COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

June 4, 2008

Appearances:

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

Rolf Pritchard/Stephen Mills . . . . Her Majesty in Right of NL

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

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

Chesley 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\
Stacey O'Dea. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

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DR. GERSHON EJECKAM - RESUMES THE STAND

THE COMMISSIONER:
Q. Please be seated. Mr. Coffey.
DR. GERSHON EJECKAM, EXAMINATION BY BERNARD COFFEY, Q.C. (CONT'D)
COFFEY, Q.C.:
Q. Thank you, Commissioner. Good morning, Doctor. If we could, Registrar, please, Exhibit P-0113, page five, please? Now Doctor, this is the June 19th 2003 memorandum that you had written to Mr. Gulliver. Doctor, why did you write this to Mr. Gulliver, address it to him?
DR. EJECKAM:
A. Madame Commissioner, my understanding then was that Mr. Gulliver, he was the program director and also controlled the staff and the budget of the Department, therefore if there was any need for any change which requires some investment that he would be the one to do it or, you know, he would be the one to address that to. So I addressed this concern to him, basically to one of the potential risk. There was no problem at that point actually, but just had the potential, that we haven't gotten to the optimal level that we needed to be.

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COFFEY, Q.C.:
Q. You had not gotten to the optimum level?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Yes.
DR. EJECKAM:
A. But work was going on, and there was no danger to anybody at that point.
COFFEY, Q.C.:
Q. And I take it though that in writing the memo, I take it, from your perspective, if certain things were not done in the future, that there could be a risk?
DR. EJECKAM:
A. Yeah, the possibility of it.
COFFEY, Q.C.:
Q. Review of it. Doctor, if I could, Registrar, please, page seven? Now this is the end of the memo. Why did you copy it to Dr. Robb?
DR. EJECKAM:
A. Robb was the chairman of the department and then Don Cook was the clinical chief.
COFFEY, Q.C.:
Q. So why would you copy it to--and to Dr. Parai,

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the site chief, why would you copy it to the three physicians?
DR. EJECKAM:
A. My understanding, the line of authority then that these other people could also have influence in achieving what we're looking at.
COFFEY, Q.C.:
Q. And what you were suggesting in fact?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Okay. In terms of the contents of the memo, the actual contents itself, some of the subject matter in it, had you discussed these matters with Dr. Robb, Dr. Cook or Dr. Parai before you wrote it?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. If I could, page five, please? Thank you. Doctor, you do write, as you point out in the first paragraph, middle sentence, "despite the fact that the problem seems to have been arrested, the state of immunostain at the General Hospital, Department of Laboratory

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Medicine and Pathology, is still unsatisfactory," and then you go and list the reasons, from your perspective, as to what is unsatisfactory.
The first is "the physical location of this facility is unsatisfactory" and you wanted it put into a separate room with proper humidity control. I take it, Doctor, that in the absence of proper humidity control, that can create problems for IHC stains?
DR. EJECKAM:
A. It's a possibility to do that. It doesn't have to happen, but it's a possibility.
COFFEY, Q.C.:
Q. It's possible. What can be the effect of improper humidity?
DR. EJECKAM:
A. Well, we are doing tests that looking at antigen antibody reaction and if you're going to have proper temperature environment, that may affect the result one way or the other.
COFFEY, Q.C.:
Q. Okay, the effectiveness of the actual procedure -
DR. EJECKAM:

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A. Yes.
COFFEY, Q.C.:
Q. - may be impaired?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. You point out "immunohistochemical stain is not just another special stain." This is paragraph two. "It's affected by far more numerous factors than may apply in other special stains. It is an extremely sensitive procedure. Therefore a haphazard and laisser faire approach to it is not the way to go." What you saw there at the time, what were you referring to as a haphazard and laisser faire approach? What were you -
DR. EJECKAM:
A. I was thinking of the way the technologists were deployed. They had other duties. They will do grossing and then go back to doing immunohistochemistry and they were quite busy. So I thought that with that dedicated staff to be on that job without doing other things, their attention may be taken away from that and at that time, I think we were doing partly

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manual, partly automated and you might start off something and then you're called off somewhere for some other duties somewhere. Time you come back at it, timing may have elapsed or something may have happened. So these were the things I was looking at, I was thinking about in that paragraph.

COFFEY, Q.C.:

Q. And as you say, I take it at the time, the equipment was semi-automated, that's the DAKO system?

DR. EJECKAM:

A. Yeah, yeah.

COFFEY, Q.C.:

Q. Doctor, on that point, the DAKO equipment at the time it was there, did you have any concerns about the actual machine or equipment itself?

DR. EJECKAM:

A. No.

COFFEY, Q.C.:

Q. Okay. You were satisfied. Had you had any familiarity with that machine before?

DR. EJECKAM:

A. We used the DAKO in Doha, even though I wasn't

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working on it myself, and I was satisfied that the technology knew what to do with it. So I wasn't worried about the machine itself. DAKO was probably the first leader in this area in diagnostic pathology.

COFFEY, Q.C.:

Q. And paragraph three, you refer to "the staff arrangement as it stands now is grossly inadequate and unacceptable for problem free or minimal problem operations," and you then stipulate, "there has to be a dedicated staff to take over this special procedure," and you go on to say--and that's what you're referring to, I take it, that the staff were not dedicated solely to this?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And it was a concern of yours?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. You go on to say, "the staff is expected to read wide on the subject and to understand the theory and practical aspects of

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immunohistochemistry." When you arrived in 2002 and then we're into now halfway through 2003, was there any reading material there for the staff related to immunohistochemistry?

DR. EJECKAM:

A. I don't recall any textbook that was there. I think they borrowed mine if they wanted to look at something, but we eventually bought--I think we ordered books for them.

COFFEY, Q.C.:

Q. When was that?

DR. EJECKAM:

A. Much, much later.

COFFEY, Q.C.:

Q. Much later?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. This is in 2005 or '06. This is when -

DR. EJECKAM:

A. Yeah, 2004/05, I don't remember the exact time, but we ordered books.

COFFEY, Q.C.:

Q. And the staff, when you first arrived, how much did they--in your interaction with them,

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how much did you feel that they knew about the theory of immunohistochemistry?

DR. EJECKAM:

A. I didn't go into that aspect, but they were doing their practical work reasonably okay, so I wasn't--I didn't discuss the theory of the subject with them, but like I said, if one is doing these on a daily basis, there'd be need for slightly wider reading to get more information about what's going on.

COFFEY, Q.C.:

Q. Because when you go on to speak about that in this memo, this point, you say "the staff" and you go on to the next page, "should be a problem shooter and that can only materialize through thorough understanding of the subject." You were saying that it would be helpful or more beneficial for them to have much greater appreciation of the theory of it?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And "besides the designated staff, there should be a need for standby staff in case of holidays or illness of the designated staff."

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You wanted staff who were even going to substitute to be trained?

DR. EJECKAM:

A. Yeah, well, I mean, here even I should have said number of people. I mean, if you have one person doing it dedicated, that's great, but if he doesn't come to work, what happens? So you needed somebody else, minimum of two or--well, three people usually, so that at all times there's someone who is familiar with what is going on.

COFFEY, Q.C.:

Q. And you go on to say then, "the dedicated staff, if there were such dedicated staff, should cut and stain all cases while the assistant/standby staff does that twice a week," which I take it would be in substitution?

DR. EJECKAM:

A. Yeah, I was just making a suggestion, you know.

COFFEY, Q.C.:

Q. Sure. So what you've described here then is a suggested kind of work arrangement?

DR. EJECKAM:

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A. Yes, whoever is going to standby will have handle of what's going on. He don't have to wait until the other guy goes and he comes in and he's new to the process. So he has to take part in the process periodically so that, you know, he knows what's going on.

COFFEY, Q.C.:

Q. And you go on to say "the designated staff uses this valuable time for housekeeping jobs in immuno. This will include dealing with ordering and titrating new antibodies."

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. "This ensures that the standby staff is in tune with the procedure and can produce acceptable results when the need arises." And so this was a plan, as it were, a suggestion by yourself as to how it might be accomplished with dedicated staff?

DR. EJECKAM:

A. Yeah, that's one way, in my mind, a suggestion I was making. There could be other ways.

COFFEY, Q.C.:

Q. Sure. And you conclude by saying "to do less

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will simply become a gamble where you may win or lose. This obviously will spell disaster."

So Doctor, those two sentences, what were you intending to do with those or by using those?

DR. EJECKAM:

A. I just want to drive home the need for the point I was making, that if you don't have dedicated staff and you don't have a substitute staff, then you are dealing with the situation where, you know, the results may not be what you expect, because you needed somebody to be dedicated to the job and you needed somebody to standby in case the dedicated staff is not there, unless you're willing to shut down the system when somebody goes on holidays or is ill or is taken away for personal other reasons.

COFFEY, Q.C.:

Q. Now Doctor, on this point, just as a general proposition, if, from your perspective, and you have I gather a significant amount of experience with IHC, if a facility is to be involved in IHC work, significantly engaged in it, okay, providing a service -

DR. EJECKAM:

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A. Yeah.

COFFEY, Q.C.:

Q. - if a facility is not prepared to actually do what's required to ensure there is a quality product being done consistently, should they be involved in it at all, from your perspective?

DR. EJECKAM:

A. Most laboratories start small. Not everything will be there before you start, so you get everyone to offer the service, what you had there was good enough to start and then--because if you don't start, you don't know what to check on. So I think from that standpoint, you don't have to wait until every bit of thing is there. What was at the hospital at that time, even though the location wasn't optimal, was good enough to start doing that and then correct what may be wrong.

COFFEY, Q.C.:

Q. And I gather though here, in light of the tone of this memorandum, you were--I gather what you're telling the Commissioner is at the time you felt like it's acceptable what's being

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turned out right now, with you there to assist, and with the changes you'd implemented, but on a go-forward basis, if they were continuing--if they were going to continue to do this and involve new antibodies and so on, get more and more involved, did you feel--how did you feel about whether or not they should continue to be involved and expand, if they didn't address your concerns?

DR. EJECKAM:

A. Well, I feel that if we continued doing the job without addressing some of this, we may run into some difficulty down the road. We may or may not, but there's a potential for it.

COFFEY, Q.C.:

Q. Now paragraph four, Doctor, you've pointed out--you go on to say "the volume of immunohistochemical procedures continues to increase. Every day more diagnostic antibodies are added to the armamentarium of immunohistochemistry. Each new antibody poses its own special problem that needs to be mastered and solved before reliable, reproducible and consistent results can be

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obtained. Since this is the only centre in the province that performs this test, there is enough case to be made for identifying this activity as special and unique, therefore requires financing and staff."

Well, Doctor, I take it the last point is you need more--to do it properly, perhaps more money and more dedicated people?

DR. EJECKAM:

A. Yeah, I mean, if they're going to hire more staff, create more positions, there would be some budget for it, and like I said, being the only centre for Newfoundland, I thought we could make a case to the authorities that funding should be provided to expand the services, in terms of more antibodies and staff positions.

COFFEY, Q.C.:

Q. Doctor, in this paragraph, you do, in the third sentence, say "each new antibody poses its own special problem that needs to be mastered and solved before reliable, reproducible and consistent results can be obtained." Can you explain briefly to the Commissioner what is involved in bringing in a

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new antibody? What are you talking about there?

DR. EJECKAM:

A. Madame Commissioner, what you do that when we buy a new antibody or something that we never used before, the commercial--the maker will give you some data, but it's advisable not just to take the data and start doing clinical work right away. You need to find suitable control in your laboratory. You need to run the tests with your own tissue in the laboratory and ascertain the positivity and negativity or specificity or sensitivity of that particular antibody, and you need to do this not just once. You need to do it on a series of material and then satisfy yourself that that antibody that is new is now ready to go into for diagnostic work. We don't get it from the makers and then put it--unless, if you used it before and you buy another one, the same batch number, then the same batch number, you have no problem. But even when you have used that antibody and you purchase another one that's a different batch number, you need to again make sure that it's doing

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what it's supposed to be doing before you put it into use, and this can be time consuming.

COFFEY, Q.C.:

Q. And was that being done when you arrived, that approach? Was that -

DR. EJECKAM:

A. I believe they were doing that. I believe that the techs were doing that. I cannot testify that I saw them doing it, but I believe they were doing this, because they had that procedure.

THE COMMISSIONER:

Q. Is there a set procedure, to your knowledge, in the lab, I mean in the sense of a manual that says when we get a new batch or a new antibody, these are the things that have to be done with it before we use it for the testing purposes or for diagnostic purposes?

DR. EJECKAM:

A. I don't recall any written manual that these are information that they have.

THE COMMISSIONER:

Q. Okay.

DR. EJECKAM:

A. And then, of course, later on, we started

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organizing to write a laboratory manual for immunohistochemistry and I believe that would have been included in the manual that was being prepared.

THE COMMISSIONER:

Q. Okay.

COFFEY, Q.C.:

Q. I take it then that when you arrived, there was no such manual?

DR. EJECKAM:

A. I don't recall seeing any.

COFFEY, Q.C.:

Q. Well, if you had--later on, if you had to start to create one, I take it no one said "well, we've already got on"?

DR. EJECKAM:

A. Yeah, yeah.

COFFEY, Q.C.:

Q. Doctor, paragraph five, you do say that "the present staff performing this procedure are doing the best they can, but with the myriad of other duties that take them away from the immunostain fairly regularly, it is virtually impossible for them to devote the time required to master the intricacies of this

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procedure." So that's what you're talking about, I take it, that because they were being required to do different things -

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. - didn't have the sufficient time and concentration time to be able to, from your perspective, master it?

DR. EJECKAM:

A. Yes, they had other duties to do and they will start the immuno and they will then halfway probably go to their other duties, depending on when they're required to do the other things. They were doing grossing. They were probably doing other things. So that was what I was referring to here.

COFFEY, Q.C.:

Q. You go on to say, Doctor, that "The fairly good stain we have now," this was in June, mid June of 2003, "is a credit to them, but they do not have enough time to spare. It's my understanding, too, that some of them have less than two or three years in the establishment and their exit will create a

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vacuum and another period of uncertainty for immunohistochemistry." What were you referring to there?

DR. EJECKAM:

A. They were trying to build a code (phonetic) and they were producing results that we could use. The station wasn't optimal. That's one. Two, I understand that one or two of them were getting ready to their retirement age or when they want to leave the service, and unless you have younger people come in while they were there, to understudy them, then if they retire, then you have to bring in new person and you have to start all over again. But to have a nice--my suggestion here that they bring new people while the older ones were there so that they can understudy what they are doing before they retire.

COFFEY, Q.C.:

Q. And paragraph 6 you go on to say, "Finally, it is pertinent to mention the results of immunostains are extremely important in histopathologic diagnosis, especially where classification of lymphomas and determination of benign or malignancy of certain lesions,

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for example, in the prostate biopsies depend on crisp, reliable and reproducible staining results. Diagnosis based on inappropriate immunostain will surely jeopardize patient care and may even expose the Health Care Corporation of St. John's to litigation. Therefore it will be ill advised to operate an unreliable and erratic immunohistochemical procedures in our laboratory." And you conclude by saying, "I, therefore, advise that you kindly take a hard look at the above and then commit the necessary resources, human and financial, to this special, all important and only service in the Province of Newfoundland." And you signed your name to it. Doctor, the last paragraph, paragraph 6, the numbered paragraph, paragraph 6 you refer to, in particular, prostate biopsies and lymphomas?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. You recall that in your April 4th memo you had referred to four lymphoma stains and one prostate stain?

DR. EJECKAM:

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A. Yes.
COFFEY, Q.C.:
Q. Was there anything, was that why you referred to those here, that you had encountered the problem with these other five stains and you were just -
DR. EJECKAM:
A. No, just an example of what could happen, it could have been another, I could you have used another antibody in this paragraph, it's an example.
COFFEY, Q.C.:
Q. And your statement that "Diagnosis based on inappropriate immunostain will surely jeopardize patient care and even expose the Health Care Corporation to litigation." At that time did you have any reason to believe then that there was any state of affairs that would then expose the Health Care Corporation to litigation?
DR. EJECKAM:
A. There was no incident, there was no problem at that time, but with my concerns it's possible that I was thinking ahead and if we don't have what we consider optimal stains that

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interpretation may be a problem and that may expose both the staff and the hospital to some difficulties.
COFFEY, Q.C.:
Q. Now, just so--you then go on to say, "It would be ill advised to operate an unreliable and erratic immunohistochemical procedures in our laboratory." Doctor, at that point, on June 19th, 2003, did you believe that the laboratory then was operating an unreliable and erratic immunohistochemical procedure at that point?
DR. EJECKAM:
A. No, no.
COFFEY, Q.C.:
Q. Okay. And you do use the verb "will" which is the future tense, it will be advised. So I take then that in writing this, you weren't saying to Mr. Gulliver and the other--and the doctors that I am--"we are operating an unreliable, erratic" -
DR. EJECKAM:
A. No, I didn't mean that. I was just wondering about the future possibilities.
COFFEY, Q.C.:

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Q. Sure. Now, Doctor, you wrote it. Doctor, had you ever written anything like this before? Like this, I mean, this is a fairly, I'm going to suggest to you, for a physician, you know, of your experience, okay, it's a fairly emphatic statement, is it not?
DR. EJECKAM:
A. Well, that was my concern and I put it down the best way I could.
COFFEY, Q.C.:
Q. Yeah. And you've indicated to the Commissioner yesterday you did this, no one asked you to do this, this wasn't kind of a set up, you know, for someone -
DR. EJECKAM:
A. No, no.
COFFEY, Q.C.:
Q. - down the road to use as a tool to get something. You were stating your own views?
DR. EJECKAM:
A. I wasn't asked to do this.
COFFEY, Q.C.:
Q. You've indicated to the Commissioner afterward you did speak to Dr. Robb. First you heard nothing and then at one point you did speak to

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Dr. Robb?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And he told you what you've told the Commissioner yesterday and then he was ill and -
DR. EJECKAM:
A. I saw him in the corridor, because his office next door to mine, opposite mine, and he said, "Yes, I've got the letter and I will arrange for a meeting for all the stakeholders to discuss it." Unfortunately, he didn't get around to doing that. And also I did say that I did ask Terry about it, too, in the corridor near the laboratory, I saw him then, he said, "I will reply to you," that was the response he gave me at that time.
COFFEY, Q.C.:
Q. And there never was--you told the Commissioner there never was a reply?
DR. EJECKAM:
A. Yeah, there was no response.
COFFEY, Q.C.:
Q. Doctor, when you didn't receive a response,

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why didn't you ever take it up with them again?

DR. EJECKAM:

A. I had already written a memo indicating my concerns and when I didn't hear anything from them, I followed it up by asking did you get the memo and they said, yes. I didn't think it was any more necessary for me to pursue this matter knowing that a number of people were copied with it and I think that I had done my own bit at that point.

COFFEY, Q.C.:

Q. Okay. And so you don't recall any meetings arising out your memo itself?

DR. EJECKAM:

A. No, I don't recall any meeting, someone to discuss this issue.

COFFEY, Q.C.:

Q. Now, in relation to what it is you suggest here, which is really dedicated staff and a particular dedicated location, did the dedicated location occur at that point?

DR. EJECKAM:

A. Later on there was a move to--the immunohistochemistry was moved out of the

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where it was and moved into a different location, dedicated location. So, you know, that was--that took place after the letter.

COFFEY, Q.C.:

Q. Yeah. Sometime after it was moved to the back of -

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. The lab larger area?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Was it walled off?

DR. EJECKAM:

A. It was walled off. Just as I say (unintelligible) the location was okay.

COFFEY, Q.C.:

Q. Okay. It was moved after. And do you know if there was humidity control for it?

DR. EJECKAM:

A. It was okay because it was not much going on in the lab and it was good for air condition, so that was acceptable as far as I could tell.

COFFEY, Q.C.:

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Q. And what about your suggestion about the dedicated staff, did that occur?

DR. EJECKAM:

A. I don't remember the work process there, but I know that later on had three of the techs, senior techs doing immunohistochemistry. I would suspect two of them were doing that as their main job or doing the job but maybe one of them probably helped do other things. That's kind of, that--it wasn't my position to know what the details or what they were doing actually.

COFFEY, Q.C.:

Q. Okay. If we could, please, Exhibit, let me just see, P-1572? Now these are the minutes of the first meeting of the surgical pathology review committee of April 15th, 2003, and we looked at that briefly yesterday. Doctor, so this is the first meeting, I take it?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. We looked at the agenda, and this is your first meeting. Doctor, your memo of April 4th, 2003 predates this first meeting?

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DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Your initiative in relation to the IHC stains, those eight stains, and IHC generally, but in particular those eight stains on April 4th, that initial initiative, did that have anything actually to do with the surgical pathology review committee?

DR. EJECKAM:

A. No.

COFFEY, Q.C.:

Q. That was your--and you described to the Commissioner yesterday, that arose out of your meetings with the local pathologists within the General Hospital and the St. Clare's people when they would come over?

DR. EJECKAM:

A. No, the surgical pathology committee was set up Don Cook, the clinical chief.

COFFEY, Q.C.:

Q. For a different -

DR. EJECKAM:

A. As a quality assurance process. It had nothing to do with the memo or

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immunohistochemistry.
COFFEY, Q.C.:
Q. But now in this at page 2, please, of the memo, at paragraph 3.1 there is a reference to the ER and PR receptors? You see that?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. So why was this being talked about then, the ER/PR matter in the surgical pathology review committee meetings when, as you pointed out, they didn't really have a whole lot, if anything to do with each other because they were separate activities?
DR. EJECKAM:
A. No, what I was said was the setting up of surgical pathology review committee had nothing to do with immunohistochemistry, but part of the duty of that committee was to review the surgical reports that have come in on it and also review what had come into the laboratory. Therefore, when we stop this stain and membership to that committee, the oncologists were there, other users of that result were there, so I thought it was

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necessary to let the committee know that this test is not being done for a period of time.
COFFEY, Q.C.:
Q. Okay. So your initiative in relation to the IHC stains, you took up on your own with the concurrence of your fellow pathologists?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And you've described that. And when the committee itself was set up by Dr. Cook under your chairmanship.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. It had a, the surgical pathology review committee was a quality assurance issue?
DR. EJECKAM:
A. That's what it was supposed to be.
COFFEY, Q.C.:
Q. And just in the course of its proceedings, you thought it prudent to let them know this is going on?
DR. EJECKAM:
A. Yes.

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COFFEY, Q.C.:
Q. Okay. Did the surgical pathology review committee ever actually oversee your work in relation to the IHC?
DR. EJECKAM:
A. They are not supposed to.
COFFEY, Q.C.:
Q. If we could, please, and I just--Exhibit P-1573? Doctor, this is a memo written by yourself, I'll show you, it's, yes, chair of that committee to all pathologists in the Health Sciences Centre and St. Clare's, April 21st, 2003. And I take it this is to inform everybody that the surgical review committee was up and running?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And what they would be involved with. And you point out in the second sentence, "This will require the pathologists flag cases suitable for discussion in the committee." And "From our standpoint incomplete surgical pathology request forms meet the criteria for review. In particular cases that have (1) No or

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relevant clinical history. No site of tissue. Absence of working clinical diagnosis especially for major surgical specimens." And "(4) All cases where the clinical diagnosis vary very significantly from the pathologic diagnosis." And I take it this was to alert the pathologists to your initiative, we're going to try to fix this problem with requisition forms?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Okay. If we could, please, Exhibit P-1575? Doctor, this is again minutes of a meeting of the surgical pathology review committee, September 23rd, 2003. You're chairing, see there. And Dr. Siddiqui, Parai, Tennent are present. Ms. Connors is there as secretary. And a call to order by yourself. The minutes of the previous--you asked if there were any changes needed to the previous minutes. Dr. Siddiqui moved to accept them and Dr. Parai seconded it. And I gather they were probably accepted. The earlier meeting, is that the April 15th one, would this be the second

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meeting of your committee?
DR. EJECKAM:
A. That may be the second or third one, I'm not sure now.
COFFEY, Q.C.:
Q. Can't recall. This one you do say here in the business arising at paragraph 2.1 "Estrogen and Progesterone Status. Dr. Ejeckam stated that the technical problem with staining for ER and PR stains has been solved." So that was -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Satisfied. And I take it that reflected what you said in your May 2nd memo to all pathologists?
DR. EJECKAM:
A. Yeah, yeah.
COFFEY, Q.C.:
Q. And here you go on to say, "Dr. Siddiqui" here it goes on to say, "Dr. Siddiqui asked what were the standards for performing Her2/neu. Some discussion took place with regards to this. It was decided that ER and PR will be

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done at the time of diagnosis and Her2/neu will be done by request. Dr. Siddiqui asked what about turn around time for Her2/neu. Dr. Ejeckam explained that Her2/neu will have to be done in batched because of cost associated with the test. It is usually performed once a week." Doctor, what was this about, this aspect of the matter?
DR. EJECKAM:
A. Now, do the test you do for breast cancer, ER/PR and Her2/neu, they were doing immunohistochemistry for those tests. Now, what we're saying here, that when we received a tissue that is malignant breast cancer, we should immediately request for estrogen and progesterone receptors to be done. Now, Her2/neu is another marker for aggressive tumors and they were just coming on board, and then we--the confirmation of that test required some more complicated tests that we were not doing at that time, what we are doing immunohistochemistry on it. And then some--if we needed, actually, those were sent out to other--Toronto or somewhere else. And for us to do it, if you open the vial and use just

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that for one, I don't know the cost exactly, but so cost that you needed to collect enough specimens so that if you open up a vial, then you would justify using it up. So it's not a test you do every day. You could do that for the ER/PR, but not with Her2/neu.
COFFEY, Q.C.:
Q. Okay. And this is to address that problem?
DR. EJECKAM:
A. For breast cancer, for breast cancer.
COFFEY, Q.C.:
Q. Okay.
DR. EJECKAM:
A. Cancers that are very malignant, poorly differentiated, most of them would be positive for Her2/neu. Neither advance for estrogen receptors. Estrogen receptors, progesterone receptors tend to be positive for low-grade tumors. They could be positive for low-grade tumors and negative for Her2/neu. The reverse is true for highly malignant tumors.
COFFEY, Q.C.:
Q. Doctor, here in the second page of this, of these minutes under "business arising", there's a discussion about, again the issue of

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no clinical history, proper clinical history being given and you had flagged cases involving hysterectomies, in particular here. And you said, "Again, no clinical history was being given or had been given for about 24 percent of the cases flagged." And you go in the bottom paragraph here to say, the minutes say, "How do we solve this problem? Some discussion took place with regards to this. It was suggested that Dr. Ejeckam to ask Dr. Williams, vice-president of Medical Services to address this problem in a memo sent to all physicians indicating the problem and asking that they co-operate in filling out the requisitions properly."
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. So in relation to this, what was the relationship between you, as chair of this committee and Dr. Williams?
DR. EJECKAM:
A. This committee when it was set up, was supposed to send reports directly to the vice-president of Medical and that's what we did.

