Two Models of Medical Error Reduction Programs in Radiation Oncology

by

Ed Kline

RadPhysics Services LLC

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]
- In radiation oncology, variety of injuries and errors can occur in the diagnostic imaging or therapeutic treatment delivery processes

[1] Hurtado 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, Arons 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.

Introduction

- This presentation describes the design, implementation, and results of two QA/medical error reduction programs
- Both programs are designed for
  - Reducing preventable systems-related medical errors (i.e., sentinel events, “near misses”)
  - Preventing violations of regulatory requirements (i.e., State/NRC)
  - Ensuring compliance with recommended standards (i.e., JCAHO, ACR, ACRO, etc.)

History

- Institute of Medicine (IOM) report[5]
  - 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.

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

History

- IOM Costs[6]
  - 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

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

History

- Federal initiatives[7] taken by former President Clinton on 2/22/00 based on IOM recommendations[8]
  - Comprehensive strategy for health providers to reduce medical errors
  - Creation of external reporting systems to identify and learn from errors so as to prevent future occurrences
  - Creation of national patient safety center to set goals
  - At least 50% reduction of errors over 5 years

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

[8] 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

- Key legislation
  - Patient Safety Quality Improvement Act[9]
    - Certifies patient safety organizations in each State to collect data and report on medical errors
  - State Patient Safety Centers
    - In past 5 years, 6 states have enacted legislation supporting creation of state patient safety centers
    - 5 of the 6 states now operate patient safety centers
    - Separate mandatory reporting systems for serious adverse events
    - Centers are housed within state regulatory agencies

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

History

- Patient safety centers include[10]
  - The Florida Patient Safety Corporation
  - The Maryland Patient Safety Center
  - The Betsy Lehman Center for Patient Safety and Medical Error Reduction (Massachusetts)
  - The New York Center for Patient Safety
  - The Oregon Patient Safety Commission
  - The Pennsylvania Patient Safety Authority

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

History

- State reporting: mandatory vs voluntary[11]
  - **Mandatory reporting:** Colorado, Florida, Kansas, Nebraska, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington
  - **Voluntary reporting:** District of Columbia, Georgia, New Mexico, North Carolina, Oregon, Wyoming
  - **Considering new legislation:** Arizona, California, Maine
  - **Mandatory reporting but considering new legislation:** Massachusetts, New Jersey

[11] *National Conference of State Legislatures*, National Academy for State Health Policy, 12/03, Accessed through www.nashp.org.

History

- JCAHO revises standards
  - 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[12]

[12] *Patient Safety - Essentials for Health Care*, 2nd edition, Joint Commission on Accreditation of Healthcare Organizations. Oakbrooke Terrace, IL: Department of Publications, 2004.

History

- JCAHO's sentinel event policy[13]
  - Implemented in 1996
  - Identify sentinel events
  - Take action to prevent their recurrence
  - Complete a thorough and credible root cause analysis
  - Implement improvements to reduce risk
  - Monitor the effectiveness of those improvements
  - Root cause analysis must focus on process and system factors
  - Improvements must include documentation of a risk-reduction strategy and internal corrective action plan
  - Action plan must include measurements of the effectiveness of process and system improvements to reduce risk

[13] *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

- JCAHO's Office of Quality Monitoring
  - Receives, evaluates and tracks complaints and reports of concerns about health care organizations relating to quality of care issues
  - Conducts unannounced on-site evaluations
- JCAHO and CMS agreement[14]
  - Effective 9/16/04
  - Working together to align Hospital Quality Measures (JC's ORYX Core Measures and CMS'7th Scope of Work Quality of Core Measures)

[14] *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

- CMS quality incentives[15]
  - Quality Improvement Organizations (QIOs)
    - Contracted by CMS to operate in every State
    - 67% of QIOs perform independent quality audits
  - Premier Hospital Quality Initiative
    - 3-year demonstration project recognizes and provides financial reward
    - CMS partnership with Premier Inc., nationwide purchasing alliance
    - Hospitals in top 20% of quality for specific diagnosis get financial reward
      - Top decile gets 2% Diagnosis Related Group (DRG) bonus
      - 2nd decile get 1% DRG bonus
    - Hospitals performing below 9th and 10th decile baseline levels, DRG payments reduced 1% and 2%, respectively

[15] *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

- CMS quality incentives
  - CMS consumer website
    - Beginning in 4/05, hospital quality data available at www.HospitalCompare.hhs.gov or 1-800-MEDICARE
  - Data indicators[16]
    - In 2006, hospitals reporting quality data to Medicare receive 3.7% increase in inpatient payments
    - Non-reporters receive 3.3% increase
    - Data covers 10 quality indicators for cardiology
    - Plans are to expand into other disciplines

