Error Reduction Software Program in Radiation Oncology

by

Ed Kline

Acknowledgements

A debt of appreciation goes out to the physicians, management and staff of

PHILADELPHIA CANCER TREATMENT Radiation Oncology Center

Located in Philadelphia, PA

NMCC New Mexico Cancer Center

Located in Albuquerque, NM

for their permission to use the **MERP** medical error reduction software program in their clinic and share their experience.

Introduction

- Presentation describes
  - Historical basis for error reduction initiative
  - Published errors and rates of occurrence
  - Prototype paper-based model
  - Design and implementation of software-based model
  - Deployment of software-based model in 2 radiation oncology centers
  - Results of implementation

Introduction

- Patient safety
  - Freedom from accidental injury due to medical care, or absence of medical errors[1,2]

    or
  - Absence of misuse of services[3,4]
- Error
  - The failure of planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)[5]

[1] Hurt ado M, Swift E, Corrigan JM, eds. *Envisioning the National Health Care Quality Report*. Washington, DC: National Academy of Sciences; 2001.

[2] McNutt R, Abrams R, Aarons D. *Patient Safety Efforts Should Focus on Medical Errors*. *JAMA*. 2002;287(15):1997-2001.

[3] Department of Health and Human Services. *The Challenge and Potential for Assuring Quality of Health Care for the 21st Century*. Washington, DC: Department of Health and Human Services; 2000.

[4] The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. *Quality First: Better Health Care for All Americans*; 1998.

[5] *To Err is Human: Building a Safer Health System.* Institute of Medicine (IOM). The National Academies (11/29/99).

Introduction

- In radiation oncology, variety of injuries and errors can occur in the diagnostic imaging or therapeutic treatment delivery processes.
- Various descriptors
  - Unintended deviation
  - Incident
  - Accident
  - Error
  - Mistake
  - Unusual occurrence
  - Recordable event
  - Adverse event
  - Misadministration
  - Medical event
  - Sentinel event

History
1999

- Institute of Medicine (IOM) report[6]
  - Focused a great deal of attention on the issue of medical errors and patient safety
  - 44,000 to 98,000 deaths per year in U.S. hospitals each year as the result of medical errors
  - 10,000 deaths per year in Canadian hospitals
  - Exceeds annual death rates from road accidents, breast cancer, and AIDS combined in U.S.

[6]*To Err is Human: Building a Safer Health System.* Institute of Medicine (IOM). The National Academies (11/29/99).

History
1999

- IOM Costs[7]
  - Approximately $37.6 billion per year
  - About $17 billion are associated with preventable errors
  - Of that $17 billion, about $8 to $9 billion are for direct health care costs
  - Updated estimates place costs between $17 billion and $29 billion per year in hospitals nationwide[8]

[7]*To Err is Human: Building a Safer Health System.* Institute of Medicine (IOM). National Academies (11/29/99).

[8]*2007 Guide to State Adverse Event Reporting Systems: State Health Policy Survey Report, National Academy for State Health Policy, Vol. 1, No. 1, December 2007.*

History
1999

- Healthcare Research and Quality Act of 1999[9]
  - Required Agency for Healthcare Research and Quality (AHRQ) to support research and build private-public partnerships
    - Identify causes of preventable health care errors & patient injury
    - Develop, demonstrate, and evaluate strategies for reducing errors & patient injury
    - Disseminate such strategies

[9]*Advancing Patient Safety – A Decade of Evidence, Design, and Implementation,* Agency for Healthcare Research and Quality, U.S. Department of Health & Human Services, Accessed through www.ahrq.gov/qual/advptsafety.htm .

History
1999

- Federal initiatives[10] taken by former President Clinton on 2/22/00 based on IOM recommendations[11]
  - Comprehensive strategy to reduce medical errors
  - Creation of external reporting systems
  - Creation of national patient safety centers
  - At least 50% reduction of errors over 5 years

[10]Announced by President Clinton and senior administration officials in James S. Brady Press Briefing Room on February 2, 2000.

[11] Recommendations issued in report entitled *To Err is Human: Building a Safer Health System* by the Institute of Medicine (IOM) of the National Academies (11/29/99).

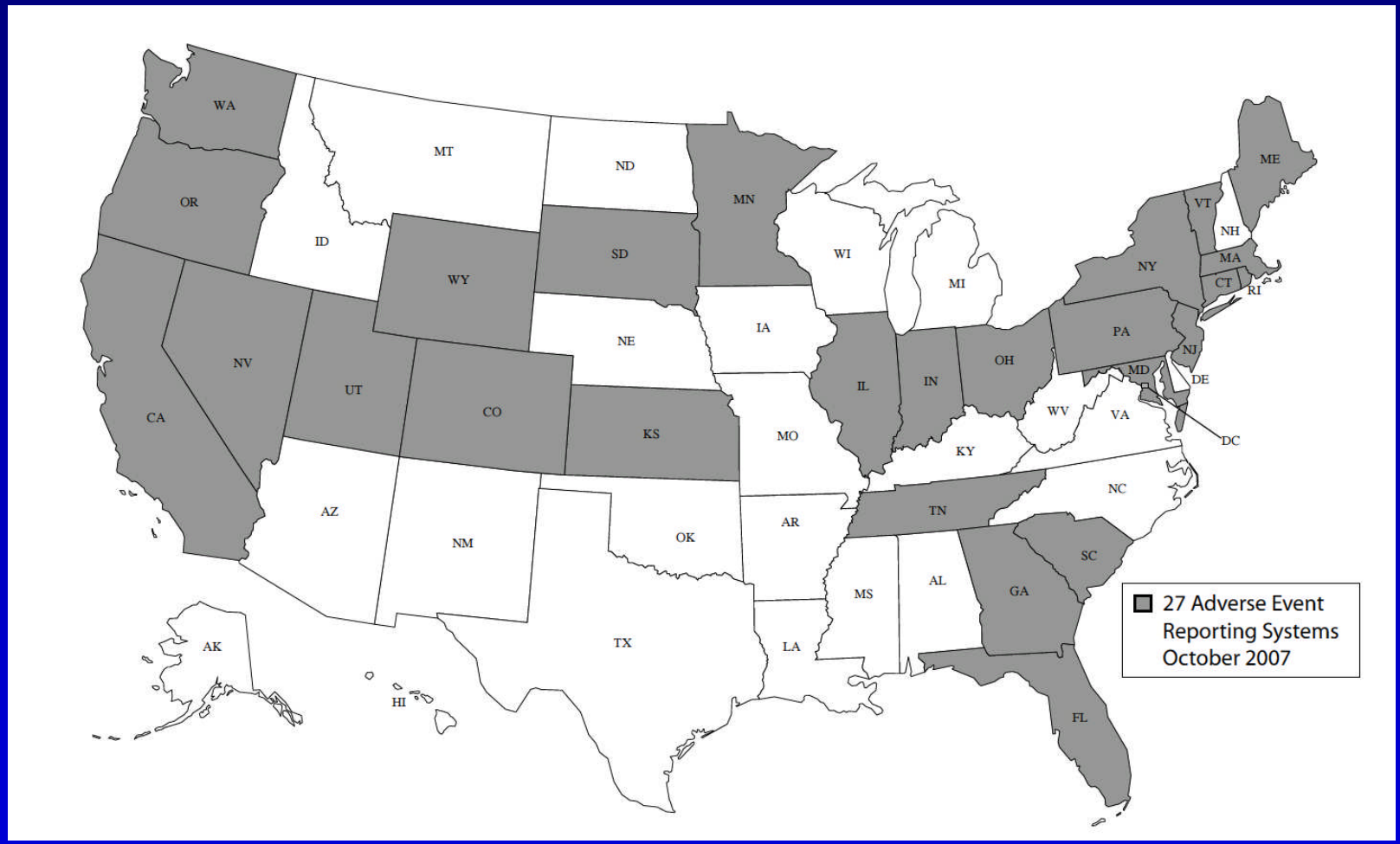
History
2000

- Key legislation
  - Patient Safety and Quality Improvement Act[12]
    - Certifies patient safety organizations in each State to collect data and report on medical errors
  - State Patient Safety Centers[13]
    - Since 2000, 27 states & DC have passed legislation or regulations related to hospital reporting of adverse events to state
    - Mandatory reporting systems for serious adverse events
    - National Academy for State Health Policy's directive:
      - States MUST **Demand Quality and Efficiency from Health Care System**

[12]*Reducing Medical Errors*, Issue Module, Kaiser EDU.org, Accessed through www.kaiseredu.org.

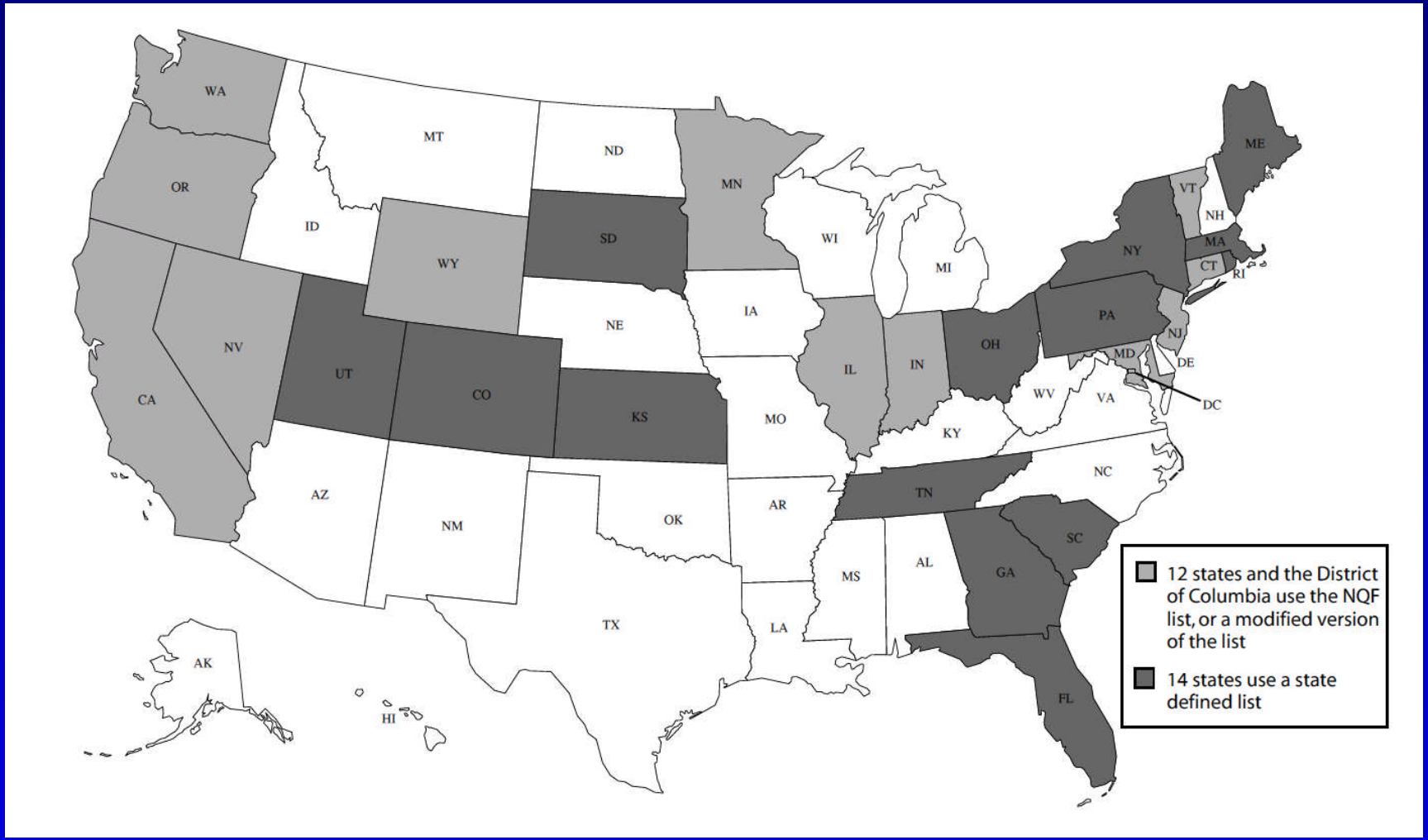
[13]*Authorizing Statues and Regulations*, National Academy for State Health Policy, Accessed September 28, 2010 through www.nashp.org.

Authorized Adverse Event Reporting Systems, October 2007[14]



[14]Jill Rosenthal et al., *2007 Guide to State Adverse Event Reporting Systems*, National Academy for State Health Policy, State Health Policy Survey Report - December 2007.

Source of Reportable Events List Used in Adverse Event Reporting Systems[15]



[15]Jill Rosenthal et al., *2007 Guide to State Adverse Event Reporting Systems*, National Academy for State Health Policy, State Health Policy Survey Report - December 2007.

History

2000 to Present

- Patient safety advisory groups created[16]
  - Health Care Risk Manager Advisory Council (FL)
  - Illinois Adverse Health Care Events Reporting Advisory Council
  - Betsy Lehman Center for Patient Safety and Medical Error Reduction (Massachusetts)
  - Nevada Hospital Association Sentinel Events Registry Work Group
  - Patient Safety Authority Board of Directors (PA)

[16]*State Patient Safety Centers: A New Approach to Promote Patient Safety*, The Flood Tide Forum, National Academy for State Health Policy, 10/04, Accessed & updated through www.nashp.org.

History
2001

- JCAHO revises standards[17]
  - Patient safety standards effective 7/1/01
  - Requires all JCAHO hospitals (5,000) to implement ongoing medical error reduction programs
  - Almost 50 percent of JCAHO standards are directly related to safety[18]
- JCAHO's sentinel event policy[18]
  - Identify sentinel events
  - Take action to prevent their recurrence
  - Complete a thorough and credible root cause analysis
  - Implement action plan

[17]*Patient Safety - Essentials for Health Care*, 2nd edition, Joint Commission on Accreditation of Healthcare Organizations. Oakbrooke Terrace, IL: Department of Publications, 2004.
[18]*Sentinel Event Policies and Procedures - Revised: July 2002*, Joint Commission on Accreditation of Healthcare Organizations, Accessed through www.jcaho.org/accredited+organizations/long+term+care/sentinel+events/index.htm.

History
2002

- National Quality Foundation (NQF)[19]
  - Issued list of 27 serious ("never") reportable events
  - State Medicare programs no longer reimburse providers for events

[19] *A National Survey of Medical Error Reporting Laws*, Yale Journal of Health Policy, Law, and Ethics, 2008.

History
2003

- AHRQ establishes safety indicators (PDIs)[20]
  - Measuring & monitoring tool
  - 20 hospital level & 7 regional measures
- AHRQ *WebM&M*
  - Online forum & journal for patient safety & quality issues

[20] *Advancing Patient Safety – A Decade of Evidence, Design, and Implementation*, Agency for Healthcare Research and Quality, U.S. Department of Health & Human Services, Accessed through www.ahrq.gov/qual/advptsafety.htm .

History
2004

- JCAHO's Office of Quality Monitoring
  - Receives, evaluates and tracks complaints and reports of concerns about health care organizations
  - Unannounced on-site evaluations
- JCAHO and CMS agreement[21]
  - Working together to align Hospital Quality Measures (JC's ORYX Core Measures and CMS'7th Scope of Work Quality of Core Measures)

[21] *Joint Commission, CMS to Make Common Performance Measures*, Joint Commission on Accreditation of Healthcare Organizations, Accessed through www.jcaho.org/accredited+organizations/long+term+care/sentinel+events.

History
2005

- CMS quality incentives[22]
  - Quality Improvement Organizations (QIOs)
    - Contracted by CMS to operate in every State
    - Perform independent quality audits
  - Premier Hospital Quality Initiative
    - 3-year demonstration project with 280 hospitals recognizes and provides financial reward
    - CMS partnership with Premier Inc., nationwide purchasing alliance
    - Hospitals in top 20% of quality for 5 clinical areas get financial reward
      - Top decile gets 2% Diagnosis Related Group (DRG) bonus
      - 2nd decile get 1% DRG bonus
    - In year 3, hospitals performing below 9th and 10th decile baseline levels, DRG payments reduced 1% and 2%, respectively

[22] *Medicare Looks for Ways to Boost Quality Care Comments Sought on New Plan for Quality Improvement Organizations*, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.

History
2005

- CMS quality incentives
  - Medicare/State Children's Health Insurance Program (SCHIP) Quality Initiative
  - Pay-For-Performance (P4P)[23]
    - 12 states have adopted some form
      - Performance measurement
      - Efforts are to align payment with quality
      - Working with JCAHO, NCQA, HQA, AQA, NQF, medical specialty societies, AHRQ, and VA
    - Medicare service payments are tied to efficiency, economy, and **quality of care standards**

[23]*Letter Announcing Medicare/State Children's Health Insurance Program (SCHIP) Quality Initiative*, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.

History
2005

- CMS quality incentives
  - Medicare Value Purchasing (MVP) Act of 2005. Requires Medicare implement a P4P program covering at least a portion of payments made.[24]
  - 104 P4P provider programs in US in 2005[25]
    - P4P attempts to "introduce market forces and competition to promote payment for quality, access, efficiency, and successful outcomes."
    - P4P to extend beyond HMOs to include specialties, PPOs, self insured, and consumer-direct programs.

[24] Baker, G., Carter, B., *Provider Pay for Performance Incentive Programs: 2004 National Study Results. 8/2/05. Accessed through www.medvantageinc.com.*

[25] *Pay for Performance's Small Steps of Progress.* PricewaterhouseCoopers. *8/2/05. Accessed through www.pwchealth.com.*

History
2005 - 2006

- CMS quality incentives
  - CMS consumer website
    - CMS contracted with NQF & worked with JCAHO to develop hospital quality measures for public reporting
    - Hospital quality data became available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
  - Data indicators[26]
    - Hospitals reporting quality data to Medicare receive 3.7% increase in inpatient payments
    - Non-reporters receive 3.3% increase
    - Starts with 10 quality indicators for cardiology
    - Expand into other disciplines

[26]*Medicare to Pay Hospitals for Reporting Quality Data*, Modernhealthcare, accessed through www.modernhealthcare.com.

History
2006

- CMS quality incentives
  - 2006 Physician Voluntary Reporting Program[27]
    - Physicians voluntarily report information to CMS
      - 36 evidence-based measures
      - Information collected through Healthcare Common Procedure Coding System (HCPCS)
    - CMS will provide feedback on physician's level of performance
    - Discontinued and replaced with Physician Quality Reporting Initiative (PQRI) in 2007

[27] *Medicare Takes Key Step Toward Voluntary Quality Reporting for Physicians*, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.

History
2007

- CMS quality incentives
  - 2007 Physician Quality Reporting Initiative (PQRI)[28]
    - Financial incentive to participate in voluntary reporting
      - 77 evidence-based quality measures
      - Bonus payment of 1.5%

[28]*Physician Quality Reporting Initiative*, Centers for Medicare & Medicare Services (CMS), Accessed through www.cms.hhs.gov.

History
2008 - 2009

- National Priority Partnership (NPP) in 2008[29]
  - Deemed 1 of 6 national priorities
  - 555 endorsed measures
  - Approx. 100 measures related to patient safety
- NPP in 2009 endorsed
  - 34 safe practices (*Safe Practices for Better Healthcare*)
  - 28 serious reportable events

[29]*Patient Safety Measures - National Voluntary Consensus Standards for Patient Safety*, Accessed thru www.qualityforum.org.

History
2008 - 2009

- CMS quality incentives
  - 2008 PQRI[30]
    - Physicians report on 119 quality measures
      - 2% incentive payment
    - New tracking of 5 quality measures in adoption of healthcare information technology (EMR)
      - 2% additional for e-prescribers
    - PQRI data available for public WITH performance rates
  - 2009 PQRI[31]
    - A total of 153 quality measures
      - 2% incentive payment
    - E-prescribing removed, separate incentive program

[30]*CMS Ups Quality-Reporting Program Measures*, Modern Health Care, 12/10/07. Accessed through www.modernhealthcare.com

[31]*Proposed 2009 Changes to Payment Policies and Rates Under Medicare Physician Fee Schedule*, CMS, 6/30/08. Accessed through www.cms.hhs.gov.

History
2010

- CMS quality incentives
  - 2010 PQRI[32]
    - Physicians report on 179 quality measures
      - 2% incentive payment
    - New tracking of 10 quality measures in adoption of electronic health record (EHR)
      - 2% additional for e-prescribers

[32]*Proposed 2010 Changes to Payment Policies and Rates Under Medicare Physician Fee Schedule*, CMS, Accessed through www.cms.hhs.gov.

Ongoing Mandates

- Tax Relief and Health Care Act of 2006[33]
  - OIG must report to Congress on "never events/adverse events"
    - Payment by Medicare or beneficiaries for services
    - Process that CMS uses to identify such events and deny or recoup payments
  - Hospitals, as a condition of participation in Medicare and Medicaid, must develop and maintain a quality assessment and performance improvement (QAPI) program

[33] *Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services – Office of the Inspector General, March 2010, Accessed through www.cms.hhs.gov.

