COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

October 16, 2008

Appearances:

Bernard Coffey, Q.C. . . . . Commission Co-counsel
Sandra Chaytor, Q.C. . . . . Commission Co-counsel

Rolf Pritchard/Jackie Brazil, Q.C. . Her Majesty in Right of NL

Peter Browne, Q.C./Jane Hennebury . . . Doctors Kara Laing et al

Daniel Simmons . . . . . Eastern Regional Integrated
. . . . . Health Authority

Darlene Russell.. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

Mark Pike, Q.C. . . . . NL Medical Association
Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
Blair Pritchett. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

LIST OF EXHIBITS

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THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor.

MS. HEATHER PREDHAM, EXAMINATION BY SANDRA CHAYTOR, Q.C. (CONT'D)

CHAYTOR, Q.C.:

Q. Good morning, Commissioner. Good morning, Ms. Predham.

MS. PREDHAM:

A. Good morning.

CHAYTOR, Q.C.:

Q. Commissioner, we have three new exhibits, please, this morning that I'd ask to have entered, P-3051, P-3055 and P-3369.

THE COMMISSIONER:

Q. Entered.

EXHIBIT ENTERED AND MARKED P- 3051

EXHIBIT ENTERED AND MARKED P- 3055

EXHIBIT ENTERED AND MARKED P- 3369

CHAYTOR, Q.C.:

Q. Just bring up for a moment, please, one of the new exhibits, Registrar, P-3369. This is a document, Ms. Predham, called Risk Management Plan of Canadian Council on Health Services Accreditation that you provided us with.

MS. PREDHAM:

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A. Yes.
CHAYTOR, Q.C.:
Q. And I haven't had a chance to look through it, we just got it this morning, but I'm wondering, it doesn't have a date. Can you tell us, is it current or -
MS. PREDHAM:
A. 2005.
CHAYTOR, Q.C.:
Q. 2005, okay, and we'll come back and perhaps have a few questions when we have a chance to look at it, and if we could have, please, P-3051? This is your CV, thank you, we received last evening, and I just want to have you go back through some of the titles and positions that you've held. So I think we're up to Risk Manager at the Health Care Corporation and you held that position, according to your CV, from January 1998 to January 2004. Then you were the Director of Quality and System Improvement in an acting capacity with the Health Care Corporation again from January 2004 to October 2006 (sic.), and then you go on to the Manager of Quality and Risk with the Health Care Corporation from November 2005 to June 2006,

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and your current position, Risk Management Consultant/Assistant Director Quality and Risk Management and that's with Eastern Health from June 2006 to the present.

So perhaps we'll go back to the Risk Manager position, Ms. Predham, and tell us what your duties were with the Health Care Corporation during this time period, 1998 to 2004, January 2004.

MS. PREDHAM:
A. My main duty as Risk Manager was to coordinate any risk management activities throughout the organization. The risk manager position, like all of quality, Quality Initiatives, I guess, was our department at that time, is as a support department. So the programs are responsible for quality and risk management activities within their area, and we provide a support to any programs and departments.

That being said, the risk manager then is responsible to coordinate the occurrence reporting system, to liaise with the insurer, legal counsel, to manage any claims, investigate any adverse events and also for that period of time, I was also linked as a

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quality facilitator, for want of a better term, to several departments, as part of the Quality Initiatives department.
CHAYTOR, Q.C.:
Q. I'm sorry, what was that last part? You were -
MS. PREDHAM:
A. The quality facilitators, as I explained yesterday, were linked to different programs.
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:
A. But because there was only three, the risk manager, utilization manager and the director were linked as well. So we had that type of support role with programs as well.
CHAYTOR, Q.C.:
Q. Okay. So in your role then, as risk manager in this time period, who would you have been reporting to?
MS. PREDHAM:
A. Reporting to?
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:

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A. The director of Quality Initiatives.
CHAYTOR, Q.C.:
Q. And who held that position at that time?
MS. PREDHAM:
A. From '98 to 2000, I'm pretty sure on those dates, it was Regina Coady, and from 2000 to 2004, it would have been Sharon Smith.
CHAYTOR, Q.C.:
Q. Okay, and who would have been reporting to you, as risk manager?
MS. PREDHAM:
A. No one.
CHAYTOR, Q.C.:
Q. No one, okay, and then you move into the Director of Quality and System Improvement, and that's an acting capacity, for almost a two-year period. What were your duties at that time, and perhaps you can contrast that and tell us how it differed from being risk manager?
MS. PREDHAM:
A. Well, at that time, our department was slightly different. We had three divisions. So I had the infection control nurses reported directly to me, so that was six frontline

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nurses. We also had our quality and risk management division. So the risk manager position became the manager of that division. The quality facilitators reported to that manager and that manager reported to me. Our patient relations officer reported directly to me, and then we had our division of management engineering and the manager of that area reported to me.

CHAYTOR, Q.C.:

Q. And the patient relations officer at that time period, would that have been Nancy Parsons?

MS. PREDHAM:

A. Yes, it would have.

CHAYTOR, Q.C.:

Q. Okay. So Nancy reported directly to you in that time period?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And the quality facilitators reported indirectly through?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

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Q. Okay, and how was this--what was the difference in terms of holding this position? Were you still responsible, for example, for investigating incidents or occurrences and did you still have that liaison with the insurer during this period of time?

MS. PREDHAM:

A. Not as directly. From the period of 2002, probably the end of 2001 to 2004, we went through a great deal of turnover in the Quality department, and as risk manager, I took a lot of--a lot more responsibility or, you know, for investigating complaints because we had new staff in the quality facilitator roles. So we had a great deal of turnover during that period of time. So when, in January 2004, we had a relatively very new staff in as quality risk management. So I was more hands on than I would have been if we had more experienced staff in that area.

CHAYTOR, Q.C.:

Q. Okay, and so in terms of then the liaison with the insurer or the lawyers handling any particular claim, who would have had that role?

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MS. PREDHAM:

A. The manager of quality and risk management.

CHAYTOR, Q.C.:

Q. And who was that?

MS. PREDHAM:

A. That was Pamela King-Jesso.

CHAYTOR, Q.C.:

Q. Pamela King-Jesso, and with respect though to the ER/PR issue, which occurred within this period, it comes up in the spring of 2005, who had the liaison role for that particular issue?

MS. PREDHAM:

A. At that time, Ms. King-Jesso was off for a period of time, so I was in that role in her stead for a bit of that.

CHAYTOR, Q.C.:

Q. Okay, and did you continue on then in that role?

MS. PREDHAM:

A. She left the department in September of '05. So yes, I carried on then.

CHAYTOR, Q.C.:

Q. Okay. So for our purposes here in dealing with the ER/PR issue, you are the person who

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would have been the liaison with the insurer or with the solicitors handling any claims arising from the ER/PR issue?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and in terms then also of the other issues that you would have been dealing with had you held Ms. King-Jesso's role, with respect to ER/PR, were you also the person then who continued on in her capacity with respect to, for example, investigating any investigation that needed to take place, any occurrence reporting, who was handling that for the ER/PR issue?

MS. PREDHAM:

A. After when she left in September?

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. We did--well, we had a very small department at that time, and it was--we were becoming Eastern Health, so we were getting requests from the new parts of Eastern Health that we weren't familiar with, and the various quality

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people in the legacy boards had left. The majority of them had left and gone to other positions, so between the people who remained in the quality and risk management division, we divvied it up between us.

CHAYTOR, Q.C.:

Q. So her position wasn't filled when she left?

MS. PREDHAM:

A. No, because that was September 2005.

CHAYTOR, Q.C.:

Q. So then from September 2005, when does the position then get filled?

MS. PREDHAM:

A. Until June.

CHAYTOR, Q.C.:

Q. June of 2006?

MS. PREDHAM:

A. 2006.

CHAYTOR, Q.C.:

Q. Okay, and so then that's the role that you take on as risk manager, management consultant, assistant director of quality and risk management, and you take that on in June 2006?

MS. PREDHAM:

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A. Yes. Now it's a little bit different. It seems like there's provisos for everything I say here, but the way the department is structured now, the quality safety leaders, which would be the type of quality facilitator position, has a primary role for risk management and investigation and complaints. The difficulty was, in June of 2006, the majority of those staff were new to this area and required a lot of direction. So the risk management consultant position is intended to be that, not hands on into the investigation part, but, you know, for the next year or so, it had to be that because you had a lot of new staff who had to learn how to do this.

CHAYTOR, Q.C.:

Q. Yes, okay. So I just want to be clear in terms of--because we don't see Ms. King-Jesso's name doesn't appear very often in the documentation that we're dealing with.

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. So in terms of you're saying she left in September 2005, but was she ever tasked with

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any risk management, in terms of the ER/PR issue?

MS. PREDHAM:

A. No. When it first came up, she was off, and when she came back, she had, I guess, a limited ability to--she had to be limited in her activities at that time. So where she was off when it started, it was just as well for me to carry on at that time.

CHAYTOR, Q.C.:

Q. Okay, and so she had been off for some period of time and while she was off, you were carrying out her duties?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and so in this period of time here that we see when you were acting director of Quality and Systems Improvement from January 2004, is this--when, I guess--my question is when did you start carrying out her duties? Is this it?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

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Q. This is a different position?

MS. PREDHAM:

A. It was during that position. It would probably have been in June of 2005, and carrying out her duties, I guess there was a very small group of us and it was--we picked up her duties amongst us. So anything that had to be done, the quality facilitators were taking that role as well of liaisoning with the risk management, with the insurer and with the lawyers for the areas they were responsible with. But it would have been--she would have been, you know, fully acting in that role from January 2004 until -

CHAYTOR, Q.C.:

Q. She went on leave in June of 2005?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and so, and the position that you're in here as Director of Quality and Systems Improvement in an acting position -

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

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Q. - you then, in fact, take on a second acting position as of June 2005, in essence?
MS. PREDHAM:
A. In essence.
CHAYTOR, Q.C.:
Q. In essence, without the formal title, I guess, you take on -
MS. PREDHAM:
A. No. Well, we -
CHAYTOR, Q.C.:
Q. - you take on her duties as well?
MS. PREDHAM:
A. Well, part of her duties. Like I said, the other quality facilitators took on part of those duties as well.
CHAYTOR, Q.C.:
Q. Yes, okay. Then the position that you take up in--okay, so the manager of quality and risk, from November 2005 to June 2006 -
MS. PREDHAM:
A. That was Ms. King-Jesso's position.
CHAYTOR, Q.C.:
Q. That's her position, and that's when you take on your second--and although it says November 2005 here, you're saying that the reality is

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that you took on a lot of those duties in June of 2005?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And is there any difference in what you would have been doing as the manager of quality and risk and what you were doing as the risk manager for the Health Care Corporation from 1998 to January 2004?
MS. PREDHAM:
A. Well, yes, because the quality facilitators reported to the manager of quality and risk and you weren't solely responsible for risk management activities there. Although the risk manager was linked as a quality facilitator role with certain programs, now you were manager of the three quality facilitators and you had to--you know, you were responsible for quality activities and the risk management activities.
CHAYTOR, Q.C.:
Q. So you were responsible then for both?
MS. PREDHAM:
A. Yes.

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CHAYTOR, Q.C.:
Q. And you then had the quality facilitators reporting to you?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So was this a--when I hear that, it sounds like there were additional duties. You still had all the duties you had as risk manager and then you also became responsible for quality and had people then directly reporting to you?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So it was additional duties added on as of November 2005?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. Then that brings us to your current position, which you took up in June of 2006 and perhaps you can tell us what, if any, differences there were in your duties in your current position.
MS. PREDHAM:

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A. Well, as assistant director, I would be assisting the director in activities that help run the entire department. I also have infection control report directly to me and that would be the manager of infection control, rather than the frontline nurses, and then the intent is the position would be more of a consultant role to risk management and would move more into proactive activities, rather than just solely reactive. Also, as time went on, we have two new positions that report to me as well, the quality information coordinator and the claims manager, and they report to me.
CHAYTOR, Q.C.:
Q. And when did the quality information manager position come on?
MS. PREDHAM:
A. October 2006.
CHAYTOR, Q.C.:
Q. Okay, and the other one was the claims manager?
MS. PREDHAM:
A. Claims manager.
CHAYTOR, Q.C.:

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Q. Okay, and when was that position put in place?
MS. PREDHAM:
A. February 2007.
CHAYTOR, Q.C.:
Q. And who do you report to in your current position?
MS. PREDHAM:
A. The Director of Quality and Risk Management.
CHAYTOR, Q.C.:
Q. And that person is?
MS. PREDHAM:
A. Pam Elliott.
CHAYTOR, Q.C.:
Q. And while you were manager of quality and risk and director of quality and system improvement in your acting capacity, who were you reporting to in these positions?
MS. PREDHAM:
A. As the acting director, I reported to Pat Pilgrim. Well, yes, I reported to Pat Pilgrim, and as the manager in quality risk, I reported to Pam Elliott because she had just--she started as the Regional Director for Quality and Risk Management.
CHAYTOR, Q.C.:

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Q. Okay, and she started her position the same time you started yours, in November 2005?
MS. PREDHAM:
A. Yes, because when I--when she started in her position, then I moved back to my previous position, which was different.
CHAYTOR, Q.C.:
Q. Yes. So once Ms. Elliott took on her position, you, in essence, went back to the risk management position?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. With the additional responsibilities. So then did Ms. Elliott become the manager of quality and risk?
MS. PREDHAM:
A. No, she was a regional director.
CHAYTOR, Q.C.:
Q. Regional director, okay. So you were reporting to her and had been reporting to her since November 2005?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

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Q. And with respect to the ER/PR issue, from June of 2005 until Ms. Elliott is in her position in November 2005, would you have been reporting to Ms. Pilgrim?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And did you report to anyone else on that issue?
MS. PREDHAM:
A. Well, Dr. Williams took the lead on that issue. So he coordinated activities.
CHAYTOR, Q.C.:
Q. So I would take it then, you would take direction or instruction from either Dr. Williams or Ms. Pilgrim?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, thank you, I think that's clearer for us. I'd like to go back and ask you a few questions of a few terms that came up yesterday when we started on your educational background.
MS. PREDHAM:

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A. Certainly.
CHAYTOR, Q.C.:
Q. And one issue that came up was root cause analysis, and I believe you indicated that that was something that you studied in the--was it the year-long correspondence course that you completed?
MS. PREDHAM:
A. No, that's a--I guess it really came to a head or really came to the forefront during the patient safety movement and that was more in the 2000's that that was coming forefront. Root cause analysis is a technique to investigate and get to the root cause of an adverse event, and during this period of time when I was risk manager, myself and the risk manager at Western Health, we founded a risk management network across the province, and we were having difficulty, as a group, getting education in root cause analysis because it was a tool that you could benefit from using. Well, we were using it as well as we could from, you know, doing our own education, and we were having difficulty getting funding and training. So we arranged a train-the-trainer

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session with the Institute for Safe Medication Practice and CPSI to come down and hold a train-the-trainer session here in 2005 actually, November 2005.

CHAYTOR, Q.C.:

Q. Okay, and the issue, I think you referred to a fishbone diagram.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And perhaps you could explain to us what that is and how that is a tool that's sometimes used?

MS. PREDHAM:

A. When you investigate--it doesn't have to be an adverse event. If you're involved in quality and you're doing a process improvement team as a quality project, you know, that there's some difficulty or something you want to get involved in. There's various tools that you can use to help illustrate or get to the root of the problem. A fishbone diagram would be a cause and effect type of tool in which, you know, you have your issue or your process and then you're looking at various things that

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could contribute and influence that process. So it's just one of those tools that you can use to--when you have your team, that you can illustrate that and kind of focus your activity.

CHAYTOR, Q.C.:

Q. And again, and the purpose being to try and identify any issues, whether it's quality, ongoing quality exercise or whether it is to investigate an occurrence?

MS. PREDHAM:

A. Right. When you have a team together, you have like a lot of frontline staff and when you're investigating something and a lot of times, it's--I know myself, I'm a very concrete thinker. I like seeing things laid out, and it's easier when you have a group for them to see that, you know, especially if they're doing a process for a long time, there tends to be, you know, with anything, you tend to get used to that and comfortable with that process. So until you have someone like myself coming from outside and asking a lot of questions and getting them to work through that process, they're usually too close to

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that, that they could see these are contributing factors.

So something like a cause and effect, a fishbone diagram, can help them actually see, yes, okay, there's the problem here or whatever, when they haven't stopped and looked at it that way.

CHAYTOR, Q.C.:

Q. Right, so you come in with an independent objective perspective and lay it out for them and you use this sort of fishbone diagram to assist?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. If we could look, please, bring up P-3075? And this, Ms. Predham, is a performance evaluation for the time period January 2006 to September 2007. So again, that would cover the period of--I guess it overlaps, you're in the manager quality and risk portfolio and then into your current position, and I'll just bring up in terms of what it indicates to be your primary job responsibilities on this diagram, and it says "provides guidance and

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direction to staff and physicians regarding risk management issues and activities, leads and facilitates process improvement teams and investigation of adverse events." So is that an accurate description of what you would have been doing in this time period, from January 2006 to September 2007?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and perhaps you can just tell us what is the process improvement teams? What's their roles? What's the role of a process improvement team?

MS. PREDHAM:

A. At its very fundamental, if you have a problem, and I guess it leads back to when I mentioned Edward Demmings' work yesterday. His process or his philosophy and his basis of CQI is this 80/20 rule. Sometimes it's cited as 85/15 rule. That 85 percent of the time or 80 percent of the time, if you're having a problem, you're having a problem because of the way things are done, not the people that are actually doing it. So that is the

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fundamental philosophy behind quality improvement, and our whole department, almost everything that we do. Now my experience is more like it's 95 rather than 85 percent, but so with that focus, when you go into these things, it's very important to look at the way that things are done. So a process improvement team looks at the way things are done and then tries to determine how to improve it, based on that whole process.

The idea now is more in systems theories is how it's referred to and I know you've heard discussion about the swiss cheese model and that type of thing. So that's the fundamental philosophy behind it. So a process improvement team would lay out the process the way it is now and go through some method, whether it's fishbone diagram, a flow chart or anything, to identify where problems are and then how can we improve it, and then implement that or make a proposal for implementation and then find out some way to evaluate it.

CHAYTOR, Q.C.:

Q. And are they only put in place if an incident

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occurs or are they used proactively to try and identify if there is an issue?

MS. PREDHAM:

A. Well, a process improvement team usually there's something. It may not be an incident. It could be, you know, that there's some flow problems or there's usually something which would cause that there, but the big tool now, as a proactive one, would be a failure mode effects analysis, and really that's the same type of concept.

THE COMMISSIONER:

Q. I'm sorry, what was that again?

MS. PREDHAM:

A. A failure mode effects analysis.

THE COMMISSIONER:

Q. Failure mode effects analysis?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Thank you.

MS. PREDHAM:

A. It's an engineering tool and it is, you plot out your process right through and then you, as a group, you try to look at the higher risk

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areas or the more problem prone that you're anticipating and the whole thing is that you're doing this proactively, so before this process gets in place. So if a new program is coming in or a new test is being done or something like that, you'd sit down with the key people involved and you'd facilitate them speaking about how is this going to work, and you'd have to go into great detail on that, and then once you pick out those areas, then you have to say okay, what can go wrong at each one of these steps. So it's a lot of brain storming. It's a lot of forcing these people to--not forcing them, but you know, facilitating them to think about, "okay, if we do this, what can go wrong?" So then there's a rating--there's tools to help you rate that and you identify the areas where you have to rate that and then the highest--you'd focus in on those highest problem prone ones and you'd put things in to prevent it from happening.

CHAYTOR, Q.C.:

Q. Okay. So for example, back in 1997/1998 when ER/PR was switching over to the IHC method, if there had been such a thing as failure mode

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effects analysis, at that point in time, you could have sat down with the people involved in the process, the pathologists, technologists, the people bringing this on, and go through and try and identify any particular issues or problems that might arise?

MS. PREDHAM:

A. If it had been around, yeah.

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. And that's what it's designed to do. The difficulty is that it's very intensive. So you have to have the resources to be able to do it, but you also have to have that lead time. You need to take the time and have the time to do it before the program gets in. So it's really important that the leadership and, you know, the organization throughout knows about this tool, rather than us, because when we find out that something is starting, you've got a very short time. It's when something is being conceived that, okay, we'd like to start doing this. That's when you'd like to do

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that.
CHAYTOR, Q.C.:
Q. Okay, and was there--while there was no failure mode effects analysis back in that time period, was there a similar tool that was being used in the quality and risk management world for doing such assessments?
MS. PREDHAM:
A. Not before, not that proactive, that side. We would do a process improvement team, but again, there was usually some problem or some, you know, near miss, you know, that type of thing that would cause that, or some backlog or patient complaint or something that would cause us to look at an issue.
CHAYTOR, Q.C.:
Q. So if there were a new test coming on in your institution or a new way of doing things, there was no--none of that kind of proactive assessment beforehand?
MS. PREDHAM:
A. Oh no, I'm not saying--no, I'm not saying that. The people responsible for that would do that, but it wouldn't be that systematic looking through that in a very, you know,

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systematic flow charty way. They would do that, they would assess that, the process as they go through, but it would be a proposal stage and people would be looking at it. They'd be doing the research, you know, all that kind of thing, but it wouldn't be that systematic plotting out of the process and getting the frontline staff to sit down and say "what would you anticipate your process is going to be?" and you know, it's that level of detail.
CHAYTOR, Q.C.:
Q. And was there any system in place where your department or the quality department and risk department would have been involved?
MS. PREDHAM:
A. Back in '97/98 when a new system -
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:
A. Not necessarily. It would be if the program director involved us, you know, there could be. We would be involved, but unless they did, we wouldn't.
CHAYTOR, Q.C.:

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Q. Okay, and do you know whether or not anybody was involved, from your department, in setting up the ER/PR in 1997?
MS. PREDHAM:
A. Oh no.
CHAYTOR, Q.C.:
Q. There was no one involved?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Okay, in terms of -
THE COMMISSIONER:
Q. Wait now, I just want to make sure I understand. Your description of the failure mode effect analysis, is there really any difference in what you do in that and what you would be doing following either an adverse event or a request by a department, because they were concerned about something, other than the timing?
MS. PREDHAM:
A. Well, I guess the biggest difference, other than it's before, is that also you're anticipating what you're going to do, because the processes haven't been set up yet. So you

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have to get people to really say how would you do this, how would you work through this, how would you do that. So you're not actually saying "what do you do?" You're just going to say "what would you do if this went in this way?" So I guess that's the biggest difference.
THE COMMISSIONER:
Q. All right. But essentially, it's the same process, it seems to me. It is what are the steps, either anticipated by virtue of what you're bringing them in or what are the steps that you are actually doing, A, B, C, D, E in analysing the--presumably the actions taken in the persons who are taking the action, roles, etcetera, etcetera, to determine whether or not it is the, I presume, best, most efficient, safest, are those your goals?
MS. PREDHAM:
A. Are those our goals? Yes.
THE COMMISSIONER:
Q. Okay.
MS. PREDHAM:
A. Well, the safest would be the ultimate goal.
CHAYTOR, Q.C.:

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Q. And Ms. Predham, while this is the interim performance appraisal indicated from January 2006 through September 2007, insofar as you assumed the role of Manager Quality and Risk in an acting capacity from June of 2005, would those have been your same primary job responsibilities, from June 2005 onwards?

MS. PREDHAM:

A. Well, no, because I had the entire--as acting director, I had the entire department. So I had to manage frontline nursing staff in infection control. I also had a management engineering division. So although I was involved in issues like that, I totally relied on the quality facilitators to assist me in that and take on part of that.

CHAYTOR, Q.C.:

Q. So it would be this plus the other?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And the process improvement teams, those come in place, I understand, those can be either looking for some area to improve or they can come into place after an event or an

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occurrence to try and investigate well, why did this event take place?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And was there a process improvement team put in place with respect to the ER/PR issue?

MS. PREDHAM:

A. ER/PR was a very different process because it was very large. Every time there's an adverse event, you kind of have to look at what you're going to do or how you're going to investigate it, and ER/PR was a little bit different on all aspects, even going down, when I did the quality review or went down to start the quality review in August of 2005. That was mostly, you know, how would we look into this, how would we go into this process, and it was very difficult because the process that they were using was not the process that we were most concerned about. So, you know, you couldn't even go through that step by step as much. So it wasn't a formal process improvement team that we had here, because, you know, there was a lot of, not

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disagreement, but a lot of information that, you know, to varying what we were dealing with, I guess is the thing.

So from July when I got into the details of it to August when I went down into the lab, there was a lot of different factors that were being talked about of what was really here at play, and when I went down to the lab to do that, it was--I wouldn't have been able to do a good quality review. It needed to have lab people to do that, needed to have a skill set and for our comfort level, we had to go outside like we did.

CHAYTOR, Q.C.:

Q. Okay, and I'll take you through that as we go through. So in terms of usually a process improvement team, would that normally though be people who are involved in the particular program?

MS. PREDHAM:

A. Well, yes, because they're the ones who have to tell you what you've actually done. You know, if there's been a miscommunication issue and that is especially key when you have a large organization, but also when, you know,

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like back in '96, '97, '98 when we were forming the Health Care Corp and of course, in the past few years with Eastern Health, you have a large organization that's busy and complex anyway and then you're merging it with other busy, complex organizations. So especially at times like that, it's very important to have everyone around because that's the way things happen. It gets a bit tangly when you start changing things on the outside. So it's very important to find out what's going on as you're going through that process.

CHAYTOR, Q.C.:

Q. So in terms of not doing anything internally with actually setting up a process improvement team, I can understand, and I'll take you through the decision to go outside and have external reviews carried out, but the decision not to have then anything in the way of from within examining what was happening was because there was--is it too complicated or there's communication issues? Why couldn't there be both?

MS. PREDHAM:

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A. Well, I think there was a variety of factors at the time. You know, we had a--I remember investigating an adverse event a couple of years ago where we watched the staff go through a process with the equipment, just to get a feel of that. So you didn't have that ability here, because at the time, we were--you know, you had the DAKO--the process, the manual system of the process with the DAKO system was of concern, because if you have any kind of manual process the staff are doing, you know, you have that risk of human error anyway. So you didn't have that same process as they were going through.

At the time, we also--we stopped retesting, so it wasn't like the pressure wasn't on us to fix it right now. We had that ability to bring somebody in and review it from external and then assess it from there.

CHAYTOR, Q.C.:

Q. Okay. The occurrence reporting system, and you would have been responsible for the occurrence reporting system in your risk management portfolio?

MS. PREDHAM:

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A. Yes.

CHAYTOR, Q.C.:

Q. And would they, the reports that would come forward, occurrence reporting, they would go to your department?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what would you then do with them?

MS. PREDHAM:

A. Well, everyone--in our department, everyone is linked to a program and whoever gets the occurrence reports for those programs would review them. They've already been reviewed by the manager of that area and in some areas, been reviewed by the program director, and then we would get that. Review them for any action that needs to be taken immediately, and then go through--code them, so they can be entered into the database. Then they would get entered into the database and then reports would be generated.

CHAYTOR, Q.C.:

Q. Okay, and just one question back to the failure mode effects analysis. When did that become a tool that you would use?

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MS. PREDHAM:

A. We started seeing that appearing in the literature probably the end of 2004, somewhere 2005, and in the spring of 2006, we asked ISMP to come down and do that train-the-trainer session again for us.

CHAYTOR, Q.C.:

Q. Okay, and in terms of the--you would also have had responsibility for the, it says, investigation of adverse events. What was in place in terms of policies in the Health Care Corporation which required the reporting of adverse events?

MS. PREDHAM:

A. Well, we had the occurrence reporting policy and then I think in '98, might have been 2000, we also had the critical occurrence policy.

THE COMMISSIONER:

Q. I'm sorry, the what?

MS. PREDHAM:

A. Critical occurrence policy.

THE COMMISSIONER:

Q. Critical, thank you.

CHAYTOR, Q.C.:

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Q. Okay, and when you took on your role as risk manager originally in 1998, would you have been--were those policies in place at that time?

MS. PREDHAM:

A. The occurrence reporting policy was in place. I was part of the development of that as a quality facilitator, but that was in place then in '98, and the critical occurrence policy, we put that in place--I guess we had a fairly significant incident and we had--the way the incident went, it crossed a couple of programs. The program directors happened to be on holidays at that time and there was a lot of miscommunication in the--there was no coordination in the handling of it. It was a very unique situation, but at the time, we felt that there needed to be something else to kind of give guidance to people when something significant happens, something you couldn't rely on an occurrence report. You needed that quick notification, you know, immediate notification, that pulling together everybody immediately, and moving on from there.

CHAYTOR, Q.C.:

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Q. Okay, so perhaps then is the difference between occurrence reporting, and the critical occurrence reporting which you've brought in, is it the magnitude and urgency of the situation?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So what would you expect to show up in an occurrence report, what types of incidents?
MS. PREDHAM:
A. An occurrence report is very broad. Fundamentally, it's anything unexpected, something that you couldn't anticipate. If anything didn't follow policy like a medication occurrence, so if medications were mislabelled, if they were given to the wrong patient or the wrong time or they weren't given, you know, could be any of those varieties, slip and fall, property loss, property damage, a fire, elopement, you know, the very broad numerous ones. Each program and department has been encouraged to identify occurrences in their area themselves, so what's important to them. It's not

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necessarily something in the routine of their work as an occurrence. Like, they need to have that discussion with their frontline staff of what is an occurrence to them. For example, in diagnostic imaging, if you come in to get a CT scan and you have to get contrast, the DI tech will ask you have you ever had a CT scan before, have you had contrast before, are you allergic to anything. So if you're not allergic to anything and you never had this before, you never had a contrast before, and then you broke out in hives, well, that's an adverse reaction to the contrast, but it's not an occurrence because it's an anticipated implication of this. Now if you came in and you did have that and it's on your chart that you're allergic to contrast and we gave it to you, anyway, that's an occurrence.
CHAYTOR, Q.C.:
Q. That's an incident, right, okay.
MS. PREDHAM:
A. Yeah.
CHAYTOR, Q.C.:
Q. So someone getting the wrong medication would be an occurrence?

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you'd expect an occurrence report to go forward?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And so then the critical occurrence would be what, what's the difference?
MS. PREDHAM:
A. Well, something very significant that requires immediate reaction. So if it's somebody--a patient is severely harmed or there's a potential that you think that the patient may be harmed, that, you know--I mean, fundamentally that's the critical occurrence, around patient harm, but anything of that nature.
CHAYTOR, Q.C.:
Q. So imminent danger to a person?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So when you came into the position, you were

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instrumental then in bringing in a critical occurrence policy?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And how do you educate the staff that they should be filling out occurrence reports when those incidents arise?
MS. PREDHAM:
A. Well, it's a continual thing. We've done a lot of occurrence reporting education over the year in--we do them every now and then as it goes on. We do--whenever there's a change to the form or anything, we've done education sessions to all staff or as many staff as we can, but a very systematic scheduled throughout the organization. Any new staff who come in get information on occurrence reporting in the orientation. Medical students, nursing students, they all get occurrence reporting education.
CHAYTOR, Q.C.:
Q. And would you expect occurrence reports to not only cover actual occurrences, but the near miss situation? The patient didn't get the

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wrong medication, but may have had they followed through and not caught it?

MS. PREDHAM:

A. And that's why it's called occurrence rather than incident reporting. Back in '96 when we came together, several of the sites used the term "incident reporting" and that implies that something has happened. So we went with the term "occurrence reporting" because that was--an occurrence could be something that didn't actually reach the patient, so it is that near miss, but that wasn't the terminology that we had at the time.

CHAYTOR, Q.C.:

Q. Okay, and what would you have been calling it at that time?

MS. PREDHAM:

A. Well, it was an occurrence that included the near miss, but near miss is more of a patient safety term that came out in the 2000s.

CHAYTOR, Q.C.:

Q. And has that improved over time in terms of--the time period we're looking at here is from 1997 through to 2005. Has the sophistication of education of the staff improved in terms of

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their awareness of the importance of reporting occurrences?

MS. PREDHAM:

A. Well, we hope so because we continually do them. Now I can only speak to Health Care Corporation, but we've done a lot of education and when patient safety is--patient safety movement was coming, and once we understood, you know, the concepts that are in there, it's even more critical that frontline staff be aware of that. So we've done a lot of education over the years on occurrence reporting, patient safety, system error, individual error. We do that with a lot of areas, we do it with a lot of med students, nursing students. You know, every year I speak to nursing students about occurrence reporting, patient safety, individual error. I do orientation with the med students when they come to work with Eastern Health now, but with the Health Care Corporation. I do--every two years I do education on this with medical residents, and I've done numerous in services throughout, both with professional practice groups--so I would do a session with social

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workers or a session with physiotherapists, and then with the various areas, you know, they have an education day and we get asked to come and present at those.

CHAYTOR, Q.C.:

Q. So have you seen improvement with all your efforts over the years, has there been improvement?

MS. PREDHAM:

A. Yes, I--in 2004, we did a proposal in--we had an internal award system within the Health Care Corporation, a purple and green award, and for the life of me right now, I can't remember the difference between the two, but they were a monetary award that you got. It's a Board initiative to do some kind of process that you would not normally, you know, have the funding to do. So we applied for one or the other of them and got money to launch a patient safety plan. So in anticipation of that, we had done focus groups with our staff, talking about patient safety, and looking at what were the key issues that they were discovering, and then we developed a plan. We had a committee, we had a logo, the branding,

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so we had the money to do all those nice things, and we launched that with a big conference during patient safety week. I do believe it was patient safety week.

CHAYTOR, Q.C.:

Q. And when was this?

MS. PREDHAM:

A. That was in 2004. So then every year we tried to have a conference as well to bring down a national level speaker talking about patient safety, open it for all staff. So it has been more focused since 2004, but before that, we also tried to do that and a lot of the work that went into that came from that risk management network I mentioned that we tried to get national speakers down talking to us about this type of issue.

CHAYTOR, Q.C.:

Q. Is there also a system in place whereby an employee can report a practice that he or she may perceive as posing a risk?

MS. PREDHAM:

A. If they consider that it's--you know, if it's a risk, frontline staff call me all--not all the time, but they do call me and say, you

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know, I think this issue is a risk. There's also--they have professional practice reports which are more professional practice issues. Sometimes they overlap, sometimes they don't, and I do believe all the professional bodies such as--well, I know nursing has it, but I think all the OT, social worker, and all that have that same process.

