

# Physics Billing and QA Documentation in Radiation Oncology

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# The Partnership

Medical physics, quality management, CPT billing, and the clinical physicians and staff are symbiotic partners in radiation oncology. A successful program *must* integrate these disciplines and individuals to provide the highest quality of patient care, compliance, and cost effectiveness.

# Part I

## Physics Billing Documentation

# Dosimetry

## Dosimetry Levels

- 77300 - Basic Dosimetry
- 77305 - Simple
- 77310 - Intermediate
- 77315 - Complex
- 77321 - Special Beam
- 77331 - Special Dosimetry

# 77300 - Basic Dosimetry

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## CPT Code Uses

- Central axis (CAX) depth dose
- Off-axis factor calculation
- Gap factor
- Tissue inhomogeneity factors
- Breast angle calculation
- MU calculation for electron field
- TDF (time-dose factor) calculation
- NSD (nominal standard dose) calculation

# 77300 - Basic Dosimetry

## CPT Code Documentation

- All procedures must be documented in chart
  - Physician must prescribe treatment (via written directive)
  - Special calculation forms should be used to document results
  - All associated calculations must be signed and dated
    - Physician
    - Physics

# 77305 - Simple Isodose Planning



# 77305 - Simple Isodose Planning

- Teletherapy, isodose plan (whether hand or computer generated)
  - One or two parallel opposed unmodified ports directed to a single area of interest
  - Includes irregular field isodose calculation
- Must generate computer printout or document manual calculation(s)
- Dose calculation checks must be documented

# 77305 - Simple Isodose Planning

## Additional Uses

- Dose volume histogram (DVH)
  - Must be ordered by physician
  - Must printout histogram

# 77310 - Intermediate Isodose Planning

# 77310 - Intermediate Isodose Planning

- Teletherapy, isodose plan (whether hand or computer generated)
  - Three or more treatment portals directed to a single area of interest
  - Beam shaping may be used
- Must generate computer printout or document manual calculation(s)
- Dose calculation checks must be documented

# 77315 - Complex Isodose Planning

# 77315 - Complex Isodose Planning

- Teletherapy, isodose plan (whether hand or computer generated)
  - Involves five or more ports converging on a single area of interest, rotation, or arc isodose plans
  - May include customized beam shaping, combination of photon and electron fields, and multiple dose points
    - Complex (mantle or inverted Y)
    - Tangential ports
    - Wedges
    - Compensators
    - Complex blocking
    - Rotational beams

# 77315 - Complex Isodose Planning (Cont'd.)

- Must generate computer printout or document manual calculation(s)
- Dose calculation checks must be documented

# 77321 - Special Teletherapy Port Plan

- Special teletherapy port plan, particles, hemibody, total body
  - Plan for any special beam consideration is required (electrons or heavy particles)
  - Special physician involvement
- Must generate computer printout or document manual calculation(s)
- Dose calculation checks must be documented



# 77331 - Special Dosimetry

# 77331 - Special Dosimetry

- Special dosimetry only when prescribed (via written directive)
  - Thermoluminescent dosimetry (TLD)
  - Solid state diode probes (diodes)
  - Special dosimetry probes
  - Film dosimetry
  - Direct request by physician
- Results must be documented
  - Signed and dated by physician and physicist
  - Should be maintained in chart
- Checks must be documented

# 77331 - Special Dosimetry Electron Output Calibration

- Calibration of electron cutouts requires use of a specific physics form
- Should be maintained in chart
- Physician and physics must sign and date calculations

# 77331 - Special Dosimetry

## Diodes and TLDs

- Physician must order diodes or TLDs
- Physics should utilize a document that records:
  - Actual measured dose
  - Expected dose
  - Difference between actual vs measured (%)
  - Action taken if % exceeds established tolerance
- Therapist should record TLD measurement results
  - Recommend documenting in “Comment” or “Note” section of chart on date performed
- Physician and physicist must sign

77336 - Continuing Medical  
Physics Services

# 77336 - Continuing Medical Physics Services

## Physics Weekly Chart Checks

- Must verify accurate dose calculations, data entry, patient positioning, beam orientation, patient safety, and dose summation
- Effective 1999, termed “continuing medical physics consultation”
  - Must include assessment of treatment parameters, QA of dose delivery, and review of patient treatment documentation
  - Reported each week of radiotherapy
  - Physics must document key areas reviewed at weekly chart check (via chart check list). Note: Physicist’s initials alone in chart are no longer acceptable.

# 77336 - Continuing Medical Physics Services (Cont'd.)

## Physics Weekly Chart Checks

- QA program
  - All QA related activities are considered part of the continuing medical physics consultation
    - Accelerator measurements and checks (i.e, AAPM TG40)
      - Daily, weekly, monthly annual, five years
    - Simulator measurements and checks (i.e, AAPM TG40)
      - Daily, weekly, monthly annual, five years
  - Must be documented and signed by physicist

# 77336 - Continuing Medical Physics Services (Cont'd.)

## Physics Weekly Chart Checks

- Weekly Physics Billings
  - Every five treatments
  - Number of weekly physics charges must match number of physician management charges
  - Physics cannot charge for
    - Initial chart checks
    - R & V checks
    - Chart summaries (final chart check)



**77370 - Special Medical Physics  
Consultation**

# 77370 - Special Medical Physics Consultation

- Must be ordered by physician
- Physicist must develop a special written report
- Documentation must include:
  - Physician's reason for request
  - Results (summary of calculations or written recommendations)
  - Signature of physicist and physician with dates

# Part II

## Quality Assurance

# What Must We Do Now?

- Identify your violations first:
  - State & Federal agencies give credit for self-identification of violation(s) (non-cited)
  - Mitigates enforcement action
- Ensure patient and worker safety.
- Perform audits for compliance.
- Establish solid policies and procedures with training.

