Same and

RICHARD W. SCHULE

 $MARYLOU\,ZIMMERMAN,\ et \ al.\ vs.$

THE CLEVELAND CLINIC FOUNDATION

	1	3	
	IN THE COURT OF COMMON PLEAS	1	
	CUYAHOGA COUNTY, OHIO	2 (Thereupon, Plaintiff's Schule Exhibit	
	MARY LOU ZIMMERMAN, et al.,	3 1 was mark'd for purposes of identification.)	
4	Plaintiffs,	4	
5		5 RICHARD W. SCHULE, of lawful age, called b	у
6	JUDGE BURNSIDE -vs- CASE NO. 399411	6 the Plaintiffs for the purpose of cross-examination	n,
7	THE CLEVELAND CLINIC FOUNDATION,	7 as provided by the Rules of Civil Procedure, being	g
8	Defendant.	8 by me first duly sworn, as hereinafter certified,	
9	Defendant.	9 deposed and said as follows:	
10		10 CROSS-EXAMINATION OF RICHARD W. SCH	IULE
11	Deposition of RICHARDW. SCHULE, taken as if upon	11 BY MR. LINTON:	
12	cross-examination before Laura L. Ware, a Notary	12 Q. Mr. Schule, my name is Bob Linton, and I'm one	of
13	Public within and for the State of Ohio, at The	13 the lawyers that represents Mary Lou Zimmerman	n and
14	Cleveland Clinic Foundation, 9500 Euclid Avenue,	14 her husband, Sherman Zimmerman. We met duri	ng the
15	PACU Classroom, Building H, 3rd Floor, Cleveland,	15 inspection you provided several weeks ago down	in
16	Ohio, at 9:00 a.m . on Wednesday, March 14, 2001,	16 the SPD department.	
17	pursuant to notice and/or stipulations of counsel,	17 A Yes.	
18	on behalf of the Plaintiffs in this cause.	18 Q. I'm here today to take your deposition. Have you	u
19		19 ever been deposed before?	
20		20 A. No, I haven't.	
_0 21		21 Q. Have you ever been through this process?	
22	WARE REPORTING SERVICE 21860 CROSSBEAM LANE ROCKY RIVER, OH 44116 (216) 533-7606 FAX (440) 333-0745	22 A. No, I haven't.	
23	ROCKY RIVER, OH 44116 (216) 533-7606 FAX (440) 333-0745	23 Q. Lassume you had a chance to meet with Mr. Mal	one
23 24	(210) 333 7368 776 (440) 333 6743	24 today before preparing for your deposition?	one
24 25		25 A Yes, sir.	
2.5		23 A 163, SIL	
))	
1	2 APPEARANCES:	4 1 Q. It's important, as I'm sure you've been told, that	
2		2 you understand all the questions that I ask you, and	nd
3	Robert F. Linton, Jr., Esq. Linton & Hirshman Hovt Block Building - Swite 300	3 if you don't understand a question please stop me	
4	Hovi Biock Building - Swite 300 700 West St. Clair Avenue Cleveland, Ohio 44113 (216) 771-5800,	4 and I'll rephrase the question, do whatever I need	
5	(216) 771-5800,	5 to to make sure that you understand what I'm	
6	On behalf of the Plaintiffs;	6 asking. Okay?	
7	James P. Malone, Esq.	7 A. Yes, sir.	
8	Reminger & Reminger 113 St. Clair Avenue Cleveland, Ohio 44114 (216) 687-1311,		
	(216) 687-1311,	8 Q. If you answer the question without asking for	
9 10	On behalf of the Defendant.	9 clarification, we're then going to assume that you	
10		10 understand the question. Is that fair?	
11		11 A. Yes, sir.	
12		12 Q. What have you done to prepare for your deposition	on
13		13 today?	
14	EXHIBIT INDEX	14 A. I had a meeting with Mr. Malone a week or so ago),
15	PAGE	15 and that's about it.	
16	Plaintiffs Schule Exhibit 1 3	16 Q. How long did that meeting last?	
17		17 A. Ibelieve	
18		18 MR. MALONE: Objection. Go ahead.	
19		19 A. I believe we	
20		20 MR. MALONE: Are you going to challenge	
21		21 my time entries and my bill in this; is that	
22		22 why we're going through this?	
23		23 MR. LINTON: Maybe.	
24		24 A. Between a half hour and an hour, I believe.	
25		25 Q. We've been handed what's been marked as Exhib	oit No.
24		24 A. Between a half hour and an hour, I believe.	Ł

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THE CLEVELAND CLINIC FOUNDATION

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- 1 **1. Is** that a copy of your current **CV?**
- 2 A. Yes.
- 3 Q Any additions, subtractions?
- 4 A. The only additions, that would be any additional
- 5 publications that I've had recently. There may be
- 6 one or two that are off there.
- 7 Q. One or two publications?
- a A. Yeah. I write for a hobby and I publish in some of
- 9 the professional articles as well as I speak.
- 10 Q. What additional publications are not listed on
- 11 here?
- 12 A. I'd have -- I don't recall. I'd have to look.
- 13 There's a couple of them that I've worked on, and I
- 14 don't know.
- 15 Q. As of what date was the CV current?
- 16 A. Well, it looks -- as of last year, it looks like I
- 17 have the '99, and then I have one article that was
- published in 2000, January, so it's about 12 monthsold.
- 20 Q. What was the topic of the new article?
- 21 A. Usually write about quality, dealing with
- 22 patient -- or not patient, OR reaction --
- 23 interaction with CS personnel. Kind of warm fuzzy
- 24 type stuff.
- 25 Q. You're talking in code here.

- 1 A. l'msorry.
- 2 Q. What are those --
- 3 A. Interpersonal communication skills between employees

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- 4 of various departments.
- 5 Q. How long have you been employed by The Cleveland
- 6 Clinic?
- 7 A Iwas -- I have been employed since September 2nd of
 1998, if I'm correct.
- 9 Q. And what was your position upon hire?
- 10 A. Position upon hire was as manager of the Surgical
- 11 Processing Department.
- 12 Q. Same position you presently hold?
- 13 A. Yes, sir.
- 14 Q. Had you held that same position with another
- 15 hospital?
- 16 A. Yes, titled differently but still the same
- 17 responsibilities.
- 18 Q. I don't know how you measure size in your business.
- 19 How do you measure size?
- 20 A. We base it on bed size, we also base it on surgical
- 21 procedure size.
- 22 Q. Using those standards, what was the bed size of
- 23 Akron General Medical Center?
- 24~ A ~ I believe Akron General is about a 520 bed hospital,
- 25 give or take a bed or two.

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	1	Q. And how about the Clinic?		
	2	A Ibelieve the Clinic is in the neighborhood of 900,		
	3	just under a thousand.		
	4	Q. And how about in terms of surgical procedures, Akron		
	5	General versus the Cleveland Clinic?		
-	6	A. Akron General does approximately 24,000 procedures a		
	7	year, and the Clinic is doing approximately 35,000.		
	8	Q. I would expect the numbers to be bigger.		
	9	MR. MALONE: Bigger than 35,0001		
	10	MR. LINTON: Well, relative to Akron		
	11	General I expected it to be a lot bigger.		
	12	MR. MALONE: Off the record.		
	13			
	14	(Thereupon, a discussion was had off		
	15	the record.)		
	16			
	17	Q. What do you do as manager of SPD?		
	18	A I have the responsibilities of budget, annual		
	19	budget, I have responsibilities of capital planning		
	20	and acquisition, I have the responsibilities of		
	21	foreseeing where our needs are into the future,		
	22	either doing a three-year plan or what have you.		

- 23 I oversee or am responsible for processing all
- the surgical instruments on campus, that includes
- α the training, the orientation and competency of the

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1	staff underneath me. I'm responsible for the
2	interaction and development of the various different
3	surgical services, and then I interact with the
4	management team assisting them in planning as far as
5	if they need more instrument trays, or \mathbb{I} can help
6	them become more efficient where they choose to use
7	me as a resource.
8	I have the responsibility of maintaining those
9	surgical instrument trays, make sure the scissors
10	are sharpened, etcetera, etcetera, and payroll, et
1	cetera. I mean, all the administrative stuff.
2	Q. How many surgical instruments do you process in your
3	department?
4	A. I couldn't give you a specific number at this time.
5	Q. Can you give me an estimate?
6	A. Estimate, I believe
7	MR. MALONE: You mean daily, weekly?
8	Q. However you can quantify it.
9	MR. MALONE: Do you understand,
20	Richard?
!I	THE WITNESS: I understand the
2	question.
'3	MR. MALONE: He's asking about
4	instruments. I think, not travs.

- 4 instruments, Ithink, not trays.
- '5 A. We're doing I want to say it's about three million

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- instruments a year. I mean, it's a very large 1
- 2 number.
- Q. And is there a difference between trays versus 3
- instruments? 4
- 5 A. There can be.
- Q. Let me back up to something earlier. Your CV shows 6
- that your employment began in October of '98. You 7
- 8 had said earlier it was September 2nd of '98. This
- 9 particular surgery involved in this case was on
- 10 September 22nd, 1998. Do you know for a fact if you
- 11 had come and were working as the manager of the SPD
- 12 department on that date?
- 13 A. I believe that might be incorrect, but I remember --
- I don't remember. I can find that information out 14
- specifically, but I'm pretty sure it was --15
- 16 Q. If you can just let Mr. Malone know that. That's
- important. 17
- MR. MALONE: We know the surgical date 18
- 19 he give us is correct. When you say incorrect
- 20 date, you're not sure about your hire date?
- THE WITNESS: Exactly. 21
- 22 MR. LINTON: His start date, whether
- 23 it's before or after.
- 24 A. We can find out.
- Q. Going back to 1998, how many employees did you 25

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- supervise? 1
- 2 A. In the neighborhood of 65.
- Q. And what levels of employees would you have 3
- supervised? 4
- 5 A. The various -- rephrase the question.
- Q. Sure. Tell me generically the positions of the 6
- 7 employees you would have supervised.
- 8 A. I have an education coordinator, I have a
- coordinator that runs the shift, and I have three 9
- shifts. I have lead techs in each of my SPD 10
- departments, and I have three of those in each 11
- 12 area. I have a Tech II, which is the surgical
- 13 processing technician, I have service assistants
- which help restock the rooms, and I believe that 14
- covers all the different titles. 15
- 16 Q. Are there three separate shift coordinators?
- 17 A. Yes, there are.

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- 18 Q. And you said there are three different departments 19 in SPD?
- 20 A Logistically, I have three SPD departments.
- 21 Q. And how do you break those down?
- 22 A They're broken down as the E building, the M
- 23 building and the G building.
- 24 MR. MALONE: Those are physically
- 25 different units, Bob, is what he's telling

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- you. There's three areas in the hospital where
- 2 processing is done.
- 3 Q. Do they do different types of processing in those
- 4 departments in each of those buildings?
- 5 A. The policies are universal, procedures are 6 universal.
- 7 Q. So for example, neurosurgical instruments could be
- processed in any of those three buildings? 8
- 9 A. Yes, sir.
- 10 Q. How is it decided where particular instruments are 1i processed?
- 12 A. Based on logistics of where the cases are taking
- place. We have a number of ORs in each of those 13
- 14 buildings, and to help prevent long runs of
- 15 equipment we kind of isolate in those areas.
- 16 Q. Based on what you know about this case, can you teil
- 17 us what building the instruments would have been
- 18 processed in?
- 19 A. The E building.
- 20 Q. How do you know that?
- 21 A. To the best of my recollection, the room that this
- 22 case occurred is located in the E building, and
- 23 therefore the instruments would have been processed
- 24 in the E building.
- 25 Q. What records, if any, would be kept as of this point

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- 1 relating to the surgical instruments that would have
- 2 been used during Mary Lou Zimmerman's surgery?
- 3 A. Specifically what are you --
- Q. Anything of any kind that would relate to sterile 4
- 5 processing of those surgical instruments.
- 6 A. Generally we have records of biologicals that are
- 7 performed on the sterilizers. We have records of
- 8 load configurations, and load configurations meaning
- 9 what was in that particular load for sterilization.
- 10 I believe that would cover your question.
- 11 Q. Are you required by any law or agency to maintain
- 12 those records?

on premise.

gas sterilizer?

