IN THE COURT OF COMMON PLEAS

CUYAHOGA COUNTY, OHIO

MARY LOU ZIMMERMAN, et al.,

Plaintiffs,

-vs- JUDGE BURNSIDE CASE NO. 399411

THE CLEVELAND CLINIC FOUNDATION,

Defendant.

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Deposition of RICHARD W. SCHULE, taken as if upon cross-examination before Laura L. Ware, a Notary Public within and for the State of Ohio, at The Cleveland Clinic Foundation, 9500 Euclid Avenue, PACU Classroom, Building H, 3rd Floor, Cleveland, Ohio, at 9:00 a.m. on Wednesday, March 14, 2001, pursuant to notice and/or stipulations of counsel, on behalf of the Plaintiffs in this cause.

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APPEARANCES:

Robert F. Linton, Jr., Esq.
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On behalf of the Plaintiffs;

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On behalf of the Defendant.

EXHIBIT INDEX

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(Thereupon, Plaintiff's Schule Exhibit 1 was mark'd for purposes of identification.)

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RICHARD W. SCHULE, of lawful age, called by the Plaintiffs for the purpose of cross-examination, as provided by the Rules of Civil Procedure, being by me first duly sworn, as hereinafter certified, deposed and said as follows:

CROSS-EXAMINATION OF RICHARD W. SCHULE

BY MR. LINTON:

Q. Mr. Schule, my name is Bob Linton, and I'm one of the lawyers that represents Mary Lou Zimmerman and her husband, Sherman Zimmerman. We met during the inspection you provided several weeks ago down in the SPD department.

A. Yes.

Q. I'm here today to take your deposition. Have you ever been deposed before?

A. No, I haven't.

Q. Have you ever been through this process?

A. No, I haven't.

Q. I assume you had a chance to meet with Mr. Malone today before preparing for your deposition?

A. Yes, sir.

Q. It's important, as I'm sure you've been told, that you understand all the questions that I ask you, and if you don't understand a question please stop me and I'll rephrase the question, do whatever I need to to make sure that you understand what I'm asking. Okay?

A. Yes, sir.

Q. If you answer the question without asking for clarification, we're then going to assume that you understand the question. Is that fair?

A. Yes, sir.

Q. What have you done to prepare for your deposition today?

A. I had a meeting with Mr. Malone a week or so ago, and that's about it.

Q. How long did that meeting last?

A. I believe--

MR. MALONE: Objection. Go ahead.

A. I believe we --

MR. MALONE: Are you going to challenge my time entries and my bill in this; is that why we're going through this?

MR. LINTON: Maybe.

A. Between a half hour and an hour, I believe.

Q. We've been handed what's been marked as Exhibit No.

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

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A. I'm sorry.
Q. What are those --
A. Interpersonal communication skills between employees of various departments.
Q. How long have you been employed by The Cleveland Clinic?
A. I was -- I have been empioyed since September 2nd of 1998, if I'm correct.
Q. And what was your position upon hire?
A. Position upon hire was as manager of the Surgical Processing Department.
Q. Same position you presently hold?
A. Yes, sir.
Q. Had you held that same position with another hospital?
A. Yes, titled differently but still the same responsibilities.
Q. I don't know how you measure size in your business. How do you measure size?
A. We base it on bed size, we also base it on surgical procedure size.
Q. Using those standards, what was the bed size of Akron General Medical Center?
A. I believe Akron General is about a 520 bed hospital, give or take a bed or two.

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Q. And how about the Clinic?
A. I believe the Clinic is in the neighborhood of 900, just under a thousand.
Q. And how about in terms of surgical procedures, Akron General versus the Cleveland Clinic?
A. Akron General does approximately 24,000 procedures a year, and the Clinic is doing approximately 35,000.
Q. I would expect the numbers to be bigger.
MR. MALONE: Bigger than 35,0001
MR. LINTON: Well, reiative to Akron General I expected it to be a lot bigger.
MR. MALONE: Off the record.
- - - -
(Thereupon, a discussion was had off the record.)
- - - -
Q. What do you do as manager of SPD?
A. I have the responsibilities of budget, annual budget, I have responsibilities of capital planning and acquisition, I have the responsibilities of foreseeing where our needs are into the future, either doing a three-year plan or what have you.
I oversee or am responsibie for processing all the surgical instruments on campus, that includes the training, the orientation and competency of the

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staff underneath me. I'm responsible for the interaction and development of the various different surgical services, and then I interact with the management team assisting them in planning as far as if they need more instrument trays, or I can help them become more efficient where they choose to use me as a resource.
I have the responsibilityof maintaining those surgical instrument trays, make sure the scissors are sharpened, etcetera, etcetera, and payroll, et cetera. I mean, all the administrative stuff.
Q. How many surgical instruments do you process in your department?
A. I couldn't give you a specific number at this time.
Q. Can you give me an estimate?
A. Estimate, I believe --
MR. MALONE: You mean daily, weekly?
Q. However you can quantify it.
MR. MALONE: Do you understand, Richard?
THE WITNESS: I understand the question.
MR. MALONE: He's asking about instruments, I think, not trays.
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 number.
Q. And is there a difference between trays versus instruments?
A. There can be.
Q. Let me back up to something earlier. Your CV shows that your employment began in October of '98. You had said earlier it was September 2nd of '98. This particular surgery involved in this case was on September 22nd, 1998. Do you know for a fact if you had come and were working as the manager of the SPD department on that date?
A. I believe that might be incorrect, but I remember -- I don't remember. I can find that information out specifically, but I'm pretty sure it was --
Q. If you can just let Mr. Malone know that. That's important.
MR. MALONE: We know the surgical date he give us is correct. When you say incorrect date, you're not sure about your hire date?
THE WITNESS: Exactly.
MR. LINTON: His start date, whether it's before or after.
A. We can find out.
Q. Going back to 1998, how many employees did you

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supervise?
A. In the neighborhood of 65.
Q. And what levels of employees would you have supervised?
A. The various -- rephrase the question.
Q. Sure. Tell me generically the positions of the employees you would have supervised.
A. I have an education coordinator, I have a coordinator that runs the shift, and I have three shifts. I have lead techs in each of my SPD departments, and I have three of those in each area. I have a Tech II, which is the surgical processing technician, I have service assistants which help restock the rooms, and I believe that covers all the different titles.
Q. Are there three separate shift coordinators?
A. Yes, there are.
Q. And you said there are three different departments in SPD?
A. Logistically, I have three SPD departments.
Q. And how do you break those down?
A. They're broken down as the E building, the M building and the G building.
MR. MALONE: Those are physically different units, Bob, is what he's telling

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you. There's three areas in the hospital where processing is done.
Q. Do they do different types of processing in those departments in each of those buildings?
A. The policies are universal, procedures are universal.
Q. So for example, neurosurgical instruments could be processed in any of those three buildings?
A. Yes, sir.
Q. How is it decided where particular instruments are processed?
A. Based on logistics of where the cases are taking place. We have a number of ORs in each of those buildings, and to help prevent long runs of equipment we kind of isolate in those areas.
Q. Based on what you know about this case, can you teil us what building the instruments would have been processed in?
A. The E building.
Q. How do you know that?
A. To the best of my recollection, the room that this case occurred is located in the E building, and therefore the instruments would have been processed in the E building.
Q. What records, if any, would be kept as of this point

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relating to the surgical instruments that would have been used during Mary Lou Zimmerman's surgery?
A. Specifically what are you --
Q. Anything of any kind that would relate to sterile processing of those surgical instruments.
A. Generally we have records of biologicals that are performed on the sterilizers. We have records of load configurations, and load configurations meaning what was in that particular load for sterilization. I believe that would cover your question.
Q. Are you required by any law or agency to maintain those records?
A. We have requirements by state, and then also I believe there's some federal implications there.
Q. And what type of records would be maintained presently relating to biologicals?
A. Biologic --we have a record of the biologicals for all our sterilizers, either steam or gas, which is ethylene oxide. Ethylene oxide, by requirements, we have to keep on board, and then the steam records we have to keep on board either stored off premise or on premise.
Q. How long do you maintain the biologicals from the gas sterilizer?
A. Well, the biologicals themselves are not

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maintained. The record?
Q. The records.
A. The record results, how many years, about seven years.
Q. And who is the record custodian of those records; who would you go to to ask to get copies of a record from 1998?
A. I have to call a pager, and it's located in the Sears Building at this present time.
Q. Who do you call?
A. I don't recall his name. I believe his name is Rodney, or I'm sorry, Aaron. Aaron is the supervisor, I believe.
Q. And what information would be contained on that record?
A. It would ask for -- everything is boxed by month and year, so in this particular case I would ask for the sterilization records of September of 1998 for the E building.
Q. And how would those be broken down then?
A. They're broken down in the sense that the steam records are bagged together, the ethylene oxide records are bagged together.
Q. And what EO records would be --what information would be on the EO records?

