

AT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

**NATIONAL MAMMOGRAPHY QUALITY ASSURANCE
ADVISORY COMMITTEE**

Tuesday, October 28, 1997

9:05 a.m.

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Conference Room 6

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1 P R O C E E D I N G S

2 DR. MONSEES: Good morning. I am Barbara Monsees,
3 the chair of the NMQAAC.

4 Before we get started with the actual agenda of
5 the meeting, we are going to turn the mike over to our
6 Executive Secretary, Dr. Finder, who is going to address
7 conflict of interest.

8 DR. FINDER: First, I would like to welcome
9 everybody to the National Mammography Quality Assurance
10 Advisory Committee, and I would like to begin by reading the
11 conflict of interest statement.

12 The following announcement addresses conflict of
13 interest issues associated with this meeting and is made a
14 part of the record to preclude even the appearance of any
15 impropriety.

16 To determine if any conflict existed, the agency
17 reviewed the submitted agenda and all financial interests
18 reported by the committee participants. The conflict of
19 interest statutes prohibit special government employees from
20 participating in matters that could affect their or their
21 employer's financial interests, however, the agency has
22 determined that participation of certain consultants and
23 members, the need for whose services outweighs the potential
24 conflict of interest involved, is in the best interests of

1 the government. Full waivers are in effect for 13 out of 17
2 participants because of their financial involvement with
3 facilities that will be subject to FDA's regulations on
4 mammography quality standards, with accrediting, certifying,
5 or inspecting bodies or with the manufacturers of
6 mammography equipment since these organizations could be
7 affected by the committee's deliberations.

8 The participants include Dr. Tamsen Bassford, Ms.
9 Rita Heinlein, Ms. Maria Romero, Mr. Roland Fletcher, Dr.
10 Peter Dempsey, Dr. Ellen Mendelson, Dr. Laura Moore-Farrell,
11 Dr. Barbara Monsees, Dr. Edward Sickles, Mr. Michael Mobley,
12 Ms. Patricia Wilson, Ms. Patricia Hawkins, and Mr. Robert
13 Pizzutiello.

14 Copies of these waivers may be obtained from the
15 Agency's Freedom of Information Office, Room 12A-15 of the
16 Parklawn Building.

17 Since Mr. Robert Pizzutiello, Dr. David
18 Winchester, Dr. Edward Hendrick, and Dr. Lawrence Bassett
19 participated in the development of the ACR-ACS agreement on
20 quality standards for stereotactic breast biopsy, we have
21 limited their participation in this matter to a presentation
22 of details of the agreement. They can talk about the facts
23 of the agreement and how they were developed, but will
24 refrain from giving their opinions or voting on the

1 agreement.

2 Out of abundance of caution, we have also limited
3 Dr. Edward Sickles, Dr. Lawrence Bassett, and Dr. Edward
4 Hendrick's participation in equipment standards because of
5 their involvement with mammography devices. They are
6 allowed to discuss mammography technologies including
7 digital devices, as well as talk about their observations
8 and experiences with these products, however, they will
9 refrain from voting on specific equipment standards.

10 Although we don't anticipate any discussion of
11 state certifications at this meeting, we would like to note
12 for the record that when this issue is discussed, we will
13 limit the participation of Mr. Pizzutiello, Ms. Hawkins, Mr.
14 Mobley, and Dr. Moore-Farrell because each is affiliated
15 with a state-run regulatory body.

16 Also, several of our members and consultants
17 reported that they received compensation for lectures they
18 have given or will give on mammography-related topics,
19 however, they have affirmed that these lectures were offered
20 to them because of their expertise in the subject matter,
21 and not because of their membership on the committee.

22 In the event that the discussions involve any
23 other matters not already on the agenda, in which an FDA
24 participant has a financial interest, the participants

1 should exclude themselves from such involvement, and their
2 exclusion will be noted for the record.

3 We would also like to acknowledge that the
4 Executive Secretary, Dr. Charles Finder, is a member of the
5 ACR. We also have a guest speaker, Dr. Rebecca Zuurbier
6 from Georgetown University Hospital in Washington, D.C.

7 With respect to all other participants, we ask in
8 the interest of fairness that all persons making statements
9 or presentations disclose any current or previous financial
10 involvement with accreditation bodies, states doing
11 mammography inspections under contract to FDA, certifying
12 bodies, mobile units, breast implant imaging, consumer
13 complaints, and mammography equipment.

14 I would like to make an announcement for those who
15 have been anxiously awaiting the publication of the
16 Mammography Final Regulations. I do believe that they were
17 published today and we will try and get copies of the
18 document to the committee as soon as possible. We hope to
19 get it to them before the end of the meeting, but if not, we
20 will certainly mail it to the people.

21 DR. MONSEES: Thank you very much.

22 This is for the most part a new committee. There
23 are many new committee members and I am the new chair of
24 this committee, so what I ask is that people indulge me and

1 let me get used to this new role while we are trying to keep
2 the ball rolling in the right direction.

3 This is, of course, not a free-for-all. We would
4 like to have an organized discussion of interventional
5 mammography over the next two days. The questions which
6 were mailed to the panelists ahead of time, I hope you have
7 considered and you are ready to speak on some of these
8 issues.

9 Please speak your mind. If your opinion is not
10 concordant with others on the panel, that's okay. That is
11 what your job is, is to speak your mind here. So please ask
12 to be recognized even if you have a dissenting opinion. We
13 don't expect, I don't believe we expect to find that we are
14 going to achieve consensus on this panel.

15 What we want to do is air all of the issues that
16 are important to this matter, so that consideration can be
17 made as to whether or not interventional mammography should
18 be regulated and how, if it is, it will benefit the practice
19 of medicine and our patients in the community.

20 I will ask those of you who would like to speak to
21 raise your hand. Your mikes will be turned on by these
22 gentlemen over here when you are recognized. Please briefly
23 state what you would like to, please don't go off on a
24 tangent. If so, I will be forced to ask you to go back on

1 track. We do want to try to keep the agenda.

2 If you feel that you have a conflict of interest
3 about something that you are about to say, think again and
4 ask for advice from Dr. Finder, who we are all going to be
5 asking for advice for these matters, and he will point us in
6 the right direction.

7 Likewise, when we have the public hearing, we had
8 10 people on the agenda, we now have nine people on the
9 agenda. When you come to the microphone, we want to hear if
10 you have a conflict of interest. I want to know who you
11 are, who you represent. If you did not pay your own way, I
12 would like to hear who did, so that we will know whether
13 there is a conflict of interest from those of you who are
14 going to be speaking in the audience.

15 We are going to be doing didactic sessions after
16 the public hearing this morning and then this afternoon the
17 committee really starts its discussion, although I am sure
18 we will find some time and I am sure we will find some way
19 to interject some questions of the public speakers and the
20 people who are presenting during the course of the meeting.

21 Tomorrow, we will conclude the discussion of
22 interventional mammography. We are to skew it, so that
23 today we talk primarily about stereotactic core biopsy and
24 tomorrow I think we will probably start talking about some

1 of the other interventional procedures.

2 With that, I think we will go ahead and get
3 started.

4 **Alternative Standards Requests**

5 DR. FINDER: Let me briefly go over - we have a
6 10-minute session here to talk about alternative standards.
7 For the new members on the committee, let me just go over a
8 little what I am talking about.

9 In the regulations, there is a section that allows
10 certain groups, including facilities, to apply for an
11 alternative standard to the standard regulations. The
12 committee in the past has asked that they be updated on any
13 requests for alternative standards, and we have set aside
14 this time for that.

15 To make it brief, there were no requests for
16 alternative standards, so that is the end of that unless
17 anybody has any questions about the alternative standard
18 process.

19 **Open Public Hearing**

20 DR. MONSEES: Thank you all for being here and I
21 think we are going to be a very patient group. We are going
22 to respect each other's comments and we are going to say
23 what we need to say to get this job done.

24 We have nine speakers. Let me read to you the

1 order that we intend to hear people. Since we are starting
2 early, if somebody is not here, we will give an opportunity
3 to those who have come late.

4 We have Eleanor Sherman, Margaret Fay, Alan
5 Kravitz, Joseph Rush, Malee Shay, Philip Burns, Kambiz
6 Dowlat, Philip Israel, Armando Santelices, and Robert
7 Caplan.

8 That is the order that we have. There are a few
9 changes from this list.

10 Is Eleanor Sherman here? Ten minutes, Ms.
11 Sherman.

12 MS. SHERMAN: First, I am going to present for Dr.
13 Margaret Fay, who is unable to be here, and she asked me to
14 deliver it.

15 To the National Mammography Quality Assurance
16 Advisory Panel Members: I regret that I cannot be present
17 to express my interest and concern regarding appropriate
18 quality standards and regulations for mammography facilities
19 In my absence, I have asked Eleanor Sherman to read my
20 statement into the record.

21 As a patient who recently underwent breast
22 screening, ultrasound, and subsequent bilateral surgery for
23 multiple lesions, I would like to express my support for
24 interventional mammography standards and ask that this panel

1 incorporate specific infection control guidelines for
2 mammography equipment and practices.

3 Most women who enter a radiology procedure room to
4 have a routine mammogram or undergo an invasive diagnostic
5 procedure do not consider the possibility that contact with
6 equipment or interventional biopsy instruments may expose
7 them to infection through contamination of bloodborne
8 contaminated equipment. For women with non-intact skin,
9 damage dermatitis from radiation therapy, postmastectomy
10 wounds, or open wound contamination during the course of
11 biopsy, the risk is substantial.

12 In May 1997, I was subjected to an elective
13 mammogram, which confirmed the presence of multiple masses
14 in both breasts. The procedure was carried out at a highly
15 respected university-based women's health center.

16 After registration, I changed into a gown and was
17 escorted from the changing room to the mammography procedure
18 room. As I was entering the room, another woman was
19 exiting. I observed that no attempt was made to disinfect
20 the mammography unit, no handwashing facilities or sink were
21 available in the room.

22 No attempt was made by the mammography
23 technologist to disinfect the unit or wash her hands. No
24 antiseptic creams or disinfectant agents by which the

1 technologist could disinfect her hands prior to touching me
2 were noted in the room.

3 Further, the technologist did not wear gloves when
4 handling my breasts. I have multiple cutaneous skin lesions
5 on my torso, arms, legs, and back from an autoimmune
6 condition. My non-intact skin places me at greater risk of
7 infection from contact exposure to contaminated surface than
8 women with intact skin do. Yet, no steps were taken to
9 ensure the equipment was properly disinfected. The risk of
10 cross-contamination from the unwashed hands of the
11 mammography technologist placed me at risk.

12 Hippocrates relied on wine-soaked linen to protect
13 wounds. The English surgeon Joseph Lister described and
14 introduced aseptic technique in the 1860s. Today, adherence
15 to principles of asepsis are accepted standards of practice
16 and a key factor in reducing the risk of nosocomial
17 infection.

18 In a surgeon's office, when a needle biopsy is
19 carried out, aseptic practice is followed. The woman lies
20 on a clean table surface, equipment is sterilized, the
21 biopsy site is prepped with appropriate antimicrobial. The
22 physician dons sterile gloves, and the pathology specimen is
23 contained and labeled by a nurse wearing exam gloves. The
24 same standard of care is given in outpatient settings,

1 urgent care facilities, and even nursing homes.

2 When an I.V. is started, a dressing changed, a
3 laceration sutured, or a liver transplanted, health
4 professionals carry out routine asepsis to protect the
5 patient. They adhere to principles of aseptic practice in
6 an effort to reduce the risk of cross-contamination and to
7 ensure patient safety. However, if the needle biopsy is
8 carried out in the radiologist's office, or in a hospital
9 radiology department, most offices will not have autoclaves.
10 This is a double standard.

11 I believe the same standard of care should be
12 applied in mammography and radiology procedures as is
13 applied in hospital, surgical, and outpatient care centers.

14 I applaud the steps taken by the Center for
15 Devices and Radiological Health to date, however, I would
16 urge this committee to consider incorporating the following
17 recommendations into the 21 CFR MQSA regulations to ensure,
18 so far as possible, patient health and safety.

19 1. Principles of infection control should be
20 specified in the MQSA 21 CRF regulations for mammography,
21 and also, all radiological procedures. A method of auditing
22 compliance should be also delineated in the regulation.

23 2. Routine handwashing should be carried out
24 before and after patient contact.

1 3. Powder-free gloves should be worn by personnel
2 when touching patient's skin or tissue, when handling soiled
3 instruments, or touching potentially contaminated equipment.
4 Contamination may be caused by spontaneous nipple discharge
5 during patient breast compression, causing contamination of
6 the bucky and compression paddles with potential bloodborne
7 pathogens.

8 Literature shows that direct touch contamination
9 or aerosolized powder particulate may be the cause of
10 artifacts on x-ray films, possibly leading to diagnostic
11 errors and/or misdiagnosis.

12 4. All patient contact surfaces should be
13 thoroughly cleaned with a high level disinfectant
14 immediately after use before the next patient is brought
15 into the room. If equipment cannot be safely disinfected
16 due to construction and design of the equipment time
17 constraints, some form of nonattenuating FDA-approved
18 barrier drape should be employed to prevent direct contact
19 between the contaminated equipment and the patient.

20 5. During interventional procedures in which
21 blood or body fluid exposure is anticipated, the same
22 aseptic practices and infection control standards employed
23 in other clinical units, such as OR, ER, labor and delivery,
24 the cardiac cath lab should be adhered to in mammography and

1 all radiology procedure rooms.

2 6. The material used in cleaning equipment should
3 be regarded as clinical waste and should be disposed of
4 accordingly.

5 7. I would like to thank this committee for its
6 ongoing interest and for concern for the well-being of women
7 undergoing diagnostic interventional and stereotactic
8 procedures.

9 Sincerely, Margaret F. Fay, R.N., Ph.D.

10 DR. MONSEES: Thank you. if there are panel
11 members that have a question, do you feel that you can field
12 those?

13 MS. SHERMAN: I think I can. Dr. Fay also wrote
14 an additional letter, which is on the table. She specified
15 much more deeply the kinds of infections that the patient
16 would be exposed.

17 DR. MONSEES: Does anybody on the panel have a
18 question for the person who is not here, perhaps Ms. Sherman
19 can help to answer that question?

20 Yes, Dr. Hendrick.

21 DR. HENDRICK: It is Margaret Fay, is that right?

22 MS. SHERMAN: Yes.

23 DR. HENDRICK: Is she claiming to have contracted
24 an infection?

1 MS. SHERMAN: You asked me that a couple of years
2 ago. You wanted to know if another registered nurse, who
3 was contaminated, actually contracted --

4 DR. HENDRICK: That was a different case.

5 MS. SHERMAN: I know, but you wanted to see a
6 body. I mean you told me you wanted to see a body. She
7 just had this. I mean this was a very early procedure. I
8 don't know whether she contracted a disease, and I really
9 don't think it really matters whether she did because there
10 are 2 million cases of contracted infections done in a
11 hospital that we don't know where it is contracted from.

12 I don't think we have to see a woman dead in a
13 coffin before we do anything.

14 DR. HENDRICK: But her implication is that she
15 felt -- I mean she makes statements about the technologist
16 not washing her hands.

17 MS. SHERMAN: This is standard procedure. This is
18 from the CDC. I mean this is not new stuff.

19 DR. HENDRICK: I am asking about the specific
20 case. There is always the implication that something
21 happened in the letters or the people that you bring
22 forward, but there is no evidence that something happened
23 here.

24 MS. SHERMAN: She is still alive, thank God.

1 DR. HENDRICK: Well, good.

2 MS. SHERMAN: I mean I think it is a ridiculous
3 question and I really find it offensive that you want to see
4 a body before we start cleaning.

5 DR. HENDRICK: I don't want to see a body. I want
6 to know the full story about what happened.

7 MS. SHERMAN: I can just report that she was
8 exposed to contaminated equipment.

9 DR. MONSEES: All right. I have a question also,
10 if you don't mind.

11 This lady has an unusual circumstance in that she
12 had skin lesions, most women don't. Did she express her
13 concern to the technologist when she entered the room, so
14 that the technologist could take certain precautions? Did
15 she give that opportunity to the technologist?

16 MS. SHERMAN: I was not in the room, but I could
17 tell you that Margaret Fay was scared to death. She was
18 facing major reconstruction surgery, and she was the
19 patient, not the health care worker, and she -- this letter
20 that I just read into testimony spoke as the patient.

21 DR. MONSEES: Okay. Let's move on to you speaking
22 as Eleanor Sherman.

23 MS. SHERMAN: My name is Eleanor Sherman.

24 DR. MONSEES: Would you reset the clock, please.

1 MS. SHERMAN: And by the way, Margaret Fay has no
2 reason to make any money on this or is not affiliated with
3 anybody that is making -- so, there is no conflict of
4 interest that I know of anyway.

5 DR. MONSEES: How about yourself?

6 MS. SHERMAN: My name is Eleanor Sherman. I am
7 the president of Technowipe, Incorporated, which has nothing
8 to do really -- my voice is gone.

9 DR. MONSEES: Can you help us out with the mike?
10 She is having a hard time speaking up.

11 MS. SHERMAN: I manufacture lint-free wipes to
12 clean cassettes. Back in 1991, I was an x-ray technologist,
13 a mammographer, and I became very concerned about the
14 possibility of disease transmission, and since then I have
15 become an inventor and hold a patent on a disposable
16 protective barrier for the bucky and compression paddle. I
17 have not made a dime on it, so there is no economic, and I
18 am not licensed.

19 I will go on. I would like to take this
20 opportunity to thank the National Mammography Quality
21 Assurance Advisory Panel for the opportunity to share my
22 concerns. I am requesting specific protocols and education
23 for infection control procedures be incorporated into the
24 MQSA regulations, as well as an audit system to assure

1 compliance.

2 I would like to commend this panel for their
3 continued dedication and commitment to developing
4 mammography quality standards that will better assure early
5 detection of breast cancer.

6 I would also like to thank you for acknowledging
7 the potential risk of cross-contamination of bloodborne
8 pathogens by incorporating the need for infection control
9 procedures specified on page 14920 of 21 CFR Part 900, dated
10 April 3, 1996, in the Federal Register.

11 Again addressing your concerns about the need for
12 infection control procedures for mammography equipment as
13 published in the winter 1997 issue of Mammography Matters,
14 Volume 4, Issue 1, stating that the FDA expects the device
15 manufacturers to provide adequate cleaning and disinfecting
16 instructions or for providing the use of barrier devices as
17 preventive measures based on well-established infection
18 control procedures outlined in the Center for Disease
19 Control and Prevention Guidance documents on infection
20 control practices.

21 The winter issue of Mammography Matter alerts all
22 mammography facilities and their personnel they should be
23 aware of, and follow the cleaning and disinfecting
24 procedures recommended by each manufacturer for its own

1 devices. This wish for proper disinfecting cannot be
2 accomplished chemically and the device manufacturers have
3 not made barriers available for use for their specific
4 mammography equipment, not have the device manufacturers
5 provided appropriate disinfecting instructions for
6 bloodborne contaminated equipment that makes any practical
7 sense.

8 I have brought today and disseminated to the panel
9 members and left some issues on the table outside the most
10 recent issue of Clinical Focus, Volume 4, 1997, published in
11 the United Kingdom by Green Moon Healthcare.

12 Page 8 of this article has a peer review called,
13 "Breast Screening, Life-Saving or Life Threatening."
14 Reviewing an article that I co-authored with Margaret Fay
15 back in July of 1996, before Peggy's five masses were found,
16 and published in advance for science professions. The
17 article was titled, "MQSA, do Proposed Rules Fully Address
18 Infection Control?"

19 Clinical Focus highlights the following:
20 Screening mammography equipment is a source of carrying out
21 significant risk of cross-contamination between patients
22 caused by nipple discharge during the compression of the
23 breast. It validated that shaving under arms, eczema,
24 Paget's disease are likely to result in deposits of blood-

1 stained, serous fluid on the mammography equipment.

2 Certain pathogens, such as hepatitis or resistant
3 bacterial strains, can survive in dried secretion for
4 prolonged periods. The implications are clear, the article
5 cites, mammography equipment must not merely look clinically
6 clean, it must be clinically clean.

7 Clinical Focus peer reviewers go on to say that
8 although MQSA guidelines appear simple, in fact, they are
9 difficult to interpret. The article lists the potential
10 risks associated with a recommended high level chemical
11 disinfectants, such as damaging equipment, risking the
12 health of the mammographer, and the serious problems of high
13 level disinfectants pose to the patient.

14 It was apparent to the reviewers that high level
15 disinfecting, which requires soaking for 45 minutes and
16 rinsing with sterile water, is not possible. The reviewers
17 recommend for optimum infection control the use of
18 protective radiolucent sleeves over the equipment for use,
19 and concludes the mammogram is of particular interest
20 because it readily becomes part of the well woman practice.

21 The article also brings to light a very important
22 issue that is unique to mammography x-ray equipment. They
23 comment that most women will have at least one mammogram
24 during their adult lives in which healthy people mix

1 potentially on a very intimate level with ill people.
2 Professionals must therefore ensure that the mammography
3 center does not become a source of nosocomial colonization.
4 How many medical devices can you think of that are actually
5 shared by healthy population and ill people alike? The
6 answer is not many. Women should not have to share body
7 fluids of others to have a mammogram to detect saving their
8 lives from breast cancer and be forced to risk contracting a
9 bacteria or virus during this exam.

10 There are over 2 million nosocomial infections
11 occurring in the United States annually. We know that many
12 of these infections are caused by health care workers not
13 following aseptic technique, not washing their hands, and
14 studies have not been conducted how many are caused by lack
15 of cleanliness and disinfecting of medical devices.

16 Sinks and washing facilities are not placed in
17 most x-ray rooms. Technologists do not wash their hands
18 between patients and gloves are not worn. Consideration of
19 the powder that may be incorporated in those gloves is not
20 given. X-ray technologists touch body fluids, sick
21 patients, contaminating equipment.

22 Technologists pass these pathogens by touch by
23 cross-contaminating the control panel knobs and buttons that
24 are shared by many technologists through the course of the

1 working day without ever cleaning these surfaces.

2 Instructions for proper disinfecting, sanitation,
3 and hygiene are never given to technologists in their
4 training, and unique consideration due to the procedures we
5 do should be given.

6 For instance, Clinical Focus recommends the use of
7 disposable gloves, but if the gloves are selected that have
8 powder, this powder will create havoc for proper film
9 reading because of the artifacts the powder will create.

10 I have just read Peggy Fay's recent experience as
11 a patients since co-authoring our article 16 months ago.
12 Peggy has an autoimmune disease that causes her lesions on
13 her body. Peggy Fay could not have a safe mammogram because
14 there was no manufacturer of any mammography equipment that
15 made an FDA-approved barrier to protect the equipment from
16 potential cross-contamination coming between Peggy and
17 potentially contaminated equipment surfaces.

18 High level disinfecting was not possible for her.
19 What was Peggy's choice? Peggy was forced to risk having a
20 mammogram, which found five masses at the expense of
21 exposing her non-intact skin to potentially dangerous
22 pathogens.

23 Patients receiving radiation therapy are also
24 forced to make the same choice after receiving radiation

1 therapy, having compromised skin from the radiation
2 treatment, and others face the same risk from other
3 disorders.

4 The difference is that the other patients are not
5 informed and not told of their risk. This is wrong, this is
6 bad medicine, and this must be changed. This panel has the
7 power to make that change. Your panel is meeting today to
8 start to develop guidelines for interventional procedures
9 performed during mammography, such as stereotactic needle
10 biopsies. These procedures draw blood and that blood will
11 ooze onto the equipment surfaces, contaminating the bucky
12 and compression paddles. Only high level disinfecting or
13 sterilization or the approved infection control procedures
14 to follow. Technologists and physicians cannot offer only
15 an impression of hygiene, but must offer appropriate
16 disinfecting or barriers to protect the patients.

17 DR. MONSEES: Ms. Sherman, please sum up. We have
18 one minute left.

19 MS. SHERMAN: Clinical Focus confirms high level
20 chemical disinfecting is not possible. There is no reason
21 why a woman should have to share contaminated equipment that
22 may appear to be visibly clean, but that is actually
23 contaminated with bloodborne viruses or perhaps even
24 antibiotic-resistant bacteria.

1 I am therefore requesting this panel to
2 incorporate in the protocol for their inspection in order to
3 assure that the medical device manufacturers have provided
4 the facilities with instructions for low, intermediate, and
5 high level disinfecting in accordance with the Center for
6 Disease Control.

7 If barriers are available, that the amount of
8 barriers ordered match the patient load to assure that these
9 barriers are used and not reused. The device manufacturers
10 have not taken the lead, and have ignored the potential risk
11 posed by contaminated equipment.

12 I believe that only through assuring that
13 infection control guidelines published in MQA will be
14 implemented and no longer ignored is to have MQSA inspectors
15 ordered for infection control protocols during the
16 facilities. Technologists must be better informed through
17 education and standards developed that meet their unique
18 specifications. Proper education will save lives, reduce
19 infections, and reduce ultimate costs for health care.

20 I urge this committee to incorporate specific
21 infection control procedures in the MQSA guidelines along
22 with auditing them to assure safer and better mammography
23 and biopsy exams.

24 Thank you.

1 DR. MONSEES: Do we have any questions or comments
2 from panel members?

3 MS. SHERMAN: I would like to make one more
4 comment. You said most women do not have autoimmune disease
5 or skin lesions. That is not true. Many women,
6 particularly large-breasted women, will have dermatitis.
7 Other women will have scratch marks, bite marks, and there
8 are many diseases that do have irritation, bra irritation.
9 So, women are exposed. Women shave under their arms.

10 DR. MONSEES: Thank you for your comments.

11 We will move on to the next speaker, please. Dr.
12 Alan Kravitz. Is he in the audience?

13 DR. KRAVITZ: Yes.

14 My name is Dr. Alan Kravitz and I am a general
15 surgeon from Rockville, Maryland.

16 First of all, I would like to thank the committee
17 for allowing me to speak before it. I have never testified
18 before a government committee before, and I hope you will
19 find my thoughts appropriate and helpful.

20 I am Chief of Surgery at Shady Grove Adventist
21 Hospital in Rockville, Maryland. Almost three years ago,
22 minimally invasive breast surgery became a reality. My
23 fellow surgeons in Montgomery County were concerned that
24 none of our local hospitals had the capability to perform

1 stereotactic breast biopsies.

2 We organized into a corporation and purchased a
3 Lorad machine, so that we could offer our patients the most
4 up-to-date and minimally invasive capabilities to evaluate
5 mammographic abnormalities. We have done over 800
6 biopsies, which is more than any other facility in our area.
7 Still, not all of the local hospitals have acquired a
8 stereotactic machine.

9 I am very proud to say that almost all of the
10 general surgeons in our county are performing stereotactic
11 biopsies, and the number of open, wire localization biopsies
12 performed is much less than it had been.

13 I come to you today to share my concerns about
14 possible federal regulation of physicians performing these
15 biopsies and the adverse and unforeseen consequences that ma
16 await us.

17 It is important to realize the processes by which
18 surgeon learn new techniques. It has been said that
19 surgeons do not learn only operations in their residency,
20 but they also learn how to operate. The most recent example
21 of a new operation in my specialty was the laparoscopic
22 cholecystectomy, which was a radically new and less invasive
23 method of removing a diseased gallbladder. I am sure that
24 there are members of this audience and perhaps some on the

1 committee who have had this operation. It was a dramatic
2 departure from conventional open surgery. Although we
3 surgeons had removed many gallbladders, very few of us had
4 done much laparoscopy. Surgeons generally taught each other
5 this new operation. It was a very tricky operation at first
6 and the early ones lasted three hours with two to three
7 surgeons on each case. Now, of course, most of us can do it
8 in 45 minutes with two nurses as assistants. With 12
9 months, the surgeons in the United States radically changed
10 their treatment of gallbladder disease to minimally invasive
11 technique without the Federal Government helping their
12 credentialing.

13 This was done by hospitals, as is all
14 credentialing. In fact, new operations and surgical
15 techniques are continuously learned by surgeons in all
16 specialties without a hint of federal regulation. The
17 surgeons are bound by their duty to provide safe care for
18 their patients and by the need to avoid substandard care
19 which might leave them exposed to malpractice suits.

20 Credentialing for these new procedures is done b
21 hospitals and surgery centers. Indeed, these facilities are
22 required to perform the credentialing in order to obtain
23 their certification.

24 The stereotactic breast biopsy was no different

1 than any of these other new surgical techniques. For years,
2 surgeons have needed to be familiar with using the two-
3 dimensional mammogram to guide a three-dimensional surgical
4 biopsy. The wire localization procedure that the
5 stereotactic biopsy is replacing required the surgeon to be
6 able to do this. Performing a stereotactic breast biopsy is
7 just an extension of this skill.

8 It should also be noted that looking a mammograms
9 is part of the daily work of most breast surgeons, although
10 I know of no surgeons who interpret mammograms independently
11 of a radiologist. In fact, it is the radiologists who
12 trigger most of the referrals we see.

13 Although the Mammography Quality Standards Act has
14 done a great job of standardizing the mammographic
15 equipment, there is still great variability in the
16 interpretations by the radiologists. Some of our
17 radiologists seem more likely than others to label a
18 mammogram as "indeterminate." These mammograms also usually
19 include the recommendation that, "surgical consultation is
20 advised."

21 This means that it is often up to the surgeon to
22 decide which patients need immediate biopsy and which can be
23 followed with another mammogram. Fortunately, surgeons have
24 also been trained to perform breast examinations, and so we

1 generally feel comfortable following these patients in our
2 offices.

3 Most of the surgeons are very selective when
4 referring patients for any type of biopsy, in fact, at our
5 stereotactic facility, 23 percent of all biopsies were
6 either malignant or atypical.

7 But I am very concerned that the approaching hoof
8 beats of the federal cavalry may disrupt this established
9 system of breast screening. It would be counterproductive
10 to make it difficult for general surgeons to perform
11 minimally invasive biopsy surgery. We should be encouraging
12 surgeons to do this procedure. It should be public policy
13 to steer women to have stereotactic biopsies performed as
14 opposed to an open procedure.

15 Logically, a surgeon who is not allowed to perform
16 stereotactic biopsies will be more likely to recommend that
17 a patient get a wire localization biopsy -- which, by the
18 way, pays much better than the stereotactic procedure.

19 Just we are all trying to minimize the number of
20 mastectomies performed, imagine, if you will, what would
21 happen if the Federal Government in its infinite wisdom
22 began limiting the number of surgeons who are permitted to
23 perform lumpectomies. Those surgeons who are not allowed to
24 do lumpectomies would then do more mastectomies.

1 Confusing and difficult to enforce federal
2 regulations could make it hard for some patients to have
3 access to this new technique. It would also not make that
4 much sense for the Federal Government to begin credentialing
5 this minimally invasive technique, when similar
6 credentialing would not be done for more difficult and
7 dangerous operations, such as mastectomies and wire
8 localization techniques.

9 The other dark cloud that I see on the horizon is
10 the American College of Radiology, which I suspect would
11 like nothing better than to force women to have the
12 procedures performed only by radiologists. In my county,
13 most of the radiologists have never even done one, and many
14 of them have never even seen one, and it would not be in the
15 public interest to funnel patients in their direction.

16 I also review claims for the Cigna Health Plan in
17 the Baltimore-Washington area, and I can assure this
18 committee that surgeons all over the area are doing these
19 stereotactic procedures.

20 The other problem with having only radiologists
21 perform these procedures is that it will certainly increase
22 the number of unnecessary biopsies that are being done, and
23 many patients with so-called indeterminate mammograms will
24 get referred by the mammogram facility to a stereotactic

1 machine conveniently located at the same location.

2 This happens frequently with breast ultrasound,
3 and I have seen many patients get talked into an unwanted
4 and unnecessary breast ultrasound by an overly cautious
5 radiologist.

6 I know that this committee is aware of cases where
7 patients have received apparently substandard care with
8 regard to stereotactic breast biopsies. Unfortunately,
9 suboptimal outcomes can occur with any surgical procedure
10 including wire localization biopsy, lumpectomy, and
11 mastectomy. Even the safest surgical procedure in the most
12 capable of hands has the potential to turn into a bad
13 outcome. With this new procedure, dissatisfied patients
14 have been few and far between.

15 Mechanisms dealing with substandard medical care
16 are already in place at the state level. In Maryland, for
17 example, the Board of Physician Quality Assurance deals with
18 all patient complaints regarding inappropriate care.
19 Credentialing, as I have mentioned, is already done at the
20 hospitals and the facilities. It is unnecessary to add a
21 duplicate layer of federal regulation and bureaucracy.

22 In the hands of the community surgeons,
23 stereotactic breast biopsy has been very safe in our
24 experience and in our practice there have been no missed

1 cancers. The physicians are moving over to minimally
2 invasive breast surgery without any help from the Federal
3 Government, and we would like to continue doing so.

4 We appreciate the need to make sure that the
5 equipment is safe and accurate and that the technicians are
6 well trained. I hope that the Food and Drug Administration
7 will not take the plunge into credentialing physicians for a
8 surgical procedure. It is a task that they have had no
9 experience with and one which will not be the best interests
10 of our patients.

11 Thank you very much.

12 DR. MONSEES: Thank you for your comments.

13 Do we have any questions or comments from the
14 panel? Yes.

15 MR. MOBLEY: You noted in your comments that --
16 and I might not express this exactly as you did -- but you
17 noted that a number of referrals are made by radiologists to
18 surgeons because of the radiologist not clearly being able
19 to see one way or the other, make a determination.

20 Of those referrals, how many does the surgeon make
21 the clear determination not to do surgery, not to do further
22 followup or whatever just from evaluating the patient's film
23 or whatever?

24 DR. KRAVITZ: In this area -- let me explain a

1 little bit how the patient flow works -- in this area, this
2 is very heavily into managed care, so patients generally
3 don't see anybody without a referral. The general sequence
4 of events is that the patient has a mammogram, and sometimes
5 that mammogram will be interpreted as indeterminate with the
6 proviso that a surgical consultation is advised.

7 That report goes back to the primary care
8 physician. The primary care physician is then looking at
9 this report, and they don't want to deal with it. They
10 don't know what to do with it. So, that patient then always
11 gets referred to a surgeon -- I mean almost always.

12 The referral doesn't actually come from the
13 radiologist, they are not allowed to make referrals, but it
14 is what is written in the report that triggers the referral
15 to the surgeon. The surgeon then is left with looking at
16 this patient and wondering, you know, should we do a biopsy
17 or can we watch it.

18 A lot of times these are women in their 30s
19 getting mammograms, and still, you know, many of these
20 patients can be observed. We know that mammography for
21 women in their 30s is not that accurate and that often just
22 observation and followup mammogram is safe in six months,
23 but that decision is made by the surgeons, because we are
24 the ones who see the patient with the mammogram, and we are

1 the ones who have to make that decision.

2 MR. MOBLEY: I understand that. I am just trying
3 to get a handle on exactly where the decision is made
4 regarding the followup, and you are saying it is made with
5 the surgeon.

6 DR. KRAVITZ: Yes, it is.

7 MR. MOBLEY: Can you then give me an idea of how
8 many patients would not have surgery at that point in time?

9 DR. KRAVITZ: I don't really know. I have never
10 tabulated in our practice which percentage of patients with
11 indeterminate mammograms end up getting a biopsy. I am
12 guessing it is about -- it might be about half.

13 MR. MOBLEY: Thank you.

14 DR. MONSEES: Any other questions or comments from
15 the panelists? Yes.

16 DR. HENDRICK: I think I understood from your
17 comments that you are concerned about the Federal Government
18 regulating credentialing of physicians doing this procedure.
19 Do you also have concerns about credentialing of others
20 involved in the procedure, say, technologists, medical
21 physicists?

22 DR. KRAVITZ: No, I do not.

23 DR. HENDRICK: Or equipment standards being
24 propagated by the FDA?

1 DR. KRAVITZ: No. In fact, we are very happy with
2 that. We have been very -- surgeons, as a group, have been
3 very happy with the standardization of the mammograms. We,
4 as a specialty, used to struggle with substandard
5 mammograms, and now the mammograms, the films generally have
6 been of good quality, and we appreciate that.

7 DR. HENDRICK: Thank you.

8 DR. MONSEES: Thank you for your comments.

9 DR. KRAVITZ: Thank you very much.

10 DR. MONSEES: We will move on to the next speaker.

11 Dr. Joseph Rush. Is he in the audience?

12 [No response.]

13 DR. MONSEES: We will move then to the next
14 speaker. Malee Shay.

15 Please state who you are and who you represent.

16 MS. SHAY: My name is Malee Shay. I am a patient,
17 a concerned patient, and I am speaking on my own behalf and
18 on the behalf of other women that perhaps experienced what I
19 experienced.

20 DR. MONSEES: Can you speak into the microphone
21 and let me remind you, Ms. Shay, that you have 10 minutes.

22 MS. SHAY: Yes. I paid my own way this year and
23 last year. Okay. I reside in Seattle, Washington. One
24 year ago I spoke before this committee as a concerned

1 patient regarding my experience in undergoing a stereotactic
2 breast biopsy in 1993. I do not intend to repeat my
3 statements of 1996 today, as a copy of my prior comments
4 have been enclosed in the notebooks I have provided to you.
5 I have also provided newspaper articles and discovery
6 exhibits.

7 Since I am advised that presently two-thirds of
8 the committee is new, I believe a brief description of my
9 experience is in order.

10 In the fall of 1993, I was advised following a
11 routine mammogram that I had suspicious findings and
12 following magnified view, that I needed an immediate biopsy
13 of my left breast.

