08-03604-03
03001325/2009001

From: Rosanna.C.Chan@Medstar.net
Sent: Tuesday, February 16, 2010 3:29 PM
To: Lanzisera, Penny; Nguyen, Janice
Cc: Alka.Shah@Medstar.net; Shashadhar.M.Mohapatra@Medstar.net; Catherine.Monge@Medstar.net
Subject: Respond to" Inspection exit" email sent to Shashi on 2/1/2010
Attachments: NRC reply.pdf; NRC_Flowchart_1.pdf; NRC_Flowchart_2.pdf; NRC_Flowchart_3.pdf

Hi Janice and Penny,

It has come to our attention that there may be certain irregularities pertaining to our Novoste intravascular brachytherapy treatment (IVBT) procedures.
Per request, I am presenting you my previous reply in flowchart form. One detailing the IVBT procedure used for the past 8 - 9 years, and another showing the changes we have made since your last visit. A copy of my previous reply is also attached.
I hope those flowcharts can help clarify our thought processes and procedures used.
We have been visited by the NRC six times prior to your visit in November 2009. These included visits by yourself in May 2003, and March 2005. On each of these occasions, our IVBT program and charts were audited and approved. We were not once made aware that there were any potential issues with regards to our IVBT program. However, since your last visit in November 2009, we have updated our processes and hope this meets your approval.

Please contact us with any further questions you may have.

(See attached file: NRC reply.pdf)(See attached file: NRC_Flowchart_1.pdf)(See attached file: NRC_Flowchart_2.pdf)(See attached file: NRC_Flowchart_3.pdf)

Sincerely,

Rosanna

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[redacted]

E-mail Properties

Mail Envelope Properties (OFBE48478E.D17F4527-ON852576CC.006AACF7-852576CC.00707F38)

Subject: Respond to" Inspection exit" email sent to Shashi on 2/1/2010
Sent Date: 2/16/2010 3:30:10 PM
Received Date: 2/16/2010 3:30:10 PM
From: Rosanna.C.Chan@Medstar.net

Created By: Rosanna.C.Chan@Medstar.net

Recipients:
Penny.Lanzisera@nrc.gov (Lanzisera, Penny)
Tracking Status: None
Janice.Nguyen@nrc.gov (Nguyen, Janice)
Tracking Status: None
Alka.Shah@Medstar.net (Alka.Shah@Medstar.net)
Tracking Status: None
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Tracking Status: None
Catherine.Monge@Medstar.net (Catherine.Monge@Medstar.net)
Tracking Status: None

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Files	Size	Date & Time
MESSAGE	103088	2/16/2010
NRC reply.pdf	20882	
NRC_Flowchart_1.pdf	24213	
NRC_Flowchart_2.pdf	21506	
NRC_Flowchart_3.pdf	21888	

Options
Expiration Date:
Priority: olImportanceNormal
ReplyRequested: False

Return Notification: False

Sensitivity: olNormal
Recipients received:

Statement to NRC (Jan. 2010)

The rationale behind the fact that authorized user signature was done immediately after Novoste IVB treatment instead of before is that it is a timely procedure. The Radiation Oncologist is put into a sterile environment as soon as he gets to the lab before evaluating the final IVUS result for dose prescription. 10 CFR35.(40) (1) states that " ***If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive."*** Based on our interpretation, we opt to do an oral directive which is immediately written onto the prescription form by the Radiation Safety staff and signed off by the Radiation Oncologist at the completion of treatment. This way the Radiation Oncologist does not have to break sterility and prolong the time the delivery catheter has to stay inside the patient. Since both the prescription dose and dwell time are verbally confirmed and verified by all parties involved before treatment starts, there is very minimal chance of misadministration.

At Washington Hospital Center (WHC), Intravascular Brachytherapy treatment (IVBT) is always performed under sterile conditions. Patient consultation done by the Interventional Cardiologist prior to starting the angiogram may include a **possible** IVBT treatment based on the history of the patient. IVBT can only be confirmed after patient is under anesthesia and angioplasty has been completed by the Cardiologist. Once confirmed the Radiation team is called to the cardiology lab. The team includes a Radiation Oncologist, a Medical Physicist and a Radiation Safety staff. Normally it takes 15 -20 minutes for the team to get all the equipment and get to the lab. The procedure is usually an urgent one requiring immediate preparation of the equipment and delivery of treatment in a timely manner to minimize the time that the patient is under anesthesia and to reduce the amount of time that the radiation treatment catheter is in place. The latter can result in cardiac ischemia and potentially severe chest pain for the patient. Due to this being a sterile procedure, Radiation Oncologist is gowned and gloved immediately upon arrival to prepare the source for treatment. Majority of the time, the cardiologist is on his or her last angioplasty. A final ultrasound (IVUS) is performed prior to treatment to determine treatment depth and length for radiation prescription. The Radiation Oncologist will verbally communicate the prescription to the medical physicist for calculating the treatment time. After calculation, the dose and the treatment time are reported by the Physicist to the Radiation Oncologist and Cardiologist and verified by the Radiation Oncologist. The Radiation Safety staff documents all the information into the hospital approved Brachytherapy treatment record form prior to delivery which includes all information pertinent to the 10 CRF 40 requirements. In addition, the medical transcriber in the lab also documents that (dose, dwell time, source etc.) into the patient's electronic chart immediately. Once the radioactive source is in position, as verified by cine, medical physicist starts time. Normal treatment time is 3 to 4 minutes per step depending on the prescribed dose and activity of source at time of treatment. A minute by minute count down is done by the physicist throughout treatment. Upon completion of treatment and source is removed, the written directive is immediately signed by the Radiation Oncologist and filed in the patient's medical record.