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

History

- CMS quality incentives
  - Physician Voluntary Reporting Program[17]
    - Beginning in 1/06
    - 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

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

Radiation Oncology Errors

- Not well established
- No comprehensive numbers available for number of errors resulting in death[18]
- Reported error rates range 0.1% to 0.2% of fields treated[17]
- Studies not relying on self-reporting show actual rates of up to 3%[17]

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

Significant Medical Events in Radiation Oncology

Incidents	Author	Time Interval	Event	Total Patients	Outcome	Direct Causes
Panama	Vatnisky S, et al., Radiother Oncol., 2001	2001	Overdose	23	**8 - Deaths** **15 - Severe late complications**	Incorrect entry of shielding blocks in Tx planning computer
UK	McKenzie AL, British Institute of Radiology, 1996	1988	Overdose (+25%)	207		Teletherapy activity calculation error
UK	McKenzie AL, British Institute of Radiology, 1996	1982-1991	Underdose (-25%)	1,045		Misunderstanding of algorithm in Tx planning computer
World Wide	IAEA, 2000		Overdose (up to 166%)	50	**Several - deaths or serious injury**	Miscalibration of dosimeters; incorrect calc techniques, calibration of Tx machines, and use of Tx machines
US	Ricks CR, REAC/TS Radiation Incident Registry, 1999	1944-1999	Overdose		**13 - Deaths** **(OH - 10, PA - 1, TX - 2)** **1 – Serious Injury (WA)**	Incorrect calibrations, incorrect computer programming, equipment maintenance/repair negligence

Medical Error Rates in Radiation Oncology – Table 1

Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx	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 error 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
	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

Medical Error Rates in Radiation Oncology – Table 2

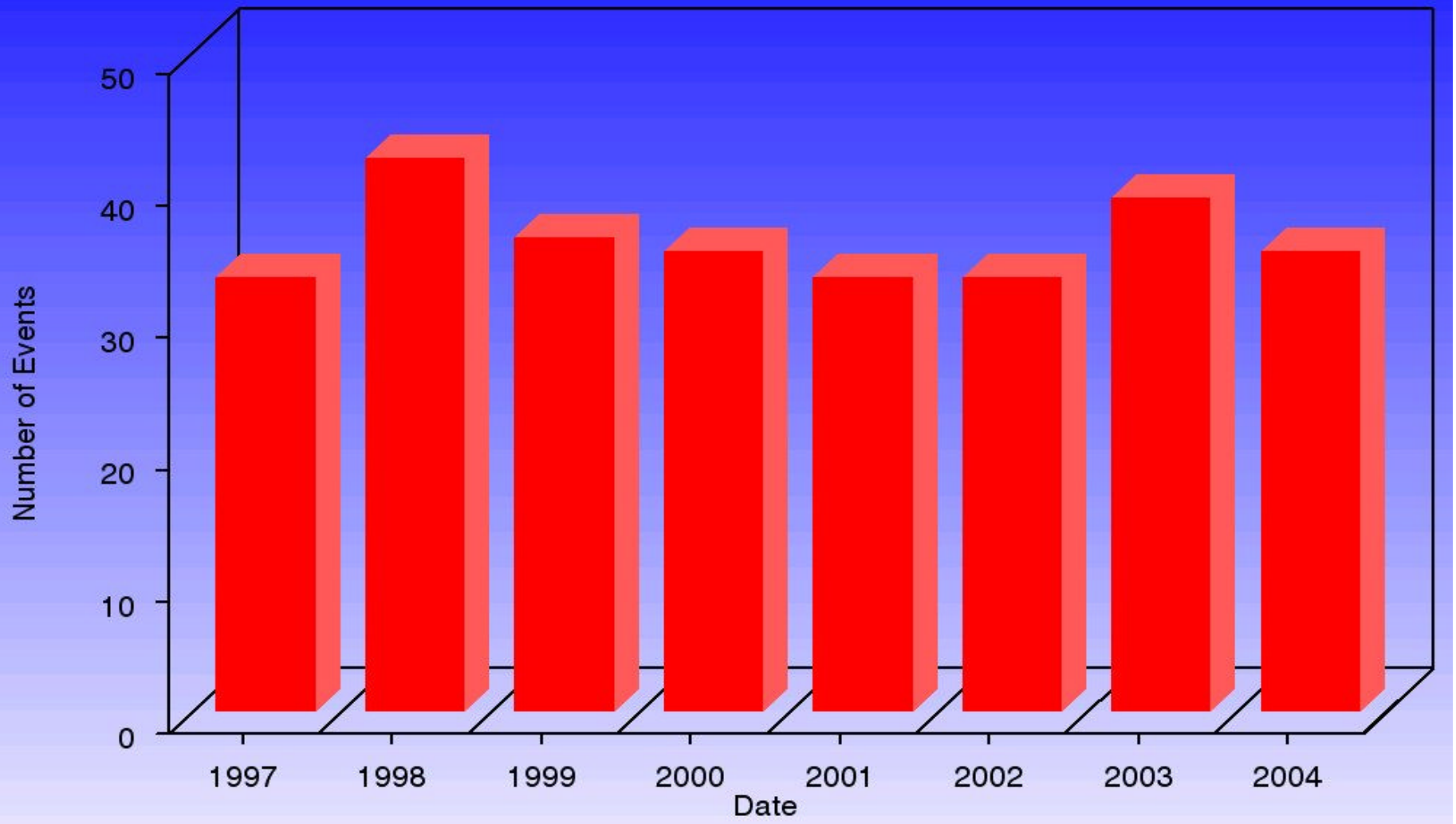
Study	Author	Time Interval	Crse of Tx	Total Tx Fx's	Total Tx Fields	Tx Field Errors	Error Specifics	Error Rate
	Noel A, et al., Radiother Oncol, 1995	5 years					Of 7519 treatments: 79 total errors - Of 79, 78 are human origin - Of 78, 39 would have > 10% dose Δ	1.05%: errors per treatment
US	Kartha 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%: reported error rate/year
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						3.22%: of all delivered Tx fields had at least 1 error
Canada	Yeung TK, Abstract-NEORCC, 1996	1994						3.3%

