

<p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">July 28, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. Commission Co-counsel Sandra Chaytor, Q.C. Commission Co-counsel</p> <p>Rolf Pritchard/Jackie Brazil Her Majesty in Right of NL</p> <p>Peter Browne/Jane Hennebury Doctors Kara Laing et al</p> <p>Daniel Simmons/Beth Whalen Eastern Regional Integrated Health Authority</p> <p>Darlene Russell. Members of the Breast Cancer Testing Class Action</p> <p>Mark Pike NL Medical Association Jennifer Newbury Canadian Cancer Society (NL Division) Blair Pritchett. Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p>	<p style="text-align: center;">LIST OF EXHIBITS</p> <p>EXHIBIT P-2480 Pg. 104 EXHIBITS P-2440 THROUGH P-2479 Pg. 179</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>DR. SUSHIL PARAI - RESUMES THE STAND</p> <p>Examination by Bernard Coffey, Q.C. - Cont'd . . . Pgs. 4 - 106 Examination by Daniel Simmons Pgs. 106 - 120 Examination by Jennifer Newbury Pgs. 120 - 151 Examination by Peter Browne Pgs. 151 - 168 Re-examination by Bernard Coffey, Q.C. Pgs. 168 - 171 Examination by The Commissioner Pgs. 171 - 178</p> <p>DR. BEVERLEY CARTER - AFFIRMED</p> <p>Examination by Bernard Coffey, Q.C. Pgs. 178 -</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 THE COMMISSIONER: 2 Q. Mr. Coffey. 3 DR. SUSHIL PARAI, RESUMES STAND, EXAMINATION BY BERNARD 4 COFFEY, Q.C. (CONT'D) 5 COFFEY, Q.C.: 6 Q. Thank you, Commissioner. Good morning. Good 7 morning, Dr. Parai. 8 DR. S. PARAI: 9 A. Morning. 10 COFFEY, Q.C.: 11 Q. Now we'll be able to hear each other, I hope. 12 Registrar, could we see Exhibit P-0113, 13 please? Doctor, this is Dr. Ejeckam's memo of 14 April 4th, 2003, and of course, it's to 15 pathologists at the Health Sciences Centre, 16 which would have included yourself, and you 17 were the site chief in any case. Doctor, I'm 18 going to ask you, please, first of all, we 19 understand Dr. Ejeckam came to the General 20 Hospital in 2002. 21 DR. S. PARAI: 22 A. Yes. 23 COFFEY, Q.C.: 24 Q. Could you tell us, please, what, if anything, 25 you learned about his background at the time?</p>

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

3 DR. S. PARAI:

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

12 COFFEY, Q.C.:

13 Q. Yes.

14 DR. S. PARAI:

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

23 COFFEY, Q.C.:

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

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

4 DR. S. PARAI:

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

8 COFFEY, Q.C.:

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

13 DR. S. PARAI:

14 A. That is correct.

15 COFFEY, Q.C.:

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

21 DR. S. PARAI:

22 A. You're talking about the pathology rounds?

23 COFFEY, Q.C.:

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

25 DR. S. PARAI:

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1 A. That was correct.

2 COFFEY, Q.C.:

3 Q. Doctor, those rounds, what were they about?

4 Because you were the site chief at the time,
5 could you tell us like how often they were
6 held and what was discussed, what sorts of
7 things?

8 DR. S. PARAI:

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

25 COFFEY, Q.C.:

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1 Q. And that was the weekly round for lymphomas?

2 DR. S. PARAI:

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

8 COFFEY, Q.C.:

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

15 DR. S. PARAI:

16 A. Yes.

17 COFFEY, Q.C.:

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

21 DR. S. PARAI:

22 A. Yes.

23 COFFEY, Q.C.:

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

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1 DR. S. PARAI:
 2 A. All the pathologists, pathology resident.
 3 COFFEY, Q.C.:
 4 Q. And that practice of meeting weekly, how long
 5 had that been going on for?
 6 DR. S. PARAI:
 7 A. Well, it has been going on long time, since I
 8 moved to the General Hospital, it was there.
 9 COFFEY, Q.C.:
 10 Q. So it predated yourself in fact?
 11 DR. S. PARAI:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Doctor, were there any minutes kept of these
 15 meetings?
 16 DR. S. PARAI:
 17 A. Initially, there was no minutes, but later on,
 18 we started to document the attendance of those
 19 meetings and the topics discussed. That came
 20 later on.
 21 COFFEY, Q.C.:
 22 Q. Do you recall when it was that that started?
 23 DR. S. PARAI:
 24 A. I don't recall.
 25 COFFEY, Q.C.:

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1 Q. Had it--do you know if it had started by the
 2 time Dr. Ejeckam arrived?
 3 DR. S. PARAI:
 4 A. I don't recall.
 5 COFFEY, Q.C.:
 6 Q. Okay, and Doctor, who keeps those minutes?
 7 DR. S. PARAI:
 8 A. There was no minutes. As I said, there were
 9 some -
 10 COFFEY, Q.C.:
 11 Q. Well notes, I suppose.
 12 DR. S. PARAI:
 13 A. Notes. There were some attendance sheets.
 14 You will see in some exhibits, I showed some
 15 samples of attendance sheet.
 16 COFFEY, Q.C.:
 17 Q. Yes.
 18 DR. S. PARAI:
 19 A. And topics discussed in the back on that
 20 attendance sheet.
 21 COFFEY, Q.C.:
 22 Q. So it was relatively informal, I take it,
 23 compared to some of the other documents we've
 24 seen where--like the site chief's meetings
 25 would have an agenda and would have minutes

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1 and so on.
 2 DR. S. PARAI:
 3 A. It was different.
 4 COFFEY, Q.C.:
 5 Q. Different. Doctor, at these meetings, do you
 6 recall whether or not the quality of the IHC
 7 stains was ever discussed?
 8 DR. S. PARAI:
 9 A. It was discussed.
 10 COFFEY, Q.C.:
 11 Q. And what do you recall about that? In what
 12 context did it arise and what sorts of things
 13 were discussed?
 14 DR. S. PARAI:
 15 A. Context would be discussion of a case.
 16 Example, if we discuss a lymphoma, we tried to
 17 determine what type of lymphoma, was it T cell
 18 or B cells, and the immuno marker for T cell
 19 or B cell or monoclonal pattern of the
 20 lymphoid malignancy would be discussed.
 21 COFFEY, Q.C.:
 22 Q. And would the quality or concerns about the
 23 quality of the stains sometimes arise?
 24 DR. S. PARAI:
 25 A. Quality will be discussed as well.

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

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1 DR. S. PARAI:
 2 A. Weak stain, weak control stain.
 3 COFFEY, Q.C.:
 4 Q. I'm sorry, weak control?
 5 DR. S. PARAI:
 6 A. Weak control stain.
 7 COFFEY, Q.C.:
 8 Q. Yes.
 9 DR. S. PARAI:
 10 A. Indicating perhaps stain not working.
 11 COFFEY, Q.C.:
 12 Q. And why is that? Why does that indicate that
 13 perhaps the stain was not working, a weak
 14 control stain?
 15 DR. S. PARAI:
 16 A. Well, external control is an indicator,
 17 whether the test result is working or not.
 18 COFFEY, Q.C.:
 19 Q. And I take it if you think you are utilizing a
 20 control tissue that is strongly or should
 21 strongly stain and it's weakly staining,
 22 that's an indication perhaps that the process
 23 is not what it should be, possibly? Is that
 24 what you're -
 25 DR. S. PARAI:

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1 A. Well, we always compare with the control.
 2 Intensity is important, and it was not one
 3 parameter. Of course, intensity is one of the
 4 parameter.
 5 COFFEY, Q.C.:
 6 Q. So Doctor, was the stain or were the slides,
 7 the staining of the slides variable at time?
 8 Sometimes it would be a particular--for
 9 example, here's an example, Doctor. Control
 10 tissue, control tissue A I'll call it, one day
 11 would stain what you would think would--in the
 12 way you would expect, and then a couple of
 13 days later, it would stain weakly and then
 14 might stain the way you'd expect it again.
 15 DR. S. PARAI:
 16 A. Similar to that.
 17 COFFEY, Q.C.:
 18 Q. That sort of -
 19 DR. S. PARAI:
 20 A. Similar to it.
 21 COFFEY, Q.C.:
 22 Q. - that was happening at times, I take it?
 23 DR. S. PARAI:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. Doctor, there are four other stains mentioned
 2 here in this memo. There's the four
 3 lymphomas. Were the other stains, other IHC
 4 stains, the non-lymphoma stains, were they
 5 occasionally discussed in these weekly
 6 meetings?
 7 DR. S. PARAI:
 8 A. Yes, it was.
 9 COFFEY, Q.C.:
 10 Q. And were concerns expressed about them at
 11 those meetings?
 12 DR. S. PARAI:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Dr. Ejeckam has--he's also told us that after
 16 he arrived and during the fall of '02, if I
 17 recall correctly, and the early winter of '03,
 18 he recalled at meetings that sometimes people
 19 would be expressing concerns about the stains
 20 in the way you've described it.
 21 DR. S. PARAI:
 22 A. That is correct.
 23 COFFEY, Q.C.:
 24 Q. Doctor, this expression of concern, how far
 25 back did that date?

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1 DR. S. PARAI:
 2 A. I don't recall, but would be at the mostly
 3 early part of 2003.
 4 COFFEY, Q.C.:
 5 Q. Mostly in 2003?
 6 DR. S. PARAI:
 7 A. 2003.
 8 COFFEY, Q.C.:
 9 Q. In particular you remember that?
 10 DR. S. PARAI:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. And with these expressions of concern, would
 14 they come from just one pathologist or a
 15 number of pathologists?
 16 DR. S. PARAI:
 17 A. Well, not only one pathologist, other
 18 pathologists as well.
 19 COFFEY, Q.C.:
 20 Q. Yes, that's what I'm saying. So it wasn't
 21 just--it wasn't limited to one pathologist?
 22 DR. S. PARAI:
 23 A. No.
 24 COFFEY, Q.C.:
 25 Q. It was a number of pathologists who would

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1 attend these?

2 DR. S. PARAI:

3 A. Yes.

4 COFFEY, Q.C.:

5 Q. And it might vary from stain to stain and from

6 week to week?

7 DR. S. PARAI:

8 A. Yes.

9 COFFEY, Q.C.:

10 Q. That was the--Doctor, as the site chief at the

11 time, did you approach anybody about that?

12 DR. S. PARAI:

13 A. Well, we have discussion in our--among our

14 pathologists. The context of the stain, as I

15 discussed, was mainly at the rounds, two

16 rounds in a week, so there was some discussion

17 when we have problem and then we communicated

18 those stain. Dr. Ejeckam was in charge of

19 immunohistochemistry lab at that time and he

20 communicated to the technologists, to the

21 immunohistochemistry lab.

22 COFFEY, Q.C.:

23 Q. Doctor, could you tell us, please, how it came

24 about that Dr. Ejeckam, as you put it, was in

25 charge of the IHC lab at the time or IHC

Page 18

1 aspect of the lab at that time? How had that

2 come about?

3 DR. S. PARAI:

4 A. When he came to work for the General Hospital,

5 I knew his background and experience in

6 immunohistochemistry. I approached to him,

7 discussed many time to consider take over or

8 look after the immunohistochemistry lab. He

9 showed interest right from the beginning and

10 he said, yes, he could help me in our lab in

11 that area, and in the surgical pathology

12 rounds, Dr. Cook asked him to take over the

13 charge of immunohistochemistry and he gladly

14 accepted.

15 COFFEY, Q.C.:

16 Q. And had that occurred before this memo?

17 DR. S. PARAI:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. So Doctor, do you recall what then led--first

21 of all, did you know that Dr. Ejeckam--did you

22 have any warning or I shouldn't use the word

23 "warning", any--were you advised beforehand by

24 Dr. Ejeckam that he was going to send out this

25 memo?

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1 DR. S. PARAI:

2 A. I don't recall any -

3 COFFEY, Q.C.:

4 Q. Heads up, as it were, you don't recall being

5 told in advance?

6 DR. S. PARAI:

7 A. No.

8 COFFEY, Q.C.:

9 Q. When you received the memo, first of all, I

10 take it then the fact that Dr. Ejeckam,

11 because you associated Dr. Ejeckam with IHC,

12 you weren't surprised that it would come from

13 a doctor like him?

14 DR. S. PARAI:

15 A. There was some discussion, as I mentioned, in

16 the meeting rounds that these are the--some of

17 the tests are going wrong and so some

18 discussion were how to inform the lab. So far

19 I recall there was discussion that it has to

20 be communicated to the immunohistochemistry

21 and he was in charge, so this was his--this is

22 the way he wanted to be appropriate to raise

23 the issue.

24 COFFEY, Q.C.:

25 Q. And then when you received this memo, Doctor,

Page 20

1 did you act upon this yourself? Did this

2 require anything of you or did you do

3 anything?

4 DR. S. PARAI:

5 A. Well, I discussed with him and I thought the

6 memo was what he thought appropriate and I had

7 no problem with this memo.

8 COFFEY, Q.C.:

9 Q. Other than Dr. Ejeckam, did you discuss the

10 memo with anyone else?

11 DR. S. PARAI:

12 A. Mr. Barry Dyer came, I believe, following day

13 or one or two days to my office and he

14 expressed some concern.

15 COFFEY, Q.C.:

16 Q. And do you recall what it was he said?

17 DR. S. PARAI:

18 A. Well, he said he was in charge of the

19 immunohistochemistry lab. He was the manager,

20 so a memo of this sort come, it should be from

21 him. He expressed that Dr. Ejeckam has

22 perhaps no authority to write this kind of

23 memo.

24 COFFEY, Q.C.:

25 Q. And what did you say to him about that?

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1 DR. S. PARAI:
 2 A. I discussed with him and I explained that
 3 these are the immuno--problem in the lab you
 4 got to understand and how Dr. Ejeckam is in
 5 charge of the immunohistochemistry lab by the
 6 clinical chief, Dr. Cook, so I think he had
 7 the authority to write this memo, and I did
 8 not see any problem with this memo. It was
 9 just awareness to all the pathologists and the
 10 staff that something is going wrong. We have
 11 to look after it.
 12 COFFEY, Q.C.:
 13 Q. You have to address it, I take it?
 14 DR. S. PARAI:
 15 A. Yes, have to address this.
 16 COFFEY, Q.C.:
 17 Q. Doctor, what then happened in relation to
 18 this?
 19 DR. S. PARAI:
 20 A. Dr. Ejeckam took a lot of time over the next
 21 following several weeks to correct those
 22 deficiency he identified and finally when--and
 23 finally it was done.
 24 COFFEY, Q.C.:
 25 Q. And I take it, if we could look then at--well,

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

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

Page 24

1 about fixation?
 2 DR. S. PARAI:
 3 A. That was my understanding.
 4 COFFEY, Q.C.:
 5 Q. Yeah, and so the pathologists generally were
 6 aware, at least by 2003 were aware ER/PR, in
 7 particular, there were certain aspects of it
 8 that should be considered very carefully as is
 9 set out in this memo?
 10 DR. S. PARAI:
 11 A. He raised something in the first paragraph of
 12 this memo that they got to be careful about
 13 the tissue fixation and all pathologists who
 14 knew this thing, fixation is important and we
 15 always practice with the optimal fixation of
 16 the breast tissue concerned.
 17 COFFEY, Q.C.:
 18 Q. Doctor, as a site chief, do you know if this
 19 was communicated, for example, to the peri-
 20 operative staff?
 21 DR. S. PARAI:
 22 A. Doctor Ejeckam communicated. At that time he
 23 was in charge of the immunohistochemistry, so
 24 I believe he did.
 25 COFFEY, Q.C.:

Page 25

1 Q. Because this is addressed to pathologists.
 2 You can see that in the first one after the
 3 "to" word, and then he copies it to the site
 4 chief, that's yourself, and to Dr. Cook, Barry
 5 Dyer, and all technical staff in IHC, but that
 6 would not include the operating room staff,
 7 peri-operative staff. So do you know if, in
 8 fact, they were alerted to his expressions of
 9 the caution about the fixation issues?
 10 DR. S. PARAI:
 11 A. I'm not clear what other staff you're asking.
 12 COFFEY, Q.C.:
 13 Q. The peri-operative, up in the PR where the
 14 fixation actually begins with the excision of
 15 the tissue. Do you know if the OR people were
 16 advised of the contents of this memo?
 17 DR. S. PARAI:
 18 A. I'm not aware of that.
 19 COFFEY, Q.C.:
 20 Q. Doctor, just to look back at page one, the
 21 April 4th, 2003, memo. At the time -- this is
 22 addressed to all of you, all pathologists.
 23 These eight stains are listed and he describes
 24 them as "Have remained unreliable, erratic,
 25 and therefore, unhelpful for diagnostic

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1 purposes". Would you -- did you at the time
 2 agree with that statement?
 3 DR. S. PARAI:
 4 A. Well, it was his memo and I thought myself it
 5 was a good memo.
 6 COFFEY, Q.C.:
 7 Q. So with the eight stains at that time, by
 8 April of 2003, you understood at least those
 9 eight stains could be described, accurately
 10 perhaps, described as unreliable, erratic, and
 11 unhelpful for diagnostic purposes, and it says
 12 "remained", suggesting that that had been so
 13 for a period of time. This hadn't started,
 14 like, the week before.
 15 DR. S. PARAI:
 16 A. I don't know what he meant "remained" or how
 17 long. It is not clear from that sentence to
 18 me.
 19 COFFEY, Q.C.:
 20 Q. But at the time, from your own knowledge,
 21 Doctor, as the site chief, how far back had
 22 this problem extended?
 23 DR. S. PARAI:
 24 A. I don't recall how far. We reviewed this
 25 thing, I think, one or two weeks, this -- in

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1 our round, and then Dr. Ejeckam thought it is
 2 time to remind everybody, a short period of
 3 time, couple of weeks. I think one meeting
 4 and then following meeting, we wanted to see
 5 whether it is continuing or not.
 6 COFFEY, Q.C.:
 7 Q. Doctor, at the time in 2003 -- before this
 8 April 4th memo or, in fact, after it, was it
 9 ever discussed by the pathologists, to your
 10 knowledge, by any pathologist in St. John's
 11 that in light of this statement by Dr.
 12 Ejeckam, in light of the underlying facts
 13 which is the stains, at least some of them
 14 were unreliable at times, was any thought
 15 given to going back in time and retesting?
 16 DR. S. PARAI:
 17 A. I was not aware.
 18 COFFEY, Q.C.:
 19 Q. So it didn't come up, it didn't occur to you,
 20 and as far as you know, no one discussed it?
 21 DR. S. PARAI:
 22 A. No.
 23 COFFEY, Q.C.:
 24 Q. Doctor, here on page three of the exhibit --
 25 page two of the May 2nd memo, paragraph three,

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1 there's a reference to internal controls,
 2 check normal breast acini in your sections as
 3 internal controls, this is a second level
 4 control, and he goes on to talk about that.
 5 Now were you aware of this before you got this
 6 memo?
 7 DR. S. PARAI:
 8 A. This was the first time I was aware of the
 9 internal control.
 10 COFFEY, Q.C.:
 11 Q. When you got Dr. Ejeckam's memo, this May 2nd
 12 memo?
 13 DR. S. PARAI:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. At that time, having learned that, that would
 17 be in May of 2003, did you discuss that with
 18 any other pathologists?
 19 DR. S. PARAI:
 20 A. I don't recall.
 21 COFFEY, Q.C.:
 22 Q. And what I'm getting at is if you hadn't known
 23 it yourself, and you indicated you had not
 24 known that before, perhaps other pathologists
 25 were in the same position. So you didn't

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1 discuss it with anybody?

2 DR. S. PARAI:

3 A. I don't recall.

4 COFFEY, Q.C.:

5 Q. Was Dr. Ejeckam's April -- just go back here.

6 April 4th memo, 2003, was that generally

7 discussed amongst the pathologists, the fact

8 that he'd stopped the staining for eight

9 stains?

10 DR. S. PARAI:

11 A. I don't recall.

12 COFFEY, Q.C.:

13 Q. Okay, the May 2nd, 2003 memo, the one about ER

14 and PR in particular, was that discussed

15 amongst the pathologists, do you know?

16 DR. S. PARAI:

17 A. I don't recall.

18 COFFEY, Q.C.:

19 Q. Like, for example, at these weekly meetings

20 afterward?

21 DR. S. PARAI:

22 A. It came in the discussion in the round, and

23 everybody knew that we stopped those stains,

24 and we are looking for when it is corrected

25 and stain comes. After May 2nd, when the

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1 stain resumed; yes, we discussed in our rounds

2 and we found it was satisfactory.

3 COFFEY, Q.C.:

4 Q. So it was after the May 2nd memo in these

5 weekly rounds that pathologists, it's your

6 recollection, did discuss from their

7 perspective the view that the new slides, the

8 current slides, after May 2nd slides, they

9 were satisfactory?

10 DR. S. PARAI:

11 A. Correct.

12 COFFEY, Q.C.:

13 Q. But the actual rest of the contents of this

14 memo, and whether or not people were or were

15 not aware of particular aspects of it, was not

16 discussed?

17 DR. S. PARAI:

18 A. It was -- this time to time came in the

19 discussion, that was the time, the internal

20 control, and briefly discussed, but I don't

21 recall details.

22 COFFEY, Q.C.:

23 Q. Doctor, the June 19th, 2003 memo at page five

24 of this exhibit, and it's Dr. Ejeckam's memo

25 of June 19th, 2003, and it's copied to Dr.

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1 Desmond Robb, as chair of the Discipline of

2 Laboratory Medicine, copied to Drs. Cook and

3 yourself, Parai, and Mr. Dyer, Manager of

4 Histopathology. Now this June 19th, 2003

5 memo, had Dr. Ejeckam told you that he was

6 going to send this out?

7 DR. S. PARAI:

8 A. So far I recall, he did. We had a lot of

9 discussion about the immunostain, although it

10 was working at that time, and he expressed

11 there is some concern at the

12 immunohistochemistry lab and he explained that

13 in his memo of June 19th, he discussed, and I

14 think it is good advice to that.

15 COFFEY, Q.C.:

16 Q. So he told you "I'm going to send out the

17 memo"?

18 DR. S. PARAI:

19 A. Well, so far I recall, he discussed the issues

20 to be addressed and I said, all right, okay,

21 and he discussed them briefly.

22 COFFEY, Q.C.:

23 Q. Now, Doctor, when you received this June 19th

24 memo, did you do anything about it, did you

25 discuss it with anybody?

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1 DR. S. PARAI:

2 A. This memo is addressed to Mr. Terry Gulliver,

3 and follow up discussion with Dr. Ejeckam, I

4 understood Dr. Ejeckam also had a discussion

5 with Mr. Gulliver, and he indicated he's going

6 to address those issues.

7 COFFEY, Q.C.:

8 Q. From your perspective as the site chief, how

9 if at all were they addressed?

10 DR. S. PARAI:

11 A. We discussed in our rounds sometimes came that

12 we realized at the time what he was talking

13 about, the facility, dedicated histo tech and

14 resources, and we always raised this concern

15 to the division manager, to clinical chief.

16 COFFEY, Q.C.:

17 Q. Well, you raised the concerns, and you

18 continued to, you say?

19 DR. S. PARAI:

20 A. Yes.

21 COFFEY, Q.C.:

22 Q. Was it addressed? I appreciate you are

23 raising concerns about it. The people you

24 were raising the concerns with, which would be

25 Mr. Gulliver and Dr. Cook, from your

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1 perspective, did they actually do anything
 2 about it?
 3 DR. S. PARAI:
 4 A. I would say no.
 5 COFFEY, Q.C.:
 6 Q. Did they explain why not?
 7 DR. S. PARAI:
 8 A. They did not explain. Their authority is
 9 superior to me.
 10 COFFEY, Q.C.:
 11 Q. Doctor, these three memos, the April 4th, May
 12 2nd, and the June 19th memos, did you ever
 13 discuss them with Dr. Williams?
 14 DR. S. PARAI:
 15 A. I did not have any -- I did not have any way
 16 to meet Dr. Williams. The divisional
 17 structure, as I discussed with you, site chief
 18 will report to the divisional chief or
 19 clinical chief, and any concern or issue, he
 20 will take it to Dr. Williams. I had no
 21 reporting mechanism to meet Dr. Williams.
 22 COFFEY, Q.C.:
 23 Q. I appreciate that there was no formal
 24 reporting. I'm asking you did you ever
 25 discuss the memo or their contents with Dr.

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1 Williams. It's one thing -- I appreciate not
 2 in a formal setting, but did you discuss it
 3 with him, do you know?
 4 DR. S. PARAI:
 5 A. Not that I recall.
 6 COFFEY, Q.C.:
 7 Q. Did you discuss this, in particular -- well,
 8 either the earlier two memos, the April 4th or
 9 the May 2nd one, or the June 19th one with Dr.
 10 Robb?
 11 DR. S. PARAI:
 12 A. Well, yes, I discussed with him. He was quite
 13 concerned about the facility, dedicated -- all
 14 this issue raised in the memo, yes.
 15 COFFEY, Q.C.:
 16 Q. The June 19th memo?
 17 DR. S. PARAI:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. Do you recall if you discussed the earlier two
 21 memos or their contents with Dr. Robb?
 22 DR. S. PARAI:
 23 A. Yes, Dr. Robb would have been the chairman of
 24 the discipline. We had always discussion with
 25 him and advice and feedback.

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1 COFFEY, Q.C.:
 2 Q. So from your perspective as the site chief at
 3 the time this was going on in April and May,
 4 Dr. Ejeckam's intervention we've been referred
 5 to it as, Dr. Robb knew about it just like you
 6 did?
 7 DR. S. PARAI:
 8 A. Oh, yes.
 9 COFFEY, Q.C.:
 10 Q. The June 19th memo itself, Doctor, when you
 11 got it and reviewed it, did you agree with its
 12 contents?
 13 DR. S. PARAI:
 14 A. When I looked at them I did not -- more or
 15 less.
 16 COFFEY, Q.C.:
 17 Q. Was there anything in particular, I'll put it
 18 another way, that you disagreed with or would
 19 not have endorsed? Just take your time if you
 20 want and -- the first part of it where he says
 21 he's worked closely with the technical staff
 22 in order to rectify the problem. He says,
 23 "The state of immunostain at the General
 24 Hospital is still unsatisfactory", and he then
 25 talks about the physical location being

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1 unsatisfactory, he wanted a separate room with
 2 proper humidity control. Were you in
 3 agreement with that, this part?
 4 DR. S. PARAI:
 5 A. Well, the only thing I would say, he mentioned
 6 that the state of immunostain at the General
 7 Hospital still unsatisfactory, I think that
 8 would be some disagreement. It was working.
 9 COFFEY, Q.C.:
 10 Q. Oh, it was working?
 11 DR. S. PARAI:
 12 A. Yeah.
 13 COFFEY, Q.C.:
 14 Q. But he does refer to physical location of the
 15 facility is unsatisfactory.
 16 DR. S. PARAI:
 17 A. Yes, that I will agree.
 18 DR. S. PARAI:
 19 A. You agree with him on that?
 20 DR. S. PARAI:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. "Immunostain is not just another special
 24 stain", and he says it's affected by many
 25 factors that may apply than in other special

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1 stains. It's an extremely sensitive
 2 procedure. You understood all that?
 3 DR. S. PARAI:
 4 A. I agree with this.
 5 COFFEY, Q.C.:
 6 Q. He says "The staff arrangement as it stands
 7 now is grossly inadequate and unacceptable for
 8 problem free or minimal problem operation.
 9 There has to be dedicated staff".
 10 DR. S. PARAI:
 11 A. I agree.
 12 COFFEY, Q.C.:
 13 Q. You agree. He talks at some length then about
 14 the staff. I'm not going to take you through
 15 it word for word, but I take it you did agree
 16 that there should be dedicated staff and they
 17 should have educational opportunities in
 18 relation to the staining processes?
 19 DR. S. PARAI:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. The volume of immunohistochemical procedures
 23 continuing to increase, that was so at the
 24 time?
 25 DR. S. PARAI:

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1 A. I agree.
 2 COFFEY, Q.C.:
 3 Q. The end of paragraph four, "Since this is the
 4 only centre in the province that performs this
 5 test, there is enough case to be made for
 6 identifying this activity special and unique,
 7 and, therefore, requires financing and
 8 staffing".
 9 DR. S. PARAI:
 10 A. I agree.
 11 COFFEY, Q.C.:
 12 Q. And he says at paragraph five, "Because of the
 13 other duties of the technical staff, present
 14 staff, the other duties that take them away
 15 from immunostain fairly regularly, it's
 16 virtually impossible for them to devote the
 17 time required to master the intricacies".
 18 DR. S. PARAI:
 19 A. I agree.
 20 COFFEY, Q.C.:
 21 Q. Of the procedure. Paragraph six, the second
 22 part of it, he says, "Diagnosis based on
 23 inappropriate immunostain will surely
 24 jeopardize patient care and even expose the
 25 Health Care Corporation of St. John's to

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1 litigation. Therefore, it will be ill-advised
 2 to operate unreliable and erratic
 3 immunohistochemical procedures in our
 4 laboratory", and then he asks Mr. Gulliver to
 5 take a hard look at the above and commit the
 6 necessary resources. Doctor, did you agree
 7 with the assertion that inappropriate
 8 immunostain could jeopardize patient care?
 9 DR. S. PARAI:
 10 A. Well, of course I -- yes, I understand that.
 11 COFFEY, Q.C.:
 12 Q. Doctor, I'm going to ask you this, in light of
 13 the three memos, April, May and June we just
 14 looked at, and at the time as a site chief,
 15 what was your understanding of how far up in
 16 the administration they were aware, people had
 17 been made aware of this problem and its
 18 potential ramifications? I mean, I appreciate
 19 you knew that Dr. Cook new.
 20 DR. S. PARAI:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. And Dr. Robb.
 24 DR. S. PARAI:
 25 A. Dr. Cook, Dr. Robb, Mr. Terry Gulliver, Mr.

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1 Barry Dyer and I can't answer whether anybody
 2 above our level to leadership knew, I can't
 3 answer.
 4 COFFEY, Q.C.:
 5 Q. And I appreciate you can't--because you didn't
 6 speak to, for example, Dr. Williams and I
 7 understand that. Did you, at the time, as the
 8 site chief, make any assumptions about people
 9 further up having been notified?
 10 DR. S. PARAI:
 11 A. Well I don't recall.
 12 COFFEY, Q.C.:
 13 Q. Would you have expected that they would be, as
 14 a site chief?
 15 DR. S. PARAI:
 16 A. Yes, I would expected, yes. Particularly the
 17 third memo from Dr. Ejeckam, these are the
 18 recommendations, these are good
 19 recommendations, we have to implement in the
 20 lab and he was expecting that recommendation.
 21 He had a follow-up discussion with Mr. Terry
 22 Gulliver and after that, we discussed--and
 23 discussion did not stop at June, 2003, and we
 24 continued to discuss and Dr. Ejeckam continued
 25 to monitor the lab, but nothing happened.

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1 COFFEY, Q.C.:

2 Q. Did Dr. Ejeckam ever express to you any

3 thoughts as to how he felt about that, as time

4 went on?

5 DR. S. PARAI:

6 A. He was not happy, disappointed, he--what I

7 understood that he wanted those problem be

8 corrected, addressed.

