation' is not answered as 'Not infected; preventive treatment started' or 'Latent Infection; preventive treatment started' or 'Positive skin test; active disease not ruled out', disable 'Preventive Therapy Start Date', 'Preventive Therapy Regimen', 'Preventive Therapy Stop Date', 'Preventive Therapy Stop Reason' and 'Was the contact on Directly Observed Preventive Therapy?'
- If 'Contact Evaluation' is answered as either 'Not infected; preventive treatment started' or 'Latent Infection; preventive treatment started', then 'Preventive Therapy Start Date' and 'Preventive Therapy Regimen' must be answered.
- For Contact lab page, follow Common lab rules.
- Statistical Summary Page
 - All numeric fields on this page ≥ 0 .
 - If 'How many of those tested were not read?' or 'How many of those tested had insignificant results?' or 'How many of those tested had significant results?' is/are answered, then 'How many people were skin tested?' must be answered.
 - If 'How many people were skin tested?' is not answered, then disable 'How many of those tested were not read?', 'How many of those tested had insignificant results?' and 'How many of those tested had significant results?'
 - If 'How many people were skin tested?' is answered as '0', then disable 'How many of those tested were not read?', 'How many of those tested had insignificant results?' and 'How many of those tested had significant results?' and populate each one of them with '0'.
 - The values for 'How many of those tested were not read?', 'How many of those tested had insignificant results?' and 'How many of those tested had significant results?' must add up to equal the value for 'How many people were skin tested?'
 - If 'Number infected without disease, started Preventative Therapy' or 'Number infected without disease, no Preventative Therapy' or 'Number infected without disease, previously treated' or 'Number infected with active disease' is/are answered, then 'How many of those tested had significant results?' must be answered.
 - If 'How many of those tested had significant results?' is not answered, then disable 'Number infected without disease, started Preventative Therapy', 'Number infected without disease, no Preventative Therapy', 'Number infected without disease, previously treated' and 'Number infected with active disease'.
 - If 'How many of those tested had significant results?' is answered as '0', then disable 'Number infected without disease, started Preventative Therapy', 'Number infected without disease, no Preventative Therapy', 'Number infected without disease, previously treated' and 'Number infected with active disease' and populate each one of them with '0'.
 - The values for disable 'Number infected without disease, started Preventative Therapy', 'Number infected without disease, no Preventative Therapy', 'Number infected without

disease, previously treated' and 'Number infected with active disease' must add up to equal the value for 'How many of those tested had significant results?'

- Close Investigation
 - If Case Status is 'Confirmed', Disposition must be 'Completed'.
 - If Case Status is 'Not a Case', Disposition must be any value other than 'Completed'
 - At 'Close Investigation', Null and 'Suspect' are not valid values for Case Status, if the User clicks on 'Send to IDPH'. The valid values are 'Confirmed' and 'Not a Case'.
- Admin Review
 - Count Date cannot be a future date.
 - If 'Count Date' is after TB's 'CDC Cut off date' and is in the same MMWR year, the Count Date' MMWR Year should be the current Year.
 - If 'Count Date' is on or before TB's 'CDC Cut off date' and is in the same MMWR year, the Count Date's MMWR Year can be the current MMWR Year or (MMWR Year -1).

| Example using fictitious dates | | | |
|--|--|---|---|
| Jan 5 th 2007 (1 st date of MMWR year 2007) | March 10 th 2007 (TB's CDC cut off date) | Dec 30 th 2007 (1 st date of MMWR year 2008) | |
| ↓ | ↓ | ↓ | |
| Allow Count Dates with MMWR Year 2006 only. | Allow Count Dates with MMWR Year 2006 and 2007 | Allow Count Dates with MMWR Year 2007 only. | Allow Count Dates with MMWR Year 2007 and 2008. |

2.2 Calculations and Derived Fields

The following are derived/calculated fields that are associated with a TB case for reporting purposes only and do not need to be displayed in the application unless otherwise specified.

2.2.1 Case Verification (TIMS variable name: "vercrit")

This field is displayed on the Admin Review page. The User has the rights to overwrite only 'Suspect' with either "Verified by provider Diagnosis" or "Not a Verified Case". All other values are System generated.

- **Not a Verified Case**
 - If "Reason Therapy Stopped" on Follow up 2 page = "Not TB", then Set TB Case Verification = "Not a Verified Case"
- **Positive Culture**
 - If Calculated Variable 'Culture Positive' = 'Yes', then Set TB Case Verification = "Positive Culture"

○ **Positive Smear/Tissue**

- If

Calculated Variable 'Smear Positive' is 'Yes'

AND

Calculated Variable 'Culture Positive' = 'No'.

○ **Clinical Case Definition**

- Case Definition A

If 'Where is the major site of disease?' or 'Where is the additional site of disease?' is answered as either 'Pulmonary' or 'Pleural' or 'Lymphatic: Intrathoracic'.

AND

'Sputum Culture Result' and 'Culture of Tissue and Other Body Fluids Result' are answered as either 'Negative' or 'Not Done' or 'Unknown'.

AND

'Chest X-Ray Result' is answered as 'Abnormal'

AND

'If abnormal, select the abnormality' is answered as either 'Cavitary' or 'Noncavitary - Consistent with TB'

AND

'If abnormal, select the condition' is answered as either 'Worsening' or 'Improving'

AND

['Tuberculin (Mantoux) Skin Test at Diagnosis Result' is answered as 'Positive' OR 'Blood Test Result' is answered as 'Positive']

AND

At least two drugs are selected in the first drug regimen on Treatments page.

OR

- Case Definition B

If Case Definition A is not met

AND

'Where is the major site of disease?' or 'Where is the additional site of disease?' is answered as either 'Lymphatic: Cervical' or 'Lymphatic: Other' or 'Lymphatic: Unknown' or 'Bone and/or Joint' or 'Genitourinary' or 'Miliary' or 'Meningeal' or 'Peritoneal' or 'Other'

AND

'Sputum Culture Result' and 'Culture of Tissue and Other Body Fluids Result' are answered as either 'Negative' or 'Not Done' or 'Unknown'

AND

['Tuberculin (Mantoux) Skin Test at Diagnosis Result' is answered as 'Positive' OR 'Blood Test Result' is answered as 'Positive']

AND

At least two drugs are selected in the first drug regimen on Treatments page.

