COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 7, 2008

Appearances:

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

Ches Crosbie, Q.C. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

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

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THE COMMISSIONER:

Q. Please be seated. Mr. Coffey.

DR. DONALD COOK, EXAMINATION BY BERNARD COFFEY, Q.C. (CONT'D)

COFFEY, Q.C.:

Q. If we could, please, Registrar, Exhibit P-1290? And I believe this is a letter that, Dr. Cook, you wrote September 26th, 2005 to Dr. Williams. It's concerning the issue of the timing of mastectomy breast biopsy operations, and you had noted here "I would strongly recommend that all mastectomies, needle localizations and lumpectomies should be booked first thing in the morning in the OR from Monday to Friday," and you had written here, "spoke to Shirley, divisional manager, regarding possibility of scheduling breast cancer earlier mornings. Shirley states many issues regarding rescheduling of breast, follow-up to my August memo." Doctor, I did refer you to this last week, but one thing I wanted to follow up with you on is this, how has that, from your perspective, finally played itself out, you know, at the General Hospital and St. Clare's, in terms of

scheduling of operations?

DR. COOK:

A. Well, I think they did everything they could to reschedule the breast surgery. They were done first things in the morning. In this particular case, on Friday afternoons, I noticed that the surgeon was operating earlier in the afternoon, say 2 or 3:00. Now that may not always be the case in all time periods, but if that was so, then if there was a breast that was performed late in the afternoon and it went over hours, then the pathologist on call would come in and handle the specimen, and that's what--I wanted that continuity played out.

COFFEY, Q.C.:

Q. So that's the way, as things stand now, as we are here this morning, the arrangement in Eastern Health is that if breast surgery does occur at other than first thing in the morning, if it occurs at odd hours, outside the regularly scheduled times -

DR. COOK:

A. Yes.

COFFEY, Q.C.:

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Q. - there are arrangements in place to have a pathologist -

DR. COOK:

A. Arrangements--we do have pathologists on call 24 hours a day. They are to be called in and then to handle the case.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0647, please? Now Doctor, this is an e-mail of October 17th, 2005. I shouldn't say so much an e-mail. I take it it's from an information system. The subject is ER/PR testing. I take it it's concerning a meeting scheduled for October 17th, 2005 and required attendees are listed as yourself, Ms. Predham, Nancy Parsons, Susan Bonnell, Robert Williams or Dr. Williams, Dr. Laing, and Chris -

DR. COOK:

A. I can't pick out that name.

COFFEY, Q.C.:

Q. Okay, and a C. Power. Who is C. Power? Do you know that, Doctor? Anyhow, if you don't, that's fine. It says--but here, is this your handwriting?

DR. COOK:

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A. Yes.

COFFEY, Q.C.:

Q. Okay, it says "one, start media campaign"

DR. COOK:

A. Yeah.

COFFEY, Q.C.:

Q. "Two, information for public."

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, what was this about?

DR. COOK:

A. I guess it was a strategy to decide how to go public, who would be involved as the point person, to represent the corporation, I understand, in dealing with the media.

COFFEY, Q.C.:

Q. Now Doctor, the subject matter of ER/PR had gone public on October 2nd, which is about just over two weeks before October 17th.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. I understand that at this point in time, around the 17th, there was, in fact, a media--

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actual, a media campaign, in the sense of advertisements and so on being thought about and ultimately purchased, advertising space in newspapers throughout Newfoundland.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. So what I wanted to ask you about was this, your involvement or why you were involved in this aspect of the matter at all?

DR. COOK:

A. Well, I guess they were asking me to provide what sort of background information we had with the ER/PR issue and to provide them with up-to-date information of what was going on so far. My major focus, which Dr. Williams wanted me to do, was to remain confined to the lab, to focus on the review that was taking place and to provide him with any necessary information on request.

COFFEY, Q.C.:

Q. Okay, so that was--you weren't there to decide whether or not there should be a media campaign or not, what its format should be or not, but to provide technical information?

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DR. COOK:

A. Yes, to provide what information I could or what I knew at the time to that process.

COFFEY, Q.C.:

Q. The Exhibit P-1314, and Doctor, this is a letter of October 24th, 2005 from yourself to Dr. Banerjee thanking him for the receipt of his report of October 17th, and you note here "your report will be shared will the leadership team of the Laboratory Medicine program, as well as the Vice President of Quality Diagnostic and Medical Services." So that would be, in effect, the leadership team of the Laboratory Medicine program was yourself, Terry Gulliver and Bob Williams?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. You've indicated last week in your testimony that at one point you had read, you think probably in November of 2005, you read the full contents of Dr. Banerjee's report to a group of pathologists?

DR. COOK:

A. That's correct.

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COFFEY, Q.C.:
Q. And you had gotten permission from Dr. Williams to do that?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. What was the understanding with respect to whether or not copies of the report could be given out?
DR. COOK:
A. Oh, I didn't have the authority to give out copies of the report. There were only four copies issued, I believe. One went to myself, Mr. Gulliver, Dr. Williams and Heather Predham.
COFFEY, Q.C.:
Q. And I take it, it was understood between the four of you that it was otherwise copies were not to be distributed?
DR. COOK:
A. That's correct, that's the instructions that I had.
COFFEY, Q.C.:
Q. Do you recall who they were from?
DR. COOK:

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A. Dr. Williams.
COFFEY, Q.C.:
Q. At the time you asked Dr. Williams--I take it you asked him if you could read out the contents of the report to the pathologists?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. And he responded "yes"
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. But not give them copies?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. What was the rationale?
DR. COOK:
A. Well, I guess the rationale, where this is-- this was regarded as a peer review from Dr. Williams' perspective, that the information was protected under legislation, so that was his reasons for not producing copies of those reports. To the best of my knowledge, those are the main two reasons.

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COFFEY, Q.C.:
Q. And from your--and it was his decision? How this was to be handled, from your perspective, was Bob Williams' decision?
DR. COOK:
A. That was basically his decision.
COFFEY, Q.C.:
Q. Okay. Exhibit P-1313, please? Doctor, this is a letter of October 24th, 2005, the same date, to Dr. Banerjee again.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. And it's re: national standards for immunohistochemistry testing. You write "I have been asked by the President/CEO," which would be Mr. Tilley, "and Vice President of Medical Services," that would be Bob Williams, "as to whether the issue of immunohistochemistry testing could be brought forward to the Canadian Association of Pathologists. I think the whole issue of national standards for laboratories across Canada could be spearheaded by the Canadian Association of Pathologists and brought

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forward to the Federal Minister of Health. I wonder if we could put this on the agenda for our next face-to-face meeting of the executive in late November?" and you've copied it to Dr. Williams, this letter?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Doctor, you refer here "our next face-to-face meeting of the executive in late November."
DR. COOK:
A. That's correct. The executive of the Canadian Association of Pathologists, that's correct.
COFFEY, Q.C.:
Q. And were you a member of the executive at the time?
DR. COOK:
A. I am and was.
COFFEY, Q.C.:
Q. And this face-to-face meeting occurred where?
DR. COOK:
A. This occurred in Ottawa.
COFFEY, Q.C.:
Q. And was this added to the agenda?
DR. COOK:

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A. Yes.
COFFEY, Q.C.:
Q. And what was the result then? Was it discussed at the time?
DR. COOK:
A. That was correct. What I did was bring forth the issue of ER and PR testing here in Newfoundland. I went very much--do you want me to describe the -
COFFEY, Q.C.:
Q. Yes, if you would, please, what happened, Doctor?
DR. COOK:
A. All right. I went very much through the sequence of events, as best as I could remember them at the time, talking about the index case, how we had retested on the Ventana system, how we had a conversion rate of approximately 60 to 65 percent on the Ventana system. Again, talked about that these were selected cases at ten percent cut-off. Talked to them about what I knew about our positivity rates at that time, which the figures that I had from Mr. Gulliver were around 73-74 percent, and basically, said that I had a big

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concern, not only what was happening in St. John's, but expressed concern what was happening across the country. I referred to my survey, the fact that we had contacted different labs throughout the country. There was no apparent standardization on how the test was done. Hospitals were using different platforms with different interpretations. There were different positivity rates. So I expressed concern that this could be a major issue for labs and pathologists across Canada.

Now the issue that I had also brought up was not necessarily what was happening today, because some of the members pointed out that, you know, in terms of what was happening today, it may not be an issue, but I said "the issue that many of you have to consider is what were you doing six-seven years ago," and I said "that may very well become an issue, and it's an issue that we're going to have to address." Now in the meantime, I said "I think we should try to collaborate with other organizations, such as the Canadian Association of Medical Oncologists, Radiation Oncologists, the Canadian Cancer Strategy

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area, the Canadian Society of--Canadian Cancer Society and whatnot and try to put forth some sort of a coalition and seek funding and legislative advice from the Federal Government." So basically that was, from what I can remember, the gist and theme of the conversation.
COFFEY, Q.C.:
Q. Was the group, was the executive receptive?
DR. COOK:
A. They were.
COFFEY, Q.C.:
Q. And what then happened afterward?
DR. COOK:
A. Dr. Banerjee was there and we decided to write a letter to the various stakeholders and quite a number of organizations were cc'ed on that letter, highlighting the need for national standards and a collaborative approach in dealing with this.
COFFEY, Q.C.:
Q. Okay.
THE COMMISSIONER:
Q. Excuse me, Mr. Coffey, but Dr. Cook, I'm not sure I understand what it is that one needs a

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national standard for, in the sense of some others who have been witnesses have said things like well, cutoff rates perhaps is something that one should look to a national standard for. But in your world, I'm assuming, for example, it is not unusual for there to be, in labs, equipment from different manufacturers which essentially do the same thing.
DR. COOK:
A. Um-hm.
THE COMMISSIONER:
Q. And which might require different chemicals to be used, but the end product is seen as somewhat similar. Would national standards, in your view, interfere at all with that or is that just--would national standards be a concern with the product that comes out of it and what one should expect to see by way of other range of results or types of results out of a particular piece of equipment, given the particular antibodies used, etcetera, etcetera? I'm just having difficulty understanding the role that national standards would play, particularly in ER/PR and while it

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sounds intuitively good that one would have national standards, it seems to me that there are so many little bits and pieces along the way in this subject that it would be a very difficult thing to get consensus on.

DR. COOK:

A. Commissioner, I think you're right. I don't-- now, we've only just started the national standards committee for immunohistochemistry, which I'm on, and we've only had one or two meetings. So we haven't really got into the roots of the issue as yet, but the way that I see it is benchmarks or outcomes, how are labs doing with comparing results? I mean, there is no way, I don't think, you can say that we can dictate to a lab what piece of equipment you're going to buy, what antibody you are going to use. I think the most important thing is what's the end result, what's the product that that lab is doing and you compare it to other labs and compare those labs to a central source. I don't see us getting to the point where we can say here is a particular piece of equipment that you can buy.

But now, that being said, I think you

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have to try to develop standards in terms of external proficiency testing programs, making sure that labs have their own internal quality assurance programs, that various procedures are being documented, that various procedures are being carried out through, and that they are being audited.

THE COMMISSIONER:

Q. Okay.

DR. COOK:

A. The other issue that I look at is eventually getting into an area where labs are mandated to be part of a national standards program and be able to identify labs that are deficient. Now that deficiency could be in terms of documentation, specific personnel in specific areas or what their outcomes are.

Now the next issue is do you have the power to close down that particular lab, and that's another issue that I think we have to look at, and whether that becomes a national responsibility or a provincial responsibility. I'd like to see it on a national basis because I'd like to see labs from coast to coast follow the same national standards and

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protocol. Now it's quite easy to close a lab, but what I'd like to see coming out of this particular committee that we have in place is a response team. If you identify a lab that has deficiencies, instead of closing it down, you bring in a group of experts to identify where those deficiencies are, help that lab correct those deficiencies and keep them running. We can't afford to lose any more labs in this country. So that's personally -- now I haven't really had a chance to discuss this at the committee level meeting, but that personally, this is where I'd like to see the National Standards Committee go.

COMMISSIONER:

Q. I take it from information which I've received from other sources that, in fact, there are very few national standards currently operating in your world, is that correct?

DR. COOK:

A. That's correct. I mean, we have no standards, national standards, on how a pathologist grows a specimen, how many sections that pathologist would take, how many deeper levels on a particular block that pathologist would take.

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So there are lots of areas where -- there's lots of work to be done where I think we have to get down and try to bring in some uniformity to the system. The more we can standardize, the more we can produce.

COMMISSIONER:

Q. Well, it's almost like a "catch 22", because if you're trying to compare what's coming out of different labs, and the kinds of things you're now describing are not standardized, then one begins to question whether or not they're comparable, in any event.

DR. COOK:

A. Well, I think the end product, you've got to work on whether that end product is comparable, and then route back -- go back and see why that end product is not comparable. It's a difficult process and it's going to be a very time consuming process and it's not going to happen overnight.

COMMISSIONER:

Q. Has this kind of thing been done on a large scale in other countries?

DR. COOK:

A. Probably -- it's beginning to now. I think

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the Americans are looking very closely at national standards in immunohistochemistry. They're looking at their proficiency testing and revamping their proficiency testing. The United Kingdom, I think, is certainly well ahead of us in terms of developing national standards for their programs, and they've had major issues five to six years ago. I don't know if it's similar to ours, but they've had major issues which spearheaded their effort to bring in national standards for how labs operate, and how they document and how they produce results, and a standardization of the results that are being produced. Does that answer your question?

COMMISSIONER:

Q. It does. Thank you very much.

COFFEY, Q.C.:

Q. Exhibit P-0371, please. Doctor, just to follow your e-mail through, this is Dr. Banerjee's reply and e-mail of October 24th, 2005, to yourself, and it's stating, "I guess this is an important topic that needs discussion. We should add it to the agenda along with the national standards of practice

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topic", which you've just referred to then in responding to a question from the Commissioner. The idea then of -- and it's capitalized here, "National Standards of Practice", topic. So the topic of national standards of practice was, I take it, in the fall of 2005 just getting onto the agenda?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Is that also being pursued?

DR. COOK:

A. It is, not to the same extent as we are into the immunohistochemistry. You got to remember, Mr. Coffey, that the Canadian Association of Pathologists is a very small organization, and -- now we have the expertise in Canada, I think, to develop these standards. The issue is funding, and, you know, where is that funding going to come from. I think we have to go after the Federal Government for that.

COFFEY, Q.C.:

Q. Exhibit P-01322, please. Doctor, this is a letter of Canadian Association of Pathologists

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letterhead to yourself from Dr. Banerjee, copied to Dr. Bob Williams. I take it this is formally advising you that the topic, national standards for immunohistochemical testing, was added to the CAP Executive agenda in November?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Exhibit P-01318, please. Doctor, this is an e-mail -- well, actually, two e-mails. The one -- the first at the bottom of the page, the bottom of the exhibit here, is October 25th, 2005, from yourself to Dr. Mullen, status of ER/PR review, "Hi Bren, I'm wondering how's it going with the review and when we can expect some more results. I can appreciate that Mount Sinai is probably at capacity levels. Could you update me". I take it this is your handwriting, Doctor?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Also e-mail sent from Mr George Tilley to CEO of Mount Sinai, and lab director of Mount Sinai, October 19th to the 21st, 2005. I take

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it, Doctor, that by the end of October your e-mail to Dr. Mullen and your reference to these other e-mails here that you understood had been sent, were -- I'll phrase it as a gentle pressure on Mount Sinai to try to get the results of the retesting as soon as possible?

DR. COOK:

A. Yeah, we knew that Mount Sinai was under pressure, and I did know they were handling a lot of their own cases. In speaking to Dr. Pritzker at times, I knew they were under a lot of pressure, but they were doing the best that they could.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0337. Doctor, this is a report of a laboratory medicine program to the clinical chiefs and (audio cuts out) for September/October, 2005. Doctor, the reference to September/October, 2005, does that mean that this was a report for that period?

DR. COOK:

A. What it means, that the same report that you see there goes to both clinical chiefs and then to medical advisory. So the clinical

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chiefs meeting would have been held in September, the medical advisory would have been held in October of '05.

COFFEY, Q.C.:

Q. Okay, and -- so this report then would have been given -- submitted to the clinical chiefs meeting in September and the MAC meeting in October?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. The second page of this, paragraph five is quality initiatives. It's written, "There's currently a review of our ER and PR. This review involves all negative ER cases from May, '97 to August 9, 2005", and then there's an outline summary of the history up to a certain extent, and you go on to say then, "This high conversion rate also raises questions about the Ventana System, especially regarding its sensitivity. As a result, all negative samples since 1997 will be sent to an external laboratory for retesting", and you talk about the hold on reporting of ER and PR by all pathologists locally and the fact that

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all current requests for those tests are being forwarded to Mount Sinai, and you conclude by saying, "I will keep you updated on this matter".

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Doctor, when you reported to the MAC -- well, first of all, the clinical chiefs in September, and then the MAC in October, were the physicians in both those groups when you actually submitted this report, were they actually already aware of this issue, do you recall?

DR. COOK:

A. I can't say how many were aware or were not aware, Mr. Coffey.

COFFEY, Q.C.:

Q. Okay. Do you recall what if any response, questions, or reactions you got from the clinical chiefs group in September and then the MAC group in October?

DR. COOK:

A. The only comment that I got -- I remember one comment is that we follow standard of care,

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and that was a comment that I had tried to explain, and what I was saying to them, that's a difficult question, there are no standards in Canada. We were looking at our positivity rates of about 73 to 74 percent, which was the information that I had at that time, and we seemed to be comparable to the other labs, but I said, you know, positivity rates are one thing. You've got to look at where the different cut off levels were over those years. I mean, you could look fine with positivity rates of 73/74 percent, but those may pick up all your various low expressers and what not. So it became a question or do you look at clinical cut-offs, or you look at technical cut-offs. So what I said to them it's not as simple as that, and all I can say was there was no standards in Canada, and I said I really didn't know where we stood in regards to standard of care and where other labs in Canada stood to standards of care.

COFFEY, Q.C.:

Q. The reference to standard of care, that phrase in that context means what?

DR. COOK:

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A. Were we providing a similar standard to a similar size hospital in Canada. That was my take on that.

COFFEY, Q.C.:

Q. Do you recall who you raised the issue with?

DR. COOK:

A. I think it was one of the clinical chiefs from the emergency room. I just can't remember his name right now offhand.

COFFEY, Q.C.:

Q. And, Doctor, and subsequently while you were main clinical chief, you would occasionally then report to the MA clinical chiefs group and MAC?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Afterward about this. How much was this topic discussed in those two groups afterward?

DR. COOK:

A. It was brought up, I believe, at every meeting subsequent to that.

COFFEY, Q.C.:

Q. And discussed to what extent?

DR. COOK:

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A. Well, when I got into the complexities of the test and describing the 40 to 50 step process, I was basically describing the amount of variability with the test, the issues that we had with the large human factor, both at the technical aspect and at the interpretive aspect, and I think once I got into the fact that this test was complicated, I think there was a general understanding amongst the clinical chiefs that this was not straightforward. It was not like any other test where you can do a blood test, put it into another analyzer and get a result. So there seemed to be a general understanding, in my opinion, that once I mentioned to some individuals the fact that this was a 40 to 50 step process, that this was a very complicated procedure and prone to a lot of variability.

COFFEY, Q.C.:

Q. I take it when they understood that, the questions then kind of trail off?

DR. COOK:

A. I would say to a certain extent, yes.

COFFEY, Q.C.:

Q. Exhibit P-0673, please. Doctor, this is an e-mail from yourself to Dr. Williams, November 1st, 2005. You write, "Hi Bob, these are rough figures based on what I've just received from Mount Sinai. 169 cases reported, 559 cases left to report, of which 219 blocks are cut and 26 cases are stained. These are approximately figures. It looks like it's going to take some time before all cases are reported. Regards, Don". I take it, Doctor, as of November 1st, 2005, you had reached the conclusion that it was going to be at least some period of time before the results were back?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Exhibit P-01323, please. Doctor, this is an exhibit which I understand is a distribution list for the November 9, 2005, report of Trish Wegrynowski, four copies provides, one of four to Mr. Gulliver.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Two of four to yourself, three or four to Heather Predham/Pam Elliott, and four of four to Dr. Williams. So -- and I've asked you already about Dr. Banerjee's report and the limited distribution of that.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. I take it was it the same approach then to Ms Wegrynowski's report?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. When you received Ms. Wegrynowski's report and you described your reaction last week in your testimony last week, did you ever disclose the contents of that to the pathologist?

DR. COOK:

A. No, I didn't, and the reason for that was mainly under Mr. Gulliver. Mr. Gulliver was overseeing the technical aspect of the laboratory medicine program, and that report, certainly from the direction I received from Dr. Williams, the impression I received from Dr. Williams, it was up to Mr. Gulliver to distribute to the technologists.

COFFEY, Q.C.:

Q. Exhibit P-097, please. Doctor, this is two e-mails. The one at the bottom of the page is from Moira Hennessey, November 3rd, 2005, to Dr. Williams, and none of these e-mails is from or to you, but the topic here in Ms. Hennessey's e-mail to Dr. Williams is -- she asked about contacting the patients, and then she continues, "Have you received the report from the BC pathologist and the Mount Sinai technologist. If yes, what is the general finding or findings". Doctor, did Dr. Williams ever discuss with you the topic or issue as to whether or not copies of Dr. Banerjee's or Trish Wegrynowski's report should be distributed, for example, to the Department of Health?

DR. COOK:

A. I can't remember per se whether he actually said to me that these are not going to the Department of Health. My general impression of it was that this was regarded as a peer review at the time and it was to remain confined within Eastern Health or Health Care Corporation of St. John's.

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COFFEY, Q.C.:
Q. Did anyone ever discuss with you your views or expressed to you any views as to whether or not these reports should be distributed outside the original four or five people who got them?
DR. COOK:
A. No, I can't recall anyone having -
COFFEY, Q.C.:
Q. I'm not suggesting they did, I'm just asking you.
DR. COOK:
A. No, just can't recall, Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you. So if that discussion occurred, it occurred at a level higher in the hierarchy than yourself?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Exhibit P-0681 please? Now, Doctor, here there's an e-mail from yourself, November 15th, 2005, to Nancy Good at Mount Sinai, it's regarding ER and PR stains, slides. You write "Hi, Nancy, as far as I'm aware, staining of

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ER/PR slides will stay at Mount Sinai to be read and interpreted by Mount Sinai pathologists. Regards, Don Cook." And then you've got some handwritten notes here, I gather.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Follow up with phone call to Nancy, November 15th, 2:30 p.m., stated to her to send ER and PR slides back to us once entire review is completed and all interpretations were done. Spoke to George Tilley November 15th, 9:20 a.m., both of us concerned about slow pace of Mount Sinai report. George considering to speak to Mount Sinai CEO to see what could be done to speed up the reporting. So these slides that are being discussed in the e-mail, I take it are the ones being prepared by Mount Sinai?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. And you wanted those slides back why?
DR. COOK:

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A. I would want those slides back?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. Oh, after the end of the review?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. To have them, use them as a source of information, if times we needed to go back to look at particular cases, we could. But I thought it would be best to have the slides sent back to St. Clare's as part of the patient's record.
COFFEY, Q.C.:
Q. If I could, please, Exhibit P-0154? Doctor, perhaps if I could, please, P-153 first, to put this in context for Dr. Cook. Now, Doctor Cook, this is an e-mail, November 18th, 2005 from Tansy Mundon to Deborah Thomas-Pennell and Susan Bonnell. It's copied to George Tilley, Darrell Hynes and John Abbott. And she says, "Susan, Deborah, further to our briefing yesterday with George and Dr. Williams, I attach the following questions

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that the Minister would like answered in advance of the House of Assembly opening on Monday, if at all possible. Many thanks, Tansy." And if we turn to the second page, Doctor, the fifth bullet says "Has a review occurred to determine how this could have happened, how could there be inaccurate tests for a period of five years without being detected? Will there be disciplinary action taken?" And if we could then open, please, Exhibit P-0154 again? This is an e-mail from Ms. Thomas Pennell to Tansy Mundon. Subject is "ER/PR Questions" and she writes, "As requested, Tansy." And we look at, Doctor, pages 2 and 2, are the questions and answers, the answers are in bold print, and the question on page 3 of the exhibit here is "Has a review occurred to determine how this could have happened? How could there be inaccurate tests for a period of five years without being detected? Will there be disciplinary action taken?" And the response here is "This is still an ongoing investigation into the situation; however, there is ample literature to suggest that these tests have limitations

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and are not guided by national standards. In the meantime, until all the results from retesting are obtained, it is impossible to determine the exact details of the cause of the problem. Three reviews have taken place of our current testing procedure, pathology services and our technical services. Recommendations are being made and are being acted upon, which will immediately ensure the quality and reproducibility of results." And they go on to talk about the reference to disciplinary action. Doctor, that question that's posed there, "Has a review occurred to determine how this could have happened? How could there be inaccurate tests for a period of five years without being detected?"

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Were you asked for a response to that question?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. At any point in this whole matter, had anyone

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posed that question to you?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. I'm going to pose it to you now, okay. From your perspective, now obviously a review had occurred, from your perspective, how could there have been inaccurate tests for a period of five years or more, for that matter, without there being detected--that being detected?

DR. COOK:

A. Yeah, well that's a long question, I think a lot of it has to do with quality assurance activities, did we have appropriate quality assurance activities in relation to ER and PR? Now when you look at the quality assurance activities that we had, they were pretty broad based. I believe they, for the most part, represented general list sign-out, which we had. I think, I mean, I strongly think that if we had been able or would have subspecialized around those particular times and by subspecialized, had a group of three or four individuals solely looking at these

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cases, I truly believe we would have picked up a trend a lot earlier. Not only that, we would have developed quality assurance activities that were centred around subspecialized groups. Now, to develop quality assurance activities, you need the funding in places and the resources in places and you also need individuals whose job it is to monitor various benchmarks and results and trends and whatnot. We did not have that in place and for me, as clinical chief, I've always had a job over the past few years in trying to identify specific indicators. I didn't have indicators being forwarded to me on a regular basis. It was only when I tried to claw out indicators of the program that I was able to, you know, act on certain areas. And we only act on complaints, we're not a program that should be prospective, it's a reactive program. So all things being considered, I do believe that if we had to have the ability to subspecialize or should have subspecialized, I think this would have been picked up earlier and we would have identified trends.

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COFFEY, Q.C.:

Q. And, Doctor, if--because you've noted last week, I believe, that at least in your review of some of the original slides, that there were problems you noted with internal controls?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. If physicians had paid more, well apparent attention to internal controls, to use Dr. Banerjee's wording, do you think the matter might have been picked up earlier?

DR. COOK:

A. Possibly, possibly, the thing about it is we were only seeing one or two cases a month or maybe three cases a month. If you look at the large number of other cases we were putting through, it would be pretty hard to identify trends, but if you've got a subspecialty group and you're looking at an entire batch of these cases, which we had in our subspecialty group, I think you would have picked up any trends with or without internal controls much more readily.

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COFFEY, Q.C.:
Q. And in fact, that sort of large--well particularized volume or relatively large volume, you experienced in July of 2005 when you looked at the original slides and -
DR. COOK:
A. Yes, when I sat down and I guess for the first time, I mean, it was, I don't know, a couple of hundred slides, through that two or three day period, then, you know, a lot of issues came to light which certainly opened my eyes to what I saw there.
COFFEY, Q.C.:
Q. Exhibit -
THE COMMISSIONER:
Q. Sorry, Mr. Coffey, I interrupt again, just because it's flowing through my head, you may have been asked about this last week, but I just want to come back to it, the business of internal controls within the ER/PR test -
DR. COOK:
A. Yes, Commissioner.
THE COMMISSIONER:
Q. And how unusual is it in IHC to be looking for internal controls?

