FCDS DATA VALIDATION AUDIT with E-PATH VERIFICATION

Diagnosis Year: 2012

Cancer Sites: Breast, Colon

Hospital Analytic Cases Only

Facilities: Appendix A

Preface

The Centers for Disease Control and Prevention National Program of Cancer Registries (CDC NPCR) requires that all states receiving funding under this program meet all NPCR Program Standards as defined in the NPCR Program Manual, v2.0 and the NPCR Program Standards 2012-2017. These standards are based on authority provided to the CDC under the Public Health Service Act (Title 42, Chapter 6A, Sub-Chapter II, Part M, § 280e) and subsequent amendments, and apply to all reportable cancers as defined in the Act and any amendments.

The Florida Department of Health (Florida DOH) also requires that Florida's statewide central cancer registry, the Florida Cancer Data System (FCDS), must meet all NPCR Program Standards as defined in the NPCR Program Manual, v2.0 and the NCPR Program Standards 2012-2017. FCDS operates the state cancer registry under contract with the Florida DOH.

The quality of data collected and reported by cancer registries depends upon the completeness of case identification, the completeness and accuracy of case reports, practices in place at the hospital and central cancer registry level, data quality monitoring including editing and record review, and adherence to national program standards (i.e. text documentation).

At least once every 5 years, a combination of re-casefinding (completeness) and re-abstracting (data validation) audits from a sampling of source documents are conducted for each hospital-based reporting facility in the state of Florida. Feedback is provided to individual reporting sources on data quality validation and completeness. Non-hospital based reporting facilities undergo audit sampling as well, but have yet to be included in data validation (re-abstracting) studies, only re-casefinding.

FCDS conducts annual re-casefinding audits via discharge diagnosis and procedures index submitted to the state Agency for Health Care Administration (AHCA) for 100% of in-patient encounters and 100% of ambulatory care patient encounters (hospital/non-hospital) occurring in the state of Florida each year.

FCDS conducts annual re-abstracting (data validation) audits from a sampling of hospitals utilizing a sampling of source documents. The abstract, itself is a source document for the central cancer registry in that it is a primary source document for both patient and tumor consolidation, critical program components. Hence, inclusion of source documents for both the hospital and the central registry may reveal data quality issues or abstracting/reporting circumstance(s) for both the hospital-based reporting facility and the state central registry. Each may identify issues in need of attention at either or both the hospital-level or the central registry level in one or more key areas (i.e. data acquisition, data reliability, interpretation of rules/coding systems (including staging), patient/tumor consolidation, and overall data quality.

Audits may include manual/visual review of one or more source documents, data linkages of one or more electronic files from reporting facilities with the central cancer registry database with a cross-walk and/or comparison of output results.

This audit is designed to manually/visually review electronically matched e-pathology reports to hospital-submitted registry abstracts in combination with concentrated visual editing of analytic (diagnosed/treated at the audit facility) breast and colon cancer cases that were treated surgically at the facility to be audited. Text Documentation of specific data items has been an ongoing cancer reporting requirement for more than a decade with both requirements and expectations reinforced back to Florida registrars on a regular basis. The concentrated visual editing component of this audit is modeled after the NPCR Visual Editing Audit conducted early in 2013 for 2010 diagnoses, utilizes FCDS standard visual editing procedures routinely used to convey review findings across the state with similar selection and review criteria.

The audit methodology and design is intended to utilize existing and readily available source documents submitted by pathology labs (independent and hospital-based) and hospitals across the state of Florida to validate coded data and text from routinely reported original source abstracts and electronic surgical pathology reports routinely submitted by anatomic pathology labs across the state of Florida. Two levels of audit will be performed on each original record.

There will be no travel required and no need to gain access to any facility-based EMR System or multiple EMR Systems.

Hospitals will be required to complete a reconciliation phase when re-abstracted data (data abstracted during this audit) do not match the original data submitted from the facility base abstract or the electronic surgical pathology report(s).

Final results and recommendations to reporting facilities will include analysis of missing or incomplete pathology reports, missing or incomplete text documentation, accuracy of code selection (interpretation of coding rules and guidelines and proper code selection) for key data items, and other critical information identified as data quality concern(s).

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LIST OF ABBREVIATIONS

FCDS	Florida Cancer Data System
FCDS DAM	FCDS Data Acquisition Manual
FCDS IDEA	FCDS (Secure) Internet Date Entry and Abstracting Portal
DOH	Florida Department of Health
CDC	Centers for Disease Control and Prevention
NPCR	National Program of Cancer Registries
NAACCR	North American Association of Central Cancer Registries
E-Path	Electronic Anatomic Surgical Pathology Report
QC	Quality Control
EMR	Electronic Medical Records

1. BACKGROUND

A re-abstracting or data validation audit compares original abstract information and coded data to one or more source documents to validate the accuracy and "correctness" or validity of the data captured and coded when compared to original at-the-source documents (i.e. medical records or specific medical reports). The abstract is an original source document submitted by hospitals and ambulatory care centers to FCDS as part of routine cancer surveillance and state cancer reporting, and is utilized as such for case matching, un-duplication and both patient and tumor consolidation procedures. Completeness of text documentation, coding accuracy and validity of data are part of the triad of quality control measures for cancer registries (completeness, accuracy and timeliness). Completeness is a term used when assessing; completeness of case identification (casefinding), completeness of case reporting (abstract or other cancer report submission), and completeness of the text and/or data included in the abstract or cancer report. Accuracy is how correct or close to the original report (validity) the originally coded/abstracted data represent the case. Timeliness is the speed with which central registry data are collected, processed, analyzed, and made available for use.