- **Suspect**
 - All new TB records are set as TB Case Verification = "Suspect" unless they meet the criteria for another Case Verification value or is overwritten by the User.
- **Verified by Provider Diagnosis**
 - User has option to set TB Case Verification to "Verified by provider Diagnosis".
- **Not a Verified Case**
 - User has option to set TB Case Verification to "Not a Verified Case".

2.2.2 Age at Month-Year Reported (TIMS variable name: "ageatrept")

- The calculation is Date LHD Received – Date of Birth. Set Date LHD Received to the last day of the month. The *Age at Month-Year Reported* is the number of whole years completed in the client's life. For example, both 29 years three months and 29 years 11 months would be calculated as 29 years.
- This calculation is used to populate the 'Age at Report' field on General Illness page.

2.2.3 Site of Disease (TIMS variable name: "siteofdisease")

- **Pulmonary**
 - 'Where is the major site of disease?' is answered as "Pulmonary"AND
'Where is the additional site of disease?' is Null.
- **Site Not Stated**
 - 'Where is the major site of disease?' is answered as "Site not Stated"
- **Missing**
 - 'Where is the major site of disease?' is NullAND
'Where is the additional site of disease?' is Null.
- **Extrapulmonary**
 - Condition A
 - 'Where is the major site of disease?' is a value other than "Pulmonary" or "Miliary" or "Site not Stated"AND
'Where is the additional site of disease?' is Null.

OR

- Condition B
 - 'Where is the major site of disease?' is a valid value other than "Pulmonary" or "Miliary"

AND

'Where is the additional site of disease?' is a valid value other than "Pulmonary".

○ **Both**

- Condition A
'Where is the major site of disease?' is answered as "Miliary"
- Condition B
'Where is the major site of disease?' is answered as "Pulmonary"
AND
'Where is the additional site of disease?' is a valid value.
- Condition C
'Where is the major site of disease?' is a valid value other than "Pulmonary", "Miliary" and "Site not Stated"
AND
'Where is the additional site of disease?' is answered as "Pulmonary".

2.2.4 Initial Drug Regimen (TIMS Variable Name "initdrc")

- **No Drugs**
 - If no drug is selected in any drug regimen page under Treatments.
- **One Drug**
 - If in the drug regimen with the earliest 'Start Date', only one drug is selected.
- **INH, RIF, PZA and EMB or SM**
 - If in the drug regimen with the earliest 'Start Date', only Isoniazid, Rifampin, Pyrazinamide and Ethambutol are selected
- OR
- If in the drug regimen with the earliest 'Start Date', only Isoniazid, Rifampin, Pyrazinamide and Streptomycin are selected.
- **INH, RIF and PZA**
 - If in the drug regimen with the earliest 'Start Date', only Isoniazid, Rifampin, and Pyrazinamide are selected.
- **INH and RIF**

- If in the drug regimen with the earliest 'Start Date', only Isoniazid and Rifampin are selected.
- **Any Other Multiple Drug Combination**
 - If in the drug regimen with the earliest 'Start Date', two or more drugs are selected but does not fit the criteria for '**INH, RIF, PZA and EMB or SM**' or '**INH, RIF and PZA**' or '**INH and RIF**'.

2.2.5 Alive at Diagnosis

- Values
 - **Alive**
 - **Dead**
- Recalculate whenever Start Date on Drug Regimen and Deceased Date changes.
 IF 'Deceased Date' is null, then set 'Alive at Diagnosis' to 'Alive'
 ELSE IF calculated variable '**Initial Drug Regimen**' is not equal to '**No Drugs**' or '**One Drug**'
 AND
 the 'Start Date' for at least 2 drugs is at least 1 day before 'Deceased Date'
 THEN Set '**Alive at Diagnosis**' to 'Alive'
 ELSE set '**Alive at Diagnosis**' to 'Dead'

2.2.6 State Case Number

- The State Case number has 15 characters. It is of the format **YYYYSSYYFFNNNN**.
- Display this field on Case Header also.

| Column | Description |
|----------|---|
| 1-4 YYYY | 4-digit Year based on the MMWR derived from Case's 'Count Date'. |
| 5-6 SS | 2-digit FIPS (Federal Information Processing Standard) code for Illinois which is 17. |
| 7-8 YY | 2 digit Year field. |
| 9-11 | If Jurisdiction is 'IDPH Program Area', use 205. ELSE use 3 digit FIPS code for County of Patient's address NOT Jurisdiction of the Case. 'Address at Report' is used to determine 'County'. If County is 'Cook', then see Jurisdiction: Westside Center for Disease Control (CDPH) – 310 Cook County Health Department - 300 |
| 12-15 | NNNN – Sequentially increased number. Starts at 0001 for each MMWR year |

| | | | | | | | | | | | | | |
|---|---|---|-----------------|---|------------------|---|------------------|---|---------------|---|------------------|---|------------------|
| | <p>for each County/Jurisdiction.</p> <p>If Jurisdiction is 'IDPH Program Area', generate sequentially increased number.</p> <p>ELSE see Patient 'County' from 'Address at Report'.</p> <p>If County is 'Cook', then see Jurisdiction and generate separate counts for 'Westside Center for Disease Control (CDPH)' and 'Cook County Health Department'.</p> <p>If Jurisdiction is 'Westside Center for Disease Control (CDPH)', 1st character of NNNN is the numeric code of the TB Clinic. Generate separate counts for each TB clinic:</p> <table style="margin-left: 20px;"> <tr><td>1</td><td>Lawndale Clinic</td></tr> <tr><td>2</td><td>Englewood Clinic</td></tr> <tr><td>3</td><td>Stroger Hospital</td></tr> <tr><td>4</td><td>Uptown Clinic</td></tr> <tr><td>5</td><td>Private or Other</td></tr> <tr><td>6</td><td>West Town Clinic</td></tr> </table> | 1 | Lawndale Clinic | 2 | Englewood Clinic | 3 | Stroger Hospital | 4 | Uptown Clinic | 5 | Private or Other | 6 | West Town Clinic |
| 1 | Lawndale Clinic | | | | | | | | | | | | |
| 2 | Englewood Clinic | | | | | | | | | | | | |
| 3 | Stroger Hospital | | | | | | | | | | | | |
| 4 | Uptown Clinic | | | | | | | | | | | | |
| 5 | Private or Other | | | | | | | | | | | | |
| 6 | West Town Clinic | | | | | | | | | | | | |

