Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: Initial analysis 1/18/2010

Signature Ronald E Goans, MD

Licensee Name Veterans Affairs Healthcare System, San Diego
3350 La Jolla Village Drive
San Diego, CA 92161

License No. 03-23853-01VA
Docket No. 030-34325
Event No. 45383

Facility Name: Radiation Oncology Department
Veterans Affairs Healthcare System, San Diego

Incident Dates: 9/21-9/25, 2009
Date of Notification: Initial notification 9/26/2009

Individual's / Patient Physician Name and Address:

Ernest Belezzouli, MD
Director, Radiation Oncology
Veteran Affairs Healthcare System, San Diego
3350 La Jolla Village Drive
San Diego, CA 92161

Individuals Contacted During Investigation:

Ernest Belezzouli, MD
Director, Radiation Oncology
Veteran Affairs Healthcare System, San Diego
3350 La Jolla Village Drive
San Diego, CA 92161
(858) 552 7511

Rene Michel, MS, RSO
Veteran Affairs Healthcare System, San Diego
3350 La Jolla Village Drive
San Diego, CA 92161
(858) 642 1059

Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
2. NRC Preliminary Notification of Event (Event # 45383)
3. NRC Medical Event Reporting and supporting literature
4. NRC Notes on the event
5. Department of Veterans Affairs Medical Center correspondence to the NRC
6. Internal Dose Calculations of Michael Stabin, PhD, CHP
7. REAC/TS working notes on internal dose calculations

Estimated Dose to Individual or Target Organ:

17-19 Gy to the gastric wall. See notes below.

Probable Error Associated with Estimation: <20 %, primarily due to uncertainty in source geometry. Monte Carlo Method with full beta spectrum and all photons from I-131.

Prescribed Dose (Medical Misadministration Only): 200 mCi I-131 for metastatic thyroid cancer.

Method Used to Calculate Dose: Clinical dose profile by Monte Carlo and physical dosimetry using the point kernel technique.

Description of Incident:

The NRC was notified, pursuant to 10 CFR 35.3045, of a medical event that occurred at the VA San Diego Healthcare System in San Diego, California. Nominal prescribed activity 200 mCi I-131 NaI.

An activity of 187 millicuries of I-131 sodium iodide was administered to a 63 year old patient with metastatic thyroid carcinoma through a feeding tube (Kimberly-Clark MIC Gastrostromy feeding tube; g-tube) on September 21, 2009. The patient was kept in a shielded room at the facility. Daily measurements of the exposure rate at one meter from the patient showed only a small decrease, consistent with radioactive decay, but not the expected biological elimination. The feeding tube was replaced on September 25, 2009. The activity in the feeding tube after removal from the patient was estimated as over 80 millicuries. At this time, it is estimated that the patient received less than half of the administered dose. Most of the activity (~160 mCi) I-131 had been injected into the balloon port rather than into the medication port as intended.

The basis for the medical event derives from the fact that the total dosage delivered differs from the prescribed dosage by more than 20 percent. The facility has notified the patient of the medical event and has notified the referring physician. The facility has also assessed any adverse medical effects on the patient. The NHPP is performing a reactive inspection regarding the medical event. A 15-day written report for the medical event has been submitted to NRC Region III.

Clinical Course

An activity of 187 mCi (6920 MBq) of Na I-131, was administered to a patient through a silicon G-tube on September 21, 2009. It is estimated that 112-160 mCi (4100-5900 MBq) of this activity was inadvertently injected into the balloon compartment, which contained 7-10 cc of distilled water. The patient was ambulatory and received nutrition through the feeding tube. The

G-tube was surgically removed from the patient on September 25, 2009. At the time of the incident the RSO called for assistance from the Radiation Emergency Assistance Center/Training Site (REAC/TS). This reviewer is a radiation medicine consultant to REAC/TS and participated in initial dose calculations for this case. With the little information initially available, a preliminary dose of 14-15 Gy to the stomach wall was estimated.