# What Can We Gain?

- Protects upper management and physicians from radiation incidents resulting in regulatory enforcement action & litigation.
- Lowers liability insurance premiums:
  - Facility and/or hospital
  - Physicians and physicists
- Increases efficiency of physics, engineering, and therapists resources.

# What Can We Gain? - Cont'd.

- Reduces operating costs by minimizing “rework”:
  - Demonstrates a continuous improvement program (TQM)
  - Lowers medical costs and increases profitability
- Enhances marketability of services to the public, HMO's, managed care contracts and referring MD's.
- Minimizes occurrence of negative publicity from radiation incidents and increases community assurances.

# What Goals Should We Set?

- Establish a continuous improvement model
- Meet ACR standards for accreditation
- Participate in RTOG protocols

# What Is Coming Next?

- Federal initiatives<sup>1</sup> taken by President Clinton on 2/22/00 based on IOM recommendations<sup>2</sup>
  - Comprehensive strategy for health providers to reduce medical errors
  - Creation of national patient safety center to set goals
  - At least 50% reduction of errors over 3 years
- New HCFA regulations this year will require all hospitals participating in the Medicare program (over 6,000) to implement ongoing medical error reduction programs

<sup>1</sup> Announced by President Clinton and senior administration officials in James S. Brady Press Briefing Room on February 2, 2000.

<sup>2</sup> 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).



# What Is Coming Next? - Cont'd.

- Mandatory & voluntary reporting system
  - Currently mandatory at VA and DOD hospitals (11 million patients)
  - If states do not adopt after years, mandatory federal legislation will be introduced to require state reporting
  - Proposes that incidence of medical errors be available to general public for all hospitals:
    - Mandatory reporting criteria (death or serious harm) would become public
    - Voluntary reporting criteria (little or no harm) would be confidential and protected

# Human Errors In Medicine

- Injuries within the health care context, including those resulting from human error, are referred to as “iatrogenic”.
- Harvard Medical Practice Study reported that nearly 4% of patients hospitalized in New York in 1984 suffered an iatrogenic injury based upon random sampling technique. (Brennan *et al.*, 1991; Leape *et al.*, 1991)
  - Preventable adverse events was 58%

# Human Errors In Medicine - Cont'd.

- Harvard Medical Practice Study in New York corroborated by study of adverse events (injury caused by medical management) in Colorado and Utah in 1992 showed adverse events occurred in almost 3% of hospitalizations in each state. (Thomas, *et al.*, 2000)
  - Preventable adverse events was 53%
- Institute of Medicine of the National Academies estimates between 44,000 and 98,000 people die in hospitals each year as a result of preventable medical errors. (American Hospital Association, 1999; Thomas, Studdert, Burstin, Helen, *et al.*, 2000; Brennan, Leape, Laird, Nan, *et al.*, 1991)

# Human Errors In Medicine - Cont'd.

- Two studies of a university hospital and large teaching hospital found that 36% had an iatrogenic illness (included diagnostic and therapeutic procedures) and 46% had an adverse event, respectively. (Steel, Gertman, Crescenzi, *et al.*, 1981; Andrews, *et al.*, 1997)
- Two studies at children's teaching hospitals showed 4.5 and 4.9 errors per 1,000 medication orders, respectively. (Koren, Gideon, Haslam, 1994; and Perlstein, Callison, White, *et al.*, 1979)

# Human Errors In Medicine - Cont'd.

- Recent investigation of pharmacists in Massachusetts estimate that 2.4 million prescriptions are filled improperly each year with 88% of errors involving wrong drug or wrong strength. (Knox, 1999)
- Outpatient prescription error rates have been measured at 3.4 to 12.4 percent. (Guernsey *et al.*, 1983; Allan *et al.*, 1990)
- Estimate the mortality rate from anesthesia at 1:200,000 to 1:300,000 patients/anesthetics administered. (*Jt Comm J Qual Improv*, 1998)

# Human Errors in Medicine- Cont'd.

- The U.S. Pharmacopoeia (USP) runs a voluntary program for radiopharmaceutical users which reported 42 “problems” over a 2 year period. Other USP problem reporting programs estimate that these reports represent 10% of actual problems.
- The FDA runs a voluntary program for practitioners for reporting adverse reactions to medications. Of 235,000 reports received annually, 90% come from manufacturers and only 10% come from practitioners via MedWeb. (Brewer, Colditz, 1999)

# Reported Misadministration Rate In Radiation Oncology

- Published rates<sup>3</sup> 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.

<sup>3</sup>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.

# Reported Misadministration Rate In Radiation Oncology - Cont'd.

- The causes are characterized by<sup>4</sup>:
  - Insufficient supervision
  - Deficient procedures or failure to follow procedures
  - Inattention to detail
  - Inadequate training

<sup>4</sup> Policy Issue, SECY-93-007, *Aspects of the National Medical Use Program Related to Prevention of Medical Misadministrations*, U.S. Nuclear Regulatory Commission: Washington, DC, 1993.