Ongoing Mandates

- Hospital requirements to comply with QAPI[34]
  - Hospitals must measure, analyze, and track quality indicators, including adverse patient events.
  - Hospitals must implement preventive actions and mechanisms w/ feedback & feedback/learning throughout hospital

[34]*Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services – Office of the Inspector General, March 2010, Accessed through www.cms.hhs.gov.

Ongoing Mandates

- How do hospitals comply?[35]
  - State survey agencies perform surveys and review functions for Medicare
  - Hospitals may report adverse events to Patient Safety Organizations (PSO)
  - PSOs are public, private for-profit, and not-for profit organizations
  - AHRQ certifies that PSOs have process to collect and analyze reported events
  - PSOs report data to Health & Human Services

[36] *Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services – Office of the Inspector General, March 2010, Accessed through www.cms.hhs.gov.

Ongoing Mandates

- No Charge Policy Effective 2008
  - State associations have/are looking at policy where hospitals will discontinue billing patients and insurers for medical errors[36]
    - Colorado, Massachusetts, Michigan, Minnesota, and Vermont
  - CMS no longer pays for 10 "reasonably preventable" conditions caused by medical errors
  - AETNA no longer pays for 28 so-called "Never Events"[37]
  - Wellpoint (nation's largest insurer by membership) no longer pays for serious medical errors[38]

[36] *State's Rights and Wrongs: Part 2,* Modern Health Care, 12/10/07. Accessed through www.modernhealthcare.com.
[37] *AETNA to Quit Paying for "Never Events", 1/15/08.* Accessed through www.modernhealthcare.com.
[38] *Wellpoint to Stop Paying for "Never Events", 4/2/08.* Accessed through www.modernhealthcare.com.

Future Incentive

- Secretary of HHS Quality Incentive
  - Value-Based Purchasing Program in 2012[39]
  - Applies to certain cancer treatment facilities
  - Must meet minimum number of measures for performance standards
    - Proposed 2-5% of hospital's base operating payment for each discharge payment (DRG) contingent on performance of specific of measures
      - 1st year, 100% incentive based on reporting
      - 2nd year, 50% reporting & 50% performance
      - 3rd year, 100% reporting

[39]*Hospital Value-Based Purchasing Program*, Bricker & Eckler Attorneys at Law. Accessed through www.bricker.com.

US Grades

- 7th Annual "HealthGrades Patient Safety in American Hospitals" assessment report for Medicare patients[40]
  - Evaluated 39.5 million hospitalization records from 5,000 nonfederal hospitals between 2006 and 2008
  - Rate of medical harm estimated to be > than 40,000/day
  - 958,202 total patient safety events occurred
    - $8.9 billion of excess cost
  - Good: 6 of 15 patient safety indicators improved
  - Bad: 8 of 15 indicators worsened
  - Medicare patients experiencing 1 or > patient safety events had 1 in 10 chance of dying (99,180 patients)

[40] *HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals*: March 2010, accessed thru www.healthgrades.com.

US Grades

- Large safety gaps[41]
  - Patients treated at top-performing hospitals
    - On average, 43% lower chance of medical errors vs. poorest-performing hospitals
- 400,000 preventable drug-related injuries occur each year in hospitals costing $3.5 billion[42]
- Medical errors cost $50 billion a year in avoidable medical expenses – approximately 30% of all health care costs[43]

[41]*HealthGrades – HealthGrades Seventh Annual Patient Safety in American Hospitals*: March 2010, accessed thru www.healthgrades.com.

[42]*Medication Errors Injure 1.5 Million People and Costs Billions of Dollars Annually: Report Offers Comprehensive Strategies for Reducing Drug-Related Errors*, Office of News and Public Information, National Academy of Sciences, 7/20/06March 2010, accessed thru www.nationalacademies.org.

[43]*Fixing Hospitals*, Forbes, (6/20/05).

US Grades

- Has patient safety improved?[44]
  - For 2009, patient safety received a B - minus
  - In 2004, received a C - plus
- According to Dr. Wachter - editor of AHRQ Web M & M
  - "In that [QAPI] error-reporting system, it looks like a hospital with fewer error reports is much safer, but it may not be"
  - "Hospital self-reporting in an unreliable indicator of quality"

[44]*Patient Safety Improving Slightly, 10 Years After IOM Report on Errors*, amednews.com, December 28, 2009, accessed thru www.ama-assn.org.

Canada Grades

- 185,000 adverse events occur annually in Canadian hospitals[45]
  - 70,000 preventable
    - 9,000 to 24,000 people die each year[46]
- Approximates a 7.5% error rate
- Similar rates found in other countries

[45] Lee RC, *Life, Death, and Taxes: Risk Management in Health Care*. Canadian Operations Society Annual Meeting (2005).

[46] Baker GR, et. al., *The Canadian Adverse Events Study: The Incidence of Adverse Events Amongst Hospital Patients in Canada*. Canadian Medical Association Journal (2004).

Physicians on Error-Reporting

- Most physicians believe error-reporting systems are inadequate[46]
  - Of 1,100 physicians in Missouri and Washington State between July 2003 and March 2004:
    - 56% were involved in a serious medical error
    - 74% were involved with a minor error
    - 66% were involved with a near miss
  - Of those physicians, 54% believe that medical errors are usually caused by failures of care delivery, not failures of individuals
  - 45% of physicians do not know whether a reporting system exists at their facility

[46] *Docs See Error-Reporting as Inadequate*, Modern Health Care, 1/10/08. Accessed through www.modernhealthcare.com.

Disclosure of Errors

- Survey of 603 patients who experienced 845 adverse events showed[47]
  - Only 40% of those events were disclosed
  - For preventable events, disclosure rate was only 28%
- Physicians reluctance to disclose events due to concerns over litigation
- However, findings show informed patients more likely to be pleased with quality of care

[47] *Transparency in Adverse Event Reporting Pleases Patients*. Medscape Medical News, 4/8/08. Accessed through www.medscape.com.

Consumer Beliefs[48]

- 40% do not believe nation's quality of health care has improved
- 48% are concerned about the safety of health care
- 55% are dissatisfied with quality of health care
- 34% say they or family member experienced a medical error in their life

[48]*Five Years After IOM on Medical Errors, Nearly Half of All Consumers Worry About the Safety of Their Health Care.* Kaiser Family Foundation. 11/17/04. Accessed through www.kff.org.

Consumer Beliefs[49]

- 92% say reporting serious medical errors should be required
  - 63% want information released publicly
- 79% say requiring hospitals to develop systems to avoid medical errors would be “very effective”
- 35% have seen information comparing of health plans and hospitals in last year
- 19% have used comparative quality data information about health plans, hospitals, or other providers to make decisions about their care
- 11-14% have sued that experienced a medical error[50]

[49]*Five Years After IOM on Medical Errors, Nearly Half of All Consumers Worry About the Safety of Their Health Care*. Kaiser Family Foundation. 11/17/04. Accessed through www.kff.org.
[50]Duffy J, *The QAIP* Quest. Advance News Magazines. Accessed thru www.health-care it.advanceweb.com.

Medical Errors

- In U.S., adverse events occur to approx. 3 - 4% of patients[51]
- Average intensive care unit (ICU) patient experiences almost 2 errors per day[52]
  - Translates to level of proficiency of approx. 99%
  - Sounds good, right?
  - **NOT REALLY**
- If performance levels of 99.9%, substantially better than found in ICU, applied to airline & banking industries, this equates to:
  - 2 dangerous landings per day at O'Hara International Airport, and
  - 32,000 checks deducted from the wrong account per hour.[53]

[51, 52, 53] *Doing What Counts for Patient Safety - Federal Actions to Reduce Medical Errors and Their Impact*. Access thru www.quic.gov.

Medical Errors

- OIG thru Department of Health & Human Services[54]
  - Pilot study "Adverse Events in Hospitals: A case Study of Incidence Amongst Medicare Beneficiaries in Two Counties"
    - Estimated 15% of hospitalized Medicare beneficiaries in 2 counties experienced adverse events
    - Resulted in harm during their hospital stay
    - Another 15% experienced less serious occurrences "temporary harm events"

[54] *Adverse Events in Hospitals: Methods for Identifying Events*, Department of Health and Human Services, Office of Inspector General, March 2010.

Medical Errors

- Underreporting of adverse events is estimated to range between 50 – 60% annually[55]
- No "comprehensive nationwide monitoring system" exists for medical reporting[56]
- Recent attempts to estimate error rates show little improvement in actual error incidence nationwide[57]

[55]*Reporting and Preventing Medical Mishaps: Lessons Learned from Non-Medical Near Miss Reporting Systems*, BMJ, Vol. 320, March 18, 2000.
citing Agency for Healthcare Research & Quality, 2004.
[56, 57]*National Survey of Medical Error Reporting Laws*, Yale Journal of Health Policy, Law, and Ethics, 2008, citing Agency for Healthcare Research & Quality, 2004.

Radiation Oncology Errors

- Not well established
- No comprehensive numbers available for number of errors resulting in death[58]
- Reported error rates range 0.1% to 0.2% of fields treated[59]
- Studies not relying on self-reporting show actual rates of up to 3%[60]

[58, 59, 60] French, J, *Treatment Errors in Radiation Therapy*. Radiation Therapist, Fall 2002, Vol.11, No. 2; 2002.

Radiation Oncology Errors

- WHO research of errors 1976 to 2007[61]
  - Peer-review journals
  - Conference proceedings
  - Working papers
  - Organizational reports
  - Local, national, and international databases
- 7,741 incidents & near misses
  - 3,125 incidents of harm (underdose increasing risk of recurrence to overdose causing toxicity)
  - 38 patient deaths
- Risk of mild to moderate injurious outcome
  - 1,500 per 1,000,000 treatment courses
- Review hampered by lack of data & systematic bias in reporting mistakes caused by clinical judgment

[61]WHO – World Alliance for Patient Safety, Radiotherapy and Oncology, *International Review of Patient Safety Measures in Radiotherapy Practice*, 2009, Vol. 92:1, pp.15-21.

Radiation Oncology Errors

"… it is likely that many more incidents have occurred but either went unrecognized, were not reported to the regulatory authorities, or were not published in the literature."[62]

[62]ICRP. *Radiological Protection and Safety in Medicine.* ICRP 73. Annuals of the ICRP, 1996, Vol. 26, Num. 2.

Adverse Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
US	Ricks CR, REAC/TS Radiation Incident Registry, 1999	1974-1976	Overdose		**426 - Overdose toxicity**	Incorrect calibration of Co-60 unit at commissioning, falsified documentation
UK	McKenzie AL, British Institute of Radiology, 1996	1982-1991	Underdose (-5 to 35%)	1,045	**492 - Developed local recurrences**	Misunderstanding of algorithm in Tx planning computer
USA & Canada	WHO, Radiotherapy Risk Profile, 2008	1985-1987	Overdose	6	**6 - Overdose toxicity:** **3 - Deaths**	Therac-25 software programming error in Tx delivery
Germany	IAEA, Safety Report Series No.38, 2006	1986-1987	Overdose (various)	86	**86 - Overdose toxicity**	Co-60 dose calculations based on erroneous dose tables, no independent checks
UK	McKenzie AL, British Institute of Radiology, 1996	1988	Overdose (+25%)	250	**250 - Overdose toxicity**	Teletherapy activity calculation error during commissioning
UK	IAEA, Safety Report Series No.38, 2006	1988-1989	Over and under dose (-20 to +10%)	22	**22 - Overdose toxicity**	Error in identification of Cs-137, brachytherapy sources, no independent check of source strength

Adverse Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
US	IAEA, Safety Report Series No.38, 2006	1988-1989	Overdose (+75%)	33	**33 - Overdose toxicity**	Computer file for use of trimmers not updated for new Co-60 source, no manual or independent verification of calculated Tx
Spain	IAEA, Safety Report Series No.38, 2006	1990	Overdose (+200-600%)	27	**18 - Overdose toxicity:** **9 - Deaths**	Error in maintenance of linac, procedures not followed, conflicting signals not analyzed, no beam verification procedures
Japan	WHO, Radiotherapy Risk Profile, 2008	1990-1991 1995-1999	Overdose	276	**276 - Overdose toxicity**	Differences of interpretations for prescribed dose between RO & RT, lack of communication
		1998-2004		146	**146 - Overdose toxicity**	Wedge factor input error in renewal of treatment planning system
US	WHO, Radiotherapy Risk Profile, 2008	1992	Overdose	1	**1 - Overdose toxicity:** **1 - Death**	Brachytherapy source (High Dose Rate) dislodged and left inside the patient
Costa Rica	IAEA, Safety Report Series No.38, 2006	1996	Overdose (+60%)	114	**114 - Overdose toxicity:** **6 - Deaths**	Error in calibration of Co-60 unit, lack of independent beam calibration, recommendation of external audit ignored

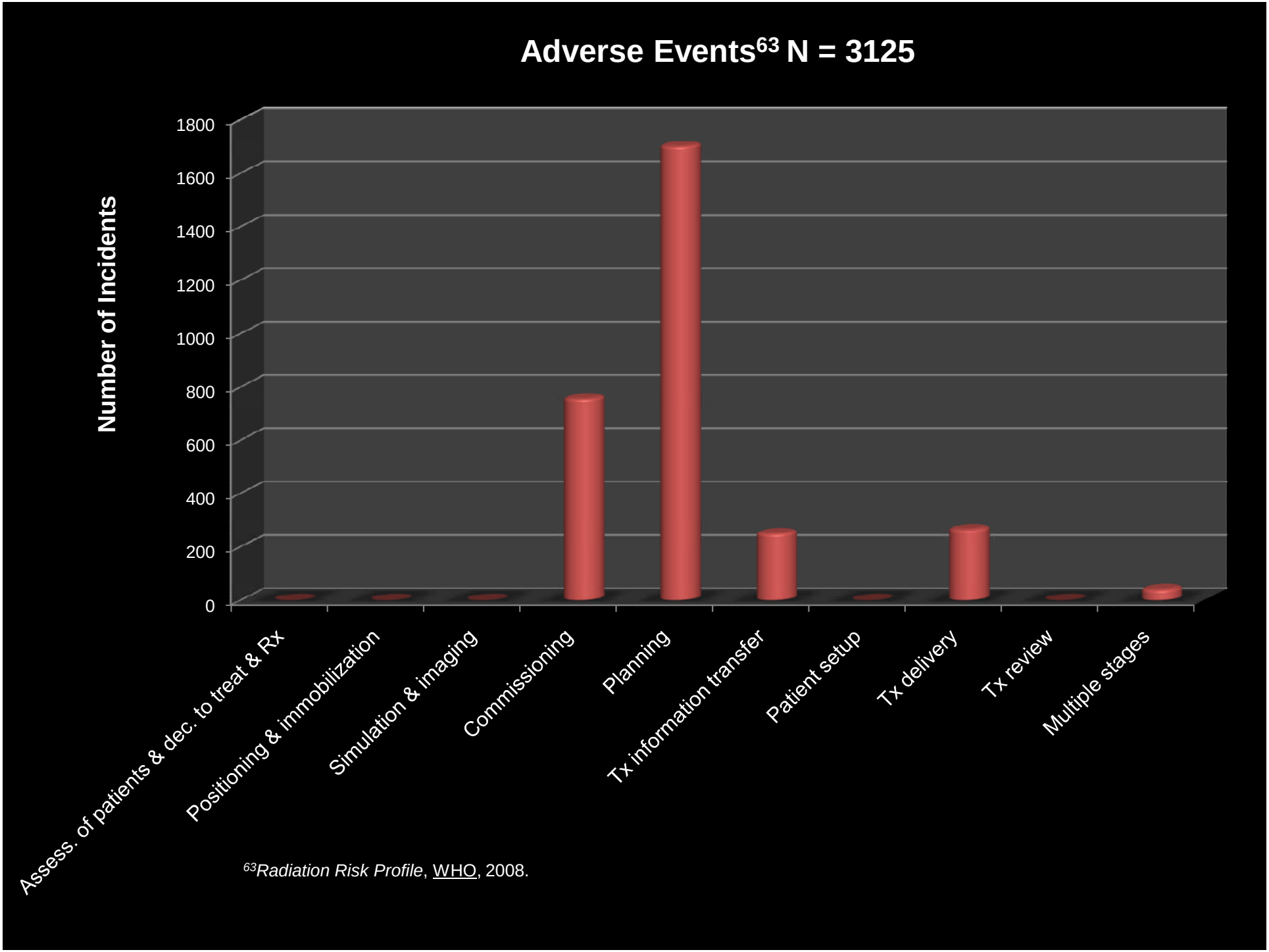
Adverse Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
Japan	WHO, Radiotherapy Risk Profile, 2008	1999-2003	Underdose	31	**31 - Underdose**	Output factor input error in renewal of treatment p planning system
		1999-2004		256	**256 - Underdose**	Insufficient dose delivery caused by an incorrect operation of dosimeter
Panama	IAEA, Safety Report Series No.38, 2006	2000 -2001	Overdose	28	**28 - Overdose toxicity:** **11 - Deaths**	Error shielding block related data entry into TPS resulted in prolonged treatment time
Poland	IAEA, Safety Report Series No.38, 2006	2001	Overdose	5	**5 - Severe injuries**	Failure of more than 1 layer of safety in electron accelerator (monitor chambers and interlock)
Japan	WHO, Radiotherapy Risk Profile, 2008	2003	Suspected Overdose	1	**1 - Suspected death**	Input error of combination of transfer total dose and fraction number
		2003-2004	Overdose	25	**25 - Overdose toxicity**	Misapplication of tray factor to treatment delivery without tray
France	WHO, Radiotherapy Risk Profile, 2008	2004-2005	Overdose	18	**18 - Overdose toxicity:** **5 - Deaths**	Wrong setting of linac after introduction of new TPS
				8	**2 - Overdose toxicity:** **1 - Death** **5 - Unknown health conseq.**	Miscommunication of field size estimation, error in patient identification, incorrect implantation of source during brachytherapy

Adverse Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
Canada	Keen C, auntannie.com 2008	2004-2007	Underdose (-83%)	326		Error in calculation of output tables on orthovoltage unit, understaffed & overworked physicists, no comprehensive independent check, inadequate QA program
	WHO, Radiotherapy Risk Profile, 2008		Underdose (3-17%)		**326 - Underdose**	
US	Healthimaging.com, 2010	2004-2009	Overdose (+50%)	76		Error in calculation of output factor of SRS unit, wrong measurement equipment, no independent check
US	Sickler M, St. Petersburg Times, 2005	12 Months	Overdose (+50% or >)	77	**19 - Unsafe Levels**	Programming error using wrong formula in Tx planning computer, no independent second dose verification
UK	WHO, Radiotherapy Risk Profile, 2008	2005-2006	Overdose	5	**5 - Overdose Toxicity:** **1 - Death**	Change in operational procedures while upgrading data management systems resulting in incorrect treatment dose
Scotland	Scottish Ministers, Report of an Investigation, 2006	2006	Overdose (+58%)	1	**1 - Overdose toxicity:** **1 - Death**	Tx planning computer software was upgraded. Old correction factor was applied to new calculation program.

