

NAACCR

**Electronic Pathology (E-Path)
Reporting Guidelines**

**Approved by the NAACCR Board of Directors
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¹ WG agreed to set the recommended timeline as 5 – 8 months.

² WG agreed to embed the Business Rules as a table entry following the step in which the rule is needed. Rules may be required in more than one step, in which case they will appear under each step.

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Preface

The purpose of this manual is to describe procedural guidelines for electronic pathology (E-Path) reporting from a pathology laboratory to a cancer registry. This manual is a complement to Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 2.0, which contains recommended message or format standards for electronic transmission of reports (pathology, cytology, and hematology) from pathology laboratories to central cancer registries. Whereas Volume V is designed for those in information technology, this manual is designed for those in registry and laboratory operations.

It is the hope of the North American Association of Central Cancer Registries, Inc. (NAACCR) Pathology Laboratory Subcommittee that making the Volume V standards and these procedural guidelines available to the community will make it easier for pathology laboratories, central cancer registries, and software vendors to adopt a uniform method for report transmission and processing. Our goals are to: (1) develop resources that will support standardized collection of pathology report data for cancer cases that are not identified in the traditional hospital setting, and (2) facilitate the nationwide electronic reporting of pathology reports to cancer registries.

The content of this manual provides guidance for central cancer registries to develop methods to electronically receive and process reports from pathology laboratories. The manual will evolve over time as changes occur in laboratory technology, electronic reporting and other information technologies, standardized vocabularies and codes, reporting regulations, and requirements to protect the confidentiality of patient data. This manual is based, in part, on the original NAACCR electronic pathology standards documentation published in January 1996; NAACCR Volume II, Chapter 6, published in September 2000; and the draft E-Path Reporting Process document developed in March 2005.

We would like to acknowledge the pioneering work of the previous NAACCR Pathology Laboratory Subcommittee Co-Chairs: Frank Caniglia, Pennsylvania Cancer Registry; Robin Otto, Pennsylvania Cancer Registry; Susan Gershman, Massachusetts Cancer Registry; Warren Williams, CDC-NPCR; and Herman Menck, Los Angeles Cancer Surveillance Program. In addition, a special note of appreciation goes to David Lyalin for his facilitation and modeling assistance in developing the use case and diagrams; and to all NAACCR members and committees that have collaborated on the ongoing E-Path efforts. Thank you.

Sincerely,

Ken Gerlach, Chair
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NAACCR Electronic Pathology Subcommittee

1 Problem Statement, Goals, and Scope of This Document

Monitoring the occurrence of cancer³ is a cornerstone of cancer control decision-making. This monitoring, referred to as cancer surveillance, can be used to trigger case investigations, follow trends, evaluate the effectiveness of prevention measures such as screening and early detection programs, and suggest public health priorities. Because most cancers are definitively diagnosed by histology, cancer surveillance programs may utilize pathology reports to identify new cases and collect further information on cases previously reported.

The Problem

One of the major changes in the health care delivery system in the late 1990s, and specifically with respect to the cancer patient, is the shift in diagnostic and treatment procedures from hospital to clinic and other non-hospital settings. This shift presents challenges to central cancer registries, which have traditionally relied on hospital registries as their primary source for ascertainment of reportable cancer cases. It is essential that central cancer registries develop mechanisms for ascertaining cases from non-hospital sources to maintain a complete and accurate count of cancer cases occurring within the population that they serve.

An essential information source for complete cancer data collection is the pathology laboratory, which may be an independent pathology laboratory or located within a facility that may provide services only for a single hospital, or which may have a broad range of clients, including hospital facilities, clinics, and other medical practices. To date, the lack of a standardized system for reporting by pathology laboratories has required each central registry to develop procedures for capturing cases directly from pathology laboratory reports. Pathology laboratories also must comply with the different specifications from each state or province to which they are required to report. The time and cost for such endeavors are frequently barriers encountered during implementation of direct reporting from the laboratories to the central registries.

The Proposed Solution

An E-Path Documentation Workgroup of the NAACCR Information Technology (IT) Committee was formed to develop a recommended approach for implementing electronic pathology reporting. The result of this E-Path Workgroup's efforts is the documentation contained in this manual. Implementation guidelines have been developed to specify the reporting process, and thereby to enhance the completeness, timeliness, consistency, and efficiency with which cancer data are transmitted by pathology laboratories, and then received and processed by central cancer registries.⁴

Goal of This Document

The goal of this document is to define the recommended approach for implementing standards for E-Path reporting between pathology laboratories and central cancer registries, vendors, and other entities that may be involved as senders or recipients of cancer pathology reports as required by state law.

Objectives of the implementation effort are to:

- Describe the complete standards for E-Path implementation from a variety of partner perspectives, including the role of each partner, to enhance understanding of each component;
- Describe the uses of electronic pathology reports within the central registry;
- Provide detailed approaches, business rules and methods for performing each E-Path component, including identification and recruitment of participating laboratories, preparation of transmission files, testing, quality control, and monitoring efforts;

³ The term *cancer* in this document relates to all reportable conditions, including benign brain and central nervous system tumors, in situ and invasive cancers.

⁴ See *Appendix A* for a description of the methodology used to create these guidelines.

- Provide terms and definitions used in electronic pathology reporting to enhance communication between partners.

Scope of This Document

The scope of this document is limited to:

- (1) Implementation guidelines and business rules to assist central registries, pathology laboratories, and vendors in North America to respond to the call for direct pathology reporting in a uniform manner;
- (2) Guidelines for using E-Path reports within the central cancer registry.

These implementation guidelines provide assistance in implementing the recommended standards described in NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 2.0, which describes data items, data item definitions, and transmission specifications.

HIPAA⁵

The Health Insurance Portability and Accountability Act (HIPAA, or the Act), P.L. 104-191, was enacted on August 21, 1996. HIPAA includes provisions related to insurance coverage, and requires that standards be adopted for certain uniform financial and administrative transactions. HIPAA also includes provisions for adopting standards for the privacy of health information, and pre-empts state laws and imposes civil monetary penalties and prison terms for certain violations.

HIPAA also made some changes in the membership and duties of the National Committee on Vital and Health Statistics (NCVHS). HIPAA provides that the NCVHS will make recommendations and legislative proposals to the Secretary of Health and Human Services on the adoption of uniform data standards for patient medical record information and the electronic exchange of such information. HIPAA addresses state regulatory reporting by stating, “[N]othing in this part shall limit the ability of a state to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.”

For public health authorities, HIPAA states, “Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” Covered entities that are named in the HIPAA legislation are “health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction referred to in Section 1173(a) of the Act.” The regulation implementing the HIPAA privacy provisions allows public health exemptions for disclosure without patient consent of individually identifiable health information for the purposes quoted above.

Under HIPAA, state cancer registries qualify as a public health authority operating as an agency authorized by law to “collect or receive such information for the purposes of preventing or controlling disease ... and for the conduct of public health surveillance, public health investigations, and public health interventions.” (45 CFR 164.512) As such, public health reporting to state agencies from pathology laboratories is exempt from HIPAA privacy rules. Pathology laboratories, as covered entities, may report this public health information to state cancer registries using the HL7 standard as described here, and HIPAA provisions will not constrain their ability to report.

⁵NAACCR provides interpretation of HIPAA as it relates to cancer registration, along with FAQs (frequently asked questions). It can be found on their website at <http://www.naacr.org>

2 Introduction to Electronic Pathology Reporting in the Central Registry

E-Path reporting is the most efficient method for ascertaining cases from pathology laboratories, where the laboratories have the capability to report and the registries have the capability to receive electronic data streams. Reportable diagnoses made within the hospital and at external pathology laboratories can be transmitted to the central registry in a near real-time basis, and incident cases can be made immediately available for analysis.

Pathology Reporting Process in Context of Overall Pathology Testing

The Clinical Process

A health care provider collects a specimen (tissue, fluid, etc.) from a patient and submits the specimen to the pathology laboratory. The health care provider may be located in the hospital served by the pathology laboratory, or in a physician's office, medical clinic, surgery center, urgent care facility, or other health service setting.

The pathology laboratory receives the specimen, logs it into the laboratory system, and prepares the specimen for analysis. The pathologist analyzes the specimen and dictates his/her findings, which are then transcribed into the laboratory system. The pathologist verifies the accuracy of the report and signs the transcribed report.

This medical process is the same whether the reporting process follows the traditional method using paper pathology reports or an E-Path reporting system (**Figure 1**).

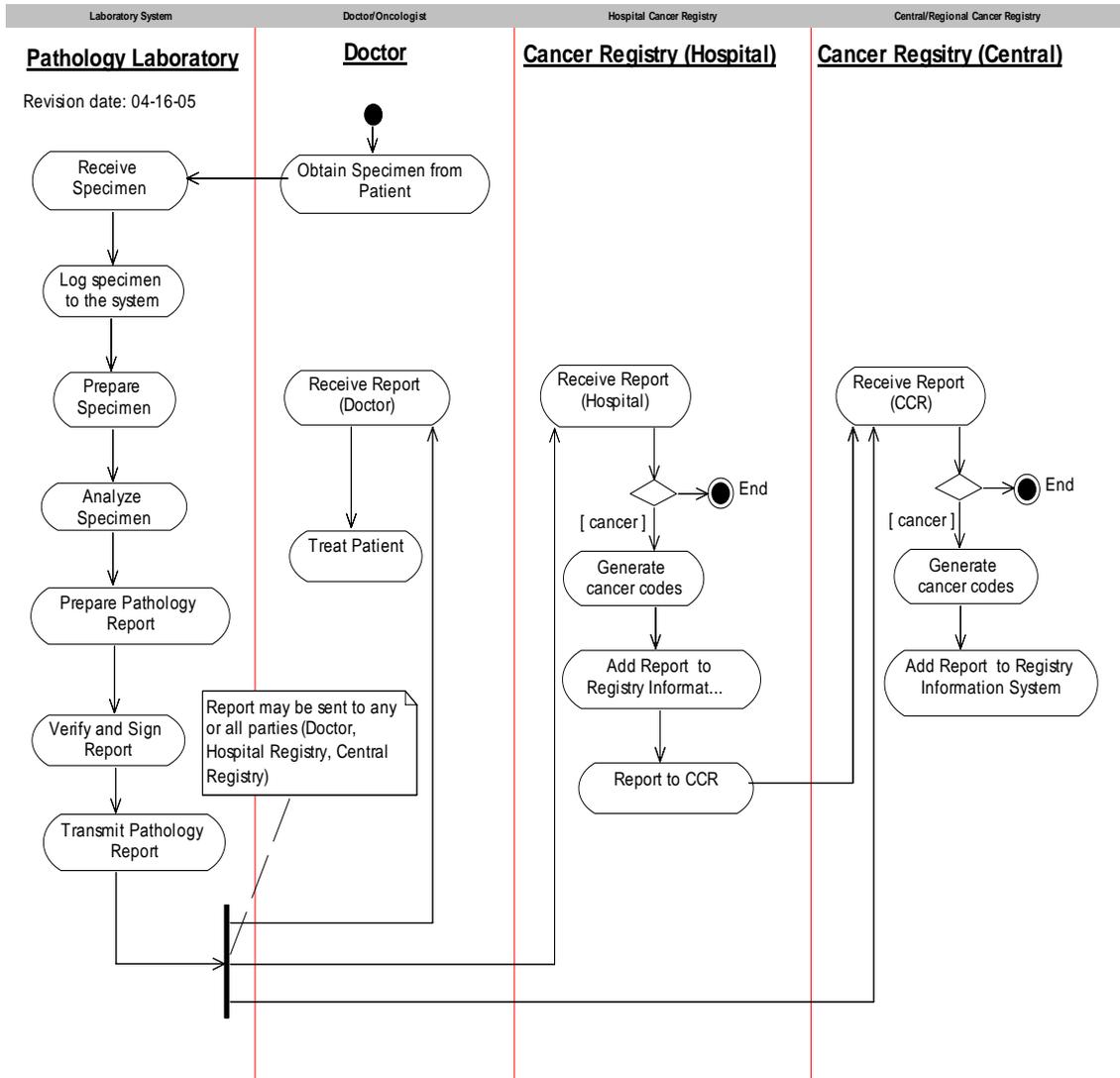
The Reporting Process

In a traditional setting, the paper pathology report may be sent to:

- (1) The health care provider – who uses the findings to treat the patient.
- (2) The hospital cancer registry – where the report is reviewed for a reportable diagnosis as defined by the state registry. If an eligible diagnosis is identified, the case is entered into the registry suspense system and cancer codes are assigned. The medical record is reviewed, and the suspended case is abstracted into the full registry database. When the case is complete, it is electronically submitted to the central cancer registry in the NAACCR data exchange record layout, usually in a batch mode with other cases completed within a specified time period.
- (3) The central cancer registry – where all reports other than those that will be abstracted by a hospital registry are collected, reviewed for reportability, and assigned codes for primary site and histology. The central registry software system then links each report to an existing case in the database if one exists, and then consolidates the pathology data from multiple reports within the registry database into records about single primary tumors according to established registry principles.⁶

⁶Johnson CH (ed.), SEER Program Coding and Staging Manual 2004. National Cancer Institute, NIH Publication number 04-5581, Bethesda, MD 2004.