The Veteran Affairs Healthcare System, San Diego subsequently contacted Mike Stabin, PhD, CHP at Vanderbilt University of provide more extensive dose estimation. Dr. Stain's complete report is attached in Appendix I.

There are no available model dose factors that can estimate the dose from the balloon to the stomach wall or other tissues of the patient. Thus, Dr. Stabin was created a mathematical model in the MCNP Monte Carlo code (Briesmeister 1997). From this analysis, doses were estimated to several tissues of interest in the problem. The thickness of the skin was set to 0.2 cm, as suggested by Cristy and Eckerman. The stomach was modeled as suggested by Cristy and Eckerman, namely as two concentric ellipsoids, the inner representing the stomach contents (250 ml) and the space between the two ellipsoids representing the stomach wall (152 ml). The source was then modeled as a simple sphere of 10 ml in contact with the stomach wall.

The full beta spectrum of I-131, as provided by the RADAR dose information group (Stabin and da Luz 2002), was used in the transport calculations, as well as the energies of all discrete electrons and photons. Sufficient particle histories (200,000) were run to reduce uncertainties in most reported values below 1%. The number of disintegrations estimated for 160 mCi (5900 MBq) residing in this balloon for 91.7 hours, accounting for the radioactive decay of the I-131, was 1.65x1015. The estimated doses to the various modeled structures are shown in Tables 1 and 2.

When one averages all energy absorbed throughout the entire stomach wall, the dose is estimated to be about 17 Gy; this is remarkably close to the REAC/TS result, derived using the point kernel method. In addition, a small region in the stomach wall right adjacent to the source received an estimated dose of 135 Gy. Similarly for the skin, an average over the entire region is estimated to be 0.28 Gy, but the small region modeled in the skin near the source has an estimated dose of 11 Gy.

I have been assured by Dr. Ernest Belezzouli that there have been no adverse effects to the patient. Specifically, I asked about ulceration in the stomach or erythema to the anterior abdominal wall. Dr. Belezzouli has kindly provided sequential pictures of the patient's anterior abdominal wall and there is no clinically significant erythema. Furthermore, there appears to have been no gastric bleeding to date. Both of these are positive indicators for the patient.

References

Briesmeister, J. MCNP - A general Monte Carlo n-particle transport code, version 4B. Los Alamos National Laboratory, report LA-12625-M, 1997.

Cristy, M. and Eckerman, K. (1987): Specific absorbed fractions of energy at various ages from internal photons sources. ORNL/TM-8381 V1. Oak Ridge National Laboratory, Oak Ridge, TN.

Fajardo L-G, LF, Berthrong, M, and Anderson, RE. *Radiation Pathology*. Oxford Press. 2001.

Fletcher GH. Textbook of Radiotherapy. 3rd edition. Lippincott, Williams& Wilkins, 1980.

Goans RE. Clinical Care of the Radiation Accident Patient: Patient Presentation, Assessment, and Initial Diagnosis. In The *Medical Basis for Radiation-Accident Preparedness. The Clinical Care of Victims.* Eds. Robert C. Ricks, Mary Ellen Berger, and Frederick M. O'Hara, Jr. Proceedings of the Fourth International REAC/TS Conference on the Medical Basis for Radiation-Accident Preparedness, March 2001, Orlando, FL. The Parthenon Publishing Group, 2002.

Stabin MG, da Luz CQPL. New Decay Data for Internal and External Dose Assessment, Health Phys. 83(4):471-475, 2002.

Stabin MG, Sparks RB, and Crowe E. OLINDA/EXM: The Second-Generation Personal Computer Software for Internal Dose Assessment in Nuclear Medicine. J Nucl Med 2005;46 1023-1027.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

No patient contact resulted from this consult.