Adverse Events[63] N = 3125

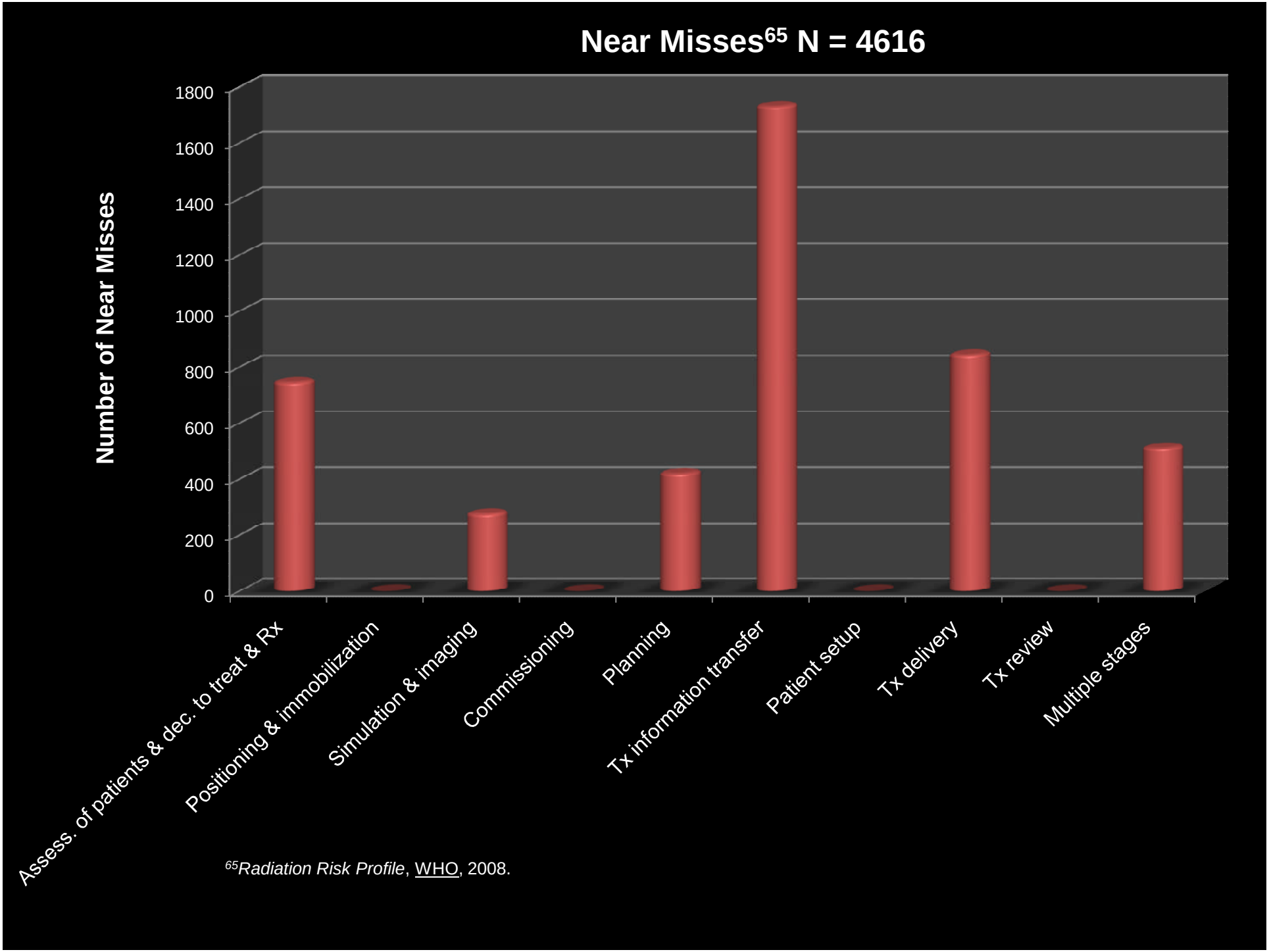


[63]*Radiation Risk Profile*, WHO, 2008.

Near Misses in Radiation Oncology

- Near Misses[64]
  - 1992 to 2007: Australia, UK, Other European Countries, and US
    - How many?
      - 4,616 reported incidents that lead to near misses
      - No recognized patient harm
    - How collected?
      - Published literature
      - Unpublished incident reporting databases (ROSIS)

[64] *Radiation Risk Profile*, WHO, 2008.



[65]*Radiation Risk Profile*, WHO, 2008.

Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
UK	Sutherland WH, Topical Reviews in Radiother and Oncol, 1980	Over 6 years between 1970-1980					- Potential mistakes (found in checks): 4,122 - Potential errors of >5% from Rx dose: 742	**2.1% - 4% per year**
US	Swann-D'Emilia B, Med Dosime, 1990	1988-1989					87 misadministrations	**<0.1%: based on no. of fields Tx'ed**
US	Muller-Runkel R, et al., 1991	1987-1990					- Before R&V: 39 major, 25 minor errors - After R&V: 4 major, 5 minor errors	**90% overall reduction**
Belgium	Leunens G, et al., Radiother Oncol, 1992	9 months					Data transfer errors: 139 of 24,128	**Affected 26% of overall treatments** **Sig. potential 5%**
Italy	Calandrino R, et al., Radiother Oncol, 1993	9/91-6/92					Out of 890 calculations: - 33 total errors - 17 serious errors	**3.7%: total error rate**
Italy	Valli MC, et al., Radiother Oncol, 1994							**10.5%: incorrect or missing data**

Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
France	Noel A, et al., Radiother Oncol, 1994	5 years					Of 7519 treatments: 79 total errors - Of 79, 78 are human origin - Of 78, 39 would have > 10% dose Δ	**1.05%: errors per treatment**
Canada	Yeung TK, Abstract-NEORCC, 1996	1994						**3.3%**
US	Kartha PKI, Int J Radiat Oncol Biol Phys, 1997	1997					Error rates per patient setup	**1.4%: linear accelerators** **3%: cobalt units**
US	Macklis RM, et al., J Clin Oncol, 1998	1 year	1,925		93,332	168	15%: causally related to R&V	**0.18%: error rate/field**
US	Fraas BA, et al., Int J Radiat Oncol Biol Phys, 1998	7/96-9/97		~34,000	~114,000			**0.44%: Tx fractions** **0.13%: Tx fields**
Belgium	Barthelemy-Brichant N, et al., Radiother Oncol, 1999	6 months					147,476 parameters examined: - 678 (0.46%) set incorrectly	**3.22%: of all delivered Tx fields had at least 1 error**

Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Canada	Pegler R, et al., Abstract-Clin Invest Med, 1999	2 years						**0.12 - 0.06%**
US	Pao WJ, et al., Abstract-ACSO, 2001	6 years	17,479 avg./yr.					**0.17% avg./year per patient**
Canada	French J, Radiat Ther, 2002	1/1/96-9/31/01	11,355	195,100	483,741	631	177 total incidents - 20: correctable - 129: noncorrectable and clinic. sig. - 28: noncorrectable and potentially clinically sig.	**0.13%: all units (fields tx'ed incorrect/ total no. fields tx'ed)** **0.32%: errors/fraction** **0.037%: errors/field**
US	Patton G, et al., Radiat Oncol Biol Phys 2002	1 year	22,542					**0.17%: errors/Tx**
Ireland & Sweden	Holmberg O, et al., J of Radioth Ther, 2002	3 years	15,386 Tx plans				13.8 near misses/each reported Tx error in Tx preparation chain	**3.4%: error rate per Tx plan**

Error Rates in Radiation Oncology

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Canada	Yeung, et al., Radiother Oncol, 2004	11/92-12/02	13,385				624 incidents - 42.1%: documentation errors (data transfer/com-munication) - 40.4%: patient set-up errors - 13.0%: Tx planning errors	**Use of portal imaging reduced patient set-up errors by 85%.** **40% of dose errors discovered before 1st Tx**
Canada	Huang G, et al., Int J Radiat Oncol Biol Phys, 2005	1/1/97-12/31/02	28,136				555 total errors	**1.97%: error rate per patient** **0.29%: error rate per fraction (7/00 - 12/02)**
US	Klein E, et al., J of Appl Clin Med Phys, 2005	30 months	3,964					**0.48 to <0.1%: for diff methods of detection w/R&V**
Canada	Marks L, et al., Int J Radiat Oncol Biol Phys, 2007							**0.5%: error rate per fraction** **1.2 - 4.7%: error rate per patient**

Error Rates in Radiation Oncology

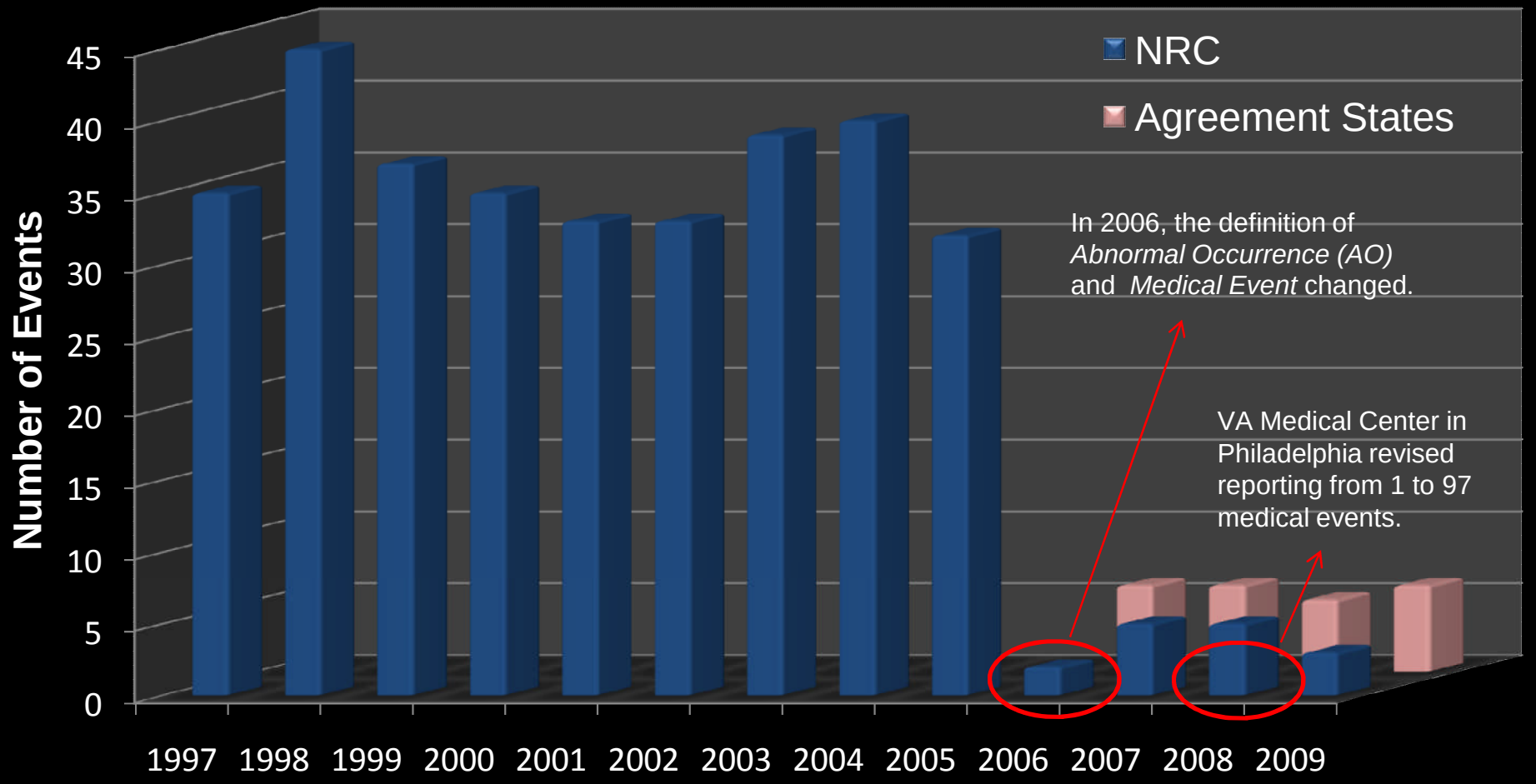
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
Italy	Baiotto B, et al., J of Experi & Clinical Oncol Tumori, 2009	10/00 – 12/06	7,768	34,114	148,145		452 errors Error types: - 2.2%: general - 3.3%: dosimetric - 4.2% delivered dose	**0.69%: error rate of audited patients**
US	Margalit D, et al., J Clinical Oncol, 2010	1/04 – 1/09			241,546		155 total errors - Types: IMRT 0.033% vs 2D/3D RT 0.072%	**0.064%: error rate per Tx field**

Who Reports the Errors Within a RO Center?[66]

Category	Number of Errors	Percent
Dosimetrist	43	5%
Radiation Oncologist	70	8%
Other	22	3%
Physicist	92	11%
Engineer	1	0%
Therapist-Sim/CT	37	4%
Therapist-Tx machine	591	69%

[66] *ROSIS* database. 2/25/10. Accessed through www.rosis.info.

NRC Reported AO/Medical Events



PA Patient Safety Authority

Radiation Oncology Event Types Reported to the Pennsylvania Patient Safety Authority, 6/2004 - 1/2009[67]		
Type of Error	**Number of Reports**	**% of Total**
Wrong dose	10	40%
Wrong patient	4	16%
Wrong location	3	12%
Wrong side	3	12%
Wrong setup	2	8%
Wrong treatment	1	4%
Wrong treatment device	1	4%
Equipment other	1	4%
Total	**25**	**100%**

[67]Reprinted article - 2009 *Pennsylvania Patient Safety Authority*, Vol. 6, No. 3. September 2009.

PA Dept. of Environmental Health

Medical Accelerator Event Types Reported to the Pennsylvania Department of Environmental Protection, 2/2004 - 1/2009[68]

Type of Error	Number of Reports	% of Total
Incorrect site	17	46%
Wrong patient treated	10	27%
Incorrect dosage	8	21%
Underestimated medical procedure duration	1	3%
Inattention to detail	1	3%
Total	**37**	**100%**

[68]PA Patient Safety Advisory, PA Department of Environmental Protection, Bureau of Radiation Protection. *Errors in Radiation Therapy*, 2/09.

State of NY: Published Tx Errors

Radiation Mistakes in the State of New York as Analyzed by The New York Times, 1/2001 - 1/2009[69]		
Type of Error	**Number of Reports**	**% of Total**
Quality assurance flawed	355	28%
Data entry or calculation errors by personnel	252	20%
Misidentification of patient or treatment location	174	14%
Blocks, wedges or collimators misused	133	11%
Patient's physical setup wrong	96	8%
Treatment plan flawed	77	6%
Hardware malfunction	60	5%
Staffing	52	4%
Computer, software or digital info transfer malfunction	24	2%
Override of computer data by personnel	19	2%
Miscommunication	14	1%
Unclear/other	8	1%
Total	**1264**	**100%**

[69]The New York Times, *Radiation Mistakes: One State's Tally.* www.nytimes.com, 1/24/10.

Paper-Based Model

Objective of Paper-Based Model

- Provide a unified, total quality management and continuous improvement program
- Minimize occurrence of errors identified in the patient treatment process and regulatory arena
- Designed for 17 geographically dispersed radiation oncology clinics
- Located in 9 states of varying regulatory oversight and enforcement philosophy

Design of a Paper-Based Model

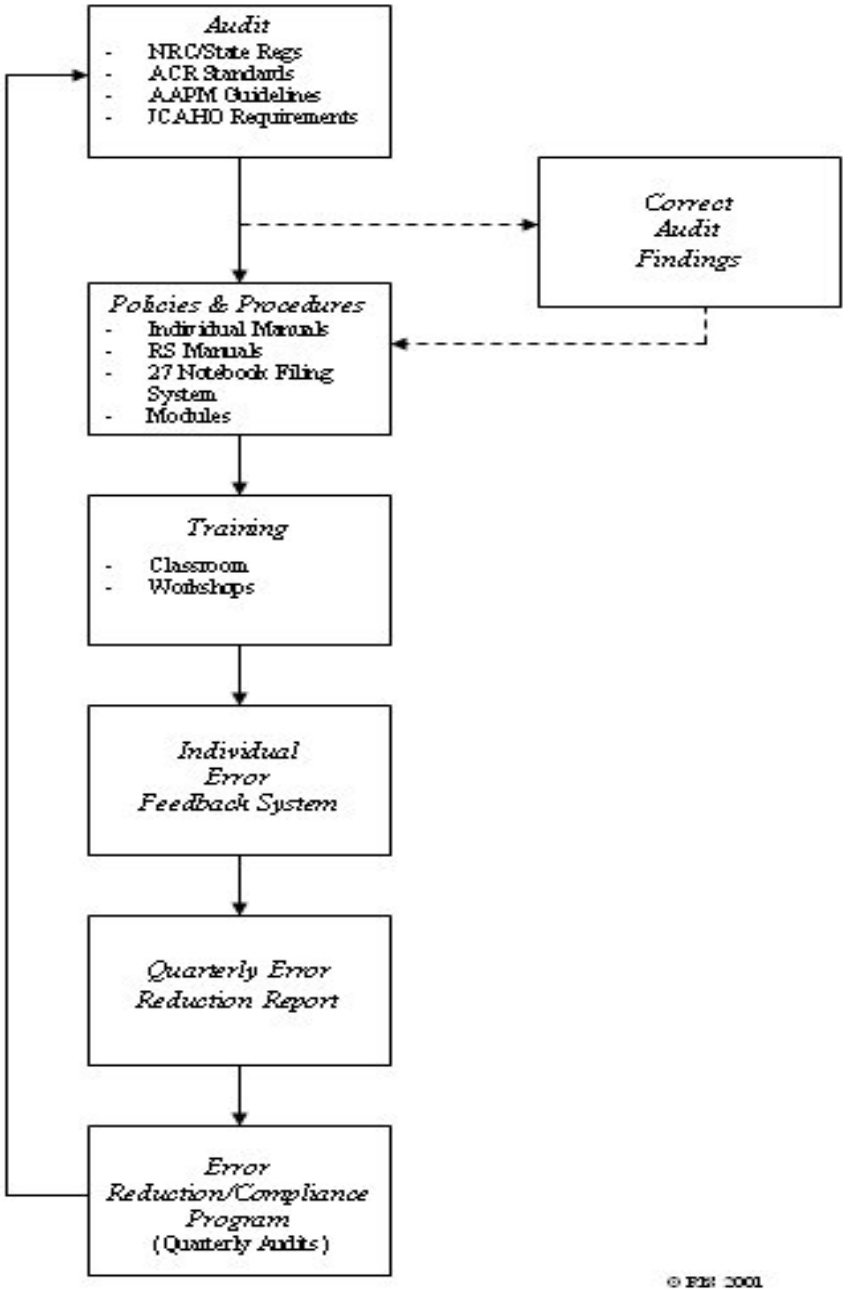
- Established a consistent set of QA procedures for the 17 facilities following the strictest state requirements in which each facility resides.
- Analyzed the process of delivering radiation therapy to identify the steps used in all aspects of this modality.
- Developed a reporting codification system for errors detected, and the appropriate forms and procedures for reporting these errors. This includes a staging system for classifying the importance of an error.

Design of a Paper-Based Model

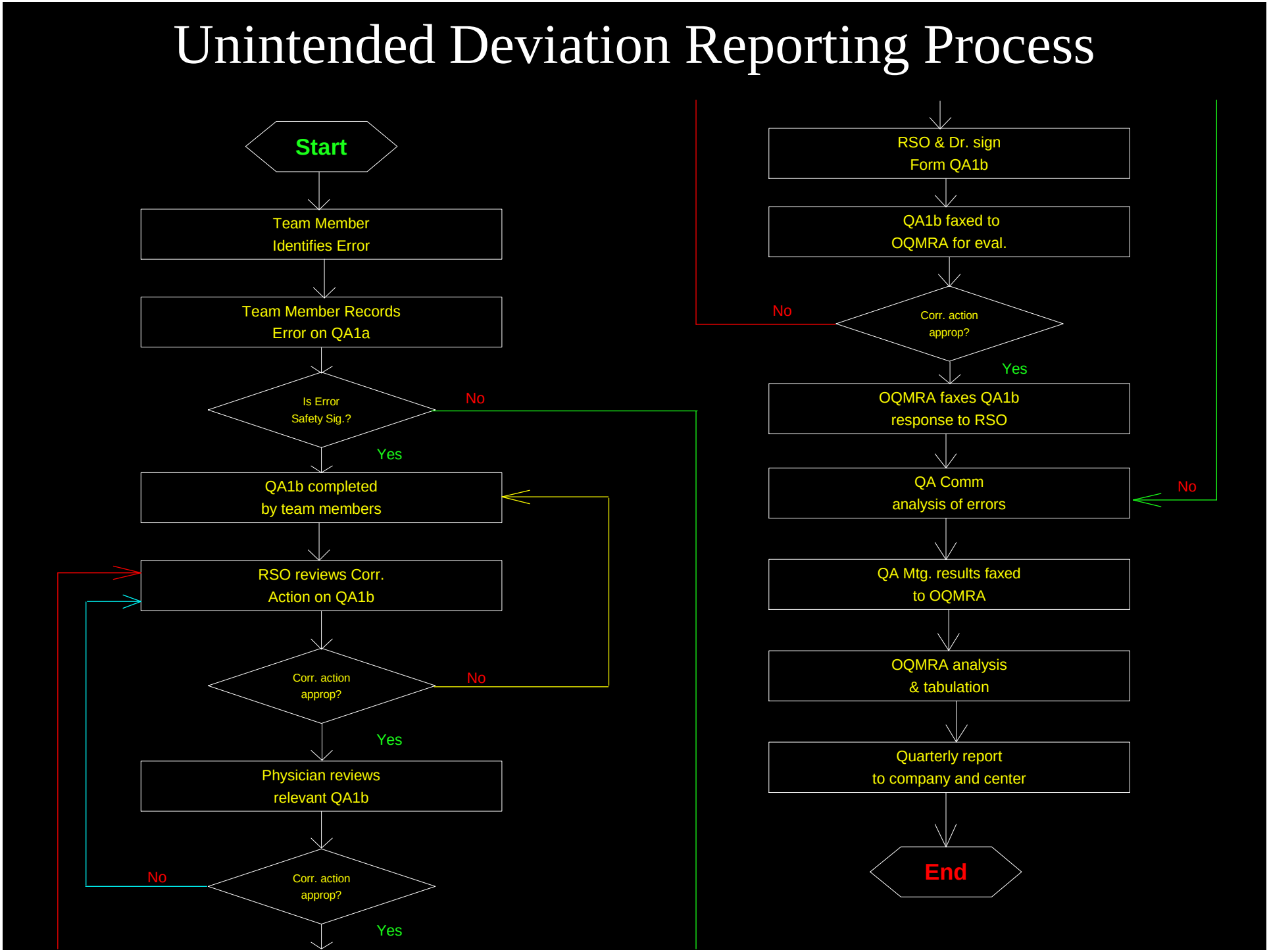
- Provided an internal feed-back mechanism of corrective action to close the loop
  - Independent review/recommendations for corrective action regarding all self-identified significant errors/violations
- Produced a quarterly report summarizing errors/violations
  - Perform trend analysis of reported errors at center and company levels
  - Recommended company wide corrective actions based on results of trend analysis

RPS

QA Implementation Process for a Radiation Oncology Center



Unintended Deviation Reporting Process



The Unintended Deviation System

- Name was selected to convey an unintentional error discovered either by the one having committed the error or by another physician/staff member.
- Management emphasizes that self-identification and reporting of errors will not result in disciplinary action.
- Provides for identification, evaluation, and documentation of all errors within the process of radiation therapy delivery.
- Suggests possible causes and solutions for correction of individual errors as well as programmatic errors with discoverable trends.

