Technical Quality Assurance Program in Radiation Oncology Physics

by
Ed Kline, MS
RadPhysics Services, Inc.

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The Partnership

Medical physics, quality management, 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.
What Should We Be Doing Now?

• Ensure compliance with State and Federal regulations.
• Comply with management oversight requirements dictated by NRC and Agreement States.
• Strive to meet ACR standards and AAPM recommendations
What’s The Worst That Could Happen?

• Patient overexposures/misadministrations:
  – Civil Penalties
  – Orders (desist, modify and/or revoke licenses and remove staff)
  – Newspaper releases (AP and local news media)
  – Litigation (patient and facilities)
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\(^1\) taken by President Clinton on 2/22/00 based on IOM recommendations\(^2\)
  – 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

\(^1\) Announced by President Clinton and senior administration officials in James S. Brady Press Briefing Room on February 2, 2000.

\(^2\) 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 the 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
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)
• 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$^3$ 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.

$^3$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:\(^\text{4}\):
  – Insufficient supervision
  – Deficient procedures or failure to follow procedures
  – Inattention to detail
  – Inadequate training

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
    • 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**: 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)

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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
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 > ± 5%, source exchange, calibrated instrument
      – Output within ± 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)
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.
• 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

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

Significant Unintended Deviation

Dates of Occurrence: ____________________________________________
Identified By: ________________________________________________

<table>
<thead>
<tr>
<th>Category</th>
<th>Error Code</th>
<th>Category</th>
<th>Error Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Entry</td>
<td>1</td>
<td>Treatment Chart</td>
<td>5</td>
</tr>
<tr>
<td>Simulation</td>
<td>2</td>
<td>Treatment of Patient</td>
<td>6</td>
</tr>
<tr>
<td>Blocks</td>
<td>3</td>
<td>Quality Assurance</td>
<td>7</td>
</tr>
<tr>
<td>Dose Calculation</td>
<td>4</td>
<td>Radiation Safety</td>
<td>8</td>
</tr>
</tbody>
</table>

Description: ______________________________________________________________________________________
______________________________________________________________________________________________
______________________________________________________________________________________________

Evaluation: ______________________________________________________________________________________
______________________________________________________________________________________________
______________________________________________________________________________________________

___Recordable Event ___Misadministration ___Personnel Overexposure

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

___Facility RSO Signature: __________________________________ Copy faxed to OQMRA
___Physician Notified (if applicable) __Adjustment of treatment (if necessary)
___Correction of documentation __Adjustment of equipment or machine
Other: __________________________

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

___Additional training ___Increased oversight or supervision
___Improved procedure ___Other: __________________________________________________________

Office of Quality Management and Regulatory Affairs Use Only

Evaluation: ______________________________________________________________________________________
______________________________________________________________________________________________
______________________________________________________________________________________________
______________________________________________________________________________________________

Recommendations: ______________________________________________________________________________
______________________________________________________________________________________________
______________________________________________________________________________________________
______________________________________________________________________________________________

