COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 28, 2008

Appearances:

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Blair Pritchett. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

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DR. BEVERLEY CARTER - AFFIRMED

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COFFEY, Q.C.:
Q. Thank you, Commissioner. Good morning. Good morning, Dr. Parai.
DR. S. PARAI:
A. Morning.
COFFEY, Q.C.:
Q. Now we'll be able to hear each other, I hope. Registrar, could we see Exhibit P-0113, please? Doctor, this is Dr. Ejeckam's memo of April 4th, 2003, and of course, it's to pathologists at the Health Sciences Centre, which would have included yourself, and you were the site chief in any case. Doctor, I'm going to ask you, please, first of all, we understand Dr. Ejeckam came to the General Hospital in 2002.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Could you tell us, please, what, if anything, you learned about his background at the time?

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Did he have any particular interest in IHC, and if so, what you learned about it?

DR. S. PARAI:

A. I know his background. He was trained residency training in pathology, Ottawa University, and then he worked some time at the Grace General Hospital in St. John's before he went to Nigeria and then to Middle East. When he applied for the position of staff pathologist at the General Hospital, would be latter part of 2001.

COFFEY, Q.C.:

Q. Yes.

DR. S. PARAI:

A. And he came for an interview. I was impressed with his curriculum vitae. He's well qualified and experienced pathologist, and he accepted our offer and came to work in General Hospital in September 2002. He had experience in immunohistochemistry and laboratory management, so he was well experienced pathologist.

COFFEY, Q.C.:

Q. Doctor, you indicated that, of course, when he came to be interviewed in 2001, is what you

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recall, from the Middle East, you understood he had experience in IHC. Did you understand in particular what that experience was?

DR. S. PARAI:

A. He was director of surgical pathology at Doha General Hospital and he used to introduce immunohistochemistry in his lab in Doha.

COFFEY, Q.C.:

Q. Then Doctor, we have been told by Dr. Ejeckam that when he arrived, I think if I recall correctly, he arrived around September 2002 at the General Hospital.

DR. S. PARAI:

A. That is correct.

COFFEY, Q.C.:

Q. He's referred to--told the Commissioner about meetings that used to be held weekly involving staff pathologists at the General Hospital, I think on Tuesdays and Wednesdays, I think he referred to.

DR. S. PARAI:

A. You're talking about the pathology rounds?

COFFEY, Q.C.:

Q. Yes, I suspect that what's it was.

DR. S. PARAI:

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A. That was correct.

COFFEY, Q.C.:

Q. Doctor, those rounds, what were they about? Because you were the site chief at the time, could you tell us like how often they were held and what was discussed, what sorts of things?

DR. S. PARAI:

A. There were two rounds in the week. One round was exclusively for lymphoma and in that rounds, we discussed various lymphoma or lymphoid malignancies with immunostains. Now lymphoma is one of the cancer, lymphoid cancer we use immunostain extensively. Many new and common antibodies immunohistochemistry use for long time, more than 15 years in the lab, and there is a good correlation with the flow cytometer to run, which is another marker stain for immunohistochemistry, and the surgical pathology round, we discussed the challenging, interesting, difficult cases weekly, correlation with the immunohistochemistry stain. So these are in brief both rounds.

COFFEY, Q.C.:

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Q. And that was the weekly round for lymphomas?

DR. S. PARAI:

A. Lymphoma, as well as surgical pathology rounds, similar rounds. Challenging cases are discussed with correlation and diagnosis. Immunohistochemistry was also used in that round.

COFFEY, Q.C.:

Q. So just so the Commissioner is clear then, these--there were, in effect, two sets of weekly rounds. One was kind of weekly lymphomas would come up at one of the rounds, devoted to lymphomas. Do I understand that correctly?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And then the other round was a surgical pathology rounds more general? It wasn't lymphomas, it was everything else?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And what sorts of individuals would attend those meetings, Doctor?

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DR. S. PARAI:
A. All the pathologists, pathology resident.
COFFEY, Q.C.:
Q. And that practice of meeting weekly, how long had that been going on for?
DR. S. PARAI:
A. Well, it has been going on long time, since I moved to the General Hospital, it was there.
COFFEY, Q.C.:
Q. So it predated yourself in fact?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, were there any minutes kept of these meetings?
DR. S. PARAI:
A. Initially, there was no minutes, but later on, we started to document the attendance of those meetings and the topics discussed. That came later on.
COFFEY, Q.C.:
Q. Do you recall when it was that that started?
DR. S. PARAI:
A. I don't recall.
COFFEY, Q.C.:

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Q. Had it--do you know if it had started by the time Dr. Ejeckam arrived?
DR. S. PARAI:
A. I don't recall.
COFFEY, Q.C.:
Q. Okay, and Doctor, who keeps those minutes?
DR. S. PARAI:
A. There was no minutes. As I said, there were some -
COFFEY, Q.C.:
Q. Well notes, I suppose.
DR. S. PARAI:
A. Notes. There were some attendance sheets. You will see in some exhibits, I showed some samples of attendance sheet.
COFFEY, Q.C.:
Q. Yes.
DR. S. PARAI:
A. And topics discussed in the back on that attendance sheet.
COFFEY, Q.C.:
Q. So it was relatively informal, I take it, compared to some of the other documents we've seen where--like the site chief's meetings would have an agenda and would have minutes

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and so on.
DR. S. PARAI:
A. It was different.
COFFEY, Q.C.:
Q. Different. Doctor, at these meetings, do you recall whether or not the quality of the IHC stains was ever discussed?
DR. S. PARAI:
A. It was discussed.
COFFEY, Q.C.:
Q. And what do you recall about that? In what context did it arise and what sorts of things were discussed?
DR. S. PARAI:
A. Context would be discussion of a case. Example, if we discuss a lymphoma, we tried to determine what type of lymphoma, was it T cell or B cells, and the immuno marker for T cell or B cell or monoclonal pattern of the lymphoid malignancy would be discussed.
COFFEY, Q.C.:
Q. And would the quality or concerns about the quality of the stains sometimes arise?
DR. S. PARAI:
A. Quality will be discussed as well.

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COFFEY, Q.C.:
Q. And because when we look at this particular memo, this is April 4th, 2003, there are eight stains, IHC stains mentioned here. I understand four of them are lymphoma stains or commonly used for lymphomas.
DR. S. PARAI:
A. That is correct.
COFFEY, Q.C.:
Q. Doctor, so would discussion about, for example, those concerns about those particular types of stains, those four stains, did that arise and what do you recall about that? And in what context would it arise? Would people be complaining about it or expressing concerns about it or what?
DR. S. PARAI:
A. There was no external complaint. We discussed the stain in context with some case and the number of slide would be for those marker as well as control along with those marker and we found some problem with those stains, as well as those corresponding controls.
COFFEY, Q.C.:
Q. What sorts of problems, Doctor?

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DR. S. PARAI:
A. Weak stain, weak control stain.
COFFEY, Q.C.:
Q. I'm sorry, weak control?
DR. S. PARAI:
A. Weak control stain.
COFFEY, Q.C.:
Q. Yes.
DR. S. PARAI:
A. Indicating perhaps stain not working.
COFFEY, Q.C.:
Q. And why is that? Why does that indicate that perhaps the stain was not working, a weak control stain?
DR. S. PARAI:
A. Well, external control is an indicator, whether the test result is working or not.
COFFEY, Q.C.:
Q. And I take it if you think you are utilizing a control tissue that is strongly or should strongly stain and it's weakly staining, that's an indication perhaps that the process is not what it should be, possibly? Is that what you're -
DR. S. PARAI:

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A. Well, we always compare with the control. Intensity is important, and it was not one parameter. Of course, intensity is one of the parameter.
COFFEY, Q.C.:
Q. So Doctor, was the stain or were the slides, the staining of the slides variable at time? Sometimes it would be a particular--for example, here's an example, Doctor. Control tissue, control tissue A I'll call it, one day would stain what you would think would--in the way you would expect, and then a couple of days later, it would stain weakly and then might stain the way you'd expect it again.
DR. S. PARAI:
A. Similar to that.
COFFEY, Q.C.:
Q. That sort of -
DR. S. PARAI:
A. Similar to it.
COFFEY, Q.C.:
Q. - that was happening at times, I take it?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:

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Q. Doctor, there are four other stains mentioned here in this memo. There's the four lymphomas. Were the other stains, other IHC stains, the non-lymphoma stains, were they occasionally discussed in these weekly meetings?
DR. S. PARAI:
A. Yes, it was.
COFFEY, Q.C.:
Q. And were concerns expressed about them at those meetings?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Dr. Ejeckam has--he's also told us that after he arrived and during the fall of '02, if I recall correctly, and the early winter of '03, he recalled at meetings that sometimes people would be expressing concerns about the stains in the way you've described it.
DR. S. PARAI:
A. That is correct.
COFFEY, Q.C.:
Q. Doctor, this expression of concern, how far back did that date?

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DR. S. PARAI:
A. I don't recall, but would be at the mostly early part of 2003.
COFFEY, Q.C.:
Q. Mostly in 2003?
DR. S. PARAI:
A. 2003.
COFFEY, Q.C.:
Q. In particular you remember that?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And with these expressions of concern, would they come from just one pathologist or a number of pathologists?
DR. S. PARAI:
A. Well, not only one pathologist, other pathologists as well.
COFFEY, Q.C.:
Q. Yes, that's what I'm saying. So it wasn't just--it wasn't limited to one pathologist?
DR. S. PARAI:
A. No.
COFFEY, Q.C.:
Q. It was a number of pathologists who would

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attend these?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And it might vary from stain to stain and from week to week?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. That was the--Doctor, as the site chief at the time, did you approach anybody about that?
DR. S. PARAI:
A. Well, we have discussion in our--among our pathologists. The context of the stain, as I discussed, was mainly at the rounds, two rounds in a week, so there was some discussion when we have problem and then we communicated those stain. Dr. Ejeckam was in charge of immunohistochemistry lab at that time and he communicated to the technologists, to the immunohistochemistry lab.
COFFEY, Q.C.:
Q. Doctor, could you tell us, please, how it came about that Dr. Ejeckam, as you put it, was in charge of the IHC lab at the time or IHC

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aspect of the lab at that time? How had that come about?
DR. S. PARAI:
A. When he came to work for the General Hospital, I knew his background and experience in immunohistochemistry. I approached to him, discussed many time to consider take over or look after the immunohistochemistry lab. He showed interest right from the beginning and he said, yes, he could help me in our lab in that area, and in the surgical pathology rounds, Dr. Cook asked him to take over the charge of immunohistochemistry and he gladly accepted.
COFFEY, Q.C.:
Q. And had that occurred before this memo?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. So Doctor, do you recall what then led--first of all, did you know that Dr. Ejeckam--did you have any warning or I shouldn't use the word "warning", any--were you advised beforehand by Dr. Ejeckam that he was going to send out this memo?

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DR. S. PARAI:
A. I don't recall any -
COFFEY, Q.C.:
Q. Heads up, as it were, you don't recall being told in advance?
DR. S. PARAI:
A. No.
COFFEY, Q.C.:
Q. When you received the memo, first of all, I take it then the fact that Dr. Ejeckam, because you associated Dr. Ejeckam with IHC, you weren't surprised that it would come from a doctor like him?
DR. S. PARAI:
A. There was some discussion, as I mentioned, in the meeting rounds that these are the--some of the tests are going wrong and so some discussion were how to inform the lab. So far I recall there was discussion that it has to be communicated to the immunohistochemistry and he was in charge, so this was his--this is the way he wanted to be appropriate to raise the issue.
COFFEY, Q.C.:
Q. And then when you received this memo, Doctor,

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did you act upon this yourself? Did this require anything of you or did you do anything?
DR. S. PARAI:
A. Well, I discussed with him and I thought the memo was what he thought appropriate and I had no problem with this memo.
COFFEY, Q.C.:
Q. Other than Dr. Ejeckam, did you discuss the memo with anyone else?
DR. S. PARAI:
A. Mr. Barry Dyer came, I believe, following day or one or two days to my office and he expressed some concern.
COFFEY, Q.C.:
Q. And do you recall what it was he said?
DR. S. PARAI:
A. Well, he said he was in charge of the immunohistochemistry lab. He was the manager, so a memo of this sort come, it should be from him. He expressed that Dr. Ejeckam has perhaps no authority to write this kind of memo.
COFFEY, Q.C.:
Q. And what did you say to him about that?

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DR. S. PARAI:
A. I discussed with him and I explained that these are the immuno--problem in the lab you got to understand and how Dr. Ejeckam is in charge of the immunohistochemistry lab by the clinical chief, Dr. Cook, so I think he had the authority to write this memo, and I did not see any problem with this memo. It was just awareness to all the pathologists and the staff that something is going wrong. We have to look after it.
COFFEY, Q.C.:
Q. You have to address it, I take it?
DR. S. PARAI:
A. Yes, have to address this.
COFFEY, Q.C.:
Q. Doctor, what then happened in relation to this?
DR. S. PARAI:
A. Dr. Ejeckam took a lot of time over the next following several weeks to correct those deficiency he identified and finally when--and finally it was done.
COFFEY, Q.C.:
Q. And I take it, if we could look then at--well,

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actually, the same exhibit, just page two, the May 2nd, 2003 memo from Dr. Ejeckam to the pathologists in general, and where he writes, "I am glad to inform you that we have rectified the difficulties related to the immunostain of ER/PR and therefore we can now resume requests for these antibody stains. I would, however, like to bring the following information to your attention," and then he lists a number of different things. Doctor, did Dr. Ejeckam tell you again that he was going to send out this memo before he did so?
DR. S. PARAI:
A. We had a lot of discussion, almost every day, after the first memo or even before the first memo. We discussed how to--what are the deficiencies and how to correct it and some recommendation, possible recommendation not to repeat the same deficiencies. So he discussed with me and this memo came out from him and it is a good memo.
COFFEY, Q.C.:
Q. Now, Doctor, this not only advises all the pathologists that they've resumed or are going to resume ER/PR testing, but there are a

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number of other comments here concerning ER/PR testing, and results of the immunostains may be affected by, and he lists "A" through "F", and he goes on at some length. The Commissioner has seen this referred to a number of times now. Doctor, how would you characterize this memo? You've referred to it as a good memo, but what was your understanding of what it was meant to do, to accomplish?
DR. S. PARAI:
A. The way I would read this memo is this is kind of his expertise. He's reflecting in this memo pathologist technical stuff, all people concerned be aware of this, what can affect this test and how to minimize it, or reduce it, or correct it.
COFFEY, Q.C.:
Q. So, Doctor, was it known within the pathologist staff, pathology staff, pathologists on the staff at the time that there were a number of potential problems with ER and PR stains, a number of things you had to look out for or be careful about, which is what he refers to here, significant concerns

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about fixation?
DR. S. PARAI:
A. That was my understanding.
COFFEY, Q.C.:
Q. Yeah, and so the pathologists generally were aware, at least by 2003 were aware ER/PR, in particular, there were certain aspects of it that should be considered very carefully as is set out in this memo?
DR. S. PARAI:
A. He raised something in the first paragraph of this memo that they got to be careful about the tissue fixation and all pathologists who knew this thing, fixation is important and we always practice with the optimal fixation of the breast tissue concerned.
COFFEY, Q.C.:
Q. Doctor, as a site chief, do you know if this was communicated, for example, to the peri-operative staff?
DR. S. PARAI:
A. Doctor Ejeckam communicated. At that time he was in charge of the immunohistochemistry, so I believe he did.
COFFEY, Q.C.:

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Q. Because this is addressed to pathologists. You can see that in the first one after the "to" word, and then he copies it to the site chief, that's yourself, and to Dr. Cook, Barry Dyer, and all technical staff in IHC, but that would not include the operating room staff, peri-operative staff. So do you know if, in fact, they were alerted to his expressions of the caution about the fixation issues?

DR. S. PARAI:

A. I'm not clear what other staff you're asking.

COFFEY, Q.C.:

Q. The peri-operative, up in the PR where the fixation actually begins with the excision of the tissue. Do you know if the OR people were advised of the contents of this memo?

DR. S. PARAI:

A. I'm not aware of that.

COFFEY, Q.C.:

Q. Doctor, just to look back at page one, the April 4th, 2003, memo. At the time -- this is addressed to all of you, all pathologists. These eight stains are listed and he describes them as "Have remained unreliable, erratic, and therefore, unhelpful for diagnostic

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purposes". Would you -- did you at the time agree with that statement?

DR. S. PARAI:

A. Well, it was his memo and I thought myself it was a good memo.

COFFEY, Q.C.:

Q. So with the eight stains at that time, by April of 2003, you understood at least those eight stains could be described, accurately perhaps, described as unreliable, erratic, and unhelpful for diagnostic purposes, and it says "remained", suggesting that that had been so for a period of time. This hadn't started, like, the week before.

DR. S. PARAI:

A. I don't know what he meant "remained" or how long. It is not clear from that sentence to me.

COFFEY, Q.C.:

Q. But at the time, from your own knowledge, Doctor, as the site chief, how far back had this problem extended?

DR. S. PARAI:

A. I don't recall how far. We reviewed this thing, I think, one or two weeks, this -- in

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our round, and then Dr. Ejeckam thought it is time to remind everybody, a short period of time, couple of weeks. I think one meeting and then following meeting, we wanted to see whether it is continuing or not.

COFFEY, Q.C.:

Q. Doctor, at the time in 2003 -- before this April 4th memo or, in fact, after it, was it ever discussed by the pathologists, to your knowledge, by any pathologist in St. John's that in light of this statement by Dr. Ejeckam, in light of the underlying facts which is the stains, at least some of them were unreliable at times, was any thought given to going back in time and retesting?

DR. S. PARAI:

A. I was not aware.

COFFEY, Q.C.:

Q. So it didn't come up, it didn't occur to you, and as far as you know, no one discussed it?

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. Doctor, here on page three of the exhibit -- page two of the May 2nd memo, paragraph three,

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there's a reference to internal controls, check normal breast acini in your sections as internal controls, this is a second level control, and he goes on to talk about that. Now were you aware of this before you got this memo?

DR. S. PARAI:

A. This was the first time I was aware of the internal control.

COFFEY, Q.C.:

Q. When you got Dr. Ejeckam's memo, this May 2nd memo?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. At that time, having learned that, that would be in May of 2003, did you discuss that with any other pathologists?

DR. S. PARAI:

A. I don't recall.

COFFEY, Q.C.:

Q. And what I'm getting at is if you hadn't known it yourself, and you indicated you had not known that before, perhaps other pathologists were in the same position. So you didn't

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discuss it with anybody?
DR. S. PARAI:
A. I don't recall.
COFFEY, Q.C.:
Q. Was Dr. Ejeckam's April -- just go back here. April 4th memo, 2003, was that generally discussed amongst the pathologists, the fact that he'd stopped the staining for eight stains?
DR. S. PARAI:
A. I don't recall.
COFFEY, Q.C.:
Q. Okay, the May 2nd, 2003 memo, the one about ER and PR in particular, was that discussed amongst the pathologists, do you know?
DR. S. PARAI:
A. I don't recall.
COFFEY, Q.C.:
Q. Like, for example, at these weekly meetings afterward?
DR. S. PARAI:
A. It came in the discussion in the round, and everybody knew that we stopped those stains, and we are looking for when it is corrected and stain comes. After May 2nd, when the

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stain resumed; yes, we discussed in our rounds and we found it was satisfactory.
COFFEY, Q.C.:
Q. So it was after the May 2nd memo in these weekly rounds that pathologists, it's your recollection, did discuss from their perspective the view that the new slides, the current slides, after May 2nd slides, they were satisfactory?
DR. S. PARAI:
A. Correct.
COFFEY, Q.C.:
Q. But the actual rest of the contents of this memo, and whether or not people were or were not aware of particular aspects of it, was not discussed?
DR. S. PARAI:
A. It was -- this time to time came in the discussion, that was the time, the internal control, and briefly discussed, but I don't recall details.
COFFEY, Q.C.:
Q. Doctor, the June 19th, 2003 memo at page five of this exhibit, and it's Dr. Ejeckam's memo of June 19th, 2003, and it's copied to Dr.

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Desmond Robb, as chair of the Discipline of Laboratory Medicine, copied to Drs. Cook and yourself, Parai, and Mr. Dyer, Manager of Histopathology. Now this June 19th, 2003 memo, had Dr. Ejeckam told you that he was going to send this out?
DR. S. PARAI:
A. So far I recall, he did. We had a lot of discussion about the immunostain, although it was working at that time, and he expressed there is some concern at the immunohistochemistry lab and he explained that in his memo of June 19th, he discussed, and I think it is good advice to that.
COFFEY, Q.C.:
Q. So he told you "I'm going to send out the memo"?
DR. S. PARAI:
A. Well, so far I recall, he discussed the issues to be addressed and I said, all right, okay, and he discussed them briefly.
COFFEY, Q.C.:
Q. Now, Doctor, when you received this June 19th memo, did you do anything about it, did you discuss it with anybody?

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DR. S. PARAI:
A. This memo is addressed to Mr. Terry Gulliver, and follow up discussion with Dr. Ejeckam, I understood Dr. Ejeckam also had a discussion with Mr. Gulliver, and he indicated he's going to address those issues.
COFFEY, Q.C.:
Q. From your perspective as the site chief, how if at all were they addressed?
DR. S. PARAI:
A. We discussed in our rounds sometimes came that we realized at the time what he was talking about, the facility, dedicated histo tech and resources, and we always raised this concern to the division manager, to clinical chief.
COFFEY, Q.C.:
Q. Well, you raised the concerns, and you continued to, you say?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Was it addressed? I appreciate you are raising concerns about it. The people you were raising the concerns with, which would be Mr. Gulliver and Dr. Cook, from your

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perspective, did they actually do anything about it?

DR. S. PARAI:

A. I would say no.

COFFEY, Q.C.:

Q. Did they explain why not?

DR. S. PARAI:

A. They did not explain. Their authority is superior to me.

COFFEY, Q.C.:

Q. Doctor, these three memos, the April 4th, May 2nd, and the June 19th memos, did you ever discuss them with Dr. Williams?

DR. S. PARAI:

A. I did not have any -- I did not have any way to meet Dr. Williams. The divisional structure, as I discussed with you, site chief will report to the divisional chief or clinical chief, and any concern or issue, he will take it to Dr. Williams. I had no reporting mechanism to meet Dr. Williams.

COFFEY, Q.C.:

Q. I appreciate that there was no formal reporting. I'm asking you did you ever discuss the memo or their contents with Dr.

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Williams. It's one thing -- I appreciate not in a formal setting, but did you discuss it with him, do you know?

DR. S. PARAI:

A. Not that I recall.

COFFEY, Q.C.:

Q. Did you discuss this, in particular -- well, either the earlier two memos, the April 4th or the May 2nd one, or the June 19th one with Dr. Robb?

DR. S. PARAI:

A. Well, yes, I discussed with him. He was quite concerned about the facility, dedicated -- all this issue raised in the memo, yes.

COFFEY, Q.C.:

Q. The June 19th memo?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Do you recall if you discussed the earlier two memos or their contents with Dr. Robb?

DR. S. PARAI:

A. Yes, Dr. Robb would have been the chairman of the discipline. We had always discussion with him and advice and feedback.

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COFFEY, Q.C.:

Q. So from your perspective as the site chief at the time this was going on in April and May, Dr. Ejeckam's intervention we've been referred to it as, Dr. Robb knew about it just like you did?

DR. S. PARAI:

A. Oh, yes.

COFFEY, Q.C.:

Q. The June 19th memo itself, Doctor, when you got it and reviewed it, did you agree with its contents?

DR. S. PARAI:

A. When I looked at them I did not -- more or less.

COFFEY, Q.C.:

Q. Was there anything in particular, I'll put it another way, that you disagreed with or would not have endorsed? Just take your time if you want and -- the first part of it where he says he's worked closely with the technical staff in order to rectify the problem. He says, "The state of immunostain at the General Hospital is still unsatisfactory", and he then talks about the physical location being

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unsatisfactory, he wanted a separate room with proper humidity control. Were you in agreement with that, this part?

DR. S. PARAI:

A. Well, the only thing I would say, he mentioned that the state of immunostain at the General Hospital still unsatisfactory, I think that would be some disagreement. It was working.

COFFEY, Q.C.:

Q. Oh, it was working?

DR. S. PARAI:

A. Yeah.

COFFEY, Q.C.:

Q. But he does refer to physical location of the facility is unsatisfactory.

DR. S. PARAI:

A. Yes, that I will agree.

DR. S. PARAI:

A. You agree with him on that?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. "Immunostain is not just another special stain", and he says it's affected by many factors that may apply than in other special

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stains. It's an extremely sensitive procedure. You understood all that?

DR. S. PARAI:

A. I agree with this.

COFFEY, Q.C.:

Q. He says "The staff arrangement as it stands now is grossly inadequate and unacceptable for problem free or minimal problem operation. There has to be dedicated staff".

DR. S. PARAI:

A. I agree.

COFFEY, Q.C.:

Q. You agree. He talks at some length then about the staff. I'm not going to take you through it word for word, but I take it you did agree that there should be dedicated staff and they should have educational opportunities in relation to the staining processes?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. The volume of immunohistochemical procedures continuing to increase, that was so at the time?

DR. S. PARAI:

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A. I agree.

COFFEY, Q.C.:

Q. The end of paragraph four, "Since this is the only centre in the province that performs this test, there is enough case to be made for identifying this activity special and unique, and, therefore, requires financing and staffing".

DR. S. PARAI:

A. I agree.

COFFEY, Q.C.:

Q. And he says at paragraph five, "Because of the other duties of the technical staff, present staff, the other duties that take them away from immunostain fairly regularly, it's virtually impossible for them to devote the time required to master the intricacies".

DR. S. PARAI:

A. I agree.

COFFEY, Q.C.:

Q. Of the procedure. Paragraph six, the second part of it, he says, "Diagnosis based on inappropriate immunostain will surely jeopardize patient care and even expose the Health Care Corporation of St. John's to

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litigation. Therefore, it will be ill-advised to operate unreliable and erratic immunohistochemical procedures in our laboratory", and then he asks Mr. Gulliver to take a hard look at the above and commit the necessary resources. Doctor, did you agree with the assertion that inappropriate immunostain could jeopardize patient care?

DR. S. PARAI:

A. Well, of course I -- yes, I understand that.

COFFEY, Q.C.:

Q. Doctor, I'm going to ask you this, in light of the three memos, April, May and June we just looked at, and at the time as a site chief, what was your understanding of how far up in the administration they were aware, people had been made aware of this problem and its potential ramifications? I mean, I appreciate you knew that Dr. Cook new.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And Dr. Robb.

DR. S. PARAI:

A. Dr. Cook, Dr. Robb, Mr. Terry Gulliver, Mr.

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Barry Dyer and I can't answer whether anybody above our level to leadership knew, I can't answer.

COFFEY, Q.C.:

Q. And I appreciate you can't--because you didn't speak to, for example, Dr. Williams and I understand that. Did you, at the time, as the site chief, make any assumptions about people further up having been notified?

DR. S. PARAI:

A. Well I don't recall.

COFFEY, Q.C.:

Q. Would you have expected that they would be, as a site chief?

DR. S. PARAI:

A. Yes, I would expected, yes. Particularly the third memo from Dr. Ejeckam, these are the recommendations, these are good recommendations, we have to implement in the lab and he was expecting that recommendation. He had a follow-up discussion with Mr. Terry Gulliver and after that, we discussed--and discussion did not stop at June, 2003, and we continued to discuss and Dr. Ejeckam continued to monitor the lab, but nothing happened.

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COFFEY, Q.C.:
Q. Did Dr. Ejeckam ever express to you any thoughts as to how he felt about that, as time went on?
DR. S. PARAI:
A. He was not happy, disappointed, he--what I understood that he wanted those problem be corrected, addressed.
COFFEY, Q.C.:
Q. If I could please, Exhibit P-1576? Doctor, this is a Division of Anatomical Pathology, pathologists' meeting at the General Hospital site, minutes of a meeting of September--well, this is the agenda, page two, the minutes of the meeting of September 24th, 2003. There are a list of doctors present, your name is the last one. Doctor, on paragraph 4.1, Laboratory Technical Quality, "This issue was discussed with Barry Dyer, Terry Gulliver and Dr. Cook. The discussion included the technical quality of the slides, error of labelling, floater and others. Some of these issues have been documented. Doctor Ejeckam has given a lecture on quality assurance of a laboratory which was attended by one senior

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technologist. This program is available for the lab technical staff at a suitable time of interest and a log book is available in the reporting room to record all problems." So, Doctor, I take it then, as you've pointed out, in April, May and June, this didn't end, the discussion about quality issues or concerns, in particular in relation to--well just staining in general, in fact this suggests, was being discussed in September of '03?
DR. S. PARAI:
A. It was discussed in the meeting, yes.
COFFEY, Q.C.:
Q. Doctor, if we could, please, Registrar, Exhibit P-2320? Again, this is an agenda for a meeting of, a pathologists' meeting of the Division of Anatomical Pathology, page 2 on the agenda, page 3 on the minutes on December 11th, 2003. Again, you're listed as present, Doctor; in fact, you called the meeting to order. And, Doctor, in paragraph 3.2, the QA Program, reads "This will be further discussed at the next site chiefs' meeting. After appropriate revision and editing, a booklet will be printed out as soon as possible."

