COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

September 12, 2008

Appearances:

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

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

Peter Browne/Jane Hennebury . . . . . Doctors Kara Laing et al

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

Laura Brocklehurst. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

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

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DR. NEBOJSA (NASH) DENIC, EXAMINATION BY BERNARD COFFEY, Q.C. (CONT'D)

THE COMMISSIONER:

Q. Mr. Coffey?

COFFEY, Q.C.:

Q. Good morning, Commissioner, and thank you. Exhibit P-2068, please?

THE COMMISSIONER:

Q. Registrar has anticipated you again.

COFFEY, Q.C.:

Q. Oh yes. Doctor, we were looking at this yesterday. On page three of the exhibit, there's a reference to pathology assistants, and I think I was about to ask you about them. This is when it began. They're about to be trained. It's noted here "manuals and policies must be developed for the pathology assistants. They will be trained according to the standards in the United States."

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Who is responsible for organizing their training or who has been responsible?

DR. DENIC:

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A. The site chief at the Health Sciences is responsible still for developing the manual and actually job description, which all has been done, and the manual for the pathology assistants. She would be a coordinator and some of this manual has been developed by the pathology assistants themselves, since we have senior pathology assistant even now certified in the United States by the College of Pathology Assistants.

COFFEY, Q.C.:

Q. So the person responsible for organizing this and overseeing it as it moved ahead, their training, their actual performing as pathology assistants, was the site chief at the General Hospital. Who is the current site chief?

DR. DENIC:

A. Dr. Lynn Morris-Larkin.

COFFEY, Q.C.:

Q. And how long has Dr. Larkin been site chief?

DR. DENIC:

A. She used to be even my mentor, so -

COFFEY, Q.C.:

Q. No, but how long as she been the site chief?

DR. DENIC:

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A. As the site chief, she was appointed in 2006 after Dr. Dan Fontaine stepped down.

COFFEY, Q.C.:

Q. And Doctor, I think you just indicated one has been certified in the United States, did you say?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And who is that?

DR. DENIC:

A. Miss Jessica Swain.

COFFEY, Q.C.:

Q. And this certification, American certification, when was that received?

DR. DENIC:

A. That was recently. She sat her exam month or two ago.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. But when she came, she was fully trained as a pathology assistant from Ontario, where she practised for several years.

COFFEY, Q.C.:

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Q. And okay, Doctor, the next thing listed on this page is -

THE COMMISSIONER:

Q. Sorry, Mr. Coffey, but while it's in my head, can you tell us the current status of the number of pathology assistants?

DR. DENIC:

A. Current status is four.

THE COMMISSIONER:

Q. There's actually four working now?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And while I'm on it, the four that are there now, at what stages is each of them in their training or experience as a pathology assistant?

DR. DENIC:

A. Three of them have completed the training. The fourth one is still in training.

COFFEY, Q.C.:

Q. Doctor, in terms of person power, I take it, there are four there now in the position, there are four positions?

DR. DENIC:

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A. That's correct.

COFFEY, Q.C.:

Q. Is it anticipated that it will remain at four?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. For the future, for the foreseeable future?

DR. DENIC:

A. I think the number is sufficient for this department.

COFFEY, Q.C.:

Q. Doctor, here there's a reference next on the page to a tissue express processor, and this would be the--is it Sakura?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. The Commissioner has heard references to this before and notes Dr. Wadden wants to go record as being totally opposed to using it, using the Express again, I'm sorry, because I take it that one of the recommendations or suggestions anyway, by Dr. Banerjee -

DR. DENIC:

A. And I believe Ms. Wegrynowski also made the

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suggestion -

COFFEY, Q.C.:

Q. Anyway, coming out of one or both of their recommendations or reports, recommendations was that consideration be given to using it. It says using it again, I take it it had been used at one point and discontinued?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And were you involved in the decision to discontinue it?

DR. DENIC:

A. I could be the part of the group--I was a part of the group that validated the machine. I could have been the part of the group that was against the machine at one point, but the most objection came actually from the General Hospital site.

COFFEY, Q.C.:

Q. And so what is the current situation in relation to that?

DR. DENIC:

A. The current situation, the machine is inactive for several reasons. One of the reasons is

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that the stoppage of machine was due to one of the reagents is not working properly. I think technologists can talk about that much better. The other thing is that immunohistochemistry, if you read the--if you want to perform immunohistochemistry using the Sakura, it completely use different technique for fixation, which is the microwaving, and you cannot utilize it in immunohistochemistry of the breast. It's even recommended don't use microwaving if you want to do HER2/neu or predictive markers as such. The other additional problem that the pathologists found with this machine, because it's a different process of fixation as such, the basic morphology that we got used to using the regular tissue processor is not the same. For example, if the needle core biopsies of the prostate would be processed, certain cell details would be much more accentuated if it goes through the tissue processor and some of these nuclear details are very crucial in diagnosis of the cancer. So if this is very prominent in prostate, somebody can call it cancer, otherwise it wouldn't. So that's one

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of the objective that we came through.

Through our trip down to Toronto actually and visiting Mount Sinai, I inquired about it. Even Mount Sinai got rid of it. So they're not using it. They said that they couldn't organize properly the work flow because you still need to have a regular tissue processor. Then you have to--some tissue can be put on a Tek Xpres, so the work flow was also the problem. So that's why I didn't venture to reinstate this because there was a lot of unknown. Mr. Gulliver and I, we were discussing what we can do about it. Mount Sinai managed to return the machine and while they loss some money, they recovered some money. So if we go that route, maybe we could purchase any other instrumentation that we might use in our lab.

While Tek Xpres has been used in some institutions as well, maybe we should also explore those ones and just to see how they are doing. So at this particular moment, I think it's not really a time, due to the ER/PR and everything else, and different--and loss of crucial staffing for us, to go and again

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now explore this. So at this particular moment, this machine is inactive and it's going to stay until we make a decision.

COFFEY, Q.C.:

Q. And just exploring that with you, Doctor, simply because it came up before the Commissioner, it has come up as a topic before the Commissioner and you're the first person that has been a position to actually elaborate on the current status, that's why. Doctor, here, there's a note that Dr. Matheson thinks the Express should be the first thing evaluated by the new QA committee. Do you know if the QA committee ever actually addressed the Express issue, that you're aware of?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. You've explained what happened with it, and I just wanted to--in terms of how it was handled.

DR. DENIC:

A. And because it's never been touched ever after, you know, and for the various reasons.

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COFFEY, Q.C.:
Q. And you've noted here that it will not be used unless it is properly evaluated and that process is still outstanding?
DR. DENIC:
A. And that's as it stands now.
COFFEY, Q.C.:
Q. Doctor, the next reference here is to Dynacare. It notes that you've informed the group there's a backlog of cases going to Dynacare, due to red tape and administrative problems. The turnaround time is two to three weeks at the present time. The Dynacare doctors will call the clinicians and in the case of a positive cancer report, there have been some patient complaints about their cases going out of province for interpretation. Doctor, you told the Commissioner yesterday that--referred to Dynacare, utilization of Dynacare and how that came about. I take it that the usage of Dynacare by Eastern Health continues to this day?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:

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Q. And it varies from time to time, the volume?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And it's a function of, I take it, the availability of the staff internally?
DR. DENIC:
A. You're correct.
COFFEY, Q.C.:
Q. Is there any--is what is sent to Dynacare at all influenced by the type of case? Are there certain cases, you know, that are directed to Dynacare?
DR. DENIC:
A. According to the various phases, how we subclassify those cases, and in this first year, I would say that most of the cases that went to Dynacare, what we would call the low yield cases, the cases that we wouldn't expect to contain the cancer. We wouldn't send the cases where on requisition was any kind of query that this could be a cancer. Large specimens were not sent until a certain point in time.
COFFEY, Q.C.:

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Q. For the first year, it was low yield?
DR. DENIC:
A. Low yield. The skin was sent, you know, for the various inflammatory diseases and Dynacare, as well, utilized one of a well-known subspecialty trained pathologist, Dr. Prokopez, skin pathologist. So from one point, it also benefitted sending it out.
COFFEY, Q.C.:
Q. And after the first year, what has happened? Have there been points where, I won't call them high yield cases, but none low yield cases have been sent to Dynacare?
DR. DENIC:
A. Then we have a phase where, from Health Sciences would like a intermediate type of yield, type of specimens like cervical biopsies, again, but we were trying like cone biopsies that if they were taken for the various lesion, but not for cancer, again. So the specimen would be bigger. But you have to understand that we didn't send our wet tissue. We didn't send the specimens, but the slides taken from it and accompanied with a surgical report. The slides would down for report, and

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only the period of time in 2008, after the system really at St. Clare's pretty much came to the collapse. At one point, it was only Dr. Ford Elms and myself there, and I was -
COFFEY, Q.C.:
Q. And how many pathologists should -
DR. DENIC:
A. There should have been six, and I was--you remember those days, I was more outside talking to the politicians and giving the interviews and everything else, so Dr. Ford Elms stayed behind trying to handle frozen sections, autopsies, observing what the pathology assistants are doing. So he didn't even have a chance to read a single slide. So at that time, I think I publicly said that this is a time that we have to send even the larger specimens that might have cancer in it.
COFFEY, Q.C.:
Q. And so for a period of time, what I'll refer to as high yield cases or potentially high yield cases were being sent to Dynacare?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:

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Q. Or at least some. Doctor, and what is the current situation?
DR. DENIC:
A. What is the current situation is we still continued to send the cases. As you know, we are still short of people. We recently just acquired Dr. Makretsov, so it's four of us on staff, for example, at St. Clare's, which I'm almost taking 100 percent administrative duties and trying to help them out as much as I can, and I'm not happy about it. I only think that this is temporarily, but still, so you have three people, three pathologists doing the job which was designated for six.
COFFEY, Q.C.:
Q. So as of now, is it low, intermediate or high yield?
DR. DENIC:
A. Some cases may go, like a thyroid can go and we usually send the thyroids for benign lesions, but if a cancer is found in the slides, you know, you come back. So we still think that the turnaround time that Dynacare is providing is--it's optimal. It's not the best one, but it's optimal, because we're

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receiving in three to four weeks our results back.
COFFEY, Q.C.:
Q. So that's what I was going to ask you, the final question on Dynacare really was--well, second last question on Dynacare was what has been your experience with their service.
DR. DENIC:
A. It was very good service, and as you see from all of this, in case they find something unusual that the clinicians should act upon, they would act.
COFFEY, Q.C.:
Q. They would notify St. John's right away?
DR. DENIC:
A. St. John's, and trying to contact the physicians, in particular, which is on requisition because they have the name on the requisition who is the physician that the report has to go to. They all are certified pathologists, some of them with subspecialty training. Dynacare is a CAP, College of American Pathologists, accredited institution, and they're all paying liabilities.
COFFEY, Q.C.:

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Q. So Doctor, have any breast cancer cases been sent out to Dynacare?
DR. DENIC:
A. I believe not, Mr. Coffey. I cannot be sure that one case didn't slip, or two, but breast cases, I believe that we didn't send any breast cases, unless some of the pathologists took a breast case that I wouldn't know of.
COFFEY, Q.C.:
Q. But your understanding is not had?
DR. DENIC:
A. That's not the practice.
COFFEY, Q.C.:
Q. Doctor, Dynacare, I take it, has not been used for ER/PR testing?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. That has remained with Mount Sinai.
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. When you've had to go outside, you've gone to Mount Sinai for that?
DR. DENIC:

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A. That's correct.
COFFEY, Q.C.:
Q. Okay, sir.
DR. DENIC:
A. In an occasion, in a few occasions, they went to Sunnybrook, because Sunnybrook also had a very good service and one of the leader in breast pathology, Dr. Wedad Hanna, is present in Sunnybrook.
COFFEY, Q.C.:
Q. And Doctor, here, and the note in relation to Dynacare in this exhibit, Dr. Larkin had asked at the time how long Dynacare would be used, and you indicated that as of March 2006, you had a six-month contract in place, with the possibility of an extension if necessary. As it turns out, there have been a number of extensions, I take it?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, in relation to that, who has to approve of the utilization of Dynacare and the extensions from time to time?
DR. DENIC:

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A. It has to go through the VP's office, which would be Dr. Williams at that time, and Dr. Oscar Howell, but I believe it even went higher up, so the CEO would know about it.

COFFEY, Q.C.:

Q. Have you been refused any request to use Dynacare? Any request by yourself to utilize Dynacare, have you been refused? I'm not suggesting -

DR. DENIC:

A. You mean by the senior management?

COFFEY, Q.C.:

Q. Yes, by the senior management.

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Okay. Doctor, we'll look, please, at Exhibit P-2092? Doctor, this is a document entitled "laboratory program to your operational plan, April 2006 to March 2008, division pathology. Priority issue, focus area, integrated clinical system, regional policies and procedures. Detailed activity plan." And delegated, we'll see it under operational goals, directors operational objectives,

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action required, resources delegated to, individuals are named, and the start date and the end date are the columns. Doctor, were you involved in the preparation of this at the time?

DR. DENIC:

A. Yes, to a certain extent, and we even received training by one of the Eastern Health coordinator orientation.

COFFEY, Q.C.:

Q. And just around the time the Commission started it's public hearings was the end date for this two-year operational plan. In a general way, how did you make out, in terms of achieving the goals?

DR. DENIC:

A. Not all goals have been achieved through all of this because we went into the period of with ER/PR and I think that affected spreading our wings towards the different areas as well, and a lot of people from the program got involved through all of this, and especially the managers and the program director and while this is March, I just took the position, you know, just so some of the things have been

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dealt with.

COFFEY, Q.C.:

Q. Some have been accomplished.

DR. DENIC:

A. I think the policies and procedures, I think they're still on the way, but I think the large number of these, significant number have been fulfilled. I think that establishing the coordinator for quality assurance, she's been hired and -

COFFEY, Q.C.:

Q. So Doctor, here, in fact perhaps I will take you--it's an organized--provides an organized manner of reviewing what has happened really in effect in the past two, two and a half years. The operational goal initially was by March 2008, lab medicine will have developed a plan and consolidated key policies and procedures, and the director's operational objectives would be to have "each division will have reviewed and updated policies and procedures," and this division itself is pathology. So has that happened?

DR. DENIC:

A. It did happen, so we have policies and

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procedures, but you have to understand that this is a living document.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. So, and I think you have that document in your possession.

COFFEY, Q.C.:

Q. And I will be asking you a little bit more about that. That's that three--well, it's well over 300 pages.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. The document we have, and the bottom one here is "each division will identify key policies and procedures and develop a schedule for consolidation." That was consolidation of what?

DR. DENIC:

A. Policies.

COFFEY, Q.C.:

Q. Policies, okay, and I take it that has that-- that has been ongoing?

DR. DENIC:

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A. That has been ongoing.
COFFEY, Q.C.:
Q. In relation to this, on the bottom of the page here, "identified key policies to be implemented on a regional basis," under actions required. That's in the process of being done?
DR. DENIC:
A. That's in the process of being done. All these policies, as we have spoken and mentioned, the book of policies has been delivered to the regions. So they have them.
COFFEY, Q.C.:
Q. And when was that, Doctor? When did you deliver the book of--Registrar, it is 2157. We'll continue--continue to answer, Doctor.
DR. DENIC:
A. Some of the policy has been e-mailed to the regions as such, but some of them, I personally brought too, recently, because I didn't know what did they receive or what they didn't receive. So I brought my book of policies and procedures to Carbonear and Clarenville and personally delivered them, asked them to make the copies, and they

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shipped them back the following day.
COFFEY, Q.C.:
Q. And when was that, Doctor?
DR. DENIC:
A. That was, I went August of this year.
COFFEY, Q.C.:
Q. And before you visited Clarenville and Carbonear and brought the--I take it, the full set of policies and procedures as existed at the time?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Before that, your understanding is that some would have been sent out by e-mail or by paper, but there was no--you weren't satisfied yourself, before you went out to both these places, that they had everything?
DR. DENIC:
A. That's right. I want to be sure.
COFFEY, Q.C.:
Q. To be thorough.
DR. DENIC:
A. That's right, I want to be sure that they have everything what we have up to date.

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COFFEY, Q.C.:
Q. And is there any--as you've indicated, this is an active living document. Is there any policy or procedure in place to ensure that as they change, that the other regions--I'm sorry, the other regions, the other institutions will receive this?
DR. DENIC:
A. That goes through Ms. Lynn Wade at this particular point, and what we are working right now is working on a control of the document, a system. That system, as you can see, some of this document are just stamped, really not the control document, but this is not the way to go. This is the best what we have. So Mr. Wayne Miller and Ms. Lynn Wade, as we speak, work on software that does controlling of the documents and I had recently conversation with both of them, and I think a day or two ago, I received the e-mail that there's a plan what we need that the software can cover in the policies and the procedures, you know. So that portion is ongoing, and a part of this is going to be while we have integrated system, IT system

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between the regions, then all of this is going to be -
COFFEY, Q.C.:
Q. You have or when you have?
DR. DENIC:
A. When we have.
COFFEY, Q.C.:
Q. When we have, okay.
DR. DENIC:
A. When we have integrated IT system, but they can still access these policies and procedures through the internet.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. So there's the internet and I believe these policies, not all procedures, but the policy has been lifted up on internet. So everybody can access the policies. So this has been done and they can access the policies definitely and going to take time just to put all procedures on it. So it is in work and I think it's a good progress. Again, I don't see why paper copy or e-mail wouldn't follow through all of these stations that they need

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to have it.
COFFEY, Q.C.:
Q. And, Doctor, in relation to that, because I take it kind of the master copy, as it were, each of these documents is kept at the General Hospital?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And what you've referred to as applying to Carbonear and Clarenville, plan in that regard, did that also apply to St. Clare's? Because although St. Clare's is not a -
DR. DENIC:
A. Applies on every single lab. There are 17 labs of which we have the bigger labs, you know, St. Clare's, Health Sciences, Janeway, as well, but also Carbonear, Clarenville, Burin, and they're still around peripheral small labs, while they don't necessarily need to have entire policies and procedure, I think why not give everything what you have in case somebody ask them something, they don't perform but somebody might have interest. So I believe that all of this is going to be

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submitted as a binder to all labs, so they're going to be accessible to all labs.
COFFEY, Q.C.:
Q. And all clinical laboratories. And when it is available via the internet, the labs would be able, all the labs then would be able to get it via the internet, as well?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay. Doctor, in relation to that and following up, I appreciate you work for Eastern Health, okay?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. What about the other regional health authorities and their laboratories in relation to that, this whole issue of policies and procedures and bearing in mind that you are a tertiary care centre, which you referred to you yesterday, so how do you plan to handle that?
DR. DENIC:
A. The plan was and has been, really, as you

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know, to share certain number of policies and procedures with the other labs. We did that officially by me sending some of the policies and procedures in regard to the breast and fixation in May of 2007. And even recently I e-mailed new president of Newfoundland Association of Pathologists, Dr. Barry Gallagher, that was recent, I e-mailed him the table of content and I told him this, listen, this is what we have. I think that you should contact the other lab directors, see what they have. They should put this on internet, as well, what kind of policies and procedures, because maybe we can utilize each other's rather--because some of the policies could be redundant and we're going to save time and we're going to be more efficient to in a shorter period of time complete all the policies and procedures. So that was done and this was done in August.
COFFEY, Q.C.:
Q. So the current status of discussing the matter as to whether there'll be kind of province-wide approach to this was taken up in August of this year and it's in the process of being

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discussed amongst the lab directors, you understand?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. At least you suggested that be done. How about amongst the pathologists throughout the province? I'm sorry, you -
DR. DENIC:
A. Lab directors are mostly pathologists.
COFFEY, Q.C.:
Q. Okay, lab directors, okay.
DR. DENIC:
A. Dr. Paul Neil, the Dr. Dankwa -
COFFEY, Q.C.:
Q. Okay, the lab directors in this context are the physician lab directors throughout the province, okay.
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. And, Doctor, in terms of, what's the word I'll use, seeing that initiative through, is there any one person or persons who are--have taken on the responsibility to ensure that that

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plays itself out, as it were, as it should, in the sense of you've made the initial step, but I'm trying to get some sense for the Commissioner of is there any formal mechanism, even informal mechanism to ensure that, look, this initiative started, but it actually go somewhere?

DR. DENIC:

A. The initiate started, obviously, we started initiative, I pass to the, I think to the president of Newfoundland Association of Pathologists. I think this is the body that should coordinate that we are all on the same page, as such. While within Eastern Health, you know, I can see that part of my department, the quality management program for the pathology make sure that also all the policies relating to the pathology goes to the pathology. But not everything is about pathology.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. There are other divisions, as well. So that have to be coordinated on a more organized

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way. I think this is very early stage of it. It is the initiative. We are telling that we are open to share. We're going to be more happier when we get the software for the document control because you want to control the document, that this document is not modified and eventually loses its value and the content and becomes something that doesn't look any more as original. So we have to go through these phases before we move this further.

COFFEY, Q.C.:

Q. Doctor, within Eastern Health it's your understanding in terms of coordinating with the other regional health authorities, that wouldn't be so much at your level, that would be above you?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. That would be Dr. Howell?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. VP medical?

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DR. DENIC:

A. Yes, and that's going to be turn over to the VP medicals in the other integrated regional authorities.

COFFEY, Q.C.:

Q. And do you know whether or not--do you know what status that is? Have you been told where Dr. Howell is with that?

DR. DENIC:

A. I don't think so, I haven't been told. I think I would have. But I know that Dr. Howell works very closely with Ms. Lynn Wade, who is actually the coordinator now for the region for quality -

COFFEY, Q.C.:

Q. But what will -

DR. DENIC:

A. - and safety.

COFFEY, Q.C.:

Q. So Ms. Wade will be along here to testify, so maybe at that point she'll be able to--she can tell us.

DR. DENIC:

A. Yeah, she can probably clarify some of the issue where we are now.

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COFFEY, Q.C.:

Q. Doctor, here and speaking of Ms. Wade, okay, at the top, if we could go back, please, to P-2092? Here under QC, quality, that would be "Quality Control Implementation. Develop a Q"--see that?

DR. DENIC:

A. Yes, "QC Implementation."

COFFEY, Q.C.:

Q. "Implementation." "Develop a QC department for anatomical and surgical pathology, clinical and technical policies." Doctor, tell us then what happened in relation to that, how that unfolded?

DR. DENIC:

A. We started from March of 2006 when the quality management program was created by Dr. Bev Carter and myself and Dr. Bob Williams and endorsed, as well, by Mr. Gulliver. So we start working through the meetings and developing these policies and one of the first policies that we were working was fixation because lot had been said about it and we wanted to complete the fixation. So a large number of policies was start coming to this

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meeting, they were written, they had to be read, they had to be corrected, approved, put in certain formats and moved on. There have been changes along the way. The number of people present at the quality management program as we started first with a few of us, Dr. Bev Carter, myself and Mr. Dyer and Ms. Janet Laidly from the quality department working on these policies. Later on in 2007 the number of people grew.

COFFEY, Q.C.:

Q. So how did it go initially, Doctor, I mean, because here, and the Commissioner has seen, you did by May--this is March, 2006, this kind of initiative, this plan starts, the two years start to run, and it was May 31st, 2007, and we'll look at it later in the day, that you sent out that first five or six or seven policies related to fixation and certain, handlings of certain types of breast tissue. And I gather from looking at, if we go through Exhibit P-2157, which is that, the great book of those, when we look at them, were actually only brought into force early in 2008. So I appreciate there's a certain amount of time

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required to do them, but were there any--why did it take as long as it did? And what I'm asking, I suppose, is were there problems?

DR. DENIC:

A. I'll tell you what are the problems. Developing and working on the policies and procedure you have to understand that this is something, something as a new initiative, number one. This is initiative that requires dedication of certain number of people and time. And time is something that we didn't have, especially neither technologists or pathologists, as such. But if you can see through some probably of early days of this, of the creation of the QMP, you can see that we embarked right away on developing these policies. It took time to circulate the policies among the members of the committee and some of them even went further on to all pathologists to read them. And until the comments came back and some places the comments wouldn't come back because the policy was sitting on the desk on a busy pathologist who had to come and to do some extra search and review and make the comments and send it

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back takes time. This is not something that can be done overnight and not especially when you don't have people to do the regular workload, which was piling up and therefore we were sending the tissue out. Minor problem that I see as well was at a certain point we didn't have a full number of people attending these meetings and in that regard we, actually, I sent a letter of reminder of intention that these meetings are important and that the people should attend them as frequently as possible. And I know there are some reasons at the time that people couldn't attend. And I can even remember when Mr. Barry Dyer couldn't come, he said I had to go to court due to the union problems, then I didn't come because I had to collect the slides, sending them out. And there was always a reason because that was the daily living in the department. So that was one of the reasons. However, we did move these policies and some of them got approved even in December. Why you seeing this in the format that you're seeing it now, it's not that the policies were written in two days, because I

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think 300 policies bear the same date on them, maybe one day difference, that can only tell that these policies had been written before. But the format, as such, we start putting when Ms. Wade took her position.

COFFEY, Q.C.:

Q. And when was that, Doctor?

DR. DENIC:

A. She took her position in May, but she was still doing the duties, her previous duties at the service client department.

COFFEY, Q.C.:

Q. That was May of '06?

DR. DENIC:

A. That's right. And, no, I believe that was in '07.

COFFEY, Q.C.:

Q. '07, I apologize. Okay, May of '07.

DR. DENIC:

A. And Mr. Rob Lobes at the time, I'm trying to remember, was here on vacation. But they were supposed to switch and she had overlapping duties. So I think she start her active role in the fall of 2007, which is probably September, October. And Ms. Wade start

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working on a proper format, actually, of these policies have to be put. While for me at the time, frankly speaking, was very important that the policy in any form be written, because it's important to have the policy that people can act and to me at that time I would say, forget what kind of format, what's going to be on the top, I'll assign these policies and we'll move on it. Of course, the right way to do it would be to put in a format which is CSLI format and this is the proper format. And took time, actually, to adjust the policies that were already written, put them under the certain headings. And some of these policies even been amended in this period of time, like even fixation been amended, I think, in the fall of 2007 and eventually end up in the document that as you can see in front of you.

COFFEY, Q.C.:

Q. Yes, we're looking here at page 9 of Exhibit P-2092. I'm sorry, Exhibit P-2157. Doctor, did you ever become aware of any dissention or disagreement within the people who were involved in this committee?

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DR. DENIC:

A. In regards to the certain policy or overall?

COFFEY, Q.C.:

Q. Yes, overall and in certain policy and overall. Not so much a certain policy as overall.

DR. DENIC:

A. There was a disagreement in June of 2007 between Dr. Beverley Carter at the time and the other members who were present at the meeting.

COFFEY, Q.C.:

Q. And what was the nature of the disagreement?

DR. DENIC:

A. While I wasn't of disagreement for the reason that I was on vacation at the time and I found that aftermath when Dr. Bev Carter submitted a resignation. The nature of disagreement, as I was told, is disagreement about the principles of the quality management program and Dr. Carter would state that this is program too manage the quality and not the program to create policies and procedures. I think that's the gist of disagreement.

COFFEY, Q.C.:

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Q. Dr. Carter, your understanding is, while you were, as it turned out, you happened to be on leave, on vacation at the time, when you returned, she had resigned from her involvement in that particular committee?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And I gather that you, in fact, got involved yourself then, in the sense that you were already involved, but you became more active?