9 COFFEY, Q.C.:

10 Q. If I could please, Exhibit P-1576? Doctor,

11 this is a Division of Anatomical Pathology,

12 pathologists' meeting at the General Hospital

13 site, minutes of a meeting of September--well,

14 this is the agenda, page two, the minutes of

15 the meeting of September 24th, 2003. There

16 are a list of doctors present, your name is

17 the last one. Doctor, on paragraph 4.1,

18 Laboratory Technical Quality, "This issue was

19 discussed with Barry Dyer, Terry Gulliver and

20 Dr. Cook. The discussion included the

21 technical quality of the slides, error of

22 labelling, floater and others. Some of these

23 issues have been documented. Doctor Ejeckam

24 has given a lecture on quality assurance of a

25 laboratory which was attended by one senior

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1 technologist. This program is available for

2 the lab technical staff at a suitable time of

3 interest and a log book is available in the

4 reporting room to record all problems." So,

5 Doctor, I take it then, as you've pointed out,

6 in April, May and June, this didn't end, the

7 discussion about quality issues or concerns,

8 in particular in relation to--well just

9 staining in general, in fact this suggests,

10 was being discussed in September of '03?

11 DR. S. PARAI:

12 A. It was discussed in the meeting, yes.

13 COFFEY, Q.C.:

14 Q. Doctor, if we could, please, Registrar,

15 Exhibit P-2320? Again, this is an agenda for

16 a meeting of, a pathologists' meeting of the

17 Division of Anatomical Pathology, page 2 on

18 the agenda, page 3 on the minutes on December

19 11th, 2003. Again, you're listed as present,

20 Doctor; in fact, you called the meeting to

21 order. And, Doctor, in paragraph 3.2, the QA

22 Program, reads "This will be further discussed

23 at the next site chiefs' meeting. After

24 appropriate revision and editing, a booklet

25 will be printed out as soon as possible."

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1 What was that about, Doctor?

2 DR. S. PARAI:

3 A. Basically the QA Program, what we are trying

4 to develop since 2001 is a manual about

5 technical and clinical responsibility and the

6 assurance of the test in the lab.

7 COFFEY, Q.C.:

8 Q. The lab technical quality, paragraph 3.3, "a

9 log book for the technical quality is being

10 maintained in the reporting room. Mr. Barry

11 Dyer informed that he is following this log

12 book and taking action." What was that about,

13 Doctor.

14 DR. S. PARAI:

15 A. That was a log book we put in the

16 pathologists' reporting room asking the

17 pathologists to put down their comment on the

18 quality of the slide, it's not only H&E stain,

19 immuno stain as well and any recommendation,

20 so Mr. Barry Dyer would look at those log book

21 regularly and take action.

22 COFFEY, Q.C.:

23 Q. And, Doctor, here under paragraph 4.5,

24 "Pathologist assistant, pathologist manpower,

25 Dr. Robb discussed in detail the need for

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1 three pathologist assistants and a new

2 pathologist position. Surgical workload for

3 this site has increased tremendously and a new

4 pathologist in the Division of Anatomical

5 Pathology for the Health Sciences Centre is

6 needed to handle the workload." So this is as

7 the end of 2003, Dr. Robb is still lobbying

8 for pathology assistants?

9 DR. S. PARAI:

10 A. Yes, it has been a continue process, continued

11 effort to recruit pathologist assistants.

12 COFFEY, Q.C.:

13 Q. And what, if anything, do you recall about

14 what you were told about why that didn't

15 happen?

16 DR. S. PARAI:

17 A. So far as I recall, it was a funding problem,

18 lab administration informed us we have no

19 money to recruit such positions.

20 COFFEY, Q.C.:

21 Q. And, Doctor, I show you an exhibit, P-1913.

22 Now these are the minutes of a meeting, a site

23 chiefs and divisional managers' meeting of

24 March 31st, 2004. Dr. Cook, Dr. Robb and

25 yourself are present and here, Doctor, on the

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1 second page of the exhibit under "New
 2 Business", paragraph 4.2 "New Technology. The
 3 immunoperoxidase stainer appears to be working
 4 generally well; however, there continues to be
 5 some problems with estrogen and progesterone
 6 receptors." Now, Doctor, this
 7 immunoperoxidase stainer would have been the
 8 Ventana system by this point in time, this is
 9 March of '04?
 10 DR. S. PARAI:
 11 A. Yes, I think so.
 12 COFFEY, Q.C.:
 13 Q. Do you recall then what this was about?
 14 DR. S. PARAI:
 15 A. I don't recall any specific problem, I think
 16 raised by--I don't recall who raised, however
 17 it indicated there are some problem with ER/PR
 18 and at that point, Dr. Ejeckam was in charge
 19 of the immunohistochemistry lab.
 20 COFFEY, Q.C.:
 21 Q. So certainly this concern about, a suggestion
 22 there continues to be some problems with
 23 estrogen and progesterone receptors, you
 24 didn't raise it yourself because you didn't
 25 know that.

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1 DR. S. PARAI:
 2 A. No.
 3 COFFEY, Q.C.:
 4 Q. And do you recall--and if we just look back,
 5 Mr. Dyer wasn't there and so it's Dr. Cook or
 6 Dr. Robb, do you recall who, between the two
 7 of them, raised that concern?
 8 DR. S. PARAI:
 9 A. Oh I don't recall.
 10 COFFEY, Q.C.:
 11 Q. Do you recall the nature of the problems being
 12 discussed?
 13 DR. S. PARAI:
 14 A. No.
 15 COFFEY, Q.C.:
 16 Q. Now, Doctor, here on paragraph 3.8 "Pathology
 17 Manpower". "Two potential vacancies will
 18 occur in the spring and summer of this year.
 19 Dr. Barron will be switching from hospital
 20 base to university base position. Dr. Bev
 21 Carter is interested in one of the hospital
 22 positions." Now, Dr. Carter was actually
 23 already working by this point in time in St.
 24 John's, wasn't she? By March of '04, she had
 25 been doing locums?

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1 DR. S. PARAI:
 2 A. I think so, yes.
 3 COFFEY, Q.C.:
 4 Q. Did you understand that Dr. Carter had any
 5 particular expertise or training over and
 6 above the normal pathologist -
 7 DR. S. PARAI:
 8 A. She had fellowship training in breast
 9 pathology, so she had an interest in breast
 10 cancer.
 11 COFFEY, Q.C.:
 12 Q. And she was, of course, stationed at,
 13 physically at St. Clare's Hospital?
 14 DR. S. PARAI:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. Exhibit P-2406 please? Doctor, these are the
 18 minutes of a meeting of Division of Anatomical
 19 Pathology, General Hospital site pathologists'
 20 meeting of September 1st, 2004 and present are
 21 a number of individuals, including yourself.
 22 You called the meeting to order. I take it
 23 you would do that because you were the site
 24 chief?
 25 DR. S. PARAI:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. And here, Doctor, in paragraph 3.6, under
 4 "Business Arising". "HER2/neu, ER and PR
 5 immunostaining, Dr. D. Fontaine"--that would
 6 be Dan Fontaine--"did mention that Dr. B.
 7 Carter would like to review all the new
 8 HER2/neu, ER and PR immunostaining before
 9 returning to the reporting pathologists. Some
 10 members of the division expressed that this is
 11 unnecessary and they will continue reporting
 12 their own cases." Now, Doctor, what do you
 13 recall about this?
 14 DR. S. PARAI:
 15 A. As I recall that this was not clear whether
 16 she wanted--Dr. Carter wanted to report ER/PR
 17 and HER2/neu, I don't recall, so far I recall
 18 Dr. Fontaine said she was interested to look
 19 at the ER/PR staining and assess the quality,
 20 so that's what really the first few lines of
 21 this memo and then in our division, some
 22 pathologists were interested too for the ER/PR
 23 reporting and they expressed that perhaps they
 24 would like to continue their experience, but
 25 there was no opinion that we don't later to

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1 look at ER/PR and HER2/ neu. It is the
 2 reporting I believe they wanted to look at
 3 themselves and continue, but if she had--she was
 4 interested to look at those stains before we
 5 report, I don't think anyone was against that.
 6 That's my recollection.
 7 COFFEY, Q.C.:
 8 Q. Well what then happened, Doctor, about this
 9 issue?
 10 DR. S. PARAI:
 11 A. It was not a clear decision, if you look at
 12 from the memo and so, and Dr. Ejeckam was at
 13 that time was in charge of the
 14 immunohistochemistry lab, so he was in the
 15 meeting, I don't know what happened after
 16 that.
 17 COFFEY, Q.C.:
 18 Q. Now the problems that had been referred to in
 19 the March 31st, 2004 minutes, there continues
 20 to be some problems with estrogen and
 21 progesterone receptors, how long did those
 22 problems continue for?
 23 DR. S. PARAI:
 24 A. I don't recall.
 25 COFFEY, Q.C.:

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1 Q. Because, you see, if Dr. Carter, as of
 2 September 1st, 2004, wanted to look at the ER
 3 and PR stains and look at the quality of them,
 4 was it still a problem at that time?
 5 DR. S. PARAI:
 6 A. I don't recall. It was not raised
 7 specifically in any meeting or informal
 8 meeting, discussion. Dr. Ejeckam was in
 9 charge at that time in the lab.
 10 COFFEY, Q.C.:
 11 Q. So these discussions about quality of stains
 12 which you recall had certainly arisen in the
 13 beginning of 2003, before Dr. Ejeckam
 14 intervened, you remember those eight stains?
 15 DR. S. PARAI:
 16 A. No, it was in the 2003, not before.
 17 COFFEY, Q.C.:
 18 Q. What I want to ask you about there is this, he
 19 intervened.
 20 DR. S. PARAI:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. The testing of those stains started again in
 24 '03.
 25 DR. S. PARAI:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. We've seen a reference in March of '04, at
 4 least one is minuted at least once, that ER
 5 and PR continue, there continues to be
 6 problems with those two stains. We just
 7 looked at that, March of '04, and now Dr.
 8 Carter, in September of '04, is asking to look
 9 at HER2/neu, ER and PR stains. So I'm asking
 10 you at these weekly meetings or otherwise,
 11 were there discussions about concerns
 12 expressed by pathologists, even after May of
 13 '03, about ER and PR staining?
 14 DR. S. PARAI:
 15 A. Not at the General Hospital Site, we were not
 16 doing too many ER/PR at this site, so I
 17 wouldn't be able to answer that. Exhibit P-
 18 0021 please? Now, Doctor, this is a MAC
 19 minutes of their meeting of January 12th--I'm
 20 sorry, if we could go please to page 21?
 21 These are the minutes of the meeting, Doctor,
 22 you'll see it there, of March 16th, 2005, top
 23 of the page. Toward the very bottom of the
 24 page, "A new site chief, General Hospital,
 25 Laboratory Medicine, Dr. Sushil Parai is

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1 indicated he does not wish to renew his term
 2 as site chief of General Hospital site,
 3 effective March 31, 2005" and then Dr.
 4 Fontaine is noted to have accepted or agreed
 5 to become your replacement effective April 1.
 6 So, Doctor, can you tell the Commissioner why
 7 you didn't want to renew your position as site
 8 chief?
 9 DR. S. PARAI:
 10 A. I had a couple of job offer in around that
 11 time in the early part of 2005, so I was
 12 intending to move to accept a new job in other
 13 provinces. And that was the formation of
 14 Eastern Health, so there will be, operation
 15 would be more wide based, not only St. John's,
 16 it will include to Clarenville, Carbonear and
 17 so -
 18 COFFEY, Q.C.:
 19 Q. Yes, because as of April 1, 2005, the Health
 20 Care Corporation did not exist.
 21 DR. S. PARAI:
 22 A. It did not exist.
 23 COFFEY, Q.C.:
 24 Q. It did not exist as of April 1 and it was
 25 replaced by Eastern Health and I take it you

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1 understood that there'd be changes, would
 2 follow that?
 3 DR. S. PARAI:
 4 A. Yes.
 5 COFFEY, Q.C.
 6 Q. Doctor, if we could, Registrar, please, look
 7 at P-2407. Now, Doctor, you recognize this
 8 type of form. This a Health Care Corporation
 9 of St. John's special procedure request form.
 10 It's a requisition form for IHC testing. You
 11 recognize this type of form?
 12 DR. S. PARAI:
 13 A. Yes.
 14 COFFEY, Q.C.
 15 Q. Okay. Doctor, this particular one on page one
 16 of the exhibit has "repeat" written on the top
 17 right hand side. Pathologist in question
 18 happens to be Dr. Cook. It's December 14,
 19 2000 and the test is estrogen and progesterone
 20 receptors and then there are two signatures,
 21 Ms. Welsh and Ms. Butler. And the reporting
 22 the HER2/neu is the third line. So, this is a
 23 repeat here of ER/PR, Doctor, this particular
 24 one of a by is surgical number SS420-94. It's
 25 quite an older block. Page three of the

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1 exhibit is same date, different surgical
 2 number, SS6278-00, 2000 case, a repeat and
 3 again it's for ER/PR, the signatures of Ms.
 4 Welsh and Ms. Butler are there, December 19
 5 and probably 27th or so, it's hard to tell.
 6 Now, Doctor, if we go then please to page
 7 six of the exhibit, this is a June 6, '01
 8 requisition form SS4023-01 is the surgical
 9 number and here it's noted that "ER/PR
 10 controls checked by Dr. S. Parai". So, I take
 11 it and we can look through a number of these--
 12 I'll just take you to page eight of the same
 13 exhibit, hard to know what the surgical number
 14 is, but it's something S-805-01, June 7th, '01
 15 and again "ER/PR controls checked by Dr. S.
 16 Parai, June 13, '01". So, Doctor, you were, I
 17 take it, then routinely checking controls at
 18 times, if you happen to be the one scheduled
 19 to do so.
 20 DR. S. PARAI:
 21 A. Yes.
 22 COFFEY, Q.C.
 23 Q. And there's another one for yourself at page
 24 10 and then--here, Doctor, I'm going to put
 25 this in context for the Commissioner. At page

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1 12 of the exhibit is surgical number S2459/01,
 2 July 3rd, 2001 and the controls "Des Robb", so
 3 Dr. Robb would occasionally be checking them
 4 as well, and others.
 5 DR. S. PARAI:
 6 A. Yes.
 7 COFFEY, Q.C.
 8 Q. Is there any particular schedule associated
 9 with that, Doctor, in terms of like, whose
 10 turn it was or who--first of all, whose turn
 11 it was to check the controls for ER/PR?
 12 DR. S. PARAI:
 13 A. There is no particular schedule site chief or
 14 on call pathologist or another pathologist.
 15 We are working in a rotation, always one
 16 member are not present. So, we obtain 11
 17 pathologists and technologists can approach to
 18 any pathologists and they would be happy to
 19 look at the controls.
 20 COFFEY, Q.C.
 21 Q. Doctor, the checking of ER/PR controls, did
 22 the pathologist who, from time to time, was
 23 scheduled to do it, did he or she need any
 24 particular training in that regard or receive
 25 any particular training in that regard?

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1 DR. S. PARAI:
 2 A. In my opinion, all of them are experienced.
 3 They knew how to read ER/PR control. I was
 4 aware (phonetic) of any specials training, if
 5 you wanted to know.
 6 COFFEY, Q.C.
 7 Q. Page 33, please. Now here, Doctor, this one
 8 is June 25, 2001, it's noted, marked repeat
 9 and we can see it's an ER/PR, check and see at
 10 the bottom. It's repeated, I believe, July
 11 3rd and then repeated on the 18th, probably
 12 the 18th, 15th or 18th, 2001. Now, Doctor--
 13 just bring up page 47, please. Doctor, this
 14 is an August 6th, 2001 ER/PR test, S2875/01.
 15 And it's noted to be repeated here, August 8th
 16 first and then August 14th repeated.
 17 Now, Doctor, I can take you through this
 18 at some length, perhaps page 50, again. It's
 19 hard to know if this one is repeat, but it's
 20 August 16th, 2001, surgical number is S10427-
 21 01 and there are two signatures at the bottom
 22 of the page. It's hard to know in this
 23 particular instance whether the second one is
 24 for the HER2/neu or is a repeat of the ER/PR.
 25 Doctor, we've seen and I can take you through

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1 it, a number of repeats in 2001 and 2002,
 2 noted on these requisition forms for ER/PR, I
 3 can take you through them, and there are a
 4 number of them. Doctor, were you aware that
 5 the ER and PR tests or stains were being
 6 repeated in 2001 on a number of occasions and
 7 then in 2002?
 8 DR. S. PARAI:
 9 A. Occasionally.
 10 COFFEY, Q.C.
 11 Q. And occasionally, in that context, what did
 12 you understand in terms of frequency?
 13 DR. S. PARAI:
 14 A. My understanding was that only a few tests
 15 were repeated, but I did not know the number
 16 and how often.
 17 COFFEY, Q.C.
 18 Q. Who brought it to your attention?
 19 DR. S. PARAI:
 20 A. I noticed it from these when I was checking
 21 controls, but nobody bought it to my
 22 attention.
 23 COFFEY, Q.C.
 24 Q. So, you noticed it when you were checking the
 25 controls, I take it, you could see written on

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1 the requisition forms.
 2 DR. S. PARAI:
 3 A. Yes.
 4 COFFEY, Q.C.
 5 Q. That if you're looking at the controls and you
 6 could see that, well this, has already been
 7 run before and you were looking at this
 8 control for the repeat test and you noticed
 9 it. Did you ever make any inquiries about why
 10 that was?
 11 DR. S. PARAI:
 12 A. No, I did not make any inquiry. I thought it
 13 was--many test we order repeat, it's not only
 14 immunohistochemistry, special stain, even H &
 15 E too.
 16 COFFEY, Q.C.
 17 Q. Were there any other stains, in particular IHC
 18 stains being repeated as often as the ER/PR
 19 stain was.
 20 DR. S. PARAI:
 21 A. Yes, immuno stain for lymphoma and immuno
 22 stain for sarcoma, immuno stain for melanoma,
 23 quite often we did.
 24 COFFEY, Q.C.
 25 Q. Now, Doctor, did you ever order or re-order

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1 any of these tests yourself, ER/PR?
 2 DR. S. PARAI:
 3 A. I don't recall.
 4 COFFEY, Q.C.
 5 Q. Was it ever brought to your attention that
 6 upon repeat testing that there was a different
 7 result?
 8 DR. S. PARAI:
 9 A. I don't recall. Is the question, you mean, a
 10 even different result means a--can I ask you--
 11 whether it is in the control or in the test
 12 slide?
 13 COFFEY, Q.C.
 14 Q. Well, Doctor, the test slide -
 15 DR. S. PARAI:
 16 A. Or both?
 17 COFFEY, Q.C.
 18 Q. The test slide, first of all.
 19 DR. S. PARAI:
 20 A. I do not recall, I was not informed.
 21 COFFEY, Q.C.
 22 Q. Okay. How about both controls, the different
 23 result.
 24 DR. S. PARAI:
 25 A. If the control had difference result, the

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1 negative control would turn to positive, but
 2 when there was any negative control, there
 3 will be no reporting on -
 4 COFFEY, Q.C.
 5 Q. The first test.
 6 DR. S. PARAI:
 7 A. - test, patient. So, they will stop until the
 8 control is repeated and the test is repeated
 9 as well.
 10 COFFEY, Q.C.
 11 Q. Now, Doctor, why were these tests being
 12 repeated?
 13 DR. S. PARAI:
 14 A. I cannot answer that.
 15 COFFEY, Q.C.
 16 Q. The ER/PR testing. If, for example, the
 17 control worked because presumably if the
 18 control didn't work, the first tissue slide,
 19 patient's tissue slide wouldn't have gone
 20 anywhere.
 21 DR. S. PARAI:
 22 A. It is the methodology, all tests and the
 23 controls be run in the same environment at the
 24 same time with the proper temperature, all the
 25 technical details there should be the same

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1 time.
 2 COFFEY, Q.C.
 3 Q. What I'm asking you, Doctor, is is this, is
 4 why if a patient's tissue slide was produced,
 5 a control was produced and the control was
 6 okay, it went to whomever, it went to a
 7 pathologist, what sorts of reasons were you
 8 aware of were being given for request repeats
 9 of ER and PR? Why were people re-ordering or
 10 ordering that it be done again on that
 11 particular block?
 12 DR. S. PARAI:
 13 A. I don't understand your question.
 14 COFFEY, Q.C.
 15 Q. Here's an example, I'll just bring one up,
 16 page 103 please. This is October 22nd, 2001
 17 it's SS-7453-01. Look down here, Doctor, this
 18 apparently was repeated, initially done
 19 October 25 and October 29 and then November 1.
 20 It's an ER/PR. For example, October 25th,
 21 2001 when Ms. Butler signed this, date
 22 completed, she produced a patient's slides and
 23 presumably some control existed somewhere.
 24 DR. S. PARAI:
 25 A. Yes.

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1 COFFEY, Q.C.
 2 Q. Apparently the test got repeated, date
 3 completed of the repeat is October 29, 2001.
 4 What sort of thing would had to have happened
 5 to cause the repeat to be requested? What
 6 sorts of problems were pathologists
 7 encountering -
 8 DR. S. PARAI:
 9 A. I think it would be helpful if you look at the
 10 top of the sheet, mention that the control was
 11 very weak, repeat very weak control. So,
 12 that's the reason the control repeated.
 13 COFFEY, Q.C.
 14 Q. And then we look back here, Ms. Butler
 15 produced, completed it October 29th, '01, sent
 16 it out again and apparently had to repeat the
 17 test again, and completed that November 1st,
 18 2001. So, Doctor, are you telling the
 19 Commissioner that your understanding would be
 20 perhaps that the control slides would come
 21 back twice of every week, that sort of -
 22 DR. S. PARAI:
 23 A. That's what I would think. As I said before,
 24 that until the control is satisfactory, we
 25 would not report a test and this is not only

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

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

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1 page 17, we have a request form dated June
 2 11th, '02, it appears to be probably S845-02,
 3 it's from Dr. Baker, a request by him, and we
 4 look here at the bottom of the page, we'll see
 5 "M. Butler, date completed June 19th '02"
 6 It's for ER/PR, and then it's noted here "ER"
 7 and then it's "/PR" the PR is scribbled out,
 8 so it's just "ER control weak, but still okay.
 9 Checked by Dr. S. Parai." Now Doctor, why
 10 would you write that the control was weak, but
 11 still okay?
 12 DR. S. PARAI:
 13 A. It means that we could--I could still see the
 14 nucleus stain and as I mentioned before, there
 15 is intensity of nuclear stain. It's a brown
 16 black stain, could be weak, moderate and
 17 strong. So it means it was weak, but still it
 18 is readable, acceptable.
 19 COFFEY, Q.C.:
 20 Q. Doctor, for patient tissue that itself was
 21 actually weakly ER positive, could that be
 22 then problematic? If the patient S845-02,
 23 that patient, this is this particular one
 24 right here, if that particular patient's
 25 tumour tissue was in fact actually weakly ER

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1 positive and yet the control slide here which
 2 you expected strongly positive was only weakly
 3 positive, the control was weak -
 4 DR. S. PARAI:
 5 A. I did not see the patient -
 6 COFFEY, Q.C.:
 7 Q. I appreciate that, but if it was, if it in
 8 fact was weakly positive and yet the control
 9 is noted here to be weak, is there potential
 10 in that situation, if it's sent out, is there
 11 a potential for the test process not to reveal
 12 the presence of ER in the patient's tissue?
 13 Because you've told me earlier this morning
 14 that, in fact, if the controls were weak
 15 generally the test should be repeated.
 16 DR. S. PARAI:
 17 A. Well, it all depends how weak it is. As I
 18 say, it is the relativity; it is the degree of
 19 the stain and it is again, interpretation
 20 based on our judgment and experience. So I
 21 could--the first part what you are talking
 22 about, what would be the patient test result,
 23 it's hard for me to say, where I did not see
 24 that stain slide.
 25 COFFEY, Q.C.:

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1 Q. Okay. Now here in particular, Doctor, and we
 2 just--page 21, please? This is a request form
 3 dated June 19th '02. It's for ER/PR and
 4 "repeat and send to Grand Falls" is noted here
 5 in the comments section. This particular,
 6 June 19th, we go to the next page, two pages
 7 along, at page 23, it's noted to be repeat.
 8 It's dated--original request is June 21/02.
 9 Bottom right-hand side, repeat ER and it's
 10 reported June 25/02. Just going to go to page
 11 27, July 4th '02, request form. It's an ER/PR
 12 test, bottom of the page, "M. Butler, July
 13 11th '02, and repeated P. Welsh, July 16th
 14 '02." Page 29 of the exhibit, July 8th '02 is
 15 the date of the requisition form. Bottom of
 16 the page, Ms. Butler does the test, notes it
 17 completed July 12th, repeats it completed July
 18 23rd, and had to repeat, tissue washing off.
 19 So Doctor, in 2002, in the spring and
 20 summer, say June, July, August period, were
 21 there problems, do you recall, in particular,
 22 with ER/PR?
 23 DR. S. PARAI:
 24 A. I was not aware.
 25 COFFEY, Q.C.:

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1 Q. If we could go back to page 24 of this
 2 exhibit, something I wanted to ask you about
 3 on this. This is a form dated June 21/02.
 4 It's for surgical number S2289-02. The
 5 requesting pathologist is Dr. Dalton. If we
 6 look here on the side of the page, it says
 7 "slides and block returned. Controls checked,
 8 KG." We look down here, KG is Ken Green. The
 9 next page of the exhibit, June 27th '02 is the
 10 requisition form. It's from Western Memorial
 11 Hospital. The surgical number is 3998-02.
 12 Toward the bottom of the page, it's an ER/PR
 13 test. Note here on comments "ER/PR controls
 14 checked at Health Sciences Centre. Positive.
 15 P. Welsh."
 16 Now Doctor, were you aware, while you
 17 were site chief, whether at any time while you
 18 were site chief, that the ER and PR controls,
 19 ER and/or PR controls were being checked by
 20 the technologists and not by a pathologist?
 21 DR. S. PARAI:
 22 A. I was not aware.
 23 MR. SIMMONS:
 24 Q. Commissioner, I think that's stated as -
 25 COFFEY, Q.C.:

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1 Q. I apologize.
 2 MR. SIMMONS:
 3 Q. (Inaudible).
 4 COFFEY, Q.C.:
 5 Q. The way I--I didn't--were you aware of whether
 6 or not that ever happened?
 7 DR. S. PARAI:
 8 A. I was not aware.
 9 COFFEY, Q.C.:
 10 Q. Okay. I'll have to check the record as to
 11 whether or not some of the techs actually said
 12 they did or didn't, but you yourself are not
 13 aware?
 14 DR. S. PARAI:
 15 A. No.
 16 COFFEY, Q.C.:
 17 Q. If it happened, it wasn't supposed to happen?
 18 Is that -
 19 DR. S. PARAI:
 20 A. As I said, I was not aware of -
 21 COFFEY, Q.C.:
 22 Q. What was the procedure in relation to that,
 23 Doctor? In relation to whether or not the
 24 technologists, what they had to do before they
 25 sent, for example, the slides back to Grand

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

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1 Q. But in terms of whether or not there was ever
 2 any actual record, any policy to actually
 3 record who the pathologist was that had
 4 checked them, when the pathologist checked
 5 them, there was nothing actually in place
 6 formally to do that?
 7 DR. S. PARAI:
 8 A. Who was the pathologist, that was either site
 9 chief or on-call pathologist and in their
 10 absence, another, any pathologist, but there
 11 was no regular roster for that.
 12 COFFEY, Q.C.:
 13 Q. Was there any record for it, though, to be
 14 kept of who that was from time to time?
 15 DR. S. PARAI:
 16 A. It was understanding, as I explained last
 17 week, that either site chief, on call
 18 pathologist -- in his absence, on call
 19 pathologist for the day. If on call
 20 pathologist sometimes not available because
 21 they are busy with something else, another
 22 pathologist. So mainly site chief and on call
 23 pathologist, and in absence, a pathologist.
 24 COFFEY, Q.C.:
 25 Q. And if that pathologist did not write that

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1 down or the technologist did not write down
 2 who that pathologist was, there would be no
 3 record of it, who it was?
 4 DR. S. PARAI:
 5 A. At that time -- our practice has been since I
 6 was at the General Hospital even before, that
 7 the pathologist communicate verbally to the
 8 technologist to keep -- my understanding was
 9 they will keep just a check sign or some
 10 record.
 11 COFFEY, Q.C.:
 12 Q. But not who the pathologist was?
 13 DR. S. PARAI:
 14 A. They will mention the name of the pathologist.
 15 COFFEY, Q.C.:
 16 Q. In some cases when we look at the sheets,
 17 they're there, but quite a number of the
 18 sheets don't have any pathologist's name on
 19 them as checking the controls?
 20 DR. S. PARAI:
 21 A. I can't comment on that.
 22 COFFEY, Q.C.:
 23 Q. Doctor, for example, on the repeats that you
 24 saw, because you've indicated to the
 25 Commissioner that at times you'd be asked to

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1 check the controls and you would look at the
 2 requisition form and realize that this had
 3 been run before --
 4 DR. S. PARAI:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. And at times, though, if you looked at the
 8 sheet there's no record on the sheets of who
 9 the pathologist was that may have checked the
 10 controls before you did the first time around.
 11 DR. S. PARAI:
 12 A. No.
 13 COFFEY, Q.C.:
 14 Q. So as the site chief, you would have been
 15 aware that if it's being recorded, it's not
 16 being recorded necessarily on these sheets
 17 somewhere who the pathologist is?
 18 DR. S. PARAI:
 19 A. The second time repeat -- you mean, repeat
 20 second or third time?
 21 COFFEY, Q.C.:
 22 Q. Yes.
 23 DR. S. PARAI:
 24 A. Or the first time checked, is that your --
 25 COFFEY, Q.C.:

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1 Q. Yes, and whose name --
 2 DR. S. PARAI:
 3 A. I don't recall, but whether that repeat was
 4 done at the request of a pathologist or not,
 5 that -- are you saying they repeat second or
 6 third time at the request of pathologist or
 7 technologist, first time control is not
 8 working? That is not clear to me.
 9 COFFEY, Q.C.:
 10 Q. And who that pathologist was wouldn't be clear
 11 to you? Unless you went and actually asked
 12 around, you wouldn't know who it was, would
 13 you?
 14 DR. S. PARAI:
 15 A. That would be correct.
 16 COFFEY, Q.C.:
 17 Q. Doctor, if we could, please, the ER/PR matter
 18 that brings us here today -- because you
 19 finished up as site chief, March 31, 2005. Up
 20 to the point when you finished up as the site
 21 chief, had anyone ever brought to your
 22 attention the circumstances of any patient who
 23 had had an ER or PR test redone and the
 24 results were different?
 25 DR. S. PARAI:

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1 A. No, not that I recall.
 2 COFFEY, Q.C.:
 3 Q. Was there any mechanism in place to bring that
 4 -- to have people aware that if that was to
 5 happen, they should bring it to the site
 6 chief's attention?
 7 DR. S. PARAI:
 8 A. I would think so. I was not aware of any
 9 mechanism in place until there is a call from
 10 the clinician.
 11 COFFEY, Q.C.:
 12 Q. Doctor, when then did you first become aware
 13 of the matter that brings us here, the ER/PR
 14 matter, because it was -- who told you about
 15 it and what happened?
 16 DR. S. PARAI:
 17 A. This sort of talk came in July, 2005. There
 18 was no official information to me. One day
 19 Dr. Cook came to the General Hospital site,
 20 that would be late July, and called the
 21 available pathologist at the time and he
 22 informed that there is a new protocol for
 23 ER/PR reporting, and he instructed the
 24 guidelines of the ER/PR reporting, and I think
 25 that was the first time, end of July. In

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1 August of that year, August date he send out
 2 the memo, that we are not reporting any ER/PR
 3 at the site.
 4 COFFEY, Q.C.:
 5 Q. Doctor, had you heard about this informally
 6 before?
 7 DR. S. PARAI:
 8 A. Well, I heard rumour. From what I recall,
 9 that would have been summer, 2005.
 10 COFFEY, Q.C.:
 11 Q. Do you recall when, Doctor?
 12 DR. S. PARAI:
 13 A. Around July, end of July.
 14 COFFEY, Q.C.:
 15 Q. So the -- Dr. Cook came over at the end of
 16 July to the General Hospital site and had a
 17 meeting. You just described that. How long
 18 before that meeting as it that you first heard
 19 the --
 20 DR. S. PARAI:
 21 A. Around the same time, maybe a week earlier.
 22 COFFEY, Q.C.:
 23 Q. Just before that. Doctor, at the time -- were
 24 you given to understand at the time you met
 25 with Dr. Cook, given to understand anything

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1 about the time frame they were investigating,
 2 any particular year or years they were looking
 3 at?
 4 DR. S. PARAI:
 5 A. He was not talking about investigation in
 6 July. He was talking about the new guidelines
 7 of reporting ER/PR. That's the -- and what is
 8 our opinion. That's informal discussion, but
 9 they don't mention about the testing.
 10 COFFEY, Q.C.:
 11 Q. Doctor, the rumours then that you heard about
 12 a week before, what were people saying at that
 13 time?
 14 DR. S. PARAI:
 15 A. The rumour what I heard, one of the tests was
 16 done at the General Hospital tested negative
 17 ER, became positive in another centre in USA.
 18 COFFEY, Q.C.:
 19 Q. Another?
 20 DR. S. PARAI:
 21 A. Another lab.
 22 COFFEY, Q.C.:
 23 Q. Yes.
 24 DR. S. PARAI:
 25 A. In United States. That was the rumour I heard,

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1 that our negative result became positive in
 2 another lab.
 3 COFFEY, Q.C.:
 4 Q. Upon retesting in another lab?
 5 DR. S. PARAI:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. That's what you were first given to
 9 understand?
 10 DR. S. PARAI:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. And I appreciate, as you say, it's a rumour,
 14 just people talking amongst themselves is what
 15 you're telling the Commissioner.
 16 DR. S. PARAI:
 17 A. Right.
 18 COFFEY, Q.C.:
 19 Q. Doctor, now you certainly are aware that --
 20 did you ever become aware that that was not
 21 the case, that the retest had occurred in St.
 22 John's?
 23 DR. S. PARAI:
 24 A. I was not aware. I was not aware at that
 25 time.

