

COMMISSION OF INQUIRY  
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 7, 2008

Appearances:

- Bernard Coffey, Q.C. . . . . . Commission Co-counsel
- Sandra Chaytor, Q.C. . . . . . Commission Co-counsel
- Rolf Pritchard/Jackie Brazil . . . . Her Majesty in Right of NL
- Peter Browne/Jane Hennebury . . . . . Doctors Kara Laing et al
- Daniel Simmons . . . . . Eastern Regional Integrated  
. . . . . Health Authority
- 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

1 THE COMMISSIONER:  
 2 Q. Please be seated. Mr. Coffey.  
 3 DR. DONALD COOK, EXAMINATION BY BERNARD COFFEY, Q.C.  
 4 (CONT'D)  
 5 COFFEY, Q.C.:  
 6 Q. If we could, please, Registrar, Exhibit P-  
 7 1290? And I believe this is a letter that,  
 8 Dr. Cook, you wrote September 26th, 2005 to  
 9 Dr. Williams. It's concerning the issue of  
 10 the timing of mastectomy breast biopsy  
 11 operations, and you had noted here "I would  
 12 strongly recommend that all mastectomies,  
 13 needle localizations and lumpectomies should  
 14 be booked first thing in the morning in the OR  
 15 from Monday to Friday," and you had written  
 16 here, "spoke to Shirley, divisional manager,  
 17 regarding possibility of scheduling breast  
 18 cancer earlier mornings. Shirley states many  
 19 issues regarding rescheduling of breast,  
 20 follow-up to my August memo." Doctor, I did  
 21 refer you to this last week, but one thing I  
 22 wanted to follow up with you on is this, how  
 23 has that, from your perspective, finally  
 24 played itself out, you know, at the General  
 25 Hospital and St. Clare's, in terms of

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Certificate

1 scheduling of operations?  
 2 DR. COOK:  
 3 A. Well, I think they did everything they could  
 4 to reschedule the breast surgery. They were  
 5 done first things in the morning. In this  
 6 particular case, on Friday afternoons, I  
 7 noticed that the surgeon was operating earlier  
 8 in the afternoon, say 2 or 3:00. Now that may  
 9 not always be the case in all time periods,  
 10 but if that was so, then if there was a breast  
 11 that was performed late in the afternoon and  
 12 it went over hours, then the pathologist on  
 13 call would come in and handle the specimen,  
 14 and that's what--I wanted that continuity  
 15 played out.  
 16 COFFEY, Q.C.:  
 17 Q. So that's the way, as things stand now, as we  
 18 are here this morning, the arrangement in  
 19 Eastern Health is that if breast surgery does  
 20 occur at other than first thing in the  
 21 morning, if it occurs at odd hours, outside  
 22 the regularly scheduled times -  
 23 DR. COOK:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. - there are arrangements in place to have a  
 2 pathologist -  
 3 DR. COOK:  
 4 A. Arrangements--we do have pathologists on call  
 5 24 hours a day. They are to be called in and  
 6 then to handle the case.  
 7 COFFEY, Q.C.:  
 8 Q. If we could, please, Exhibit P-0647, please?  
 9 Now Doctor, this is an e-mail of October 17th,  
 10 2005. I shouldn't say so much an e-mail. I  
 11 take it it's from an information system. The  
 12 subject is ER/PR testing. I take it it's  
 13 concerning a meeting scheduled for October  
 14 17th, 2005 and required attendees are listed  
 15 as yourself, Ms. Predham, Nancy Parsons, Susan  
 16 Bonnell, Robert Williams or Dr. Williams, Dr.  
 17 Laing, and Chris -  
 18 DR. COOK:  
 19 A. I can't pick out that name.  
 20 COFFEY, Q.C.:  
 21 Q. Okay, and a C. Power. Who is C. Power? Do  
 22 you know that, Doctor? Anyhow, if you don't,  
 23 that's fine. It says--but here, is this your  
 24 handwriting?  
 25 DR. COOK:

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1 A. Yes.  
 2 COFFEY, Q.C.:  
 3 Q. Okay, it says "one, start media campaign"  
 4 DR. COOK:  
 5 A. Yeah.  
 6 COFFEY, Q.C.:  
 7 Q. "Two, information for public."  
 8 DR. COOK:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. Doctor, what was this about?  
 12 DR. COOK:  
 13 A. I guess it was a strategy to decide how to go  
 14 public, who would be involved as the point  
 15 person, to represent the corporation, I  
 16 understand, in dealing with the media.  
 17 COFFEY, Q.C.:  
 18 Q. Now Doctor, the subject matter of ER/PR had  
 19 gone public on October 2nd, which is about  
 20 just over two weeks before October 17th.  
 21 DR. COOK:  
 22 A. Um-hm.  
 23 COFFEY, Q.C.:  
 24 Q. I understand that at this point in time,  
 25 around the 17th, there was, in fact, a media--

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1 actual, a media campaign, in the sense of  
 2 advertisements and so on being thought about  
 3 and ultimately purchased, advertising space in  
 4 newspapers throughout Newfoundland.  
 5 DR. COOK:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. So what I wanted to ask you about was this,  
 9 your involvement or why you were involved in  
 10 this aspect of the matter at all?  
 11 DR. COOK:  
 12 A. Well, I guess they were asking me to provide  
 13 what sort of background information we had  
 14 with the ER/PR issue and to provide them with  
 15 up-to-date information of what was going on so  
 16 far. My major focus, which Dr. Williams  
 17 wanted me to do, was to remain confined to the  
 18 lab, to focus on the review that was taking  
 19 place and to provide him with any necessary  
 20 information on request.  
 21 COFFEY, Q.C.:  
 22 Q. Okay, so that was--you weren't there to decide  
 23 whether or not there should be a media  
 24 campaign or not, what its format should be or  
 25 not, but to provide technical information?

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1 DR. COOK:  
 2 A. Yes, to provide what information I could or  
 3 what I knew at the time to that process.  
 4 COFFEY, Q.C.:  
 5 Q. The Exhibit P-1314, and Doctor, this is a  
 6 letter of October 24th, 2005 from yourself to  
 7 Dr. Banerjee thanking him for the receipt of  
 8 his report of October 17th, and you note here  
 9 "your report will be shared will the  
 10 leadership team of the Laboratory Medicine  
 11 program, as well as the Vice President of  
 12 Quality Diagnostic and Medical Services." So  
 13 that would be, in effect, the leadership team  
 14 of the Laboratory Medicine program was  
 15 yourself, Terry Gulliver and Bob Williams?  
 16 DR. COOK:  
 17 A. That's correct.  
 18 COFFEY, Q.C.:  
 19 Q. You've indicated last week in your testimony  
 20 that at one point you had read, you think  
 21 probably in November of 2005, you read the  
 22 full contents of Dr. Banerjee's report to a  
 23 group of pathologists?  
 24 DR. COOK:  
 25 A. That's correct.

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<p>1 COFFEY, Q.C.:</p> <p>2 Q. And you had gotten permission from Dr.</p> <p>3 Williams to do that?</p> <p>4 DR. COOK:</p> <p>5 A. Um-hm.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. What was the understanding with respect to</p> <p>8 whether or not copies of the report could be</p> <p>9 given out?</p> <p>10 DR. COOK:</p> <p>11 A. Oh, I didn't have the authority to give out</p> <p>12 copies of the report. There were only four</p> <p>13 copies issued, I believe. One went to myself,</p> <p>14 Mr. Gulliver, Dr. Williams and Heather</p> <p>15 Predham.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. And I take it, it was understood between the</p> <p>18 four of you that it was otherwise copies were</p> <p>19 not to be distributed?</p> <p>20 DR. COOK:</p> <p>21 A. That's correct, that's the instructions that I</p> <p>22 had.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. Do you recall who they were from?</p> <p>25 DR. COOK:</p>	<p>1 COFFEY, Q.C.:</p> <p>2 Q. And from your--and it was his decision? How</p> <p>3 this was to be handled, from your perspective,</p> <p>4 was Bob Williams' decision?</p> <p>5 DR. COOK:</p> <p>6 A. That was basically his decision.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. Okay. Exhibit P-1313, please? Doctor, this</p> <p>9 is a letter of October 24th, 2005, the same</p> <p>10 date, to Dr. Banerjee again.</p> <p>11 DR. COOK:</p> <p>12 A. Um-hm.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. And it's re: national standards for</p> <p>15 immunohistochemistry testing. You write "I</p> <p>16 have been asked by the President/CEO," which</p> <p>17 would be Mr. Tilley, "and Vice President of</p> <p>18 Medical Services," that would be Bob Williams,</p> <p>19 "as to whether the issue of</p> <p>20 immunohistochemistry testing could be brought</p> <p>21 forward to the Canadian Association of</p> <p>22 Pathologists. I think the whole issue of</p> <p>23 national standards for laboratories across</p> <p>24 Canada could be spearheaded by the Canadian</p> <p>25 Association of Pathologists and brought</p>
<p>Page 10</p> <p>1 A. Dr. Williams.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. At the time you asked Dr. Williams--I take it</p> <p>4 you asked him if you could read out the</p> <p>5 contents of the report to the pathologists?</p> <p>6 DR. COOK:</p> <p>7 A. That's correct.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. And he responded "yes"</p> <p>10 DR. COOK:</p> <p>11 A. Yes.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. But not give them copies?</p> <p>14 DR. COOK:</p> <p>15 A. Yes.</p> <p>16 COFFEY, Q.C.:</p> <p>17 Q. What was the rationale?</p> <p>18 DR. COOK:</p> <p>19 A. Well, I guess the rationale, where this is--</p> <p>20 this was regarded as a peer review from Dr.</p> <p>21 Williams' perspective, that the information</p> <p>22 was protected under legislation, so that was</p> <p>23 his reasons for not producing copies of those</p> <p>24 reports. To the best of my knowledge, those</p> <p>25 are the main two reasons.</p>	<p>Page 12</p> <p>1 forward to the Federal Minister of Health. I</p> <p>2 wonder if we could put this on the agenda for</p> <p>3 our next face-to-face meeting of the executive</p> <p>4 in late November?" and you've copied it to Dr.</p> <p>5 Williams, this letter?</p> <p>6 DR. COOK:</p> <p>7 A. Um-hm.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. Doctor, you refer here "our next face-to-face</p> <p>10 meeting of the executive in late November."</p> <p>11 DR. COOK:</p> <p>12 A. That's correct. The executive of the Canadian</p> <p>13 Association of Pathologists, that's correct.</p> <p>14 COFFEY, Q.C.:</p> <p>15 Q. And were you a member of the executive at the</p> <p>16 time?</p> <p>17 DR. COOK:</p> <p>18 A. I am and was.</p> <p>19 COFFEY, Q.C.:</p> <p>20 Q. And this face-to-face meeting occurred where?</p> <p>21 DR. COOK:</p> <p>22 A. This occurred in Ottawa.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. And was this added to the agenda?</p> <p>25 DR. COOK:</p>

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

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1 concern, not only what was happening in St.  
 2 John's, but expressed concern what was  
 3 happening across the country. I referred to  
 4 my survey, the fact that we had contacted  
 5 different labs throughout the country. There  
 6 was no apparent standardization on how the  
 7 test was done. Hospitals were using different  
 8 platforms with different interpretations.  
 9 There were different positivity rates. So I  
 10 expressed concern that this could be a major  
 11 issue for labs and pathologists across Canada.  
 12 Now the issue that I had also brought up  
 13 was not necessarily what was happening today,  
 14 because some of the members pointed out that,  
 15 you know, in terms of what was happening  
 16 today, it may not be an issue, but I said "the  
 17 issue that many of you have to consider is  
 18 what were you doing six-seven years ago," and  
 19 I said "that may very well become an issue,  
 20 and it's an issue that we're going to have to  
 21 address." Now in the meantime, I said "I  
 22 think we should try to collaborate with other  
 23 organizations, such as the Canadian  
 24 Association of Medical Oncologists, Radiation  
 25 Oncologists, the Canadian Cancer Strategy

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

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

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1 sounds intuitively good that one would have  
 2 national standards, it seems to me that there  
 3 are so many little bits and pieces along the  
 4 way in this subject that it would be a very  
 5 difficult thing to get consensus on.  
 6 DR. COOK:  
 7 A. Commissioner, I think you're right. I don't--  
 8 now, we've only just started the national  
 9 standards committee for immunohistochemistry,  
 10 which I'm on, and we've only had one or two  
 11 meetings. So we haven't really got into the  
 12 roots of the issue as yet, but the way that I  
 13 see it is benchmarks or outcomes, how are labs  
 14 doing with comparing results? I mean, there  
 15 is no way, I don't think, you can say that we  
 16 can dictate to a lab what piece of equipment  
 17 you're going to buy, what antibody you are  
 18 going to use. I think the most important  
 19 thing is what's the end result, what's the  
 20 product that that lab is doing and you compare  
 21 it to other labs and compare those labs to a  
 22 central source. I don't see us getting to the  
 23 point where we can say here is a particular  
 24 piece of equipment that you can buy.  
 25 But now, that being said, I think you

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1 have to try to develop standards in terms of  
 2 external proficiency testing programs, making  
 3 sure that labs have their own internal quality  
 4 assurance programs, that various procedures  
 5 are being documented, that various procedures  
 6 are being carried out through, and that they  
 7 are being audited.  
 8 THE COMMISSIONER:  
 9 Q. Okay.  
 10 DR. COOK:  
 11 A. The other issue that I look at is eventually  
 12 getting into an area where labs are mandated  
 13 to be part of a national standards program and  
 14 be able to identify labs that are deficient.  
 15 Now that deficiency could be in terms of  
 16 documentation, specific personnel in specific  
 17 areas or what their outcomes are.  
 18 Now the next issue is do you have the  
 19 power to close down that particular lab, and  
 20 that's another issue that I think we have to  
 21 look at, and whether that becomes a national  
 22 responsibility or a provincial responsibility.  
 23 I'd like to see it on a national basis because  
 24 I'd like to see labs from coast to coast  
 25 follow the same national standards and

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1 protocol. Now it's quite easy to close a lab,  
 2 but what I'd like to see coming out of this  
 3 particular committee that we have in place is  
 4 a response team. If you identify a lab that  
 5 has deficiencies, instead of closing it down,  
 6 you bring in a group of experts to identify  
 7 where those deficiencies are, help that lab  
 8 correct those deficiencies and keep them  
 9 running. We can't afford to lose any more  
 10 labs in this country. So that's personally --  
 11 now I haven't really had a chance to discuss  
 12 this at the committee level meeting, but that  
 13 personally, this is where I'd like to see the  
 14 National Standards Committee go.  
 15 COMMISSIONER:  
 16 Q. I take it from information which I've received  
 17 from other sources that, in fact, there are  
 18 very few national standards currently  
 19 operating in your world, is that correct?  
 20 DR. COOK:  
 21 A. That's correct. I mean, we have no standards,  
 22 national standards, on how a pathologist grows  
 23 a specimen, how many sections that pathologist  
 24 would take, how many deeper levels on a  
 25 particular block that pathologist would take.

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1 So there are lots of areas where -- there's  
 2 lots of work to be done where I think we have  
 3 to get down and try to bring in some  
 4 uniformity to the system. The more we can  
 5 standardize, the more we can produce.  
 6 COMMISSIONER:  
 7 Q. Well, it's almost like a "catch 22", because  
 8 if you're trying to compare what's coming out  
 9 of different labs, and the kinds of things  
 10 you're now describing are not standardized,  
 11 then one begins to question whether or not  
 12 they're comparable, in any event.  
 13 DR. COOK:  
 14 A. Well, I think the end product, you've got to  
 15 work on whether that end product is  
 16 comparable, and then route back -- go back and  
 17 see why that end product is not comparable.  
 18 It's a difficult process and it's going to be  
 19 a very time consuming process and it's not  
 20 going to happen overnight.  
 21 COMMISSIONER:  
 22 Q. Has this kind of thing been done on a large  
 23 scale in other countries?  
 24 DR. COOK:  
 25 A. Probably -- it's beginning to now. I think

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1 the Americans are looking very closely at  
 2 national standards in immunohistochemistry.  
 3 They're looking at their proficiency testing  
 4 and revamping their proficiency testing. The  
 5 United Kingdom, I think, is certainly well  
 6 ahead of us in terms of developing national  
 7 standards for their programs, and they've had  
 8 major issues five to six years ago. I don't  
 9 know if it's similar to ours, but they've had  
 10 major issues which spearheaded their effort to  
 11 bring in national standards for how labs  
 12 operate, and how they document and how they  
 13 produce results, and a standardization of the  
 14 results that are being produced. Does that  
 15 answer your question?  
 16 COMMISSIONER:  
 17 Q. It does. Thank you very much.  
 18 COFFEY, Q.C.:  
 19 Q. Exhibit P-0371, please. Doctor, just to  
 20 follow your e-mail through, this is Dr.  
 21 Banerjee's reply and e-mail of October 24th,  
 22 2005, to yourself, and it's stating, "I guess  
 23 this is an important topic that needs  
 24 discussion. We should add it to the agenda  
 25 along with the national standards of practice

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1 topic", which you've just referred to then in  
 2 responding to a question from the  
 3 Commissioner. The idea then of -- and it's  
 4 capitalized here, "National Standards of  
 5 Practice", topic. So the topic of national  
 6 standards of practice was, I take it, in the  
 7 fall of 2005 just getting onto the agenda?  
 8 DR. COOK:  
 9 A. Yes.  
 10 COFFEY, Q.C.:  
 11 Q. Is that also being pursued?  
 12 DR. COOK:  
 13 A. It is, not to the same extent as we are into  
 14 the immunohistochemistry. You got to  
 15 remember, Mr. Coffey, that the Canadian  
 16 Association of Pathologists is a very small  
 17 organization, and -- now we have the expertise  
 18 in Canada, I think, to develop these  
 19 standards. The issue is funding, and, you  
 20 know, where is that funding going to come  
 21 from. I think we have to go after the Federal  
 22 Government for that.  
 23 COFFEY, Q.C.:  
 24 Q. Exhibit P-01322, please. Doctor, this is a  
 25 letter of Canadian Association of Pathologists

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1 letterhead to yourself from Dr. Banerjee,  
 2 copied to Dr. Bob Williams. I take it this is  
 3 formally advising you that the topic, national  
 4 standards for immunohistochemical testing, was  
 5 added to the CAP Executive agenda in November?  
 6 DR. COOK:  
 7 A. That's correct.  
 8 COFFEY, Q.C.:  
 9 Q. Exhibit P-01318, please. Doctor, this is an  
 10 e-mail -- well, actually, two e-mails. The  
 11 one -- the first at the bottom of the page,  
 12 the bottom of the exhibit here, is October  
 13 25th, 2005, from yourself to Dr. Mullen,  
 14 status of ER/PR review, "Hi Bren, I'm  
 15 wondering how's it going with the review and  
 16 when we can expect some more results. I can  
 17 appreciate that Mount Sinai is probably at  
 18 capacity levels. Could you update me". I  
 19 take it this is your handwriting, Doctor?  
 20 DR. COOK:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. Also e-mail sent from Mr George Tilley to CEO  
 24 of Mount Sinai, and lab director of Mount  
 25 Sinai, October 19th to the 21st, 2005. I take

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1 it, Doctor, that by the end of October your e-  
 2 mail to Dr. Mullen and your reference to these  
 3 other e-mails here that you understood had  
 4 been sent, were -- I'll phrase it as a gentle  
 5 pressure on Mount Sinai to try to get the  
 6 results of the retesting as soon as possible?  
 7 DR. COOK:  
 8 A. Yeah, we knew that Mount Sinai was under  
 9 pressure, and I did know they were handling a  
 10 lot of their own cases. In speaking to Dr.  
 11 Pritzker at times, I knew they were under a  
 12 lot of pressure, but they were doing the best  
 13 that they could.  
 14 COFFEY, Q.C.:  
 15 Q. If we could, please, Exhibit P-0337. Doctor,  
 16 this is a report of a laboratory medicine  
 17 program to the clinical chiefs and (audio cuts  
 18 out) for September/October, 2005. Doctor, the  
 19 reference to September/October, 2005, does  
 20 that mean that this was a report for that  
 21 period?  
 22 DR. COOK:  
 23 A. What it means, that the same report that you  
 24 see there goes to both clinical chiefs and  
 25 then to medical advisory. So the clinical

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1 chiefs meeting would have been held in  
 2 September, the medical advisory would have  
 3 been held in October of '05.  
 4 COFFEY, Q.C.:  
 5 Q. Okay, and -- so this report then would have  
 6 been given -- submitted to the clinical chiefs  
 7 meeting in September and the MAC meeting in  
 8 October?  
 9 DR. COOK:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. The second page of this, paragraph five is  
 13 quality initiatives. It's written, "There's  
 14 currently a review of our ER and PR. This  
 15 review involves all negative ER cases from  
 16 May, '97 to August 9, 2005", and then there's  
 17 an outline summary of the history up to a  
 18 certain extent, and you go on to say then,  
 19 "This high conversion rate also raises  
 20 questions about the Ventana System, especially  
 21 regarding its sensitivity. As a result, all  
 22 negative samples since 1997 will be sent to an  
 23 external laboratory for retesting", and you  
 24 talk about the hold on reporting of ER and PR  
 25 by all pathologists locally and the fact that

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1 all current requests for those tests are being  
 2 forwarded to Mount Sinai, and you conclude by  
 3 saying, "I will keep you updated on this  
 4 matter".  
 5 DR. COOK:  
 6 A. Uh-hm.  
 7 COFFEY, Q.C.:  
 8 Q. Doctor, when you reported to the MAC -- well,  
 9 first of all, the clinical chiefs in  
 10 September, and then the MAC in October, were  
 11 the physicians in both those groups when you  
 12 actually submitted this report, were they  
 13 actually already aware of this issue, do you  
 14 recall?  
 15 DR. COOK:  
 16 A. I can't say how many were aware or were not  
 17 aware, Mr. Coffey.  
 18 COFFEY, Q.C.:  
 19 Q. Okay. Do you recall what if any response,  
 20 questions, or reactions you got from the  
 21 clinical chiefs group in September and then  
 22 the MAC group in October?  
 23 DR. COOK:  
 24 A. The only comment that I got -- I remember one  
 25 comment is that we follow standard of care,

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1 and that was a comment that I had tried to  
 2 explain, and what I was saying to them, that's  
 3 a difficult question, there are no standards  
 4 in Canada. We were looking at our positivity  
 5 rates of about 73 to 74 percent, which was the  
 6 information that I had at that time, and we  
 7 seemed to be comparable to the other labs, but  
 8 I said, you know, positivity rates are one  
 9 thing. You've got to look at where the  
 10 different cut off levels were over those  
 11 years. I mean, you could look fine with  
 12 positivity rates of 73/74 percent, but those  
 13 may pick up all your various low expressers  
 14 and what not. So it became a question or do  
 15 you look at clinical cut-offs, or you look at  
 16 technical cut-offs. So what I said to them  
 17 it's not as simple as that, and all I can say  
 18 was there was no standards in Canada, and I  
 19 said I really didn't know where we stood in  
 20 regards to standard of care and where other  
 21 labs in Canada stood to standards of care.  
 22 COFFEY, Q.C.:  
 23 Q. The reference to standard of care, that phrase  
 24 in that context means what?  
 25 DR. COOK:

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1 A. Were we providing a similar standard to a  
 2 similar size hospital in Canada. That was my  
 3 take on that.  
 4 COFFEY, Q.C.:  
 5 Q. Do you recall who you raised the issue with?  
 6 DR. COOK:  
 7 A. I think it was one of the clinical chiefs from  
 8 the emergency room. I just can't remember his  
 9 name right now offhand.  
 10 COFFEY, Q.C.:  
 11 Q. And, Doctor, and subsequently while you were  
 12 main clinical chief, you would occasionally  
 13 then report to the MA clinical chiefs group  
 14 and MAC?  
 15 DR. COOK:  
 16 A. Yes.  
 17 COFFEY, Q.C.:  
 18 Q. Afterward about this. How much was this topic  
 19 discussed in those two groups afterward?  
 20 DR. COOK:  
 21 A. It was brought up, I believe, at every meeting  
 22 subsequent to that.  
 23 COFFEY, Q.C.:  
 24 Q. And discussed to what extent?  
 25 DR. COOK:

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1 A. Well, when I got into the complexities of the  
 2 test and describing the 40 to 50 step process,  
 3 I was basically describing the amount of  
 4 variability with the test, the issues that we  
 5 had with the large human factor, both at the  
 6 technical aspect and at the interpretive  
 7 aspect, and I think once I got into the fact  
 8 that this test was complicated, I think there  
 9 was a general understanding amongst the  
 10 clinical chiefs that this was not  
 11 straightforward. It was not like any other  
 12 test where you can do a blood test, put it  
 13 into another analyzer and get a result. So  
 14 there seemed to be a general understanding, in  
 15 my opinion, that once I mentioned to some  
 16 individuals the fact that this was a 40 to 50  
 17 step process, that this was a very complicated  
 18 procedure and prone to a lot of variability.  
 19 COFFEY, Q.C.:  
 20 Q. I take it when they understood that, the  
 21 questions then kind of trail off?  
 22 DR. COOK:  
 23 A. I would say to a certain extent, yes.  
 24 COFFEY, Q.C.:  
 25 Q. Exhibit P-0673, please. Doctor, this is an e-

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1 mail from yourself to Dr. Williams, November  
 2 1st, 2005. You write, "Hi Bob, these are rough  
 3 figures based on what I've just received from  
 4 Mount Sinai. 169 cases reported, 559 cases  
 5 left to report, of which 219 blocks are cut  
 6 and 26 cases are stained. These are  
 7 approximately figures. It looks like it's  
 8 going to take some time before all cases are  
 9 reported. Regards, Don". I take it, Doctor,  
 10 as of November 1st, 2005, you had reached the  
 11 conclusion that it was going to be at least  
 12 some period of time before the results were  
 13 back?  
 14 DR. COOK:  
 15 A. That's correct.  
 16 COFFEY, Q.C.:  
 17 Q. Exhibit P-01323, please. Doctor, this is an  
 18 exhibit which I understand is a distribution  
 19 list for the November 9, 2005, report of Trish  
 20 Wegrynowski, four copies provides, one of four  
 21 to Mr. Gulliver.  
 22 DR. COOK:  
 23 A. Uh-hm.  
 24 COFFEY, Q.C.:  
 25 Q. Two of four to yourself, three or four to

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1 Heather Predham/Pam Elliott, and four of four  
 2 to Dr. Williams. So -- and I've asked you  
 3 already about Dr. Banerjee's report and the  
 4 limited distribution of that.  
 5 DR. COOK:  
 6 A. Uh-hm.  
 7 COFFEY, Q.C.:  
 8 Q. I take it was it the same approach then to Ms  
 9 Wegrynowski's report?  
 10 DR. COOK:  
 11 A. Yes.  
 12 COFFEY, Q.C.:  
 13 Q. When you received Ms. Wegrynowski's report and  
 14 you described your reaction last week in your  
 15 testimony last week, did you ever disclose the  
 16 contents of that to the pathologist?  
 17 DR. COOK:  
 18 A. No, I didn't, and the reason for that was  
 19 mainly under Mr. Gulliver. Mr. Gulliver was  
 20 overseeing the technical aspect of the  
 21 laboratory medicine program, and that report,  
 22 certainly from the direction I received from  
 23 Dr. Williams, the impression I received from  
 24 Dr. Williams, it was up to Mr. Gulliver to  
 25 distribute to the technologists.

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1 COFFEY, Q.C.:  
 2 Q. Exhibit P-097, please. Doctor, this is two e-  
 3 mails. The one at the bottom of the page is  
 4 from Moira Hennessey, November 3rd, 2005, to  
 5 Dr. Williams, and none of these e-mails is  
 6 from or to you, but the topic here in Ms.  
 7 Hennessey's e-mail to Dr. Williams is -- she  
 8 asked about contacting the patients, and then  
 9 she continues, "Have you received the report  
 10 from the BC pathologist and the Mount Sinai  
 11 technologist. If yes, what is the general  
 12 finding or findings". Doctor, did Dr.  
 13 Williams ever discuss with you the topic or  
 14 issue as to whether or not copies of Dr.  
 15 Banerjee's or Trish Wegrynowski's report  
 16 should be distributed, for example, to the  
 17 Department of Health?  
 18 DR. COOK:  
 19 A. I can't remember per se whether he actually  
 20 said to me that these are not going to the  
 21 Department of Health. My general impression  
 22 of it was that this was regarded as a peer  
 23 review at the time and it was to remain  
 24 confined within Eastern Health or Health Care  
 25 Corporation of St. John's.



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1 COFFEY, Q.C.:

2 Q. Did anyone ever discuss with you your views or

3 expressed to you any views as to whether or

4 not these reports should be distributed

5 outside the original four or five people who

6 got them?

7 DR. COOK:

8 A. No, I can't recall anyone having -

9 COFFEY, Q.C.:

10 Q. I'm not suggesting they did, I'm just asking

11 you.

12 DR. COOK:

13 A. No, just can't recall, Mr. Coffey.

14 COFFEY, Q.C.:

15 Q. Thank you. So if that discussion occurred, it

16 occurred at a level higher in the hierarchy

17 than yourself?

18 DR. COOK:

19 A. That's correct.

20 COFFEY, Q.C.:

21 Q. Exhibit P-0681 please? Now, Doctor, here

22 there's an e-mail from yourself, November

23 15th, 2005, to Nancy Good at Mount Sinai, it's

24 regarding ER and PR stains, slides. You write

25 "Hi, Nancy, as far as I'm aware, staining of

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1 ER/PR slides will stay at Mount Sinai to be

2 read and interpreted by Mount Sinai

3 pathologists. Regards, Don Cook." And then

4 you've got some handwritten notes here, I

5 gather.

6 DR. COOK:

7 A. Uh-hm.

8 COFFEY, Q.C.:

9 Q. Follow up with phone call to Nancy, November

10 15th, 2:30 p.m., stated to her to send ER and

11 PR slides back to us once entire review is

12 completed and all interpretations were done.

13 Spoke to George Tilley November 15th, 9:20

14 a.m., both of us concerned about slow pace of

15 Mount Sinai report. George considering to

16 speak to Mount Sinai CEO to see what could be

17 done to speed up the reporting. So these

18 slides that are being discussed in the e-mail,

19 I take it are the ones being prepared by Mount

20 Sinai?

21 DR. COOK:

22 A. That's correct.

23 COFFEY, Q.C.:

24 Q. And you wanted those slides back why?

25 DR. COOK:

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1 A. I would want those slides back?

2 COFFEY, Q.C.:

3 Q. Yes.

4 DR. COOK:

5 A. Oh, after the end of the review?

6 COFFEY, Q.C.:

7 Q. Yes.

8 DR. COOK:

9 A. To have them, use them as a source of

10 information, if times we needed to go back to

11 look at particular cases, we could. But I

12 thought it would be best to have the slides

13 sent back to St. Clare's as part of the

14 patient's record.

15 COFFEY, Q.C.:

16 Q. If I could, please, Exhibit P-0154? Doctor,

17 perhaps if I could, please, P-153 first, to

18 put this in context for Dr. Cook. Now, Doctor

19 Cook, this is an e-mail, November 18th, 2005

20 from Tansy Mundon to Deborah Thomas-Pennell

21 and Susan Bonnell. It's copied to George

22 Tilley, Darrell Hynes and John Abbott. And

23 she says, "Susan, Deborah, further to our

24 briefing yesterday with George and Dr.

25 Williams, I attach the following questions

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1 that the Minister would like answered in

2 advance of the House of Assembly opening on

3 Monday, if at all possible. Many thanks,

4 Tansy." And if we turn to the second page,

5 Doctor, the fifth bullet says "Has a review

6 occurred to determine how this could have

7 happened, how could there be inaccurate tests

8 for a period of five years without being

9 detected? Will there be disciplinary action

10 taken?" And if we could then open, please,

11 Exhibit P-0154 again? This is an e-mail from

12 Ms. Thomas Pennell to Tansy Mundon. Subject

13 is "ER/PR Questions" and she writes, "As

14 requested, Tansy." And we look at, Doctor,

15 pages 2 and 2, are the questions and answers,

16 the answers are in bold print, and the

17 question on page 3 of the exhibit here is "Has

18 a review occurred to determine how this could

19 have happened? How could there be inaccurate

20 tests for a period of five years without being

21 detected? Will there be disciplinary action

22 taken?" And the response here is "This is

23 still an ongoing investigation into the

24 situation; however, there is ample literature

25 to suggest that these tests have limitations

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1 and are not guided by national standards. In  
 2 the meantime, until all the results from  
 3 retesting are obtained, it is impossible to  
 4 determine the exact details of the cause of  
 5 the problem. Three reviews have taken place  
 6 of our current testing procedure, pathology  
 7 services and our technical services.  
 8 Recommendations are being made and are being  
 9 acted upon, which will immediately ensure the  
 10 quality and reproducibility of results." And  
 11 they go on to talk about the reference to  
 12 disciplinary action. Doctor, that question  
 13 that's posed there, "Has a review occurred to  
 14 determine how this could have happened? How  
 15 could there be inaccurate tests for a period  
 16 of five years without being detected?"  
 17 DR. COOK:  
 18 A. Uh-hm.  
 19 COFFEY, Q.C.:  
 20 Q. Were you asked for a response to that  
 21 question?  
 22 DR. COOK:  
 23 A. No.  
 24 COFFEY, Q.C.:  
 25 Q. At any point in this whole matter, had anyone

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1 posed that question to you?  
 2 DR. COOK:  
 3 A. No.  
 4 COFFEY, Q.C.:  
 5 Q. I'm going to pose it to you now, okay. From  
 6 your perspective, now obviously a review had  
 7 occurred, from your perspective, how could  
 8 there have been inaccurate tests for a period  
 9 of five years or more, for that matter,  
 10 without there being detected--that being  
 11 detected?  
 12 DR. COOK:  
 13 A. Yeah, well that's a long question, I think a  
 14 lot of it has to do with quality assurance  
 15 activities, did we have appropriate quality  
 16 assurance activities in relation to ER and PR?  
 17 Now when you look at the quality assurance  
 18 activities that we had, they were pretty broad  
 19 based. I believe they, for the most part,  
 20 represented general list sign-out, which we  
 21 had. I think, I mean, I strongly think that  
 22 if we had been able or would have  
 23 subspecialized around those particular times  
 24 and by subspecialized, had a group of three or  
 25 four individuals solely looking at these

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

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1 COFFEY, Q.C.:  
 2 Q. And, Doctor, if--because you've noted last  
 3 week, I believe, that at least in your review  
 4 of some of the original slides, that there  
 5 were problems you noted with internal  
 6 controls?  
 7 DR. COOK:  
 8 A. That's correct.  
 9 COFFEY, Q.C.:  
 10 Q. If physicians had paid more, well apparent  
 11 attention to internal controls, to use Dr.  
 12 Banerjee's wording, do you think the matter  
 13 might have been picked up earlier?  
 14 DR. COOK:  
 15 A. Possibly, possibly, the thing about it is we  
 16 were only seeing one or two cases a month or  
 17 maybe three cases a month. If you look at the  
 18 large number of other cases we were putting  
 19 through, it would be pretty hard to identify  
 20 trends, but if you've got a subspecialty group  
 21 and you're looking at an entire batch of these  
 22 cases, which we had in our subspecialty group,  
 23 I think you would have picked up any trends  
 24 with or without internal controls much more  
 25 readily.