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DR. COOK:
A. Well it shouldn't be unusual, I think, you know, when you -
THE COMMISSIONER:
Q. But I was thinking of it, IHC generally, as opposed to just ER/PR?
DR. COOK:
A. Oh, it may not be unusual because many times we do have tumours that have no surrounding normal tissue, so you could have, say, an excisional biopsy of a sarcoma and that's all you have is just tumour, nothing else. So you have to rely on your external controls to make sure that the tissue is working. So it is not unusual in many other instances to examine tissue from other systems in which there is no internal control.
THE COMMISSIONER:
Q. Okay, thank you.
COFFEY, Q.C.:
Q. Exhibit P-1331? Now, Doctor, this is a letter of November 23rd, 2005, from Trish Wegrynowski from Dr. Williams. He's thinking her for her report and it's copied to yourself and Mr. Gulliver. And he concludes by saying "I'm

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sure Mr. Gulliver or Dr. Cook may wish to contact you further to get ongoing advice as we move forward in implementing the recommendations in your report."
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. With respect to any subsequent contact with Ms. Wegrynowski, did you have any -
DR. COOK:
A. I think I only had one contact with her regarding some cases some time in October or whatever, but I didn't contact her on a regular basis. My reason for that being that this was mainly had to do with technical issues and this was under the control of the program director.
COFFEY, Q.C.:
Q. Exhibit P-0909 please? Doctor, this is a letter of the same date, except this one is to yourself, marked "private and confident" to yourself and Mr. Gulliver, and it's from Dr. Williams and he writes "I have had an opportunity to review in detail the reports of Dr. Banerjee and Ms. Wegrynowski with respect

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to the IHC services offered by Eastern Health. I wonder if you could prepare a spreadsheet to capture all the recommendations embodied in both of those reports, i.e., this should include all recommendations, even ones such as refrigeration and storage referenced on page 4 of Trish Wegrynowski's report. Preparing the spreadsheet and the current status with respect to implementation of these recommendations, you should assume that funding will be provided based upon the document you prepared for me on October 13th, 2005. I understand Sharon Lehr is following up with Terry on the financial parameters embodied in that document. Once you have the spreadsheet developed and the current status of our implementation, I would like to meet with you as soon as possible to review where we go from here, especially in dealing with the institution of the IHC services." Now, Doctor, having received this, were you involved in the preparation of a spreadsheet?
DR. COOK:
A. Most of the preparation of a spreadsheet came from Mr. Gulliver and so I received a copy of

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this spreadsheet and would review it.
COFFEY, Q.C.:
Q. And do you recall if you added anything to it or -
DR. COOK:
A. I can't recall for sure.
COFFEY, Q.C.:
Q. So I take it the plan at that point was having the spreadsheet and then get, as possible, each of the recommendations implemented as time went on?
DR. COOK:
A. Yes, use that as the template.
COFFEY, Q.C.:
Q. Template for it. Now this spreadsheet, what kind of distribution did that have?
DR. COOK:
A. I believe that only went to myself and Mr. Gulliver and I'm not sure if Dr. Williams got a copy of that, I can't be absolutely sure of it.
COFFEY, Q.C.:
Q. Exhibit P-1333 please? Why did that have limited distribution, the spreadsheet?
DR. COOK:

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A. I don't know for sure, Mr. Coffey, again, this was probably in relation to the, what came out of the recommendations of the Banerjee and Wegrynowski report and the fact that these, at the time, were still regarded as peer review, I mean, that's the only -
COFFEY, Q.C.:
Q. Which would include the listing of recommendations?
DR. COOK:
A. The listing of recommendations, I mean, that's the only reason I can give you.
COFFEY, Q.C.:
Q. Now, Doctor, here there's an e-mail of November 24th, 2005 from yourself to Dr. Pritzker, copied to Dr. Williams, ER/PR update, and you're looking for an update on the operational status of Mount Sinai's new batch stainer, but you've written here "received direction from tumour board round on November 17th, 2005, not to report ER and PRs on DCIS or LCIS cases."
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:

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Q. And I take it LCIS is lobular carcinoma in situ?
DR. COOK:
A. Correct.
COFFEY, Q.C.:
Q. What was this about, your note?
DR. COOK:
A. Well this is in regards to the panelling process and we don't order ERs and PRs at least at St. Clare's or the General Hospital on DCIS's or LCIS's, but there was a case I remember receiving a call from Nancy Parsons of a woman who was diagnosed with ductal carcinoma in situ. This woman was quite anxious and quite upset and she requested to order an ER and PR on a case of DCIS. So I thought it would be in the best interests to order that test, considering the emotional state of the lady and the fact that we were trying to help people in any which way we can, so I went ahead and ordered the ER and PR on the DCIS.
COFFEY, Q.C.:
Q. But I take it in the main they were not being -

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DR. COOK:
A. No, but I mean, if I, you know, got wind of somebody who was really upset who I thought it, you know, provided a sort of comfort factor, that if I could order that test, I would order it.
COFFEY, Q.C.:
Q. Okay. Exhibit P-0684 please? Now here, Doctor, there's an e-mail of November 24th, 2005 from Heather Predham to Dr. Williams, but it's copied to yourself and others. And the subject is "Update on ER/PR". And after referring to that, she says, "Dr. Kwan made a suggestion at the last panel that I should track those we may have potentially harmed. We had agreed to classify patients as being converted with or without recommendations, but Dr. Kwan and rightly so, felt that it didn't accurately reflect those who had been impacted. For example, if a person was initially diagnosed with breast cancer of the left breast and was ER/PR negative and then had metastases to the right breast which was ER/PR positive, the patient would be then treated with Tamoxifen, so when we panelled

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the person after their first results converted, the panel would have no recommendations, but there has been a potential impact, at the last panel meeting out of the 17 panel, there was 7 patients that were potentially negatively impacted after review, all the patients panelled, will try to have this complete information for you next week. As always, if you have any questions, just call me. Heather." And there's attached her briefing note of November 23rd?

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Doctor, do you recall what then became of this, this idea of keeping track of--tracking those who we may potentially harmed?

DR. COOK:

A. We were trying to develop, you know, what I was interested in was the number of people, the number of patients that required treatment recommendations, that was the number that I was really interested in. Trying to get an idea of how many patients that had converted, but more so trying to identify those that

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required treatment recommendations. That was the major figure I was looking at.

COFFEY, Q.C.:

Q. And, I take it -- do you know if there was ever any effort afterwards by this panelling process to keep track of those we may have potentially harmed? I appreciate you're looking for treatment changes, but Dr. Kwan apparently is looking for something a bit wider than that? Do you know?

DR. COOK:

A. I can't say -- I can't say for sure, Mr. Coffey.

COFFEY, Q.C.:

Q. Okay. Exhibit P-0686, please. Doctor, several e-mails here on this exhibit. One in the middle of the page from Kevin Watters at McGill to yourself, November 28th, 2005, re; cases from Newfoundland, "Sorry, Don, I approached Marie Laure Brisson at the Jewish General Hospital for you, and unfortunately she is unable as well to accommodate out of province material at this point in time. Signed, Kevin", and then you forwarded that the next day on to Dr. Williams.

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DR. COOK:

A. Right.

COFFEY, Q.C.:

Q. Do you recall what this was about?

DR. COOK:

A. Well this was another big issue that was coming on the scene, and this was concerning a manpower shortage, and as you've seen in my notes to the clinical chiefs, we were reaching a crisis situation with our manpower. We were -- around that time, I'm not sure if it was at that time, but approaching 25 percent reduction in the manpower. I was getting a lot of concerns and complaints from our pathologists regarding the workload. I was getting pretty concerned about the stress level of our pathologists, the ability to sign out cases, and we were getting into backlogs. I think around that time we were starting to get into a couple of hundred, 200 or 300 case backlogs each month. So I had approached Dr. Watters in looking at the possibility of Montreal able to accommodate our cases and interpret our cases. I thought that we -- we came close to an agreement, however, that fell

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through, and Kevin mentioned to me that he'll try some other institutions for me to see if they're able to accommodate our request to handle our excess workload.

COFFEY, Q.C.:

Q. And how did the workload eventually get handled then?

DR. COOK:

A. Well, again the issue with Montreal fell through. I remember myself and Dan Fontaine contacting labs throughout Canada. I believe we contacted approximately 9 to 10 labs to see if they can take our excess workload. The inn was full in all of those particulars labs, there's no way that anyone could accommodate us. I remember being in the -- pathology update in Toronto at the University of Toronto in early November of 2005, actually scouring the conference floor asking my colleagues and friends if they had any excess capacity to take our workload, and no one had excess capacity to be able to help me. There were some individuals who wanted to take a select, but I was looking for an institution to cover a widespread of our surgicals. Then I heard

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about the DynaCare Group, and I heard about that from members of our Executive, and I remember phoning the President of DynaCare at that particular time and he -- I explained to him our situation in St. John's, the fact that we had the shortages, the fact now that we were getting backlogs, and had serious concerns over that, and his response to me was, Dr. Cook, we have capacity to handle your situation and it was like words from heaven. It was the first bit of good news that I've heard in a tremendous amount of time. So we then began the long task of setting up the logistics to send these cases out to DynaCare.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-01334. Now, Doctor, this is a multiple page exhibit and it's not necessarily all in the order in which it may have been originally -- the documents may have originally been created, but it's the order in which the Commission received them. It's a letter dated December 1, 2005, to Dr. Williams. It's on Department of Health stationery, Physician Services Division letterhead. It says, "Adult Pathology

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Services, HSC and St. Clare's. This letter is to follow up to your correspondence dated November 3rd and our meeting of November 23rd regarding anticipated physician resource challenges in pathology, more particularly for the next nine months. And this reduction of 25 percent you referred to capacity locally is referenced here, and the idea of approaching Montreal General is discussed in the bottom paragraph.

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. But then, I don't know where the rest of that letter is, but there's a letter then of--this third page of the exhibit, January 27th, 2006.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. It's addressed to yourself. Subject is pathology services for Eastern Health Authority and this, I take it, is what turned out to be the agreement with DynaCare?

DR. COOK:

A. That's correct.

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COFFEY, Q.C.:

Q. Okay. Exhibit P-0688, please? Here, Doctor, this is an e-mail from yourself to Maria Mendes, December 2nd, 2005, 2:45 p.m., "last batch of ER/PR cases" is the subject. You write "Hi, Maria, we are sending off what appears to be the last batch of cases re: ER/PR review. These are cases that are from hospitals outside of St. John's. This batch contains approximately 130 to 140 blocks. You should receive these cases sometime early next week. I appreciate the work that you folks have done to date. Regards, Dr. Cook." And then you make a note that you'd spoken to Dr. Pritzker on December 2nd, 2005 and you've noted "should have cases cleared up by the end of January. Spoke to him about the Tech Express. Says Mount Sinai looking at DAKO automated system sometime in the new year."

So Doctor, here then, I take it, it was only at the beginning of December of 2005 that what was then thought to be the final group of 130 to 140 blocks was going from Newfoundland to Mount Sinai?

DR. COOK:

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A. That's what I thought, yeah.

COFFEY, Q.C.:

Q. And these blocks had been from, I take it from other regions throughout the province?

DR. COOK:

A. I think they were mainly from the peripheral hospitals, yes.

COFFEY, Q.C.:

Q. Exhibit P-1335, please? Doctor, this is an e-mail of December 2nd, 2005 from yourself to Dr. Banerjee and you write "Hi, Diponkar. As I mentioned to you in Ottawa, we will be receiving funding for the upgrading of our IHC services. We will be planning a number of meetings with our key pathologists and technical people concerning the implementation of recommendations. I would appreciate your advice and guidance. I wonder if you can participate in some of these meetings on a conference call. I predict there will be a number of differing opinions on how to implement and when to decide on the start-up date. I will certainly welcome an outside perspective in helping me achieve a consensus approach to full implementation."

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So Doctor, the approach here then with respect to Dr. Banerjee was anticipated to be what?

DR. COOK:

A. Well, to come down and review our situation to date, to make a recommendation on what we had done so far, to review the situation, what we had done so far, and also try to work towards a consensus opinion. What we were--the big problem I was having at that particular time is that there were so many different opinions on when we should start the system, how to start the system.

COFFEY, Q.C.:

Q. Start the system in the sense of ER/PR, I take it?

DR. COOK:

A. Yes, that's right because we already were conducting IHC testing, but there was still a lot of differing opinions on what time the system should be started. So I was looking for Dr. Banerjee to come down and act as an objective outside source to look at the situation and assess it for us.

COFFEY, Q.C.:

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Q. Now that references potential conference calls. Were there such conference calls?

DR. COOK:

A. No, we didn't have conference calls. We talked about that and I think probably we decided that the best route to go would be to have him come down and personally look at what we were doing.

COFFEY, Q.C.:

Q. Exhibit P-0101, please? Doctor, this is a letter of December 7th, 2005. It's from Dr. Carter. It's copied to yourself, Mr. Gulliver and Dr. Ejeckam. It's addressed to Dr. Williams and she says--begins by saying, "I was most recently asked by Dr. Don Cook to comment on the suggestion of Mr. Barry Dyer that stated that he felt the Ventana testing for ER/PR and HER2/neu could be started at any time. I find this comment quite startling in the face of the two fairly damning reports sent by Dr. Banerjee and Trish Wegrynowski on the review of our IHC lab, with special emphasis on the predictive factors for breast cancer patients." And she goes on at some length.

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DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. The Commissioner has seen this letter already.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. I take it, Doctor, that you had asked for Dr. Carter's opinion?

DR. COOK:

A. I did.

COFFEY, Q.C.:

Q. And had you asked that it be expressed to you or Dr. Williams or just generally?

DR. COOK:

A. I asked for it to be in general. Then she replied to me "would you mind if I write a letter?" I said "not at all." I thought the letter would initially come to me, but the letter was forwarded to Dr. Williams.

COFFEY, Q.C.:

Q. And what did you think of the contents of the letter?

DR. COOK:

A. Well, it showed that we still had a long ways

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to go in terms of the start up. Personally, I didn't see the need to start it up immediately. We were sending out our cases for ER and PR, our current cases for ER and PR and HER2/neu. My feeling at the time was we'd start up--should start up the system when we have all the recommendations in place. I think at that particular time, we still hadn't had an opportunity to send our technologists out to outside institutions such as Montreal or Mount Sinai. So I certainly wanted that to be in place, to give them an opportunity to see what other institutions were doing, in terms of their set up and quality assurance protocols and activities and whatnot. So those were sort of the things at least were going through my mind when that letter came out.

COFFEY, Q.C.:

Q. Did you subsequently speak with Dr. Carter about the contents of her letter?

DR. COOK:

A. We've had correspondence, verbal correspondence. I thought that basically she covered all the points in that particular

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letter.
COFFEY, Q.C.:
Q. Exhibit P-0694, please? Now this is Dr. Williams' response of December 14th, 2005 to Dr. Carter. He copied it to yourself and Mr. Gulliver and Dr. Ejeckam and were you supportive of Dr. Williams' position as set out here?
DR. COOK:
A. Yes, overall.
COFFEY, Q.C.:
Q. Exhibit P-0693, please? Doctor, this is an e-mail of December 13th, 2005 from Heather Predham to Dr. Williams, Patricia Pilgrim, yourself, Terry Gulliver and Pam Elliott. It's copied to other individuals. She says "we have received a Statement of Claim regarding ER/PR. Eastern Health is the only one named and it is concerning the ER/PR results we obtained on Michelle Hanlon. It appears that Ms. Hanlon was one of the first five that we retested and she outlines numerous, from the letter A to Q, on how we were negligent and liable," and her lawyer is named there. "If you have any questions,

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please let me know."
Doctor, what was your understanding of why, in December 2005, you were being sent a copy of the Statement of Claim?
DR. COOK:
A. I have no idea.
COFFEY, Q.C.:
Q. Okay.
DR. COOK:
A. I guess it was because I was clinical chief of the program and sent to the leadership team, just informing me of, you know, what was taking place.
COFFEY, Q.C.:
Q. I take it there was no response expected of you, that you understood?
DR. COOK:
A. I understood, yes.
COFFEY, Q.C.:
Q. Exhibit P-0695, please? Doctor, this is an e-mail--well, it's a couple of e-mails, but one in particular from Dr. Pritzker, December 20th, 2005 to yourself and he says "Don, as of today, everything is tracking towards successful completion at end of January 2006.

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All the best for the holidays and the new year." Signed Ken. You had, on the day before, on December 19th, written to Doctor--e-mailed Dr. Pritzker saying "Dr. Williams has asked me to follow up with you on the status of ERs and PRs," and you had understood there was a push on this after Christmas with a view to completion at the end of January 2006. So I take it, Doctor, that just before Christmas, 2005, it was anticipated that this would be concluded, at least in the retesting report results by the end of January?
DR. COOK:
A. That's what we were hoping, yes.
COFFEY, Q.C.:
Q. Exhibit P-0696, please? Doctor, this is a note, December 21, 2005, Mr. Tilley, Ms. Elliott, Ms. Predham, "slides from presentation Dr. Don Cook attended which in part dealt with ER/PR issues." Signed Bob. And then there's--page two, Molecular Diagnostics in Breast Pathology. It's a presentation by Dr. Anthony Magliocco, I apologize if I mispronounced his name, from the University of Calgary, UFT Pathology

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Update Course, November 2005.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. So you had attended this?
DR. COOK:
A. Yeah, that was the same course that I was trying to find various other labs and individuals to take our excess specimens.
COFFEY, Q.C.:
Q. And when you came back, I take it you had a copy of the slide presentation that had been given in this regard and distributed it?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P, I think it's 0347? I apologize, 0847. The portion of it I have is cut off. Thank you. No, and I apologize, Commissioner, I'll just come back to that. Exhibit P-1348? Now Doctor, some e-mails, I take it by the end of January--by the middle of January, January 19th, 2006, you are again asking Dr. Pritzker about whether or not this matter is going to be concluded by the

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end of January.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. And within a day or so, Dr. Mullen advises you that he's in the final stages of it.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Doctor, if we could, while I'm at it, I'll come back to that in a minute, I apologize, Commissioner, but Ms. Chaytor has provided me with the number of that exhibit I wanted to ask the doctor about, P-1347. Now Doctor--thank you, Registrar. What sort of a form is this, Doctor?
DR. COOK:
A. That's a goals and objectives form that serves as a review conducted by Dr. Williams on each of the clinical chiefs in the program. So this is conducted on an annual basis. So this is an example of the goals and objectives that we would discuss at the beginning of each year and then we review the status on that during the year.

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COFFEY, Q.C.:
Q. Doctor, here it's signed off, I believe, January--by Dr. Williams, January 4th, 2006, yourself January 17th, 2006, and date proposed is December 10th, 2004. I take it that was the -
DR. COOK:
A. I think that's the wrong date there. It should be--it's not 2004.
COFFEY, Q.C.:
Q. Okay, and under final comments, it's "Dr. Cook has dedicated himself to the stabilization and enhancement of laboratory services with Eastern Health, staying on an extra year to deal with recent problems in immunohistochemistry. Plans to step down as clinical chief at the end of February 2006, but will stay on as a site chief at St. Clare's and continue his leadership at that level." Now Doctor, the reference to the idea that you had stayed on for an extra year, was that correct?
DR. COOK:
A. That's what we decided. There was many discussions between myself and Dr. Williams

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particularly in early January and February of 2005, which I expressed to him that the interest of--I wished to step down possibly near the end of June of '05 or certainly at the latest by September of '05.
COFFEY, Q.C.:
Q. And just--and it turned out then, it was early in '06 that -
DR. COOK:
A. That's right.
COFFEY, Q.C.:
Q. Doctor, here, just looking back at it, performance goals and objectives for clinical chiefs '04/05 for yourself, "as of December 2004, one, complete an annual review of all pathologists credentialed in the Laboratory Medicine program."
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. And by April 1, 2005, it indicates this is well in hand.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:

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Q. And so you were pursuing that, and then by October 2005, this had been delayed because of the ER/PR matter, I take it?
DR. COOK:
A. Yeah, there was a lot of things that went off the rails at that time.
COFFEY, Q.C.:
Q. Just so the Commissioner gets some sense of what was planned before the ER/PR came up and then how things worked out, paragraph two, "December '04, work towards filling all pathology positions," and paragraph three, "work on the major quality assurance issues of developing a policies and procedures manual for the division of anatomical pathology."
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. So that as of December 2004, you understood, as the clinical chief, that there was a major quality assurance issue in relation to the development of policies and procedures manuals for that division?
DR. COOK:
A. Yeah, I mean, what I was trying to do was to

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get movement towards developing this, trying to find manpower to develop this, develop a quality assurance committee to integrate both the medical and technical arms of the Laboratory Medicine program, and looking more for just quality assurance. I was looking for QC/QA, but also QMP, quality management, to be able to monitor whether people had received various policies, whether they had read through the various policies, were policies being followed up. So I was looking for something to develop an auditing process, in terms of whether policies were actually being carried out and, as you can see there, Dr. Bev Carter headed up that committee and in my opinion, she was an ideal person in dealing with that.

COFFEY, Q.C.:

Q. In fact, as of April 1, 2005, you have seven bullets, seven different initiatives, as it were -

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. - set out there. By October 7th, 2005, in

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this regard, "work ongoing targeted at CAP accreditation for the immunohistochemistry section of the lab" and "December 9, 2005, work progressing."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. So I take it that that suggests, Doctor, look back at the text of number three, that you understood, before the beginning of 2005, that things should be reduced to writing, they should be organized?

DR. COOK:

A. Yeah, there were a lot of things that I was certainly unhappy about in the program, that we certainly--you know, we needed where to go. There had to be a dedicated quality assurance program and committee set up, and we were doing a lot of quality assurance activities, as you see there, but I wanted a coordinated approach to a lot of the QA that we were doing.

COFFEY, Q.C.:

Q. And then, Doctor, paragraph five is "continue to support and work on implementing

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recommendations of the Surgical Pathology Review Committee."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. And as of April 1, you had asked the committee to focus on tissue audit.

DR. COOK:

A. Yeah.

COFFEY, Q.C.:

Q. And of course, we've followed some of that through. As of October '05, the form was completed and we've seen that. So going into the calendar year 2005, I take it, Doctor, you had certain goals -

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. - set out, and as you've indicated, they kind of got derailed in some ways by the amount of time you had to spend on the ER/PR matter.

DR. COOK:

A. Yes, but there were also areas there that I wasn't too happy about the lab. I mean, I found, over the years, that I was responding

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to complaints, as opposed to being proactive, and what I wanted was a process to be put in place that I would get indicators on a monthly basis, how we were doing. I mean, not only in terms of turnaround times, but outstanding reports, but on the quality of the reports and quality of frozen sections, how we were dealing with our clinicians. Were our clinicians happy with our reports? Were patients responding as they should? So there's a lot of information there that I was not obtaining, but as clinical chief, I felt that there should be a process and a mechanism in place to obtain that type of information. So there were concerns about, you know, quality assurance and having the information act.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1919? Now this is an interoffice memo of October 14th, 2004. It's to Dr. Ejeckam, Barry Dyer, Ms. Thomas. It's from Dr. Carter. It's first meeting-- it's copied to yourself. "I'd like to set up the first meeting of the Quality Assurance Committee for Tuesday, November 4th, 2004 at

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St. Clare's. Enclosed is an introductory document which should be read prior to the meeting, as well as an agenda for the meeting." And this then is a document dated-- a memo of August 31st, 2004 to yourself from Dr. Carter. The subject is quality control and quality assurance committee on surgical pathology for the Health Care Corporation of St. John's. I take it this is the committee that you were speaking of?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Okay, and so the idea of setting up the committee dated at least to sometime before the middle of 2004?

DR. COOK:

A. Yeah, I think we talked about it September of '04.

COFFEY, Q.C.:

Q. What happened with that committee afterward, Doctor?

DR. COOK:

A. That committee, like many other things that we start within Eastern Health or Health Care

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Corporation, you start off going great. Then trying to sustain various committees becomes a major problem. Trying to get individuals to attend committees is a major problem. Sustainability is a major problem. Again, trying to get physicians to attend committees is--and when they'd be dealing with heavy workloads, it becomes a major issue. So this committee, over a period of time, certainly did not work out the way that I wanted it to work out, mainly because of trying to get attendants. Attendance was a problem with, I think, Dr. Ejeckam who was dealing with heavy workload, so he was saying at that time, and particularly with Mr. Barry Dyer, our technical manager, who I believe was heavily inundated with a lot of service work.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1711? Now Doctor, this is an e-mail from Dr. Mullen, January 20th, 2006 to yourself and he says "attached please find the ER/PR results for the Newfoundland retrospective review" and so I take it, in the main then, this was the bulk of the retest results?

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DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Now Doctor, if we could look, please, at Exhibit P-1976? This is a memo to a number of, I take it, pathologists throughout Newfoundland.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. And the other health authorities, as well as St. John's, Dr. Fontaine, and it's from yourself as clinical chief, February 1/06, ER/PR reports from Mount Sinai. "We have received most of the results from Mount Sinai regarding the ER/PR review process. The results from Mount Sinai were issued on Excel spreadsheets. I will be issuing individual reports on patients and submitting these to you at your respective sites. When you receive these reports, please ensure they are incorporated in your hospital information or laboratory information systems. I expect that you will be receiving the first of these reports within the next two weeks."

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DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. So Doctor, you did what then in relation to each of these patients' results from Mount Sinai?

DR. COOK:

A. Well, when they came in, I would enter them into the hospital information system and then issue hard copy reports.

COFFEY, Q.C.:

Q. So I take it that they would be entered into a Meditec chart for the patient in the Eastern Health system?

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Even if the patient was from Corner Brook?

DR. COOK:

A. Yes. We were trying to establish at least a database within the Meditec system.

COFFEY, Q.C.:

Q. And then the hard copy of the report, i.e. those pages of Meditec, the pathology report would be printed off and forwarded -

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DR. COOK:
A. And sent out, yeah.
COFFEY, Q.C.:
Q. - to Corner Brook or Grand Falls or wherever?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Here you've noted "spoke to Gary Baker, February 9th, and Paul"--that would be Paul Neil, I take it?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. "Wednesday, February 10th, ensuring they got my memo. Spoke to Dr. Summers, February 17th to ensure they got my memo."
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. So I take it, Doctor, that even after sending it out, you did follow up to ensure that -
DR. COOK:
A. Yeah, was -- there are some key people there that I just wanted to make sure the memo was getting out, and again any questions that

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people were having, I wanted to hear what those questions were. The big problem was I was sending out stuff, but I wasn't getting any feedback from people. You know, even though I made myself available, there was very little feedback from many people.
COFFEY, Q.C.:
Q. Go to Exhibit P-02046, please. Doctor, this is an agenda for the Laboratory Medicine Program and the minutes of a meeting of January 6th, 2006, the actual minutes. If you'll look at page four of the exhibit, ER/PR receptors is noted, "Terry updated on status and recommendations for the service to be re-instituted. Dr. Cook is planning a meeting in early February to determine internal consensus to put ER/PR testing back in service", and then it goes on, paragraph 12, organization structure, "Dr. Williams informed that he has not brought the laboratory's proposed management structure to Executive Management Team for approval. Dr. Williams has verbally approved the proposal and indicated that we proceed as if it was approved". Doctor, what was that again?

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DR. COOK:
A. Again the organizational structure in terms of Eastern Health. He was mainly looking at the technical aspect of it, how we were going to deal with the managers, particularly outside of St. John's, and who they were going to report to. The issue that I had concerned the medical side and I was expressing concern about the clinical chief in St. John's area having to oversee the medical arms of the Carbonear and Clarenville area. So I was against any extension of clinical chief authority from St. John's to those particular areas at that time.
COFFEY, Q.C.:
Q. Why is that?
DR. COOK:
A. Just too large an operation. I mean, I felt that it was difficult -- I mean, I was having trouble even in St. John's trying to keep a handle on what was going on in the St. John's situation, with me being based at St. Clare's and much of the activity taking place at the General Hospital. I felt even within Health Care Corporation of St. John's that I didn't

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have a firm handle on things, a finger on the pulse, and here we were going to a much larger organization and I just didn't see how it was going to be able to monitor what was going on in terms of physician's activities in those particular areas.
COFFEY, Q.C.:
Q. Exhibit P-01748, please. Doctor, these, I take it, are your handwritten notes of a meeting of February 8th, 2006.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. In regard, update on implementation of ER and PR. Present are yourself, Dr. Ejeckam, Dr. Carter, Dr. Fontaine, Mr Gulliver, Mr. Dyer, and Les Simms, Ken Green, and Mary Butler. I would take it then these are your notes as to what happened at this meeting?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And it began with both Ken Green and Mary giving written reports on their experiences at Mount Sinai.

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DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Mary, and Montreal Jewish General for Ken, and -- so, Doctor, without going through this in detail, what was the overall result at this point in time vis a vis re-implementation of ER/PR?
DR. COOK:
A. Well, we were moving towards implementation. I think, if I remember correctly, we were getting good correlations on the ERs with Mount Sinai. There was some problems with the PR, still a bit erratic in terms of correlating results with Mount Sinai on the PR. There was a lot of discussion on the image analysis, and this was something that Mr. Gulliver was keen on bringing in to have a look at, and subsequently that was brought in to try to assess whether we can deal with the issue of the pathology and interpretation and try to provide greater standardization in the post analytic aspect of the interpretation to the ERs, PRs and HER2/neu's.
COFFEY, Q.C.:

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Q. Exhibit P-02062, please. Doctor, these are handwritten notes.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And you begin them at the top of the page here, "Things to do, Monday, March 6th".
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And there's -- you're going to follow up on slides and follow up, follow up, and then call Paul Neil further down the page, and e-mails to Brendan Mullen. At the bottom of the page, you have, "Spoke to Paul Neil on these cases, March 8th, 2006", and then it goes on for a couple of other pages dealing with particular block numbers and results. I take it -- I refer you to this, Doctor, in respect of -- I take it then going into March of 2006, as you were ending your time as clinical chief, I take it you were still involved, though, in the nitty-gritty of dealing with the results from Mount Sinai?
DR. COOK:

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A. That shows the amount of work that we had to do to follow up cases. I mean, in many instances the wrong block may have been sent up, or the lesion in question may have been cut through on deeper levels, and it required sending out letters or correspondence to the hospitals bringing in cases to review, trying to identify more appropriate piece of tissue to send up to Mount Sinai. So that was occupying a fair amount of time and took a lot of effort.
COFFEY, Q.C.:
Q. And as an example again, I'm not going to belabour the point, but Exhibit P-02063, and, Doctor, this is your handwritten notes of March 9th, 2006, are they? These are your notes?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And again, I take it, there's a whole listing of block numbers, particular information on them. The first of them is an '04 case review by Dr. Cook and Carter, and you talk about there is definitely strong nuclear staining

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and infiltrating carcinoma cells for PR.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. I take it then, Doctor, this would be an example of again the sort of nitty-gritty work involved in this?
DR. COOK:
A. Yeah, a lot of that going on.
COFFEY, Q.C.:
Q. Exhibit P-01749. Doctor, this is two e-mails of March 6th, 2006. The first is from Denise Dunne to yourself and others saying, "I want to advise you that Trish Wegrynowski will be coming to visit us again to go over our program. She will be arriving late on the evening of March 29th, 2006, and staying until March 31st, 2006. I will follow up with each of you on this issue later this week, Signed, Bob", and then sends an e-mail the same date, "Further to my e-mail below with respect to Trish, Terry, I wonder if you would follow up with her directly. She will like some information, to update her". Did -- so in relation then to Trish Wegrynowski's second

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visit here, I take it you didn't have a lot of contact with her?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. Exhibit P-01590. Doctor, this is an e-mail -- I'm sorry, a fax to Heather Predham, March 7th, 2006, from yourself. The second page of the exhibit is a memo from you to Dr. Dan Fontaine, Gershon Ejeckam, Terry Gulliver, and Barry Dyer, "As clinical chief, implementation of immunohistochemical antibodies, and all new antibodies that are requested by pathologists for immuno service have to be approved by the c h i e f p a t h o l o g i s t o v e r s e e i n g immunohistochemistry. No new antibodies to enter the system until they're signed off on the protocol formed by the pathologist overseeing the immunohistochemistry service".

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. So I take it, Doctor, was this new at this point or --

DR. COOK:

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A. Well, more solidification of the role of the individual overseeing immunohistochemical service, and trying to bring in a role for that particular individual, trying to solidify that individual with a view of honing up the service and bringing in a firm structure.