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What was that about, Doctor?
DR. S. PARAI:
A. Basically the QA Program, what we are trying to develop since 2001 is a manual about technical and clinical responsibility and the assurance of the test in the lab.
COFFEY, Q.C.:
Q. The lab technical quality, paragraph 3.3, "a log book for the technical quality is being maintained in the reporting room. Mr. Barry Dyer informed that he is following this log book and taking action." What was that about, Doctor.
DR. S. PARAI:
A. That was a log book we put in the pathologists' reporting room asking the pathologists to put down their comment on the quality of the slice, it's not only H&E stain, immuno stain as well and any recommendation, so Mr. Barry Dyer would look at those log book regularly and take action.
COFFEY, Q.C.:
Q. And, Doctor, here under paragraph 4.5, "Pathologist assistant, pathologist manpower, Dr. Robb discussed in detail the need for

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three pathologist assistants and a new pathologist position. Surgical workload for this site has increased tremendously and a new pathologist in the Division of Anatomical Pathology for the Health Sciences Centre is needed to handle the workload." So this is as the end of 2003, Dr. Robb is still lobbying for pathology assistants?
DR. S. PARAI:
A. Yes, it has been a continue process, continued effort to recruit pathologist assistants.
COFFEY, Q.C.:
Q. And what, if anything, do you recall about what you were told about why that didn't happen?
DR. S. PARAI:
A. So far as I recall, it was a funding problem, lab administration informed us we have no money to recruit such positions.
COFFEY, Q.C.:
Q. And, Doctor, I show you an exhibit, P-1913. Now these are the minutes of a meeting, a site chiefs and divisional managers' meeting of March 31st, 2004. Dr. Cook, Dr. Robb and yourself are present and here, Doctor, on the

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second page of the exhibit under "New Business", paragraph 4.2 "New Technology. The immunoperoxidase stainer appears to be working generally well; however, there continues to be some problems with estrogen and progesterone receptors." Now, Doctor, this immunoperoxidase stainer would have been the Ventana system by this point in time, this is March of '04?

DR. S. PARAI:

A. Yes, I think so.

COFFEY, Q.C.:

Q. Do you recall then what this was about?

DR. S. PARAI:

A. I don't recall any specific problem, I think raised by--I don't recall who raised, however it indicated there are some problem with ER/PR and at that point, Dr. Ejeckam was in charge of the immunohistochemistry lab.

COFFEY, Q.C.:

Q. So certainly this concern about, a suggestion there continues to be some problems with estrogen and progesterone receptors, you didn't raise it yourself because you didn't know that.

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DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. And do you recall--and if we just look back, Mr. Dyer wasn't there and so it's Dr. Cook or Dr. Robb, do you recall who, between the two of them, raised that concern?

DR. S. PARAI:

A. Oh I don't recall.

COFFEY, Q.C.:

Q. Do you recall the nature of the problems being discussed?

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. Now, Doctor, here on paragraph 3.8 "Pathology Manpower". "Two potential vacancies will occur in the spring and summer of this year. Dr. Barron will be switching from hospital base to university base position. Dr. Bev Carter is interested in one of the hospital positions." Now, Dr. Carter was actually already working by this point in time in St. John's, wasn't she? By March of '04, she had been doing locums?

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DR. S. PARAI:

A. I think so, yes.

COFFEY, Q.C.:

Q. Did you understand that Dr. Carter had any particular expertise or training over and above the normal pathologist -

DR. S. PARAI:

A. She had fellowship training in breast pathology, so she had an interest in breast cancer.

COFFEY, Q.C.:

Q. And she was, of course, stationed at, physically at St. Clare's Hospital?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Exhibit P-2406 please? Doctor, these are the minutes of a meeting of Division of Anatomical Pathology, General Hospital site pathologists' meeting of September 1st, 2004 and present are a number of individuals, including yourself. You called the meeting to order. I take it you would do that because you were the site chief?

DR. S. PARAI:

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A. Yes.

COFFEY, Q.C.:

Q. And here, Doctor, in paragraph 3.6, under "Business Arising". "HER2/neu, ER and PR immunostaining, Dr. D. Fontaine"--that would be Dan Fontaine--"did mention that Dr. B. Carter would like to review all the new HER2/neu, ER and PR immunostaining before returning to the reporting pathologists. Some members of the division expressed that this is unnecessary and they will continue reporting their own cases." Now, Doctor, what do you recall about this?

DR. S. PARAI:

A. As I recall that this was not clear whether she wanted--Dr. Carter wanted to report ER/PR and HER2/neu, I don't recall, so far I recall Dr. Fontaine said she was interested to look at the ER/PR staining and assess the quality, so that's what really the first few lines of this memo and then in our division, some pathologists were interested too for the ER/PR reporting and they expressed that perhaps they would like to continue their experience, but there was no opinion that we don't later to

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look at ER/PR and HER2/ neu. It is the reporting I believe they wanted to look at themself and continue, but if she had--she was interested to look at those stains before we report, I don't think anyone was against that. That's my recollection.

COFFEY, Q.C.:

Q. Well what then happened, Doctor, about this issue?

DR. S. PARAI:

A. It was not a clear decision, if you look at from the memo and so, and Dr. Ejeckam was at that time was in charge of the immunohistochemistry lab, so he was in the meeting, I don't know what happened after that.

COFFEY, Q.C.:

Q. Now the problems that had been referred to in the March 31st, 2004 minutes, there continues to be some problems with estrogen and progesterone receptors, how long did those problems continue for?

DR. S. PARAI:

A. I don't recall.

COFFEY, Q.C.:

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Q. Because, you see, if Dr. Carter, as of September 1st, 2004, wanted to look at the ER and PR stains and look at the quality of them, was it still a problem at that time?

DR. S. PARAI:

A. I don't recall. It was not raised specifically in any meeting or informal meeting, discussion. Dr. Ejeckam was in charge at that time in the lab.

COFFEY, Q.C.:

Q. So these discussions about quality of stains which you recall had certainly arisen in the beginning of 2003, before Dr. Ejeckam intervened, you remember those eight stains?

DR. S. PARAI:

A. No, it was in the 2003, not before.

COFFEY, Q.C.:

Q. What I want to ask you about there is this, he intervened.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. The testing of those stains started again in '03.

DR. S. PARAI:

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A. Yes.

COFFEY, Q.C.:

Q. We've seen a reference in March of '04, at least one is minuted at least once, that ER and PR continue, there continues to be problems with those two stains. We just looked at that, March of '04, and now Dr. Carter, in September of '04, is asking to look at HER2/neu, ER and PR stains. So I'm asking you at these weekly meetings or otherwise, were there discussions about concerns expressed by pathologists, even after May of '03, about ER and PR staining?

DR. S. PARAI:

A. Not at the General Hospital Site, we were not doing too many ER/PR at this site, so I wouldn't be able to answer that. Exhibit P-0021 please? Now, Doctor, this is a MAC minutes of their meeting of January 12th--I'm sorry, if we could go please to page 21? These are the minutes of the meeting, Doctor, you'll see it there, of March 16th, 2005, top of the page. Toward the very bottom of the page, "A new site chief, General Hospital, Laboratory Medicine, Dr. Sushil Parai is

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indicated he does not wish to renew his term as site chief of General Hospital site, effective March 31, 2005" and then Dr. Fontaine is noted to have accepted or agreed to become your replacement effective April 1. So, Doctor, can you tell the Commissioner why you didn't want to renew your position as site chief?

DR. S. PARAI:

A. I had a couple of job offer in around that time in the early part of 2005, so I was intending to move to accept a new job in other provinces. And that was the formation of Eastern Health, so there will be, operation would be more wide based, not only St. John's, it will include to Clarenville, Carbonear and so -

COFFEY, Q.C.:

Q. Yes, because as of April 1, 2005, the Health Care Corporation did not exist.

DR. S. PARAI:

A. It did not exist.

COFFEY, Q.C.:

Q. It did not exist as of April 1 and it was replaced by Eastern Health and I take it you

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understood that there'd be changes, would follow that?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Doctor, if we could, Registrar, please, look at P-2407. Now, Doctor, you recognize this type of form. This a Health Care Corporation of St. John's special procedure request form. It's a requisition form for IHC testing. You recognize this type of form?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Okay. Doctor, this particular one on page one of the exhibit has "repeat" written on the top right hand side. Pathologist in question happens to be Dr. Cook. It's December 14, 2000 and the test is estrogen and progesterone receptors and then there are two signatures, Ms. Welsh and Ms. Butler. And the reporting the HER2/neu is the third line. So, this is a repeat here of ER/PR, Doctor, this particular one of a by is surgical number SS420-94. It's quite an older block. Page three of the

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exhibit is same date, different surgical number, SS6278-00, 2000 case, a repeat and again it's for ER/PR, the signatures of Ms. Welsh and Ms. Butler are there, December 19 and probably 27th or so, it's hard to tell.

Now, Doctor, if we go then please to page six of the exhibit, this is a June 6, '01 requisition form SS4023-01 is the surgical number and here it's noted that "ER/PR controls checked by Dr. S. Parai". So, I take it and we can look through a number of these-- I'll just take you to page eight of the same exhibit, hard to know what the surgical number is, but it's something S-805-01, June 7th, '01 and again "ER/PR controls checked by Dr. S. Parai, June 13, '01". So, Doctor, you were, I take it, then routinely checking controls at times, if you happen to be the one scheduled to do so.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. And there's another one for yourself at page 10 and then--here, Doctor, I'm going to put this in context for the Commissioner. At page

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12 of the exhibit is surgical number S2459/01, July 3rd, 2001 and the controls "Des Robb", so Dr. Robb would occasionally be checking them as well, and others.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Is there any particular schedule associated with that, Doctor, in terms of like, whose turn it was or who--first of all, whose turn it was to check the controls for ER/PR?

DR. S. PARAI:

A. There is no particular schedule site chief or on call pathologist or another pathologist. We are working in a rotation, always one member are not present. So, we obtain 11 pathologists and technologists can approach to any pathologists and they would be happy to look at the controls.

COFFEY, Q.C.

Q. Doctor, the checking of ER/PR controls, did the pathologist who, from time to time, was scheduled to do it, did he or she need any particular training in that regard or receive any particular training in that regard?

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DR. S. PARAI:

A. In my opinion, all of them are experienced. They knew how to read ER/PR control. I was aware (phonetic) of any specials training, if you wanted to know.

COFFEY, Q.C.

Q. Page 33, please. Now here, Doctor, this one is June 25, 2001, it's noted, marked repeat and we can see it's an ER/PR, check and see at the bottom. It's repeated, I believe, July 3rd and then repeated on the 18th, probably the 18th, 15th or 18th, 2001. Now, Doctor-- just bring up page 47, please. Doctor, this is an August 6th, 2001 ER/PR test, S2875/01. And it's noted to be repeated here, August 8th first and then August 14th repeated.

Now, Doctor, I can take you through this at some length, perhaps page 50, again. It's hard to know if this one is repeat, but it's August 16th, 2001, surgical number is S10427-01 and there are two signatures at the bottom of the page. It's hard to know in this particular instance whether the second one is for the HER2/neu or is a repeat of the ER/PR. Doctor, we've seen and I can take you through

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it, a number of repeats in 2001 and 2002, noted on these requisition forms for ER/PR, I can take you through them, and there are a number of them. Doctor, were you aware that the ER and PR tests or stains were being repeated in 2001 on a number of occasions and then in 2002?

DR. S. PARAI:

A. Occasionally.

COFFEY, Q.C.

Q. And occasionally, in that context, what did you understand in terms of frequency?

DR. S. PARAI:

A. My understanding was that only a few tests were repeated, but I did not know the number and how often.

COFFEY, Q.C.

Q. Who brought it to your attention?

DR. S. PARAI:

A. I noticed it from these when I was checking controls, but nobody bought it to my attention.

COFFEY, Q.C.

Q. So, you noticed it when you were checking the controls, I take it, you could see written on

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the requisition forms.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. That if you're looking at the controls and you could see that, well this, has already been run before and you were looking at this control for the repeat test and you noticed it. Did you ever make any inquiries about why that was?

DR. S. PARAI:

A. No, I did not make any inquiry. I thought it was--many test we order repeat, it's not only immunohistochemisty, special stain, even H & E too.

COFFEY, Q.C.

Q. Were there any other stains, in particular IHC stains being repeated as often as the ER/PR stain was.

DR. S. PARAI:

A. Yes, immuno stain for lymphoma and immuno stain for sarcoma, immuno stain for melanoma, quite often we did.

COFFEY, Q.C.

Q. Now, Doctor, did you ever order or re-order

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any of these tests yourself, ER/PR?

DR. S. PARAI:

A. I don't recall.

COFFEY, Q.C.

Q. Was it ever brought to your attention that upon repeat testing that there was a different result?

DR. S. PARAI:

A. I don't recall. Is the question, you mean, a even different result means a--can I ask you--whether it is in the control or in the test slide?

COFFEY, Q.C.

Q. Well, Doctor, the test slide -

DR. S. PARAI:

A. Or both?

COFFEY, Q.C.

Q. The test slide, first of all.

DR. S. PARAI:

A. I do not recall, I was not informed.

COFFEY, Q.C.

Q. Okay. How about both controls, the different result.

DR. S. PARAI:

A. If the control had difference result, the

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negative control would turn to positive, but when there was any negative control, there will be no reporting on -

COFFEY, Q.C.

Q. The first test.

DR. S. PARAI:

A. - test, patient. So, they will stop until the control is repeated and the test is repeated as well.

COFFEY, Q.C.

Q. Now, Doctor, why were these tests being repeated?

DR. S. PARAI:

A. I cannot answer that.

COFFEY, Q.C.

Q. The ER/PR testing. If, for example, the control worked because presumably if the control didn't work, the first tissue slide, patient's tissue slide wouldn't have gone anywhere.

DR. S. PARAI:

A. It is the methodology, all tests and the controls be run in the same environment at the same time with the proper temperature, all the technical details there should be the same

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time.
COFFEY, Q.C.
Q. What I'm asking you, Doctor, is is this, is why if a patient's tissue slide was produced, a control was produced and the control was okay, it went to whomever, it went to a pathologist, what sorts of reasons were you aware of were being given for request repeats of ER and PR? Why were people re-ordering or ordering that it be done again on that particular block?
DR. S. PARAI:
A. I don't understand your question.
COFFEY, Q.C.
Q. Here's an example, I'll just bring one up, page 103 please. This is October 22nd, 2001 it's SS-7453-01. Look down here, Doctor, this apparently was repeated, initially done October 25 and October 29 and then November 1. It's an ER/PR. For example, October 25th, 2001 when Ms. Butler signed this, date completed, she produced a patient's slides and presumably some control existed somewhere.
DR. S. PARAI:
A. Yes.

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COFFEY, Q.C.
Q. Apparently the test got repeated, date completed of the repeat is October 29, 2001. What sort of thing would had to have happened to cause the repeat to be requested? What sorts of problems were pathologists encountering -
DR. S. PARAI:
A. I think it would be helpful if you look at the top of the sheet, mention that the control was very weak, repeat very weak control. So, that's the reason the control repeated.
COFFEY, Q.C.
Q. And then we look back here, Ms. Butler produced, completed it October 29th, '01, sent it out again and apparently had to repeat the test again, and completed that November 1st, 2001. So, Doctor, are you telling the Commissioner that your understanding would be perhaps that the control slides would come back twice of every week, that sort of -
DR. S. PARAI:
A. That's what I would think. As I said before, that until the control is satisfactory, we would not report a test and this is not only

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ER/PR, all the immunohistochemistry and a repeat is not only in the ER/PR, quite often in lymphoma marker and sarcoma markers, some carcinoma and some melanoma marker. So, it is not unusual to have repeat test and control.
COFFEY, Q.C.
Q. Page 110, please. Doctor, this is a request form dated October 24th, 2001, it's repeat PR ER, HSC, the number is redacted, washed off. And we look down through this under comments, "S. Parai, ER/PR" and this is one of those that went through three times, October 30th, November 1 and November, probably, 13th, it's hard to tell if it's the 3rd or the 13th, '01. So, Doctor, an instance where "washed off", what would that deal with?
DR. S. PARAI:
A. It mean the tissue was not enough on the slide, most of the tissue fell off from the slide, maybe there are some. So, that's the way I would think. I haven't seen the slide, so I cannot give it opinion, that would be my assessment.
COFFEY, Q.C.
Q. Exhibit, please, P-2149. Doctor, this is a

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requisition form dated January 28th, 2002, it's ER/PR, you'll see. This is, again, the beginning of January into February of 2002, this test had to be--well it was done and then repeated twice more. Doctor, perhaps I'll just take you to another page in the same time frame, page 8 please? This is March 4th, '02, requisition form dated that, it's from Western Memorial and here, it's on the form that we can see here, M. Butler, March 6th, '02, repeat, P. Welsh, March 14th, '02. There's another one here on page 9 of the exhibit, Exhibit P-2149, March 13th, '02. It's requested by Dr. Denic, it's handwritten in cap, adhered to the bottom left hand side, repeat, and the first test was reported or date completed, March 17th, '02 and then repeated by Ms. Butler and sent out April 3rd, '02. So, Doctor, if we could look please at page 17. Before I go to page 17, page 16 of the exhibit, appears to be June 12, 2002, it's SU3702, I believe, the number, here at the bottom, it's June 14, '02, completed by P. Welsh and it notes under comments, "controls checked by Dr. S. Parai, positive". And then

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page 17, we have a request form dated June 11th, '02, it appears to be probably S845-02, it's from Dr. Baker, a request by him, and we look here at the bottom of the page, we'll see "M. Butler, date completed June 19th '02" It's for ER/PR, and then it's noted here "ER" and then it's "/PR" the PR is scribbled out, so it's just "ER control weak, but still okay. Checked by Dr. S. Parai." Now Doctor, why would you write that the control was weak, but still okay?

DR. S. PARAI:

A. It means that we could--I could still see the nucleus stain and as I mentioned before, there is intensity of nuclear stain. It's a brown black stain, could be weak, moderate and strong. So it means it was weak, but still it is readable, acceptable.

COFFEY, Q.C.:

Q. Doctor, for patient tissue that itself was actually weakly ER positive, could that be then problematic? If the patient S845-02, that patient, this is this particular one right here, if that particular patient's tumour tissue was in fact actually weakly ER

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positive and yet the control slide here which you expected strongly positive was only weakly positive, the control was weak -

DR. S. PARAI:

A. I did not see the patient -

COFFEY, Q.C.:

Q. I appreciate that, but if it was, if it in fact was weakly positive and yet the control is noted here to be weak, is there potential in that situation, if it's sent out, is there a potential for the test process not to reveal the presence of ER in the patient's tissue? Because you've told me earlier this morning that, in fact, if the controls were weak generally the test should be repeated.

DR. S. PARAI:

A. Well, it all depends how weak it is. As I say, it is the relativity; it is the degree of the stain and it is again, interpretation based on our judgment and experience. So I could--the first part what you are talking about, what would be the patient test result, it's hard for me to say, where I did not see that stain slide.

COFFEY, Q.C.:

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Q. Okay. Now here in particular, Doctor, and we just--page 21, please? This is a request form dated June 19th '02. It's for ER/PR and "repeat and send to Grand Falls" is noted here in the comments section. This particular, June 19th, we go to the next page, two pages along, at page 23, it's noted to be repeat. It's dated--original request is June 21/02. Bottom right-hand side, repeat ER and it's reported June 25/02. Just going to go to page 27, July 4th '02, request form. It's an ER/PR test, bottom of the page, "M. Butler, July 11th '02, and repeated P. Welsh, July 16th '02." Page 29 of the exhibit, July 8th '02 is the date of the requisition form. Bottom of the page, Ms. Butler does the test, notes it completed July 12th, repeats it completed July 23rd, and had to repeat, tissue washing off.

So Doctor, in 2002, in the spring and summer, say June, July, August period, were there problems, do you recall, in particular, with ER/PR?

DR. S. PARAI:

A. I was not aware.

COFFEY, Q.C.:

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Q. If we could go back to page 24 of this exhibit, something I wanted to ask you about on this. This is a form dated June 21/02. It's for surgical number S2289-02. The requesting pathologist is Dr. Dalton. If we look here on the side of the page, it says "slides and block returned. Controls checked, KG." We look down here, KG is Ken Green. The next page of the exhibit, June 27th '02 is the requisition form. It's from Western Memorial Hospital. The surgical number is 3998-02. Toward the bottom of the page, it's an ER/PR test. Note here on comments "ER/PR controls checked at Health Sciences Centre. Positive. P. Welsh."

Now Doctor, were you aware, while you were site chief, whether at any time while you were site chief, that the ER and PR controls, ER and/or PR controls were being checked by the technologists and not by a pathologist?

DR. S. PARAI:

A. I was not aware.

MR. SIMMONS:

Q. Commissioner, I think that's stated as -

COFFEY, Q.C.:

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Q. I apologize.
MR. SIMMONS:
Q. (Inaudible).
COFFEY, Q.C.:
Q. The way I--I didn't--were you aware of whether or not that ever happened?
DR. S. PARAI:
A. I was not aware.
COFFEY, Q.C.:
Q. Okay. I'll have to check the record as to whether or not some of the techs actually said they did or didn't, but you yourself are not aware?
DR. S. PARAI:
A. No.
COFFEY, Q.C.:
Q. If it happened, it wasn't supposed to happen? Is that -
DR. S. PARAI:
A. As I said, I was not aware of -
COFFEY, Q.C.:
Q. What was the procedure in relation to that, Doctor? In relation to whether or not the technologists, what they had to do before they sent, for example, the slides back to Grand

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Falls, out to Grand Falls or to Corner Brook?
DR. S. PARAI:
A. As I explained in my last testimony, Friday, that when the control would be ready, when the test would be ready, along with the control, technologists at the lab will check the control and that's the first check and will bring the slide to the reporting room. There was a particular box for controls, and a pathologist will check the control and inform the technologist if the control are all right, so he can send these slides requested from other sites, that could be anywhere outside Health Sciences Centre.
COFFEY, Q.C.:
Q. So they certainly weren't supposed to send them out, if they did? I'm not saying--whether they did or didn't, that's for the Commissioner, finally, I suppose, to decide, but if they--if that did happen, that wasn't supposed to happen? The pathologists were supposed to check them?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:

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Q. But in terms of whether or not there was ever any actual record, any policy to actually record who the pathologist was that had checked them, when the pathologist checked them, there was nothing actually in place formally to do that?
DR. S. PARAI:
A. Who was the pathologist, that was either site chief or on-call pathologist and in their absence, another, any pathologist, but there was no regular roster for that.
COFFEY, Q.C.:
Q. Was there any record for it, though, to be kept of who that was from time to time?
DR. S. PARAI:
A. It was understanding, as I explained last week, that either site chief, on call pathologist -- in his absence, on call pathologist for the day. If on call pathologist sometimes not available because they are busy with something else, another pathologist. So mainly site chief and on call pathologist, and in absence, a pathologist.
COFFEY, Q.C.:
Q. And if that pathologist did not write that

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down or the technologist did not write down who that pathologist was, there would be no record of it, who it was?
DR. S. PARAI:
A. At that time -- our practice has been since I was at the General Hospital even before, that the pathologist communicate verbally to the technologist to keep -- my understanding was they will keep just a check sign or some record.
COFFEY, Q.C.:
Q. But not who the pathologist was?
DR. S. PARAI:
A. They will mention the name of the pathologist.
COFFEY, Q.C.:
Q. In some cases when we look at the sheets, they're there, but quite a number of the sheets don't have any pathologist's name on them as checking the controls?
DR. S. PARAI:
A. I can't comment on that.
COFFEY, Q.C.:
Q. Doctor, for example, on the repeats that you saw, because you've indicated to the Commissioner that at times you'd be asked to

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check the controls and you would look at the requisition form and realize that this had been run before --

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And at times, though, if you looked at the sheet there's no record on the sheets of who the pathologist was that may have checked the controls before you did the first time around.

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. So as the site chief, you would have been aware that if it's being recorded, it's not being recorded necessarily on these sheets somewhere who the pathologist is?

DR. S. PARAI:

A. The second time repeat -- you mean, repeat second or third time?

COFFEY, Q.C.:

Q. Yes.

DR. S. PARAI:

A. Or the first time checked, is that your --

COFFEY, Q.C.:

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Q. Yes, and whose name --

DR. S. PARAI:

A. I don't recall, but whether that repeat was done at the request of a pathologist or not, that -- are you saying they repeat second or third time at the request of pathologist or technologist, first time control is not working? That is not clear to me.

COFFEY, Q.C.:

Q. And who that pathologist was wouldn't be clear to you? Unless you went and actually asked around, you wouldn't know who it was, would you?

DR. S. PARAI:

A. That would be correct.

COFFEY, Q.C.:

Q. Doctor, if we could, please, the ER/PR matter that brings us here today -- because you finished up as site chief, March 31, 2005. Up to the point when you finished up as the site chief, had anyone ever brought to your attention the circumstances of any patient who had had an ER or PR test redone and the results were different?

DR. S. PARAI:

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A. No, not that I recall.

COFFEY, Q.C.:

Q. Was there any mechanism in place to bring that -- to have people aware that if that was to happen, they should bring it to the site chief's attention?

DR. S. PARAI:

A. I would think so. I was not aware of any mechanism in place until there is a call from the clinician.

COFFEY, Q.C.:

Q. Doctor, when then did you first become aware of the matter that brings us here, the ER/PR matter, because it was -- who told you about it and what happened?

DR. S. PARAI:

A. This sort of talk came in July, 2005. There was no official information to me. One day Dr. Cook came to the General Hospital site, that would be late July, and called the available pathologist at the time and he informed that there is a new protocol for ER/PR reporting, and he instructed the guidelines of the ER/PR reporting, and I think that was the first time, end of July. In

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August of that year, August date he send out the memo, that we are not reporting any ER/PR at the site.

COFFEY, Q.C.:

Q. Doctor, had you heard about this informally before?

DR. S. PARAI:

A. Well, I heard rumour. From what I recall, that would have been summer, 2005.

COFFEY, Q.C.:

Q. Do you recall when, Doctor?

DR. S. PARAI:

A. Around July, end of July.

COFFEY, Q.C.:

Q. So the -- Dr. Cook came over at the end of July to the General Hospital site and had a meeting. You just described that. How long before that meeting as it that you first heard the --

DR. S. PARAI:

A. Around the same time, maybe a week earlier.

COFFEY, Q.C.:

Q. Just before that. Doctor, at the time -- were you given to understand at the time you met with Dr. Cook, given to understand anything

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about the time frame they were investigating, any particular year or years they were looking at?

DR. S. PARAI:

A. He was not talking about investigation in July. He was talking about the new guidelines of reporting ER/PR. That's the -- and what is our opinion. That's informal discussion, but they don't mention about the testing.

COFFEY, Q.C.:

Q. Doctor, the rumours then that you heard about a week before, what were people saying at that time?

DR. S. PARAI:

A. The rumour what I heard, one of the tests was done at the General Hospital tested negative ER, became positive in another centre in USA.

COFFEY, Q.C.:

Q. Another?

DR. S. PARAI:

A. Another lab.

COFFEY, Q.C.:

Q. Yes.

DR. S. PARAI:

A. In United States. That was the rumour I heard,

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that our negative result became positive in another lab.

COFFEY, Q.C.:

Q. Upon retesting in another lab?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. That's what you were first given to understand?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And I appreciate, as you say, it's a rumour, just people talking amongst themselves is what you're telling the Commissioner.

DR. S. PARAI:

A. Right.

COFFEY, Q.C.:

Q. Doctor, now you certainly are aware that -- did you ever become aware that that was not the case, that the retest had occurred in St. John's?

DR. S. PARAI:

A. I was not aware. I was not aware at that time.

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COFFEY, Q.C.:

Q. When did you first become aware?

DR. S. PARAI:

A. This is the first time I heard that it was retested in St. John's as well.

COFFEY, Q.C.:

Q. Right now?

DR. S. PARAI:

A. Right now.

COFFEY, Q.C.:

Q. Doctor, you had been the site chief from 2000 through 2005, the dates you've already told the Commissioner about. Did anyone ever come to you in 2005 or since that time, come to you and ask you about what you knew about what went on while you were site chief?

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. So not Dr. Cook, Dr. Carter, Dr. Ejeckam, Mr. Gulliver, Dr. Williams, none of those ever came to you and asked you?

DR. S. PARAI:

A. Except Dr. Ejeckam. Dr. Ejeckam, we are in close discussion since 2002 until onwards, but

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none of the other personnel you mentioned.

COFFEY, Q.C.:

Q. And after this whole retesting effort started in 2005, okay, and you became -- by August you were aware that they were stopping testing locally and they were going to do some retesting. You understood that in August, 2005?

DR. S. PARAI:

A. Yes, and that was as per Dr. Cook's memo.

COFFEY, Q.C.:

Q. Doctor, did you ever discuss that -- this matter then after that point with Dr. Ejeckam?

DR. S. PARAI:

A. No, not that I recall.

COFFEY, Q.C.:

Q. So when you say you talked to Dr. Ejeckam, that would have been since -- when he first came on the staff in 2002, and 2003, and -- well, yes, the 2003 memos and the aftermath of that, you discussed the IHC with him and ER/PR?

DR. S. PARAI:

A. Yes, until July, 2005, yes, we discussed, yes.

COFFEY, Q.C.:

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Q. Had Dr. Ejeckam ever -- other than what you've told us already, did he express any other concerns about ER and PR?

DR. S. PARAI:

A. No, not anything other than his memo and discussion. The only thing I want to mention, the only thing he mentioned, there is inter-laboratory variation of the test, in terms there were variations, so false negative. This is the general discussion, but nothing specifically particular to our lab here.

COFFEY, Q.C.:

Q. Commissioner, if we could take the morning break right now, and I'll come back then and very briefly finish off.

COMMISSIONER:

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

BREAK

COMMISSIONER:

Q. Mr. Coffey.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Doctor, look please at Exhibit P-2408. Doctor, this is a document. It's Hamad Medical Corporation, Quality Control and Quality Assurance,

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Anatomic Pathology, 2004. Just look at the -- it's Quality Assurance and Division of Anatomic Pathology, prepared by Dr. Ejeckam in 1997, and then updated. Doctor -- and effective date, May, 2004. Doctor, had you ever seen this before?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And can you tell us, please, how you came to see it and what, if anything, was done with it?