14 I was never shown the films, given a copy of the
15 report, or advised in any way by the radiologist of the
16 nature of the findings other than to be told that they were
17 suspicious for cancer.

18 I was caused to believe that the situation was
19 urgent, although I later found that the written report
20 described the findings as only mildly suspicious. My
21 primary care provider was a nurse practitioner who relied
22 solely on the recommendation of this radiologist, who was a
23 so-called expert in stereotactic core biopsies.

24 On the day of my magnified views, I was told by

1 several members of the staff that the radiologist would meet
2 with me regarding her findings and the upcoming biopsy
3 procedure, however, she chose to leave the clinic while I
4 was waiting for our meeting in the lobby. No meeting ever
5 occurred.

6 I am typically a very conscientious and informed
7 consumer. I was terrified. The staff reassured me that I
8 was in the hands of an expert and lucky to be in their
9 clinic. I agreed to the biopsy virtually without question.

10 In the radiologist's own words to my subsequent
11 doctor, the procedure was a disaster. In brief, I was not
12 properly anesthetized and experienced excruciating pain with
13 the taking of each of the 10 samples. There were two
14 physicians in the room, the radiologist who presumably had
15 read my films, and one who was never introduced to me, nor
16 identified in my medical records.

17 These physicians engaged in a continued argument
18 throughout the procedure as to how it ought to be performed.
19 Immediately after the first five samples were taken, I was
20 told they were all useless. Another five samples were then
21 taken.

22 The unidentified doctor did not return for the
23 second attempt. No vital signs were taken even though the
24 procedure took over two hours and I was administered Valium

1 throughout the entire procedure. I was black from bruising
2 on my entire left side completely down my rib cage.

3 Following the procedure, as a result of expressing
4 numerous concerns to my nurse practitioner, I was referred
5 to a highly regard breast surgeon who remains my current
6 physician. The radiologist clinic at which my biopsy had
7 been performed refused to release my records, thus
8 obstructing my medical care and requiring me to retain an
9 attorney to secure my records.

10 My new physician told me that in her view I had
11 not needed the biopsy at all and a blind second read of my
12 films by a second radiologist resulted in a clear diagnosis
13 of milk of calcium. To add insult to injury, one year later
14 when my mammograms were compared to the previous views, it
15 was discovered that the radiologist who performed my biopsy
16 had missed a clearly visible mass in my right breast, which
17 thankfully turned out to be benign.

18 I later raised questions concerning the lack of a
19 bill from the radiology clinic, and was cheerfully advised
20 there would be no bill because the procedure was considered
21 experimental. The clinic said the first hundred patients
22 would not be billed, only the insurance carriers would pay,
23 and pay they did as the clinic triple-billed my insurance
24 company, who later requested a partial refund.

1 In answer to my complaint that I was subjected to
2 an experimental procedure without my consent, the clinic
3 started also billing me and continued to do so on a monthly
4 basis until our state medical board started their formal
5 investigation.

6 My efforts to work with our state Quality
7 Assurance Commission were both frustrating and useless.
8 State medical boards cannot be relied upon to initiate or
9 enforce regulations. Although I submitted a 350-page
10 complaint with detailed documentation, in the end, which was
11 26 months later, they did not even address the refusal of
12 the clinic to release my records, which was a clear
13 violation of our State Health Care Information Act.

14 I also submitted my documentation to the American
15 College of Radiology, the King County Medical Society, and
16 the FDA. My present doctor, who is considered an expert in
17 breast disease, also wrote to your state board indicating
18 that my biopsy was predicated upon the acquisition of a new
19 piece of equipment rather than medical necessity.

20 In an effort to obtain full information about the
21 reasons behind my unfortunate experience with this
22 procedure, and in an effort to find some accountability for
23 what had occurred, I reluctantly commenced litigation
24 against the clinic and the radiologist in 1996.

1 That litigation has recently been resolved and
2 although I cannot discuss the terms of the agreement, I want
3 this committee to know that my primary motivation in
4 resolving the litigation was that I consider the work of
5 this committee and consumer awareness to be a much greater
6 issue.

7 I would like to share with the committee some of
8 the disturbing facts which were confirmed through our
9 investigation and the discovery process. Some issues don't
10 pertain directly to the stereotactic procedure, but show
11 what a consumer might face going through the process.

12 The radiologist who performed my procedure was and
13 is a well-educated, highly-credentialed physician, who
14 appears to have been well trained in breast imaging. She
15 came to Washington State and became employed at the clinic
16 where my procedure was performed approximately two months
17 prior to my biopsy.

18 None of the institutions at which she had worked
19 previously possessed a stereotactic table. She has since
20 been terminated by the facility and according to our
21 information, she is now in her second position since being
22 terminated. She is no longer practicing in Washington
23 State.

24 Mysteriously, after my suit was filed, the

1 radiology clinic seemed to dissolve and reappear under a new
2 corporate name. The table on which my biopsy took place was
3 manufactured by the Lorad Company. Although my physician
4 had apparently attended a seminar regarding the Fischer
5 table, she had absolutely no training or experience on the
6 Lorad table prior to coming to Seattle.

7 In spite of numerous requests for information over
8 three years, it took filing of a lawsuit for me to determine
9 that I was at the beginning of this physician's learning
10 curve. Documents obtained through litigation demonstrated
11 clearly that this physician was having repeated serious
12 problems performing this procedure prior to my biopsy. It
13 is on record that she had refused training in spite of
14 repeated recommendations by the manufacturer and distributor
15 of the table.

16 Documents also stated that the technicians at this
17 facility were overworked, distracted, and ill trained.

18 DR. MONSEES: Ms. Shay, sum up. You have between
19 one and two minutes left.

20 MS. SHAY: I have enclosed for you some of this
21 documentation and I would urge you to review it. I believe
22 it clearly demonstrates that the radiologist in my cases was
23 not competent in the procedure at the time of my biopsy.

24 This is information I deserve to be informed of

1 prior to making a very important decision regarding my
2 health care. I have also enclosed a letter written by the
3 radiologist to the manufacturer of the table. This letter
4 was written in response to a letter from the distributor of
5 the table to the director of the clinic.

6 In this correspondence, the radiologist admits
7 that other radiologists at this facility were having
8 problems and the table is blamed. She further describes a
9 case she was performing in which the needle passed
10 completely through the patient's breast. This incident
11 apparently occurred in the presence of an application
12 specialist who was attempted to train my radiologist.

13 These documents and other information obtained in
14 our lawsuit clearly paint the picture of a physician who was
15 not properly trained and who was knowingly experimenting on
16 unsuspecting patients.

17 Members of the committee, the issues before you
18 are extremely important to the thousands of American women
19 each year who find themselves in the same position as I was
20 in the fall of 1993. I consider these issues so important
21 that I have traveled here for the second time from Seattle,
22 Washington, to speak to you today.

23 I have chosen to resolve my lawsuit, so that my
24 interest in these greater issues will not be misconstrued.

1 According to one stereotactic expert with whom my attorney
2 has spoken, there are hundreds of physicians throughout the
3 country performing this procedure who are not properly
4 trained to do so.

5 He described it as the biggest mess he has ever
6 seen in the course of his long and distinguished medical
7 career. The health issues involved are too important to be
8 caught in the crossfire of a turf war between surgeons and
9 radiologists. I wish I had been given the opportunity to
10 consult with a surgeon who would have had much more
11 experience in the area of counseling patients regarding the
12 need for, and the specifics of, surgery.

13 Instead, I received no counsel whatsoever from a
14 radiologist who likely had spent her career detached from
15 the every-day physician-patient contact routinely
16 experienced by a breast surgeon.

17 However, I understand that there are aspects of
18 this procedure which demand expertise in radiologic
19 interpretation. Whatever the result of the struggle between
20 these two specialty areas, however, the overriding and
21 guiding principle must be that the physician performing the
22 procedure is adequately trained.

23 I am currently in the process of preparing a
24 document to submit to the Governor and selected legislators

1 in Washington State, focusing continued attention on this
2 issue, as well as exposing the ineffectiveness of our state
3 medical board.

4 My work has already generated media interest on
5 the state and national level, and I intend to continue to
6 pursue the issue of regulation and consumer awareness.

7 I am once again confirming the need for the
8 committee to implement strict guidelines and regulations to
9 ensure that this important medical procedure be performed on
10 informed patients by competently trained physicians. Please
11 keep the patient in mind.

12 Thank you.

13 DR. MONSEES: Thank you for your comments.

14 Is there anybody on the panel who would like to
15 make a comment or a question of Ms. Shay?

16 Thank you. Thank you very much.

17 We will move down to R. Philip Burns, physician.

18 DR. BURNS: Thank you, Dr. Monsees.

19 I am Philip Burns and I am a surgeon from
20 Chattanooga, Tennessee, and I represent the Advisory Council
21 of the American College of Surgeons here.

22 I appreciate the opportunity to address you and to
23 introduce my colleagues who are pioneers in the field of
24 image-guided breast biopsy, specifically stereotactic breast

1 biopsy.

2 I am a general surgeon. I am the Chairman of the
3 Department of Surgery at the University of Tennessee in
4 Chattanooga, and I serve in several capacities as regards
5 the College of Surgeons and the Southeastern Surgical
6 Congress in terms of program development and education.

7 I am also a practicing general surgeon with an
8 emphasis on breast disease, but I also perform vascular
9 surgery, as well as laparoscopic surgery in a variety of
10 disease states.

11 In our community, as has already been alluded
12 here, surgeons are the primary caregivers for breast
13 disease. We find that a lot of women are confused about the
14 status of breast disease and breast evaluation, and
15 mammogram is not enough to decide which patients absolutely
16 must and must not be treated. Physical examination and
17 clinical judgment are very important, and it falls to a lot
18 of the surgeons in our community to do that.

19 Three years ago we purchased a stereotactic biopsy
20 unit for our faculty. We placed it in our clinic. We have
21 made this technique available to both private and indigent
22 patients that we care for. We also utilize aggressively
23 ultrasound evaluation and ultrasound image biopsy, as well
24 as we have had a long-standing interest in ultrasound

1 through evaluation of vascular disease, as well.

2 Our residents are trained in the techniques of
3 breast disease evaluation and thusly, in our facilities,
4 stereotactic breast biopsy, ultrasound guided biopsy. They
5 perform these procedures under faculty guidance, and when
6 they leave our training program now, they are credentialed
7 in our mind to perform these procedures as they go into
8 practice. So, it has become an integral part of our
9 education program in Chattanooga.

10 We have published our data in peer-reviewed
11 journals in relationship to our statistics involving
12 patients from the initiation of utilization of this
13 procedure, but we have also published our data in terms of
14 the needle-directed excisional breast biopsy, as well. And,
15 by the way, our results in terms of malignancy rate,
16 incidents of biopsy related to BIRAD's classification of
17 breast lesions, is essentially the same between those two
18 studies which involves essentially patient cohorts that we
19 assume would be the same as they come to our clinic or
20 through our practice for their treatment.

21 We currently participate in the newly developed
22 image-guided breast biopsy registry that is coordinated at
23 the University of Louisville by Dr. Mike Edwards, and we
24 look forward to results from this nationwide in terms of the

1 assessment of this technique further in addition to that,
2 that we have in our local community.

3 We think that it is extremely important for long
4 term followup to be documented. This registry will help
5 with that a great deal in addition to augmenting our own
6 prospective analysis of this.

7 We perform approximately 600 core biopsies a year
8 in our facility. We frankly do a few more ultrasound-guided
9 biopsies than we do stereotactic biopsies, and again it
10 depends on the clinical judgment of the physician at the
11 time as to which you use.

12 It has already alluded to the fact that across the
13 country, this technology has exploded in the surgical
14 community, and that is because it is proven effective in
15 both the evaluation of breast disease and certainly, we
16 think, in reducing the fear and anxiety that women have of
17 breast disease, in that it is less invasive and in most
18 circumstances certainly far less painful to the patient.

19 My primary mission other than defining what I do
20 myself is to take the opportunity and the privilege to
21 identify or introduce you to my two colleagues who are here.
22 Some of you met them last year, those that are new to the
23 committee might not have met them. Dr. Phil Israel and Dr.
24 Kambiz Dowlat.

1 Dr. Israel is a pioneer in the clinical
2 application of stereotactic core biopsy, utilizing this
3 aggressively in his practice which is isolated to the
4 treatment of breast disease at the Breast Center in
5 Marietta, Georgia.

6 In addition to performing this procedure in over
7 5,000 patients, he has maintained a prospective analysis, he
8 and his group of physicians, maintained a prospective
9 analysis of their patients and have published them in peer-
10 reviewed journals, the earliest one being in the American
11 Surgeon in 1994 that detailed well over 500 cases performed
12 in the stereotactic setting.

13 He has also trained in a well-organized training
14 program 750 surgeons and 100 radiologists in the techniques
15 of stereotactic breast biopsy, and he has also been very
16 much involved in the development of the training courses
17 that have been offered in this technology at the
18 Southeastern Surgical Congress and at the American College
19 of Surgeons.

20 My other colleague is Dr. Kambiz Dowlat, who is
21 really the pioneer in both the research and clinical
22 applications of this technology. He is a professor at Rush
23 Medical School in Chicago, but early on developed a research
24 interest in this technique, spent a lot of time in Sweden,

1 then came back to the United States and brought the first
2 stereotactic biopsy unit to this country.

3 He applied it to the research setting first, then
4 to clinical application, and then published his first data in
5 1987. He has had multiple other publications since that
6 time.

7 His current research interestingly includes
8 interest in application of this stereotactic technique to
9 the treatment of breast cancer through the utilization of
10 laser technology and perhaps he will explain that to you
11 some when he talks.

12 We are really fortunate to have him agree, at the
13 College of Surgeons level, to spearhead the development of
14 our education courses in offering the opportunity for
15 surgeons around the country to come and learn the techniques
16 of image-guided breast biopsy. He has done a wonderful job
17 with this. We have regularly scheduled courses sponsored
18 and developed by the American College of Surgeons through
19 Dr. Dowlat's leadership.

20 At this point, I would like to let Dr. Dowlat take
21 the floor and proceed from this point.

22 Thank you very much.

23 DR. MONSEES: Thank you for your comments. We
24 will call upon Dr. Dowlat, please.

1 DR. DOWLAT: Good morning, ladies and gentlemen.

2 I would like to thank you for giving me the
3 opportunity to briefly go over specifically the course that
4 the American College of Surgeons has organized to teach and
5 train the individual physicians, surgeons, or radiologists,
6 or otherwise, to use this interventional technique.

7 DR. MONSEES: Sir, are you representing the
8 American College of Surgeons at this meeting?

9 DR. DOWLAT: I am sorry, no. Yes, I am, as Dr.
10 Burns said, I am a surgeon in Chicago, and the American
11 College of Surgeons has asked me to give an account of the
12 course that is given for training of the surgeons all over
13 the country.

14 DR. MONSEES: So you are representing the American
15 College of Surgeons at this meeting here?

16 DR. DOWLAT: Yes, I suppose that is correct.

17 DR. MONSEES: Thank you.

18 DR. DOWLAT: As Dr. Burns alluded early on, I was
19 involved in training and teaching of this technique from
20 years ago, independently, at the University of Chicago and
21 subsequently at Rush, to radiologists and to surgeons, and
22 more recently, because of the increased interest of the
23 surgeons from all over the country, we have organized these
24 regular courses on a three-monthly basis for whoever wants

1 to have the training.

2 Specifically, the courses are organized on a two-
3 day basis, didactic the first day, and the second day is
4 work stations where the trainees actually do procedures on
5 phantoms and examine live patients by ultrasound, so this is
6 a course given for image-guided breast biopsy including both
7 ultrasound and stereotaxic.

8 The faculty, we have a roster of 40 faculty, all
9 very distinguished individuals from all over the country
10 including radiologists. We have had the pleasure of having
11 Dr. Larry Bassett and Dr. Carl Dorsey. I would like to
12 acknowledge their teaching and their lecturing at this
13 course.

14 We also have had Dr. Laslo Tobar, an
15 internationally known lecturer and pioneer in mammography,
16 give a whole day course lecture and presentation to the
17 individuals. Also, I would like to acknowledge Dr. Robert
18 Pizzutiello, who has given the lecture on the medical
19 physics, as well as risks of radiation to the physicians.

20 These courses have been very successful. The
21 evaluation has been extremely favorable. More recently, we
22 have tried to also test the individuals who have taken the
23 course and to see how much they have actually learned, and
24 this again we are in the process of learning how to perform

1 this evaluation.

2 The trainees are asked questions before and after
3 using error system which seems to be very effective. It was
4 used for the ATLS training and we are trying to do the same
5 for the image-guided breast biopsy.

6 On the skill stations, we also tried to test the
7 individuals at the end of the day to see how much they have
8 actually learned, how to examine patients and how to
9 evaluate and obviously conduct interventional steps on
10 phantoms.

11 What are the future plans for us? We are offering
12 these course on a quarterly basis all over the country, and
13 we would like to come up with some kind of guidelines, which
14 I think Dr. Winchester and others will refer to later on in
15 terms of credentialing the physicians who take this course.

16 Obviously, they too require some preceptorship
17 after they take the course, and in order to start the
18 practice at their individual hospitals.

19 I think at this point I stop and take any
20 questions that you have.

21 DR. MONSEES: Thank you.

22 Do we have any questions from the panel or any
23 comments? Yes.

24 MR. MOBLEY: Is there any requirement that before

1 a surgeon would start doing this technique, that they would
2 have to take this course or a similar course?

3 DR. DOWLAT: Any particular requirement you mean
4 by previous training? The surgeons who come and register
5 for this course are those who have breast surgery as part of
6 their practice, and they would like to perform minimally
7 interventional biopsy technique, and there is no particular
8 qualification for that.

9 MR. MOBLEY: You said you hoped to develop
10 credentialing criteria or something to that effect, but in
11 essence, is there any requirement or any specific necessity
12 for a surgeon going through this training, or is it just
13 simply those that desire the training, get it, and those
14 that don't desire it, don't get it?

15 DR. DOWLAT: That is correct. These are the
16 individuals who desire to learn this, and because they
17 probably plan to perform the needle biopsy in their
18 community hospitals or wherever they practice.

19 I am sorry. They have to be board-certified
20 surgeons and obviously, to have their credentials in place.
21 I think this was well documented in statement by the College
22 of Surgeon published three years ago in the Bulletin of the
23 College of Surgeons.

24 DR. MONSEES: Another question.

1 MR. FLETCHER: Roland Fletcher. Do you have any
2 idea of the ratio between those who have taken this training
3 and those who have not, who are performing?

4 DR. DOWLAT: That is a very difficult question. I
5 guess we thought that there are about 2,000 surgeons in the
6 United States who practice breast surgery. The ones who
7 have taken to date, we have offered five courses, and I
8 would say over 500 of them, 500 surgeons have taken these
9 courses.

10 Besides this formal course, there are the private
11 courses given in the country. Maybe Dr. Philip Israel will
12 enlarge on that. I would say I think Dr. Burns mentioned
13 that 700 other surgeons have taken this course. There are
14 courses given by radiologists that surgeons participate and
15 learn this procedure, so some of them do it once, maybe some
16 do it twice, and so on.

17 MR. FLETCHER: Thank you.

18 DR. MONSEES: Yes. First, Dr. Smith.

19 DR. SMITH: Do you have an opinion, though, as to
20 whether these courses should be required or very strongly
21 encouraged rather than the pursuit of, let's say, on-the-job
22 training or just a general sense that this is doable? Ms.
23 Shay's material portrayed I think an extreme example of
24 someone who thought that they could get away without having

1 a course.

2 I guess the next question I would have is your
3 opinion as to whether or not there should be some
4 standardization, formal or informal, of course materials and
5 what sorts of materials are presented.

6 DR. DOWLAT: The answer to your first question is
7 yes, I think the technology has become quite complex now.
8 The first unit that I brought to the United States was very
9 simple. It was like an old car with four wheels and a
10 steering wheel and an engine, and you got into it and went
11 from A to B, but now you have got highly computerized
12 technology and it is becoming more and more complex.

13 There is quite a competition in the country,
14 therefore, the formal courses are necessary, I believe, in
15 order for the individuals who are going to practice this to
16 do it properly.

17 The answer to your second question is that we are
18 trying to standardize this and it is not very easy because
19 of the rapidly changing scene, both in stereotaxic and
20 ultrasound. We are, in fact, in the process of
21 standardizing the whole course from A to Z, so that each
22 part or each segment of it is given to an individual without
23 duplication or redundancies.

24 DR. MONSEES: We have another question down here.

1 Dr. Sickles next.

2 DR. SICKLES: Just to amplify on that, I
3 understand from your answer, then, that it is your opinion
4 that physicians, not just surgeons, but physicians who
5 perform these procedures should be educated and credentialed
6 in doing this, or just educated?

7 To amplify that, do you think that if they are to
8 be credentialed as opposed simply educated, that this should
9 require not only an initial education period, but continuing
10 education?

11 DR. DOWLAT: You are putting it in a very broad
12 term, Dr. Sickles. Education, that covers a whole lot of
13 things. Specifically, if you refer to the stereotaxic
14 needle biopsy, you really mean training in that particular
15 technology.

16 I think they should be trained in this technology.
17 Whether the credentialing I think should be renewable
18 because, for two reasons. This is something which an
19 individual may go back and don't practice it, and then maybe
20 two or three years later, comes and says no, I want to do
21 it. So, there should be some kind of monitoring or
22 regulation in that respect.

23 There is also the question of the complexity of
24 this technology. Initially, we used very simple, a fine-

1 needle aspiration, then core biopsy, then bigger cores, and
2 now ABBI system, and so on, and so on, and we are moving
3 into the area of treatment of these small breast tumors with
4 either excision or in-situ coagulation with laser.

5 So, the maintenance of proficiency, I think is
6 important, that it should be included in the future plans.

7 DR. MONSEES: Dr. Winchester, please.

8 DR. WINCHESTER: Following up on the sort of theme
9 of the questions of the committee, do you think it is
10 possible for any surgeon or any radiologist to just pick up
11 an article and seem to be interested in this procedure, and
12 then just start doing it in their hospital, or do you think
13 that local credentialing committees have some guidelines in
14 place locally to have some requirements for education and
15 proctoring at their local level based upon emerging
16 technologies?

17 I think it would be good to standardize that --
18 going back to Dr. Smith or Dr. Sickles -- it would be good
19 to have some kind of standard algorithm for the physicians
20 who would like to do this in order to help the credentialing
21 committees of the hospitals.

22 The credential committees are looking to the
23 bodies like American College of Radiology and American
24 College of Surgeons, and it would be good to have a joint

1 statement say these are the minimum amount of training
2 needed for the individual surgeon to start, and these are
3 the requirements for maintenance of proficiency.

4 DR. MONSEES: Mr. Pizzutiello.

5 MR. PIZZUTIELLO: Dr. Dowlat, we have been talking
6 primarily about surgeons who are currently in practice. Can
7 you tell us a little bit about how young surgeons going
8 through their residency training are learning this new
9 procedure and how that might be documented, so that it is
10 clear that they know what they are doing?

11 DR. DOWLAT: I think that is also recently being
12 agreed upon -- correct me, Dr. Winchester, if I am wrong --
13 that the American Board of Surgery has accepted to or is
14 planning to have this training system introduced or
15 implemented in the residency program, so that the residents
16 in their senior years take the course or take the training,
17 if they are going to be specifically breast surgeons, to be
18 competent.

19 DR. WINCHESTER: If I could just clarify that.

20 DR. MONSEES: Yes. Dr. Winchester.

21 DR. WINCHESTER: It has officially become part of
22 the required curriculum in general surgery, and thus will be
23 subject to review after completion of training in the form
24 of board certification. Both the written and qualifying

1 examinations will include this as part of the exam.

2 DR. MONSEES: Do we have any other comments? Yes,
3 Dr. Hendrick.

4 DR. HENDRICK: I have a couple of sort of clean-up
5 questions that I would like to ask. There was some allusion
6 to needing to be a board-certified surgeon to do these kinds
7 of procedures, is that correct now or not?

8 DR. DOWLAT: I think so. This is board-certified
9 surgeons are asked by their local credential committees,
10 surgeons, to be board certified in order to practice in
11 their committees. Again, Dr. Winchester, am I correct?

12 DR. MONSEES: Go ahead. Yes, you may.

13 DR. WINCHESTER: Not really. That is not stated
14 as a board certification requirement, and that was just in
15 an article in the Bulletin of the college a couple of years
16 ago. I don't believe we allude to it in the personnel
17 qualifications for either radiology or surgery.

18 DR. HENDRICK: Then, I had a couple of other
19 questions.

20 In your course that is I assume mainly aimed at
21 surgeons, can other people attend beyond the surgeons,
22 radiologists, or other physicians who aren't surgeons?

23 DR. DOWLAT: The course is offered to all
24 physicians, be it radiologists, surgeons, or gynecologists.

1 DR. HENDRICK: And in the course curriculum, as it
2 currently stands, are you including treatment guided by
3 stereotactic?

4 DR. DOWLAT: No, not currently. Currently, we
5 just focus on the diagnosis.

6 DR. HENDRICK: Thank you.

7 DR. DOWLAT: I also would like to thank you for
8 your contribution to the course. I forgot to mention that
9 early on.

10 DR. MONSEES: Are there any other questions?

11 If not, we will move on. Thank you very much.

12 DR. DOWLAT: My pleasure.

13 DR. MONSEES: Our next speaker is Dr. Philip
14 Israel.

15 Please state who you are.

16 DR. ISRAEL: Thank you. Members of the committee
17 and participants, thank you for the opportunity to speak
18 today. My name is Dr. Philip Israel and I am Director of
19 the Breast Center in Marietta/Atlanta.

20 I address the issue before us today from the
21 viewpoint of an individual private practice surgeon and also
22 on behalf of the American College of Surgeons. The purpose
23 of this hearing today is to consider the issue should
24 interventional mammography be regulated.

1 My remarks I would like to be underlined by an
2 overriding concern for quality of care and for the safety of
3 the patient. I personally have been involved in
4 stereotactic breast biopsy since 1991. I have had the
5 unique opportunity to observe this technology evolve both in
6 the radiology community, locally and nationally, and in the
7 surgical community.

8 I trained with Steve Parker in Denver. I have had
9 the opportunity over the last two and a half years to
10 participate in Dr. Parker's stereotactic and ultrasound
11 courses as a member of his faculty, so I have taught both
12 surgeons and radiologists, and I have seen them both
13 perform.

14 In our own center, we have six surgeons. I would
15 like to give you just a little background from where I am
16 coming. We have six surgeons in our center. We do only
17 breast work. We have access to three stereotactic units,
18 two of which are in surgery centers, one of which is in my
19 office.

20 We have done over 5,000 stereotactic breast
21 biopsies. We have kept I think extremely complete outcome
22 data. We have published our data in the American Surgeon in
23 1995, looking at the sensitivity and specificity and
24 accuracy of the procedure.

1 We have also been involved in training, and as
2 been mentioned, we have trained almost 1,000 radiologists
3 and surgeons over the last five years.

4 This committee, of course, is interested in
5 quality of care and assuring that the American woman gets
6 the best possible service. We want to know that experienced
7 and responsible individuals are doing these procedures.

8 From my viewpoint and my experience, I have been
9 very gratified in that the surgeons that we have taught have
10 self-selected themselves out of a large number of surgeons,
11 and these are surgeons that have large breast practices,
12 they know about this technology, they want to be involved,
13 and from my experience, they are eminently qualified into
14 moving into this area of stereotactic breast biopsy.

15 I have seen them go out into their communities
16 around the country. Many of them have opened breast centers
17 themselves since they were primarily doing a majority of
18 their work in breast, and they have all kept good auditing
19 outcome data. I am in constant touch with these doctors,
20 and I am very pleased that they have made sure that they
21 have received the maximum training.

22 They attend, not just one and not just two
23 courses, they attend multiple courses, they do it annually,
24 they work on their imaging skills, and I am very proud to

1 say that I think they have been very responsible.

2 On the other hand, in my own community, I have
3 offered to train any surgeon, free of charge, that wants to
4 do stereotactic breast biopsy. Many of these surgeons do
5 very little breast work. Some of those surgeons, out of
6 curiosity I think, have taken advantage of my offer and they
7 have been trained, but interestingly enough, they have not
8 shown up to do stereotactic work.

9 I think this self-selection process on the part of
10 the surgeon is probably the best credentialing that we can
11 rely on, and what I am seeing is that the surgeons who are
12 not interested, who are not heavily involved in breast work,
13 are not trying to do this procedure.

14 Surgeons are embracing this technology in an
15 amazing manner around this country, and all of the major
16 surgical organizations, including the American College of
17 Surgeons, the American Society of General Surgeons, the
18 Southeastern Surgical Congress, and all the state surgical
19 societies are offering courses to interested individuals,
20 and these courses almost always are oversubscribed by the
21 surgeons.

22 The stereotactic units that are being installed
23 around this country, there has been an enormous shift in
24 where these units are going. For the first four or five

1 years, they went into radiology departments and mammography
2 centers. That is no longer the case.

3 Recently, the majority of these units are going
4 into operating rooms and into free-standing surgical
5 centers.

6 An interesting advance is all of this technology
7 has been the explosion of the needle technology. The
8 engineers for the surgical companies in this country are
9 really becoming involved. They are producing new types of
10 instruments to collect tissue. Some of these instruments
11 collect very large portions of tissue, such as the ABBI and
12 a new instrument that I saw at the American College of
13 Surgeons in Chicago a few weeks ago.

14 These collection devices or biopsy devices require
15 almost a surgical procedure. They require a large incision.
16 It results in harvesting a large amount of tissue. It
17 involves suturing an incision and bleeding control and wound
18 management, of course, of which surgeons are, I think,
19 eminently qualified.

20 As a second thought, I see that if the FDA does
21 become involved in credentialing and monitoring this type of
22 operative procedure, it is going to make a drastic change in
23 the makeup of your committee.

24 You will have to have surgeons, a lot more

1 surgeons involved. You will have to have operating room
2 supervisors, operating room technicians, and probably even
3 monitors going into operating rooms to evaluate sterility,
4 wound management, and all the other myriad of things that go
5 into surgical biopsies.

6 The surgeons have started a national data
7 registry, looking at and tracking the indications for breast
8 biopsies, for stereotactic breast biopsies, the type of
9 breast biopsy is this stereotactic or ultrasound, the type
10 of instrument used to collect the tissue, of which, as I
11 have mentioned, there are a myriad of instruments today, and
12 this will track the false negatives, the false positives,
13 the accuracy of the procedure, as well as the complications.

14 This has been set up by Dr. Mike Edwards at the
15 University of Louisville, and all of the surgeons in the
16 country that have been recognized, that are doing these
17 procedures, have been sent data collection sheets, and are
18 contributing data.

19 I was very interested in the public testimony this
20 morning because most of the complaints and the problems in
21 the public sector have to do with the surgical aspect of
22 this procedure, and not the imaging aspect.

23 It has to do with non-surgeons who are now moving
24 into the arena of performing breast biopsies, where they

1 have to deal with sterility, informed consent. This is
2 where I think the public is having a problem.

3 Fortunately, these are issues that surgeons will
4 have no problem with. Surgeons have dealt with sterility
5 for decades, we deal with it every day. Informed consent,
6 we tried stereotactic breast biopsy as if it is an operative
7 procedure, not an extension of the mammogram, which means we
8 get informed consent, we talk to the patient about options.
9 There is a bonding with the patient. We do a good physical
10 examination to make sure there is no coexisting disease.
11 This is part of our modus operandi on a regular basis.

12 Other, non-surgeons, are going to have to acquire
13 these skills in order to satisfy the consumer, and not
14 create the kind of problems that we are hearing testimony
15 about today.

16 I will end my comments at this point and entertain
17 any questions that there are.

18 DR. MONSEES: Thank you.

19 Do we have any questions or comments from the
20 panel? Yes, Dr. Farrell.

21 DR. MOORE-FARRELL: What needle system are you
22 predominantly using or do you have one that you use mostly?

23 DR. ISRAEL: Fortunately, we have had experience
24 with almost all of the needle technology. We have not

1 abandoned the standard, 14-gauge TruCut. That is part of
2 our armamentarium. Certainly, suction device instruments
3 like the Mammatome. We do all of our microcalcifications
4 with Mammatome. We do most of our nodular densities with
5 14-gauge or 12-gauge TruCut.

6 DR. MOORE-FARRELL: On the Mammatome, are you
7 using the 14 gauge or the 11 gauge?

8 DR. ISRAEL: Initially, we used both, but all of
9 the seven doctors in my group have migrated towards the
10 larger needle. We collect more tissue with that, and we
11 don't have any additional pain or bleeding.

12 DR. MONSEES: Dr. Sickles.

13 DR. SICKLES: Is it your contention from your
14 experience as a teacher and going around the country, that
15 all surgeons now performing this procedure are fully trained
16 in doing it?

17 DR. ISRAEL: Of course, I can't answer that
18 because I don't know all of the surgeons that are doing
19 stereotactic biopsy, but I am impressed at those that I am
20 aware of that are doing it, appear to be doing it in a very,
21 very responsible manner, and are showing up at meeting after
22 meeting after meeting and really making a conscientious
23 effort to become trained and specialist in this area.

24 DR. SICKLES: Do you tend to see the same people

1 coming back?

2 DR. ISRAEL: We see a lot of the same people
3 coming back in addition to individuals who are testing the
4 water to see if they want to become involved, and as I have
5 said before, generally, this is a self-selection process and
6 those doctors who have high volume breast practices are the
7 ones that want to and are getting involved.

8 DR. SICKLES: I understand that. Are you aware of
9 any surgeons or, for that matter non-surgeons, who are doing
10 this procedure, who are not trained?

11 DR. ISRAEL: Yes.

12 DR. SICKLES: So there are such.

13 DR. ISRAEL: Yes.

14 DR. MONSEES: Dr. Dempsey.

15 DR. DEMPSEY: Dr. Israel, I just want to clarify
16 your statement at the end there. Are you saying that only
17 surgeons talk to the patient and obtain informed consent for
18 this procedure, because that is what your statement kind of
19 --

20 DR. ISRAEL: No, I think that the complaints that
21 we hear before this committee are involved with lack of
22 informed consent, lack of bonding, lack of communication
23 with the doctors they have encountered, and I limit my
24 remarks to that. Certainly, radiologists talk to patients,

1 surgeons talk to patients. I think that there will be
2 certainly varying degrees of personal involvement by the
3 physician.

4 I would say that I think that surgeons are more
5 accustomed to interacting with patients prior to a
6 procedure, doing physical examinations, giving options, and
7 receiving informed consent, but I think this is an area that
8 the radiologists will have to improve upon since it is not,
9 has not been in the past a part of their general approach
10 would be my opinion.

11 DR. DEMPSEY: Even in things like interventional
12 radiology?

13 DR. ISRAEL: I don't want to extend my remarks to
14 that area because I have no information about that.

15 DR. DEMPSEY: The blanket statement was out there
16 and I just wanted to clarify that.

17 DR. ISRAEL: I don't want to leave any false
18 impression. Certainly, I think that radiologists, as
19 mammographers in particular, who focus in this area, can do
20 all of these facets of interacting as well as a surgeon.

21 DR. MONSEES: Dr. Smith.

22 DR. SMITH: Two questions on the last point. The
23 issue of dealing with informed consent, patient reassurance,
24 that sort of thing, could be strongly emphasized in courses

1 any physicians were taking.

2 DR. ISRAEL: Yes.

3 DR. SMITH: I presume that is in the courses that
4 you are teaching.

5 DR. ISRAEL: Yes.

6 DR. SMITH: The next question is, is it your
7 opinion that after one of these courses, which typically
8 runs over two to three days, the physician who has taken
9 this course for the first time, are they fully competent to
10 begin performing these procedures on their own?

11 You emphasized that you get a lot of repeat
12 attendance, so obviously people are coming back to hear new
13 ideas, but perhaps they are also coming back to reinforce
14 the training that they have already had, benefiting from
15 some redundancy.

16 So, the question is, I mean a weekend happens to
17 be a period of time off, it works out that way, and it is
18 only so long. Do people coming back from these courses, are
19 they ready to go in your judgment or what else might be
20 required?

21 DR. ISRAEL: I think we weekend course is a
22 beginning. It's not the middle and it's not the end. It's
23 the beginning of a learning process for surgeon and
24 radiologists. I think both radiologists and surgeons will

1 recognize that you will not learn to do this procedure in a
2 weekend. It is more like an art form. It's like asking a
3 painter, when they are fully trained, I think every day an
4 artist learns to improve his technique, and I think these
5 procedures are no different.

6 The imaging skills, the surgical skills, the
7 communication skills can always be improved. It's a
8 continuing learning process.

9 DR. MONSEES: Yes.

10 MS. HEINLEIN: Dr. Israel, what personnel are
11 involved in the procedure? I mean is it you and a nurse, is
12 it you and a technologist, is it only you? Can you share
13 that with us?

14 DR. ISRAEL: It is myself and a technologist. In
15 our teaching, we certainly recommend that no radiologist and
16 no surgeon do this procedure without a double-registered
17 technologist. However, I think that the physician always
18 has to be in control, the technologist does not make the
19 decision this is the lesion to be biopsied. The
20 technologist does not mark the area of access for the cores.
21 That relationship has to be established and maintained.

22 In our center, we do not involve a radiologist. A
23 radiologist has never been in our center for the 5,000 cores
24 that we have harvested. This was a very hard decision for

1 us, because in a way we were very much pioneers at this
2 time.

3 When we started doing this procedure -- do I have
4 a moment to answer that question, maybe a minute -- when we
5 started doing this procedure, I actually lobbied the
6 radiologists in my community to get a stereotactic unit for
7 two years, and it was never done.

