THE UNIVERSITY OF TEXAS
MD Anderson ~~Cancer~~ Center

Interventional Radiology Patient Radiation Safety Program

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Purpose:

1. To identify, inform and appropriately consent patients undergoing potentially high radiation dose procedures.
2. To develop interactive, real time dose monitoring and communication between the technologist and attending IR physician. Such communication would lead to dose limiting technical modifications or termination of the study when necessary.
3. To establish a follow up program to track any patient receiving over 3 Gy during a single procedure.

Background:

Patient safety during fluoroscopically guided interventions has been a growing health care concern. Severe skin injuries have been reported in the literature [1, 2]and the Joint Commission has defined a cumulative dose of greater than 15 Gy to any skin site as a reportable sentinel event.[3].

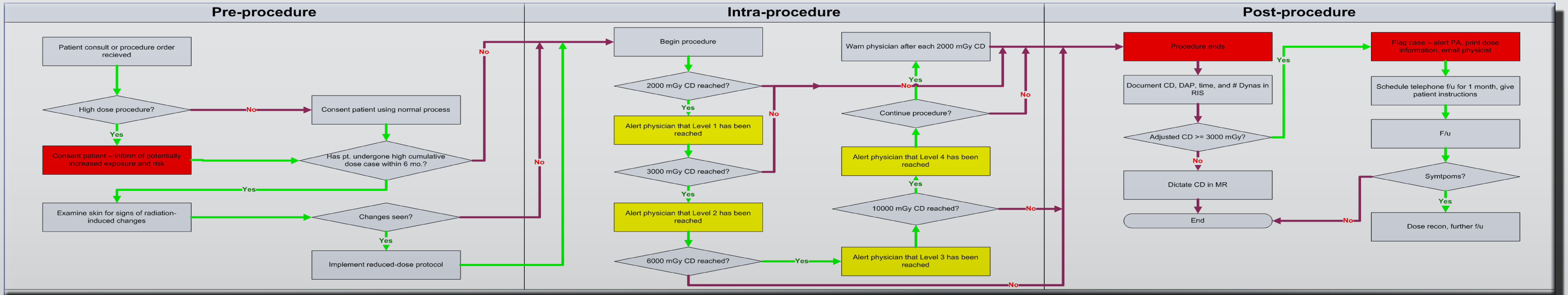
In response, professional societies and individual have attempted the following:
1. Quantify the dose delivered during fluoroscopically-guided interventions
2. Formulate dose decreasing recommendations
3. Better identify patients who are at risk for skin injury

The RAD-IR study was a multi-center study that tabulated cumulative dose (CD) and dose area product (DAP) for a variety of interventions, and identified those procedures with the highest likelihood of substantial patient skin dose.[4, 5] These findings corroborate previously reported results in ICRP 85[6].

In 2009, the Society of Interventional Radiology Safety and Health Committee released guidelines for radiation dose management [7]. Drawing heavily from the previous publications of Miller, Wagner, Stecker and Balter [7-11], these guidelines outline a detailed process for monitoring and managing patient radiation dose from interventional procedures. Our IR patient radiation safety program is an attempt to take the various recommendations, and create a real-time, fully functioning dose limiting and tracking system.

Materials and Methods:

A single-center prospective program was initiated on July 20, 2009 to improve patient safety by monitoring and decreasing radiation exposure during complex interventional procedures. The ongoing program consists of three parts: pre-procedure evaluation, intra-procedure monitoring and post-procedure counseling.



Pre-procedure evaluation

Using the findings from the RAD-IR study [5], the recent Dauer paper [12], and MDACC historical case data, potentially high dose cases were identified. These included the following:
1. Any embolization procedure
2. Biliary drainage (initial access with external or internal/external drainage)
3. TIPS (rarely performed at MDACC)
4. Vascular intervention requiring balloon angioplasty and/or stent

Selected patients underwent additional counseling, risk assessment and consent in order to better inform them of their increased deterministic risk (skin burns, hair loss).

Intra-procedure monitoring

During the performance of all interventional cases utilizing fluoroscopy, technologists continuously monitored the cumulative dose. As predetermined dose thresholds were met (2 Gy, 3 Gy, etc), the IR attending was informed. Discussion between the technologist and physician followed and various options were reviewed including: continuation of the procedure, initiation of a dose reduction protocol (lower pulse rate, decreased dose per pulse and/or modified automatic dose rate control curve), or termination of the case.