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1 COFFEY, Q.C.:

2 Q. And in fact, that sort of large--well

3 particularized volume or relatively large

4 volume, you experienced in July of 2005 when

5 you looked at the original slides and -

6 DR. COOK:

7 A. Yes, when I sat down and I guess for the first

8 time, I mean, it was, I don't know, a couple

9 of hundred slides, through that two or three

10 day period, then, you know, a lot of issues

11 came to light which certainly opened my eyes

12 to what I saw there.

13 COFFEY, Q.C.:

14 Q. Exhibit -

15 THE COMMISSIONER:

16 Q. Sorry, Mr. Coffey, I interrupt again, just

17 because it's flowing through my head, you may

18 have been asked about this last week, but I

19 just want to come back to it, the business of

20 internal controls within the ER/PR test -

21 DR. COOK:

22 A. Yes, Commissioner.

23 THE COMMISSIONER:

24 Q. And how unusual is it in IHC to be looking for

25 internal controls?

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1 DR. COOK:

2 A. Well it shouldn't be unusual, I think, you

3 know, when you -

4 THE COMMISSIONER:

5 Q. But I was thinking of it, IHC generally, as

6 opposed to just ER/PR?

7 DR. COOK:

8 A. Oh, it may not be unusual because many times

9 we do have tumours that have no surrounding

10 normal tissue, so you could have, say, an

11 excisional biopsy of a sarcoma and that's all

12 you have is just tumour, nothing else. So you

13 have to rely on your external controls to make

14 sure that the tissue is working. So it is not

15 unusual in many other instances to examine

16 tissue from other systems in which there is no

17 internal control.

18 THE COMMISSIONER:

19 Q. Okay, thank you.

20 COFFEY, Q.C.:

21 Q. Exhibit P-1331? Now, Doctor, this is a letter

22 of November 23rd, 2005, from Trish Wegrynowski

23 from Dr. Williams. He's thinking her for her

24 report and it's copied to yourself and Mr.

25 Gulliver. And he concludes by saying "I'm

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1 sure Mr. Gulliver or Dr. Cook may wish to

2 contact you further to get ongoing advice as

3 we move forward in implementing the

4 recommendations in your report."

5 DR. COOK:

6 A. Uh-hm.

7 COFFEY, Q.C.:

8 Q. With respect to any subsequent contact with

9 Ms. Wegrynowski, did you have any -

10 DR. COOK:

11 A. I think I only had one contact with her

12 regarding some cases some time in October or

13 whatever, but I didn't contact her on a

14 regular basis. My reason for that being that

15 this was mainly had to do with technical

16 issues and this was under the control of the

17 program director.

18 COFFEY, Q.C.:

19 Q. Exhibit P-0909 please? Doctor, this is a

20 letter of the same date, except this one is to

21 yourself, marked "private and confident" to

22 yourself and Mr. Gulliver, and it's from Dr.

23 Williams and he writes "I have had an

24 opportunity to review in detail the reports of

25 Dr. Banerjee and Ms. Wegrynowski with respect

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1 to the IHC services offered by Eastern Health.

2 I wonder if you could prepare a spreadsheet to

3 capture all the recommendations embodied in

4 both of those reports, i.e., this should

5 include all recommendations, even ones such as

6 refrigeration and storage referenced on page 4

7 of Trish Wegrynowski's report. Preparing the

8 spreadsheet and the current status with

9 respect to implementation of these

10 recommendations, you should assume that

11 funding will be provided based upon the

12 document you prepared for me on October 13th,

13 2005. I understand Sharon Lehr is following

14 up with Terry on the financial parameters

15 embodied in that document. Once you have the

16 spreadsheet developed and the current status

17 of our implementation, I would like to meet

18 with you as soon as possible to review where

19 we go from here, especially in dealing with

20 the institution of the IHC services." Now,

21 Doctor, having received this, were you

22 involved in the preparation of a spreadsheet?

23 DR. COOK:

24 A. Most of the preparation of a spreadsheet came

25 from Mr. Gulliver and so I received a copy of

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1 this spreadsheet and would review it.  
 2 COFFEY, Q.C.:  
 3 Q. And do you recall if you added anything to it  
 4 or -  
 5 DR. COOK:  
 6 A. I can't recall for sure.  
 7 COFFEY, Q.C.:  
 8 Q. So I take it the plan at that point was having  
 9 the spreadsheet and then get, as possible,  
 10 each of the recommendations implemented as  
 11 time went on?  
 12 DR. COOK:  
 13 A. Yes, use that as the template.  
 14 COFFEY, Q.C.:  
 15 Q. Template for it. Now this spreadsheet, what  
 16 kind of distribution did that have?  
 17 DR. COOK:  
 18 A. I believe that only went to myself and Mr.  
 19 Gulliver and I'm not sure if Dr. Williams got  
 20 a copy of that, I can't be absolutely sure of  
 21 it.  
 22 COFFEY, Q.C.:  
 23 Q. Exhibit P-1333 please? Why did that have  
 24 limited distribution, the spreadsheet?  
 25 DR. COOK:

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

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1 Q. And I take it LCIS is lobular carcinoma in  
 2 situ?  
 3 DR. COOK:  
 4 A. Correct.  
 5 COFFEY, Q.C.:  
 6 Q. What was this about, your note?  
 7 DR. COOK:  
 8 A. Well this is in regards to the panelling  
 9 process and we don't order ERs and PRs at  
 10 least at St. Clare's or the General Hospital  
 11 on DCIS's or LCIS's, but there was a case I  
 12 remember receiving a call from Nancy Parsons  
 13 of a woman who was diagnosed with ductal  
 14 carcinoma in situ. This woman was quite  
 15 anxious and quite upset and she requested to  
 16 order an ER and PR on a case of DCIS. So I  
 17 thought it would be in the best interests to  
 18 order that test, considering the emotional  
 19 state of the lady and the fact that we were  
 20 trying to help people in any which way we can,  
 21 so I went ahead and ordered the ER and PR on  
 22 the DCIS.  
 23 COFFEY, Q.C.:  
 24 Q. But I take it in the main they were not being  
 25 -

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1 DR. COOK:  
 2 A. No, but I mean, if I, you know, got wind of  
 3 somebody who was really upset who I thought  
 4 it, you know, provided a sort of comfort  
 5 factor, that if I could order that test, I  
 6 would order it.  
 7 COFFEY, Q.C.:  
 8 Q. Okay. Exhibit P-0684 please? Now here,  
 9 Doctor, there's an e-mail of November 24th,  
 10 2005 from Heather Predham to Dr. Williams, but  
 11 it's copied to yourself and others. And the  
 12 subject is "Update on ER/PR". And after  
 13 referring to that, she says, "Dr. Kwan made a  
 14 suggestion at the last panel that I should  
 15 track those we may have potentially harmed.  
 16 We had agreed to classify patients as being  
 17 converted with or without recommendations, but  
 18 Dr. Kwan and rightly so, felt that it didn't  
 19 accurately reflect those who had been  
 20 impacted. For example, if a person was  
 21 initially diagnosed with breast cancer of the  
 22 left breast and was ER/PR negative and then  
 23 had metastases to the right breast which was  
 24 ER/PR positive, the patient would be then  
 25 treated with Tamoxifen, so when we panelled

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

12 DR. COOK:  
 13 A. Uh-hm.

14 COFFEY, Q.C.:  
 15 Q. Doctor, do you recall what then became of  
 16 this, this idea of keeping track of--tracking  
 17 those who we may potentially harmed?

18 DR. COOK:  
 19 A. We were trying to develop, you know, what I  
 20 was interested in was the number of people,  
 21 the number of patients that required treatment  
 22 recommendations, that was the number that I  
 23 was really interested in. Trying to get an  
 24 idea of how many patients that had converted,  
 25 but more so trying to identify those that

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

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

11 DR. COOK:  
 12 A. I can't say -- I can't say for sure, Mr.  
 13 Coffey.

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

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1 DR. COOK:  
 2 A. Right.

3 COFFEY, Q.C.:  
 4 Q. Do you recall what this was about?

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

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

5 COFFEY, Q.C.:  
 6 Q. And how did the workload eventually get  
 7 handled then?

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

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

15 COFFEY, Q.C.:

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

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1 Services, HSC and St. Clare's. This letter is  
 2 to follow up to your correspondence dated  
 3 November 3rd and our meeting of November 23rd  
 4 regarding anticipated physician resource  
 5 challenges in pathology, more particularly for  
 6 the next nine months. And this reduction of  
 7 25 percent you referred to capacity locally is  
 8 referenced here, and the idea of approaching  
 9 Montreal General is discussed in the bottom  
 10 paragraph.

11 DR. COOK:  
 12 A. That's correct.

13 COFFEY, Q.C.:

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

17 DR. COOK:  
 18 A. Um-hm.

19 COFFEY, Q.C.:

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

24 DR. COOK:  
 25 A. That's correct.

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1 COFFEY, Q.C.:

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

20 So Doctor, here then, I take it, it was  
 21 only at the beginning of December of 2005 that  
 22 what was then thought to be the final group of  
 23 130 to 140 blocks was going from Newfoundland  
 24 to Mount Sinai?

25 DR. COOK:

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1 A. That's what I thought, yeah.

2 COFFEY, Q.C.:

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

5 DR. COOK:  
 6 A. I think they were mainly from the peripheral  
 7 hospitals, yes.

8 COFFEY, Q.C.:

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

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1 So Doctor, the approach here then with  
 2 respect to Dr. Banerjee was anticipated to be  
 3 what?  
 4 DR. COOK:  
 5 A. Well, to come down and review our situation to  
 6 date, to make a recommendation on what we had  
 7 done so far, to review the situation, what we  
 8 had done so far, and also try to work towards  
 9 a consensus opinion. What we were--the big  
 10 problem I was having at that particular time  
 11 is that there were so many different opinions  
 12 on when we should start the system, how to  
 13 start the system.  
 14 COFFEY, Q.C.:  
 15 Q. Start the system in the sense of ER/PR, I take  
 16 it?  
 17 DR. COOK:  
 18 A. Yes, that's right because we already were  
 19 conducting IHC testing, but there was still a  
 20 lot of differing opinions on what time the  
 21 system should be started. So I was looking  
 22 for Dr. Banerjee to come down and act as an  
 23 objective outside source to look at the  
 24 situation and assess it for us.  
 25 COFFEY, Q.C.:

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1 Q. Now that references potential conference  
 2 calls. Were there such conference calls?  
 3 DR. COOK:  
 4 A. No, we didn't have conference calls. We  
 5 talked about that and I think probably we  
 6 decided that the best route to go would be to  
 7 have him come down and personally look at what  
 8 we were doing.  
 9 COFFEY, Q.C.:  
 10 Q. Exhibit P-0101, please? Doctor, this is a  
 11 letter of December 7th, 2005. It's from Dr.  
 12 Carter. It's copied to yourself, Mr. Gulliver  
 13 and Dr. Ejeckam. It's addressed to Dr.  
 14 Williams and she says--begins by saying, "I  
 15 was most recently asked by Dr. Don Cook to  
 16 comment on the suggestion of Mr. Barry Dyer  
 17 that stated that he felt the Ventana testing  
 18 for ER/PR and HER2/neu could be started at any  
 19 time. I find this comment quite startling in  
 20 the face of the two fairly damning reports  
 21 sent by Dr. Banerjee and Trish Wegrynowski on  
 22 the review of our IHC lab, with special  
 23 emphasis on the predictive factors for breast  
 24 cancer patients." And she goes on at some  
 25 length.

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1 DR. COOK:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. The Commissioner has seen this letter already.  
 5 DR. COOK:  
 6 A. Yes.  
 7 COFFEY, Q.C.:  
 8 Q. I take it, Doctor, that you had asked for Dr.  
 9 Carter's opinion?  
 10 DR. COOK:  
 11 A. I did.  
 12 COFFEY, Q.C.:  
 13 Q. And had you asked that it be expressed to you  
 14 or Dr. Williams or just generally?  
 15 DR. COOK:  
 16 A. I asked for it to be in general. Then she  
 17 replied to me "would you mind if I write a  
 18 letter?" I said "not at all." I thought the  
 19 letter would initially come to me, but the  
 20 letter was forwarded to Dr. Williams.  
 21 COFFEY, Q.C.:  
 22 Q. And what did you think of the contents of the  
 23 letter?  
 24 DR. COOK:  
 25 A. Well, it showed that we still had a long ways

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1 to go in terms of the start up. Personally, I  
 2 didn't see the need to start it up  
 3 immediately. We were sending out our cases  
 4 for ER and PR, our current cases for ER and PR  
 5 and HER2/neu. My feeling at the time was we'd  
 6 start up--should start up the system when we  
 7 have all the recommendations in place. I  
 8 think at that particular time, we still hadn't  
 9 had an opportunity to send our technologists  
 10 out to outside institutions such as Montreal  
 11 or Mount Sinai. So I certainly wanted that to  
 12 be in place, to give them an opportunity to  
 13 see what other institutions were doing, in  
 14 terms of their set up and quality assurance  
 15 protocols and activities and whatnot. So  
 16 those were sort of the things at least were  
 17 going through my mind when that letter came  
 18 out.  
 19 COFFEY, Q.C.:  
 20 Q. Did you subsequently speak with Dr. Carter  
 21 about the contents of her letter?  
 22 DR. COOK:  
 23 A. We've had correspondence, verbal  
 24 correspondence. I thought that basically she  
 25 covered all the points in that particular

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

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1 please let me know."  
 2 Doctor, what was your understanding of  
 3 why, in December 2005, you were being sent a  
 4 copy of the Statement of Claim?  
 5 DR. COOK:  
 6 A. I have no idea.  
 7 COFFEY, Q.C.:  
 8 Q. Okay.  
 9 DR. COOK:  
 10 A. I guess it was because I was clinical chief of  
 11 the program and sent to the leadership team,  
 12 just informing me of, you know, what was  
 13 taking place.  
 14 COFFEY, Q.C.:  
 15 Q. I take it there was no response expected of  
 16 you, that you understood?  
 17 DR. COOK:  
 18 A. I understood, yes.  
 19 COFFEY, Q.C.:  
 20 Q. Exhibit P-0695, please? Doctor, this is an e-  
 21 mail--well, it's a couple of e-mails, but one  
 22 in particular from Dr. Pritzker, December  
 23 20th, 2005 to yourself and he says "Don, as of  
 24 today, everything is tracking towards  
 25 successful completion at end of January 2006.

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1 All the best for the holidays and the new  
 2 year." Signed Ken. You had, on the day  
 3 before, on December 19th, written to Doctor--  
 4 e-mailed Dr. Pritzker saying "Dr. Williams has  
 5 asked me to follow up with you on the status  
 6 of ERs and PRs," and you had understood there  
 7 was a push on this after Christmas with a view  
 8 to completion at the end of January 2006. So  
 9 I take it, Doctor, that just before Christmas,  
 10 2005, it was anticipated that this would be  
 11 concluded, at least in the retesting report  
 12 results by the end of January?  
 13 DR. COOK:  
 14 A. That's what we were hoping, yes.  
 15 COFFEY, Q.C.:  
 16 Q. Exhibit P-0696, please? Doctor, this is a  
 17 note, December 21, 2005, Mr. Tilley, Ms.  
 18 Elliott, Ms. Predham, "slides from  
 19 presentation Dr. Don Cook attended which in  
 20 part dealt with ER/PR issues." Signed Bob.  
 21 And then there's--page two, Molecular  
 22 Diagnostics in Breast Pathology. It's a  
 23 presentation by Dr. Anthony Magliocco, I  
 24 apologize if I mispronounced his name, from  
 25 the University of Calgary, UFT Pathology

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1 Update Course, November 2005.  
 2 DR. COOK:  
 3 A. Um-hm.  
 4 COFFEY, Q.C.:  
 5 Q. So you had attended this?  
 6 DR. COOK:  
 7 A. Yeah, that was the same course that I was  
 8 trying to find various other labs and  
 9 individuals to take our excess specimens.  
 10 COFFEY, Q.C.:  
 11 Q. And when you came back, I take it you had a  
 12 copy of the slide presentation that had been  
 13 given in this regard and distributed it?  
 14 DR. COOK:  
 15 A. That's correct.  
 16 COFFEY, Q.C.:  
 17 Q. If we could, please, Exhibit P, I think it's  
 18 0347? I apologize, 0847. The portion of it I  
 19 have is cut off. Thank you. No, and I  
 20 apologize, Commissioner, I'll just come back  
 21 to that. Exhibit P-1348? Now Doctor, some e-  
 22 mails, I take it by the end of January--by the  
 23 middle of January, January 19th, 2006, you are  
 24 again asking Dr. Pritzker about whether or not  
 25 this matter is going to be concluded by the



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

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

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1 particularly in early January and February of  
 2 2005, which I expressed to him that the  
 3 interest of--I wished to step down possibly  
 4 near the end of June of '05 or certainly at  
 5 the latest by September of '05.  
 6 COFFEY, Q.C.:  
 7 Q. And just--and it turned out then, it was early  
 8 in '06 that -  
 9 DR. COOK:  
 10 A. That's right.  
 11 COFFEY, Q.C.:  
 12 Q. Doctor, here, just looking back at it,  
 13 performance goals and objectives for clinical  
 14 chiefs '04/05 for yourself, "as of December  
 15 2004, one, complete an annual review of all  
 16 pathologists credentialed in the Laboratory  
 17 Medicine program."  
 18 DR. COOK:  
 19 A. Um-hm.  
 20 COFFEY, Q.C.:  
 21 Q. And by April 1, 2005, it indicates this is  
 22 well in hand.  
 23 DR. COOK:  
 24 A. Um-hm.  
 25 COFFEY, Q.C.:

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

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

18 COFFEY, Q.C.:  
 19 Q. In fact, as of April 1, 2005, you have seven  
 20 bullets, seven different initiatives, as it  
 21 were -

22 DR. COOK:  
 23 A. Um-hm.

24 COFFEY, Q.C.:  
 25 Q. - set out there. By October 7th, 2005, in

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

5 DR. COOK:  
 6 A. Um-hm.

7 COFFEY, Q.C.:  
 8 Q. So I take it that that suggests, Doctor, look  
 9 back at the text of number three, that you  
 10 understood, before the beginning of 2005, that  
 11 things should be reduced to writing, they  
 12 should be organized?

13 DR. COOK:  
 14 A. Yeah, there were a lot of things that I was  
 15 certainly unhappy about in the program, that  
 16 we certainly--you know, we needed where to go.  
 17 There had to be a dedicated quality assurance  
 18 program and committee set up, and we were  
 19 doing a lot of quality assurance activities,  
 20 as you see there, but I wanted a coordinated  
 21 approach to a lot of the QA that we were  
 22 doing.

23 COFFEY, Q.C.:  
 24 Q. And then, Doctor, paragraph five is "continue  
 25 to support and work on implementing

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1 recommendations of the Surgical Pathology  
 2 Review Committee."

3 DR. COOK:  
 4 A. Um-hm.

5 COFFEY, Q.C.:  
 6 Q. And as of April 1, you had asked the committee  
 7 to focus on tissue audit.

8 DR. COOK:  
 9 A. Yeah.

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

16 DR. COOK:  
 17 A. Yes.

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

22 DR. COOK:  
 23 A. Yes, but there were also areas there that I  
 24 wasn't too happy about the lab. I mean, I  
 25 found, over the years, that I was responding

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

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

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1 St. Clare's. Enclosed is an introductory  
 2 document which should be read prior to the  
 3 meeting, as well as an agenda for the  
 4 meeting." And this then is a document dated--  
 5 a memo of August 31st, 2004 to yourself from  
 6 Dr. Carter. The subject is quality control  
 7 and quality assurance committee on surgical  
 8 pathology for the Health Care Corporation of  
 9 St. John's. I take it this is the committee  
 10 that you were speaking of?  
 11 DR. COOK:  
 12 A. That's correct.  
 13 COFFEY, Q.C.:  
 14 Q. Okay, and so the idea of setting up the  
 15 committee dated at least to sometime before  
 16 the middle of 2004?  
 17 DR. COOK:  
 18 A. Yeah, I think we talked about it September of  
 19 '04.  
 20 COFFEY, Q.C.:  
 21 Q. What happened with that committee afterward,  
 22 Doctor?  
 23 DR. COOK:  
 24 A. That committee, like many other things that we  
 25 start within Eastern Health or Health Care

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1 Corporation, you start off going great. Then  
 2 trying to sustain various committees becomes a  
 3 major problem. Trying to get individuals to  
 4 attend committees is a major problem.  
 5 Sustainability is a major problem. Again,  
 6 trying to get physicians to attend committees  
 7 is--and when they'd be dealing with heavy  
 8 workloads, it becomes a major issue. So this  
 9 committee, over a period of time, certainly  
 10 did not work out the way that I wanted it to  
 11 work out, mainly because of trying to get  
 12 attendants. Attendance was a problem with, I  
 13 think, Dr. Ejeckam who was dealing with heavy  
 14 workload, so he was saying at that time, and  
 15 particularly with Mr. Barry Dyer, our  
 16 technical manager, who I believe was heavily  
 17 inundated with a lot of service work.  
 18 COFFEY, Q.C.:  
 19 Q. If we could, please, Exhibit P-1711? Now  
 20 Doctor, this is an e-mail from Dr. Mullen,  
 21 January 20th, 2006 to yourself and he says  
 22 "attached please find the ER/PR results for  
 23 the Newfoundland retrospective review" and so  
 24 I take it, in the main then, this was the bulk  
 25 of the retest results?

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1 DR. COOK:  
 2 A. That's correct.  
 3 COFFEY, Q.C.:  
 4 Q. Now Doctor, if we could look, please, at  
 5 Exhibit P-1976? This is a memo to a number  
 6 of, I take it, pathologists throughout  
 7 Newfoundland.  
 8 DR. COOK:  
 9 A. Um-hm.  
 10 COFFEY, Q.C.:  
 11 Q. And the other health authorities, as well as  
 12 St. John's, Dr. Fontaine, and it's from  
 13 yourself as clinical chief, February 1/06,  
 14 ER/PR reports from Mount Sinai. "We have  
 15 received most of the results from Mount Sinai  
 16 regarding the ER/PR review process. The  
 17 results from Mount Sinai were issued on Excel  
 18 spreadsheets. I will be issuing individual  
 19 reports on patients and submitting these to  
 20 you at your respective sites. When you  
 21 receive these reports, please ensure they are  
 22 incorporated in your hospital information or  
 23 laboratory information systems. I expect that  
 24 you will be receiving the first of these  
 25 reports within the next two weeks."

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1 DR. COOK:  
 2 A. Um-hm.  
 3 COFFEY, Q.C.:  
 4 Q. So Doctor, you did what then in relation to  
 5 each of these patients' results from Mount  
 6 Sinai?  
 7 DR. COOK:  
 8 A. Well, when they came in, I would enter them  
 9 into the hospital information system and then  
 10 issue hard copy reports.  
 11 COFFEY, Q.C.:  
 12 Q. So I take it that they would be entered into a  
 13 Meditec chart for the patient in the Eastern  
 14 Health system?  
 15 DR. COOK:  
 16 A. Um-hm.  
 17 COFFEY, Q.C.:  
 18 Q. Even if the patient was from Corner Brook?  
 19 DR. COOK:  
 20 A. Yes. We were trying to establish at least a  
 21 database within the Meditec system.  
 22 COFFEY, Q.C.:  
 23 Q. And then the hard copy of the report, i.e.  
 24 those pages of Meditec, the pathology report  
 25 would be printed off and forwarded -

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1 DR. COOK:  
 2 A. And sent out, yeah.  
 3 COFFEY, Q.C.:  
 4 Q. - to Corner Brook or Grand Falls or wherever?  
 5 DR. COOK:  
 6 A. Um-hm.  
 7 COFFEY, Q.C.:  
 8 Q. Here you've noted "spoke to Gary Baker,  
 9 February 9th, and Paul"--that would be Paul  
 10 Neil, I take it?  
 11 DR. COOK:  
 12 A. Um-hm.  
 13 COFFEY, Q.C.:  
 14 Q. "Wednesday, February 10th, ensuring they got  
 15 my memo. Spoke to Dr. Summers, February 17th  
 16 to ensure they got my memo."  
 17 DR. COOK:  
 18 A. Um-hm.  
 19 COFFEY, Q.C.:  
 20 Q. So I take it, Doctor, that even after sending  
 21 it out, you did follow up to ensure that -  
 22 DR. COOK:  
 23 A. Yeah, was -- there are some key people there  
 24 that I just wanted to make sure the memo was  
 25 getting out, and again any questions that

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

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

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

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1 DR. COOK:  
 2 A. Uh-hm.  
 3 COFFEY, Q.C.:  
 4 Q. Mary, and Montreal Jewish General for Ken, and  
 5 -- so, Doctor, without going through this in  
 6 detail, what was the overall result at this  
 7 point in time vis a vis re-implementation of  
 8 ER/PR?  
 9 DR. COOK:  
 10 A. Well, we were moving towards implementation.  
 11 I think, if I remember correctly, we were  
 12 getting good correlations on the ERS with  
 13 Mount Sinai. There was some problems with the  
 14 PR, still a bit erratic in terms of  
 15 correlating results with Mount Sinai on the  
 16 PR. There was a lot of discussion on the  
 17 image analysis, and this was something that  
 18 Mr. Gulliver was keen on bringing in to have a  
 19 look at, and subsequently that was brought in  
 20 to try to assess whether we can deal with the  
 21 issue of the pathology and interpretation and  
 22 try to provide greater standardization in the  
 23 post analytic aspect of the interpretation to  
 24 the ERS, PRs and HER2/neu's.  
 25 COFFEY, Q.C.:

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

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

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

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1 visit here, I take it you didn't have a lot of  
 2 contact with her?  
 3 DR. COOK:  
 4 A. No.  
 5 COFFEY, Q.C.:  
 6 Q. Exhibit P-01590. Doctor, this is an e-mail --  
 7 I'm sorry, a fax to Heather Predham, March  
 8 7th, 2006, from yourself. The second page of  
 9 the exhibit is a memo from you to Dr. Dan  
 10 Fontaine, Gershon Ejeckam, Terry Gulliver, and  
 11 Barry Dyer, "As clinical chief, implementation  
 12 of immunohistochemical antibodies, and all new  
 13 antibodies that are requested by pathologists  
 14 for immuno service have to be approved by the  
 15 chief pathologist overseeing  
 16 immunohistochemistry. No new antibodies to  
 17 enter the system until they're signed off on  
 18 the protocol formed by the pathologist  
 19 overseeing the immunohistochemistry service".  
 20 DR. COOK:  
 21 A. Uh-hm.  
 22 COFFEY, Q.C.:  
 23 Q. So I take it, Doctor, was this new at this  
 24 point or --  
 25 DR. COOK:

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1 A. Well, more solidification of the role of the  
 2 individual overseeing immunohistochemical  
 3 service, and trying to bring in a role for  
 4 that particular individual, trying to solidify  
 5 that individual with a view of honing up the  
 6 service and bringing in a firm structure.  
 7 COFFEY, Q.C.:  
 8 Q. Exhibit P-02070. Doctor, this is a letter of  
 9 April 4, 2006, from Dr. Paul Neil, Western  
 10 Health Authority, to yourself, and you've  
 11 noted at the top of the page, "Spoke to Paul,  
 12 June 19, 2006", and he writes, "You recently  
 13 gave me a list of patients to follow for ER/PR  
 14 testing from Mount Sinai. Here are some  
 15 problems I encountered".  
 16 DR. COOK:  
 17 A. Uh-hm.  
 18 COFFEY, Q.C.:  
 19 Q. "We reported DCIS on the first patient. We  
 20 reported DCIS on another block".  
 21 DR. COOK:  
 22 A. Uh-hm.  
 23 COFFEY, Q.C.:  
 24 Q. And so on. Doctor, in the first half of 2006,  
 25 how much time and effort did you spend in

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1 relation to this DCIS matter?  
 2 DR. COOK:  
 3 A. A fair bit, Mr. Coffey. There was that, along  
 4 with many other issues that -- to identify  
 5 issues concerning DCIS. So I was fairly busy  
 6 doing other work as well, but trying to spend  
 7 as much time as I can to deal with the issues  
 8 at hand.  
 9 COFFEY, Q.C.:  
 10 Q. Exhibit P-02071. Doctor, this is a redacted  
 11 spreadsheet entitled "breast receptors".  
 12 That's your handwriting I take it, "Cases that  
 13 arrived late January 20th '06 from St.  
 14 Anthony".  
 15 DR. COOK:  
 16 A. That's correct.  
 17 COFFEY, Q.C.:  
 18 Q. "Sent to Mount Sinai Hospital, January 25,  
 19 2006", and there are a number of -- I think  
 20 it's ten cases at least listed here on this  
 21 particular page. So, Doctor, what was the  
 22 situation in relation to that -- the matter of  
 23 St. Anthony from your perspective?  
 24 DR. COOK:  
 25 A. Although they're late getting their blocks in,

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1 I don't think I was too happy because my  
 2 understanding was that all the cases were in.  
 3 I remember having a conversation with Maria  
 4 Mendes saying that as far as I knew all the  
 5 cases were up and thanked her for her help,  
 6 and then we got another batch from St. Anthony  
 7 that came in all of a sudden.  
 8 COFFEY, Q.C.:  
 9 Q. And they were sent back in late January and  
 10 reported in February?  
 11 DR. COOK:  
 12 A. Yes, we got the report sometime the middle of  
 13 February.  
 14 COFFEY, Q.C.:  
 15 Q. Exhibit P-02072, please. Doctor, this is an  
 16 e-mail of April 7, 2006, from yourself to  
 17 Marie Mendes. You say, "Hi, Maria: We are  
 18 rechecking our master list and have come  
 19 across some patients that did not come up on  
 20 the initial computer screen. There may be 15  
 21 to 20 such cases. We are sending up six of  
 22 these within the next few days. These may be  
 23 entered as retro cases and given RS numbers.  
 24 I'm also sending up cases that require another  
 25 block. These are the NT, which would be "no

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1 tumour" cases that could not be reported. We  
 2 will be sending these up over the next week.  
 3 Regards, Dr. Cook". Doctor, what were these  
 4 15 to 20 cases about?  
 5 DR. COOK:  
 6 A. These were new cases that came out of the blue  
 7 which weren't previously captured in the  
 8 initial screening process. So we were  
 9 beginning to find cases that were coming up  
 10 that weren't captured in the original  
 11 spreadsheet.  
 12 COFFEY, Q.C.:  
 13 Q. And these were being identified by whom,  
 14 brought to your attention by whom?  
 15 DR. COOK:  
 16 A. It could have been Mr. Gulliver. I think he  
 17 would be -- also by Heather Predham.  
 18 COFFEY, Q.C.:  
 19 Q. I take it there was reviews somehow going on,  
 20 clerical reviews going on, and cases were  
 21 being identified from time to time that had  
 22 not been -- should have been retested within  
 23 the criteria utilized and hadn't been?  
 24 DR. COOK:  
 25 A. And hadn't been identified. We were

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1 discovering that there were cases that were  
 2 not totally captured.  
 3 COFFEY, Q.C.:  
 4 Q. Exhibit P-02073. Doctor, this is your  
 5 handwritten note.  
 6 DR. COOK:  
 7 A. Uh-hm.  
 8 COFFEY, Q.C.:  
 9 Q. You write, "Spoke to Joy McCarthy, April 10,  
 10 2006. Attended a recent meeting where  
 11 standard practice among oncologists is to  
 12 prescribe with Tamoxifen if ER/PR greater than  
 13 one percent. This goes against NCIC guideline  
 14 where 10 percent is the cut off point. Many  
 15 labs are just reporting as positive or  
 16 negative. If this is the case, we may have to  
 17 change our report as positive or negative and  
 18 not give percentage. We will discuss further.  
 19 Joy claims that oncologists have no real  
 20 evidence to show why they are using greater or  
 21 equal to one percent".  
 22 DR. COOK:  
 23 A. Uh-hm.  
 24 COFFEY, Q.C.:  
 25 Q. Now, Doctor, who was the one who attended the

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1 recent meeting? Was that you or Dr. McCarthy?  
 2 DR. COOK:  
 3 A. That would have been Dr. McCarthy.  
 4 COFFEY, Q.C.:  
 5 Q. So she had contact -- you had contact with  
 6 each other about this issue?  
 7 DR. COOK:  
 8 A. We spoke. I can't remember where exactly we  
 9 spoke about that, but she had concerns about  
 10 what was happening across North America.  
 11 Different oncologists were using different cut  
 12 off points, and there didn't appear to be  
 13 standardization how the receptors were being  
 14 reported.  
 15 COFFEY, Q.C.:  
 16 Q. So did that -- did you, in fact, change your  
 17 approach subsequently or continue on with the  
 18 percentage?  
 19 DR. COOK:  
 20 A. I continued on with the percentage.  
 21 COFFEY, Q.C.:  
 22 Q. Okay. Exhibit P-01369. Now, Doctor, this is  
 23 a letter of May 3, 2006. It's from yourself,  
 24 its copied to Dr. Denic and Ms. Predham. You  
 25 write, "Currently we have documented ER/PR

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1 results from 17 deceased patients on whom we  
 2 have received results from Mount Sinai, and  
 3 are currently on our hospital information  
 4 system. These patients have not signed out  
 5 for release from the system. I would  
 6 appreciate direction on how to proceed further  
 7 with these cases". Doctor, what was this  
 8 about?  
 9 DR. COOK:  
 10 A. Well, we had come up with deceased patients  
 11 and I was wondering what to do with these  
 12 patients. We had not entered them into the  
 13 system, so I was looking for direction from  
 14 Dr. Williams on what to do with them.  
 15 COFFEY, Q.C.:  
 16 Q. Enter them in the sense of, I take it, into  
 17 the Meditec System?  
 18 DR. COOK:  
 19 A. Meditec System.  
 20 COFFEY, Q.C.:  
 21 Q. You had the result from Mount Sinai?  
 22 DR. COOK:  
 23 A. Yeah.  
 24 COFFEY, Q.C.:  
 25 Q. Results, but --

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1 DR. COOK:  
 2 A. They weren't entered.  
 3 COFFEY, Q.C.:  
 4 Q. And you wanted direction?  
 5 DR. COOK:  
 6 A. Yeah.  
 7 COFFEY, Q.C.:  
 8 Q. Now, Doctor, in that regard, I take it that  
 9 led to what, your request?  
 10 DR. COOK:  
 11 A. Well, I assumed it led to that -- Bob then  
 12 asking for an ethics consult.  
 13 COFFEY, Q.C.:  
 14 Q. And did you participate in that?  
 15 DR. COOK:  
 16 A. I did.  
 17 COFFEY, Q.C.:  
 18 Q. What was the nature of your involvement in  
 19 that?  
 20 DR. COOK:  
 21 A. I guess basically to bring forth information  
 22 to the Ethics Committee and to ask -- answer  
 23 any questions they may have.  
 24 COFFEY, Q.C.:  
 25 Q. So you attended the meeting?