The purposes of a re-abstracting audit are to:

- Identify discrepancies in the interpretation of abstracting and coding rules and instructions as well as abstracting tools available to registrars; or in the interpretation of information available in patient records.
- Identify missing information to determine if it was missed or truly unavailable.
- Estimate concurrence or agreement rates between the original data collector and the auditor—do the abstractor and the outside auditor both arrive at the same code?
- Identify any trends or patterns that may further characterize incorrect data. Thus providing potential opportunity for education and training, and to improve the interpretation/abstracting of the medical records among data collectors through educational opportunities based on the results of the audit.

A re-abstracting (data validation) audit serves as a surrogate measure of data accuracy for the central registry when the audit is conducted using a sample from a specific time period. Problems in the overall quality of central registry data can be identified and addressed immediately when abstracting issues are identified from the sample of cases.

Most re-abstracting (data validation) audits are not corrective or punitive in nature, but assess understanding of rules and guidelines for abstracting and provide opportunities for abstractor education and professional development.

Re-abstracting audits are designed to evaluate:

- Data quality, reliability and consistency—quality is fitness for use; reliability is assurance that two people will arrive at the same code given the same information in the medical record; consistency is minimizing changes over time in how data are interpreted.
- Registry performance—are the facilities providing data to the central registry doing a good job of accurately representing the medical record in coded form.

Re-abstracting audits also identify:

- Opportunities for quality improvement (e.g. can the central registry data base be made better through identification and correction of data issues).
- Training issues (e.g. are cases being miscoded for particular reasons, such as lack of education).
- Strengths and deficiencies in reporting facilities in data quality and reliability (e.g. are there systematic problems with specific types of cases being inaccurately or inconsistently coded).

Reference: NPCR NETS Module 3 – Quality Control for Central Registries

2. OBJECTIVES

- Assess the validity and completeness of text, codes and text-supported codes provided to FCDS as a part of routine cancer case submission by selected Florida hospitals (data reliability, data quality, reliability).
- Assess the validity of data submitted when source abstract codes are compared to e-pathology coded data.

3. ELIGIBILITY

- Facilities will be selected according to 5-year selection criteria
- Case Selection will be based upon the following criteria:
    - Date of Diagnosis 01/01/2012-12/31/2012
    - Primary Site = C180-C189 (colon) or C500-C509 (breast)
    - Behavior = 2 (in-situ) or 3 (malignant)
    - Central Sequence = 00 (only 1 cancer ever reported)
    - ICD-O-3 Histology Not = 9590-9992 (no lymphoma, leukemia, or other hematopoietic malignancy)
    - Class of Case = 10, 11, 12, 13, 14, 20, 21, 22 (hospital analytic – diagnosed and/or treated at facility)
    - RX SUMM Surgery of Primary Site = 20-70 (a resection of the primary site was performed)
- Case Selection will include at least 5 Breast Cases and 5 Colon Cases
- Case Selection will include no more than 10 Breast Cases and 10 Colon Cases
- Pathology Selection will be based on any e-pathology report(s) with Date of Specimen within 30 days of the original Date of Diagnosis (plus or minus 30 days) as documented/coded on the original case abstract.

4. STUDY DESIGN

- Audit Process
    - Facility Selection – as noted in Appendix A
    - Case Selection – random selection with minimum of 5 each and maximum of 10 each – 10 preferred for all
    - Pathology Selection - any available pathology report(s) with Date of Specimen within 30 days plus or minus of the original Date of Diagnosis as submitted with the original case abstract
    - Data Validation of Abstracted Case (completeness of text documentation and accuracy of coded data based on abstracted text – includes adherence to standard coding rules) – abstract text-to-code validation
    - Data Validation of E-Pathology Text (review of only 2012 e-pathology report(s) linked to Abstracted Case) (accuracy of abstract codes when compared to original source medical record)– e-path text-to-code validation
    - Reconciliation – All Data Discrepancies and all Audit Team Notes are Returned to Originating Hospital for Facility-Level Review, Resolution of Discrepancies, Clarification, or More Information (Additional Text). The facility will have all information available from the original abstract, re-abstracted text, and re-abstracted e-pathology data for any discrepancy. The facility will select and document which of the 3 codes is correct.
    - Manager Review of Data Validation Discrepancy Results, Facility Reconciliation, and Final Arbitration
    - Analysis of Audit Results in 2 Tiers
        - Abstract Text-to-Code Validation – original, 1st coded re-abstract, 1st coded e-path, reconciliation
        - E-Pathology Report Text-to-Code Validation – original, 1st coded re-abstract, 1st coded e-path, reconciliation
    - Final Report and Recommendations

- **Data Items to be included in Data Validation of Abstracted Case** (completeness of text documentation and accuracy of coded data including adherence to standard coding rules) – abstract text-to-code validation

Item Name	Item #
Cancer Diagnosis Information	
Date of Diagnosis	390

Primary Site	400
Laterality	410
Histologic Type	522
Behavior	523
Grade	440
Stage of Disease Information	
CS Tumor Size	2800
CS Extension	2810
CS Lymph Nodes	2830
Number of Regional Nodes Positive	820
Number of Regional Lymph Nodes Examined	830
CS Metastasis at Diagnosis	2850
Derived SS 2000	3020
CS Site Specific Factors for Breast SSF1 – Estrogen Receptor Assay SSF2 – Progesterone Receptor Assay SSF15 – HER2 Result	 2880 2890 2869
Treatment Information	
Rx Summ – Surgery of Primary Site	1290
Scope of Regional Lymph Node Surgery	1292
Rx Summ – Radiation	1380
Radiation Modality	1570
Rx Summ – Chemotherapy	1390
Rx Summ – Hormone	1400
Rx Summ – BRM	1410
Rx Summ – Other	1420
Text Documentation	
All Text Fields Related to Above Data Items	2520-2690

- **Data Items to be included in Data Validation of E-Pathology Text** (accuracy)– e-path text-to-code validation