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WARE REPORTING SERVICE

- 13 A. We have requirements by state, and then also I
- 14 believe there's some federal implications there.
- Q. And what type of records would be maintained 15
- 16 presently relating to biologicals?
- 17 A. Biologic --we have a record of the biologicals for
- 18 all our sterilizers, either steam or gas, which is
- 13 ethylene oxide. Ethylene oxide, by requirements, we
- 23 have to keep on board, and then the steam records we have to keep on board either stored off premise or

Q. How long do you maintain the biologicals from the

Page 9 to Page 12

A. Well, the biologicals themselves are not

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- maintained. The record?
- Q. The records. 2
- 3 A. The record results, how many years, about seven

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- 4 vears.
- 5 Q. And who is the record custodian of those records;
- who would you go to to ask to get copies of a record 6 7 from 1998?
- 8 A. I have to call a pager, and it's located in the
- 9 Sears Building at this present time.
- 10 Q. Who do you call?
- 11 A. Idon't recall his name. I believe his name is
- Rodney, or I'm sorry, Aaron. Aaron is the 12
- 13 supervisor, I believe.
- 14 Q. And what information would be contained on that
- 15 record?
- 16 A. It would ask for -- everything is boxed by month and
- year, so in this particular case I would ask for the 17
- sterilization records of September of 1998 for the E 18 19 buildina.
- 20 Q. And how would those be broken down then?
- 21 A. They're broken down in the sense that the steam
- records are bagged together, the ethylene oxide 22
- 23 records are bagged together.
- Q. And what EO records would be --what information 24
- 25 would be on the EO records?

14

- 1 A. Information on the EO records would identify load
- configuration or what items were in that particular 2
- 3 load, it would identify load parameters or
- sterilization parameters that took place for that 4
- specific load. 5
- Q. Meaning temperature, time? 6
- A. Correct. 7
- Q. Humidity? 8
- A. Correct. 9
- Q. Anything else? 10
- 11 A. EO exposure, staurolitic exposure.
- 12 Q. Exposure in terms of time or exposure in terms of
- percentage or concentration? 13
- 14 A. Exposure in time.
- 15 Q. So there would be load configuration showing the
- items that were sterilized, the sterilization 16
- 17 parameters. Anything else?
- 18 A. I believe that's it.
- 19 Q. And what would you call that, a biological record?
- 20 A. A biological record.
- 21 Q. So you'd have to call this number, talk to Aaron and
- 22 say I'd like the biological records for the E
- 23 building for September of 1998 in --
- 24 A. Biological records are kept in our computer system.
- 25 Q. Okay.

- 15 A. So specifically you asked what was in the box. The box would have the steam and the ethylene oxide load configuration records, and on it would have the parameters that it was exposed and the printout from the equipment. Biologicals are housed in a computer database. results of the biologicals are entered into the computer, and we maintain those computer records. We try to go paperless when we can. 10 Q. I may be slow here, so bear with me. The boxed records, what would you call those documents? You would call up and ask for --13 A. Sterilization records for September of 1998 for the E building. Q. And I assume those are broken down by day, are they? 17 A. Yeah. Well, they're just grouped together as steam records and the EO. They may be broken down by a specific sterilizer, bur if my memory serves me
- 20 right we usually just group them together, and then
- 21 it would be in chronological order starting with
- 22 September 1st through September 30th or 31st,
- 23 however many days September has.
- 24 Q. And are those sterilization records kept
- 25 contemporaneously? In other words, are they kept ---

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- 1 A. I'm not understanding.
- 2 Q. The record, the sterilization record, I assume those
- entries are made as the sterilization is occurring? 3
- 4
- 5 Q. And then eventually they go over to another building for storage? 6
- 7 A. Yes.
- а
- would apply to the instrumentation used during Mary 9
- 10 Lou Zimmerman's surgery?
- 11 A L cannot.
- Q. Is there some way to do that? 12
- 13 A. No.

14 MR. MALONE: Bob, that's the problem,

- 15 we don't know when -- I mean, you could get
- 16 September records. We don't know this thing
- 17 was even sterilized in September.
- 18 MR. LINTON: Well, that's what I was
- 19 going to ask. That's my next question.
- 20 MR. MALONE I don't think there's any
- 21 shelf life on sterilization.
- 22 Q. is there any shelf life on sterilized equipment?
- 23 A. Specify your date.
- 24 Q. Well, let's taik about back in 1998 for surgical
 - instruments that would have been used during Mary

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- A Correct.
- Q. How would you determine which sterilization record

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- 1 Lou Zimmerman's case.
- 2 A. I don't recall what the specific -- my recollection
- 3 is that when I came on board everything was event
- 4 related sterility. It was not time dated.
- 5 Q. Meaning what?
- 6 A. Okay, event related sterility, you have to have
- 7 various parameters in place in order to be
- 8 considered event related. And event related is
- 9 based on if you have your coffee mug there and it's
- 10 intact, it's complete, I would be looking for holes
- 11 in that coffee mug to see if we have potential
- 12 contamination, okay. There's various specs that are
- 13 looked at. Time related is based on **a** specific
- 14 period of time, either 30 days, 60 days, one year.
- 15 Q. Itake it now they're time related sterility?
- 16 A. No, we're event related. Time was the old, event
- 17 related is the present modern time.
- 18 Q.] see. When did it change?
- 19 A. Idon't know.
- 20 Q. What would you have to look at to see when it
- 21 changed?
- 22 A I don't know.
- 23 Q. How would you determine when that change occurred?
- 24 A. By asking questions.
- 25 Q. Of whom?

18

- 1 A. I could investigate.
- 2 Q. When you came on board, was it time related?
- 3 A. Yes.
- 4 Q. Did it remain time related through 1998?
- 5 A. Yes.
- 6 Q. So at the time of Mary Lou Zimmerman's surgery,
- 7 September 22nd, 1998, obviously the instruments had
- 8 to be processed before that day, well, at least
- 9 before the time of surgery?
- 10 A. Yes.
- 11 Q. And they would have been time related as of that12 point?
- 13 A. No, they would have been event related.
- 14 Q. I'm misunderstanding.
- 15 A. Okay. You had asked me if back in 1998 if we were
- time related or event related, and the best of my,
- 17 if I go back, remembering correctly, what I said was
- 18 to the best of my reelection we were on an event
- 19 related system. If I said that incorrectly, I
- 20 apologize.

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- 21 Q. Is it -- what is it now?
- 22 A. It's event related.
- 23 Q. When was it time related?
- 24 A. And I believe I said I don't know, it was before my
- time. I can't answer intelligently on that.

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- 1 Q. But in 1998 you think it was still time related?
- 2 A. No, event related.
- 3 Q. When you came on board it was event related?
- 4 MR. MALONE: You misspoke a minute
- 5 ago. You had me confused as well.
- 6 A. l apologize.
- 7 Q. Can we safely say that at the time these instruments
- 8 were sterilized that it would have been event
- 9 related?
- 10 A. To the best of my knowledge, yes.
- 11 Q. And what's, first of all, the specifications used to
- 12 decide when something should no longer be used
- 13 according to the event related criteria; is that
- 14 something that's in writing?
- 15 A. Yes.
- 16 Q. And what do you call those?
- 17 A. Recommended guidelines.
- 18 Q. Who publishes them?
- 19 A. There's a number of organizations.
- 20 Q. Who publishes the ones used here at The Cleveland
- 21 Clinic?
- 22 A. We utilize AAMI, A-A-M-I.
- 23 Q. Which stands for?
- 24 A. Ibelieve the Association for Advancement of Medical
- 25 Instrumentation.

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- 1 Q. And were those in use in 1998 when you came to the
- 2 Clinic?
- 3 A. I'm not sure.
- 4 Q. Do you have a memory of using any different
- 5 guidelines since you came to the Clinic?
- 6 A. Since I've been here, no.
- 7 Q. So to the best of your knowledge, the AAMI
- 8 recommended guidelines would have been in place when
- 9 you came to The Cleveland Clinic?
- 10 A. Again, if the previous monitor used them, I don't
- 11 know.
- 12 Q. I'mtalking about since you came here.
- 13 A. Since I've been here, I utilized AAMI.

Q. How about the current guidelines?

Q. Do you have a copy of those?

14 Q. Was that something you implemented or was it

Q. Who would you go to to get a copy of those?

15 existing when you came here?

A. 1998, I have not a clue.

Q. Do you have an office?

- 16 A. Idon't recall.
- 17 Q. Do you have a copy of these recommended guidelines?

Page 17 to Page 20

18 A. No, I do not.

A. Yes.

A. 2001.

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MARCH 14, 2001

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- 1 A. Yes. 2 Q. Where is your office located?
- 3 A. E building, basement, EB 76.
- Q. Any other written specification used to determine 4

21

- 5 event related criteria besides the AAMI guidelines
- used here at The Cleveland Clinic? 6
- 7 A. No.
- Q. What are the general criteria set forth for 8
- 9 determining whether something is no longer sterile
- 10 according to the event related criteria?
- 11 A. That criteria, you would look at a package, has the
- integrity been violated? And that integrity would 12
- be a hole, a tear in the wrapper. If the proper 13
- 14 banding is on the sterilizing containers, if that's
- the type of packaging that was used, are there any 15
- 16 water stains or dirt on the packaging, time and
- temperature of storage. I believe that covers them 17 18 all.
- 19 Q. And I assume that a human being is the person that
- 20 has to determine whether that criteria has been
- 21 met?
- 22 A. Yes. sir.
- 23 Q. What level employees make that determination?
- 24 A. I can only comment on my staff.
- 25 Q. Right. And understand, any of these questions

22

- relate to what you know since coming to The 1
- 2 Cleveland Clinic.
- 3 A. My staff is instructed or trained on proper storage
- 4 and what to be looking for when they pull --
- sterilize an item or when they set up a case cart to 5 6 go upstairs.
- Q. And what position employee is required to do that? 7
- 8 A. The Tech IIs and the S -- well, all of them actually
- 9 from the coordinators on down, but predominantly the
- 10 ones pulling the cases are doing the sterilization
- or the work. The working force are the Tech lls and 11
- the SAs and the Tech Is. 12
- 13 Q. I'm sorry, Tech IIs, Tech Is and S --
- 14 A. Service assistants or processing assistants.
- 15 Q. And in the hierarchy of things, who was the lowest
- 16 level employee in your department?
- 17 A. Service assistants.
- 18 Q. And then Tech IIs?
- 19 A. Yes.
- 20 Q. And then Tech is?
- 21 A. Yes.
- 22 Q. What is required to be an SA?
- 23 A. Be specific, rephrase your question.
- 24 Q. You're responsible for hiring SAs?
- 25 A. Yes.

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23

- 1 Q. What are the job responsibilities required to be an
 - SA in your department?
- A. Good communications, ability to read, the ability to 3
- follow direction. That's pretty much it. Δ
- 5 Q. Is a high school diploma required?
- A. No. 6
- 7 Q. Is a college diploma required?
- 8 A. No.
- 9 Q. Is prior experience in the field required?
- A. It is -- it would be nice, but, no. 10
- 2 Q. Do any of your SAs have college degrees?
- A. I couldn't answer that intelligently. I want to say
- 3 one of them does, but I'm not sure, to be honest
- |4 with you.

5

- 5 Q. How many SAs do you have?
- A. I believe I have seven. 6
- 7 Q. What does an SA do?
- 8 A. They're restocking the rooms, they're pulling for
- 10 cases, they're helping out in decontamination, running items to the room that are called for,
- 21 delivery, restocking of shelves.
- 2 MR. MALONE: Did you say what SA stands for?
 - MR. LINTON: Service assistant. THE WITNESS: Service assistant.
- 24 MR. MALONE: I missed that. 1 2 Q. And is a service assistant the one primarily 3 responsible for pulling the cases and restocking the 4 shelves? A. Rephrase primarily, what you're talking about. 5 Q. Well, are those responsibilities typically done by 6 7 SAs as opposed to the other --A. It's a task shared by all. 8 9 Q. In terms of the percentage of cases, are the 0 majority of the cases pulled by SAs as opposed to 1 other level employees? 2 A. I don't know. 3 Q. How many Tech lis do you have? 4 MR. MALONE: Again, these numbers are 5 all current as of today, not necessarily 6 September of '98, just so --7 MR. LINTON: I understand. 8 MR. MALONE: I mean, I'm not objecting, q Bob. I just don't want it to be confusing later on. This may be bigger now than I 0 1 suspect it was in '98. A. The majority of the work force is Tech IIs. 2 3 Specific numbers, I want to say 45, give or take, 4 maybe a little less. I'm not sure. Q. And an estimated range is fine. Going back to 1998 5

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- 1 when you started, was the majority of the work force
- 2 likewise Tech IIs?
- 3 A. Yes, sir.
- 4 Q. In terms of a range of numbers, would it have been approximately the same range?
- 6 A. A little less.
- 7 Q. A little less?
- 8 A. Approximate. It may have been in the high 30s, give
- 9 or take.
- 10 Q. Fair enough. And in terms of requirements, is a
- 11 college diploma required to be a Tech II?
- 12 **A.** No.
- 13 Q. Is a high school diploma required?
- 14 **A.** No.
- 15 Q. Is prior field experience required?
- 16 A. It is asked, but no.
- 17 Q. What are the duties of a Tech II in your
- 18 department?
- 19 A. Tech II is responsible for everything identified as
- 20 the SAs, and they're also responsible for steam and
- 21 gas, they do more intensive instrument assembly. I
- 22 believe that's it.
- 23 Q. The event related criteria, if I'm phrasing this
- 24 incorrectly help me out here, but the way it's set
- 25 up right now is the items basically stay in

26

1 inventory unless they are determined to no longer

- 2 meet the criteria?
- 3 A. Correct.
- 4 Q. All right. What do you call that criteria? Just so
- 5 you and I are on the same wavelength so we know what
- 6 we're talking about.
- 7 A. The criteria would be sterilization.
- 8 Q. Okay. So they remain in inventory until they no
- 9 longer meet the sterilization criteria as determined
- 10 by the guidelines?
- 11 A Correct.
- 12 Q. And the person determining whether or not they still
- 13 meet those sterilization criteria for the most part
- 14 are the **SAs** and the Tech **IIs**?
- 15 A. And the Tech is.
- 16 Q. And the Tech is. What does a Tech I do?
- 17 A. Tech **l is** the lead tech of the area. They're the
- 18 ones that help coordinate work flow, they motivate,
- 19 they're the catalyst of the work force.
- 20 Q. Give me an approximate number of instruments that
- would be processed in your department on a givenday.
- 23 A. In a given day, anywhere from five to a thousand.
- 24 Q. Five hundred?
- 25 A. Five hundred to a thousand.