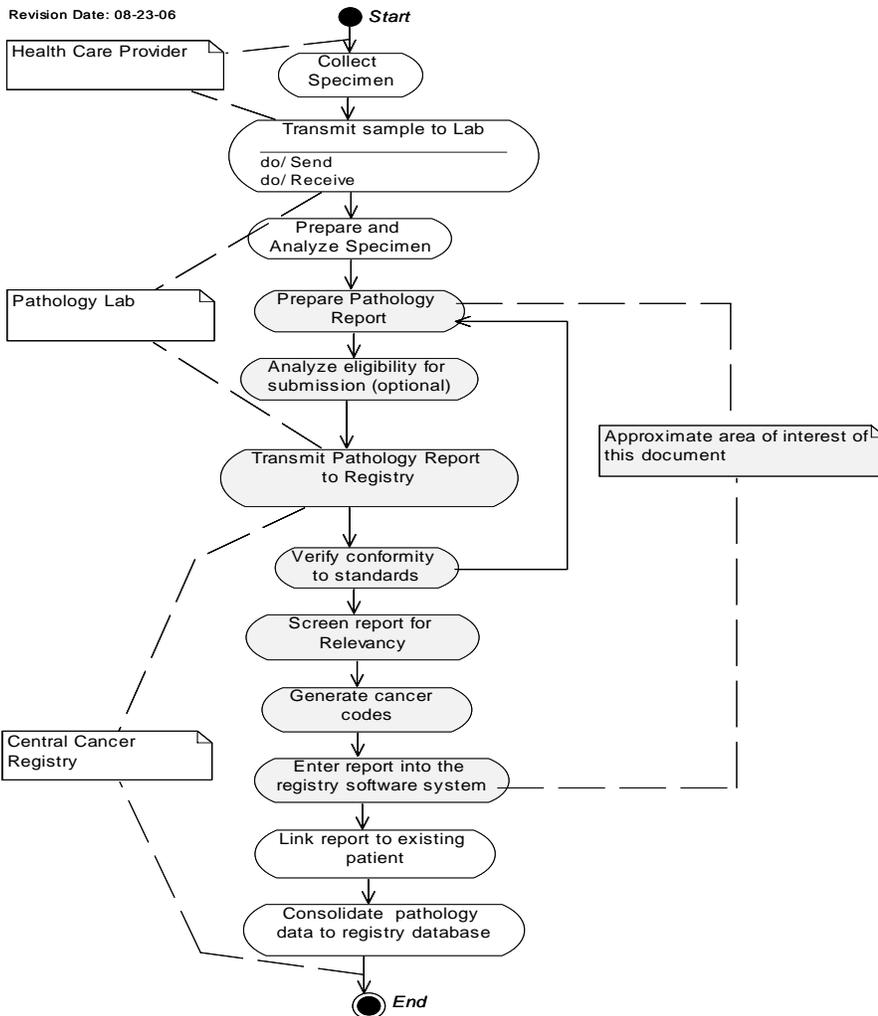
Figure 1. Pathology Reporting Process in Context of Overall Pathology Testing. High-Level Overview.



In an electronic reporting setting, a copy of the pathology report is transmitted electronically to the central registry.⁷ The process begins when the pathologist completes the pathology report, marking it as “final”; the process ends when the E-Path report data are loaded into the central registry’s information system and is ready for use in the central registry (i.e., casefinding, updating existing records with additional information, special studies, etc.).

Figure 2. Scope of E-Path Reporting

Pathology Reporting Process Overview (cancer registration perspective)



▷

⁷ A single case entry system may be designed by the central registry to assist laboratories in submitting a small number of pathology reports electronically. The single case data entry method works well only for a small number of cases. The time involved and increased risk of entry errors makes this method impractical on a large scale.

Benefits and Challenges for E-Path Reporting

As with any process, there are benefits and challenges for all partners. An E-Path reporting system offers many of the same benefits to both the *Hospital* and the *Central Registry*:

- (1) Improves casefinding and follow-back for diagnoses in non-hospital data sources.
- (2) Decreases the amount of time required by registry staff to perform case ascertainment and data entry/transcription.
- (3) Improves the timeliness of cases in the registry, enabling rapid ascertainment functions for clinical studies within the health care facility and for specific studies conducted by epidemiologists.
- (4) Allows the registry to produce more current preliminary cancer incidence statistics for forecasting and tracking trends in the cancer care continuum.
- (5) Provides a database of E-Path report information, beyond the coded information, which can be used for research purposes, dependent on the language processing tools available.
- (6) Ensures that consistent and uniform data identification criteria are used.
- (7) Facilitates the automated assignment of codes to identified elements within the report, allowing a shift in the use of registry staff resources from initial coding/data entry to review activities.
- (8) Allows the entire pathology report to be transmitted, so that the full report can be reviewed for coding purposes.
- (9) Promotes flexibility in database design, with an opportunity to capture/recapture and code new data elements of clinical significance from a stored database of pathology reports.
 - a. Diagnostic patterns, waiting times, trend analysis.
- (10) Facilitates compilation of multiple reports to consolidate into a single cancer diagnosis from histologic perspective on almost a real-time basis.
- (11) Eliminates the need to review all pathology reports, cancer related as well as non-cancer related.
- (12) Automatically maintains HIPAA Disclosure logs.

Additionally, E-Path reporting allows central registries to compare hospital registry reports with E-Path reports for quality control of registry data, including quality parameters of timeliness, completeness, and accuracy of coding.

Benefits for the *Laboratory* include:

- (1) Reduces staff time involved in identifying, copying, and mailing paper pathology reports.
- (2) Eliminates the costs associated with submitting paper pathology reports to registries.
- (3) Eliminates the need for registry personnel to use the laboratory's workspace and computer to perform casefinding.
- (4) Automates reporting with minimal human supervision.
- (5) Inherently improves HIPAA compliance.
 - a. Provides a more secure and confidential reporting than traditional manual methods.
 - b. Reduces the risk of disclosure of patient identifiers.
 - c. Restricts viewing of non-cancer reports because the computer eliminates those that are not relevant for cancer.
 - d. Maintains a complete electronic audit log of reports submitted to the registry.

E-Path reporting presents certain challenges to all partners, the most critical being the personnel resources needed to develop, test, and implement a system. IT resources are particularly scarce at the laboratory, hospital, and central registries. Coordinating the priority level of E-Path reporting within each partner's operational plan is a difficult process and can have an adverse impact on the timeline for fully implementing E-Path reporting. A champion, someone who is dynamic, well respected, and actively supportive of implementing E-Path reporting in the registry and the laboratory, increases the likelihood of timely implementation.

Challenges for all partners, the **Laboratory**, the **Hospital**, and the **Central Registry**:

- (1) Administrative approval at multiple levels.
- (2) Evaluating purchase of software and/or hardware for secure transmission of messages/files.
- (3) Development of testing mechanisms to verify complete reporting of required pathology reports and data items, accuracy of data values.
- (4) Confidentiality issues:
 - a. Reporting of non-reportable conditions.
 - b. Reporting on out-of-state residents.
 - c. Out-of-state laboratories not covered by State data confidentiality statutes and regulations.

Challenges for the **Laboratory** include:

- (1) Planning and implementing an interface between laboratory information systems (LIS) and the registry systems.
- (2) Resources to create a message file.
- (3) Possible modification to data formats.
- (4) May require infrastructure modification (i.e., firewall configuration, hardware/server).

Challenges for the **Hospital** and the **Central Registry**:

- (1) Requires reassignment of registry staff time/duties to take advantage of new pathology information available in electronic form.
- (2) Requires development of new quality control procedures.
- (3) Requires additional software and possibly additional hardware to process and store E-Path reports. For the central registry, there will be a need to scale up to an “enterprise” level computing environment from their local intranet environment.
- (4) Differences in hospital and central registry timelines can occur. The availability of the pathology report in the central registry may change their timeline needs for the additional data that hospital registries provide.

E-Path reporting also will increase central registry staff time needed to review multiple pathology reports per single reportable diagnosis and compile them into a single tumor/cancer abstract.

3 Central Registry Use of Electronically Submitted Pathology Reports

A. Traditional Cancer Surveillance Activities

E-Path reporting supports and facilitates the performance of many surveillance activities traditionally undertaken by central cancer registries.

Case ascertainment: E-Path reports represent a stream of data from which relevant reports can be electronically extracted and moved into the registry database. The reports may be a new accessible and productive case-finding source for registries that have not traditionally reviewed pathology reports. For those registries that have reviewed paper reports, electronic reporting promotes greater efficiency in report processing, allowing the registry to combine casefinding, coding, and data entry into a single in-house procedure. Many of the required data elements can be directly captured from the incoming data message and distributed into the registry's database system. Depending on the sophistication of coding at the laboratory end of the process and the language processing software at the registry end, reportability decisions and coding of primary site and histology may be performed electronically, with the registrar trained to oversee the process and to intervene as necessary. In a less automated system, the registrar may review each incoming report, decide on reportability, and apply correct cancer codes in a single step.

Because the information about cases that have not been reported is already in electronic format, and because electronic communication channels are being maintained between reporting entities and the registries, an electronic communication process can be established to alert hospital registries of cases missed in their own casefinding activities, and hospital registries also can generate and send electronic reports to central registries regarding pathology reports for recurrent diagnoses already reported or diagnoses that they will not accession for a variety of reasons.

E-Path reporting also allows the automated accumulation of descriptive statistics on pathology reports and coding, and data entry activities that may be of interest in quantifying the activities of the central registry.

Rapid case ascertainment: Because the E-Path reports are coming into the registry on a near real-time basis depending on the volume, they can be coded and made available to researchers performing rapid case ascertainment studies with very little delay from the time of final diagnosis. E-Path reporting thus facilitates the conduct of studies that include contact with patients in the initial stages of their disease. If the registry suffers a delay in processing pathology reports on a regular basis, the electronic format allows for the identification of the reports of interest for the rapid ascertainment study. These reports can be collected in a separate file and presented for immediate processing to meet study obligations.

Verification of reporting from hospital registries and other reporting sources: Central registries can expand their quality review activities in monitoring hospital reporting, not only for completeness of case ascertainment but also for accuracy of coding site, histology, and other data elements such as staging parameters, which are becoming more usual on pathology reports. Central registries have another resource for assessing data quality, in addition to comparison of coding and abstracted text, re-abstracting studies, and standardized edits.

Consolidation of multiple reports into a single tumor/cancer record: E-Path reporting adds another dimension to case consolidation, in that registry software must be developed to correctly link all E-Path reports for particular diagnoses from hospital laboratories with the abstracts for those cancers coming from the hospital registry databases. E-Path reports frequently do not contain all demographic data items, creating a challenge for accurate patient linkage. Enhancement of existing linkage software may be needed to minimize the additional number of records that must be manually reviewed and linked. Tumor linkage and data item consolidation software becomes more important when registries have E-Path reporting. Manually processing the increased

number of records is time consuming and expensive. Automated tools to process a significant percentage of these records are recommended.

B. Expanded Cancer Surveillance Activities

Expanded coding from pathology reports: Pathology reports contain information in addition to site and histology that may be of interest to central cancer registries, particularly with the increasing use of synoptic information standardized on the College of American Pathologists (CAP) Cancer Protocols and Checklists for specific cancer sites/histologies.⁸ As more software developers incorporate the SNOMED-CT encoded CAP Checklists into pathology laboratory information systems, the E-Path reports also will become a primary source of electronically available pathologic staging information. To use this information appropriately, central registries will need to develop protocols for combining pathology reports from a staging perspective, similar to protocols currently used to consolidate records from a cancer diagnostic perspective. Again, registrars can be trained to oversee and intervene in automated processes, and can perform coding/data entry for staging information in the absence of electronic decision support software.

Expanded use of pathology reports on cancer cases where there is no residual malignancy: Pathology reports with no residual malignancy have not traditionally been picked up or maintained by central cancer registries. Reports where “no residual tumor” is found may be of particular interest to a central registry to validate stage and treatment information submitted by hospital cancer registries. Reports with “no residual tumor” diagnosed occur most frequently in breast cancer and melanoma cases, and similar language also is seen in bone marrow specimens assessing disease following chemotherapy for leukemias.

Database resource for evolving clinical/registry concepts: The availability of the text of the E-Path reports presents a great resource for the identification and analysis of clinical and registry concepts embodied in the pathology reports, which may not have been coded at the time the report was initially processed. As an example of a change in registry procedures, SEER has introduced two new data concepts for coding starting with diagnoses in 2007, tumor multiplicity and ambiguous terminology. If a central registry decides to include these concepts in coding of pathology reports but is not ready to implement this change when it starts to receive 2007 reports, it should be able to develop an automated search mechanism to review stored reports and present candidates for the new coding. The capability of searching stored electronic reports may support or promote greater flexibility in making modifications to database structure. Depending on the natural language processing and other software tools available to the central registry, the presence of the E-Path report database also may support or encourage data mining or analytic activities involving pathology information.

Review/verification/standardization of pathology report content: Hospital registrars currently engage in dialogues with their pathologists regarding the appropriate coding diagnoses on the pathology report. The collaboration of pathology laboratories and registries in the development of electronic reporting processes provides an opportunity for registrars to engage in studies and discussions with pathologists about terminology and coding on pathology reports to explore the potential of electronic reporting and to realize the greatest efficiencies from the process. As an example, with the new data item, Ambiguous Terminology DX [422], to identify a case diagnosed using ambiguous terminology, the registrar has objective data to present to the pathologists on the number of cases that are affected by ambiguous terminology. A discussion on the impact of these diagnoses on incidence rates may help reduce the use of ambiguous terminology. Working in concert, the parties should be able to define the precision of coding and language that will be supplied by the medical practitioner and the level of review that will be conducted by the registrar to result in a standardized tumor/cancer record.

