North American Association of Central Cancer Registries, Inc. (NAACCR)

2016 Implementation Guidelines and Recommendations

(For NAACCR Standards Volume II, Data Standards and Data Dictionary, Version 16, effective with cases diagnosed on or after January 1, 2016)

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1 Introduction

The North American Association of Central Cancer Registries, Inc. (NAACCR), has been working with the American College of Surgeons (ACoS) Commission on Cancer (CoC), National Cancer Institute (NCI) Surveillance Epidemiology and End Results (SEER) Program, Centers for Disease Control and Prevention (CDC) National Program of Cancer Registries (NPCR), Canadian Council of Cancer Registries (CCCR), central cancer registries, and cancer registry software vendors to develop an implementation plan for NAACCR Standards for Cancer Registries Volume II, Data Standards and Data Dictionary Version 16 (Standards Volume II, Version 16). The 2016 data standards have been developed in response to requested revisions from a broad set of constituents. Data Transmission standards should be consistently maintained among all hospital and central cancer registries and should be implemented in a planned and timely manner. Changes to the set of standards have potential consequences, and implementation must be evaluated by each program, central cancer registry, software vendor, and reporting facility during the planning process. Delays in implementation may result in inconsistent data collection.

Effective with Standards Volume II, Version 16, there are several new geocoding data items. Most significantly, there are numerous changes and many new data items associated with the transition from the Collaborative Stage System to collection of directly-assigned staging components. Since requirements associated with the staging component data items vary by standard setter, it is important for all users of this document to be knowledgeable regarding the distinctions. Most of these changes, including all definitions of the new items and modifications in the column assignments are specified in Version 16: http://www.naaccr.org/StandardsandRegistryOperations/VolumeII.aspx.

2 New Data Items

Four new County at DX Geocode data items [94-97] were introduced in order to identify an address's geocode relative to each given decennial census. This is necessary because for some states and counties there have been changes to county boundaries, and therefore county of some particular addresses, over time. Appropriate county-census tract combinations are important for deriving census-related socioeconomic factors, such as poverty indicators.

The RuralUrban Continuum 2013 [3312] captures the population size and degree of urbanization by county to aide researchers when investigating how proximity to metropolitan areas and urbanization correlate to the burden of cancer. This data item is derived electronically and should not be entered by an abstractor.

The data items listed below have been introduced as part of the staging transition and data collection requirements that vary among standard setters (see section 6 for more details):

- Six Mets at DX data items [1112-1117]
- Three Tumor Size data items [752-754]
- Eleven derived TNM data items [3605, 3610, 3614, 1616, 1618, 3620, 3622, 3624, 3626. 3650, 3655]

Standards Volume II, Version 16			
New Data Items			
Data Item Name	Item#	Column	Source of Standard
County at DX Geocode 1990	94	464-466	NAACCR
County at DX Geocode 2000	95	467-469	NAACCR
County at DX Geocode 2010	96	470-472	NAACCR
County at DX Geocode 2020	97	473-475	NAACCR
RuralUrban Continuum 2013	3312	476-477	NAACCR
Mets at DX-Bone	1112	838-838	SEER
Mets at DX-Brain	1113	839-839	SEER
Mets at DX-Distant LN	1114	840-840	SEER
Mets at DX-Liver	1115	841-841	SEER
Mets at DX-Lung	1116	842-842	SEER
Mets at DX-Other	1117	843-843	SEER
Tumor Size Clinical	752	844-846	SEER
Tumor Size Pathologic	754	847-849	SEER
Tumor Size Summary	756	850-852	NPCR/CoC
Derived SEER Path Stg Grp	3605	853-857	SEER
Derived SEER Clin Stg Grp	3610	858-862	SEER
Derived SEER Cmb Stg Grp	3614	863-867	SEER
Derived SEER Combined T	3616	868-872	SEER
Derived SEER Combined N	3618	873-877	SEER
Derived SEER Combined M	3620	878-882	SEER
Derived SEER Cmb T Src	3622	883-883	SEER
Derived SEER Cmb N Src	3624	884-884	SEER
Derived SEER Cmb M Src	3626	885-885	SEER
SEER Primary Tumor*	772	886-888	SEER
SEER Regional Nodes*	774	889-891	SEER
SEER Mets*	776	892-893	SEER
Derived SS2017*	762	894-894	SEER
Directly Assigned SS2017*	764	895-895	SEER
NPCR Derived Clin Stg Grp	3650	896-899	NPCR
NPCR Derived Path Stg Grp	3655	900-903	NPCR

^{*}These new data items will not be collected for 2016.

3 Changed Data Items

3.1 Record Layout Changes

The overall record layout remains the same length. Column spaces for some of the data items have been moved in the record layout in order to accommodate the new data items and expanded length of the TNM Clin Staged By and TNM Path Staged By data items, see section 3.5.

In the Demographic section the length of Reserved 02 changed to 50 characters to accommodate the addition of the new data items County at DX Geocode 1990, 2000, 2010 and 2020 and the RuralUrban Continuum 2013.

In the Hospital Specific section, the length of Reserved 04 changed to 30 characters to accommodate the new staging data items and the relocation of TNM Path Staged By and TNM Clin Staged By to the beginning of the Stage/Prognostic Factors section. Reserved 19 and Reserved 20 were added to the layout where the TNM Staged By data items were previously located.

3.2 Addition of Clinical and Pathologic Indicators to AJCC T, N, and M

Clinical and pathologic indicators are being added to six of the AJCC T, N, and M data items [940, 950, 960, 880, 890, and 900]. The indicators are to be added by modifying the existing values for the individual T, N, and M data items. The revisions will be incorporated into software look ups to allow for selection of necessary 'p' values within the clinical codes and selection of necessary 'c' values within the pathologic codes when abstracting. See section 4.2 and Appendix C for complete details.

3.3 Sex [220]

The word hermaphrodite formerly classified under code 3 in Sex is an outdated term. The definition was updated to code 3 Other (intersex, disorders of sexual development/DSD).

3.4 Census Ind Code 2010 [272] and Census Occ Code 2010 [282]

The Census Ind Code 2010 and Census Occ Code 2010 were renamed to Census Ind Code 2010 CDC and Census Occ Code 2010 CDC. "Blank" has been added as an allowable value for both data items when coding has not been attempted. Alternative names were added for each field, along with revisions to the Description, Rationale, and Coding Instruction to clarify that the field uses NIOSH non-paid worker codes in addition to U.S. Census Bureau codes to improve consistency of data for research use.

3.5 TNM Path Staged By [930] and TNM Clin Staged By [990]

The length of both Staged By data items has been expanded to 2 digits to accommodate new codes.

Refer to the most recent version of *FORDS* for additional coding instructions. See <u>Appendix A</u> for the conversion crosswalk from the 1 character codes to the expanded 2 character codes.

Codes

- 00 Not staged
- 10 Physician, NOS, or physician type not specified in codes 11-15
- 11 Surgeon
- 12 Radiation Oncologist
- 13 Medical Oncologist
- 14 Pathologist
- 15 Multiple Physicians; tumor board, etc.
- 20 Cancer registrar
- 30 Cancer registrar and physician
- 40 Nurse, physician assistant, or other non-physician medical staff
- 50 Staging assigned at another facility
- 60 Staging by Central Registry
- 88 Case is not eligible for staging
- 99 Staged but unknown who assigned stage

3.6 Wording changes to accommodate EHR reporting

The data items listed in <u>Appendix B</u> were updated to harmonize Standards Volume II, Version 16 with data coming in from electronic health record (EHR) reporting. For example, in the description and/or rationale for many of these data items, reference to "hospital" was replaced with "reporting facility".

3.7 SEER Coding Sys-Current and Original [2120 and 2130]

Code G was added for the use of the 2016 SEER Coding Manual.

4 Other Changes

4.1 Staging Transition

This section provides a brief summary of the staging transition efforts. See <u>section 6</u>, Standard Setters Reporting Requirements for 2016, for detailed information and requirements.

The Collaborative Stage Transition Newsletter provides communications from the standard setters regarding the transition from Collaborative Stage. The following is a link to the newsletters: http://seer.cancer.gov/registrars/cs-tnm/.

CCCR: Canada will continue to use the Collaborative Stage Data Collection System Version 02.05 to stage their new cases until the end of the 2016 diagnosis year.

CoC: The CoC's transition away from use of Collaborative Stage includes the requirement of AJCC clinical and pathologic stage (enforced via edits), SEER Summary Stage 2000, and new Tumor Size Summary and Mets at Diagnosis data items. The CoC will continue to use the Collaborative Stage Data Collection System Version 02.05 for cases diagnosed 2004-2015, and only for the collection of Site-specific Factors (SSF) for cases diagnosed 1/1/2016 and forward. The CoC has made no changes to their SSF requirements. In addition to the SSFs, Regional Nodes Positive and Examined and Lymph-vascular Invasion will continue to be required. All other CS input data items are no longer required.

CDC NPCR: Effective with cases diagnosed in 2016, CDC requires directly-assigned SEER Summary Stage 2000 and AJCC TNM 7th Edition Clinical and Pathologic Stage in lieu of CSv2. The Collaborative Stage Data Collection System Version 02.05 will continue to be used for cases diagnosed 2004-2015 and for the collection of the Site-Specific Factors (SSFs) for cases diagnosed 1/1/2016 and forward. In addition to the SSFs, Regional Nodes Positive and Examined and Lymph-vascular Invasion will continue to be required. All other CS input data items are no longer required.

NCI SEER: All SEER registries will submit directly-assigned clinical and pathologic TNM 7th Edition T, N, M and either directly-assigned stage group values or stage group values assigned by the SEER software. Approximately one half of SEER registries will continue the collection of CS v.02.05 for cases diagnosed 1/1/2016 and forward. Those registries will use the CS algorithm to calculate the SEER Summary Stage 2000 and the Derived AJCC TNM 7th Edition values (in addition to coding the directly-assigned fields). SEER registries not collecting CS will submit the directly-assigned SEER Summary Stage 2000. All SEER registries will continue to collect the required CSv2 SSFs. In addition to the SSFs, Regional Nodes Positive and Examined and Lymph-vascular Invasion will continue to be required. The Collaborative Stage Data Collection System Version 02.05 will continue to be used for cases diagnosed 2004-2015.

4.2 Addition of Clinical and Pathologic indicators to AJCC T, N, and M Values

The primary considerations when assigning AJCC staging classifications are timeframe and criteria. The clinical staging (or classification) timeframe includes information obtained from the time of diagnosis throughout the diagnostic workup and ends at the initiation of definitive treatment. Within the clinical staging timeframe, criteria include physical exam, imaging, endoscopies, and diagnostic biopsies. It is important to emphasize that the mere existence of a pathology report that includes microscopic assessment does not exclude it from the clinical staging criteria. If the assessment was a part of the diagnostic workup, it has occurred within the clinical timeframe and can be used for clinical staging.

The pathologic staging/classification timeframe includes information obtained from the moment of diagnosis and throughout the diagnostic workup (i.e., all information from clinical classification), the operative findings and pathology report from the definitive surgery. Within the pathologic staging timeframe, criteria include all of the clinical staging criteria, operative findings from the surgeon, and the pathology report for the resected specimen. Observations from the surgeon in the operative findings that are not accompanied by a biopsy are included in the pathologic staging criteria (e.g., observation of extension without a tissue sample for pathologic review). Similarly, involvement found on imaging is considered in the pathologic staging criteria even in the absence of tissue biopsy.

According to the AJCC manual and trainings, the appropriate T, N, and M categories should be assigned based on the above AJCC rules. This may entail allowing, for example, the pathologic staging M category to be properly assigned as cM1. However, cancer registry abstracting software is currently set up to code two separate and mutually exclusive clinical and pathologic strings of T, N, M, and stage categories, with an implied "c" in the clinical TNM string, and an implied "p" in the pathologic TNM string. Upon abstraction, the registrar has no way of recording the appropriate M category for the pathologic stage if it is cM1. This discrepancy between registry software data items and AJCC staging classification rules causes a dilemma for registrars when abstracting the T, N, and M data items and results in inconsistent coding practices and data loss.