Medical Error Rates in Radiation Oncology – Table 3

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 clinically sig. - 28: noncorrectable and potentially clinically sig.	**0.13%: overall (fields tx'ed incorrect/ total no. fields tx'ed)** **0.32%: errors/fraction** **0.037%: errors/field**
Canada	Grace H, et al., Int J Radiat Oncol Biol Phys	1/1/97-12/31/02	28,136				555 total errors - 87 (15.6%): incorrect programming in R&V	**1.97%: error rate per patient**
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**

NRC Reported Medical Events

(10 CFR Part 35)



Objective of a "QA/Medical Error Reduction Program"

Objective was to provide a unified, total quality management and continuous improvement program for minimizing the occurrence of errors identified in the patient treatment process and regulatory arena. The program was designed for 17 geographically dispersed radiation oncology clinics located in 9 states of varying regulatory oversight and enforcement philosophy.

Design of QA/Medical Error Reduction Program

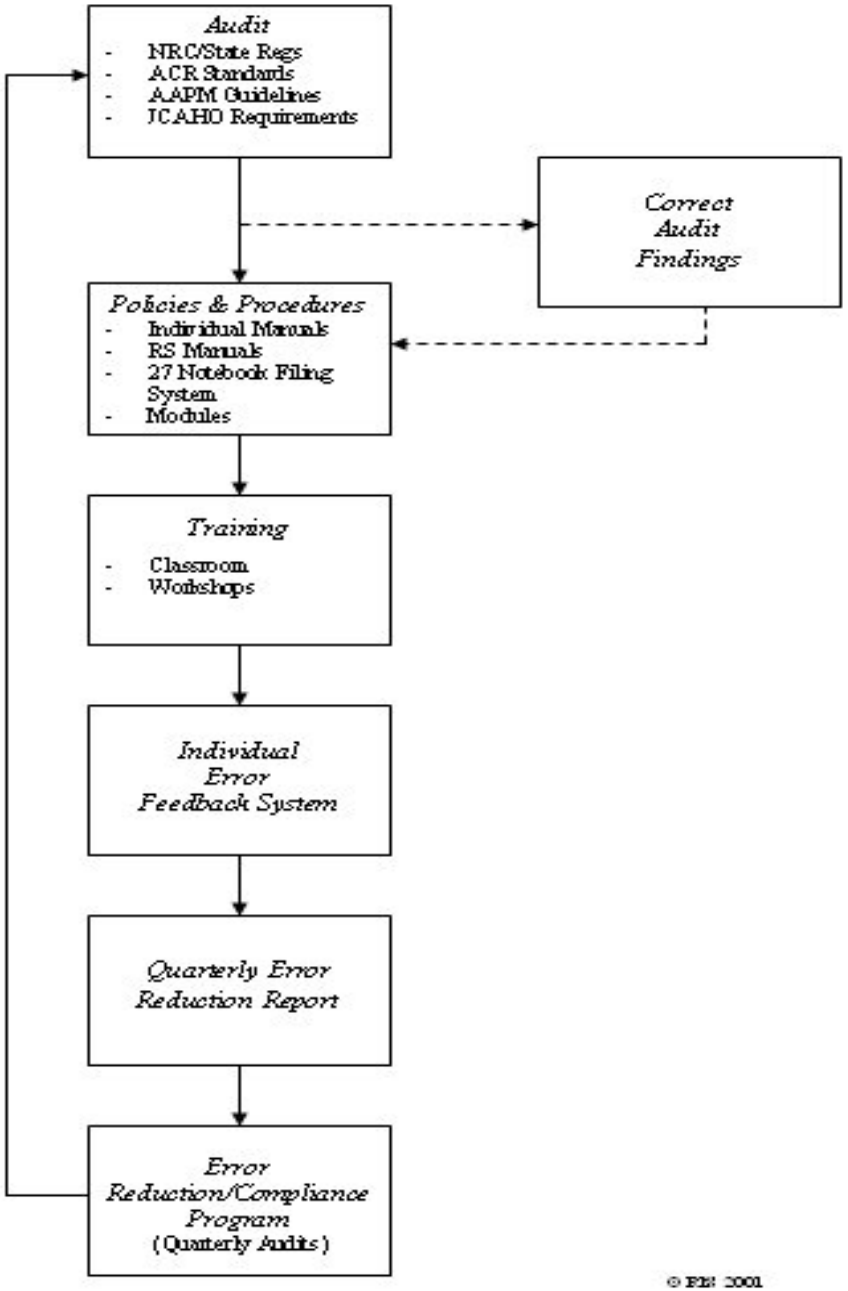
- Established a consistent set of of QA procedures for the 17 facilities following the strictest state requirements in which each facility resides.
- Analyzed the process of delivering radiation therapy to identify the steps used in all aspects of this modality.
- Developed a reporting codification system 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 QA/Medical Error Reduction Program