- The User should be able to overwrite the system generated State Case Number and Save it. If County = 'Cook' and Jurisdiction = 'Westside Center for Disease Control (CDPH)', this is limited to the last 3 digits. Otherwise, it is limited to the last 4 digits.
- When generating a new State Case Number, the System should use the highest number that was saved by the user and increment it by one. It should not use the last number that was generated by the System.
- The System should not let the user save and overwrite a number that is currently used for a Case. A number should be considered used up only when the User chooses to save that number on the Admin Review page. It is not considered to be used, if the User chooses to 'Cancel' and not 'Save' after the System generated the number.
- The System should verify that the number the User is trying to save is consistent with the format 'YYYYSSYYFFNNNN' and conforms to the above mentioned rules.
- FIPS codes:

| | | |
|-----|------------------|----|
| 001 | Adams County | IL |
| 003 | Alexander County | IL |
| 005 | Bond County | IL |
| 007 | Boone County | IL |
| 009 | Brown County | IL |
| 011 | Bureau County | IL |
| 013 | Calhoun County | IL |
| 015 | Carroll County | IL |
| 017 | Cass County | IL |
| 019 | Champaign County | IL |
| 021 | Christian County | IL |
| 023 | Clark County | IL |

| | | |
|-----|-------------------|----|
| 025 | Clay County | IL |
| 027 | Clinton County | IL |
| 029 | Coles County | IL |
| 031 | Cook County | IL |
| 033 | Crawford County | IL |
| 035 | Cumberland County | IL |
| 039 | De Witt County | IL |
| 037 | DeKalb County | IL |
| 041 | Douglas County | IL |
| 043 | DuPage County | IL |
| 045 | Edgar County | IL |
| 047 | Edwards County | IL |
| 049 | Effingham County | IL |
| 051 | Fayette County | IL |
| 053 | Ford County | IL |
| 055 | Franklin County | IL |
| 057 | Fulton County | IL |
| 059 | Gallatin County | IL |
| 061 | Greene County | IL |
| 063 | Grundy County | IL |
| 065 | Hamilton County | IL |
| 067 | Hancock County | IL |
| 069 | Hardin County | IL |
| 071 | Henderson County | IL |
| 073 | Henry County | IL |
| 075 | Iroquois County | IL |
| 077 | Jackson County | IL |
| 079 | Jasper County | IL |
| 081 | Jefferson County | IL |
| 083 | Jersey County | IL |
| 085 | Jo Daviess County | IL |
| 087 | Johnson County | IL |
| 089 | Kane County | IL |
| 091 | Kankakee County | IL |
| 093 | Kendall County | IL |
| 095 | Knox County | IL |
| 099 | La Salle County | IL |
| 097 | Lake County | IL |
| 101 | Lawrence County | IL |
| 103 | Lee County | IL |
| 105 | Livingston County | IL |
| 107 | Logan County | IL |
| 115 | Macon County | IL |

| | | |
|-----|--------------------|----|
| 117 | Macoupin County | IL |
| 119 | Madison County | IL |
| 121 | Marion County | IL |
| 123 | Marshall County | IL |
| 125 | Mason County | IL |
| 127 | Massac County | IL |
| 109 | McDonough County | IL |
| 111 | McHenry County | IL |
| 113 | McLean County | IL |
| 129 | Menard County | IL |
| 131 | Mercer County | IL |
| 133 | Monroe County | IL |
| 135 | Montgomery County | IL |
| 137 | Morgan County | IL |
| 139 | Moultrie County | IL |
| 141 | Ogle County | IL |
| 143 | Peoria County | IL |
| 145 | Perry County | IL |
| 147 | Piatt County | IL |
| 149 | Pike County | IL |
| 151 | Pope County | IL |
| 153 | Pulaski County | IL |
| 155 | Putnam County | IL |
| 157 | Randolph County | IL |
| 159 | Richland County | IL |
| 161 | Rock Island County | IL |
| 165 | Saline County | IL |
| 167 | Sangamon County | IL |
| 169 | Schuyler County | IL |
| 171 | Scott County | IL |
| 173 | Shelby County | IL |
| 163 | St. Clair County | IL |
| 175 | Stark County | IL |
| 177 | Stephenson County | IL |
| 179 | Tazewell County | IL |
| 181 | Union County | IL |
| 183 | Vermilion County | IL |
| 185 | Wabash County | IL |
| 187 | Warren County | IL |
| 189 | Washington County | IL |
| 191 | Wayne County | IL |
| 193 | White County | IL |
| 195 | Whiteside County | IL |

| | | |
|-----|--|----|
| 197 | Will County | IL |
| 199 | Williamson County | IL |
| 201 | Winnebago County | IL |
| 203 | Woodford County | IL |
| 205 | IDPH Program Area | |
| 310 | Westside Center for Disease Control (CDPH) | |
| 300 | Cook County Health Department | |

Source – <http://wonder.cdc.gov/wonder/help/Populations%5CBridged-Race%5CCountyList-Vintage2002.html>

Note: The codes 205, 300 and 310 are not true FIPS codes but are codes used by the IDPH TB Section in lieu of FIPS codes for these specific jurisdictions and are therefore not from the original CDC source.