Consequently, as part of the transition away from Collaborative Stage towards directly-assigned TNM stage, all of the standard setting organizations have agreed to address this issue by adding clinical and pathologic indicators to the AJCC T, N, and M data items [940, 950, 960, 880, 890, and 900]. The indicators will be incorporated by adding the prefixes of "c" and "p" to existing valid clinical and pathologic T, N, and M codes respectively, modifying a few of the existing codes for the individual T, N, and M data items, as well as adding and deleting specific existing codes newly prefixed with a 'c' or 'p' (for example, addition of c0, c1, c1A, c1B, c1C, c1D, and c1E to the list of valid values for pathologic M data item). In addition, in some cases conversion of historical data will be required (see section 6 for standard setter-specific conversion requirements).

This will allow for selection of necessary 'p' values within the clinical string and selection of necessary 'c' values within the pathologic string within NAACCR Version 16-compliant abstraction software (See Appendix C for a complete listing of valid values for each of the 6 individual data items). The benefits of this implementation will reduce coding confusion and increase registrar confidence in coding AJCC stage, decrease data compromise and loss and increase data integrity, and reduce the time and resources registrars and standard setters currently spend addressing these issues. AJCC will be providing trainings to reinforce the proper abstraction of clinical and pathologic T, N, and M data items and assignment of AJCC stage. See FORDS Revised for 2016 for valid values and instructions for coding.

4.2.1 TNM Classification Designator Impact for Central Registries

With the implementation of the TNM c and p classification designators (TNM c and p 'prefixes' or 'indicators'), central registries will need to consider how to best operationalize receiving directly-assigned pre-2016 TNM data from reporting facilities. This includes issues and options central registries should consider for receiving both converted and non-converted directly-assigned pre-2016 TNM data. A NAACCR Task Force was developed to identify and itemize the issues and options central registries should consider. The NAACCR Task Force findings are included in Appendix H.

4.3 ICD-O-3 Histologies

4.3.1 New Terms and Codes Not Yet Implemented

The NAACCR Guidelines for ICD-O-3 Update Implementation (published December 2013) included a table of new ICD-O-3 codes and terms effective for 2015; however, the use of the new codes was postponed due to issues with adding these codes to the CSv2 software. For diagnosis year 2016, all standard setters have agreed to postpone these codes once again, and to use the alternate codes published in Table 2 of the NAACCR Guidelines for ICD-O-3 Update Implementation (Appendix D). It is anticipated that these codes will be implemented in 2017 when the AJCC-TNM 8th Edition goes into effect.

Hospital registrars should look for use, by their pathologists, of the terms included in <u>Appendix D</u>. Since these terms have not yet been officially adopted for cancer surveillance in North America, registrars should abstract cases using the acceptable codes listed in <u>Appendix D</u> to report them to central registries and to CoC.

4.3.2 Newly Reportable Conditions

SEER implemented reporting of additional terms and codes as newly reportable over the course of 2014 and 2015. CDC and CoC are adding some or all of these terms to their respective reportability lists for cases diagnosed January 1, 2016 and later. See Section 6 for the changed reporting requirements specific to each of the Standard Setters.

5 EDITS

The Standards Volume II, Version 16 metafile includes new edits for the new and modified data items as specified in Standards Volume II, Version 16. The edits and edit sets are consistent with the reporting requirements as specified in this document by CoC, NPCR, SEER, and CCCR. Of particular note are many new TNM edits.

The Version 16 metafile was released June 20, 2016, and will be available to download from the NAACCR Web site: http://www.naaccr.org/StandardsandRegistryOperations/VolumeIV.aspx . As additional changes are made to the metafile, NAACCR Listserv messages will be sent out to the cancer registry community.

Hospital registries preparing a submission for NCDB should download their metafile from https://www.facs.org/quality-programs/cancer/ncdb/datasub/edits

Of note are the additional 4 new edit sets. Three of the edit sets are for use only by central registries and are related to the TNM Classification Designators. See <u>Appendix H</u> for additional information. The 4th new edit set is for use by hospital registries that are required to continue to collect all CS data items. This edit set differs from the standard CoC hospital edit set in that it allows all CS values to be collected whereas the

standard CoC hospital edit sets forces all non-required CS data items to be blank. See <u>section 6</u> for additional information on CS reporting requirements. The four new edits sets are listed below:

- Pre2016 no c, p in codes
- Pre2016 c, p required
- Pre2016 c, p mixed bag
- Hosp: Vs16 COC Required All + CS

It should also be noted that changes that were made to the NAACCR v15A metafile, will be carried over into the v16 metafile. These changes will have no effect on edits results and will not be noticeable to the end users of the edits. However, users of the EditWriter software need to be aware of these changes as they generate their v16 edits metafiles in particular when importing between metafiles. To accommodate future versions of the EditWriter software (currently under development), all binary tables have been replaced with DBF tables.

Contact Jim Hofferkamp@naaccr.org with any questions or concerns about the v16 NAACCR metafile.

6 Standard Setters Reporting Requirements for 2016

6.1 CoC Reporting Requirements

For all cases diagnosed on or after January 1, 2016, the Commission on Cancer (CoC) will require its accredited programs to use Facility Oncology Registry Data Standards (FORDS): Revised for 2016; Collaborative Stage Data Collection System Version 02.05 for the collection of Site-specific Factors only; continued use of 7th Edition of the AJCC Cancer Staging Manual; the most current multiple primary and histology rules; the Hematopoietic rules; and, the SEER*RX systemic therapy application.

Revisions to CoC reporting requirements for 2016 are minimal and are primarily due to the discontinued use of Collaborative Stage to stage cancer cases. Other than the below-specified revisions, CoC data reporting requirements remain the same (including requirement of CS Site-Specific Factors):

Newly-reportable Conditions/Tumors:

- 1. Non-invasive mucinous cystic neoplasm of the pancreas with high-grade dysplasia replaces mucinous cystadenocarcinoma, non-invasive (8470/2).
- 2. Solid pseudopapillary neoplasm of pancreas (8452/3) is synonymous with solid pseudopapillary carcinoma (C25.).
- 3. Cystic pancreatic endocrine neoplasm (CPEN). Assign 8150/3 unless specified as a neuroendocrine tumor, Grade 1 (8240/3) or neuroendocrine tumor, Grade 2 (8249/3).
- 4. Mature teratoma of the testes in adults is malignant (assign 9080/3), but continues to be non-reportable in prepubescent children (9080/0). Report only if pubescence is explicitly stated in the medical record. Do not report if there is no mention of pubescence in the medical record.

Data Items No Longer Required (Required historically for cases diagnosed 2004-2015):

CS Tumor Size [2800]

CS Extension [2810]

CS Tumor Size/Ext Eval [2820]

CS Lymph Nodes [2830]

CS Lymph Nodes Eval [2840]

CS Mets at DX Data Items [2850-2854]

CS Mets Eval [2860]

CS Version Derived [2936]

Derived AJCC-6 Data Items [2940-3000]

Derived SS and Flag Data Items [3010-3050]

Derived AJCC-7 Data Items [3400-3430]

Specific Data Items with Continuing Requirement (Required for cases diagnosed 2004+):

Regional Nodes Positive [820]

Regional Nodes Examined [830]

Lymph-vascular Invasion [1182]

CS Site-specific Factors [2861-2880, 2890-2930]

CS Version Input Original [2935]

CS Version Input Current [2937]

Note: CoC's requirements for the Site-specific Factors have **not changed from 2015**; the data items of CS Version Input Original and Current continue to be required to accommodate continued collection of the SSFs.

Newly-required Data Items (Required for cases diagnosed 2016+):

Tumor Size Summary [756]

SEER Summary Stage 2000 [759]

New Mets at DX Data Items [1112-1117]

Implementation of Clinical and Pathologic Indicators for the AJCC T, N, and M Data Items

CoC will require CoC-Approved Cancer Programs to add clinical and pathologic indicators to the AJCC T, N, and M data items [940, 950, 960, 880, 890, and 900] and convert historical data upon upgrading to NAACCR version 16-compliant software. See Appendix C for a listing of look-up value tables that will be implemented in CoC-accredited hospitals for cases of all diagnosis years abstracted using NAACCR version 16-compliant software.

See <u>Appendix C</u> for conversion specifications for historical data. Conversion of historical data for the diagnosis years of 2015 and earlier is being carried out for the purposes of formatting the data to accommodate consistent viewing, abstraction and editing of the data across all diagnosis years. As a result, it is important to avoid inferring, by data analysis, presentation, or other methods, any meaning to the "c" and "p" prefixes for cases diagnosed in 2015 and earlier. The indicators are only intended to reflect clinical significance for cases diagnosed January 1, 2016 and later, and should not be analyzed in any fashion for cases diagnosed earlier.

Requirement of Clinical and Pathologic AJCC Stage Enforced by Edits

Beginning with cases diagnosed January 1, 2016 and later, both clinical and pathologic AJCC stage will be required for data submission to the NCDB. Requirement will be enforced via edits.

No Submission of Derived Stage to the NCDB for Cases Diagnosed 2016 and Later

For cases diagnosed 2016 and later, no software-derived values should be submitted in the directly-assigned AJCC Stage data items [910, 970]. Registrars are encouraged to fully understand how their vendor software functions, and should never manually copy over any derived values.

Documenting Clinical and Pathologic AJCC Stage

Physicians are responsible for documenting physician-assigned clinical and pathologic stage in the patient medical record. Hospital registrars are responsible for recording the physician-assigned stage in the registry database. HOWEVER,

- a. If the stage assigned by the physician is inconsistent with the documentation in the medical record, the registrar should assign the stage and record the registrar-assigned stage in the registry database. The registrar should verify the case information with the physician, as he or she may have additional information that would aid in the assignment of a stage. However, it is outside the realm of the responsibility of the registrar to educate the physician. The registrar should inform the registry physician advisor and refer identified coding issues to the Cancer Committee for quality improvement activities.
- b. If no physician-assigned stage can be found in the medical record, the registrar should assign the stage and record it in the registry database. The registrar should inform the registry physician advisor and refer identified documentation issues to the Cancer Committee for quality improvement activities.

CoC Cancer Program Standard 1.10, Clinical Educational Activity, states that the required cancer-related educational activity offered to physicians, nurses, and other allied health professionals is to be focused on the use of AJCC (or other appropriate) staging. The cancer committee is encouraged to use AJCC-developed materials for this purpose.

6.2 CDC NPCR Reporting Requirements

Beginning with cases diagnosed 1/1/2016 and forward, CDC-NPCR will adopt the new record layout and data collection requirements as published in NAACCR Standards Volume II, Version 16. Revisions to CDC reporting requirements for 2016 are primarily due to the discontinued use of Collaborative Stage to stage cancer cases. Specific changes to the 2016 Required Status table for CDC are described below and included in Appendix E.

NPCR's Guidance Regarding C and P Conversion

CDC's position on how NPCR registries collect and/or consolidate directly-assigned AJCC TNM data collected for diagnosis years prior to 2016 – CDC's NPCR is not requiring states to submit directly-assigned AJCC TNM data collected for diagnosis years prior to 2016, and thus has no requirements or preferences for how states collect and/or consolidate such data. The following provides details of CDC's position.

Edits. NPCR required or recommended that edit sets include a minimal number of edits of pre-2016 directly-assigned AJCC TNM data.

Primary Site, AJCC M – Ed 7, ICD3 (NPCR)	
Primary Site, AJCC N – Ed 7, ICD3 (NPCR)	BLANKS ALLOWED
Primary Site, AJCC Stage Group- Ed 7, ICDO3 (NPCR)	

Primary Site, AJCC T – Ed 7, ICDO3 (NPCR)	
TNM Clin Descriptor, Data of Diagnosis (NPCR)	
TNM Edition Number, Date of Diagnosis (NPCR)	BLANKS SKIPPED
TNM Path Descriptor, Date of Diagnosis (NPCR	
TNM Edition Number, TNM Fields (NPCR)	If any TNM has a value,
	Edition cannot be blank

Calls for Data. Except for when required in special studies, CDC will not request pre-2016 directly-assigned AJCC TNM be submitted in calls for data.