8 A surgical center offered to buy the equipment and
9 I said, yes, please buy it, this technology needs to be
10 offered in this community. At that time, I already had four
11 years of breast only, and I had improved my imaging skills,
12 but I had to make the decision am I competent with my
13 imaging skills to do this without radiology assistance, and
14 I gave this a lot of serious consideration.

15 In the end, I said yes, I think I can do this, and
16 so we embarked in that manner, and we have not had any
17 radiology assistance in image interpretation in our center.

18 DR. MONSEES: Do we have any other questions here?

19 I would like to just ask a brief question. I am a
20 little confused because one of the major advantages that
21 accrue to patients who undergo stereotactic core biopsy is
22 that it has moved the biopsy procedure out of the operating
23 room into an office type practice, and we have done less and
24 less invasive things.

1 Do I get from the drift of what you described
2 having seen at the American College of Surgeons with more
3 invasive biopsy devices, that you see an advantage to those
4 larger core devices, one, and two, are you predicting a move
5 back to the operating room when, in fact, we were raving
6 over the last couple of years about a major advantage that
7 we have moved out of the operating room?

8 DR. ISRAEL: Thank you for asking those questions
9 because they are very important. Personally, I don't like
10 the larger core biopsy instruments. They don't serve my
11 purpose. I want to make a diagnosis with this instrument.
12 I can do it with much smaller needle devices.

13 The second part of your question, do we want to
14 see these procedures moved back into the operating room?
15 Absolutely not. When the device is placed in an operating
16 room arena, it usually is placed in an area where outpatient
17 surgery is performed, separate from the actual operating
18 room area.

19 So, I think that we must, first of all, make a
20 commitment to continue minimally invasive work. We don't
21 need to make a 2-centimeter incision to achieve a diagnosis,
22 but there are some doctors that don't agree with me, and
23 they feel more comfortable using larger core instruments.

24 I think the practicing habits of the doctors will

1 eventually determine which of these biopsy instruments will
2 survive and which will fail, but I certainly support
3 minimally invasive work in an outpatient setting.

4 DR. MONSEES: Thank you.

5 Do we have any other final questions here?

6 Thank you very much.

7 DR. ISRAEL: Thank you.

8 We will move on to Dr. Armando Santelices.

9 DR. SANTELICES: Good morning and, first of all,
10 thank you very much for allowing me the opportunity to come
11 once again and testify before this panel. I bring you
12 greetings from South Florida, the world champions.

13 DR. MONSEES: Dr. Santelices, are you representing
14 yourself or an organization?

15 DR. SANTELICES: I am going to give you a long
16 list.

17 DR. MONSEES: Thank you.

18 DR. SANTELICES: First and foremost, I am
19 representing myself. I have a breast center which was
20 opened in 1991. My numbers are not as staggering as Dr.
21 Israel, but I have done over 2,000 biopsies. The machine
22 that was placed in my center was machine number 98,
23 manufactured by the Fischer Company.

24 Like Dr. Israel, I took my first training with Dr.

1 Parker, which by the way, created the first turf battle
2 because at the end of his lecture, he had a radiologist
3 stabbing a surgeon with a Bard-Parker needle and saying that
4 in the future, breast biopsies would be in the domain of
5 radiologists, not surgeons. So, that is one conflict,
6 because obviously I am representing my personal interest,
7 but obviously, my interests are of my patients.

8 I am also the new medical director of a center of
9 excellence for Health South that has been created in South
10 Florida, which will have a multidisciplinary approach to
11 breast diseases including radiologists, nutritionists,
12 psychologists, internists, and surgeons.

13 My plane ticket was purchased by the American
14 Society of Breast Surgeons. Yesterday, I received a phone
15 call from Dr. Caplan, who said if I wouldn't mind reading a
16 letter that he would prepare for you, and that as a return,
17 he would pay for the plane ticket. I would have read the
18 letter anyway, but if he was going to pay for the plane
19 ticket, of course, I took it.

20 Last but not least, I am currently under
21 negotiations to enter into a contract agreement with U.S.
22 Surgical, because of the research and development that is
23 being done with regards to new needles. In addition to
24 this, U.S. Surgical Corporation just bought out a company

1 called Neovision, who does sonographically-guided, computer-
2 guided biopsies, and my center was one of the clinical trial
3 centers, and we have done over 100 ultrasound-guided
4 biopsies uses computer technology.

5 So, I think that will give you a brief overview of
6 all my conflict of interest. I would like for the record
7 also to state that I am not board certified, and therefore,
8 if we follow the board certification route, I would be out
9 of the picture immediately. I have been 17 years in private
10 practice, I have never been sued once. I am the Chief of
11 Surgery at Palmetto General Hospital and I have been there
12 for the last eight years.

13 Giving you an overview of where I come from, I
14 still think of myself as a country doctor. My credentials
15 are not gigantic and I have never published a paper on
16 stereotactic biopsies, basically, because every time I saw a
17 paper, the numbers that I saw mimic mine, and I didn't think
18 I had anything else to add.

19 They say an expert is one who creates and writes a
20 lot of papers, so I guess in that respect I am not an
21 expert, but I know the definition of an expert is somebody
22 who come and travels 500 miles away from their home and
23 testifies, so in that case I may be an expert.

24 When stereotactic biopsy started to become

1 something that was written in the literature, it started out
2 in Sweden with Dr. Laslo Tobar, and he started doing work
3 with fine-needle aspirations.

4 As a surgical resident, every time we need a
5 needle wire localization, and we had to go in there and
6 extract a piece of tissue, humongously large, and sometimes
7 the incision would be done at what I call Tallahassee,
8 Florida, and the needle wire would be at Key West, I always
9 kept asking myself is there a better mousetrap, is there a
10 better way.

11 When I started reading up on it, and I became
12 aware of the advent of this machine, I went ahead and leased
13 one, I didn't purchase one, no down payment with the lease,
14 and I took a risk and I put the machine to work.

15 As I stated, I took the course with Dr. Parker,
16 and following that, and we did lots of eggplants, never a
17 patient, I prepared myself to start stereotactic biopsy work
18 utilizing a very, very narrow group of patients. I didn't
19 go for the micros at first, and I didn't go for lesions that
20 were less than 1 centimeter in order to acquire a learning
21 curve of my own.

22 No course and no weekend course can give you that
23 kind of experience unfortunately, and no matter how much
24 they charge you for it, they are not ever going to let you

1 make the cut in the lady and put the needle. That is
2 something that sooner or later you have to do on your own or
3 with preceptorship, which is not what is coming about.

4 Because I was a surgeon, the first surgeon in the
5 State of Florida to do this, I felt it was very important to
6 keep numbers, because I know sooner or later somebody was
7 going to try to hammer me in the head with it, I was called
8 a quack. My own surgical group felt that this was
9 inappropriate, and the radiologists weren't buying into it
10 at the time. I am happy to see that now it has become a
11 matter of who is going to do it and when.

12 So, obviously, those of us who had first started
13 at this, and like Dr. Israel, can sit here and feel
14 gratified that our forethought or our vision came to.

15 I am here to say that I am very concerned when
16 something becomes so regulated that it may exclude the likes
17 of myself. I know this sounds self-serving, but it is the
18 truth. I am not board certified and I don't have four hours
19 of radiation physics. Does that mean I can't do it?

20 At the same token, if I was board certified, and I
21 took a weekend course, does that mean I know how to do it?
22 So, my presence here is to make sure that when you make your
23 decision, first of all, it is not political; second of all,
24 that you take in consideration that there are individuals,

1 such as myself, that may be adversely affected; but, most
2 important, whatever decision you do be for the patients'
3 welfare.

4 I don't have a problems with radiologists doing
5 this procedure if they are trained in surgical techniques,
6 just like the radiologists should not have a problem if I
7 told them I know how to interpret a mammogram. I don't read
8 them, I know my BIRADs.

9 As a matter of fact, as a surgeon, I go to
10 probably more radiology meetings than I go to surgical
11 meetings, because in order to be "a breast surgeon with
12 imaging experience," that is where I need to go.

13 The American College has not put a course yet on
14 how to interpret mammography, and you don't sit there and go
15 from screen to screen to screen, and look at 40 cases and
16 test yourself, but the American College of Radiologists
17 does, and I have taken that course.

18 So, what I am asking you to do is please consider
19 the possibility of creating a set of regulations that does
20 not exclude, but actually includes, that it makes sure that
21 it addresses the real needs, which may not be some of the
22 needs that have been addressed today, it may be all the
23 needs that were addressed today.

24 The patient is the ultimate recipient of our

1 knowledge, our technology, and our care and our love and our
2 attention, and a lot of that cannot be learned in a two-day
3 course, and certainly board certification does not give you
4 that.

5 The light still is green. I think I have about
6 2.8 minutes, so what I will do is I will leave it open for
7 any questions, because a question sometimes allows me to
8 expand on a subject. I didn't come with a written
9 testimony, so I did it off the cuff, so I would rather just
10 answer questions.

11 DR. MONSEES: Thank you, sir.

12 Do we have any questions from the panel? Yes.

13 DR. SICKLES: You had sort of side statement that
14 I would clarify. I understand your concerns about
15 regulations that require board certification because that is
16 an extremely difficult thing to acquire.

17 On the other hand, in with that you talked about a
18 few hours of education in radiation physics. Do you not
19 feel it is important to have some understanding of the way
20 in which the equipment that produces the x-rays that you are
21 using works, so that if it isn't working, you might
22 understand how it would --

23 DR. SANTELICES: I certainly agree with that. As
24 a trained surgeon, I did interpretive cholangiograms for God

1 know how many years, and I certainly utilized fluoroscopy at
2 the time, and part of my training was learning about the
3 radiation hazards that occur, and the stuff that occurs with
4 that. And by the way, at 2 o'clock in the morning,
5 interpretive cholangiogram seldom gets read by a radiologist
6 at that moment, so I was also taught to interpret radiologic
7 findings at the time of an emergency, and when I trained in
8 trauma, and we did a peripheral vascular study for a gunshot
9 wound and did an arteriogram, I certainly was almost self-
10 trained in the sense that your senior resident teaches you,
11 and you teach the lower resident to interpret.

12 So, yes, I don't disagree that the training has to
13 occur. I am very concerned of starting to put four hours of
14 this, three hours of that, two hours of the other, because
15 in the State of Florida, I have five of HIV, two of domestic
16 violence -- I can give you a list, and it goes on and goes
17 on. That's all.

18 DR. SICKLES: But you do understand that a certain
19 amount of basic training might be needed?

20 DR. SANTELICES: Of course, yes, sir. I have no
21 qualms with that.

22 DR. MONSEES: Yes.

23 MR. FLETCHER: At the time that you began and
24 essentially self-taught --

1 DR. SANTELICES: No, I was trained by Dr. Parker
2 with an eggplant and an olive inside. By the way, I got
3 green, red, green, and that means I got it right in the
4 center, the pimento, you know, the pimento-filled olive.

5 MR. FLETCHER: I guess my question is, with the
6 courses that are available now, how would you advise a
7 young surgeon who wanted to do this?

8 DR. SANTELICES: I would not only recommend, but
9 as the Chairman of the Credentials Committee of my hospital,
10 I demanded that whoever wanted to do stereotactic biopsies
11 present with a course, knowing quite well that the course
12 may only be the beginning, but at least gave us an idea that
13 this individual had at least went somewhere and took the
14 necessary preliminary teachings required for this. I took
15 the course, you know.

16 But the question still remains is that course the
17 end-all to the end-all, and I think Dr. Israel stated quite
18 clearly that it's just the beginning, it's a continuous
19 learning process.

20 Yes, sir?

21 MR. MOBLEY: You noted the lack of a requirement
22 for a preceptorship or you made some statement regarding
23 that, and you are saying there that there is a need from
24 your perspective as the chair at your hospital, there is a

1 need for the basic training.

2 What kind of proposal would you make regarding the
3 preceptorship?

4 DR. SANTELICES: I think that there has been a
5 document that came out between the American College of
6 Surgeons and American College of Radiology, that pretty much
7 deals with it. The proposal -- I am not here to actually,
8 and I am sorry, I may be here not fixing the wheel, but at
9 the same token, I am not going to give you numbers -- there
10 is a proposal on the table, 12 has been the number that I
11 think has come out.

12 It is not a scientific number, by the way. There
13 is no way or no mathematic equation to come out that if you
14 did 12, then, you are an expert, because Shay here, her
15 doctor may have done 13, and she got into trouble.

16 At the same token, I think that 12 was a result of
17 one per month, 480 mammograms was the result in my mind of
18 40 per month, 10 per week. Is there a scientific basis into
19 a learning curve? I don't think so. I think that better
20 off would be to have the preceptor sign off on the
21 candidate. It may take him one, it may take him 200. He
22 might should change the job if it's 200.

23 MR. MOBLEY: I asked you the question because you
24 seemed to be out there --

1 DR. SANTELICES: In the fringes. I am
2 disenfranchised. I don't even get a letter requesting my
3 information. You know, if you don't publish, you perish,
4 but I am, like I told you, I am not here to pretentious, I
5 am just a Hialeah boy and doing my job.

6 MR. MOBLEY: Thank you. By the way, I am not a
7 boy anymore, I am getting older.

8 MS. HEINLEIN: You used a table --

9 DR. SANTELICES: Yes, ma'am, I use the Fischer. I
10 have had it for six years. I started out the oldfangled
11 little thing you put the films on, and I am now into
12 digital, I am into computer guidance, and I am still paying
13 the lease company because every time I buy a new piece of
14 equipment, there goes the bill again.

15 MS. HEINLEIN: What personnel are involved while
16 the procedure is going on?

17 DR. SANTELICES: I have a double-certified
18 mammographer. I stole her from the hospital. She has over
19 20 years experience. But she was being asked to do barium
20 enemas and upper GI's, and the like, so when I gave her the
21 opportunity to do strictly breast, she took it, and I took
22 her, and she has been with me ever since.

23 DR. MONSEES: Any other questions from the panel?

24 Okay. We will move on to our last scheduled

1 speaker.

2 DR. SANTELICES: Thank you very much.

3 DR. MONSEES: That you very much.

4 DR. SANTELICES: Now comes my plane ticket.

5 DR. MONSEES: Excuse me?

6 DR. SANTELICES: I have to read the letter.

7 DR. MONSEES: I am sorry, you are Number 10 also,
8 is that right?

9 DR. SANTELICES: Yes, ma'am.

10 DR. MONSEES: That's correct.

11 DR. SANTELICES: Dr. Caplan called me yesterday at
12 my office prior to leaving and said can I fax you a letter
13 that I want you to read. This morning when I spoke to Dr.
14 Winchester, I discussed it with him, and I think it is
15 appropriate that I read the letter.

16 I also think it is appropriate that it is
17 understood that I am not speaking on his behalf, but rather
18 just reading a letter that he wrote. Okay?

19 DR. MONSEES: Thank you very much. Why don't you
20 go ahead.

21 DR. SANTELICES: He wrote in little tiny letters,
22 and I need to get my glasses and go slowly here.

23 This letter is written to obviously -- not
24 obviously -- it is written to Dr. Charles A. Finder,

1 National Mammography Quality -- I am sorry, Madam Chairman,
2 it was not addressed to you, but Dr. Finder, at the time I
3 guess was in contact with Dr. Caplan -- and to the members
4 of the committee.

5 Dear Committee Members: It is my testimony before
6 this committee one year ago as a breast surgeon and
7 President of the American Society of Breast Surgeons, I
8 stated that regulations of a surgical procedure should not
9 be, in my opinion, within the jurisdiction of the FDA.

10 I am today still convinced that this is the
11 correct position. The fact that the American College of
12 Surgeons and the American College of Radiologists have
13 signed off on a document stating their position on joint
14 credentialing for performance of stereotactic breast biopsy
15 procedures does not justify an FDA position in this matter.

16 I am reading verbatim.

17 This document is a feeble attempt to compromise
18 political positions and to end an unpleasant turf battle.
19 It contains no proven guidelines that would guarantee the
20 quality of the service to our citizens. In fact, I firmly
21 believe that it would do just the opposite.

22 As a breast surgeon, I have more than three years
23 experience and over 400 cases in stereotactic biopsies with
24 a record equal to the best radiologists in the country, and

1 yet under this guidelines, even I could no longer qualify to
2 perform this procedure, because I cannot document four hours
3 of CME in radiation physics.

4 Nowhere in the document does it state that a
5 physician must have four hours of CME in breast biopsy
6 procedures. I could offer objections to every other part of
7 this document, but this not the purpose of my statement
8 today.

9 I am against the FDA accepting such a document
10 under any circumstances or compromises for the purpose of
11 regulating a surgical procedure. Instead, I would like to
12 offer the following.

13 The FDA should regulate stereotactic breast biopsy
14 procedures because it is an imaging procedure and, as such,
15 should come under an MQSA, but I believe that only the
16 stereotactic site should be regulated to ensure the public
17 that it is safe as far as an imaging device is concerned and
18 that certain guidelines are followed regardless of the
19 specialty of the physician performing the procedure.

20 As to whether this physician is qualified to
21 perform a stereotactic procedure, it should be left up to
22 the credential committee at the local medical facility that
23 determines credentials for all the physicians on its staff.

24 How could this be done effectively? The

1 stereotactic biopsy facility would be regulated much the
2 same way as mammography facility. Certain installations and
3 quality assurance measures would be required, as well as
4 initial and yearly inspection by the radiation physicist.

5 A mammographic technologist would be required to
6 operate the equipment and record all case histories and
7 maintain appropriate review of records, films of every
8 procedure, as well as copies of the initial mammographic
9 report, pathology report, and the biopsies, as well as a
10 followup report from the radiologist stating that the biopsy
11 was either in concordance with the mammogram or that an open
12 surgical biopsy would be required.

13 Also, a recommended followup exam would be stated
14 in the report. This method of documentation is considerably
15 more reliable in determining the qualifications and
16 expertise of the operator than any arbitrary number of
17 mammograms that an individual must review or the number of
18 cases that must be performed on an annual basis.

19 This determination is best left up to the local
20 credentialing body, who should have better knowledge of the
21 physician's experience in these areas.

22 In summary, then, my recommendation to this
23 committee will be to establish an accreditation process for
24 a stereotactic biopsy site with annual inspections by the

1 FDA and radiation physicists. All the local credential
2 committees to credential the physicians as they do in all
3 other medical and surgical procedures.

4 This would assure the public of a safe and
5 qualified stereotactic site, while at the same time not
6 require that the FDA involve itself in medical
7 credentialing.

8 These recommendations may not satisfy those whose
9 intent is only to politicize the issue for their own
10 interests, but it will guarantee to the women in this
11 country continuing access to quality breast cares which are
12 both safe and responsible.

13 Thank you. Robert B. Caplan, M.D.

14 DR. MONSEES: Thank you. Well read. I don't know
15 whether or not you feel that you can answer any questions,
16 but there was one part that I didn't quite hear, that maybe
17 you can just clarify for me by referring to that document.

18 DR. SANTELICES: Yes, ma'am.

19 DR. MONSEES: It was the concordance/discordance
20 issue. Did he feel that it was the technologist's job to
21 establish whether there was -- I didn't quite get that.

22 DR. SANTELICES: Not from reading the letter, I
23 didn't get the gist. I thought from reading the letter, he
24 meant the radiologist. Now, like Dr. Israel, I do not use a

1 radiologist for that purpose, concordance or discordance. I
2 use him to read about 2,500 mammograms that are done in my
3 breast centers on an annual basis, but the concordance
4 really comes at the time of reading the pathology report.

5 If I was looking for micros, and I didn't get
6 them, the first thing I do, I ask the pathologist to do more
7 serial cuts. If he tells me, "You didn't get them," I will
8 then repeat the mammogram and work on that basis, however, I
9 do specimen films and many times I have told the pathologist
10 you may not see them, but here they are, and there is two
11 cores and there are all the little micros right there.

12 So, at times you can have a path report that
13 doesn't say you have micros, but yet your specimen film
14 shows it. Now, if I am looking for something that should be
15 at least fibrocystic, and I just get fibroadipose tissue, I
16 don't feel I have concordance. In cases like that, we
17 repeat the mammogram.

18 DR. MONSEES: Thank you.

19 MS. HEINLEIN: I, too, got the gist from the
20 reading of the document that it was the responsibility of
21 the technologist to do the followup and medical audit
22 information. Would you mind just going back to the document
23 and reading that sentence that is in there?

24 DR. SANTELICES: Yes, ma'am. I may start a little

1 before, so I can get the whole meaning.

2 A mammographic technologist would be required to
3 operate the equipment, and records of quality and case
4 histories would be maintained for review during an annual
5 inspection as is currently required for a mammography
6 facility. In addition, either the local credentialing body
7 and/or the FDA would also require the facility to maintain
8 the digital film records of every procedure, as well as
9 copies of the initial mammographic report, pathology report
10 on the biopsies, and a followup report from the radiologist
11 stating that the biopsy either was concordant with the
12 mammogram or that an open surgical biopsy would be required.

13 Also, I recommend the followup exam would be
14 stated in the report. This method of documentation is
15 considerably more reliable in determining the qualifications
16 and expertise of the operator than any arbitrary number.

17 So, I didn't see, I didn't read that.

18 DR. MONSEES: Thank you. I didn't hear that
19 initially. What he is saying is that the surgeon would do
20 the biopsy and the radiologist would determine whether there
21 is concordance or discordance.

22 DR. SANTELICES: That is what the letter states.
23 I brought to your attention that in my case, I don't, and
24 Dr. Israel doesn't.

1 DR. MONSEES: Right. Thank you.

2 I think probably we should put a copy of the
3 letter in the record. Likewise, the letter that you read,
4 we would like to have probably also put. Thank you.

5 DR. HENDRICK: There is a new concept introduced
6 in this letter, which is that the medical board -- I think
7 is the phrase that was used -- should be sufficient to
8 ensure the credentials of the physician performing this
9 procedure, and I don't fully understand the realm of
10 governance of medical boards, but I thought they had to do
11 with hospitals.

12 DR. SANTELICES: Right, and he stated
13 credentialing body of the hospital or/and facility. As the
14 Chairman of the Credentials Committee and dealing with
15 something that was brought up as a matter of record,
16 laparoscopic cholecystectomies, when they first started out,
17 we really didn't know how many numbers to ask of the
18 physician, and each hospital sort of set up their own little
19 guidelines, three on your own, three with preceptorship,
20 bring a copy of the course, but what I do know as far as
21 credentialing, that any new procedure that is done in the
22 hospital needs to be approved by the Credential Ethics
23 Committee, and then anybody who is going to do it, whether
24 it is transesophageal sonography, whether it is

1 transcutaneous pacemaker, or percutaneous, whatever, first,
2 the procedure gets approved, and then the physicians have to
3 provide qualifications for the procedure.

4 Each hospital does take different parameters.
5 Some hospitals require three, some hospitals require five,
6 some hospitals say if you prove it on the first shot, you
7 don't need to do it on the second or the third.

8 DR. HENDRICK: Just to follow up on that, what is
9 the issue with non-hospital settings for performing
10 stereotactic biopsies?

11 DR. SANTELICES: Well, non-hospitals, short of a
12 Dr. Israel or myself or maybe two out of three, don't really
13 exist. This machine is very expensive and nowadays the
14 financial remuneration for the biopsy has gone down so low,
15 I don't think that one person alone can ever be involved.

16 So, it usually falls into a single day surgery,
17 outpatient surgery, that has their own credentialing body.
18 They all have their own bylaws. Nowadays, starting in 1998,
19 they are going to be checked out by the Joint Commission
20 also. Right now they are in a voluntary state of being
21 evaluated, but starting next year I think that the
22 outpatient facilities are going to fall in the Joint
23 Commission also.

24 So, there is a whole set of credentialing and

1 guidelines that go on.

2 DR. HENDRICK: I know of some non-hospital
3 settings in which stereotactic is being done.

4 DR. SANTELICES: Of course, because when this
5 first started, like Dr. Dowlat said, it was first a car with
6 four wheels and a steering wheel, and a lot of people got
7 access to it.

8 As it has grown in complexity, and with complexity
9 and as it has grown in expenses, not very many people have a
10 quarter of a million dollars to spend on a machine whose
11 remuneration is about \$350 combined global fee. You have to
12 do a lot of breast biopsies to be able to pay for that
13 machine if you are by yourself.

14 But you are an institution that has 10, 12
15 surgeons, four or five radiologists, all working in unison,
16 then, you can afford the machine, and that is where that
17 machine is going.

18 I think, like everything else, when the Wright
19 Brothers got into the first airplane, you know, and the FAA
20 and 1997, there is a whole variety of circumstances.

21 DR. MONSEES: I think we have another question
22 from the panel. Dr. Sickles.

23 DR. SICKLES: I just wanted to clarify this a
24 little bit. It would seem to me there might be a problem

1 had there been reasonable numbers of outpatient facilities
2 operated just by the individual or a few individuals who
3 were doing it and credentialing themselves.

4 DR. SANTELICES: Right.

5 DR. SICKLES: What you are trying to tell us is
6 that those facilities are few and far between?

7 DR. SANTELICES: Yes, sir. Again, I never came
8 here professing to be an expert in the worldwide use of this
9 equipment, just in Hialeah, along which by now has three in
10 the city that one is enough.

11 The machine is very expensive and the complexity
12 of all the apparatus that are added on is also very
13 expensive. Very few centers right now, unless they have a
14 very large budget backing them, can afford it.

15 Now, you are going to have, you know, your
16 grandfather period of the first four or five years of
17 anything that you are going to have to deal with somehow,
18 but I think that if you put it under MQSA as a site
19 facility, if you do stereos, you are probably doing mammos.

20 DR. SICKLES: Are you concerned with proliferation
21 of this equipment beyond its need? This is actually
22 something that happens frequently with imaging equipment.

23 DR. SANTELICES: I think that the medical
24 economists are always concerned that new technology calls

1 for new testing, and the proliferation of that technology
2 calls for the overusage of the technology. I want to echo
3 Dr. Israel's word and the first surgeon -- I apologize I
4 can't remember his name -- as surgeons, and we don't read
5 mammography, we really act upon a read mammographic report.

6 I encourage this body to encourage the American
7 College of Radiology to encourage the BIRAD's reading,
8 because still to this date, I get a two-page mammographic
9 report that has got a lot of flowers in it, but at the end
10 it leaves you like whoa, where is this coming from, and it
11 is sitting in your hands. They are the ones who are
12 actually telling you surgical correlation, surgical
13 consultation requested, and it falls at the end, the surgeon
14 decide I am going to biopsy this, I am not going to biopsy,
15 depending on the surgeon and the psyche of the lady, because
16 many times the surgeon may feel comfortable not biopsying
17 it, but if he is smart, he is astute, and he knows how to
18 read his patients well, he knows that this lady is going to
19 be better off with a biopsy, because if you tell her no, she
20 is going to go someplace else anyway because she is certain
21 she needs to have it done. That is what bedside manner are.

22 DR. MONSEES: Thank you, Dr. Santelices.

23 DR. SICKLES: Getting back to the question that I
24 was trying to get at --

1 DR. SANTELICES: I didn't elude you, did I?

2 DR. SICKLES: No, but you went beyond. I have
3 some concern in allowing facilities to credential themselves
4 if there is proliferation of equipment to the point where
5 facilities are at an individual level, because then the
6 individual would be credentialing himself or herself.

7 DR. SANTELICES: Correct. I agree with you.

8 DR. SICKLES: And that is my concern, and I am
9 just wondering whether in your experience you see this
10 coming. I know you can't testify for the man who wrote the
11 letter.

12 DR. SANTELICES: No, I don't see it coming for the
13 economic reasons that I told you. I also don't see it
14 coming because with the MQSA Act, the centers which are
15 doing stereos, if they can afford stereo machine, rest
16 assured they have a mammogram machine. I think that what
17 Dr. Caplan was trying to lead to is that what you would be
18 looking at is to make sure that the site is regulated, and
19 once you set a regulation in the site, the site has no
20 choice but to go ahead and hire physicists to come once a
21 month to do the quality assurance, to do the followups, to
22 keep you tracking, which is what MQSA was all about.

23 DR. MONSEES: With that, I thank you very much for
24 your comments.

1 I would like to make one more call, because we
2 started early, for Joseph Rush. Has he come?

3 Okay. We will at this time move to our break.
4 Let me tell you we will reconvene promptly. At 11:45, we
5 will begin the session, so please be seated a few moments
6 before then.

7 [Recess.]

8 **Overview of Interventional Mammographic Procedures**

9 DR. MONSEES: This morning we have heard important
10 statements from people from the community and now we are
11 going to hear an overview of interventional mammographic
12 procedures by Dr. Rebecca Zuurbier, Assistant Professor of
13 Radiology and Director of Breast Imaging at Georgetown
14 University Medical Center.

15 She will be outlining, for those of us who are
16 less familiar, with the different interventional breast
17 procedures, so that when we go into our more detailed
18 discussion of what needs to be addressed, those of you are
19 less familiar will be conversant with this.

20 Following her presentation, which she estimates
21 will be less than the appointed time, there will be some
22 time hopefully for a question and answer session.

23 Can we do anything else for you?

24 DR. ZUURBIER: No, thanks.

1 DR. MONSEES: She has been invited by the FDA to
2 make this presentation, and we thank her very much for doing
3 that. Please go ahead.

4 DR. ZUURBIER: It is a pleasure. I appreciate the
5 invitation.

6 [Slides.]

7 I know that Dr. Finder, when he called me up, said
8 that this was going to be a mixture of initiated and
9 uninitiated individuals, and I am afraid I might see more
10 initiated individuals in the crowd than not, so I apologize.
11 I hope most of you don't assume the demeanor of the young
12 lady on the left.

13 In any event, I know, especially when I teach my
14 residents, that it is very important to limit the topic to
15 no more than four or five things, otherwise, the attention
16 span goes down as the heat in the room goes up, and hunger
17 levels increase, as well.

18 So, my talk today is going to be focusing -- and
19 please excuse my back, I will try and minimize my shadow
20 here -- to four topics: stereotactic breast biopsy, which
21 most of you are familiar with, fine-needle aspiration
22 cytology, preoperative needle localization, and
23 galactography, in other words, when x-rays and needles
24 collide, and these are the four things that can happen.

1 [Slides.]

2 My first focus will be on stereotactic core breast
3 biopsy. Now, that is a multiple line slide, which I want
4 you to read and digest again. Stereotactic core breast
5 biopsy. I think we all realize by now that it is an
6 accurate, reliable, cost-saving alternative to open surgical
7 biopsy when we have to manage mammographically detected
8 breast lesions.

9 I like to say that mammography isn't free, just
10 like freedom isn't free, mammography isn't free. It's a
11 wonderful test widely available, known to decrease the
12 number of deaths from biopsy cancer for women screened 40
13 and above -- ironically, we actually have more proof of this
14 efficacy for women in their 40s now than for the 50 and
15 above level -- but it comes with a price tag, and the
16 largest induced price tag is that incurred with the surgical
17 consultation and biopsy it is estimated at \$2.3 billion.

18 Not only is there a fiscal price tag, there is one
19 that is physical and psychological and mammographic when we
20 consider the psychological scarring, the physical scarring,
21 and the scarring that can occur on a mammogram subsequent to
22 the open surgical biopsy.

23 So, we have a great debt, and I think Dr. Parker's
24 name has been invoked before here for developing a

1 technology and having the skill, as it were, to put together
2 the need with the answer, the technology with the answer.

3 [Slides.]

4 Stereotactic core breast biopsy involves about
5 four things. We use a prone table with an aperture,
6 preferring the prone table because it eliminates the
7 potential complications of the vasovagal reaction, the
8 fainting that might occur, as well as the motion as a woman
9 is approached with a 14- or 11-gauge needle into her breast.

10 Digital imaging capability has really revitalized
11 the technology. Before, you had to take a film, run it
12 through your rollers in your processing room, hopefully,
13 have a speedy technologist with sneakers, and that could
14 take a three-minute process in between these diagnostic
15 mammograms.

16 Now we have digital imaging capability, which
17 simply means you press a button and the image comes up on a
18 computer screen within a matter of seconds, a biopsy device,
19 and this is an area of high interest, I will be showing you
20 what is typically used and then a couple evolutions on that
21 theme, and finally, a patients with a mammographic lesion,
22 and I say that tongue in cheek, but not really.

23 We really want to commit ourselves to biopsying
24 only those things that required biopsy. It shouldn't be an

1 excuse for a lazy mammographic workup or inappropriate
2 counseling of a patient with a probably benign lesion for
3 which we would otherwise recommend mammographic followup.
4 So a patient needs to have a mammographic lesion, a real
5 one, a true one, one for which a radiologist would recommend
6 biopsy.

7 [Slides.]

8 I give equal time to the manufacturers that are
9 preeminent currently in the field. The Lorad and the
10 Fischer tables. The Lorad table, the patient can lie with
11 their head either to the left or the right, affording a 360-
12 degree access to the patient's breast.

13 The Fischer table, the patient lies with their
14 head on one end, the breast is suspended through an
15 aperture, and the system works, if I can just take a minute
16 to step up, just like getting a mammogram taken except you
17 are lying on your stomach.

18 So, we have the table. We have the x-ray device.
19 The patient lies prone, and many mammograms are taken.
20 These mammograms are typically 2 inches by 2 inches in
21 diameter.

22 In between this mini-mammographic unit is the
23 biopsy device, and this is where we will be focusing a
24 little more later on. I throw in the computer here because

1 this is that 2-inch by 2-inch mammographic picture that is
2 blown up on the computer screen, and being on a computer,
3 that affords us an ability to manipulate the image. We can
4 adjust the contrast and the magnification.

5 [Slides.]

6 I think this the hardest part of the procedure,
7 and that is not making sure you are well coiffed with
8 lipstick and nails done for the stock slide. The hardest
9 part is occurring right down here, which is getting that
10 mammographic lesion reliably depicted in again a small area.
11 Here is that 2-inch by 2-inch window, and it is
12 noncompressed, so we can't separate structures as
13 effectively as we can out here on either side.

14 So, I find as a radiologist that that is probably
15 the most challenging portion of the procedure, both for the
16 technologist and the radiologist working together. What we
17 do is take two stereo pictures, and simply put, a
18 stereotactic device is easily found in between your
19 shoulders. It is your head, two eyes and your brain, which
20 is to say that if you put your finger in front of your nose,
21 and you only had one eye open, you couldn't tell how far
22 your finger was from your nose. So, your eyes act like
23 stereotactic devices. One eye opens. If you alternate, you
24 see your finger seems to shift in space. We do this when

1 things get slow in the radiology department.

2 But you need two eyes, and that is where the
3 computer is, to tell you exactly where that finger is in
4 relationship to your nose. So, if I only had one picture, I
5 would only be able to tell you, for example, that the lesion
6 was here. I know where it is in my horizontal plane, right
7 here, I know where it is in my vertical plane, the y axis
8 here, but how deep does my needle need to go in to get to
9 it, and so these stereo views are taken.

10 This is the same breast, nobody is moving, the
11 camera is moving, and it looks like the lesion moves in
12 space. In fact, it doesn't. Then, we target it, and here
13 are these two squares there targeting the center of the
14 lesion, and the circles around it are the other offsets or
15 areas of the lesion which we will be sampling.

16 Now, this is what is used most often now, which is
17 a spring-loaded gun device. We will be talking a little bit
18 about other evolutions on that theme, but the idea of core
19 biopsy is to sample the lesion, and so we sample it that
20 way. We identify it, we find it.

21 [Slides.]

22 Then, as I said before, this is just the computer
23 depiction of it. We can magnify this area. Again, we are
24 targeting with the square, providing offsets, and here is

1 the information. This is the depth that my needle has to go
2 into the breast. So, there is very little human error that
3 can be applied except for the depth adjustment using -- this
4 is with the Fischer table that we use currently.

5 [Slides.]

6 The patient is then anesthetized. This is the
7 surgical portion here where we apply a lidocaine that is
8 buffered, so there is very little, if any, burning
9 experienced by the patient. We make a small nick in the
10 skin, and then we will be introducing the needle.

11 [Slides.]

12 We obtain what are called pre-fire pictures to
13 ascertain that the lesion is indeed in the vicinity of the
14 needle. In fact, we want the needle tip to be just proximal
15 to it in both views.

16 I apologize. This is a separate lesion here. You
17 will note this is a soft tissue mass. These are
18 microcalcifications. Here is the pre-fire picture. We
19 press the button. The spring-loaded gun is deployed and
20 with the velocity of a .22-gauge or caliber -- somebody in
21 the military corrected me, and I was too flustered to
22 remember which one -- it is really darn fast. It will
23 sample the lesion.

24 [Slides.]

1 The typical specimen that we obtain is with a 14-
2 gauge gun is about the caliber of a number 2 pencil lead,
3 and it is about an inch long, and this is how you can see it
4 before we place it into the test tube to send off to the
5 pathologist.

6 Now, I want you to again focus on what is
7 happening underneath the table. This is what I think is
8 most commonly used right now, is a spring-loaded gun. We
9 use the Biopty gun. We can use it to sample -- it has been
10 used to sample solid organs, the kidney, the liver, the
11 prostate, and so it samples it.

12 So, basically, after you are done sampling your
13 lesion, your lesion looks like one of those FBI target
14 things that you use when you are practicing your aim. It
15 has little holes in it. As big as that guy is, that's how
16 many holes may be carpeting that guy.

17 We typically take about nine samples. Five is the
18 minimum number recommended. It is done by placing the
19 needle in, bang, withdraw. Put it in your saline for
20 subsequent transfer to your formalin. Put it in again,
21 bang, and the whole procedure takes less than an hour if
22 everybody is doing everything right and everything can be
23 found.