CHAYTOR, Q.C.:

Q. But is there an actual--so if there's something that's an occurrence or could be an occurrence, your near misses or something that actually happens, there's a formal process, you fill out a form, it comes to your department and then all these are looked at?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. All are looked at to see if you have any trends, and we talked a little about the importance of doing that. Is there a similar type of form or process where an employee could fill out if they saw something that they think this is really getting to the point where we think there's a patient safety issue

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here and we should fill out this, or have they been told, like, the chain that they should go through in addressing those types of issues?

MS. PREDHAM:

A. I think they would fill out an occurrence report for that. We've seen occurrence reports on that type of issue because they would consider that, you know, something is going to happen or something could happen here.

CHAYTOR, Q.C.:

Q. And once then you receive these reports and if you notice a trend, do you or people then within your department have a role then to play in terms of investigating what could be causing the trend?

MS. PREDHAM:

A. Well, we would link with the manager or director of that area and that would be, you know, because we need their--you know, they're responsible for that and we have to support them, but we'd have to go into that area and investigate it.

CHAYTOR, Q.C.:

Q. Okay, and I take your goal to be to try and

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find out what could have caused it and to come to some sort of resolution after having identified the cause?

MS. PREDHAM:

A. Yes. Now in the literature, it's well recognized that there's under reporting in occurrence reporting, so one of our challenges and one of the reasons we do so much education is that we have to encourage staff to report, and we've done up a--we did up a proposal in 2005 for an electronic occurrence reporting system and we were successful in getting funding and that's currently being implemented now.

CHAYTOR, Q.C.:

Q. And I think when we last met for your interview, which is almost a year ago, 11 months ago in November, you had indicated then for electronic occurrence reporting, and it was 1.6 million dollars -

MS. PREDHAM:

A. 1.8 million.

CHAYTOR, Q.C.:

Q. 1.8 million dollars that you received for that.

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MS. PREDHAM:

A. Yeah.

CHAYTOR, Q.C.:

Q. So what stage is that at?

MS. PREDHAM:

A. That--we're in the process of the pre go-live stage implementing that in one area to work out the--you know, we have it all tentatively worked out with the software. We have the Taxonomy done, we have the training plan already done, so we have to work it out in one little area. I guess you could call it a pilot, or that's what I would refer to it as, to work out the logistics of it, and then we move it on. The whole concept, though, behind the proposal of what we--there was a couple of key messages with our proposal and one was that we were trying to use it as a tool to encourage patient safety, to change that culture of patient safety. So it wasn't like, oh, here's your occurrence reporting system, you can stop using paper now, you can use this. It was to say this is what patient safety is all about and this is why it's important to do that. So the focus wasn't on

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the tool, the focus was on the patient safety culture.

CHAYTOR, Q.C.:

Q. On the education of the staff to this patient safety culture.

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. Okay.

MS. PREDHAM:

A. And the other key thing is that we would have our taxonomy, the way the occurrences are described, it's the leverage of both British Columbia, which also got money from Canada Health Infoway, so, you know, it's almost to have that pan Canadian ability to report or compare trends and that across Canada. We've also based it on--the World Health Organization has come out with a draft taxonomy, so we've used that as the fundamental there, so if there's anything worldwide like that, we would have the basic structure of how the occurrences are named so we would be able to do trending like that. We'd have, like, all the same things.

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CHAYTOR, Q.C.:

Q. Okay, and so now there's no difference, I take it, in the actual policy that's in place in terms of occurrence reporting, but the mechanism for reporting will now be done electronically?

MS. PREDHAM:

A. Yes, well, the policy will have to be updated a bit because it was an internal thing that we put in place, but, yes, the fundamentals are no different. If we were just going to--you know, it would have been so easy just to get the software, put it in, and say here you go, this is how you report it right now because it's technically not very difficult to do, but the cumbersome part, the hard part, is to make sure that people are aware of this and use it as an opportunity to try to change the culture.

CHAYTOR, Q.C.:

Q. So if you--if staff sees fit to fill out an occurrence report, it's not currently in place, I take it?

MS. PREDHAM:

A. No.

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CHAYTOR, Q.C.:

Q. It's soon to come on.

MS. PREDHAM:

A. Soon to come on.

CHAYTOR, Q.C.:

Q. So the process will be that they'll actually electronically fill out the form and it goes to you or -

MS. PREDHAM:

A. It will go to the manager and the quality safety leader assigned to that area simultaneously, so there won't be any lag then in time because before we were waiting for a piece of paper to make its way throughout the organization. So that's a great benefit, and the other ability is that the reporter will have a way to get feedback on that if they so wish because that's the other, I guess, a hinderance to people filling out occurrence report, if I'm filling out an occurrence report and I send it away and I don't get that feedback, you know, there is that--you like to know that you're making a difference or that there's a point of filling these things out. So that's one thing that we really wanted in

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this electronic system.

CHAYTOR, Q.C.:

Q. And then so the software that you have, would it--in terms of trying to track any kinds of trends, would it allow you more easily to be able to do that?

MS. PREDHAM:

A. Yes, definitely. I mean, right now to do trending or reporting, you know, we do have limited reporting ability on that, but it's very cumbersome, it's not quick, it's not easy, and if you want to do anything off the standard, just listing of these are the ones that you've had for this area, you have to put it in Excel, you have to--and whatever. Just one click of the button, the manager can do it. So there will be set reports that the manager would like to have that will be available to them, so all they have to do is this week they can go in, how is everything going here and click a button, and there's their information.

CHAYTOR, Q.C.:

Q. Right, so you could search key words? Like, if you need to search "fixation" it would be

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there?
MS. PREDHAM:
A. You could do that.
CHAYTOR, Q.C.:
Q. If you needed to search ER/PR, it would be there?
MS. PREDHAM:
A. It could.
CHAYTOR, Q.C.:
Q. You hope not.
MS. PREDHAM:
A. We hope not.
CHAYTOR, Q.C.:
Q. We heard recently--we heard recently there was a review done of the labs here in St. John's at the request of the Commission, and there was a problem with tissue processors and the charcoal filters hadn't been changed for six months. Would that be an occurrence that would be expected to require a report to be filled out?
MS. PREDHAM:
A. It could be, but sometimes when things are well known or gets this immediate reaction, occurrence report doesn't get filled out. You

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know, usually, and I've always said it, the biggest things that happen in our organization, we never got an actual occurrence report on it because everybody knows about it immediately, and nobody stops to say, oh, I got to let quality know and fill out this occurrence report because we're already involved and we're already in that process. So, you know, it could be, but sometimes it isn't.
CHAYTOR, Q.C.:
Q. But in terms of--so I guess two questions arise. In terms of the--I see the importance of the occurrence report to get the communication to you, but what about the importance of the report for historical documentation so that next year if you're not there, or the next person five years down the road and they can search and see, well, there was a similar situation back in 2008?
MS. PREDHAM:
A. That is a problem, and that's one of the things that we're trying to tighten up with this new system. The old system was so cumbersome to search, there wasn't--you know,

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we didn't see the benefit of, you know, okay, make sure now you fill an occurrence report because then we can search for it, but now where we have that ease and that ability it will make it that much more important to make sure that we do something on that line.
CHAYTOR, Q.C.:
Q. And I take it the policy itself is not optional, that you don't have to fill out an occurrence report if certain people already know, the policy is "you shall fill out your occurrence report".
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And similarly back at the beginning of August, 2005, there was an issue in terms of the Ventana machine and the maintenance not being carried out. At that time, do you know whether or not there was any occurrence report filled out about that?
MS. PREDHAM:
A. No, there was no occurrence report.
CHAYTOR, Q.C.:
Q. No occurrence report, and the recent incident

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in terms of the tissue processor, from what you're saying is that was an immediate situation, we knew about it, there was no occurrence report then filled out?
MS. PREDHAM:
A. Well, I can't say that for sure because I -
CHAYTOR, Q.C.:
Q. You haven't seen one, I take it?
MS. PREDHAM:
A. No, I haven't been there, but I haven't seen one, no.
CHAYTOR, Q.C.:
Q. And you're assuming that if it's not, it's because they know you're well aware of it?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. What if any investigation have you caused to take place as a result of the tissue processor incident?
MS. PREDHAM:
A. Well, I haven't been at work for the past couple of weeks, so I haven't been involved in anything.
CHAYTOR, Q.C.:

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Q. What are others undertaking?
MS. PREDHAM:
A. I don't know.
CHAYTOR, Q.C.:
Q. Okay, but you would anticipate that there will be an investigation of that issue?
MS. PREDHAM:
A. Oh, yes.
CHAYTOR, Q.C.:
Q. And you indicated that one new policy that you saw fit to bring in was the critical occurrence policy. Were there any other policies initiated by you or that have come in since you took on the risk management function?
MS. PREDHAM:
A. Well, I mean, there's lots of policies. I don't think that I initiated them so much. The disclosure guidelines came in place when I was risk manager and the consent policy for Health Care Corporation came in effect.
CHAYTOR, Q.C.:
Q. And you would have worked on both of those, I take it?
MS. PREDHAM:

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A. The consent policy came more as a package. I did the education throughout the Health Care Corporation on that policy, but I didn't have much feedback on that. I was anxiously awaiting it, but it was a large document that was done between ethics and legal counsel. The disclosure policy, I was more part of that policy development. It was originally developed, I think again by ethics, but Dr. Williams and myself were more into finalizing that and communicating that throughout the organization.
CHAYTOR, Q.C.:
Q. And, Ms. Predham, what happens when a matter is brought to your attention either through an occurrence report, or as you say, often major things are just verbally communicated and you learn about it that way, what happens when a matter is brought to your attention that might, in your experience and knowledge in risk management, trigger in your mind that liability could accrue as a result of this?
MS. PREDHAM:
A. Well, once you got the internal processes set up, then you would have to notify the insurer.

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CHAYTOR, Q.C.:
Q. And so if you're thinking there might be some liability for the Health Authority then, you notify the insurer. Is there anything else you do, do you open up a file, do you--is there any difference in how you handle the matter? What do you actually do? So something lands on your desk, you look at it and think this is something that could result in liability ultimately, you phone the insurer and put the insurer on notice, and what else do you actually do?
MS. PREDHAM:
A. Well, I guess, just for clarification, when something comes there, that's not the primary focus, the liability. The primary focus would be that there was a risk or a problem here that needs to be investigated. So the first contact, if it hasn't been from the program director or clinical chief, then is to get the program director and clinical chief involved. At that point, you know, you have to get the key players together to get a plan in place and that's your first step. So depending on the issue, it depends on who you get together.

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It may only be the program director and clinical chief, but it may be depending on that you're going to need some expert advice right from the beginning. If it's an infection control issue, then you're going to need the medical director of infection control, your manager of infection control, around the table as well because you're going to need their feedback to guide you as you go through this. Depending on the issue, if it's a certain subspecialty area, you would need to have a division chief or the manager of that area there to give you that extra information. So the first session--the first meeting would be kind of to set out the plan, who needs to be involved, and then it's how are you going to investigate this, what do you need to do, and every issue like that changes a bit. You know, to come up with how you're going to investigate it, you really need to understand what it is you're talking about and then come up with a plan on how to investigate it, and for every one that we've done, I'm sure they've all been slightly different, depending on who the group is that we get together and

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how often we get together. If there is some kind of potential, you know, if it's a patient complaint and they're very upset, you'd have to involve communications. You had to determine who's going to be the liaison with the patient or the family. So all those things had to be determined.

CHAYTOR, Q.C.:

Q. Yes, and I'm just thinking more from your point of view and, I guess, your determination in your own mind or your own assessment as to whether or not liability, this may be something for which the authority is held liable, or potential liability, that could happen when you--when the reports lands on your desk, that could happen, you may need to investigate, have those meetings that you're referring to, get your team in place, carry out some other investigations, but once you arrive at that point, I'm just wondering if there's any difference in how you, yourself, go about handling the situation from that point onwards? Once you've now made the determination, well, this is the situation, I've had to pick up the phone or e-mail the

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insurer and put them on notice, is there any difference in how you would then handle the situation internally?

MS. PREDHAM:

A. No, because--well, you have to consider what the insurer needs because you've notified them and you're carrying on with your investigation. Sometimes the insurance adjuster would like to take statements from the staff and sometimes that can wait and you can talk to the staff at the same time and get your information at the same time just because you don't want to put them through it twice, but more often than not you've already talked to the staff involved and gotten the information and then they have to sit down with the insurance adjuster. So the insurance adjuster needs certain pieces of information and they need to do certain things, but, you know, you have to do your own thing as well.

CHAYTOR, Q.C.:

Q. And in terms of opening up a file, do you open up a file for every occurrence that's reported to you or to your department?

MS. PREDHAM:

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A. Not every occurrence, but every occurrence that requires, you know, a bit of feedback beyond a piece of paper, beyond a follow up phone call or anything. So if it's beyond one or two pieces of paper that could be stapled to the occurrence report, you would open up a file.

CHAYTOR, Q.C.:

Q. Okay. So I would take it something such as the ER/PR issue, for example, you'd open up a file?

MS. PREDHAM:

A. Yes, certainly.

CHAYTOR, Q.C.:

Q. Several files.

MS. PREDHAM:

A. Several, yeah, a couple of boxes.

CHAYTOR, Q.C.:

Q. And I take it that in terms of opening up that file and how you--and the type of file that you open up, does that differ in terms of whether or not it's a situation for which there may be potential liability?

MS. PREDHAM:

A. No, there's no difference at that point. The

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only time there's a different file as such is if we get a Statement of Claim. So at that point--and my goal, being involved in risk management, is that I don't want to get a Statement of Claim without knowing about it in the first place. That does happen, but I would like to think that--you know, the majority of them we do have some knowledge about that and investigated at that certain level. So when we do get either a Statement of Claim or a letter from a lawyer advising us to notify our insurer, then that's when they go into like a separate area and they're handled a bit differently because then you've got, you know, more focused liaison with legal counsel and the insurer.

CHAYTOR, Q.C.:

Q. Okay. So the trigger for that happening and things being handled somewhat differently is not necessarily when you make the assessment there might potential liability and you've contacted the insurer, it's when you actually receive either a Statement of Claim or notification from a lawyer that they're involved?

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And so then what -
MS. PREDHAM:
A. That mightn't--just to clarify, that mightn't change anything I'm doing. It's just the fact that things get a little bit more formal then, you know, so that there's notification, they have to get that within ten days, there has to be--you know, so we keep that in a separate file and, you know.
CHAYTOR, Q.C.:
Q. Okay, so the legal process itself, getting the Defense filed within the appropriate time period. I'm just wondering what else, what else changes in terms of how the matter is handled once you are notified that you, in fact--legal counsel is engaged basically, what happens?
MS. PREDHAM:
A. Well, it's--I mean, there's not a lot that changes internally, but it's that you have to be aware that there is lawyers involved and you have to take direction, I guess, anything

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that's going to influence or impact on their case, they had to be made aware of, you know, anything, new information, and they also are looking for certain things in--you know, in their--more requests will come in for me, you know, do you have a policy on this, or do you have--you know, that kind of--that kind of thing.
CHAYTOR, Q.C.:
Q. Okay, so then you--and when you say the lawyers who are handling the case, I take it you mean the lawyers who are handling it on behalf of Eastern Health?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So then you keep them in the loop as to what's happening?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you--in terms of them yourself and your role in taking direction on the handling of a matter, does that change once legal counsel have been engaged?

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MS. PREDHAM:
A. Not really, other than they're looking for specific things. Well, you know, you'd have to keep them up to date, they're looking for certain things. They may have a different perspective on that. You know, they might be more concerned about a different aspect on it that we're not directly concerned about, or that we feel is handled. Now that may have an influence on--you know, it may be something we never thought of, but, no, usually it's, you know, we just have to follow that process along with them.
CHAYTOR, Q.C.:
Q. And what's the importance of keeping the lawyers handling the case informed, what's the importance of doing that?
MS. PREDHAM:
A. Well, you don't want to undermine your insurance coverage. I guess that's the key thing, so you have to make sure that they're aware and in order to provide our defense, part of our policy or agreement with our insurers is that we notify them of all potential claims and keep them aware of that

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information. So, you know, you wouldn't want to keep them in the dark about something if they're going ahead because they're going on their own way down that legal route, and I don't know everything that they're doing as they go along that, so I wouldn't want to have some information that they've gone down a certain away and unaware that this is what's happening over here.
CHAYTOR, Q.C.:
Q. Or take a particular course of action that may ultimately end up undermining your insurance coverage?
MS. PREDHAM:
A. Well, exactly, because that's--you know, you wouldn't do that for your house or your car insurance either.
THE COMMISSIONER:
Q. I just didn't quite understand what it is you were saying when you said that you didn't want to undermine the insurance company--the insurance coverage, sorry?
MS. PREDHAM:
A. Okay, the--I guess just that fundamental, that you don't want to, you know, do something in

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which you're inadvertently admitting to liability unbeknownst to--you know, you're doing some action that could be perceived that you're admitting to liability here. I guess that's the ultimate thing, you don't want to do something that, you know, you're going to admit--to be held that you're going to admit to something and you're not really.

THE COMMISSIONER:

Q. Okay.

MS. PREDHAM:

A. I guess it's just--you know, if you get into a car accident and on that little plastic thing that's in your glove box and it says, you know, do not admit blame, that's that type of thing, so you want to make sure that any actions that the organization is doing, that you're not going to admit blame inadvertently when you don't really mean to.

CHAYTOR, Q.C.:

Q. And would you also not want to do anything which could potentially create a cause of action where one might not otherwise exist?

MS. PREDHAM:

A. Oh, definitely.

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CHAYTOR, Q.C.:

Q. Because that might undermine your insurance coverage as well?

MS. PREDHAM:

A. Yes, yeah.

CHAYTOR, Q.C.:

Q. And when I started asking you about this and how things differ once legal counsel are engaged, you started to say in terms of you have to take direction, and I'm just wondering, you have to take direction from whom at that point in time?

MS. PREDHAM:

A. Well, it depends. It could be the insurance adjuster. Certain claims are handled at that level entirely. It could be legal counsel as well. They could pass it off to legal counsel. It all depends on the situation.

CHAYTOR, Q.C.:

Q. And if legal counsel or the insurance company or their representatives were to indicate to you that if you take a certain course of action, you could potentially undermine your insurance coverage for a given claim, I take it that would be fairly significant advice for

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you then to take?

MS. PREDHAM:

A. Well, I'd certainly have to pass that on very quickly and -

CHAYTOR, Q.C.:

Q. To others.

MS. PREDHAM:

A. Make sure that people are aware of that because that's---you know, that's something that would require a decision, you know, higher than me.

CHAYTOR, Q.C.:

Q. And that could have significant influence then on the course of action that you choose to take?

MS. PREDHAM:

A. Yes. There have been circumstances, not very often, where--you know, I can think of one in particular in which someone wanted to be reimbursed for cost that we totally agreed with, and it was taking myself and Dr. Williams an exceedingly long period of time to get them to agree to that, the insurance company to agree to that, and actually I was to the point where I was almost embarrassed to

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pick up the phone from that family any more, and Dr. Williams agreed to reimburse that family for that cost, you know, and we'd have to live with whatever the insurance company--however mad they got at us for that. So there are circumstances in which we've done that, but that's not taken very lightly.

CHAYTOR, Q.C.:

Q. And the insurance company's concern would be that you would confirm the cause of action by making any payment?

MS. PREDHAM:

A. Yeah, I guess that's the way you would put it.

CHAYTOR, Q.C.:

Q. In terms of the ER/PR issue, when did you open up your file?

MS. PREDHAM:

A. I think it was July 12th I actually got the details of it and it was then, that's what I opened up my file and I think that's also when I notified our insurance adjustor.

CHAYTOR, Q.C.:

Q. And I'm sorry, when was that?

MS. PREDHAM:

A. July 12th.

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CHAYTOR, Q.C.:
Q. July 12th.
THE COMMISSIONER:
Q. What did you say, you notified whom?
MS. PREDHAM:
A. I notified our insurance adjustor.
THE COMMISSIONER:
Q. The adjustor.
CHAYTOR, Q.C.:
Q. And in this context, that would be whom?
MS. PREDHAM:
A. That was Ray Walsh at the time.
CHAYTOR, Q.C.:
Q. And what happened on July 12th to make you make the decision that I need to open up a file and I need to phone Mr. Walsh?
MS. PREDHAM:
A. Well I had a meeting with Dr. Williams the beginning of June, I can't remember the date now, but it was about other issues and at that meeting, he said there's a problem in the lab and he gave me a slight overview of it and he gave me a copy of a letter that Dr. Cook had given him. In that, Dr. Cook had said that he didn't know if it was a big issue or not at

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that time and, but if it was, he was going to have to get our department involved. So Dr. Williams was giving me a heads up on it and said this could be nothing or this could be something big. And I asked him what he wanted me to do at this time and he said, nothing right now, I'll let you know what comes out, they're further investigating and I'll let you know at that time.
CHAYTOR, Q.C.:
Q. Do you recall when in June that was?
MS. PREDHAM:
A. I'm thinking June 10th, but I'd have to look at an actual--it was on a Thursday, probably the first or second week of June, yes.
CHAYTOR, Q.C.:
Q. Yes, okay. Sorry, okay, you can go ahead.
MS. PREDHAM:
A. So June 12th I had a meeting--Dr. Williams asked me to come over to a meeting with himself, Mr. Gulliver and Dr. Cook, and that's when I got the details of what was going on.
CHAYTOR, Q.C.:
Q. Okay, so was it June 12th then that you -
MS. PREDHAM:

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A. July 12th, sorry, I said June, didn't I.
CHAYTOR, Q.C.:
Q. July 12th, okay, so between June 10th and July 12th, things were quiet on your end with respect to this issue?
MS. PREDHAM:
A. Yes, very quiet.
CHAYTOR, Q.C.:
Q. So you heard nothing after that initial meeting with Dr. Williams when he gave you a little bit of a heads up, but it may be nothing or it could be something. And then July 12th is when you have your meeting.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And coming out of that meeting then is when you opened your file and phoned Mr. Walsh?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and I'll take you to that in a little while. I just want to go back to a moment then in terms of what you do in the general and broader sense, in terms of your quality

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and risk management. And I'm wondering whether or not the quality department, and forgive me if that's not the actual term, but -
MS. PREDHAM:
A. That's okay, we've had so many names over the years, quality is just as good as any.
CHAYTOR, Q.C.:
Q. Yes. I'm wondering what your department does to ensure-what it does, if anything, to ensure that the various programs have in place an appropriate quality assurance program?
MS. PREDHAM:
A. We can't--well the program directors are responsible for--the program directors, the clinical chiefs, the department directors are responsible for quality and risk management in their areas. They report into a portfolio committee currently in Eastern Health, which reports into Regional Quality Council, and they have to report on a regular basis. Each of the quality safety leaders are linked with the leadership and are in close contact with them. So they would be aware of the type of thing that they're monitoring, the type of

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occurrences that they have and through that, would have a comfort level with what type of quality activities that they have on that area.

CHAYTOR, Q.C.:

Q. That's the current process?

MS. PREDHAM:

A. Which is much the same as it was in the old Health Care Corporation.

CHAYTOR, Q.C.:

Q. So the program director and the clinical chief would be responsible for making sure that there's an appropriate quality assurance program for their particular program and they would report up to which committee, up to, say, 2005?

MS. PREDHAM:

A. Up to 2005, it would be corporate quality initiatives and that was the corporate wide quality committee.

CHAYTOR, Q.C.:

Q. And so if there were any short comings in a Quality Assurance Program for any given area, you would expect the Corporate Quality Initiatives Committee to be made aware of it?

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MS. PREDHAM:

A. Yes, they would have to report annually on that. There was a structure that they would have to report to use to do that, and so with their indicators, you could see that they would have a broad base there and you'd have-- there was a format to develop your indicators, so there were eight dimensions of quality and they would like to have indicators in each of those dimensions and they should be reflected in the documents that come up in Regional Quality Council.

CHAYTOR, Q.C.:

Q. And are you aware as to whether or not any issue ever got brought to the Corporate Quality Initiatives Program regarding any inadequacies in the Laboratory Medicine Program, Quality Assurance Program?

MS. PREDHAM:

A. No.

THE COMMISSIONER:

Q. Are you aware or no, there was none.

MS. PREDHAM:

A. No, I wasn't aware.

CHAYTOR, Q.C.:

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Q. You're not aware if anything got brought forward to that committee?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And so, for example, we've heard here that the IHC component of the pathology lab did not have any external proficiency testing in place in the relevant time period, that's not something that was ever brought to the attention of the Corporate Quality Initiatives Program?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And is that something that was ever brought to your attention or your department's attention?

MS. PREDHAM:

A. No, until ER/PR came up, I never knew what immunohistochemistry was or that there was a portion of the pathology lab was dedicated to that, so this was all new, a new area.

CHAYTOR, Q.C.:

Q. So July 12th, you had a steep learning curve ahead of you.

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MS. PREDHAM:

A. Very steep.

CHAYTOR, Q.C.:

Q. Well you're in good company. And in terms then, what else your department does in the overall quality aspect, a little bit more on the quality aspect, would you be involved at all, for example, in performing any audits?

MS. PREDHAM:

A. We have from time to time, we're more involved in developing the audits or assisting the programs in developing the audits. It depends on what the audit is for and it's usually initiated on request of the area. There was a documentation committee, there may still be, but I'm not on that, but as part of that, we were involved in developing and documentation audit and we would assist areas in doing the analysis of the audits when they get them done for that matter. Depending on an issue, you know, in certain areas you would have specific issues that they would like to take a period of time to audit and look at that and focus in on that area for a period of time. And we've done that over a period of time as well.

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CHAYTOR, Q.C.:
Q. Okay, and in this particular case, we've heard of some short comings in the Laboratory Medicine Program in terms of documentation, for example documentation to verify that routine maintenance is being carried out on equipment, documentation in terms of standard operating procedures, were those things ever brought to the attention of the Quality Department?
MS. PREDHAM:
A. Not that I'm aware of, no.
CHAYTOR, Q.C.:
Q. And when did you first become aware of those issues?
MS. PREDHAM:
A. When I went over in August to just start that quality review.
CHAYTOR, Q.C.:
Q. Okay, and we'll come to that. And do you know whether or not those issues were ever brought to the attention of the Corporate Quality Initiatives Department?
MS. PREDHAM:
A. I never sat on Corporate QI until I became

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acting director, but I'm not aware of, I don't think so.
CHAYTOR, Q.C.:
Q. And that would have been in January, 2004 that you became the acting director.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So in terms of any function that your department would have in carrying out documentation audits, it would, should that happen, I take it look for things, such as is your daily, monthly maintenance being carried out? What documentation do you have in place in terms of standard operating procedures, those are the kinds of things that you would be looking at?
MS. PREDHAM:
A. Well, you'd like to do that because if staff had to document things, you want them to make sure that they're documenting something that's meaningful. So if you have staff who are spending, you know, have tick off lists of two sides of it, you want to make sure that it's meaningful and you also want it to reflect the

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practice that they're doing. So we've been involved in documentation issues where, you know, there's a tick off list which the staff have been doing for ever and a day, but it no longer effectively reflects what they're doing and no longer effectively documents what they're actually doing. It's just that this has been in practice forever and nobody really thought about it, it's just something we always did. So we've been involved in that kind of thing. Also in areas where you want to cut down on the amount of documentation that they're doing, that they're spending a lot of time or documentation is not getting done because it's so cumbersome, but in fact, it's a lot of extra stuff, you don't really need to get--you're not really documenting the important things. So situations where we have been involved in that, that's the type of thing that we've been looking at.
CHAYTOR, Q.C.:
Q. Okay, and in terms of what each department would be acquired to submit to the Quality Initiatives Department and, of course, we've talked about occurrence reports. Are they

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also required to submit annual reports to the Quality Initiatives Department?
MS. PREDHAM:
A. Not to us because we're only a support department, so they are responsible for quality and risk management, that's the way the framework or the structure has, so they submit those to Corporate QI, that's Corporate Quality Initiatives, as well as their VP or whoever they report to would have to get a copy of that. So that's that line responsibility, as well as the quality committee structure, so we could be involved in the development of their quality program and that changed, of course, over time. I mean if you're linked with a program director and back in '97, you're over meeting and coming up with the way their quality report is going to be, by the time 2004 rolls around and it's you and the same quality director, you're not involved--like, they're well on their way of doing that on their own.
CHAYTOR, Q.C.:
Q. Okay, so we've seen quality initiative reports here coming out of the Laboratory Medicine

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Program, so those go directly to the Corporate Quality Initiatives Committee?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. That's where those go.

MS. PREDHAM:

A. Right.

CHAYTOR, Q.C.:

Q. And your staff, the quality facilitators may be involved in helping them come up with the annual report and the content for the report, but you don't actually get a copy of the report?

MS. PREDHAM:

A. No. We may, now it depends on, you know, the program director may send it to the facilitator, but I guess that just depends on the individuals involved.

CHAYTOR, Q.C.:

Q. And does your department, the Quality Department, have any role in ensuring performance evaluations are carried out on the staff in the various programs?

MS. PREDHAM:

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A. Not directly, we do have a role with accreditation and so that is always an issue with accreditation, so we'd have a role from that aspect of it and also as an indicator, you know, if the percent--the number of people that are doing occurrence reports who have actually got it done, that would be one of the indicators that we would look at. But Human Resources would take more of a direct role on ensuring that.

CHAYTOR, Q.C.:

Q. And if it were, though, to come to the attention of your department that performance evaluations were not being carried out on a regular basis, is that something that your department would be interested in addressing?

MS. PREDHAM:

A. We'd be interested in it, but I don't think that we've got that--there was a lot of effort put into that from Human Resources, so I don't think we would add anything to that, as such.

CHAYTOR, Q.C.:

Q. Okay. And I may have asked you this last day, but your current location, the Quality Initiatives Department, where are you

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currently located?

MS. PREDHAM:

A. The St. John's, well, the bulk of our department is at Southcott Hall, down by the Miller Centre and we have quality safety leaders located at Cordage Place, at Hoyles Home, Carbonear, Clarenville.

CHAYTOR, Q.C.:

Q. Okay, and in terms of having quality and safety -

MS. PREDHAM:

A. Leaders.

CHAYTOR, Q.C.:

Q. Leaders, are there -

MS. PREDHAM:

A. They were the quality facilitators.

CHAYTOR, Q.C.:

Q. They're the quality facilitators.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, so there's one at the Hoyles Home and is that person then for all of the long-term care facilities?

MS. PREDHAM:

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A. Yes.

CHAYTOR, Q.C.:

Q. And the person in Carbonear covers what area?

MS. PREDHAM:

A. Rural Avalon.

CHAYTOR, Q.C.:

Q. Rural Avalon. And where is the St. John's person located, in your offices or Cordage Place, is it?

MS. PREDHAM:

A. We have two now in St. John's that are located at Southcott Hall for the St. John's hospitals, well one is for St. John's hospitals, one is for regional services.

CHAYTOR, Q.C.:

Q. So there's no personnel from your department located directly within either St. Clare's or the Health Sciences Centre?

MS. PREDHAM:

A. No, anyone from St. John's hospitals is located with us at Southcott Hall.

CHAYTOR, Q.C.:

Q. At Southcott Hall. And when did you move to Southcott Hall?

MS. PREDHAM:

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A. In January 2004.
CHAYTOR, Q.C.:
Q. Okay.
THE COMMISSIONER:
Q. You said that your department was only a support department?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. So I just sort of want to be clear I understand roles and where there are obligations, so is the reporting of incidents, which you've described earlier in the morning, and--let's start with the reporting. Is that the sole function where somebody has an obligation to report to you, as opposed to somebody going to your department to say in carrying out this role that we have, we would like your assistance?
MS. PREDHAM:
A. Just so I get clear what you're asking, if a frontline nurse fills out an occurrence report, that goes to their manager who has to investigate that.
THE COMMISSIONER:

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Q. Uh-hm.
MS. PREDHAM:
A. After that investigation is done, it comes to our department then to review it, to see if there's any further investigation from our perspective or if there needs to be any assistance.
THE COMMISSIONER:
Q. Yes, but that's a clear line that nobody can-- as I understand what's been said, but perhaps I'm incorrect, there would be--if, once an occurrence report is filled out, it should get to you.
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. At some point.
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. But what I'm really wanting to know is whether or not within a department that has its own quality person, with its own quality initiatives, have they any obligatory contact with you or is it just if within that

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department they feel they want your assistance because they're developing a new approach or just because they want somebody to review their procedures or for any other of a myriad of reasons, is that the kind of circumstances they come to you or is there a role for your department to walk in and say, okay, do you have quality initiatives and let me have a look?
MS. PREDHAM:
A. For a person in the department being a quality person in the department, that's a new structure for us, so I guess we're working that out.
THE COMMISSIONER:
Q. Okay.
MS. PREDHAM:
A. They would be responsible to ensure that the quality policies, procedures, the frameworks are all in place there and certainly they can ask our assistance, and have. But if there's any occurrences or anything, we have to take the responsibility of making sure that the follow up was done and that it's there. We've never gone in, I guess no one in quality as a

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big stick, you know, for want of a better term. We have, diplomacy, I guess is our biggest tool and we have to go in there and work with staff to do that, so we're not an auditing type of department.
THE COMMISSIONER:
Q. Uh-hm.
MS. PREDHAM:
A. Once we get in there to look at something, we can say, well is that really showing you what you need to look at? Do you have this? Where is that, well you really need -
THE COMMISSIONER:
Q. But in the reporting procedure at the end of the day, as I understand your evidence a little earlier, it goes to a committee, not to you.
MS. PREDHAM:
A. No, yes.
THE COMMISSIONER:
Q. So it's only that occasionally you might call up somebody and wander in, in your own diplomatic way that you get to put your fingers into a department, as it were.
MS. PREDHAM:

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A. Well it's linkages between the quality facilitator or the quality person linked with that department and the leadership team. And those, the quality facilitators in our structure that we have now, are on the portfolio committees where all the program directors and where those reports come in. So they have a more, you know, they're involved in that more than they were with the Health Care Corporation on that level.

THE COMMISSIONER:

Q. Okay.

MS. PREDHAM:

A. Does that answer your question?

THE COMMISSIONER:

Q. Well, it does in the sense that I now know where the information goes, but I'm still understanding that in fact within your department the only flow of information that is required is the incident reports.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Okay, thank you. Oh, while I'm at it, what about staff safety, is that covered in an

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incident report or does that go through another system?

