



CoC Operative Standards (Standards 5.3–5.8) Frequently Asked Questions

Compliance & Implementation

CoC Operative Standards (Standards 5.3-5.8) Reference Material:

- 2024 Site Visit Instructions and Sample Agenda
- Overview of Compliance Requirements and Site Visit Process for the CoC Operative Standards
- Operative Standards Toolkit
- Quick Reference Guide for CoC Operative Standards (Standards 5.3-5.8) (Standards 5.3-5.8)
- Operative Standards for Cancer Surgery, Volumes 1, 2, and 3
- Operative Standards References
 - o <u>CoC Standards 5.3 and 5.4 Editorial</u>
 - o <u>CoC Standard 5.5 Editorial</u>
 - o <u>CoC Standard 5.7 Editorial</u>
 - o CoC Standard 5.8 Editorial
 - Adherence to surgical and oncologic standards improves survival in breast cancer patients
 - Adherence with operative standards in the treatment of gastric cancer in the United States
 - o <u>Technical Standards for Cancer Surgery: Commission on Cancer Standards 5.3-5.8</u>
 - <u>Technical Standards for Cancer Surgery: Improving Patient Care through Synoptic</u> Operative Reporting
 - <u>Meeting the New Commission on Cancer Operative Standards: Where do we stand</u> <u>now?</u>
 - <u>Development of an Electronic Health Record Registry to Facilitate Collection of</u> <u>Commission on Cancer Metrics for Patients Undergoing Surgery for Breast Cancer</u>
 - Implementation of a Synoptic Operative Report for Rectal Cancer: A Mixed-Methods Study
 - o <u>Technical Standards for Cancer Surgery: Commission on Cancer Standards 5.3-5.8</u>
 - <u>Technical Standards for Cancer Surgery: Improving Patient Care through Synoptic</u> <u>Operative Reporting</u>

What are the requirements for compliance with the operative standards? What year will compliance be enforced?

Current ratings and compliance information for Standards 5.3 through 5.8 can be found on the <u>Operative Standards Timeline and Compliance Information</u> webpage along with the implementation timelines.





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How will site reviewers be evaluating compliance with the operative standards? Site reviewers will assess 7 charts for each operative standard (42 total) to determine whether reports

meet the requirements outlined in Standards 5.3–5.8. Please refer to the <u>Timeline and Compliance</u> Information webpage for details.

How many cases will be reviewed for a network? Is this determined by the number of facilities? Each hospital in an Integrated Network Cancer Program (INCP) will have 7 charts assessed per standard. The INCP will then be rated cumulatively. For example, an INCP with 10 hospitals would have 70 charts reviewed per standard (7 charts × 10 hospitals). 49 of the 70 charts assessed would need to meet all requirements to achieve 70 percent compliance, or 56 of the 70 charts to achieve 80 percent compliance. Compliance levels depend on the standard being assessed and the year of the site visit. Specific requirements can be found on the <u>Timeline and Compliance Information</u> webpage.

If our facility rarely performs/does not ever perform a certain operation that is included in the operative standards, does that standard still apply to our facility?

If a program has fewer than 7 charts within the scope of a specific standard, then all charts within the scope of the standard from the applicable timeframe will be reviewed by the site reviewer If a program has no charts within the scope of a specific standard, they are exempt from that standard.

What is the penalty for not meeting compliance with the operative standards at the site visit?

A non-compliant rating will be given to a program that does not meet the required percentage during the medical record review. However, during 2024 site visits, an internal audit of compliance with Standards 5.3, 5.4, 5.5, and/or 5.6 and an action plan that addresses compliance issues may be considered by Site Reviewers when rating the standard. The internal audit and resulting action plan must be documented in cancer committee minutes from a 2023 or 2024 meeting and must be from before the Site Reviewer selects the cases to be reviewed during the site visit. The internal audit must outline the specific issue(s) affecting compliance and the interventions that will be implemented to achieve compliance. An action plan must be documented for each potentially non-compliant standard.