24 [Slides.]

1 The interesting variations are evolutions of this,
2 are clouding the area in between minimally invasive to
3 excisional biopsy. We can move into now what is called
4 mammotomy or the Mammatome device, which is vacuum assisted.
5 Now you only have to put the needle in once, and a vacuum
6 actually will suck the material of concern into a similarly
7 sized notch there. It can actually be up to 11 gauge in
8 size.

9 What is the advantage here? The advantage is you
10 only need to place the needle in once. You obtain
11 continuous samples that maybe have higher integrity. It has
12 been shown that you have a more reliable collection of
13 microcalcifications and larger size of your material to send
14 to the pathologist, and in the pathologist's world, more is
15 more, so the more tissue you give them, the better and more
16 confident their diagnosis is.

17 So, the vacuum assist device is another evolution
18 on the way. Some concerns, well, sometimes you can actually
19 eliminate the whole lesion. For example, if that were the
20 microcalcification cluster, that ended up being a in-situ or
21 invasive carcinoma, where do you go back to tell the
22 surgeon, you kind of apologize and say, it's in that area
23 and you hope you still have a tatoo with some air holes or
24 some hematoma.

1 But somebody answered that question, too, and said
2 let's deploy a little titanium clip, and so a clip can be
3 deployed into that area to mark the site if there is concern
4 that the whole lesion has been sampled.

5 [Slides.]

6 Let's advance one more step toward excisional
7 biopsy, and that is the ABBI system. Now, those of your
8 that are still alert will note that this is not actual
9 diameter size, but just to point out that the ABBI system
10 can vary the caliber lesion accumulation.

11 Let's go back to our analogy of that little target
12 that you use in firing range practice, and with the spring-
13 loaded gun, you get a guy that looks like he has Swiss
14 cheese hold in him. With the vacuum assist device, you can
15 core out and core out, and you can take out heart, and if
16 the lesion is as big as his lungs, you can just keep
17 vacuuming that area out.

18 With the ABBI device, you can just take that whole
19 poster and bring it with you. The advantage to that may be
20 that you have, again in the pathologist's world, more is
21 more. There may be some down sides, which I don't feel
22 comfortable commenting on whether they are going to be
23 cumulative enough or non-cumulative enough to warrant
24 further use, but there is concern about cosmesis.

1 [Slide.]

2 All the things that made stereotactic core breast
3 biopsy a beautiful thing, cost savings, improved cosmesis,
4 no mammographic scarring, very low complication rate with
5 hematoma, are now called into question a little bit on the
6 side of getting more tissue for the pathologist, which is to
7 say Langer's lines, which are important to most breast
8 surgeons, which follow the curvature of the biopsy, help
9 eliminate any notable scarring. You might not be able to
10 appreciate a Langer's line when a patient is prone on a
11 table and when you are making a 2-centimeter incision to
12 take out that column of tissue, you do have greater worry
13 about hemostasis, about extraneous tissue collection because
14 you are taking that whole column in front of the lesion. So
15 bleeding and infection concerns, you have to use suture
16 material if it's a big incision to address that.

17 Then, we have unanswered questions about what is
18 the effect on the mammogram also, so is there going to be
19 mammographic scarring as a result of a larger core
20 accumulation. So I just point out that there are advantages
21 and disadvantages to all of these, and it is kind of a
22 progression of invasiveness from the stereotactic spring-
23 loaded biopsy device through the vacuum assist, through the
24 ABBI system, which can afford larger core sampling, until we

1 get to, well, why don't we just a preoperative needle
2 localization.

3 [Slides.]

4 Well, I offer this vignette. My sister, who is a
5 breast surgeon, an excellent breast surgeon actually, and
6 she will be the first to tell you that, will chide me at the
7 Thanksgiving dinner table -- and I am really looking forward
8 to the holidays -- for the radiologists at her facility have
9 a needle localization that she orders preoperatively is
10 really helpful only to her to identify which breast the
11 lesion is in, and then it is only right 50 percent of the
12 time. So, this is what I deal with. This is what we deal
13 with as radiologists.

14 It is funny, but it is not. I point out the need
15 to have very good communication with the radiologist and the
16 surgeon. This is a very cooperative effort. You need to
17 know the limits of your talents and their talents, what they
18 will tolerate, but let me just go through and show you how
19 this works.

20 Preoperative needle localization, when do we use
21 it? When you can't feel it, and it has got to come out.
22 So, it is for a nonpalpable mammographic lesion which was
23 recommended for biopsy.

24 Our objective is to position the needle/wire

1 system in or through a lesion to guide the surgeon to the
2 area of concern.

3 [Slide.]

4 Before the localization again, do the dance with
5 the surgeon or the surgeon should do the dance with the
6 radiologist, review the imaging workup. There is nothing I
7 hate more than canceling a needle localization because
8 somebody had not worked that milk of calcium appropriately
9 on the outside, or had not found it appropriately. This
10 delays your schedule and creates all kinds of hand wringing
11 and the patient of course is not happy about it either.

12 We avoid premedicating the patient. We like to
13 obtain lucid informed consent. We also need their
14 cooperation to sit and maintain position while we are doing
15 this procedure. It is a procedure that I like to tell my
16 patients sounds worse than it is, not that is great and I
17 would want to have this done in my lifetime, but it is very
18 well tolerated by the patients especially after good
19 counseling.

20 The idea is to take the shortest approach to the
21 lesion and most people do it parallel to the chest wall.
22 Some people do it free hand, but we are going to be
23 addressing how I think the mainstream does it.

24 So, first we identify the lesion on the mammogram,

1 and if you aren't familiar with mammography, this is the
2 view basically from the side of the breast, side to side, so
3 the head is up here, the feet are down here, the nipple is
4 here.

5 So, the shortest distance to the lesion is looking
6 right here, but let's look at the view from top to bottom of
7 the breast. We call it the craniocaudal view. So, the
8 nipple is here, her lungs are here safely out of the way,
9 her armpit is here, her sternum is here.

10 The lesion is here. It is not going to be very
11 prudent to come a long way here, long way here. Let's take
12 the shortest distance. It helps the surgeon, helps the
13 patient, so we choose the shortest distance to the lesion.

14 [Slides.]

15 My thanks to Dr. Kopans, whom I have lifted these
16 films from his book. I trained under him, so I feel I
17 contributed somehow and could copy these films. This is a
18 picture from his book, which demonstrates how we do it.

19 We need an alphanumeric grid. Sometimes people
20 have little Swiss cheese grids, one of those grids that has
21 a bunch of holes in them. I like this one. It is very
22 accurate for the purposes of the surgeon.

23 We take a picture. Now we have decided we will
24 come from the top, and so we make a little X at -- this is

1 kind of like Battleship -- E and 1.5.

2 [Slides.]

3 We put a little X there, and then I turn on the
4 light that is provided by the mammographic unit, and I turn
5 off the lights in the room, because that light shining down
6 is going to help me avoid any shadowing of the needle, so I
7 can have a very precise downward placement of the needle
8 without any angulation.

9 Dr. Kopans has done just a few of these. In fact,
10 this is his needle/wire system, and so we can see that he
11 has placed the needle beautifully. There is very minimal
12 angulation of the needle. That is a long needle and that is
13 the only part of the shaft that we see.

14 We typically don't use a skin anesthetic. We used
15 to use a spray anesthetic. They are not manufacturing that
16 anymore, but they found that the patients actually, when
17 they did a study, had a higher perception of pain when you
18 gave them lidocaine than if you just stuck the darn needle
19 in. A needle stick is a needle stick. Again, I haven't had
20 one done yet. I don't know if I can justifiably say.

21 [Slides.]

22 We then take a picture from the side or from the
23 opposite view of where we started with the needle in place.
24 Now, we intentionally overshoot the lesion. If you leave

1 the surgeon with a needle like that, he or she is going to
2 be irritated because once they get that far, this is a 360-
3 degree question that they have, which way do I go.

4 So, we want to get across the lesion with the
5 needle, and then with the Kopans wire system, we would place
6 in through that needle a very thin wire that has a little
7 barb on the end of it, and when that deploys, that stays and
8 anchors the needle in the breast, and to give the surgeon a
9 tactile orientation, it has a thickened segment indicated by
10 those short arrows. This is a nice placement with the
11 lesion right at the center of that thickened segment.

12 The surgeon has the option of dissecting down from
13 the top to the lesion or perhaps make a periareolar incision
14 which may be more cosmetically appropriate, and work their
15 way back to the lesion.

16 At Georgetown, we actually also use the Homer
17 needle, which has some variations on it, as well. I call it
18 resident-proof, because the wire at the end of it isn't a
19 barb, it's a retractable, like a fishhook thing, so if the
20 resident makes a mistake, we can just start over and provide
21 another positioning.

22 [Slides.]

23 The lesion is then dissected and to make sure that
24 there has been an appropriate sampling of the lesion or

1 excision of the lesion, we actually take an x-ray, and we
2 like to see the bulk of the lesion contained within it.

3 The potential complications are similar to when
4 you get a blood sample taken - bleeding and infection. I
5 don't usually mention vasovagal reaction because that is a
6 very suggestive thing, but I monitor the patient very
7 carefully, and I have smelling salts available in case there
8 is any problem, and pneumothorax, I don't indicate as a
9 potential complication if I am going parallel to the chest
10 wall. Like I said, some people still do it freehand and
11 kind of guesstimate where it is, and go back and take some
12 pictures. Pneumothorax is reported with those types of
13 approaches.

14 [Slides.]

15 We are going to move on to our number three issue,
16 and that is the fine-needle aspiration cytology. When would
17 you use fine-needle aspiration cytology? If you have a new
18 mammographic lesion and you want to sample it, but you
19 really don't want to take it out. When it is something that
20 the surgeon can feel, and when you, as a radiologist, just
21 can't tell the patient if it is a complex cyst meaning it's
22 okay, but it has some debris, hemorrhage, proteinaceous
23 material in it that could mimic a solid lesion.

24 So, in those cases, I, as a radiologist, like to

1 do a needle aspiration. Typically, if it's a palpable mass,
2 the surgeon will use their fingers as a guidance, and I
3 don't typically use mammography to guide me.

4 [Slides.]

5 However, there is a suggested method for it. I
6 think it is used especially if you are concerned that what
7 you are sampling mammographically is or is not the same
8 thing that you see at ultrasound. So, if there is a
9 correlation concern, I may use mammographic guidance.

10 [Slides.]

11 But the typical scenario would be this new nodule
12 that we find on the mammogram, ultrasound shows us this
13 circle that is not completely round, and it's a little gray
14 in the middle of it. Is this a solid lesion? Is this a
15 complex cyst? I don't know. Let's stick a needle into it
16 and find out.

17 [Slides.]

18 One can do that actually using a grid localization
19 device. One would proceed, just as with a needle
20 localization, using an x-ray picture with a grid
21 superimposed to guide placement of the needle.

22 Aspiration is applied, and the material is put on
23 a slide and fixed, and preferably you will have a
24 cytopathologist there, if it is a solid lesion, to identify

1 whether there is sufficient material. If it is fluid, we
2 just send off the test tube and that is a controversial area
3 also. Some people don't send off the fluid at all.

4 [Slides.]

5 I want to emphasize that fine-needle aspiration
6 cytology is usually performed with ultrasound guidance,
7 because we can, under real-time, follow that needle going
8 into the breast, and frankly, we don't hardly use
9 mammographically-guided fine-needle aspiration cytology at
10 all.

11 [Slides.]

12 Now, let's step back and do a little comparison
13 shopping thing. What is the difference then between the
14 fine-needle aspiration cytology and the core breast biopsy?
15 Needle size. Thin needle for fine-needle aspiration
16 cytology. I can bend it with my finger, a 20- to 25-gauge.

17 Core biopsy, I have to use my arms and maybe my
18 foot to step on it, so it's a longer, thicker, bigger
19 needle, 11 to 14 gauge. It results in a different type of
20 tissue and material that we are looking at.

21 We only get to look at the cells when we do
22 cytology, so it only sucks up those little tiny wispy little
23 cells. With the core biopsy, we get the tissue. We can see
24 the structure that the cells are forming, and we can make a

1 more accurate diagnosis.

2 Not only can we say benign versus malignant, which
3 is basically what fine-needle aspiration cytology can do,
4 core biopsy can allow us to say invasive, non-invasive, we
5 can do all kind of estrogen/progesterone testing on it, so
6 it gives us a lot of information for your buck.

7 With fine-needle aspiration cytology, you have to
8 trust your pathologist who has been specially trained to
9 look at just the cells, where with core biopsy, you don't
10 need a trained cytopathologist.

11 Fine-needle aspiration cytology, possibly less
12 accurate. As I described before, it only gives you an idea
13 of benign versus malignant, and if that is all you really
14 want, that is all you are going to get. Thirty percent of
15 the time, though, up to 30 percent of the time, the
16 pathologist will say insufficient material, can't tell you
17 either way.

18 Core biopsy, very accurate. Tissue is the issue,
19 and they can make a definitive diagnosis, and insufficient
20 sample would be very rare. So, the cheaper versus expensive
21 aspect, I think is very debatable and I tend not to use the
22 fine-needle aspiration cytology. If you are going to use
23 imaging guidance to get a needle in there, make sure you are
24 getting the answer when you are there, but some people still

1 like fine-needle aspiration cytology, like I said with
2 ultrasound guidance.

3 [Slides.]

4 We are going to move on to the final topic, which
5 is a galactography or the alternate is ductography. I think
6 this is most underutilized and most fun procedure to do.
7 When do we do it? Well, again, okay, I haven't had one, but
8 it's fun for me down the other side.

9 It is to aid evaluation of a clinically suspicious
10 nipple discharge, and what is clinically suspicious?
11 Usually, one that is unilateral and spontaneous. Most of us
12 can get some -- most of us women can get some type of an
13 aspirate from our nipple. In fact, we use it at Georgetown
14 as a test to see if we can actually predict cancer in the
15 duct system, but the important one isn't the one that you
16 can express with aspiration, but rather the one that is
17 spontaneous.

18 You might see a spotting in the bra and typically,
19 it is unilateral, so it is for a clinically suspicious
20 nipple discharge.

21 [Slides.]

22 The galactogram is a very elegant road map. I am
23 not sure how some of the surgeons in here use it or
24 appreciate it, but at Georgetown, many of our surgeons

1 appreciate its ability to answer several important questions
2 before they would go in and do the duct dissection, which is
3 where does the duct go.

4 You have about 8 to 10 separate holes on the
5 surface of the nipple, and not all of them predict
6 accurately which way they are going to go. For example, on
7 the nipple at 12 o'clock, the duct system might actually
8 subtend the area more toward 3 o'clock. It might
9 communicate with a different duct system.

10 So, how does it branch, does it communicate with
11 another system? Is the duct system normal-looking, is it
12 abnormal-looking? Are there lesions? Where are the
13 lesions, nearer to the nipple, way back yonder? Those are
14 the questions that we can answer with a diagnostic study.

15 We also aid the surgeon preoperatively by doing a
16 study that has contrast mixed with a blue dye, so that we
17 can tell them this is where the branching duct system goes.

18 [Slides.]

19 So, what do we need? These are galactography
20 essentials. I use a 30-gauge blunt tip needle. A 27-gauge
21 is the largest that I think you would feel comfortable
22 using, and it is a needle that we actually use also to
23 cannulate your salivary glands, a very small, fine needle,
24 blunt-tipped. We don't want to do any damage to the

1 orifice.

2 We use high-density contrast. Why? Because it is
3 going to be mixing in with all that duct discharge, and it
4 is going to be getting diluted. Goofy magnifying glasses,
5 the most critical part. You need not only your glasses or a
6 2 times magnifying glass, at least a 5 to 10 times
7 magnifying system to see exactly where that little discharge
8 is coming from on the surface of the nipple.

9 Of course, the nipple discharge, if the patient
10 doesn't present that day, or you can't elicit the nipple
11 discharge on the day of the study, you ain't doing the
12 study.

13 [Slides.]

14 The patient is out of the field of view save for
15 her nipple right here. Here are the aforementioned Goofy
16 glasses. This is the contrast material. It is connected by
17 tubing and this person has successfully cannulated or it
18 looks like they are about to successfully cannulate that
19 tiny orifice on the nipple.

20 After we inject contrast into the nipple system,
21 and we inject just to the level of when the patients may say
22 I feel fullness, we have efflux of material from around the
23 needle, or I actually feel some pressure or some pushing
24 back on the syringe plunger, I will stop and take a few

1 pictures.

2 My initial pictures are made with the needle in
3 place. Now, I say this is fun, because it really doesn't
4 hurt that much, maybe a little uncomfortable as I trying to
5 cannulate it, but we are not piercing skin. If it hurts,
6 you are doing it wrong. We want to go through an
7 established hole in the breast that is usually lubricated by
8 the discharge itself.

9 So, once you plump it in there, you take some
10 pictures and there are fun things that you can find in
11 there, and unexpected things. This patient has an
12 abnormally dilated duct system.

13 I can tell the surgeon the duct system goes, for
14 example here, and it actually branches off here, and here is
15 a large filling defect. That is where you have got to be
16 real careful while you are doing your dissection.

17 This other patient alternatively had a pretty
18 simple non-dilated duct system, but multiple filling
19 defects, and they extend far posteriorly. So, again, to
20 tell them where the duct system goes, where the lesions are,
21 and how many there may be, a very important system.

22 [Slides.]

23 I will close my talk here by just saying that this
24 is not my child, although I think I feel like I have to get

1 home early now for some reason.

2 But mammography is a wonderful tool, it saves
3 lives, but there are mammography problem children where
4 things where we just need a needle to collide with a
5 mammogram and the breast to find out the answers to some of
6 the questions that mammography raises.

7 [Slides.]

8 So, I offer again, in summary, stereotactic core
9 breast biopsy, which I think is a revolutionary, probably
10 the quietest revolution in health care today, as a cost
11 saving alternative to open surgical biopsy of the breast.

12 [Slides.]

13 Preoperative needle localization. It is a dance
14 the radiologist and the surgeon should do in concert and
15 accurately, and that is also an acceptable procedure.

16 [Slides.]

17 Mammographically guided fine-needle aspiration
18 cytology, don't really do it much under mammography. I show
19 this picture, which is actually a ultrasound picture, and
20 here is a needle approaching a lesion, and I can, under
21 real-time, follow this needle into and through the lesion.

22 So, I tend to use fine-needle aspiration cytology
23 using ultrasound guidance.

24 [Slides.]

1 Finally, galactography, just because you don't
2 know what you will find, and this is an abnormal dilated
3 duct system with multiple filling defects in it.

4 With that, I will thank you for your kind
5 attention. I hope I didn't bore too many of you. If Dr.
6 Monsees pleases, I would be glad to answer any questions.

7 DR. MONSEES: If you don't mind, any questions
8 that may come up, you want to field them, or there are other
9 qualified members of the panel that might be able to answer
10 specific questions.

11 Does anybody on this panel have any specific
12 questions? Dr. Winchester is going to ask a question.

13 DR. WINCHESTER: How many radiologists really care
14 about galactography?

15 DR. ZUURBIER: I would say, in the metropolitan
16 area, there are probably five to 10 radiologists that do it
17 reliably and happily. The vast majority are afraid of it
18 and that is why I say it is underutilized, I think.

19 Our surgeons, most of them favor it. I would say
20 half of them say I can do without it, thank you anyway, but
21 I think it affords, without a lot of pain or hassle, good
22 information for an accurate duct dissection.

23 DR. WINCHESTER: Our surgical experience is that
24 it takes a radiologist with a special interest in this, and

1 there aren't as many around as we would like to see.

2 Do you think regulating this procedure would
3 encourage more or discourage more radiologists to do this?

4 DR. WINCHESTER: I think I would just favor more
5 fellowships that would excite and emphasize the field
6 itself. I don't think the regulation is going to improve
7 the interest in it from a personal standpoint.

8 DR. MONSEES: Yes.

9 MS. HAWKINS: You mentioned that in the issue of
10 informed consent, that you don't really go into a couple of
11 the issues there, potentials. Do you think that this gives
12 a consumer enough information to make an informed decision?

13 DR. ZUURBIER: I mentioned that. Since I don't
14 use freehand technique, I don't mention pneumothorax. I
15 think that is a legitimate exclusion of that potential
16 complication.

17 As a physician and seeing my personal experience
18 in how you may faint, actually suggests the process, and I
19 am going to watch them anyway, I typically don't suggest it.
20 Fortunately, I don't have that as a complication. I think I
21 can't even tell you that anybody has really fainted in
22 recent history.

23 So, it is something that can happen to anybody
24 walking into the mammography suite can faint, and we watch

1 out for it, but I don't like to mention it. Some people do
2 and will, and that's fine, but I think it is a personal
3 style point that I have more success if I don't necessarily
4 mention it.

5 MS. HAWKINS: But do you think, though, that puts
6 the consumer at a disadvantage by not having that
7 information?

8 DR. ZUURBIER: No, because we are prepared for it
9 as an eventuality, and we assume that all patients will
10 faint.

11 MS. HAWKINS: You don't think it will affect
12 somebody's decision as to whether or not they would undergo
13 it?

14 DR. ZUURBIER: Having trained at an institution
15 where we did mention it, it did not dissuade anyone from
16 having the procedure. If the panel has experience
17 otherwise, there are more years of experience here than
18 probably in my end.

19 DR. MONSEES: Does any other mammographer here
20 care to mention their experience with that and informed
21 consent?

22 Dr. Sickles.

23 DR. SICKLES: I have probably done 10,000 of these
24 procedures in my career. There have been women who fainted.

1 We always mention that to patients in our consenting. I
2 have not had any woman decline to have the procedure done
3 because of it. That doesn't stop me from mentioning it.
4 But I have never had a woman say now that you tell me that,
5 I don't want to have the procedure.

6 MS. HAWKINS: Well, see, one of my concerns would
7 be is that it is not something that the average woman can
8 pick up, you know, from the TV shows where they get much
9 medical advice, from the magazines, and so forth, so it is
10 not something that is very well known, and so coming into a
11 physician's office, you are not really in a position to
12 question.

13 I know that oftentimes physician, you know,
14 recommendations, can be somewhat persuasive. So, that would
15 be my concern.

16 DR. SICKLES: The important part of discussing
17 this with a woman is to not bring it up in a threatening way
18 because as you have heard, if it is described as a frequent
19 -- and that it not true, it is infrequent -- complication,
20 then, you can sometimes bring it about in a woman who is
21 marginal in terms of staying with the procedure. You don't
22 want to overly concern a woman about a very infrequent
23 complication.

24 There are ways of discussing this very effectively

1 without alarming a woman.

2 DR. ZUURBIER: I think the complication level is
3 similar to getting a blood sample taken. So, when I get my
4 blood sample taken, I am sitting up, nobody tells me that I
5 am going to faint even though I feel like I will once in a
6 while.

7 DR. MONSEES: Yes.

8 DR. HENDRICK: Isn't there also a written informed
9 consent that accompanies the procedure that would mention
10 adverse effects like this?

11 DR. ZUURBIER: The informed consent that we use at
12 Georgetown is a standard one, so the patient has signed one
13 just like that for the actual surgical procedure prior to
14 coming into my suite. I will list on the side the specific
15 potential complications which are bleeding and infection of
16 which I think she should be aware of and it would be helpful
17 to her in making her decision.

18 DR. MONSEES: Yes. Dr. Moore-Farrell.

19 DR. MOORE-FARRELL: Do you ever use your
20 stereotactic table for wire localization?

21 DR. ZUURBIER: Since our residents primarily use
22 the Homer needle system in which the needle is kept in the
23 breast, we don't use it. In my experience, we are pretty
24 speedy and also our core biopsy room is located around the

1 corner, so we typically do not use it, but some people do,
2 and if anyone want to comment on the pleasure or displeasure
3 with it, but we are just as fast without it and you don't
4 have to rev up the machine, do your calibration. It is a
5 little simpler from the prep standpoint.

6 DR. MONSEES: Yes.

7 MS. HEINLEIN: You mentioned with the stereo that
8 you used the table. Have you had any experience with an
9 add-on unit at all?

10 DR. ZUURBIER: None.

11 MS. HEINLEIN: I wonder if there is anyone else on
12 the panel that has had experience with an add-on unit. Can
13 you comment on the motion that you talked about, that with
14 the table that you don't have a motion problem?

15 DR. MONSEES: Dr. Sickles.

16 DR. SICKLES: I have had considerable experience
17 with add-on units although I don't use them currently.
18 Earlier on, before the tabletop units were available, there
19 were add-on units, and we probably did 500 patients with
20 that approach.

21 It takes longer. It does result in vasovagal
22 reactions in somewhere between maybe 1 percent and 5 percent
23 of patients. It requires a women -- any stereotactic
24 procedure requires a women to stay perfectly still, and it

1 is harder to stay perfectly still when you are sitting up
2 than when you are lying down. So, those are the
3 difficulties with the add-on units -- which does not mean
4 that the don't work well. If they are operating correctly
5 by people who know how to use them, they can operate very
6 successfully.

7 DR. MONSEES: Yes.

8 DR. HOUN: Florence Houn. Can you just comment on
9 your background and training in terms of issues like
10 sterility and wound control, wound care as it pertains to
11 these invasive procedures?

12 DR. ZUURBIER: My training just as a medical
13 student and a student in surgery, and participant in Dr.
14 Parker's eggplant course affords me just basic principles of
15 sterility. Our technologists are the ones that handle the
16 equipment sterility end of things. I handle the patient
17 sterility end of things.

18 So, we will use appropriate handwashing. We use
19 sterile technique in terms of maintaining sterility of the
20 needle shaft itself. It all goes asunder when you are
21 touching the actual biopsy device housing, so really, the
22 only thing that you can maintain sterility of reliably is
23 the needle itself.

24 In our experience, having done almost done 500 in

1 three years of operation is that we have had no
2 complications of infection and one complication of hematoma.

3 DR. MONSEES: Do I have any other questions
4 pertaining to this?

5 Thank you very, very much.

6 It is now 12:30. We have actually managed to stay
7 ahead of schedule which is wonderful. You will be the
8 beneficiaries of this, because what we will do is extend the
9 lunch break a little bit, but please be cautioned that we
10 will begin the actual presentation promptly at 2 o'clock.

11 DR. WINCHESTER: Do we need an hour and a half for
12 lunch?

13 DR. MONSEES: I am just afraid that maybe people
14 are scheduled to come and hear the presentation at 2
15 o'clock, and that if we start early -- let me just ask Dr.
16 Houn whether or not we can do that. Could we start early if
17 we wanted to? Before you leave, let's answer this question.

18 DR. HOUN: I think that since this presentation is
19 going to be rather lengthy, you could start early, and if
20 people missed parts, I still think they would be able to
21 hear the majority of this presentation.

22 DR. MONSEES: With that okay, then, we will begin
23 at 1:45, so please be here promptly. We will begin at 1:45.
24 Thank you.

1 [Whereupon, at 12:30 p.m., the proceedings were
2 recessed, to be resumed at 1:45 p.m. the same day.]

AFTERNOON PROCEEDINGS

[1:50 p.m.]

DR. MONSEES: We are going to begin this afternoon's session 15 minutes early, so we have some additional time.

Joint Presentation:**American College of Surgeons/****American College of Radiology**

We are going to start with a presentation by these three gentlemen who are sitting at this front table. They are Drs. David Dershaw, David Winchester, and Robert Pizzutiello, and not necessarily in that order.

This is a joint presentation of the American College of Radiology and the American College of Surgeons. I will have Dr. Dershaw make some introductory remarks and then the three of you, if you don't mind, can speak in the order that you have agreed to. Hopefully, there will be some time for a question and answer at the completion of that.

DR. DERSHAW: Thank you, Dr. Monsees.

I am here representing the American College of Radiology and I appreciate the opportunity to come before the committee to make some comments. I have been asked, and Dr. Winchester has been asked, to put together a

1 presentation on an established accreditation program, and we
2 have asked Robert Pizzutiello to address the issues that are
3 involved in equipment specifically, and then I think Dr.
4 Winchester and I will more specifically address other issues
5 that are involved in accreditation and/or regulations.

6 I am going to ask Bob to first start, again
7 addressing equipment issues in these programs.

8 MR. PIZZUTIELLO: Good afternoon. My name is Bob
9 Pizzutiello and I am a medical physicist.

10 [Slide.]

11 I am involved with the American College of
12 Radiology in their accreditation program, and I have been
13 asked to speak on some of the technical aspects of
14 stereotactic breast biopsy primarily quality control and the
15 medical physics aspects.

16 In the earlier presentation before lunch, we heard
17 a very nice and thorough and delightfully pleasant
18 discussion of many of the clinical aspects involving
19 interventional breast procedures, and we know that there is
20 also a significant technical component involved in these
21 procedures, and that is what I would like to cover for the
22 next little bit.

23 [Slide.]

24 What I am going to discuss is I will start off by

1 talking about the difference between mammography and
2 stereotactic breast biopsy, to clarify that distinction
3 since we have heretofore been talking primarily about
4 diagnostic and screening mammography.

5 I would like to make the case for quality control,
6 talk about the physics of stereotactic localization, some
7 words about the stereotactic breast biopsy equipment, the x-
8 ray system, the patient positioning system, whether they be
9 for prone or add-on units, and the image receptor and image
10 processing. These are aspects of the stereotactic
11 equipment.

12 I will address some issues about patient dose in
13 stereotactic breast biopsy. Radiation dose to the patient
14 is something we always need to be careful about whenever we
15 are using x-rays for imaging.

16 I will finally talk about the details of quality
17 control.

18 Maybe I will first start with some reflections on
19 the case for quality control. I was doing a site survey for
20 the American College of Radiology one time a year or so ago,
21 and we reviewed a facility which had extremely fine clinical
22 images. It was a relatively new facility, they had been
23 open about a year. But in reviewing the quality control
24 program, there were significant holes in the quality control

1 program. Many of the quality control tests were not being
2 done or were not being done properly, and they were not
3 being followed up on.

4 So, the question arose how can this be. Maybe
5 quality control isn't so important because here is a
6 facility that is obviously doing extremely good clinical
7 work, but yet the quality control program seems like it's
8 not working.

9 I pondered that for a few moments, and I think the
10 answer is relevant here, and that is that in human life we
11 have learned that when things are going well, there are no
12 problems, when the wind is at our back, as the Irish
13 blessing says. But we also know that things do go wrong and
14 if you are medical physicist or a physicist, you might know
15 about the law of entropy that says that in the universe,
16 things get more disordered unless we make an effort and put
17 energy into the system to make them more ordered.

18 If you are a religious person, you might think
19 about original sin, but whatever the cause, things do go
20 wrong. We all experience that in our lives.

21 In this facility, nothing had yet gone wrong, so
22 the fact that the clinicians were doing an extremely good
23 job was evident in the fact that the quality of the service
24 was good, but without an adequate quality control program,

1 not if, but when things did go wrong, they were at risk of
2 having significant loss in the quality of their work, and in
3 fact, the quality of their work, in the absence of a QC
4 program, would not be noticed until the images got so bad
5 that the radiologist said, you know, I am really not
6 comfortable with what is happening here.

7 I think that is the issue that quality control
8 addresses is to detect problems in an imaging modality
9 before they become so serious that the clinician is
10 uncomfortable and feels that something may be compromising
11 the patient care. So, that is the case for quality control
12 in all of imaging.

13 [Slide.]

14 For just a moment, let's distinguish between
15 detection and diagnosis. Detection is accomplished by
16 breast self-exam, physician physical exam, diagnostic or
17 screening mammography, and ultrasound. The purpose there is
18 to detect abnormalities from a large quantity of patients
19 who are predominantly normal.

20 Diagnosis is really more the issue for
21 stereotactic breast biopsy, whether it be done with biopsy
22 cytology or histology. It is performed on a selected
23 subpopulation who have been found to be at higher risk for
24 malignancy, so diagnosis is really what we are trying to

1 accomplish with stereotactic breast biopsy.

2 [Slide.]

3 As a result of the distinction, there are some
4 differences in the equipment that we use. In diagnostic and
5 screening mammography, we are looking for detection of
6 abnormalities in a population that is overwhelmingly normal.
7 The background is very complex and primarily what we are
8 looking for is microcalcifications, masses, architectural
9 distortion of some sort.

10 The field of view that is used for diagnostic and
11 screening mammography is sufficient to image the entire
12 breast, 18 by 24 centimeters, or 24 by 30 centimeters in the
13 larger format for the larger breast.

14 It is also important to be able to image the
15 borders of microcalcifications and masses to help to decide
16 whether we are very concerned or only slightly concerned
17 about these lesions as being potentially abnormal.

18 Again, since we are screening a predominantly
19 normal population, the radiation risk is to a very large
20 number of women who are predominantly normal.

21 [Slide.]

22 Now, if we contrast that to stereotactic breast
23 biopsy, we are looking for localization, not detection of
24 abnormalities, and specifically what that means is that the

1 abnormalities have already been detected on a diagnostic
2 quality mammogram, and now it is important to localize those
3 that the needle can go to the right location.

4 There are a limited number of normals in
5 comparison with diagnostic mammography. The background is
6 just as complex. We are still looking microcalcifications
7 and masses. A limited field of view is needed because we
8 don't need to look at the whole breast, we need to
9 concentrate only on the area of interest in the breast.

10 Again, the radiation risk is to a selected
11 population who are at higher risk for malignancy. That is
12 why they are having this interventional procedure in the
13 first place.

14 [Slide.]

15 The distinction between mammography and
16 stereotactic has to do with the localization. Whenever you
17 have any radiographic image, a single radiographic image, it
18 takes a 3-dimensional anatomy and projects it down onto a 2-
19 dimensional image. In order to position the needle in the
20 right location for stereotactic work, we need to do a 3-
21 dimensional localization, and the principle of triangulation
22 is needed to determine the depth coordinate.

23 [Slide.]

24 Now, there are probably lots of highly scientific

1 ways to conceive of stereotactic imaging, and the example we
2 saw this morning about looking from one eye to the next is
3 also a very good one. This is one that I thought of and I
4 figured that Newton discovered gravity by having an apple
5 fall on his head, and I wondered if the person who developed
6 the stereotactic technique was a bowler. Bowling is one of
7 the most popular activities, and I kind of hesitate to call
8 it sport in the United States, but when you bowl, you
9 probably all have had the experience of you are starting off
10 looking a full set of tenpins, and when you look, your brain
11 interprets a series of pins because you are looking straight
12 on at these pins.

13 [Slide.]

14 And if you are sort of a marginal bowler like I
15 am, since I don't do it very often, you throw your first
16 ball and you don't get all the pins down. I remember this
17 happened to me very distinctly. I was looking down at the
18 mess I had created, and I found that there were four pins
19 that I didn't hit. Then, I rolled the ball and there was
20 one more pin that I never saw. That is this pin right over
21 here.

22 [Slide.]

23 This slide shows perhaps the origin of the
24 stereotactic view, and that is, if you move to the side when

1 you are bowling, and go out towards one of the alleys and
2 look down, then, you can see this pin which was previously
3 obscured. It is giving you a view of perhaps about 15
4 degrees, and that is the way we are able to determine the
5 difference between overlying structures and of course in the
6 stereotactic breast biopsy, that is what gives us the depth
7 coordinate.

8 [Slide.]

9 The purpose of having the depth coordinate is so
10 that we can position the needle in the right location. In
11 this slide, this round circle is the lesion, and the tan
12 tissue is shown here. The needle is positioned before the
13 lesion, then, the stylet is advanced through the lesion, and
14 the cutting needle comes through to collect the core sample.

15 So, it is very critical that we be able to
16 position the tip of this needle in exactly the right
17 location to sample the tissue that is desired.

18 [Slide.]

19 Since I am a physicist, you can't hear one without
20 having at least one equation, so this is the mandatory
21 minimum one equation, and it is basic trigonometry. What we
22 are looking to do is to image this lesion. The x-ray beam
23 comes from the floor. Here is the breast, here is the
24 lesion we are trying to image. The image receptor is back

1 here, and the breast is compressed between the compression
2 paddle and the breast support.

3 In order to position the needle at exactly the
4 right location, what we need to really do is to calculate
5 the distance from the needle to the image receptor, and that
6 distance we will call Z.

7 Since we know that the stereo images are taken at
8 15-degree angles, we have a fairly simple trigonometry
9 problem, and that says that the distance coordinate Z equals
10 $X \tan 15$, which is the stereo shift divided by twice the tangent
11 of 15 degrees. If you do the numbers, it means that the Z
12 coordinate is about 2 times the stereo shift.

13 [Slide.]

14 If we see how this is accomplished in a piece of
15 equipment, an image might be taken at minus 15 degrees with
16 the image receptor, and perhaps a grid if it is used, taken
17 at this angle, and then the machine is toggled over to the
18 alternate position in the detent, and another image is taken
19 at plus 15 degrees.

20 When we look at the two images, this is a well-
21 targeted lesion. At least it shows the needle in the center
22 of the lesion. Normally, we went the needle before the tip
23 of the lesion, but in this case, for demonstration purposes,
24 you can see that in the two, 15-degree views, we are right

1 there in the center.

2 But things aren't always as good as we would like
3 them to be. This image on the right shows that if the
4 needle is not properly positioned with respect to the
5 lesion, then, we get stereo images which are different from
6 what we are trying to achieve, and that would tell the
7 physician who is performing the procedure that the tip of
8 the needle is not in the right location.

9 All this has to happen with approximately 1
10 millimeter accuracy in order to adequately sample the
11 lesions that we are looking for.

12 [Slide.]