If yes, would the individual like to be included in the program? N/A

COMPLETE FOR MEDICAL MISADMINISTRATION
(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred – Yes. Circumstances of this event were largely documented in the Department of Veteran Affairs National Health Physics Program memorandum.

b. Effect on the patient – Patient records were examined and my independent dose estimates generally agree with those provided by the hospital. The patient is said to be in satisfactory condition.

c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC, once the index case was noted..

d. Improvements needed to prevent recurrence **-** Yes. This is a multiple human factors issue, correctable by education and improved procedures. I don't expect a recurrence.

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33, provide the basis for your opinion: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33?
N/A

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patient in question will be followed clinically by the San Diego VA medical center. After discussion with all of the principal participants, I feel that the VA system will institute an effective program to prevent a recurrence of these events.

Appendix 1

RADIATION DOSE ESTIMATES FOR AN 131I SOURCE IN A BALLOON SOURCE IN THE STOMACH OF A PATIENT AT THE VA HOSPITAL IN SAN DIEGO, CALIFORNIA
C O N F I D E N T I A L R E P O R T

Michael G. Stabin, PhD, CHP
Department of Radiology and Radiological Sciences Vanderbilt University 1161 21st Avenue
South Nashville, TN 37232-2675
November 6, 2009

INTRODUCTION
An activity of 187 mCi (6920 MBq) of Na I-131, was administered to a patient through a silicon G-tube on September 21, 2009. It is estimated that 112-160 mCi (4100-5900 MBq) of this activity was inadvertently injected into the balloon compartment, which contained 7-10 cc of distilled water. The patient was ambulatory and received nutrition through the feeding tube. The G-tube was surgically removed from the patient on September 25, 2009. This report summarizes efforts to estimate the radiation dose to tissues of the patient.

METHODS
Figure 1 shows the geometry of the problem, as provided by representatives of the VA Hospital in San Diego, CA.

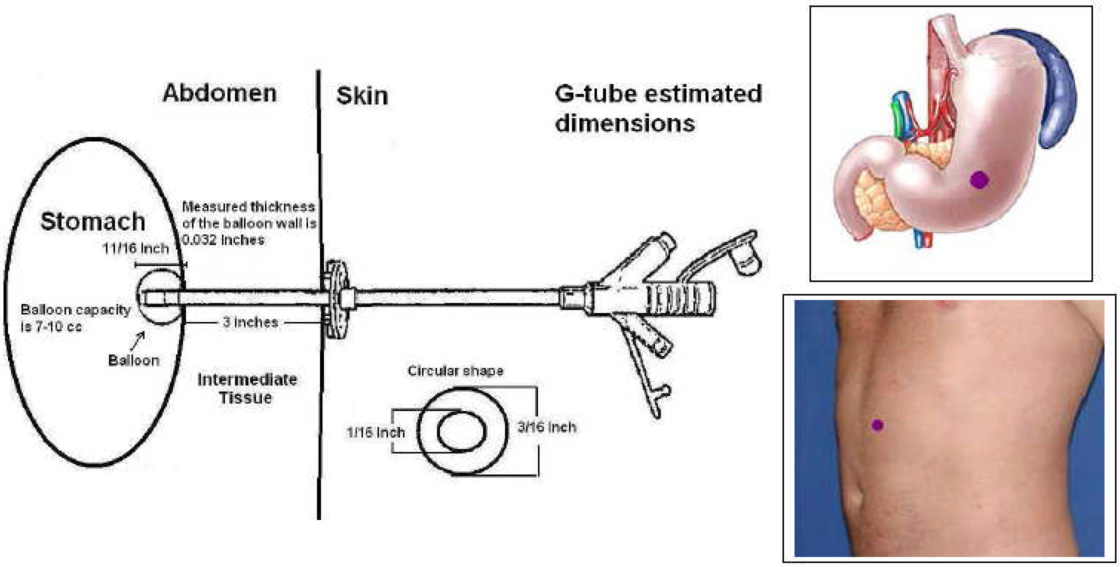


Figure 1. Geometry of the G-tube in the patient

There are no available model dose factors that can estimate the dose from the balloon to the stomach wall or other tissues of the patient. Thus, a new model was created in the MCNP Monte Carlo code (Briesmeister 1997) and doses were estimated to several tissues of interest in the problem. Figure 2 shows a representation of the cross section from the model developed. The whole body was designed as a cylinder with the dimensions of the trunk used in the model of the adult male suggested by Cristy and Eckerman (1987).