# How Can We Sleep At Night?

- Take the following three steps
  - Step #1: Establish system for effective clinical, quality assurance, and regulatory processes following:
    - NRC and/or Agreement State regulations  
and
    - ACR standards and AAPM recommendations
  - Step #2: Integrate medical physics, quality assurance, radiation safety, and quality management as “one” functional unit.
  - Step #3: Provide for process of self-identification and correction of errors with emphasis on the *technical* aspects of radiation oncology.

# What Standards Are We Required To Follow?

- Musts: NRC and State regulations
  - Federal register
    - *10 CFR Parts 2, 19, 20, 21, 30, 32, 33, 35, 40, 71*
    - *49 CFR Parts 170 - 189*
  - State regulations
    - X-ray producing machines & radioactive materials
- Shoulds/Musts<sup>5</sup>: ACR Standards
  - *Physical Aspects of Quality Assurance (4/6/90)*
  - *Radiation Oncology (1/1/00)*
  - *Radiation Oncology Physics for External Beam Therapy (1/1/99)*

<sup>5</sup> Some states require registrants to have a QA program in accordance with guidelines promulgated by ACR, AAPM or another accredited organization (i.e., PA)

# What Standards Are We Required To Follow? - Cont'd.

- Shoulds/Musts: ACR Standards - Cont'd.
  - *Quality Assurance of Radiation Oncology Dose-Distribution Calculation and Implementation (1/1 99)*
  - *3-D External Beam radiation Planning and Conformal Therapy (1/1/98)*
  - *Performance of Stereotactic Radiation Therapy/Radiosurgery (1/1/98)*
  - *Performance of Brachytherapy Physics: Manually-Loaded Sources (1995)*
  - *Performance of Low-Dose-Rate Brachytherapy (1996)*
  - *Performance of High-Dose-Rate Brachytherapy (1996)*

# What Standards Are We Required To Follow? - Cont'd.

- Shoulds/Musts: ACR Standards - Cont'd.
  - *Performance of Therapy with Unsealed Radionuclide Sources (1996)*
  - *Communication: Radiation Oncology (1/1/00)*
  - *Continuing Medical Education (1996)*
- Shoulds/Musts: AAPM Recommendations
  - *Comprehensive QA for Radiation Oncology: TG 40 (April 1994)*

# NRC/State Inspections

## What Will The Inspector Review?

### Teletherapy Facility

- Inspector reviews:
  - Any open violations from previous inspection
  - Organization and scope of program
    - Structure, RSO (appointed, fulfills duties, has sufficient authority), authorized users (physicist & physician meets criteria), visiting authorized user (permission, authorized, 60-day/year limit), RS program (minor changes documented, annual review), records
  - Training, retraining, and instruction to workers
    - Instruction to workers, individual's understanding of procedures, operating/emergency procedures, retraining, supervision criteria

# NRC/State Inspections

## What Will The Inspector Review?

### Teletherapy Facility - Cont'd.

- Inspector reviews:
  - Teletherapy facilities
    - Interlocks, indicator lights, observation monitors
  - Unit operation
    - Security (key), gantry/head restrictions
  - Dosimetry system
    - Calibrated, AAPM accredited lab/intercomparison
  - Facility equipped with permanent radiation monitor
    - Visible & operational, backup, checks performed

# NRC/State Inspections

## What Will The Inspector Review?

### Teletherapy Facility - Cont'd.

- Inspector reviews - cont'd:
  - Materials
    - Isotopes, possession limits, leak tests, inventories
  - Receipt and transfer of RAM
    - Records of transfer
  - Teletherapy servicing
    - 5 years, authorized party
  - Radiation surveys
    - Appropriate/operable survey instruments, calibration documented, surveys of head & adjacent areas, complies with Part 20 dose limits

# NRC/State Inspections

## What Will The Inspector Review?

### Teletherapy Facility - Cont'd.

- Inspector reviews - cont'd:
  - Full calibration
    - TG21/51, yearly, spot-checks indicate output  $> \pm 5\%$ , source exchange, calibrated instrument
      - Output within  $\pm 3\%$  of expected for all parameters/conditions, coincidence light/radiation field, uniformity with beam angle, timer constancy & linearity, end effect, accuracy of measuring & localization devices, output corrected monthly (decay), records
  - Spot checks
    - Monthly, procedures by physicist, 15-day review by physicist (if performed by other), calibrated instrument
      - Timer constancy & linearity, end effect, coincidence light/radiation field, accuracy of all measuring & localization devices, output under set conditions (measured vs expected), interlock & safety system checks (viewing system, emergency off switches, lights, room door), records



# NRC/State Inspections

## What Will The Inspector Review?

### Teletherapy Facility - Cont'd.

- Inspector reviews - cont'd:
  - Personnel radiation protection
    - Monitors workers, NVLAP monitors approved, exchange frequency, max exposures within Part 20 limits, declared pregnant worker criteria met, ALARA program, records (exposure, surveys, monitoring, evaluations)
  - Misadministrations and recordable events
    - Evaluation of incident, reported properly, records
    - Quality Management Program reviewed (using separate inspection field notes)
  - NRC independent measurements
    - Inspector's measurements compared to licensee's results

# NRC/State Inspections

## What Will The Inspector Review?

### Teletherapy Facility - Cont'd.

- Inspector reviews - cont'd:
  - Notification and Reports
    - Compliance with: reports to individuals, public & occupational, monitored per Part 20; incidents, overexposures, high radiation levels
  - Posting and Labeling
    - “Notice to Workers”, emergency procedures, notice to where required documents maintained, other posting & labeling
  - Recordkeeping for Decommissioning
    - Records maintained at independent location with required information