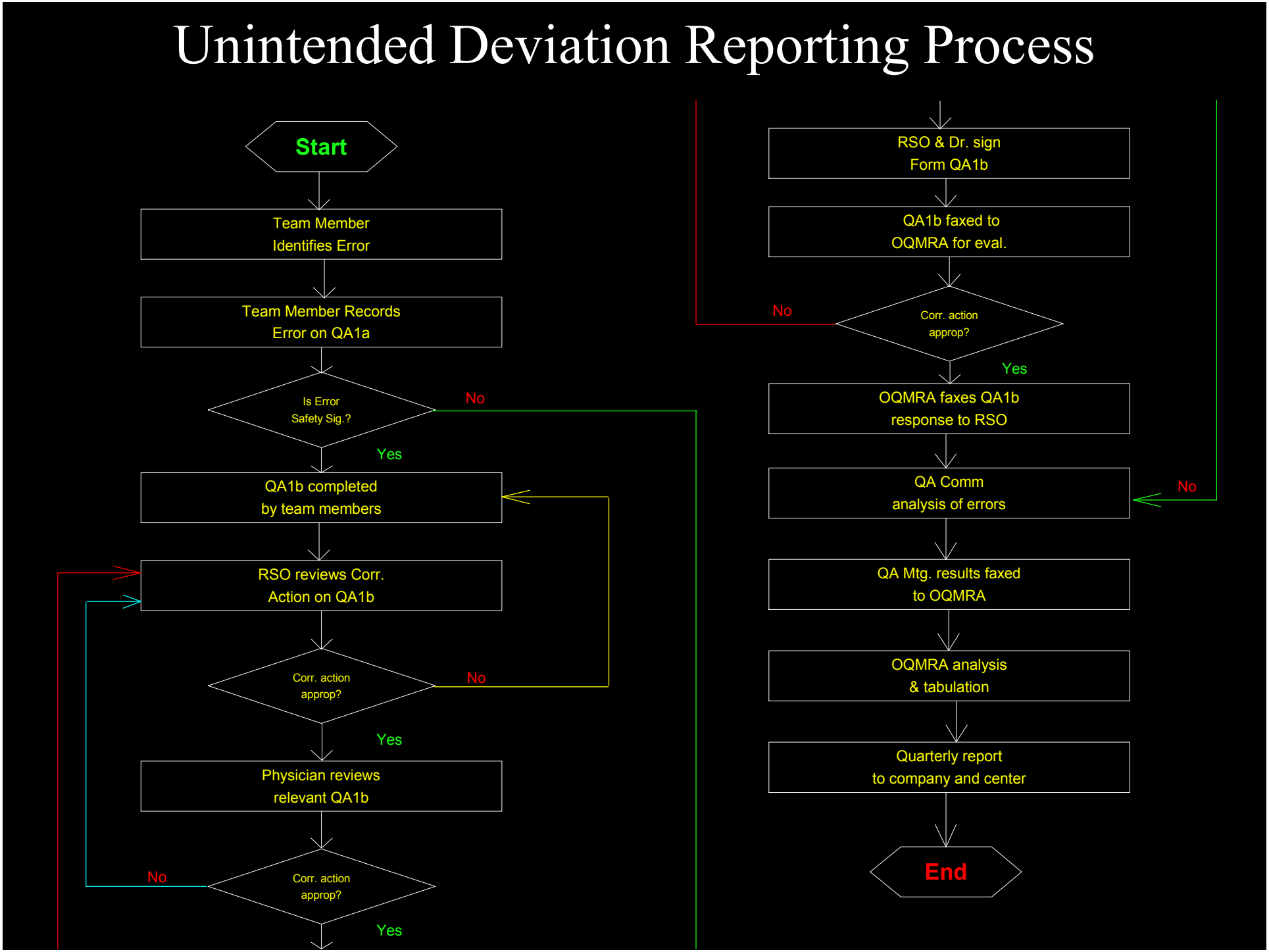
- Provided an internal feed-back mechanism of corrective action to close the loop
  - Independent review/recommendations for corrective action regarding all self-identified significant errors/violations
- Produced a quarterly report summarizing errors/violations
  - Perform trend analysis of reported 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

