

Reporting Guidelines for Clinical Laboratory Reports in Surgical Pathology

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• **Context.**—The surgical pathology report (SPR) is an essential part of patient care because it documents the pathologic findings in tissues removed from patients for diagnostic or therapeutic reasons. Despite the importance of the SPR, exhaustive guidelines outlining the various elements of the SPR have not, to our knowledge, been published.

Objectives.—To outline recommendations delineating the required, preferred, and optional elements that should be included in the SPR. These guidelines, if implemented, will bring uniformity to the reporting of surgical pathology specimens.

Data Sources.—The Surgical Pathology Resource Com-

mittee of the College of American Pathologists compiled and prioritized the elements that have been included in various institutional SPRs. Additional data sources include the College of American Pathologists Laboratory Accreditation Program checklists and the recommendations of the Association of Directors of Anatomic and Surgical Pathology. Each element was assigned a priority of *required, preferred, or optional*. These priorities were discussed and consensus was reached. This report does not address issues of formatting or style substantively.

Conclusions.—These recommendations afford a framework for the creation of an SPR containing all of the components that are required or optimal for patient care.

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The surgical pathology report (SPR) is the final written product of the surgical pathology laboratory, and it contains critical information that drives patient care, especially in the oncologic setting. A variety of individuals, including physicians, nurses, statisticians, epidemiologists, support personnel, and patients, use the information contained in the SPR. Because of the variety of people who access the SPR and the importance of the information contained therein, the report must contain a minimal amount of standard content and must be presented in such a way as to efficiently and accurately convey its information.

The College of American Pathologists (CAP) has developed guidelines for the content of SPRs. Similar guidelines were developed in the past by the Association of Directors of Anatomic and Surgical Pathology (see <http://www.adasp.org/papers/position/Standardization.htm>, last accessed March 14, 2008); additionally, various organizations have called for report standardization.¹ In this article, we have compiled an exhaustive list of elements to be included in the SPR. Some of these recommendations are contained in the CAP Laboratory Accreditation Program

checklists (see <http://www.cap.org>, last accessed March 14, 2008). This article is meant to convey guiding principles regarding the elements that should be contained in the SPR. Additionally, this article serves to rank these elements by degree of importance.

A summary of the body of the recommendations is contained in Tables 1 through 10. These tables are organized by the various sections of a typical SPR. It is not the intent of this article to dictate the format of the report, which might include properties such as font, type size, and position of the various elements on the typed page, nor is it our intent to dictate that the various elements be located in the particular sections delineated in the tables. However, it is clear that a well-designed SPR more effectively conveys critical information to the reader.² The location of the constituents within the SPR is ultimately at the discretion of its creators. The exception to this is text color, which should always be black because many methods of duplication (eg, copy machines, facsimile) do not reproduce nonblack colors well. It is our intent, however, to provide a standardized list of the content elements to be included in the various sections of the SPR so that all readers, be they certified coders, billing clerks, or paramedical or medical personnel, can be assured that all required information will be present in the SPR, regardless of the laboratory of origin.

The SPR is being generated with ever-increasing frequency in electronic format. These guidelines should be applied to the SPR, regardless of the mode in which it is published; however, certain elements, such as the subsequent-page header or footer (Table 2), might be eliminated if SPRs are generated in a purely electronic format. In the tables of this manuscript, some elements are not preceded by a symbol. These are deemed *required* elements that

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Table 1. First-Page Report Header

<p>* Report header graphics (such as service/trademark) Laboratory name and address Laboratory phone number(s); multiple phone numbers may be included, including reporting, billing, and customer service numbers</p> <p>† Laboratory facsimile (fax) number † Laboratory uniform resource locator (URL) † Clinical Laboratory Improvement Amendments of 1988 (CLIA) number</p> <p>* Laboratory medical director name Laboratory performing service, such as routine histology or immunohistochemistry, if applicable</p> <p>Patient name§ Patient date of birth Medical record number, if applicable</p> <p>† Billing number * Patient age * Patient gender </p> <p>Submitting physician * Submitting physician's phone number † Submitting physician's pager, URL, and fax number Physician(s) to receive copies of report</p> <p>Case accession number</p> <p>Patient history/clinical information Patient preoperative and postoperative diagnosis (if applicable)</p> <p>† Clinical laboratory data</p> <p>Date of specimen collection * Time of specimen collection Date specimen received in laboratory * Time specimen received in laboratory † Specimen collection site (eg, hospital, office, clinic, operating room)</p> <p>Report title (for special report templates, eg, "Surgical Pathology Report") Report status indicator (eg, Preliminary Report, Amended Report, etc)</p> <p>Report page number (including total number of pages for multiple-paged reports) * Report print date and time Date and time the original report was printed (see text)</p>
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* indicates preferred elements; †, optional elements; all remaining entries are required.