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A. Information on the EO records would identify load configuration or what items were in that particular load, it would identify load parameters or sterilization parameters that took place for that specific load.
Q. Meaning temperature, time?
A. Correct.
Q. Humidity?
A. Correct.
Q. Anything else?
A. EO exposure, staurolitic exposure.
Q. Exposure in terms of time or exposure in terms of percentage or concentration?
A. Exposure in time.
Q. So there would be load configuration showing the items that were sterilized, the sterilization parameters. Anything else?
A. I believe that's it.
Q. And what would you call that, a biological record?
A. A biological record.
Q. So you'd have to call this number, talk to Aaron and say I'd like the biological records for the E building for September of 1998 in --
A. Biological records are kept in our computer system.
Q. Okay.

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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.
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 --
A. Sterilization records for September of 1998 for the E building.
Q. And I assume those are broken down by day, are they?
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 right we usually just group them together, and then it would be in chronological order starting with September 1st through September 30th or 31st, however many days September has.
Q. And are those sterilization records kept contemporaneously? In other words, are they kept --

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A. I'm not understanding.
Q. The record, the sterilization record, I assume those entries are made as the sterilization is occurring?
A. Correct.
Q. And then eventually they go over to another building for storage?
A. Yes.
Q. How would you determine which sterilization record would apply to the instrumentation used during Mary Lou Zimmerman's surgery?
A. I cannot.
Q. Is there some way to do that?
A. No.
MR. MALONE: Bob, that's the problem, we don't know when -- I mean, you could get September records. We don't know this thing was even sterilized in September.
MR. LINTON: Well, that's what I was going to ask. That's my next question.
MR. MALONE I don't think there's any shelf life on sterilization.
Q. Is there any shelf life on sterilized equipment?
A. Specify your date.
Q. Well, let's taik about back in 1998 for surgical instruments that would have been used during Mary

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Lou Zimmerman's case.
A. I don't recall what the specific -- my recollection is that when I came on board everything was event related sterility. It was not time dated.
Q. Meaning what?
A. Okay, event related sterility, you have to have various parameters in place in order to be considered event related. And event related is based on if you have your coffee mug there and it's intact, it's complete, I would be looking for holes in that coffee mug to see if we have potential contamination, okay. There's various specs that are looked at. Time related is based on a specific period of time, either 30 days, 60 days, one year.
Q. I take it now they're time related sterility?
A. No, we're event related. Time was the old, event related is the present modern time.
Q. I see. When did it change?
A. I don't know.
Q. What would you have to look at to see when it changed?
A. I don't know.
Q. How would you determine when that change occurred?
A. By asking questions.
Q. Of whom?

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A. I could investigate.
Q. When you came on board, was it time related?
A. Yes.
Q. Did it remain time related through 1998?
A. Yes.
Q. So at the time of Mary Lou Zimmerman's surgery, September 22nd, 1998, obviously the instruments had to be processed before that day, well, at least before the time of surgery?
A. Yes.
Q. And they would have been time related as of that point?
A. No, they would have been event related.
Q. I'm misunderstanding.
A. Okay. You had asked me if back in 1998 if we were time related or event related, and the best of my, if I go back, remembering correctly, what I said was to the best of my reelection we were on an event related system. If I said that incorrectly, I apologize.
Q. Is it -- what is it now?
A. It's event related.
Q. When was it time related?
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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Q. But in 1998 you think it was still time related?
A. No, event related.
Q. When you came on board it was event related?
MR. MALONE: You misspoke a minute ago. You had me confused as well.
A. I apologize.
Q. Can we safely say that at the time these instruments were sterilized that it would have been event related?
A. To the best of my knowledge, yes.
Q. And what's, first of all, the specifications used to decide when something should no longer be used according to the event related criteria; is that something that's in writing?
A. Yes.
Q. And what do you call those?
A. Recommended guidelines.
Q. Who publishes them?
A. There's a number of organizations.
Q. Who publishes the ones used here at The Cleveland Clinic?
A. We utilize AAMI, A-A-M-I.
Q. Which stands for?
A. I believe the Association for Advancement of Medical Instrumentation.

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Q. And were those in use in 1998 when you came to the Clinic?
A. I'm not sure.
Q. Do you have a memory of using any different guidelines since you came to the Clinic?
A. Since I've been here, no.
Q. So to the best of your knowledge, the AAMI recommended guidelines would have been in place when you came to The Cleveland Clinic?
A. Again, if the previous monitor used them, I don't know.
Q. I'mtalking about since you came here.
A. Since I've been here, I utilized AAMI.
Q. Was that something you implemented or was it existing when you came here?
A. I don't recall.
Q. Do you have a copy of these recommended guidelines?
A. No, I do not.
Q. Who would you go to to get a copy of those?
A. 1998, I have not a clue.
Q. How about the current guidelines?
A. Yes.
Q. Do you have a copy of those?
A. 2001.
Q. Do you have an office?

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A. Yes.
Q. Where is your office located?
A. E building, basement, EB 76.
Q. Any other written specification used to determine event related criteria besides the AAMI guidelines used here at The Cleveland Clinic?
A. No.
Q. What are the general criteria set forth for determining whether something is no longer sterile according to the event related criteria?
A. That criteria, you would look at a package, has the integrity been violated? And that integrity would be a hole, a tear in the wrapper. If the proper banding is on the sterilizing containers, if that's the type of packaging that was used, are there any water stains or dirt on the packaging, time and temperature of storage. I believe that covers them all.
Q. And I assume that a human being is the person that has to determine whether that criteria has been met?
A. Yes, sir.
Q. What level employees make that determination?
A. I can only comment on my staff.
Q. Right. And understand, any of these questions

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relate to what you know since coming to The Cleveland Clinic.
A. My staff is instructed or trained on proper storage and what to be looking for when they pull -- sterilize an item or when they set up a case cart to go upstairs.
Q. And what position employee is required to do that?
A. The Tech IIs and the S -- well, all of them actually from the coordinators on down, but predominantly the ones pulling the cases are doing the sterilization or the work. The working force are the Tech IIs and the SAs and the Tech Is.
Q. I'm sorry, Tech IIs, Tech Is and S --
A. Service assistants or processing assistants.
Q. And in the hierarchy of things, who was the lowest level employee in your department?
A. Service assistants.
Q. And then Tech IIs?
A. Yes.
Q. And then Tech Is?
A. Yes.
Q. What is required to be an SA?
A. Be specific, rephrase your question.
Q. You're responsible for hiring SAs?
A. Yes.

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Q. What are the job responsibilities required to be an SA in your department?
A. Good communications, ability to read, the ability to follow direction. That's pretty much it.
Q. Is a high school diploma required?
A. No.
Q. Is a college diploma required?
A. No.
Q. Is prior experience in the field required?
A. It is -- it would be nice, but, no.
Q. Do any of your SAs have college degrees?
A. I couldn't answer that intelligently. I want to say one of them does, but I'm not sure, to be honest with you.
Q. How many SAs do you have?
A. I believe I have seven.
Q. What does an SA do?
A. They're restocking the rooms, they're pulling for cases, they're helping out in decontamination, running items to the room that are called for, delivery, restocking of shelves.
MR. MALONE: Did you say what SA stands for?
MR. LINTON: Service assistant.
THE WITNESS: Service assistant.

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MR. MALONE: I missed that.
Q. And is a service assistant the one primarily responsible for pulling the cases and restocking the shelves?
A. Rephrase primarily, what you're talking about.
Q. Well, are those responsibilities typically done by SAs as opposed to the other --
A. It's a task shared by all.
Q. In terms of the percentage of cases, are the majority of the cases pulled by SAs as opposed to other level employees?
A. I don't know.
Q. How many Tech IIs do you have?
MR. MALONE: Again, these numbers are all current as of today, not necessarily September of '98, just so --
MR. LINTON: I understand.
MR. MALONE: I mean, I'm not objecting, Bob. I just don't want it to be confusing later on. This may be bigger now than I suspect it was in '98.
A. The majority of the work force is Tech IIs. Specific numbers, I want to say 45, give or take, maybe a little less. I'm not sure.
Q. And an estimated range is fine. Going back to 1998

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

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inventory unless they are determined to no longer meet the criteria?
A. Correct.
Q. All right. What do you call that criteria? Just so you and I are on the same wavelength so we know what we're talking about.
A. The criteria would be sterilization.
Q. Okay. So they remain in inventory until they no longer meet the sterilization criteria as determined by the guidelines?
A. Correct.
Q. And the person determining whether or not they still meet those sterilization criteria for the most part are the SAs and the Tech IIs?
A. And the Tech Is.
Q. And the Tech Is. What does a Tech I do?
A. Tech I is the lead tech of the area. They're the ones that help coordinate work flow, they motivate, they're the catalyst of the work force.
Q. Give me an approximate number of instruments that would be processed in your department on a given day.
A. In a given day, anywhere from five to a thousand.
Q. Five hundred?
A. Five hundred to a thousand.