2.2.7 Date Therapy Started

- Use the earliest among the 'Start Date' fields from all Drug Regimen pages to calculate this field which will be available for running reports only.

2.2.8 Sex at Report

- Use 'Sex' on Demographic page to populate this field.

2.2.9 Race at Report

- Use 'Race' on Demographic page to populate this field.

2.2.10 Ethnicity at Report

- Use 'Ethnicity' on Demographic page to populate this field.

2.2.11 Country of Origin at Report

- Use 'Country of Origin' on Epidemiologic Data page to populate this field.

2.2.12 Age at Report

- Use 'Age at Month-Year Reported' calculation to populate this field.

2.2.13 Resistance Patterns

- Display the following on the Case Header section along with State Case Number and Local Case Number.
 - **Initial Resistance**

- If 'Was drug susceptibility testing done?' on Follow up Report 1 is answered as 'Yes' then use the abbreviations of Drugs selected in the 'Drugs – Resistant' field to populate this field.
 - If 'Drugs – Resistant' field is NULL, set it to 'No Resistance'.
- If 'Was drug susceptibility testing done?' on Follow up Report 1 is NOT answered as 'Yes' then set it to 'Not Done'
- **Final Resistance**
 - If 'Was final drug susceptibility testing done?' on Follow up Report 2 is answered as 'Yes' then use the abbreviations of Drugs selected in the 'Drugs – Resistant' field to populate this field.
 - If 'Drugs – Resistant' field is NULL, set it to 'No Resistance'.
 - If 'Was final drug susceptibility testing done?' on Follow up Report 2 is NOT answered as 'Yes', then set it to 'Not Done'

2.2.14 Culture Positive

- **Yes**
 - If either 'Sputum Culture Result' OR 'Culture of Tissue and Other Body Fluids Result' is answered as 'Positive'
- **No**
 - If neither 'Sputum Culture Result' nor 'Culture of Tissue and Other Body Fluids Result' is answered as 'Positive'

2.2.15 Smear Positive

- **Yes**
 - If either 'Sputum Smear Result' OR 'Microscopic Exam of Tissue and Other Body Fluids Result' is answered as 'Positive'.
- **No**
 - If neither 'Sputum Smear Result' nor 'Microscopic Exam of Tissue and Other Body Fluids Result' is answered as 'Positive'.

2.3 TB Case Closure rules

In INEDSS, by default three sets of rules are fired at the time of Case closure:

- Case Completion rules
- Mandatory Rules
- Validation rules

In addition for TB, the Case Status Rules are fired.

2.3.1 Case Completion Rules

These rules are fired when a user chooses to Close Investigation with Investigation Status is 'Complete – Needs Closure' and Disposition is 'Completed'.

- Patient's last name.
- Patient's first name.
- Patient's Address – County field for patient's residential types
- Onset Date – **Not required for TB**
 - For CDC and VPD diseases, a formula is used to estimate Onset Date. **It should not be estimated for TB section.**
- If info about the specimen is added, then one of the fields "Organism Identified", "Test Result" and "Measured Result" on its associated the lab result page must be answered.
 - Message - If a **Lab Specimen** is added, then you must select "*Organism Identified*", "*Test Result*" or "*Measured Result*" on the associated **Lab Result** screen
- If "Deceased" question on Demographics is answered: NO, UNKNOWN or left blank, then the follow up question on General Illness: "Did the patient die due to the disease under investigation?" must not be answered "YES".
 - Message - If "Did the patient die due to the disease or condition under investigation?" on General Illness is answered as "Yes", then "Deceased" on Demographic page must be answered as "Yes".

2.3.2 Mandatory Rules

The following mandatory fields will need to be completed before a case can be transferred and completed for investigation with the disposition equal to one of these ("Completed" or "Not Completed-Unable to locate" or "Not Completed-Patient refused cooperation" or "Not Completed-Provider refused cooperation" or "Not Completed-Patient resides out-of-jurisdiction" or "Out of State")

- First Name is required
- Last Name is Required
- Disease is Required
- Earliest Report Date is Required
- LHD Received Date is Required

2.3.3 Validation Rules

All the page level field validations are rerun again at the time of 'Close Investigation' and Case Completion for all Dispositions and Case Statuses. This is done to ensure data integrity.

2.3.4 Tuberculosis Case Status Rules

These rules define the checklist of fields where information needs to be entered in order for the Local Health Department User to be able to deem the Case Complete and send it across to the State

Department of Public Health. These should be fired at the time of 'Close Investigation' and 'Admin Review'.

- **All these rules should be fired only if the Case Status is set to 'Confirmed'.**
- If the Case has a 'State Case Number', fire all Case Completion Rules. If it does not have 'State Case Number', fire RVCT rules only.

2.3.4.1 RVCT Case Completion Rules

- These rules are fired at all times whenever a LHD user does a 'Close Investigation' and when and IDPH user does an Admin Review. These rules specify the fields that are required at the time of case completion.

2.3.4.1.1 Demographic

- Patient's Last Name
- Patient's First Name
- Date of Birth
- Sex
- Ethnicity
- Race
- Deceased

2.3.4.1.2 General Illness

- Address at Reporting
 - Address Line 1
 - City
 - State
 - Zip code
 - County
- Local Case Number

2.3.4.1.3 TB Diagnostics

- If Jurisdiction = 'Westside Center for Disease Control (CDPH)' then, 'TB Clinic (For CDPH only)' is required at completion.
- Previous Diagnosis of Tuberculosis
- Where is the major site of disease?
- Sputum Smear Result
- Sputum Culture Result
- Microscopic Exam of Tissue and other Body Fluids Result
- Culture of Tissue and Other Body Fluids Result

- Nucleic Acid Amplification Test Result
- Chest X-ray Result
- Tuberculin (Mantoux) Skin Test at Diagnosis Result
- Blood Test Result
- Fire the Anatomic Code validations from Appendix 3.1 related to 'Sex', since 'Sex' is not required at the time of case entry, but it is required at completion.