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After each meeting, we sent minutes, copies of our minutes to Dr. Williams and a copy to Dr. Cook.

COFFEY, Q.C.:

Q. Would you, having sent the minutes, would you speak to Dr. Williams too about the -

DR. EJECKAM:

A. No, I didn't go discussing that with him, you know, I just send the minutes up to him.

THE COMMISSIONER:

Q. Just a point you made earlier, a small point I think in respect of clarification, when you said that it was decided that ER/PR will be done at the time of diagnosis and Her2/neu would be done on request?

DR. EJECKAM:

A. Yes.

THE COMMISSIONER:

Q. Do I take it then that from the perspective of the pathologist, whether it was on the request or not, you would automatically do the ER/PR or is that a decision for a pathologist in any event?

DR. EJECKAM:

A. That is a pathologist's decision to make, any

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breast cancer that the pathologist sees and after diagnosing it's malignant on H--on hematoxylin eosin stain, you will fill out the request form to the immunohistochemistry lab for estrogen and progesterone assay.

THE COMMISSIONER:

Q. Okay, so that's a pathologist decision in any event?

DR. EJECKAM:

A. Yes.

THE COMMISSIONER:

Q. And what about Her2/neu, is that a pathologist decision?

DR. EJECKAM:

A. Not really, Her2/neu is reserved to people who have metastasis or would have recurrent disease and the pathologist have no way of knowing this, this request would have to come from (unintelligible) surgeon or the oncologist.

THE COMMISSIONER:

Q. Okay, thank you.

COFFEY, Q.C.:

Q. Further down on the same page, Doctor, under "New Business" there's a reference to

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guidelines needed for request for second opinion and it's written here, "Some discussion took place with regards to this. It was decided that a review request form is to be drafted by Doctor Ejeckam, it should state reason for review, external or internal consult sought or specify if they want another pathologist in the department to review the case. Then the site chiefs to look after this once it is received in the department. Also it needs to be clarified who pays when a physician requests to have a case sent to another site for a second opinion, even when the Health Care Corporation of St. John's' pathologists do not consider the consultation necessary." And you initial these minutes. Doctor, what was this about, the idea of, like a second opinion and how did that work when you arrived?

DR. EJECKAM:

A. A second opinion is done if a surgeon receives a pathologic report and he needs, he is not happy with it or he needs some clarification, he will have the right to request that someone else look at that tissue. And rather than do

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it haphazardly, we, in Doha, devised that you fill out a form indicating why you want it to be done, why you want it done in-house, that is one pathologist in that department to look at it or you want it sent out to a different centre, so you know, the idea that the surgeon, or whoever sends, will have the freedom to request for a second opinion. Now what we want to avoid is while you are doing your work, somebody phones you, one that you have sent away, one that you have sent to Dr. A or Dr. B, that would not be the way to go, so if somebody wants a second opinion and he has a right to ask for that and then he should come down and complete this request form and the procedure will take off.

COFFEY, Q.C.:

Q. Okay. And this, I take it, this aspect of the matter here, at this point in time, September of 2003, was to kind of formalize in the way of have some documents and a procedure set out that if you're looking for a second opinion, this is the way it should be done?

DR. EJECKAM:

A. In a way, yes.

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COFFEY, Q.C.:
Q. Doctor, in relation to that, you've referred to surgeon, okay, the pathologist's reports in respect of breast cancer, in particular ER and PR results, because by then the diagnosis was done and you're reporting on ER and PR statuses. Those reports would also go to oncologists, I take it?
DR. EJECKAM:
A. I don't know, I know our business is to send the report to whoever made the request. If the surgeon gets it, he then may refer to oncologist, but we are not involved in referring the case outside of the person who made the request to the laboratory.
COFFEY, Q.C.:
Q. Doctor, what was the procedure to be if for example you reported, not you, but a pathologist reported a particular ER result and PR result and the person to whom it was reported, the surgeon or the oncologist or both, for that matter, wanted it done again, they had some question about the result, how was that to be handled?
DR. EJECKAM:

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A. He should come in and talk to the pathologist who reported it and ask that you would like it repeated and he would state his reason, he would discuss it with the pathologist and there's usually no problem in asking the technologist to repeat it.
COFFEY, Q.C.:
Q. And here's an example in respect of breast cancer, you had pointed out in your memo of May 2nd, 2003, that there are certain types of breast cancers that are generally positive or more often or almost always positive, depending upon which type you're talking about. So if an oncologist, for example, got such a report, I'll just pick lobular cancer -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And it was negative and if they wanted to have it redone because they didn't--there was some question about the validity of the result.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. It was your view at the time and the practice

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was, I take it, that they should approach the reporting pathologist.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And just simply ask that it be done again?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Did that ever happen, do you know, in your own experience?
DR. EJECKAM:
A. I don't recall that happening and nobody approached me to repeat that and I don't know what happened with my colleague's practice, so if anybody made such a request, I wouldn't know.
COFFEY, Q.C.:
Q. If there were such requests made, they weren't made to you.
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. And they weren't reported to you, if they were going on, the people weren't tell you that

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this is -
DR. EJECKAM:
A. No, and the way it went on, they probably wouldn't have reported to me because to me, it's not a second opinion issue, it's a question of repeating a test and the surgeons who request, fill out that form and the technologist will go ahead and repeat it.
THE COMMISSIONER:
Q. Did I understand you yesterday to say that there were occasions when a pathologist himself or herself would decide to repeat a test in those kinds of circumstances?
DR. EJECKAM:
A. Yes, because the tests are done and sent to him and he looks at it and if he's not happy with it, he will not make a report, he will ask for repeats.
THE COMMISSIONER:
Q. Okay, and could that happen in the same kind of situation that Mr. Coffey is now describing one where you saw, assuming that you knew what the diagnosis was, the type of cancer you were dealing with, that that might be one where the chances of having a negative result on ER/PR,

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for example, was very low, and you saw that there was a negative one, would you sort of say, "Um", maybe -

DR. EJECKAM:

A. Yeah, that's possible, that's possible.

THE COMMISSIONER:

Q. I guess what I'm asking is that the kind of information that a pathologist would take when looking at the test result and say, make a determination as to whether or not that maybe it should be run again or not?

DR. EJECKAM:

A. Yes, the pathologist will, looking at the histology first and when you get a result and if he thinks a discrepancy, he will then decide to call on the techs and say please repeat this, basically what's going on here?

THE COMMISSIONER:

Q. Okay, thank you.

COFFEY, Q.C.:

Q. In respect of in St. John's, with respect to ER/PR, did you ever, do you recall doing any retests yourself for that reason?

DR. EJECKAM:

A. Oh yes, but not ER/PR--well yeah, some ER/PR

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and some other antibodies, if we received any stain and weren't happy with it, we requested a repeat.

COFFEY, Q.C.:

Q. And in circumstances like that when it was repeated and if you got the second result and it was acceptable, you know, the slide, would you make any further inquiries at that time as to well why the first slide, the first process didn't work?

DR. EJECKAM:

A. Sometimes yes, sometimes no.

COFFEY, Q.C.:

Q. And do you recall if any of these did involve ER or PR repeats?

DR. EJECKAM:

A. I don't remember that. I know that in general practice when you receive a stain that you're not happy with, you ask the techs to repeat it and they will do that and if, I mean, this was the way we arrived at the first instance to stop some immunos because when they are repeated and they were not particularly helpful, well then we stop and solve the problem. And after that, I don't know, I

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mean, I don't remember any major issues involving retesting at that point, I mean, repeating the immuno stain.

COFFEY, Q.C.:

Q. Doctor, do you recall whether or not in dealing with ER and PR you encountered any failure of, by involving internal controls.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Okay, when was that? When did you -

DR. EJECKAM:

A. I can't put a date to it, but in the process of evaluating the stain, we found that the-- that was part of the reason why we had to stop and then work on it.

COFFEY, Q.C.:

Q. Okay, so that's back in late 2002, early 2003?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. That time period. You had, yourself, encountered some failures of internal controls?

DR. EJECKAM:

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A. Yes.

COFFEY, Q.C.:

Q. And that caused you concern why?

DR. EJECKAM:

A. Because they should be positive.

COFFEY, Q.C.:

Q. Yes.

DR. EJECKAM:

A. It should be--it's a critical point for us, so if that was not staining, question the internal may be positive, but internal control if it's not staining, then it becomes a problem and we need to repeat it and be sure that something haven't gone wrong.

COFFEY, Q.C.:

Q. Now those particular cases, did you repeat those?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. And what happened on the repeat?

DR. EJECKAM:

A. We were happy with what we're getting.

COFFEY, Q.C.

Q. The internal control did stain then on repeat.

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DR. EJECKAM:
A. Yes, yes.
COFFEY, Q.C.
Q. And so I take it that the first time, like, a particular slide in the internal control didn't stain, from what you told the Commissioner yesterday, as a pathologist, that's unreportable, should not be reported.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. That was your view.
DR. EJECKAM:
A. I mean, I'm assuming that the pathologists are aware of this, but as I explained yesterday, this is a stain that hasn't really--it's not like an HNE that was started two or three hundred (phonetic) years ago. So, if a particular pathologist is unaware of internal control and then he sees that the tumor cells are staining one way or the other on negative, then he may be pushed to--he may report that, appreciating the potential of that.
COFFEY, Q.C.
Q. But in your case, when you came along with

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your experience, when you arrived in St. John's in 2002 you encountered some internal controls for ER/PR that did not stain, you realized from -
DR. EJECKAM:
A. From my--yeah.
COFFEY, Q.C.
Q. You realized, this is not right, you know, in your world, based upon your experience is something -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. - not right here. You made further inquiries and you had the test, in fact, re-run and if the internal controls stained then, you would go ahead then and report the case -
DR. EJECKAM:
A. Yes.
DR. EJECKAM:
A. - as you saw, the tumors you saw fit.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. When the internal control initially failed,

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ie. failed to stain, do you recall whether or not the tumor itself had stained at the time?
DR. EJECKAM:
A. Sometimes it would stain; sometimes it would be negative.
COFFEY, Q.C.
Q. Okay. Now, in these meetings when you were, when this was, as you pointed out, these Tuesday and Wednesday meetings -
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. - were going on, did you raise this in these meetings, this particular problem with ER/PR internal controls?
DR. EJECKAM:
A. I didn't need to raise it because other people were having the same problem, not just in internal control problem, with consistency would be ER/PR, that was why the stain was stopped.
COFFEY, Q.C.
Q. Okay.
DR. EJECKAM:
A. And we started titrating, we started doing the

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timing for the antigen retrieval and the one we were happy that we were getting something to rely on, then we'll put back the stain into the stream.
THE COMMISSIONER:
Q. So, the impetus for the shutdown in the work that you did at the time was this inconsistency, was it, that you were seeing slides that seemed to have been properly processed and the internal control was stained, et cetera, and may be the next one wouldn't be. Is that the idea because it was being -
DR. EJECKAM:
A. Yeah, is one of the reasons for shutting down.
THE COMMISSIONER:
Q. But that's only one of them.
DR. EJECKAM:
A. Another reason was that who would get a good stain, control, today and tomorrow, the same block that was used as control, that would show up differently. So that wasn't consistent.
THE COMMISSIONER:
Q. Okay.

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DR. EJECKAM:
A. So, these cause us to, cause me to say now, let's stop this and then look at what the problem was.
THE COMMISSIONER:
Q. All right, thank you.
COFFEY, Q.C.
Q. So, it's inconsistency in the staining of the control blocks, external control block slides from day to day, some time an internal control wouldn't stain or a patient's internal control tissue wouldn't stain, you'd rerun and it and it would stain -
DR. EJECKAM:
A. And sometimes the tumor, the patient sample is not good. Like if we saw that the patient sample has no normal breast tissue, then we have to repeat. You have to look for a block that has normal breast tissue or the tendency is not to report that, even if it's positive, it's all only tumor. It would be a good idea to look for a section that has normal breast tissue in it.
COFFEY, Q.C.
Q. And that was certainly your own practice? You

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would look for something -
DR. EJECKAM:
A. Yeah, that's what I would do.
COFFEY, Q.C.
Q. And I take it that's why you included it in your memo of May 2nd, 2003. There is a paragraph refers to having normal acini in your -
DR. EJECKAM:
A. Yes. Well, I mean, that's general information. It wasn't based on what I found in house, but that's general information to have--if someone didn't know this, that that's something to have.
COFFEY, Q.C.
Q. Doctor, that memo, when I think about it, because you were--you did have teaching responsibilities yourself as part of the--you were on the staff of the medical school at the time?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. That May 2nd, 2003 memo, okay, the contents of it, would that be the sort of lesson, as it

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were, or outline of information that you would give to a resident who was dealing with or learning--you know, was doing breast pathology at the time? Is that the sort of thing you'd give to a resident?
DR. EJECKAM:
A. The information was valid for either resident or pathologists.
COFFEY, Q.C.
Q. For pathologists as well, I appreciate that.
DR. EJECKAM:
A. Yes, yeah.
COFFEY, Q.C.
Q. It's addressed to all pathologists.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. But is it the sort of thing that you, at the time, in 2003, there were residents being trained here in St. John's at the time, I take it?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. So that's the sort of thing that you would

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want to ensure that your own residents, people working for you -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. - would know?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. You'd expect them, when you finished teaching them, you'd expect them to know that?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. If we could, please--after the changes were made in 2003, you know, that you've described to the Commissioner, involving those eight stains, in particular ER/PR, in particular, in your work afterward, throughout '03 and through '04 and into '05, 2005, did you ever, afterward, notice any failure of internal controls involving ER/PR?
DR. EJECKAM:
A. I don't recall that.
COFFEY, Q.C.

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Q. I'm not suggesting you did at all, just saying you can't recall.
DR. EJECKAM:
A. No.
COFFEY, Q.C.
Q. After you made your changes -
DR. EJECKAM:
A. Yes, after the changes, I don't remember any of those again.
COFFEY, Q.C.
Q. Any failure of internal controls.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. Doctor, just on a more general point, if you can assist the Commissioner in this regard, in your experience and you pointed out you worked in Qatar for many years, and after the changes were made here, in '03, that you implemented, if a tissue sample is properly fixated, fixed, and it's the appropriate sort of block to have an ER and PR test done on, it's got a proper mixture of tumor and normal tissue and all the laboratory procedures are being properly run and they're all, every I is being dotted,

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every T being crossed, everything is being done precisely, have you ever had occasion to encounter a situation where a particular slide was run, ER test was done and you got a particular result and you were satisfied that the internal and external controls all worked. Is it possible that if the test was done a second time and all the controls worked, the result could be different?
DR. EJECKAM:
A. It's possible. I mean, if it was a second time and the antigen retrieval time had changed or somebody missed out anything, that's a possibility, but if all the procedures are followed that the way you describe it, it should come out okay.
COFFEY, Q.C.
Q. Should come out the same the second time -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. - if the procedures are precise and is the same each time.
DR. EJECKAM:
A. Yeah, that's what I consider being consistent

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because already controls are run on a daily basis the same way. So, they ought to come out positive all the time, if it's a positive control or negatives, a negative control.
COFFEY, Q.C.
Q. If we could, please--and on this issue of internal controls, after you made your adjustments in 2003, I appreciate you didn't encounter any problem with internal controls for ER/PR afterward, yourself, were there any reported to you afterward? Any other pathologists come along and say -
DR. EJECKAM:
A. No, no.
COFFEY, Q.C.
Q. - Gershon, you know, it's -
DR. EJECKAM:
A. No.
COFFEY, Q.C.
Q. Okay. So, after the changes were implemented, there were no more complaints about internal controls?
DR. EJECKAM:
A. Nobody complained to me and if they existed and they took care of it, I wouldn't know.

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COFFEY, Q.C.
Q. Sure, okay. If, for example, a particular pathologist had a problem with the internal control and had the test re-run, they wouldn't necessarily tell you?
DR. EJECKAM:
A. They have access to the technology, you know, they didn't have to go through me to them. So, they would directly ask them to repeat it and if they did it and the partic--laboratory is happy with the result, then he wouldn't report it.
COFFEY, Q.C.
Q. Doctor, at the time in 2003, I take it that looking at a slide, if there's a problem with fixation of the tissue, is that apparent to you as a pathologist?
DR. EJECKAM:
A. You need some degree of experience when you look at the HNE, not on immunohistochemistry because you have to (unintelligible) the HNE. If there are problems of processing, non-fixation, non-dehydration, whatever, you might be able to--you require some degree of experience to notice on the HNE that it is, to

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show it's improperly fixed because if it wasn't properly fixed, the staining characteristics in the area that wasn't fixed would be different from the area that's properly fixed.

COFFEY, Q.C.

Q. And that's the HNE standard -

DR. EJECKAM:

A. HNE, you know--and then if you have that kind of vision you probably would not pick that particular block to send to the techs for immunohistochemistry.

COFFEY, Q.C.

Q. On an IHC slide, is a problem with fixation, a person of your experience, is it apparent when you look at a IHC slide?

DR. EJECKAM:

A. Sometimes you could, blurry and then you have to wonder what went wrong. It's not always easy to do that on IHC.

COFFEY, Q.C.

Q. So the identification of fixation problems, if they exist, in your experience, you would generally do that at the HNE slide stage?

DR. EJECKAM:

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A. It's a lot easier to pick it up at HNE level.

COFFEY, Q.C.

Q. Now, during your time in St. John's, between 2002 and 2006, did you notice problems with fixation on HNE slides?

DR. EJECKAM:

A. Sometimes. I mean, you process thousands of sections on a monthly basis or, you know--there's going to be some slide that may have problem with them. And two things happen, if the difficulties on the slide are not critical, let's say if you can make a diagnosis, despite non-optimum fixation didn't go ahead, but if he has rendered the section un-interpretable, then you send it back to the techs.

COFFEY, Q.C.

Q. With a view to doing what? If it's un-interpretable, would you send back -

DR. EJECKAM:

A. They may have to re-process it or if you have tissue left, you may go back and put that additional tissue for fresh processing.

COFFEY, Q.C.

Q. Okay. How did the, looking back on it, your

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observations about fixation or fixation problems such, you know, whenever they existed, how did that compare with your experience in Qatar, the fixation quality in Newfoundland and Labrador -

DR. EJECKAM:

A. It's not very different. Fixation problem is the same problem over the world for HNE because those who send specimen from the OR to the laboratory tend to have factually the same sense in that sometimes you have enough formalin, sometimes you don't have enough. So, on average, it's almost the same.

COFFEY, Q.C.

Q. I take it as well, with respect to fixation because you were telling the Commissioner yesterday that, I take it, in terms of large--tissue samples that are big in volume, large samples, have to sliced, thinly sliced -

DR. EJECKAM:

A. Yes, big solid masses, if you want it to fix properly, you slice it thin and then put it in the formalin. Because if--especially if it's encapsulated, if it's encapsulated and you dump it in formalin like that, you're going to

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get maybe three or four millimetre penetration of formalin, the centre area will not be fixed, why the periphery would be fixed.

COFFEY, Q.C.

Q. In the central area in the meantime, starts to deteriorate.

DR. EJECKAM:

A. Yeah, I mean, you're going to (unintelligible). So, this is a problem you're going to get. So, to avoid that, what we do, one will get the specimen, breast or lymph nodes or masses in the neck, thyroid, will slice them and then put them in formalin to fix and then you process them probably the next day, allow to fix.

COFFEY, Q.C.

Q. What was the--in terms of that, what was the practice in St. John's in respect of breast tissue when you arrived, in terms of slicing the tissue? What did you -

DR. EJECKAM:

A. Breast tissue, they come in fresh, they are sliced and fixed.

COFFEY, Q.C.

Q. And who was doing the slicing?

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DR. EJECKAM:
A. The pathologist or the resident in the grossing.
COFFEY, Q.C.
Q. And was there--you pointed in your memo of May 2 that there's an optimum fixation time for breast tissue.
DR. EJECKAM:
A. For immunohistochemistry.
COFFEY, Q.C.
Q. I apologize, you did say immunohistochemistry, 18 - 24 hours.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. Was there--within St. John's, within the General Hospital, for example, or St. Clare's for that matter, was there any timer or any record kept of how long the tissue was being immersed in formalin?
DR. EJECKAM:
A. No, and that record is not kept in any laboratory that I know of.
COFFEY, Q.C.
Q. I was trying--in terms of how would you figure

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out that it was 18 - 24 hours, that's the -
DR. EJECKAM:
A. I mean, you have an OR, at least you know when the surger was done, they generally put the date and the time, or sometimes in the request, from time the tissue was obtained. And then on the form, you be able to calculate when we receive tissue. Sometimes a tissue is brought in fresh and look at it and it is as fresh, is now ready to go into the tissue processor. Then you leave it until the next day. So, most of them will come within that period of time.
COFFEY, Q.C.
Q. In your experience though, there was not-- people, on a form, weren't keeping track or in a computer system, were not keep track of, you know, the surgery occurred at 4:00 p.m. on a particular day and you'd be in the pathology lab at 5:00 and would know by looking at the form that it's 4:00 and I'm doing the slicing and the next day at 10:00 in the morning you could calculate the number of hours that had gone by. I take it there was no kind of record like that -

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DR. EJECKAM:
A. No, no, I mean, no, I don't know that anybody keep that kind of record in histopathology laboratory because, I mean, it's within that period of time, 18 - 24 hours, somebody has surgery, like you said, at 4:00, it comes in, by next day it is fixed to go to be processed. So, it's not even, it comes within that 18 - 24 hours.
COFFEY, Q.C.
Q. But if it doesn't get, I take it grossed that evening, if it's just left in the formalin overnight in a mass, that can create a problem, if it's not sliced up until the next morning.
DR. EJECKAM:
A. Yes, but by that wasn't the problem with breast tissue because you, they remove the breast, they will call because one will call for the pathologist or the resident that a breast mass was coming. I don't recall an any breast that was removed and dumped in formalin without anybody seeing it until the next day. I don't recall any one, like -
COFFEY, Q.C.

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Q. I take it, you tell the Commissioner, in terms of the idea of keeping track of, like, literally the timing of the surgery, the timing of the grossing, the length of time the tissue remained in the formalin, that didn't go on in Qatar either. The idea of keeping -
DR. EJECKAM:
A. No, we didn't keep log books of the timing, but you could tell from the time of surgery, the time it come--sometimes they leave the specimen in OR maybe during the weekend, you should be able to now call and tell them that the--first of all, apart from the timing, this patient has been delayed for 48 hours in the OR. Therefore, they shouldn't complain about the late result, that's part of it and then if the specimen has deteriorated, they should now note that as incident report, but we don't keep, we didn't keep, I don't know if in laboratory that would keep the time the specimen had been formalin unless doing a study.
COFFEY, Q.C.
Q. If we could please, Exhibit P-1576. Now, Doctor, this is a "Division of Anatomical

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Pathology Pathologists Meeting". I take it these are the minutes of the meeting of September 24, 2003. This is actually the agenda and then the minutes are on page two of the exhibit. Present are a number of doctors including yourself, Dr. Fernandez, Chittal, Parai, Pirzada, Carter, Barron, Fontaine and again, another Dr. Parai. These are all pathologist?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.

Q. And Dr. S. Parai would have been the site chief at the time?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.

Q. And, Doctor, there's a reference here under "Business Arising" to Cantext. Now, this particular Cantext matter, I take it, involves prostate needle core biopsies and GI biopsies and endometrial biopsies and endocervical biopsies and others. Cantext, what is Cantext?

DR. EJECKAM:

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A. I don't use that word, but understanding of it is that you kind of sterotype a brief description for small samples that doesn't require pathology, you know, gross description. So, those small samples could have one type of description, you know, and make life a little bit easier and faster for those who are grossing them.

COFFEY, Q.C.

Q. Well, there's a reference in 3.2 to "Q.A. Program", quality assurance program, that would be? Q.A. would be quality assurance program?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.

Q. Okay. "The final Q.A. program will be completed soon after a final meeting with Dr. D. Cook and Barry Dyer. However, the present practice of mentioning the name of the consulting pathologist in the microscopic description will continue". Do you recall what this was about?

DR. EJECKAM:

A. I'm not 100 percent sure here, but my

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recollection might be that when we're talking about Cantext, gross description by techs, who have to do the gross description, dealing with small samples that they could describe what does one type of description for. Now, when it comes to the microscopy, now we are discussing whether you also have one type of description for appendix, for skin or that kind of thing. And based on what is shown--say, well, may be difficult to do, then it going to be the name of the pathologist who signed that out because if you don't put it, then the surgeon will not know whom to call or whom to deal with if there's a problem with that particular case. That's my recollection of (unintelligible) sign that.

COFFEY, Q.C.

Q. And why I ask you about it is not so much that it has anything directly to do with the ER/PR matter, but the reference to the Q.A. program, I take it that at this point in time, in 2003, September 2003, there's some effort being made to address quality assurance in respect of the surgical pathology review committee and this division of anatomical pathology?