During the site visit, the medical record review will be conducted. If the expected compliance percentage is not met, the site reviewer will evaluate the results of the site's internal audit and action plan as documented in the cancer committee minutes. A "deficient but resolved" rating may then be given.

This is a temporary alternative pathway for compliance with Standards 5.3-5.6. At this time, it has only been approved for 2024 site visits. A site taking advantage of this alternative compliance pathway is expected to be fully compliant with Standards 5.3-5.6 at its next site visit. This option is not available for Standard 5.7 or 5.8 compliance.

If the program does not meet the compliance threshold for Standards 5.7 or 5.8 and is deemed noncompliant, the program must complete a random sample review of 10 reports eligible for the noncompliant standard to determine whether the synoptic elements and responses were met. The audit of the reports must be documented in the cancer committee minutes. The cancer committee should designate who should conduct the audit. The number of reports reviewed and the number of reports





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that were compliant must also be documented. If a program has less than 10 cases in this time period, the audit should include all applicable cases. The reports reviewed must be from procedures occurring after the period reviewed during the site visit. The outcome must meet the original threshold of compliance to resolve the standard. Additional information can be found on the <u>Timeline and</u> <u>Compliance Information</u> webpage.

What do I need to do to prepare for my next site visit? When do we need to start synoptic operative documentation?

In 2022, programs were required to document their final plan for implementing Standards 5.3–5.6 at their institution. Plans will be reviewed at site visits in 2023, 2024, and 2025. Sites were required to start synoptic operative documentation for compliance with Standards 5.3–5.6 on January 1, 2023. Assessment of operative reports will begin with site visits in 2024, which will review operative reports from 2023. The CSSP has developed an <u>Overview of Compliance Requirements & Site Visit Process</u> which further details compliance requirements for Standards 5.3–5.8 and the site visit process.

Can amended/addended reports meet the requirements of the CoC Operative Standards?

While not recommended, amended or addended operative reports can meet the requirements of Standards 5.3–5.6. Likewise, amended or addended pathology reports can meet the requirements of Standards 5.7 and 5.8; however, reports should only be corrected when the change will affect clinical care. All the required elements and responses must be included in the operative report of record.

Which date is used to determine case eligibility for the CoC Operative Standards?

The date of the operative report (for Standards 5.3 through 5.6) or pathology report (for Standards 5.7 and 5.8) is used to determine whether a case is eligible for review for one of the CoC Operative Standards.

If a surgeon does a resection that would otherwise be within the scope of these standards, but does not know it is cancer at the time of the resection, and the resection ends up being cancer, do the standards apply to this case?

If the cancer is unknown prior to surgery, then the case is not included in the scope of these standards.

What clinically determines when going into a surgery that the intent is curative?

Intent should be assigned postoperatively by the operating surgeon based on preoperative evaluation and intraoperative management.

Is an emergent non-oncology focused operation excluded from the category of curative intent? If the operating surgeon states that the operation was not conducted with curative intent, then the standard will not apply.

Is a procedure performed at an off-site surgery center expected to be in synoptic format?

If the off-site surgery center where the operation was performed is not part of your hospital's accreditation, then the standard would not apply to this case.



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Synoptic Reporting

What is a synoptic report?

A synoptic report is a document that has standardized data elements organized as a structured checklist or template. The value for each data element is "filled in" using a pre-specified format. The purpose of the synoptic report is to format information in a manner where information can be easily collected, stored, and retrieved. The CoC is not able to preapprove operative report formats. To meet the requirements of the CoC Operative Standards, the data elements and response options need to be the same as those listed in the standard. Please refer to the 2020 Standards manual to ensure compliance with these requirements.

Why is synoptic reporting important?