DR. DENIC:

A. That's correct. I had -

COFFEY, Q.C.:

Q. Something that you -

DR. DENIC:

A. - after all the duties I have, I didn't have anybody at that time to replace Dr. Carter so I had to take the role, too, as much as I could.

COFFEY, Q.C.:

Q. And, Doctor, what then was the approach after Dr. Carter left? Which approach was adopted, was it the one she had advocated or the one that the rest of the group had advocated, what

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one was adopted?

DR. DENIC:

A. It was approach of developing our policies and procedures.

COFFEY, Q.C.:

Q. The actual policies and procedures?

DR. DENIC:

A. And an adopted amendment.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. So if you read the submission, actually, that Dr. Carter put forwards, as well, in that submission it states that the goals of this program is to monitoring the analytical, pre-analytical and post-analytical phase, as such. But there's also a couple of sentences stated developing other policies manuals, as such. It was my belief, as well, you know, that it's difficult to monitor something if you don't have policies in place, so I think that it never should have been separated. So the policies, procedures and management goes together.

COFFEY, Q.C.:

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Q. So the current situation is, is that committee, and what is it called, what's its current name?
DR. DENIC:
A. It's QMP, Quality Management Program.
COFFEY, Q.C.:
Q. For pathology?
DR. DENIC:
A. For pathology.
COFFEY, Q.C.:
Q. Quality Management Program for pathology, QMP for pathology, their current responsibilities or responsibility is to create and maintain written policies and procedures?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. For the pathology department?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And to manage, to manage the issue of whether or not they're actually being followed?
DR. DENIC:
A. That's correct. And not only policies, but to

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measure also the indicators of the quality management program.
COFFEY, Q.C.:
Q. And the person in charge of that right now?
DR. DENIC:
A. Dr. Lynn Morris-Larkin.
COFFEY, Q.C.:
Q. And who else is involved currently?
DR. DENIC:
A. We have involvement of the pathology assistants, as well, because they are technologists and they are involve the--we have technologists from the bench, as well, and managers, which Mr. Barry Dyer, Ms. Lynn Wade and -
COFFEY, Q.C.:
Q. And she is, her role is what, Mr. Wade's role right now is what?
DR. DENIC:
A. She's still--well, she, her role is more brought about in terms of monitoring how this is developed. I think she's a great resource as advisor and lot of these policies also goes through her desk and she is very knowledgable in regards of managing the quality for the

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laboratories.
COFFEY, Q.C.:
Q. Are you actually a member of this committee yourself?
DR. DENIC:
A. Now I am, but ad hoc.
COFFEY, Q.C.:
Q. Okay. So it's -
DR. DENIC:
A. And Mr. Terry Gulliver, too.
COFFEY, Q.C.:
Q. So and the committee then reports, I take it reports to you?
DR. DENIC:
A. They report to the, actually, Dr. Oscar Howell's now portfolio.
COFFEY, Q.C.:
Q. Okay. Directly?
DR. DENIC:
A. Directly.
COFFEY, Q.C.:
Q. Okay, so -
DR. DENIC:
A. But let me tell, in practice the connection is there. I was always involved, advised, told

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and especially I have a very close relationship with Ms. Wade, who is not really under my jurisdiction, but she is in Dr. Oscar Howell's portfolio, but we work almost on a daily basis. There's no time that we don't communicate.
COFFEY, Q.C.:
Q. And, Doctor, what, if any, policies and procedures that might in any way relate to ER and PR testing, okay, have yet to be created? Are there any policies and procedures that you are aware of that have yet to be created in relation--that might have an effect on or be related to ER/PR?
DR. DENIC:
A. I think most of these are covered.
COFFEY, Q.C.:
Q. Yes, and I appreciate that.
DR. DENIC:
A. I cannot recall, I mean -
COFFEY, Q.C.:
Q. Who would be the--I'm asking you, but who else, if you had to ask somebody else, is there anything else that we haven't covered off, who would you ask?

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DR. DENIC:
A. I would ask Dr. Ford Elms, who is responsible for that. And of course, he would also ask Mr. Ken Greening -
COFFEY, Q.C.:
Q. Ken Greening.
DR. DENIC:
A. - who is the lead tech and Ms. Jane Gamburg.
COFFEY, Q.C.:
Q. And your understanding, I take it, as the chief of laboratory medicine is, though, is it your understanding that certainly as of today and as of sometime ago that all such policies and procedures were to have been created and already exist?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. That's your understand?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. Exhibit P-2386. Doctor, in relation to that, I just--have you had anyone outside the Eastern Health examine the documents in

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Exhibit P-2157? Like the policies and procedures manual, have you had anyone else outside kind of look through them?
DR. DENIC:
A. You mean outside the -
COFFEY, Q.C.:
Q. Outside Eastern Health, like, in terms of who--you know, ask somebody else's opinion as to, in relation to their adequacy?
DR. DENIC:
A. There was some comment given, not to all of these policies and procedures. I think QMPLS people reflected to that -
COFFEY, Q.C.:
Q. Yeah. And most of these--QMPLS was here December 7th, '07.
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. And most of these -
DR. DENIC:
A. But nobody that we submitted externally that I know of because -
COFFEY, Q.C.:
Q. When QMPLS was here, these documents had not

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been issued and certainly not in the way they are?
DR. DENIC:
A. Not in this form, but they had, for example, fixation, they have some policies in immunohistochemistry -
COFFEY, Q.C.:
Q. Some.
DR. DENIC:
A. - written, so they had the book of policies and procedures for immunohistochemistry, maybe not in this format and to this extent, what we see now, but they were available to the reviewers.
COFFEY, Q.C.:
Q. Okay. What existed at the time was available to them?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. In the form it existed?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. I'm sorry, yes, this Exhibit P-2386, April

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17th, 2006, it's to all pathologists, it's from Dr. Ejeckam, referring to the VIAS Image Analysis machine, the role -
DR. DENIC:
A. But it is analyzer, really.
COFFEY, Q.C.:
Q. And it's an analyzer, yes, an image analyzer. And there's going be a medical session sponsored. This is a notice of it. And we look at the second page, it occurred, apparently, April 25th, 2006. And, Doctor, did you attend this session?
DR. DENIC:
A. Yes, I did.
COFFEY, Q.C.:
Q. Okay. And I gather, Doctor, that the decision was made, ultimately, by Eastern Health not to purchase or lease the machine at this point in time, at that point in time?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And ultimately that decision was made by whom, would it be Mr. Gulliver or yourself?
DR. DENIC:

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A. It wasn't Mr. Gulliver. Mr. Gulliver was supportive for this machine. Some of the pathologists had objection about the machine, thinking that machine not going to benefit much based on the literature at that time. And I think it's published in Dr. Allan Gown's lab. They were doing this research of the accuracy between the machine and the eyeballing for the estrogen, progesterone receptors and they didn't find significance. The cost of the machine at that time was around $30,000 and some of the pathologists they thought maybe this money should be utilized for something else, that what we need more. And I did set up the group of people to review the machine and just to go and click few slides and just to see what happened. And eventually I got the letter from Dr. Elms stating that the group believes that at this time you shouldn't be getting this machine. And decision was made, as such.

COFFEY, Q.C.:

Q. And has there been any further thought given since then to utilizing an image analyzer?

DR. DENIC:

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A. At the time of the practice of Dr. Carter's and Dr. Cook they would not use the image analyzer -

COFFEY, Q.C.:

Q. No, I appreciate they didn't use it. But I'm just asking you has any thought been given since, up to today?

DR. DENIC:

A. Since, yes.

COFFEY, Q.C.:

Q. And when was that, when was it looked into again?

DR. DENIC:

A. The new pathologist that came recently, Dr. Nik Makretsov, he wrote me that maybe there is benefit of using the image analyzer.

COFFEY, Q.C.:

Q. Did he explain to you why or why that might be so?

DR. DENIC:

A. He didn't explain why we didn't go into details because that came, I came back from vacation, I spoke to Nik on--I came 21st or 22nd. The following day I spoke to him about the stuff and asked him to write me down what

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he thinks about where the program should go. And this is something that you have in your submissions.

COFFEY, Q.C.:

Q. So that's one of the lists -

DR. DENIC:

A. In the list, and he said image analyzer, as well. I believe that came probably in UK they're utilizing more than what they're utilizing in North America. The way that even Mr. Gulliver at that time was arguing for is the use for the, almost like a quality insurance, you know, that you can take the picture of it, said, okay, I made my assessment based on this, and you click, take a picture and put that in the file, which of course I think is beneficial from that point. I personally don't know how beneficial is that the machine is going to be better than a human eye of counting the numbers of cells because you can be bias, like you can be bias yourself.

COFFEY, Q.C.:

Q. So -

DR. DENIC:

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A. So if you look at the fields that don't have an expression and click on those one and don't click and take a picture on the ones they express, in that case the true number of expression are not going to be right. So there's some limitation and I personally don't know much about it. And it is something that we can explore, not necessarily that we should go immediately, but explore that.

COFFEY, Q.C.:

Q. So that's as current as we are here?

DR. DENIC:

A. That's what I understand now.

COFFEY, Q.C.:

Q. That's where it is now, and if we look, please, at Exhibit P-2366. Doctor, these are laboratory medicine program minutes, and just when we look at the second page, of course, the--paragraph seven, I'm sorry, refers to ER/PR receptors, and the fact that Ms. Wergynowski has been to the lab by that point and Dr. Banerjee was then due the next week. I was asking you about generally your recollection of their visits yesterday. You did receive the reports?

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DR. DENIC:
A. Eventually I did.
COFFEY, Q.C.:
Q. And P-0048, I believe.
THE COMMISSIONER:
Q. Are we talking about the first reports, the second reports, or both reports.
COFFEY, Q.C.:
Q. At this point the second reports because I'm going to go back to the first reports. This is May 2nd, 2006. This will be Ms. Wegrynowski's report, the second report, Doctor, and it's dated May 2nd, 2006. If we could bring up, please, Exhibit P-0049. This is the letter of May 23rd, 2006, from Dr. Banerjee to Dr. Williams. It's post-implementation, external quality review, May 21st, 2006, and these would have arrived in your hands in May of '06?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, at that point did you have the original reports, the two original reports?
DR. DENIC:

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A. No.
COFFEY, Q.C.:
Q. When did you, yourself, first receive the two original reports?
DR. DENIC:
A. In May of 2007.
COFFEY, Q.C.:
Q. Can you tell the Commissioner why it wasn't until May of 2007 that you actually received a copy of the original reports?
DR. DENIC:
A. Probably nobody offered me is one of the reasons. The other --
COFFEY, Q.C.:
Q. That was the first one. That's what I want to ask you about, okay, no one offered you.
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. The second --
DR. DENIC:
A. The second one, I didn't ask.
COFFEY, Q.C.:
Q. And why didn't you ask?
DR. DENIC:

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A. I don't know why I didn't ask, and I was thinking because we have spreadsheets created by Mr. Gulliver that reflects what's in the reports.
COFFEY, Q.C.:
Q. Why in May of 2007 then did you go and get a copy of the first two reports?
DR. DENIC:
A. I think that was at request of Mr. Tilley.
COFFEY, Q.C.:
Q. Could you tell us about that?
DR. DENIC:
A. That was sometime, I believe, after media briefing.
COFFEY, Q.C.:
Q. So it's after May 15th, 2007, which is when this really first got into the media in May?
DR. DENIC:
A. Yes, we had the media briefing, it was on May 18th.
COFFEY, Q.C.:
Q. May 18th, yes.
DR. DENIC:
A. May 18th, and the only thing that I received a call from his office or himself, I can't

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remember, from his office that they need all the copies of the reports. I think the Department of Health was requesting those reports.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. So I--since I didn't have--I had only two of these, the recent one, relatively recent at that time. I didn't have the other two, so I went to Dr. Cook and I went to Mr. Gulliver asking them for the copies, and I was supposed to make some also copies as well, and some of these copies you can see they are initialled by my name.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. And I send them down to Mr. Tilley's office and that was the end of my knowledge what happened with them.
THE COMMISSIONER:
Q. Sorry, I wasn't quite sure what you meant about what you had actually sent to Mr. Tilley's office. Did you send a copy of each

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or did you send more than one copy of each?
DR. DENIC:
A. It could be more copy of each. I think he was supposed to send to the Department of Health and something to--probably to keep for himself, so I can't tell you exactly how many, but a few copies of each document. So there were four documents, and could have been sent two or three copies or more at a time.
COFFEY, Q.C.:
Q. Bring up P-0046 again, please. Doctor, this is the October 17th, 2005, report and it's written down here copy five of eight, May 23, '07. I take it they're your initials?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. So as of May 23rd '07, you had certainly by that point received this request from Mr. Tilley, and had by then seen Dr. Cook, received his copy?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Made your own--made copies of that, I take it?

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DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And then took the trouble to write on it, copy five of eight, dated it, and initialled it?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Why did you do that?
DR. DENIC:
A. Why would I initial?
COFFEY, Q.C.:
Q. And as well, write copy five of eight? Presumably then there's six of eight, seven of eight.
DR. DENIC:
A. I'll tell you why, because the original copies, I think they had marks of them one of four, or two of four, something like that, and I remember they needed these copies almost like immediately, and after that--I even remember Dr. Cook being in my office and he was telling me what are you doing and I was trying to write five of eight--five of eight, you know, I was rushing, but I wanted to write

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how many copies was made. So eight copies was made. I kept one copy for myself since I didn't have it.
COFFEY, Q.C.:
Q. So --
DR. DENIC:
A. And I initialled it.
COFFEY, Q.C.:
Q. So the purpose was, I take it, to keep track of them?
DR. DENIC:
A. Keep the track because this is a document now created--not created by me, but it was in my hands and I'm forwarding that somewhere.
COFFEY, Q.C.:
Q. And bring up P-0047, please. This is--here, Doctor, towards the bottom of the page where we have this copy, seven of eight?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. May 23rd '07 and your initials, and this one does have on it copy one of four?
DR. DENIC:
A. Yes.

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COFFEY, Q.C.:
Q. So Ms. Wegrynowski's report, November 9th, 2005, had been so labelled, and you saw that labelling, I take it?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. One of four on this one.
DR. DENIC:
A. I said let me try to count how many copies and which copy is this one.
THE COMMISSIONER:
Q. So just following this, it would appear that one of four was held by either Mr. Gulliver or --
DR. DENIC:
A. Dr. Donald Cook.
THE COMMISSIONER:
Q. Dr. Cook.
DR. DENIC:
A. And Dr. Williams and could have been somebody from quality department.
THE COMMISSIONER:
Q. But the copy which read one of four was the one that you used to make the copies that you

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were making?
DR. DENIC:
A. That's correct.
THE COMMISSIONER:
Q. And then this particular edition that we have turned out to be seven of what was then eight copies by then?
DR. DENIC:
A. That's correct.
THE COMMISSIONER:
Q. All right, thank you.
COFFEY, Q.C.:
Q. And, Doctor, you obtained this from--the one that was copied one of four on it, you obtained that from whom, do you recall?
DR. DENIC:
A. I believe it came from Mr. Gulliver.
THE COMMISSIONER:
Q. That's because it's Ms. Wegrynowski's report.
DR. DENIC:
A. Respecting --
THE COMMISSIONER:
Q. You would have gotten that from him, and you would have gotten Dr. Banerjee's from Dr. Cook?

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DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And if we could go then to 48, please, P-0048. Doctor, here this May 2nd, 2006 one has one of four on it. See that?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. Is that your handwriting?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Okay, and if we could go, please, to P-0049. This is the May 21st, 2006, Dr. Banerjee's report. It has handwritten on it, copy two of four. That's not your handwriting either, I take it?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. The copy of these reports, I'll call them the May, 2006 reports, the copies that you received at the time, they had written on it copy--yours was one of four, two of four,

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three of four, whatever?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Yours was numbered?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. So you would have been aware then for a year that the second reports had been handled by numbering them. So when you were asked to go get the first reports for Mr. Tilley, keeping track of them, you were already aware that the reports at least you had had for a year were, in fact, numbered, labelled?
DR. DENIC:
A. Yes, I did, but I wouldn't give any great significance to it.
COFFEY, Q.C.:
Q. Doctor, having received at least the May, 2006, reports, did you distribute them to anybody?
DR. DENIC:
A. Did I distribute?
COFFEY, Q.C.:

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Q. Yes.
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Why not?
DR. DENIC:
A. I was told that these documents are peer review documents, they are protected by the Evidence Act, not to be --
COFFEY, Q.C.:
Q. Who told you that?
DR. DENIC:
A. Dr. Williams. That not to be copied, distributed. It was almost like for your eyes only.
COFFEY, Q.C.:
Q. And Dr. Cook, the year before in '05, had read Dr. Banerjee's report to the group.
DR. DENIC:
A. I understand that.
COFFEY, Q.C.:
Q. Did you do anything like that at that point?
DR. DENIC:
A. I did in June.
COFFEY, Q.C.:

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Q. In June of '06?
DR. DENIC:
A. '06.
COFFEY, Q.C.:
Q. Perhaps you could tell the Commissioner then about this.
DR. DENIC:
A. I asked for the permission from Dr. Williams. I said that, well, reports were written, these reports probably should be known and acted from the people who this recommendation goes to.
COFFEY, Q.C.:
Q. Yeah.
DR. DENIC:
A. So I did read the reports, not copied, and I got permission from him to --
COFFEY, Q.C.:
Q. Dr. Williams agreed.
DR. DENIC:
A. Agreed that I can read, but not distribute, not to copy, and not give anybody the reports.
COFFEY, Q.C.:
Q. And who was the audience at the time?
DR. DENIC:

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A. The audience was three people; Dr. Ejeckam, Dr. Makarla, and Dr. Elms.
COFFEY, Q.C.:
Q. And I take it Dr. Makarla, Elms, and Ejeckam were the individuals at that time involved with immunohistochemistry?
DR. DENIC:
A. Exactly. So I didn't know what would be the different way to tell them what to look for and where to go from this point and how to correct the issue if they don't know what's written.
COFFEY, Q.C.:
Q. Which reports did you read to them? Did you read both of the reports that you had at that time?
DR. DENIC:
A. Both reports.
COFFEY, Q.C.:
Q. So that was Dr. Banerjee's May, 2006 report, and Ms. Wegrynowski's May, 2006, report?
DR. DENIC:
A. That's right, and another which was, I think, Mr. Gown's.
COFFEY, Q.C.:

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Q. Okay, and, Doctor, in relation to that because you would have known--if we could, Exhibit P-0277. You indicated it was June, 2006, you had your meeting with these three individuals and read them the reports. Do you recall when in June that was?
DR. DENIC:
A. I think it was June 6th. It's the first week of June because Dr. Ejeckam was supposed to do a locum for us in immunohistochemistry.
COFFEY, Q.C.:
Q. So as of that point in time, and this is-- because we have a number of spreadsheets, but as of early June, 2006, I gather the most recent spreadsheet is this one, P-0277, because it's updated April 25th, 2006.
DR. DENIC:
A. Okay.
COFFEY, Q.C.:
Q. This is the one with--just going to go back here now to the beginning. Yes, April 25th, '06. We looked at this yesterday, but this is the one that's got 30 recommendations on it?
DR. DENIC:
A. That's correct.

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COFFEY, Q.C.:
Q. So, Doctor, if the list of recommendations existed, I take it was there any restriction on the circulation of the list in the spreadsheet recommendations?
DR. DENIC:
A. No, I don't believe so. Nobody told me that the list is restricted.
COFFEY, Q.C.:
Q. So you certainly then could have distributed this list at the time to the three individuals and you probably did, in fact, at the time. Do you know if you distributed that to --
DR. DENIC:
A. I can't remember did I distribute the list, but the reason I went to read them is it's of different nature.
COFFEY, Q.C.:
Q. So, Doctor, I was going to ask you about--the list wouldn't suffice, this list, or this sort of a list wouldn't suffice for your purpose at the time. What was it about the reports that you thought required you to read the reports as opposed to simply giving out a list of spreadsheet of recommendations?

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DR. DENIC:
A. But the spreadsheets--the nature of the spreadsheet is just to give the basic information and you can put your correction action like done, or going--and what is referred to. The document as such has more information because every single recommendation probably has a three line written in the document and maybe explains the certain recommendation better. So that was the whole point to read them from the original document.
COFFEY, Q.C.:
Q. Doctor, I take it then from your perspective, and at that time you certainly viewed yourself as responsible for all this now, I mean, you're in charge, so if you're in charge, you got permission from your superior to read the reports because you felt it would be necessary to convey the appropriate amount of information to the people who needed to know?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, did it occur to you at the time that

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maybe the same thing might apply in relation to the first two reports?
DR. DENIC:
A. In which sense, Mr. Coffey?
COFFEY, Q.C.:
Q. In the sense of letting these people know, these three individuals know what it was exactly, for example, that Dr. Banerjee had said in his October report because, for example, the reasons for test failure as an example, that part of that report, is not reproduced in the second report. It's not reproduced in his May report. So I'm just asking you did it occur to you at the time that it might be of benefit for Dr. Ejeckam, Dr. Elms, and--I'm sorry, Dr. Makarla, and I appreciate they had presumably had the opportunity to have it read to them what you had in the fall, but you pointed out that just listening is a problem.
DR. DENIC:
A. It didn't occur to me because it was a list of recommendation compiled based on this. We now have a document as such which I don't believe it's a large discrepancy between two documents

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written by Ms. Wergynowski first time and the second one. So she still states lot of recommendations in it.
COFFEY, Q.C.:
Q. Doctor, here looking at Exhibit P-0277. This is the one updated June 30th '06, and, Doctor, here at page four and page five, we get up to 52 recommendations. It went from 30 to 52. So, Doctor, I take it those 22 recommendations were added to the spreadsheet because of the May 2006 reports?
DR. DENIC:
A. That is my understanding.
COFFEY, Q.C.:
Q. That's your understanding. So upon the return visit by late June, it was understood within Eastern Health that the recommendation list has gone from 30, and I appreciate some of them had been implemented, all the way up to 52?
DR. DENIC:
A. It appears, yes.
COFFEY, Q.C.:
Q. Doctor, if you could look, please, at Exhibit P-1119. Actually, I apologize, just before I

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leave this whole issue about reports, if I could first of all go to P-1371. Doctor, this is a listing of the distribution, for example, for Ms. Wegrynowski's report of May 2nd, 2006. So apparently this was being kept track of.
DR. DENIC:
A. Number of copies.
COFFEY, Q.C.:
Q. Yes. Yours is listed as 2 of 4 and it even lists the date that you picked it up. So in effect, Doctor, then I take it you understood that those two May, 2006 reports were, in effect, top secret, as it were, for your eyes only?
DR. DENIC:
A. That's what I was told.
COFFEY, Q.C.:
Q. Doctor, the pathologists themselves as a group by this point in time, by May/June, 2006, certainly by June, 2006, had they been told what the results were for their own patients on the retests?
DR. DENIC:
A. No.
COFFEY, Q.C.:

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Q. Were they ever told?
DR. DENIC:
A. They had opportunity to be told.
COFFEY, Q.C.:
Q. And when was that?
DR. DENIC:
A. November of 2007.
COFFEY, Q.C.:
Q. Okay, and that opportunity was presented by whom?
DR. DENIC:
A. By me.
COFFEY, Q.C.:
Q. It was your offer. That was an initiative of yourself?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. We'll come to that when we get to the fall, but in terms of yourself in this period and you're now two or three months into the job, you didn't think it necessary to tell the pathologists, get them all together and tell them, look, this is what's going on, this is the state we're in, Banerjee has been here a

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second time, Ms. Wegrynowski has been here a second time, and kind of discuss where this whole matter was. I'm thinking about from a morale perspective.
DR. DENIC:
A. I think the pathologists knew that the--through the various sources--I'm not saying that it had been done officially, and I didn't do it, but they knew that there was a lot of deficiency found in the lab, and they were aware of that, you know, and nobody made any bigger inquiries in that regard for the reason that was left again to the clinical chief to deal with the issue, a lab director, Mr. Gulliver, vice president, and they have to work towards that. So it's--this kind of stuff cannot be hidden, you know, but no official meeting that said, okay, this is what they found, no.
COFFEY, Q.C.:
Q. Exhibit P-1119. Doctor, this is a fax to yourself from Dr. Cook, April 27th, 2006. It involves a--it's from Dr. Williams, a letter to Peter Dawe, for your review and comments. Doctor, I'll just take you down through this.

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Do you recall being asked to comment--review this and comment upon it, a communication?
DR. DENIC:
A. I remember receiving--I don't think so I commented anything on this letter. It was fine to me at the time.
COFFEY, Q.C.:
Q. So from your perspective at the time as clinical chief, you would have had no problem with having that letter sent?
DR. DENIC:
A. I have to just remind myself what's in the letter, of course.
COFFEY, Q.C.:
Q. Sure, go ahead.
DR. DENIC:
A. What would be the --
COFFEY, Q.C.:
Q. Okay. "I'm writing in follow-up to discussions we've had in the past and our most recent discussion today's date. I strongly support your endeavours to get the issue of hormone receptor testing on the national agenda. I've attached a dossier of the literature".

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DR. DENIC:
A. Yes, to put this on the agenda of Canadian Association of Pathologists, and discuss the issues with oncology group. He was talking in general that this issue really is global issue and should involve the various agencies across the board.
COFFEY, Q.C.:
Q. And there's a reference in the last paragraph, or second last paragraph, "As I advised you, our two consultants have revisited the province to review our efforts here, and once we receive their reports, we'll be making a decision concerning reinstituting testing within the laboratory services in St. John's" and there will be an update and briefing session and he's extended an opportunity to be involved in that process. So you had no problem with that, I take it, going out, Doctor?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. The idea of involving a representative of the Cancer Society in this proposed update and

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briefing session, did you have any problem with that?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Did you ever have any dealings yourself with Mr. Dawe in relation to this whole matter?

DR. DENIC:

A. Until 2008.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. That's the first time I met him.

COFFEY, Q.C.:

Q. If we could look, please, at Exhibit P-1130. Doctor, this is an exchange of e-mails between yourself and Dr. Brendan Mullen. Look down at the bottom of the page here, May 19th, 2006. You identify yourself as the new clinical chief for Eastern Health. You in the middle of the paragraph say, "However, I still have to ask you for another favour, probably the last one, that if you can retest the group of seven patients who turned out to be retroconverters. We would like first to deal

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with this group of patients as the therapy might not be appropriate. The list of patients is enclosed". Doctor, what was this about?

DR. DENIC:

A. There was discussion in May, and I was a part of that discussion, was going through check and balances. Dr. Williams was there, and Ms. Heather Predham could have been, and Mr. Gulliver too. I can't remember all. I think I have a note in my notebook, and I think you probably have those notes, a discussion where are we at that particular point and it was brought up the term "retroconversion" at that time, saying that it could be a certain number of patients they were reported positive, but on a retesting they were negative. So that means they were retroconversion, and the decision was made that Ms. Heather Predham send me a list of these people so I can send them for retesting again just to completely be sure that this is done. So I think the following day or one of the following days, she e-mailed me the list. At that time, I think it was 17 patients on that list, but she

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also told me wait until I consult with Dr. Kara Laing because this might not be it. Eventually I received the revised list of seven patients, which oncologists had the issue actually with and they were thinking they may be retroconverters. That was the list that I'm talking about, and this is the spreadsheet that I send to Dr. Mullen.