Analyses. If any NPCR registries do submit such data to CDC, CDC will exclude it from all analysis files, so the presence or absence of c's and p's will not be an issue.

Northcon Conversion Utility. In order to assist states with implementing whatever strategy they prefer, the Northcon conversion utility is being designed to give users the option to convert or not convert pre-2016 AJCC TNM data with the c and p prefixes.

NPCR's Guidance Regarding Software Upgrade

CDC's position on how to handle collection of 2016 cancer cases before NAACCR Version 16-compliant software is available - For cases diagnosed in 2016 that are initially abstracted in NAACCR version 15-compliant software, the T, N, and M categories will not be converted fully (i.e., existing T, N, and M categories will be copied over but the c and p prefixes will not be added by the conversion process). When abstracting these cases registrars should be sure to clearly document the appropriate T, N, and M categories in text. For these 2016 cases, upon upgrade to NAACCR Version 16-compliant software, only the original T, N, and M categories assigned by the registrar will be retained. As a result, these cases will not pass the new v16 TNM data quality edits that require a c or p prefix for the T, N, and M data items. Therefore, the registrar will have to accurately re-assign the new T, N, and M categories (that include c and p designations) for these cases from within their NAACCR Version 16-compliant software based on review of the textual documentation.

Effective with cases diagnosed in 2016, the Collaborative Stage Data Collection System will no longer be used for deriving stage; however, the CSv2 items and algorithm will remain in place for coding historical cases diagnosed from 2004-2015. The existing CSv2 fields will also continue to be used for capturing required SSFs for 2016 diagnosis forward. Both directly-assigned SEER Summary Stage 2000 and AJCC-TNM Clinical and Pathologic Stage are now required for all cases except for those cases when stage is not applicable.

Each component of the AJCC stage is important. Even if complete AJCC TNM information is not available in the record, any piece of staging information should be collected and reported. For example, if the T and N are available but no information is available on M, the T and N should be reported.

CDC is developing an Application Program Interface (API) to assist NPCR registries with the collection of AJCC TNM Staging. The software will have two purposes:

- 1) Coding assistance for data entry, provided via site-specific pick lists for the clinical and pathologic T, N, and M elements and the directly-assigned stage groups based on the AJCC TNM Manual content.
- 2) Quality control and consolidation assistance at the central registry, provided via a derivation algorithm that will calculate clinical and pathologic stage groups based on TNM values and any related biomarkers or prognostic factors used in the AJCC staging tables. Two new calculated data items (NPCR Derived Clin Stg Grp and NPCR Derived Path Stg Grp) have been created to capture this information. These calculated values for consolidated data will be required in future data submissions to CDC.

With permission from AJCC, the full CDC API will be incorporated into the CDC Registry Plus software and also made available to NPCR grantees with their own home-grown software systems. For NPCR grantees that use vendor-based systems for their central registry, the API will be made available with the derivation functionality operational, but access to the copyright-protected AJCC content will be disabled. Commercial software vendors for central registries and hospitals should contact AJCC (Martin Madera, mmadera@facs.org) to discuss using copyright-protected AJCC content in their application. All NPCR grantees will be required to use the API to derive and submit the new NPCR calculated clinical and pathologic stage group data items.

NPCR will include edits in the NAACCR 2016 metafile to help ensure standardized data collection of all directly coded TNM items throughout the NPCR program. There will be edits that validate codes for each item and also edits that enforce relationships among data items. Where NPCR edits differ from those of other standard setters, data from NPCR registries will be expected to pass NPCR's edits.

For the implementation of clinical and pathologic indicators for the AJCC T, N, and M data items (see <u>section 4.2</u>) CDC will not require conversion of existing TNM data to 2016 data standards. CDC will work with the NPCR registries on managing TNM data from 2015 diagnoses and earlier submitted by CoC hospitals that may have c and p prefixes added retroactively.

Required Site-Specific Factors: SSFs necessary to calculate Derived Summary Stage 2000 or Derived AJCC 7 Stage Group (for Collaborative Stage) are no longer required for cases diagnosed in 2016; however, site-specific factors that impact directly-assigned AJCC-TNM 7th Edition Stage Group (e.g. PSA for prostate) or that are prognostic factors of interest, remain important to collect for cancer surveillance. The Collaborative Stage SSF data items will continue to be used for this purpose. SSFs that will be required by CDC-NPCR are listed in Tables 1 and 2 below. CS Version Input Original and CS Version Input Current must continue to be populated for as long as the SSFs are being collected using the CS DLL.

Table 1. CDC NPCR SSFs Required for Directly-Assigned AJCC TNM Stage			
Site (CS Schema)	SSF	Description	
Appendix	SSF11	Histopathologic Grading	
GISTPeritoneum	SSF 5 and 10	Mitotic Count; Location of Primary Tumor	
GIST Esophagus, GIST Small Intestine, GIST	SSF 6	Mitotic Count	
Stomach			
GIST Appendix, GIST Colon, GIST Rectum	SSF 11	Mitotic Count	
MycosisFungoides	SSF 1	Peripheral Blood Involvement	
Placenta	SSF 1	Prognostic Scoring Index	

Table 1. CDC NPCR SSFs Required for Directly-Assigned AJCC TNM Stage			
Site (CS Schema)	SSF	Description	
Prostate	SSF 1, 8 and 10	PSA Lab Value, Gleason Score	
Testis	SSF 13, 15, 16	Post Orchiectomy AFP, hCG, and LDH Range	
BileDuctsDistal, BileDuctsPerihilar,	25	Schema Discriminator	
CysticDuct, EsophagusGEJunction,			
LacrimalGland, LacrimalSac, Melanoma			
CiliaryBody, Melanomalris, Nasopharynx,			
PharyngealTonsil, Stomach			

Table 2. CDC NPCR SSFs required by NPCR (but not for AJCC Staging)			
Site (CS Schema)	SSF	Description	
Brain, CNS Other, Intracranial Gland	1	WHO Grade	
Breast	1	ERA	
	2	PRA	
	8	HER2: IHC Value	
	9	HER2: IHC Interpretation	
	11	HER2: FISH Interpretation	
	13	HER2: CISH Interpretation	
	14	HER2: Result of other test	
	15	HER2: Summary Result testing	
	16	Combination of ERA, PRA and HER2	
		Testing	

Newly Required Data Items (See also Appendix E):

Census County 1990 [94] - Central Registry Only

Census County 2000 [95] – Central Registry Only

Census County 2010 [96] - Central Registry Only

Tumor Size Summary [756]

TNM Path T [880]

TNM Path N [890]

TNM Path M [900]

TNM Path Stage Grp [910]

TNM Path Descriptor [920]

TNM Clin T [940]

TNM Clin N [950]

TNM Clin M [960]

TNM Clin Stage Grp [970]

TNM Clin Descriptor [980]

TNM Edition Number [1060]

RX Summ-Surg/Rad Seq [1380]

RX Summ Systemic/Sur Seq [1639]

Rural Urban Continuum 2013 [3312] – Central Registry Only

NPCR Derived Clin Stg Grp [3650] – Central Registry Only

NPCR Derived Path Stg Grp [3655] – Central Registry Only

CSv2 Data Items that Continue to be Required:

Regional Nodes Positive [820]

Regional Nodes Examined [830]

Lymph-Vascular Invasion [1182]

CS Version Input Original [2935]

CS Version Input Current [2937]

CS Site-Specific Factors 1, 2, 5, 6, 8, 9, 10, 11, 13, 14, 15, 16, 25 [2880, 2890, 2920, 2930, 2862-2865, 2867-2870, 2879] (See Tables 1 and 2)

Data Items No Longer Required/Required Historically (See Appendix E):

CS Site-Specific Factors 3, 4, 7, 12, 17-24 [2900, 2910, 2861, 2866, 2871-2878]

CS Tumor Size [2800]

CS Extension [2810]

CS Tumor Size/Ext Eval [2820]

CS Lymph Nodes [2830]

CS Mets at DX [2850]

CS Version Derived [2936]

Derived SS2000 [3020]

Derived SS2000-Flag [3050]

CS Lymph Nodes Eval [2840]

CS Mets Eval [2860]

Derived AJCC-7 T [3400]

Derived AJCC-7 T Descript [3402]

Derived AJCC-7 N [3410]

Derived AJCC-7 N Descript [3412]

Derived AJCC-7 M [3420]

Derived AJCC-7 M Descript [3422]

Derived AJCC-7 Stage Grp [3430]

Over-ride CS 1-20 [3750-3769]

Newly Reportable Conditions/Tumors:

In 2014 and 2015 SEER added new reportable histology terms to their Program and Coding Manual. These terms had not been included in any ICD-O-3 errata and therefore were not addressed throughout the cancer surveillance community. CDC has reviewed the terms and determined that the following are reportable. While there has not been an official errata to address these histology terms, CDC recommends adding them to ICD-O-3 Manuals and educating reporting sources about these new updates.

- 1. Non-invasive mucinous cystic neoplasm of the pancreas with high-grade dysplasia replaces mucinous cystadenocarcinoma, non-invasive (8470/2).
- 2. Solid pseudopapillary neoplasm of pancreas (8452/3) is synonymous with solid pseudopapillary carcinoma (C25.)
- 3. Based on pathologist consultation, metastases have been reported in some cystic pancreatic endocrine neoplasm (CPEN) cases. With all other pancreatic endocrine tumors now considered malignant, CPEN will also be considered malignant, until proven otherwise. Most CPEN cases are non-functioning and are REPORTABLE using histology code 8150/3, unless the tumor is specified as a neuroendocrine tumor, grade 1 (assign code 8240/3) or neuroendocrine tumor, grade 2 (assign code 8249/3)
- 4. Laryngeal intraepithelial neoplasia, grade III (LINIII) (8077/2), C320-C329)

- 5. Squamous intraepithelial neoplasia, grade III (SINIII) (8077/2), except Cervix and Skin
- 6. Mature teratoma of the testes in adults is malignant and REPORTABLE as 9080/3, but continues to be non-reportable in prepubescent children (9080/0). The following provides additional guidance:
 - Adult is defined as post puberty
 - Pubescence can take place over a number of years
 - Do not rely solely on age to indicate pre or post puberty status. Review all information (physical history, etc.) for documentation of pubertal status. When testicular teratomas occur in adult males, pubescent status is likely to be stated in the medical record because it is an important factor of the diagnosis.
 - Do not report if unknown whether patient is pre or post pubescence. When testicular teratoma occurs in a male and there is no mention of pubescence, it is likely that the patient is a child, or pre-pubescent, and the tumor is benign.

6.3 NCI SEER Reporting Requirements

All SEER registries will submit directly-assigned clinical and pathologic TNM 7th Edition T, N, M and either directly-assigned stage group values or stage group values assigned by the SEER software. Approximately one half of SEER registries will continue the collection of CS v.02.05 for cases diagnosed 1/1/2016 and forward. Those registries will use the CS algorithm to calculate the SEER Summary Stage 2000 and the Derived AJCC TNM 7th Edition values (in addition to coding the directly-assigned fields). SEER registries not collecting CS will submit the directly-assigned SEER Summary Stage 2000. All SEER registries will continue to collect the required CSv2 SSFs. In addition to the SSFs, Regional Nodes Positive and Examined and Lymph-vascular Invasion will continue to be required. Changes in NCI SEER requirements for 2016 are listed in Appendix F.