	27

- 1 Q. Five hundred to a thousand. You're not suggesting
- 2 that the lead tech goes through all the inventory
- 3 and makes sure that every sterilized package meets
- 4 the sterilization criteria?
- 5 A. No.
- 6 Q. Most of that work on a day-to-day basis would be
- 7 done by a Tech II or by an SA?
- 8 A. That's the responsibilities of everybody.
- 9 Q. And I appreciate that. We all wear many hats, but
- 10 in terms of the number of packages that are checked
- on a given day, most of the time it's going to be an
- 12 SA or a Tech II that will be pulling the package to
- 13 see if it meets the sterilization criteria?
- 14 A. Probably so.
- 15 Q. I mean, there's not a Tech I supervisor looking over
- the shoulder, literally, of a Tech II or an **SA** every
- 17 time a package is pulled off the shelf to see if it
- 18 meets the sterilization criteria?
- 19 A. No.
- 20 Q. You have to delegate those responsibilities to
- 21 someone who's properly trained?
- 22 A. Correct.
- 23 Q. And you have to rely on the Tech lis and the SAs to
- 24 do their job as properly trained?
- 25 A. Correct.

28

1 Q. And we can agree that we've got human beings working 2 for you and human beings sometimes make mistakes? 3 A. Yes. 4 Q. And it's the responsibility of the supervisor to 5 monitor to see if those mistakes are being made? A. Yes. 6 Q. And if mistakes are being made to take the 7 appropriate disciplinary action and correct those 8 9 mistakes, true? 10 A. Yes. 11 Q. Since coming to The Cleveland Clinic have you had to 12 discharge any of the employees in your SPD 13 department? 14 MR. MALONE: Well, show an objection. 15 I mean, give us a little narrower parameters. 16 For what reason? 17 MR. LINTON: Any reason. 18 MR. MALONE: Well, I'm going to 19 object. Don't answer that because if we have 20 people fired for off campus improper conduct or things of that sort, that's not proper. If you 21 22 want to know if he's had to discipline people 23 - I think this whole area is objectionable. 24 I mean, you're talking about one of the biggest 25 SPDs in the world, and do people from time to

RICNARD W. SCNULE

5

THE CLEVELAND CLINIC FOUNDATION

	29
1	time have to be disciplined or terminated, I
2	think the answer to that is yes, but the
3	specifics
4	Q. Let's talk about terminated. How many people have
5	you had to fire or have been fired since you came on
6	board?
7	MR. MALONE: I'm sorry, I'm going to
8	object and instruct him not to answer that. If
9	I get ordered by the Judge to answer this, I'll
10	really be surprised. I think we're way, way
11	off into a fishing area.
12	Q. You're not going to say how many people have been
13	fired?
14	MR. MALONE: He's not going to answer
15	that question under instruction of counsel.
16	MR. LINTON: And you're not going to
17	allow me to get into this area of inquiry?
18	MR. MALONE: No, it has nothing to do
19	with this case. It's all after the fact. We
20	don't even know for sure he was there in '98.
21	Q. Well, you were here in '98.
22	MR. MALONE: Well, you asked about
23	specifically September 22, and he says he
24	thinks he was here in September of '98 and he's
25	going to re-check the hire date.

30

Q. And I assume, Mr. Schule, when you came in you 1 2 wanted to make sure this department was running the way you wanted to have it run with the best possible 3 4 people doing the best possible work, correct? 5 A. Yes. 6 Q. It's kind of like Butch Davis stepping in with the Cleveland Browns, I mean, there's certain personnel 7 you want to keep and there may be certain personnel 8 you want to release, certain people you want to 9 hire? 10 11 MR. MALONE: Objection. This is not a 12 professional football franchise. We're not 13 going to respond. Come on, Robert. 14 Q. You're not going to answer that? 15 MR. MALONE: No, we're not going to 16 compare the SPD of The Cleveland Clinic to a professional football team in the NFL. 17 18 Q. Have you had to fire --strike that. 19 MR. LINTON: We'll get a Court order 20 and come back. 21 Q. When a person is discharged, is that a decision that you make, or is that a decision made by somebody 22 23 else in your department? MR. MALONE: Objection. Go ahead. 24

25 A. That is a decision that is initiated by me and that

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- 1 is critiqued or reviewed by Human Resources.
- 2 Q. Who in Human Resources would have to --
- 3 A. I don't know.
- 4 Q. Who had your position before you came to The
 - Cleveland Clinic?
- 6 A. Rephrase the question.
- 7 Q. Who was the manager of Surgical Processing before
- 8 you came to the Clinic?
- 9 A. There was an acting manager.
- 10 Q. Who was the acting manager?
- 11 A. Penny Sonters.
- 12 Q. l'msorry?
- 13 A. Penny, as in the penny, and then Sonters,
- 14 S-O-N-T-E-R-S.
- 15 Q. Is she still at the Clinic?
- 16 A. Yes, she is.
- 17 Q. What does she do now?
- 18 A. She's a scrub nurse.
- 19 **Q**. l'msorry?
- 20 A. She's a surgical scrub nurse in the OR.
- 21 Q. She's no longer in your department?
- 22 A. Correct.
- 3 Q. How long had she been acting manager?
- 4 A. Idon't know.
- 5 Q. When was the last time there was a formal manager of

32

- 1 the SPD department before you came on board?
- 2 A. Specific date, I don't know.
- 3 Q. Was it in 19981
- 4 A. Idon'tknow.
- 5 Q. Was there an assistant manager?
- 6 A. We don't have an assistant manager in the
- 7 department.
- 8 Q. To whom do you report?
- 9 A I report directly to the OR director of surgical
- 10 services.
- 11 Q. Who is that?
- 12 A. Specifically specify a time.
- 13 Q. How about when you came on board in '98?
- 14 A. Lois Bach.
- 15 Q. Is she still here? I'm sorry, did you say Louis?
- 16 A. Lois, L-O-I-S.
- 17 Q. Is she still here?
- 18 A. She's here at The Cleveland Clinic.
- 19 Q. What is she doing now?
- 20 A. She's a Director of Nurse Recruitment and Retention
- in Human Resources.
- 22 Q. And who is the current OR director?
- 23 A. Currently, we do not have one, we have an acting
- 24 director.
- 25 Q. Who is that?

MARCH 14, 2001

RICHARD W. SCHULE

MARYLOU ZIMMERMAN, et al. vs.

THE CLEVELAND CLINIC FOUNDATION

- 1 A. Betty Bush.
- 2 Q. In your experience, is the time --excuse me. Is

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- 3 the event related criteria for determining
- 4 sterilization a better technique than a time related
- 5 sterilization?
- 6 A. Yes.
- 7 Q. Why is that?
- 8 A. It is better in the realm that it focuses
- 9 individuals on the aspect of the parameters of
- 10 sterilization and not just a keypunch function.
- 11 With time sterilization, you just automatically pull
- 12 something off the shelf after 30 days, or whatever
- 13 the time specific period **is**, and without thinking of
- 14 what those parameters are. With event related
- 15 you've raised the level of quality.
- 16 Q. Because, what do you call them, loads, packages,
- 17 what are they?
- 18 A. You can say packages.
- 19 Q. Sterilized packages. They're sterilized packages of
- 20 surgical instruments, correct?
- 21 A. Correct.
- 22 $\,$ Q. There may be packages that $no\ longer\ meet$ the
- 23 sterilization criteria even though they would still
- 24 meet the time criteria?
- 25 A. Correct.

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- 1 Q. Likewise, there may be packages that are beyond the
- 2 time criteria but still meet the event criteria?
- 3 A. No, because with event related you have no time
- 4 criteria, **so** time criteria is not an issue.
- 5 Q. Right. The time criteria, when that was used, was
- 6 that according to published guidelines?
- 7 A. Yes.
- 8 Q. Who publishes guidelines on time criteria?
- 9 A. It would have -- AAMI would have had a partake in
- 10 that, various professional organizations, AORN,
- 11 which is the surgical nurse organization.
- 12 Q. For example, can you think of a time criteria that
- 13 would apply for neurosurgical instruments?
- 14 A. No.
- 15 Q. If it, let's say, was 90 days under the time
- 16 criteria, under the event criteria there might be a
- 17 package of neurosurgical instruments that is on the
- 18 shelf for six months but still meets the
- 19 sterilization criteria?
- 20 A. Yes.
- 21 Q. Do you follow me?
- 22 A. Yes.

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- 23 $\,$ Q. Is it more cost effective to go with event criteria
- 24 as opposed to time criteria?
- 25 MR. MALONE: Objection. Go ahead.

- 35
- 1 A. Yes, there is an economical cost value.
- 2 Q. Okay. And how do you determine that it is more cost
- 3 effective to do event criteria as opposed to time
- 4 criteria?
- 5 A. There's two issues, you're looking at labor to
- 6 reprocess the items, you're looking at consumables
- 7 that are used to reprocess the items.
- 8~ Q. But how are you able to know that the event criteria
- 9 is more cost effective than a time criteria?
- 10 A. I can't answer that question.
- 11 Q. You just know? I mean, you do budgets, you've got
- 12 to do projections, you've got to do costs.
- 13 A. But there's a lot of things in consideration to
- 14 that. To identify it solely to event related is, to
- 15 my understanding, is not captioned because in that
- same period of time you can have increase in volume,
- 17 **so** you're not getting a true reflection. The fact
- 18 that you're able to utilize your staff more
- 19 efficiently instead of just arbitrarily going and
- 20 pulling dated items off the shelf has increased
- 21 quality. We're not wasting our time pulling a time
- 22 event -- not time, a time sequenced item off the
- 23 shelf anymore.
- 24 Q. Is anything done to -- back up. Tell me how it
- 25 works. You've got a package on the shelf --
- 1 A. Uh-huh.
- 2 Q. -- that an SA or a Tech II determines no longer
 - meets the sterilization criteria?
- 4 A. Right.
- 5 Q. First of all, is there any record of that, that it
- 6 no longer meets the criteria?
- 7 A. No.

3

8 Q. What is the employee supposed to do once he decides

36

- 9 does it meet the criteria?
- 10 A. Does or does not?
- 11 Q. Does not.
- 12 A. The item is removed from the shelf, it's broken
- 13 down, repackaged, reassembled, and put back into
- 14 sterilization.
- 15 Q. Reprocessed?
- 16 A. Correct.

that.

17 Q. There is nothing done to determine whether or not it

Q. So if the employee suspects that --well, strike

your knowledge, that have talked about the

Are there any studies that have been done, to

effectiveness, either a quality standpoint or a cost

standpoint, between the event criteria and the time

Page 33 to Page 36

- 18 is, in fact, no longer sterile?
- 19 A. No.