2.3.4.1.4 Epidemiologic Data

- Case Opened Date (System Generated)
- Country of Origin
- HIV Status
- Was the patient homeless within the past year?
- Was the patient a resident of a correctional facility at the time of diagnosis?
- Was the patient a resident of a long-term care facility at time of diagnosis?
- Injecting drug use within the past year?
- Non-injecting drug use within the past year?
- Excess alcohol use within the past year?
- Patient Occupation (Select all that apply within the past 24 months)

2.3.4.1.5 Reporting Source

- Earliest Report Date
- Date LHD Received

2.3.4.1.6 Date fields

- Implementation detail: When an LHD user does a 'Close Investigation', fire the RVCT rules. Once the user fixes those errors, fire an alert 'Please verify that you have answered all the dates for the RVCT fields if all the following date fields are not answered. This is just a warning message and the user can click OK and go past this alert. The User can click Cancel to go back and enter those missing dates.
 - Epidemiologic Data Page
 - 'Date of Arrival (if foreign born)' if 'Country of Origin' is not answered as 'United States'
 - TB Diagnostics Page
 - 'Sputum Smear Test Date' if 'Sputum Smear Result' is answered as either 'Positive' or 'Negative'.
 - 'Sputum Culture Test Date' if 'Sputum Culture Result' is answered as either 'Positive' or 'Negative'.
 - Microscopic Exam Test Date if 'Microscopic Exam of Tissue and Other Body Fluids Result' is answered as either 'Positive' or 'Negative'.

- Culture of Tissue Test Date if 'Culture of Tissue and Other Body Fluids Result' is answered as either 'Positive' or 'Negative'.
- Nucleic Acid Amplification Test Collection Date if 'Nucleic Acid Amplification Test Result' is answered as either 'Positive' or 'Negative'.
- Chest X-Ray Date if 'Chest X-Ray Result' is answered as either 'Normal' or 'Abnormal'.
- Condition Date (Normally a follow up X-Ray) if 'Chest X-Ray Result' is answered as 'Abnormal'.
- Tuberculin Skin Test Date if 'Tuberculin (Mantoux) Skin Test at Diagnosis result' is answered as either 'Positive' or 'Negative'.
- Blood Test Date if 'Blood Test Result' is answered as either 'Positive' or 'Negative'.

2.3.4.2 Non – RVCT Completion Rules

- These rules are fired whenever a LHD user does a 'Close Investigation' and when and IDPH user does an Admin Review, **only** when the case has a 'State Case Number assigned to it.

2.3.4.2.1 Follow up Report 1

- If the calculated variable '**Culture Positive**' is 'Yes', then 'Was drug susceptibility testing done?' must be answered.
-
- 'If yes, enter date first isolate collected for which drug susceptibility was done' must be on or after 'Date of Arrival (if foreign born)'.

2.3.4.2.2 Follow up Report 2

- If 'Sputum Culture Result' is answered as 'Positive' AND the calculated variable '**Initial Drug Regimen**' is not '**No Drugs**', 'Sputum Culture Conversion Documented' must be answered.
- If the calculated variable '**Initial Drug Regimen**' is not '**No Drugs**', then 'Reason Therapy Stopped' must be answered.
- If the calculated variable '**Culture Positive**' is '**Yes**' and 'Was drug susceptibility testing done?' is 'yes', then 'Was final drug susceptibility testing done?' must be answered.
-
- 'If yes, date specimen collected on initial positive sputum culture' must be on or after 'Date of Arrival (if foreign born)'.
-
- 'If yes, date specimen collected on first consistently negative culture' must be on or after 'Date of Arrival (if foreign born)'.
- 'If yes, enter date final isolate collected for which drug susceptibility was done' must be on or after 'Date of Arrival (if foreign born)'.
- If the difference between the earliest 'Start Date' and the latest 'Stop Date' across all Drug Regimen pages is greater than 365 days, then 'Reason Therapy Extending over 12 months' must be answered.

2.3.4.2.3 Treatments

- 'Date Therapy Started' must be on or after 'Date of Arrival (if foreign born)'.
- Every Drug Regimen entry must have a 'Stop Date'.

2.3.4.2.4 Laboratory Tests

- Were Lab tests done?

2.3.4.2.5 Contacts

- Date Contact Identified
- Contact Evaluation
- If 'Preventive Therapy Start Date' is answered, 'Preventive Therapy Regimen', 'Preventive Therapy Stop Date', 'Preventive Therapy Stop Reason' and 'Was the contact on Directly Observed Preventive Therapy' must be answered.

2.3.4.2.6 Statistical Summary

- 'How many people were skin tested?' must be answered. (It should at least be answered as '0')

2.3.4.2.7 Date fields

- Implementation detail: When an LHD user does a 'Close Investigation' and the Case has a 'State Case Number', fire the non- RVCT rules. Once the user fixes those errors, fire an alert 'Please verify that you have answered all the dates for the non - RVCT fields if all the following date fields are not answered. This is just a warning message and the user can click OK and go past this alert. The User can click Cancel to go back and enter those missing dates.
 - Follow Up 1 Report Page
 - 'If yes, enter date first isolate collected for which drug susceptibility was done' if 'Was drug susceptibility testing done?' is answered as 'Yes'
 - Follow up 2 Report Page
 - 'If yes, date specimen collected on initial positive sputum culture' if 'Sputum Culture Conversion Documented' is answered as 'Yes'.
 - 'If yes, date specimen collected on first consistently negative culture' if 'Sputum Culture Conversion Documented' is answered as 'Yes'.
 - 'If yes, enter date final isolate collected for which drug susceptibility was done' if 'Was final drug susceptibility testing done?' is answered as 'Yes'.