13 There are different types of stereotactic breast
14 biopsy equipment. There are dedicated prone tables which we
15 have heard about this morning and seen, and they have
16 advantages of speed of a procedure, they are considered
17 rather patient-friendly in terms of comfort and lack of
18 problems with fainting, and so on, and they are also very
19 convenient for scheduling, because you can have one
20 dedicated room that is always used for stereotactic
21 procedures.

22 In trying to schedule a busy department, if all of
23 a sudden you decide that a stereotactic procedure is needed,
24 it may tie up an extra 45 minutes or an hour in a room and

1 interrupt the schedule for the day.

2 So, those are the dedicated prone tables.

3 Another type of technology that is used is an add-
4 on stereotactic unit where a basic mammography unit is used
5 with a stereotactic system that allows precise positioning
6 of the needle. It is almost an identical positioning system
7 to what is used in the prone table, but this difference is
8 that the patient may be sitting up or the patient may be
9 recumbent depending upon the model and the chairs, and some
10 of the patient-friendly things that are used.

11 Add-on units are available at less cost because
12 most of the cost is in the mammography unit, and you just
13 need to buy the additional add-on device. They don't take
14 up the space of an additional room, they are ideal for a
15 small number of biopsies, and many facilities use them where
16 they are only doing a few biopsies perhaps a week.

17 So, those are the two types of x-ray equipment.

18 The imaging modality is primarily in the past was
19 done with screen film imaging, and that uses a film image
20 like we are familiar with in mammography, and those films
21 then get digitized into the computer, so that the computer
22 can calculate the Z coordinate.

23 In recent years, it has become much preferable to
24 use digital image receptors, and these have the advantages

1 of fast turnaround and shorter procedure time. As we heard
2 this morning, once that digital image is exposed, the image
3 comes up on the computer screen within just a couple of
4 seconds.

5 Common to all units is digital targeting software.
6 This is the computer software that performs the
7 triangulation calculation and informs the physician where to
8 put the tip of the needle.

9 [Slide.]

10 This slide shows the picture that you have already
11 seen for the prone table, and if we move up here to the
12 right, you can see a conventional mammography unit with the
13 stereotactic device literally being added on in this
14 photograph.

15 [Slide.]

16 Because digital imaging is an important part of
17 the way most stereotactic procedures are performed now, just
18 a word to distinguish between screen film and digital. In
19 screen film imaging, film is used to capture the image,
20 display the image, and to store it. So, since one sheet of
21 film has to accomplish those three different tasks, there is
22 always a tradeoff between how we can achieve the right
23 performance.

24 In a digital imaging system, it is possible to

1 have individual modalities to individual components to
2 capture the image, to display the image, and to store the
3 image. As such, engineers can design and optimize each of
4 those three individual components.

5 [Slide.]

6 The basic method that is used in stereotactic
7 systems for digital imaging is the CCD, the charge-coupled
8 device image receptor, and it is not terribly different from
9 the charge-coupled devices that have become popular in home
10 camcorders.

11 These camcorders use an integrated circuit, a
12 chip, which contains light-sensitive detectors on the
13 surface, and these detectors collect a light image and then,
14 through amplifiers, generate an electronic image that can go
15 into the computer.

16 [Slide.]

17 In order to have a light image in the first place,
18 we also have to convert the x-ray image into a light image,
19 and in this slide, what you can see on the right is that
20 here is the x-ray target, the patient is in position here,
21 and then this is an x-ray image that is created. That image
22 gets converted into a light image using a screen similar as
23 to what would be found in a mammography cassette or
24 radiography cassette.

1 That image then is relatively large and gets
2 minified down to fit onto the size for this CCD.

3 [Slide.]

4 Other important components of the equipment for
5 digital image and stereotactic is the CRT, the computer
6 monitor, a standard VGA monitor, has a resolution of about
7 640 by 480 pixels, and a pixel is an individual element of a
8 digital image that can be any one of 4,000 or so shades of
9 gray.

10 What is also highly important for being able to
11 use these images in stereotactic imaging is the fact that
12 image processing is available. Once that image is taken,
13 the x-ray picture is taken, then, by adjusting the display
14 on the computer, we can window and level that image to
15 adjust the contrast, and we can adjust that contrast to
16 visualize dense tissue, to visualize fatty tissue, and to
17 bring up microcalcifications so that they are more visible.

18 [Slide.]

19 This is sort of a closeup view of a prone table
20 and this is the digital image receptor. It sits on the back
21 of the machine. The x-ray tube is over here. The x-rays
22 travel down. The patient is compressed in this position,
23 and the digital image receptor sits here.

24 [Slide.]

1 This slide shows what the computer station looks
2 like. This is sort of a familiar computer keyboard with
3 some software that allows the images to be shown, some
4 magnification. The images can be inverted, and so on.

5 [Slide.]

6 It is important, as I said earlier, to be aware of
7 the dose in any procedure that we do involving x-rays. When
8 the medical physicist evaluates the dose, we use the data
9 from the technique chart. We want to measure the entrance
10 skin exposure from a standard condition, from the ACR
11 phantom.

12 We know that the dose varies considerably with the
13 different breast composition and the different breast
14 thickness, and the technique factors. So, rather than
15 measure the dose for every individual patient, it has been
16 agreed that, as medical physicists, we measure the dose
17 under a standard set of conditions, and those standard set
18 of conditions are for the ACR phantom, which is a specific
19 thickness made up of a mixture of fat and glandular tissue
20 or at least made to simulate that tissue.

21 The medical physicist measures the half-value
22 layer, which allows us to determine a factor called the DgN,
23 and from looking up these values in the table, we can
24 calculate the average glandular dose.

1 This is determined by an article written in the
2 late seventies and this is the standard way of measuring
3 dose average through the glandular tissue at risk. That
4 dose is required to be less than 300 millirads per view in
5 mammography as a regulatory issue. There is no current
6 requirements since stereotactic breast biopsy is not
7 regulated.

8 For screen film imaging, the dose is related to
9 the optical density. If the image is too light, then there
10 is a good chance that inadequate dose was used, and if the
11 image is too dark, it is probably the other way around, but
12 there is a significant factor of film processing which also
13 has to be addressed.

14 With digital imaging it is not like that. The
15 dose, the noise, and the image processing are all
16 interrelated in a way that is not always obvious to the
17 operator.

18 [Slide.]

19 These are the factors that affect the breast dose
20 in stereotactic breast biopsy with digital imaging. The kVp
21 and the mAs that are either set, or the machine chooses if
22 it is in automatic mode. If film is used, then the exposure
23 time can also have a small effect on the dose. Primary
24 factors are the breast thickness and composition. Thicker

1 breasts require more dose and dense breasts require more
2 dose.

3 As I said earlier, the optical density of the film
4 was a prime indicator, but that is not the case in digital
5 imaging. In any case, multiple exposures, every time an
6 individual patient exposure is made in a stereotactic
7 procedure, the patient receives that dose of radiation. If
8 it takes six x-ray exposures to image during the procedure,
9 then the patient receives six times that dose. If it takes
10 20, then it takes 20 times that dose.

11 [Slide.]

12 The quality control issues are such that the team
13 approach is necessary in order to maintain the quality of
14 the service, and that is that the medical physicist must
15 work together with the radiologist or the physician
16 performing the procedure, and the x-ray technologists.

17 It is important that there be training and that
18 the personnel understand the issues of targeting accuracy
19 and the errors that are involved. It is important that the
20 personnel understand the factors that can contribute to
21 degradation of image quality or to increase in dose, and be
22 able to manage that in an environment where the patient may
23 experience some pain and discomfort.

24 [Slide.]

1 There are some unique problems associated with
2 stereotactic breast biopsy quality control. For example,
3 many medical physicists have not seen these units. They are
4 relatively small in number compared with the vast number of
5 mammography units, perhaps 12- or 14,000 out there in this
6 country. So, medical physicists may be unfamiliar with the
7 equipment, the procedure, or the need for quality control.

8 This may also be true of physicians who have not
9 previously been involved in the accreditation program and
10 accreditation process. Radiologists are not always
11 involved.

12 There is a limited regulatory history. We stand
13 in the face of a greater than 10-year experience with the
14 mammography accreditation program from the American College
15 of Radiology, but roughly a year and a half experience with
16 the stereotactic accreditation program.

17 The horizontal configuration of the prone table
18 causes some problems in quality control, particularly for
19 the medical physicist. In standard mammography units,
20 gravity works very nicely to allow us to set up our
21 equipment in a reproducible way, and that is not the case
22 with the prone units.

23 The small field of view causes some problems in
24 the digital image receptors, and these problems occur with

1 the phantom images and the ion chamber measurements.
2 Medical physicists must be trained to know what is the
3 proper method to make these measurements, so that they can
4 avoid problems.

5 [Slide.]

6 There are some quality control problems that are
7 also unique. There is a large heel effect on many x-ray
8 units which again makes the positioning of the instruments
9 very critical for the medical physicist.

10 In mammography, we make all our measurements
11 through the compression paddle, but since in a stereotactic
12 unit there is an open window that is always in place for
13 imaging, medical physics measurements must be made using the
14 compression device window open.

15 For many institutions that use digital imaging
16 only, there may be a lack of a quality hardcopy device. It
17 is not required that there be hardcopy. There may also be a
18 lack of digital image storage. Again, it is not required
19 that there be digital image storage. Among my clients, we
20 have eight facilities that do stereotactic imaging, and some
21 have no hardcopy and some have no long-term digital image
22 storage.

23 For the medical physicists who are accustomed to
24 working with instruments and computers, we have to work with

1 pointy needles and gushy phantoms, because we too have to be
2 present and be involved in the localization simulation. So,
3 that is something else that we have to learn.

4 The software for digital field uniformity analysis
5 is something that is available on some digital systems, and
6 that is a measurement that we hope to make in the
7 stereotactic quality control program for the medical
8 physicist, and we need to learn how to do that.

9 [Slide.]

10 This slide shows that it is actually not terribly
11 trivial to position a test instrument in the horizontal
12 position reproducibly, but we found that it works well to
13 use a stanchion like this and a little support, but if you
14 don't have that, people try using tape and tissue boxes, and
15 it can get very difficult and certainly not reproducible and
16 not scientific.

17 [Slide.]

18 So since things go wrong, the quality control
19 programs were developed by the American College of Radiology
20 Stereotactic Breast Biopsy Accreditation Program, and there
21 are a number of tests that are required by the x-ray
22 technologists, and these tests are listed here, at varying
23 frequencies from before each patient to every day, down to
24 quarterly and semiannually.

1 [Slide.]

2 If screen film imaging is used, then there are
3 additional quality control tests which are not required for
4 facilities that do digital, and these tests largely mimic
5 the quality control requirements from the mammography
6 accreditation program.

7 [Slide.]

8 Now, like in the mammography program, under the
9 stereotactic accreditation program, medical physicists have
10 quality control tests, 11 tests that are specified, and you
11 can see them listed here. I won't go through them at all
12 except to say that the ones in yellow are significantly
13 different than the quality control tests that medical
14 physicists are accustomed to performing under the
15 mammography accreditation program.

16 So, physicists need to have specific training in
17 performing more than half of these tests, so that they can
18 be knowledgeable and provide valuable input to the facility
19 performing stereotactic breast biopsy.

20 [Slide.]

21 There are two phantoms that can be used for image
22 quality analysis and for dose measurement under the
23 stereotactic systems. The phantom on the right is the
24 familiar mammography accreditation phantom that has been

1 around for a long time.

2 The phantom on the left was developed out at Mayo
3 Clinic. It is marketed by Nuclear Associates, and that was
4 specifically designed to contain most of the information we
5 need from an image quality point of view in a smaller field
6 of view, in a field of view designed to fit within the 5 by
7 5 centimeter field of the stereotactic unit.

8 [Slide.]

9 Since the digital imaging system has different
10 imaging capabilities, there are different scoring
11 requirements for the different phantoms. Shown here are the
12 mammography accreditation program requirements for passing
13 scores of fibers, specks, and masses. This uses the ACR
14 accreditation phantom.

15 In the digital mode, under the stereotactic
16 accreditation program, these are the required passing
17 scores. If the mini-phantom is used from Nuclear
18 Associates, the passing scores are quite different. So, it
19 is important that individuals who are using these phantoms
20 understand the difference. It is not possible to obtain
21 this score or this score for fibers, for example, on the
22 digital mini-phantom on most units.

23 [Slide.]

24 This slide shows the technical problem of imaging

1 the full field mammography accreditation phantom with the
2 digital field of view that is about the size of the yellow
3 image. So, for facilities that use the large phantom, they
4 need to take four separate images of the phantom, and then
5 take a fifth image that demonstrates the TLC chip, and these
6 TLDS are used by the American College of Radiology program
7 to measure the dose in the half-value layer.

8 [Slide.]

9 Since the medical physics requirements are
10 somewhat different, there are some different requirements in
11 terms of knowledge and experience, the medical physics
12 qualifications are shown here - a board certification or
13 alternate requirements, 15 hours of continuing education in
14 mammography physics every three years. Those are the
15 mammography type requirements.

16 Prior to June of '97, medical physicists would be
17 qualified to do stereotactic breast biopsy surveys if they
18 performed three hands-on surveys or if they performed one
19 hands-on survey under the guidance of a qualified medical
20 physicist who has done stereotactic breast biopsy.

21 That window has closed and effective June of '97,
22 medical physicists who have not done anything previously
23 must do one hands-on stereotactic survey under the guidance
24 of a medical physicist who has been previously qualified.

1 In addition, for a medical physicist to be
2 qualified, they must perform at least one stereotactic
3 breast biopsy medical physics survey per year and receive
4 three hours of continuing education in stereotactic breast
5 biopsy physics every three years.

6 So, the medical physicists need to receive some
7 specific training in stereotactic physics.

8 [Slide.]

9 So, to summarize, mammography is about detection,
10 stereotactic breast biopsy is about diagnosis. Quality
11 control is necessary because things do go wrong. It is not
12 a question of if, it is only a question of when they go
13 wrong.

14 We talked about the physics of stereotactic
15 localization, some of the specific equipment requirements,
16 and I would like to kind of close with an important comment
17 about patient dose in stereotactic breast biopsy.

18 One of the problems with digital imaging is that
19 if operators are not familiar with all the factors that
20 contribute to dose, then, patients can receive unacceptably
21 high doses from these stereotactic digital systems.

22 The reason is that if excessive dose is used on
23 the front end, the image processing can be used to adjust
24 the window and level, so that the image looks very good, and

1 that is something that obviously we need to avoid. So, it
2 is important that everyone be educated and that the medical
3 physicist be part of the team that performs quality
4 stereotactic breast biopsy.

5 Thank you.

6 DR. MONSEES: Thank you very much.

7 Can we have the lights, and we will move on to the
8 next portion of the presentation before we have questions
9 and answers.

10 DR. WINCHESTER: Dr. Monsees, members, and
11 consultants of the National Mammography Quality Assurance
12 Advisory Committee, FDA staff, thank you for the opportunity
13 to make this presentation on behalf of the American College
14 of Surgeons.

15 I would like to emphasize at the outset that the
16 representatives from the American College of Surgeons and
17 from the American College of Radiology on the joint task
18 force have worked together over many months in a collegial
19 manner with the dedication to quality patient care and a
20 real attempt to avoid turf issue discussions.

21 You have in your packet a publication entitled
22 Stereotactic Core Needle Biopsy of the Breast, a report of
23 the Joint Task Force of the American College of Radiology,
24 American College of Surgeons, and College of American

1 Pathologists.

2 We believe that this represents an important
3 summary of the best available scientific knowledge with
4 regard to this procedure. The trick now is to find out how
5 many people will read this and what the diffusion time into
6 the practicing community will be.

7 We have had past experiences with guidelines,
8 standards, and diffusion into the community is very slow, so
9 I would hope that this is read. Our committee, really our
10 joint task force in this exercise, undertook the task of
11 doing this for that very reason. We thought it was
12 necessary with relatively new technology to define the
13 indications, contraindications, and some of the subtleties
14 that the people who were beginning to do this might not
15 appreciate.

16 A separate task, consisting of four surgeons from
17 the American College of Surgeons and four radiologists from
18 the American College of Radiology, along with senior staff
19 from the American College of Radiology, developed the
20 document included in your packet entitled Physician
21 Qualifications for Stereotactic Breast Biopsy.

22 The Board of Regents of the American College of
23 Surgeons and the Board of Chancellors of the American
24 College of Radiology officially approved this document after

1 some minor modifications.

2 The September 1997 issue of the Bulletin of the
3 American College of Surgeons published the document
4 regarding personnel requirements in its entirety, along with
5 an overview which I provided.

6 Our joint task force completed the Physician
7 Qualification document with the realization that precise
8 numbers are somewhat arbitrary and subject to considerable
9 debate along with many other elements in the document.

10 We attempted to simplify and systematize practice
11 qualifications in an exceedingly complex national
12 environment. Nonetheless, we identified the two major
13 models of practice in the United States, that is, physicians
14 working in a collaborative setting or physicians working
15 independent of one another.

16 Clearly, the joint task force favored the
17 collaborative model, but recognized in some centers the
18 procedure could be done independently.

19 I think it is important for me to take a few
20 minutes now to describe the major objections which have been
21 expressed by the surgical community in response to physician
22 qualifications for stereotactic breast biopsy.

23 Madam Chairman, I could list all the names and
24 origin of the 12 or 15 surgeons, but if I may not do that, I

1 think that in the interest of time --

2 DR. MONSEES: A summary would be appreciated.

3 Thank you.

4 DR. WINCHESTER: So, these are quotes from a wide
5 variety of surgeons from a wide variety of sites around the
6 country:

7 Surgeons have always played a central role in the
8 complete continuum of care and the management of the breast
9 patient. We need to draw attention to the fact that the
10 performance of a surgical minimally invasive biopsy
11 procedure utilizing imaging is only one small part in the
12 total evaluation and care of the patient.

13 The surgeon evaluates patients fully prior to any
14 form of biopsy. The surgeon correlates the approach used
15 for the biopsy in preplanning for any eventual larger
16 cancer-directed procedure.

17 Addressing the radiology community doing this in a
18 totally independent setting without surgical consultation,
19 some of the remarks are as follow:

20 If a radiologist is to perform this procedure
21 independently as a direct referral from the primary care
22 physician without the benefit of surgical consultation, then
23 many of our surgeons believe that the requirements for a
24 radiologist practicing independently as stated in the

1 document are inadequate.

2 The 15 hours of CME in breast imaging including
3 "benign and malignant breast disease," should focus not on
4 breast imaging, but an understanding of benign and malignant
5 breast disease.

6 It has been pointed out that radiologists may lack
7 clinical skills when practicing independently, and some of
8 the points along those lines that have been brought forth by
9 surgeons and suggestions for improving those clinical skills
10 are as follows:

11 That the radiologist observe at least 12 open
12 surgical breast biopsies performed by a board-certified
13 general surgeon with attention to sterile technique, tissue
14 handling, wound management, and hemostasis, clinically
15 interact for at least 12 hours with a board-certified
16 general surgeon for physical examination of the breast and
17 for presentation of surgical options to the potential
18 stereotactic patient including benefits, risks, and
19 complications.

20 Attend on a regular basis hospital tumor board
21 conferences or breast conferences. In our institution, for
22 example, we have a weekly multidisciplinary breast cancer
23 conference review with Pathology, Radiology, Surgical
24 Oncology, Medical Oncology, everybody who takes care of the

1 breast cancer patient, and the radiologists I think benefit,
2 and have told us that they benefit considerably from being
3 present at that conference.

4 Take a one-week rotation through the hospital
5 pathology department. That might be kind of tough to do.
6 Be responsible for face-to-face postbiopsy communication
7 with the patient including the diagnosis of benign and
8 malignant disease. Again, all these suggestions are for a
9 radiologist practicing in a totally independent setting.

10 Future treatment options for cancer, referral to
11 surgeons, oncologists, and radiation therapists.
12 Communicate with the primary referring physician regarding
13 appropriate clinical, mammographic, and surgical followup,
14 and risk assessment, and attend a national multidisciplinary
15 breast cancer symposium every three years.

16 Further comments. Imaging is performed as an
17 adjunct to the biopsy, to allow positioning of the biopsy
18 device itself. The physician locates the abnormality
19 previously identified by a qualified MQSA physician. There
20 are many other instances where x-ray imaging is used as an
21 adjunct in the performance of diagnostic and therapeutic
22 procedures by surgeons.

23 A few examples of these include stereotactic
24 intracranial neurosurgical procedures, intraoperative

1 fluoroscopy for the placement of central venous catheters,
2 intraoperative fluoroscopy in numerous orthopedic
3 procedures, fluoroscopy used in coronary angioplasty, and
4 cholangiography.

5 None of these examples require the supervision of
6 radiologists, even though they utilize x-ray imaging. To
7 require stereotactic breast biopsy to come under MQSA merely
8 because screening mammography identified the abnormality in
9 the first place, in one surgeon's words, "was inappropriate
10 and unnecessary."

11 Many surgeons have expressed the opinion that the
12 number of mammogram reviews of 480 is arbitrary and too
13 high. This has been the most commonly voice objection to
14 the document. Surgeons do not believe that MQSA
15 requirements for interpretive skills of 480 mammograms per
16 year for screening mammography applied to the skills
17 required for a surgeon practicing in an independent setting
18 to review an abnormal mammogram which has been officially
19 interpreted by an MQSA radiologist, target the lesion, and
20 perform the biopsy.

21 Finally, a quote from a surgeon in Georgia, "The
22 surgeons in our community are the only physicians performing
23 stereotactic breast biopsy. Our results indicate that we
24 are doing it in a quality manner. We do not individually

1 review 480 mammograms per year per surgeon. Does this mean
2 that no stereotactic breast biopsies could be performed in
3 our community?"

4 There are many other communications I have
5 received from surgeons around the country, but in the
6 interest of time, I will no longer dwell on this broad-based
7 surgical feedback, but simply acknowledge that the "final
8 draft" of any document must take into account criticisms
9 such as those which I have described.

10 Having just attended the annual clinical congress
11 of the American College of Surgeons, and viewing the wares
12 of the stereotactic manufacturers, it is apparent that this
13 equipment is becoming increasingly sophisticated.

14 The BIRAD system of the American College of
15 Radiology has promoted proper selection of patients with
16 mammographic abnormalities for stereotactic breast biopsy.
17 Even so, the demand for the performance of this procedure is
18 exceedingly high and legitimate.

19 Practicing surgeons around the country are
20 learning this procedure through formal courses, such as
21 those described this morning by Dr. Israel and Dr. Dowlat
22 from American College of Surgeons, and the Society of
23 Surgical Oncology.

24 These physicians are then going back to their home

1 institution and being proctored by other surgeons or
2 radiologists according to local credentialing body
3 requirements. Many of them are being trained to not only
4 perform the procedure, but to train others.

5 The American College of Surgery has now formally
6 included this procedure in their curriculum so that future
7 graduates of training programs in surgery will become board-
8 certified, will be qualified to perform this procedure much
9 in the same way that board-certified radiologists qualify as
10 interpreters of screening mammography under MQSA.

11 As you know, the American College of Radiology has
12 a voluntary accreditation program for stereotactic core
13 needle biopsy in place. The Board of Regents of the
14 American College of Surgeons, which met in Chicago this
15 month, unanimously approved the concept of the establishment
16 of a voluntary accreditation program for the performance of
17 stereotactic breast biopsy through the American College of
18 Surgeons.

19 A task force of the college is in the process of
20 developing the details of this accreditation program. We
21 have discussed this with the American College of Radiology.
22 They have offered to help us put this together. They have,
23 in fact, offered to have representatives from the college
24 sit on their committee that developed their accreditation

1 program.

2 Following this resolution, the American College of
3 Surgeons and the American College of Radiology communicated
4 with one another and have forwarded letters to FDA,
5 suggesting that consideration be given to a voluntary
6 accreditation program or approach rather than the
7 development of regulations under MQSA.

8 Finally, if FDA determines that interventional
9 radiology should be included under MQSA, then the
10 composition of the National Mammography Quality Assurance
11 Advisory Committee needs to be changed to represent a proper
12 balance of clinicians on the committee from the disciplines
13 of radiology, surgery, and pathology.

14 A final remark is in the form of a question to
15 FDA. It is hard to sit down and read the 1992 Act word for
16 word, but somehow I did it and got through it, and when I
17 did that, I was looking specifically for language which
18 indicated to me why we are here talking about the regulation
19 of interventional mammography.

20 The Act states that the National Mammography
21 Quality Assurance Advisory Committee shall, "report on new
22 developments concerning breast imaging that should be
23 considered in the oversight of mammography facilities."

24 The only other reference in the Act to anything

1 other than screening mammography is under Section 35-4A
2 under Definitions. "The term facility means a hospital,
3 outpatient department, clinic, radiology practice or mobile
4 unit, an office of a physician, or other facility as
5 determined by the Secretary, that conducts breast cancer
6 screening or diagnosis through mammography activities."

7 I couldn't find anything else and, Dr. Finder, I
8 had talked to you before about the Advisory Committee and
9 the advice about not to regulate this, there wasn't enough
10 state-of-the-art information. Could you please clarify for
11 me this question?

12 DR. FINDER: I will try. Basically, when you go
13 to the definition of what mammography is or what a mammogram
14 is, it refers to radiography or radiographic images produced
15 of the breast. Under that, the interventional procedures
16 which are used for radiography of the breast or mammography
17 are included under that definition.

18 When the Interim Regulations were first
19 promulgated, at the time there wasn't enough information,
20 there were no standards available to include interventional
21 procedures, so at that time these procedures were
22 specifically excluded from regulation, but there was always
23 the impression and always the feeling that at some point
24 this issue would be looked at again to see if the science

1 had progressed enough and if the standards had progressed
2 enough to bring these procedures under regulation.

3 DR. WINCHESTER: But who initiated the request to
4 look at it in the first place? I can't find the language of
5 stereotactic breast biopsy, needle localization,
6 galactography. I can't find any of that language in the
7 1992 MQSA Act. Where is the language? Where did it come
8 from? Who authorized it? I just don't understand where it
9 came from. It is not in the Act.

10 DR. FINDER: Right, and as I say, those terms were
11 not used, but in terms of regulation of mammography,
12 anything that uses radiography of the breast is included.
13 As I said, it was specifically excluded because at that time
14 we had no standards or accreditation bodies or any mechanism
15 to deal with it. That is why it was excluded.

16 Now as for the calls to bring interventional
17 mammographic procedures, one of the areas that called for it
18 was this committee. I can't remember which meeting it was
19 at.

20 DR. HOUN: That was in May of 1994, the Advisory
21 Committee at that time, we were faced with an October 1
22 deadline of making sure all facilities in the U.S. were
23 certified by FDA. Otherwise, if they were not certified,
24 they would be performing mammography illegally.

1 At that May 1994 meeting, we were discussing this
2 area of stereotactic and interventional procedures using x-
3 rays that had not had an accreditation process developed and
4 that if we did not do something about them by October 1 of
5 1994, these procedures would be banned by law because we did
6 not have an accreditation and certification process in
7 place.

8 So, at that time most of the members of the
9 Advisory Committee did advise us to not regulate this and to
10 exempt stereotactic and other interventional mammography
11 procedures. Not all of them did, but most did, and we had
12 the American College of Surgeons participate in that
13 discussion, as well.

14 So, what Dr. Finder is saying is that the Act, by
15 defining mammography very broadly, and with our history of
16 wanting to make sure that breast cancer screening and
17 diagnosis using that technology is of high quality
18 standards, this committee has helped us in giving advice on
19 what we should do with this new technology.

20 DR. WINCHESTER: I raise the question because this
21 committee has gone through a metamorphosis, there are a lot
22 of new members, and I have been here for a year, and I still
23 don't understand it. So, I was hoping that this could be
24 clarified.

1 It seems to me that if this moves forward, there
2 needs to be an amendment to the Act, because the language
3 does not reflect the intent.

4 DR. HOUN: I don't think so, because we have --

5 DR. WINCHESTER: I don't think so either.

6 DR. HOUN: I think what happened is that in terms
7 of legality, those matters are reviewed by our general
8 counsel, and that has already been reviewed several times,
9 that this particular technology, if FDA chose to regulate
10 it, would be covered by the Act.

11 DR. WINCHESTER: And has that been challenged?

12 DR. HOUN: It has not been challenged.

13 DR. MONSEES: Let's put that issue aside for now
14 and continue with this presentation.

15 Dr. Dershaw.

16 DR. DERSHAW: Thank you, Dr. Monsees.

17 Again, thank you for the opportunity to be here to
18 represent the American College of Radiology. I will try not
19 to take up too much time, so that we can have time left for
20 questioning.

21 The procedures that we have been talking about
22 this morning and this afternoon compromise a very difficult
23 number of procedures for women in the United States to
24 calculate.

1 Based on HCFA CPT coding, estimating that these
2 codes represent about one-third of procedures that are
3 performed, we have estimated that there are between 4- and
4 500,000 of these interventional x-ray-guided breast
5 procedures that are performed.

6 About half of these are needle localizations,
7 slightly over 200,000, and again these numbers are very
8 rough estimates.

9 Galactograms or ductograms compromise a paltry
10 4,000 or so procedures, and the most difficult number to
11 ascertain is the number of needle biopsies that are actually
12 performed, but it appears that there are 200,000 plus of
13 those procedures.

14 Needle localizations appear to be done by
15 radiologists about 90 percent of the time. Ductograms, I
16 think we can reasonably assume are almost always done by
17 radiologists, certainly a 90 percent plus number is a
18 reasonable guesstimate on that, and the number of imaging-
19 guided needle biopsy procedures that we are talking about
20 here today is really difficult to calculate, but maybe as
21 high as 80 percent of those procedures are done by
22 radiologists.

23 Now, let me very briefly just discuss the non-
24 biopsy procedures that have been mentioned here so far

1 today. Needle localizations, you heard a very beautiful
2 discussion off this morning. If one looks at the published
3 literature on needle localization, there is an institutional
4 failure rate that is reported in the 1 to 4 percent rate in
5 peer-reviewed literature.

6 What goes in the community in this procedure, as
7 in other procedures that don't get into the literature, are
8 not peer reviewed, I think it is very difficult to
9 ascertain. However, I think there is a general sense of
10 these procedures being performed in a competent fashion in
11 the general community, and I do not think that there is a
12 sense that there is a need for regulation of needle
13 localization procedures.

14 Ductograms, as you can appreciate, are unusual
15 procedures. Failure rates are not published on this
16 procedure. Again, I do not believe that there is any
17 consensus that these need to be under any kind of
18 regulation.

19 I will be happy to talk more about those
20 procedures during the question period if there are any
21 questions about those procedures.

22 Let me go on to image-guided breast biopsies. You
23 have heard a lot about these. I don't think there is any
24 need to redefine these procedures, but let me just remind

1 you that the purpose of these procedures is in a safe,
2 comfortable, non-deforming, rapid, and inexpensive fashion
3 to obtain cells or pieces of tissue from the breast which
4 make it possible in most cases to make a definitive decision
5 about what else needs to be done with a patient who has
6 usually a nonpalpable mammographically detected abnormality.

7 It is accepted that in some cases, a surgical
8 biopsy will be needed for definitive diagnosis. So, that is
9 the purpose of those procedures, and I will spend the rest
10 of the few minutes that I am up here addressing you looking
11 at methods in which it is possible to optimize the quality
12 of the procedure that is being performed, so that one can do
13 with these biopsy procedures what it has been possible to do
14 with mammography in the United States, and that is
15 essentially guaranteed to a woman that there will be a
16 reasonable level of quality of care and a reasonable level
17 of safety when she, in a relatively blindly fashion, goes to
18 a facility to have one of these procedures done.

19 By definition, the areas that are undergoing
20 biopsy are small, nonpalpable lesions. These are sometimes,
21 as you can all appreciate, difficult to see on a mammogram
22 where there has been full compression that has been done and
23 where we have an imaging system which has undergone a level
24 of quality control to optimize the quality of imaging that

1 results from that system.

2 The difficulty in seeing these lesions can be
3 increased, not only by the lack of compression, as has been
4 demonstrated, but also by the fact that there is an
5 anesthetic that is injected into the breast which may
6 obscure the lesion. There is hemorrhage that occurs during
7 the procedure which can further obscure the lesion.

8 Difficulty in appreciating the lesion can be
9 increased by the fact that, in fact, the area of the breast
10 containing the lesion may be displaced by the needle tip
11 during the biopsy, changing its location within the breast,
12 changing its location on the image that is obtained.

13 Now, what kind of skills are necessary to perform
14 these procedures in an acceptable fashion? Let me go
15 through the steps that are involved in actually performing
16 the procedures and address the kinds of skills that are
17 necessary to optimize the quality of care during each stage
18 of the procedure.

19 The first step again, as you have already heard,
20 is the imaging, making sure that the patient has gone
21 through the appropriate imaging steps, so that a reliable
22 decision has been made, an appropriate decision has been
23 made whether or not the patient needs a biopsy.

24 A biopsy is not -- I don't think it is acceptable

1 to anyone in this room -- a biopsy is not a replacement for
2 imaging, and biopsies that can be eliminated by appropriate
3 imaging should of course be eliminated.

4 So, the physician who is selecting a patient must,
5 first of all, appreciate that, understand that an
6 appropriate imaging, a reliable imaging workup has been done
7 and that the patient in fact needs a biopsy.

8 When it has been ascertained that a patient needs
9 a biopsy, the physician then needs to determine what kind of
10 biopsy may, in fact, be appropriate for the patient, not
11 what kind of biopsy the patient must undergo because this
12 remains her decision.

13 In some cases, I think we would all agree that, in
14 fact, a surgical biopsy may be a better biopsy procedure
15 than a needle biopsy. That may be because of patient
16 preference. That may be because we are worried about a
17 certain kind of histology that requires a larger volume of
18 tissue to be excised rather than a smaller volume of tissue
19 to make a definitive diagnosis, and in those situations, a
20 surgical biopsy may be more appropriate.

21 We have already heard that there are two kinds of
22 needle biopsies that can be performed - fine-needle
23 aspiration for cytology, or a large core needle biopsy for
24 histologic assessment of the specimen.

1 A decision about which of those procedures should
2 be done needs to be made. In addition to that, although we
3 are talking about x-ray-guided procedures, a decision needs
4 to be made if a core biopsy is being done or an FNA, is
5 stereo guidance optimal, should sonographic guidance be
6 performed instead.

7 So, the physician needs to understand what the
8 indications and the contraindications are for these
9 procedures, the relative risks that are involved for the
10 patients, and must also appreciate other medical problems
11 that may be involved - does the patient have a bleeding
12 diathesis, is the patient on medication that may increase
13 the likelihood of complication.

14 Once we have made the decision that a patient will
15 undergo one of these biopsies, we have to be certain, if we
16 are guaranteeing quality of care to the patient, that the
17 equipment that we are using for the procedure has been
18 appropriately selected and has been appropriately
19 maintained.

20 Certainly, we wouldn't expect in a surgical
21 procedure that a scalpel that wasn't adequately sharp to cut
22 into the tissue that we were going to cut through would be
23 used in the procedure.

24 You have already heard a very elegant discussion

1 on the complexities of the kind of imaging equipment, the
2 stereo biopsy units that are available, the kinds of imaging
3 that is available with those biopsy units, how complex this
4 equipment is, and how complicated the acceptance testing at
5 the time of purchase, as well as the quality control
6 programs that are necessary to hopefully abort the
7 overwhelming number of problems that may occur.

8 If you have equipment that has been well
9 maintained, and if you have selected the appropriate
10 equipment, you then need to understand how to operate the
11 equipment - what are the appropriate exposure settings, kVp
12 and mAs for different patients, how do these need to be
13 altered in different densities of breasts, in different
14 thicknesses of breasts, how must you alter your settings if
15 you are doing calcifications rather than masses.

16 Just as difficult, I think, is dealing with the
17 individual geometry of the patient, not just the
18 configurations of different pieces of equipment - how do we
19 position the patient on the table appropriately, so that we
20 have enough thickness to accommodate the positioning of the
21 needle in the breast and the movement of the needle through
22 the breast, how do we select the different gun needle
23 combinations that may be available to us, so that we
24 minimize the likelihood of complication, but optimize the

1 likelihood of making a diagnosis.

2 When we are actually performing the procedure,
3 perhaps the most difficult part of the procedure, and
4 certainly one of the key elements of the procedure, is
5 knowing what the relationship of our biopsy device is to the
6 lesion that we are seeing within the breast. This is what
7 the procedure is all about, getting the needle into a small
8 nonpalpable lesion.

9 We must be competent in understanding what it is
10 that is going on in either the film that we are exposing or
11 on the digital imaging system that we are using. We must
12 understand when we are biopsying masses that do not contain
13 calcifications what the relationship of the needle is before
14 we fire and after we fire. It is the only documentation we
15 have during the procedure to know whether or not we have
16 done something of service to the patient.

17 When we are biopsying calcifications, you have
18 already seen specimen radiographs that we take during the
19 procedure, but as simple as the specimen radiographs appear
20 to be to interpret when they are shown up on slides, I must
21 remind you that there are artifacts that can appear on
22 specimen radiographs, most commonly dust that can mimic
23 calcifications. The physician performing the procedure
24 needs to be sensitive to these mimickers of disease and has

1 to understand when they may or may not be present and when
2 to repeat the specimen radiograph.

3 After the specimen has been retrieved, the
4 physician performing the procedure must adequately handle
5 the specimen, so that there is not degradation of the
6 specimen, making it more difficult for the pathologist to
7 interpret. The physician must understand what information
8 needs to be communicated to the pathologist to make it
9 easier for him or her to make an appropriate diagnosis.