COFFEY, Q.C.:

Q. Okay, and he agreed to do them?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. And we'll take that up in a moment as to what happened with the retroconverters. Exhibit P-0779. Doctor, here this is a series of e-mails of May 19th, 2006. The first of them is from Rick Singleton to a number of individuals, including yourself. The subject is an ethics consult, re; disclosure of info on deceased patients, and he writes, "Hi, I've been asked to organize an ethics consult to discuss the ethical issues regarding disclosure of information ER/PR results from Mount Sinai to families of deceased patients".

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He says, "When organizing it, we need to get the right mix of people to have a discussion and generate reasonable recommendations. For this discussion, we need Dr. Pullman, Dr. Cook, Dr. Denic, Dr. Laing. We will recruit others as needed", and he's trying to schedule it. Doctor, what was your understanding of why you were invited or asked to participate in this?

DR. DENIC:

A. I mean, just to be informed first as the clinical chief what's going on, and if I have any kind of input of this, just to be available for it.

COFFEY, Q.C.:

Q. I'm sorry, what?

DR. DENIC:

A. If I have any kind of input in this issue or matter.

COFFEY, Q.C.:

Q. What sort of input did you--would you think that you might be asked to bring to it?

DR. DENIC:

A. I wasn't certain really at that time. This is the Ethics Committee and it's the first time I

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was attending any ethics committee, so without any big questioning why I'm there, I said probably I belong there.

COFFEY, Q.C.:

Q. Was this the first Ethics Committee meeting you had ever attended?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. In fact, you wouldn't--it would be new to you, you wouldn't really know what you were getting yourself involved in?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Okay. Doctor, if we could look, please, at Exhibit P-0781. Doctor, I'm going to ask you first of all, though, what you recall about what happened in that meeting?

DR. DENIC:

A. At that meeting, there were several of us. I think Dr. Joy McCarthy, Dr. Cook, myself, Mr. Rick Singleton, Mr. Dan Boone, Heather Predham, and Dr. Bandrauk. So what I remember from the meeting, it was Dr. Cook gave brief

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overview what happened and how all of this happened, and then we discussed about how we going to disclose the results to deceased patients families, and as a conclusion actually from that meeting is that we should--Eastern Health should advertise that certain number of patients being tested and that results are available, and if anybody has an interest in those results, they should contact Eastern Health. It was also decided that Eastern Health should ensure that the appropriate person is on the phone in order to give the right answer, and I think another decision was that while not all the patients were--deceased patients were retested, that if family would like their loved one tissue to be retested again, that's going to be available to them.

COFFEY, Q.C.:

Q. Doctor, if we could bring up, please, Exhibit P-0782 before I go to this one. This is a report, June 20th, 2006, to Dr. Williams. It's from Mr. Singleton. It lists as present --it's an ethics consult, June 19th, 2006. Present are Mr. Boone, Dan Boone, Heather

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Predham, Dr. Joy McCarthy, Dr. Don Cook, Dr. Nash Denic, Dr. Natalie Bandrauk, and Rick Singleton. Doctor, have you ever seen a copy of this?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. I'm just--the issue was framed, "In the summer of 2005, the Director of Laboratory Medicine became aware that there had been some problems with testing of samples from breast cancer patients that were processed to determine appropriate follow-ups with patients. A test for the presence of hormone receptors in the tumour which may impact follow-up treatment, ER/PR, and the problem with the results was rooted in the test procedures used in the time period from 1997 to 2005. In 2005, samples known to have been processed from this batch of patients were forwarded to Mount Sinai for retesting at their lab", and it talks then about the number of deceased--samples from deceased patients and so on. It continues, "Important facts to the history and understanding of this case include the

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following; there were no mistakes or technical errors at the root of this problem. It's impossible to know in any specific case if the outcome for any individual patient would have been different, and intervention for post-menopausal women had positive impact by lengthening life in 47 percent of patients treated". Now, Doctor, in relation to the assertion here that there were no mistakes or technical errors at the root of this problem, as of June 19th, 2006, was that your view that there had been no mistakes or technical errors at the root of the problem?

DR. DENIC:

A. What we said--I'm trying to recollect what we talked about it. It was different term here, nobody said --

COFFEY, Q.C.:

Q. And I appreciate no one ever sent you this.

DR. DENIC:

A. Nobody said the error didn't occur at some point along the way. We were talking about the processes that have effect on the outcome, which is the stain, and we said this is a long process with the fixation--even the tissue,

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before it comes to the lab, can affect it, and then go to the processors and 40 of those steps that have been said so many times. So the only thing that I understand at that time and that we didn't know what, in particular, went wrong. Obviously, the results had changed, but this is a view.

COFFEY, Q.C.:

Q. It is not accurate to say, you didn't believe it to be accurate to say that there were no mistakes or technical errors at the root of the problem?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. And on that point, Doctor, because you were in the room at the time, did you hear anyone make that assertion?

DR. DENIC:

A. No, because that's something that I still believe today, there's a lot of factors that could--involved in it, that the outcome was what we had.

COFFEY, Q.C.:

Q. Doctor, during that meeting, were the people

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present told about what Dr. Banerjee had identified as his reasons for test failure, or whatever that phrase is? When was he told about the problems with internal controls--or the people there told about that, internal controls?

DR. DENIC:

A. I don't believe so, but I cannot be absolutely certain.

COFFEY, Q.C.:

Q. Exhibit P-0781. Doctor, this is an e-mail from Rick Singleton to Dr. Williams, June 20th. He says, "Hi Bob, yesterday we had the ethics consult, ER/PR, a very good discussion and outcome. I will forward the summary later. In the meantime, an issue came up that I want to give you a heads up on. Dr. Denic had a document or report from an external reviewer of the lab processes, etc, here. He read from it and mentioned that he would use the report as part of information he was sharing with others. It seems the report or opinion had been done for Dan Boone, and he did not want the information shared as at this time it is privileged. Dr. Denic understood

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from you that he was not to copy it, but Dan seemed to be a bit concerned that it was being quoted, the expert being referred to. Dan's concern seems to be about the privilege status of the report which he may need in proceedings later on. Anyway, just thought you might want to know there was a bit of a fuss about this", signed Rick. Do you remember that?

DR. DENIC:

A. I vaguely remember. I don't think I produced a document. I'm just trying to think why would I have the document for the Ethics Committee, but I did at one point refer to the single statement from that document.

COFFEY, Q.C.:

Q. And the document in question was a report by whom?

DR. DENIC:

A. By Dr. Gown.

COFFEY, Q.C.:

Q. And what statement?

MR. SIMMONS:

Q. Excuse me, Commissioner. The report itself, I believe, has previously been acknowledged here as having been something that's subject to

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privilege, and to disclose the statement in the report at this point would be violating that privilege.

COFFEY, Q.C.:

Q. If I could, Commissioner, I'm not asking him to show us the report. Presumably, those in the room, Commissioner, at the time on June 19th heard whatever it was that Dr. Denic said to the group. They presumably took that into account in acting in the manner that they did and coming to the conclusions they did. I don't see where the solicitor/client in the sense it would still be maintainable in respect of that one statement, whatever it is.

MR. SIMMONS:

Q. Well, Commissioner, the privilege attaches to the contents of the report. It's not the physical document that is solely privileged, it's the information that is contained in it, and that's the intent and purpose for which it was prepared, and it's very clear that this was a report prepared for the purpose of instructing or assisting the lawyers who are involved in litigation at this stage.

THE COMMISSIONER:

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Q. Excuse me, Mr. Simmons, but it seems to me that this is an issue in which other counsel have to weigh in. And why don't we delay the answering of this question until after we can have an appropriate argument by counsel, say at the end of the morning, and we won't have to have Dr. Denic sit here and listen to us argue about what the extent of the solicitor/client privilege is and it gives other counsel opportunity to decide how they want to weigh in on it.

COFFEY, Q.C.:

Q. Just before we leave that and just as an evidentiary issue, the people present, Doctor, do you know who Dr. Bandrauk works for?

DR. DENIC:

A. She's an intensivist and she has a background in ethics.

COFFEY, Q.C.:

Q. She work for Memorial University? Is she a part of Eastern Health, that's what I'm -

DR. DENIC:

A. Yeah, she's part of Eastern Health in the intensive care unit.

COFFEY, Q.C.:

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Q. And you are, Dr. Cook would be, Mr. Singleton, Dr. McCarthy, Ms. Predham and Mr. Boone. Okay, I just wanted to canvass that. So we'll continue on and we'll come back to that, Commissioner?

THE COMMISSIONER:

Q. Yes.

COFFEY, Q.C.:

Q. Thank you. If we could look, please, at Exhibit P-2647? Doctor, this is an e-mail from Dr. Carter to yourself and others. It's June 26th, 2006. It's, the attachment is fixation protocol. I take it, "Please find enclosed the initial draft of the fixation policy and protocol. Comments and corrections, please?" And she notes "This will change the way small biopsies are handled in the lab. It may also mean call back for pathologists or pathology assistants for large specimens." And "Needs to be discussed with the perioperative program" and so on, okay. So this is the beginning, really, of the circulation of -

DR. DENIC:

A. That's correct, yes, that's the summer of

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2006.

COFFEY, Q.C.:

Q. Doctor, look, please, at Exhibit P-1139? These are Dr. Williams' notes, I believe, of a meeting of June 30th, 2006 regarding the start up of ER/PR testing. There are quite a number of individuals present there, you can see them listed. Your name heads the list. Doctor, I take it that this is perhaps the first meeting, formal meeting to discuss the idea of reinstituting ER/PR?

DR. DENIC:

A. It was done before in May when we were talking about recommendations, as well, but in a general sense I would take it as a more official.

COFFEY, Q.C.:

Q. Yes, official and kind of organized and this begins to deal with details?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, who, from your perspective, then, was responsible from this point in, then, in, quarterbacking, as it were, managing the

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reinstitution of ER/PR? I appreciate you would have been responsible in the chain of command, but who was responsible for -

DR. DENIC:

A. Dr. Elms and Dr. Makarla, they would be the ones to work on validation and optimization of the test. And in the background you would have the other people working towards fulfilment of the recommendations which were technical.

COFFEY, Q.C.:

Q. Doctor, had you ever consulted anyone about what are the appropriate qualifications for a pathologist who is to be the director or a director of immunohistochemistry in a tertiary care centre?

DR. DENIC:

A. Yes, I did.

COFFEY, Q.C.:

Q. And when did you do that and who?

DR. DENIC:

A. I did that in May.

COFFEY, Q.C.:

Q. May of?

DR. DENIC:

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A. 2006.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. I felt the need, knowing the background, that general pathologists would have in immunohistochemistry that this is not enough for somebody to run the lab of such nature, so I contacted Dr. Allan Gown himself. Before that I wrote the letter, I think that was before that or maybe immediately after that conversation to Dr. Williams asking to support the trip, educational trip for Dr. Elms and Dr. Makarla and he agreed for that. So I made a phone call to Dr. Allan Gown asking -
THE COMMISSIONER:
Q. Excuse me, Dr. Denic. Mr. Simmons, the problems with statements by Dr. Gown does not run to this -
MR. SIMMONS:
Q. No, Commissioner -
THE COMMISSIONER:
Q. - exchange, does it?
MR. SIMMONS:
Q. - that's in relation, I think, to the

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arranging for Dr. Elms to go to Dr. Gown's lab -
THE COMMISSIONER:
Q. All right.
MR. SIMMONS:
Q. - were there any considerations of that, so it's a separate matter.
THE COMMISSIONER:
Q. Thank you. Sorry, continue.
DR. DENIC:
A. Asking him can he take him. I was planning to send Dr. Elms, actually, to his lab and Dr. Makarla in some other labs in Canada, really. And asking him what would be a proper period of time that Dr. Elms could acquire a degree of knowledge that he can start the lab and run the lab, and I was told at the time, two to three weeks. And he also told me that the coordinator for the fellowship program down there is going to be in touch with me and let me know about the details when he can come and what would be the best period of time. So she e-mailed me and she told me that they decided that the two weeks would be sufficient and they designated the slot sometime the end of

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October, beginning of November. And then I passed out correspondence between them to Dr. Elms to follow that up. So eventually he went to Seattle in that period of time, as designated.
COFFEY, Q.C.:
Q. And so you contacted Dr. Gown because of your perception that he had some expertise in this area, he and his laboratory?
DR. DENIC:
A. I think he was running one of the biggest immunohistochemistry laboratory in North America.
COFFEY, Q.C.:
Q. And he advised you that a general pathologist, person with general pathology training or anatomical training could spend between two and three weeks in a laboratory such as Dr. Gown is involved with and be able to leave that and manage as a director an immunohistochemistry lab at a tertiary care centre?
DR. DENIC:
A. That's what I was advised by him.
COFFEY, Q.C.:

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Q. That was his advice, okay. Did you explore with him at the time as to what Doctor, a person like Dr. Makarla or Dr. Elms might be expected to learn in two or three weeks?
DR. DENIC:
A. Not really. Let me tell you, because immunohistochemistry and the lab director in immunohistochemistry it's really unknown in this part of the hemisphere and so I didn't know what to expect, really. And the whole purpose of him going is just to see what is the operation, what are the expectations, how they do the business and -
COFFEY, Q.C.:
Q. And then actually I take it you didn't expect him to actually learn a whole lot about the nitty gritty of immunohistochemistry in two to three weeks also learning -
DR. DENIC:
A. No, I don't think so that would be enough time. But since I told Dr. Allan Gown what are my goals and he said this is the period of time that is sufficient for him, so I didn't argue anything again.
COFFEY, Q.C.:

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Q. And you told him your goals were what?
DR. DENIC:
A. That somebody takes a role as a director immunohistochemistry and learn the basic that he can run the lab.
COFFEY, Q.C.:
Q. Exhibit P-2650? This is an e-mail, Doctor, from--well, it's an exchange of e-mails of July 7th and 10th between yourself and Dr. Mullen. You write on July 7th, "We had a meeting with the hospital executive and the new director of immunohistochemistry and the decision is to reopen the testing for ER/PR and HER2/neu in September, 2006. I am asking you for a favour, if you can still help us out until then. We do not anticipate more than five to six cases a week and only rare cases from the past, such as when the relatives from the deceased patients want the test to be repeated." I'm sorry. And on the 10th Dr. Mullen reply, "I've discussed your request with my colleagues. We have the technical capacity to continue the ER and PR and HER2/neu immunohistochemistry testing until September. I anticipate we will be able to

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extend that if required. Sincerely, Dr. Mullen." So, Doctor, as of July 7th there had been a decision taken to begin testing for ER/PR in St. John's as of September, '06?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And who, if anyone, would have been trained in ER/PR and in respect of, for example, being a director of immunohistochemistry by September of '06?
DR. DENIC:
A. Going now back through all of this, obviously it was unrealistic to start. But the reason that we're talking about September, if you remember, Dr. Ejeckam was even in June and even he managed to control ER/PR from before. So he was passing his expertise to Dr. Makarla and Dr. Elms, you know. So in terms of the procedure, as such, such as validation and optimization and the quality, that was my understanding just talking to Dr. Makarla and Dr. Ford Elms at the time that we probably going to be ready for September in terms of the procedure, as such. But entire endeavour

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that to train Dr. Elms is only--it's beyond just validation of the test.
THE COMMISSIONER:
Q. Mr. Coffey, wherever you can find a convenient spot, we'll take the morning break.
COFFEY, Q.C.:
Q. Thank you. This is convenient, actually, Commissioner.
THE COMMISSIONER:
Q. All right, we'll do that. In the meantime, counsel, I've indicated I need to hear from other counsel in respect of the matter relating to the claim for solicitor privilege, but I'm assuming, of course, that you all want to weigh in. Would you just let counsel know whether or not you believe you want to. Frankly, what we'll then do is break that much earlier in terms of the estimated time in the morning, let Dr. Denic have a longer lunch than the rest of us and I'll hear anybody who wants to weigh in on the subject. But what I'd like to do is just break the questioning a little earlier and deal with that application and then reconvene after lunch with the witness. So if you just let counsel know if

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you feel that it's a subject matter you want to make submissions on, then we'll judge it accordingly in terms of when we break. In the meantime, we'll take 15 minutes.
(RECESS)
THE COMMISSIONER:
Q. Please be seated.
COFFEY, Q.C.:
Q. Commissioner, on that matter of the June 19th meeting, I discussed the matter briefly with Mr. Browne and Mr. Simmons just before we reconvened and I'm going to suggest that we revisit that after lunch, because we'll have the lunch hour then to--revisit the whole issue about whether or not I'll pursue it at all, okay. So just -
THE COMMISSIONER:
Q. Sorry, Dr. Denic, there goes your longer lunch.
COFFEY, Q.C.:
Q. But just to let you--because you referred to bringing it up -
THE COMMISSIONER:
Q. Yes, thank you.
COFFEY, Q.C.:

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Q. - before lunch. Doctor, if I could show you Exhibit P--or have you shown Exhibit C-0233, please? Doctor, these are handwritten notes that were kept in relation to a meeting of July 12th, 2006. You attended, Dr. Laing, and a patient and maybe a patient's relative. I take it you did participate, Doctor, in certain meetings with patients yourself?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And what sorts of meetings, what sorts of patients were they, what classification would they fall into?

DR. DENIC:

A. They are patients that were misdiagnosed. Actually, they were diagnosed with basic cancer which actually turned to be DCIS. Patients that the size of the tumour wasn't as it was reported. They were diagnosed with the cancer but probably there's a differences in the size of the tumour.

COFFEY, Q.C.:

Q. So the size of the tumour was overestimated before?

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DR. DENIC:

A. Overestimated.

COFFEY, Q.C.:

Q. Overestimated originally?

DR. DENIC:

A. And the patients who retroconverted, really, from being positive to negative.

COFFEY, Q.C.:

Q. Did you participate in all those interviews that involved Eastern Health's patients, to your knowledge? Any -

DR. DENIC:

A. I was involved in three such disclosures, one in June of, I'm sorry, in summer of 2006, the second one was the summer of 2007 and the third one was a recent one, a month ago, so.

COFFEY, Q.C.:

Q. And, Doctor, the one again, of course I don't want to know anything about the patient's identity or anything like that, but the one in the summer of 2006, what sort of category did that meeting fall into, which sort of, was it a retroconverter, do you recall or a person who was -

DR. DENIC:

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A. I think it was a mixed of the patients, mixed in terms of what category they belonged to. One was they were misdiagnosed, one was -

COFFEY, Q.C.:

Q. And at this particular, you don't--do you recall the 2006 one, even just looking at these, can you tell what kind of--you had, you're quoted as saying you had DCIS, which is a precancerous lesion. "They will certainly develop a new cancer if we do not take it out." And "How could I have been treated differently?" So this is one of the--this is one where a person who was told originally she had invasive cancer and, in fact, had DCIS?

DR. DENIC:

A. That's right. I think it had been a couple of, but if this is the patient with the initials "ML", I believe so.

COFFEY, Q.C.:

Q. Okay. So -

DR. DENIC:

A. Yes, I believe that this could be her, you know, just without -

COFFEY, Q.C.:

Q. Okay. So, Doctor, now the organizing of these

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interviews or meetings with patients, who was responsible for doing the organizing for that?

DR. DENIC:

A. Ms. Nancy Parsons, actually, from the patient relationship, she would organize these meetings, of course, through the quality department.

COFFEY, Q.C.:

Q. And I take it your role, you were there because you're clinical chief?

DR. DENIC:

A. I'm a clinical chief.

COFFEY, Q.C.:

Q. At the time.

DR. DENIC:

A. And it's one of my roles to discuss any kind of pathology issue with a patient.

COFFEY, Q.C.:

Q. And, Doctor, and you were bringing with--because this involved a pathology matter, you were bringing pathology expertise to the meeting?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

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Q. The purpose of you being there?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Somebody such as Dr. Laing would be there as an oncologist to provide oncology expertise?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, and these patients that were in, originally told they were invasive and were finally concluded to be actually DCIS, do you recall how many there were?
DR. DENIC:
A. Overall I think at the time, four.
COFFEY, Q.C.:
Q. Four. And have there been any since, do you know?
DR. DENIC:
A. It's been a few cases that diagnosis changed from or DCIS or from benign lesions to other since that time when we reported four.
COFFEY, Q.C.:
Q. To there have been cases since then?
DR. DENIC:

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A. Since then.
COFFEY, Q.C.:
Q. Within Eastern Health cases?
DR. DENIC:
A. I think from outside.
COFFEY, Q.C.:
Q. Yes, I was going to say because -
DR. DENIC:
A. Okay, from outside. No, from the Eastern Health I think it is the four cases.
COFFEY, Q.C.:
Q. And but since, certainly since December of 2006 when you had the media briefing since then, there had been some cases outside Eastern Health?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. That involved people who were originally diagnosed with invasive carcinoma and upon review it has been judged to be DCIS?
DR. DENIC:
A. That's correct, or have been diagnosed with invasive carcinoma and turned out to be a completely benign lesion.

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COFFEY, Q.C.:
Q. Okay. And the dealing with those patients would have been the responsibility of the other health authorities?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, do you know if in relation to these DCIS cases, I'll call them, as well as the retroconverters, how many retroconverters were there, do you know?
DR. DENIC:
A. I think four.
COFFEY, Q.C.:
Q. Four. Have there been any retroconverters since December of '06?
DR. DENIC:
A. I don't believe so, Mr. Coffey, but I cannot 100 percent be sure.
COFFEY, Q.C.:
Q. Okay. Who would have that information?
DR. DENIC:
A. That information would be garnered from the quality and risk management. They were the keepers of all the results, you know, and they

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would work in cooperation with the Cancer Centre and -
COFFEY, Q.C.:
Q. Now, Doctor, as you were involved directly in or certainly had knowledge of these eight Eastern Health cases for DCIS and for retroconverters, do you know if there was any incident report or adverse event report ever filed in relation to those eight cases?
DR. DENIC:
A. Not that I know of.
COFFEY, Q.C.:
Q. And as these DCIS cases and retroconverters cases involve pathology, that it related to -
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. - mistakes or errors or whatever term one wants to--and interpretation -
DR. DENIC:
A. Misinterpretation is the right word, really.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. Because what we are doing, we are interpreting

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tissue.
COFFEY, Q.C.:
Q. Changed results, okay. In relation to that, is it your understanding that if, for example, there was to be, this afternoon, a changed result such as could involve a treatment change, would there be an adverse event filed, do you think?
DR. DENIC:
A. Would there be -
COFFEY, Q.C.:
Q. If there was a DCIS case this afternoon came to your attention that happened three weeks ago, would you file an adverse event?
DR. DENIC:
A. Would I file it?
COFFEY, Q.C.:
Q. Yes, or would you cause one file it?
DR. DENIC:
A. I would file it, and I would inform the quality and risk management right away.
COFFEY, Q.C.:
Q. So as the clinical chief, at least now, you would see it as part of your duties, if it came to your attention?

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DR. DENIC:
A. That's correct. Anything that comes of clinical significance that can affect patient care would be filed with a incident report and reported to the risk and quality management.
COFFEY, Q.C.:
Q. Doctor, do you know, can you tell the Commissioner then why, in terms of the entire involvement in this ER/PR matter, I've only asked you about the four DCIS and the four retroconverters, but there were no incident reports filed for anyone else, any of the other cases, were there, all the conversions?
DR. DENIC:
A. You mean filed by the pathology department?
COFFEY, Q.C.:
Q. Yes, pathology department.
THE COMMISSIONER:
Q. So is your question really was, was there not one done earlier?
COFFEY, Q.C.:
Q. Yes, done earlier and since, for that matter.
THE COMMISSIONER:
Q. For the -
COFFEY, Q.C.:

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Q. For any of these cases.
THE COMMISSIONER:
Q. - the four DCIS that Mr. Coffey has asked you about.
COFFEY, Q.C.:
Q. The four DCIS, the four retroconverters and all the conversions.
DR. DENIC:
A. I mean, this is something that was identified through this search, and these patient, while we had looking at diagnosis and changed their diagnosis, and filed the diagnosis, the diagnosis had to go first to the clinician, just to see what are the implications and ramifications, and the quality management program was involved from the very beginning. So was there paperwork? There was no paperwork except for the report that we would issue and that report would be in the hands of the quality and risk management department too, so -
THE COMMISSIONER:
Q. So your answer is that because of--because the ones that we are talking about now that became known out of the process of retesting were

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all--were known to the quality and risk management department because they were involved in the retesting, you would not have done it?
DR. DENIC:
A. No, because they had firsthand knowledge that this is done, and they might have filed it themselves, so I don't know that.
COFFEY, Q.C.:
Q. Okay, Doctor, you do understand that Eastern Health and its predecessor, Health Care Corporation, and Eastern Health have adverse event policies?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And those policies required or require that in such cases that a patient be told about it?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And as well, that if known, the patient be told about the reasons?
DR. DENIC:
A. That's correct.

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COFFEY, Q.C.:
Q. The reason or reasons for the event having occurred?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. Okay. Exhibit C-0232, please. Doctor, these are notes of a meeting of October 5th, 2006. You're listed as being in attendance, as is Dr. Laing and Ms. Parsons, Nancy Parsons. There's a gentleman there and you express, you're noted as having expressed condolences to him, and you ask him is he familiar with estrogen and progesterone receptors and you're noted--he's noted to respond yes, and then you're noted to have said "in 1999, your wife was 10 to 15 percent positive tumour cells," and it goes on from there, and I take it that this gentleman's wife, by the point October 5th, 2006, was deceased?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. This meeting occurred at whose request? Was it his request?

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DR. DENIC:
A. I'm not sure about that.
COFFEY, Q.C.:
Q. Okay, and at the bottom of the page, first page, the gentleman is noted as saying "I have no problem if it is the testing that is more advanced than it was. I know there is more knowledge now than there was in 1999. The news items that I have read suggest that there may have been negligence." And then you're noted here to have responded by saying "there's no black and white answers in medicine. The old method, biochemical assay, said if you have anything less than 30 percent, it is considered negative. I am quite convinced her testing was accurately done for that era." And he's noted to have said "the new results are done through a different method?" He's asking a question, and you responded saying "the antibodies now are more sensitive. The results are done by the human eye, so I can say 20 percent positive, another pathology might say like 25 percent positive." I apologize, yes. "There is also the issue of weak and strong staining," and then he's noted to have said "I just want to satisfy myself that things were done right. I understand protocol has changed as time progresses. We had complete faith in our doctors and the treatment that was given." And you're noted to have said "in this particular case, I believe everything appropriate was done." And then Dr. Laing is quoted as saying "30 percent was our cut off back then," and another thing is, and he goes on to talk about a medical condition the patient had had and was a reason not to give Tamoxifen, and "when would the Tamoxifen have been introduced?" the gentleman has asked, and Dr. Laing responds "after her chemo. Even knowing what we know now, Herceptin, which she was given, would still be appropriate," and it goes on about her treatment, and she's noted "it is unlikely"--she had been told, "it is unlikely the Tamoxifen would have had any benefit," she's telling the patient's relative, and "her chemotherapy would also be different today. We treated her the same as all the other patients at that time."
Doctor, this gentleman, in the meeting

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with you, look at the first page and the comment attributed to it, "I have no problem"--he says "I have read--the news items that I have read, suggest there may have been negligence" and this is the October 5th, 2006. Now Doctor, by that point in time, you were certainly aware of or had been made aware of Dr. Banerjee's observations from October.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And in fact, were aware of Ms. Wegrynowski's observations in the fall of 2005 as well?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. There's no suggestion here, or there's no suggestion in the notes here that you advised this gentleman that there were in fact problems, technical problems that had caused this, interpretation problems that potentially caused the error. I gather there was a conversion here, in the sense -
DR. DENIC:
A. Not the conversion.