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

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

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time have to be disciplined or terminated, I think the answer to that is yes, but the specifics --

Q. Let's talk about terminated. How many people have you had to fire or have been fired since you came on board?

MR. MALONE: I'm sorry, I'm going to object and instruct him not to answer that. If I get ordered by the Judge to answer this, I'll really be surprised. I think we're way, way off into a fishing area.

Q. You're not going to say how many people have been fired?

MR. MALONE: He's not going to answer that question under instruction of counsel.

MR. LINTON: And you're not going to allow me to get into this area of inquiry?

MR. MALONE: No, it has nothing to do with this case. It's all after the fact. We don't even know for sure he was there in '98.

Q. Well, you were here in '98.

MR. MALONE: Well, you asked about specifically September 22, and he says he thinks he was here in September of '98 and he's going to re-check the hire date.

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Q. And I assume, Mr. Schule, when you came in you wanted to make sure this department was running the way you wanted to have it run with the best possible people doing the best possible work, correct?

A. Yes.

Q. It's kind of like Butch Davis stepping in with the Cleveland Browns, I mean, there's certain personnel you want to keep and there may be certain personnel you want to release, certain people you want to hire?

MR. MALONE: Objection. This is not a professional football franchise. We're not going to respond. Come on, Robert.

Q. You're not going to answer that?

MR. MALONE: No, we're not going to compare the SPD of The Cleveland Clinic to a professional football team in the NFL.

Q. Have you had to fire --strike that.

MR. LINTON: We'll get a Court order and come back.

Q. When a person is discharged, is that a decision that you make, or is that a decision made by somebody else in your department?

MR. MALONE: Objection. Go ahead.

A. That is a decision that is initiated by me and that is critiqued or reviewed by Human Resources.

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Q. Who in Human Resources would have to --

A. I don't know.

Q. Who had your position before you came to The Cleveland Clinic?

A. Rephrase the question.

Q. Who was the manager of Surgical Processing before you came to the Clinic?

A. There was an acting manager.

Q. Who was the acting manager?

A. Penny Sonters.

Q. I'msorry?

A. Penny, as in the penny, and then Sonters, S-O-N-T-E-R-S.

Q. Is she still at the Clinic?

A. Yes, she is.

Q. What does she do now?

A. She's a scrub nurse.

Q. I'msorry?

A. She's a surgical scrub nurse in the OR.

Q. She's no longer in your department?

A. Correct.

Q. How long had she been acting manager?

A. I don't know.

Q. When was the last time there was a formal manager of the SPD department before you came on board?

A. Specific date, I don't know.

Q. Was it in *19981*

A. Idon'tknow.

Q. Was there an assistant manager?

A. We don't have an assistant manager in the department.

Q. To whom do you report?

A. I report directly to the OR director *of* surgical services.

Q. Who is that?

A. Specifically specify a time.

Q. How about when you came on board in '98?

A. Lois Bach.

Q. Is she still here? I'm sorry, did you say Louis?

A. Lois, L-O-I-S.

Q. Is she still here?

A. She's here at The Cleveland Clinic.

Q. What is she doing now?

A. She's a Director of Nurse Recruitment and Retention in Human Resources.

Q. And who is the current OR director?

A. Currently, we do not have one, we have an acting director.

Q. Who is that?

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A. Betty Bush.
Q. In your experience, is the time --excuse me. Is the event related criteria for determining sterilization a better technique than a time related sterilization?
A. Yes.
Q. Why is that?
A. It is better in the realm that it focuses individuals on the aspect of the parameters of sterilization and not just a keypunch function. With time sterilization, you just automatically pull something off the shelf after 30 days, or whatever the time specific period is, and without thinking of what those parameters are. With event related you've raised the level of quality.
Q. Because, what do you call them, loads, packages, what are they?
A. You can say packages.
Q. Sterilized packages. They're sterilized packages of surgical instruments, correct?
A. Correct.
Q. There may be packages that no longer meet the sterilization criteria even though they would still meet the time criteria?
A. Correct.

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Q. Likewise, there may be packages that are beyond the time criteria but still meet the event criteria?
A. No, because with event related you have no time criteria, so time criteria is not an issue.
Q. Right. The time criteria, when that was used, was that according to published guidelines?
A. Yes.
Q. Who publishes guidelines on time criteria?
A. It would have -- AAMI would have had a partake in that, various professional organizations, AORN, which is the surgical nurse organization.
Q. For example, can you think of a time criteria that would apply for neurosurgical instruments?
A. No.
Q. If it, let's say, was 90 days under the time criteria, under the event criteria there might be a package of neurosurgical instruments that is on the shelf for six months but still meets the sterilization criteria?
A. Yes.
Q. Do you follow me?
A. Yes.
Q. Is it more cost effective to go with event criteria as opposed to time criteria?
MR. MALONE: Objection. Go ahead.

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A. Yes, there is an economical cost value.
Q. Okay. And how do you determine that it is more cost effective to do event criteria as opposed to time criteria?
A. There's two issues, you're looking at labor to reprocess the items, you're looking at consumables that are used to reprocess the items.
Q. But how are you able to know that the event criteria is more cost effective than a time criteria?
A. I can't answer that question.
Q. You just know? I mean, you do budgets, you've got to do projections, you've got to do costs.
A. But there's a lot of things in consideration to that. To identify it solely to event related is, to my understanding, is not captioned because in that same period of time you can have increase in volume, so you're not getting a true reflection. The fact that you're able to utilize your staff more efficiently instead of just arbitrarily going and pulling dated items off the shelf has increased quality. We're not wasting our time pulling a time event -- not time, a time sequenced item off the shelf anymore.
Q. Is anything done to -- back up. Tell me how it works. You've got a package on the shelf --

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A. Uh-huh.
Q. -- that an SA or a Tech II determines no longer meets the sterilization criteria?
A. Right.
Q. First of all, is there any record of that, that it no longer meets the criteria?
A. No.
Q. What is the employee supposed to do once he decides does it meet the criteria?
A. Does or does not?
Q. Does not.
A. The item is removed from the shelf, it's broken down, repackaged, reassembled, and put back into sterilization.
Q. Reprocessed?
A. Correct.
Q. There is nothing done to determine whether or not it is, in fact, no longer sterile?
A. No.
Q. So if the employee suspects that --well, strike that.
Are there any studies that have been done, to your knowledge, that have talked about the effectiveness, either a quality standpoint or a cost standpoint, between the event criteria and the time

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criteria?
A. There are. I cannot recall specifics, but that research is available to anybody.
Q. Who would publish that information?
A. Any of the professional organizations.
Q. Such as?
A. AAMI, AORN, IAHCSMM, ASHCSP.
Q. Are those reliable organizations in your field?
A. They're looked upon -- highly looked upon.
Q. And do you look upon them as well respected authorities in your field?
A. Yes.
Q. What is your current budget?
MR. MALONE: Objection. You know, Bob, I think that might be proprietary to the institution. I'm not going to let him answer that. I mean, I've got to clear that with other people. I personally don't have a problem, but I think that may be their proprietary business.
MR. LINTON: So you can provide that to me later on after checking if you --
MR. MALONE: I don't know if I will or if I can, but really, quite frankly, for the current budget, I mean, I can't imagine what

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possible relevance that can have to 1998 in September, but be that as it may, I think it may well be a proprietary item of how they do business.
Q. How about the budget in 1998?
A. I can't recall because I didn't develop it.
Q. What items would be included on the budget? Obviously you've got labor costs.
MR. MALONE: Today, you're talking about?
MR. LINTON: I'm talking about 1998.
MR. MALONE: He didn't do the budget in '98.
MR. LINTON: I understand, but a budget is a budget. Any time something new has been added to it in terms of generic categories, a budget, you have certain costs that are generated.
MR. MALONE: I'm going to show an Objection. I don't think a budget is a budget.
MR. LINTON: What is --
MR. MALONE: Please let me finish my statement, Robert. I may or may not let him answer it, but I disagree that a budget is a

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budget. I have not permitted this witness to testify to budgeting at The Cleveland Clinic Foundation. I'm not going to let him testify as to the budgeting at the Cleveland Clinic Foundation, and I'm not going to let him testify to the components that go into the analysis.
MR. LINTON: We'll take that up with the Court then.
MR. MALONE: That's fine.
Q. What is the rate of pay for an SA?
MR. MALONE: Again, that's a question about current, 199 -- or 2001?
MR. LINTON: We'll start there.
MR. MALONE: Geez, my God. All right, go ahead, Richard, if you know.
A. For an SA?
Q. Yes, sir.
A. To the best of my recollection, I believe they start in the range of 7.85.
Q. And I assume they were not making any more than that back in 1998; is that fair?
A. I couldn't give you an educated guess --
Q. Could not?
A. -- or answer. I mean, I would say they wouldn't be

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making any more than that.
MR. MALONE: I'll object to this on the grounds of relevancy, but I'm going to let him answer.
Q. And how about a Tech II employee, what is the Tech II employee's current rate of pay?
A. I believe they're starting out at 9.25.
Q. And likewise, would it be fair to say they were not making any more than that back in 1998?
A. Assumption, probably so.
Q. And how about a Tech I?
A. That one I'm not specific on.
Q. You have no idea?
A. I can be specific that it's more than the Tech II.
Q. Can you give me a range?
A. Maybe eleven.
Q. In the neighborhood of eleven dollars an hour?
A. Right.
Q. Are there written job descriptions for Tech Is, Tech IIs, SAs?
A. Yes.
Q. Do you generate those, or are those generated by somebody else?
A. I -- yes, with the work with HR.
Q. You generate them with the input of HR?