SEER SSFs No Longer Applicable

Schema/Chapter	SSF	Rationale for no longer needed
Prostate	#3	Becomes pathologic T
Retinoblastoma	#1	Becomes pathologic T
Appendix	#2	Becomes clinical N
Carcinoid Appendix	#2	Becomes clinical N
Colon/Rectum	#2	Becomes clinical N
Esophagus/Esophagus GE Junction	#1	Becomes clinical N
Lacrimal Gland	#3	Becomes clinical N
Melanoma Skin	#3	Becomes clinical N
Merkel Cell	#3	Becomes clinical N
NET Colon	#2	Becomes clinical N
NET Rectum	#2	Becomes clinical N
NET Stomach	#1	Becomes clinical N
Skin Eyelid	#3	Becomes clinical N
Small Intestine	#2	Becomes clinical N
Stomach	#1	Becomes clinical N
BileDuctsIntrahepatic	#10	T4 definition

Peritoneum/Peritoneum Female Gen	#25	Using data item sex directly
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For the implementation of clinical and pathologic indicators for the AJCC T, N, and M data items (see <u>section 4.2</u>) NCI SEER will not require conversion of existing TNM data to 2016 data standards. NCI SEER will work with our registries on managing TNM data from 2015 diagnoses and earlier submitted by CoC hospitals that may have c and p prefixes added retroactively.

SEER registries will make use of the SEER Registrar Staging Assistant (SEER*RSA) to help them assign stage and code predictive and prognostic factors. Data from the SEER*RSA will be made available in SEER*DMS and on the SEER website. SEER*RSA data are provided via both an API and software libraries. The centerpiece of the new setup is the SEER*API, which is a mechanism used to "get" data. The staging section of the SEER*API knows how to get both UICC TNM and CSv02.05.50 data and how to calculate CS stage, TNM stage, and Combined Stage. The API has the capability to return the same information that is currently returned by the CS DLL for CSv02.05.50. The API also has the capability to return UICC TNM data, such as the list of schemas to be collected for cases diagnosed January 1, 2016 and forward, which data items are required for staging for each schema, which SSFs are required to be collected by the various standard setters for TNM, what the permissible values are for each data item, as well as being able to stage cases using UICC TNM staging rules. The SEER*API can be used directly free of charge. Visit https://api.seer.cancer.gov for more information. Alternatively, a Java library can be used in an offline capacity. This library is open source and can be accessed at https://github.com/imsweb/staging-client-java. A C++ library is coming soon.

6.4 CCCR Reporting Requirements

Beginning with cases diagnosed on or after January 1, 2016, the Canadian Council of Cancer Registries (CCCR) will implement the data collection, and submission requirements as published in the Standards Volume II, Version 16, Chapter VIII, Required Status Table CCCR column.

The Canadian registries will not be implementing any of the new data items in <u>section 2</u> for 2016 diagnoses. None of the changed data items in <u>section 3</u> are applicable to Canada for 2016 diagnosis.

Canada will continue to use the Collaborative Stage Data Collection System Version 02.05 to stage their new cases until the end of the 2016 diagnosis year. Beginning with cases diagnosed January 1, 2017, Canada plans to implement TNM stage data collection to coincide with the expected release of the AJCC Cancer Staging Manual 8th Edition. Specific stage variables that will be required for collection are not yet defined.

Cases will be submitted to the Canadian Cancer Registry during Statistic Canada's Canadian Cancer Registry Call for Data. Provincial/Territorial registries can reference the Canadian Cancer Registry Input Record layout of the Canadian Cancer Registry System Guide for a more comprehensive listing.

Newly Reportable Conditions/Tumors:

In 2012, the CCCR added the following newly reportable condition/term: non-invasive mucinous cystic neoplasm of the pancreas with high-grade dysplasia replaces mucinous cystadenocarcinoma, non-invasive (8470/2).

Effective in 2015, the following conditions/tumors became reportable:

- 1) Solid pseudopapillary neoplasm of pancreas (8452/3) is synonymous with solid pseudopapillary carcinoma (C25._)
- 2) Cystic pancreatic endocrine neoplasm (CPEN) (8150/3), unless the tumor is specified as a neuroendocrine tumor, grade 1 (assign code 8240/3) or neuroendocrine tumor, grade 2 (assign code 8249/3)
- 3) Laryngeal intraepithelial neoplasia, grade III (LINIII) (8077/2), C320-C329)
- 4) Squamous intraepithelial neoplasia, grade III (SINIII) (8077/2), except Cervix and Skin
- 5) Mature teratoma of the testes in adults (9080/3), but non-reportable in prepubescent children (9080/0).

7 Summary for Central Cancer Registries

7.1 Record Length, New Data Items, and Changed Data Items

7.1.1 Record Length

Significant changes have been made to the Record Layout; see section 3.1 for details.

7.1.2 New Data Items

A total of thirty new data items have been implemented. Central cancer registries should review each new data item to determine which are required to be reported to meet individual requirements to national standard setters (see section 6). See section 2 and Standards Volume II, Version 16 for detailed description of the new fields.

7.1.3 Changed Data Items

Significant changes have been made to existing data items. See <u>section 3</u> and Standards Volume II, Version 16 for details.

7.2 Staging Transition

See <u>section 6</u> and the Standards Volume II, Version 16 Required Status Table (chapter VIII) to determine which staging data items are required to be collected by the various standards setters. Communicating these changes to the reporting facilities and to software vendors should be undertaken as soon as possible.

7.3 ICD-O-3 Histologies

Consistent with decisions of the standard setters, there will not be any changes to reportable histology codes for 2016 diagnoses. Since new terms and codes were previously approved for use by the College of American Pathologists, hospital registrars should find out if their pathologists are using new terms that have not been officially adopted for cancer surveillance in North America. If so, they should report those conditions to central registries using the currently acceptable codes, as enumerated in Appendix D. The contents of the table have not been changed since the ICD-O-3 Implementation Update document was released.

Central Registries need to review reportability changes specific to their respective standards setters (see section 6).

7.4 Central Registry Edits

The central cancer registry should review the EDITS metafile for Standards Volume II, Version 16 (see <u>section 5</u>), to determine the edits that it will implement for incoming records and for consolidated items in the central registry's database. Central cancer registries should review the NAACCR v16 metafile documentation in parallel with the newly required data items and include every applicable edit in their state-specific EDITS metafile. Of particular note are the new TNM edits that have been written and tested during the past year.

Central cancer registries should note that edits in the metafile may need to be revised to accommodate central registry-specific or state-specific reporting requirements, and that special edits may need to be developed for central registry-specific data items. Implementation, testing, and distribution of central registry-specific EDITS metafiles to reporting facilities and vendors should be considered as central cancer registries develop their requirements for 2016 reporting. Central cancer registries that generate and distribute their own metafiles should have a plan to keep them updated.

The central cancer registry should evaluate the time required to correct errors in previous years' data that appear after retrospectively applying new edits, particularly when there are no guidelines that limit diagnosis years to which the new edit(s) should be applied. Taking into account the relative importance of the affected data items and the amount of time required to edit the records, central registries should prioritize and fix these retrospectively-identified errors.

7.5 Software Implementation Plan

Central cancer registries that receive submissions from facilities using commercial software to generate their files should pay close attention to the new releases of these products and coordinate their own Standards Volume II, Version 16 implementation plan accordingly. Every new vendor version should be reviewed to ensure compliance with the new record layout version and with registry requirements, before files are merged into the central cancer registry's database. Various methods can be used to test a data submission for compliance with standards, including visual review and the application of an EDITS metafile. The use of a test environment into which submissions can be loaded and viewed as they would appear in the active database is recommended.

A reporting facility's first transmission in Standards Volume II, Version 16 should be tested as thoroughly as possible to identify layout and/or code problems before v16 records are accepted from that facility. Some central registries require a "test file" from each software vendor or reporting facility.

7.6 Communication with Reporting Facilities and Software Vendors

Central cancer registries will need to distribute their implementation plan and timeline to reporting facilities and software vendors as early as possible. The communication should include a new reportability list and an updated list of required data items, including explicit instructions for state/province/territory-specific items. Changes to the implementation plan or the timeline should be forwarded immediately to all affected parties. Reporting facilities that are not CoC-accredited cancer programs may be less aware of upcoming changes and may need more transition time. Facilities that do not use a vendor for their reporting software will need extra attention.

Central registries relying on vendor software for their own systems and/or their reporting facilities should be aware that delays in the communication of this information to software vendors may result in a delay in receiving and/or incorporating 2016 cases.

Until each reporting facility is fully converted to Standards Volume II, Version 16, vendors and central registries will need to provide continued support for reporting and processing of records diagnosed 2015 and earlier in Standards Volume II, Version 15 record format.

7.7 Education and Training

Central cancer registries will have to provide training to their reporting facilities on changes identified in this document. The most significant changes are related to the direct coding of AJCC TNM values and SEER Summary Stage. Trainings should focus on continued education of coding these fields. Central registry staff will also have to be trained on newly-required data items, and on rules for consolidation of newly required information coming from multiple sources for the same tumors. The NAACCR Data Item Consolidation Manual prescribing best practices for many standard data items should be distributed to central registry staff, with the rules followed manually until they can be implemented automatically in the central registry software.

8 Summary for Software Developers and Vendors

All software vendors will be responsible for identifying required software changes, accommodating new and changed data items; providing support for the transition away from CS to TNM and directly coded SEER Summary Stage; performing data conversion where necessary, and providing continued access to updated supplementary coding resources. Vendors will also need to address testing and implementation issues, as well as technical support and training. Instruction to development staff should address the following:

8.1 Identify Software Changes

Software specifications generated to adapt programs will be vendor-specific and will vary for reporting facility applications and central registry applications. Specifically, vendors will need to accommodate the following changes and additions documented in this guide:

Section Number	Section Contents
<u>2</u>	New data items (some items may require additional codes and labels for pick
	lists)
<u>3.1</u>	Record layout changes
<u>3.2</u>	Addition of Clinical and Pathologic Indicators to AJCC T, N, and M
<u>3.3</u>	Sex – code 3 definition change
<u>3.4</u>	Census codes name change – (for central registry software)
<u>3.5</u>	TNM Staged By data items length increase and code conversion
<u>3.6</u>	Wording changes in description or rationale - only a consideration for help
	systems
3.7 4.2 5 6.1	SEER Coding Sys-Current and Original [2120 and 2130]
<u>4.2</u>	Addition of Clinical and Pathologic indicators to AJCC T, N, and M values
<u>5</u>	EDITS
<u>6.1</u>	CoC Reporting Requirements. New c and p TNM prefix indicators require
	additional codes and labels for pick lists.
<u>6.2</u>	CDC NPCR Reporting Requirements
<u>6.3</u>	NCI SEER Reporting Requirements
<u>6.4</u>	CCCR Reporting Requirements

8.2 Data Conversion

The length of TNM Clin Staged By and TNM Path Staged By data items were expanded to 2 digits to accommodate new codes, see section 3.5. The NAACCR Record Version will be converted from 150 to 160. Any conversion crosswalks will be made available on the NAACCR Web site, as well as incorporated into Northcon 16, the CDC conversion program. Northcon 16 will be available six weeks from the receipt of the final detailed specifications. Modification to the specifications may cause delay in releasing the program.

8.3 Staging Transition Support

The current version of CS, CSv02.05, will not change in 2016. The CSv2 items and algorithm will remain for cases diagnosed from 2004 to 2015 for some registries.

Consider displaying the Site Specific Factor data items for viewing and/or editing on the screen where the directly-assigned T, N, and M are coded (see <u>section 6</u> for standard setter requirements). See <u>section 6.2</u> for a discussion of the API to assist NPCR registries with the collection of AJCC TNM staging and <u>section 6.3</u> for information about the SEER API for TNM stage assignment.

Commercial software vendors for central registries and reporting facilities should contact AJCC (Martin Madera, mmadera@facs.org) to discuss using copyright-protected AJCC content in their application.