⁸ At the current time, there is limited use of the CAP Cancer Checklists by pathology laboratories in the United States.

Description of the cancer event from a pathologic viewpoint: Central registries have developed case consolidation rules to identify and put together multiple records describing single diagnoses. Registries also may collect multiple pathology reports for cases not reported by hospital registries, and generally extend the consolidation rules for multiple hospital registry reports to cover the pathology reports as well. The availability of E-Path reports documenting all the events of cancer diagnosis, surgical treatment, and recurrence should encourage the development of more sophisticated algorithms for consolidating record information, based on the natural history of the disease from a pathologic perspective. This approach may require the coding of more information from the pathology report than has been done traditionally to more fully describe the event generating the report. Registries can obtain surgical treatment data within a shorter timeframe than is currently possible from the hospital registry reporting. A more sophisticated algorithm for record consolidation also may result in a more fully automated process that can be implemented with less manual intervention, again freeing registrar skills for oversight, review, quality control activities, and refinement of processes.

E-Path assistance in identifying pathology specimen material for research through virtual, real, or discard repositories:⁹ Pathology specimens in the form of microscopic slides (on which the information in pathology reports is based) and/or paraffin tissue blocks from which the slides have been prepared are proving to be an increasingly valuable source for research material when fresh or frozen tissue is not available. This is particularly the case in population-based retrospective studies that involve subjects from more than one hospital or laboratory facility. Slides are used in research studies by single or a few pathologists to verify the accuracy and reproducibility of initial diagnoses, which are often made by many individual pathologists. The tissue remaining in paraffin blocks is usually the only remaining material from the original specimen, and as such, with increasingly sophisticated technologies, provides the only source of material for retrospective molecular or protein expression studies.

The extensive files of paraffin blocks retained in individual laboratories provide a “virtual” repository of blocks that may be obtainable. The E-Path reports on cancer-related specimens thus have a significant usefulness in obtaining slides and/or paraffin blocks because when available, the pathology report allows the investigator to identify which specimens may be useful and/or have enough tissue remaining. In addition, because of cost constraints on laboratories, many laboratories discard these blocks after a fixed period of time, often 5 to 10 years, so they are no longer available. To preclude this loss, some population-based cancer registries have attempted to obtain these cancer-related blocks at the time they are to be discarded, and have obtained real or “discard” block repositories. For this to be effective, the pathology number and report must be obtained to allow for appropriate decisions regarding the storage and or use of this material. Clearly, having the pathology report electronically available is invaluable, both at the time of block accession and when the material is needed.

C. Quality Control and Monitoring the E-Path Reporting Process

Quality control of E-Path reporting looks at:

- Timeliness and completeness of reporting;
- Timeliness, completeness, and quality of registry incorporation of pathology report data into the registry database;
- Accuracy and consistency of report content;
- Accuracy and consistency of registry coding and data entry.

Timeliness and completeness of reporting: Assessment of these characteristics of the reporting process is based on electronic monitoring of the number of reports received by the registry through an established reporting time

⁹This activity is being supported by the NCI, SEER program and has been incorporated into the Iowa Cancer Registry’s operation.

period, and the number of present or missing required data elements. Requests for missing information by the registry and the time to respond also can be tracked. If the registry receives all pathology reports from the laboratory, the electronic format allows the series of report numbers across different types of reports to be recorded, so that the registry can be assured that it has received and reviewed all reports generated by the laboratory.

Timeliness, completeness, and quality of registry incorporation of pathology report data into the registry database: The electronic format also facilitates the recording of descriptive statistics on the time between receipt of a data file and its processing into coded cancer information by the registry. The time required to code and process an individual report may be tracked as well, if the registry is interested in documenting workflow production statistics, estimating resource needs, and/or monitoring the impact of targeted training over time. Coding and/or review times for individual reports also may be used to readily identify types of pathology reports or report contents that present particular challenges for registrars, where coding principles may need clarification or where the registry needs to engage in further discussions with reporting pathologists to clarify terms and meanings. The registry may use statistics on large time lags between receipt of E-Path reports and data entry to justify requirements for more staff or staff training; alternatively the registry may use statistics on very timely processing of pathology reports to attract researchers interested in rapid case ascertainment studies.

Accuracy and consistency of report content: E-Path reporting facilitates automated review of certain content items within the pathology report, for example, a frequency distribution of unknown versus known laterality for specified paired body sites. If E-Path reports contain both free text and synoptic cancer information that could be directly transferred into the registry database, the electronic format presents a feasible mechanism for comparing the accuracy of the synoptic information against the body of the pathology report, to assess the utility of relying on the synoptic codes for an automated data collection system. To achieve the greatest benefits from monitoring the content of the reports themselves, the registry would collaborate with the reporting laboratories to address problems at the laboratory side of the process.

Accuracy and consistency of registry coding and data entry: If the registry on the receiving end of the E-Path reporting stream uses staff resources for coding/data entry of the report information, the format can support a double-coding design, whereby the first registrar will identify and code all reportable diagnoses, and a second registrar will review all decisions and code assignments. A more efficient design for this approach to quality control might be to develop a robust automated reportability decision program, allowing the first coder to review reportability decisions and assign ICD-O-3 codes, and use the second coder to review code assignment only on reportable diagnoses. For a single coder system, random or targeted reviews of coding decisions are a quality control method traditionally available to and used by central registries, regardless of the method of data acquisition. As registry experience with E-Path reporting grows, registries and laboratories will increase their interactions to solve data consistency issues. Additionally, electronic collection and assignment of ICD-O-3 codes will become more amenable to software decisions. Registrars' functions will increasingly shift toward involvement in quality control activities with regard to the E-Path reports, performing review of automated decisions and investigation of cases that lie outside the capabilities of the software.

D. Inclusion of E-Path Reports as an Individual Source Record or Stored as a Reference for Casefinding and Quality Control Processes

One of the decisions a central registry must make when implementing E-Path reporting is the ultimate status of stored electronic pathology reports in comparison with other electronic source reports. Two general approaches may be adopted.¹⁰ One approach uses E-Path reports for reference purposes. The other approach creates abstracted

¹⁰ These approaches can also be used for paper pathology reports.

source reports from the E-Path reports. A registry may determine to use only one approach or may adopt both approaches depending on the source of the E-Path reports. For example, a central registry receiving pathology reports from hospital-based laboratories may choose to use them as a reference for quality control for the hospital. On the other hand, pathology reports from an independent laboratory may represent the sole source for some reports and the registry may choose to abstract these reports.

For the reference approach, these reports can be stored and linked with the patient records to identify cases that have not been reported by the registry's official reporting sources and to perform quality control studies between the pathology report data and the registry's data. Registries most often choose this method when their primary purpose for E-Path reporting is to identify missing cases. Matched cases can either be discarded or permanently linked with the existing cases. Missing cases are followed back to the clinician with a request to complete a notification form following the registry's routine case reporting methods. When E-Path reports do not match an existing case and clinicians do not complete a routine case report, the case must be specifically added to the patient database as "Pathology Laboratory Only" reporting source. Specific software must be developed to perform this task, some of which may in fact require manual intervention. Depending on the design and flexibility of the central registry's database system, it may be necessary to store reference reports in an external database. In this situation, performing quality control and data accuracy checks with E-Path reports outside the main database may be cumbersome and may require the development of specialized software to perform these tasks.

Alternately, for the abstract approach, a registry creates a regular source record for the E-Path report in the registry database. This method allows the software that processes routine case abstracts from official facilities to be used for the E-Path reports, ensuring that all data are processed consistently, regardless of reporting source, and using the same linkage, consolidation and resolution criteria, and procedures.

Of course, this approach also requires more resources to abstract the encoded data elements. Fortunately, automated software applications exist that assist in this process. E-Path reports that are incorporated as abstracted reports at the time they are received decreases the lag time between diagnosis and the availability of the case information for analyses. Rapid ascertainment studies can locate their cases using the same mechanism as for retrospective studies. Incidence data [the type of cancer, age grouping] for 95% of cases can be available within 2 to 3 months of diagnosis, rather than the traditional 18–24 months. Over-counts due to unknown residency and the inability to confirm the number of primaries for certain patients will occur; however, these can be identified during analysis, minimizing their impact on the results.

Incorporating E-Path reports as abstracted source records in the registry database requires more sophisticated tumor linkage and consolidation software to minimize the manual resources required to adjudicate discrepancies between reporting sources. Weighting of reporting source is required for selecting a data item value among various values, as is a high-level decision on whether a non-exact match is significant, which requires manual review and resolution, or whether it is an acceptable variation. Additionally, a standard for data items needs to be included on a "Pathology Laboratory Only" source record to ensure that consistent data are available and default values are used.

Reports that do not link to an official facility record will eventually be followed back in the same manner as described above. If the clinician does not submit a routine case report form, the case is already in the database, identified as a pathology report submission. The final reporting source for this cancer can automatically be updated to "Pathology Reporting Only" at the end of the clean-up year.

4 Preparation for Electronic Pathology Reporting

Selection of Laboratories

Registries initiating an E-Path reporting system should select their partner laboratories carefully. Even in a registry where E-Path reporting is mandated, critical criteria are the laboratory's active interest in and the ability to implement an E-Path reporting process.

Additional selection criteria include:

- Current lack of reporting of cases by the laboratory;
- Number of reportable pathology reports currently submitted;
- Timeliness of reporting;
- Amount of quality control activities currently required for the laboratory;
- Relationship of the laboratory to the hospital with reporting cancer registry.

Methods for identifying laboratories for E-Path reporting include:

- Laboratory self-identifies its interest;
- Request for proposals for laboratories to report electronically;
- Solicitation of laboratories by telephone or letter. Lists can be developed with the help of:
 - State health departments;
 - CLIA lists;
 - State pathology associations (www.cap.org);
 - Hospital registrars;
 - Central registry field staff.

Pathology associations can be effective partners for implementing and expanding E-Path reporting. Communications with pathologists and pathology laboratory personnel through the professional associations enhances the legitimacy of E-Path reporting as a best practice method for meeting cancer reporting requirements.

Partners for electronic laboratory reporting beyond cancer

Central registries may benefit from partnering with other programs that have laboratory reporting, such as the communicable disease programs within the state health department. Resources can be pooled to work with the same laboratories to develop a common system for electronically reporting all state-required diseases. Laboratories benefit from having a single source for developing and implementing electronic reporting of their required cases. There are, however, challenges to address. The process needs to accommodate different data needs, standards, and time requirements for reporting. Timelines for implementation of E-Path reporting among partners can be complex due to a variety of differences, including funding cycles, availability of final standards, and priority of implementation within the program.

Timeline for Implementing E-Path Reporting

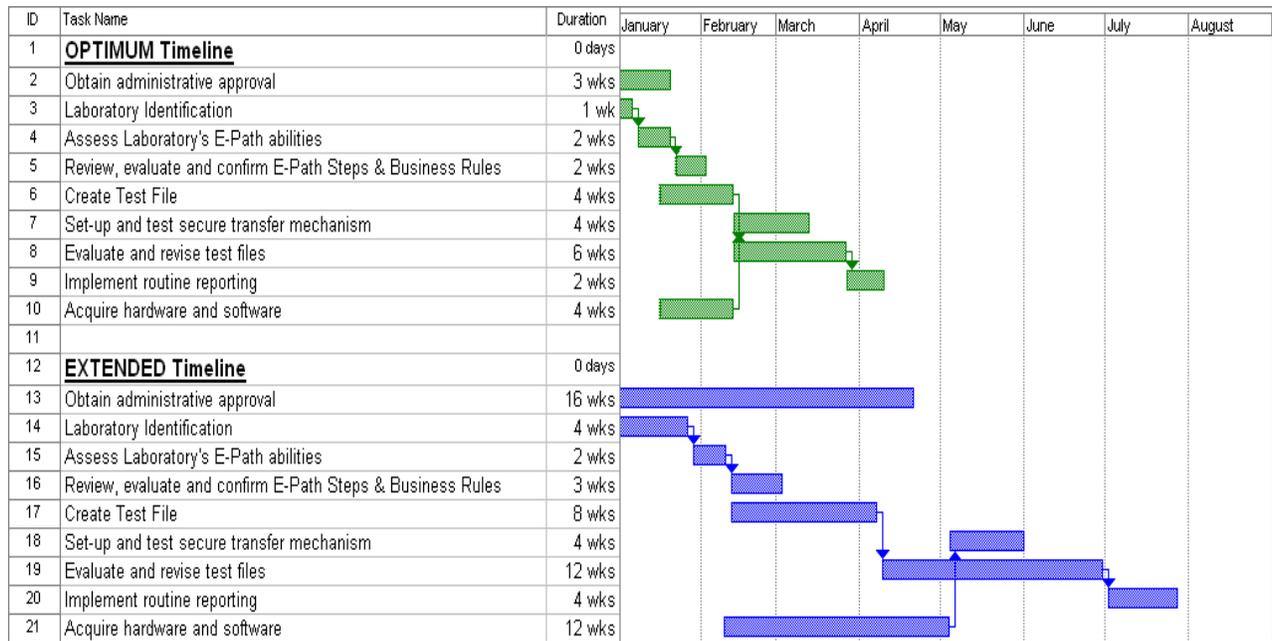
The timeline for E-Path reporting depends on many factors. If all partners are committed to a short-interval for implementation, routine E-Path reporting can begin in as little as 5 months. Many factors, however, can slow the implementation, causing the process to extend to 9 months or even longer. These factors include:

- Administrative approval from multiple levels;
- Priority of project within the laboratory;
- Skill level of laboratory and central registry personnel (LOINC, SNOMED, HL7);
- Pathology department having vendor conversion or updating their systems;

- Ability to link software systems within the laboratory (i.e., billing and clinical systems);
- Acquisition of hardware and software by the registry.