MS. PREDHAM:

A. That goes through Occupational Health & Safety. There are times when an occurrence report and an employee incident report will be completed for the same issue.

THE COMMISSIONER:

Q. Yes, uh-hm.

MS. PREDHAM:

A. But that goes through Human Resources.

THE COMMISSIONER:

Q. So, for example, if we're dealing with a laboratory where, as I understand it there may be dangerous material, that becomes an issue that would probably be handled, not by you because it's unlikely that a patient would necessarily be involved, et cetera, et cetera.

MS. PREDHAM:

A. Well if there was a spill, you know, that was not handled correctly, that, you know, should be filled out on two forms, whether or not it is or not, you know -

THE COMMISSIONER:

Q. So it's a question of whether or not it falls

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within the definition of an occurrence, but it may not, it may be handled entire on the Occupational Health & Safety side.

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. All right, thank you.

CHAYTOR, Q.C.:

Q. Ms. Predham, the failure mode affects analysis, I understood your description of that is to evaluate any new system or testing coming into effect. Is there any similar process in place to evaluate your current or existing systems and processes?

MS. PREDHAM:

A. Well that would be our process improvement team, that's what we've done all along.

CHAYTOR, Q.C.:

Q. Okay, so that's the type of issue that we discussed earlier as to what -

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And they could do that on a proactive basis, as well as after an incident?

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MS. PREDHAM:

A. Well, yes, you know, but I guess the failure mode affects analysis is for an anticipated program or something because you want to have that fully upfront before you have it running, before any problems occur after it's set up. But if you had, if there were concerns that weren't fill out occurrences, you could put in a process improvement team to try and work that out, or it may be a situation where, you know, you've got information from another board or from somewhere else and look, they had this problem, let's look at our system and see what we have here. So you could do a process improvement team that way.

CHAYTOR, Q.C.:

Q. Okay, and I guess what I'm wondering is any other proactive aspects to Eastern Health's quality and risk management practices.

MS. PREDHAM:

A. Other than the staff education and trying to utilize occurrence reporting, you know, that whole near miss concept that you're getting it before it actually something happens. It's very difficult with the resources that we've

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had to be proactive as much as you would like to be, you know, you don't want anything to ever happen. I mean, things are going to happen, but you want to be able to deal with it beforehand and you certainly don't want to ever get in a situation where you investigate it with staff and staff are telling you that, geez, this is only a matter of time this happened, that's your worse case scenario, you don't want ever to have that happen.

CHAYTOR, Q.C.:

Q. Okay, and who is responsible for ensuring that appropriate policies and procedures are in place for each program? Is that also the leadership team of that program?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So that's the clinical chief and the program director.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And making sure that they are updated when required, that falls within their

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responsibility.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And does your program do anything to monitor that?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And is your program involved at all in policy development for the various programs?

MS. PREDHAM:

A. Not for the various programs, up to 2006, we were responsible for the Admin Policy Manual and co-ordinating the development of the policies in that.

CHAYTOR, Q.C.:

Q. And the admin policy development would have included the institution-wide disclosure policy?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Who is responsible for that generally?

MS. PREDHAM:

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A. That's in Policy and Research, I think that's the name of the department now, I think.

CHAYTOR, Q.C.:

Q. The example that you gave in terms of when I was asking you about taking direction from the insurer's representatives from time to time, in terms of not wanting to undermine any--your insurance coverage and you gave the example of Dr. Williams, this family was waiting to have, to be reimbursed for travel expenses and I understand from what you're saying, you took the chance and paid them, this family had waited long enough. In doing that, and paying out in light of any caution by the insurer, I take it it would depend on what value or quantum the claim ultimately might be. For example, if that were a multi-million dollar potential liability, you'd probably be more prone to take your direction from the insurer?

MS. PREDHAM:

A. Yes. And that was, you know, a very unusual circumstance as well.

CHAYTOR, Q.C.:

Q. Now, Ms. Predham, you indicated that your knowledge level prior to this coming on in

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2005 in terms of immunohistochemistry, anyhow, would have been fairly low, as was I would think a lot of people who ultimately got involved. In terms of the laboratory medicine program overall, you indicated yesterday that at one point you were the quality facilitator for the laboratory medicine program. Had you spent much time actually in the laboratory, either St. Clare's or at the Health Sciences?

MS. PREDHAM:

A. Over the years I've had the opportunity to be in the lab several times, different parts of the lab, and, you know, we've had occurrence that have happened that have required an investigation, that I've talked to various technicians and physicians throughout the lab over those years.

CHAYTOR, Q.C.:

Q. Okay, and in -

MS. PREDHAM:

A. But never immunohistochemistry.

CHAYTOR, Q.C.:

Q. Never in the IHC portion of the lab?

MS. PREDHAM:

A. No.

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CHAYTOR, Q.C.:
Q. So no experience at all with that, okay. If we could have, please, P-0697, and these are minutes of a meeting of the laboratory program, divisional managers meeting, and it's March 4th of 2007, and you'll see that Vern Whelan is present, Lynn Wade, and these are just names that we've heard before, and Mr. Gulliver is absent. Under QI issues on page two of this exhibit, it says, "The Internal Advisory Committee for the laboratory program has been set up and the first meeting held. The membership is as follows", and again we see Mr. Whelan as program director, Dr. Haegert as clinical chief, and then a number of other physicians, and then Lynn Wade, manager of client services, and we see yourself mentioned as QI facilitator, and it says, "Membership will rotate and the terms of reference are being established. Divisional sub-committees will be set up and will report back to the IAC, which will probably meet every second month, and the IHC will report once a year to the Senior Advisory Committee". What do you recall about this, the setting of

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an Internal Advisory Committee for the lab program and what was to be the mandate of that committee?
MS. PREDHAM:
A. Well, the structure at the time, each program was asked to, and department as well, was asked to set up internal and external advisory committees, and the internal advisory committee would be looking at, you know, the goals, the objectives, indicators, policies within that program and department, and fundamentally would advise the program director and clinical chief on developing their quality report which would go to--it was called Senior Advisory Committee at that time, that was early '97, but became Corporate Quality Initiatives.
CHAYTOR, Q.C.:
Q. So that's the same as Corporate Quality, okay.
MS. PREDHAM:
A. I'm pretty sure, yeah.
CHAYTOR, Q.C.:
Q. And I believe Dr. Haegert had thought that you were instrumental in initiating this internal advisory committee?

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MS. PREDHAM:
A. Oh, it might have been. That was -
CHAYTOR, Q.C.:
Q. He wanted to give you credit.
MS. PREDHAM:
A. Oh, did he? Good. Well, the structure was set up, the quality structure was set up, and all our--especially at that time we were only new to the job and establishing, so I guess instrumental would have been "we have to set up an internal advisory committee and I think it's about time".
CHAYTOR, Q.C.:
Q. So it may have been your suggestion?
MS. PREDHAM:
A. Yes, but the structure was this was what all program leadership were asked to do. The External Advisory Committee was more successful in some programs than others. That was--the concept behind the external one was that they would look at stakeholders in the organization or outside the organization who use the service, and that would be who would be on the External Advisory Committee. Certain areas such as mental health had a much

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more successful one because they were--they were--they had a patient/client advisory committee set up at the Waterford that preexisted that. So with the lab, with an external advisory committee, it would be more users of their system was the intent there.
CHAYTOR, Q.C.:
Q. Okay, and according to these minutes, terms of reference were being established. Did those ever get drafted?
MS. PREDHAM:
A. I do believe so. I think the lab Internal Advisory Committee did meet for a period of time.
CHAYTOR, Q.C.:
Q. And that was going to be my next question, whether or not--what happened to this committee, did it get off the ground, how frequently did it meet, and what ultimately happened to it?
MS. PREDHAM:
A. I do remember the committee meeting. I can remember a couple of meetings distinctly, like, right off the top of my head. I remember talking about, you know, certain

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issues that were--I guess one of the key things at this point in time was that they had to come up with standardized practice throughout the city, throughout the Health Care Corporation, and for a service department like the lab, that was--that was a key thing that they had to do. If you have a certain practice in one area, you had to have the same practice in all areas now that you're one organization, or you have to have reasons why you can't have that, and also with the lab, I know one of the first things that they were doing was they were combining the biochemistry labs and the microbiology labs. I'm not sure of the timelines on that, but that would have been some key activities that they would have been involved in, but also practices that they had--I can remember this meeting distinctly, but I can also remember another meeting that was held in which the discussion of panic values, you know, what the process is if you get a panic value in the lab. The practice was slightly different at the different hospitals, so they had to come up with a standard policy for that. So I can remember

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that draft policy coming to this group and having that discussion on the process there.

CHAYTOR, Q.C.:

Q. And so you were--this was after the Health Care Corporation came into existence?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you were trying to standardize processes for the laboratory medicine program?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. At that time. By the time you were no longer responsible as QI facilitator for the laboratory program, was this committee still active?

MS. PREDHAM:

A. I can't remember that. I know--if this was--I think this was March of '97. So I wouldn't have been linked with them after January of '98, but I can remember a couple of meetings, like I said, but I don't know.

CHAYTOR, Q.C.:

Q. Okay, and if we could have then, please, P-

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0056, and this is an administrative policy manual and the section is quality and it's consumer feedback. If we could--actually, I think it's page 12, the one I was more interested in bringing your attention to. Yes, this is the occurrence reporting one. So I assume this is the one we spoke of earlier?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. This particular one is dated October 22nd, 1997. That's the original date, I understand the "O" to mean, and it's from quality occurrence reporting, VP Corporate Affairs, and do you recognize this signature?

MS. PREDHAM:

A. George Tilley.

CHAYTOR, Q.C.:

Q. George Tilley, and the policy states, "The occurrence reporting process is a component of the Health Care Corporation's quality plan in ensuring the ongoing monitoring, evaluation, and improvement of quality care and service", and occurrence is defined as any event, accident, error, or circumstance which is not

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in keeping with expected process or outcome of care or service, and occurrences may result in any injury to an individual, damage, or loss of equipment or property, and this is the one that was in place when you took on risk management, I take it, in 1998?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Or the risk manager, I should say, position, and then you told us that you had another critical incident policy?

MS. PREDHAM:

A. Critical occurrence policy.

CHAYTOR, Q.C.:

Q. Critical occurrence policy also drafted. On page 13 of the document, it refers to clinical outcome, "The assessment and treatment the patient may need arising from an occurrence", and--sorry, over here, if you see outcome, the result of a particular event, and then we have clinical outcome, the assessment and treatment a patient may need arising from an occurrence. Then page 14, "Responsibility. Occurrence report forms are available through stores at

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each site, and any staff members that observes/discovers the occurrence, after providing immediate attention to the situation, shall initiate an occurrence report at the time of the occurrence according to the guidelines", which include, and then there's a list of guidelines, and document facts, a patient's condition on health record where applicable, do not place occurrence report or reference occurrence report on the health record. Ms. Predham, what did you understand why was that the policy not to put the occurrence record or even reference that one had been filled out on the health record?

MS. PREDHAM:

A. That is as old as when I first came into nursing. That was always the thing that you do not do that. The primary thing, I guess, is to ensure confidentiality of the person filling it out, like, you wanted to make sure that it's a fairly confidential process if you're going to fill one out and put your name on it, but also is--you know, later when the Evidence Act came in, is to try to ensure that it remains protected under the Evidence Act.

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It's not part of the health record, it's not part of the clinical process, it's a quality assurance activity, and I guess it's to differentiate between the two of those.

CHAYTOR, Q.C.:

Q. So while the person who is filling out the occurrence report signs their name, they understand that they're doing that confidentially and that that will never be disclosed?

MS. PREDHAM:

A. Right.

CHAYTOR, Q.C.:

Q. And were occurrence reports then treated with a degree of protection from subsequent disclosure?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what was the basis for that, what is--is it because it was considered to be a quality initiative?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

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Q. And something then protected under the Evidence Act?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And that was always the position taken by Health Care Corporation, and you say as long as you've been a nurse, so even before that?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what about the current situation in terms of how are occurrence reports treated?

MS. PREDHAM:

A. The same--the same way. When we decided to put in the electronic version, it would be much easier if we could link it somehow with some kind of database of patient demographics, it would save a lot of time, but we didn't want to integrate it any part with the clinical record, we wanted it to remain as a standalone system.

CHAYTOR, Q.C.:

Q. And the program department management section, this is now on page 15 of the exhibit, and I

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take it this means the program/department management, that would be the program who's reporting the incident?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. As well as--or the department at that time. That doesn't refer to the--does that refer at all to the QI department?

MS. PREDHAM:

A. No, no, that's--the Health Care Corporation had program management for the clinical programs, but all the other, either support programs, or clinical support, or support programs were referred to as departments. So anywhere you see program, it would be program/department. You're just referring to the different areas in the organization.

CHAYTOR, Q.C.:

Q. So review the occurrence, initiate an investigation and follow up process, that would be the department or program, for example, the laboratory medicine program?

MS. PREDHAM:

A. Right.

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CHAYTOR, Q.C.:
Q. But your department would also have a role once you received the occurrence report? You would have a role in actually initiating and following up?
MS. PREDHAM:
A. Yes, and I think there should be a section there about our department's role.
CHAYTOR, Q.C.:
Q. "Discuss all occurrences resulting in actual or potential patient injury, or that have implication for significant complaint. Forward completed occurrence form within 48 hours to your staff", to staff of Quality Initiatives, "and report significant occurrences immediately to the applicable VP or Vice President on call, and to Risk Manager by next working day". Okay, so they would be expected if it were what seemed to be a significant occurrence to let the VP know and yourself?
MS. PREDHAM:
A. And that was--when we did the critical occurrence policy, it was always there as part of the policy, but we wanted to strengthen

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that and put more substance around it.
CHAYTOR, Q.C.:
Q. Okay, and then page 16 is the part for the quality initiatives program, and it says, "To monitor trend and provide summary reports on occurrences to the program department leadership on a quarterly basis and upon request". So I guess more frequently if requested. "Retain all original occurrence reports and copies of related follow up forms", and does that still happen, Ms. Predham, or do you keep them for a certain period of time?
MS. PREDHAM:
A. We keep them two years plus the fiscal, and I think we wrote up--when we decided we were actually running out of room, we wrote up a policy to confidentially destroy them after a certain period of time.
CHAYTOR, Q.C.:
Q. And will that still be the situation once it's done electronically or will you be able to keep them longer?
MS. PREDHAM:
A. Well, there won't be any paper copies then.

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It'll be all on the database and we'll have them.
CHAYTOR, Q.C.:
Q. But -
MS. PREDHAM:
A. We do have a -
CHAYTOR, Q.C.:
Q. But it still exists, the document--the record would still exist?
MS. PREDHAM:
A. Right, we do have--whatever goes in the database is still there from '97, so we still have that, but we don't have the paper--pieces of paper.
CHAYTOR, Q.C.:
Q. Okay. "Assist programs/departments in identifying, controlling or preventing their risk issues". I take it that's the proactive aspect, and the "Risk Manager liaises with the insurer and/or legal counsel as appropriate", and we discussed that. Then if I could have, please, P-0056, page eight, and this is the critical occurrence incident review, the original date being September 30th, 1999, and it's revised June 20th, 2002. So I take it

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this is the policy that you were involved in having created?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And it pertains to critical occurrences incidents review. It was--and it's signed off here by Pamela Elliott, and it was revised in June of 2002, and do you recall were you involved in that time and what the revisions would have been about?
MS. PREDHAM:
A. I can't remember what the revisions were about. I remember we revised it and we also did a lot of education around the organization as well with the managers about that, but I can't remember what the revisions would have been.
CHAYTOR, Q.C.:
Q. Okay, and this is similar to what we discussed we have on page nine of the document, the procedure, and who would play various roles and, for example, you mentioned about meeting to determine who will chair the investigative team and designate who liaises with the

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family, and the role of the VP and the clinical chief and then quality initiatives risk manager notifies insurer, secures and reviews chart and related documents and equipment. If student is involved, notifies appropriate school. So it would be the responsibility of the risk manager, and we've talked about notifying the insurer, but securing and reviewing the chart and related documents and equipment, what would that be referring to?

MS. PREDHAM:

A. Well, that's--you know, you'd have to look at the chart, see what the chart says. It's one of the processes that you would go through, one of the activities that you would go through, anyway, and, of course, you mentioned in the occurrence report there was loss control, so any documents or equipment that was involved, you'd have to ensure that that was retained and locked up.

CHAYTOR, Q.C.:

Q. Okay.

MS. PREDHAM:

A. Or secured.

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CHAYTOR, Q.C.:

Q. And on page 10, it says here, "Note. If any of the leadership team members are involved in the critical occurrence, the vice president will designate alternates to investigate, and I take it the reason there being that you wouldn't want to those people to be put in any potential perceived or actual conflict of interest?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And if we could have, please, page 18 of this document, and this section is called legal/ethics guidelines on disclosure of adverse events, and this is dated September 9th, 2004, and signed. Do you recognize this signature?

MS. PREDHAM:

A. I assume it's George Tilley, but that looks like a "J" at the beginning.

CHAYTOR, Q.C.:

Q. And August 1st, 2005, and I think we may have heard that it was Dr. Williams, but I'm not sure now, it's been a while.

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THE COMMISSIONER:

Q. VP of Medical Services.

CHAYTOR, Q.C.:

Q. VP Medical.

MS. PREDHAM:

A. Yeah, but it looks like a "J" at the beginning.

CHAYTOR, Q.C.:

Q. And then this indicates the definition of an adverse event and how it's defined, and this is originating on September 9th, 2004. Do you know, Ms. Predham, was there a similar disclosure policy prior to this?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. There was nothing in place before?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And you were involved in drafting this?

MS. PREDHAM:

A. There was a draft done, I believe through Ethics had done an original draft. It was much longer than this is my memory of it, but

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I was involved in finalizing this draft and a lot of the communication with the clinical chiefs before it was finally approved.

CHAYTOR, Q.C.:

Q. Okay, and an adverse event is defined "as an unexpected and undesired incident directly associated with the care or services provided to the patient and/or an incident that occurs during the process of providing health care and results in patient injury or death and/or an adverse outcome for a patient, including an injury or a complication", and I'm just wondering in terms of by this point in time, the difference between an adverse event and a critical occurrence event?

MS. PREDHAM:

A. Well, see at this time patient safety literature was growing and there was some disagreement on what you would call, you know, an occurrence, and adverse event was more in the literature. As well, just before this, there was a provincial patient safety committee established that was coordinated through the Department of Health, and they had surveyed all the boards and asked if we could

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agree to use the definitions that were used by the patient safety dictionary provincially for consistency purposes, which we all agreed to, and then this was the first one where we used one, so we had agreed to do that and we weren't really happy with the definition, but--you know, because it's kind of cumbersome, but that's the terminology that we went forward with.

CHAYTOR, Q.C.:

Q. Okay, so if something were, though--I take it the other policy I had just directed you to which came out of--it was a quality policy on the critical occurrence/incident review, that remained in effect?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Because that was more geared towards how -

MS. PREDHAM:

A. To investigate it.

CHAYTOR, Q.C.:

Q. - you were going to go about investigating the issue, and then this is dealing with how it's actually going to be disclosed?

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MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. So both of those policies continue to exist side by side?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay.

THE COMMISSIONER:

Q. Ms. Chaytor, wherever you can find a convenient spot, we'll take the morning break.

CHAYTOR, Q.C.:

Q. And in terms of the procedure, "provide prompt attention to the situation or eliminate or reduce immediate and potential risk, and initiate an occurrence report" and then it actually refers back to your policy on occurrence reporting, and it's the same number as what I'd shown you on page 12. So that policy too, I take it, was still in existence?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Yes, okay. This would be a convenient time, thank you.

THE COMMISSIONER:

Q. All right then, we'll take 15 minutes.

(BREAK)

THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. Registrar, if we could have, please, P-0057? And those, we understand, are some current policies that are in place.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you'll see the first one here on page one is Disclosure of Adverse Events, and original approval date is August 28th, 2007, and to be reviewed then December 2007, and do you know whether or not the review of this policy took place?

MS. PREDHAM:

A. It's currently under review now. We were waiting--we put this in as an interim policy with Eastern Health waiting the disclosure guidelines that CPSI were releasing. So in

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anticipation of that, we figured that it would be around that time, but I think it was more in the spring that they got released.

CHAYTOR, Q.C.:

Q. So it's still currently under review?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And so this document is still the document that's in effect?

MS. PREDHAM:

A. Yes, because the other one is being developed right now.

CHAYTOR, Q.C.:

Q. Okay, and this, of course, discusses, as the name suggests, "disclosure of adverse and sentinel events to patients, clients, residents, and substitute decision makers must occur in a candid and timely fashion and follow specific standardized protocol" and then under the disclosure itself, it speaks of "the person making the disclosure must: concentrate on what happened and the possible consequences, remain factual, refrain from opinions on care and/or service of others,

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take the lead in disclosure, outline a plan of care to rectify the harm and prevent recurrence for this person and others," and what would you expect that to include?

MS. PREDHAM:

A. Just before I answer that question, this policy and the preceding one was always--was written in a single patient kind of mind set when we wrote that. So you had a single patient that something happened to and you were telling them about that. So that's where that came from. So here, the clinician or the person who is speaking to the patient or the family would be saying this is what we've done since then and this is how we're going to prevent that from happening again.

CHAYTOR, Q.C.:

Q. Yes, and of course, there were such meetings with respect to the ER/PR issue where there were individual meetings with patients.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So this would be--D would be talking about well, here's how we're going to -

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MS. PREDHAM:

A. It could be handling your individual care right now, so you know, you are going--this is what we're going to have to do now. You're going to have to have this other test done. You're going to have to have surgery, whatever. And this is what we've put in place to prevent this from happening again.

CHAYTOR, Q.C.:

Q. Okay. So it would have to involve some discussion with the patient or the person affected as to what had happened and what was being done to rectify the issues that had been identified?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Yes?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And it says "document the discussion in the health record," and then the linkages for this particular policy refer to the occurrence reporting policy, sentinel event policy and

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the consent policy, and the next page has the definition of adverse event again. And then on page five, we have the--and again, this is quality and risk management's occurrence reporting, and this one was approved as well August 28th, 2007, December 2007, and has this one been reviewed?

MS. PREDHAM:

A. No, because the new policy will come in place when we're establishing the electronic occurrence reporting system, so you know.

CHAYTOR, Q.C.:

Q. So you'll update it then?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, all at the same time. So currently, this is the existing policy, without any revisions?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And under overview, "the occurrence reporting process is a key component of Eastern Health's quality and risk management framework in

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pursuit of improved patient, client, resident safety" and "the system facilitates the identification, monitoring and analysis of adverse events, sentinel events, hazards, incidents and near misses" and we've discussed some of that this morning. "Occurrence reporting is not designed to place blame on individuals. Eastern Health is committed to upholding the following characteristics of a culture of safety. Individuals are encouraged to raise concerns about actual and potential hazards and risks and safety issues. Individual and organization accountability are promoted."

And I'm wondering, Ms. Predham, what this means "individual and organization accountability are promoted" and how it's promoted through this?

MS. PREDHAM:

A. Well, I guess, as I mentioned, you know, the 85/15 rule, 80/20 rule, it's a system error and that you have that understanding that the majority of things that go wrong in an organization is because of the way that we do things. However, you do have a small part of

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that in which the individual is accountable for their actions and I guess, it's just recognizing that.

CHAYTOR, Q.C.:

Q. Okay, so while somebody can be accountable or held accountable for their actions, the occurrence reporting in and of itself is not designed to place any blame on any particular individual?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. So it's a differentiation between someone being blamed, as opposed to someone being held accountable, should it be deemed appropriate for that to happen?

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. And "investigating errors requires evaluating of all systemic factors that may have contributed to errors, instead of focusing on individuals to blame. Investigation of occurrences provides opportunities to improve the safety of services delivered. Feedback on

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occurrences is important to learning. Under the Evidence Act, occurrence reports are protected from legal proceedings." And I'm just wondering with respect to that, and if we look back to page two, the disclosure policy, and documenting the discussion in the health record, including the discussion of how to rectify the harm and prevent recurrence, how do you go about doing that while at the same time the occurrence report being afforded any protection?

MS. PREDHAM:

A. Well, I guess, if you're--you know, you're sitting down and disclosing to a patient and part of it is that you're going to outline a plan of care. I don't know, looking at that now, how much detail would be in a health record from, you know, clinicians disclosing an adverse event, how much would be in there about what steps we're doing to prevent this from happening again actually, now that I read this in this venue. But you know, it would be very appropriate to put in there that, you know, discuss the implications and the impact on this patient and what we're planning on

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doing to rectify, you know, whether the care or treatment or whatever. There may be some reference to discuss current procedures or changes that have been made, but I don't think that there would be a lot of detail put into the health record about what as going forward.

CHAYTOR, Q.C.:

Q. And whether it's in the health record or not, in terms of disclosing it to the patient in the meeting with the patient, would there be any difficulty in doing that?

MS. PREDHAM:

A. No, because you're disclosing facts and facts are never held back. They're not--you know, they're not privileged or anything like that, the facts of it all. The reason that you encourage the occurrence reporting is to be kept confidential is that the--even though you want them to report the facts only, there tends to be a lot of opinion in occurrence reporting.

CHAYTOR, Q.C.:

Q. So for example, your understanding is under the Evidence Act, while the occurrence report, you could claim that the occurrence report is

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privileged, any facts that are contained in the occurrence report would not be afforded protection?

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. Okay, and that would be true also of any external review reports or any reports that are claimed to be peer review reports?

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. Okay. So for example, any finding by Dr. Banerjee that pathologists were not--that he'd saw instances, looking at slides, where pathologists were not looking for internal controls, that would be a fact?

MS. PREDHAM:

A. That's a fact.

CHAYTOR, Q.C.:

Q. Okay, and there wouldn't be any particular protection of that information? That's your understanding?

MS. PREDHAM:

A. That's my understanding.

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CHAYTOR, Q.C.:
Q. So in terms of what then--what would be held back from being told to the patient or otherwise disclosed?
MS. PREDHAM:
A. From a peer review, quality review, that type of -
CHAYTOR, Q.C.:
Q. Yes, from either what shows up in your occurrence report, because I would think an occurrence report, this is your employee writing down, here's what happened. What would be held back from an occurrence report that wouldn't be able to be disclosed?
THE COMMISSIONER:
Q. It seems to me that there's two different questions here. One thing is what's being told to the patients.
CHAYTOR, Q.C.:
Q. Yes.
THE COMMISSIONER:
Q. What's being put on the chart, and the other is what goes in the occurrence report.
CHAYTOR, Q.C.:
Q. Yes.

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THE COMMISSIONER:
Q. Do you make any distinction between what's being told to the patient and what goes on the chart?
MS. PREDHAM:
A. No. I mean, if the--the way the disclosure typically happens, and that's covered off with a disclosure policy, is that the physician who's involved in the situation or it could be the clinical chief in that area, depending on the circumstances, would sit and talk to the family and say "this happened to you. We have to tell you, you know, you've received the wrong treatment" or the wrong surgery or whatever, and disclose that information to them, and then that discussion there would be reflected in the patient's record. So you have a record in their health record that they have been disclosed this information.
THE COMMISSIONER:
Q. But if you have a discussion with a patient's family or a patient having disclosed an error, it's one thing to walk in and say, you know, "I took off the wrong leg" and that's all pretty factual and pretty evident, in terms of your being able to say well, that's just factual. But it seems to me that the conversation which follows is going to involve the expression of an opinion in the normal course. If you have received the wrong medication, if you have been misdiagnosed, if you have had an incident in the OR during the course of removal of one organ and the other one gets damaged, it seems to me that unless you're going to tell the patient the mere fact that it occurred, the following dialogue has to involve the opinion of the person telling them about the impact, how it occurred, the impact on the family, or otherwise it's going to be a strange conversation, and it's going to sound to the patient like you're trying to keep information from them rather than disclose.

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MS. PREDHAM:
A. And I guess, just taking it back a little bit. If we had--if we got a call tomorrow that, you know, someone had the wrong organ removed in the OR, you'd have to--you know, you have to disclose them and tell them that an investigation is underway to determine how exactly that happened, because of course, they had to be told immediately. During that investigation, you may go through a quality review process where you get other people involved and you want them to have the ability to tell you exactly what they think, like it could have been this person's fault or that person, you know, whatever, that type of discussion. But the facts of what you piece together at the end of the day has to be told to the patient because that's--this is what we think happened. This is what we think the facts are, or this is what we know the facts are.

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So I guess, unless I gave you an actual concrete example, it's hard to explain, but it's--quality review, peer review is a critical tool that we have to keep the concept of it protected because we have to make sure that people are willing to talk to us and tell us exactly what they think and be fully open with us. So if we don't keep that protected, then we won't have--they won't come forward and tell us what they think happened, because that's the only way that we're going to know.

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In a circumstance like that, the best that you could probably do is that we think this is what happened, or we think that these are the contributing factors, and then that's what you go forward and tell the family, because that's what you believe really happened. But it wouldn't be, you know, Doctor so and so really thinks it's this and Doctor so and so thinks it's that. It would be this is our understanding of what could have happened here, and this is what we tell them. You have to be completely honest with the family, but you also have to protect that ability for people to tell you what they really think happened.

THE COMMISSIONER:

Q. When you bring it down to the kinds of information that I've been getting here, it seems to me that there is a--I will say possibility, but perhaps a probability that in that process of protecting the information which you hold so dear, you could mislead.

MS. PREDHAM:

A. I would say that there could be a possibility, but I don't think that there would be. I know

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that sounds a bit odd, but I've been involved in a lot of circumstances where I had to tell family members bad news, and--I'm sorry. But, in those circumstances--can we just -

CHAYTOR, Q.C.:

Q. Take your time.

MR. SIMMONS:

Q. Would you like to take a break?

THE COMMISSIONER:

Q. Do you want to take a break? Take a couple of moments.

MS. PREDHAM:

A. A couple of minutes.

THE COMMISSIONER:

Q. Sure.

(BREAK)

THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. You okay now?

MS. PREDHAM:

A. Yes, sorry about that.

CHAYTOR, Q.C.:

Q. No troubles. Ms. Predham, I just want to explore this a bit further, in terms of how

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you balance then what you understand can be protected as opposed to what gets told to the patient and just explore that a little bit more with you, and in the example that you were given, in terms of if you had Dr. A say one thing and Dr. B say something else, in that situation, what do you tell the patient?

MS. PREDHAM:

A. You'd have to--you know, you'd have to work through and you'd have to feel very comfortable that you've got the story of what happened here. If people had different opinions, then that would lead you to further investigation. So if somebody had "I think this is a contributing factor, I think," well then, you'd have to go and investigate that. You'd have to look at--if somebody is saying that's not the proper practice or this is what we need to do here or we didn't do this and this is what should be done, well then, you have to investigate that to see what you can determine, and at the end of the day, you should be able to piece the story together exactly what happened, and you know, sometimes--each one is different, but you try

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to actually get to what happened, and with a family member, we, more than one time, have gone through a step-by-step process of what led to the circumstances which have affected either them or their family member, and given that to them in writing that at such and such a time this has happened, just a concrete type steps and then use that to say this is a contributing factor.

There have been times when we have given a summary of opinion and, you know, not said to this is so and so's opinion or Dr. so and so's opinion, that this is what happened, this is the best guess that we can have that happened here, you know, and basically, that's what it is. We can't narrow it down any further, but this is what we think has happened.

CHAYTOR, Q.C.:

Q. And so, and again, your understanding is that anything that's facts, any facts that you've determined or any expert retained on your behalf have determined, any factual--anything that's factual would be told to the patient and your understanding is that that's

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permitted, in terms of any protection claimed under the Evidence Act?

MS. PREDHAM:

A. Oh yes.

CHAYTOR, Q.C.:

Q. And that's been the position of Eastern Health for some time?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And I take it that's been--there's been legal advice sought on that and that's the opinion?

MS. PREDHAM:

A. Oh yes.

CHAYTOR, Q.C.:

Q. Okay, and so for example then, in the ER/PR issue and anything that may have contributed or caused what ultimately happened in resulting in changed results over a period of time, issues such as fixation issues, lack of standard operating procedures, lack of documentation in general, issues of pathologists not checking the internal controls and whether or not that may have been able to determine anything, but not having

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done that, those types of things, those would be facts?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. So all of that information could have been disclosed?

MS. PREDHAM:

A. Yes. Now they're facts as such as those were things that were found that could be a contributing factor, but how big a role that they played, that would take the analysis of the, you know, fundamental data, I guess, from the NLCHI database to go through and say okay, for fixation, for example, we had these many conversions that went from zero to whatever. How many of these had poor fixation? For the ones that went from a low expressor to a high expressor, how many of these had low fixation? So we'd have to--and then how many that stayed the same, how many had low fixation? So that part, as far as I'm aware, unless that's being done right now, up to a little while ago, that hadn't been done and that's a critical part that has to be looked at.

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CHAYTOR, Q.C.:

Q. But in terms of overall, in terms of--and as you say, this is a different situation. You weren't dealing with an individual case. So overall, looking at the massive retesting and how these may have been contributing factors, there'd be no--there would have been no difficulty in coming out and stating these are issues that have been identified? These are the facts that we've been able to under cover or others, on our behalf, have been able to ascertain?

MS. PREDHAM:

A. Yes, yes and no. I guess we didn't validate--whenever you have a person who comes in to do an external review, they're giving their opinion on what they see and what process they see, and I think before we went out and said that these are contributing factors, although we're--yes, okay, fixation, it's very clear that that seems to be that. I think we'd need to have the data just to validate that as there, just for our comfort level, to say that that is that contributing factor, and I think that may have been a bit hesitant in doing

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that until we had that information.

CHAYTOR, Q.C.:

Q. I'm sorry, what data is it that -

MS. PREDHAM:

A. You know, the overall, the retest results. So the overall retest results and how many times did fixation, that poor fixation was evident on the ones that converted.

CHAYTOR, Q.C.:

Q. And what was Eastern Health doing to try and ascertain that?

MS. PREDHAM:

A. Well, that was part of the analysis that we were going to be doing once all the results were back and the patients were notified and all that. That was a critical part in that analysis that had to be done.