Upon completion of the interventional procedure the following data were recorded and placed into an IR dose database:
1. Cumulative dose
2. Dose area product
3. Total fluoroscopy time
4. Number of DynaCTs (rotational angiography)

Post-procedure counseling

Immediately following the procedure, all patients who received a CD > 3 Gy were counseled by a physician and PA. The increased risk of deterministic effects was reviewed and additional information was provided, as recommended by the SIR[7] and NCRP. An information form and an easily customized dose diagram were developed and presented to each patient.

One month following their procedure, patients were contacted via telephone and clinic appointments were scheduled and performed when clinically appropriate. Findings were documented in the patient's medical record.

Analysis

All cases performed and recorded in the database were reviewed and analyzed using statistical software (MiniTab 16). Control charts were created from cases with CD > 3 Gy and significant outliers were identified and further reviewed. Technologist compliance rates and patient complications (deterministic effects) were measured.

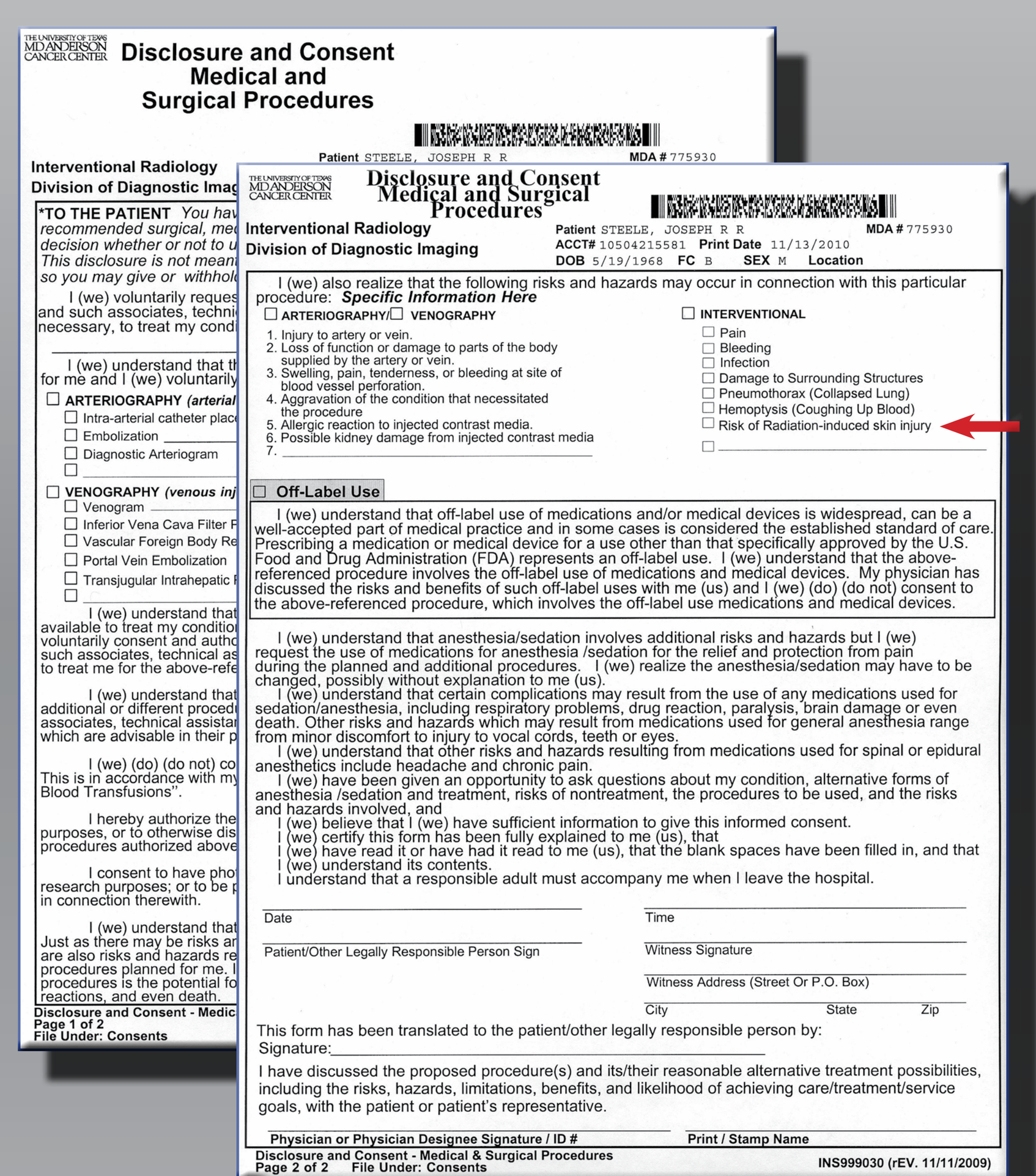


Figure 1:
The UT MD Anderson interventional radiology consent form has been modified such that patients can be specifically consented for the deterministic effects of radiation. Any patient undergoing a potentially high dose case described above will be educated, informed and consented for increased deterministic risks.