Procedural Change

To be in full compliance of 10 CFR 35 (40)(a), we redesigned our Brachytherapy form(attachment A) to include a separate signature line for the Radiation Oncologist. The Radiation Oncologist is to sign the prescription form before gowning up for the sterile procedure. In addition form is streamlined to be more concise for recording treatment with the Novote source. Implementation is immediate upon approval by the Radiation Safety Committee.

ATTACHEMNT "A"

MRN		Patient Sequence Number:		Date of Procedure:	/	/
				dd	mmm	yy

Novoste IVBT Prescription

Patient Name: _____

Site (Artery) _____ Vessel Length: _____cm Diameter: _____cm

Treatment Device: Novoste _____seeds Total Activity: _____ mCi (Sr/Y-90)

Prescribed Dose: _____ Gy to 2mm point from source center No. of steps: _____

Dwell Time: _____' _____" per step

Radiation Oncologist Signature : _____Date:_____

Treatment Record

Patient ID Method : ☐ Photo ☐ Name ☐ ID Bracelet Cath Lab # : _____

Treatment Device : Novoste _____seeds Total Activity: _____ mCi (Sr/Y-90)

S/N : _____ Calculated Treatment Time : _____' _____" for ____Gy

Artery: _____ No. of Steps: _____

Step:	1	2	3
Position:			
Start Time:			
End Time:			
Dwell Time:			
Dose delivered:			