§ See text for notes regarding formatting of Latino names.

|| These items are strongly recommended, unless the inclusion of these items is precluded by hospital policy.

must be included in all reports. Other elements are considered *preferred*, as designated by the * symbol. The preferred entries are considered important to convey to the reader and should be included in some fashion, unless their inclusion is precluded by hospital policy or some other extenuating circumstance. A few of the elements are considered *optional* and are designated by a dagger (†).

Table 2. Subsequent-Page Header and/or Footer§

<p>Patient name (includes last name, first name and, at least, middle initial) Medical record number Accession number Report page number (including total number of pages for multiple-paged reports) † Report print date and time</p>
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† indicates optional elements; all remaining entries are required.

§ These data elements must appear in the header or footer of each page after the first page of each surgical pathology report.

Table 3. Diagnosis Field

<p>* Specimen designator (delimited by, eg, 1, 2, 3 or A, B, C)§ Body site (may place in quotation marks if citing label or requisition)§ Subsite (may place in quotation marks if citing label or requisition)§</p> <p>* Surgical procedure (may place in quotation marks if citing label or requisition)§ Final diagnosis</p> <p>* College of American Pathologists cancer checklists or synoptic reports§</p> <p>† Diagrams</p> <p>Slides from outside source * When specimen was procured * Outside accession number (per block) * Block/slide designations *‡ Name of outside laboratory</p> <p>† Transcriptionist(s) (if any)</p>

* indicates preferred elements; †, optional elements; ‡, may be located elsewhere in the report; all remaining entries are required.

§ See text for further explanation.

The content that follows includes a detailed description of the SPR elements and the reasoning behind our decisions regarding the necessity of the various constituents.

FIRST-PAGE REPORT HEADER

The header on the first page of the SPR (Table 1) contains critical information, including information about the laboratory, the patient, and the type of report. As such, a delimiter, such as a box or line, below the header is often used to separate its contents from the remainder of the report. Within this header, one group of elements is the detailed laboratory identifying information that must, minimally, include the laboratory's name, address, and main phone number. If the laboratory has multiple phone numbers, which might include customer service, billing, or reporting offices, these may be included as well. These identifying elements must be present on every report for easy recognition of the responsible laboratory by the reader. Additionally, the laboratory's or hospital's identifying logo or trademark, if available, should appear on every report. We recognize that some laboratory information systems may not support the inclusion of such graphics on reports; however, we feel that this is an element that provides easy identification of the origin of the SPR, and thus, we have categorized this element as preferred. Additional optional elements that provide contact information or data regarding the laboratory's credentials include facsimile phone numbers, uniform resource locator (URL) for electronic access via the World Wide Web, and Clinical Laboratory Improvement Amendments of 1988 (CLIA) number. As a preferred element, the name of the laboratory's medical director should also appear in the portion of the header that contains the laboratory's contact information. We consider this an important component of the SPR because it provides the reader with supervisory contact information, should the pathologist-of-record be unavailable, or if a discussion with the laboratory's leadership is required.

If a secondary laboratory is involved in the routine processing of tissue or ancillary testing, such as immunohistochemistry or histochemical staining, and no separate report is issued by that laboratory, that reference laboratory's contact information, including address and phone num-

Table 4. Gross/Macroscopic Description

Specimen identification on requisition form
Specimen container number
Specimen label
Specimen state upon receipt (eg, fresh, formalin fixed)
Macroscopic description
Size(s) and weight(s) (if applicable)
Margins (if applicable)
Ink codes (if applicable)
Orientation (if applicable)
† Specimen diagram
* Gross photography and/or specimen radiographs, if taken
Grossing personnel
† Transcriptionist's name or initials
Processing information:
Type of fixative (if any) or other preservative (eg, RPMI)
† Estimated time in preservative
† Estimated time in fixative
Decalcification
† Type of decalcification
† Estimated time in decalcification
Tissue disposition
Key of blocks submitted
Entire tissue submitted vs representative sampling
Blocks submitted subsequent to initial block submission
Tissue submitted for additional studies (eg, cytogenetics, molecular testing)
Sent out for additional tests
Kept for research purposes (if done, must be documented in report)
Sent to biorepository (if done, must be documented in report)
† Preservation method for retained or sent-out tissue (fresh, frozen, fixative/preservative)
Slides from outside source
† Submitting laboratory/physician (if available)
Original date of service
Outside accession number(s)
Specimens received (eg, slides, blocks, frozen tissues)§
* Document that patient name and slide designations match report (if received)
*‡ Portions of original gross description, if required for full interpretation
† Disposition of consult materials after consult is complete

* indicates preferred elements; †, optional elements; ‡, may be located elsewhere in the report; all remaining entries are required.
§ See text for details.

Table 5. Intraoperative Consultation (IOC)

* Specimen designator (delimited by, eg, 1, 2, 3 or A, B, C)
Body site (may place in quotation marks if citing label or requisition)
* Surgical procedure (may place in quotation marks if citing label or requisition)
IOC procedure performed
Frozen section
Gross examination
Intraoperative cytology
Tissue submitted for flow cytometry
Tissue submitted for cytogenetics/molecular/genetic studies
Tissue submitted for electron microscopy
Tissue submitted for microbiologic studies
IOC diagnosis (if applicable)
IOC pathologist's name
† Name (and title, if not physician) of person to whom the report was given
† Time and date report was given

* indicates preferred elements; †, optional elements; all remaining entries are required.