Other specific elements of their whole body phantom, like legs and head, were not modeled, rather the body was represented as a simple cylinder whose height (111 cm) was chosen to provide the approximate correct mass for the whole body (70 kg). A second cylinder was placed within the outer cylinder, with the space between them representing the skin. The thickness of the skin was set to 0.2 cm, as suggested by Cristy and Eckerman also. The stomach was modeled as suggested by Cristy and Eckerman, namely as two concentric ellipsoids, the inner representing the stomach contents (250 ml) and the space between the two ellipsoids representing the stomach wall (152 ml). The source was then modeled as a simple sphere of 10 ml in contact with the stomach wall.

Table 2. Doses to the modeled structures, Gy.

	Doses (Gy)		
Target Region	Photons	Electrons	Total
Rest of body	4.12E-01	0.00E+00	4.12E-01
Skin	2.76E-01	0.00E+00	2.76E-01
Stomach contents	2.98E+01	3.95E+00	3.37E+01
Stomach wall	1.67E+01	5.81E-02	1.67E+01
Source	3.36E+02	4.79E+03	5.12E+03
Small stomach wall region	1.24E+02	1.08E+01	1.35E+02
Small skin region	1.10E+01	0.00E+00	1.10E+01

The full beta spectrum of I-131, as provided by the RADAR dose information group (Stabin and da Luz 2002), was used in the transport calculations, as well as the energies of all discrete electrons and photons. Sufficient particle histories (200,000) were run to reduce uncertainties in most reported values below 1%. Dose to the entire stomach wall was estimated in the simulations, but the localized dose to the stomach wall was also estimated by placing a small sphere of the diameter of the stomach wall inside of the stomach wall near the source (not shown in Figure 2). A small sphere was also placed in the skin region, with the diameter of the skin thickness, to estimate the highest dose to the skin expected (also not shown in Figure 2).

The number of disintegrations occurring in the source region was calculated assuming that the entire 166 mCi was present in the balloon for the time span noted in the Introduction (i.e. 91.7 hours). Doses to other organs were estimated by assuming that the source was uniform within the stomach contents and employing the dose factors from the OLINDA/EXM software program (Stabin et al. 2005), using the adult male model.

RESULTS

The number of disintegrations estimated for 160 mCi (5900 MBq) residing in this balloon for 91.7 hours, accounting for the radioactive decay of the I-131, was 1.65x1015. The estimated doses to the various modeled structures are shown in Tables 1 and 2.

Table 1. Doses to the modeled structures, Gy/disintegration in the source region. Doses (Gy) per disintegration in the source region		
Target Region	Photons	Electrons
Rest of body	2.49E-16	0.00E+00
Skin	1.66E-16	0.00E+00
Stomach contents	1.80E-14	2.39E-15
Stomach wall	1.02E-14	3.51E-17
Source	2.03E-13	2.89E-12
Small stomach wall region	7.50E-14	6.55E-15
Small skin region	6.68E-15	0.00E+00