- The 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 recording 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

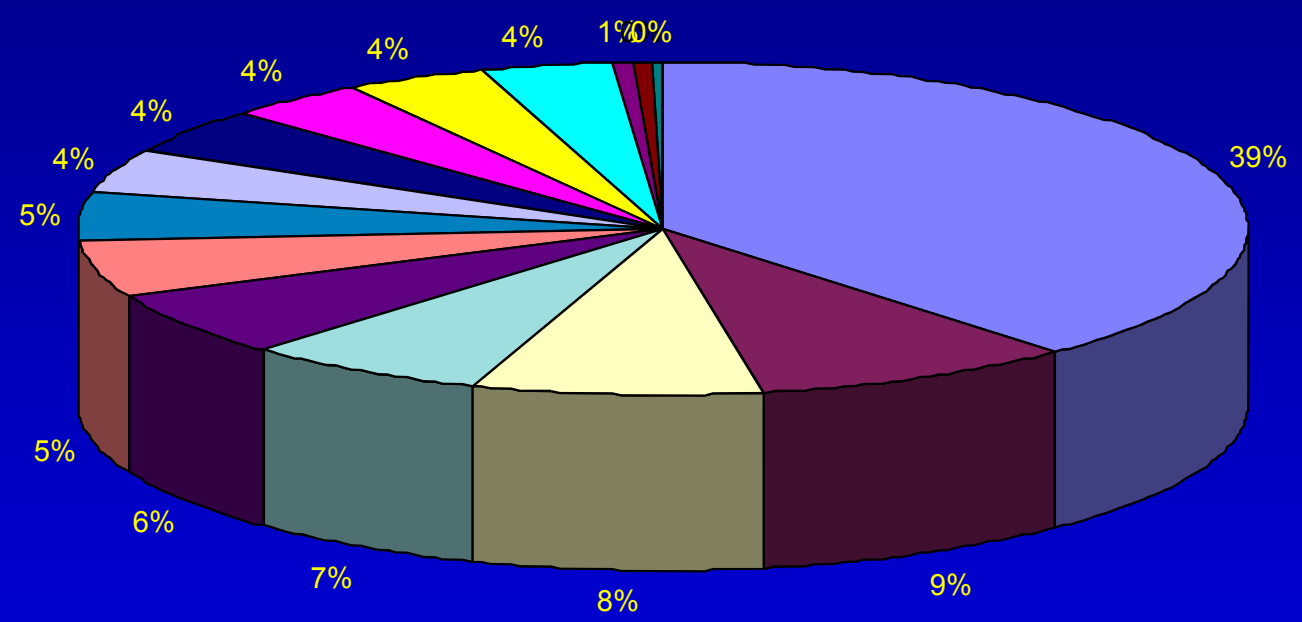
Monitored Category	Frequency By Category	Frequency By Significance Level					Frequency By Key Processes ?	
		1	2	3	4	5	Yes	No
Tx Planning								
R & V - Prescription								
R & V - Tx Field Definition								
Sim - Patient Setup								
Sim - Films								
Block Fabrication								
Dose Calc - Hand								
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 Activity	Total	Total	Total	Total	Total	Total	Total