8.4 SEER Hematopoietic & Lymphoid Database

The latest version of the Hematopoietic & Lymphoid Database by NCI SEER was published in January 2015. The Hematopoietic & Lymphoid Database is available in two formats: a web-based tool and as stand-alone software. Vendors may want to consider inclusion of a link to the web-based format from within their software as updates are automatic: users do not have to install anything to access the latest revisions, and this option eliminates problems for users who do not have permission to install software on their work computers. However, vendors should give consideration to the fact that users may need the stand-alone software because they may not have access to the Internet. NCI SEER has announced that they will be implementing a new feature that will automatically update the standalone version whenever the user accesses the Internet.

8.5 SEER*Rx Drug Database

The latest version of the SEER*Rx drug database was released in September 2014 (web version) and June 2015 (software update). If you have not already done so, vendors may want to consider inclusion of a link to the web-based format from within their software as updates are automatic: users do not have to install anything to access the latest revisions, and this option eliminates problems for users who do not have permission to install software on their work computers. However, vendors should give consideration to the fact that users may need the standalone software because they may not have access to the Internet.

8.6 Programming, Testing, and Implementation

Clear communication with central cancer registries and reporting facility customers is critical to avoid delays in delivering software that can deliver and process 2016 cases. Software vendors should provide programming instructions to support the necessary changes for Standards Volume II, Version 16, as well as testing (if time allows, beta site testing) and implementing the items listed elsewhere in this document. Software vendors need to revise/develop, test, distribute, and install software prior to implementation dates set by standard setting organizations and central cancer registries.

Central cancer registries may require software vendors to submit test files prior to approval in reporting in the Standards Volume II, Version 16 format. Testing should determine that appropriate values are validated within the software. Testing should also accommodate verification of revisions for data import and export, revisions to the software interface, addition of look-ups for new and changed data items where applicable, data entry verifications internal to the software (if available within the software), data item consolidation where applicable, and standard as well as ad hoc report writing. Any changes to the implementation timeline should be immediately reported to all involved parties. If there are delays to the standards or errata that have not yet been identified, the software vendor programs will be at risk of delay. Individual changes to the state-specific state requestor section must also be communicated early in the coding and implementation period in order to be accommodated for software release.

8.7 New Online Help Files

Changes to any software's online help system (if available) will need to be made in conjunction with Standards Volume II, Version 16-related changes made to the software. New Registry Plus Online Help for Standards Volume II, Version 16 will be made available from CDC. For vendors that do not use CDC's Registry Plus Online Help within their software, or those that supplement it with extra information, updates will need to be made to online help.

8.8 Technical Support and Training

Software vendors are expected to support the data changes in Standards Volume II, Version 16 in the software and provide their clients with training and documentation appropriate to use the updated software. For reporting facility level applications, this will include instruction regarding export of records for transmission to their respective central registries in the correct format with correctly coded and error free data, as well as import from their previously supported casefinding interface. Documentation to support the updated software may include information presented via the software's online help system and/or training or tutorial guides. Training and support on new coding rules should be referred to the appropriate standard setting organization.

8.9 Communication with Central Cancer Registries and Hospital Registries

Software vendors should provide a timeline to the central registries indicating when they will be able to produce software that is able to process and produce Standards Volume II, Version 16 case records. Vendors should have an avenue for timely communication from all central registry clients so that proper support of state-specific changes in required data reporting are made, including mapping of state-specific data items in the state/requestor section of the record. In addition, vendors should implement state edit sets as provided by the registries. Central registry clients should be aware that delays in communication of this information from state registry clients to the software vendor may result in a delay in reporting 2016 cases. Until each state registry client is fully converted to Standards Volume II, Version 16, vendors will need to provide continued support for reporting and processing of records diagnosed 2015 and earlier in NAACCR Version 15.0 record format.

9 Summary for Hospital Cancer Registrars and Reporting Facilities

The CoC, NPCR, SEER, and CCCR would like to collectively thank hospital registrars for their perseverance in excellence during this time of annual change. Cancer registration is an ever-evolving field, and without the

continued level of dedication demonstrated by hospital registrars across North America these organizations would not be able to adapt to change and meet their goals.

Although there are numerous new and revised data items for 2016, many of the changes are intended for implementation at the central registry level (e.g., derivation of new derived staging data items, geocoded data items), or are informational in nature (e.g., wording changes to accommodate EHR reporting). The scope of changes being implemented at the level of the hospital registry is minimal. There are a few changes that registrars need to be aware of in order to smoothly transition to using new and changed data items and updated software. In particular, there are new data items being implemented to accommodate the transition away from Collaborative Stage. It is imperative that hospital registrars be familiar with the specific reporting requirements of the standard setter(s) (see section 6) to which their data are ultimately reported, as there are differences in requirements, specifically for staging information.

Cases diagnosed on or after January 1, 2016, must be collected and reported in accordance with the standards and definitions of the Standards Volume II, Version 16.

9.1 Prioritize Case Abstracting

Registrars should prioritize their abstracting. Ideally, abstracting of cases diagnosed prior to January 1, 2016, should be completed before converting registry data or beginning to use Standards Volume II-based, Version 16 software upgrades.

9.2 New Data Items

The following new data items all are being implemented to accommodate transition away from Collaborative Stage:

- Mets at DX-Bone [1112]
- Mets at DX-Brain [1113]
- Mets at DX-Distant LN [1114]
- Mets at DX-Liver [1115]
- Mets at DX-Lung [1116]
- Mets at DX-Other [1117]
- Tumor Size Clinical [752]
- Tumor Size Pathologic [754]
- Tumor Size Summary [756]

NOTE: Reporting requirements of the standard setter(s) for these new data items vary (see section 6).

9.3 Changed Data Items

The majority of changes to existing data items were made for the purpose of implementing updated terminology (Sex code 3, replacement of the label hermaphrodite), interoperability (wording changes to accommodate EHRs) or are not applicable at the level of the reporting facility (changes to Census industry and occupation data items) (see <u>section 3</u>). Registrars need to be aware of the following changes:

9.3.1 Addition of Clinical and Pathologic Indicators to AJCC T, N, and M

Clinical and pathologic indicators are being added to the AJCC T, N, and M data items [940, 950, 960, 880, 890, and 900]. The indicators are to be added by modifying the existing values for the individual T, N, and M data items and adding a minimal number of new codes, while deleting some existing codes. The revisions will be incorporated into software look ups to allow for selection of necessary 'p' values within the clinical

codes and selection of necessary 'c' values within the pathologic codes when abstracting. See <u>section 4.2</u> for complete details.

9.3.2 TNM Path Staged By [930] and TNM Clin Staged By [990]

The length of both data items has been expanded to 2 digits to accommodate new codes. Refer to the most recent version of *FORDS* for revised coding instructions.

9.3.3 SEER Coding Sys-Current and Original [2120 and 2130]

Code G was added to accommodate the 2016 SEER Coding Manual. If your registry reports to a SEER central registry you will need to ensure that your software vendor has this new value appropriately defaulted.

9.4 Staging Transition Issues

Although the field of cancer registration is transitioning away from the Collaborative Stage system for staging cancer cases, use of CSv2 version 02.05.50 data items and derivations will continue for the abstraction of cases diagnosed from 2004-2015, as well as for continued collection of Site-specific Factors for cases diagnosed in 2016. Canadian facilities will continue to use CSv2 for all staging items. As mentioned earlier, hospital registrars need to familiarize themselves with the differing stage data item requirements by standard setter (see section 6). Some important highlights follow:

- As always, central registries will be providing support to their reporting facilities in the form of clear documentation of reporting requirements.
- Directly-assigned SEER Summary Stage 2000 [759] is required for facilities reporting to CDC NPCR state central cancer registries and the CoC NCDB, however, some facilities reporting to NCI SEER state central cancer registries will be required to abstract either SEER Summary Stage 2000 or Collaborative Stage.
- The new Tumor Size Summary [756] data item is required for facilities reporting to CDC NPCR state
 central cancer registries and the CoC NCDB, while the new Tumor Size Clinical [752] and
 Tumor Size Pathologic [754] data items are required for facilities reporting to NCI SEER state central
 cancer registries.
- Some facilities reporting to NCI SEER state central cancer registries and all Canadian registries will
 continue to use CSv2 version 02.05.50 data items and derivations for the abstraction of cases
 diagnosed in 2016.
- In 2016, use of CSv2 version 02.05.50 will continue to collect CS Site-Specific factors using the same NAACCR data layout and definitions. For CoC approved reporting hospitals reporting to CoC NCDB, and reporting facilities that report to NCI SEER central registries, there are no changes in CS SSF reporting requirements for 2016. However, facilities that report only to CDC NPCR central registries will need to be aware of changes in CS SSF reporting requirements (see section 6).

9.4.1 New AJCC TNM Stage Data Item Edits

A new sub-workgroup of the NAACCR EDITS Workgroup was formed to specifically generate new, more robust data quality edits for the AJCC T, N, M and stage data items. The work product of this workgroup to-date will be incorporated into the NAACCR Version 16 edits metafile. As a result, registrars should be aware that they may need to address new edit errors upon the implementation of the v16 edits within their abstraction software.

9.5 Conversion Consideration

Conversion from NAACCR version 15- to NAACCR version 16-based software affects very few data items (primarily AJCC T, N, and M data items [940, 950, 960, 880, 890, and 900], TNM Path Staged By [930], TNM Clin Staged By [990], and NAACCR Record Version [50]). However, it is always good practice for registrars to review and apply data quality edits to their data and resolve any coding discrepancies or edit errors prior to conversion.

Northcon Conversion Utility. In order to assist states with implementing whatever strategy they prefer, the Northcon conversion utility is being designed to give users the option to convert or not convert pre-2016 AJCC TNM data with the c and p prefixes.

9.6 Communicate with Software Vendors and Central Cancer Registries

Hospital registries should contact their software vendors to ascertain when the Version 16 software upgrade will be available, and then make arrangements with their facility IT staff to have someone available to oversee the upgrade process. Schedule firm implementation dates as early as possible to avoid delays.

Registries that are prepared for and have an interest in being involved in early implementation of software upgrades should consider offering to be a beta test site for their software provider. This will allow the registry to obtain the software upgrades at the earliest opportunity and contribute valuable feedback regarding the upgrade process to their software provider (thus facilitating upgrades for other registries using the software).

When planning for the software upgrade, registries should contact their central registries to find out when they may begin transmitting in the upgraded version as this will impact the implementation date scheduled with their software vendor and facility IT staff.

9.7 Education and Training

Registrars and abstractors should attend education and training provided by regional, state, or national programs. These may include any combination of webinars, face-to-face training sessions at meetings, self-instructional material, and making time to work slowly through coding while becoming familiar with the changes. In particular, registrars should plan on attending or reviewing the AJCC Curriculum for Registrars found at: https://cancerstaging.org/CSE/Registrar/Pages/AJCC-Curriculum.aspx

In addition, registrars may find the following resources helpful:

- http://training.seer.cancer.gov/
- http://seer.cancer.gov/registrars/
- https://educate.fhcrc.org/LandingPage.aspx
- https://www.facs.org/quality-programs/cancer
- http://www.cdc.gov/cancer/npcr/index.htm
- http://www.naaccr.org/
- http://www.ncra-usa.org/i4a/pages/index.cfm?pageid=1

10 Appendix A Conversion of TNM Path Staged By [930] and TNM Clin Staged By [990]

The following conversion tables are designed to expand the 1-character codes formerly assigned to the TNM Path Staged By and TNM Clin Staged By data items to 2-character codes. Refer to the most recent version of FORDS for code definitions. The conversion below will be performed across all diagnosis years (cases diagnosed in 2016 for which abstraction is started in NAACCR Version 15-compliant software will be converted). These conversions are mutually exclusive. Blank fields are not included in the below tables and should remain blank.

Part 1: TNM Clin Staged By and TNM Path Staged By codes 0-8 Conversion

The first step of the conversion is a direct conversion of the 1-character TNM Clin Staged By and TNM Path Staged By codes to the corresponding 2-character codes.