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A. Yes.
Q. Let's go back to 1998, and the reason why I ask about what's going on today is because obviously you know what's happening today, you might not have as clear a recollection of what happened back in 1998, but if you're like most of us you can say, well, I'm doing what I'm doing today and I've always been doing it or at some point I made a change. Do you follow me?
A. Yes, sir.
Q. So that's why I'm asking about today, and then I go back to 1998, but I'm interested in what happened in 1998 as best you knew it when you came and joined in the fall of 1998. Okay?
A. Yes.
Q. First of all, in the, let's say, the fall of 1998, when you came on board, did you make any changes with the way in which neurosurgical instruments were being processed?
A. Not that I recall.
Q. If you did make a change, would there be a record of that someplace?
A. Yes.
Q. And where would there be a record?
A. It would be department policies.

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Q. And are you responsible for maintaining department policies?
A. Yes.
Q. Do you keep a copy of that in your office?
A. No, we keep a copy in our classroom.
Q. In your classroom?
A. I have a copy of it, but the masters are kept in the classroom.
Q. And what classroom is that?
A. EB 80.
Q. So if there was a revision to that policy, it would obviously say in the policy the date in which it was revised?
A. Correct.
Q. Walk me through the process of sterilizing neurosurgical instruments, gas sterilization, like the kind of instruments that would have been used in Mary Lou Zimmerman's case.
A. Rephrase and specifically ask what you're asking.
Q. You had previously given us a tour of your department?
A. Correct.
Q. Unfortunately, I didn't take that down, so now I need to get in words what it is that we saw during that inspection, so can you just generically walk

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

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as I showed, as well as the stickers or the labels that go on the outside of the package. Trays are assembled by the technician, they're wrapped or cased, placed in the sterilization area specifically for the EO that you asked for, then the items added to our load configuration list would be gone.
In other words, we would open up a load on the computer, we would scan those items to the load, the specific process would be identified with EO, items would be sterilized. Upon completion they would be pulled, scanned again to the shelf or delivered upstairs to the using service, because we do not maintain all the instruments downstairs, and then the case cart pulled and items, you know, used from there.
Q. What do you call the area of your department where the sterilized packages are kept in inventory?
A. Sterile storage.
Q. Have you --
A. Or I should say clean storage. I mean, to say a sterile item, it's not -- it's clean storage.
Q. It's a clean storage of sterile items?
A. Yeah. I don't want to misuse that term.
Q. Well, what does sterile mean to you?
A. Sterile to the industry identifies a specific number

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of organisms that are removed from an item. The industry standard uses what they call 10 to the negative 6th relative assurance in the removal or the killing of those organisms.
Q. Where is this industry standard published?
A. I'll see it in AAMI, IAHCSMM, ASHCSP, AORN. It's a recognized industry standard.
Q. And what does that mean, what does that criteria, I mean--
A. To the best of my recollection, without actually a written document out of a text, if you were to take, say, a million microorganisms and then after that first minute that million drops down to 100,000, and then after the next minute it drops down to 10,000, it's an exponential number that occurs over time.
Q. And what, ultimately, is the percentage of organisms left?
A. Well, 10 to the negative 6th. You have to -- I mean, in my opinion, my professional opinion, it's undetermined. You don't know what you started out with.
Q. Have you made any changes to the clean storage area since you took over the department?
MR. MALONE: Objection. Go ahead.
A. Rephrase the question.

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Q. Sure.
A. Specific --
Q. The clean storage department is an area in which there are shelves holding sterilized equipment --
A. Uh-huh.
Q. -- and instruments, correct?
A. Yes
Q. Have you made any changes to that since you took over the department?
MR. MALONE: Same objection.
A. What you saw on the tour is, the best of my knowledge, the same that it was in 1998 with the exception that we may have added additional storage areas because our volumes have increased, and therefore capacity, we need to maintain proper storage. So other than expansion, the answer would be, no, to the best of my recall.
Q. And do you store those items by service?
A. Instrumentation we store by service, consumable supplies are a generic pull so they're grouped.
Q. But the sterilized instruments that would be used in a neurosurgical procedure are all housed on the same shelves?
A. No.
Q. Okay. Why is that incorrect? How is it incorrect?

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

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stored before they were used in surgery?
A. No.
Q. You're familiar with the kind of instruments that were used during her procedure, you've now become aware of it, I assume?
A. Yes, sir.
Q. Would those type of instruments -- could those type of instruments be stored in clean storage in your department?
A. I cannot answer that at this time because I don't remember in 1998.
MR. MALONE: No, he's asking if they could be stored.
Q. If they could.
MR. MALONE: We don't know if they were, we don't know where they were, but the question is could it have been kept in clean storage.
Q. Is there any reason they could not have been in clean storage?
A. They would have to have gone up to the OR.
Q. They would have been put on the cart?
A. It's possible.
Q. How is it to be determined where the instruments are to be stored?

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

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the sense of how they want to dictate that they want their items stored.
Q. Okay. Assuming that it is placed in storage in your department, is there then a shelf for neurosurgical instruments?
A. Yes.
Q. And is there a shelf for other type of surgical instruments?
A. Yes.
Q. Explain to me how that is broken down. If we start -- if we're looking at the shelves, we've got a neurosurgical shelf of instruments?
A. Yes.
Q. And what is beside that, what's --
A. I don't recall.
MR. MALONE: It's in the video. Didn't you look at the video yet; haven't you got it yet?
MR. LINTON: Yes.
MR. MALONE: I mean, it's in there. They say neurosurgery, vascular, or whatever the services are.
Q. And to the best of your knowledge -- strike that.
MR. MALONE: Sort of like a grocery store.

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MR. LINTON: Right.
Q. Does your SPD department run three shifts a day?
A. Yes.
Q. Seven days a week?
A. No.
Q. How many days a week?
A. Monday through Friday three shifts, and then on the weekends we have 12-hour shifts.
Q. Any days off, on the holidays?
A. Yes.
Q. I mean, are you ever closed in your department?
A. Never closed.
Q. The gas sterilizers that we saw during our inspection, have those gas sterilizers been in place since you joined the department?
A. To the best of my knowledge, yes.
Q. And as I understand it, there are four gas sterilizers, two large ones and two small ones?
A. Yes.
Q. Which sterilizer would have been used for -- understanding you were not here most likely when Mary Lou Zimmerman's were sterilized, but if you were to sterilize those type of instruments the day you started, which gas sterilizer would or could have been used to sterilize those?

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A. Don't know.
Q. Why is that, they could be any of the four?
A. No, there's no way of identifying what instruments were used on the case. You can give me an identification of a tray of instruments, but you have to understand the volume that I have here I cannot specifically tell you which tray it was that was used, so therefore I can't tell you which sterilizer was used.
Q. When you say a tray of instruments, what do you mean?
A. Well, identify an instrument that was used on her case.
Q. Okay. Do you know what instruments were used in her case?
A. I have a vague idea. Specifically, I don't know all of them.
Q. You don't know all of them?
A. I haven't been asked specifically to look at anything.
Q. Well, let me show you a couple of them and we'll start from there. I'm going to show you what has been identified as photo number 9 of 50 and tell you that that was the tray that was set up the morning of our inspection to show the instruments that would

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have been used during Mary Lou Zimmerman's case.
MR. MALONE: I'm sorry, showing exemplars of the instruments used. We do not know whether they were the instruments used in her case.
Q. Do you recognize any of those instruments?
A. Yes, I do.
Q. What instruments do you recognize?
A. I recognize the wand in the back middle of the table. I recognize it looks to be a ruler or measuring device, drills, needle drivers, hemostats, basins, Bovie, a retractor arm.
Q. First of all, showing you what has been marked as photo number 27 of 50, do you recognize that as a stereotactic wand?
A. I understand it as a wand. Specific name of it, I'm not sure.
Q. And Exhibit 28 of 50, does that show an exemplar wand in its sterilized package?
A. That could be one of the packages.
Q. Are you able to determine in which of the four gas sterilizers -- strike that.
First of all, is this gas sterilized, the wand, or is this steam sterilized?
A. Without identifying the manufacturer's instructions,

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I couldn't honestly tell you.
Q. How would you determine that?
A. By referring to the manufacturer's instructions.
Q. And where would you find that?
A. A phone call to the manufacturer, or if it's on -- if the nurse manager has it.
Q. Well, how do you or how does your department know how to sterilize a wand like that?
A. By contacting the manufacturer and referring to their instructions.
Q. And you don't keep a copy of those instructions any place in your department?
A. Not that I recall. Some items we do, not all.
Q. Well, I'm confused. These wands are reusable and sterilized by your department, correct?
A. Correct.
Q. How do you know how to sterilize them if you don't know what the manufacturer requires?
A. That was done before I got here in '98, so I don't know what system they used before I got here.
Q. What system have you used since '98?
A. We've changed wands, if I'm correct. I believe they also have --the manufacturer has tried to get friendlier and I believe they have a wand that they're able to steam sterilize now.