CHAYTOR, Q.C.:

Q. And by the time this Inquiry is called in May of 2007, had Eastern Health undertaken that?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. Okay. Ms. Predham, and the issue, I guess, of any quality assurance measures or lack of

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quality control measures that may have been an issue or come into play, and those would have been some things that, I take it, in your own investigation, you would have determined?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. You would have seen yourself, and some of the issues that already spoke of, certainly would have been identified by Dr. Carter?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Apart from the external reviewers, Dr. Carter. So in terms of being able to mention those, those would be considered facts?

MS. PREDHAM:

A. The fact that there was no documentation and -

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And that there was no overall quality assurance program, that there was no external

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proficiency testing taking place for the IHC laboratory.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. All of those are facts?

MS. PREDHAM:

A. All those are facts.

THE COMMISSIONER:

Q. You said a little earlier that there might be, at the end of the day, a kind of summary of opinion. Did I get that right, when you're communicating to somebody?

MS. PREDHAM:

A. There might have been--I guess what I was trying to say that if you were investigating something, you may not ever know exactly what went wrong in a certain circumstance. So then you'd have to say, you know, I guess, this is our best guess. This is, of talking to everybody, doing an external review, this is the opinion that we've come--that we, of what has happened in your circumstance. So really, you are still only giving an opinion, but you have to give a reason of what happened.

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THE COMMISSIONER:

Q. So are you--well, if you have a situation where the only opinions you have are those from sources that might be protected, are you saying that you could do a summary of that opinion for the purpose of the discussion with the patient, but you couldn't actually let them see what the opinion was?

MS. PREDHAM:

A. Well, yes, I guess in a way you can, because you wouldn't want to say that Dr. X thinks this happens, you know, think that this happened or this is a contributing factor. You could say "we, investigating this, taking all the information that we have, think that this is what happened." There's been very few times that we actually haven't been able to elicit exactly what happened. I can't think of anything where I haven't been able to explain to people that this is what happened, these are the series of facts or these are the--you know, this is what happened.

CHAYTOR, Q.C.:

Q. And Ms. Predham, in this situation, ER/PR testing resumed at Eastern Health in February

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2007. So I take it, by that point in time, Eastern Health had assured itself that it had identified the key factors or the contributing factors and causes of the issue and had addressed them prior to putting the testing back in place?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Ms. Predham, you attended some meetings with patients regarding the ER/PR issue?

MS. PREDHAM:

A. Yes, not very many, but yes, I did.

CHAYTOR, Q.C.:

Q. And did you attend any--was it just DCIS patient meetings or were there others as well?

MS. PREDHAM:

A. I didn't attend those. Actually, I think I only attended one early on with Dr. McCarthy.

CHAYTOR, Q.C.:

Q. Okay, and was it a patient who had changed results?

MS. PREDHAM:

A. It was the sister of a patient who had changed results.

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CHAYTOR, Q.C.:
Q. And was that relative told any of the facts that I just listed?
MS. PREDHAM:
A. Well, that was early on, so we didn't know any of that. That was, I think the beginning of September 2005.
CHAYTOR, Q.C.:
Q. Okay. So anything that Dr. Carter had done, in terms of her review, would you have known that at that point in time?
MS. PREDHAM:
A. I don't think I knew a lot of details of what Dr. Carter had found at that time.
CHAYTOR, Q.C.:
Q. To your knowledge, during the meetings with the patients, do you know what was told to patients, in terms of disclosing the causes or potential causes of the problem?
MS. PREDHAM:
A. No, I don't know actually. I don't know how they came up. I know I've spoken to lots of patients on the phone, the confirmed negatives, and some people wanted to know what happened and some people didn't want to know

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much of anything, and you know, I guess the message that I gave to them was that we were investigating it at that time, up to February of 2006, but also that, you know, we couldn't confirm that we were doing the test as best that we could at the time. So we had to stop doing it right now and then we had to retest.
CHAYTOR, Q.C.:
Q. And in speaking to the patients who wanted to know, did you tell them any of the potential causes that had been identified up to that point in time?
MS. PREDHAM:
A. I didn't get into detail of saying that there was fixation. We knew that there was--I guess the biggest message I was trying to tell them was that there wasn't anything obviously the cause, there wasn't one thing that there was a cause, that we had identified several issues that had to be addressed and you know, and we were looking further into it at that level.
CHAYTOR, Q.C.:
Q. And in terms of telling them what some of those, whether it's one thing or many things, in terms of telling them the many things that

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had been identified, did you ever tell them any of those things, such as fixation, such as the lack of quality assurance and quality control measures, the lack of any issues that may have come up in the lab, in terms of standard operating procedures? Were they ever told -
MS. PREDHAM:
A. I didn't get into detail, other than there was--they wanted to know if it was a person or if it was one, like one thing, like what was the cause, and I said that we had found that there was a contribution of many things that could have caused this but that there was no one individual or a thing that could have caused this.
CHAYTOR, Q.C.:
Q. And so in asking what is the cause, you understood them to be looking for just one thing?
MS. PREDHAM:
A. The people I was talking to was looking for that.
CHAYTOR, Q.C.:
Q. And in your experience in investigating

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incidents and occurrences, is there usually one cause?
MS. PREDHAM:
A. Sometimes there has been one cause. Sometimes there is, you know, one contributing factor that you can fix and take care of, but most of the times it is a series of events.
CHAYTOR, Q.C.:
Q. Thinking of the swiss cheese.
MS. PREDHAM:
A. Yes. But even in the swiss cheese event, usually it's just a gap in a process that is not a cause as such. It's just a -
CHAYTOR, Q.C.:
Q. It's a contributing factor.
MS. PREDHAM:
A. If that had been in place, this wouldn't have happened.
CHAYTOR, Q.C.:
Q. Yes, it's a contributing factor.
MS. PREDHAM:
A. It's like a stop gap or a double check. But this one here, there was a lot of things that could have contributed to it that we had no way to confirm whether or not it did or not.

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You know, like during the process, because the process wasn't there any more, because there was no documentation, we couldn't go through and look and say, okay, there's a period of time that there was a lot of conversions or something and this lot number of a dilutant was used, or you know, there was--so there was no way, and we'll never know if there was any kind of process thing or documentation or that the wrong dilution was used or any of those times were wrong or humidity was wrong because there's no documentation to verify it.

CHAYTOR, Q.C.:

Q. Okay, and why isn't there any documentation to verify that?

MS. PREDHAM:

A. Those processes weren't set up to document all that.

CHAYTOR, Q.C.:

Q. And do you know what--where that documentation, in terms of your dilutions over a period of time, where that information may have been kept?

MS. PREDHAM:

A. As far as I could ascertain, it wasn't kept.

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Now I know there was some information that would be computerized, but I've only found that out recently, like within the past six months, I suppose, but at the time when I was over investigating that, there was no records at that time. What I was looking for wasn't in existence.

CHAYTOR, Q.C.:

Q. Okay, and so that came to your attention about six months ago, you say, in terms of computerized records that may have been available?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and how did it come to your attention six months ago?

MS. PREDHAM:

A. I can't really remember now the circumstances, but I know it was--I found out that there was other documentation that was in the computer and that IT had to be involved in getting that out. I think I got notified by IT, whether or not I was aware of any records or if I could point them in a direction of exactly what they

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were looking for, and at that time, I found out that there were some records.

CHAYTOR, Q.C.:

Q. And so in your investigation of this, that was never brought to your attention?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And I take it six months ago it would be the Ventana records that you were looking at?

MS. PREDHAM:

A. Yes, it must have been. Yes, that it would have been in the computerized system in that, I guess.

CHAYTOR, Q.C.:

Q. Well -

MS. PREDHAM:

A. I can't -

CHAYTOR, Q.C.:

Q. - Eastern Health didn't have -

MS. PREDHAM:

A. - I really can't think of it right now.

CHAYTOR, Q.C.:

Q. - Eastern Health didn't have the DAKO machine -

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MS. PREDHAM:

A. Didn't have the computer, no.

CHAYTOR, Q.C.:

Q. - in its possession any more.

MS. PREDHAM:

A. So it must have been the Ventana.

CHAYTOR, Q.C.:

Q. Yes.

THE COMMISSIONER:

Q. I'm sorry, I'm not understanding that. Did I take it that IT consulted you because they'd been asked to do something and they weren't quite sure what they needed to do?

MS. PREDHAM:

A. Well, they called about--I hadn't really thought about this lately, exactly what it was. It was a bit vague and it was something to do with some records that were sent over and they couldn't locate them, and it was for the Commission, I do believe, but they called over just in case I knew what--any further description because I think, you know, somebody who had taken it may have been on holidays, so you had somebody who was trying to look for something, could I describe this

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in any detail, and I didn't know what they were talking about.

THE COMMISSIONER:

Q. So you, from that conversation, believed that there might be records, computerized records which had to do with?

MS. PREDHAM:

A. Something internal of the processing that they went through, some processing part.

THE COMMISSIONER:

Q. So some part of the process involved in ER/PR?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Might have been computerized--might have involved a computer and there might be records?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Which this particular person was trying to retrieve?

MS. PREDHAM:

A. Right.

THE COMMISSIONER:

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Q. But they didn't quite know what it was they had to retrieve because they were calling you?

MS. PREDHAM:

A. Yes.

MR. SIMMONS:

Q. Commissioner, if I might help?

THE COMMISSIONER:

Q. If you can.

MR. SIMMONS:

Q. Those are the records from the Ventana machine that have been produced, and I think there was just IM & T were trying to locate the backup disc on which the information had been stored. It was located after and those have been produced.

THE COMMISSIONER:

Q. All right. So we're talking here about the Ventana records?

MR. SIMMONS:

Q. Right, the ones from when the Ventana machine was first put into use in January of, going to say -

MS. PREDHAM:

A. '04.

MR. SIMMONS:

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Q. - '04.

CHAYTOR, Q.C.:

Q. The ones that were produced during Barry Dyer's evidence?

MR. SIMMONS:

Q. Yes, exactly.

THE COMMISSIONER:

Q. Thank you, Mr. Simmons.

CHAYTOR, Q.C.:

Q. Ms. Predham, so did--in saying that then, did it--are you saying that while then it occurred to you when this request came to you, approximately six months ago, well that it occurred to you if this exists on the Ventana machine, is there similar documentation we could have had from the DAKO computer over the relevant time period?

MS. PREDHAM:

A. Well, I mean, yes, it occurred to me, but the machine was no longer around anywhere, so it--at the time, even when we went over, it was no longer there. So you know, any documentation that could be in there, and I wouldn't know exactly what it was, was lost.

CHAYTOR, Q.C.:

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Q. And six months ago when that notion dawned on you because of the request regarding the Ventana, did you then pursue that with anyone? Did you take it up with Mr. Gulliver, Mr. Dyer, anyone else to inquire as to well, do we have similar records anywhere, even though the computer is not here, do we have these records on a disk anywhere or are there hard copies? Did you take that up?

MS. PREDHAM:

A. Well, I had gone through all that at the time, in 2005, with them about records, focusing mostly on the DAKO at the time.

CHAYTOR, Q.C.:

Q. But you didn't understand--I'm understanding you to say you wouldn't have known enough about it at the time to ask for those particular types of records. So six months ago when you're asked for a similar request or it's brought to your attention regarding the Ventana and then it occurs to you, "well, if it exists on this system, what about on the old system?" Did you then go and specifically ask anyone about do such records exist from the DAKO days?

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MS. PREDHAM:
A. Not at that time, no.
CHAYTOR, Q.C.:
Q. And have you ever since?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Okay. Just go back to what you tell and don't tell a patient, in terms of any causative factors. If it is multiple issues involved and we're looking at our swiss cheese and no one incident probably in and of itself or one factor could have caused the event, but it contributed and without it, the event would not have occurred. Do you tell then each step along the way, so that this happened to you because A, B, C, D and unfortunately on the particular day that we were dealing with your care, all of those holes lined up and we have your event. So is that the kind of factual information that you would give to the patient?
MS. PREDHAM:
A. It really depends on what the patient wants to hear and how much detail that they want to

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have, and sometimes when--in my experience in talking to people, the first time you give them information and then about six months or something, they come back and want some more detail, and you know, then it depends on that circumstance. You know, I've talked to people about, you know, some terrible things and you know, some of the contributing factors, they seem so futile, you know, like so unfortunate.
CHAYTOR, Q.C.:
Q. Yes, okay. So in terms of we just think about some of the factors that we've heard about certainly in this Inquiry which may have contributed, things that Ms. Wegrynowski found, things that Dr. Carter noticed, things you yourself found, and I'll take you through some of that in terms of what you yourself were able to ascertain in your investigation, and things that Dr. Banerjee found. So taking all of those different factors and for example, the internal controls or not looking at internal controls.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

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Q. While that, in and of itself, didn't cause the problem, the fact that you have that hole in the cheese and if pathologists had been checking for the internal controls, could it have been picked up earlier -
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. - you know, in 2003, 2004, as opposed to when it ultimately is picked up. So in terms of that being a hole in the cheese, would that-- you'd have no hesitation should the patient want that kind of detail, you'd have no hesitation in disclosing that type of information to the patient?
MS. PREDHAM:
A. No, no.
CHAYTOR, Q.C.:
Q. That these are the issues that not only do we think contributed, may have, in fact, caused this problem to go undetected for a period of time?
MS. PREDHAM:
A. Yes, and the circumstances in which I was telling people, it was unusual, I was on a

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phone talking to people. I was calling the people who were confirmed negative, so their treatment hadn't changed, you know, they stayed the same and, you know, the other thing was that when I tell them this, I give them my number, my name, and my contact number, and all the people who called the confirmed negatives would do the same thing, and that if they had any questions, they could tell us about it, they could call and ask, and, you know, it was--you were telling them a lot of information at this time, and it's a very complicated, you know, thing, and each one was so different that--when you were on the phone with the people. So the amount of information that you're giving them is kind of judged on that. It's hard--it was a hard disclosure to make because you're on the phone and you don't know how much they're understanding what you're saying anyway.
CHAYTOR, Q.C.:
Q. You had a script, I believe, that you were following?
MS. PREDHAM:
A. We drafted up a script to kind of stick to,

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but you can't really stick to that as you're going along. You do get the concepts out and it's good to refer to, to make sure you've covered everything off.

CHAYTOR, Q.C.:

Q. I just want to be clear then, any of the patients who did ask you and were interested in knowing what happened or what may have caused this, your answer to them was, "It wasn't any one thing", and at no point did you tell anyone it may have been or we have some reason to believe these are some of the things that may have contributed?

MS. PREDHAM:

A. No, I never went in that detail.

CHAYTOR, Q.C.:

Q. I'm wondering, I guess, then, Ms. Predham, in the spirit of openness and disclosure to the patient, why you wouldn't have?

MS. PREDHAM:

A. Well, I guess I was just taking the lead from talking to them on the phone. It was--you know, like I said, in my past experience in talking to patients and you give them the information, you kind of take the lead on how

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much information they want and they need, and you give them the opportunity to call you back and go through that discussion with them. No one had asked for greater detail than that, and, you know, that's just the circumstances that arose.

CHAYTOR, Q.C.:

Q. And so in asking what caused this and answering that question, you didn't just tell them everything that you knew up to that point in time?

MS. PREDHAM:

A. Well, I guess, at that point, Ms. Chaytor, if you're talking to someone and I'm explaining this test to them, and a lot of people didn't know that they had this test done, you know, so you're--you're explaining that this is an ER/PR test, that this was used. You had to differentiate the fact that this was not anything telling them that they didn't have breast cancer or not, that this was not a mammogram, this was not the diagnostic test, this was the--especially if they were negative and confirmed negative, this may not have even been in the scope of them disclosing that, so

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in that conversation where you're having this fact that you had this test, it was negative, it came back, you're confirmed negative, so everything is the same with you, there's no impact on your treatment, and then, you know, and having that discussion of again who you are, and that you can call back, and that you can, of course, call your doctor and if you have any questions, call me back. There was a lot of information to be giving over the phone, and it was also difficult to judge what people were taking in because some people just said, yes, yes, yes, no questions.

CHAYTOR, Q.C.:

Q. But the ones that come back and say, well, what happened?

MS. PREDHAM:

A. There was very rarely anybody who wanted more information than what I had told them.

CHAYTOR, Q.C.:

Q. Right, but there were people who asked you what happened, and you didn't tell them everything that you knew up to the point that you're speaking to them?

MS. PREDHAM:

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A. I didn't tell them about fixation, and I didn't get into that level of detail.

CHAYTOR, Q.C.:

Q. Did you tell them anything that you knew as to what may have gone wrong?

MS. PREDHAM:

A. I told them that there was not one thing--there wasn't one thing that went wrong, there was a multiple of things, that we weren't 100 percent sure what it was, and that we were investigating it.

THE COMMISSIONER:

Q. Ms. Predham, you referred to the difficulty of doing this over the phone. What was your position--let me go back further. Were you part of the group that decided to do it over the phone?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. And were you in favour of doing it over the phone or not, and if you were in favour; why, and if not, why?

MS. PREDHAM:

A. At the time, I think there was a lot of

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logistical problems. When we came to the meeting that we were going to disclose to the people who were going to be retested, we were still talking about a letter, and there was a lot of logistical things with the letter, you know, the addresses, registered mail, we had problems with MCP numbers, you know, this type of thing, and I remember at that meeting that Dr. Williams said forget it, we're going to call people, and just call them, that would be easier. In ways it was easier because you could actually have that conversation and you could--instead of somebody just going to the post office and getting a letter with this information in it, you could have this discussion with them, but, you know, at times it was--sometimes it was hard. I had one I can remember so distinctly this lady, a conversation with her, and she--she had cancer, different cancers. Her family had so much cancer in it, and she was telling me all the different cancers that they had in their family, and we had a long discussion about ER/PR and how--not how this happened, I don't think she ever asked me how this happened, but

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she was glad that the results were back, she was glad they were the same, and the next morning when I walked in my office, the phone was ringing and this was her, and she asked me if I was telling her that she didn't have cancer any more. So my conversation with her was at least 45 minutes long and I felt she had a very good understanding of what I was saying, and then for her to be questioning her diagnosis the next morning, then--she was probably one of the last ones I was talking to that I started really thinking, wow, you know, like, I never--she shocked me coming back with that question because I didn't expect her to misunderstand that.

CHAYTOR, Q.C.:

Q. And was she offered to come in and having a meeting with people who could explain it to her?

MS. PREDHAM:

A. Oh, yes, definitely, you know, do you want to speak to your physician, do you want--you know, she seemed fine after we had that conversation, and I think she started second guessing it after I hung up because--and maybe

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it could have been because we had such a long conversation that she kind of got lost in the point of why I was calling her. You know, that's -

CHAYTOR, Q.C.:

Q. Okay. Perhaps we'll go back to P-0057. I just want to finish up with this document. On page six, and I will have more questions about the actual contacting, of course, of the patients and how that took place. It says, "An occurrence reporting form must be completed for all adverse events, hazards, incidents, near misses, and sentinel events", and for specific details, they're referred to the sentinel event policy. "Occurrence reports must be submitted to the respective manager responsible for the area where the occurrence happened. Managers must ensure completion of the occurrence reporting form and submit it to all appropriate quality and clinical safety leader. If further follow up is required, the manager must document all follow up activities on the occurrence". I think this note answers the Commissioner's question earlier in terms of employee related

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incidents, "The purpose of occurrence reporting is to provide a database of clinical safety issues and the corrective actions taken, promote consistency and timeliness in reporting occurrences, facilitate response by the Quality and Risk Management Department to potential liability, exposure, monitor, track, and trend so that high priority areas for improvement can be identified and actioned and reoccurrence prevented. Use as a tool in the improvement of quality of patient client resident care, provide opportunities to provide feedback, dialogue, and problem solving", and, Ms. Predham, I take it in our discussion today that this has been basically the purpose of occurrence reporting throughout?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. There's nothing--even though the policy here is new, these are--have always been well understood to be the purpose for occurrence reporting?

MS. PREDHAM:

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A. Yes.
CHAYTOR, Q.C.:
Q. And the idea of having a database of clinical safety issues and the corrective actions taken, I take it that's going to be improved now, and we've discussed that with your electronic reporting, and prior to what you were doing was keeping any occurrence reports that came to your attention, you were keeping your own Excel spreadsheets?
CHAYTOR, Q.C.:
Q. Right.
CHAYTOR, Q.C.:
Q. Of those, and keeping track in that respect as best you could?
MS. PREDHAM:
A. As best we could.
CHAYTOR, Q.C.:
Q. Yes. So even if you hadn't received an actual report filled out regarding an occurrence, but it came to your attention, and you said, for example, earlier in your evidence that if it were, you know, a major issue, a big concern, you'd know about it, it gets through to you fairly quickly.

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So even if you didn't have the report filled out, would it still end up on your spreadsheet or in your database?
MS. PREDHAM:
A. Probably not in our old system because, like I said, the benefit of having it in there for any kind of data trending or anything wasn't there because it was so cumbersome to work with, but we'd certainly have to keep track of that and make sure that it gets in there in our new system.
CHAYTOR, Q.C.:
Q. So any--the only things that ended up in your spreadsheet would be things that--or in your database as it was, were things that came to your attention by way of occurrence reports, an actual written occurrence report?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So anything, even though it may be a major occurrence, if there wasn't a form filled out, it wasn't kept track of in your database?
MS. PREDHAM:
A. Well, I'd keep track of that separate. That would be, like, you'd have a list of your critical occurrences or your sentinel events, so you'd keep track of it that way.
CHAYTOR, Q.C.:
Q. So there would be a separate list for those?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And I'm wondering did Peggy Dean, and her case, was there ever an occurrence report filled out?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Was she kept track of on your sentinel or critical event list?
MS. PREDHAM:
A. Well, the whole ER/PR was one whole occurrence.
CHAYTOR, Q.C.:
Q. But at the time in April when her test was repeated and there was a change, and she was

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advised of that and her treatment changed, at that point in time no occurrence report was filled out?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. It comes to your attention. The first time you learn about it is in June, is that correct?
MS. PREDHAM:
A. I learned about the issue in June. I didn't learn about her until July.
CHAYTOR, Q.C.:
Q. And at that point in time, does her case get put on your list?
MS. PREDHAM:
A. Not as a separate--she wasn't a separate entity. She was part of -
CHAYTOR, Q.C.:
Q. So there was her and several others by that point?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And all of their names got placed on your

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list?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And does that list still exist, Ms. Predham?
MS. PREDHAM:
A. Well, they wouldn't be out separate by name on this list. This would be just like issues. So it would just be ER/PR as a whole.
CHAYTOR, Q.C.:
Q. So you have a list somewhere where you have ER/PR occurs?
MS. PREDHAM:
A. Well, I mean, the way it goes is that you would have--you know, you'd open up a file and then we would have a list of all the current files that are open. So at that time, I was providing a monthly report to corporate QI, so it would be on that list. That's where I would take that information, put that in that report, and that would go monthly to corporate QI.
CHAYTOR, Q.C.:
Q. Okay, so there's no separate list for those critical incidents or major occurrences that

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occur that don't otherwise make your database?
MS. PREDHAM:
A. No, not--there's not a database list. There's our filing system and our list of files, and these are our current ones that we're working on, these are, you know, the active ones, and then there are the inactive ones.
CHAYTOR, Q.C.:
Q. And is that--that, you're saying, will not continue to be your practice once the electronic reporting comes on, everything will go into your electronic reporting database?
MS. PREDHAM:
A. Yes, and we'll still have--you know, if it's a critical occurrence or a large occurrence, it's going to have a big file, it's going to be bigger than just an occurrence report because you're going to have follow up, and you're going to be actively involved in that, so you're going to have a physical file and that will be--and there would be a list of those files, but we'll have to ensure that it's in the database. So we'll have to fill out an occurrence report on it as such to make sure that it's in there for trending purposes.

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CHAYTOR, Q.C.:
Q. For trending down the road?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So at some point before that file is closed out or at the time of closing out the file, you then put it into your database?
MS. PREDHAM:
A. Right, and -
CHAYTOR, Q.C.:
Q. If that takes years -
MS. PREDHAM:
A. But see, well, the way it is now, and, you know, the past couple of months I've kind of had to back away from this process, just this part, but the part where the quality safety leader, the documentation of the follow up and all that is a very robust system, and we may work out if that's going to be our documentation of certain dates and all that, so it will be an ongoing thing, that we can keep track of things in that.
CHAYTOR, Q.C.:
Q. Yes, I'm just thinking in terms of, you know,

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having--the whole purpose, as we see here, of why you would want to keep a database and a complete database, what you're saying the practice has been in terms of any major incidents or sentinel events, I guess, those weren't put into your database until whenever down the road the matter was actually concluded?
MS. PREDHAM:
A. They weren't ever put in the database because there wasn't any benefit of putting them there. We weren't able to go in and search for them. This is the old system. So we didn't--it wasn't easily searched or trended, but in this one we will have to because we're going to have a complete system, it's much easier to be searched, and we're going to have a numerical outcome rating on it. So, you know, we may not--but this is all--we're just in developing it now, we're just trying to figure out how we're going to utilize that.
CHAYTOR, Q.C.:
Q. I guess I'm missing why it wouldn't be beneficial to put the major things in your database, but it is beneficial to put in more

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minor things.
MS. PREDHAM:
A. Because, I guess, the major ones were all physically--you know, had physical files, were physically separated and we had--we considered them active files, and we had a record of those current active files ongoing, so we kept track of them separately.
CHAYTOR, Q.C.:
Q. But if it's--if the purpose of having it in one place is for continuity for the next person coming through the door into your office, for the purpose of you while you're there, and everyone else being able to track trends, whether it's quarterly or at the end of the year, wouldn't it be important to have your major occurrences as part of that picture?
MS. PREDHAM:
A. Well, yes, but that's why we putting the proposal to get this. It was so cumbersome--our old system was so cumbersome to do that, the fact that it was all the same people working along, we hadn't developed that practice, and it was something that we

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recognized that we really needed to do that, so that's why we've been working through this.
CHAYTOR, Q.C.:
Q. So, for example, if you were to put Peggy Dean's case into what you had for your database to say that patient had had IHC testing done, ER/PR, in 2002; retested in 2005, and converted, needed a change in treatment, that's the type of information, I take it, that you would capture?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And that wasn't done, that wasn't put -
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. In the database. If we could look at, please, P-0113, and I take it, neither was it done, nor was an occurrence report filled out for the patient after Peggy Dean, nor the next one, nor -
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:

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Q. Nor any of them?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. There was never occurrence reports filled out, and that was true for the first, say, five patients?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you would have learned then, I guess, on July 12th--you learned that Ms. Dean's test had actually been repeated back in April. Did you inquire at that point in time why an occurrence report hadn't been filled out?
MS. PREDHAM:
A. No, I didn't. I guess with all the information I was getting, I didn't inquire.
CHAYTOR, Q.C.:
Q. Ms. Predham, these are the Dr. Ejeckam memos, which I assume you're familiar with, April 4th, 2003. In April of 2003 is the first memo here, and it states--this is going, of course, to pathologists and copied to Barry Dyer and technical staff, "Kindly note that

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immunohistochemical stains with the following antibodies", and they're listed, including ER and PR, "have remained unreliable, erratic, and, therefore, unhelpful for diagnostic purposes, and consequently the above staining with these antibodies shall stop forthwith until we can solve the reliability, sensitivity, and specificity of problems. Efforts are underway, and hopefully a solution will be found". Were you or anybody else in the QI Department in 2003 notified of the concerns raised by Dr. Ejeckam?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And is this something that you think should have been brought to the attention of Quality and Risk Management?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And have you since made any inquiries as to why that didn't happen?
MS. PREDHAM:
A. Well, I guess, not the why. I guess, you

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know, the fact that the literature indicates that occurrence reporting is under reported and things don't recognize--people don't recognize that something is an occurrence or needs to be reported outside of their area, then, you know, that--I guess that's the reason why. They didn't recognize that it should be reported to us. The fact that--I did say, yes, that an occurrence report should be there, but I guess--and that's with the understanding that this is something not a usual practice. If this was a usual thing that could happen from time to time in the lab that there would be erratic staining and they would have to suspend that until they fine tune something and then they go that up, if that's an expected practice in the lab, then, no, I wouldn't expect an occurrence report. If it was an unexpected thing, then I would expect one.

CHAYTOR, Q.C.:

Q. And if this memo had landed on your desk back in 2003, what if anything would you have done or caused to have done?

MS. PREDHAM:

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A. Well the first thing that I would have done would be to call Dr. Cook and Mr. Gulliver and try to get some understanding of the situation. And try to get that, is this something that you would expect? Is this something that you wouldn't expect? So what's the significance of it? And then, of course, it would be what would be the impact. So because if this had been unreliable erratic and unhelpful in the past, what do we need to do or what needs to be done. And after I talked to them, I'd have to talk to Dr. Ejeckam then and, you know, get that sense of what was going on.

CHAYTOR, Q.C.:

Q. So you would have carried out some inquiries and contacted the key people, had this been brought to your attention at the time.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you would have been concerned to identify whether or not there is an issue with any prior testing that had taken place.

MS. PREDHAM:

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A. Yes.

CHAYTOR, Q.C.:

Q. And would you have expected the fact that the concerns that he raises and the fact that it was a temporary stoppage of certain stains and, well I guess his May 4th memo also identifies then in putting ER/PR back a number--or he certainly makes a number of recommendations in terms of carrying out or interpreting the immunostain of ER and PR. So his concerns through this memo, the May 2nd one, the April 4th, May 2nd and then on into the June 19th one and I'll take you to that, would you expect that it would appear or be mentioned in the Laboratory Medicine Program's annual report to the Quality Initiative's Committee?

MS. PREDHAM:

A. Yes, if it was an unexpected process in the lab that occurred, yes, I would expect it.

CHAYTOR, Q.C.:

Q. And if it's a process which required that the stains be suspended for a period of time because, in his opinion, they were unreliable erratic and there had been a shut down and he

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did whatever else he needed to do before bringing it back on line, that's the type of thing that Quality Initiatives would expect to see in the report from the program.

MS. PREDHAM:

A. Yes. Now I just note I never saw this memo until, I don't know if it makes any difference, May of 2007.

CHAYTOR, Q.C.:

Q. Yes, so this memo in and of itself wasn't brought to your attention at all in your investigation?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. Ms. Predham, what about the contents of the memo? The fact that Dr. Ejeckam said -

MS. PREDHAM:

A. I knew that he had suspended staining and I had seen the second one, but I never saw this one.

CHAYTOR, Q.C.:

Q. You saw the second one, the May 4th?

MS. PREDHAM:

A. Yes. And the third one, obviously.

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CHAYTOR, Q.C.:
Q. And who brought the--so you did see the June 19th one as well?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And who brought the May 4th and the June 19th ones to your attention?
MS. PREDHAM:
A. The second meeting I had about ER/PR, we talked about the fact that he had suspended staining in 2003 for six weeks at that first meeting that I had in July and the second one I had, I got a copy of the third memo at that. And I can't remember where I acquired the second one, it was somewhere along the way, but I didn't see that one until May, 2007.
CHAYTOR, Q.C.:
Q. And who gave you the June 19th memo during the July 12th meeting?
MS. PREDHAM:
A. It was either Mr. Gulliver or Dr. Cook.
CHAYTOR, Q.C.:
Q. And what was the purpose in giving you that memo?

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MS. PREDHAM:
A. I guess it was, you know, additional information about what happened. We had talked about the suspension of staining at that first meeting, July 10th, I think, and so that questions were, well, why did they stop, you know, what were more details about that, you know, what was going on. So what happened to, you know, when it restarted, what was the comfort level, you know, that kind of thing. And then at the next meeting then one of them brought the letter.
CHAYTOR, Q.C.:
Q. So the first meeting you're referring to is June 10th?
MS. PREDHAM:
A. July.
CHAYTOR, Q.C.:
Q. July 10th, okay.
MS. PREDHAM:
A. 10th, yeah, it was Dr. Cook, Mr. Gulliver and Dr. Williams and myself.
CHAYTOR, Q.C.:
Q. And then you meet again on July 12th and one of them brought you the June 19th memo.

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. At some point then later, you acquire the next, the May 4th memo.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And in May of 2007, how is it that you come into possession of the April 4th, 2003 memo?
MS. PREDHAM:
A. I think we released them publicly and I got a copy of them then.
CHAYTOR, Q.C.:
Q. And were you--who at that point in time then gave you the memo, the April 4th memo?
MS. PREDHAM:
A. Susan Bonnell must have sent it over.
CHAYTOR, Q.C.:
Q. Okay, and were you surprised, were you surprised by the content or -
MS. PREDHAM:
A. Well I was a bit concerned because of the listing of the other antibodies.
CHAYTOR, Q.C.:

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Q. And were you concerned in terms of what was being stated as to the reasons for shutting down the staining of all of those antibodies?
MS. PREDHAM:
A. Well, I mean, the wording was concern, but I guess at that point I must have heard that that was what he thought at the time or that's why--I must have heard that, I wasn't really surprised by the content of that part, the unreliable, erratic--because I think I must have got that--I think that's the wording in the other memos.
CHAYTOR, Q.C.:
Q. And so what caused you concern was that this just wasn't ER and PR, there were other stains involved?
MS. PREDHAM:
A. Well the second one, the detail in the second one only referred to ER/PR.
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:
A. And I didn't realize that there was a listing of other ones that were there.
CHAYTOR, Q.C.:

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Q. And the June 19th memo is his memo directed specifically to Terry Gulliver and in this one, he certainly refers to following persistent erratic results of immunostains in our laboratory. So this one is certainly not limited to ER/PR.

MS. PREDHAM:

A. But at the time when I got that, I wouldn't have realized that there was a lot of other immunostains, other than ER/PR. And that was, you know, that was my learning curve too, to understand that.

CHAYTOR, Q.C.:

Q. And in getting it then, the April memo and having it spelled out for you that there's six other stains, why were you concerned?

MS. PREDHAM:

A. Well I didn't know what those stains were for, what they were used for and I guess at that point in time why we had focused in on ER/PR, but what did we do with the other ones.

CHAYTOR, Q.C.:

Q. Okay, and did you cause inquiries to be made as to what were these stains and what happened?

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MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what were you told?

MS. PREDHAM:

A. They were used in a different way than ER/PR, that it was a different--they were one of many things that would be used for diagnosis and they were utilized in a different way by clinicians.

CHAYTOR, Q.C.:

Q. And who told you that? Who gave you that information?

MS. PREDHAM:

A. Well, it would have to have been either Mr. Gulliver, Dr. Denic or Dr. Cook, or a combination of the three.

CHAYTOR, Q.C.:

Q. So while you didn't have the April 4th, 2003 memo in 2005 when you were looking into this matter, did you otherwise ever become advised that there may have been other stains involved in 2003 that were of concern to Dr. Ejeckam?