TNM Clin Staged By and TNM	Convert TNM Clin Staged By and
Path Staged By (Version 15)	TNM Path Staged By (Version 16)
0	00
1	10
2	14
3	15
4	10
5	20
6	30
7	50
8	88

Part 2: TNM Clin Staged By and TNM Path Staged By code 9 Conversion

The second step of the conversion determines how to convert TNM Clin Staged By (see **A** below) and TNM Path Staged By (see **B** below) code 9 using the related TNM T, N, M, and Stage Group values.

Α.

If TNM Clin Staged By (version 15) = 9 and			Then convert TNM	
TNM Clin T	TNM Clin N	TNM Clin M	TNM Clin Stage Group	Clin Staged By
(version 15) =	(version 15) =	(version 15) =	(version 15) =	(version 16) to
Blank	Blank	Blank	Blank	00
Х	Х	Х	99	00
88	88	88	88	88

В.

If TNM Path Staged By (version 15) = 9 and			Then convert TNM	
TNM Path T	TNM Path N	TNM Path M	TNM Path Stage Group	Path Staged By
(version 15) =	(version 15) =	(version 15) =	(version 15) =	(version 16) to
Blank	Blank	Blank	Blank	00
Χ	X	X	99	00
88	88	88	88	88

C. Remaining cases with TNM Clin Staged By and TNM Path Staged By = 9 are to be converted to 99

11 Appendix B Data Items with Wording Changes to Accommodate EHR Reporting

Standards Volume II, Data Items with Wording Changes to A	
Data Item Name	Item #
Accession NumberHosp	550
Primary Payer at DX	630
RX HospSurg Prim Site	670
RX HospScope Reg LN Sur	672
RX HospSurg Oth Reg/Dis	674
RX HospReg LN Removed	676
RX HospHormone	710
RX HospOther	730
RX HospSurg Site 98-02	746
RX HospScope Reg 98-02	747
RX HospSurg Oth 98-02	748
Place of DeathState	1942
Place of DeathCountry	1944
NPIInst Referred To	2425
Institution Referred To	2420
TextDX ProcPE	2520
TextDX ProcX-ray/Scan	2530
TextDX ProcScopes	2540
TextDX ProcLab Tests	2550
TextDX ProcOp	2560
TextDX ProcPath	2570
TextPrimary Site Title	2580
TextHistology Title	2590
TextStaging	2600
RX TextSurgery	2610
RX TextRadiation (Beam)	2620
RX TextRadiation Other	2630
RX TextChemo	2640
RX TextHormone	2650
RX TextBRM	2660
RX TextOther	2670
TextRemarks	2680
TextPlace of Diagnosis	2690
Comorbid/Complication 1	3110
Comorbid/Complication 2	3120
Comorbid/Complication 3	3130
Comorbid/Complication 4	3140
Comorbid/Complication 5	3150
Comorbid/Complication 6	3160
Comorbid/Complication 7	3161

Standards Volume II, Version 16		
Data Items with Wording Changes to Accommodate EHR Reporting Data Item Name Item #		
Comorbid/Complication 8	3162	
Comorbid/Complication 9	3163	
Comorbid/Complication 10	3164	
Secondary Diagnosis 1	3780	
Secondary Diagnosis 2	3782	
Secondary Diagnosis 3	3784	
Secondary Diagnosis 4	3786	
Secondary Diagnosis 5	3788	
Secondary Diagnosis 6	3790	
Secondary Diagnosis 7	3792	
Secondary Diagnosis 8	3794	
Secondary Diagnosis 9	3796	
Secondary Diagnosis 10	3798	

12 Appendix C Revised Valid Values for AJCC T, N, and M

C.1 Revised look-up tables for use within Version 16.0 software and listing of added/deleted codes for AJCC T, N, and M data items

Table 1. TNM Clin T [940]

C 11 114141 CHIII 1 [5-10]		
Code	Definition	
(blank)	Not recorded	
cX	cTX	
c0	сТО	
рА	рТа	
pIS	pTis	
pISU	pTispu	
pISD	pTispd	
c1MI	cT1mi, cT1 mic	
c1	cT1	
c1A	cT1a	
c1A1	cT1a1	
c1A2	cT1a2	

Code	Definition
c1B	cT1b
c1B1	cT1b1
c1B2	cT1b2
c1C	cT1c
c1D	cT1d
c2	cT2
c2A	cT2a
c2A1	cT2a1
c2A2	cT2a2
c2B	cT2b
c2C	cT2c
c2D	cT2d
Ticl ICD	I [Ticoul ISDI

Code	Definition
c 3	c T3
c3A	cT3a
сЗВ	cT3b
c3C	cT3c
c3D	cT3d
c4	cT4
c4A	cT4a
c4B	cT4b
c4C	cT4c
c4D	cT4d
c4E	cT4e
88	Not applicable

Deleted codes: A [Ta], IS [Tis], ISPU [Tispu], ISPD [Tispd] Added codes: pA [pTa], pIS [pTis], pISU [pTisu], pISD [pTisd]

Table 2. TNM Path T [880]

<u>c 2. 114141 i dtil i [000]</u>		
Code	Definition	
(blank)	Not recorded	
pX	pTX	
р0	рТ0	
рА	рТа	
pIS	pTis	
pISU	pTispu	
pISD	pTispd	
p1MI	pT1mi, pT1 mic	
p1	pT1	
p1A	pT1a	
p1A1	pT1a1	
p1A2	pT1a2	

Code	Definition
p1B	pT1b
p1B1	pT1b1
p1B2	pT1b2
p1C	pT1c
p1D	pT1d
p2	pT2
p2A	pT2a
p2A1	pT2a1
p2A2	pT2a2
p2B	pT2b
p2C	pT2c
p2D	pT2d

Code	Definition
р3	pT3
р3А	pT3a
р3В	pT3b
p3C	pT3c
p3D	pT3d
p4	pT4
p4A	pT4a
p4B	pT4b
p4C	pT4c
p4D	pT4d
p4E	pT4e
88	Not applicable

Added codes: pISU [pTisu], pISD [pTisd]

Table 3. TNM Clin N [950]

Code	Definition	
(blank)	Not recorded	
cX	cNX	
c0	cN0	
c0A	cN0a	
c0B	cN0b	
c1	cN1	
c1A	cNla	

Code	Definition
c1B	cN1b
c1C	cN1c
c2	cN2
c2A	cN2a
c2B	cN2b
c2C	cN2c
c3	cN3

Code	Definition
c3A	cN3a
сЗВ	cN3b
C3C	cN3c
c4	cN4
88	Not applicable

Deleted codes: c0I- [cN0i-], c0I+ [cN0i+], c0M- [cN0m-], c0M+ [cN0m+], c1MI [cN1mi] (used for pathologic staging only)

Table 4. TNM Path N [890]

C 4: 1141VI I dell'14 [050]				
Code	Definition			
(blank)	Not recorded			
pX	pNX			
c0	cN0			
p0	pN0			
p0I-	pN0i-			
p0I+	pN0i+			
p0M-	pN0m-			
p0M+	pN0m+			
p1MI	pN1mi			

Code	Definition
p0A	pN0a
p0B	pN0b
p1	pN1
p1A	pNla
p1B	pN1b
p1C	pN1c
p2	pN2
p2A	pN2a
p2B	pN2b

Code	Definition
p2C	pN2c
р3	pN3
p3A	pN3a
р3В	pN3b
p3C	pN3c
p4	pN4
88	Not applicable

Added code: of c0 [cN0] (In 2016, this new category is to be used for in situ only; use of this category will be expanded for the AJCC 8th Edition).

Table 5. TNM Clin M [960]

Code	Definition
(blank)	Not recorded
c0	сМ0
c0I+	cM0(i+)
c1	cM1
c1A	сМ1а
c1B	cM1b
c1C	cM1c
c1D	cM1d
c1E	cM1e

Code	Definition		
p1	pM1		
p1A	pM1a		
p1B	pM1b		
p1C	pM1c		
p1D	pM1d		
p1E	pM1e		
88	Not applicable		

Added codes: p1, p1A, p1B, p1C, p1D, and p1E [pM1, pM1a, pM1b, pM1c, pM1d, pM1e, respectively]

Table 6. TNM Path M [900]

Code	Definition		
(blank)	Not recorded		
c0	cM0		
c0I+	cM0(i+)		
p1	pM1		
p1A	pM1a		
p1B	pM1b		

Code	Definition
p1C	pM1c
p1D	pM1d
p1E	pM1e
c1	cM1
c1A	cM1a
c1B	cM1b

Code	Definition		
c1C	cM1c		
c1D	cM1d		
c1E	cM1e		
88	Not applicable		

Deleted code: 0 [M0]

Added codes: c0 [cM0], c0I+ [cM0(i+)], c1 [cM1], c1A, c1B, C1C, C1D, and C1E [cM1a, cM1b, cM1c, cM1d, cM1e, respectively]

C.2 Conversion Specifications for AJCC T, N, and M data items [940, 950, 960, 880, 890, and 900] for Historical Data

- 1. Add prefix "c" to any existing clinical T (except A, IS, ISPU, ISPD, SU, SD)
- 2. Add prefix "c" to any existing clinical N and M value
- 3. Do not prefix blank or 88
- 4. Add prefix "p" to any existing pathologic T (except ISPU, ISPD, SU, SD)
- 5. Add prefix "p" to any existing pathologic N and M value
- 6. Do not prefix blank or 88
- 7. For **clinical T**:
 - a. Revise the following values:
 - i. A [Ta] to pA [pTa]
 - ii. IS [Tis] to pIS [pTis]
 - iii. ISPU [Tispu] to pISU [pTisu]
 - iv. ISPD [Tispd] to pISD [pTisd]
 - v. SU [Tsu] to pISU [pTisu]
 - vi. SD [Tsd] to pISD [pTisd]
- 8. For **pathologic T**:
 - a. Revise the following values:
 - i. ISPU [Tispu] to pISU [pTisu]
 - ii. ISPD [Tispd] to pISD [pTisd]
 - iii. SU [Tsu] to pISU [pTisu]
 - iv. SD [Tsd] to pISD [pTisd]

SU and SD were valid for 5th and 6th editions of AJCC.

13 Appendix D ICD-O-3 Histology Code Crosswalk

Continued Use of ICD-O-3 Histology Code Crosswalk:

The following table is an excerpt from the NAACCR Guidelines for ICD-O-3 Update Implementation (December 2013). The complete document can be found on the NAACCR web site: <u>Guidelines for ICD-O-3 Update Implementation</u>

ICD-O-3 Change	ICD-O-3 Histology Code (do NOT use these codes)	Description	Comment	Use this Histology Code in 2015 and 2016
New term and code	8158/1	Endocrine tumor, functioning, NOS	Not reportable	
New related term	8158/1	ACTH-producing tumor	Not reportable	
New term and code	8163/3	Pancreatobiliary- type carcinoma (C24.1)	DO NOT use new code	8255/3
New synonym	8163/3	Adenocarcinoma, pancreatobiliary-type (C24.1)	DO NOT use new code	8255/3
New term	8213/3	Serrated adenocarcinoma		8213/3*
New code and term	8265/3	Micropapillary carcinoma, NOS (C18, C19.9, C20.9)	DO NOT use new code	8507/3*
New code and term	8480/1	Low grade appendiceal mucinous neoplasm (C18.1)	Not reportable	
New term and code	8552/3	Mixed acinar ductal carcinoma	DO NOT use new code	8523/3
New term and code	8975/1	Calcifying nested epithelial stromal tumor (C22.0)	Not reportable	
New term and code	9395/3	Papillary tumor of the pineal region	DO NOT use new code	9361/3*

ICD-O-3 Change	ICD-O-3 Histology Code (do NOT use these codes)	Description	Comment	Use this Histology Code in 2015 and 2016
New term and code	9425/3	Pilomyxoid astrocytoma	DO NOT use new code	9421/3
New term and code	9431/1	Angiocentric glioma	DO NOT use new code	9380/1*
New term and code	9432/1	Pituicytoma	DO NOT use new code	9380/1*
New term and code	9509/1	Papillary glioneuronal tumor	DO NOT use new code	9505/1
New related term	9509/1	Rosette-forming glioneuronal tumor	DO NOT use new code	9505/1
New term and code	9741/1	Indolent systemic mastocytosis	Not reportable	

^{*} ICD-O-3 rule F applies (code the behavior stated by the pathologist). If necessary, over-ride any advisory messages.