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1 COFFEY, Q.C.:
 2 Q. When did you first become aware?
 3 DR. S. PARAI:
 4 A. This is the first time I heard that it was
 5 retested in St. John's as well.
 6 COFFEY, Q.C.:
 7 Q. Right now?
 8 DR. S. PARAI:
 9 A. Right now.
 10 COFFEY, Q.C.:
 11 Q. Doctor, you had been the site chief from 2000
 12 through 2005, the dates you've already told
 13 the Commissioner about. Did anyone ever come
 14 to you in 2005 or since that time, come to you
 15 and ask you about what you knew about what
 16 went on while you were site chief?
 17 DR. S. PARAI:
 18 A. No.
 19 COFFEY, Q.C.:
 20 Q. So not Dr. Cook, Dr. Carter, Dr. Ejeckam, Mr.
 21 Gulliver, Dr. Williams, none of those ever
 22 came to you and asked you?
 23 DR. S. PARAI:
 24 A. Except Dr. Ejeckam. Dr. Ejeckam, we are in
 25 close discussion since 2002 until onwards, but

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1 none of the other personnel you mentioned.
 2 COFFEY, Q.C.:
 3 Q. And after this whole retesting effort started
 4 in 2005, okay, and you became -- by August you
 5 were aware that they were stopping testing
 6 locally and they were going to do some
 7 retesting. You understood that in August,
 8 2005?
 9 DR. S. PARAI:
 10 A. Yes, and that was as per Dr. Cook's memo.
 11 COFFEY, Q.C.:
 12 Q. Doctor, did you ever discuss that -- this
 13 matter then after that point with Dr. Ejeckam?
 14 DR. S. PARAI:
 15 A. No, not that I recall.
 16 COFFEY, Q.C.:
 17 Q. So when you say you talked to Dr. Ejeckam,
 18 that would have been since -- when he first
 19 came on the staff in 2002, and 2003, and --
 20 well, yes, the 2003 memos and the aftermath of
 21 that, you discussed the IHC with him and
 22 ER/PR?
 23 DR. S. PARAI:
 24 A. Yes, until July, 2005, yes, we discussed, yes.
 25 COFFEY, Q.C.:

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1 Q. Had Dr. Ejeckam ever -- other than what you've
 2 told us already, did he express any other
 3 concerns about ER and PR?
 4 DR. S. PARAI:
 5 A. No, not anything other than his memo and
 6 discussion. The only thing I want to mention,
 7 the only thing he mentioned, there is inter-
 8 laboratory variation of the test, in terms
 9 there were variations, so false negative.
 10 This is the general discussion, but nothing
 11 specifically particular to our lab here.
 12 COFFEY, Q.C.:
 13 Q. Commissioner, if we could take the morning
 14 break right now, and I'll come back then and
 15 very briefly finish off.
 16 COMMISSIONER:
 17 Q. All right then, we'll take fifteen minutes.
 18 BREAK
 19 COMMISSIONER:
 20 Q. Mr. Coffey.
 21 COFFEY, Q.C.:
 22 Q. Thank you, Commissioner. Doctor, look please
 23 at Exhibit P-2408. Doctor, this is a
 24 document. It's Hamad Medical Corporation,
 25 Quality Control and Quality Assurance,

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1 Anatomic Pathology, 2004. Just look at the --
 2 it's Quality Assurance and Division of
 3 Anatomic Pathology, prepared by Dr. Ejeckam in
 4 1997, and then updated. Doctor -- and
 5 effective date, May, 2004. Doctor, had you
 6 ever seen this before?
 7 DR. S. PARAI:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. And can you tell us, please, how you came to
 11 see it and what, if anything, was done with
 12 it?
 13 DR. S. PARAI:
 14 A. Dr. Ejeckam provided me a copy of this -- not
 15 this version, previous version.
 16 COFFEY, Q.C.:
 17 Q. An earlier version of the same thing?
 18 DR. S. PARAI:
 19 A. Earlier version.
 20 COFFEY, Q.C.:
 21 Q. Okay, and why was that, why did he --
 22 DR. S. PARAI:
 23 A. We were developing a quality control assurance
 24 program for our corporate-wide division since
 25 -- started 2001, and we used the College of

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1 American Pathologist template or protocol, and
 2 it was too big program, and Dr. Ejeckam, when
 3 he came, he said I have a quality QA program,
 4 you can take a look and incorporate some of
 5 it. So that was the reason I asked him to
 6 give me one, and he did.
 7 COFFEY, Q.C.:
 8 Q. Just a moment, please, Commissioner. Exhibit
 9 P-2404, please. Now this document, Doctor,
 10 Quality Assurance, Division of Anatomic
 11 Pathology, Health Care Corporation of St.
 12 John's. Have you seen this before?
 13 DR. S. PARAI:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. And what is this, Doctor?
 17 DR. S. PARAI:
 18 A. This is one of the program -- this is a later
 19 version of the program we initiated 2001, as I
 20 mentioned.
 21 COFFEY, Q.C.:
 22 Q. In 2001, you indicated the program --
 23 DR. S. PARAI:
 24 A. Yes, but this is a later version.
 25 COFFEY, Q.C.:

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1 Q. Okay.
 2 DR. S. PARAI:
 3 A. Of the same program.
 4 COFFEY, Q.C.:
 5 Q. Do you recall - I stand to be corrected,
 6 Doctor, but I don't think it's dated. Do you
 7 recall what time frame this would have been in
 8 place, this particular one?
 9 DR. S. PARAI:
 10 A. I don't recall. We have been developing it
 11 since 2001, as I said, four or five revisions
 12 and additions was done. This is the later
 13 version incorporated with a lot of Dr.
 14 Ejeckam's reference, and I want to mention is
 15 about this QA program are the guidelines of
 16 the College of American Pathologists, both Dr.
 17 Ejeckam used CAP reference and we did so. So
 18 this is the compiled version of what Dr.
 19 Ejeckam used, as well as some of the CAP
 20 guidelines.
 21 COFFEY, Q.C.:
 22 Q. So this particular version of this grew out of
 23 incorporating CAP guidelines and Dr. Ejeckam -
 24 - the earlier version of Dr. Ejeckam's
 25 document, the one we just looked at?

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1 DR. S. PARAI:
 2 A. Yes, and which has been edited many times.
 3 COFFEY, Q.C.:
 4 Q. Sure.
 5 DR. S. PARAI:
 6 A. And I can give you a little bit of follow up
 7 on that.
 8 COFFEY, Q.C.:
 9 Q. If you would, please, Doctor.
 10 DR. S. PARAI:
 11 A. May I?
 12 COFFEY, Q.C.:
 13 Q. Yes, go right ahead, yes.
 14 DR. S. PARAI:
 15 A. So we are trying to develop -- when I came to
 16 the General Hospital, there is no manual of
 17 the QA program. There was no written QA
 18 program in place in --
 19 COFFEY, Q.C.:
 20 Q. No written? I didn't hear the word, Doctor.
 21 DR. S. PARAI:
 22 A. There was no QA program manual, so - but there
 23 is some fragmented manual. So we wanted to
 24 compile everything and develop a program for
 25 corporate-wide use.

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1 COFFEY, Q.C.:
 2 Q. Uh-hm.
 3 DR. S. PARAI:
 4 A. And we started 2001 initially CAP program, and
 5 when I got Dr. Ejeckam's program, we
 6 incorporated, and it is a compiled and concise
 7 program. So we developed for our corporation.
 8 So at the end of -- I believe when Dr. Carter
 9 became the chairman of the QA program, I
 10 handed over to her to finalize and implement.
 11 COFFEY, Q.C.:
 12 Q. I'm sorry, when you finished as --
 13 DR. S. PARAI:
 14 A. When it was in the final version in 2004.
 15 COFFEY, Q.C.:
 16 Q. Okay, yes.
 17 DR. S. PARAI:
 18 A. So it was not implemented by the leadership,
 19 laboratory leadership. So Dr. Carter became
 20 the chairman of Quality Assurance Program
 21 around the end of 2004.
 22 COFFEY, Q.C.:
 23 Q. Yes.
 24 DR. S. PARAI:
 25 A. So I handed over this copy to her for

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1 implementation and follow up.
 2 COFFEY, Q.C.:
 3 Q. And up to the time that you finished as site
 4 chief?
 5 DR. S. PARAI:
 6 A. Yes, at that time, as I mentioned, I was
 7 contemplating to move to other job.
 8 COFFEY, Q.C.:
 9 Q. Doctor, I believe as of October, 2005, you
 10 began to take some annual leave that you had
 11 and you were gone then at the end of 2005?
 12 DR. S. PARAI:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. The last month of 2005. Up to the time that
 16 you left, had that document been implemented
 17 or a version of it been implemented?
 18 DR. S. PARAI:
 19 A. I was not aware whether it was officially
 20 implemented or not.
 21 COFFEY, Q.C.:
 22 Q. Doctor, when you took over then as site chief
 23 in 2000 at the General Hospital, was there any
 24 similar document?
 25 DR. S. PARAI:

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1 A. No, there was no such document.
 2 COFFEY, Q.C.:
 3 Q. Now, Doctor, just before we could conclude
 4 then, if we could look, please, at Exhibit P-
 5 1936, page eight, please. Doctor, these are
 6 notes of Dr. Cook, I understand. Here he
 7 says, "meeting with pathologists, August 1,
 8 2005". There's a number of doctors listed;
 9 yourself, the other Dr. Parai, Dr. Fontaine,
 10 Dr. Pirezada, and Dr. Cook. Would this be the
 11 first meeting, do you think?
 12 DR. S. PARAI:
 13 A. A meeting of --
 14 COFFEY, Q.C.:
 15 Q. You had indicated there was a meeting, Dr.
 16 Cook came over at the end of July. Do you
 17 know if it was the end of July or -- I'm not
 18 saying it wasn't the end of July, it's just he
 19 has a note here, August 1, 2005.
 20 DR. S. PARAI:
 21 A. I can't recall.
 22 COFFEY, Q.C.:
 23 Q. You can't recall. Exhibit P-1994. Doctor,
 24 these are notes and text that Dr. Cook
 25 provided the Commission with, a meeting of

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1 pathologists, and there are a number of
 2 physicians listed. You are not one of them,
 3 okay, your name does not appear here, but it's
 4 August 5, 2005, and it does read, "This is a
 5 list of some concerns which have engaged --
 6 which have emerged, sorry, during
 7 conversations about the current problem.
 8 Included are some of our suggestions about how
 9 to approach this". Doctor, have you seen this
 10 document before?
 11 DR. S. PARAI:
 12 A. No, not that I recall.
 13 COFFEY, Q.C.:
 14 Q. When you met with Dr. Cook at the end of July,
 15 toward the end of July or early in August,
 16 whenever it was, and you've described that
 17 meeting --
 18 DR. S. PARAI:
 19 A. I believe it was end of July, if I recall.
 20 COFFEY, Q.C.:
 21 Q. Yes, and that was the talk - the purpose of
 22 the meeting was to tell you about what?
 23 DR. S. PARAI:
 24 A. How to report the ER/PR, a new protocol.
 25 That's what I recall, but there are a few

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1 other issues discussed, but I don't recall.
 2 COFFEY, Q.C.:
 3 Q. Now, Doctor --
 4 DR. S. PARAI:
 5 A. I don't recall there was minutes for that
 6 meeting. That was informal meeting sharing
 7 some information.
 8 COFFEY, Q.C.:
 9 Q. Now, Doctor, here there is a reference to on
 10 this page, Exhibit P-1994, talks about the
 11 current problem, an ongoing study, if you look
 12 down here, "We should ensure that no bias is
 13 introduced into the ongoing study. The
 14 purpose is to compare methods and the
 15 following are important features", and it goes
 16 on from there. Doctor, finally it concludes
 17 with, "We are not working in a culture where
 18 pathologists feel they are being -- we should
 19 not be working in a culture where pathologists
 20 feel they're being criticized for past
 21 performances. Avoid generalized statements,
 22 such as", and it lists three of them here.
 23 Doctor, do you recall any such discussions
 24 generally at the General Hospital site amongst
 25 pathologists?

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1 DR. S. PARAI:
 2 A. I don't recall.
 3 COFFEY, Q.C.:
 4 Q. What, if anything, did you understand about
 5 what was going on in relation to the
 6 investigation of the matter in 2005?
 7 DR. S. PARAI:
 8 A. I was not aware of any investigation, so far
 9 as I recall, and at that time--that's what I
 10 say.
 11 COFFEY, Q.C.:
 12 Q. You were not aware?
 13 DR. S. PARAI:
 14 A. I was not aware of an investigation going on.
 15 COFFEY, Q.C.:
 16 Q. Did you eventually learn?
 17 DR. S. PARAI:
 18 A. I learned when I was in Alberta, when I was in
 19 Alberta in 2006.
 20 COFFEY, Q.C.:
 21 Q. Okay, so it was then that you learned about
 22 the investigation?
 23 DR. S. PARAI:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. Into ER/PR and how extensive the problem might
 2 be and what had caused it?
 3 DR. S. PARAI:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. Doctor, have you ever seen a copy of Dr.
 7 Banerjee's reports? He did two reports.
 8 DR. S. PARAI:
 9 A. Recently, yes.
 10 COFFEY, Q.C.:
 11 Q. Exhibit P-1957. Now, Doctor, this is a copy,
 12 we have a couple of different copies of this,
 13 of Doctor--my mouse is gone dead. Oh, there
 14 it is. Okay. No, my -
 15 REGISTRAR:
 16 Q. Your mouse is not working again?
 17 COFFEY, Q.C.:
 18 Q. It's not working again, no. Wait now, there
 19 it is. This is a cover letter. It's
 20 generally not working here. It's very
 21 delayed.
 22 REGISTRAR:
 23 Q. What page did you want to go to?
 24 COFFEY, Q.C.:
 25 Q. If we could, please, page three? Doctor, this

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1 is the--just scroll down a bit, please,
 2 Registrar. This is Dr. Banerjee's October
 3 17th, 2005 report. So you've seen this
 4 recently, the October 17th one?
 5 DR. S. PARAI:
 6 A. Yes, I did.
 7 COFFEY, Q.C.:
 8 Q. And upon reviewing it, Doctor, can you tell
 9 us, please, whether or not you take issue with
 10 anything or any of the assertions by Dr.
 11 Banerjee?
 12 DR. S. PARAI:
 13 A. May I see the--what issue he list?
 14 COFFEY, Q.C.:
 15 Q. Oh yes, I'm sorry, go ahead. Perhaps, in
 16 fact, the mouse may work on yours. It just
 17 doesn't work on mine, Doctor.
 18 THE COMMISSIONER:
 19 Q. In front of you, there's a mouse. Just under
 20 your screen, there's a mouse which hopefully
 21 will allow you to control that, if you just
 22 try that yourself. Does it work for you?
 23 Yours is not working either?
 24 DR. S. PARAI:
 25 A. No.

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1 THE COMMISSIONER:
 2 Q. We have continuing problems with mice around
 3 here.
 4 COFFEY, Q.C.:
 5 Q. Okay, Doctor, perhaps we could just scroll
 6 down slowly through this for the Doctor and
 7 you watch the screen, Doctor, and see then--he
 8 says--go back up a bit, please, Registrar. It
 9 begins with background and then the incident
 10 problem case. You'll note that in the
 11 incident problem case, in the first paragraph
 12 there, Doctor, he says that "when retested in
 13 2005 on the Ventana Benchmark, the case of the
 14 patient with invasive lobular carcinoma, that
 15 patient was strongly positive for both
 16 receptor proteins." So the test was redone in
 17 St. John's, and that's Ms. Deane's case. It
 18 refers to four other patients having been
 19 retested. It goes on then to a review of
 20 cases and he notes that "all of the cases that
 21 had converted from negative to positive by
 22 switching platforms had one or more of the
 23 following characteristics: 1. poor fixation;
 24 2. negative internal controls; 3. absent
 25 internal controls. It is apparent that too

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1 much reliance is being placed on external
 2 positive controls with no attention paid to
 3 internal controls." So did you take any issue
 4 with any of that, Doctor?
 5 DR. S. PARAI:
 6 A. Well, I have some issue, review of the cases
 7 starting from there. Now what he mentioned,
 8 he's reviewed some of the cases from 2002.
 9 COFFEY, Q.C.:
 10 Q. Yes.
 11 DR. S. PARAI:
 12 A. He did not mention how many cases, and did he
 13 review any cases before 2002? Did he review
 14 1997 cases or 2005 cases? So I don't want to--
 15 I don't know what you are saying on how many
 16 cases, so there is a number and the year
 17 concerned, and secondly, the poor fixation,
 18 what poor fixation? I did not review these
 19 cases with him, so I could not say what he was
 20 talking about poor fixation. But my question
 21 here is that if there is poor fixation in our
 22 lab, there are eight laboratories in the
 23 province and the retesting done since 1997 to
 24 2005, how come all of them, they found poor
 25 fixation? How come all the lab can make the

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1 similar error? So some of the issue is still
 2 not clear to me, and when they retested in
 3 Mount Sinai from '97 to 2005, what happened to
 4 test patient's slide? Did they find any
 5 fixation problem there? If there, how did
 6 they interpret it? So these are the few
 7 things not clear to me.
 8 COFFEY, Q.C.:
 9 Q. Doctor, you would--you do--or would you agree,
 10 I'll ask you, put it to you this way, that
 11 it's quite possible to have, in any ten
 12 patients, eight of them, there's no problem
 13 with fixation and two there might be?
 14 DR. S. PARAI:
 15 A. I can't say, until I review the slide myself.
 16 COFFEY, Q.C.:
 17 Q. No, I appreciate that, but that's--it would be
 18 quite possible to happen, couldn't it?
 19 DR. S. PARAI:
 20 A. I can't say.
 21 COFFEY, Q.C.:
 22 Q. Well, Doctor, for example, if nine patients
 23 out of ten, if nine of them are properly--
 24 tissues dealt with appropriately, but one of
 25 them, it isn't -

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1 DR. S. PARAI:
 2 A. It is possible.
 3 COFFEY, Q.C.:
 4 Q. It's possible, isn't it?
 5 DR. S. PARAI:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. So the idea that there might be poor fixation
 9 in particular cases would not be surprising to
 10 you?
 11 DR. S. PARAI:
 12 A. No.
 13 COFFEY, Q.C.:
 14 Q. Did you, at the time you were site chief, have
 15 any understanding that there was generally a
 16 problem or potential problem with fixation?
 17 DR. S. PARAI:
 18 A. No, I was not.
 19 COFFEY, Q.C.:
 20 Q. How often were problems related to fixation
 21 brought to your attention?
 22 DR. S. PARAI:
 23 A. Nobody brought to my attention, but I found
 24 that sometimes there are fixation problem.
 25 This is not only in breast particularly, other

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

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

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

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1 A. I was not aware.
 2 COFFEY, Q.C.:
 3 Q. So did you take part--you would have known
 4 after July or in the beginning of August,
 5 certainly August 8th, that there was a retest
 6 going on?
 7 DR. S. PARAI:
 8 A. Not in August. I don't recall I was aware the
 9 retest is going on in July, no.
 10 COFFEY, Q.C.:
 11 Q. No, but in August 2005, did you become aware
 12 that they were retesting?
 13 DR. S. PARAI:
 14 A. No, I was busy for my move, so I don't recall.
 15 I was aware while I was in Alberta.
 16 COFFEY, Q.C.:
 17 Q. So before you left for Alberta, you weren't
 18 aware that they were doing this massive
 19 retesting?
 20 DR. S. PARAI:
 21 A. I was not.
 22 COFFEY, Q.C.:
 23 Q. Doctor, yourself, did you have any particular
 24 training in relation to IHC?
 25 DR. S. PARAI:

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1 A. May I--do I understand your question that
 2 training in particular IHC area -
 3 COFFEY, Q.C.:
 4 Q. Yes.
 5 DR. S. PARAI:
 6 A. - in the residency or post residency
 7 fellowship or any of that nature?
 8 COFFEY, Q.C.:
 9 Q. Yes.
 10 DR. S. PARAI:
 11 A. No, I did not. When I was doing residency,
 12 IHC was not there. It was in early '80s, 1980
 13 to '84.
 14 COFFEY, Q.C.:
 15 Q. And since that time, I take it, like ongoing
 16 training, have you attended any seminars about
 17 IHC in particular?
 18 DR. S. PARAI:
 19 A. That I did. I went to convention, that was
 20 the continued medical education, but not a
 21 formal training, so that continuing medical
 22 education helped me to educate how to
 23 interpret IHC. I attended every year to
 24 continue medical education, either Canadian
 25 Association of Pathologists convention, and

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1 Clinical--American Society of Clinical
 2 Pathologists meeting, and also various
 3 Canadian Academy of Pathologists meeting, many
 4 national and international convention.
 5 COFFEY, Q.C.:
 6 Q. Doctor, did you ever attend any where you
 7 taught to interpret ER/PR IHC?
 8 DR. S. PARAI:
 9 A. It was also there. It was also in a
 10 convention, there are so many seminars, so
 11 many post start (phonetic) those are the
 12 formal talk given by some expert in IHC on
 13 ER/PR, yes.
 14 COFFEY, Q.C.:
 15 Q. When was that?
 16 DR. S. PARAI:
 17 A. Well, it was ASCP meeting in Atlanta.
 18 COFFEY, Q.C.:
 19 Q. I'm sorry, when?
 20 DR. S. PARAI:
 21 A. ASCP meeting in Atlanta and in New Orleans,
 22 that would be--it is--would be either 2000,
 23 2001. Sorry, 2000 and 2001, both.
 24 COFFEY, Q.C.:
 25 Q. At that time, did they talk about internal

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

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1 Anatomical Pathology and Doctor blank has
 2 attended the pathology rounds for a total of,
 3 in this particular instance, 22 credit hours,
 4 CAP performance improvement program, 20 hours
 5 in ASCP, check sample review, four hours. So
 6 I take it, Doctor, that you would complete
 7 these sorts of forms for physicians working at
 8 the General?
 9 DR. S. PARAI:
 10 A. Yes, this is the -
 11 COFFEY, Q.C.:
 12 Q. I'm sorry, go ahead, Doctor, you were about to
 13 say?
 14 DR. S. PARAI:
 15 A. As I said, since 2001, I was trying to
 16 implement a QA program at the General Hospital
 17 particularly, but it was even for the
 18 corporate wide. Dr. Cook was involved, Dr.
 19 Haegert, Dr. Robb, Mr. Terry Gulliver, Barry
 20 Dyer, but QA program has in lab two
 21 components, technical component and clinical
 22 component. As a pathologist and site chief,
 23 my role was to implement the clinical
 24 component. So we started rounds, these are
 25 the QA rounds and while it is self explained

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1 what is the sort of program we are doing at
 2 the General Hospital to improve for the
 3 pathologist QA.
 4 COFFEY, Q.C.:
 5 Q. They're the questions I have, Commissioner.
 6 Thank you. Thank you, Doctor.
 7 DR. S. PARAI:
 8 A. Thanks.
 9 THE COMMISSIONER:
 10 Q. Mr. Pritchard?
 11 MR. PRITCHARD:
 12 Q. Thank you, Commissioner. I don't have any
 13 questions for this witness. Thank you for
 14 your evidence, Doctor.
 15 THE COMMISSIONER:
 16 Q. Mr. Simmons?
 17 DR. SUSHIL PARAI, EXAMINATION BY MR. DANIEL SIMMONS
 18 MR. SIMMONS:
 19 Q. Thank you, Commissioner. Good morning, Dr.
 20 Parai. I'm Dan Simmons. I'm here for Eastern
 21 Health, and I have a couple things I want to
 22 follow up on with you. In 2003, we know that
 23 Dr. Ejeckam had done a memo in June, which I
 24 gather that you saw at the time, and which you
 25 spoke to him about, and that was the memo

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1 where he spoke of some changes that he wanted
 2 made in the immunohistochemistry service. You
 3 recall that?
 4 DR. S. PARAI:
 5 A. Yes.
 6 MR. SIMMONS:
 7 Q. And after that, that was June of 2003, were
 8 you aware that by the end of 2004, there was a
 9 physical move made to move to the
 10 immunohistochemistry portion of the pathology
 11 laboratory into a separate room in the lab or
 12 did that happen after you left?
 13 DR. S. PARAI:
 14 A. So far I recall, it happened later on. The
 15 present immunohistochemistry lab -
 16 MR. SIMMONS:
 17 Q. Yes.
 18 DR. S. PARAI:
 19 A. - now look at it, happened later on.
 20 MR. SIMMONS:
 21 Q. Okay. Now, I apologize if I'm unclear of
 22 this. Did you leave for Alberta in October of
 23 2004 or 2005?
 24 DR. S. PARAI:
 25 A. '05.

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1 MR. SIMMONS:
 2 Q. 2005. So were you aware, before you left in
 3 October of 2005, that that move had taken
 4 place and that the laboratory had moved?
 5 DR. S. PARAI:
 6 A. I don't recall it took place at that time.
 7 MR. SIMMONS:
 8 Q. You don't recall?
 9 DR. S. PARAI:
 10 A. No.
 11 MR. SIMMONS:
 12 Q. Okay. So you weren't aware of that?
 13 DR. S. PARAI:
 14 A. No.
 15 MR. SIMMONS:
 16 Q. And regarding the duties of the three
 17 technologists who did the immunohistochemistry
 18 work, as site chief, were you very familiar
 19 with yourself about how those duties were
 20 broken up, what they did at different times
 21 and the things were that they did, other than
 22 doing the IHC testing?
 23 DR. S. PARAI:
 24 A. Well, this was the responsibility of Mr. Barry
 25 Dyer, divisional chief, so I did not pay too

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

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1 DR. S. PARAI:
 2 A. Yes.
 3 MR. SIMMONS:
 4 Q. Yes, okay, and was anything--were you aware of
 5 any discussion or any communication from
 6 anybody about whether it was expected that
 7 that change would have any effect on the
 8 quality of the staining?
 9 DR. S. PARAI:
 10 A. There was some discussion with Dr. Ejeckam.
 11 MR. SIMMONS:
 12 Q. Yes.
 13 DR. S. PARAI:
 14 A. But since he was in charge, he was doing all
 15 this investigation, all this information,
 16 everything in place.
 17 MR. SIMMONS:
 18 Q. So you left it in Dr. Ejeckam's hands then to
 19 deal with the issues such as the work of the
 20 technologists and how well dedicated they were
 21 to IHC, instead of other things, and you left
 22 it to him as well to deal with any changes
 23 that would result from moving from the DAKO to
 24 the Ventana, did you?
 25 DR. S. PARAI:

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

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

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1 you weren't a member of this committee, but
 2 you would have been aware that this committee
 3 existed and the type of work that it was
 4 doing, were you?
 5 DR. S. PARAI:
 6 A. Yes.
 7 MR. SIMMONS:
 8 Q. Okay, and on the previous--Dr. Ejeckam was the
 9 chairman of it, and I believe he was at the
 10 meeting we just looked at the minutes from,
 11 which was the following day on September 24th,
 12 and if we look at this, it says, in 2.1 "Dr.
 13 Ejeckam stated that the technical problem with
 14 staining for ER/PR stains has been solved,"
 15 and I just wonder if that would help you
 16 recall what might have been the discussion on
 17 the following day when there is discussion
 18 about the staining, and it might help now if
 19 we go back to 1576 again, just to look at that
 20 in it, and have a look at what the discussion
 21 was there and I wonder if that would help you
 22 recall what type of staining or issues might
 23 have been under discussion then?
 24 DR. S. PARAI:
 25 A. This was not--this was in general stain. All

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1 the stain, routine H & E, and immuno, all the
 2 stains, so far I recall.
 3 MR. SIMMONS:
 4 Q. Not ER/PR staining in particular?
 5 DR. S. PARAI:
 6 A. I don't think it was raised at that meeting.
 7 I don't recall.
 8 MR. SIMMONS:
 9 Q. And if you look at that note there, on
 10 September 24th, it doesn't appear that there's
 11 any particular discussion of IHC staining
 12 there either, correct?
 13 DR. S. PARAI:
 14 A. That is correct.
 15 MR. SIMMONS:
 16 Q. Just some questions--oh yes, P-1913 please?
 17 These are minutes from March 31st, 2004,
 18 attended by Dr. Cook, Dr. Robb and yourself,
 19 with Mr. Dyer absent. And you were shown a
 20 portion here under 4.2 which is under "New
 21 Business". It says "New technology, the
 22 immunoperoxidase stainer appears to be working
 23 generally well; however, there continues to be
 24 some problems with estrogen and progesterone
 25 receptors." Would you know whether this was

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1 around the time of the transition from the
 2 DAKO technology to the Ventana technology?
 3 DR. S. PARAI:
 4 A. I don't recall exact timing, but--could you go
 5 up and see the date of this?
 6 MR. SIMMONS:
 7 Q. 31st of March, 2004.
 8 DR. S. PARAI:
 9 A. It's around that time, the transition period,
 10 yes.
 11 MR. SIMMONS:
 12 Q. Now we understand that this was around the end
 13 of the transition period from the DAKO
 14 technology to the Ventana technology and the
 15 minutes says "the immunoperoxidase stainer
 16 appears to be working generally well", so that
 17 would seem to be a reference to the new
 18 Ventana stainer, and then it goes on to say
 19 "there continues to be some problems with the
 20 ER and PR receptors." Now are you able to
 21 tell us whether those problems relate to the
 22 reporting of ER/PR staining on patient tests,
 23 or whether that has anything to do with the
 24 validation process for the transition from
 25 staining on one technology to staining on

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1 another, or do you know?
 2 DR. S. PARAI:
 3 A. I cannot recall.
 4 MR. SIMMONS:
 5 Q. Okay. You were asked a number of questions
 6 about repeated tests and shown a number of
 7 requisitions from 2001 and 2002. In the
 8 testing in general, not even restricted to
 9 ER/PR or immunohistochemistry, but for special
 10 stains or even H&Es, are there times when
 11 there are repeated tests ordered for various
 12 reasons?
 13 DR. S. PARAI:
 14 A. Yes.
 15 MR. SIMMONS:
 16 Q. And would those be ordered because for one
 17 reason or another the pathologist is not happy
 18 with the first slide that they get and they
 19 want to have it rerun so they can get a second
 20 slide to look at?
 21 DR. S. PARAI:
 22 A. Yes.
 23 MR. SIMMONS:
 24 Q. In your experience, is that something that
 25 would be unique to the General Hospital or St.