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

QAId

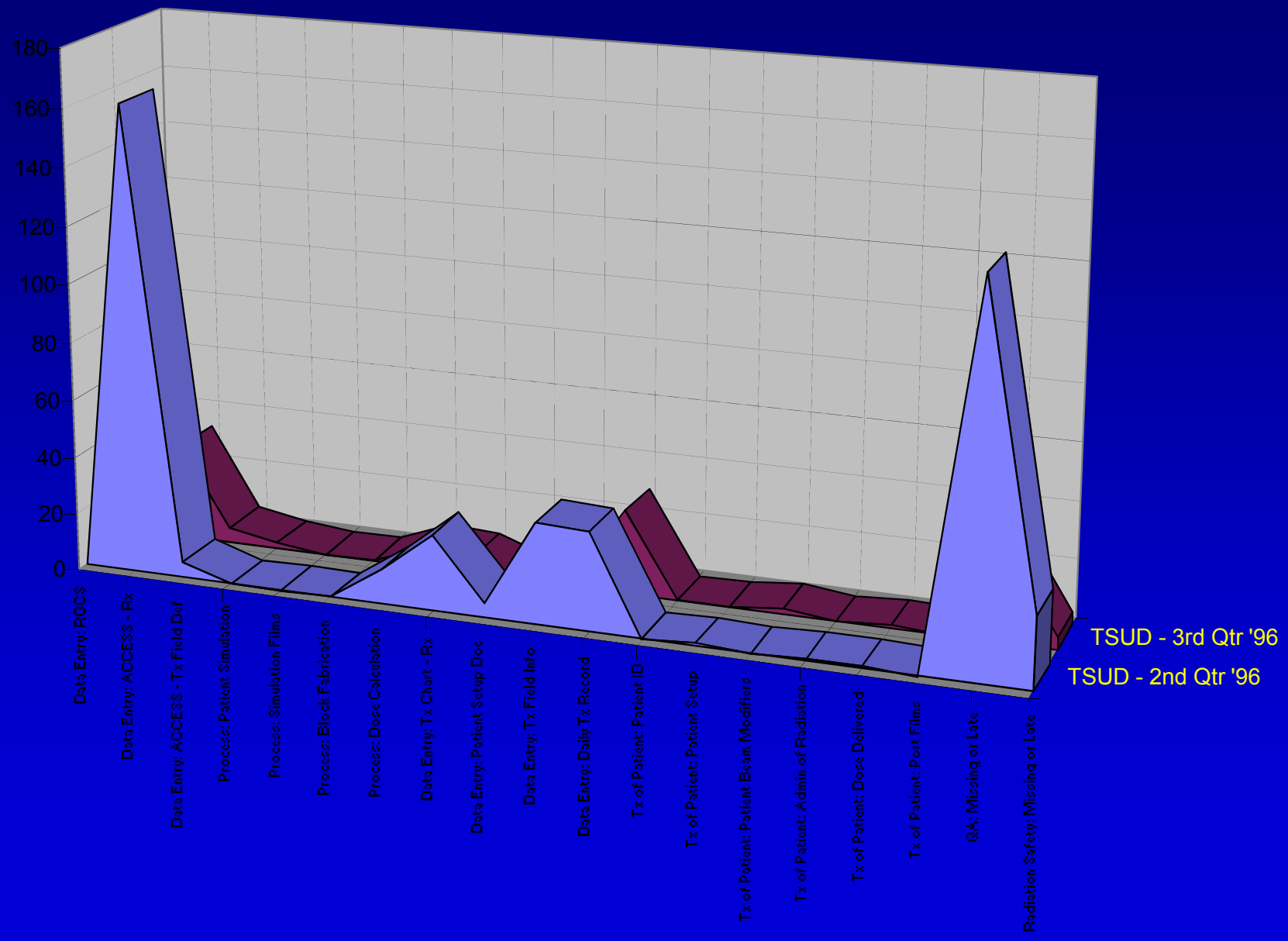
Unintended Deviations	TMUD - 2nd Qtr '96	TSUD - 2nd Qtr '96	Total - 2nd Qtr '96	TMUD - 3rd Qtr '96	TSUD - 3rd Qtr '96	Total - 3rd Qtr '96
Data Entry: RTOS	0	0	0	0	0	0
Data Entry: ACCESS - Rx	0	162	162	0	33	32
Data Entry: ACCESS - Tx Field Def	25	5	30	19	5	23
Process: Patient Simulation	59	0	59	22	2	23
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