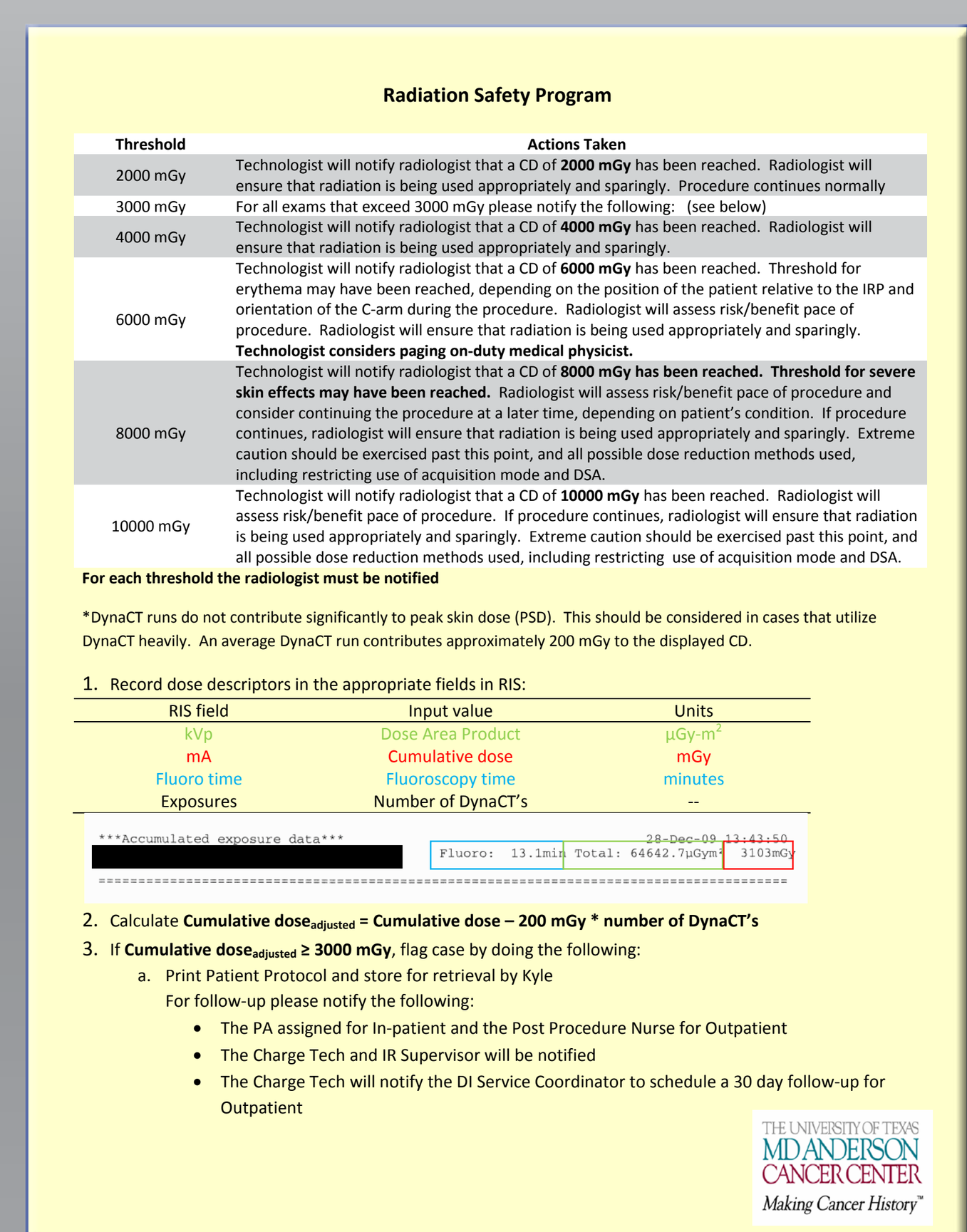


Figure 2:
Laminated and posted adjacent to every IR technical control station are cumulative dose thresholds, which trigger the technologist to communicate dose information to the attending physician. Also provided are instructions on how to calculated dose data and which data must be manually input into the radiology information system.