Definition - Unintended Deviation

- An unintended deviation is any error in the planned patient simulation, setup, treatment, or data entry in these processes.
- Any deviation from the planned course of treatment
- Any error in calculation
- Any missing or incomplete information
- Any failure to perform or follow required quality assurance and radiation safety policies or procedures
- Unintended deviations can be classified as:
  - Pre or post-tx error
  - A minor unintended deviation (Level 3-5)
  - A significant unintended deviation (Level 1-2)
    - A Recordable Event
    - A Misadministration

Name Cancer Center: Post-Treatment Unintended Deviations[4] - Page 1 of 2 **Dates of ___ to ___**

Code	Identified	Description/SL/Process/Resp. Party
Treatment Planning: Data Entry		
1010		Treatment site 2 ◆ P
1011		Plan identification 3 P
1012		Field names and numbers 3 ◆ P
R & V: Data Entry		
1110		Course 4 ◆ M
1111		Prescription site 2 ◆ M
1112		Technique 2 ◆ M
1113		Modality (photons or electrons) 1 ◆ M
1114		Dose specification 2 ◆ M
1115		Depth 2 ◆ M
1116		Total dose 1 ◆ M
1117		Fraction dose 1 ◆ M
1118		Fractions 2 ◆ M
1119		Pattern 2 ◆ M
1120		Prescription note[1] 2 ◆ M
1121		Elect. Approval before 1st Fx (R&V) 1 ◆ M
1130		Misc._____ M
Treatment Field Definition		
1210		Prescription site 1 ◆ P
1211		Field name 3 P
1212		Machine 3 P
1213		Type 3 ◆ P
1214		Modality 1 ◆ P
1215		Energy 1 ◆ P
1216		MU 3 ◆ P
1217		Dose > ±3% 2 ◆ P
1218		Dose < ±3% 3 P
1219		Incorrect wedge angle 2 ◆ P
1220		Incorrect wedge orientation 2 ◆ P
1221		No wedge specified, wedge in plan 1 ◆ P
1222		Incorrect compensator 2 ◆ P
1223		No comp specified; comp in plan 1 ◆ P
1224		Incorrect block entered 2 ◆ P
1225		No block specified; blocks in plan 2 P
1226		Incorrect bolus entered 3 ◆ P
1227		No bolus entered; bolus in plan 3 ◆ P
1228		Incorrect TSD 3 ◆ P
1229		Incorrect gantry angle 4 ◆ P
1230		Incorrect collimator angle 4 ◆ P
1231		Incorrect field size 4 ◆ P
1232		Incorrect asymmetric jaw 4 ◆ P
1233		Incorrect couch vertical 4 ◆ P
1234		Incorrect couch angle 4 ◆ P

Code	Identified	Description/SL/Process/Resp. Party
Patient Simulation		
Patient Setup		
1310		Pt position not iso. to midline (SAD) 3 ◆ T
1311		Pt position not to specified SSD 3 ◆ T
1320		Missing AP SSD 2 ◆ T
1321		Missing PA SSD 2 ◆ T
1322		Missing RL/Medial SSD 2 ◆ T
1323		Missing LL/Medial SSD 2 ◆ T
1324		Missing calc. pt. SSD 2 ◆ T
1325		Table vert. does not agree w/SSD 3 ◆ T
1326		SSD read incorrectly 2 ◆ T
1330		Separation does not agree w/SSD 3 ◆ T
1331		Separation missing 2 ◆ T
1340		Incorrect contour 3 ◆ T
1350		Failure to capture all Tx fields 2 ◆ T
1351		Failure to capture setup fields 2 ◆ T
1360		Setup instructions incorrect 3 ◆ T
1361		Setup instructions miss./incomp. 3 ◆ T
1370		Misc._____ T
Simulation Films		
1400		Miss./incorr. pt. info. 4 ◆ T
1401		Miss./incorr. field info 4 ◆ T
1402		Miss./incorr. field markers 3 ◆ T
1403		Miss./incorr. SFD 4 ◆ T
1410		Misc._____ T
Block Fabrication		
1500		Blocks cut incorr. 3 ◆ T
1501		Hand set blocks mounted incorr. 3 ◆ T
1502		Custom blocks mounted incorr. 3 ◆ T
1503		Missing or late block checks 4 ◆ T
1510		Misc._____ T
Dose Calculation		
1600		Incorr./miss. Tx site 2 ◆ P
1610		Incorr./miss. field names 3 ◆ P
Hand Calculations		
1620		Incorr. Energy 2 ◆ P
1621		Incorr. Field size 3 ◆ P
1622		Incorr. SSD 3 ◆ P
1623		Incorr. depth 2 ◆ P
1624		Incorr/miss. tray factor 3 ◆ P
1625		Incorr/miss. wedge factor 1 ◆ P
1626		Incorr/miss. bolus 3 ◆ P
1627		Calc w/bolus, bolus not Rx'd 3 ◆ P
1628		Wrong coll. scatt. factor 3 ◆ P

Code	Identified	Description/SL/Process/Resp. Party
1630		Wrong inverse sq. factor 2 ◆ P
1631		Math error 3 ◆ P
1632		Calc. using incorr. dose 2 ◆ P
1633		Tx plan not approved 1 ◆ M
1640		Misc._____ P
Computer Calculations		
1650		Incorr. energy 1 ◆ P
1651		Incorr. mode of Tx 1 ◆ P
1652		Incorr. field size 3 ◆ P
1653		Incorr. asymmetric jaw 3 ◆ P
1654		Incorr. SSD 3 ◆ P
1655		Incorr depth 2 ◆ P
1656		Incorr. gantry angle 3 ◆ P
1657		Incorr. coll. angle 3 ◆ P
1658		Incorr. tray factor 3 ◆ P
1659		Incorr. wedge angle 2 ◆ P
1660		Incorr. bolus 3 ◆ P
1661		Calc. to wrong point 2 ◆ P
1662		Calc. using wrong dose 2 ◆ P
1663		Calc. not normalized correctly 2 ◆ P
1670		Misc._____ P
Cutout Measurements		
1680		Used incorr. cutout 2 ◆ P
1681		Dose incorr. 2 ◆ P
1682		Energy incorr. 1 ◆ P
1683		Cone size incorr. 2 ◆ P
1684		SSD incorr. 2 ◆ P
1685		Depth incorr. 2 ◆ P
1686		Isodose line incorr. 2 ◆ P
1687		Depth of meas. incorr. 2 P
1688		Energy or modality used incorr. 1 ◆ P
1690		Misc._____ P
Treatment Chart		
1700		Diagnosis 1 ◆ M
1701		Histology 4 ◆ M
1702		H/P grade 4 ◆ M
1703		TNM stage 4 ◆ M
1704		Treatment intent 3 ◆ M
1705		Surgery 4 ◆ M
1706		Chemotherapy 2 ◆ M
1707		Previous RT 2 ◆ M
1708		Special precautions 3 ◆ M
1709		Rx: Date 2 ◆ M

Legend: Significance Level - 1 (most significant), 2, 3, 4, 5 (least significant) ◆ - Key Process M - M.D. P - Physics T - Therapist R - Facility RSO Q - QI Coordinator

Footnotes: [1] To include wedges, blocks, bolus, compensator, and no. of fr./day & fr./wk. (if not recorded under *Pattern*)
[2] Misadministration (Note: Some Agreement states have more restrictive dose requirements.)
[3] Recordable Event
[4] All information contained in this document is *Client-Attorney Privileged.*

Name Cancer Center

Unintended Deviation Reporting Form [1]
For Significance Level 1 and 2 Events (Recorded on Forms QA1a and QA1b)

Date(s) of Occurrence: _____ **Identified By:** _____
Date Identified: _____ **Patient Chart/UD No:** _____ / _____

☐ **Pre-Treatment Unintended Deviation** ☐ **Post-Treatment Unintended Deviation**

Category	Frequency	Code	Category	Frequency	Code
Treatment Planning			Treatment Chart		
R & V			Treatment of Patient		
Patient Simulation			Patient Identification		
Block Fabrication			Port Films		
Dose Calculation			Quality Assurance		
Cutout Measurement			Radiation Safety		

Description: _____

_____

_____

Evaluation: _____

_____

☐ **Δ Daily Dose (±)** _____% ☐ **Δ Weekly Dose (±)** _____% ☐ **Δ Total Dose (±)** _____%

☐ **Recordable Event** ☐ **Misadministration** ☐ **Personnel Overexposure**

Immediate Corrective Action Taken (Check all that apply):
Date of Immediate Action: _____

☐ Correction of documentation ☐ Adjustment of equipment or machine
☐ Adjustment of treatment (if necessary) ☐ Other: _____

Long-Term Corrective Action (Check all that apply):

☐ Additional training ☐ Increased oversight or supervision
☐ Improved procedure ☐ Other: _____

Approved:

☐ *Physicist initials/date:* _____ ☐ *RSO initials/date:* _____ ☐ *MD initials/date:* _____

Physicist or RSO Use Only

Evaluation: _____

_____

_____

Recommendations: _____

_____

_____

Date Received: **Date Reviewed:**
Date of Feedback to Facility: **Reviewer's Initials:**

[1] Complies with state and federal enforcement policies regarding licensee-identified violations and reporting of unintended deviations pursuant to the Quality Management Program. All information in this document and any attachments are *Client – Attorney Privileged*.

Name Cancer Center

Post-Treatment
Quarterly Unintended Deviation
Summary Report[1, 2]

□1st □2nd □3rd □4th Calendar Quarter 200

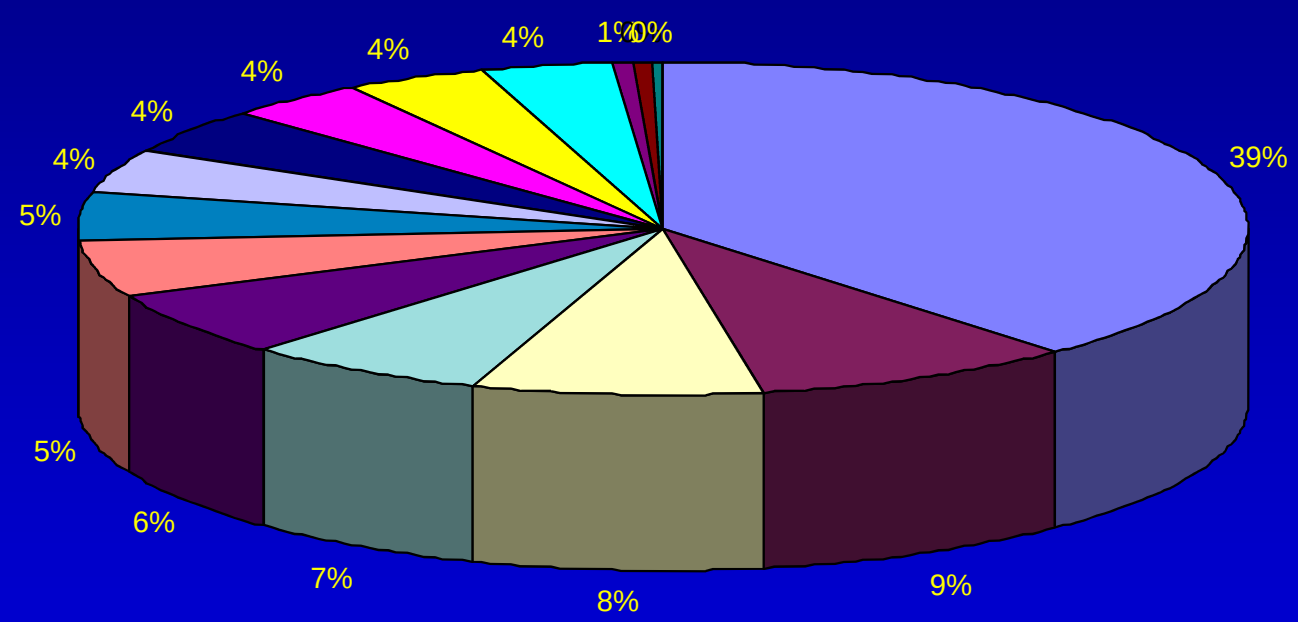
Monitored Category	Frequency By Category	Frequency By Significance Level					Frequency By Key Processes?	
		1	2	3	4	5	Yes	No
Tx Planning								
R & V - Prescription								
R & V - Tx Field Definition								
Sim - Patient Setup								
Sim - Films								
Block Fabrication								
Dose Calc - Hand								
Dose Calc - Computer								
Cutout Measurements								
Tx Chart - Rx								
Tx Chart - Patient Setup Doc								
Tx Chart - Tx Field info								
Tx of Patient - Daily Tx								
Tx of Patient - Patient ID								
Tx of Patient - Port Films								
Tx of Patient - Patient Setup								
Tx of Patient - Beam Modifiers								
Admin of Radiation								
QA								
Radiation Safety								
	total/Month	total	total	total	total	total	total	total

[3] File in Incidents Notebook XX - Section A.3. Send copy to QC.
[4] All information contained in this document and any attachments are *Client-Attorney Privileged*.

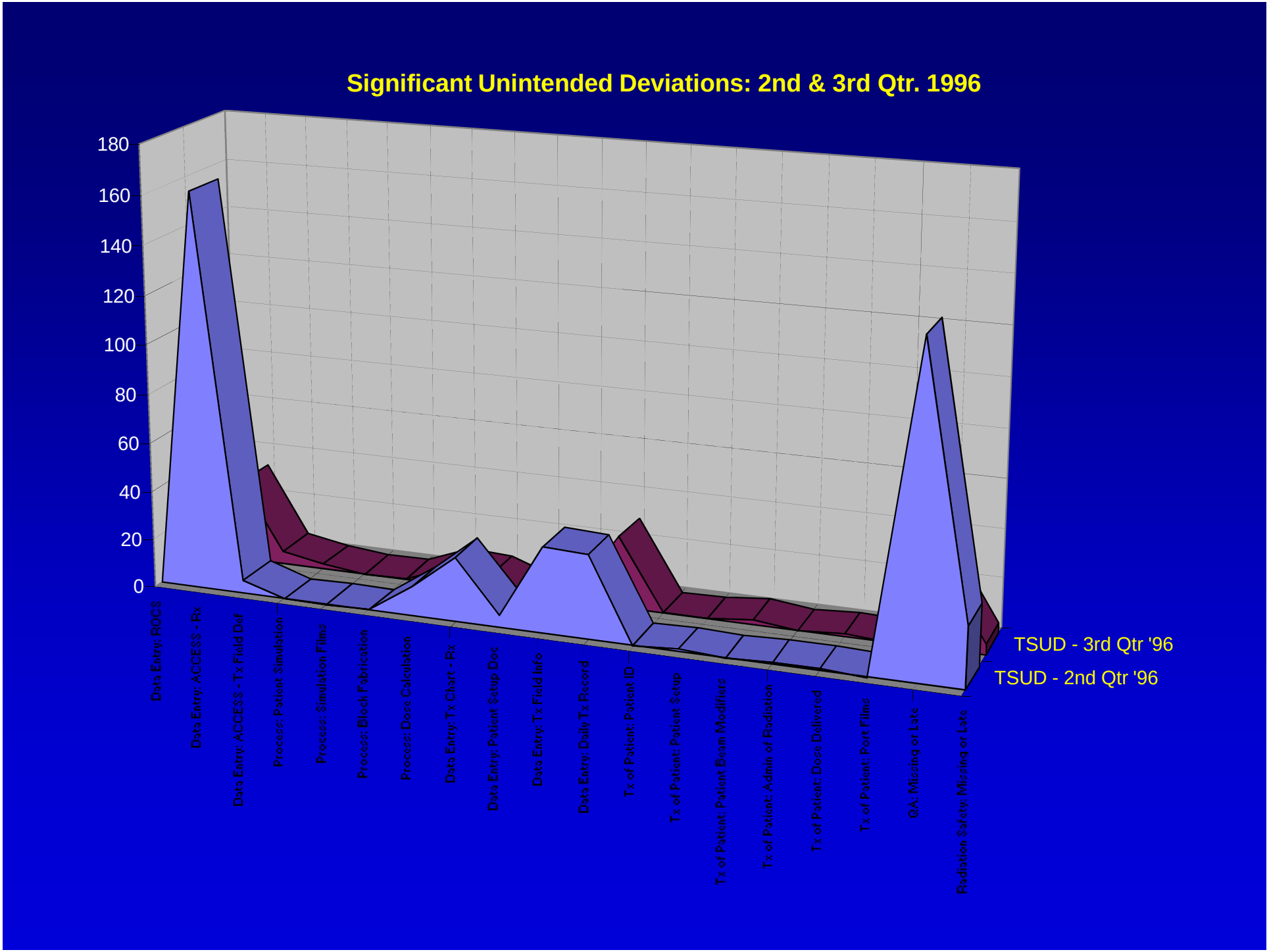
QAld

Unintended Deviations	TMUD - 2nd Qtr '96	TSUD - 2nd Qtr '96	Total - 2nd Qtr '96	TMUD - 3rd Qtr '96	TSUD - 3rd Qtr '96	Total - 3rd Qtr '96
Data Entry: ROCS	0	0	0	0	0	0
Data Entry: ACCESS - Rx	0	162	162	0	33	32
Data Entry: ACCESS - Tx Field Def	25	5	30	19	5	23
Process: Patient Simulation	59	0	59	22	2	23
Process: Simulation Films	24	0	24	25	0	21
Process: Block Fabrication	20	0	20	12	0	9
Process: Dose Calculation	17	12	29	11	7	18
Data Entry: Tx Chart - Rx	34	26	60	15	6	21
Data Entry: Patient Setup Doc	18	5	23	11	0	9
Data Entry: Tx Field Info	70	35	105	13	4	17
Data Entry: Daily Tx Record	216	34	250	107	29	125
Tx of Patient: Patient ID	0	0	0	1	0	1
Tx of Patient: Patient Setup	1	1	2	1	0	1
Tx of Patient: Patient Beam Modifiers	32	0	32	12	2	10
Tx of Patient: Admin of Radiation	2	1	3	0	0	0
Tx of Patient: Dose Delivered	0	1	1	0	1	1
Tx of Patient: Port Films	23	0	23	18	0	18
QA: Missing or Late	34	132	166	10	33	36
Radiation Safety: Missing or Late	3	25	28	2	4	5
TOTAL	**578**	**439**	**1017**	**279**	**126**	**370**
ABSOLUTE DIFF BETWEEN QTRS				**-299**	**-313**	**-647**
PERCENT INCREASE/DECREASE				**-51.7%**	**-71.3%**	**-63.6%**

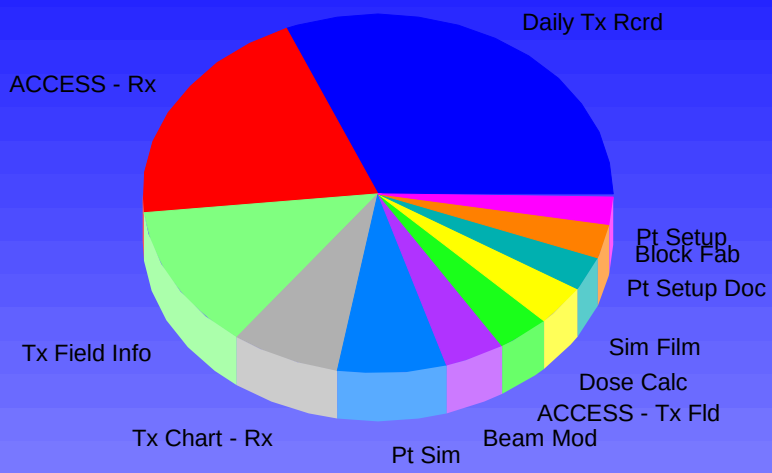
Minor Unintended Deviations: 3rd Qtr. 1996