Item Name	Item #
Cancer Diagnosis Information	
Date of Diagnosis	390
Primary Site	400
Laterality	410
Histologic Type	522
Behavior	523
Grade	440
Stage of Disease Information	
CS Tumor Size	2800
CS Extension	2810
CS Lymph Nodes	2830
Number of Regional Nodes Positive	820
Number of Regional Lymph Nodes Examined	830

5. DATA COLLECTION PROCEDURES

- All data and reports to be used in this audit are readily available to FCDS Audit Team and are part of the greater Florida Cancer Data System. FCDS will build upon existing resources to build a custom audit data capture tool.
- Text from Abstracted Cases will be accessed by CTR Audit Team via secure https at FCDS IDEA.
- CTR Audit Team will code referenced data items using only the original source abstract text documentation.
- If text documentation is insufficient to code referenced data items, the data item will be coded "unknown"
- Text from E-pathology Cases will be accessed by CTR Audit Team via secure https at FCDS IDEA.
- CTR Audit Team will code referenced e-pathology data items using only the original source e-pathology report. However, they will have the FCDS Site Code Displayed so they know if the case is Colon or Breast.
- Cases will be alternately reviewed by a different member of the CTR Audit Team – so no single reviewer will be responsible for the review of both the original source abstract report and the original source e-pathology report.
- Comparison of Data and Statistical Reports will be produced using SAS or other statistical software.
- Disparate Data and Auditor Notes will be returned back to the originating facility via secure https at FCDS IDEA.
- Facility Responses to Disparate Data (case reconciliation) will be made via secure https at FCDS IDEA.
- FCDS Senior Quality Control Manager will serve as final arbiter when disparate data are noted. Final Coding Decisions will be documented in the FCDS audit record and updates made to source abstracts as needed.
- Auditor Instructions will be provided via FCDS Webcast and will be recorded and available for playback.
- Reconciliation Instructions will be provided via FCDS Webcast and will be recorded and available for playback.

6. DATA ANALYSIS

- Florida Standard Major/Minor Discrepancies for Audit

7. QUALITY CONTROL/QUALITY ASSURANCE

- The FCDS Data Validation Audit with E-Pathology Verification is a quality control/quality assurance activity involving multi-level independent and blinded reviews by FCDS Audit Team CTR staff, reconciliation at the originating institution, and final arbitration of disparate data by the FCDS Senior Manager of Quality Control.
- All national standard cancer surveillance coding rules and guidelines will be strictly followed in this audit.
- Original Reviews will be conducted by qualified CTRs with experience in data quality studies.
- Reconciliation Reviews will be conducted by staff at the original reporting institution, usually a CTR.
- Final Reviews will be conducted by the FCDS Senior Manager of Quality Control, also a CTR.
- Feedback on data quality and case completeness will be shared back to each originating institution as well as CTR Review Staff and will be presented in summary at the next FCDS Annual Conference.

8. REGULATORY REQUIREMENTS

8.1 FLORIDA STATUTE(S)

- Cancer reporting to FCDS is mandated by Florida statutes. All cancer cases seen in any health facility licensed under Florida Statute Section 395 or Section 408.07 must be reported to FCDS according to Florida Statutes Section 385.202. This includes all hospitals, ambulatory diagnostic and treatment centers, clinical laboratories and physicians' offices.

- State of Florida Cancer Reporting Statutes
  - *Florida Statute 381.0031*
  - *Florida Statute 385.202*
  - *Florida Statute 395*
  - *Florida Statute 405.01*
  - *Florida Statute 408.07*
  - *Florida Statute 483*
- State of Florida Administrative Code
  - *Rule 64D-3.004*
  - *Rule 64D-3.034*

8.2 Confidentiality

- According to Florida Statute 381, Public Health: General Provisions, "Information submitted in reports required by this section is confidential, exempt from the provisions of s.119.07 (1), and is to be made public only when necessary to public health. A report so submitted is not a violation of the confidential relationship between practitioner and patient." The Health Insurance Portability and Accountability Act of 1996 (HIPAA) became law April 14, 2001.

- HIPAA allows for the reporting of identifiable cancer data to public health entities. Because the Florida Cancer Data System falls under the definition of a public health entity, HIPAA allows your facility to continue to report data to us in compliance with state law. Written informed consent from each cancer patient reported to public health entities is not required under HIPAA; rather hospitals must simply document that reporting has occurred.

- FCDS continues to adhere to all Florida Statues and Department of Health guidelines, and follow strict security measures to assure patient and institutional confidentially.

- No institution or individual complying with Florida statutes 385.202, 405.01, 381.0031, and Florida State Administrative Code(may not have latest update) Rules 64D-3.004 and 64D3.034 shall be civilly or criminally liable for divulging information or providing materials to the statewide registry as required by the law.

9. REFERENCES

- 2013 FCDS Data Acquisition Manual (FCDS DAM) - *http://www.fcds.med.miami.edu/inc/DAM.shtml*
- 2007 Multiple Primary and Histology Coding Rules for Solid Tumors - *http://seer.cancer.gov/tools/mphrules*
- International Classification of Diseases for Oncology, 3rd Edition – World Health Organization, 2000
- Collaborative Stage Data Collection System, v02.04 - *http://www.cancerstaging.org/cstage*
- SEER*Rx - *http://seer.cancer.gov/tools/seerrx*

- National Program of Cancer Registries – NPCR Program Manual and NETS Training Module 3 - *http://www.cdc.gov/cancer/npcr*
- North American Association of Cancer Registries – Volume II: Data Standards and Data Dictionary – *http://naaccr.org*
- Florida Department of Health - *http://www.floridahealth.gov/diseases-and-conditions/cancer/cancer-registry/index.html*
- Florida Cancer Data System – *http://www.fcds.med.miami.edu*
- State of Florida Cancer Reporting Statutes
    - *Florida Statute 381.0031*
    - *Florida Statute 385.202*
    - *Florida Statute 395*
    - *Florida Statute 405.01*
    - *Florida Statute 408.07*
    - *Florida Statute 483*
- State of Florida Administrative Code
    - *Rule 64D-3.004*
    - *Rule 64D-3.034*