14 Appendix E CDC NPCR Changes to 2016 Required Status Table

CDC NPCR 2016 Requirements				
Item Item Name Status Change(s)				Rationale
94	Census County 1990	D	New	Populated through the geocoding process
95	Census County 2000	D	New	to ensure appropriate county for the
96	Census County 2010	D	New	decennial Census used to assign Census
				Tract.
756	Tumor Size Summary	R	New	Captures a single best tumor size from all
				information available.
3312	Rural Urban Continuum	D	New	Codes can be derived electronically, using
	2013			patients' state and county at diagnosis.
3650	NPCR Derived Clin Stg Grp	R	New	Central Registry Only: Intended to
3655	NPCR Derived Path Stg Grp	R	New	capture stage group derived from AJCC-
				TNM tables and assist central registries
				post-consolidation.
880	TNM Path T	R	RN to R	Transition from CSv2 to directly-assigned
890	TNM Path N	R	RN to R	AJCC-TNM. Required from ALL facilities.
900	TNM Path M	R	RN to R	
910	TNM Path Stage Group	R	RN to R	
920	TNM Path Descriptor	R	RN to R	
940	TNM Clin T	R	RN to R	
950	TNM Clin N	R	RN to R	
960	TNM Clin M	R	RN to R	
970	TNM Clin Stage Group	R	RN to R	
980	TNM Clin Descriptor	R	RN to R	
1060	TNM Edition Number	R	RN to R	
1380	RX Summ - Surg/Rad Seq	R	RN to R	Helpful in assessing neoadjuvant therapy.
1639	RX Summ – Systemic/Sur	R	RN to R	Required from ALL facilities
	Seq			
2861	CS SSF7	RH	RS* to RH	No longer needed for 2016+
2864	CS SSF10	RS	RS* to RS	See Table 2 below
2866	CS SSF12	RH	RS* to RH	No longer needed for 2016+
2871	CS SSF17	RH	RS* to RH	No longer needed for 2016+
2872-	Site Specific Factors 18-24	Blank/Not	RS* to Blank	These data items were never used to
2878		Required		calculate Derived Summary Stage 2000 or Derived AJCC-TNM Stage and were never
				prognostic factors of interest.
2900	CS SSF3	RH	RS to RH	No longer needed for 2016+
2910	CS SSF4	RH	RS* to RH	No longer needed for 2016+
2920	CS SSF5	RS	RS* to RS	See Table 2 below
2930	CS SSF6	RS	RS* to RS	See Table 2 below
2800	CS Tumor Size	RH	R to RH	
2810	CS Extension	RH	R to RH	

	CDC NPCR 2016 Requirements							
Item	Item Name	Status	Change(s)	Rationale				
2820	CS Tumor Size/Ext Eval	RH	R to RH	These data items are required historically				
2830	CS Lymph Nodes	RH	R to RH	for deriving SEER Summary Stage for				
2850	CS Mets at DX	RH	R to RH	cases diagnosed 2004-2015.				
2936	CS Version Derived	RH	R to RH					
3020	Derived SS2000	RH	R to RH					
3050	Derived SS2000Flag	RH	R to RH					
2840	CS Lymph Nodes Eval	RH*	R* to RH*	These data items are required				
2860	CS Mets Eval	RH*	R* to RH*	historically, <u>as available</u> , for deriving AJCC				
3400	Derived AJCC-7 T	RH*	D* to RH*	TNM Stage for cases diagnosed 2011-				
3402	Derived AJCC-7 T Descript	RH*	D* to RH*	2015.				
3410	Derived AJCC-7 N	RH*	D* to RH*					
3412	Derived AJCC-7 N Descript	RH*	D* to RH*					
3420	Derived AJCC-7 M	RH*	D* to RH*					
3422	Derived AJCC-7 M Descript	RH*	D* to RH*					
3430	Derived AJCC-7 Stage Grp	RH*	D* to RH*					
3750-	Over-ride CS 1-19	Blank/Not	R to Blank	These data items were never defined or				
3768		Required		used for data collection.				
3769	Over-ride CS 20	RH	R to RH	Required historically for cases that were				
				assigned directly coded SS00 in lieu of CS				
				derived SS due to resource limitations.				

R = REQUIRED; R* = REQUIRED, WHEN AVAILABLE; RS = REQUIRED, SITE-SPECIFIC; RS* REQUIRED, SITE-SPECIFIC, WHEN AVAILABLE; D* = DERIVED, SITE-SPECIFIC; RN = IMPLEMENT ACCORDING TO NPCR STAGE TRANSITION PLAN; RH = REQUIRED HISTORICALLY; RH* = REQUIRED HISTORICALLY, WHEN AVAILABLE

15 Appendix F NCI SEER Changes to 2016 Required Status Table

Changes in NCI SEER Requirements for 2016						
Item#	Item Name	SEER Collect	SEER Transmit	Note	Rationale	
94	County at DX Geocode 1990	D	R			
95	County at DX Geocode 2000	D	R			
96	County at DX Geocode 2010	D	R			
97	County at DX Geocode 2020	D	R			
752	Tumor Size Clinical	R	R	New		
754	Tumor Size Pathologic	R	R	New		
756	Tumor Size Summary	S	S	New		
759	SEER Summary Stage 2000	R+	R+	Revised	Required, either directly-assigned (759) or derived from CS (3020)	
762	Derived SS2017			New	Not required for 2016 cases	
764	Directly Assigned SS2017			New	Not required for 2016 cases	
772	SEER Primary Tumor	•		New	Not required for 2016 cases	
774	SEER Regional Nodes	•		New	Not required for 2016 cases	
776	SEER Mets	•		New	Not required for 2016 cases	
880	TNM Path T	R	R	Revised		
890	TNM Path N	R	R	Revised		
900	TNM Path M	R	R	Revised		
910	TNM Path Stage Group	S	S	Revised		
920	TNM Path Descriptor	R	R	Revised		
930	TNM Path Staged By	R	R	Revised		
940	TNM Clin T	R	R	Revised		
950	TNM Clin N	R	R	Revised		
960	TNM Clin M	R	R	Revised		
970	TNM Clin Stage Group	S	S	Revised		
980	TNM Clin Descriptor	R	R	Revised		
990	TNM Clin Staged By	R	R	Revised		
1060	TNM Edition Number	R	R	Revised		
1112	Mets at DX–Bone	R	R	New		
1113	Mets at DX–Brain	R	R	New		
1114	Mets at DX-Distant LN	R	R	New		
1115	Mets at DX–Liver	R	R	New		
1116	Mets at DX-Lung	R	R	New		
1117	Mets at DX-Other	R	R	New		
1320	RX SummSurgical Margins R		R*		Required when available	
1782	Surv-Date Active Followup	D	R	New		

	Changes in NCI SEER Requirements for 2016						
Item #	Item Name	SEER Collect	SEER Transmit	Note	Rationale		
1783	Surv-Flag Active Followup	D	R	New			
1784	Surv-Mos Active Followup	D	R	New			
1785	Surv-Date Presumed Alive	D	R	New			
1786	Surv-Flag Presumed Alive	D	R	New			
1787	Surv-Mos Presumed Alive	D	R	New			
1788	Surv-Date DX Recode	D	R	New			
1942	Place of DeathState	R*	R*		Required when available		
1944	Place of DeathCountry	R*	R*		Required when available		
1981	Over-ride SS/NodesPos	R	R				
1982	Over-ride SS/TNM-N	R	R				
1983	Over-ride SS/TNM-M	R	R				
2355	Addr CurrentSupplementl	R*			Required to collect when available		
2440	Following Registry	RH			No longer required for 2016 cases		
2445	NPIFollowing Registry	RH*			No longer required for 2016 cases		
2800	CS Tumor Size	S	S		Required for SEER registries collecting CS for 2016 cases		
2810	CS Extension	S	S		Required for SEER registries collecting CS for 2016 cases		
2820	CS Tumor Size/Ext Eval	S	S		Required for SEER registries collecting CS for 2016 cases		
2830	CS Lymph Nodes	S	S		Required for SEER registries collecting CS for 2016 cases		
2840	CS Lymph Nodes Eval	S	S		Required for SEER registries collecting CS for 2016 cases		
2850	CS Mets at DX	S	S		Required for SEER registries collecting CS for 2016 cases		
2851	CS Mets at Dx-Bone	RH	RH				
2852	CS Mets at Dx-Brain	RH	RH				
2853	CS Mets at Dx-Liver	RH	RH				
		RH	RH				
2854	CS Mets at Dx-Lung	КП	КП		Required for SEER registries		
2860	CS Mets Eval	S	S		collecting CS for 2016 cases		
2935	CS Version Input Original	S	S		Required for SEER registries collecting CS for 2016 cases		
2936	CS Version Derived	D*	S		Required for SEER registries collecting CS for 2016 cases		
2937	CS Version Input Current	S	S		Required for SEER registries collecting CS for 2016 cases		

Changes in NCI SEER Requirements for 2016						
Item#	Item Name	SEER Collect	SEER Transmit	Note	Rationale	
2940	Derived AJCC-6 T	D*	S		Required for SEER registries collecting CS for 2016 cases	
2950	Derived AJCC-6 T Descript	D*	S		Required for SEER registries collecting CS for 2016 cases	
2960	Derived AJCC-6 N	D*	S		Required for SEER registries collecting CS for 2016 cases	
2970	Derived AJCC-6 N Descript	D*	S		Required for SEER registries collecting CS for 2016 cases	
2980	Derived AJCC-6 M	D*	S		Required for SEER registries collecting CS for 2016 cases	
2990	Derived AJCC-6 M Descript	D*	S		Required for SEER registries collecting CS for 2016 cases	
3000	Derived AJCC-6 Stage Grp	D*	S		Required for SEER registries collecting CS for 2016 cases	
3010	Derived SS1977	D*	S		Required for SEER registries collecting CS for 2016 cases	
3020	Derived SS2000	D+	R+		Required, either directly-assigned (759) or derived from CS (3020)	
3030	Derived AJCCFlag	D*	S		Required for SEER registries collecting CS for 2016 cases	
3040	Derived SS1977Flag	D*	S		Required for SEER registries collecting CS for 2016 cases	
3050	Derived SS2000Flag	D*	S		Required for SEER registries collecting CS for 2016 cases	
3230	RX Date Systemic	RC	RC			
3231	RX Date Systemic Flag	RC	RC			
3312	RuralUrban Continuum 2013	D	R			
3400	Derived AJCC-7 T	D*	S		Required for SEER registries collecting CS for 2016 cases	
3402	Derived AJCC-7 T Descript	D*	S		Required for SEER registries collecting CS for 2016 cases	
3410	Derived AJCC-7 N	D*	S		Required for SEER registries collecting CS for 2016 cases	
3412	Derived AJCC-7 N Descript	D*	S		Required for SEER registries collecting CS for 2016 cases	
3420	Derived AJCC-7 M	D*	S		Required for SEER registries collecting CS for 2016 cases	
3422	Derived AJCC-7 M Descript	D*	S		Required for SEER registries collecting CS for 2016 cases	

Changes in NCI SEER Requirements for 2016						
Item#	Item Name	SEER Collect	SEER Transmit	Note	Rationale	
3430	Derived AJCC-7 Stage Grp	D*	S		Required for SEER registries collecting CS for 2016 cases	
3605	Derived SEER Path Stg Grp	D	R	New		
3610	Derived SEER Clin Stg Grp	D	R	New		
3614	Derived SEER Cmb Stg Grp	D	R	New		
3616	Derived SEER Combined T	D	R	New		
3618	Derived SEER Combined N	D	R	New		
3620	Derived SEER Combined M	D	R	New		
3622	Derived SEER Cmb T Src	D	R	New		
3624	Derived SEER Cmb N Src	D	R	New		
3626	Derived SEER Cmb M Src	D	R	New		