DR. S. PARAI:

A. Dr. Ejeckam provided me a copy of this -- not this version, previous version.

COFFEY, Q.C.:

Q. An earlier version of the same thing?

DR. S. PARAI:

A. Earlier version.

COFFEY, Q.C.:

Q. Okay, and why was that, why did he --

DR. S. PARAI:

A. We were developing a quality control assurance program for our corporate-wide division since -- started 2001, and we used the College of

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American Pathologist template or protocol, and it was too big program, and Dr. Ejeckam, when he came, he said I have a quality QA program, you can take a look and incorporate some of it. So that was the reason I asked him to give me one, and he did.

COFFEY, Q.C.:

Q. Just a moment, please, Commissioner. Exhibit P-2404, please. Now this document, Doctor, Quality Assurance, Division of Anatomic Pathology, Health Care Corporation of St. John's. Have you seen this before?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And what is this, Doctor?

DR. S. PARAI:

A. This is one of the program -- this is a later version of the program we initiated 2001, as I mentioned.

COFFEY, Q.C.:

Q. In 2001, you indicated the program --

DR. S. PARAI:

A. Yes, but this is a later version.

COFFEY, Q.C.:

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Q. Okay.

DR. S. PARAI:

A. Of the same program.

COFFEY, Q.C.:

Q. Do you recall - I stand to be corrected, Doctor, but I don't think it's dated. Do you recall what time frame this would have been in place, this particular one?

DR. S. PARAI:

A. I don't recall. We have been developing it since 2001, as I said, four or five revisions and additions was done. This is the later version incorporated with a lot of Dr. Ejeckam's reference, and I want to mention is about this QA program are the guidelines of the College of American Pathologists, both Dr. Ejeckam used CAP reference and we did so. So this is the compiled version of what Dr. Ejeckam used, as well as some of the CAP guidelines.

COFFEY, Q.C.:

Q. So this particular version of this grew out of incorporating CAP guidelines and Dr. Ejeckam -- the earlier version of Dr. Ejeckam's document, the one we just looked at?

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DR. S. PARAI:
A. Yes, and which has been edited many times.
COFFEY, Q.C.:
Q. Sure.
DR. S. PARAI:
A. And I can give you a little bit of follow up on that.
COFFEY, Q.C.:
Q. If you would, please, Doctor.
DR. S. PARAI:
A. May I?
COFFEY, Q.C.:
Q. Yes, go right ahead, yes.
DR. S. PARAI:
A. So we are trying to develop -- when I came to the General Hospital, there is no manual of the QA program. There was no written QA program in place in --
COFFEY, Q.C.:
Q. No written? I didn't hear the word, Doctor.
DR. S. PARAI:
A. There was no QA program manual, so - but there is some fragmented manual. So we wanted to compile everything and develop a program for corporate-wide use.

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COFFEY, Q.C.:
Q. Uh-hm.
DR. S. PARAI:
A. And we started 2001 initially CAP program, and when I got Dr. Ejeckam's program, we incorporated, and it is a compiled and concise program. So we developed for our corporation. So at the end of -- I believe when Dr. Carter became the chairman of the QA program, I handed over to her to finalize and implement.
COFFEY, Q.C.:
Q. I'm sorry, when you finished as --
DR. S. PARAI:
A. When it was in the final version in 2004.
COFFEY, Q.C.:
Q. Okay, yes.
DR. S. PARAI:
A. So it was not implemented by the leadership, laboratory leadership. So Dr. Carter became the chairman of Quality Assurance Program around the end of 2004.
COFFEY, Q.C.:
Q. Yes.
DR. S. PARAI:
A. So I handed over this copy to her for

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implementation and follow up.
COFFEY, Q.C.:
Q. And up to the time that you finished as site chief?
DR. S. PARAI:
A. Yes, at that time, as I mentioned, I was contemplating to move to other job.
COFFEY, Q.C.:
Q. Doctor, I believe as of October, 2005, you began to take some annual leave that you had and you were gone then at the end of 2005?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. The last month of 2005. Up to the time that you left, had that document been implemented or a version of it been implemented?
DR. S. PARAI:
A. I was not aware whether it was officially implemented or not.
COFFEY, Q.C.:
Q. Doctor, when you took over then as site chief in 2000 at the General Hospital, was there any similar document?
DR. S. PARAI:

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A. No, there was no such document.
COFFEY, Q.C.:
Q. Now, Doctor, just before we could conclude then, if we could look, please, at Exhibit P-1936, page eight, please. Doctor, these are notes of Dr. Cook, I understand. Here he says, "meeting with pathologists, August 1, 2005". There's a number of doctors listed; yourself, the other Dr. Parai, Dr. Fontaine, Dr. Pirzada, and Dr. Cook. Would this be the first meeting, do you think?
DR. S. PARAI:
A. A meeting of --
COFFEY, Q.C.:
Q. You had indicated there was a meeting, Dr. Cook came over at the end of July. Do you know if it was the end of July or -- I'm not saying it wasn't the end of July, it's just he has a note here, August 1, 2005.
DR. S. PARAI:
A. I can't recall.
COFFEY, Q.C.:
Q. You can't recall. Exhibit P-1994. Doctor, these are notes and text that Dr. Cook provided the Commission with, a meeting of

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pathologists, and there are a number of physicians listed. You are not one of them, okay, your name does not appear here, but it's August 5, 2005, and it does read, "This is a list of some concerns which have engaged -- which have emerged, sorry, during conversations about the current problem. Included are some of our suggestions about how to approach this". Doctor, have you seen this document before?

DR. S. PARAI:

A. No, not that I recall.

COFFEY, Q.C.:

Q. When you met with Dr. Cook at the end of July, toward the end of July or early in August, whenever it was, and you've described that meeting --

DR. S. PARAI:

A. I believe it was end of July, if I recall.

COFFEY, Q.C.:

Q. Yes, and that was the talk - the purpose of the meeting was to tell you about what?

DR. S. PARAI:

A. How to report the ER/PR, a new protocol. That's what I recall, but there are a few

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other issues discussed, but I don't recall.

COFFEY, Q.C.:

Q. Now, Doctor --

DR. S. PARAI:

A. I don't recall there was minutes for that meeting. That was informal meeting sharing some information.

COFFEY, Q.C.:

Q. Now, Doctor, here there is a reference to on this page, Exhibit P-1994, talks about the current problem, an ongoing study, if you look down here, "We should ensure that no bias is introduced into the ongoing study. The purpose is to compare methods and the following are important features", and it goes on from there. Doctor, finally it concludes with, "We are not working in a culture where pathologists feel they are being -- we should not be working in a culture where pathologists feel they're being criticized for past performances. Avoid generalized statements, such as", and it lists three of them here. Doctor, do you recall any such discussions generally at the General Hospital site amongst pathologists?

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DR. S. PARAI:

A. I don't recall.

COFFEY, Q.C.:

Q. What, if anything, did you understand about what was going on in relation to the investigation of the matter in 2005?

DR. S. PARAI:

A. I was not aware of any investigation, so far as I recall, and at that time--that's what I say.

COFFEY, Q.C.:

Q. You were not aware?

DR. S. PARAI:

A. I was not aware of an investigation going on.

COFFEY, Q.C.:

Q. Did you eventually learn?

DR. S. PARAI:

A. I learned when I was in Alberta, when I was in Alberta in 2006.

COFFEY, Q.C.:

Q. Okay, so it was then that you learned about the investigation?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

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Q. Into ER/PR and how extensive the problem might be and what had caused it?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, have you ever seen a copy of Dr. Banerjee's reports? He did two reports.

DR. S. PARAI:

A. Recently, yes.

COFFEY, Q.C.:

Q. Exhibit P-1957. Now, Doctor, this is a copy, we have a couple of different copies of this, of Doctor--my mouse is gone dead. Oh, there it is. Okay. No, my -

REGISTRAR:

Q. Your mouse is not working again?

COFFEY, Q.C.:

Q. It's not working again, no. Wait now, there it is. This is a cover letter. It's generally not working here. It's very delayed.

REGISTRAR:

Q. What page did you want to go to?

COFFEY, Q.C.:

Q. If we could, please, page three? Doctor, this

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is the--just scroll down a bit, please, Registrar. This is Dr. Banerjee's October 17th, 2005 report. So you've seen this recently, the October 17th one?

DR. S. PARAI:

A. Yes, I did.

COFFEY, Q.C.:

Q. And upon reviewing it, Doctor, can you tell us, please, whether or not you take issue with anything or any of the assertions by Dr. Banerjee?

DR. S. PARAI:

A. May I see the--what issue he list?

COFFEY, Q.C.:

Q. Oh yes, I'm sorry, go ahead. Perhaps, in fact, the mouse may work on yours. It just doesn't work on mine, Doctor.

THE COMMISSIONER:

Q. In front of you, there's a mouse. Just under your screen, there's a mouse which hopefully will allow you to control that, if you just try that yourself. Does it work for you? Yours is not working either?

DR. S. PARAI:

A. No.

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THE COMMISSIONER:

Q. We have continuing problems with mice around here.

COFFEY, Q.C.:

Q. Okay, Doctor, perhaps we could just scroll down slowly through this for the Doctor and you watch the screen, Doctor, and see then--he says--go back up a bit, please, Registrar. It begins with background and then the incident problem case. You'll note that in the incident problem case, in the first paragraph there, Doctor, he says that "when retested in 2005 on the Ventana Benchmark, the case of the patient with invasive lobular carcinoma, that patient was strongly positive for both receptor proteins." So the test was redone in St. John's, and that's Ms. Deane's case. It refers to four other patients having been retested. It goes on then to a review of cases and he notes that "all of the cases that had converted from negative to positive by switching platforms had one or more of the following characteristics: 1. poor fixation; 2. negative internal controls; 3. absent internal controls. It is apparent that too much reliance is being placed on external positive controls with no attention paid to internal controls." So did you take any issue with any of that, Doctor?

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DR. S. PARAI:

A. Well, I have some issue, review of the cases starting from there. Now what he mentioned, he's reviewed some of the cases from 2002.

COFFEY, Q.C.:

Q. Yes.

DR. S. PARAI:

A. He did not mention how many cases, and did he review any cases before 2002? Did he review 1997 cases or 2005 cases? So I don't want to--I don't know what you are saying on how many cases, so there is a number and the year concerned, and secondly, the poor fixation, what poor fixation? I did not review these cases with him, so I could not say what he was talking about poor fixation. But my question here is that if there is poor fixation in our lab, there are eight laboratories in the province and the retesting done since 1997 to 2005, how come all of them, they found poor fixation? How come all the lab can make the similar error? So some of the issue is still not clear to me, and when they retested in Mount Sinai from '97 to 2005, what happened to test patient's slide? Did they find any fixation problem there? If there, how did they interpret it? So these are the few things not clear to me.

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COFFEY, Q.C.:

Q. Doctor, you would--you do--or would you agree, I'll ask you, put it to you this way, that it's quite possible to have, in any ten patients, eight of them, there's no problem with fixation and two there might be?

DR. S. PARAI:

A. I can't say, until I review the slide myself.

COFFEY, Q.C.:

Q. No, I appreciate that, but that's--it would be quite possible to happen, couldn't it?

DR. S. PARAI:

A. I can't say.

COFFEY, Q.C.:

Q. Well, Doctor, for example, if nine patients out of ten, if nine of them are properly--tissues dealt with appropriately, but one of them, it isn't -

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DR. S. PARAI:
A. It is possible.
COFFEY, Q.C.:
Q. It's possible, isn't it?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. So the idea that there might be poor fixation in particular cases would not be surprising to you?
DR. S. PARAI:
A. No.
COFFEY, Q.C.:
Q. Did you, at the time you were site chief, have any understanding that there was generally a problem or potential problem with fixation?
DR. S. PARAI:
A. No, I was not.
COFFEY, Q.C.:
Q. How often were problems related to fixation brought to your attention?
DR. S. PARAI:
A. Nobody brought to my attention, but I found that sometimes there are fixation problem. This is not only in breast particularly, other

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tissue as well, particularly lymphoid tissue, carcinoma of colon, carcinoma of kidney. So always it has been an issue, but nothing major.
COFFEY, Q.C.:
Q. What, if anything, was done to address the problems?
DR. S. PARAI:
A. Well, if there would be some fixation problem, if we had received a specimen without any fixation from the operating room or the day surgery, we will notify the surgeon. There would be occurrence report that we receive specimen without any formalin and specimen was not in a good condition. That was the standard practice. But if it was received properly in a proper fixative, it would go right.
COFFEY, Q.C.:
Q. Would it be followed up on, Doctor? Would you follow up with the people that you'd send the occurrence report to to ask them, "well, what have you done about it?"
DR. S. PARAI:
A. That would be--this would be filed by the

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technical manager, manager of the lab. It is a technical issue, so I would assume that he would follow up.
COFFEY, Q.C.:
Q. Doctor, he also refers to negative internal controls and absent internal controls. Now you've told the Commissioner that until you got Dr. Ejeckam's memo of May 2nd, 2003, you weren't alert to the potential significance of internal controls for ER and PR.
DR. S. PARAI:
A. Well, everybody knew this internal control would be a useful thing, but not any particular. We did not personally--we did not--well, I cannot speak for everybody. Some pathologists might have been aware of this thing, but internal control has also some drawback with false, too. Completely rely on the internal control is not also safe.
COFFEY, Q.C.:
Q. Completely relying upon it, perhaps wouldn't be a good idea either, but -
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:

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Q. - to rely--but completely ignoring it might not be a good idea as well, which is, I take it, what Dr. Banerjee is referring to here potentially.
DR. S. PARAI:
A. I think he's saying that, yes.
COFFEY, Q.C.:
Q. Doctor, on the--if we could go, please, to the next page, down the page, please? Conclusions about the reasons for test failure. There's a reference to "is the DAKO system faulty?" and then "is the Ventana system too sensitive?" Paragraphs one and two there, you'll see the first one, "is the DAKO system faulty?" and Dr. Banerjee says "this is unlikely" and then "is the Ventana system too sensitive?" and he says "there is no evidence that the Ventana system creates false positive results." Doctor, before you left for Alberta, before you went on leave and then went to Alberta, was there any discussion amongst the pathologists that you were aware of about the involvement, if any, of the DAKO system and the Ventana system in this?
DR. S. PARAI:

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A. I was not aware.
COFFEY, Q.C.:
Q. So did you take part--you would have known after July or in the beginning of August, certainly August 8th, that there was a retest going on?
DR. S. PARAI:
A. Not in August. I don't recall I was aware the retest is going on in July, no.
COFFEY, Q.C.:
Q. No, but in August 2005, did you become aware that they were retesting?
DR. S. PARAI:
A. No, I was busy for my move, so I don't recall. I was aware while I was in Alberta.
COFFEY, Q.C.:
Q. So before you left for Alberta, you weren't aware that they were doing this massive retesting?
DR. S. PARAI:
A. I was not.
COFFEY, Q.C.:
Q. Doctor, yourself, did you have any particular training in relation to IHC?
DR. S. PARAI:

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A. May I--do I understand your question that training in particular IHC area -
COFFEY, Q.C.:
Q. Yes.
DR. S. PARAI:
A. - in the residency or post residency fellowship or any of that nature?
COFFEY, Q.C.:
Q. Yes.
DR. S. PARAI:
A. No, I did not. When I was doing residency, IHC was not there. It was in early '80s, 1980 to '84.
COFFEY, Q.C.:
Q. And since that time, I take it, like ongoing training, have you attended any seminars about IHC in particular?
DR. S. PARAI:
A. That I did. I went to convention, that was the continued medical education, but not a formal training, so that continuing medical education helped me to educate how to interpret IHC. I attended every year to continue medical education, either Canadian Association of Pathologists convention, and

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Clinical--American Society of Clinical Pathologists meeting, and also various Canadian Academy of Pathologists meeting, many national and international convention.
COFFEY, Q.C.:
Q. Doctor, did you ever attend any where you taught to interpret ER/PR IHC?
DR. S. PARAI:
A. It was also there. It was also in a convention, there are so many seminars, so many post start (phonetic) those are the formal talk given by some expert in IHC on ER/PR, yes.
COFFEY, Q.C.:
Q. When was that?
DR. S. PARAI:
A. Well, it was ASCP meeting in Atlanta.
COFFEY, Q.C.:
Q. I'm sorry, when?
DR. S. PARAI:
A. ASCP meeting in Atlanta and in New Orleans, that would be--it is--would be either 2000, 2001. Sorry, 2000 and 2001, both.
COFFEY, Q.C.:
Q. At that time, did they talk about internal

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controls?
DR. S. PARAI:
A. I don't recall any internal control, but I recall that ER/PR was an issue at that time. People would be giving so many papers and showing what are the positive control, what are the test results, so many poster (phonetic) would have been there in those two meetings.
COFFEY, Q.C.:
Q. Okay. Exhibit P-2480, Commissioner, I believe I'd have to ask to enter that.
THE COMMISSIONER:
Q. P-2480, yes, that's not yet entered. Do you want it to be entered now?
COFFEY, Q.C.:
Q. Please, Commissioner.
THE COMMISSIONER:
Q. All right, entered.
EXHIBIT ENTERED AND MARKED P-2480
COFFEY, Q.C.:
Q. If we could open that, please, Registrar? Doctor, this is a certificate of attendance form for 2001 and it's to be completed by yourself as coordinator of the Division of

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Anatomical Pathology and Doctor blank has attended the pathology rounds for a total of, in this particular instance, 22 credit hours, CAP performance improvement program, 20 hours in ASCP, check sample review, four hours. So I take it, Doctor, that you would complete these sorts of forms for physicians working at the General?

DR. S. PARAI:

A. Yes, this is the -

COFFEY, Q.C.:

Q. I'm sorry, go ahead, Doctor, you were about to say?

DR. S. PARAI:

A. As I said, since 2001, I was trying to implement a QA program at the General Hospital particularly, but it was even for the corporate wide. Dr. Cook was involved, Dr. Haegert, Dr. Robb, Mr. Terry Gulliver, Barry Dyer, but QA program has in lab two components, technical component and clinical component. As a pathologist and site chief, my role was to implement the clinical component. So we started rounds, these are the QA rounds and while it is self explained

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what is the sort of program we are doing at the General Hospital to improve for the pathologist QA.

COFFEY, Q.C.:

Q. They're the questions I have, Commissioner. Thank you. Thank you, Doctor.

DR. S. PARAI:

A. Thanks.

THE COMMISSIONER:

Q. Mr. Pritchard?

MR. PRITCHARD:

Q. Thank you, Commissioner. I don't have any questions for this witness. Thank you for your evidence, Doctor.

THE COMMISSIONER:

Q. Mr. Simmons?

DR. SUSHIL PARAI, EXAMINATION BY MR. DANIEL SIMMONS

MR. SIMMONS:

Q. Thank you, Commissioner. Good morning, Dr. Parai. I'm Dan Simmons. I'm here for Eastern Health, and I have a couple things I want to follow up on with you. In 2003, we know that Dr. Ejeckam had done a memo in June, which I gather that you saw at the time, and which you spoke to him about, and that was the memo

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where he spoke of some changes that he wanted made in the immunohistochemistry service. You recall that?

DR. S. PARAI:

A. Yes.

MR. SIMMONS:

Q. And after that, that was June of 2003, were you aware that by the end of 2004, there was a physical move made to move to the immunohistochemistry portion of the pathology laboratory into a separate room in the lab or did that happen after you left?

DR. S. PARAI:

A. So far I recall, it happened later on. The present immunohistochemistry lab -

MR. SIMMONS:

Q. Yes.

DR. S. PARAI:

A. - now look at it, happened later on.

MR. SIMMONS:

Q. Okay. Now, I apologize if I'm unclear of this. Did you leave for Alberta in October of 2004 or 2005?

DR. S. PARAI:

A. '05.

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MR. SIMMONS:

Q. 2005. So were you aware, before you left in October of 2005, that that move had taken place and that the laboratory had moved?

DR. S. PARAI:

A. I don't recall it took place at that time.

MR. SIMMONS:

Q. You don't recall?

DR. S. PARAI:

A. No.

MR. SIMMONS:

Q. Okay. So you weren't aware of that?

DR. S. PARAI:

A. No.

MR. SIMMONS:

Q. And regarding the duties of the three technologists who did the immunohistochemistry work, as site chief, were you very familiar with yourself about how those duties were broken up, what they did at different times and the things were that they did, other than doing the IHC testing?

DR. S. PARAI:

A. Well, this was the responsibility of Mr. Barry Dyer, divisional chief, so I did not pay too

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much attention or interfere there.
MR. SIMMONS:
Q. So after Dr. Ejeckam's memo of June 2003, did you do any follow up yourself to see if there were any changes made in those duties by Mr. Dyer or what those changes were?
DR. S. PARAI:
A. What I understood is that there might have been some change or some move to change those thing happening, but Dr. Ejeckam was in charge, so I did not want to interfere.
MR. SIMMONS:
Q. Okay, and regarding the performance of the testing itself, at the time Dr. Ejeckam wrote his memo in June of 2003, would you have been aware that they were then using the DAKO technology, the DAKO autostainer in order to do the ER/PR and other IHC testing?
DR. S. PARAI:
A. That was my understanding, yes.
MR. SIMMONS:
Q. And was the newer Ventana technology machine acquired before you left for Alberta in October of '05? Did you know whether it was or not?

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DR. S. PARAI:
A. Yes.
MR. SIMMONS:
Q. Yes, okay, and was anything--were you aware of any discussion or any communication from anybody about whether it was expected that that change would have any effect on the quality of the staining?
DR. S. PARAI:
A. There was some discussion with Dr. Ejeckam.
MR. SIMMONS:
Q. Yes.
DR. S. PARAI:
A. But since he was in charge, he was doing all this investigation, all this information, everything in place.
MR. SIMMONS:
Q. So you left it in Dr. Ejeckam's hands then to deal with the issues such as the work of the technologists and how well dedicated they were to IHC, instead of other things, and you left it to him as well to deal with any changes that would result from moving from the DAKO to the Ventana, did you?
DR. S. PARAI:

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A. Well, how it would be done, that would be Mr. Barry Dyer's responsibility, not Dr. Ejeckam's responsibility.
MR. SIMMONS:
Q. So how it would be done would be Mr. Dyer's responsibility, but from the pathologist's point of view, inquiring into what was being done and determining whether it was satisfactory or not, you would leave to Dr. Ejeckam instead of take it on yourself as site chief, would you?
DR. S. PARAI:
A. He would monitor and monitor the clinical aspect of the immunohistochemistry lab. That was his responsibility, not the overall.
MR. SIMMONS:
Q. Okay. So when you say that there was no response to the June '03 memo from Dr. Ejeckam, I presume then you're telling us that you weren't aware of there being any particular response to it at the time, were you? For example, did Dr. Ejeckam or anyone else report back to you that there was a plan to move the lab into its own separate space?
DR. S. PARAI:

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A. I was not aware of.
MR. SIMMONS:
Q. Or was there any report back to you that there was a plan to continue trying to change the duties of the technologists so that they'd be more devoted to the IHC work?
DR. S. PARAI:
A. Well, all I note is that some technologists took special interest. Some pathologists both--sorry, some technologists move from the St. Clare to the General Hospital, but I did not see any plan.
MR. SIMMONS:
Q. Okay, thank you. You were shown some minutes, P-1576, please. These were from pathologists' meeting at the General Hospital site on September 24th '03, and you were shown 4.1 here which referred to laboratory technical quality and some discussions regarding technical quality of the slides, and this was the 24th of September. I'd like to show you a document from the day before, on the 23rd, and it's at P-0113, page eight, please? Thank you. This is a minute from the Surgical Pathology Review Committee and I understand

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you weren't a member of this committee, but you would have been aware that this committee existed and the type of work that it was doing, were you?

DR. S. PARAI:

A. Yes.

MR. SIMMONS:

Q. Okay, and on the previous--Dr. Ejeckam was the chairman of it, and I believe he was at the meeting we just looked at the minutes from, which was the following day on September 24th, and if we look at this, it says, in 2.1 "Dr. Ejeckam stated that the technical problem with staining for ER/PR stains has been solved," and I just wonder if that would help you recall what might have been the discussion on the following day when there is discussion about the staining, and it might help now if we go back to 1576 again, just to look at that in it, and have a look at what the discussion was there and I wonder if that would help you recall what type of staining or issues might have been under discussion then?

DR. S. PARAI:

A. This was not--this was in general stain. All

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the stain, routine H & E, and immuno, all the stains, so far I recall.

MR. SIMMONS:

Q. Not ER/PR staining in particular?

DR. S. PARAI:

A. I don't think it was raised at that meeting. I don't recall.

MR. SIMMONS:

Q. And if you look at that note there, on September 24th, it doesn't appear that there's any particular discussion of IHC staining there either, correct?

DR. S. PARAI:

A. That is correct.

MR. SIMMONS:

Q. Just some questions--oh yes, P-1913 please? These are minutes from March 31st, 2004, attended by Dr. Cook, Dr. Robb and yourself, with Mr. Dyer absent. And you were shown a portion here under 4.2 which is under "New Business". It says "New technology, the immunoperoxidase stainer appears to be working generally well; however, there continues to be some problems with estrogen and progesterone receptors." Would you know whether this was

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around the time of the transition from the DAKO technology to the Ventana technology?

DR. S. PARAI:

A. I don't recall exact timing, but--could you go up and see the date of this?

MR. SIMMONS:

Q. 31st of March, 2004.

DR. S. PARAI:

A. It's around that time, the transition period, yes.

MR. SIMMONS:

Q. Now we understand that this was around the end of the transition period from the DAKO technology to the Ventana technology and the minutes says "the immunoperoxidase stainer appears to be working generally well", so that would seem to be a reference to the new Ventana stainer, and then it goes on to say "there continues to be some problems with the ER and PR receptors." Now are you able to tell us whether those problems relate to the reporting of ER/PR staining on patient tests, or whether that has anything to do with the validation process for the transition from staining on one technology to staining on

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another, or do you know?

DR. S. PARAI:

A. I cannot recall.

MR. SIMMONS:

Q. Okay. You were asked a number of questions about repeated tests and shown a number of requisitions from 2001 and 2002. In the testing in general, not even restricted to ER/PR or immunohistochemistry, but for special stains or even H&Es, are there times when there are repeated tests ordered for various reasons?

DR. S. PARAI:

A. Yes.

MR. SIMMONS:

Q. And would those be ordered because for one reason or another the pathologist is not happy with the first slide that they get and they want to have it rerun so they can get a second slide to look at?

DR. S. PARAI:

A. Yes.

MR. SIMMONS:

Q. In your experience, is that something that would be unique to the General Hospital or St.

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John's or would you know whether that is the type of thing that occurs more generally in other labs, with other pathologists?

DR. S. PARAI:

A. Well I can speak only for our lab, it is not unusual to order repeat stain.

MR. SIMMONS:

Q. Right, and in your lab have you had pathologists who have come--since you've been here, who've come from working in other institutions and other countries and other places and have come into the General Hospital and worked with you?

DR. S. PARAI:

A. I haven't discussed this thing, it is possible.

MR. SIMMONS:

Q. Are you aware if anyone who came from other places ever commented or said this is unusual to have repeats, we don't see them elsewhere or anything to that effect?

DR. S. PARAI:

A. No, it is not unusual.

MR. SIMMONS:

Q. Okay. And when you do get a test slide from a

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patient and you have a control slide to look at, I think you've told us fairly clearly that if you're not satisfied with the control, you don't report the patient slide, do you?

DR. S. PARAI:

A. That's correct.

MR. SIMMONS:

Q. And if the test is repeated and the control was still unsatisfactory, what would you do?

DR. S. PARAI:

A. You repeat again.

MR. SIMMONS:

Q. And do you recall having any occasions yourself with ER/PR testing when you actually had to order a repeat of the ER/PR test?

DR. S. PARAI:

A. I don't recall.

MR. SIMMONS:

Q. Okay. With this type of testing, generally, when you get one that you have to order a repeat on because there's been a, something you didn't like about the control slide, do you generally regard that as being a problem that would require some further investigation or an indicator or something wrong in the

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process or how would you regard a case like that?

DR. S. PARAI:

A. We repeat the stain and if a control is good, working well, then if that's all right, we'll just continue. It is not unusual to have this kind of a repeat.

MR. SIMMONS:

Q. Okay, so is that something that you would regard as somewhat inherent in the process, in the type of testing which is being done, that there will be occasions when a control will not be satisfactory and it will have to be repeated?

DR. S. PARAI:

A. Well I would say we would repeat, but I can't say if it is inherent or not, but it happens.

MR. SIMMONS:

Q. Good, thank you very much, Dr. Parai, that's all I have for you.

THE COMMISSIONER:

Q. Mr. Pritchett?

MR. PRITCHETT:

MR. SIMMONS:

Q. No questions, Commissioners, thank you.

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THE COMMISSIONER:

Q. Ms. Newbury?

DR. SUSHIL PARAI, EXAMINATION BY MS. JENNIFER NEWBURY

MS. NEWBURY:

Q. Good morning, Dr. Parai, my name is Jennifer Newbury and I represent the Canadian Cancer Society, Newfoundland and Labrador division. And I have a couple of topics to talk to you about this morning. First of all, I wanted to know if you felt that external consultations that might be requested pertaining to laboratory test results, pathology test results, would be considered a component of quality assurance or quality control?

DR. S. PARAI:

A. Yes, it is and we have used this external consultation a lot for our lab.

MS. NEWBURY:

Q. And is it considered to be a quality assurance specific to the patient whose results are being reviewed by the external consultant, or is it more of a systemic type of a quality assurance program?