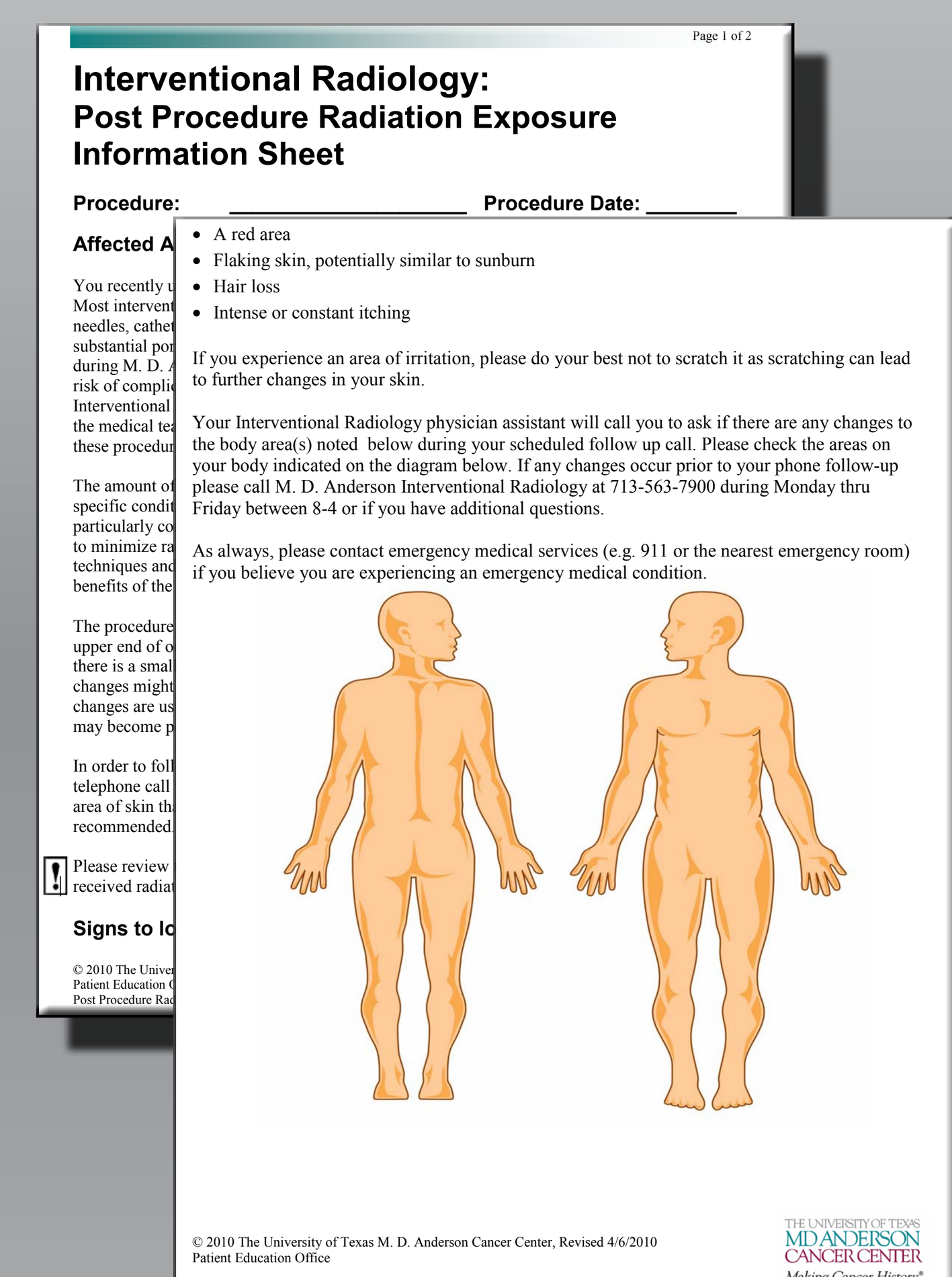


Figure 3:
After any procedure delivering a CD > 3 Gy, the patient education form is reviewed with the patient and their family. The specific anatomic location at highest risk for deterministic effect is marked clearly on the diagram. The patients are encouraged to call with any questions and a one month telephone