Synoptic reporting has repeatedly been shown to improve both the completeness and the accuracy of clinical documentation.^{1–23} Reporting accuracy and completeness is of particular importance in cancer care where multiple providers are involved in the care of a single patient and any omissions or inaccuracies in surgery or pathology reporting may adversely impact downstream decisions. It has also been shown to improve the ability for downstream functions such as registry extraction and compliance. While more long-term experience and critical assessment is available for synoptic pathology reports, there are also abundant reports showing the benefits of synoptic operative reports. The <u>Operative</u> <u>Standards Toolkit</u> includes a number of publications on synoptic operative reporting. We encourage programs to review these references and share with pertinent staff.

Is the use of routine phrases the same as a synoptic report?

In contrast to narrative reporting, synoptic reporting uses a checklist format—though synoptic reports may have data elements that allow for free form text to be entered. Routine narrative phrases are most used to reduce the burden of reporting in narrative format when an activity or description is the same from one surgery to the next, and typically consist of sentences copied into a narrative operative report. Such phrases may include information about routine placement of incisions or ports, or they may be used to repeat information that is also documented by anesthesia or nurse providers. Although synoptic reports can be constructed using "smart text" phrases, routine phrases used within a narrative report generally do not serve the same function, nor do they typically ensure that information unique to the patient is captured in a standardized format.

Is the synoptic operative report different from the synoptic pathology report?

¹ Eryigit Ö, van de Graaf FW, Lange JF. A Systematic Review on the Synoptic Operative Report Versus the Narrative Report in Surgery. *World J Surg.* 2019;43(9):2175-2185.

² Stogryn SE, Hardy K, Mullan MJ, Park J, Andrew C, Vergis A. Synoptic operative reporting: assessing the completeness, accuracy, reliability, and efficiency of synoptic reporting for Roux-en-Y gastric bypass. *Surg Endosc.* 2018;32(4):1729-1739.

³ Messenger DE, McLeod RS, Kirsch R. What impact has the introduction of a synoptic report for rectal cancer had on reporting outcomes for specialist gastrointestinal and nongastrointestinal pathologists? *Arch Pathol Lab Med*. 2011;135(11):1471-1475.





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The synoptic operative report documents details of a surgical procedure and is different from the synoptic pathology report, which collects pathologic information on specimens. Standards 5.3, 5.4, 5.5, and 5.6 require specific data elements/responses in synoptic format in the operative report. Standards 5.7 and 5.8 require specific data elements/responses in synoptic format in the pathology report.

Do the required elements and responses need to be in a separate note, or can these elements be baked into a standard descriptive operative report as a separate section as long as it meets the language and specifications?

The required elements and responses must be in the operative report of record. It can be part of your standard operative note or embedded into your narrative operative report, but the synoptic section must be distinct and have all the required elements/responses together in synoptic format. A uniform synoptic reporting format should be used by all surgeons at the facility.

Can the required synoptic information be in the immediate post-op note/brief op note and still be compliant?

To meet requirements for compliance, the synoptic elements/responses listed in CoC Standards 5.3-5.6 must be included in the operative report of record. If the brief op note is incorporated into the operative report at your institution, then this could be compliant, but this is not usually the case. If the brief op note is a separate entry in the EMR (as is usually the case), then this would not meet the requirement. The only exception to these requirements is for programs utilizing the fillable PDF option, which is intended as a stop gap measure for institutions who cannot otherwise meet these standards for January 2023 requirements. Additional information can be found on the <u>Implementation Options</u> webpage.

Are we only required to put the elements/responses that are listed in each standard in the updated 2020 Standards Manual into the operative report? Or is there more information required to be in the operative report?

To be compliant with CoC Standards 5.3–5.6, in addition to fulfilling the surgical/technical measures of compliance, the required elements and responses listed in the <u>2020 Standards</u> must be included in the operative note in synoptic format. No additional information is required to be in the operative note in synoptic format.

Can my program modify the elements/responses from Standards 5.3–5.6 for our operative reports?