Table 6. Microscopic Description (Optional)

‡ Special stains
* Documentation that controls stained appropriately
† Reference ranges (if applicable)
Interpretation of each stain
Analyte-specific reagent comments and similar, if required

* indicates preferred elements; †, optional elements; ‡, may be located elsewhere in the report; all remaining entries are required.

ber(s), should also appear in the report. The inclusion of this information is essential for quality assurance because it may provide the only documentation of the site at which those technical services were performed. The information regarding the laboratory that provides those services need not be included in the first-page report header, but it must be included somewhere within the report.

The patient's identifying information is, without doubt, one of the most crucial aspects of the report. As such, this information should be displayed prominently within the header. The patient's name is often formatted as last name, first name, middle initial. However, other formatting conventions are acceptable as hospital or laboratory policy dictates. Additionally, it is common in Hispanic cultures for patients to use both the paternal and maternal last names. When that is the case, the paternal and maternal last names should be joined by a hyphen so the paternal surname is not confused with the middle name (eg, Jose Luis Martinez-Rendon). The inclusion of the patient's full middle name is regarded as an optional element because it may help resolve some identity issues. Additional patient identifying information must include the patient's medical record number (if applicable) assigned by the institution and date of birth (see GEN.40750 in the CAP Laboratory General Checklist, available at <http://www.cap.org>). Some institutions incorporate a billing or fiscal number in addition to the medical record number to track individual physician visits. If such a tracking system is in place, that number may also be included. Many institutions also use other patient identifiers, such as age and sex. Both age and sex are considered preferred elements because they give pathologists additional, readily accessible information that often has a clinical bearing on the case. Additionally, conspicuous reporting of age and sex may occasionally serve to highlight and resolve patient identity discrepancies. The name of the submitting physician must be included in the report; the submitting physician's office phone number, however, is a preferred element. Inclusion of the phone number is preferable because it gives readers direct, efficient access to the submitting clinician's contact information; however, some laboratories may elect not to include it because of clinician preference.

Table 7. Comments/Notes (Optional)

† Diagnosis explanation
† Differential diagnosis
† Correlation with clinical/radiologic findings
Documentation of review of previous pathology materials
Documentation of conversation with clinician (as appropriate)
† Time and date of conversation
† Pertinent references
† Treatment recommendations

† indicates optional elements; all remaining entries are required.

Table 8. Addendum Reports

Results of adjunct diagnostic studies:
Flow cytometry
Electron microscopy
Special stains (histochemistry and immunohistochemistry)
Immunofluorescence
Molecular/genetic studies
Cytogenetic studies
Cultures
Results of decalcified sections
Results of deeper sections or slides from reprocessed or re-embedded tissues blocks
Results of additional tissue sections (including block summary, if not included in initial gross description)
Results of extradepartmental consultations (second opinions)
‡ Name of original sign-out pathologist
Name of addendum-reporting pathologist
Date and time of addendum sign-out
Documentation of conversation with clinician (as appropriate)
† Time and date of conversation
† Transcriptionist(s) (if any)

† indicates optional elements; ‡, may be located elsewhere in the report; all remaining entries are required.

Similarly, the submitting physician's pager information, URL, and facsimile number may be included; these data are considered less important than the clinician's direct office phone number. In addition to the submitting clinician, other clinicians who are to receive additional copies of the report must be included. This gives readers quick access to other physicians who are directly involved in the patient's care.

Clearly, the surgical pathology accession number is one of the most critical elements contained in the report because it serves as a unique identifier for the case. As such, the accession number should be prominently placed on the first-page header of the report. Additionally it must be placed on the header or footer of subsequent pages (see below).

The various elements that constitute the history portion of the report include the patient's clinical history provided by the clinician, preoperative diagnosis, postoperative diagnosis, and clinical laboratory data. Of these components, all but the relevant clinical laboratory data must be included in the report because they provide documentation of the information that is conveyed to the laboratory by our clinical colleagues and give the clinicians important feedback that the time they took to write a clinical history on the requisition slip was noted by the pathologist. These clinical data are often critical in the proper

Table 9. Amended Reports

Reason for amended report
Original/unamended entry
Amended entry
‡ Name of original sign-out pathologist
Name of amended-report pathologist
Date/time of amended report sign-out
Documentation of conversation with clinician (as appropriate)
† Time and date of conversation
† Transcriptionist(s) (if any)

† indicates optional elements; ‡, may be located elsewhere in the report; all remaining entries are required.

Table 10. Other Data Elements

Sign-out pathologist(s)
Sign-out date
† Sign-out time
† Attending-pathologist attestation
* Resident/fellow names or initials (if applicable)
† Previous pathology accession numbers/specimens/diagnoses
† Photomicrographs or other images
† Prognostic data
† Patient educational information, including diagrams, graphics, charts, text, photos
† ICD, CPT, SNOMED codes§

* indicates preferred elements; †, optional elements; all remaining entries are required.