COFFEY, Q.C.:

Q. Exhibit P-02070. Doctor, this is a letter of April 4, 2006, from Dr. Paul Neil, Western Health Authority, to yourself, and you've noted at the top of the page, "Spoke to Paul, June 19, 2006", and he writes, "You recently gave me a list of patients to follow for ER/PR testing from Mount Sinai. Here are some problems I encountered".

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. "We reported DCIS on the first patient. We reported DCIS on another block".

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. And so on. Doctor, in the first half of 2006, how much time and effort did you spend in

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relation to this DCIS matter?

DR. COOK:

A. A fair bit, Mr. Coffey. There was that, along with many other issues that -- to identify issues concerning DCIS. So I was fairly busy doing other work as well, but trying to spend as much time as I can to deal with the issues at hand.

COFFEY, Q.C.:

Q. Exhibit P-02071. Doctor, this is a redacted spreadsheet entitled "breast receptors". That's your handwriting I take it, "Cases that arrived late January 20th '06 from St. Anthony".

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. "Sent to Mount Sinai Hospital, January 25, 2006", and there are a number of -- I think it's ten cases at least listed here on this particular page. So, Doctor, what was the situation in relation to that -- the matter of St. Anthony from your perspective?

DR. COOK:

A. Although they're late getting their blocks in,

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I don't think I was too happy because my understanding was that all the cases were in. I remember having a conversation with Maria Mendes saying that as far as I knew all the cases were up and thanked her for her help, and then we got another batch from St. Anthony that came in all of a sudden.

COFFEY, Q.C.:

Q. And they were sent back in late January and reported in February?

DR. COOK:

A. Yes, we got the report sometime the middle of February.

COFFEY, Q.C.:

Q. Exhibit P-02072, please. Doctor, this is an e-mail of April 7, 2006, from yourself to Marie Mendes. You say, "Hi, Maria: We are rechecking our master list and have come across some patients that did not come up on the initial computer screen. There may be 15 to 20 such cases. We are sending up six of these within the next few days. These may be entered as retro cases and given RS numbers. I'm also sending up cases that require another block. These are the NT, which would be "no

tumour" cases that could not be reported. We will be sending these up over the next week. Regards, Dr. Cook". Doctor, what were these 15 to 20 cases about?

DR. COOK:

A. These were new cases that came out of the blue which weren't previously captured in the initial screening process. So we were beginning to find cases that were coming up that weren't captured in the original spreadsheet.

COFFEY, Q.C.:

Q. And these were being identified by whom, brought to your attention by whom?

DR. COOK:

A. It could have been Mr. Gulliver. I think he would be -- also by Heather Predham.

COFFEY, Q.C.:

Q. I take it there was reviews somehow going on, clerical reviews going on, and cases were being identified from time to time that had not been -- should have been retested within the criteria utilized and hadn't been?

DR. COOK:

A. And hadn't been identified. We were

discovering that there were cases that were not totally captured.

COFFEY, Q.C.:

Q. Exhibit P-02073. Doctor, this is your handwritten note.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. You write, "Spoke to Joy McCarthy, April 10, 2006. Attended a recent meeting where standard practice among oncologists is to prescribe with Tamoxifen if ER/PR greater than one percent. This goes against NCIC guideline where 10 percent is the cut off point. Many labs are just reporting as positive or negative. If this is the case, we may have to change our report as positive or negative and not give percentage. We will discuss further. Joy claims that oncologists have no real evidence to show why they are using greater or equal to one percent".

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Now, Doctor, who was the one who attended the

recent meeting? Was that you or Dr. McCarthy?

DR. COOK:

A. That would have been Dr. McCarthy.

COFFEY, Q.C.:

Q. So she had contact -- you had contact with each other about this issue?

DR. COOK:

A. We spoke. I can't remember where exactly we spoke about that, but she had concerns about what was happening across North America. Different oncologists were using different cut off points, and there didn't appear to be standardization how the receptors were being reported.

COFFEY, Q.C.:

Q. So did that -- did you, in fact, change your approach subsequently or continue on with the percentage?

DR. COOK:

A. I continued on with the percentage.

COFFEY, Q.C.:

Q. Okay. Exhibit P-01369. Now, Doctor, this is a letter of May 3, 2006. It's from yourself, its copied to Dr. Denic and Ms. Predham. You write, "Currently we have documented ER/PR

results from 17 deceased patients on whom we have received results from Mount Sinai, and are currently on our hospital information system. These patients have not signed out for release from the system. I would appreciate direction on how to proceed further with these cases". Doctor, what was this about?

DR. COOK:

A. Well, we had come up with deceased patients and I was wondering what to do with these patients. We had not entered them into the system, so I was looking for direction from Dr. Williams on what to do with them.

COFFEY, Q.C.:

Q. Enter them in the sense of, I take it, into the Meditec System?

DR. COOK:

A. Meditec System.

COFFEY, Q.C.:

Q. You had the result from Mount Sinai?

DR. COOK:

A. Yeah.

COFFEY, Q.C.:

Q. Results, but --

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DR. COOK:
A. They weren't entered.
COFFEY, Q.C.:
Q. And you wanted direction?
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. Now, Doctor, in that regard, I take it that led to what, your request?
DR. COOK:
A. Well, I assumed it led to that -- Bob then asking for an ethics consult.
COFFEY, Q.C.:
Q. And did you participate in that?
DR. COOK:
A. I did.
COFFEY, Q.C.:
Q. What was the nature of your involvement in that?
DR. COOK:
A. I guess basically to bring forth information to the Ethics Committee and to ask -- answer any questions they may have.
COFFEY, Q.C.:
Q. So you attended the meeting?

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DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And what -- if I could, please, Exhibit P-0783. Now, Doctor, it's an e-mail of June 22nd from Rick Singleton, who I take it, organized the ethics consult to Dr. Williams and Louise Jones, and this is his report of June 23rd, 2006.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Did you ever receive a copy of the report itself?
DR. COOK:
A. No, I didn't.
COFFEY, Q.C.:
Q. He wrote here, "Important facts to the history and understanding of this case include the following; there were no mistakes or technical errors at the route of this problem. It's impossible to know in any specific case if the outcome for any individual patient would have been different. Intervention for post menopausal women had positive impact by

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lengthening life in 47 percent of patients treated. The main ethical issue in this case pertains to disclosure", and it goes on from there. Now, Doctor, the idea that there were no mistakes or technical errors at the route of this problem, from your perspective as of June, 2006, would you have maintained that that was an accurate statement?
DR. COOK:
A. I wouldn't have made that statement. I don't know where that came from at that meeting.
COFFEY, Q.C.:
Q. Certainly your recollection of the meeting was you didn't offer that opinion yourself?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. And I'm not suggesting you did at all.
DR. COOK:
A. No, I don't know where that came from.
COFFEY, Q.C.:
Q. Was the cause or causes of the problem discussed at the meeting, do you know?
DR. COOK:
A. We would have used a word like "system"

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describing concerns that we had, how the tissue was prepared, how it was tested, how it was interpreted. So we were looking in terms of discussion at system. This is what the -- I guess if anything, that would be the terms that we were using and probably discussing what was going on with the rest of Canada with the testing and the United States, and the problems with the testing in general.
COFFEY, Q.C.:
Q. P-0297, please.
COMMISSIONER:
Q. Mr. Coffey (inaudible).
COFFEY, Q.C.:
Q. Thank you, Commissioner. These are your handwritten notes, Doctor, of June 30th, 2006?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And it's notes of a meeting. Present are yourself, Morris-Larkin, Dr. Denic, Dr. Elms, Mark -- I'm sorry --
DR. COOK:
A. Dr. Makarla.
COFFEY, Q.C.:

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Q. I apologize. Dr. Carter, Dr. Williams, and other individuals, re; implementation of ER/PR testing.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. I take it that this was a meeting on June 30th to discuss what was required to move this matter ahead?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And they're -- I'm going to suggest here, fairly detailed notes by yourself as to what was said?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Now, Doctor, why I raised this with you is this, is that you were no longer -- you're site chief, but you're not longer clinical chief?
DR. COOK:
A. That's right.
COFFEY, Q.C.:

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Q. In what capacity were you at this meeting?
DR. COOK:
A. I was capacity -- well, as a site chief, and I suppose just acting as a resource person providing any background information that individuals would need.
COFFEY, Q.C.:
Q. Okay. So in terms of authority figure, by that point in time who was actually, from the perspective of the clinical laboratory program pathologists, who was in charge?
DR. COOK:
A. Oh, that wold be Dr. Denic.
COFFEY, Q.C.:
Q. Okay. If we could, please, Commissioner, before we break, Exhibit P-02104. Doctor, these are your handwritten note of July 14, 2006.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. You've noted you spoke to Paul Neil, Dr. Neil.
DR. COOK:
A. u\Uh-hm.
COFFEY, Q.C.:

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Q. And you write, "Paul wishes to review any discrepancies in DCIS himself with his pathologists and disclose it themselves".
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. "Will review his 20 odd DCIS and compare it with original pathology report to confirm as confirmed DCIS". So, Doctor, what was this about, this whole matter?
DR. COOK:
A. Well we were getting new issues with DCIS and I spoke with Paul as to whether he wanted us, myself and Dr. Carter, to review the cases of DCIS and he'd prefer that he'd handle his own review and that that would be conducted by himself and his staff out in Corner Brook.
COFFEY, Q.C.:
Q. And this review was necessary why?
DR. COOK:
A. Because we were picking up discrepancies with DCIS's, cases that were called, more so called infiltrating ductal carcinomas were really DCIS's and cases so called DCIS's, I believe, we may have picked up a few that were

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invasive.
COFFEY, Q.C.:
Q. And so why were you still involved at this point in time? This is July of '06.
DR. COOK:
A. Yeah, I was still involved because Dr. Denic asked me, along with Dr. Carter, to still play a role in reviewing these cases and not only that, we were formulating a breast site group.
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. And as part of that group, there were four of us in that group, Dr. Denic asked us to stay, keep still involved with the process.
COFFEY, Q.C.:
Q. Thank you, Commissioner, break please?
THE COMMISSIONER:
Q. Fifteen minutes.
(RECESS)
THE COMMISSIONER:
Q. Please be seated. Mr. Coffey?
COFFEY, Q.C.:
Q. Thank you, Commissioner. Some final points, Doctor, if we could, Exhibit P-1711? Doctor,

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this is that e-mail of January 20th from Dr. Mullen to yourself, sending you what was then thought to be a spreadsheet, was then thought to be the conclusion of the retesting results.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Dr. Mullen concluded by saying "When you have had an opportunity to review the results, I would like to discuss some of the technical difficulties we encountered with processing and staining of specimens. Some of the same issues are present in the current Newfoundland and Labrador material."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Did you ever discuss that matter, these technical difficulties?

DR. COOK:

A. Yes, I remember having a brief discussion with him.

COFFEY, Q.C.:

Q. Do you recall when that was and what was said?

DR. COOK:

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A. Oh, that may have been a day or two after that e-mail, I can't remember exactly when, Mr. Coffey, but I remember phoning him and thanking him for the work that he done and he brought forth the issue that we had technical difficulties, particularly in the issue of fixation. And there was a discussion about what was encountered in other hospitals and I can't remember for sure if he was talking about hospitals out of St. John's, but there was general discussion on what he was encountering even in hospitals in the Ontario area concerning how to deal with the fixation process. My conversation to him was, well if you're dealing with hospitals from the outside, how are you going to deal with the issue of standardization and how are you going to deal with the issue of making the fixation a standardized protocol? I mean, you're dealing with different hospitals, with different resources? So his response to that was, well basically you issue a rider on the report and that was basically the end of the conversation, and remember I was called to a frozen section around that particular time, so

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I thanked him for his remarks and his effort and I indicated I would try to get back to him later on.

COFFEY, Q.C.:

Q. And what happened with that?

DR. COOK:

A. Well I never did get a chance to get back to him later on. I remember speaking shortly after to Bev Carter and I said, you know, I had a conversation with Dr. Mullen and the issue of how to deal with the fixation problem, particularly outside of St. John's, I said it's one thing to issue policies and procedures, but how are you going to be able to ensure that the policies and procedures are actually being carried out and do these institutions have the resources to carry that out in a standardized fashion. That was the big issue that I had.

COFFEY, Q.C.:

Q. And where did that go?

DR. COOK:

A. That basically didn't go too far. I can't remember if I had any other conversations with any of the directors outside of St. John's,

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but that basically was something that I was mulling about. I looked at the fixation problem as being primarily centered around the need to have pathology assistants, that was the only way that I could see that a standardized fixative process could be in place.

COFFEY, Q.C.:

Q. So I take it then you don't have any recollection of having taken it up with your counterparts in the other health authorities?

DR. COOK:

A. I don't, I mean, there may have been a discussion back and forth, there were numerous phone calls, but there's no, you know, I can't say for sure whether I discussed it with my other colleagues or not.

COFFEY, Q.C.:

Q. Doctor, we--just before the break we were speaking about the ethics consult.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Doctor, your actual letter of May 3rd, you were looking for direction in how to proceed

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further with these cases, i.e. with respect to, I take it entering the results into Meditec.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. The actual--what was the result of your request for direction in that regard?

DR. COOK:

A. Well I didn't get any direction from that, I spoke to Bob Williams and I said I'm still up in the air what to do with these deceased and I remember speaking to Bob and there was another meeting where I spoke to Heather Predham and Nash Denic and said look, I got these cases here, they're still not signed off in the system. I said I'm going to go ahead and sign them off in the system, at least if they're in the system, if there are any inquires about it.

COFFEY, Q.C.:

Q. So is that what you did?

DR. COOK:

A. That's what I did, I signed them off in the system.

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COFFEY, Q.C.:

Q. So in that context, for the Commissioner, that means what, sign off?

DR. COOK:

A. They were entered and I gave my signature and they were available for anyone who had access to the system to get the results.

COFFEY, Q.C.:

Q. Thank you, Exhibit P-2089 please? Doctor, here these are the minutes for the breast cancer site group for guideline development, June 8th, 2006.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. And I'm not going to take you through all the material involving this group, but I take it that you were involved with this group from its initiation from the middle of 2006?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. And do you continue to be involved with them?

DR. COOK:

A. That's correct.

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COFFEY, Q.C.:

Q. And the purpose of this group is what?

DR. COOK:

A. The main purpose was trying to get key players who were handling breast lesions, to get together in one room and start communicating and liaisoning with each other. What we found out through the ER/PR issue was a lack of effective communication and liaison between the different groups. So you can see there that this is a multi-disciplinary approach, we've got individuals from surgery, radiation, oncology, medical oncology, diagnostic imaging, there was nurses from various representatives who were overseeing the care of cancer patients, the idea is to get together and then formulate policies and hopefully act on them.

COFFEY, Q.C.:

Q. Exhibit P-2090 please? Now, Doctor, this is a letter of June 16th, 2006 to yourself from Bruce Hollett, the acting president, it's copied to Karen Kennedy. It's on College of North Atlantic stationary, office of the president and he writes, "I am writing in

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response to your letter"--that's your letter of May 25th, 2006--"in which you express the concerns of the Medical Laboratory Services Program Advisory Committee of the high rate of attrition in the program."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. "It is my understanding the Dean of the Health Sciences Program, Karen Kennedy, is acting on these concerns and requested approval from the colleges, school team committee, to conduct a program review of the first year Medical Science Program during the fall of 2006." Then it goes on to talk about that. Doctor, what was your involvement in this?

DR. COOK:

A. Well as chair person of a laboratory of that particular committee and the issue had come up over the high attrition of students that were losing in the medical technology program and it was asked if I could write a letter looking at the entrance requirements and whether we could jack up the entrance requirements. I think if I remember correctly the average was

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60 percent entrance, what Karen Kennedy was looking for was to make the entrance requirements more similar to Memorial University. It was sort of a feeling that people were going in and thinking that that particular program was an easy program but it was one of the most challenging programs that was available in the College of the North Atlantic.

COFFEY, Q.C.:

Q. Okay, and the graduates of that program, I take it, would end up as technologists, potentially?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. That's your linkage there?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. With why you would be involved with this. Exhibit P-2092 please? Now, Doctor, this is a document, it's a spreadsheet format, laboratory program to your operational plan, April 2006 to March 2008 and detailed activity

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plan, operational goals, director's operational objectives, actions required, delegated to, start date and end date.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Were you involved in the preparation of this?

DR. COOK:

A. Not in the preparation, no.

COFFEY, Q.C.:

Q. Okay, and I asked you about that because it's in the switch over from yourself to Dr. Denic's time as clinical chief.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. You were passing off to Dr. Denic. So you weren't involved in the creation of the document, but I take it some of the responsibilities or tasks here, your name is listed as being delegated to at least some of them.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

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Q. Okay, and I'll take that up with Dr. Denic then. Doctor, as 2006 then, into the summer of 2006 and into the fall of '06, we understand that there was a media briefing in the fall of 2006. Did you participate in that?

DR. COOK:

A. With the media?

COFFEY, Q.C.:

Q. Yes.

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. Okay, how about the briefing for Eastern Health personnel in November of 2006?

DR. COOK:

A. Yes, I was involved in that.

COFFEY, Q.C.:

Q. And what was the nature of your involvement?

DR. COOK:

A. Just basically to give the background of how the ER/PR issue arose, some of the history, the chronology and again, answer any questions that people would pose regarding that time period.

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COFFEY, Q.C.:

Q. Okay, and you prepared a slide show for that?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Did you get any feedback afterward concerning that or any response from the people you presented it to?

DR. COOK:

A. Regarding my preparation?

COFFEY, Q.C.:

Q. Yes.

DR. COOK:

A. No, very little.

COFFEY, Q.C.:

Q. Okay. If we could, please, Exhibit P-2118? Doctor, here these are your notes?

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Handwritten notes and they cover a number of dates, January 10th, 2007, 4 in breast group.

DR. COOK:

A. Right.

COFFEY, Q.C.:

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Q. May 28th, 2007, only two left in group.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. So who are the two?
DR. COOK:
A. That would be myself and Dr. Carter.
COFFEY, Q.C.:
Q. And then how many are left now?
DR. COOK:
A. None basically.
COFFEY, Q.C.:
Q. And that's that breast group that we saw the formation of earlier?
DR. COOK:
A. Yes, that was formulated in November of '07, I believe, or '06, to try and bring in subspecialization into the breast pathology.
COFFEY, Q.C.:
Q. Okay, so that's--that group is the breast pathology group in fact?
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Now approximately May 17th, 2007, you had

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another conversation with Dr. Dalton, a "liaison years ago regarding issues of ER/PR, can't remember specifics or details, but did get a response from someone, technical believes issue was absence of controls."
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. What was that about?
DR. COOK:
A. I don't know, this was one of my long conversations with Morris Dalton and I may have asked him, Morris, is there any way over the years that we could have picked up the problems with ERs and PRs and was there anything that he had come across in his mind that were problems with ER and PR, and he did mention this particular letter or so or I don't know if it was a letter or a conversation with a technologist concerning the issue of absence of controls that were being sent with these slides. He couldn't remember any of the specifics or details on it, but he did get response from someone technical in St. John's, so that was about all

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he could recollection. So, I mean, I thought that was something interesting that I would note, but I couldn't get anything more from Morris on that particular issue.
COFFEY, Q.C.:
Q. And May 24th, 2007, you've got a 10:00 a.m. conversation with Dr. Bibi re: issue of Clarenville discontinuing ER/PR from St. John's. She states "Dr. Yassa not happy with ER/PR as no controls were sent, states there was no letter or documentation to this effect. No one in St. John's notified."
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. So I take it that this, I think we've seen an earlier reference to a similar thing.
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Why were you making notes of this source of material like in May of 2007?
DR. COOK:
A. Because I was wondering, Mr. Coffey, was there something in the past that we could have

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picked up, you know, the whole ER and PR issue, could we have identified something before and if we did, could we bring it to attention and deal with it. This was a second conversation that I had with Dr. Nagebi regarding that and then trying to reiterate what were the issues she had or they had surrounding the ER and PR, and was there any contact with anybody in St. John's concerning that because I truly believe that if there had of been an issue surrounding this or particularly Dr. Yassa, where he was American trained, I figured he would be used to a certain type of standard from the institution that he came from, and if he came to Newfoundland and looked at the quality of our slides and wasn't happy, I would have thought that that would be something that maybe someone should have been notified and maybe we could have acted on a lot earlier.
COFFEY, Q.C.:
Q. Now, Doctor, I just several minutes ago asked you about the presentation that you made in 2006, November '06 to Eastern Health personnel. If I could ask, Registrar please,

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Exhibit P-2107? And, Doctor, this is an e-mail from Heather Predham, November 19th, 2006 to Pam Elliott and Patricia Pilgrim and she says, "I met with Bev Carter, Ford Elms, Don Cook, Nash Denic and Susan Bonnell on Friday afternoon. We reviewed the presentation for Monday and it's very good and comprehensive, as always. Bev's comments in the meeting were a bit alarmist in nature, but she is only speaking about ER/PR testing at the presentation. Dr. Howell called me on Friday afternoon and told me that it would be anticipated that I would be asked on the executive meeting on Tuesday and if I felt there was everything that was done, that could be done in the lab, as per the external reviews. And he arranged for Nash to give me the summary document of the reviewer's recommendations and the lab's actions. It has not been updated since June, a lot of communications have ongoing next to it." Now, Doctor, this e-mail is not sent to you, nor did it come from you, but I want to ask you about this, this assertion here, because apparently you attended this meeting?

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DR. COOK:

A. Yes, attended the presentation.

COFFEY, Q.C.:

Q. The presentation, well here it says, Ms. Predham says "I met with Bev Carter, Ford Elms, Don Cook, Nash Denic and Susan Bonnell on Friday afternoon." So that's a Sunday, so it's probably November 17th, Friday. Did you ever interpret what you heard from Bev Carter as alarmist?

DR. COOK:

A. No, I didn't, Mr. Coffey.

COFFEY, Q.C.:

Q. Okay, and I take it as a pathologist you expected at least based upon your background and training you would be in a position to make an informed judgment on that?

DR. COOK:

A. Alarmist in what way?

COFFEY, Q.C.:

Q. I don't know and I will be asking some of the authors and recipients of this, but there's a reference to this meeting and there's an assertion here that Bev's comments were a bit alarmist in nature, and I'm just asking you

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did you ever see Dr. Carter's comments as alarmist in nature?

DR. COOK:

A. Well certainly I didn't think they were when she was going through the presentation.

COFFEY, Q.C.:

Q. What about otherwise at the meeting?

DR. COOK:

A. I beg your pardon?

COFFEY, Q.C.:

Q. What about otherwise, like at the meeting?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. Doctor, can you tell the Commissioner please, in 2007 were you ever asked to go to any meetings around the time that this broke in the media, in May of 2007?

DR. COOK:

A. There was a meeting I had with Mr. Tilley and Dr. Howell and Mr. Gulliver, Dr. Denic and myself, I think this was a time that story broke from the Ejeckam memos, I believe.

COFFEY, Q.C.:

Q. Go ahead, what do you recall about that?

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DR. COOK:

A. Well, Dr. Howell asked if I could come up and discuss the issue of the Ejeckam memos. So when I got there, there was already Mr. Tilley, Mr. Gulliver, Dr. Howell and Susan Bonnell in the room, myself and Nash arrived around the same time. And they wanted to know the background of the Ejeckam memos, so we basically told him that these memos came out at around that time period, that I felt that they were all part of quality assurance, quality assurance activities and that Ejeckam as looking, regarded him as a circuit breaker in the system. He was improving and enhancing the quality and crispness of the stains. We talked a bit about the various classes of immunohistochemical stains, class 1 verses class 2, and the fact that we didn't identify a patient care problem at that particular time, nor did we have evidence of an index case.

COFFEY, Q.C.:

Q. Doctor, did you ever attend any meetings in 2007 with the minister of health, deputy minister of health concerning this matter,

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ER/PR?
DR. COOK:
A. That would be Mr. Osborne, is it?
COFFEY, Q.C.:
Q. Well, I'll ask you first about Mr. Osborne, first of all -
DR. COOK:
A. No, I haven't.
COFFEY, Q.C.:
Q. How about Mr. Wiseman? I apologize, how could I ever forget Mr. Wiseman's name?
DR. COOK:
A. No, I haven't.
COFFEY, Q.C.:
Q. Okay. Exhibit P-2126, please. Doctor, this is an e-mail of July 5, 2007 from yourself to Pat Pilgrim, accepted analysis of ER/PR, you've written here, "meeting with Pat Pilgrim, Nash Denic, Kara Laing and Heather Predham, analysis of ER/PR still not done. Spreadsheet has to be formulated with critical event".
DR. COOK:
A. That's right.
COFFEY, Q.C.:

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Q. Lab medicine reports to clinical chiefs, November '03 to February '06.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. I take it somebody wanted a copy of the lab medicine reports.
DR. COOK:
A. Probably in relation to gathering information for the Commission of Inquiry, I think.
COFFEY, Q.C.:
Q. What's this about this, "analysis on ER/PR still not done, spreadsheet has to formulated with critical event".
DR. COOK:
A. We still, I mean, this was something that Dr. Denic and I were pushing for to get a complete analysis on the ER and PR issue. We wanted breakdown as to the number of conversions per month, per year; trying to formulate that with the critical events going on in the organization at the time, such as the closure of the Grace, the centralization of technical services at St. Clare's. So, trying to correlate critical events in the organization,

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whether they had any impact or not on the ER/PR issue, but more so trying to get as much information from breakdown of information, what specific times of the year, what years did we have the most problems with the ER/PR.
COFFEY, Q.C.:
Q. And was that ever forthcoming?
DR. COOK:
A. No, I can't remember seeing that.
COFFEY, Q.C.:
Q. Who, if anyone, within Eastern Health at the time was tasked, in your view, or should have been tasked with doing that?
DR. COOK:
A. I think that would have been Heather, I'm not sure if Pat Pilgrim was involved.
COFFEY, Q.C.:
Q. And if there is such a document or documents to this day, you haven't seen them?
DR. COOK:
A. I haven't seen those, no.
COFFEY, Q.C.:
Q. Was this the first time that you raised that topic?
DR. COOK:

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A. It was raised a number of topics with myself and Dr. Denic and I remember Dr. Denic getting on the phone a few times talking to Heather trying to get this type of spreadsheet in place. And I remember Dr. Williams too being involved and trying to get movement on this.
COFFEY, Q.C.:
Q. Exhibit P-2136, please. Doctor, these are the minutes of site chief meeting of November 7, 2007, present are Morris-Larkin, Denic and yourself. And one, "fixation policy, it was agreed that the OR will need to document the time the tissue was initially submitted in formalin so it can be incorporated into the fixation policy. The PAs will need to document the date of processing as well. Dr. Denic will also liaison with Dr. Howell regarding this. A copy of the fixation policy will be forwarded by Dr. Denic to the clinics and OR once the policy if finalized". So, I take it, Doctor, that as of the beginning of November 2007, the fixation policy had not yet then been finalized?
DR. COOK:
A. Not formally finalized. I mean, we were--what

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was happening though, we were getting the specimens coming up from the lab at a timely fashion and they were being handled, but in terms of having a formal fixation policy, that was still being discussed and thrown about.

COFFEY, Q.C.:

Q. Okay. Is there such a policy in place now, fixation policy?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. The formal written one is -

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Exhibit P-0488, please, page 100, Registrar. Doctor, these are, if you look at the top, executive management minutes, 14 November, 2007 and paragraph 3.13, ER/PR, it reads, "with respect to the testing of ER/PR Eastern Health, St. John's unilaterally decided, ie. director and manager, to go back to January 1997 when the first testing was carried out. However, in correspondence from the clinical chief, Dr. Donald Cook, to the other Boards,

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it is referenced May 1997. Pat Pilgrim and Oscar Howell are following up on the reasons why Eastern Health managers retested back to January 1997". Do you recall what this was about, Doctor? Did anybody ever speak to you about this?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. Okay. And I take it that in terms of the reference in the material involving yourself, not particularly this, but we've see a memo from yourself, May of 1997.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. That is the start date for the material being requested was why?

DR. COOK:

A. That was information that came from me for Mr. Gulliver as to when we actually started testing for ER and PR with the immunohistochemical technique.

COFFEY, Q.C.:

Q. Okay. If we could please, Exhibit P-670.

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And, Doctor, I'm not going to take you through these. I went by them without going them in detail. I just want to have you confirm. These are your handwritten notes for activities, October 28 through October 31, 2005.

COFFEY, Q.C.:

Q. Yeah.

COFFEY, Q.C.:

Q. Dealing with what you were doing at the time particularly involving contact with Dr. Dalton, Terry Gulliver, Dr. Baker, Dr. Barry Gallagher and Ms. Predham, as we look down through.

DR. COOK:

A. Okay.

COFFEY, Q.C.:

Q. And just on this point, Doctor, in the materials, at times there's dates, times, fairly detailed notes from yourself and then there'll be periods where there's no written records.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

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Q. In a sense of hand written notes.

DR. COOK:

A. Right.

COFFEY, Q.C.:

Q. Why the differences from time to time, could you explain that to the Commissioner?

DR. COOK:

A. There were times, I'd say, I would be in my office documenting things. There'd be other times I would receive phone calls outside my office, my binders may not be with me at all times. There are other times I would be on a telephone conversation, get interrupted in the middle of a conversation, go down to handle a frozen section case or any other issues that the lab techs would have. So, there'd be times that, yes, I would document; other times that I wouldn't document. I didn't keep up much on the documentation after I was finished with the clinical chief program. But it would vary from day to day and again, depending on the circumstances in that day. So, there'd be times I'd try to document as much as possible and other times, I didn't document.

COFFEY, Q.C.:

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Q. Exhibit P-2148, please. Doctor, we've seen the first page of this exhibit before, but I just wanted to refer you to--the second page of this, I take it, are your notes of the debriefing meeting, March 31, 2006 involving Ms. Wegrynowski.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. And here, you've noted here, a bullet here, I think it's the third one down, "QA at infancy stage".