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DR. EJECKAM:

A. Yeah, the surgical pathology review committee, even they say quality assurance process is not responsible for poor tests run in the laboratory. What was being tried here was to set up a quality assurance program or manual for the department, I mean, division of anatomic pathology, completely separate and different from such group of regular review committee.

COFFEY, Q.C.

Q. If we look at paragraph 4.1 of this same exhibit it says, "laboratory technical quality" and this is under the heading, "new business", this was discussed with Barry Dyer, Terry Gulliver and Dr. D. Cook. The discussion included the technical quality of the slides, error labelling, floater and others. Some of these issues have been documented. Dr. G. Ejeckam has given a lecture on quality assurance of the laboratory which was attended by one senior technologist. This program is available for all the lab technical staff at a suitable time, if interested. A log book is available in the

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reporting room to record all problems".
Now, what was going on here, Doctor, what was this?
DR. EJECKAM:
A. What I was request--I mean, I had lecture notes from quality assurance that we had used in Doha and I thought we could give a lecture to our residents and our staff. So, this was made an open thing for the residents and the technical staff to attend. Like was noted here, unfortunately, they were very busy doing something and only one of the techs attended, but this lecture was given to residents, doctors who are training along with the techs.
COFFEY, Q.C.
Q. So, I take it that this was--was this, from your perspective, a new initiative?
DR. EJECKAM:
A. Well, one of the initiatives was quality assurance in the laboratory.
COFFEY, Q.C.
Q. And at the time, coming from Qatar, what was the state of quality assurance protocols or procedures in the lab at that time?
DR. EJECKAM:

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A. Over the period I spent 13 years there, it wasn't that way before and it wasn't started by me, there are people before me, but over the period who have developed quality assurance manual for each of the divisions, for safety manual for the autopsy rooms, quality assurance for immunohistochemistry. So, these were developed over a period of time. And by the time I left, we had this in place.
COFFEY, Q.C.
Q. Left?
DR. EJECKAM:
A. By the time I left Doha -
COFFEY, Q.C.
Q. Doha, and this was developed during your time -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. So, when you arrived then in St. John's, how did what you find in St. John's compare to what you had left in Doha?
DR. EJECKAM:
A. I don't recall finding manuals, quality

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assurance manual and that led to discussion to produce one, but they have that procedures anyway in the Cantext, the techs use for their work.
COFFEY, Q.C.
Q. But it was certainly no manual overall?
DR. EJECKAM:
A. I don't recall seeing any one of those.
COFFEY, Q.C.
Q. And the idea of--I take it that your lecture then was about the need to even have manuals.
DR. EJECKAM:
A. Well, yeah, part of it, yes, what you need to do.
COFFEY, Q.C.
Q. You brought the manual from Doha with you?
DR. EJECKAM:
A. Yeah, my copy, yes.
COFFEY, Q.C.
Q. Did you provide a copy to anybody?
DR. EJECKAM:
A. Yes, I think I provided a copy of it to the site chief.
COFFEY, Q.C.
Q. That would be Dr. Parai?

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DR. EJECKAM:
A. Yeah, and I think that was the--I don't know the exact word, yeah, maybe used as a template or to produce one for the laboratory in St. John's.
COFFEY, Q.C.:
Q. So I take it that was your purpose in providing it?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall when it was in your time here that you would have provided that copy?
DR. EJECKAM:
A. I don't remember the time, but I made it available to the site chief.
COFFEY, Q.C.:
Q. Would it have been in 2003, do you think, when you were involved in this?
DR. EJECKAM:
A. Possibly, but I can't be sure about the dates.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-1577? Now, these are notes of a meeting of the laboratory medicine program, September 26th, 2003. The

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attendees are Doctors Cook, Williams and Mr. Gulliver. In particular, please, Registrar, page 4? And this, in paragraph 5 on this page, Doctor, is a reference to the surgical pathology review committee, Dr. Cook apparently is reporting to this, to Mr. Gulliver and Dr. Williams that, he said, "Dr. Cook indicated that this group chaired by Dr. Ejeckam will meet twice a year and a copy of the minutes will come to this group." which is the laboratory medicine leadership team. So it was envisaged that your committee, surgical pathology committee would meet twice a year?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1578? Now, this is a memo, Doctor, again it's from September 30th, 2003. The subject is "Surgical Pathology Review Committee Meeting." It's from yourself to Dr. Williams. You've signed it. And you say, "Please find attached the summary and recommendations of the surgical pathology review committee meeting. Some of the problems discussed in the

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meeting." And you've copied it to Dr. Cook. It's got a received by the vice president's offices, October 3rd, 2003 stamp on it right there. And, Doctor, if you just look at the second page of this, it says, in bold print, "Summary of meeting of the surgical pathology review committee and recommendation to vice president medical affairs." And you reference "In a meeting of the committee held on September 23rd, 2003 reviews of request forms for histopathology showed a disturbing trend of tissues sent to the laboratory for diagnosis without any relevant clinical history. Generally it will be safe to say that over 80 percent of the request forms have one form of deficiency or the other ranging from the absence of the name of the requesting physician, scanty to absolutely no clinical history." And, Doctor, I'm not going to take you through this in detail, but I take it then that this was the, really, from the committee's perspective in dealing with the vice president of medical, this was the opening attempt to have that problem addressed?

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DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. In a formal way?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And here on the second page of the memo there's a heading, "Request for a Second or Third Opinion on Laboratory Diagnosis." And this, I take it, was you're formally advising Dr. Williams, you, the committee, as to the committee's position in terms of second opinions?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And the way they should be handled. If we could, please, Exhibit P-1579? Doctor, these are minutes of the medical advisory committee, the MAC, of December 10th, 2003. Page 3, please, of the exhibit? And there's, I gather, a report here by Dr. Cook to the MAC about the surgical pathology review committee. You can see that from the first sentence where

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it talks about your review, your committee's review of the requisition forms. Doctor, did you understand that the surgical pathology review committee's reports were going to, at least in some form, end up before the MAC?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And as the chair of that committee, how did you feel about the efforts that followed to implement your recommendations?

DR. EJECKAM:

A. We were happy that Dr. Cook was taking action, was sending, discussing the issue with Dr. Williams and they also moved to the medical advisory committee where most of the consultants or those who use the services were. So that was an effort he was making and we were satisfied as he has taken the case to where he should go to.

COFFEY, Q.C.:

Q. So you're satisfied that Dr. Cook, at least, has taken up the effort?

DR. EJECKAM:

A. Yes, yes.

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COFFEY, Q.C.:
Q. And if we could look, please, at Exhibit P-1580? And, Doctor, this is--I'm just going to go to--this is the agenda for March 9th, 2004 for the surgical pathology review committee. But that would be for that meeting on March 9th. But attached to it, the exhibit, is a letter of November 27th, 2003, it's to yourself from Dr. Cook, copied to Dr. Williams. And he writes, that's Dr. Cook writes, "As previously discussed with you, I would like a representative from the Surgical Pathology Review Committee to be involved in a Quality Care Initiatives by the Division of Gastroenterology (Medicine Program)." And further down in that paragraph he says, "More specifically, there is a need to standardize pathology requisitions between the St. Clare's and General Sites to eliminate site differences. There is also a review and assessment of the standardization of language used in pathology reports, as well as a review of the standardization of equipment used, and procedures and techniques of taking biopsies between the two sites. It has been suggested

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that once the standardization relating to gastric biopsies is complete, this information needs to be shared with the Surgical Program." I appreciate this does not deal with breast cancer.
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. But, Doctor, the idea or the acknowledgement of inconsistency in reporting formats between the two sites was a problem, I take it, or acknowledged to be a potential problem involving gastroenterology?
DR. EJECKAM:
A. No, I -
COFFEY, Q.C.:
Q. Was it a -
DR. EJECKAM:
A. - call it inconsistency. There's a question of different style of reporting.
COFFEY, Q.C.:
Q. Oh, and I--okay, so and could you--what was the concern, Doctor? I take it there must have been some concern if they're going to make -

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DR. EJECKAM:
A. My recollection about this that Dr. Cook mentioned that we have conferences with the gastroenterology unit and I took up the matter with Dr. Bussey to find the time so that we can interact. It's a kind of a way of pathology and the clinicians coming together, discuss cases and the thrust is to make sure that to have better patient care services, because if we don't talk to each other, wouldn't know what the problem the other is going through. Unfortunately we couldn't agree on the time to have this conference, you know, in the laboratory, so it was--it didn't take off.
COFFEY, Q.C.:
Q. Doctor, in respect of ER and PR and breast cancer reporting by pathologists, were you aware of any differences in approaches between the two sites in terms of the reporting formats?
DR. EJECKAM:
A. I'm not aware of any.
COFFEY, Q.C.:
Q. Okay.

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DR. EJECKAM:
A. If they existed, I don't know.
COFFEY, Q.C.:
Q. Okay. Exhibit, please, P-1582? Now, this is a memo of June 14th, 2004, it's from Dr. Kwan, who is the co-clinical chief of the peri-operative program to all surgeons at the Health Sciences site. "Specimen Without Clinical History." And he writes, "Dear Colleague, Enclosed is a memo from Dr. Ejeckam, Chairperson, Surgical Pathology Review Committee regarding pathology without adequate clinical history. This has been going on for some time with no improvement with friendly persuasions." I see you're smiling, Doctor. "This is to advise you that the history is to be completed with the pathology requisition form before the specimen goes out of the operating room. I have also advised the OR nurses to remind all physicians to do this or the specimen will not leave the operating suite unless the clinical history has been completed. Thank you for your attention in this matter. Enclosed you will find a memo I received from Dr. Ejeckam which

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I think is quite a reasonable request. Sincerely, Alan Kwan." And if we could look at the second page, Doctor, this is your memo of June 9th, 2004 to Dr. Kwan, and you sign as chair of the Surgical Pathology Review Committee. And you write, "At the last meeting of the Surgical Pathology Review Committee, members continued to show concern over noncompliance by many physicians with regards to completing the surgical pathology request forms adequately. It was decided to request that the OR committee adopt a policy whereby no specimen leaves the OR for the laboratory without adequate clinical history. I request that you kindly evolve a 'modus operandi' to realize this decision." So I take it, Doctor, that your efforts and Dr. Cook's--your efforts, the committee's efforts to have the forms filled out properly had not met with any success up to this, or had not met with sufficient success up to this point?

DR. EJECKAM:

A. Yeah, it hasn't come to the level that would give us comfort.

COFFEY, Q.C.:

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Q. Doctor, does the failure to fill out such forms properly, could that have implications for patient care?

DR. EJECKAM:

A. It is possible, that's why I would have requested. But again, more importantly, if you don't have it, that means for the pathologist, if he needs this information, will have then have to call for it. I mean, he wouldn't report at a case that he needed clinical information where it was critical, he will not report on--he will either have to look for the information himself or phone up the physician. We want to avoid this waste of time calling up physician or leaving the gross bench and running to the computer to get information. And most hospitals if you send in material to the laboratory, you got to fill information. But it's not particular to St. John's, surgeons, material from OR are known to really come with scanty information most places. Of course, people there have evolved methods to cure that by all the effort we are making.

COFFEY, Q.C.:

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Q. And one of the methods you were suggesting here to Dr. Kwan was to tell the surgeons it's not leaving the OR unless you fill out the forms?

DR. EJECKAM:

A. Yes, yeah.

COFFEY, Q.C.:

Q. Okay. So that would be, I take it, somewhat of a course of measure?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. To try and shape compliance. Doctor, if we could look, please, at Exhibit P-1583? This is a Division of Anatomical Pathology pathologists meeting, General Hospital site, November 2nd, 2004. It's the agenda. Look at page 2 of it, the minutes attached for that meeting, the November 2nd meeting. A number of people present, including yourself, see your name there in the middle of the first line, quite a number of pathologists present. Dr. Parai chaired. And in relation to this I have a couple of questions. On the second page, under paragraph 4 there's a reference to

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new business, "4.1 Pathologist Assistant. Much discussion on this issue. It was agreed by the pathologists that this issue should be brought to the attention of the vice president of medical services. Dr. D. Robb, Chair of the discipline, will write to Dr. R. Williams recommending pathologists assistants as per the Royal College recommendation. It is also pointed out that the Anatomical Pathology division is earning over $100,000 per year by billing for the technical work. It is expected that some of the money should be given to the pathology budget to hire pathologist assistants." Now, Doctor, what was this about pathologist assistants? This is late in 2004. When had this idea first arisen and who was pushing it?

DR. EJECKAM:

A. In most laboratories, the mainland and United States now, pathologists do not do grossing of tissue any more because that is, you know, so -

COFFEY, Q.C.:

Q. If I could just this moment. So you're saying now, Doctor, you mean in 2008 or in 2004? I'm

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just trying to -
DR. EJECKAM:
A. 2004.
COFFEY, Q.C.:
Q. Okay. I apologize, go ahead.
DR. EJECKAM:
A. 2004, Commissioner, mainland and some other hospitals elsewhere the laboratory had pathologist assistants, and their job would be to take over some of the mundane duties that a pathologist will do to make it difficult for him to have enough time to devote to his either research or patient diagnostic work. Like we talk about counting the small samples that trained staff, well not--they may have a colleague or some kind of school to train these fellows and they can do good job, they can do good job. They can do grossing, they can even do gross autopsy, then pathologist will come in and look at and interpret the findings. So we thought that if this can happen to us, then that will enable us to have more time to devote to diagnostic work.
COFFEY, Q.C.:
Q. As opposed to actually having to do the

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grossing yourself?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Because -
DR. EJECKAM:
A. Pathologists still do some, because there's some gross bowel, breast, there's some big specimens that because they are not doctors, they may have difficulty in knowing the anatomy of what they have, so those are not--those are few, so that would limit the time the pathologist spends on grossing bench.
COFFEY, Q.C.:
Q. And that was thought, I take it, locally here, by yourself and by Dr. Robb, for example, to be a good thing, the idea of having pathology assistants was something that was desirable?
DR. EJECKAM:
A. Oh, everybody agreed to it, yes.
COFFEY, Q.C.:
Q. So what--when you arrived in 2002, was the idea of pathology assistants being desirable, was that accepted here at the time?
DR. EJECKAM:

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A. I'm not sure whether I discussed with them, but it's something that's happening other places.
COFFEY, Q.C.:
Q. And who do you recall as pushing it, who was the leader of the push for it?
DR. EJECKAM:
A. I can't put my finger on any particular person.
COFFEY, Q.C.:
Q. Okay. And well, here, by November, 2004 there's a note that Dr. Robb will be writing to Dr. Williams to advocate for it. So certainly Dr. Robb, I gather, was one of the leaders in pushing for this?
DR. EJECKAM:
A. He was the chairman of department.
COFFEY, Q.C.:
Q. Chair, okay. And what happened with respect to it? I mean, everybody, I gather your recollection of it is pretty well everybody amongst the pathologists was in favour of it?
DR. EJECKAM:
A. We didn't have pathology assistant, maybe they have it now, it wasn't there until I left. So

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it was being on the discussion, but they didn't get to hire until I left the services, 2006.
COFFEY, Q.C.:
Q. So the pathologists are pushing for it. What's your understanding of why it wasn't done back in 2004?
DR. EJECKAM:
A. I don't remember, but it looks like maybe budgetary problem.
COFFEY, Q.C.:
Q. There's a reference here to, it says, "Will write to Dr. Williams recommending pathologist assistants as per the Royal College recommendation." So there was a recommendation by the Royal College -
DR. EJECKAM:
A. I have not seen the recommendation. There must be, I didn't see it.
COFFEY, Q.C.:
Q. Okay. You, yourself, at the time, were you in favour of using pathology assistants that were properly trained?
DR. EJECKAM:
A. Yes, yes.

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COFFEY, Q.C.:
Q. If you look, please, at the next page under "New Business Cont'd", paragraph 4.7. I shouldn't say the next page, it's page 4, actually, of the exhibit. 4.7 the title is "FISH for Her2/neu. This will be automatically done when the Her2/neu is reported 2 plus. Dr. G. Ejeckam is the head of the immuno lab and consultation with him is suggested for any related issue." Now, sir, the--I take it this related to the usage of FISH test in certain Her2/neu results?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Okay. And you're described here as the head of the immuno lab and "consultation with him is suggested for any related issue" involving this. First of all, at the time would you have described yourself as the head of the immuno lab, at that time?
DR. EJECKAM:
A. I was a resource person for immunochemistry lab, resource.
COFFEY, Q.C.:

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Q. I'm sorry, you were?
DR. EJECKAM:
A. I was a resource person -
COFFEY, Q.C.:
Q. Oh, resource, I apologize, yeah. I just--so you were a resource person?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. So I take it you would--and you would certainly back then have thought of yourself as a resource person for the immunolab.
DR. EJECKAM:
A. Yeah, that's what I was. I wouldn't call myself head of immuno.
COFFEY, Q.C.:
Q. At -
DR. EJECKAM:
A. But there was no administrative structure created for me to be head.
COFFEY, Q.C.:
Q. Yeah.
DR. EJECKAM:
A. I offered to help in the laboratory and that's what I did, but in terms of being head, there

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was no administrative structure to create that.
COFFEY, Q.C.:
Q. There was no administrative structure that would allow for that at the time?
DR. EJECKAM:
A. Well, you know, these are a question of use of word, I mean, by the, whoever made the minutes that I'm head. But all I knew I had some responsibilities to it, but not, I wasn't appointed head.
COFFEY, Q.C.:
Q. What were your responsibilities, do you think, at the time? Like, looking back on it in late 2004 up to that point, into the beginning of 2005, from your own view at the time?
DR. EJECKAM:
A. As a resource person when I came involved with the--when I became involved with the technologists, as I said earlier, I got impression from them they were happy, for the first time they have someone they could relate to, they could ask questions about what they were doing. So my response to them was to help them become more efficient, help them

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source proper controls, help them review what they are doing to make sure the results coming out are adequate.
COFFEY, Q.C.:
Q. Okay. If we could look, please, at Exhibit P-0067? Doctor, this is a memorandum, the Commission has seen this before, it's dated May 24th, 2005 to Dr. Williams. It's from Dr. Cook in his capacity as clinical chief. And this relates to the, what leads--it's the beginning of ER/PR issue in 2005. Doctor, when did you first become aware of the index case in conversion?
DR. EJECKAM:
A. I don't remember a date, but I heard it through the grapevine. I didn't have an official indication that it was happening.
COFFEY, Q.C.:
Q. Okay.
DR. EJECKAM:
A. But general discussion in the laboratory, that's how I learned about it. But it could been either 2005 or six.
COFFEY, Q.C.:
Q. But this is certainly 2005, the reference

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here, and I'll be showing you certain documents in that year, and you say in kind of general discussion in the lab is the way you found out?

DR. EJECKAM:

A. Yes, from the grapevine I will say. There was no announcement, official document saying this has happened.

COFFEY, Q.C.:

Q. And do you recall what it was you heard initially?

DR. EJECKAM:

A. Pardon?

COFFEY, Q.C.:

Q. What was your understanding initially as to what had happened? Of the grapevine -

DR. EJECKAM:

A. What I had thought was said was that some case was stained in our laboratory, it looked like normal and it was negative, and then got stained elsewhere, it was positive and redone in our laboratory and became positive.

COFFEY, Q.C.:

Q. Now that -

DR. EJECKAM:

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A. That's my understanding of it.

COFFEY, Q.C.:

Q. Yes, via the grapevine as you say.

DR. EJECKAM:

A. Yeah, yeah.

COFFEY, Q.C.:

Q. And this grapevine would have involved, I take it, words from either a technologist or perhaps other pathologists?

DR. EJECKAM:

A. Possibly.

COFFEY, Q.C.:

Q. Having heard that at the time, do you recall whether there was discussion then in the lab amongst the pathologists about that, the issue?

DR. EJECKAM:

A. There wasn't great discussion. It wasn't an agenda for discussion as such. I mean, if people mentioned it along the corridor probably, but not--it wasn't an agenda. I don't recall that being an agenda in a meeting.

COFFEY, Q.C.:

Q. Did anybody approach you about it at the time?

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DR. EJECKAM:

A. No, I don't recall that.

THE COMMISSIONER:

Q. Mr. Coffey, wherever you can find a good time, we'll take the morning break.

COFFEY, Q.C.:

Q. Thank you, Commissioner. If I could just go back to page one of this exhibit, Doctor, I'm just going to--in the course of writing this letter, and Dr. Cook has written to Dr. Williams in the second paragraph saying "on May 17th, 2005, a meeting was held which included myself," which would be Dr. Cook, "Dr. Bev Carter, our resource person for breast pathology, Mr. Barry Dyer, divisional chief for anatomical pathology, and Doctors Joy McCarthy and Kara Laing, medical oncologists." And there's a long discussion here about what went on during the meeting.

Doctor, you would have been working at this point in time, in May, in St. John's?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. April and May of 2005?

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DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Do you recall what time you took your vacation that year?

DR. EJECKAM:

A. I don't remember now.

COFFEY, Q.C.:

Q. Okay. There is a reference in the summer, and I will point you to it, okay, in the minutes of a meeting that in the middle of the summer, apparently you were away at some point, yourself and Mr. Dyer. So I'll refer you to that, but in the spring, I take it, you would have been here?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. Doctor, it's apparent from the materials here that the Commission has seen that you're not listed as an attendee in any of these early meetings.

DR. EJECKAM:

A. No.

COFFEY, Q.C.:

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Q. In April or May or June?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. Have you ever asked anyone why you weren't asked to those meetings?
DR. EJECKAM:
A. No, I didn't ask.
COFFEY, Q.C.:
Q. Okay. Have you ever wondered why?
DR. EJECKAM:
A. I don't want to speculate about that. I would hear that they have these meetings and I'm the resource for immunohistochemistry and if they chose to--I didn't know what the agenda was, so it probably didn't concern me, so I didn't--I wasn't curious in that direction.
COFFEY, Q.C.:
Q. So having heard then about this index case, as you say via the grapevine, did you go to, for example, Dr. Cook or the site chief and ask "what's going on?"
DR. EJECKAM:
A. No, I didn't do that.
COFFEY, Q.C.:

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Q. Okay, and why not?
DR. EJECKAM:
A. There was nothing to gain from that. I mean, if they--I mean, they didn't inform me about it and I wasn't involved in anything about it, and I didn't think it was necessary to go fishing for it.
COFFEY, Q.C.:
Q. I take it that they, from your perspective, if they wanted to talk to you, they knew where to find you? That would be the--in terms of that, they knew where you worked and -
DR. EJECKAM:
A. Yeah, I think so.
COFFEY, Q.C.:
Q. Thank you, Commissioner, if we could.
THE COMMISSIONER:
Q. We'll take 15 minutes.
(BREAK)
THE COMMISSIONER:
Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. If we could look, please, at Exhibit P-0920? Now, Doctor, this is a letter written May 20th--dated May 27th

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2005 addressed to Dr. Williams. It's from yourself as chairperson of the surgical pathology review committee, copied to Dr. Cook, clinical chief, and you say "Dr. Williams, please find attached the recommendations of the surgical pathology review committee. These recommendations were approved in a meeting of the committee held on Tuesday, May 24th, 2005. We hope that the HCCSJ will embrace and implement these recommendations."
So I take it, Doctor, that there was a meeting held Tuesday, May 24th, 2005, of that committee?
DR. EJECKAM:
A. I should think so, yes.
COFFEY, Q.C.:
Q. Yes, and do you recall whether or not the ER and PR matter made it on to the proceedings or agenda of the pathology review committee, surgical pathology review committee?
DR. EJECKAM:
A. I don't recall that, and -
COFFEY, Q.C.:
Q. When I say that, I mean in '05 now, not in

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'03.
DR. EJECKAM:
A. No, I don't think we discussed that.
COFFEY, Q.C.:
Q. And here, looking at page two of this, of the exhibit is a document entitled "surgical review committee - update" and you note "the surgical review committee was set up as a quality assurance and control committee. The mandate includes scrutiny of pathology request forms and surgical reports. This committee has met on several occasions and reviewed over 1,000 request forms when one includes the initial screening of the forms by committee chairman, Dr. Ejeckam. A number of issues were raised and recommendations sent to the vice president, Medical Services, with copies to the clinical chief, Dr. Donald Cook. It would appear that despite the reports of the committee, little change, if any, has occurred in the way surgical requesting clinicians complete request forms."
So I take it that you hadn't--you're reporting here that the committee hasn't had much success in that effort?

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DR. EJECKAM:
A. Yeah, that would be right.
COFFEY, Q.C.:
Q. and you make reference then to small and large intestine and uteri, concerns about those, in terms of the requisition forms and lack of clinical information. Then you say "it is the view of this committee that to achieve a meaningful, comprehensive, quality control and assurance in the practice of the Health Care Corporation of St. John's, a more elaborate action will be needed. One, a department of quality assurance and control should be established. Two, a director of the quality assurance and quality control is appointed. This should be a full-time job, or if part-time performed by any of the clinicians or other staff, appropriate remuneration should apply. Three, this department should have at least two clerks with knowledge of records department of the Corporation. Four, the quality control and quality assurance department shall encourage, supervise and coordinate the establishment of departmental quality assurance and quality control units,

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and shall liaise with them to establish Health Care Corporation of St. John's quality assurance and quality control meetings. Five, all cases of quality control and quality assurance and monthly departmental quality assurance and quality control reports shall be lodged with the Health Care Corporation of St. John's Quality Assurance and Quality Control department and discussed in the quality assurance and quality control meetings. Six, all departments, clinical and non-clinical, shall be represented in the quality assurance and quality control meetings."

And then you conclude saying "to continue to look at pathology request forms and make recommendations that may not be implemented is considered a waste of valuable time of the staff that had agreed to serve on the surgical review committee. The hospital community has been sensitized to the problem of inadequate clinical history on the request forms and as indicated above, compliance may not be achieved or improved by repeating the process. We thank you for the opportunity to serve on this committee and hope that you will consider

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this our last recommendation/suggestion."

So I take it, Doctor, that the committee had done, from its perspective, what it could in this regard and this was advising Dr. Williams accordingly?