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1 John's or would you know whether that is the
 2 type of thing that occurs more generally in
 3 other labs, with other pathologists?
 4 DR. S. PARAI:
 5 A. Well I can speak only for our lab, it is not
 6 unusual to order repeat stain.
 7 MR. SIMMONS:
 8 Q. Right, and in your lab have you had
 9 pathologists who have come--since you've been
 10 here, who've come from working in other
 11 institutions and other countries and other
 12 places and have come into the General Hospital
 13 and worked with you?
 14 DR. S. PARAI:
 15 A. I haven't discussed this thing, it is
 16 possible.
 17 MR. SIMMONS:
 18 Q. Are you aware if anyone who came from other
 19 places ever commented or said this is unusual
 20 to have repeats, we don't see them elsewhere
 21 or anything to that effect?
 22 DR. S. PARAI:
 23 A. No, it is not unusual.
 24 MR. SIMMONS:
 25 Q. Okay. And when you do get a test slide from a

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1 patient and you have a control slide to look
 2 at, I think you've told us fairly clearly that
 3 if you're not satisfied with the control, you
 4 don't report the patient slide, do you?
 5 DR. S. PARAI:
 6 A. That's correct.
 7 MR. SIMMONS:
 8 Q. And if the test is repeated and the control
 9 was still unsatisfactory, what would you do?
 10 DR. S. PARAI:
 11 A. You repeat again.
 12 MR. SIMMONS:
 13 Q. And do you recall having any occasions
 14 yourself with ER/PR testing when you actually
 15 had to order a repeat of the ER/PR test?
 16 DR. S. PARAI:
 17 A. I don't recall.
 18 MR. SIMMONS:
 19 Q. Okay. With this type of testing, generally,
 20 when you get one that you have to order a
 21 repeat on because there's been a, something
 22 you didn't like about the control slide, do
 23 you generally regard that as being a problem
 24 that would require some further investigation
 25 or an indicator or something wrong in the

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1 process or how would you regard a case like
 2 that?
 3 DR. S. PARAI:
 4 A. We repeat the stain and if a control is good,
 5 working well, then if that's all right, we'll
 6 just continue. It is not unusual to have this
 7 kind of a repeat.
 8 MR. SIMMONS:
 9 Q. Okay, so is that something that you would
 10 regard as somewhat inherent in the process, in
 11 the type of testing which is being done, that
 12 there will be occasions when a control will
 13 not be satisfactory and it will have to be
 14 repeated?
 15 DR. S. PARAI:
 16 A. Well I would say we would repeat, but I can't
 17 say if it is inherent or not, but it happens.
 18 MR. SIMMONS:
 19 Q. Good, thank you very much, Dr. Parai, that's
 20 all I have for you.
 21 THE COMMISSIONER:
 22 Q. Mr. Pritchett?
 23 MR. PRITCHETT:
 24 MR. SIMMONS:
 25 Q. No questions, Commissioners, thank you.

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1 THE COMMISSIONER:
 2 Q. Ms. Newbury?
 3 DR. SUSHIL PARAI, EXAMINATION BY MS. JENNIFER NEWBURY
 4 MS. NEWBURY:
 5 Q. Good morning, Dr. Parai, my name is Jennifer
 6 Newbury and I represent the Canadian Cancer
 7 Society, Newfoundland and Labrador division.
 8 And I have a couple of topics to talk to you
 9 about this morning. First of all, I wanted to
 10 know if you felt that external consultations
 11 that might be requested pertaining to
 12 laboratory test results, pathology test
 13 results, would be considered a component of
 14 quality assurance or quality control?
 15 DR. S. PARAI:
 16 A. Yes, it is and we have used this external
 17 consultation a lot for our lab.
 18 MS. NEWBURY:
 19 Q. And is it considered to be a quality assurance
 20 specific to the patient whose results are
 21 being reviewed by the external consultant, or
 22 is it more of a systemic type of a quality
 23 assurance program?
 24 DR. S. PARAI:
 25 A. You mean the particular result or as a group

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

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

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1 all of those external consultations just to
 2 look at the data on a comprehensive basis?
 3 DR. S. PARAI:
 4 A. Yes.
 5 MS. NEWBURY:
 6 Q. And how would that be done?
 7 DR. S. PARAI:
 8 A. We can do that, go to the computer and in this
 9 context I did review while I was at the Grace
 10 Hospital, 10 years, external consultation
 11 report and our consultation report and we can
 12 compare the result of, between ours and the
 13 external consultation. I found it was very
 14 satisfactory, error rate was less than .05
 15 percent. It's not error, this comprehensive -
 16 MS. NEWBURY:
 17 Q. Sure, lack of concordance, I guess.
 18 DR. S. PARAI:
 19 A. Yes.
 20 MS. NEWBURY:
 21 Q. And whether or not it's as a result of an
 22 error from one of the other--you'd have to
 23 analyze that further.
 24 DR. S. PARAI:
 25 A. Yes.

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

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1 do that?

2 DR. S. PARAI:

3 A. Yes.

4 MS. NEWBURY:

5 Q. And do you know if that has ever been done

6 with regard to ER/PR testing over that

7 timeframe?

8 DR. S. PARAI:

9 A. Well at the General Hospital we did not do

10 that many ER/PR, only few cases per year. I

11 don't recall any study has been done.

12 MS. NEWBURY:

13 Q. Okay. You were shown a couple of sets of

14 minutes and I'm going to bring them up quickly

15 for you to refresh your memory. One is at

16 Exhibit P-1876 please? And here, I think it's

17 on the first page, so this is the minutes for

18 April 25th, 2001, anatomical pathology site

19 chiefs and divisional managers' meeting, and

20 there's a note there on page one about, under

21 quality control of immunoperoxidase staining,

22 "Generally the immunos appear to be very good,

23 there appears to be some problems with the

24 estrogen and progesterone receptors." So

25 that's one of the sets of minutes that I want

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1 to refer you to. And the second is Exhibit P-

2 1913 please? And these are the minutes of the

3 Division of Anatomical Pathological Site

4 Chiefs and Divisional Managers, and this is

5 three years later, almost, March 31st, 2004

6 and you've been referred to this a couple of

7 times. And on page 2, under the heading "New

8 Technology", there's a note that "the

9 immunoperoxidase stainer appears to be working

10 generally well; however, there continues to be

11 some problems with estrogen and progesterone

12 receptors." And my question--and I believe

13 that you couldn't recall specifically what

14 those problems were referring to, in either

15 sets of minutes, and it's not described in any

16 detail in the minutes themselves and you can't

17 recall today specifically what the problems

18 were, is that correct?

19 DR. S. PARAI:

20 A. Well in the first minute referred, there is

21 some--well as I mentioned before, there was a

22 study going on for the assessment of the

23 immunostain as a whole, not only ER/PR, other

24 stain as well, so we find it, after the study,

25 we found that the immunostain was generally

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1 good, very good, I think that was the overall,

2 this study came from the ten pathologists,

3 maybe ten or eleven pathologists, not only one

4 single person and their opinion was

5 satisfactory or very good and although also

6 mention that there are some problem with ER/PR

7 and so far I recall, it was positive control

8 was weak, sometime weak, sometime moderate and

9 then after a follow up for another couple of

10 months, in June, I found that that was

11 corrected, it was working satisfactory levels

12 and this, in 2002, diminish what you are

13 showing now.

14 MS. NEWBURY:

15 Q. Uh-hm.

16 DR. S. PARAI:

17 A. I don't recall what particular issue that was

18 at the time, what transpired, the transition

19 was going on from DAKO to Ventana system and

20 Dr. Ejeckam was in charge of the

21 immunohistochemistry lab, we were quite happy

22 that he was in control and this one I recall

23 one particular issue.

24 MS. NEWBURY:

25 Q. Okay, and back to the earlier meeting, April

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1 25th, 2001, I must have missed your

2 description of it when you were describing

3 that, I think on Friday. I had understood

4 that you couldn't recall specifically what the

5 problem was, but you think that it had to do

6 with the positive control was showing to be

7 weak?

8 DR. S. PARAI:

9 A. Occasionally, yes. It was a matter of

10 interpretation, if I say positive, another

11 pathologist would say, no, it is all right, it

12 is nuclear still staining and the

13 characteristic nuclear stain is important,

14 it's not only a few browns, it is a diffuse

15 granular brown black grease or greased stain

16 describe. On the other hand, the benign, it's

17 a different, so we knew, all the pathologists

18 knew what would be the positive control and

19 positive stain for the patient.

20 MS. NEWBURY:

21 Q. But the concern, I guess from a more technical

22 standpoint at the time was that some of the

23 positive controls were showing to be weak,

24 they weren't strong positive controls?

25 DR. S. PARAI:

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1 A. I don't recall, I think that--yeah, that was
 2 something I think of.
 3 MS. NEWBURY:
 4 Q. There isn't a detailed record here in these
 5 minutes of meeting, would there be any record
 6 anywhere that you could access that would
 7 describe in detail what specifically the
 8 problems were, how frequent the problems were
 9 and who was involved in rectifying the
 10 problems and how exactly they were resolved,
 11 assuming that they were.
 12 DR. S. PARAI:
 13 A. I'm not aware of any such record keeping.
 14 MS. NEWBURY:
 15 Q. And so there's no system in place to record
 16 these types of issues?
 17 DR. S. PARAI:
 18 A. Yes, I think so.
 19 MS. NEWBURY:
 20 Q. You don't think there is or you do?
 21 DR. S. PARAI:
 22 A. Well I don't think so.
 23 MS. NEWBURY:
 24 Q. Okay, and from a quality assurance or quality
 25 control perspective, would it be beneficial or

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

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

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

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1 and I take it by that time you would have been
 2 aware that well previously we didn't have the
 3 system in place.
 4 DR. S. PARAI:
 5 A. Yes.
 6 MS. NEWBURY:
 7 Q. And is there any reason why the pathologists
 8 would not have made such a suggestion before,
 9 in terms of keeping a log book there? Because
 10 there is, obviously, an interaction between
 11 the pathologists and the technologists, there
 12 is a point in time where the pathologist says
 13 I'm seeing some problems here, so we have a
 14 role to play here in terms of keeping records
 15 of what's going on. Is there any reason why
 16 that wasn't done earlier?
 17 DR. S. PARAI:
 18 A. Well I think we had always communication with
 19 the technologists, although they are not
 20 reportable to the pathologists, we work side
 21 by side in a friendly atmosphere, good
 22 atmosphere and always communicated verbally.
 23 A verbal communication is more important than
 24 written documents and sometimes written
 25 document may be--it is also important, written

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1 document, we have all this communication that
 2 look, this is the area and they always tried
 3 to address the issue, but some of the
 4 discussion came, maybe this is the time we
 5 keep a record, it came later on, yes.
 6 MS. NEWBURY:
 7 Q. So you were relying primarily then on the
 8 verbal communication between the pathologist
 9 and the technologists?
 10 DR. S. PARAI:
 11 A. Yes, also in the meeting, the division manager
 12 would attend our site chiefs' meeting, all the
 13 issues will be discussed there and he would be
 14 the person to address those issues.
 15 MS. NEWBURY:
 16 Q. You were discussing earlier this morning the
 17 weekly surgical pathology rounds and lymphoma
 18 rounds and the fact that there was some issues
 19 raised regarding stains at around, I think you
 20 said most of the issues were raised in 2003
 21 and that, I believe eventually led to Dr.
 22 Ejeckam preparing three memos that you saw
 23 earlier to address some of those issues.
 24 There was a direct correlation, I believe, to
 25 the concerns that were being noted in the

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1 surgical pathology rounds and Dr. Ejeckam's
 2 memos.
 3 DR. S. PARAI:
 4 A. Yes.
 5 MS. NEWBURY:
 6 Q. And during the surgical pathology rounds and
 7 prior to Dr. Ejeckam's direct involvement with
 8 the memos, did any of the pathologists raise
 9 any concern or issues about whether or not the
 10 stains had been properly optimized or
 11 validated?
 12 DR. S. PARAI:
 13 A. I was not aware.
 14 MS. NEWBURY:
 15 Q. Okay, and the concerns or I guess the issues
 16 raised about the stains during the surgical
 17 pathology rounds, had those types of issues
 18 been raised before 2003?
 19 DR. S. PARAI:
 20 A. Indeed in other stain as well.
 21 MS. NEWBURY:
 22 Q. In other stains, so IHC stains generally,
 23 including ER/PR or an even broader category of
 24 stains?
 25 DR. S. PARAI:

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1 A. It's a broader category, issue raised in the
 2 lymphoma marker initially many times, but
 3 that's the time only ER/PR issue raised in
 4 2003.
 5 MS. NEWBURY:
 6 Q. Okay, so prior to 2003, were there ever any
 7 stains specifically relating to ER/PR, any
 8 stain issues raised specifically for ER/PR
 9 testing?
 10 DR. S. PARAI:
 11 A. No, not that I recall.
 12 MS. NEWBURY:
 13 Q. Okay, and can you explain or do you have any
 14 understanding why such issues may not have
 15 been raised before 2003? Do you know, for
 16 example, that there was any reason to pinpoint
 17 the cause of the problem and why these issues
 18 first became apparent in 2003?
 19 DR. S. PARAI:
 20 A. I can't answer why it was not raised. Maybe
 21 nobody noticed and perhaps it was working
 22 well.
 23 MS. NEWBURY:
 24 Q. Okay, so you don't know whether they were
 25 indeed working well before 2003 and there was

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1 nothing to notice -
 2 DR. S. PARAI:
 3 A. Well I would say it was working well.
 4 MS. NEWBURY:
 5 Q. You think it was working well?
 6 DR. S. PARAI:
 7 A. Yes.
 8 MS. NEWBURY:
 9 Q. Okay, so you think that the problem first
 10 started in 2003, but you don't know why it
 11 started in 2003?
 12 DR. S. PARAI:
 13 A. Yes.
 14 MS. NEWBURY:
 15 Q. And do you know if that's ever been
 16 investigated by anyone or were there any steps
 17 to identify what exactly was the event in
 18 2003, was there a change of technique or
 19 change of personnel, you know, why exactly has
 20 this all of a sudden started in 2003?
 21 DR. S. PARAI:
 22 A. Well there was no investigation, Dr. Ejeckam
 23 closely worked at the lab, there was no
 24 significant change in the lab personnel, so we
 25 could not explain why, but it happened, as I

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

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

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1 of the significance of internal controls, did
 2 you have any concerns or reservations about
 3 your own previous diagnosis, your previous
 4 pathology reports, particularly in the year
 5 2003?
 6 DR. S. PARAI:
 7 A. I was not concerned because there was no issue
 8 with, I did not get any information or any
 9 complaint from any clinician or, on any
 10 colleagues that -
 11 MS. NEWBURY:
 12 Q. So until you had some concern raised by an
 13 oncologist about questioning the results, you
 14 assumed that everything is okay?
 15 DR. S. PARAI:
 16 A. Yes.
 17 MS. NEWBURY:
 18 Q. And how is it that you understand an
 19 oncologist can determine whether or not the
 20 results of the ER/PR testing are likely to be
 21 appropriate for the particular patient?
 22 DR. S. PARAI:
 23 A. Year, you are talking about 2001, 2003 or
 24 1999?
 25 MS. NEWBURY:

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1 Q. At the time, focusing on the 2003 year, the
 2 year that you find out that internal controls
 3 are significant and you have not previously
 4 understood that and you indicated that you
 5 didn't have any reservations about your prior
 6 pathology reports, even though Dr. Ejeckam had
 7 raised some concerns about the reliability of
 8 some of the immunostains, my question and your
 9 answer was that you weren't concerned because
 10 no clinician had raised any issues with you,
 11 but my question for you now is how is it that
 12 an oncologist can confirm your results? Is
 13 there anything from clinical observations or
 14 anything else about the patient's medical
 15 history that you're aware of that could
 16 confirm at that time whether or not the
 17 results from your ER/PR test report are likely
 18 to be accurate?
 19 DR. S. PARAI:
 20 A. Well they are twofold, one is that they we
 21 check the control and if the positive control
 22 was working well and they are reported, we
 23 would be very good help for them. The other
 24 thing is the type of tumour, some of the
 25 tumour, an issue with different result, what

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1 was our understanding, would raise some
 2 concern that some of the low grade tumour are
 3 not positive, they would raise well why
 4 they're not positive for ER, so -
 5 MS. NEWBURY:
 6 Q. So in terms of the clinical observations of an
 7 oncologist as far as you're aware if they know
 8 that this is a type of cancer that is likely
 9 not to be ER negative, then they might
 10 question your result?
 11 DR. S. PARAI:
 12 A. Yes.
 13 MS. NEWBURY:
 14 Q. And did that ever happen?
 15 DR. S. PARAI:
 16 A. Not to my knowledge.
 17 MS. NEWBURY:
 18 Q. And is there anything else about the physical
 19 features of the tumour that in your view can
 20 help to confirm or contradict the ER/PR
 21 results? Was there anything about the size or
 22 any other description about the tumour that
 23 might help to confirm -
 24 DR. S. PARAI:
 25 A. If the tumour has extensive necrosis, that can

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1 interfere with the result. If the tumour has
 2 significant fixation problem, poorly fixed,
 3 that will raise some concern.
 4 MS. NEWBURY:
 5 Q. Right. But in terms of whether or not an
 6 oncologist can look at the clinical picture of
 7 a patient and say well, I have doubts about
 8 this ER/PR test result because of a), b) or
 9 c), a) you've identified to be the type of
 10 tumour, but the poor fixation, is that
 11 something that an oncologist would be looking
 12 for?
 13 DR. S. PARAI:
 14 A. No, they would not, but in their report will
 15 mention if there is a significant fixation
 16 problem, we always make a comment that due to
 17 poor fixation, a result cannot be--we make
 18 some comments, sometime in the microscope a
 19 description, but not that often.
 20 MS. NEWBURY:
 21 Q. Okay. And what would the oncologist do if you
 22 did make such a note on your report?
 23 DR. S. PARAI:
 24 A. I can't answer that.
 25 MS. NEWBURY:

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1 Q. Okay, do you have any experience of having
 2 made such a note on your report and having
 3 interaction or a phone call from an
 4 oncologist?
 5 DR. S. PARAI:
 6 A. Well we would communicate, if there is some
 7 problem, we would communicate with the
 8 oncologist by telephone to make them aware
 9 that there is, we cannot make a definite
 10 diagnosis or interpretative, if there is
 11 something happens. No, I haven't done any -
 12 MS. NEWBURY:
 13 Q. Okay, and did you discuss with anyone the fact
 14 that you were not previously focusing on
 15 internal controls or you weren't specifically
 16 looking for internal controls prior to 2003
 17 for your ER/PR tests?
 18 DR. S. PARAI:
 19 A. Discuss with any particular person?
 20 MS. NEWBURY:
 21 Q. Discuss with anyone, you know, clinical chief
 22 or Dr. Ejeckam, anyone there to, just to, you
 23 know, put your heads together to see if that
 24 could be significant, or did you just
 25 immediately say this isn't a concern?

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

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

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

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

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1 well?
 2 DR. S. PARAI:
 3 A. You are asking that there was any system in
 4 place to -
 5 MS. NEWBURY:
 6 Q. Is there any system or protocol -
 7 DR. S. PARAI:
 8 A. No, I was not aware.
 9 MS. NEWBURY:
 10 Q. Okay, and do you know if this is the type of
 11 activity or protocol that might exist in other
 12 health organizations outside of the province?
 13 DR. S. PARAI:
 14 A. Well this is a technical quality issue of the
 15 technical manager should follow and I can't
 16 answer that. There might be, but I can't
 17 answer.
 18 MS. NEWBURY:
 19 Q. So in your view, this is not a clinical issue,
 20 this is a technical issue?
 21 DR. S. PARAI:
 22 A. Well it is of some relationship with, although
 23 (unintelligible) but more specifically says
 24 exclusively, I would say that the technical
 25 manager had more role to that.

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1 MS. NEWBURY:
 2 Q. So in terms of whether or not other
 3 laboratories and other health care
 4 organizations in Canada, for example, have, it
 5 may or may not be unusual or not uncommon for
 6 these other institutions to also repeat tests,
 7 but whatever systems they might have in place
 8 in terms of dealing with that, you're not
 9 aware of what such systems might be, if they
 10 have any at all?
 11 DR. S. PARAI:
 12 A. There was no such system at the General
 13 Hospital site, but other institution, it is
 14 possible.
 15 MS. NEWBURY:
 16 Q. Okay, but you don't know specifically what
 17 they might be?
 18 DR. S. PARAI:
 19 A. No.
 20 MS. NEWBURY:
 21 Q. Thank you, Dr. Parai, those are all the
 22 questions I have for you.
 23 THE COMMISSIONER:
 24 Q. Thank you. Ms. Taylor--I'm sorry, Ms.
 25 Russell?

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1 MS. RUSSELL:
 2 Q. No questions, Commissioner.
 3 THE COMMISSIONER:
 4 Q. Mr. Pike?
 5 MR. PIKE:
 6 Q. No questions, Commissioner.
 7 THE COMMISSIONER:
 8 Q. Mr. Browne?
 9 MR. BROWNE:
 10 Q. Thank you, Commissioner.
 11 DR. SUSHIL PARAI, EXAMINATION BY MR. PETER BROWNE
 12 MR. BROWNE:
 13 Q. Good morning, Dr. Parai, just a couple of
 14 areas I'm going to cover with you. Going way
 15 back to the start and your background, were
 16 you trained -- we've heard several of your
 17 colleagues come before the Commissioner and
 18 talk about their training. Were you trained
 19 as an anatomical pathologist or general
 20 pathologist?
 21 DR. S. PARAI:
 22 A. Well, mainly anatomical pathology. Also I had
 23 extra training in general pathology.
 24 MR. BROWNE:
 25 Q. And we notice as well in your curriculum

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

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

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

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

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1 of Pathology. We also used the QE II Health
 2 Sciences Centre, Halifax, and we also used
 3 some consultant of BC cancer agencies, and
 4 also some personal consultant whom we knew, or
 5 individual pathologist knew, they will send
 6 them directly to them.
 7 MR. BROWNE:
 8 Q. So --
 9 DR. S. PARAI:
 10 A. So involving -- mostly Toronto, some in United
 11 States.
 12 MR. BROWNE:
 13 Q. And this would -- I think you mentioned that
 14 this would be driven by the initiative of a
 15 particular pathologist or would it be the
 16 department itself doing this?
 17 DR. S. PARAI:
 18 A. Both.
 19 MR. BROWNE:
 20 Q. Both, okay, and would it cover all areas of
 21 pathology?
 22 DR. S. PARAI:
 23 A. Yes.
 24 MR. BROWNE:
 25 Q. Now leading into that, Dr. Parai, you've

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1 spoken both on Friday and today about the
 2 initiatives that were undertaken at the
 3 General Hospital from about 2001 onward on
 4 quality assurance, and I just want -- there
 5 are a couple of exhibits here in addition you
 6 were shown by Mr. Coffey this morning, a
 7 certificate of attendance, and you explained
 8 that document, but there are a couple of
 9 others I just want to run through quickly.
 10 The first is -- I'll click on this, Exhibit
 11 2427. Has that been entered?
 12 REGISTRAR:
 13 Q. Yes.
 14 MR. BROWNE:
 15 Q. Okay. Doctor, this is a --
 16 COMMISSIONER:
 17 Q. Taking over her job.
 18 MR. BROWNE:
 19 Q. Oh, I'm sorry. I apologize.
 20 COMMISSIONER:
 21 Q. Well, when she wants a day off, she just might
 22 be looking for you, Mr. Browne.
 23 MR. BROWNE:
 24 Q. Well, I don't envy that position, Registrar,
 25 it's a very important position and I think you

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1 do an extremely good job on it. Could you
 2 explain to me what this document is, Dr.
 3 Parai? It's entitled "Maintenance of
 4 certification and attendance and evaluation of
 5 activity attended".
 6 DR. S. PARAI:
 7 A. This is a document to maintain the attendance
 8 of the physician in our department, and these
 9 rounds are pre-approved by the Vice-Dean of
 10 Professional Development of Memorial
 11 University, and we had to send a proposal
 12 about the type of this meeting, what is the
 13 content, and what is it called, and Vice-Dean
 14 approved that this content of this meeting is
 15 acceptable by the Royal College of Canada for
 16 the maintenance of a certification for credit
 17 hours. So one hour of this meeting would be
 18 equivalent to one hour credit CME by the Royal
 19 College.
 20 MR. BROWNE:
 21 Q. And we've heard -- Mr. Coffey asked you about
 22 these Tuesday and Wednesday rounds. Are these
 23 the sheets that would follow these rounds on
 24 Tuesdays and Wednesday, or is this a separate
 25 session?

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1 DR. S. PARAI:
 2 A. No, this is the same form used for them, and
 3 every pathologist has to sign and document it.
 4 MR. BROWNE:
 5 Q. And these were in existence for -- do you
 6 recall when these came into effect, what year?
 7 DR. S. PARAI:
 8 A. Well, it came in 2001.
 9 MR. BROWNE:
 10 Q. 2001. Registrar, you're going to have to help
 11 me. I'm going to click out of this and move
 12 to the next -- oh, there we go. Can we go to
 13 -- Registrar, I'll let you control this,
 14 Exhibit 2428, please. We've heard about the
 15 check path, Doctor. Is this an example of
 16 what you refer to? It's called "check
 17 sample", American Society of Clinical
 18 Pathologists, and it's surgical pathology and
 19 there's two authors, Espejo and Jasnosz, both
 20 assistants; one a resident and assistant
 21 professor of pathology, in Pennsylvania. Are
 22 there several topics that this -- if we can
 23 just go through it briefly here. It gives a
 24 history, a clinical history, and then findings
 25 and so on. This one is testicular

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1 plasmacytoma. So just if you could explain
 2 for -- this is just one example that you
 3 picked.
 4 DR. S. PARAI:
 5 A. This is the example I'm showing you that we
 6 started 2000. If you look at the number on
 7 the top right hand corner, it's SP200-1. That
 8 means 2000, number one, showing that we have
 9 this program in place for CME, continuing
 10 medical education, and we used to get this
 11 program to help in surgical pathology. That
 12 is once a month that this material will be
 13 mailed with the appropriate images of slides,
 14 would be passed to every pathologist. They
 15 will review them and there will be question
 16 and answer at the end of this program, and
 17 they will fill out the answer and we review
 18 monthly. We will review them monthly under
 19 microscope and get feedback and send -there
 20 was also a form to send to the ASCP, our
 21 information and our diagnosis.
 22 MR. BROWNE:
 23 Q. And then would there be a response from the
 24 ASCP with regard to that information?
 25 DR. S. PARAI:

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1 A. In this particular program, there would be no
 2 response, but the annual there will be review
 3 -- they'll send us what is the performance of
 4 various institution, but not individual.
 5 MR. BROWNE:
 6 Q. Individual. So the ASCP issues on an annual
 7 basis performances of institutions in a
 8 overall document, is that right?
 9 DR. S. PARAI:
 10 A. Yes.
 11 MR. BROWNE:
 12 Q. Now you had another --
 13 DR. S. PARAI:
 14 A. It means they will send a certificate that --
 15 well, not certificate, they will send some
 16 information that these are the various
 17 institutions participated in this program.
 18 MR. BROWNE:
 19 Q. There was another document, which is Exhibit
 20 2439, Doctor. Just bear with me. This is the
 21 PIT Program that, I think, you mentioned as
 22 well. Could you -- and it's performance
 23 improvement program in diagnostic surgical
 24 pathology. Now this, I think, is monitored by
 25 the CAP, is that right?

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1 DR. S. PARAI:
 2 A. Yes.
 3 MR. BROWNE:
 4 Q. Can you explain to the Commissioner, again is
 5 this just another example of sort of this
 6 program you subscribe to at the General
 7 Hospital and what did this involve? This one
 8 is -- I think it's called "Final Critiques",
 9 and it has a number of areas listed in the
 10 Table of Contents. So it's not just one area,
 11 there's -- I guess, is it across the board in
 12 pathology that this program entails?
 13 DR. S. PARAI:
 14 A. This is a program we introduced in 2000, if
 15 you look at the paper number, and the program
 16 speaks for it, performance improvement program
 17 for every pathologist to improve their medical
 18 knowledge, and we would get this 40 in full A,
 19 B, C, D, per year. Reported cases will be sent
 20 to us quarterly, and we will review them and
 21 send the report -- result to them and there
 22 will be certification to follow to individual
 23 pathologists.
 24 MR. BROWNE:
 25 Q. Okay. So in this program, there is an

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1 evaluation of each pathologist in terms of
 2 their assessment, is that correct?
 3 DR. S. PARAI:
 4 A. There are both ways. Once this program would
 5 be coming to our department, we'll circulate
 6 it among the pathologists, and in a monthly or
 7 quarterly, we'll review among the pathologists
 8 multi-headed microscope, and we'll send an
 9 institutional result answers -- it is a kind
 10 of test, and also pathologists can send their
 11 own answer to get a certification of their
 12 own.
 13 MR. BROWNE:
 14 Q. Okay. Now in terms of -- again staying with
 15 the topic of quality assurance, in 2000 --
 16 we've heard from a number of witnesses, both
 17 from the administration down, about the tough
 18 times financially that health care experienced
 19 in early 2000, late 1990s. Was there any
 20 discussion about -- we now have a quality
 21 control manager, I understand, in place at the
 22 General Hospital. Was there any discussion in
 23 looking at the years from the time you were
 24 site chief about bringing in a quality control
 25 manager?

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1 DR. S. PARAI:
 2 A. Yes, there was, started in early 2001, and
 3 ended up until my tenure, 2005. There was
 4 always discussion of a quality control
 5 manager.
 6 MR. BROWNE:
 7 Q. And who was -- if we could, Doctor, just if
 8 you recall when did this first come up, who
 9 brought it up, and what sort of -- in what
 10 direction did it head?
 11 DR. S. PARAI:
 12 A. The quality control program was discussed in
 13 the site chief and division manager meeting in
 14 early -- well, in 2001, the division manager,
 15 Mr. Gulliver, was presented at that time a
 16 letter, and Mr. Barry Dyer, and every time we
 17 raised this issue that we needed quality
 18 control manager to implement this program.
 19 MR. BROWNE:
 20 Q. And what was sort of the response, in terms of
 21 generally, do you recall whether they agreed
 22 with the notion and whether or not it was
 23 achievable?
 24 DR. S. PARAI:
 25 A. Well, also the discussion went on with the

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1 clinical chief, as the site chief I can have
 2 this information. My request will go to the
 3 clinical chief, which was Dr. Haegert and Dr.
 4 Cook later on, and these meeting were with
 5 combined meeting between two sides, clinical
 6 chief and division managers, and raised many
 7 time we need to address the issue of quality
 8 control manager. It was ongoing. So far I
 9 recall, there was funding problem and there
 10 was no position could be created because of
 11 the funding constraint.
 12 MR. BROWNE:
 13 Q. So financial constraints prevented this from
 14 advancing forward? Is that your general
 15 understanding?
 16 DR. S. PARAI:
 17 A. Yes.
 18 MR. BROWNE:
 19 Q. It's not necessary, Doctor, to bring up the
 20 document, but you were shown by Mr. Coffey and
 21 Ms. Newbury again this morning, the April 25th
 22 2001 meeting, and the mention of a survey
 23 being conducted, and as I understand your
 24 evidence that there was feedback from about 10
 25 or 11 pathologists about the quality of the

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1 slides. Is that right?
 2 DR. S. PARAI:
 3 A. Yes.
 4 MR. BROWNE:
 5 Q. And among those included ER/PR?
 6 DR. S. PARAI:
 7 A. Yes.
 8 MR. BROWNE:
 9 Q. And that information, do I understand
 10 correctly from your evidence previously on
 11 Friday, that information was given to Mr.
 12 Gulliver, who was, I think, the manager at the
 13 time, to then take back and sort of chase down
 14 those issues with his technical, quality of
 15 the slides?
 16 DR. S. PARAI:
 17 A. Yes.
 18 MR. BROWNE:
 19 Q. Now Doctor, customarily, witnesses are asked
 20 whether or not they wish to make any
 21 statements or recommendations to the
 22 Commissioner at the end of their evidence. Is
 23 it your intention to make any comment or
 24 remark to the Commissioner before you conclude
 25 your evidence today?