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COFFEY, Q.C.:
Q. It's not a conversion?
DR. DENIC:
A. I mean, she was 10 to 15 percent at that time, so she was reported positive. This is not that she was negative estrogen, so 10 to 15 percent of the cells were picked up at that time, based on technology that we used and whichever we used it.
COFFEY, Q.C.:
Q. Was she retested, her sample?
DR. DENIC:
A. I don't know what was her test, so I wouldn't say that -
COFFEY, Q.C.:
Q. Well, here's--we'll go back, we'll just go back, because the notes themselves actually, in the first page, you know--you're telling the gentleman, "In '99 and on, your wife was 10 to 15 percent positive tumour cells," and goes on about that. "Using the equipment we had at the time"--I'll read it out. "In 1999, your wife was 10 to 15 percent positive tumours cells, in 1999. We were using the equipment we had at the time and the medical

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literature available. 10 to 15 percent was considered negative. Last year, your wife's sample was retested at Mount Sinai. The antibodies we use now are more sensitive. Her retesting shows she was 50 percent positive for estrogen. I will say that if she had been treated as 15 percent positive today, she would have been treated with Tamoxifen. As you know, her disease was not good and had already spread to the lymph nodes," and then the quote I referred to earlier appears, "I have no problem," the gentleman says.

So Doctor, this is a patient, a deceased patient whose tissue sample had been originally reported as 10 to 15 in 1999. Now, on retest, was 50 and the gentleman is asking about issues of negligence. Doctor, if we read all the way through the notes here, at least the notes there of that meeting, there's no indication, that I can see anyway, that this gentleman was told anything about the problems or what had been found, and why is that? Why wouldn't you tell an individual who's asking about the cause or causes?
DR. DENIC:

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A. I mean, he's asking about the negligence and there's no negligence in this done. I mean, that was something that he come across reading through the newspaper that it was negligence as well. So that wasn't the issue. The issue why these patients were here to be told the truth, the results and what are the meanings of the results and to explain. I didn't think that this was the venue to talk about the gentleman about fixation, what might have been the problem, internal controls might have been a problem, that for the various reasons, even today, are probably going to discuss, I am not quite certain what are the factors that could influence, but since 10 to 15 percent of the cells were identified as positive mean the test worked under those conditions in 1999, I believe that this case was.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. So there is nothing that I believe was a negligence, was wrong done, and while we have a 50 percent today for the estrogen receptor, this wasn't my concern, because as we

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discussed before, even today, you can go in the best lab and their own results, they can retest, they're going to get a different result on every single retest. So we are talking about '98 procedures, antibodies, and detection systems. Whatever was done, I think was done right for the patient, so there was nothing here to do and the purpose of this was not to talk to the patients about 52 recommendations, which I think was very inappropriate.
COFFEY, Q.C.:
Q. Doctor, would a person who was originally reported as 10 to 15 and on retest was reported as 50, and if it had--certainly if it had clinical, potential clinical ramifications for the patient, would that be an adverse event?
DR. DENIC:
A. You're talking about two different -
COFFEY, Q.C.:
Q. Wouldn't -
DR. DENIC:
A. Mr. Coffey, I think we are talking about two different time. We are talking about '98 and

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we are trying to bring the results from '98 to the time of 2000, and I don't think so, that that's the right thing to do really. Comparing one time of practice of the medicine.

COFFEY, Q.C.:

Q. So Doctor, on that point, so you, your own view, the conversions that occurred on retest, the conversions, are not adverse events?

DR. DENIC:

A. This is a result of change.

COFFEY, Q.C.:

Q. I'm just asking, on the conversions that occurred on retest at Mount Sinai, those that were conversions, would that fall into the category of being adverse events?

DR. DENIC:

A. They would if they--I really cannot answer this because we are talking about completely different times, different technology. Today, I would say yes. If today I have the patients as such, I would say yes, she was negative and we retest and she was not treated properly today, and the new results come, I would say yes. But we are now trying to over breach ten

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years period of time. So I really don't have opinion on that.

COFFEY, Q.C.:

Q. Okay, so you, for you, in your current capacity, whether or not you're still--haven't made up your mind about whether or not the conversions that occurred here on the retest, the whole of the retest process, you're still not satisfied that they would fall into the category of being an adverse event?

DR. DENIC:

A. I never thought about it, Mr. Coffey, and -

COFFEY, Q.C.:

Q. The reason I ask that is this, Doctor, is the adverse event policy has certain requirements associated with it, and one of them is, as you just indicated, that the patient be told the reason or reasons, okay.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. So if, in your mind, you treat it as an adverse event, then there are responsibilities, as clinical chief, that are associated with that, aren't there?

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DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. That's the purpose in you being at the meeting.

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. So as you sit here now, you still haven't made up your mind about whether or not if you were to meet with a patient tomorrow, in relation to this matter, whether or not you would explain to the patient the reasons for test failure or at least tell them what you knew about it?

DR. DENIC:

A. And I believe I said to this patient what I believe in this particular instance that went wrong.

COFFEY, Q.C.:

Q. Well, Doctor, if we could bring up, please, P-0046? This is Dr. Banerjee's report, and here on page four of the exhibit, there's a heading, "conclusions about the reasons for test failure," okay. So I take it then that

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you believed at the time, or do you even believe to this point, to this day, that there was test failure?

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. Okay. So if there was a failure occurred, where did it occur?

DR. DENIC:

A. Excuse me, is that your question?

COFFEY, Q.C.:

Q. If there is failure--you said, you just told us that you think -

DR. DENIC:

A. Oh, okay.

COFFEY, Q.C.:

Q. - test failure occurred, and I'm asking you where did the failure occur?

THE COMMISSIONER:

Q. I understand you'll be asking the witness his opinion as -

COFFEY, Q.C.:

Q. Yes, his opinion, oh yes, yeah. It's his, yes.

THE COMMISSIONER:

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Q. Not what--necessarily what others might have -
COFFEY, Q.C.:
Q. Oh no, you're -
DR. DENIC:
A. In terms of the test, as such, where I believe it may have occurred, I don't think it's a single factor that can define. There are multiple factors involved, and I believe that one of the factors could be the factor of fixation, but not to any great extent, and I can elaborate, if you want me, now or later and substantiate that. The other step that I think is the step of really processing, which is antigen retrieval. And the third part in-- and this is my experience that I still believe that that piece of equipment could have had certain failure.
COFFEY, Q.C.:
Q. So you're talking about the particular machine or -
DR. DENIC:
A. Just particular--I'm not talking about the system, DAKO system is completely fine, because a lot of people do it, but that particular machine.

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COFFEY, Q.C.:
Q. And what is it about that machine?
DR. DENIC:
A. In my experience, just looking through these cases, I encountered the cases where estrogen was reported zero, progesterone was reported 100. On retest, estrogen turned into the over 90, but we know it's now 100 that we usually now report now over 90, but it was 100, and it was lightning like a Christmas tree. It was progesterone still stayed 100. I went to the requisition. I look into the piece of the tissue, the size of the tissue, tried to estimate the time that this all could have been processed and left in formalin and everything else, and came to the conclusion that this is between 24 to 48 hours on that one, just estimate. So pre-analytical phase was out of the question. You have the progesterone nicely. The tissue on H & E stains looked well fixed, so the fixation wasn't the problem. So what's left is that the antibody never get in touch with the tissue. So where are we now with that? A few reason could be. There was no antibodies, and

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the other one is that the machine itself gives a problem, random problem.
But now going back on the latter one, in May of this year, knowing that I'm going to lose breast pathologist, I contacted the pathologist from St. John, New Brunswick asking her whether she would like to take on a job and come down and she has a great interest in breast pathology, and in our conversation, like "by the way, I heard before from Dr. Cook you had a problem with your DAKO machine." She said, "yes." I said "what was the problem?" She said "it was a problem with the pump. The pump wouldn't express the antibody or in enough concentration or wouldn't express it at all." So this is the conversation that I had, and then when Dr. Nik Makretsov came on staff, I think I mentioned that before to this Court, that in their lab in United Kingdom, Cambridge, because they are working on biomarkers, while they were not using DAKO machine, they were using a different technology for staining, they realized that there's intermittent, random drop of the staining in certain slides, but they realized

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that because they were producing like hundreds of the slides in a lot of trays, so when you look in the tray, so you can see brown, brown, there's no stain, and then go a few more and said no stain. So they realized and investigated that issue, and he told me that it was a problem with random clog up of the system that expresses the antibody. So looking again, coming back to the case, doing any kind of analysis that I could do, of course, very limited. That's why I said you cannot rule out failure of that particular piece of equipment.
I've been a forensic pathologist for years and working on traffic accidents. When a traffic accident occurs, investigators want to examine the vehicle first, and unfortunately, that piece of instrument wasn't there, and I really don't know where it is. But it is not something that--nobody put it in equation here and consider it, and I think it could have played the role in certain number of cases. I'm not saying that all cases are related to that.
COFFEY, Q.C.:

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Q. And Doctor, was there any quality assurance-- what quality assurance measures existed before August 2005 in that laboratory, to your knowledge, that would or could have detected problems, mechanical problems with the machine?
DR. DENIC:
A. To the best of my knowledge, what I learned in the aftermath, that they didn't have.
COFFEY, Q.C.:
Q. They didn't have any, did they?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. And in fact, to your knowledge, you learned that when? In your clinical chief days, early on in your clinical chief days?
DR. DENIC:
A. That's right, and through the reports as such.
COFFEY, Q.C.:
Q. So you knew that quality assurance, in pathology anyway, had been lacking?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:

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Q. And Doctor, one of the purposes of utilizing internal controls in ER/PR stains, in fact, is to pick up just that sort of problem, isn't it? Because if the internal control hasn't stained on the patient's slide, that ER slide that was zero, okay, and if the internal control tissue hasn't stained, you understand, certainly now, that one should perhaps then question whether you should report the slide at all? Isn't that so?
DR. DENIC:
A. It is now, Mr. Coffey, and but again, that's what we know now.
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. And we learned certain lessons, of course, throughout this, but what we knew then about internal controls as such is--the thing is, certain percentages of patients, I think, range from 10 to 20 percent of the patients which really is a large number, especially when you look and work one or two cases a month. So -
COFFEY, Q.C.:

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Q. But you understand, Doctor, that many of your colleagues in fact, you understand many of them weren't looking for internal controls?
DR. DENIC:
A. Yes, I do understand that.
COFFEY, Q.C.:
Q. So if you don't know to look for them, then you're unlikely to see them.
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. So here, Doctor, what I wanted to ask you about in terms of this now is this, then in dealing with this particular patient at C-0232--I'm sorry, patient's relative at C-0232, and for that matter, any other relative or patient that you dealt with face to face, where someone such as this person, in effect, just simply wanted to know what happened, what you knew about what happened, why not just simply tell him or her that you knew there'd been no quality assurance measures, that you knew there'd been a problem identified with fixation, and whether you agree that it contributed as much as Dr. Banerjee suggested

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it did or not, that was the outside consultant's view. Why not simply tell people that it was a fixation problem, why not simply tell people that it's been identified that we were not seeing certain things, internal controls, that a number of my colleagues were not identifying--why not simply tell the people who were inquiring, and who arguably had suffered an adverse event, what you knew?
DR. DENIC:
A. I have no problem saying--Mr. Coffey, if you can see in some of this, I said error was made like in the diagnosis, I was--pathologist made the error. So it's --
COFFEY, Q.C.:
Q. I'm not asking about diagnosis.
DR. DENIC:
A. No, no, but just to tell that I was always open to this patient. What has happened to this particular patient was internal control-- I can't tell you because I don't remember reviewing the slide on this particular patient saying she was reported 10 to 15 percent. If this particular patient --
COFFEY, Q.C.:

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Q. Doctor --
DR. DENIC:
A. Was done right, why would I go into the full motion and these people are emotional, they want to know what does this mean for me, and just to carry a bit of treatment, in effect, to talk to them about we didn't have quality control in our lab, but when I look your tissue, you're done right. Somehow it's --
COFFEY, Q.C.:
Q. So, Doctor, being full and open, frank and open with patients doesn't involve telling them what you know, in effect, fully what you know about this? I mean, is that--that's the case here, isn't it?
DR. DENIC:
A. But in this particular case, I told you what I --
COFFEY, Q.C.:
Q. This one or other ones, because you --
DR. DENIC:
A. Yes, that's right.
MR. BROWNE:
Q. Commissioner, I think the witness is attempting to explain the rationale at the

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time.
COFFEY, Q.C.:
Q. This particular one, but I'm asking about further as well, other --
THE COMMISSIONER:
Q. Just a minute now. Now I'm not sure what the question is. Let's--my understanding of what Dr. Denic was saying was he was explaining in terms of this patient. Your question was in terms of wider?
COFFEY, Q.C.:
Q. Yes.
THE COMMISSIONER:
Q. Okay. So your response was not a response to the question he had raised.
COFFEY, Q.C.:
Q. That's what I --
THE COMMISSIONER:
Q. Let's make sure I understand.
COFFEY, Q.C.:
Q. Sure, Commissioner, I apologize if there's a misunderstanding.
THE COMMISSIONER:
Q. Because at the end, I'm the one that has to understanding.

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COFFEY, Q.C.:
Q. Yes.
THE COMMISSIONER:
Q. I'm taking from what Dr. Denic is saying is that he is saying in other cases he would go into detail, but in this case he was not satisfied that that was necessary.
DR. DENIC:
A. That's correct, in this particular case.
THE COMMISSIONER:
Q. For the reason that you have already explained.
DR. DENIC:
A. That's correct.
THE COMMISSIONER:
Q. Next question, Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you. If we could look, please, at Exhibit --
THE COMMISSIONER:
Q. If you're moving on, Mr. Coffey, there's one point that I wanted to make sure I was crystal clear of. The term "conversion" and the term "change" have been used by both you and by Mr. Coffey, Dr. Denic, and I have discovered that

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people have different views of what they mean, so can you tell me what conversion means to you and what change means to you in this context?
DR. DENIC:
A. Conversion for me would be that in terms of the estrogen and progesterone receptors --
THE COMMISSIONER:
Q. Uh-hm.
DR. DENIC:
A. That if somebody has zero and turns into any number on retesting. This particular patient has positive value at that time, but she unfortunately fell into category of 30 percent cutoff that was the part of our cutoff.
THE COMMISSIONER:
Q. So when you are talking conversion, you are looking at it from the perspective of the pathologist who measures in terms of whether or not there is any evidence of the presence of estrogen in the sample?
DR. DENIC:
A. That's correct.
THE COMMISSIONER:
Q. And if it's--there is any estrogen present,

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then it becomes a change in your view because the numbers of the percentage might change, but you would not see it as a conversion?

DR. DENIC:

A. No.

THE COMMISSIONER:

Q. Because from your perspective, there was an amount of estrogen showing up at the time?

DR. DENIC:

A. That's correct.

THE COMMISSIONER:

Q. Whereas from the perspective of perhaps an oncologist, this might be seen as being a conversion because it would have gone from what they considered negative to what was positive?

DR. DENIC:

A. That's completely correct.

THE COMMISSIONER:

Q. All right, then, and I suppose a change can be all of the above, but a change to you would be something that the numbers changed?

DR. DENIC:

A. The numbers change, you know, and what they mean for the oncologist and what I mean today,

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we all know they mean different in certain period of time.

THE COMMISSIONER:

Q. Sorry, Mr. Coffey, I interrupted again.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Exhibit P-1170. Doctor, this is a letter from Dr. Carter of August 10, 2006, to yourself as clinical chief. She writes, "In order to implement the fixation policy enclosed, the following actions will have to be considered", and she lists a number of them. The third of them is, "In house and outside clinics must be made aware of the fixation policy and adjust their practice to reflect these changes". See that?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. "In house and outside clinics must be made aware of laboratory hours and processing schedules so that they may adjust their practices". Who are these outside clinics?

DR. DENIC:

A. Some small procedure could be done in doctor's offices. Clinics of dermatology clinics,

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sometimes they take lumps and bumps, you know, they excise the tissue.

COFFEY, Q.C.:

Q. Doctor --

DR. DENIC:

A. But they don't do breast.

COFFEY, Q.C.:

Q. Here, this is not--I stand to be corrected, but I don't see the word breast anywhere there.

DR. DENIC:

A. She's talking in general, but just for clarification, they don't do any breast procedures.

COFFEY, Q.C.:

Q. So, Doctor, then I take it then in the aftermath of this, this fixation policy was implemented within Eastern Health?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. I guess we should look at the policy itself, look at the second page, in fact, of the exhibit, there it is. So it's St. John's Hospitals of Eastern Health, limited to here.

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Doctor, the pathology lab performs services for the entire province, pathology lab at the General Hospital. Why then was the fixation policy not distributed to the other hospitals that were utilizing your services until May 31st, 2007?

DR. DENIC:

A. It's a good question and my answer, I don't know. For the reason being that a lot of things that I have and everybody else on our daily plate, to think first about ourselves and stabilize our systems to working to the policies and procedures, and as you see, I eventually did share those ones. You know, it is difficult to expect even from me to run an entire province and their labs, but before this was implemented as such, if you remember from the teleconference meeting that we had in November, I invited them to also come to our lab to discuss the issues, to see what's been done. So, you know, the cooperation has to go both ways rather than to expect that I'm going to be supplying entire information for the entire province, and in most instances we are trying to keep our head above the water.

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COFFEY, Q.C.:
Q. I take it then that when this became an issue involving Minister of Health in May of '07 and his understanding or misunderstanding as to who was doing what with ER/PR within the province, that within about a week of that certainly, within days if not a week, anyway, there's a May 24th teleconference, I believe, and then on May 31st, the distribution of that fixation policy, and other policies?
DR. DENIC:
A. That's correct. Then they get the other policies --
COFFEY, Q.C.:
Q. Within a week of that happening roughly, the Minister being involved --
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. The policy got distributed?
DR. DENIC:
A. That's correct, but--because in the meantime, we also have more policy to share.
COFFEY, Q.C.:
Q. Doctor, if we could look at, please, P-2464,

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and I refer you to this, Doctor, just--this is a meeting of August, minutes of a meeting of August 18, 2006, laboratory medicine program. Just simply to give the Commissioner some sense of the status of the reimplementation process, if you'll look at paragraph five, ER/PR receptors, "Terry updated on the recent status of ER/PR testing" and the spreadsheet of June 30th, recommendations of Trish and Dr. Banerjee are contained there. "Terry also informed that Dr. Carter and Catherine Parnell are in place for the QA program and have had meetings with Janet Laidly from QI. Educational sessions are booked for September for Dr. Carter, and all agreed that by September 25th the laboratory leadership team should be in a position to recommend the reinstitution of this service. Terry informed that the lab technical staff have completed three UK proficiency tests and have scored very high". So at that time, this is mid August, it was thought maybe late September. Doctor, why didn't it happen then, why wasn't --
DR. DENIC:

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A. Obviously, the test was working as such, but at this point Dr. Elms still hasn't completed his sabbatical at Allan Gown's office, so we were waiting for him to come back as well and just to see--again to go through check and balances and to see whether we are ready.
COFFEY, Q.C.:
Q. Exhibit P-2653, please. Doctor, this is an e-mail from Dr. Carter to a number of individuals, including yourself. She says, "Very shortly we will begin the process of building policy and procedure manuals. This is the process envisaged for disbursement of P & P's", and there's a listing there.
DR. DENIC:
A. Policies and procedures.
COFFEY, Q.C.:
Q. Oh, yes, I appreciate it's policies and procedures. So this then would be late August 2006 is when this process if really finally getting underway in the sense of things will be distributed?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:

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Q. And input would be sought, and this is the process that it will take, it's actually written out?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Exhibit P-2389. Doctor, this is a memo to all pathologists from yourself. That's all pathologists within Eastern Health, St. John's Hospitals of Eastern Health, August 29th, 2006, subspecialization?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And you write, "As part of our future practice and development, with the goal of delivering the highest quality pathology patient service in an efficient cost-effective manner, we are looking at developing subspecialty groups in specific areas of anatomical pathology", and you go on then to talk about that process.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. So is this the first formal notification by

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yourself and request for expressions of interest?
DR. DENIC:
A. That's correct. The first discussion, as you know, started in March of 2006, that I brought it up at a meeting. I think we already had that --
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. And this is just a follow-up from that meeting.
COFFEY, Q.C.:
Q. And you, in fact, note what subspecialty pathologists should be?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. A list of things that--characteristics they should have and skills they should have. Doctor, that list of characteristics or skills that a subspecialty pathologist should exhibit, did you obtain that from anywhere?
DR. DENIC:
A. That list was obtained from the outside source

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which would be one of the journals. I think, from the--submissions of the Director in Anatomical Pathology. That's American Directors of--Anatomical Pathology Directors.
COFFEY, Q.C.:
Q. So in terms of what, I won't ask you to remember it right off the top of your head, but if you could identify--locate that particular journal.
DR. DENIC:
A. If I can locate it.
COFFEY, Q.C.:
Q. Locate that --
DR. DENIC:
A. I will try.
COFFEY, Q.C.:
Q. Pass that on to Mr. Browne, and he can pass it on to the Commission, okay.
DR. DENIC:
A. Okay, sure.
COFFEY, Q.C.:
Q. Thank you.
DR. DENIC:
A. There might be some changes, but --
COFFEY, Q.C.:

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Q. And I appreciate that.
COFFEY, Q.C.:
Q. But using it as a template.
COFFEY, Q.C.:
Q. That's what I'm asking about. Then the list on the second page of this, the list of subspecialties that you envisaged at the time is set out there, the goal.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. There are 16 of them, and breast pathology is the third one on the list. Doctor, what then happened then as we get into the fall of 2006, what do you recall?
DR. DENIC:
A. In terms of?
COFFEY, Q.C.:
Q. ER/PR.
DR. DENIC:
A. In terms of ER/PR I think we are getting now in November.
COFFEY, Q.C.:
Q. Well, here, if we could look at -
DR. DENIC:

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A. September -
COFFEY, Q.C.:
Q. - P-0420, this may assist you, Doctor, it's an actual e-mail, P-0420. Doctor, this is an e-mail from, well, there's a number of e-mails, but here it involved another doctor, actually, and I gather, the potential recruitment of another physician.
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. But the top e-mail, September 13th, 2006 and you write to Denise Dunn saying "Thanks, Denise. Did you contact Dr. Williams? You can cancel the 18th of September previously scheduled for our presentation since we do not have the data and some of the presenters will be away. The presentation has to be rescheduled for the next month. Let me know what Dr. Williams thinks about it." Signed, "Nash." So is this the ER/PR presentation that finally -
DR. DENIC:
A. That's the ER/PR presentation that -
COFFEY, Q.C.:

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Q. That occurred in November?
DR. DENIC:
A. - eventually being held in November.
COFFEY, Q.C.:
Q. And the numbers here at the time--I'm sorry, the data, not the numbers, the data, "since we do not have the data", what data were you looking for at the time?
DR. DENIC:
A. I was at least that we're going to have data how many patients been affected through this process, at least that we can tell -
COFFEY, Q.C.:
Q. And you were looking--who was going to provide that to you?
DR. DENIC:
A. Ms. Heather Predham.
COFFEY, Q.C.:
Q. Exhibit P-1173. This is an e-mail from Denise Dunn, September 13th to yourself. The subject here is ER/PR presentation. She says, "I spoke to Dr. Williams, explained the data won't be ready for presentation until October. He said okay, but he's planning to be out of the province for October." Signed, "Denise."

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So, Doctor, when do you recall the data was actually first available?
DR. DENIC:
A. I received the data sometime in November.
COFFEY, Q.C.:
Q. Okay. And you received it from whom?
DR. DENIC:
A. From Ms. Heather Predham.
COFFEY, Q.C.:
Q. And was that the data that eventually was used for the presentation to your fellow clinicians and -
DR. DENIC:
A. Just a portion, just the main figure, which was the number of patients who were recommended for the treatment change.
COFFEY, Q.C.:
Q. So were eventually used. Which data did you receive, I'll just ask you that?
DR. DENIC:
A. At some point I received the data that maybe the same or the similar one that was presented to the minister in November.
COFFEY, Q.C.:
Q. Okay. So this is a summary, as it were, of

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the various classes or categories of patients?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And were you involved in the preparation of that at all, the actual data?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Doctor, what was your understanding about how firm or reliable the data was that you were being given? You got this from Ms. Predham, I take it, am I right?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay. What was your understanding about how reliable or firm the data was?
DR. DENIC:
A. I mean, it's difficult to say. I'll tell you what was my approach, actually, when we--I think from the last, one of the last meetings in May and everything else that we went on a summer break, if you will, but it wasn't a break at all, without any big actions, that

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Ms. Predham was trying, actually, to find somebody who was going to do any kind of statistical analysis. And in a few instances I did inquire about it, did that happen, did the statistician get involved so that we can get anything meaningful, as such. So I didn't take anything differently, I received the data and I was thinking that whatever she provided me, that she provided me to the best of her knowledge and whatever to the best of what she had.
COFFEY, Q.C.:
Q. Were you ever given or expressed to you any concerns or caveats about it or reservations?
DR. DENIC:
A. I don't believe so, you know.
COFFEY, Q.C.:
Q. Like, here it is, Doctor, but, you know, I'm not certain, you don't recall being warned or cautioned about that?
DR. DENIC:
A. I mean, myself, I was always thinking, you know, just it's a lot of numbers down there, you know, just are they all these numbers, what do they mean. And, as I said, they were

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not statistically processed because the entire endeavour that clinicians went through is to try to identify the patients that can be helped. So really, the number for me at the time and that really even told your colleagues at the time was the number of this 117, I would say. I don't know what is that 104 that we said or 117 at the meeting, but it's about that.

COFFEY, Q.C.:

Q. Doctor, you had anticipated, then, going into the summer of 2006 that there would be a statistical analysis done of some sort?

DR. DENIC:

A. That was my understanding.

COFFEY, Q.C.:

Q. Did you ever see any such statistical analysis?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Have you ever asked about whether one was done?

DR. DENIC:

A. I did.

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COFFEY, Q.C.:

Q. Who did you ask, when, and what were you told?

DR. DENIC:

A. Ms. Heather Predham. And -

COFFEY, Q.C.:

Q. When was that?

DR. DENIC:

A. - I was told that they were trying to recruit somebody and I think she had even name at the time, and for whatever reason that didn't go through.

COFFEY, Q.C.:

Q. And when was this?

DR. DENIC:

A. This is in the period from May to the time that I received the data.

COFFEY, Q.C.:

Q. In November of 2006?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Exhibit P-2654, please? Doctor, these are minutes of a laboratory medicine program meeting, September 15th, 2006. You are present, as is Dr. Howell and Mr. Gulliver.

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Page 2, paragraph 5, ER/PR receptors. And it's noted here "Dr. Denic indicated that he will arrange a meeting with Dr. Williams, Mr. Tilley, etcetera, to recommend the reinstitution of ER/PR testing in our pathology lab. Dr. Denic and Heather Predham are putting together statistics for the meeting. Dr. Denic indicated that the technical piece of the testing is fine, however he still needs to get final agreement from the pathologists." So does that accurately reflect the state of affairs in the middle of September?

DR. DENIC:

A. Difficult to recall. I know this meeting never happened between Mr. Tilley and myself and Williams. I don't recall such meeting that happened. Technical piece was obviously right and I think that was mostly based on proficiency testing coming from the UK was telling us that we are doing a good job with ER/PR. And as it says here that we are waiting for final agreement from the pathologists, mostly likely meaning pathologists of the group or I was thinking at

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that time that would have been Dr. Bev Carter.