20

21

22

23

24

25

THE CLEVELAND CLINIC FOUNDATION

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1	criteria?
2	A. There are. I cannot recall specifics, but that
3	research is available to anybody.
4	Q. Who would publish that information?
5	A. Any of the professional organizations.
6	Q. Such as?
7	A. AAMI, AORN, IAHCSMM, ASHCSP.
8	Q. Are those reliable organizations in your field?
9	A. They're looked upon highly looked upon.
10	Q. And do you look upon them as well respected
11	authorities in your field?
12	A. Yes.
13	Q. What is your current budget?
14	MR. MALONE: Objection. You know, Bob,
15	I think that might be proprietary to the
16	institution. I'm not going to let him answer
17	that. I mean, I've got <i>to</i> clear that with
18	other people. I personally don't have a
19	problem, but i think that may be their
20	proprietary business.
21	MR. LINTON: So you can provide that to
22	me later on after checking if you
23	MR. MALONE: I don't know if I will or
24	if I can, but really, quite frankly, for the
25	current budget, I mean, I can't imagine what

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	38
1	possible relevance that can have to 1998 in
2	September, but be that as it may, Ithink it
3	may well be a proprietary item of how they do
4	business.
5	Q. How about the budget in 1998?
6	A. Ican't recall because I didn't develop it.
7	Q. What items would be included on the budget?
8	Obviously you've got labor costs.
9	MR. MALONE: Today, you're talking
10	about?
11	MR. LINTON: I'mtalking about 1998.
12	MR. MALONE: He didn't do the budget in
13	'98.
14	MR. LINTON: I understand, but a budget
15	is a budget. Any time something new has been
16	added to it in terms of generic categories, a
17	budget, you have certain costs that are
18	generated.
19	MR. MALONE: I'm going to show an
20	Objection. I don't think a budget is a
21	budget.
22	MR. LINTON: What is
23	MR. MALONE: Please let me finish my
24	statement, Robert. I may or may not let him
25	answer it, but I disagree that a budget is a

		39
	1	budget. I have not permitted this witness to
	2	testify to budgeting at The Cleveland Clinic
	3	Foundation. I'm not going to let him testify
	4	as to the budgeting at the Cleveland Clinic
	5	Foundation, and I'm not going to let him
	6	testify to the components that go into the
	7	analysis.
	8	MR. LINTON: We'll take that up with
	9	the Court then.
	10	MR. MALONE: That's fine.
	11	Q . What is the rate of pay for an SA?
	12	MR. MALONE: Again, that's a question
	13	about current, 199 or 2001?
	14	MR. LINTON: We'll start there.
	∜5	MR. MALONE: Geez, my God. All right,
	16	go ahead, Richard, if you know.
	117	A. For an SA?
	18	Q. Yes, sir.
	19	A. To the best of my recollection, I believe they start
	20	in the range of 7.85.
	21	Q. And I assume they were not making any more than that
	22	back in 1998; is that fair?
Ì	23	A. I couldn't give you an educated guess
	24	Q. Could not?
	25	A or answer. I mean I would say they wouldn't be

25 A. -- or answer. I mean, I would say they wouldn't be

40

	1	making any more than that.
	2	MR. MALONE: 1'11 object to this on the
	3	grounds of relevancy, but I'm going to let him
	4	answer.
	5	Q. And how about a Tech II employee, what is the Tech
	6	Il employee's current rate of pay?
	7	A. I believe they're starting out at 9.25.
	8	Q. And likewise, would it be fair to say they were not
	9	making any more than that back in 1998?
	10	A. Assumption, probably so.
	11	Q. And how about a Tech I?
	12	A. That one I'm not specific on.
	13	Q. You have no idea?
	14	A. I can be specific that it's more than the Tech II.
	15	Q. Can you give me a range?
	16	A. Maybeeleven.
	17	Q. In the neighborhood of eleven dollars an hour?
	18	A. Right.
	19	Q. Are there written job descriptions for Tech Is, Tech
	20	lls, SAs?
	21	A. Yes.
6	22	Q. Do you generate those, or are those generated by
	23	somebody else?
	24	A. I yes, with the work with HR.
	25	Q. You generate them with the input of HR?
_ 1		

1 A. Yes.

- Q. Let's go back to 1998, and the reason why lask 2
- about what's going on today is because obviously you 3

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- know what's happening today, you might not have as 4
- 5 clear a recollection of what happened back in 1998,
- but if you're like most of us you can say, well, I'm 6
- 7 doing what I'm doing today and I've always been
- doing it or at some point I made a change. Do you 8
- follow me? 9
- 10 A. Yes, sir.
- Q. So that's why I'm asking about today, and then I go 11
- 12 back to 1998, but I'm interested in what happened in
- 1998 as best you knew it when you came and joined in 13
- 14 the fall of 1998. Okay?
- 15 A. Yes.
- 16 Q. First of all, in the, let's say, the fall of 1998,
- 17 when you came on board, did you make any changes
- with the way in which neurosurgical instruments were 18
- 19 being processed?
- A. Not that I recall. 20
- 21 Q. If you did make a change, would there be a record of
- that someplace? 22
- 23 A. Yes.
- Q. And where would there be a record? 24
- A. It would be department policies. 25

42

- Q. And are you responsible for maintaining department 1
- 2 policies?
- 3 A. Yes.
- 4 Q. Do you keep a copy of that in your office?
- A. No, we keep a copy in our classroom. 5
- Q. In your classroom? 6
- A. I have a copy of it, but the masters are kept in the 7
- classroom. 8
- q Q. And what classroom is that?
- A. EB 80. 10
- Q. So if there was a revision to that policy, it would 11
- obviously say in the policy the date in which it was 12
- revised? 13
- 14 A. Correct.
- 15 Q. Walk me through the process of sterilizing
- 16 neurosurgical instruments, gas sterilization, like
- 17 the kind of instruments that would have been used in
- 18 Mary Lou Zimmerman's case.
- 19 A Rephrase and specifically ask what you're asking.
- 20 Q. You had previously given us a tour of your
- 21 department?
- 22 A. Correct.
- Q. Unfortunately, I didn't take that down, so now I 23
- 24 need to get in words what it is that we saw during
- 25 that inspection, so can you just generically walk

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- through what would be involved in gas sterilizing 1 2 neurosurgical instruments like the kind used in Mary 3 Lou Zimmerman's surgery? 4 MR. MALONE: Those that are appropriate 5 for gas sterilization versus those that are 6 not? 7 MR. LINTON: I want to focus just on 8 gas sterilization. 9 A. Okay. As from the tour, we started out in the 10 decontamination area. I explained to you in the 11 tour that the instruments were scanned into 12 decontam., and at the time in 1998 when I came on 13 board I cannot recall what instrument trays were 14 actually trackable. The system was new and I was 15 brought on board to try and raise -- you know, to do 16 some things with that system. So when I talk it's 17 in generic terms as far as what it could do, the 18 functions of that system in 1998. 19 Instruments are scanned into decontam., the 20 technicians then wash the instruments, either a 21 manual or an automated method. Once the instruments 22 are cleaned, they're delivered into the --- they're 23 received into the package and assembly area. In the 24 package and assembly area the instruments are
- 25 scanned once again and count sheets are developed,

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	••
·1	as I showed, as well as the stickers or the labels
2	that go ${ m on}$ the outside of the package. Trays are
З	assembled by the technician, they're wrapped or
4	cased, placed in the sterilization area specifically
5	for the EO that you asked for, then the items added
6	to our load configuration list would be gone.
7	In other words, we would open up a load on the
8	computer, we would scan those items to the load, the
\$	specific process would be identified with EO, items
18	would be sterilized. Upon completion they would be
11	pulled, scanned again to the shelf or delivered
12	upstairs to the using service, because we do not
13	maintain all the instruments downstairs, and then
14	the case cart pulled and items, you know, used from
15	there.
16	Q. What do you call the area of your department where
17	the sterilized packages are kept in inventory?
18	A. Sterile storage.
1\$3	Q. Have you
20	A. Or I should say clean storage. I mean, to say a
21	sterile item, it's not it's clean storage.
22	Q. It's a clean storage of sterile items?
23	A. Yeah. I don't want to misuse that term.
24	Q. Well, what does sterile mean to you?
25	A. Sterile to the industry identifies a specific number

25 A. Sterile to the industry identifies a specific number

WARE REPORTING SERVICE

MARY LOU ZIMMERMAN, et al. vs.

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- 1 of organisms that are removed from an item. The
- 2 industry standard uses what they call 10 to the
- 3 negative 6th relative assurance in the removal or
- 4 the killing of those organisms.
- 5 Q. Where is this industry standard published?

6 A. I'll see it in AAMI, IAHCSMM, ASHCSP, AORN. It's a

- 7 recognized industry standard.
- 8 Q. And what does that mean, what does that criteria, I
 9 mean--
- 10 A. To the best of my recollection, without actually a
- 11 written document out of a text, if you were to take,
- 12 say, a million microorganisms and then after that
- 13 first minute that million drops down to 100,000, and
- 14 then after the next minute it drops down to 10,000,
- 15 it's an exponential number that occurs over time.
- 16 Q. And what, ultimately, is the percentage of organisms17 left?
- 18 A. Well, 10 to the negative 6th. You have to -- I
- 19 mean, in my opinion, my professional opinion, it's
- 20 undetermined. You don't know what you started out
- 21 with.
- $\ensuremath{\text{22}}$ $\ensuremath{\mbox{ Q}}$. Have you made any changes to the clean storage area
- 23 since you took over the department?
- 24 MR. MALONE: Objection. Go ahead.
- 25 A. Rephrase the question.

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- 1 Q. Sure.
- 2 A. Specific --
- 3 Q. The clean storage department is an area in which
- 4 there are shelves holding sterilized equipment --
- 5 A. Uh-huh.
- 6 Q. -- and instruments, correct?
- 7 A. Yes

10

- 8 Q. Have you made any changes to that since you took
- 9 over the department?
 - MR. MALONE: Same objection.
- 11 A. What you saw on the tour is, the best of my
- 12 knowledge, the same that it was in 1998 with the
- 13 exception that we may have added additional storage
- 14 areas because our volumes have increased, and
- 15 therefore capacity, we need to maintain proper
- 16 storage. So other than expansion, the answer would
- 17 be, no, to the best of my recall.
- 18 Q. And do you store those items by service?
- 19 A. Instrumentation we store by service, consumable
- 20 supplies are a generic pull **so** they're grouped.
- 21 Q. But the sterilized instruments that would be used in
- 22 a neurosurgical procedure are all housed on the same
- 23 shelves?

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- 24 A. No.
- 25 Q. Okay. Why is that incorrect? How is it incorrect?

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- 1 A. It's incorrect because we have multiple carts and
- 2 not all the neurosurgical instruments are stored in
- 3 my department.
- 4 Q. You have multiple, what did you say, carts?
- 5 A. We have multiple carts of neurosurgery instruments.
- 6 The premise is it's stored in the same location that
- 7 you saw, but that's not the only storage area.
- 8 Q. Is that the only storage area for instruments
- 9 processed in your department?
- 10 A. No.
- 11 Q. Okay.
- I2 MR. MALONE: Bob, when you were in the
- 3 OR, there were racks outside of the OR, you saw
- all this stuff, where instruments are kept as
- 15 well and carts are kept on the floor of the
- 6 operating room. They're moved out of his
- 17 department. I mean, they're kept ---
- 8 MR. LINTON: I got you.
- 9 Q. Because there are some items that are stored or
- 20 warehoused in the clean storage department in SPD,
- 21 others that go outside the OR; is that what you're
- 2 saying?
- 3 A. Correct.
- 24 Q. Is there any way to determine in this case where
- 35 Mary Lou Zimmerman's instruments would have been

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- 1 stored before they were used in surgery?
- 2 A. No.
- 3 Q. You're familiar with the kind of instruments that
- 4 were used during her procedure, you've now become
- 5 aware of it, I assume?
- 6 A. Yes, sir.

8

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2

'4

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WARE REPORTING SERVICE

- 7 Q. Would those type of instruments -- could those type
 - of instruments be stored in clean storage in your
- 9 department?
- 0 A. I cannot answer that at this time because I don't
- 1 remember in 1998.
 - MR. MALONE: No, he's asking if they
- *3* could be stored.

clean storage?

- 4 Q. If they could.
 - MR. MALONE: We don't know if they
- 6 were, we don't know where they were, but the
- 7 question is could it have been kept in clean

1 A. Theywould have to have gone up to the OR.

Q. They would have been put on the cart?

8 storage.

'3 A. It's possible.

to be stored?

9~ Q. Is there any reason they could not have been in

Q. How is it to be determined where the instruments are

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1

MARYLOU ZIMMERMAN, et al. vs.

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- 1 A. Nurse manager.
- 2 Q. How does --
- 3 A. They dictate to me if they choose that they want the
- 4 items closer at hand or they can logistically handle
- 5 them having them downstairs.
- 6 Q. They're not in both locations?
- 7 A. The same type of instrument?
- 8 Q. Yes.
- 9 A. No. For efficiency purposes, no.
- 10 Q. Currently they're stored outside the OR?
- 11 A. I cannot answer that because I'm not in control of
- 12 what's stored upstairs.
- 13 Q. Well, don't you know what's stored in your clean
- 14 storage versus what goes up to the floor?
- 15 A. \perp know what 1'm responsible for upstairs. See, once
- 16 an item is done and I have successfully sterilized
- 17 that item, I either store it on my shelves or it's
- 18 scanned out to the service that it belongs. Once it
- 19 leaves my department, I'm no longer responsible for
- 20 it.
- 21 Q. And how is it determined if a package of
- 22 neurosurgical instruments is going to go on your
- 23 shelf or going to go up to the OR; is there a record
- 24 kept of that?
- 25 A. No. It's collaboration with the nurse manager in

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1 the sense of how they want to dictate that they want

- 2 their items stored.
- 3 Q. Okay. Assuming that it is placed in storage in your
- 4 department, is there then a shelf for neurosurgical
- 5 instruments?
- 6 A. Yes.
- 7 Q. And is there a shelf for other type of surgical
- 8 instruments?
- 9 A. Yes.
- 10 Q. Explain to me how that is broken down. If we
- 11 start -- if we're looking at the shelves, we've got
- 12 a neurosurgical shelf of instruments?
- 13 A. Yes.
- 14 Q. And what is beside that, what's --
- 15 A. I don't recall.
- 16 MR. MALONE: It's in the video. Didn't
- 17 you look at the video yet; haven't you got it
- 18 yet?
- 19 MR. LINTON: Yes.
- 20 MR. MALONE: I mean, it's in there.
- 21 They say neurosurgery, vascular, or whatever
- 22 the services are.
- 23 Q. And to the best of your knowledge -- strike that.
- 24 MR. MALONE: Sort of like a grocery
- 25 store.