2.4 Tuberculosis Case rules for determining a Recurrence vs. a New Case

- Definition: If the patient is disease free for 365 days after completion of therapy, a new incidence of disease would be recorded as a new case. If it is less than 365 days, it is considered a recurrence.
 - Determine the earliest date among the following dates and set it as 'TB Suspicion Date'.
 - 'Earliest Report Date' from Reporting Source Page
 - Sputum Smear Test Date

- Sputum Culture Test Date
 - Microscopic Exam Test Date
 - Culture of Tissue Test Date
 - Nucleic Acid Amplification Test Collection Date
 - Chest X-Ray Test Date
 - Tuberculin Skin Test Date
 - Blood Test Date
- Compare 'TB Suspicion Date' to the latest among all the 'Stop Date' fields from all 'Drug Regimen' pages from all **other** TB cases for this person and if the difference is \leq 365 days, display an alert to User 'This is a recurrence of a TB Case' and set the Disposition to 'Not a Case – Recurrence'.
 - Fire the above rule, every time one of the dates involved in the calculation is saved.
 - Fire the above rule again when the Admin User Clicks 'Count Case' on Admin Review page. If the criterion is met, display the alert 'This is a recurrence of a TB Case', set the Disposition to 'Not a Case – Recurrence' and do not generate a State Case Number.
 - If the data is changed after the State Case Number is assigned such that the case now meets the criteria for a Recurrence, **fire the rules as they are and display the alert 'This is a recurrence of a TB Case' and set the Disposition to 'Not a Case – Recurrence'. Leave the Case Number as it is and consider it a Used Case Number. The disposition should indicate that this case should not be included in case counts.**

2.5 Case Update deadlines

- The CDC cut off date for TB Section is different from that used by the CD and VPD sections.
 - As in CD and VPD sections, the fields in the Case record cannot be updated if the Case's Investigation Status is 'Closed'. If it is 'Closed' and past the cut off date, only an 'Admin' user can reopen the case and edit it using the 'Reopen Case' link.
 - The Disposition 'Reported too late to be counted' does not apply to TB section as they report cases whenever IDPH gets a completed case that is deemed eligible for CDC reporting. They report in the reporting year that is current for that point in time and so there is never a scenario where a case is considered 'Too late to be counted'.
 - When the TB cases for a person are displayed on a page such as 'Person Summary', the System should display all the TB cases associated with this person regardless of when the case was Counted.
 - In addition, for the TB section, the following fields should not be open to editing after the CDC cut off date for TB section (for any user **except** 'Admin'):
 - All the RVCT fields (Fields on TB Diagnostics and Epidemiologic Data)
 - General Illness
 - Local Case Number – Text

- TB Diagnostics
 - TB Clinic (For CDPH only) – Single select
 - Previous Diagnosis of Tuberculosis – Y/N/U
 - If yes, year of previous diagnosis – Date (CCYY)
 - Was there more than one previous diagnosis? - Y/N/U
 - Where is the major site of disease? – Single select
 - If other major site, select other type – Single select
 - Where is the additional site of disease? – Multi select
 - If other additional site, select additional site type – Multi select
 - Sputum Smear Result – Single Select
 - Sputum Smear Test Date - Date
 - Sputum Culture Result – Single select
 - Sputum Culture Test Date - Date
 - Microscopic Exam of Tissue and Other Body Fluids Result – Single select
 - If Microscopic exam test is positive, select site(s) – Multi select
 - Microscopic Exam Test Date - Date
 - Culture of Tissue and Other Body Fluids Result – Single select
 - If Culture of Tissue test is positive, select site(s) – Multi select
 - Culture of Tissue Test Date - Date
 - Nucleic Acid Amplification Test Result – Single select
 - If Nucleic Acid Amplification test is positive, select site(s) – Multi select
 - Nucleic Acid Amplification Test Collection Date - Date
 - Chest X-Ray Result – Single select
 - Chest X-Ray Date - Date
 - If abnormal, select the abnormality – Single select
 - If abnormal, select the condition – Single select
 - Condition Date (Normally a follow up X-Ray) – Date
 - Tuberculin (Mantoux) Skin Test at Diagnosis result – Single select
 - Tuberculin Skin Test Date
 - mm. of Induration
 - Blood Test Result – Single select
 - Blood Test Type - Single select
 - Blood Test Date - Date
- Epidemiologic Data

- Case Status
 - Country of Origin
 - HIV Status – Single select
 - If positive HIV status, what is it based on? – Single select
 - Was the patient homeless within the past year? – Y/N/U
 - Was the patient a resident of a correctional facility at the time of diagnosis? – Y/N/U
 - If yes, select correctional facility – Single select
 - Was the patient a resident of a long term care facility at time of diagnosis? – Y/N/U
 - If yes, select long-term care facility – Single select
 - Injecting drug use within the past year? – Y/N/U
 - Non-injecting drug use within the past year? – Y/N/U
 - Excess alcohol use within the past year? – Y/N/U
 - Patient Occupation (Select all that apply within the past 24 months) – Multi select
 - Additional TB Risk Factors – Multi-select value list
 - 'At Report' fields':
 - Address at Report
 - Age at Report
 - Sex at Report
 - Race at Report
 - Ethnicity at Report
 - 'Country of Origin' at Report
 - Date Therapy Started
 - Initial Drug Regimen
 - Alive at Diagnosis
 - State Case Number(not editable even by Admin User after the Cut off date)
- At the time of displaying matching cases for a Report or Case of TB, all cases that do have an Investigation Status of 'Closed' should be displayed as potential matches if other criteria are met for a match per the de-duplication algorithm. In contrast to CD and VPD sections, this includes cases that are past the Cut-off date. With Cases that are past the cut-off date, the above mentioned rule of not being able to edit certain data after the cut-off date still holds true.