To be found compliant with CoC Standards 5.3–5.6, operative reports must use the exact wording as the data elements and responses listed in the 2020 Standards. However, programs may include additional data elements and responses in synoptic format in the operative report as desired. These additional data elements would not impact compliance.

Can our program include all the required elements in a narrative report and be compliant? Can the required elements/responses be dictated?

All required elements/responses must be recorded in the operative report in synoptic format. All core elements must be reported (whether applicable or not). All core elements must be reported in a





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"diagnostic parameter pair" format, in other words, data element followed by response (answer). Each diagnostic parameter must be listed on a separate line or in a tabular format to achieve visual separation. All core elements must be listed together in one location in the operative or pathology report. Operative reports may be dictated if all CoC required elements and responses are incorporated into the operative report of record and they are arranged into a synoptic format after they are dictated.

On the day of the site visit, how will the site reviewer review the operative reports?

Operative and pathology reports may either be uploaded to a secure, HIPAA-compliant platform provided by the program OR a HIPAA-secure videoconference may be set up during which the program navigates through the required components of the medical record for each case selected by the site reviewer. Note: Pathology and/or operative reports cannot be uploaded into the Quality Portal (QPort). Medical record information must be uploaded to a HIPAA-secure platform. Review the <u>2024 Site Visit</u> Instructions and Sample Agenda document for further information.

If my institution's EMR has a character limit on data elements/responses, are we able to shorten them and still be compliant with Standards 5.3–5.6?

If your EMR has a character limit, your institution can abbreviate the element and/or responses. However, the original language of the standard should be replicated as closely as possible. This modification is only permitted if your EMR has these limitations, and we recommend a more comprehensive synoptic reporting tool in the long run.

Other

What other cancer operations will be added to the operative standards in the future?

For now, the focus is on Standards 5.3–5.8 and ensuring that CoC sites have the resources they need to be compliant with the existing standards. However, beginning in 2026, the CoC will be working towards implementing expanded requirements for synoptic operative reporting with the goal of transitioning to full synoptic operative reports. Additional cancer features in synoptic format will likely be required, along with currently required elements/responses. In the coming years new operative standards will be implemented for disease sites not already represented in the CoC standards for accreditation.

Standard 5.3 – Sentinel Node Biopsy for Breast Cancer Standard 5.4 – Axillary Lymph Node Dissection for Breast Cancer

Do Standards 5.3 and 5.4 include all histologies for breast cancer (e.g., infiltrating ductal, lobular, inflammatory etc.)?

CoC Standards 5.3 and 5.4 apply to all cases with breast cancer where a sentinel lymph node surgery or axillary lymph node dissection is performed.

Does a case that falls within the scope of both 5.3 and 5.4 need to have synoptic operative reports for both?



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Both Standard 5.3 and 5.4 require specific data elements/responses in synoptic format in the operative report. If axillary nodal surgery (SLN or ALND) is not performed and if nodes are not removed, CoC Standards 5.3 or 5.4 do not apply.

Will both blue and radioactive SLN be required for compliance with Standard 5.3?

Dual tracer is not required by Standard 5.3 to remove all sentinel nodes. However, the most accurate method employs a dual tracer technique.

Are programs able to modify the drop-down menu to specify "Lymphozurin/ Nethylene Blue" instead of "Dye" and maintain compliance?

To be compliant with the standard, the required data elements and the response options need to be the same as in the CoC Standard. Your program is welcome to add more synoptic data elements and responses if you would like to capture this information in your operative reports.

Does Standard 5.3 require that patients who have undergone neoadjuvant chemotherapy and clip placement have the clipped node removed?

Standard 5.3 does not require the clipped node to be removed. To achieve compliance, the documentation will need to include whether the clipped node was removed or was not removed.

Do Standards 5.3 and 5.4 apply to DCIS cases?

Yes, CoC Standards 5.3 and 5.4 apply for procedures done for DCIS.