DR. EJECKAM:
A. Yes, Commissioner.
COFFEY, Q.C.:
Q. From your perspective, as chair, was there a certain amount of frustration involved in your ability to--inability to make headway?
DR. EJECKAM:
A. Well, in a way, yes, but it wasn't necessarily because--what we found that a number of the members of the committee were consistently absent and that the regular members would be the chairman and the other pathologists and Dr. Siddiqui and one or two other people, and of course, we had exhausted this process and we thought the best thing is to put down our recommendations and then, and also inform officials that we are no more going to meet. They shouldn't expect anything any more from this committee.
COFFEY, Q.C.:

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Q. Now Doctor, here, in the middle of the page, you write or it was written, "it is the view of this committee that to achieve a meaningful, comprehensive quality control and assurance in the practice of the Health Care Corporation of St. John's, a more elaborate action will be needed" and you have six paragraphs numbered there.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Six recommendations. I take it that you were recommending this because at that point, none of this existed in a formalized way?
DR. EJECKAM:
A. I wouldn't know. I can't--sincerely, I don't know whether there was a quality assurance department. I know it was mentioned quality assurance initiative, that's the word used, so I don't know if there was a director or someone responsible. But it wasn't recommended because none existed. This is what we thought was appropriate to put in place.
COFFEY, Q.C.:

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Q. And was this a consensus of the committee?
DR. EJECKAM:
A. Yes, yes.
COFFEY, Q.C.:
Q. Universal consensus of the committee that this was appropriate?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. So at the time, I take it that if the committee is recommending this and the committee has been in existence for then two years -
DR. EJECKAM:
A. About that.
COFFEY, Q.C.:
Q. - yes, from April of '03, and it's now May of '05. So that's just over two years, and the committee is not just dealing with forms here. You're actually talking about suggesting setting up a department?
DR. EJECKAM:
A. Yes, yes.
COFFEY, Q.C.:
Q. That's actually what it spells out.

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DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. So there was perceived by the committee to be a need for such a department, properly funded and -
DR. EJECKAM:
A. Yes, there was need for it because what the surgical review committee was was a quality assurance initiative and, you know, we thought that to have it achieve its full aim, there has to be a bigger body and then some officer responsible for this kind of activity.
COFFEY, Q.C.:
Q. Now Doctor, that sort of a body or organized, you know, formally recognized and organized body within a department, like a tertiary care hospital such as the General Hospital was and is, does such a department, to your knowledge, exist in other facilities, other comparable facilities?
DR. EJECKAM:
A. Yes, we had this in Doha.
COFFEY, Q.C.:
Q. In Doha, there was?

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DR. EJECKAM:
A. Yes, we had director of quality assurance, and then we have a department of quality assurance, the committee.
COFFEY, Q.C.:
Q. And was this a department that involved physicians being involved in it?
DR. EJECKAM:
A. Involved physicians and technologists. In the laboratory it would be pathologists and technologists, and clerical staff, because there's different areas to look at.
COFFEY, Q.C.:
Q. Okay. Doctor, did you ever get any response, you or the committee get any response to this?
DR. EJECKAM:
A. I think there was a reply from Dr. Williams.
COFFEY, Q.C.:
Q. Okay, and was your recommendation implemented?
DR. EJECKAM:
A. I didn't check whether each one of them was taken care of, but I think in his reply, he did acknowledge my letter and I think he did mention that he would be doing something about it.

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COFFEY, Q.C.:
Q. Doctor, while I'm thinking of it, you indicated that the laboratory manual that you had brought out of Doha with you and you'd passed on to the site chief in St. John's?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Who was the site chief that you passed it on to?
DR. EJECKAM:
A. Who was the site chief? Dr. Parai.
COFFEY, Q.C.:
Q. Which?
DR. EJECKAM:
A. S. Parai, Sushil.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-0493? Doctor, this is a letter again to Dr. Williams, June 14th 2005. I'll just show you, Doctor, it's from Dr. Cook and the subject matter is "re: preliminary update on false negative results for estrogen and progesterone receptors" and he writes that "further to my letter of May 24, 2005, we reviewed reports of the estrogen

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and progesterone receptors in 160 breast cancer patients that originated from the division of anatomical pathology, Laboratory Medicine program, at the Health Care Corporation of St. John's. These 160 cases are also confined to patients and attending surgeons within the Health Care Corporation of St. John's. Of the 160 cases that have estrogen and progesterone receptors, 50 percent of these are reported as ER/PR negative. That is following a preliminary review of the pathology reports."

And he says, "it also seems that most of the negative ER/PR results started sometime around June 24th 2002. We are in the process of retesting all negative ER/PR cases with our newer, more sensitive Ventana benchmark immunoperoxidase method for the year 2002." And he goes on from there.

Doctor, in the middle of June of 2005, were you aware that such an effort was going on?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

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Q. Okay, and how were you--why were you aware of it?

DR. EJECKAM:

A. I think I got information from the technologists. I wasn't informed that--I didn't know when this material was being sent out to be done, but I eventually knew that it was being done.

COFFEY, Q.C.:

Q. So you, in effect, initially then, in terms of the actual effort being made to look at the older cases or cases going back to 2002 and other years, you found out after the grapevine comment from the technologists?

DR. EJECKAM:

A. Yes, I think so.

COFFEY, Q.C.:

Q. And that would be Mr. Green?

DR. EJECKAM:

A. Les, Ken, you know.

COFFEY, Q.C.:

Q. Les Simms, yes. Les Simms and Mary Butler, that group.

DR. EJECKAM:

A. Yeah.

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COFFEY, Q.C.:

Q. Okay. Now Doctor, between the spring of '03, when you got involved in the effort to improve the quality of the slides and you worked with the technologists then, I gather, to do that, and this is the spring into the summer of '05, how much interaction did you have with the technologists, as the reference person?

DR. EJECKAM:

A. I interacted with them very closely. I would go into the laboratory and discuss with them and after their staining of cases, I would take them to the multiple head microscope in the resident's room. We would look at things together. So we had very close relationship.

COFFEY, Q.C.:

Q. And your under--looking back on it, from your perspective, if they had a question about something or a concern, did they--do you think they felt free to come to you about it?

DR. EJECKAM:

A. They were free to come to me anytime and we had good time. There was no barrier between me and they, at that time.

COFFEY, Q.C.:

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Q. Doctor, there's a reference in that letter to the Ventana, so-called Ventana benchmark immunoperoxidase method. Now you had come to St. John's, when you arrived in 2002, they were using the DAKO?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. And we have reason to believe that the Ventana probably arrived on the site in December of '04 and started to be used early in '05. Trying to get it up and running.

DR. EJECKAM:

A. That's possible, yes.

COFFEY, Q.C.:

Q. Did you--were you ever consulted about the obtaining of--'04, yeah, December '04, and they started--I'm sorry, December of '03, I apologize, and it was early '04, they started to use it, okay, and I apologize. She just corrected me on the date.

DR. EJECKAM:

A. I don't remember the dates myself.

THE COMMISSIONER:

Q. Why don't we start all over again.

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COFFEY, Q.C.:
Q. Thank you. Doctor, first of all, were you asked about the advisability of switching from the DAKO to the Ventana?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. When did you first learn that it was going to occur?
DR. EJECKAM:
A. When I learned that -
COFFEY, Q.C.:
Q. That the Ventana was--there was going to be a--the DAKO was going and the Ventana was coming.
DR. EJECKAM:
A. No, no, I saw the Ventana machine in the laboratory.
COFFEY, Q.C.:
Q. Okay.
DR. EJECKAM:
A. And when I saw it, then of course, we started looking at the cases with it. I started looking at the cases with the test, when they started doing stains on it, and compared it

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with the stains from the other machine.
COFFEY, Q.C.:
Q. The DAKO?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Which you were still then using for reporting initially?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Okay. So you were involved in the process of calibrating the Ventana or getting it up and running?
DR. EJECKAM:
A. Well, I would say in a way I was because what happened then, if I recollect properly, that they would do para staining in Ventana and also DAKO and then we would look at them and evaluate the positivity or negativity or crispness of the stains.
COFFEY, Q.C.:
Q. And who was doing the evaluating?
DR. EJECKAM:
A. I would do that.

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COFFEY, Q.C.:
Q. Okay, you were doing it.
DR. EJECKAM:
A. Yeah, they showed me the--yeah, I would evaluate whether it's good or bad or whatever.
COFFEY, Q.C.:
Q. So, and I gather--there will be evidence, Commissioner, that the--I understand that the DAKO showed up in--I'm sorry, the Ventana, I apologize, the Ventana showed up in December of '03 and in early '04, January, February and March of '04, this comparison was going on that you refer to.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. And from a pathologist's perspective, I take it you were the person who was overseeing this comparison?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And then the usage of the DAKO was finally discontinued?
DR. EJECKAM:

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A. Yes.
COFFEY, Q.C.:
Q. Were you satisfied then to take up and use the Ventana yourself, in the sense of to have the lab go ahead and use the Ventana?
DR. EJECKAM:
A. Yeah, the machine was okay. I have no problem with the product that we're getting.
THE COMMISSIONER:
Q. Did the Ventana arrive in the sense of already having been acquired or did it arrive for you to do the assessment as to whether or not you would switch to it?
DR. EJECKAM:
A. No, everything just had--it had been acquired. It just arrived as part of our equipment.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-0069, please? Now Doctor, this is a letter dated July 14th 2005. It's to Dr. Donald Cook. It's from Dr. Beverley Carter. It's copied to Dr. Williams. In this letter, Dr. Carter says "as per our many recent discussions, I agree with you that

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our estrogen receptor status reports prior to 2003 require immediate investigation." And she talks about "our recent examples of patients converting from estrogen receptor negative to estrogen receptor positive status is quite concerning. The factors identified on those slides clearly show problems with the technique of estrogen receptor testing and the interpretation of same." And she makes reference to the paperwork, her inability to yet review it.

And she continues "I am therefore eager to review the estrogen receptor status of all patients seen in our laboratory from May 1997 when the immunohistochemical staining for estrogen receptor status first became available up until March 2004 when analysis and readjustment of the estrogen receptor status protocol was carried out by Dr. G. Ejeckam. I think that it is vital that we expediently review these cases and let patients know as quickly as possible of any change in their estrogen receptor status."

Now Doctor, I take it you hadn't seen this letter in '05?

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DR. EJECKAM:

A. No.

COFFEY, Q.C.:

Q. One thing I wanted to ask you about was this, there's a reference to up until March, 2004, when analysis and readjustment of the estrogen and receptor status protocol was carried out by Dr. G. Ejeckam, now I take it that that's not accurate, is it, the date's not accurate, your readjustment of the estrogen receptor status protocol was carried out in 2003? Would that be -

DR. EJECKAM:

A. I don't know, I think I suppose what's she referring to is when the Ventana came in and we are trying to validate that by doing stains on it and also on DAKO. I suspect that is what she is referring to here.

COFFEY, Q.C.:

Q. As opposed to the 2003.

DR. EJECKAM:

A. As opposed to when we stopped the stains and-- because we worked with DAKO at that time, not with Ventana.

COFFEY, Q.C.:

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Q. Okay. Now in the second, in the next paragraph, in the middle of it, she says, "All of the slides from the cases"--it begins right here, Doctor, with the cursor--"including the estrogen receptor slides need to be pulled and organized. All these slides then need to be reviewed by me, both estrogen receptor negative and estrogen receptor positive patients." And she goes on from there, okay, with a plan of action, as it were. Were you made aware that this effort was planned? That this was the sort of effort that was going to be undertaken?

DR. EJECKAM:

A. No.

COFFEY, Q.C.:

Q. If we could please, bring up Exhibit P-1586, now, Doctor, this is a draft of--well it's an e-mail and then a draft of a briefing note. If we could look at page 4, please, you will notice it's dated July 20th, that e-mail, and under additional notes, it's been written here that "Dr. Williams has also asked that an investigation be conducted into the five-week stoppage of immunoperoxidase staining for

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ER/PR receptors in 2003 by Dr. Ejeckam." And the author has said "this raises concerns." As well, if we could, please, bring up Exhibit P-0075? That, I gather, Doctor, what we just looked at then is an earlier draft of, if we can look at page 3 of this, this is the actual July 20th official briefing note, you'll see that on the bottom of the page there, date prepared, July 20th, 2005. And this was apparently prepared, Doctor, just to let you know, it was prepared for the Minister of Health at the time, the Department of Health. On this page, the second last paragraph reads, "Eastern Health's Vice-President of Quality and Diagnostic and Medical Services, Dr. Robert Williams, has also asked that an investigation be conducted into the five-week stoppage of immunoperoxidase staining for ER/PR receptors in 2003 by Dr. Ejeckam." Now, Doctor, in July or August or September of 2005, were you ever asked--did anybody ever inquiry of you as to what had happened in 2003?

DR. EJECKAM:

A. I don't recall any discussion about this. I

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don't think anybody asked--I wasn't questioned about it.

COFFEY, Q.C.:

Q. You weren't questioned about it.

DR. EJECKAM:

A. No.

COFFEY, Q.C.:

Q. And did you ever bring it up with anybody?

DR. EJECKAM:

A. No, there was no need for it.

COFFEY, Q.C.:

Q. And I take it there was no need, well from your perspective, why is that?

DR. EJECKAM:

A. I didn't see any need for that because, I mean, I wasn't aware of what was going on anyway, so there was no way of bringing any matter up because I wasn't aware that this was--all these investigations and meetings were going on.

COFFEY, Q.C.:

Q. Yes. And Doctor, I take it that you had written the memos to, as you pointed out to the Commissioner earlier, to the people involved, failures of error, so in 2003 they'd

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known.

DR. EJECKAM:

A. Yeah, I've sent a memo and I believe they received it and it was my take that if further action was required, they would rather come back to me or take it up from there.

COFFEY, Q.C.:

Q. If we could, please, while I'm on the topic, because you stayed in St. John's working as a pathologist until the end of April of 2006.

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. If we could look at, please, Exhibit P-0394, page 15, please? Now, Doctor, this is a photocopy of actually the same memo with some handwriting on it and it will be difficult, I anticipate on the screen for you to read it. In March of 2006, Doctor, and this would have been just about the month before you left, okay?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. The second last month you were here, it is

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probably dated, I understand March 8th, '06, you'll see there on the side, it is difficult to pick out.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, did anyone, do you recall in March of 2006, ask you about the 2003 initiative in relation to whether or not it was a quality assurance initiative at the time?

DR. EJECKAM:

A. No, I don't remember that at all.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0527? Now, Doctor, this is a memo, it's from Dr. Cook, you'll see, clinical chief to all pathologists, as well as Mr. Gulliver, Mr. Dyer and Dr. Williams. The subject is reporting of estrogen and progesterone receptors and he writes, "When reporting the ER and PR receptors, please use the following canned test, this will be issued as an addendum report." And there is then a particular format or protocol for reporting, he's referred to Meditech Canned Text and for

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negative ER/PR and for positive ER/PR and they conclude by saying, "The reporting of ER and PR receptors should include information on whether the nuclear staining is weak, moderate or strong and an estimation of the percentage of invasive neoplastic cells showing staining which can include a range. Controls should be described as adequate or absent." And then on the second page he's got an example here. Do you recall receiving this?

DR. EJECKAM:

A. I don't remember, but I may have received it, since it was sent to everybody.

COFFEY, Q.C.:

Q. In relation to this, Doctor, like the usage of this sort of canned text for the reporting of, for example ER/PR, had you ever encountered that before?

DR. EJECKAM:

A. You mean elsewhere?

COFFEY, Q.C.:

Q. Yes.

DR. EJECKAM:

A. I will say, it's a question of volume and the number of people reporting the case. I guess

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the problem may be that where the number of pathologists who are dealing with the cases here.

COFFEY, Q.C.:

Q. Okay. And I take it the fact that there are a number involved, I take it that it would be useful to have a certain standardized approach to it.

DR. EJECKAM:

A. Yes.

THE COMMISSIONER:

Q. Dr. Ejeckam, what is your view of the difference of having a number of people involved in reporting this particular test? Is there an advantage or disadvantage to limiting the number of pathologists to deal with this test in the same way that you would limit the number of technologists?

DR. EJECKAM:

A. It would be useful to have dedicated pathologists dealing with major decisions of clinical service, like breast pathology and that applies to the other divisions too. So, if you have two people or maximum three, depending on the number of staff you have, but

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if everyone is looking at it and making a calling because you may not see enough, have enough experience to deal with it, so it could be advantageous to limit to a group of people, one or two or three, depends on the number of, what number of staff you have.

COFFEY, Q.C.:

Q. Doctor, were you ever aware, I'll refer to it, I believe it was probably September of 2004, it will come up in a document before the Commission eventually, but certainly 2004, a request by Dr. Carter to look at all ER and PR slides? And it would have been raised by--I gather, by Dr. Fontaine?

DR. EJECKAM:

A. I don't remember that. If that request was made, I don't remember it.

COFFEY, Q.C.:

Q. Okay.

THE COMMISSIONER:

Q. Can I just add a second to that earlier question about the advantages of having a smaller number of people do ER/PR? Is there a point at which--are there a number of cases below which you shouldn't be doing any ER/PR

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if you're not doing that number? I'm explaining this badly, but it seems to me that one might argue that if you are doing tests that require a skill that needs to be maintained and you're not getting very many of those tests per year, for example, then there may be a difficulty with losing the skill you have and reading ER/PR tests. Is that a concern at all?

DR. EJECKAM:

A. Yeah, in a way this can be important in certain type of--especially with like Her2/neu, but for ER/PR and for Newfoundland in particular, you're not going to manufacture cases, you're going to deal with a number of cases that you have.

THE COMMISSIONER:

Q. Uh-hm.

DR. EJECKAM:

A. So if this number is below any arbitrary cut-off number, you still have people to read it, so the way to go would probably be to limit the number of people, so those further--whether that number is below or not this, at least concentrate on it and then they will be

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seeing most of it and they acquire experience and then have standard that they will have to follow.

THE COMMISSIONER:

Q. So as a practical matter because they have to be read -

DR. EJECKAM:

A. Yes.

THE COMMISSIONER:

Q. While it might be best to have an optimum level, if you don't have that, then the next best thing is to make sure that there is a limited number of pathologists actually reading them?

DR. EJECKAM:

A. Yes, Commissioner.

THE COMMISSIONER:

Q. Thank you.

COFFEY, Q.C.:

Q. And if there was a request by Dr. Carter back in 2004, not to report the cases but just to look at them, because she, I gather you understood she had additional training as a breast pathologist.

DR. EJECKAM:

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A. Yes.
COFFEY, Q.C.:
Q. As a pathologist, a working staff pathologist at the General Hospital, would you have had any concerns about your slides being seen by Bev Carter yourself?
DR. EJECKAM:
A. The only way I would have concern if it's being seen without my knowledge. If I know that, well there's no problem another pathologist to review any other patient's case, but it should not be done surreptitiously or, you know, if we are told it is being done, that shouldn't be any problem then.
COFFEY, Q.C.:
Q. Yes, I appreciate that, Doctor, in terms of-- so if there was a general request by somebody like Bev Carter, who is a breast pathologist and who is relatively new here in St. John's in 2004, relatively speaking, as long as you knew that look, all of my ER/PR slides at some--I'll report them, but if Bev wants to have a look at them -
DR. EJECKAM:

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A. Yeah, and couldn't stop her actually.
COFFEY, Q.C.:
Q. So from your perspective it was as long as--it was just a professional courtesy that you'd know.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Okay. And in fact I just mentioned Dr. Carter, if some other pathologist who had a particular interest in a particular aspect of pathology wanted to look at all your slides, I don't know, all of your gastrointestinal slides or your lung slides -
DR. EJECKAM:
A. Oh yeah, people do studies, people pull out cases of, let's say prostrate to look at, it's not only yours they are going to look at, they're going to look at other people's cases. They are telling the site chief who would know that this study is going on, so it's not going behind--you're not going to be given a new report, they're not going to be looking at it and sending a counter report, you want to look at it and maybe tabulate your result and maybe

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present it for any particular reason, but to be a problem if you pull the cases out and give a second report without the pathologist knowing.
COFFEY, Q.C.:
Q. Without the pathologist being told that this second opinion was going out there because then it would be out there circulating without the original pathologist knowing.
DR. EJECKAM:
A. Yeah, if it's a second opinion, a second--and the first person probably should know that that's being done and he should have no difficulty with that.
COFFEY, Q.C.:
Q. If I could, please, exhibit P-0516? Now, Doctor, these are Dr. Williams' notes and I don't anticipate you ever saw his handwritten notes, but we have a typed version of them, okay. These are July 21st, 2005, the attendees at that particular meeting were Mr. Gulliver, Dr. Cook and Dr. Williams, but No. 9 says, "When Barry Dyer and Dr. Ejeckam return, they will work with Dr. Cook and Dr. Gulliver to develop Q.A. and proficiency testing

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program." Now I reference this simply because as of July 21, it suggests that yourself and Mr. Dyer were aware at the time, so that's why I was asking about your vacation earlier. So it is possible, I take it, that you were gone during a certain point in July.
DR. EJECKAM:
A. Possibly.
COFFEY, Q.C.:
Q. If we could please, exhibit P-0532. Now this is a handwritten note and I gather it was obtained from the office of Dr. Williams, but I gather it was probably Dr. Cook's note. It's dated July 28th, 2005. It says, "Spoke to Dan Fontaine to begin negative controls for ER and PR", do you see that? Were you aware in late July that there was a discussion about using negative controls, was that brought to your attention?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. The idea of using negative controls for ER/PR, were you aware -
DR. EJECKAM:

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A. It's not a new thing, it depends on the volume of work you had to do, you either use a positive control or negative control and in any event there are also, if you look hard within the tissue, you might find blood vessels and things that you could use as negative control within the tissue. So it's not a-- something new, but I did not bother the reason for them to look after it.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0534, now this is a memo of Health Care Corporation St. John's' letterhead. It's to all pathologists in St. John's' hospitals, Eastern Health and all laboratory directors across Newfoundland, to Mr. Gulliver, Mr. Dyer and Dr. Williams. It's from Dr. Cook, July 28th, 2005. It's re Her2/neu and I'm not going to read the first part of it, but the last paragraph reads, "As a reminder when choosing blocks to send for both hormone receptor testing and Her2/neu testing, please select a section that contains both tumor and normal or benign epithelium. The normal and/or benign epithelium acts as an internal control for immunohistochemical

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staining." So I take it that's the idea of using an internal control for ER/PR was what you'd refer to in your May 2nd, 2003 memo.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. It's the same. And were you consulted on this memo, the sending of this memo?

DR. EJECKAM:

A. No, I wasn't consulted, I may have received it as one of the pathologists, I wasn't consulted.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0076. Now this is a memo again on Health Care Corporation of St. John's' letterhead to all pathologists and pathology residents in the Department of Pathology, St. John's' hospitals, Eastern Health. It's from Dr. Donald Cook and Dr. Bev Carter. The date is July 28th, 2005 and is re: optimal assessment and reporting of hormone receptor status in infiltrating carcinoma. And it begins, "When ordering report ER/PR status on infiltrating carcinoma of the breast"--and there are actually nine

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suggestions, do you see that? And I'll just go on, there's a space for their signatures. Do you know if you ever actually received this?

DR. EJECKAM:

A. I don't remember if I seen this, but sometime I could have got it, but I don't remember seeing that memo signed by both of them, both Cook, Dr. Cook and Dr. Carter.

COFFEY, Q.C.:

Q. You don't recall--I'm not suggesting you did, you actually got one because this doesn't have any -

DR. EJECKAM:

A. I may have gotten it, but -

COFFEY, Q.C.:

Q. Well, Doctor, just to briefly run down through these, number one, "Select a block that contains illustrating carcinoma and normal and/or benign breast epithelium." That was in your May memo -

DR. EJECKAM:

A. Yeah, that's okay.

COFFEY, Q.C.:

Q. May, 2003 memo. "When reporting, always check

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internal and external controls." I take it that that was implicit in your May memo.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Three, "The external positive controls should show some variability of staining throughout the tissue section."

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. That's an accurate statement, isn't it?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Four, "The external negative control, if made available should show no staining."

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And you would agree with that. Five, "The internal negative control, example stroma, vascular, endothelium should show no staining." You would agree with that?

DR. EJECKAM:

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A. Yes.
COFFEY, Q.C.:
Q. Six, "Internal breast epithelium should show some positivity, but not diffuse." That was, you agree with that?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. "If the external positive control is negative, the test is invalid." Would that be correct, the external positive control doesn't work, you wouldn't report it?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. You make inquiries.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And, "If the external negative control is positive, the test is invalid." You would agree with that?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:

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Q. Finally, Doctor, it says, "If the internal control shows aberrant staining, the test may be invalid. Please refer to Dr. Bev Carter." Now in terms of the internal control for ER/PR, what was your view on that?
DR. EJECKAM:
A. That was critical to me and as for ductal epithelium, I needed to see that positive before I read the slide.
COFFEY, Q.C.:
Q. Read the tumor part of the slide.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. So from your perspective, if the internal control didn't stain positive, stain appropriately positive -
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Then it was your view that you would not report?
DR. EJECKAM:
A. Yes, we would have to look at the, after the period of staining, the procedure.