§ ICD indicates *International Statistical Classification of Diseases and Related Health Problems*; CPT, *Current Procedural Terminology*; and SNOMED, *Systematized Nomenclature of Medicine*.

interpretation of the case. Relevant clinical laboratory data are often included in the SPR from particular anatomic sites, such as liver, renal, and bone marrow biopsies; inclusion of these data adds a more comprehensive view of the patient's underlying pathologic condition and obviates the need to look in multiple places for sometimes disparate laboratory and anatomic pathology results. In such cases, only the laboratory data relevant to the pathologic specimen should be included. Many modern laboratory information systems contain functionality that automatically imports particular laboratory results into reports to decrease the possibility of transcription errors.

The date of specimen collection and the date the specimen was received in the laboratory are critical data in the tracking of specimens and the creation of turnaround time reports; these data are also included in information that is sent to insurance companies for billing. As such, these elements are required. The time of specimen collection and the time that the specimen arrived in the laboratory are categorized as preferred elements. Tracking these times is important for accurate construction of turnaround time reports and may help resolve issues of specimen tracking in medical centers where ancillary personnel transport specimens to the surgical pathology laboratory. Additionally, inclusion of these times on the report more accurately communicates issues of turnaround time and chain of custody to the reader. Lastly, these data are becoming more critical as time of fixation and similar measures are needed to maximize standardization for biomarker interpretation. Prefixation ischemic time and fixation time are regarded as essential data elements by the CAP; however, they are categorized as preferred with the knowledge that these data may not be attainable in all circumstances and that some laboratories prefer to record these data internally rather than in the body of the report. Optionally, the site of specimen collection may be included as well and serves to inform the reader which department within the institution collected the specimen. This information might assist in specimen resolution or identity discrepancies.

The title of the report is an important component because it gives the reader a conceptual framework from which to interpret the report. Most laboratories simply use the title "Surgical Pathology Report." However, some laboratory information systems allow various types of reports to create different formats that cater to various clinician subsets, for example, "Dermatopathology Report" or "He-

matopathology Report.” The report type should be preceded or followed by the report status indicator. Report status indicators might include “Final Report” and “Addendum Report.” These designators inform the reader about the report’s contents; for example, “Addendum Report” notifies the reader that the report’s contents are intended to convey additional information that expounds on the original final diagnosis (see below for further details).

Both the page number and the total number of pages must be displayed on every page of the report, but they do not need to appear in the header on the first page (see below). The time and date that the original report was printed is a required element. This information gives the reader a time point from which further copies of the report can be referenced and, thus, can be instrumental in accounting for changes in the report’s content over time, especially for addendums or amended reports. The actual time that a particular hard copy of the report is printed (“Report print date and time” in Table 1) is considered a preferred element; its presence on the report provides a comparison to the original report date and time and may, in certain circumstances, provide data to account for changes in the report’s content.

SUBSEQUENT-PAGE HEADER AND FOOTER

Certain critical identifying elements must appear in the header or footer (Table 2) of each page of the SPR after the first page. These elements include the patient’s name, preferably in the same format as in the first-page header (see above), medical record number, and surgical pathology accession number. These components serve to inform readers of the patient’s identifying information on each page and obviate potential identification issues should a multipage report be separated into individual pages. The report page number and total number of pages must appear so that the reader can account for every page in the report and can be informed of the total number of pages. The presence of the report print date and time could be useful to include because they tell the reader the age of the hard copy. If the print date is quite removed from the current day, it might alert the reader that a more current version of the report may exist.

DIAGNOSIS FIELD

In general, the diagnosis field (Table 3) contains all the information that pertains to the pathologic diagnosis. Not surprisingly, this is perhaps the most highly examined portion of the report, and as such, it is often positioned directly after the header on the first page of the report.

The SPR, by definition, gives readers diagnoses on all specimens that are delivered to the pathology department from one operation or patient visit to a single clinician on a particular day. The diagnoses for each specimen should be separated by a specimen designator, which may be arabic numerals, roman numerals, alphabetic characters, or should be clearly linked back to a summary table, such as the block summary or the list of submitted blocks in the gross description. Following this specimen designator, the specimen title appears, which includes the body site, body subsite, and surgical procedure and is typically formatted as “Body site, subsite, surgical procedure,” for example, Right breast, upper inner quadrant, excisional biopsy for calcifications.

If a portion of the specimen title is quoted directly from the surgical pathology requisition, it may be contained in

quotation marks. The use of this format standardizes the specimen-labeling syntax and allows readers of SPRs to expect the same format from institution to institution. We understand that the inclusion of the surgical procedure portion of the specimen title might not be desirable because, in some institutions, the exact surgical procedure might not be known and may lead to discrepancies in the medical record should the procedure be assumed by the pathologist of record. Because of this possibility, we have classified the surgical procedure as a preferred element. The pathologic diagnosis is self-explanatory; however, there must be a diagnosis for each specimen submitted, and it should be placed in the report in such a way as to facilitate its easy identification by readers.