APPENDICES

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Appendix A

Facilities to Be Audited for 2012 Diagnosis Year

1300	GULF COAST MEDICAL CENTER
1306	BAY MEDICAL CENTER
1505	CAPE CANAVERAL HOSPITAL
1506	PARRISH MEDICAL CENTER
1546	HOLMES REGIONAL MEDICAL CENTER
1548	WUESTHOFF MEDICAL CENTER MELBOURNE
1800	FAWCETT MEMORIAL HOSPITAL
1905	CITRUS MEMORIAL HOSPITAL
2000	ORANGE PARK MEDICAL CENTER
2347	UNIVERSITY OF MIAMI HOSPITAL*
2372	U OF MIAMI HOSPITAL CLINICS*
2606	SHANDS JACKSONVILLE MEDICAL CENTER
2636	BAPTIST REGIONAL CANCER CENTER-JAX
2648	MEMORIAL HOSPITAL JACKSONVILLE
3715	SPRING HILL REGIONAL HOSPITAL
3836	FLORIDA HOSPITAL HEARTLAND DIVISION
4105	INDIAN RIVER MEMORIAL HOSPITAL
4770	CAPITAL REGIONAL MEDICAL CENTER
5202	WEST MARION COMMUNITY HOSPITAL
5610	SACRED HEART HOSP EMERALD COAST
6206	LARGO MEDICAL CENTER
6704	GULF BREEZE HOSPITAL
7005	VILLAGES REGIONAL HOSPITAL
7405	BERT FISH MEDICAL CENTER
7406	HALIFAX HOSPITAL MEDICAL CENTER
7407	FLORIDA HOSPITAL DELAND
7446	FLORIDA HOSPITAL FISH MEMORIAL
7448	FLORIDA HOSPITAL MEMORIAL MED CTR
	*DOH Requested Audit of Facility

Appendix A

History of Facilities Audited for 2006-2013 Diagnosis Years

2006 DX Audit (FCDS)	2007 DX Audit (FCDS)	2008 DX Audit (NPCR)	2009 DX Audit (FCDS)	2010 DX (NPCR - VE)	2010 DX (NPCR - Con)	2006-2010 Combined	2011 DX CER FAC	2012 DX Audit (FCDS)	2013-2015 DX Non-CER FAC
1306	1170	1601	1405	1505	1100	1100	1100	1300	1170
1605	1548	1836	1602	1605	1170	1170	1547	1306	1508
1900	1636	2358	1688	1607	1300	1300	1601	1505	1510
1905	1647	2660	2205	1609	1306	1306	1602	1506	1836
2304	1681	3906	2336	1900	1505	1405	1605	1546	1846
2338	1686	3977	2359	2348	1546	1505	1606	1548	1900
2376	1800	5836	2606	2372	1548	1546	1607	1800	2130
2377	1836	5851	2636	2372	1602	1548	1609	1905	2140
2379	2000	6201	2640	2374	1605	1601	1610	2000	2246
2383	2246	6278	2648	3932	1606	1602	1636	2347	2310
2405	2302	6305	3701	3932	1607	1605	1645	2372	2359
2650	2310	7405	2973	3937	1609	1606	1647	2606	2605
2672	2351		5100	5836	1610	1607	1649	2636	2640
3907	2605		5105	5848	1636	1609	1676	2648	2660
3937	2700		5110	5848	1645	1610	1681	3715	2672
3977	2738		5505	5848	1647	1636	1686	3836	2700
4206	3705		5606	6069	1681	1645	1687	4105	2736
4546	3805		6105	6305	1686	1647	1688	4770	2738
4601	3932		6106	6446	1687	1681	2146	5202	2870
5200	3938		6206	6570	1688	1686	2302	5610	3701
5670	3978		6248	8702	1800	1687	2304	6206	3890
5705	5390		6274	8727	1836	1688	2305	6704	4206
5805	5446		6570		1846	1800	2306	7005	4516
5849	5471		6600		2146	1836	2307	7405	4601
5850	5607		6870		2302	1846	2336	7406	4605
5891	5610		7005		2304	1900	2338	7407	4645
5969	5836				2305	1905	2347	7446	4647
6001	5848				2306	2146	2348	7448	5200
6003	5936				2307	2205	2349		5406
6045	5967				2336	2302	2351		5505
6047	6172				2338	2304	2353		5616
6171	6205				2347	2305	2356		5607
6203	6246				2348	2306	2357		5610
6251	6250				2351	2307	2358		5670
6252	6347				2353	2310	2372		5705
6273	6348				2356	2336	2374		6106
6305	6805				2357	2336	2376		6172
6707	7407				2358	2338	2377		6201
7405	7446				2372	2347	2378		6205
7406					2374	2348	2379		6346
7448					2376	2351	2383		6347
					2377	2353	2650		6348
					2378	2356	3705		6446
					2379	2357	3805		6570