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COFFEY, Q.C.:
Q. Did you ever discuss that aspect of pathology with Dr. Carter, her views of the internal control issue verses your own?
DR. EJECKAM:
A. No, I don't remember, no.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-0938? Now, Doctor, this is a letter, it's dated July 29th, it should read 2005, there's just an extra zero in there, it's addressed to yourself as chairperson of the Surgical Pathology Review Committee and it's from Dr. Williams, you will see there, copied to Dr. Cook and Heather Predham. Now did you know who Heather Predham was?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. And here, Doctor, Dr. Williams writes, "It was a pleasure to meet with you and Dr. Cook on July 15th, 2004 to discuss the activities of the surgical pathology review committee." Do you think that that's--is that 2004, is that-- that should be -

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DR. EJECKAM:
A. That should be 2005, perhaps, yeah.
COFFEY, Q.C.:
Q. So this letter was being written about two weeks after your meeting?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. And he points outs, "We concur that as a quality assurance committee, there should be a linkage between the work of the committee and the overall quality initiative efforts within this organization. I'll copy this letter to Ms. Heather Predham, I will ask her to follow up with you on the matter to see what reports the Quality and System's Improvement Department might give to your activities." Did you ever hear from Ms. Predham about that?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. Or anybody from her department?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:

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Q. Did you actually receive this letter yourself? It's addressed to you?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Because you, in fact earlier made reference to the fact that you thought there was a response to your -
DR. EJECKAM:
A. Yeah, that was a response to a letter and it somewhere got sent over to Dr. Williams, that's what I think.
COFFEY, Q.C.:
Q. So I take it then, Doctor, at the bottom of the first page, Dr. Williams says, "After further medical leadership follow up, it was decided to modify the requisition form for surgical pathology specimens"--and outlined in bold red letters--"that added medical information would need to be provided before the specimens were processed. I understand this new form has been prepared and gone forward to the forms committee." So I take it that that was at least making an effort then to address your concerns.

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DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. In the second page, it says, "In our meeting Dr. Cook brought up the issue of tissue audit with respect to the Surgical Pathology Review Committee now taking on responsibility for reviewing tissue samples and the medical history to see if there are problems in terms of a valid reason for these procedures. We agree that you felt that this should be under the auspices of this organization's Quality Assurance Committee, so that adequate resources can be available to get the information together for the committee. I will ask Heather Predham to follow up with you on this matter to see if one of her staff members can be made available to assist in this worthwhile endeavour. This issue was captured within the initial Terms of Reference set up for the Surgical Pathology Review Committee in reference to the April 15th, 2003 agenda. I trust this is satisfactory and look forward to a greater improvement in the quality of information that is received from

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physicians." And then it goes on to conclude. Doctor, I take it then that it was the committee's view that this whole tissue, audit issue, should be moved to a wider forum than the committee itself?
DR. EJECKAM:
A. No, the Tissue Audit Committee or Surgical Pathology Review Committee is a valid committee (unintelligible) recommended that there should be a Quality Assurance Control Committee for the hospital.
COFFEY, Q.C.:
Q. Yes.
DR. EJECKAM:
A. That should be kind of an umbrella or the main forum that's controlling all of the quality assurance initiatives in the hospital.
COFFEY, Q.C.:
Q. And at the time, while you were at Eastern Health, as it then was by that point in time, was your view in that regard and the committee's view in that regard ever accepted, do you know, that there should be an institution-wide approach?
DR. EJECKAM:

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A. I think looking at Dr. William's letter, it looks to me that he accepts that that notion that that should be created.
COFFEY, Q.C.:
Q. Were there any further steps up to the time you left, that you were aware of that were taken to do that?
DR. EJECKAM:
A. No, no.
COFFEY, Q.C.:
Q. There weren't. If we could look, please, at Exhibit P-0538, actually I'll pass on from that, if we could, Exhibit P-0079 please? Now, Doctor, this is a letter from Dr. Carter in fact to Dr.--it's dated August 2nd, 2005, it's from Dr. Carter and it's copied to Dr. Williams. It's addressed to Dr. Cook and she begins by saying, "Regretfully I inform you that I wish to withdraw from my organizational role in the investigation of the problems of ER/PR testing at the Health Care Corporation of St. John's from '97 to 2004, and a planning of solutions to the current issues discovered with the Ventana Automated System". Doctor, were you aware of this on large scale review

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that Dr. Carter had started to undertake -
DR. EJECKAM:
A. I said I wasn't -
COFFEY, Q.C.:
Q. Okay. So, I take it then, did you ever become aware that she had resigned from it?
DR. EJECKAM:
A. What I heard was she resign her appointment. I didn't--this is the first time that I'm seeing her role in the ER/PR thing. But I heard that she resign her appointment.
COFFEY, Q.C.:
Q. I'm sorry, what?
DR. EJECKAM:
A. I heard that she resigned her appointment.
COFFEY, Q.C.:
Q. Her appointment, oh.
DR. EJECKAM:
A. Not, maybe that's what they meant, but you know, I didn't get any details.
COFFEY, Q.C.:
Q. Okay. And to get some sense again of what was going on at this point in time, if we could look at Exhibit P-0542? Now, Doctor, this is a memo on Health Care Corporation St. John's'

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letterhead, it's to all pathologists in the Division of Anatomical Pathology, as well as to Mr. Gulliver and Mr. Dyer. It's from Dr. Cook, clinical chief, August 2, 2005, re: resource individual for immunohistochemistry. And Dr. Cook has written, "Dr. Gershon Ejeckam is currently our resource person for immunohistochemistry. All inquiries regarding immunohistochemistry should be referred to Dr. Ejeckam. In the event that Dr. Ejeckam is not available, all inquiries should be referred to the site chief, General Hospital site, who is currently Dr. Dan Fontaine." Were you aware that this was going to be written?
DR. EJECKAM:
A. No, I received it, but I wasn't aware of it.
COFFEY, Q.C.:
Q. And did this actually change anything?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. I take it, this was written confirmation that you were the resource person and you understood that?
DR. EJECKAM:

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A. I had function of the resource person and maybe he decided--maybe you can see why it was written, Bev says she wasn't getting involved August 2, he may have decided to write this, but I don't know.
COFFEY, Q.C.:
Q. And I'll ask Dr. Cook about why he wrote it, but from your perspective, at the time, you weren't given a heads up that this is being written?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. And having received it, you didn't interpret anything as being changed?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-0545? Now Doctor, these are Dr. Williams' handwritten notes, but happily, we have a typed version of them on page two. It's dated August 3rd, 2005 and it's notes on ER/PR issues, and there's a reference here to "met with Dr. Don Cook and Heather Predham, times two. QI, quality

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initiatives, follow up and interviews were held with techs involved in the immunohistochemistry in the a.m.. Heather Predham gave me a debriefing on the issue and the lack of communication between techs and pathologists. Heather Predham gave Dr. Cook and general site chief, Dr. Dan Fontaine, a briefing on her interview in the p.m. Met with Dr. Cook afterwards and discussed issue and need for techs to have a pathologist who they can go to for advice and communication. Dr. Cook and I will follow up with Dr. Gulliver and on broad and specific communications issues identified. Dr. Cook waiting to hear back from Mount Sinai re: completing all negative ER/PR testing on a very expeditious basis."
Now Doctor, in late July or early August 2005, did anyone come to you about any concerns about lack of communication between the techs and the pathologists?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. And you, I take it, were the resource person

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for immunohistochemistry?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. You had been for quite a while.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. And you had been dealing with the technologists, if they had a question or concern, you would try to address it?
DR. EJECKAM:
A. Yeah, I mean, these notes here are surprising to me because the technologists had easy access to me all through.
COFFEY, Q.C.:
Q. And what about the pathologists, the other pathologists, if they had a concern about technologists, would they come to you and have you deal with the techs or -
DR. EJECKAM:
A. Oh no, they had access to the techs. There was no restriction.
COFFEY, Q.C.:
Q. Okay. Did you ever--were you ever made aware

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of any concerns expressed by the technologists, not about their interaction with you, but about the fact that it was not only with you? There were others, other pathologists might come to them not having gone to you? Did they ever complain to you about the fact that "look, we want to deal with you, Dr. Ejeckam, but we have to deal with Dr. A and B and C"?
DR. EJECKAM:
A. There was no complaint to me and they needed to deal with everybody. I mean, they didn't have to deal with me only. They're working for--their job is doing slides for everybody, so the other pathologists have right to go talk to them anytime they chose, and they didn't have to go through me.
COFFEY, Q.C.:
Q. And if we could, please, Exhibit P-0555? Doctor, were you ever told by the technologists that they, perhaps at times, were getting conflicting opinions from pathologists on certain matters?
DR. EJECKAM:
A. No, they didn't tell me that. I'm not aware

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of--and I don't know the scenario where that will occur.
COFFEY, Q.C.:
Q. Now were you ever involved in trying to train the technologists? I mean, I appreciate, and you've referred to the double-headed microscope -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. - and so on, but was there ever a formal or semi-formal arrangement that you were involved in to train the technologists?
DR. EJECKAM:
A. Well, the way I was training them was the way to do at that time. They had finished their training as a technologist, so this is an additional thing and the only way to train them was to discuss slides with them periodically and of course when we made arrangement to send them out to a bigger laboratory where specimens were being processing for them to see what was being done, because they have learned already the real methods that, you know, the process.

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COFFEY, Q.C.:
Q. Yes, okay, and I'll be getting to them being sent out in a moment. Looking at this, the handwritten portion of this says "meeting of pathologists" and it lists a number of pathologists, although your name is not amongst those, and it's dated August 5, 2005, three p.m., and the typed portion of this says "this is a list of some concerns that have emerged during conversations about the current problem. Included are some of our suggestions about how to approach this," and the Commissioner has seen this before, and it deals with--well, first of all, I'll ask you, have you ever seen this, this document?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. Okay. I'll just take you briefly through it. "Included are some of our suggestions about how to approach this," and then it says "it is important that we work together and support each other as a department. Important features of the ongoing process should include: cooperation, transparency,

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communication, dissemination of information as the process evolves, avoidance of finger pointing to either individuals or a group of individuals, input into the procedure and quality control and assurance initiatives surrounding it. We should ensure that no bias is introduced into the ongoing study. If the purpose is to compare methods, then the following are important features: assume that the pathologist reported the original test correctly; then only the report needs to be compared to the result of the current accepted method; send an addendum if there is, in fact, a change in the result. Persons conducting the study do not need to know which pathologist signed the report originally. Anything else is an audit of individual pathologists, and if that is the aim, this is not the proper procedure for an audit of pathologist's performance. We should not be working in a culture where pathologists feel they are being criticized for past performances. Avoid generalized statements such as 'pathologists don't know how to report the ER/PR' 'a single pathologist has

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repeatedly reported the ER/PR incorrectly' and 'keeping statistics on an individual pathologist.' These statements, as well as loud discussions around the issue in corridors with high public traffic are threatening and demoralizing. We all assume that we are the pathologist being referred to however anonymously. This issue concerns pathologists outside of the Health Care Corporation and they also need to be informed and reassured that the procedure"--I'm sorry, "that the process is proceeding in a fair and productive manner."

Now Doctor, the pathologists that are listed here at the top, Dr. Fontaine, Dr. Larkin, Dr. M. Parai, Dr. Barron and there's some others, Dr. Cook and two other names, difficult to pick out, what site were they on? Were they on the Health--the General Hospital or St. Clare's? I appreciate Dr. Cook was at St. Clare's.

DR. EJECKAM:

A. Yeah, Cook was at St. Clare's.

COFFEY, Q.C.:

Q. The others?

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DR. EJECKAM:

A. I think the rest of them were at the Health Sciences.

COFFEY, Q.C.:

Q. Did the subject--I apologize, Doctor.

DR. EJECKAM:

A. Dan, Lyn, Parai, Pirzada, Barron, they're all at the Health Sciences.

COFFEY, Q.C.:

Q. Now Doctor, and this is early August, August 5 2005. Were you aware of concerns by the pathologists at the General Hospital site, these sorts of concerns?

DR. EJECKAM:

A. I don't know. I wasn't--maybe I was on holiday. I'm not sure I was in St. John's at this time. I may have travelled to Nigeria. But I think when this issue of the index case broke, there was general discussion about concerns by pathologists, even at the conferences or just, you know, just discussing generally, but I wasn't aware of any meeting that was called to discuss the issue. So they may have held this meeting when I wasn't there, when I left, was on holidays, maybe to

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address what may have been--people may have been talking. From reading through that, it looks to me like maybe somebody may have gone out in a different forum, criticize the work of their fellow pathologists and maybe the group wanted to have a meeting and then forge a common front against that kind of behaviour. That's what I read into this.

COFFEY, Q.C.:

Q. Did you become aware, in the summer of 2005 or early fall of 2005, that that was the feeling amongst pathologists, that's reflected here?

DR. EJECKAM:

A. Yeah, I got a feeling that people were unhappy and concerned that, you know, maybe flippant statements might be jeopardizing the integrity of the fellow pathologists.

COFFEY, Q.C.:

Q. Now Doctor, if we could look, please, at Exhibit P-0560? This is a memo on Health Care Corporation letterhead to all pathologists in Eastern Health, St. John's hospitals, Eastern Health, as well as Mr. Dyer, Gulliver, and Dr. Williams. It's from Dr. Cook, August 8th 2005. This particular one is re: estrogen

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receptors and progesterone receptors on current cases, and the opening paragraph reads "There will be a hold on the reporting of ER and PRs by all pathologists in the division of anatomical pathology, St. John's Hospitals, Eastern Health." Then it goes on from there, okay. I'm not going to--I take it you would have gotten a copy of this?

DR. EJECKAM:

A. Yeah, I would have gotten it.

COFFEY, Q.C.:

Q. Yes, and the second paragraph says "all ER and PRs will be forwarded to Mount Sinai Hospital for immunohistochemical processing and reporting." Doctor, when did you first become aware that, at least then for the foreseeable future, they were going to do current cases at Mount Sinai? When and how did you become aware of that?

DR. EJECKAM:

A. I don't remember the time, but it must have been after all these stories about the index case became open.

COFFEY, Q.C.:

Q. Do you recall how it was you were first

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informed that we're not going to do ER/PR in St. John's. We're going to do it--have it done at Mount Sinai? Like who told you that?

DR. EJECKAM:

A. I think it's through this memo.

COFFEY, Q.C.:

Q. This memo?

DR. EJECKAM:

A. Yeah, I think so.

COFFEY, Q.C.:

Q. And in looking at that, those notes of August 5 we just looked at a moment ago, they suggest, I think in reading them, and would you agree, that there's a certain unease amongst the pathologists and a lack of information that they have about what's going on?

DR. EJECKAM:

A. I'm not sure whether it was lack of information or not, but there was some degree of uneasiness about the entire case. People were apprehensive.

COFFEY, Q.C.:

Q. So if this memo of August 8th was the first time that you learned that for current cases

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they're going to be done at Mount Sinai, ER/PR, and you were the resource person for immunohistochemistry, I take it that you were not being exactly kept in the loop as it were?

DR. EJECKAM:

A. Not what it looks like.

COFFEY, Q.C.:

Q. If we could look, please, at Exhibit P-0561? This is again a memo from Dr. Cook to all pathologists, St. John's Hospitals, Eastern Health, Dr. Williams, Mr. Dyer and Mr. Gulliver. It's August 8th 2005, ER and PR on cases from May 1997 to August 9th, 2005. It says, it begins by saying "cases from May 1997 to March 31, 2004 that are ER negative, except those from patients who are deceased, will be referred to Mount Sinai," and it goes on then to talk about the procedure for doing the retesting.

So is this the first--would this memo have been where you first learned that they were going to do this mass retesting back to 1997?

DR. EJECKAM:

A. I think so.

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COFFEY, Q.C.:

Q. Were you ever consulted about the advisability of doing it and how they might go about it?

DR. EJECKAM:

A. No. I know that when I got--I think when I got this memo, item number three, I did tell Dr. Cook that I didn't agree with that particular aspect of it, that he should allow the pathologists who reported the case to sign in the addendum when the report came back from Mount Sinai.

COFFEY, Q.C.:

Q. And now just for the benefit of people here, once the--number three says "once the Mount Sinai report has been received at the St. Clare's site, an addendum will be issued by Dr. Cook or Dr. Carter in the hospital information system."

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. When you received this, you expressed the view to Dr. Cook -

DR. EJECKAM:

A. Yes.

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COFFEY, Q.C.:
Q. - that when Mount Sinai does report a retest result, the individual pathologist who did the original report should be the one who enters that information as an addendum?
DR. EJECKAM:
A. Yes, that was my view.
COFFEY, Q.C.:
Q. And why is that, Doctor?
DR. EJECKAM:
A. Well, I think that if a pathologist did the diagnosis and they refer out to another hospital to do ER/PR, there was no justification for someone else to enter that into the system, and it now creates two people signing out a report, and without probably appreciating it, it may, may or may not, may create some kind of confidence difficulties in the mind set of the oncologist that the first pathologist probably didn't know what he was doing, that's why the second person had to sign it in. He don't know how to interpret it. But usually, they should have been better at that the result has come in and has been vetted and then the person who did the first

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report in calling the tissue malignant, should then send in the addendum and he's going to say the result came from Mount Sinai anyway. He's not going to claim that he did it or she did it in the centre here.
COFFEY, Q.C.:
Q. Doctor, what was Dr. Cook's response to that?
DR. EJECKAM:
A. He told me it was his responsibility to do as clinical chief. And I told him I don't agree with that, but that was his, he was the clinical chief and he had to do what he had to do.
COFFEY, Q.C.:
Q. Now, looking at--was there any other concern you had with any part of that memo that you expressed?
DR. EJECKAM:
A. I remember this item that we discussed. I don't think there was any other area that I raised any concerns.
COFFEY, Q.C.:
Q. Doctor, the idea of doing this retesting at Mount Sinai, did you have any concerns about that when you became aware of it?

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DR. EJECKAM:
A. No, in the sense that since this issue and Mount Sinai has an accredited laboratory, we could use it to--the only concern I had was that comparing Mount Sinai results with what we had here, I knew that we were using Ventana machine and Mount Sinai was using DAKO, so we got to be careful comparing their results with ours because it's not going to be exactly same thing. They probably use the different clones of antibody and then also had different machine, so we're going to get slightly different percentages of positivity, you know, in those two systems. That was my concern.
COFFEY, Q.C.:
Q. You anticipated that there would be a slightly different read -
DR. EJECKAM:
A. Yes, going to be, yeah.
COFFEY, Q.C.:
Q. - or possibly?
DR. EJECKAM:
A. It probably didn't matter too much unless somebody puts a lot of weight on the percentage, but I expect that the two machines

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should be able to read positive, positive, negative, negative.
COFFEY, Q.C.:
Q. Okay. And if we could, please, -
CROSBIE, Q.C.:
Q. What number was that, Mr. -
COMMISSIONER:
Q. The number of this exhibit?
CROSBIE, Q.C.:
Q. Yes. 0561?
COMMISSIONER:
Q. 0561.
COFFEY, Q.C.:
Q. Yes. And, Doctor, you know, by this point in time, it was August, early August of 2005 you realize now they're going to go back, well, to a period long before, in fact, you had been in St. John's, '97 through 2002. And part of it involved the time period you had been in St. John's. How did you feel about it at the time? Had you ever encountered any such kind of large scale review before in your career?
DR. EJECKAM:
A. No. But, you know, I don't remember any kind of incident that (unintelligible) to, so.

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COFFEY, Q.C.:
Q. Yes. And, Doctor, do you recall whether or not you anticipated that there might be large scale, when I say large scale, quite a number of conversions?
DR. EJECKAM:
A. I have no opinion on that because I really didn't think about--I mean, I didn't know what was going on other than cases were being sent. I didn't know the number that was being sent and being retested, so, you know, I wasn't in a position to start speculating on percentage or whatever.
COFFEY, Q.C.:
Q. Okay. See, on that point, this is why I asked that, is is that we've heard evidence, well, you heard today or yesterday, but we've heard evidence, for example, in the first wave of people tested on the Ventana, retested on the Ventana, there was 25 people, 16 of them converted, 16 patients' tissue samples converted. And I mean, that works out at a percentage of about 64 percent conversion in that first group. Were you--was that kind of thing being talked about within the pathology

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departments at the time? I mean, as a pathologist were you aware that that, in the initial group that there was a conversion of about 60 percent?
DR. EJECKAM:
A. I wasn't aware of percentage other than I knew that there was a talk about conversions. So, you know, but in terms of number, I had no information to that effect.
COFFEY, Q.C.:
Q. So that wasn't made generally known within the pathology departments as to what the findings -
DR. EJECKAM:
A. I don't think so. It may have been, the information the clinical chief and Bev Carter may know about it, but I didn't know what other pathologists know. They could have known, you know, so depends on, you know, where they were at that particular time, they may have known this information. I didn't have that information.
COFFEY, Q.C.:
Q. And what I'm--from the Commissioner's perspective to know, Doctor, to get some sense

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of by the time this retesting effort, major retesting efforts starts in August and things are sent to Mount Sinai and so on, as we come into Labour Day of 2005, early September. As a pathologist working here in St. John's, because you were working here, you continued to work, how much did, from your perspective, were you kept informed about what was going on? I mean, you knew there was a retesting going on?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And you knew all current cases were being done at Mount Sinai?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. ER/PR. But other than that, how much were you being kept in the loop, as it were, or being told anything?
DR. EJECKAM:
A. I think that's all I personally I knew about it.
COFFEY, Q.C.:

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Q. As a staff pathologist how did you feel about that, did you think, have any feelings about whether or not you should be kept better informed or, from time to time as to what was going on?
DR. EJECKAM:
A. Well, I personally didn't feel any--I didn't have any opinion one way or the other because it looks like someone is taking care of the situation and, you know, it didn't come into the normal routine of our work, so it didn't really become an issue with me.
COFFEY, Q.C.:
Q. And if we could, please, Exhibit P-0637? Now, Doctor, this is a letter dated October 13th, 2005. And I'll deal with this in a moment. But there has been evidence here that on October 2nd, 2005 this issue hit the media, you know, in the sense of it became publicly known in The Independent newspaper story. Had you been aware or made--were you made aware before it became public that it was about to be made public?
DR. EJECKAM:
A. I don't remember that. I know that Don used

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to drop into the Health Sciences and we have a chat and he would go so, and it wasn't a formal meeting with agenda and the minutes, so if it was discussed, if he said it was discussed, probably so, but I don't remember that.

COFFEY, Q.C.:

Q. Do you recall whether or not were you ever consulted in the summer of 2005 or September, 2005, asked about your views as to whether or not patients should be told about the fact that their tissue was being retested?

DR. EJECKAM:

A. No, no, I didn't get an consultation specifically for that kind of information.

COFFEY, Q.C.:

Q. No one came to you kind of canvassed you, well, Gershon, what do you think? They didn't -

DR. EJECKAM:

A. I don't remember that.

COFFEY, Q.C.:

Q. Sure. Looking at this, doctor, this is a letter of October 13th, 2005, it's addressed to yourself as a staff pathologist. It's from

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Dr. Cook, signed by me and it's copied to Dr. Dan Fontaine, Terry Gulliver and Dr. Bob Williams, Robert Williams. And it says, "Dear Dr. Ejeckam, As discussed, I appreciate your continuing role in overseeing the immunoperoxidase service. As you know, we were in the process of developing a specialized service with technologists solely dedicated to immunohistochemical technique. As agreed, you will oversee all aspects of the immunoperoxidase operation, have direct supervision over the technologists involve in the service. You will also provide direction to all pathologists involved in the immunoperoxidase interpretation. In areas where we hope to develop subspecialized service, there will obviously be consultation between you and the appropriate pathologists on immunoperoxidase staining. If you feel that there is any deviation from this, you should report this immediately to both the clinical chief of the laboratory medicine program and the vice president of quality, diagnostic and medical services at Eastern Health. Once again, I thank you for your

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important contribution, guidance and expertise to our organization in this area. Sincerely yours, Donald Cook." Now, Doctor, were you consulted about this appointment before it occurred?

DR. EJECKAM:

A. I'm not sure. I think what probably prompted this letter may have been that as a resource person, quote, unquote, you know, dealing with the technologists, they were also still, you know, they had to take their orders from Barry, the manager, and then probably from other sources, and that may have created some problem in terms of work process, and I may have discussed this with Don saying, look, if I have to now be a resource person, there may be difficulty that if you ask, order an antibody, somebody may say, no, they're not going to do it or I have to go to beg or to ask somebody that I need an antibody ordered. I didn't need to do that if I told the techs that we needed antibody A, then they have to follow the process of ordering it to bring it in. If somebody now stopped them doing it, then that probably will create a problem. I

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wasn't sure whether that was the issue, but I think we had discussion in that line, that's why he went ahead to write this letter, maybe to emphasize that the techs, I'm responsible for what goes on in that division.

COFFEY, Q.C.:

Q. Because here in the third line and the third sentence it says, "As agreed," I take it that's agreed between you and him?

DR. EJECKAM:

A. Yeah, yeah.

COFFEY, Q.C.:

Q. You, that's Dr. Gershon Ejeckam, "will oversee all aspects of the immunoperoxidase operation and have direct supervision over the technologists involved in the service." So I take it before this that wasn't the case, you didn't have supervisory responsibility for the techs?

DR. EJECKAM:

A. Well, it wasn't--I'm saying there was a dichotomy here, it was they had to report to Barry and taking orders from, instruction from different directions. So I think there may have been discussed and he decided to spell it

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out in this memo.
COFFEY, Q.C.:
Q. Yeah. And it goes on to say, as well, "You," that's Dr. Ejeckam, "will also provide direction to all pathologists involved in the immunoperoxidase interpretation." So before this had you been providing such direction to all pathologists?
DR. EJECKAM:
A. If they needed it. If anyone needed help -
COFFEY, Q.C.:
Q. If they needed help, oh, yes.
DR. EJECKAM:
A. Yeah. But, I mean, that direction I will say was that, because during our informal rounds I would give my contribution, interpretation of the immunostain done or during our Tuesday rounds, I will give my input and interpretation of any of the immunohistochemistry done in terms of usage for diagnosis. So that would be giving direction or helping my colleagues or with my opinion, you know. I mean, I wasn't the only one giving the opinion. The rest of them, more so. I mean, the other pathologists have

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knowledge of immunohistochemistry, so we will discuss each case together and then come to a conclusion.
COFFEY, Q.C.:
Q. And he concludes in the first paragraph saying, "In areas where we hope to develop subspecialized service, particular areas, there will obviously be consultation between you and the appropriate pathologists on immunoperoxidase staining." So I take it there was some thought at this point to developing a subspecialized service?
DR. EJECKAM:
A. Yeah, yeah, it should be a subspecialized unit of its own, and then if people wanted to introduce a new antibody, let's say a pathologist wanted to have a new antibody, then they will pass that through me, then we will allow, procure it and then do some titration before we sign it into--I was supposed to sign it into system that the titration has been done and found efficacious and found good enough.
COFFEY, Q.C.:
Q. Yeah. So that's from this point on?