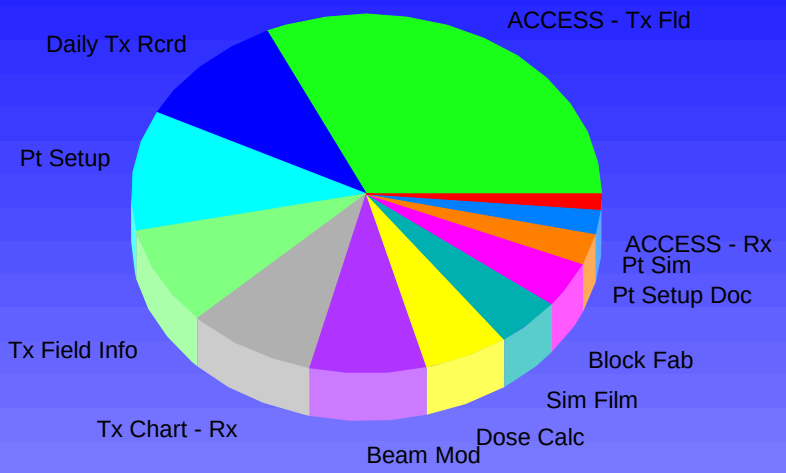


- Data Entry: Daily Tx Record
- Process: Simulation Films
- Process: Patient Simulation
- Data Entry: ACCESS - Tx Field Def
- Tx of Patient: Port Films
- Data Entry: Tx Chart - Rx
- Data Entry: Tx Field Info
- Process: Block Fabrication
- Tx of Patient: Patient Beam Modifiers
- Process: Dose Calculation
- Data Entry: Patient Setup Doc
- QA: Missing or Late
- Radiation Safety: Missing or Late
- Tx of Patient: Patient ID
- Tx of Patient: Patient Setup


Significant Unintended Deviations: 2nd & 3rd Qtr. 1996
180
160
140
120
100
80
60
40
20
0
Data Entry: ROCS
Data Entry: ACCESS - Rx
Data Entry: ACCESS - Tx Field Def
Process: Patient Simulation
Process: Simulation Films
Process: Block Fabrication
Process: Dose Calculation
Data Entry: Tx Chart - Rx
Data Entry: Patient Setup Doc
Data Entry: Tx Field Info
Data Entry: Daily Tx Record
Tx of Patient: Patient ID
Tx of Patient: Patient Setup
Tx of Patient: Patient Beam Modifiers
Tx of Patient: Admin of Radiation
Tx of Patient: Dose Delivered
Tx of Patient: Port Films
QA: Missing or Late
Radiation Safety: Missing or Late
TSUD - 3rd Qtr '96
TSUD - 2nd Qtr '96

Total Unintended Deviations versus Time

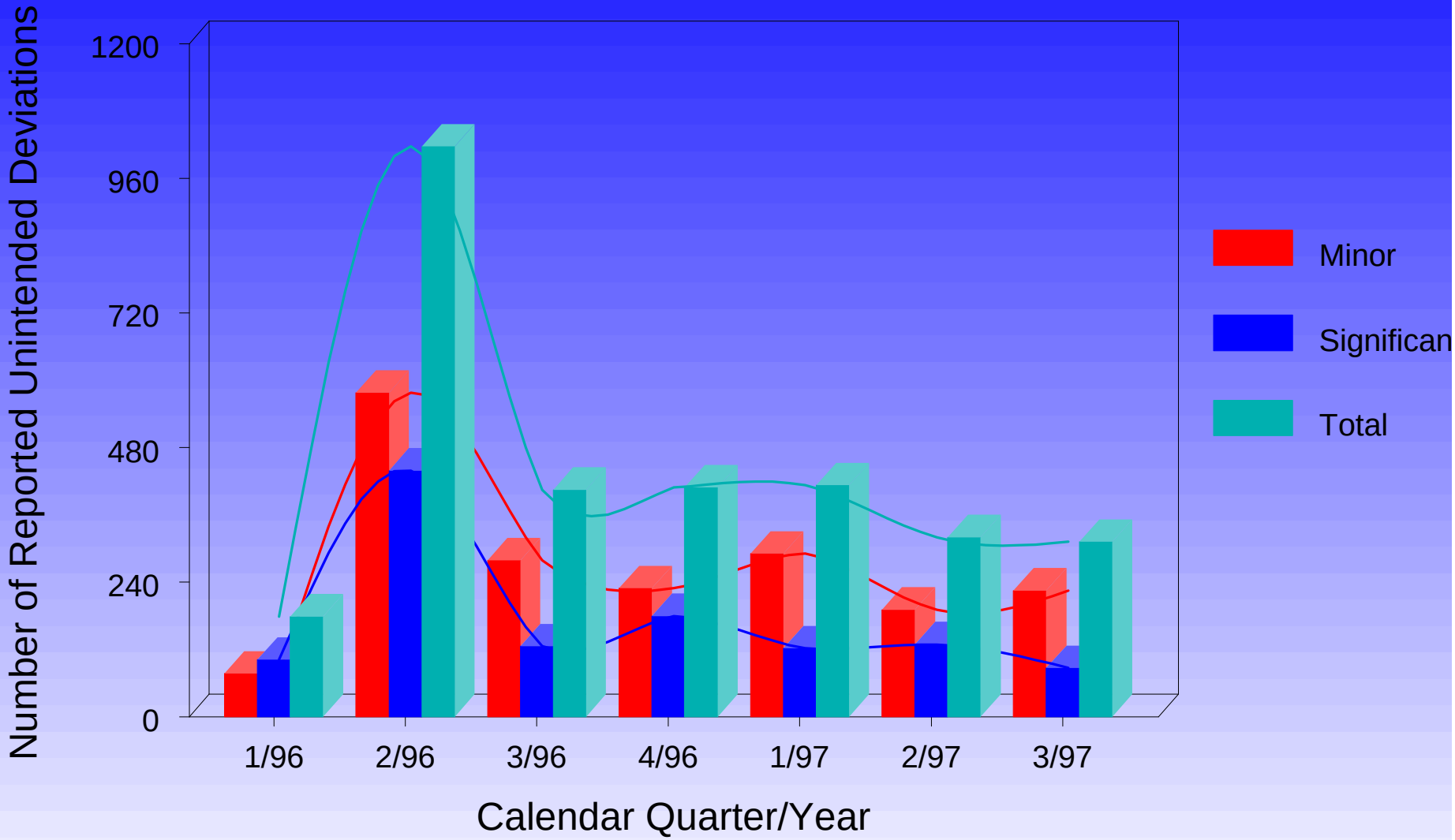




Parameter	2nd Quarter '96	2nd Quarter '97	% Change
Data Entry: ROCS	0	0	0
Data Entry: ACCESS - Rx	162	9	-1800
Data Entry: ACCESS-Tx Field Def	30	45	+150
Process: Pt Sim	59	6	-983
Process: Sim Films	24	5	-480
Process: Block Fab	20	4	-500
Process: Dose Calc	29	8	-363
Data Entry: Tx Chart-Rx	60	25	-240
Data Entry: Pt Setup Doc	23	3	-768
Data Entry: Tx Field Info	105	44	-239

Parameter	2nd Quarter '96	2nd Quarter '97
Data Entry: Daily Tx Rcd	250	125
Tx of Pt: Pt ID	0	0
Tx of Pt: Pt Setup	2	1
Tx Pt: Pt Beam Mod	32	12
Tx Pt: Admin of Rad	3	0
Tx of Pt: Dose Deliv	1	0
Tx of Pt: Port Films	23	3
QA: Missing/Late	166	24
RS: Missing/Late	28	6

Summary of Total Unintended Deviations



Reported Misadministration Rate In Radiation Oncology

Published rates[70] for *reported* misadministrations in therapeutic radiation oncology is 0.0042 percent (4.2/100,000 fractions) based upon 20 fractions/patient for NRC regulated states only. Based upon internal NRC documents, it is speculated that the rate may be as high as 0.04 percent.

[70]NRC memorandum dated March 8, 1993: Data based on information obtained from the American College of Radiology (*Manpower Committee, Patterns of Care Study*, and *Commission of Human Resources*). Additional reference from Institute of Medicine (*Radiation in Medicine - A Need For Regulatory Reform*), 1996.

Calculated Error Rates

Paper-Based Model

- Based upon the total number of treatment fields delivered as recorded by R&V at 17 radiation oncology centers and the total number of unintended deviations self-reported by the system, excluding the initial two quarters for the “learning curve effect”, the overall average error rate for both minor and significant unintended deviations within the system was approximately 0.052% (5.2 in 10,000 patient fractions).
- The minor unintended deviation reporting rate for the same period was approximately 0.034%.

Measured vs Published Misadministration Rate

Radiation Oncology

- The significant unintended deviation reporting rate that could lead to a misadministration was calculated to be approximately 0.018% (1.8 in 10,000 patient fractions).[71]
- Based upon the model's experience of one reported misadministration (having no deterministic or measurable effect) over 2 years, the measured misadministration rate was 0.017%.

[71] Reporting rate is based on the number of significant interactions occurring in the treatment delivery process that could lead to a misadministration (criteria based on 10 CFR Part 35) vs the total number of treatment fields administered for 17 centers.

Measured vs Published Misadministration Rate

Radiation Oncology

- When compared to what the NRC speculates is the actual misadministration rate of 0.04 (4 in 10,000), this rate is a factor of 2.35 lower.
- Though this program helped in minimizing the occurrence of misadministrations, the overall focus was to reduce the number and nature of all errors in the therapy process.

Cost Benefit Analysis

Paper-Based Model

- After implementation of the QA/Medical Error Reduction Program, the 17 radiation oncology centers experienced a reduction of 326% in error rate from 3/96 to 12/97 (not including the “learning curve effect”):
  - Direct cost savings of approximately **$450,000**
  - Direct & indirect cost savings of approximately **$600,000**

Cost Benefit Analysis

Paper-Based Model

- Experience with the one reported misadministration that occurred at a center in Florida between 3/96 and 12/97 (with no measurable effect) resulted in a total direct cost (man-hours, travel, etc.) of approximately $25,000.
- Physician malpractice insurance premiums for the 17 oncology centers were reduced by 10%.

Summary of Results

Paper-Based Model

- Overall average error rate was 0.052% (SL 1 – 5)
- Calculated misadministration rate[72] was 0.018%
- Actual misadministration rate was 0.017%
- NRC misadministration rate was 0.042% (a factor of 2.35 higher than actual misadministration rate)
- Reduced overall error rate by 326% over 21 months
- Direct cost savings of **$450,000**
- Direct & indirect cost savings of **$600,000**
- Other significant incidents averted by using program

[72]Misadministration criteria based on definitions found in NRC 10CFR35.2, rev. 1996; and CRCPD recommended Agreement State regulations dated 2007.

Other Center Studies

Paper-Based Model

Summary of Results - 1998

Oncology Company With 10 Freestanding Centers

- Three significant radiation treatment errors, that if left undetected would have required reporting to the State and notifying the referring physician and patient, were caught.
- A misadministration at one center, involving possible civil penalties and sanctions, was mitigated by the State by demonstrating that the error leading to the misadministration was isolated based on empirical data.

Other Center Studies

Paper-Based Model

Summary of Results - Calendar Year 2002

Cancer Center #1

- Aside from the 1st quarter "learning curve", total errors decreased by **70.5%** (334 vs 99) between the 2nd and 3rd quarters.
- Total errors decreased by **27.3%** (99 vs 72) between the 3rd and 4th quarters.
- The total decrease in errors between the 2nd and 4th quarters was **78.4%** (334 vs 72).

Cancer Center #2

- Aside from the 1st quarter "learning curve", total errors decreased by **66.4%** (113 vs 38) between the 2nd and 3rd quarters.
- Total errors decreased by **18.4%** (38 vs 31 between the 3rd and 4th quarters
- The total decrease in errors between the 2nd and 4th quarters was **72.6%** (113 vs 31).

Lessons Learned

Paper-Based Model

- **Limitations**
  - Inefficient
  - Time intensive
  - Intrusive
  - Complex industrial engineering model
  - Requires paper trail
- **Weaknesses**
  - Learning error codification system
  - Triggering required regulatory actions
  - Faxing of errors
  - Tracking UDs
  - Management review
  - Trending and analysis
  - Report generation
  - Timely action
  - Credible root cause analysis

Software-Based Model

Design of Software-Based Model

- What is needed?
  - Automated tracking of errors
  - Non-intrusive data gathering
  - Preset standardized gathering
  - Scoring of risk (FMEA)
  - Immediate analysis of errors
  - Short and long-term corrective actions
  - Tracking and trending of errors
  - Automated regulatory report launching

Design of Software-Based Model

MERP Program

- **Monitored Areas**
  - Clinical
  - QA
  - Radiation Safety
- **Identification and Tacking of Errors**
  - Preset standardized error codes
  - Classification of pre and post-treatment errors
  - Assignment of severity levels (I - V)
  - Calculation of *Risk Priority Number*
  - Designation of clinical significance
  - Designation of significant unintended deviation
- **Identification and Tacking of Errors (conti.)**
  - "Near Miss" categorization
  - Sentinel events (internal and JCAHO reportable)
  - Instant analysis of patterns and trends
  - Recordable events
  - Misadministrations (medical events)
  - Regulatory violations
  - Possible regulatory violations

Design of Software-Based Model

MERP Program

- **Step-By-Step Root Cause Analysis**
  - Determination of credible root cause analysis
  - Identification of causal factors
  - Identification of opportunities for improvement
- **Action Plan Road Map**
  - Risk-reduction strategy
  - Short-term corrective action
  - Long-term corrective action
  - Assignment of responsible individuals
- **Patient Dose Error Calculation Wizard**
  - Calculates % error in daily, weekly & total doses
- **Patient Dose Error Calculation Wizard (cont.)**
  - Automatically triggers levels for report generation
    - JCAHO root cause analysis and action plans
    - State regulatory notifications
- **Procedure Generation**
  - Drafting of procedure as part of corrective action plan
  - Serves as tutorial in training new employees/annual refresher
- **Review and Approval**
  - Queue action plan(s) for review and approval
  - Accept or reject routine corrective action(s)

Design of Software-Based Model

MERP Program

- **Reports and Chart Generation**
  - Generate reports showing characterization of errors and corrective actions
  - Show charts stratifying error types and severity levels
  - Select time intervals for charting of data
- **Audit Compliance Tool**
  - MERP used to inspect regulatory performance
    - Complies with State radiation safety requirement for annual reviews
    - Meets State QMP rule for annual reviews
    - Follows CMS compliance objectives
    - Complies with JCAHO standards

Design of Software-Based Model

MERP Program

- **Customization Features**
  - Customize and create data collection areas for performance improvement priorities
    - Categories
    - Subcategories
    - Attributes
  - Designate who reviews/approvals routine errors and corrective actions
  - Assign which errors violate State requirements
  - Designate severity levels, clinically significant, and significant unintended deviations
- **Standards/Requirements Referenced by Code**
  - JCAHO 2010 patient safety standards show basis for question
  - ACR and ACRO standards demonstrate benchmark for measuring performance
  - CRCPD (Agreement State) recommended regulations (as of 9/08) show legal text

MERP Implementation Strategy

Preparation

- **Step #1 - Benchmark Procedures**
  - Created manual
  - Included step-by-set processes
  - Covered technical delivery system
    - QA
    - Radiation safety
    - QMP
- **Step #2 - Training**
  - Provided classroom hours
    - 18 hours in procedures
    - 6 hours in MERP
  - Presented at new center start-up or over 1 hour lunch break (existing)
  - Took 3 days (new center) vs 2 months (existing center)
  - Issued category ‘A’ credit thru ASRT
  - Met annual state radiation safety training requirements

MERP Implementation Strategy

Phased Rollout

- **Step #3 - Superusers**
  - Designated key point guards
    - Controlled data input
    - Tracked status of UDs
    - Tracked completion of corrective action plans
- **Step #4 - Phases**
  - Group 1
    - Therapists
    - CT/X-ray technologists
    - Physics (physicists & dosimerists)
    - Billing
  - Group 2
    - Radiation oncologists
  - Group 3
    - Admissions/registration staff

NMCC

RO MERP

Unintended Deviation (UD) Reporting Form

Date(s) of Occurrence: _____ **Date Identified:** _____

Identified by: _____ **Patient ID #:** _____

Patient Name: _____ **UD #:** _____

Patient Related			Non-Patient Related	
Clinical ☐	QA ☐	RS ☐	QA ☐	RS ☐
Pre-Tx ☐	Post-Tx ☐	Affected Tx ☐		

Description of UD:

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Initials: _____ **Date:** _____