2006 DX Audit (FCDS)	2007 DX Audit (FCDS)	2008 DX Audit (NPCR)	2009 DX Audit (FCDS)	2010 DX (NPCR - VE)	2010 DX (NPCR - Con)	2006-2010 Combined	2011 DX CER FAC	2012 DX Audit (FCDS)	2013-2015 DX Non-CER FAC
					2383	2358	3903		6600
					2605	2359	3906		6647
					2638	2372	3936		6707
					2640	2374	3937		6846
					2648	2376	3938		6870
					2650	2377	3973		6905
					2700	2378	3977		7205
					2736	2379	3978		
					2738	2383	3988		
					2870	2405	4170		
					3701	2605	4546		
					3903	2606	4547		
					3906	2636	4690		
					3907	2636	4705		
					3932	2638	5100		
					3937	2640	5105		
					3988	2648	5110		
					4516	2650	5205		
					4546	2660	5346		
					4547	2672	5805		
					4601	2700	5806		
					4605	2736	5836		
					4645	2738	5848		
					4690	2870	5849		
					4705	2973	5850		
					5100	3701	5936		
					5105	3705	5967		
					5110	3805	5969		
					5200	3903	5970		
					5205	3906	6001		
					5346	3907	6003		
					5471	3932	6005		
					5670	3937	6036		
					5836	3938	6045		
					5848	3977	6046		
					5849	3978	6047		
					5850	3988	6048		
					5936	4206	6068		
					5967	4516	6069		
					5969	4546	6070		
					5970	4547	6074		
					6003	4601	6105		
					6005	4605	6170		
					6036	4645	6171		
					6046	4690	6203		
					6047	4705	6246		
					6048	5100	6248		

2006 DX Audit (FCDS)	2007 DX Audit (FCDS)	2008 DX Audit (NPCR)	2009 DX Audit (FCDS)	2010 DX (NPCR - VE)	2010 DX (NPCR - Con)	2006-2010 Combined	2011 DX CER FAC	2012 DX Audit (FCDS)	2013-2015 DX Non-CER FAC
					6068	5105	6249		
					6074	5110	6250		
					6105	5200	6251		
					6106	5205	6273		
					6170	5346	6274		
					6171	5390	6278		
					6172	5446	6305		
					6201	5471	6349		
					6205	5505	6805		
					6206	5606	6810		
					6249	5607	6910		
					6250	5610	6936		
					6251	5670	7705		
					6252	5705	7788		
					6278	5805	8017		
					6305	5836	8020		
					6349	5848	8048		
					6390	5849	8050		
					6570	5850	8069		
					6600	5851	8116		
					6647	5891	8335		
					6707	5936	8401		
					6805	5967	8446		
					6846	5969	8467		
					6870	5970	8608		
					6905	6001	8609		
					6936	6003	8610		
					7005	6005	8630		
					7405	6036	8631		
					7406	6045	8632		
					7407	6046	8633		
					7446	6047	8650		
					7448	6048	8656		
					7788	6068	8673		
					8047	6069	8702		
					8111	6074	8709		
					8182	6105	8714		
					8469	6106	8725		
					8655	6170	8726		
					8663	6171	8727		
					8702	6172	8736		
					8707	6201	8745		
					8709	6203	8747		
					8720	6205	8755		
					8727	6206	8769		
					8728	6246	8770		
					8745	6248	8775		

2006 DX Audit (FCDS)	2007 DX Audit (FCDS)	2008 DX Audit (NPCR)	2009 DX Audit (FCDS)	2010 DX (NPCR - VE)	2010 DX (NPCR - Con)	2006-2010 Combined	2011 DX CER FAC	2012 DX Audit (FCDS)	2013-2015 DX Non-CER FAC
						6249	8776		
						6250	8777		
						6251	8779		
						6252	8780		
						6273	8783		
						6274			
						6278			
						6305			
						6347			
						6348			
						6349			
						6390			
						6446			
						6570			
						6600			
						6647			
						6707			
						6805			
						6846			
						6870			
						6905			
						6936			
						7005			
						7405			
						7406			
						7407			
						7446			
						7448			
						7788			
						8047			
						8111			
						8182			
						8469			
						8655			
						8663			
						8702			
						8702			
						8707			
						8709			
						8720			
						8727			
						8727			
						8728			
						8745			
				Audited > 1 This					

2006 DX Audit (FCDS)	2007 DX Audit (FCDS)	2008 DX Audit (NPCR)	2009 DX Audit (FCDS)	2010 DX (NPCR - VE)	2010 DX (NPCR - Con)	2006-2010 Combined	2011 DX CER FAC	2012 DX Audit (FCDS)	2013-2015 DX Non-CER FAC
				Cycle					
				Non-Hosp Cases					

Appendix B

FCDS Data Validation and Visual Editing – Standard Text Documentation Guidelines and Instructions

Text documentation is an essential component of a complete cancer registry abstract and is heavily utilized in quality control activities to validate data on a routine basis, for FCDS, NPCR, or external Audit, and for special studies. **Text documentation is required to justify coded values** and to supplement information not transmitted with coded values. **FCDS recommends that abstractors print and post this document for easy reference.** Adequate text is a data quality indicator and is a major part of QC. Below is a list of FCDS Required Data Items that carry an additional requirement of complete and accurate text documentation. See Table on Following Page for Text and Date Examples for each Text Area.

DATA ITEMS REQUIRING COMPLETE TEXT DOCUMENTATION *Data Items to be Included in Data Validation Audit (Appendix C and D)	
Date of DX *	RX Summ – Surg Prim Site *
Seq No	RX Summ – Scope Reg LN Surgery *
Sex	RX Summ – Surg Oth Reg/Distant
Primary Site *	RX Date – Surgery
Subsite	RX Summ – Radiation *
Laterality *	Rad Rx Modality *
Histologic Type *	RX Date – Radiation
Behavior Code *	RX Summ – Chemo *
Grade *	RX Date – Chemo
	RX Summ – Hormone *
CS Tumor Size *	RX Date – Hormone
CS Ext *	RX Summ – BRM/Immunotherapy *
CS Tumor Ext/Eval	RX Date – BRM/Immunotherapy
Regional Nodes Positive *	RX Summ – Transplant/Endocrine
Regional Nodes Examined *	RX Date – Transplant/Endocrine
CS LN *	RX Summ – Other *
CS LN Eval	RX Date - Other
CS Mets *	
CS Mets Eval	Any Unusual Case Characteristics
Breast CS SSFs 1 (ER), 2 (PR), 15 (HER2) *	Any Pertinent Patient/Family History

***See Appendix C and Appendix D for selected data items to be included in this data validation audit.**

Data items were selected to reflect case completeness and overall data quality and to reinforce basic rules and instruction regarding abstracting cancer cases in the state of Florida. At this time, only these data items are included in routine visual editing. Other data items may be added to the list based on availability, changes to data collection rules, or other reason.