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1 DR. COOK:  
 2 A. Yes.  
 3 COFFEY, Q.C.:  
 4 Q. And what -- if I could, please, Exhibit P-  
 5 0783. Now, Doctor, it's an e-mail of June  
 6 22nd from Rick Singleton, who I take it,  
 7 organized the ethics consult to Dr. Williams  
 8 and Louise Jones, and this is his report of  
 9 June 23rd, 2006.  
 10 DR. COOK:  
 11 A. Uh-hm.  
 12 COFFEY, Q.C.:  
 13 Q. Did you ever receive a copy of the report  
 14 itself?  
 15 DR. COOK:  
 16 A. No, I didn't.  
 17 COFFEY, Q.C.:  
 18 Q. He wrote here, "Important facts to the history  
 19 and understanding of this case include the  
 20 following; there were no mistakes or technical  
 21 errors at the route of this problem. It's  
 22 impossible to know in any specific case if the  
 23 outcome for any individual patient would have  
 24 been different. Intervention for post  
 25 menopausal women had positive impact by

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1 lengthening life in 47 percent of patients  
 2 treated. The main ethical issue in this case  
 3 pertains to disclosure", and it goes on from  
 4 there. Now, Doctor, the idea that there were  
 5 no mistakes or technical errors at the route  
 6 of this problem, from your perspective as of  
 7 June, 2006, would you have maintained that  
 8 that was an accurate statement?  
 9 DR. COOK:  
 10 A. I wouldn't have made that statement. I don't  
 11 know where that came from at that meeting.  
 12 COFFEY, Q.C.:  
 13 Q. Certainly your recollection of the meeting was  
 14 you didn't offer that opinion yourself?  
 15 DR. COOK:  
 16 A. No.  
 17 COFFEY, Q.C.:  
 18 Q. And I'm not suggesting you did at all.  
 19 DR. COOK:  
 20 A. No, I don't know where that came from.  
 21 COFFEY, Q.C.:  
 22 Q. Was the cause or causes of the problem  
 23 discussed at the meeting, do you know?  
 24 DR. COOK:  
 25 A. We would have used a word like "system"

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1 describing concerns that we had, how the  
 2 tissue was prepared, how it was tested, how it  
 3 was interpreted. So we were looking in terms  
 4 of discussion at system. This is what the --  
 5 I guess if anything, that would be the terms  
 6 that we were using and probably discussing  
 7 what was going on with the rest of Canada with  
 8 the testing and the United States, and the  
 9 problems with the testing in general.  
 10 COFFEY, Q.C.:  
 11 Q. P-0297, please.  
 12 COMMISSIONER:  
 13 Q. Mr. Coffey (inaudible).  
 14 COFFEY, Q.C.:  
 15 Q. Thank you, Commissioner. These are your  
 16 handwritten notes, Doctor, of June 30th, 2006?  
 17 DR. COOK:  
 18 A. Uh-hm.  
 19 COFFEY, Q.C.:  
 20 Q. And it's notes of a meeting. Present are  
 21 yourself, Morris-Larkin, Dr. Denic, Dr. Elms,  
 22 Mark -- I'm sorry --  
 23 DR. COOK:  
 24 A. Dr. Makarla.  
 25 COFFEY, Q.C.:



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1 Q. I apologize. Dr. Carter, Dr. Williams, and  
 2 other individuals, re; implementation of ER/PR  
 3 testing.  
 4 DR. COOK:  
 5 A. Uh-hm.  
 6 COFFEY, Q.C.:  
 7 Q. I take it that this was a meeting on June 30th  
 8 to discuss what was required to move this  
 9 matter ahead?  
 10 DR. COOK:  
 11 A. Uh-hm.  
 12 COFFEY, Q.C.:  
 13 Q. And they're -- I'm going to suggest here,  
 14 fairly detailed notes by yourself as to what  
 15 was said?  
 16 DR. COOK:  
 17 A. Uh-hm.  
 18 COFFEY, Q.C.:  
 19 Q. Now, Doctor, why I raised this with you is  
 20 this, is that you were no longer -- you're  
 21 site chief, but you're not longer clinical  
 22 chief?  
 23 DR. COOK:  
 24 A. That's right.  
 25 COFFEY, Q.C.:

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1 Q. In what capacity were you at this meeting?  
 2 DR. COOK:  
 3 A. I was capacity -- well, as a site chief, and I  
 4 suppose just acting as a resource person  
 5 providing any background information that  
 6 individuals would need.  
 7 COFFEY, Q.C.:  
 8 Q. Okay. So in terms of authority figure, by  
 9 that point in time who was actually, from the  
 10 perspective of the clinical laboratory program  
 11 pathologists, who was in charge?  
 12 DR. COOK:  
 13 A. Oh, that would be Dr. Denic.  
 14 COFFEY, Q.C.:  
 15 Q. Okay. If we could, please, Commissioner,  
 16 before we break, Exhibit P-02104. Doctor,  
 17 these are your handwritten note of July 14,  
 18 2006.  
 19 DR. COOK:  
 20 A. Uh-hm.  
 21 COFFEY, Q.C.:  
 22 Q. You've noted you spoke to Paul Neil, Dr. Neil.  
 23 DR. COOK:  
 24 A. Uh-hm.  
 25 COFFEY, Q.C.:

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

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1 invasive.  
 2 COFFEY, Q.C.:  
 3 Q. And so why were you still involved at this  
 4 point in time? This is July of '06.  
 5 DR. COOK:  
 6 A. Yeah, I was still involved because Dr. Denic  
 7 asked me, along with Dr. Carter, to still play  
 8 a role in reviewing these cases and not only  
 9 that, we were formulating a breast site group.  
 10 COFFEY, Q.C.:  
 11 Q. Yes.  
 12 DR. COOK:  
 13 A. And as part of that group, there were four of  
 14 us in that group, Dr. Denic asked us to stay,  
 15 keep still involved with the process.  
 16 COFFEY, Q.C.:  
 17 Q. Thank you, Commissioner, break please?  
 18 THE COMMISSIONER:  
 19 Q. Fifteen minutes.  
 20 (RECESS)  
 21 THE COMMISSIONER:  
 22 Q. Please be seated. Mr. Coffey?  
 23 COFFEY, Q.C.:  
 24 Q. Thank you, Commissioner. Some final points,  
 25 Doctor, if we could, Exhibit P-1711? Doctor,

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1 this is that e-mail of January 20th from Dr.  
 2 Mullen to yourself, sending you what was then  
 3 thought to be a spreadsheet, was then thought  
 4 to be the conclusion of the retesting results.  
 5 DR. COOK:  
 6 A. Uh-hm.  
 7 COFFEY, Q.C.:  
 8 Q. Dr. Mullen concluded by saying "When you have  
 9 had an opportunity to review the results, I  
 10 would like to discuss some of the technical  
 11 difficulties we encountered with processing  
 12 and staining of specimens. Some of the same  
 13 issues are present in the current Newfoundland  
 14 and Labrador material."  
 15 DR. COOK:  
 16 A. Uh-hm.  
 17 COFFEY, Q.C.:  
 18 Q. Did you ever discuss that matter, these  
 19 technical difficulties?  
 20 DR. COOK:  
 21 A. Yes, I remember having a brief discussion with  
 22 him.  
 23 COFFEY, Q.C.:  
 24 Q. Do you recall when that was and what was said?  
 25 DR. COOK:

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

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1 I thanked him for his remarks and his effort  
 2 and I indicated I would try to get back to him  
 3 later on.  
 4 COFFEY, Q.C.:  
 5 Q. And what happened with that?  
 6 DR. COOK:  
 7 A. Well I never did get a chance to get back to  
 8 him later on. I remember speaking shortly  
 9 after to Bev Carter and I said, you know, I  
 10 had a conversation with Dr. Mullen and the  
 11 issue of how to deal with the fixation  
 12 problem, particularly outside of St. John's, I  
 13 said it's one thing to issue policies and  
 14 procedures, but how are you going to be able  
 15 to ensure that the policies and procedures are  
 16 actually being carried out and do these  
 17 institutions have the resources to carry that  
 18 out in a standardized fashion. That was the  
 19 big issue that I had.  
 20 COFFEY, Q.C.:  
 21 Q. And where did that go?  
 22 DR. COOK:  
 23 A. That basically didn't go too far. I can't  
 24 remember if I had any other conversations with  
 25 any of the directors outside of St. John's,

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1 but that basically was something that I was  
 2 mulling about. I looked at the fixation  
 3 problem as being primarily centered around the  
 4 need to have pathology assistants, that was  
 5 the only way that I could see that a  
 6 standardized fixative process could be in  
 7 place.  
 8 COFFEY, Q.C.:  
 9 Q. So I take it then you don't have any  
 10 recollection of having taken it up with your  
 11 counterparts in the other health authorities?  
 12 DR. COOK:  
 13 A. I don't, I mean, there may have been a  
 14 discussion back and forth, there were numerous  
 15 phone calls, but there's no, you know, I can't  
 16 say for sure whether I discussed it with my  
 17 other colleagues or not.  
 18 COFFEY, Q.C.:  
 19 Q. Doctor, we--just before the break we were  
 20 speaking about the ethics consult.  
 21 DR. COOK:  
 22 A. Uh-hm.  
 23 COFFEY, Q.C.:  
 24 Q. Doctor, your actual letter of May 3rd, you  
 25 were looking for direction in how to proceed

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1 further with these cases, i.e. with respect  
 2 to, I take it entering the results into  
 3 Meditec.  
 4 DR. COOK:  
 5 A. Uh-hm.  
 6 COFFEY, Q.C.:  
 7 Q. The actual--what was the result of your  
 8 request for direction in that regard?  
 9 DR. COOK:  
 10 A. Well I didn't get any direction from that, I  
 11 spoke to Bob Williams and I said I'm still up  
 12 in the air what to do with these deceased and  
 13 I remember speaking to Bob and there was  
 14 another meeting where I spoke to Heather  
 15 Predham and Nash Denic and said look, I got  
 16 these cases here, they're still not signed off  
 17 in the system. I said I'm going to go ahead  
 18 and sign them off in the system, at least if  
 19 they're in the system, if there are any  
 20 inquires about it.  
 21 COFFEY, Q.C.:  
 22 Q. So is that what you did?  
 23 DR. COOK:  
 24 A. That's what I did, I signed them off in the  
 25 system.

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1 COFFEY, Q.C.:  
 2 Q. So in that context, for the Commissioner, that  
 3 means what, sign off?  
 4 DR. COOK:  
 5 A. They were entered and I gave my signature and  
 6 they were available for anyone who had access  
 7 to the system to get the results.  
 8 COFFEY, Q.C.:  
 9 Q. Thank you, Exhibit P-2089 please? Doctor,  
 10 here these are the minutes for the breast  
 11 cancer site group for guideline development,  
 12 June 8th, 2006.  
 13 DR. COOK:  
 14 A. Uh-hm.  
 15 COFFEY, Q.C.:  
 16 Q. And I'm not going to take you through all the  
 17 material involving this group, but I take it  
 18 that you were involved with this group from  
 19 its initiation from the middle of 2006?  
 20 DR. COOK:  
 21 A. Yes.  
 22 COFFEY, Q.C.:  
 23 Q. And do you continue to be involved with them?  
 24 DR. COOK:  
 25 A. That's correct.

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1 COFFEY, Q.C.:  
 2 Q. And the purpose of this group is what?  
 3 DR. COOK:  
 4 A. The main purpose was trying to get key players  
 5 who were handling breast lesions, to get  
 6 together in one room and start communicating  
 7 and liaisoning with each other. What we found  
 8 out through the ER/PR issue was a lack of  
 9 effective communication and liaison between  
 10 the different groups. So you can see there  
 11 that this is a multi-disciplinary approach,  
 12 we've got individuals from surgery, radiation,  
 13 oncology, medical oncology, diagnostic  
 14 imaging, there was nurses from various  
 15 representatives who were overseeing the care  
 16 of cancer patients, the idea is to get  
 17 together and then formulate policies and  
 18 hopefully act on them.  
 19 COFFEY, Q.C.:  
 20 Q. Exhibit P-2090 please? Now, Doctor, this is a  
 21 letter of June 16th, 2006 to yourself from  
 22 Bruce Hollett, the acting president, it's  
 23 copied to Karen Kennedy. It's on College of  
 24 North Atlantic stationary, office of the  
 25 president and he writes, "I am writing in

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1 response to your letter"--that's your letter  
 2 of May 25th, 2006--"in which you express the  
 3 concerns of the Medical Laboratory Services  
 4 Program Advisory Committee of the high rate of  
 5 attrition in the program."  
 6 DR. COOK:  
 7 A. Uh-hm.  
 8 COFFEY, Q.C.:  
 9 Q. "It is my understanding the Dean of the Health  
 10 Sciences Program, Karen Kennedy, is acting on  
 11 these concerns and requested approval from the  
 12 colleges, school team committee, to conduct a  
 13 program review of the first year Medical  
 14 Science Program during the fall of 2006."  
 15 Then it goes on to talk about that. Doctor,  
 16 what was your involvement in this?  
 17 DR. COOK:  
 18 A. Well as chair person of a laboratory of that  
 19 particular committee and the issue had come up  
 20 over the high attrition of students that were  
 21 losing in the medical technology program and  
 22 it was asked if I could write a letter looking  
 23 at the entrance requirements and whether we  
 24 could jack up the entrance requirements. I  
 25 think if I remember correctly the average was

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1 60 percent entrance, what Karen Kennedy was  
 2 looking for was to make the entrance  
 3 requirements more similar to Memorial  
 4 University. It was sort of a feeling that  
 5 people were going in and thinking that that  
 6 particular program was an easy program but it  
 7 was one of the most challenging programs that  
 8 was available in the College of the North  
 9 Atlantic.  
 10 COFFEY, Q.C.:  
 11 Q. Okay, and the graduates of that program, I  
 12 take it, would end up as technologists,  
 13 potentially?  
 14 DR. COOK:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. That's your linkage there?  
 18 DR. COOK:  
 19 A. Yes.  
 20 COFFEY, Q.C.:  
 21 Q. With why you would be involved with this.  
 22 Exhibit P-2092 please? Now, Doctor, this is a  
 23 document, it's a spreadsheet format,  
 24 laboratory program to your operational plan,  
 25 April 2006 to March 2008 and detailed activity

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1 plan, operational goals, director's  
 2 operational objectives, actions required,  
 3 delegated to, start date and end date.  
 4 DR. COOK:  
 5 A. Uh-hm.  
 6 COFFEY, Q.C.:  
 7 Q. Were you involved in the preparation of this?  
 8 DR. COOK:  
 9 A. Not in the preparation, no.  
 10 COFFEY, Q.C.:  
 11 Q. Okay, and I asked you about that because it's  
 12 in the switch over from yourself to Dr.  
 13 Denic's time as clinical chief.  
 14 DR. COOK:  
 15 A. Yes.  
 16 COFFEY, Q.C.:  
 17 Q. You were passing off to Dr. Denic. So you  
 18 weren't involved in the creation of the  
 19 document, but I take it some of the  
 20 responsibilities or tasks here, your name is  
 21 listed as being delegated to at least some of  
 22 them.  
 23 DR. COOK:  
 24 A. Yes.  
 25 COFFEY, Q.C.:

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1 Q. Okay, and I'll take that up with Dr. Denic  
 2 then. Doctor, as 2006 then, into the summer  
 3 of 2006 and into the fall of '06, we  
 4 understand that there was a media briefing in  
 5 the fall of 2006. Did you participate in  
 6 that?  
 7 DR. COOK:  
 8 A. With the media?  
 9 COFFEY, Q.C.:  
 10 Q. Yes.  
 11 DR. COOK:  
 12 A. No.  
 13 COFFEY, Q.C.:  
 14 Q. Okay, how about the briefing for Eastern  
 15 Health personnel in November of 2006?  
 16 DR. COOK:  
 17 A. Yes, I was involved in that.  
 18 COFFEY, Q.C.:  
 19 Q. And what was the nature of your involvement?  
 20 DR. COOK:  
 21 A. Just basically to give the background of how  
 22 the ER/PR issue arose, some of the history,  
 23 the chronology and again, answer any questions  
 24 that people would pose regarding that time  
 25 period.

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1 COFFEY, Q.C.:  
 2 Q. Okay, and you prepared a slide show for that?  
 3 DR. COOK:  
 4 A. Yes.  
 5 COFFEY, Q.C.:  
 6 Q. Did you get any feedback afterward concerning  
 7 that or any response from the people you  
 8 presented it to?  
 9 DR. COOK:  
 10 A. Regarding my preparation?  
 11 COFFEY, Q.C.:  
 12 Q. Yes.  
 13 DR. COOK:  
 14 A. No, very little.  
 15 COFFEY, Q.C.:  
 16 Q. Okay. If we could, please, Exhibit P-2118?  
 17 Doctor, here these are your notes?  
 18 DR. COOK:  
 19 A. Uh-hm.  
 20 COFFEY, Q.C.:  
 21 Q. Handwritten notes and they cover a number of  
 22 dates, January 10th, 2007, 4 in breast group.  
 23 DR. COOK:  
 24 A. Right.  
 25 COFFEY, Q.C.:

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1 Q. May 28th, 2007, only two left in group.  
 2 DR. COOK:  
 3 A. Uh-hm.  
 4 COFFEY, Q.C.:  
 5 Q. So who are the two?  
 6 DR. COOK:  
 7 A. That would be myself and Dr. Carter.  
 8 COFFEY, Q.C.:  
 9 Q. And then how many are left now?  
 10 DR. COOK:  
 11 A. None basically.  
 12 COFFEY, Q.C.:  
 13 Q. And that's that breast group that we saw the  
 14 formation of earlier?  
 15 DR. COOK:  
 16 A. Yes, that was formulated in November of '07, I  
 17 believe, or '06, to try and bring in  
 18 subspecialization into the breast pathology.  
 19 COFFEY, Q.C.:  
 20 Q. Okay, so that's--that group is the breast  
 21 pathology group in fact?  
 22 DR. COOK:  
 23 A. Uh-hm.  
 24 COFFEY, Q.C.:  
 25 Q. Now approximately May 17th, 2007, you had

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

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

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1 picked up, you know, the whole ER and PR  
 2 issue, could we have identified something  
 3 before and if we did, could we bring it to  
 4 attention and deal with it. This was a second  
 5 conversation that I had with Dr. Nagebi  
 6 regarding that and then trying to reiterate  
 7 what were the issues she had or they had  
 8 surrounding the ER and PR, and was there any  
 9 contact with anybody in St. John's concerning  
 10 that because I truly believe that if there had  
 11 of been an issue surrounding this or  
 12 particularly Dr. Yassa, where he was American  
 13 trained, I figured he would be used to a  
 14 certain type of standard from the institution  
 15 that he came from, and if he came to  
 16 Newfoundland and looked at the quality of our  
 17 slides and wasn't happy, I would have thought  
 18 that that would be something that maybe  
 19 someone should have been notified and maybe we  
 20 could have acted on a lot earlier.  
 21 COFFEY, Q.C.:  
 22 Q. Now, Doctor, I just several minutes ago asked  
 23 you about the presentation that you made in  
 24 2006, November '06 to Eastern Health  
 25 personnel. If I could ask, Registrar please,

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1 Exhibit P-2107? And, Doctor, this is an e-mail from Heather Predham, November 19th, 2006

2 to Pam Elliott and Patricia Pilgrim and she

3 says, "I met with Bev Carter, Ford Elms, Don

4 Cook, Nash Denic and Susan Bonnell on Friday

5 afternoon. We reviewed the presentation for

6 Monday and it's very good and comprehensive,

7 as always. Bev's comments in the meeting were

8 a bit alarmist in nature, but she is only

9 speaking about ER/PR testing at the

10 presentation. Dr. Howell called me on Friday

11 afternoon and told me that it would be

12 anticipated that I would be asked on the

13 executive meeting on Tuesday and if I felt

14 there was everything that was done, that could

15 be done in the lab, as per the external

16 reviews. And he arranged for Nash to give me

17 the summary document of the reviewer's

18 recommendations and the lab's actions. It has

19 not been updated since June, a lot of

20 communications have ongoing next to it." Now,

21 Doctor, this e-mail is not sent to you, nor

22 did it come from you, but I want to ask you

23 about this, this assertion here, because

24 apparently you attended this meeting?

25

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1 DR. COOK:

2 A. Yes, attended the presentation.

3 COFFEY, Q.C.:

4 Q. The presentation, well here it says, Ms.

5 Predham says "I met with Bev Carter, Ford

6 Elms, Don Cook, Nash Denic and Susan Bonnell

7 on Friday afternoon." So that's a Sunday, so

8 it's probably November 17th, Friday. Did you

9 ever interpret what you heard from Bev Carter

10 as alarmist?

11 DR. COOK:

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

13 COFFEY, Q.C.:

14 Q. Okay, and I take it as a pathologist you

15 expected at least based upon your background

16 and training you would be in a position to

17 make an informed judgment on that?

18 DR. COOK:

19 A. Alarmist in what way?

20 COFFEY, Q.C.:

21 Q. I don't know and I will be asking some of the

22 authors and recipients of this, but there's a

23 reference to this meeting and there's an

24 assertion here that Bev's comments were a bit

25 alarmist in nature, and I'm just asking you

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1 did you ever see Dr. Carter's comments as

2 alarmist in nature?

3 DR. COOK:

4 A. Well certainly I didn't think they were when

5 she was going through the presentation.

6 COFFEY, Q.C.:

7 Q. What about otherwise at the meeting?

8 DR. COOK:

9 A. I beg your pardon?

10 COFFEY, Q.C.:

11 Q. What about otherwise, like at the meeting?

12 DR. COOK:

13 A. No.

14 COFFEY, Q.C.:

15 Q. Doctor, can you tell the Commissioner please,

16 in 2007 were you ever asked to go to any

17 meetings around the time that this broke in

18 the media, in May of 2007?

19 DR. COOK:

20 A. There was a meeting I had with Mr. Tilley and

21 Dr. Howell and Mr. Gulliver, Dr. Denic and

22 myself, I think this was a time that story

23 broke from the Ejeckam memos, I believe.

24 COFFEY, Q.C.:

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

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1 DR. COOK:

2 A. Well, Dr. Howell asked if I could come up and

3 discuss the issue of the Ejeckam memos. So

4 when I got there, there was already Mr.

5 Tilley, Mr. Gulliver, Dr. Howell and Susan

6 Bonnell in the room, myself and Nash arrived

7 around the same time. And they wanted to know

8 the background of the Ejeckam memos, so we

9 basically told him that these memos came out

10 at around that time period, that I felt that

11 they were all part of quality assurance,

12 quality assurance activities and that Ejeckam

13 as looking, regarded him as a circuit breaker

14 in the system. He was improving and enhancing

15 the quality and crispness of the stains. We

16 talked a bit about the various classes of

17 immunohistochemical stains, class 1 verses

18 class 2, and the fact that we didn't identify

19 a patient care problem at that particular

20 time, nor did we have evidence of an index

21 case.

22 COFFEY, Q.C.:

23 Q. Doctor, did you ever attend any meetings in

24 2007 with the minister of health, deputy

25 minister of health concerning this matter,

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1 ER/PR?

2 DR. COOK:

3 A. That would be Mr. Osborne, is it?

4 COFFEY, Q.C.:

5 Q. Well, I'll ask you first about Mr. Osborne,

6 first of all -

7 DR. COOK:

8 A. No, I haven't.

9 COFFEY, Q.C.:

10 Q. How about Mr. Wiseman? I apologize, how could

11 I ever forget Mr. Wiseman's name?

12 DR. COOK:

13 A. No, I haven't.

14 COFFEY, Q.C.:

15 Q. Okay. Exhibit P-2126, please. Doctor, this

16 is an e-mail of July 5, 2007 from yourself to

17 Pat Pilgrim, accepted analysis of ER/PR,

18 you've written here, "meeting with Pat

19 Pilgrim, Nash Denic, Kara Laing and Heather

20 Predham, analysis of ER/PR still not done.

21 Spreadsheet has to be formulated with critical

22 event".

23 DR. COOK:

24 A. That's right.

25 COFFEY, Q.C.:

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1 Q. Lab medicine reports to clinical chiefs,

2 November '03 to February '06.

3 DR. COOK:

4 A. Um-hm.

5 COFFEY, Q.C.:

6 Q. I take it somebody wanted a copy of the lab

7 medicine reports.

8 DR. COOK:

9 A. Probably in relation to gathering information

10 for the Commission of Inquiry, I think.

11 COFFEY, Q.C.:

12 Q. What's this about this, "analysis on ER/PR

13 still not done, spreadsheet has to be formulated

14 with critical event".

15 DR. COOK:

16 A. We still, I mean, this was something that Dr.

17 Denic and I were pushing for to get a complete

18 analysis on the ER and PR issue. We wanted

19 breakdown as to the number of conversions per

20 month, per year; trying to formulate that with

21 the critical events going on in the

22 organization at the time, such as the closure

23 of the Grace, the centralization of technical

24 services at St. Clare's. So, trying to

25 correlate critical events in the organization,

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1 whether they had any impact or not on the

2 ER/PR issue, but more so trying to get as much

3 information from breakdown of information,

4 what specific times of the year, what years

5 did we have the most problems with the ER/PR.

6 COFFEY, Q.C.:

7 Q. And was that ever forthcoming?

8 DR. COOK:

9 A. No, I can't remember seeing that.

10 COFFEY, Q.C.:

11 Q. Who, if anyone, within Eastern Health at the

12 time was tasked, in your view, or should have

13 been tasked with doing that?

14 DR. COOK:

15 A. I think that would have been Heather, I'm not

16 sure if Pat Pilgrim was involved.

17 COFFEY, Q.C.:

18 Q. And if there is such a document or documents

19 to this day, you haven't seen them?

20 DR. COOK:

21 A. I haven't seen those, no.

22 COFFEY, Q.C.:

23 Q. Was this the first time that you raised that

24 topic?

25 DR. COOK:

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1 A. It was raised a number of topics with myself

2 and Dr. Denic and I remember Dr. Denic getting

3 on the phone a few times talking to Heather

4 trying to get this type of spreadsheet in

5 place. And I remember Dr. Williams too being

6 involved and trying to get movement on this.

7 COFFEY, Q.C.:

8 Q. Exhibit P-2136, please. Doctor, these are the

9 minutes of site chief meeting of November 7,

10 2007, present are Morris-Larkin, Denic and

11 yourself. And one, "fixation policy, it was

12 agreed that the OR will need to document the

13 time the tissue was initially submitted in

14 formalin so it can be incorporated into the

15 fixation policy. The PAS will need to

16 document the date of processing as well. Dr.

17 Denic will also liaison with Dr. Howell

18 regarding this. A copy of the fixation policy

19 will be forwarded by Dr. Denic to the clinics

20 and OR once the policy is finalized". So, I

21 take it, Doctor, that as of the beginning of

22 November 2007, the fixation policy had not yet

23 then been finalized?

24 DR. COOK:

25 A. Not formally finalized. I mean, we were--what

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1 was happening though, we were getting the  
 2 specimens coming up from the lab at a timely  
 3 fashion and they were being handled, but in  
 4 terms of having a formal fixation policy, that  
 5 was still being discussed and thrown about.  
 6 COFFEY, Q.C.:  
 7 Q. Okay. Is there such a policy in place now,  
 8 fixation policy?  
 9 DR. COOK:  
 10 A. Yes.  
 11 COFFEY, Q.C.:  
 12 Q. The formal written one is -  
 13 DR. COOK:  
 14 A. Yes.  
 15 COFFEY, Q.C.:  
 16 Q. Exhibit P-0488, please, page 100, Registrar.  
 17 Doctor, these are, if you look at the top,  
 18 executive management minutes, 14 November,  
 19 2007 and paragraph 3.13, ER/PR, it reads,  
 20 "with respect to the testing of ER/PR Eastern  
 21 Health, St. John's unilaterally decided, ie.  
 22 director and manager, to go back to January  
 23 1997 when the first testing was carried out.  
 24 However, in correspondence from the clinical  
 25 chief, Dr. Donald Cook, to the other Boards,

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1 it is referenced May 1997. Pat Pilgrim and  
 2 Oscar Howell are following up on the reasons  
 3 why Eastern Health managers retested back to  
 4 January 1997". Do you recall what this was  
 5 about, Doctor? Did anybody ever speak to you  
 6 about this?  
 7 DR. COOK:  
 8 A. No.  
 9 COFFEY, Q.C.:  
 10 Q. Okay. And I take it that in terms of the  
 11 reference in the material involving yourself,  
 12 not particularly this, but we've see a memo  
 13 from yourself, May of 1997.  
 14 DR. COOK:  
 15 A. Um-hm.  
 16 COFFEY, Q.C.:  
 17 Q. That is the start date for the material being  
 18 requested was why?  
 19 DR. COOK:  
 20 A. That was information that came from me for Mr.  
 21 Gulliver as to when we actually started  
 22 testing for ER and PR with the  
 23 immunohistochemical technique.  
 24 COFFEY, Q.C.:  
 25 Q. Okay. If we could please, Exhibit P-670.

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1 And, Doctor, I'm not going to take you through  
 2 these. I went by them without going them in  
 3 detail. I just want to have you confirm.  
 4 These are your handwritten notes for  
 5 activities, October 28 through October 31,  
 6 2005.  
 7 COFFEY, Q.C.:  
 8 Q. Yeah.  
 9 COFFEY, Q.C.:  
 10 Q. Dealing with what you were doing at the time  
 11 particularly involving contact with Dr.  
 12 Dalton, Terry Gulliver, Dr. Baker, Dr. Barry  
 13 Gallagher and Ms. Predham, as we look down  
 14 through.  
 15 DR. COOK:  
 16 A. Okay.  
 17 COFFEY, Q.C.:  
 18 Q. And just on this point, Doctor, in the  
 19 materials, at times there's dates, times,  
 20 fairly detailed notes from yourself and then  
 21 there'll be periods where there's no written  
 22 records.  
 23 DR. COOK:  
 24 A. Um-hm.  
 25 COFFEY, Q.C.:

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1 Q. In a sense of hand written notes.  
 2 DR. COOK:  
 3 A. Right.  
 4 COFFEY, Q.C.:  
 5 Q. Why the differences from time to time, could  
 6 you explain that to the Commissioner?  
 7 DR. COOK:  
 8 A. There were times, I'd say, I would be in my  
 9 office documenting things. There'd be other  
 10 times I would receive phone calls outside my  
 11 office, my binders may not be with me at all  
 12 times. There are other times I would be on a  
 13 telephone conversation, get interrupted in the  
 14 middle of a conversation, go down to handle a  
 15 frozen section case or any other issues that  
 16 the lab techs would have. So, there'd be  
 17 times that, yes, I would document; other times  
 18 that I wouldn't document. I didn't keep up  
 19 much on the documentation after I was finished  
 20 with the clinical chief program. But it would  
 21 vary from day to day and again, depending on  
 22 the circumstances in that day. So, there'd be  
 23 times I'd try to document as much as possible  
 24 and other times, I didn't document.  
 25 COFFEY, Q.C.:



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1 Q. Exhibit P-2148, please. Doctor, we've seen  
 2 the first page of this exhibit before, but I  
 3 just wanted to refer you to--the second page  
 4 of this, I take it, are your notes of the  
 5 debriefing meeting, March 31, 2006 involving  
 6 Ms. Wegrynowski.  
 7 DR. COOK:  
 8 A. Yes.  
 9 COFFEY, Q.C.:  
 10 Q. And here, you've noted here, a bullet here, I  
 11 think it's the third one down, "QA at infancy  
 12 stage".  
 13 DR. COOK:  
 14 A. That's correct.  
 15 COFFEY, Q.C.:  
 16 Q. So, that was what Ms. Wegrynowski was -  
 17 DR. COOK:  
 18 A. I think she's mainly referring to the  
 19 technical aspect of QA and the technical  
 20 aspect of the lab. We didn't get into her  
 21 with various quality assurance activities with  
 22 what was going on on the medical side in terms  
 23 of the proficiency testing, the fact that we  
 24 had royal college maintenance or certification  
 25 processes, the wide variety of rounds that we

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1 were doing, the interdepartmental  
 2 consultations, the referral to extra  
 3 departmental areas such at the Mayo Clinic,  
 4 the AFIP and the fact that we were already  
 5 accredited by the Royal College of Physicians  
 6 and Surgeons of Canada as a teaching program.  
 7 So, we didn't touch any of that that was  
 8 mainly directed at the technical aspect of the  
 9 program.  
 10 COFFEY, Q.C.:  
 11 Q. Because she wasn't down to look at what the  
 12 pathologists were doing; she was down to look  
 13 at the technology end of it.  
 14 DR. COOK:  
 15 A. Yes, that was my viewpoint on all of that.  
 16 COFFEY, Q.C.:  
 17 Q. Doctor, just as a matter, I take it, was March  
 18 31 your last day as -  
 19 DR. COOK:  
 20 A. No, my last day was March 10, I believe.  
 21 COFFEY, Q.C.:  
 22 Q. Okay. And that's your last day as clinical  
 23 chief?  
 24 DR. COOK:  
 25 A. Um-hm.

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1 COFFEY, Q.C.:  
 2 Q. And the third page and fourth page of this  
 3 exhibit, Doctor, I take it, are your exit  
 4 meeting notes of April 25, 2006 involving Dr.  
 5 Banerjee's visit.  
 6 DR. COOK:  
 7 A. Yes.  
 8 COFFEY, Q.C.:  
 9 Q. Now, here Doctor, Dr. Ejeckam was at this  
 10 meeting.  
 11 DR. COOK:  
 12 A. Um-hm.  
 13 COFFEY, Q.C.:  
 14 Q. Why was he there?  
 15 DR. COOK:  
 16 A. Well, we were getting him more involved in the  
 17 process. A lot of the planning had taken  
 18 place. We got financial resources in place;  
 19 recommendations were being made. So, Ejeckam  
 20 was there to firm up the role of a  
 21 immunohistochemistry to firm up the whole role  
 22 of having a director of immunohistochemistry  
 23 and giving that individual director status.  
 24 COFFEY, Q.C.:  
 25 Q. Here there's--you've attributed the following

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1 comment, "need to have stipend for director of  
 2 immunohistochemistry, need to recognize  
 3 workload, need time for" -  
 4 DR. COOK:  
 5 A. Monitoring the lab and documentation.  
 6 DR. COOK:  
 7 A. - "monitoring the lab and documentation, need  
 8 direct clinical support". Dr. Ejeckam that  
 9 the point in time was already on his way out,  
 10 I take it?  
 11 DR. COOK:  
 12 A. Yes, I think he was on his way out, but we  
 13 were looking to provide financial remuneration  
 14 for this type of activity and giving the  
 15 individual control and authority over the IHC  
 16 in terms of control and authority over the  
 17 technical aspect.  
 18 COFFEY, Q.C.:  
 19 Q. Okay. Now, Doctor, the report then of Ms.  
 20 Wegrynowski and Dr. Banerjee in the spring of  
 21 '06. Did you get copies of those?  
 22 DR. COOK:  
 23 A. I didn't get copies of those.  
 24 COFFEY, Q.C.:  
 25 Q. Did you ever read them?