MERP Results

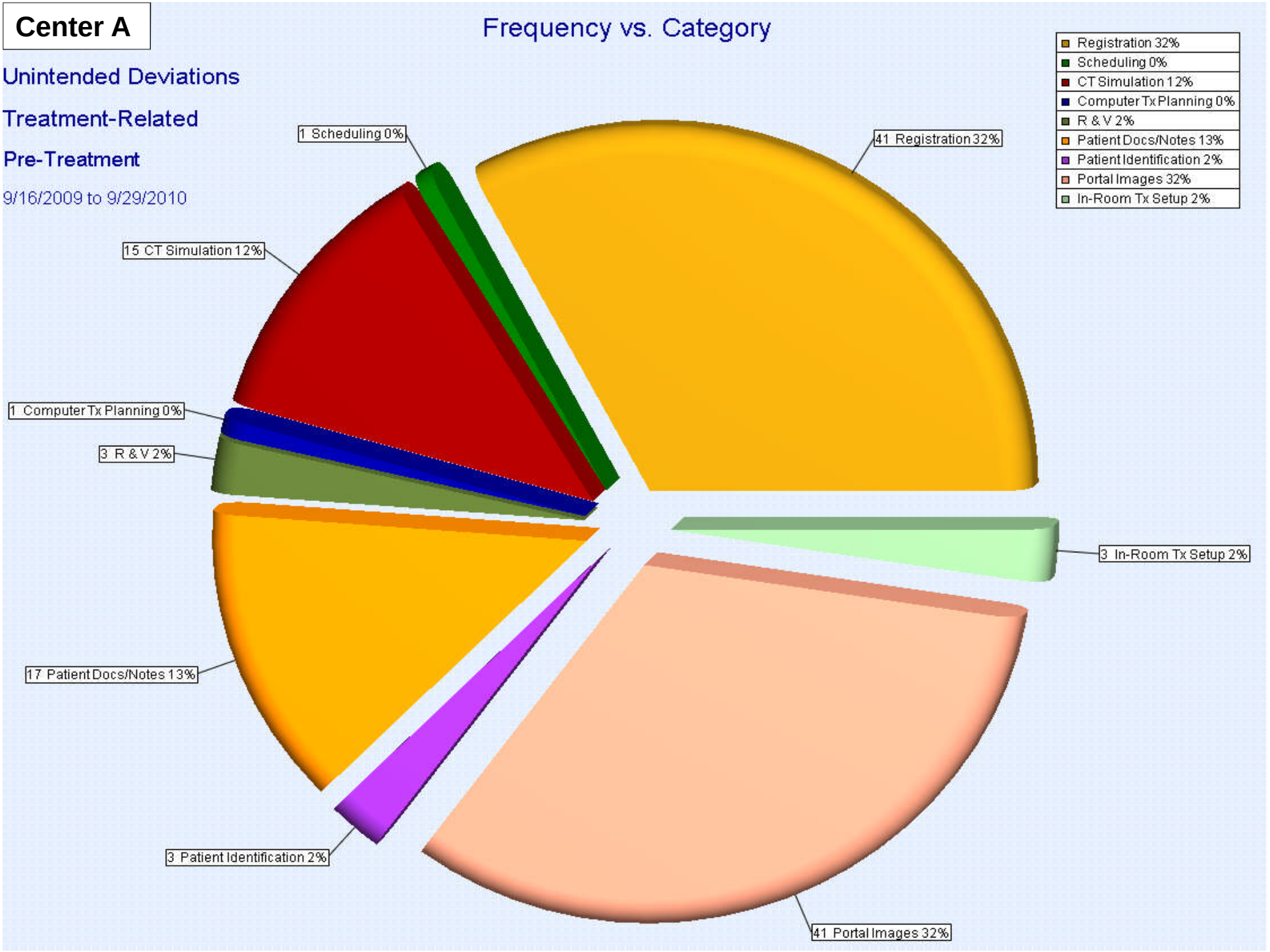
Center A

Unintended Deviations

Treatment-Related

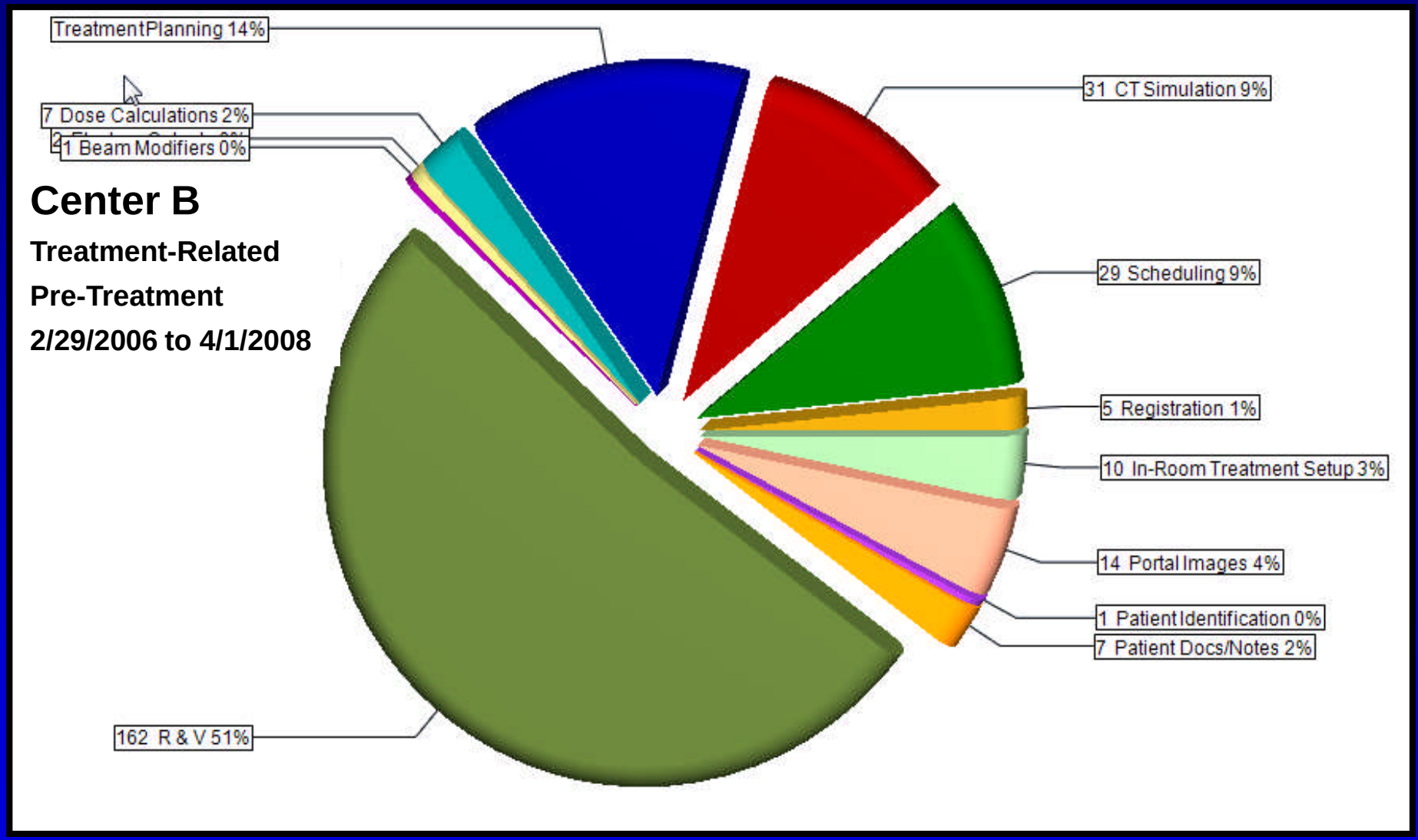
Pre-Treatment

9/16/2009 to 9/29/2010



MERP Results

Center B



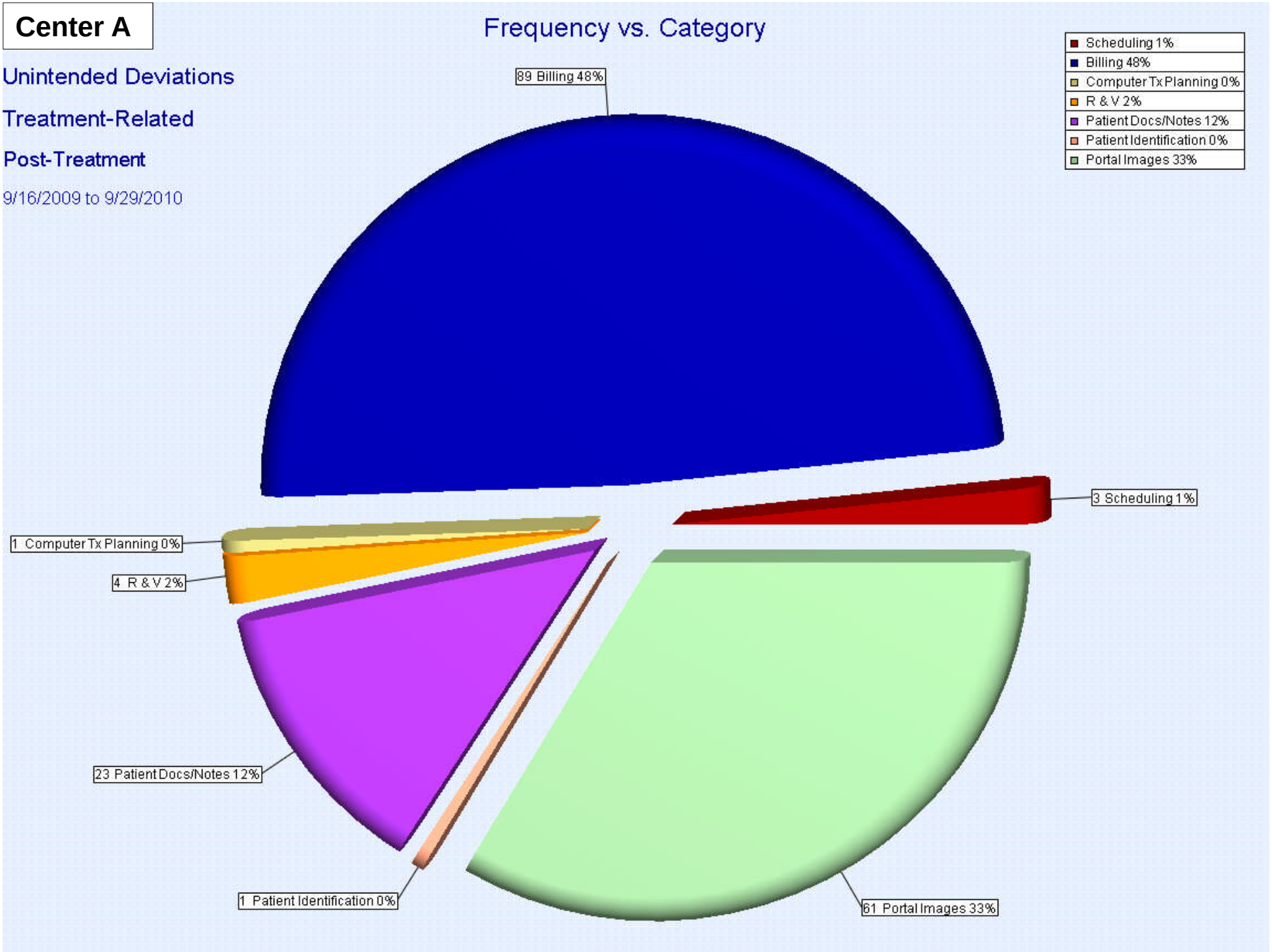
Center A

Unintended Deviations

Treatment-Related

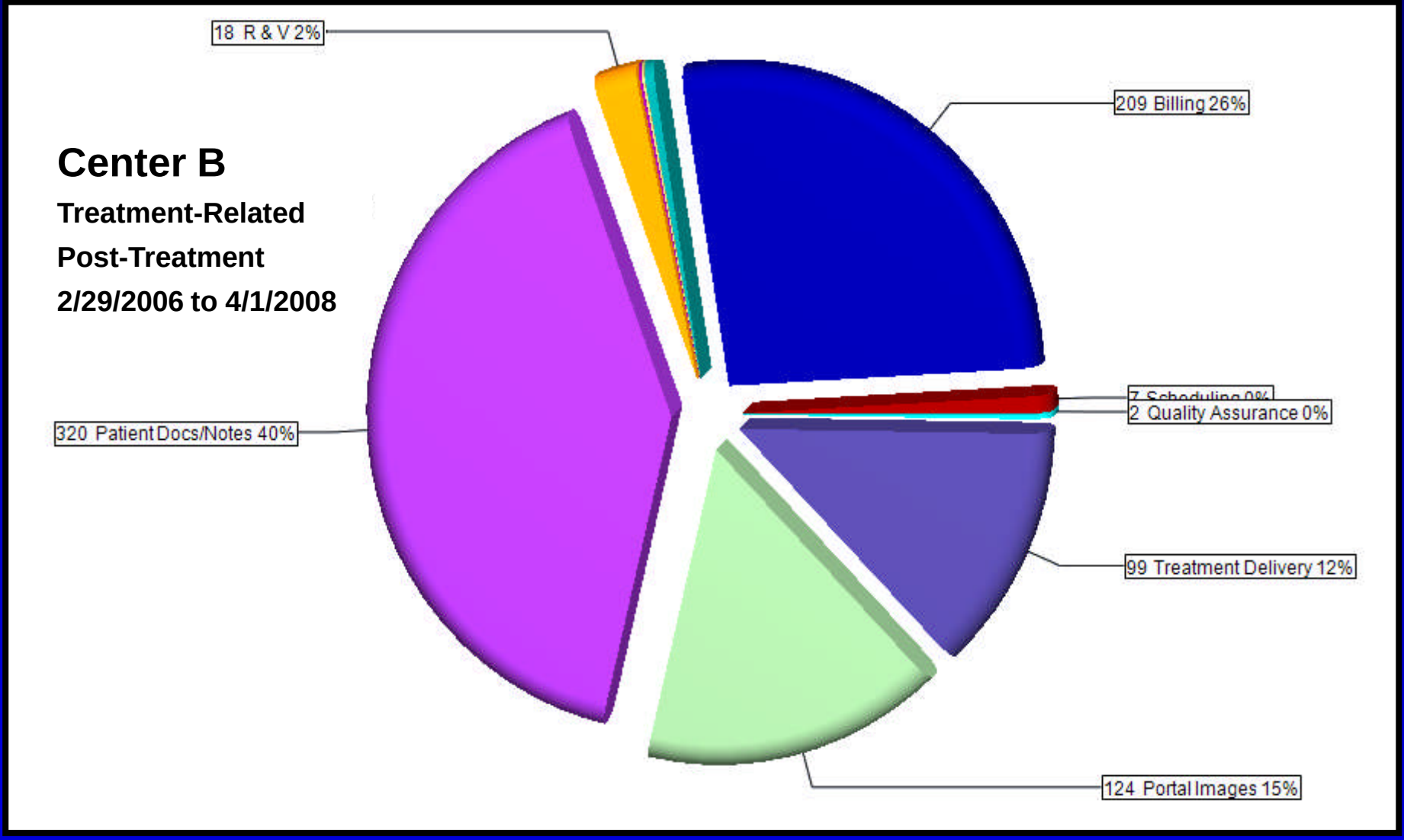
Post-Treatment

9/16/2009 to 9/29/2010



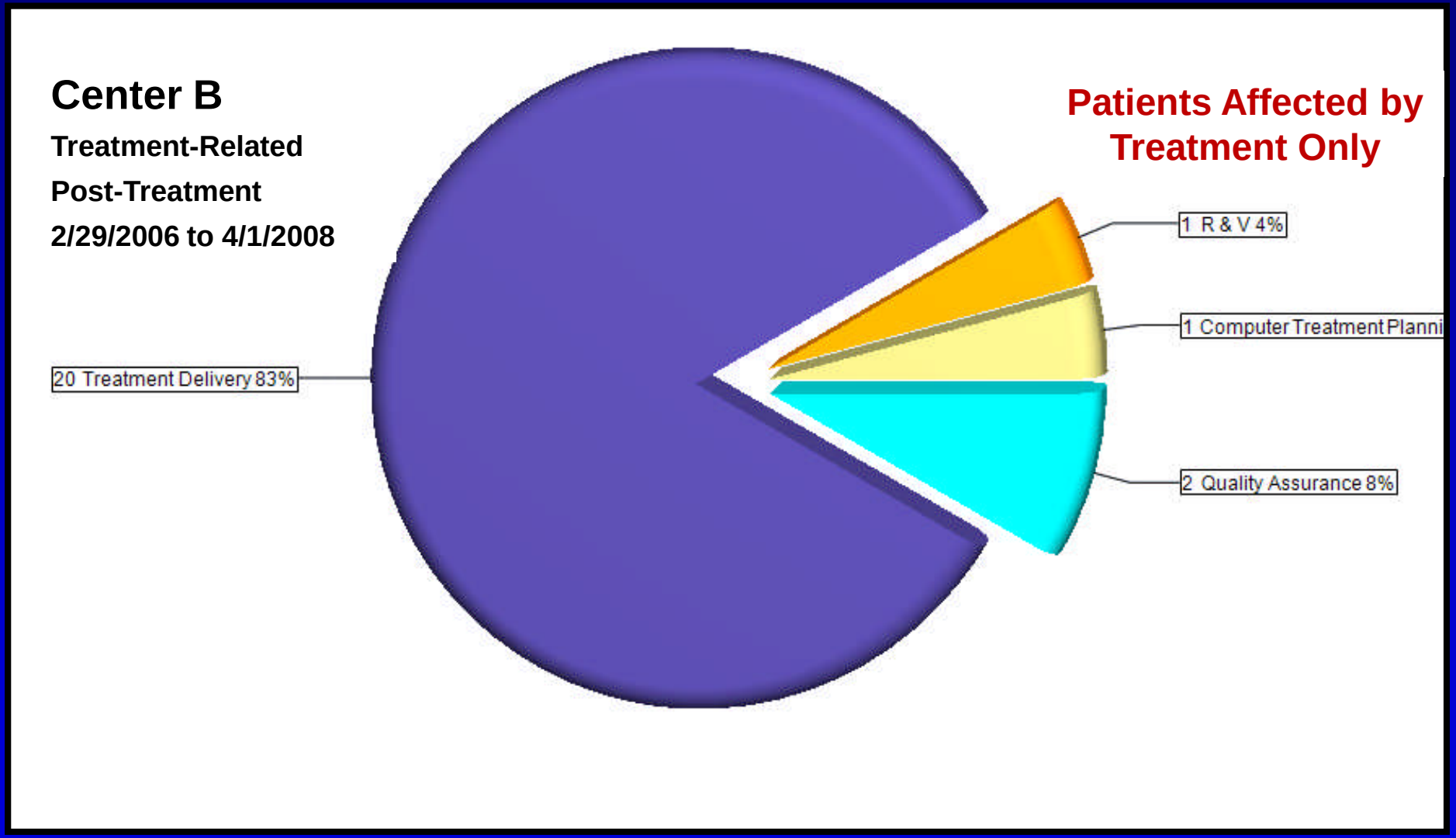
MERP Results

Center B



MERP Results

Center B



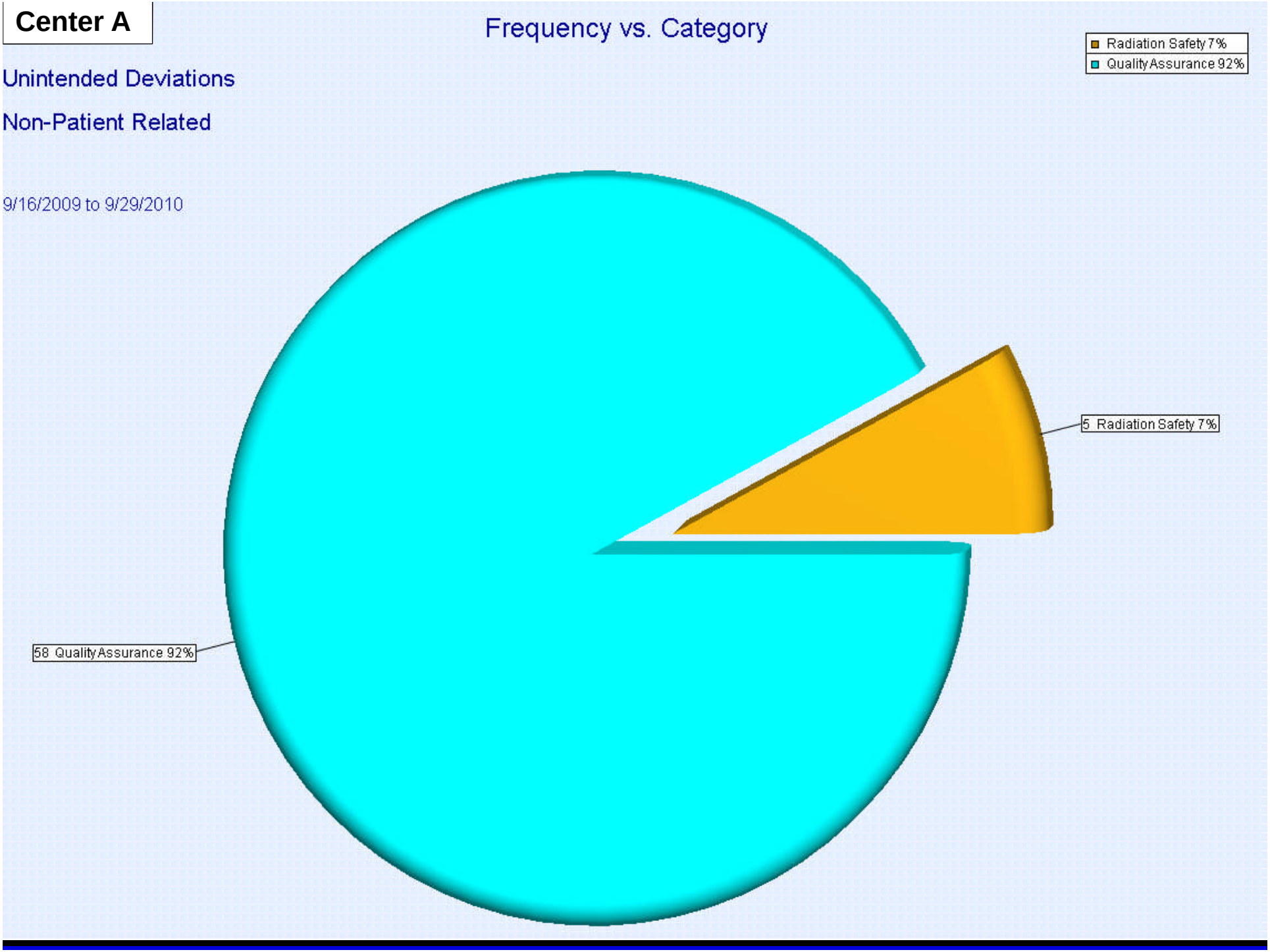
Center A

Frequency vs. Category

Unintended Deviations

Non-Patient Related

9/16/2009 to 9/29/2010



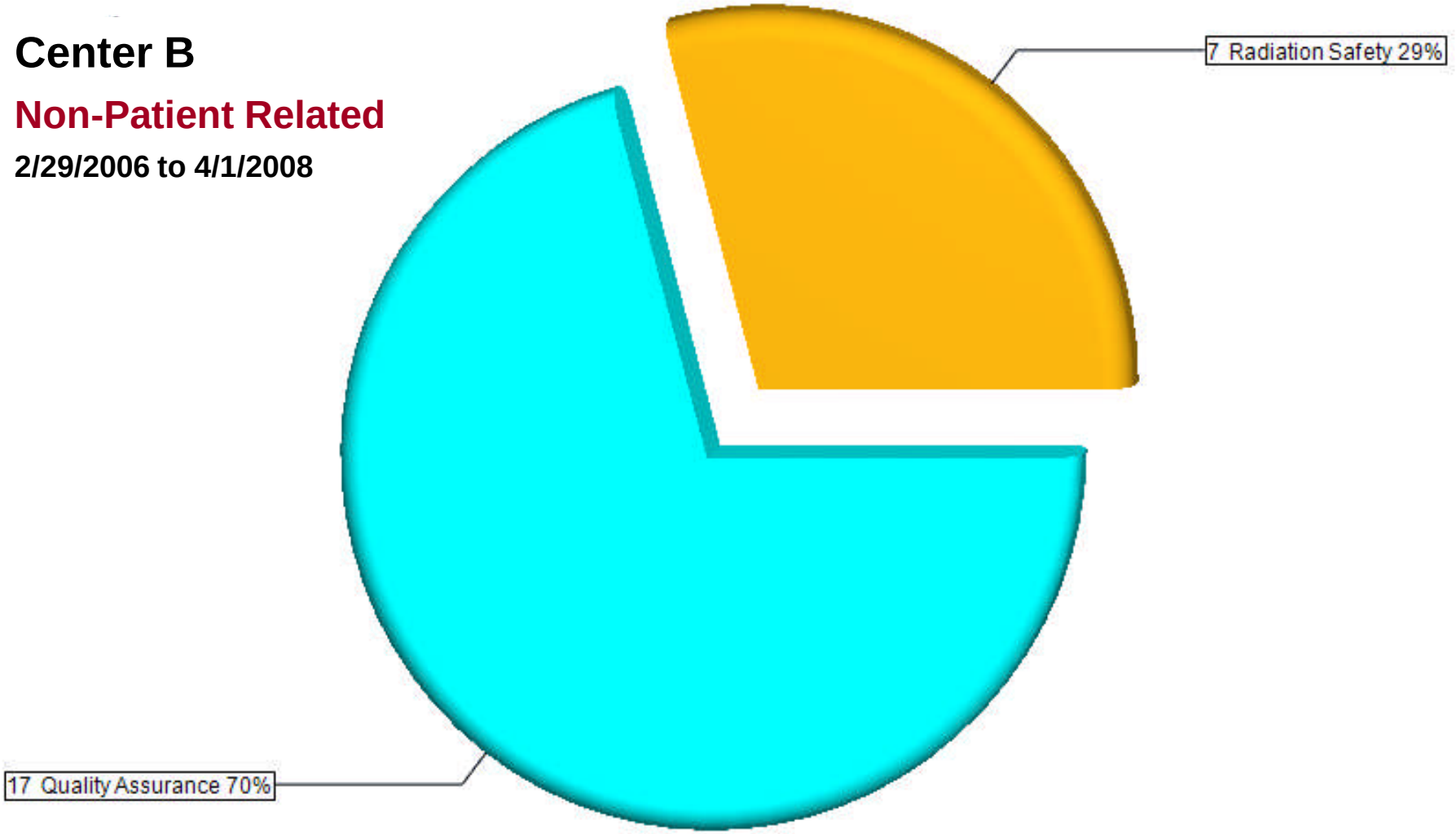
MERP Results

Center B

Center B

Non-Patient Related

2/29/2006 to 4/1/2008



Center B - Errors of Greatest Frequency

This screen shows you the list of all Errors which have been reported in this system in descending order of occurrence.