The use of cancer-reporting checklists has received much attention of late. These checklists have been created by several national and international associations and serve to standardize the reporting of key pathologic findings in definitive cancer resections. These checklists also ensure inclusion of all relevant pathologic parameters. Therefore, all information from the relevant cancer-reporting checklist should be included in appropriate cases. Laboratories may use any nationally or internationally approved reporting scheme, which might include those developed by the CAP (<http://www.cap.org>, last accessed March 14, 2008), the Association of Directors of Anatomic and Surgical Pathology (<http://www.adasp.org/Checklists/checklists.htm>, last accessed March 14, 2008), or the International Federation of Gynecology and Obstetrics (http://www.igo.org/docs/staging_booklet.pdf, last accessed January 4, 2008) for gynecologic malignancies. It should be noted, however, that the use of the CAP templates is mandated in the standards for accreditation of tumor registries. Alternatively, institutions may elect to create one or more documents that fulfill their own particular clinical or individual needs. These homemade checklists should, at minimum, contain the mandatory elements present in nationally or internationally accepted checklists. Although a synoptic report format is not required, provided that all the checklist elements are included in the report, use of synoptic reports is strongly preferred because they have been shown to increase both the completeness of the reporting and the comprehension by the reader.³ If reported synoptically, the checklist may appear in another field of the SPR; however, it should be referenced in the diagnostic fields (eg, “see tumor summary”).

Some laboratories use pictorial diagrams to visually identify the biopsy site, especially for the prostate or the gastrointestinal tract. These diagrams are purely optional and might appear within the diagnostic section or elsewhere in the report.

Most surgical pathology laboratories accession cases that have been previously interpreted by other laboratories, when second opinions are requested by pathologists or clinicians from other institutions. Additionally, when patients are referred from other institutions, their relevant pathology is often reexamined by the pathology department at the receiving institution. In these cases, the date of original specimen procurement, outside accession number, block/slide designations, and the name and location of the outside laboratory should be contained within the diagnostic field, for example, Left thigh, core biopsy (Beth Israel Deaconess Medical Center Department of Pathology, Boston, MA; S07-XXXXX, slide A; 1/1/06). This infor-

mation must be included in every consultation report to ensure accurate documentation of the material examined. However, some laboratories might elect to include these data in the gross description field (see below) and, therefore, inclusion of these elements in the diagnosis field is regarded as preferred.

If applicable, the transcriptionist's name and initials are optional. The presence of the transcriptionist's initials on the report can aid in the resolution of typographical or transcription errors and would help in quality assurance issues surrounding report accuracy. However, this element is not mandatory because many laboratory information systems automatically store this information within its databases so that it can be accessed easily without requiring these initials on the report.

GROSS/MACROSCOPIC DESCRIPTION

The gross/macroscopic description section (Table 4) contains the written description of all tissue or removed foreign materials received by the surgical pathology laboratory; it also includes vital documentation of the specimen's handling within the laboratory and the tissue's disposition.

The specimen title or designation is typically reproduced verbatim from the information contained on the surgical pathology requisition form. A list of these specimen designations following the specimen number might be organized in a tabular format that precedes or follows the gross description. Alternatively, it might be incorporated into the gross description itself.

The body of the macroscopic description is most commonly written in a prose style with each specimen described separately and separated into paragraphs. When series of similarly sized biopsies are described, most commonly in the case of prostate or gastrointestinal biopsies, some laboratories elect to condense the gross description of all specimens into one paragraph that aggregates the specimen measurements into one measurement (eg, "the specimens measure from 0.1 cm to 0.3 cm in greatest dimension"). Although this approach does simplify the gross description of specimens, we feel that the creation of separate gross descriptions for each specimen, with distinct sets of specimen dimensions, is preferable because this information can more accurately be used to resolve block or slide labeling discrepancies.

The body of the gross description begins with the specimen number, which is immediately followed by the designation written on the specimen label. As noted above, the specimen label should be reproduced verbatim from the label written on the specimen container. When there is no site designated on the specimen container or when there is a discrepancy between the sites designated on the specimen container and on the requisition, that information should be clearly stated in the gross description. Most often, the specimen label is followed by the state of the specimen upon receipt in the laboratory, which might include, for example, fresh or fixed in formalin.

The macroscopic description follows the specimen number, specimen label, and specimen state. The description should be a concise, yet substantive, description of the type of specimen, salient macroscopic findings, processing information, and the disposition of the tissue. A comprehensive description of the appropriate treatment and description of gross specimens is beyond the scope of this article, and many texts have been published on the sub-

ject.^{4,5} However, all gross descriptions must contain the size and weight of the specimens, as appropriate. A description is required for the specimen's orientation, or lack thereof, and the presence of clinically important surgical margins. A detailed description of the of specimen's inking in relation to the specimen's orientation is a required element.