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1 DR. COOK:  
 2 A. I read them.  
 3 COFFEY, Q.C.:  
 4 Q. And when did you read them? Some time, I take  
 5 it after '06.  
 6 DR. COOK:  
 7 A. I can't tell you the exact date, but it was  
 8 some time I got them.  
 9 COFFEY, Q.C.:  
 10 Q. And Ms. Wegrynowski's report first of all, how  
 11 did you feel about that at the time?  
 12 DR. COOK:  
 13 A. Well, there's still a lot of recommendations  
 14 not in place. There was something that she  
 15 referred to, the calibration of pipette which  
 16 I understand from Mr. Gulliver and Mr. Dyer  
 17 that it's no longer being used in the Ventana  
 18 system. But still there was a lot of work  
 19 that needed to be done in getting the  
 20 recommendations implemented.  
 21 COFFEY, Q.C.:  
 22 Q. And Dr. Banerjee's report in the spring of  
 23 '06, you did see that?  
 24 DR. COOK:  
 25 A. Yes.

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1 COFFEY, Q.C.:  
 2 Q. How did you feel about that?  
 3 DR. COOK:  
 4 A. I was fairly happy with that. That was moving  
 5 in the right direction. We were moving  
 6 forward on getting the pathology assistants in  
 7 place and moving ahead on IHC. One of the  
 8 things that I wasn't particularly happy about  
 9 was the slow pace of reorganization of the  
 10 laboratory management structure. So, I felt  
 11 that that's something that needed to be  
 12 addressed and it was addressed later on.  
 13 COFFEY, Q.C.:  
 14 Q. Doctor, is there anything that we haven't  
 15 covered that you think the Commissioner should  
 16 know?  
 17 DR. COOK:  
 18 A. Just like to iterate that as clinical chief I  
 19 wish I had to have had the role that Dr. Denic  
 20 has now with reporting of the lab and medical  
 21 structures towards a central person. I wish I  
 22 had to have a good quality assurance program  
 23 in place that is there now with indicators  
 24 being fed into the clinical chief and at least  
 25 some discretionary funding in place that I

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1 would have been able to direct towards areas  
 2 of need.  
 3 COFFEY, Q.C.:  
 4 Q. Commissioner, those are the questions I have,  
 5 thank You.  
 6 THE COMMISSIONER:  
 7 Q. Mr. Pritchard?  
 8 MR. PRITCHARD:  
 9 Q. Thank you, Commissioner, I don't have any  
 10 questions for the doctor. Thank you for your  
 11 evidence, sir.  
 12 THE COMMISSIONER:  
 13 Q. Mr. Simmons?  
 14 MR. SIMMONS:  
 15 Q. Thank you, Commissioner. I don't have any  
 16 questions arising out of Commission counsel's  
 17 questions of Dr. Cook. Dr. Cook, I know has  
 18 representation here in his capacity as a  
 19 physician, Mr. Brown. Once other counsel have  
 20 completed their questioning, there may be a  
 21 possibility that if something new comes up in  
 22 relation (unintelligible) duties for Eastern  
 23 Health's clinical chief, that I might want to  
 24 consider asking (unintelligible) ask any  
 25 questions then. But I'll reserve that request

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1 (unintelligible) if it becomes necessary.  
 2 THE COMMISSIONER:  
 3 Q. Mr. Pritchett?  
 4 MR. PRITCHETT:  
 5 Q. We have no questions, thank you.  
 6 THE COMMISSIONER:  
 7 Q. Ms. Newbury.  
 8 DR. DONALD COOK, EXAMINATION BY MS. JENNIFER NEWBURY  
 9 MS. NEWBURY:  
 10 Q. Good afternoon, Dr. Cook. Jennifer Newbury  
 11 for the Canadian Cancer Society, Newfoundland  
 12 and Labrador division. I just have a few  
 13 questions for you this morning on a couple of  
 14 different topic areas.  
 15 DR. COOK:  
 16 A. Um-hm.  
 17 MS. NEWBURY:  
 18 Q. And I wanted to bring you back, first of all,  
 19 to your involvement in the parallel studies  
 20 that you mentioned back in 1997 when IHC  
 21 testing for ER and PR was brought into the  
 22 Health Care Corporation of St. John's.  
 23 DR. COOK:  
 24 A. Right.  
 25 MS. NEWBURY:

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1 Q. And at that time, I just wanted to be clear  
 2 that I understood what was going on, in terms  
 3 of your involvement in that, and I took from  
 4 your evidence that there were three sets of  
 5 tests being done on certain samples. Some  
 6 were--some samples were tested at the General  
 7 Hospital site for the biochemistry method.  
 8 Some were tested at the General Hospital site  
 9 for the IHC method.  
 10 DR. COOK:  
 11 A. Um-hm.  
 12 MS. NEWBURY:  
 13 Q. And then also at the Mayo Clinic for IHC?  
 14 DR. COOK:  
 15 A. Um-hm.  
 16 MS. NEWBURY:  
 17 Q. That's correct, is it?  
 18 DR. COOK:  
 19 A. That's correct, yeah.  
 20 MS. NEWBURY:  
 21 Q. Okay, and also at the time, you'd indicated  
 22 that records of this testing were not kept and  
 23 the only records that would have existed were  
 24 your own handwritten notes.  
 25 DR. COOK:

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1 A. I didn't have any records at all from--  
 2 regarding to the Mayo Clinic, no. I had  
 3 handwritten notes at that time, but that was  
 4 years ago and they were discarded.  
 5 MS. NEWBURY:  
 6 Q. Right, okay. So is this your own personal  
 7 records wouldn't have been kept or is it your  
 8 understanding that there would be no records  
 9 at all within, at the time, Health Care  
 10 Corporation of St. John's?  
 11 DR. COOK:  
 12 A. Well, they were just notes that I had written  
 13 down on a writing pad, just roughly  
 14 correlating our results from the Mayo Clinic  
 15 with the biochemical assay.  
 16 MS. NEWBURY:  
 17 Q. Right, but in terms of what you were looking  
 18 at, would there be reports coming in from the  
 19 Mayo Clinic and reports coming to you  
 20 regarding the biochemistry testing?  
 21 DR. COOK:  
 22 A. Oh no, the only report we got from the Mayo  
 23 Clinic was the report on the--we send down the  
 24 paraffin block. The Mayo would issue the  
 25 report, either positive or negative.

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1 MS. NEWBURY:  
 2 Q. Okay.  
 3 DR. COOK:  
 4 A. And I believe I incorporated that into our  
 5 hospital information system.  
 6 MS. NEWBURY:  
 7 Q. Okay, so there are reports there, but just not  
 8 correlating or tying together all of the three  
 9 types of testing methods?  
 10 DR. COOK:  
 11 A. The only type of report there from the Mayo  
 12 Clinic report itself, but not correlating the  
 13 Mayo results with the biochemistry results and  
 14 our own immunohistochemical results.  
 15 MS. NEWBURY:  
 16 Q. Okay. So it's not that they don't generate  
 17 any reports at all. There would be reports  
 18 coming from the Mayo Clinic, but what you were  
 19 referring to was the actual sitting down and  
 20 comparing the three test results for the two  
 21 samples.  
 22 DR. COOK:  
 23 A. Yeah, they--there's nothing there. It's just  
 24 a hard copy report from the Mayo Clinic.  
 25 MS. NEWBURY:

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1 Q. Now the samples that were tested, are these  
 2 ongoing patient samples or do you go back in  
 3 your system and look for past specimens for -  
 4 DR. COOK:  
 5 A. You mean in terms of the Mayo Clinic report?  
 6 MS. NEWBURY:  
 7 Q. For the parallel studies that you were talking  
 8 about back in 1997. I'm just wondering if  
 9 these are active patient specimens that are  
 10 being tested or do you go back into your  
 11 inventory, I guess, to come up with some  
 12 specimens for the purposes of the study?  
 13 DR. COOK:  
 14 A. I can't be sure what Dr. Khalifa did. You'll  
 15 have to--that's a question you have to ask  
 16 him.  
 17 MS. NEWBURY:  
 18 Q. Okay. So you wouldn't have any familiarity  
 19 with that at that time?  
 20 DR. COOK:  
 21 A. No.  
 22 MS. NEWBURY:  
 23 Q. Okay, and just generally in terms of record  
 24 keeping for quality assurance activities,  
 25 would you generally keep records, not keep

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1 records? Has there been any change in that  
 2 practice since 1997?  
 3 DR. COOK:  
 4 A. That was a problem, getting the infrastructure  
 5 in place to have dedicated people to record  
 6 all of this. We were doing a lot of it. The  
 7 issue is having a separate person or a  
 8 separate department recording all those  
 9 activities, and that was a frustrating thing  
 10 for me over the years, that we were doing a  
 11 lot of it, but you didn't have the capability  
 12 to go back and review, the personnel to go  
 13 back and review a specific question. Like for  
 14 instance, I might want to go back and look at  
 15 the quality of pathology reports over the last  
 16 two or three years. So was there a resource  
 17 person that I could have there and say "here,  
 18 look, I want to look at that quality, look at  
 19 whether all the information was included in  
 20 synoptic reports, and issue me a report" and  
 21 it could be, say, for a six-month period over  
 22 a particular year. So that's what was  
 23 frustrating about the whole system is that I  
 24 didn't have the available manpower to do these  
 25 type of audits.

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1 MS. NEWBURY:  
 2 Q. But once you, for some reason, take it upon  
 3 yourself to do that, even if it's in sort of a  
 4 rudimentary form, would there be a practice of  
 5 keeping, you know, even handwritten notes, as  
 6 time went on, after 1997?  
 7 DR. COOK:  
 8 A. That's hard to say because I used to have to  
 9 file. I did all my own secretarial work  
 10 myself. The secretary that we had was  
 11 covering four or five other pathologists, so  
 12 if you look at my filing system, it's not the  
 13 greatest. So you know, there may be notes  
 14 there and there may not. I mean, I just  
 15 didn't have a good way of going back and  
 16 retrieving that stuff.  
 17 MS. NEWBURY:  
 18 Q. Okay, and that hasn't been improved since -  
 19 DR. COOK:  
 20 A. Oh, it has. Since this whole ER/PR issue now,  
 21 the Chief of Laboratory Medical now has a  
 22 dedicated secretary to do all his or her  
 23 filing, and that's only come in recently.  
 24 MS. NEWBURY:  
 25 Q. Okay. Last week, you were talking about some

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1 various types of quality assurance that were  
 2 taking place. You didn't have specific  
 3 quality assurances, I understand it, for ER/PR  
 4 testing, but you were talking about sort of  
 5 the broader quality assurance type activities  
 6 that were taking place there.  
 7 DR. COOK:  
 8 A. Um-hm.  
 9 MS. NEWBURY:  
 10 Q. And you've mentioned that sometimes there  
 11 would be quality--there would be extra  
 12 departmental reviews that would take place?  
 13 DR. COOK:  
 14 A. That's correct, yeah.  
 15 MS. NEWBURY:  
 16 Q. Okay, and would this just be for difficult  
 17 cases?  
 18 DR. COOK:  
 19 A. It could be difficult cases or even relatively  
 20 simple cases that we were looking at  
 21 correlation ourselves with major reference  
 22 centres across Canada and the United States.  
 23 Usually what would happen, we have what is  
 24 known as quality control rounds, which we meet  
 25 once a week, all the pathologists, say for

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1 instance, at St. Clare's and it's a similar  
 2 situation over to General, where they meet for  
 3 their slide rounds where pathologists would  
 4 bring difficult cases to that round for  
 5 discussion amongst various pathologists and we  
 6 would try to get a consensus opinion. If  
 7 we're unable to get a consensus opinion, then  
 8 we would refer the case out, usually to a  
 9 major reference centre, and they would act as  
 10 sort of an arbitrator in that particular case.  
 11 The opinions would come back and we would  
 12 review them at that particular round.  
 13 MS. NEWBURY:  
 14 Q. Okay, but would the cases that ultimately be  
 15 sent outside to a major reference centre, and  
 16 I think you'd mentioned the Mayo Clinic, BC  
 17 Cancer Agency, and the Armed Forces Institute  
 18 that you tended to use. The cases that  
 19 ultimately got referred out to these major  
 20 reference centres, would they typically be the  
 21 difficult cases versus the more simple cases?  
 22 DR. COOK:  
 23 A. More typically difficult and ones where there  
 24 was not a consensus of opinion in the  
 25 department.

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

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

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

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

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1 a case out for an outside opinion and gave the  
 2 surgeon reassurance and yourself reassurance.  
 3 MS. NEWBURY:  
 4 Q. Okay, and in terms of the, I guess, the  
 5 difficult cases that are sent for outside  
 6 consultant report, if you got a result back  
 7 that wasn't consistent with your own  
 8 interpretation, would that not raise a red  
 9 flag because you'd already identified it as  
 10 something being difficult?  
 11 DR. COOK:  
 12 A. Well, the report wasn't signed out. You send  
 13 out a preliminary report, and these would be  
 14 red flags that you identify with the surgeon  
 15 or attending surgeon. You would say "look,  
 16 you know, I got a case here which there may be  
 17 borderline malignancy. I'm not sure if it's  
 18 totally malignant or not. Wait until I get  
 19 the final report back from the referring  
 20 institution before you do anything," or even  
 21 say you can still speak to the patient, and  
 22 say "look, we got a problem with this case.  
 23 The pathologist has sent it out, which we'll  
 24 hopefully have a result back in a week or  
 25 two." So hopefully you would try to, you

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1 know, nip the problem in the bud before it got  
 2 too bad and dealing with--you know, you get  
 3 the results back from the Mayo Clinic and then  
 4 once you got that, you contact the surgeon and  
 5 say "here's the result. Here's our impression  
 6 of it. Do you agree with that" and I would  
 7 review the slides and that that would come  
 8 back from the Mayo Clinic and check the  
 9 correlation with our reports and their  
 10 reports. So it's all part of, you know, what  
 11 I saw as good patient care and good back up  
 12 and follow up.  
 13 MS. NEWBURY:  
 14 Q. Right, and I do appreciate that, but I'm just  
 15 wondering, in terms of the ability of that to  
 16 highlight any sort of underlying problems that  
 17 there might be in some test procedures, if all  
 18 you sent out are difficult cases, perhaps you  
 19 wouldn't be that alarmed if you got a  
 20 different result back. Just because of the  
 21 very nature of the specimen that's going out  
 22 for testing, you're perhaps anticipating it,  
 23 if not unlikely, that there would be different  
 24 results?  
 25 DR. COOK:

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1 A. Well, that's one thing. I mean, but the other  
 2 process that we had in place that every time  
 3 we get a case, we also get a spreadsheet or a  
 4 previous reports on a particular case. We  
 5 could have, say, a superficial esophageal  
 6 biopsy of which we had multiple biopsies over  
 7 the past two-three years. So we would get a  
 8 print out with those diagnosis on that  
 9 particular sheet. So for instance, let's say  
 10 I picked up a carcinoma in a superficial  
 11 biopsy that had been previously biopsied, say  
 12 over two or three years. I would have those  
 13 previous diagnosis there and my first  
 14 inclination was to go back and review those  
 15 biopsies to make sure we hadn't missed a  
 16 particular lesion. So that was going on quite  
 17 common and by all pathologists and that's how  
 18 we picked up a number of issues. So that was  
 19 more of a broader range process that we had in  
 20 place and that was basically a standard that  
 21 we had in place.  
 22 MS. NEWBURY:  
 23 Q. Now that didn't involve, necessarily an extra  
 24 departmental review or sending something to a  
 25 major referral centre. That's just what you

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1 did internally?  
 2 DR. COOK:  
 3 A. Well, it could. I mean, if I saw, for  
 4 instance, a biopsy that was malignant  
 5 currently and then went back and reviewed the  
 6 original biopsies, which it could be four or  
 7 five biopsies over two or three years, I could  
 8 bring that to our quality controls rounds, get  
 9 an opinion from the others as to what--if  
 10 something was missed or whatnot, and take it  
 11 from there.  
 12 MS. NEWBURY:  
 13 Q. And can you say whether or not any cases  
 14 involving ER/PR testing ever were subject of  
 15 these types of extra departmental reviews or  
 16 any of these internal reviews?  
 17 DR. COOK:  
 18 A. Not that I can remember, no. The ER/PR issue  
 19 was basically a non-issue. I mean, we had  
 20 covered a lot of other things, but this issue,  
 21 we didn't zero in on.  
 22 MS. NEWBURY:  
 23 Q. Dr. Cook, last week you were questioned about  
 24 Dr. Ejeckam's memo dated April 2003. Perhaps  
 25 we can bring up the exhibit just in case.

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1 It's P-0113, page one, and just to refresh  
 2 your memory, and you were questioned in  
 3 particular about the comment of Dr. Ejeckam  
 4 that eight stains were unreliable, erratic and  
 5 therefore unhelpful for diagnostic purposes.  
 6 DR. COOK:  
 7 A. Um-hm.  
 8 MS. NEWBURY:  
 9 Q. And you commented at that time, at in the  
 10 world of immunohistochemistry, stains can vary  
 11 from day to day and can vary in intensity and  
 12 can vary in staining characteristics, and you  
 13 considered IHC to be a variable event.  
 14 DR. COOK:  
 15 A. That's right.  
 16 MS. NEWBURY:  
 17 Q. And I'm just wondering, and this is arising  
 18 from some comments of Dr. O'Malley when she  
 19 gave evidence last week. Could the intensity  
 20 of the stain be a feature of the tumour  
 21 itself?  
 22 DR. COOK:  
 23 A. It may. It may not. I mean, there's so many  
 24 factors. You're dealing with a 40 to 50 step  
 25 process with the DAKO system. It's highly

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1 manual, so therefore you've got a lot of human  
 2 intervention there.  
 3 MS. NEWBURY:  
 4 Q. Sure.  
 5 DR. COOK:  
 6 A. So to make sure that you're able to carry on  
 7 the same step every day is quite a significant  
 8 task. Now when you compare the DAKO system to  
 9 the Ventana automated system, I wouldn't  
 10 expect the same degree of erratic or  
 11 unreliability or variation in stain because  
 12 you're getting a much more uniform procedure,  
 13 a much more standardized procedure and you're  
 14 taking the human element, to a certain degree,  
 15 out of this process.  
 16 MS. NEWBURY:  
 17 Q. And last week or a couple of weeks ago, Dr.  
 18 O'Malley had referenced the Allred score for  
 19 determining whether or not a patient should be  
 20 treated with Tamoxifen or hormone therapy, and  
 21 that had two components, a proportion score  
 22 for staining and an intensity score, and now I  
 23 think the intensity score wasn't as  
 24 significant as the proportion score. That's  
 25 what I took from her evidence.

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1 DR. COOK:  
 2 A. Um-hm.  
 3 MS. NEWBURY:  
 4 Q. And you're familiar with that, that issue?  
 5 DR. COOK:  
 6 A. Um-hm.  
 7 MS. NEWBURY:  
 8 Q. When you're looking at a slide, how do you  
 9 determine if the issue that you saw with  
 10 intensity of staining varying from day to day  
 11 is due to some of those human--you know, just  
 12 the vagaries of IHC testing, at that time,  
 13 particularly with DAKO, and the expected  
 14 variations in intensity which, I think, are  
 15 related to the tumour itself?  
 16 DR. COOK:  
 17 A. When I go back and do a review, I mean, how I  
 18 read a DAKO slide is totally different,  
 19 different than how I read a Ventana slide. I  
 20 mean, the DAKO, I mean, if there was even the  
 21 slightest intensity, the slightest stain, I  
 22 would interpret that as being positive because  
 23 of the fact that we were dealing with a semi-  
 24 automated procedure. But would I make the  
 25 same interpretation today on a Ventana system?

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1 No. If I looked at a very weak intensity  
 2 stain on the Ventana system, I wouldn't call  
 3 that positive, as I did on the DAKO system,  
 4 because we're dealing with two different types  
 5 of platforms.  
 6 MS. NEWBURY:  
 7 Q. And would the use of controls assist you in  
 8 differentiated between intensity related to  
 9 the staining versus intensity related--changes  
 10 or variability related -  
 11 DR. COOK:  
 12 A. It would help me because, I mean, I'm looking  
 13 at, now again, the Ventana automated system,  
 14 more standardization and I'm getting--now  
 15 we're using three types of controls on our  
 16 system. We're using the negative, the  
 17 intermediate and high expressers. So I would  
 18 expect, with the automated system, to have  
 19 equal intensity with the controls, as opposed  
 20 to your test tissue.  
 21 MS. NEWBURY:  
 22 Q. And how about with the DAKO?  
 23 DR. COOK:  
 24 A. The DAKO, no, again, we were dealing with a  
 25 lot of variability there, a different system

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

10 MS. NEWBURY:  
 11 Q. And how about internal controls, would that  
 12 play any role in that? Would you -

13 DR. COOK:  
 14 A. Well, internal control still would have played  
 15 a role with the DAKO system, as does the  
 16 Ventana system today.

17 MS. NEWBURY:  
 18 Q. But would that assist you at all in  
 19 differentiating between the variability of  
 20 staining due to -

21 DR. COOK:  
 22 A. Well, you should have variability in staining  
 23 on your internal control and even in your  
 24 tissue itself. It just boils down to seeing  
 25 as much as you can. I mean, what happened

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

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

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

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1 MS. NEWBURY:  
 2 Q. Okay, and it's your understanding that this  
 3 information is, first of all, all input into  
 4 the system that this individual would use?

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

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

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1 total number of patients -

2 DR. COOK:  
 3 A. Possibly. If we can type in key words in the  
 4 Meditec System like infiltrating lobular  
 5 carcinoma, we could retrieve the number of  
 6 cases of infiltrating lobular carcinoma and  
 7 then our QA supervisor would be able to  
 8 possibly manually check how many of those  
 9 infiltrating lobulars were ER and PR negative.

10 MS. NEWBURY:  
 11 Q. So, I take it then, that you are not  
 12 completely sure what could be available and  
 13 it's best to ask the --

14 DR. COOK:  
 15 A. That's correct, I don't want to say --

16 MS. NEWBURY:  
 17 Q. QA supervisor.

18 DR. COOK:  
 19 A. With absolute certainty what's going on there.

20 MS. NEWBURY:  
 21 Q. Okay, and when you're talking about this, is  
 22 this for Eastern Health generally or just for  
 23 St. Clare's?

24 DR. COOK:  
 25 A. No, this is for Eastern Health.



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1 COMMISSIONER:  
 2 Q. Do you have any reason to believe that search  
 3 capabilities of systems that you now have are  
 4 any different than they were in 2005?  
 5 DR. COOK:  
 6 A. That's a good question, Commissioner. I  
 7 really can't answer that for sure.  
 8 COMMISSIONER:  
 9 Q. I'm sure that somebody will come along who  
 10 will be in a position to answer that. Thank  
 11 you.  
 12 DR. COOK:  
 13 A. Yes.  
 14 MS. NEWBURY:  
 15 Q. And your QA supervisor now is?  
 16 DR. COOK:  
 17 A. Bev Rowe. I believe she's supervisor for the  
 18 Division of Anatomical Pathology. She took  
 19 over from Catherine Parnell who recently  
 20 retired, and then we have Lynn Wade, whose  
 21 overall quality assurance supervisor for lab  
 22 and DI, I believe.  
 23 MS. NEWBURY:  
 24 Q. So Lynn Wade is the supervisor of Bev Rowe?  
 25 DR. COOK:

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

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

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1 Eastern Health?  
 2 DR. COOK:  
 3 A. Well, we would get the request, a patient,  
 4 say, who was transferred for treatment, say,  
 5 in Toronto.  
 6 MS. NEWBURY:  
 7 Q. Uh-hm.  
 8 DR. COOK:  
 9 A. Before she's being treated with chemo  
 10 radiotherapy, there would be a request from  
 11 that particular institution to refer our cases  
 12 to them, and they would then review it, you  
 13 get a second opinion, and a report would be  
 14 issued. Remember I referred to the Cleveland  
 15 situation back in 2000/2001. So that was a  
 16 situation where our cases were reviewed by  
 17 outside pathologists and reports issued.  
 18 MS. NEWBURY:  
 19 Q. But who initiated that review?  
 20 DR. COOK:  
 21 A. That review was initiated usually by the  
 22 institution itself to whom you refer the  
 23 patient to. So if you refer to Cleveland  
 24 Medical Centre, they would request us to send  
 25 them the slides and all information

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<p>1 surrounding that patient to their 2 organization. 3 MS. NEWBURY: 4 Q. But who within Eastern Health would have 5 initiated the review, sending the patients to 6 the Cleveland Medical Centre? 7 DR. COOK: 8 A. You mean those patients back in 2000/2001? 9 MS. NEWBURY: 10 Q. Yes. 11 DR. COOK: 12 A. Oh, my, I can't tell you who. 13 MS. NEWBURY: 14 Q. So it wasn't the laboratory medicine program? 15 DR. COOK: 16 A. To have the patient treated in Cleveland? 17 MS. NEWBURY: 18 Q. Yes. 19 DR. COOK: 20 A. Oh, no, no. 21 MS. NEWBURY: 22 Q. And that just came up that while these 23 patients were being treated by the Cleveland 24 Medical Clinic, as part and parcel of that, 25 they wanted to do a review of the slides?</p>	<p>1 A. Not off the chart, but you try to keep on top 2 on the report that comes back and you do a 3 correlation with what the outside institution 4 has said and what we found. 5 MS. NEWBURY: 6 Q. Uh-hm. Would you do an exercise that you'd 7 referred to earlier that sometimes when you 8 get a result back, you might go back and check 9 all of the biopsies done over the last couple 10 of years? Would you do that sort of exercise? 11 DR. COOK: 12 A. Only on a specific case, or if we became aware 13 of a trend, we might want to go ahead and do a 14 wider review. 15 MS. NEWBURY: 16 Q. Okay. 17 DR. COOK: 18 A. And that gets back to having people in the 19 organization to do the audit for you, like a 20 quality assurance supervisor. You could 21 charge her with that task of identifying what 22 cases need to be hauled out, over what time 23 period, and then brought to the reviewing 24 pathologist. 25 MS. NEWBURY:</p>
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<p>1 DR. COOK: 2 A. Yes, and they would review the x-ray reports, 3 possibly the x-rays themselves, and 4 information from the chart. 5 MS. NEWBURY: 6 Q. And would you expect that every time there is 7 a consultation that's initiated by another 8 physician within Eastern Health, that you 9 would always become aware that that's taking 10 place? 11 DR. COOK: 12 A. Most of the time. It may not be all the time, 13 but most of the time I would be aware that 14 there would be a request of a physician to 15 have a second opinion on a particular case, or 16 an outside institution wanting to have a 17 second opinion on a particular case. 18 MS. NEWBURY: 19 Q. And for those situations where you do become 20 aware of it, do you have a process or 21 procedure in place that a review will be 22 conducted of that patient's chart just to see 23 if there's any correlation or any 24 discrepancies? 25 DR. COOK:</p>	<p>1 Q. Okay. So it's not necessarily a trigger in 2 each and every event that there's an outside 3 consultation and it will be a review? 4 DR. COOK: 5 A. There wouldn't necessarily be a trigger. 6 Again depending on the situation, I mean, you 7 might just find it's an isolated event, but if 8 you get into something that you're finding 9 it's more than an isolated event, that would 10 be cause for alarm and it could trigger a 11 wider review. 12 MS. NEWBURY: 13 Q. Uh-hm. How about if there are patients who 14 might be subject to different tests within 15 Eastern Health or perhaps among the different 16 regional health authorities? Is that a 17 possibility that there might be different 18 specimens tested at different times, perhaps 19 within a short time frame? 20 DR. COOK: 21 A. It's possible. Again if a patient, say, is 22 coming in from Grand Falls for treatment in 23 St. John's, the attending surgeon may ask for 24 a second opinion on the case that's coming in 25 from Grand Falls for a review, or even the</p>

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1 oncologist, for that matter.  
 2 MS. NEWBURY:  
 3 Q. Okay. Is there a system in place, as an  
 4 example, of a couple of different pathologists  
 5 happened to be involved in doing -- reading  
 6 slides for a particular patient? Is there a  
 7 system in place that there will be a check of  
 8 all other results in the system to make sure  
 9 that there is consistency?  
 10 DR. COOK:  
 11 A. Not necessarily. You would go back and review  
 12 the printout that you have on your  
 13 accompanying requisition. If you see any  
 14 discrepancy there in the diagnosis, yes, it  
 15 could trigger something, but it wouldn't be  
 16 absolute.  
 17 MS. NEWBURY:  
 18 Q. Okay, and the requisition would come from the  
 19 treating oncologist?  
 20 DR. COOK:  
 21 A. The requisition would come from treating  
 22 oncologist or the attending surgeon, and you  
 23 would get the printout of the previous  
 24 histologies and what not.  
 25 MS. NEWBURY:

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

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

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1 system for them to ascertain, you know, here  
 2 are the results for this patient, are they the  
 3 same throughout?  
 4 DR. COOK:  
 5 A. Well, they would have the ability to go into  
 6 the Meditec System.  
 7 MS. NEWBURY:  
 8 Q. Okay.  
 9 DR. COOK:  
 10 A. Go into your menu and you could look at the  
 11 previous pathology reports.  
 12 MS. NEWBURY:  
 13 Q. And that would have all of the information  
 14 that that oncologist needs just to ensure  
 15 everything is okay for that particular  
 16 patient?  
 17 DR. COOK:  
 18 A. I believe so. Now I can't be absolutely sure  
 19 on what type of menu the oncologist have,  
 20 whether they have access to all the  
 21 pathological diagnosis on the Meditec System.  
 22 I can't be absolutely sure on that.  
 23 MS. NEWBURY:  
 24 Q. Okay.  
 25 DR. COOK:

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

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

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1 clinically significant impact.  
 2 MS. NEWBURY:  
 3 Q. Right, and again regardless of whether the 60  
 4 percent number is used or the 40 percent  
 5 number is used, either way that would be  
 6 considered ER positive?  
 7 DR. COOK:  
 8 A. Yes.  
 9 MS. NEWBURY:  
 10 Q. Do you know how many other of the four or five  
 11 cases that you're familiar with being seen at  
 12 the Cleveland Medical Clinic were also ER  
 13 positive?  
 14 DR. COOK:  
 15 A. I can't remember. All I remember was they  
 16 correlated from what we had, and again I'm  
 17 going back now five or six years trying to  
 18 remember what was there, and it was the actual  
 19 slides that were seen by Cleveland Medical  
 20 Clinic from what I understand.  
 21 MS. NEWBURY:  
 22 Q. Okay, and would -- these were random patients  
 23 that were seen?  
 24 DR. COOK:  
 25 A. Oh, no, these were patients that as a result

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1 of the oncology shortage back in 2000 and  
 2 2001, we didn't have enough medical  
 3 oncologists to treat the patients, and so they  
 4 were referred to Cleveland for treatment. So  
 5 they weren't randomly selected. They were --  
 6 we had to deal with them because of the  
 7 oncology shortage.  
 8 MS. NEWBURY:  
 9 Q. Sure, but they weren't chosen because they had  
 10 infiltrating lobular carcinoma or any  
 11 particular type of breast cancer, would they?  
 12 DR. COOK:  
 13 A. Not to my knowledge, no, they weren't -- I  
 14 don't think they were selected out in terms of  
 15 the type of cancer they had.  
 16 MS. NEWBURY:  
 17 Q. They just happened to be the patients who were  
 18 diagnosed at the time needing treatment?  
 19 DR. COOK:  
 20 A. Diagnosed with breast cancer. We didn't have  
 21 the manpower in terms of oncology at that time  
 22 to treat these patients, so I believe the  
 23 government looked for an outside source and  
 24 came up with Cleveland.  
 25 MS. NEWBURY:

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1 Q. Okay. So when you recently thought about --  
 2 you were thinking back on the Cleveland  
 3 Medical Clinic cases that were sent out, and  
 4 taken some comfort from the fact that there  
 5 weren't any conversions at the time, did you  
 6 consider whether you should have a close look  
 7 at whether they were ER negatives versus ER  
 8 positive in light of the fact that your focus  
 9 here in the retesting was on ER negative?  
 10 DR. COOK:  
 11 A. Well, the focus on that time wasn't on ER and  
 12 PR. The focus was on were we making the  
 13 correct diagnosis of infiltrating ductal  
 14 versus lobular, how were we doing in the  
 15 synoptic reports, were we getting good  
 16 correlation with our synoptic reports and the  
 17 Cleveland reports, and were we calling things  
 18 metastatic to the lymphnode, correlating that  
 19 with Cleveland. So there was a whole lot of  
 20 other factors that as the reports came in, I  
 21 would quickly scan down through to see if  
 22 there was any discrepancies with the entire  
 23 report. I mean, at that time I simply wasn't  
 24 focused on ER/PR. I was focusing on the  
 25 diagnosis and correlations with synoptic

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1 reports.  
 2 MS. NEWBURY:  
 3 Q. Right, but after the ER/PR problem became  
 4 apparent back in 2005, and sometime later you  
 5 came to think about the Cleveland Medical  
 6 situation and you recognized that there were  
 7 no conversions and there was a fairly minor  
 8 discrepancy, I guess, in one of the tests  
 9 which wouldn't result in any new treatment  
 10 changes, but did you think to look whether or  
 11 not any of those cases were actually ER  
 12 negative cases?  
 13 DR. COOK:  
 14 A. No, I did not, and again the reason being  
 15 again that interpretations were made on that  
 16 slide. I would have been more focused on the  
 17 fact of involving those Cleveland cases in a  
 18 general review and in having the paraffin  
 19 blocks themselves being retested, restained,  
 20 and reinterpreted.  
 21 MS. NEWBURY:  
 22 Q. Uh-hm. You weren't concerned about -- well,  
 23 it seems now since the ER/PR testing issue  
 24 became apparent, the concern has been with  
 25 false negatives, not the false positives?