DR. S. PARAI:

A. You mean the particular result or as a group

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of large number of results?
MS. NEWBURY:
Q. I guess my question is this, if you have a reason to request an external consultation from another lab, such as the Mayo Clinic, do you do so only for the benefit of quality assurance for that particular patient, or do you have a program or system in place where you collect and monitor the results of various patient samples that might be sent out for external consultation over the year or do you just look at it on a patient-by-patient basis?
DR. S. PARAI:
A. It is both, it is both for the patient, as well as our learning, we review--when the external consultation record come, we review ourself and compare what they are saying and what we are saying and also sometimes we review with our colleagues to see if there is any new information.
MS. NEWBURY:
Q. Okay, and would that be on an ad hoc basis, say for example you received a result back from the May Clinic, as an example, and the result was different from what had been

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generated from a pathologist at Eastern Health or the Health Care Corporation, is it only when that pathologist decides, well this is an interesting case, perhaps I'll raise this at the next rounds for the surgical pathology, or is there a system in place whereby these types of issues have to be monitors and brought to someone's attention?
DR. S. PARAI:
A. To answer the first, we bring the case and review with other pathologists in our rounds.
MS. NEWBURY:
Q. So it's only basically when a pathologist feels it's interesting or warrants some review that it would be brought to the attention of other pathologists in the institution?
DR. S. PARAI:
A. Yes, yes.
MS. NEWBURY:
Q. And if, for example, you wanted to look at a period of time, say 2001 to 2003, just to see what had been happening over that period of time with regard to external consultations, just to see if there are any trends, is there a means that you can pull, quickly pull out

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all of those external consultations just to look at the data on a comprehensive basis?
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. And how would that be done?
DR. S. PARAI:
A. We can do that, go to the computer and in this context I did review while I was at the Grace Hospital, 10 years, external consultation report and our consultation report and we can compare the result of, between ours and the external consultation. I found it was very satisfactory, error rate was less than .05 percent. It's not error, this comprehensive -
MS. NEWBURY:
Q. Sure, lack of concordance, I guess.
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. And whether or not it's as a result of an error from one of the other--you'd have to analyze that further.
DR. S. PARAI:
A. Yes.

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MS. NEWBURY:
Q. So do you know if that would be something that could be done to look at ER/PR test results over a period of time, would you be able to go through that same exercise just to see how many ER/PR test results had been subject to external consultation, say from 1997 to 2005 and what is the rate of concordance between those results?
DR. S. PARAI:
A. Yes, could be.
MS. NEWBURY:
Q. And who would be responsible for digging out that information? Would you be able to do that or another pathologist there?
DR. S. PARAI:
A. Well we need our secretary, our secretary they can go and find out all this information from the information system. Also the manager can do that, laboratory manager, some people have the access to do that kind of search, not all of them have the information system access to look at those reports.
MS. NEWBURY:
Q. And it's on the Meditec system that they would

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do that?
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. And do you know if that has ever been done with regard to ER/PR testing over that timeframe?
DR. S. PARAI:
A. Well at the General Hospital we did not do that many ER/PR, only few cases per year. I don't recall any study has been done.
MS. NEWBURY:
Q. Okay. You were shown a couple of sets of minutes and I'm going to bring them up quickly for you to refresh your memory. One is at Exhibit P-1876 please? And here, I think it's on the first page, so this is the minutes for April 25th, 2001, anatomical pathology site chiefs and divisional managers' meeting, and there's a note there on page one about, under 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." So that's one of the sets of minutes that I want

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to refer you to. And the second is Exhibit P-1913 please? And these are the minutes of the Division of Anatomical Pathological Site Chiefs and Divisional Managers, and this is three years later, almost, March 31st, 2004 and you've been referred to this a couple of times. And on page 2, under the heading "New Technology", there's a note that "the immunoperoxidase stainer appears to be working generally well; however, there continues to be some problems with estrogen and progesterone receptors." And my question--and I believe that you couldn't recall specifically what those problems were referring to, in either sets of minutes, and it's not described in any detail in the minutes themselves and you can't recall today specifically what the problems were, is that correct?
DR. S. PARAI:
A. Well in the first minute referred, there is some--well as I mentioned before, there was a study going on for the assessment of the immunostain as a whole, not only ER/PR, other stain as well, so we find it, after the study, we found that the immunostain was generally

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good, very good, I think that was the overall, this study came from the ten pathologists, maybe ten or eleven pathologists, not only one single person and their opinion was satisfactory or very good and although also mention that there are some problem with ER/PR and so far I recall, it was positive control was weak, sometime weak, sometime moderate and then after a follow up for another couple of months, in June, I found that that was corrected, it was working satisfactory levels and this, in 2002, diminish what you are showing now.
MS. NEWBURY:
Q. Uh-hm.
DR. S. PARAI:
A. I don't recall what particular issue that was at the time, what transpired, the transition was going on from DAKO to Ventana system and Dr. Ejeckam was in charge of the immunohistochemistry lab, we were quite happy that he was in control and this one I recall one particular issue.
MS. NEWBURY:
Q. Okay, and back to the earlier meeting, April

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25th, 2001, I must have missed your description of it when you were describing that, I think on Friday. I had understood that you couldn't recall specifically what the problem was, but you think that it had to do with the positive control was showing to be weak?
DR. S. PARAI:
A. Occasionally, yes. It was a matter of interpretation, if I say positive, another pathologist would say, no, it is all right, it is nuclear still staining and the characteristic nuclear stain is important, it's not only a few browns, it is a diffuse granular brown black grease or greased stain describe. On the other hand, the benign, it's a different, so we knew, all the pathologists knew what would be the positive control and positive stain for the patient.
MS. NEWBURY:
Q. But the concern, I guess from a more technical standpoint at the time was that some of the positive controls were showing to be weak, they weren't strong positive controls?
DR. S. PARAI:

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A. I don't recall, I think that--yeah, that was something I think of.
MS. NEWBURY:
Q. There isn't a detailed record here in these minutes of meeting, would there be any record anywhere that you could access that would describe in detail what specifically the problems were, how frequent the problems were and who was involved in rectifying the problems and how exactly they were resolved, assuming that they were.
DR. S. PARAI:
A. I'm not aware of any such record keeping.
MS. NEWBURY:
Q. And so there's no system in place to record these types of issues?
DR. S. PARAI:
A. Yes, I think so.
MS. NEWBURY:
Q. You don't think there is or you do?
DR. S. PARAI:
A. Well I don't think so.
MS. NEWBURY:
Q. Okay, and from a quality assurance or quality control perspective, would it be beneficial or

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helpful to keep these types of records so that you can keep track and monitor over the years what exactly is happening in the lab?
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. And that's not something that you were attune to at the time that you were site chief?
DR. S. PARAI:
A. Well I was just involved in the clinical component of the lab, quality assurance of the clinical, although the program was not officially implemented by the leadership, in the parallel I was doing clinical component that we pathologists to indicate aware of the problem, we get experience and continue our responsibility of the QA program of the lab.
MS. NEWBURY:
Q. And I know that you've been interested since you started in 2001 as site chief in quality, generally speaking, but is it the division between the clinical and the technical that would have prevented you from getting involved in ensuring that there are proper records kept of this?

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DR. S. PARAI:
A. Well, it would have been, you know, the technical part of the lab is a parallel reporting system, parallel system, all the technical quality or and the work was under the supervision of the division manager of the anatomical pathology lab and the site chief was clinical part. So because of this parallel system, it was extremely difficult to correlate or, I would say, to say something to the technical quality or technical issue, although we have liaison. We have discussed in our site chief divisional manager's meeting, and sometimes we invited all division managers at the later part to our departmental pathologist meeting. Sometime he came and these issues I raised many times.
MS. NEWBURY:
Q. So you have raised those issues over the years, so you were aware that there was inadequate record keeping of these types of technical problems?
DR. S. PARAI:
A. Well I can't say how they kept the record, I had no authority to review their record, but

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these issues discussed -
MS. NEWBURY:
Q. So is it fair to say then that in terms of the fact that you didn't have records of technical problems, how they were addressed, specifically what the problems were and who was involved in rectifying the problems, you weren't even aware at the time that there are no such records of all of these issues?
DR. S. PARAI:
A. We introduced a log book at latter part, I don't recall, that was 2004, I believe.
MS. NEWBURY:
Q. I think it was around 2003 or 2004.
DR. S. PARAI:
A. Yes, it was kept in a particular area of the lab, the reporting room. If any issue of the technical quality raised by any pathologist to report them in the log book and we took comment what is the problem and the agreement was that the manager, divisional manager will review all this comment every week and correct it. So -
MS. NEWBURY:
Q. Okay, so something was eventually implemented

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and I take it by that time you would have been aware that well previously we didn't have the system in place.

DR. S. PARAI:

A. Yes.

MS. NEWBURY:

Q. And is there any reason why the pathologists would not have made such a suggestion before, in terms of keeping a log book there? Because there is, obviously, an interaction between the pathologists and the technologists, there is a point in time where the pathologist says I'm seeing some problems here, so we have a role to play here in terms of keeping records of what's going on. Is there any reason why that wasn't done earlier?

DR. S. PARAI:

A. Well I think we had always communication with the technologists, although they are not reportable to the pathologists, we work side by side in a friendly atmosphere, good atmosphere and always communicated verbally. A verbal communication is more important than written documents and sometimes written document may be--it is also important, written

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document, we have all this communication that look, this is the area and they always tried to address the issue, but some of the discussion came, maybe this is the time we keep a record, it came later on, yes.

MS. NEWBURY:

Q. So you were relying primarily then on the verbal communication between the pathologist and the technologists?

DR. S. PARAI:

A. Yes, also in the meeting, the division manager would attend our site chiefs' meeting, all the issues will be discussed there and he would be the person to address those issues.

MS. NEWBURY:

Q. You were discussing earlier this morning the weekly surgical pathology rounds and lymphoma rounds and the fact that there was some issues raised regarding stains at around, I think you said most of the issues were raised in 2003 and that, I believe eventually led to Dr. Ejeckam preparing three memos that you saw earlier to address some of those issues. There was a direct correlation, I believe, to the concerns that were being noted in the

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surgical pathology rounds and Dr. Ejeckam's memos.

DR. S. PARAI:

A. Yes.

MS. NEWBURY:

Q. And during the surgical pathology rounds and prior to Dr. Ejeckam's direct involvement with the memos, did any of the pathologists raise any concern or issues about whether or not the stains had been properly optimized or validated?

DR. S. PARAI:

A. I was not aware.

MS. NEWBURY:

Q. Okay, and the concerns or I guess the issues raised about the stains during the surgical pathology rounds, had those types of issues been raised before 2003?

DR. S. PARAI:

A. Indeed in other stain as well.

MS. NEWBURY:

Q. In other stains, so IHC stains generally, including ER/PR or an even broader category of stains?

DR. S. PARAI:

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A. It's a broader category, issue raised in the lymphoma marker initially many times, but that's the time only ER/PR issue raised in 2003.

MS. NEWBURY:

Q. Okay, so prior to 2003, were there ever any stains specifically relating to ER/PR, any stain issues raised specifically for ER/PR testing?

DR. S. PARAI:

A. No, not that I recall.

MS. NEWBURY:

Q. Okay, and can you explain or do you have any understanding why such issues may not have been raised before 2003? Do you know, for example, that there was any reason to pinpoint the cause of the problem and why these issues first became apparent in 2003?

DR. S. PARAI:

A. I can't answer why it was not raised. Maybe nobody noticed and perhaps it was working well.

MS. NEWBURY:

Q. Okay, so you don't know whether they were indeed working well before 2003 and there was

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nothing to notice -
DR. S. PARAI:
A. Well I would say it was working well.
MS. NEWBURY:
Q. You think it was working well?
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. Okay, so you think that the problem first started in 2003, but you don't know why it started in 2003?
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. And do you know if that's ever been investigated by anyone or were there any steps to identify what exactly was the event in 2003, was there a change of technique or change of personnel, you know, why exactly has this all of a sudden started in 2003?
DR. S. PARAI:
A. Well there was no investigation, Dr. Ejeckam closely worked at the lab, there was no significant change in the lab personnel, so we could not explain why, but it happened, as I

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said, time to time, it's not all the time, from time to time we detected.
MS. NEWBURY:
Q. Now you've indicated that prior to 2003, you personally weren't aware of the significance of checking internal controls for ER/PR testing. Did you consider whether you may not have been aware of some of these problems before 2003 because of your lack of, I guess, understanding of the significance of the internal controls?
DR. S. PARAI:
A. Some pathologists may have knew at the time, I knew that internal control would be useful. This is not only ER/PR, in any other immunostains, whenever we do other immunostain there is also internal control for that, so we are aware in general, but how significant it was for ER/PR, we were not.
MS. NEWBURY:
Q. Was it significant enough for you when ordering an ER/PR test to make an effort to ensure that there is an adequate sample, including an internal control for each and every ER/PR test that you did?

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DR. S. PARAI:
A. We followed guidelines of Dr. Khalifa when he lists these ER/PR staining and have conversation with team before he left and what we were we understanding, it is not our opinion, well our understanding was the external control is important.
MS. NEWBURY:
Q. Right, so based on your knowledge at the time and based on what you had understood from Dr. Khalifa's memo, it wasn't necessary and you weren't actually endeavouring to find internal control for each of your ER/PR test slides?
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. And when you learned of this new, I guess importance or significance of internal controls for ER/PR testing and in light of Dr. Ejeckam's description of the immunostains which I think he described as unreliable, erratic and unhelpful, and in another instance he described them to be persistent, erratic results, in light of those comments, in light of the fact that you were previously unaware

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of the significance of internal controls, did you have any concerns or reservations about your own previous diagnosis, your previous pathology reports, particularly in the year 2003?
DR. S. PARAI:
A. I was not concerned because there was no issue with, I did not get any information or any complaint from any clinician or, on any colleagues that -
MS. NEWBURY:
Q. So until you had some concern raised by an oncologist about questioning the results, you assumed that everything is okay?
DR. S. PARAI:
A. Yes.
MS. NEWBURY:
Q. And how is it that you understand an oncologist can determine whether or not the results of the ER/PR testing are likely to be appropriate for the particular patient?
DR. S. PARAI:
A. Year, you are talking about 2001, 2003 or 1999?
MS. NEWBURY:

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Q. At the time, focusing on the 2003 year, the year that you find out that internal controls are significant and you have not previously understood that and you indicated that you didn't have any reservations about your prior pathology reports, even though Dr. Ejeckam had raised some concerns about the reliability of some of the immunostains, my question and your answer was that you weren't concerned because no clinician had raised any issues with you, but my question for you now is how is it that an oncologist can confirm your results? Is there anything from clinical observations or anything else about the patient's medical history that you're aware of that could confirm at that time whether or not the results from your ER/PR test report are likely to be accurate?

DR. S. PARAI:

A. Well they are twofold, one is that they we check the control and if the positive control was working well and they are reported, we would be very good help for them. The other thing is the type of tumour, some of the tumour, an issue with different result, what

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was our understanding, would raise some concern that some of the low grade tumour are not positive, they would raise well why they're not positive for ER, so -

MS. NEWBURY:

Q. So in terms of the clinical observations of an oncologist as far as you're aware if they know that this is a type of cancer that is likely not to be ER negative, then they might question your result?

DR. S. PARAI:

A. Yes.

MS. NEWBURY:

Q. And did that ever happen?

DR. S. PARAI:

A. Not to my knowledge.

MS. NEWBURY:

Q. And is there anything else about the physical features of the tumour that in your view can help to confirm or contradict the ER/PR results? Was there anything about the size or any other description about the tumour that might help to confirm -

DR. S. PARAI:

A. If the tumour has extensive necrosis, that can

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interfere with the result. If the tumour has significant fixation problem, poorly fixed, that will raise some concern.

MS. NEWBURY:

Q. Right. But in terms of whether or not an oncologist can look at the clinical picture of a patient and say well, I have doubts about this ER/PR test result because of a), b) or c), a) you've identified to be the type of tumour, but the poor fixation, is that something that an oncologist would be looking for?

DR. S. PARAI:

A. No, they would not, but in their report will mention if there is a significant fixation problem, we always make a comment that due to poor fixation, a result cannot be--we make some comments, sometime in the microscope a description, but not that often.

MS. NEWBURY:

Q. Okay. And what would the oncologist do if you did make such a note on your report?

DR. S. PARAI:

A. I can't answer that.

MS. NEWBURY:

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Q. Okay, do you have any experience of having made such a note on your report and having interaction or a phone call from an oncologist?

DR. S. PARAI:

A. Well we would communicate, if there is some problem, we would communicate with the oncologist by telephone to make them aware that there is, we cannot make a definite diagnosis or interpretative, if there is something happens. No, I haven't done any -

MS. NEWBURY:

Q. Okay, and did you discuss with anyone the fact that you were not previously focusing on internal controls or you weren't specifically looking for internal controls prior to 2003 for your ER/PR tests?

DR. S. PARAI:

A. Discuss with any particular person?

MS. NEWBURY:

Q. Discuss with anyone, you know, clinical chief or Dr. Ejeckam, anyone there to, just to, you know, put your heads together to see if that could be significant, or did you just immediately say this isn't a concern?

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DR. S. PARAI:
A. Discussed with Dr. Ejeckam, other pathologists and were aware at the time the General Hospital site we are doing only few cases, but we discussed in general, so we wanted to see how we can see the internal control and -
MS. NEWBURY:
Q. So was it generally known that at that time that some pathologists were not looking for internal controls?
DR. S. PARAI:
A. Some maybe, yes.
MS. NEWBURY:
Q. And did anyone ever raise the possibility in light of the fact that there had been some problems identified by Dr. Ejeckam with erratic staining for the immunostains, that that combined with the absence of internal controls for some of the tests might cause some doubt about the test results?
DR. S. PARAI:
A. No, he did not mention, if as I understand his memo, he did not say that the internal control are negative, of those tested he'd find not working, so the internal control mentioned in

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his recommendation in general, not any particular case.
MS. NEWBURY:
Q. Okay, so you had no doubt and no one had any doubt from your discussions with Dr. Ejeckam or other pathologists about prior test results or was that even discussed at the time?
DR. S. PARAI:
A. Can you repeat again? I don't understand your question.
MS. NEWBURY:
Q. I'm just wondering, you have a situation here where some pathologists that you're aware of, including yourself, you were not focusing on looking for internal controls, and then you have that combined with the fact that Dr. Ejeckam has identified for a period of time erratic staining with immunostain. So those two factors combined, did that cause you and your colleagues or you and any other individual at Eastern Health to discuss whether or not this calls into question any of your prior test results?
DR. S. PARAI:
A. So far as I recall, Dr. Ejeckam did not

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mention that some of the patient, the weak control or the control not working, he noticed any internal control there or not, I don't think so, but he was giving that memo in general that we should be looking for internal control, but not those patient we've identified not working. We discussed in among our pathologists and we are aware of the fact that we should be taking care of internal control, looking more carefully.
MS. NEWBURY:
Q. Right, and I understand that more from a go-forward basis that, you know, any of you who may not have been looking for internal controls, you know, this is a reminder to do so in the future, but was Dr. Ejeckam aware of, I mean, did he do any sample testing of other slides to see if there might be any concerns of slides for which there were no internal controls?
DR. S. PARAI:
A. I was not aware.
MS. NEWBURY:
Q. Okay, and did you bring to his attention that you had not previously been looking for

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internal controls and suggest that perhaps he review some of your slides just to see if there are any possible concerns?
DR. S. PARAI:
A. I don't recall.
MS. NEWBURY:
Q. You were asked by Mr. Coffey and Mr. Simmons about repeated tests and you indicated that it's not unusual to have tests repeated from time to time and is there--are you aware of any systems in place to detect the frequency, in other institutions, have you ever become aware of whether or not repeated test results are tracked to determine if there's a frequent problem with repeat tests?
DR. S. PARAI:
A. I was not aware of any.
MS. NEWBURY:
Q. Okay. And do you know if there's a system in place at Eastern Health or formally the Health Care Corporation of St. John's to ascertain whether the particular problem that has given rise to the repeat tests is unique to that specimen or whether it could have, that problem could have affected other specimens as

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well?
DR. S. PARAI:
A. You are asking that there was any system in place to -
MS. NEWBURY:
Q. Is there any system or protocol -
DR. S. PARAI:
A. No, I was not aware.
MS. NEWBURY:
Q. Okay, and do you know if this is the type of activity or protocol that might exist in other health organizations outside of the province?
DR. S. PARAI:
A. Well this is a technical quality issue of the technical manager should follow and I can't answer that. There might be, but I can't answer.
MS. NEWBURY:
Q. So in your view, this is not a clinical issue, this is a technical issue?
DR. S. PARAI:
A. Well it is of some relationship with, although (unintelligible) but more specifically says exclusively, I would say that the technical manager had more role to that.

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MS. NEWBURY:
Q. So in terms of whether or not other laboratories and other health care organizations in Canada, for example, have, it may or may not be unusual or not uncommon for these other institutions to also repeat tests, but whatever systems they might have in place in terms of dealing with that, you're not aware of what such systems might be, if they have any at all?
DR. S. PARAI:
A. There was no such system at the General Hospital site, but other institution, it is possible.
MS. NEWBURY:
Q. Okay, but you don't know specifically what they might be?
DR. S. PARAI:
A. No.
MS. NEWBURY:
Q. Thank you, Dr. Parai, those are all the questions I have for you.
THE COMMISSIONER:
Q. Thank you. Ms. Taylor--I'm sorry, Ms. Russell?

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MS. RUSSELL:
Q. No questions, Commissioner.
THE COMMISSIONER:
Q. Mr. Pike?
MR. PIKE:
Q. No questions, Commissioner.
THE COMMISSIONER:
Q. Mr. Browne?
MR. BROWNE:
Q. Thank you, Commissioner.
DR. SUSHIL PARAI, EXAMINATION BY MR. PETER BROWNE
MR. BROWNE:
Q. Good morning, Dr. Parai, just a couple of areas I'm going to cover with you. Going way back to the start and your background, were you trained -- we've heard several of your colleagues come before the Commissioner and talk about their training. Were you trained as an anatomical pathologist or general pathologist?
DR. S. PARAI:
A. Well, mainly anatomical pathology. Also I had extra training in general pathology.
MR. BROWNE:
Q. And we notice as well in your curriculum

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vitae, that you received an award in 1991, the Blair award, I believe, for cancer diagnosis. What area was that in relation to?
DR. S. PARAI:
A. This was offered by the Canadian Cancer Society to use the grant for higher training, fellowship level, to cancer diagnosis, and I used that money to do cytopathology training at Ottawa Civic Hospital mainly for the fine needle aspiration biopsy. At that time, we are introducing fine needle aspiration at our lab in St. John's. So I went there two months to upgrade.
MR. BROWNE:
Q. Now we've heard some evidence about -- from several witnesses concerning the consolidation of technical services from St. Clare's to the Health Sciences. Were you involved at any point -- I think that sort of discussion around that that we've heard so far occurred around 2002/2003. At that time you were site chief. Were you involved in any of those discussions with regard to those services coming from St. Clare's over to the Health Sciences?

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DR. S. PARAI:
A. Yes, we discussed this thing in our department site meeting at the General Hospital site, wanted opinion from the pathologists. In general, we had some concern about the technical consolidation because of this turnaround time of the slides and limitation of the facility of the lab.
MR. BROWNE:
Q. And were those concerns discussed with the managers on the technical side?
DR. S. PARAI:
A. I did. I did discuss with the manager at the time.
MR. BROWNE:
Q. Now did you have any discussions with the manager, I think it was Mr. Dyer, around that time about sort of the interaction that may occur between two sites within the politics of the pathology department both at St. Clare's and Health Sciences? There was a statement attributed to you by Mr. Dyer concerning the fact you gave him some advice about, I guess, going about this, and I think he attributed a statement of "watching your back" or something

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like that. Do you recall ever making that type of statement to Mr. Dyer?
DR. S. PARAI:
A. No, I did not have any discussion that would be political issue, neither did I say "watch your back".
MR. BROWNE:
Q. Okay. Now we've heard about as well the notion of putting the control -- because up until well after 2003, the control slides were run separately to the patient slides. The notion of putting the control on the same slide, was there any discussion about that that you recall that you were involved in at the Health Sciences site?
DR. S. PARAI:
A. Yes, Dr. Ejeckam discussed with me in the latter part of 2002 that the present way of doing best control is not right, is not appropriate, we should put control on the patient slide, same slide, yes.
MR. BROWNE:
Q. Was it ever raised in any meetings, division site meetings, that you recall?
DR. S. PARAI:

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A. We discussed in our rounds. As I recall, we are doing surgical pathology round or two rounds, and at the end of the round, we had some discussion of this sort all the time going on.
MR. BROWNE:
Q. And were you -- do you recall whether or not any of the representatives from the technical side were present for any of these discussions?
DR. S. PARAI:
A. I don't recall.
MR. BROWNE:
Q. You were asked this morning by Ms. Newbury about external consultations, and you explained the purpose of that both from a systemic point of view and from a patient point of view. One thing you didn't mention are the sorts of external consultations at the General. You can speak to the General. What sort of areas and what sort of institutions did you involve in external consultations?
DR. S. PARAI:
A. Visit with Canadian Referral Centre for Cancer Pathology in Toronto, Armed Forces Institute

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of Pathology. We also used the QE II Health Sciences Centre, Halifax, and we also used some consultant of BC cancer agencies, and also some personal consultant whom we knew, or individual pathologist knew, they will send them directly to them.
MR. BROWNE:
Q. So --
DR. S. PARAI:
A. So involving -- mostly Toronto, some in United States.
MR. BROWNE:
Q. And this would -- I think you mentioned that this would be driven by the initiative of a particular pathologist or would it be the department itself doing this?
DR. S. PARAI:
A. Both.
MR. BROWNE:
Q. Both, okay, and would it cover all areas of pathology?
DR. S. PARAI:
A. Yes.
MR. BROWNE:
Q. Now leading into that, Dr. Parai, you've

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spoken both on Friday and today about the initiatives that were undertaken at the General Hospital from about 2001 onward on quality assurance, and I just want -- there are a couple of exhibits here in addition you were shown by Mr. Coffey this morning, a certificate of attendance, and you explained that document, but there are a couple of others I just want to run through quickly. The first is -- I'll click on this, Exhibit 2427. Has that been entered?

REGISTRAR:

Q. Yes.

MR. BROWNE:

Q. Okay. Doctor, this is a --

COMMISSIONER:

Q. Taking over her job.

MR. BROWNE:

Q. Oh, I'm sorry. I apologize.

COMMISSIONER:

Q. Well, when she wants a day off, she just might be looking for you, Mr. Browne.

MR. BROWNE:

Q. Well, I don't envy that position, Registrar, it's a very important position and I think you

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do an extremely good job on it. Could you explain to me what this document is, Dr. Parai? It's entitled "Maintenance of certification and attendance and evaluation of activity attended".

DR. S. PARAI:

A. This is a document to maintain the attendance of the physician in our department, and these rounds are pre-approved by the Vice-Dean of Professional Development of Memorial University, and we had to send a proposal about the type of this meeting, what is the content, and what is it called, and Vice-Dean approved that this content of this meeting is acceptable by the Royal College of Canada for the maintenance of a certification for credit hours. So one hour of this meeting would be equivalent to one hour credit CME by the Royal College.

MR. BROWNE:

Q. And we've heard -- Mr. Coffey asked you about these Tuesday and Wednesday rounds. Are these the sheets that would follow these rounds on Tuesdays and Wednesday, or is this a separate session?

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DR. S. PARAI:

A. No, this is the same form used for them, and every pathologist has to sign and document it.

MR. BROWNE:

Q. And these were in existence for -- do you recall when these came into effect, what year?

DR. S. PARAI:

A. Well, it came in 2001.

MR. BROWNE:

Q. 2001. Registrar, you're going to have to help me. I'm going to click out of this and move to the next -- oh, there we go. Can we go to -- Registrar, I'll let you control this, Exhibit 2428, please. We've heard about the check path, Doctor. Is this an example of what you refer to? It's called "check sample", American Society of Clinical Pathologists, and it's surgical pathology and there's two authors, Espejo and Jasnosz, both assistants; one a resident and assistant professor of pathology, in Pennsylvania. Are there several topics that this -- if we can just go through it briefly here. It gives a history, a clinical history, and then findings and so on. This one is testicular

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plasmacytoma. So just if you could explain for -- this is just one example that you picked.

DR. S. PARAI:

A. This is the example I'm showing you that we started 2000. If you look at the number on the top right hand corner, it's SP200-1. That means 2000, number one, showing that we have this program in place for CME, continuing medical education, and we used to get this program to help in surgical pathology. That is once a month that this material will be mailed with the appropriate images of slides, would be passed to every pathologist. They will review them and there will be question and answer at the end of this program, and they will fill out the answer and we review monthly. We will review them monthly under microscope and get feedback and send -there was also a form to send to the ASCP, our information and our diagnosis.

MR. BROWNE:

Q. And then would there be a response from the ASCP with regard to that information?

DR. S. PARAI:

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A. In this particular program, there would be no response, but the annual there will be review -- they'll send us what is the performance of various institution, but not individual.

MR. BROWNE:

Q. Individual. So the ASCP issues on an annual basis performances of institutions in a overall document, is that right?

DR. S. PARAI:

A. Yes.

MR. BROWNE:

Q. Now you had another --

DR. S. PARAI:

A. It means they will send a certificate that -- well, not certificate, they will send some information that these are the various institutions participated in this program.

MR. BROWNE:

Q. There was another document, which is Exhibit 2439, Doctor. Just bear with me. This is the PIT Program that, I think, you mentioned as well. Could you -- and it's performance improvement program in diagnostic surgical pathology. Now this, I think, is monitored by the CAP, is that right?

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DR. S. PARAI:

A. Yes.

MR. BROWNE:

Q. Can you explain to the Commissioner, again is this just another example of sort of this program you subscribe to at the General Hospital and what did this involve? This one is -- I think it's called "Final Critiques", and it has a number of areas listed in the Table of Contents. So it's not just one area, there's -- I guess, is it across the board in pathology that this program entails?

DR. S. PARAI:

A. This is a program we introduced in 2000, if you look at the paper number, and the program speaks for it, performance improvement program for every pathologist to improve their medical knowledge, and we would get this 40 in full A, B, C, D, per year. Reported cases will be sent to us quarterly, and we will review them and send the report -- result to them and there will be certification to follow to individual pathologists.