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- MR. LINTON: Right.
- 2 Q. Does your SPD department run three shifts a day?

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- 3 A. Yes.
- 4 Q. Seven days a week?
- 5 A. No.
- 6 Q. How many days a week?
- 7 A. Monday through Friday three shifts, and then on the
- 8 weekends we have 12-hour shifts.
- 9 Q. Any days off, on the holidays?
- 10 A. Yes.
- 11 Q. I mean, are you ever closed in your department?
- 12 A. Never closed.
- 13 Q. The gas sterilizers that we saw during our
- 14 inspection, have those gas sterilizers been in place
- 15 since you joined the department?
- 16 A. To the best of my knowledge, yes.
- 17 Q. And as I understand it, there are four gas
- 18 sterilizers, two large ones and two small ones?
- 19 A. Yes.
- 20 Q. Which sterilizer would have been used for --
- 21 understanding you were not here most likely when
- 22 Mary Lou Zimmerman's were sterilized, but if you
- 23 were to sterilize those type of instruments the day
- 24 you started, which gas sterilizer would or could
- 25 have been used to sterilize those?
- 1 A. Don't know.
- 2 Q. Why is that, they could be any of the four?
- 3 A. No, there's no way of identifying what instruments

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- 4 were used on the case. You can give me an
- 5 identification of a tray of instruments, but you
- 6 have to understand the volume that I have here I
- 7 cannot specifically tell you which tray it was that
- 8 was used, **so** therefore I can't tell you which
- 9 sterilizer was used.
- 10 Q. When you say a tray of instruments, what do you 11 mean?
- A. Well, identify an instrument that was used on her
 case.
- 14 Q. Okay. Do you know what instruments were used in her15 case?
- 16 A. I have a vague idea. Specifically, I don't know all

Q. Well, let me show you a couple of them and we'll

start from there. I'mgoing to show you what has

that that was the tray that was set up the morning

been identified as photo number 9 of 50 and tell you

of our inspection to show the instruments that would

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- 17 of them.
- 18 Q. You don't know all of them?
- 19 A. I haven't been asked specifically to look at
- 20 anything.

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- 1 have been used during Mary Lou Zimmerman's case.
 - MR. MALONE: I'm sorry, showing
- 3 exemplars of the instruments used. We do not
- 4 know whether they were the instruments used in 5 her case.
- Q. Do you recognize any of those instruments? 6
- 7 A. Yes. I do.

2

- 8 Q. What instruments do you recognize?
- A. I recognize the wand in the back middle of the 9
- table. I recognize it looks to be a ruler or 10
- 11 measuring device, drills, needle drivers, hemostats,
- 12 basins, Bovie, a retractor arm.
- Q. First of all, showing you what has been marked as 13
- 14 photo number 27 of 50, do you recognize that as a
- 15 stereotactic wand?
- 16 A. I understand it as a wand. Specific name of it, I'm not sure. 17
- 18 Q. And Exhibit 28 of 50, does that show an exemplar
- 19 wand in its sterilized package?
- A. That could be one of the packages. 20
- 21 Q. Are you able to determine in which of the four gas
- 22 sterilizers -- strike that.
- 23 First of all, is this gas sterilized, the wand,
- or is this steam sterilized? 24
- 25 A. Without identifying the manufacturer's instructions,

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- 1 I couldn't honestly tell you.
- Q. How would you determine that? 2
- A. By referring to the manufacturer's instructions. 3
- Q. And where would you find that? 4
- A. A phone call to the manufacturer, or if it's on --5
- 6 if the nurse manager has it.
- Q. Well, how do you or how does your department know 7
- 8 how to sterilize a wand like that?
- 9 A. By contacting the manufacturer and referring to
- 10 their instructions.
- 11 Q. And you don't keep a copy of those instructions any 12 place in your department?
- 13 A. Notthat I recall. Some items we do, not all.
- Q. Well, I'm confused. These wands are reusable and 14
- 15 sterilized by your department, correct?
- 16 A. Correct.
- Q. How do you know how to sterilize them if you don't 17
- know what the manufacturer requires? 18
- 19 A. That was done before I got here in '98, so I don't
- 20 know what system they used before I got here.
- 21 Q. What system have you used since '98?
- 22 A. We've changed wands, if I'm correct. I believe they
- 23 also have -- the manufacturer has tried to get
- 24 friendlier and I believe they have a wand that
- 25 they're able to steam sterilize now.

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- 1 Q. Steam sterilization is less expensive than gas
- 2 sterilization? 3 A. Yes. sir.
- Q. What does it cost to sterilize a load of gas 4
- 5 sterilization in a small load?
- 6 A. You'd have to be specific on the process. The
- 7 process -- the equipment that you saw during the
- 8 tour, we have two different types, small autoclaves
- 9 were a hundred percent cartridge, the larger were a
- 10 mixture.
- 11 Typically your mixture, larger autoclayes are a
- 12 lot more expensive than a smaller one. The
- 13 cartridges run about eight dollars a piece, whereas
- 14 your canisters run much more expensive. It may run
- 15 a hundred dollars or more to run a large autoclaves.
- 16 Q. So a small load in the neighborhood of eight
- 17 dollars, a large load a hundred dollars or more?
- 18 A. Give or take.
- 19 Q. And to the best of your knowledge, the wand or the
- 20 type of wand shown in photo 27 and 28 has not been
- 21 sterilized by your department since you came here?
- 2 A. I don't understand the question.
- 23 Q. The wand that we see in photographs 27 and 28, to
- 24 the best of your knowledge, has not been processed
- 25 in your department since you came in here?

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- MR. MALONE: He can't say that. You 1 2 saw these things sterile the day you were here 3 a couple of weeks ago. These were sterile --4 that was a sterilized instrument the day we saw 5 it. You broke the thing out of sterilization 6 so you could take pictures of it. 7 Q. Ithought you said you don't know how this is to be 8 sterilized? 9 A. This wand could have been sterilized in gas in 1998. The wand that you saw on your tour could be the same wand that was sterilized in gas, and 2 according -- if I'm looking at this picture, it was
- 3 exposed to gas because of the indicators, and it
- 4 also says on the tape that it's a gas process. What
- 5 I'm telling you is some of these wands the
- 6 manufacturer has improved on and some of them were
- 7 steam -- could be steam sterilized.
- 8 Q. But looking at this photograph, 27 and 28, you know
- now that this was gas sterilized according to the 10 indicator strip, correct?
- A. For your tour, yes. 2
 - Q. What do you mean for our tour?
- 3 A. This is not what was used on the case. I can't
- :4 reflect on what was used on the case process.
- :5 You're showing me something that you took on a tour,

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 - 1

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- so the best of my knowledge, yes, it could -- it 1
- 2 probably was gas sterilized.
- 3 Q. Well, let me back up, and I'm not trying to make
- this difficult. 4
- 5 A. Okay.
- Q. Obviously, we're here in 2001 trying to recreate 6
- what happened in 1998. 7
- A. Junderstand. 8
- Q. We asked to see an exemplar instrument, and this is 9
- 10 what was shown to us as being an exemplar of the
- wand used during Mary Lou Zimmerman's case. 11
- 12 A. Okay.
- 13 Q. Are there any written guidelines or written
- manufacturing instructions or anything in your 14
- department that would show how this instrument is 15
- gas sterilized? 16
- 17 A. I can't answer that right now.
- Q. What would you have to check to answer that 18
- 19 question?
- 20 A. Files.

1

A. No.

- 21 Q. What files?
- 22 A. To see -- files that I have in my office on
- manufacturer stuff or talking to the nurse manager. 23
- 24 Q. You don't have a notebook or a document that you can
- 25 go to to determine how that's sterilized?

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- Q. Do you know how this was sterilized, this particular 2
- item shown in the photograph, 27 and 28? 3
- MR. MALONE: Yeah, he told you, gas. 4
- 5 He's testified to it because of the indicators
- on the package that are in the photo. 6
- 7 MR. LINTON: But in terms of -- okay.
- Q. Do you recognize the item shown in photograph 13 of 8
- 50? This has been identified as a probe and a 9
- 10 sheath.
- 11 A, Okay. No, I--to answer your question, no.
- 12 Q. You have not seen one **d** those before?
- 13 A. No.
- 14 Q. Do you know how they're sterilized?
- 15 A. No.
- 16 Q. What would you have to do to find that out?
- A. Same, go back to the nurse manager, identify what 17
- set this came out of and identify what process we've 18 put in place. 19
- 20 Q. And you haven't attempted to do that before now?
- 21 A. No, sir.
- Q. Do you know if it's gas or steam sterilized? 22
- 23 A. From this picture, no.
- Q. Looking at photograph 18 of 50, do you see this 24
- container that's marked specials? 25

- A. Yes. sir.
- Q. What would you call that, just generically, so we 2

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- 3 can put a label on it?
- A. Sterilization container. 4
- Q. Can you tell, looking at that sterilization 5
- container, how it would be sterilized? 6
- 7 A. From the container itself, no, because that
- 8 container is used both for EO as well as steam.
- Q. Looking at photograph 20 of 50, can you tell how it 9
- 10 would have been sterilized?
- A. From the label I can tell you how but not from the 11 12 container.
- 13 Q. What do you mean the label?
- 14 A. The tracking label identifies gas process, and our
- 15 gas -- and our process is such that an item that is
- 16 scanned into our ethylene oxide loads recognize gas
- 17 items. Items that are scanned into our steam load,
- 18 if a gas item was to try and get there, it would
- 19 flag it, it wouldn't allow us to proceed.
- 20 Q. Just so I understand, you can't tell us how this
- 21 instrument would be gas sterilized?
- 2**2** MR. MALONE: How it would be gas

23 sterilized?

- 24 A. Well, we have, I mean, we have two methods of gas
- 25 sterilization, either from the hundred percent or we
- 60 1 have a mix. 2 Q. Okay. And which would be used in this case? A. Go back to your wand, to the -- okay. You'll see З 4 gas cold, you'll see gas regular. Cold is a colder 5 cycle by temperature. With this, this would have 63 been done on a regular cycle. 7 If it was a hundred percent versus the mix, I ន can't tell you, but I can tell you that one is 3 temperature sensitive to the other. It has nothing 10 to do with organisms that are left over. What it 11 does is to protect the instrument we run it at a 12 lower temperature cycle, which is a longer cycle. 13 Q. Would there be any written standards or guidelines 14 that the employees in your department would follow 15 to sterilize an instrument like that shown in 16 Exhibit 20 of 50, the probe and sheath? 17 A. Notthat I recall off the top of my head right now. 183 We group low temperature sterilized items, gas 13 items, we group steam items. We tend not to get 20 specific unless we have to look at the 21 manufacturer's instruction. Industry has stainless 22 steel to stainless steel. 23 Q. Do you know what this probe is made out of? 24 A From looking at it in this picture, no, I do not. MR. MALONE Off the record.

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(Thereupon, a discussion was had off
the record.)
MR. LINTON: Let's go back on the
record.
MR. MALONE: Ithink you're actually
making it more complicated than it needs to be.
MR. LINTON: I probably am, and forgive
me if I am.
Q. Who is responsible for sterilizing an instrument
like the surgical probe shown in Exhibit 20 of 50?
A. I am ultimately responsible.
Q. All right. But what level employee actually does
the manual task of packaging it, putting it in the
machine and making sure it's sterilized?
A. Tech I.
MR. MALONE: In fairness, I don't think
there's one employee that does ali of those
things, it's a staged process which you saw and
which he has testified to.
MR. LINTON: All right.
Q. What level employee is responsible for
decontaminating the surgical probe?
A. All the people that I listed earlier in this

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1	meeting.
	mooung.

- 2 Q. A shift supervisor?
- A. Shift supervisor, the educator, everybody along the 3
- 4 line.
- Q. And I'm probably using the wrong term when I say 5
- responsible. I don't mean responsible in the chain 6
- of command, I'm talking about who is actually there 7
- doing the task? 8
- 9 MR. MALONE: He wants to know who the 10 dishwasher is.
- 11 MR. LINTON: Thank you.
- 12 A. It could be the Tech II, it could be the Tech I, it
- 13 could be the SA.
- Q. All right. And why do you decontaminate a probe? 14
- 15 A. Why? You cannot sterilize an item if it's not clean. 16
- Q. And if, for whatever reason, it is not fully 17
- cleaned, that can affect the sterilization? 18
- 19 A. It can.
- 20 Q. Because the gas may not penetrate if the item is not completely cleaned? 21
- 22 A That is true.
- 23 Q. And the instrument then may be contaminated if not properly cleaned? 24
- 25 A Rephrase your question.