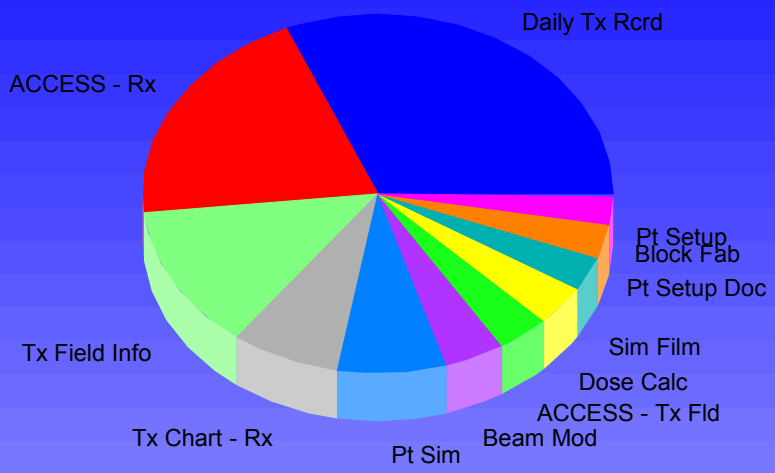


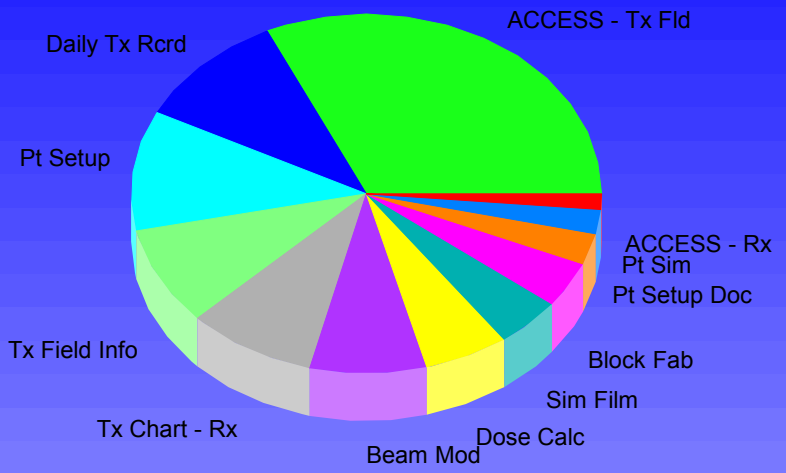
- Data Entry: Daily Tx Record
- Process: Simulation Films
- Process: Patient Simulation
- Data Entry: ACCESS - Tx Field Def
- Tx of Patient: Port Films
- Data Entry: Tx Chart - Rx
- Data Entry: Tx Field Info
- Process: Block Fabrication
- Tx of Patient: Patient Beam Modifiers
- Process: Dose Calculation
- 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