Position notation:
P = proximal
M = middle
D = Distal
nA if only one step

Patient Survey in mR/hr with Ludlum3, S/N _____ Calibration Date: _____

Before Tx.				@ 1 m
During Tx.				@ patient surface
				@ 1 m
After Tx.				@ 1 m

Source Removed: ☐ Y ☐ N Room Survey : ☐ Y ☐ N

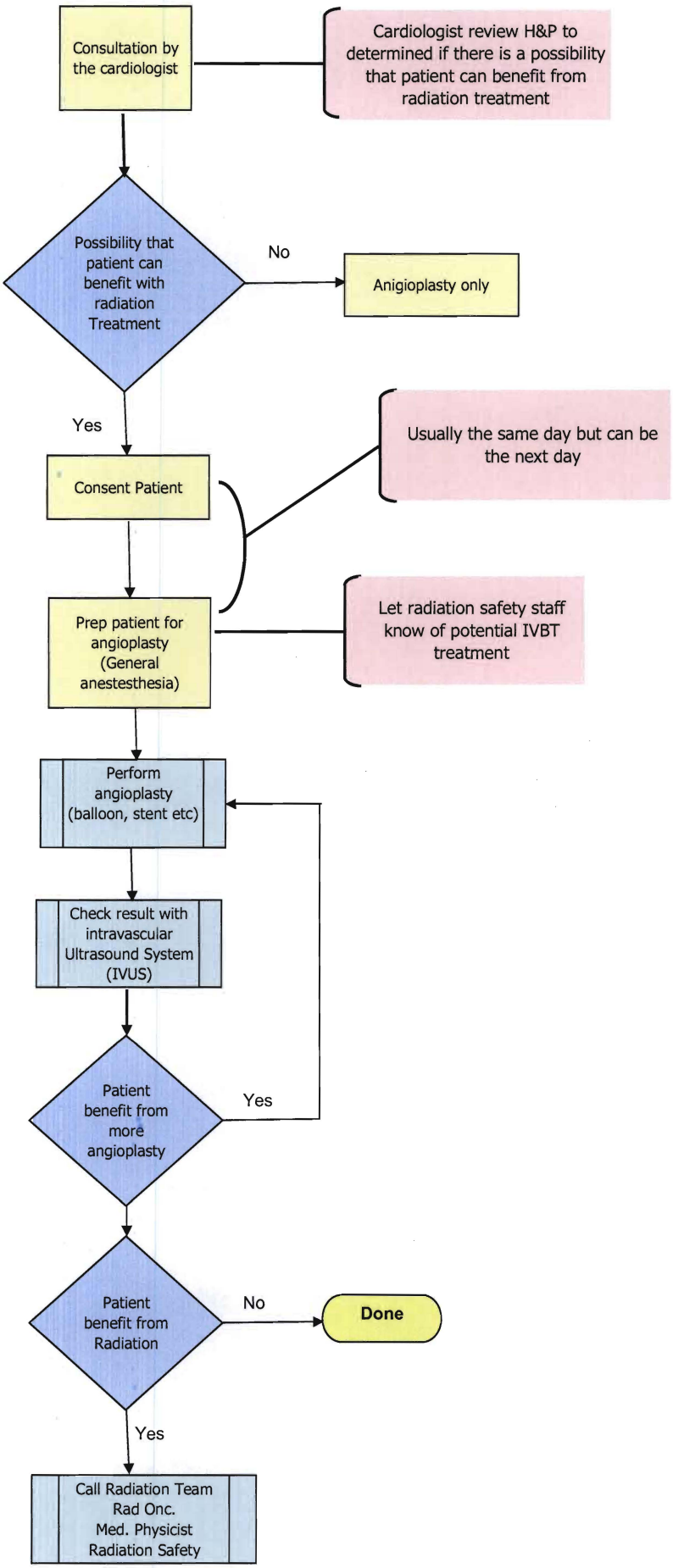
Comment:_____