follow-up appointment is made prior to their discharge.

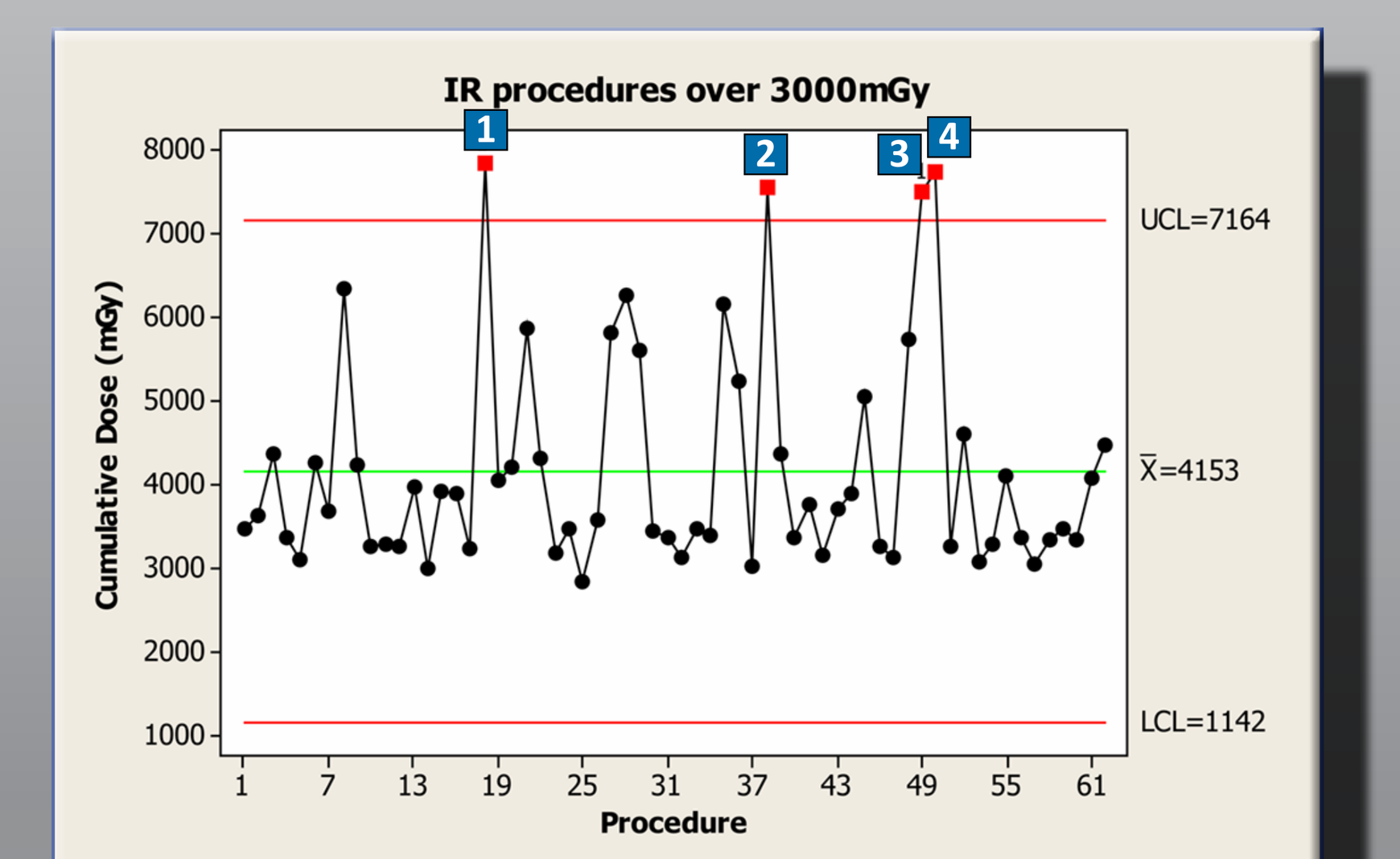


Figure 4:
An individual moving range (XmR) Control Chart created from data for all cases over 3 Gy. Four cases were out of control (outside of the calculated control limits), demonstrating special cause variation. They were individually reviewed and evaluated.