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1	MR. LINTON: Could you read that back,
2	please.
3	MR. MALONE: Ithink he's asking you is
4	the instrument contaminated if it's not
5	properly decontaminated.
6	MR. LINTON: If it doesn't make sense,
7	just tell me. Let her read it back.
8	
9	(Thereupon, the requested portion of
10	the record was read by the Notary.)
11	
12	A There's a possibility.
13	Q. And how does that occur, or why does that occur?
14	MR. MALONE: Why does what occur?
15	A. Now I'm lost. Now I'm really lost.
16	MR. MALONE: You got me lost too.
17	Q. If it is not properly cleaned and the instrument
18	becomes contaminated, why does that happen?
19	MR. MALONE: Wait a minute, Bob.
20	Please, now you're confusing yourself and
21	everybody else. The instrument comes
22	contaminated from an OR.
23	MR. LINTON: I understand.
24	MR. MALONE: You just said it isn't
25	cleaned and then becomes contaminated. It

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1	starts off contaminated, presumptively. That's
2	the process. It's like the dishes that go back
3	to the kitchen in the restaurant, for a really
4	crude analogy. They've got to be scraped,
5	rinsed, put in a cleaning machine.
6	Q. Using that analogy, if they're not properly cleaned
7	the gas can't properly sterilize the instrument?
8	MR. MALONE: Well, it may. A
9	dishwasher, yeah. The machine takes it off.
10	A. The industry identifies that.
11	Q. l'msorry?
12	A. Industries identify papers have identified that.
13	Q. That that occurs?
14	A. Yes.
15	Q. Now, is this instrument machine washed or is this
16	hand washed in the decontamination process?
17	A. More than likely this would have been hand washed.
18	Q. And why is that?
19	A. Because of the deticate nature of this.
20	Q. And would you agree that there is the possibility
21	for human error when that occurs?
22	A. I can't intelligently answer that.

- 23 Q. You can't --
- 24 A. Are you asking me a philosophical question? Does
- 25 human error exist, right, human error exists. Does

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- 1 it exist with the particular cleaning of this
- 2 instrument, I don't know because I'm not there.
- 3 Q. Right, it can occur?
- 4 A. I answered the question.
- 5 Q. Correct?
- 6 A. Yeah, it can occur.
- 7 Q. Okay. Now, the next step in the process is you get
- 8 to the pack and assembly area?
- 9 A. Uh-huh.
- 10 Q. And does the employee there have to be -- do they
- 11 use sterile -- how do you maintain the integrity of
- 12 the instrument after it's been decontaminated before
- 13 it's packaged?
- 14 A Instruments that are decontaminated are rendered
- 15 safe to handle with hands.
- 16 Q. Hands?
- 17 A. Yes.
- 18 Q. And the instruments, assuming that the probe is then
- 19 placed in a case like we see in Exhibit 20 --
- 20 A. Uh-huh.
- 21 Q. --who actually assembles that for sterilization?
- 22 A One of the technicians that works for me.
- 23 Q. In the pack and assembly area?
- 24 A. Yes.
- 25 Q. And would that be an SA or a Tech II?

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- 1 A. I couldn't identify that.
- 2 Q. It could be either?
- 3 A. It could be either.
- 4 Q. And what steps have to be taken to make sure an item
- 5 like the probe shown in 20 is properly packaged for
- 6 sterilization?
- 7 A. If this particular tray has a count sheet
- 8 identified, as I showed you on the tour, there's
- 9 instructions on that count sheet of what needs to be
- 10 in that tray. It will identify any special
- 11 instructions, if anything needs to be protected or
- 12 taken care of.
- 13 MR. MALONE: Can we take a time out.
- 14 -
- 15 (Thereupon, a discussion was had off
- 16 the record.)
- 17 ----
- 18 Q. Just tell me the alphabet soup after your name, what
- 19 each of these stand for, if you can, please.
- 20 A. I have a Bachelor of Science in health care
- 21 management, I'm a Certified Surgical Scrub
- 22 Technician, I'ma Certified Registered Central
- 23 Service Technician, Certification in Health Concepts
- 24 of Material Management, and Idid my fellowship in
- 25 certification.

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- 1 Q. What was required to obtain these last three
 - credentials?
- 3 A. For the CRCST, I took a course that was underwritten
- 4 by Perdue University. I sat for a final exam and I
- 5 sat for a national certification.
- 6 Q. How long was the course?
- 7 A. The course is a year long. You have up to a year to
- 8 doit.
- 9 Q. How many hours do you actually spend in the course?
- 10 A. Maybe 100,120.
- 11 Q. Okay.
- 12 A. The Certification in Health Concepts and Material
- 13 Management, again, that was a course underwritten by
- 11.4 Perdue University, same amount of time, sat for
- 15 certification -- or sat for the final exam and then
- 16 sat for national certification.
- 17 With the fellowship, I had to write a paper on
- 18 a specific technology after doing research and then
- 19 sit for an oral exam.
- 20 Q. If we could go back to the SPD processing, and that
- 21 by the way is Sterile or Surgical Processing
- 22 Department?
- 23 A. It's a play on words.
- 24 Q. I've seen both.
- 25 A For here it's the Surgical Processing Department.

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- 1 Q. During our inspection when we got to the prep and
- 2 pack area, you said that there was a computer log-in
- 3 sheet which can print out a recipe for the
- 4 particular device.
- 5 A. Okay.
- 6 Q. What did you mean by that?
- 7 A I'm referring to the count sheet that we print out,
- 8 or the menu of items, **so** that if you had this item,
- 9 and we were talking specifically for this, if there
- 10 is indeed one for this item --
- 11 Q. This being the probe?
- 12 A. This being the probe, it would print out on there
- 13 that one probe is needed, or a probe, and then tell
- 14 you how many -- what the par level is for that
- 15 item. If there's cannulas or other items in here,
- again, it would be a line item and tell you what the

A. Par level is an indicated number for that particular

tray. If we have a tray of instruments, you may

require, six, eight or ten of them in there.

have what they call a Kelly hemostat, and it may

Q. Par level being the number of instruments that you

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17 par level is for that.18 Q. What is a par level?

can put into one load?

A. No, into that container.

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1	Q. Into that container being this
2	A. Look at it as if you're a simple recipe, you're
3	baking cookies
4	MR. MALONE: Now you're trying to teach
5	him. Just answer his questions.
6	MR. LINTON: He's doing fine.
7	MR. MALONE: Answer the question.
8	MR. LINTON: Okay. Why don't you read
9	me back the question, please.
10	
11	(Thereupon, the requested portion ${ m of}$
12	the record was read by the Notary.)
13	
14	Q. What is a par level?
15	A. Maybe I'm using the par level incorrectly. It's the
16	number of instruments in a tray.
17	Q. Okay. What is a tray?
18	A It is a container used to sterilize.
19	Q. Is the silver container shown in this photograph 20
20	a tray?
21	A Yes

- Q. So the recipe would show the number of instruments 22
- 23 that could be put into this container to properly
- 24 sterilize it?
- 25 A. Yes.

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Q. The recipe would not show how the instruments are to 1 be packaged in that tray? 2 3 A. No. Q. How does a tech or an SA know how to properly 4

- 5 package the instruments in a tray like that shown in
- number 20? 6
- A. Through training. 7
- Q. Is there anything in writing that shows them that? 8
- A. Not that I recall. I can't answer that 9
- intelligently. 10
- Q. If there is something in writing, where would it be 11 located? 12
- A. Classroom. 13
- 14 Q. Under what?
- A. Prep and pack, or sterilization, handling of 15
- 16 instruments.
- 17 Q. And what are these, notebooks, handbooks, what would you 🕶 18
- A. It could be loose leaves, it could be texts. 19
- Q. Well, if you had to tell somebody to go to the 20
- classroom and retrieve that information, what would 21
- 22 you ask them to look for?
- 23 A. If we had it or if it was on-the-job training?
- Q. Right, either one. 24
- 25 A. There's --- I cannot identify the specific policy at

		71
1	this time.	
2	Q. Well, why is that?	

- 3 A. Because we have many policies that deal with prep
- and pack assembly and sterilization.
- 5 Q. And where would those policies be, where would they
- 6 be written down?

- 7 A. In the classroom in the loose leaf.
- Q. Okay. So we're going in circles here. 8
 - MR. MALONE: I thought you were.
- 10 Q. All right. You can't physically go in the
- classroom, you've got to ask somebody to look for 2 these. What do you ask them to look for?
- 33 A. We --
- Q. What do you ask them to check? Is it a notebook, is
- it a file, is it a published book? 16
 - A. It's a binder.
- 7 Q. It's a binder. What is the name of the binder?
- a A. Policies and procedures.
- 9 Q. Okay. And is that a single binder or is it a multi binder?
- 1 A. Single, if I remember correctly.
- Q. And if there was a policy or procedure, it would be contained in that binder?
- A. Yes.

MR. MALONE: If there's a formal

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- 1 written policy. There are probably lots of
- 2 them that aren't written.
- 3 Q. I'mtalking about anything that would be written,
- 4 right.
- Now, have you ever trained any employees on how 5
- 6 to package probes like that shown in Exhibit 20?
- A. No, I have not. 7
- Q. Do you know if anybody else in your department has? 8
- 9 A. I do not know.
- Q. Who would be in charge of education presently?
 - A. Presently at this time, Ken Wagner.
- 2 Q. Who had that job when you came here in '98?
- 3 A. Yes.

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- Q. He had it then, okay. Now, what affect does the 4
- 5 presence of air have on gas sterilization?
 - MR. MALONE: The presence of air?
 - MR. LINTON: Yes.
 - MR. MALONE: Simply that gas is not air
- 9 or that air is not gas because from my 8th
- **'**0 grade science they're both sort of
- interchangeable. There's gas in air and !1
- 2 there's air in gas.
 - MR. LINTON: All right.
 - MR. MALONE: If I don't understand the
 - question, I'm doing this just to keep myself

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- 1 awake and interested, Robert, because quite
- 2 frankly we've gotten so far field.
- 3 MR. LINTON: I don't want you to be
- 4 awake. I don't want you to be interested.
- 5 **Just** you go to sleep.
- 6 MR. MALONE: I'm struggling to pay
- 7 attention.
- a Q. The sterilizer has a vacuum pump, does it not?
- 9 A. Yes, sir.
- 10 Q. What is the purpose of a vacuum pump?
- 11 A. To remove air from the chamber.
- 12 Q. Why do you want to remove air from the chamber with
- 13 the vacuum pump?
- 14 A. To expose the sterilant.
- 15 Q. And what happens if all the air is not properly
- 16 removed from the vacuum pump? Strike that.
- 17 What happens if air is not fully removed?
- 18 A. Specifically, I can't honestly answer that without
- 19 checking some references, but it impedes the
- 20 sterilization process.
- 21 Q. And how does it do that?
- 22 A. By removing the air, you're helping the sterilant
- 23 attach or expose itself to the item being
- 24 sterilized.
- 25 Q. Because if there were air pockets, the sterilizer

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- 1 cannot properly penetrate the pocket to completely
- 2 sterilize the surface?
- 3 A. That's possible. Again, I need to refer to
- 4 technical references. I don't memorize that stuff.
- 5 Q. What reference would you refer to?
- 6 A. The operator's manual, manufacturer's instructions.
- 7 Q. And where is that located?
- a A If I don't have a copy, then clinical engineering
- 9 might have a copy.
- 10 Q. And there would be a separate one for each machine,
- 11 I would assume?
- 12 A. Yes, there would be.
- 13 Q. And when is the last time you consulted any of the
- 14 manuals for any of your gas sterilizers?
- 15 A. For my gas sterilizers? I've had no need to
- 16 recently.
- 17 Q. Can you think of the last time you consulted it?
- 18 A. Maybe a couple months ago.
- 19 Q. There's a sterilization strip that's supposed to be
- 20 in each container sterilized?
- 21 A. Yes.

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- 22 Q. What do you call that?
- 23 A. It can be referred to as an indicator, it can be
- 24 referred to as an integrator.
- 25 Q. The indicator strip shows what?