# NRC/State Inspections

## What Will The Inspector Review?

### Teletherapy Facility - Cont'd.

- Inspector reviews - cont'd:
  - Bulletins and Information Notices
    - Received & appropriate action taken in response, special license conditions followed
  - Performance Evaluation Factors (PEF)
    - Lack of senior management involvement with RS program and/or RSO, RSO too busy, insufficient staffing, RCC fails to meet or functions inadequately, inadequate consulting services or inadequate audits
    - Regional follow-up on PEF citations

# ACR Accreditation

## Physics Aspects Only

- Surveyor reviews:
  - 25 patient treatment records from 5 disease sites
  - Prior NRC or State inspection results
  - QA & Improvement process and meetings (i.e., identifying treatment errors, violations)
  - Radiation safety program (i.e., personnel monitoring)
  - Documented physics QA/QC procedures (i.e., TG 40)
  - Dosimetry (i.e., dose calculation methodologies)
  - Quality management program (i.e., calculation checks)
  - Treatment planning processes (i.e., patient planning)

# ACR Accreditation

## Physics Aspects Only - Cont'd.

- Surveyor reviews - cont'd:
  - Treatment planning system QA program (i.e., commissioning/acceptance)
  - Equipment/instrumentation calibration (i.e., electrometer & chamber system)
  - Output measurements (i.e., TG 21/51 protocols)
  - Machine mechanical checks (i.e., accelerator, simulator, HDR)
  - Verification of independent TLD checks (i.e., MD Anderson)
  - Staffing levels (i.e., physics)

# The Task Before Us

## Results of a Tested “QA Compliance Model”

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 nine states of varying regulatory oversight and enforcement philosophy.

# Design of QA Compliance Model

- Established a consistent set of QA procedures for the 17 facilities consistent with 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 Compliance Model - Cont.'d

- 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



# Design of QA Compliance Model - Cont.'d

- Performed independent quarterly audits of facilities
  - Validates self-reporting of errors
  - Identifies missed violations and/or treatment process errors
- Provided training and/or procedures in areas of weakness identified in quarterly reports and audits
- Established unified *Quality Assurance /Compliance Record-Keeping System*
  - Comprised of 27 notebooks for maintaining required NRC, State, and ACR records

# Specifics of QA Program

- Quality Assurance Program
  - External beam radiation therapy equipment
  - Treatment planning computer systems
  - Clinical aspects
- Radiation Safety Program
  - Radiation Safety Committee
  - Radiation Safety Officer
  - Policies and procedures
- Quality Management Program
  - Written directives
  - Linear accelerator
  - Periodic reviews

# Specifics of QA Program - Cont.'d

- Unintended Deviation System (Error Reduction Program)
- Modules
  - Patient chart protocol
  - Diode acceptance/protocol
  - Treatment planning computer acceptance/commissioning protocol
  - Machine annual calibrations
  - HDR, prostate, SRS protocols
- Roles and Responsibilities

# 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 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:
  - A Minor Unintended Deviation (Level 3-5)
  - A Significant Unintended Deviation (Level 1-2)
    - A Recordable Event
    - A Misadministration

# A Sample of the Unintended Deviations Grid

## Unintended Deviations: Error Codes

Code	Identified	Description	Code	Identified	Description
Patient Simulation			Dose Calculation		
21300		Pt position not to specified SSD	41432		Hand Calc: Calc with bolus, bolus not rx'd
22110		Missing AP SSD	41510		Hand Calc: Wrong coll. scatter factor
22120		Missing PA SSD	41520		Hand Calc: Wrong phantom scatter factor
22130		Missing Rt lateral/medial SSD	41530		Hand Calc: Wrong inverse square factor
22140		Missing Lt lateral/medial SSD	41540		Hand Calc: Math error
22150		Missing calculation point SSD	41600		Hand Calc: Calc. using incorrect dose 
22200		Table vert. does not agree with PA SSD	42110		ROCS Calc: Incorrect energy 

# A Sample of Unintended Deviations Reporting Form

Significant Unintended Deviation <sup>1</sup>			
Dates of Occurrence: _____			
Identified By: _____			
Category	Error Code	Category	Error Code
Data Entry	1	Treatment Chart	5
Simulation	2	Treatment of Patient	6
Blocks	3	Quality Assurance	7
Dose Calculation	4	Radiation Safety	8
Description: _____ _____			
Evaluation: _____ _____			
<input type="checkbox"/> Recordable Event <input type="checkbox"/> Misadministration <input type="checkbox"/> Personnel Overexposure			
Date of Immediate Action: _____			
Immediate Action Taken (Check all that apply):			
<input type="checkbox"/> Facility RSO Signature: _____		<input type="checkbox"/> Copy faxed to OQMRA	
<input type="checkbox"/> Physician Notified (if applicable)		<input type="checkbox"/> Adjustment of treatment (if necessary)	
<input type="checkbox"/> Correction of documentation		<input type="checkbox"/> Adjustment of equipment or machine	
Other: _____			
Long-Term Corrective Action (Check all that apply):			
<input type="checkbox"/> Additional training		<input type="checkbox"/> Increased oversight or supervision	
<input type="checkbox"/> Improved procedure		<input type="checkbox"/> Other: _____	
<b>Office of Quality Management and Regulatory Affairs Use Only</b>			
Evaluation: _____ _____			
Recommendations: _____ _____			