What are the requirements for Standards 5.3 and 5.4 in cases of bilateral breast cancer?

In cases of bilateral breast cancer, the synoptic elements and responses should be completed for each side. Each side should be clearly labeled as right or left.

If a positive node is found on frozen section during the sentinel node procedure and an axillary dissection is performed, do the required elements/responses for sentinel node biopsy and axillary dissection need to be included in the operative report?

Yes, if both procedures fall within the scope of the standards, the requirements for both Standard 5.3 and 5.4 would apply.

Does a targeted axillary dissection, defined as removal of a target/clipped node plus a sentinel lymph node biopsy, fall within Standard 5.4?

Target axillary dissections would be included as part of Standard 5.3 (Sentinel Node Biopsy for Breast Cancer) and not for Standard 5.4 (Axillary Lymph Node Dissection for Breast Cancer).

Does a case qualify if the path report shows DCIS and no residual, but sentinel LN biopsy was performed?

Standard 5.3 applies to all cases of breast cancer where a sentinel lymph node surgery was performed, including procedures done for DCIS.





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Standard 5.5 – Wide Local Excision for Primary Cutaneous Melanoma

If a surgeon takes a margin wider than recommended in Standard 5.5, is this a problem or issue with compliance? For example, a tumor with a 0.6mm Breslow thickness having a 2cm inked/excised margin when the standard only recommends 1cm margin.

As indicated in the Measure of Compliance for Standard 5.5, clinical margin width for wide local excision should be 1 cm for invasive melanomas less than or equal to 1 mm in thickness. A 2 cm margin would therefore not fulfill this requirement. Overtreatment should be avoided and, in the rare situation when deviation from the standard is judged to be the best option for care, we encourage the surgeon to document why a wider margin was chosen, e.g., presence of satellite lesions. However, margins wider than those set by Standard 5.5 are not compliant. The threshold compliance rate is less than 100% to account for these exceptions.

Regarding melanoma in-situ cases, the NCCN guidelines have a range for the recommended clinical margins from 5 to 10 mm whereas CoC Standard 5.5 simply says, "at least 5 mm". Can margins be of any size and still fulfill the requirements of Standard 5.5?

There is no deficiency for having too large of a margin for melanoma in-situ. However, evidence-based recommendations would not recommend a gross margin at the time of resection over 1cm.

What do we do when a dermatologist has done a shave biopsy on melanoma?

The definitive surgical resection margin is the goal of Standard 5.5 and is based upon the Breslow depth of the biopsy, even if it is a shave biopsy.

What if the depth of melanoma was deeper on the final pathology than on the initial biopsy diagnosing the melanoma regarding the wide local excision margin?

Standard 5.5 sets margins for wide local excision based on the Breslow thickness of the primary tumor as indicated on the initial biopsy pathology report. The CoC revised the language of Standard 5.5 in early 2021 to clarify this definition.

Will wide local excisions performed by a dermatologist or plastic surgeon in offices located on our CoC hospital's campus be within the scope of Standard 5.5?

We recommend identifying whether the office location in question is included in your accredited hospital's Tax ID. If the office where the WLE was performed is included in your hospital's accreditation, and the case would be submitted for your hospital's analytic caseload, then the WLE would be included in the scope of Standard 5.5. This is regardless of who is performing the procedure.

Does Standard 5.5 apply to Mohs technique?

No, Standard 5.5 does not apply to Mohs Technique as Mohs is not a wide local excision. Standard 5.5 applies to patients with a diagnosis of invasive melanoma or melanoma in situ who undergo a wide local excision with curative intent.

When a surgeon is performing reoperation for involved/close margins of a melanoma already treated with wide local excision prior to referral, does Standard 5.5 apply?