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DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. Before this did you have to sign in the -
DR. EJECKAM:
A. No, no, before this I wasn't doing that.
COFFEY, Q.C.:
Q. Okay. So what I'm coming to then in this, this memo, did this change things, was it meant to change the structure?
DR. EJECKAM:
A. I looked at this memo as the way to, for information to the lab manager and tell him that I have to deal with the technologists directly. But it hasn't changed very much because there's no actual structure making me head of the unit, just work and there's no-- I'm not aware of any appointment. I mean, if I was, I mean, that isn't an appointment letter. This is something that gives me some kind of leeway to deal with the staff, and that's the way I looked at it, and I wasn't looking for any big title there. And then I continued doing the work, anyway, so this letter didn't change the way I related to the

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technologists who we had a good relationship and we worked together to ensure we got good result in the laboratory.
COFFEY, Q.C.:
Q. But what it did do, I take it, was was it informed the technologists supervisors -
DR. EJECKAM:
A. Right.
COFFEY, Q.C.:
Q. - in a formal way, look -
DR. EJECKAM:
A. They should not interfere with my dealing with the technologists. I think that's the main thrust of this letter, that they should not interfere with my dealings with the technologists.
COFFEY, Q.C.:
Q. And in respect of directed at the other pathologists, it was where we're going to get into subspecialization, where we are, you have to talk to Dr. Ejeckam about the IHC aspect of that?
DR. EJECKAM:
A. Yes, if they needed to introduce a new antibody, that's basically there. But the

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general discussion on IHC had always been good enough in our conferences.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0531? And in relation to that letter, I mean, this happens, this exhibit happens to be dated--I said 0531, I meant 0351, I apologize. I apologize, Doctor. 0351. This document is a review of the immunohistochemistry lab, the General Hospital site, St. John's, Eastern Health. It's prepared for Dr. Williams by Mr. Gulliver and Dr. Cook dated October 13th, 2005. It's the same date as the letter to yourself. Doctor, that letter itself, the one we just looked at, did you, after receiving it, discuss it, did it come up afterward in conversation with people, was there any controversy about it?

DR. EJECKAM:

A. I'm not aware of any controversy.

COFFEY, Q.C.:

Q. And looking here at this, particular aspects of this memo, were you consulted by Mr. Gulliver or Dr. Cook, do you recall, about this review? I believe your name is referred

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to a number of places in it I'm going to show you.

DR. EJECKAM:

A. No.

COFFEY, Q.C.:

Q. Okay. If we could look at page four, please. I apologize, perhaps we could go back to page two, I apologize. Under objective, paragraph 1.2, it says "the objective of this proposal is to identify the requirements needed to implement a quality--complete quality assurance program for the immunohistochemistry lab, ensuring that we provide a standardized and reliable service, equivalent to the Mount Sinai reference lab in Toronto."

And scope, 1.3, "the scope of the proposal includes a review of all components of the immunohistochemistry service, from grossing the specimen to pathologists' interpretation," and 1.4, the methodology, if I could, says "work processes were reviewed internally by the lab program including the pathology manager, technologist, site chief, clinical chief and program director. Additionally, suggestions from the QI review

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by Heather Predham and the on-site visits by Dr. B.D. Banerjee from the B.C. Cancer Agency and Trish Wegrynowski from Mount Sinai are also incorporated in this proposal."

So I noticed there that your name is not listed or your position in 1.4. You're not--you weren't consulted about this?

DR. EJECKAM:

A. No.

COFFEY, Q.C.

Q. Okay. Now in relation to this, Dr. Banerjee, did you ever meet Dr. Banerjee?

DR. EJECKAM:

A. Yes, I know him.

COFFEY, Q.C.

Q. When did you meet him?

DR. EJECKAM:

A. I don't remember the month, but when he visited to evaluate the laboratory, I met--Don Cook brought him to my office and I knew him anyway. We trained together in Ottawa, so -

COFFEY, Q.C.

Q. Okay.

DR. EJECKAM:

A. - somebody I knew.

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COFFEY, Q.C.

Q. So you had known him back in the 70s then?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.

Q. Okay, back in the 70s, early 80s, okay. So whenever your CV says you were in Ottawa, that's the time you would have known Dr. Banerjee?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.

Q. From decades before. And was it on his first--because he was here twice.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.

Q. He was here in September of '05 and April of '06. Did you meet him both times?

DR. EJECKAM:

A. Yes, I suspect, yes. The first time he came to my office. I think the second time was a meeting that, you know, had together with other people, I don't remember everybody there now, but I believe I met him on the two

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occasions that he arrived.
COFFEY, Q.C.
Q. And the first time that he visited, you say Dr. Cook brought him to your office.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. Do you recall what you discussed?
DR. EJECKAM:
A. General things, family and then we talked about our immunohistochemistry and, you know, fleetingly because, you know, he was going to review cases anyway, so.
COFFEY, Q.C.
Q. Okay. Do you recall if you offered any views to him or opinions?
DR. EJECKAM:
A. I may have offered my view about (unintelligible) staff from the--or appointing, having somebody responsible for, you know, a particular division. I may have done that, I'm not sure.
COFFEY, Q.C.
Q. Well, if we could look then at Exhibit, I'm sorry, page four of the exhibit. Now, this

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is, paragraph 2.2, pathologist interpretation, it says, "currently each pathologist requesting immunohistochemistry procedures based upon the type of tissue and possible type of cancer they are investigating. The technologist completes the procedures and returns the slides to the pathologist. There's a need for sub-specialization of pathologists particularly in breast cancer where interpretation of immunoperoxidase stains and monitoring of trends is crucial. There's also a need for a single pathologist to oversee the service and to provide direction to technical staff and to liaise and consult with pathologists. It is recommended that (f) one pathologist be assigned the responsibility for all aspects of the immunohistochemistry service". So, I take it, that's--you recall, you told Dr. Banerjee that was your view?
DR. EJECKAM:
A. Yeah, well that's what I'm saying, I may have mentioned this to him, but I believe he knew that because they have a good lab too.
COFFEY, Q.C.

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Q. And (g) says, "while all pathologists will continueto interpret/report immunohistochemistry cases, it is recommended that they be given the opportunity to subspecialize for certain cases, example, two to three pathologists would interpret all breast cancers". From that perspective--now, I'll ask you, did you ever see this report, do you know, this October 13 -
DR. EJECKAM:
A. No.
COFFEY, Q.C.
Q. You didn't.
DR. EJECKAM:
A. I didn't, this is the first time I've seen this.
COFFEY, Q.C.
Q. The idea though expressed here that while all pathologists will continue to interpret and report, there should be sub-specialization, and you thought it was a good idea.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. The quality assurance, paragraph 3, says,

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third line, "the lab does not participate in outside proficiency testing for immunohistochemistry. The lab has never had the opportunity to participate in either conferences, tele-conferences or able to network with other immunoperoxidase labs, IP labs". First of all, was the lab, at that point, participating in outside proficiency testing for IHC, at that point?
DR. EJECKAM:
A. I believe so. I think we had CAP already and I think, well, College of American Pathologists, I believe goes on.
COFFEY, Q.C.
Q. And it goes on to say, "it is recommended that (h) the immunohistochemistry lab enrol in outside proficiency testing, example CAP and I take it, you understood they were already enrolled in that.
DR. EJECKAM:
A. I thought they were, but I wasn't involved with CAP, I was involved with the UK one.
COFFEY, Q.C.
Q. And paragraph (i), "all recommendations by Trish Wegrynowski be implemented". And

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there's a listing of them here with an et cetera. And (j) "recommend a separate C.E. budget be established for books, journals and conferences". I take it that's something that you've been recommending for a while.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.

Q. Doctor, Trish Wegrynowski, did you meet her?

DR. EJECKAM:

A. No, I saw her in the laboratory, but I didn't sit down to talk to her.

COFFEY, Q.C.

Q. Did you ever speak to her the first or second time she was here, do you recall?

DR. EJECKAM:

A. No.

COFFEY, Q.C.

Q. Okay. Now, the first time around that Dr. Banerjee was here, you met him in your office, did you participate in his exit interview that time, the first time or was it the second time?

DR. EJECKAM:

A. I know after discussing with him in my office,

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we review some slides together in the multiple headed microscope and we showed him estrogen receptors and other, immunohistochemistry and other antibody, what we were doing, we all sat together to look at it and he was quite happy with what we were doing at that--I mean, the results we're getting at that time.

COFFEY, Q.C.

Q. And when Dr. Banerjee was here in the fall, September of '05, were you made aware of his findings at that time?

DR. EJECKAM:

A. No. Well, I shouldn't say no. Dr. Don Cook read the paper, read the findings in a meeting of the entire pathologists. After reading it, were not giving copies, so I just kind of remember what was said at that time. So, we didn't have copies of the report, it was read to us.

COFFEY, Q.C.

Q. Do you recall when that was?

DR. EJECKAM:

A. After he came in, but I'm not too good with dates now, but it was after, shortly after, maybe weeks or so after he had come and gone.

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COFFEY, Q.C.

Q. And did you recall if Dr. Cook read the whole of the report?

DR. EJECKAM:

A. Yeah, I think he read the whole report in the meeting and then said that he wouldn't give copies, that it was confidential material. And I said to myself, if I'm in charge of the immunohistochemistry, why won't I have report how to improve it. And I think he said if I wanted to read it again, I could come and read it, come to his office to read it. I didn't go.

COFFEY, Q.C.

Q. Okay. And from your perspective, whereby that point in time, in the fall of 2005, by the time the report came in and Dr. Cook would have read it to the group, you were then the head--October 13 you'd been made responsible for the IHC part of the lab. You'd agreed to take it on and you were concerned when you--you thought you should have a copy of the report.

DR. EJECKAM:

A. Yes.

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COFFEY, Q.C.

Q. Because the report, I take it, was aimed at the IHC aspect of the lab.

DR. EJECKAM:

A. Yes, yes.

COFFEY, Q.C.

Q. Doctor, was there any discussion among the pathologists, I mean, you're sitting in a meeting, Dr. Cook reads the report, do the pathologists afterward discuss it, do you know?

DR. EJECKAM:

A. I'm sure some people made comment, but I don't remember what is said.

COFFEY, Q.C.

Q. Okay.

THE COMMISSIONER:

Q. Wherever you can find a good spot, we'll break for the luncheon break.

COFFEY, Q.C.

Q. What was--when you were looking at the slides with Dr. Banerjee, what were you talking about, do you recall?

DR. EJECKAM:

A. We just showed him a number of sections that

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we stained for ER/PR and for other antibodies and just for him to see the product from our laboratory and that's what we were talking about. And not just me, the techs were there and I think a few of the doctors were looking through the multiple head microscope.

COFFEY, Q.C.

Q. Would these be current slides at the time?

DR. EJECKAM:

A. Yeah, current -

COFFEY, Q.C.

Q. Current product -

DR. EJECKAM:

A. Current slides.

COFFEY, Q.C.

Q. If he went and looked at historic slides -

DR. EJECKAM:

A. No, no, we're not looking at those cases that are being retested. We are looking at what our lab was producing -

COFFEY, Q.C.

Q. Currently producing at that time.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.

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Q. Commissioner, we can break and come back and take this up and finish off. Thank you.

THE COMMISSIONER:

Q. All right. 2:05.

(LUNCH BREAK)

THE COMMISSIONER:

Q. Please be seated. Mr. Coffey.

COFFEY, Q.C.

Q. Thank you, Mr. Coffey. If I could, there's one thing I did want to look back at, exhibit P-0113, page three please. Now Doctor, this is that May 2 memo, May 2, 2003 memo. In paragraph five, there's just one point that I wanted to ask you about. You are here, reporting of ER/PR several formulae are in the literature and you spell them out, different ones. Then what I wanted to point you to, you've quoted here from Consensus Statement on Adjuvant Therapy of Breast Cancer, November 1 - 3, 2000, National Institute of Health, "any positive nuclear ER immunostaining is considered to be a positive result and should be a definitive reason for instituting anti-estrogen therapy for a patient". And you go on to note then for you fellow pathologist,

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"the medical oncologist may require percentage of tumor positivity". In relation to the reference to the consensus statement, okay, where would you have obtained that from?

DR. EJECKAM:

A. From the literature, immunohistochemistry book by DABBS.

COFFEY, Q.C.

Q. And this National Institute of Health was an American -

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.

Q. - Institute. Did you have any conversation with any oncologists about this?

DR. EJECKAM:

A. No.

COFFEY, Q.C.

Q. Did any of the pathologists to whom you sent the memo speak to you about it?

DR. EJECKAM:

A. No.

COFFEY, Q.C.

Q. Okay. I'm sorry, I just wanted to cover that off because I had, unfortunately, not done so

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when we went through it. If we could look please, at exhibit P-0351, page five, please. Now, Doctor, at the top of the page there, there's a reference to Trish Wegrynowski and her recommendations. Did you ever see a list of her recommendations?

DR. EJECKAM:

A. No.

COFFEY, Q.C.

Q. Doctor, I asked you, before lunch, if you recall having met her, okay. Did you--I'm just going to--because I had some understanding of what she, I anticipate, may say to the Commission, do you recall ever having an informal conversation with her, just -

DR. EJECKAM:

A. I don't recall discussing anything with her. I believe that I may have seen her in the laboratory.

COFFEY, Q.C.

Q. Okay. Is it -

DR. EJECKAM:

A. But I'm not 100 percent sure. I mean, I'm not sure whether I discussed with her or not.

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COFFEY, Q.C.
Q. Okay. So, if she was to testify that she did have a discussion with you, an informal discussion, -
DR. EJECKAM:
A. Well, I'll accept that, if she remembered any discussion, then that's fine.
COFFEY, Q.C.
Q. Okay, because I understand she certainly does remember yourself, but I just want to canvas that.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. We look here at paragraph four on this page, the space, in the second sentence of the paragraph where it says, upon recommendation by Dr. Ejeckam, this section moved adjacent to the main lab in the former hormone assay lab space. Plans have been in place for several years to have the pathology lab, as a whole, renovated incorporating the former hormone assay lab which had been identified as a new separate immunohistochemistry lab". So, I take it this suggests that your recommendation

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in '03, at least, was partially implemented.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. Were you aware that there were plans in place to have the lab redesigned in the sense of the layout of the lab, which is referred to here.
DR. EJECKAM:
A. Well, I may have had it because the other-- they were renovating the other sections of the laboratory and I would have had--anatomic pathology would be there later with--so I think they were doing hematology and then maybe they're coming down to -
COFFEY, Q.C.
Q. Okay, doing it in phases?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. Steps.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. Okay. Here at paragraph 5(a) "overall impact analysis, impact/analysis recommendations.

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(a) most grossing/dissecting functions to be formed by trained technologists, pathologists assistants".
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.
Q. I take it this is what yourself and Dr. Robb and company had been looking for in 2004?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. And though by the time you left in April of '06, it still hadn't been arranged.
DR. EJECKAM:
A. No, techs were still--senior techs were still doing grossing for us. I don't remember any of them being redesignated pathology assistants.
COFFEY, Q.C.
Q. Okay.
DR. EJECKAM:
A. But they were already doing the job anyway.
COFFEY, Q.C.
Q. If we could, please, page 6, paragraph--just get the--yes, this is under the heading

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"overall impact/analysis of recommendations", paragraph (f) says, "one pathologist be assigned the responsibility for all aspects of the immunohistochemistry service" and it says, "completed Dr. Ejeckam has accepted this responsibility". So, that letter, I take it, are the same date -
DR. EJECKAM:
A. Yes, yes.
COFFEY, Q.C.
Q. - okay, of October 13. Paragraph (f), just go down, sorry, "the immunohistochemistry lab enrol in outside proficiency testing, for example CAP. Currently enrolled in CAP, cost per year is $5,000.00", which is your memory of it, in fact, that you were already in CAP when you showed up in 2002.
DR. EJECKAM:
A. Yeah, right.
COFFEY, Q.C.
Q. "And Dr. Ejeckam has requested to enrol in the UK proficiency testing program and it's going to cost about $7,000.00 a year".
DR. EJECKAM:
A. Yes.

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COFFEY, Q.C.
Q. That was your request?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. Doctor, I take it then you told us that you, at one point Dr. Cook read yourself and your fellow pathologists Dr. Banerjee's written report.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. You read it once and you weren't provided with a copy. Did you ever see a list of his recommendations, Dr. Banerjee's recommendations, an actual list?
DR. EJECKAM:
A. No, just it was read out in a meeting, that was all.
COFFEY, Q.C.
Q. And Trish Wegrynowski's report, we know that she has a report dated, I think it's November 9th, 2005, but it is November 2005, did you ever see a copy of her report?
DR. EJECKAM:

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A. No.
COFFEY, Q.C.
Q. Was it ever read to you?
DR. EJECKAM:
A. No.
COFFEY, Q.C.
Q. And you never saw a list of her recommendations either?
DR. EJECKAM:
A. No.
COFFEY, Q.C.
Q. Okay. Doctor, is the person responsible-- well, it says responsible for the IHC, do you think it was wise or how wise do you think it was that you weren't provided with a list of recommendations, at least?
DR. EJECKAM:
A. Well, my answer here would be that whoever was asked to be responsible for this division of laboratory work ought to have sent or had copies of this--because he is going to implement some of the changes. So, I would think that it would be necessary for whoever is going to be responsible for the implementation to see the reports. Otherwise,

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they wouldn't know what to implement or somebody else would be doing it and, you know, on your behalf or someone like that.
COFFEY, Q.C.
Q. If we could, please, to take up another thread in this, Exhibit P-1282, please, and page three please. Now, this is a note apparently from Denise who worked, I gather, for Dr. Williams. It's dated September 6, 2005, "re: surgical pathology form" and it says, "Dora Cooper said the form is being printed today. There was a delay in printing because the printing machine needed for this particular service was out of service". And Denise is nothing that she had informed Dr. Cook about this. So, I take it, finally, at least the form was being changed, as you requested?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.
Q. If we can look please at Exhibit 1283, page two, please. These are what are entitled, "Terms of Reference for the External Quality Review of the Immunohistochemistry Service". This is what apparently the Terms of Reference

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that we are given to understand, Dr. Banerjee and Trish Wegrynowski were given. Were you consulted about this at all?
DR. EJECKAM:
A. No.
COFFEY, Q.C.
Q. Okay. If we could look at exhibit P-1302 please. Now Doctor, the first page of this is a letter dated October 17, 2005 to Dr. Donald Cook, scroll down through it and you'll see it's a letter from Dr. Banerjee enclosing his external quality review of the immunohistochemistry service. And we look at the second page of this, this is the report itself, the cover page, November 17, 2005. And then the, this is the text of the report. Doctor, have you ever had the opportunity to review the report? I mean, I appreciate it was read to you, you've told us but -
DR. EJECKAM:
A. Yeah, no, I didn't have a chance to read it on my own.
COFFEY, Q.C.
Q. Pardon me?
DR. EJECKAM:

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A. I didn't read it then.
COFFEY, Q.C.
Q. Oh, then. Have you had a chance to read it since?
DR. EJECKAM:
A. Since I came in, I think, yeah.
COFFEY, Q.C.
Q. In preparation for coming to the Commission of Inquiry.
DR. EJECKAM:
A. Yes, yes, yes.
COFFEY, Q.C.
Q. Okay. Doctor, I ask you to think back to the time that Dr. Cook read it to you as a group, do you recall what your reaction was to what Dr. Banerjee had apparently said? Were you surprised by it or not or how did you react to it?
DR. EJECKAM:
A. At that time--right now--at the time, when I saw it this time for preparation, I just didn't remember what he read.
COFFEY, Q.C.
Q. Yes.
DR. EJECKAM:

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A. But when I looked at it now, I wasn't surprised. Most of what he said was exactly what I would say. So, it does--making the same recommendation with a few additions to what I had indicated needed to be done with the laboratory.
COFFEY, Q.C.
Q. In fact, when you look at, for example, in the--and you say in preparation here now, to come here, in reviewing this and looking back on it, you're not surprised by the recommendations, for example?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. The recommendations, I'm just going to, if I could, begin at the bottom of page five of the exhibit, and then they continue on, and there are ten of them, in fact, actually spelled out. Now the references to--in the report to "conclusions about the reasons for test failure" and I appreciate here, Doctor, when you look back at this, to put this in context, Dr. Banerjee has reported on the first page that in the review of cases and in the

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paragraph before that, right in here he says "this led to a review of 50--of their 57 cases reported in 2002 as negative, which on retesting on the Ventana benchmark resulted in a high conversion rate from negative to positive, 38 over 57, 67 percent."
And then he says "I have a reviewed a number of cases from their retrospective testing set with Dr. Donald Cook. All of the cases that had converted from negative to positive by switching platforms had one or more of the following characteristics: poor fixation, negative internal controls, or absent internal controls. It is apparent that too much reliance is being placed on external positive controls with no attention paid to internal controls." And that was--I think you've already communicated to the Commissioner, your--the significance and the importance to you of the internal controls in ER/PR?
DR. EJECKAM:
A. It is very critical.
COFFEY, Q.C.:
Q. Okay. If we could, while we're at it, in the

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conclusions about the reasons for test failure, I'm not going to take you through them in detail, Doctor, but in effect, in paragraph one, he says it's not the DAKO system's fault. That's not a problem. I take it that while you were there, while the DAKO was there and you were there, the DAKO system, as far as you knew, was working?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. You had no reason to doubt its operational -
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. - utility. The Ventana system too sensitive. Did you have any reason yourself to believe it was too sensitive?
DR. EJECKAM:
A. I didn't think so. All I'd seen, the different machine, the range of positive may be different. They're not going to be exactly the same as DAKO because it's a different machine, it has a different clone of antibody that was used in these tests.

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COFFEY, Q.C.:
Q. Okay. So the fact that the positivity percentage might be different wouldn't surprise you?
DR. EJECKAM:
A. Yeah. No, no.
COFFEY, Q.C.:
Q. But the fact that it went from, for example, zero/zero to 100/100, that kind of a thing, that would surprise you?
DR. EJECKAM:
A. Yeah, that would be a problem.
COFFEY, Q.C.:
Q. That would be a problem, and perhaps if there's a significant change, I take it, that would be a problem?
DR. EJECKAM:
A. Yeah, if ten percent and 80 percent positivity, that's too wide a range. So one would worry about that.
COFFEY, Q.C.:
Q. A range from 10 to 15?
DR. EJECKAM:
A. It's not a big deal, 20 percent.
COFFEY, Q.C.:

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Q. He says "is there a problem with tissue fixation?" and he then posits that "there appears to be inadequate attention paid by the grossing pathologist to the thickness of tissue slices." Had you been aware of that, the assertion that he makes here that apparently the pathologists are not slicing the tissue thin enough?
DR. EJECKAM:
A. I'm not aware of that as a problem, and again, I know he mentioned it's possible poor fixation may be due to--like I explained earlier, the tissue may not have been--let's say the tissue wasn't brought down to the laboratory in time, then even if you section it after it lays overnight, fixation will not be adequate. You may fix it a little bit, but because already the damage has been done before the pathologist got to it.
COFFEY, Q.C.:
Q. And when the damage is done in that regard, it can't be -
DR. EJECKAM:
A. I mean, you might be able to get at some result, but it's not going to be optimal

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because if they had a big mass and it was put in formalin bucket, it wasn't sliced, the central part of that will not fix properly, and if you come in the next day to slice it and then take section, most of the central area may have not been properly fixed and you're going to have the effect when you do the stain. So the problem is not necessarily pathologist not slicing. It's you have to deal with how the sample was brought in, what form it was brought in.
COFFEY, Q.C.:
Q. It could be either/or or even both for that matter? It could be -
DR. EJECKAM:
A. I wouldn't put this on the pathologist, for the mere fact that all the pathologists, they were trained and I know that the sections you take can't be thicker than the cassette anyways, and the cassette, if you have a thicker slice, it wouldn't close. So whatever is able to be accommodated in that cassette should fix.
COFFEY, Q.C.:
Q. Okay. He says, in paragraph four, "inadequate

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or no attention is being paid by the reporting pathologist to the status of internal controls with inappropriately exclusive reliance on external positive controls." Doctor, had you been aware or would you have--you know, would you have been aware that a state of affairs existed that would result in this sort of a statement by a person such a Dr. Banerjee?
DR. EJECKAM:
A. I'm not aware that the pathologists had problem identifying internal control.
COFFEY, Q.C.:
Q. You weren't aware?
DR. EJECKAM:
A. Like I said in the beginning, before, one, you need to be aware that those controls are necessary to look at and if anybody didn't have that information, that's, you know, benefitted from my memo.
COFFEY, Q.C.:
Q. Yes. Anybody who hadn't known about it before your May 2nd memo, certainly if they got that and read it would have been aware of it?
DR. EJECKAM:
A. Yes.