The Project Management Gantt chart below depicts the optimum and extended timeline for each step in the E-Path implementation process. As the chart below shows, some steps are dependent on the completion of previous steps; other steps can be performed simultaneously.

E-Path Implementation Timeline: Optimum and Extended



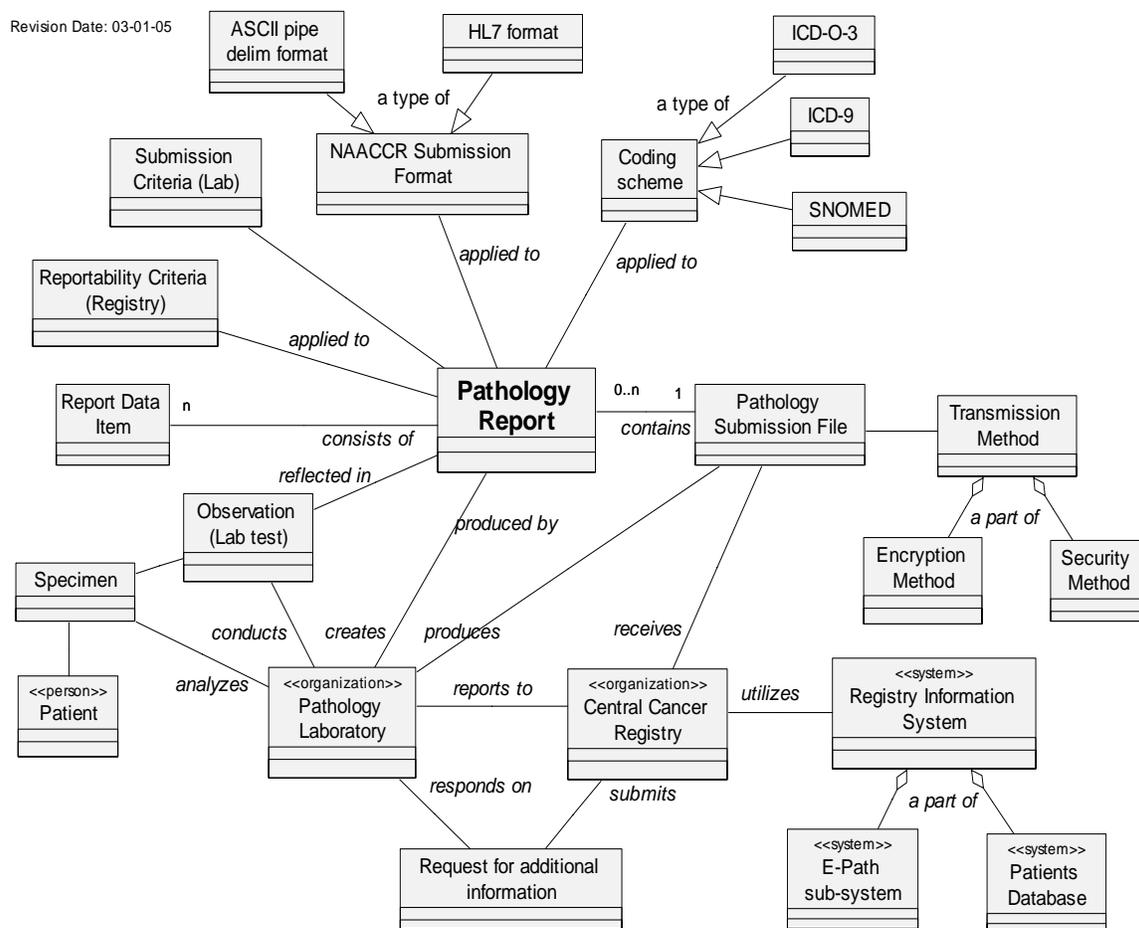
5 The Electronic Pathology Reporting Process

Description of Relationships Within the E-Path Reporting Process

A domain diagram¹ for the E-Path reporting process (**Figure 3**), shows the major business entities involved in the process, their relationships and responsibilities. It is a high-level static representation of the main “things” (entities) involved in the E-Path reporting process, including a description of how these “things” (entities) are related.

A domain diagram also captures a business vocabulary. It presents terminology and concepts that appear in the process description, laying out definitions and meanings agreed on by the domain practitioners. A domain diagram provides a foundation for other modeling diagrams.¹¹

Figure 3. E-Path Reporting Domain Diagram



The Pathology Laboratory conducts an Observation (Lab test) to analyze a Specimen from a Patient and produces a Pathology Report. The Pathology Report contains zero, one, or more Coding Schemes (ICD-O, ICD-9, SNOMED), and consists of Reportable Data Items.

¹¹ Remove date

Reportability Criteria (Registry) and Submission Criteria (Lab) are applied to the Pathology Report. The Pathology Laboratory produces a Pathology Submission File that contains zero, one, or more pathology reports in the NAACCR Submission Format.¹²

The Central Registry receives the Pathology Submission File from the Pathology Laboratory using a Transmission Method that includes an Encryption Method and a Security Method. The Central Registry utilizes a Registry Information System that includes an E-Path sub-system and a Patients Database to process the Pathology Submission File. The Central Registry communicates with the Pathology Laboratory as needed, and the Pathology Laboratory responds to the Central Cancer Registry.

The E-Path Reporting Process Overview (Figure 4)

There are two **Key Actors/Participants** in the electronic reporting process:

- Central cancer registry (Registry)
- Pathology laboratory (Laboratory)

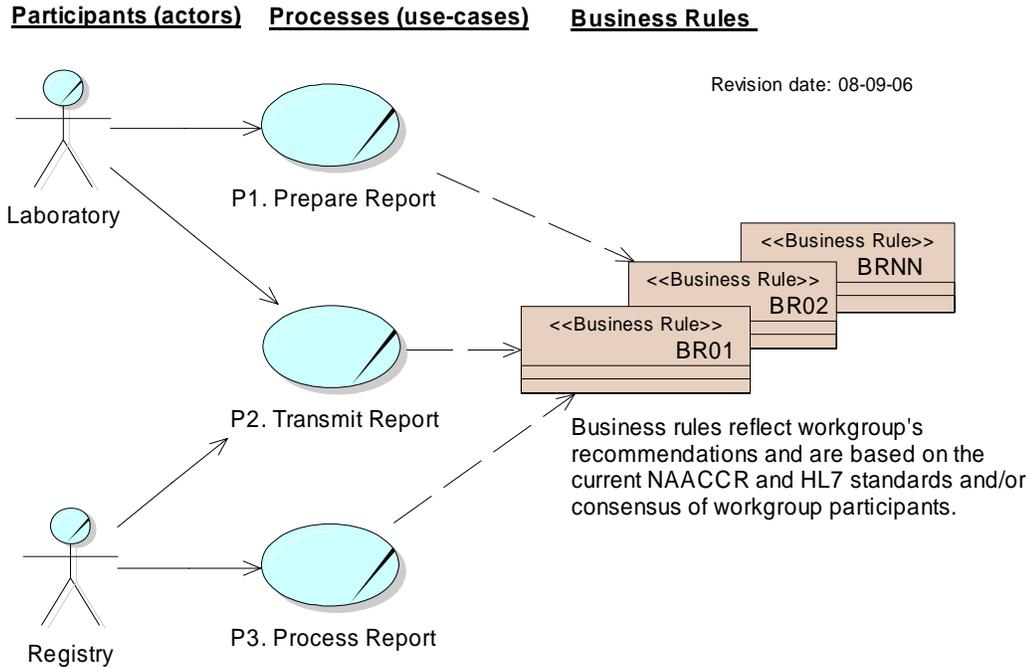
There are three main **Processes (Use cases)** involved in reporting pathology findings to the central registry:

- **Process 1 (P1): Prepare report.**
 - Key Actor(s): Laboratory
- **Process 2 (P2): Transmit report.**
 - Key Actor(s): Collaboration between Laboratory and Registry that includes Send and Receive components.
- **Process 3 (P3): Process Report.**
 - Key Actor(s): Registry

A supplementary/supporting process is described as a Business Precondition for Process 1. During the initial contact, the central registry conducts an assessment of the Laboratory, to identify areas of concern and barriers to implementation, and to determine that requirements by both the Registry and Laboratory can mutually be met.

¹²*NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 2.0.*

Figure 4. E-Path Reporting Process Overview



E-Path Processes

Introduction: For each Process (P1, P2, P3), a set of conditions called Business Preconditions must be met before the procedure can begin. Following the preconditions, the Process steps for the main or best-case scenario are laid out. The main scenario describes the steps required to achieve the best possible result. Each step has one or more related business rules, which include a set of agreed on criteria for accomplishing a task in the best possible manner.

There may be alternatives to the main scenario steps for a variety of reasons. The alternative steps are given in the Alternate Scenarios sections, using the same numbers as the main scenario tasks with alpha modifiers. The alternate scenarios should be used by registries as needed, when the consensus scenario is prohibited.

P1: Prepare Report

Business Preconditions

1. Laboratory completed assessment process and is ready for E-Path reporting to Registry. [BR01, BR02]

BR	Business Rule Statement	Purpose	Remarks/Links
01	Laboratory must successfully complete the assessment process to participate in E-Path reporting to a Registry.	To validate preparedness of Laboratory for E-Path reporting.	This rule assesses the laboratory's ability to participate in E-Path reporting. See other rules (below) for ensuring the accuracy and completeness of the actual reporting process.
02	Assessment must address the following components: <ul style="list-style-type: none"> • Laboratory Contact person for E-Path reporting • Verify Laboratory CLIA license number • Laboratory information system software and hardware • Record layout format: NAACCR HL7 Format <or> NAACCR ASCII Pipe Delimited Format • Communications process (protocol) • Schedule for reporting • Version of SNOMED 	Document E-Path system information, addressing all critical aspects of E-Path reporting.	<i>See Appendix A for sample Assessment Forms.</i> IF SNOMED version is based on ICD-O-2, laboratories need to upgrade to ICD-O-3 so that the current histology codes are used to select valid cancer reports (i.e., new hematopoietic codes).

Main Scenario

1. The process begins when the Pathology Report is signed in the laboratory as “completed.”
2. The laboratory either allocates the Pathology Report for submission to the Registry [BR05] or evaluates the eligibility of the Pathology Report for submission to the Registry [BR06, BR07]

Related Business Rules [BR03, BR04].

Discussion: The decision to require all pathology reports to be submitted to the registry, regardless of whether the diagnosis is reportable, or to require the laboratory to select the relevant reports to be submitted must be made by each registry. The NAACCR E-Path Subcommittee provides for both options in the main scenario as neither can be considered the consensus method. Registries must work with their pathology laboratories to make this decision according to:

- State laws/regulations/rules;
- The registry’s specific E-Path reporting objectives;
- The laboratory’s ability and willingness to perform the selection process;
- The registry’s ability to process large files of pathology reports.

BR	Business Rule Statement	Purpose	Remarks/Links
03	Time interval for reporting from a Pathology Laboratory to a Central Cancer Registry should be established based on the volume of reporting.	Provide a meaningful guideline for selecting a time interval for reporting.	Option: A daily reporting interval provides a simple QC method of verifying that the reporting process is active and functional. Note: Registry may process the reports in a different time interval than the receipt of reports from the laboratory.
04	The types of laboratory reports to be submitted must be agreed on by the Laboratory and the Registry.		Laboratory reports that are usually submitted include: Surgical pathology (histopathology report, flow cytometry); Autopsy; Hematology (bone marrow, peripheral smear); Cytology (Non-GYN and GYN); Review of Outside Slides; << other reports >>

2.a. The Laboratory allocates the Pathology Report for Submission (regardless of diagnosis)

BR	Business Rule Statement	Purpose	Remarks/Links
05	All final (completed, corrected/amended, supplemental) pathology reports must be submitted to the Registry. Preliminary and pending reports should not be submitted.	Achieve complete reporting of all pathology reports to allow the Registry to determine relevancy of each pathology finding.	

2.b. The Laboratory evaluates the eligibility of the Pathology Report for submission to the Registry (cancer diagnoses).

BR	Business Rule Statement	Purpose	Remarks/Links
06	Laboratory may submit all pathology reports to the Registry or may conduct a preliminary screening of Pathology Reports for relevancy to cancer registration, reducing the volume of reporting to the Registry.	Accommodate state-specific, privacy-related restrictions and/or restrictions related to the Registry's infrastructure.	Determined mutually by the Registry and the Laboratory.
07	Laboratories that are not sending 100% of the pathology reports must use eligibility criteria established by a recognized cancer registry source.	Ensure completeness of reporting.	<p><i>Automated</i> eligibility criteria include:</p> <ul style="list-style-type: none"> • NAACCR Search Term List at www.naacr.org SNOMED Codes: 80000 – 99999 • SEER ICD-O-3 Selection Criteria Others: ICD-9, ICD-10, ICD-O-3, Pathologist indicator. <p><i>Manual</i> determination of eligibility by Laboratory personnel (pathologist or other qualified personnel).</p>

2b1. Laboratory decides to report

Laboratory allocates Pathology Report for submission to the Registry.