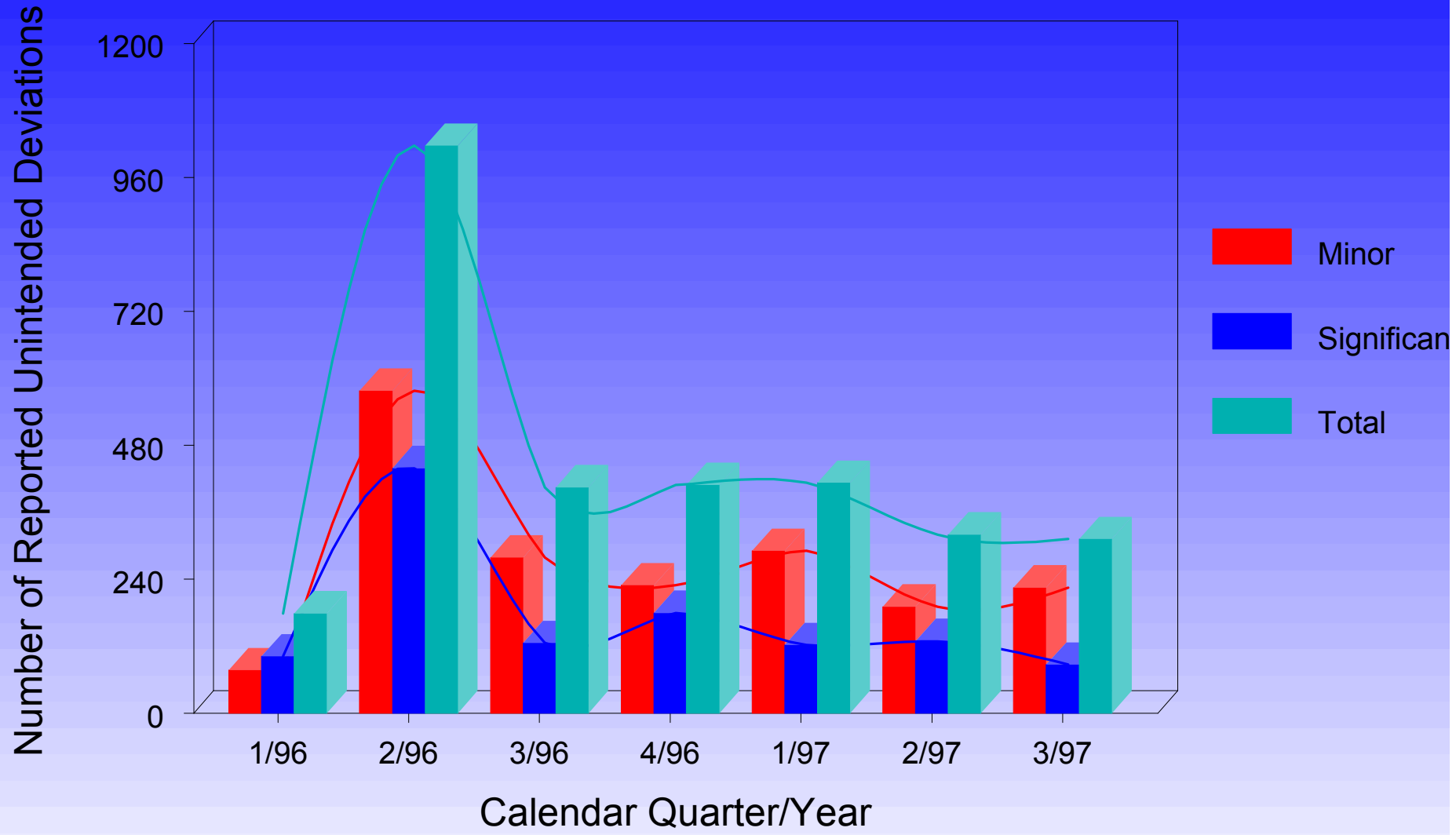
Total Unintended Deviations versus Time





Parameter	2nd Quarter '96	2nd Quarter '97	% Change	Parameter	2nd Quarter '96	2nd Quarter '97
Data Entry: ROCS	0	0	0	Data Entry: Daily Tx Rcd	250	125
Data Entry: ACCESS - Rx	162	9	-1800	Tx of Pt: Pt ID	0	0
Data Entry: ACCESS-Tx Field Def	30	45	+150	Tx of Pt: Pt Setup	2	1
Process: Pt Sim	59	6	-983	Tx Pt: Pt Beam Mod	32	12
Process: Sim Films	24	5	-480	Tx Pt: Admin of Rad	3	0
Process: Block Fab	20	4	-500	Tx of Pt: Dose Deliv	1	0
Process: Dose Calc	29	8	-363	Tx of Pt: Port Films	23	3
Data Entry: Tx Chart-Rx	60	25	-240	QA: Missing/Late	166	24
Data Entry: Pt Setup Doc	23	3	-768	RS: Missing/Late	28	6
Data Entry: Tx Field Info	105	44	-239			

Summary of Total Unintended Deviations



Reported Misadministration Rate In Radiation Oncology

- Published rates[19] for *reported* misadministrations in therapeutic radiation oncology is 0.004 percent (4/100,000 administrations) based upon 20 treatments/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.

[19] 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 treatments).
- 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 treatments).[20]
- 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%.

[20] 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

- 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

- 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[21] was 0.018%
- Actual misadministration rate was 0.017%
- NRC misadministration rate was 0.04% (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

[21] Misadministration criteria based on definitions found in NRC 10CFR35.2, rev. 1996.

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 With 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

Design of Software-Based Model

- What is needed?
  - Automated tracking of errors
  - Non-intrusive data gathering
  - Preset standardized gathering
  - 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 Features

- **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)
  - Designation of clinical significance
  - Designation of significant unintended deviation
  - "Near Miss" categorization
  - Sentinel events (internal and JCAHO reportable)
  - Instant analysis of patterns and trends
- **Identification and Tacking of *Violations***
  - Preset standardized unintended deviation codes
  - Assignment of severity levels (I - V)
  - Recordable events
  - Misadministrations (medical events)
  - Regulatory violations
  - Possible regulatory violations
  - Instant analysis of patterns and trends

Design of Software-Based Model

MERP Program Features

- **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
- **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 Features

- **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**
  - Use MERP to inspect regulatory performance
    - Complies with State radiation safety requirement for annual review
    - Meets State QMP rule for annual review

Design of Software-Based Model

MERP Program Features

- **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 2005 patient safety standards show basis for question
  - ACR and ACRO standards demonstrate benchmark for measuring performance
  - CRCPD (Agreement State) recommended regulations (as of 9/04) show legal text

Conclusion

- Based on the experience gained from the clinical application of the paper-based model at over **42** centers throughout the country (**29** described in this presentation), a software-based medical error reduction program (MERP) was developed.
- MERP provides a non-intrusive and efficient means to address medical error reduction in a systematic manner. Through implementation of MERP, errors that affect patient safety and/or result in regulatory violations can be minimized and often prevented for recurring.
- The initial results from the clinical application of MERP appear very promising with clinical testing to completed by 3/06. MERP will be commercially available by 4/06.