MR. BROWNE:

Q. Okay. So in this program, there is an evaluation of each pathologist in terms of their assessment, is that correct?

DR. S. PARAI:

A. There are both ways. Once this program would be coming to our department, we'll circulate it among the pathologists, and in a monthly or quarterly, we'll review among the pathologists multi-headed microscope, and we'll send an institutional result answers -- it is a kind of test, and also pathologists can send their own answer to get a certification of their own.

MR. BROWNE:

Q. Okay. Now in terms of -- again staying with the topic of quality assurance, in 2000 -- we've heard from a number of witnesses, both from the administration down, about the tough times financially that health care experienced in early 2000, late 1990s. Was there any discussion about -- we now have a quality control manager, I understand, in place at the General Hospital. Was there any discussion in looking at the years from the time you were site chief about bringing in a quality control manager?

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DR. S. PARAI:

A. Yes, there was, started in early 2001, and ended up until my tenure, 2005. There was always discussion of a quality control manager.

MR. BROWNE:

Q. And who was -- if we could, Doctor, just if you recall when did this first come up, who brought it up, and what sort of -- in what direction did it head?

DR. S. PARAI:

A. The quality control program was discussed in the site chief and division manager meeting in early -- well, in 2001, the division manager, Mr. Gulliver, was presented at that time a letter, and Mr. Barry Dyer, and every time we raised this issue that we needed quality control manager to implement this program.

MR. BROWNE:

Q. And what was sort of the response, in terms of generally, do you recall whether they agreed with the notion and whether or not it was achievable?

DR. S. PARAI:

A. Well, also the discussion went on with the

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clinical chief, as the site chief I can have this information. My request will go to the clinical chief, which was Dr. Haegert and Dr. Cook later on, and these meeting were with combined meeting between two sides, clinical chief and division managers, and raised many time we need to address the issue of quality control manager. It was ongoing. So far I recall, there was funding problem and there was no position could be created because of the funding constraint.

MR. BROWNE:

Q. So financial constraints prevented this from advancing forward? Is that your general understanding?

DR. S. PARAI:

A. Yes.

MR. BROWNE:

Q. It's not necessary, Doctor, to bring up the document, but you were shown by Mr. Coffey and Ms. Newbury again this morning, the April 25th 2001 meeting, and the mention of a survey being conducted, and as I understand your evidence that there was feedback from about 10 or 11 pathologists about the quality of the

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slides. Is that right?

DR. S. PARAI:

A. Yes.

MR. BROWNE:

Q. And among those included ER/PR?

DR. S. PARAI:

A. Yes.

MR. BROWNE:

Q. And that information, do I understand correctly from your evidence previously on Friday, that information was given to Mr. Gulliver, who was, I think, the manager at the time, to then take back and sort of chase down those issues with his technical, quality of the slides?

DR. S. PARAI:

A. Yes.

MR. BROWNE:

Q. Now Doctor, customarily, witnesses are asked whether or not they wish to make any statements or recommendations to the Commissioner at the end of their evidence. Is it your intention to make any comment or remark to the Commissioner before you conclude your evidence today?

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DR. S. PARAI:

A. Well, one point I want to mention, in the previous testimony how many cases of -

MR. BROWNE:

Q. Yes, sorry, I meant to cover that with you, Doctor. I know you wanted to clarify that point. You had mentioned, I think, early on in your evidence, and you were probably a bit nervous on Friday, about you had mentioned that there were two to three hundred breast cancer surgeries conducted at the Grace annually and I think you -

DR. S. PARAI:

A. Well, I misunderstood the question. It was not annually. I would say during my tenure in Grace Hospital as a whole. We are not getting too many, we are not doing too many breast cancer at the Grace Hospital. The centre for the breast cancer was designated at the St. Clare's Hospital and that was centralized there. Remember, before the Health Care Corporation come, there was--that was the phase two. Phase one was the centralization of the services in the site. So the St. Clare was identified as the centre for the breast

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care, breast tumour care, including mammogram, and surgical, involving surgery as well as pathology. So we are not doing that many at the Grace.

MR. BROWNE:

Q. And is there any further clarifications or any remarks you wish to make to the Commissioner?

DR. S. PARAI:

A. No.

MR. BROWNE:

Q. Okay, thank you. That's all the questions I have. Thank you, Commissioner.

THE COMMISSIONER:

Q. Thank you, Mr. Browne.

MR. BROWNE:

Q. Mr. Coffey may have any -

THE COMMISSIONER:

Q. Do you have anything arising, Mr. Coffey?

DR. SUSHIL PARAI, RE-EXAMINATION BY BERNARD COFFEY, Q.C.

COFFEY, Q.C.:

Q. Yes, just one, one thing, Commissioner. Doctor, in answering Ms. Newbury's questions, you indicated that, you know, looking back on it, you believe that the problem, as it were, with the stains started probably in 2003. I

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think that's what you told Ms. Newbury.
DR. S. PARAI:
A. That's the first time we identified.
COFFEY, Q.C.:
Q. Yes, you identified it.
DR. S. PARAI:
A. Detect it.
COFFEY, Q.C.:
Q. And Doctor, I'm just--she asked you questions about, you know, what was discussed amongst yourselves as to, you know, well, the fact that you didn't know about internal--weren't really alerted to the potential significance of internal controls yourself and whether the pathologists discussed it, and you were asked about any concerns that the pathologists might have had about earlier cases. One thing I wanted to ask you was, is this, leaving aside the pathologists, do you know if the oncologists were alerted to this? You're all aware of it as pathologists in 2003. Were the oncologists alerted to this, the fact that all the pathologists are discussing this?
DR. S. PARAI:
A. In official, you mean, or personal level?

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COFFEY, Q.C.:
Q. In 2003?
DR. S. PARAI:
A. 2003?
COFFEY, Q.C.:
Q. Yes.
DR. S. PARAI:
A. I was not aware that there was any official information given to the oncologists.
COFFEY, Q.C.:
Q. How about unofficial?
DR. S. PARAI:
A. I can't answer, and this memo from Dr. Ejeckam was the internal memo. It was only for the pathologist group, and how he believed that it is a small and short time problem and it is working, but irregular, so and he was confident that it can be corrected and which he did, and then we retested.
COFFEY, Q.C.:
Q. And I appreciate that, but in terms of the oncologists, you don't recall ever, yourself, as site chief, being approached by them or discussing that with them?
DR. S. PARAI:

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A. No, none, I recall.
COFFEY, Q.C.:
Q. Now, just--and I--because Ms. Newbury asked you about it, and there is a document and there will be other documents, I anticipate, that the Commission will be referred to where oncologists do, in 2003--oncologists in 2003, do ask for retests. So I'm just wondering, as the site chief, was it brought to your attention?
DR. S. PARAI:
A. No, not to my attention.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Appreciate that.
DR. SUSHIL PARAI, EXAMINATION BY THE COMMISSIONER
THE COMMISSIONER:
Q. Thank you. Dr. Parai, in answer to a question put to you earlier today by Ms. Newbury, you, as I understood it, when discussing the question of how one might become aware of problems with testing, you sort of said none of the oncologists had raised the question with you, and as I understood it, effectively you were saying that they didn't see a problem. Did I misinterpret that or is that

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the point you were making?
DR. S. PARAI:
A. I would say to your first question, but second question, I can't answer. I was not aware any oncologists were aware of the problem.
THE COMMISSIONER:
Q. Okay.
DR. S. PARAI:
A. Is it -
THE COMMISSIONER:
Q. Well, I'm interested in the notion that if there is a problem with the testing being done in the laboratory or with the reports being produced by a pathologist then one of the criteria for determining whether or not one should have known about the problem would be well, the pathologist didn't say--I'm sorry, the oncologist didn't say "we've got a problem."
DR. S. PARAI:
A. Well -
THE COMMISSIONER:
Q. How would they know? That was my question.
DR. S. PARAI:
A. During the problem when we identified,

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identified or detected the problem, we did not do any reporting, that period, from April until May, until the problem was corrected and retesting was done. So that particular period, so far I recall, I don't think there was any report produced by our, particularly General Hospital site.

THE COMMISSIONER:

Q. Well, that's really my question. Could an oncologist be expected to know if there was a problem with, in this case, ER/PR testing in any event, and if so, how would they know?

DR. S. PARAI:

A. The communication, well, you would be going--Dr. Ejeckam was in charge of the immunohistochemistry lab. I don't recall whether he communicated with the oncologists or not. I can't answer that.

THE COMMISSIONER:

Q. But from--the issue arose, I think, in the context of your discussion with Ms. Newbury about whether, for example, certain results should tell an oncologist or a pathologist, for that matter, that there may be a problem with the testing?

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DR. S. PARAI:

A. Testing prior to 2003 you mean?

THE COMMISSIONER:

Q. In theory. I'm not talking about the particulars. I'm just interested in the notion of whether or not, as a pathologist, you would say "well, we didn't recognize there was a problem with a particular test, and what's more, the people who we serve, the oncologists, didn't tell us that they were having a problem with it. So how would we be expected to know that?" and my question is could an oncologist be expected to know if there was a problem with a test that was being done by a pathologist?

DR. S. PARAI:

A. Well, for a short time, for this, we consider this as a minor problem, only temporary, and it is also a lab--what we do if something is delayed for retesting, we wait for the test is right and report it, or if it wasn't for a short period of time, we did not--Dr. Ejeckam, when I discussed, I think, did not feel to notify them.

THE COMMISSIONER:

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Q. Okay. But there's nothing in the nature of the testing itself that should be evident to an oncologist that there was a problem, is there?

DR. S. PARAI:

A. Well, the one would be -

THE COMMISSIONER:

Q. I don't think I'm communicating my question properly. As I understand it, your role is to either in diagnosis or in tests like ER/PR to examine the tissue having gone through a certain process and give your opinion, within your particular sphere of expertise, as to, in the case of ER/PR, whether or not the results are considered positive or negative, and then you prepare your report and that goes on to an oncologist.

DR. S. PARAI:

A. Yes.

THE COMMISSIONER:

Q. Would it be normal, for example, for an oncologist to call you up and say "are you sure that's right?" because of this, this and this, or do the oncologists say "umph, that's what the report is from the pathology

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department and I accept that" and carry on on the basis of that?

DR. S. PARAI:

A. Well, it is normal for oncologists to raise any question we produce and they call us and then discuss. Yes, they will say "are you sure?" Yes, they do.

THE COMMISSIONER:

Q. Okay, and in the context of ER/PR, on what basis would they have that kind of conversation with you? You know, I can see it as being perhaps more common if you're looking at diagnosis and they're saying "we have all these other factors, and are you sure this fits in with?"

DR. S. PARAI:

A. Well there is no conversation with the oncologist I could think of during the period, but if the answer is low grade and if ER is negative, they will always raise the question "are you sure the test is right?" There are two component we do in hormone receptor ER and PR. If PR is positive and ER is negative, they will raise concern that "why PR is positive and ER is negative? Will you retest

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it?" So these are the two point I could think of.

THE COMMISSIONER:

Q. All right. So, and would that have been the practice over the full period of time from the late 90s into now or is that more the current practice?

DR. S. PARAI:

A. I can't answer that, but it should have been all the time. It is known from '97 and onwards that these are the things, a low grade tumour should be positive and PR positive tumour would be ER positive as well, except there are five to ten percent of PR positive tumour not ER positive.

THE COMMISSIONER:

Q. Yes. Yes, I think other witnesses have said that as well. Okay then, thank you very much for that information and indeed for all of your evidence.

DR. S. PARAI:

A. Thank you.

THE COMMISSIONER:

Q. In light of the time, I suggest we take the luncheon break and then continue with the next

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witness after lunch. We'll meet again at ten after two. Thank you.

(LUNCH BREAK)

DR. BEVERLEY CARTER, AFFIRMED, EXAMINATION BY BERNARD COFFEY, Q.C.

REGISTRAR:

Q. Would you please state and spell your complete name for the Commission?

DR. CARTER:

A. My name is Beverley Carter, B-E-V-E-R-L-E-Y C-A-R-T-E-R.

REGISTRAR:

Q. Thank you.

COFFEY, Q.C.:

Q. Good afternoon, Dr. Carter.

DR. CARTER:

A. Good afternoon, Mr. Coffey.

COFFEY, Q.C.:

Q. Commissioner, there are a number of other exhibits that I'm going to ask be entered, please. They would be, Commissioner, Exhibits P-2440 through P-2479, I'm sorry, 24-yes-79, inclusive. 2440 through 2479 inclusive.

THE COMMISSIONER:

Q. Entered.

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EXHIBITS ENTERED AND MARKED P-2440 THROUGH P-2479

COFFEY, Q.C.:

Q. And there will be some C exhibits, but I'll come to them eventually.

THE COMMISSIONER:

Q. Okay then.

COFFEY, Q.C.:

Q. Dr. Carter, I'm going to refer you to an exhibit to start, Exhibit P-2440, please, Registrar? And here, Dr. Carter, there on the screen in front of you, I believe this is your CV?

DR. CARTER:

A. Yes, it is.

COFFEY, Q.C.:

Q. And have you identify it as yours. Doctor, I'm not going to take you through each of the lines of it. I'm going to ask you, please, to tell the Commissioner, give an overview of your professional, educational background and then your professional experience.

DR. CARTER:

A. I entered medical school in 1985 at Memorial University and graduated in 1989.

COFFEY, Q.C.:

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Q. If I could, Commissioner, it I could just intervene here, Doctor, I appreciate, because you're starting with your actual medical training itself, Doctor, but you happen to have been involved in, I believe, pharmacy before?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Okay. Could you tell the Commissioner, please, about that? Because it will give her some sense then of kind of your own actual background, not only your medical background, but in fact, you've been exposed to the subject of medicine and medical matters before you ever entered medical school, so perhaps you could tell her about that?

DR. CARTER:

A. In 1975, I finished high school and I entered pharmacy school at what would be known now as CONA, and graduated in 1978. I worked as a pharmacist until 1984 when I went to Memorial University and started medical school in 1985. I graduated in 1989 and then went to Dalhousie University for a rotating internship and a

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year of obstetrical training. I practised as a general practitioner until 1994. At that time, I entered a pathology residency at McMaster University and I was granted my fellowship in 1998 from the Royal College of Physicians and Surgeons of Canada. At that time, I went to Vanderbilt University as a research fellow, and I completed a one-year fellowship in breast pathology with Dr. David Page, and in 1999, I returned to McMaster University as an assistant professor and as a pathologist with the Hamilton Regional Laboratory Medicine Program. In 2003, I began locum work at what was then the Health Care Corporation of St. John's, and in 2004, I began work as a full-time service pathologist at St. Clare's Mercy Hospital here in St. John's.

COFFEY, Q.C.:

Q. Doctor, could you explain to the Commissioner, please, what a research scholar fellow in breast pathology, what does that mean or what does that involve?

DR. CARTER:

A. From 1998 to 1999, you're talking about?

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COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. I went to Vanderbilt University. Research scholar is the designation that they would give you on your work visa to go there. I basically did a year of consultation breast pathology and research with Dr. David Page.

COFFEY, Q.C.:

Q. Doctor, can you--of course, Vanderbilt is in the United States?

DR. CARTER:

A. In Nashville, yes.

COFFEY, Q.C.:

Q. Doctor, is there, in the United States or in Canada, any particular designation as a breast pathologist?

DR. CARTER:

A. No, there is not. The Royal College is strict on that. I am an anatomic pathologist.

COFFEY, Q.C.:

Q. Anatomic pathologist, and how about in the United States, do you know what their system -

DR. CARTER:

A. I don't think that there's a recognized breast pathology fellowship with examinations. I don't think so, but I'm not sure.

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COFFEY, Q.C.:

Q. So that from the perspective of being a breast pathologist per se, because there's--in a number of documents, you're referred to as that.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. In practice, what does that mean?

DR. CARTER:

A. In practice, most people who would designate themselves as a breast pathologist would have usually somewhere between three to six months or more training as a breast pathologist or someone whose practice is largely dedicated to that.

COFFEY, Q.C.:

Q. And in your case, I take it during that year at Vanderbilt, you would have been studying breast pathology itself for that -

DR. CARTER:

A. Yes, for the entire year.

COFFEY, Q.C.:

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Q. - for that entire year. Doctor, could you -

THE COMMISSIONER:

Q. I'm sorry, is that true of pathology generally, there's no sort of sub-specialization categorization by the Royal College?

DR. CARTER:

A. In Canada, you can be an anatomic pathologist, a general pathologist, a neuropathologist and a hematopathology and right now, it's still being, you know, figured out, but you can probably be a forensic pathologist by designation, but the Royal College is very strict about what you call yourself. What we call ourselves when we're talking to one another, I mean, it's quite different, but I wouldn't be able to advertise that I'm a breast pathologist. I'm an anatomic pathologist.

THE COMMISSIONER:

Q. All right, thank you.

COFFEY, Q.C.:

Q. Doctor, looking at your resume, Doctor, I take it that in fact at one point, you did spend some time back at Vanderbilt?

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DR. CARTER:
A. In May of 2004, I went back to Vanderbilt as a visiting scholar, again a visa designation, for two months and while I was there, I worked on some textbook chapters that I was writing for two textbooks of breast pathology.
COFFEY, Q.C.:
Q. You've referred to David Page. I take it that's Dr. David Page?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And who, in your world, is Dr. Page?
DR. CARTER:
A. He is an internationally recognized breast pathologist. He's also an epidemiologist. He has a huge consultation practice from all over the world, but largely from the United States, and he's written hundreds of papers, but many seminal papers for breast pathology and breast practice.
COFFEY, Q.C.:
Q. Now Doctor, you have indicated that you ended up here in St. John's, I take it, in Newfoundland, particularly in St. John's,

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doing locums at one point?
DR. CARTER:
A. Yes, in 2003.
COFFEY, Q.C.:
Q. If we could, just again to give the Commissioner some sense of the times, okay, Exhibit P-2442, please, 2442? Page eight, please? These happen to be Board of Trustee minutes for a meeting of September 25, 2003. In those minutes, there's a note under the Laboratory Medicine Program, Dr. Bev Carter, temporary privileges to perform a locum in the Laboratory Medicine Program, division of anatomical pathology, August 4th to October 4th, 2003. So would that be your -
DR. CARTER:
A. I may not have worked from August 4th to October 4th, but they would have granted the privileges for that time, and I might have had a week off or something in between. I was covering for vacations at that time.
COFFEY, Q.C.:
Q. So Doctor, was this the beginning then of the locums? Do you recall was it the summer of '03?

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DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And where were you working at that time, which hospitals?
DR. CARTER:
A. When I came here in August, I worked at the General site. I'll probably call it the Health Science Centre throughout the next few days.
COFFEY, Q.C.:
Q. Sure.
DR. CARTER:
A. But at the General site, and I first started working at St. Clare's, the first time I worked there was a locum that was in December.
COFFEY, Q.C.:
Q. Of that -
DR. CARTER:
A. Of 2003.
COFFEY, Q.C.:
Q. While we're on it, Exhibit P-2443, please? Now these are the minutes of a meeting of the Board of Trustees of October 30th, 2003. Particular at page three, Doctor, under

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Laboratory Medicine Program, there's a reference to yourself, "extension of temporary privileges to perform a locum in the Laboratory Medicine Program, October 4th, 2003 to January 30th, 2004."
DR. CARTER:
A. But again, I didn't work all of that time.
COFFEY, Q.C.:
Q. All the time. Beginning in August, what you did work, you spent at the General Hospital, Health Sciences site, until December of '03 when you spent--started to do some work at St. Clare's?
DR. CARTER:
A. And I think from then until May, any locums I did were at St. Clare's, but I'm not 100 percent certain of that.
COFFEY, Q.C.:
Q. While we're looking at it, Exhibit P-2449, please? Now these are the MAC minutes of January 15th, 2004. On page--I apologize, that is on page three of the exhibit, there's again a reference to yourself, "extension of temporary privileges, January 30th, 2004 to May 7th, 2004." So you continued then to do

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locums?
DR. CARTER:
A. Yes, throughout that time.
COFFEY, Q.C.:
Q. Doctor, perhaps you could advise the Commissioner, what sort of work then does a person doing a locum in that context do? What actually happens?
DR. CARTER:
A. Most of the locums that I was hired for would be for vacation relief. So I would take that person's place in the call schedule. So I would do routine service duties. I don't think that I would have had much to do with administrative things or meetings, those sorts of things, more of a service person.
COFFEY, Q.C.:
Q. And to fill in then wherever in a functional way?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Wherever you were needed at the time?
DR. CARTER:
A. Yes.

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COFFEY, Q.C.:
Q. Exhibit P-1913, please? Now these are the minutes of a site chiefs and divisional managers meeting of March 31st, 2004. Doctors Cook, Parai and Robb were present, Doctor. When we look at paragraph 3.8, under pathology manpower, it reads "two potential vacancies will occur in the spring and summer of this year. Dr. Barron will be switching from a hospital-based to university-based position. Dr. Bev Carter is interested in one of the hospital positions" and they go on about another possibility. Doctor, I take it then that it was--well, what would be winter in St. John's, in March, you were then looking to, if possible, take one of the hospital positions?
DR. CARTER:
A. Yes, take a permanent position here in St. John's.
COFFEY, Q.C.:
Q. Doctor, can you explain to the Commissioner what the difference is between a hospital position and a university-based position?
DR. CARTER:
A. University-based position would be 80 percent

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hospital position and 20 percent academic position. Academic position would consist of teaching at the medical school, the pharmacy school, an expectation that you would participate in the administration of the medical school and also that you would participate in and produce research. In a service position, you would be more involved in just the running of the clinical service for the hospital.
COFFEY, Q.C.:
Q. Is there, in a clinical position, or hospital-based position, is there any expectation that you were--you've referred to an 80/20 split for the university.
DR. CARTER:
A. Um-hm.
COFFEY, Q.C.:
Q. 20 percent would be clinical, I take it?
DR. CARTER:
A. 80 percent would be clinical work and 20 percent would be academic work.
COFFEY, Q.C.:
Q. Oh, okay, I'm sorry, 80/20, I misunderstood. For university positions, 80 percent clinical,

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20 -
DR. CARTER:
A. Academic.
COFFEY, Q.C.:
Q. - academic, and the hospital-base would be 100 percent -
DR. CARTER:
A. Service work, but within that, I mean, you would still have to teach residents. You would probably take part in collaborative research, things like that.
COFFEY, Q.C.:
Q. Okay, and Doctor, I take it that you did apply for that position?
DR. CARTER:
A. Yes, I did.
COFFEY, Q.C.:
Q. And you were offered a position and accepted it. When did you start then?
DR. CARTER:
A. In August of 2004.
COFFEY, Q.C.:
Q. Exhibit P-2332, 2332 please? These are MAC minutes of June 9th, 2004, Doctor. If we could, Registrar, page seven, please? Here,

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Doctor, under Laboratory Medicine Program, there's a reference to "temporary privileges to perform a locum, July 26th, 2004 to August 16th, 2004, and then associate staff, August 16th, 2004 to August 16th, 2005." So I take it that this last line here is your appointment to the hospital -

DR. CARTER:

A. Full-time position, yes.

COFFEY, Q.C.:

Q. - full-time position. What is the situation then, Doctor, with respect to being appointed to associate staff for a year? Because we understand, and we've seen a number of references to longer periods of time after the initial year.

DR. CARTER:

A. I'm not really certain.

COFFEY, Q.C.:

Q. Okay.

DR. CARTER:

A. Maybe you better ask some of the administration. I think it's sort of a probationary kind of period, but I'm not sure.

COFFEY, Q.C.:

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Q. Okay, and as you don't know much about it, in your world, it didn't really figure prominently. You applied for the job, obtained it.

DR. CARTER:

A. You have the job and -

COFFEY, Q.C.:

Q. And then just -

DR. CARTER:

A. - you would assume that life would just go on, yes.

COFFEY, Q.C.:

Q. Doctor, could you tell the Commissioner, please, about your own introduction to ER and PR IHC type testing?

DR. CARTER:

A. Here in St. John's or -

COFFEY, Q.C.:

Q. No, just generally.

DR. CARTER:

A. In general. It would have been as a part of my residency program, you would have on-the-job training with pathologists. So you would be signing out breast cases with them and signing out estrogen and progesterone receptor

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cases with them. Also, as part of the resident's academic half day was a half day a week of didactic lectures. As mandated by the Royal College, we would have had a series of lectures on laboratory methods and part of that would have been immunohistochemistry's theory and practice.

COFFEY, Q.C.:

Q. And that would be while you were at McMaster doing your residency?

DR. CARTER:

A. From '94 to '98.

COFFEY, Q.C.:

Q. How much actual--well, back up a bit. Would you actually go to the IHC part of the lab?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And how much would you actually learn about the nitty gritty of performing the test?

DR. CARTER:

A. Well, we would have to know basic theory of, you know, how the test is performed and how the reactions takes place and what the chromogens are. More, we would be interested

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in, you know, it's application to clinical cases, that sort of thing.

COFFEY, Q.C.:

Q. And would you be at all involved as a resident in, like, if there was a problem with a stain or stains, IHC stains, would you be involved in troubleshooting?

DR. CARTER:

A. If it was my case, yes.

COFFEY, Q.C.:

Q. Okay, but if it was not your case, I take it - - the point I'm getting at is you wouldn't attend lectures or lessons dealing with troubleshooting in IHC, in a general sense?

DR. CARTER:

A. No, it would be more on the job training.

COFFEY, Q.C.:

Q. Doctor, while I'm on the topic, to this day, for example, locally for the residents, pathology residents, how much involvement, to your knowledge, how much exposure do they get to IHC?

DR. CARTER:

A. Again they would receive it largely on their day to day sign outs, and when they work with

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me, I mean, I make them do the case from start to end.

COFFEY, Q.C.:

Q. Sure.

DR. CARTER:

A. So they would see it then. We have a series of lectures here as well for resident, academic half day, and I'm pretty sure there are lectures on immunohistochemistry or around the topic of immunohistochemistry in that. We also have a Friday morning departmental lecture that was just started, I think, this year, or maybe a year and a half, and immunohistochemistry lab takes part in that and the residents are mandated to attend that as well.

COFFEY, Q.C.:

Q. So I take it generally, though, the residents today have a -- you've told us locally would have a similar sort of exposure to IHC as you received in McMaster, bearing in mind that the stains have -- you know, there are many more stains and so on as time has gone on, but a kind of systematic exposure to it is about the same?

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DR. CARTER:

A. Basically, it would be equivalent, in my opinion, the training.

COFFEY, Q.C.:

Q. Doctor, just looking back then, you began in St. John's doing locums, as best you can recall, and your first one was at the General Hospital?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Health Sciences site beginning some time in August of 2003?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, when you arrived, how much contact had you had with the local pathologist community before your arrival?

DR. CARTER:

A. I had been attending tumour boards, the Wednesday morning multi-disciplinary tumour boards for a few months prior to that, and I had also participated in some residency teaching for a few months prior to that.

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COFFEY, Q.C.:

Q. So you had been in St. John's?

DR. CARTER:

A. I was in St. John's from the October before.

COFFEY, Q.C.:

Q. Okay, the fall of '02 then, 2002?

DR. CARTER:

A. Okay.

COFFEY, Q.C.:

Q. Because that will bring us up to the spring and summer of 2003. Doctor, were you aware of -- I'll just bring it up now, P-0113, please, Registrar. These are the three Dr. Ejeckam memos that the Commission has seen. When did you first see these memos? I can take you through them if you like, but this is the April 4th one, this is the one where the utilization of the eight stains for at least a period of time is suspended, and then there's the May 2nd reinstitution of ER/PR stains, and then there's the June 19th one where Dr. Ejeckam writes to Mr. Gulliver generally about his concerns.

DR. CARTER:

A. Okay. I would have heard of these sometime in

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the summer of 2005 when we began to investigate.

COFFEY, Q.C.:

Q. That's what I was going to ask you about. Before that, before the summer of 2005, this subject was not brought to your attention, I take it?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. That you can recall.

DR. CARTER:

A. Not that I recall.

COFFEY, Q.C.:

Q. And not only -- you didn't see -- if they're listed as two pathologists, I take it, whoever was distributing them didn't think, even if you were attending rounds around that time --

DR. CARTER:

A. I wouldn't have been officially associated with -- it was a much drop-in basis. I mean, I came in to teach the residents and then go back home.

COFFEY, Q.C.:

Q. This is April 4th, 2003. You certainly didn't

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get a copy of this until 2005, or even become aware of it until 2005?

DR. CARTER:

A. Yes, and then I --

COFFEY, Q.C.:

Q. And the second one of these is the May 2nd one, Doctor, 2003. You did not receive a copy of this, and the subject matter, the whole idea of it, they had to suspend the utilization of eight stains.

DR. CARTER:

A. No, I didn't -- I didn't know about that.

COFFEY, Q.C.:

Q. You weren't told about that, and that Dr. Ejeckam in May of 2003 had sent around, I'll refer to it as a briefing memo, as it were, on ER/PR. It's several pages -- it's three pages long. You weren't aware that that had happened?

DR. CARTER:

A. No, and this is the first time actually that I've seen that piece of paper, so --

COFFEY, Q.C.:

Q. Okay. So in 2005, you learned generally about the fact that something had happened in 2003?

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DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And I'll be asking you about that.

DR. CARTER:

A. Uh-hm.

COFFEY, Q.C.:

Q. You hadn't seen them. This is the -- for your interest, this is the June 19th, 2003 memo. You didn't see that back in '03?

DR. CARTER:

A. No, I didn't.

COFFEY, Q.C.:

Q. And the idea that, "following persistent erratic results of immunostains in our laboratory", that idea, when you showed up in 2003 --

DR. CARTER:

A. No. I'm sorry, I'm reading it because this one as well, this is the first time I've seen it.

COFFEY, Q.C.:

Q. Okay.

DR. CARTER:

A. So I'm reading. No, I didn't really even know

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that there was any problem in the immuno lab until 2005.

COFFEY, Q.C.:

Q. Doctor, when you started at St. Clare's -- well, you did your first work at St. Clare's, I think as best you can recall, was December of '03.