3 APPENDICES

3.1 Appendix 1

If 'Where is the major site of disease?' and/or 'Where is the additional site of disease?' is answered with a value in the left column, the list of valid sites of Disease for 'If Microscopic exam test is positive, select site(s)', 'If Culture of Tissue test is positive, select site(s)' and 'If Nucleic Acid Amplification Test is positive, select site' is on the right column,

| Where is the major site of disease? / Where is the additional site of disease? | If Microscopic exam test is positive, select site(s) / If Culture of Tissue test is positive, select site(s)/ If Nucleic Acid Amplification Test is positive, select site |
|--|---|
| Pulmonary | Blood Lymph node Bronchus Bronchiole Lung Bronchial fluid Gastric aspirate Gastrointestinal contents (feces) Pus Unknown |
| Pleural | Blood Lymph node Pleura Pleural fluid Pus Unknown |
| Lymphatic: Cervical | Blood Lymph node Pus Unknown |
| Lymphatic: Intrathoracic | Blood Lymph node Pus Unknown |
| Lymphatic: Other | Blood Lymph node Pus Unknown |

| | |
|--------------------|---|
| Lymphatic: Unknown | Blood Lymph node Pus Unknown |
| Bone and/or Joint | Blood Lymph node Bone (not otherwise specified) Skeletal system (bones of head, rib cage, and vertebral column) Skeletal system (bones of shoulder, girdle, pelvis, and extremities) Soft tissue (not otherwise specified) Soft tissue (muscles of head, neck, mouth and upper extremity) Soft tissue (muscles of trunk, perineum, and lower extremity) Tendon and tendon sheath Ligament and fascia Joints (synovial tissue) Synovial fluid Pus Unknown |
| Genitourinary | If Sex = Male, valid sites are: Blood Lymph node Kidney Renal pelvis Ureter Urinary bladder Urethra Penis Prostate and seminal vesicle Testis Epididymis, vas deferens, spermatic cord and scrotum Urine Male genital fluids Pus Unknown If Sex = Female, valid sites are: Blood Lymph node Kidney Renal pelvis Ureter Urinary bladder Urethra Urine Vulva, labia, clitoris, and Bartholin's gland Vagina |

| | |
|---------|--|
| | Uterus Cervix Endometrium Myometrium Fallopian tube, broad ligament, parametrium, and paraovarian region Ovary Female genital fluids Pus Unknown |
| Miliary | If Sex = Male, valid sites are: Skin and skin appendages Subcutaneous tissue Breast Bone marrow Spleen Blood Lymph node Bone (not otherwise specified) Skeletal system (bones of head, rib cage, and vertebral column) Skeletal system (bones of shoulder, girdle, pelvis, and extremities) Soft tissue (not otherwise specified) Soft tissue (muscles of head, neck, mouth and upper extremity) Soft tissue (muscles of trunk, perineum, and lower extremity) Tendon and tendon sheath Ligament and fascia Joints (synovial tissue) Synovial fluid Nose Accessory sinus Nasopharynx Epiglottis and larynx Trachea Bronchus Bronchiole Lung Pleura Upper respiratory fluids Bronchial fluid Pleural fluid Pericardium Heart Cardiac valve Pericardial fluid Blood vessel Mouth Lip Tongue |

Tooth, gum and supporting structures of the tooth
Salivary gland
Liver
Gallbladder
Extrahepatic bile duct
Pancreas
Saliva
Bile and pancreatic fluid
Pharynx, oropharynx, and hypopharynx
Tonsils and adenoids
Esophagus
Stomach
Small intestine - duodenum
Small intestine - jejunum & ileum
Appendix
Colon
Rectum
Anus
Gastric aspirate
Gastrointestinal contents (feces)
Omentum and peritoneum
Peritoneal fluid
Kidney
Renal pelvis
Ureter
Urinary bladder
Urethra
Penis
Prostate and seminal vesicle
Testis
Epididymis, vas deferens, spermatic cord and scrotum
Urine
Male genital fluids
Pituitary gland
Adrenal gland
Thyroid or parathyroid gland(s)
Thymus
CSF (cerebrospinal fluid)
Meninges, dural sinus, choroid plexus
Brain
Spinal cord
Cranial, spinal and peripheral nerve
Eye and ear appendages
Ear and mastoid cells
Pus
Other
Multiple sites
Unknown

If Sex = Female, valid sites are:

Skin and skin appendages
Subcutaneous tissue
Breast
Milk
Bone marrow
Spleen
Blood
Lymph node
Bone (not otherwise specified)
Skeletal system (bones of head, rib cage, and vertebral column)
Skeletal system (bones of shoulder, girdle, pelvis, and extremities)
Soft tissue (not otherwise specified)
Soft tissue (muscles of head, neck, mouth and upper extremity)
Soft tissue (muscles of trunk, perineum, and lower extremity)
Tendon and tendon sheath
Ligament and fascia
Joints (synovial tissue)
Synovial fluid
Nose
Accessory sinus
Nasopharynx
Epiglottis and larynx
Trachea
Bronchus
Bronchiole
Lung
Pleura
Upper respiratory fluids
Bronchial fluid
Pleural fluid
Pericardium
Heart
Cardiac valve
Pericardial fluid
Blood vessel
Mouth
Lip
Tongue
Tooth, gum and supporting structures of the tooth
Salivary gland
Liver
Gallbladder
Extrahepatic bile duct
Pancreas
Saliva
Bile and pancreatic fluid

Pharynx, oropharynx, and hypopharynx
Tonsils and adenoids
Esophagus
Stomach
Small intestine - duodenum
Small intestine - jejunum & ileum
Appendix
Colon
Rectum
Anus
Gastric aspirate
Gastrointestinal contents (feces)
Omentum and peritoneum
Peritoneal fluid
Kidney
Renal pelvis
Ureter
Urinary bladder
Urethra
Urine
Vulva, labia, clitoris, and Bartholin's gland
Vagina
Uterus
Cervix
Endometrium
Myometrium
Fallopian tube, broad ligament, parametrium, and paraovarian region
Ovary
Female genital fluids
Placenta, umbilical cord, and implantation site
Fetus and embryo
Pituitary gland
Adrenal gland
Thyroid or parathyroid gland(s)
Thymus
CSF (cerebrospinal fluid)
Meninges, dural sinus, choroid plexus
Brain
Spinal cord
Cranial, spinal and peripheral nerve
Eye and ear appendages
Ear and mastoid cells
Pus
Other
Multiple sites
Unknown