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1 DR. S. PARAI:
 2 A. Well, one point I want to mention, in the
 3 previous testimony how many cases of -
 4 MR. BROWNE:
 5 Q. Yes, sorry, I meant to cover that with you,
 6 Doctor. I know you wanted to clarify that
 7 point. You had mentioned, I think, early on
 8 in your evidence, and you were probably a bit
 9 nervous on Friday, about you had mentioned
 10 that there were two to three hundred breast
 11 cancer surgeries conducted at the Grace
 12 annually and I think you -
 13 DR. S. PARAI:
 14 A. Well, I misunderstood the question. It was
 15 not annually. I would say during my tenure in
 16 Grace Hospital as a whole. We are not getting
 17 too many, we are not doing too many breast
 18 cancer at the Grace Hospital. The centre for
 19 the breast cancer was designated at the St.
 20 Clare's Hospital and that was centralized
 21 there. Remember, before the Health Care
 22 Corporation come, there was--that was the
 23 phase two. Phase one was the centralization
 24 of the services in the site. So the St. Clare
 25 was identified as the centre for the breast

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1 care, breast tumour care, including mammogram,
 2 and surgical, involving surgery as well as
 3 pathology. So we are not doing that many at
 4 the Grace.
 5 MR. BROWNE:
 6 Q. And is there any further clarifications or any
 7 remarks you wish to make to the Commissioner?
 8 DR. S. PARAI:
 9 A. No.
 10 MR. BROWNE:
 11 Q. Okay, thank you. That's all the questions I
 12 have. Thank you, Commissioner.
 13 THE COMMISSIONER:
 14 Q. Thank you, Mr. Browne.
 15 MR. BROWNE:
 16 Q. Mr. Coffey may have any -
 17 THE COMMISSIONER:
 18 Q. Do you have anything arising, Mr. Coffey?
 19 DR. SUSHIL PARAI, RE-EXAMINATION BY BERNARD COFFEY, Q.C.
 20 COFFEY, Q.C.:
 21 Q. Yes, just one, one thing, Commissioner.
 22 Doctor, in answering Ms. Newbury's questions,
 23 you indicated that, you know, looking back on
 24 it, you believe that the problem, as it were,
 25 with the stains started probably in 2003. I

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1 think that's what you told Ms. Newbury.
 2 DR. S. PARAI:
 3 A. That's the first time we identified.
 4 COFFEY, Q.C.:
 5 Q. Yes, you identified it.
 6 DR. S. PARAI:
 7 A. Detect it.
 8 COFFEY, Q.C.:
 9 Q. And Doctor, I'm just--she asked you questions
 10 about, you know, what was discussed amongst
 11 yourselves as to, you know, well, the fact
 12 that you didn't know about internal--weren't
 13 really alerted to the potential significance
 14 of internal controls yourself and whether the
 15 pathologists discussed it, and you were asked
 16 about any concerns that the pathologists might
 17 have had about earlier cases. One thing I
 18 wanted to ask you was, is this, leaving aside
 19 the pathologists, do you know if the
 20 oncologists were alerted to this? You're all
 21 aware of it as pathologists in 2003. Were the
 22 oncologists alerted to this, the fact that all
 23 the pathologists are discussing this?
 24 DR. S. PARAI:
 25 A. In official, you mean, or personal level?

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1 COFFEY, Q.C.:
 2 Q. In 2003?
 3 DR. S. PARAI:
 4 A. 2003?
 5 COFFEY, Q.C.:
 6 Q. Yes.
 7 DR. S. PARAI:
 8 A. I was not aware that there was any official
 9 information given to the oncologists.
 10 COFFEY, Q.C.:
 11 Q. How about unofficial?
 12 DR. S. PARAI:
 13 A. I can't answer, and this memo from Dr. Ejeckam
 14 was the internal memo. It was only for the
 15 pathologist group, and how he believed that it
 16 is a small and short time problem and it is
 17 working, but irregular, so and he was
 18 confident that it can be corrected and which
 19 he did, and then we retested.
 20 COFFEY, Q.C.:
 21 Q. And I appreciate that, but in terms of the
 22 oncologists, you don't recall ever, yourself,
 23 as site chief, being approached by them or
 24 discussing that with them?
 25 DR. S. PARAI:

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

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1 the point you were making?
 2 DR. S. PARAI:
 3 A. I would say to your first question, but second
 4 question, I can't answer. I was not aware any
 5 oncologists were aware of the problem.
 6 THE COMMISSIONER:
 7 Q. Okay.
 8 DR. S. PARAI:
 9 A. Is it -
 10 THE COMMISSIONER:
 11 Q. Well, I'm interested in the notion that if
 12 there is a problem with the testing being done
 13 in the laboratory or with the reports being
 14 produced by a pathologist then one of the
 15 criteria for determining whether or not one
 16 should have known about the problem would be
 17 well, the pathologist didn't say--I'm sorry,
 18 the oncologist didn't say "we've got a
 19 problem."
 20 DR. S. PARAI:
 21 A. Well -
 22 THE COMMISSIONER:
 23 Q. How would they know? That was my question.
 24 DR. S. PARAI:
 25 A. During the problem when we identified,

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1 identified or detected the problem, we did not
 2 do any reporting, that period, from April
 3 until May, until the problem was corrected and
 4 retesting was done. So that particular
 5 period, so far I recall, I don't think there
 6 was any report produced by our, particularly
 7 General Hospital site.
 8 THE COMMISSIONER:
 9 Q. Well, that's really my question. Could an
 10 oncologist be expected to know if there was a
 11 problem with, in this case, ER/PR testing in
 12 any event, and if so, how would they know?
 13 DR. S. PARAI:
 14 A. The communication, well, you would be going--
 15 Dr. Ejeckam was in charge of the
 16 immunohistochemistry lab. I don't recall
 17 whether he communicated with the oncologists
 18 or not. I can't answer that.
 19 THE COMMISSIONER:
 20 Q. But from--the issue arose, I think, in the
 21 context of your discussion with Ms. Newbury
 22 about whether, for example, certain results
 23 should tell an oncologist or a pathologist,
 24 for that matter, that there may be a problem
 25 with the testing?

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1 DR. S. PARAI:
 2 A. Testing prior to 2003 you mean?
 3 THE COMMISSIONER:
 4 Q. In theory. I'm not talking about the
 5 particulars. I'm just interested in the
 6 notion of whether or not, as a pathologist,
 7 you would say "well, we didn't recognize there
 8 was a problem with a particular test, and
 9 what's more, the people who we serve, the
 10 oncologists, didn't tell us that they were
 11 having a problem with it. So how would we be
 12 expected to know that?" and my question is
 13 could an oncologist be expected to know if
 14 there was a problem with a test that was being
 15 done by a pathologist?
 16 DR. S. PARAI:
 17 A. Well, for a short time, for this, we consider
 18 this as a minor problem, only temporary, and
 19 it is also a lab--what we do if something is
 20 delayed for retesting, we wait for the test is
 21 right and report it, or if it wasn't for a
 22 short period of time, we did not--Dr. Ejeckam,
 23 when I discussed, I think, did not feel to
 24 notify them.
 25 THE COMMISSIONER:

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1 Q. Okay. But there's nothing in the nature of
 2 the testing itself that should be evident to
 3 an oncologist that there was a problem, is
 4 there?
 5 DR. S. PARAI:
 6 A. Well, the one would be -
 7 THE COMMISSIONER:
 8 Q. I don't think I'm communicating my question
 9 properly. As I understand it, your role is to
 10 either in diagnosis or in tests like ER/PR to
 11 examine the tissue having gone through a
 12 certain process and give your opinion, within
 13 your particular sphere of expertise, as to, in
 14 the case of ER/PR, whether or not the results
 15 are considered positive or negative, and then
 16 you prepare your report and that goes on to an
 17 oncologist.
 18 DR. S. PARAI:
 19 A. Yes.
 20 THE COMMISSIONER:
 21 Q. Would it be normal, for example, for an
 22 oncologist to call you up and say "are you
 23 sure that's right?" because of this, this and
 24 this, or do the oncologists say "umph, that's
 25 what the report is from the pathology

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1 department and I accept that" and carry on on
 2 the basis of that?
 3 DR. S. PARAI:
 4 A. Well, it is normal for oncologists to raise
 5 any question we produce and they call us and
 6 then discuss. Yes, they will say "are you
 7 sure?" Yes, they do.
 8 THE COMMISSIONER:
 9 Q. Okay, and in the context of ER/PR, on what
 10 basis would they have that kind of
 11 conversation with you? You know, I can see it
 12 as being perhaps more common if you're looking
 13 at diagnosis and they're saying "we have all
 14 these other factors, and are you sure this
 15 fits in with?"
 16 DR. S. PARAI:
 17 A. Well there is no conversation with the
 18 oncologist I could think of during the period,
 19 but if the answer is low grade and if ER is
 20 negative, they will always raise the question
 21 "are you sure the test is right?" There are
 22 two component we do in hormone receptor ER and
 23 PR. If PR is positive and ER is negative,
 24 they will raise concern that "why PR is
 25 positive and ER is negative? Will you retest

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1 it?" So these are the two point I could think
 2 of.
 3 THE COMMISSIONER:
 4 Q. All right. So, and would that have been the
 5 practice over the full period of time from the
 6 late 90s into now or is that more the current
 7 practice?
 8 DR. S. PARAI:
 9 A. I can't answer that, but it should have been
 10 all the time. It is known from '97 and
 11 onwards that these are the things, a low grade
 12 tumour should be positive and PR positive
 13 tumour would be ER positive as well, except
 14 there are five to ten percent of PR positive
 15 tumour not ER positive.
 16 THE COMMISSIONER:
 17 Q. Yes. Yes, I think other witnesses have said
 18 that as well. Okay then, thank you very much
 19 for that information and indeed for all of
 20 your evidence.
 21 DR. S. PARAI:
 22 A. Thank you.
 23 THE COMMISSIONER:
 24 Q. In light of the time, I suggest we take the
 25 luncheon break and then continue with the next

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1 witness after lunch. We'll meet again at ten
 2 after two. Thank you.
 3 (LUNCH BREAK)
 4 DR. BEVERLEY CARTER, AFFIRMED, EXAMINATION BY BERNARD
 5 COFFEY, Q.C.
 6 REGISTRAR:
 7 Q. Would you please state and spell your complete
 8 name for the Commission?
 9 DR. CARTER:
 10 A. My name is Beverley Carter, B-E-V-E-R-L-E-Y C-
 11 A-R-T-E-R.
 12 REGISTRAR:
 13 Q. Thank you.
 14 COFFEY, Q.C.:
 15 Q. Good afternoon, Dr. Carter.
 16 DR. CARTER:
 17 A. Good afternoon, Mr. Coffey.
 18 COFFEY, Q.C.:
 19 Q. Commissioner, there are a number of other
 20 exhibits that I'm going to ask be entered,
 21 please. They would be, Commissioner, Exhibits
 22 P-2440 through P-2479, I'm sorry, 24-yes-79,
 23 inclusive. 2440 through 2479 inclusive.
 24 THE COMMISSIONER:
 25 Q. Entered.

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1 EXHIBITS ENTERED AND MARKED P-2440 THROUGH P-2479
 2 COFFEY, Q.C.:
 3 Q. And there will be some C exhibits, but I'll
 4 come to them eventually.
 5 THE COMMISSIONER:
 6 Q. Okay then.
 7 COFFEY, Q.C.:
 8 Q. Dr. Carter, I'm going to refer you to an
 9 exhibit to start, Exhibit P-2440, please,
 10 Registrar? And here, Dr. Carter, there on the
 11 screen in front of you, I believe this is your
 12 CV?
 13 DR. CARTER:
 14 A. Yes, it is.
 15 COFFEY, Q.C.:
 16 Q. And have you identify it as yours. Doctor,
 17 I'm not going to take you through each of the
 18 lines of it. I'm going to ask you, please, to
 19 tell the Commissioner, give an overview of
 20 your professional, educational background and
 21 then your professional experience.
 22 DR. CARTER:
 23 A. I entered medical school in 1985 at Memorial
 24 University and graduated in 1989.
 25 COFFEY, Q.C.:

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1 Q. If I could, Commissioner, it I could just
 2 intervene here, Doctor, I appreciate, because
 3 you're starting with your actual medical
 4 training itself, Doctor, but you happen to
 5 have been involved in, I believe, pharmacy
 6 before?
 7 DR. CARTER:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. Okay. Could you tell the Commissioner,
 11 please, about that? Because it will give her
 12 some sense then of kind of your own actual
 13 background, not only your medical background,
 14 but in fact, you've been exposed to the
 15 subject of medicine and medical matters before
 16 you ever entered medical school, so perhaps
 17 you could tell her about that?
 18 DR. CARTER:
 19 A. In 1975, I finished high school and I entered
 20 pharmacy school at what would be known now as
 21 CONA, and graduated in 1978. I worked as a
 22 pharmacist until 1984 when I went to Memorial
 23 University and started medical school in 1985.
 24 I graduated in 1989 and then went to Dalhousie
 25 University for a rotating internship and a

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1 year of obstetrical training. I practised as
 2 a general practitioner until 1994. At that
 3 time, I entered a pathology residency at
 4 McMaster University and I was granted my
 5 fellowship in 1998 from the Royal College of
 6 Physicians and Surgeons of Canada. At that
 7 time, I went to Vanderbilt University as a
 8 research fellow, and I completed a one-year
 9 fellowship in breast pathology with Dr. David
 10 Page, and in 1999, I returned to McMaster
 11 University as an assistant professor and as a
 12 pathologist with the Hamilton Regional
 13 Laboratory Medicine Program. In 2003, I began
 14 locum work at what was then the Health Care
 15 Corporation of St. John's, and in 2004, I
 16 began work as a full-time service pathologist
 17 at St. Clare's Mercy Hospital here in St.
 18 John's.
 19 COFFEY, Q.C.:
 20 Q. Doctor, could you explain to the Commissioner,
 21 please, what a research scholar fellow in
 22 breast pathology, what does that mean or what
 23 does that involve?
 24 DR. CARTER:
 25 A. From 1998 to 1999, you're talking about?

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1 COFFEY, Q.C.:
 2 Q. Yes.
 3 DR. CARTER:
 4 A. I went to Vanderbilt University. Research
 5 scholar is the designation that they would
 6 give you on your work visa to go there. I
 7 basically did a year of consultation breast
 8 pathology and research with Dr. David Page.
 9 COFFEY, Q.C.:
 10 Q. Doctor, can you--of course, Vanderbilt is in
 11 the United States?
 12 DR. CARTER:
 13 A. In Nashville, yes.
 14 COFFEY, Q.C.:
 15 Q. Doctor, is there, in the United States or in
 16 Canada, any particular designation as a breast
 17 pathologist?
 18 DR. CARTER:
 19 A. No, there is not. The Royal College is strict
 20 on that. I am an anatomic pathologist.
 21 COFFEY, Q.C.:
 22 Q. Anatomic pathologist, and how about in the
 23 United States, do you know what their system -
 24 DR. CARTER:
 25 A. I don't think that there's a recognized breast

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1 pathology fellowship with examinations. I
 2 don't think so, but I'm not sure.
 3 COFFEY, Q.C.:
 4 Q. So that from the perspective of being a breast
 5 pathologist per se, because there's--in a
 6 number of documents, you're referred to as
 7 that.
 8 DR. CARTER:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. In practice, what does that mean?
 12 DR. CARTER:
 13 A. In practice, most people who would designate
 14 themselves as a breast pathologist would have
 15 usually somewhere between three to six months
 16 or more training as a breast pathologist or
 17 someone whose practice is largely dedicated to
 18 that.
 19 COFFEY, Q.C.:
 20 Q. And in your case, I take it during that year
 21 at Vanderbilt, you would have been studying
 22 breast pathology itself for that -
 23 DR. CARTER:
 24 A. Yes, for the entire year.
 25 COFFEY, Q.C.:

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1 Q. - for that entire year. Doctor, could you -
 2 THE COMMISSIONER:
 3 Q. I'm sorry, is that true of pathology
 4 generally, there's no sort of sub-
 5 specialization categorization by the Royal
 6 College?
 7 DR. CARTER:
 8 A. In Canada, you can be an anatomic pathologist,
 9 a general pathologist, a neuropathologist and
 10 a hematopathology and right now, it's still
 11 being, you know, figured out, but you can
 12 probably be a forensic pathologist by
 13 designation, but the Royal College is very
 14 strict about what you call yourself. What we
 15 call ourselves when we're talking to one
 16 another, I mean, it's quite different, but I
 17 wouldn't be able to advertise that I'm a
 18 breast pathologist. I'm an anatomic
 19 pathologist.
 20 THE COMMISSIONER:
 21 Q. All right, thank you.
 22 COFFEY, Q.C.:
 23 Q. Doctor, looking at your resume, Doctor, I take
 24 it that in fact at one point, you did spend
 25 some time back at Vanderbilt?

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1 DR. CARTER:
 2 A. In May of 2004, I went back to Vanderbilt as a
 3 visiting scholar, again a visa designation,
 4 for two months and while I was there, I worked
 5 on some textbook chapters that I was writing
 6 for two textbooks of breast pathology.
 7 COFFEY, Q.C.:
 8 Q. You've referred to David Page. I take it
 9 that's Dr. David Page?
 10 DR. CARTER:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. And who, in your world, is Dr. Page?
 14 DR. CARTER:
 15 A. He is an internationally recognized breast
 16 pathologist. He's also an epidemiologist. He
 17 has a huge consultation practice from all over
 18 the world, but largely from the United States,
 19 and he's written hundreds of papers, but many
 20 seminal papers for breast pathology and breast
 21 practice.
 22 COFFEY, Q.C.:
 23 Q. Now Doctor, you have indicated that you ended
 24 up here in St. John's, I take it, in
 25 Newfoundland, particularly in St. John's,

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1 doing locums at one point?
 2 DR. CARTER:
 3 A. Yes, in 2003.
 4 COFFEY, Q.C.:
 5 Q. If we could, just again to give the
 6 Commissioner some sense of the times, okay,
 7 Exhibit P-2442, please, 2442? Page eight,
 8 please? These happen to be Board of Trustee
 9 minutes for a meeting of September 25, 2003.
 10 In those minutes, there's a note under the
 11 Laboratory Medicine Program, Dr. Bev Carter,
 12 temporary privileges to perform a locum in the
 13 Laboratory Medicine Program, division of
 14 anatomical pathology, August 4th to October
 15 4th, 2003. So would that be your -
 16 DR. CARTER:
 17 A. I may not have worked from August 4th to
 18 October 4th, but they would have granted the
 19 privileges for that time, and I might have had
 20 a week off or something in between. I was
 21 covering for vacations at that time.
 22 COFFEY, Q.C.:
 23 Q. So Doctor, was this the beginning then of the
 24 locums? Do you recall was it the summer of
 25 '03?

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1 DR. CARTER:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. And where were you working at that time, which
 5 hospitals?
 6 DR. CARTER:
 7 A. When I came here in August, I worked at the
 8 General site. I'll probably call it the
 9 Health Science Centre throughout the next few
 10 days.
 11 COFFEY, Q.C.:
 12 Q. Sure.
 13 DR. CARTER:
 14 A. But at the General site, and I first started
 15 working at St. Clare's, the first time I
 16 worked there was a locum that was in December.
 17 COFFEY, Q.C.:
 18 Q. Of that -
 19 DR. CARTER:
 20 A. Of 2003.
 21 COFFEY, Q.C.:
 22 Q. While we're on it, Exhibit P-2443, please?
 23 Now these are the minutes of a meeting of the
 24 Board of Trustees of October 30th, 2003.
 25 Particular at page three, Doctor, under

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

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1 locums?
 2 DR. CARTER:
 3 A. Yes, throughout that time.
 4 COFFEY, Q.C.:
 5 Q. Doctor, perhaps you could advise the
 6 Commissioner, what sort of work then does a
 7 person doing a locum in that context do? What
 8 actually happens?
 9 DR. CARTER:
 10 A. Most of the locums that I was hired for would
 11 be for vacation relief. So I would take that
 12 person's place in the call schedule. So I
 13 would do routine service duties. I don't
 14 think that I would have had much to do with
 15 administrative things or meetings, those sorts
 16 of things, more of a service person.
 17 COFFEY, Q.C.:
 18 Q. And to fill in then wherever in a functional
 19 way?
 20 DR. CARTER:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. Wherever you were needed at the time?
 24 DR. CARTER:
 25 A. Yes.

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

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1 hospital position and 20 percent academic
 2 position. Academic position would consist of
 3 teaching at the medical school, the pharmacy
 4 school, an expectation that you would
 5 participate in the administration of the
 6 medical school and also that you would
 7 participate in and produce research. In a
 8 service position, you would be more involved
 9 in just the running of the clinical service
 10 for the hospital.
 11 COFFEY, Q.C.:
 12 Q. Is there, in a clinical position, or hospital-
 13 based position, is there any expectation that
 14 you were--you've referred to an 80/20 split
 15 for the university.
 16 DR. CARTER:
 17 A. Um-hm.
 18 COFFEY, Q.C.:
 19 Q. 20 percent would be clinical, I take it?
 20 DR. CARTER:
 21 A. 80 percent would be clinical work and 20
 22 percent would be academic work.
 23 COFFEY, Q.C.:
 24 Q. Oh, okay, I'm sorry, 80/20, I misunderstood.
 25 For university positions, 80 percent clinical,

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1 20 -
 2 DR. CARTER:
 3 A. Academic.
 4 COFFEY, Q.C.:
 5 Q. - academic, and the hospital-base would be 100
 6 percent -
 7 DR. CARTER:
 8 A. Service work, but within that, I mean, you
 9 would still have to teach residents. You
 10 would probably take part in collaborative
 11 research, things like that.
 12 COFFEY, Q.C.:
 13 Q. Okay, and Doctor, I take it that you did apply
 14 for that position?
 15 DR. CARTER:
 16 A. Yes, I did.
 17 COFFEY, Q.C.:
 18 Q. And you were offered a position and accepted
 19 it. When did you start then?
 20 DR. CARTER:
 21 A. In August of 2004.
 22 COFFEY, Q.C.:
 23 Q. Exhibit P-2332, 2332 please? These are MAC
 24 minutes of June 9th, 2004, Doctor. If we
 25 could, Registrar, page seven, please? Here,

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1 Doctor, under Laboratory Medicine Program,
 2 there's a reference to "temporary privileges
 3 to perform a locum, July 26th, 2004 to August
 4 16th, 2004, and then associate staff, August
 5 16th, 2004 to August 16th, 2005." So I take
 6 it that this last line here is your
 7 appointment to the hospital -
 8 DR. CARTER:
 9 A. Full-time position, yes.
 10 COFFEY, Q.C.:
 11 Q. - full-time position. What is the situation
 12 then, Doctor, with respect to being appointed
 13 to associate staff for a year? Because we
 14 understand, and we've seen a number of
 15 references to longer periods of time after the
 16 initial year.
 17 DR. CARTER:
 18 A. I'm not really certain.
 19 COFFEY, Q.C.:
 20 Q. Okay.
 21 DR. CARTER:
 22 A. Maybe you better ask some of the
 23 administration. I think it's sort of a
 24 probationary kind of period, but I'm not sure.
 25 COFFEY, Q.C.:

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1 Q. Okay, and as you don't know much about it, in
 2 your world, it didn't really figure
 3 prominently. You applied for the job,
 4 obtained it.
 5 DR. CARTER:
 6 A. You have the job and -
 7 COFFEY, Q.C.:
 8 Q. And then just -
 9 DR. CARTER:
 10 A. - you would assume that life would just go on,
 11 yes.
 12 COFFEY, Q.C.:
 13 Q. Doctor, could you tell the Commissioner,
 14 please, about your own introduction to ER and
 15 PR IHC type testing?
 16 DR. CARTER:
 17 A. Here in St. John's or -
 18 COFFEY, Q.C.:
 19 Q. No, just generally.
 20 DR. CARTER:
 21 A. In general. It would have been as a part of
 22 my residency program, you would have on-the-
 23 job training with pathologists. So you would
 24 be signing out breast cases with them and
 25 signing out estrogen and progesterone receptor

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1 cases with them. Also, as part of the
 2 resident's academic half day was a half day a
 3 week of didactic lectures. As mandated by the
 4 Royal College, we would have had a series of
 5 lectures on laboratory methods and part of
 6 that would have been immunohistochemistry's
 7 theory and practice.
 8 COFFEY, Q.C.:
 9 Q. And that would be while you were at McMaster
 10 doing your residency?
 11 DR. CARTER:
 12 A. From '94 to '98.
 13 COFFEY, Q.C.:
 14 Q. How much actual--well, back up a bit. Would
 15 you actually go to the IHC part of the lab?
 16 DR. CARTER:
 17 A. Yes.
 18 COFFEY, Q.C.:
 19 Q. And how much would you actually learn about
 20 the nitty gritty of performing the test?
 21 DR. CARTER:
 22 A. Well, we would have to know basic theory of,
 23 you know, how the test is performed and how
 24 the reactions takes place and what the
 25 chromogens are. More, we would be interested

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1 in, you know, it's application to clinical
 2 cases, that sort of thing.
 3 COFFEY, Q.C.:
 4 Q. And would you be at all involved as a resident
 5 in, like, if there was a problem with a stain
 6 or stains, IHC stains, would you be involved
 7 in troubleshooting?
 8 DR. CARTER:
 9 A. If it was my case, yes.
 10 COFFEY, Q.C.:
 11 Q. Okay, but if it was not your case, I take it -
 12 - the point I'm getting at is you wouldn't
 13 attend lectures or lessons dealing with
 14 troubleshooting in IHC, in a general sense?
 15 DR. CARTER:
 16 A. No, it would be more on the job training.
 17 COFFEY, Q.C.:
 18 Q. Doctor, while I'm on the topic, to this day,
 19 for example, locally for the residents,
 20 pathology residents, how much involvement, to
 21 your knowledge, how much exposure do they get
 22 to IHC?
 23 DR. CARTER:
 24 A. Again they would receive it largely on their
 25 day to day sign outs, and when they work with

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1 me, I mean, I make them do the case from start
 2 to end.
 3 COFFEY, Q.C.:
 4 Q. Sure.
 5 DR. CARTER:
 6 A. So they would see it then. We have a series
 7 of lectures here as well for resident,
 8 academic half day, and I'm pretty sure there
 9 are lectures on immunohistochemistry or around
 10 the topic of immunohistochemistry in that. We
 11 also have a Friday morning departmental
 12 lecture that was just started, I think, this
 13 year, or maybe a year and a half, and
 14 immunohistochemistry lab takes part in that
 15 and the residents are mandated to attend that
 16 as well.
 17 COFFEY, Q.C.:
 18 Q. So I take it generally, though, the residents
 19 today have a -- you've told us locally would
 20 have a similar sort of exposure to IHC as you
 21 received in McMaster, bearing in mind that the
 22 stains have -- you know, there are many more
 23 stains and so on as time has gone on, but a
 24 kind of systematic exposure to it is about the
 25 same?

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1 DR. CARTER:
 2 A. Basically, it would be equivalent, in my
 3 opinion, the training.
 4 COFFEY, Q.C.:
 5 Q. Doctor, just looking back then, you began in
 6 St. John's doing locums, as best you can
 7 recall, and your first one was at the General
 8 Hospital?
 9 DR. CARTER:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. Health Sciences site beginning some time in
 13 August of 2003?
 14 DR. CARTER:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. Doctor, when you arrived, how much contact had
 18 you had with the local pathologist community
 19 before your arrival?
 20 DR. CARTER:
 21 A. I had been attending tumour boards, the
 22 Wednesday morning multi-disciplinary tumour
 23 boards for a few months prior to that, and I
 24 had also participated in some residency
 25 teaching for a few months prior to that.

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1 COFFEY, Q.C.:
 2 Q. So you had been in St. John's?
 3 DR. CARTER:
 4 A. I was in St. John's from the October before.
 5 COFFEY, Q.C.:
 6 Q. Okay, the fall of '02 then, 2002?
 7 DR. CARTER:
 8 A. Okay.
 9 COFFEY, Q.C.:
 10 Q. Because that will bring us up to the spring
 11 and summer of 2003. Doctor, were you aware of
 12 -- I'll just bring it up now, P-0113, please,
 13 Registrar. These are the three Dr. Ejeckam
 14 memos that the Commission has seen. When did
 15 you first see these memos? I can take you
 16 through them if you like, but this is the
 17 April 4th one, this is the one where the
 18 utilization of the eight stains for at least a
 19 period of time is suspended, and then there's
 20 the May 2nd reinstatement of ER/PR stains, and
 21 then there's the June 19th one where Dr.
 22 Ejeckam writes to Mr. Gulliver generally about
 23 his concerns.
 24 DR. CARTER:
 25 A. Okay. I would have heard of these sometime in

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1 the summer of 2005 when we began to
 2 investigate.
 3 COFFEY, Q.C.:
 4 Q. That's what I was going to ask you about.
 5 Before that, before the summer of 2005, this
 6 subject was not brought to your attention, I
 7 take it?
 8 DR. CARTER:
 9 A. No.
 10 COFFEY, Q.C.:
 11 Q. That you can recall.
 12 DR. CARTER:
 13 A. Not that I recall.
 14 COFFEY, Q.C.:
 15 Q. And not only -- you didn't see -- if they're
 16 listed as two pathologists, I take it, whoever
 17 was distributing them didn't think, even if
 18 you were attending rounds around that time --
 19 DR. CARTER:
 20 A. I wouldn't have been officially associated
 21 with -- it was a much drop-in basis. I mean,
 22 I came in to teach the residents and then go
 23 back home.
 24 COFFEY, Q.C.:
 25 Q. This is April 4th, 2003. You certainly didn't

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1 get a copy of this until 2005, or even become
 2 aware of it until 2005?
 3 DR. CARTER:
 4 A. Yes, and then I --
 5 COFFEY, Q.C.:
 6 Q. And the second one of these is the May 2nd
 7 one, Doctor, 2003. You did not receive a copy
 8 of this, and the subject matter, the whole
 9 idea of it, they had to suspend the
 10 utilization of eight stains.
 11 DR. CARTER:
 12 A. No, I didn't -- I didn't know about that.
 13 COFFEY, Q.C.:
 14 Q. You weren't told about that, and that Dr.
 15 Ejeckam in May of 2003 had sent around, I'll
 16 refer to it as a briefing memo, as it were, on
 17 ER/PR. It's several pages -- it's three pages
 18 long. You weren't aware that that had
 19 happened?
 20 DR. CARTER:
 21 A. No, and this is the first time actually that
 22 I've seen that piece of paper, so --
 23 COFFEY, Q.C.:
 24 Q. Okay. So in 2005, you learned generally about
 25 the fact that something had happened in 2003?