DR. CARTER:

A. Uh-hm.

COFFEY, Q.C.:

Q. Your stint there. When did you actually take your position and actually get the office at St. Clare's in the sense of have your own office?

DR. CARTER:

A. In August of 2004. Even when I came back for the locum in July, I was still operating out of a different office.

COFFEY, Q.C.:

Q. When you were appointed Associate Staff, that's when you would have gotten your own office?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

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Q. That office, who is your next door neighbour?

DR. CARTER:

A. Dr. Cook.

COFFEY, Q.C.:

Q. Okay, and did you -- you kept that office then over the -- you kept that office over the years?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Until, I take it, recently?

DR. CARTER:

A. Until I resigned recently.

COFFEY, Q.C.:

Q. Exhibit P-2406. Doctor, these are the minutes of Division of Anatomical Pathology meeting at the General Hospital site, actually, September 1, 2004. You can see the doctors listed there.

DR. CARTER:

A. Uh-hm, yes.

COFFEY, Q.C.:

Q. And this could be really -- you started in August, so --

DR. CARTER:

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A. A couple weeks later.
COFFEY, Q.C.:
Q. Two weeks later. This meeting occurred September 1, 2004, and paragraph 3.6 reads, "HER2/neu ER/PR immunostaining. Dr. D. Fontaine did mention that Dr. B. Carter would like to receive all the new HER2/neu ER/PR immunostaining before returning to the reporting pathologist. Some members of the division expressed that this is unnecessary and they will continue reporting their own cases". Now, Doctor, what can you tell us about how this came up between yourself and Dr. Fontaine?
DR. CARTER:
A. I have no specific memory of this, and my assumption is that when I came to St. John's, even when I was doing locums, I expressed my wish to see as many breast cases as I could. I was quite worried about losing the skills that I had with breasts, the numbers here in St. John's were quite low compared to the numbers that I was seeing in McMaster. So I had extended to many pathologists that I would look at their cases, give them back to them

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for reporting, if that's what they wished, or I would sign the cases out for them. It wasn't limited to HER2/neu ER/PR immunostaining. It was to any sort of breast case that we had. So I'm not sure how this came to be in this form in this memo.
COFFEY, Q.C.:
Q. Doctor, do you recall ever having any discussions with Dr. Fontaine about the idea of sub-specialization and it being desirable?
DR. CARTER:
A. Yes, but not specifically with Dr. Fontaine, but, yes, I've made that conversation with many people.
COFFEY, Q.C.:
Q. And, I take it, in McMaster, that had been the case?
DR. CARTER:
A. We had partial sub-specialization or -- most of my work was breast, but I did do other things.
COFFEY, Q.C.:
Q. Doctor, you did practice in Hamilton, and I do have that right, do I, between 1998 and 2003?
DR. CARTER:

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A. Hamilton, Ontario, yes.
COFFEY, Q.C.:
Q. And there, was there any particular facility that you practised in?
DR. CARTER:
A. At the Henderson Hospital and at the Hamilton Regional Cancer Centre, which has now changed its name. I'm not sure what the new name is.
COFFEY, Q.C.:
Q. Doctor, what was the situation there in respect of specialization of sub-specialization?
DR. CARTER:
A. In our laboratory at the Henderson?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. Each one of the pathologists that worked there had a recognized sub-specialty. Some of us crossed over into a second sub-specialty, but usually our academic training was in one area, and then you would pick up another area as you were interested in it. Probably 50 percent of the work was divided down the sub-specialty line, but you would still be expected to take

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a wide variety of somewhat easier specimens, or ones that didn't require sub-specialists sign out is probably a better way to put it. I would take part in other general duties of pathology, but as a breast pathologist then, I would be expected to go to breast disease site group meetings, to breast rounds, to tumour boards that were concerned with breast, and to participate in research.
COFFEY, Q.C.:
Q. So, Doctor, when you arrived in St. John's -- of course, you'd been doing locums for a while, as you've described, before you took up this permanent position in August of 2004. You, I take it, had expressed your views that maybe sub-specialization might be desirable?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. To anyone who would listen, as it were?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And Dr. Fontaine has told the Commissioner -- he's been here and he told the Commissioner

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that, in fact, he was of the same mind as yourself in that regard. Doctor, your view in that regard at that time, was it that there should be sub-specialization, period, or at least partial sub-specialization was desirable?

DR. CARTER:

A. Partial sub-specialization. I don't think that you can have full sub-specialization unless you're in a very large academic institution, but just necessities of cross coverage and covering operating rooms, you'd still need to require some basic pathology skills, and partial sub-specialization allows the more difficult cases -- I know for patients all cases are difficult, but, you know, cases that would require a little bit more finesse would go to somebody with sub-specialty knowledge of that area.

COFFEY, Q.C.:

Q. And, Doctor, what then in the 2004 and, well, I'll bring you up to the middle of 2005 at least initially. What was the reaction that you received when you would raise this?

DR. CARTER:

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A. Some people were for the idea in theory, but had a lot of difficulty with seeing how in practice you would institute it. Other people were -- like, Dr. Fontaine, were quite happy with the concept and familiar with it, and some people preferred to retain their skills and do all of their own sign out.

COFFEY, Q.C.:

Q. So they were not in favour?

DR. CARTER:

A. They were not in favour.

COFFEY, Q.C.:

Q. Exhibit P-1919. Now, Doctor, this is an interoffice memorandum to Dr. Ejeckam, Mr. Dyer, and Ms. Thomas. Who's Ms. J. Thomas, do you recall?

DR. CARTER:

A. She's the secretary -- one of the secretaries at the department in St. Clare's Mercy Hospital site. She was also the private secretary to the clinical chief. She shared both duties.

COFFEY, Q.C.:

Q. And Mr. Dyer was the manager of pathology?

DR. CARTER:

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A. Yes.

COFFEY, Q.C.:

Q. And Dr. Ejeckam -- why was this addressed to Dr. Ejeckam, because you're writing in your capacity as chair, Quality Assurance Committee?

DR. CARTER:

A. I had spoken to Dr. Cook probably in the first part of October. I think you may have a memo from Dr. Cook about that time. He asked me was I interested in quality management programs, and asked me would I be interested in chairing the committee, and we discussed it. I gave him a proposal of what I thought our duties should be. I think it may be the second page in this exhibit.

COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. And he spoke to Dr. Ejeckam. We felt that there should be a pathologist from each site on the committee, Mr. Dyer would be there in his capacity as lab manager, and Judy agreed -- Ms. Thomas agreed because we wanted representation from the clerical staff as

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well.

COFFEY, Q.C.:

Q. And there was - Dr. Ejeckam had been chairing the surgical pathology review committee, which goes back to the spring of 2003. In fact, it predates your involvement.

DR. CARTER:

A. Those committees would be unrelated to the one I --

COFFEY, Q.C.:

Q. I appreciate that, but he was chairing.

DR. CARTER:

A. And he was interested in QA.

COFFEY, Q.C.:

Q. So here's October 14th, and, of course, it's copied to Dr. Cook, as clinical chief, and you're setting up the first meeting. You conclude by saying, "I've enclosed an introductory document which should be read prior to the meeting, as well as an agenda for the meeting".

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, here's the memo itself. It's dated

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August 31st, 2004. It's to Dr. Cook from yourself. It's re; quality control and quality assurance committee in surgical pathology for the Health Care Corporation of St. John's.

DR. CARTER:

A. Uh-hm.

COFFEY, Q.C.:

Q. So, in effect, within two weeks of you taking your full time --

DR. CARTER:

A. Full time position.

COFFEY, Q.C.:

Q. Full time position --

DR. CARTER:

A. But I had been there since July 26th.

COFFEY, Q.C.:

Q. Yes, that yourself and Dr. Cook had discussed this, I take it?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And you produced this memo as a result of your discussion?

DR. CARTER:

A. Yes.

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COFFEY, Q.C.:

Q. Now, Doctor, when you arrived, was there a quality control and quality assurance committee in surgical pathology?

DR. CARTER:

A. Not that I knew of. My understanding was that I was being asked to form one.

COFFEY, Q.C.:

Q. To create it, and from your perspective, Doctor, was there a need for one?

DR. CARTER:

A. I think there's a general need for them in all pathology laboratories.

COFFEY, Q.C.:

Q. And where you had been in Hamilton, was there one there? Whatever it was called, was there the equivalent of that there?

DR. CARTER:

A. Yes, there was the equivalent of that there.

COFFEY, Q.C.:

Q. And how about down in Vanderbilt?

DR. CARTER:

A. In Vanderbilt as well.

COFFEY, Q.C.:

Q. Back in the 90s?

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DR. CARTER:

A. Yes, but, I mean, that is probably two very unusual institutions. I mean, it certainly wasn't a standard practice, but it was not uncommon practice.

COFFEY, Q.C.:

Q. On that point, Doctor, you refer to standard practice, at the time in the middle of 2004, how common or uncommon would the existence of a quality control and quality assurance committee be in respect of surgical pathology?

DR. CARTER:

A. If you look further down in the memo, I mean, we're talking a lot about pathologist's practice and that would be -- it wouldn't be a common occurrence. I just can't think of just a little less common qualifier. It wouldn't be rare, but it wouldn't be common. Quality control, quality assurance in the basic laboratory would be common.

COFFEY, Q.C.:

Q. But in pathologist practice, clinical practice, it would not have been common at that point?

DR. CARTER:

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A. Not in an organized program.

COFFEY, Q.C.:

Q. In an organized program. But now for the laboratory itself, the technical end of the laboratory -

DR. CARTER:

A. I think that's been sort of standard practice in labs.

COFFEY, Q.C.:

Q. Since before your time?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Did you at the time have any understanding about whether there was a quality control or quality assurance committee or by whatever name in existence in the laboratory technical end of it?

DR. CARTER:

A. I don't think that I had any knowledge at that time, I would have just probably assumed that it was happening.

COFFEY, Q.C.:

Q. And as you've pointed out here, Doctor, you begin the memo by saying, "After reviewing the

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literature on quality control and quality assurance on surgical pathology, I would like to make the following recommendations for setting up a quality control and quality assurance committee and program in surgical pathology. The main goals of this committee will be to ensure the accuracy, timeliness and completeness of the diagnosis issue by the anatomic pathologists within the department at the Health Care Corporation of St. John's. One, members of QC/QA committee, one anatomic pathologist as chair, the second one, one from the second site"--which I take it is the other, well wherever the chair was from, the person from the other institution.

DR. CARTER:

A. The other site, yes.

COFFEY, Q.C.:

Q. Second pathologist, and Mr. Dyer will be there as technical manager and member of the clerical staff if possible. Which is why, I take it on your interoffice memo -

DR. CARTER:

A. Yes, Ms. Thomas had agreed to serve on the committee.

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COFFEY, Q.C.:

Q. "The components of a monthly QA within the department, intradepartmental consultation review, minutes from the weekly meetings for intradepartmental consultation should be forwarded to the committee, as well as the final surgical pathology report for the cases under discussion. Quality assurance, quality control committee will ensure that appropriate protocol is followed during the intradepartmental consultation meeting and that the discussion is included in the final report." Doctor, what was that about?

DR. CARTER:

A. When a pathologist has a case that they think is a difficult or unusual, usually we'll seek consultation, it may be from someone in your department or he may decide to go to an outside expert and once you solicit that opinion, then that opinion should be included in the chart and if there is a difference of opinion, that should be reconciled, so the committee was going to monitor that practice so for cases sent out, as you heard this morning to the Mayo Clinic or the AFIP, we

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wanted to make sure that that consultative opinion got on the chart, was up loaded into Meditec, that the clinician was aware on the other end that the consultation had taken place and to see if there was any discrepancy in the opinions and same thing when you asked for a consult within your department. So if I asked Dr. Cook formally for a consultation, then I'm obliged to put that consultation into the patient's chart somehow.

COFFEY, Q.C.:

Q. I take it that up to this point in time, August and then September and October of 2004, there was no process in place to address that?

DR. CARTER:

A. No, I think people were having the consultations, if it was from the outside, I can't think of anyone who would not include that in the report. If it was from your neighbour, you may or may not, so we were just trying to formalize the process and monitor it and correct it if we found any deficiencies in the process.

COFFEY, Q.C.:

Q. So the, for example, within the department

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consultation or from one hospital to the other within the Health Care Corporation, the practice might vary from pathologist to pathologist, whether or not he or she would include a reference to the consultation and might even vary with a particular pathologist from time to time?

DR. CARTER:

A. Yes, this would be unusual for people not to include it, but you know, you're very strict when it comes from the Mayo Clinic, you make sure that you put that in the chart.

COFFEY, Q.C.:

Q. Then there's a reference to the top of the next page to frozen section review to be undertaken weekly by the QA, QC anatomic pathologist. Doctor, why the particular focus here on frozen section review?

DR. CARTER:

A. It's a standard facet of quality management programs for anatomic pathology department, so if you look at documents from the College of American Pathologists or from the Association of Directors of Anatomic and Surgical Pathology had asked, this would be a standard

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facet of a quality management program and it's there because frozen sections--do people know what frozen sections are?

COFFEY, Q.C.:

Q. You go ahead and tell the Commissioner, it never hurts for us to be reminded -

DR. CARTER:

A. It will be the true emergency for pathologists, for anatomical pathologists and general pathologists, when the surgeon is in the middle of an operation, they ask you to come down to the operating room, look at the tissues for them and help them make a decision as to how they should go about, you know, treating the patient at the time so the patient is under anesthesia. There are some time constraints to it, the most common things that we go down for at St. Clare's site, for example, is a woman with breast cancer or a man with breast cancer, we'll take a small biopsy of their lymph nodes in their arm pits and tell the surgeon whether or not they're positive. If they're negative, the surgeon will close them up. If they're positive, the surgeon will do a bigger exploration of their

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arm and they can end up with difficulties moving their arm and those sorts of things. So for us, it's an emergent and probably our most stressful time, so because it's emergent, it's the time where you will probably have errors, if I can use that word, occur, so there always has to be some statement when you sign out the report, well Dr. Carter said a frozen section that the sentinel lymph node was negative, but I looked at it, you know, in my leisure time and with more testing, and it's positive.

COFFEY, Q.C.:

Q. That would be the lymph node tested through having gone through the whole fixation process.

DR. CARTER:

A. Yes. So it's an area for us that is prone, can be prone to problems and it's an area for us where we want to make sure our skills are really sharp.

COFFEY, Q.C.:

Q. And hence the concentration by -

DR. CARTER:

A. Yes.

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COFFEY, Q.C.:

Q. - the College of American Pathologists and others on that particular aspect of ensuring QA/QC is carried out there.

DR. CARTER:

A. Yes.

THE COMMISSIONER:

Q. Are you anticipating here, when you talk about frozen section review, some kind of review of each or review of those where there was a difference or some kind of a representative sample?

DR. CARTER:

A. What we would do, because it's not that common, it was more common at the St. Clare's site than at the Health Science Centre, but you may end up talking maybe 30 cases per week, so the secretarial staff would pull--I was initially doing this, so they would pull the 30 frozen section diagnoses and the corresponding 30 final reports and I would just look at them to see if they concurred and to see if a statement was made by the pathologist. So it would be all of them.

COFFEY, Q.C.:

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Q. And the next bullet, the second bullet on this page, Doctor, says "A random review of two percent of surgical pathology cases should be carried out on a weekly basis. This duty should rotate between all the Anatomic Pathologists in the Health Care Corporation of St. John's. The pathologist would comment on both the quality of the final report and the quality of the product from the Histology Lab. On a monthly basis, a similar procedure should be carried out on a randomly selected autopsy case. In both of these incidences, the clerical staff who was a member of the Surgical Pathology Committee, would evaluate and comment on the quality of the clerical report, as well as the accuracy of the coding issues." First of all, this Surgical Pathology Committee there, was that Dr. Ejeckam's committee?

DR. CARTER:

A. No, that should be the QA committee. I type a lot of my own memos, so that may be recurring thing.

COFFEY, Q.C.:

Q. Okay, the clerical staff, in this case as it

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turns out it was Ms. Thomas?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Okay, the clerical staff who was a member of your committee, in fact, the QC/QA Committee, I'll call it.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Would evaluate and comment on the quality of the clerical report, as well as the accuracy of the coding issues. So Ms. Thomas would be counted upon to do that?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. That's her background.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Then you have "a random review of two percent of surgical pathology cases would be carried out on a weekly basis." Could you tell us what was envisaged here?

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DR. CARTER:
A. A person would randomly go back, because usually you'd have one of the secretaries just go back and pick, if 500 cases were done in the last month, she would pick two percent of that and just pick the cases, the numbers out of her head and those were the ones that we would go back and review. One to two percent is the standard figure again from ADASP or the CAP and the random review is to ensure quality at frozen sections, even though it is a difficult time, everybody knows that it's a time when all eyes are going to be on the report, so a random review is just to look at what you're doing every day.
COFFEY, Q.C.:
Q. So anybody doing frozen section, knows full well that or can anticipate full well that that's going to be reviewed.
DR. CARTER:
A. Well you know full well the surgeon is very interested in what you have to say, so they're going to be looking at the case pretty closely.
COFFEY, Q.C.:

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Q. And as well--up to this point, had frozen sections been reviewed?
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. Okay, they weren't being.
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. Okay, so the person who would be looking at it critically and carefully would be the surgeon.
DR. CARTER:
A. Yes, and so people always know that they're under scrutiny when they're doing a frozen section, so random review is more reflective of what's going on in your department.
COFFEY, Q.C.:
Q. And up to this point in time was there any such random review going on?
DR. CARTER:
A. Not that I know of.
COFFEY, Q.C.:
Q. And "This duty should rotate between all of the Anatomic Pathologists in the Health Care Corporation." Now this would be the duty to

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carry out this two percent check, I take it?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. So the idea was if you were -
DR. CARTER:
A. I can't review my own work, so there needs to be another pathologist and just to rotate the duty, time constraints job -
COFFEY, Q.C.:
Q. So the idea would be one week Dr. Carter would do two percent of last week's cases and randomly pick them and review them.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And the next week Dr. Cook might and the next week Dr. Denic might.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. That sort of -
DR. CARTER:
A. Yes.
COFFEY, Q.C.:

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Q. And it would just kind of go on all the way through the Health Care Corporation. Now on both the quality of the final report, they were expected to common on, the quality of the final report and the quality of the product from the histology lab, I want to ask you about that, now this report of two percent cases, what in practice would that involve? Like if your number was up and you were going to do review, Dr. "X"'s case, because that's one of the random ones, what would you expect as the reviewer, what was expected of you?

DR. CARTER:

A. You would receive the slides on that case and you would receive the surgical block--or sorry, the surgical report, so you would read the surgical report. If we're going to stay in the realm of breast, so if you had a breast biopsy that was called infiltrating carcinoma, so you'd have that report, then you would go to the slides and make some sort of comment on the quality of the slides and I know people have talked about that a lot, so you would comment on the staining and whether or not the tissue is adequate, those sorts of things.

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And then you would do your own evaluation and make your own diagnosis and see if you agreed with the original pathologist.

COFFEY, Q.C.:

Q. What was expected then or what did you envisage would happen then? You reviewed, say I'm a fellow pathologist, you reviewed my case and made your observations, what would happen then?

DR. CARTER:

A. Then you would call that a discrepant case and -

COFFEY, Q.C.:

Q. If you found discrepancies.

COFFEY, Q.C.:

Q. And so one of the first things that happened was that you'd need then to write a policy about what you do about discrepant cases. What we had decided to do was discrepant cases would be brought to Dr. Denic or Dr. Cook, whoever was the clinical chief at the time, I can only remember going to Dr. Denic once, so it may have been done, may have been around when we had discrepant cases, and then Dr. Denic would look at the report in the case and

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if he felt it was within the realm of what he could do, he would have a look at it or refer to one of the people who were, in essence, practising such specialty, a pathology there and if he needed an outside consultation, that would happen, but most of them will be resolved around a meeting around the microscope.

COFFEY, Q.C.:

Q. And the next bullet says, "Clinical parameter review should take place on a monthly basis." What is clinical parameter review?

DR. CARTER:

A. Again, this is standard from ADASP and CAP, that once a month you would take either a disease site, specific disease process or specific surgical pathology specimen, so for one month you could look at all of the gallbladders that came in for whatever reason and go down through them and do the same things that I just talked about. Again, it's a random review of cases that come through the department, but it gives you more of an idea if you happen to hit upon an area where there may be problems with the diagnosis.

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COFFEY, Q.C.:

Q. Doctor, here it says, "specimen or a disease will be selected, all appropriate cases from that month will be reviewed by an anatomic pathologist", I take it again that's somebody whose name has just come up.

DR. CARTER:

A. Somebody in one of the two sites, yes.

COFFEY, Q.C.:

Q. And forwarded to the chair of the QA/QC Committee. What would be forwarded, the person's--the reviewer's views?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And again, I take it this was not being done at that time?

DR. CARTER:

A. Not that I know if, no.

COFFEY, Q.C.:

Q. "Inter-institutional reviews should be forwarded on a monthly basis to the chair of the QC/QA Committee." What are they, inter-institutional reviews?

DR. CARTER:

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A. So if you asked the person in the next office for their opinion or everybody on your site for their opinion. No, sorry, these are the outside consults, not the inside--these are the outside consults, so anything that was sent outside, so if I sent something to Dr. Page for his opinion on a case that I found difficult or if one of the oncologists said would you mind sending this up to Sunnybrook, the patient is going up there for a MRI, or if the patient had said I would like my case to go down to the Mayo Clinic, so all of those outside consultation, the same thing, we would make sure that there was a concordance between the two diagnoses.

COFFEY, Q.C.:

Q. The diagnosis originally within the institution itself?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And the outside views upon review. And up to that point in time, was that going on?

DR. CARTER:

A. Not in a formal way, but as I explained

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earlier, most people would do that as a matter of course in their practice.

COFFEY, Q.C.

Q. They'd put it on the patient's chart certainly?

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. "On a weekly basis, the technical member of the committee should forward a report to the chair of the committee which includes a special adequacy record, the lost specimen record, a histology slide delivery record, a quality control to histology record and a quality control from histology record". Could you explain to the Commissioner what this -

DR. CARTER:

A. Well, the first one is a specimen adequacy record, not a special adequacy record. So, specimens that come into the lab from -

COFFEY, Q.C.

Q. It should read specimen.

DR. CARTER:

A. Should read specimen, yes. Specimens that come into the lab from outside clinics or form

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the operating rooms or from the outpatient clinics within the hospital will be assessed by the intake person, clerical and sometimes technical for adequacy. So, that would be adequacy of history; do they have all of the information that we require; do things match; is it in the right amount of formalin; is there actually a specimen present in the container? So, they would make some evaluation of the specimen adequacy.

Lost specimen records, one of the most traumatic thing, I guess, that happens in pathology is when patients' specimens are lost. So, it's usually recommended that you have a lost specimen record.

Histology slide delivery record, because it was a partially amalgamated lab, slides are being delivered from one site to another, so there was a necessity to have tight control over that process so that no slides would be lost.

Quality control to histology and quality control from histology was a bilateral process where the technologists would feel free and comfortable to write a report on the type of

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tissue that they have received from the pathologist or the pathologist assistances. So, things I think that you've heard about here, this tissue is too big for the block or this is too soft, or conversely if it was a bone, this is too hard, not decalcified enough, so the technologists could make comments like that and refer it back to the committee and also the pathologists could make comment on the quality of the slides that they have received from the lab. So, it's just a formalization of a process that was happening verbally.

COFFEY, Q.C.

Q. Now, the technical member of the committee, in this context, would have been whom?

DR. CARTER:

A. Barry Dyer, Mr. Dyer.

COFFEY, Q.C.

Q. And so here, it would either be him or his nominee.

DR. CARTER:

A. Yes, yes.

COFFEY, Q.C.

Q. That would be the idea, whoever -

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DR. CARTER:
A. The understanding was not that the four people on the committee do all of the work, it would have to be distributed.
COFFEY, Q.C.
Q. And that may have been going on informally, but it certainly wasn't going on formally or -
DR. CARTER:
A. No.
COFFEY, Q.C.
Q. How much was it really going on informally, in terms of -
DR. CARTER:
A. I think the specimen adequacy record, I'm not sure that they were keeping records of it, but they would check for that. And if they found, in fact, that there was no specimen, they would fill out incident reports or if they found that there was an error in the labelling of the specimen, they would bring it back to the operating room or telephone somebody from the clinic to come and to rectify it. The loss specimen record, I've said, histology slide delivery record, that wasn't happening at all. Quality control to histology and from

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histology, that was happening sporadically.
COFFEY, Q.C.
Q. And detailed protocols on policies for the above mentioned programs will be provided to the members of the laboratory staff, both technical and medical in the form of a quality control, quality assurance manual. Was there a quality control, quality assurance manual at that point that you were aware of?
DR. CARTER:
A. There were quality control manuals on site at St. Clare's and I think as well from the General, but they were quite old.
COFFEY, Q.C.
Q. And you say "quite old", when had they last been updated? From your perspective, when you say "quite old" -
DR. CARTER:
A. The one from the General is the one that I'm most familiar with and I mean, it was typed, it was not a computer, so -
COFFEY, Q.C.
Q. Okay, so the days of IBM Seletrics, that kind of--1980s or perhaps it even pre-dates you.
DR. CARTER:

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A. Yeah.
COFFEY, Q.C.
Q. But certainly, just looking at it you could tell it had been typed on a typewriter as opposed to using a computer printer.
DR. CARTER:
A. Um-hm.
COFFEY, Q.C.
Q. So, at the time, I take it, detailed protocols and policies for these programs did not, at least in any kind of an up-to-date format did not exist.
DR. CARTER:
A. No, and these are relatively new developments in the field of anatomical pathology.
COFFEY, Q.C.
Q. And Doctor--Exhibit P-2450. This is a report of a laboratory medicine program to clinical chiefs and MAC for September and October 2004, paragraph four, "quality initiatives". "Dr. Bev Carter has agreed to become our quality assurance co-ordinator for the division of anatomical pathology. A QC/QA committee in surgical pathology will be set up with representation from the General and St.

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Clare's sites. The main goals of the committee are to ensure accuracy, timeliness and completeness of diagnosis by pathologists within the division". Doctor, the driving force behind this was whom?
DR. CARTER:
A. Dr. Cook, Don Cook.
COFFEY, Q.C.
Q. And if we could go back please to Exhibit P-1919, I apologize. Doctor, I didn't look at the last page of it, page four which is the QA meeting, scheduled for November 9, 2004. I take it that would probably have been the first -
DR. CARTER:
A. Yes, that would be the first meeting.
COFFEY, Q.C.
Q. So, the end of 2004, this is being organized? Exhibit P-2451. Now, Doctor, this is a form entitled "Annual Review of Medical Staff" for the year 2004. The person being reviewed is yourself.
DR. CARTER:
A. Yes.
COFFEY, Q.C.

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Q. I ask you about, on the second page of this, of the exhibit, there's a reference to Atlantic Breast Cancer Network newsletter.
DR. CARTER:
A. Yes.
COFFEY, Q.C.
Q. "Breast Cancer Pathology Report, the Role of your Pathologist".
DR. CARTER:
A. Yes.
COFFEY, Q.C.
Q. Doctor, I take it that this would have been completed in relation to the calendar year 2004, this document?
DR. CARTER:
A. Yes, that would be my academic review for 2004.
COFFEY, Q.C.
Q. Doctor, I'm going to ask you about the communication between, that you found when you arrived here in St. John's in '03 for you locums and then '04, your permanent position. What sorts of communications occurred between pathologists and then from pathologists to oncologists or other physicians, formal and

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informal. Could you tell us about that?
DR. CARTER:
A. At the General site, formally they would have, for pathologists, they would have a site meeting each month where they would discuss issues pertinent to the lab, minuted and at St. Clare's we were much less formal, but it was a very tight lab, I would say. So, we talked a lot about all of our issues, all of the time. Communications with oncologists, I found it very open, quickly got to know many of the oncologists, that's my interest besides breast, is also oncology. So, it's an area that I would be interested in, but it was quite a nice relationship. Formally, we would have Wednesday morning rounds which were a mixed tumour board of interdisciplinary, but -
COFFEY, Q.C.
Q. Where did that occur?
DR. CARTER:
A. Various places. When I was just sort hanging out, it was in the pathology lab actually that it took place. And then it moved over to, I think, the radiation oncology area of the cancer clinic and then it moved into the

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conference room in the cancer clinic. It kept growing over time as well with more interested parties.
COFFEY, Q.C.
Q. So, this was already in existence when you arrived in '03?
DR. CARTER:
A. Yes.
COFFEY, Q.C.
Q. And what sorts of physicians would go to this?
DR. CARTER:
A. Pathology, surgery, radiology, medical oncology, radiation oncology, palliative care, medicine.
COFFEY, Q.C.
Q. Was there any structure to this meeting?
DR. CARTER:
A. Yes, they would be chaired by one of the-- usually by Dr. McCarthy, I think, and then she would have a designate when she wasn't around. Sometimes it would be radiation oncology, sometimes medical, so, usually one of the clinical oncologists. And cases would be presented, various aspects of them, maybe pathology, maybe radiology, maybe just a

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treatment issue and it would be discussed amongst the appropriate disciplines and then a consensus reached and then those notes would be transcribed by Dr. McCarthy. I'm not sure what happened to them; I assume they went on the chart.
COFFEY, Q.C.
Q. Here Doctor, I raise that in this context is that the subject is your breast cancer pathology report, the role of your pathologist.
DR. CARTER:
A. Yes.
COFFEY, Q.C.
Q. What was that about? First of all, who was this written for? What audience was this written for?
DR. CARTER:
A. This is the Atlantic Breast Cancer Network which is an e-group from Atlantic Canada. And I was speaking to one of the women who works there, she was the editor of it and she actually asked me would I agree--they have different sections, would I agree to be the "Ask an Expert" for the pathology section.