Select the Date Range for the query : Custom | Start Date 2/20/2006 | End Date 4/ 1/2008 | Search

Results

Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	141
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	112
Pre-Tx	R & V	Prescription	Electronic approval before 1st fx miss.	90
Post-Tx	Patient Docs/Notes	Simulation Notes	Tx planning sim note not completed	84
Post-Tx	Patient Docs/Notes	Simulation Notes	Field verification sim note not completed	74
Post-Tx	Patient Docs/Notes	Simulation Notes	Isocenter verification sim note not completed	60
Post-Tx	Patient Docs/Notes	Simulation Notes	CT sim note not completed	59
Post-Tx	Treatment Delivery	Patient Setup	RTT note incorr./miss.	50
Post-Tx	Billing	Audits	Final chart audits miss./late	47
Pre-Tx	R & V	Diagnosis	Diagnosis category (disease site) incorr./miss.	24
Pre-Tx	R & V	Diagnosis	Diagnosis type (new primary, recurrent) incorr./miss.	20
Post-Tx	Patient Docs/Notes	Simulation Notes	Special physics consultation request not completed	17
Pre-Tx	Computer Treatment Planning	Tx Plan	Tx plan not signed	17
Post-Tx	Billing	Codes	No. of charges incorr./miss.	12
Post-Tx	Patient Docs/Notes	Simulation Notes	Electron boost sim note not completed	11
Post-Tx	Portal Images	Electronic Imager	Weekly images not acquired	10
Post-Tx	Treatment Delivery	Patient Setup	Field setup photos incorr./miss.	10
Pre-Tx	CT Simulation	Patient Setup	Field note incorr./miss.	10
Pre-Tx	Scheduling	Appointments	Appointment activity incorr./miss.	10
Pre-Tx	Computer Treatment Planning	Tx Plan	Shifts from CT user origin to CAX incorr./miss.	9
Post-Tx	Treatment Delivery	Beam Modifiers	Bolus required, no bolus used	9
Pre-Tx	R & V	Treatment Field Definition	Field name incorr./miss.	8
Pre-Tx	Portal Images	Electronic Imager	Weekly images not approved	7
Pre-Tx	CT Simulation	Patient Setup	Sim note incorr./miss.	7
Post-Tx	Treatment Delivery	Patient Setup	Sim note incorr./miss.	7
Post-Tx	Patient Docs/Notes	Default	Initial consultation not completed	6
Post-Tx	Patient Docs/Notes	Default	Follow-up evaluation not completed	6
Post-Tx	R & V	Diagnosis	Diagnosis type (new primary, recurrent) incorr./miss.	6
Pre-Tx	Computer Treatment Planning	Tx Plan	DRRs incorr./miss.	6
Pre-Tx	CT Simulation	Patient Setup	Field setup photos incorr./miss.	5
Pre-Tx	Scheduling	Appointments	Appointment dates incorr./miss.	5
Pre-Tx	In-Room Treatment Setup	Fields	Immobilization device missing	5

Detailed Example of Above

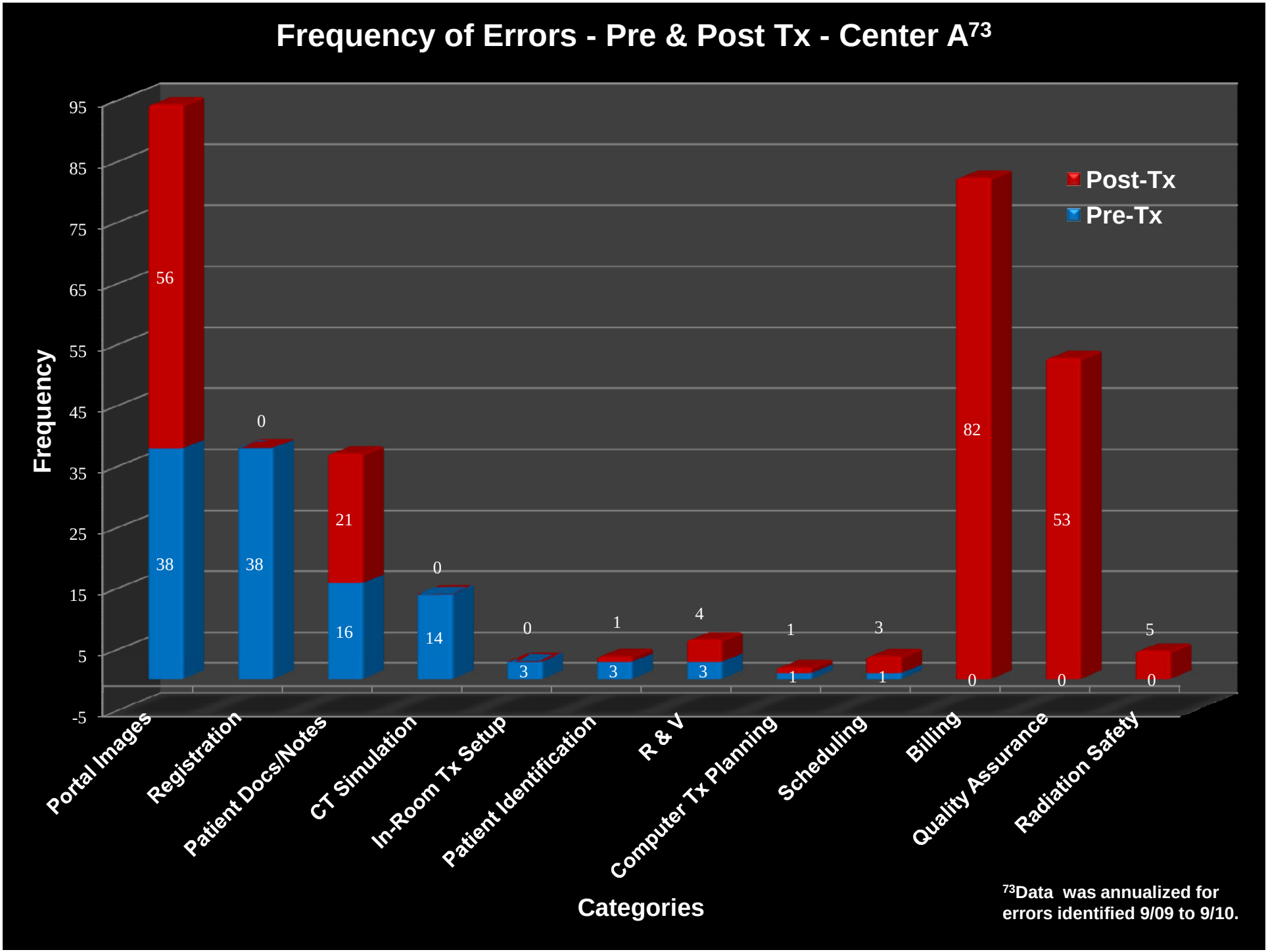
Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	141
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	112
Pre-Tx	R & V	Prescription	Electronic approval before 1st fx miss.	90
Post-Tx	Patient Docs/Notes	Simulation Notes	Tx planning sim note not completed	84
Post-Tx	Patient Docs/Notes	Simulation Notes	Field verification sim note not completed	74
Post-Tx	Patient Docs/Notes	Simulation Notes	Isocenter verification sim note not completed	60
Post-Tx	Patient Docs/Notes	Simulation Notes	CT sim note not completed	59
Post-Tx	Treatment Delivery	Patient Setup	RTT note incorr./miss.	50

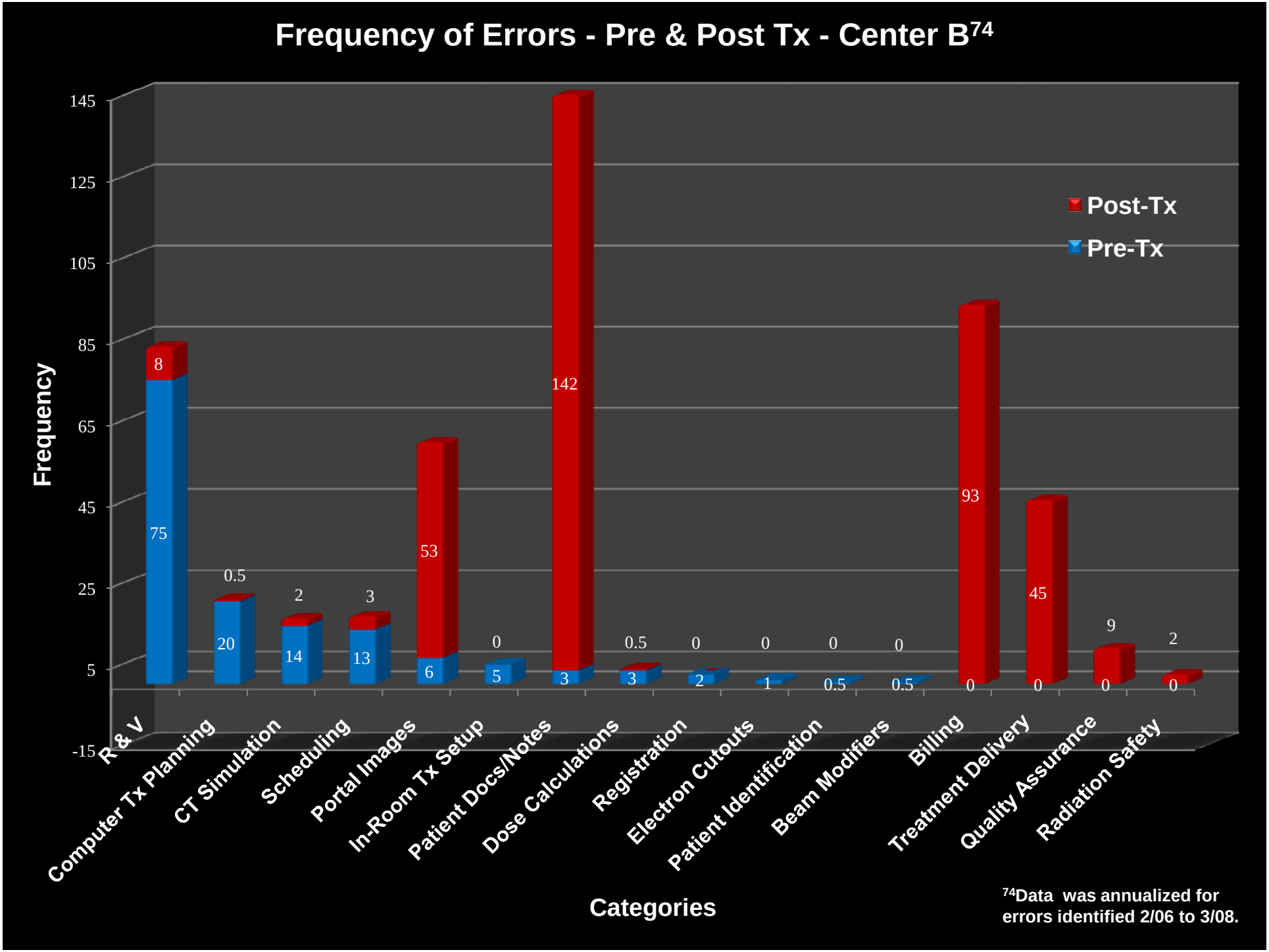
Center B - Errors of Greatest Frequency

Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	141
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	112
Pre-Tx	R & V	Prescription	Electronic approval before 1st fx miss.	90
Post-Tx	Patient Docs/Notes	Simulation Notes	Tx planning sim note not completed	84
Post-Tx	Patient Docs/Notes	Simulation Notes	Field verification sim note not completed	74
Post-Tx	Patient Docs/Notes	Simulation Notes	Isocenter verification sim note not completed	60
Post-Tx	Patient Docs/Notes	Simulation Notes	CT sim note not completed	59
Post-Tx	Treatment Delivery	Patient Setup	RTT note incorr./miss.	50

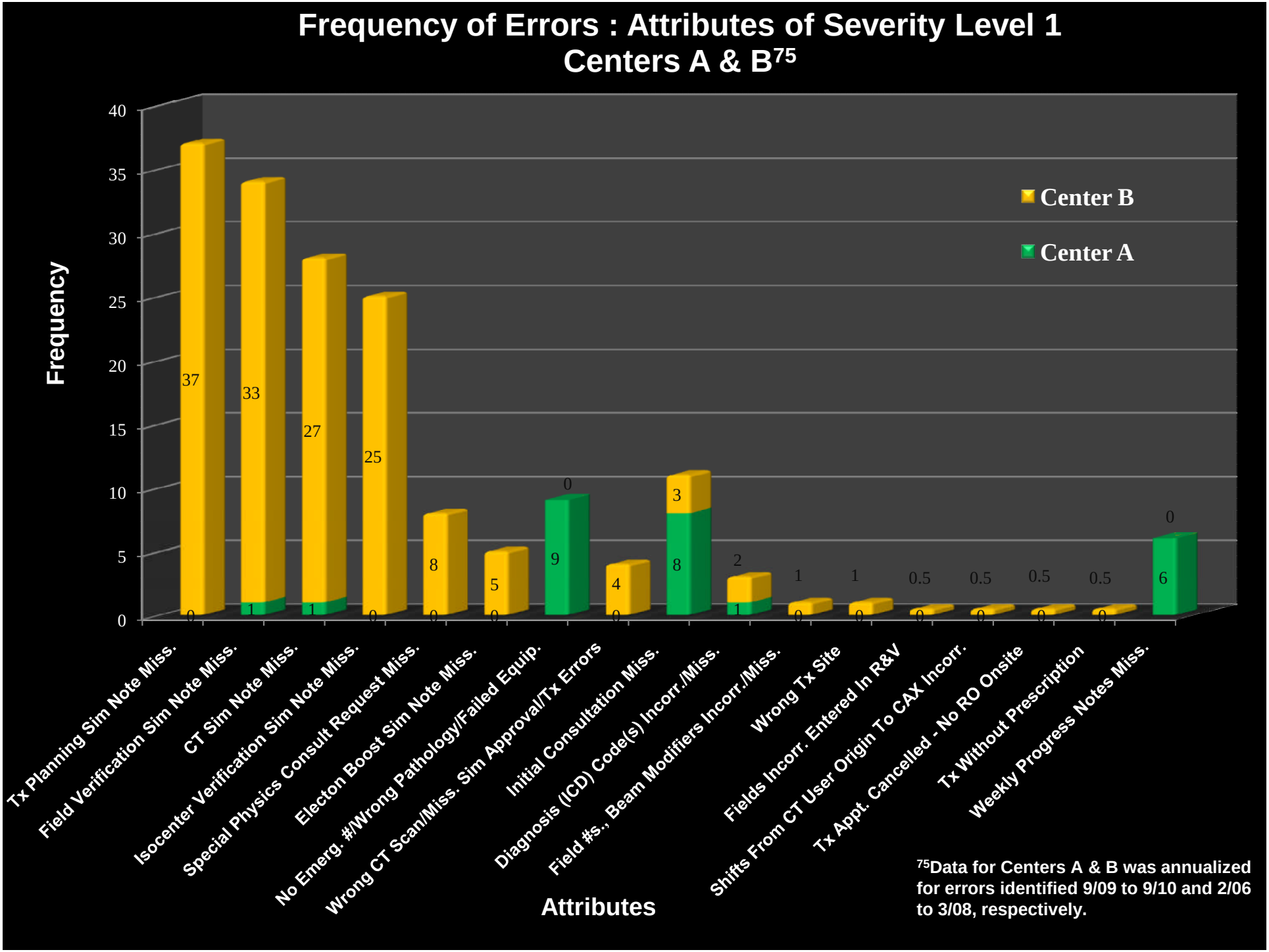
Center A - Errors of Greatest Frequency

Pre/Post	Category	Subcategory	Attribute	Occurrences
Post-Tx	Billing	Codes	CPT code incorr./miss.	78
Post-Tx	Portal Images	Electronic Imager	Weekly images not approved	56
Pre-Tx	Portal Images	Electronic Imager	Custom attribute SL 2	40
Pre-Tx	Registration	Emergency	Home phone incorr./miss.	34
Post-Tx	Quality Assurance	Checks	Weekly physics chart checks miss./late	17
Pre-Tx	Patient Docs/Notes	Default	Initial consultation not completed	13
Pre-Tx	CT Simulation	Patient Setup	Sim note incorr./miss.	9
Post-Tx	Patient Docs/Notes	Default	Initial consultation not completed	9

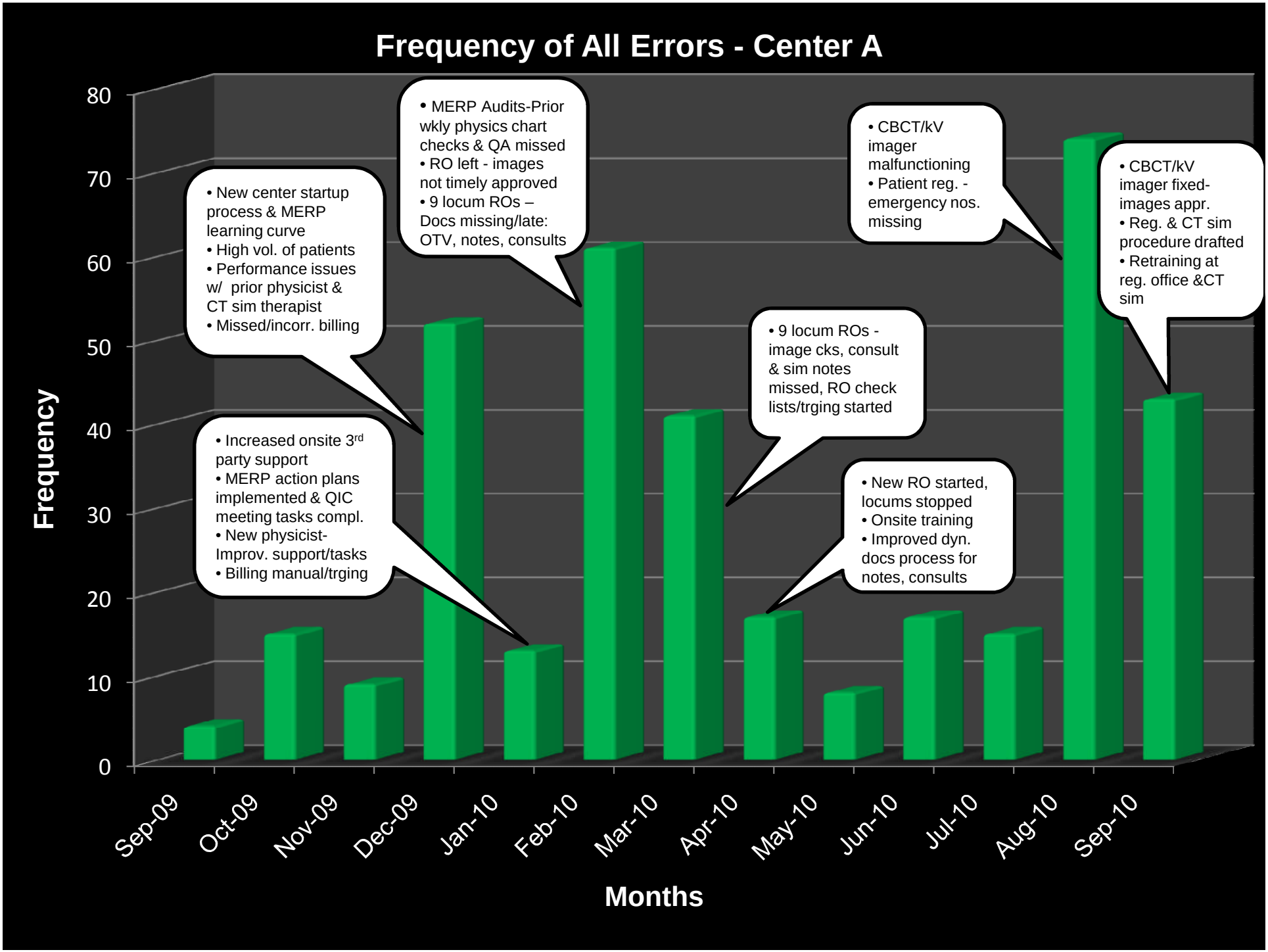

Frequency of Errors - Pre & Post Tx - Center A[73]
Frequency
95
85
75
65
55
45
35
25
15
5
-5
Post-Tx
Pre-Tx
56
38
0
38
21
16
0
14
0
3
1
3
4
3
1
1
3
1
82
0
53
0
5
0
Portal Images
Registration
Patient Docs/Notes
CT Simulation
In-Room Tx Setup
Patient Identification
R & V
Computer Tx Planning
Scheduling
Billing
Quality Assurance
Radiation Safety
Categories
[73]Data was annualized for errors identified 9/09 to 9/10.