What Should Be Included in Text Fields:

- Date(s) – include date(s) references – this allows the reviewer to determine event chronology
- Date(s) – note when date(s) are estimated [i.e. Date of DX 3/15/2014 (est.)]
- Location – include facility/physician/other location where the event occurred (test/study/treatment/other)
- Description – include description of the event (test/study/treatment/other) – include positive/negative results
- Details – include as much detail as possible – document treatment plan even if treatment is initiated as planned
- Include "relevant-to-this-person/cancer" information only – edit your text documentation
- DO NOT REPEAT INFORMATION from section to section
- DO USE Standard Abbreviations
- DO NOT USE non-standard or stylistic shorthand
- Enter "N/A" or "not available" when no information is available related to any specific text area.

Discrepancy: A discrepancy is defined as the quality or state of being discrepant, i.e., disagreeing, being at variance. A discrepancy arises when text documentation is absent or when a more appropriate code should have been selected for a data item based on the submitted text. Documented text must support coded values for all items noted in this appendix.

Quality Control of Audit Staff: In order to evaluate the quality of FCDS Audit Staff, the automated software program, allows FCDS to monitor the quality of visual editors. In addition, FCDS conducts routine (monthly/quarterly/annual) recoding audits on each FCDS auditor. All audit staff are CTRs in good standing.

Quality Improvement – Closing the Loop with Education and Training: In order to be consistent in the determination of what constitutes a discrepancy, the Florida Cancer Data System will conduct periodic quality control teleconferences, webcasts, or in-person meetings to discuss visual editing issues.

Educational workshops for cancer registry personnel are conducted by both the regional and central registry. In addition, both state and local cancer registrars associations hold educational workshops. It is important for cancer registry personnel to make every effort to attend these workshops.

SAMPLE TEXT DOCUMENTATION BY TEXT FIELD

Text Data Item Name **NAACCR Item #** **Field Length**	**Text Documentation Source and Item Description** *FCDS Required Text Documentation* **Example:**
Text - Physical Exam H&P NAACCR Item #2520 Field Length = 1000	Enter text information from history and physical exams. *History and physical examination findings that relate to family history or personal history of cancer diagnosis, physical findings on examination, type and duration of symptoms, reason for admission.* **Example: Hx RCC Rt Kidney – Dx 9/2011 in Georgia. Adm c/o fever and night sweats. Adm for w/u and found to have enlarged axillary nodes which on biopsy revealed diffuse B-cell lymphoma.**
Text - X-rays/Scans NAACCR Item #2530 Field Length = 1000	Enter text information from diagnostic imaging reports, including x-rays, CT, MRI, and PET scans, ultrasound and other imaging studies. *Date, facility where procedure was performed, type of procedure, detailed findings (primary site, size of tumor, location of tumor, nodes, metastatic sites), clinical assessment, positive/negative results* **Example: 4/12/14 (Breast Center xyz) Mammo - Rt Breast w/1.5cm mass at 12:00 o'clock**
Text - Scopes NAACCR Item #2540 Field Length = 1000	Enter text information from diagnostic endoscopic examinations. *Date of Procedure, facility where procedure was performed, type of procedure, detailed findings (primary site, extent of tumor spread, satellite lesions), clinical assessment, positive/ negative results* **Example: 4/12/13 (Endoscopy Ctr xyz) EGD: gastric mucosa w/ evidence of large tumor occupying half of the stomach. Numerous satellite tumors seen on opposite wall of the stomach**
Text - Lab Tests NAACCR Item #2550 Field Length = 1000	Enter text information from diagnostic/prognostic laboratory tests (not cytology or histopathology). **Text for Collaborative Stage Site Specific Factor or SSF documentation.** *Date(s) of Test(s), facility where test was performed, type of test(s), test results (value and assessment)* **Example: 4/12/14 (Hosp xyz) ER +, PR - , HER2 neg by IHC method, PSA 5.3 (elevated)**