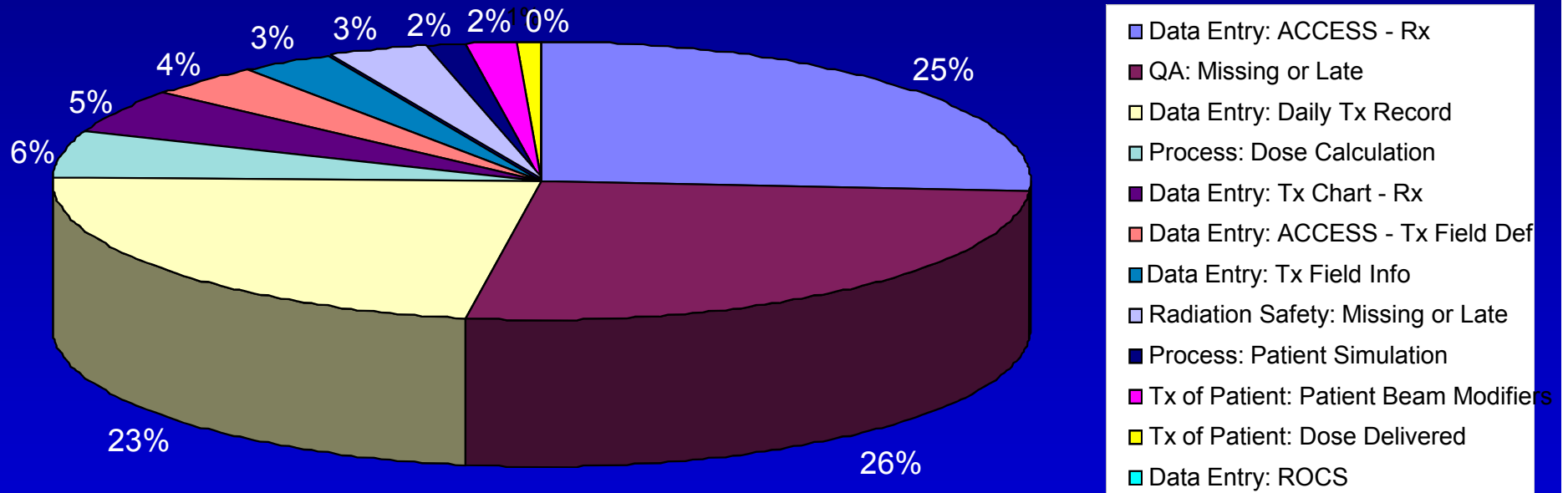
<sup>1</sup> Complies with state and federal enforcement policies regarding licensee identified violations and recording of unintended deviations pursuant to the Quality Management Program.

# A Sample of Unintended Deviations Quarterly Report

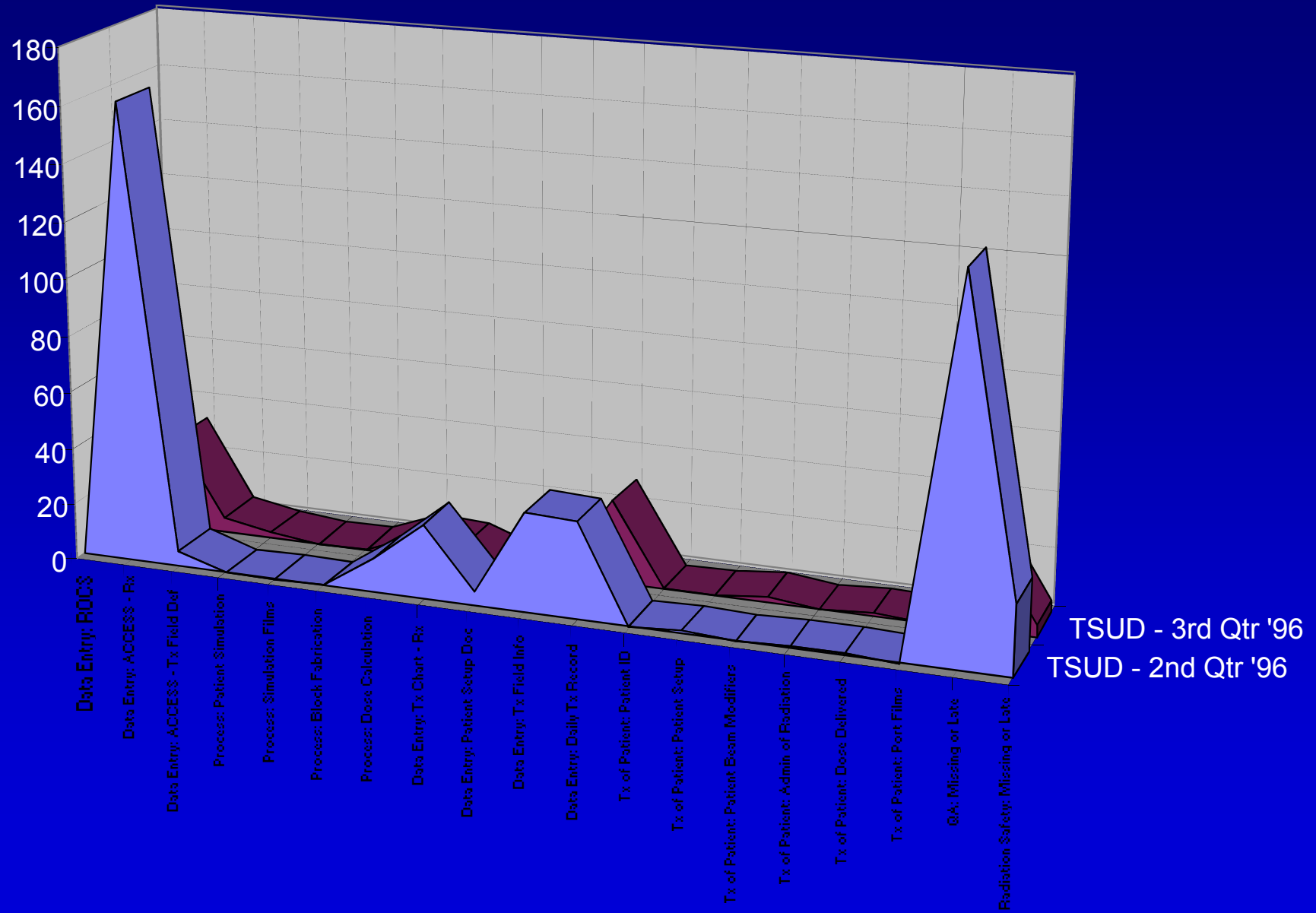
Unintended Deviations	TMUD - 2nd Qtr '96	TSUD - 2nd Qtr '96	Total - 2nd Qtr '96	TMUD - 3rd Qtr '96	TSUD - 3rd Qtr '96	Total - 3rd Qtr '96
Data Entry: ROCS	0	0	0	0	0	0
Data Entry: ACCESS - Rx	0	162	162	0	33	32
Data Entry: ACCESS - Tx Field Def	25	5	30	19	5	23
Process: Patient Simulation	59	0	59	22	2	23
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
<b>TOTAL</b>	<b>578</b>	<b>439</b>	<b>1017</b>	<b>279</b>	<b>126</b>	<b>370</b>
<b>ABSOLUTE DIFF BETWEEN QTRS</b>				<b>-299</b>	<b>-313</b>	<b>-647</b>
<b>PERCENT INCREASE/DECREASE</b>				<b>-51.7%</b>	<b>-71.3%</b>	<b>-63.6%</b>