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1 DR. COOK:  
 2 A. Most of the concern was -- and this was the  
 3 problem with the test itself, the high false  
 4 negative rate.  
 5 MS. NEWBURY:  
 6 Q. Right, and in terms of getting any comfort  
 7 from the Cleveland cases as to whether or not  
 8 a problem that you've been investigating since  
 9 2005 was likely to be detected, wouldn't you  
 10 need to know whether those cases were ER  
 11 negative?  
 12 DR. COOK:  
 13 A. Again there was some comfort in the fact that  
 14 our diagnosis were correlating well, but again  
 15 we only had -- from what I know now, there may  
 16 have actually been more, but only about four  
 17 or five cases that I was aware of.  
 18 MS. NEWBURY:  
 19 Q. And you can't say today whether any of them  
 20 was actually ER negative?  
 21 DR. COOK:  
 22 A. No. What I would have been looking for would  
 23 have been conversations that I had with  
 24 oncology because how that particular case came  
 25 up with that variation was a phone call, I

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1 believe, from Dr. Laing at that particular  
 2 time and she picked up the discrepancy. At  
 3 that particular time, the cases weren't  
 4 confined to St. John's, it was throughout the  
 5 whole of the province, and I remember asking  
 6 her were there any other issues that she had  
 7 concerning the quality reports. I may have  
 8 even said ER/PR at that time. So there was no  
 9 issues that she had concerning the quality of  
 10 the reports. Therefore, most of those reports  
 11 province-wide would have been channelled  
 12 through oncology.  
 13 MS. NEWBURY:  
 14 Q. Uh-hm.  
 15 DR. COOK:  
 16 A. So had there been again a widespread problem,  
 17 I'm sure oncology would have picked it up and  
 18 notified us. This is where -- they were the  
 19 focal point in all of this back in 2000/2001.  
 20 COMMISSIONER:  
 21 Q. Ms. Newbury, it's near the luncheon break, so  
 22 wherever there's a convenient spot we'll break  
 23 for the lunch.  
 24 MS. NEWBURY:  
 25 Q. I just have a couple of more points on this

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

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1 Q. Right, and that's the four to five that you're  
 2 talking about, or the 33?  
 3 DR. COOK:  
 4 A. The 33 would have originated province-wide,  
 5 and only one or two of those ERs and PRs, I  
 6 believe, would have originated from St.  
 7 Clare's.  
 8 MS. NEWBURY:  
 9 Q. Okay.  
 10 DR. COOK:  
 11 A. Again I can't be absolutely sure of the  
 12 figures.  
 13 MS. NEWBURY:  
 14 Q. But in terms of the program now of quality  
 15 assurance specifically for ER/PR testing,  
 16 would that sample be large enough to give you  
 17 comfort that --  
 18 DR. COOK:  
 19 A. You mean four or five cases?  
 20 MS. NEWBURY:  
 21 Q. Yes.  
 22 DR. COOK:  
 23 A. No, but at that particular time, thinking  
 24 back, I was thinking back to the 33 and --  
 25 MS. NEWBURY:

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1 Q. You're just thinking there was no red flag at  
 2 that time?  
 3 DR. COOK:  
 4 A. There was no red flag at that particular time,  
 5 and the other area I was thinking of at that  
 6 time, what was going on in tumour board  
 7 rounds. These are where we have our  
 8 pathologists, oncologists, and surgeons  
 9 attending these board rounds, and was there  
 10 any issues regarding the quality of the ER/PR  
 11 reports, and how the patients were responding  
 12 to treatment because that's one of the big  
 13 clinical indicators, and are your ER/PR  
 14 negative patients responding as they should,  
 15 or are your ER/PR positive patients responding  
 16 as they should. So that would be a forum if  
 17 there was a concern from oncologists to notify  
 18 our pathologists and we would then take a  
 19 review.  
 20 MS. NEWBURY:  
 21 Q. And in terms of the response by a patient, is  
 22 that the only method that you're aware of that  
 23 oncologists would have to compare the clinical  
 24 response of the patient?  
 25 DR. COOK:

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

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1 because one of the other big differentials  
2 could be small cell carcinoma. So those are  
3 sort of the questions that we would be banging  
4 around to look at the correlation between our  
5 histology, radiology, and clinical outcomes.  
6 MS. NEWBURY:  
7 Q. And in terms of the ER/PR testing, in  
8 particular, do you know how quickly an  
9 oncologist might be able to make that decision  
10 whether or not the ER/PR result is actually  
11 consistent with how -- with the clinical  
12 observations of the oncologist, or would there  
13 be a delay because you can't watch the tumour  
14 over three months and see whether or not it's  
15 reacting as you expect based on your ER/PR  
16 results?  
17 DR. COOK:  
18 A. There could be a delay. The big problem I find  
19 too with oncology is that they were in the  
20 same boat as we were. You had this high  
21 turnover of oncologists over that time period.  
22 I think the time period we're talking about is  
23 anywhere around 25 oncologists. So if we had  
24 been able to maintain a stable population of  
25 oncologists, maybe they would have picked up

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1 some trends and notified us.  
2 MS. NEWBURY:  
3 Q. And do you actually know if they have  
4 information available. You've mentioned that  
5 they might be able to look at some of the  
6 information about the types of cancers and  
7 procedures?  
8 DR. COOK:  
9 A. I don't know for sure. You'll have to ask the  
10 oncology.  
11 MS. NEWBURY:  
12 Q. So that's not something you relied upon as  
13 being a given fact that oncologists have this  
14 information, we can take some comfort from  
15 that, they're going to be tracking trends and  
16 looking for discrepancies?  
17 DR. COOK:  
18 A. Well, that's something we may be again doing  
19 now as a result of this whole issue, but I  
20 don't know how much tracking of trends the  
21 oncologists have. I mean, they again were in  
22 much the same boat as we were.  
23 MS. NEWBURY:  
24 Q. Sure. Thank you. This is a good time to  
25 break.

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1 COMMISSIONER:  
2 Q. Okay. We'll break until 10 after 2.  
3 (LUNCH BREAK)  
4 COMMISSIONER:  
5 Q. Ms. Newbury.  
6 MS. NEWBURY:  
7 Q. Good afternoon, Dr. Cook. Just a quick  
8 question on the Cleveland Medical Clinic cases  
9 again before I continue. Did you indicate  
10 that the review was conducted of the slides  
11 that had already been originally prepared by  
12 pathologists at Eastern Health or Health Care  
13 Corporation of St. John's?  
14 DR. COOK:  
15 A. That's correct. It's my understanding we  
16 issued the interpretations and they went out  
17 as final reports. When Cleveland would review  
18 them, they would review the pathology reports  
19 and the histological slides and issue their  
20 own report.  
21 MS. NEWBURY:  
22 Q. Okay. So you're not aware that they did any  
23 new slides themselves?  
24 DR. COOK:  
25 A. No, I'm not aware.

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1 MS. NEWBURY:  
2 Q. The week before last Dr. Mullen was here and  
3 testified, and indicated that he had expected  
4 that the pathologists at Eastern Health would  
5 review cases and confirm his opinion before  
6 issuing a report.  
7 DR. COOK:  
8 A. Uh-hm.  
9 MS. NEWBURY:  
10 Q. I'm just wondering if that's the procedure  
11 that was followed by you, and to your  
12 knowledge, other pathologists -- or any other  
13 pathologists at Eastern Health?  
14 DR. COOK:  
15 A. No, that wasn't the case in this particular  
16 issue. Normally we do when consults come back  
17 from, you know, such places as the Mayo Clinic  
18 and AFIP, usually we have a second set of  
19 slides that we make a copy of. So reports  
20 come back, we review the slides, and we  
21 correlate with what the Mayo people of the AFI  
22 people say, but in this particular case  
23 because of the magnitude of the volumes, and  
24 we also had faith in Dr. Mullen, we put the  
25 results directly into the computer system.

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1 MS. NEWBURY:  
 2 Q. Okay. So that's for the retrospect of review,  
 3 just for --  
 4 DR. COOK:  
 5 A. That's for the retrospect of review.  
 6 MS. NEWBURY:  
 7 Q. So there was no actual review just to compare  
 8 his report with the slides that they prepared  
 9 to --  
 10 DR. COOK:  
 11 A. No, we were quite confident in him and his  
 12 ability.  
 13 MS. NEWBURY:  
 14 Q. Did you have any discussions with Dr. Mullen  
 15 about this at the time, about what the  
 16 procedure would be, were you aware of what his  
 17 expectations might have been in this regard?  
 18 DR. COOK:  
 19 A. My point person was Maria Mendes and Dr.  
 20 Pritzker. I just looked at Dr. Mullen as  
 21 providing a completely objective view and I  
 22 wanted an objective opinion from him.  
 23 MS. NEWBURY:  
 24 Q. And you didn't have any discussions with Maria  
 25 Mendes or Dr. Pritzker in that regard either,

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

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1 Q. Okay.  
 2 DR. COOK:  
 3 A. And then we would ask questions of Dr. Mullen  
 4 regarding that, but not an overall general  
 5 review of the Mount Sinai cases.  
 6 MS. NEWBURY:  
 7 Q. So in a situation where you had two different  
 8 slides with conflicting results from Mount  
 9 Sinai, you would review the slide, but --  
 10 DR. COOK:  
 11 A. We didn't have the slides back, but I would e-  
 12 mail Dr. Mullen as to what his -- his  
 13 explanation of discrepancy.  
 14 MS. NEWBURY:  
 15 Q. Didn't you get the slides back at the end of  
 16 the --  
 17 DR. COOK:  
 18 A. We got them back at the end of the review.  
 19 MS. NEWBURY:  
 20 Q. Okay, and that would have been in about  
 21 February, 2006, or was it later than that?  
 22 DR. COOK:  
 23 A. It was certainly after the review had been  
 24 completed. I can't tell you the exact date we  
 25 got back the slides.

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



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

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1 handwritten notes, I understand, dated July  
 2 22nd, 2005, from a call to Dr. Ann O'Brien in  
 3 St. John, New Brunswick, and -- I'm just going  
 4 to scroll down to the bottom of the page. On  
 5 the last line it says, "Uses ASCP checkpath  
 6 sample and proficiency testing".  
 7 DR. COOK:  
 8 A. Uh-hm.  
 9 MS. NEWBURY:  
 10 Q. And what was your understanding at that time  
 11 as to what that was all about?  
 12 DR. COOK:  
 13 A. I think that was in regards to the  
 14 interpretation because ASCP checkpath is what  
 15 we also use in evaluating our pathology  
 16 interpretations. They would send up slides  
 17 which are already stained with H & E staining  
 18 and ask us for our interpretation, and we  
 19 would send the interpretation on an antraciet  
 20 (phonetic) and fax those down to ASCP, and  
 21 they would be correlated with other labs.  
 22 MS. NEWBURY:  
 23 Q. Okay, and was that the only quality assurance  
 24 activity that you discussed with Dr. O'Brien  
 25 at that time?

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1 DR. COOK:  
 2 A. I believe so. I mean, to the best of my  
 3 knowledge, that was the only one that I  
 4 discussed.  
 5 MS. NEWBURY:  
 6 Q. And can you recall if that related  
 7 specifically to ER/PR testing?  
 8 DR. COOK:  
 9 A. I may have asked her what she has in the way  
 10 of external proficiency testing. So that  
 11 could have come up in that conversation.  
 12 MS. NEWBURY:  
 13 Q. Okay, for ER/PR testing?  
 14 DR. COOK:  
 15 A. Well, not necessarily for ER and PR, what did  
 16 she have in her lab in general.  
 17 MS. NEWBURY:  
 18 Q. So you don't know then whether or not they  
 19 might be in the same situation as your lab  
 20 where you don't have anything that relates  
 21 specifically to ER/PR testing at the time?  
 22 DR. COOK:  
 23 A. I can't say for sure. They may and they may  
 24 not, I can't say.  
 25 MS. NEWBURY:

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1 Q. If I can bring up Exhibit P-01998, please, and  
 2 this is your notes of a call. I think it's  
 3 the 21st there of July. I think that's what  
 4 you indicated last week.  
 5 DR. COOK:  
 6 A. Uh-hm.  
 7 MS. NEWBURY:  
 8 Q. Laurette Guldahays, and she's with Halifax, I  
 9 think you indicated?  
 10 DR. COOK:  
 11 A. That's correct.  
 12 MS. NEWBURY:  
 13 Q. I don't see anything there about any quality  
 14 assurance or external proficiency testing.  
 15 DR. COOK:  
 16 A. No.  
 17 MS. NEWBURY:  
 18 Q. Can you recall if you would have discussed  
 19 that with Dr. Guldahays at that time?  
 20 DR. COOK:  
 21 A. I probably did discuss that with her and asked  
 22 her what they had in that regard, or whether  
 23 they had a medical director or what not. I  
 24 know for a period of time in Halifax that they  
 25 were without a medical director of

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1 immunohistochemistry, but they eventually got  
 2 an individual to oversee that operation. She  
 3 did get back to me with her positivity rates,  
 4 by the way, about a week or so later.  
 5 MS. NEWBURY:  
 6 Q. Right.  
 7 DR. COOK:  
 8 A. But I can't really comment on what they have  
 9 in the way of quality assurance or what not.  
 10 MS. NEWBURY:  
 11 Q. Okay. Exhibit P-01933, please. I'm going to  
 12 refer you to the second page here.  
 13 DR. COOK:  
 14 A. Uh-hm.  
 15 MS. NEWBURY:  
 16 Q. Which is a call that you made on the 28th of  
 17 July, 2005. This is to Dr. Norman Pettigrew  
 18 with HSC in Winnipeg.  
 19 DR. COOK:  
 20 A. Uh-hm.  
 21 MS. NEWBURY:  
 22 Q. And I just wanted to show you that to give you  
 23 a chance to look there because I'm looking for  
 24 anything that relates to quality assurance or  
 25 external proficiency testing. I couldn't see

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1 anything there myself, but --  
 2 DR. COOK:  
 3 A. That's not to say he hadn't, but it just  
 4 didn't come up in the conversation. I  
 5 probably would have been interested more on  
 6 his knowledge in general, if he knew what was  
 7 happening across Canada in terms of trends and  
 8 what not, and zeroing on such things as  
 9 positivity rates at the time.  
 10 MS. NEWBURY:  
 11 Q. And why was that? Why would you focus on  
 12 positivity rates and not on something like  
 13 quality assurance?  
 14 DR. COOK:  
 15 A. Well, because we were -- if you look at our  
 16 positivity rates that Mr. Gulliver had  
 17 supplied, I mean, we were pretty much in the  
 18 ball park. We identified a fair number of  
 19 problems and issues within the program, and  
 20 that was one of the points that I made to the  
 21 Executive of the CAP that when we went around  
 22 the table, people were talking about  
 23 positivity rates, and I said be careful of  
 24 placing too much reliance on positivity rates,  
 25 they don't tell the whole story.

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1 MS. NEWBURY:  
 2 Q. Uh-hm.  
 3 DR. COOK:  
 4 A. So, you know -- because initially, I thought  
 5 we were in the ball park with 73 or 74  
 6 percent, but we soon found out we had quite a  
 7 number of issues and problems.  
 8 MS. NEWBURY:  
 9 Q. So you were aware at the time that positivity  
 10 rates wouldn't tell the whole story?  
 11 DR. COOK:  
 12 A. Well, at that time I was placing some emphasis  
 13 on positivity rates, but as you're gone  
 14 further into the process, that wasn't the  
 15 case.  
 16 MS. NEWBURY:  
 17 Q. What was your understanding as of that period  
 18 of time, the last ten days or so of July, as  
 19 to what quality assurance was in place in the  
 20 lab that related specifically to ER/PR  
 21 testing?  
 22 DR. COOK:  
 23 A. Well, we had very little in relation to the  
 24 ER/PR testing. As I said earlier, any time we  
 25 did immunoperoxidase stains, we always sent

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1 those out as part of a package with the H & E  
 2 stains and with the interpretation for outside  
 3 institutions. Sometimes we would send out the  
 4 stains themselves along with the H & E stains  
 5 to have a consultant look at the stains and  
 6 give an interpretation, or sometimes we would  
 7 hold off on the stains and send out the  
 8 paraffin block and let the consultant decide  
 9 what type of stains he would order in order to  
 10 make his or her interpretation.  
 11 MS. NEWBURY:  
 12 Q. Uh-hm, but -- and you were aware at that time,  
 13 the last part of July, 2005, that that was the  
 14 state of affairs, you weren't under any notion  
 15 that they had external proficiency testing  
 16 that might relate specifically to ER/PR?  
 17 DR. COOK:  
 18 A. Not specifically to ER/PR.  
 19 MS. NEWBURY:  
 20 Q. And would it not have told, I guess, the other  
 21 part of the story at that time, to find out  
 22 what other labs may or may not have been doing  
 23 for quality assurance, and in particular,  
 24 whether or not they were using external  
 25 proficiency testing for ER/PR?

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<p>1 DR. COOK:</p> <p>2 A. Possibly, but at that particular time, I was</p> <p>3 trying to get a handle on did anybody have</p> <p>4 issues concerning ER and PR across the</p> <p>5 country.</p> <p>6 MS. NEWBURY:</p> <p>7 Q. Right.</p> <p>8 DR. COOK:</p> <p>9 A. Much the same way as we had, and had anybody</p> <p>10 gone back over five, six, seven year period to</p> <p>11 do reviews. So I was basically telling these</p> <p>12 individuals what I had found the review had</p> <p>13 done, and could they comment on anything</p> <p>14 similar to this happening across the country,</p> <p>15 across the United States.</p> <p>16 MS. NEWBURY:</p> <p>17 Q. I guess what I'm curious about is that if you</p> <p>18 found out that other labs tended to have very</p> <p>19 rigorous programs of external proficiency</p> <p>20 testing, that might actually decrease the</p> <p>21 chance that they would have a problem, or if</p> <p>22 they had a problem, it was short-lived, it was</p> <p>23 picked up and rectified?</p> <p>24 DR. COOK:</p> <p>25 A. Possibly, but there is problems with</p>	<p>1 of American Pathologists are in the process</p> <p>2 now of looking at that and trying to address</p> <p>3 those concerns.</p> <p>4 MS. NEWBURY:</p> <p>5 Q. Uh-hm, but that's not something that you were</p> <p>6 focused on at that time?</p> <p>7 DR. COOK:</p> <p>8 A. No, I was not aware of that at the time.</p> <p>9 That's more information that came to light</p> <p>10 with -- the further I dealt into the issue.</p> <p>11 MS. NEWBURY:</p> <p>12 Q. I wonder if I could have Exhibit P-01996,</p> <p>13 please. This is your call to Dr. Dogan, who</p> <p>14 as I understand your evidence, he had been</p> <p>15 with NEQAS in the UK?</p> <p>16 DR. COOK:</p> <p>17 A. Yes, I believe he was with the UK group.</p> <p>18 MS. NEWBURY:</p> <p>19 Q. And he was now at the Mayo Clinic?</p> <p>20 DR. COOK:</p> <p>21 A. Yeah.</p> <p>22 MS. NEWBURY:</p> <p>23 Q. And he indicates here, and you discussed this</p> <p>24 last week, I believe, that he has ID'd a huge</p> <p>25 variability in staining and report?</p>
<p>1 proficiency testing.</p> <p>2 MS. NEWBURY:</p> <p>3 Q. Okay.</p> <p>4 DR. COOK:</p> <p>5 A. And I found out later proficiency testing may</p> <p>6 or may not have picked up our problem,</p> <p>7 particularly the CAP. One of the issues that</p> <p>8 we were concerned about in the Committee of</p> <p>9 Immunohistochemistry is how reliable is the</p> <p>10 CAP proficiency testing because you tend to</p> <p>11 compare one lab to another lab, and the</p> <p>12 emphasis is not necessarily on accuracy, but</p> <p>13 whether you produce a stain. So the problem</p> <p>14 is do you compare all labs to a central</p> <p>15 source. So you may have, say, 70 percent of</p> <p>16 your labs, and which we could be in that 70</p> <p>17 percent group comparing our stains to one</p> <p>18 another, but the actual and most accurate</p> <p>19 number of labs could be the 30 percent</p> <p>20 outliers.</p> <p>21 MS. NEWBURY:</p> <p>22 Q. Uh-hm.</p> <p>23 DR. COOK:</p> <p>24 A. So there are issues and problems with CAP with</p> <p>25 proficiency testing, and I think the College</p>	<p>1 DR. COOK:</p> <p>2 A. That's correct.</p> <p>3 MS. NEWBURY:</p> <p>4 Q. Okay, and up above, he says that they have no</p> <p>5 idea whether they are over calling or under</p> <p>6 calling?</p> <p>7 DR. COOK:</p> <p>8 A. That's correct.</p> <p>9 MS. NEWBURY:</p> <p>10 Q. And indicated as well that he perceived that</p> <p>11 to be a huge problem.</p> <p>12 DR. COOK:</p> <p>13 A. Yeah.</p> <p>14 MS. NEWBURY:</p> <p>15 Q. Did you have any discussion with him at that</p> <p>16 time whether they had any quality assurance</p> <p>17 programs or external proficiency programs?</p> <p>18 DR. COOK:</p> <p>19 A. No, I was actually shocked by that</p> <p>20 conversation. I appreciated the fact that he</p> <p>21 was quite open and frank and told me the</p> <p>22 issues that he saw at the Mayo Clinic. I</p> <p>23 mean, the Mayo Clinic is one of the top notch</p> <p>24 medical centres in the United States, and</p> <p>25 having disclosed that information to me, it</p>

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

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1 outside of --  
 2 DR. COOK:  
 3 A. Mostly Canadian standards, but again in  
 4 talking to various individuals in  
 5 immunohistochemistry, and I had a chance to  
 6 talk to one individual, in particular, the  
 7 feeling is the problem may be worse in the  
 8 United States than in Canada.  
 9 MS. NEWBURY:  
 10 Q. Okay. And were these just general comments or  
 11 did you actually canvas with each of these  
 12 individuals that you called, and you'd also  
 13 spoken to Mr. Lath Dabbagah in Edmonton --  
 14 DR. COOK:  
 15 A. Uh-hm.  
 16 MS. NEWBURY:  
 17 Q. Did you actually canvas with each of them what  
 18 antibodies were they using, what  
 19 concentration?  
 20 DR. COOK:  
 21 A. No, I didn't get into that depth of the  
 22 conversation. These were general comments  
 23 made by a large variety of people about the  
 24 lack of standardization in Canada, and also,  
 25 you know, reviewing the literature, quite a

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

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

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1 A. Um-hm.  
 2 CROSBIE, Q.C.:  
 3 Q. And she was a lady 46 years old when she  
 4 passed away. She was diagnosed in 1998, he  
 5 told us, and we also had access to some of the  
 6 medical documents at the time. She tested ER  
 7 and PR negative here originally, after her  
 8 diagnosis. She went to Boston and was tested  
 9 positive in Boston. She came back here and  
 10 arrived here retested and decided that--found  
 11 that she was 50 percent positive for ER and 15  
 12 percent positive PR. She was treated by  
 13 various oncologists, a Dr. Wasil, a Dr.  
 14 Maghfoor. You may or may not remember those

1 people.  
 2 DR. COOK:  
 3 A. Maghfoor, I briefly remember.  
 4 CROSBIE, Q.C.:  
 5 Q. There's been a high turnover of oncologists as  
 6 well as pathologists.  
 7 DR. COOK:  
 8 A. Um-hm.  
 9 CROSBIE, Q.C.:  
 10 Q. And also Dr. Laing, who is more familiar to  
 11 us. She was started on Tamoxifen in October

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1 1999, after a round of chemotherapy, and  
 2 unfortunately died in March of 2000. Sir, was  
 3 this a sentinel case?  
 4 DR. COOK:  
 5 A. It should have been a case that I think should  
 6 have arose -  
 7 MR. BROWNE:  
 8 Q. Commissioner, perhaps Mr. Crosbie would be so  
 9 kind as to ask Mr. Cook, first of all, if he  
 10 actually was aware of this case and if he had  
 11 involvement in the case, was it brought to his  
 12 attention.  
 13 THE COMMISSIONER:  
 14 Q. My understanding is that he's--Mr. Crosbie can  
 15 correct me if I'm wrong. You're asking the  
 16 witness whether or not the case, as described,  
 17 amounts to a sentinel case?  
 18 CROSBIE, Q.C.:  
 19 Q. Correct.  
 20 THE COMMISSIONER:  
 21 Q. As opposed to the details of this particular  
 22 case? Did I get you wrong, Mr. Crosbie? I  
 23 think you're interested in whether or not  
 24 that--those details, if accepted, amounts to a  
 25 sentinel case?

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1 CROSBIE, Q.C.:  
 2 Q. That's the question at the moment.  
 3 THE COMMISSIONER:  
 4 Q. As far as I'm concerned, Mr. Browne, that's  
 5 acceptable. But we have to make sure we're  
 6 talking about the same sentinel case, in the  
 7 sense of the way it is used within Eastern  
 8 Health, I presume you're asking?  
 9 CROSBIE, Q.C.:  
 10 Q. Well, that's what I'm trying to explore.  
 11 THE COMMISSIONER:  
 12 Q. Yes, okay.  
 13 DR. COOK:  
 14 A. So what you're saying, Mr. Crosbie, if I  
 15 understand it, she was tested ER and PR  
 16 negative here at the Health Care Corporation,  
 17 went down to Boston and tested ER and PR  
 18 positive? I mean, that was basically the -  
 19 CROSBIE, Q.C.:  
 20 Q. And then came back here, was retested ER/PR  
 21 positive.  
 22 DR. COOK:  
 23 A. I mean, by and large, I mean, it should have  
 24 required a further investigation, further  
 25 questions.

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1 CROSBIE, Q.C.:

2 Q. Who should have initiated the further

3 investigation or questions?

4 DR. COOK:

5 A. Well, you look back to our situation back in

6 May of 2005, that was initiated by our

7 oncologists who then notified me, or the

8 clinical chief at the time.

9 CROSBIE, Q.C.:

10 Q. What about the pathologist who interpreted the

11 second time here in St. John's, would that

12 medical doctor have any professional

13 responsibility to initiate inquiries?

14 DR. COOK:

15 A. I think that individual should have notified

16 the clinical chief.

17 CROSBIE, Q.C.:

18 Q. You aren't aware of any such notification in

19 relation to this case or any other case, other

20 than the Deane case, were you?

21 DR. COOK:

22 A. That's correct.

23 CROSBIE, Q.C.:

24 Q. So then if the following people knew of the

25 conversion from false negative to positive,

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1 the three treating oncologists and the

2 pathologist who examined the specimen the

3 second time here in St. John's, all, if they

4 knew about this, had a responsibility to take

5 further steps?

6 DR. COOK:

7 A. Well, should have inquired further into it. I

8 mean, at least have done that.

9 CROSBIE, Q.C.:

10 Q. What would that involve?

11 DR. COOK:

12 A. That may involve, what I asked with Dr. Laing,

13 I mean, were there any other cases that you're

14 worried about? Was there a need to send off

15 any other cases that you were worried about to

16 an outside institution?

17 CROSBIE, Q.C.:

18 Q. Would the topic come up, "maybe we should do a

19 selective look back to see how our tests are

20 going"?

21 DR. COOK:

22 A. Possibly. I mean, I can't comment on the very

23 thought processes at that particular time, and

24 what those people were thinking.

25 CROSBIE, Q.C.:

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1 Q. When Dr. Ejeckam testified here, he told us

2 that he would have recommended a look back in

3 2003, but there was no sentinel case.

4 DR. COOK:

5 A. Um-hm.

6 CROSBIE, Q.C.:

7 Q. Might it be that if he knew of the Christine

8 Purcell case, he would have recommended a look

9 back in 2003?

10 DR. COOK:

11 A. Possibly. I can't say for sure.

12 CROSBIE, Q.C.:

13 Q. What makes for a sentinel case?

14 DR. COOK:

15 A. One that has an adverse effect that changes

16 the treatment recommendation and could result

17 in an altered outcome.

18 CROSBIE, Q.C.:

19 Q. Dr. Laing was the same oncologist who treated

20 Peggy Deane.

21 DR. COOK:

22 A. That's correct, I understand, yes.

23 CROSBIE, Q.C.:

24 Q. I suppose there might be other such cases,

25 sentinel cases, that were not reported either.

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1 DR. COOK:

2 A. It's possible, Mr. Crosbie. I simply don't

3 know.

4 CROSBIE, Q.C.:

5 Q. Sir, the Oxford Canadian Dictionary defines

6 botched as "bungled or spoiled work." The

7 press often refers to botched lab tests when

8 they cover this particular story. You may

9 have noticed that.

10 DR. COOK:

11 A. Um-hm.

12 CROSBIE, Q.C.:

13 Q. You had the results from Sinai back by the end

14 of January, 2006?

15 DR. COOK:

16 A. Most of them. We got some more results in

17 February of 2006.

18 CROSBIE, Q.C.:

19 Q. Certainly by the end of February?

20 DR. COOK:

21 A. Um-hm.

22 CROSBIE, Q.C.:

23 Q. You knew from that that the lab had around

24 half of the tests that you sent up to Sinai

25 wrong.

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1 DR. COOK:  
 2 A. It depends what your definition of wrong is,  
 3 Mr. Crosbie.  
 4 CROSBIE, Q.C.:  
 5 Q. They were false negatives.  
 6 DR. COOK:  
 7 A. What's the definition of false negative?  
 8 CROSBIE, Q.C.:  
 9 Q. You're the expert, sir. Why don't you explain  
 10 that?  
 11 DR. COOK:  
 12 A. Well, it depends on what your cutoff point is.  
 13 I mean, we had three different cutoff points  
 14 from 30 percent, down to ten percent, and if  
 15 you look at the technical cutoff, it's at  
 16 greater than one percent. So you may have  
 17 clinical cutoff and you have technical cutoff.  
 18 CROSBIE, Q.C.:  
 19 Q. Sir, we explored that with Dr. Mullen and if  
 20 the Registrar would, please, bring up page  
 21 three--first of all, page 320, if you would,  
 22 please? Actually -  
 23 THE COMMISSIONER:  
 24 Q. Sorry, did you want to change the number?  
 25 Page 320 you wanted? I just -

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1 REGISTRAR:  
 2 Q. I think he's looking for the transcript of Dr.  
 3 Mullen. Is it June 27th transcript?  
 4 CROSBIE, Q.C.:  
 5 Q. June 27th, page 319 will do for a starter.  
 6 THE COMMISSIONER:  
 7 Q. Was it--did you say clinical and technical cut  
 8 off when you were answering Mr. Crosbie, Dr.  
 9 Cook?  
 10 DR. COOK:  
 11 A. Clinical and technical cutoffs.  
 12 THE COMMISSIONER:  
 13 Q. And technical, I think you referred to last  
 14 week, clinical was the 30 and the 10, correct?  
 15 DR. COOK:  
 16 A. 30 and the 10, Commissioner, yes.  
 17 THE COMMISSIONER:  
 18 Q. And the technical would be the -  
 19 DR. COOK:  
 20 A. Greater than one percent.  
 21 THE COMMISSIONER:  
 22 Q. - greater than one, thank you. Now there's  
 23 your excerpt, I think, Mr. Crosbie.  
 24 CROSBIE, Q.C.:  
 25 Q. Thank you. So we see here that I asked Dr.

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1 Mullen about the percentages of positivity in  
 2 the retrospective cases that he did.  
 3 DR. COOK:  
 4 A. Um-hm.  
 5 CROSBIE, Q.C.:  
 6 Q. And he says "let me look at my cards," and  
 7 there's a bit more there, and then if we go  
 8 over to 320, if you would, Registrar? He gets  
 9 down to around line seven and he says "so in  
 10 my classification, I would have ER negative of  
 11 46.3, ER positive of 53.7. Using Eastern  
 12 Health criteria, I would have 53.2 percent  
 13 negative and 46.8 percent positive," he says  
 14 at line 13. So it would seem that he's got  
 15 both statistics available. His classification  
 16 would be his cutoff criteria and Eastern  
 17 Health criteria would be your cutoff criteria.  
 18 DR. COOK:  
 19 A. Well, the two--and again, two different  
 20 criteria you want to use. I mean, do you use  
 21 your clinical criteria, which we use at 10 and  
 22 30 percent, or the technical criteria at one  
 23 percent. So there was variations in labs and  
 24 how they report conversion rates, based on  
 25 different cutoffs.

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1 CROSBIE, Q.C.:  
 2 Q. Sir, do you wish to dispute that you had about  
 3 a 50 percent false negative rate?  
 4 DR. COOK:  
 5 A. I think our false negative rate, based on  
 6 around 30 to--based on about 30 percent  
 7 cutoff, is around 30 to 33 percent.  
 8 CROSBIE, Q.C.:  
 9 Q. Do you accept the statistics Dr. Mullen stated  
 10 and I just read?  
 11 DR. COOK:  
 12 A. I'm not sure I accept those statistics. I  
 13 mean, where were those statistics from?  
 14 CROSBIE, Q.C.:  
 15 Q. Well, we can only point to the transcript.  
 16 Maybe it's too late to take that up with Dr.  
 17 Mullen.  
 18 DR. COOK:  
 19 A. Um-hm.  
 20 CROSBIE, Q.C.:  
 21 Q. So why don't we leave it at this then, and  
 22 pass on, you dispute his statistics?  
 23 DR. COOK:  
 24 A. I'm not sure I'm happy with those statistics.  
 25 CROSBIE, Q.C.:

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1 Q. Very good. If he were right, would the press  
2 be right to call this a botched test?  
3 MR. SIMMONS:  
4 Q. Commissioner, I don't know what the probative  
5 value or the usefulness is of trying to assign  
6 a descriptive word like that here. That's not  
7 helping us explore anything that's (inaudible)  
8 the terms of reference of the Inquiry. It's  
9 just feeding information that might be  
10 intended for another audience on another day.  
11 THE COMMISSIONER:  
12 Q. Mr. Crosbie?  
13 CROSBIE, Q.C.:  
14 Q. If I may, Commissioner, I represent a group of  
15 people, many of whom have been grievously  
16 injured by the activities that you've been  
17 mandated to look into. I always thought that  
18 cross-examination involved confrontation and  
19 that's what I'm doing.  
20 THE COMMISSIONER:  
21 Q. I agree that one has a great deal of liberty  
22 on cross-examination, but frankly, whether or  
23 not one describes it--put it this way, it's of  
24 more benefit to me to clarify what the numbers  
25 are than it is to characterize it by one word

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1 or another.  
2 CROSBIE, Q.C.:  
3 Q. Thank you, Commissioner.  
4 THE COMMISSIONER:  
5 Q. And I'm assuming at some point down the road,  
6 we will, in fact, have some clarification of  
7 the numbers, whether you use 30 percent, 10  
8 percent or otherwise.  
9 CROSBIE, Q.C.:  
10 Q. So, Dr. Cook, Sinai received only blocks and  
11 slides from cases that were characterized as  
12 negative here?  
13 DR. COOK:  
14 A. That's correct.  
15 CROSBIE, Q.C.:  
16 Q. When Dr. Mullen talks about Sinai cutoffs and  
17 he states 46.3 percent and 53.7, I took it  
18 that he meant the cutoffs that Mount Sinai had  
19 in effect at the relevant period of time that  
20 the slide fit into. Is that what you would  
21 assume?  
22 DR. COOK:  
23 A. Well, I mean, you apply those same cutoffs to  
24 our situation.  
25 CROSBIE, Q.C.:

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1 Q. I thought he applied your cutoffs to your  
2 situation.  
3 DR. COOK:  
4 A. We looked at cutoffs of 30 percent, 10 percent  
5 and also a technical cutoff of greater than  
6 one percent.  
7 CROSBIE, Q.C.:  
8 Q. Yes, and why is it you think his numbers are  
9 wrong?  
10 DR. COOK:  
11 A. Well -  
12 CROSBIE, Q.C.:  
13 Q. He seemed to be pretty adept with numbers when  
14 I was here.  
15 DR. COOK:  
16 A. Well, where did he get those numbers?  
17 CROSBIE, Q.C.:  
18 Q. Well, we don't have him here right now. We  
19 only have the transcripts, so we're going to  
20 have to move on, and I'm afraid -  
21 MR. BROWNE:  
22 Q. Commissioner -  
23 THE COMMISSIONER:  
24 Q. Mr. Browne?  
25 CROSBIE, Q.C.:

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1 Q. - we can't assist the Commissioner.  
2 MR. BROWNE:  
3 Q. Dr. Cook makes a good point. Mr. Crosbie had  
4 an opportunity of exploring that with Dr.  
5 Mullen when he was on the stand and did not.  
6 THE COMMISSIONER:  
7 Q. Mr. Browne, Mr. Crosbie has just indicated, I  
8 understood, that since we don't have the  
9 numbers, he's moving on until he presumably  
10 gets the numbers a little later down the road.  
11 Did I misunderstand you, Mr. Crosbie?  
12 CROSBIE, Q.C.:  
13 Q. I can't do anything to assist the Commission  
14 more than point to what Dr. Mullen told us in  
15 sworn evidence.  
16 THE COMMISSIONER:  
17 Q. Yes.  
18 CROSBIE, Q.C.:  
19 Q. He had a bunch of cards on the table in front  
20 of him. No one had asked him about these  
21 ratios before, and I stood up and I asked him,  
22 and there it is.  
23 THE COMMISSIONER:  
24 Q. All right. Can I interject here though? Dr.  
25 Cook, you said you thought the false negative



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1 rate, based on 30 percent, is 33 percent?

