**Overview of Compliance Requirements & Site Visit Process for the CoC Operative Standards (5.3 through 5.8)**

The Scope of Standard and Measure of Compliance for each standard can be found in the *Optimal Resources for Cancer Care (2020 Standards)*.

Table 1. Summary of CoC Operative Standards

| Number | Standard Name | Documentation Assessed | Date Implemented |
|---|---|---|---|
| 5.3 | Sentinel Node Biopsy for Breast Cancer | Operative reports | January 1, 2023 |
| 5.4 | Axillary Lymph Node Dissection for Breast Cancer | Operative reports | January 1, 2023 |
| 5.5 | Wide Local Excision for Primary Cutaneous Melanoma | Operative reports | January 1, 2023 |
| 5.6 | Colon Resection | Operative reports | January 1, 2023 |
| 5.7 | Total Mesorectal Excision | Pathology reports | January 1, 2021 |
| 5.8 | Pulmonary Resection | Pathology reports | January 1, 2021 |

**Implementation and Site Visits for the CoC Operative Standards**

- Standards 5.3 through 5.6 will be implemented at CoC-accredited programs in a phased approach with full implementation beginning January 1, 2023. Standards 5.7 and 5.8 took effect on January 1, 2021. See Table 1.
    - Threshold compliance levels begin at 70% for the first year of site visits and will increase to 80% for following years (see Table 2).
    - Since these standards are being phased in, some programs will have charts from only the previous 1 or 2 years assessed at their site visit. For example, the 2022 site visit will only assess pathology reports from 2021. Eventually, all programs will be assessed on 3 years of charts during each site visit.
- Site reviewers will assess 7 charts for each standard (7 charts × 6 standards → 42 charts total) from the specified time duration (1, 2, or 3 years) for compliance (see Table 2).
    - 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 time frame will be reviewed by the site reviewer. For these programs, the threshold compliance level will be 70% for charts assessed at 2022 site visits and will increase to 100% starting with charts assessed at 2023 site visits.
    - If a program has no charts within the scope of a specific standard, they are exempt from that standard.
    - There is no adjustment to these requirements (e.g., reduced number of charts assessed) for new CoC programs.
- 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 within it would have 70 reports reviewed (7 reports for each hospital within the network) per standard. 49 of the 70 charts assessed would need to meet all criteria to achieve 70% compliance for that standard.
- The site reviewer may choose to include a portion of the 14 charts reviewed for Standards 5.7 and 5.8 in the sample to determine compliance with Standard 5.1 (CAP Synoptic Reporting).

Table 2. What will be assessed at site visits each year?

| Visit Year | Standard | Materials Assessed | Requirement |
|---|---|---|---|
| **2022** | 5.3-5.6 | No requirements for this site visit year. | N/A |
| | 5.7 | 7 rectal pathology reports from 2021 | 70% compliance |
| | 5.8 | 7 lung pathology reports from 2021 | 70% compliance |
| **2023** | 5.3-5.6 | Implementation plan for Standards 5.3-5.6 | Plan documented in 2022 |
| | 5.7 | 7 rectal pathology reports from 2021-2022 | 80% compliance |
| | 5.8 | 7 lung pathology reports from 2021-2022 | 80% compliance |
| **2024** | 5.3-5.6 | Implementation plan for Standards 5.3-5.6 | Plan documented in 2022 |
| | 5.3 | 7 breast SLNB operative reports from 2023 | 70% compliance |
| | 5.4 | 7 breast ALND operative reports from 2023 | 70% compliance |
| | 5.5 | 7 melanoma operative reports from 2023 | 70% compliance |
| | 5.6 | 7 colon operative reports from 2023 | 70% compliance |
| | 5.7 | 7 rectal pathology reports from 2021-2023 | 80% compliance |
| | 5.8 | 7 lung pathology reports from 2021-2023 | 80% compliance |
| **2025** | 5.3-5.6 | Implementation plan for Standards 5.3-5.6 | Plan documented in 2022 |
| | 5.3 | 7 breast SLNB operative reports from 2023-2024 | 80% compliance |
| | 5.4 | 7 breast ALND operative reports from 2023-2024 | 80% compliance |
| | 5.5 | 7 melanoma operative reports from 2023-2024 | 80% compliance |
| | 5.6 | 7 colon operative reports from 2023-2024 | 80% compliance |
| | 5.7 | 7 rectal pathology reports from 2022-2024 | 80% compliance |
| | 5.8 | 7 lung pathology reports from 2022-2024 | 80% compliance |

**Site Visit Process for Standards 5.7 (Total Mesorectal Excision) & 5.8 (Pulmonary Resection)**

1. In preparation for their site visit, programs will generate a list of all the cases from the specified years that are eligible for Standard 5.1 (CAP Synoptic Reporting), which will include rectal and lung cases eligible for Standard 5.7 and 5.8.
2. The site reviewer will select 7 rectal cancer cases to assess for compliance with Standard 5.7 and 7 lung cancer cases to assess for compliance with Standard 5.8.
    a. The program will need to determine whether the cases selected were performed with curative intent. If any of the selected cases were NOT performed with curative intent, the program will need to inform the site reviewer so that other cases may be selected instead. The site reviewer may ask programs to elaborate on why specific cases cannot be reviewed.
    b. For Standard 5.7 (TME), the program will need to determine whether the rectal cases selected were mid/low rectal tumors. This information can be found in the NAPRC synoptic reports (if applicable) or in the CAP pathology report. See Table 3.
3. The site reviewer will confirm whether all measures of compliance have been met for each case being assessed (see Table 4 below).
4. The site reviewer will select a rating for each standard (Compliant, Noncompliant, or Not Applicable) based on whether the threshold compliance level has been met for the standard.