MS. PREDHAM:

A. I did not understand that, you know, and whether it was something that I missed that was explained to me and I just didn't appreciate that, but you know, right from the beginning the focus was on ER/PR and I did not appreciate the fact that there were other ones.

CHAYTOR, Q.C.:

Q. So until you received the April 4th, 2003 memo in May of 2007, you were unaware of any issue with any other stains?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And did you make any inquiries then of anyone as to, well, why did you give me the other two memos and I haven't seen this particular memo, how -

MS. PREDHAM:

A. Well, at the time in May, 2007, it was unusual times anyway, it was all--there was a lot of questions being asked and I did ask that, but I don't think I ever got a, you know, I don't know if I ever got a clear answer why I didn't get that one at the time.

CHAYTOR, Q.C.:

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Q. And who did you ask it of?

MS. PREDHAM:

A. Well it would have been Mr. Gulliver and Dr. Cook, either one or the other--or both provided the letter in the first place.

CHAYTOR, Q.C.:

Q. If we could just have a look then at the June 19th, 2003 memo and he writes, "Following persistent erratic results of immunostains in our laboratory, I accepted to work closely with the technical staff in order to rectify this problem, despite the fact that the problem seems to have been arrested, the state of the immunostain at the General Hospital, Department of Laboratory Medicine and Pathology is still unsatisfactory." And then he lists physical location, the fact that the immunohistochemical stain is not just another special stain, the staff arrangement in his opinion is grossly inadequate and talks about dedication of staff and more education in essence for the staff. "The volume of immunohistochemical procedures continued to increase. The present staff performing this procedure are doing the best they can." And

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he talks about them having many other duties. "The fairly good stain we now have is a credit to them, but they do not have enough time to spare. It is my understanding too that some of them have less than two or three years"-- and he's worried about succession. "Finally, it is pertinent to mention that results of immunostains are extremely important in histopathological diagnosis, especially where classification of lymphomas and determination of benign or malignancy of certain lesions, for example in the prostate biopsies depend on crisp, reliable and reproducible staining results." So in reading this, Ms. Predham, it didn't occur to you that he's talking about something besides ER/PR?

MS. PREDHAM:

A. Well, I mean, to tell you the truth when I saw that memo first, I mean the overall memo, I don't think I got into that fine sentence there about the prostate biopsies, it probably did cross my mind and I have even asked at the time if he was talking about the whole thing somewhere along the way, but I don't really have a memory of it. My focus was always at

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that time on ER/PR and there was a lot of information in that memo that concerned me. So, you know, I can't remember if I picked up that it was talking about the prostate biopsies or -

CHAYTOR, Q.C.:

Q. Or lymphomas.

MS. PREDHAM:

A. Yeah.

CHAYTOR, Q.C.:

Q. "And diagnosis based on inappropriate immunostainer will surely jeopardize patient care and may even expose the Health Care Corporation of St. John's to litigation; therefore, it will be ill advised to operate an unreliable and erratic immunohistochemical procedure in our laboratory." And I take it in terms of things written in this memo that caused you, as risk manager, concern, these would--this would--your antenna would go up, your risk management antenna would go up when you read something like that.

MS. PREDHAM:

A. Oh I think line two or three, I think it was starting to go up when I, you know, right from

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the beginning.

CHAYTOR, Q.C.:

Q. And so by the time you get to these two sentences, what are you thinking?

MS. PREDHAM:

A. Okay, well what happened after this memo was written and, you know, when you see something like this after something has happened, after the fact, you know, it's almost like it's predicting the future, I mean, that again is your worse case scenario, you don't want to see that. So you want to say, okay, well somebody wrote this two years ago, then what did we do? Where is the follow up, where is the response?

CHAYTOR, Q.C.:

Q. And this memo in particular and you being the person to liaise with the insurer and the person who is looking after risk management for your institution, should this have been brought to your attention in 2003?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And did you ask Mr. Gulliver or Dr. Ejeckam or

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any of the people who are copied on the memo as to why it had not been?

MS. PREDHAM:

A. My understanding it wasn't--because they felt it was something that they could handle within the lab and that the tone of it was more the way that Dr. Ejeckam spoke, was that he was, you know, he tended to speak into this tone more than other people. Over the years, I have had instances where people who wanted to get, you know, attention, usually attention from the risk management department to fix something, will speak in this, in this way and talk about litigation and risk.

CHAYTOR, Q.C.:

Q. Did you meet with Dr. Ejeckam?

MS. PREDHAM:

A. No, I didn't.

CHAYTOR, Q.C.:

Q. Why not?

MS. PREDHAM:

A. In 2005?

CHAYTOR, Q.C.:

Q. At any point in time throughout your investigation of the matter, did you go speak

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to Dr. Ejeckam?
MS. PREDHAM:
A. I met with him later on. He went on holidays. I think Dr. Cook was going to talk to him first and then he went on holidays for four or five weeks and in September I think I met with him.
CHAYTOR, Q.C.:
Q. September of 2005?
MS. PREDHAM:
A. I think, it could have been October, somewhere in, you know, later on when this was progressing.
CHAYTOR, Q.C.:
Q. So you're saying in July you didn't meet with him, but when he got back from holidays, I met with him, and you believe it to be around September 2005.
MS. PREDHAM:
A. Right.
CHAYTOR, Q.C.:
Q. Okay, and did you find him to speak in an exaggerated manner?
MS. PREDHAM:
A. Not when he was speaking to me, no.

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CHAYTOR, Q.C.:
Q. And have you met with him or had discussions with him since your discussion in September 2005?
MS. PREDHAM:
A. I may have been in a meeting with him there, but I never had, you know, a one-on-one conversation with him after.
CHAYTOR, Q.C.:
Q. Okay, and when you met with him in September, 2005, what did you discuss with him?
MS. PREDHAM:
A. We were talking more, he was explaining the test and the reading of the slides.
CHAYTOR, Q.C.:
Q. I'm sorry?
MS. PREDHAM:
A. He was explaining the test and the reading of the slide--the interpretation, that part of it.
CHAYTOR, Q.C.:
Q. Oh, he was explaining the ER/PR test to you.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

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Q. Because he was still overseeing the IHC lab at that point in time.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. What about the memo, though, of June 19th, 2003? Did you ask Dr. Ejeckam, I have this memo, what on earth did you mean?
MS. PREDHAM:
A. No, actually I didn't at that time because I know that Dr. Cook had followed up and Dr. Williams had spoken to him about that.
CHAYTOR, Q.C.:
Q. And you didn't bring it up with him at all?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And so your understanding is that Dr. Cook and Dr. Williams had both already followed up with Dr. Ejeckam to find out what he meant in June of 2003.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And had that information been relayed back to

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you?
MS. PREDHAM:
A. Well, the fact that he did have concerns about that area, I mean, there were some very concrete things that he had in there that were addressed by Mr. Gulliver about the physical location of the facility, and you know, those things that were--they were very concrete things and that he didn't like the crispness of the staining or whatever the terminology he used about the staining and that he stopped and wanted to address it.
CHAYTOR, Q.C.:
Q. So I just want to be clear, so they came back--it was left in their hands to follow up with Dr. Ejeckam. And Dr. Cook and Dr. Williams came back and told you what Dr. Ejeckam had to say or who told you what Dr. Ejeckam had to say?
MS. PREDHAM:
A. Well they didn't come back to report to me and tell me what they did. I just happened to be there when they were discussing what Dr. Ejeckam had said, you know. I guess it was, I mean, you couldn't argue with his, what he was

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saying and what he was saying that there was issues here and all of that, you couldn't argue with that because we were faced with the situation. So, I mean, that was what it was.

CHAYTOR, Q.C.:

Q. It had come to pass what he -

MS. PREDHAM:

A. Exactly, so I mean, there was no arguing-- there was no debate about that, but the, I guess the concern was, was the response to this memo and what had taken place and what had anybody done and was he satisfied with it at that time. And as I understood he was char of the Surgical Pathology Committee and he had the ability to go to Dr. Williams with concerns that he felt weren't being resolved at that level and that he had, in fact, had gone forward with a concern about histories on -

CHAYTOR, Q.C.:

Q. Clinical histories -

MS. PREDHAM:

A. On requisitions. But he didn't go forward with this issue, so I think that was, that was part of the discussion that Dr. Williams had

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had with him.

CHAYTOR, Q.C.:

Q. And I take it then there was no discussion as to whether or not they felt, in fact, Dr. Ejeckam was blowing things out of proportion or exaggerating in terms of what he had written in the memo?

MS. PREDHAM:

A. No, we didn't discuss that part at all.

THE COMMISSIONER:

Q. Ms. Chaytor, wherever you can find a spot, we'll take the luncheon break.

CHAYTOR, Q.C.:

Q. And after receiving this memo yourself, what did you do with it?

MS. PREDHAM:

A. I shared it with Ms. Pilgrim.

CHAYTOR, Q.C.:

Q. And did you share it with anyone else?

MS. PREDHAM:

A. I sent a copy to our insurance adjustor.

THE COMMISSIONER:

Q. When you say "this memo" are we talking about the one on the screen now, the June 19th?

CHAYTOR, Q.C.:

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Q. The June 19th, yes.

THE COMMISSIONER:

Q. Okay, thank you.

CHAYTOR, Q.C.:

Q. And did you do that also for the May 4th one as well?

MS. PREDHAM:

A. I really can't remember because it was later, I got that later on.

CHAYTOR, Q.C.:

Q. For the May 2nd, I should say--oh, that was April 4th, no, the May 2nd one.

MS. PREDHAM:

A. No, the May 2nd one, I can't remember when I got that. I know I got it somewhere along the way, but I really can't remember.

CHAYTOR, Q.C.:

Q. Okay, but you certainly sent the June 19th one on to Ms. Pilgrim and on to HIROC?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. This is a good place, please, Commissioner.

THE COMMISSIONER:

Q. All right then, we'll take the luncheon break.

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2:15?

(ADJOURNED FOR LUNCH)

THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Good afternoon, Commissioner. Good afternoon, Ms. Predham. We have a new exhibit this afternoon, Commissioner, C-0275, if that could be entered please?

THE COMMISSIONER:

Q. Entered.

EXHIBIT ENTERED AND MARKED C-0275

CHAYTOR, Q.C.:

Q. And, Registrar, if you could bring up again, please, P-0113? These are Dr. Ejeckam's memos, Ms. Predham, that we were looking at before the break, and in the June 19th, 2003 memo, which I understand you to say that you did have it in July of 2005, this one was the first one given to you.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you said in reading this, I brought you specifically to paragraph 6, but you said in

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reading down through this, there were things that caught your attention and were of concern to you. Are there any--if you want to just take us through and tell us in reading this at that time, what specific things were jumping out at you in terms of a risk management perspective?

MS. PREDHAM:

A. Well I guess, you know, given the circumstances of, you know, the discussion that we had a couple of days before, you know, with the situation and being explained what the situation was, so then when you read this, even the first line with "Following persistent erratic results", you know, that would have me concerned. So do you want me to go through -

CHAYTOR, Q.C.:

Q. Yes, please, continue on.

MS. PREDHAM:

A. Well also going through, I guess, looking at it that the physical location was unsatisfactory, the haphazard and laisser faire approach to it, you know, these types of things were, you know, grossly inadequate, staff arrangements, all that type of

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terminology, of course, would get me concerned.

CHAYTOR, Q.C.:

Q. Yes. And if I could just take you to this part here in terms of "the staff should be a problem shooter and that can only materialize through understanding of the subject." Were those statements of concern to you as well?

MS. PREDHAM:

A. Well it was all a concern, I don't know if that first time reading through that I would have focused in on that as much. I think more the ones that I mentioned there and then down below, you know, it was, "Do less would be a gamble where you may win or lose, this obviously will spell disaster." Those are the ones that got my attention.

CHAYTOR, Q.C.:

Q. Yes, that type of language certainly got your attention.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And again, of course, the portions that I brought your attention to earlier.

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MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And if we could just go back then please, or I can do that, to the April 4th memo and this one wasn't brought to your attention until May of 2007, after it became or was going to be released to the public, this document. And your concern, you said, in having, in receiving this then at that time was that it spelled out for you that there were, in fact, other stains involved?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Prior to--and none of this, as you've said, was brought to your attention or the Quality Initiatives Department in 2003.

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. Prior to 2005, was there any issue with respect to the Laboratory Medicine Program and in particular, the types of issues that are dealt with in these memos, the

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immunohistochemistry portion of the lab, were there any concerns brought to your attention or the Quality Initiatives Department's attention regarding that aspect of the program?

MS. PREDHAM:

A. No, and like I said before, I never knew there was an immunohistochemistry portion of the lab.

CHAYTOR, Q.C.:

Q. And what about other areas which may impact on the quality of work that the lab could produce, for example, were there any issues of fixation brought to the attention of yourself or the Quality Initiatives Department prior to 2005?

MS. PREDHAM:

A. I can't remember--most of the issues that had came forward over the years, I mean, there were issues, there's been issues in all areas of the organization, but I can't remember one that was a global issue with fixation, it was more a one-off, if there was anything--seems that there's a memory of something to do with fixation, but it was more a one-off type of

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situation. But that's just a vague memory. There have been issues over the years, but you know, we had addressed those, but none that, like I said, I didn't realize there was an immunohistochemical service.

CHAYTOR, Q.C.:

Q. There had been what kinds of issues over the years?

MS. PREDHAM:

A. Well there was issues with, you know, there were adverse events or occurrences that happened.

CHAYTOR, Q.C.:

Q. Within the lab, you mean?

MS. PREDHAM:

A. Within the lab. Some of those could have bene a delay in reports, you know, that happened, misinterpretation of or incorrect diagnosis, you know, those types of things that have occurred from time to time throughout the years.

CHAYTOR, Q.C.:

Q. Yes, but anything in looking back on it and in your investigation of the issue, anything that would be relevant to what ultimately unfolds

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in the ER/PR issue?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And the one-off that you mentioned of fixation, did that--when you say "one-off" when this then arises and you become aware of an issue regarding fixation, did you have cause to go back and look at that situation?

MS. PREDHAM:

A. No, I only have a vague memory of that, but it was, it was not this type of issue. It was something that was, you know, left too long, like an individual thing was left too long somewhere or something. It was an individual event that was unusual for the time.

CHAYTOR, Q.C.:

Q. Yes, like a specimen left too long in either the OR or -

MS. PREDHAM:

A. Yes, something like that, it was, you know, it was a mistake at that time. It was--it wasn't, you know, handled in the proper way and it was an unusual, you know, not the typical process and that's just the--I'd have

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to go back, it's only a vague memory.

CHAYTOR, Q.C.:

Q. And in terms of any other issues regarding the Laboratory Medicine Program over the years, was there ever any issue in terms of tissue processing brought to your attention or to the attention of Quality Initiatives?

MS. PREDHAM:

A. No, not to that--the only other one up to that point about tissue processing was one time a sample had, they're in little baskets when they get embedded and the tissue had come out of the basket and it was just to go through the process of how that happened, but that was, again, I think the little plastic basket that it was in had cracked or something and the tissue had come out of it.

CHAYTOR, Q.C.:

Q. So nothing else in terms of the histology portion of the lab brought to your attention?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. Okay. And if we could look, please, at P-1853? And before we do that, though, I should

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ask you if we could go back to P-0113 please, sorry. Is there anything in terms of this April 4th, 2003 memo in the language that Dr. Ejeckam used about the stains being unreliable, erratic and unhelpful for diagnostic purposes, this--and I guess also the memo that I just showed you of June 19th, that type of language and in your career of risk management, have you ever been presented with documents, memos, letters of this nature? I know you said there are times when people will say, you know, we're going to be sued if you don't take certain measures, but in terms of the language that we see here used by Dr. Ejeckam, have you ever had a similar experience where there's that type of strong language used?

MS. PREDHAM:

A. Strong language, not necessarily those same words because, of course, the circumstances would have been different, but yes, I've had memos that have had strong language in it.

CHAYTOR, Q.C.:

Q. And what do you do in those circumstances?

MS. PREDHAM:

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A. Well you'd have to go back to the leadership team and get some context around it and then talk to the person involved and see what the situation is.

CHAYTOR, Q.C.:

Q. And I guess you evaluate the risk and see whether or not the language is warranted?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, I'm sorry, if we could go then please to P-1853? And Ms. Predham, these are answers to interrogatories that you provided and I understand there are two different sets of answers that you've provided and this particular set is in answer to interrogatories of the Plaintiff dated June 14th, 2007 and this, of course, is in the Class Action lawsuit. And those answers are sworn to on August 3rd, 2007.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And in coming up with the answers in this document, did you have assistance from other

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people?

MS. PREDHAM:

A. Yes, we had--I had to arrange for a conference call with Mr. Gulliver, Dr. Cook, Dr. Denic, Dr. Williams, Dr. Laing. I have to think--that's about all of them, and to help me answer them because I couldn't answer them on my own.

CHAYTOR, Q.C.:

Q. Okay, and so it does say that, "You make oath and say to the best of my knowledge, information, and belief, based on my review of the medical literature and my experiences and interactions with oncologists, pathologists, and other medical professionals on the topic of breast cancer and breast cancer testing as follows".

MS. PREDHAM:

A. And I couldn't sign it without that proviso being there.

CHAYTOR, Q.C.:

Q. Yes, okay, and if we could just look at page two, paragraph four, and it deals with the memorandum of Dr. Ejeckam, June 19th, 2003, "As to the memorandum written by Dr. Ejeckam

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on June 19th, 2003, and appended hereto, was consideration given to retesting breast cancer specimens for ER/PR status which had been tested during the period when Dr. Ejeckam considered that results had been erratic; whose responsibility was it to consider and recommend or not recommend retesting; where in 2003 did ultimate authority to make such a decision lie; where did it lie in 2005; who recommended retesting, and who decided that the retesting would be done", and the answer that you provided is, "I have no direct knowledge of Dr. Ejeckam's memo of June 19th, 2003, and the circumstances surrounding same. My response is based solely on the information that has been provided to me". Who amongst the individuals you mentioned would have then given you the information to enable you to be able to respond?

MS. PREDHAM:

A. Dr. Cook and Mr. Gulliver.

CHAYTOR, Q.C.:

Q. "I understand that the changes referenced in Dr. Ejeckam's memo of June 19th, 2003, were seen as an enhancement and improvement of the

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stains as a quality improvement activity and as part of the development/enhancement of the continuing quality assurance program". So where did that information come from?

MS. PREDHAM:

A. That would have been Mr. Gulliver.

CHAYTOR, Q.C.:

Q. And what is the--in 2003, what continuing quality assurance program did you understand existed in the laboratory medicine program and specifically the section of the lab dealing with IHC?

MS. PREDHAM:

A. The quality assurance that they had in 2003 up to 2005 was limited, but was based on the feedback of the pathologists. So when the stains were done, they relied on the feedback of the pathologists back to the technologists, and that was considered their quality assurance program.

CHAYTOR, Q.C.:

Q. And in 2007, August, 2007, when you're swearing these answers to the interrogatories, did you have any concern in stating that this was done as part of the development and

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enhancement of the continuing quality assurance program?
MS. PREDHAM:
A. That was their understanding of the quality assurance program at that time, that was what, you know, they had established as a quality assurance program, and that's all I could say to that. At 2003, that's what they considered that to be.
CHAYTOR, Q.C.:
Q. "I do not believe the retesting, the ER and PR results was discussed or considered at that time", and who would have given you that information?
MS. PREDHAM:
A. Well, both Dr. Cook and Mr. Gulliver for that.
CHAYTOR, Q.C.:
Q. "Unlike in 2005, I do not believe that there was a conversion or sentinel event", and what information would you have had available to you to be able in August, 2007, to swear to that as being an accurate statement?
MS. PREDHAM:
A. That was the information that I had, that there hadn't been at that time a conversion.

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CHAYTOR, Q.C.:
Q. And do you still believe that to be the truth?
MS. PREDHAM:
A. No, I know that's not true now.
CHAYTOR, Q.C.:
Q. And when did you learn the difference?
MS. PREDHAM:
A. I think it was when the patients were testifying here.
CHAYTOR, Q.C.:
Q. So that was the first time that you became aware was here through this process in 2008 that, in fact, there had been conversions?
MS. PREDHAM:
A. The names--I didn't recognize the names of some of the patients or family members that you had on the witness list, so then when checking into it, I discovered that there were retests.
CHAYTOR, Q.C.:
Q. And did you go back and make any inquiries of Mr. Gulliver or Dr. Cook, knowing that you had given a sworn statement otherwise, to say how that could have been overlooked or not brought to your attention earlier?

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MS. PREDHAM:
A. Well, I didn't go because I made a sworn statement. I went because I was -
CHAYTOR, Q.C.:
Q. Out of concern.
MS. PREDHAM:
A. I was concerned that this information was there.
CHAYTOR, Q.C.:
Q. Fair enough.
MS. PREDHAM:
A. So--and I'm not sure that either one of those gentlemen were aware of it at that point in time. It seemed to be something that the clinicians involved, either the pathologists or the oncologists involved, were aware of, but did not appreciate the information at the time.
CHAYTOR, Q.C.:
Q. So Mr. Gulliver, in having reviewed the pathology reports for purpose of retesting, didn't indicate to you whether he had, in fact, come across cases that had been retested previously?
MS. PREDHAM:

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A. No, I--and actually it never even crossed my mind that he would have seen that, you know, going through that.
CHAYTOR, Q.C.:
Q. And when you spoke to him about it in 2008, he didn't indicate that to be the case, that in fact he had seen tests that had been retested in the past?
MS. PREDHAM:
A. I don't remember him mentioning that to me. I'm sure I would have remembered it.
CHAYTOR, Q.C.:
Q. And you specifically went to him with that question?
MS. PREDHAM:
A. We had that discussion with--you know, with Dr. Denic as well, you know, so it was a general discussion.
CHAYTOR, Q.C.:
Q. And if we could bring up then, please, C-175. I'm just going to show you--these are pathology reports that we've redacted, Ms. Predham, and this particular one, I'll take you to the ER/PR portion, and you'll see that it is 2003, so the time period that's referred

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to in your answers to the interrogatories, and the first addendum is May 6th, 2003, and when compared to controls, the specimen is negative for HER2/neu, ER and PR, and then May 9th, 2003, the ER and PR were repeated due to quality assurance issues. The repeated stains shows the following; ER positive in 80 percent of the cells, PR positive in 10 percent of the cells. I take it, this wasn't--this particular incident, there was no occurrence report filed with Quality Initiatives regarding this particular change?

MS. PREDHAM:

A. And--well, really in this circumstance, I would not have even expected as such because the quick turnaround time between the 6th and the 9th, you know, quality assurance is there to catch problems, so if they did--if there was some reason they tested that in that short period of time, that would be an expected, you know, program, it got caught and got retested and it went on. So I wouldn't necessarily expect an occurrence report.

CHAYTOR, Q.C.:

Q. Even if the results changed?

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MS. PREDHAM:

A. Well, see when--in things that happen in an organization, you have a double check on--for instance, take the pharmacy. So the pharmacist does up the medication, it goes through, and before it leaves the pharmacy, there's a double check, and if that person doing the double check catches a mistake or a mislabelling or some kind of error, there isn't an occurrence report filled out because that's why the double check is there. There's an expectation that there's going to be a problem, so you put the double check in to catch it. So that wouldn't be necessarily a basis of an occurrence report. The pharmacy keeps track of it themselves, and then goes back and looks to see if there's patterns and all that, but there's not an occurrence report as such. If it gets outside the pharmacy and gets past the double check, then it's an occurrence report.

CHAYTOR, Q.C.:

Q. So we don't--so this is not considered a near miss?

MS. PREDHAM:

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A. It could be. It depends on what the quality assurance program is here. If the quality assurance program going through, if the pathologist sees this and says, oh, look, there's a problem here with the lab, you're going to have to redo this, that's--I would expect that that is the normal thing, that is the normal practice that would go through and they would have to reissue that. Be that as it may, it depends on what--you know, I'd have to talk to Dr. Cook or Dr. Denic and say, you know, but I could see that this could be -

CHAYTOR, Q.C.:

Q. But how would you even get an opportunity to do that if it's not brought to your attention?

MS. PREDHAM:

A. But that's--I guess that's the whole thing of having those discussions. The example I gave with pharmacy, that was discussions that we had with the pharmacy leadership and with the managers in there, that this is their process, what is an occurrence, when does an occurrence report get filled out.

CHAYTOR, Q.C.:

Q. Ms. Predham, and bear in mind that the service

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had been shut down and brought back on line by Dr. Ejeckam, according to his memo, on May 4th, 2003, and so this is now May 6th, 2003, and again May 9th, 2003, and I just want to be clear in terms of when an occurrence report--so would that in the background as well in terms of--and I realize your department is not aware that the service had been shut down, but the pathologists certainly would have been aware of that?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Pathologists would have been aware that the service is shut down, and then we have within the three day period, different results. In that context, would you expect that an occurrence report would be brought to your attention?

MS. PREDHAM:

A. And I guess I'm trying to give you, like, a bit of supposition here. It would be nice to get an occurrence report on this, but I can see that there would be reasons why it wouldn't be done.

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CHAYTOR, Q.C.:
Q. And, Ms. Predham, it's also--this is entered and signed out, and it replaces the pervious report, and there is a phone call apparently made to the Cancer Clinic regarding this. So, of course, it could be that the patient has already been treated on the basis of the first signed out report.
MS. PREDHAM:
A. That is a fair observation. If the pathologist signed it out, then for some reason there would have been a reason to go back, so you're right, it would have been more of an occurrence than a basic quality assurance activity.
CHAYTOR, Q.C.:
Q. So in that circumstance, it would follow, looking at your policy on the reporting of occurrences, that this should have had an occurrence report filed?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. If we could have C-228, please. I'll take you to the second page of this document, Ms.

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Predham--actually, it's probably the fourth page of the document, and this one you'll see that the original test is March 17th, 2003, estrogen and progesterone immunoperoxidase method, ER occasional positive less than 1 percent, PR 15 percent positivity, and in brackets [no controls available], and then Addendum Two was entered May 28th, 2003, as requested, repeat estrogen and progesterone receptors by immunoperoxidase staining, and estrogen is 40 percent positive, progesterone is 73 percent positivity, and again both of these are signed out; one in March, and one in May, by the pathologist, and there's a conversion. This wasn't brought to your attention at the time. Would you have expected that there would be an occurrence report filed for this particular incident?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. If we could have, please, C-174. This one there's even a longer period of time between the two tests. I'll just take you to the last page, I believe, of the document, page four,

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and in this one the original test is done August 29th, 2002, and immunohistochemical staining for progesterone is positive in approximately 15 percent of lesional cells, and immunohistochemical staining for estrogen receptors is negative, and you'll see again that's August 29th, 2002. Then it's repeated and entered on the chart, June 11th, 2003, at the request of Dr. Zaidi, immunohistochemical staining for estrogen and progesterone receptors has been repeated. Estrogen receptors show faint positivity in approximately 10 to 15 percent of lesional cells, progesterone receptors are unequivocally positive in approximately 75 percent of lesional cells, and again would you expect that to have been brought to your attention by way of an occurrence report?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and Ms. Predham, those that I've shown you, this one being June 11th, 2003, and the first one that I showed you was the repeat was May 28th, 2003--I'm sorry, May 9th, 2003, and

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then it was May 28th, 2003, and then the third repeat is June 11th, 2003. So there were three incidents of conversions in approximately a one month period in 2003. Had that been brought to your attention, would that have triggered to you a trend?
MS. PREDHAM:
A. Oh, definitely. I mean, it was something that would require investigation.
CHAYTOR, Q.C.:
Q. And at that point in time then, Ms. Predham, what would you have done or caused to have been done?
MS. PREDHAM:
A. I mean, you'd have to look and, you know, investigate it to see what was going on, see what to expect in the processes, see what was out there in the literature, see what we're doing, see what--you know, you'd have to go through almost everything that we did in the fall or summer of 2005.
CHAYTOR, Q.C.:
Q. Yes, okay. Ms. Predham, in looking at this last case, and of course, this one is in August of 2002 and we now know, of course,

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what ends up being referred to as the sentinel case was in 2002, summer of 2002 as well, and this particular case was then repeated less than a year later, in June of 2003. Would there be any distinction drawn between Peggy Deane's case and how you responded to Peggy Deane's case and how this is in this particular case?

MS. PREDHAM:

A. You mean would I respond the same?

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. Definitely, you know, the same type of issue. I don't know if--the one other category with her is that they were all--the type of cancer that she had was expected to be all positive, so that was another criteria, but that wouldn't have made neither here nor there. You'd still have to investigate it.

CHAYTOR, Q.C.:

Q. If we could have then, please, P-0030? This is a meeting of the Corporate Quality Initiatives Committee and we've spoke a little bit about that this morning, this committee,

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January 27th, 2005. Ms. Pilgrim is the chairperson and you are a member on the committee. Just actually, the document I wanted to refer you to is further along. It's not this particular one. It's on page 50, I believe, Registrar. Okay, take you back to the first page of these particular minutes. Here we go. Yes, sorry.

This particular meeting is September 22nd, 2005. Ms. Pilgrim is still the chairperson, and you are in attendance at the meeting. Page 50, laboratory--tell you where this shows up, for your reference.

MS. PREDHAM:

A. I think that's my monthly report.

CHAYTOR, Q.C.:

Q. Report by Director of Quality and Systems Improvement. So this is you making this report?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and the following was highlighted from the June, July and August 2005 report. "A patient initially tested in 2002 for ER/PR and

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was found to be negative was retested and was strongly positive. Four other patients were retested and all now tested positive. A full review of services, including an external review of the immunohistochemistry service, is being conducted. All ER/PR testing and supporting by this lab is presently on hold awaiting outcome of review." And I take it that's Ms. Deane's case that's being referred to and then the four that followed?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And "occurrence reporting is now completely up to date. First quarter reports for 2005 have been sent out to program areas. A multiple year report for 1998 through to 2005 was reviewed, transcription errors," and it goes on from there. So I take it, at this meeting, you would also bring forward any occurrence reports that are relevant?

MS. PREDHAM:

A. Well, right there, what I was referring to, the end of the previous year, our occurrence reporting database had crashed, I guess, for a

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better term, and we couldn't utilize it any more. So our data entry of the occurrence reports was behind. So Information Management had to rebuild our database and then we were behind a lot of data entry. So it was at this point in time we had caught up to where we were.

CHAYTOR, Q.C.:

Q. Okay, and Ms. Predham, at this point in time, now it's September 22nd, 2005, and I will take you back chronologically in time, but if you had known in 2003 of the three cases that I've pointed out to you within approximate one month period, I take it there would be no different reaction than what we see here following on the index patient and the four other patients, and a full review would have been conducted in 2003?

MS. PREDHAM:

A. Yes, and I think that highlights the importance of the people who are doing the work valuing occurrence reporting, because if they know of things and they don't tell anybody about it, really can't, as an organization, you can't do anything about it.

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CHAYTOR, Q.C.:
Q. Yes, and if we could have page 60 please, in this document? And this is continuing on with Corporate Quality Initiatives Committee and this particular meeting is November 24th, 2005. Again, Ms. Pilgrim is chairing and you are in attendance, and on page 60, there is reference to Baker Norton report, and under standing agenda items, patient safety plan, "Ms. Predham requested direction on the patient safety plan initiative, i.e. whether it should continue or be put on hold. Members felt the initiative has gained momentum and currently there is an opportunity to begin and grow in stable program level areas. Ms. Pilgrim will seek input on a direction from Louise Jones and Pamela Elliott." And I'm just wondering, you're seeking direction at this point in time as to the patient safety plan initiative. What was that initiative and what was ultimately decided to do?
MS. PREDHAM:
A. Well, that was the initiative that I mentioned this morning that we had gotten the money, the funding for to launch that. So that was in

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the old Health Care Corporation patient safety plan. We had a lot of structure put in place around that and I really didn't know what to do with it now, when we got to this point, because we were Eastern Health. There were-- it was the opportunity to keep it in areas that hadn't changed fundamentally, and I think what was decided was that there would be a broader clinical safety plan brought throughout the whole organization. The directions, the initiatives that, you know, the stable and, I guess, that's the area, the program level that didn't change, like in St. John's hospitals that were previous part of the Health Care Corporation could keep those going because they had set up patient safety committees within their program and they could keep their initiatives going, but that the overall work on the patient safety plan would be on hold while the clinical safety plan for Eastern Health would subsume it, I guess.
CHAYTOR, Q.C.:
Q. Okay, and if we could have, please, P-1905?
THE COMMISSIONER:
Q. Sorry, I'm not sure I followed that. What

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would be the difference in what you were doing under the clinical safety plan within Eastern Health, and which was now a bigger organization, and the continuing operation of what you had developed for Health Care Corp?
MS. PREDHAM:
A. Well, there were only certain areas that stayed stable, weren't affected by the amalgamation. So that would be like the surgery program in the St. John's hospitals or the medicine program or critical care. So the clinical programs in the St. John's hospitals really were not affected directly by the amalgamation in Eastern Health.
THE COMMISSIONER:
Q. Um-hm.
MS. PREDHAM:
A. Whereas all the other ones were, you know, like support programs. Pharmacy became regionalized. We became regionalized. We also are now in community health, long-term care, so the same patient safety plan wouldn't be applicable to those areas. So I guess that was the consideration that the stable areas, the ones that weren't affected, could carry on

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in that direction that they were doing, but organizationally, we needed to have a new plan.
THE COMMISSIONER:
Q. And was it intended that once the new plan came in, it would replace the one from Health Care Corporation in those areas that had been stable?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. Oh, okay, thanks.
MS. PREDHAM:
A. And that being said, like all the other legacy boards would have had their own direction on patient safety anyway. So it was to, you know, consolidate all that.
THE COMMISSIONER:
Q. Okay, yes, now I understand. Thank you.
CHAYTOR, Q.C.:
Q. Thank you, Registrar, it's P-1905, and these are notes of a meeting, Laboratory Medicine Program, February 27th, 2004, and it's Doctors Cook, Williams and Mr. Gulliver in attendance. I'll just bring you then to page two. This is

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dealing with pathology technical consolidation. "We are still awaiting--we are still waiting on final recommendation from Heather Predham, QI, in regards to risk management concerns expressed by St. Clare's pathologists." And there's also follow up then on this issue at P-1912, please? And again, this is another meeting of the Laboratory Medicine Program, the next month, March 26th, 2004, and at page three, there's reference again to pathology technical consolidation. "Some discussion in regards to the final assessment from Heather Predham in regards to risk management issues and concerns brought forward from St. Clare's pathologists. Ms. Predham, in her analysis, did not find any risk management issues related to the pathologist consolidation, and Dr. Williams will arrange a meeting with George Tilley, Terry and Dr. Cook to make a final decision."