Other optional elements that might be included within this portion of the report include specimen diagrams. These graphics can be quite helpful in orientation of complex resection specimens. The inclusion of these diagrams clarifies the origin of microscopic sections taken from the specimen. However, the integration of specimen diagrams or photographs is difficult for some laboratory information systems, and thus, these materials may be kept in the paper record. If gross photographs were taken, a statement to that effect should appear in the report because it informs the reader about the existence of gross photographs; the same holds true for specimen radiographs. The name or initials of the grossing personnel must appear as a separate element in the report because it informs the reader of the person(s) who was responsible for grossing the case and is important for quality assurance and tracking of the specimen's chain of custody. As an optional element, the transcriptionist's name or initials may appear in the report. Again, the inclusion provides ready access to this information for all readers of the report. However, with most modern-day laboratory information systems, this information is easily accessed by laboratory staff; in which case, the transcriptionist's identifying information does not need to be present on the report.

One of the key portions of the gross description is the method by which the specimen was processed. Mandatory elements include the type of fixative or preservative in which the tissue was submitted and the presence or absence of decalcification. Inclusion of the type of fixative or preservative is critical in informing the reader about the state of the tissue and the existence of tissue fixed by other means. This information is particularly important as molecular testing becomes more commonplace because that testing often requires tissue be treated differently from routine formalin fixation. The presence or absence of decalcification treatment has direct billing implications because charging for decalcification (*Current Procedural Terminology* code 88311) requires the process be documented in the SPR. Although decalcification performed must be documented in the report, the type of decalcification and the estimated time for decalcification are optional elements. The various types of commercially available decalcification solutions are known to variably affect the antigenicity of proteins in the tissue, which may significantly affect the results of immunohistochemistry. As such, the inclusion of the type of decalcification solution might inform the reader as to the state of the decalcified tissue. Similarly, the time the tissue was exposed to preservative or fixative can be an optional element in the report. Again, the time the tissue is exposed to fixative affects the results of the assays performed on that tissue. It is known that excessive or inadequate exposure to formalin fixation alters the reactivity of the tissue to certain antigens,^{6,7} and thus, the documentation of fixation time will likely increase in importance as initiatives that call for the standardization of tissue-based assays increase.⁸

Another fundamental portion of the gross description section is the documentation of the tissue's disposition.

Critical elements of this portion include a key to the paraffin blocks submitted; a tabular format is preferred because it is easier to read. However, many laboratories integrate the block key into the gross description. Further, a statement in the gross description or specimen key must include whether the tissue was submitted in its entirety or if it was sampled in a representative fashion. If additional blocks are submitted after the case has been signed out, they must be added to the report, typically, as an addendum report (see below); if the diagnosis is modified as a result of the findings in these additional blocks, that must be changed as well, usually in the format of an amended report (see below). Also, if tissue is procured for additional studies within the laboratory, such as flow cytometric, cytogenetic, or molecular testing, that must be mentioned within the gross description.

Increasingly, tissue is sent to ancillary laboratories for additional testing, stored for possible future research purposes, or sent to biorepositories. If any of these activities are performed, they must be documented in the report. In the case of additional testing done at an outside laboratory, the name of the outside laboratory must be included. Optionally, the preservation method for this retained material or tissue sent to outside laboratories might be included.

The format of the gross description is modified when slides from outside surgical pathology laboratories are examined. In this situation, required elements include the name and full address of the submitting laboratory (if available), the original date of service, and the outside accession number(s). The nature of the material received must be explicitly documented in this type of report, which includes the quantity of slides received, slide labels, type of stain present on the slides (eg, hematoxylin-eosin, trichrome stain), and paraffin block designators (if applicable). In the case of immunohistochemically stained slides, the stain name and antibody clone, if available, should also be included in the gross description. A sentence documenting that the patient's name and slide labeling information matches the accompanying original SPR is a preferred element. Addition of this statement explicitly confirms to the reader that this information was checked and verified by the accessioning personnel. Additionally, portions of the original gross description might be included in cases that require that information for full pathologic interpretation. For example, the tumor size should be included in cases of gastrointestinal stromal tumors because tumor size is a major determinant of prognosis. Although that information should be added to the gross description, it may appear in another area of the report, as necessary. Lastly, the disposition of the consult slides or blocks after the consult is an optional element (eg, "all slides and blocks were returned to the submitting institution"); that information provides explicit documentation of the handling of consult materials after the consultation is complete.