1 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

<table>
<thead>
<tr>
<th>Unintended Deviations</th>
<th>TMUD - 2nd Qtr '96</th>
<th>TSUD - 2nd Qtr '96</th>
<th>Total - 2nd Qtr '96</th>
<th>TMUD - 3rd Qtr '96</th>
<th>TSUD - 3rd Qtr '96</th>
<th>Total - 3rd Qtr '96</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Entry: ROCS</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Data Entry: ACCESS - Rx</td>
<td>0</td>
<td>162</td>
<td>162</td>
<td>0</td>
<td>33</td>
<td>32</td>
</tr>
<tr>
<td>Data Entry: ACCESS - Tx Field Def</td>
<td>25</td>
<td>5</td>
<td>30</td>
<td>19</td>
<td>5</td>
<td>23</td>
</tr>
<tr>
<td>Process: Patient Simulation</td>
<td>59</td>
<td>0</td>
<td>59</td>
<td>22</td>
<td>2</td>
<td>23</td>
</tr>
<tr>
<td>Process: Simulation Films</td>
<td>24</td>
<td>0</td>
<td>24</td>
<td>25</td>
<td>0</td>
<td>21</td>
</tr>
<tr>
<td>Process: Block Fabrication</td>
<td>20</td>
<td>0</td>
<td>20</td>
<td>12</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Process: Dose Calculation</td>
<td>17</td>
<td>12</td>
<td>29</td>
<td>11</td>
<td>7</td>
<td>18</td>
</tr>
<tr>
<td>Data Entry: Tx Chart - Rx</td>
<td>34</td>
<td>26</td>
<td>60</td>
<td>15</td>
<td>6</td>
<td>21</td>
</tr>
<tr>
<td>Data Entry: Patient Setup Doc</td>
<td>18</td>
<td>5</td>
<td>23</td>
<td>11</td>
<td>0</td>
<td>9</td>
</tr>
<tr>
<td>Data Entry: Tx Field Info</td>
<td>70</td>
<td>35</td>
<td>105</td>
<td>13</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Data Entry: Daily Tx Record</td>
<td>216</td>
<td>34</td>
<td>250</td>
<td>107</td>
<td>29</td>
<td>125</td>
</tr>
<tr>
<td>Tx of Patient: Patient ID</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Tx of Patient: Patient Setup</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Tx of Patient: Patient Beam Modifiers</td>
<td>32</td>
<td>0</td>
<td>32</td>
<td>12</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>Tx of Patient: Admin of Radiation</td>
<td>2</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tx of Patient: Dose Delivered</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Tx of Patient: Port Films</td>
<td>23</td>
<td>0</td>
<td>23</td>
<td>18</td>
<td>0</td>
<td>18</td>
</tr>
<tr>
<td>QA: Missing or Late</td>
<td>34</td>
<td>132</td>
<td>166</td>
<td>10</td>
<td>33</td>
<td>36</td>
</tr>
<tr>
<td>Radiation Safety: Missing or Late</td>
<td>3</td>
<td>25</td>
<td>28</td>
<td>2</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>578</strong></td>
<td><strong>439</strong></td>
<td><strong>1017</strong></td>
<td><strong>279</strong></td>
<td><strong>126</strong></td>
<td><strong>370</strong></td>
</tr>
<tr>
<td><strong>ABSOLUTE DIFF BETWEEN QTRS</strong></td>
<td></td>
<td></td>
<td></td>
<td>-299</td>
<td>-313</td>
<td>-647</td>
</tr>
<tr>
<td><strong>PERCENT INCREASE/DECREASE</strong></td>
<td></td>
<td></td>
<td></td>
<td>-51.7%</td>
<td>-71.3%</td>
<td>-63.6%</td>
</tr>
</tbody>
</table>
Significant Unintended Deviations: 3rd Qtr. 1996

- Data Entry: ACCESS - Rx: 26%
- QA: Missing or Late: 25%
- Data Entry: Daily Tx Record: 23%
- Process: Dose Calculation: 23%
- Data Entry: Tx Chart - Rx: 23%
- Data Entry: ACCESS - Tx Field Def: 22%
- Data Entry: Tx Field Info: 16%
- Radiation Safety: Missing or Late: 11%
- Process: Patient Simulation: 9%
- Tx of Patient: Patient Beam Modifiers: 6%
- Tx of Patient: Dose Delivered: 4%
- Data Entry: ROCS: 3%
Significant Unintended Deviations: 2nd & 3rd Qtr. 1996
Summary of Total Unintended Deviations

Number of Reported Unintended Deviations

Calendar Quarter/Year

0 1200
0 720
0 240

1/96 2/96 3/96 4/96 1/97 2/97 3/97
Total Unintended Deviations versus Selected Areas of Performance

Number of Reported Unintended Deviations

Calendar Quarter \ Year

ACCESS - Rx
Chart - Tx Rcd
QA
Total Unintended Deviations versus Time

<table>
<thead>
<tr>
<th>Parameter</th>
<th>2nd Quarter '96</th>
<th>2nd Quarter '97</th>
<th>% Change</th>
<th>Parameter</th>
<th>2nd Quarter '96</th>
<th>2nd Quarter '97</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Entry: ROCS</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Data Entry: Daily Tx Rcd</td>
<td>250</td>
<td>125</td>
</tr>
<tr>
<td>Data Entry: ACCESS - Rx</td>
<td>162</td>
<td>9</td>
<td>-1800</td>
<td>Tx of Pt: Pt ID</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Data Entry: ACCESS-Tx Field Def</td>
<td>30</td>
<td>45</td>
<td>+150</td>
<td>Tx of Pt: Pt Setup</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Process: Pt Sim</td>
<td>59</td>
<td>6</td>
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<td>Process: Block Fab</td>
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<td>RS: Missing/Late</td>
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<td>44</td>
<td>-239</td>
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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.
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.
• 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 (HCFA) is coming!