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No, Standard 5.5 only applies to the first wide local excision performed with curative intent after diagnostic excisional biopsy. Repeat wide local excisions performed for involved/close margins are outside the scope of Standard 5.5. However, this is distinct from performing a wide local excision after a diagnostic excisional biopsy, which is the index operation for Standard 5.5.

Are synoptic elements required for all definitive melanoma procedures including repeat excisions for close margins? Or only the index procedure?

Repeat wide local excisions being performed for involved/close margins are outside of the scope of Standard 5.5.

Standard 5.6 – Colon Resection

How are colectomies performed on an emergent basis measured and tracked? How does this standard apply to truly emergent operations for obstruction?

Standard 5.6 applies to "all resections performed with curative intent for patients with colon cancer and applies to all approaches." An indication for emergent surgery, (e.g., obstruction) does not necessarily preclude the performance of proximal vascular ligation and en bloc lymphadenectomy. If the high ligation cannot be performed due to an "emergency situation", then it should be documented in the operative note.

Are rectosigmoid tumors included within the scope of Standard 5.6?

Yes, rectosigmoid tumors are included within the scope of Standard 5.6.

Do two colon primaries require two synoptic reports (if the surgery is at the same time)?

If the surgeon performs one resection with two primary tumors, the synoptic elements and responses should be completed once (response options allow "select all that apply"). If two resections are performed for two primary tumors, the synoptic elements and responses should be completed for each resection.

For the "Extent of colon and vascular resection" data element required for Standard 5.6, what should be documented if the resection that was performed does not correlate with any of the options listed?

The focus of Standard 5.6 is on the proximal vascular ligation at the origin of the primary feeding vessel(s). Surgeons can use the "Other" response option any time the resection is not one of those described by the other listed response options and describe the extent of the colon and vascular resection as part of their explanation.

If a neuroendocrine tumor occurs in the colon, does Standard 5.6 apply?

Standard 5.6 applies to adenocarcinomas, not neuroendocrine tumors.

How will the registrar know whether a resected colon cancer case was performed with curative intent or not?





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The curative intent synoptic data item is included in the required elements/ responses for Standard 5.6 to assist with identifying eligible cases. If a case is performed with curative intent, then the "Operation performed with curative intent" item needs to be present. If a case is not performed with curative intent, then that operative report would not be assessed for compliance with Standard 5.6 and therefore the responses/ elements for Standard 5.6 do not need to be included. As such, it is up to your institution if/how you want to implement these data elements for cases that are not for curative intent.

Standard 5.7 – Total Mesorectal Excision

How will mid and low rectal cancer cases be selected for compliance with Standard 5.7? Will all rectal cancer cases need to be provided?

Programs will provide an accession list of all eligible rectal cancer patients that underwent surgery during the period being reviewed. The site reviewer will preselect 7 cases for review. If any of the cases selected were for cancer in the high rectum, the program will notify the site reviewer to select additional cases so that only mid and low cancers are reviewed.

How can a registrar tell if the rectal tumor location is low to mid since rectum only has one primary code site? Does the CAP pathology report have a field for tumor location?

This information can be found in the NAPRC synoptic reports (if applicable) or in the CAP pathology report. In the NAPRC synoptic report, the "Location of tumor within rectum" data element will specify high, middle, or low. In the CAP pathology report, a response of "Entirely above anterior peritoneal reflection" to the "Rectal Tumor Location" data element indicates a high rectal tumor response.

If we follow the CAP protocol for all our cases, should our program be at 100% compliance with Standard 5.7?

CoC-accredited programs must meet ALL of the measures of compliance under Standard 5.7 for 70% of cases starting January 2021 in order to be compliant with the standard. If for every mid and low rectal cancer case the CAP report is accurately documented, most of the standard is met. The standard does mandate that the specimen be "complete" or "near-complete", so there is a technical component based on the surgeon's quality of dissection.

Will there be certain fields that the surgeons must complete as well, or is only the pathology report assessed for this standard?