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. So, that was what Ms. Wegrynowski was -

DR. COOK:

A. I think she's mainly referring to the technical aspect of QA and the technical aspect of the lab. We didn't get into her with various quality assurance activities with what was going on on the medical side in terms of the proficiency testing, the fact that we had royal college maintenance or certification processes, the wide variety of rounds that we

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were doing, the interdepartmental consultations, the referral to extra departmental areas such at the Mayo Clinic, the AFIP and the fact that we were already accredited by the Royal College of Physicians and Surgeons of Canada as a teaching program. So, we didn't touch any of that that was mainly directed at the technical aspect of the program.

COFFEY, Q.C.:

Q. Because she wasn't down to look at what the pathologists were doing; she was down to look at the technology end of it.

DR. COOK:

A. Yes, that was my viewpoint on all of that.

COFFEY, Q.C.:

Q. Doctor, just as a matter, I take it, was March 31 your last day as -

DR. COOK:

A. No, my last day was March 10, I believe.

COFFEY, Q.C.:

Q. Okay. And that's your last day as clinical chief?

DR. COOK:

A. Um-hm.

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COFFEY, Q.C.:

Q. And the third page and fourth page of this exhibit, Doctor, I take it, are your exit meeting notes of April 25, 2006 involving Dr. Banerjee's visit.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Now, here Doctor, Dr. Ejeckam was at this meeting.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Why was he there?

DR. COOK:

A. Well, we were getting him more involved in the process. A lot of the planning had taken place. We got financial resources in place; recommendations were being made. So, Ejeckam was there to firm up the role of a immunohistochemistry to firm up the whole role of having a director of immunohistochemistry and giving that individual director status.

COFFEY, Q.C.:

Q. Here there's--you've attributed the following

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comment, "need to have stipend for director of immunohistochemistry, need to recognize workload, need time for" -

DR. COOK:

A. Monitoring the lab and documentation.

DR. COOK:

A. - "monitoring the lab and documentation, need direct clinical support". Dr. Ejeckam that the point in time was already on his way out, I take it?

DR. COOK:

A. Yes, I think he was on his way out, but we were looking to provide financial remuneration for this type of activity and giving the individual control and authority over the IHC in terms of control and authority over the technical aspect.

COFFEY, Q.C.:

Q. Okay. Now, Doctor, the report then of Ms. Wegrynowski and Dr. Banerjee in the spring of '06. Did you get copies of those?

DR. COOK:

A. I didn't get copies of those.

COFFEY, Q.C.:

Q. Did you ever read them?

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DR. COOK:
A. I read them.
COFFEY, Q.C.:
Q. And when did you read them? Some time, I take it after '06.
DR. COOK:
A. I can't tell you the exact date, but it was some time I got them.
COFFEY, Q.C.:
Q. And Ms. Wegrynowski's report first of all, how did you feel about that at the time?
DR. COOK:
A. Well, there's still a lot of recommendations not in place. There was something that she referred to, the calibration of pipette which I understand from Mr. Gulliver and Mr. Dyer that it's no longer being used in the Ventana system. But still there was a lot of work that needed to be done in getting the recommendations implemented.
COFFEY, Q.C.:
Q. And Dr. Banerjee's report in the spring of '06, you did see that?
DR. COOK:
A. Yes.

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COFFEY, Q.C.:
Q. How did you feel about that?
DR. COOK:
A. I was fairly happy with that. That was moving in the right direction. We were moving forward on getting the pathology assistants in place and moving ahead on IHC. One of the things that I wasn't particularly happy about was the slow pace of reorganization of the laboratory management structure. So, I felt that that's something that needed to be addressed and it was addressed later on.
COFFEY, Q.C.:
Q. Doctor, is there anything that we haven't covered that you think the Commissioner should know?
DR. COOK:
A. Just like to iterate that as clinical chief I wish I had to have had the role that Dr. Denic has now with reporting of the lab and medical structures towards a central person. I wish I had to have a good quality assurance program in place that is there now with indicators being fed into the clinical chief and at least some discretionary funding in place that I would have been able to direct towards areas of need.
COFFEY, Q.C.:
Q. Commissioner, those are the questions I have, thank You.
THE COMMISSIONER:
Q. Mr. Pritchard?
MR. PRITCHARD:
Q. Thank you, Commissioner, I don't have any questions for the doctor. Thank you for your evidence, sir.
THE COMMISSIONER:
Q. Mr. Simmons?
MR. SIMMONS:
Q. Thank you, Commissioner. I don't have any questions arising out of Commission counsel's questions of Dr. Cook. Dr. Cook, I know has representation here in his capacity as a physician, Mr. Brown. Once other counsel have completed their questioning, there may be a possibility that if something new comes up in relation (unintelligible) duties for Eastern Health's clinical chief, that I might want to consider asking (unintelligible) ask any questions then. But I'll reserve that request

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(unintelligible) if it becomes necessary.
THE COMMISSIONER:
Q. Mr. Pritchett?
MR. PRITCHETT:
Q. We have no questions, thank you.
THE COMMISSIONER:
Q. Ms. Newbury.
DR. DONALD COOK, EXAMINATION BY MS. JENNIFER NEWBURY
MS. NEWBURY:
Q. Good afternoon, Dr. Cook. Jennifer Newbury for the Canadian Cancer Society, Newfoundland and Labrador division. I just have a few questions for you this morning on a couple of different topic areas.
DR. COOK:
A. Um-hm.
MS. NEWBURY:
Q. And I wanted to bring you back, first of all, to your involvement in the parallel studies that you mentioned back in 1997 when IHC testing for ER and PR was brought into the Health Care Corporation of St. John's.
DR. COOK:
A. Right.
MS. NEWBURY:

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Q. And at that time, I just wanted to be clear that I understood what was going on, in terms of your involvement in that, and I took from your evidence that there were three sets of tests being done on certain samples. Some were--some samples were tested at the General Hospital site for the biochemistry method. Some were tested at the General Hospital site for the IHC method.

DR. COOK:

A. Um-hm.

MS. NEWBURY:

Q. And then also at the Mayo Clinic for IHC?

DR. COOK:

A. Um-hm.

MS. NEWBURY:

Q. That's correct, is it?

DR. COOK:

A. That's correct, yeah.

MS. NEWBURY:

Q. Okay, and also at the time, you'd indicated that records of this testing were not kept and the only records that would have existed were your own handwritten notes.

DR. COOK:

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A. I didn't have any records at all from--regarding to the Mayo Clinic, no. I had handwritten notes at that time, but that was years ago and they were discarded.

MS. NEWBURY:

Q. Right, okay. So is this your own personal records wouldn't have been kept or is it your understanding that there would be no records at all within, at the time, Health Care Corporation of St. John's?

DR. COOK:

A. Well, they were just notes that I had written down on a writing pad, just roughly correlating our results from the Mayo Clinic with the biochemical assay.

MS. NEWBURY:

Q. Right, but in terms of what you were looking at, would there be reports coming in from the Mayo Clinic and reports coming to you regarding the biochemistry testing?

DR. COOK:

A. Oh no, the only report we got from the Mayo Clinic was the report on the--we send down the paraffin block. The Mayo would issue the report, either positive or negative.

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MS. NEWBURY:

Q. Okay.

DR. COOK:

A. And I believe I incorporated that into our hospital information system.

MS. NEWBURY:

Q. Okay, so there are reports there, but just not correlating or tying together all of the three types of testing methods?

DR. COOK:

A. The only type of report there from the Mayo Clinic report itself, but not correlating the Mayo results with the biochemistry results and our own immunohistochemical results.

MS. NEWBURY:

Q. Okay. So it's not that they don't generate any reports at all. There would be reports coming from the Mayo Clinic, but what you were referring to was the actual sitting down and comparing the three test results for the two samples.

DR. COOK:

A. Yeah, they--there's nothing there. It's just a hard copy report from the Mayo Clinic.

MS. NEWBURY:

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Q. Now the samples that were tested, are these ongoing patient samples or do you go back in your system and look for past specimens for -

DR. COOK:

A. You mean in terms of the Mayo Clinic report?

MS. NEWBURY:

Q. For the parallel studies that you were talking about back in 1997. I'm just wondering if these are active patient specimens that are being tested or do you go back into your inventory, I guess, to come up with some specimens for the purposes of the study?

DR. COOK:

A. I can't be sure what Dr. Khalifa did. You'll have to--that's a question you have to ask him.

MS. NEWBURY:

Q. Okay. So you wouldn't have any familiarity with that at that time?

DR. COOK:

A. No.

MS. NEWBURY:

Q. Okay, and just generally in terms of record keeping for quality assurance activities, would you generally keep records, not keep

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records? Has there been any change in that practice since 1997?

DR. COOK:

A. That was a problem, getting the infrastructure in place to have dedicated people to record all of this. We were doing a lot of it. The issue is having a separate person or a separate department recording all those activities, and that was a frustrating thing for me over the years, that we were doing a lot of it, but you didn't have the capability to go back and review, the personnel to go back and review a specific question. Like for instance, I might want to go back and look at the quality of pathology reports over the last two or three years. So was there a resource person that I could have there and say "here, look, I want to look at that quality, look at whether all the information was included in synoptic reports, and issue me a report" and it could be, say, for a six-month period over a particular year. So that's what was frustrating about the whole system is that I didn't have the available manpower to do these type of audits.

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MS. NEWBURY:

Q. But once you, for some reason, take it upon yourself to do that, even if it's in sort of a rudimentary form, would there be a practice of keeping, you know, even handwritten notes, as time went on, after 1997?

DR. COOK:

A. That's hard to say because I used to have to file. I did all my own secretarial work myself. The secretary that we had was covering four or five other pathologists, so if you look at my filing system, it's not the greatest. So you know, there may be notes there and there may not. I mean, I just didn't have a good way of going back and retrieving that stuff.

MS. NEWBURY:

Q. Okay, and that hasn't been improved since -

DR. COOK:

A. Oh, it has. Since this whole ER/PR issue now, the Chief of Laboratory Medical now has a dedicated secretary to do all his or her filing, and that's only come in recently.

MS. NEWBURY:

Q. Okay. Last week, you were talking about some

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various types of quality assurance that were taking place. You didn't have specific quality assurances, I understand it, for ER/PR testing, but you were talking about sort of the broader quality assurance type activities that were taking place there.

DR. COOK:

A. Um-hm.

MS. NEWBURY:

Q. And you've mentioned that sometimes there would be quality--there would be extra departmental reviews that would take place?

DR. COOK:

A. That's correct, yeah.

MS. NEWBURY:

Q. Okay, and would this just be for difficult cases?

DR. COOK:

A. It could be difficult cases or even relatively simple cases that we were looking at correlation ourselves with major reference centres across Canada and the United States. Usually what would happen, we have what is known as quality control rounds, which we meet once a week, all the pathologists, say for

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instance, at St. Clare's and it's a similar situation over to General, where they meet for their slide rounds where pathologists would bring difficult cases to that round for discussion amongst various pathologists and we would try to get a consensus opinion. If we're unable to get a consensus opinion, then we would refer the case out, usually to a major reference centre, and they would act as sort of an arbitrator in that particular case. The opinions would come back and we would review them at that particular round.

MS. NEWBURY:

Q. Okay, but would the cases that ultimately be sent outside to a major reference centre, and I think you'd mentioned the Mayo Clinic, BC Cancer Agency, and the Armed Forces Institute that you tended to use. The cases that ultimately got referred out to these major reference centres, would they typically be the difficult cases versus the more simple cases?

DR. COOK:

A. More typically difficult and ones where there was not a consensus of opinion in the department.

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MS. NEWBURY:
Q. And would there be--upon receipt of results back, would there be anyone on a look-out, I guess, for discrepancies between what the Health Care Corporation or Eastern Health might have been doing and what these major reference centres -
DR. COOK:
A. Usually the pathologist in charge of the case would do the correlations and many times these would come in through the fax machine in my office and I tended to scan through many of these and recollect many of the cases that we had discussed. So in terms of correlations, we were doing pretty good, say, within 90-95 percent. There was always some cases that there was a disagreement on, but what happened in many of those cases, before the case was actually signed out and actioned upon, we would always wait for the results to come back from the referring institution.
MS. NEWBURY:
Q. And would there be a system in place for monitoring in a collective fashion, you know, the types of issues that you might be seeing

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on that or would these reviews be considered more quality assurance on a patient specific basis?
DR. COOK:
A. More quality assurance issues and trying to deal with an issue before it became a problem. So therefore, if there was a concern about a particular case, about the interpretation, before a final report was issued, we would issue a preliminary report saying that the case was sent out. There'd be communication with the attending surgeon and we were awaiting a final result from the referring institution. So try to, you know, get at a problem before it became a major problem.
MS. NEWBURY:
Q. So do I take it from your answer then that it wouldn't just be a patient specific exercise, in terms of the quality assurance as it related to one specific patient, but you would look at it in a broader perspective to see -
DR. COOK:
A. Well, I looked at it as all part of our quality assurance activities and we would send out anywhere from maybe 30 to 40 a year,

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probably up to 70 a year, depending on the year, the number of cases that went out.
MS. NEWBURY:
Q. And you said that the correlation generally was very good?
DR. COOK:
A. Generally pretty good. I mean, we would send out an accompanying letter with the case. I mean, in the case of myself, I always give my original opinion on what I thought the case would be, give it to the consultants, and then compare that with what came back from the reference centre.
MS. NEWBURY:
Q. Okay.
DR. COOK:
A. So the major--you know, the problems that we generally had with our cases were reflected in the consultants concerns, and it was also a good educational experience because many of these consultants would phone you individually about your case, particularly from the Mayo Clinic. There'd be lots of conversations over the phone with various specialists over the nature of the case and it also gave us a

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chance to gain more information from specialists about the latest updates and this, that or the other thing.
MS. NEWBURY:
Q. Okay, and you said that the consultants would have the same issues that Eastern Health -
DR. COOK:
A. Generally speaking, they were experiencing the same types of problems that we were. We would come up with differential diagnosis and pose questions to the consultant about what the particular issue was concerning the case. Now some cases were particularly simple. I mean, I can give an example where, say, a surgeon would call me and thinking something was malignant and I was saying it was benign on the phone. So in order to give reassurance to that particular individual, I'd say "well, let's send it off for an outside opinion and see what comes back," because always the big thing was the telephone conversation. You gleaned an awful lot talking to your surgeons or internists about the feel of the case, and if there was a discrepancy, clinical discrepancy, it was only quite simple to send

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a case out for an outside opinion and gave the surgeon reassurance and yourself reassurance.

MS. NEWBURY:

Q. Okay, and in terms of the, I guess, the difficult cases that are sent for outside consultant report, if you got a result back that wasn't consistent with your own interpretation, would that not raise a red flag because you'd already identified it as something being difficult?

DR. COOK:

A. Well, the report wasn't signed out. You send out a preliminary report, and these would be red flags that you identify with the surgeon or attending surgeon. You would say "look, you know, I got a case here which there may be borderline malignancy. I'm not sure if it's totally malignant or not. Wait until I get the final report back from the referring institution before you do anything," or even say you can still speak to the patient, and say "look, we got a problem with this case. The pathologist has sent it out, which we'll hopefully have a result back in a week or two." So hopefully you would try to, you

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know, nip the problem in the bud before it got too bad and dealing with--you know, you get the results back from the Mayo Clinic and then once you got that, you contact the surgeon and say "here's the result. Here's our impression of it. Do you agree with that" and I would review the slides and that that would come back from the Mayo Clinic and check the correlation with our reports and their reports. So it's all part of, you know, what I saw as good patient care and good back up and follow up.

MS. NEWBURY:

Q. Right, and I do appreciate that, but I'm just wondering, in terms of the ability of that to highlight any sort of underlying problems that there might be in some test procedures, if all you sent out are difficult cases, perhaps you wouldn't be that alarmed if you got a different result back. Just because of the very nature of the specimen that's going out for testing, you're perhaps anticipating it, if not unlikely, that there would be different results?

DR. COOK:

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A. Well, that's one thing. I mean, but the other process that we had in place that every time we get a case, we also get a spreadsheet or a previous reports on a particular case. We could have, say, a superficial esophageal biopsy of which we had multiple biopsies over the past two-three years. So we would get a print out with those diagnosis on that particular sheet. So for instance, let's say I picked up a carcinoma in a superficial biopsy that had been previously biopsied, say over two or three years. I would have those previous diagnosis there and my first inclination was to go back and review those biopsies to make sure we hadn't missed a particular lesion. So that was going on quite common and by all pathologists and that's how we picked up a number of issues. So that was more of a broader range process that we had in place and that was basically a standard that we had in place.

MS. NEWBURY:

Q. Now that didn't involve, necessarily an extra departmental review or sending something to a major referral centre. That's just what you

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did internally?

DR. COOK:

A. Well, it could. I mean, if I saw, for instance, a biopsy that was malignant currently and then went back and reviewed the original biopsies, which it could be four or five biopsies over two or three years, I could bring that to our quality controls rounds, get an opinion from the others as to what--if something was missed or whatnot, and take it from there.

MS. NEWBURY:

Q. And can you say whether or not any cases involving ER/PR testing ever were subject of these types of extra departmental reviews or any of these internal reviews?

DR. COOK:

A. Not that I can remember, no. The ER/PR issue was basically a non-issue. I mean, we had covered a lot of other things, but this issue, we didn't zero in on.

MS. NEWBURY:

Q. Dr. Cook, last week you were questioned about Dr. Ejeckam's memo dated April 2003. Perhaps we can bring up the exhibit just in case.

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It's P-0113, page one, and just to refresh your memory, and you were questioned in particular about the comment of Dr. Ejeckam that eight stains were unreliable, erratic and therefore unhelpful for diagnostic purposes.

DR. COOK:

A. Um-hm.

MS. NEWBURY:

Q. And you commented at that time, at in the world of immunohistochemistry, stains can vary from day to day and can vary in intensity and can vary in staining characteristics, and you considered IHC to be a variable event.

DR. COOK:

A. That's right.

MS. NEWBURY:

Q. And I'm just wondering, and this is arising from some comments of Dr. O'Malley when she gave evidence last week. Could the intensity of the stain be a feature of the tumour itself?

DR. COOK:

A. It may. It may not. I mean, there's so many factors. You're dealing with a 40 to 50 step process with the DAKO system. It's highly

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manual, so therefore you've got a lot of human intervention there.

MS. NEWBURY:

Q. Sure.

DR. COOK:

A. So to make sure that you're able to carry on the same step every day is quite a significant task. Now when you compare the DAKO system to the Ventana automated system, I wouldn't expect the same degree of erratic or unreliability or variation in stain because you're getting a much more uniform procedure, a much more standardized procedure and you're taking the human element, to a certain degree, out of this process.

MS. NEWBURY:

Q. And last week or a couple of weeks ago, Dr. O'Malley had referenced the Allred score for determining whether or not a patient should be treated with Tamoxifen or hormone therapy, and that had two components, a proportion score for staining and an intensity score, and now I think the intensity score wasn't as significant as the proportion score. That's what I took from her evidence.

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DR. COOK:

A. Um-hm.

MS. NEWBURY:

Q. And you're familiar with that, that issue?

DR. COOK:

A. Um-hm.

MS. NEWBURY:

Q. When you're looking at a slide, how do you determine if the issue that you saw with intensity of staining varying from day to day is due to some of those human--you know, just the vagaries of IHC testing, at that time, particularly with DAKO, and the expected variations in intensity which, I think, are related to the tumour itself?

DR. COOK:

A. When I go back and do a review, I mean, how I read a DAKO slide is totally different, different than how I read a Ventana slide. I mean, the DAKO, I mean, if there was even the slightest intensity, the slightest stain, I would interpret that as being positive because of the fact that we were dealing with a semi-automated procedure. But would I make the same interpretation today on a Ventana system?

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No. If I looked at a very weak intensity stain on the Ventana system, I wouldn't call that positive, as I did on the DAKO system, because we're dealing with two different types of platforms.

MS. NEWBURY:

Q. And would the use of controls assist you in differentiated between intensity related to the staining versus intensity related--changes or variability related -

DR. COOK:

A. It would help me because, I mean, I'm looking at, now again, the Ventana automated system, more standardization and I'm getting--now we're using three types of controls on our system. We're using the negative, the intermediate and high expressers. So I would expect, with the automated system, to have equal intensity with the controls, as opposed to your test tissue.

MS. NEWBURY:

Q. And how about with the DAKO?

DR. COOK:

A. The DAKO, no, again, we were dealing with a lot of variability there, a different system

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entirely. So there are areas which I could expect a different--higher intensity control staining versus a test tissue, and don't forget, we were probably--we were running one control with a particular batch. So that control, by itself, would be a different type of tissue, maybe a high expressers and subjected to different fixation and processing.

MS. NEWBURY:

Q. And how about internal controls, would that play any role in that? Would you -

DR. COOK:

A. Well, internal control still would have played a role with the DAKO system, as does the Ventana system today.

MS. NEWBURY:

Q. But would that assist you at all in differentiating between the variability of staining due to -

DR. COOK:

A. Well, you should have variability in staining on your internal control and even in your tissue itself. It just boils down to seeing as much as you can. I mean, what happened

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previously, we had circulated the slides over to too many pathologists. If you start having a small subgroup of individuals, you can pick out the variations yourself and you get a good feeling, a good idea of how a stain should be.

MS. NEWBURY:

Q. Dr. Cook, in terms of--you've mentioned monitoring some of the trends regarding ER and PR positive results or, I guess, different features of ER/PR testing, and I'm just wondering, over the past year, as an example, if you wanted to check, for example, how many patients were tested ER negative and PR positive, how would you go about doing that for say the period July 2007 to July 2008?

DR. COOK:

A. Well, right now we have a quality assurance supervisor within the Division of Anatomical Pathology. I would go to her and say here's the information I need, can you get that out of the system for me, and she's well versed on the various Meditec Systems, or should be well versed with Meditec Systems and should be able to retrieve that information for me within at least a day or two.

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MS. NEWBURY:

Q. Okay, and it's your understanding that this information is, first of all, all input into the system that this individual would use?

DR. COOK:

A. Well, yes. Again if I'm looking for, say, positivity rates of ERs and PRs for a particular year -- I'm not sure, and again it's something you might have to follow up, whether we can actually get down to where there are determined how many infiltrating lobulars we have positive and that sort of thing. So I can't answer that question with any degree of certainty.

MS. NEWBURY:

Q. That was my next question. I was just wondering how much information could be made available at this time if you were just curious for your own interest or maybe you had some case that came up that caused you a little bit of concern and you wanted to check on ER negative, PR positive, which I understand to be not a common occurrence, could you go in and look at how many patients in the past year had that result versus the

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total number of patients -

DR. COOK:

A. Possibly. If we can type in key words in the Meditec System like infiltrating lobular carcinoma, we could retrieve the number of cases of infiltrating lobular carcinoma and then our QA supervisor would be able to possibly manually check how many of those infiltrating lobulars were ER and PR negative.

MS. NEWBURY:

Q. So, I take it then, that you are not completely sure what could be available and it's best to ask the --

DR. COOK:

A. That's correct, I don't want to say --

MS. NEWBURY:

Q. QA supervisor.

DR. COOK:

A. With absolute certainty what's going on there.

MS. NEWBURY:

Q. Okay, and when you're talking about this, is this for Eastern Health generally or just for St. Clare's?

DR. COOK:

A. No, this is for Eastern Health.

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COMMISSIONER:
Q. Do you have any reason to believe that search capabilities of systems that you now have are any different than they were in 2005?
DR. COOK:
A. That's a good question, Commissioner. I really can't answer that for sure.
COMMISSIONER:
Q. I'm sure that somebody will come along who will be in a position to answer that. Thank you.
DR. COOK:
A. Yes.
MS. NEWBURY:
Q. And your QA supervisor now is?
DR. COOK:
A. Bev Rowe. I believe she's supervisor for the Division of Anatomical Pathology. She took over from Catherine Parnell who recently retired, and then we have Lynn Wade, whose overall quality assurance supervisor for lab and DI, I believe.
MS. NEWBURY:
Q. So Lynn Wade is the supervisor of Bev Rowe?
DR. COOK:

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A. For the whole laboratory medicine program. I think she covers too the diagnostic imaging program, and then we have Bev Rowe who recently took on the position from Catherine Parnell to look specifically in the Division of Anatomical Pathology.
MS. NEWBURY:
Q. Okay, and whatever system that you're talking about, is it your understanding that that system is a general system that might apply to immunohistochemical testing generally or the laboratory medicine program generally? You don't have a separate system just for ER/PR?
DR. COOK:
A. No, I think it's all part of the Meditec. Now I could be wrong on that, but that's my belief.
MS. NEWBURY:
Q. Okay, and are you aware of any plans to do any revisions or improvements to whatever system they do have in place now?
DR. COOK:
A. I'm aware of talk of improving our data collection systems and hospital information systems. That's about all I'm aware of.

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MS. NEWBURY:
Q. And where did you learn that information?
DR. COOK:
A. You can get it from -- I would say Mr. Gulliver should be able to get you that information, what specifically is being done in the lab, and our information IT people, and I can't give you a name of a point person who you can approach there.
MS. NEWBURY:
Q. That's fine, thank you. Dr. Cook, you were just speaking a little while ago about having referrals to major reference centres that, I guess, you've requested these referrals yourself or another pathologist would request it.
DR. COOK:
A. Uh-hm.
MS. NEWBURY:
Q. Do you know if there are outside consultations that are not requested by someone in your department that may, even if it's not directly, you know, a referral for a pathology interpretation, but a referral of a case generally that might make its way outside of

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Eastern Health?
DR. COOK:
A. Well, we would get the request, a patient, say, who was transferred for treatment, say, in Toronto.
MS. NEWBURY:
Q. Uh-hm.
DR. COOK:
A. Before she's being treated with chemo radiotherapy, there would be a request from that particular institution to refer our cases to them, and they would then review it, you get a second opinion, and a report would be issued. Remember I referred to the Cleveland situation back in 2000/2001. So that was a situation where our cases were reviewed by outside pathologists and reports issued.
MS. NEWBURY:
Q. But who initiated that review?
DR. COOK:
A. That review was initiated usually by the institution itself to whom you refer the patient to. So if you refer to Cleveland Medical Centre, they would request us to send them the slides and all information

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surrounding that patient to their organization.

MS. NEWBURY:

Q. But who within Eastern Health would have initiated the review, sending the patients to the Cleveland Medical Centre?

DR. COOK:

A. You mean those patients back in 2000/2001?

MS. NEWBURY:

Q. Yes.

DR. COOK:

A. Oh, my, I can't tell you who.

MS. NEWBURY:

Q. So it wasn't the laboratory medicine program?

DR. COOK:

A. To have the patient treated in Cleveland?

MS. NEWBURY:

Q. Yes.

DR. COOK:

A. Oh, no, no.

MS. NEWBURY:

Q. And that just came up that while these patients were being treated by the Cleveland Medical Clinic, as part and parcel of that, they wanted to do a review of the slides?

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DR. COOK:

A. Yes, and they would review the x-ray reports, possibly the x-rays themselves, and information from the chart.

MS. NEWBURY:

Q. And would you expect that every time there is a consultation that's initiated by another physician within Eastern Health, that you would always become aware that that's taking place?

DR. COOK:

A. Most of the time. It may not be all the time, but most of the time I would be aware that there would be a request of a physician to have a second opinion on a particular case, or an outside institution wanting to have a second opinion on a particular case.

MS. NEWBURY:

Q. And for those situations where you do become aware of it, do you have a process or procedure in place that a review will be conducted of that patient's chart just to see if there's any correlation or any discrepancies?

DR. COOK:

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A. Not off the chart, but you try to keep on top on the report that comes back and you do a correlation with what the outside institution has said and what we found.

MS. NEWBURY:

Q. Uh-hm. Would you do an exercise that you'd referred to earlier that sometimes when you get a result back, you might go back and check all of the biopsies done over the last couple of years? Would you do that sort of exercise?

DR. COOK:

A. Only on a specific case, or if we became aware of a trend, we might want to go ahead and do a wider review.

MS. NEWBURY:

Q. Okay.

DR. COOK:

A. And that gets back to having people in the organization to do the audit for you, like a quality assurance supervisor. You could charge her with that task of identifying what cases need to be hauled out, over what time period, and then brought to the reviewing pathologist.

MS. NEWBURY:

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Q. Okay. So it's not necessarily a trigger in each and every event that there's an outside consultation and it will be a review?

DR. COOK:

A. There wouldn't necessarily be a trigger. Again depending on the situation, I mean, you might just find it's an isolated event, but if you get into something that you're finding it's more than an isolated event, that would be cause for alarm and it could trigger a wider review.

MS. NEWBURY:

Q. Uh-hm. How about if there are patients who might be subject to different tests within Eastern Health or perhaps among the different regional health authorities? Is that a possibility that there might be different specimens tested at different times, perhaps within a short time frame?