10 Once the pathologist has done his or her deed, the
11 physician next needs to understand what the pathology report
12 means, understand what it means in terms of what it is that
13 has been seen on imaging studies. It is, in fact, the final
14 step at which we ascertain whether or not the lesion in
15 question has been biopsied.

16 If it looks like a cancer, and we don't get
17 something back that says cancer, we must be very concerned
18 that, in fact, we missed a cancer. If we get something back
19 that says, for example, fibrocystic change with
20 microcalcifications, does that make sense in terms of what
21 it is we actually biopsied.

22 So, we have to be able to know on the basis of
23 that report, looking back on the imaging, whether or not we
24 missed a lesion, and if so, we have to repeat the biopsy or

1 a biopsy has to be repeated.

2 Once we get the report, we need to know how the
3 report fits into patient management, and we have to be able
4 to do that ourselves or we have to be able to appreciate
5 when the patient needs to be referred to a subspecialist who
6 will deal with breast disease.

7 So, if we get back a high risk lesion, we have to
8 appropriately deal with the patient who now has the
9 diagnosis of that high risk lesion. The diagnosis of cancer
10 is reasonably straightforward in dealing with that issue, I
11 think.

12 We have to be certain that results will be
13 appropriately communicated. I think there is nothing more
14 tragic than delivering good medical care to the patient and
15 then failing to follow through. Communication of results I
16 do not think is a problem, but certainly it is part of the
17 performance of these procedures.

18 Those are things that the doc who is doing the
19 procedure has to do, but this is not solely a procedure that
20 is done by physicians, and it is not solely a physician
21 procedure.

22 We have talked a lot about equipment maintenance
23 and equipment calibration, and your procedure will only be
24 as good as the equipment that you are using. If your

1 calibration is not good, there is no way you are going to
2 get the needle to where it needs to go.

3 If you are delivering the patient an excessive
4 amount of radiation during the procedure, then you may not
5 be doing her a service.

6 In addition to have quality equipment, it needs to
7 be set up appropriately. It needs to be set up
8 appropriately, so that it is functioning well, so that is
9 has been calibrated well, so that it is clean, in fact, it
10 is sterile, the parts that need to be sterile during the
11 procedure, and sterile technique is an important part of
12 this, and personnel involved in these procedures need to
13 adequately use a sterile technique during these procedures.

14 Now, there has obviously been concern over the
15 utilization of these biopsy procedures and perhaps the lack
16 of skill in some professionals performing these procedures.
17 That is why we are talking about this today.

18 As you all know, this has resulted in the
19 established of an accreditation program by the American
20 College of Radiology, the stereotactic-guided breast
21 biopsies, and concerns, in fact, over the utilization of
22 ultrasound for the same thing, have resulted in the
23 development of a program for ultrasound also.

24 The concepts in the development of the

1 accreditation program are based on an understanding that the
2 quality of the service delivered to the patient is based on
3 the ability of the facility, not the individual components,
4 but all the components of the whole, performing the biopsy,
5 to appropriately select and manage patients who are to be
6 biopsied, the ability to perform the biopsy with the skill
7 that comes from adequate training and experience, the
8 ability to use equipment that has been well maintained and
9 tested, so that practitioners can minimize the likelihood of
10 mechanical failure during the procedure, optimize the
11 imaging capabilities of the equipment, and keep the
12 radiation dose adequately low during the procedure to
13 increase safety to the patient.

14 If those goals are achieved, the likelihood of
15 failed biopsies should be minimized, facilities should fully
16 understand, in addition, how the results of the biopsy
17 should be used for patient management including in whom
18 these procedures have failed and the biopsy needs to be
19 repeated.

20 The risk for patient complication and excessive
21 exposure to radiation should be reduced by these kinds of
22 accreditation programs. The likelihood of excessive pain
23 and prolonged or incompetently performed procedures we hope
24 will also be reduced.

1 In assessing the quality of a facility, the ACR
2 program includes accessing the equipment, assessing the
3 personnel including the physician, the technologist, and the
4 medical physicist, and looking at facility outcome data and
5 results of any individual facility.

6 As you have already heard, and you have I believe
7 among your handouts are an agreement between the College of
8 Radiology and the College of Surgeons indicating a belief
9 that the qualifications for personnel, for physicians, can
10 be adequately met either by an individual physician or by a
11 team of physicians at an individual facility.

12 However, we do believe that these qualifications
13 need to be met. Technologists and physicists individually
14 must fulfill the qualifications for technologists and
15 physicists.

16 The requirements for personnel include
17 requirements for adequacy of initial training including
18 understanding of the rule of techniques in patient care, and
19 hands-on training in performing these biopsies. Also,
20 requires maintenance of skills by continued performance of
21 procedures and by CME.

22 I am not going to go through what is in your
23 handout. For those of who wish to peruse that, it is there.
24 Perhaps if you have trouble sleeping tonight, these

1 documents might help you with that.

2 The equipment maintenance requirements have
3 already been reviewed for you.

4 Facility outcome data are collected and include
5 during an indicated period of time, the volume of procedures
6 which are the basis for the analysis being submitted by the
7 facility. It looks at the complication rate, it looks at
8 the repeat biopsy rate, the reasons for repeat biopsy, and
9 it looks at the outcome of all the biopsies, how many
10 benign, how many malignant, and how many in other
11 categories.

12 The facility outcome data is, first of all,
13 educational for the individual facility. Secondly, we hope
14 that some point in time, numbers such as repeat biopsy rate
15 due to inadequate sampling and complication rates may, in
16 fact, be able to be fitted into a wider body of data to
17 indicate perhaps the quality of care that is available at an
18 individual facility. It is also educational for an
19 individual facility.

20 Additionally, accumulating these data mandate that
21 an individual facility adequately track patients, and we
22 believe increases the likelihood that appropriate care after
23 cancer or high risk diagnoses will be delivered to an
24 individual patient.

1 Finally, let me say that patients undergoing
2 percutaneous imaging-guided needle biopsy procedures cannot
3 be assured of the skill of practitioners performing these
4 procedures or of the safety of the equipment being operated
5 when they select facilities at random without any kind of
6 neutral third party establishing standards for these
7 facilities.

8 We believe that this is not unlike the situation
9 in mammography before the American College of Radiology
10 began its accreditation program. The accreditation program
11 for a stereotaxic biopsy that was established by the ACR was
12 done in the believe that it is possible to maximize the
13 safety and quality of these interventions.

14 The success of the ACR mammography accreditation
15 program followed by MQSA regulation has demonstrated that
16 this expectation is I believe a realistic one.

17 Regulation of interventional breast procedures may
18 not be necessary if accreditation programs are utilized to
19 establish appropriate standards for facilities and to attest
20 to the public that individual facilities have attained these
21 high standards, and if there is a motivation for facilities
22 to become accredited.

23 We believe that the imaging-guided breast biopsy
24 accreditation programs established by the ACR define the

1 standards that are necessary to accomplish these goals.
2 Training, experience, and quality control programs can
3 improve the general quality of these interventions and can
4 help assure women of competence and safety of facilities
5 offering these procedures.

6 Thank you for your attention.

7 DR. MONSEES: Thank you.

8 Now what I would like to do is ask panel members
9 if they have specific questions to the three presenters
10 here, and I would like to start out and just ask a quick
11 question of Dr. Winchester.

12 The joint agreement which the American College of
13 Surgeons and the American College of Radiology agreed to the
14 qualifications, was agreed to prior to the American College
15 of Surgeons volunteering that they were going to begin an
16 accreditation program.

17 DR. WINCHESTER: That's right.

18 DR. MONSEES: How would you propose or have they
19 discussed this at all that a facility decide who would
20 accredit them? If it were a practitioner, say, a
21 radiologist by themselves, you would propose that they apply
22 to the American College of Radiology, if it is a solo
23 surgeon, they apply to the American College of Surgeons, and
24 what if they work in conjunction, do they apply to both?

1 Has any thought and discussion been given to having two
2 different bodies perhaps with two different sets of
3 standards?

4 DR. WINCHESTER: This just happened two weeks ago,
5 so not much has happened in terms of concrete development at
6 the College of Surgeons level. Conceptually, it seems to me
7 if it is a radiologist, it should be ACR voluntarily
8 accredited, if it is a surgeon, for surgical skills, it
9 should be the College of Surgeons accreditation, but the
10 College of Surgeons, I do not believe at this point in time
11 has any interest in all in getting into the field of
12 facility and equipment certification. They are not
13 qualified to do that. So, that would be come a joint
14 effort, I would think, between the two voluntary
15 accreditation programs.

16 DR. MONSEES: So, what you would see would be two
17 ways to enter the system, but that it would be some sort of
18 merged endeavor, is that what you would envision?

19 DR. WINCHESTER: I would think it would have to be
20 because it is not just the personnel, as it has been pointed
21 out here, that is important in the performance of this
22 procedure. It would have to be some kind of a joint
23 arrangement.

24 DR. MONSEES: I would like to ask the panel if

1 they have any specific questions.

2 DR. MOORE-FARRELL: I have concerns on the same
3 issue because I am in just such a practice where
4 approximately five radiologists and five general surgeons
5 share one stereotactic machine, and I cannot be ACR-
6 certified even though I meet all the requirements because
7 individually, I think I would fit, but by the facility I
8 can't because the surgeons use it, so I have great concerns
9 on that very matter.

10 MS. HEINLEIN: In that same vein, if there is an
11 accrediting body that -- I mean you talked about that there
12 would have to be a merger somewhere down the line -- it
13 sounds as if the American College of Surgeons feels that
14 they are capable at this point to accredit personnel only.
15 Is that correct?

16 DR. WINCHESTER: The task force hasn't met yet. I
17 can't predict what they are going to say. That is just my
18 concept of it. In a general sense, the American College of
19 Surgeons has been involved for decades in accrediting
20 facilities for trauma through ATLS. That is both people and
21 facilities.

22 They have, for 75, 80 years accredited programs
23 and people within it for cancer programs through the
24 Commission on Cancer, so, you know, we have the history of

1 being able to do something like this, but a stereotactic
2 unit is somewhat foreign to surgeons, and I don't know what
3 the task force is going to say about this, but I think we
4 are going to work with the College of Radiology on that one,
5 and I think that that is quite feasible given our track
6 record of working together on this project.

7 MS. HEINLEIN: Especially to ensure that there
8 will be comparable standards, then, between the accrediting
9 body, so that everyone is making sure that everyone is being
10 accredited to the same level of standards.

11 DR. WINCHESTER: Nobody in the committee or in the
12 audience has seen the letter, because it came out late, but
13 it is a common letter from the American College of Surgeons
14 and the American College of Radiology, which I could read if
15 you want me to, but if you don't -- it is not very long. It
16 answers some of the questions about a voluntary
17 accreditation program versus a regulatory program.

18 DR. MONSEES: Is there any new information in it
19 that we haven't heard in summary?

20 DR. WINCHESTER: I would say two things perhaps,
21 and that was the question about comparability. "Both our
22 organizations are committed to comparable quality
23 accreditation programs on a voluntary basis and believe
24 these programs will assist in providing optimal health care

1 to patients afflicted with breast disease."

2 Secondly, a final statement that, "The American
3 College of Radiology and the American College of Surgeons
4 would monitor the effectiveness of the voluntary process."

5 MS. HEINLEIN: Speaking on the voluntary process,
6 which I guess is a question I pose to all three panel
7 members, if this is a voluntary process, then what
8 motivation, what would encourage facilities to go through
9 the process if it was voluntary?

10 DR. WINCHESTER: Reimbursement. It might come to
11 that. Looking at the ACS initiatives and the ACR
12 initiatives and quality care for screening mammography, I
13 think the consumers, the women of this country are looking
14 for some indications there is a quality program in place. I
15 think it would be patient driven, and probably industry -- I
16 don't know, what do you think?

17 DR. DERSHAW: I think it makes no sense to talk
18 about these kind of programs as true voluntary programs,
19 because there is no motivation for anybody to use them. The
20 overwhelming majority of facilities out there can, in fact,
21 ignore these programs.

22 So, there has to be some kind of non-voluntary
23 component to these voluntary programs. The most obvious one
24 is tying accreditation to reimbursement schedules.

1 DR. WINCHESTER: The other thing that has happened
2 historically with the cancer programs of the college is a
3 good example. The Commission on Cancer surveys cancer
4 programs every four years now, and we have 1,600 programs,
5 which doesn't sound like a big number, but it represents 80
6 percent of all newly diagnosed cancer patients in the United
7 States. It is a voluntary program.

8 Why would hospitals want to pay a tumor registrar
9 and put together a whole team of people that has to respond
10 to a survey, and the answer is marketing. They market
11 themselves as a quality cancer program to their service
12 area. The American Cancer Society is now establishing an
13 Infonet program, a 1-800 number that a cancer patient or a
14 family will call. I know this is off the subject, but it
15 just another way of answering your question.

16 They will be given so far two levels of
17 information. One is hospitals that are approved by the
18 Commission on Cancer, and those who are not approved will
19 not be listed for these callers.

20 Secondly, caseload. My mother has a colon cancer.
21 How many colon cancers were done at Highland Park Hospital
22 last year versus three or four other hospitals in the
23 geographic area? The third tier of information, which I
24 think is going to come forth is outcome, survival rates.

1 So, that is just another example of how the public
2 will use this.

3 MR. PIZZUTIELLO: I would like to add something to
4 that. In my practice as a consultant physicist, I have been
5 asked by many of my clients why do the accreditation
6 programs when they are not mandated.

7 If you look at the mammography accreditation
8 program as a history and model, there were very many
9 facilities who were doing good work, lots of facilities
10 learned that they can do better, and they continued to learn
11 that they can do better as we see that not all facilities
12 pass accreditation on the first try these days, even 1997.

13 So, there was a continuing education process and
14 improving of quality that we have seen through mammography
15 accreditation program. We also saw, as Dr. Houn mentioned,
16 the sort of charge to get certified at the end of 1994.
17 There were a large number of facilities who continued to
18 ignore the general trend towards let's do better, let's show
19 our quality, let's market ourselves by being accredited.
20 There were a large number of facilities who never did
21 anything until the time it was required whether either they
22 get accredited, get in the process, or shut down.

23 So, that is always a problem. It would be very
24 sensible in the free market economy of this country to have

1 all the control be exercised through reimbursement, however,
2 I don't know that this committee has very much to say about
3 reimbursement.

4 I also will say that some of the facilities that I
5 see that are marginal, say that, well, this is really a lot
6 of work for us to do, but we provide this procedure as a
7 service to our patients, why should we have to jump through
8 these high quality hoops.

9 My response to those facilities is that if you are
10 providing a service that is not out of standard of care,
11 then, you are providing a convenience to the patient which
12 may, in fact, be a disservice. So, I think that that is
13 something we need to be aware of, that not all facilities
14 will take the high road.

15 DR. MONSEES: Ms. Hawkins.

16 MS. HAWKINS: I wanted to ask Mr. Pizzutiello,
17 related to your remarks on quality assurance, do you see the
18 role for another entity to look at patient satisfaction
19 under quality assurance, that perhaps some consumer group,
20 for instance, especially as we deal with many older adults
21 that will come into this process, we have a national aging
22 network that is out there?

23 MR. PIZZUTIELLO: I should clarify first that the
24 role of the medical physicist is primarily in quality

1 control, which is more in equipment and technical-related
2 aspects. Quality control is a subset of quality assurance,
3 and a distinct part of all quality assurance program that I
4 know of is are we satisfying the customer.

5 So, I think that any facility in 1997 will be
6 remiss if they didn't pay some attention to how they are
7 handling the patients. I don't know that that needs to be
8 done through an outside agency. I think it is probably
9 being done right now.

10 DR. WINCHESTER: In today's tough competitive
11 environment, in fact, hospitals that are not measuring
12 patient satisfaction, and facilities that are not measuring
13 patient satisfaction in responding to deficiencies are not
14 doing well, and they all realize that they must do this and
15 it is a very important. I think it is being done at the
16 local level rather vigorously.

17 DR. MONSEES: For mammography, which is regulated,
18 there is a complaint mechanism that is stipulated, I
19 believe, and likewise, if a voluntary accreditation program
20 would supplant some sort of regulated activity, I think that
21 it should be considered that there be a complaint mechanism
22 by the college or whichever college or combination of
23 colleges might consider having a voluntary accreditation
24 program.

1 DR. MOORE-FARRELL: I have a question for Dr.
2 Dershaw and then kind of a followup for Dr. Winchester.

3 At a facility such as mine, where the radiologists
4 and surgeons practice together, is there a mechanism now
5 with the ACR, where the radiologist could become accredited?

6 DR. DERSHAW: The ACR accreditation program now
7 includes the parameters for accreditation that have been
8 jointly adopted by the ACR and the ACS. So, a facility that
9 has physicians involved in these procedures, that meet those
10 criteria, is an accreditable facility.

11 DR. MOORE-FARRELL: Who do you apply to?

12 DR. DERSHAW: The ACR. A facility cannot be
13 accredited if practitioners at that facility actually
14 involved in the procedure do not meet the standards. So, if
15 some of the people who are there are qualified, but some of
16 the people who are doing the procedure are not qualified,
17 then, accreditation by any accrediting body would be of no
18 value to the public because it would not guarantee to them
19 that, in fact, qualified personnel were the only ones that
20 would offer that procedure to them.

21 DR. MOORE-FARRELL: So, if certain people chose
22 to, but the others did not wish to participate because it
23 was voluntary, then, there would be no way you could be
24 accredited.

1 DR. DERSHAW: That is correct.

2 DR. MONSEES: So, there is no way to be accredited
3 under the collaborative model proposed by the joint task
4 force, is that correct?

5 DR. DERSHAW: The criteria for MQSA-qualified
6 physicians and non-MQSA-qualified physicians performing the
7 procedure have been incorporated into the ACR accreditation
8 program. So, you do not have to be an MQSA-qualified
9 physician participating in stereo in order for your facility
10 to be accredited by the ACR. The joint recommendation of
11 the two colleges --

12 DR. MOORE-FARRELL: But it has to be everyone.

13 DR. DERSHAW: We will not accredit a facility
14 which only some participants in the procedure being
15 accreditable, meeting the criteria for accreditation,
16 whether that is physicians, technologists, or your medical
17 physicist.

18 DR. MOORE-FARRELL: And, Dr. Winchester, the same
19 would go for you since it is collaborative, if the surgeons
20 there wanted to, but the radiologists weren't interested,
21 there would still be no way.

22 DR. WINCHESTER: Or if the radiologists weren't
23 qualified after the voluntary accreditation program is
24 developed.

1 DR. MONSEES: Dr. Hendrick.

2 DR. HENDRICK: A year ago when we met on this
3 issue, it was my impression, and perhaps incorrectly, but my
4 impression that the committee was in favor of having
5 stereotactic breast biopsy included under MQSA. That is not
6 as a voluntary accreditation program, but as a mandated
7 certification program under MQSA.

8 What I am hearing today I think is somewhat
9 different from that, both from the American College of
10 Surgeons and the American College of Radiology.

11 I just want to make sure what I am hearing, my
12 impression today is correct, and that you are saying both
13 colleges feel that this is better done as a voluntary
14 program not under the auspices of MQSA at all then as a
15 required certification program. Is that correct?

16 DR. WINCHESTER: If I may quote the letter signed
17 by both colleges, "The American College of Radiology and the
18 American College of Surgeons are writing to you to reinforce
19 their belief that voluntary accreditation operational in
20 each college is the best method to serve the public in the
21 area of stereotactic breast biopsy."

22 DR. DERSHAW: Might I add to that, though, that
23 accrediting bodies must all have the same high standards
24 that compromise the standards among a menu of accrediting

1 bodies is not acceptable, and that accreditation, if it is
2 going to mean something, has to have some force behind it.
3 It can't just be, you know, fill out the coupon in the back
4 of your monthly journal and you will be accredited.

5 We have established standards for accreditation.
6 We believe that those are the appropriate standards for
7 accreditation, and those standards should be required
8 by all bodies that are offering their services as
9 accrediting bodies.

10 DR. MONSEES: This side of the table. I am sorry
11 I have neglected this side. We will start with Dr. Smith.

12 DR. SMITH: This question is directed to both Drs.
13 Dershaw and Winchester representing the two colleges. We
14 all watched the American College of Radiology's
15 accreditation program gain momentum over time, but during
16 the period of time leading up to MQSA, there was lots of
17 press coverage, lots of problems that were continually
18 identified that the accreditation program on a voluntary
19 basis just really wasn't enough.

20 In hindsight, can you now, as proposing a
21 voluntary standard as opposed to a regulatory standard, see
22 new ways to have accreditation not only have new teeth, but
23 gain the kind of momentum at a faster pace that under
24 mammography it did not?

1 I think there probably are potentially new
2 incentives now because the whole climate of health care has
3 changed under managed care, but there is an opportunity I
4 think to get the kind of support from the various consumer
5 groups, in particular the Cancer Society, if the
6 accreditation program serves its purposes.

7 I mean that kind of tradeoff would have to be
8 demonstrated. So, I am wondering what kind of plans the two
9 colleges have to make accreditation a reality in all
10 facilities and a reality that means something, and what kind
11 of timetable would you be looking for.

12 Right now you can't start saying to consumers look
13 for an accredited facility, because it is a little soon.

14 DR. MONSEES: Which one of you gentlemen would
15 like to start answering that one? You can answer
16 collaboratively, yes.

17 DR. WINCHESTER: I think you should comment on the
18 historical question about the evolution of the ACR
19 accreditation program and how it gained momentum.

20 DR. DERSHAW: Well, let me just tell you where the
21 ACR accreditation program is now as a start. I think part
22 of your question actually you have answered yourself, part
23 of it doesn't have an answer, and part of is kind of hanging
24 out there in space at the moment.

1 We have had about 300 facilities that have applied
2 for accreditation, slightly less than 100 facilities have so
3 far been accredited. I must say that when the program was
4 first instituted, we were happy not to be overwhelmed with
5 numbers of facilities applying because, as you can all
6 appreciate, the initial mechanics of putting a new program
7 into action are often not very well oiled, so we were happy
8 to get the program up and going a little bit.

9 Some of the initial problems in the program also I
10 believe, I hope have been dealt with by the agreement with
11 the American College of Surgery. As I think probably all of
12 you appreciate, these procedures are done sometimes by
13 radiologists, sometimes by surgeons, but I think, in a very
14 large number of facilities, in fact, are a joint endeavor of
15 surgeons and radiologists.

16 The difficulty in establishing criteria for non-
17 MQSA physicians to participate in these procedures was, in
18 fact, overcome by efforts with the American College of
19 Surgery and has made it possible to offer accreditation
20 through the ACR to a much greater number of facilities than
21 it was possible for us to offer it initially.

22 A list of certified facilities is made available
23 to the public through the Cancer Society. I think the
24 sophistication on the part of the public having learned

1 about certification for accreditation or regulation through
2 the experience with mammography has resulted in I hope a
3 greater awareness on the part of the public in terms of the
4 value of accreditation, whether it comes from the ACR or
5 whether it comes from another body.

6 I think that is where we are with it so far. It
7 remains a voluntary program. I think one difference perhaps
8 in this than in other procedures that we may talk about is
9 often a patient, when she gets to the point that she needs a
10 breast biopsy, is in a system, is in a medical system, is in
11 a hospital system, is in a referral pattern, had a
12 radiologist or a surgeon or a gynecologist whom she trusts
13 to make an appropriate referral for her.

14 So, I think the awareness of the value of
15 accreditation through these kind of programs may, in fact,
16 be diminished in the eyes of the individual patient because
17 she has already placed herself, I think, often in a medical
18 situation of trust. She has established her health care
19 network at that point.

20 But anyway, I think that is where we are today
21 with the program.

22 DR. WINCHESTER: I think the level of
23 consciousness and of the efficacy of this procedure and the
24 publication in the media about this procedure is reaching a

1 high level and that there will be a public demand for this
2 to be done in a quality way.

3 I think that the ACR and ACOS or ACS logos
4 together on a document is an important historical precedent.
5 It makes a strong statement about two very large
6 organizations primarily involved in this procedure, the fact
7 that they were able to get together and put something
8 together, which I regard as a stopgap measure, because
9 remember, we are dealing with a technology that is being
10 applied out in the community by radiologists and surgeons
11 who were never trained to do this.

12 So, we have a problem to deal with in a few year
13 window of opportunity here to educate, and prospectively,
14 through our training programs in radiology and in surgery,
15 we will produce radiologists and surgeons who will be
16 certified by their respective boards and tested in this
17 procedure.

18 Laparoscopic cholecystectomy is a good example.
19 This hit the papers. The American College of Surgeons, such
20 a big machine, it couldn't even respond in time with
21 educational programs. There were courses that jumped up all
22 over the country, and surgeons were scrambling, and I was
23 one of them, to find a course that I could quickly get
24 enrolled in, so I could learn this and do it in a couple of

1 weeks after I was proctored maybe three weeks.

2 Those courses went on for about three or four
3 years. You can't find one now, they are gone. Why are they
4 gone? They are gone because the surgeons that are being
5 produced in this country now are skilled when they come out
6 of their training program, and they are certified by the
7 American College of Surgery to perform this procedure in a
8 competent way.

9 The courses aren't there anymore. The courses on
10 stereotactic core needle biopsy are going to go away. They
11 are going to go away in a few years because we are going to
12 produce prospectively skilled people to do this procedure,
13 and of course, that will change. There will be new
14 technology and in year 2004, we will be going through this
15 again with, you know, we have got a new gadget now, how are
16 we going to respond to all the people that are out there
17 doing it. Well, we can teach the residents and they will
18 learn it. We are going to go through cycles like this, on
19 and on.

20 DR. MONSEES: We are going to go to break shortly
21 and we will have to come back and finish this, because there
22 is no way, it looks like, we are about to come to closure
23 here with this group of individuals.

24 I would like to ask a quick question. You

1 mentioned the numerator, 300 facilities have applied and 100
2 were accredited. How many facilities are there out there,
3 do we know?

4 DR. DERSHAW: No.

5 DR. MONSEES: Is there anybody in the audience
6 from industry who is willing to stand up here and tell us a
7 number, how many units do we have in the United States?
8 Does anybody have that knowledge that is willing to
9 volunteer that information to us?

10 DR. HENDRICK: Maybe you should specify what kind
11 of units.

12 DR. MONSEES: We are talking about stereotactic
13 units, either prone and/or add-ons. Let's start with prone
14 units. Is there any manufacturer out here that is willing
15 to tell us?

16 [No response.]

17 DR. MONSEES: That is what I thought.

18 Dr. Israel?

19 DR. ISRAEL: I haven't seen this number tabulated,
20 but I have asked both the Lorad and the Fischer, who make
21 the prone tables, and this does not include upright tables,
22 but it is my impression there are between 1,300 and 1,500
23 prone stereotactic units that have been sold and installed
24 in the United States.

1 That is my estimate. I don't have those figures,
2 but that is my impression.

3 DR. MONSEES: Thank you.

4 I think we will go to break now. We will
5 reconvene promptly at the appointed time, 3:45, and we will
6 continue this discussion. Thank you.

7 [Recess.]

8 DR. MONSEES: We are going to reconvene.

9 We want to continue the discussion that was
10 occurring just before the break. I will ask Dr. Dershaw to
11 contribute to the discussion and to answer questions as they
12 come up from the other panel members.

13 Where we left off, I believe there was a question
14 on this side. Dr. Sickles, go ahead and ask a question.

15 DR. SICKLES: My concern relates, not to the
16 agreement that the two organizations have come to -- which I
17 think is a big step in the right direction -- but rather to
18 the issue of voluntary versus mandatory.

19 I think back to the period of time when ACR
20 accreditation for mammography was voluntary, and became
21 mandatory with implementation of MQSA. For those of you on
22 the panel who weren't involved in this, at that point, my
23 understanding is about 50 percent of the mammography
24 facilities in the country were accredited, another 25

1 percent or so were in the process of being accredited, and
2 some of that might have been due to the fact that they knew
3 that it was coming in a mandatory fashion.

4 But then there were approximately 25 percent of
5 facilities in the country that did not even attempt
6 accreditation until it was mandatory by MQSA. My opinion --
7 and apparently it is shared by Dr. Dershaw and I would
8 presume by Dr. Winchester -- is that a voluntary program
9 that attempts to establish standards for the whole country
10 will succeed only if it is virtually 100 percent utilized,
11 because if we have a voluntary program that is utilized by,
12 say, 75 percent of the people in the country, and there is
13 no really firm impetus to be sure that that remaining 25
14 percent get certified appropriately, that they are not going
15 to do it.

16 Unfortunately, the 25 percent that won't do it
17 until they have to, are the 25 percent that really must do
18 it because they are the ones who look at these many, many
19 tests and say, you know, not only is it difficult, but we
20 may not be able to meet those standards.

21 So, I think we have to be very cautious about
22 adopting voluntary programs until we have some very good
23 assurance that the compliance level with the voluntary
24 programs will approach 100 percent.

1 If this can somehow be tied with reimbursement,
2 that will come to pass, I have no doubt about that, but
3 there is, to my knowledge -- and maybe you can educate me --
4 no steps right immediately in the pipeline or even I am not
5 aware of anything in the not too distant future which will
6 force the issue of tying this type of accreditation to
7 reimbursement.

8 If you are aware of any of this, I think the panel
9 should know, because I think that would overcome the
10 objection that I am addressing. If you are not aware of it,
11 then perhaps any approach that started with a voluntary
12 program should have a time frame beyond which if we didn't
13 get close to 100 percent compliance, we would have to kick
14 into a mandatory program.

15 Do the two of you have opinions on this?

16 DR. WINCHESTER: What was the question? I get the
17 gist of it.

18 I would think that if the voluntary accreditation
19 program for stereotactic breast biopsy, the two colleges
20 became part of the American Cancer Society Infonet, and that
21 people called in the 1-800 number to find out what facility
22 in their geographic area was accredited by the two national
23 organizations, that you would see a mighty rapid rush for
24 accreditation. I know we are going to see the same thing in

1 the cancer programs now. We already have 80 percent of the
2 cancer patients. I think when Infonet kicks in, that it is
3 going to come up to any facility that feels like they can do
4 it above 90 percent, we are going to be virtually
5 population-based then. It hasn't happened yet, but folks,
6 it is coming.

7 I think public pressure, public demand for quality
8 care and some kind of a national certification program with
9 reputable college names like your college and my college --
10 and that is why, by the way, your college I believe sent
11 this letter along with our college recommending
12 accreditation. Both the colleges think that it can happen.
13 We really believe that it can happen, and there are various
14 ways of getting from point A to point B.

15 But I understand what you are saying. I think you
16 are quite perceptive in asking about timetables and asking
17 about how you are going to get some teeth into this. That
18 is one just off the top of my head, one mechanism to do
19 that. We have seen that with the cancer program and ATLS.

20 DR. DERSHAW: I would agree with everything you
21 said, Dr. Sickles. I am not aware of anything going on with
22 reimbursement that you are not aware of going on with
23 reimbursement.

24 That issue was solely raised as an example, I

1 think not a very bad example, of how you can make a
2 voluntary program somewhat less than voluntary.

3 I also agree that the proof of the pudding is in
4 the tasting. If you have accreditation programs out there,
5 and they are not being utilized as voluntary programs, then,
6 they are not accomplishing what the accreditation programs
7 are designed to accomplish.

8 DR. WINCHESTER: Part of this agreement was for
9 the two colleges to monitor the effectiveness of the
10 process. So, what would happen if we monitored this for 12
11 months and found that the compliance was 28 percent? One
12 possible step would be to make it mandatory, that if the
13 surgeons or radiologists wish to perform this, they have to
14 show us with surveys objectively that they are meeting the
15 criteria that have been outlined, and that could happen.

16 DR. SICKLES: I have one practical followup
17 question. It has to be addressed to Dr. Dershaw now because
18 it is premature to address it to you.

19 Let's say that publicity gets out to the radiology
20 community in the next few months that this would be a really
21 good thing to do, for whatever the reason. Could the ACR
22 handle the 1,300 units that are out there in a reasonable
23 amount of time?

24 DR. DERSHAW: Could you define a reasonable amount

1 of time, Dr. Sickles?

2 DR. SICKLES: Well, tell me what you think a
3 reasonable time would be.

4 DR. DERSHAW: Well, I don't know. Maybe staff
5 could better answer that question than I could, and I would,
6 if I might, refer that question.

7 DR. SICKLES: The reason I am asking you is that
8 it is unfair to establish a deadline if people cannot meet
9 the accreditation because the mechanisms just go too slow to
10 make it happen, and I understand in the institution of a
11 program, and the ACR program, although it has been around
12 for a year and a half, still is not in high gear, that is a
13 difficult task.

14 DR. DERSHAW: Could I just be reminded how long it
15 took FDA to regulate screening mammography? I have lost
16 track of the time. From start to finish, how long was it?

17 DR. HOUN: I can tell you that for about 4,500
18 facilities who had not been accredited previously, came in t
19 meet the 10-1-94 deadline, and it took 4,500 facilities to
20 go through mammography accreditation roughly six months plus
21 three months, so a total of nine months. Most of them made
22 it through within nine months.

23 DR. MONSEES: Dr. Hendrick.

24 DR. HENDRICK: I share Dr. Sickles' concerns

1 especially about the sites that would not participate in
2 this voluntarily. One of the concerns I have is that we may
3 not know the state of practice even if there is a voluntary
4 ACR program and voluntary ACS program.

5 The big concern I have is that we will have very
6 little in the way of good surveillance of the practice of
7 stereotactic breast biopsy throughout the country. Even if
8 we monitor the voluntary sites and their practices in both
9 of those programs, we won't know how many sites are
10 accredited by either program.

11 So, I would just like to put that as a challenge
12 to the Advisory Committee and the FDA to try to come up with
13 a methodology by which we would know what is really
14 happening, at least in terms of how many sites there are
15 doing different types of stereotactic breast biopsy, how
16 many are accredited and what the state of quality is in
17 those that aren't.

18 A second concern I have is that I heard discussion
19 of two different accreditation programs, one by the ACR and
20 one by the ACS, and I heard two completely different things.
21 One was more on the model of the mammography accreditation
22 program, which includes all the personnel, equipment, QA,
23 and other which was really more of a physician credentialing
24 accreditation, if you want to put it that way.

1 I shared some concerns that were expressed
2 previously about the difference between those types of
3 models of accreditation and the results that they would have
4 on the facilities working under those different
5 accreditations. So, that is also a concern under this
6 voluntary model.

7 DR. MONSEES: Yes. Go ahead, Mr. Pizzutiello.

8 MR. PIZZUTIELLO: I have a comment about the
9 difference between board certification and accreditation. I
10 am not certain that the problem will go away when all the
11 surgeons come through training, receive this training in
12 their residency, and are tested in their certification
13 process, because almost all the radiologists that do
14 mammography are board certified, yet, it became important
15 and clear that the quality of mammography was not being
16 ensured just by having radiologists be board certified.

17 So, there is yet another level beyond board
18 certification that says can you demonstrate a minimum
19 proficiency with this procedure, the examination of
20 mammography. So, I am not sure that board certification by
21 itself will do it for surgeons as it hasn't for
22 radiologists.

23 Also, just to clarify Ed Hendrick's point, the
24 number that I have heard about the number of stereotactic

1 units out in the country is more like 3,000 instead of the
2 1,500 that Dr. Israel suggested. Now, nobody knows that
3 number, but if we are trying to monitor the ability of the
4 voluntary accreditation programs to see how close they are
5 to getting at the whole universe of stereo units, we don't
6 know what if the denominator is 1,500 or 3,000. That makes
7 a very big difference.

8 DR. WINCHESTER: I was speculating that once we
9 get this prospective, then we have trainees out who have
10 been trained to do this at the entry level, that they would
11 be qualified at entry to do it, but I didn't mean to imply,
12 I think I mentioned CME, that there would need to be a
13 focused continuing program on a voluntary accreditation
14 basis that would monitor in terms of CME and medical audit
15 performance and evidence that there had been ongoing
16 education and procedure.

17 DR. FINDER: I just want to make one point at this
18 juncture about conflict of interest. I want to bring that
19 back in. The people that were mentioned in the conflict of
20 interest statement that had been involved in this issue
21 should keep their statements just to the facts, and not
22 really opinions.

23 So, if you can either just stick to the exact
24 facts of the document or the program or how that program was

1 developed, that would be appropriate, but we have to be very
2 careful about people giving opinions who have written these
3 documents.

4 DR. MONSEES: There are surely some additional
5 questions for this group of individuals who presented this
6 afternoon, and I would like to address some of those
7 questions that other panel members have, but just to let you
8 know where we are going, what I would like to do, after we
9 are finished with that, is move towards talking about
10 personnel issues this afternoon.

11 Then, tomorrow morning resume talking about
12 voluntary versus regulation, because that is what is on the
13 agenda, and I would like to make sure that we cover
14 particularly the physician personnel issues this afternoon,
15 but also probably some of the technologist personnel issues.

16 I have a quick question for Dr. Houn. Is there
17 any way to mandate that core biopsy be a reportable event,
18 so that we can have an accurate number? If we are going to
19 data keep and look at what is going on and if the voluntary
20 accreditation programs are going to join together and they
21 are going to monitor themselves, you need to know how many
22 are going on.

23 Is there any way to mandate it as a reportable
24 event and the number of units that they have to register or

1 something like that, is this possible?

2 DR. HOUN: I really don't know at this time. I
3 know that the law says that in applying for FDA
4 certification, they have to supply numbers of units,
5 personnel involved, but you are saying without certification
6 can FDA collect this information on an exempt technology,
7 and I think that is a real -- it sounds difficult for us to
8 do, and it would have to be looked at by general counsel,
9 but since it is exempt now, I think that carries a lot of
10 weight in terms of what we can do and what we can ask of
11 these entities.