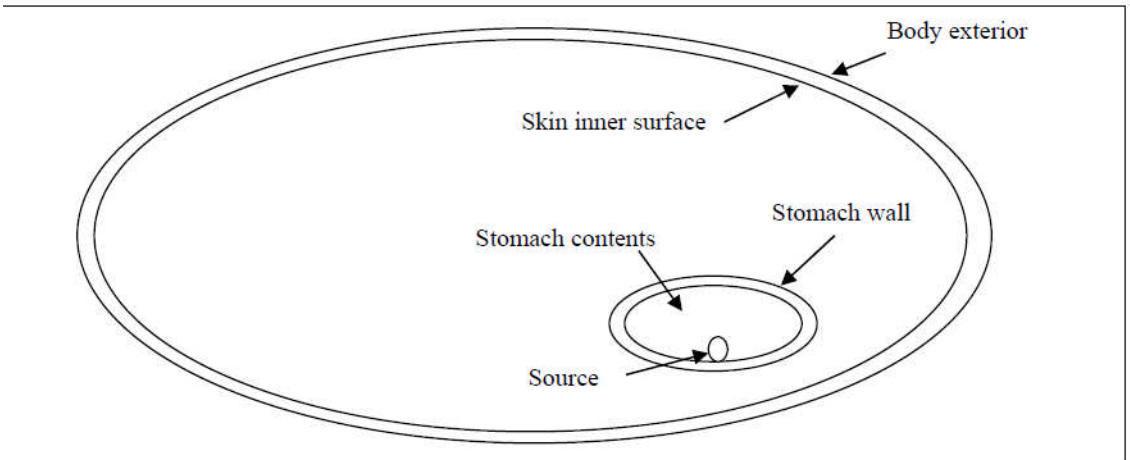
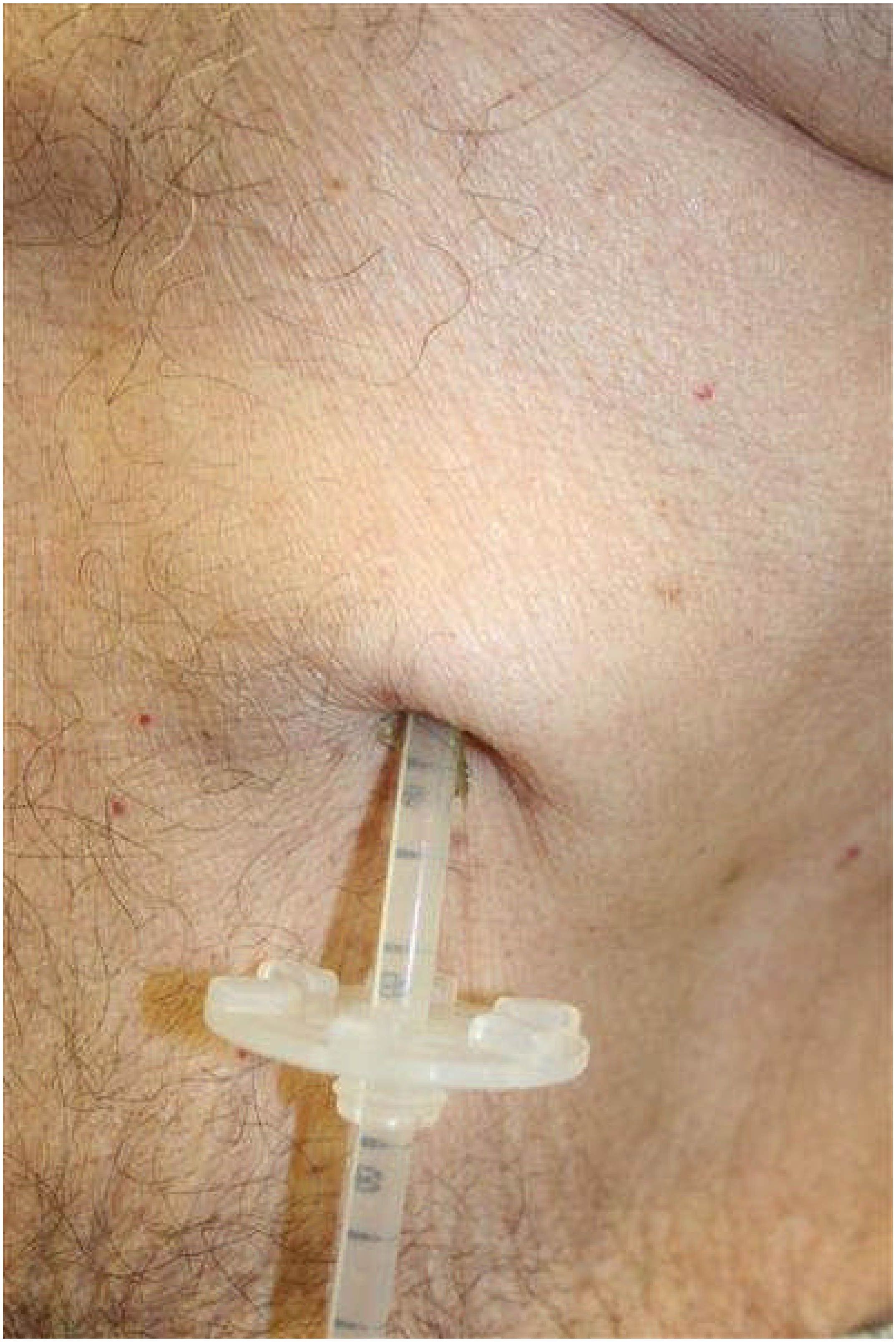
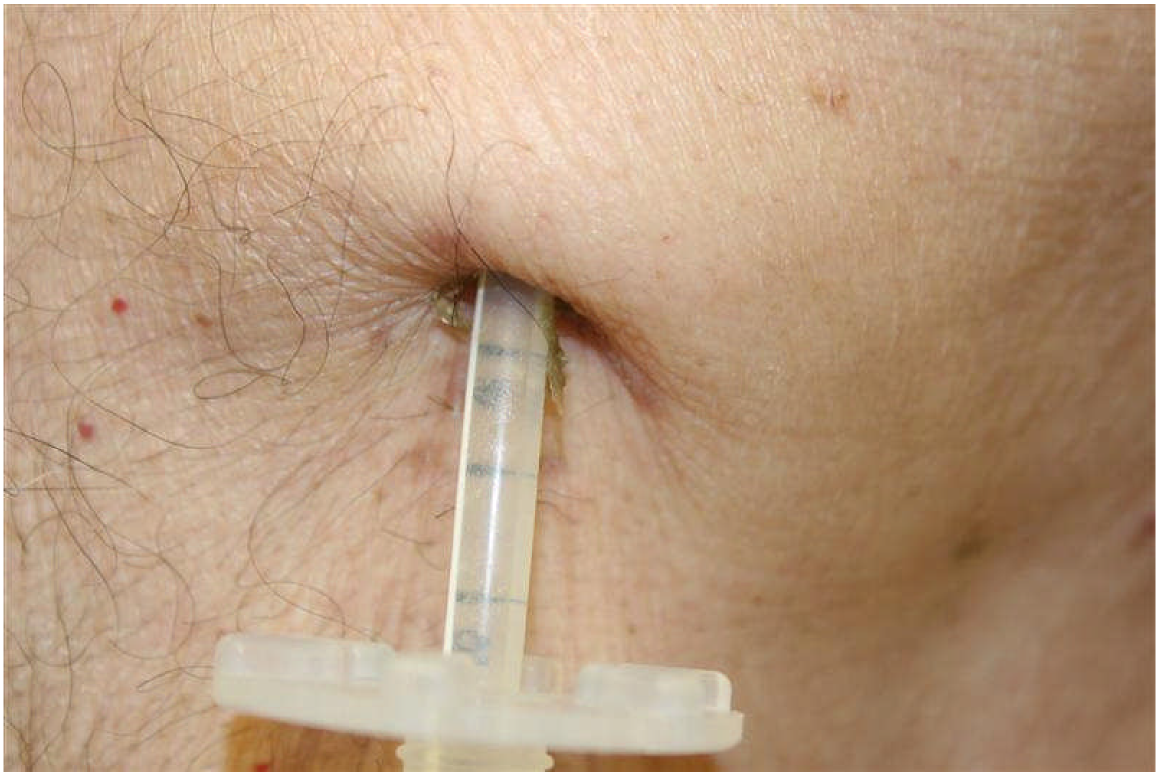