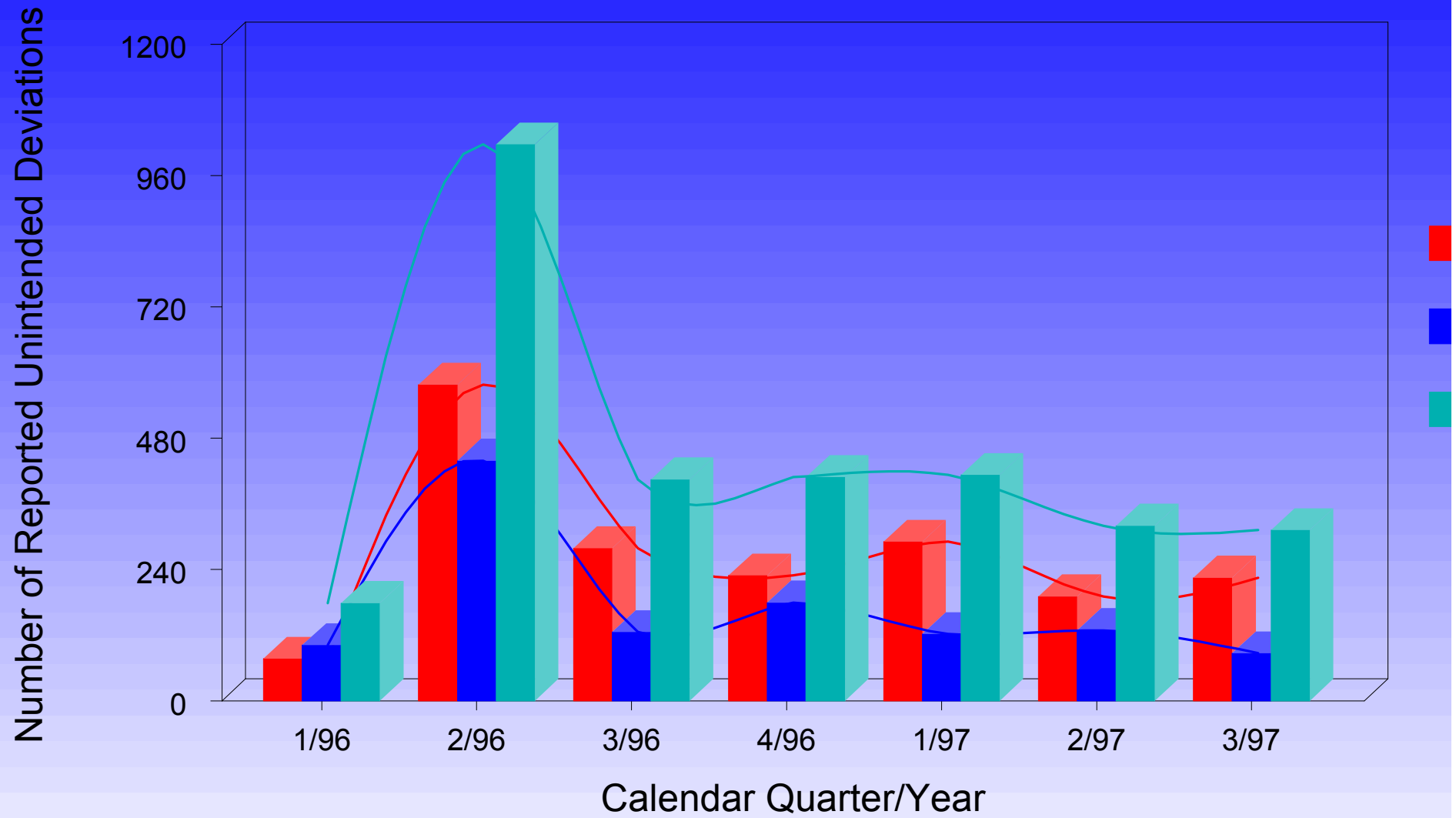
# Significant Unintended Deviations: 3rd Qtr. 1996