Ms. Predham, what do you recall about the issue of consolidation of pathology services to one site and your involvement in analysing that situation?

MS. PREDHAM:

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A. This was an issue that the lab had planned to consolidate the pathology over on one site, which they had done with microbiology and had done with another division of their lab, which escapes me right now, biochemistry. And so now it came to here and some concerns were raised, from a risk management perspective. So I met with the pathologists at St. Clare's, Dr. Cook, Mr. Dyer and Mr. Gulliver, and went through their concerns and there mostly were concerns regarding transport between sites and that type of issue.

CHAYTOR, Q.C.:

Q. Transport of specimens, I take it?

MS. PREDHAM:

A. Yes, and I guess the turnaround times, any effect on that, from a risk management perspective. They had given me names of different hospitals, some which were consolidated and were multi-site and consolidated services and some which weren't. So I checked with those areas. I checked with HIROC to see if they had any risk management concerns concerning consolidation only. It was limited to that part, changing the

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practice of that. And I couldn't find any evidence, but I did recommend that they--you know, I couldn't find any evidence of any risk management concerns regarding consolidation or not consolidation.

CHAYTOR, Q.C.:

Q. And at the time when you were asked--I take it they invited your input on this?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And did St. Clare's have particular concerns? It says there were concerns brought forward from St. Clare's pathologists.

MS. PREDHAM:

A. It was mostly concerned around the turnaround time, because surgery would still carry on at St. Clare's and then, of course, it would have to get over to the Health Sciences. So it was mostly transport of specimens in a timely way.

CHAYTOR, Q.C.:

Q. I guess the specimens then coming from St. Clare's to the Health Sciences and then being processed and the blocks or slides shipped back to St. Clare's for interpretation by the

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pathologists there?

MS. PREDHAM:

A. No, I believe all the pathology services would be over at the Health Sciences, the pathologists would be over there as well.

CHAYTOR, Q.C.:

Q. Okay, so the whole site. So it's not just the technical consolidation at this point in time. This was--your review was for the entire pathology should be consolidated on one site?

MS. PREDHAM:

A. That's my memory.

CHAYTOR, Q.C.:

Q. Okay, and in your discussions with the laboratory medical program around this issue, did you detect any problems between--communication problems or management problems between the clinical side of the program and the technical side of the program? So between the clinical chief and the program director, were there any issues that you were able to sense between the two branches of the program?

MS. PREDHAM:

A. I didn't sense any communication issues, but there was--I guess it was the driver, from Mr.

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Gulliver and Mr. Dyer's side, they had, you know, the budgetary pressures. I think the Hay report had been before that. So it was all this of trying to keep things under budget, trying to--this is a cost savings to do that and then it was the concerns on the pathologists side about the quality--I mean, not saying that Mr. Gulliver and Mr. Dyer weren't concerned about quality of service, but you know, that there, but they had that extra pressure that the pathologists didn't have. So there was that, I guess, a different viewpoint as opposed to--but not communication issues. They were very clear on where they were coming from.

CHAYTOR, Q.C.:

Q. On communicating with one another their positions?

MS. PREDHAM:

A. Yes, yeah.

CHAYTOR, Q.C.:

Q. Yes, okay, and what about any other--did you detect any other problem then in terms of any divide, as such, between the management and clinical sides of the program?

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MS. PREDHAM:

A. Just that aspect of it. I mean, it was a difference of opinion, but also, you know, there was the--I got a sense that there was the--you know, they didn't want to see St. Clare's--from the pathologists, they wanted the services to stay at St. Clare's, and you know, this is the way it is and it's been like that and they're content with that and the service is good like that, but we've been through a lot of that over the years, you know, so that was--and that was a valid concern that people had.

CHAYTOR, Q.C.:

Q. I want to take you then to the--and I take it there's now going to be the consolidation of the pathology service to the Health Science. Have you been involved in the issue since?

MS. PREDHAM:

A. No, that was my only involvement.

CHAYTOR, Q.C.:

Q. That's your only involvement, okay. I'll take you then to the ER/PR issue and you told us that in June of 2005, there was a brief comment made by Dr. Cook just to give you a

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heads up.

MS. PREDHAM:

A. Dr. Williams.

CHAYTOR, Q.C.:

Q. Dr. Williams, sorry, and then you have a meeting on July 12th.

MS. PREDHAM:

A. July 10th, I think.

CHAYTOR, Q.C.:

Q. July 10th, I'm sorry, yes, July 10th, and again July 12th. And on July 10th, that's when you first learn about Peggy Deane's case, is it?

MS. PREDHAM:

A. Yes, and I never knew her name, you know.

CHAYTOR, Q.C.:

Q. Right, okay, and what were you told in that meeting? What were you told about Peggy Deane's case, the index case, in that meeting?

MS. PREDHAM:

A. I can't really remember exactly what I was told in that meeting. I know a couple of days later when we had the larger meeting with the oncologists and the surgeons, we went through that story again. So it's pretty hard to

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differentiate what I was told one or the other, but -

CHAYTOR, Q.C.:

Q. Okay, that's fine, yes. I'm just wondering what--yes, what in fact were you told, whether it's July 10th, July 12th.

MS. PREDHAM:

A. Yeah, because it's hard to differentiate between one and other.

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. Basically that this lady was diagnosed in 2002. I believe it's with lobular type breast cancer. She was ER/PR negative and her disease progressed. She was very ill at this time, and her oncologist wanted to see whether or not there was anything that could be done, anything else that was available, and had sent the chart or a synopsis of the chart to an oncologist at Sloan-Kettering in the States and who said basically, you know, you've done everything available. However, it's highly unusual that this lady would be ER/PR negative with this diagnosis. You should probably get

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her retested. So then she was, and she did convert. She went from negative to strongly positive and that caused some discussion. I guess that was discussed in a broader sense. So they brought that to Dr. Cook's attention and they retested several others, which had converted as well.

CHAYTOR, Q.C.:

Q. Okay, and in being told about the contact with the United States, were you told that it was Sloan Kettering?

MS. PREDHAM:

A. Definitely by later that week. I don't know if I was told that immediately, but definitely it was Sloan Kettering was later that week.

CHAYTOR, Q.C.:

Q. Okay, and were you told anything in terms of any research or review that may have taken place at Sloan Kettering?

MS. PREDHAM:

A. Well, when they questioned that, they did say that, you know, they were just about to publish an article and in fact, they were going to--they weren't even going to do ER/PR on I think it's lobular cancer right now

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because they considered them all positive.

CHAYTOR, Q.C.:

Q. Okay, and who was telling you this, in terms of what's happening at Sloan Kettering?

MS. PREDHAM:

A. My memory is that it was Dr. McCarthy, but it might be Dr. Laing, but that's my memory is that it was Dr. McCarthy.

CHAYTOR, Q.C.:

Q. And by the time you're brought in and involved in this on July 10th, were you made aware of any other tests that had been repeated and converted, other than the index case?

MS. PREDHAM:

A. I think they had only done the five or it may have been--they did two groups after that, and it may have been the first group. I'm not sure if the results were back on that first group or not then.

CHAYTOR, Q.C.:

Q. Okay. There had been a meeting in mid May, May 17th, 2005 on this. Were you aware that meeting had taken place?

MS. PREDHAM:

A. No, not until at this time.

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CHAYTOR, Q.C.:

Q. I'm sorry, which time?

MS. PREDHAM:

A. Not until in July.

CHAYTOR, Q.C.:

Q. In July, okay, and there's correspondence from Dr. Cook to Dr. Williams, May 24th, 2005, and perhaps we could just bring that up. It's P-0324. And when you met then in July, I'll just show you this correspondence and bring you down through. Does this look familiar to you?

MS. PREDHAM:

A. Oh yes.

CHAYTOR, Q.C.:

Q. And when would you have first seen this correspondence?

MS. PREDHAM:

A. It would have been after that meeting I had with Dr. Williams in June. I'm thinking--I don't remember when he actually gave it to me, but I'm thinking he must have given it to me at that time or shortly after, because there's no date stamp from our department on it, and if it had come--if he had sent it in the mail

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or faxed it, it would have been date stamped by our department, but it only has his date stamp on it. So I'm thinking he probably gave it to me.

CHAYTOR, Q.C.:

Q. So in between him mentioning it to you in June and then -

MS. PREDHAM:

A. The meeting in July.

CHAYTOR, Q.C.:

Q. - the meeting in July, you would have come in receipt of this?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and of course, then this would have referred to the May 17th meeting and it talks a little bit about what receptor status influences, in terms of treatment, and then it refers to "in early 2003, Dr. Ejeckam, our point man for immunoperoxidase testing at the General Hospital site, discontinued testing of the ER and PR receptors for a six-week period. A memo was circulated to all pathologists across the province stating this. The

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technique was temporarily halted because of erratic staining, which required readjustments of titration and staining times. Once Dr. Ejeckam felt confident in the reliability of the staining, the test was reintroduced."

And then "at the conclusion of the May 17th meeting, it was decided to retest all negative ERs and PRs for the year 2002 and possibly 2001. I have no idea at this point in time, knowing whether these are a few isolated cases or whether we are dealing with a much bigger issue. For now, we have agreed if there is a receptor conversion that the oncologists would inform the patient that we have retested the ER and PR receptors under our newer more sensitive technique. However, if it is identified that we have a much more significant conversion factor problem, involving many patients, we would need to seek advice and guidance from QI on how best to disclose this information, as this involves breast cancer patients across the province."

And then, in closing, there is a plan set out including establishing an external proficiency testing, establishing a separate

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immunoperoxidase service, the training of the technologists in a major immuno referral lab that has a well-established quality control and troubleshooting program and appropriate CME funding for the technologists.

So when you received this then sometime between June and your meeting of July 10th, 2005, did this cause you any more concern than the comment that had been made by Dr. Williams originally in terms of not knowing if it's going to be a big issue or not?

MS. PREDHAM:

A. Well, I was concerned, but then, you know, I mean, Dr. Cook also referred to it that he didn't know if this was just--I can't remember his wording now, towards the end, if this was a big issue or he has no idea at that point in time whether these are a few isolated cases or a much bigger issue. So I had to take it on face value that I had to wait until we found out.

CHAYTOR, Q.C.:

Q. But they're going to be retesting all their negatives for 2002 and possibly 2001?

MS. PREDHAM:

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A. Yes.

CHAYTOR, Q.C.:

Q. So you still though, at this point in time, sat it out and waited and didn't notify the insurer, for example, or take any other measures yourself in terms of looking into this?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. Okay, and the issue here in terms of what would be communicated to the patients, "for now, we have agreed that if there is a receptor conversion that the oncologists would inform the patient that we have retested the ER and PR receptors under the newer more sensitive technique." Did that cause you any concern when you read it?

MS. PREDHAM:

A. No, I did note it, that they were doing that, and that's an appropriate thing.

CHAYTOR, Q.C.:

Q. So is this your marks here?

MS. PREDHAM:

A. Yes.

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CHAYTOR, Q.C.:

Q. Okay, and this is your handwriting?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and so when you received the document, you wrote on here, "did we make determination?" Is that what that says?

MS. PREDHAM:

A. Yes, I think I'm wondering--I wasn't clear here at the time. It said "interpretation of these stains were made by those pathologists who were assigned the cases. The stains were also circulated to pathologists across the province according to which lab the cases originated from." So I wasn't clear whether or not we read the slides or if the pathologist outside did so.

CHAYTOR, Q.C.:

Q. So who did the interpretation is what you were querying?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. In the time period mentioned.

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MS. PREDHAM:
A. Usually when I get a document like this and I read it, I ask questions to myself just for later.
CHAYTOR, Q.C.:
Q. Yes, and I take it then you went back and asked those questions of the appropriate individuals?
MS. PREDHAM:
A. In July, when we met.
CHAYTOR, Q.C.:
Q. Okay, and -
MS. PREDHAM:
A. And that one you're highlighting now, that would have been a note that I had made when we met in July.
CHAYTOR, Q.C.:
Q. Okay. So you wrote "came in September 2002."
MS. PREDHAM:
A. That was Dr. Ejeckam came in September.
CHAYTOR, Q.C.:
Q. You're talking about Dr. Ejeckam, okay. And you have memory specific--you have good memory enough to be able to say when you even made the comments that are written here?

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MS. PREDHAM:
A. Oh, I can--I distinctly remember this, yes.
CHAYTOR, Q.C.:
Q. Yes, okay. And over here, you write "why was it looked in the past?" Is that what it says?
MS. PREDHAM:
A. I guess it's did we go back. Did we look at anything before that.
CHAYTOR, Q.C.:
Q. And saying why did he shut down the testing? Is that what you're asking?
MS. PREDHAM:
A. Yes, yeah.
CHAYTOR, Q.C.:
Q. And again, those questions would have been posed by you to whom and when?
MS. PREDHAM:
A. Well, that was just when I was reading through. That was just so I'd remember. When I read it, when I went to a meeting, these are things that I wanted to ask.
CHAYTOR, Q.C.:
Q. Okay, and so then did you bring this up with--at your meeting on July 10th?
MS. PREDHAM:

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A. Yes.
CHAYTOR, Q.C.:
Q. And you asked those questions then of Doctors Cook and Mr. Gulliver?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And controls, what does it say here?
MS. PREDHAM:
A. "Controls go through all the same process, but they are optimally fixed tissue."
CHAYTOR, Q.C.:
Q. And what is that referring to?
MS. PREDHAM:
A. I guess I must have asked about or been told about the control process, the controls that are run during this issue.
CHAYTOR, Q.C.:
Q. Okay, and when would this comment have been made?
MS. PREDHAM:
A. It would have been made at--usually when I'm asking myself questions, for some reason, I write them down on this side and then when I've got other issues or I'm making notes, I

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put them down this side.
CHAYTOR, Q.C.:
Q. Okay. So usually that's--and that's how you're able to remember that too, or it helps in your memory. So these over here would be notes made -
MS. PREDHAM:
A. Before the meeting.
CHAYTOR, Q.C.:
Q. - and it's probably different ink too, if we had the originals, we'd see.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. But this is beforehand and these are questions or information that's being given to you during the meeting of July 10th?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And so the idea that "controls go through the same process, but they are optimally fixed tissue," who in the meeting would have told you that?
MS. PREDHAM:

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A. Mr. Gulliver, I would assume. I can't distinctly remember who told me that, but Mr. Gulliver usually told me about the controls and that.

CHAYTOR, Q.C.:

Q. So was there a concern expressed in this meeting that the patients tissues may be other than optimally fixed?

MS. PREDHAM:

A. No, not that they would be anything other than optimally fixed, but that the controls were set aside as being optimally fixed. I guess that was what I was taking away from it.

CHAYTOR, Q.C.:

Q. And I think that's all the comments that you made then on this particular document. So perhaps then you can take us to the July 10th meeting and what else you recall about that meeting.

MS. PREDHAM:

A. Well, Mr. Gulliver took us through--or Dr. Cook took us through the issue, and I guess most of the content of what we discussed here, and Mr. Gulliver described the test, the fact that we had DAKO and that we had Ventana, and

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we went through that process.

CHAYTOR, Q.C.:

Q. Okay. So Mr. Gulliver described to you the DAKO days and the use of the DAKO machine, and I take it then the difference in bringing on the Ventana?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. There was discussion about Dr. Ejeckam and what happened in 2003?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what did Dr. Cook contribute to the discussion?

MS. PREDHAM:

A. Well, I guess his was, you know, what he had learned talking to the oncologists, and what we had planned to do, the process of what we had sent already off, his communication across the province, and then it was, you know, the fact that we were going to have to talk to the surgeons and the oncologists, and also we came up with a list of things that we had to do or

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that had to be done that we needed more information on.

CHAYTOR, Q.C.:

Q. Okay, and was it following this meeting or the July 12th meeting that you contacted the insurer, contacted Ray Walsh?

MS. PREDHAM:

A. I think it was after the last meeting.

CHAYTOR, Q.C.:

Q. The second meeting?

MS. PREDHAM:

A. The second meeting.

CHAYTOR, Q.C.:

Q. So then at the July 12th meeting, who attends that?

MS. PREDHAM:

A. I think we had two meetings that day. One was with Dr. Cook, Mr. Gulliver, and Dr. Williams and myself, and then the next one was a larger group of oncologists and surgeons; Dr. Laing, Dr. McCarthy, Dr. Gardiner, Dr. Kwan, Dr. Felix.

CHAYTOR, Q.C.:

Q. And perhaps then we could look at P-2940. I'm sorry, let's try 925, P-0925. These are notes

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of Dr. Williams, and on page--I believe it's three of these--no, page two, July 12th, 2005.

MS. PREDHAM:

A. Okay.

CHAYTOR, Q.C.:

Q. And this is Dr. Cook, Ms. Predham, Mr. Gulliver, and Dr. Williams. So is this the first meeting you would have had?

MS. PREDHAM:

A. This must have been the first meeting, so it was July 12th, not the 10th.

CHAYTOR, Q.C.:

Q. Not the 10th. So July 12th?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Was the first meeting you have?

MS. PREDHAM:

A. I remember because it was--I can remember the--Mr. Gulliver, I can distinctly remember how he saw the Ventana System at the Montreal Jewish Hospital and then they brought it in in January, 2004. So for him to be telling us that, it was that initial meeting I went to.

CHAYTOR, Q.C.:

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Q. Okay, so this says there was follow up on status by testing ER/PR receptors, but this is the first time you've been brought in to this?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and prior to 2004, there's the discussion of the DAKO testing procedure, which you recall having been discussed, and there was a system of positive controls; October, 2003, visiting the Ventana System at Montreal Jewish; January, 2004, Ventana System purchased, training commenced. So you remember, I guess, this was Mr. Gulliver speaking to this?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And they had pulled all the cases in September, 2001, to review findings and retests. There was an issue of erratic staining in early 2003 and testing pulled for six weeks. Titration times and staining times were adjusted. Tests sent out for six weeks to other labs. So at the time that's what I

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take it you would have been told that testing was sent out?
MS. PREDHAM:
A. Yes, I think we understand now that they just put a hold on the testing at that time.
CHAYTOR, Q.C.:
Q. Yes, and this issue here for breast tissue samples should be in formalin for 48 to 72 hours, controls are in formalin for optimal time. So there appears in the July 12th meeting there was some discussion about fixation. Do you recall that?
MS. PREDHAM:
A. No, it doesn't stand out. It may have been discussed, but it doesn't stand out right now.
CHAYTOR, Q.C.:
Q. And it does refer to first being alerted when patient was seen in USA. "An oncologist there felt patient testing should have been positive for ER/PR, and on retesting here it was. Ventana takes the human factor out of the equation". Who do you recall making that statement?
MS. PREDHAM:
A. It would have been Mr. Gulliver.

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CHAYTOR, Q.C.:
Q. And the decision coming out of the July 12th meeting is to test all samples of living patients, what are positive rates for infiltrating lobular and ductal cancer, and what did you understand the reason would be for looking at positivity rates for those two types of cancer?
MS. PREDHAM:
A. Well--and I believe it's lobular. I may be mistaken, but -
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:
A. But the information that we had gotten in this story of what happened was that comment by Sloan-Kettering that all lobulars should be 100 percent positive, so, you know, okay, let's look at ours and see what our positivity rate is for that.
CHAYTOR, Q.C.:
Q. And was that after being told to you, or were you aware of that by this point in time as to what Sloan-Kettering had said?
MS. PREDHAM:

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A. I must have been told that--I guess Dr. Cook must have told me at that time or given us a background of it.
CHAYTOR, Q.C.:
Q. And who made this suggestion to look at our positivity rates?
MS. PREDHAM:
A. It may have been me, but I guess it was a consensus between the four of us.
CHAYTOR, Q.C.:
Q. And then it says, "Look at our rate of positivity by year". Who would have suggested that?
MS. PREDHAM:
A. The same thing, I'm not sure exactly who, but it would have been the consensus of the four of us.
CHAYTOR, Q.C.:
Q. And what would the purpose in doing that be?
MS. PREDHAM:
A. Well, there was some discussion that there is an established positivity rate for ER/PR, and I can remember the problem being so many pathologists reading that, you know, without going to one person, you would really not see-

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-a pathologist would not identify that, you know, that they're getting more negatives than they should be, and I do remember clearly the discussion that if you had--say, if it was like a 90 percent lobular positivity, and you had--you know, if you were a pathologist out of town and you don't get a lot of breast cancer and you had one that was negative, you wouldn't even think twice at it because you don't see that many of them. So it would take a few of those for you to even start questioning it. It was that -

CHAYTOR, Q.C.:

Q. Did you understand, though--had you been told that Sloan-Kettering weren't even going to bother testing for ER/PR for infiltrating lobulars any more because they assumed they were all positive?

MS. PREDHAM:

A. I don't know if I was told that they weren't even going to test any more. I don't know, that might have been later, but I do know that they said they should have been positive as almost all--that was the first message I think I got, almost all of that diagnosis were

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positive.

CHAYTOR, Q.C.:

Q. And at some point in time, did you understand them to be saying that all, not almost all, but all were positive?

MS. PREDHAM:

A. That was my understanding, yeah.

CHAYTOR, Q.C.:

Q. And you got that from the oncologist, either Dr. McCarthy or Dr. Laing?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And in terms of--so in your trying to figure out then by testing or checking out the positivity rates whether or not that would have been a useful exercise over the years, is that what you were trying to determine, well, maybe if we'd been checking our positivity rates, we could have picked up on this earlier, is that your thinking?

MS. PREDHAM:

A. No, no, it was--at that point in time, it was, you know, how are we doing, do we have a problem in the past, did we have a problem,

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was our positivity rate within the established range all these years, or did we have too many negatives.

CHAYTOR, Q.C.:

Q. And I guess, though, by July 12th the decision is made that you're going to test all living--the samples of all living patients. So a determination as to whether or not you had a problem was going to come out at the retesting. So I'm just wondering why--what would be the benefit at the same time of looking at your positivity rates when you have a big undertaking ahead of you, in any event, to get all these samples together, identify the patients, and start the retesting? What's the additional benefit in looking at positivity rates?

MS. PREDHAM:

A. Well, I remember thinking--you know, our thought at the time, it could focus our activities, you know, to a certain area, but, you know, you're making a very valid point that we decided to test all samples, but I guess that was the intent is that it could focus our activities on one or two years or,

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you know -

CHAYTOR, Q.C.:

Q. So if you were off in any given year, then you could probably zone in and concentrate on that particular time period?

MS. PREDHAM:

A. Yeah.

CHAYTOR, Q.C.:

Q. And we understand that this continued, the exercise to track the positivity rates continued on and Mr. Gulliver has given evidence about his involvement in that, and did you have--other than perhaps being the person to suggest it initially, did you have any further involvement in the tracking of positivity rates or the collection of that data?

MS. PREDHAM:

A. No, just the--I saw the results, but I didn't--I wasn't involved in getting them.

CHAYTOR, Q.C.:

Q. So you would be provided the results?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

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Q. And what was the purpose in giving you the results?
MS. PREDHAM:
A. Well, I guess just--we were all part of that. One of the other things here, and it's noted up there, is that you have--the Ventana here we were told was ten times more sensitive. So if it is more sensitive, then you were going to expect conversions, you know, if you went back and retested. That was my thinking at the time, so if you've got positivity rates that were in a norm, you know, that this is the range and this was okay, now you'd have new technology and were going back, well, then, you know, you could see whether or not that's the reason for conversions as opposed to, you know, there was a problem and we had too many negatives at the time.
CHAYTOR, Q.C.:
Q. And I take it this comment about the Ventana System being ten times more sensitive, that's Mr. Gulliver was providing that information?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:

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Q. The Ventana was more sensitive than what?
MS. PREDHAM:
A. Than the DAKO machine.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. The DAKO System or process.
CHAYTOR, Q.C.:
Q. And he's attributing that, according to the comment written here, to the company having said that?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. In terms of getting the positivity rates, that information, what did you then do with the information when it was passed to you? Did you pass it along to anyone else?
MS. PREDHAM:
A. I'm not--well, see the positivity rates were circulated to all of us in the group.
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:
A. So other than probably discussing it in our

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department, I don't think I was sharing it with anybody else because they were all there around the table.
CHAYTOR, Q.C.:
Q. And did you share it externally to anyone outside of Eastern Health?
MS. PREDHAM:
A. I don't recall.
CHAYTOR, Q.C.:
Q. For example, in terms of keeping the insurer up to date, would you have passed that information along to the insurer?
MS. PREDHAM:
A. I may have, but I don't recall. I may have just said our positivity rates, or, you know--I don't recall saying, oh, look, I have this, I must send this over.
CHAYTOR, Q.C.:
Q. And if we could look, please, at P-2940, and we understand these to be your own handwritten notes, Ms. Predham?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And on page three, you have written on the

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top, "Dr. W. Dr. C. Terry and me", and -
MS. PREDHAM:
A. This would have been the second meeting. The one you had up first would have been that July 12th, and this would have been the one after.
CHAYTOR, Q.C.:
Q. Okay, so this would be the one after, being July 14th?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So you had two meetings. You had another meeting--wait now, let me be clear, because you thought you had two meetings on the same day, July 12th, is that right?
MS. PREDHAM:
A. July 12th, we met, that was the first meeting, and then later that week we had a meeting with just the four of us, and I thought it was the same day later that evening that we met with the surgeons and the oncologists. Now it may have been the day after, but I thought it was the same day.
CHAYTOR, Q.C.:
Q. Okay, all right, so you don't believe this to

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be the notes from the July 12th meeting?
MS. PREDHAM:
A. No, it definitely wasn't.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. Because I didn't get Dr. Ejeckam's memo until we had the second meeting.
CHAYTOR, Q.C.:
Q. Okay, and to the best of your recollection, if the first occurred July 12th, the second one occurred when?
MS. PREDHAM:
A. July 14th, I think.
CHAYTOR, Q.C.:
Q. Now July 14th, we know was the meeting with a larger group of people. You would have met with the oncologists on that day.
MS. PREDHAM:
A. So this would have been earlier that day.
CHAYTOR, Q.C.:
Q. So this is July 14th?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:

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Q. Just to make sure I'm--the mark on this, there were--before you met with a larger group, there were in fact two meetings of Dr. Williams, Mr. Gulliver, Dr. Cook, and yourself?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. The first of which we believe occurred on July 12th?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. And the second on July 14th?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. And the larger meeting which included the oncologists and surgeons, etc, also occurred you believe on the 14th?
MS. PREDHAM:
A. Yes, in the evening.
THE COMMISSIONER:
Q. Okay, thank you.
CHAYTOR, Q.C.:

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Q. I'll take you back to page one of your notes, and they're not dated, so I was trying to piece it together as best I could, is this your notes from the July 12th meeting?
MS. PREDHAM:
A. Yes, because I remember the Jewish General, and I remember that was discussed at that first one.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. And he described--Mr. Gulliver described how they purchased it, they sent up staff for training, and then it was going then, so I remember that.
CHAYTOR, Q.C.:
Q. And what have you written here, "We opted for Ventana rather than DAKO because", what's this word, is it -
MS. PREDHAM:
A. Well, it's supposed to be DAKO, but I guess that's how I was spelling it at the time, DATCO, instead of DAKO.
CHAYTOR, Q.C.:
Q. And you didn't finish, okay. What did you

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understand then, why was it that they went with the Ventana System rather than the DAKO at the time?
MS. PREDHAM:
A. There was a--I don't think the DAKO was semi-automated, they wanted to get that automated part of it, and I don't think the DAKO version of that was out yet. I think that's the rationale why they went with Ventana.
CHAYTOR, Q.C.:
Q. Did they have any concern in terms of the antigen retrieval under the DAKO, the old DAKO system, the antigen retrieval process that was used?
MS. PREDHAM:
A. The concerns that they had in my memory or my knowledge were all limited to the amount of manual work that had to go into this, and, you know, the descriptions I had was that you had to boil the slides--boil the tissue, you know, between 15 minutes and 20 minutes, and if you did it less than 15, you didn't get the release of the antigens, and if you put it over 20, then you destroyed the tissue. So it was that manual process that they wanted to

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eliminate, and when they had seen this one up at Jewish General, they liked that system, they liked that ability and that's what they went for.

CHAYTOR, Q.C.:

Q. And it does talk then about things that the Ventana system could do, and here, you're right, it says the ten times greater sensitivity which is consistent with Dr. Williams note for the same date, and went back and pulled all cases, October, 2001, and can you read your own note there?

MS. PREDHAM:

A. "Recut and retested".

CHAYTOR, Q.C.:

Q. Recut and retested, and I think you stopped in mid thought again.

MS. PREDHAM:

A. I stopped in mid sentence again.

CHAYTOR, Q.C.:

Q. And they followed the manual. "Terry has this locked up". What's that referring to?

MS. PREDHAM:

A. Referring to the procedures that they would have been following for this process, you

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know, what the techs had done. So I had asked Mr. Gulliver if he had secured that document.

CHAYTOR, Q.C.:

Q. And he indicated to you that he had?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what would be the importance of doing that?

MS. PREDHAM:

A. Well, just to make sure that we still have it, you know, in case it inadvertently got lost or whatever.

THE COMMISSIONER:

Q. On page two, are we still in the meeting of July 12th or are we now into the -

MS. PREDHAM:

A. No, July 12th.

THE COMMISSIONER:

Q. Okay, thank you.

CHAYTOR, Q.C.:

Q. And where did you understand Mr. Gulliver then stored the manual?

MS. PREDHAM:

A. I assumed it was in his office or Mr. Dyer's

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office.

CHAYTOR, Q.C.:

Q. Was there anything else that you asked him to secure or ask whether or not had been secured?

MS. PREDHAM:

A. Well, I guess all documentation would, you know would have been a part of my request of everything that they had would have to be secured, and on the top corner here on the left, Thursday morning at 9, that must have been the subsequent meeting that we had on the 14th.

CHAYTOR, Q.C.:

Q. Okay, so then the 14th, okay, yes. At this point in time then your first--I take it, this is the first real--other than having in your possession the May 24th correspondence, this is your first initiation into the issue and your first opportunity to ask any questions to help get this straight in your own mind?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Because--and you're hearing all this for the first time.

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MS. PREDHAM:

A. Yeah.

CHAYTOR, Q.C.:

Q. In terms of then Mr. Gulliver informing you about the change in the machines going from the DAKO to the Ventana, did you ask him do we still have the DAKO machine?

MS. PREDHAM:

A. At that time, oh, yes.

CHAYTOR, Q.C.:

Q. And what did he tell you?

MS. PREDHAM:

A. That we no longer had it.

CHAYTOR, Q.C.:

Q. And did you ask him where it was, or where it went?

MS. PREDHAM:

A. He didn't know where it went.

CHAYTOR, Q.C.:

Q. He didn't know where it went, and have you since learned otherwise?

MS. PREDHAM:

A. Well, yes, I understood that I think it was last week that it was sold to somebody.

CHAYTOR, Q.C.:

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Q. And throughout the entire investigation of this issue by yourself and others, did Mr. Gulliver ever tell you otherwise, other than in the past couple of weeks?
MS. PREDHAM:
A. No, I had no knowledge of where it actually went.
CHAYTOR, Q.C.:
Q. So other than on the first day when you asked--your first meeting with him you asked where's the DAKO machine and he said he didn't know where it went, the subject never came up again after that?
MS. PREDHAM:
A. I think it may have come up, you know, we wondered where it was, and I think too that they had a flood at the Health Sciences and it may have been--you know, he may have thought it went somewhere in that, or that kind of thing. I got some kind of vague impression there, but, you know, it did come up every now and then, but not--if we didn't have it, we didn't have it.
CHAYTOR, Q.C.:
Q. And whenever it did come up, I take it Mr. Joe

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White's name never came up?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And the fact that he had taken the machine?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. And the first time you heard that was in the last couple of weeks?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And have you had an opportunity to have any further discussion with Mr. Gulliver about that?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. I guess he's probably been with us in that time period?
MS. PREDHAM:
A. Yes, I think he's been.
CHAYTOR, Q.C.:
Q. And have you had discussion with anyone else

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about that? Were you surprised to learn that, that now there's a name of who actually had the machine?
MS. PREDHAM:
A. Oh yes, I was surprised.
CHAYTOR, Q.C.:
Q. You were surprised, okay. And would that have been of relevance to you at the time when you were conducting, looking into this and trying to piece together what was happening, would that have been of relevance to you to know where the machine had gone and whether or not you might still be able to find it?
MS. PREDHAM:
A. Well it would have been an answer to a question, you know, and then we'd have to check into could we find it, what did it mean, did we need it, you know, those types of things, at least we would have, you know, had some direction there, we could go down that road and explore it.
CHAYTOR, Q.C.:
Q. And I appreciate this is really early days here, July 12th and 14th for you in dealing with this issue and did you even understand at

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this point in time that there would be a computer with the machine or a computer used to help operate the machine?
MS. PREDHAM:
A. No, I can remember my first impression was that, you know, it was like a hot plate and a pot and, you know, very simplistic, I never had an idea that it was actually a machine, I don't think at that time, so I probably didn't even ask him at that time until later. I know, my impression it was very manual and, you know, I didn't really think about an actual machine. It was more the process and the slides and antigens and stuff that we had purchased. But that was just, you know, when I'm hearing all this information, this is what I had visualized.
CHAYTOR, Q.C.:
Q. Okay, and at some point in time you come to appreciate though that there's a computer also involved.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And I take it not too long into the process

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you're in that lab and you're talking to people and looking around, looking at the equipment and trying to learn as much as you can about this testing process.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you said earlier today that about six months ago when the request for the Ventana computer records came up, at that point it dawned on you to, well, was there a computer with the DAKO and that's the first time that that would have come to your realization. Did you ask where's the computer for the DAKO machine? What about that, is that still in existence or any records from the DAKO computer?

MS. PREDHAM:

A. Well I would have asked all along for records during this period of time.

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. And I don't know if I asked a second time at that time or not.