2 DR. COOK:

3 A. Well, around 30 percent cutoff, the false--our

4 calculations were anywhere from about 24 up to

5 30 percent. Those were rough calculations

6 that we made.

7 THE COMMISSIONER:

8 Q. Is that assuming that all the cases that went

9 were cutoff at 30 percent?

10 DR. COOK:

11 A. There were cutoffs--no, if you assume that it

12 was 30 percent, it was probably around 30

13 percent conversion. If they were around ten

14 percent, it might be slightly lower than that.

15 If it was around one percent, then you may be

16 talking something in the orders of 19 or 20

17 percent, rough. Those are rough calculations

18 that we had made.

19 THE COMMISSIONER:

20 Q. So are you saying that from the calculations

21 within Eastern Health, they never would have

22 been the numbers that Mr. Crosbie has given to

23 you?

24 DR. COOK:

25 A. That's what I'm saying.

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1 THE COMMISSIONER:

2 Q. All right.

3 DR. COOK:

4 A. The numbers that Mr. Crosbie are saying are

5 too high.

6 THE COMMISSIONER:

7 Q. Okay. That clarifies it for me. Thank you.

8 Mr. Crosbie.

9 CROSBIE, Q.C.:

10 Q. Yes. How many patients were in the group

11 between 30 percent and ten percent, do you

12 know?

13 DR. COOK:

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

15 CROSBIE, Q.C.:

16 Q. Would you look at--could you bring up Exhibit

17 P-1852, please 3 please? I may have to, over

18 break, have a further look for this, but I

19 thought that we were told by Ms. Predham in

20 her sworn evidence in the answer that there

21 were only 13 patients in that category?

22 DR. COOK:

23 A. Ms. Predham had all the numbers. She was the

24 one that kept the tab on the numbers, I mean,

25 I was just concerned with supplying the

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1 information to panelling process and setting

2 up a process to get the cases retested.

3 CROSBIE, Q.C.:

4 Q. Okay, I may have to come back to that after we

5 get a break. While we're on the transcript of

6 Dr. Mullen, can we go back to page 31A please?

7 And at line, at around line 8, I'm asking Dr.

8 Mullen, "Is optimizing something which is

9 optional?" And he says at 15, "It is

10 mandatory". And at 19, "It is not optional."

11 DR. COOK:

12 A. Uh-hm.

13 CROSBIE, Q.C.:

14 Q. Do you agree with him, sir?

15 DR. COOK:

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

17 as possible.

18 CROSBIE, Q.C.:

19 Q. Sir, would you agree that if a lab is not

20 going to optimize, then it shouldn't be doing

21 the test?

22 DR. COOK:

23 A. Well that depends, now you have to speak to

24 our technical people on that, those were

25 individuals who were involved in the

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1 optimization of the antibodies, the antibody

2 concentrations, incubation times, so that was

3 mainly at a technical aspect of the lab.

4 CROSBIE, Q.C.:

5 Q. Optimizing then I take it is not something

6 that you take responsibility for, as either

7 site chief or clinical chief?

8 DR. COOK:

9 A. No, I see optimizing mainly as a technical

10 component involving the technical aspect of

11 the Laboratory Medicine Program.

12 CROSBIE, Q.C.:

13 Q. Do you have any opinion on that statement, if

14 you're not going to optimize, then don't do

15 the test?

16 DR. COOK:

17 A. Well you'd have to talk to our technical

18 people regarding that.

19 CROSBIE, Q.C.:

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

21 DR. COOK:

22 A. Well I think optimizing should be done, but

23 again, that's a technical opinion and you'll

24 have to speak to our technical people on it.

25 CROSBIE, Q.C.:

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1 Q. That's out of your sphere of expertise?  
 2 DR. COOK:  
 3 A. Yes.  
 4 CROSBIE, Q.C.:  
 5 Q. Overall, Dr. Mullens seemed to be of the  
 6 opinion that the majority of slides which he  
 7 reviewed were technically poor?  
 8 DR. COOK:  
 9 A. Well that's his opinion.  
 10 CROSBIE, Q.C.:  
 11 Q. You reviewed a lot of these slides yourself,  
 12 what was your opinion?  
 13 DR. COOK:  
 14 A. My opinion is that most of those slides were  
 15 interpretable, they were all interpretable,  
 16 there were varying degrees of fixation  
 17 artifacts there, some of the slides was  
 18 probably less than five percent of the surface  
 19 area, some of the areas are up to about 20  
 20 percent.  
 21 CROSBIE, Q.C.:  
 22 Q. Did Dr. Carter seem to be of the opinion that  
 23 the slides were technically poor?  
 24 DR. COOK:  
 25 A. I believe she felt they were technically poor.

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1 CROSBIE, Q.C.:  
 2 Q. Was Dr. Banerjee of that opinion?  
 3 DR. COOK:  
 4 A. Yes.  
 5 CROSBIE, Q.C.:  
 6 Q. And broadly speaking, you, as well?  
 7 DR. COOK:  
 8 A. Certain slides I felt were technically poor,  
 9 yes.  
 10 CROSBIE, Q.C.:  
 11 Q. Dr. Mullen thought some slides should not have  
 12 been reported at all.  
 13 DR. COOK:  
 14 A. Uh-hm.  
 15 CROSBIE, Q.C.:  
 16 Q. Do you disagree with him on that?  
 17 DR. COOK:  
 18 A. Well I would have to look at the slides that  
 19 he's talking about.  
 20 CROSBIE, Q.C.:  
 21 Q. You may not have seen those particular slides?  
 22 DR. COOK:  
 23 A. No, I may not have.  
 24 CROSBIE, Q.C.:  
 25 Q. Is it fair to say Dr. Mullen thinks that

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1 quality control is mandatory?  
 2 DR. COOK:  
 3 A. Quality control certainly in a technical  
 4 aspect of the lab is mandatory, yes.  
 5 CROSBIE, Q.C.:  
 6 Q. So you agree?  
 7 DR. COOK:  
 8 A. I agree.  
 9 CROSBIE, Q.C.:  
 10 Q. Is it fair to say Dr. Mullen thinks that  
 11 quality assurance is mandatory?  
 12 DR. COOK:  
 13 A. Yes.  
 14 CROSBIE, Q.C.:  
 15 Q. And you agree that it is mandatory?  
 16 DR. COOK:  
 17 A. I agree that it would.  
 18 CROSBIE, Q.C.:  
 19 Q. Dr. Cook, IHC was a sophisticated new lab  
 20 service which, of course, we instituted here  
 21 in 1997.  
 22 DR. COOK:  
 23 A. Oh it was here before that, Mr. Crosbie.  
 24 CROSBIE, Q.C.:  
 25 Q. Pardon me?

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1 DR. COOK:  
 2 A. The IHC was here before that.  
 3 CROSBIE, Q.C.:  
 4 Q. In relation to ER/PR, we instituted this  
 5 service in 1997.  
 6 DR. COOK:  
 7 A. In relation to ER/PR.  
 8 CROSBIE, Q.C.:  
 9 Q. And it was in the process of being, for that  
 10 purpose, adopted in North America and Europe  
 11 in this period.  
 12 DR. COOK:  
 13 A. Uh-hm.  
 14 CROSBIE, Q.C.:  
 15 Q. As the gold standard for doing these stains.  
 16 DR. COOK:  
 17 A. That's open to debate.  
 18 CROSBIE, Q.C.:  
 19 Q. It was thought to be superior to the method  
 20 that was being used here before.  
 21 DR. COOK:  
 22 A. The biochemical assay.  
 23 CROSBIE, Q.C.:  
 24 Q. Yes.  
 25 DR. COOK:

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1 A. But some regard the biochemical assay is a  
2 gold standard.  
3 CROSBIE, Q.C.:  
4 Q. What's your opinion?  
5 DR. COOK:  
6 A. My opinion is the IHC is superior in that we  
7 can actually identify the tumour cells that  
8 are staining with the stain.  
9 CROSBIE, Q.C.:  
10 Q. That must have been the consensus of all the  
11 pathologists here in 1997 because we know you  
12 adopted it.  
13 DR. COOK:  
14 A. Uh-hm.  
15 CROSBIE, Q.C.:  
16 Q. As a matter of good management practice, would  
17 you expect that a service assessment or cost  
18 benefit analysis would be informed to  
19 establish what resources would be needed  
20 before a lab embarked on a new service of this  
21 kind?  
22 DR. COOK:  
23 A. Uh-hm.  
24 CROSBIE, Q.C.:  
25 Q. That would be good practice?

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1 DR. COOK:  
2 A. I think that would be good practice.  
3 CROSBIE, Q.C.:  
4 Q. Management would want to know things like what  
5 training might be needed?  
6 DR. COOK:  
7 A. Uh-hm.  
8 CROSBIE, Q.C.:  
9 Q. What physical space was needed? What new  
10 equipment, maybe?  
11 DR. COOK:  
12 A. Uh-hm.  
13 CROSBIE, Q.C.:  
14 Q. The cost of that?  
15 DR. COOK:  
16 A. Uh-hm.  
17 CROSBIE, Q.C.:  
18 Q. Whether the pathology staff had the necessary  
19 expertise?  
20 DR. COOK:  
21 A. Uh-hm.  
22 CROSBIE, Q.C.:  
23 Q. Whether it would require professional time to  
24 be taken away from other lab services, these  
25 are all things you might want to know?

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1 DR. COOK:  
2 A. Uh-hm, and those were investigated, I believe,  
3 by the program director and clinical chief of  
4 the day.  
5 CROSBIE, Q.C.:  
6 Q. This is Dr. Khalifa?  
7 DR. COOK:  
8 A. No, that would be Dr. Haegert, I believe and  
9 Mr. Vern Whalen.  
10 CROSBIE, Q.C.:  
11 Q. There should be a budget drawn up.  
12 DR. COOK:  
13 A. Well the savings that you had from the  
14 biochemical assay would be transferred over to  
15 the division of anatomical pathology.  
16 CROSBIE, Q.C.:  
17 Q. That sounds nice, but how do you know?  
18 DR. COOK:  
19 A. Well I don't know for sure because I was  
20 relying on the management team at that  
21 particular time, the program director to  
22 handle the finances.  
23 CROSBIE, Q.C.:  
24 Q. So you wouldn't know unless a budget was done  
25 up?

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1 DR. COOK:  
2 A. Unless I saw the budget.  
3 CROSBIE, Q.C.:  
4 Q. Which you did or didn't?  
5 DR. COOK:  
6 A. I didn't see the budget.  
7 CROSBIE, Q.C.:  
8 Q. How do you know there's a budget?  
9 DR. COOK:  
10 A. Well it's a budget for the whole lab.  
11 CROSBIE, Q.C.:  
12 Q. Well I'm talking about a specific cost benefit  
13 analysis before this service, IHC for ER/PR  
14 was instituted, did you see a budget for that?  
15 DR. COOK:  
16 A. I didn't see the budget for that, but I mean,  
17 that would have been under the program  
18 director at the time.  
19 CROSBIE, Q.C.:  
20 Q. Well I haven't seen a budget for it in all the  
21 paperwork that we've been provided, it maybe  
22 that one of these good people behind me have  
23 and they can draw our attention to it, but I  
24 have not.  
25 DR. COOK:

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1 A. The money would have been transferred, I  
 2 think, from a savings that you had in the  
 3 biochemical assay over to the division of  
 4 immunology to account for the extra workload  
 5 in the IHC. That was my understanding at that  
 6 particular time.  
 7 CROSBIE, Q.C.:  
 8 Q. Is it desirable to know whether it would be  
 9 cheaper to refer out and pay a reference lab  
 10 to do the test?  
 11 DR. COOK:  
 12 A. The problem with that is you're dependant on a  
 13 reference lab, if they decide to cut your  
 14 services at any time, they could very well do  
 15 it.  
 16 CROSBIE, Q.C.:  
 17 Q. So you're vulnerable to the reference lab.  
 18 DR. COOK:  
 19 A. In some ways you are.  
 20 CROSBIE, Q.C.:  
 21 Q. Could you even maintain a residency program  
 22 without doing that service?  
 23 DR. COOK:  
 24 A. It would be difficult to maintain a residency  
 25 program if you're sending out the bulk of your

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1 work to an outside lab.  
 2 CROSBIE, Q.C.:  
 3 Q. Well we're just talking the bulk of this work,  
 4 but this is important work, isn't it?  
 5 DR. COOK:  
 6 A. It is important work, yes.  
 7 CROSBIE, Q.C.:  
 8 Q. If you didn't have that service at Eastern  
 9 Health, it might jeopardize the residency  
 10 program?  
 11 DR. COOK:  
 12 A. It's difficult to say, you would have to  
 13 depend on the Royal College Accreditors to  
 14 come in and make that assessment.  
 15 CROSBIE, Q.C.:  
 16 Q. It's not going to help though, is it?  
 17 DR. COOK:  
 18 A. It depends on what the accreditors say. If  
 19 you've got IHC in there, that's a favourable  
 20 item to have, just because you lose ER and PR,  
 21 it may or may not affect your accreditation  
 22 process, that's up to the accreditors.  
 23 CROSBIE, Q.C.:  
 24 Q. Dr. Cook, just assume for the moment that to  
 25 offer this new service for ER/PR involved a

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1 budgetary commitment of several extra hundred  
 2 thousand dollars, would that have to be routed  
 3 to the VP Medical for a final decision and  
 4 maybe the CEO?  
 5 DR. COOK:  
 6 A. Possibly, if it puts the program in debt to  
 7 that tune, there has to be an explanation why  
 8 the program is in debt, so that would go to  
 9 the VP.  
 10 CROSBIE, Q.C.:  
 11 Q. Could we bring up exhibit P-0121, it's the  
 12 review that you and Mr. Gulliver undertook,  
 13 October 13th, 2005.  
 14 DR. COOK:  
 15 A. Yes.  
 16 CROSBIE, Q.C.:  
 17 Q. Review of immunohistochemistry lab, General  
 18 Hospital site, St. John's, Eastern Health,  
 19 prepared for Dr. Williams, Vice-President. It  
 20 sets out an objective at page 2, if you would,  
 21 Registrar, item 1.2. And the objective is "to  
 22 identify the requirements needed to implement  
 23 a complete quality assurance program for the  
 24 IHC lab, ensure that we provide a standardized  
 25 and reliable service equivalent to the Mount

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1 Sinai reference lab in Toronto."  
 2 DR. COOK:  
 3 A. Uh-hm.  
 4 CROSBIE, Q.C.:  
 5 Q. And you were one of the authors of that  
 6 statement.  
 7 DR. COOK:  
 8 A. Uh-hm.  
 9 CROSBIE, Q.C.:  
 10 Q. Sir, the document is dated October, 2005, can  
 11 we just go to the very end of it, please?  
 12 Just perhaps the previous page. Somewhere in  
 13 here, I think you'll remember there's an added  
 14 budget proposed of--yes, there it is,  
 15 \$282,000?  
 16 DR. COOK:  
 17 A. Uh-hm.  
 18 CROSBIE, Q.C.:  
 19 Q. So in order to achieve the objective of  
 20 providing a service equivalent to the Mount  
 21 Sinai reference lab, it seemed that you were  
 22 running the lab up until this point in time a  
 23 couple thousand dollars short to be able to  
 24 achieve that.  
 25 DR. COOK:

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1 A. Yes.

2 CROSBIE, Q.C.:

3 Q. It would have been better to do the analysis

4 before the service was started or at least

5 before 2005, wouldn't it?

6 DR. COOK:

7 A. The analysis should have been done at the time

8 of '97, '98.

9 CROSBIE, Q.C.:

10 Q. I suggest to you, sir, it wasn't.

11 DR. COOK:

12 A. I can't be sure, Mr. Crosbie, that was done

13 by--that would have been done by the program

14 director of the day and the clinical chief of

15 the day.

16 CROSBIE, Q.C.:

17 Q. Sir, do you know what the look back cost?

18 DR. COOK:

19 A. Roughly ballpark figure, I'd say probably

20 around three hundred thousand, around there,

21 can't be absolutely sure on the exact amount.

22 CROSBIE, Q.C.:

23 Q. Who would know the exact amount?

24 DR. COOK:

25 A. I would say Mr. Terry Gulliver would know that

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1 amount and possibly the vice-president of

2 Medical Services.

3 THE COMMISSIONER:

4 Q. I'm sorry, the vice-president of which?

5 DR. COOK:

6 A. Medical Services.

7 THE COMMISSIONER:

8 Q. Thank you.

9 CROSBIE, Q.C.:

10 Q. Can we bring up document P-0697? These are

11 minutes of the Laboratory Program, 1997 03 04,

12 page 1, please?

13 DR. COOK:

14 A. Uh-hm.

15 CROSBIE, Q.C.:

16 Q. Could you go down to the bottom half of the

17 page, see the topic "Financial Issues"?

18 DR. COOK:

19 A. Yes.

20 CROSBIE, Q.C.:

21 Q. And we're seeing there that the lab at this

22 point in time was \$120,000 in the red?

23 DR. COOK:

24 A. That's what it looks like.

25 CROSBIE, Q.C.:

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1 Q. And if we go down to the final paragraph

2 beginning, "Mr. Whelan and Dr. Haegert:--it

3 seems that you were being asked or the lab was

4 being asked to save one million in the coming

5 year's budget.

6 DR. COOK:

7 A. Uh-hm.

8 CROSBIE, Q.C.:

9 Q. Now if we could go to document P-0698 please?

10 These are minutes from divisional manager's

11 meeting, 1997-06-24 and at the bottom of the

12 page, page 1, we see "Financial Issues". "The

13 '97/'98 budget is last year's actual, as

14 projected as of February minus \$700,000 that

15 was deducted from the total laboratory

16 budget."

17 DR. COOK:

18 A. Uh-hm.

19 CROSBIE, Q.C.:

20 Q. I take it from that that you had to run the

21 lab on \$700,000 less, that someone had fought

22 off the request to save a million, but you

23 still had to find a saving of \$700,000?

24 DR. COOK:

25 A. That's correct.

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1 CROSBIE, Q.C.:

2 Q. Dr. Cook, I'm suggesting there was no analysis

3 comparable to the one that you undertook with

4 Mr. Gulliver in October, 2005, setting out the

5 preconditions for a viable IHC service up to

6 par with Mount Sinai, that there is no such

7 analysis done before institution of the

8 service?

9 DR. COOK:

10 A. Mr. Crosbie, you have to ask the program

11 director and the clinical chief of the day

12 regarding -

13 CROSBIE, Q.C.:

14 Q. And I will, so let's assume it for the time

15 being and maybe I'll turn out to be wrong, but

16 if we assume that to be a fact, wouldn't that

17 put the lab at a disadvantage in dealing with

18 requests for budgetary cuts?

19 DR. COOK:

20 A. Oh absolutely.

21 CROSBIE, Q.C.:

22 Q. Because you can't come forward to the

23 authorities and say we can't give you that

24 money because if we do, we won't be able to

25 run this service up to snuff.

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1 DR. COOK:  
 2 A. Uh-hm.  
 3 CROSBIE, Q.C.:  
 4 Q. That's one of the reasons why you need a  
 5 proper financial analysis of the type we've  
 6 been talking about and which you did in  
 7 October, 2005?  
 8 DR. COOK:  
 9 A. Well yes, we did.  
 10 CROSBIE, Q.C.:  
 11 Q. I'd like to talk about DCIS for a minute.  
 12 DR. COOK:  
 13 A. Uh-hm.  
 14 CROSBIE, Q.C.:  
 15 Q. The lab was doing IHC staining for DCIS  
 16 patients and those are ductal carcinoma in  
 17 situ, non invasive patients, it would seem on  
 18 the advice of this panel that was established,  
 19 is that correct?  
 20 DR. COOK:  
 21 A. Well we didn't do, you mean in terms of the  
 22 immunoperoxidase, ER and PR on that test, on  
 23 that particular item?  
 24 CROSBIE, Q.C.:  
 25 Q. Uh-hm.

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1 DR. COOK:  
 2 A. We didn't, as a standard, perform ER and PR on  
 3 DCIS, unless we were requested to by the  
 4 oncologist.  
 5 CROSBIE, Q.C.:  
 6 Q. Prior to 2005?  
 7 DR. COOK:  
 8 A. Again, I can't say for sure what all  
 9 pathologists were doing, I know what we were  
 10 doing at St. Clare's, but there may be cases  
 11 where upon a request of an oncologist, for  
 12 whatever reason, there would be a request for  
 13 an ER/PR on a DCIS.  
 14 CROSBIE, Q.C.:  
 15 Q. I had understood there were 52 women--I assume  
 16 women, perhaps 52 patients who were DCIS and  
 17 who were tested and who it was proposed to  
 18 have retested; in other words, they tested  
 19 negative at Mount Sinai.  
 20 DR. COOK:  
 21 A. Uh-hm.  
 22 CROSBIE, Q.C.:  
 23 Q. Do you know whether that's true?  
 24 DR. COOK:  
 25 A. We had about fifty cases there. Again, I'm

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

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1 A. Could be.  
 2 CROSBIE, Q.C.:  
 3 Q. I'm sorry?  
 4 DR. COOK:  
 5 A. It could be, yes.  
 6 CROSBIE, Q.C.:  
 7 Q. Well, could it be or was it?  
 8 DR. COOK:  
 9 A. Well, I mean, some individual pathologists may  
 10 order that on a request from oncology or  
 11 surgeon, but I, in terms of what my practice  
 12 was at St. Clare's, we did not order ER and PR  
 13 on DCIS's. So I can't say what was happening  
 14 with other oncologists or other pathologists.  
 15 If an oncologist requests an ER and PR on a  
 16 DCIS, he or she usually has a reason.  
 17 CROSBIE, Q.C.:  
 18 Q. Could we go to Exhibit P-1896 please? 1898,  
 19 I'm sorry, P-1898. Dr. Cook, you, yourself,  
 20 served as a site chief and later as a clinical  
 21 chief.  
 22 DR. COOK:  
 23 A. Um-hm.  
 24 CROSBIE, Q.C.:  
 25 Q. This is a document originated from Dr.

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1 Khalifa, April 1999 and it's a sort of job  
 2 description entitled "some of my chores as a  
 3 site chief 1996 - 1999". And if we look  
 4 through that, he says that item number 3, for  
 5 example, he mentions preparing controls for  
 6 immunohistochemistry, troubleshooting with  
 7 failed tests and so forth. Five, Tuesday  
 8 conference as tool for the limited QA we have.  
 9 Preparing and following up on policies,  
 10 maintaining statistics.  
 11 DR. COOK:  
 12 A. Um-hm.  
 13 CROSBIE, Q.C.:  
 14 Q. And aide is missing breast, taken away uterus,  
 15 I guess specimens would, from time to time, go  
 16 missing.  
 17 DR. COOK:  
 18 A. Well, he would follow up on something like  
 19 that, yes.  
 20 CROSBIE, Q.C.:  
 21 Q. Well, what does he mean when he says at three,  
 22 "preparing controls for immunohistochemistry".  
 23  
 24 DR. COOK:  
 25 A. He would, say, pick out--if he had a tissue

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1 breast case with a high expression of ER and  
 2 PR for instance, he could very well submit  
 3 that for to be used as a control.  
 4 CROSBIE, Q.C.:  
 5 Q. What was the Tuesday conference which he says  
 6 "a tool for limited QA" -  
 7 DR. COOK:  
 8 A. I don't know what he's talking about there. I  
 9 can't be for sure what he's mention--this took  
 10 place at the general hospital site.  
 11 CROSBIE, Q.C.:  
 12 Q. Having served in a similar job, is that a  
 13 reasonable description of the chores of a site  
 14 chief?  
 15 DR. COOK:  
 16 A. Reasonable, I would say.  
 17 CROSBIE, Q.C.:  
 18 Q. Anything you care to add?  
 19 DR. COOK:  
 20 A. No, that's pretty well it.  
 21 CROSBIE, Q.C.:  
 22 Q. What about specifically in relation to ER/PR  
 23 testing?  
 24 DR. COOK:  
 25 A. Again, that would come under responding to

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1 technical problems.  
 2 CROSBIE, Q.C.:  
 3 Q. Could we now turn -  
 4 DR. COOK:  
 5 A. If he identified them.  
 6 CROSBIE, Q.C.:  
 7 Q. He identified them.  
 8 DR. COOK:  
 9 A. If he identified them.  
 10 CROSBIE, Q.C.:  
 11 Q. Could we turn to document P-1850, page two,  
 12 please. You see on page two he's talking  
 13 about phase two and he says, "this phase will  
 14 start March 1, 1998".  
 15 THE COMMISSIONER:  
 16 Q. Sorry, Mr. Crosbie, what is this document,  
 17 just to orient myself.  
 18 CROSBIE, Q.C.:  
 19 Q. I'm sorry, I did go straight to page two;  
 20 bring us back to page one, please. So,  
 21 Commissioner, you can see this is the  
 22 memorandum in which Dr. Khalifa described the  
 23 state of readiness of the program and  
 24 basically launched it.  
 25 THE COMMISSIONER:

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1 Q. Thank you.  
 2 CROSBIE, Q.C.:  
 3 Q. Page two, please. It's dated February 16,  
 4 1998 and at page two Dr. Khalifa is announcing  
 5 that starting March 1, 1998 immunostain slides  
 6 will be mailed back to each pathologists with  
 7 positive controls whenever it is technically  
 8 possible.  
 9 DR. COOK:  
 10 A. Um-hm.  
 11 CROSBIE, Q.C.:  
 12 Q. What does that mean, "whenever it's  
 13 technically possible"?  
 14 DR. COOK:  
 15 A. The problem was at that particular time there  
 16 was an issue of having controls sent with  
 17 every batch. The issue that arose was the  
 18 financial restraint that we were under at that  
 19 particular period of time and that because of  
 20 the financial restraint, the program basically  
 21 couldn't afford to sent positive controls with  
 22 every bath. So, in lieu of that, before the  
 23 cases went out, the positive controls would be  
 24 checked and verified by the site chief of the  
 25 General Hospital.

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1 CROSBIE, Q.C.:

2 Q. This is motivated by budgetary constraint?

3 DR. COOK:

4 A. Budgetary constraint, yes.

5 CROSBIE, Q.C.:

6 Q. So, he doesn't actually mean whenever it's

7 technically possible. He means financially

8 possible.

9 DR. COOK:

10 A. That was basically what it boiled down to.

11 CROSBIE, Q.C.:

12 Q. Sort of a euphanism.

13 DR. COOK:

14 A. Well, you could use that word.

15 CROSBIE, Q.C.:

16 Q. And he goes on to say "with each run, I will

17 still be responsible for reviewing the

18 positive controls here in our laboratory and

19 the slides will not be mailed to you unless

20 adequate staining is noted in the positive

21 controls".

22 DR. COOK:

23 A. Um-hm.

24 CROSBIE, Q.C.:

25 Q. So, what's he saying he's doing to do there?

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1 DR. COOK:

2 A. He's saying if you send out, if I get the

3 cases and I don't have a positive control,

4 then you make the assumption that he's

5 reviewed the positive controls before the

6 cases are gone out.

7 CROSBIE, Q.C.:

8 Q. He's saying, I will professionally guarantee

9 that the controls are in good order.

10 DR. COOK:

11 A. That's what he's saying.

12 CROSBIE, Q.C.:

13 Q. I will be responsible for reviewing positive

14 controls and slides will not be mailed without

15 adequate staining is what he's saying.

16 DR. COOK:

17 A. Well, he's going to check the controls and

18 make sure they work.

19 CROSBIE, Q.C.:

20 Q. And this is Dr. Khalifa's professional

21 guarantee that only adequately stained slides

22 would be released.

23 DR. COOK:

24 A. That's what he's saying.

25 CROSBIE, Q.C.:

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1 Q. So, the system was that one pathologist reads

2 all the controls at the lab, at the only lab

3 doing the IHC.

4 DR. COOK:

5 A. Um-hm.

6 CROSBIE, Q.C.:

7 Q. And the controls may or may not be provided to

8 the pathologist doing the interpretation of

9 the patient slide.

10 DR. COOK:

11 A. Well, if the controls are provided, then it's

12 a responsibility of the pathologist then to

13 verify those controls. So, it is possible

14 that the controls, say, would have gone over

15 to the Grace, the pathologist there would be

16 aware of the controls with the batch and they

17 would look the controls.

18 CROSBIE, Q.C.:

19 Q. No doubt. Dr. S. Parai succeeded Dr. Khalifa

20 as site chief at the Health Sciences in about

21 later 1999.

22 DR. COOK:

23 A. Yes.

24 CROSBIE, Q.C.:

25 Q. So, Dr. Parai must have taken responsibility

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1 for the adequacy of all these controls from

2 late 1999 to March 2005 when he ceased to

3 exercise the function of site chief.

4 DR. COOK:

5 A. I believe so, yes.

6 CROSBIE, Q.C.:

7 Q. So, if we want to look for responsibility for

8 the adequacy of positive controls from 1997 to

9 2005, we should look to the site chiefs

10 Khalifa and Parai.

11 DR. COOK:

12 A. I guess you can make that statement, yes.

13 CROSBIE, Q.C.:

14 Q. Thank you. I'd like to switch to Dr. Banerjee

15 for a moment. You told the Commissioner you

16 agree with basic conclusions of the Banerjee

17 report.

18 DR. COOK:

19 A. Um-hm.

20 CROSBIE, Q.C.:

21 Q. If the site chiefs were responsible for the

22 adequacy of controls, sir, they didn't seem to

23 do a very good job of it.

24 DR. COOK:

25 A. Site chief at the General Hospital site you



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1 mean?

2 CROSBIE, Q.C.:

3 Q. The ones who were responsible, Parai and

4 Khalifa, for guaranteeing the adequacy of the

5 controls.

6 DR. COOK:

7 A. Well, that's a matter of opinion, Mr. Crosbie.

8 I can't state for sure.

9 CROSBIE, Q.C.:

10 Q. It would seem to be Dr. Banerjee's opinion

11 because he was quite critical of the controls.

12 MR. SIMMONS:

13 Q. Commissioner, Dr. Banerjee, I think, spoke of

14 internal controls in the discussion

15 (inaudible) external controls.

16 CROSBIE, Q.C.:

17 Q. Would you bring up document P-0046 please.

18 THE COMMISSIONER:

19 Q. We must remember there's a period of time

20 after Dr. Ejeckam where external controls got

21 on the same slide as internal controls. So,

22 we have to make that distinction as well.

23 MR. SIMMONS:

24 Q. Exactly (inaudible).

25 THE COMMISSIONER:

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1 Q. Yes.

2 CROSBIE, Q.C.:

3 Q. Page four, please. A little further down the

4 page, please, little bit further. I'm

5 interested in conclusions about the reasons

6 for test failure.

7 THE COMMISSIONER:

8 Q. Yes, right in front of you, Mr. Crosbie.

9 CROSBIE, Q.C.:

10 Q. Yes, that's what I'm just saying, to bring it

11 to that. And he talks about "the reason for

12 test failure in paragraph 1 was most likely

13 due to a lack of test optimization" and so

14 forth "as positive controls showed weak

15 staining in general. And internal controls

16 failed in all the false negative cases".

17 DR. COOK:

18 A. Um-hm.

19 CROSBIE, Q.C.:

20 Q. So, when I say that the site chiefs who are

21 taking on professional responsibilities for

22 the adequacy of the staining of controls, did

23 not do a good job of it in the opinion of Dr.

24 Banerjee, I am correct, aren't I?

25 DR. COOK:

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1 A. You can make that statement, that the site

2 chiefs generally oversaw the controls at the

3 General Hospital site.

4 CROSBIE, Q.C.:

5 Q. Because in that statement we just read he does

6 differentiate between the positive controls

7 and the internal ones, doesn't he?

8 DR. COOK:

9 A. He does.

10 CROSBIE, Q.C.:

11 Q. The internal ones having failed in all of the

12 false negative cases.

13 DR. COOK:

14 A. Um-hm.

15 CROSBIE, Q.C.:

16 Q. Sir, Dr. Parai is a bit of a mystery. He

17 appears very infrequently in the record that

18 we have and gosh only know the record is

19 extensive.

20 DR. COOK:

21 A. Um-hm.

22 CROSBIE, Q.C.:

23 Q. He's almost like a ghost on the record. Do

24 you have any explanation for that?

25 DR. COOK:

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1 A. He was at the meetings. He was a site chief

2 there at the General for quite some time.

3 There was an expectation that he would

4 actively take a role in overseeing the

5 pathologists, acting as liaison between the

6 pathology and the technical department. He

7 was a very important individual.

8 CROSBIE, Q.C.:

9 Q. He just didn't generate much in the way of

10 paper.

11 DR. COOK:

12 A. I guess you can say that Mr. Crosbie.

13 CROSBIE, Q.C.:

14 Q. I'd like to talk to you for a moment about

15 confirmation. Before a lab switches from one

16 testing method to another, it does this

17 process called confirmation. That's what I've

18 picked up so far.

19 DR. COOK:

20 A. Validation is a term that's used. I mean, I'm

21 not sure about confirmation. Where'd you get

22 that term?