12 DR. MONSEES: We have some questions on this side
13 of the table. Yes, Mr. Mobley.

14 MR. MOBLEY: In terms of answering this specific
15 question, it would seem to me FDA has equipment reports
16 regarding installed equipment or equipment sales that could
17 be used to at least define the universe of equipment sales
18 that had occurred.

19 I presume these would be reportable pieces of
20 medical diagnostic x-ray equipment -- these may not be
21 diagnostic. I don't know, I was just thinking there is an
22 equipment standard. There are reports regarding that
23 equipment that have to be filed, and that is one way to get
24 a picture of the universe in terms of installed equipment.

1 I may be overstating the case, but that seems you
2 could go in and you query the computer on these units and
3 there they are.

4 DR. MONSEES: Is that possible?

5 DR. FINDER: I don't think it is as easy as it
6 should be. We have been trying to look and get numbers, and
7 so far we have not got a comprehensive number yet, but we
8 are continuing to look and to search the databases that we
9 do have access to, but we don't have an exact number.

10 MR. MOBLEY: Whether it is 3,001 or 3,002 --

11 DR. FINDER: It's not even that. I am not talking
12 about.

13 MR. MOBLEY: We have got 1,300, 1,500, 3,000.

14 DR. MONSEES: Dr. Dempsey.

15 DR. DEMPSEY: I would like to ask Dr. Winchester a
16 question that is not exactly equipment related at all, but I
17 think it bears a great deal on what will happen in the
18 future.

19 It is obvious that this joint statement from both
20 colleges has been reached by people who are very
21 conscientious and level-headed, and I think have the
22 patients' best interests at heart. Over the past two years,
23 unfortunately, I think there has been a sense of deep
24 contentiousness that has existed, and there are probably

1 many reasons for that out there, but this idea of a turf war
2 that encompasses patient control and remuneration and
3 division of work, et cetera, and I think it is important to
4 get a sense, Dr. Winchester, as how you view your membership
5 at large as responding to this effort that has been
6 published.

7 Is that same level of cooperation, do you think,
8 out there, is it going to change the other feeling that I
9 think, unfortunately, has been out there for at least a
10 couple of years?

11 DR. WINCHESTER: Well, of course, feelings run
12 both ways, in both directions, and they are hard to assess.
13 The college has 54,000 fellows. We have about 30,000
14 general surgeons. I don't know how many of those general
15 surgeons are doing this procedure, but I brought along my
16 file, and I felt obligated to report to this group the
17 feedback that I had had.

18 I have 15 letters out of 30,000 surgeons, and
19 sometimes the vocal minority makes a lot of an impression.
20 I didn't get 30,000 letters, I didn't get 2,000 letters. I
21 didn't get a lot of compliments either. I don't have a good
22 file and a bad file.

23 So, it hasn't been overwhelming. We all look at
24 our experiences, at our settings, and in my setting,

1 everything is fine. We have a collegial relationship, a
2 good breast center, we work together. Someone else made the
3 statement earlier. I think by and large, a great majority
4 of facilities that are doing this, are doing it in that
5 manner, and not in a contentious manner.

6 So, I think we need to be careful about the degree
7 to which we react to pointed criticism.

8 DR. MONSEES: Mr. Fletcher had a question.

9 MR. FLETCHER: I wanted to do an add-on to what
10 Mike was asking, because I know that for every device, every
11 machine, x-ray machine that comes in the State of Maryland
12 has a document trail. If we don't know right now what we
13 have, is there a way we can find out, because there has got
14 to be a document trail to let us know where these devices
15 are. I am just curious to know do we intend to look into
16 identifying how to keep track of these devices.

17 DR. FINDER: Yes. I mean we are attempting to get
18 that information, we just don't have it now. We are going
19 through various mechanisms. It is not as simple as hitting
20 a computer button and getting the data to spit out, but
21 there are mechanisms that we can go down to try and get this
22 information, and we are trying to do that now.

23 DR. MONSEES: Ms. Heinlein.

24 MS. HEINLEIN: A question for Dr. Dershaw. This

1 morning the number of surgeons presented and discussed the
2 training programs that are available in the country right
3 now for surgeons to learn how to do stereotactic breast
4 biopsy. Can you tell us about what type of programs -- are
5 there programs available for radiologists, and what kind of
6 programs there are available?

7 DR. DERSHAW: There are programs in stereotactic
8 breast biopsy in CME courses, and these include didactic
9 lectures and hands-on experience, not with patients, but
10 hands-on with apples and phantoms and eggplants, and a
11 variety of other grocery store products.

12 The training is included in breast fellowship
13 programs, in residency programs. The ACR is in the process
14 of establishing a formalized, standardized program that will
15 include not only again CME credits in courses and hands-on
16 experience, but a videotape of information and procedures
17 that can be distributed.

18 So, I think there is a fairly wide training
19 experience that is available.

20 DR. MONSEES: Yes, Dr. Hendrick.

21 DR. HENDRICK: I wanted to go back to the document
22 that you have brought before us, the personnel, physician
23 qualifications, and in particular, I want to try to see if I
24 can understand the model in which the radiologist and breast

1 surgeon or other physician practice collaboratively.

2 Under number 1 on page 1, the last statement in
3 there is, "The physician should be present at the
4 appropriate time during the procedure." I don't know what
5 that means. Does that mean the radiologist should be there
6 when the button is pushed to fire the biopsy gun, and the
7 surgeon should be somewhere else, or does it mean that
8 either the radiologist or the surgeon should be there at
9 that point? I was just hoping for some clarification about
10 what that sentence really means.

11 DR. WINCHESTER: I think the intent was related to
12 the environment that we are now working in and the challenge
13 of billing for a procedure when you are not there, whether
14 it is a stereotactic breast biopsy or a thoracotomy or you
15 name it, whatever, the wire localization, and training
16 programs with fellows and residents.

17 DR. MONSEES: This pertains to Medicare basically
18 reimbursement under Medicare stipulates that the physician
19 be present during the key part of the procedure to bill it,
20 the billing issue.

21 DR. WINCHESTER: It relates to that technicality
22 rather than the surgeon or the radiologist being there, or
23 both of them being there, the intent was it depends on who
24 is doing it. They don't need both need to be there.

1 DR. HENDRICK: But is the model that either the
2 radiologist or the surgeon could be performing the
3 procedure, but the point is that if they are billing for the
4 procedure, they had better be there when it is being
5 performed?

6 DR. WINCHESTER: Yes.

7 DR. HENDRICK: Another question I had was toward
8 the end of the document, on page 4 under B, in the situation
9 where a surgeon or other physician practices stereotactic
10 breast biopsy independently, "the surgeon or other physician
11 is required to -- and the first dot there under Initial
12 Training and Qualifications is, "have evaluated at least 480
13 mammograms per year in the prior two years in consultation
14 with a physician who is qualified to interpret them."

15 I guess my question is what does evaluate mean?

16 DR. WINCHESTER: That is in almost all these
17 letters. It does require clarification I think by the
18 process we are going through today, I would hope that it
19 would clarify, but the intent of this was that if a surgeon
20 is doing this independently, say they have rented a
21 building, they have bought a piece of equipment, and they
22 have hired a radiologic technologist, and they have
23 satisfied all the equipment standards, they are not MQSA, so
24 they are not interpreting mammograms.

1 They are referred a patient with need for a
2 stereotactic breast biopsy with a mammographic abnormality,
3 which has been interpreted by MQSA is the setting we are
4 talking about now. That doesn't mean that the radiologist
5 needs to walk in with that mammogram in that suite and put
6 it up with the surgeon and say here is what I said in my
7 report.

8 What it means is that the surgeon quite logically
9 is not going to perform this procedure without reviewing the
10 mammogram and the report by an MQSA radiologist or physician
11 before embarking upon this.

12 So, review in our sense as our task force looked
13 at it, review was in that spirit, and a couple of members of
14 that committee here could agree or disagree.

15 DR. BASSETT: The surgeon wouldn't be interpreting
16 and making a report on the examination, but would be
17 reviewing the images, reviewing the findings, reviewing the
18 report on a number of cases to ensure that they knew how to
19 identify abnormalities.

20 DR. SICKLES: This 480 mammograms doesn't relate,
21 though, does it, to the specific patient who is undergoing
22 stereotactic biopsy.

23 DR. BASSETT: No.

24 DR. SICKLES: This 480 relates to some experience

1 in breast imaging, not necessarily producing an
2 interpretation with your name on the report, but rather some
3 kind of consultative review with an MQSA radiologist.

4 DR. BASSETT: It usually occurs when they are
5 seeing the patient.

6 DR. SICKLES: And this certainly does not have to
7 include the specific women undergoing stereotactic biopsy.
8 It can undergo all women in that surgeon's practice who have
9 mammograms.

10 DR. WINCHESTER: That is a very important point.
11 You are not going to get to 480 very many places without
12 that.

13 DR. HENDRICK: Farther down on page 4, actually,
14 the second bullet from the bottom, "be responsible for the
15 supervision of the radiologic technologist and the medical
16 physicist."

17 How would the surgeon or other physician know how
18 to supervise the medical physicist?

19 DR. MONSEES: I wondered that myself.

20 DR. DERSHAW: In the mammography program, MQSA
21 program, the responsibility for the entire quality assurance
22 of the procedure is the physician's responsibility, and the
23 responsibility for the entire quality assurance of the
24 procedure, performance and quality performance of the

1 procedure remains the physician's responsibility in this
2 procedure whether it is a radiologist, whether it is a
3 surgeon, whether it is an MQSA-certified physician or not.

4 This is merely to indicate that the responsibility
5 for all the professional personnel and all the quality
6 assurance of the procedure is the physician's
7 responsibility.

8 DR. HENDRICK: I understand that, but I hesitate
9 to accept that, say, four hours of radiation physics as an
10 educational background would really equip a physician, even
11 a highly educated physician like the surgeon, to be able to
12 supervise a medical physicist and know what the medical
13 physicist had done is really appropriate, inappropriate, how
14 to take action on the interpretation, say, at the medical
15 physicist's report, things like that.

16 DR. MONSEES: Likewise, the same may be the case
17 for supervising the radiologic technologist.

18 DR. WINCHESTER: I guess I have a practical
19 question because I don't know what happens in the real
20 world, but does the radiologist supervise the physicist? Be
21 honest now.

22 DR. MONSEES: Yes, the radiologist interacts with
23 --

24 DR. WINCHESTER: Interacts, but supervises? Is

1 the word supervisor the wrong word?

2 DR. MONSEES: What you do is you make sure that
3 the physicist not only provides the appropriate service, but
4 that is called in when appropriate. That is not always so
5 easy to know. Anytime there is any question in quality
6 control, you consult your physicist. You make sure you do.
7 If something changes with the equipment, you consult your
8 physicist, and you have to be able to speak the same lingo
9 to understand what is going on. You can't just -- at least
10 in my estimation -- have somebody tell you everything is
11 okay, you could just go on now without really understanding
12 some of what that means.

13 Any other comments from any other radiologists
14 here who deal with this in their practice? Do you have
15 anything to add?

16 DR. WINCHESTER: I guess the question really
17 hasn't been answered yet, it is an important question. Is
18 four hours of something enough to qualify somebody who has
19 graduated from medical school and gone through the rigors of
20 a surgical residency to supervise a radiologic technologist
21 and a medical physicist.

22 I believe it is legal. Charley, I don't want to
23 do something bad here. Is it legal for me to ask, for
24 example, Dr. Israel or somebody in the audience who does

1 this procedure frequently in this model, where they are
2 independent, of how they would answer the question?

3 DR. FINDER: I think it is up to the chair. I
4 don't think it is illegal.

5 DR. MONSEES: No, it is not illegal.

6 DR. FINDER: But if it is, we will arrest you
7 later.

8 [Laughter.]

9 DR. MONSEES: They haven't give me handcuffs, so I
10 will allow it. Who would you like to have answer this
11 question?

12 DR. WINCHESTER: Dr. Israel is sitting closest
13 here, Dr. Dowlat also.

14 DR. MONSEES: Let's try and make it brief if we
15 can rather than call a large number of people. Let's see if
16 Dr. Israel can handle this.

17 DR. ISRAEL: What we do is comply with state
18 regulations in terms of imaging equipment. We have a
19 medical physicist review our facility and our equipment
20 twice a year. We also have our service contractor with whom
21 we have a commitment to service our facility to come
22 quarterly. This is the way we operate.

23 We meet all of the requirements of the state in
24 terms of the safeguards of the equipment.

1 DR. MONSEES: Have you yourself ever noticed
2 anything where you got on the phone and called your
3 physicist and asked him to come in for a consultation
4 because you were concerned about an issue?

5 DR. ISRAEL: No, I have not.

6 DR. MONSEES: How many years have you been doing
7 this, does the technologist do this for you?

8 DR. ISRAEL: We do it collaboratively, the
9 technologist and myself. We have the routine surveys and we
10 have not encountered any problems in between those surveys.
11 Hopefully, if we had imaging deterioration, et cetera, that
12 we would recognize it and we would call for assistance.

13 DR. MONSEES: Fair enough. Any other questions
14 from the panel of Dr. Israel?

15 Dr. Mendelson has a question.

16 DR. MENDELSON: I wondered if Dr. Israel would
17 tell us, please, what independence the radiologic
18 technologist has in working collaboratively with you, a the
19 surgeon acting alone -- and this is the area of this
20 document we are working with -- if a surgeon acting alone is
21 responsible for patient selection, but relies on the
22 radiologist's interpretation, how is that patient selection
23 made, who does the actual targeting, this patient
24 eligibility for core biopsy? Is that your assessment of the

1 mammograms? That was one question.

2 Once that decision has been made, how do you
3 interact with the radiologic technologist, does he or she
4 have an independent that you respect by virtue of their
5 training and yours?

6 DR. ISRAEL: Not in terms of image interpretation.
7 We see these patients generally in the office after they
8 have had a screening mammogram, an abnormality has been
9 identified. We inspect the images, and there are times when
10 I see images that have been graded a BIRAD's 4, that I think
11 should be a BIRAD's 3.

12 When that happens, I call my radiologist and I ask
13 them if they would like to or feel it would be appropriate
14 to amend their report, so that there is a place for
15 monitoring this patient.

16 I take the responsibility along with the patient.
17 Sometimes if there is a BIRAD's 3 recommendation, and I am
18 looking at the mammograms with the patient, if this
19 patient's mother and sister have had a breast cancer, and
20 this is an indeterminate lesion, even though it may be of
21 low suspicion, I will proceed to do a stereotactic biopsy,
22 and I will not contact the radiologist. The patient and I
23 will make that decision.

24 The technologist plays no part, zero or minus

1 zero, in making these decisions. In terms of the images
2 that are acquired during the course of the procedure, I make
3 all of the interpretations. I decide if the image that has
4 been portrayed on the digital monitor is indeed the image
5 that we are targeting for.

6 I do my own targeting. The technologist is not
7 responsible for any of that. I accept full responsibility
8 for that.

9 DR. HENDRICK: Dr. Israel, who at your site
10 reviews the preventive maintenance reports, the technologist
11 QC records, and the medical physics reports?

12 DR. ISRAEL: The technologist reviews those
13 records, and she brings to my attention anything that she
14 may have a question about.

15 DR. HENDRICK: So, she reviews her own QC surveys
16 of, let's say, the processor or phantom image quality, and
17 stuff like that?

18 DR. ISRAEL: Yes.

19 DR. HENDRICK: I rest my case.

20 DR. MONSEES: Thank you.

21 **Stereotactic Core Biopsy - Personnel**

22 I would like to move now towards discussing
23 specific personnel issues. This is something that we have
24 danced around a little bit. We need to talk about what

1 qualifications do we think -- I will ask people here at this
2 table -- need to be the qualifications of a physician who is
3 going to be doing this procedure, and I would like to talk
4 more. We have talked very little about the technologist's
5 qualifications, and I will rely on some of the technologists
6 on this panel to help pinpoint some of the important issues
7 here.

8 Let's start with the physician, but please, let's
9 keep in mind that we need to move on and talk about
10 technologist issues, as well. Tomorrow, I think we may have
11 some time to talk more about quality control issues and
12 physicist qualifications.

13 So, with that I would like to start by asking
14 perhaps the people on the panel if they have any specific
15 comments about what the qualifications should be for
16 somebody who is going to do this procedure independently.

17 Do we agree that 480 mammograms is the appropriate
18 number, that these numbers for the ongoing requirements are
19 appropriate, et cetera? We can't just I think accept what
20 is given to us without looking at it at least.

21 I would like to go around the table and see if
22 people think this is about where we should be. Does anybody
23 want to start? I would like to talk about what the ballpark
24 is, are we in the right ballpark here? We are not accepting

1 this as what we are going to recommend, but I think we
2 should start the conversation with this, and we can go from
3 there.

4 Do I see any hands? Yes, Dr. Sickles.

5 DR. SICKLES: If your question relates to the 480
6 mammograms for the non-MQSA physician, as long as the review
7 with MQSA radiologist is a meaningful review, it would seem
8 to me that is perfectly appropriate because it is the same
9 number that radiologists have to meet to be an MQSA
10 physician.

11 The difference is that the non-MQSA physician
12 doesn't have to fulfill all of the requirements because what
13 he or she is doing is in consultation, so they don't have to
14 go through all the other steps, but the number, it seems to
15 me reasonable because it is the same number that
16 radiologists have to meet.

17 I would be very interested from Dr. Winchester or
18 from anyone else as to whether that is an onerous number for
19 the average non-MQSA physician who would be performing these
20 procedures, who you would be happy performing these
21 procedures.

22 Remember that these, as we were told this morning,
23 tend to be non-MQSA physicians who do a lot of these, who
24 are interested in it, who are building a practice that

1 heavily involves it. So, I would be interested in knowing
2 whether 480 is unrealistic, but historically, it makes
3 sense.

4 DR. MONSEES: Well, the reason that I am bringing
5 this up is that it is one of the objections that Dr.
6 Winchester said that he had almost uniformly in the angry
7 letters that he received. So, I think we need to put this
8 on the table and see do we think that it is reasonable or
9 not.

10 DR. SICKLES: I agree fully, but what I don't
11 know, and maybe we can get the answer, is whether these are
12 just 15 out of 36,000, or whether this is really a
13 substantial problem.

14 DR. WINCHESTER: One of the issues I think is the
15 central issue here is whether the same requirements, the
16 interpretive skills for screening mammography applied to
17 working in collaboration with the radiologist or working
18 alone and getting an MQSA report.

19 I think Dr. Dershaw's presentation today would
20 suggest that the 480 is appropriate for a surgeon even
21 though he or she is "evaluating" and working with an MQSA
22 radiologist. Maybe that is not true, but that is the
23 central question, are the two really equivalent.

24 The other issue that I have gotten feedback from

1 is access to care issue in community hospitals. They are
2 not big, high-powered academic centers, they don't have the
3 caseload, and while we don't want this procedure done by
4 somebody who doesn't see very much of this, I think there
5 needs to be some realistic sensitivity to access to care in
6 smaller communities where one of the specific letters I
7 cited where the surgeons were doing the procedure and doing
8 it well by their own audit, but they didn't have 480 per
9 surgeon, which would be necessary under these requirements,
10 and those patients would have to travel someplace else in
11 Texas to a "bigger" center to get these things done.

12 So, I guess that those are the two issues I would
13 raise and ask Larry and perhaps Dave to respond to since I
14 have worked with both of them in the genesis of this. We
15 certainly, as surgeons, don't believe that surgeons should
16 be doing this as an occasional thing.

17 It is going to take a lot more than a casual
18 interest in mammography and breast disease. It is going to
19 take a major interest in breast disease, and I think, as has
20 been pointed out, that surgeons have self-selected
21 themselves in this process, and if they are not interested
22 in breast disease, they are not doing this.

23 We have seen a large volume of it, they are very
24 much interested in doing this.

1 DR. MONSEES: Dr. Bassett.

2 DR. BASSETT: I just wanted to remind everyone
3 that or the interpreting physician doesn't have to read 480
4 original mammograms, that they can share some that were done
5 by someone else, so in the practice, if there isn't 480
6 apiece for those surgeons, they could double up reading on
7 some of the same cases, not reading, but reviewing of the
8 same cases that have interpretations with them.

9 I am not saying that I know that 480 is the magic,
10 correct number. I am just saying that you can, it is I
11 think appropriate to look at cases that you are not
12 necessarily seeing as the primary consultant yourself, and
13 that is how radiologists or interpreting physicians in low-
14 volume areas overcome the 480 number. They either share
15 cases with someone else or look at cases from somebody
16 else's practice. So, there are ways around that.

17 I think what they want is the experience. It
18 doesn't have to be on original cases of their own.

19 DR. MONSEES: Does anybody else have any comments
20 about this number, 480, and about the experience? Yes.

21 DR. MOORE-FARRELL: I don't have a question about
22 the number. I just have a question about how would you
23 document the 480, does someone sign off, I mean do you have
24 a plan for that, either the American College of Surgeons or

1 the ACR?

2 DR. MONSEES: If it were voluntary or if it were
3 regulated?

4 DR. HOUN: I think he has already given advice on
5 how to document it for radiologists who are double reading.
6 Certainly, if there is a mammography report that says
7 interpreted by so-and-so, double read or reread by such and
8 such, you have got firm documentation on the medical report,
9 but if that doesn't happen, you can keep -- physicians are
10 keeping their own logs of patients they are reading.

11 They cannot submit them without having the
12 facility sign that indeed these films were double read. So,
13 FDA does not accept attestation on this. It has to be
14 confirmed by some other senior member of the group, senior
15 member of the facility, some other party.

16 DR. MONSEES: Dr. Israel, I don't mean to pick on
17 you, but as a physician who obviously is committed to breast
18 surgical practice, we are relying on some of your opinions
19 here. Do you think that a surgeon who is going to perform
20 this procedure, as Dr. Sickles was asking, should see 10
21 mammograms per week in order to keep his eye up and be able
22 to do this appropriately? Do you think that is an
23 appropriate number, should they do at least that?

24 DR. ISRAEL: I think it is too high, and I have

1 given this a lot of thought over a lot of years. I also
2 have a lot of feedback from surgeons around the country as
3 does Dr. Winchester. I think it is too high. I think it is
4 appropriate for screening mammography. I think it is too
5 high for identifying or reproducing a lesion that has been
6 identified in order to do a biopsy.

7 Also, I really don't like the numbers game because
8 we do have to have some numbers, I suppose, but it doesn't
9 in any way equate with responsibility or relate to
10 competency. There are some people, I think, who could read
11 1,000 and not be competent.

12 Of course, we do have to have some numbers. I
13 personally think the number is too high and I can tell you
14 that this is as big, big contention with the surgeons. I
15 would have no problems in complying with this myself, nobody
16 in my group would have any problem, but there are other
17 surgeons who are heavily involved in breast care work in
18 this country that don't do only breast work.

19 They may do 30, 40, or 50 percent of their
20 practice. I think they might have a problem complying.

21 I have a couple of questions relating to this that
22 I think really need to be clarified in terms of what we mean
23 by interpretation. It has been addressed today, just a few
24 minutes ago, but I wasn't sure what was said.

1 Now, am I to believe, then, that these 480, if
2 that number persists, that a surgeon must take 480
3 mammograms for two years, sit down with a radiologist person
4 to person, and review each one of those mammogram, is that a
5 yes or a no, or is there some flexibility here where the
6 surgeon can review a number of mammograms, can keep a log of
7 what he reviews, review it along with the mammogram report,
8 come to his own conclusions, keep this in a log without
9 having a consultation with the radiologist?

10 I don't want to compound the question, but one
11 other part of the question is, if we have a course that is
12 led by someone like Dr. Laslo Tobar, and in the course of
13 this three or four day meeting, a surgeon reviews 400
14 mammograms, does this count, and if so, where does it fit
15 into the picture?

16 DR. MONSEES: Dr. Bassett, would you like to take
17 a stab at that, please?

18 DR. BASSETT: Yes.

19 DR. MONSEES: Since you were involved and you know
20 the spirit of what was written here.

21 DR. BASSETT: Well, my understanding, the way I
22 would see it is that the latter explanation you gave would
23 be the correct one. However, there are differences in
24 different practices. For example, in our practice, we are

1 actually down in the breast center when the surgeons are
2 seeing their patients, and they bring us every case out and
3 we talk about it and discuss the abnormality, and what
4 should be done next.

5 So, that would count for them, I believe, as
6 having reviewed it. There may be other circumstances, the
7 one you described, where you are reviewing the case, the
8 patient you are seeing, you review the mammogram, you look
9 at the abnormality, that would count, as well.

10 Then, I also mentioned the third scenario where
11 you are looking at some cases that were from your associate
12 in order to make up the numbers you don't have, which we
13 might equate with double reading, although it is not the
14 same thing.

15 So, I think that the intent was to have reviewed
16 the case, reviewed the interpretation, identified the
17 abnormality, in a process that did involve looking at the
18 images and looking at the interpretation, whether it is
19 given orally or on a report.

20 And then the issue about doing them in a course
21 that is CME approved. I would have to have Flo address
22 that, but I think that was acceptable, as well.

23 DR. MONSEES: Dr. Sickles.

24 DR. SICKLES: I am addressing it to the people who

1 were involved in planning this, and maybe Dr. Israel would
2 have a comment, as well.

3 I get the sense from what I am hearing now that
4 the purpose of this 480 or whatever number, and this would
5 certainly be my belief, would be to try to include rather
6 than exclude as many physicians as possible with the
7 ultimate aim of being sure that they have enough skill in
8 looking at mammograms to know that they are looking at
9 important lesions rather than unimportant lesions.

10 Is that the intent?

11 DR. BASSETT: Yes.

12 DR. MONSEES: While you are still there, before
13 you sit down, please, do you think that the number of
14 biopsies that is listed in this document, the initial number
15 and then 12 per year is an appropriate ballpark for somebody
16 that is going to be proficient and that is going to be
17 involved in this, and for patient safety issues, all of the
18 important things, what we are really trying to get at here?
19 Is that number, that minimum number okay?

20 DR. ISRAEL: No. In my opinion, no, it's too low.

21 DR. MONSEES: It's too low.

22 DR. ISRAEL: Too low.

23 DR. MONSEES: What would you suggest then?

24 DR. ISRAEL: One biopsy per month will not promote

1 proficiency.

2 DR. MONSEES: So what do you think the learning
3 curve takes to become proficient and then to what level
4 would you say that somebody needs to continue to perform
5 these procedures in order to operate at a satisfactory
6 level? We are not talking about the best level here, we are
7 talking about an adequate level.

8 DR. ISRAEL: I think that 15 to 20 would be a more
9 appropriate level. A doctor that is doing one procedure a
10 month, be it a radiologist or a surgeon, what that tells me
11 is they don't have a very busy practice, they don't have the
12 volume to accomplish or beat the learning curve. I think
13 that is too low.

14 I mentioned that last year, and I didn't get much
15 support from the radiologist community. I think the
16 radiologist community wanted to keep it at that level. But
17 I do believe that radiologists and surgeons who have a
18 sufficient volume -- and I think a surgeon who has a 30
19 percent breast practice is going to see enough cases where
20 he will do at least 15 to 20 per year.

21 DR. MONSEES: Thank you. Don't sit down. And Dr.
22 Dowlat may want to answer this.

23 MR. MOBLEY: I have a similar question I think. I
24 am not a physician, so I need to help myself understand

1 this. Some of the questions that you just asked helped me,
2 but I want to see if I have a handle on how this process
3 works, because I really liked the process discussion that we
4 had earlier.

5 A screening mammogram is made and then if there
6 are suspicious findings, that patient would be recommended
7 to the surgeon or radiologist for further review as to
8 whether a stereo procedure should be performed.

9 So, at that point, the physician reviewing that
10 film is not looking at the film to determine is there
11 something suspicious here, there has already been something
12 suspicious identified and pointed out as to where it is, et
13 cetera.

14 So, the question in my mind is I don't understand
15 why the 480 number is the magic number here or what the real
16 importance there is. The real importance is can I identify
17 this, having it pointed out to me, and can I take action
18 pursuant thereto based on my interpretation of the
19 information I have.

20 So, it wouldn't seem like that that physician at
21 that point needs to meet the same basic criteria as the
22 screening physician. So, I am wondering, and you answered
23 this to some extent, it seems like then that the issue of
24 the stereo procedure is maybe more important than the issue

1 of the 480 mammograms, which I think is some of what you
2 said, but is my understanding there correct?

3 DR. ISRAEL: Yes, it is correct, and I think you
4 have put it very properly, and this has been a problem that
5 I have had to address all along, and that is trying to
6 equate the skill that is needed to be an MQSA screening
7 physician. Surgeons have no aspirations to do screening
8 mammography.

9 We only want to take a lesion that has been
10 identified. We want to reproduce that lesion and we want to
11 do what we have always done with patients, biopsy that
12 lesion.

13 This does require some skills and it does require
14 some imaging skills. To be fair about it, there are
15 deficiencies in the radiology community, and there are
16 deficiencies in the surgical community. At these hearings,
17 we really only seem to address the deficiencies in the
18 surgical community, and surgeons will readily admit they
19 need to enhance their image interpretation skills, and they
20 are working to do that and they will make that
21 accomplishment.

22 On the other hand, there are deficiencies in the
23 radiology community which need to be bolstered and worked on
24 that are very important, that have been highlighted by the

1 public discussions this morning. I think they are equally
2 important, and I would like the committee to address both of
3 those deficiencies both in the radiology community and in
4 the surgeon community.

5 But getting back to the number 480, I do not think
6 it is necessary for a surgeon who is reproducing a lesion
7 for a biopsy to do 480 mammogram interpretations.
8 Certainly, a number needs to be put in there. I would say
9 half that would be adequate.

10 Surgeons are going to accept responsibility for
11 what they do when they biopsy these lesions. They are very
12 responsible, they are not going to biopsy lesions that they
13 cannot interpret, and I have a rule in my center, when we
14 reproduce a lesion and it comes up on the digital monitor,
15 and I look at that, I don't biopsy that lesion if I have to
16 say to myself I think that is the lesion. The patient
17 doesn't get a biopsy.

18 I have to say that is the lesion. Then, that
19 patient will get a biopsy. We are not going to take
20 chances, we are not going to put patients at jeopardy. I
21 don't think that the imaging skills need to be at the level
22 of an MQSA interpreting physician to do stereotactic biopsy.
23 They need to be good and they need to be worked on and
24 enhanced, but they don't need to be at that level.

1 DR. MONSEES: Thank you, sir.

2 Dr. Dowlat, would you like to give us your
3 impression about the numbers that we are talking about, the
4 ongoing experience, the number of biopsies that need to be
5 performed, are we too high or too low here, and the number
6 of mammograms, what do you think, what is your opinion?

7 DR. DOWLAT: I think the 480, I don't know the
8 history of it, but I take it, it was developed because of
9 the MQSA physicians or radiologists were required to be
10 exposed to that many cases a year in order to be proficient
11 and to be certified, am I correct in that?

12 DR. MONSEES: That is correct.

13 DR. DOWLAT: Those 480, 10 percent of them, 5
14 percent had abnormalities. The rest of them were normal
15 mammograms. Now, here, we are transferring that number to
16 surgeons who are facing an abnormal mammogram, and asking
17 them to look at 480 abnormal mammograms. I don't think that
18 is right. I think that number is too high.

19 Admittedly, during the year, the surgeon will come
20 across some normal mammograms, but the majority of the time
21 that the patient comes to him or her, is with a set of films
22 and the report saying there is something to be biopsied,
23 surgical consultation is required. So, I think maybe they
24 are talking about apples and oranges here.

1 The second thing is about the number you ask for
2 initial training and subsequent proficiency of a physician
3 who is doing the stereotaxic needle biopsy. I agree with
4 Dr. Israel that one a month is not enough. I personally do
5 about five a week, an average of five a week, and if I go
6 away for a week or two, and I come back, I find myself a
7 little bit rusty.

8 As I said earlier today, the technology, the table
9 is not as simple as it used to be. There is a lot of
10 complexities attached to it. Already I am seeing during the
11 courses that some people have become a specialist in the
12 ABBI system only. They have difficulty in doing the needle
13 biopsy, ordinary core biopsy. Why? Because there is so
14 much, they have to focus their attention on that, on doing
15 ABBI system or doing ABBI biopsy.

16 DR. MONSEES: It is kind of like a reconstructive
17 surgeon using only one method for all people, isn't it?

18 DR. DOWLAT: Well, I am just saying that this has
19 become a sub-subspecialization. So, I would like to see the
20 person who is coming and who wants to do image-guided breast
21 biopsies especially with the stereotaxic should do more than
22 one a month.

23 I think one a month is inadequate. I think they
24 will start cutting corners and they run into trouble.

1 DR. MONSEES: Thank you.

2 MS. HEINLEIN: So far, both Dr. Israel and Dr.
3 Dowlat have said that one is not enough, one a month is not
4 enough, but there is no -- any idea, I mean would you say
5 one a week? He said 15 to 20, but 15 is just three more
6 than 12. So, I don't get how that does anything.

7 DR. DOWLAT: Rita, I think one a week is minimal.
8 I think a person should do something like 50 a year in order
9 to remain proficient.

10 DR. MONSEES: Dr. Bassett.

11 DR. BASSETT: I would be careful about this, and
12 here is the reason. You have got practices where you have,
13 for example, in our practice we have three radiologists who
14 are doing the procedures, and many of the procedures are
15 better done with ultrasound guidance.

16 What we were concerned about in looking at these
17 numbers was would we be compelling facilities to do biopsies
18 that weren't necessary, in other words, if you had a certain
19 number you had to do, would you change some of those
20 probably benigns to suspicious because you wanted to get
21 your numbers, if you didn't, you might lose your
22 accreditation and lose the ability to practice?

23 Would you take cases that really should undergo --
24 in our practice, we have seen a trend over the last couple

1 of years to go from stereotactic to ultrasound guided much
2 more frequently that we did before, where now it is almost
3 just calcifications that undergo stereotactic.

4 So, could we just switch some of those ultrasound
5 over to stereotactic in order to get our numbers up? And I
6 don't want to see it become a numbers game.

7 So, in a practice like ours, where there is three
8 of us who are doing it, teaching it, and so on, it would
9 become a task to try to continue to keep our mind on these
10 numbers. In fact, not too long ago, my chief technologist
11 said to me, well, maybe you had better do this under
12 stereotactic to make sure you have enough stereotactic
13 numbers for your accreditation, because I had been out of
14 town for a while.

15 I just don't want to see it go to that. I think
16 that we can keep good quality without having that.

17 Peter, could you comment on that, because you are
18 a practice where you do a lot of ultrasound guided, and
19 don't you think that there is more of a trend to go that
20 way, and that we might compel people to do stereotactic
21 cases that should have been done under ultrasound?

22 I am sorry, Barbara.

23 DR. MONSEES: That is okay. I am anxious to hear
24 the answer.

1 DR. DEMPSEY: No, absolutely, I couldn't agree
2 more. In our particular practice -- and we have no ax to
3 grind -- we have a prone table and we do ultrasound guided,
4 but I can tell you the statistics right now, 87 percent of
5 our core biopsies are done with ultrasound guidance, 87
6 percent.

7 MS. HEINLEIN: Can I do a followup to that?

8 DR. MONSEES: Yes, please.

9 MS. HEINLEIN: Then, I think that that is that
10 extreme, but you also don't want to say, well, let's make
11 the number so low that then we won't have a numbers game,
12 but we also won't have proficiency in the performance of the
13 exam.

14 DR. BASSETT: Well, if people have to do one a
15 month, that will keep them involved, and then their partners
16 are also doing it assumingly. I mean it becomes a problem
17 when you have more than one person in your practice who is
18 doing these, because then you start fighting over the cases.

19 MS. HEINLEIN: But maybe you don't need to have
20 all five radiologists doing stereotactic --

21 DR. BASSETT: I said three, first of all.

22 MS. HEINLEIN: Well, all right. Maybe all three
23 don't need to do it.

24 DR. BASSETT: And when you say you have to do 50,

1 well, if you are doing 87 percent under ultrasound, start
2 thinking about your numbers.

3 MS. HEINLEIN: I understand that, but what I am
4 saying is that this is the dilemma in trying to find a
5 balance between not making it a numbers game either way.

6 DR. BASSETT: I understand, but you can't run a
7 practice where we can only do the stereotactic biopsy on
8 this patient on Thursday because that is that Maria is
9 there, and I am not allowed to do them anymore. So, there
10 is as lot of practicalities in running a practice, that
11 don't mean that you are going to lower the quality of the
12 performance of the examination to keep people involved.

13 I am just concerned if we make the number high,
14 that we may be really making people do procedures or at
15 least leading them into the pathway of doing procedures
16 either that are not necessary or that could have been better
17 done with another modality.

18 MS. HEINLEIN: And I agree with you in that. So,
19 what would you suggest would be an appropriate number, so
20 that that would not happen?

21 DR. BASSETT: This number of 12 a year was come up
22 as a compromise on that.

23 MS. HEINLEIN: And you feel that that one a month
24 would help to maintain someone's proficiency then?

1 DR. BASSETT: I think it is unlikely that most
2 people are going to be in that position. I know we are
3 going to do more than that per person, but I think at least
4 that will guarantee, and then if you are also really
5 concerned about the underserved areas or the areas that have
6 few procedures, which I have heard many times today, those
7 are the ones who are really going to be affected by this.
8 They may end up having to put all their patients on
9 stereotactic biopsy in order to meet a higher number.