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

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

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so the best of my knowledge, yes, it could -- it probably was gas sterilized.
Q. Well, let me back up, and I'm not trying to make this difficult.
A. Okay.
Q. Obviously, we're here in 2001 trying to recreate what happened in 1998.
A. I understand.
Q. We asked to see an exemplar instrument, and this is what was shown to us as being an exemplar of the wand used during Mary Lou Zimmerman's case.
A. Okay.
Q. Are there any written guidelines or written manufacturing instructions or anything in your department that would show how this instrument is gas sterilized?
A. I can't answer that right now.
Q. What would you have to check to answer that question?
A. Files.
Q. What files?
A. To see -- files that I have in my office on manufacturer stuff or talking to the nurse manager.
Q. You don't have a notebook or a document that you can go to to determine how that's sterilized?

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

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A. Yes, sir.
Q. What would you call that, just generically, so we can put a label on it?
A. Sterilization container.
Q. Can you tell, looking at that sterilization container, how it would be sterilized?
A. From the container itself, no, because that container is used both for EO as well as steam.
Q. Looking at photograph 20 of 50, can you tell how it would have been sterilized?
A. From the label I can tell you how but not from the container.
Q. What do you mean the label?
A. The tracking label identifies gas process, and our gas -- and our process is such that an item that is scanned into our ethylene oxide loads recognize gas items. Items that are scanned into our steam load, if a gas item was to try and get there, it would flag it, it wouldn't allow us to proceed.
Q. Just so I understand, you can't tell us how this instrument would be gas sterilized?
MR. MALONE: How it would be gas sterilized?
A. Well, we have, I mean, we have two methods of gas sterilization, either from the hundred percent or we

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have a mix.
Q. Okay. And which would be used in this case?
A. Go back to your wand, to the -- okay. You'll see gas cold, you'll see gas regular. Cold is a colder cycle by temperature. With this, this would have been done on a regular cycle.
If it was a hundred percent versus the mix, I can't tell you, but I can tell you that one is temperature sensitive to the other. It has nothing to do with organisms that are left over. What it does is to protect the instrument we run it at a lower temperature cycle, which is a longer cycle.
Q. Would there be any written standards or guidelines that the employees in your department would follow to sterilize an instrument like that shown in Exhibit 20 of 50, the probe and sheath?
A. Not that I recall off the top of my head right now. We group low temperature sterilized items, gas items, we group steam items. We tend not to get specific unless we have to look at the manufacturer's instruction. Industry has stainless steel to stainless steel.
Q. Do you know what this probe is made out of?
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.)

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MR. LINTON: Let's go back on the record.

MR. MALONE: I think 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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meeting.

Q. A shift supervisor?

A. Shift supervisor, the educator, everybody along the line.

Q. And I'm probably using the wrong term when I say responsible. I don't mean responsible in the chain of command, I'm talking about who is actually there doing the task?

MR. MALONE: He wants to know who the dishwasher is.

MR. LINTON: Thank you.

A. It could be the Tech II, it could be the Tech I, it could be the SA.

Q. All right. And why do you decontaminate a probe?

A. Why? You cannot sterilize an item if it's not clean.

Q. And if, for whatever reason, it is not fully cleaned, that can affect the sterilization?

A. It can.

Q. Because the gas may not penetrate if the item is not completely cleaned?

A. That is true.

Q. And the instrument then may be contaminated if not properly cleaned?

A. Rephrase your question.

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MR. LINTON: Could you read that back, please.

MR. MALONE: I think he's asking you is the instrument contaminated if it's not properly decontaminated.

MR. LINTON: If it doesn't make sense, just tell me. Let her read it back.

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(Thereupon, the requested portion of the record was read by the Notary.)

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A. There's a possibility.

Q. And how does that occur, or why does that occur?

MR. MALONE: Why does what occur?

A. Now I'm lost. Now I'm really lost.

MR. MALONE: You got me lost too.

Q. If it is not properly cleaned and the instrument becomes contaminated, why does that happen?

MR. MALONE: Wait a minute, Bob. Please, now you're confusing yourself and everybody else. The instrument comes contaminated from an OR.

MR. LINTON: I understand.

MR. MALONE: You just said it isn't cleaned and then becomes contaminated. It

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starts off contaminated, presumptively. That's the process. It's like the dishes that go back to the kitchen in the restaurant, for a really crude analogy. They've got to be scraped, rinsed, put in a cleaning machine.

Q. Using that analogy, if they're not properly cleaned the gas can't properly sterilize the instrument?

MR. MALONE: Well, it may. A dishwasher, yeah. The machine takes it off.

A. The industry identifies that.

Q. I'msorry?

A. Industries identify -- papers have identified that.

Q. That that occurs?

A. *Yes.*

Q. Now, is this instrument machine washed or is this hand washed in the decontamination process?

A. More than likely this would have been hand washed.

Q. And why is that?

A. Because of the deticate nature of this.

Q. And would you agree that there is the possibility for human error when that occurs?

A. I can't intelligently answer that.

Q. You can't --

A. Are you asking me *a* philosophical question? Does human error exist, right, human error exists. Does

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

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

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

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Q. During our inspection when we got to the prep and pack area, you said that there was a computer log-in sheet which can print out a recipe for the particular device.
A. Okay.
Q. What did you mean by that?
A. I'm referring to the count sheet that we print out, or the menu of items, so that if you had this item, and we were talking specifically for this, if there is indeed one for this item --
Q. This being the probe?
A. This being the probe, it would print out on there that one probe is needed, or a probe, and then tell you how many -- what the par level is for that item. If there's cannulas or other items in here, again, it would be a line item and tell you what the par level is for that.
Q. What is a par level?
A. Par level is an indicated number for that particular tray. If we have a tray of instruments, you may have what they call a Kelly hemostat, and it may require, six, eight or ten of them in there.
Q. Par level being the number of instruments that you can put into one load?
A. No, into that container.

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Q. Into that container being this --
A. Look at it as if you're -- a simple recipe, you're baking cookies --
MR. MALONE: Now you're trying to teach him. Just answer his questions.
MR. LINTON: He's doing fine.
MR. MALONE: Answer the question.
MR. LINTON: Okay. Why don't you read me back the question, please.
- - - -
(Thereupon, the requested portion of the record was read by the Notary.)

Q. What is a par level?
A. Maybe I'm using the par level incorrectly. It's the number of instruments in a tray.
Q. Okay. What is a tray?
A. It is a container used to sterilize.
Q. Is the silver container shown in this photograph 20 a tray?
A. Yes.
Q. So the recipe would show the number of instruments that could be put into this container to properly sterilize it?
A. Yes.

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Q. The recipe would not show how the instruments are to be packaged in that tray?
A. No.
Q. How does a tech or an SA know how to properly package the instruments in a tray like that shown in number 20?
A. Through training.
Q. Is there anything in writing that shows them that?
A. Not that I recall. I can't answer that intelligently.
Q. If there is something in writing, where would it be located?
A. Classroom.
Q. Under what?
A. Prep and pack, or sterilization, handling of instruments.
Q. And what are these, notebooks, handbooks, what would you --
A. It could be loose leaves, it could be texts.
Q. Well, if you had to tell somebody to go to the classroom and retrieve that information, what would you ask them to look for?
A. If we had it or if it was on-the-job training?
Q. Right, either one.
A. There's -- I cannot identify the specific policy at this time.