Process continues from Main Scenario: Step 3.

2b2. Laboratory decides not to report.

Process ends.

3. Laboratory adds certain data items to the “completed” Pathology Report according to the requirements for reporting to the Registry. [BR08, BR09]

BR	Business Rule Statement	Purpose	Remarks/Links
08	All data items listed as “Required” (R) or “Required if available” (R*) must be included in the submitted reports to Registry. Reference: <i>NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting Version 2.0 (November 2005)</i>	Ensure the proper scope of reporting.	Modifications to the required data item list may be agreed on by the Registry and the Laboratory.
09	Data items submitted using laboratory specific codes must have a codes and definitions table provided to the Registry.	Ensure accurate processing of coded data items.	

4. Laboratory formats resulting in a Report according to NAACCR E-Path record layout standards. [BR10, BR11]

BR	Business Rule Statement	Purpose	Remarks/Links
10	One of the two NAACCR E-Path Layout Structures must be used: <ul style="list-style-type: none"> HL7 Layout (pipe delimited format) - <i>preferred</i> ASCII Layout (pipe delimited format) Reference: <i>NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting Version 2.0 (November 2005)</i>	Achieve uniformity and consistency.	Note: Given the nature of the HL7 message with multiple notations and segments, conformance testing is particularly important to ascertain that the format conforms to the required messaging standard. <i>Conformance software</i> can be used by the Laboratory to ensure that the message created conforms to the NAACCR specifications and by the Registry to verify conformance.
11	Only one message must be sent per pathology report. The report may include results from multiple specimens taken on the same occasion (for example a 12-point prostate biopsy would all be included within one HL7 message or ASCII record).		<i>See Appendix B for a discussion on this topic.</i>

Laboratory repeats Steps 2-4 for each Pathology Report, accumulating reports allocated for submission to the Registry, until the end of the selected time interval for reporting (e.g., a day, a week, a month). [BR03.]

5. Laboratory combines Pathology Reports into a single Pathology Submission File. Process ends.

Alternative Scenarios

5a. No reports found. [BR12]

Laboratory creates a “Nothing To Report” message for submission to the Registry.

BR	Business Rule Statement	Purpose	Remarks/Links
12	A message indicating that there are no pathology reports to be transmitted must be submitted if no reports are found.	Ensure prompt identification of transmission problems.	An empty message allows a simple QC method to be used to verify that the reporting process is active and functional. Lack of a report each day indicates that the transfer mechanism is malfunctioning.

5a. Laboratory submits Pathology Reports in real time one-by-one. [BR13]¹³

BR	Business Rule Statement	Purpose	Remarks/Links
13	“Single report” Pathology Submission File is created at the time each report is marked “Complete.”	Report pathology diagnosis rapidly.	Each message/file will only include one pathology report.

Process ends.

¹³Information on real time reporting can be found within the *NAACCR Real Time Reporting Task Force’s Report to the Board, Jan 2006* at http://www.naacr.org/filesystem/pdf/RTR%20Final_02-21-06_without%20tracking.pdf

P2: Transmit Report¹⁴

Business Preconditions

1. Pathology Submission File is ready for transmission from the Laboratory to the Registry.

Main scenario

1. Laboratory sends Pathology Submission File via a secure connection to the Registry. [BR14]

BR	Business Rule Statement	Purpose	Remarks/Links
14	File must be transmitted via secure connection (encrypted), using appropriate network protocols.	Ensure confidentiality.	Secure connection implies digital-cert and HTTPS. If the receiving server uses a digital-cert and HTTPS protocol, then the submission file or the individual laboratory reports record from the laboratory does not need to be encrypted. The receiving server's digital-cert and HTTPS protocol handles this.

¹⁴P2. *Transmit Report* is intended to provide a set of general technology-neutral functional requirements and is not a description of specific solution/design or implementation.

**2. Registry obtains Pathology Submission File and electronically enters it into the audit log.
[BR15]**

BR	Business Rule Statement	Purpose	Remarks/Links
15	A Registry audit log includes: <ul style="list-style-type: none"> • receipt date, • sending Laboratory, • message ID, • number of records, • accession number or other report ID number of reports included in the message/file. 	To maintain a record of files received for auditing and quality assurance.	Registry may allow a laboratory to access its own submission records in the Registry's E-Path audit log.

**3. The Registry sends acknowledgment to the Laboratory that the message/file was received.
[BR16]**

BR	Business Rule Statement	Purpose	Remarks/Links
16	Receipt acknowledgment includes: <ul style="list-style-type: none"> • Received date, • registry name, • message identifier, • number of records for each Laboratory transmission, • accession number or report ID number of reports included in the message/file. 	To ensure file has been received.	

4. The Laboratory receives acknowledgment that the registry received the message/file.

Process ends.

Alternative Scenarios

1a. Laboratory records Pathology Submission File on CD/Disk and mails it to Registry. [BR17, BR18]

BR	Business Rule Statement	Purpose	Remarks/Links
17	File must be encrypted.	Ensure confidentiality.	<p>Pretty Good Privacy is a well-known application for file-based encryption: http://www.pgp.com/</p> <p>GNU Privacy Guard (OpenPGP) also should be viable as an open source alternative following the OpenPGP standard. http://www.gnupg.org/</p> <p>PKZIP with password is not a sufficient encryption method.</p>
18	Large files may be compressed before upload using the DOS/Windows ZIP compression standard.	To decrease size of transmission files.	PKZIP or WINZIP are examples of programs that produce the correct compressed format.

3a. The Registry does not receive a file at the scheduled time. [BR19]

3.a.1 Registry contacts the Laboratory to determine where the transmission error occurred.

BR	Business Rule Statement	Purpose	Remarks/Links
19	Registry and Laboratory mutually determine time delay before a message/file is considered “not received.”	Ensure that errors in transmission are identified and resolved in a timely manner.	

4a. The Laboratory does not receive an acknowledgment from the Registry that the file is received. [BR20]

4.a.1 The Laboratory contacts Registry to determine where transmission error occurred.

BR	Business Rule Statement	Purpose	Remarks/Links
20	Registry and Laboratory mutually determine time delay before a message/file is considered “not received.”	Ensure that errors in transmission are identified and resolved in a timely manner.	Registry should acknowledge receipt of the file as soon as possible, even if further processing of the contents does not occur immediately.

P3: Process Report (at the Registry)

Business Preconditions

1. Pathology Submission File successfully transmitted from the Laboratory to the Registry.

Main Scenario

1. The process begins at the end of the selected time interval for processing of received Pathology Submission Files. [BR21]

BR	Business Rule Statement	Purpose	Remarks/Links
21	Registry determines time interval for processing file.		Depends on volume of reports coming in, as well as registry operations and resources available.

2. Registry validates that the message meets the HL7 requirements. [BR22]

BR	Business Rule Statement	Purpose	Remarks/Links
22	Registry ensures that the message structure is correct. HL7 message: Follows standards for NAACCR HL7 message. ASCII Pipe delimited file: File length and number of items are correct.	Ensures that the message/ file can be processed by the Registry's software.	Validation of the content within the record (required data items are included and are in the correct format) is performed at a later step. Open source tools for validating HL7 messages are available: HAPI - HL7 application programming interface; hl7api.sourceforge.net/

3. Registry validates each Pathology Report within the Pathology Submission File(s) for the presence of report number and report text. [BR 23]

BR	Business Rule Statement	Purpose	Remarks/Links
23	Pathology report number and report text must be present.	Pathology report number required to uniquely identify the pathology report to the laboratory if there are questions. Text required to identify relevant reports.	Validating that the text is present at this step allows registries to check for relevancy/reportability before time and resources are spent to validate the contents of non-reportable reports.

4. Registry verifies that the Pathology Report is *not* a duplicate report and does *not* contain duplicate sections within the report. [BR24, BR25]

BR	Business Rule Statement	Purpose	Remarks/Links
24	Specific data to identify the pathology report is added to a tracking table.	Identifies duplicate reports for special handling.	Data items to be included in the Pathology Report Number tracking table: Laboratory, specimen date, pathology report number, received date.
25	A duplicate is identified by an incoming report having the same Pathology Report Number (and specimen ID number if appropriate) as a previously submitted report.		A duplicate Pathology Report can emerge because of a Laboratory-initiated update or correction (supplemental report, addendum, etc.) or the Registry requested additional information (step 2a1). <i>See Chapter 6 for a discussion on duplicates.</i>

5. Registry validates each Pathology Report within the Pathology Submission File(s) for relevancy to cancer registration.¹⁵ [BR26]

BR	Business Rule statement	Purpose	Remarks/Links
26	A Registrar must review reports designated as “relevant” by automated eligibility criteria to make a final decision regarding report’s relevancy (reportability).	Ensure completeness of reporting	<i>Automated</i> eligibility criteria include: <ul style="list-style-type: none"> • NAACCR Search Term List at www.naacr.org • SNOMED CT Codes: 80000 – 99999 • SEER ICD-O-3 Selection Criteria Manual determination of eligibility by a Registrar.

¹⁵There may be a wide variation in the percentage of relevant reports processed by a laboratory, dependent on its type and specialty. The Registry should evaluate the percentage of relevant reports to ensure it is within the appropriate range for that laboratory type.

6. Registry validates the Pathology Report for completeness to ensure that a minimum set of required data items is present; and for accuracy, to ensure that correct/valid values are present. [BR08, BR09, BR27]

BR	Business Rule Statement	Purpose	Remarks/Links
08	All data items listed as “Required” (R) or “Required if available” (R*) must be included in the submitted reports to the Registry. Reference: <i>NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 2.0 (November 2005)</i>	Ensure the proper scope of reporting.	Modifications to the required data item list may be agreed on by the Registry and the Laboratory.
09	Data items submitted using laboratory specific codes must have a codes and definitions table provided to the Registry.	Ensure accurate processing of coded data items.	
27	Data item values must be converted according to NAACCR and registry specific standards.	Ensure accurate processing of coded data items.	

7. Registry enters the Pathology Report into the Registry Information System.

Process ends.

Alternative Scenarios

1a. The process begins when the Registry receives the Pathology Submission File from the Laboratory (real-time processing).

Note: Real-time processing may apply to:

- (a) Single Pathology Report (submitted in a “real time” within a single Pathology Submission File);
- (b) Single Pathology Submission File (submitted based on time interval for reporting from the Laboratory, which contains zero, or one, or many Pathology Reports).

In both cases, the Registry is dealing with a single Pathology Submission File.

Process continues from the Main Scenario: Step 2 (P3 – Process Report).

3a. Pathology Report is incomplete – report number and/or report text are missing.

- 2a1. Registry stores the report and requests missing information from the Laboratory.
- 2a2. Registry maintains a tracking system of requests for resubmission.
- 2a2. Laboratory resubmits the entire Pathology Report with missing information.

Process will begin at P1. Prepare report.

4a. Pathology Report is duplicate (or supplemental, or addendum).

- 2b1. Registry compares the duplicate Pathology Report with the original pathology report.
- 2b2a. Registry identifies new/different information on the duplicate pathology report.
Registry updates the record with new/updated information.
Registry appends the duplicate report to the original report and stores it in the database.
- 2b2b. Registry determines that the duplicate report has no additional/improved information.
Registry discards the duplicate report.

Process ends.

5a. Pathology Report is NOT relevant for cancer registration. [BR28]

5.a.1 The pathology report is discarded.

Note: See Chapter 6: Quality Control/Quality Assurance for a discussion on this topic.

BR	Business Rule Statement	Purpose	Remarks/Links
28	Pathology reports that are not relevant for cancer are discarded.	Ensures that non-relevant reports are not available to the Registry.	This is a “best practice.” Registries are allowed access to review non-relevant reports to ensure that all relevant reports have been identified; however, no record of non-relevant reports should be maintained in the Registry.

Process ends.

6a. Pathology Report is incomplete – some of the required data items are missing.

- 6a1. Registry requests missing information from the Laboratory.
- 6a2. Laboratory resubmits the entire Pathology Report with missing information within the time frame agreed on.

Process will begin at P1. Prepare report.

Note: See Chapter 6: Quality Control/Quality Assurance for a discussion on this topic.

Process Diagrams

Figure 5. Process diagram for P1. Prepare report.