DR. COOK:

A. It's possible. Again if a patient, say, is coming in from Grand Falls for treatment in St. John's, the attending surgeon may ask for a second opinion on the case that's coming in from Grand Falls for a review, or even the

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oncologist, for that matter.
MS. NEWBURY:
Q. Okay. Is there a system in place, as an example, of a couple of different pathologists happened to be involved in doing -- reading slides for a particular patient? Is there a system in place that there will be a check of all other results in the system to make sure that there is consistency?
DR. COOK:
A. Not necessarily. You would go back and review the printout that you have on your accompanying requisition. If you see any discrepancy there in the diagnosis, yes, it could trigger something, but it wouldn't be absolute.
MS. NEWBURY:
Q. Okay, and the requisition would come from the treating oncologist?
DR. COOK:
A. The requisition would come from treating oncologist or the attending surgeon, and you would get the printout of the previous histologies and what not.
MS. NEWBURY:

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Q. I'm just wondering if there's a chance for someone to slip between the cracks, maybe a patient has conflicting results on their chart, there might be a biopsy, IHC testing, ER/PR testing, and had one result by one pathologist and another result a couple of months later for whatever reason by another pathologist, whether or not that could slip between the cracks and not get picked up?
DR. COOK:
A. Well, oncologists are pretty on top of things, and usually something like that is picked up by oncology, and if they see a discrepancy there, they usually phone us for clarification or review. I mean, I find our oncologists pretty good in that regard.
MS. NEWBURY:
Q. Do you see it as the responsibility of the oncologists to do that?
DR. COOK:
A. If they saw a discrepancy, yes. I mean, if they had -- or any physician, surgeon, or whatever, if you saw a pathology report that didn't match your clinical situation, or you had questions about it, yes, notify the

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pathologist and we're only too happy to go ahead and do a review of that particular case.
MS. NEWBURY:
Q. And what about some of the areas outside of St. John's who may not necessarily have the patient seeing the same oncologist over the course of the period of time -- I'm not sure if you're familiar with that being the state of affairs for outside of St. John's, but if that were the case and you don't have the same consistency in treatment by an oncologist?
DR. COOK:
A. Well, usually the oncologists who go out there are originally from St. John's. So again if they saw any discrepancy in the local pathologist's report, or again if they had questions or a patient is not responding as that patient should, then they usually request that pathologist to refer the cases to one of us and we would have a review.
MS. NEWBURY:
Q. Okay. So it would be up to that oncologist who might -- maybe on April 1 an oncologist goes out, and October a different oncologist goes out. There's no readily accessible

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system for them to ascertain, you know, here are the results for this patient, are they the same throughout?
DR. COOK:
A. Well, they would have the ability to go into the Meditec System.
MS. NEWBURY:
Q. Okay.
DR. COOK:
A. Go into your menu and you could look at the previous pathology reports.
MS. NEWBURY:
Q. And that would have all of the information that that oncologist needs just to ensure everything is okay for that particular patient?
DR. COOK:
A. I believe so. Now I can't be absolutely sure on what type of menu the oncologist have, whether they have access to all the pathological diagnosis on the Meditec System. I can't be absolutely sure on that.
MS. NEWBURY:
Q. Okay.
DR. COOK:

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A. But I believe they do.
MS. NEWBURY:
Q. Okay. In terms of the Cleveland Medical Clinic cases that were sent down there, I think you had indicated there were about four or five that you were familiar with?
DR. COOK:
A. To my knowledge. Now there may be more or less. I can't be absolutely sure on that.
MS. NEWBURY:
Q. And you'd mentioned that one of those cases, you were aware of as including a conversion?
DR. COOK:
A. I didn't say conversion. It was a --
MS. NEWBURY:
Q. Change result.
DR. COOK:
A. There was a change in result. I think that was a case where one of our St. John's pathologists had reported as 60 percent or so, and Cleveland pathologists had reported at about 40 percent, and when I spoke to the oncologist about that I looked at the slides, it was again the interpretation of the intensity because what I think had happened,

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where we had interpreted the low intensity as being positive, that Cleveland pathologist may have looked at the same intensity and regarded it as negative. So there's a lot of subjective interpretation between pathologists on this.
MS. NEWBURY:
Q. So there was varying intensity on the same slide and the pathologists here attributed a larger number of the cells, I guess --
DR. COOK:
A. It's like looking -- if you get a bunch of jelly beans and you lay them out flat on the table, you've got varying different shades of brown. You've got very weak staining, intermediate, and high staining. Now there's no problem with people picking up the mediate and high intensity stains or high intensity signals. The issue comes with who calls the weak staining positive and who calls it negative. So at the end of the day, there's still a lot of subjective interpretation to it. If I remember that case, I mean, it had no impact on whether -- in terms of her treatment. We had variation, but no

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clinically significant impact.
MS. NEWBURY:
Q. Right, and again regardless of whether the 60 percent number is used or the 40 percent number is used, either way that would be considered ER positive?
DR. COOK:
A. Yes.
MS. NEWBURY:
Q. Do you know how many other of the four or five cases that you're familiar with being seen at the Cleveland Medical Clinic were also ER positive?
DR. COOK:
A. I can't remember. All I remember was they correlated from what we had, and again I'm going back now five or six years trying to remember what was there, and it was the actual slides that were seen by Cleveland Medical Clinic from what I understand.
MS. NEWBURY:
Q. Okay, and would -- these were random patients that were seen?
DR. COOK:
A. Oh, no, these were patients that as a result

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of the oncology shortage back in 2000 and 2001, we didn't have enough medical oncologists to treat the patients, and so they were referred to Cleveland for treatment. So they weren't randomly selected. They were -- we had to deal with them because of the oncology shortage.
MS. NEWBURY:
Q. Sure, but they weren't chosen because they had infiltrating lobular carcinoma or any particular type of breast cancer, would they?
DR. COOK:
A. Not to my knowledge, no, they weren't -- I don't think they were selected out in terms of the type of cancer they had.
MS. NEWBURY:
Q. They just happened to be the patients who were diagnosed at the time needing treatment?
DR. COOK:
A. Diagnosed with breast cancer. We didn't have the manpower in terms of oncology at that time to treat these patients, so I believe the government looked for an outside source and came up with Cleveland.
MS. NEWBURY:

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Q. Okay. So when you recently thought about -- you were thinking back on the Cleveland Medical Clinic cases that were sent out, and taken some comfort from the fact that there weren't any conversions at the time, did you consider whether you should have a close look at whether they were ER negatives versus ER positive in light of the fact that your focus here in the retesting was on ER negative?

DR. COOK:

A. Well, the focus on that time wasn't on ER and PR. The focus was on were we making the correct diagnosis of infiltrating ductal versus lobular, how were we doing in the synoptic reports, were we getting good correlation with our synoptic reports and the Cleveland reports, and were we calling things metastatic to the lymphnode, correlating that with Cleveland. So there was a whole lot of other factors that as the reports came in, I would quickly scan down through to see if there was any discrepancies with the entire report. I mean, at that time I simply wasn't focused on ER/PR. I was focusing on the diagnosis and correlations with synoptic

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reports.

MS. NEWBURY:

Q. Right, but after the ER/PR problem became apparent back in 2005, and sometime later you came to think about the Cleveland Medical situation and you recognized that there were no conversions and there was a fairly minor discrepancy, I guess, in one of the tests which wouldn't result in any new treatment changes, but did you think to look whether or not any of those cases were actually ER negative cases?

DR. COOK:

A. No, I did not, and again the reason being again that interpretations were made on that slide. I would have been more focused on the fact of involving those Cleveland cases in a general review and in having the paraffin blocks themselves being retested, restained, and reinterpreted.

MS. NEWBURY:

Q. Uh-hm. You weren't concerned about -- well, it seems now since the ER/PR testing issue became apparent, the concern has been with false negatives, not the false positives?

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DR. COOK:

A. Most of the concern was -- and this was the problem with the test itself, the high false negative rate.

MS. NEWBURY:

Q. Right, and in terms of getting any comfort from the Cleveland cases as to whether or not a problem that you've been investigating since 2005 was likely to be detected, wouldn't you need to know whether those cases were ER negative?

DR. COOK:

A. Again there was some comfort in the fact that our diagnosis were correlating well, but again we only had -- from what I know now, there may have actually been more, but only about four or five cases that I was aware of.

MS. NEWBURY:

Q. And you can't say today whether any of them was actually ER negative?

DR. COOK:

A. No. What I would have been looking for would have been conversations that I had with oncology because how that particular case came up with that variation was a phone call, I

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believe, from Dr. Laing at that particular time and she picked up the discrepancy. At that particular time, the cases weren't confined to St. John's, it was throughout the whole of the province, and I remember asking her were there any other issues that she had concerning the quality reports. I may have even said ER/PR at that time. So there was no issues that she had concerning the quality of the reports. Therefore, most of those reports province-wide would have been channelled through oncology.

MS. NEWBURY:

Q. Uh-hm.

DR. COOK:

A. So had there been again a widespread problem, I'm sure oncology would have picked it up and notified us. This is where -- they were the focal point in all of this back in 2000/2001.

COMMISSIONER:

Q. Ms. Newbury, it's near the luncheon break, so wherever there's a convenient spot we'll break for the lunch.

MS. NEWBURY:

Q. I just have a couple of more points on this

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issue.
COMMISSIONER:
Q. Okay.
MS. NEWBURY:
Q. In terms of the -- I guess, any comfort that you might take from the Cleveland Medical Clinic slides, you have four or five cases, some of which -- well, at least one of which is not ER negative to begin with, but would that size of a sample be large enough for quality assurance purposes?
DR. COOK:
A. Not really. The 33 cases overall in terms of overall quality of the breast reports would have been, but what I was taking some sort of comfort in at that time was the question that I posed to Dr. Laing, whether she had seen any other variations that were of clinical significance both in the reporting and in the ER/PR status, and she had none. So I was looking at a very much broader view because only a small percentage of cases actually in the Cleveland situation originated from St. Clare's.
MS. NEWBURY:

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Q. Right, and that's the four to five that you're talking about, or the 33?
DR. COOK:
A. The 33 would have originated province-wide, and only one or two of those ERs and PRs, I believe, would have originated from St. Clare's.
MS. NEWBURY:
Q. Okay.
DR. COOK:
A. Again I can't be absolutely sure of the figures.
MS. NEWBURY:
Q. But in terms of the program now of quality assurance specifically for ER/PR testing, would that sample be large enough to give you comfort that --
DR. COOK:
A. You mean four or five cases?
MS. NEWBURY:
Q. Yes.
DR. COOK:
A. No, but at that particular time, thinking back, I was thinking back to the 33 and --
MS. NEWBURY:

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Q. You're just thinking there was no red flag at that time?
DR. COOK:
A. There was no red flag at that particular time, and the other area I was thinking of at that time, what was going on in tumour board rounds. These are where we have our pathologists, oncologists, and surgeons attending these board rounds, and was there any issues regarding the quality of the ER/PR reports, and how the patients were responding to treatment because that's one of the big clinical indicators, and are your ER/PR negative patients responding as they should, or are your ER/PR positive patients responding as they should. So that would be a forum if there was a concern from oncologists to notify our pathologists and we would then take a review.
MS. NEWBURY:
Q. And in terms of the response by a patient, is that the only method that you're aware of that oncologists would have to compare the clinical response of the patient?
DR. COOK:

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A. Clinical response of the patient, plus they may have data there looking at various -- percentages of various types of cancers in the province and what not, but I think on a one to one basis you would want to see how that patient is responding to a particular treatment. I'll give you an example. We were involved in board tumour rounds. That's mainly where I was involved at St. Clare's, where we would go in and sit down with our surgeons and oncologists, radiologists, and what not, and we'd do a correlation between our histology and our radiology first of all, but we also would discuss how is this patient responding. So I could have a lesion, say, in the lung and call it a lymphoma, for instance, and they would treat the patient as per lymphoma protocol. Now does the patient respond as per lymphoma protocol; are they responding, is the lesion decreasing in size. If not, there's a difference in how that patient is responding. Information like that would be brought back to chest board tumour rounds, we would reevaluate the case and determine if, in fact, it was a lymphoma,

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because one of the other big differentials could be small cell carcinoma. So those are sort of the questions that we would be banging around to look at the correlation between our histology, radiology, and clinical outcomes.

MS. NEWBURY:

Q. And in terms of the ER/PR testing, in particular, do you know how quickly an oncologist might be able to make that decision whether or not the ER/PR result is actually consistent with how -- with the clinical observations of the oncologist, or would there be a delay because you can't watch the tumour over three months and see whether or not it's reacting as you expect based on your ER/PR results?

DR. COOK:

A. There could be a delay. The big problem I find too with oncology is that they were in the same boat as we were. You had this high turnover of oncologists over that time period. I think the time period we're talking about is anywhere around 25 oncologists. So if we had been able to maintain a stable population of oncologists, maybe they would have picked up

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some trends and notified us.

MS. NEWBURY:

Q. And do you actually know if they have information available. You've mentioned that they might be able to look at some of the information about the types of cancers and procedures?

DR. COOK:

A. I don't know for sure. You'll have to ask the oncology.

MS. NEWBURY:

Q. So that's not something you relied upon as being a given fact that oncologists have this information, we can take some comfort from that, they're going to be tracking trends and looking for discrepancies?

DR. COOK:

A. Well, that's something we may be again doing now as a result of this whole issue, but I don't know how much tracking of trends the oncologists have. I mean, they again were in much the same boat as we were.

MS. NEWBURY:

Q. Sure. Thank you. This is a good time to break.

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COMMISSIONER:

Q. Okay. We'll break until 10 after 2.

(LUNCH BREAK)

COMMISSIONER:

Q. Ms. Newbury.

MS. NEWBURY:

Q. Good afternoon, Dr. Cook. Just a quick question on the Cleveland Medical Clinic cases again before I continue. Did you indicate that the review was conducted of the slides that had already been originally prepared by pathologists at Eastern Health or Health Care Corporation of St. John's?

DR. COOK:

A. That's correct. It's my understanding we issued the interpretations and they went out as final reports. When Cleveland would review them, they would review the pathology reports and the histological slides and issue their own report.

MS. NEWBURY:

Q. Okay. So you're not aware that they did any new slides themselves?

DR. COOK:

A. No, I'm not aware.

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MS. NEWBURY:

Q. The week before last Dr. Mullen was here and testified, and indicated that he had expected that the pathologists at Eastern Health would review cases and confirm his opinion before issuing a report.

DR. COOK:

A. Uh-hm.

MS. NEWBURY:

Q. I'm just wondering if that's the procedure that was followed by you, and to your knowledge, other pathologists -- or any other pathologists at Eastern Health?

DR. COOK:

A. No, that wasn't the case in this particular issue. Normally we do when consults come back from, you know, such places as the Mayo Clinic and AFIP, usually we have a second set of slides that we make a copy of. So reports come back, we review the slides, and we correlate with what the Mayo people of the AFI people say, but in this particular case because of the magnitude of the volumes, and we also had faith in Dr. Mullen, we put the results directly into the computer system.

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MS. NEWBURY:
Q. Okay. So that's for the retrospect of review, just for --
DR. COOK:
A. That's for the retrospect of review.
MS. NEWBURY:
Q. So there was no actual review just to compare his report with the slides that they prepared to --
DR. COOK:
A. No, we were quite confident in him and his ability.
MS. NEWBURY:
Q. Did you have any discussions with Dr. Mullen about this at the time, about what the procedure would be, were you aware of what his expectations might have been in this regard?
DR. COOK:
A. My point person was Maria Mendes and Dr. Pritzker. I just looked at Dr. Mullen as providing a completely objective view and I wanted an objective opinion from him.
MS. NEWBURY:
Q. And you didn't have any discussions with Maria Mendes or Dr. Pritzker in that regard either,

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about what procedure was followed just to make sure you all understood what the other --
DR. COOK:
A. No, they were to issue me the reports, and what we did with the reports, we would discuss ourselves and within the tumour panelling process, and also with our Executive Committee, Dr. Williams, with our surgeons, that I would enter it directly into the hospital information system.
MS. NEWBURY:
Q. Do you know if the tumour panel itself ever gave rise to a review or triggered a review of the slide itself? Out of the cases that were referred to the tumour panel, do you know of any case where they said, listen, we'd like to just double check that?
DR. COOK:
A. You mean a review of the Mount Sinai results?
MS. NEWBURY:
Q. Yes.
DR. COOK:
A. Only when we came up with a different result from different tumour blocks.
MS. NEWBURY:

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Q. Okay.
DR. COOK:
A. And then we would ask questions of Dr. Mullen regarding that, but not an overall general review of the Mount Sinai cases.
MS. NEWBURY:
Q. So in a situation where you had two different slides with conflicting results from Mount Sinai, you would review the slide, but --
DR. COOK:
A. We didn't have the slides back, but I would e-mail Dr. Mullen as to what his -- his explanation of discrepancy.
MS. NEWBURY:
Q. Didn't you get the slides back at the end of the --
DR. COOK:
A. We got them back at the end of the review.
MS. NEWBURY:
Q. Okay, and that would have been in about February, 2006, or was it later than that?
DR. COOK:
A. It was certainly after the review had been completed. I can't tell you the exact date we got back the slides.

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MS. NEWBURY:
Q. So you're not aware of any incidents of the tumour panel wishing to have some further look into it just to make sure that they're comfortable with the opinion provided by Mount Sinai?
DR. COOK:
A. Not to review his slides, no, but issues did come up when we did have a difference in the report from, say, the consultative report versus the retro review because sometimes you had one block sent up under the review, and another one on the same patient sent up on the consultations.
MS. NEWBURY:
Q. And in terms of other consultations, not this retrospective review, but, for example, the Cleveland Medical Clinic cases or any other outside referral to a major referral centre, is there a protocol in place as to whether or not you might have to do your own review of what the outside consultant said, whether it involves a review of the slide or a review of the file?
DR. COOK:

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A. A written protocol saying if something comes back from the Cleveland Medical Clinic, I am to review all their histology? Is that what you're talking about?
MS. NEWBURY:
Q. I guess just to have a comfort level for the pathologists who ultimately signs off?
DR. COOK:
A. No, we don't have a written protocol there. We just do it as a standard of practice, and you always review the consultant's report and, you know, correlate with your own opinion for, if nothing else, continuing medical education purposes.
MS. NEWBURY:
Q. Okay, and you consider that to be a standard of practice?
DR. COOK:
A. That's standard, yeah.
MS. NEWBURY:
Q. Dr. Cook, you were shown a few of your own handwritten notes from the latter part of July, 2005, last week, and I'll bring a couple of these up for you. If we could start with Exhibit P-02002, please. These are your

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handwritten notes, I understand, dated July 22nd, 2005, from a call to Dr. Ann O'Brien in St. John, New Brunswick, and -- I'm just going to scroll down to the bottom of the page. On the last line it says, "Uses ASCP checkpath sample and proficiency testing".
DR. COOK:
A. Uh-hm.
MS. NEWBURY:
Q. And what was your understanding at that time as to what that was all about?
DR. COOK:
A. I think that was in regards to the interpretation because ASCP checkpath is what we also use in evaluating our pathology interpretations. They would send up slides which are already stained with H & E staining and ask us for our interpretation, and we would send the interpretation on an antraciet (phonetic) and fax those down to ASCP, and they would be correlated with other labs.
MS. NEWBURY:
Q. Okay, and was that the only quality assurance activity that you discussed with Dr. O'Brien at that time?

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DR. COOK:
A. I believe so. I mean, to the best of my knowledge, that was the only one that I discussed.
MS. NEWBURY:
Q. And can you recall if that related specifically to ER/PR testing?
DR. COOK:
A. I may have asked her what she has in the way of external proficiency testing. So that could have come up in that conversation.
MS. NEWBURY:
Q. Okay, for ER/PR testing?
DR. COOK:
A. Well, not necessarily for ER and PR, what did she have in her lab in general.
MS. NEWBURY:
Q. So you don't know then whether or not they might be in the same situation as your lab where you don't have anything that relates specifically to ER/PR testing at the time?
DR. COOK:
A. I can't say for sure. They may and they may not, I can't say.
MS. NEWBURY:

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Q. If I can bring up Exhibit P-01998, please, and this is your notes of a call. I think it's the 21st there of July. I think that's what you indicated last week.
DR. COOK:
A. Uh-hm.
MS. NEWBURY:
Q. Laurette Guldahays, and she's with Halifax, I think you indicated?
DR. COOK:
A. That's correct.
MS. NEWBURY:
Q. I don't see anything there about any quality assurance or external proficiency testing.
DR. COOK:
A. No.
MS. NEWBURY:
Q. Can you recall if you would have discussed that with Dr. Guldahays at that time?
DR. COOK:
A. I probably did discuss that with her and asked her what they had in that regard, or whether they had a medical director or what not. I know for a period of time in Halifax that they were without a medical director of

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immunohistochemistry, but they eventually got an individual to oversee that operation. She did get back to me with her positivity rates, by the way, about a week or so later.

MS. NEWBURY:

Q. Right.

DR. COOK:

A. But I can't really comment on what they have in the way of quality assurance or what not.

MS. NEWBURY:

Q. Okay. Exhibit P-01933, please. I'm going to refer you to the second page here.

DR. COOK:

A. Uh-hm.

MS. NEWBURY:

Q. Which is a call that you made on the 28th of July, 2005. This is to Dr. Norman Pettigrew with HSC in Winnipeg.

DR. COOK:

A. Uh-hm.

MS. NEWBURY:

Q. And I just wanted to show you that to give you a chance to look there because I'm looking for anything that relates to quality assurance or external proficiency testing. I couldn't see

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anything there myself, but --

DR. COOK:

A. That's not to say he hadn't, but it just didn't come up in the conversation. I probably would have been interested more on his knowledge in general, if he knew what was happening across Canada in terms of trends and what not, and zeroing on such things as positivity rates at the time.

MS. NEWBURY:

Q. And why was that? Why would you focus on positivity rates and not on something like quality assurance?

DR. COOK:

A. Well, because we were -- if you look at our positivity rates that Mr. Gulliver had supplied, I mean, we were pretty much in the ball park. We identified a fair number of problems and issues within the program, and that was one of the points that I made to the Executive of the CAP that when we went around the table, people were talking about positivity rates, and I said be careful of placing too much reliance on positivity rates, they don't tell the whole story.

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MS. NEWBURY:

Q. Uh-hm.

DR. COOK:

A. So, you know -- because initially, I thought we were in the ball park with 73 or 74 percent, but we soon found out we had quite a number of issues and problems.

MS. NEWBURY:

Q. So you were aware at the time that positivity rates wouldn't tell the whole story?

DR. COOK:

A. Well, at that time I was placing some emphasis on positivity rates, but as you're gone further into the process, that wasn't the case.

MS. NEWBURY:

Q. What was your understanding as of that period of time, the last ten days or so of July, as to what quality assurance was in place in the lab that related specifically to ER/PR testing?

DR. COOK:

A. Well, we had very little in relation to the ER/PR testing. As I said earlier, any time we did immunoperoxidase stains, we always sent

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those out as part of a package with the H & E stains and with the interpretation for outside institutions. Sometimes we would send out the stains themselves along with the H & E stains to have a consultant look at the stains and give an interpretation, or sometimes we would hold off on the stains and send out the paraffin block and let the consultant decide what type of stains he would order in order to make his or her interpretation.

MS. NEWBURY:

Q. Uh-hm, but -- and you were aware at that time, the last part of July, 2005, that that was the state of affairs, you weren't under any notion that they had external proficiency testing that might relate specifically to ER/PR?

DR. COOK:

A. Not specifically to ER/PR.

MS. NEWBURY:

Q. And would it not have told, I guess, the other part of the story at that time, to find out what other labs may or may not have been doing for quality assurance, and in particular, whether or not they were using external proficiency testing for ER/PR?

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DR. COOK:
A. Possibly, but at that particular time, I was trying to get a handle on did anybody have issues concerning ER and PR across the country.
MS. NEWBURY:
Q. Right.
DR. COOK:
A. Much the same way as we had, and had anybody gone back over five, six, seven year period to do reviews. So I was basically telling these individuals what I had found the review had done, and could they comment on anything similar to this happening across the country, across the United States.
MS. NEWBURY:
Q. I guess what I'm curious about is that if you found out that other labs tended to have very rigorous programs of external proficiency testing, that might actually decrease the chance that they would have a problem, or if they had a problem, it was short-lived, it was picked up and rectified?
DR. COOK:
A. Possibly, but there is problems with

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proficiency testing.
MS. NEWBURY:
Q. Okay.
DR. COOK:
A. And I found out later proficiency testing may or may not have picked up our problem, particularly the CAP. One of the issues that we were concerned about in the Committee of Immunohistochemistry is how reliable is the CAP proficiency testing because you tend to compare one lab to another lab, and the emphasis is not necessarily on accuracy, but whether you produce a stain. So the problem is do you compare all labs to a central source. So you may have, say, 70 percent of your labs, and which we could be in that 70 percent group comparing our stains to one another, but the actual and most accurate number of labs could be the 30 percent outliers.
MS. NEWBURY:
Q. Uh-hm.
DR. COOK:
A. So there are issues and problems with CAP with proficiency testing, and I think the College

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of American Pathologists are in the process now of looking at that and trying to address those concerns.
MS. NEWBURY:
Q. Uh-hm, but that's not something that you were focused on at that time?
DR. COOK:
A. No, I was not aware of that at the time. That's more information that came to light with -- the further I dealt into the issue.
MS. NEWBURY:
Q. I wonder if I could have Exhibit P-01996, please. This is your call to Dr. Dogan, who as I understand your evidence, he had been with NEQAS in the UK?
DR. COOK:
A. Yes, I believe he was with the UK group.
MS. NEWBURY:
Q. And he was now at the Mayo Clinic?
DR. COOK:
A. Yeah.
MS. NEWBURY:
Q. And he indicates here, and you discussed this last week, I believe, that he has ID'd a huge variability in staining and report?

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DR. COOK:
A. That's correct.
MS. NEWBURY:
Q. Okay, and up above, he says that they have no idea whether they are over calling or under calling?
DR. COOK:
A. That's correct.
MS. NEWBURY:
Q. And indicated as well that he perceived that to be a huge problem.
DR. COOK:
A. Yeah.
MS. NEWBURY:
Q. Did you have any discussion with him at that time whether they had any quality assurance programs or external proficiency programs?
DR. COOK:
A. No, I was actually shocked by that conversation. I appreciated the fact that he was quite open and frank and told me the issues that he saw at the Mayo Clinic. I mean, the Mayo Clinic is one of the top notch medical centres in the United States, and having disclosed that information to me, it

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came as quite a shock.
MS. NEWBURY:
Q. Okay. So you didn't get into, well, don't you have external proficiency --
DR. COOK:
A. No, I didn't get into the nuts and bolts of their quality assurance program.
MS. NEWBURY:
Q. I believe in your evidence last week, you had indicated that following your call to lab directors in the latter part of July -- I'm not sure if you're including the non-Canadian or was it just the Canadian that you were focusing on. You had indicated that you found there were no national standards, that people across the country are using different platforms, methodology, antibodies, concentrations, incubation temperatures, incubation times, methodologies of reporting.
DR. COOK:
A. Uh-hm.
MS. NEWBURY:
Q. Was your comment directed at Canadian only when you refer to national standards or do you also include some of these calls to people

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outside of --
DR. COOK:
A. Mostly Canadian standards, but again in talking to various individuals in immunohistochemistry, and I had a chance to talk to one individual, in particular, the feeling is the problem may be worse in the United States than in Canada.
MS. NEWBURY:
Q. Okay. And were these just general comments or did you actually canvas with each of these individuals that you called, and you'd also spoken to Mr. Lath Dabbagah in Edmonton --
DR. COOK:
A. Uh-hm.
MS. NEWBURY:
Q. Did you actually canvas with each of them what antibodies were they using, what concentration?
DR. COOK:
A. No, I didn't get into that depth of the conversation. These were general comments made by a large variety of people about the lack of standardization in Canada, and also, you know, reviewing the literature, quite a

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number of articles again talking about the lack of standardization, more so in the United States than in Canada because this is where most of the articles tend to concentrate on.
MS. NEWBURY:
Q. Okay, so you wouldn't really be able to get into detailed discussion as to how great the disparity is among the labs, or whether there's 20 different systems?
DR. COOK:
A. No.
MS. NEWBURY:
Q. Or maybe two or three types of systems?
DR. COOK:
A. Those would be general discussions with individuals and general discussion at the executive level of the CAP. So these were just general impressions that we had with the state of affairs out there.
MS. NEWBURY:
Q. And did you think at that time of trying to get into a little bit more detail as to what the standards were for -
DR. COOK:
A. Well, I was so focused on getting the review

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initiated and bringing in external reviewers, dealing with the issues that we had at hand in the Laboratory Medicine program with the manpower situation. There was so many other issues on the go that I myself didn't have time to dwell into it, nor did I have the manpower around to do that type of study.
MS. NEWBURY:
Q. Okay, thank you. Those are all the questions that I have. Thank you.
THE COMMISSIONER:
Q. Thank you, Ms. Newbury. Mr. Crosbie?
DR. DONALD COOK, EXAMINATION BY CHESLEY CROSBIE, Q.C.
CROSBIE, Q.C.:
Q. Thank you. Good afternoon, Doctor. I probably don't need to tell you that I represent the members of the Breast Cancer Testing Class Action.
DR. COOK:
A. Right.
CROSBIE, Q.C.:
Q. Brian Purcell testified here on the 24th of March of this year, having to do with his wife, Christine.
DR. COOK:

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A. Um-hm.

CROSBIE, Q.C.:

Q. And she was a lady 46 years old when she passed away. She was diagnosed in 1998, he told us, and we also had access to some of the medical documents at the time. She tested ER and PR negative here originally, after her diagnosis. She went to Boston and was tested positive in Boston. She came back here and arrived here retested and decided that--found that she was 50 percent positive for ER and 15 percent positive PR. She was treated by various oncologists, a Dr. Wasil, a Dr. Maghfoor. You may or may not remember those people.

DR. COOK:

A. Maghfoor, I briefly remember.

CROSBIE, Q.C.:

Q. There's been a high turnover of oncologists as well as pathologists.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. And also Dr. Laing, who is more familiar to us. She was started on Tamoxifen in October

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1999, after a round of chemotherapy, and unfortunately died in March of 2000. Sir, was this a sentinel case?

DR. COOK:

A. It should have been a case that I think should have arose -

MR. BROWNE:

Q. Commissioner, perhaps Mr. Crosbie would be so kind as to ask Mr. Cook, first of all, if he actually was aware of this case and if he had involvement in the case, was it brought to his attention.

THE COMMISSIONER:

Q. My understanding is that he's--Mr. Crosbie can correct me if I'm wrong. You're asking the witness whether or not the case, as described, amounts to a sentinel case?

CROSBIE, Q.C.:

Q. Correct.

THE COMMISSIONER:

Q. As opposed to the details of this particular case? Did I get you wrong, Mr. Crosbie? I think you're interested in whether or not that--those details, if accepted, amounts to a sentinel case?

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CROSBIE, Q.C.:

Q. That's the question at the moment.

THE COMMISSIONER:

Q. As far as I'm concerned, Mr. Browne, that's acceptable. But we have to make sure we're talking about the same sentinel case, in the sense of the way it is used within Eastern Health, I presume you're asking?