COFFEY, Q.C.:

Q. Now, there's a reference there to you and Ms. Predham putting together statistics for the meeting, it was anticipated. Were you actually involved in putting together statistics yourself?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Okay. So that would be -

DR. DENIC:

A. I don't know exactly what it means there.

COFFEY, Q.C.:

Q. It's not an accurate description of what was going on?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Exhibit P-2484? Now, Doctor, this is an e-mail from, well, here it's from Sharon Hopkins, who is described as the administrative officer for the VP, vice president of medical. By this point in time, and this is copied to George Tilley and Oscar

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Howell, so Dr. Howell has taken over from Dr. Williams, and sent to yourself and Ms. Predham. And it says, "A note from Dr. Robert Williams. I have been briefing Dr."--sorry, "Mr. Peter Dawe, the Canadian Cancer Society, on a regular basis for ER/PR status. I advised him that as soon as we make a decision to retest here we will advise him and bring him on the status of the retesting and approach for the future. He has been asked by the Canadian Cancer Society to work on their behalf on any national standard setting in reference to laboratory approach that we have lobbied for nationally. I feel this is very important to keep Mr. Dawe in the loop after we have met and made decisions and have information to share with Mr. Dawe. Thanks, Bob." So, Doctor, I take it you were aware then or would have the understanding at the time that Mr. Dawe would be so involved, as described?

DR. DENIC:

A. To a certain point, yes.

COFFEY, Q.C.:

Q. Yes, oh, yes. Were you ever made aware at any

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point in 2006 that Mr. Dawe was not going to be so involved, were you told that -

DR. DENIC:

A. No.

THE COMMISSIONER:

Q. Wherever you can find a convenient spot, Mr. Coffey, we'll break for lunch.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Exhibit P-2328, please? Doctor, these are the minutes of a pathology quality management committee for October 3rd, and this would be 2006. It's not written 2006, but if you read the contents, it would have occurred in 2006. And present are Doctors Carter, yourself, Ms. Parnell, Mr. Dyer, Ms. Laidly, Ms. Chafe. And paragraph 2 refers to implementation of policies. And they are listed as fixation, accessioning, embedding, specimen refusal and renal biopsies. And then the policy on error management discussion says "We need the corporate policy on disclosure. Anatomic pathology policy on disclosure will be based on this." Ms. Parnell was to obtain the disclosure policy. And then the "Laboratory

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management to develop a policy and procedure for management of pathologists related discrepancies detected by the QMP. Barry Dyer to do the same for technologists related discrepancies." How far did or what status is this action item right now?

DR. DENIC:

A. Procedures for management pathology related discrepancies, I wrote that policy in 2006 and submitted this policy to the quality department, actually, Dr. Carter submitted to the quality department through Ms. Janet Laidly. And that policy was sitting in their department for over a year, you know, I think, for various reasons that I'm probably not familiar with. And eventually we asked for policy and it was released to us. Because this policy defines, really, what are the course of actions to be taken in case some discrepancies are found in the pathology reports.

COFFEY, Q.C.:

Q. Is that policy in place right now?

DR. DENIC:

A. It's in draft.

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COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. It's in draft and I think it's ready for signature, I was told by Ms. Bev Rowe, who is now the new coordinator for the QMP because not much been changed in that policy. And based on that policy that all the big discrepancies, significant discrepancies actually goes through me and direct be reported to the quality management program.

COFFEY, Q.C.:

Q. Thank you, Commissioner.

THE COMMISSIONER:

Q. We'll meet at five after two.

(LUNCH BREAK)

THE COMMISSIONER:

Q. Mr. Coffey?

COFFEY, Q.C.:

Q. Thank you, Commissioner. Commissioner, just to let you know that the matter of the Gown report, the remark in relation to it, I propose to--I canvassed this with counsel, conclude my examination of Dr. Denic in chief, have the cross-examination done and then if

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necessary pursue that matter before you, okay.
THE COMMISSIONER:
Q. Okay, everybody's in agreement with that?
COFFEY, Q.C.:
Q. Yes, I think so.
THE COMMISSIONER:
Q. All right, then.
COFFEY, Q.C.:
Q. Exhibit, Registrar, P-1179? Doctor, this is an e-mail exchange, it doesn't involve yourself directly, but on October 4th, I'm going to go down through it, Ms. Predham e-mail--well, actually, I apologize, it does involve yourself, it goes to Kara Laing and yourself, carboned to others. And she advises you a lady, name redacted, "called Nancy on Monday asking if she had been retested. Apparently she had called in the fall asking if there was retesting and would she be involved. She was told yes and that someone would be in touch. She called in on Monday asking if there has been any word on her retesting and she hadn't heard anything. She was diagnosed with cancer in 1999. Her original ER/PR from May, '99 showed faint

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positivity in less than 20 percent of cells. There is an addendum on her pathology report dated November 4, 2005 with Mount Sinai results of ER 90 percent, PR 40 percent. I have gone through every scrap of paper related to the ER/PR that I have and I cannot find her name anywhere. We certainly didn't panel her. I may quickly her via phone or something and then get the letter to her GP. Would that be appropriate? She was seeing Dr. Tang at the Cancer Clinic. And I'd appreciate your advice." Doctor, what, if anything, because you having been advised of this in the beginning of October, 2006, the kind of missed, I'll say missed, not in the sense of was retested, but missed in terms of the communications, okay, because she had been retested. Did you get involved then in any of the process of checking to see if everybody had been identified, first of all, for retesting at that point and then contacted? You weren't -
DR. DENIC:
A. No.
COFFEY, Q.C.:

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Q. Okay. I just -
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Okay. I just -
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. It was a process that was started, I gather, or there was a final check done around this time and I just wanted to know, you weren't asked to check in the lab further?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Okay. Exhibit P-2657? Doctor, these are minutes of October 10th, 2006, laboratory medicine program. You in attendance. Page 2, pathologist manpower. Paragraph 6 is a discussion on the recruitment and retention of pathologists and the government's workload review of pathologists. So I take it this was a matter involving pathologists' remuneration and having enough of you there?
DR. DENIC:

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A. That's correct.
COFFEY, Q.C.:
Q. Was a recurrent theme in different contexts?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And then it says, "Terry expressed regret that the pathologists have asked the VIAS currently placed in the lab on a trial basis be sent back to Ventana" suggesting that Mr. Gulliver was in favour of keeping it there and -
DR. DENIC:
A. That is correct.
COFFEY, Q.C.:
Q. - for the reasons you've explained, you didn't -
DR. DENIC:
A. That is correct. He was in favour from very beginning.
COFFEY, Q.C.:
Q. Doctor, raising the matter of recruitment and retention of pathologists in this context, in a laboratory medicine program, maybe it's self-evident, but I'll ask you, was it being raised in this context because it potentially

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had implications for the ability to provide proper care?

DR. DENIC:

A. That's correct. Because this is the year when four residents came out from our program and eventually we lost them, as well.

COFFEY, Q.C.:

Q. Doctor, I'm going to ask you to look at Exhibit P-2658? Doctor, this is an e-mail from Ms. Barrington to a number of individuals, including yourself, October 20th, 2006. She attaches an article from The Independent newspaper of October 20th, 2006. It's related to the class action. I'll just turn to page 2 there and you look, you'll see it. There it is. Entitled "Thirty-nine breast cancer patients behind class action suit against Eastern Health lawyer applies for certification." Thank you, Registrar. Doctor, and we'll see a number, your name on a number of occasions appears on the distribution list for e-mails relating to media clippings and transcripts.

DR. DENIC:

A. What is -

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COFFEY, Q.C.:

Q. That's what this particular one is, although the subject matter of the e-mail here deals with something else, as well. But what was your understanding about why you were on the distribution list for the media coverage?

DR. DENIC:

A. Because I was clinical chief and the pathology was involved and they wanted just keep me informed that my involvement may be sought.

COFFEY, Q.C.:

Q. I notice by this point in time Dr. Cook's name is not on the list. See that? Ms. Predham and Smith, Mr. Gulliver, yourself, Dr. Howell, Mr. Boone and Ms. Bonnell. So by this point in time, October of 2006, had Dr. Cook kind of withdrawn generally from this matter?

DR. DENIC:

A. Every now and then depends of the issue arising, if it's anything to be tracked through his books, if the questions in regards to some of the patients comes from the quality department, they were looking for answers, he would be still involved and some of these letters would be cc'ed to him too and just to

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see who's going to resolve the problem.

COFFEY, Q.C.:

Q. In relation to particular patients, particular issues or questions that arose, he'd have the paper?

DR. DENIC:

A. He'd have the paperwork, that's right.

COFFEY, Q.C.:

Q. The records, and they'd approach him. But by this point in time, by October of 2006 I take it that not only were you clinical chief but the management of the ER/PR matter, from the pathology department's perspective, was in your hands?

DR. DENIC:

A. Yes. But I think he still continued the role -

COFFEY, Q.C.:

Q. In a consultative role?

DR. DENIC:

A. In a consultative role, that's right.

COFFEY, Q.C.:

Q. Doctor, can you--would you be able to tell the Commissioner kind of when, looking back on it, that really occurred, the turnover or the

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change over or was it so gradual that you wouldn't have noticed it? The management of ER/PR, because when you first got involved, the management of ER/PR really, as you've told the Commissioner, was still going to remain with Dr. Cook. This is about seven months later and it's now in your hands. Can you identify a point where it changed?

DR. DENIC:

A. Maybe that was the point, really, that we came to the end where they are trying to say that some results were gathered. Obviously we know that this wasn't the end of all of this, so -

COFFEY, Q.C.:

Q. So somewhere in the summer of 2006, spring, summer, early fall?

DR. DENIC:

A. I would say once--I would say by October, November.

COFFEY, Q.C.:

Q. Because the DCIS cases you handled, not Dr. Cook?

DR. DENIC:

A. That's correct. But it was in--he was still dealing with the other issues.

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COFFEY, Q.C.:
Q. Yes. So the DCIS were yours, the retroconverters dealing with them was yours and -
DR. DENIC:
A. Partially.
COFFEY, Q.C.:
Q. Partially. And Dr. Cook?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And the conversions at large, he was still dealing, he had been still dealing with?
DR. DENIC:
A. That's correct. And I dealt with, subsequently with the deceased.
COFFEY, Q.C.:
Q. And, Doctor, here you're asked or Ms. Barrington says, after referring to the article, "I am going to begin to put together a communication strategy around the release around the rate of error results as well as the announcement of us beginning to retest. After speaking with Heather we'd like to aim for an end of November announcement. Terry,

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Nash, will we be ready by then?" What did you tell Ms. Barrington, if anything, about whether -
DR. DENIC:
A. I don't think we answer on this -
COFFEY, Q.C.:
Q. There's no actual answer. Do you recall -
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Do you recall -
DR. DENIC:
A. That was November. I don't think so we were ready for reopening then, still, and obviously we didn't reopen until February of the following year.
COFFEY, Q.C.:
Q. Doctor, here there's a reference to release of the rate of error results. See that in the -
DR. DENIC:
A. Error results, that's correct.
COFFEY, Q.C.:
Q. Did you ever object the usage of the word "rate of error" or usage of the word "error"? Did you ever express any objection to it?

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DR. DENIC:
A. I might have.
COFFEY, Q.C.:
Q. Do you recall doing so?
DR. DENIC:
A. There was a lot of discussion about error rate and what is the error rate. I mean, I think that could be sometimes in November.
COFFEY, Q.C.:
Q. Okay, so when getting ready for the actual media technical briefing?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay. Doctor, Exhibit P-2275? And, Doctor, here if I could, I apologize, if we could look, please, at Exhibit P-1188? Doctor, if we look at this, this is a series of e-mails. But on page 2 of the exhibit, there's an e-mail of October 26th, 2006, 8:38 a.m. from Ms. Predham to a number of people, including yourself. Just bring it up here. And she refers to a particular patient's circumstances. And she has classified this as another issue with ER/PR. And after

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discussing the background in the case she says, "Yesterday afternoon Nancy received a phone call from" and individual is redacted, "Apparently doctor sent a letter to the family physician. Doctor called and gave her the letter and called Nancy to get contact information on the group that is suing Eastern Health. She was declined." And she then refers to "I can only assume that Mr. Crosbie will now have another story." It goes on from there. Now, Doctor, this, I take it, involved, again, a patient that had not been advised of, when you look through it, had not been advised of what the results were, the findings were and the treatment recommendation was. So, Doctor, here, and again, on the point of identifying patients and ensuring that they were all, you know, told, you were aware of it but you weren't asked to give any input into what should be done?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. When--and we have heard in matters, and we'll see them, about patients having been missed in

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the sense of not identified for retesting. When did that first arise in your involvement?

DR. DENIC:

A. The group that I remember was given to me as a part of the group of deceased, as well, that we send it along. Maybe was an individual case that I cannot reflect to at this particular moment, but somehow I remember the patients at that time, which would be 2007.

COFFEY, Q.C.:

Q. So that would be later. Doctor, Exhibit P-2275? Doctor, this is series of e-mails of November 2, 2006, a couple between yourself and Ms. Predham. She writes to you saying, "I guess we need a plan to address the retesting of patients whose samples are not in our control." Actually, I'll go down below, first of all, to put it in context. "Dr. Neil called back. That particular patient was not retested because she is deceased and they have not been given any instruction--have not been given any instructions to retest any deceased patients. He," that's Dr. Neil, "is willing to send this lady's sample for retesting if we wish, but someone has to let him know. I will

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call him back," some individual relative back "and tell him we did not yet retest her sample." That is Ms. Parsons tells Ms. Predham that on October 30th. Ms. Predham, on November 2nd, advises you of that, forwards the e-mail and says, "We need a plan to address the retesting of patients whose samples are not in our control. Should we get the regions to send them out or will we get them sent in and do the retesting? I would prefer the second option because we would be able to keep track of the results." And she asks then "As her husband has requested the results, can we arrange for her to be retested?" And then, Doctor, you responded to on the same day, to Ms. Predham, saying, "I think that we should send them for retesting since we already have a channel with Mount Sinai open. Tell them to send us the blocks. When we resume the testing in our lab, then we should retest them here." Signed, "Nash." So, Doctor, I take it that as of November, 2006 there was no plan in place as to how the deceased were to be handled?

DR. DENIC:

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A. That's correct, not at the time.

COFFEY, Q.C.:

Q. This is really the beginning of it?

DR. DENIC:

A. That was the beginning to address the issue.

COFFEY, Q.C.:

Q. So, Doctor, initially, from your perspective as the clinical chief, you envisaged, look, as we're not doing ER/PR at that point in our lab, we will send it off to Mount Sinai?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Presumably any of our own if people ask, we will send them?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And if relatives ask and if the other regions need them done, they can go through us to Mount Sinai?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And when we resume the testing locally, we

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will do them here?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Now, that's not what eventually happened because in the--they weren't retested locally. Why is that? When the deceased patients as a group got retested, why were they retested -

DR. DENIC:

A. They were not retested locally, we had a meeting in that regard and that meeting, I think Dr. Oscar Howell, Dr. Kara Laing, myself, Pam Elliott, Heather Predham, Mr. Gulliver, and we were discussing what should--how we going to do this and what would be the most feasible and quickest way to do. And my recommendation at the time was why don't we do them in house, because we were already testing for current patients, the living ones. We have the group of designated pathologists who are reading.

COFFEY, Q.C.:

Q. Yes.

DR. DENIC:

A. We were following the results, we were

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satisfying with the work that we are doing. We were guaranteed the results, as such, and we were thinking that this would be the quickest way to process this group of patients and get results as soon as possible. One of the objections that we received was that--or maybe, yes, we are doing it, but since the issue is sensitive and some patient or patients families, at this particular moment, might say "but you guys retested the entire group at Mount Sinai, why don't you retest our group in Mount Sinai?" I think that was the reason that the entire group of these patients that had been affected sent to Mount Sinai in order to have the same source that we're going to be dealing with and that the patient's family confidence would be in Mount Sinai.

COFFEY, Q.C.:

Q. So who then made the decision as to what was finally to be done?

DR. DENIC:

A. Dr. Oscar Howell, and I think that he conveyed it to Mr. Tilley or, 2007, no, to--that would be Louise Jones and the executives.

COFFEY, Q.C.:

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Q. That would be the summer, into the fall of 2007?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Exhibit P-2660, 2660. Doctor, this is a couple of e-mails of November 3rd and 6th, between yourself and Dr. Mullen. You write it on the 3rd to Dr. Mullen saying "I'd like to ask for another extension regarding the above," and I note that he responds saying that's fine, and you go on to say "while all the cases have been retested, there may be additional cases coming our way. Our lab has not yet resumed testing. However, according to my IHC lab director, who is currently in Seattle for training, is expecting that ER/PR to be operational by the end of this month," which is November.

DR. DENIC:

A. Yeah.

COFFEY, Q.C.:

Q. And you thank him for his help. Doctor, these--"while all of the cases have been retested," see that here? So I take it that

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was your understanding at that point?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. "There may be additional cases coming our way." What additional cases were you -

DR. DENIC:

A. But in case that's of new identifiers or there's new requests of any sort. What I am just trying to tell him that while we think that pretty much everything was done, but not necessarily everything is done, and that the job might not have been finished and that he can expect to receive more cases.

COFFEY, Q.C.:

Q. Exhibit P-2106. Doctor, this is a site chief's meeting of minutes of November 6th, 2006. The new business is pathology assistants, and there's a description here from what was going on at the time involving, Doctor, the pathology assistants and Dr. Morris-Larkin, circulating drafts of their training and so on. So I take it that this reflects, does it, these minutes, the state of development of pathology assistants at the

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time?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Now Doctor, if we could, Exhibit P-0423. This is an e-mail of November 6th, 2006 from Denise Dunn to a number of individuals and she notes, apologize to Gregory, Michelle Gregory in this case. She just notes "as discussed on the phone, Dr. Denic will be giving a presentation to a large group, November 20th, at five, to include" and it lists a number of people, administrators, doctors, and clinicians.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And others, and at that point, it was anticipated that the third presentation would be given to the media, looking at November 30th. So I take it, Doctor, by that point, this point in time, you were prepared or anticipated being prepared to give your presentation to whomever required it, by November 20th?

DR. DENIC:

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A. That's correct.
COFFEY, Q.C.:
Q. And the actual scheduling of it, you'd make yourself available?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. In terms of the choice of December 11th, for example, did you have any input into that?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Exhibit P-0396? Doctor, page two--apologize, page--if you could bring up, please, just to put it in context for you, Doctor, page 16. This is a memo to surgeons, oncologists, pathologists and lab technologists from Dr. Howell, November 7th, 2006, advising him about the presentation. It says "Dr. Nash Denic, clinical chief, and the team, will be giving this presentation as part of our quality assurance review of ER/PR testing" and advises of the time. Doctor, what then did you see as your role in this? Were you the leader of the team that was presenting this?

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DR. DENIC:
A. I was given the task to organize the presentation and to pick up really the people who are going to be presenting. So that's what I did. I went to Dr. Ford Elms, Dr. Cook and Dr. Kara Laing and Dr. Beverley Carter to be a part of the presentation.
COFFEY, Q.C.:
Q. And page 50, please, of the same exhibit, Registrar? Doctor, this is a slide presentation. I apologize for the quality, poor quality of this particular copy of it, but the first slide is "how have we responded? What have we done to improve the service?" and that's your presentation, Nash Denic.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, if we could, I'm just going to--not going to take you through the presentation, because it--Ms. Chaytor points out that there may be a better quality version at P-1425. Perhaps if we could go then, let me see, to around page 45 or so. Apologize, thank you. In that particular one, it's in a different

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spot. Actually, no, it wouldn't be because it was four per page. They go three per page on the exhibit we looked at.
Doctor, this particular presentation, I take it that you would have flashed this onto the screen and then kind of made remarks to supplement it?
DR. DENIC:
A. That's correct. I mean, this is just a quick overview of the stuff and the problems.
COFFEY, Q.C.:
Q. Here, Doctor, at page 103 of the exhibit, the external review, that's the October 2005 and May 2006 technical review, Mount Sinai. "All recommendations implemented, in process. Professional review BC Cancer Centre, most of the recommendations implemented, in progress. Subspecialty task groups formed. All recommendations documented and regularly updated." Now Doctor, were, at that point, in November 20th, 2006, were all Trish Wegrynowski's recommendations implemented?
DR. DENIC:
A. No.
COFFEY, Q.C.:

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Q. Had all of Dr. Banerjee's recommendations been implemented?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. So why would you have said "all" in respect of this?
DR. DENIC:
A. Or in progress.
COFFEY, Q.C.:
Q. Oh, I apologize.
DR. DENIC:
A. Because that's implemented or in progress, so we were--they were all acted on.
COFFEY, Q.C.:
Q. Okay, and Doctor -
DR. DENIC:
A. And some of them are implemented.
COFFEY, Q.C.:
Q. - so at that point, it was anticipated that all of the recommendations, in fact from both reports, would be -
DR. DENIC:
A. Acted on.
COFFEY, Q.C.:

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Q. - acted upon. Was it anticipated at the time that they would all actually be implemented?
DR. DENIC:
A. At that time?
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. No, no, but that they would eventually be implemented?
DR. DENIC:
A. Oh yes, yes, and they are.
COFFEY, Q.C.:
Q. And when you say "they are," I appreciate some things were continuous. They would involve continuous activities.
DR. DENIC:
A. Yes, that's correct.
COFFEY, Q.C.:
Q. But when would you say then they all were, by what point in time do you think that they all were? That you could kind of look at it, the spreadsheet, and say "they're all done"?
DR. DENIC:

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A. I would say they all were probably even 2008.
COFFEY, Q.C.:
Q. And before they were final -
DR. DENIC:
A. I mean, just to be on a safe note, or late 2007, but I would say some of them could have been--some of the SOPs could have been written in 2008.
COFFEY, Q.C.:
Q. Sure. Doctor, in terms of that then, do you ever recall an instance or a time when the whole list of recommendations was in front of you and somebody went through them and signed off or checked to see that everyone of them is done? "We're finished" in the sense of we've got them all done.
DR. DENIC:
A. We did that a couple of times at least. One was before QMPLS came for the review of the lab. That's one of the times when we more thoroughly as well went, and I think the last time, it was done in--it was this year, probably April or something like that.
COFFEY, Q.C.:
Q. And were any records kept at the time of that, do you know?
DR. DENIC:
A. Records of?
COFFEY, Q.C.:
Q. Kept at the time to indicate that, look, you know, we've had our meeting. We've gone through it all, and we all agree that they're all done, or they're all done but one or two? Do you know if records were kept?
DR. DENIC:
A. I believe that was our only time when we met and went through the recommendations in April, for example, of 2008, and felt that the recommendations, and still at that time, as I said, there was probably one outstanding, which is the Tek Xpres, and the deputy director or assistant director for the immunohistochemistry. So we did compile even some documents to reflect that we addressed those issues.
COFFEY, Q.C.:
Q. Was, as such, a meeting held just prior to the re-implementation of testing in February of '07?
DR. DENIC:

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A. We did late November, December. Dr. Oscar Howell was asking Ms. Predham as well to come down to the lab and just to go as well through the recommendations and be sure that all recommendations been acted on or been done or completed or where we are at that particular point, and we did that. Dr. Ford Elms, myself, Heather Predham. I think Dr. Beverley Carter was as well there, so we went -
COFFEY, Q.C.:
Q. Do you know if a record was kept of that at the time?
DR. DENIC:
A. I wasn't certain that we were going one by one and to say this is done, this is done, this is in progress, and maybe Ms. Heather kept the notes.
COFFEY, Q.C.:
Q. Doctor, here, it talks about what's been done with respect to designating the IHC as a separate department and so on, the training, technologists and pathologists. Consolidation of breast cases for examination to be reported from a particular group. IHC proficiency testing is talked about, and this external

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quality assurance programs. Now Doctor, here, on this page 107, consolidating and developing policies and procedures in IHC. So as of November 2006, there weren't actually a whole lot of those written, were there?

DR. DENIC:

A. Not a whole lot. They had the manual that was left from Dr. Ejeckam as well that Mr. Ken Greene revised, and when Dr. Ford Elms came back from his sabbatical, they took some time off and I gave Dr. Elms, as well, a couple of weeks off. So they were start writing the policiesand proceduresfor immunohistochemistry.

COFFEY, Q.C.:

Q. So as a substantive effort, in terms of actually producing such written policies and procedures -

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. - that had just really, in effect, in a large sense, gotten underway, just around the time of this meeting, just before it?

DR. DENIC:

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A. That's correct.

COFFEY, Q.C.:

Q. "The quality control program in IHC performed on a daily basis and recorded to ensure consistency and reproducibility of results." What quality control program in IHC was done daily?

DR. DENIC:

A. They were taking the temperatures. They were taking the pH's, monitoring the antibodies. That's as far as my knowledge, but I know that the paperwork was done on a daily basis.

COFFEY, Q.C.:

Q. The reference to "external and internal controls verified in each case."

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And I take it here, this is talking about--is this talking about ER/PR by itself?

DR. DENIC:

A. ER/PR by itself.

COFFEY, Q.C.:

Q. Okay, and at that point in time though, were there any ER/PR cases being done?

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DR. DENIC:

A. No, but they were--since they were doing the test runs and everything, they would make sure that external controls were verified and they were working very closely with Dr. Carter.

COFFEY, Q.C.:

Q. You were advised then, the audience, of the establishment of the quality management program, who was involved, and the pathology assistants, and the reference to the Ventana Benchmark Autostainer had been purchased. Well, that had been done, in fact, sometime before. That had been done back in -

DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. - 2004? That's the machine they're talking about there?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. And "what was the problem in ER/PR testing?" and then what you have told them is "the scientific understanding about ER/PR has evolved. Reporting scoring cut offs range

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from one to 30 percent. Different technology. Immunohistochemical assay, before '97, versus semi-automated with DAKO, 1997 to 2004, versus automated Ventana platforms, current, all FDA approved. Antibodies, 1D5 DAKO, 6F11 Ventana and SP1, antigen retrieval techniques, boiling versus microwave, etcetera. No standardized IHC testing methodologies worldwide, and there's no national laboratory accreditation progress for IHC labs. 2006 initiative of CAP," of Canadian Association of Pathologists. "The IHC process is a complex process, over 40 steps" and you go through them. "Something can go wrong on each step. Testing laboratory has no control over the pre-analytic phase. Across the other provincial labs that utilize the service of the testing laboratory," and I take it that's pointing out that we can't control what goes on in Grand Falls or Gander?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And there's a quotation here, "the immunohistochemistry tests are probabilistic, not accurate," quoting a Dr. Magliocco,

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Associate Professor of Oncology from the University of Calgary, at a update, UFT pathology update course, November 2005. "No resources, financial constraints affects educational activities for technologists, absent QMP, pathology assistants, etcetera, and lack of continued external quality assessment programs, lack of documentation of procedures and technical and clinical quality monitoring of immunohistochemical stains, large turnover of pathologists and possibly develop subspecialized service, large turnover of oncologists, difficult to monitor, correlate and clinically validate ER results.