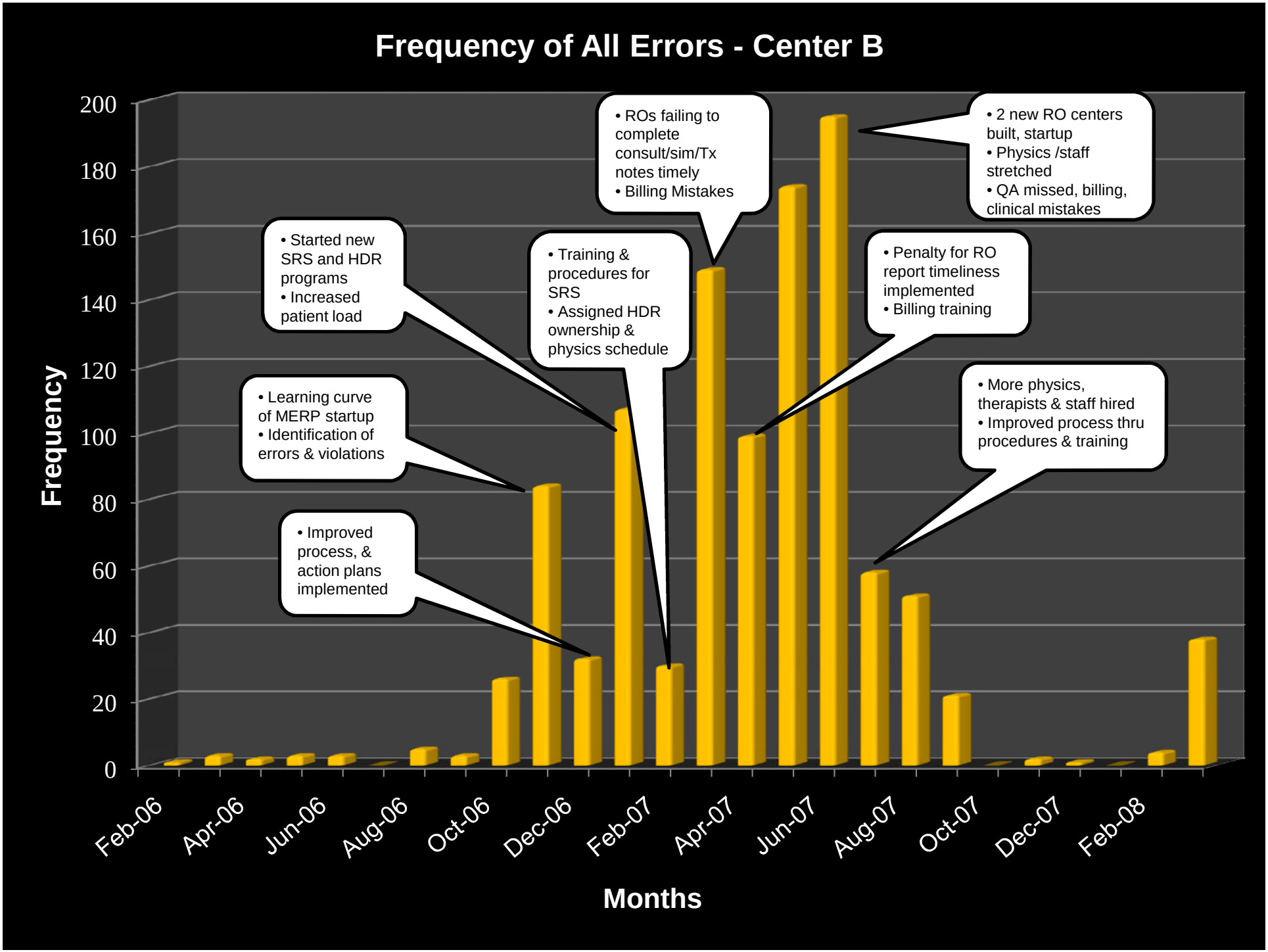

Frequency of Errors - Pre & Post Tx - Center B74
Frequency
145
125
105
85
65
45
25
5
-15
Post-Tx
Pre-Tx
8
75
0.5
20
2
14
3
13
53
6
0
5
142
3
0.5
3
0
2
0
1
0
0.5
0
0.5
93
0
45
0
9
0
2
0
R & V
Computer Tx Planning
CT Simulation
Scheduling
Portal Images
In-Room Tx Setup
Patient Docs/Notes
Dose Calculations
Registration
Electron Cutouts
Patient Identification
Beam Modifiers
Billing
Treatment Delivery
Quality Assurance
Radiation Safety
Categories
74Data was annualized for errors identified 2/06 to 3/08.

Frequency of Errors : Attributes of Severity Level 1
Centers A & B[75]

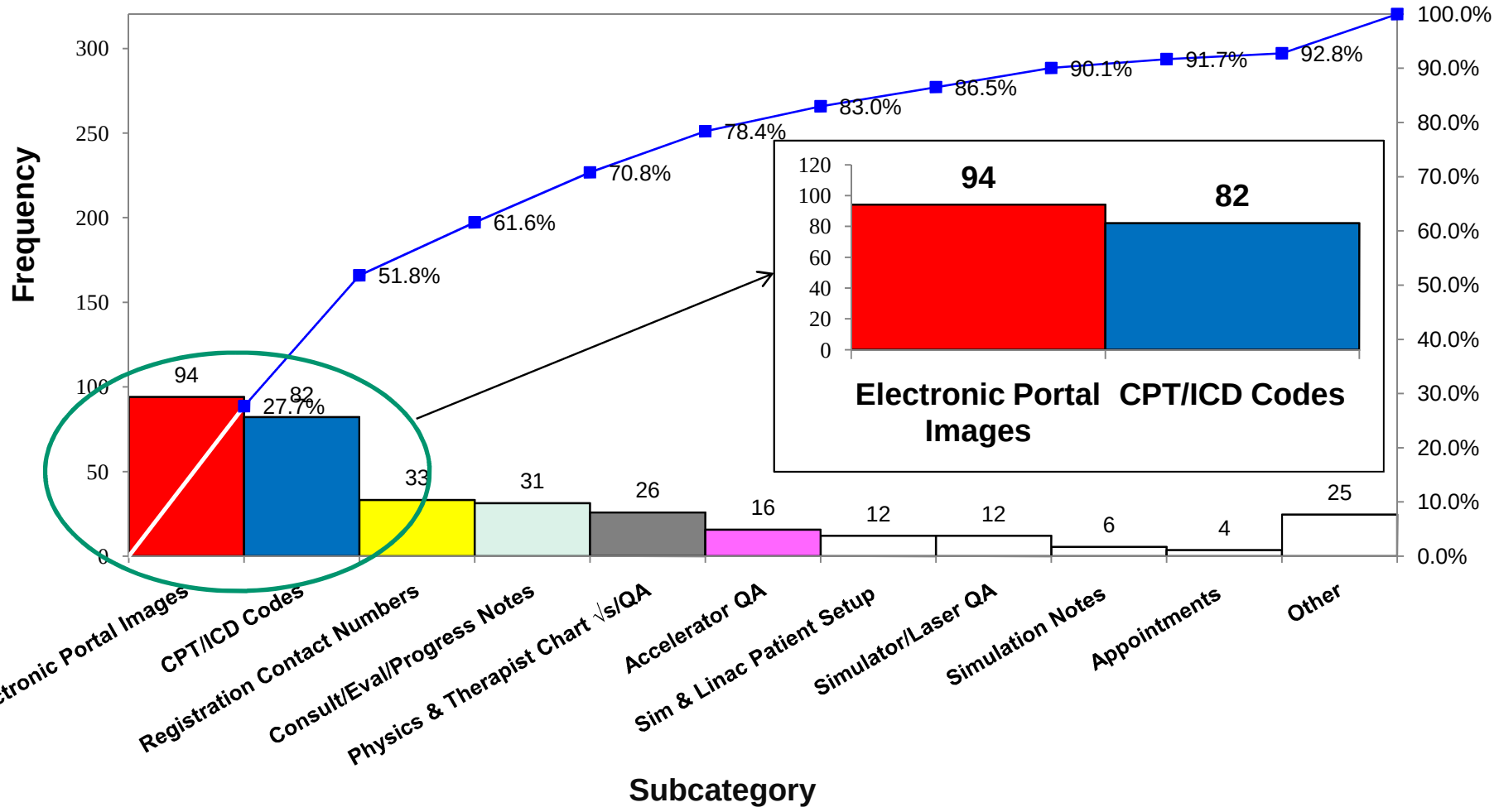


[75]Data for Centers A & B was annualized for errors identified 9/09 to 9/10 and 2/06 to 3/08, respectively.


Frequency of All Errors - Center A
Frequency
80
70
60
50
40
30
20
10
0
Sep-09
Oct-09
Nov-09
Dec-09
Jan-10
Feb-10
Mar-10
Apr-10
May-10
Jun-10
Jul-10
Aug-10
Sep-10
Months
• New center startup process & MERP learning curve
• High vol. of patients
• Performance issues w/ prior physicist & CT sim therapist
• Missed/incorr. billing
• Increased onsite 3rd party support
• MERP action plans implemented & QIC meeting tasks compl.
• New physicist-Improv. support/tasks
• Billing manual/trging
• MERP Audits-Prior wkly physics chart checks & QA missed
• RO left - images not timely approved
• 9 locum ROs – Docs missing/late: OTV, notes, consults
• 9 locum ROs - image cks, consult & sim notes missed, RO check lists/trging started
• New RO started, locums stopped
• Onsite training
• Improved dyn. docs process for notes, consults
• CBCT/kV imager malfunctioning
• Patient reg. - emergency nos. missing
• CBCT/kV imager fixed-images appr.
• Reg. & CT sim procedure drafted
• Retraining at reg. office &CT sim

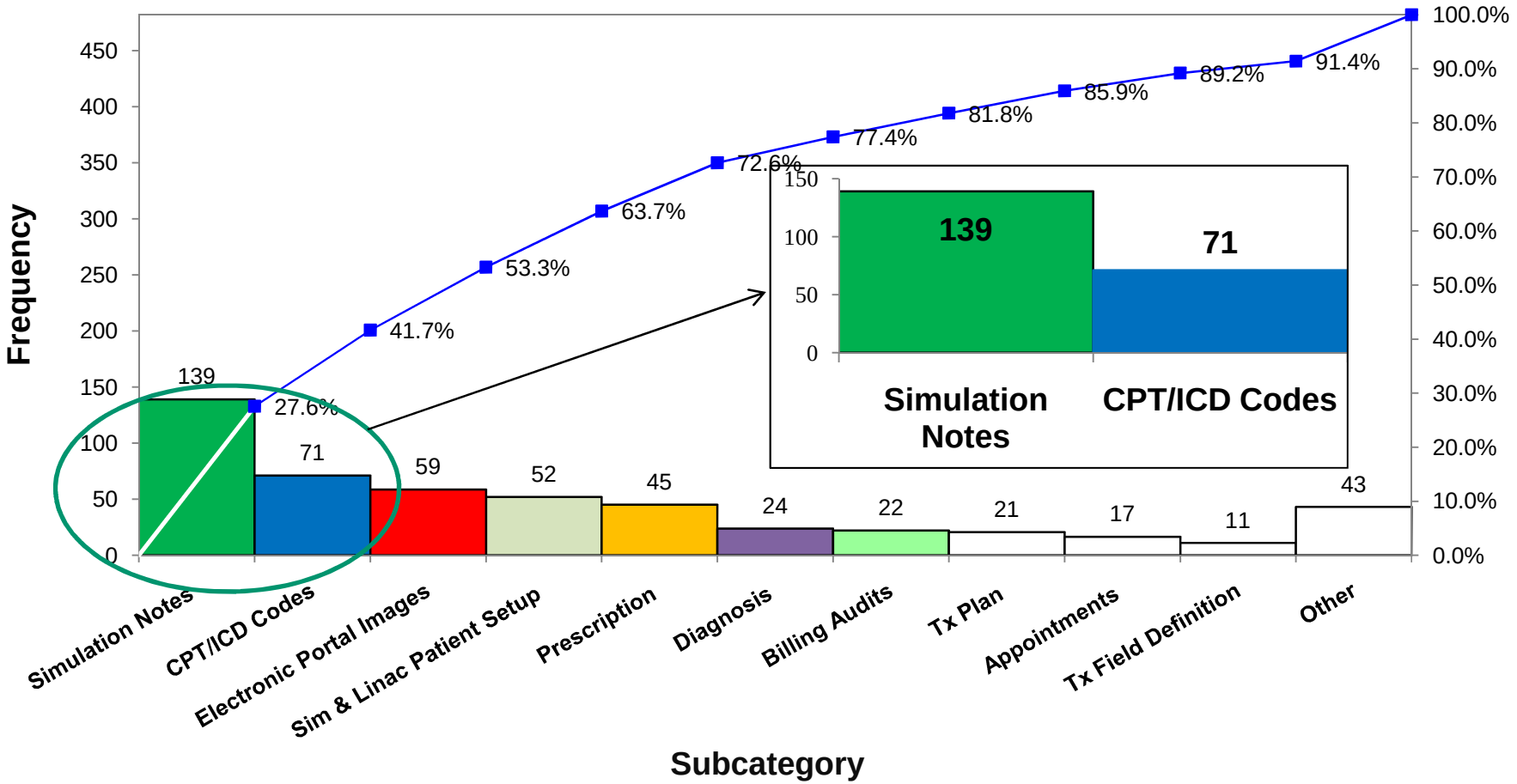

Frequency of All Errors - Center B
Frequency
200
180
160
140
120
100
80
60
40
20
0
Feb-06
Apr-06
Jun-06
Aug-06
Oct-06
Dec-06
Feb-07
Apr-07
Jun-07
Aug-07
Oct-07
Dec-07
Feb-08
Months
• Started new SRS and HDR programs
• Increased patient load
• Learning curve of MERP startup
• Identification of errors & violations
• Improved process, & action plans implemented
• Training & procedures for SRS
• Assigned HDR ownership & physics schedule
• ROs failing to complete consult/sim/Tx notes timely
• Billing Mistakes
• Penalty for RO report timeliness implemented
• Billing training
• 2 new RO centers built, startup
• Physics /staff stretched
• QA missed, billing, clinical mistakes
• More physics, therapists & staff hired
• Improved process thru procedures & training

Frequency & Cumulative % of Errors per Subcategory
Center A[76]



[76]Data was annualized for all errors (pre-Tx and post-Tx) collected 9/09 to 9/10.

Frequency & Cumulative % of Errors per Subcategory
Center B[77]



[77]Data was annualized for all errors (pre-Tx and post-Tx) collected 2/06 to 3/08.

MERP Results

Error Rates in Entire Treatment Process Using MERP[78]

Error Category	Pre-Tx		Post-Tx		Pre-Tx + Post Tx	
	Center A	Center B	Center A	Center B	Center A	Center B
	115 errors	145 errors	225 errors	362 errors	340 errors	477 errors
Per Patient, %	37.20	10.10	72.80	25.40	81.80	27.33
Per Fraction, %	1.10	0.34	2.10	0.85	2.40	0.92
Per Field, %	0.14	0.004	0.28	0.01	0.31	0.01

[78]Data for Centers A and B was annualized for all pre-Tx and post-Tx errors (all aspects of the treatment process from registration to completion of treatment) identified from 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Error Rates in Treatment Delivery[79, 80]

Error Category	This Work MERP Center A	This Work MERP Center B	Kline et al.	Frass et al.	French	Huang et al.	Marks et al.	Macklis et al.	Patton et al.	Margalit et al.
Per Patient, %	0.32	3.20				1.97	1.2 - 4.7			
Per Fraction, %	0.01	0.11		0.44	0.32	0.29	0.5			
Per Field, %	0.001	0.001		0.13	0.037			0.18	0.17	0.064
Overall Per Field, %	0.28 [a]	0.009 [a]	0.05 [a]		0.13 [b]					

[79]Treatment delivery means the administration of radiation.

[80]Data for Centers A and B was annualized for post-Tx errors in the treatment delivery process identified from 9/09 to 9/10 and 2/06 to 3/08, respectively.

[a] Errors per field in the entire post-Tx delivery process (from initial patient consultation to completion of Tx).

[b] Errors per total Tx units.

MERP Results

QA & Radiation Safety Failures[81, 82]		
Error Category	**Center A**	**Center B**
Per Patient, %	18.8	0.78
Per Fraction, %	0.55	0.026
Per Field, %	0.072	0.0003

[81]Failures are non-patient related and include regulatory infractions.

[82]Data for Centers A and B was annualized for all data collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Misadministration Rates[83]										
Error Category	**Kline et al.**		**This Work MERP Center A**		**This Work MERP Center B**		**US NRC[84]**		**US NRC + Agreement States[85]**
Per Patient, %			0		0.065				
Per Fraction, %	0.017		0		0.002		0.004		0.002
Per Field, %			0		0.00002				

[83]Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively. US NRC data was also annualized.

[84, 85]Institute of Medicine (IOM). *Radiation in Medicine: A Need for Regulatory Reform*.1996.

MERP Results

Clinically Significant Errors[86, 87]		
	Post-Tx	
Error Category	**Center A** 0 errors	**Center B** 7 errors
Per Patient, %	0	0.45
Per Fraction, %	0	0.02
Per Field, %	0	0.00002

[86]*Clinically Significant* dose trigger levels: single fx (non-SRS) - 10%, weekly difference - 15%.

[87]Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Likelihood of Occurrence - Infractions of Federal/State Regulations per Patient[88]		
Category	**Center A** 309 patients	**Center B** 659 patients
Billing, %	26.54 [a]	5.1 [b]
QA, %	2.59	0.19
Radiation Safety, %	1.62	0.23

[88]Data for Centers A and B was annualized for all data collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

[a]Approximately 80% of the infractions were caught/corrected at time of charge capture and before exporting to CMS or insurance company.

[b]Approximately 50% of the infractions were caught/corrected at time of charge capture and before exporting to CMS or insurance company.

MERP Results

Errors in Tx Delivery Process[89, 90]		
Error Category	**Post-Tx**	
	Center A 62 errors	**Center B** 120 errors
Per Patient, %	20.10	18.20
Per Fraction, %	0.58	0.61
Per Field, %	0.077	0.007

[89]Includes post-Tx errors in Tx delivery process except Registration, Patient/Docs/Notes, Scheduling, Billing, Radiation Safety, and QA.

[90]Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

Near Misses[91]		
Error Category	**Post-Tx**	
	Center A 2 misses	**Center B** 4 misses
Per Patient, %	0.65	0.607
Per Fraction, %	0.019	0.020
Per Field, %	0.003	0.0002

[91]Data for Centers A and B was annualized for all post-Tx errors collected 9/09 to 9/10 and 2/06 to 3/08, respectively.

MERP Results

- A total of 1,460 (438 pre-Tx and 1,022 post-Tx) errors were identified at both centers
- Centers A and B experienced 0 vs. 2 medical events and 2 vs. 4 near misses, respectively.
- Center B had 7 clinically significant errors, defined as a single fraction dose difference of > than 10% and weekly dose > than15%.

Lessons Learned With MERP Software Model

- **Upfront Homework**
  - History of error reduction important
  - Why must we embrace to be competitive
  - Philosophy of “goodness”
  - Non-punitive actions will be watched by staff
  - Incentives to encourage reporting a must
- **Practical Implementation**
  - Rewards system must be established
  - Superusers serve as point guards
  - Phased in approach minimizes overload
  - Initial paper recording of UDs prevents corrupt/inaccurate data entry
  - Brief weekly group meetings serve as bulletin board for errors
  - Individuals must be assigned responsibility for drafting procedures required by corrective action plans
  - Track closure of corrective action plans
  - Present overall results at quarterly QIC meetings

Conclusion

- The paper-based model was effective at minimizing errors but proved to be cumbersome and inefficient in practice.
- A software-based error reduction program (**MERP**) was developed.
- **MERP** proved efficient at identifying and correcting errors.
- Overall quality and regulatory compliance improved while reducing costs.