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CHAYTOR, Q.C.:

Q. And I take it who would you have been making that request of for any records that may have existed?

MS. PREDHAM:

A. Oh it would have been Mr. Gulliver or Mr. Dyer.

CHAYTOR, Q.C.:

Q. And what were you told in terms of the existence of any relevant records?

MS. PREDHAM:

A. We didn't have any.

THE COMMISSIONER:

Q. Ms. Chaytor, wherever you can find a spot, we'll take the afternoon break.

CHAYTOR, Q.C.:

Q. Okay, well actually this would be a good place, please, Commissioner.

THE COMMISSIONER:

Q. All right, we'll take a break.

(RECESS)

THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor.

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. Registrar, if we could have, please, P-2152? And page 8, please of this document. Ms. Predham, this is kind of small, I don't know if we can make it a little bit bigger please, Registrar.

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MS. PREDHAM:

A. I can see that.

CHAYTOR, Q.C.:

Q. Okay. Ms. Predham, I'll just show you this document, it was called an immunohistochemical report and it's either May 6th, 1998 or June 5th, 1998, and there's no patient name noted. There is a field for patient name, but it's not there, case number with a surgical number and we understand this is central, is the CMH. The doctor is Khalifa and the technician is Peggy. Slide number 19 and 20, antibodies ER 1 to 50 we understand to be dilution, 30 minutes; PR 1 to 10, 30 minutes and then a protocol set out over here. Ms. Predham, we understand from a previous witness that this is the type of information that would be on the DAKO records for the DAKO machine, for running whatever the antibodies were on any particular time. And this one was in relation to--and this might answer my question, it looks like it's June 2nd, 1998 and then Peggy Welsh, June 5th, 1998. And so this is the type of information that might be stored on the DAKO computer. If you had been aware of the possible existence of this information throughout your investigation and of the ER/PR issue, might this type of information have been of relevance or assistance to you?

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MS. PREDHAM:

A. Well, it could, I mean, you'd have to check in and see what it meant, it would have to be explained to me and then you would have to look at the dates and see that, but you'd want to look and see, you'd want to rule out that there was any other factors that were there, you know, was it something with, you know, the ratio that they using or the timing or, you know, was there a pattern of anything. So, it was just part of the investigation that whatever you have could be totally irrelevant, but at least you've reviewed it and you've explored the possibility of it.

CHAYTOR, Q.C.:

Q. Yes, to look at whether or not, for example, on any given date or any particular time

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period the same protocols were being used.

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. For example. Also, would it be of some assistance in terms of identifying the technicians, for example, who ran the test?

MS. PREDHAM:

A. I mean, it may be, you know, you don't know until--part of when you're looking at an investigation into anything like that, you're trying to look for patterns and you're trying to eliminate things, so until you've got the documentation in front of you and you can see, especially over this long period of time, you really don't know until you start investigating what you can look at, any kind of pattern that you can come up with.

CHAYTOR, Q.C.:

Q. So if you had the document for every test that was run on ER/PR during the time period that the DAKO was in existence, you could then sit down and look through it and see if there's any pattern, trend or anything else that might be relevant to your investigation?

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MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So in that respect, would it have been of use to you to know that this type of information might exist?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Did anyone bring to your attention that this is the type of information that might be in the DAKO computer?

MS. PREDHAM:

A. No.

THE COMMISSIONER:

Q. I would assume that it was just as valuable to you if there were no pattern in the sense of -

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. - part of your job would be eliminating as well as looking for -

MS. PREDHAM:

A. Exactly. So if, you know, everything run had exactly the same percentage and minutes and

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all that, well then you can eliminate that as a question.

THE COMMISSIONER:

Q. Okay, thank you.

CHAYTOR, Q.C.:

Q. Okay, if we can go back, please, I think we were looking at P-2940 and we've talked about what the comments here mean, and again, this is your meeting, your first meeting of July 12th and can you just read for us, please, DAKO's recommendations compared to what we did?

MS. PREDHAM:

A. Well whatever DAKO was telling us how we had to proceed, verses what we actually did. So, you know, and I guess that's the understanding that we had documentation to say this is what we did, so what the manufacturer of the equipment was saying we should do and what we actually did--if there was any difference.

CHAYTOR, Q.C.:

Q. Okay, so that's what--and these are numbered one through six. Is there any particular relevance or these are just points that come up in the meeting?

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MS. PREDHAM:

A. They were just points at the end, I guess we summed up where we were going from.

CHAYTOR, Q.C.:

Q. Okay, so did this mean that somebody was going to do a comparison from what DAKO, the manufacturer, would have recommended in terms of the procedure to be followed, compared to what was actually taking place?

MS. PREDHAM:

A. Yes. And that's, the note I guess is in reference to that is that they followed whatever the manual told them to do.

CHAYTOR, Q.C.:

Q. Okay, so there is to be no follow up on that, Terry has indicated to you that they followed the manual?

MS. PREDHAM:

A. Well it would have been, you know, if there was documentation that I could have gone back to look at, it would have been a comparison to what was recommended at the time, compared to what was documented, so that, you know, would have been an intent to do that.

CHAYTOR, Q.C.:

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Q. Okay, and then you would do that in your follow up investigation and make those inquiries?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And I'll bring you to that in terms of any discussions you had with the lab technologists regarding that. Number two, dates of -
MS. PREDHAM:
A. Dates of those that are different. So what were the dates of the ones that converted, year to year, rate of positivity by year and over there, I've got pattern for rates.
CHAYTOR, Q.C.:
Q. Okay, and so you're looking to see if there's any, I take it, correlation between the, whether or not the same time period or you can narrow down the time period.
MS. PREDHAM:
A. One of the things that Mr. Gulliver described to us in the 40 steps, in the manual process of that, is that they would get a--I can't remember the technical terms, but it was a reagent, say, for lack of a better term,

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they'd get a small bottle of reagent from DAKO and they would have to pipette microlitres out, dilute that in a solution and then that would be used for months or a period of months in the preparation of the slides. And I guess just coming from my perspective, that's one step which is an obvious room for error. If the reagent was a problem from the manufacturer and they had, you know, what was the lot number of that, who did the pipetting, where was it stored, how long was it in use, you know, these were the types of things that you would have to go--because if you use that for six weeks and you had a pile of conversions for six weeks and the rest of the year was okay, well then maybe it's something to do with that.
CHAYTOR, Q.C.:
Q. Yes, or the accuracy of the pipettes for that matter that's being used.
MS. PREDHAM:
A. Yeah.
CHAYTOR, Q.C.:
Q. Thirdly, individual lab -
MS. PREDHAM:

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A. Positivity rate with DAKO testing.
CHAYTOR, Q.C.:
Q. Okay, and what are you referring to there?
MS. PREDHAM:
A. Depending upon diagnosis, rates for infiltrating lobular and ductal carcinoma are positive.
CHAYTOR, Q.C.:
Q. Okay, and this piece, I believe there's a similar note in Dr. Williams' notes, "Individual lab, positivity rate with DAKO testing", is that, do you know what you're referring to there?
MS. PREDHAM:
A. No, I'm not sure what I meant by individual lab.
CHAYTOR, Q.C.:
Q. And why do you have "lab" written over to the left -
MS. PREDHAM:
A. They were going to follow up on that.
CHAYTOR, Q.C.:
Q. So these are Dr. Cook and Mr. Gulliver to follow up?
MS. PREDHAM:

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A. Yes.
CHAYTOR, Q.C.:
Q. Test all samples for living patients, that's self explanatory; need a -
MS. PREDHAM:
A. A meeting to inform oncologists and Cancer Clinic Program.
CHAYTOR, Q.C.:
Q. Okay, and so up to this point in time, they hadn't been informed?
MS. PREDHAM:
A. Well I guess the ones that were involved in this up to that point in time, but not as a group.
CHAYTOR, Q.C.:
Q. Not as a group, okay. And what does this say?
MS. PREDHAM:
A. Check with Dr. Ejeckam regarding a memo--or dash memo.
CHAYTOR, Q.C.:
Q. And who was to do that?
MS. PREDHAM:
A. Dr. Cook.
CHAYTOR, Q.C.:
Q. Meaning the memo at this point in time, the

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only one that you were referred to was the July 19th or June 19th -

MS. PREDHAM:

A. I hadn't seen it yet, but there was a reference that there was a memo, that he had sent to all pathologists I think was the--and it was probably the earlier one, actually.

CHAYTOR, Q.C.:

Q. And then when you got the June 19th one, though, that was sent to Terry Gulliver, it didn't occur to you at the time, well I thought the memo went to all pathologists?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. So coming out of then the first meeting, what was it that you were to do?

MS. PREDHAM:

A. After that first meeting, I didn't have anything that I actually had to do before Thursday at 9:00.

CHAYTOR, Q.C.:

Q. Okay, so the next time you get together then is Thursday, July 14th?

MS. PREDHAM:

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A. Yes.

CHAYTOR, Q.C.:

Q. And you're not to necessarily do anything in the meantime?

MS. PREDHAM:

A. Well I told our department about it and -

CHAYTOR, Q.C.:

Q. You told your department?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And you leave this meeting and you call the insurer and inform the insurer?

MS. PREDHAM:

A. I'm not sure if I told them at this one or after the next one, it was one or the other.

THE COMMISSIONER:

Q. Where it says "test all samples for living patients"--No. 4, that is "patients" isn't it?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. What did you understand that meant?

MS. PREDHAM:

A. Right there it sounds like we're going to test

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everyone, but I think, I think it was always only negative, but it does look there that we were thinking all of them.

THE COMMISSIONER:

Q. And all meant all? What did all mean?

MS. PREDHAM:

A. Well my memory is that we always considered just negative patients, negative ER, negative patients.

THE COMMISSIONER:

Q. Yes, but what I'm thinking of is what year range at that--were you thinking of testing all patients for a particular year or a particular time frame or, you know, what was the--who was going to be lumped into "all" at that point?

MS. PREDHAM:

A. Sorry, all the patients tested on DAKO from '97 to 2004.

THE COMMISSIONER:

Q. So that decision was made at that point.

MS. PREDHAM:

A. Yes. I think it was made before that with Dr. Cook and Dr. Williams.

THE COMMISSIONER:

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Q. Okay.

CHAYTOR, Q.C.:

Q. And then if we continue on then to the next page, is this then the meeting of you and Drs. Cook and Williams and Mr. Gulliver on July 14th?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And so this is a meeting that occurs prior to the larger group meeting which we know occurred July 14th.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And if we look ahead in your notes, for example, we see then up at page 6, meeting and a list of individuals.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And would this be the same date, July 14th and the larger group meeting?

MS. PREDHAM:

A. Yes.

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CHAYTOR, Q.C.:
Q. Okay. And so then between page 3, page 4, page 5, are these all notes from the same meeting of the smaller group on July 14th? Do you want to just have a look down through?
MS. PREDHAM:
A. Can I just scroll down through?
CHAYTOR, Q.C.:
Q. Sure, absolutely. This notebook, maybe that's a question I should ask you, this notebook, was this just used for ER/PR?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. This was used for other things and you've gone through and identified the relevant portions, I take it.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. The ER/PR issue.
MS. PREDHAM:
A. And as you can tell, I was not very good at writing dates down, so I went through and figured out the dates. Yes, that was up to

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that point, up to here, that was from that same meeting.
CHAYTOR, Q.C.:
Q. Okay. And then we go into the next page, top of page 6 and then there's a meeting of the larger group and I take it the line is drawn so the next meeting starts after the line and where you've written the people in attendance?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. So I'll take you then through those notes back to page 3 of the exhibit, June 19th, 2003 memo, Dr. Ejeckam spoke with Terry and Barry. So this is what's being--you've now been presented, I take it, with the June 19th memo.
MS. PREDHAM:
A. And Mr. Gulliver is telling us what happened around that.
CHAYTOR, Q.C.:
Q. Okay, and the senior tech left in April. What was that in reference to?
MS. PREDHAM:
A. One of the techs in that area had left in

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April and these were, the issues were after she left, I think.
CHAYTOR, Q.C.:
Q. I'm sorry, the issues -
MS. PREDHAM:
A. In Dr. Ejeckam's memo were belated until after she left.
CHAYTOR, Q.C.:
Q. Okay, and was that somehow being suggested to be relevant to what Dr. Ejeckam was concerned about?
MS. PREDHAM:
A. Well I think he referenced in his memo about workflow and other duties and succession planning, you know, with the people who were leaving. And I guess that was just a factor that there was a senior tech there who left in April and then there was some turnover of staff and that.
CHAYTOR, Q.C.:
Q. Okay. "Isn't enough work to have three people dedicated to immunostains". Who was expressing that?
MS. PREDHAM:
A. Mr. Gulliver.

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CHAYTOR, Q.C.:
Q. And what did you understand to be the status as of--this is July 14th, 2005, were the technologists dedicated to immunohistochemistry?
MS. PREDHAM:
A. I think I noted it just down a little bit farther where it says "after the memo, they were limited to grossing and staining", so they would do some grossing work, they would rotate through there and then do the immunostains.
CHAYTOR, Q.C.:
Q. Okay. And No. 3, is there any significance to this No. 3?
MS. PREDHAM:
A. I think it was the third point on Dr. Ejeckam's memo that I was referring to. Before, this was before he wrote the memo or to that point, they were doing routine work as well and the volumes had been going up in immunostains.
CHAYTOR, Q.C.:
Q. And after memo, then they were committed to grossing and staining.

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So that's what you understood took place to address Dr. Ejeckam's concern -
MS. PREDHAM:
A. In response to -
CHAYTOR, Q.C.:
Q. - regarding the staff rotations.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Or the staff not being dedicated. "And senior tech then again left in April. Senior tech came over from St. Clare's for six weeks to be orientated."
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And who told you that the senior tech came over for six weeks of orientation?
MS. PREDHAM:
A. I would assume that would be Mr. Gulliver.
CHAYTOR, Q.C.:
Q. Okay, and in your questioning on this issue,

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did you learn any or speaking to the technologists themselves, did you learn any different than that as to the length of time by which any of them had been orientated?
MS. PREDHAM:
A. I don't think so.
CHAYTOR, Q.C.:
Q. And would you have spoken with Mr. Simms, Les Simms?
MS. PREDHAM:
A. Oh yes.
CHAYTOR, Q.C.:
Q. And did that question come up with him, did you ask him how long he had been orientated or is that an issue that never came up?
MS. PREDHAM:
A. I can't remember, I don't remember anything about orientation.
CHAYTOR, Q.C.:
Q. Okay, and "proficiency testing in pathology, can we be one hundred percent sure that the Ventana work?" And then "No." What's this about?
MS. PREDHAM:
A. Well I guess that was a question that was

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raised in our discussion about the Ventana and, you know, how are we--how do we know that it works, like how can we be sure that it works. And I guess that led to getting the Ventana representative down to verify that we had it set up and it was running well.
CHAYTOR, Q.C.:
Q. And who would have said that you couldn't be a hundred percent sure? Who would have responded no to that question?
MS. PREDHAM:
A. I'm not sure, like I said again, that must have been the consensus around the table.
CHAYTOR, Q.C.:
Q. And "PD", I take it it's Peggy Deane?
MS. PREDHAM:
A. Oh it could be, yes.
CHAYTOR, Q.C.:
Q. So you know her identify at this point?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "Infiltrating lobular carcinoma, very unusual to be negative." And reference to oncologists.

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And who in your meeting with Mr. Gulliver and Mr. Cook would be relaying this information?
MS. PREDHAM:
A. It would have been either, I would say Dr. Cook or Dr. Williams.
CHAYTOR, Q.C.:
Q. And I take it up to this point in time, you haven't had any discussions with the oncologist, anything you're learning about Peggy Deane's case is being relayed through Mr. Gulliver or Dr. Cook or Dr. Williams?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And then there's reference to some percentages here, "50 to 80 percent should be positive. 2002"--is that 50 percent positive?
MS. PREDHAM:
A. That's 50 percent positive.
CHAYTOR, Q.C.:
Q. Okay. And who is providing these statistics and what's being referred to?

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MS. PREDHAM:
A. Again, it would have to be Dr. Cook or Mr. Gulliver and the 50 to 80 percent should be positive, I guess was the, you know, established what they understood to be the literature saying what the positivity rate should be and from their review at that time, they found that in 2002, there was a 50 percent positive rate based on our St. John's results, because that's all they would have been able to -
CHAYTOR, Q.C.:
Q. And that's ER positivity, I take it?
MS. PREDHAM:
A. Yes. Now I say that now, that it is that, because we looked at--as it went along when we were trying to determine how to identify patients, the discussion was about just limiting to the ER because we couldn't always be sure that the PR was treatable, and along the way it's, you know, were we always focusing on the ER or were we looking at the combination of ER/PR, it's a big vague now in those early days.
CHAYTOR, Q.C.:

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Q. Okay. And Sunnybrook is 75 percent positive, so somebody in attendance is able to say they've checked with Sunnybrook for their positivity rates?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And May, 1997, got the DAKO system?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And this 16 out of 25 positive in second group?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So I take it that's the results of the testing that had taken place in house, in 16 out of 25 had converted to positive?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And then again you have a list, so this is what, I take it the consensus or decisions coming out of the meeting?

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "Identify the affected people, assign resources to Bev." I take it that's Bev Carter?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And what did you understand Dr. Carter was going to do?
MS. PREDHAM:
A. That she was going to co-ordinate this process, you know, she was going to determine who the affected people were and co-ordinate the retesting.
CHAYTOR, Q.C.:
Q. Okay, and would she also do any type of an investigation in terms of looking at the original slides or trying to piece together for those cases that converted how that could be?
MS. PREDHAM:
A. Well certainly she would do that and I don't know--I don't know if I would have understood

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the nuances between the slides and the blocks at that time and relooking at the slides and what that would have meant. It could have been that I knew that at that time or not.
CHAYTOR, Q.C.:
Q. Okay, but you did understand that in addition to co-ordinating the retesting process, she'd be doing some investigative work to try and ascertain what the contributing cause or causes might be?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And here you do note testing of all negative and then testing of all live patients. So I take it you meant it was going to be all negatives and whether it was narrowed down to ERs, you're not sure at this point.
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. But it would be the negative live patients.
MS. PREDHAM:
A. Yes, and I guess, you know, at this point it was the concept of negative because that was

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the people who were affected, you know, because of treatment. And it wasn't until we started saying, okay, exactly how are we going to identify them? What is negative? Then that's when we narrowed it down to only we'd focus on ER to generate the list to identify patients.

CHAYTOR, Q.C.:

Q. Okay, and then meet with the surgeons and oncologists. And thirdly, "tell the public two to three hundred people." And is this consensus coming from you and Mr. Gulliver and Dr. Cook and Dr. Williams?

MS. PREDHAM:

A. Well it would have been--well it wouldn't be consensus for me because I wouldn't be able to put any information into it, that would have to be from Dr. Cook and Mr. Gulliver.

CHAYTOR, Q.C.:

Q. And Dr. Williams is in attendance too.

MS. PREDHAM:

A. Yes, well I guess he would have, he wouldn't have known first hand how many people it would have affected.

CHAYTOR, Q.C.:

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Q. Okay, in terms of the numbers of people.

MS. PREDHAM:

A. Right.

CHAYTOR, Q.C.:

Q. Yes, okay, yes, I see what you're saying. So the numbers of two to three hundred people, that's coming from Mr. Gulliver and Dr. Cook.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And the decision to tell however the public, what's being referred to here, you're going to tell the public what? What exactly would the public be told?

MS. PREDHAM:

A. I guess at that stage that we have an issue and that we're going to have to go back and retest people.

CHAYTOR, Q.C.:

Q. And that there might be two to three hundred people being rested or is that what this is?

MS. PREDHAM:

A. Mostly likely that's why--that it would affect two to three hundred people or it would be two to three hundred people retested, I'm not

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really sure now.

CHAYTOR, Q.C.:

Q. And in terms of the decision to tell the public, that's what's coming out of the meeting here with Drs. Williams, Cook, yourself and Mr. Gulliver?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. And did you have any difficulty with that?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. "Assess current testing, cross-referencing with another lab."

MS. PREDHAM:

A. And that was, I guess, to verify that question as well with the Ventana is to just make sure that, you know, our results, our current results were good.

CHAYTOR, Q.C.:

Q. "And assess our standards and quality of service. External consultant to be brought in." So this again is July 14th and the

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decision to bring an external consultant in and the purpose of that at this point in time, what was envisioned would be the mandate for an external consultant?

MS. PREDHAM:

A. Well that would be to review our current practice, so you know, do we have the system set up correctly, are we following the protocols, are we, you know, that kind of thing.

CHAYTOR, Q.C.:

Q. And would that be then, is that referenced to the Ventana consultant or -

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. This is who this is, okay. At this point in time Trish Wegrynowski hasn't been thought of or -

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And in the discussion to tell the public, was there any discussion as well about what to tell the patients?

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MS. PREDHAM:
A. At that point, I don't think we got into a lot of detail at that, at that point. I mean, certainly that's something we would have to discuss and determine.
CHAYTOR, Q.C.:
Q. And then that's it for that page. The top of the next page, page six of the exhibit, it's written here "Radio Noon interview tomorrow" and asterisk "news release." Do you recall what that is referencing?
MS. PREDHAM:
A. I have a vague memory that it was an option that somebody could be interviewed on Radio Noon as early as tomorrow. Like I can remember that statement being made, and it's just there out of the blue. It doesn't look like it's related to the previous one because nobody around that table would have been thinking that, and I don't know if I had talked to Ms. Bonnell before that and that happened to be a discussion or not. It just-- it's a random note there.
CHAYTOR, Q.C.:
Q. Okay, yes, because if we look down through

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your--it's not written onto your page of notes -
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. - from that meeting, but it's at the top of the page before you go into the larger meeting that same day?
MS. PREDHAM:
A. Yes. So it's almost like something, a conversation that I must have had in between the two meetings, and there seems to be some vague memory of "well, we could go on Radio Noon tomorrow," you know, or -
CHAYTOR, Q.C.:
Q. For an interview tomorrow?
MS. PREDHAM:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay, and the idea of a news release, perhaps that was discussed as well with Ms. Bonnell?
MS. PREDHAM:
A. Right.
CHAYTOR, Q.C.:
Q. Okay, and the patients that out of the 16

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patients, 16 out of 25 your handwritten note referred to here, were you told any information as to how many of them had already been informed of their changes in their results?
MS. PREDHAM:
A. I think I understood that they were all informed at that time. I think, and you know, it's hard to know what you know at a certain point in time, where it was so quick, it quickly evolved.
CHAYTOR, Q.C.:
Q. So it was your understanding that all of them knew or some significant portion, ten out of 16 does that ring any bells?
MS. PREDHAM:
A. Well, you know, my memory is that they were in the process of being informed or informed and I didn't have any concerns that there were people who had to be informed. Like I had no concern, that concern that there were people whose test results had converted and they hadn't been informed.
CHAYTOR, Q.C.:
Q. And were you told what they had been told?

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MS. PREDHAM:
A. Well, that the results have changed, you know. That's all I remember.
CHAYTOR, Q.C.:
Q. Okay, and in terms of what Dr. Carter was going to be doing, did you see anything in writing outlining what the plan basically was, her plan of action, or summarizing what it was planned for her to do?
MS. PREDHAM:
A. I don't think so at that time. I think I've seen something since then, but I don't think I saw it at that time.
CHAYTOR, Q.C.:
Q. Okay, and then we'll continue on then with the meeting of the larger group and you've written here, Dr. Gardiner, Kwan--Drs. Gardiner, Kwan, Felix, Laing, McCarthy, Ms. Bonnell, Ms. Deborah Thomas, Dr. Williams and yourself.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And were there others in attendance besides or is this everyone that you recall being there?
MS. PREDHAM:

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A. That's it. I mean, if there was somebody else, I would have wrote it in, I would think.
CHAYTOR, Q.C.:
Q. Okay, and what did you understand the purpose for this meeting?
MS. PREDHAM:
A. Although Dr. Cook is not there. Usually he would be there, you know. This is a--we had discussed earlier that we had to inform the oncologists and the surgeons and this was the meeting to do that.
CHAYTOR, Q.C.:
Q. Okay, and so in terms of--and if we could look then, please, at 0925, and I'll just come back to this, but 0925, please, and page three of this document then? We have--this is Dr. Williams' notes, so he indicates--this is his list of who was in attendance, and it does have -
MS. PREDHAM:
A. Dr. Cook.
CHAYTOR, Q.C.:
Q. - Dr. Cook in attendance, and everyone else is the same as yours.
MS. PREDHAM:

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A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and if we could go back then, please, to 2940? And so in terms of informing the oncologists as to what's happening, and the surgeons, who would have been taking the lead at this meeting?
MS. PREDHAM:
A. Well--oh, who would have been conducting -
CHAYTOR, Q.C.:
Q. Yes.
MS. PREDHAM:
A. Dr. Williams would have been taking the lead in that meeting.
CHAYTOR, Q.C.:
Q. Okay, and it's "1997 to March 2004, they just retested their lobular cancer and got 100 percent confirmed that it would be" is that "published in pathology journal"?
MS. PREDHAM:
A. Yes, I think that's the information from Sloan-Kettering.
CHAYTOR, Q.C.:
Q. Okay, and who in the meeting--is this what you were saying that you thought either Dr.

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McCarthy or Dr. Laing was relaying?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and so you understood that Sloan-Kettering had retested their lobular cancers and 100 percent of them were positive?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And these are notes you're making in the meeting?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you understood that whatever had come from that exercise, it was going to be published in a pathology journal?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And then you have "40-50 positive, negative, but were now strongly positive." Do you recall what that's referencing?
MS. PREDHAM:

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A. I think that was--no, I don't know if it was the second batch now or if it was something that they had. Like I'm not sure.
CHAYTOR, Q.C.:
Q. Okay, and the next sentence looks like "Ford said there was a problem with the system, but it was fixed."
MS. PREDHAM:
A. I do recall that sentence being made. That was Dr. McCarthy, I believe, said that she knew there was a problem back in the day, only because she was in a meeting in with Dr. Elms had said that there was a problem with the system but now it's fixed, and she mentioned that she knew that there was a problem earlier on.
CHAYTOR, Q.C.:
Q. Okay, and Dr. Cook is in attendance at this meeting when Dr. McCarthy would have stated that, and did Dr. Cook--I know he's not on your list, but he's in Dr. Williams' list.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Did Dr. Cook raise any concern with that

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statement or challenge it in any way?
MS. PREDHAM:
A. I don't recall. She just kind of made it as a, you know, this is what she had heard earlier.
CHAYTOR, Q.C.:
Q. Okay, and if Dr. Cook had said something to the contrary, would we expect that you would have made a note of that as well?
MS. PREDHAM:
A. Yes, if there was any response, my memory is that there was just some--yes, Dr. Ejeckam stopped testing and, you know, whatever, and he made some comment on that in that general line. I don't have any--you know, he never said "hold on, there was no problem" or anything. It was just that type of thing.
CHAYTOR, Q.C.:
Q. Okay, and this is reference to the meeting on May 17th, Joy McCarthy, Kara Laing, was there any other discussion about that meeting?
MS. PREDHAM:
A. I guess the other discussion was like the next point, the fact that they took 25 patients, mostly from 2002, breast cancer, who were

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negative, I assume. 16 out of 25, in the process of going through 33 more.
CHAYTOR, Q.C.:
Q. And is this sampling 2002?
MS. PREDHAM:
A. Yeah.
CHAYTOR, Q.C.:
Q. And what -
MS. PREDHAM:
A. And I guess 2001 and 2000, I guess, you know, probably somebody said we were sampling 2002 and somebody else may have said well, we've got some 2001 and 2000 here.
CHAYTOR, Q.C.:
Q. Okay, and then you have an asterisk, and it looks like "about at least 12."
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And what are you referring to there?
MS. PREDHAM:
A. I have no idea.
CHAYTOR, Q.C.:
Q. And is that--and then there's reference -
MS. PREDHAM:

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A. You know, there was a lot of discussion about Tamoxifen and who were candidates, and you know, there was pre-menopausal, post-menopausal, because over time, the criteria for being a candidate of Tamoxifen changed. So I think they were into this discussion and I just couldn't keep up with what they were saying, so I was just writing down.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. But I have no idea what "about at least 12" -
CHAYTOR, Q.C.:
Q. And whether or not that's 12 out of the 16, for example? One possibility it might be that 12 out of 16 informed or don't know, not sure?
MS. PREDHAM:
A. I have no idea.
CHAYTOR, Q.C.:
Q. "Treatment would have been very different" then you got three asterisks. "Controls are supposed to be done every day and documented. Were they done?"
MS. PREDHAM:
A. Well, that's a note to me to -

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CHAYTOR, Q.C.:
Q. Follow up on that?
MS. PREDHAM:
A. Yeah.
CHAYTOR, Q.C.:
Q. Okay, so this is why you made this with three asterisks, that you're going to go away and find out?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "Controls on a separate slide versus the"--what is this?
MS. PREDHAM:
A. Test, I guess.
CHAYTOR, Q.C.:
Q. Versus the test.
MS. PREDHAM:
A. TE.
CHAYTOR, Q.C.:
Q. Okay, versus the test, the sample, I guess, the specimen. Okay, and "who is responsible for the patient? Oncologist, surgeon." So was there a discussion about that in the room?
MS. PREDHAM:

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A. Well, that was part of the disclosure. So when the results come back, who did they go back to? Who was responsible for the patient to have that discussion with them?

CHAYTOR, Q.C.:

Q. Okay, and then you lose your thought here, "if they still have -

MS. PREDHAM:

A. And I think that that was part of the discussion was there had been so much turnover of oncologists, it was possible that they may not still have an oncologist that -

CHAYTOR, Q.C.:

Q. Oh, if they still have such physician, okay.

MS. PREDHAM:

A. Yeah.

CHAYTOR, Q.C.:

Q. And then going into the next page, is this still the same meeting?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. There's a plan, okay, and the plan is a hotline and -

MS. PREDHAM:

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A. We need results.

CHAYTOR, Q.C.:

Q. - results, I'm sorry, so what does that refer to?

MS. PREDHAM:

A. Well, we'd need to have, you know, some place for people to call. If we were going to go public, we'd need to have some place for people to call and also we needed a plan with the results, how, once we got the results, how were they going to get communicated.

CHAYTOR, Q.C.:

Q. Okay, and the discussion to have--to go public and to use a hotline for people to be able to call to, was there any discussion in the room in terms of any concern expressed to doing that, to going public? Was there any concern expressed?

MS. PREDHAM:

A. No, not then, you know, that we would have to--we'd have to get the hotline in place for people to call and respond when they hear it, because you know, it would be a big announcement, you know, that would--and they'd need to call somebody for more information.

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CHAYTOR, Q.C.:

Q. And the oncologists and surgeons are present at this meeting, and the purpose being to inform them, and did they express any concern that their preference would be to have a hotline, for example, set up somewhere where the patients could be calling, as opposed to inundating their offices, for example, with calls?

MS. PREDHAM:

A. And possibly that's where the idea of having that central line to come in, because I guess, you know, if you see people who have cancer and you're coming out saying that we have cancer test results that are inaccurate, you're going to be inundated with calls. So maybe that's where that came from, but it makes sense, but I really don't remember that.

CHAYTOR, Q.C.:

Q. Okay, and "guideline to how we deal with the treatment, Kara Laing and Joy McCarthy." Do you recall what that was about?

MS. PREDHAM:

A. There was some kind of discussion, and I guess it came from the previous thought that if they

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didn't have an oncologist right now, how would a GP know what to do with the new results or whatever. So there had to be some kind of guideline on how to deal with those treatment decisions.

CHAYTOR, Q.C.:

Q. Okay.

MS. PREDHAM:

A. And they were going to go away and think about that.

CHAYTOR, Q.C.:

Q. Okay, and "farm it out" you've written here.

MS. PREDHAM:

A. That's for the retesting to--because they were concerned about the delay too, the time lines and I don't think it was this meeting, I think it was probably the next one, they were very concerned about how accurate our time lines were and how if we went out too soon, there'd be too long of a period of time. They wanted to be very sure on what we were doing and how long--how quickly we were going to get the results back so people would understand. I don't think that was really discussed at that point. I think they had to go away and think

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about that and the implications of that.
CHAYTOR, Q.C.:
Q. And that comes up later?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, so farming it out, at this point is referring to the retesting though or was it in--at this point in time, was the plan to have the retesting done in house?
MS. PREDHAM:
A. I think it was done in house, if we could do it. I think that may be the question was there, is if we could handle the volume.
CHAYTOR, Q.C.:
Q. And you're also contemplating having the Ventana person come in to check out your current system?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you have three asterisks again, so "June 13th" is that correct, "send them in and get them retested."
MS. PREDHAM:

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A. I believe that's when Dr. Cook notified the other pathologists to send in their blocks and slides.
CHAYTOR, Q.C.:
Q. Okay, and then resources, and it looks like "social work and nursing," is that correct?
MS. PREDHAM:
A. And that was we were talking about what resources we could tap into for the hotline.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. And so PPCs for social work and nursing would be good.
CHAYTOR, Q.C.:
Q. I'm sorry, what's PPC?
MS. PREDHAM:
A. Oh, professional practice coordinator, sorry.
CHAYTOR, Q.C.:
Q. Okay, and was there any consideration to consulting social work, social workers in terms of patient communication or how patient communication should be handled?
MS. PREDHAM:
A. No. The note there was more of utilizing them

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when the hotline got set up.
CHAYTOR, Q.C.:
Q. Okay, to use them to answer the phones?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And why would social work and nursing be appropriate people to be answering the calls?
MS. PREDHAM:
A. Well, I guess our thinking was that you'd like to have someone with a clinical background and someone who was used to talking patients about issues, and that would seem like an option.
CHAYTOR, Q.C.:
Q. Okay, and then it's "Cancer Registry, 1997 list of live patients."
MS. PREDHAM:
A. Well, it came up, you know, our plan had been to retest the live patients first, and it was trying to determine who were the live patients. So Dr. McCarthy suggested that she could get me in touch with the IT people at the Cancer Clinic and get access to the Cancer Registry for breast cancer patients, because that would tell us who was alive and who was

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deceased.
CHAYTOR, Q.C.:
Q. And then the final page, that appears to be -
MS. PREDHAM:
A. And this was just notes from--Dr. McCarthy was--the name that's blacked out there was the IT person.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. And this was information that we could get -
CHAYTOR, Q.C.:
Q. We weren't sure. We were erring on the side of caution.
MS. PREDHAM:
A. The information there was the information that was available from the Cancer Registry. So it would have the names of the patients, the MCP number, the surgical--the specimen number is actually what it is, and their status, whether they were alive or deceased.
CHAYTOR, Q.C.:
Q. Okay, and the IT person, was that person to be consulted in terms of what?
MS. PREDHAM:

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A. Oh, he was to get the information out of the Registry for me.
CHAYTOR, Q.C.:
Q. Okay, for the list of names?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and did that prove to be a good source for you?
MS. PREDHAM:
A. It was a period of time before I got it, and the information was incomplete. I thought I had--I think I had a different perception of what actually the Cancer Registry was, you know, and I was a bit surprised that it wasn't as complete as I thought it would be. I thought it was something that was linked with Vital Stats or whatever, but it wasn't. That was not how they did, I think the term is death clearance, in the Registry.
CHAYTOR, Q.C.:
Q. And when did you learn that difference, Ms. Predham? When did you learn that they weren't actually linked to Vital Statistics?
MS. PREDHAM:

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A. I guess it was, you know, when I started looking at there was a lot of gaps in the information, and I guess at that point in time, you know, it was just, I guess, registering, slowly coming into me that they weren't registered. I'm not really sure when I learned that they weren't--they were a stand-alone type of -
CHAYTOR, Q.C.:
Q. Is it after you start into the process of results coming back and patients having to be notified? Is it that late in the process?
MS. PREDHAM:
A. It may have been. I know it was when I got it and trying to determine who was deceased and who wasn't. There were a lot of gaps in the information. There were problems with the MCP numbers, that type of thing. So I started, you know, questioning how do you get your information or where does this come from.
CHAYTOR, Q.C.:
Q. Okay, and what were you expecting? How was it less than what you were expecting?
MS. PREDHAM:
A. Oh, I just thought there would be some process

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with Vital Statistics that, you know, if somebody was deceased, it would be in there and that would be how they would--I never really thought about it. I thought there'd be some kind of connection between Vital Statistics to the Cancer Registry and that information would flow. Like I said, I never really thought about it before that.
CHAYTOR, Q.C.:
Q. Okay, and other than consulting this person with the blacked out name, the IT person, was IT or Information Management otherwise consulted to assist in coming up with a list of patients?
MS. PREDHAM:
A. I went to the Health Care Corporation's IT department to see what they could get from me--from me--for me, and in our Meditech system, they were able to get everybody who had an ER/PR test ordered at that, but done, I thought at the time, and with the exception of 1997 and part of 1998. So after that, they could just--there would be no results, but it would just be the name and the specimen number.