Surgeons will not have fields to complete on the CAP report. The quality of their submitted specimen, as graded by the pathologist on the CAP report, is the main contribution of the surgeon. We also encourage communication amongst surgeons, pathologists, and registrars to optimize documentation for appropriate cases. Intent should be assigned postoperatively by the operating surgeon on the basis of preoperative evaluation and intraoperative management and should be clearly documented in the operative report for any operation covered by these standards.

When there is no residual tumor in a neoadjuvant specimen and synoptic reporting is not required by CAP, how should this situation be handled?





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The CoC revised Standard 5.7 in early 2021 to align with the CAP cancer protocol template for rectal cancer resections. The revisions show that Standard 5.7 does not apply to primary resection specimens with no residual cancer (e.g., following neoadjuvant therapy).

Does Standard 5.7 apply to in situ lesions?

No, in situ lesions are excluded from Standard 5.7.

The pathology report for the resection stated that mesorectal excision was incomplete. In the operative report, the surgeon was aware of and intending to perform a TME, however, upon pathologic review it was incomplete. Would the surgeon's intent be taken into consideration for compliance with this standard?

While the surgeon is encouraged to document the integrity of the mesorectum in their operative report, the pathologist must grade the mesorectum independently from the surgeon and only the synoptic pathology report will be assessed when determining compliance for Standard 5.7. As such, the case would be found non-compliant due to incomplete TME.

If a surgeon performs radical procedure on a rectal cancer but records in the synoptic op template: Curative Intent: "no", is the case excluded from review regardless of the results of TME in the pathology synoptic comment?

If the surgeon states that the surgery was not conducted with curative intent, then the standard will not apply.

Is there a plan to add a surgical technical component or requirement for this standard?

Standard 5.7 does not include documentation requirements for operative reports. To fulfill the compliance criteria for Standard 5.7, a complete or near complete total mesorectal excision (TME) must be performed for all patients undergoing radical surgical resection of mid and low rectal cancers. Therefore, the operation must be done as outlined in the standard. In addition, pathology reports following curative resections of rectal adenocarcinoma must include the quality of the TME resection (complete, near complete, or incomplete) in synoptic format as per the College of American Pathologists (CAP) cancer protocol template for rectal cancer resections. We also encourage communication amongst surgeons, pathologists, and registrars to optimize documentation for appropriate cases. Intent should be assigned postoperatively by the operating surgeon on the basis of preoperative evaluation and intraoperative management and should be clearly documented in the operative report for any operation covered by these standards.

Standard 5.8 – Pulmonary Resection

If a mediastinoscopy/EBUS is performed prior to the curative resection, can these procedures qualify for Standard 5.8, and do they have to be included within the curative resection pathology report or can they remain in a separate report to qualify?

As endobronchial ultrasound (EBUS) does not remove nodes, those nodes do not count toward the requirements of Standard 5.8. Nodes biopsied during EBUS should be removed at surgery as additional confirmation of benign versus malignant pathology.





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Nodes from mediastinoscopy must be included on the same pathology report as the lung resection to count toward the requirements of Standard 5.8. If nodes are sampled at the time of mediastinoscopy performed at a separate operation on a separate day prior to surgery, then those nodes would satisfy the requirement only if documented within the pathology report from the curative intent operation. It is recommended that when pathologists complete the CAP synoptic pathology report for the lung resection, they should also include mediastinal nodal histology results from any other setting. Nodal station must be identified. EBUS cytology alone does not comply with the standard. In general, the surgeon should always strive to obtain lymph nodes from at least one hilar station and at least three distinct mediastinal stations. However, we recognize that there may be infrequent clinical situations in which the standard is not able to be achieved, which is why the threshold compliance rate is less than 100%.

Do hilar nodes evaluated in the lobe with hilar nodes count as N1?

Yes (which encourages pathology to do due diligence in their specimen dissection). Surgeons should not rely solely upon hilar nodes being found by their pathology colleagues and should conduct interlobar hilar nodal dissection as well (levels 10 and 11).