INTRAOPERATIVE CONSULTATION

The intraoperative consultation (IOC; Table 5) is defined as a service performed on tissue resected in an operative setting that results in immediate information that affects the procedure as it is being performed. The elements that pertain to the IOC can be placed into a separate section of the report or, more commonly, can be integrated into the gross description. As described above in the diagnosis section, the IOC diagnosis should be preceded by the

specimen designator, body site, and the surgical procedure. However, in the IOC section, the possibility of typographical errors or discrepancies in the specimen designator might result in unnecessary confusion when compared with the final diagnosis; as a result, some laboratories elect to exclude specimen designators from the IOC section, and they are, therefore, regarded as preferred elements. Possible intraoperative procedures include frozen section, gross examination, intraoperative cytology (eg, fine-needle aspirations, smear preparations), and dissection with the intent of procurement of tissue for ancillary procedures, including flow cytometry, cytogenetics, molecular studies, and electron microscopy. The exact procedure performed must be included in the report for both documentation and billing purposes. The IOC diagnosis is self-explanatory; however, at least one diagnosis must appear for each specimen examined in the intraoperative setting. Documentation about the pathologist(s) who rendered the IOC diagnosis must also appear. The time, date, and name of the physician or staff member who received the diagnosis are optional elements. The inclusion of this information in the report ensures its formal documentation in the patient's medical record.

MICROSCOPIC DESCRIPTION

Classically, the microscopic description section (Table 6) describes the salient histopathologic findings of the case. However, in the modern era of high-volume surgical pathology laboratories, the microscopic description is becoming less common. Because this portion of the report does little to assist readers in the interpretation of the clinical impact of the diagnoses, the section is optional. However, many laboratories use this section to record the results of histochemical and immunohistochemical stains. If such results are entered here, the documentation of appropriate positive and negative control staining, as well as all pertinent information regarding the stain method or antibody clone used, should be included; if reference ranges are applicable, they might also be documented. The results of each special stain must be included in the report, although they need not be present in the microscopic description section. As mandated by the CAP Laboratory Accreditation Program, Anatomic Pathology Checklist, ANP.12425, a disclaimer regarding the use of class I analyte-specific reagents, if applicable, must be stated in reports that use these reagents. This disclaimer may appear in the microscopic description section or elsewhere in the report.

COMMENTS/NOTES

The comments/notes field (Table 7) is optional and typically includes supplementary information that documents or expounds on additional information that is directly relevant to the pathologic diagnoses rendered in the diagnosis section. These notes are usually added when subtleties of differential diagnosis or when correlation with the clinical, laboratory, or radiologic data is required. Further, this area might be used to document specimen discrepancies or to provide an explanation of disagreements in the interpretation of frozen section diagnoses.

If previous pathology was reviewed in the course of interpretation of the case, the fact that this material was reviewed must be documented in the report (see also CAP Laboratory Accreditation Program, Anatomic Pathology Checklist, Item ANP.10050). When clinicians are contacted

regarding the pathologic findings or to clarify aspects of the case, these conversations must be documented in the report. Potential scenarios where clinicians might be contacted regarding pathologic diagnoses include an unexpected finding of malignancy, the lack of chorionic villi in a missed abortion sample, or the unexpected finding of infectious organisms. In addition to the name of the clinician or medical staff, the time and date of the conversation might be included. Lastly, references to the relevant medical literature may be included. Many laboratories include this informational material in the case of rare or diagnostically difficult cases. The comment field may also contain recommendations for further treatment or biopsy from the pathologist.

ADDENDUM REPORTS

An addendum report (Table 8) is a type of ancillary report that contains additional information, typically the results of ancillary diagnostic studies completed after the original SPR has been released; addendum reports, by definition, only add information to a report that has been previously finalized. If the intent of this ancillary report is to change a previously rendered diagnosis or to change other content, then the report should be titled "Amended Report" (see below). For example, an addendum report might be issued to report the results of adjunct studies (eg, flow cytometry, electron microscopy, histochemistry, immunochemistry, immunofluorescence, molecular/genetic studies, cytogenetics, or microbiologic cultures of tissue), microscopic findings in additional or decalcified tissue sections, results of deeper sections if they do not change the diagnosis, the findings on slides from reprocessed or re-embedded blocks, and the results of extra-departmental consultations. If any of the ancillary studies were performed at an outside laboratory, the name and location of this laboratory must be included.

The name of the pathologist who signed out the addendum report, the original pathologist of record, and the date/time of addendum sign-out must also be included. However, the original sign-out pathologist need not be reproduced in the addendum if the original, final SPR is included when the addendum is printed or displayed electronically. If the results contained in the addendum were discussed directly with a physician or other medical staff, the name of the physician must, and the date and time of this conversation should, be included in the report for the purposes of documentation. Additionally, the name of the transcriptionist, if applicable, is optional.

AMENDED REPORTS

Like addenda, amended reports (Table 9) are added after the completion of the final report. However, amended reports are created to correct errors or discrepancies in the original final report. Typical reasons to create an amended report include correction of typographical errors, modification of the final diagnosis, or documentation of the resolution of a specimen-labeling discrepancy. In the case of typographical errors, an amended report must be issued only if that error could potentially lead to a misinterpretation of the diagnosis. When amended reports are created, the amended portion of the report must also include a reproduction of the original, unamended entry, or a reference to the incorrect information that was originally reported. It is generally desirable to provide an explanation as to why the amendment was created. The re-

maining elements listed in Table 9 are identical to those in the addendum section (Table 8); see above for additional explanation.