_____
Medical Physicist Signature

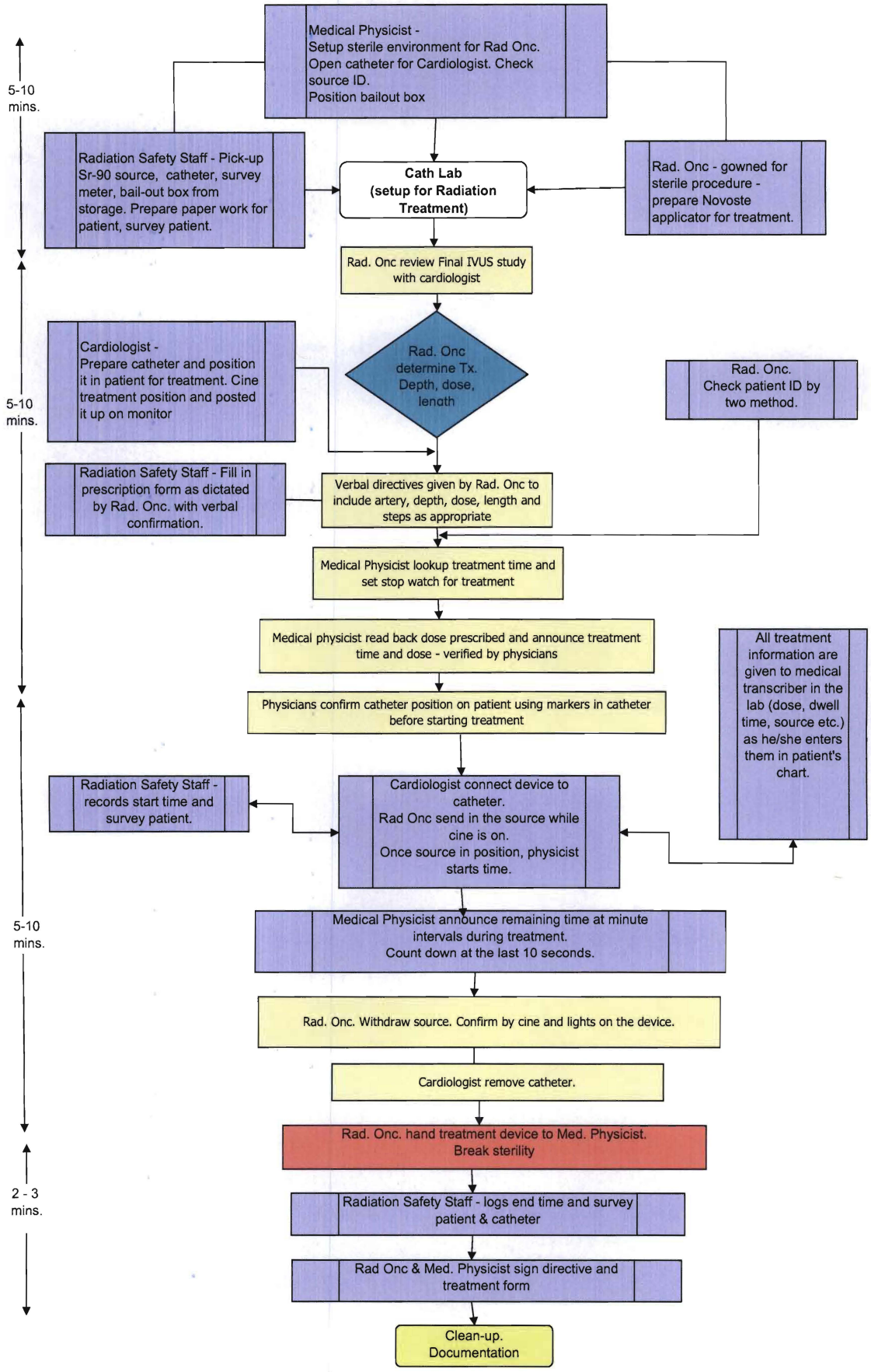
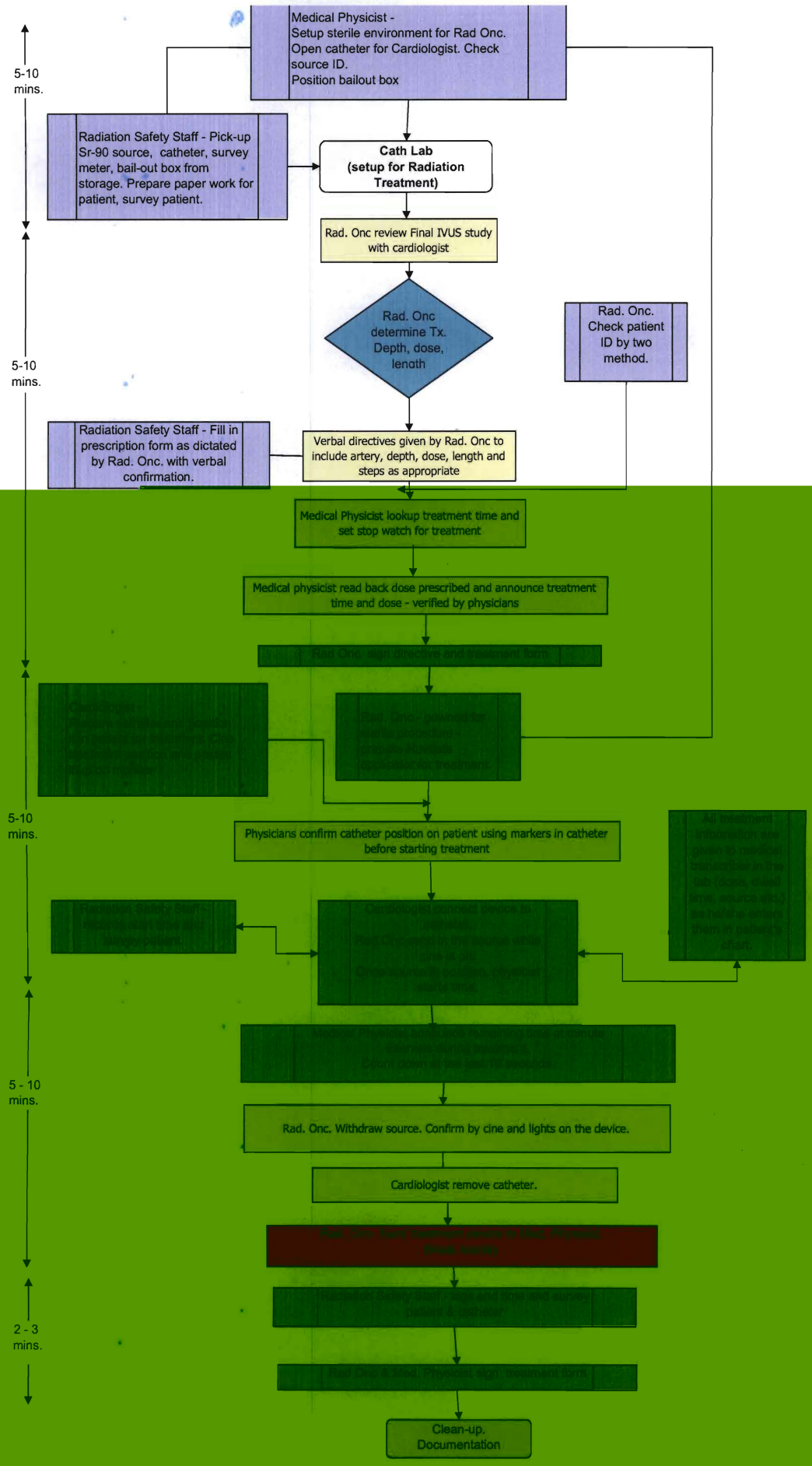
_____
Radiation Oncologist Signature

Place Patient ID Label here

Cardiology Pre-radiation Process



Novoste Treatment Procedure



Revised Novoste Treatment Procedure (effective date - January 20, 2010)