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1 DR. CARTER:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. And I'll be asking you about that.
 5 DR. CARTER:
 6 A. Uh-hm.
 7 COFFEY, Q.C.:
 8 Q. You hadn't seen them. This is the -- for your
 9 interest, this is the June 19th, 2003 memo.
 10 You didn't see that back in '03?
 11 DR. CARTER:
 12 A. No, I didn't.
 13 COFFEY, Q.C.:
 14 Q. And the idea that, "following persistent
 15 erratic results of immunostains in our
 16 laboratory", that idea, when you showed up in
 17 2003 --
 18 DR. CARTER:
 19 A. No. I'm sorry, I'm reading it because this
 20 one as well, this is the first time I've seen
 21 it.
 22 COFFEY, Q.C.:
 23 Q. Okay.
 24 DR. CARTER:
 25 A. So I'm reading. No, I didn't really even know

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1 that there was any problem in the immuno lab
 2 until 2005.
 3 COFFEY, Q.C.:
 4 Q. Doctor, when you started at St. Clare's --
 5 well, you did your first work at St. Clare's,
 6 I think as best you can recall, was December
 7 of '03.
 8 DR. CARTER:
 9 A. Uh-hm.
 10 COFFEY, Q.C.:
 11 Q. Your stint there. When did you actually take
 12 your position and actually get the office at
 13 St. Clare's in the sense of have your own
 14 office?
 15 DR. CARTER:
 16 A. In August of 2004. Even when I came back for
 17 the locum in July, I was still operating out
 18 of a different office.
 19 COFFEY, Q.C.:
 20 Q. When you were appointed Associate Staff,
 21 that's when you would have gotten your own
 22 office?
 23 DR. CARTER:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. That office, who is your next door neighbour?
 2 DR. CARTER:
 3 A. Dr. Cook.
 4 COFFEY, Q.C.:
 5 Q. Okay, and did you -- you kept that office then
 6 over the -- you kept that office over the
 7 years?
 8 DR. CARTER:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. Until, I take it, recently?
 12 DR. CARTER:
 13 A. Until I resigned recently.
 14 COFFEY, Q.C.:
 15 Q. Exhibit P-2406. Doctor, these are the minutes
 16 of Division of Anatomical Pathology meeting at
 17 the General Hospital site, actually, September
 18 1, 2004. You can see the doctors listed
 19 there.
 20 DR. CARTER:
 21 A. Uh-hm, yes.
 22 COFFEY, Q.C.:
 23 Q. And this could be really -- you started in
 24 August, so --
 25 DR. CARTER:

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1 A. A couple weeks later.

2 COFFEY, Q.C.:

3 Q. Two weeks later. This meeting occurred

4 September 1, 2004, and paragraph 3.6 reads,

5 "HER2/neu ER/PR immunostaining. Dr. D.

6 Fontaine did mention that Dr. B. Carter would

7 like to receive all the new HER2/neu ER/PR

8 immunostaining before returning to the

9 reporting pathologist. Some members of the

10 division expressed that this is unnecessary

11 and they will continue reporting their own

12 cases". Now, Doctor, what can you tell us

13 about how this came up between yourself and

14 Dr. Fontaine?

15 DR. CARTER:

16 A. I have no specific memory of this, and my

17 assumption is that when I came to St. John's,

18 even when I was doing locums, I expressed my

19 wish to see as many breast cases as I could. I

20 was quite worried about losing the skills that

21 I had with breasts, the numbers here in St.

22 John's were quite low compared to the numbers

23 that I was seeing in McMaster. So I had

24 extended to many pathologists that I would

25 look at their cases, give them back to them

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1 for reporting, if that's what they wished, or

2 I would sign the cases out for them. It

3 wasn't limited to HER2/neu ER/PR

4 immunostaining. It was to any sort of breast

5 case that we had. So I'm not sure how this

6 came to be in this form in this memo.

7 COFFEY, Q.C.:

8 Q. Doctor, do you recall ever having any

9 discussions with Dr. Fontaine about the idea

10 of sub-specialization and it being desirable?

11 DR. CARTER:

12 A. Yes, but not specifically with Dr. Fontaine,

13 but, yes, I've made that conversation with

14 many people.

15 COFFEY, Q.C.:

16 Q. And, I take it, in McMaster, that had been the

17 case?

18 DR. CARTER:

19 A. We had partial sub-specialization or -- most

20 of my work was breast, but I did do other

21 things.

22 COFFEY, Q.C.:

23 Q. Doctor, you did practice in Hamilton, and I do

24 have that right, do I, between 1998 and 2003?

25 DR. CARTER:

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1 A. Hamilton, Ontario, yes.

2 COFFEY, Q.C.:

3 Q. And there, was there any particular facility

4 that you practised in?

5 DR. CARTER:

6 A. At the Henderson Hospital and at the Hamilton

7 Regional Cancer Centre, which has now changed

8 its name. I'm not sure what the new name is.

9 COFFEY, Q.C.:

10 Q. Doctor, what was the situation there in

11 respect of specialization of sub-

12 specialization?

13 DR. CARTER:

14 A. In our laboratory at the Henderson?

15 COFFEY, Q.C.:

16 Q. Yes.

17 DR. CARTER:

18 A. Each one of the pathologists that worked there

19 had a recognized sub-specialty. Some of us

20 crossed over into a second sub-specialty, but

21 usually our academic training was in one area,

22 and then you would pick up another area as you

23 were interested in it. Probably 50 percent of

24 the work was divided down the sub-specialty

25 line, but you would still be expected to take

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1 a wide variety of somewhat easier specimens,

2 or ones that didn't require sub-specialists

3 sign out is probably a better way to put it.

4 I would take part in other general duties of

5 pathology, but as a breast pathologist then, I

6 would be expected to go to breast disease site

7 group meetings, to breast rounds, to tumour

8 boards that were concerned with breast, and to

9 participate in research.

10 COFFEY, Q.C.:

11 Q. So, Doctor, when you arrived in St. John's --

12 of course, you'd been doing locums for a

13 while, as you've described, before you took up

14 this permanent position in August of 2004.

15 You, I take it, had expressed your views that

16 maybe sub-specialization might be desirable?

17 DR. CARTER:

18 A. Yes.

19 COFFEY, Q.C.:

20 Q. To anyone who would listen, as it were?

21 DR. CARTER:

22 A. Yes.

23 COFFEY, Q.C.:

24 Q. And Dr. Fontaine has told the Commissioner --

25 he's been here and he told the Commissioner

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1 that, in fact, he was of the same mind as
 2 yourself in that regard. Doctor, your view in
 3 that regard at that time, was it that there
 4 should be sub-specialization, period, or at
 5 least partial sub-specialization was
 6 desirable?
 7 DR. CARTER:
 8 A. Partial sub-specialization. I don't think
 9 that you can have full sub-specialization
 10 unless you're in a very large academic
 11 institution, but just necessities of cross
 12 coverage and covering operating rooms, you'd
 13 still need to require some basic pathology
 14 skills, and partial sub-specialization allows
 15 the more difficult cases -- I know for
 16 patients all cases are difficult, but, you
 17 know, cases that would require a little bit
 18 more finesse would go to somebody with sub-
 19 specialty knowledge of that area.
 20 COFFEY, Q.C.:
 21 Q. And, Doctor, what then in the 2004 and, well,
 22 I'll bring you up to the middle of 2005 at
 23 least initially. What was the reaction that
 24 you received when you would raise this?
 25 DR. CARTER:

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1 A. Some people were for the idea in theory, but
 2 had a lot of difficulty with seeing how in
 3 practice you would institute it. Other people
 4 were -- like, Dr. Fontaine, were quite happy
 5 with the concept and familiar with it, and
 6 some people preferred to retain their skills
 7 and do all of their own sign out.
 8 COFFEY, Q.C.:
 9 Q. So they were not in favour?
 10 DR. CARTER:
 11 A. They were not in favour.
 12 COFFEY, Q.C.:
 13 Q. Exhibit P-1919. Now, Doctor, this is an
 14 interoffice memorandum to Dr. Ejeckam, Mr.
 15 Dyer, and Ms. Thomas. Who's Ms. J. Thomas, do
 16 you recall?
 17 DR. CARTER:
 18 A. She's the secretary -- one of the secretaries
 19 at the department in St. Clare's Mercy
 20 Hospital site. She was also the private
 21 secretary to the clinical chief. She shared
 22 both duties.
 23 COFFEY, Q.C.:
 24 Q. And Mr. Dyer was the manager of pathology?
 25 DR. CARTER:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. And Dr. Ejeckam -- why was this addressed to
 4 Dr. Ejeckam, because you're writing in your
 5 capacity as chair, Quality Assurance
 6 Committee?
 7 DR. CARTER:
 8 A. I had spoken to Dr. Cook probably in the first
 9 part of October. I think you may have a memo
 10 from Dr. Cook about that time. He asked me
 11 was I interested in quality management
 12 programs, and asked me would I be interested
 13 in chairing the committee, and we discussed
 14 it. I gave him a proposal of what I thought
 15 our duties should be. I think it may be the
 16 second page in this exhibit.
 17 COFFEY, Q.C.:
 18 Q. Yes.
 19 DR. CARTER:
 20 A. And he spoke to Dr. Ejeckam. We felt that
 21 there should be a pathologist from each site
 22 on the committee, Mr. Dyer would be there in
 23 his capacity as lab manager, and Judy agreed -
 24 - Ms. Thomas agreed because we wanted
 25 representation from the clerical staff as

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1 well.
 2 COFFEY, Q.C.:
 3 Q. And there was - Dr. Ejeckam had been chairing
 4 the surgical pathology review committee, which
 5 goes back to the spring of 2003. In fact, it
 6 predates your involvement.
 7 DR. CARTER:
 8 A. Those committees would be unrelated to the one
 9 I --
 10 COFFEY, Q.C.:
 11 Q. I appreciate that, but he was chairing.
 12 DR. CARTER:
 13 A. And he was interested in QA.
 14 COFFEY, Q.C.:
 15 Q. So here's October 14th, and, of course, it's
 16 copied to Dr. Cook, as clinical chief, and
 17 you're setting up the first meeting. You
 18 conclude by saying, "I've enclosed an
 19 introductory document which should be read
 20 prior to the meeting, as well as an agenda for
 21 the meeting".
 22 DR. CARTER:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. Doctor, here's the memo itself. It's dated

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1 August 31st, 2004. It's to Dr. Cook from
 2 yourself. It's re; quality control and quality
 3 assurance committee in surgical pathology for
 4 the Health Care Corporation of St. John's.
 5 DR. CARTER:
 6 A. Uh-hm.
 7 COFFEY, Q.C.:
 8 Q. So, in effect, within two weeks of you taking
 9 your full time --
 10 DR. CARTER:
 11 A. Full time position.
 12 COFFEY, Q.C.:
 13 Q. Full time position --
 14 DR. CARTER:
 15 A. But I had been there since July 26th.
 16 COFFEY, Q.C.:
 17 Q. Yes, that yourself and Dr. Cook had discussed
 18 this, I take it?
 19 DR. CARTER:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. And you produced this memo as a result of your
 23 discussion?
 24 DR. CARTER:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. Now, Doctor, when you arrived, was there a
 3 quality control and quality assurance
 4 committee in surgical pathology?
 5 DR. CARTER:
 6 A. Not that I knew of. My understanding was that
 7 I was being asked to form one.
 8 COFFEY, Q.C.:
 9 Q. To create it, and from your perspective,
 10 Doctor, was there a need for one?
 11 DR. CARTER:
 12 A. I think there's a general need for them in all
 13 pathology laboratories.
 14 COFFEY, Q.C.:
 15 Q. And where you had been in Hamilton, was there
 16 one there? Whatever it was called, was there
 17 the equivalent of that there?
 18 DR. CARTER:
 19 A. Yes, there was the equivalent of that there.
 20 COFFEY, Q.C.:
 21 Q. And how about down in Vanderbilt?
 22 DR. CARTER:
 23 A. In Vanderbilt as well.
 24 COFFEY, Q.C.:
 25 Q. Back in the 90s?

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1 DR. CARTER:
 2 A. Yes, but, I mean, that is probably two very
 3 unusual institutions. I mean, it certainly
 4 wasn't a standard practice, but it was not
 5 uncommon practice.
 6 COFFEY, Q.C.:
 7 Q. On that point, Doctor, you refer to standard
 8 practice, at the time in the middle of 2004,
 9 how common or uncommon would the existence of
 10 a quality control and quality assurance
 11 committee be in respect of surgical pathology?
 12 DR. CARTER:
 13 A. If you look further down in the memo, I mean,
 14 we're talking a lot about pathologist's
 15 practice and that would be -- it wouldn't be a
 16 common occurrence. I just can't think of just
 17 a little less common qualifier. It wouldn't
 18 be rare, but it wouldn't be common. Quality
 19 control, quality assurance in the basic
 20 laboratory would be common.
 21 COFFEY, Q.C.:
 22 Q. But in pathologist practice, clinical
 23 practice, it would not have been common at
 24 that point?
 25 DR. CARTER:

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1 A. Not in an organized program.
 2 COFFEY, Q.C.:
 3 Q. In an organized program. But now for the
 4 laboratory itself, the technical end of the
 5 laboratory -
 6 DR. CARTER:
 7 A. I think that's been sort of standard practice
 8 in labs.
 9 COFFEY, Q.C.:
 10 Q. Since before your time?
 11 DR. CARTER:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Did you at the time have any understanding
 15 about whether there was a quality control or
 16 quality assurance committee or by whatever
 17 name in existence in the laboratory technical
 18 end of it?
 19 DR. CARTER:
 20 A. I don't think that I had any knowledge at that
 21 time, I would have just probably assumed that
 22 it was happening.
 23 COFFEY, Q.C.:
 24 Q. And as you've pointed out here, Doctor, you
 25 begin the memo by saying, "After reviewing the

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1 literature on quality control and quality
 2 assurance on surgical pathology, I would like
 3 to make the following recommendations for
 4 setting up a quality control and quality
 5 assurance committee and program in surgical
 6 pathology. The main goals of this committee
 7 will be to ensure the accuracy, timeliness and
 8 completeness of the diagnosis issue by the
 9 anatomic pathologists within the department at
 10 the Health Care Corporation of St. John's.
 11 One, members of QC/QA committee, one anatomic
 12 pathologist as chair, the second one, one from
 13 the second site"--which I take it is the
 14 other, well wherever the chair was from, the
 15 person from the other institution.
 16 DR. CARTER:
 17 A. The other site, yes.
 18 COFFEY, Q.C.:
 19 Q. Second pathologist, and Mr. Dyer will be there
 20 as technical manager and member of the
 21 clerical staff if possible. Which is why, I
 22 take it on your interoffice memo -
 23 DR. CARTER:
 24 A. Yes, Ms. Thomas had agreed to serve on the
 25 committee.

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1 COFFEY, Q.C.:
 2 Q. "The components of a monthly QA within the
 3 department, intradepartmental consultation
 4 review, minutes from the weekly meetings for
 5 intradepartmental consultation should be
 6 forwarded to the committee, as well as the
 7 final surgical pathology report for the cases
 8 under discussion. Quality assurance, quality
 9 control committee will ensure that appropriate
 10 protocol is followed during the
 11 intradepartmental consultation meeting and
 12 that the discussion is included in the final
 13 report." Doctor, what was that about?
 14 DR. CARTER:
 15 A. When a pathologist has a case that they think
 16 is a difficult or unusual, usually we'll seek
 17 consultation, it may be from someone in your
 18 department or he may decide to go to an
 19 outside expert and once you solicit that
 20 opinion, then that opinion should be included
 21 in the chart and if there is a difference of
 22 opinion, that should be reconciled, so the
 23 committee was going to monitor that practice
 24 so for cases sent out, as you heard this
 25 morning to the Mayo Clinic or the AFIP, we

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1 wanted to make sure that that consultative
 2 opinion got on the chart, was up loaded into
 3 Meditec, that the clinician was aware on the
 4 other end that the consultation had taken
 5 place and to see if there was any discrepancy
 6 in the opinions and same thing when you asked
 7 for a consult within your department. So if I
 8 asked Dr. Cook formally for a consultation,
 9 then I'm obliged to put that consultation into
 10 the patient's chart somehow.
 11 COFFEY, Q.C.:
 12 Q. I take it that up to this point in time,
 13 August and then September and October of 2004,
 14 there was no process in place to address that?
 15 DR. CARTER:
 16 A. No, I think people were having the
 17 consultations, if it was from the outside, I
 18 can't think of anyone who would not include
 19 that in the report. If it was from your
 20 neighbour, you may or may not, so we were just
 21 trying to formalize the process and monitor it
 22 and correct it if we found any deficiencies in
 23 the process.
 24 COFFEY, Q.C.:
 25 Q. So the, for example, within the department

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1 consultation or from one hospital to the other
 2 within the Health Care Corporation, the
 3 practice might vary from pathologist to
 4 pathologist, whether or not he or she would
 5 include a reference to the consultation and
 6 might even vary with a particular pathologist
 7 from time to time?
 8 DR. CARTER:
 9 A. Yes, this would be unusual for people not to
 10 include it, but you know, you're very strict
 11 when it comes from the Mayo Clinic, you make
 12 sure that you put that in the chart.
 13 COFFEY, Q.C.:
 14 Q. Then there's a reference to the top of the
 15 next page to frozen section review to be
 16 undertaken weekly by the QA, QC anatomic
 17 pathologist. Doctor, why the particular focus
 18 here on frozen section review?
 19 DR. CARTER:
 20 A. It's a standard facet of quality management
 21 programs for anatomic pathology department, so
 22 if you look at documents from the College of
 23 American Pathologists or from the Association
 24 of Directors of Anatomic and Surgical
 25 Pathology had asked, this would be a standard

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1 facet of a quality management program and it's
 2 there because frozen sections--do people know
 3 what frozen sections are?
 4 COFFEY, Q.C.:
 5 Q. You go ahead and tell the Commissioner, it
 6 never hurts for us to be reminded -
 7 DR. CARTER:
 8 A. It will be the true emergency for
 9 pathologists, for anatomical pathologists and
 10 general pathologists, when the surgeon is in
 11 the middle of an operation, they ask you to
 12 come down to the operating room, look at the
 13 tissues for them and help them make a decision
 14 as to how they should go about, you know,
 15 treating the patient at the time so the
 16 patient is under anesthesia. There are some
 17 time constraints to it, the most common things
 18 that we go down for at St. Clare's site, for
 19 example, is a woman with breast cancer or a
 20 man with breast cancer, we'll take a small
 21 biopsy of their lymph nodes in their arm pits
 22 and tell the surgeon whether or not they're
 23 positive. If they're negative, the surgeon
 24 will close them up. If they're positive, the
 25 surgeon will do a bigger exploration of their

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1 arm and they can end up with difficulties
 2 moving their arm and those sorts of things.
 3 So for us, it's an emergent and probably our
 4 most stressful time, so because it's emergent,
 5 it's the time where you will probably have
 6 errors, if I can use that word, occur, so
 7 there always has to be some statement when you
 8 sign out the report, well Dr. Carter said a
 9 frozen section that the sentinel lymph node
 10 was negative, but I looked at it, you know, in
 11 my leisure time and with more testing, and
 12 it's positive.
 13 COFFEY, Q.C.:
 14 Q. That would be the lymph node tested through
 15 having gone through the whole fixation
 16 process.
 17 DR. CARTER:
 18 A. Yes. So it's an area for us that is prone,
 19 can be prone to problems and it's an area for
 20 us where we want to make sure our skills are
 21 really sharp.
 22 COFFEY, Q.C.:
 23 Q. And hence the concentration by -
 24 DR. CARTER:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. - the College of American Pathologists and
 3 others on that particular aspect of ensuring
 4 QA/QC is carried out there.
 5 DR. CARTER:
 6 A. Yes.
 7 THE COMMISSIONER:
 8 Q. Are you anticipating here, when you talk about
 9 frozen section review, some kind of review of
 10 each or review of those where there was a
 11 difference or some kind of a representative
 12 sample?
 13 DR. CARTER:
 14 A. What we would do, because it's not that
 15 common, it was more common at the St. Clare's
 16 site than at the Health Science Centre, but
 17 you may end up talking maybe 30 cases per
 18 week, so the secretarial staff would pull--I
 19 was initially doing this, so they would pull
 20 the 30 frozen section diagnoses and the
 21 corresponding 30 final reports and I would
 22 just look at them to see if they concurred and
 23 to see if a statement was made by the
 24 pathologist. So it would be all of them.
 25 COFFEY, Q.C.:

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1 Q. And the next bullet, the second bullet on this
 2 page, Doctor, says "A random review of two
 3 percent of surgical pathology cases should be
 4 carried out on a weekly basis. This duty
 5 should rotate between all the Anatomic
 6 Pathologists in the Health Care Corporation of
 7 St. John's. The pathologist would comment on
 8 both the quality of the final report and the
 9 quality of the product from the Histology Lab.
 10 On a monthly basis, a similar procedure should
 11 be carried out on a randomly selected autopsy
 12 case. In both of these incidences, the
 13 clerical staff who was a member of the
 14 Surgical Pathology Committee, would evaluate
 15 and comment on the quality of the clerical
 16 report, as well as the accuracy of the coding
 17 issues." First of all, this Surgical
 18 Pathology Committee there, was that Dr.
 19 Ejeckam's committee?
 20 DR. CARTER:
 21 A. No, that should be the QA committee. I type a
 22 lot of my own memos, so that may be recurring
 23 thing.
 24 COFFEY, Q.C.:
 25 Q. Okay, the clerical staff, in this case as it

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1 turns out it was Ms. Thomas?
 2 DR. CARTER:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. Okay, the clerical staff who was a member of
 6 your committee, in fact, the QC/QA Committee,
 7 I'll call it.
 8 DR. CARTER:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. Would evaluate and comment on the quality of
 12 the clerical report, as well as the accuracy
 13 of the coding issues. So Ms. Thomas would be
 14 counted upon to do that?
 15 DR. CARTER:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. That's her background.
 19 DR. CARTER:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. Then you have "a random review of two percent
 23 of surgical pathology cases would be carried
 24 out on a weekly basis." Could you tell us
 25 what was envisaged here?

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

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1 Q. And as well--up to this point, had frozen
 2 sections been reviewed?
 3 DR. CARTER:
 4 A. No.
 5 COFFEY, Q.C.:
 6 Q. Okay, they weren't being.
 7 DR. CARTER:
 8 A. No.
 9 COFFEY, Q.C.:
 10 Q. Okay, so the person who would be looking at it
 11 critically and carefully would be the surgeon.
 12 DR. CARTER:
 13 A. Yes, and so people always know that they're
 14 under scrutiny when they're doing a frozen
 15 section, so random review is more reflective
 16 of what's going on in your department.
 17 COFFEY, Q.C.:
 18 Q. And up to this point in time was there any
 19 such random review going on?
 20 DR. CARTER:
 21 A. Not that I know of.
 22 COFFEY, Q.C.:
 23 Q. And "This duty should rotate between all of
 24 the Anatomic Pathologists in the Health Care
 25 Corporation." Now this would be the duty to

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1 carry out this two percent check, I take it?
 2 DR. CARTER:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. So the idea was if you were -
 6 DR. CARTER:
 7 A. I can't review my own work, so there needs to
 8 be another pathologist and just to rotate the
 9 duty, time constraints job -
 10 COFFEY, Q.C.:
 11 Q. So the idea would be one week Dr. Carter would
 12 do two percent of last week's cases and
 13 randomly pick them and review them.
 14 DR. CARTER:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. And the next week Dr. Cook might and the next
 18 week Dr. Denic might.
 19 DR. CARTER:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. That sort of -
 23 DR. CARTER:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. And it would just kind of go on all the way
 2 through the Health Care Corporation. Now on
 3 both the quality of the final report, they
 4 were expected to common on, the quality of the
 5 final report and the quality of the product
 6 from the histology lab, I want to ask you
 7 about that, now this report of two percent
 8 cases, what in practice would that involve?
 9 Like if your number was up and you were going
 10 to do review, Dr. "X"'s case, because that's
 11 one of the random ones, what would you expect
 12 as the reviewer, what was expected of you?
 13 DR. CARTER:
 14 A. You would receive the slides on that case and
 15 you would receive the surgical block--or
 16 sorry, the surgical report, so you would read
 17 the surgical report. If we're going to stay
 18 in the realm of breast, so if you had a breast
 19 biopsy that was called infiltrating carcinoma,
 20 so you'd have that report, then you would go
 21 to the slides and make some sort of comment on
 22 the quality of the slides and I know people
 23 have talked about that a lot, so you would
 24 comment on the staining and whether or not the
 25 tissue is adequate, those sorts of things.

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1 And then you would do your own evaluation and
 2 make your own diagnosis and see if you agreed
 3 with the original pathologist.
 4 COFFEY, Q.C.:
 5 Q. What was expected then or what did you
 6 envisage would happen then? You reviewed, say
 7 I'm a fellow pathologist, you reviewed my case
 8 and made your observations, what would happen
 9 then?
 10 DR. CARTER:
 11 A. Then you would call that a discrepant case and
 12 -
 13 COFFEY, Q.C.:
 14 Q. If you found discrepancies.
 15 COFFEY, Q.C.:
 16 Q. And so one of the first things that happened
 17 was that you'd need then to write a policy
 18 about what you do about discrepant cases.
 19 What we had decided to do was discrepant cases
 20 would be brought to Dr. Denic or Dr. Cook,
 21 whoever was the clinical chief at the time, I
 22 can only remember going to Dr. Denic once, so
 23 it may have been done, may have been around
 24 when we had discrepant cases, and then Dr.
 25 Denic would look at the report in the case and

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1 if he felt it was within the realm of what he
 2 could do, he would have a look at it or refer
 3 to one of the people who were, in essence,
 4 practising such specialty, a pathology there
 5 and if he needed an outside consultation, that
 6 would happen, but most of them will be
 7 resolved around a meeting around the
 8 microscope.
 9 COFFEY, Q.C.:
 10 Q. And the next bullet says, "Clinical parameter
 11 review should take place on a monthly basis."
 12 What is clinical parameter review?
 13 DR. CARTER:
 14 A. Again, this is standard from ADASP and CAP,
 15 that once a month you would take either a
 16 disease site, specific disease process or
 17 specific surgical pathology specimen, so for
 18 one month you could look at all of the
 19 gallbladders that came in for whatever reason
 20 and go down through them and do the same
 21 things that I just talked about. Again, it's
 22 a random review of cases that come through the
 23 department, but it gives you more of an idea
 24 if you happen to hit upon an area where there
 25 may be problems with the diagnosis.

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1 COFFEY, Q.C.:
 2 Q. Doctor, here it says, "specimen or a disease
 3 will be selected, all appropriate cases from
 4 that month will be reviewed by an anatomic
 5 pathologist", I take it again that's somebody
 6 whose name has just come up.
 7 DR. CARTER:
 8 A. Somebody in one of the two sites, yes.
 9 COFFEY, Q.C.:
 10 Q. And forwarded to the chair of the QA/QC
 11 Committee. What would be forwarded, the
 12 person's--the reviewer's views?
 13 DR. CARTER:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. And again, I take it this was not being done
 17 at that time?
 18 DR. CARTER:
 19 A. Not that I know if, no.
 20 COFFEY, Q.C.:
 21 Q. "Inter-institutional reviews should be
 22 forwarded on a monthly basis to the chair of
 23 the QC/QA Committee." What are they, inter-
 24 institutional reviews?
 25 DR. CARTER:

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

16 COFFEY, Q.C.:
 17 Q. The diagnosis originally within the
 18 institution itself?

19 DR. CARTER:
 20 A. Yes.

21 COFFEY, Q.C.:
 22 Q. And the outside views upon review. And up to
 23 that point in time, was that going on?

24 DR. CARTER:
 25 A. Not in a formal way, but as I explained

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

3 COFFEY, Q.C.
 4 Q. They'd put it on the patient's chart
 5 certainly?

6 DR. CARTER:
 7 A. Yes.

8 COFFEY, Q.C.
 9 Q. "On a weekly basis, the technical member of
 10 the committee should forward a report to the
 11 chair of the committee which includes a
 12 special adequacy record, the lost specimen
 13 record, a histology slide delivery record, a
 14 quality control to histology record and a
 15 quality control from histology record". Could
 16 you explain to the Commissioner what this -

17 DR. CARTER:
 18 A. Well, the first one is a specimen adequacy
 19 record, not a special adequacy record. So,
 20 specimens that come into the lab from -

21 COFFEY, Q.C.
 22 Q. It should read specimen.

23 DR. CARTER:
 24 A. Should read specimen, yes. Specimens that
 25 come into the lab from outside clinics or form

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

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

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

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

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

14 COFFEY, Q.C.
 15 Q. Now, the technical member of the committee, in
 16 this context, would have been whom?

17 DR. CARTER:
 18 A. Barry Dyer, Mr. Dyer.

19 COFFEY, Q.C.
 20 Q. And so here, it would either be him or his
 21 nominee.

22 DR. CARTER:
 23 A. Yes, yes.

24 COFFEY, Q.C.
 25 Q. That would be the idea, whoever -

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1 DR. CARTER:
 2 A. The understanding was not that the four people
 3 on the committee do all of the work, it would
 4 have to be distributed.
 5 COFFEY, Q.C.
 6 Q. And that may have been going on informally,
 7 but it certainly wasn't going on formally or -
 8 DR. CARTER:
 9 A. No.
 10 COFFEY, Q.C.
 11 Q. How much was it really going on informally, in
 12 terms of -
 13 DR. CARTER:
 14 A. I think the specimen adequacy record, I'm not
 15 sure that they were keeping records of it, but
 16 they would check for that. And if they found,
 17 in fact, that there was no specimen, they
 18 would fill out incident reports or if they
 19 found that there was an error in the labelling
 20 of the specimen, they would bring it back to
 21 the operating room or telephone somebody from
 22 the clinic to come and to rectify it. The
 23 loss specimen record, I've said, histology
 24 slide delivery record, that wasn't happening
 25 at all. Quality control to histology and from

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

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

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1 Clare's sites. The main goals of the
 2 committee are to ensure accuracy, timeliness
 3 and completeness of diagnosis by pathologists
 4 within the division". Doctor, the driving
 5 force behind this was whom?
 6 DR. CARTER:
 7 A. Dr. Cook, Don Cook.
 8 COFFEY, Q.C.
 9 Q. And if we could go back please to Exhibit P-
 10 1919, I apologize. Doctor, I didn't look at
 11 the last page of it, page four which is the QA
 12 meeting, scheduled for November 9, 2004. I
 13 take it that would probably have been the
 14 first -
 15 DR. CARTER:
 16 A. Yes, that would be the first meeting.
 17 COFFEY, Q.C.
 18 Q. So, the end of 2004, this is being organized?
 19 Exhibit P-2451. Now, Doctor, this is a form
 20 entitled "Annual Review of Medical Staff" for
 21 the year 2004. The person being reviewed is
 22 yourself.
 23 DR. CARTER:
 24 A. Yes.
 25 COFFEY, Q.C.