10 DR. MOORE-FARRELL: I also think that one a month
11 is a reasonable number. I am from not an urban area, and as
12 I said before, in my practice general surgeons use the table
13 as well, and out of all the core biopsies, I will say 70
14 percent are done under ultrasound and 30 percent are done
15 under stereotactic guidance, and the surgeons are very good
16 about sending the appropriate cases for ultrasound-guided
17 biopsies, because it is efficient and it's cost effective,
18 but I believe that if there was a question of keeping those
19 numbers up, they would not. They would keep those patients
20 to keep their numbers up.

21 DR. HENDRICK: I would just like to suggest that
22 maybe a better measure of quality is how many image-guided
23 biopsies are performed overall, not trying to break it down
24 into x-ray or ultrasound guided, and perhaps another, better

1 surrogate of quality would be whether the physician adjusts
2 the biopsy device to suit the patient or the particular type
3 of lesion rather than using the one technology that they may
4 have just obtained.

5 DR. MONSEES: Along those lines, Dr. Winchester,
6 if a voluntary accreditation program were going to be
7 designed that would be a cooperative effort between ACS and
8 ACR, do you think that the American College of Surgeons
9 would be willing to expand this into all image-guided
10 biopsy, and not just stereotactic biopsy?

11 DR. WINCHESTER: That is not covered under MQSA.

12 DR. MONSEES: I realize that, but if we are
13 talking about a voluntary program, then we are talking about
14 may be doing it a different way, maybe a better way.

15 DR. WINCHESTER: Both colleges are in the process
16 of working on the ultrasound component of this, not just in
17 breast. ACR I think is just breast so far, right? But the
18 college surgeons are looking at a broader ultrasound
19 accreditation program. The answer is I think yes.

20 DR. MONSEES: I will move to you and then we have
21 a couple of questions from these gentlemen that we have
22 pressed upon, so I am going to let them ask questions. Go
23 ahead.

24 DR. DEMPSEY: I think there is one other factor

1 that has to be looked at in a department's total biopsy
2 experience, and that is that in the departments that do have
3 excellent cytology backup, that much of your biopsy work is
4 actually done FNA under ultrasound guidance, not core, which
5 is an image-guided biopsy, which is extremely efficient for
6 patient care, because you get the diagnosis in 15 minutes.

7 I think that also has to be put into the
8 continuum. You know, we are lucky enough in our department,
9 we have a prone table, we have ultrasound guidance, we do
10 FNA, we do core. We do it all. I think that Dr. Bassett's
11 point that if you are going to have to say, well, let's see,
12 I have got three of Category 1, and I have got one of
13 Category 2, so tomorrow I had better do them all this way or
14 all that way, and you are not thinking about what is best
15 for the patient, but you are thinking about getting your
16 numbers. That is extremely dangerous and counterproductive
17 to what we are trying to do here.

18 What we are trying to do here is what is best for
19 the patient and who is the most qualified to do it.

20 DR. MONSEES: Dr. Dowlat.

21 DR. DOWLAT: I wholeheartedly support Dr. Dempsey,
22 but I have one question for you. You said 83 percent of
23 your biopsies are ultrasound guided?

24 DR. DEMPSEY: 87.

1 DR. DOWLAT: You mean you do some
2 microcalcifications with ultrasound, too?

3 DR. DEMPSEY: From 1991 until 1996, we very
4 definitely skewed our population, so that we stayed away
5 from microcalcifications. We did that for a very good
6 reason. We were on certain protocols and we were trying to
7 prove a certain point.

8 We increased the positive predicted value of
9 nodules going to surgery from 30 percent positive to, in
10 1996, 78 percent positive. So, what we were trying to do
11 was to make the surgeons' work more efficient, that the only
12 thing the surgeon operated on primarily was cancer. So, we
13 have proven that point with nodules, and now we are going
14 into microcalcifications more.

15 So, I suspect, as you allude to, that that number
16 in the mid to high 80s will come down as we are doing more
17 microcalcifications. That is true, but by the same token,
18 if you have a number of image-guided procedures, you want to
19 be guided by what is best for the patient, not how many
20 numbers you have in that particular slot.

21 DR. MONSEES: That is a very important point.

22 Dr. Israel.

23 DR. ISRAEL: Not to belabor this issue -- which is
24 what I am going to do -- I would like to respond, and to Dr.

1 Bassett, I would like to say that we do a lot of ultrasound-
2 guided biopsies. We do all -- I would say 95 percent of our
3 nodular densities we do with ultrasound, but all of our
4 microcalcifications -- and 50 percent of your lesions are
5 going to be microcalcifications -- and when Dr. Dempsey
6 starts doing all the microcalcifications, he is going to do
7 a lot more core biopsies.

8 The issue of 12 being enough, I said it wasn't
9 enough. I believe that. It is not enough to maintain
10 proficiency. If a surgeon asks me, he says I am going to do
11 one stereotactic breast biopsy a month, my advice to him
12 don't do it at all. I would say the same thing to a
13 radiologist, if you can only do one a month, don't do them.

14 In Dr. Bassett's case, maybe only one of those
15 radiologists needs to be doing this procedure. One a month
16 is not enough. And I don't think that we should compromise
17 that number to satisfy other situations. If 12 is not
18 enough, it is not enough.

19 DR. MONSEES: Thank you.

20 I would like to move on technologist issues, but I
21 don't want to cut anybody off if they have any other
22 comments about these numbers and about physician
23 qualifications. Are there any other pressing issues here?
24 Do people on the panel have any questions or comments before

1 we move on to technologist issues?

2 We have probably another half-hour, maybe another
3 hour if we go until 6:00. I would like to try and see if we
4 can reach closure at 5:30.

5 MS. HEINLEIN: Just one issue that was actually
6 brought up by Ed Hendrick to see if there was any consensus
7 or other feelings about the four hours of the CME and
8 medical radiation physics for surgeons practicing
9 independently and whether or not that was felt to be
10 sufficient for supervision of the technologist and medical
11 physicist.

12 DR. MONSEES: Let's put that on the table. Would
13 you like to comment on that?

14 MS. HEINLEIN: No.

15 DR. MONSEES: Anybody on this panel like to
16 comment on that? Dr. Winchester, do you have something to
17 say? You were headed towards the microphone.

18 DR. WINCHESTER: I have had a fair amount of
19 feedback from the surgical community about that, and they
20 think that number is excessive. I don't know anything about
21 this subject. I think others, coming from the other
22 perspective, they think it ought be 12 hours or 10 hours,
23 and I don't know the answer to that.

24 After watching the presentation from Bob today, I

1 think I would need a couple days.

2 DR. MONSEES: He only showed one formula, don't
3 forget.

4 Dr. Bassett, you helped to formulate this report.
5 Can you tell us where you got that number and maybe -- I
6 know you didn't just pull it out of the air, but do you want
7 to give us some more information about this?

8 DR. BASSETT: I think there was an attempt to
9 compare it to what was being required for other things like
10 what the interpreting physician was required to do, and the
11 alternative pathway that was an alternative for doing
12 interpretation. Part of it came out of the air, I guess,
13 but I think there was some attempt to try to make it a
14 reasonable amount.

15 David, do you want to comment on that?

16 DR. DERSHAW: Yes. Let me make a specific comment
17 and a general comment. I have kind of mixed them all up.
18 There was I think an appreciation that the skills that are
19 involved in doing this procedure are the same whatever the
20 postgraduate medical education is that a physician has had,
21 whether he or she is a radiologist or a surgeon or whatever,
22 the same skills are involved in performing these procedures
23 with a high level of competence.

24 It is not expected, and it is an inappropriate

1 expectation, that radiologists will become surgeons in order
2 to perform this and that surgeons will become radiologists
3 in order to perform this, that there are surgeons and
4 radiologists who are extremely expert in performing these
5 procedures, and there are surgeons and radiologists who are
6 performing these procedures who are not very good at it,
7 and, in fact, probably shouldn't be performing these
8 procedures.

9 The numbers that constitute this document are
10 obviously compromise numbers. Do they guarantee an
11 extraordinary level of expertise in any physician who is
12 performing these procedures? No, they certainly do not.

13 May they, in fact, end up excluding some
14 physicians who might do this procedure very well? Perhaps
15 they might, but they are an attempt to look at the skills
16 that are required in order to perform the procedures well,
17 and try and see what kind of training and what kind of
18 experience is necessary for physicians in various specialty
19 groups to perform those procedures well.

20 I think that the document is a reasonable document
21 and I think that the level of skill that a physician has, if
22 he or she has met the criteria spelled out in this document,
23 is reasonably high in terms of performing these procedures.

24 We may argue about this number or that number, and

1 this committee can go through the same kind of arguments
2 that our committee went through in terms of this. These
3 were not an attempt to make people happy.

4 These were not an attempt to go back to our
5 members -- and we were very successful in that -- these were
6 not an attempt either to go back to the membership of the
7 individual colleges and say look what we have done for you.
8 These were an attempt to look at physicians and other
9 personnel involved in these procedures and say what kind of
10 training and experience do you have to have initially and in
11 an ongoing fashion in order to be competent in this.

12 Four hours of CME in physics does not give a
13 surgeon the same level of competence that a radiologist has
14 in looking at these numbers, but it hopefully gives a non-
15 radiologist some level of sophistication, some level of
16 insight in order to be able to have a discussion with the
17 medical physicist and the technologist involved in the
18 procedures, so there is a level of understanding about what
19 the equipment is and what the problems that arise in the
20 equipment may be.

21 I agree with you that three weeks of physics
22 would, in fact, be better, but it is unrealistic that non-
23 radiologists are going to have that kind of experience.

24 DR. HENDRICK: On the other hand, if you are

1 serious about having these as the responsible physician,
2 anyone, I don't care who it is, as the responsible physician
3 overseeing all of quality control, overseeing the work of
4 the technologist, the work of the medical physicist, you
5 can't substitute the background of a radiologist who has
6 gone through four years of residency getting physics,
7 training in mammography, getting physics specifically
8 directed at mammography.

9 I mean I can't tell you how many hundreds of
10 lectures I have given on quality control in mammography to
11 radiologists, you know, how to review a physicist's report,
12 how to work with the technologist and the medical physicist.

13 I would like to think that that has had some value
14 in mammography, and I don't think it is really replaced by
15 four hours, especially for someone who hasn't been involved
16 in the radiology environment the way radiologists have.
17 That's all.

18 DR. MONSEES: Which brings me to ask a question
19 about the technologist, which is something I would like to
20 get to this afternoon.

21 Do you think that as a substitute perhaps that if
22 a technologist had added qualifications, and were going to
23 take on more responsibility in a type of practice where the
24 surgeons were running the show, that that would suffice,

1 that if there were some additional education for a
2 technologist that was running this practice in conjunction
3 with the surgeon, that that would be an alternative? Would
4 you care to answer that?

5 DR. HENDRICK: Yes. The technologist is not
6 running the practice.

7 DR. MONSEES: No, in conjunction. If that
8 technologist had some additional -- I am not saying that
9 this is what I suggest, I am asking you is this a
10 possibility.

11 DR. HENDRICK: No, I think it is a model that
12 doesn't work, because I think the medical responsibility
13 lies with the physician, the supervision responsibility lies
14 with the physician, and to try to supplant that in the case
15 where the physician isn't really knowledgeable about all the
16 things the tech does, or the physicist does, is just
17 complicating the issue, because they never have the control
18 or the power to exercise that responsibility even if you
19 assign it to them.

20 DR. MONSEES: The reason I asked that is that at
21 least in our community and what I have noticed is that there
22 are some surgeons not of the caliber of these surgeons in
23 the audience today who do a large number of these
24 procedures, but that do the occasional case, and I think

1 they rely heavily on a technologist that is very facile with
2 the equipment, to set it up, position the patient, target
3 the lesion, and do everything but shoot.

4 I think that we all know that this exists, and
5 what I would like to know is do we think that that is
6 satisfactory or not.

7 MR. MOBLEY: Maybe it is because this is my first
8 meeting, but as I read this in preparing for the meeting, I
9 did not see that there was any -- and it is not intended to
10 address that -- but I did not see that there were any basic
11 requirements there in terms of the technologist or the
12 medical physicist. They are just listed radiologic
13 technologist.

14 In looking at it, I would think, well, maybe that
15 is a technologist that is certified in mammography, maybe
16 that is a medical physicist that meets certain criteria, but
17 that is not listed here or elucidated here or anywhere else
18 that I am aware of. Now, maybe it is elsewhere.

19 DR. MONSEES: You are correct.

20 MR. MOBLEY: The question is do you just roll over
21 the requirements for technologist from the basic mammography
22 standard, or is there something else that I am missing here?

23 MS. HEINLEIN: It is in the ACR. It is in this
24 folder here, this one.

1 DR. MONSEES: You are talking about the MQSA
2 qualifications?

3 MS. HEINLEIN: It's in the ACR stereo.

4 DR. MONSEES: Oh, yes, for the voluntary
5 accreditation program.

6 MS. HEINLEIN: Right.

7 MR. MOBLEY: Can I then assume that this is the
8 basic that we are working from in reference to this?

9 DR. MONSEES: Well, the ACR accreditation program
10 did not include the collaborative or the surgeon working
11 alone, and therefore this other document was drawn up for
12 the physician component, but I think what they are saying is
13 that the technologist and the physicist qualifications would
14 remain the same regardless of what type of practice. Is
15 that correct?

16 DR. DERSHAW: That is correct. First of all, let
17 me say that what was distributed was the old application
18 form, so you will get a new one tomorrow morning, and those
19 of you who are going to apply for certification for your
20 practices, don't use this form, but it is correct that this
21 document, which is the College of Surgeons and College of
22 Radiology joint document, pertains only to physician
23 qualifications, the physician requirements, the requirements
24 for technologists, for medical physicists, for quality

1 control, and for practice outcome data are all included in
2 the application document.

3 DR. MONSEES: Dr. Winchester.

4 DR. WINCHESTER: Ed Hendrick, I had a question.
5 You have had a lot of experience in teaching surgeons
6 through the college courses, and I think other courses, you
7 have interfaced with them on many occasions. How many hours
8 do you think you need with surgeons to teach them what they
9 need to know to do this?

10 DR. HENDRICK: I have only taught the surgeons
11 course once. Bob Pizzutiello, I think has taught it a
12 number of other times. But in that course, I had I believe
13 it was either an hour or an hour and a half, and it was
14 painfully deficient at that level.

15 I discussed with Dr. Dowlat much longer periods,
16 but this was trying to be fit into a weekend course, and the
17 physics got trimmed down to I think it was an hour. Is that
18 right, Bob?

19 MR. PIZZUTIELLO: About an hour.

20 DR. HENDRICK: But I think that seeing what the
21 questions were back and the issues, I think much more than
22 an hour is needed, probably much more than five hours is
23 needed to really get at -- if you wanted to get a surgeon to
24 the point of being the responsible physician in a breast

1 biopsy practice, that is, responsible for the technologist
2 and the medical physicist and the quality of the images that
3 are coming out of that equipment.

4 So, I don't have a number for you, but I do think
5 four hours is deficient, and I just wanted to add one other
6 thing, that I thought we were talking about these basic
7 requirements for technologists and physicists from this
8 document that is entitled, "Basic Requirements for ACR
9 Stereotactic Breast Biopsy Accreditation." Is that correct?

10 MR. PIZZUTIELLO: Yes.

11 DR. HENDRICK: And that is not going to change,
12 right?

13 MR. PIZZUTIELLO: Correct.

14 DR. HENDRICK: It is the application that is
15 changed.

16 DR. MONSEES: Dr. Dowlat, I am sorry. By this
17 time I am seeing hands all over the place. Yes.

18 DR. DERSHAW: Dr. Hendrick, you have mentioned
19 that you have given lots of lectures to radiologists. How
20 did they perform? What was your evaluation of their
21 understanding of what is needed in order to do a stereotaxic
22 needle biopsy?

23 DR. HENDRICK: Well, unfortunately, they don't
24 have to perform at all. They just have to stay there in the

1 room. But we have tried in the context of a number of
2 educational efforts through the ACR to actually test what
3 they get out of the QC components of the coursework like ACR
4 viewbox symposium, things like that, and the QC, I mean Ed
5 Sickles and other people here can address this more, Larry
6 Bassett, but we have tried to embed the QC types of
7 questions into viewing of images at the viewbox and
8 assessment of image quality and what do you do about -- what
9 is the problem, do you find a problem, and then what do you
10 about it if there is a problem.

11 So, it has been addressed. Not all radiologists
12 test well on QC.

13 DR. MONSEES: I will point out also that
14 radiologists do take written boards on radiation biology and
15 basic radiation physics, so we do have some certain
16 qualifications now. Of course, many of us were boarded
17 before stereotactic biopsy came in, so the specifics
18 pertaining to that would be new, but it is taught in
19 training programs.

20 Now, I don't know whether or not the written board
21 questions -- does anybody know whether the written board
22 questions will pertain to this part of physics, do you know,
23 written board questions?

24 DR. HENDRICK: Some do.

1 DR. MONSEES: Dr. Sickles?

2 DR. SICKLES: I can answer your question about
3 radiologists' performance. The American College of
4 Radiology has developed a self-assessment examination for
5 radiologists, tests, image interpretation, and embedded in
6 this, as you have heard, are questions that relate to image
7 quality and image quality physics. They are purposely put
8 in there.

9 Radiologists who take this test -- and there have
10 been hundreds and hundreds of radiologists who have taken
11 the test in various installations -- performed just as well,
12 no better, no worse, on image quality and image quality
13 physics as they do in areas like detection of lesions and
14 analysis of lesions. So, there is no reason to believe that
15 education of radiologists in physics is any better or any
16 worse than it is in regular education.

17 DR. DOWLAT: Dr. Sickles, I am trying to be
18 constructive here, and I really want to learn, I want to
19 take a message away as how to incorporate that test or that
20 instruction into the courses that we are giving in the
21 future, so if there is a lesson that I can learn or I can
22 convey, please let me know.

23 DR. SICKLES: I could make a suggestion to you
24 that that particular test is geared more to image

1 interpretation, which is really not what the non-MQSA
2 physician has to do. They have already been told there is a
3 finding there that needs a biopsy. They need to know how to
4 target it and how to evaluate that it is an appropriate
5 lesion to be targeted.

6 But what I would suggest that you do in planning
7 your courses, if you are the one who is in charge of the
8 course, is to direct the physicists who are teaching to
9 concentrate their lectures on what the non-MQSA physician
10 needs to know about working with a physicist as opposed to
11 all of medical physics that has to do with mammography.

12 I think you should direct them to the areas where
13 they have to perform as opposed to all areas where maybe i
14 it is not so important they perform.

15 DR. DOWLAT: Nevertheless, the area at the time
16 when the surgeon and radiologist are doing the
17 interventional procedure using this stereotaxic, which these
18 days is mostly digital, and the quality of the image is
19 good, is not adequate, at that time they should know what
20 the problem is. I think this is what Hendrick was alluding
21 to earlier on.

22 DR. SICKLES: Exactly, and with digital systems,
23 as well as with film systems, the quality is not guaranteed
24 to be good, as you may know.

1 DR. DOWLAT: Correct.

2 DR. SICKLES: At least at a minimum, whatever the
3 background of the physician performing a stereotactic
4 biopsy, the image quality is not adequate to proceed, they
5 have to know, number one, it is not adequate to proceed, and
6 number two, what to do about it.

7 If what to do about it is simply not to do the
8 procedure and call the physicist, that's fine, but they have
9 to know that much, and I think the education has to be
10 directed to that.

11 DR. DOWLAT: I think that is the probably most
12 important lesson that a surgeon can learn from medical
13 physicist while doing this procedure, because if the machine
14 breaks down and the lights go out, I mean anyone can say
15 that.

16 DR. MONSEES: We need to cover a few more things
17 today. Is it going to be quick?

18 DR. ISRAEL: It has to do with the issue that we
19 were just discussing. There is no way that Dr. Hendrick can
20 teach me in probably any amount of time to supervise a
21 medical physicist. There is no way.

22 So, what I would suggest is that my situation,
23 having a stereotactic unit in a facility where there are no
24 radiologists, if we are talking about the equipment, let's

1 say that I and all surgeons who use equipment will have a
2 radiologist to work with the radiation physicist in making
3 sure the equipment is safe and operative. I certainly will
4 be willing to do that, and I think all other surgeons would,
5 I think -- and I shouldn't speak so fully -- but I think
6 that those surgeons who have equipment and there are no
7 radiologists around, that we get a radiologist to supervise
8 the physicist.

9 DR. MONSEES: Shall we tell Dr. Winchester to
10 forward those letters and E-mails to you?

11 DR. ISRAEL: I am not sure, but now, on the other
12 hand -- you haven't heard the other hand yet -- on the other
13 hand, those surgeons who are working on a stereotactic unit
14 that is in a radiology department or where there is
15 radiology support, that those surgeons not be required to
16 take four hours of radiation physics.

17 DR. MONSEES: They are not in the collaborative
18 practice. This is only in the setting where they were
19 solely --

20 DR. ISRAEL: I think we are talking about such a
21 small number, so even those surgeons that do the procedure
22 independently, I think a lot of them are doing them on
23 stereotactic units that are located in radiology departments
24 or where a radiologist is present. I think it is a very

1 small number who represent doctors like myself and Dr.
2 Dowlat.

3 DR. MONSEES: Thank you.

4 I think Mr. Pizzutiello wanted to make a comment
5 and then I am going to ask you all about technologists and
6 about physicists. Start thinking about this because you
7 need to answer quickly, are the qualifications outlined in
8 the ACR voluntary accreditation program appropriate for
9 technologist and physicists, and before we get to that, did
10 you want to ask a question?

11 MR. PIZZUTIELLO: I just wanted to comment on what
12 I saw as a starting point for the physics portion for the
13 surgeons, which was some basic understandings of what
14 radiation is and the issues of radiosensitivity of the
15 breast and radiation dose, and just the scratching the
16 surface of the equipment.

17 I guess I don't want to give opinions, so I will
18 just say that that is what I have done. The plan is for
19 that to be the beginning. It is in no way -- I want to make
20 it clear that one hour of physics is in no way considered to
21 be adequate, and more hours are planned.

22 DR. MONSEES: Let's turn to first technologist
23 issues. Does anybody want to talk about this first? How
24 about a technologist? Rita Heinlein.

1 MS. HEINLEIN: I think that what is here is fine,
2 only I would add "include training in QC procedures related
3 to stereotactic breast biopsy procedures," because there is
4 nothing, nowhere does it say that they have to have any
5 training in QC procedures, so I would add that.

6 DR. MONSEES: Any other comments on the
7 technologist? How much training?

8 MS. HEINLEIN: I wasn't going to touch how much, I
9 mean because I think many of them will have come with some
10 understanding of basic QC, and that is why I said just
11 training in the QC procedures related to stereo as opposed
12 to putting a number to it, unless, Patricia, you feel that
13 there should be one.

14 DR. MONSEES: Dr. Sickles.

15 DR. SICKLES: I have a question for Rita. As with
16 plain mammography in terms of QC, would you be comfortable
17 with a lead QC technologist during stereo and having the
18 other technologist simply perform the procedures, but having
19 a lead technologist do the stereo QC?

20 MS. HEINLEIN: Yes, I would be very comfortable
21 with that.

22 DR. MONSEES: That would be very parallel to the
23 current program.

24 MS. HEINLEIN: Yes, I think that would be good.

1 DR. MONSEES: Did you have a comment? I am
2 pointing to you, Dr. Hendrick.

3 DR. HENDRICK: I wanted to give an opportunity for
4 Pat to comment.

5 DR. MONSEES: Speak up.

6 MS. WILSON: I think that the qualifications for
7 12 per year is not enough in my opinion for a technologist
8 to stay adequate. I would think 12 every six months.

9 DR. MONSEES: So double it is what you would
10 think. We can ask you how you designed it and how you got
11 the 12, but I think we will be going around about.

12 Let's just hear opinions. Is there anybody else
13 on this panel that has an opinion about whether or not it is
14 too high or too low or appropriate? Does anybody want to
15 venture a comment?

16 MS. HEINLEIN: I think we are back to the same
17 position that we were in with the physician. I think one a
18 month is not enough, however, you know, you get back to the
19 same situation, then, do you have just one or two
20 technologists doing it. I think you are back at the same
21 situation that you had with the physicians and how do you
22 run your practice and maintain proficiency.

23 So, I mean I think you are dealing basically with
24 the same situation.

1 DR. MONSEES: Any other comments?

2 DR. FINDER: I promised I wouldn't ask questions,
3 but it is late in the day and I figured I have to get at
4 least one in.

5 DR. MONSEES: Go for it.

6 DR. FINDER: I would like some clarification on
7 the initial qualification for the technologist where they
8 took about five hands-on procedures under the guidance of a
9 qualified physician or technologist.

10 I am wondering under what conditions would a
11 technologist not be under the guidance of a qualified
12 physician at least.

13 DR. MONSEES: Dr. Dershaw, would you like to
14 comment on that?

15 DR. DERSHAW: We weren't sure, but we wanted to
16 make sure that it was under these circumstances.

17 DR. MONSEES: So you just want to stipulate that
18 it had to be. I see.

19 DR. SICKLES: Perhaps what they were referring to
20 is if qualified meant MQSA qualified physician, but they
21 were a non-MQSA physician. Maybe that is what they were
22 talking about.

23 DR. FINDER: Well, that is why we are here and
24 that's what we could use the clarification on.

1 DR. DERSHAW: By "qualified," we meant someone who
2 had been accredited by the program is what a qualified
3 physician is.

4 DR. SICKLES: Stereo qualified.

5 DR. DERSHAW: Stereo qualified. Not an
6 application specialist.

7 DR. MONSEES: Do you need any more clarification
8 on that or are you okay? Dr. Hendrick.

9 DR. HENDRICK: I would just like to also ask the
10 technologists here if three hours of category A continuing
11 education in stereotactic breast biopsy is a sufficient
12 initial qualification, and then three hours every three
13 years is sufficient continuing education for a qualified
14 tech in this area.

15 DR. MONSEES: Can we hear from our technologist
16 representatives on the panel?

17 MS. HEINLEIN: My first look was the 15 hours, and
18 I was thinking no, I think 15 hours is more than sufficient,
19 but I see that is just in mammography. I don't know that
20 three hours -- three hours would be the didactic training in
21 stereo breast biopsy.

22 DR. HENDRICK: It doesn't have to be didactic. It
23 has to be category A, though.

24 MS. HEINLEIN: I see it as didactic and then the

1 clinical part would be the five hands-on procedures.

2 DR. MONSEES: Okay.

3 MS. HEINLEIN: I don't know, how did you come up
4 with the number 3?

5 DR. DERSHAW: It parallels the physician.

6 DR. MONSEES: Any other comments on that?

7 DR. HOUN: Just for reference sake, I know while
8 we were discussing the MQSA final regs for new modalities,
9 we did put in training needed prior to new modalities, and
10 that was eight hours that I think the committee had
11 discussion on.

12 DR. HENDRICK: I thought we said six.

13 DR. MONSEES: For the technologist?

14 DR. HOUN: I think six hours was related to
15 continuing education in your new modality.

16 DR. MONSEES: That would be significantly higher
17 than what is in the voluntary accreditation.

18 MR. MOBLEY: Under technologist there are two
19 bullets that seem to be much the same. I am trying to
20 understand exactly what the intent there is. The third
21 bullet says three hours of category A, continuing education,
22 et cetera, and then the last bullet says three hours of
23 category A, continuing education every three years after
24 initial qualifications are met.

1 DR. MONSEES: That is a continuing requirement.

2 MR. MOBLEY: That is an initial requirement.

3 Okay. It just wasn't really clear that that is what that
4 was. That is the initial requirement. Okay. I just
5 wondered was there supposed to be some other difference
6 there, but that first one is initial requirement.

7 DR. MONSEES: Last but not least, I would like to
8 move on to -- in the last few minutes, and then we are going
9 to break for the night -- the medical physicist. I am sorry
10 we are going to have to do this tonight.

11 Did you want to comment on that Dr. Winchester?

12 DR. WINCHESTER: I wasn't done with the
13 physicians.

14 DR. MONSEES: I am sorry. Well, we will be taking
15 that up again tomorrow. Are you going to be here?

16 DR. WINCHESTER: Yes.

17 DR. MONSEES: We will do that first thing in the
18 morning.

19 Can we move on to the physicist now, and then we
20 will continue the discussion pertaining to personnel first
21 thing in the morning and then we will move on to non-
22 personnel issues.

23 MS. HEINLEIN: Can I bring up one other thing
24 about the technologist?

1 DR. MONSEES: Yes.

2 MS. HEINLEIN: I just want to make sure I get
3 clarification from Dr. Houn. It was eight hours for initial
4 training in a new modality, right? Then, perhaps it should
5 be eight hours here then, too. This would be initial
6 training in stereo.

7 DR. HOUN: This is not an FDA program. You can
8 recommend this to the voluntary folks, but I just wanted to
9 give you --

10 MS. HEINLEIN: What I am wondering is are we
11 bringing up any of this to make suggestions? I mean is this
12 going to go under regulation?

13 DR. MONSEES: These are suggestions, so that if it
14 decided that this will be regulated, that they would have a
15 ballpark for the first draft if they wrote a draft for
16 regulations. So, if you would like to suggest that three is
17 not enough, they are listening. If it should come to this
18 being regulated, they want to know what you have to say
19 about it. It doesn't matter what the ACR says. It doesn't
20 matter what somebody else says, what do you think.

21 MS. HEINLEIN: Well, since this committee and the
22 FDA has made a decision that for a new modality, it would be
23 eight hours, then, I would suggest if this becomes regulated
24 that there be consistency and that that number turn into

1 eight hours.

2 DR. MONSEES: The hour is late. I would like to
3 know whether or not we should try and discuss the medical
4 physicist today or should we attack that the first thing in
5 the morning?

6 May I see a show of hands who would like to
7 adjourn now and attack that in the morning, and then go on
8 to other personnel issues?

9 Okay. The physicists. Are you happy about
10 talking about this in the morning or would you like to talk
11 about this tonight? Let's do it. One more notch on the
12 belt.

13 Would you like to start using perhaps the document
14 here as a starting point, comment on that, and make any
15 suggestions that you would like to add to it, any
16 disagreements perhaps, how do you feel about it?

17 DR. HENDRICK: Like the discussion about
18 technologists, I think there does need to be --

19 DR. MONSEES: Did he write it? Did you write
20 this?

21 DR. HENDRICK: No. Well, I was involved in
22 writing this.

23 DR. FINDER: If we can get factual information,
24 but we really can't get your opinion because we assume that

1 you agreed with what you wrote.

2 DR. MONSEES: So, we won't ask you.

3 DR. HENDRICK: This was written by committee. It
4 certainly wasn't my dictation, but it will shorten if I
5 don't say anything.

6 DR. MONSEES: Did you write this?

7 MR. PIZZUTIELLO: Yes.

8 DR. MONSEES: Do we have anybody here who didn't
9 write this? Yes, sir.

10 MR. MOBLEY: I just need some information and
11 maybe Ed can respond or Ed or Bob. In the hearing
12 discussions today, we heard the discussions of the digital
13 imaging, and I know that digital imaging has been discussed
14 for years as being the coming thing, but I don't think it
15 has got there except just in very certain areas, this one
16 area in particular.

17 That is different than the normal kinds of imaging
18 operations that medical physicists usually see, and as I
19 read this, I didn't see anything on here that led me to
20 believe that there was a lot of extra effort necessary and I
21 heard this morning that because of the differences in the
22 digital imaging systems, there is some extra effort and some
23 extra understanding, and I have not heard a lot addressing
24 that in the other areas, the technologist, the physician,

1 and somebody needs to be very cognizant of what these
2 differences are and how this equipment needs to perform and
3 then how it needs to be modified to perform like it is
4 supposed to once it is installed and put into operation.

5 Has that been addressed?

6 DR. MONSEES: I think that is a very important
7 point and, in fact, as a starting point it is probably most
8 important for the physicist, so can you address that,
9 please? Should we -- I know you wrote this -- but would you
10 reconsider and do you think that we should specify in here
11 that there needs to be some CME pertaining to digital?

12 DR. HENDRICK: In Bob's presentation, he mentioned
13 that six or seven of what used to be 10, now are 11, QC
14 tests for the medical physicist are changed in stereotactic
15 by the implementation, primarily the implementation of
16 digital and the small field of view that comes with digital.

17 So, I think initially there will be need for
18 education specifically on the QC tests done by the medical
19 physicist in order to be cognizant of all those changes and
20 really know how to do the test correctly, and I don't think
21 this gets at that in its present form.

22 DR. MONSEES: As a matter of fact, Rita suggested
23 the same thing for the technologist, so I think we can be
24 specific, not only QC, but QC related to digital technology,

1 which should probably be put in there and the wording
2 perhaps should be considered at least to put in there.

3 How many hours do you think additional training
4 would that take, would you like to take that question
5 pertaining to digital, additional hours?

6 MR. PIZZUTIELLO: I guess I want to say, first,
7 that when we came up with these qualifications, it was
8 probably a year and a half before we really coalesced what
9 we felt the 11 tests needed to be, so this was written
10 before we knew exactly what the 11 tests are.

11 So, I would say that some training in digital and
12 digital QC is important, and it is probably on the order of
13 two to three hours to review, as I say, as a minimum, two to
14 three hours to review the actual performance of the digital
15 QC test.

16 Does that seem reasonable, Ed?

17 DR. HENDRICK: I would say at least three.

18 MR. PIZZUTIELLO: I would be happy with three.

19 DR. MONSEES: Any other comments from any other
20 individuals on this panel pertaining to the technologist or
21 the physicist qualifications, initial and ongoing?

22 MS. HEINLEIN: I just want to make sure I
23 understand where we are now. We are adding that for both
24 the technologist and the medical physicist, that that would

1 include training and QC procedures related to stereo and
2 digital?

3 DR. MONSEES: Yes.

4 MS. HEINLEIN: A minimum of three hours is what
5 was discussed, and then as far as the technologist, if this
6 becomes regulation to be consistent with what is currently
7 in the regulation as far as eight hours of continuing
8 education as part of the initial training, and then six
9 hours as part of the continuing education, and that would
10 make it consistent with what is in the regulation.

11 DR. MONSEES: I don't think those numbers are
12 written in stone. Those were just the numbers that were
13 thrown from this panel previously, talking about new
14 technologies, is that correct? Okay.

15 MS. HEINLEIN: Just to be consistent with whatever
16 is written in stone.

17 DR. MONSEES: I don't think anybody is writing
18 anything in stone right now.

19 DR. HENDRICK: As far as stereotactic.

20 DR. MONSEES: Correct, as far as stereotactic,
21 correct.

22 Any other comments about physicist and the
23 technologist qualifications? Yes.

24 MR. MOBLEY: I just want to be sure I understand

1 exactly what it is that we are suggesting here. The three-
2 hour minimum you were talking about, Ed, was initial
3 training for digital systems. What would be additional
4 training for the QC that is necessary for these digital
5 systems?

6 DR. HENDRICK: I think when I was addressing that,
7 it was three hours of initial training in QC of
8 stereotactic, which would include the digital components,
9 and we talk about what you do if it is a film screen system.
10 So, basically, an overall, at least three hours on QC of
11 stereotactic without specifying specifically digital or
12 film.

13 DR. MONSEES: Yes, ma'am.

14 MR. HAWKINS: Pat Hawkins. I just wanted to ask
15 in regards to looking at qualifications for technologist and
16 medical physicist, especially as it relates to previous
17 requirements that have been set by FDA. Have these created
18 access problems in rural areas?

19 DR. MONSEES: Funny you should ask.

20 DR. HOUN: No, they have not in terms of the
21 availability of technologists and a physicist. I think we
22 have had a couple of studies done, one was a subcommittee of
23 this committee last year submitted a review on the qualified
24 physicist and potential shortage areas under MQSA, and I

1 think the one area of the country that seemed vulnerable was
2 Montana.

3 But in terms of technologists, we have not
4 encountered a problem with that. I think initially when the
5 new regulations on 10-1-94 came down, there was a lot of
6 concern, but a lot of courses and teaching has come around
7 and actually have proliferated to try to get the proper
8 training that was required.

9 I don't know if Rita or Pat would like to comment
10 on technologists, what they think about access.

11 MS. WILSON: We have found that we have, with the
12 onset of MQSA, had much more access to technologist
13 training. The BCCCP program has provided many, many hours,
14 workshops, weekends, and working with a local AHECs, like
15 some years our technologists will have 40 hours of training
16 in mammography. We think it has helped our program
17 tremendously having these regulations because people have
18 recognized the fact that a good technologist does not end at
19 their training, that it is an ongoing process.

20 DR. MONSEES: Plus the courses are more available
21 obviously, because they are needed.

22 DR. HENDRICK: I think part of it is having this
23 as a regulation has enabled technologists to get the time
24 off and to get sometimes the support. Often they pay their

1 own way, but to get at least the time off and the
2 encouragement to get these hours that are required rather
3 than the way it used to be which was that they were
4 discouraged from taking time away from the practice to even
5 get continuing education.

6 So it has recognized the need and it has
7 encouraged the acquisition regardless of whether they are
8 rural or urban.

9 DR. MONSEES: If there are no other additional
10 comments on technologist or physicists, I think we are going
11 to adjourn for the evening. We will start up tomorrow
12 morning at 8:00 a.m., and we will start revisiting personnel
13 issues until we have resolved that, and then we will move on
14 to non-personnel issues.

15 [Whereupon, at 5:45 p.m., the hearing was
16 recessed, to reconvene at 8:00 a.m., Wednesday, October 29,
17 1997.]