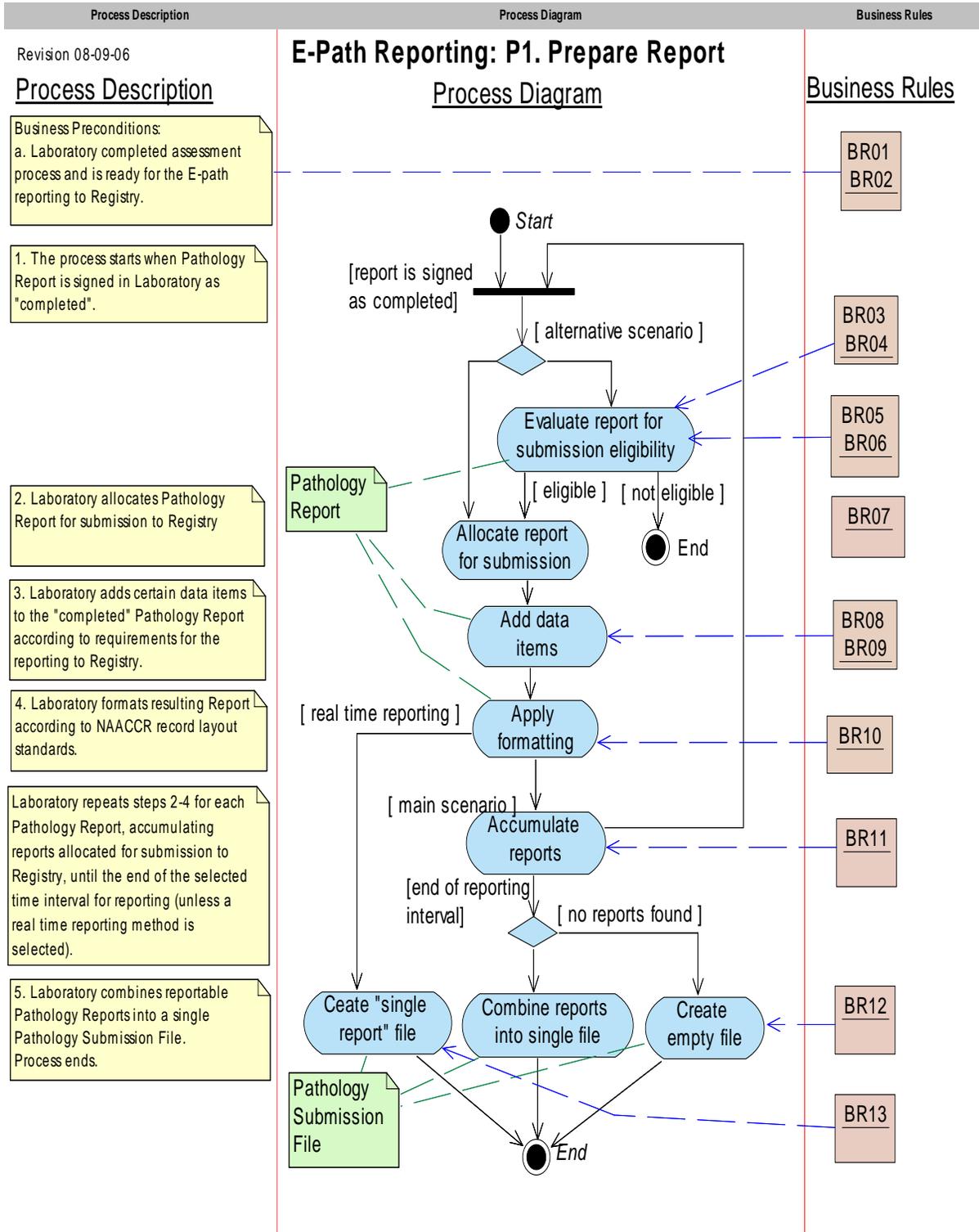
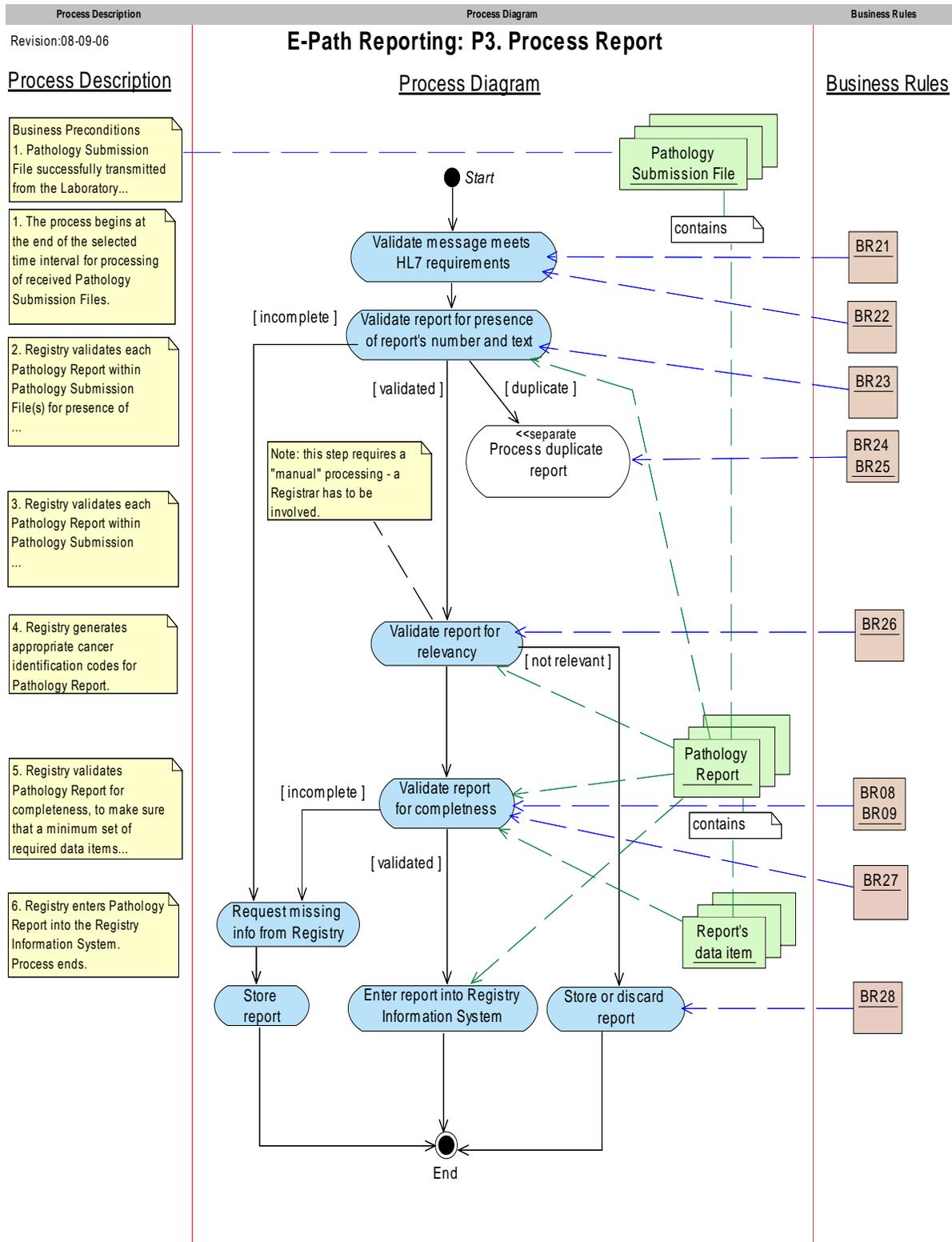


Figure 6. Process diagram for P3. Process report.



6 Quality Control/Quality Assurance of the Electronic Pathology Reporting Process

Completeness of Reporting

The registry needs to ensure that all of the reports that they are expecting are submitted (final reports, addendums, supplemental, types of reports such as histopathology, cytology, bone marrow) in addition to verifying that the selection criteria are accurate. Methods to ensure completeness of reporting also will depend on whether a registry is receiving all pathology reports, regardless of relevance to cancer, or if the laboratory is performing screening to identify and submit only the relevant reports. As mentioned in Business Rule 07 (Main Scenario, Step 2), the screening could be computer screening using automated search criteria or by manual selection by laboratory personnel. To assist in monitoring, a table of pathology report numbers submitted for each facility should be maintained by the registry.

All reports received regardless of relevancy:

On a regular basis, the registry identifies missing pathology accession numbers within a sequence and provides a list to the pathology laboratory to review and resolve. The registry will need to routinely evaluate whether addendum and supplemental reports are being submitted by the laboratory.

Relevant pathology reports received:

Relevant reports may be missed by laboratories performing the screening for a variety of reasons, including:

- Amended/supplemental reports are not re-screened for relevant diagnoses;
- A pathology report may not get coded with SNOMED-CT and/or ICD codes;
- The selection method may restrict the dates of reports under review such that reports completed outside the routine completion timeframe may be missed.

A registry will need to implement a quality control procedure to ensure that these and other situations are not causing relevant reports to be missed.

Duplicate Reports

A pathology report may be sent to the registry more than once. They are called “duplicate reports” because the report has been identified as having been previously submitted by registry criteria. A “duplicate report” may mean different things to different registries. A pathology report may be resubmitted for a variety of reasons, including:

- Laboratory corrects an item on the original report;
- Laboratory adds (amends) information to the original report;
- Laboratory resends the original report with no changes (true duplicate).

A second type of “duplicate report” can occur when the E-Path transmission method itself causes a duplicate report by including portions of the report within the message more than once. Identification and processing of these reports is addressed at the cancer registry through certain automated processes and manual review. A large test file of all types of reports to be included in E-Path reporting can help identify this problem and allow it to be corrected prior to implementation.

The registry must develop specific procedures to identify and process reports that have been submitted more than once. Identification may be performed by software to identify duplicate pathology report accession numbers; however, the evaluation and correct processing of the second report must be performed by the registrar to accurately determine whether new information has been added or pertinent information has been modified. It is helpful during the evaluation and implementation phase to discuss with the laboratory the scenarios that may lead to a report being resent to develop the best methods for identification and processing.

Missing Data Items Within a Pathology Report

The list of data items required for a pathology report submission is shorter than that required for a hospital registry submission. The NAACCR Standards Volume V¹⁶ lists the data items that should be reported on an electronic pathology report record; however, a registry will need to determine which of these data items must actually be present to accurately process the report according to local standards within the registry's area. In some situations, a required data item may be missing from a pathology report and still be able to be used by the registry. It may be acceptable for an E-Path report to have missing required data items as other data sources may contribute the missing data item value to complete the full tumor/cancer record within the central registry. For example, although social security number is required for an E-Path submission, it may be acceptable to allow the data to remain missing as the social security number will most likely be submitted by another data source.

If the pathology report does not link with an existing record, the registry may choose to follow back to the relevant health care provider/clinician to obtain the required information (such as sex, race, date of birth, social security number). This method requires that a database of physicians and their clinic address be maintained by the registry. Currently, this is a labor-intensive process. The proposed implementation of a national provider information number (NPI) will greatly improve the accuracy and efficiency of the follow-back process.

Patient address is one of the most frequently absent data items, and one which affects reportability. A registry should develop policies and procedures for confirming residency of those patients whose pathology report did not match with an existing record within the registry. This helps to exclude those patients that do not fall within the registry's population area. Registries with a non-transient population may choose to consider these patients as residents of the state, with an unknown specific location, and only follow-up on those patients whose reports were provided by a laboratory close to the state's border. E-Path reports from large reference laboratories, which frequently perform tests for clinicians and facilities outside of the laboratory's business location, may need to be scrutinized closely for residency.

¹⁶NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 2.0 (November 2005)

Appendix A: Approach for Analyzing Processes and Developing Recommendations for E-Path Reporting

Business engineering, facilitation, and Web-conferencing techniques were employed to analyze E-Path reporting processes and to develop the workgroup's recommendations.¹⁷

The Workgroup used a pragmatic results-oriented business modeling approach which proved to be effective for modeling of cancer registration and immunization registration operations over the past years. Employed modeling notation and techniques are simple enough for the correct intuitive interpretation by a non-technical person.

- Standard diagrams of the Unified Modeling Language (UML) were applied for the analysis and the incremental, consensus-based modeling and recommendations development process.
- Preparatory “off-line” work (analysis of processes and development of modeling components) was performed by a Business Analyst and a small group of Subject Matter Experts (SMEs). During subsequent “on-line” teleconferences, a large workgroup of SMEs have been reviewing these components, providing inputs and formulating consensus-based recommendations.
- The following business modeling techniques were employed: use-case modeling – for a textual step-by-step description of the process; business rules – for a textual description of restrictions, rules, and operational policies; activity diagram – for the visual presentation of the process and process-related parties collaborations; and domain diagram – for the visual presentation of entities involved in the process and their relationships. Also, facilitation techniques were used to conduct a modeling work during the teleconferences.
- The business model (the **Expected Product**) that resulted includes the following components: process description (textual and visual/diagrammatic), a table of business rules (each business rule is related to a proper area within a process description), and domain diagram (entities involved and their relationships).
- The Workgroup used the CDC Web conferencing tool that allowed for the visual presentation of materials in real time during the teleconferences.

¹⁷E-Path Reporting Process, E-Path Reporting Process Workgroup, Version 0.27, March 16, 2005 [results of preparatory work for this document – Procedural Guidelines for Electronic Pathology Reporting]

Appendix B: Sample Laboratory Assessment Templates/Questionnaires for Electronic Pathology Reporting

Artificial Intelligence in Medicine, Inc.
New York Department of Health Cancer Registry
Florida Cancer Data Service

Artificial Intelligence in Medicine, Inc.



Reporting Site Information Checklist

ALL RESPONSES SHALL BE KEPT CONFIDENTIAL

Revision 1.2

Please Take Note....

This form is a screen-fillable Adobe Acrobat PDF Form. It may be completed on the screen before being printed. If you are using the free Acrobat Reader software, YOU CANNOT SAVE THIS FORM WITH THE FILLED-IN DATA. You will need to use the purchased version of Adobe Acrobat in order to do this. The free reader software will, however, allow you to save the blank form itself for use at a later time.