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Q. Well, why is that?
A. Because we have many policies that deal with prep and pack assembiy and sterilization.
Q. And where would those policies be, where would they be written down?
A. In the classroom in the loose leaf.
Q. Okay. So we're going in circles here.
MR. MALONE: I thought you were.
Q. All right. You can't physically go in the classroom, you've got to ask somebody to look for these. What do you ask them to look for?
A. We --
Q. What do you ask them to check? Is it a notebook, is it a file, is it a published book?
A. It's a binder.
Q. It's a binder. What is the name of the binder?
A. Policies and procedures.
Q. Okay. And is that a single binder or is it a multi binder?
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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written policy. There are probably lots of them that aren't written.
Q. I'm talking about anything that would be written, right.
Now, have you ever trained any employees on how to package probes like that shown in Exhibit 20?
A. No, I have not.
Q. Do you know if anybody else in your department has?
A. I do not know.
Q. Who would be in charge of education presently?
A. Presently at this time, Ken Wagner.
Q. Who had that job when you came here in '98?
A. Yes.
Q. He had it then, okay. Now, what affect does the presence of air have on gas sterilization?
MR. MALONE: The presence of air?
MR. LINTON: Yes.
MR. MALONE: Simply that gas is not air or that air is not gas because from my 8th grade science they're both sort of interchangeable. There's gas in air and 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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awake and interested, Robert, because quite frankly we've gotten so far field.
MR. LINTON: I don't want you to be awake. I don't want you to be interested. Just you go to sleep.
MR. MALONE: I'm struggling to pay attention.
Q. The sterilizer has a vacuum pump, does it not?
A. Yes, sir.
Q. What is the purpose of a vacuum pump?
A. To remove air from the chamber.
Q. Why do you want to remove air from the chamber with the vacuum pump?
A. To expose the sterilant.
Q. And what happens if all the air is not properly removed from the vacuum pump? Strike that.
What happens if air is not fully removed?
A. Specifically, I can't honestly answer that without checking some references, but it impedes the sterilization process.
Q. And how does it do that?
A. By removing the air, you're helping the sterilant attach or expose itself to the item being sterilized.
Q. Because if there were air pockets, the sterilizer

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cannot properly penetrate the pocket to completely sterilize the surface?
A. That's possible. Again, I need to refer to technical references. I don't memorize that stuff.
Q. What reference would you refer to?
A. The operator's manual, manufacturer's instructions.
Q. And where is that located?
A. If I don't have a copy, then clinical engineering might have a copy.
Q. And there would be a separate one for each machine, I would assume?
A. Yes, there would be.
Q. And when is the last time you consulted any of the manuals for any of your gas sterilizers?
A. For my gas sterilizers? I've had no need to recently.
Q. Can you think of the last time you consulted it?
A. Maybe a couple months ago.
Q. There's a sterilization strip that's supposed to be in each container sterilized?
A. Yes.
Q. What do you call that?
A. It can be referred to as an indicator, it can be referred to as an integrator.
Q. The indicator strip shows what?

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A. Shows exposure to a sterilant.
Q. And if it changes colors, then the load has been properly sterilized?
A. Theoretically.
Q. And that's what you rely on for determining if an instrument is properly sterilized?
A. No.
Q. What is relied on?
A. Multiple parameters.
Q. Well, does the strip have any role in that?
A. Yes, it does.
Q. So it is relied on in part for determining if a load is sterilized?
A. Yes.
Q. What other parameters?
A. Time, temperature, exposure time.
Q. Do the current gas sterilizers have an automatic abort feature if those parameters are not properiy met?
A. Without referring to the manual, I can't intelligently answer that.
Q. The manual being the --
A. Operator's manual.
Q. Is a record generated from the machine that monitors those parameters?

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A. Be specific. On --
Q. A piece of paper?
A. Uh-huh.
Q. What do you call that?
A. Printout.
Q. A printout is generated for each load in your gas sterilizers?
A. Yes.
Q. And what information is contained on that printout?
A. Time, temperature, exposure time.
Q. And whose job is it to check that printout to make sure that the parameters are met?
A. The operator.
Q. And what employees serve as operators for the machine, SAs?
A. No.
Q. Tech IIs?
A. Yes.
Q. Tech Is?
A. Yes.
Q. Is a permanent file maintained of that printout?
A. Yes.
Q. Where is it maintained?
A. Either off site or on premise.
Q. Where would the records for 1998 presently be

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located?
A. Presently, in my office.
Q. How far back do the records in your office go for those printouts?
A. September of 1998.
Q. Is there something magic about September of 1998?
MR. MALONE: That's when he started.
Q. When you started, I mean, is that why? I'm not trying to be facetious. I mean, it started in September of 1998, is that because that's when you started or is there a three-year retention policy?
A. No.
Q. Why September of 1998?
A. Because that's a box that I had asked for.
Q. For the purposes of this case?
A. Yes.
Q. Where did you obtain those records?
A. From the building that I was talking about at the beginning of this conversation.
Q. What records are contained in there besides the printouts showing the parameters for the gas sterilizer?
A. Load configuration.
Q. Now, do you have to rely on your employees to properly do their job in order to monitor the

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parameters shown on that printout?
A. One more time.
Q. Sure. Well, tell me what your employees do with the printout. How does that --what is their job responsibility with respect to the printout?
A. They review it, they compare it to the cycle that they requested, or what was requested, compare times to make sure everything matches up, it's attached to the load configuration record.
Q. And again, you have to rely on a human being to do that job, to do that, physically check the printout to make sure that what came out matched what it was supposed to be?
A. Yes.
Q. And obviously there's room there for operator error?
A. Yes.
Q. And is there anything on the record that would indicate whether or not -- strike that.
Is there anything that can be done now, retrospectively, to see if the load, in fact, matched what the parameters were on the printout?
MR. MALONE: What load?
MR. LINTON: The load that was being sterilized.

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MR. MALONE: This particular instrument tray for this particular patient?
MR. LINTON: Just generically.
MR. MALONE: Could a load be -- you got me baffted. Where are we going?
MR. LINTON: Let me start again.
Q. Once the load comes out --
A. Uh-huh.
Q. Strike that. Once the load is sterilized, a printout is generated that shows the parameters, correct?
A. Yes.
Q. And the operator's job is to look at the printout to make sure that it meets the parameters that were required to sterilize this load?
A. Yes.
Q. And if it does not, is there any record of that kept?
A. Yes.
Q. What record is kept?
A. It would be identified on that record itself.
Q. And how would it be indicated?
A. Identified or circled, brought to the attention of the equipment -- or the coordinators.
Q. And then what happens?

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A. It's reviewed.
Q. To see if, in fact, the operator is reading it properly?
A. Yes.
Q. Would there be any mark on the record to indicate that it was reviewed, does the supervisor have to initial or make any sort of markings on the record?
A. Not necessarily.
Q. Why did you get the records only to September of 1998 for this case?
MR. MALONE: Don't answer that. I asked him *to* do that. You're going into advice of counsel now. You don't have to respond to any of this stuff.
Q. What happens if the operator and the supervisor then determine that the parameters were not met?
A. It's brought to my attention.
Q. And then what happens?
A. Then I do a review on it.
Q. And what do you do?
A. I review it to identify what was asked of the equipment, I review the parameters to see each individual parameter I'm reviewing, I look to see if human error was a part of it, I refer to the other indicators, if I'm showing exposure, and I can refer

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to the biological as well.
Q. How do you determine if there's human error involved?
A. Simple mathematics. They're writing in the time, the fact if they didn't understand the readout.
Q. All right. So in order to determine if a load is properly sterilized, one looks at the parameters on the printout as well as the indicator strip?
A. No.
Q. How is that incorrect?
A. It's incorrect because you don't see that until it's opened up on the field.
Q. So in terms of what your department does to confirm if a load is properly sterilized, it would be just a printout record?
A. No.
Q. What else?
A. You have external indicator tape.
Q. And that changes from what color to what color?
A. If I'm correct, a yellow or a beige to a red, in that particular process.
Q. And this strip is shown on Exhibit 28, correct?
A. I don't know. I didn't read what you said. Photo 28 of 50, yeah.
Q. Can those strips ever generate a false positive or a

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false negative?
MR. MALONE: A what?
Q. A false positive or --
A. You mean can it change colors without being processed?
Q. Right. Can it indicate a changed color but in fact have not been properly sterilize? Let me ask it this way, is it possible for the indicator strip to show that it has been sterilized and still the items have not been properly sterilized?
A. Without confirming data, I couldn't honestly give you an intelligent answer on that.
Q. What data would you have to check?
A. AAMI requirements, manufacturer printouts, specifications on a product.
Q. So tell me what other steps are taken in your department to make sure that the load is properly gas sterilized. We talked about the parameters, we talked about the indicator strip, what else?
A. Biological.
Q. And tell me about the biological, how does that work?
A. The biological is an organism, or spore, actually, and it's exposed to the sterilant, it is eradicated or killed and gives us a result.