OTHER DATA ELEMENTS

These other data elements (Table 10) do not have an intuitive location within the report; however, that does not discount their importance. The critical elements in this table include the name of the sign-out pathologist(s) with the sign-out date and time. Although these data must appear somewhere in the report, the location of these entries varies. Some laboratories place these data into the header on the first page or immediately following the diagnosis, whereas others place the sign-out pathologist at the very end of the report. Most laboratories use electronic signature technology and, if applicable, the phrase "Electronically Signed by" must also be included. The name of the diagnosing pathologist should be preceded or followed by "Diagnosing Pathologist," "Sign-out Pathologist" or similar wording. The pathologist's full name and credentials (eg, MD; MD, PhD; or DO) should be included. Some institutions may choose to add the name or initials of pathologists who are involved in specific portions of the pathologic examination. For example, if one pathologist performed the macroscopic examination and another examined the microscopic slides, the name or initials of the grossing pathologist might optionally be included in the report. The date of sign-out is a required element and is typically located adjacent to the sign-out pathologist's name. The time of sign-out is optional and might be included as data to facilitate quality assurance documentation, such as turnaround time reports. Many laboratories also include a statement attesting that the pathologist of record personally reviewed the pathologic material referenced in the report; this statement is an optional element because it only emphasizes the implicit responsibility of the sign-out pathologist. In laboratories that support pathology-training programs, the name or initials of the responsible trainee should be present. The inclusion of these data assist clinical staff in contacting the resident or fellow for additional information, if this is in agreement with hospital or departmental policy. Information pertaining to the patient's previous pathology testing may be included as an optional element. The inclusion of these data on the report gives readers quick access to information on the patient's previous pathology results. Additionally, the amount of information included in this element varies. Many laboratories simply list previous accession numbers, whereas others include the specimen designators as well.

Representative reproductions of photomicrographs or other images are included in the reports by some surgical pathology laboratories; however, their inclusion is optional. Additionally, some laboratories include educational or prognostic information, in certain instances. For example, some laboratories include the Partin tables, which are prognostic nomograms for prostatic adenocarcinoma, whereas others add diagrams and biopsy-site labels for both prostate biopsies and luminal biopsies of the gastrointestinal tract. Although the inclusion of this material might add some ancillary information to the interpretation of the report, it is considered strictly optional. Lastly, some laboratories include billing and diagnostic coding information in the report to more readily track that data. Possible codes that might be added include the *International Statistical Classification of Diseases and Related Health Prob-*

lems (ICD-9), Current Procedural Terminology (CPT), and the Systematized Nomenclature of Medicine (SNOMED); again the inclusion of this information is optional.

CONCLUSIONS

The SPR is a critical document, used by many parties in medical care; it has the potential to guide diagnosis, treatment, and prognosis in a variety of disease processes. As such, this report must be clearly constructed and must include a variety of elements in pursuit of this goal. In this article, the Surgical Pathology Committee of the CAP puts forth its recommendations regarding the required, preferred, and optional elements that should be included in SPRs. Adoption of these guidelines will go far in standardizing these reports, which should minimize errors, and thus, improve patient care.

FEEDBACK

To provide feedback, please forward your comments to pvasalo@cap.org or dmurphy@cap.org. These and updated versions of these guidelines will be posted on the CAP Web site at <http://www.cap.org>.

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References

1. Rushing L, Joste N. The surgical pathology report: standardizing the "gold standard." *J Surg Oncol*. 1997;65:1-2.
2. Valenstein PN. Formatting pathology reports: applying four design principles to improve communication and patient safety. *Arch Pathol Lab Med*. 2008;132:84-94.
3. Hammond EH, Flinner RL. Clinically relevant breast cancer reporting: using process measures to improve anatomic pathology reporting. *Arch Pathol Lab Med*. 1997;121:1171-1175.
4. Lester SC. *Manual of Surgical Pathology*. Philadelphia, Pa: Churchill Livingstone; 2001.
5. Westra WH, Hruban RH, Phelps TH, Isacson C. *Surgical Pathology Dissection: An Illustrated Guide*. New York, NY: Springer-Verlag; 2003.
6. De Marzo AM, Fedor HH, Gage WR, Rubin MA. Inadequate formalin fixation decreases reliability of p27 immunohistochemical staining: probing optimal fixation time using high-density tissue microarrays. *Hum Pathol*. 2002;33:756-760.
7. Goldstein NS, Ferkowicz M, Odish E, Mani A, Hastah F. Minimum formalin fixation time for consistent estrogen receptor immunohistochemical staining of invasive breast carcinoma. *Am J Clin Pathol*. 2003;120:86-92.
8. Wolff AC, Hammond MEH, Schwartz JN, et al. American Society of Clinical Oncology/College of American Pathologists guideline recommendations for human epidermal growth factor receptor 2 testing in breast cancer. *Arch Pathol Lab Med*. 2007;131:18-43.