75

- 1 A. Shows exposure to a sterilant.
- 2 Q. And if it changes colors, then the load has been
- 3 properly sterilized?
- 4 A. Theoretically.
- 5 Q. And that's what you rely on for determining if an
- 6 instrument is properly sterilized?
- 7 A. No.
- 8 Q. What is relied on?
- 9 A. Multiple parameters.
- 10 Q. Well, does the strip have any role in that?
- 11 A. Yes, it does.
- 12 Q. So it is relied on in part for determining if a load
- 13 is sterilized?
- 14 A. Yes.
- ⁻15 Q. What other parameters?
- 16 A. Time, temperature, exposure time.
- 17 Q. Do the current gas sterilizers have an automatic
- abort feature if those parameters are not properly
- 19 met?
- 20 A. Without referring to the manual, I can't
- 21 intelligently answer that.
- 212 Q. The manual being the --
- 23 A. Operator's manual.
- 24 Q. Is a record generated from the machine that monitors
- 25 those parameters?
- 76
- 1 A. Be specific. On --
- Q. Apieceof paper?
- 3 A. Uh-huh.
- 4 Q. What do you call that?
- 5 A. Printout.
- 6 Q. A printout is generated for each load in your gas
- 7 sterilizers?
- 8 A. Yes.
- 9 Q. And what information is contained on that printout?
- 10 A. Time, temperature, exposure time.
- 11 Q. And whose job is it to check that printout to make
- 12 sure that the parameters are met?
- 13 A. The operator.
- 14 Q. And what employees serve as operators for the

21 Q. Is a permanent file maintained of that printout?

Q. Where would the records for 1998 presently be

Page 73 to Page 76

- 15 machine, SAs?
- 16 A. No.

20

24

25

WARE REPORTING SERVICE

1a A. Yes.

22 A. Yes.

17 Q. Techlls?

19 Q. Tech Is?

23 Q. Where is it maintained?

A. Either off site or on premise.

A. Yes.

1

2

3

4

6

MARYLOU ZIMMERMAN, et al. vs.

THE CLEVELAND CLINIC FOUNDATION

1 located?

2 A. Presently, in my office.

Q. How far back do the records in your office go for 3

77

- those printouts? 4
- A. September of 1998. 5
- Q. Is there something magic about September of 1998? 6 MR. MALONE: That's when he started. 7
- Q. When you started, I mean, is that why? I'm not 8
- trying to be facetious. I mean, it started in 9
- September of 1998, is that because that's when you 10
- started or is there a three-year retention policy? 11
- 12 A. No.
- 13 Q. Why September of 1998?
- 14 A. Because that's a box that I had asked for.
- 15 Q. For the purposes of this case?
- 16 A. Yes.
- 17 Q. Where did you obtain those records?
- A. From the building that I was talking about at the 18
- beginning of this conversation. 19
- 20 Q. What records are contained in there besides the
- printouts showing the parameters for the gas 21
- sterilizer? 22
- 23 A. Load configuration.
- 24 Q. Now, do you have to rely on your employees to
- properlydo their job in order to monitor the 25

78

- parameters shown on that printout? 1
- 2 A. One more time.
- Q. Sure. Well, tell me what your employees do with the 3
- printout. How does that --what is their job 4
- responsibility with respect to the printout? 5
- A. They review it, they compare it to the cycle that 6
- 7 they requested, or what was requested, compare times
- to make sure everything matches up, it's attached to 8
- the load configuration record. 9
- 10 Q. And again, you have to rely on a human being to do
- that job, to do that, physically check the printout 11
- to make sure that what came out matched what it was 12
- supposed to be? 13
- 14 A. Yes.
- 15 Q. And obviously there's room there for operator
- error? 16
- 17 A. Yes.
- 18 Q. And is there anything on the record that would
- indicate whether or not -- strike that. 19
- Is there anything that can be done now, 20
- retrospectively, to see if the load, in fact, 21
- 22 matched what the parameters were on the printout?
- 23 MR, MALONE: What load?
- MR. LINTON: The load that was being 24
- 25 sterilized.

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- 79
- MR. MALONE: This particular instrument
 - tray for this particular patient?
- MR. LINTON: Just generically.
- MR. MALONE: Could a load be -- you got
- 5 me baffted. Where are we going?
 - MR. LINTON: Let me start again.
- 7 Q. Once the load comes out --
- A. Uh-huh. 8
- 9 Q. Strike that. Once the load is sterilized, a
- 10 printout is generated that shows the parameters,
- correct? 11
- 12 A. Yes.
- 13 Q. And the operator's job is to look at the printout to
- 14 make sure that it meets the parameters that were
- required to sterilize this load? 15
- 16 A. Yes.
- 17 Q. And if it does not, is there any record of that
- 18 kept?
- 19 A Yes.
- Q. What record is kept? 20
- 21 A. It would be identified on that record itself.
- Q. And how would it be indicated? 22
- 23 A. Identified or circled, brought to the attention of
- 24 the equipment --- or the coordinators.
- 25 Q. And then what happens?
 - 80
- 1 A. It's reviewed.
- 2 Q. To see if, in fact, the operator is reading it
- 3 properly?
- 4 A. Yes.
- 5 Q. Would there be any mark on the record to indicate
- 6 that it was reviewed, does the supervisor have to
- 7 initial or make any sort of markings on the record?
- A. Not necessarily. 8
- Q. Why did you get the records only to September of 9 10 1998 for this case?
- 11 MR. MALONE: Don't answer that. I
- 12 asked him to do that. You're going into advice
- 13 of counsel now. You don't have to respond to
- 14 any of this stuff.
- 15 Q. What happens if the operator and the supervisor then

equipment, I review the parameters to see each

human error was a part of it, I refer to the other

individual parameter I'm reviewing, I look to see if

indicators, if I'm showing exposure, and I can refer

Page 77 to Page 80

determine that the parameters were not met? 16

21 A. I review it to identify what was asked of the

- A. It's brought to my attention. 17
- Q. And then what happens? 18
- 19 A. Then I do a review on it. Q. And what do you do?

20

22

23

24

25

2

THE CLEVELAND CLINIC FOUNDATION

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- to the biological as well. 1
- 2 Q. How do you determine if there's human error
- involved? 3
- 4 A. Simple mathematics. They're writing in the time,
- the fact if they didn't understand the readout. 5 Q. All right. So in order to determine if a load is 6
- properly sterilized, one looks at the parameters on 7
- the printout as well as the indicator strip? 8
- 9 A. No.
- 10 Q. How is that incorrect?
- 11 A. It's incorrect because you don't see that until it's
- opened up on the field. 12
- Q. So in terms of what your department does to confirm 13
- if a load is properly sterilized, it would be just a 14
- printout record? 15
- 16 A. No.
- 17 Q. What else?
- A. You have external indicator tape. 18
- Q. And that changes from what color to what color? 19
- 20 A. If I'm correct, a yellow or a beige to a red, in
- 21 that particular process.
- Q. And this strip is shown on Exhibit 28, correct? 22
- 23 A. I don't know. I didn't read what you said. Photo

28 of 50, yeah. 24

25 Q. Can those strips ever generate a false positive or a

82

- 1 false negative?
- MR. MALONE: A what? 2
- 3 Q. A false positive or --
- A. You mean can it change colors without being 4
- 5 processed?
- Q. Right. Can it indicate a changed color but in fact 6
- have not been properly sterilize? Let me ask it 7
- this way, is it possible for the indicator strip to 8
- show that it has been sterilized and still the items 9
- 10 have not been properly sterilized?
- 11 A. Without confirming data, I couldn't honestly give
- 12 you an intelligent answer on that.
- 13 Q. What data would you have to check?
- A. AAMI requirements, manufacturer printouts, 14
- specifications on a product. 15
- Q. So tell me what other steps are taken in your 16
- department to make sure that the load is properly 17
- gas sterilized. We talked about the parameters, we 18
- 19 talked about the indicator strip, what else?
- 20 A. Biological.

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- 21 Q. And tell me about the biological, how does that
- 22 work?
- A. The biological is an organism, or spore, actually, 23
- and it's exposed to the sterilant, it is eradicated 24
- or killed and gives us a result. 25

- a3
- Q. And is that run for each load in the gas 1
 - sterilizer?
- 3 A. In a gas sterilizer, yes.
- 4 Q. So every time a load is put into the gas sterilizer,
- 5 there's a biological placed in with it?
- 6 A. Yes.
- 7 Q. And that indicates --- that shows what?
- 8 A. With relative assurety that the item was exposed and
- 9 sterilized.
- 10 Q. And what is the relative assurety?
- 11 A. I would have to consult the tech manuals.
- 12 Q. What manuals would you consult?
- A. Thecompany. 13
- 14 Q. The manufacturer's manuals?
- 15 A. Yes.
- 16 Q. Do you know why there is what seems to be a metal
- tube contained in Exhibit 20 inside the tray? 17
- 18 A. Do I know why?
- 19 Q. Correct.
- 210 A. No, sir.
- 21 Q. Would there be some reason why you would have to
- 212 have the probe, or a probe like instrument, put
- 23 inside a metal tube for sterilization purposes?
- 24 A. I can't intelligently answer that. I don't
- 25 provide -- I don't do the procedure.

84

- 1 Q. Who would be able to best provide that information?
- A. I probably would ask the physician that performed 2
- the case. 3
- 4 Q. Well, the tube, is that a tube something that the
- physician --5
- A. I don't know. 6
- 7 Q. -- suggests or is that something processing
- 8 suggests?
- A. I don't know. I'm not familiar with the tube. 9
- Q. Or the probe? 10
- 11 A. No.

20

21

22

23

24

25

WARE REPORTING SERVICE

- 12 Q. Can any processing errors occur in sterilization
- 13 because of the way the items are positioned within 14 the tray?
- A. I can't intelligently answer that at this time. 15
- 16 O. Why is that?

process?

A. Yes.

- 17 A. Because you have different configurations.
- Q. What do you mean different configurations? 18
- 19 A. You have tray setups with various variations of the way trays are assembled, referring to technical

Q. So the way in which instruments are configured

within a tray is important in a sterilization

manuals, I'm sure we could list a number of things.

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- 1 Q. And it's important because if they're not properly
- 2 configured within the tray that can affect the
- 3 sterilization process?
- 4 A. Yes.
- 5 Q. And is there anything in writing you can consult in
- 6 terms of how --strike that.
- 7 Just tell me generically how item
- 8 configuration --strike that.
- 9 How can the way items are configured in a tray
- 10 affect sterilization?
- 11 A. The simplest one is the number of instruments in a
- 12 tray.
- 13 Q. If you have too many?
- 14 A. Possibly too many.
- 15 Q. Okay.
- 16 A. If clamps are opened versus closed or locked is a
- 17 simplistic method.
- 18 Q. Are they supposed to be opened or closed?
- 19 A. Opened.
- 20 Q. Because if they're closed they may not be --
- 21 A, You are eliminating surface exposure. Those are the
- 22 two I can recall, the wand, but again, I would have
- 23 to quote my references.
- 24 Q. What references would you have to check?
- 25 A. Again, I'd refer to AAMI, AORN, IAHCSMM, ASHCSP.

86

- 1 Q. Are there any written -- strike that.
 - Is there anything in writing that currently
- 3 exists in your department that would talk about
- 4 configuration of loads?
- 5 A. Not that I recall.
- 6 Q. Is there anything in writing your employees would
- 7 rely on on how to properly configure a load like a
- 8 surgical probe?
- 9 A. Not that I recall.
- 10 Q. They would know about that based on their training?
- 11 A. Yes.

2

- 12 Q. And we can agree that there's room for operator
- 13 error in terms of how a load is configured?
- 14 A. You can speculate.
- 15 Q. You can speculate?
- 16 A. I mean, I can't intelligently answer that.
- 17 Q. Well, why can't you intelligently answer that?
- 18 A. Because I didn't assemble that, and I'm not
- 19 overseeing -- I'm not by my staff when they assemble
- 20 all the trays in my department.
- 21 Q. lunderstand. The possibility exists for human
- 22 error in terms of how instruments are configured in
- 23 a tray?

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- 24 A. Yes.
- 25 Q. Because it's human beings that are doing the

- .
- configuration, correct?
- 2 A. Yes.

1

3 Q. And obviously you don't have a supervisor looking

87

- 4 over an employee's shoulder for every tray being
- 5 configured?
- 6 A. Yes.
- 7 Q. You have to rely on the employees doing their job
- 8 properly?
- 9 A. Yes.
- 10 Q. Because if they don't do their job properly, they
- 11 don't configure properly in a tray, that can cause a
- 12 problem with sterilization?
- 13 A. Possibly.
- 14 Q. And even if all the parameters are met, and even if
- 115 the indicator strip shows that it's been properly
- 16 sterilized, the instrument itself may not be
- 17 properly sterilized if it's not properly configured
- 18 by an employee, true?
- 19 A. Not necessarily.
- 20 Q. Can that happen?
- 21 A. I couldn't intelligentlyanswer that. This is all
- 22 speculation.

23

- MR. MALONE: Should I order lunch in,
- 24 Bob, perhaps dinner?
- 25 MR. LINTON: Maybe.