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Q. And is that run for each load in the gas sterilizer?
A. In a gas sterilizer, yes.
Q. So every time a load is put into the gas sterilizer, there's a biological placed in with it?
A. Yes.
Q. And that indicates -- that shows what?
A. With relative assurety that the item was exposed and sterilized.
Q. And what is the relative assurety?
A. I would have to consult the tech manuals.
Q. What manuals would you consult?
A. Thecompany.
Q. The manufacturer's manuals?
A. Yes.
Q. Do you know why there is what seems to be a metal tube contained in Exhibit 20 inside the tray?
A. Do I know why?
Q. Correct.
A. No, sir.
Q. Would there be some reason why you would have to have the probe, or a probe like instrument, put inside a metal tube for sterilization purposes?
A. I can't intelligently answer that. I don't provide -- I don't do the procedure.

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Q. Who would be able to best provide that information?
A. I probably would ask the physician that performed the case.
Q. Well, the tube, is that a tube something that the physician --
A. I don't know.
Q. -- suggests or is that something processing suggests?
A. I don't know. I'm not familiar with the tube.
Q. Or the probe?
A. No.
Q. Can any processing errors occur in sterilization because of the way the items are positioned within the tray?
A. I can't intelligently answer that at this time.
Q. Why is that?
A. Because you have different configurations.
Q. What do you mean different configurations?
A. You have tray setups with various variations of the way trays are assembled, referring to technical manuals, I'm sure we could list a number of things.
Q. So the way in which instruments are configured within a tray is important in a sterilization process?
A. Yes.

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Q. And it's important because if they're not properly configured within the tray that can affect the sterilization process?
A. Yes.
Q. And is there anything in writing you can consult in terms of how --strike that.
Just tell me generically how item configuration --strike that.
How can the way items are configured in a tray affect sterilization?
A. The simplest one is the number of instruments in a tray.
Q. If you have too many?
A. Possibly too many.
Q. Okay.
A. If clamps are opened versus closed or locked is a simplistic method.
Q. Are they supposed to be opened or closed?
A. Opened.
Q. Because if they're closed they may not be --
A, You are eliminating surface exposure. Those are the two I can recall, the wand, but again, I would have to quote my references.
Q. What references would you have to check?
A. Again, I'd refer to AAMI, AORN, IAHCSMM, ASHCSP.

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Q. Are there any written -- strike that.
Is there anything in writing that currently exists in your department that would talk about configuration of loads?
A. Not that I recall.
Q. Is there anything in writing your employees would rely on on how to properly configure a load like a surgical probe?
A. Not that I recall.
Q. They would know about that based on their training?
A. Yes.
Q. And we can agree that there's room for operator error in terms of how a load is configured?
A. You can speculate.
Q. You can speculate?
A. I mean, I can't intelligently answer that.
Q. Well, why can't you intelligently answer that?
A. Because I didn't assemble that, and I'm not overseeing -- I'm not by my staff when they assemble all the trays in my department.
Q. I understand. The possibility exists for human error in terms of how instruments are configured in a tray?
A. Yes.
Q. Because it's human beings that are doing the

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configuration, correct?
A. Yes.
Q. And obviously you don't have a supervisor looking over an employee's shoulder for every tray being configured?
A. Yes.
Q. You have to rely on the employees doing their job properly?
A. Yes.
Q. Because if they don't do their job properly, they don't configure properly in a tray, that can cause a problem with sterilization?
A. Possibly.
Q. And even if all the parameters are met, and even if the indicator strip shows that it's been properly sterilized, the instrument itself may not be properly sterilized if it's not properly configured by an employee, true?
A. Not necessarily.
Q. Can that happen?
A. I couldn't intelligentlyanswer that. This is all speculation.
MR. MALONE: Should I order lunch in, Bob, perhaps dinner?
MR. LINTON: Maybe.

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Q. Let's use a clamp example. If the clamps are closed --
A. Yes.
Q. --there are two surfaces that are in contact with each other?
A. Yes.
Q. That may not be permeated by gas during the sterilization process, correct?
A. It is not the best case scenario, correct.
Q. Well, in fact, it would be against procedure for an employee in your department to do that, wouldn't it?
A. It is against procedure.
Q. Now, assuming that an employee did that, for whatever reason, you could still have a load itself that was properly sterilized, correct?
A. Yes.
Q. The parameters on a printout would look fine, correct?
A. Yes.
Q. And the strip on the outside would look fine, it would change color, correct?
A. Yes.
Q. And even if you had a little indicator strip inside the tray that the surgical team would check, that

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too would show a change, correct?
A. Yes.
MR. MALONE: And then a scrub nurse would see it in the OR when the tray was opened.
MR. LINTON: One would.
MR. MALONE: One would, that's the way it works. That's why there are so many checks. God almighty, spare me. There's a chance that that ceiling tile over your head could fall on you, Robert, and I'm starting to hope it does.
Q. What is a recall notice?
A. I'm sorry?
Q. What is a recall notice?
A. A recall notice would be if we've identified a potential issue with a sterilization load that we would go out and we recall the items for that particular load configuration.
Q. And you're recalling them from where?
A. Recalling them from our shelves, locations up in the OR.
Q. And what documents are generated when there is a recall?
A. The retaking the load configuration and identifying

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that that was needed is the only document at this time.
MR. LINTON: Could you read that back, please.
(Thereupon, the requested portion of the record was read by the Notary.)
Q. I don't follow you. What is the document?
A. The document is the load itself, the configure -- the load printout of what the configuration is.
Q. After you print out the record, that has the parameters, right?
A. Yes, sir.
Q. And you have separately a load configuration record?
A. Yes, it lists the items that were in that load.
Q. So let's just talk about there would currently be a record here at The Cleveland Clinic that would show the load in which Mary Lou Zimmerman's probe was sterilized, but we just have no way of checking which load that is?
A. I don't understand the question.
MR. MALONE: I don't either.
Q. The load configuration sheet shows the items that were being sterilized in the load?

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A. Yes.
Q. So it would show probe, it would show forceps, it would show whatever the instruments were, it would be a listing of those items?
A. Yes.
Q. What other information would be contained on that record?
A. The time that it was sterilized, the operator, and the date.
Q. Now, has there ever been a case since you've been here at The Cleveland Clinic where you have learned later that a load or an instrument was not properly sterilized and a recall was then issued?
MR. MALONE: Objection. Go ahead. You're asking him if he's ever issued a recall?
MR. LINTON: Right.
MR. MALONE: I mean, it's simple. If we can get a simple --
MR. LINTON: Yeah, sure.
A. Yes, I have issued a recall.
Q. And how many times has that been done?
A. I don't recall.
Q. On a percentage basis, how frequently does that occur?

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A. Less than a hundredth of one percent.
Q. Can you give me a range of the number of recall notices you would have issued? Would it be more than ten?
A. In what time period?
Q. Since you came here in 1998, would it be more than ten?
A. No.
Q. Have you ever had a recall --strike that.
Have you ever issued a recall notice and found out that the item had already been used?
MR. MALONE: Objection. Go ahead and answer.
A. I do not recall specifically. We've been very good at recovering every item.
Q. During the time in which you've been here, have there been any mechanical problems with any of the gas sterilizers?
MR. MALONE: Objection. Go ahead.
A. Yes.
Q. What mechanical problems are you aware of?
MR. MALONE: Objection.
A. Specifically, I can't identify at this time.
Q. What would you have to do to identify those problems?

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

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Are there any reports that you or your department complete in the event of an adverse incident, unusual occurrence, a mistake, an error of any kind in the processing of surgical instruments?
MR. MALONE: Objection.
A. Not that I recall at this time.
Q. Why do you say that as opposed to no?
A. Because I'd have to refer to the policy.
Q. The binder of policies we talked about before?
A. Yes, sir.
Q. Located in the classroom?
A. Yes, sir.
Q. Are there any videotapes that are used to train your employees?
A. Yes.
Q. Who would maintain a list of those videotapes?
A. A list, I'm not sure.
Q. Where are they located?
A. In the classroom.
Q. Who's in charge of maintaining the materials, the written and video materials in the classroom?
A. Ken Wagner.
Q. I'msorry?
A. Ken Wagner and myself.
Q. What professional journals or publications do you

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subscribe to for your job?
A. Infection Control Today, MPS is Medical Product Sales, HPN, Healthcare Purchasing News, IAHCSMM, International Association of Healthcare Central Service Materiel Management, Surgical Technologist Association, their periodical, there's a safety journal that I get.
Q. What's that called?
A. I don't recall off the top of my head, and there might be one or two others that I'm drawing -- OR Manager, Motivational Manager. That's about the best I can do right now.
Q. Do you subscribe to those to stay current in your field?
A. Yes, sir.
Q. Are those reliable sources of information in your field?
A. Yes, sir.
Q. Are you familiar with what's called a Kelly probe as identified in Exhibit 25 and 24?
A. No, I'm not.
Q. Do you know how that instrument -- strike that.
You would not know how that instrument is sterilized, correct?
A. That's incorrect. I would know. I would know based

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on what you have pictured in the photo, that it was exposed to a gas process, and in this case, as iliustrated earlier, it is a gas process and more than likely was a warm cycle.
Q. What information is contained on the sticker?
A. That particular sticker you're pointing to?
Q. Yes, that's shown in photograph 25.
A. It's identifying the service it belongs to, it's identifying the name of the instrument, it's identifying a code number that's associated, you have the bar code itself, which is specific, it's located or it's maintained or housed or stored after sterilization in the core A, it was sterilized on the 14th of February of this year, 2001, Cleveland Clinic identifies that it comes from this area, process of sterilization, the initials of the person who assembled it, not necessarily sterilized it, and then just a breakdown code of again the name of the instrument.
Q. Would there be any record of who actually sterilized it?
A. Yes, it's identified on this sticker here, little sticker, control number.
Q. What information is contained on the load sticker number?