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And in the course of our conversation, we talked about this idea, just been coming on in many places in the United States and larger centres in Canada and we talked about getting something like that for on the website for women and men. And she asked me to write this article, which I did.

COFFEY, Q.C.

Q. Which is, I take it, describes what it is a pathologist's role is in breast cancer.

DR. CARTER:

A. Yes, but also what people should know about their pathology report and what they should understand when the oncologist, whether that's the surgeon or the medical oncologist tells them, you have a 1.2 centimetre, grade 3 with LVI. I mean it explained all those things for them.

COFFEY, Q.C.

Q. And the significance potentially of -

DR. CARTER:

A. In basic detail.

COFFEY, Q.C.

Q. Basic detail, yes. Doctor, not for the general audience, for the particular audience

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of oncologists, we've heard certain evidence here about pathologists did not and do not have, they certainly haven't up until very recently have not had a uniform way or reporting particular things very often. An example, breast pathology would be ER/PR, sometimes the word positive and negative is used, sometimes percentages, sometimes a combination of percentages and words.

DR. CARTER:

A. Yes.

COFFEY, Q.C.

Q. Doctor, before the middle of 2005, what, if any, understanding did you have about how much oncologists understood, for example, about ER/PR positive/negative? I mean you would use the word negative, did you have any understanding of what they understood you meant by negative?

DR. CARTER:

A. Here in St. John's?

COFFEY, Q.C.

Q. Yes, and was this sort of thing ever discussed?

DR. CARTER:

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A. I think it would have been discussed at the tumour boards when we were talking about patients. My understanding shortly after I came here was that ten percent was being used as a cutoff by the oncologists.

COFFEY, Q.C.

Q. And you would have gotten that understanding from whom, do you think?

DR. CARTER:

A. From the oncologists at tumour boards. I probably would have asked, what are you using for your cutoff?

THE COMMISSIONER:

Q. Could you explain exactly what a tumour board is?

DR. CARTER:

A. Multiple disciplines get together and one of the physicians who has a difficult case for a variety of reasons will submit that patient's name to the tumour board and when we got into the tumour board, that physician will present the case, the radiologist will have the radiology reports at hand. I'll have the pathology reports at hand. So, they may be asking questions about what's the best way to

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approach this surgically or do you think I should give them another treatment or do I need to have the pathology reviewed. So, we'll discuss it as a group and try to come up with some sort of consensus. It's usually for difficult cases.

THE COMMISSIONER:

Q. So, what's the difference in doing a round and doing a tumour board, your Wednesday morning rounds?

DR. CARTER:

A. Did I say Wednesday morning rounds? I would mean the tumour boards -

THE COMMISSIONER:

Q. Well, there was a reference to what you called rounds on Wednesday morning and I'm just wondering what the difference is, if any, between rounds and tumour boards?

DR. CARTER:

A. If I said rounds, I meant tumour boards.

THE COMMISSIONER:

Q. Oh, okay.

DR. CARTER:

A. If it's somebody else, like, I -

COFFEY, Q.C.

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Q. Well, on that point, is there a difference?
DR. CARTER:
A. Between rounds and tumour boards?
COFFEY, Q.C.
Q. Yes.
DR. CARTER:
A. I think rounds, word that is used often for clinical meetings where you would be presenting, like medical grand rounds or surgical grand rounds. If pathologists meet together to discuss cases, we would call that rounds.
COFFEY, Q.C.
Q. And would these tumour board meetings, panels, tumour boards, would they, almost because of their very nature, be considered rounds, a form of rounds?
DR. CARTER:
A. Yes.
COFFEY, Q.C.
Q. But there would be round that would not tumour boards?
DR. CARTER:
A. Yes.
COFFEY, Q.C.

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Q. The rounds is the wider, more generic term.
DR. CARTER:
A. Yes.
COFFEY, Q.C.
Q. Exhibit P-1395, please. Doctor, this is a report of the laboratory medicine program to clinical chiefs and MAC for January/February 2005, paragraph four, under quality initiative, "Dr. Bev Carter, our quality assurance co-ordinator is currently working on documenting policies and procedure in the division of anatomical pathology. Some of Dr. Carter's priorities include better document of quality control and intra-department rounds, as well as correlation of intra-operative frozen section interpretations with the final pathology report. It is my help"--that would be Dr. Cook's help"--to generate a quality assurance report from this division as part of our annual program report" and a space for Dr. Cook's signature is on the next page. Doctor, so you'd had a meeting back in November, 2004 and then how far then did this initiative advance?
DR. CARTER:

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A. We met in November of 2004. Initially there were four of us on the committee, and we began to work on the reviews and the frozen section and started some of the policies around what you should do with a discrepant result, you know, and who you should report to. We had a few more meetings throughout the spring. Dr. Ejeckam decided, after the first meeting, that he really didn't want to be on the committee and we then recruited two other pathologists. It would be about every six weeks. I mean, you try for four. It would end up to be about six weeks. So we met probably about every six weeks, until I think, the end of May or the end of June, but that was our last meeting until September. We made the decision, and we had some plans for the summer, and then the estrogen receptor thing happened, but we did a lot of work on the reviews and the frozen sections, those sorts of things.
THE COMMISSIONER:
Q. Mr. Coffey, wherever you can find a convenient spot, we'll break for the afternoon break.
COFFEY, Q.C.:
Q. Well, that's a convenient point, because it's

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the estrogen and progesterone is about to happen in time. Thank you.
THE COMMISSIONER:
Q. All right then, we'll take the afternoon break.
(BREAK)
THE COMMISSIONER:
Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Registrar, Exhibit P-1395, please? Just before I leave this, Doctor, I want to clarify something. "Better documentation of quality control and intradepartmental rounds." These rounds, is that both of these, quality control and intradepartmental rounds?
DR. CARTER:
A. Yes. At the St. Clare's site, they were called quality control rounds and at the Health Sciences, they were called intradepartmental. Essentially both are when the pathologists sit around together and show difficult or unusual cases and ask for opinions.
COFFEY, Q.C.:

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Q. And is what you just referred to earlier this afternoon about the fact that this was going on, but it should be formalized?
DR. CARTER:
A. More formally documented.
COFFEY, Q.C.:
Q. This quality assurance report that's referred to there by Dr. Cook, do you know if that was ever produced?
DR. CARTER:
A. I don't know.
COFFEY, Q.C.:
Q. Exhibit P-0067? Now Doctor, this is Dr. Cook's May 24th, 2005 letter to Dr. Williams. Doctor, can you tell us, please, about how the estrogen receptor, progesterone receptor matter, as it evolved in 2005, how it first came to your attention?
DR. CARTER:
A. Early in May, and I don't know what date it was, but it was early in May, Dr. Cook came into my office with some slides and I talked earlier about, you know, when you want a formal opinion, but often we walk into each other's office and just show slides and, you

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know, ask their opinion. So he brought in several slides and showed them to me and they were estrogen receptor, progesterone receptor on the index case, and I told him that I thought that they were positive and that he agreed.
COFFEY, Q.C.:
Q. So this is on the index case, this is Peggy Deane's case?
DR. CARTER:
A. Yes, it is.
COFFEY, Q.C.:
Q. Okay.
DR. CARTER:
A. And he agreed that they were positive, and we had a very short discussion at that time. He told me that she had been given a report prior to this as negative and it was just a very brief discussion of, you know, how those things can happen, and then a few days later, over the next week or so, I got a second request from--I think it was from Dr. McCarthy on another patient that she was requesting it on, and again, Don and--Dr. Cook and I were talking about those cases. So we had the two

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cases then, and started talking more and more about, you know, is this is an issue or is this an isolated case.
COFFEY, Q.C.:
Q. Just so I'm clear, Doctor, so one day, and I take it, you wouldn't have documented it because yourself and Dr. Cook would be back and forth to each other's offices routinely?
DR. CARTER:
A. Most of us will go to each other's office, if you know the answer and you know what the diagnosis is, but you just--we call it hand holding. You just want somebody--so it's usually a diagnosis of importance. So if you're first diagnosing cancer in someone, for example, or in some cases when you tell them they got high grade pre-malignant changes, it's very important for treatment decisions. So things like that where you know what your diagnosis is, but you just want somebody else to pat you on the head, you would bring it in. So it was that sort of thing. He knew it was positive. He had no difficulty with it. He just wanted a second set of eyes on it.
COFFEY, Q.C.:

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Q. And so he'd come into your office with these slides and said "Bev, would you have a look?"
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. "Tell me what you think." And you looked and they certainly looked positive to you?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And this was, these were the slides, I take it the retest slides for Peggy Deane?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, you indicated just now that you did have a brief discussion with him at the time about how these things can happen?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. What did you mean by that?
DR. CARTER:
A. He had shown me the slides and said that this patient was negative before. So he would have

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asked, you know, had I seen it before, you know, yes.

COFFEY, Q.C.:

Q. Had you seen what?

DR. CARTER:

A. Had I seen this phenomenon, you know, happen before. I mean, I would have answered yes. We would have talked about, you know, what kind of things can cause cases to be negative in one instance and positive in the other, but I mean, it was just a very brief -

COFFEY, Q.C.:

Q. So what, if anything, did you have to say to Dr. Cook at the time about how this sort of phenomenon can occur?

DR. CARTER:

A. I can't remember the specific conversation, but I can tell you what I think I would have said.

COFFEY, Q.C.:

Q. Sure.

DR. CARTER:

A. At the time, I mean I probably, you know, would have talked about false negatives in general, you know, patients who are weak

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expressers. Have you--you've come across that?

COFFEY, Q.C.:

Q. Well, perhaps you could just--we've heard the term, but you could expand upon that to the Commissioner.

DR. CARTER:

A. Most patients, when you look at their breast cancer cases for estrogen receptor and progesterone receptor testing, mostly for estrogen receptor testing, they're either easily recognizable as positive or completely negative. So about 80 percent of your patients will be either negative or greater than 75 percent ER positivity. A small percentage of them are somewhere in between and a very small percentage of them are somewhere between say five and 15 percent, and you would call that a weak expressers, because it's around the treatment point. And if they were a weak expresser, and then your test wasn't optimized, you may have, in the one instance, that person being negative and then in another instance, that person being positive. Problems with the testing being

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run, just those sorts of things, but it was just a very general and not a specific conversation.

COFFEY, Q.C.:

Q. These particular slides for Ms. Deane, the slides that you looked at, I take it because you understood they were the retest slides?

DR. CARTER:

A. They would have been the new slides.

COFFEY, Q.C.:

Q. The new slides, you've indicated that they were readily apparently positive?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. They weren't something that was negative and was now a weak positive. They were positive?

DR. CARTER:

A. They were positive.

COFFEY, Q.C.:

Q. Doctor, do you recall, at that time, being told anything about what the original classification of them had been?

DR. CARTER:

A. That it was negative. I knew that, but I

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didn't know anything about percents or anything like that.

COFFEY, Q.C.:

Q. I take it you didn't see the original slides at that point?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. Have you ever seen Ms. Deane's original slides?

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. Doctor, you indicated as well that not too long after that, you were contacted by Dr. McCarthy?

DR. CARTER:

A. Yes, I'm pretty sure that it was Dr. McCarthy.

COFFEY, Q.C.:

Q. And at the time that Dr. Cook spoke to you, just before I leave that, initially, was there any discussion about the type of cancer that Ms. Deane had, invasive lobular?

DR. CARTER:

A. At the time that he showed me the positives?

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COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I don't think at the time, but I mean, there was a lot happened in those three or four weeks. That issue came up in the next two or three weeks, but I don't know if it was that day.
COFFEY, Q.C.:
Q. So when Dr. McCarthy though, in any case, you recall she contacted you.
DR. CARTER:
A. And I believe she had a patient who was infiltrating lobular. It was either that or the patient was post menopausal, small low grade tumour, something that you would expect to be positive.
COFFEY, Q.C.:
Q. So -
DR. CARTER:
A. I know by the time that Joy, that Dr. McCarthy called, those sorts of surrogate issues had come up.
COFFEY, Q.C.:
Q. And did Dr.--when Dr. McCarthy contacted you,

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was she contacting you to say that "I have a second patient and I'd like the patient retested," or "I have had a second patient retested and this is the result," do you recall?
DR. CARTER:
A. I think it would have been to ask me to retest, but again, I'm not certain.
COFFEY, Q.C.:
Q. You can't recall. So what then happened, Doctor? Can you just describe then, you've got two cases, both of which have converted, to use that term that's been used here?
DR. CARTER:
A. And I thought that there was a third as well.
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I thought that we had Peggy's case and then two sort of -
COFFEY, Q.C.:
Q. There were two others in that, yes.
DR. CARTER:
A. - highly selected. I thought I've seen some

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memos where they talk about two in total, but I thought there were three.
COFFEY, Q.C.:
Q. And on that point, Doctor, your memory will be borne out. We'll see from the documents as we go along.
DR. CARTER:
A. Okay. And there was a lot of talk in the lab at St. Clare's about, you know, what could be happening and I think Don, Dr. Cook was talking to the oncologists and Dr. Williams about, you know, whether or not this was an issue or a few isolated highly selected cases that you would expect to, you know, to convert. So we had a meeting on May 17th, I think it was, with the two oncologists who have been involved with the patients who we were talking about at this time, myself and Dr. Cook and the lab manager, Mr. Dyer, and discussed the issue to see if we could come up with a plan of how we were going to discover whether or not this was an isolated case, several isolated cases, something that was confined to the time of Peggy Deane's testing, or if it was something that was more

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widespread than that, and at the end of the meeting, we decided to look back at 2002 and look at all of the negatives at that time, both look at the old slides and retest the cases and perhaps go into 2001, if we didn't have a big enough number to draw any sort of conclusion. Because I think one of the new cases was in 2001, and perhaps take it outside of St. John's, and look at cases from 2002 that were done from other hospitals around St. John's.
COFFEY, Q.C.:
Q. So why 2002, Doctor?
DR. CARTER:
A. Because that was where the index case had come from. So it just served as an idose (phonetic), no real scientific reason for it, but it would serve an idose and we would move out from there.
COFFEY, Q.C.:
Q. Start where the -
DR. CARTER:
A. Where the problem arose.
COFFEY, Q.C.:
Q. - in the same time frame where Ms. Deane's

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case was and move on from there?
DR. CARTER:
A. Yeah, and see--move out from there and see if you can--just we were more or less doing a broad based approach to see if we could gather any information about what was going on.
COFFEY, Q.C.:
Q. Go ahead, Doctor, what then happened?
DR. CARTER:
A. Where am I?
COFFEY, Q.C.:
Q. Well, you've gone through your meeting of May 17th, okay.
DR. CARTER:
A. And we began to look at some of the cases from 2002 and we had also agreed that as patients came in to oncologists' office, if they felt that they wanted somebody who was originally diagnosed in 2003 retested that we would do that. So we had kind of a mixture of patients. I think the first group that we had looked at, and I would probably do better with the exhibits, but I'll give you my rough estimates.
COFFEY, Q.C.:

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Q. I'm going to take you through the exhibits, Doctor.
DR. CARTER:
A. Okay.
COFFEY, Q.C.:
Q. I'm just trying to get an overview. From the Commissioner's perspective, sometimes one can lose sight of the forest for the trees when you're in the nitty gritty of it, so just kind of looking back on it, your memory of it.
DR. CARTER:
A. So we were looking at cases that were a mixture of 2002 and whatever was coming in from the oncologists. In our first group, when we pulled them together and had a chance to sit down and talk to one another about it, there were 25 patients, I believe of which 16 had changed from a negative to a positive status, so we began to get an idea that this was probably, you know, a more serious problem, not an isolated incident, and we talked a lot about how to best investigate it, because the question at that time was what went wrong. You know, can you pinpoint what went wrong? So we decided to have sort of a

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broad approach to it, like descriptive kind of research where you would start right at one end of the whole procedure and go right to the other end of the procedure, and just describe all of the steps that were in between. I mean, it's unlikely, but you know, I'll give you the less likely examples. We could have found out that, you know, all the wrong tests were read by Dr. Cook, or we could have found out that all the wrong tests were performed on a Saturday and then, you know, your problem is solved. So we were looking at things from the time that the specimen spent in formaldehyde before it was grossed, sectioned, you know, and how long it was fixed in formaldehyde for, how it was processed, what kind of testing, what were the controls, who read it, who performed it, you know, that sort of thing.
COFFEY, Q.C.:
Q. Every different factor?
DR. CARTER:
A. Facet of the whole procedure to try to see if we could find trends. We had a second group, I think it was 33, and of the 33, I'm not sure what the conversion is, I think 17 maybe, I'm

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not sure what it was, but again, now we had a fair number of cases with a greater than 50 percent conversion rate. We still proceeded along trying to gather the information that I wanted and I was having a lot of difficulty with that. I don't know if you want me to go into all that.
COFFEY, Q.C.:
Q. Sure, if you would.
DR. CARTER:
A. Okay. I was having a lot of difficulty getting some of the information that I needed. It was my understanding when I started to sort of broaden the scope of what we were looking at, so probably by mid June was that this was an agreement that, you know, everybody was in agreement that this was what I would do. I would begin to look at the process from one end to the other and try to see if we could identify any trends. I was having a lot of difficulty getting information from the technical side of things.
COFFEY, Q.C.:
Q. What sorts of information, Doctor?
DR. CARTER:

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A. Things that I wanted to look at were, in fact, who the patients are. So I didn't want a stack of papers and say these are the patients. I wanted to see how did you find those patients, how did you search, you know, for those negatives, are we missing people, that sort of thing. I wanted to look at the external controls that had been read, as you were shown this morning, and I'm sure other times, to look at the external controls and try to correlate them to specific test results. I wanted to look at the policies and procedures that they had in the immunohistochemistry lab, I wanted to see the optimization of the protocol for ER/PR testing, the validation, the antibodies, the spec sheets for the antibodies, the QA that was going on in the lab, and then look at the slides themselves.

COFFEY, Q.C.:

Q. That would be the original and the retest -- you would have probably the retest slides, but the original slides too?

DR. CARTER:

A. A lot of them hadn't had retests and I was pulling them, so both things were happening

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simultaneously.

COFFEY, Q.C.:

Q. I apologize.

DR. CARTER:

A. So look at the original slides, make assessments on those about whether or not I agreed with the original pathologist, status of the control tissues, were they present, were they positive, general assessment of the slides themselves, what the quality of the slide was, looking at the report, looking at things that will be considered surrogate markers, so sub-types, grading, those sorts of things.

COFFEY, Q.C.:

Q. And, Doctor, we do have a letter of yours. I believe it's July 14th, and I'll be looking at that. The list really you've just set out is there.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. In a formal way. Doctor, so I take it that you were prepared, in effect, to undertake a full scale review of this?

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DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And that's certainly --

DR. CARTER:

A. To begin one, at least.

COFFEY, Q.C.:

Q. You were certainly going to try.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. You planned to.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. And that only -- involved not only the pathologist's work itself, whatever pathology reports and the slides that they would have looked at, but as well, I take it, what went on and was going on in the laboratory itself?

DR. CARTER:

A. Yes, and the -- to a lesser extent, to the operating room.

COFFEY, Q.C.:

Q. Yes, relating to the fixation matter?

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DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Aspect of the matter. So what did you find then, Doctor? This was your plan.

DR. CARTER:

A. Well, I wasn't able to obtain a lot of information from -- documentation from the laboratory. I wasn't able to see very many of the external controls. I'm not sure that I saw any of the external controls at all, but I wasn't able to see any of those. I was never able to see the search parameters for identifying these patients. Slides and blocks were with the spreadsheets -- I guess we'll go through them, and we had a fair number, I think, by the time that I finished, but they were definitely slow in coming. I had difficulty getting support staff to carry out the functions that I needed when I looked at the slides.

COFFEY, Q.C.:

Q. And I'll get to that in a moment. So, Doctor, you say you had difficulty. Was that because, at least in respect of some of this material,

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it didn't exist, or you were told it didn't exist?
DR. CARTER:
A. Yes, in terms of documentation for the laboratory and even for the external controls. They were filed. There was no way of matching August 8th with August 8th.
COFFEY, Q.C.:
Q. 2003, for example?
DR. CARTER:
A. Right.
COFFEY, Q.C.:
Q. Or 2002.
DR. CARTER:
A. Yes. So they could show you that there was controls there, but they couldn't match them up.
COFFEY, Q.C.:
Q. And can you just describe that? For example, if a patient's ER and PR slides were produced on August 8th, 2002, I'll just use that date, in runs by the lab that day, what was your understanding, and if indeed there were ER and PR control slides run that day, what was the difficulty in matching those control slides

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with that patient's ER/PR slides? What was the --
DR. CARTER:
A. I was never able to get the external controls, but my understanding is that there was no way to match this control with this patient. You simply had a number of patient cases and a number of control cases, but you didn't know which ones had been run at the same time?
COFFEY, Q.C.:
Q. The control slides, did you ever see any control slides, ER and PR control slides, you know, during this review?
DR. CARTER:
A. I don't -- I don't think so, but I've seen some since, so it's really hard --
COFFEY, Q.C.:
Q. Hard to tell.
DR. CARTER:
A. There's so much going on in the last three years, but I don't think I saw any at that point, or if I did, they were very few.
COFFEY, Q.C.:
Q. How were they identified? A control slide was identified in what way?

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DR. CARTER:
A. It would be marked ER control.
COFFEY, Q.C.:
Q. ER control. Would it be dated?
DR. CARTER:
A. Not the ones that I saw, because that was the problem, if you had the date, you could kind of correlate them roughly.
COFFEY, Q.C.:
Q. So you ran into a problem with documentation, being provided with documentation which you had requested. The external controls were problematic, from your perspective, in the sense of being able to match them up with cases done years before.
DR. CARTER:
A. What I was able to find out about them, yes.
COFFEY, Q.C.:
Q. Doctor, in a broad strokes approach to this right now, what then happened? I mean, you're faced with this and you had looked at some original slides, I gather?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:

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Q. And there were a number of -- I think there's a third batch of retests go on. In July, there's 25, roughly 33, and then there's another group, and we'll see that --
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Conversions. What then happened, Doctor?
DR. CARTER:
A. I looked at some of the slides that had been reviewed by other people. I --
COFFEY, Q.C.:
Q. In an overview way, what did you find in that?
DR. CARTER:
A. In the slides?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. I shouldn't say other people because, as you know, I was in there too.
COFFEY, Q.C.:
Q. Yes, you're one of them too.
DR. CARTER:
A. But "us" people. I found that there was problems with fixation that you could identify

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by looking at the slide, that there were a number of slides without internal control, and a number of slides that internal control --

COFFEY, Q.C.:

Q. Was present.

DR. CARTER:

A. Was present, but not staining, and I found a number of slides that I found no problem with.

COFFEY, Q.C.:

Q. And what -- this would have been, I take it, during June and July of 2005, Doctor?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Did you tell anybody this, what you've just told me now?

DR. CARTER:

A. I would have told Dr. Cook. I would assume that most of the pathologists on the St. Clare's site would have known that because it's a small place and we're all next to one another. I'm not sure if it officially went any further than that.

COFFEY, Q.C.:

Q. Doctor, all this time this is going on,

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because you had otherwise been working -- you had a job.

DR. CARTER:

A. And still was working.

COFFEY, Q.C.:

Q. And was working still. So you were still doing your regular --

DR. CARTER:

A. Regular work.

COFFEY, Q.C.:

Q. Regular job.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Taking patients as you were normally scheduled?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. At any point in this process were you told, Beverley, you can put aside your regular work and we'll take care of that, you just go ahead with this? Do you recall that --

DR. CARTER:

A. That was one of the plans. I had talked to

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Dr. Cook about it being difficult to get information, block slides, support staff, etc, and he had spoken to Dr. Williams and had a meeting with Dr. Williams and Mr. Gulliver, and they had decided at that time that I would be taking off of service, which could not happen in the summer, I mean, there just wasn't enough staff to cover it, and I was supposed to have, I think, Judy Quinlan report just to me, and Mary Butler from the immunohistochemistry lab help with that sort of thing.

COFFEY, Q.C.:

Q. And we've seen the documentation to that effect, and I appreciate it's written down. What actually happened?

DR. CARTER:

A. Well, as I said, there was no way that I could be taken off my service. There was just nobody to do the work. I mean, it was summertime, there was only a few of us working there, so, no, I couldn't be taken off my service unless they hired a new pathologist.

COFFEY, Q.C.:

Q. Sure.

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DR. CARTER:

A. So that was an option for the administration.

COFFEY, Q.C.:

Q. Did that -- did that actually happen?

DR. CARTER:

A. No. Judy Quinlan, who is our lab technician, have you met her?

COFFEY, Q.C.:

Q. We've heard her name. Who is she?

DR. CARTER:

A. She's a technician who works in the lab at St. Clare's site, and she's generally a organizer for the lab, so she will be in charge of things such as storage and filing, and when you need things pulled, she will pull them for you. So she was supposed to be working with me full time. Often when I would go to see her to ask her, you know, I need these ten cases or how many ever cases it was, she would be pulled to do other duties in the lab.

COFFEY, Q.C.:

Q. So despite any assurance you received that she'd be working for you full time, that, in practice, didn't happen?

DR. CARTER:

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A. Didn't happen, and the same with Mary. I don't think Mary was understood to be full time with me, but certainly she was -- my understanding was that she was supposed to spend a significant part of her time with me. So she would be the one who's looking for, you know, the external controls, things that would be filed on the Health Science Centre site. Judy worked at St. Clare's; Mary worked at the Health Science. So a lot of those things would be that she couldn't find them and she was doing other things, and she would get to it when she had some time.

COFFEY, Q.C.:

Q. When she had the time. So she -- her actual, the amount of time she could devote to working for you turned out to be limited?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. You were told.

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Okay, then what happened, Doctor? Again in a broad strokes way, what happened?

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DR. CARTER:

A. Well, then this was probably then towards the end of July and I was getting more and more frustrated with the whole exercise, trying to get it done. There was a routine meeting of the administration with the CEO, George Tilley, to give him an update on, I guess, the ER issue, and I asked could I attend that meeting because I wanted to ask Mr. Tilley to allow me to do those things, so talk to whoever needed to be talked to do those things, and so I attended the meeting on --

COFFEY, Q.C.:

Q. That would be August 1st.

DR. CARTER:

A. August 1st.

COFFEY, Q.C.:

Q. And what happened there?

DR. CARTER:

A. You're not going to lead me through? I went to the meeting and the first thing that happened at the meeting was that there was a press release that was read--I'm not sure if it was a press release, sorry, it was a release that they were preparing. The woman from PR and I don't know who exactly was at the meeting because there was a lot of people that I hadn't met before.

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COFFEY, Q.C.:

Q. I take it you didn't routinely -

DR. CARTER:

A. No, this was a meeting I had asked to attend. So I think it was Susan Bonnell, but I'm not sure. She read a release that they had, I'm not sure if it was for the government or the press or who it was for, about how they had a problem with the estrogen receptor testing and it was due to the DAKO system and now they had a Ventana system which was much more sensitive and therefore, you know, they knew what the cause of the problem was. I objected to that statement being released to anybody or even it being true and -

COFFEY, Q.C.:

Q. I take it you took issue with that?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. You, based upon a review you had conducted to that point, knew that that was not accurate.

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DR. CARTER:

A. Just I know that that's not accurate at all, there's no difference between the two machineries, in terms of getting results, it's just knowing how to use the two pieces of machinery. So a very long and very heated debate took place with myself and mainly myself, Mr. Gulliver and Mr. Dyer, to a lesser extent Dr. Williams would jump in every now and then, at which point we agreed that it was not the DAKO system's fault and the Ventana system will be fine. The person from PR and the person who is from risk management or quality initiatives, again, I don't know what that person's name was, then became very upset because they had been ready to release or have this ready for release, this piece of documentation, so they were upset that the lab didn't have consensus within its self that some people in the lab were saying one thing, some people in the lab were saying another thing. So there was, again, another long and heated discussion about that, about the lab, you know, making sure that they knew what they

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were talking about before they came to these things. In the course of that discussion, we started talking more about different aspects of immunohistochemistry, positivity rates, expected positivity rates and was again, mainly myself, Mr. Gulliver, Mr. Dyer, occasionally people from the clinical side of things.

COFFEY, Q.C.:

Q. That would be the oncologist, I take it?

DR. CARTER:

A. Oncologists and surgeons were there.

COFFEY, Q.C.:

Q. And surgeons, I'm sorry.

DR. CARTER:

A. When we started talking about statistics, Dr. Williams, you know, had some things to say about, you know, our math and the stats that we were talking about. And then I asked Mr. Tilley if I could be sort of given the resources and given the control to do this retrospective review that they wanted done and he explained that, management, you know, very nicely, he was the calmest person there, you know very nicely what the management structure

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was and that was the way that the management structure was and that we had to learn to get along, sort of thing, and figure it out amongst ourselves sort of in the lab. And the meeting ended and -

COFFEY, Q.C.:

Q. So it was a polite way of--you asked him for, I take it, for support in proceeding with what you had laid out for Dr. Cook?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. The approach. You explained this to the people at the meeting, you asked for Mr. Tilley's support and did he say yes or no or really not answer the question.

DR. CARTER:

A. Well he didn't say yes. I mean, what he said was this is the way that the management structure is, so you have to work within that structure, so if I was saying that management structure was not co-operative with me, you know, the answer was, well you have to learn--well not you, as in me, but the group of us, you know, have to learn how to work this out

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kind of thing. But no, there would not be changes made to the management of the laboratory for this.

COFFEY, Q.C.:

Q. And so then the meeting ended.

DR. CARTER:

A. And then the meeting ended and I stayed behind and talked to some of my clinical colleagues because it was a very stressful meeting, went about my evening activities and thought about it and thought well, I wasn't getting the support that I needed from the administration in the lab or of the hospital to do this retrospective review and that I would resign from that aspect of it and continue to offer my services as a consultant on it, if they wanted my opinion, and also to get involved with the prospective cases that were coming in.