23 CROSBIE, Q.C.:

24 Q. Well, when I was asking Ms. Wegrynowski about

25 it, I spoke of the switch to

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

17 DR. COOK:  
 18 A. Well, I call it correlations.

19 CROSBIE, Q.C.:  
 20 Q. And you have another term for it, as  
 21 correlation.

22 DR. COOK:  
 23 A. Um-hm.

24 CROSBIE, Q.C.:  
 25 Q. In any event, no matter what the term you use

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

5 DR. COOK:  
 6 A. Um-hm.

7 CROSBIE, Q.C.:  
 8 Q. You agreed?

9 DR. COOK:  
 10 A. Um-hm.

11 CROSBIE, Q.C.:  
 12 Q. Was this a large enough series to constitute a  
 13 statistically reliable correlation?

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

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

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

3 DR. COOK:  
 4 A. I mean, I can only tell you back then what the  
 5 ballpark figure was.

6 CROSBIE, Q.C.:  
 7 Q. Document P-1893, Please.

8 THE COMMISSIONER:  
 9 Q. Mr. Crosbie, when you're through with your  
 10 questioning on this particular item, perhaps  
 11 we can take the afternoon break.

12 CROSBIE, Q.C.:  
 13 Q. Yes, it will only be a minute.

14 THE COMMISSIONER:  
 15 Q. Thank you.

16 CROSBIE, Q.C.:  
 17 Q. This is entitled, "contract" and registrar, if  
 18 you bring us down a bit, you'll see a  
 19 signature line there. It's contract for the  
 20 DAKO auto stainer signed the 27th of May,  
 21 1998, signed by Mr. Gulliver on behalf of  
 22 Health Care Corporation of St. John's. So  
 23 simply we can see from this that the contract  
 24 for the machine, the DAKO auto stainer wasn't  
 25 executed until May, 1998. There is on the

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1 document and that's what we can see.

2 DR. COOK:  
 3 A. Uh-hm.

4 CROSBIE, Q.C.:  
 5 Q. Do you know if the auto stainer was in use any  
 6 earlier than May, 1998?

7 DR. COOK:  
 8 A. I don't know, Mr. Crosbie. I can't tell you.

9 CROSBIE, Q.C.:  
 10 Q. You don't know exactly when it got into  
 11 service?

12 DR. COOK:  
 13 A. No, I had to rely on Mr. Gulliver to tell me  
 14 that.

15 CROSBIE, Q.C.:  
 16 Q. Mr. Gulliver, yes.

17 DR. COOK:  
 18 A. He's your man.

19 CROSBIE, Q.C.:  
 20 Q. It would appear that the confirmation series  
 21 was run with DAKO kits, but not with the DAKO  
 22 auto staining machine.

23 DR. COOK:  
 24 A. Uh-hm.

25 CROSBIE, Q.C.:

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

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1 starting, "Any trial of a new technique".  
 2 DR. COOK:  
 3 A. Uh-hm.  
 4 CROSBIE, Q.C.:  
 5 Q. Could you do that, sir, and read it out loud?  
 6 DR. COOK:  
 7 A. "Any trial of a new technique needs to be done  
 8 in parallel with a well established one before  
 9 you switch could be safely made".  
 10 CROSBIE, Q.C.:  
 11 Q. And you wouldn't disagree with that?  
 12 DR. COOK:  
 13 A. No.  
 14 CROSBIE, Q.C.:  
 15 Q. Please read the first four lines of the second  
 16 paragraph as well.  
 17 DR. COOK:  
 18 A. "Mr. Gulliver, I do not think you fully  
 19 appreciate the delicacy of this test, its  
 20 clinical consequences, and the overall  
 21 emotional charge in the public regarding this  
 22 very sensitive procedure. I am also uncertain  
 23 whether our service is being run as smoothly  
 24 as it should. The medical legal implications  
 25 of delaying this test are huge, and I want to

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1 clearly document my concerns at this time".  
 2 CROSBIE, Q.C.:  
 3 Q. Thank you. Is Dr. Khalifa essentially  
 4 complaining that Mr. Gulliver is sabotaging  
 5 his confirmation series?  
 6 DR. COOK:  
 7 A. Well, I can't say what Dr. Khalifa is actually  
 8 saying or whether he would use the word  
 9 "sabotage". I mean, you'll have to ask Dr.  
 10 Khalifa that.  
 11 CROSBIE, Q.C.:  
 12 Q. He is saying that Gulliver's actions carried  
 13 medical legal, and presumably patient safety  
 14 considerations?  
 15 DR. COOK:  
 16 A. Well, there was a concern there, yes.  
 17 CROSBIE, Q.C.:  
 18 Q. Could that jeopardize the validity of the  
 19 confirmation series of the correlation, as you  
 20 call it?  
 21 DR. COOK:  
 22 A. It could, Mr. Crosbie.  
 23 CROSBIE, Q.C.:  
 24 Q. Thank you, I have no more on this topic, and  
 25 it's time for a break.

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

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1 2007. I think I provided it, but it's  
 2 possible, again, that I did not. In any  
 3 event, it may not turn up, but I made a call  
 4 and I had a note of what Ms. Predham deposed  
 5 in the affidavit and I can tell you what she  
 6 said, and I can certainly provide the  
 7 affidavit tomorrow for cross-reference. But  
 8 before I go to what was said in the affidavit,  
 9 perhaps we'll give up looking for it. I guess  
 10 it's not coming up there, is it, Registrar?  
 11 Could I ask you to go back to the June 27th,  
 12 2008 transcript of Dr. Mullen's testimony  
 13 then? And now I'm looking for paragraph 321,  
 14 and this, by the way, Commissioner, I'm trying  
 15 to relate to Dr. Mullen's statements about 38  
 16 point something percent, using his  
 17 classification, 53 point something percent  
 18 using theirs.

19 THE COMMISSIONER:  
 20 Q. As in the explanation for it, you mean?  
 21 CROSBIE, Q.C.:  
 22 Q. Yes.  
 23 THE COMMISSIONER:  
 24 Q. All right then. Is this--you said paragraph,  
 25 I think, but the page is brought up, so -

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1 CROSBIE, Q.C.:  
 2 Q. I'm sorry, page 321.  
 3 THE COMMISSIONER:  
 4 Q. - is it page? 321, there you go.  
 5 CROSBIE, Q.C.:  
 6 Q. We're on line 16. I'm asking Dr. Mullen, "I'm  
 7 trying to understand the effect of shifting  
 8 cutoff points from 30 percent to ten percent  
 9 to one percent." Line 22, "on your positivity  
 10 rate, will it have much effect or will it have  
 11 a really fairly minor effect, if the  
 12 distribution of positivity is in the higher  
 13 ranges?" and Dr. Mullen says "yes, it  
 14 shouldn't have much effect." So that's my  
 15 understanding, Doctor, is that the  
 16 distribution of positivity will be in the  
 17 higher ranges, in the 60-70 percent, 90  
 18 percent, not in the range of 30-20-10 percent.

19 DR. COOK:  
 20 A. It depends again, how you look at positivity  
 21 rates, I mean, Mr. Crosbie. You could have a  
 22 case of ER/PR say two percent two percent and  
 23 you can have another case that's at ten  
 24 percent ten percent, another case at 30  
 25 percent 30 percent, another case at 40 percent

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1 40 percent. If you use a cutoff of greater  
 2 than one percent, all those cases are going to  
 3 be regarded as positive and going to be  
 4 included in your positivity rates.

5 CROSBIE, Q.C.:  
 6 Q. So the question was, given the distribution of  
 7 positivity in the higher ranges, how much  
 8 effect will it have, and we have the affidavit  
 9 of Ms. Predham, as I mentioned, February 2005,  
 10 at paragraph 22. She says "13 patients saw no  
 11 change in ER/PR status but the standard for  
 12 interpretation for what constituted a positive  
 13 test result had changed." So there are only  
 14 13 patients affected by the change in cutoff  
 15 point from 30 percent to ten. That's in her  
 16 affidavit.

17 DR. COOK:  
 18 A. Yeah, well that's--she would have the numbers.

19  
 20 CROSBIE, Q.C.:  
 21 Q. It's not a large number, is it?  
 22 DR. COOK:  
 23 A. It's not a large number, but she would have  
 24 the numbers and she was tabulating all the  
 25 numbers.

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1 CROSBIE, Q.C.:  
 2 Q. Well, we have a statistician coming, so  
 3 perhaps we'll -

4 DR. COOK:  
 5 A. Um-hm.

6 CROSBIE, Q.C.:  
 7 Q. - leave these matters to -

8 DR. COOK:  
 9 A. Sure.

10 CROSBIE, Q.C.:  
 11 Q. - statistical experts.

12 REGISTRAR:  
 13 Q. Excuse me, Mr. Crosbie. The affidavit I think  
 14 you wanted was P-0375?

15 CROSBIE, Q.C.:  
 16 Q. That's Dr. Gown. Yes, so now we'd go to  
 17 another topic. When Dr. Ejeckam testified, he  
 18 told the Commissioner numerous times that he  
 19 considered the reading of internal controls to  
 20 be critical. I have citations for this, but I  
 21 don't think it's necessary to go there unless  
 22 someone thinks it is. We don't have to go  
 23 there, Registrar, but by way of example, June  
 24 3rd, 2008, page 262, and it's all through his  
 25 testimony. He emphasizes the importance of

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1 internal controls and that they are the  
 2 critical control.  
 3 DR. COOK:  
 4 A. Um-hm.  
 5 CROSBIE, Q.C.:  
 6 Q. Would you agree that internal controls are the  
 7 critical control?  
 8 DR. COOK:  
 9 A. Agree on that, but it also depends on your  
 10 interpretation and how strongly staining the  
 11 cells are. So somebody could interpret an  
 12 internal control as positive. Another can  
 13 interpret it as negative, depending on the  
 14 intensity.  
 15 CROSBIE, Q.C.:  
 16 Q. They should always be positive, shouldn't  
 17 they?  
 18 DR. COOK:  
 19 A. Well, no, it depends on the intensity. If you  
 20 got a very weak intensity stain there, it may  
 21 be interpreted differently by pathologists.  
 22 This is the issue that I referred to in the  
 23 Cleveland situation where we have differences  
 24 in variations in percentages, based on -  
 25 CROSBIE, Q.C.:

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1 Q. Shouldn't that be screened out by your  
 2 positive external control?  
 3 DR. COOK:  
 4 A. It may not happen because a positive external  
 5 control may be fixed differently or it may be  
 6 a high expresser as compared to what's going  
 7 on in your test tissue.  
 8 CROSBIE, Q.C.:  
 9 Q. What's the reason the internal control is so  
 10 important?  
 11 DR. COOK:  
 12 A. To further evaluate that the test is working.  
 13 CROSBIE, Q.C.:  
 14 Q. It's because that internal control, which is  
 15 ductal epithelium or perhaps lobular tissue?  
 16 DR. COOK:  
 17 A. Usually ductal.  
 18 CROSBIE, Q.C.:  
 19 Q. Acini as Dr. Ejeckam referred to it?  
 20 DR. COOK:  
 21 A. Yes.  
 22 CROSBIE, Q.C.:  
 23 Q. It's because it's gone through exactly the  
 24 same conditions and treatment as the tumour on  
 25 the slide that it accompanies?

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1 DR. COOK:  
 2 A. That's correct, the internal control. But you  
 3 have to, again, look at the stain in intensity  
 4 and that can vary, and that's open to  
 5 interpretation.  
 6 CROSBIE, Q.C.:  
 7 Q. You first learned the importance of internal  
 8 controls at--I'm a little confused. Did you  
 9 say 2000, 2002, when was it?  
 10 DR. COOK:  
 11 A. I guess it was around 2000, I believe.  
 12 CROSBIE, Q.C.:  
 13 Q. And it was while reading literature?  
 14 DR. COOK:  
 15 A. Yes.  
 16 CROSBIE, Q.C.:  
 17 Q. Can you tell us which literature was that?  
 18 DR. COOK:  
 19 A. I think that was in Tavassoli's book, vintage  
 20 1999.  
 21 CROSBIE, Q.C.:  
 22 Q. Tavassoli, and the title?  
 23 DR. COOK:  
 24 A. Breast Pathology.  
 25 CROSBIE, Q.C.:

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1 Q. Sir, the importance of this control only  
 2 dawned on you in 2000. Did it occur to you  
 3 that other pathologists might not understand  
 4 the critical role with internal controls as  
 5 well, who were working here?  
 6 DR. COOK:  
 7 A. That I looked at as just part of my reading,  
 8 part of keeping update with various things  
 9 that were going on in pathology. Most  
 10 pathologists do that. They read books and  
 11 text and may not notify you of any advances -  
 12 CROSBIE, Q.C.:  
 13 Q. We hope.  
 14 DR. COOK:  
 15 A. - in various conditions.  
 16 CROSBIE, Q.C.:  
 17 Q. They're not all site chiefs or clinical chief,  
 18 are they?  
 19 DR. COOK:  
 20 A. No.  
 21 CROSBIE, Q.C.:  
 22 Q. You had responsibilities.  
 23 DR. COOK:  
 24 A. Um-hm.  
 25 CROSBIE, Q.C.:

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1 Q. Within the organization.  
 2 DR. COOK:  
 3 A. Um-hm.  
 4 CROSBIE, Q.C.:  
 5 Q. You just weren't the average pathologist. You  
 6 had duties.  
 7 DR. COOK:  
 8 A. No, I was a site chief.  
 9 CROSBIE, Q.C.:  
 10 Q. Did you think to ask any of the other  
 11 pathologists or to make inquiries as to  
 12 satisfy yourself as to whether they were aware  
 13 of the importance of internal controls?  
 14 DR. COOK:  
 15 A. No, that was all part of my general reading  
 16 and I made the assumption, you know, that  
 17 people were reading their books and reading  
 18 their journals. You make that assumption.  
 19 CROSBIE, Q.C.:  
 20 Q. You do make that assumption, do you?  
 21 DR. COOK:  
 22 A. Um-hm.  
 23 CROSBIE, Q.C.:  
 24 Q. Are there pathologists who haven't cracked a  
 25 book in years, sir?

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1 DR. COOK:  
 2 A. I can't say, Mr. Crosbie. I mean, I think  
 3 we're all pretty well actively involved in  
 4 continuing medical education, going to various  
 5 conferences and rounds. I don't think there's  
 6 a pathologist around that hasn't opened up a  
 7 book.  
 8 CROSBIE, Q.C.:  
 9 Q. Well, when you did ask in 2005, you told us  
 10 that most were not using internal controls.  
 11 DR. COOK:  
 12 A. That was basically that information I gleaned  
 13 around 2005 when the whole issue broke as to  
 14 what -  
 15 CROSBIE, Q.C.:  
 16 Q. That's right, yes.  
 17 DR. COOK:  
 18 A. But I didn't know that back in 2000.  
 19 CROSBIE, Q.C.:  
 20 Q. But you might have found out if you asked.  
 21 DR. COOK:  
 22 A. If I asked, but we ask about a lot of other  
 23 different things, not necessarily on ER and  
 24 PR.  
 25 CROSBIE, Q.C.:

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

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1 This was a very narrow band of work that we  
 2 were doing.  
 3 CROSBIE, Q.C.:  
 4 Q. Surely that doesn't mean it was unimportant  
 5 work.  
 6 DR. COOK:  
 7 A. Oh, it was just as important, Mr. Crosbie, but  
 8 I'm telling you in terms of the actual amount  
 9 of work that we were doing, there were much  
 10 more exchange of information regarding the  
 11 further interpretation and diagnosis of other  
 12 tumours.  
 13 CROSBIE, Q.C.:  
 14 Q. Sir, you started to become aware of the scope  
 15 of the problem with internal controls, you  
 16 told us, in the last week of July 2005?  
 17 DR. COOK:  
 18 A. Yes.  
 19 CROSBIE, Q.C.:  
 20 Q. And if you could bring up document 0076,  
 21 please? That's when you drafted the memo to  
 22 all pathologists with Dr. Carter dated July  
 23 28th. Can you scroll down to item two and  
 24 six, please? So in items two and six, you  
 25 actually spell out the following "when

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1 reporting, always check internal and external  
 2 controls."  
 3 DR. COOK:  
 4 A. Um-hm.  
 5 CROSBIE, Q.C.:  
 6 Q. And at six, "internal breast epithelium should  
 7 show some positivity, some positivity but not  
 8 diffuse." So you took the trouble to spell  
 9 that out because it seemed that not all  
 10 pathologists were aware of these fundamentals.  
 11 DR. COOK:  
 12 A. Which came to my knowledge in around July of  
 13 '05.  
 14 CROSBIE, Q.C.:  
 15 Q. You could have done such a memo back in 2000,  
 16 if you'd inquired.  
 17 DR. COOK:  
 18 A. I could have done a memo on many other things  
 19 in pathology, so should other pathologists.  
 20 We do make continual inquiries on cases and  
 21 update our knowledge on various things.  
 22 CROSBIE, Q.C.:  
 23 Q. Could we go to document 1287, please, 1287,  
 24 page six? In fact, Dr. Ejeckam did instruct  
 25 all pathologists on the importance of internal

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1 controls in this memo of May 2nd, 2003.  
 2 DR. COOK:  
 3 A. Um-hm.  
 4 CROSBIE, Q.C.:  
 5 Q. If you look at item three, kindly read that  
 6 out.  
 7 DR. COOK:  
 8 A. "Check normal breast acini in your sections as  
 9 internal controls. This is a second level  
 10 control. Nuclear staining in normal breast  
 11 tissue is heterogenic and varies with the  
 12 menstrual cycle."  
 13 CROSBIE, Q.C.:  
 14 Q. So he's saying read your internal controls.  
 15 DR. COOK:  
 16 A. That's what he's saying and he's acting there  
 17 as a resource person for immunohistochemistry.  
 18 He's circulating that out for general  
 19 knowledge.  
 20 CROSBIE, Q.C.:  
 21 Q. And let you learned in 2005 that despite this  
 22 memo, most pathologists were not using  
 23 internal controls?  
 24 DR. COOK:  
 25 A. Well, I don't know to what percentage, but I

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1 believe most weren't. There were some that  
 2 were doing it, but I can't say to what  
 3 percentage.  
 4 CROSBIE, Q.C.:  
 5 Q. Something Dr. Ejeckam referred to as critical?  
 6 DR. COOK:  
 7 A. Um-hm.  
 8 CROSBIE, Q.C.:  
 9 Q. I'd like to come back to when Dr. Ejeckam was  
 10 asked to do his what we've been referring to  
 11 intervention in 2003.  
 12 DR. COOK:  
 13 A. Um-hm.  
 14 CROSBIE, Q.C.:  
 15 Q. Was it pathologists complaining or oncologists  
 16 or both or what?  
 17 DR. COOK:  
 18 A. In regards to what?  
 19 CROSBIE, Q.C.:  
 20 Q. Well, I had the impression there were  
 21 complaints, and that's what prompted--  
 22 something propelled Dr. Ejeckam into the lab  
 23 where, as we know, he shut it down for five or  
 24 six weeks. What was it?  
 25 DR. COOK:

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1 A. I don't know.  
 2 CROSBIE, Q.C.:  
 3 Q. You can't tell us why he went in there?  
 4 DR. COOK:  
 5 A. He must have saw some variability in the  
 6 staining himself and took action on it.  
 7 CROSBIE, Q.C.:  
 8 Q. I thought he was asked to go there by a  
 9 committee.  
 10 DR. COOK:  
 11 A. What committee?  
 12 CROSBIE, Q.C.:  
 13 Q. You're saying -  
 14 MR. BROWNE:  
 15 Q. I think, Mr. Crosbie, you're confusing--Dr.  
 16 Ejeckam's evidence concerning his reason to  
 17 intervene related to surgical rounds, surgical  
 18 pathology rounds at the Health Sciences, where  
 19 there was discussion about crispness of the  
 20 slides, and on that basis the review began  
 21 (inaudible).  
 22 CROSBIE, Q.C.:  
 23 Q. You can't assist us with any more information  
 24 about why Dr. Ejeckam did the intervention,  
 25 can you?

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1 DR. COOK:  
 2 A. No, I mean, I made the--I assume he looked at  
 3 the stains and he saw variability in stains,  
 4 was not used to a standard that he was and you  
 5 know, being our resource person in  
 6 immunohistochemistry, he took it upon himself  
 7 to improve the quality and crispness of the  
 8 stains.  
 9 CROSBIE, Q.C.:  
 10 Q. I see. Were you aware that some oncologists  
 11 were sending all their slides out for reading  
 12 elsewhere?  
 13 DR. COOK:  
 14 A. I became aware that--you mean oncologists?  
 15 CROSBIE, Q.C.:  
 16 Q. Yes.  
 17 DR. COOK:  
 18 A. Not oncologists, no.  
 19 CROSBIE, Q.C.:  
 20 Q. Surgeons then.  
 21 DR. COOK:  
 22 A. No.  
 23 CROSBIE, Q.C.:  
 24 Q. Are you sure?  
 25 DR. COOK:

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1 A. What slides are you talking about?  
 2 CROSBIE, Q.C.:  
 3 Q. Surgical specimens that they didn't trust the  
 4 lab to process correctly.  
 5 DR. COOK:  
 6 A. Can you give me--can you be more specific?  
 7 CROSBIE, Q.C.:  
 8 Q. I can't do that without betraying information  
 9 that was given to me in confidence.  
 10 DR. COOK:  
 11 A. Well, I'm not aware of what you're talking  
 12 about. Are you talking about surgical cases?  
 13 CROSBIE, Q.C.:  
 14 Q. If you don't -  
 15 DR. COOK:  
 16 A. Pathology reports?  
 17 CROSBIE, Q.C.:  
 18 Q. If you don't know, that's fine, I accept your  
 19 answer. You weren't aware.  
 20 THE COMMISSIONER:  
 21 Q. I'm not sure what the question is, Mr.  
 22 Crosbie.  
 23 CROSBIE, Q.C.:  
 24 Q. The question was, was he aware that some  
 25 surgeons or oncologists were sending their

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

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1 CROSBIE, Q.C.:  
 2 Q. He wasn't given a copy of the Banerjee report,  
 3 was he?  
 4 DR. COOK:  
 5 A. He was--I read out the copy to him, along with  
 6 others, but he was not--I couldn't have--I  
 7 didn't have the authority to give him a copy  
 8 of the Banerjee report, and he could see it  
 9 any time he wanted to see it.  
 10 CROSBIE, Q.C.:  
 11 Q. Who instructed you as to who could see it?  
 12 DR. COOK:  
 13 A. The Vice President of Medical Services.  
 14 CROSBIE, Q.C.:  
 15 Q. Why was he not involved by you in the October  
 16 13, 2005 review of the lab, the document we  
 17 looked at a while ago?  
 18 DR. COOK:  
 19 A. You mean the report submitted by myself and Mr  
 20 Gulliver?  
 21 CROSBIE, Q.C.:  
 22 Q. Mr Gulliver, yeah.  
 23 CROSBIE, Q.C.:  
 24 Q. We did a -- that was a task that was assigned  
 25 to us by Dr. Williams to assess the cost of



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1 bringing in new resources to the lab.  
 2 CROSBIE, Q.C.:  
 3 Q. And Dr. Ejeckam had nothing to offer you to be  
 4 of assistance in that process?  
 5 DR. COOK:  
 6 A. We were just merely just trying to cost out  
 7 the resources.  
 8 CROSBIE, Q.C.:  
 9 Q. He didn't meet with Dr. Banerjee, did he?  
 10 DR. COOK:  
 11 A. I believe he met with Dr. Banerjee, yeah.  
 12 CROSBIE, Q.C.:  
 13 Q. Oh, he did.  
 14 DR. COOK:  
 15 A. Yeah.  
 16 CROSBIE, Q.C.:  
 17 Q. Did he meet with Dr. Gown?  
 18 DR. COOK:  
 19 A. Yes, he met with Dr. Gown.  
 20 CROSBIE, Q.C.:  
 21 Q. Dr. Ejeckam described DABBS as the Bible when  
 22 he was here.  
 23 DR. COOK:  
 24 A. Uh-hm.  
 25 CROSBIE, Q.C.:

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1 Q. On IHC technique. Would you dispute that  
 2 glowing description?  
 3 DR. COOK:  
 4 A. No, that's a pretty good book and many of us  
 5 use it.  
 6 CROSBIE, Q.C.:  
 7 Q. Document 01568, please. This should be DABBS  
 8 page -- and I'm looking for page 17  
 9 specifically. Page 17. I'm sorry, I'm mixing  
 10 it up. It's 17 in DABBS, but three in this  
 11 excerpt, so we're on the right page. Go down  
 12 to quality control, please, the heading. Just  
 13 go up again. Are we on page three? We're on  
 14 1568. I'm looking for 1569, page three.  
 15 DABBS there gives a definition of quality  
 16 control in this setting. Have you read this  
 17 before?  
 18 DR. COOK:  
 19 A. Yes.  
 20 CROSBIE, Q.C.:  
 21 Q. It's a good definition?  
 22 DR. COOK:  
 23 A. I agree with that.  
 24 CROSBIE, Q.C.:  
 25 Q. Further down the paragraph, there's a

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1 statement there, "Daily records of control".  
 2 DR. COOK:  
 3 A. Uh-hm.  
 4 CROSBIE, Q.C.:  
 5 Q. You can see that, sir?  
 6 DR. COOK:  
 7 A. Yeah.  
 8 CROSBIE, Q.C.:  
 9 Q. And it says, "Daily records of control results  
 10 are maintained and corrective actions are  
 11 undertaken and documented when results are  
 12 unacceptable".  
 13 DR. COOK:  
 14 A. Uh-hm.  
 15 CROSBIE, Q.C.:  
 16 Q. And that would be good practice?  
 17 DR. COOK:  
 18 A. Yes.  
 19 CROSBIE, Q.C.:  
 20 Q. Go to document 02095. This is going to be a  
 21 number of pages in. Perhaps I can ask you to  
 22 go to the next page. Further down, please.  
 23 This may take a while to find.  
 24 COMMISSIONER:  
 25 Q. Can you be more specific about what you're

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

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1 DR. COOK:  
 2 A. It's my understanding that there was  
 3 documentation taking place and that  
 4 understanding came from Mr. Gulliver that  
 5 there was documentation over there that the  
 6 controls were being run.  
 7 CROSBIE, Q.C.:  
 8 Q. That's what he told you?  
 9 DR. COOK:  
 10 A. That's my understanding, yes.  
 11 CROSBIE, Q.C.:  
 12 Q. He told you, in fact, that samples were always  
 13 run with controls?  
 14 DR. COOK:  
 15 A. Uh-hm.  
 16 CROSBIE, Q.C.:  
 17 Q. Could we have document 02141, please. This is  
 18 March 2006 note, your note of talking to -- I  
 19 think she's nicknamed Bibi, is she?  
 20 DR. COOK:  
 21 A. Bibi Naghibi.  
 22 CROSBIE, Q.C.:  
 23 Q. And, of course, she's saying there "lack of  
 24 external controls".  
 25 DR. COOK:

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1 A. Uh-hm.  
 2 CROSBIE, Q.C.:  
 3 Q. And I think you linked that earlier in your  
 4 evidence in my questioning to budgetary  
 5 issues?  
 6 DR. COOK:  
 7 A. At that time, yes, that was a major issue for  
 8 not providing controls for each of the cases.  
 9 CROSBIE, Q.C.:  
 10 Q. Can we go to document 0524. I see there -- I  
 11 guess that's your note again.  
 12 DR. COOK:  
 13 A. Uh-hm.  
 14 CROSBIE, Q.C.:  
 15 Q. "Barry admits documentation is bad".  
 16 DR. COOK:  
 17 A. Uh-hm.  
 18 CROSBIE, Q.C.:  
 19 Q. What kind of documentation was Barry talking  
 20 about?  
 21 DR. COOK:  
 22 A. Well, it would be documentation about -- it  
 23 could be anything; incubation times, length of  
 24 incubation times, it could have been  
 25 documentation regarding concentration, could

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1 be documentation of controls, who is actually  
 2 documenting the controls. So there may be a  
 3 whole wide range of items that could be  
 4 documented.  
 5 CROSBIE, Q.C.:  
 6 Q. Maybe it got destroyed in the flood.  
 7 DR. COOK:  
 8 A. Maybe it did.  
 9 CROSBIE, Q.C.:  
 10 Q. Maybe Mr. Dyer will tell us more about that.  
 11 DR. COOK:  
 12 A. I think he's your best man to talk to you  
 13 about that.  
 14 CROSBIE, Q.C.:  
 15 Q. Can we go to document 01852, please, page five  
 16 of that. This is Ms. Predham's answers to  
 17 interrogatories.  
 18 DR. COOK:  
 19 A. Uh-hm.  
 20 CROSBIE, Q.C.:  
 21 Q. And just go down -- I think it's paragraph 12  
 22 -- or 13. The question is there, "Does the  
 23 documentation show the controls were working  
 24 in all documented cases", and Ms Predham's  
 25 answer is, "Not all pathologists referred to

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

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1 pathologists would include it in their reports  
 2 and others wouldn't. So you're hoping that --  
 3 my understanding was that controls were being  
 4 documented and read before any of the cases  
 5 were sent outside the lab.  
 6 CROSBIE, Q.C.:  
 7 Q. You testified last Thursday that Dr. Carter  
 8 told you she personally observed the absence  
 9 of controls?  
 10 DR. COOK:  
 11 A. That was -- I found that out around July 21st  
 12 of '05.  
 13 CROSBIE, Q.C.:  
 14 Q. Going back to the issue of positivity  
 15 statistics --  
 16 DR. COOK:  
 17 A. Uh-hm.  
 18 CROSBIE, Q.C.:  
 19 Q. Dr. Mullen told the Commissioner that he'd  
 20 looked for a statistical performance of 79 to  
 21 80 percent positivity, and that appears at  
 22 page 324.  
 23 DR. COOK:  
 24 A. Uh-hm.  
 25 CROSBIE, Q.C.:

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1 Q. Of June 27th transcript. By the way, do you  
 2 accept that as a standard?  
 3 DR. COOK:  
 4 A. No, the range, generally speaking -- again  
 5 what years are you referring to, Mr Crosbie?  
 6 I mean, are you talking about positivity  
 7 ranges from '97 to 2005 or --  
 8 CROSBIE, Q.C.:  
 9 Q. I think he probably meant in the contemporary  
 10 period.  
 11 DR. COOK:  
 12 A. What is the contemporary period?  
 13 CROSBIE, Q.C.:  
 14 Q. The last few years.  
 15 DR. COOK:  
 16 A. What is the last few years?  
 17 CROSBIE, Q.C.:  
 18 Q. Say from 2005 to now.  
 19 DR. COOK:  
 20 A. 2005 to now? After 2005 to now?  
 21 CROSBIE, Q.C.:  
 22 Q. Yes.  
 23 DR. COOK:  
 24 A. Possibly, yes, it depends on the lab. So I  
 25 would say around 75 percent would be the

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1 average.  
 2 CROSBIE, Q.C.:  
 3 Q. Doctor, that book that you relied on when you  
 4 gave advice to Dr. Williams, the Vice  
 5 President of Medical Services, that positivity  
 6 range between 50 percent and 85 percent,  
 7 that's a medical student textbook, isn't it?  
 8 DR. COOK:  
 9 A. It's used by both undergraduates and  
 10 postgraduates and practising pathologists  
 11 throughout Canada and the United States.  
 12 CROSBIE, Q.C.:  
 13 Q. When you're giving advice to the Vice  
 14 President of Medical Services on a very  
 15 disturbing matter that may affect the patient  
 16 care for hundreds of people and carries  
 17 medical legal consequences, and you're a  
 18 fellowship trained specialist in pathology,  
 19 would you -- why wouldn't you look at the most  
 20 contemporary literature when you're stating  
 21 statistics like that?  
 22 DR. COOK:  
 23 A. The most contemporary literature may only  
 24 provide you information in the last year or  
 25 so. So we looked at 2005, you look at 2004

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1 and '03, and you would find positivity rates  
 2 of 70 to 80 percent. The thing is we went  
 3 back to '97. So what are positivity rates in  
 4 North America for the period from '97 to 2005.  
 5 I was unable to find that going back to '97.  
 6 There's very little information on positivity  
 7 rates that were '97, '98, and '99.  
 8 CROSBIE, Q.C.:  
 9 Q. I believe there's an article in the database  
 10 here from NEQUAS, the NEQUAS group, the same  
 11 group that your institution is enrolled with  
 12 now for external proficiency review, and they  
 13 go back over a series of 7000 patients plus.  
 14 DR. COOK:  
 15 A. But how far back do they go back?  
 16 CROSBIE, Q.C.:  
 17 Q. They're talking about the late 90s. Now I'm  
 18 not going to stop here and look for that  
 19 because at this rate, I may have a chance to  
 20 do so overnight. It may take me a moment to  
 21 find it, but I put it to you, sir, that there  
 22 is literature that state those statistics for  
 23 the late 90s, and it's something we can come  
 24 back to.  
 25 DR. COOK:

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1 A. Uh-hm.  
 2 CROSBIE, Q.C.:  
 3 Q. Now Dr. Gown is an expert you recommended to  
 4 insurance company, correct?  
 5 DR. COOK:  
 6 A. That's correct.  
 7 CROSBIE, Q.C.:  
 8 Q. He gave us -- well, he gave an affidavit in  
 9 court, document 0375.  
 10 DR. COOK:  
 11 A. Okay.  
 12 CROSBIE, Q.C.:  
 13 Q. Page two, please, paragraph 6. At paragraph  
 14 6, he's saying he reviewed data indicating a  
 15 positivity rate for your institution in the  
 16 range of 65 to 75 percent.  
 17 DR. COOK:  
 18 A. Uh-hm.  
 19 CROSBIE, Q.C.:  
 20 Q. With a seven year average of 74 percent.  
 21 DR. COOK:  
 22 A. Uh-hm.  
 23 CROSBIE, Q.C.:  
 24 Q. So if your standard, as you mentioned a moment  
 25 ago, is 75 percent, that's not too bad.

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

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

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1 DR. COOK:  
 2 A. We were nothing more than a glorified  
 3 community lab, Mr. Crosbie, when you look at  
 4 the resources we had, the financial sources.  
 5 Even though we were classed as a university  
 6 tertiary care centre, in reality we're nothing  
 7 more than a community lab.  
 8 CROSBIE, Q.C.:  
 9 Q. Explain that please.  
 10 DR. COOK:  
 11 A. Glorified community lab. We didn't have the -  
 12 we had a high turnover of pathologists, we  
 13 didn't have the degree of sub-specialization  
 14 that you would like to have. There was again  
 15 budgetary restraints, you know, and we just  
 16 didn't have a stable situation in that lab.  
 17 CROSBIE, Q.C.:  
 18 Q. So you're describing a situation for a  
 19 university affiliated, medical school  
 20 affiliated --  
 21 DR. COOK:  
 22 A. Uh-hm.  
 23 CROSBIE, Q.C.:  
 24 Q. School of Pharmacy, School of Nursing  
 25 affiliated.