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CHAYTOR, Q.C.:
Q. Okay, and in the long run, how complete did that list prove to be?
MS. PREDHAM:
A. Well, it was fairly complete. We didn't--we know now, of course, that there were instances where the test wasn't ordered in Meditech, which didn't have an impact on whether the test was done or not. It just it wasn't ordered, and therefore it didn't show up on that list. But at the time, we weren't aware that that was an issue.
CHAYTOR, Q.C.:
Q. Okay, and so your list though, and how you went about compiling a list was somewhat different from what Mr. Gulliver did?
MS. PREDHAM:
A. Well, he had the actual pathology reports. I guess, the primary reason that I got involved in this part at this point was just to identify the patients that were deceased. There was no easy way to determine that. Mr. Gulliver wouldn't be able to determine that from his access in the lab, so we were exploring ways to identify those patients who

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were deceased, since our focus was on the living.

CHAYTOR, Q.C.:

Q. And you were aware of Vital Statistics yourself?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. You were aware of that registry, and did it occur to you that that might be the most accurate source to take your list or take Mr. Gulliver's list and then cross reference that with any information from Vital Statistics?

MS. PREDHAM:

A. Not at that time, it didn't.

CHAYTOR, Q.C.:

Q. Okay. So that appears to be it for the second meeting on July 14th, and I'm just wondering then, so out of the items discussed -

MS. PREDHAM:

A. I thought there was a list, a numbered list of -

CHAYTOR, Q.C.:

Q. Numbered list.

MS. PREDHAM:

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A. - things to do at the end of that.

CHAYTOR, Q.C.:

Q. Okay.

MS. PREDHAM:

A. Or maybe I had that wrong.

CHAYTOR, Q.C.:

Q. Maybe there is, but maybe there's a gap because I was thinking it was the end, because there's nothing.

MS. PREDHAM:

A. Oh, there it is.

CHAYTOR, Q.C.:

Q. Here it is, okay. So even though there's a gap, your item list starts on the next page.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So this belongs to that meeting?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. So then, Don, I guess that's Dr. Cook, is that correct?

MS. PREDHAM:

A. Yes.

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CHAYTOR, Q.C.:

Q. Identify the patients?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. One and a half techs?

MS. PREDHAM:

A. I guess that's who he was able to get to assist him to do that.

CHAYTOR, Q.C.:

Q. "Terry will find out -

MS. PREDHAM:

A. "That we"--I guess Terry will try to determine the time lines in which we can do that.

CHAYTOR, Q.C.:

Q. Okay, and Dr. Cook, what does this say?

MS. PREDHAM:

A. "Don to follow up with colleagues regarding why they have -

CHAYTOR, Q.C.:

Q. And do you recall then what that was about?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And thirdly, "controls were done every day and

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documented" and is -

MS. PREDHAM:

A. And I think this was the meeting I had a note that I had to check on those controls.

CHAYTOR, Q.C.:

Q. Yes, and so you're going to go away and follow up on that? Is that correct?

MS. PREDHAM:

A. Yeah.

CHAYTOR, Q.C.:

Q. And did you do that?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And what were you able to determine?

MS. PREDHAM:

A. That the--you know, I was told that the controls were done every day, but the documents weren't there to say that they were done every day.

CHAYTOR, Q.C.:

Q. Okay, and who did -

MS. PREDHAM:

A. Well, it wasn't what I expected them to be, the documentation.

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CHAYTOR, Q.C.:
Q. Well, then perhaps you can tell us what did you expect?
MS. PREDHAM:
A. Well, I expected that I would be able to tell that slide number two would have control number 24 run at the same time or run at that time, or that was the control that was used.
CHAYTOR, Q.C.:
Q. That there'd be some--at least some cross referencing to tell you which control slides belonged to which patient slides?
MS. PREDHAM:
A. Right, yeah.
CHAYTOR, Q.C.:
Q. Okay, and you didn't find anything like that?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Okay, and who did you speak with that assured you that controls were done every day?
MS. PREDHAM:
A. I think it was already noted that Mr. Gulliver had told me that.
CHAYTOR, Q.C.:

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Q. Okay, but did you go away to--you were going to go away to verify that they were done and documented. So did you ask anyone else whether or not the controls were done?
MS. PREDHAM:
A. I'm not sure if I went to Mr. Gulliver or Mr. Dyer was back at that time, but I would have gone to them to get the documents.
CHAYTOR, Q.C.:
Q. And did you speak with the technologists who were actually carrying out the work and ask them any -
MS. PREDHAM:
A. Not at that time.
CHAYTOR, Q.C.:
Q. Later on, you meet with them in August?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And did you ask them then in terms of what were their practices in running controls?
MS. PREDHAM:
A. They did describe their practices for running controls. For the life of me, I can't really recall them right now, but my concern was that

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the documentation wasn't there to support that practice or to support what they were saying. There wasn't comprehensive documentation.
CHAYTOR, Q.C.:
Q. And in fact, was there any documentation that you could link to controls, other than what may or may not be recorded in a pathology report for a given patient, and was there anything else in the lab's own records that dealt with controls?
MS. PREDHAM:
A. I don't think so. I'd have to go through my notes and make sure, but that's -
CHAYTOR, Q.C.:
Q. And we'll come back to it again then when we come to your note from your conversations with them, okay. So also following from this meeting, Don Cook was there, "a change in sensitivity that affect results."
MS. PREDHAM:
A. And I guess that's the whole Ventana, but also there were changes over the period of time from '97 on in antigens or whatever in that process and that, of course, each time something got changed, the idea was to

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increase the sensitivity of the reporting, you know, to increase the release of antigens, and so it was that are our findings now consistent with their findings? So is it--was there changes over time. So would you expect a certain amount of change or conversion over time. If something was done in '97, would you--if it was retested now, would you automatically expect, because of changes that have happened over that period of time, that there would be a change in 2005.
CHAYTOR, Q.C.:
Q. Okay, and changes such as change in antibodies is what you're thinking?
MS. PREDHAM:
A. Yeah, that type of, yeah.
CHAYTOR, Q.C.:
Q. Okay. "Are our findings consistent with their findings?" and who are you referring to there?
MS. PREDHAM:
A. Well, I guess we were--anybody else who had retested, were we finding that there were different--were they finding there were differences.
CHAYTOR, Q.C.:

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Q. Okay, and then five, six and seven, five is hotline
MS. PREDHAM:
A. Coordination.
CHAYTOR, Q.C.:
Q. Coordination, and that's QSI, so Quality Services.
MS. PREDHAM:
A. Quality and System Improvement.
CHAYTOR, Q.C.:
Q. Quality and System Improvement, so that's your department is going to look after that.
MS. PREDHAM:
A. Yeah.
CHAYTOR, Q.C.:
Q. Media release, Susan Bonnell, I take it, is going to look after that.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And then you've got "me" written by "HIROC and other sites." So what were you to do?
MS. PREDHAM:
A. We were going to contact other pathology labs across the country to see if they've had these

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issues, what they monitor, the positivity rate, if they had come up with this issue and did they go back and retest, that type of information, and also, I was going to contact the risk management side of HIROC and find out if they had--this issue had come up before with them.
CHAYTOR, Q.C.:
Q. And again--so in terms of the go forward on the public announcement, a hotline to be set up and Susan Bonnell, I guess, to work on a media release, and at the end of the meeting on July 14th, that was the plan?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And there was no concerns expressed about going public at this point in time?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. Okay. Ms. Predham, in this meeting, and again this is a meeting with the oncologists and surgeons, was there any discussion in terms of identifying the patients because Dr. Cook is

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to identify the patients--was there any discussion about cutoffs and 30 percent and 10 percent?
MS. PREDHAM:
A. Well, I think that's--at that point in time, there was so much information and so much that it wasn't until, like, you actually stepped back, so, okay, we're all agreed we going to do this, and then we step back and say, okay, all right, it's okay to say it in the hypothetical, but now you got to have some concrete structure around it. So it's all right to have a bullet there and say that our department is going to coordinate the hotline, but we needed information, we needed to--you know, we needed more detail, so there was a lot of work that had to go into that. So the same thing with Dr. Cook. So he's going to go away and identify the patients, and that's pretty clear, but then, of course, you've got that, the cutoff, the treatment thing. So I think that came after when he started to is where do I start, what's the cutoffs for what is negative.
CHAYTOR, Q.C.:

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Q. Okay. So at this point in time, he was going away to identify who was negative, and at some point in time he needs further direction as to, well, how are we defining negative?
MS. PREDHAM:
A. Exactly.
CHAYTOR, Q.C.:
Q. This issue here about Sloan-Kettering and they just retested their lobulars and got cancer and got 100 percent, and it was referenced that there was going to be a publication, did you ever have occasion later to search for such a publication?
MS. PREDHAM:
A. Oh, I did. I never did find it. I haven't recently, but at the time for that fall I did, but I never found it.
CHAYTOR, Q.C.:
Q. So over that fall, you spent time looking for this publication?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And did you have occasion to go back and ask Drs. Laing or Dr. McCarthy any further

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information about it that might help you be able to find such a publication?

MS. PREDHAM:

A. Oh, I asked them if they had heard if it was out or if they had seen it or that--yeah.

CHAYTOR, Q.C.:

Q. What did they tell you?

MS. PREDHAM:

A. They hadn't at that point in time.

CHAYTOR, Q.C.:

Q. And did you ever have any further discussions about this whole issue about Sloan-Kettering having retested and a publication supposedly coming forward?

MS. PREDHAM:

A. I think it came up again--it may have been, you know, like, later when the Centre for Health Information was over. I can remember thinking I'm going to have to search for that again now and see if it ever came up, or ask somebody, but I don't think I ever did.

CHAYTOR, Q.C.:

Q. Okay.

MS. PREDHAM:

A. Nobody circulated and said, oh, look, here's

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the article that they were talking about.

CHAYTOR, Q.C.:

Q. And did you ever have any occasion to speak to Dr. Williams about this issue of Sloan-Kettering and what they may have done?

MS. PREDHAM:

A. Oh, we talked about it a lot at that time.

CHAYTOR, Q.C.:

Q. And did you ever contact Sloan-Kettering yourself?

MS. PREDHAM:

A. No, I didn't.

CHAYTOR, Q.C.:

Q. And why not?

MS. PREDHAM:

A. I think that was one of the labs that Dr. Cook contacted the pathologist at.

CHAYTOR, Q.C.:

Q. And what did you understand to have been the outcome of Dr. Cook's contact with the pathologist at Sloan-Kettering?

MS. PREDHAM:

A. I can't remember right now, I really can't remember, but I don't think it was anything, you know -

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CHAYTOR, Q.C.:

Q. Nothing germane to this issue?

MS. PREDHAM:

A. Yeah, nothing that contributed to it any further.

CHAYTOR, Q.C.:

Q. And nothing that dissuaded you in your efforts to try and find the publication?

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. Dr. Cook didn't come back and say, well, I've spoken to the pathologist about that. Did you understand that he even pursued that with anyone, or was that a different issue?

MS. PREDHAM:

A. No, I thought he--I thought he did contact Sloan-Kettering, but now that you're asking me about it, I really can't remember the outcome of that.

CHAYTOR, Q.C.:

Q. And what led you to believe that there was such a publication?

MS. PREDHAM:

A. It was either Dr. McCarthy or Dr. Laing said

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that they said that they were going to publish it.

CHAYTOR, Q.C.:

Q. Okay. If we could look, please, at 925, please, page--I think we have it up there. Yes, thanks, Registrar, page three, and I'll just take you through Dr. Williams notes of the same meeting, and general background and he's got his own name by that specific overview, "Dr. Cook issue of results specifically in 2002", and there's reference to the change in 1997, switching then to the Ventana System, and "Dr. Laing, new information, lobular CAs should all be ER positive. Sloan-Kettering went from 75 percent to 100 percent positivity". I'll just show you there's some issue as to whether--I only have the typed version here, but there's been some issue in terms of these handwritten notes, if it's 75 percent of 95 percent that should be. "As a result asked to--sorry, Dr. Laing requested retesting" and strongly positive results, "as a result, asked to retest some patients, followed up on a lot of patients from 2002. Sixteen out of 25 on

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retesting are positive. Doing another 38 patients in process, farm out testing outside the province". So your note to farm out testing outside the province, is this--do you recall was this Dr. Laing suggesting farming out the testing?

MS. PREDHAM:

A. No, I don't remember.

CHAYTOR, Q.C.:

Q. "Dr. Cook to get info on who to follow up", and I believe that's it for Dr. Williams notes on the meeting. So this issue here in terms of Sloan-Kettering, new information, lobular CA should all be ER positive, at Sloan-Kettering went from 75 or 95 percent to 100 percent positive, is that consistent with what you recall being said in the meeting about Sloan-Kettering?

MS. PREDHAM:

A. And, I mean, I guess the--the fundamental message was that all lobular cancers should be ER/PR positive.

CHAYTOR, Q.C.:

Q. And you wrote in your note that that came about as a result of retesting at Sloan-

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Kettering?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And that's what you understood had happened? I'm sorry, I know you're nodding, but we have to pick it up on the transcript.

MS. PREDHAM:

A. Sorry. Yes.

THE COMMISSIONER:

Q. This farm out testing outside the province, which is similar to something in your own note -

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. And what did you understand that to mean?

MS. PREDHAM:

A. I really can't remember other than, you know, it was what we were trying to do--what we ended up doing with Mount Sinai as getting some place else to do it, I guess, in an effort to be timely, and I'm not sure -

THE COMMISSIONER:

Q. Do you remember whether--were you talking at

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that time about the current testing, or were you talking about the retesting?

MS. PREDHAM:

A. The retesting.

THE COMMISSIONER:

Q. So you recall this related to retesting?

MS. PREDHAM:

A. Yes, because we hadn't questioned--we really didn't question Ventana until we looked at the positivity results and they were--they were high.

CHAYTOR, Q.C.:

Q. Then why would you be considering going outside to do the retest?

MS. PREDHAM:

A. I can't--I really can't remember other than the fact that maybe it was a time issue.

CHAYTOR, Q.C.:

Q. If we could look at P-0505, please. This is page--this is the handwritten portion of the July 14th, 2005 notes that Dr. Williams took, and you'll see how kind he was to us to have had them transcribed.

MS. PREDHAM:

A. Yes.

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CHAYTOR, Q.C.:

Q. And this is the note here, Dr. Laing, and then there's a number of bullets.

MS. PREDHAM:

A. It does look like from 75 percent to 100 percent.

CHAYTOR, Q.C.:

Q. Okay. Do you recall any number being given yourself in the meeting?

MS. PREDHAM:

A. Not now. You know, the message that I took out of that was all the lobulars are--and they weren't even--they were considering not even testing them any more, and that was the message I got.

CHAYTOR, Q.C.:

Q. Yes. If we could have, please, P-0070. I take it then, Ms. Predham, after this meeting and the next few days, do you recall much happening in terms of your involvement in the issue?

MS. PREDHAM:

A. Well, at this time, the next day I did contact the risk management department with HIROC. I talked to our staff about we needed to set up

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a hotline, what information we needed to be able to answer questions on the other end. So we started, you know, having that process, and the other thing we had to do was check across the country. So we were coming up with what questions to ask, what hospitals to check with.

CHAYTOR, Q.C.:

Q. And you were checking across the country about positivity rates, is that right?

MS. PREDHAM:

A. Well, pathology--there were specific things that we were looking at, which include positivity rates, if they had ever had any issue like this, if they had any opportunity to go back and retest, if they did retest, that type of -

CHAYTOR, Q.C.:

Q. Okay, and the effort that you came across in doing that, did you find anyone who had had such a situation and found the need to go back and retest?

MS. PREDHAM:

A. I think one they did a couple of retests, but nobody had gone back and retested everybody.

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CHAYTOR, Q.C.:

Q. Okay. So you found in making inquiries across the country, one place where you believe they may have done one or two retests but nothing that warranted a full massive retesting?

MS. PREDHAM:

A. Nothing like we had done.

CHAYTOR, Q.C.:

Q. Okay.

MS. PREDHAM:

A. I think one of them, and I'd have to refer to the notes, I think one of them may have had a conversion or something on that line.

CHAYTOR, Q.C.:

Q. And that's what caused them to go back and -

MS. PREDHAM:

A. But they didn't do a big retest like we did.

CHAYTOR, Q.C.:

Q. And if we could then--and this exhibit is an e-mail from Susan--sorry, Deborah Thomas to Susan Bonnell, the next day, Friday, July 15th, and she writes, "Hi Susan; Here's today's update from Heather Predham". Do you recall were you providing update to the communications department?

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MS. PREDHAM:

A. No, I think we just had a conversation on the phone and I had never seen this before--I mean, I've seen it now, but I hadn't seen it at that time, and I think I was just having conversation with Deborah.

CHAYTOR, Q.C.:

Q. Okay, and she says, "Nancy is thinking about how to implement a hotline". So that's what's happening in your department, Nancy Parsons. "Heather is proving an overview/synopsis for George". I take it that's Mr. Tilley?

MS. PREDHAM:

A. Yes, Dr. Williams asked me to give an update of our activity to date.

CHAYTOR, Q.C.:

Q. So Dr. Williams asked you to come up with something for Mr. Tilley, and did you understand he was already informed about the issue?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And how long had he been brought into the loop, how long had he been told?

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MS. PREDHAM:

A. I'm not sure, but I think--I had the impression that he knew. I really can't remember how long.

CHAYTOR, Q.C.:

Q. And "George wants to disclose this info to the Board next week. Dr. Williams is trying to talk him out of it". Do you recall telling that or anything along those lines to Ms. Thomas?

MS. PREDHAM:

A. No, and when I actually saw this at some point in time when you showed it to somebody, I can't recall it at all, and I certainly didn't have that type of relationship that Dr. Williams would be saying, you know, George wants to give it to the board, but, you know, I want to talk him out of it. I didn't have that type of relationship with Dr. Williams, so I can't imagine him even saying it to me.

CHAYTOR, Q.C.:

Q. So you have no idea where Ms. Thomas would have got that and why she would have attributed it to an update coming from you?

MS. PREDHAM:

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A. No, unless, you know--I have no idea.
CHAYTOR, Q.C.:
Q. Did you yourself have any concerns about the board being informed about the issue?
MS. PREDHAM:
A. Absolutely not.
CHAYTOR, Q.C.:
Q. And did you hear anyone else express any concern about informing the board?
MS. PREDHAM:
A. No.
CHAYTOR, Q.C.:
Q. "The lab has pulled names and numbers and thinks that they may be able to do retesting in-house, completing in about two weeks". So is that consistent at this point in time? Does that sound -
MS. PREDHAM:
A. Well, Ms. Thomas and Susan--Ms. Bonnell were both at that meeting the day before where we had questioned farming it out, so I guess this was new information that had come out that Friday morning.
CHAYTOR, Q.C.:
Q. "Terry Gulliver says he has documentation that

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shows positive controls were done daily [Heather yet to see it]". So in terms of you telling Ms. Thomas that Mr. Gulliver has documentation, says he has such documentation, do you recall that, did Mr. Gulliver tell you that, that there is documentation that shows positive controls were done daily?
MS. PREDHAM:
A. And I think that was in my notes before we had seen, that that was the message that I had gotten.
CHAYTOR, Q.C.:
Q. That he had told you that.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. But you had yet to see it, and you've told us that that remains the case to today?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. "Heather checking other hospitals to see if they have any issues pertaining to this", and you've told us about that. "Hoping this could be just a matter of a dramatic improvement in

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technology [if indeed all controls were in place]". Do you recall making such a statement or expressing anything similar to Ms. Thomas?
MS. PREDHAM:
A. well, I guess that was the thinking at the previous meeting when we were talking about changes that could have happened here. If we had the controls, and my understanding at that point of what these controls were, was that the test worked, you know, and that this would verify that the test did in fact work. So if the test worked and now we're getting these, could it be that those changes--and this ten times increased level of sensitivity, that could we be seeing this. So that was the thinking at that time that we were hoping that's what it could be. We hadn't ruled it out to say that's what exactly it was, but that's what we were hoping.
CHAYTOR, Q.C.:
Q. And "thinking we may want to release mid to late next week", so that's meaning the public release, I take it?
MS. PREDHAM:

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A. Yes.
CHAYTOR, Q.C.:
Q. And everybody continued on to work towards that end, I take it?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. If we could have then, please, P-0925, page four.
THE COMMISSIONER:
Q. Sorry, before we leave this, "Heather is providing an overview/synopsis for George", now as I understand it, this is Friday, July 15th. Aside from that sort of heads up that you had had in June, really your knowledge all came from -
MS. PREDHAM:
A. That week.
THE COMMISSIONER:
Q. The 12th, 13th, 14th, and whatever you got the morning of the 15th?
MS. PREDHAM:
A. Yes.
THE COMMISSIONER:
Q. So was Dr. Williams--did you take the

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instruction from Dr. Williams to be--you were to gather all the information that was happening everywhere, or was yours a narrower scope in terms of what you had to prepare for Mr. Tilley?

MS. PREDHAM:

A. It was just, I guess, a summary of everything we had done in that past week fundamentally. It would be everything that had happened and where we were from--I think it was from the last letter that Dr. Cook wrote Dr. Williams.

THE COMMISSIONER:

Q. Okay, you, for some magic reason, got to be the historian, keeping all the notes, and this process?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Even though you might not have been involved in the things that you would be covering in this memo for Mr. Tilley?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Okay, thank you.

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CHAYTOR, Q.C.:

Q. And on page four, these again are Dr. Williams notes, and the next day there's a meeting, July 15th, 2005, and you're not in attendance at this one, it's Mr. Gulliver, Drs. Cook and Williams, and it says, "Reviewed meeting of July 14th, 2005 re; identifying all patients, and getting tests done as soon as possible. Plan, pull one to two people to start process and assign Mary. Dr. Cook to contact pathologists in other centres to get cases submitted. Terry advises that each patient slide was processed along with the control slide and the control slides were read, and no reporting done until the control read as positive. Dr. Carter to check with Mount Sinai to see if change in sensitivity over time with testing they used. Heather Predham advised Terry Malone of the Cancer Registry. He will have a list of all patients that are currently alive and deceased. Dr. Cook to see if Dr. Laing can provide article from Sloan-Kettering on research in change of ER/PR receptor testing". You're mentioned here in terms of you had advised Terry Malone of the

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Cancer Registry?

MS. PREDHAM:

A. Well, I was advised to contact him. That was the name that was redacted from the previous page, and that he would get this list for me of all the patients that are currently alive and deceased.

CHAYTOR, Q.C.:

Q. Okay, and so that's what this is in reference to?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. We've already talked about that, and the information here that Terry advised each patient's slide was processed along with the control slide, and the control slides were read and no reporting done until control read as positive, were you provided with similar information from Mr. Gulliver to that effect?

MS. PREDHAM:

A. That was the information that I was looking for and documentation.

CHAYTOR, Q.C.:

Q. And--okay, so that's the same information that

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you were trying to find documentation to substantiate?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. If we could have, please, P-0323, and this is a memo from Dr. Williams to Mr. Tilley, and it is an update on ER/PR receptor testing, and it's a two page document. Is this the document that you prepared for Mr. Tilley, the update for Mr. Tilley?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And if we could have then, please, P-01930, and this is July 18th, 2005. It's from yourself to Drs. Williams, Cook, and Mr. Gulliver, and cc'd to Denise Dunn. I take it that was Dr. Williams' assistant, is that correct?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Update for Mr. Tilley. "Hi, here's the update for Mr. Tilley. Please review it and add

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anything you feel necessary. I'm not sure who this should go from, so I left it blank. I didn't include any information, re; Dr. Ejeckam's memos ... should we? Thanks, Heather". You'll see then attached here, here's your draft left blank as to who it's coming from, and the two pages. Ms. Predham, why didn't you include any information re; Dr. Ejeckam's memos?

MS. PREDHAM:

A. Well, I--the fact that Dr. Ejeckam had stopped testing was mentioned in Dr. Cook's letter from May 24th, and the memos--Dr. Williams wanted an update of our activity, I guess, that's how he phrased it, and Dr. Ejeckam's memos were significant, but they weren't really affecting the activity as to that date. The other part of it is that meeting where we saw that memo, I knew that Dr. Williams hadn't seen that memo before, and he was quite concerned about it, and I didn't know how he wanted to approach that with Mr. Tilley with Mr. Tilley or not; if he wanted me to just put it in here, and--I really didn't know what to say about them.

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CHAYTOR, Q.C.:

Q. Okay. So, up to this point in time, the May 24th letter, as you say, have reference to Dr. Ejeckam's memos and -

MS. PREDHAM:

A. Well, had reference to -

CHAYTOR, Q.C.:

Q. Reference to that that had happened with Dr. Ejeckam.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And that letter was between, from Dr. Cook to Dr. Williams.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And Mr. Tilley wouldn't have been aware of that correspondence.

MS. PREDHAM:

A. I think I was attaching it to this update.

CHAYTOR, Q.C.:

Q. So, you were going to give Mr. Tilley a copy of the May 24th correspondence plus this update.

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MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And did you ultimately do that?

MS. PREDHAM:

A. I sent this over to Dr. Williams and I assume that that was what was done.

CHAYTOR, Q.C.:

Q. So, you sent this over and you thought Dr. Williams would include the May 24th correspondence.

MS. PREDHAM:

A. Can you just go back to the--didn't I say I had attached that May 24th letter?

CHAYTOR, Q.C.:

Q. On this?

MS. PREDHAM:

A. Can you just go back up? Oh, I thought I attached it. That was--my understanding was this was an update from that letter for Mr. Tilley. So, it wouldn't make much sense for him if he didn't see the update because I'm saying this is what happened since this memo occurred.

CHAYTOR, Q.C.:

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Q. Yes. And if we go back then to 0323.

REGISTRAR:

Q. (Inaudible).

CHAYTOR, Q.C.:

Q. Oh, look at that. Thank you.

MS. PREDHAM:

A. Oh, it is attached.

CHAYTOR, Q.C.:

Q. And it says attached. This is your final version?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. So, the reference to Dr. Ejeckam is the reference in the May 24, 2005 letter.

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And in terms of including the memos, you're saying that Dr. Williams haven't see them himself until the meeting of--is that the July 12th meeting.

MS. PREDHAM:

A. 14th.

CHAYTOR, Q.C.:

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Q. 14th meeting, he hadn't seen them before, himself. So, that's the same day that you see the memo.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And that was just the July 19th memo at that point?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And if we could go back then to P-1930, go back to page one, your e-mail. And you're referring here to plural memos. So, by this point on July 18th, are you aware of more than one memo?
MS. PREDHAM:
A. Well, I knew that he had sent one around to pathologists. I don't think I had seen it at that point in time, but I did get a copy of it at that time, but he did send a memo to pathologists.
CHAYTOR, Q.C.:
Q. So, the May 2nd, I believe it is, May 2nd memo that you ultimately end up with, you have the

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June 19th one as of July 14th.
MS. PREDHAM:
A. Right.
CHAYTOR, Q.C.:
Q. And you end up with the May 4th or 2nd, whichever it is, you have that by the time you're writing this?
MS. PREDHAM:
A. I may have. I may have--I got it somewhere in that period of time, but I can't remember when, but I did know it existed.
CHAYTOR, Q.C.:
Q. And you're asking should you include it because you're not sure whether or not this is how you want, how Dr. Williams would want Mr. Tilley to learn of the issue?
MS. PREDHAM:
A. Well, you know, Dr. Williams asked me to give an update of our activity. And I really didn't know--I didn't know how to address it, how to put it in there or whether it should go in this route or whether Dr. Williams wanted to tell Mr. Tilley directly.
CHAYTOR, Q.C.:
Q. Okay. And you said when Dr. Williams received

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the memo himself on July 14th, he was concerned about it.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Yes. And I guess that was, again, the same sort of concerns you had given the language that was used in it.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. So, was that your concern about Mr. Tilley reading the memo and the language that's used in there and how serious the message is that Dr. Ejeckam is conveying in the memos.
MS. PREDHAM:
A. Well, I guess it wasn't something you'd like to send in the internal mail for him to sit down and say oh, by the way, this--you know, this got sent two years ago. I think you'd like to give it some kind of context when you gave it to him.
CHAYTOR, Q.C.:
Q. Okay. The May 24th letter insofar as that referred to what had happened, that wouldn't

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be sufficient context?
MS. PREDHAM:
A. Well, I didn't know and that's why I was asking the question.
THE COMMISSIONER:
Q. Ms. Chaytor, it's five after five, so when you get an appropriate spot, we'll break.
CHAYTOR, Q.C.:
Q. If we could look then, please, at P-2950. Okay. And this is a response back from Mr. Gulliver to you. "Heather, looks fine to me. I would not include Dr. Ejeckam's letter. I think Dr. Williams or Dr. Cook should send the memo". And what did you understand Mr. Gulliver to be telling you in his response?
MS. PREDHAM:
A. That he read over the letter, the content was fine, that he didn't think Dr. Ejeckam's letter should be included and that either Dr. Williams or Dr. Cook should sign it.
CHAYTOR, Q.C.:
Q. Should sign the memo that's going out.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

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Q. Okay. And did you also receive a response from Dr. Cook?
MS. PREDHAM:
A. I spoke to him on the phone.
CHAYTOR, Q.C.:
Q. Okay. And what did Dr. Cook tell you?
MS. PREDHAM:
A. I think, as I remember, he wanted it left to Dr. Williams about Dr. Ejeckam's letter, about how he wanted to handle that.
CHAYTOR, Q.C.:
Q. I'm sorry?
MS. PREDHAM:
A. He left it to Dr. Williams to decide how he wanted to handle that. And there was some questions that I had in the memo and he answered those for me.
CHAYTOR, Q.C.:
Q. And did you have any response from Dr. Williams in terms of your query about whether or not to include Dr. Ejeckam's memos?
MS. PREDHAM:
A. I must have, since I didn't include it. So, he must have told me that he was going to handle it another way, but I don't remember

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talking to Dr. Williams about it actually.
CHAYTOR, Q.C.:
Q. Okay. And so you didn't include the memos. You included the letter of May 24th.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay. And if we could look at P-0300 please? And this is an e-mail of July 18th, 2005, Heather Predham to Dr. Williams and it's ER/PR Receptor letter and you say you've "heard back from Dr. Cook and Terry Gulliver re: the letter and the changes have been made. Both agree that it should come from you. I was speaking to Deborah Thomas today and the Department of Health has been notified and is now involved. They would like a letter sent to each woman outlining the problem and the steps we are taking to address it. That draft letter will have to be seen by our lawyer first, of course. And I'll take up the rest, this part of the correspondence with you, but I just wanted to--in terms of, I take it, this is the update going to Mr. Tilley, the first part of this e-mail.

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And do you know whether or not--so, the update that you did for Mr. Tilley that went or you did for Dr. Williams and it went on to Mr. Tilley, it included the May 24th correspondence with the reference to Dr. Ejeckam. And do you know whether or not Mr. Tilley, at any subsequent point in time, received Dr. Ejeckam's memos?
MS. PREDHAM:
A. I don't know for a fact. I just assumed that he did.
CHAYTOR, Q.C.:
Q. And did you see Dr. Ejeckam's memos as being an important piece of information from Mr. Tilley as CEO to have regarding the ER/PR issue?
MS. PREDHAM:
A. It was important because it was, you know, it didn't affect what we were doing now, but it was a red flag that could have been picked up before.
CHAYTOR, Q.C.:

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Q. So, you would have given him the memos or at least had--made sure that it came to his attention in the appropriate manner.
MS. PREDHAM:
A. Oh, no problem. I mean, I'd already sent it to Ms. Pilgrim, Dr. Williams had it. So, I mean, members of executive team had copies of it.
CHAYTOR, Q.C.:
Q. Thank you, Commissioner.
THE COMMISSIONER:
Q. 9:30 in the morning.
Upon conclusion at 5:11 p.m.

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 16th day of October, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 16th day of October, A.D., 2008

Judy Moss

-B-

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