Text Data Item Name **NAACCR Item #** **Field Length**	**Text Documentation Source and Item Description** *FCDS Required Text Documentation* **Example:**
Text - Operative Report NAACCR Item #2560 Field Length = 1000	Enter text information from surgical operative reports (not diagnostic needle, incisional biopsy). Include observations at surgery, tumor size, and extent of involvement of primary or metastatic sites. *Date of procedure, facility where procedure was performed, type of surgical procedure, detailed surgical findings, documentation of residual tumor, evidence of invasion of surrounding areas* **Example: 4/12/14 (Hosp xyz) right colon resection - Pt was found to have extensive disease in the pelvis (carcinomatosis) and resection was aborted, no biopsies were taken, no specimen obtained.**
DX Text - Pathology NAACCR Item #2570 Field Length = 1000	Enter text information from cytology and histopathology reports. *Date of specimen/resection, facility where specimen examined, pathology accession #, type of specimen, final diagnosis, comments, addenda, supplemental information, histology, behavior, size of tumor, tumor extension, lymph nodes (removed/biopsied), margins, some special histo studies* **Example: 2/5/14 (Hosp xyz) – Path Acc # - Rectum: Final Dx: adenoca, 2.5cm, ext. to pericolic fat. 1/22 lymph nodes + , margins neg, S100 stain is positive (melanoma, sarcoma), pT3N1Mx**
DX Text - Staging NAACCR Item #2600 Field Length = 1000	Enter **Details of Collaborative Stage** and other stage information not already entered in other text areas. Include specific information on Tumor Size, Extension of Primary Tumor, Metastatic Sites, etc. *Organs involved by direct extension, size of tumor, status of margins, sites of distant metastasis, special consideration for staging, overall stage, etc*. **Text for SSF documentation if not under Labs**. **Example: 2/15/14 - T2aN1a per path, distant mets in lungs, ER/PR neg, HER2 neg by IHC method**
RX Text - Surgery NAACCR Item #2610 Field Length = 1000	Enter text describing the surgical procedure(s) performed as part of 1st course treatment. *Treatment plan, date surgery performed, type of procedure, facility where surgery was performed* **Example: 2/15/14 (Hosp xyz) - rt breast mrm w/ax ln dissection**
RX Text **Radiation (Beam)** NAACCR Item #2620 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with radiation. *Treatment Plan (if no treatment given), date treatment initiated/completed, facility where treatment administered, type of radiation, dose (if known)* **Example: 2/15/14-3/15/14 (Hosp xyz) – 45 Gy orthovoltage with 20 Gy boost to tumor bed**
RX Text **Radiation (Other)** NAACCR Item #2630 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with radiation. *Treatment Plan (if no treatment given), date treatment initiated/completed, facility where treatment was administered, type of radiation, dose (if known),* **Example: 2/15/14 (Hosp xyz) - radioactive seed implant, radioisotopes (I-131)**
RX Text - Chemo NAACCR Item #2640 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with chemotherapy. *Date treatment initiated, facility/physician office where administered/prescribed, name of agent(s)/protocol, dose/cycle (if known), treatment plan(if known)* **Example: 2/15/14 (Dr Smith) – Start 6 cycles R-CHOP14 – standard dose at 2-week intervals**

Text Data Item Name **NAACCR Item #** **Field Length**	**Text Documentation Source and Item Description** *FCDS Required Text Documentation* **Example:**
RX Text - Hormone NAACCR Item #2650 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with hormone. *date treatment initiated, facility/physician office where administered/prescribed, name of hormone/anti-hormone agent or procedure, dose (if known), Treatment Plan* **Example: 2/15/14 (Dr Jones) - tamoxifen (dose/duration not stated) or bilateral orchiectomy**
RX Text - BRM NAACCR Item #2660 Field Length = 1000	Enter information regarding the treatment of the tumor being reported with biological response modifiers or immunotherapy. *date treatment initiated, facility/physician office where administered/prescribed, name of BRM or immunotherapy agent or procedure, dose (if known), Treatment Plan,* **Example: 2/15/14 (Hosp xyz) - interferon or BCG (dose/duration not stated)**
RX Text - Other NAACCR Item #2670 Field Length = 1000	Enter information regarding treatment that cannot be defined as surgery, radiation, or systemic therapy. *Date treatment planned/initiated, name of other therapy, agent or procedure, dose (if known), facility where performed* **Example: 2/15/14 (Hosp xyz) - blinded clinical trial or hyperthermia (may include study number)**
Text - Remarks NAACCR Item #2680 Field Length = 1000	Document information not provided in any other text field or overflow from text fields. Document personal history of carcinogenic exposure (arsenic, drinking water, uranium, asbestos), other **Example: 40 year h/o of working in ship building and construction w/ lots of asbestos exposure**

Appendix C

Data Items to be Validated – Abstract Review

Data Items to be Validated Abstract Review	
Date of DX	RX Summ – Surg Prim Site
Primary Site	RX Summ – Scope Reg LN Surgery
Laterality	RX Summ – Radiation
Histologic Type	Rad Rx Modality
Behavior Code	RX Summ – Chemo
Grade	RX Summ – Hormone
CS Tumor Size	RX Summ – BRM/Immunotherapy
CS Ext	RX Summ – Other
Regional Nodes Positive	
Regional Nodes Examined	Auditor Text Field(s)
CS LN	
CS Mets	
CS SSFs – Breast Only – SSFs; 1 (ER), 2 (PR), 15 (HER2)	

Appendix D

Data Items to be Validated – E-Pathology Review

Data Items to be Validated E-Path Review
Date of DX
Primary Site
Laterality
Histologic Type
Behavior Code
Grade
CS Tumor Size
CS Ext
Regional Nodes Positive
Regional Nodes Examined
CS LN
Auditor Text Field(s)

Appendix E

Florida Statewide Cancer Registry

2014 Data Validation Audit with E-Path Verification – Facility Information Sheet

The Florida Cancer Data System (FCDS) is charged with providing the highest quality data possible for annual cancer case reporting to the Florida Department of Health and the CDC National Program of Cancer Registries (NPCR). Data must meet rigorous quality standards to be included in local, regional, state, and national cancer rates, reports to Congress, and cancer-related health investigations. FCDS conducts many types of data processing and data quality checks including on-site and remote audits in various formats to ensure all data quality standards continue to be met and to identify areas that may require further education and training.

A Re-Abstracting (Data Validation) Audit will be performed for this facility using electronic copies of primary medical record documents submitted by this facility (electronic pathology reports plus cancer registry abstracts). The audit has been designed to assess the quality of abstracting and the accuracy of coded data items for cases submitted to the Florida Cancer Data System (FCDS). These audits allow FCDS to assess consistency in interpretation of data definitions, adherence to coding rules and guidelines, policies and procedures and to identify areas that require further education and training. A copy of the audit protocol is available from FCDS.

FCDS is utilizing a new approach this year, hoping to make better use of available electronic medical reports in an effort to reduce the burdens that come with on-site audits including; detailed planning, auditor travel, workspace, internet access, and other on-site coordination. There will be no in-person travel required. Code and data item reconciliation is required for each discrepant data item.