"Conclusions," you write, "in regard to reporting of ER/PR, we conduct a self-critical internal review of all ER negative breast carcinomas in the period from 1997 to 2004. We invited external reviewers and after implementation of their recommendations, both recommended to reinstate ER/PR testing. We discovered the critical issues and points and the vast majority of them got corrected. We are ready to proceed according to standards of practice and resume testing for ER and PR, and

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do not forget, immunohistochemistry tests are probabilistic, not accurate", and then questions. Now, Doctor, you would acknowledge that there's no reference to--certainly in any detailed way, to the reasons for test failure identified by Dr. Banerjee?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. In any detailed way, there's certainly no reference to the observations of Ms. Wegrynowski, not in a detailed way?

DR. DENIC:

A. No, that wasn't really the purpose of the whole presentation.

COFFEY, Q.C.:

Q. But you did see fit to refer to the 40 steps having had no control over what went on in other hospitals outside St. John's, and pointing out that different machinery, different times, and different antibodies?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Now, Doctor, why didn't you tell your audience

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about the internal controls issue identified and at least the--and the fixation issue identified? The fixation wasn't limited to outside agencies, it was--also involved St. John's.

DR. DENIC:

A. We were discussing briefly not necessary that you say--difficult to say what was said at that time, but fixation was discussed as one of possibility for test failure. I think it was part as well of Dr. Carter's presentation, and this was also--confirmed that the fixation could play a role, and again the role of this is just to give the overview about the problems that we had, how it started, what we have done, and that overview in that 15 minutes of presentation of each of us, really that as much information one could convey.

COFFEY, Q.C.:

Q. Doctor, I take it--was a conscious decision made, look, we're not going to speak about internal controls, that issue? I mean, that would have been foremost in your mind coming into this, wouldn't it, one of the foremost things, this observation by Dr. Banerjee that

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involved you and your colleagues, so why not simply tell the assembled audience, many of whom are physicians that an outside--or we have reason to believe that there was a problem related to internal controls? Why not simply tell people?

DR. DENIC:

A. I don't think that was conscious decision made not to talk about it. I think--I don't know if in any of this presentation Dr. Carter mentioned the problem of internal control has to be looked, as such.

COFFEY, Q.C.:

Q. I believe she did refer to the fact that you do have to look at internal controls.

DR. DENIC:

A. I think she did.

COFFEY, Q.C.:

Q. But she didn't point out that there had been a problem with people apparently not looking at them, she didn't say that, did she?

DR. DENIC:

A. I don't remember what she said, but I know she was talking about internal controls.

COFFEY, Q.C.:

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Q. Doctor, if I could have you look at then, please, P-2661. Doctor, again just so the-- this is an e-mail of November 10th, 2006, from yourself to Ms. Predham--I apologize, I meant to say 2662. November 16th, 2006, there's an e-mail from Ms. Predham to yourself, briefing note to the Minister of Health. She says, "Hi, here are the numbers. If you need anything else, call me, but I think I have the breakdown as you requested. Heather". She then resends it to you, but this then on page two of the exhibit is a description of total retested, 939, and then a number of other numbers and text. So this is the first numbers you got from Ms. Predham? Would this be the first time you got the numbers, do you think?

DR. DENIC:

A. From Ms. Heather Predham?

COFFEY, Q.C.:

Q. Yes, from Heather Predham, November 16th.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And these are these numbers that she had promised or told you she'd get the day before?

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DR. DENIC:

A. Yes.

COFFEY, Q.C.:

Q. Was that the first time then you would have seen a kind of final breakdown of the numbers, final such as it was at the time?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And it was anticipated here that they would be utilized for whatever purposes, but including to tell the Minister?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, your presentation was November 20th. Do you know if the numbers were utilized in the presentation?

DR. DENIC:

A. I think only the final number was told was 117. We might have said 104, whatever reason, I'm not quite certain, but --

COFFEY, Q.C.:

Q. Had a change in treatment?

DR. DENIC:

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A. Change in treatment.

COFFEY, Q.C.:

Q. Doctor, Exhibit P-2467. Doctor, this is an e-mail from Ms. Predham to Pam Elliott and Patricia Pilgrim, and relates to the ER/PR matter, November 19th '06. The Commissioner has seen this before. Ms. Predham writes, "I have met with Bev Carter, Ford Elms, Don Cook, Nash Denic, and Susan Bonnell, on Friday afternoon. We reviewed the presentation for Monday and it's very good and comprehensive. As always, Bev's comments in the meeting were a little bit alarmist in nature, but she's only speaking about ER/PR testing at the presentation", and she goes on to talk about other things which I will ask you about in a moment, but did you ever view Bev Carter's comments in your dealings with her as alarmist?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Ms. Predham goes on to say that Dr. Howell had called her on Friday afternoon, "and told me that he would anticipate that I would be asked

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at the Executive meeting on Tuesday if I felt everything was done that could be done in the lab as per the external reviews. He arranged for Nash to give me the summary document of the reviewer's recommendations and the labs actions. It has not been updated been updated since June and a lot of the recommendations have "ongoing" next to it. At Friday's meeting, we decided that Monday a.m. we will meet and do a CAP audit of the lab and see how we do. This will be an audit of documentation mostly, and I'll update you on how it goes". Now is this the meeting you're talking about?

DR. DENIC:

A. That's right.

COFFEY, Q.C.:

Q. That was the meeting --

DR. DENIC:

A. That was the meeting that we went to the lab and we were thinking to do besides those recommendations, CAP recommendations, College of American Pathologists, for the immunohistochemistry, and that's what we are talking about.

COFFEY, Q.C.:

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Q. Exhibit P-2108. Doctor, these are minutes of an executive management meeting of November 21st, 2006. There are a number of people present, and, of course, guests for the ER/PR presentation include a number of individuals, including yourself, and here, Doctor, under presentation the note minutes read, "ER/PR. Dr. Denic's presentation focused on the reliability of the testing and the variables that influence the results. Discussion focused on documentation, standardized procedure, semi-automatic systems versus the new Ventana System". So the variables that influence the results, and you've talked about those already to the Commissioner. I take it you would have told the Executive Committee about them?

DR. DENIC:

A. That's right, we did a presentation which was very short and brief because we had a limited time.

COFFEY, Q.C.:

Q. So did they see that slide show?

DR. DENIC:

A. Yes, but it was--we had to run through them really and I might have take out a couple of

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those because time was very limited. I think they gave us fifteen minutes.

COFFEY, Q.C.:

Q. Doctor, was the executive management meeting at the time told about the internal controls issue or observation?

DR. DENIC:

A. They knew about the reports, they knew about the reports of the reviewers.

COFFEY, Q.C.:

Q. They knew they existed. Did they know the reasons for test failure?

DR. DENIC:

A. Mr. Coffey, I still don't believe that all tests failed because of the internal controls.

COFFEY, Q.C.:

Q. No, and I'm not suggesting they do. I'm just asking do you know if they were told at the executive management meeting of the --

DR. DENIC:

A. I don't think so they were told in a 15/20 minute presentation as such.

THE COMMISSIONER:

Q. Two questions, Dr. Denic. The first was whether or not it arose in the presentation,

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but you said they knew about--were you suggesting that they had other knowledge that might tell them this?

DR. DENIC:

A. I didn't know what kind of knowledge they had, but they knew about the reports, so I didn't even know whether they have--they were executive, whether they have seen the reports and that's what I'm referring to.

THE COMMISSIONER:

Q. All right, thank you.

COFFEY, Q.C.:

Q. Exhibit P-2663. Doctor, this is a series of e-mails between a number of different individuals, November 23rd, 2006, and just go to the very end of the exhibit, page three, it's November 23rd, 2006, at 9:15 in the morning and it's Joyce Penney, Executive Assistant to Mr. Tilley. It's advising Mr. Tilley the Minister would like to meet at 3:30. George, who else would you like to have to attend the meeting", and Dr. Howell, and she's got dots, in other words, who does Mr. Tilley want there. This series of e-mails involves then the scheduling of the meeting

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and who's going to appear, okay. If we could go back to page one, Doctor, here at the bottom of that page at 10:34 a.m. Ms. Penney is advising a number of individuals. At that point in time you're not included, I don't believe, at that point in time, but she's advising everybody involved in the mailing list that there's a meeting the Minister has requested for ER/PR today, November 23rd, 2006, at 3:30 in the Clerk's Boardroom outside of the House of Assembly, and Dr. Howell is recommending to the team; Dr. Denic, Dr. Laing, Heather Predham, Susan Bonnell, and George Tilley meet in his office at 2:30 to strategize and prepare for the 3:30 meeting, Please find space in your area for the meeting. There are--people asked then to contact you and Dr. Laing to advise of it. Doctor, I take it you had no more notice of this meeting than appears here?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. So what was your involvement--what did you understand your role to be, what happened?

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DR. DENIC:
A. My involvement as a clinical chief in case that the Minister have any kind of questions which are related to the pathology practice or technical that I could shed light at. That's why I was called to come along.
COFFEY, Q.C.:
Q. Okay, that's what you understood your role was. Did you have any input into the meeting? You went to it, I take it.
DR. DENIC:
A. Yes, I did.
COFFEY, Q.C.:
Q. What do you recall about it?
DR. DENIC:
A. I know that we just presented the data to the Minister. He asked--Mr. Tilley is the one who mostly did conversation with Minister himself. There was discussion about the deceased, as I can recall, between Dr. Kara Laing and I think that was Mr. Haynes, Darrell Haynes.
COFFEY, Q.C.:
Q. Yes, Darrell Hynes, yes.
DR. DENIC:
A. Hynes, and that we brought up the issue of

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recruitment and retention of the pathologists. I remember just telling Minister on my way out I hope so we're going to meet again on this issue. He was rushing actually to go to the House of Assembly, the meeting was very short. Not good recollection of the questions --
COFFEY, Q.C.:
Q. Did you have any input yourself that you recall?
DR. DENIC:
A. Not really.
COFFEY, Q.C.:
Q. Actually --
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. What was the discussion about the deceased, do you recall?
DR. DENIC:
A. I can't recall exactly what was the--I think Mr. Hynes, he had some kind of question and Kara Laing, she would answer those questions.
COFFEY, Q.C.:
Q. So, Doctor, if we could, please, Exhibit P-0022, page 65. This is MAC minutes of

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November 29th, 2006. You are present. You're the fourth name on the left hand side. If we could go, please, to page 67. It's an entry under laboratory medicine program, "Dr. Denic represented the report of the Laboratory Medicine Program for information highlighting the following; human resources. Two pathologists, Dr. Yousif and Markala, have submitted their resignations effective December 31st", and then it says, "Dr. Fontaine, effective February 5th, 2007". You point out that Dr. Fontaine's resignation as a cytopathologist, the loss of his service currently provided in the province will be major. Doctor, I take it then this is the--I won't say the beginning, but this is a significant loss.
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. In late '06, early '07. Doctor, if you would look, please, at Exhibit P-0184. This is an e-mail of December 9th, 2006, from Ms. Bonnell to a number of individuals including yourself. The attachments are a number of documents.

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They generally turn out to be the presentation of December 11th, 2006. The Commissioner has seen them before. The second paragraph, she notes, "I guess the most significant change you will note from the original material is the lack of reference to "rate of error". We can anticipate this will be a major pressing point with the media, but the approach we will be taking here is that we can't indicate that an error has actually occurred. The whole process wasn't about identifying a rate of error, anyways, it was about identifying patients whose treatment would change as a result of the review and the panelling, and hence the number of individuals impacted has changed from 104 to 117, taking into account the 13 who had no change in the results, but because of the new definition of positivity should have been offered Tamoxifen. We won't be spelling that out like that, though". Why was that? Do you know why, or do you know why that was so?
DR. DENIC:
A. I really don't know what she meant when she was referring to the rate of error. I don't

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know.
COFFEY, Q.C.:
Q. And we'd seen references--one or two earlier today, and, in fact, I could take you through a number of them otherwise. It wasn't uncommon to see earlier references to rate of error in correspondence within Eastern Health. So, Doctor, what if any input did you have into the decision as to what would be said or talked about at that meeting and what wouldn't be said? What was your involvement, if any?
DR. DENIC:
A. We had discussion before all of this happened, December 11th, trying to explain what would be best to give forward to the media, to the public. While there was some numbers produced at the time, yes, we discussed the error, and what did the error rate--my personal problem with the error rate is, and it was, how we define the error rate. We know that patients did change from estrogen negative clinically to positive eventually. We knew that some of the cases here, the progesterone positive, estrogen negative. So they did have the receptor status positive and some of them are

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treated--actually large number of those treated as well. So the problem that we didn't know the error--define by conversion as well, 10 percent, 30 percent, or should we look 1 percent as such as against those parameters. Even what would be the denominator because we examined, let's say, thousand patients and this what was thought. So what does that tell us. Statistically, it doesn't tell us much really because performance of one test, you have to look all tests really in the lab. So through all of this, the decision was made what is the number that really have the meaning for the public and what is it--what is the hypothesis when the physicians started through this process at that time, and the decision was made to disclose the number of the patients that directly affected and they needed their therapy to be changed.
COFFEY, Q.C.:
Q. So do I understand, based upon what you've just told the Commissioner, that you were in agreement with the final decision and the final approach?
DR. DENIC:

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A. That's right, we all made--we all went through the check and balances, we talk about this out, and the agreement was to go with this number.
COFFEY, Q.C.:
Q. And what about if, as was anticipated, the media would ask about what caused this, what was the understanding amongst the group about that?
DR. DENIC:
A. The understanding of the group there are various factors that can influence, and I think we were again talking about the complexity of the tests and that anything along this lines can fail. At that time, and I don't believe even today, it wasn't a single factor that was isolated and said, yes, at the end of the day, fixation is the problem. Obviously, that's not the case.
COFFEY, Q.C.:
Q. So, Doctor, you agreed then with the decision in that regard?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:

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Q. In terms of not talking about causes, except in generalities?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Not actually to refer to actual findings or observations by objective outside observers?
DR. DENIC:
A. In that regard, again those reports are considered as peer review documents, and --
COFFEY, Q.C.:
Q. But you certainly --
DR. DENIC:
A. You couldn't talk about it since they were considered peer review documents.
COFFEY, Q.C.:
Q. And were you made aware--had you been at that point in time made aware that Dr. Cook and Dr. Carter had reached the same--in fact, the same conclusions in many ways, or at least in some ways, as Dr. Banerjee eventually did, that they had reached those conclusions in the summer of 2005? Did either Dr. Carter or Cook tell you that, because their views were not covered by any kind of privilege?

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DR. DENIC:
A. They told me that there was a problem--they saw the problem with the fixation as such on the slides, but they also told me that the antigen retrieval could be the problem, could be a problem with the pH, but they didn't come to the direct conclusion, yes, we know, we identified this is what went wrong. They put their observations, the quality of the slides they found.
COFFEY, Q.C.:
Q. Was the media to be told on December 11th that there had been no quality assurance program in place in pathology at the time? Was the media told that?
DR. DENIC:
A. I'm just --
COFFEY, Q.C.:
Q. Do you recall--if not, why not?
DR. DENIC:
A. I don't remember that. I don't remember because we had the slide presentation that I put forward in the auditorium at the time, lack of documentations.
COFFEY, Q.C.:

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Q. But what I'm asking you is in terms of the media on December 11th, 2006, are being briefed on this whole matter, and you described why certain things were and weren't said. I'm just asking you, because you've told the Commissioner already you were aware that there was no QA program in pathology up until your time as clinical chief. So was the media told that there had been no QA program in pathology prior to you becoming clinical chief?
DR. DENIC:
A. I don't know.
COFFEY, Q.C.:
Q. Okay. Exhibit P-2662. Doctor, we just looked at this a moment ago. This is the numbers you'd gotten on November 16th, and which in the end the numbers got reproduced in what the Minister was given on November 23rd. Doctor, what was the problem, from your perspective, with simply giving the numbers to the media on December 11th, 2006?
DR. DENIC:
A. These numbers were collected along the way. I don't think so that any of these numbers were

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cross-checked, none of these numbers were--and I wasn't really doing any of this.
COFFEY, Q.C.:
Q. Well, was there any discussion about whether we should give the media on December 11th the numbers we gave the Minister two weeks ago, and they were certainly thought reliable enough to give to the Minister? So was there any discussion amongst the group or the team about whether we should give out the numbers?
DR. DENIC:
A. It might have been discussion, I think, but at the end of the day, I think, decision was made just to come out with the most meaningful number which would be the number of patients affected.
COFFEY, Q.C.:
Q. Well--okay. If we could, please--the presentation of December 11th, 2006, occurred, it was reported in the media afterward. Were you made aware of or did you follow the media coverage afterward?
DR. DENIC:
A. To some extent probably.
COFFEY, Q.C.:

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Q. And were you aware that there were still questions being posed in the media as to what had caused this, why it had occurred, and as to how many tests that had changed results? Were you aware those questions were still being posed?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. Okay, so did you anticipate at that point in time that that information would ever become public?
DR. DENIC:
A. At that time, I wasn't--I wasn't--I knew that the patients were going to be told their results, all the patients that were tested, but whether at that time anything else going to come out, I wasn't aware of.
COFFEY, Q.C.:
Q. Doctor, the ER/PR testing resumed, I believe, February/March--February of 2007 at St. John's. Did you discuss at that point or just around that time with other health authorities whether they would utilize your services?
DR. DENIC:

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A. I offered them actually at that teleconference as well, I told them that we were going to be ready to resume and there was a question how do we know that you guys are now doing everything as we are doing, and then I invited all directors to come down and just to visit us--pay us a visit, actually discuss all the stuff, recommendations, and that was done in November.

COFFEY, Q.C.:

Q. Did any of them--that was November of '06?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Did any of them take you up on that?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Doctor, what then happened, Doctor, in terms of ER/PR?

DR. DENIC:

A. We started ER/PR for St. John's hospitals only, and we were trying to develop HER2/neu as well testing because this is one of the reasons that I didn't push any more for the--

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to provide a service for other labs because if you want to offer them the test, you better offer them three test, which is ER/PR and HER2/neu, which is done on--should be done on a single block. So we were performing ER/PR in-house and we still would be sending the block to Mount Sinai for HER2/neu.

COFFEY, Q.C.:

Q. Doctor, what then happened?

DR. DENIC:

A. Then we are coming into May that I remember, and in May a few things had happened.

COFFEY, Q.C.:

Q. Yes. How did the fact that there was something happening at all come to your attention? Do you recall how you were informed about the fact that this was in the media or did you hear --

DR. DENIC:

A. It was in the media about the affidavit being filed.

COFFEY, Q.C.:

Q. So that's the first really you heard --

DR. DENIC:

A. That's right. I didn't even know the

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affidavit was filed.

COFFEY, Q.C.:

Q. Okay.

DR. DENIC:

A. I didn't have knowledge of it, and that the numbers were obviously -

COFFEY, Q.C.:

Q. Were in the affidavit.

DR. DENIC:

A. In the affidavit.

COFFEY, Q.C.:

Q. The same numbers generally that -

DR. DENIC:

A. The same numbers generally, that's correct.

COFFEY, Q.C.:

Q. We just looked at.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Were you surprised, Doctor?

DR. DENIC:

A. Yes, I mean, it would be quite logical to say why had not release the numbers a month before, and really it wasn't my decision, and I didn't even know that affidavit is going to

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be filed, you know, so -

COFFEY, Q.C.:

Q. Doctor, you've told us then about being involved or being requested by Mr. Tilley to provide the reports in May of 2007. You had to go to -

DR. DENIC:

A. At some point.

COFFEY, Q.C.:

Q. At some point, May, 2007. Doctor, then it went into the media. You've already referred to May 18th, 2007.

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. When you took part in that presentation for the media, I take it?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Did you take part in any presentation for House of Assembly members?

DR. DENIC:

A. Yes, I did.

COFFEY, Q.C.:

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Q. And those presentations, I take it, from your perspective, were they similar to the ones you had done before?
DR. DENIC:
A. That's correct, a little bit--I had only a few slides to show them.
COFFEY, Q.C.:
Q. Altered to fit the audience?
DR. DENIC:
A. That's right, and they had great difficulty to understand really. They were asking me to put this in layman's term, and I tried to do my best, but they didn't understand.
COFFEY, Q.C.:
Q. Doctor, if we could look, please, at Exhibit P-2676. Now this is an e-mail exchange of November 23rd and 24th, but the 24th, Ms. Predham sends an e-mail to yourself and Dr. Howell saying, "We never looked at regional differences before. What would you like me to have ready for ten? I'll see what I can get. Also, Terry had a sheet done up with the number of tests by region on it. There were some errors in the last one I received, but he did up a final one for Jane Bussey. Do either

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of you have that or do you want me to get it from him? Do you want to chat before ten". I take it this is the conference call that was set up for 10 a.m, November--I'm sorry, May 24th? See that there?
DR. DENIC:
A. Yeah.
COFFEY, Q.C.:
Q. So, Doctor, this conference call, do you recall this conference call involving pathologists?
DR. DENIC:
A. I really don't have recollection about this happened. I'm reading obviously it was my name there. That was May 24th, 2007. This is not the one of Mr. Abbott?
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. It is?
COFFEY, Q.C.:
Q. Oh, yes.
DR. DENIC:
A. Okay, so this is the one.
COFFEY, Q.C.:

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Q. My understanding is there were quite a number of individuals involved, people have testified to that?
DR. DENIC:
A. Yes, yes, okay. So the--reading this text, the body of the text.
COFFEY, Q.C.:
Q. So what do you recall about that, Doctor? The purpose of the conference call, what happened?
DR. DENIC:
A. Just to see where are with the ER/PR, why the ER/PR is not carried through the entire province. A discussion of the fixation was moderated by Mr. Abbott who was on other side of the phone. I was present with Mr. Terry Gulliver and Oscar Howell, could have been Heather Predham, I'm not quite certain, in Dr. Howell's office. On the other lines I can recall Dr. Paul Neil, Dr. Alteen, Dr. Dankwa, Dr. Ken Jenkins and I think Dr. Murray Dalton was somewhere else that he connected from. I don't think so he was in his office.
COFFEY, Q.C.:
Q. So there were all the, in effect, all the lab directors, VP medicals?

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DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And various people from government?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. You know, senior administrators. The purpose of this was to discuss what you've just referred to. During that call was there any discussion about fixation protocols or policies and procedures?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. What do you recall about that?
DR. DENIC:
A. I think it was discussed because of the problem that had been reflected in some of the reviewers' reports, that the fixation has to be standardized and we should work towards standardization of fixation and that's a major problem.
COFFEY, Q.C.:
Q. And, Doctor, was there any expression of

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surprise from any of the participants in the call about them being first, this is the first they heard of this? And if it came, it would have come from some pathologists?

DR. DENIC:

A. I don't remember that anybody was overly surprised.

COFFEY, Q.C.:

Q. Coming out of the phone call then, what did you decide or what did you decide to do in relation to this matter involving protocols -

DR. DENIC:

A. Decided to eventually share everything what we had in our possession, not only fixation policy, but the handling, as well, of the breast tissue and other tissue.

COFFEY, Q.C.:

Q. Exhibit P-2679, please?

THE COMMISSIONER:

Q. Excuse me, Mr. Coffey, before we leave that point. You indicate that there was discussion of fixation during the conversation?

DR. DENIC:

A. That's correct.

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THE COMMISSIONER:

Q. Was that because somebody from Eastern Health raised the subject of fixation or was fixation raised by somebody else and, if so, by whom?

DR. DENIC:

A. I wouldn't remember who raised the issue, but I know we discussed it. I don't know whether Mr. Abbott would know about it, but -

THE COMMISSIONER:

Q. Well, that was my next question. Who would know about fixation -

DR. DENIC:

A. I mean, it could be us.

THE COMMISSIONER:

Q. - besides those out of Eastern Health?

DR. DENIC:

A. That's what I'm saying, it would be us. So if it's raised, probably it's raised by us.

THE COMMISSIONER:

Q. All right.

COFFEY, Q.C.:

Q. And I take it in the context of, in fact, if you're going to be in the future doing any ER/PR work for other regions, other health authorities, you'd have to have them utilizing

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the same practices and procedures?

DR. DENIC:

A. Procedures and practices.

COFFEY, Q.C.:

Q. For fixation as you did?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. That would be the idea. Doctor, here, this is an e-mail of May 31st, 2007 to Dr. Dankwa, but as well it went to all the other pathologists throughout the province?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Outside St. John's. Doctor, this, I take it, is the distribution of these -

DR. DENIC:

A. Policies.

COFFEY, Q.C.:

Q. - policies and procedures?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And that, I take it, the material you sent out

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at that time reflected what existed at that time, the then current state of affairs?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. And anything that might affect breast cancer that existed at the time?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. That you had. So whether it was draft or not or whatever -

DR. DENIC:

A. No, this is already policies.

COFFEY, Q.C.:

Q. Yes. But if there were even any draft ones that--you know, I'm not saying they were, I'm just asking you, at the time if a policy or procedure existed, in final form or draft, you shared them with -

DR. DENIC:

A. We shared them, yeah.

COFFEY, Q.C.:

Q. Okay. And, Doctor, if we could look, please, at Exhibit P-2680? And, Doctor, this is an e-

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mail of May 31st, 2007 to Dr. Cook and yourself. Dr. Cook is back involved again. Retesting of deceased patients. And she says, "I was speaking to Dr. Howell yesterday and he asked me to begin coordination of the outstanding deceased patients." Because, I take it, Mr. Tilley had made a commitment publicly to retest -

DR. DENIC:

A. That's right, on a -

COFFEY, Q.C.:

Q. All of the deceased.

DR. DENIC:

A. - technical briefing.

COFFEY, Q.C.:

Q. And the third paragraph says, "Dr. Cook, will I send it over to you to coordinate retesting? I know that you're going to be away next week, so Nancy and I are getting a list compiled today. I have also to get in touch with Kara to get the panelling done for this group. I will be in touch with that information, as well." So, Doctor, who ended up coordinating the retesting for the deceased?

DR. DENIC:

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A. I think that came again from Ms. Heather Predham and that was coordinated through Mr. Dyer, the manager, Mr. Terry Gulliver and eventually myself.

COFFEY, Q.C.:

Q. And, Doctor, I take it there was some--it took some period of time to get the deceased retested?

DR. DENIC:

A. Yes, it did.

COFFEY, Q.C.:

Q. And why was that?

DR. DENIC:

A. We started, Mr. Dyer was supposed to--they came up with the list first. And then somebody had to organize collection of the slides and blocks. I think we are coming into the summer, as well. And during the summer I remember July, August when the big batch of last slides were brought to me, I organized review of the slides so Dr. Beverley Carter and myself, we reviewed the biggest batch of these cases. We reviewed them in two days. And we picked up the slides which actually going to turning to the blocks that have to be

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sent to Mount Sinai for retesting. So we did that job, the bulk of the job in two days. I gave those reports, actually, to Mr. Dyer, and he send them off to Mount Sinai.

COFFEY, Q.C.:

Q. And then?

DR. DENIC:

A. And then in that period of time we didn't hear anything from Mount Sinai. And I think Ms. Pilgrim was e-mailing me and just say can you find out what's happening, why we are not receiving the results. So I contacted Mount Sinai, Ms. Mendes, asking what's happening, why we are not receiving the results. They said that they had a workload issue problems and they're going to look into this, to this issue and probably start reporting like five cases a week. And then in the meantime I was given an additional list that was supposed to be prioritized for some of the patients who were new identified through the additional search, searches, and some of the patients that, or the family of the deceased that might--were very anxious to get the results back. So I was forwarding that list and asked

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them to priorize these patients, which they did. Act actually the first results we started receiving in November of 2007. And then it was a stoppage and I think I phoned Ms. Mendes at the time and she told me that Dr. Mullen was on vacation, too. And I think the last results we received in January of 2008.