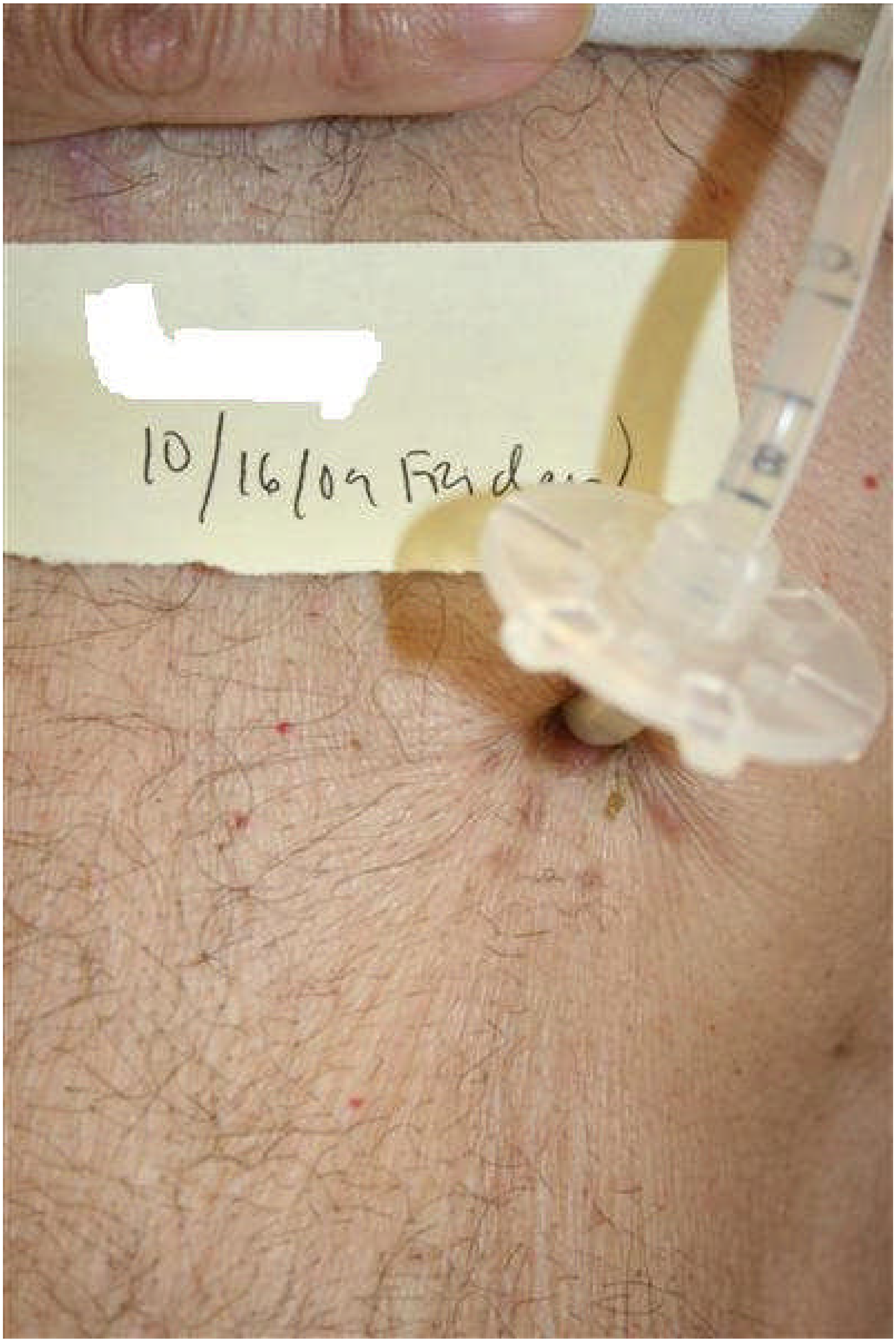


Figure 2. Cross section showing approximate problem geometry modeled in MCNP.

Appendix 2 Anterior Abdominal Wall Pictures



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