Up to 10 cases of primary breast cancer and up to 10 cases of primary colon cancer from calendar year 2012 diagnoses will be audited. Each case will be "hospital analytic" (e.g. patient diagnosed and/or all or part of first course of treatment performed at your hospital).

AUDIT PROCEDURES and INSTRUCTIONS

1. **To obtain a PDF copy or to reprint this Information Sheet,** please go to the FCDS website *http://fcds.med.miami.edu* and log in to FCDS IDEA. If you have Admin or QC User Role - go to the Quality Control Menu. Select FCDS 2014 Quality Assurance Audit then select Information Sheet. A PDF version of this letter will open which can be saved and/or printed at your discretion.
2. **Each Case will undergo Two Distinct Audit Evaluations** with distinct code comparisons and "best value" resolution required.
    a. The **first evaluation** will be a review/recode of abstracted text compared to original abstract codes as a "visual review" with "data validation" of key data items. Undocumented values will be recoded as "unknown/not available". Text is a critical element in all internal FCDS data quality assessments as well as external third party data quality assessment procedures. FCDS, CDC, and the Florida Department of Health have been requiring full text documentation for key variables since 1995.
    b. The **second assessment** will be a comparison of original abstract codes compared to recoded values from the text contained within the electronic pathology report from the surgery of the primary site. This part of the re-abstracting audit will identify areas where abstractors may have incorrectly read, interpreted or coded histology/behavior/grade of tumor; overlooked key staging information included in the surgical pathology report; or missed other information when coding the original abstract.
3. **Coding Inconsistencies** will be documented and returned to the originating facility to be reconciled by a facility registrar. This does not have to be the original case abstractor as this is an audit of overall facility-submitted data quality and not the abstractor.
4. **Reconciliation of Facility-Level Data Discrepancies is required for this audit.** During this part of the audit, the originating institution has an opportunity to rebut any findings with additional documentation from the record or provide a rationale for not including required text or code(s) selected while abstracting the original cancer incident report. **Reconciliation is time sensitive**.
5. **4 Week Deadline for Reconciliation** - Facilities will have four (4) weeks to complete the reconciliation process and address any concerns or inconsistencies between the original text documentation, coded data and both sets of re-abstracted/re-coded data. The facility must select a "best value" for any data item found to have a coding and/or documentation discrepancy. If reconciliation has not been completed within this time frame, all audit recode findings will be reviewed with FCDS Review selected as "final".
6. **Final Reviews** will be conducted by the FCDS Senior Manager for Data Quality/Quality Control and Education.
7. **Audit Case Report:** Key data items will be audited following FCDS Standard Data Validation and Visual Editing Procedures with adherence to all national coding standards, rules and guidelines. Individual cases may be printed with all original and discrepant data, text, recodes, and final decisions including notes printed in a standard format that can be saved as a PDF.
8. **Facility Audit Summary Report:** Facility-specific audit summary findings will be aggregated by facility into a Facility Audit Summary Report. The report will be presented in FCDS standard format with major and minor annotated and summarized for comparison to the State Audit Summary Report. Recommendations for improvements may be included in your facility report.
9. **State Audit Summary Report:** All Facility Audit Summary Reports will be aggregated into a State Audit Summary Report.
10. **Education Planning:** Aggregate findings and recommendations will be used in planning statewide education and training events.

Questions: Please contact Steven Peace at 305-243-4601 or via email at *speace@med.miami.edu.*

Appendix F

Sample Auditor Orientation for Webcast

1. Contract Questions
2. Discuss Protocol-Driven Audit
3. Orientation to 2012 DX Year Audit Objectives and Facility Selection
4. Discuss Pathology Report(s) Selection and Display of Cancer Type for E-Path Coding
5. Discuss Specifics of Audit Reviews and Documentation Requirements related to this Audit
    a. Original Abstract Text Documentation
    b. Original E-Pathology Report Text
    c. Auditor Text Documentation
    d. Final Review Text Documentation
6. Discuss Alternating Abstract Review and E-Path Review for Each Case in the Audit – "blinded" reviews
7. FCDS will send a 2014 Data Quality Assurance Audit Information Sheet to each facility selected for audit – this will serve both as an audit notification as well as provide information the audited facility will need to participate.
8. DO NOT CONTACT ANY FACILITY ABSTRACTOR, CONTRACTOR, REGISTRAR, or MANAGER
9. DO keep FCDS fully informed should you run into unusual or unforeseen circumstances during the audit
10. Auditors will be granted access to specified documents linked to each abstract to be audited
11. Re-Abstracting and Data Validation will be based only on the documents available to the auditor
12. Please adhere to ALL FCDS policy and procedures regarding secure data access using FCDS IDEA
13. FCDS will schedule an Audit Orientation for the Facilities to be Audited – you may attend as "silent"
14. You may not reproduce any abstracts, reports, or other documents in part or in total used during the audit
15. You must complete all audit-related work on or before July 31, 2014
16. Demonstration of audit data collection tool and how to access FCDS IDEA to use the audit data collection tool
17. Instructions to Auditors – DOCUMENT/DOCUMENT/DOCUMENT – YOU are the EXPERT
18. Post-Audit Requirements – NONE
19. Call Steve with any questions 305-243-4601 or email at *speace@med.miami.edu*
20. Questions?

Appendix G

Sample Reports

TBD

Appendix H

Audit Timeline

01/2014	02/2014	03/2014	04/2014	05/2014	06/2014	7/2014	8/2014	9/2014	10/2014
Protocol Development	Protocol Development	Final Protocol							
		Software Development	Software Development	Software Development					
				Identify Audit Team	Audit Orientation Webcast	Follow-Up Audit Team			
					Audit	Audit			
							Reconciliation		
								Final Review	
									Update FCDS Record
								Preliminary Audit Report	Final Audit Report