Case #1

Performed by Dr. MW. The patient is a 65 year old male with right renal cell carcinoma and a highly vascular tumor thrombus extending from the kidney to the right atrium. Digital subtraction angiograms demonstrated tumor perfusion from multiple branches of the right inferior phrenic, right T10 intercostal as well as the middle hepatic arteries. A decision was made to proceed, since thorough embolization was necessary in order for the patient to undergo their best treatment option of surgical resection.

Case #2

Performed by Dr. RM. The patient is a 50 year old male with metastatic carcinoma of the sigmoid colon to the liver and lungs. Treatment included Y-90 therapy to the liver. Complex anatomy was noted on the angiogram and additional embolization of right gastric artery and an intrahepatic branch supplying the gastroesophageal junction was necessary prior to delivery of the radiopharmaceutical. Radioactive microsphere therapy (SirSphere) was administered to the right and left lobes of liver separately. A decision was made to proceed with the case since the Y-90 had been prepared and delaying the case would void its use, requiring additional radiopharmaceutical to be ordered and a second procedure, all at significant cost to the patient.

Case #3

Performed by Dr. DM. The patient is a 54 year old male with history of adrenal carcinoma and osseous metastasis. A large vertebral body metastasis is present at the level of T4 with subsequent spinal canal narrowing. The patient requires extensive pre-operative embolization of the mass. Confounding factors include 1) a BMI of 29 and 2) necessary magnified views to insure adequate vascular visualization and minimization of potential non-target embolization to spinal arteries. A three level, bilateral spinal embolization was performed from T3-T5. The anterior spinal artery was visualized at T5. Review of the case demonstrated that all imaging was appropriate and necessary. Going forward, we may use more rotational angiography (to decrease skin dose) and the "fluoroscopy store" function on post-embolization runs.

Case #4

Performed by Dr. DM. The patient is a 48 year old female with a history of prior bilateral nephrostomy tube placement and subsequent decreasing hematocrit. A CT scan shows a left perinephric hematoma and displacement of the left nephrostomy tube. An angiogram was performed to evaluate for bleeding. The patient was not comfortable and could not be positioned comfortably. Thus, a large amount of motion artifact was encountered. In combination with numerous magnified DSA runs attempting to identify the source of extravasation, the cumulative dose was well above 3 Gy. Upon further review, a decision was made to increase the utilization of the anesthesia services when conscious sedation is inadequate.

Results:

Complete dose information was recorded for 3701 cases out of 5718 performed between July 20, 2009 and September 1, 2010. The technologist compliance rate was 65%.

Sixty-two cases exceeded the 3 Gy threshold, and all these patients underwent post procedure counseling and follow-up. No deterministic effects were seen.

Using a control chart (XmR), the 62 cases over 3Gy were analyzed. Three cases were found to represent statistically significant special cause variation. These cases were individually reviewed.

Education of technologists with in-service lectures, and end of procedure checklists increased compliance with the patient radiation safety program.

Conclusion:

Improving patient safety in healthcare has been a primary concern since the initial publication of "To Err is Human" by the Institute of Medicine is[13]. Because of progressively more complex and repeated cases, interventional radiology patients are subjected to significant amounts of radiation exposure. Our patient radiation safety program has proven effective for three reasons:
1. Better informed patients and a more complete consent process.
2. Identifying and counseling 62 patients receiving greater than 3 Gy who would have otherwise gone unnoticed.
3. Furthermore, identifying four cases of significantly elevated dose exposure which were subsequently reviewed.

Incomplete dose information was a result of the technologist not recording dose after what were perceived as very low dose cases (e.g. nephrostomy tube change) or cases performed primarily with ultrasound. After six months, an in-service was given by the imaging physicist. Education and end of procedure checklists increased the compliance rate to over 75% for the last 7 months of the project.

References:

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