COFFEY, Q.C.:

Q. And, Doctor, we've heard evidence that in the beginning of the summer of 2007 there was certainly some question arose about whether people had been missed for retesting. Were you involved in trying to identify any patients that were missed?

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Okay. And that's from that point until this day you haven't been involved?

DR. DENIC:

A. No, that wasn't my role.

COFFEY, Q.C.:

Q. Doctor, we've heard evidence that, we've touched on this yesterday that there was Dr.

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Trudeau was -
DR. DENIC:
A. Maureen?
COFFEY, Q.C.:
Q. Maureen Trudeau was contacted in, I believe, April of this year?
DR. DENIC:
A. About April, I would say.
COFFEY, Q.C.:
Q. Did you participate in that?
DR. DENIC:
A. In?
COFFEY, Q.C.:
Q. In the contact?
DR. DENIC:
A. In the contact, no.
COFFEY, Q.C.:
Q. Okay, so you weren't involved in that?
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. In terms of the current status of things and the retesting, is there anything that you are involved in right now?
DR. DENIC:

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A. What I was involved in this short period of time in 2008, as well, the patients who were positive originally, they were asked to be retested.
COFFEY, Q.C.:
Q. Some patients, yes, were offered that?
DR. DENIC:
A. That's right.
COFFEY, Q.C.:
Q. So any patient who had an original positive result who has requested to be retested?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. You were involved in that?
DR. DENIC:
A. That's right. The way that that was going through is that I would receive the call from Ms. Parsons at the time or Heather Predham, Pat Pilgrim, Ms. Sharon Smith or anybody and tell us we have the patient to be retested, so that would come through my desk. I would review the case and do a retesting.
COFFEY, Q.C.:
Q. Doctor, and anything else, Doctor, in terms of

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the ER/PR matter?
DR. DENIC:
A. No. We were doing ER/PR until May 23rd.
COFFEY, Q.C.:
Q. And you've described the reason for suspension at that point in time?
DR. DENIC:
A. So suspension, we start sending the cases now out to Mount Sinai, as today they are going to Mount Sinai along still with HER2/neu and that we are planning, probably, if everything goes well, to restart in October.
COFFEY, Q.C.:
Q. Bring up, please, Exhibit P-2728? Two-eight. That's it. Okay.
REGISTRAR:
Q. (Inaudible).
COFFEY, Q.C.:
Q. Perhaps could it be entered, Commissioner, if we will?
THE COMMISSIONER:
Q. Yes.
COFFEY, Q.C.:
Q. Thank you.
THE COMMISSIONER:

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Q. 2728.
EXHIBIT ENTERED AND MARKED P-2728.
THE COMMISSIONER:
Q. Has that been provided to everybody else in disclosure in respect of that witness?
COFFEY, Q.C.:
Q. I think so, yes. I certainly think so. In fact, I would--I thought it was in, but anyway.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. Doctor, this is a letter of July 22nd, 2008, it's to yourself. And this if from Doctor -
DR. DENIC:
A. Nik Makretsov.
COFFEY, Q.C.:
Q. Makretsov. And this is the letter that you spoke about, I take it? Earlier you said he had put in writing his view or his plan or suggestions?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And, Doctor, I notice here that there are a

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number of checks. You see that?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Are they yours?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:
Q. Okay. So I take it check means or does it signify agreed, agreed, agreed?
DR. DENIC:
A. Pretty much. You know, we discussed briefly and he is recommending like number one, synoptic reporting, another guideline that he is bringing from UK. I said I'm very receptive, you know, he's now in charge, anything that can make anybody's life easier, go ahead.
COFFEY, Q.C.:
Q. The weekly mandatory interdepartmental breast slides review?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. And "Adequate secretarial support is

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necessary."
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Now, on that point, I wanted to ask you about that, what's the status right now of administrative secretarial support in your department?
DR. DENIC:
A. It's getting better, Mr. Coffey. I even finally got my secretary after two years dealing with these issues and the paperwork.
COFFEY, Q.C.:
Q. So when did you get yours?
DR. DENIC:
A. She started in May, but she took a vacation, she actually started in June.
COFFEY, Q.C.:
Q. Of 2008?
DR. DENIC:
A. 2008.
COFFEY, Q.C.:
Q. So you have secretarial or administrative assistance. How about other people?
DR. DENIC:

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A. With the other people how it works at the St. Clare's we have one secretary and we have two stenos. And we asked for additional secretarial support which was approved by Ms. Louise Jones and we're going to get additional one scenographer and two secretaries, but that's going to be for the program, as well, because we need secretaries for the quality department, as well, and we need a secretary for the genetic department and we need another steno. So we are--that's been advertised, it's not been filled yet.
COFFEY, Q.C.:
Q. So, Doctor, just looking at this, paragraph three refers to "reinstate breast pathology, radiology weekly rounds tentatively in August upon Dr. Wadden's return."
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. "From holidays. An adequate secretarial support is necessary." I take it that would be because you want to have some record of what is done at the rounds?
DR. DENIC:

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A. That's correct. But I'll tell you what is all about is that radiologists, they submit the list of the patients that we want to discuss and they submit a list usually to one of the secretaries. And that been in place since Dr. Carter came and so what she would do then she make sure that she pulls out the slides for those rounds, glass slides, and prints the reports along with those ones. And also would e the sheet that you record what's been said, what are the recommendations, those sheets pathologists have and radiologists have. So what was made as a decision that record about these rounds being held and the case being discussed but put in radiology report and they usually give recommendation for six months follow-up or we do a recommendation that the patient has to see a surgeon.
COFFEY, Q.C.:
Q. So I take it you need, as it's termed here, secretarial support in order to keep records to kind of make it all work, in effect?
DR. DENIC:
A. Definitely, definitely.
COFFEY, Q.C.:

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Q. Four is, I think, self-explanatory. It says what, it was your handwritten note?
DR. DENIC:
A. "Combined with number three."
COFFEY, Q.C.:
Q. Okay, "Combined with three." And four is "organizational steps toward the creation of a multidisciplinary breast unit engaging pathology, radiology, medical oncology and medical radiology, nursing and psychosocial support specialists, weekly collaborative management meetings similar to Cambridge University Hospital Breast Unit meetings."
DR. DENIC:
A. This is one of the template that he was suggesting that been run in UK. This is that I find similar to our breast disease site group with the way we have the forum of the various specialists, although in some of the centres in the UK they go further, almost it's like a unit that has everybody available around, you know, so almost patient goes from one station to another, you know, so that's something that he saw. It's not in every single centre, of course.

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COFFEY, Q.C.:
Q. And, doctor, does he have documentation, do you know, related to this?
DR. DENIC:
A. He gave me the position paper that was written about it, but nothing more than that.
COFFEY, Q.C.:
Q. And if--have you given that to Mr. Browne to pass on, if you could, pass it on to -
DR. DENIC:
A. I would be glad to share that.
COFFEY, Q.C.:
Q. Thank you. Number five is "Dedicate two pathologist assistants to breast pathology as a primary duty, perform all gross examinations of breast specimens on one site. Currently St. Clare's for breast pathologist grossing bench support is readily available. This is to ensure continuity of breast pathology standard practice and other guidelines endorsed in number one." And you've noted here, "After lab consolidation."
DR. DENIC:
A. That's right.
COFFEY, Q.C.:

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Q. I wanted to ask you about that. What's the status of the lab consolidation?
DR. DENIC:
A. We haven't moved yet. As the situation stands, it's very difficult to move portions of the lab. Where the situation is the blueprint has been signed off by me and Mr. Gulliver, I think even in April of this year. We are phasing out this, so one of the phases to move one of the part of the lab from General Hospital site, which is immunology, back to St. Clare's site and to vacant that space and turn into the offices. So it's going to take some time. So why this hasn't been done yet, because we need to prepare the room now for the immunology to be moved to St. Clare's, they need the certain instrumentation such as ultra light freezers, then you have to tender for those freezers, it takes time and when you order, of course, takes time, so everything takes time.
COFFEY, Q.C.:
Q. Doctor, is there any projected date by which the lab will have been consolidated?
DR. DENIC:

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A. We already passed that projected date.
COFFEY, Q.C.:
Q. Is there a -
DR. DENIC:
A. And we hope so, that sometime until the middle of next year that we move.
COFFEY, Q.C.:
Q. In relation to that, perhaps then you could-- and I'll leave this for you to talk to Mr. Simmons and Mr. Browne about, you know, whatever the latest is on that, in writing, okay, if there is anything, or it comes up between now and the time we conclude here that it could be passed on, so at least the Commissioner has some idea of what the latest plan is. Okay?
DR. DENIC:
A. In terms of consolidation?
COFFEY, Q.C.:
Q. Yes.
DR. DENIC:
A. Okay. Once we get any closer, I can keep you posted.
THE COMMISSIONER:
Q. If someone waves a major wand for you and you

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actually get consolidated, I'd like to know.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. Thank you.
THE COMMISSIONER:
Q. On the other hand, if someone tells me or tells you, you're not going to get consolidated for another two years, I'd like to know that too.
COFFEY, Q.C.:
Q. That's in -
DR. DENIC:
A. I don't want to hear that too, Madam Cameron. I'm usually on the ball and start pressing, but some things doesn't roll the way you want.
COFFEY, Q.C.:
Q. Doctor, number six says "to implement the specimen audit in breast pathology and to develop appropriate documentation, NHS samples are available." This NHS is National Health Service, I take it, British, UK?
DR. DENIC:
A. That's correct.

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COFFEY, Q.C.:
Q. Have you seen those NHS samples, written samples?
DR. DENIC:
A. I don't think so, but they are available as such. This is going to be part that we're going to implement in our regular QC, because we have reviewed the cases. We have reviewed the various parameters. So I think this is going to just fit in what we are doing currently.
COFFEY, Q.C.:
Q. Okay. If there is such documentation and it is going to be utilized or planned to be or potentially utilized at Eastern Health, if you could identify that and have that passed on through your solicitors to us?
DR. DENIC:
A. I will be happy to do that.
COFFEY, Q.C.:
Q. And you've noted "to be done," so you plan to do this. That's your handwriting?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:

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Q. And Doctor, here, number seven, "immunohistochemistry for ER/PR and HER2/neu" and then the doctor goes on to talk about "considering tissue microrays and image analysis as a robust approach to provide 'sealed' multiple external controls on the same slide with the test sample" and he goes on then to discuss the pros and cons, the strengths and weaknesses, and I'm not going to read it out to you right here and now, because you have read this before and the Commissioner can read it. Doctor, and you've noted here on the side, "approved."
DR. DENIC:
A. For that.
COFFEY, Q.C.:
Q. For that too, and so I take it then that in terms of how this whole matter of ER/PR is to be handled, in terms of the types of controls, the microrays, whether to use them or not, the idea of using an image analyzer, I take it, you've already indicated that this doctor himself favours it. How this is then to be organized, I take it, within reason, is you're adopting his approach?

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DR. DENIC:
A. Why I said "approved" in this, because when I discussed about this approach, especially about microray at this particular moment, rather that as image analyzer, because I think a image analyzer, if you have two or three people reading it, ER/PR, I think, and making consensus which how that looks like is I look at the slide and I say that "this is 60," and then Dr. Elms says "I think it's 50," and then you have Dr. Nikita Makretsov said, "I think it's 65," you take the average and you come to the consensus of--and that's how it will be practised. So you have three people. Image analyzer, it has it's own biases. So however, I find very interesting about these, if we want to call it machine for the microray, because what you can do, you can preserve your controls. You can have so many controls with a minute portion of the tissue and don't exhaust the controls as we do right now, because we don't have this ability. So microray takes from the various blocks, takes thinner than a tip of the pin pieces of tissue and they embed them like that, so you can--on

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one block, you can embed 40 to 50 different pieces of tissue and you can, based on what kind of tissue you have, you have a map and you say "okay, this one should be positive. This one should be weakly positive. This one will be strongly positive." So you can see how your test works. So this kind of approach being utilizes even through the CIQC, that's a new initiative through the CAP. So while it has some limitations obviously, I think it's a great tool. So what I told Dr. Makretsov to search where we can purchase this, and that we build up again the business project, the instrumentation, it doesn't appear that expensive, I think in the range of 15 to 20,000, but still you have to go through the process and build the project on that and then I'm going to submit it to Dr. Oscar Howell for final approval.

COFFEY, Q.C.:

Q. And Doctor, here, and the doctor concludes paragraph seven by saying "this will allow us to monitor sensitivity and specificity of ER/PR and HER2 stains based on a non-biased assessment of intensity of the immunostains

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using digital image analysis based monitoring, and will eventually make us national leaders in breast cancer biomarker quality assurance."

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. So that is certainly an ambitious goal, but I take it this is your understanding of this new physician's attitude and approach?

DR. DENIC:

A. But not his attitude, as well, it's mine too.

COFFEY, Q.C.:

Q. Okay, but this is his actual detailed suggestion as to how you might accomplish this?

DR. DENIC:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, in relation then to where the lab is overall, information systems, information management, has consideration been given to consulting other hospitals, other institutions, about how one might accomplish getting a better pathology information management system?

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DR. DENIC:

A. There's been some initiatives. I think first generally IT system has to be done, and I think I seen a part of the document that one of the government's initiative for 2009 is to invest in information system in laboratories because we need to connect obviously. We proved through this, all of this, that information system is not well developed, neither not well connected. So that's -

THE COMMISSIONER:

Q. Pardon me? I didn't -

DR. DENIC:

A. So that's the initiative as such. Cancer Centre, they informed me about it, but they are working also on the national level of implementation of software program that all synoptic reporting are going to be done as such, through synoptic, and going to be easily accessible through a single main frame, but connect with all laboratories throughout the province.

COFFEY, Q.C.:

Q. Who's responsible for this?

DR. DENIC:

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A. Cancer Centre's initiative, and Ms. Sharon Smith is working on it. I received an e-mail when, yesterday, day before, I couldn't even answer it. They already had a meeting and they might come up with Federal Government's money for that kind of project.

THE COMMISSIONER:

Q. Mr. Coffey, it's well past break time for the witness.

COFFEY, Q.C.:

Q. Actually, I'm--that was about it. Commissioner, we could take the break. If I have anything else, I could just ask it right at the very beginning.

THE COMMISSIONER:

Q. Okay. We'll take an afternoon break.

COFFEY, Q.C.:

Q. Thank you.

(BREAK)

THE COMMISSIONER:

Q. Please be seated. Mr. Coffey?

COFFEY, Q.C.:

Q. Yes, Doctor, Commissioner, I have looked at the list I'd made, and Doctor, Commissioner, if I could ask several more questions.

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They're brief. They cover certain things off.
THE COMMISSIONER:
Q. Shouldn't have given you that break, Mr. Coffey.
COFFEY, Q.C.:
Q. Exactly. Thank you, Commissioner. Doctor, the Commissioner has heard evidence that there was a briefing note prepared by Cabinet Secretariat, dated August 18th, 2006. Okay, I'll just let you know that, okay. In the briefing note and in the drafts leading up to it, there's a reference to, I believe the words used are "22 patients were affected" and "22 patients were greatly affected." Okay, that's depending on which draft. You just raised your eyebrows. You're puzzled?
DR. DENIC:
A. Right.
COFFEY, Q.C.:
Q. So I wanted to ask, were you ever consulted, in the summer of 2006, the spring or summer 2006, about how many patients were affected or greatly affected in relation to this?
DR. DENIC:
A. No.

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COFFEY, Q.C.:
Q. Okay, I wanted to ask because you were clinical chief at the time, and I thought I'd ask.
DR. DENIC:
A. No.
COFFEY, Q.C.:
Q. Doctor, you've already referred to the fact that you did read the second reports, the '06 external review reports to the small group. Have you ever read any portion of the external review reports to a larger group of pathologists?
DR. DENIC:
A. Yes, I did.
COFFEY, Q.C.:
Q. Okay, could you tell the Commissioner, please, about that?
DR. DENIC:
A. That happened in December of 2007 when these two reports became the centre of attention for everybody, whether or not these are peer review documents, are they protected by the Evidence Act. So at that time, I did read a portion of it, of Dr. Banerjee's report to the

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pathologists.
COFFEY, Q.C.:
Q. The October 17th, 2005 one? That's the first report, Dr. Banerjee's first report. Was it his first or second report?
DR. DENIC:
A. The first one.
COFFEY, Q.C.:
Q. First one.
DR. DENIC:
A. The first one.
COFFEY, Q.C.:
Q. Do you recall which portion?
DR. DENIC:
A. I think these are a few paragraphs at the very end where he said -
COFFEY, Q.C.:
Q. Exhibit P-0046.
DR. DENIC:
A. - what went wrong or what was the--what are the flaws, or he's using different terms.
THE COMMISSIONER:
Q. We'll bring it up now and you can look at it.
COFFEY, Q.C.:
Q. Yes, Doctor, yes, you'll be able to look at it

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here. This is--so that's the background, the incident problem case, review of cases, literature review, literature review again, choice of antibody, inter-laboratory variability, conclusions about the reasons for test failure, other system flaws observed, and then recommendations. So do you recall which? You take your time and look, Doctor, if you want.
DR. DENIC:
A. Could you go further up? You can stop there for a second.
COFFEY, Q.C.:
Q. Sure.
THE COMMISSIONER:
Q. You do have a mouse there in front of you, you can scroll yourself, Dr. Denic.
DR. DENIC:
A. Oh, yes, okay. I got used to it because -
COFFEY, Q.C.:
Q. I've been doing it. Fine, Doctor.
DR. DENIC:
A. It said there's a problem with the fixation.
COFFEY, Q.C.:
Q. That's paragraph three.

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DR. DENIC:

A. Three, and "there appears to be inadequate attention paid by the grossing pathologists to the thickness of the tissue slice, quality and adequacy of fixation, and there's no standardized fixation protocol that everyone adheres to." That was the paragraph three. That's what I read.

Paragraph four, "inadequate or no attention is being paid by the reporting pathologists to the status of internal controls with inappropriate, exclusive reliance on external positive controls. Negative test results, in the absence of positive internal controls, should have triggered corrective procedures, optimization of method choice or better fixed block, choice of a block with the benign duct epithelium included, etcetera, and should not have been released without troubleshooting, and in the event that the poor fixation resulted in internal control failure in all available blocks, it should have been noted in the reports as an interpreter causes due to the failure or absence of internal controls."

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Number seven, I think I read, "inappropriate choice of blocks with no representative normal ductal epithelium."

COFFEY, Q.C.:

Q. That's paragraph C.

DR. DENIC:

A. And "better education requiring for technologists, pathologists, clinicians, about the pitfalls of immunohistochemistry, the importance of the quality control interpretation in immunohistochemistry results." So these are the paragraphs that I read to the pathologists on the meeting.

COFFEY, Q.C.:

Q. This is a program meeting of the large group?

DR. DENIC:

A. That's a program meeting.

COFFEY, Q.C.:

Q. Did you have anyone's permission to read them? Did you ask anybody's -

DR. DENIC:

A. No.

COFFEY, Q.C.:

Q. Okay, and your purpose in doing so was?

DR. DENIC:

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A. To consult my colleagues, because I think I was asked first whether I think that this is peer review document, and while at the time I never objected to this document being presented to you, so that you guys see the scope of the problems, we were thinking that these documents are protected and they are peer review based on what's written inside. So I consulted my colleagues and I read them this and asked for their opinion, and their opinion is as well that based what's written, this is a peer review document.

COFFEY, Q.C.:

Q. Doctor, if I could have you look, please, finally at Exhibit P-0051? Doctor, you've referred to QMP-LS, December 7th, 2007 visit to St. John's. This is a confidential on-site consultation report by them. It's date and time of on-site consultation is December 7th, 2007. Dr. Flynn, Brian Hewlett and Lori Mason are noted to be the consultants. Dr. Flynn is the team leader. If we go through this, Doctor, it's eight pages long, or actually nine, including the references. Doctor, were you involved in retaining QMP-LS to do this?

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DR. DENIC:

A. Yes, I was.

COFFEY, Q.C.:

Q. And the purpose in doing so was what?

DR. DENIC:

A. To have objective and third party review of our lab, so that we know how we are doing.

COFFEY, Q.C.:

Q. Doctor, and you've already spoken about this, but one thing I wanted to ask you about is this, is has there ever been a list of recommendations, a spreadsheet or a list of recommendations prepared arising out of this?

DR. DENIC:

A. It wasn't, but was a plan. I remember vividly when Dr. Ford Elms told me that he was going to do one, because I suggested to put similar like the one that Mr. Gulliver did it, and that fell obviously out of the track because we went into the period of time that two of us were doing the service for six and a period of time he was the only one doing a service that six pathologists would do. So that fell off of the list then. But recently, I asked Ms. Lynn Wade to help him out to create the list,

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as such, so that we can go item by item.
COFFEY, Q.C.:
Q. Does such a list exist, to your knowledge, as of now?
DR. DENIC:
A. I'm not aware. I've been away for a few days now. It might have.
COFFEY, Q.C.:
Q. So your request was that recent, in terms of -
DR. DENIC:
A. It's a recent request.
COFFEY, Q.C.:
Q. Okay. Well, when -
DR. DENIC:
A. Because he needs help as well. He's very busy with immunohistochemistry. We're still short on staff, very short on staff, again trying to keep the nose above the water and going through all of this, it takes time.
COFFEY, Q.C.:
Q. So when you say recent, that would be within the past, certainly within the past month?
DR. DENIC:
A. Yes.
COFFEY, Q.C.:

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Q. Okay, and there is a plan then to prepare such a list and then to see where you are with it and go through it, you know, step by step?
DR. DENIC:
A. That's correct.
COFFEY, Q.C.:
Q. Okay.
DR. DENIC:
A. And if we can see, the part of this recommendations are really not even close as serious that we had. Some of these recommendations are more--some of them are experimental even, in a sense, where he recommends fixation of certain time and that sort of thing with hopefully one day it becomes obsolete if everybody is using the same fixation protocols.
COFFEY, Q.C.:
Q. So if such a--if when you go back to your office on Monday, or tonight, for that matter, there is a list there or subsequently there is such a list, a spreadsheet, if you could provide that to Mr. Browne or Mr. Simmons or both?
DR. DENIC:

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A. Okay.
COFFEY, Q.C.:
Q. And they can provide it to us, thank you.
DR. DENIC:
A. I'm going to charge Mr. Browne for that.
COFFEY, Q.C.:
Q. Okay. Well, if it's between them, they can figure it out.
MR. BROWNE:
Q. (Inaudible).
COFFEY, Q.C.:
Q. Doctor, Commissioner, in relation to the issue of the remark, the portion of or small portion of Dr. Gown's report we were speaking of earlier, I did have some questions in relation to that. I don't know that we will get to that today. I'd prefer to leave any such questions, it would only be two or three of them, but to leave that until--actually address it at the one time.
THE COMMISSIONER:
Q. All right.
COFFEY, Q.C.:
Q. After examination and cross-examination.
THE COMMISSIONER:

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Q. Well, on the understanding that other counsel may, in fact, have questions arising out of yours related to that.
COFFEY, Q.C.:
Q. Yes, of course, Commissioner.
THE COMMISSIONER:
Q. Yes, okay.
COFFEY, Q.C.:
Q. Thank you, Commissioner.
THE COMMISSIONER:
Q. Thank you.
COFFEY, Q.C.:
Q. Thank you, Doctor.
DR. DENIC:
A. Thank you.
THE COMMISSIONER:
Q. Mr. Pritchard?
MR. PRITCHARD:
Q. I don't have any questions, Commissioner. Thank you for your evidence, Dr. Denic.
THE COMMISSIONER:
Q. Mr. Simmons?
DR. NEBOJSA (NASH) DENIC, EXAMINATION BY DANIEL SIMMONS
MR. SIMMONS:
Q. Good afternoon, Dr. Denic.

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DR. DENIC:
A. Good afternoon.
MR. SIMMONS:
Q. I'm going to pick up where Mr. Coffey left off, with the QMP-LS report that was done in December. Was that report regarded with any degree of confidentially in the way that the reports from Dr. Banerjee and Ms. Wegrynowski were regarded?
DR. DENIC:
A. No.
MR. SIMMONS:
Q. Was that report available to be freely circulated around the lab, used by whoever wanted to see what was in it?
DR. DENIC:
A. That's correct.
MR. SIMMONS:
Q. So whereas for the external review reports, the recommendation spreadsheets were a working document that could be more widely circulated, was there the same immediate need to prepare any such separate set of recommendations from the QMP-LS report?
DR. DENIC:

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A. That's correct.
THE COMMISSIONER:
Q. Sorry, Mr. Simmons, excuse me, I wonder could we get that window--I'm assuming that window is causing this echo, so perhaps if--it might make things a little warm in here, but it'd be easier to hear. Thank you. Now, Mr. Simmons.
MR. SIMMONS:
Q. Thank you. And you told us that the purpose in getting that report done in December of last year was to see where the lab was then in its IHC program. Was it also contemplated, before the report was obtained, before it was commissioned, that it would be provided to this Commission of Inquiry once it was received, regardless of what the content of it was?
DR. DENIC:
A. That's correct.
MR. SIMMONS:
Q. Now I'll go back to the beginning of your evidence, starting yesterday, and one of the first things that you told Mr. Coffey about was that, I believe in June of this year, you had visited Ontario and you'd been to four

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laboratories there.
DR. DENIC:
A. That's correct.
MR. SIMMONS:
Q. Those would have all been laboratories that are accredited under the Ontario Laboratory Accreditation Program and accredited by the QMP-LS program, would they?
DR. DENIC:
A. That's correct.
MR. SIMMONS:
Q. Okay, and did you have--what was the purpose in reviewing those labs? What sorts of information were you looking for when you were there?
DR. DENIC:
A. We were looking, two purpose of this trip was to discuss the organizational structure, is one, and the second one, just to see how they do their quality processes, as such.
MR. SIMMONS:
Q. Okay. Did you make any observations about the organizational structures you found in those laboratories, compared to the program management structure that had been in place

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here and the evolution of that to the current arrangement that exists in Newfoundland today?
DR. DENIC:
A. I was really surprised that I didn't find a difference at all. Being in these laboratories, you can see on the top of the organizational structure is clinical chief and next to it would be manager or, in our capacity, like it would be Mr. Terry Gulliver. So that's something that I found in Kingston. I found that in London and I found the same stuff in UHN, University Health Network. So technologists and pathologists would be in the same box.
MR. SIMMONS:
Q. Okay, and did you get any information from those visits about the effectiveness of that structure at those institutions?
DR. DENIC:
A. They were pleased with the way that--they say they have a cooperation and they are working very well, and it works for them.
MR. SIMMONS:
Q. Okay. The other purpose of your visit was to look at the quality assurance programs and

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systems that were in place at those laboratories, was it?

DR. DENIC:

A. That's correct.

MR. SIMMONS:

Q. Did you find anything there that was helpful or useful information that you could bring back to your laboratory?

DR. DENIC:

A. I think, impression is they have a lot of resources for the quality, although even they complained that they would like to have more people being involved as quality managers, as such. While they are fortunate that they have a provincial body to go to their labs and work with them, I think they find it very beneficial. We even learn, you know, that even those labs have some deficiencies, even the biggest one that we talk about it, they said we had accreditation and they still came with recommendation of such. So this is the daily living. We get a sense that nobody is perfect, in that sense, and everybody has the same goal, best patient care, and do this right.