COFFEY, Q.C.:

Q. And I take it in effect go back to your routine job?

DR. CARTER:

A. And also become more involved in the prospective cases, so the come-forward cases,

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so if somebody from 2003 walked into Dr. Laing's office tomorrow, even though she was part of the retrospective review, she would have to be pulled out, tested because she was there. So I would take care of those cases, I was doing more work with determining whether or not the Ventana system was appropriate for what, you know, we were having, designing QA for the lab, those sorts of things.

COFFEY, Q.C.:

Q. And perhaps again in an overview way you could take us on from there, then, Doctor, what happened?

DR. CARTER:

A. So I resigned from the committee. Don wrote me a letter saying that he accepted the resignation. I went back to work, I'm not sure what it is you're looking for?

COFFEY, Q.C.:

Q. Okay, well then what then--Doctor, because I take it at this point in time, based upon what we've heard today, that this was not public knowledge in the sense of the fact that there was this review going on in the lab and the problem existed.

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DR. CARTER:
A. The general public didn't know about it?
COFFEY, Q.C.:
Q. Yes, the general public didn't know. Were you ever asked for your opinion as to whether or not the general public should be told and if so, when and how? And for that matter, the patients, if so, when and how?
DR. CARTER:
A. I don't know if I was ever asked -
COFFEY, Q.C.:
Q. I'm not suggesting you were, I'm just asking.
COFFEY, Q.C.:
Q. I don't know if I was ever asked sort of that question, but I know it would be discussed and I think my belief then was that the patient should know as soon as we know, I really wouldn't have anything to say about when the general public should know, it's not my -
COFFEY, Q.C.:
Q. And, Doctor, we understand that at some point in the summer of 2005 that Ms. Wegrynowski was contacted?
DR. CARTER:
A. Yes.

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COFFEY, Q.C.:
Q. And do I understand from Dr. O'Malley that in fact she was contacted even before Ms. Wegrynowski was?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And you have been named in that process.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Can you tell the Commissioner what you recall about that?
DR. CARTER:
A. Again, Dr. Cook and I had been talking and he thought that he would want someone to come down to oversee the lab, and when I say Dr. Cook wanted this, it may have been conversations he had with Dr. Williams, I mean, I wouldn't be privy to those, but Don and I would be talking and so this would come up and he asked, you know, did I know anyone that would want to come down and we discussed it and he suggested Francis--sorry, Dr. O'Malley and I know Dr. O'Malley from when we

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both worked in Ontario, so I called Dr. O'Malley and she didn't think that she would really have a whole lot to add and it sounded more like they needed a technical person and she recommended Ms. Wegrynowski and I e-mailed her and asked her was she interested and just gave her a very brief, two or three sentences maybe, about what it was, and she said that she would be interested and then I forwarded her name to Dr. Cook to make the arrangements.
COFFEY, Q.C.:
Q. Doctor, then as we get into September, October and November, December, 2005, that fall, in the wintertime, certainly in the fall, what were you--were you involved in this at all?
DR. CARTER:
A. I would be involved with the go-forward cases. I would still be offering, you know, consultative advice to anyone if they asked me for specific events, I don't recall, but if I could have the specifics of it -
COFFEY, Q.C.:
Q. And we will and I'll be taking you through that, again I'm just trying to, I'll come back, just like the thing with Dr. O'Malley

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just then, it's something -
DR. CARTER:
A. Yeah, you need to be tweaked and -
COFFEY, Q.C.:
Q. Tweaked on that, just trying to get some sense for the Commissioner what kind of--what stands out in your mind. We have seen a letter, December 7th, 2005, the issue of restarting the testing -
DR. CARTER:
A. Okay, sure.
COFFEY, Q.C.:
Q. That came up, we gather in the--do you recall how that, how you first became aware of that as a topic and -
DR. CARTER:
A. Well I guess -
COFFEY, Q.C.:
Q. Perhaps we can back up a bit then because Ms. Wegrynowski was here in September.
DR. CARTER:
A. Yes, I was going to then talk about the two of those things.
COFFEY, Q.C.:
Q. And Dr. Banerjee.

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DR. CARTER:
A. Both of those people when they came, I spoke to them briefly, maybe a half hour, an hour, I took Trish on a tour of the lab at the St. Clare's site and just introduced her to some of the technologists but didn't stay once she talked to them, if she wanted to and took her to the operating room, grossing room, those sorts of things and when Dr. Banerjee came, I spoke to him for about, maybe a half hour, an hour again. That was right at the beginning of his review tour, I can't think of the proper word. And we just spoke briefly about what I thought was going on in the lab.
COFFEY, Q.C.:
Q. What did you tell him at the time?
DR. CARTER:
A. Basically probably would have just told you about it, that I had difficulty getting, you know, external controls, paperwork, those sorts of things, so I didn't have a good handle about what had gone on in the lab at the time, that I was able to look at a number of slides, I think it ended up being 97 or something that I ended up looking at and that

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I did find problems with fixation, control issues, just the handling of tissue, a lot of the slides had tissue missing, those sorts of things. I would have talked to him about the type of practice that I had and subspecialization, he was very keen on that. He also talked about salaries, those sorts of things. And then on December 7th -
COFFEY, Q.C.:
Q. So you weren't involved in the exit interviews?
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. I'm not suggesting you were, I just wanted to ask you about that.
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. We understand that Dr. Banerjee's report came in on October of 2005 and Ms. Wegrynowski's in November, 2005, their initial reports, did you see a copy of those at the time?
DR. CARTER:
A. No, when I wrote the letter in December, I saw

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a copy of the recommendations that Trish had made, but not the report and I didn't see Dr. Banerjee's report.
COFFEY, Q.C.:
Q. And did you note generally though what he had found?
DR. CARTER:
A. I would characterize it as generally because, you know, you hear it in the halls and all of a sudden you're getting a new fridge or all of a sudden everybody is talking about subspecialty sign-out, so generally, yes, you would know what -
COFFEY, Q.C.:
Q. You could infer.
DR. CARTER:
A. Yes, but not specifically.
COFFEY, Q.C.:
Q. Without seeing the original document.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And, Doctor, we've heard testimony, if I recall correctly from Dr. Cook at one point in the fall of 2005 he, at least to some

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pathologist read Dr. Banerjee's report to them. Do you recall that happening with you there?
DR. CARTER:
A. No, and I thought it was Dr. Denic read a part of his report at a meeting, I didn't think it was Dr. Cook.
COFFEY, Q.C.:
Q. And it may be that both of them did it at separate times.
DR. CARTER:
A. Could have been.
COFFEY, Q.C.:
Q. Different places. From the perspective of yourself, you don't recall sitting and listening to Dr. Cook?
DR. CARTER:
A. No.
COFFEY, Q.C.:
Q. And then the topic of retesting or resuming ER/PR testing came up, how did that come up and how did you first hear about it and what happened?
DR. CARTER:
A. Once the two reviews had come in, well

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everybody knew that there was a lot of changes that had been recommended because you could see all the activity going on in the lab and amongst the pathologists as well. And I'm not sure what day, if we could look at the letter -

COFFEY, Q.C.:

Q. December 7th.

DR. CARTER:

A. Okay, so probably December 5th, Dr. Cook came into my office, said that he had been at a meeting with Dr. Williams, Mr. Gulliver and Dr. Dyer and Mr. Dyer said that the Ventana system which we had switched off in July was ready to be switched back on and we could do estrogen receptor and progesterone receptor testing. The machine hadn't been switched off, just that particular testing had been switched off, and Don felt that we had a long way to go before that could happen and he was very upset that it could happen again, but he told me, so it wasn't at the meeting, but Mr. Gulliver and Mr. Dyer felt that that was a reasonable thing to pursue. Dr. Williams wanted it then investigated, so Don asked me

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as the person who would be eventually reporting these estrogen receptors and progesterone receptors, what I thought of it and would I write a letter expressing any concerns that I had about the lab, which I did.

COFFEY, Q.C.:

Q. And so, if I could, the actual exhibit is P-0101 and Doctor, the actual letter itself is dated December 7th, but when you refer to December 5th, you say--here in the letter you say to Dr. Williams, "I was most recently asked by Dr. Cook to comment."

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. So in terms of, it may have been two days before that actually Dr. Cook and you spoke and he asked you -

DR. CARTER:

A. It would have been within a few days of December 7th.

COFFEY, Q.C.:

Q. And you then wrote this letter. What then happened? So you put your thoughts and I take

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it what's expressed there is the way you thought, felt at the time?

DR. CARTER:

A. And I sent the letter to Dr. Williams, I think with a carbon copy to Dr. Cook, if not, I would have given him a carbon copy and I think there was another meeting held and at that time, they decided to make a spreadsheet of all of the recommendations that had been made by each one of the physicians, another exhibit is a letter that Dr. Williams wrote me shortly after that, explaining that that was what was going to be done. And they had the spreadsheet and they would go through it, I guess on a daily, weekly, whatever basis as things were being changed.

COFFEY, Q.C.:

Q. Then what happened, Doctor, in terms of your involvement, if anything?

DR. CARTER:

A. Without the exhibit -

COFFEY, Q.C.:

Q. Okay, I'll prompt you, we understand that the great bulk of the retest results started, well were back by the end of January, 2006?

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DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. They came back before that, some, but then the great wave of them came in spreadsheet format. Were you involved in the retest results?

DR. CARTER:

A. I would be involved in, I think we're calling it the tumour panel for the purposes of the inquiry.

COFFEY, Q.C.:

Q. Okay, yes, in the fall.

DR. CARTER:

A. Yes, so I would have been involved in that, but in terms of the lab and the retrospective review, no, I wouldn't have been involved.

COFFEY, Q.C.:

Q. And I will be asking you, some exhibits in respect of the tumour panel, but in overall, what was your involvement, again, in a general description, what was the nature of your involvement in the tumour panel?

DR. CARTER:

A. Oh, for the tumour panel?

COFFEY, Q.C.:

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Q. Yes.
DR. CARTER:
A. Again, it was an inter-disciplinary, multi-disciplinary team where each patient who had been identified in the retrospective review would be brought to the panel and the previous estrogen progesterone receptor reports would be compared to the retrospective review, report and then a discussion of the case would ensue and then treatment changes would be discussed. So my role in it would be to read the pathology reports and for subtleties that would help the clinicians make treatment changes recommendations, small things, such as size of tumour and presence of lympovascular invasion is sometimes helpful. So the pathologist's role is to be able to quickly go through that and assimilate the information often off two or three or four pathology reports, put it all together and then quickly give them, you know -
COFFEY, Q.C.:
Q. A summary.
DR. CARTER:
A. Yes. And once I acted as the acting chair

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where I would write the letters of the recommendations of the group.
COFFEY, Q.C.:
Q. And, Doctor, looking back on it, the activities of that panel, how much actual involvement did you have, like on a routine meeting, how much would they call upon you?
DR. CARTER:
A. It was a minor, but a present one. Often the pathology would have to be reviewed, the ER/PR would have to be reviewed in each case, so I mean, I had a role there, but it wasn't the most important one.
COFFEY, Q.C.:
Q. And I take it it was to give to the clinicians quickly an overall synopsis of the pathology aspect of the matter so that they could make whatever clinical decisions they saw fit?
DR. CARTER:
A. Yes, yes.
COFFEY, Q.C.:
Q. The great wave of results came back in January, 2006.
DR. CARTER:
A. Okay.

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COFFEY, Q.C.:
Q. Were you involved then in handling of those, except as a member of the tumour panel?
DR. CARTER:
A. Not in a specific role.
COFFEY, Q.C.:
Q. Nothing in particular. Dr. Cook, in terms of dealing with them, having those recorded in the Meditec system, anything like that?
DR. CARTER:
A. No, I may have put some in that will come at the request of a clinician who wanted to know the report on such a person, and also I was doing what I call the go-forward cases, as I explained earlier if Mrs. Smith was a part of that big retrospective review, but she was also sitting in Dr. McCarthy's office and they wanted that information, I would just go get another block from that case. So you will see my name in 2005 and '06 on cases from 1997, but those are what I call go-forwards.
COFFEY, Q.C.:
Q. They were consult cases--they were treated as consults by Mount Sinai.
DR. CARTER:

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A. Yes. And they would go actually to a different, that's right, they would go to Trish's lab as opposed to Maria's lab.
COFFEY, Q.C.:
Q. And would be reported separately by Dr. Mullen or whomever reported?
DR. CARTER:
A. Whoever was on duty for that.
COFFEY, Q.C.:
Q. Doctor, we understand that Trish Wegrynowski and Dr. Banerjee came back to St. John's in April, I believe, of 2006. They revisited the lab. Were you involved in that at all?
DR. CARTER:
A. No, I was actually unaware.
COFFEY, Q.C.:
Q. There's also, Doctor -- we've seen reference to an effort in the spring and summer of 2006 to create an interdisciplinary group of doctors dealing with breast treatment.
DR. CARTER:
A. Breast site group?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:

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A. Yes.
COFFEY, Q.C.:
Q. Can you tell the Commissioner, please, what you recall about that?
DR. CARTER:
A. This had arisen from one of the meetings that had taken place and I know that Dr. Williams was present there because he had sort of started the idea that if there was a guidelines group, that perhaps that would be helpful, an interdisciplinary -- multidisciplinary, sorry, guidelines group. Dr. McCarthy and I had both come from institutes that had breast disease site groups and were quite familiar with it, so we agreed to canvas people, I guess, if they were interested in this and to outline what we felt the role and responsibilities of the committee would be, and what sort of staffing or funding we would require.
COFFEY, Q.C.:
Q. And then what happened with respect to that?
DR. CARTER:
A. We had a meeting in June, 2005.
COFFEY, Q.C.:

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Q. '06, actually.
DR. CARTER:
A. Six?
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. Sorry, I need my exhibits. June of 2006, and we had people from a lot of disciplines there; palliative care, pharmacy, pathology, medical oncology, radiation oncology, and everybody was pretty on board for the idea, and Joy and I had agreed to act as co-chairs, at least for the first year, and we scheduled meetings then for September because it was summer holidays and over the summer Joy and I worked on the document. We started having meetings in September. We had quite a bit of difficulty getting the staffing that we had asked for, but eventually we did get a full time nurse to come in and to be sort of the person who was the breast site group, and write guidelines -- begin to write guidelines.
COFFEY, Q.C.:
Q. And what then happened with that particular group?

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DR. CARTER:
A. I think it's still ongoing.
COFFEY, Q.C.:
Q. When were you last involved in it?
DR. CARTER:
A. Maybe before December.
COFFEY, Q.C.:
Q. December of '07?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Okay. So you would have continued with that then throughout '06 into '07?
DR. CARTER:
A. Yes, as long as we were having meetings. After the first year, I was no longer the co-chair, I was just a regular member of the group.
COFFEY, Q.C.:
Q. Doctor, we understand that in the fall of 2006 -- of course, there was in December -- December 11th, 2006, there was a technical media briefing. Were you part of that?
DR. CARTER:
A. No.

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COFFEY, Q.C.:
Q. We understand as well that just past mid November, probably around November 20th/21st, 2006 -- November 20th to the 22nd, I can't recall off the top of my head right now which date, there was a briefing note for Eastern Health staff about the results of the review and --
DR. CARTER:
A. I wasn't involved.
COFFEY, Q.C.:
Q. But there's a slide show with your name on it?
DR. CARTER:
A. Oh, the teleconference, okay.
COFFEY, Q.C.:
Q. The teleconference, yes.
DR. CARTER:
A. This was for the province.
COFFEY, Q.C.:
Q. Yes. Could you tell the Commissioner, please, about that, what you recall about how you got involved in it and the nature of your involvement?
DR. CARTER:
A. I was asked to be involved with it. I think

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Dr. Howell was here by then.
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. And he wanted a province-wide comprehensive presentation done because there was a lot of questions. People in Eastern Health and around the province who were involved in the issue didn't really know what the issue was, didn't feel that they had enough information. So we gave five presentations. Dr. Laing talked about why estrogen receptor testing is important to oncologists and how they use it to make decisions. I talked about estrogen receptor testing in the lab, the pitfalls of it. Dr. Elms talked about basic immunohistochemistry. Dr. Cook talked about the issue, what had happened in 2005, and Dr. Denic, I think, talked about on a go forward basis, but I'm not sure what Dr. Denic's topic was, and this was telecast to any hospital site in the province.
COFFEY, Q.C.:
Q. Doctor, we understand as well that following that there was this December 11th technical

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media briefing, and you were not involved in that?
DR. CARTER:
A. I don't think so.
COFFEY, Q.C.:
Q. That you can recall. We understand as well that in February of 2007, the ER/PR testing resumed.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. At the General Hospital. Were you involved in that decision?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, could you tell us please about the nature of your involvement?
DR. CARTER:
A. Dr. Elms, I think, was the medical director of immunohistochemistry at that time. It had gone through a number of different people. I think he was taking it on as a sole person at that time. Dr. Denic was the clinical chief, and myself and Don, and I think Dr. Naghibi

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was still here then as well, so there would have been three of us on the breast team, and Dr. Elms and Dr. Denic presented to us, you know, not in detail, but presented to us in detail that they were happy with the validation, all the different aspects of it, and we looked for a short while at cases stained in St. John's and cases stained at - simultaneously cases stained, and we agreed that it was very good service and moved forward.
COFFEY, Q.C.:
Q. So what then happened? Testing resumed, I take it.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. In St. John's.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. What then was your involvement? You said there were three of you in the group initially?
DR. CARTER:

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A. Yes. I think Dr. Naghibi was still there. She -- I thought she left in the summer.
COFFEY, Q.C.:
Q. Yes. So what was this group supposed to do?
DR. CARTER:
A. This was the breast pathology sub-specialty group. So our mandate was to write polices about how breast should be treated. For Eastern Health, this was. We would look at needle core biopsies, especially those derived from radiologists because they require a little extra, and we were going to take needle localization wire biopsies which is another type of sub-specialized breast case, and we would read the estrogen receptor and progesterone receptor. We used to meet on Thursday afternoons. Because it was such an issue, we read all of the estrogen receptor and progesterone receptor testing as a group. Sometimes we take residents with us or sometimes Dr. Denic would come if he was there, and we would read difficult cases than the other groups, but if you were on for needle core biopsies and you were fine with all your cases, you wouldn't bring those, but

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we would bring difficult cases, and all the ER/PR and read them as a group.

COFFEY, Q.C.:

Q. Now, Doctor, to get some sense then, and you continued then in that position until when?

DR. CARTER:

A. Until June 20th of 2008.

COFFEY, Q.C.:

Q. So there was initially yourself, Dr. Cook, and --

DR. CARTER:

A. Naghibi.

COFFEY, Q.C.:

Q. Naghibi.

DR. CARTER:

A. Uh-hm.

COFFEY, Q.C.:

Q. Dr. Naghibi, as best you can recall, had left by the summer of 2007?

DR. CARTER:

A. Yes, she took a year leave of absence, and I think she has since given a formal resignation.

COFFEY, Q.C.:

Q. So after she left, there was yourself and Dr.

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Cook?

DR. CARTER:

A. Yes, and sometimes Dr. Denic would fill in on an as needed basis, but essentially myself and Dr. Cook.

COFFEY, Q.C.:

Q. And Dr. Cook then, I gather, took a leave of absence when?

DR. CARTER:

A. End of March, 2008.

COFFEY, Q.C.:

Q. So March of '08, and so the months then after that until you resigned, and this year you would have been --

DR. CARTER:

A. I would have been doing them myself, and then if I had difficulty with estrogen receptor or wanted hand holding, I would talk to Dr. Elms.

COFFEY, Q.C.:

Q. Sure.

DR. CARTER:

A. Or Dr. Denic.

COFFEY, Q.C.:

Q. Doctor, May of 2007, we understand there's -- of course, this matter became a matter of some

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public, took on some significant public interest in the middle of May, 2007, with the CBC report about the contents of an affidavit that had been filed in a class action. Doctor, when that happened in the middle of May, 2007, were you involved in this or brought into this in any way?

DR. CARTER:

A. Not in any official capacity, I don't think.

COFFEY, Q.C.:

Q. I'm not suggesting you were. I'm just --

DR. CARTER:

A. I mean, I knew about it and everybody knew about it.

COFFEY, Q.C.:

Q. Doctor, then after August 2nd, 2005, you wrote that letter resigning.

DR. CARTER:

A. Okay.

COFFEY, Q.C.:

Q. From that particular aspect of the matter as set out in your letter. In terms of the retrospective review, other than dealing with Dr. Banerjee and Ms. Wegrynowski in the way you did when they came in September of '05,

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did you have any further involvement in the retrospective review?

DR. CARTER:

A. Well, I would act on a consultative basis to them, so if they wanted something, you know, somebody to look at slides today, I mean, I would so that, so I didn't completely divorce myself, but I more divorced myself from the organizational aspect of it, but I was still helping out as needed.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0046, please? Now Doctor, this is Dr. Banerjee's report of October 17th, 2005, okay?

DR. CARTER:

A. Um-hm.

COFFEY, Q.C.:

Q. And you've indicated you would not have actually seen the text of this until 2007?

DR. CARTER:

A. When it was--Mr. Williams had it on the floor. No, this is not this one. That's the other one. I think when it came out as an exhibit for this process.

COFFEY, Q.C.:

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Q. In relation to the Commission of Inquiry?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. How about Ms. Wegrynowski's, had you seen -
DR. CARTER:
A. Actually, I had seen her recommendations, but I have only read her report like in the last little while, last six months.
COFFEY, Q.C.:
Q. So in terms of the actual--because there are two reports from '05 and two from '06, those four reports, you've actually only seen really since the Commission -
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. - the actual text of them, since the Commission of Inquiry got involved in this. Doctor, here, under "review of cases" Dr. Banerjee had written, "I reviewed a number of cases from the retrospective testing set with Dr. Donald Cook. All the cases that had converted from negative to positive by switching platforms had one or more of the

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following characteristics: 1. poor fixation; 2. negative internal controls (normal ductal epithelium when present was completely negative); and 3. absent internal controls (no normal ductal epithelium present to evaluate). It is apparent that too much reliance is being placed on external positive controls with no attention paid to internal controls."
Now Doctor, you've indicated to the Commissioner that in 2005, you had reviewed, if I recall you said approximately 90 odd cases?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. And I'll be taking--we'll deal with those tomorrow morning, but in terms of as a general statement, is what he says here consistent with what you had found?
DR. CARTER:
A. As a general statement.
COFFEY, Q.C.:
Q. As a general statement?
DR. CARTER:
A. Yes.

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COFFEY, Q.C.:
Q. And of course, your remarks would be limited to the approximately 90 odd cases that you looked at? They wouldn't be limited to 2002. They would involve some other years?
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. But in the main, they were '02?
DR. CARTER:
A. And I didn't look at this group, so I don't know what -
COFFEY, Q.C.:
Q. Sure, what particular ones he looked at.
DR. CARTER:
A. - subset he's looking at.
COFFEY, Q.C.:
Q. And Doctor, here, under "conclusions about the reasons for test failure," paragraph one, "is the DAKO system faulty? This is unlikely as there are many laboratories using the DAKO system successfully. The reason for test failure was most likely due to a lack of test optimization, including antigen retrieval method and antibody detection system

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titration, as positive controls showed weak staining in general and internal controls failed in all of the false negative cases." Again, bearing in mind he's talking about a particular subset of cases when he talks about internal controls failing, and all false negative cases, but as a general proposition, do you agree with the statement in paragraph one?
DR. CARTER:
A. Yes, it's unlikely that it was the DAKO system.
COFFEY, Q.C.:
Q. The DAKO, which you've told us earlier this afternoon. And number two, "is the Ventana system too sensitive? There is no evidence that the Ventana system creates false positive results. However, the system still requires optimization to avoid non-specific cytoplasmic staining." Now Doctor, we have heard some evidence that you did express some concerns, and we'll deal with some of those tomorrow, and I say concerns, perhaps that may not be an appropriate choice of word, but that you did express some cautions or you wanted the

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Ventana system at least looked at a bit further?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. In the summer of ’05?

DR. CARTER:

A. Yes.

COFFEY, Q.C.:

Q. Knowing what you do now, overall, when he says "there’s no evidence that the Ventana system creates false positive results," as a general proposition, would you agree with him?

DR. CARTER:

A. I would disagree, you know, is our Ventana system too sensitive, there was evidence that our Ventana system created false positive results. As a general statement, Ventana doesn’t cause false positive results. It’s the use of it.

COFFEY, Q.C.:

Q. Okay, so then at the time, you felt, and we’ll explore some of that further tomorrow, that perhaps the -

DR. CARTER:

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A. Even the summer of ’05, we had some false positives.

COFFEY, Q.C.:

Q. Summer of ’05, there were some false positives.

DR. CARTER:

A. Yes. I don’t know if he was aware of those, can’t comment.

COFFEY, Q.C.:

Q. But as a general proposition, you have no problem -

DR. CARTER:

A. The Ventana doesn’t cause or not cause false positives.

COFFEY, Q.C.:

Q. So it’s not the machine, as you pointed out.

DR. CARTER:

A. It’s not the machine.

COFFEY, Q.C.:

Q. It’s not the machine. It’s not a machine problem per se.

DR. CARTER:

A. No.

COFFEY, Q.C.:

Q. "3. Is there a problem with tissue fixation?

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There appears to be inadequate attention paid by the grossing pathologist to the thickness of tissue slices, quality and adequacy of fixation and there is no standardized fixation protocol that everyone adheres to." The problem with tissue fixation, you had recognized that at least in some slides yourself? So you agreed with that?

DR. CARTER:

A. I would agree with that statement, yes.

COFFEY, Q.C.:

Q. "Inadequate attention paid by the grossing pathologist to the thickness of tissue slices," what would he be referring to there, do you think?

DR. CARTER:

A. Usually when you cut tissue slices--you’ve gone through the whole cassette thing?

COFFEY, Q.C.:

Q. Yes.

DR. CARTER:

A. And so when you cut the tissue to put into the cassettes, it should be between three to five millimetres, often down around three millimetres in order for the formalin to

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penetrate appropriately, and also there’s a limited size to the tissue that you can put into the cassette. So often the technologist would complain that the tissue is too big for the cassettes.

COFFEY, Q.C.:

Q. And the potential negative consequence of that was what?

DR. CARTER:

A. The tissue would have variable fixation, so I mean, there’s lots of debate on fixation. I’m sure that you’re familiar with some of it. In my opinion, variable fixation would give you more of heterogeneity or more variability in your staining. So I talked about absolute positive, absolute negatives. With poor fixation, you’re going to get some variability to that return.

COFFEY, Q.C.:

Q. And the quality and adequacy--okay, "inadequate attention paid by the grossing pathologist to the thickness of tissue slices, quality and adequacy of fixation." Was there a standardized fixation protocol at that time?

DR. CARTER:

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A. No.
COFFEY, Q.C.:
Q. I take it that eventually you drafted one, in due course?
DR. CARTER:
A. We drafted several for breast cases and a generalized fixation protocol for the lab.
COFFEY, Q.C.:
Q. And we'll deal with--we'll address some of those with you tomorrow. From your perspective, in the summer of 2005, based upon what you had observed, would you have come to the same conclusion here as he sets out here in three?
DR. CARTER:
A. There was definitely issues with fixation. I mean, I would have to go back and look at my slides again and all that stuff before I made a definitive statement, but I have no problem with that. I think that there was some issues with fixation.
COFFEY, Q.C.:
Q. "Inadequate or no attention is being paid by the reporting pathologist to the status of internal controls with inappropriately

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exclusive reliance on external positive controls." Had you found -
DR. CARTER:
A. Again, I mean, that was an issue. It's the "inadequate or no attention," you know, part that I have an issue with myself. I would have to go back and look at all of my information. I know that many of the pathologists were paying attention to internal controls. So it's just the qualifiers I have a problem with. But that is an issue, internal controls.
COFFEY, Q.C.:
Q. And because this might suggest that all pathologists fell into that category, by the reporting pathologist, and perhaps you might take issue with that, but -
DR. CARTER:
A. It's a strong statement that he's made.
COFFEY, Q.C.:
Q. But as a general statement though, an overall -
DR. CARTER:
A. There was a problem with internal controls, yes.

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COFFEY, Q.C.:
Q. And it says "negative test results in the absence of positive internal controls should have triggered corrective procedures, optimization of method, choice of a better fixed block, choice of a block with benign ductal epithelium included, etcetera, and should not have been released without troubleshooting. In the event that poor fixation resulted in internal control failure on all available blocks, this should have been noted in the reports as an uninterpretable case, due to the failure/absence of internal controls." Now would you have agreed or do you agree with that?
DR. CARTER:
A. In a general sense, I would agree with that. I wouldn't make the definitive statement that if an internal control is negative, I would not read the slide, and I assume that we will get into specifics tomorrow.
COFFEY, Q.C.:
Q. Yes.
DR. CARTER:
A. But I mean, as a general statement, yes, that

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is kind of a motherhood pathology statement.
COFFEY, Q.C.:
Q. And there are exceptions, and I'll explore those with you tomorrow.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. But as a general proposition, certainly you would agree with it as a generalization. "Inappropriate choice of blocks with no representative normal ductal epithelium."
DR. CARTER:
A. Again, there are many blocks there that had no normal ductal epithelium.
COFFEY, Q.C.:
Q. And of course, he's suggesting better education required for all those involved about the pitfalls of IHC and the importance of quality control in interpretation of IHC results.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. You would agree?
DR. CARTER:

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A. I would agree.
COFFEY, Q.C.:
Q. In fact, throughout the fall and December, in fact, of ’07--well, in fact, December of ’05, your letter addresses just that issue.
DR. CARTER:
A. Yes.
COFFEY, Q.C.:
Q. If we could then, Commissioner, perhaps--it’s been a long day. I’d like to take this up again tomorrow.
THE COMMISSIONER:
Q. It’s been a long, warm day.
COFFEY, Q.C.:
Q. Yes.
THE COMMISSIONER:
Q. All right then, we’ll meet in the morning at 9:30. Thank you.

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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 28th day of July, 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 28th day of July, A.D., 2008
Judy Moss

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