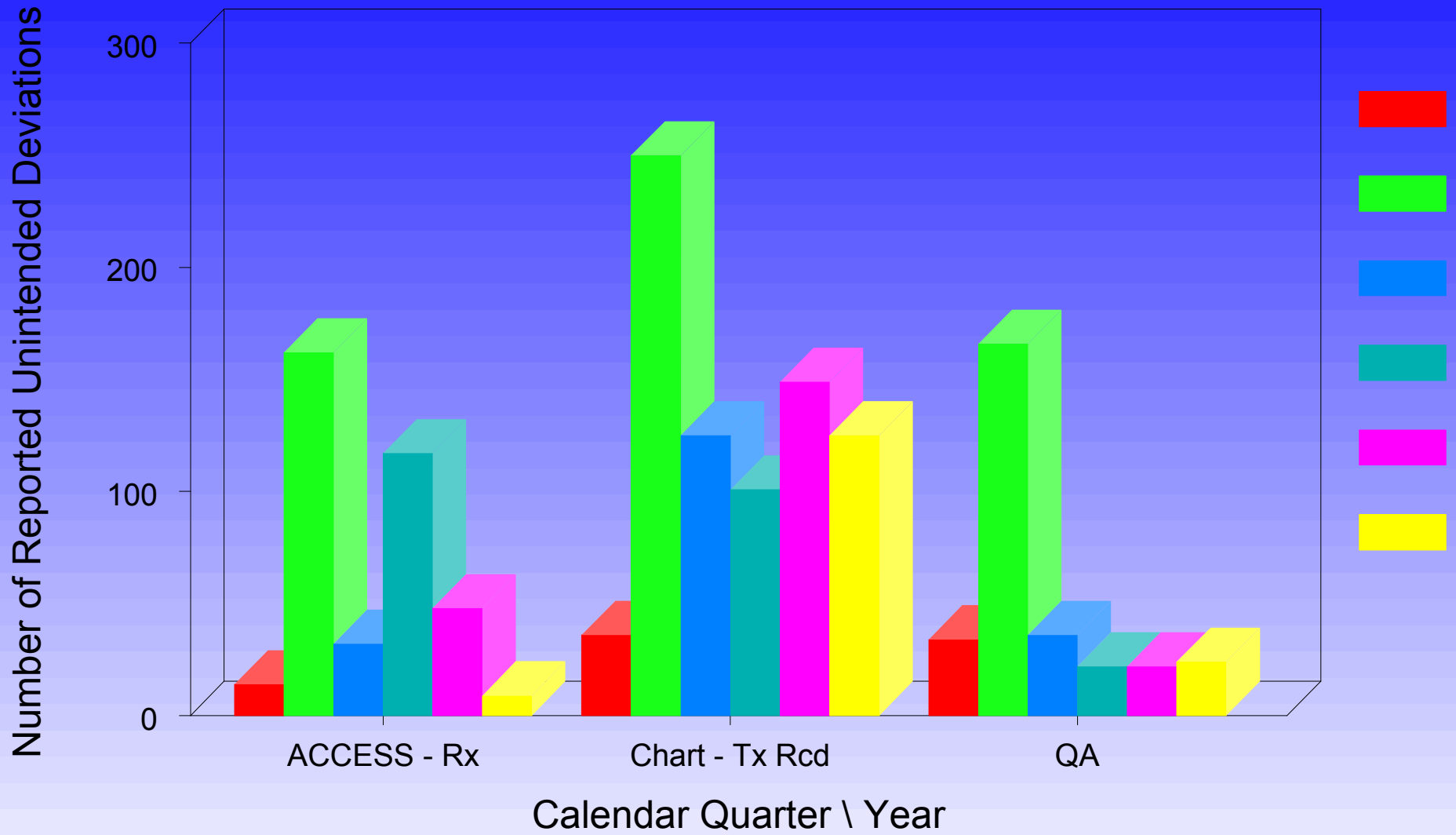
# Significant Unintended Deviations: 2nd & 3rd Qtr. 1996