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1 Q. I ask you about, on the second page of this,
 2 of the exhibit, there's a reference to
 3 Atlantic Breast Cancer Network newsletter.
 4 DR. CARTER:
 5 A. Yes.
 6 COFFEY, Q.C.
 7 Q. "Breast Cancer Pathology Report, the Role of
 8 your Pathologist".
 9 DR. CARTER:
 10 A. Yes.
 11 COFFEY, Q.C.
 12 Q. Doctor, I take it that this would have been
 13 completed in relation to the calendar year
 14 2004, this document?
 15 DR. CARTER:
 16 A. Yes, that would be my academic review for
 17 2004.
 18 COFFEY, Q.C.
 19 Q. Doctor, I'm going to ask you about the
 20 communication between, that you found when you
 21 arrived here in St. John's in '03 for you
 22 locums and then '04, your permanent position.
 23 What sorts of communications occurred between
 24 pathologists and then from pathologists to
 25 oncologists or other physicians, formal and

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

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1 conference room in the cancer clinic. It kept
 2 growing over time as well with more interested
 3 parties.
 4 COFFEY, Q.C.
 5 Q. So, this was already in existence when you
 6 arrived in '03?
 7 DR. CARTER:
 8 A. Yes.
 9 COFFEY, Q.C.
 10 Q. And what sorts of physicians would go to this?
 11 DR. CARTER:
 12 A. Pathology, surgery, radiology, medical
 13 oncology, radiation oncology, palliative care,
 14 medicine.
 15 COFFEY, Q.C.
 16 Q. Was there any structure to this meeting?
 17 DR. CARTER:
 18 A. Yes, they would be chaired by one of the--
 19 usually by Dr. McCarthy, I think, and then she
 20 would have a designate when she wasn't around.
 21 Sometimes it would be radiation oncology,
 22 sometimes medical, so, usually one of the
 23 clinical oncologists. And cases would be
 24 presented, various aspects of them, maybe
 25 pathology, maybe radiology, maybe just a

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

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1 And in the course of our conversation, we
 2 talked about this idea, just been coming on in
 3 many places in the United States and larger
 4 centres in Canada and we talked about getting
 5 something like that for on the website for
 6 women and men. And she asked me to write this
 7 article, which I did.
 8 COFFEY, Q.C.
 9 Q. Which is, I take it, describes what it is a
 10 pathologist's role is in breast cancer.
 11 DR. CARTER:
 12 A. Yes, but also what people should know about
 13 their pathology report and what they should
 14 understand when the oncologist, whether that's
 15 the surgeon or the medical oncologist tells
 16 them, you have a 1.2 centimetre, grade 3 with
 17 LVI. I mean it explained all those things for
 18 them.
 19 COFFEY, Q.C.
 20 Q. And the significance potentially of -
 21 DR. CARTER:
 22 A. In basic detail.
 23 COFFEY, Q.C.
 24 Q. Basic detail, yes. Doctor, not for the
 25 general audience, for the particular audience

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1 of oncologists, we've heard certain evidence
 2 here about pathologists did not and do not
 3 have, they certainly haven't up until very
 4 recently have not had a uniform way or
 5 reporting particular things very often. An
 6 example, breast pathology would be ER/PR,
 7 sometimes the word positive and negative is
 8 used, sometimes percentages, sometimes a
 9 combination of percentages and words.
 10 DR. CARTER:
 11 A. Yes.
 12 COFFEY, Q.C.
 13 Q. Doctor, before the middle of 2005, what, if
 14 any, understanding did you have about how much
 15 oncologists understood, for example, about
 16 ER/PR positive/negative? I mean you would
 17 use the word negative, did you have any
 18 understanding of what they understood you
 19 meant by negative?
 20 DR. CARTER:
 21 A. Here in St. John's?
 22 COFFEY, Q.C.
 23 Q. Yes, and was this sort of thing ever
 24 discussed?
 25 DR. CARTER:

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1 A. I think it would have been discussed at the
 2 tumour boards when we were talking about
 3 patients. My understanding shortly after I
 4 came here was that ten percent was being used
 5 as a cutoff by the oncologists.
 6 COFFEY, Q.C.
 7 Q. And you would have gotten that understanding
 8 from whom, do you think?
 9 DR. CARTER:
 10 A. From the oncologists at tumour boards. I
 11 probably would have asked, what are you using
 12 for your cutoff?
 13 THE COMMISSIONER:
 14 Q. Could you explain exactly what a tumour board
 15 is?
 16 DR. CARTER:
 17 A. Multiple disciplines get together and one of
 18 the physicians who has a difficult case for a
 19 variety of reasons will submit that patient's
 20 name to the tumour board and when we got into
 21 the tumour board, that physician will present
 22 the case, the radiologist will have the
 23 radiology reports at hand. I'll have the
 24 pathology reports at hand. So, they may be
 25 asking questions about what's the best way to

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1 approach this surgically or do you think I
 2 should give them another treatment or do I
 3 need to have the pathology reviewed. So,
 4 we'll discuss it as a group and try to come up
 5 with some sort of consensus. It's usually for
 6 difficult cases.
 7 THE COMMISSIONER:
 8 Q. So, what's the difference in doing a round and
 9 doing a tumour board, your Wednesday morning
 10 rounds?
 11 DR. CARTER:
 12 A. Did I say Wednesday morning rounds? I would
 13 mean the tumour boards -
 14 THE COMMISSIONER:
 15 Q. Well, there was a reference to what you called
 16 rounds on Wednesday morning and I'm just
 17 wondering what the difference is, if any,
 18 between rounds and tumour boards?
 19 DR. CARTER:
 20 A. If I said rounds, I meant tumour boards.
 21 THE COMMISSIONER:
 22 Q. Oh, okay.
 23 DR. CARTER:
 24 A. If it's somebody else, like, I -
 25 COFFEY, Q.C.

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1 Q. Well, on that point, is there a difference?
 2 DR. CARTER:
 3 A. Between rounds and tumour boards?
 4 COFFEY, Q.C.
 5 Q. Yes.
 6 DR. CARTER:
 7 A. I think rounds, word that is used often for
 8 clinical meetings where you would be
 9 presenting, like medical grand rounds or
 10 surgical grand rounds. If pathologists meet
 11 together to discuss cases, we would call that
 12 rounds.
 13 COFFEY, Q.C.
 14 Q. And would these tumour board meetings, panels,
 15 tumour boards, would they, almost because of
 16 their very nature, be considered rounds, a
 17 form of rounds?
 18 DR. CARTER:
 19 A. Yes.
 20 COFFEY, Q.C.
 21 Q. But there would be round that would not tumour
 22 boards?
 23 DR. CARTER:
 24 A. Yes.
 25 COFFEY, Q.C.

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1 Q. The rounds is the wider, more generic term.
 2 DR. CARTER:
 3 A. Yes.
 4 COFFEY, Q.C.
 5 Q. Exhibit P-1395, please. Doctor, this is a
 6 report of the laboratory medicine program to
 7 clinical chiefs and MAC for January/February
 8 2005, paragraph four, under quality
 9 initiative, "Dr. Bev Carter, our quality
 10 assurance co-ordinator is currently working on
 11 documenting policies and procedure in the
 12 division of anatomical pathology. Some of Dr.
 13 Carter's priorities include better document of
 14 quality control and intra-department rounds,
 15 as well as correlation of intra-operative
 16 frozen section interpretations with the final
 17 pathology report. It is my help"--that would
 18 be Dr. Cook's help"--to generate a quality
 19 assurance report from this division as part of
 20 our annual program report" and a space for Dr.
 21 Cook's signature is on the next page. Doctor,
 22 so you'd had a meeting back in November, 2004
 23 and then how far then did this initiative
 24 advance?
 25 DR. CARTER:

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

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1 the estrogen and progesterone is about to
 2 happen in time. Thank you.
 3 THE COMMISSIONER:
 4 Q. All right then, we'll take the afternoon
 5 break.
 6 (BREAK)
 7 THE COMMISSIONER:
 8 Q. Please be seated. Mr. Coffey.
 9 COFFEY, Q.C.:
 10 Q. Thank you, Commissioner. Registrar, Exhibit
 11 P-1395, please? Just before I leave this,
 12 Doctor, I want to clarify something. "Better
 13 documentation of quality control and
 14 intradepartmental rounds." These rounds, is
 15 that both of these, quality control and
 16 intradepartmental rounds?
 17 DR. CARTER:
 18 A. Yes. At the St. Clare's site, they were
 19 called quality control rounds and at the
 20 Health Sciences, they were called
 21 intradepartmental. Essentially both are when
 22 the pathologists sit around together and show
 23 difficult or unusual cases and ask for
 24 opinions.
 25 COFFEY, Q.C.:

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

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

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

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1 Q. And so he'd come into your office with these
 2 slides and said "Bev, would you have a look?"
 3 DR. CARTER:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. "Tell me what you think." And you looked and
 7 they certainly looked positive to you?
 8 DR. CARTER:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. And this was, these were the slides, I take it
 12 the retest slides for Peggy Deane?
 13 DR. CARTER:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. Doctor, you indicated just now that you did
 17 have a brief discussion with him at the time
 18 about how these things can happen?
 19 DR. CARTER:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. What did you mean by that?
 23 DR. CARTER:
 24 A. He had shown me the slides and said that this
 25 patient was negative before. So he would have

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1 asked, you know, had I seen it before, you
 2 know, yes.
 3 COFFEY, Q.C.:
 4 Q. Had you seen what?
 5 DR. CARTER:
 6 A. Had I seen this phenomenon, you know, happen
 7 before. I mean, I would have answered yes.
 8 We would have talked about, you know, what
 9 kind of things can cause cases to be negative
 10 in one instance and positive in the other, but
 11 I mean, it was just a very brief -
 12 COFFEY, Q.C.:
 13 Q. So what, if anything, did you have to say to
 14 Dr. Cook at the time about how this sort of
 15 phenomenon can occur?
 16 DR. CARTER:
 17 A. I can't remember the specific conversation,
 18 but I can tell you what I think I would have
 19 said.
 20 COFFEY, Q.C.:
 21 Q. Sure.
 22 DR. CARTER:
 23 A. At the time, I mean I probably, you know,
 24 would have talked about false negatives in
 25 general, you know, patients who are weak

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1 expressers. Have you--you've come across
 2 that?
 3 COFFEY, Q.C.:
 4 Q. Well, perhaps you could just--we've heard the
 5 term, but you could expand upon that to the
 6 Commissioner.
 7 DR. CARTER:
 8 A. Most patients, when you look at their breast
 9 cancer cases for estrogen receptor and
 10 progesterone receptor testing, mostly for
 11 estrogen receptor testing, they're either
 12 easily recognizable as positive or completely
 13 negative. So about 80 percent of your
 14 patients will be either negative or greater
 15 than 75 percent ER positivity. A small
 16 percentage of them are somewhere in between
 17 and a very small percentage of them are
 18 somewhere between say five and 15 percent, and
 19 you would call that a weak expressers, because
 20 it's around the treatment point. And if they
 21 were a weak expresser, and then your test
 22 wasn't optimized, you may have, in the one
 23 instance, that person being negative and then
 24 in another instance, that person being
 25 positive. Problems with the testing being

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1 run, just those sorts of things, but it was
 2 just a very general and not a specific
 3 conversation.
 4 COFFEY, Q.C.:
 5 Q. These particular slides for Ms. Deane, the
 6 slides that you looked at, I take it because
 7 you understood they were the retest slides?
 8 DR. CARTER:
 9 A. They would have been the new slides.
 10 COFFEY, Q.C.:
 11 Q. The new slides, you've indicated that they
 12 were readily apparently positive?
 13 DR. CARTER:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. They weren't something that was negative and
 17 was now a weak positive. They were positive?
 18 DR. CARTER:
 19 A. They were positive.
 20 COFFEY, Q.C.:
 21 Q. Doctor, do you recall, at that time, being
 22 told anything about what the original
 23 classification of them had been?
 24 DR. CARTER:
 25 A. That it was negative. I knew that, but I

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1 didn't know anything about percents or
 2 anything like that.
 3 COFFEY, Q.C.:
 4 Q. I take it you didn't see the original slides
 5 at that point?
 6 DR. CARTER:
 7 A. No.
 8 COFFEY, Q.C.:
 9 Q. Have you ever seen Ms. Deane's original
 10 slides?
 11 DR. CARTER:
 12 A. No.
 13 COFFEY, Q.C.:
 14 Q. Doctor, you indicated as well that not too
 15 long after that, you were contacted by Dr.
 16 McCarthy?
 17 DR. CARTER:
 18 A. Yes, I'm pretty sure that it was Dr. McCarthy.
 19 COFFEY, Q.C.:
 20 Q. And at the time that Dr. Cook spoke to you,
 21 just before I leave that, initially, was there
 22 any discussion about the type of cancer that
 23 Ms. Deane had, invasive lobular?
 24 DR. CARTER:
 25 A. At the time that he showed me the positives?

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1 COFFEY, Q.C.:

2 Q. Yes.

3 DR. CARTER:

4 A. I don't think at the time, but I mean, there

5 was a lot happened in those three or four

6 weeks. That issue came up in the next two or

7 three weeks, but I don't know if it was that

8 day.

9 COFFEY, Q.C.:

10 Q. So when Dr. McCarthy though, in any case, you

11 recall she contacted you.

12 DR. CARTER:

13 A. And I believe she had a patient who was

14 infiltrating lobular. It was either that or

15 the patient was post menopausal, small low

16 grade tumour, something that you would expect

17 to be positive.

18 COFFEY, Q.C.:

19 Q. So -

20 DR. CARTER:

21 A. I know by the time that Joy, that Dr. McCarthy

22 called, those sorts of surrogate issues had

23 come up.

24 COFFEY, Q.C.:

25 Q. And did Dr.--when Dr. McCarthy contacted you,

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1 was she contacting you to say that "I have a

2 second patient and I'd like the patient

3 retested," or "I have had a second patient

4 retested and this is the result," do you

5 recall?

6 DR. CARTER:

7 A. I think it would have been to ask me to

8 retest, but again, I'm not certain.

9 COFFEY, Q.C.:

10 Q. You can't recall. So what then happened,

11 Doctor? Can you just describe then, you've

12 got two cases, both of which have converted,

13 to use that term that's been used here?

14 DR. CARTER:

15 A. And I thought that there was a third as well.

16 COFFEY, Q.C.:

17 Q. Yes.

18 DR. CARTER:

19 A. I thought that we had Peggy's case and then

20 two sort of -

21 COFFEY, Q.C.:

22 Q. There were two others in that, yes.

23 DR. CARTER:

24 A. - highly selected. I thought I've seen some

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1 memos where they talk about two in total, but

2 I thought there were three.

3 COFFEY, Q.C.:

4 Q. And on that point, Doctor, your memory will be

5 borne out. We'll see from the documents as we

6 go along.

7 DR. CARTER:

8 A. Okay. And there was a lot of talk in the lab

9 at St. Clare's about, you know, what could be

10 happening and I think Don, Dr. Cook was

11 talking to the oncologists and Dr. Williams

12 about, you know, whether or not this was an

13 issue or a few isolated highly selected cases

14 that you would expect to, you know, to

15 convert. So we had a meeting on May 17th, I

16 think it was, with the two oncologists who

17 have been involved with the patients who we

18 were talking about at this time, myself and

19 Dr. Cook and the lab manager, Mr. Dyer, and

20 discussed the issue to see if we could come up

21 with a plan of how we were going to discover

22 whether or not this was an isolated case,

23 several isolated cases, something that was

24 confined to the time of Peggy Deane's testing,

25 or if it was something that was more

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1 widespread than that, and at the end of the

2 meeting, we decided to look back at 2002 and

3 look at all of the negatives at that time,

4 both look at the old slides and retest the

5 cases and perhaps go into 2001, if we didn't

6 have a big enough number to draw any sort of

7 conclusion. Because I think one of the new

8 cases was in 2001, and perhaps take it outside

9 of St. John's, and look at cases from 2002

10 that were done from other hospitals around St.

11 John's.

12 COFFEY, Q.C.:

13 Q. So why 2002, Doctor?

14 DR. CARTER:

15 A. Because that was where the index case had come

16 from. So it just served as an idose

17 (phonetic), no real scientific reason for it,

18 but it would serve an idose and we would move

19 out from there.

20 COFFEY, Q.C.:

21 Q. Start where the -

22 DR. CARTER:

23 A. Where the problem arose.

24 COFFEY, Q.C.:

25 Q. - in the same time frame where Ms. Deane's

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1 case was and move on from there?
 2 DR. CARTER:
 3 A. Yeah, and see--move out from there and see if
 4 you can--just we were more or less doing a
 5 broad based approach to see if we could gather
 6 any information about what was going on.
 7 COFFEY, Q.C.:
 8 Q. Go ahead, Doctor, what then happened?
 9 DR. CARTER:
 10 A. Where am I?
 11 COFFEY, Q.C.:
 12 Q. Well, you've gone through your meeting of May
 13 17th, okay.
 14 DR. CARTER:
 15 A. And we began to look at some of the cases from
 16 2002 and we had also agreed that as patients
 17 came in to oncologists' office, if they felt
 18 that they wanted somebody who was originally
 19 diagnosed in 2003 retested that we would do
 20 that. So we had kind of a mixture of
 21 patients. I think the first group that we had
 22 looked at, and I would probably do better with
 23 the exhibits, but I'll give you my rough
 24 estimates.
 25 COFFEY, Q.C.:

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

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

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

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1 A. Things that I wanted to look at were, in fact,
 2 who the patients are. So I didn't want a stack
 3 of papers and say these are the patients. I
 4 wanted to see how did you find those patients,
 5 how did you search, you know, for those
 6 negatives, are we missing people, that sort of
 7 thing. I wanted to look at the external
 8 controls that had been read, as you were shown
 9 this morning, and I'm sure other times, to
 10 look at the external controls and try to
 11 correlate them to specific test results. I
 12 wanted to look at the policies and procedures
 13 that they had in the immunohistochemistry lab,
 14 I wanted to see the optimization of the
 15 protocol for ER/PR testing, the validation,
 16 the antibodies, the spec sheets for the
 17 antibodies, the QA that was going on in the
 18 lab, and then look at the slides themselves.
 19 COFFEY, Q.C.:
 20 Q. That would be the original and the retest --
 21 you would have probably the retest slides, but
 22 the original slides too?
 23 DR. CARTER:
 24 A. A lot of them hadn't had retests and I was
 25 pulling them, so both things were happening

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1 simultaneously.
 2 COFFEY, Q.C.:
 3 Q. I apologize.
 4 DR. CARTER:
 5 A. So look at the original slides, make
 6 assessments on those about whether or not I
 7 agreed with the original pathologist, status
 8 of the control tissues, were they present,
 9 were they positive, general assessment of the
 10 slides themselves, what the quality of the
 11 slide was, looking at the report, looking at
 12 things that will be considered surrogate
 13 markers, so sub-types, grading, those sorts of
 14 things.
 15 COFFEY, Q.C.:
 16 Q. And, Doctor, we do have a letter of yours. I
 17 believe it's July 14th, and I'll be looking at
 18 that. The list really you've just set out is
 19 there.
 20 DR. CARTER:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. In a formal way. Doctor, so I take it that
 24 you were prepared, in effect, to undertake a
 25 full scale review of this?

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1 DR. CARTER:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. And that's certainly --
 5 DR. CARTER:
 6 A. To begin one, at least.
 7 COFFEY, Q.C.:
 8 Q. You were certainly going to try.
 9 DR. CARTER:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. You planned to.
 13 DR. CARTER:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. And that only -- involved not only the
 17 pathologist's work itself, whatever pathology
 18 reports and the slides that they would have
 19 looked at, but as well, I take it, what went
 20 on and was going on in the laboratory itself?
 21 DR. CARTER:
 22 A. Yes, and the -- to a lesser extent, to the
 23 operating room.
 24 COFFEY, Q.C.:
 25 Q. Yes, relating to the fixation matter?

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1 DR. CARTER:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. Aspect of the matter. So what did you find
 5 then, Doctor? This was your plan.
 6 DR. CARTER:
 7 A. Well, I wasn't able to obtain a lot of
 8 information from -- documentation from the
 9 laboratory. I wasn't able to see very many of
 10 the external controls. I'm not sure that I
 11 saw any of the external controls at all, but I
 12 wasn't able to see any of those. I was never
 13 able to see the search parameters for
 14 identifying these patients. Slides and blocks
 15 were with the spreadsheets -- I guess we'll go
 16 through them, and we had a fair number, I
 17 think, by the time that I finished, but they
 18 were definitely slow in coming. I had
 19 difficulty getting support staff to carry out
 20 the functions that I needed when I looked at
 21 the slides.
 22 COFFEY, Q.C.:
 23 Q. And I'll get to that in a moment. So, Doctor,
 24 you say you had difficulty. Was that because,
 25 at least in respect of some of this material,

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1 it didn't exist, or you were told it didn't
 2 exist?
 3 DR. CARTER:
 4 A. Yes, in terms of documentation for the
 5 laboratory and even for the external controls.
 6 They were filed. There was no way of matching
 7 August 8th with August 8th.
 8 COFFEY, Q.C.:
 9 Q. 2003, for example?
 10 DR. CARTER:
 11 A. Right.
 12 COFFEY, Q.C.:
 13 Q. Or 2002.
 14 DR. CARTER:
 15 A. Yes. So they could show you that there was
 16 controls there, but they couldn't match them
 17 up.
 18 COFFEY, Q.C.:
 19 Q. And can you just describe that? For example,
 20 if a patient's ER and PR slides were produced
 21 on August 8th, 2002, I'll just use that date,
 22 in runs by the lab that day, what was your
 23 understanding, and if indeed there were ER and
 24 PR control slides run that day, what was the
 25 difficulty in matching those control slides

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1 with that patient's ER/PR slides? What was
 2 the --
 3 DR. CARTER:
 4 A. I was never able to get the external controls,
 5 but my understanding is that there was no way
 6 to match this control with this patient. You
 7 simply had a number of patient cases and a
 8 number of control cases, but you didn't know
 9 which ones had been run at the same time?
 10 COFFEY, Q.C.:
 11 Q. The control slides, did you ever see any
 12 control slides, ER and PR control slides, you
 13 know, during this review?
 14 DR. CARTER:
 15 A. I don't -- I don't think so, but I've seen
 16 some since, so it's really hard --
 17 COFFEY, Q.C.:
 18 Q. Hard to tell.
 19 DR. CARTER:
 20 A. There's so much going on in the last three
 21 years, but I don't think I saw any at that
 22 point, or if I did, they were very few.
 23 COFFEY, Q.C.:
 24 Q. How were they identified? A control slide was
 25 identified in what way?

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1 DR. CARTER:
 2 A. It would be marked ER control.
 3 COFFEY, Q.C.:
 4 Q. ER control. Would it be dated?
 5 DR. CARTER:
 6 A. Not the ones that I saw, because that was the
 7 problem, if you had the date, you could kind
 8 of correlate them roughly.
 9 COFFEY, Q.C.:
 10 Q. So you ran into a problem with documentation,
 11 being provided with documentation which you
 12 had requested. The external controls were
 13 problematic, from your perspective, in the
 14 sense of being able to match them up with
 15 cases done years before.
 16 DR. CARTER:
 17 A. What I was able to find out about them, yes.
 18 COFFEY, Q.C.:
 19 Q. Doctor, in a broad strokes approach to this
 20 right now, what then happened? I mean, you're
 21 faced with this and you had looked at some
 22 original slides, I gather?
 23 DR. CARTER:
 24 A. Yes.
 25 COFFEY, Q.C.:

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1 Q. And there were a number of -- I think there's
 2 a third batch of retests go on. In July,
 3 there's 25, roughly 33, and then there's
 4 another group, and we'll see that --
 5 DR. CARTER:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Conversions. What then happened, Doctor?
 9 DR. CARTER:
 10 A. I looked at some of the slides that had been
 11 reviewed by other people. I --
 12 COFFEY, Q.C.:
 13 Q. In an overview way, what did you find in that?
 14 DR. CARTER:
 15 A. In the slides?
 16 COFFEY, Q.C.:
 17 Q. Yes.
 18 DR. CARTER:
 19 A. I shouldn't say other people because, as you
 20 know, I was in there too.
 21 COFFEY, Q.C.:
 22 Q. Yes, you're one of them too.
 23 DR. CARTER:
 24 A. But "us" people. I found that there was
 25 problems with fixation that you could identify

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1 by looking at the slide, that there were a
 2 number of slides without internal control, and
 3 a number of slides that internal control --
 4 COFFEY, Q.C.:
 5 Q. Was present.
 6 DR. CARTER:
 7 A. Was present, but not staining, and I found a
 8 number of slides that I found no problem with.
 9 COFFEY, Q.C.:
 10 Q. And what -- this would have been, I take it,
 11 during June and July of 2005, Doctor?
 12 DR. CARTER:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Did you tell anybody this, what you've just
 16 told me now?
 17 DR. CARTER:
 18 A. I would have told Dr. Cook. I would assume
 19 that most of the pathologists on the St.
 20 Clare's site would have known that because
 21 it's a small place and we're all next to one
 22 another. I'm not sure if it officially went
 23 any further than that.
 24 COFFEY, Q.C.:
 25 Q. Doctor, all this time this is going on,

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1 because you had otherwise been working -- you
 2 had a job.
 3 DR. CARTER:
 4 A. And still was working.
 5 COFFEY, Q.C.:
 6 Q. And was working still. So you were still
 7 doing your regular --
 8 DR. CARTER:
 9 A. Regular work.
 10 COFFEY, Q.C.:
 11 Q. Regular job.
 12 DR. CARTER:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Taking patients as you were normally
 16 scheduled?
 17 DR. CARTER:
 18 A. Yes.
 19 COFFEY, Q.C.:
 20 Q. At any point in this process were you told,
 21 Beverley, you can put aside your regular work
 22 and we'll take care of that, you just go ahead
 23 with this? Do you recall that --
 24 DR. CARTER:
 25 A. That was one of the plans. I had talked to

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1 Dr. Cook about it being difficult to get
 2 information, block slides, support staff, etc,
 3 and he had spoken to Dr. Williams and had a
 4 meeting with Dr. Williams and Mr. Gulliver,
 5 and they had decided at that time that I would
 6 be taking off of service, which could not
 7 happen in the summer, I mean, there just
 8 wasn't enough staff to cover it, and I was
 9 supposed to have, I think, Judy Quinlan report
 10 just to me, and Mary Butler from the
 11 immunohistochemistry lab help with that sort
 12 of thing.
 13 COFFEY, Q.C.:
 14 Q. And we've seen the documentation to that
 15 effect, and I appreciate it's written down.
 16 What actually happened?
 17 DR. CARTER:
 18 A. Well, as I said, there was no way that I could
 19 be taken off my service. There was just nobody
 20 to do the work. I mean, it was summertime,
 21 there was only a few of us working there, so,
 22 no, I couldn't be taken off my service unless
 23 they hired a new pathologist.
 24 COFFEY, Q.C.:
 25 Q. Sure.

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1 DR. CARTER:
 2 A. So that was an option for the administration.
 3 COFFEY, Q.C.:
 4 Q. Did that -- did that actually happen?
 5 DR. CARTER:
 6 A. No. Judy Quinlan, who is our lab technician,
 7 have you met her?
 8 COFFEY, Q.C.:
 9 Q. We've heard her name. Who is she?
 10 DR. CARTER:
 11 A. She's a technician who works in the lab at St.
 12 Clare's site, and she's generally a organizer
 13 for the lab, so she will be in charge of
 14 things such as storage and filing, and when
 15 you need things pulled, she will pull them for
 16 you. So she was supposed to be working with
 17 me full time. Often when I would go to see
 18 her to ask her, you know, I need these ten
 19 cases or how many ever cases it was, she would
 20 be pulled to do other duties in the lab.
 21 COFFEY, Q.C.:
 22 Q. So despite any assurance you received that
 23 she'd be working for you full time, that, in
 24 practice, didn't happen?
 25 DR. CARTER:

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1 A. Didn't happen, and the same with Mary. I
 2 don't think Mary was understood to be full
 3 time with me, but certainly she was -- my
 4 understanding was that she was supposed to
 5 spend a significant part of her time with me.
 6 So she would be the one who's looking for, you
 7 know, the external controls, things that would
 8 be filed on the Health Science Centre site.
 9 Judy worked at St. Clare's; Mary worked at the
 10 Health Science. So a lot of those things
 11 would be that she couldn't find them and she
 12 was doing other things, and she would get to
 13 it when she had some time.
 14 COFFEY, Q.C.:
 15 Q. When she had the time. So she -- her actual,
 16 the amount of time she could devote to working
 17 for you turned out to be limited?
 18 DR. CARTER:
 19 A. Yes.
 20 COFFEY, Q.C.:
 21 Q. You were told.
 22 DR. CARTER:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. Okay, then what happened, Doctor? Again in a

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1 broad strokes way, what happened?
 2 DR. CARTER:
 3 A. Well, then this was probably then towards the
 4 end of July and I was getting more and more
 5 frustrated with the whole exercise, trying to
 6 get it done. There was a routine meeting of
 7 the administration with the CEO, George
 8 Tilley, to give him an update on, I guess, the
 9 ER issue, and I asked could I attend that
 10 meeting because I wanted to ask Mr. Tilley to
 11 allow me to do those things, so talk to
 12 whoever needed to be talked to do those
 13 things, and so I attended the meeting on --
 14 COFFEY, Q.C.:
 15 Q. That would be August 1st.
 16 DR. CARTER:
 17 A. August 1st.
 18 COFFEY, Q.C.:
 19 Q. And what happened there?
 20 DR. CARTER:
 21 A. You're not going to lead me through? I went
 22 to the meeting and the first thing that
 23 happened at the meeting was that there was a
 24 press release that was read--I'm not sure if
 25 it was a press release, sorry, it was a

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1 release that they were preparing. The woman
 2 from PR and I don't know who exactly was at
 3 the meeting because there was a lot of people
 4 that I hadn't met before.
 5 COFFEY, Q.C.:
 6 Q. I take it you didn't routinely -
 7 DR. CARTER:
 8 A. No, this was a meeting I had asked to attend.
 9 So I think it was Susan Bonnell, but I'm not
 10 sure. She read a release that they had, I'm
 11 not sure if it was for the government or the
 12 press or who it was for, about how they had a
 13 problem with the estrogen receptor testing and
 14 it was due to the DAKO system and now they had
 15 a Ventana system which was much more sensitive
 16 and therefore, you know, they knew what the
 17 cause of the problem was. I objected to that
 18 statement being released to anybody or even it
 19 being true and -
 20 COFFEY, Q.C.:
 21 Q. I take it you took issue with that?
 22 DR. CARTER:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. You, based upon a review you had conducted to

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

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1 were talking about before they came to these
 2 things. In the course of that discussion, we
 3 started talking more about different aspects
 4 of immunohistochemistry, positivity rates,
 5 expected positivity rates and was again,
 6 mainly myself, Mr. Gulliver, Mr. Dyer,
 7 occasionally people from the clinical side of
 8 things.
 9 COFFEY, Q.C.:
 10 Q. That would be the oncologist, I take it?
 11 DR. CARTER:
 12 A. Oncologists and surgeons were there.
 13 COFFEY, Q.C.:
 14 Q. And surgeons, I'm sorry.
 15 DR. CARTER:
 16 A. When we started talking about statistics, Dr.
 17 Williams, you know, had some things to say
 18 about, you know, our math and the stats that
 19 we were talking about. And then I asked Mr.
 20 Tilley if I could be sort of given the
 21 resources and given the control to do this
 22 retrospective review that they wanted done and
 23 he explained that, management, you know, very
 24 nicely, he was the calmest person there, you
 25 know very nicely what the management structure

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1 was and that was the way that the management
 2 structure was and that we had to learn to get
 3 along, sort of thing, and figure it out
 4 amongst ourselves sort of in the lab. And the
 5 meeting ended and -
 6 COFFEY, Q.C.:
 7 Q. So it was a polite way of--you asked him for,
 8 I take it, for support in proceeding with what
 9 you had laid out for Dr. Cook?
 10 DR. CARTER:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. The approach. You explained this to the
 14 people at the meeting, you asked for Mr.
 15 Tilley's support and did he say yes or no or
 16 really not answer the question.
 17 DR. CARTER:
 18 A. Well he didn't say yes. I mean, what he said
 19 was this is the way that the management
 20 structure is, so you have to work within that
 21 structure, so if I was saying that management
 22 structure was not co-operative with me, you
 23 know, the answer was, well you have to learn--
 24 well not you, as in me, but the group of us,
 25 you know, have to learn how to work this out

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1 kind of thing. But no, there would not be
 2 changes made to the management of the
 3 laboratory for this.
 4 COFFEY, Q.C.:
 5 Q. And so then the meeting ended.
 6 DR. CARTER:
 7 A. And then the meeting ended and I stayed behind
 8 and talked to some of my clinical colleagues
 9 because it was a very stressful meeting, went
 10 about my evening activities and thought about
 11 it and thought well, I wasn't getting the
 12 support that I needed from the administration
 13 in the lab or of the hospital to do this
 14 retrospective review and that I would resign
 15 from that aspect of it and continue to offer
 16 my services as a consultant on it, if they
 17 wanted my opinion, and also to get involved
 18 with the prospective cases that were coming
 19 in.
 20 COFFEY, Q.C.:
 21 Q. And I take it in effect go back to your
 22 routine job?
 23 DR. CARTER:
 24 A. And also become more involved in the
 25 prospective cases, so the come-forward cases,

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1 so if somebody from 2003 walked into Dr.
 2 Laing's office tomorrow, even though she was
 3 part of the retrospective review, she would
 4 have to be pulled out, tested because she was
 5 there. So I would take care of those cases, I
 6 was doing more work with determining whether
 7 or not the Ventana system was appropriate for
 8 what, you know, we were having, designing QA
 9 for the lab, those sorts of things.
 10 COFFEY, Q.C.:
 11 Q. And perhaps again in an overview way you could
 12 take us on from there, then, Doctor, what
 13 happened?
 14 DR. CARTER:
 15 A. So I resigned from the committee. Don wrote
 16 me a letter saying that he accepted the
 17 resignation. I went back to work, I'm not
 18 sure what it is you're looking for?
 19 COFFEY, Q.C.:
 20 Q. Okay, well then what then--Doctor, because I
 21 take it at this point in time, based upon what
 22 we've heard today, that this was not public
 23 knowledge in the sense of the fact that there
 24 was this review going on in the lab and the
 25 problem existed.