Is needle biopsy with EBUS equivalent to removal or sampling of the nodes?

Rarely, if ever, would EBUS be performed at the same setting as curative intent pulmonary resection because one cannot accurately rely upon needle specimen assessment with ROSE (rapid on-site evaluation) to change management in the minutes prior to moving on to major surgery. Furthermore, a negative EBUS assessment of a lymph node does not satisfy the requirement for surgical lymph node harvesting at the time of surgery (EBUS and mediastinoscopy always carry a risk of false negative sampling). This is, in fact, a specific intent of Standard 5.8; surgical lymph node harvesting minimizes the risk of false negatives by confirming nodes are truly benign or are in fact malignant despite preoperative clinical staging efforts.

If the 2R and 4R packet is sent together, does this count as one N2 or two N2?

The packet should be separated and labeled appropriately if the surgeon believes the nodes have been harvested from two separate lymph node stations (i.e., separate the 2R portion from the 4R portion if possible, and label accordingly). If the surgeon ultimately obtains mediastinal lymph nodes from at least 2 other stations (7, 8R, or 9R) then the point is moot given the goal of harvesting at least 3 different mediastinal nodal stations has been accomplished. The surgeon must take responsibility for appropriately and specifically labeling lymph nodes.

If you send a fat pad from a station and label it but no nodes are found, does this count or not count as an N2 node?

This will not satisfy the requirement for harvesting an N2 lymph node but is a realistic occurrence during these operations (one cannot always know for sure if a lymph node exists within a particular fat pad). Occasionally, lymph nodes will not be present or safely accessible during the conduct of an operation. The threshold compliance rate is less than 100% to take this infrequent occurrence into consideration. Surgeons should ideally document where they looked to harvest nodes, even if none were found in a



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particular station, to provide clarity to the extent of thoroughness during the surgery (e.g., "no lymph nodes were visible within the level 9L inferior pulmonary ligament station despite thorough dissection").

A pathologist-dissected intrapulmonary node is quite different than a surgeon-dissected hilar node from a surgical quality metric. Can you confirm whether the pathologist-dissected intrapulmonary node satisfies the requirement?

Yes, nodes dissected out from the primary lung specimen by the pathologist count as hilar lymph nodes for Standard 5.8. Ideally, however, the surgeon would obtain additional nodes from levels 10 and 11.

What is the recommendation for situations where the surgeon is unable to remove nodes? Are there any expectations to the standard?

We have set the threshold of compliance at 70% in the first year, and 80% in subsequent years, to account for the inevitable and infrequent clinical situations in which the standard is not able to be achieved. Surgeons should always document when/why they could not obtain more lymph nodes.

Will a fully completed CAP Pathology Checklist serve as compliance for 5.8? Are all the critical data elements in the CAP report?

Programs must meet ALL measures of compliance under Standard 5.8 to satisfy the standard. This includes the surgical removal of the lymph nodes from the specific nodal stations listed in the standard.

Do nodes all need to be listed on separate lines in the synoptic report?

Select all that apply answers can all be on the same line and be compliant. Multi-select questions and answers with a comma or a semicolon can be on the same line if they are all selected answers from the same question. All core elements must be reported in a "diagnostic parameter pair" format, in other words, data element followed by response (answer). Each diagnostic parameter must be listed on a separate line or in a tabular format to achieve visual separation. All core elements must be listed together in one location in the operative or pathology report.

What is the rationale for the Standard? How was Standard 5.8 determined?

Please refer to the Operative Standards Toolkit (<u>Operative Standards Toolkit | ACS (facs.org</u>) and specifically the section on Standard 5.8. <u>The Society of Thoracic Surgeons Webinar on CoC Standard</u> 5.8, "Understanding and Implementing the New CoC Lung Cancer Standards (April 28, 2022)," provides the background and rationale for the standard.