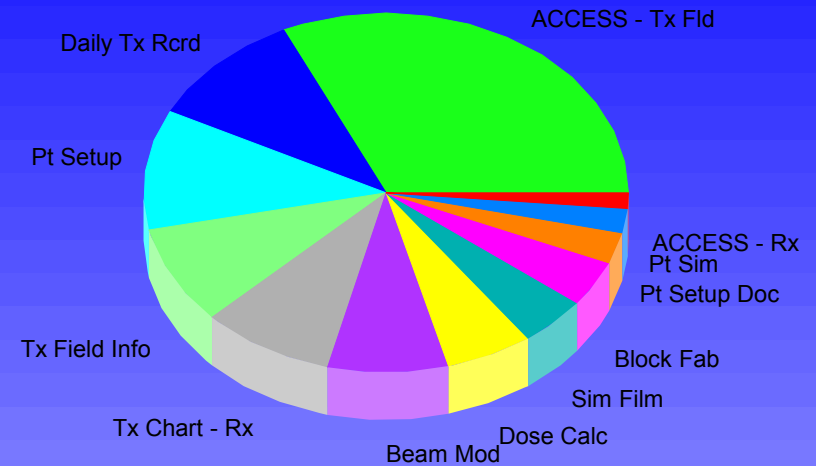
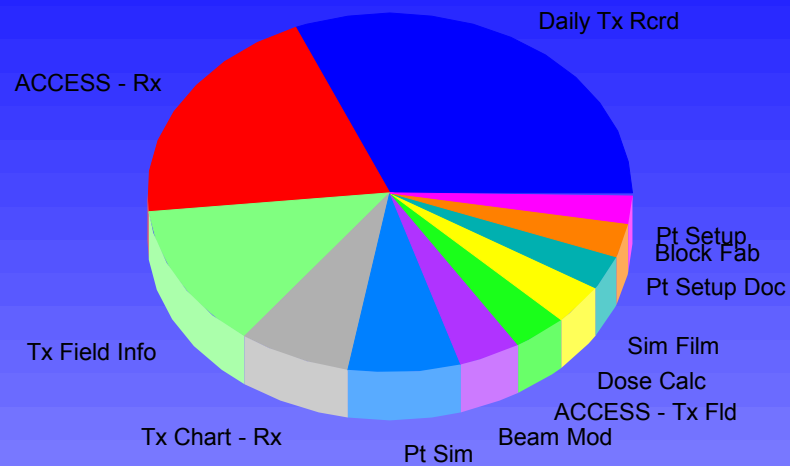
# Summary of Total Unintended Deviations



# Total Unintended Deviations versus Selected Areas of Performance



# 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			

# Calculated Error Rates In QA Compliance Model

- Based upon the total number of treatment fields delivered as recorded by R&V (IMPAC) at 17 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 percent (5.2 in 10,000 patient treatments)
- The minor unintended deviation reporting rate for the same period was calculated to be approximately 0.034 percent.

# 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 percent (1.8 in 10,000 patient treatments).
- Based upon the model's experience of one reported misadministration (having no deterministic or measurable effect) over 2 years, the calculated misadministration rate was 0.017 percent.

# Measured vs Published Misadministration Rate - Cont.'d 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

- What costs a misadministration? In November 1992, a misadministration resulted in the death of a radiotherapy (HDR) patient in Indiana, Pennsylvania. This event precipitated a week long series in the December 1992 *Cleveland Plain Dealer*, entitled “Lethal Doses: Radiation That Kills”. The federal civil penalties paid and lawsuits resulting from this death have totaled millions of dollars. This does not include lost revenues due to mandatory news media releases, public reaction and additional costs associated with the requirements of the NRC orders. Additional sanctions and legal actions were taken against the licensee by NRC’s Office of Investigation and the Department of Justice resulting in additional legal costs.

# Cost Benefit Analysis - Cont'd.

- After implementation of the QA compliance model, the 17 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
- Experience with the one reported misadministration that occurred at a center in Florida between 3/96 and 12/97 (with no effect) resulted in a total direct cost (man-hours, travel, etc.) of approximately \$25,000.

# Cost Benefit Analysis - Cont'd.

- Other benefits from using the QA compliance model:
  - Evidence of a solid QA compliance program has identified, corrected, and either diffused and/or mitigated issues surrounding the following true experiences:
    - A public relations problem occurred in Maryland regarding a community's perceived exposure to radiation from a near by center that allegedly contributed to a higher than normal rate of miscarriages to the surrounding general public. Total cost to rectify was approximately \$20,000 (man-hours and direct costs).
    - Resolution of a therapy shielding incident at a Maryland facility resulted in a total cost (man-hours and direct costs) of approximately \$30,000.
    - Correction of a past diagnostic facility shielding incident in Georgia resulted in a total cost of \$25,000 (man-hours and direct costs)

# Cost Benefit Analysis - Cont'd.

- Other benefits from using the QA compliance model - cont'd:
  - A past misadministration in Kentucky, involving possible civil penalties and sanctions, were averted by demonstrating that the error leading to the misadministration was isolated based on empirical data.
  - After implementation of the QA compliance model at a second oncology company [comprised of 10 centers] in 11/98, three significant radiation treatment errors were caught at oncology facilities that would have required reporting to state and notifying referring physician and patient.

# Cost Benefit Analysis - Cont'd.

- Other benefits from using the QA compliance model - cont'd:
  - Over 4 years experience at 27 oncology facilities has shown that the error identification system in QA compliance model has caught failures to perform billable QA (e.g., weekly chart checks, diode measurements).
  - In discussions with HCFA, it is unlawful under reimbursement guidelines to bill for various patient QA checks if the results of the checks are not acted upon when required
    - Weekly physics chart checks: An error is identified in the chart and no action is taken to correct the error but patient is billed
    - A set tolerance is exceeded and no action is taken to evaluate and/or correct (e.g., diode measurements exceed dose tolerance but patient billed)

# Why is a Technical QA Program Good?

- Significant cost savings
- Improved quality of care
- Reduced liability to patients, physicians, and workers
- Improved efficiency and effectiveness
- Improved compliance with state and federal regulations
- Improved marketability in the managed health care arena
- Enhanced ability to secure accreditation (ACR, JCAHO, ACRO)
- Federal and State legislation is coming!