Table 3. Determination of tumor height for Standard 5.7.

| | NAPRC Synoptic Report[a] | CAP Pathology Report[b] |
|---|---|---|
| **Data element name** | Location of tumor within rectum | Rectal Tumor Location |
| **"High" rectal tumor response** | High | Entirely above anterior peritoneal reflection |
| **"Mid" rectal tumor response** | Middle | Straddles anterior peritoneal reflection |
| **"Low" rectal tumor response** | Low | Entirely below anterior peritoneal reflection |

[a] From the National Accreditation Program for Rectal Cancer (NAPRC) *Optimal Resources for Rectal Cancer Care (2020 Standards)*.

[b] From the College of American Pathologists (CAP) Protocol for the Examination of Resection Specimens from Patients with Primary Carcinoma of the Colon and Rectum, Version 4.2.0.1.

**What if a program is deemed non-compliant with Standard 5.7 and/or 5.8?**

- If a program does not meet the compliance threshold, the program must complete a random sample review of 10 pathology reports eligible for the noncompliant standard to determine whether the synoptic reporting format and technical requirements were met.
- The cancer committee should designate who should conduct the audit.
- The review must be documented in the cancer committee minutes. The number of reports reviewed and the number that were compliant is documented. The outcome must meet the 70% threshold of compliance to resolve the standard.
- The pathology reports reviewed for the deficiency resolution must be from procedures occurring after the period reviewed during the site visit.

**Site Review Process for Standards 5.3 through 5.6**

- In 2022, CoC-accredited programs will need to document their final plan for how they will meet the requirements of Standards 5.3, 5.4, 5.5 and 5.6 starting on January 1, 2023. This documentation will be reviewed at site visits in 2023, 2024, and 2025. Guidelines for development of these final plans can be found in the Operative Standards Toolkit.
- Starting with site visits in 2024, site reviewers will assess 7 operative reports for each standard. Each report must meet both the technical *and* documentation requirements for the standard to be found compliant.
- Additional details on requirements for 2024 site visits for Standards 5.3 through 5.6 will be shared in the near future.

**Compliance Requirements for the CoC Operative Standards**

- For Standards 5.3 through 5.6, the required synoptic elements and responses must be in the operative report of record. They cannot be in the brief op note. The only exception is if the fillable PDF forms developed by the CSSP (available in the Standards Resource Library) are used.
- While not recommended, amended or addended operative reports can meet the requirements of Standards 5.3 through 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.

- There are currently no requirements for how the synoptic portions of operative/pathology reports are created, as long as the elements and responses that are required by the standard are present in synoptic format.
- While a uniform reporting format *should* be used by all surgeons at the facility, this is not a requirement for compliance at this time.
- For Standard 5.7, the quality of the TME resection must be reported using the "Macroscopic Evaluation of Mesorectum" data element in the CAP protocol for Colon and Rectum Resection, and only "Complete", "Near complete", "Incomplete", "Not applicable", and "Cannot be determined" are valid responses to the element component. It should be noted that "Incomplete" and "Cannot be determined" would be rated as non-compliant by the site surveyor. A "Not applicable" response would indicate that a different case should be chosen by the site reviewer. In addition, "Partially complete", "Ulcerated" or other variations of wording would not be acceptable.

Table 4. Measures of Compliance for CoC Operative Standards[a]

| Standard | Technical Requirement | Synoptic Requirement |
|---|---|---|
| 5.3 | All sentinel nodes for breast cancer are identified using tracers or palpation, removed, and subjected to pathologic analysis. | Operative reports for sentinel node biopsies for breast cancer document the required elements in synoptic format. |
| 5.4 | Axillary lymph node dissections for breast cancer include removal of Level I and II lymph nodes within an anatomic triangle comprised of the axillary vein, chest wall (serratus anterior), and latissimus dorsi, with preservation of the main nerves in the axilla. | Operative reports for axillary lymph node dissections for breast cancer document the required elements in synoptic format. |
| 5.5 | Wide local excisions for melanoma include the skin and all underlying subcutaneous tissue down to the fascia (for invasive melanoma) or the skin and the superficial subcutaneous fat (for in situ disease). Clinical margin width is selected based on original Breslow thickness *(see Standard 5.5).* | Operative reports for wide local excisions of primary cutaneous melanomas document the required elements in synoptic format. |
| 5.6 | Resection of the tumor-bearing bowel segment and complete lymphadenectomy is performed en bloc with proximal vascular ligation at the origin of the primary feeding vessel(s). | Operative reports for resections for colon cancer document the required elements in synoptic format. |
| 5.7 | Total mesorectal excision is performed for patients undergoing radical surgical resections of mid and low rectal cancers, resulting in complete or near-complete total mesorectal excision. | Pathology reports for resections of rectal adenocarcinoma document the quality of TME resection (complete, near complete, or incomplete) in synoptic format. |
| 5.8 | Pulmonary resections for primary lung malignancy include lymph nodes from at least one (named and/or numbered) hilar station and at least three distinct (named and/or numbered) mediastinal stations. | Pathology reports for curative pulmonary resection document the nodal stations examined by the pathologist in synoptic format. |

[a] From the Commission on Cancer (CoC) *Optimal Resources for Cancer Care (2020 Standards)*.