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1 DR. CARTER:
 2 A. The general public didn't know about it?
 3 COFFEY, Q.C.:
 4 Q. Yes, the general public didn't know. Were you
 5 ever asked for your opinion as to whether or
 6 not the general public should be told and if
 7 so, when and how? And for that matter, the
 8 patients, if so, when and how?
 9 DR. CARTER:
 10 A. I don't know if I was ever asked -
 11 COFFEY, Q.C.:
 12 Q. I'm not suggesting you were, I'm just asking.
 13 COFFEY, Q.C.:
 14 Q. I don't know if I was ever asked sort of that
 15 question, but I know it would be discussed and
 16 I think my belief then was that the patient
 17 should know as soon as we know, I really
 18 wouldn't have anything to say about when the
 19 general public should know, it's not my -
 20 COFFEY, Q.C.:
 21 Q. And, Doctor, we understand that at some point
 22 in the summer of 2005 that Ms. Wegrynowski was
 23 contacted?
 24 DR. CARTER:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. And do I understand from Dr. O'Malley that in
 3 fact she was contacted even before Ms.
 4 Wegrynowski was?
 5 DR. CARTER:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. And you have been named in that process.
 9 DR. CARTER:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. Can you tell the Commissioner what you recall
 13 about that?
 14 DR. CARTER:
 15 A. Again, Dr. Cook and I had been talking and he
 16 thought that he would want someone to come
 17 down to oversee the lab, and when I say Dr.
 18 Cook wanted this, it may have been
 19 conversations he had with Dr. Williams, I
 20 mean, I wouldn't be privy to those, but Don
 21 and I would be talking and so this would come
 22 up and he asked, you know, did I know anyone
 23 that would want to come down and we discussed
 24 it and he suggested Francis--sorry, Dr.
 25 O'Malley and I know Dr. O'Malley from when we

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

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1 just then, it's something -
 2 DR. CARTER:
 3 A. Yeah, you need to be tweaked and -
 4 COFFEY, Q.C.:
 5 Q. Tweaked on that, just trying to get some sense
 6 for the Commissioner what kind of--what stands
 7 out in your mind. We have seen a letter,
 8 December 7th, 2005, the issue of restarting
 9 the testing -
 10 DR. CARTER:
 11 A. Okay, sure.
 12 COFFEY, Q.C.:
 13 Q. That came up, we gather in the--do you recall
 14 how that, how you first became aware of that
 15 as a topic and -
 16 DR. CARTER:
 17 A. Well I guess -
 18 COFFEY, Q.C.:
 19 Q. Perhaps we can back up a bit then because Ms.
 20 Wegrynowski was here in September.
 21 DR. CARTER:
 22 A. Yes, I was going to then talk about the two of
 23 those things.
 24 COFFEY, Q.C.:
 25 Q. And Dr. Banerjee.

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

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1 I did find problems with fixation, control
 2 issues, just the handling of tissue, a lot of
 3 the slides had tissue missing, those sorts of
 4 things. I would have talked to him about the
 5 type of practice that I had and
 6 subspecialization, he was very keen on that.
 7 He also talked about salaries, those sorts of
 8 things. And then on December 7th -
 9 COFFEY, Q.C.:
 10 Q. So you weren't involved in the exit
 11 interviews?
 12 DR. CARTER:
 13 A. No.
 14 COFFEY, Q.C.:
 15 Q. I'm not suggesting you were, I just wanted to
 16 ask you about that.
 17 DR. CARTER:
 18 A. No.
 19 COFFEY, Q.C.:
 20 Q. We understand that Dr. Banerjee's report came
 21 in on October of 2005 and Ms. Wegrynowski's in
 22 November, 2005, their initial reports, did you
 23 see a copy of those at the time?
 24 DR. CARTER:
 25 A. No, when I wrote the letter in December, I saw

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1 a copy of the recommendations that Trish had
 2 made, but not the report and I didn't see Dr.
 3 Banerjee's report.
 4 COFFEY, Q.C.:
 5 Q. And did you note generally though what he had
 6 found?
 7 DR. CARTER:
 8 A. I would characterize it as generally because,
 9 you know, you hear it in the halls and all of
 10 a sudden you're getting a new fridge or all of
 11 a sudden everybody is talking about
 12 subspecialty sign-out, so generally, yes, you
 13 would know what -
 14 COFFEY, Q.C.:
 15 Q. You could infer.
 16 DR. CARTER:
 17 A. Yes, but not specifically.
 18 COFFEY, Q.C.:
 19 Q. Without seeing the original document.
 20 DR. CARTER:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. And, Doctor, we've heard testimony, if I
 24 recall correctly from Dr. Cook at one point in
 25 the fall of 2005 he, at least to some

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1 pathologist read Dr. Banerjee's report to
 2 them. Do you recall that happening with you
 3 there?
 4 DR. CARTER:
 5 A. No, and I thought it was Dr. Denic read a part
 6 of his report at a meeting, I didn't think it
 7 was Dr. Cook.
 8 COFFEY, Q.C.:
 9 Q. And it may be that both of them did it at
 10 separate times.
 11 DR. CARTER:
 12 A. Could have been.
 13 COFFEY, Q.C.:
 14 Q. Different places. From the perspective of
 15 yourself, you don't recall sitting and
 16 listening to Dr. Cook?
 17 DR. CARTER:
 18 A. No.
 19 COFFEY, Q.C.:
 20 Q. And then the topic of retesting or resuming
 21 ER/PR testing came up, how did that come up
 22 and how did you first hear about it and what
 23 happened?
 24 DR. CARTER:
 25 A. Once the two reviews had come in, well

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1 everybody knew that there was a lot of changes
 2 that had been recommended because you could
 3 see all the activity going on in the lab and
 4 amongst the pathologists as well. And I'm not
 5 sure what day, if we could look at the letter
 6 -
 7 COFFEY, Q.C.:
 8 Q. December 7th.
 9 DR. CARTER:
 10 A. Okay, so probably December 5th, Dr. Cook came
 11 into my office, said that he had been at a
 12 meeting with Dr. Williams, Mr. Gulliver and
 13 Dr. Dyer and Mr. Dyer said that the Ventana
 14 system which we had switched off in July was
 15 ready to be switched back on and we could do
 16 estrogen receptor and progesterone receptor
 17 testing. The machine hadn't been switched
 18 off, just that particular testing had been
 19 switched off, and Don felt that we had a long
 20 way to go before that could happen and he was
 21 very upset that it could happen again, but he
 22 told me, so it wasn't at the meeting, but Mr.
 23 Gulliver and Mr. Dyer felt that that was a
 24 reasonable thing to pursue. Dr. Williams
 25 wanted it then investigated, so Don asked me

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1 as the person who would be eventually
 2 reporting these estrogen receptors and
 3 progesterone receptors, what I thought of it
 4 and would I write a letter expressing any
 5 concerns that I had about the lab, which I
 6 did.
 7 COFFEY, Q.C.:
 8 Q. And so, if I could, the actual exhibit is P-
 9 0101 and Doctor, the actual letter itself is
 10 dated December 7th, but when you refer to
 11 December 5th, you say--here in the letter you
 12 say to Dr. Williams, "I was most recently
 13 asked by Dr. Cook to comment."
 14 DR. CARTER:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. So in terms of, it may have been two days
 18 before that actually Dr. Cook and you spoke
 19 and he asked you -
 20 DR. CARTER:
 21 A. It would have been within a few days of
 22 December 7th.
 23 COFFEY, Q.C.:
 24 Q. And you then wrote this letter. What then
 25 happened? So you put your thoughts and I take

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1 it what's expressed there is the way you
 2 thought, felt at the time?
 3 DR. CARTER:
 4 A. And I sent the letter to Dr. Williams, I think
 5 with a carbon copy to Dr. Cook, if not, I
 6 would have given him a carbon copy and I think
 7 there was another meeting held and at that
 8 time, they decided to make a spreadsheet of
 9 all of the recommendations that had been made
 10 by each one of the physicians, another exhibit
 11 is a letter that Dr. Williams wrote me shortly
 12 after that, explaining that that was what was
 13 going to be done. And they had the
 14 spreadsheet and they would go through it, I
 15 guess on a daily, weekly, whatever basis as
 16 things were being changed.
 17 COFFEY, Q.C.:
 18 Q. Then what happened, Doctor, in terms of your
 19 involvement, if anything?
 20 DR. CARTER:
 21 A. Without the exhibit -
 22 COFFEY, Q.C.:
 23 Q. Okay, I'll prompt you, we understand that the
 24 great bulk of the retest results started, well
 25 were back by the end of January, 2006?

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1 DR. CARTER:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. They came back before that, some, but then the
 5 great wave of them came in spreadsheet format.
 6 Were you involved in the retest results?
 7 DR. CARTER:
 8 A. I would be involved in, I think we're calling
 9 it the tumour panel for the purposes of the
 10 inquiry.
 11 COFFEY, Q.C.:
 12 Q. Okay, yes, in the fall.
 13 DR. CARTER:
 14 A. Yes, so I would have been involved in that,
 15 but in terms of the lab and the retrospective
 16 review, no, I wouldn't have been involved.
 17 COFFEY, Q.C.:
 18 Q. And I will be asking you, some exhibits in
 19 respect of the tumour panel, but in overall,
 20 what was your involvement, again, in a general
 21 description, what was the nature of your
 22 involvement in the tumour panel?
 23 DR. CARTER:
 24 A. Oh, for the tumour panel?
 25 COFFEY, Q.C.:

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1 Q. Yes.
 2 DR. CARTER:
 3 A. Again, it was an inter-disciplinary, multi-
 4 disciplinary team where each patient who had
 5 been identified in the retrospective review
 6 would be brought to the panel and the previous
 7 estrogen progesterone receptor reports would
 8 be compared to the retrospective review,
 9 report and then a discussion of the case would
 10 ensue and then treatment changes would be
 11 discussed. So my role in it would be to read
 12 the pathology reports and for subtleties that
 13 would help the clinicians make treatment
 14 changes recommendations, small things, such as
 15 size of tumour and presence of lymphovascular
 16 invasion is sometimes helpful. So the
 17 pathologist's role is to be able to quickly go
 18 through that and assimilate the information
 19 often off two or three or four pathology
 20 reports, put it all together and then quickly
 21 give them, you know -
 22 COFFEY, Q.C.:
 23 Q. A summary.
 24 DR. CARTER:
 25 A. Yes. And once I acted as the acting chair

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1 where I would write the letters of the
 2 recommendations of the group.
 3 COFFEY, Q.C.:
 4 Q. And, Doctor, looking back on it, the
 5 activities of that panel, how much actual
 6 involvement did you have, like on a routine
 7 meeting, how much would they call upon you?
 8 DR. CARTER:
 9 A. It was a minor, but a present one. Often the
 10 pathology would have to be reviewed, the ER/PR
 11 would have to be reviewed in each case, so I
 12 mean, I had a role there, but it wasn't the
 13 most important one.
 14 COFFEY, Q.C.:
 15 Q. And I take it it was to give to the clinicians
 16 quickly an overall synopsis of the pathology
 17 aspect of the matter so that they could make
 18 whatever clinical decisions they saw fit?
 19 DR. CARTER:
 20 A. Yes, yes.
 21 COFFEY, Q.C.:
 22 Q. The great wave of results came back in
 23 January, 2006.
 24 DR. CARTER:
 25 A. Okay.

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

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1 A. Yes. And they would go actually to a
 2 different, that's right, they would go to
 3 Trish's lab as opposed to Maria's lab.
 4 COFFEY, Q.C.:
 5 Q. And would be reported separately by Dr. Mullen
 6 or whomever reported?
 7 DR. CARTER:
 8 A. Whoever was on duty for that.
 9 COFFEY, Q.C.:
 10 Q. Doctor, we understand that Trish Wegrynowski
 11 and Dr. Banerjee came back to St. John's in
 12 April, I believe, of 2006. They revisited the
 13 lab. Were you involved in that at all?
 14 DR. CARTER:
 15 A. No, I was actually unaware.
 16 COFFEY, Q.C.:
 17 Q. There's also, Doctor -- we've seen reference
 18 to an effort in the spring and summer of 2006
 19 to create an interdisciplinary group of
 20 doctors dealing with breast treatment.
 21 DR. CARTER:
 22 A. Breast site group?
 23 COFFEY, Q.C.:
 24 Q. Yes.
 25 DR. CARTER:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. Can you tell the Commissioner, please, what
 4 you recall about that?
 5 DR. CARTER:
 6 A. This had arisen from one of the meetings that
 7 had taken place and I know that Dr. Williams
 8 was present there because he had sort of
 9 started the idea that if there was a
 10 guidelines group, that perhaps that would be
 11 helpful, an interdisciplinary --
 12 multidisciplinary, sorry, guidelines group.
 13 Dr. McCarthy and I had both come from
 14 institutes that had breast disease site groups
 15 and were quite familiar with it, so we agreed
 16 to canvas people, I guess, if they were
 17 interested in this and to outline what we felt
 18 the role and responsibilities of the committee
 19 would be, and what sort of staffing or funding
 20 we would require.
 21 COFFEY, Q.C.:
 22 Q. And then what happened with respect to that?
 23 DR. CARTER:
 24 A. We had a meeting in June, 2005.
 25 COFFEY, Q.C.:

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

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1 DR. CARTER:
 2 A. I think it's still ongoing.
 3 COFFEY, Q.C.:
 4 Q. When were you last involved in it?
 5 DR. CARTER:
 6 A. Maybe before December.
 7 COFFEY, Q.C.:
 8 Q. December of '07?
 9 DR. CARTER:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. Okay. So you would have continued with that
 13 then throughout '06 into '07?
 14 DR. CARTER:
 15 A. Yes, as long as we were having meetings.
 16 After the first year, I was no longer the co-
 17 chair, I was just a regular member of the
 18 group.
 19 COFFEY, Q.C.:
 20 Q. Doctor, we understand that in the fall of 2006
 21 -- of course, there was in December --
 22 December 11th, 2006, there was a technical
 23 media briefing. Were you part of that?
 24 DR. CARTER:
 25 A. No.

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1 COFFEY, Q.C.:
 2 Q. We understand as well that just past mid
 3 November, probably around November 20th/21st,
 4 2006 -- November 20th to the 22nd, I can't
 5 recall off the top of my head right now which
 6 date, there was a briefing note for Eastern
 7 Health staff about the results of the review
 8 and --
 9 DR. CARTER:
 10 A. I wasn't involved.
 11 COFFEY, Q.C.:
 12 Q. But there's a slide show with your name on it?
 13 DR. CARTER:
 14 A. Oh, the teleconference, okay.
 15 COFFEY, Q.C.:
 16 Q. The teleconference, yes.
 17 DR. CARTER:
 18 A. This was for the province.
 19 COFFEY, Q.C.:
 20 Q. Yes. Could you tell the Commissioner, please,
 21 about that, what you recall about how you got
 22 involved in it and the nature of your
 23 involvement?
 24 DR. CARTER:
 25 A. I was asked to be involved with it. I think

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

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1 media briefing, and you were not involved in
 2 that?
 3 DR. CARTER:
 4 A. I don't think so.
 5 COFFEY, Q.C.:
 6 Q. That you can recall. We understand as well
 7 that in February of 2007, the ER/PR testing
 8 resumed.
 9 DR. CARTER:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. At the General Hospital. Were you involved in
 13 that decision?
 14 DR. CARTER:
 15 A. Yes.
 16 COFFEY, Q.C.:
 17 Q. Doctor, could you tell us please about the
 18 nature of your involvement?
 19 DR. CARTER:
 20 A. Dr. Elms, I think, was the medical director of
 21 immunohistochemistry at that time. It had
 22 gone through a number of different people. I
 23 think he was taking it on as a sole person at
 24 that time. Dr. Denic was the clinical chief,
 25 and myself and Don, and I think Dr. Naghibi

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1 was still here then as well, so there would
 2 have been three of us on the breast team, and
 3 Dr. Elms and Dr. Denic presented to us, you
 4 know, not in detail, but presented to us in
 5 detail that they were happy with the
 6 validation, all the different aspects of it,
 7 and we looked for a short while at cases
 8 stained in St. John's and cases stained at -
 9 simultaneously cases stained, and we agreed
 10 that it was very good service and moved
 11 forward.
 12 COFFEY, Q.C.:
 13 Q. So what then happened? Testing resumed, I
 14 take it.
 15 DR. CARTER:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. In St. John's.
 19 DR. CARTER:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. What then was your involvement? You said
 23 there were three of you in the group
 24 initially?
 25 DR. CARTER:

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

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1 we would bring difficult cases, and all the
 2 ER/PR and read them as a group.
 3 COFFEY, Q.C.:
 4 Q. Now, Doctor, to get some sense then, and you
 5 continued then in that position until when?
 6 DR. CARTER:
 7 A. Until June 20th of 2008.
 8 COFFEY, Q.C.:
 9 Q. So there was initially yourself, Dr. Cook, and
 10 --
 11 DR. CARTER:
 12 A. Naghibi.
 13 COFFEY, Q.C.:
 14 Q. Naghibi.
 15 DR. CARTER:
 16 A. Uh-hm.
 17 COFFEY, Q.C.:
 18 Q. Dr. Naghibi, as best you can recall, had left
 19 by the summer of 2007?
 20 DR. CARTER:
 21 A. Yes, she took a year leave of absence, and I
 22 think she has since given a formal
 23 resignation.
 24 COFFEY, Q.C.:
 25 Q. So after she left, there was yourself and Dr.

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1 Cook?
 2 DR. CARTER:
 3 A. Yes, and sometimes Dr. Denic would fill in on
 4 an as needed basis, but essentially myself and
 5 Dr. Cook.
 6 COFFEY, Q.C.:
 7 Q. And Dr. Cook then, I gather, took a leave of
 8 absence when?
 9 DR. CARTER:
 10 A. End of March, 2008.
 11 COFFEY, Q.C.:
 12 Q. So March of '08, and so the months then after
 13 that until you resigned, and this year you
 14 would have been --
 15 DR. CARTER:
 16 A. I would have been doing them myself, and then
 17 if I had difficulty with estrogen receptor or
 18 wanted hand holding, I would talk to Dr. Elms.
 19 COFFEY, Q.C.:
 20 Q. Sure.
 21 DR. CARTER:
 22 A. Or Dr. Denic.
 23 COFFEY, Q.C.:
 24 Q. Doctor, May of 2007, we understand there's --
 25 of course, this matter became a matter of some

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1 public, took on some significant public
 2 interest in the middle of May, 2007, with the
 3 CBC report about the contents of an affidavit
 4 that had been filed in a class action. Doctor,
 5 when that happened in the middle of May, 2007,
 6 were you involved in this or brought into this
 7 in any way?
 8 DR. CARTER:
 9 A. Not in any official capacity, I don't think.
 10 COFFEY, Q.C.:
 11 Q. I'm not suggesting you were. I'm just --
 12 DR. CARTER:
 13 A. I mean, I knew about it and everybody knew
 14 about it.
 15 COFFEY, Q.C.:
 16 Q. Doctor, then after August 2nd, 2005, you wrote
 17 that letter resigning.
 18 DR. CARTER:
 19 A. Okay.
 20 COFFEY, Q.C.:
 21 Q. From that particular aspect of the matter as
 22 set out in your letter. In terms of the
 23 retrospective review, other than dealing with
 24 Dr. Banerjee and Ms. Wegrynowski in the way
 25 you did when they came in September of '05,

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1 did you have any further involvement in the
 2 retrospective review?
 3 DR. CARTER:
 4 A. Well, I would act on a consultative basis to
 5 them, so if they wanted something, you know,
 6 somebody to look at slides today, I mean, I
 7 would so that, so I didn't completely divorce
 8 myself, but I more divorced myself from the
 9 organizational aspect of it, but I was still
 10 helping out as needed.
 11 COFFEY, Q.C.:
 12 Q. If we could, please, Exhibit P-0046, please?
 13 Now Doctor, this is Dr. Banerjee's report of
 14 October 17th, 2005, okay?
 15 DR. CARTER:
 16 A. Um-hm.
 17 COFFEY, Q.C.:
 18 Q. And you've indicated you would not have
 19 actually seen the text of this until 2007?
 20 DR. CARTER:
 21 A. When it was--Mr. Williams had it on the floor.
 22 No, this is not this one. That's the other
 23 one. I think when it came out as an exhibit
 24 for this process.
 25 COFFEY, Q.C.:

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1 Q. In relation to the Commission of Inquiry?
 2 DR. CARTER:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. How about Ms. Wegrynowski's, had you seen -
 6 DR. CARTER:
 7 A. Actually, I had seen her recommendations, but
 8 I have only read her report like in the last
 9 little while, last six months.
 10 COFFEY, Q.C.:
 11 Q. So in terms of the actual--because there are
 12 two reports from '05 and two from '06, those
 13 four reports, you've actually only seen really
 14 since the Commission -
 15 DR. CARTER:
 16 A. Yes.
 17 COFFEY, Q.C.:
 18 Q. - the actual text of them, since the
 19 Commission of Inquiry got involved in this.
 20 Doctor, here, under "review of cases" Dr.
 21 Banerjee had written, "I reviewed a number of
 22 cases from the retrospective testing set with
 23 Dr. Donald Cook. All the cases that had
 24 converted from negative to positive by
 25 switching platforms had one or more of the

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

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

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

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1 Ventana system at least looked at a bit
 2 further?
 3 DR. CARTER:
 4 A. Yes.
 5 COFFEY, Q.C.:
 6 Q. In the summer of '05?
 7 DR. CARTER:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. Knowing what you do now, overall, when he says
 11 "there's no evidence that the Ventana system
 12 creates false positive results," as a general
 13 proposition, would you agree with him?
 14 DR. CARTER:
 15 A. I would disagree, you know, is our Ventana
 16 system too sensitive, there was evidence that
 17 our Ventana system created false positive
 18 results. As a general statement, Ventana
 19 doesn't cause false positive results. It's
 20 the use of it.
 21 COFFEY, Q.C.:
 22 Q. Okay, so then at the time, you felt, and we'll
 23 explore some of that further tomorrow, that
 24 perhaps the -
 25 DR. CARTER:

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1 A. Even the summer of '05, we had some false
 2 positives.
 3 COFFEY, Q.C.:
 4 Q. Summer of '05, there were some false
 5 positives.
 6 DR. CARTER:
 7 A. Yes. I don't know if he was aware of those,
 8 can't comment.
 9 COFFEY, Q.C.:
 10 Q. But as a general proposition, you have no
 11 problem -
 12 DR. CARTER:
 13 A. The Ventana doesn't cause or not cause false
 14 positives.
 15 COFFEY, Q.C.:
 16 Q. So it's not the machine, as you pointed out.
 17 DR. CARTER:
 18 A. It's not the machine.
 19 COFFEY, Q.C.:
 20 Q. It's not the machine. It's not a machine
 21 problem per se.
 22 DR. CARTER:
 23 A. No.
 24 COFFEY, Q.C.:
 25 Q. "3. Is there a problem with tissue fixation?

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1 There appears to be inadequate attention paid
 2 by the grossing pathologist to the thickness
 3 of tissue slices, quality and adequacy of
 4 fixation and there is no standardized fixation
 5 protocol that everyone adheres to." The
 6 problem with tissue fixation, you had
 7 recognized that at least in some slides
 8 yourself? So you agreed with that?
 9 DR. CARTER:
 10 A. I would agree with that statement, yes.
 11 COFFEY, Q.C.:
 12 Q. "Inadequate attention paid by the grossing
 13 pathologist to the thickness of tissue
 14 slices," what would he be referring to there,
 15 do you think?
 16 DR. CARTER:
 17 A. Usually when you cut tissue slices--you've
 18 gone through the whole cassette thing?
 19 COFFEY, Q.C.:
 20 Q. Yes.
 21 DR. CARTER:
 22 A. And so when you cut the tissue to put into the
 23 cassettes, it should be between three to five
 24 millimetres, often down around three
 25 millimetres in order for the formalin to

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1 penetrate appropriately, and also there's a
 2 limited size to the tissue that you can put
 3 into the cassette. So often the technologist
 4 would complain that the tissue is too big for
 5 the cassettes.
 6 COFFEY, Q.C.:
 7 Q. And the potential negative consequence of that
 8 was what?
 9 DR. CARTER:
 10 A. The tissue would have variable fixation, so I
 11 mean, there's lots of debate on fixation. I'm
 12 sure that you're familiar with some of it. In
 13 my opinion, variable fixation would give you
 14 more of heterogeneity or more variability in
 15 your staining. So I talked about absolute
 16 positive, absolute negatives. With poor
 17 fixation, you're going to get some variability
 18 to that return.
 19 COFFEY, Q.C.:
 20 Q. And the quality and adequacy--okay,
 21 "inadequate attention paid by the grossing
 22 pathologist to the thickness of tissue slices,
 23 quality and adequacy of fixation." Was there
 24 a standardized fixation protocol at that time?
 25 DR. CARTER:

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1 A. No.
 2 COFFEY, Q.C.:
 3 Q. I take it that eventually you drafted one, in
 4 due course?
 5 DR. CARTER:
 6 A. We drafted several for breast cases and a
 7 generalized fixation protocol for the lab.
 8 COFFEY, Q.C.:
 9 Q. And we'll deal with--we'll address some of
 10 those with you tomorrow. From your
 11 perspective, in the summer of 2005, based upon
 12 what you had observed, would you have come to
 13 the same conclusion here as he sets out here
 14 in three?
 15 DR. CARTER:
 16 A. There was definitely issues with fixation. I
 17 mean, I would have to go back and look at my
 18 slides again and all that stuff before I made
 19 a definitive statement, but I have no problem
 20 with that. I think that there was some issues
 21 with fixation.
 22 COFFEY, Q.C.:
 23 Q. "Inadequate or no attention is being paid by
 24 the reporting pathologist to the status of
 25 internal controls with inappropriately

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1 exclusive reliance on external positive
 2 controls." Had you found -
 3 DR. CARTER:
 4 A. Again, I mean, that was an issue. It's the
 5 "inadequate or no attention," you know, part
 6 that I have an issue with myself. I would
 7 have to go back and look at all of my
 8 information. I know that many of the
 9 pathologists were paying attention to internal
 10 controls. So it's just the qualifiers I have
 11 a problem with. But that is an issue,
 12 internal controls.
 13 COFFEY, Q.C.:
 14 Q. And because this might suggest that all
 15 pathologists fell into that category, by the
 16 reporting pathologist, and perhaps you might
 17 take issue with that, but -
 18 DR. CARTER:
 19 A. It's a strong statement that he's made.
 20 COFFEY, Q.C.:
 21 Q. But as a general statement though, an overall
 22 -
 23 DR. CARTER:
 24 A. There was a problem with internal controls,
 25 yes.

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1 COFFEY, Q.C.:
 2 Q. And it says "negative test results in the
 3 absence of positive internal controls should
 4 have triggered corrective procedures,
 5 optimization of method, choice of a better
 6 fixed block, choice of a block with benign
 7 ductal epithelium included, etcetera, and
 8 should not have been released without
 9 troubleshooting. In the event that poor
 10 fixation resulted in internal control failure
 11 on all available blocks, this should have been
 12 noted in the reports as an uninterpretable
 13 case, due to the failure/absence of internal
 14 controls." Now would you have agreed or do
 15 you agree with that?
 16 DR. CARTER:
 17 A. In a general sense, I would agree with that.
 18 I wouldn't make the definitive statement that
 19 if an internal control is negative, I would
 20 not read the slide, and I assume that we will
 21 get into specifics tomorrow.
 22 COFFEY, Q.C.:
 23 Q. Yes.
 24 DR. CARTER:
 25 A. But I mean, as a general statement, yes, that

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1 is kind of a motherhood pathology statement.
 2 COFFEY, Q.C.:
 3 Q. And there are exceptions, and I'll explore
 4 those with you tomorrow.
 5 DR. CARTER:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. But as a general proposition, certainly you
 9 would agree with it as a generalization.
 10 "Inappropriate choice of blocks with no
 11 representative normal ductal epithelium."
 12 DR. CARTER:
 13 A. Again, there are many blocks there that had no
 14 normal ductal epithelium.
 15 COFFEY, Q.C.:
 16 Q. And of course, he's suggesting better
 17 education required for all those involved
 18 about the pitfalls of IHC and the importance
 19 of quality control in interpretation of IHC
 20 results.
 21 DR. CARTER:
 22 A. Yes.
 23 COFFEY, Q.C.:
 24 Q. You would agree?
 25 DR. CARTER:

1 A. I would agree.
2 COFFEY, Q.C.:
3 Q. In fact, throughout the fall and December, in
4 fact, of '07--well, in fact, December of '05,
5 your letter addresses just that issue.
6 DR. CARTER:
7 A. Yes.
8 COFFEY, Q.C.:
9 Q. If we could then, Commissioner, perhaps--it's
10 been a long day. I'd like to take this up
11 again tomorrow.
12 THE COMMISSIONER:
13 Q. It's been a long, warm day.
14 COFFEY, Q.C.:
15 Q. Yes.
16 THE COMMISSIONER:
17 Q. All right then, we'll meet in the morning at
18 9:30. Thank you.

1 CERTIFICATE
2 I, Judy Moss, hereby certify that the foregoing is
3 a true and correct transcript in the matter of the
4 Commission of Inquiry on Hormone Receptor Testing,
5 heard on the 28th day of July, A.D., 2008 before
6 the Honourable Justice Margaret A. Cameron,
7 Commissioner, at the Commission of Inquiry, St.
8 John's, Newfoundland and Labrador and was
9 transcribed by me to the best of my ability by
10 means of a sound apparatus.
11 Dated at St. John's, Newfoundland and Labrador
12 this 28th day of July, A.D., 2008
13 Judy Moss

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