CROSBIE, Q.C.:

Q. Well, that's what I'm trying to explore.

THE COMMISSIONER:

Q. Yes, okay.

DR. COOK:

A. So what you're saying, Mr. Crosbie, if I understand it, she was tested ER and PR negative here at the Health Care Corporation, went down to Boston and tested ER and PR positive? I mean, that was basically the -

CROSBIE, Q.C.:

Q. And then came back here, was retested ER/PR positive.

DR. COOK:

A. I mean, by and large, I mean, it should have required a further investigation, further questions.

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CROSBIE, Q.C.:
Q. Who should have initiated the further investigation or questions?
DR. COOK:
A. Well, you look back to our situation back in May of 2005, that was initiated by our oncologists who then notified me, or the clinical chief at the time.
CROSBIE, Q.C.:
Q. What about the pathologist who interpreted the second time here in St. John's, would that medical doctor have any professional responsibility to initiate inquiries?
DR. COOK:
A. I think that individual should have notified the clinical chief.
CROSBIE, Q.C.:
Q. You aren't aware of any such notification in relation to this case or any other case, other than the Deane case, were you?
DR. COOK:
A. That's correct.
CROSBIE, Q.C.:
Q. So then if the following people knew of the conversion from false negative to positive,

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the three treating oncologists and the pathologist who examined the specimen the second time here in St. John's, all, if they knew about this, had a responsibility to take further steps?
DR. COOK:
A. Well, should have inquired further into it. I mean, at least have done that.
CROSBIE, Q.C.:
Q. What would that involve?
DR. COOK:
A. That may involve, what I asked with Dr. Laing, I mean, were there any other cases that you're worried about? Was there a need to send off any other cases that you were worried about to an outside institution?
CROSBIE, Q.C.:
Q. Would the topic come up, "maybe we should do a selective look back to see how our tests are going"?
DR. COOK:
A. Possibly. I mean, I can't comment on the very thought processes at that particular time, and what those people were thinking.
CROSBIE, Q.C.:

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Q. When Dr. Ejeckam testified here, he told us that he would have recommended a look back in 2003, but there was no sentinel case.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. Might it be that if he knew of the Christine Purcell case, he would have recommended a look back in 2003?
DR. COOK:
A. Possibly. I can't say for sure.
CROSBIE, Q.C.:
Q. What makes for a sentinel case?
DR. COOK:
A. One that has an adverse effect that changes the treatment recommendation and could result in an altered outcome.
CROSBIE, Q.C.:
Q. Dr. Laing was the same oncologist who treated Peggy Deane.
DR. COOK:
A. That's correct, I understand, yes.
CROSBIE, Q.C.:
Q. I suppose there might be other such cases, sentinel cases, that were not reported either.

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DR. COOK:
A. It's possible, Mr. Crosbie. I simply don't know.
CROSBIE, Q.C.:
Q. Sir, the Oxford Canadian Dictionary defines botched as "bungled or spoiled work." The press often refers to botched lab tests when they cover this particular story. You may have noticed that.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. You had the results from Sinai back by the end of January, 2006?
DR. COOK:
A. Most of them. We got some more results in February of 2006.
CROSBIE, Q.C.:
Q. Certainly by the end of February?
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. You knew from that that the lab had around half of the tests that you sent up to Sinai wrong.

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DR. COOK:
A. It depends what your definition of wrong is, Mr. Crosbie.
CROSBIE, Q.C.:
Q. They were false negatives.
DR. COOK:
A. What's the definition of false negative?
CROSBIE, Q.C.:
Q. You're the expert, sir. Why don't you explain that?
DR. COOK:
A. Well, it depends on what your cutoff point is. I mean, we had three different cutoff points from 30 percent, down to ten percent, and if you look at the technical cutoff, it's at greater than one percent. So you may have clinical cutoff and you have technical cutoff.
CROSBIE, Q.C.:
Q. Sir, we explored that with Dr. Mullen and if the Registrar would, please, bring up page three--first of all, page 320, if you would, please? Actually -
THE COMMISSIONER:
Q. Sorry, did you want to change the number? Page 320 you wanted? I just -

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REGISTRAR:
Q. I think he's looking for the transcript of Dr. Mullen. Is it June 27th transcript?
CROSBIE, Q.C.:
Q. June 27th, page 319 will do for a starter.
THE COMMISSIONER:
Q. Was it--did you say clinical and technical cut off when you were answering Mr. Crosbie, Dr. Cook?
DR. COOK:
A. Clinical and technical cutoffs.
THE COMMISSIONER:
Q. And technical, I think you referred to last week, clinical was the 30 and the 10, correct?
DR. COOK:
A. 30 and the 10, Commissioner, yes.
THE COMMISSIONER:
Q. And the technical would be the -
DR. COOK:
A. Greater than one percent.
THE COMMISSIONER:
Q. - greater than one, thank you. Now there's your excerpt, I think, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Thank you. So we see here that I asked Dr. Mullen about the percentages of positivity in the retrospective cases that he did.

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DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. And he says "let me look at my cards," and there's a bit more there, and then if we go over to 320, if you would, Registrar? He gets down to around line seven and he says "so in my classification, I would have ER negative of 46.3, ER positive of 53.7. Using Eastern Health criteria, I would have 53.2 percent negative and 46.8 percent positive," he says at line 13. So it would seem that he's got both statistics available. His classification would be his cutoff criteria and Eastern Health criteria would be your cutoff criteria.
DR. COOK:
A. Well, the two--and again, two different criteria you want to use. I mean, do you use your clinical criteria, which we use at 10 and 30 percent, or the technical criteria at one percent. So there was variations in labs and how they report conversion rates, based on different cutoffs.

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CROSBIE, Q.C.:
Q. Sir, do you wish to dispute that you had about a 50 percent false negative rate?
DR. COOK:
A. I think our false negative rate, based on around 30 to--based on about 30 percent cutoff, is around 30 to 33 percent.
CROSBIE, Q.C.:
Q. Do you accept the statistics Dr. Mullen stated and I just read?
DR. COOK:
A. I'm not sure I accept those statistics. I mean, where were those statistics from?
CROSBIE, Q.C.:
Q. Well, we can only point to the transcript. Maybe it's too late to take that up with Dr. Mullen.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. So why don't we leave it at this then, and pass on, you dispute his statistics?
DR. COOK:
A. I'm not sure I'm happy with those statistics.
CROSBIE, Q.C.:

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Q. Very good. If he were right, would the press be right to call this a botched test?

MR. SIMMONS:

Q. Commissioner, I don't know what the probative value or the usefulness is of trying to assign a descriptive word like that here. That's not helping us explore anything that's (inaudible) the terms of reference of the Inquiry. It's just feeding information that might be intended for another audience on another day.

THE COMMISSIONER:

Q. Mr. Crosbie?

CROSBIE, Q.C.:

Q. If I may, Commissioner, I represent a group of people, many of whom have been grievously injured by the activities that you've been mandated to look into. I always thought that cross-examination involved confrontation and that's what I'm doing.

THE COMMISSIONER:

Q. I agree that one has a great deal of liberty on cross-examination, but frankly, whether or not one describes it--put it this way, it's of more benefit to me to clarify what the numbers are than it is to characterize it by one word

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or another.

CROSBIE, Q.C.:

Q. Thank you, Commissioner.

THE COMMISSIONER:

Q. And I'm assuming at some point down the road, we will, in fact, have some clarification of the numbers, whether you use 30 percent, 10 percent or otherwise.

CROSBIE, Q.C.:

Q. So, Dr. Cook, Sinai received only blocks and slides from cases that were characterized as negative here?

DR. COOK:

A. That's correct.

CROSBIE, Q.C.:

Q. When Dr. Mullen talks about Sinai cutoffs and he states 46.3 percent and 53.7, I took it that he meant the cutoffs that Mount Sinai had in effect at the relevant period of time that the slide fit into. Is that what you would assume?

DR. COOK:

A. Well, I mean, you apply those same cutoffs to our situation.

CROSBIE, Q.C.:

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Q. I thought he applied your cutoffs to your situation.

DR. COOK:

A. We looked at cutoffs of 30 percent, 10 percent and also a technical cutoff of greater than one percent.

CROSBIE, Q.C.:

Q. Yes, and why is it you think his numbers are wrong?

DR. COOK:

A. Well -

CROSBIE, Q.C.:

Q. He seemed to be pretty adept with numbers when I was here.

DR. COOK:

A. Well, where did he get those numbers?

CROSBIE, Q.C.:

Q. Well, we don't have him here right now. We only have the transcripts, so we're going to have to move on, and I'm afraid -

MR. BROWNE:

Q. Commissioner -

THE COMMISSIONER:

Q. Mr. Browne?

CROSBIE, Q.C.:

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Q. - we can't assist the Commissioner.

MR. BROWNE:

Q. Dr. Cook makes a good point. Mr. Crosbie had an opportunity of exploring that with Dr. Mullen when he was on the stand and did not.

THE COMMISSIONER:

Q. Mr. Browne, Mr. Crosbie has just indicated, I understood, that since we don't have the numbers, he's moving on until he presumably gets the numbers a little later down the road. Did I misunderstand you, Mr. Crosbie?

CROSBIE, Q.C.:

Q. I can't do anything to assist the Commission more than point to what Dr. Mullen told us in sworn evidence.

THE COMMISSIONER:

Q. Yes.

CROSBIE, Q.C.:

Q. He had a bunch of cards on the table in front of him. No one had asked him about these ratios before, and I stood up and I asked him, and there it is.

THE COMMISSIONER:

Q. All right. Can I interject here though? Dr. Cook, you said you thought the false negative

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rate, based on 30 percent, is 33 percent?

DR. COOK:

A. Well, around 30 percent cutoff, the false--our calculations were anywhere from about 24 up to 30 percent. Those were rough calculations that we made.

THE COMMISSIONER:

Q. Is that assuming that all the cases that went were cutoff at 30 percent?

DR. COOK:

A. There were cutoffs--no, if you assume that it was 30 percent, it was probably around 30 percent conversion. If they were around ten percent, it might be slightly lower than that. If it was around one percent, then you may be talking something in the orders of 19 or 20 percent, rough. Those are rough calculations that we had made.

THE COMMISSIONER:

Q. So are you saying that from the calculations within Eastern Health, they never would have been the numbers that Mr. Crosbie has given to you?

DR. COOK:

A. That's what I'm saying.

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THE COMMISSIONER:

Q. All right.

DR. COOK:

A. The numbers that Mr. Crosbie are saying are too high.

THE COMMISSIONER:

Q. Okay. That clarifies it for me. Thank you. Mr. Crosbie.

CROSBIE, Q.C.:

Q. Yes. How many patients were in the group between 30 percent and ten percent, do you know?

DR. COOK:

A. I can't tell you, Mr. Crosbie.

CROSBIE, Q.C.:

Q. Would you look at--could you bring up Exhibit P-1852, please 3 please? I may have to, over break, have a further look for this, but I thought that we were told by Ms. Predham in her sworn evidence in the answer that there were only 13 patients in that category?

DR. COOK:

A. Ms. Predham had all the numbers. She was the one that kept the tab on the numbers, I mean, I was just concerned with supplying the

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information to panelling process and setting up a process to get the cases retested.

CROSBIE, Q.C.:

Q. Okay, I may have to come back to that after we get a break. While we're on the transcript of Dr. Mullen, can we go back to page 31A please? And at line, at around line 8, I'm asking Dr. Mullen, "Is optimizing something which is optional?" And he says at 15, "It is mandatory". And at 19, "It is not optional."

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. Do you agree with him, sir?

DR. COOK:

A. I agree that we should try to optimize as much as possible.

CROSBIE, Q.C.:

Q. Sir, would you agree that if a lab is not going to optimize, then it shouldn't be doing the test?

DR. COOK:

A. Well that depends, now you have to speak to our technical people on that, those were individuals who were involved in the

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optimization of the antibodies, the antibody concentrations, incubation times, so that was mainly at a technical aspect of the lab.

CROSBIE, Q.C.:

Q. Optimizing then I take it is not something that you take responsibility for, as either site chief or clinical chief?

DR. COOK:

A. No, I see optimizing mainly as a technical component involving the technical aspect of the Laboratory Medicine Program.

CROSBIE, Q.C.:

Q. Do you have any opinion on that statement, if you're not going to optimize, then don't do the test?

DR. COOK:

A. Well you'd have to talk to our technical people regarding that.

CROSBIE, Q.C.:

Q. So you don't have an opinion on optimizing?

DR. COOK:

A. Well I think optimizing should be done, but again, that's a technical opinion and you'll have to speak to our technical people on it.

CROSBIE, Q.C.:

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Q. That's out of your sphere of expertise?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. Overall, Dr. Mullens seemed to be of the opinion that the majority of slides which he reviewed were technically poor?
DR. COOK:
A. Well that's his opinion.
CROSBIE, Q.C.:
Q. You reviewed a lot of these slides yourself, what was your opinion?
DR. COOK:
A. My opinion is that most of those slides were interpretable, they were all interpretable, there were varying degrees of fixation artifacts there, some of the slides was probably less than five percent of the surface area, some of the areas are up to about 20 percent.
CROSBIE, Q.C.:
Q. Did Dr. Carter seem to be of the opinion that the slides were technically poor?
DR. COOK:
A. I believe she felt they were technically poor.

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CROSBIE, Q.C.:
Q. Was Dr. Banerjee of that opinion?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. And broadly speaking, you, as well?
DR. COOK:
A. Certain slides I felt were technically poor, yes.
CROSBIE, Q.C.:
Q. Dr. Mullen thought some slides should not have been reported at all.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Do you disagree with him on that?
DR. COOK:
A. Well I would have to look at the slides that he's talking about.
CROSBIE, Q.C.:
Q. You may not have seen those particular slides?
DR. COOK:
A. No, I may not have.
CROSBIE, Q.C.:
Q. Is it fair to say Dr. Mullen thinks that

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quality control is mandatory?
DR. COOK:
A. Quality control certainly in a technical aspect of the lab is mandatory, yes.
CROSBIE, Q.C.:
Q. So you agree?
DR. COOK:
A. I agree.
CROSBIE, Q.C.:
Q. Is it fair to say Dr. Mullen thinks that quality assurance is mandatory?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. And you agree that it is mandatory?
DR. COOK:
A. I agree that it would.
CROSBIE, Q.C.:
Q. Dr. Cook, IHC was a sophisticated new lab service which, of course, we instituted here in 1997.
DR. COOK:
A. Oh it was here before that, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Pardon me?

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DR. COOK:
A. The IHC was here before that.
CROSBIE, Q.C.:
Q. In relation to ER/PR, we instituted this service in 1997.
DR. COOK:
A. In relation to ER/PR.
CROSBIE, Q.C.:
Q. And it was in the process of being, for that purpose, adopted in North America and Europe in this period.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. As the gold standard for doing these stains.
DR. COOK:
A. That's open to debate.
CROSBIE, Q.C.:
Q. It was thought to be superior to the method that was being used here before.
DR. COOK:
A. The biochemical assay.
CROSBIE, Q.C.:
Q. Yes.
DR. COOK:

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A. But some regard the biochemical assay is a gold standard.

CROSBIE, Q.C.:

Q. What's your opinion?

DR. COOK:

A. My opinion is the IHC is superior in that we can actually identify the tumour cells that are staining with the stain.

CROSBIE, Q.C.:

Q. That must have been the consensus of all the pathologists here in 1997 because we know you adopted it.

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. As a matter of good management practice, would you expect that a service assessment or cost benefit analysis would be informed to establish what resources would be needed before a lab embarked on a new service of this kind?

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. That would be good practice?

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DR. COOK:

A. I think that would be good practice.

CROSBIE, Q.C.:

Q. Management would want to know things like what training might be needed?

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. What physical space was needed? What new equipment, maybe?

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. The cost of that?

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. Whether the pathology staff had the necessary expertise?

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. Whether it would require professional time to be taken away from other lab services, these are all things you might want to know?

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DR. COOK:

A. Uh-hm, and those were investigated, I believe, by the program director and clinical chief of the day.

CROSBIE, Q.C.:

Q. This is Dr. Khalifa?

DR. COOK:

A. No, that would be Dr. Haegert, I believe and Mr. Vern Whalen.

CROSBIE, Q.C.:

Q. There should be a budget drawn up.

DR. COOK:

A. Well the savings that you had from the biochemical assay would be transferred over to the division of anatomical pathology.

CROSBIE, Q.C.:

Q. That sounds nice, but how do you know?

DR. COOK:

A. Well I don't know for sure because I was relying on the management team at that particular time, the program director to handle the finances.

CROSBIE, Q.C.:

Q. So you wouldn't know unless a budget was done up?

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DR. COOK:

A. Unless I saw the budget.

CROSBIE, Q.C.:

Q. Which you did or didn't?

DR. COOK:

A. I didn't see the budget.

CROSBIE, Q.C.:

Q. How do you know there's a budget?

DR. COOK:

A. Well it's a budget for the whole lab.

CROSBIE, Q.C.:

Q. Well I'm talking about a specific cost benefit analysis before this service, IHC for ER/PR was instituted, did you see a budget for that?

DR. COOK:

A. I didn't see the budget for that, but I mean, that would have been under the program director at the time.

CROSBIE, Q.C.:

Q. Well I haven't seen a budget for it in all the paperwork that we've been provided, it maybe that one of these good people behind me have and they can draw our attention to it, but I have not.

DR. COOK:

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A. The money would have been transferred, I think, from a savings that you had in the biochemical assay over to the division of immunology to account for the extra workload in the IHC. That was my understanding at that particular time.

CROSBIE, Q.C.:

Q. Is it desirable to know whether it would be cheaper to refer out and pay a reference lab to do the test?

DR. COOK:

A. The problem with that is you're dependant on a reference lab, if they decide to cut your services at any time, they could very well do it.

CROSBIE, Q.C.:

Q. So you're vulnerable to the reference lab.

DR. COOK:

A. In some ways you are.

CROSBIE, Q.C.:

Q. Could you even maintain a residency program without doing that service?

DR. COOK:

A. It would be difficult to maintain a residency program if you're sending out the bulk of your

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work to an outside lab.

CROSBIE, Q.C.:

Q. Well we're just talking the bulk of this work, but this is important work, isn't it?

DR. COOK:

A. It is important work, yes.

CROSBIE, Q.C.:

Q. If you didn't have that service at Eastern Health, it might jeopardize the residency program?

DR. COOK:

A. It's difficult to say, you would have to depend on the Royal College Accreditors to come in and make that assessment.

CROSBIE, Q.C.:

Q. It's not going to help though, is it?

DR. COOK:

A. It depends on what the accreditors say. If you've got IHC in there, that's a favourable item to have, just because you lose ER and PR, it may or may not affect your accreditation process, that's up to the accreditors.

CROSBIE, Q.C.:

Q. Dr. Cook, just assume for the moment that to offer this new service for ER/PR involved a

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budgetary commitment of several extra hundred thousand dollars, would that have to be routed to the VP Medical for a final decision and maybe the CEO?

DR. COOK:

A. Possibly, if it puts the program in debt to that tune, there has to be an explanation why the program is in debt, so that would go to the VP.

CROSBIE, Q.C.:

Q. Could we bring up exhibit P-0121, it's the review that you and Mr. Gulliver undertook, October 13th, 2005.

DR. COOK:

A. Yes.

CROSBIE, Q.C.:

Q. Review of immunohistochemistry lab, General Hospital site, St. John's, Eastern Health, prepared for Dr. Williams, Vice-President. It sets out an objective at page 2, if you would, Registrar, item 1.2. And the objective is "to identify the requirements needed to implement a complete quality assurance program for the IHC lab, ensure that we provide a standardized and reliable service equivalent to the Mount

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Sinai reference lab in Toronto."

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. And you were one of the authors of that statement.

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. Sir, the document is dated October, 2005, can we just go to the very end of it, please? Just perhaps the previous page. Somewhere in here, I think you'll remember there's an added budget proposed of--yes, there it is, $282,000?

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. So in order to achieve the objective of providing a service equivalent to the Mount Sinai reference lab, it seemed that you were running the lab up until this point in time a couple thousand dollars short to be able to achieve that.

DR. COOK:

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A. Yes.
CROSBIE, Q.C.:
Q. It would have been better to do the analysis before the service was started or at least before 2005, wouldn't it?
DR. COOK:
A. The analysis should have been done at the time of '97, '98.
CROSBIE, Q.C.:
Q. I suggest to you, sir, it wasn't.
DR. COOK:
A. I can't be sure, Mr. Crosbie, that was done by--that would have been done by the program director of the day and the clinical chief of the day.
CROSBIE, Q.C.:
Q. Sir, do you know what the look back cost?
DR. COOK:
A. Roughly ballpark figure, I'd say probably around three hundred thousand, around there, can't be absolutely sure on the exact amount.
CROSBIE, Q.C.:
Q. Who would know the exact amount?
DR. COOK:
A. I would say Mr. Terry Gulliver would know that

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amount and possibly the vice-president of Medical Services.
THE COMMISSIONER:
Q. I'm sorry, the vice-president of which?
DR. COOK:
A. Medical Services.
THE COMMISSIONER:
Q. Thank you.
CROSBIE, Q.C.:
Q. Can we bring up document P-0697? These are minutes of the Laboratory Program, 1997 03 04, page 1, please?
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Could you go down to the bottom half of the page, see the topic "Financial Issues"?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. And we're seeing there that the lab at this point in time was $120,000 in the red?
DR. COOK:
A. That's what it looks like.
CROSBIE, Q.C.:

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Q. And if we go down to the final paragraph beginning, "Mr. Whelan and Dr. Haegert:--it seems that you were being asked or the lab was being asked to save one million in the coming year's budget.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Now if we could go to document P-0698 please? These are minutes from divisional manager's meeting, 1997-06-24 and at the bottom of the page, page 1, we see "Financial Issues". "The '97/'98 budget is last year's actual, as projected as of February minus $700,000 that was deducted from the total laboratory budget."
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. I take it from that that you had to run the lab on $700,000 less, that someone had fought off the request to save a million, but you still had to find a saving of $700,000?
DR. COOK:
A. That's correct.

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CROSBIE, Q.C.:
Q. Dr. Cook, I'm suggesting there was no analysis comparable to the one that you undertook with Mr. Gulliver in October, 2005, setting out the preconditions for a viable IHC service up to par with Mount Sinai, that there is no such analysis done before institution of the service?
DR. COOK:
A. Mr. Crosbie, you have to ask the program director and the clinical chief of the day regarding -
CROSBIE, Q.C.:
Q. And I will, so let's assume it for the time being and maybe I'll turn out to be wrong, but if we assume that to be a fact, wouldn't that put the lab at a disadvantage in dealing with requests for budgetary cuts?
DR. COOK:
A. Oh absolutely.
CROSBIE, Q.C.:
Q. Because you can't come forward to the authorities and say we can't give you that money because if we do, we won't be able to run this service up to snuff.

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DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. That's one of the reasons why you need a proper financial analysis of the type we've been talking about and which you did in October, 2005?
DR. COOK:
A. Well yes, we did.
CROSBIE, Q.C.:
Q. I'd like to talk about DCIS for a minute.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. The lab was doing IHC staining for DCIS patients and those are ductal carcinoma in situ, non invasive patients, it would seem on the advice of this panel that was established, is that correct?
DR. COOK:
A. Well we didn't do, you mean in terms of the immunoperoxidase, ER and PR on that test, on that particular item?
CROSBIE, Q.C.:
Q. Uh-hm.

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DR. COOK:
A. We didn't, as a standard, perform ER and PR on DCIS, unless we were requested to by the oncologist.
CROSBIE, Q.C.:
Q. Prior to 2005?
DR. COOK:
A. Again, I can't say for sure what all pathologists were doing, I know what we were doing at St. Clare's, but there may be cases where upon a request of an oncologist, for whatever reason, there would be a request for an ER/PR on a DCIS.
CROSBIE, Q.C.:
Q. I had understood there were 52 women--I assume women, perhaps 52 patients who were DCIS and who were tested and who it was proposed to have retested; in other words, they tested negative at Mount Sinai.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Do you know whether that's true?
DR. COOK:
A. We had about fifty cases there. Again, I'm

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not sure if that was--the order to initiate that came from the pathologist or oncologist.
CROSBIE, Q.C.:
Q. Do you know whether there was a blank--just clarify for me because you may have already answered this, are you saying there is a blanket policy at the predecessor labs, we're talking about the Grace now and Health Sciences, not to do ER/PR testing on DCIS cases?
DR. COOK:
A. There was no written policy. It was basically an understanding that we had amongst ourselves that ER and PR would not be done on a DCIS. We would only do it on an invasive carcinoma.
CROSBIE, Q.C.:
Q. And that understanding was current prior to the decision to send cases for look back testing to Mount Sinai?
DR. COOK:
A. You mean during the years '04, '03 and '02, et cetera?
CROSBIE, Q.C.:
Q. Yes, back to '97.
DR. COOK:

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A. Could be.
CROSBIE, Q.C.:
Q. I'm sorry?
DR. COOK:
A. It could be, yes.
CROSBIE, Q.C.:
Q. Well, could it be or was it?
DR. COOK:
A. Well, I mean, some individual pathologists may order that on a request from oncology or surgeon, but I, in terms of what my practice was at St. Clare's, we did not order ER and PR on DCIS's. So I can't say what was happening with other oncologists or other pathologists. If an oncologist requests an ER and PR on a DCIS, he or she usually has a reason.
CROSBIE, Q.C.:
Q. Could we go to Exhibit P-1896 please? 1898, I'm sorry, P-1898. Dr. Cook, you, yourself, served as a site chief and later as a clinical chief.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. This is a document originated from Dr.

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Khalifa, April 1999 and it's a sort of job description entitled "some of my chores as a site chief 1996 - 1999". And if we look through that, he says that item number 3, for example, he mentions preparing controls for immunohistochemistry, troubleshooting with failed tests and so forth. Five, Tuesday conference as tool for the limited QA we have. Preparing and following up on policies, maintaining statistics.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. And aide is missing breast, taken away uterus, I guess specimens would, from time to time, go missing.

DR. COOK:

A. Well, he would follow up on something like that, yes.

CROSBIE, Q.C.:

Q. Well, what does he mean when he says at three, "preparing controls for immunohistochemistry".

DR. COOK:

A. He would, say, pick out--if he had a tissue

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breast case with a high expression of ER and PR for instance, he could very well submit that for to be used as a control.

CROSBIE, Q.C.:

Q. What was the Tuesday conference which he says "a tool for limited QA" -

DR. COOK:

A. I don't know what he's talking about there. I can't be for sure what he's mention--this took place at the general hospital site.

CROSBIE, Q.C.:

Q. Having served in a similar job, is that a reasonable description of the chores of a site chief?

DR. COOK:

A. Reasonable, I would say.

CROSBIE, Q.C.:

Q. Anything you care to add?

DR. COOK:

A. No, that's pretty well it.

CROSBIE, Q.C.:

Q. What about specifically in relation to ER/PR testing?

DR. COOK:

A. Again, that would come under responding to

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technical problems.

CROSBIE, Q.C.:

Q. Could we now turn -

DR. COOK:

A. If he identified them.

CROSBIE, Q.C.:

Q. He identified them.

DR. COOK:

A. If he identified them.

CROSBIE, Q.C.:

Q. Could we turn to document P-1850, page two, please. You see on page two he's talking about phase two and he says, "this phase will start March 1, 1998".

THE COMMISSIONER:

Q. Sorry, Mr. Crosbie, what is this document, just to orient myself.

CROSBIE, Q.C.:

Q. I'm sorry, I did go straight to page two; bring us back to page one, please. So, Commissioner, you can see this is the memorandum in which Dr. Khalifa described the state of readiness of the program and basically launched it.

THE COMMISSIONER:

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Q. Thank you.

CROSBIE, Q.C.:

Q. Page two, please. It's dated February 16, 1998 and at page two Dr. Khalifa is announcing that starting March 1, 1998 immunostain slides will be mailed back to each pathologists with positive controls whenever it is technically possible.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. What does that mean, "whenever it's technically possible"?

DR. COOK:

A. The problem was at that particular time there was an issue of having controls sent with every batch. The issue that arose was the financial restraint that we were under at that particular period of time and that because of the financial restraint, the program basically couldn't afford to sent positive controls with every bath. So, in lieu of that, before the cases went out, the positive controls would be checked and verified by the site chief of the General Hospital.

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CROSBIE, Q.C.:
Q. This is motivated by budgetary constraint?
DR. COOK:
A. Budgetary constraint, yes.
CROSBIE, Q.C.:
Q. So, he doesn't actually mean whenever it's technically possible. He means financially possible.
DR. COOK:
A. That was basically what it boiled down to.
CROSBIE, Q.C.:
Q. Sort of a euphanism.
DR. COOK:
A. Well, you could use that word.
CROSBIE, Q.C.:
Q. And he goes on to say "with each run, I will still be responsible for reviewing the positive controls here in our laboratory and the slides will not be mailed to you unless adequate staining is noted in the positive controls".
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. So, what's he saying he's doing to do there?