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e path Reporting Site Information Checklist

This information checklist is supplied to pathology laboratories for the purpose of gathering site information pursuant to the implementation of electronic cancer case-finding and pathology data gathering for local, regional and state cancer registries (referred to as the E-Path system). This information will be used only for planning the implementation of the software. If you require additional writing space please use the comments area provided on the last page of this document.

Section 1: Site Information	
1) Name of Laboratory/Hospital:	
2) Address:	
Section 2: Laboratory Information System (LIS)	
3) Is pathology reporting computerized?	<input type="checkbox"/> Yes (go to Q. 6) <input type="checkbox"/> No (go to Q. 4)
4) Do you word-process pathology reports?	<input type="checkbox"/> Yes (go to Q. 5) <input type="checkbox"/> No (go to Section 3)
5) Type of word-processor used:	<input type="checkbox"/> MS Word <input type="checkbox"/> WordPerfect <input type="checkbox"/> Other: _____ Version: _____ Platform: _____ (go to Q. 9)
6) Type and Version of LIS:	
7) Type and Version of database used by LIS:	<input type="checkbox"/> Oracle <input type="checkbox"/> Sybase <input type="checkbox"/> MS SQL Server <input type="checkbox"/> Informix <input type="checkbox"/> Paradox <input type="checkbox"/> MS Access <input type="checkbox"/> Mumps <input type="checkbox"/> Pick/Universe <input type="checkbox"/> DB2 <input type="checkbox"/> Other: _____ Version: _____ Platform: _____
8) Can the LIS write out ASCII delimited files?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9) Do you have an existing HL7 integration engine?	<input type="checkbox"/> Yes <input type="checkbox"/> No (go to Q. 12)
10) Type and Version of Integration Engine:	

11) Do you currently report pathology in HL7 format?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12) Does the local network support TCP/IP?	<input type="checkbox"/> Yes	<input type="checkbox"/> No (go to Section 3)
13) Are IP addresses assigned statically or dynamically (DHCP)?	<input type="checkbox"/> Static	<input type="checkbox"/> Dynamic
Section 3: Internet Access		
14) Type of Internet Access:	<input type="checkbox"/> Via proxy/Firewall <input type="checkbox"/> None (go to Section 4)	<input type="checkbox"/> Dial-up
15) Access bandwidth:	<input type="checkbox"/> Less than 56 KBPS <input type="checkbox"/> more than 128 KBPS	<input type="checkbox"/> 56-128 KBPS
16) Do you have a firewall?	<input type="checkbox"/> Yes	<input type="checkbox"/> No (go to Section 4)
17) Type and Version of Firewall: _____		
Section 4: Pathology Reporting		
18) Approximate annual volume of pathology reporting.		
19) Is each report identified by a unique accession number or report ID?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
20) Do the report identifiers re-cycle yearly?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
21) Is the narrative text of the report divided into sections?	<input type="checkbox"/> Yes	<input type="checkbox"/> No (go to Q 23)
22) Please check all sections that may appear on a report.	<input type="checkbox"/> Clinical History <input type="checkbox"/> Gross Pathology <input type="checkbox"/> Formal Diagnosis <input type="checkbox"/> Comments <input type="checkbox"/> Other _____	<input type="checkbox"/> Nature of Specimens <input type="checkbox"/> Microscopic <input type="checkbox"/> Staging <input type="checkbox"/> Addenda
23) Please check all patient demographic fields that may appear on a report.	<input type="checkbox"/> Surname <input type="checkbox"/> Date of Birth <input type="checkbox"/> Unique Chart/MRN <input type="checkbox"/> Insurance No.	<input type="checkbox"/> Name <input type="checkbox"/> Sex <input type="checkbox"/> Insurer <input type="checkbox"/> Home Address

ALL RESPONSES SHALL BE KEPT CONFIDENTIAL

New York State Department of Health Cancer Registry Pathology Laboratory Questionnaire

Please answer each question by checking the correct response(s) or entering the information in the spaces provided. If you have any questions, please contact the NYSCR at 518-474-0971.

I. Laboratory Information: CLIA # : _____ PFI #: _____

Name of Laboratory: _____ Address: _____
 Name of Director: _____
 Telephone Number: _____
 E-mail: _____

II. Client Information:

- A. What types of providers does your laboratory serve?
- | | | |
|----------------------------------|------------------------------|-----------------------------|
| Clinics | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Diagnostic and Treatment Centers | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Hospitals | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Private Physician Practices | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Other _____ | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- B. What medical specialty/services do your clients provide?
- | | | |
|------------------------------------|------------------------------|-----------------------------|
| Cosmetic Surgery | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Dermatology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Endocrinology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Gastroenterology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Gynecology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Internal Medicine | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Infectious Diseases | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Neurology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Plastic and Reconstructive Surgery | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Hematology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Oncology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Otolaryngology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Transplantation | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Urology | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Other _____ | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- C. If possible, please enclose a listing of your clients with this form (provide name, address, and telephone number). It will help us document newly diagnosed cancer cases in New York State.

III. Specimen Information:

A. What type of pathology specimen do you process at your laboratory? Please check all that apply. If you **do not** process pathology specimens at your laboratory, please tell us what you do?

Type Melanoma	Average Number Per Year	Avg. # of Total Cancer Dx Per Year	Avg. # of Reportable* Cancer Dx Per Year	Avg. # of Dx per Year
Anatomic () _____	_____	_____	_____	
Autopsy () _____	_____	_____	_____	
Bone Marrow () _____	_____	_____	_____	
Cytology () _____	_____	_____	_____	
GYN Cytology () _____	_____	_____	_____	
Other _____ () _____	_____	_____	_____	
Other _____ () _____	_____	_____	_____	_____

***Please see separate page, Laboratory Reporting of Tumors, describing reportable and non-reportable cancers.**

B. *Is each specimen assigned a number?* () Yes () No

If Yes, are the specimen types differentiated within the specimen number? () Yes () No
(For example, specimen numbers beginning with S are surgical pathology reports, C are cytology reports, etc.)

C. What information is maintained at your laboratory? Please check all that apply.

Item	Maintained on Paper	Maintained Electronically
Patient Name	()	()
Patient SSN	()	()
Patient Sex	()	()
Patient DOB	()	()
Patient Age	()	()
Patient Race	()	()
Patient Address	()	()
Ordering Client Name	()	()
Ordering Client Telephone Number	()	()
Ordering Client Address	()	()
Ordering Client License Number	()	()

Laboratory CLIA Number	()	()
Reporting Pathologist Name	()	()
Reporting Pathologist License Number	()	()
Nature of Specimen	()	()
Specimen Number	()	()
Specimen Date	()	()
Primary Site Text	()	()
Laterality	()	()
Clinical History	()	()
Gross Pathology Text	()	()
Microscopic Pathology Text	()	()
Pathology Comment Section	()	()
Histology Text	()	()
Final Dx Text	()	()
Supplemental Reports/Addenda	()	()
ICD-CM Codes	()	()
CPT Codes	()	()
SNOMED Codes	()	()

IV. Electronic Data System Functions:

- A. What type of software package do you use for pathology reports? _____
- B. Is your laboratory able to transmit pathology reports in the HL-7 format? () Yes () No

V. Current Status of Laboratory Reporting of Tumors:

- A. At present, do you perform laboratory reporting to NYSCR through the tumor registry/records dept?
 () YES () NO Other: _____
- B. If YES, would you prefer to continue your laboratory reporting to NYSCR through current means ? () Yes () No
 If NO, would you prefer to begin laboratory reporting of tumors to NYSCR through ECLRS? () Yes () No
 Other: _____

VI. Contact Information:

- A. Whom should we contact to discuss the details of your laboratory reporting to NYSCR?
 Name: _____
 Title/Credentials: _____
 Phone Number: _____
 E-mail: _____
- B. Survey Completed By:
 Name: _____
 Title/Credentials: _____
 Date & Signature: _____

*****Thank You for Your Cooperation! *****



Clinical Laboratory Cancer Identification Program
Clinical Laboratory Information Verification Form
October 1, 2002

FCDS is looking forward to working with each Florida clinical pathology laboratory under the new FCDS/DOH Clinical Laboratory Cancer Identification Program (CLIP).

Thank you for taking the time to complete the attached Clinical Laboratory Information Verification Form. This information will be used to verify FCDS administrative contact and mail file information for each clinical laboratory in Florida as well as to provide useful planning information for FCDS as to the status of each lab's information systems and specimen documentation procedures.

Please make any changes or additions in the space provided then fax the completed form to FCDS at (305) 243-4871 or mail to FCDS at the following address: Florida Cancer Data System, PO Box 016960 (D4-11), Miami, FL 33101.

Please complete and return this form to FCDS on or before November 1, 2002.

Questions should be directed to Mayra Alvarez at (305) 243-4603 or 1-800-906-3034.

Thank You.

FCDS

**Clinical Laboratory Information Verification Form
FCDS Facility Number**

Section I - Laboratory Information:

The Florida Agency for Healthcare Administration (AHCA) files indicate that the following mailing address and contact information is correct and current for this laboratory. Please make any changes as necessary in the space provided.

CLIA Number:

Laboratory Name:

Laboratory Address:

Laboratory Telephone Number:

Laboratory Fax Number:

Administrator's Name:

Owner's Name:

Other Contact Name:

Section II – Laboratory Client Information:

What type(s) of medical facilities/practitioners does your laboratory serve?

Hospitals	___ Yes ___ No
Ambulatory Care Centers/Clinics	___ Yes ___ No
Private Physicians	___ Yes ___ No

Section III – Specimen Collection Information:

A. What type(s) of pathology specimens does this laboratory process?

Type	Yes (Y) No (N)	Average # per year	Average # with cancer diagnosis per year
Anatomic			
Cytology			
Bone marrow			
Autopsies			
Other			

B. What information is electronically maintained in the surgical pathology record?

Data Item	Data Are Collected? Y/N	Maintained in Electronic Record Y/N	Maintained in Paper Record Y/N
Ordering Client/ Attending MD Name			
Ordering Client/ Attending MD Address			
Ordering Client/ Attending MD Phone			
Reporting Pathologist Name			
Patient Last Name			
Patient First Name			
Patient Address			
Patient Date of Birth			
Patient Sex			
Patient SSN			
Surgical Path Slide #			
Date of Specimen Collection			
Text - Clinical History			
Text - Nature of Specimen			
Text - Diagnosis			
Text - GrossPathology			
Text - MicroPathology			
Text – Final Diagnosis			
Text - Comments			
SNOMED Code(s)			
ICD-9 Dx Code(s)			
CPT Code(s)			

Section IV - Laboratory Information Systems:

- A. Laboratory follows the College of American Pathologists' (CAP) Cancer Protocols to identify and describe tumor specimens? ___Yes ___No
- B. Surgical pathology reports are maintained electronically? ___Yes ___No
- C. Electronic surgical pathology reports are maintained in a word processing type of system? ___Yes ___No

Vendor/Provider Name: _____

D. Electronic surgical pathology reports are maintained in a database type of system?

___Yes ___No

Vendor/Provider Name: _____

Survey Completed By:

Name: _____

Title: _____

Signature: _____

Date: _____

Please complete and return this form to the Florida Cancer Data System on or before 11/01/2002.

You may fax the completed form to (305) 243-4871 or mail the completed form to FCDS at the following address: Florida Cancer Data System, PO Box 016960 (D4-11), Miami, FL 33101.

Thank You.

Appendix C: Supporting Documentation for Business Rules

Discussion: The contents of a pathology report frequently include information about multiple specimens/tissue samples, with each being divided into multiple sections for microscopic review and diagnosis. All information that is included within one pathology report, regardless of the number of specimens, number of slides, or number of sections, must be reported in one HL7 message. Information on how to compose a message for these reports is outlined below, using a scenario where a prostate biopsy provided 12 separate tissue specimens.

Process P1: Prepare Report, Step 4

Business Rule 10: Only one message must be sent per pathology report.

The report may include results from multiple specimens taken on the same occasion (for example, a 12-point prostate biopsy would all be included within one HL7 message or ASCII record).

The message must have one, unique number that identifies:

- The **request** (i.e., per path report, one `ObrObservationRequestKey`),
- one unique **patient identifier number** for all specimens (`PidPatientKey`),
- one unique **ObrAccessionNumber**,
- one unique **MessageMasterKey**.

The **different specimens** within the path report are identified by the **ObxObservationSubID** numbers. The sections pertaining to each one of the specimens (Nature of Specimen, Gross Path, Final Dx, etc.) are identified by corresponding LOINC codes, and the text descriptions of those LOINC codes.

There can be multiples of the following:

ObxSetID (for example 1 through 37, where you have 12 specimens (the example is a 12-point prostate biopsy), where for each specimen you have a repetition of 3x-covering the following, by using LOINC codes: Nature of Specimen, Gross Pathology, Final Dx.

Therefore, $12 \times 3 = 36$, and $+1 = 37$, where:

ObxSetID (goes from 1 through 37), where the last one (the 37th `ObxSetID`) is for Comment Section.

ObxValueType= TX (is the same for all 12 specimens, including the Comments)**ObxLoincCode**= 22633-2, or 22634-0, or 22637-3 (these three are repeated for each specimen), and 22638-1 (included only once, at the end).

ObxLoincDescription= Nature of Specimen, or Gross Pathology, or Final Dx,(these three are repeated for each specimen), and Comment Section (included only once).