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1 DR. COOK:  
 2 A. Uh-hm.  
 3 CROSBIE, Q.C.:  
 4 Q. Laboratory in the Health Sciences Complex.  
 5 DR. COOK:  
 6 A. And you look at what we actually had in that  
 7 lab in terms of resources, and compare that to  
 8 comparable resources across Canada.  
 9 CROSBIE, Q.C.:  
 10 Q. So you're saying all that was a sham?  
 11 DR. COOK:  
 12 A. No, I'm saying in reality -- it is part of a  
 13 university network. In reality, we're nothing  
 14 more than very much a glorified community  
 15 hospital lab in terms of resources, staffing,  
 16 stability in the organization.  
 17 CROSBIE, Q.C.:  
 18 Q. Sir, it goes back to my question earlier,  
 19 should your institution have offered this  
 20 test?  
 21 DR. COOK:  
 22 A. It had--well obviously the clinical chief of  
 23 the day decided that it needed to be brought  
 24 in, as well as the site chief of the General  
 25 Hospital, they felt it was necessary to bring

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

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1 question is being answered, this is Mr.  
 2 Predham's answer to interrogatories again.  
 3 DR. COOK:  
 4 A. Uh-hm.  
 5 CROSBIE, Q.C.:  
 6 Q. And how many ER/PR tests were done on a year  
 7 to year basis stating total number of tests  
 8 and total number of negatives for each year?  
 9 And if you go down through the information,  
 10 you'll see that she supplied the answer to  
 11 that question.  
 12 DR. COOK:  
 13 A. Uh-hm.  
 14 CROSBIE, Q.C.:  
 15 Q. Now if we go to document P-1841 please? This  
 16 is a table which the footnote notes or in the  
 17 bottom there was prepared by Dr. Hutton;  
 18 however, it's simply a reproducing of  
 19 information and numbers provided already to us  
 20 by Ms. Predham in her answer, her sworn  
 21 answer, with an arithmetic calculation of the  
 22 rate in percentage terms, for example in the  
 23 third column over, so you get percentage of  
 24 positive or the positivity rate in the third  
 25 column.

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1 DR. COOK:  
 2 A. Positivity rate now based on what cut off, Mr.  
 3 Crosbie?  
 4 CROSBIE, Q.C.:  
 5 Q. It's based on the information given to us by  
 6 Ms. Predham, so I assume she used the -  
 7 DR. COOK:  
 8 A. I mean, I'd like to know what the cut off  
 9 rates are.  
 10 CROSBIE, Q.C.:  
 11 Q. Yes. Well if you wish, we can go back and  
 12 look at her answer.  
 13 DR. COOK:  
 14 A. We probably need to do that.  
 15 CROSBIE, Q.C.:  
 16 Q. Can we do that, please, Registrar? That's  
 17 document P-1852, page 2? Take your time and  
 18 read it. So in the answer she does manifest  
 19 awareness of when the cut off point changed,  
 20 30 percent, then 10?  
 21 DR. COOK:  
 22 A. That's what she says.  
 23 CROSBIE, Q.C.:  
 24 Q. Do you need to read further into the  
 25 affidavit, sir?

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1 DR. COOK:  
 2 A. No, that's fine.  
 3 CROSBIE, Q.C.:  
 4 Q. What do you take from that?  
 5 DR. COOK:  
 6 A. Well when we had improved positivity rates,  
 7 improved rates in 2003, 2004 years, in terms  
 8 of the negatives being reduced.  
 9 CROSBIE, Q.C.:  
 10 Q. Can we now go back to P-1841 then?  
 11 DR. COOK:  
 12 A. Uh-hm.  
 13 CROSBIE, Q.C.:  
 14 Q. So before the Ejeckam intervention, you can  
 15 see in the third column from the left, that's  
 16 the end of 2002, the rate of positivity was 58  
 17 percent, according to this calculation.  
 18 DR. COOK:  
 19 A. You mean from May 31st, '97 onwards? 58  
 20 percent, that's from May '97 to 2002?  
 21 CROSBIE, Q.C.:  
 22 Q. Through to the end of 2002.  
 23 DR. COOK:  
 24 A. Uh-hm.  
 25 CROSBIE, Q.C.:

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1 Q. 58 percent.  
 2 DR. COOK:  
 3 A. Okay, so what are your weak negatives or weak  
 4 positives, I should say?  
 5 CROSBIE, Q.C.:  
 6 Q. I'm sorry, but I'm asking the questions here  
 7 and I'd ask you to go to the Ejeckam Committee  
 8 Intervention and you'll see in the third  
 9 column 78 percent. So after Dr. Ejeckam  
 10 intervened, he got the positivity rate up very  
 11 smartly to 78 percent  
 12 DR. COOK:  
 13 A. Right.  
 14 CROSBIE, Q.C.:  
 15 Q. However, if you look at grand totals for the  
 16 period of DAKO use, either a kit of  
 17 autostainer, it was down around 63 percent and  
 18 you can see that even with the up tick after  
 19 the Ejeckam intervention. I put it to you  
 20 sir, we looked at the Gown affidavit just a  
 21 minute ago.  
 22 DR. COOK:  
 23 A. Right.  
 24 CROSBIE, Q.C.:  
 25 Q. The information sworn to the Court by the

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1 insurance expert that you found for the  
 2 insurance company is not correct, is it?  
 3 DR. COOK:  
 4 A. Well that was information that was provided by  
 5 Mr. Gulliver, Mr. Crosbie, I mean, I relied on  
 6 Mr. Gulliver to provide the correct stats.  
 7 CROSBIE, Q.C.:  
 8 Q. I see, Mr. Gulliver. So you believed the  
 9 information to be true, did you?  
 10 DR. COOK:  
 11 A. Well I believed it was, that it was  
 12 information that was supplied by him, he was  
 13 the one who went into the Meditec system and  
 14 retrieved that information, so I was relying  
 15 on him?  
 16 CROSBIE, Q.C.:  
 17 Q. And at the time of Dr. Gown's swearing of his  
 18 affidavit, which was, well it was last year -  
 19 DR. COOK:  
 20 A. Uh-hm.  
 21 CROSBIE, Q.C.:  
 22 Q. Did you have reason to believe that those  
 23 statistics were valid or invalid?  
 24 DR. COOK:  
 25 A. You mean Mr. Gulliver's positivity rates?

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1 CROSBIE, Q.C.:  
 2 Q. The statistics that we're inferring are  
 3 reflected in Dr. Gown's affidavit where he  
 4 speaks about positivity rates.  
 5 DR. COOK:  
 6 A. I can only infer that the information supplied  
 7 by me from Mr. Gulliver was correct.  
 8 CROSBIE, Q.C.:  
 9 Q. Do you accept Mr. Gulliver's statistics today?  
 10 DR. COOK:  
 11 A. With the exception of the last year where it  
 12 was reported in '04, '05 that we had a  
 13 positivity rate of 89 percent and that, I  
 14 found out later, was subsequently reduced to  
 15 82 percent.  
 16 CROSBIE, Q.C.:  
 17 Q. So that's the only flaw in Mr. Gulliver's  
 18 statistics that you're aware of?  
 19 DR. COOK:  
 20 A. That's the only flaw that's come to my  
 21 attention that I'm aware of.  
 22 CROSBIE, Q.C.:  
 23 Q. Even today, that's the case?  
 24 DR. COOK:  
 25 A. Even today when I look at those positivity

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1 rates and I mean, I'm not--I don't have his  
 2 latest spreadsheet on the positivity rates,  
 3 that would be given to the clinical chief of  
 4 the day.  
 5 CROSBIE, Q.C.:  
 6 Q. I won't take you to it, but there's a  
 7 handwritten note "get Alan Gown" and it dates  
 8 from August 1st, 2005. How did you know Mr.  
 9 Gown or Dr. Gown?  
 10 DR. COOK:  
 11 A. Well I met Dr. Gown around September of 2000,  
 12 I believe or 2001 at a conference talking  
 13 about HER2/neu, which is an immunoperoxidase  
 14 test, so I first heard of him at that  
 15 particular time and he was quite knowledgeable  
 16 in standardization of IHC across North  
 17 America, so I thought--and he was director of  
 18 labs, pheno labs in Seattle, Washington, so he  
 19 came to mind when I was asked to provide a  
 20 name to the insurer.  
 21 CROSBIE, Q.C.:  
 22 Q. And he is a very well credentialed expert  
 23 indeed, isn't he?  
 24 DR. COOK:  
 25 A. He is.

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1 CROSBIE, Q.C.:  
 2 Q. Can we go to document P-2011? So this is from  
 3 Heather Predham to you, February 23, 2006, it  
 4 speaks of a meeting in a little board room by  
 5 Dr. Williams' office and it's asking about  
 6 confirming the presence of Barry Dyer or Terry  
 7 Gulliver and Dr. Cook.  
 8 DR. COOK:  
 9 A. Uh-hm.  
 10 CROSBIE, Q.C.:  
 11 Q. It's a Monday, February 27, 2006 on which the  
 12 meeting is to be held.  
 13 DR. COOK:  
 14 A. That's correct.  
 15 CROSBIE, Q.C.:  
 16 Q. Do you remember that meeting?  
 17 MR. SIMMONS:  
 18 Q. Excuse me, Commissioner, I'd like to mention  
 19 at this point that we know that Dr. Gown was  
 20 an expert who came in the civil action, Mr.  
 21 Crosbie is familiar and I just caution at this  
 22 point that although he has an affidavit filed  
 23 in that action, that we want to be very  
 24 careful about how far we go getting into any  
 25 discussions Dr. Cook or other people had with

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1 Dr. Gown concerning the terms of his retainer  
 2 in that class action, just a caution for -  
 3 THE COMMISSIONER:  
 4 Q. I think, Mr. Crosbie, that your friend here is  
 5 raising the obvious issue of solicitor/client  
 6 privilege as sort of shot across your bow in  
 7 case of whatever you want to ask, but we'll  
 8 deal with it when the question gets asked Mr.  
 9 Simmons.  
 10 MR. SIMMONS:  
 11 Q. Thank you, Commissioner.  
 12 CROSBIE, Q.C.:  
 13 Q. Not unexpected. Can you tell us who was there  
 14 at the meeting?  
 15 DR. COOK:  
 16 A. I think Dr. Ejeckam was there, Mr. Gulliver  
 17 was there, I was there, Mr. Dan Boon, Alan  
 18 Gown, Heather Predham, I think--I'm not sure,  
 19 that's about all I can recollect who was at  
 20 that meeting.  
 21 CROSBIE, Q.C.:  
 22 Q. Who provided to Dr. Gown the statistics that  
 23 we saw reflected in his affidavit?  
 24 MR. SIMMONS:  
 25 Q. Excuse me, Commissioner, I think if we're

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1 dealing with a meeting that legal counsel  
 2 involved in a matter that Mr. Crosbie's  
 3 (inaudible), I think we're in a situation  
 4 where that meeting was obviously for the  
 5 purpose of dealing with that matter and  
 6 anything taking place in it, should be  
 7 privileged with -  
 8 THE COMMISSIONER:  
 9 Q. Is this a meeting with--well the subject is  
 10 Dr. Gown's visit -  
 11 MR. SIMMONS:  
 12 Q. Dr. Cook has just said that Mr. Boone was  
 13 there.  
 14 THE COMMISSIONER:  
 15 Q. So you're saying that the presence of Mr.  
 16 Boone, in and of itself, makes this a  
 17 solicitor/client situation?  
 18 MR. SIMMONS:  
 19 Q. The only involvement that Dr. Gown had in the  
 20 matter has been in relation to his retainer by  
 21 the insurer and in the action, so I can't see  
 22 how there would have been anything taken place  
 23 there that wouldn't be privileged.  
 24 CROSBIE, Q.C.:  
 25 Q. The broad issue or one of them that you are

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1 seized with investigating, one of them is  
 2 communications, broad umbrella. Dr. Gown  
 3 certainly communicated with a judge of one of  
 4 the courts in this jurisdiction and I'm saying  
 5 or I'll be proving, I believe, that he  
 6 provided false and misleading information,  
 7 particularly false and misleading statistics  
 8 to a court. I'm just seeking to figure out  
 9 where this came from?  
 10 THE COMMISSIONER:  
 11 Q. But isn't that the question of whether or not  
 12 the statistics are false and misleading is, I  
 13 think, a question for the court, is it not?  
 14 CROSBIE, Q.C.:  
 15 Q. We just discussed in some detail a question of  
 16 statistics that this gentleman professes to--  
 17 the relevance, positivity rates have relevance  
 18 to quality assurance, quality control.  
 19 THE COMMISSIONER:  
 20 Q. Uh-hm.  
 21 CROSBIE, Q.C.:  
 22 Q. Not everyone seems to endorse them as, you  
 23 know, of biblical importance, but they seem to  
 24 have some utility and I'm simply trying to  
 25 find out who gave him the statistics that

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1 found their way into the affidavit. I didn't  
 2 know that it would be worth all this heavy  
 3 weather.  
 4 THE COMMISSIONER:  
 5 Q. Uh-hm. My understanding is that it's highly  
 6 unlikely that Dr. Gown would be a witness in  
 7 this inquiry and therefore, that his  
 8 particular statistic would be one of the I'm  
 9 sure many statistics which I would have to  
 10 consider, so I have some difficulty with why  
 11 the statistics used by Gown in particular are  
 12 in the context of this inquiry so very  
 13 important, but if you want to proceed on those  
 14 lines, I'm certainly prepared to hear from all  
 15 counsel on the issue and make a ruling for  
 16 you.  
 17 CROSBIE, Q.C.:  
 18 Q. Well it's not worth half an hour of argument  
 19 because we're going to see all kinds of  
 20 statistical spreadsheets when Mr. Gulliver  
 21 gets here and it's not going to be too hard to  
 22 figure it out and I suppose if I'm allowed to  
 23 ask him, he'll confirm that it was he who gave  
 24 Dr. Gown the information. So we can pass on  
 25 from that, Dr. Cook, so that we don't have to

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1 spend more time on that issue.  
 2 THE COMMISSIONER:  
 3 Q. All right then.  
 4 CROSBIE, Q.C.:  
 5 Q. Can we go to document P-1754? And can you  
 6 bring this down a little bit where it says  
 7 "note" actually a little bit further up,  
 8 "Nash", no "Nash". So this is a meeting on  
 9 June 30th, 2006, you're there, Dr. Cook, a  
 10 number of other pathologists, Re:  
 11 Implementation of ER/PR testing and Nash is,  
 12 no doubt, Dr. Denic, "gave overview of  
 13 immunohistochemistry, Dr. Gown, Dr. Banerjee,  
 14 Trish Wegrynowski". And then underneath that,  
 15 "consultants, middle of pack in North American  
 16 practice".  
 17 DR. COOK:  
 18 A. Um-hm.  
 19 CROSBIE, Q.C.:  
 20 Q. Did Dr. Banerjee inform your group that you  
 21 were middle of the pack in North American  
 22 practice?  
 23 DR. COOK:  
 24 A. Well he informed me when I was doing the  
 25 review of the slides at the multi-headed scope

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1 in September of '05 and then he made that  
 2 reference at an exit meeting with myself and  
 3 Dr. Williams and I believe Heather Predham at  
 4 that particular time.  
 5 CROSBIE, Q.C.:  
 6 Q. Because I sure don't get that from his report?  
 7 DR. COOK:  
 8 A. That was what was in the verbal conversation  
 9 with me and in the exit interview.  
 10 CROSBIE, Q.C.:  
 11 Q. To me, middle of the pack doesn't sound like  
 12 Ms. Wegrynowski either?  
 13 DR. COOK:  
 14 A. Well that didn't come from Ms. Wegrynowski,  
 15 that came from Dr. Banerjee and that was at  
 16 the exit interview and in the discussions I  
 17 had with him at the multi-headed scope.  
 18 CROSBIE, Q.C.:  
 19 Q. Sir, you see opposite Ford, and that's Dr.  
 20 Ford Elms?  
 21 DR. COOK:  
 22 A. That's right.  
 23 CROSBIE, Q.C.:  
 24 Q. "Can't afford to be average, must be  
 25 comparable" and I suppose he means comparable



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1 to Mount Sinai.  
 2 DR. COOK:  
 3 A. That was where we were hoping to go.  
 4 CROSBIE, Q.C.:  
 5 Q. And Dr. Ford was right, wasn't he?  
 6 DR. COOK:  
 7 A. Uh-hm.  
 8 CROSBIE, Q.C.:  
 9 Q. You can't afford to be average.  
 10 DR. COOK:  
 11 A. No, we got to try to be the best that we can.  
 12 CROSBIE, Q.C.:  
 13 Q. Can we go to P-0110, page 3, please? This is  
 14 Mr. Tilley's news conference, May 18th, 2007,  
 15 page 3. There's a paragraph there starts,  
 16 "George Tilley"--thank you, Registrar. If you  
 17 count down there about one, two, three, four,  
 18 five, six lines, I'm going to start reading,  
 19 "We also sought the input of technologists, a  
 20 technologist and a physician more independent  
 21 of the organization to come and give us an  
 22 objective assessment as to what we do and how  
 23 we do it." That sounds like Dr. Banerjee and  
 24 Ms. Wegrynowski.  
 25 DR. COOK:

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1 A. Well I never--it was more Dr. Banerjee.  
 2 CROSBIE, Q.C.:  
 3 Q. He does mention technologist.  
 4 DR. COOK:  
 5 A. Yes, but I was thinking more Dr. Banerjee.  
 6 CROSBIE, Q.C.:  
 7 Q. Anyway, to give an objective assessment. "I  
 8 recall that the comments of the physician were  
 9 that he considered us to be in the middle of  
 10 the pack."  
 11 DR. COOK:  
 12 A. Uh-hm.  
 13 CROSBIE, Q.C.:  
 14 Q. "In terms of laboratory services with regards  
 15 to ER/PR." By the way, did Dr. Banerjee meet  
 16 with Mr. Tilley?  
 17 DR. COOK:  
 18 A. No.  
 19 CROSBIE, Q.C.:  
 20 Q. Where would he get that expression "middle of  
 21 the pack"?  
 22 DR. COOK:  
 23 A. He would have got it, I would say from myself  
 24 or possibly Dr. Williams.  
 25 CROSBIE, Q.C.:

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1 Q. He goes on, "And to be quite frank with you,  
 2 we're not satisfied with being in the middle  
 3 of the pack. We're interested in becoming  
 4 amongst the top laboratories for this  
 5 procedure in the country."  
 6 DR. COOK:  
 7 A. Uh-hm.  
 8 CROSBIE, Q.C.:  
 9 Q. Having said that, the individuals who are not  
 10 able to point to a technique, a person, a  
 11 discipline that had done anything that would  
 12 suggest that errors would occur, is that  
 13 Banerjee?  
 14 DR. COOK:  
 15 A. I don't know who said that?  
 16 CROSBIE, Q.C.:  
 17 Q. It doesn't sound like Banerjee, does it?  
 18 DR. COOK:  
 19 A. I don't know who said that, Mr. Crosbie.  
 20 CROSBIE, Q.C.:  
 21 Q. Do you know if Mr. Tilley met with Dr. Gown?  
 22 DR. COOK:  
 23 A. Not that I'm aware of, no.  
 24 CROSBIE, Q.C.:  
 25 Q. Mr. Tilley had the reports of Wegrynowski and

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1 Banerjee.  
 2 DR. COOK:  
 3 A. Uh-hm.  
 4 CROSBIE, Q.C.:  
 5 Q. And he says that these individuals, it appears  
 6 this is what he's saying, are not able to  
 7 point to anything that would suggest errors  
 8 would occur. If that refers to Wegrynowski  
 9 and Banerjee, we know they pointed to plenty  
 10 of things that would suggest errors would  
 11 occur, don't we?  
 12 DR. COOK:  
 13 A. Well that's Mr. Tilley's interpretation of  
 14 their reports.  
 15 CROSBIE, Q.C.:  
 16 Q. I see and also the interpretation that he  
 17 offered to the public at the press conference.  
 18 DR. COOK:  
 19 A. I mean, I would assume, I mean, I never saw  
 20 this release.  
 21 CROSBIE, Q.C.:  
 22 Q. You didn't hear how it was covered at the  
 23 time?  
 24 DR. COOK:  
 25 A. Not in specific detail as what's here.

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1 CROSBIE, Q.C.:

2 Q. So you don't have any view on whether Mr.

3 Tilley was misleading the public with that

4 statement?

5 DR. COOK:

6 A. Oh I can't say that he was.

7 CROSBIE, Q.C.:

8 Q. Thank you. Disclosure policies, sir, you're

9 aware that the hospital has policies on

10 disclosure?

11 DR. COOK:

12 A. Uh-hm.

13 CROSBIE, Q.C.:

14 Q. Did you review the hospital disclosure

15 policies at the time of the Ejeckam

16 intervention in 2003?

17 DR. COOK:

18 A. I believe I did in conjunction with Dr.

19 Williams and a number of other physicians that

20 we made, we did some discussion around that.

21 CROSBIE, Q.C.:

22 Q. Did you look at the document?

23 DR. COOK:

24 A. I can't remember for sure, Mr. Crosbie, if I

25 did or not.

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1 CROSBIE, Q.C.:

2 Q. It would stand out in your memory if you

3 actually got it out and read it, wouldn't it?

4 DR. COOK:

5 A. I would assume so.

6 CROSBIE, Q.C.:

7 Q. So probably you didn't get it out and read it

8 in 2003.

9 DR. COOK:

10 A. No, I was leaving the disclosure aspect,

11 again, to our VP Medical Services.

12 CROSBIE, Q.C.:

13 Q. So again, you probably didn't read it?

14 DR. COOK:

15 A. Probably.

16 THE COMMISSIONER:

17 Q. We're talking now 2003, not 2005?

18 CROSBIE, Q.C.:

19 Q. 2003.

20 THE COMMISSIONER:

21 Q. All right.

22 CROSBIE, Q.C.:

23 Q. Which is my next question, did you review the

24 disclosure policies in 2005?

25 DR. COOK:

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1 A. I would have had discussions with that around

2 Dr. Williams. I can't remember specifically

3 sitting down and reviewing the disclosure

4 policies, that's not where my mind was in

5 2005.

6 CROSBIE, Q.C.:

7 Q. Probably you didn't do that, sit down and

8 review the policies.

9 DR. COOK:

10 A. Probably not at that particular time.

11 CROSBIE, Q.C.:

12 Q. Are you aware of anyone who did review

13 disclosure policies and who stated the result

14 of that review in your presence?

15 DR. COOK:

16 A. I'm not aware in my presence, no.

17 CROSBIE, Q.C.:

18 Q. But you were leaving that up to Dr. Williams,

19 were you?

20 DR. COOK:

21 A. That was Dr. Williams and again our quality

22 initiatives people.

23 CROSBIE, Q.C.:

24 Q. Sir, let's have a look at document P-0056?

25 There is a date of 1997-10-01, as far as I can

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1 tell, sir, this policy would be the one that

2 governed occurrences in 2003?

3 DR. COOK:

4 A. Mr. Crosbie, I can't say for sure.

5 CROSBIE, Q.C.:

6 Q. At page one, it requires, if we go down a

7 little bit further, procedure I think we're

8 interested in. Yes, page two, please. Just

9 going to try and find my unmarked copy of

10 that. Page 18. Can I go back to page one,

11 please?

12 THE COMMISSIONER:

13 Q. Part of this is consumer feedback, Mr.

14 Crosbie.

15 CROSBIE, Q.C.:

16 Q. Yes, I've got my copy marked as 0056.

17 THE COMMISSIONER:

18 Q. Is it another--this is one of 20. Is it

19 another document in that?

20 CROSBIE, Q.C.:

21 Q. They're probably entered as--do they have a

22 lot of page numbers, this exhibit?

23 REGISTRAR:

24 Q. 20 pages.

25 THE COMMISSIONER:

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1 Q. There are 20 pages.  
 2 CROSBIE, Q.C.:  
 3 Q. The one I'm looking at is dated 22/10/97. It  
 4 doesn't seem to be this one.  
 5 THE COMMISSIONER:  
 6 Q. Okay.  
 7 CROSBIE, Q.C.:  
 8 Q. Perhaps you can -  
 9 THE COMMISSIONER:  
 10 Q. Well, there should be another one at page  
 11 eight.  
 12 CROSBIE, Q.C.:  
 13 Q. Go to page eight, maybe.  
 14 THE COMMISSIONER:  
 15 Q. And this document is one of four.  
 16 CROSBIE, Q.C.:  
 17 Q. That's not the one I'm looking at either.  
 18 That's it.  
 19 THE COMMISSIONER:  
 20 Q. Occurrence reporting?  
 21 CROSBIE, Q.C.:  
 22 Q. It's the one at page 12, page 12.  
 23 THE COMMISSIONER:  
 24 Q. All right.  
 25 CROSBIE, Q.C.:

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1 Q. So, Doctor, again, I'd propose that this is  
 2 the document that would have governed in 2003  
 3 and we can see under policy there, occurrence  
 4 is discussed, "must be investigated and  
 5 reported using corporate occurrence report  
 6 forms. It's a component of the quality plan.  
 7 An occurrence is defined as any event," a  
 8 little bit further down under definitions,  
 9 Madam Registrar, "any event, accident, error  
 10 or circumstance which is not in keeping with  
 11 expected process or outcome of care or  
 12 service. Occurrences may result in an injury,  
 13 damage, etcetera." So it's a pretty broad  
 14 definition, isn't it?  
 15 DR. COOK:  
 16 A. Um-hm.  
 17 CROSBIE, Q.C.:  
 18 Q. And it required occurrences to be investigated  
 19 and reported on an occurrence report form. In  
 20 2003, testing in the lab was suspended for  
 21 five or six weeks for unreliable, erratic and  
 22 unhelpful stains.  
 23 DR. COOK:  
 24 A. Um-hm.  
 25 CROSBIE, Q.C.:

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1 Q. Unhelpful, according to Dr. Ejeckam, for  
 2 diagnostic purposes.  
 3 DR. COOK:  
 4 A. Um-hm.  
 5 CROSBIE, Q.C.:  
 6 Q. And he warned of medical legal consequences if  
 7 adequate personnel and resources were not  
 8 devoted to the problems that he described. Is  
 9 that correct?  
 10 DR. COOK:  
 11 A. Um-hm.  
 12 CROSBIE, Q.C.:  
 13 Q. Now you can't say to the Commission that you  
 14 relied on Dr. Williams to decide issues of  
 15 disclosure on this occasion, can you?  
 16 DR. COOK:  
 17 A. Not on this occasion.  
 18 CROSBIE, Q.C.:  
 19 Q. Because you didn't tell Dr. Williams about  
 20 what had happened.  
 21 DR. COOK:  
 22 A. No, because we looked at this as an internal  
 23 laboratory issue.  
 24 CROSBIE, Q.C.:  
 25 Q. Would you go to--that was page 12, then page

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1 13, 14, 15 please? I got that wrong. 12, 13,  
 2 14, 15. Yes, okay. It's--actually, it must  
 3 be the previous page then. Item four, please,  
 4 under program department management. Yes,  
 5 four. It says "report significant occurrences  
 6 immediately to the applicable vice president."  
 7 DR. COOK:  
 8 A. Um-hm.  
 9 CROSBIE, Q.C.:  
 10 Q. So your description of this as an internal  
 11 matter, that removes it from anything that  
 12 could be described as an occurrence, does it?  
 13 DR. COOK:  
 14 A. Well, we looked at it as a quality assurance  
 15 activity that Dr. Ejeckam was improving the  
 16 crispness and clarity of the stains. That's  
 17 how we looked at it.  
 18 CROSBIE, Q.C.:  
 19 Q. So it wasn't an occurrence?  
 20 DR. COOK:  
 21 A. We didn't regard it as an occurrence.  
 22 CROSBIE, Q.C.:  
 23 Q. And you had no duty, according to policy, to  
 24 report this to the vice president?  
 25 DR. COOK:

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1 A. Because I didn't see there, right there that  
 2 we had a patient care issue.  
 3 CROSBIE, Q.C.:  
 4 Q. Despite the warning from Dr. Ejeckam about  
 5 possible litigation?  
 6 DR. COOK:  
 7 A. That was on down the road. He was looking  
 8 forward. If we begin--if we didn't implement  
 9 certain things that that's a possibility on  
 10 down the road.  
 11 CROSBIE, Q.C.:  
 12 Q. So your position is that the failure to report  
 13 this suspension to Dr. Williams is not a  
 14 breach of the policy?  
 15 DR. COOK:  
 16 A. No, we just merely looked at it as a further  
 17 quality assurance activity into improve the  
 18 quality of the stains.  
 19 CROSBIE, Q.C.:  
 20 Q. Medical ethics, Dr. Cook, is a recognized area  
 21 of specialized knowledge?  
 22 DR. COOK:  
 23 A. Um-hm.  
 24 CROSBIE, Q.C.:  
 25 Q. You sought an ethics consult in May 2006?

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1 DR. COOK:  
 2 A. Um-hm. Well, Dr. Williams did.  
 3 CROSBIE, Q.C.:  
 4 Q. It was initiated by you writing to Dr.  
 5 Williams?  
 6 DR. COOK:  
 7 A. Um-hm.  
 8 CROSBIE, Q.C.:  
 9 Q. And you thought it was a good idea to have the  
 10 consult?  
 11 DR. COOK:  
 12 A. I did.  
 13 CROSBIE, Q.C.:  
 14 Q. It was on the issue of disclosure of retesting  
 15 results to deceased patients.  
 16 DR. COOK:  
 17 A. Um-hm.  
 18 CROSBIE, Q.C.:  
 19 Q. And disclosure is primarily an ethical matter?  
 20 DR. COOK:  
 21 A. Yes.  
 22 CROSBIE, Q.C.:  
 23 Q. The consult was valuable?  
 24 DR. COOK:  
 25 A. I'd say it was.

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1 CROSBIE, Q.C.:  
 2 Q. You even attended the consult, didn't you?  
 3 DR. COOK:  
 4 A. Yes, I did.  
 5 CROSBIE, Q.C.:  
 6 Q. And an opinion was stated by Mr. Rick  
 7 Singleton, who's the Director of Pastoral Care  
 8 and Medical Ethics?  
 9 DR. COOK:  
 10 A. Um-hm.  
 11 CROSBIE, Q.C.:  
 12 Q. Did you give any consideration to obtaining an  
 13 ethics consult when the crisis first arose in  
 14 2005?  
 15 DR. COOK:  
 16 A. Not me personally, no.  
 17 CROSBIE, Q.C.:  
 18 Q. In retrospect, was that a mistake?  
 19 DR. COOK:  
 20 A. No. We have many -  
 21 CROSBIE, Q.C.:  
 22 Q. You're quite satisfied that you didn't--that  
 23 it was not -  
 24 MR. BROWNE:  
 25 Q. Commissioner, I think -

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1 CROSBIE, Q.C.:  
 2 Q. - wise to seek a consult from an ethics  
 3 expert?  
 4 MR. BROWNE:  
 5 Q. Commissioner, in fairness, Mr. Crosbie, I  
 6 think Dr. Cook was attempting to answer the  
 7 question before he was interrupted and I would  
 8 ask, Commissioner, that he be able to answer  
 9 the question.  
 10 THE COMMISSIONER:  
 11 Q. Dr. Cook -  
 12 CROSBIE, Q.C.:  
 13 Q. I'm all ears.  
 14 THE COMMISSIONER:  
 15 Q. Dr. Cook did say he did not consider--he said  
 16 no to the question, but were you about to add  
 17 a reason, Dr. Cook?  
 18 DR. COOK:  
 19 A. Commissioner, what I wanted to say was, I  
 20 mean, at that particular time, my focus was in  
 21 the lab. The focus was starting the review  
 22 process, getting that in place. In terms of  
 23 an ethics consult, I mean, I felt that that's  
 24 something that again could have been in the  
 25 hands of the Vice President of Medical

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1 Services and Quality Initiatives people. I  
 2 was simply busy performing the duties and  
 3 tasks in the laboratory.  
 4 CROSBIE, Q.C.:  
 5 Q. By May 2006, you had time to attend what looks  
 6 like a committee meeting to discuss ethics.  
 7 DR. COOK:  
 8 A. I was asked to by Dr. Williams.  
 9 CROSBIE, Q.C.:  
 10 Q. All in aid of sorting out how to close off  
 11 patient charts, I believe?  
 12 DR. COOK:  
 13 A. Um-hm.  
 14 CROSBIE, Q.C.:  
 15 Q. Of deceased patients.  
 16 DR. COOK:  
 17 A. Um-hm.  
 18 CROSBIE, Q.C.:  
 19 Q. So your evidence is that an ethics consult in  
 20 relation to disclosure issues would not have  
 21 been of benefit to you or the institution in  
 22 2005?  
 23 DR. COOK:  
 24 A. My issue is, Mr. Crosbie, I had a number of  
 25 deceased patients in the system and I wanted

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1 direction on what to do with them.  
 2 CROSBIE, Q.C.:  
 3 Q. That's not the question I asked, is it?  
 4 DR. COOK:  
 5 A. Repeat the question again.  
 6 CROSBIE, Q.C.:  
 7 Q. My question was: an ethics consult in 2005  
 8 would not have been a benefit to you or the  
 9 institution?  
 10 DR. COOK:  
 11 A. I can't say that for sure.  
 12 CROSBIE, Q.C.:  
 13 Q. What is your opinion then?  
 14 DR. COOK:  
 15 A. My opinion is, Mr. Crosbie, I had a lot of  
 16 other things on my mind at that particular  
 17 time. If there was an ethics consult that was  
 18 required, that was something that should have  
 19 been considered by our quality initiatives  
 20 people and the Vice President of Medical  
 21 Services.  
 22 CROSBIE, Q.C.:  
 23 Q. So with all the other things you had on your  
 24 mind, the issue of the ethics of disclosure  
 25 was not uppermost?

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1 DR. COOK:  
 2 A. No, my primary focus was what's going on in  
 3 the lab, collecting information, trying to  
 4 collect as much information as I could.  
 5 CROSBIE, Q.C.:  
 6 Q. There was a lawyer present at the consult.  
 7 DR. COOK:  
 8 A. Um-hm.  
 9 CROSBIE, Q.C.:  
 10 Q. Do you know who that lawyer worked for?  
 11 DR. COOK:  
 12 A. That was Mr. Dan Boone. He worked for HIROC.  
 13 CROSBIE, Q.C.:  
 14 Q. Did it occur to you that advice from a lawyer  
 15 who didn't work for HIROC, but who worked for  
 16 Eastern Health might be in order?  
 17 DR. COOK:  
 18 A. Possibly. I didn't think about it much at the  
 19 time.  
 20 THE COMMISSIONER:  
 21 Q. Mr. Crosbie, whenever you can find a  
 22 convenient -  
 23 CROSBIE, Q.C.:  
 24 Q. Yes, I'm about to dwell on the ethics consult,  
 25 but this is another sheath of questions, so we

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1 can stop here.  
 2 THE COMMISSIONER:  
 3 Q. All right then. We'll break for the day and  
 4 meet again at 9:30 in the morning. Thank you  
 5 all.  
 6 UPON CONCLUSION.

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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 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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