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DR. COOK:
A. He's saying if you send out, if I get the cases and I don't have a positive control, then you make the assumption that he's reviewed the positive controls before the cases are gone out.
CROSBIE, Q.C.:
Q. He's saying, I will professionally guarantee that the controls are in good order.
DR. COOK:
A. That's what he's saying.
CROSBIE, Q.C.:
Q. I will be responsible for reviewing positive controls and slides will not be mailed without adequate staining is what he's saying.
DR. COOK:
A. Well, he's going to check the controls and make sure they work.
CROSBIE, Q.C.:
Q. And this is Dr. Khalifa's professional guarantee that only adequately stained slides would be released.
DR. COOK:
A. That's what he's saying.
CROSBIE, Q.C.:

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Q. So, the system was that one pathologist reads all the controls at the lab, at the only lab doing the IHC.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. And the controls may or may not be provided to the pathologist doing the interpretation of the patient slide.
DR. COOK:
A. Well, if the controls are provided, then it's a responsibility of the pathologist then to verify those controls. So, it is possible that the controls, say, would have gone over to the Grace, the pathologist there would be aware of the controls with the batch and they would look the controls.
CROSBIE, Q.C.:
Q. No doubt. Dr. S. Parai succeeded Dr. Khalifa as site chief at the Health Sciences in about later 1999.
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. So, Dr. Parai must have taken responsibility

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for the adequacy of all these controls from late 1999 to March 2005 when he ceased to exercise the function of site chief.
DR. COOK:
A. I believe so, yes.
CROSBIE, Q.C.:
Q. So, if we want to look for responsibility for the adequacy of positive controls from 1997 to 2005, we should look to the site chiefs Khalifa and Parai.
DR. COOK:
A. I guess you can make that statement, yes.
CROSBIE, Q.C.:
Q. Thank you. I'd like to switch to Dr. Banerjee for a moment. You told the Commissioner you agree with basic conclusions of the Banerjee report.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. If the site chiefs were responsible for the adequacy of controls, sir, they didn't seem to do a very good job of it.
DR. COOK:
A. Site chief at the General Hospital site you

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mean?
CROSBIE, Q.C.:
Q. The ones who were responsible, Parai and Khalifa, for guaranteeing the adequacy of the controls.
DR. COOK:
A. Well, that's a matter of opinion, Mr. Crosbie. I can't state for sure.
CROSBIE, Q.C.:
Q. It would seem to be Dr. Banerjee's opinion because he was quite critical of the controls.
MR. SIMMONS:
Q. Commissioner, Dr. Banerjee, I think, spoke of internal controls in the discussion (inaudible) external controls.
CROSBIE, Q.C.:
Q. Would you bring up document P-0046 please.
THE COMMISSIONER:
Q. We must remember there's a period of time after Dr. Ejeckam where external controls got on the same slide as internal controls. So, we have to make that distinction as well.
MR. SIMMONS:
Q. Exactly (inaudible).
THE COMMISSIONER:

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Q. Yes.
CROSBIE, Q.C.:
Q. Page four, please. A little further down the page, please, little bit further. I'm interested in conclusions about the reasons for test failure.
THE COMMISSIONER:
Q. Yes, right in front of you, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Yes, that's what I'm just saying, to bring it to that. And he talks about "the reason for test failure in paragraph 1 was most likely due to a lack of test optimization" and so forth "as positive controls showed weak staining in general. And internal controls failed in all the false negative cases".
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. So, when I say that the site chiefs who are taking on professional responsibilities for the adequacy of the staining of controls, did not do a good job of it in the opinion of Dr. Banerjee, I am correct, aren't I?
DR. COOK:

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A. You can make that statement, that the site chiefs generally oversaw the controls at the General Hospital site.
CROSBIE, Q.C.:
Q. Because in that statement we just read he does differentiate between the positive controls and the internal ones, doesn't he?
DR. COOK:
A. He does.
CROSBIE, Q.C.:
Q. The internal ones having failed in all of the false negative cases.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. Sir, Dr. Parai is a bit of a mystery. He appears very infrequently in the record that we have and gosh only know the record is extensive.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. He's almost like a ghost on the record. Do you have any explanation for that?
DR. COOK:

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A. He was at the meetings. He was a site chief there at the General for quite some time. There was an expectation that he would actively take a role in overseeing the pathologists, acting as liaison between the pathology and the technical department. He was a very important individual.
CROSBIE, Q.C.:
Q. He just didn't generate much in the way of paper.
DR. COOK:
A. I guess you can say that Mr. Crosbie.
CROSBIE, Q.C.:
Q. I'd like to talk to you for a moment about confirmation. Before a lab switches from one testing method to another, it does this process called confirmation. That's what I've picked up so far.
DR. COOK:
A. Validation is a term that's used. I mean, I'm not sure about confirmation. Where'd you get that term?
CROSBIE, Q.C.:
Q. Well, when I was asking Ms. Wegrynowski about it, I spoke of the switch to

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immunohistochemical staining that Dr. Khalifa was overseeing and as we'll see in a moment, it may be document P-1850, if you could bring us to that, page six actually. Let's see the first page of the document and then page six. So, this is his memorandum to all the pathologists, February 1998 and page six, please; maybe page five, just bring us back. So, what I get out of this is Dr. Khalifa is running side by side series. The old test method and then the new technique. And when I asked Ms. Wegrynowski about that, the technologists from Mount Sinai, I talked about it as a validation exercise and she told me no, no, we don't call that validation; we call it confirmation.

DR. COOK:

A. Well, I call it correlations.

CROSBIE, Q.C.:

Q. And you have another term for it, as correlation.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. In any event, no matter what the term you use

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for it, Dr. Khalifa, if we go to, again, page six, we're on a side by side correlation of 19 cases for ER and 17 for PR. That's what it shows in those tables there.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. You agreed?

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. Was this a large enough series to constitute a statistically reliable correlation?

DR. COOK:

A. Possibly not. I mean, Mr. Crosbie, when I recollect at that particular time, there was a figure of 30 stuck in my head. I don't know if there's any additional documentation that's around, but 30, to my mind, was the number that I tend to recollect.

CROSBIE, Q.C.:

Q. Well, if there is anything more on that, he refers to these 17 and 19 cases further down in the comments, there's no mention of anything else and I'm not aware of it. So, I

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can only ask my learned friends to bring to my attention if there was something else.

DR. COOK:

A. I mean, I can only tell you back then what the ballpark figure was.

CROSBIE, Q.C.:

Q. Document P-1893, Please.

THE COMMISSIONER:

Q. Mr. Crosbie, when you're through with your questioning on this particular item, perhaps we can take the afternoon break.

CROSBIE, Q.C.:

Q. Yes, it will only be a minute.

THE COMMISSIONER:

Q. Thank you.

CROSBIE, Q.C.:

Q. This is entitled, "contract" and registrar, if you bring us down a bit, you'll see a signature line there. It's contract for the DAKO auto stainer signed the 27th of May, 1998, signed by Mr. Gulliver on behalf of Health Care Corporation of St. John's. So simply we can see from this that the contract for the machine, the DAKO auto stainer wasn't executed until May, 1998. There is on the

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document and that's what we can see.

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. Do you know if the auto stainer was in use any earlier than May, 1998?

DR. COOK:

A. I don't know, Mr. Crosbie. I can't tell you.

CROSBIE, Q.C.:

Q. You don't know exactly when it got into service?

DR. COOK:

A. No, I had to rely on Mr. Gulliver to tell me that.

CROSBIE, Q.C.:

Q. Mr. Gulliver, yes.

DR. COOK:

A. He's your man.

CROSBIE, Q.C.:

Q. It would appear that the confirmation series was run with DAKO kits, but not with the DAKO auto staining machine.

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

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Q. Is that your understanding?
DR. COOK:
A. I didn't know what they were using back then at that time. I wasn't at that site, and I really can't comment on the type of methodology they were using.
CROSBIE, Q.C.:
Q. Well, let's go to document 01889, please. Right at the top of that, this is first of all a letter, March 12, 1997, although it bears another date, February 27, 1997. So you can take your pick,I guess. The important thing being that it's addressed to Mr. Gulliver by Dr. Khalifa, and he says at the outset that, "The ER/PR kit that we have, and which offered us very good and reliable results, has been totally consumed". So they were making use of DAKO kits, it would appear?
DR. COOK:
A. It looks like it, yes.
CROSBIE, Q.C.:
Q. And we're talking about validation, confirmation, correlation. If you look six lines into the first paragraph, just count down six lines, perhaps you could read that

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starting, "Any trial of a new technique".
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Could you do that, sir, and read it out loud?
DR. COOK:
A. "Any trial of a new technique needs to be done in parallel with a well established one before you switch could be safely made".
CROSBIE, Q.C.:
Q. And you wouldn't disagree with that?
DR. COOK:
A. No.
CROSBIE, Q.C.:
Q. Please read the first four lines of the second paragraph as well.
DR. COOK:
A. "Mr. Gulliver, I do not think you fully appreciate the delicacy of this test, its clinical consequences, and the overall emotional charge in the public regarding this very sensitive procedure. I am also uncertain whether our service is being run as smoothly as it should. The medica legal implications of delaying this test are huge, and I want to

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clearly document my concerns at this time".
CROSBIE, Q.C.:
Q. Thank you. Is Dr. Khalifa essentially complaining that Mr. Gulliver is sabotaging his confirmation series?
DR. COOK:
A. Well, I can't say what Dr. Khalifa is actually saying or whether he would use the word "sabotage". I mean, you'll have to ask Dr. Khalifa that.
CROSBIE, Q.C.:
Q. He is saying that Gulliver's actions carried medical legal, and presumably patient safety considerations?
DR. COOK:
A. Well, there was a concern there, yes.
CROSBIE, Q.C.:
Q. Could that jeopardize the validity of the confirmation series of the correlation, as you call it?
DR. COOK:
A. It could, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Thank you, I have no more on this topic, and it's time for a break.

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COMMISSIONER:
Q. All right then, we'll take the afternoon break. Mr. Crosbie, you wanted to find some particular point. I just wanted to remind you that you said you'd come back to it after the break.
CROSBIE, Q.C.:
Q. Yes, I am.
(BREAK)
COMMISSIONER:
Q. Mr. Crosbie.
CROSBIE, Q.C.:
Q. The sense I'm getting from you, Commissioner, is that you prefer less heat and more light. I don't know how photographic a memory the registrar has, but I believe that I provided an affidavit of Heather Predham dated the 9th of February, 2007, and I'm afraid I couldn't say when that was or what number range it would be in, and I won't waste time by dwelling on that if --
REGISTRAR:
Q. What was the date on that?
CROSBIE, Q.C.:
Q. The date of the affidavit was 9th February

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2007. I think I provided it, but it's possible, again, that I did not. In any event, it may not turn up, but I made a call and I had a note of what Ms. Predham deposed in the affidavit and I can tell you what she said, and I can certainly provide the affidavit tomorrow for cross-reference. But before I go to what was said in the affidavit, perhaps we'll give up looking for it. I guess it's not coming up there, is it, Registrar? Could I ask you to go back to the June 27th, 2008 transcript of Dr. Mullen's testimony then? And now I'm looking for paragraph 321, and this, by the way, Commissioner, I'm trying to relate to Dr. Mullen's statements about 38 point something percent, using his classification, 53 point something percent using theirs.

THE COMMISSIONER:

Q. As in the explanation for it, you mean?

CROSBIE, Q.C.:

Q. Yes.

THE COMMISSIONER:

Q. All right then. Is this--you said paragraph, I think, but the page is brought up, so -

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CROSBIE, Q.C.:

Q. I'm sorry, page 321.

THE COMMISSIONER:

Q. - is it page? 321, there you go.

CROSBIE, Q.C.:

Q. We're on line 16. I'm asking Dr. Mullen, "I'm trying to understand the effect of shifting cutoff points from 30 percent to ten percent to one percent." Line 22, "on your positivity rate, will it have much effect or will it have a really fairly minor effect, if the distribution of positivity is in the higher ranges?" and Dr. Mullen says "yes, it shouldn't have much effect." So that's my understanding, Doctor, is that the distribution of positivity will be in the higher ranges, in the 60-70 percent, 90 percent, not in the range of 30-20-10 percent.

DR. COOK:

A. It depends again, how you look at positivity rates, I mean, Mr. Crosbie. You could have a case of ER/PR say two percent two percent and you can have another case that's at ten percent ten percent, another case at 30 percent 30 percent, another case at 40 percent

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40 percent. If you use a cutoff of greater than one percent, all those cases are going to be regarded as positive and going to be included in your positivity rates.

CROSBIE, Q.C.:

Q. So the question was, given the distribution of positivity in the higher ranges, how much effect will it have, and we have the affidavit of Ms. Predham, as I mentioned, February 2005, at paragraph 22. She says "13 patients saw no change in ER/PR status but the standard for interpretation for what constituted a positive test result had changed." So there are only 13 patients affected by the change in cutoff point from 30 percent to ten. That's in her affidavit.

DR. COOK:

A. Yeah, well that's--she would have the numbers.

CROSBIE, Q.C.:

Q. It's not a large number, is it?

DR. COOK:

A. It's not a large number, but she would have the numbers and she was tabulating all the numbers.

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CROSBIE, Q.C.:

Q. Well, we have a statistician coming, so perhaps we'll -

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. - leave these matters to -

DR. COOK:

A. Sure.

CROSBIE, Q.C.:

Q. - statistical experts.

REGISTRAR:

Q. Excuse me, Mr. Crosbie. The affidavit I think you wanted was P-0375?

CROSBIE, Q.C.:

Q. That's Dr. Gown. Yes, so now we'd go to another topic. When Dr. Ejeckam testified, he told the Commissioner numerous times that he considered the reading of internal controls to be critical. I have citations for this, but I don't think it's necessary to go there unless someone thinks it is. We don't have to go there, Registrar, but by way of example, June 3rd, 2008, page 262, and it's all through his testimony. He emphasizes the importance of

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internal controls and that they are the critical control.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. Would you agree that internal controls are the critical control?

DR. COOK:

A. Agree on that, but it also depends on your interpretation and how strongly staining the cells are. So somebody could interpret an internal control as positive. Another can interpret it as negative, depending on the intensity.

CROSBIE, Q.C.:

Q. They should always be positive, shouldn't they?

DR. COOK:

A. Well, no, it depends on the intensity. If you got a very weak intensity stain there, it may be interpreted differently by pathologists. This is the issue that I referred to in the Cleveland situation where we have differences in variations in percentages, based on -

CROSBIE, Q.C.:

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Q. Shouldn't that be screened out by your positive external control?

DR. COOK:

A. It may not happen because a positive external control may be fixed differently or it may be a high expresser as compared to what's going on in your test tissue.

CROSBIE, Q.C.:

Q. What's the reason the internal control is so important?

DR. COOK:

A. To further evaluate that the test is working.

CROSBIE, Q.C.:

Q. It's because that internal control, which is ductal epithelium or perhaps lobular tissue?

DR. COOK:

A. Usually ductal.

CROSBIE, Q.C.:

Q. Acini as Dr. Ejeckam referred to it?

DR. COOK:

A. Yes.

CROSBIE, Q.C.:

Q. It's because it's gone through exactly the same conditions and treatment as the tumour on the slide that it accompanies?

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DR. COOK:

A. That's correct, the internal control. But you have to, again, look at the stain in intensity and that can vary, and that's open to interpretation.

CROSBIE, Q.C.:

Q. You first learned the importance of internal controls at--I'm a little confused. Did you say 2000, 2002, when was it?

DR. COOK:

A. I guess it was around 2000, I believe.

CROSBIE, Q.C.:

Q. And it was while reading literature?

DR. COOK:

A. Yes.

CROSBIE, Q.C.:

Q. Can you tell us which literature was that?

DR. COOK:

A. I think that was in Tavassoli's book, vintage 1999.

CROSBIE, Q.C.:

Q. Tavassoli, and the title?

DR. COOK:

A. Breast Pathology.

CROSBIE, Q.C.:

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Q. Sir, the importance of this control only dawned on you in 2000. Did it occur to you that other pathologists might not understand the critical role with internal controls as well, who were working here?

DR. COOK:

A. That I looked at as just part of my reading, part of keeping update with various things that were going on in pathology. Most pathologists do that. They read books and text and may not notify you of any advances -

CROSBIE, Q.C.:

Q. We hope.

DR. COOK:

A. - in various conditions.

CROSBIE, Q.C.:

Q. They're not all site chiefs or clinical chief, are they?

DR. COOK:

A. No.

CROSBIE, Q.C.:

Q. You had responsibilities.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

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Q. Within the organization.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. You just weren't the average pathologist. You had duties.
DR. COOK:
A. No, I was a site chief.
CROSBIE, Q.C.:
Q. Did you think to ask any of the other pathologists or to make inquiries as to satisfy yourself as to whether they were aware of the importance of internal controls?
DR. COOK:
A. No, that was all part of my general reading and I made the assumption, you know, that people were reading their books and reading their journals. You make that assumption.
CROSBIE, Q.C.:
Q. You do make that assumption, do you?
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. Are there pathologists who haven't cracked a book in years, sir?

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DR. COOK:
A. I can't say, Mr. Crosbie. I mean, I think we're all pretty well actively involved in continuing medical education, going to various conferences and rounds. I don't think there's a pathologist around that hasn't opened up a book.
CROSBIE, Q.C.:
Q. Well, when you did ask in 2005, you told us that most were not using internal controls.
DR. COOK:
A. That was basically that information I gleaned around 2005 when the whole issue broke as to what -
CROSBIE, Q.C.:
Q. That's right, yes.
DR. COOK:
A. But I didn't know that back in 2000.
CROSBIE, Q.C.:
Q. But you might have found out if you asked.
DR. COOK:
A. If I asked, but we ask about a lot of other different things, not necessarily on ER and PR.
CROSBIE, Q.C.:

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Q. You doubtless think of yourself as a competent pathologist and you're reading these tests and you learn from your own general reading something that was critical, described by that as Dr. Ejeckam, that you weren't doing.
DR. COOK:
A. And again -
CROSBIE, Q.C.:
Q. You were site chief.
DR. COOK:
A. - back in '98/99, but I mean, I looked at that as continual improvement and knowledge, right, continual reading and updating your knowledge.
CROSBIE, Q.C.:
Q. Anyway, you've told us that you didn't exert yourself to inquire with other pathologists whether they were misunderstanding the nature of their duties in reading these tests in the way that you had?
DR. COOK:
A. Well, I mean, ER/PR was less than one percent of our work. There is many other tests and evaluations that we do that we try to distribute information as much as possible.

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This was a very narrow band of work that we were doing.
CROSBIE, Q.C.:
Q. Surely that doesn't mean it was unimportant work.
DR. COOK:
A. Oh, it was just as important, Mr. Crosbie, but I'm telling you in terms of the actual amount of work that we were doing, there were much more exchange of information regarding the further interpretation and diagnosis of other tumours.
CROSBIE, Q.C.:
Q. Sir, you started to become aware of the scope of the problem with internal controls, you told us, in the last week of July 2005?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. And if you could bring up document 0076, please? That's when you drafted the memo to all pathologists with Dr. Carter dated July 28th. Can you scroll down to item two and six, please? So in items two and six, you actually spell out the following "when

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reporting, always check internal and external controls."

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. And at six, "internal breast epithelium should show some positivity, some positivity but not diffuse." So you took the trouble to spell that out because it seemed that not all pathologists were aware of these fundamentals.

DR. COOK:

A. Which came to my knowledge in around July of '05.

CROSBIE, Q.C.:

Q. You could have done such a memo back in 2000, if you'd inquired.

DR. COOK:

A. I could have done a memo on many other things in pathology, so should other pathologists. We do make continual inquiries on cases and update our knowledge on various things.

CROSBIE, Q.C.:

Q. Could we go to document 1287, please, 1287, page six? In fact, Dr. Ejeckam did instruct all pathologists on the importance of internal

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controls in this memo of May 2nd, 2003.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. If you look at item three, kindly read that out.

DR. COOK:

A. "Check normal breast acini in your sections as internal controls. This is a second level control. Nuclear staining in normal breast tissue is heterogenic and varies with the menstrual cycle."

CROSBIE, Q.C.:

Q. So he's saying read your internal controls.

DR. COOK:

A. That's what he's saying and he's acting there as a resource person for immunohistochemistry. He's circulating that out for general knowledge.

CROSBIE, Q.C.:

Q. And let you learned in 2005 that despite this memo, most pathologists were not using internal controls?

DR. COOK:

A. Well, I don't know to what percentage, but I

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believe most weren't. There were some that were doing it, but I can't say to what percentage.

CROSBIE, Q.C.:

Q. Something Dr. Ejeckam referred to as critical?

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. I'd like to come back to when Dr. Ejeckam was asked to do his what we've been referring to intervention in 2003.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. Was it pathologists complaining or oncologists or both or what?

DR. COOK:

A. In regards to what?

CROSBIE, Q.C.:

Q. Well, I had the impression there were complaints, and that's what prompted--something propelled Dr. Ejeckam into the lab where, as we know, he shut it down for five or six weeks. What was it?

DR. COOK:

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A. I don't know.

CROSBIE, Q.C.:

Q. You can't tell us why he went in there?

DR. COOK:

A. He must have saw some variability in the staining himself and took action on it.

CROSBIE, Q.C.:

Q. I thought he was asked to go there by a committee.

DR. COOK:

A. What committee?

CROSBIE, Q.C.:

Q. You're saying -

MR. BROWNE:

Q. I think, Mr. Crosbie, you're confusing--Dr. Ejeckam's evidence concerning his reason to intervene related to surgical rounds, surgical pathology rounds at the Health Sciences, where there was discussion about crispness of the slides, and on that basis the review began (inaudible).

CROSBIE, Q.C.:

Q. You can't assist us with any more information about why Dr. Ejeckam did the intervention, can you?

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DR. COOK:
A. No, I mean, I made the--I assume he looked at the stains and he saw variability in stains, was not used to a standard that he was and you know, being our resource person in immunohistochemistry, he took it upon himself to improve the quality and crispness of the stains.
CROSBIE, Q.C.:
Q. I see. Were you aware that some oncologists were sending all their slides out for reading elsewhere?
DR. COOK:
A. I became aware that--you mean oncologists?
CROSBIE, Q.C.:
Q. Yes.
DR. COOK:
A. Not oncologists, no.
CROSBIE, Q.C.:
Q. Surgeons then.
DR. COOK:
A. No.
CROSBIE, Q.C.:
Q. Are you sure?
DR. COOK:

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A. What slides are you talking about?
CROSBIE, Q.C.:
Q. Surgical specimens that they didn't trust the lab to process correctly.
DR. COOK:
A. Can you give me--can you be more specific?
CROSBIE, Q.C.:
Q. I can't do that without betraying information that was given to me in confidence.
DR. COOK:
A. Well, I'm not aware of what you're talking about. Are you talking about surgical cases?
CROSBIE, Q.C.:
Q. If you don't -
DR. COOK:
A. Pathology reports?
CROSBIE, Q.C.:
Q. If you don't know, that's fine, I accept your answer. You weren't aware.
THE COMMISSIONER:
Q. I'm not sure what the question is, Mr. Crosbie.
CROSBIE, Q.C.:
Q. The question was, was he aware that some surgeons or oncologists were sending their

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specimens outside of Newfoundland for reading because they didn't trust the lab here.
THE COMMISSIONER:
Q. The tissue specimens?
CROSBIE, Q.C.:
Q. Yes.
THE COMMISSIONER:
Q. Okay.
CROSBIE, Q.C.:
Q. And he's saying no, which is fine.
DR. COOK:
A. Well, I'm saying I don't know. I never heard of it, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Thank you. Sir, why did you not involve Dr. Ejeckam in the initial investigation of the Peggy Deane index case?
DR. COOK:
A. Well, because I looked at it as a primary breast issue. We had a competent individual in the form of Dr. Beverley Carter who was relatively new to the organization. I thought that she brought with her a certain degree of objectivity and she was knowledgeable in IHC. That was for the initial month or so.

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CROSBIE, Q.C.:
Q. He wasn't given a copy of the Banerjee report, was he?
DR. COOK:
A. He was--I read out the copy to him, along with others, but he was not--I couldn't have--I didn't have the authority to give him a copy of the Banerjee report, and he could see it any time he wanted to see it.
CROSBIE, Q.C.:
Q. Who instructed you as to who could see it?
DR. COOK:
A. The Vice President of Medical Services.
CROSBIE, Q.C.:
Q. Why was he not involved by you in the October 13, 2005 review of the lab, the document we looked at a while ago?
DR. COOK:
A. You mean the report submitted by myself and Mr Gulliver?
CROSBIE, Q.C.:
Q. Mr Gulliver, yeah.
CROSBIE, Q.C.:
Q. We did a -- that was a task that was assigned to us by Dr. Williams to assess the cost of

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bringing in new resources to the lab.
CROSBIE, Q.C.:
Q. And Dr. Ejeckam had nothing to offer you to be of assistance in that process?
DR. COOK:
A. We were just merely just trying to cost out the resources.
CROSBIE, Q.C.:
Q. He didn't meet with Dr. Banerjee, did he?
DR. COOK:
A. I believe he met with Dr. Banerjee, yeah.
CROSBIE, Q.C.:
Q. Oh, he did.
DR. COOK:
A. Yeah.
CROSBIE, Q.C.:
Q. Did he meet with Dr. Gown?
DR. COOK:
A. Yes, he met with Dr. Gown.
CROSBIE, Q.C.:
Q. Dr. Ejeckam described DABBS as the Bible when he was here.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:

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Q. On IHC technique. Would you dispute that glowing description?
DR. COOK:
A. No, that's a pretty good book and many of us use it.
CROSBIE, Q.C.:
Q. Document 01568, please. This should be DABBS page -- and I'm looking for page 17 specifically. Page 17. I'm sorry, I'm mixing it up. It's 17 in DABBS, but three in this excerpt, so we're on the right page. Go down to quality control, please, the heading. Just go up again. Are we on page three? We're on 1568. I'm looking for 1569, page three. DABBS there gives a definition of quality control in this setting. Have you read this before?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. It's a good definition?
DR. COOK:
A. I agree with that.
CROSBIE, Q.C.:
Q. Further down the paragraph, there's a

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statement there, "Daily records of control".
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. You can see that, sir?
DR. COOK:
A. Yeah.
CROSBIE, Q.C.:
Q. And it says, "Daily records of control results are maintained and corrective actions are undertaken and documented when results are unacceptable".
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. And that would be good practice?
DR. COOK:
A. Yes.
CROSBIE, Q.C.:
Q. Go to document 02095. This is going to be a number of pages in. Perhaps I can ask you to go to the next page. Further down, please. This may take a while to find.
COMMISSIONER:
Q. Can you be more specific about what you're

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looking for? Maybe we can assist.
CROSBIE, Q.C.:
Q. Yeah, I'll need a page number for this one. I think it might be page 75. Is there a 75 there?
COMMISSIONER:
Q. Do you want 75 in the top right hand corner?
CROSBIE, Q.C.:
Q. Go down a little further, please. That's the end of it, is it? Maybe it's not page 75, but what I've got written here in my note that I made word for word, I believe, somewhere in that document, we won't take the time to look for it right now, it's a briefing note to Mr Tilley and it says, "It has been determined that positive controls were conducted every day. The results were read and documented daily by a pathologist".
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. The date on that I can't give you because again we can't find the exact reference, but that was earlier in the process, and you agree that this is what should be done?

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DR. COOK:
A. It's my understanding that there was documentation taking place and that understanding came from Mr. Gulliver that there was documentation over there that the controls were being run.
CROSBIE, Q.C.:
Q. That's what he told you?
DR. COOK:
A. That's my understanding, yes.
CROSBIE, Q.C.:
Q. He told you, in fact, that samples were always run with controls?
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Could we have document 02141, please. This is March 2006 note, your note of talking to -- I think she's nicknamed Bibi, is she?
DR. COOK:
A. Bibi Naghibi.
CROSBIE, Q.C.:
Q. And, of course, she's saying there "lack of external controls".
DR. COOK:

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A. Uh-hm.
CROSBIE, Q.C.:
Q. And I think you linked that earlier in your evidence in my questioning to budgetary issues?
DR. COOK:
A. At that time, yes, that was a major issue for not providing controls for each of the cases.
CROSBIE, Q.C.:
Q. Can we go to document 0524. I see there -- I guess that's your note again.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. "Barry admits documentation is bad".
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. What kind of documentation was Barry talking about?
DR. COOK:
A. Well, it would be documentation about -- it could be anything; incubation times, length of incubation times, it could have been documentation regarding concentration, could

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be documentation of controls, who is actually documenting the controls. So there may be a whole wide range of items that could be documented.
CROSBIE, Q.C.:
Q. Maybe it got destroyed in the flood.
DR. COOK:
A. Maybe it did.
CROSBIE, Q.C.:
Q. Maybe Mr. Dyer will tell us more about that.
DR. COOK:
A. I think he's your best man to talk to you about that.
CROSBIE, Q.C.:
Q. Can we go to document 01852, please, page five of that. This is Ms. Predham's answers to interrogatories.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. And just go down -- I think it's paragraph 12 -- or 13. The question is there, "Does the documentation show the controls were working in all documented cases", and Ms Predham's answer is, "Not all pathologists referred to

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the technical and internal controls in their reports. I estimate that 50 percent of all cases -- in 50 percent of all cases the pathologists referred to the technical controls in his or her report".
DR. COOK:
A. Right.
CROSBIE, Q.C.:
Q. Does that square with your own personal observations?
DR. COOK:
A. Pretty much so. When we went through the reports for the panelling process, there was no standardized way in which pathologists were reporting the controls. Some would include the controls in their report; others wouldn't.
CROSBIE, Q.C.:
Q. So if there's a problem tracking down documentation made by the lab staff, as DABBS would seem to have contemplated on a daily basis, you might have trouble reconstructing the control story from the reports of the pathologists, wouldn't you?
DR. COOK:
A. It would be difficult because some

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pathologists would include it in their reports and others wouldn't. So you're hoping that -- my understanding was that controls were being documented and read before any of the cases were sent outside the lab.

CROSBIE, Q.C.:

Q. You testified last Thursday that Dr. Carter told you she personally observed the absence of controls?

DR. COOK:

A. That was -- I found that out around July 21st of '05.

CROSBIE, Q.C.:

Q. Going back to the issue of positivity statistics --

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. Dr. Mullen told the Commissioner that he'd looked for a statistical performance of 79 to 80 percent positivity, and that appears at page 324.

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

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Q. Of June 27th transcript. By the way, do you accept that as a standard?

DR. COOK:

A. No, the range, generally speaking -- again what years are you referring to, Mr Crosbie? I mean, are you talking about positivity ranges from '97 to 2005 or --

CROSBIE, Q.C.:

Q. I think he probably meant in the contemporary period.

DR. COOK:

A. What is the contemporary period?

CROSBIE, Q.C.:

Q. The last few years.

DR. COOK:

A. What is the last few years?

CROSBIE, Q.C.:

Q. Say from 2005 to now.

DR. COOK:

A. 2005 to now? After 2005 to now?

CROSBIE, Q.C.:

Q. Yes.

DR. COOK:

A. Possibly, yes, it depends on the lab. So I would say around 75 percent would be the

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average.