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COFFEY, Q.C.:
Q. Or could have been aware of it. The paragraph--well, there's no paragraph five numbered five, but this paragraph numbered six, "inappropriate choice of blocks with no representative normal ductal epithelium." I take it that refers to what? Your understanding they weren't picking blocks with -
DR. EJECKAM:
A. Yeah, this is a problem. I will say the pathologists, after looking at the HNE, has to pick the block that has normal tissue. Sometimes you have, you know, all just the tumor and if that's all you have, then that's the block you're going to deal with, and this issue--well, I'm not trying to point finger at any particular laboratory, but I noted this maybe more with some of the out of St. John's blocks we received. So that, you know, and you cannot do very much about the quality block they send you to do the stain on .
COFFEY, Q.C.:
Q. Now, Doctor, well you mentioned the out-of-town pathologists, were you ever contacted in

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relation to the ER/PR matter by any out of St. John's pathologists?
DR. EJECKAM:
A. No, I don't remember anyone of them calling to discuss any issues with this.
COFFEY, Q.C.:
Q. Nor to discuss either of your -
DR. EJECKAM:
A. Memos.
COFFEY, Q.C.:
Q. - memos either?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. Okay. If we could just look at other system flaws briefly, Doctor. "Lack of dedicated immunohistochemistry technologists." Well, you'd been on about that for a while, hadn't you, yourself?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. "Lack of an officially designated pathologist as director of immunohistochemistry service." I take it that actually occurred on October

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13th with that letter to you?
DR. EJECKAM:
A. Yeah, well, it didn't occur in--I mean, when you appoint someone director of anything, you need to have a structure and he knew that a director, I mean, that letter written, I took it that just confirming me as a resource person.
COFFEY, Q.C.:
Q. Resource person.
DR. EJECKAM:
A. So that I don't have any interference dealing with the techs, and that is the way I interpreted it.
COFFEY, Q.C.:
Q. And I appreciate that clarification, Doctor, because I want to be--I'd like the Commissioner to understand what you understood in your own mind as to what it was.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. I characterized it just then as appointing you director and you'd say "well, no, Mr. Coffey, that's--I didn't see it as--I wasn't director.

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I was -
DR. EJECKAM:
A. Yeah, because I mean, you see all the meetings that were going on. I would suspect that a properly appointed director should be either driving those meetings or be present at those meetings.
COFFEY, Q.C.:
Q. Sure.
DR. EJECKAM:
A. You know, so all I did was to help to make sure the laboratory produced credible good result.
COFFEY, Q.C.:
Q. Here, number four, Doctor, paragraph four, "lack of subspecialization among pathologists leading to a lack of in-depth knowledge about IHC technical and interpretation details and pitfalls." So I take it you would have been in favour of subspecialization?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Certainly, if it was possible to do it.
DR. EJECKAM:

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A. Yes.
COFFEY, Q.C.:
Q. And there's a reference to the disconnect between laboratory program director, division manager, clinical site chief and laboratory director in decision making, and he then goes on to talk about the organizational chart, indicating a complete separation of reporting structures into technical and clinical streams with no cross-reporting. Did that reflect your own thinking, now looking at this now and looking back on it? Were you concerned about the division between the clinical staff and the technical staff?
DR. EJECKAM:
A. Yes, yes. I mean, I had said this before.
COFFEY, Q.C.:
Q. Yes.
DR. EJECKAM:
A. You needed the manager to report to the site chief and you needed the program manager to report to the clinical chief. Now that wasn't the case, so parallel responsibilities, and the clinical chief and the site chief had no authority. They didn't control any budget.

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They couldn't change anything in the laboratory, in terms of buying equipment. All those would be manager and the program manager who would report then straight to, I think, to the Vice President of the hospital, leaving the clinical chief and site chief really just one of those people in there with no real authority to make any changes, and I think that is a little bit absurd.
COFFEY, Q.C.:
Q. Now Doctor, with respect to this, under the--further on in this paragraph, there's a reference to the Sakura Express. You see that?
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. And he says--well, he--this full sentence reads "the division manager and program director appear enthusiastic and keen on modernizing the laboratory, but their efforts have not been appreciated by the pathologists and work flow changes have not been mapped out and implemented, eg. example a Sakura Express implementation has failed due to lack of

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planning of work flow changes." And he goes on to say "superior outcomes could be achieved by ensuring better linkages between technical, managerial and medical leadership." I take it you would agree with the last sentence certainly?
DR. EJECKAM:
A. Yes, yes.
COFFEY, Q.C.:
Q. The Sakura Express, what was that about? Do you recall?
DR. EJECKAM:
A. I think it was a big tissue processor that could handle larger volumes of tissue, but of course, it needed to be worked in, in terms of the size of sample and the type of sample it could handle.
COFFEY, Q.C.:
Q. Did you have any--was the Sakura Express there while you were there?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Was it used at all?
DR. EJECKAM:

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A. I think it was used briefly, but after that, then they stopped using it. We had some problem. Small samples that got processed through it, some of them were a little bit--they didn't come out very well, so I think they stopped using it, but I can't be sure which of the--you know, what they did with that. I think they stopped using it.
COFFEY, Q.C.:
Q. In relation to that, did you have any involvement in that?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. The usage or stoppage of it?
DR. EJECKAM:
A. No.
COFFEY, Q.C.:
Q. Okay. You weren't consulted about it?
DR. EJECKAM:
A. I shouldn't be, because that had--it had nothing to do with me. That's a machine that does general histopathology work. It has nothing to do with immunohistochemistry.
COFFEY, Q.C.:

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Q. Okay, and paragraph six refers to "attendance by both medical and technical staff at various conferences with a focus on new technology should be encouraged," and you had no problem with that. You thought people should go to conferences?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And training, and finally, "the department needs dedicated pathology assistants," which is the same thing yourself and Dr. Robb had been on about.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. So Doctor, with the benefit of having had a chance to look at this now, in preparation for coming here to testify, do you take any issue with what's in Dr. Banerjee's report?

DR. EJECKAM:

A. I agree with what he said.

COFFEY, Q.C.:

Q. Okay. If we could, please, Exhibit P-1587? Now Dr. Ejeckam, this is a letter of October

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18th 2005 to Edward Depestre, Chief of Pathology Services at Jewish General Hospital in Montreal, and it opens by saying "we are in the process of reorganizing our immunoperoxidase service in the anatomical pathology. As part of this process, we want to develop a highly specialized team of technologists who will be dedicated solely to immunoperoxidase staining." And he goes on to talk about the Ventana system they are currently using.

This is a letter, by the way, Doctor, from Dr. Cook, you can see, and it's copied to yourself, amongst others, Dr. Fontaine who will be the site chief at Mount--I'm sorry, at the General Hospital at the time, and Dr. Williams and Mr. Gulliver. In this, in the middle of the first paragraph, Dr. Cook writes "it would be greatly appreciated if you can accommodate one of our technologists for a four-week period, hopefully in November of this year," back then?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

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Q. Were you involved in this arrangement?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Okay. Could you tell the Commissioner what you recall about that?

DR. EJECKAM:

A. My recollection was that after discussion with Dr. Cook, we agreed that it's necessary to send one of our technologists to where a Ventana machine was being used, because there was a talk of going to Mount Sinai and I advised that they shouldn't go to Mount Sinai because Mount Sinai was using DAKO. Even though they were doing--they did the tests for us. They should be sent to a hospital where the same machine that we have here is in operation, and so I agreed to research and after looking around was able to locate Jewish Hospital in Montreal. So I was a part of the decision, and I think I read the draft of this letter before it was sent out.

COFFEY, Q.C.:

Q. Okay, and you were in agreement? In fact, it was your suggestion that's where they send -

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DR. EJECKAM:

A. Yes, yes.

COFFEY, Q.C.:

Q. They're using a Ventana at Jewish General. That's where we should send our tech.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. If we could, please, I take it that--do you recall who was sent?

DR. EJECKAM:

A. Ken Green.

COFFEY, Q.C.:

Q. Ken Green, and how did that work out, do you know, from your perspective?

DR. EJECKAM:

A. It was beautiful. He was happy to have gone there. Sometimes you go to new places or conferences, may not learn a whole lot, but your confidence get reenforced and you also see there any housekeeping thing they do that we are not doing. So I think he was quite happy when he came back from there.

COFFEY, Q.C.:

Q. Your understanding was is that from--he

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communicated it was a positive experience, from his perspective?

DR. EJECKAM:

A. Pardon?

COFFEY, Q.C.:

Q. He communicated to you it was a positive experience from his perspective?

DR. EJECKAM:

A. Yes, my evaluation of, you know, his visit there was that he was happy with it and he also learned something to help improve our own laboratory.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1588? Now Doctor, this is a letter dated November 29th 2005. It's from UK NEQAS for immunohistochemistry in London, United Kingdom. It's addressed to yourself and it says "thank you for the application to join UK NEQAS scheme for immunocytochemistry." In fact, I said immunohistochemistry. It is actually titled immunocytochemistry. "I have entered your details on our database so that you will be included on future assessments and confirm that your centre has now joined the

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scheme. Your laboratory code, which you should refer to in all correspondence and which ensures your laboratory's anonymity is" that's redacted.

COFFEY, Q.C.:

Q. The second run is for 1st, April 20005 to the 31st, March, 2006 will dispatch sometime in December, 2005. Last, if there's any aspect that you would like to discuss further, please do not hesitate to contact me at the above address." Signed, "Alin Rhodes, Office Manager." So I take it, Doctor, that you had applied to join?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. The lab. And did the lab participate?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. And did it do so before you finished up in April?

DR. EJECKAM:

A. Yes. We had, I think, two, I believe we had two runs and it was very good, we were very

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happy. The evaluation from London showed that the laboratory was reading good on ER/PR and I think on lymphoma panel that we entered.

COFFEY, Q.C.:

Q. Now, Doctor, the purpose of picking UKNEQUAS was what, why did you pick them?

DR. EJECKAM:

A. Looks to me to be about the best standard of quality assurance in immunohistochemistry there is. You know, CAP is there, but the way this is carried out is a lot better. They would send you slides, then you do the stain and send back the slides to them to evaluate. The CAP one, I think, they will send you slides, you do the stain and evaluate it yourself and send them your scores, so you have a chance to cheat if you wanted to do that. But for the UK one, they will recommend this, and four different people evaluate the slide and score that and I thought that was thorough. And UK today, this body, I think, supervises all centres that do immunochemistry for ER/PR and they had the authority to shut down any laboratory that is below par over a period of time.

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COFFEY, Q.C.:

Q. In the UK?

DR. EJECKAM:

A. In the UK.

COFFEY, Q.C.:

Q. Yes. And, Doctor, I believe you had indicated that just at the point where you had left Qatar that your laboratory in Doha had just, was just getting involved in the UK -

DR. EJECKAM:

A. Yeah, they were just getting involved with this. But we had CAP -

COFFEY, Q.C.:

Q. Before that?

DR. EJECKAM:

A. - before that.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1337? Now, Doctor, this is a letter, it's written, it's December 7th, 2005. It's written to Dr. Williams. It's, actually, that version of the letter has only actually got the two pages. If we could bring up, please, Exhibit P-0101? I apologize. That particular exhibit does not have the third page on it, of the letter.

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This is the letter, it's the same letter but it's the one without the letterhead, December 7th, 2005. It's addressed to Dr. Williams, it's from Dr. Carter, copied to Doctors Cook, Gulliver and to yourself. Doctor, did you receive a copy of this letter?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Okay. And this is the one in which Dr. Carter advises Dr. Williams that she had been asked by Dr. Cook to comment on Mr. Dyer's suggestion that he felt the Ventana testing for estrogen receptor, progesterone receptor and Her2/neu could be started at any time and she says, "I find this comment quite startling in the face of the two fairly damning reports by Dr. Banerjee and Trish Wegrynowski." and goes on from there. Doctor, when you received that letter, you know, what, if anything, was your impression or what did you take from it?

DR. EJECKAM:

A. The points Dr. Carter made, Commissioner, were valid. And what surprised me too that like I keep saying, the title "Director of

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Immunohistochemistry" or "Head of Immunohistochemistry," there was a meeting held between, I think, Don Cook and Barry on this letter where Barry declared that the immunohistochemistry could now go back to doing the tests. I wasn't there and the techs weren't there. So I don't see how that judgment could have been made. I probably should have gone up to that, went in to say, well, okay, or send one of the techs to go. And I guess that's a part of the reason that maybe that's--I'm not sure because she didn't talk to me before she wrote the letter. But I agree with her observation in the letter that there are a few things that need to be done. But in terms of the what we are producing, I believe we are producing credible results at that time. And I think we had--we are producing credible results at that time.

COFFEY, Q.C.:

Q. This is December -

DR. EJECKAM:

A. We have cured the ill that was plaguing the interpretation or the staining of the ER/PR.

COFFEY, Q.C.:

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Q. And -

DR. EJECKAM:

A. I believe the Banerjee's report he did mention that some of these issues be started immediately with looking at trying to put in the other factors in place where there's some stains could be started right away, because he looked at what to produce.

COFFEY, Q.C.:

Q. As you indicated, you had shown on the current slides?

DR. EJECKAM:

A. Yes, yeah, we had shown what we were producing, yes.

COFFEY, Q.C.:

Q. And certainly--and she lists a number of things that she thinks or she says should be done, you know, before retesting of the ER/PR is re-instituted or testing of ER/PR is re-instituted. And in, your recollection is is in terms of what she sets out there, you were in agreement with it?

DR. EJECKAM:

A. Yeah, most of what she said was just repeating what Banerjee said.

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COFFEY, Q.C.:

Q. Yes.

DR. EJECKAM:

A. And these are things that we needed to improve the overall structure of the tests and everything else.

COFFEY, Q.C.:

Q. Now, by this point in time, December of '05, had the report of Dr. Banerjee already been read to you by Dr. Cook, do you think, by that time? By the time you saw Dr. Carter saying these are two fairly damning reports -

DR. EJECKAM:

A. I don't think I've seen--well, I don't remember the dates now, but I know very well that I did not see Banerjee's reports before this -

COFFEY, Q.C.:

Q. Oh, no, no, when I say--been read to you, had the report been read to you before you got Dr. Carter's reference to two fairly damning reports?

DR. EJECKAM:

A. I don't think so.

COFFEY, Q.C.:

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Q. It may have been afterward?
DR. EJECKAM:
A. It may be after that, yes.
COFFEY, Q.C.:
Q. Okay. Doctor, were you involved in meetings in relation to arising out of this letter involving trying to get the ER/PR up and running again in St. John's? Were you involved in any efforts to -
DR. EJECKAM:
A. No, they didn't stop, I didn't stop working with the techs. But what I didn't do and I probably wasn't invited, was go into the meeting for any kind of arrangement. But in terms of working with the techs, I didn't stop until I left.
COFFEY, Q.C.:
Q. Okay. And were you involved in any large efforts involving doctors and others and technologists to do what was required to restart the ER/PR?
DR. EJECKAM:
A. Yes, we--the moment we cured the ill, I went into the mode of making sure first of all, accumulating controls normal, positive

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control, establishing a logbook. And it's not only ER/PR, the other antibodies. I had a logbook where I would go in and write in the surgical number that was found to be good control. And I also mentioned to my colleagues that why are signing out cases, if they found a good control for any particular antibody, they should please pass it on to the techs and they would take it and then put it in the logbook.
COFFEY, Q.C.:
Q. Okay. So there were efforts not only involving ER/PR, but the larger effort in terms of IHC services?
DR. EJECKAM:
A. Yes, yes.
COFFEY, Q.C.:
Q. Being made. If I could, and these are particular items that Mr. Crosbie wishes to refer to, Commissioner, but if I could have entered Exhibit P-1604 and P-1605, please?
COMMISSIONER:
Q. P-1604?
COFFEY, Q.C.:
Q. 1604.

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COMMISSIONER:
Q. And 1605?
COMMISSIONER:
Q. And 1605, please, Commissioner.
COMMISSIONER:
Q. Entered.
EXHIBIT P-1604 ENTERED INTO EVIDENCE.
EXHIBIT P-1605 ENTERED INTO EVIDENCE.
COFFEY, Q.C.:
Q. Thank you. In relation to, if you could bring up, please, Exhibit P-1604? This is her handwritten notes of February 8th, 2006. They list the attendees of a meeting regarding update on the implementation of ER and PR and Doctors Cook, Ejeckam, Carter, Fontaine, Mr. Gulliver, Mr. Dyer, Mr. Simms, Mr. Green and Ms. Butler are listed as in attendance. And I'll leave the body of this to Mr. Crosbie. But there is a reference here, Doctor, to, in the middle of the page to a general discussion followed, including the prospect of bringing in digital microscopy unit image analyzer. It's a Ventana visual -
DR. EJECKAM:
A. Yeah.

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COFFEY, Q.C.:
Q. - imager. Do you recall what involvement, if any, the lab had with that, this machine, did that occur while you were still in St. John's?
DR. EJECKAM:
A. My recollection was that while the Ventana people brought in the immunohistochemistry machine, they also brought in VIAS.
COFFEY, Q.C.:
Q. VIAS.
DR. EJECKAM:
A. I think that was the name of it. Which they think might be the way to go in terms of evaluating immunohistochemistry digitally and that may help to eliminate the human error if it was properly calibrated. The machine for evaluation. It was demonstrated to us in a small group and then it was left in the laboratory and I think that time the agent said he would leave it for just two weeks and then we then make an evaluation of that machine. Of course, two weeks wasn't enough for anybody to make proper evaluation of that machine. But their demonstration looked great, but you needed to work with it and with

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our own material to satisfy ourselves that it was something that was worth looking into. It wasn't to be purchased, though, it was just kind of demo that they brought in.

COFFEY, Q.C.:

Q. Okay. Doctor, have you ever--have you had the opportunity to actually utilize such a machine yourself?

DR. EJECKAM:

A. Not, I've never seen it before. When it was brought here, it was the first time I saw it. And it's a new machine and it's probably taken--the only similarity to it is what you have in cytology. Cytology now had digitally machine that will scan and then identify abnormal cells. Then the techs still have to go and look at those abnormal cells to make a final evaluation. I believe that's what they are trying to extend that capability. That particular VIAS machine here was the first time I saw it. And I think they mentioned it's a new machine on the market in world.

COFFEY, Q.C.:

Q. Sure. And that there is a reference to it further -

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DR. EJECKAM:

A. Yeah, and it was for evaluation, not for tests.

COFFEY, Q.C.:

Q. In principle -

COMMISSIONER:

Q. Sorry. I'm just trying to make sure I--are you saying that in terms of the evaluation, the period of time which the machine was left in the lab was not sufficient to even do that?

DR. EJECKAM:

A. Yes, grossly inadequate. Two weeks and we're all busy. I know I looked at it once or twice and the other pathologists didn't have time to even look at it, so. And they wouldn't leave it more than two weeks, so, you know, or might have been three weeks, it wasn't enough time to even decide whether it was good or bad.

COFFEY, Q.C.:

Q. As a pathologist with your experience, because you have a lot of years experience as a pathologist and your involvement with IHC, in principle do you have any--do you take any issue with the idea of using such a machine, if it operates properly?

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DR. EJECKAM:

A. If it operates properly, I have no quarrel with that. But you have to convince yourself you can reproduce the results on it on what you were using. I mean, like I mentioned now, when we look at cytology, PAP smears that women do, it is normally done just by techs or a pathologist looking at it, but you're looking at millions of cells. Now, the device, a digital imaging equipment which would help you to do the scanning and then because of the way it had been programmed identify abnormal cells then that way it do the job of either not seeing an abnormal cell or looking at it for too long. So if is a machine like that and it's well satisfied that it can do that job, I don't see--I don't have any quarrel with it. But we couldn't do anything about it, we couldn't make that judgment.

COFFEY, Q.C.:

Q. For the reasons you just indicated to the Commissioner, you didn't have enough time to?

DR. EJECKAM:

A. Pardon?

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COFFEY, Q.C.:

Q. You didn't have enough time at the time?

DR. EJECKAM:

A. We never had time with it. And again, at that time being a new machine, I'm not sure there was any centre that was already using it that we could even check about its performance.

COFFEY, Q.C.:

Q. Okay. If we could, please, Exhibit P-0694? Doctor, this is a letter of December 14th, 2005. It's from Dr. Williams to Dr. Beverley Carter responding to her December 7th letter. It's copied to Doctors Cook, Mr. Gulliver and yourself. And in this Dr. Williams is, after thanking her for her letter, he says, "I've asked Dr. Don Cook and Mr. Terry Gulliver to review all the recommendations made by Dr. Banerjee and Ms. Wegrynowski and provide me with a spreadsheet of these recommendations indicating our progress and status with respect to implementation. And Dr. Banerjee has agreed to participate in a conference call, if required." He goes on to talk from there about possible timetables. "I understand that you will be involved in this

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process," he concludes, "and look forward to your input into the decision making process and the future delivery of reliable and accurate results in this area." Now, Doctor, I've asked you whether you ever saw any recommendations. I take it you didn't see the spreadsheets if there was such a thing?

DR. EJECKAM:

A. No, no.

COFFEY, Q.C.:

Q. At the time you got this letter, did you think that you would actually get a copy of the spreadsheet?

DR. EJECKAM:

A. I wasn't sure because, I mean, I wasn't involved in the formation of the sheet, so they probably would have kept it without my seeing it. So I didn't have an opinion about it, actually.

COFFEY, Q.C.:

Q. And if we could, please, Exhibit P-1590, page 2, please? Now, Doctor, this is a memo addressed to Dr. Dan Fontaine, yourself, Mr. Gulliver and Mr. Dyer, it's from Dr. Cook, March 6th, 2006 "RE: Implementation of New

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Immunohistochemical Antibodies." Dr. Cook writes, "All new antibodies that are requested by a pathologist for the immunoperoxidase service have to be approved by the chief pathologist overseeing immunohistochemistry. No new antibodies will enter the system until there is a sign-off on the protocol form by the pathologist overseeing the immunohistochemistry service." So, Doctor, was this something new at that point?

DR. EJECKAM:

A. Well, it probably wasn't new. I mean, I believe why this was written was people will now come up and say they have read about a particular antibody and that it's going to be useful in certain type of diagnosis and we didn't have that in our process. Now rather than buy the antibodies haphazardly or whatever anybody thought of, some of these may be just research material, they may not have been used clinically. I believe he did that so that when somebody--I remember getting one or two requests, they would bring it to me, then we will ask for one or two amps, ampules of that, then we'll try it out and then when

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we titrate it and it is okay, then we can sign into the system that now this antibody is now in the system and people can make requests of them.

COFFEY, Q.C.:

Q. If we can look, please, at Exhibit P-1112? Doctor, this is the letter dated March 8th, 2006, it's addressed to yourself and it's from Dr. Cook, copied to Drs. Williams, Denic--Nash Denic, and Dan Fontaine and to Mr. Gulliver, and it says, "Dear Dr. Ejeckam, as discussed on the morning of March 7th with Terry Gulliver and myself, I think it is important that we draw up a detailed job description for the director of the immunohistochemistry in the division of anatomic pathology. It would be most appreciated if you could provide me with your written response on the duties, responsibilities and reporting mechanisms associated with this position. It would be appreciated if you could address the issue of pathologists' concerns as they relate to immunohistochemistry and recommend a mechanism of how these concerns are investigated and documented with appropriate follow up.

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Sincerely your, Donald Cook." Now, Doctor up to this point, had you been the director of immunohistochemistry, from your perspective?

DR. EJECKAM:

A. I would say no, I was a resource person that's the way I would regard myself.

COFFEY, Q.C.:

Q. Now when you received this, I take it you did receive it?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. A copy of this. You understood you were being asked to do what, really?

DR. EJECKAM:

A. My impression that he decided now to appoint director of immunohistochemistry and that was looking for a write up of the job descriptions and duties and whatever that should be presented to the hospital authority to approve and then provide funding for it.

COFFEY, Q.C.:

Q. Did you respond to this?

DR. EJECKAM:

A. No, I didn't. I was already, this was 2006.

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COFFEY, Q.C.:
Q. Yes, I'm about to refer you to an exhibit where you are resigning, retiring.
DR. EJECKAM:
A. Yeah, I didn't have enough time to get to this and I did mention to him that I just couldn't get it done and when he handed it over to Denic, Denic also mentioned, called me up, had a question, I told him I didn't have time to do it at that time, they can take care of it.
COFFEY, Q.C.:
Q. That was after Don Cook handed over his clinical chief position to Nash Denic?
DR. EJECKAM:
A. Yes, yeah.
COFFEY, Q.C.:
Q. Nash contacted you.
DR. EJECKAM:
A. Yes, he called me about doing a write up too and my response was I was busy trying to clean up things and I didn't have time to do that.
COFFEY, Q.C.:
Q. Now this refers to, is discussed on the morning of March 7th, do you see that, with Terry Gulliver and myself--would be Don Cook.

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If we could look, please, at Exhibit P-1398? Now, Doctor, these, I understand are notes made by Dr. Cook and it says "Spoke to Dr. Ejeckam, with Terry Gulliver, morning of March 7th, 2006 re: the hold on certain stains in 2003. I asked him"--that would be Don Cook asked you--"what he meant by erratic? Dr. Ejeckam reported that it meant some stains worked some days and didn't work on others. I"--that would be Done Cook--"asked him if he should have recommended a review of stains at that time. He replied to me that it wasn't his place to initiate or recommend a review." Now did that conversation take place, Doctor?
DR. EJECKAM:
A. I do not remember this conversation with Terry being there and it's a little bit funny to me, when something that 2006 and being written down as composition here for 2003, that's three years after, that's a little bit, you know, I don't remember this--it could have happened, but I don't remember it.
COFFEY, Q.C.:
Q. So, just so the Commissioner -
DR. EJECKAM:

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A. That is interpretation of what I said as erratic is correct, I explained to the Commissioner that erratic, asked me the question before, that it was erratic because it wasn't giving us, you know, consistent result of what it should be and that's what I described as being erratic, one day it's okay, another day the same block, the same tissue stained by the same antibody would give a different result.
COFFEY, Q.C.:
Q. Yean, and here reports you as saying that, "He meant some stains worked some days and didn't work on others."
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And then he goes on to ask you about if you should have recommended--that's presumably back in 2003, a review of the stains at that time, in effect suggesting he talked to you about, in '06, about why in '03 you hadn't recommended going back to '02 and '01, I mean that's what this seemingly refers to.
DR. EJECKAM:

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A. Yeah.
COFFEY, Q.C.:
Q. Do you recall that coming up, Doctor Cook saying to you, look, Gershon, why didn't you go back?
DR. EJECKAM:
A. I don't remember that, but even if he said it, I wouldn't recommend going back to do anything because there was no index case. We were doing--if you are doing experiment in the laboratory, and you've done one year of experimental work and then one year plus one day, you do another one and it doesn't come out okay, that's not a reason to go and repeat what you've done the past year. What you should do is to find out why that one is not good, and that's what we did, to make sure we have good results. Until you have a trigger case that now tells me that all I've done for the past year has been all wrong, there was no reason, there was no danger to the patient at this point in time and I had no reason for me to go back to start reviewing the cases.
COFFEY, Q.C.:
Q. So in 2003 when you got involved in this

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effort that you described in 2003, did it ever cross your mind at the time, Doctor, that if the stains are erratic in January and February and March of 2003, that if they're erratic, I gather you would have had no reason to believe they weren't erratic back in December and November too?