88

- 1 Q. Let's use a clamp example. If the clamps are
- 2 closed --
- 3 A. Yes.
- 4 Q. --there are two surfaces that are in contact with
- 5 each other?
- 6 A. Yes.
- 7 Q. That may not be permeated by gas during the
- 8 sterilization process, correct?
- 9 A. It is not the best case scenario, correct.
- 10 Q. Well, in fact, it would be against procedure for an
- 11 employee in your department to do that, wouldn't
- 12 it?
- 13 A. It is against procedure.
- 14 Q. Now, assuming that an employee did that, for
- 15 whatever reason, you could still have a load itself

Q. The parameters on a printout would look fine,

Q. And the strip on the outside would look fine, it

Q. And even if you had a little indicator strip inside

the tray that the surgical team would check, that

Page 85 to Page 88

16 that was properly sterilized, correct?

would change color, correct?

17 A. Yes.

20 A. Yes.

23 A. Yes.

correct?

18

19

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22

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RICHARD W. SCHULE

THE CIEVELAND CLINIC FOUNDATION

	89
1	too would show a change, correct?
2	A. Yes.
3	MR. MALONE: And then a scrub nurse
4	would see it in the OR when the tray was
5	opened.
6	MR. LINTON: One would.
7	MR. MALONE: One would, that's the way
а	it works. That's why there are so many
9	checks. God almighty, spare me. There's a
10	chance that that ceiling tile over your head
11	could fall on you, Robert, and I'm starting to
12	hope it does.
13	Q . What is a recall notice?
14	A. I'msorry?
15	Q. What is a recall notice?
16	A. A recall notice would be if we've identified a
17	potential issue with a sterilization load that we
18	would go out and we recall the items for that
19	particular load configuration.
20	Q . And you're recalling them from where?
21	A. Recalling them from our shelves, locations up in the
22	OR.
23	Q. And what documents are generated when there is a
24	recall?
25	A. The retaking the load configuration and identifying
	90
1	that that was needed is the only document at this

1	that that was needed is the only document at this
2	time.
3	MR. LINTON: Could you read that back,
4	please.
5	••
6	(Thereupon, the requested portion of
7	the record was read by the Notary.)
a	
9	Q. I don't follow you. What is the document?
10	A. The document is the load itself, the configure
11	the load printout of what the configuration is.
12	Q. After you print out the record, that has the
13	parameters, right?
14	A. Yes, sir.
15	Q. And you have separately a load configuration record?
16	A. Yes, it lists the items that were in that load.
17	Q. So let's just talk about there would currently be a
18	record here at The Cleveland Clinic that would show
19	the load in which Mary Lou Zimmerman's probe was
20	sterilized, but we just have no way of checking
21	which load that is?
22	A. I don't understand the question.
23	MR. MALONE: I don't either.
24	Q. The load configuration sheet shows the items that
25	were being sterilized in the load?

-		THE CLEVELAND CLINIC FOUNDAT
		91
	1	A. Yes.
	2	Q. So it would show probe, it would show forceps, it
	3	would show whatever the instruments were, it would
	4	be a listing of those items?
	5	A. Yes.
	6	Q. What other information would be contained on that
	7	record?
	8	A. The time that it was sterilized, the operator, and
	9	the date.
	10	Q. Now, has there ever been a case since you've been
	11	here at The Cleveland Clinic where you have learned
	12	later that a load or an instrument was not properly
	13	sterilized and a recall was then issued?
	14	MR. MALONE: Objection. Go ahead.
	15	You're asking him if he's ever issued a
	16	recall?
	17	MR. LINTON: Right.
	18	MR. MALONE: I mean, it's simple. If
	19	we can get a simple
	20	MR. LINTON: Yeah, sure.
	21	A Yes, I have issued a recall.
	22	Q. And how many times has that been done?
	23	A. I don't recall.
	24	Q. On a percentage basis, how frequently does that
	25	occur?
		92
	1	A. Less than a hundredth of one percent.
	2	Q. Can you give me a range of the number of recall
	3	notices you would have issued? Would it be more
	4	than ten?
	5	A. In what time period?
	6	Q. Since you came here in 1998, would it be more than
	7	ten?
	а	A. No.
	9	Q. Have you ever had a recallstrike that.
	10	Have you ever issued a recall notice and found
	1 1	out that the item had already been used?
	12	MR. MALONE: Objection. Go ahead and
	13	answer.
	14	A I do not recall specifically. We've been very good

- 14 A. I do not recall specifically. We've been very good
- 15 at recovering every item.
- 16 Q. During the time in which you've been here, have
- there been any mechanical problems with any of the 17 18
- gas sterilizers? 19
 - MR. MALONE: Objection. Go ahead.
- 20 A. Yes.
- 21 Q. What mechanical problems are you aware of? 22 MR. MALONE: Objection.
- 23 A. Specifically, I can't identify at this time.
- Q. What would you have to do to identify those 24
- 25 problems?

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THE CLEVEUND CLINIC FOUNDATION

93

- 1 A. Contact clinical engineering.
- 2 Q. Who in clinical engineering?
- A. Well, there's a manager in charge of the shop, so I 3
- would just start with him. 4
- Q. Who is that? 5
- A. First name is Paul, I don't recall his last name. 6
- Q. What records are kept, either by your department or 7
- to your knowledge byengineering, clinical 8
- engineering, relating to equipment repairs, 9
- inspections or malfunctions? 10
- 11 A. Well, there's a ticket that's generated that they
- fill out that identifies labor, identifies what 12
- repair was performed on a specific piece of 13
- 14 equipment.
- 15 Q. As you sit here you have no memory of any types of
- repairs being performed on your gas sterilizers? 16
- 17 A. I cannot identify a specific repair versus a
- preventive maintenance. We do very detailed 18
- preventive maintenance here. 19
- 20 Q. Who's in charge of that, clinical engineering?
- 21 A. Yes. sir.
- Q. How often do they maintain the gas sterilizers? 22
- A. i can't intelligentlyanswer that. 23
- Q. is there any -- are there any reporting -- strike 24
- 25 that.

94

- 1 Are there any reports that you or your
- department complete in the event of an adverse 2
- incident, unusual occurrence, a mistake, an error of 3
- any kind in the processing of surgical instruments? 4
- 5 MR. MALONE: Objection.
- A. Not that I recall at this time. 6
- Q. Why do you say that as opposed to no? 7
- A Because I'd have to refer to the policy. 8
- Q. The binder of policies we talked about before? 9
- 10 A. Yes, sir.
- 11 Q. Located in the classroom?
- 12 A. Yes, sir.
- 13 Q. Are there any videotapes that are used to train your
- employees? 14
- 15 A. Yes.
- 16 Q. Who would maintain a list of those videotapes?
- 17 A. A list, I'm not sure.
- 18 Q. Where are they located?
- A. In the classroom. 19
- 20 Q. Who's in charge of maintaining the materials, the
- written and video materials in the classroom? 21
- 22 A. Ken Wagner.
- 23 Q. l'msorry?

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- 24 A. Ken Wagner and myself.
- Q. What professional journals or publications do you 25

- 95
- subscribe to for your job?
- 1 2 A. Infection Control Today, MPS is Medical Product
- 3 Sales, HPN, Healthcare Purchasing News, IAHCSMM,
- 4 International Association of Healthcare Central
- 5 Service Materiel Management, Surgical Technologist
- 6 Association, their periodical, there's a safety
- 7 journal that I get.
- 8 Q. What's that called?
- 9 A. I don't recall off the top of my head, and there
- might be one or two others that I'm drawing -- OR 10
- 11 Manager, Motivational Manager. That's about the
- 12 best I can do right now.
- 13 Q. Do you subscribe to those to stay current in your
- 14 field?
- 15 A. Yes. sir.
- 16 Q. Are those reliable sources of information in your
- field? 17

18

19

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21

22

23

24

25

WARE REPORTING SERVICE

instrument.

number?

sticker, control number.

it?

- 18 A. Yes. sir.
- 19 Q. Are you familiar with what's called a Kelly probe as
- 20 identified in Exhibit 25 and 24?
- 21 A. No. I'm not.
- 22 Q. Do you know how that instrument -- strike that.
- 23 You would not know how that instrument is
- 24 sterilized, correct?
- 25 A. That's incorrect. Iwould know. Iwould know based

96

- 1 on what you have pictured in the photo, that it was
- 2 exposed to a gas process, and in this case, as
- 3 iliustrated earlier, it is a gas process and more
- 4 than likely was a warm cycle.
- 5 Q. What information is contained on the sticker?
- 6 A. That particular sticker you're pointing to?
- 7 Q. Yes, that's shown in photograph 25.
- 8 A. It's identifying the service it belongs to, it's
- identifying the name of the instrument, it's 9
- identifying a code number that's associated, you 10
- 11 have the bar code itself, which is specific, it's
- 12 located or it's maintained or housed or stored after
- 13 sterilization in the core A, it was sterilized on
- 14 the 14th of February of this year, 2001, Cleveland
- 15 Clinic identifies that it comes from this area,
- 16 process of sterilization, the initials of the person

A Yes, it's identified on this sticker here, little

17 who assembled it, not necessarily sterilized it, and

then just a breakdown code of again the name of the

Q. Would there be any record of who actually sterilized

Q. What information is contained on the load sticker

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	97		99
1	A. On this particular one?	1	properly sterilized when she had her brain surgery
2	Q. Just identify the number.	2	here in The Cleveland Clinic September 22nd, 1998?
3	A. Photo 25 of 50, it's identified that it was	3	A. No.
4	processed, and it's faint, but I'm going to take	4	Q. Can you rule out that if she was contaminated during
5	this is a guess only, that it looks like a 78 load,	5	the surgery that it occurred due to an employee in
6	which would have identified the piece of equipment,	6	your department not properly doing his job?
7	the sterilizer.	7	A. No.
8	It was the first load. It's too fuzzy to	8	MR. LINTON: Subject to the earlier
9	identify what load number it was. The third number	9	objections, as well as some additional
10	or the two numbers, if that's a 66 or not, would	1'0	documents that we may need, that's all I have
11	have identified the operator, and then you have the	11	at this time.
12	date below that it was sterilized. Again, it's a	12	MR, MALONE: Okay. We're done.
13	little fuzzy to be real specific.	1 <i>3</i>	
14	Q. Do you know what's identified in photograph 26?	14	
15	A I know a couple of the items.	15	RICHARD W. SCHULE
16	Q. Well, which items can you identify?	16	
17	A. You have a drill, it looks like you have a chuck	1 7	
18	that would fit into a drill .	1a	
19	Q. Do you know how the drill and chuck are sterilized?	19	
20	A. Depends on the drill.	20	
21	Q. This particular	21	
22	A This particular one can be done on steam, the other	22	
23	pieces I can't tell from these photos. I need to go	23	
24	back to your original question. The chuck can be	24	
25	done in steam. I can't tell you if that drill was	25	
	98		100
1	done by us or not. Some drills come to us sterilely	1	
2	packaged from the manufacturer.	2	CERTIFICATE
3	Q. What is a Bovie, B-O-V-I-E, Dick test, D-I-C-K?	3	The State of Ohio) SS
4	A. Bovie Dick test is an industry test that identifies	4	The State of Ohio) SS: County of Cuyahdga.)
5	air removal.	5	
6	Q. How is that performed?	6	I. Laura L. Ware, a Notary Public within and
7	A. It's run in the sterilizer.	7	I. Laura L. Wate, a Notary Public Within and for the State of Ohio' do nereby certify that the within named witness, RICHARD W. SCHULE, was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth in the cause aforesaid; that the testimony then given was reduced by me to stenotypy in the presence of said witness. subsequently transcribed into typewriting under my direction, and that the foregoing is a true and correct tianscript of the testimony so given as aforesaid.
8	Q. Are any records kept of that?	а	truth, and nothing but the truth in the cause
9	A. Yes, sir.	9	by me to stenotypy in the presence of said witness.
10	Q. Would any records currentlyexist for testing that	10	direction, and that the foregoing is a true and
11	in 1998?	11	aforesaid.
12	A. I can't intelligently answer that at this time.	12	I do further certify that this deposition
13	Q. Am I correct that some neurosurgical instruments	13	I do further certify that this deposition was taken at the time and place as specified in the foregoing caption, and that I am not a relative, counsel or attorney of either party or otherwise interested in the outcome of this action.
14	would be sterilized and then sent immediately to the	14	counsel or attorney of either p ar ty or otherwise interested in the outcome of this action.
15	operating room or for storage outside the operating	15	
16	room?	16	IN WITNESS WHEREOF I have hereunto set my hand and affixed my seal of biffice at Cleveland, Ohio, this 30th day of March, 2001
17	A. Yes.	17	A RAM
18	MR, MALONE: He went through all this	1 a	(Luika A. Mahe
19	about an hour and a half ago, Bob. I mean,	19	Laura L. Ware, Ware Reporting Service 21860 Crossbeam Lane, Rocky River, Ohio 44116 My commission expires May 17, 2003.
20	some things are kept down below, some are kept	20	My commission expires May 17, 2003.
21	inside the ORs, outside the OR. It depends on	21	
22	the OR manager. Remember that?	22	
23	Q. Based on what you know about the SPD department, can	23	
23	you rule out the fact that Mary Lou Zimmerman was	21	
25	contaminated with an instrument that was not	25	

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