CROSBIE, Q.C.:

Q. Doctor, that book that you relied on when you gave advice to Dr. Williams, the Vice President of Medical Services, that positivity range between 50 percent and 85 percent, that's a medical student textbook, isn't it?

DR. COOK:

A. It's used by both undergraduates and postgraduates and practising pathologists throughout Canada and the United States.

CROSBIE, Q.C.:

Q. When you're giving advice to the Vice President of Medical Services on a very disturbing matter that may affect the patient care for hundreds of people and carries medical legal consequences, and you're a fellowship trained specialist in pathology, would you -- why wouldn't you look at the most contemporary literature when you're stating statistics like that?

DR. COOK:

A. The most contemporary literature may only provide you information in the last year or so. So we looked at 2005, you look at 2004

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and '03, and you would find positivity rates of 70 to 80 percent. The thing is we went back to '97. So what are positivity rates in North America for the period from '97 to 2005. I was unable to find that going back to '97. There's very little information on positivity rates that were '97, '98, and '99.

CROSBIE, Q.C.:

Q. I believe there's an article in the database here from NEQUAS, the NEQUAS group, the same group that your institution is enrolled with now for external proficiency review, and they go back over a series of 7000 patients plus.

DR. COOK:

A. But how far back do they go back?

CROSBIE, Q.C.:

Q. They're talking about the late 90s. Now I'm not going to stop here and look for that because at this rate, I may have a chance to do so overnight. It may take me a moment to find it, but I put it to you, sir, that there is literature that state those statistics for the late 90s, and it's something we can come back to.

DR. COOK:

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A. Uh-hm.
CROSBIE, Q.C.:
Q. Now Dr. Gown is an expert you recommended to insurance company, correct?
DR. COOK:
A. That's correct.
CROSBIE, Q.C.:
Q. He gave us -- well, he gave an affidavit in court, document 0375.
DR. COOK:
A. Okay.
CROSBIE, Q.C.:
Q. Page two, please, paragraph 6. At paragraph 6, he's saying he reviewed data indicating a positivity rate for your institution in the range of 65 to 75 percent.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. With a seven year average of 74 percent.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. So if your standard, as you mentioned a moment ago, is 75 percent, that's not too bad.

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DR. COOK:
A. Well, you got to be careful in interpreting that. You know, that doesn't mean anything by itself.
CROSBIE, Q.C.:
Q. Yes, and, in fact, as Dr. Mullen said to me when I asked him about positivity rates, he said you live or die by the patient in front of you; for that patient, it's 100 percent?
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. And I said I take your point. However, we do use these statistical measures as being helpful, don't we?
DR. COOK:
A. To a certain extent, Mr. Crosbie. To me, positivity rates mean very little now after looking into the situation.
CROSBIE, Q.C.:
Q. So those rates, a range of 65 to 75 percent, they could be defended as average performance for a community hospital, couldn't they?
DR. COOK:
A. Could be, but there's a lot more to it than

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just looking at positivity rates. I mean, as I said earlier, I mean, you could have a large percentage of your cases are lower expressers down in the range of 1 to 2 or 3 percent, and they would be regarded as positive. The question is where is your cut off point, and how -- what does the oncologist regard as positive or negative. So you could have well over 75 or 80 percent of your cases being low expressers because your test didn't work. So you're looking good on data, but in actual fact you've got a vast majority of your cases being classified as negative, depending on where the cut off point is.
CROSBIE, Q.C.:
Q. Yes, and we've discussed that at some length.
DR. COOK:
A. So that's why I don't pay too much attention to positivity rates.
CROSBIE, Q.C.:
Q. Well, there's one point, though, I want to make before we move on. I said it wouldn't look too bad for a community hospital, except that your institution is not a community hospital.

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DR. COOK:
A. We were nothing more than a glorified community lab, Mr. Crosbie, when you look at the resources we had, the financial sources. Even though we were classed as a university tertiary care centre, in reality we're nothing more than a community lab.
CROSBIE, Q.C.:
Q. Explain that please.
DR. COOK:
A. Glorified community lab. We didn't have the - we had a high turnover of pathologists, we didn't have the degree of sub-specialization that you would like to have. There was again budgetary restraints, you know, and we just didn't have a stable situation in that lab.
CROSBIE, Q.C.:
Q. So you're describing a situation for a university affiliated, medical school affiliated --
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. School of Pharmacy, School of Nursing affiliated.

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DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Laboratory in the Health Sciences Complex.
DR. COOK:
A. And you look at what we actually had in that lab in terms of resources, and compare that to comparable resources across Canada.
CROSBIE, Q.C.:
Q. So you're saying all that was a sham?
DR. COOK:
A. No, I'm saying in reality -- it is part of a university network. In reality, we're nothing more than very much a glorified community hospital lab in terms of resources, staffing, stability in the organization.
CROSBIE, Q.C.:
Q. Sir, it goes back to my question earlier, should your institution have offered this test?
DR. COOK:
A. It had--well obviously the clinical chief of the day decided that it needed to be brought in, as well as the site chief of the General Hospital, they felt it was necessary to bring

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it in.
CROSBIE, Q.C.:
Q. In your opinion, should it have been offered?
DR. COOK:
A. In my opinion? Well, I was depending on the clinical chief and the site chief who was an academic university individual. I saw it as a way of enhancing our test menu. At that time I agreed with bringing it in and supported it.
CROSBIE, Q.C.:
Q. In retrospect, was it adequately resourced and adequately thought through?
DR. COOK:
A. Well, you could look at every aspect of what we do in the lab and decide if it's adequately resourced and thought through. At the time the decision was made that it was beneficial to bring it in.
CROSBIE, Q.C.:
Q. Okay, we'll look at that a bit more intently.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Can I have document P-1852, page 2, please, paragraph 3? Sir, you can see there a

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question is being answered, this is Mr. Predham's answer to interrogatories again.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. And how many ER/PR tests were done on a year to year basis stating total number of tests and total number of negatives for each year? And if you go down through the information, you'll see that she supplied the answer to that question.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Now if we go to document P-1841 please? This is a table which the footnote notes or in the bottom there was prepared by Dr. Hutton; however, it's simply a reproducing of information and numbers provided already to us by Ms. Predham in her answer, her sworn answer, with an arithmatic calculation of the rate in percentage terms, for example in the third column over, so you get percentage of positive or the positivity rate in the third column.

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DR. COOK:
A. Positivity rate now based on what cut off, Mr. Crosbie?
CROSBIE, Q.C.:
Q. It's based on the information given to us by Ms. Predham, so I assume she used the -
DR. COOK:
A. I mean, I'd like to know what the cut off rates are.
CROSBIE, Q.C.:
Q. Yes. Well if you wish, we can go back and look at her answer.
DR. COOK:
A. We probably need to do that.
CROSBIE, Q.C.:
Q. Can we do that, please, Registrar? That's document P-1852, page 2? Take your time and read it. So in the answer she does manifest awareness of when the cut off point changed, 30 percent, then 10?
DR. COOK:
A. That's what she says.
CROSBIE, Q.C.:
Q. Do you need to read further into the affidavit, sir?

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DR. COOK:
A. No, that's fine.
CROSBIE, Q.C.:
Q. What do you take from that?
DR. COOK:
A. Well when we had improved positivity rates, improved rates in 2003, 2004 years, in terms of the negatives being reduced.
CROSBIE, Q.C.:
Q. Can we now go back to P-1841 then?
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. So before the Ejeckam intervention, you can see in the third column from the left, that's the end of 2002, the rate of positivity was 58 percent, according to this calculation.
DR. COOK:
A. You mean from May 31st, '97 onwards? 58 percent, that's from May '97 to 2002?
CROSBIE, Q.C.:
Q. Through to the end of 2002.
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:

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Q. 58 percent.
DR. COOK:
A. Okay, so what are your weak negatives or weak positives, I should say?
CROSBIE, Q.C.:
Q. I'm sorry, but I'm asking the questions here and I'd ask you to go to the Ejeckam Committee Intervention and you'll see in the third column 78 percent. So after Dr. Ejeckam intervened, he got the positivity rate up very smartly to 78 percent
DR. COOK:
A. Right.
CROSBIE, Q.C.:
Q. However, if you look at grand totals for the period of DAKO use, either a kit of autostainer, it was down around 63 percent and you can see that even with the up tick after the Ejeckam intervention. I put it to you sir, we looked at the Gown affidavit just a minute ago.
DR. COOK:
A. Right.
CROSBIE, Q.C.:
Q. The information sworn to the Court by the

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insurance expert that you found for the insurance company is not correct, is it?
DR. COOK:
A. Well that was information that was provided by Mr. Gulliver, Mr. Crosbie, I mean, I relied on Mr. Gulliver to provide the correct stats.
CROSBIE, Q.C.:
Q. I see, Mr. Gulliver. So you believed the information to be true, did you?
DR. COOK:
A. Well I believed it was, that it was information that was supplied by him, he was the one who went into the Meditec system and retrieved that information, so I was relying on him?
CROSBIE, Q.C.:
Q. And at the time of Dr. Gown's swearing of his affidavit, which was, well it was last year -
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Did you have reason to believe that those statistics were valid or invalid?
DR. COOK:
A. You mean Mr. Gulliver's positivity rates?

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CROSBIE, Q.C.:
Q. The statistics that we're inferring are reflected in Dr. Gown's affidavit where he speaks about positivity rates.
DR. COOK:
A. I can only infer that the information supplied by me from Mr. Gulliver was correct.
CROSBIE, Q.C.:
Q. Do you accept Mr. Gulliver's statistics today?
DR. COOK:
A. With the exception of the last year where it was reported in '04, '05 that we had a positivity rate of 89 percent and that, I found out later, was subsequently reduced to 82 percent.
CROSBIE, Q.C.:
Q. So that's the only flaw in Mr. Gulliver's statistics that you're aware of?
DR. COOK:
A. That's the only flaw that's come to my attention that I'm aware of.
CROSBIE, Q.C.:
Q. Even today, that's the case?
DR. COOK:
A. Even today when I look at those positivity

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rates and I mean, I'm not--I don't have his latest spreadsheet on the positivity rates, that would be given to the clinical chief of the day.

CROSBIE, Q.C.:

Q. I won't take you to it, but there's a handwritten note "get Alan Gown" and it dates from August 1st, 2005. How did you know Mr. Gown or Dr. Gown?

DR. COOK:

A. Well I met Dr. Gown around September of 2000, I believe or 2001 at a conference talking about HER2/neu, which is an immunoperoxidase test, so I first heard of him at that particular time and he was quite knowledgeable in standardization of IHC across North America, so I thought--and he was director of labs, pheno labs in Seattle, Washington, so he came to mind when I was asked to provide a name to the insurer.

CROSBIE, Q.C.:

Q. And he is a very well credentialed expert indeed, isn't he?

DR. COOK:

A. He is.

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CROSBIE, Q.C.:

Q. Can we go to document P-2011? So this is from Heather Predham to you, February 23, 2006, it speaks of a meeting in a little board room by Dr. Williams' office and it's asking about confirming the presence of Barry Dyer or Terry Gulliver and Dr. Cook.

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. It's a Monday, February 27, 2006 on which the meeting is to be held.

DR. COOK:

A. That's correct.

CROSBIE, Q.C.:

Q. Do you remember that meeting?

MR. SIMMONS:

Q. Excuse me, Commissioner, I'd like to mention at this point that we know that Dr. Gown was an expert who came in the civil action, Mr. Crosbie is familiar and I just caution at this point that although he has an affidavit filed in that action, that we want to be very careful about how far we go getting into any discussions Dr. Cook or other people had with

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Dr. Gown concerning the terms of his retainer in that class action, just a caution for -

THE COMMISSIONER:

Q. I think, Mr. Crosbie, that your friend here is raising the obvious issue of solicitor/client privilege as sort of shot across your bow in case of whatever you want to ask, but we'll deal with it when the question gets asked Mr. Simmons.

MR. SIMMONS:

Q. Thank you, Commissioner.

CROSBIE, Q.C.:

Q. Not unexpected. Can you tell us who was there at the meeting?

DR. COOK:

A. I think Dr. Ejeckam was there, Mr. Gulliver was there, I was there, Mr. Dan Boon, Alan Gown, Heather Predham, I think--I'm not sure, that's about all I can recollect who was at that meeting.

CROSBIE, Q.C.:

Q. Who provided to Dr. Gown the statistics that we saw reflected in his affidavit?

MR. SIMMONS:

Q. Excuse me, Commissioner, I think if we're

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dealing with a meeting that legal counsel involved in a matter that Mr. Crosbie's (inaudible), I think we're in a situation where that meeting was obviously for the purpose of dealing with that matter and anything taking place in it, should be privileged with -

THE COMMISSIONER:

Q. Is this a meeting with--well the subject is Dr. Gown's visit -

MR. SIMMONS:

Q. Dr. Cook has just said that Mr. Boone was there.

THE COMMISSIONER:

Q. So you're saying that the presence of Mr. Boone, in and of itself, makes this a solicitor/client situation?

MR. SIMMONS:

Q. The only involvement that Dr. Gown had in the matter has been in relation to his retainer by the insurer and in the action, so I can't see how there would have been anything taken place there that wouldn't be privileged.

CROSBIE, Q.C.:

Q. The broad issue or one of them that you are

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seized with investigating, one of them is communications, broad umbrella. Dr. Gown certainly communicated with a judge of one of the courts in this jurisdiction and I'm saying or I'll be proving, I believe, that he provided false and misleading information, particularly false and misleading statistics to a court. I'm just seeking to figure out where this came from?

THE COMMISSIONER:

Q. But isn't that the question of whether or not the statistics are false and misleading is, I think, a question for the court, is it not?

CROSBIE, Q.C.:

Q. We just discussed in some detail a question of statistics that this gentleman professes to-- the relevance, positivity rates have relevance to quality assurance, quality control.

THE COMMISSIONER:

Q. Uh-hm.

CROSBIE, Q.C.:

Q. Not everyone seems to endorse them as, you know, of biblical importance, but they seem to have some utility and I'm simply trying to find out who gave him the statistics that

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found their way into the affidavit. I didn't know that it would be worth all this heavy weather.

THE COMMISSIONER:

Q. Uh-hm. My understanding is that it's highly unlikely that Dr. Gown would be a witness in this inquiry and therefore, that his particular statistic would be one of the I'm sure many statistics which I would have to consider, so I have some difficulty with why the statistics used by Gown in particular are in the context of this inquiry so very important, but if you want to proceed on those lines, I'm certainly prepared to hear from all counsel on the issue and make a ruling for you.

CROSBIE, Q.C.:

Q. Well it's not worth half an hour of argument because we're going to see all kinds of statistical spreadsheets when Mr. Gulliver gets here and it's not going to be too hard to figure it out and I suppose if I'm allowed to ask him, he'll confirm that it was he who gave Dr. Gown the information. So we can pass on from that, Dr. Cook, so that we don't have to

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spend more time on that issue.

THE COMMISSIONER:

Q. All right then.

CROSBIE, Q.C.:

Q. Can we go to document P-1754? And can you bring this down a little bit where it says "note" actually a little bit further up, "Nash", no "Nash". So this is a meeting on June 30th, 2006, you're there, Dr. Cook, a number of other pathologists, Re: Implementation of ER/PR testing and Nash is, no doubt, Dr. Denic, "gave overview of immunohistochemistry, Dr. Gown, Dr. Banerjee, Trish Wegrynowski". And then underneath that, "consultants, middle of pack in North American practice".

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. Did Dr. Banerjee inform your group that you were middle of the pack in North American practice?

DR. COOK:

A. Well he informed me when I was doing the review of the slides at the multi-headed scope

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in September of '05 and then he made that reference at an exit meeting with myself and Dr. Williams and I believe Heather Predham at that particular time.

CROSBIE, Q.C.:

Q. Because I sure don't get that from his report?

DR. COOK:

A. That was what was in the verbal conversation with me and in the exit interview.

CROSBIE, Q.C.:

Q. To me, middle of the pack doesn't sound like Ms. Wegrynowski either?

DR. COOK:

A. Well that didn't come from Ms. Wegrynowski, that came from Dr. Banerjee and that was at the exit interview and in the discussions I had with him at the multi-headed scope.

CROSBIE, Q.C.:

Q. Sir, you see opposite Ford, and that's Dr. Ford Elms?

DR. COOK:

A. That's right.

CROSBIE, Q.C.:

Q. "Can't afford to be average, must be comparable" and I suppose he means comparable

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to Mount Sinai.

DR. COOK:

A. That was where we were hoping to go.

CROSBIE, Q.C.:

Q. And Dr. Ford was right, wasn't he?

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. You can't afford to be average.

DR. COOK:

A. No, we got to try to be the best that we can.

CROSBIE, Q.C.:

Q. Can we go to P-0110, page 3, please? This is Mr. Tilley's news conference, May 18th, 2007, page 3. There's a paragraph there starts, "George Tilley"--thank you, Registrar. If you count down there about one, two, three, four, five, six lines, I'm going to start reading, "We also sought the input of technologists, a technologist and a physician more independent of the organization to come and give us an objective assessment as to what we do and how we do it." That sounds like Dr. Banerjee and Ms. Wegrynowski.

DR. COOK:

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A. Well I never--it was more Dr. Banerjee.

CROSBIE, Q.C.:

Q. He does mention technologist.

DR. COOK:

A. Yes, but I was thinking more Dr. Banerjee.

CROSBIE, Q.C.:

Q. Anyway, to give an objective assessment. "I recall that the comments of the physician were that he considered us to be in the middle of the pack."

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. "In terms of laboratory services with regards to ER/PR." By the way, did Dr. Banerjee meet with Mr. Tilley?

DR. COOK:

A. No.

CROSBIE, Q.C.:

Q. Where would he get that expression "middle of the pack"?

DR. COOK:

A. He would have got it, I would say from myself or possibly Dr. Williams.

CROSBIE, Q.C.:

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Q. He goes on, "And to be quite frank with you, we're not satisfied with being in the middle of the pack. We're interested in becoming amongst the top laboratories for this procedure in the country."

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. Having said that, the individuals who are not able to point to a technique, a person, a discipline that had done anything that would suggest that errors would occur, is that Banerjee?

DR. COOK:

A. I don't know who said that?

CROSBIE, Q.C.:

Q. It doesn't sound like Banerjee, does it?

DR. COOK:

A. I don't know who said that, Mr. Crosbie.

CROSBIE, Q.C.:

Q. Do you know if Mr. Tilley met with Dr. Gown?

DR. COOK:

A. Not that I'm aware of, no.

CROSBIE, Q.C.:

Q. Mr. Tilley had the reports of Wegrynowski and

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Banerjee.

DR. COOK:

A. Uh-hm.

CROSBIE, Q.C.:

Q. And he says that these individuals, it appears this is what he's saying, are not able to point to anything that would suggest errors would occur. If that refers to Wegrynowski and Banerjee, we know they pointed to plenty of things that would suggest errors would occur, don't we?

DR. COOK:

A. Well that's Mr. Tilley's interpretation of their reports.

CROSBIE, Q.C.:

Q. I see and also the interpretation that he offered to the public at the press conference.

DR. COOK:

A. I mean, I would assume, I mean, I never saw this release.

CROSBIE, Q.C.:

Q. You didn't hear how it was covered at the time?

DR. COOK:

A. Not in specific detail as what's here.

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CROSBIE, Q.C.:
Q. So you don't have any view on whether Mr. Tilley was misleading the public with that statement?
DR. COOK:
A. Oh I can't say that he was.
CROSBIE, Q.C.:
Q. Thank you. Disclosure policies, sir, you're aware that the hospital has policies on disclosure?
DR. COOK:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Did you review the hospital disclosure policies at the time of the Ejeckam intervention in 2003?
DR. COOK:
A. I believe I did in conjunction with Dr. Williams and a number of other physicians that we made, we did some discussion around that.
CROSBIE, Q.C.:
Q. Did you look at the document?
DR. COOK:
A. I can't remember for sure, Mr. Crosbie, if I did or not.

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CROSBIE, Q.C.:
Q. It would stand out in your memory if you actually got it out and read it, wouldn't it?
DR. COOK:
A. I would assume so.
CROSBIE, Q.C.:
Q. So probably you didn't get it out and read it in 2003.
DR. COOK:
A. No, I was leaving the disclosure aspect, again, to our VP Medical Services.
CROSBIE, Q.C.:
Q. So again, you probably didn't read it?
DR. COOK:
A. Probably.
THE COMMISSIONER:
Q. We're talking now 2003, not 2005?
CROSBIE, Q.C.:
Q. 2003.
THE COMMISSIONER:
Q. All right.
CROSBIE, Q.C.:
Q. Which is my next question, did you review the disclosure policies in 2005?
DR. COOK:

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A. I would have had discussions with that around Dr. Williams. I can't remember specifically sitting down and reviewing the disclosure policies, that's not where my mind was in 2005.
CROSBIE, Q.C.:
Q. Probably you didn't do that, sit down and review the policies.
DR. COOK:
A. Probably not at that particular time.
CROSBIE, Q.C.:
Q. Are you aware of anyone who did review disclosure policies and who stated the result of that review in your presence?
DR. COOK:
A. I'm not aware in my presence, no.
CROSBIE, Q.C.:
Q. But you were leaving that up to Dr. Williams, were you?
DR. COOK:
A. That was Dr. Williams and again our quality initiatives people.
CROSBIE, Q.C.:
Q. Sir, let's have a look at document P-0056? There is a date of 1997-10-01, as far as I can

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tell, sir, this policy would be the one that governed occurrences in 2003?
DR. COOK:
A. Mr. Crosbie, I can't say for sure.
CROSBIE, Q.C.:
Q. At page one, it requires, if we go down a little bit further, procedure I think we're interested in. Yes, page two, please. Just going to try and find my unmarked copy of that. Page 18. Can I go back to page one, please?
THE COMMISSIONER:
Q. Part of this is consumer feedback, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Yes, I've got my copy marked as 0056.
THE COMMISSIONER:
Q. Is it another--this is one of 20. Is it another document in that?
CROSBIE, Q.C.:
Q. They're probably entered as--do they have a lot of page numbers, this exhibit?
REGISTRAR:
Q. 20 pages.
THE COMMISSIONER:

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Q. There are 20 pages.
CROSBIE, Q.C.:
Q. The one I'm looking at is dated 22/10/97. It doesn't seem to be this one.
THE COMMISSIONER:
Q. Okay.
CROSBIE, Q.C.:
Q. Perhaps you can -
THE COMMISSIONER:
Q. Well, there should be another one at page eight.
CROSBIE, Q.C.:
Q. Go to page eight, maybe.
THE COMMISSIONER:
Q. And this document is one of four.
CROSBIE, Q.C.:
Q. That's not the one I'm looking at either. That's it.
THE COMMISSIONER:
Q. Occurrence reporting?
CROSBIE, Q.C.:
Q. It's the one at page 12, page 12.
THE COMMISSIONER:
Q. All right.
CROSBIE, Q.C.:

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Q. So, Doctor, again, I'd propose that this is the document that would have governed in 2003 and we can see under policy there, occurrence is discussed, "must be investigated and reported using corporate occurrence report forms. It's a component of the quality plan. An occurrence is defined as any event," a little bit further down under definitions, Madam Registrar, "any event, accident, error or circumstance which is not in keeping with expected process or outcome of care or service. Occurrences may result in an injury, damage, etcetera." So it's a pretty broad definition, isn't it?
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. And it required occurrences to be investigated and reported on an occurrence report form. In 2003, testing in the lab was suspended for five or six weeks for unreliable, erratic and unhelpful stains.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:

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Q. Unhelpful, according to Dr. Ejeckam, for diagnostic purposes.
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. And he warned of medical legal consequences if adequate personnel and resources were not devoted to the problems that he described. Is that correct?
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. Now you can't say to the Commission that you relied on Dr. Williams to decide issues of disclosure on this occasion, can you?
DR. COOK:
A. Not on this occasion.
CROSBIE, Q.C.:
Q. Because you didn't tell Dr. Williams about what had happened.
DR. COOK:
A. No, because we looked at this as an internal laboratory issue.
CROSBIE, Q.C.:
Q. Would you go to--that was page 12, then page

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13, 14, 15 please? I got that wrong. 12, 13, 14, 15. Yes, okay. It's--actually, it must be the previous page then. Item four, please, under program department management. Yes, four. It says "report significant occurrences immediately to the applicable vice president."
DR. COOK:
A. Um-hm.
CROSBIE, Q.C.:
Q. So your description of this as an internal matter, that removes it from anything that could be described as an occurrence, does it?
DR. COOK:
A. Well, we looked at it as a quality assurance activity that Dr. Ejeckam was improving the crispness and clarity of the stains. That's how we looked at it.
CROSBIE, Q.C.:
Q. So it wasn't an occurrence?
DR. COOK:
A. We didn't regard it as an occurrence.
CROSBIE, Q.C.:
Q. And you had no duty, according to policy, to report this to the vice president?
DR. COOK:

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A. Because I didn't see there, right there that we had a patient care issue.

CROSBIE, Q.C.:

Q. Despite the warning from Dr. Ejeckam about possible litigation?

DR. COOK:

A. That was on down the road. He was looking forward. If we begin--if we didn't implement certain things that that's a possibility on down the road.

CROSBIE, Q.C.:

Q. So your position is that the failure to report this suspension to Dr. Williams is not a breach of the policy?

DR. COOK:

A. No, we just merely looked at it as a further quality assurance activity into improve the quality of the stains.

CROSBIE, Q.C.:

Q. Medical ethics, Dr. Cook, is a recognized area of specialized knowledge?

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. You sought an ethics consult in May 2006?

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DR. COOK:

A. Um-hm. Well, Dr. Williams did.

CROSBIE, Q.C.:

Q. It was initiated by you writing to Dr. Williams?

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. And you thought it was a good idea to have the consult?

DR. COOK:

A. I did.

CROSBIE, Q.C.:

Q. It was on the issue of disclosure of retesting results to deceased patients.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. And disclosure is primarily an ethical matter?

DR. COOK:

A. Yes.

CROSBIE, Q.C.:

Q. The consult was valuable?

DR. COOK:

A. I'd say it was.

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CROSBIE, Q.C.:

Q. You even attended the consult, didn't you?

DR. COOK:

A. Yes, I did.

CROSBIE, Q.C.:

Q. And an opinion was stated by Mr. Rick Singleton, who's the Director of Pastoral Care and Medical Ethics?

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. Did you give any consideration to obtaining an ethics consult when the crisis first arose in 2005?

DR. COOK:

A. Not me personally, no.

CROSBIE, Q.C.:

Q. In retrospect, was that a mistake?

DR. COOK:

A. No. We have many -

CROSBIE, Q.C.:

Q. You're quite satisfied that you didn't--that it was not -

MR. BROWNE:

Q. Commissioner, I think -

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CROSBIE, Q.C.:

Q. - wise to seek a consult from an ethics expert?

MR. BROWNE:

Q. Commissioner, in fairness, Mr. Crosbie, I think Dr. Cook was attempting to answer the question before he was interrupted and I would ask, Commissioner, that he be able to answer the question.

THE COMMISSIONER:

Q. Dr. Cook -

CROSBIE, Q.C.:

Q. I'm all ears.

THE COMMISSIONER:

Q. Dr. Cook did say he did not consider--he said no to the question, but were you about to add a reason, Dr. Cook?

DR. COOK:

A. Commissioner, what I wanted to say was, I mean, at that particular time, my focus was in the lab. The focus was starting the review process, getting that in place. In terms of an ethics consult, I mean, I felt that that's something that again could have been in the hands of the Vice President of Medical

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Services and Quality Initiatives people. I was simply busy performing the duties and tasks in the laboratory.

CROSBIE, Q.C.:

Q. By May 2006, you had time to attend what looks like a committee meeting to discuss ethics.

DR. COOK:

A. I was asked to by Dr. Williams.

CROSBIE, Q.C.:

Q. All in aid of sorting out how to close off patient charts, I believe?

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. Of deceased patients.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. So your evidence is that an ethics consult in relation to disclosure issues would not have been of benefit to you or the institution in 2005?

DR. COOK:

A. My issue is, Mr. Crosbie, I had a number of deceased patients in the system and I wanted

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direction on what to do with them.

CROSBIE, Q.C.:

Q. That's not the question I asked, is it?

DR. COOK:

A. Repeat the question again.

CROSBIE, Q.C.:

Q. My question was: an ethics consult in 2005 would not have been a benefit to you or the institution?

DR. COOK:

A. I can't say that for sure.

CROSBIE, Q.C.:

Q. What is your opinion then?

DR. COOK:

A. My opinion is, Mr. Crosbie, I had a lot of other things on my mind at that particular time. If there was an ethics consult that was required, that was something that should have been considered by our quality initiatives people and the Vice President of Medical Services.

CROSBIE, Q.C.:

Q. So with all the other things you had on your mind, the issue of the ethics of disclosure was not uppermost?

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DR. COOK:

A. No, my primary focus was what's going on in the lab, collecting information, trying to collect as much information as I could.

CROSBIE, Q.C.:

Q. There was a lawyer present at the consult.

DR. COOK:

A. Um-hm.

CROSBIE, Q.C.:

Q. Do you know who that lawyer worked for?

DR. COOK:

A. That was Mr. Dan Boone. He worked for HIROC.

CROSBIE, Q.C.:

Q. Did it occur to you that advice from a lawyer who didn't work for HIROC, but who worked for Eastern Health might be in order?

DR. COOK:

A. Possibly. I didn't think about it much at the time.

THE COMMISSIONER:

Q. Mr. Crosbie, whenever you can find a convenient -

CROSBIE, Q.C.:

Q. Yes, I'm about to dwell on the ethics consult, but this is another sheath of questions, so we

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can stop here.

THE COMMISSIONER:

Q. All right then. We'll break for the day and meet again at 9:30 in the morning. Thank you all.

UPON CONCLUSION.

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 7th day of July, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 7th day of July, A.D., 2008

Judy Moss

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