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MR. SIMMONS:

Q. Okay. You were asked a number of questions about the introduction of ER/PR staining in Newfoundland or the way it was done when you came here, and some technical questions. I had a couple things arising out of that. You had told us that the ER/PR stains are nuclear stains, so that when you look at the slides under the microscope, you're looking for staining in the nucleus of the cell, as opposed to any other part of the cell, correct?

DR. DENIC:

A. That's correct.

MR. SIMMONS:

Q. And you've told us as well that this was probably the first stain involving nuclear staining introduced here in the laboratories in St. John's.

DR. DENIC:

A. Probably.

MR. SIMMONS:

Q. Probably, and my question is, the fact that it is staining in the nucleus instead of some other part of the cell, is that something

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that's particularly new or difficult for a pathologist to adjust to and adopt or do pathologists have to look for staining in other parts of cells in other tests that are done, where they have to make similar types of differentiations?

DR. DENIC:

A. No, it wouldn't be difficult. You just look at the nuclear stain and, because you can see the remaining portion of the cell, and then you look at the nucleus and what you see.

MR. SIMMONS:

Q. So the fact that it's a nuclear stain, as opposed to some of the other IHC stains that were being done, did that add any particular level of complexity that was a problem for pathologists to adjust to or deal with?

DR. DENIC:

A. No.

MR. SIMMONS:

Q. Okay.

THE COMMISSIONER:

Q. Surely, the point is, I mean, whether people remember to look at the nuclear part of the stain or nuclear part of the cell. Isn't that

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the point? Not that it's more difficult to look at -

DR. DENIC:

A. No, it wouldn't be difficulty to look at it. There's some complexity with the staining and such, which makes it more difficult, if you have more background staining, I think, Commissioner, you heard about it.

THE COMMISSIONER:

Q. Um-hm.

DR. DENIC:

A. Sometimes the stain is not--when you are talking about quality assurance and fixing up the stuff, you're trying to diminish or erase the background stainings that can influence your judgement or decision, you know, and sometimes that could be a problem.

MR. SIMMONS:

Q. Okay. The other thing I wanted to ask you about was staining intensity and I'd like to show you a portion from Dr. Ejeckam's second memo, which is at P-0113, please. Okay, and it's the memo of May 2nd, and his point number six here, when he was giving educational information, as you described it, to the

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pathologists, was "higher staining intensity does not reflect better results," and I wonder, my question is does the intensity of the staining affect the interpretation of the percentage of stained cells? Is there any connection of the two, such that a lower intensity affects whether you call the percentage any differently than if the same slide were stained at a higher intensity?

DR. DENIC:

A. No. Even then, sometimes they will put a rider on it, a very weak staining in 10 percent or 20 percent of the test. We know today that intensity doesn't play any role in that matter, and we see that on various, even slides today, that people report minimal staining and they're confident that these are the results that they're expecting.

MR. SIMMONS:

Q. Okay. So in your experience, based on your knowledge, if we had two slides prepared from the same sample, both stained, one with the staining turning out to be intense and the other with the staining turning out to be weak, would you expect that the percentage of

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stained cells would be interpreted differently on those two?

DR. DENIC:

A. No, as long as the percentage of the stains is the same.

MR. SIMMONS:

Q. Okay. So when we see a report that the intensity of the staining has been weak, should that cause us to have any question at all about whether the percentage of staining would have been interpreted correctly or not?

DR. DENIC:

A. Shouldn't be a problem.

MR. SIMMONS:

Q. Should not affect it, okay. I'm going to bring you back to Dr. Ejeckam's first memo here on April 4th, and it was pointed out to you that Dr. Ejeckam noted in this memo that "the stains had remained unreliable, erratic and therefore unhelpful" and you've already been asked a number of questions about that. In your experience, up to this time, up to the 4th of April '03, were you aware of any occasion when any reports would have been unreliable or erratic? And this is, I'm

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drawing a distinction here between the staining on the slide, which then has to be interpreted, and reported, because there's a step between the preparation of the slide and the information reaching the clinician, and that's the reporting by the pathologist.

DR. DENIC:

A. That's correct.

MR. SIMMONS:

Q. So first of all, do you have any recollection yourself of seeing any ER/PR slides that you considered to be unreliable or erratic at this time?

DR. DENIC:

A. No, and I wouldn't report it.

MR. SIMMONS:

Q. Okay, and if you had seen a slide that you considered to be unreliable, erratic or unhelpful, you would not report it?

DR. DENIC:

A. I would not report it.

MR. SIMMONS:

Q. And is what you would do, send it back to be repeated?

DR. DENIC:

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A. That's correct.

MR. SIMMONS:

Q. Okay. So based on this memo that you see here, do you know whether any of those slides that are referred to by Dr. Ejeckam were reported by any pathologists?

DR. DENIC:

A. I cannot be certain for every single pathologist, but my practice, if a slide is unhelpful, I would never issue the report, until I am certain that what I am writing down is right.

MR. SIMMONS:

Q. Okay. In your evidence yesterday, when talking about internal controls, you gave us an example of some retested cases where you had looked at the original slides from the first test, where there had been an internal control present and it had stained positive, but the original patient test result was negative and then when that same sample was retested at Mount Sinai, the patient test result came back as positive. Do you recall mentioning that?

DR. DENIC:

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A. That was a different case. Actually, I think on that particular case, everything was negative, on that particular case what I was referring to.
MR. SIMMONS:
Q. Okay.
DR. DENIC:
A. But it's, everything, internal control was negative, tumour was negative, progesterone was internal control positive, and the tumour was highly positive 100 percent.
MR. SIMMONS:
Q. Okay.
DR. DENIC:
A. When it was repeated, everything came positive.
MR. SIMMONS:
Q. Yes.
DR. DENIC:
A. So that's why I was making--the tissue was well fixed. There was no problem with that, and the only problem was that obviously the antibody didn't fall on this.
MR. SIMMONS:
Q. So do I understand from that that because the

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internal control had stained adequately on the PR slide and that the PR and the ER were stained in the same run on the machine -
DR. DENIC:
A. They could have been stained on the same run.
MR. SIMMONS:
Q. - same run on the machine -
DR. DENIC:
A. They could have been.
MR. SIMMONS:
Q. - that your inference was that something technical had to happen with the ER slide that did not happen with the PR slide to affect the staining?
DR. DENIC:
A. I don't have any different explanation, looking at--you have to give the benefit of the doubt that--we know how many tests went wrong.
MR. SIMMONS:
Q. Yes.
DR. DENIC:
A. But while we didn't retest all of these other people, these tests are random and far in between still. So how that could have been

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picked up, because you have progesterone, there's no fixation, internal control, working fine, and suddenly you have estrogen that even in the low sensitive test, antigen retrieval that was run, would give some results. NEQAS, I think, article sort of reflect of that and said that even low sensitive test--so even if you don't validate, let's say, the test.
MR. SIMMONS:
Q. Uh-hm.
DR. DENIC:
A. If you apply that on a good expressor, and obviously it was a good expressor if you could turn 100 in Mount Sinai --
MR. SIMMONS:
Q. Right.
DR. DENIC:
A. You would expect at least weak staining, 10 percent, 20 percent of the cells, but not nothing.
MR. SIMMONS:
Q. So --
DR. DENIC:
A. So that makes me to believe that fixation is definitely not the problem.

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MR. SIMMONS:
Q. Right.
DR. DENIC:
A. And make me to believe that the solution, which is antibody, never reached the slide.
MR. SIMMONS:
Q. Uh-hm, okay.
DR. DENIC:
A. But the first part of the question, I seen -- during the review of hundreds of this--deceased patients, when Dr. Carter and I did, remarked whether this cases, original cases, have internal controls positive.
MR. SIMMONS:
Q. Uh-hm.
DR. DENIC:
A. There's a list, I think, around twelve cases, they still turn--they had internal control positive, they were called negative; they were negative, and on retesting they turned positive. So even with a positive internal control.
MR. SIMMONS:
Q. Yes.
DR. DENIC:

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A. Which tells you that in certain number of cases--in this particular case, it's twelve, that they reported patients were negative, internal controls were positive. They turn other way.

MR. SIMMONS:

Q. Okay.

DR. DENIC:

A. That makes to me this is a very complex issue.

MR. SIMMONS:

Q. You were shown some minutes from meetings of pathologists in which there was mention of problems with ER/PR testing. One of them is at P-1913, please. This is from March 31st, 2004. Do you know when the Ventana machine was introduced and replaced the DAKO machine and when it was in the process of being validated?

DR. DENIC:

A. I think it was--the Ventana machine was brought 2003.

MR. SIMMONS:

Q. Yes.

DR. DENIC:

A. And it was introduced 2004, sometime summer, or around that.

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MR. SIMMONS:

Q. March, 2004, do you know if that was the time period when the Ventana System was still being validated before being put into use for reporting patient slides?

DR. DENIC:

A. That was my understanding.

MR. SIMMONS:

Q. That's your--okay, and we've seen other evidence to suggest that this is at the end of the validation period for that machine. On these minutes, these are minutes of the site chiefs and divisional managers, although it's three pathologists present, Mr. Dyer is absent on that day, and in 4.2 it says, "The immunoperoxidase stainer appears to be working generally well. However, there continues to be some problems with estrogen and progesterone receptors". Do you know whether this is a reference to the validation process or to the production of patient slides?

DR. DENIC:

A. I really don't know.

MR. SIMMONS:

Q. Okay. 1876, please. This is another set of

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minutes you were shown, this time from April 25th, 2001, a meeting of Dr. Cook, Dr. Parai, Dr. Haegert, Mr. Gulliver, and Mr. Murphy, and there's a reference - I'll try again here. Yes, in business arising, Item #2, "Quality control of immunoperoxidase staining. Generally, the immunos appear to be very good. There appears to be some problems with the estrogen and progesterone receptors", and I believe you were asked about this, and if I recall correctly, you weren't able to add anything to what was in these particular minutes?

DR. DENIC:

A. No.

MR. SIMMONS:

Q. Dr. Cook was also asked about this, and what he said was that he thought this related to turnaround times. Does that trigger any recollection on your part?

DR. DENIC:

A. I can't reflect anything to this statement here. It may or may have not. I don't know about it.

MR. SIMMONS:

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Q. Fine, thank you. You were asked a number of questions about the communications between pathologists and oncologists particularly in relation to communications about the cutoff dates for positivity and negativity of the ER/PR results, whether it would be 10 or 30, and whether the oncologists would understand the way the pathologists were treating it. The first question is, now with the type of rounds and working groups exist today, is that the sort of issue that would now come to a table where the pathologists and the oncologists would have a clear understanding of how each were regarding it?

DR. DENIC:

A. Certainly. Since we have the breast disease site group, that is the forum actually to discuss anything related to the breast patient care.

MR. SIMMONS:

Q. Uh-hm.

DR. DENIC:

A. And in one of the meeting, I think, in December of 2007, I brought up to this table as well our stance towards the cutoff.

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MR. SIMMONS:
Q. Uh-hm.
DR. DENIC:
A. And I expressed in my opinion and what's going to be the policy of the lab really, that they should understand that they think the cutoff from the lab perspective should be 1 percent, and reason for that is two-fold. One, it's already been written in the literature that patient can benefit being 1 percent positive from Tamoxifen, and while they can fall into the group of so called low expressor, they can still benefit from it. The other thing is that through the literature you find there's still inter-laboratory variability, especially in this group of low expressors. So sensitivity in my lab not necessarily going to be the same sensitivity of the test in your lab or somebody's else lab. So from that perspective, we should be cognitive, you look at 1 percent as such and--because if the patient fall into the group of 7 percent, you shouldn't be denying the therapy because it's, for example, below 10 percent, because in Mr. Coffey's lab, it could be 12 percent. This is

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--we saw that, and I think the Commission also saw through the spreadsheets that even in Mount Sinai, which we're using as a gold standard, if they repeat the test on the same block and the same tissue, they may get different results as well. Having said that, it is of note of the complexity, and the issue is that we do ER/PR, we do that on a single slide which was cut five microns, and a micron is 1000 part of the millimetre, and represent the positivity or negativity of entire tumour, which is usually three to five centimetres. So where that brings us? How much we really exam of the tissue of a single patient. So probably for the five centimetres tissue, if you wanted to be 100 percent sure that this patient is negative, you will have to probably examine 10,000 slides and that would be the lifetime of one pathologist.
MR. SIMMONS:
Q. So the breast --
DR. DENIC:
A. So in that context, when you look at all of this, I think we should be working on a lower threshold, but again oncologists, they have

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their own criteria. They are looking at the patients that are presented in front of them, and they are looking at various parameters as such, and that's why it's left to them as well to make that kind of decision, and as you can see in the world of oncology, this is also not written in the stone as well. So in some institutions, I think in BC Cancer, Dr. Banerjee told me it's 1 percent. In some other institutions, it's 5 percent, in other institutions it's 10 percent, and these are all evidence-based numbers.
MR. SIMMONS:
Q. So is the breast disease site group then a forum in which the type of information that you've just described is shared with the oncologists who make the treatment decisions?
DR. DENIC:
A. That's correct.
MR. SIMMONS:
Q. Now prior to 2005, you've described that there were periods when there were regularly vacancies among the approved number of pathologists in St. John's?
DR. DENIC:

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A. That's correct.
MR. SIMMONS:
Q. So that the workload had to be shared among the pathologists who were available, and you've also described for us some of the effects of the turnover of pathologists coming and going. Are you aware of whether prior to 2005 there were periods when the oncologists faced the same problems with shortages and turnovers?
DR. DENIC:
A. I was aware of that, and I think I put that in my presentation. They experienced even higher turnover in a certain period of time. I think over 20 oncologists walked in and out of the Cancer Centre.
MR. SIMMONS:
Q. From your observations and your knowledge of that, what effect, if any, did those vacancies among both oncologists and pathologists and the turnover have on the ability to come together in rounds and in forums like the breast disease site group?
DR. DENIC:
A. A breast disease site group, I think at that

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point, didn't exist. I think that was 2006 initiative, but they still had turnover. We are very busy. People are working weekends, they are working after hours. We don't have a --we cannot close the door of the lab, as you know, especially pathology, we don't have any limitations, the tissue is coming. While we have clinicians who can say, okay, I'm going today to see ten patients, and that's the end of the day. We are receiving the tissue from all the clinics, ORs, and nobody is asking can you do it. It has to be processed, it has to be looked after because they're going to arrange the patient to come in seven days or two weeks, so we have to do by certain time. So you really don't have breathing time in between. That's why it's not strange to come on the weekend and to see the pathologists down there. If you go in a parking lot in the evening, while you expect to see probably the most busiest people, surgeons and everything else, and they are still there, their cars, but you can see the pathologists car too. So this is the reality, and that's a great difficulty of organizing everything else,

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meeting on a regular basis, and that's why not every single pathologist goes on every single round. Then certain pathologists like certain rounds, and they have the interest, and they go there and somebody goes there, but you still have to have people to run the lab when those rounds are in place.

MR. SIMMONS:

Q. You've told us a bit about additional staffing, and we've heard from others about additional staffing in the laboratory, support staff. You've told us about secretaries. We heard from others about technologists, quality assurance people who have been at it since 2005, and would it be correct to say that there has been since 2005 a gradual improvement and increase in support staff resources in the pathology laboratory?

DR. DENIC:

A. That's correct.

MR. SIMMONS:

Q. Has that had any impact on the ability to get the standard operating procedures written and done, and anything to do with the fact that we only began to see at the beginning of this

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year, the SOPs reaching the end of the process where they were finalized?

DR. DENIC:

A. It did affect--you know, with the pathologist assistants, for example, pathologists get a little bit more free time, if you will, although there's no such a thing. Now we don't have to do manual grossing. We still have to be available for the pathology assistant and observe what they are doing because eventually we are accountable and responsible for those specimens as well. Then you have a busy day in the frozen section room, and then you come and you read your slides, but there's a certain now slot of time left utilizing the pathology assistants. So that we can look into the policies, procedures, as such, and even--pathology assistants now got involved in this, so we have the lead pathology assistant, and she's writing a lot of policies and procedures that relate to their practice.

MR. SIMMONS:

Q. Is there more capacity now for writing and maintaining and updating things like policies and procedures than there was in 2006 even?

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DR. DENIC:

A. Yes, yes, but we still--we still need extra staff for the quality processes, and just to elaborate on that, we were asking for additional managerial staff who going to be dedicated just for the quality processes, and this is something that again maybe this Commission should address because laboratory medicine is very broad. What we are seeing here is just the pathologists, just a section. We have microbiology, we have biochemistry, we have hematology laboratory, genetics, and then we have additional satellite labs like Carbonear, Clarenville, Burin. We need people, not the technologist is going to be doing their regular job and then, okay, we said it's 10 or 20 percent of your work is going to be dedicated for the quality assurance in the program, that cannot be done. We have to have dedicated people on a daily basis that are going to be monitoring the quality in that particular lab and in that particular section. So we already asked for this additional staff. They haven't been approved yet. I hope that we're going to get them because this is the

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job that any lab can fail if this part is not strengthened because you have to understand that it's difficult for me to monitor directly what's happening 300 kilometres away.

MR. SIMMONS:

Q. Uh-hm.

DR. DENIC:

A. Like, in Bonavista Hospital. So we need to have the personnel, trained personnel, and I know Ms. Lynn Wade is working, and she's excellent communicator and organizing workshops for the people, but you still need people. You need a person dedicated to go around do the check and balances, and also write the policies and procedures, to go in and check is the temperature done, is this recorded, is the occurrence report filled. So you need people.

MR. SIMMONS:

Q. Okay. You described the standard operating procedures as a living document, and by that I take it to mean that it will be always changing?

DR. DENIC:

A. That's correct.

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MR. SIMMONS:

Q. There will always be changes to be made. Quality assurance programs, quality assurance program, does that have the same characteristic as being a living thing in that it will always be subject to re-examination and change and improvement?

DR. DENIC:

A. That's correct. I mean, we're going to revisit them every now and then just to see which one of those is performing better than the others, you know, and we are doing even proficiencies, as you know, at the various labs and we have to weigh now--we have a lot of proficiency done for the ER/PR. I don't think so that anybody in Canada for that matter has so many proficiencies done for the ER/PR, you know, but when you receive the reports and you're looking at the different quality of the reports and you're trying to see what is the best body that can give the best for the money that you're paying, who's going to explain more what the deficiencies, where you can strengthen your system. So this is, again, a living stuff that we're going to revisit every now and then.

MR. SIMMONS:

Q. Okay. We have heard from Dr. Elms, I believe, that one of the other measures that's been taken for ER/PR is to send a representative sample of cases to Mount Sinai for correlation, so that is tested as part of patient care in St. John's, and then those cases are also sent to Mount Sinai and retested and the results compared?

DR. DENIC:

A. That's correct.

MR. SIMMONS:

Q. And have you had occasion to review those results and review those correlations to see what the effectiveness of that has been?

DR. DENIC:

A. Yes, I did, and I think I submitted that as an exhibit, the spreadsheet.

MR. SIMMONS:

Q. That's 2725, please? I won't go through this in detail with you, but I take this to be a list of all ER/PR results performed at the laboratory in 2007 and 2008?

DR. DENIC:

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A. That's correct.

MR. SIMMONS:

Q. And also the ones that were performed at Mount Sinai?

DR. DENIC:

A. That's correct. So you can see that four columns and the one next to each other, ER/PR Health Sciences on the left, Mount Sinai, and PR Health Sciences and PR Mount Sinai.

MR. SIMMONS:

Q. So in any row in which we have an entry for ER Health Sciences and an entry for ER Mount Sinai, the Mount Sinai one represents the correlation testing for the same result from St. John's?

DR. DENIC:

A. That's correct.

MR. SIMMONS:

Q. And without going through those in detail can you tell me what the results have been of that correlational testing at Mount Sinai?

DR. DENIC:

A. Correlation is excellent. If you can just go to the last page?

MR. SIMMONS:

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Q. Sure.
DR. DENIC:
A. Okay, I don't know who's moving now. Okay. This is the summary, actually, what we did so far in this period of time, 2007, 2008 from the moment we started to the moment that we stopped. We in house did 217 tests and those ones that we sent for the quality assurance program are to Mount Sinai 45 cases, which represent 21 percent.
MR. SIMMONS:
Q. Um-hm.
DR. DENIC:
A. We never thought about it before that this number is going to be this high. We were thinking maximum 10 percent of the cases to be sent. But anyway, I am pleased that we did what we did. And you can see that the first ER positivity in this period of time, when we started, 78 percent, so it still falls into the almost into the middle of what was recommended.
MR. SIMMONS:
Q. Okay, good.
DR. DENIC:

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A. And the correlation is very good, I think, except for one case and that one case is, that's a case that I think I mark here, if you can see the case SS3677-08.
MR. SIMMONS:
Q. That's on page five.
DR. DENIC:
A. On page 5. We reported estrogen receptors zero, Mount Sinai reported 30; progesterone reported zero, Mount Sinai reported zero. So the problem was estrogen receptor. While this is a quality assurance part of that we did it, I did review the slides and both slides, because we got back the slide stains from the Mount Sinai, as well. Our original slide and Mount Sinai slide, they show extremely weak positivity of the nuclear in both cases.
MR. SIMMONS:
Q. So they look the same to you?
DR. DENIC:
A. They look the same to me. So now we have the interpretive difference between two experts, really.
MR. SIMMONS:
Q. Um-hm.

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DR. DENIC:
A. And so it wasn't the test itself.
MR. SIMMONS:
Q. So has anything else been done to follow-up on that?
DR. DENIC:
A. And so what I did, actually, because this patient, in particular, because I followed this with Dr. McCarthy, she had a previous biopsy done, as well, an the biopsy was performed and she was--she had some positivity of ER and she was treated with the hormonal therapy at that time.
MR. SIMMONS:
Q. Um-hm.
DR. DENIC:
A. This is her recurrence.
MR. SIMMONS:
Q. Um-hm.
DR. DENIC:
A. And that she reported on her recurrence, that's where we see this discrepancy. So I contacted Dr. Joy McCarthy, I discussed the results and I say is any of this means anything for this particular patient because

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she was already given hormonal therapy. And she told me that it might. And I said, okay, since we have two different opinions and I see why it's a different opinion, because the people say this is black and white science, it's not, this is reporting by two experts.
MR. SIMMONS:
Q. Um-hm.
DR. DENIC:
A. I decided to send it to Sunnybrook and I'm still waiting for results that might be even on my desk.
MR. SIMMONS:
Q. So we will see, you'll see eventually what the results Sunnybrook -
DR. DENIC:
A. We're going to see eventually. And this is not to say that one person is wrong and another one is right.
MR. SIMMONS:
Q. Yes.
DR. DENIC:
A. This is not the purpose, because these are interpretative problems even today in this field in the people who are well trained.

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MR. SIMMONS:
Q. Yes, okay. I have two other points just to ask you about. One concerns the--concerns external review reports. And it's not these particular reports, as such, it's more a matter of the principle of having someone come in and do an external review of a program. The idea of such a review would normally be to present recommendations for improvement and they are called recommendations. And I wonder if you could tell me what your view is on how closely you would be bound to follow such recommendations or whether you bring your own judgment to bear when it comes to assessing and implementing them?
DR. DENIC:
A. My attitude over the recommendation, a recommendation is a good recommendation. I mean, and in a sense I'm very glad that these people came to revisit while the circumstances are not pleasurable because the patients been affected, but I'm glad that they came. And they went through the lab and they made certain recommendations and which I wasn't really surprised because we didn't have any

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kind of accreditation for years. And you know yourself, if your guests are not coming to your place, you're not vacuuming every single day, so falling through the cracks, really it is possible in the lab that I will have the accreditation process. So I was glad that they came and I took them very seriously. Although in some of these recommendations you have to look reality where we are. Like, subspecializing is good, but I cannot subspecialize with five people and we still have to carry the job. And we do our best as well, as you can see, through our initiative, subspecializing. Unfortunately, living in the environment which is very volatile for the pathologists, so you invest in people today and they are gone next day. So, but still, I welcome that and this is the path that we are going and right now when I'm recruiting, I'm looking for somebody who has a subspecialty training. And there's one of person, actually, and he has a subspecialty in neuropathology. So since we have a single neuropathologist when now she can go on vacation, you know, so otherwise that would be

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a problem.
MR. SIMMONS:
Q. Okay.
DR. DENIC:
A. There are certain recommendations that has to be scrutinized, as well, as such while we--like a Tek Xpres.
MR. SIMMONS:
Q. Um-hm.
DR. DENIC:
A. And I decided no matter what I'm not going to start with it now, you know, just because I have my ideas and I heard about and we even realize that even people who recommend Tek Xpres to be used, they got rid of it. So everything has to be processed and put in a place.
MR. SIMMONS:
Q. So it's not -
DR. DENIC:
A. There are certain things like refrigeration now, refrigeration be brought, refrigerator and we are using refrigerator. But then you come up with the article written by the College of American Pathologists, actually,

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it's like QA stuff and the people are asking should we refrigerate the tissue.
MR. SIMMONS:
Q. Um-hm.
DR. DENIC:
A. And that tells you refrigeration has a detrimental effect on fixation. I think that's one of the exhibits that I submitted. So there's a lot of information around that has to be processed and really we have to choose the best of them. And I think most of these recommendations are very good recommendations and we acted upon. And I am pleased that they came and they did what they did.
MR. SIMMONS:
Q. Okay. Good, thank you. The last thing I want to ask you about is that you mentioned that there have been requests for retests from patients who had originally positive results?
DR. DENIC:
A. That's correct.
MR. SIMMONS:
Q. And have you seen the results of those retests?

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DR. DENIC:
A. Yes, I have.
MR. SIMMONS:
Q. And have any of those changes from a positive to a negative?
DR. DENIC:
A. No.
MR. SIMMONS:
Q. Okay.
DR. DENIC:
A. None of them.
MR. SIMMONS:
Q. Thank you, Dr. Denic, I don't have anything further.
DR. DENIC:
A. You're welcome.
THE COMMISSIONER:
Q. Thank you, Mr. Simmons. It's kind of the end of the day. Why don't we do the rounds of the room and see how much time we're going to need on Monday? Mr. Pritchard?
MR. PRITCHARD:
Q. We have no questions, Commissioner, thank you.
THE COMMISSIONER:
Q. Ms. Newbury, sorry? It is the end of the day.

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MS. NEWBURY:
Q. About 15 minutes.
THE COMMISSIONER:
Q. Fifteen?
MS. NEWBURY:
Q. Yes.
THE COMMISSIONER:
Q. Ms. Brocklehurst?
MS. BROCKLEHURST:
Q. We have no questions.
MR. PIKE:
Q. No questions.
THE COMMISSIONER:
Q. Mr. Pike? Mr. Browne, are you able to estimate?
MR. BROWNE:
Q. I was starting around 20 minutes. Mr. Simmons was kind enough to reduce that, I would say about ten.
THE COMMISSIONER:
Q. Okay. So we're looking at a stated half an hour. I will tell you now don't trust them.
DR. DENIC:
A. Don't trust the lawyers.
THE COMMISSIONER:

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Q. No. Half an hour grows. But we should be able to certainly complete with this witness before the break on Monday morning and get on to the next witness. Mr. Coffey still has to deal with the question of his application, however. Okay, we'll adjourn until Monday at 9:30.
DR. DENIC:
A. Thank you.
THE COMMISSIONER:
Q. Thank you.
Adjourned.

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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 12th day of September, 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 12th day of September, A.D., 2008
Judy Moss

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