R = Required; $R^* = Required$, when available; RC = Collected by SEER from CoC-accredited hospitals; R + E Required, central registries may collect either seer summary stage 2000 or collaborative stage; E Historically collected and currently transmitted; E Historically collected and currently transmitted when available; E Derived; E Derived, when available; E Derived, central registries may collect either seer summary stage 2000 or collaborative stage; E S = Supplementary/recommended

16 Appendix G Revision Control

2016 Implementation Guidelines						
Revision Control						
Version	Revision	Section	Revision Notes			
Number	Date	Section	Revision Notes			
1.1	12/4/15	Cover page	Added version number and added Revised December 2015.			
1.1	12/4/15	4.2	In the second paragraph, added the last sentence.			
1.1	12/4/15	4.2	Deleted the Note at the end of this section.			
1.1	12/4/15	6.1	Added, Implementation of Clinical and Pathologic Indicators			
			for the AJCC T, N, and M Data Items and the following two			
			paragraphs.			
1.1	12/4/15	<u>6.2</u>	Added paragraph above the Required Site-Specific Factors			
			regarding CDC NPCR implementation of clinical and			
			pathologic indicators for the AJCC T, N, and M data items.			
1.1	12/4/15	<u>6.3</u>	Added second paragraph regarding NCI SEER			
			implementation of clinical and pathologic indicators for the			
			AJCC T, N, and M data items.			
1.1	12/4/15	Appendix C	Deleted the Notes, added table numbers, added the deleted			
			codes and the added codes following each table, and revised			
			C.2.			
1.1	12/4/15	Appendix G	Added Appendix G Revision Control			
1.2	12/21/15	Appendix C	In C.1. added note after Table 3 and modified note after			
			Table 4.			
			In C.2. in 1 and 2 added SU and SD, and "do not prefix blank			
			or 88"; added 3.a.v. and 3.a.vi.; added 4.a.iii. and 4.a.iv.;			
4.0	1/12/16	1: 0	and, added the last sentence regarding SU and SD.			
1.3	1/12/16	Appendix C	Changed codes/definitions in Table 3 and Table 6 to be			
			consistent with changes made in the 2016 IG Version 1.2 and			
1.3	1/12/16	6.2	the notes below each of the tables. In Table 1 for Prostate added SSF 8 and 10, and added			
1.5	1/12/16	<u>6.2</u>	Gleason Score to Description.			
1.4	3/28/16	4.2	Replaced 1 st paragraph and added 3 new paragraphs at the			
1.4	3/28/10	4.2	beginning of this section.			
1.4	3/28/16	4.2.1	Added section 4.2.1.			
1.4	3/28/16	5	In the second paragraph, changed the Version 16 metafile			
1	3,20,10	<u> </u>	release date from February 2016 to spring 2016.			
1.4	3/28/16	6.2	Added NPCR's Guidance Regarding C and P Conversion			
	0, 20, 20	3.2	section and NPCR's Guidance Regarding Software Upgrade			
			paragraph.			
1.4	3/28/16	6.3	Added table, SEER SSFs No Longer Applicable.			
			Updated last paragraph by replacing 'Staging and Predictive			
			and Prognostic (S&PP) factors data warehouse' with 'SEER			
			Registrar Staging Assistant (SEER*RSA)'.			
1.4	3/28/16	9.5	Added Northcon Conversion Utility paragraph.			
1.4	3/28/16	Appendix A	The following sentences was added to the first paragraph:			
			The conversion below will be performed across all diagnosis			

1.4	3/28/16	Appendix C	years (cases diagnosed in 2016 for which abstraction is started in NAACCR Version 15-compliant software will be converted). The following was added to C.1: for use within Version 16.0 software. The following was revised in C.2: 1. Add prefix "c" to any existing clinical T (except A, IS, ISPU, ISPD, SU, SD) 2. Add prefix "c" to any existing clinical N and M value 3. Do not prefix blank or 88 4. Add prefix "p" to any existing pathologic T (except ISPU, ISPD, SU, SD) 5. Add prefix "p" to any existing pathologic N and M value 6. Do not prefix blank or 88	
1.4	3/28/16	Appendix H	Added Appendix H.	
1.5	6/21/16	<u>5</u>	In 2 nd paragraph, updated the release date. Updated the last three paragraphs.	

17 Appendix H TNM Classification Designator Impact (CDI): Considerations for Central Registries

NAACCR TNM CDI Task Force Members: Colleen Sherman (NY), Jenna Mazreku (CA), Julia Espinoza (WY), Steven Peace (FL), Vicki Moxley (WY), Winny Roshala (CA), Jim Hofferkamp (NAACCR)

Directive/Charge to this Task Force

To identify issues central registries need to consider as they decide how to best operationalize receiving directly-assigned pre-2016 TNM data from reporting facilities, based on the implementation of the TNM c and p classification designators (TNM c and p "prefixes" or "indicators"). This would include both converted and non-converted directly-assigned pre-2016 TNM data.

Below are several issues and options central registries should consider when determining how to manage receiving converted directly-assigned pre-2016 TNM data, incorporating the c and p designators, as well as managing non-converted directly-assigned pre-2016 TNM data, without the c and p designators from reporting facilities.

Background Information and Reminders

- 1. Depending on central registry requirements, central registries may receive both converted and non-converted directly-assigned pre-2016 TNM data from reporting facilities.
- 2. Registries will continue to use Collaborative Stage for their stage data for cases diagnosed from 2004 through 2015.
- 3. Beginning with cases diagnosed in 2016, directly-assigned AJCC TNM and Summary Stage will be the primary source for stage data. Most registries will no longer collect Collaborative Stage data beginning with cases diagnosed in 2016, except for the SSFs.
- 4. The conversion of pre-2016 TNM data to include the classification designators only pertains to directly-assigned TNM values during this time period. The conversion does not impact or apply to TNM values derived from Collaborative Stage.
- 5. With the exception of requiring central registries to collect 2015 directly-assigned TNM data from CoC approved reporting facilities when available, the CDC's NPCR and SEER do not require central registries collect directly-assigned pre-2016 TNM data. As such, the quality and accuracy of this data has not been assessed by most central registries.
- 6. The CDC's NPCR and SEER are not requiring central registries to convert directly-assigned pre-2016 TNM data to include the c and p designators.
- 7. For SEER registries, the November 2016 data submission requires the inclusion of directly-assigned 2015 TNM data from CoC approved facilities when available, however, TNM data is not required to be converted to the 2016 standard to include the c and p designators.
- 8. The Northcon Conversion Utility will provide central registries with the option to convert or not convert directly-assigned pre-2016 TNM data.
 - The Northcon Conversion Utility only converts v15 files to v16. The utility cannot be
 used to add c and p designators to a file already in the v16 layout at the time this
 document was produced.
 - If the central registry selects the "Convert TNM Clin/Path Items," c and p designators will be added to all of the directly-assigned pre-2016 TNM data items on their database.

- If any 2016 cases are on the database prior to conversion, the c and p designators will have to be added manually.
- If the central registry does not select the "Convert TNM Clin/Path Items," the conversion will occur without adding the c and p designators to directly-assigned pre-2016 TNM data items.
- CDC's NPCR is developing a separate utility that can be used by central registries to remove the c and p designators from pre-2016 cases submitted by reporting facilities. Central registries that choose this option will need to run all incoming submissions through this utility for as long as pre-2016 cases are submitted.
- 9. The conversion specifications for directly-assigned pre-2016 TNM data items are included in Appendix C of the NAACCR 2016 Implementation Guidelines and Recommendations.
- 10. The TNM c and p designators are required by the CoC, CDC's NPCR and SEER for all cases diagnosed 2016 forward.
- 11. Edit sets have been developed to accommodate each of the following scenarios for directly-assigned pre-2016 TNM data items:
 - a. C and p designators are required
 - b. C and p designators are not allowed
 - c. TNM values are allowed with or without the c and p designators

Central registries will select which edits to include in their state metafile based on how they choose to accept incoming pre-2016 cases. See options 1-3 below.

- 12. For cases diagnosed prior to 2016, but seen at the reporting facility with recurrent or persistent disease in or after 2016:
 - a. The CoC requires CoC approved reporting facilities to directly-assign TNM using the new designators, regardless of diagnosis date, once they have converted to v16 software. This applies to any case abstracted using v16 software.
 - b. The CDC's NPCR does not have a position on how grantees should handle TNM data with c and p designators for cases diagnosed before 2016, regardless of the software version used. NPCR is not requiring state registries to submit directly-assigned TNM data collected for diagnosis years prior to 2016, therefore they have not established any standards for such data.
 - c. According to SEER, they allow, but do not require, c or p designators on pre-2016 diagnosed cases submitted 2016 or later.
- 13. For cases diagnosed in 2016, but first entered in v15 software, the T, N, and M values will not be converted and thus must be reviewed and manually assign the c and p designators.

Central registries will first have to decide what to do with directly-assigned TNM data for cases diagnosed prior to 2016 currently on their database. Registries will need to either keep the directly-assigned pre-2016 TNM data without the designators or convert it to include the designators. Consideration should be given to maintaining central registry data uniformity and consistency, as well as the impact of researcher use of the data. In addition, central registries will need to consider how to process incoming directly-assigned pre-2016 TNM data.

Options to Consider

Option #1:

Convert all directly-assigned pre-2016 TNM data in the central registry to include the TNM c and p designators.

- a. Pros: Ease in accepting converted pre-2016 cases from reporting facilities, consistency with legacy data from CoC approved reporting facilities; moving forward to 2017, c and p designators are being formally written into the AJCC 8th edition. As a result, any registry that does not convert directly-assigned pre-2016 TNM data will eventually lack data uniformity for earlier years.
- b. Cons: Potential negative impact in converting data not previously required to be collected by the CDC's NPCR or SEER; converting data not previously assessed for accuracy or quality; implied accuracy of classification regarding TNM data.
- c. Process incoming directly-assigned pre-2016 TNM data: Require all reporting facilities to directly assign TNM values with the c and p designators. At the time this document was produced, a utility to add the c and p designators to v16 cases had not been developed.

Option #2:

Do not convert directly-assigned pre-2016 TNM data in the central registry database and identify methods to disallow converted directly-assigned pre-2016 TNM data into the central registry database

- a. Pros: No conversion work effort for the central registry; data remains consistent as is, without implied accuracy of classification regarding TNM data not previously required by the CDC's NPCR or SEER.
- b. Cons: Need to develop a method to disallow the c and p designators for directly-assigned pre-2016 TNM converted data; no legacy data with c and p designators leading to a lack of uniformity moving forward to 2017 data.
- c. Process incoming directly-assigned pre-2016 TNM data: Allow reporting facilities to submit with or without the c and p designators. If cases are received with the c and p designators, the CDC's NPCR utility currently under development, can be used to remove the designators prior to uploading the data to the central registry database.

Option #3:

Allow a "mixed bag" approach, so that central registries are able to accept cases with converted directly-assigned pre-2016 TNM data as well as cases without converted directly-assigned pre-2016 TNM data; the central registry could link the records and choose whether or not to consolidate the TNM stage data

- a. Pros: Allows for flexibility and agility in dealing with receiving both converted and non-converted directly-assigned pre-2016 TNM data; data exchange files can be handled accordingly; edits can be selected as needed to accommodate the TNM format within the data file.
- b. Cons: Lack of TNM data uniformity within the central registry data base; potential negative impact on data analysis, due to having a "mixed bag" of directly-assigned pre-2016 TNM data, difficulty in consolidating data from multiple facilities if the values from different facilities are not standardized.
- c. Process incoming directly-assigned pre-2016 TNM data: Allow reporting facilities to submit with or without the c and p designators. The directly-assigned TNM data values will not be modified and will be added to the central registry database as submitted by the reporting facility.

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