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A. On this particular one?
Q. Just identify the number.
A. Photo 25 of 50, it's identified that it was processed, and it's faint, but I'm going to take -- this is a guess only, that it looks like a 78 load, which would have identified the piece of equipment, the sterilizer.
It was the first load. It's too fuzzy to identify what load number it was. The third number or the two numbers, if that's a 66 or not, would have identified the operator, and then you have the date below that it was sterilized. Again, it's a little fuzzy to be real specific.
Q. Do you know what's identified in photograph 26?
A. I know a couple of the items.
Q. Well, which items can you identify?
A. You have a drill, it looks like you have a chuck that would fit into a drill.
Q. Do you know how the drill and chuck are sterilized?
A. Depends on the drill.
Q. This particular --
A. This particular one can be done on steam, the other pieces I can't tell from these photos. I need to go back to your original question. The chuck can be done in steam. I can't tell you if that drill was

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done by us or not. Some drills come to us sterilely packaged from the manufacturer.
Q. What is a Bovie, B-O-V-I-E, Dick test, D-I-C-K?
A. Bovie Dick test is an industry test that identifies air removal.
Q. How is that performed?
A. It's run in the sterilizer.
Q. Are any records kept of that?
A. Yes, sir.
Q. Would any records currentlyexist for testing that in 1998?
A. I can't intelligently answer that at this time.
Q. Am I correct that some neurosurgical instruments would be sterilized and then sent immediately to the operating room or for storage outside the operating room?
A. Yes.
MR. MALONE: He went through all this about an hour and a half ago, Bob. I mean, some things are kept down below, some are kept inside the ORs, outside the OR. It depends on the OR manager. Remember that?
Q. Based on what you know about the SPD department, can you rule out the fact that Mary Lou Zimmerman was contaminated with an instrument that was not

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properly sterilized when she had her brain surgery here in The Cleveland Clinic September 22nd, 1998?
A. No.
Q. Can you rule out that if she was contaminated during the surgery that it occurred due to an employee in your department not properly doing his job?
A. No.
MR. LINTON: Subject to the earlier objections, as well as some additional documents that we may need, that's all I have at this time.
MR. MALONE: Okay. We're done.

RICHARD W. SCHULE

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CERTIFICATE

The State of Ohio) SS:
County of Cuyahdga.)

I, Laura L. Ware, a Notary Public within and for the State of Ohio, do hereby 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.

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 actlon.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of bffice at Cleveland, Ohio, this 30th day of March, 2001.

Laura L. Ware, Ware Reporting Service
21860 Crossbeam Lane, Rocky River, Ohio 44116
My commission expires May 17, 2003.

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Curriculum Vitae

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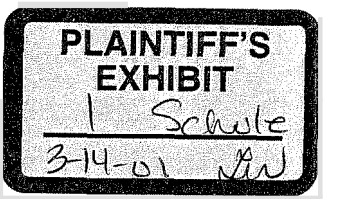

Education and Career Development:

- U.S. Navy, Hospital Corps School, 1984.
- U.S. Navy, Operating Room Technician School, 1984.
- Southern Illinois University, Bachelor of Science, Health Care Management, 1993.
- Webster University, TwQ Graduate courses toward MBA, 1993.
- Fundamentals in Total Quality Management, 1993.
- Certified Surgical Technologist, 1994.
- Certified Registered Central Service Technician, 1995.
- Attendee IAHCSMM Fall Meeting, 1995.
- Certified Health Care Material Management Concepts, 1996.
- Attendee IAHCSMM Fall Meeting, 1996.
- Attendee Medical Management Development Associates: Perioperative Clinical Paths, 1997.
- Attendee AAMI & FDA Reprocess. Medical Devices: Designing, Testing & Labeling, 1997.
- Attendee IAHCSMM Fall Meeting, 1997.
- Attendee IAHCSMM Annual Meeting, 1998.
- Fellowship, Central Service, IAHCSMM, 1998.
- Baldwin Wallace College, One Graduate course toward MBA, 1998.
- Attendee IAHCSMM Fall Meeting, 1998.
- Attendee IAHCSMM Annual Meeting, 1999.
- Attendee IAHCSMM Fall Meeting, 1999.

Professional Experience:

10/98 – Present	Manager, Surgical Processing	The Cleveland Clinic Foundation, OH.
11/94 – 10/98	Manager, Materials & Support Services	Akron General Medical Center. OH.
07/90 – 11/94	Materials Manager/Equipment Officer	Naval Hospital Camp Pendleton, CA
06/89 – 07/90	Supervisor, Central Processing	Naval Hospital Camp Pendleton, CA
02/87 – 06/89	Supervisor, Primary Care Clinic	U.S.S. Acadia AD-42, CA
08/85 – 02/87	Supervisor, Main Operating Room	U.S.S. Guam LPH-9, VA.

Professional Organizations:

- Association of Surgical Technologists, (1994 – present).
- international Association of Hospital Central Service Material Management, (1995– present).
- Mid-Ohio Chapter of IAHCSMM, (1995 – present).
- Cleveland Chapter of **ASHCSP,** (1997 – present).
- Veteran of Foreign Wars, (1996 – present).
- Boy *Scouts* of America, (1997 – present).

Committee Membership:

- Chairman of the IAHCSMM Membership Committee, (1999 – 2001).
- Editorial Advisory Board, Healthcare Purchasing News, (1999 – 2001).
- Member of IAHCSMM Fellowship Committee, (1999 – 2001).
- Member of IAHCSMM Certification Committee, (1999 – 2001).
- IAHCSMM – Board Representative, (1998 – 1999).
- President, President-Elect – Mid-Ohio Chapter IAHCSMM (1996 – 2000).
- Advisory Committee for Purdue/IAHCSMM Self-Study Lessons, (1998 – present).
- Member of Quality Improvement Committee, (1998 – present).
- Member of Ohio Central Service Educational Association, (1998 – present).
- Member of Infection Control Committee, (1994 – 1998).
- Member of Value Analysis Committee, (1994 – 1998).
- Member of Product Evaluation Committee, (1994 – present).

Educational Presentations and Programs:

- Presenter to the International Association of Central Service Material Management, November **3,** 1999, "'Safety in C.S.".
- Presenter to the American Society for Healthcare Central Service Professionals, October *25,* 1999, "Asset Management and Life Cycle Analysis".
- Presenter to the Central Service Association of Ontario, September 21, 1999, "Panel on Processing – Pasteurization".
- Presenter to the International Association of Central Service Material Management, May 2, 1999, "Pasteurization".
- Presenter to the Buckeye Central Service Association, October 10, 1998, "Pasteurization: Not **Just** For Milk".
- Presenter to the Association of Surgical Technologists National Conference, May 28, 1997, "Diversification in Sterilization: The Process".
- Presenter to the Mid-Ohio Chapter of IAHCSMM, March 15, 1997, "Pasteurization".

Awards:

- Recipient of IAHCSMM's President's Award, 1st award, 1999.
- Recipient of IAHCSMM's President's Award, 2nd award, 1999.
- Kimberly-Clark/Ruth Anne Brooks Past-President's Award, 1998.

Publications:

- Authored "CS Safety: Taking An Active Role", Medical Products Sales, January 2000.
- Authored "Surgical Processing & Operating Room **Staff** Moving Closer Toward Unity?", Medical Products Sales, November 1999.
- Authored "Let's Put Compassion Back Into Quality", IAHCSMM Communique, March/April 1999.
- Authored "Pasteurization: Not Just For Milk (Part II)", IAHCSMM Communique, November/December 1998.
- Authored "Pasteurization: Not Just For Milk (Part I)", IAHCSMM Communique, September/October 1998.
- Authored "Pasteurization: Is It Only For Milk?", Infection Control Today, September 1998.