Meningeal

Blood

| | |
|------------|--|
| | Lymph node CSF (cerebrospinal fluid) Meninges, dural sinus, choroid plexus Pus Unknown |
| Peritoneal | Blood Lymph node Omentum and peritoneum Peritoneal fluid Pus Unknown |
| Other | If Sex = Male, valid sites are those selected for 'If other major site, select other type' or 'If other additional site, select additional site type' (i.e., one or two sites from the following list): Skin and skin appendages Subcutaneous tissue Breast Bone marrow Spleen Blood Nose Accessory sinus Nasopharynx Epiglottis and larynx Trachea Pericardium Heart Cardiac valve Blood vessel Mouth Lip Tongue Tooth, gum and supporting structures of the tooth Salivary gland Liver Gallbladder Extrahepatic bile duct Pancreas Pharynx, oropharynx, and hypopharynx Tonsils and adenoids Esophagus Stomach Small intestine - duodenum Small intestine - jejunum & ileum Appendix Colon |

Rectum
Anus
Pituitary gland
Adrenal gland
Thyroid or parathyroid gland(s)
Thymus
Brain
Spinal cord
Cranial, spinal and peripheral nerve
Eye and ear appendages
Ear and mastoid cells
Other

and the following:

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Nose' or 'Accessory sinus' or 'Nasopharynx' then allow 'Upper respiratory fluids'

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Pericardium' or 'Heart', then allow 'Pericardial fluid'.

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Mouth' or 'Lip' or 'Tongue' or 'Tooth, gum and supporting structures of the tooth' or 'Salivary gland', then allow 'Saliva'

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Liver' or 'Gallbladder' or 'Extrahepatic bile duct' or 'Pancreas', then allow 'Bile and pancreatic fluid'

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Nose' or 'Accessory Sinus' or 'Nasopharynx' or 'Epiglottis and larynx' or 'Trachea' or 'Mouth' or 'Lip' or 'Tongue' or 'Tooth, gum and supporting structures of the tooth' or 'Salivary gland' or 'Liver' or 'Gallbladder' or 'Extrahepatic bile duct' or 'Pancreas' or 'Pharynx, oropharynx, and hypopharynx' or 'Tonsils and adenoids' or 'Esophagus' or 'Stomach' or 'Small intestine - duodenum', then also allow: 'Gastric aspirate'.

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Nose' or 'Accessory Sinus' or 'Nasopharynx' or 'Epiglottis and larynx' or 'Trachea' or 'Mouth' or 'Lip' or 'Tongue' or 'Tooth, gum and supporting structures of the tooth' or 'Salivary gland' or 'Liver' or 'Gallbladder' or 'Extrahepatic bile duct' or 'Pancreas' or 'Pharynx, oropharynx, and hypopharynx' or 'Tonsils and adenoids' or 'Esophagus' or 'Stomach' or 'Small intestine - duodenum' or 'Small intestine - jejunum & ileum' or 'Appendix' or 'Colon' or 'Rectum' or 'Anus', then also allow: 'Gastrointestinal contents (feces)'.

Other

If Sex = Female, valid sites are those selected for 'If other major site, select other type' or 'If other additional site, select additional site type' (i.e., one or two sites from the following list):

Skin and skin appendages
Subcutaneous tissue
Breast
Bone marrow
Spleen
Blood
Nose
Accessory sinus
Nasopharynx
Epiglottis and larynx
Trachea
Pericardium
Heart
Cardiac valve
Blood vessel
Mouth
Lip
Tongue
Tooth, gum and supporting structures of the tooth
Salivary gland
Liver
Gallbladder
Extrahepatic bile duct
Pancreas
Pharynx, oropharynx, and hypopharynx
Tonsils and adenoids
Esophagus
Stomach
Small intestine – duodenum
Small intestine - jejunum & ileum
Appendix
Colon
Rectum
Anus

Placenta, umbilical cord, and implantation site

Fetus and embryo

Pituitary gland

Adrenal gland

Thyroid or parathyroid gland(s)

Thymus

and the following:

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Nose' or 'Accessory sinus' or 'Nasopharynx' then allow 'Upper respiratory fluids'

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Pericardium' or 'Heart', then allow 'Pericardial fluid'.

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Mouth' or 'Lip' or 'Tongue' or 'Tooth, gum and supporting structures of the tooth' or 'Salivary gland', then allow 'Saliva'

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Liver' or 'Gallbladder' or 'Extrahepatic bile duct' or 'Pancreas', then allow 'Bile and pancreatic fluid'

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Nose' or 'Accessory Sinus' or 'Nasopharynx' or 'Epiglottis and larynx' or 'Trachea' or 'Mouth' or 'Lip' or 'Tongue' or 'Tooth, gum and supporting structures of the tooth' or 'Salivary gland' or 'Liver' or 'Gallbladder' or 'Extrahepatic bile duct' or 'Pancreas' or 'Pharynx, oropharynx, and hypopharynx' or 'Tonsils and adenoids' or 'Esophagus' or 'Stomach' or 'Small intestine - duodenum', then also allow: 'Gastric aspirate'.

If 'If other major site, select other type' or 'If other additional site, select additional site type' is equal to 'Nose' or 'Accessory Sinus' or 'Nasopharynx' or 'Epiglottis and larynx' or 'Trachea' or 'Mouth' or 'Lip' or 'Tongue' or 'Tooth, gum and supporting structures of the tooth' or 'Salivary gland' or 'Liver' or 'Gallbladder' or 'Extrahepatic bile duct' or 'Pancreas' or 'Pharynx, oropharynx, and hypopharynx' or 'Tonsils and adenoids' or 'Esophagus' or 'Stomach' or 'Small intestine - duodenum' or 'Small intestine - jejunum & ileum' or 'Appendix' or 'Colon' or 'Rectum' or 'Anus', then also allow: 'Gastrointestinal contents (feces)'.