ObxObservationSubID= (these come in multiples of three in this example – there can be multiples of more than three, depends on how many sections per specimen are being sent):

- 1 Nature of Specimen for Specimen 1
- 1 Gross Path for Specimen 1
- 1 Final Dx for Specimen 1
- 2 Nature of Specimen for Specimen 2
- 2 Gross Path for Specimen 2
- 2 Final Dx for Specimen 2
- 3 Nature of Specimen for Specimen 3

3 Gross Path for Specimen 3

3 Final Dx for Specimen 3

etc. until the very last one which is ObxObservationSubID=37 (for theComment Section)

Example HL7 Message

```
MSH|^~\&|HL7|SPEEDY
LAB^TESTCLIA^CLIA|ECLRS||20050815142912||ORU^R01|20050815142912|P|2.3.1|||||
||2.0 <CR>
PID|1||123-45678^^^^^SPEEDY
LAB&12D345678&CLIA|Doe^John||19330303|M|W|1 Hard Rock Avenue^^Windy
Heights^NY^12237|||||||<CR>
ORC|RE|||||||||Office of Dr. Hawkeye Sharp|Medical Center at
Old Oak Mall, 22 Green Lane, Suite 222^^Green
Village^NY^12237|^^^^^518^4445566|Medical Center at Old Oak Mall, 22 Geen
Lane, Suite 222^^Green
Village^NY^12237|<CR>
OBR|1||123-45678|22049-1^cancer identification
battery^LN||20050525|||||20050525|A44678^Hawkeye^Sharp|^^^^^518^8877665||
|123-45678|||||F|||||&Quick&Glance&&Dr.|<CR>
OBX|1|TX|22633-2^Nature of Specimen^LN|1|LLB|||||F|<CR>
OBX|2|TX|22634-0^Gross Pathology^LN|1|LLB: Media: Formalin,Specimen: 1
Core(s),Color: Tan White ,Length: 1.6 cm.|||||F|
OBX|3|TX|22637-3^Final Diagnosis^LN|1|LLB: Adenocarcinoma, Gleason's
Score 3+4=7 , involving approximately 70% of the tissue
cores.|||||F|<CR>
OBX|4|TX|22633-2^Nature of Specimen^LN|2|RLB|||||F|<CR>
OBX|5|TX|22634-0^Gross Pathology^LN|2|RLB: Media: Formalin,Specimen: 1
Core(s),Color: Tan White ,Length: 1.0 cm.|||||F|<CR>
OBX|6|TX|22637-3^Final Diagnosis^LN|2|RLB: Benign prostatic
tissue.|||||F|<CR>
OBX|7|TX|22633-2^Nature of Specimen^LN|3|RLM|||||F|<CR>
OBX|8|TX|22634-0^Gross Pathology^LN|3|RLM: Media: Formalin,Specimen: 1
Core(s),Color: Tan White ,Length: 1.1 cm.|||||F|<CR>
OBX|9|TX|22637-3^Final Diagnosis^LN|3|RLM: Benign prostatic
tissue.|||||F|<CR>
OBX|10|TX|22633-2^Nature of Specimen^LN|4|RLA|||||F|<CR>
OBX|11|TX|22634-0^Gross Pathology^LN|4|RLA: Media: Formalin,Specimen: 1
Core(s),Color: Tan White ,Length: 0.9 cm.|||||F|<CR>
OBX|12|TX|22637-3^Final Diagnosis^LN|4|RLA: Benign prostatic
tissue.|||||F|<CR>
OBX|13|TX|22633-2^Nature of Specimen^LN|5|LLM|||||F|<CR>
OBX|14|TX|22634-0^Gross Pathology^LN|5|LLM: Media: Formalin,Specimen: 1
Core(s),Color: Tan White ,Length: 1.5 cm.|||||F|<CR>
OBX|15|TX|22637-3^Final Diagnosis^LN|5|LLM: Adenocarcinoma, Gleason's
Score 3+4=7, involving approximately 50% of the tissue
cores.|||||F|<CR>
OBX|16|TX|22633-2^Nature of Specimen^LN|6|LLA|||||F|<CR>
OBX|17|TX|22634-0^Gross Pathology^LN|6|LLA: Media: Formalin,Specimen: 1
Core(s),Color: Tan White ,Length: 1.3 cm.|||||F|<CR>
```

OBX|18|TX|22637-3^Final Diagnosis^LN|6|LLA: Benign prostatic tissue with focal atrophy, and mild acute and chronic inflammation.|||||F|<CR>
OBX|19|TX|22633-2^Nature of Specimen^LN|7|LB:|||||F|<CR>
OBX|20|TX|22634-0^Gross Pathology^LN|7|LB: Media: Formalin,Specimen: 1 Core(s), Color: Tan White, Length: 1.3 cm.|||||F|<CR>
OBX|21|TX|22637-3^Final Diagnosis^LN|7|LB: Benign prostatic tissue.|||||F|<CR>
OBX|22|TX|22633-2^Nature of Specimen^LN|8|LM:|||||F|<CR>
OBX|23|TX|22634-0^Gross Pathology^LN|8|LM: Media: Formalin,Specimen: 1 Core(s), Color: Tan White, Length: 1.7 cm.|||||F|<CR>
OBX|24|TX|22637-3^Final Diagnosis^LN|8|LM: Adenocarcinoma, Gleason's Score 4+3=7 , involving approximately 70% of the tissue cores.|||||F|<CR>
OBX|25|TX|22633-2^Nature of Specimen^LN|9|LA:|||||F|<CR>
OBX|26|TX|22634-0^Gross Pathology^LN|9|LA: Media: Formalin,Specimen: 1 Core(s), Color: Tan White, Length: 1.1 cm.|||||F|<CR>
OBX|27|TX|22637-3^Final Diagnosis^LN|9|LA: Benign prostatic tissue with atrophy and chronic inflammation.|||||F|<CR>
OBX|28|TX|22633-2^Nature of Specimen^LN|10|RB:|||||F|<CR>
OBX|29|TX|22634-0^Gross Pathology^LN|10|RB: Media: Formalin,Specimen: 1 Core(s), Color: Tan White, Length: 1.1 cm.|||||F|<CR>
OBX|30|TX|22637-3^Final Diagnosis^LN|10|RB: Benign prostatic tissue.|||||F|<CR>
OBX|31|TX|22633-2^Nature of Specimen^LN|11|RM:|||||F|<CR>
OBX|32|TX|22634-0^Gross Pathology^LN|11|RM: Media: Formalin,Specimen: 1 Core(s), Color: Tan White, Length: 1.6 cm.|||||F|<CR>
OBX|33|TX|22637-3^Final Diagnosis^LN|11|RM: Benign prostatic tissue.|||||F|<CR>
OBX|34|TX|22633-2^Nature of Specimen^LN|12|RA:|||||F|<CR>
OBX|35|TX|22634-0^Gross Pathology^LN|12|RA: Media: Formalin,Specimen: 1 Core(s), Color: Tan White, Length: 1.2 cm.|||||F|<CR>
OBX|36|TX|22637-3^Final Diagnosis^LN|12|RA: Benign prostatic tissue.|||||F|<CR>
OBX|37|TX|22638-1^Comment Section^LN|| Case was reviewed in conference.|||||F|<CR>

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<http://www.naaccr.org/filesystem/pdf/davidandwarren.pdf>

Glossary¹⁸

ASCII^{(1) 19}

The common denominator of all modern computer character sets is the American Standard Code for Information Interchange (ASCII) which was published in 1968 as ANSI X3.4

Case-Finding⁽²⁾

The systematic process of identifying all cases of a disease eligible to be included in the registry database for a defined population, such as patients of a hospital or residents of a state. It is also called case ascertainment. *Active c.* is performed by registry personnel who screen the source documents themselves. *Combination c.* is the use of active review by the registrar for critical casefinding sources and passive review of other sources as provided by reliable participants in other departments. *Passive c.* is performed by other health care professionals whom the registry relies on to notify the registrar of potentially reportable cases; also called self-reporting.

Classification System⁽³⁾

A system for grouping similar diseases and procedures and organizing related information for easy retrieval; a system for assigning numeric or alphanumeric code numbers to represent specific diseases and/or procedures. Example: ICD-9, CPT, ICD-O-3.

Data Capture⁽³⁾

The process of recording healthcare-related data in a health record system or database.

Data Dictionary⁽³⁾

A descriptive list of the data elements to be collected in an information system or database; the purpose of the list is to ensure consistency of usage.

Data Element⁽²⁾

A fact, category of information, or specific item of information; also called a field. Sex, race, name, and primary site are examples of data elements.

Demographic information⁽³⁾

Information used to identify an individual such as name, address, gender, age, and other information specifically linked to a specific patient.

EDI⁽¹⁾ Electronic Data Interchange.

E-Path⁽¹⁾

Electronic Pathology – A means to automatically encode and identify reportable pathology in electronic or related databases and transmit these in digital format to a registry or similar repository.

¹⁸Glossary was compiled from the NPCR-MERP Program and from Artificial Intelligence in Medicine (AIM) documentation.

¹⁹Parenthetical numbers indicate the Definition source which is listed in full at the end of the Glossary.

Electronic Reporting (eReporting)⁽⁴⁾

eReporting is the automated, unattended (by humans) transmission of data between two or more parties.

Flat File⁽¹⁾

An ASCII File representing records from a database. The data are all in ASCII characters, and individual elements can be delimited by rows and/or columns.

FTP⁽¹⁾

Internet File Transfer Protocol.

Health Level 7 (HL7) – Organization⁽⁵⁾

Health Level Seven is one of several American National Standards Institute (ANSI) - accredited Standards Developing Organizations (SDOs) operating in the health care arena. Most SDOs produce standards (sometimes called specifications or protocols) for a particular health care domain such as pharmacy, medical devices, imaging, or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data. The HL7 stated mission is: *"To provide standards for the exchange, management and integration of data that support clinical patient care and the management, delivery and evaluation of health care services. Specifically, to create flexible, cost-effective approaches, standards, guidelines, methodologies, and related services for interoperability between health care information systems."*

Health Level 7 (HL7) – Standard⁽⁶⁾

HL7 is a formatting standard for structuring, storing, and messaging clinical data. The standard also supplies a basic set of vocabularies to be used for the attributes in the HL7 Reference Model. HL7 v.3.0 specifications describe 6 basic components:

- 1) The sets of fields or attributes that comprise a message.
- 2) The vocabularies that are needed to enforce consistent data entries in the fields.
- 3) The logical database structure for storing the records.
- 4) The messaging or transport method by which the records are shared.
- 5) The structure of the message to be shared, XML.
- 6) The relationships of the various components in an HL7 message that follow a hierarchy.

International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM)⁽³⁾

Classification system used in the United States to report morbidity and mortality information.

International Classification of Diseases for Oncology, 3rd Edition (ICD-O-3)⁽³⁾

Classification system for reporting incidences of malignant diseases.

Natural Language Processing⁽³⁾

A process by which digital text from online documents stored in an organization's information system is read directly by software and automatically coded.

ODBC⁽¹⁾

Open Database Connectivity. A standard specifying how software can interact with stored data.

Pathology Report⁽²⁾

The written description of the microscopic examination of a tissue. The *gross description* reports the physical characteristics of the tissue: size, color, and abnormalities visible with the unaided eye. The *microscopic description* reports the cellular characteristics aided by **the use of a microscope**: what cells are involved, the behavior, and the aggressiveness or grade of any abnormality. The *final diagnosis* is a summary of the findings and indicates the pathologist's impression of what was found in concise terms.

PKI⁽¹⁾

A PKI (public key infrastructure) enables users of a basically unsecure public network such as the Internet to securely and privately exchange data and money through the use of a public and private cryptographic key pair that is obtained and shared through a trusted authority. The public key infrastructure provides for a digital certificate that can identify an individual or an organization and directory services that can store and, when necessary, revoke the certificates.

Rapid Case Ascertainment⁽²⁾

A special casefinding procedure that allows early or preliminary reporting of certain types of cases to rapidly notify researchers of eligible study subjects.

SNOMED-CT⁽⁷⁾

A dynamic, scientifically validated clinical health care terminology and infrastructure that makes health care knowledge more usable and accessible. The SNOMED CT Core terminology provides a common language that enables a consistent way of capturing, sharing, and aggregating health data across specialties and sites of care.

TCP/IP⁽¹⁾

Transmission Control Protocol/Internet Protocol. The rules and protocols by which the Internet works.

Transmission Standard⁽³⁾

Standards that support the uniform format and sequence of data during transmission from one health care entity to another; also referred to as communication, messaging, and transaction standards.

Glossary Definition Sources

- (1) E-Path: Overview for Hospital & Non-Hospital Laboratories; Artificial Intelligence in Medicine, Inc (AIM) Revision 2.4, March 2003.
- (2) Cancer Registry Management Principles and Practice, 2nd Edition. Kendall/Hunt Publishing Company, 2004, pp 501-533.
- (3) Health Information Management: Concepts, Principles, and Practices American Health Information Management Association, 2002, pp 711-753.
- (4) eReporting: A New Priority. *Journal of Registry Management* 2004;31(3):92-100.
- (5) Health Level Seven home page. <http://www.hl7.org>
- (6) Public Health Information Network Functions and Specifications, Version 1.2, December 18, 2002.
- (7) SNOMED home page. www.snomed.org