DR. EJECKAM:

A. I had no reason to believe they were erratic previously. People, like I said, each time you do scientific experiment, you either get a result expected or you get something different, then you should look at why is it happening that way? Now, there was no way of now going back to say what was done years ago was wrong until there was a case showing that this was done and repeated and then found to be negative. We are talking about cases that came to us at the time we were working and we did it and were not happy, they would have repeated it and we made sure that it was okay, and if we couldn't do that, we would send the cases out to other hospitals, Toronto or Halifax. So there was no reports sent out based on inadequate staining.

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COFFEY, Q.C.:

Q. That you were aware of?

DR. EJECKAM:

A. Yes, I mean, no such thing.

COFFEY, Q.C.:

Q. And I take it, Doctor, though, in 2003 it didn't occur to you to go looking for such a case, to go back to 2002 or 2001, bearing in mind what you knew in '03, that you were seeing erratic staining?

DR. EJECKAM:

A. It didn't occur to me and I didn't think it was a proper way--work to do then.

COFFEY, Q.C.:

Q. Did anyone else suggest it to you--and I'm not suggesting they did, because you've told the Commissioner that, look, this arose out of a bunch of us talking about it, about the problem, problems we were encountering.

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. A bunch of us being pathologists.

DR. EJECKAM:

A. Yes.

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COFFEY, Q.C.:

Q. At these Tuesday and Wednesday meetings.

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. So that during these meetings and in discussing this and after your memos went out, your April 4th memo and your May 2nd memo, the topic never came up, no one ever raised the idea of, look, why don't we go back and see what was going on six months ago?

DR. EJECKAM:

A. No, no.

COFFEY, Q.C.:

Q. Or a year ago or anything.

DR. EJECKAM:

A. No, nobody raised the issue.

COFFEY, Q.C.:

Q. And on that point, Doctor, I'll just ask you this, while you were in St. John's at all, until the spring and summer of 2005, which we've heard about now about the retests and so on, had you ever become aware of any conversion of ER/PR results?

DR. EJECKAM:

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A. The one that I knew about was in this -

COFFEY, Q.C.:

Q. Yes.

DR. EJECKAM:

A. Apart from that, I heard about it, there was no record that anybody brought up.

COFFEY, Q.C.:

Q. Okay. Doctor, in dealing with--just on this subject matter, in dealing with cases referred from out of St. John's, for example from Gander or Grand Falls, okay, for ER/PR testing. I'm just going to posit a certain fact scenario to you and just see what you think. If you were asked by an oncologist in St. John's, okay, in 2003 to run a Her2/neu on a 2000 sample out of Gander, okay, and how would you have gone about getting the block?

DR. EJECKAM:

A. Getting the name of the patient, we'd get a surgical number of that hospital and we'd make a request to the pathologist over there indicating that it's a request from the oncologist to do this test, and then he would send down the block.

COFFEY, Q.C.:

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Q. He would send the block.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. Would he normally send the actual original reports, do you know?
DR. EJECKAM:
A. Sometimes they'll send the block and the report.
COFFEY, Q.C.:
Q. And sometimes, I take it, not.
DR. EJECKAM:
A. They just send the block forwarded.
COFFEY, Q.C.:
Q. And I take it then you would use the block to do whatever the oncologist asked you do, whatever the test was.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And the report that you would prepare in 2003, you would send that to whom? To the oncologist, I take it -
DR. EJECKAM:
A. Yes, the oncologist who made the request and

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the report would go to him or her.
COFFEY, Q.C.:
Q. In St. John's in 2003, did you have any immediate ability to access, for example, the Meditech system in Gander?
DR. EJECKAM:
A. No, no, couldn't do that, we were asked for the physical--either phone up and tell the secretary to phone up and obtain this, we're not accessing the -
COFFEY, Q.C.:
Q. Access by a computer, telecommunications clients.
DR. EJECKAM:
A. No,
COFFEY, Q.C.:
Q. So in 2003, if you did an ER/PR on a surgical block that the original test had been done in 2000, okay, unless you actually asked for the 2000 ER/PR result on the block, you'd have no way of knowing it, would you, in 2003?
DR. EJECKAM:
A. Yes and no, the oncologist requesting this would have known the result.
COFFEY, Q.C.:

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Q. Yes.
DR. EJECKAM:
A. And what happened that even when they have a result diagnosis of a patient, say from Gander or Corner Brook basically with a malignancy, not just breast, any malignancy, if they come in here, the oncologist would request us to review the slides and then confirm the diagnosis. So we would do that, we would request for the slides and look at it and confirm to them before they treat and that is the standard practice in most oncologist centres, you don't treat the patient in centre A with a diagnosis from centre B, you will look at a slice, your own pathologist will now make the same diagnosis, then you have legal background, standing to start treating that patient.
THE COMMISSIONER:
Q. So if a patient who normally resided in Corner Brook came to the cancer clinic in St. John's, would the pathologist in St. John's then go back through the information or would they just take the medical record from Corner Brook to look at what the diagnosis had been, what

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kind of cancer it was, what the status of ER/PR, for example, was?
DR. EJECKAM:
A. A patient with cancer from Corner Brook would refer to the oncologists. The oncologist would send that paper to the laboratory and then we will ask for the slides of the original diagnosis. They will write and say please review, then we would then look at a slide and reconfirm that diagnosis in our own report and then we'd send it to the oncologist.
THE COMMISSIONER:
Q. Okay, so they act on your--if it's you doing the second look, they would act on your advice, rather than the advice given from the original pathologist in Corner Brook, maybe a year or two before?
DR. EJECKAM:
A. Yes, this has a--well I'm not a lawyer, but it has a medical, I mean, legal implication. The patient is being treated here and there's a legal implication there that the oncologist must, should have diagnosis of that case in that place.

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THE COMMISSIONER:
Q. In the institution.
DR. EJECKAM:
A. So it may be the same slide, but we're going to say we borrowed a slide, ten slides, a hundred slides and after looking at it, this diagnosis may be the same, but even if there is a discrepancy, then there may be questions asked or something.
COFFEY, Q.C.:
Q. Doctor, on that point, in looking at any such slides, would--I appreciate you're talking about diagnosis.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. How about calculation or, you know, consideration of the ER/PR result, would you be asked to confirm the Corner Brook ER/PR result?
DR. EJECKAM:
A. The ER/PR result was done here, Corner Brook wouldn't do it, the only centre is St. John's, so we would do it and send it to them. Now if the guy in Corner Brook make an interpretation

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and they want us to look at it again, we would do that and give interpretation to it. So you have to give a composit--okay, go ahead.
COFFEY, Q.C.:
Q. Just so we're clear then so, for example, Corner Brook or Gander or Grand Falls, the tissue would be prepared, taken in surgery, it would be processed there into a block.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And the pathologist there would order ER/PR?
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And that order and the block would come into St. John's.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And it would be processed here and the slide is created.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:

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Q. And you've described how, certainly in your time before they got sent, the slides and the block got sent back to Corner Brook or Gander or Grand Falls, the technologist used to come to you to check the controls.
DR. EJECKAM:
A. Well we just look at the technical -
COFFEY, Q.C.:
Q. The technical controls.
DR. EJECKAM:
A. Yeah.
COFFEY, Q.C.:
Q. And then you'd say if they were fine, they'd go.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And the slides would then go back to Corner Brook, for example.
DR. EJECKAM:
A. Yes.
COFFEY, Q.C.:
Q. And you understood the pathologist there was, would look at the slides and would decide the ER/PR result and report it.

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DR. EJECKAM:
A. Yes, yes.
COFFEY, Q.C.:
Q. Okay. If that patient was then subsequently referred to St. John's, to oncologists in St. John's, okay, would those slides come back into St. John's for someone like yourself or another pathologist to look at in relation to the ER/PR?
DR. EJECKAM:
A. If it's for breast, yes. They would send us all the material if we request it.
COFFEY, Q.C.:
Q. If they requested it, that's what I think the Commissioner is--who would have to request it?
DR. EJECKAM:
A. We would request it if we have a request from an oncologist to review the case.
COFFEY, Q.C.:
Q. Oh, if.
DR. EJECKAM:
A. Because the oncologist will request the pathology laboratory to review that case before commencing treatment and we cannot review the case unless we have the material,

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so ask Corner Brook to send us all the slides involved in this particular case. When they send it in, it would include the ER/PR done in our laboratory. So whoever is going to review that case will look at HME and agree with the diagnosis and look at the estrogen receptor, progesterone receptor slides and make a report.

COFFEY, Q.C.:

Q. Okay. And in any such review of an ER/PR slide from outside of St. John's, did you ever have occasion to differ with -

DR. EJECKAM:

A. How do I remember, because it wasn't done by me, it could have been done by whoever the pathologist on call for that day, so if there was any difference, I wouldn't know. But personally I didn't encounter any.

COFFEY, Q.C.:

Q. If we could, please, and I'll just, Exhibit P-0022 please? Page 16 please? This is a MAC meeting for, when we look at the top of the page here, it's March 8th, 2006 and resignation listed there is Dr. Gershon Ejeckam, resignation from the laboratory

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medicine program on April 30th, 2006, that's accurate is it, Doctor?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. Okay, and if we could, please, same exhibit, page 40 please? And, Doctor, here under laboratory medicine program, again it's the MAC minutes for June 14th, 2006. You're listed here in the laboratory medicine program, Dr. Ejeckam, temporary privileges to perform a locum under the laboratory medicine program, division of pathology, June 5th to the 21st, 2006?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Did you perform the locum here?

DR. EJECKAM:

A. Yes.

COFFEY, Q.C.:

Q. Have you performed any other locums here in Newfoundland and Labrador since you've resigned on April 30th?

DR. EJECKAM:

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A. Yeah, I had a locum done in Gander.

COFFEY, Q.C.:

Q. In Gander?

DR. EJECKAM:

A. Yeah.

COFFEY, Q.C.:

Q. And when was that, do you recall?

DR. EJECKAM:

A. Last year.

COFFEY, Q.C.:

Q. Okay, in the course of doing this locum in 2006 or the one last year which would be in '07 in Gander, did you have any involvement in the ER/PR matter?

DR. EJECKAM:

A. Well this locum was purely to ER/PR--well not only ER/PR, to hand over the immunohistochemistry to Dr. Ford Elms.

COFFEY, Q.C.:

Q. Okay, so this one here, the June -

DR. EJECKAM:

A. Yes, had meetings with them and showed him what I know and then it was he and I think Don Fontaine were appointed, who took over the immunohistochemistry. So within that period

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for interaction for them to pick up where I stopped.

COFFEY, Q.C.:

Q. And what did you attempt to do in the course of that, I take it to pass on what you knew about the issue and -

DR. EJECKAM:

A. Well we looked at slides together and trying to show them what, you know, some of the stains, what they looked like, some of the directions in terms of quality assurance, in terms of controls. So these were the things we discussed.

COFFEY, Q.C.:

Q. I take it in effect, I suppose with a person with your experience, to do actually some teaching?

DR. EJECKAM:

A. Well in a way, but I won't call it teaching, they are my colleagues, they probably know as much as I do, but I had to, you know, that have session with them for them to take over the service.

COFFEY, Q.C.:

Q. And in 2007, you said you had a locum in

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Gander, was there any involvement with ER/PR at the time?

DR. EJECKAM:

A. I think I sent out one then, of course, Gander wasn't sending anything any more, they were sending straight to Toronto, so I think I must have sent one breast to Toronto and it would be done there and results sent back to them directly.

COFFEY, Q.C.:

Q. Doctor, until June of 2007, which is when I gather you were getting contacted about it, is there anything that you can think of that, you know, you think the Commissioner should know in terms of the whole ER/PR matter that transpired before June of '07 that we haven't already covered?

DR. EJECKAM:

A. I don't remember anything that's outstanding.

COFFEY, Q.C.:

Q. No, okay, I just -

DR. EJECKAM:

A. Not that I'm aware of and I think we went through everything, everything that I -

COFFEY, Q.C.:

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Q. Sure and that's what I'm really what I'm asking about because sometimes things are not written down and people are aware of them and they just recall them.

THE COMMISSIONER:

Q. Mr. Coffey, it's about time for the afternoon break.

COFFEY, Q.C.:

Q. Madam Commissioner, those are the questions I have, Commissioner, so we'll take a break and--I want to thank you, Doctor. There will be other lawyers, I anticipate will have some questions for you, but I do want to thank you for your information you provided.

DR. EJECKAM:

A. Thank you.

THE COMMISSIONER:

Q. We'll take fifteen minutes and then proceed with cross-examination.

(RECESS)

THE COMMISSIONER:

Q. Please be seated. Mr. Pritchard?

MR. PRITCHARD:

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

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DR. EJECKAM:

A. Thank you.

THE COMMISSIONER:

Q. Mr. Simmons?

MR. SIMMONS:

Q. Thank you, Commissioner.

DR. GERSHON CHUKWUEMEKA EJECKAM, EXAMINATION BY MR. DAN SIMMONS

MR. SIMMONS:

Q. Good afternoon, Dr. Ejeckam, my name is Dan Simmons and I'm here for Eastern Health. I just have a few things I want to ask you. First concerns when you spent your 13 years in Doha as the head of the immunohistochemistry laboratory there, I had understood that you described--you'd given us some of the history of the development of immunohistochemistry over that time, that the number of antibodies increased quite a bit, would it be fair to say as well that the scientific knowledge about immunohistochemistry and how to perform the tests grew over that period of time as well?

DR. EJECKAM:

A. Yes, that would be a proper conclusion.

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MR. SIMMONS:

Q. Okay, and you've told us as well that over time that you developed a manual for use in your laboratory there in performing these tests, correct?

DR. EJECKAM:

A. Yes.

MR. SIMMONS:

Q. When you did that, were there any outside sources that you could go to to find a ready-made set of procedures or did you have to develop things on your own?

DR. EJECKAM:

A. No, we combined information from the literature -

MR. SIMMONS:

Q. Yes.

DR. EJECKAM:

A. - and work we were doing in the laboratory.

MR. SIMMONS:

Q. Yes.

DR. EJECKAM:

A. It wasn't all from our heads, there was some in the literature already.

MR. SIMMONS:

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Q. Yes, so you had to go to the literature to see what studies were there and what other information was available.
DR. EJECKAM:
A. Yes.
MR. SIMMONS:
Q. Was there any single source you could go to, like a standard setting body, such as exists in some areas of health care and medicine where you could just subscribe to a set of policies or procedures to use in your laboratory?
DR. EJECKAM:
A. By the time we did this, I wasn't aware of the textbook, "Immunohistochemistry by DABBS". DABBS is like the Bible of immunohistochemistry, an evaluation, so it wasn't available then, but you could go into the index medicals, that is the library and go to the index in the medical field and then punch in the subject and you will see a lot of articles that will help you to make up a manual that you needed for that job. And then I think CAP, College of American Pathologists, has a booklet on quality assurance in anatomic

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pathology and then we would have that booklet and there are some pertinent information that we would extract from there to put into what we are doing.
MR. SIMMONS:
Q. Right. And we've heard through the course of this inquiry and just generally in the media over the last while, here in Canada, that there isn't any set of national standards that apply to the way this testing are to be done in Canada, are you aware of that?
DR. EJECKAM:
A. Well yeah, I am aware that each laboratory-- there's no national standard, that's not information that I think I'm aware of.
MR. SIMMONS:
Q. Right, and that each laboratory has to determine how they're going to perform this testing, depending on their own circumstances and their own conditions?
DR. EJECKAM:
A. Do you mean doing immunohistochemistry or doing -
MR. SIMMONS:
Q. Yes.

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DR. EJECKAM:
A. - particularly ER/PR?
MR. SIMMONS:
Q. Well immunohistochemistry generally?
DR. EJECKAM:
A. No, immunohistochemistry work has a standard of procedure, it's an antigen/antibody reaction.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:
A. Now whether you use three steps, four steps to visualize it is what a laboratory has to decide.
MR. SIMMONS:
Q. Right.
DR. EJECKAM:
A. Some people do direct staining where you couple the antibodies to the dye that would show what you did; some people put them separately, but at the end, you are getting to the same result. You either put your primary antibody, secondary antibody, then anti-peroxidase that will cut that antibody, then the DAB to make you visualize it, some other

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people's views already prepared, DAB attaches to the present antibody, but at the end, the procedure is basically the same.
MR. SIMMONS:
Q. So the basic procedure is the same, but there are variations that laboratories can choose as to how they perform the different steps of the procedure, are there?
DR. EJECKAM:
A. Well what you choose is different retirement times.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:
A. However, when you look at some nuclear antigens may require longer retirement times, so a laboratory may choose to use ten minutes and choose to do 12 minutes.
MR. SIMMONS:
Q. Right.
DR. EJECKAM:
A. Now as long as they are able to convince themselves that those times they have chosen will give them a proper result, then that's it, but it's not a big variation here. It's a

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question of the titration and is probably going to be good from ten to fifteen and some Americans say, okay, I do it ten, some will say I do it at twelve, some will say fifteen, but I don't see a big variation there.

MR. SIMMONS:

Q. Okay, so it's not a big variation in the way different laboratories will choose to do it, but is there any single set of standards or place that we can go to that sets out what the appropriate range of antigen retrieval times is, for example, aside from textbooks, is there anything that's been adopted by the profession in Canada?

DR. EJECKAM:

A. I'm not aware of any.

MR. SIMMONS:

Q. Okay.

DR. EJECKAM:

A. There may be, I'm not aware of it.

MR. SIMMONS:

Q. Okay, when you were in Doha, were you aware of anything equivalent to that that was available to you in Doha?

DR. EJECKAM:

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A. No, no.

MR. SIMMONS:

Q. Now I believe you said that when you came here to St. John's in 2002, although there wasn't a laboratory manual for immunohistochemistry, such as you had developed in Doha, I understood you to say that the technologists did have their procedures that they followed, is that correct?

DR. EJECKAM:

A. Yes.

MR. SIMMONS:

Q. And were those in writing?

DR. EJECKAM:

A. I can't recall that.

MR. SIMMONS:

Q. Okay. You were asked some questions about positivity rates for ER/PR.

DR. EJECKAM:

A. Yes.

MR. SIMMONS:

Q. And what you did when you were in Doha, because one of the things we've discussed here at this inquiry is that there is some literature available that suggests a range of

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positivity rates to say that, for example, maybe 75 percent of the ER tests that are done in the course of a year should turn out to be positive and 25 percent should turn out to be negative. There's different percentages that show up in the literature at different times. When you were in Doha, was there any process in place in your laboratory to track the rate of positivity of ER tests and PR tests in a kind of a deliberate way?

DR. EJECKAM:

A. No.

MR. SIMMONS:

Q. In the spring of 2003, you've told us how you suspended testing for eight antibodies, including ER and PR in April of 2003 and you've told us that what you did then with ER and PR antibodies was to adjust the antigen retrieval times and to adjust the titration of the antibodies until you were satisfied that you were getting the optimum results from the staining process, have I got that basically right?

DR. EJECKAM:

A. Yes.

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MR. SIMMONS:

Q. Can you tell me a little bit more about what the antigen retrieval method was that was in use then when you did that, in the laboratory here?

DR. EJECKAM:

A. I believe it was DAKO, they were using pressure cooker or something like that. I can't be a hundred percent sure about it, but I didn't do it myself.

MR. SIMMONS:

Q. Right.

DR. EJECKAM:

A. All I did was advise the technologists to try certain timing and I would look at the slides.

MR. SIMMONS:

Q. The DAKO machine that was in use has been described to us as semi-automated?

DR. EJECKAM:

A. Yes.

MR. SIMMONS:

Q. And would you have understood that the antigen retrieval step is not part of the automated procedure, that was a manual procedure that still had to be performed by the technologist?

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DR. EJECKAM:
A. That's my understanding, yes.
MR. SIMMONS:
Q. And one way or another, it involved boiling the slides in a solution for a period of time?
DR. EJECKAM:
A. Yes.
MR. SIMMONS:
Q. Yes, okay, and what you were doing by adjusting that was trying different variations of the length of time during which the slides were boiled in that solution, was it?
DR. EJECKAM:
A. Yes.
MR. SIMMONS:
Q. Okay, and when you have referred to adjusting the titration of the antibody, what I understand is that the antibodies come in a bottle, as a liquid, and they're in concentrated form?
DR. EJECKAM:
A. Yes.
MR. SIMMONS:
Q. And in order to do the test, that concentrate has to be diluted in another solution and what

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you did was tried different variations of dilutions of that antibody in order to optimize the result of the test?
DR. EJECKAM:
A. Yes, and some of them would come in diluted, so you don't need to dilute them, but those that weren't diluted, you then have to titrate it and determine for yourself which of the dilutions, one in 20, one in 50, one in 100, that would give you the best result.
MR. SIMMONS:
Q. Yes, okay, and so the dilution of the antibody was another part of the manual process that wasn't in any way automated in the DAKO system?
DR. EJECKAM:
A. Yeah.
MR. SIMMONS:
Q. In the DAKO technology.
DR. EJECKAM:
A. It was manually done.
MR. SIMMONS:
Q. Right. So if we look at performing the test over a period of time, variations in the antigen retrieval and in the dilution of the

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antibodies are something that can occur because it's something people have to do and they have to try to do time and again the same way each time?
DR. EJECKAM:
A. Yes, possible.
MR. SIMMONS:
Q. Okay. Now when the Ventana machine was put in use, am I correct in understanding that the antigen retrieval step now became part of the automated process?
DR. EJECKAM:
A. That's my understanding of Ventana, yes.
MR. SIMMONS:
Q. Yes, and that in the Ventana machine, the slide, instead of being immersed in a boiling liquid, actually sits on a metal plate which is heated and the temperature and the length of time at which it's heated is controlled by the machine. Did you understand that?
DR. EJECKAM:
A. The temperature is controlled, programmed.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:

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A. Whether it was sitting or left, the position of the slide, I don't know.
MR. SIMMONS:
Q. Okay. Yes, and I may be wrong on that too, but in any event, with the Ventana machinery, the length of time at which the slide is heated and the temperature at which it's heated is now controlled as part of the automated process?
DR. EJECKAM:
A. Yes.
MR. SIMMONS:
Q. So would that have removed an element of the human intervention and removed some risk of variation from the process?
DR. EJECKAM:
A. Well, I think you have to program--you have to program the time.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:
A. The time in there is not static for every antibody.
MR. SIMMONS:
Q. Right.

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DR. EJECKAM:
A. So I think the antibodies we're purchasing, I believe, had the antibody--antigen retrieval time.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:
A. So you have to cue that in, and you don't change it for that particular antigen that you're looking for.
MR. SIMMONS:
Q. Right. So once you set the time though in the machine, assuming the machine is going to work properly, every time you run a test, if you set the time for ten minutes, it should be ten minutes each time?
DR. EJECKAM:
A. Yes, yes, that's true.
MR. SIMMONS:
Q. Without variation from run to run?
DR. EJECKAM:
A. Yes, that's true.
MR. SIMMONS:
Q. Okay.
DR. EJECKAM:

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A. That is for that particular antigen, because if it's nuclear antigen, the retrieval time is supposed to be a little bit longer than cytoplasmic or membranous antigen. So you have to know what antigen that you're looking for.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:
A. ER/PR are both nuclear antigen. It takes a little bit longer in retrieval than let's say something like leukocyte common antigen, which is membrane, not stain.
MR. SIMMONS:
Q. Okay, and with the Ventana system, did you know whether or not the antibodies now were going to be provided pre-diluted rather than in concentrated form?
DR. EJECKAM:
A. My understanding, I remember when I was asking the techs to dilute, I think the primary antibody, I was informed, I think, that it came in diluted. So you couldn't dilute it any further.
MR. SIMMONS:

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Q. Yes.
DR. EJECKAM:
A. You have to use it the way as is.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:
A. But I believe that the secondary antibody could be diluted, if I--I may be wrong here, but this is a technical thing that they did, you know, and I looked at the slides.
MR. SIMMONS:
Q. So by having a pre-diluted antibody for the primary antibody, would that also remove some manual intervention from the process -
DR. EJECKAM:
A. Yes, yes.
MR. SIMMONS:
Q. - in that the technologists no longer had to precisely dilute the antibody each time there was a separate run?
DR. EJECKAM:
A. Yes.
MR. SIMMONS:
Q. Okay. One of the things you said earlier today was that at one point along the way,

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there was a decision made to order the ER/PR tests on all breast cancer cases that came in. I think you were referred to a document and told us about that. We've heard some reference to something we've been calling DCIS or ductal carcinoma in situ. Would there be ER/PR tests ordered for those type of cases?
DR. EJECKAM:
A. Some pathologists will argue there's just no need for it.
MR. SIMMONS:
Q. Yes.
DR. EJECKAM:
A. Others will want to do it. So it's a question of where you are and what kind of practice that you--your own school of thought.
MR. SIMMONS:
Q. Okay. The last thing I want to ask you about is when slides are prepared for the ER test and the PR test, one of the last steps in the process is for the pathologist to review the slide under the microscope and to make a determination of what the percentage of positivity is, staining positivity, and there's obviously a subjective element in

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that.

DR. EJECKAM:

A. Yes.

MR. SIMMONS:

Q. In this area, is there known to be any interim server variability or any variability among pathologists which is accepted as being a variation that occurs in how different pathologists might read the same slide?

DR. EJECKAM:

A. Yes. I mean, it is subjective. I could read it to be 50 percent and maybe I would say 55 or 60 percent. That's still acceptable. So there's variability there.

MR. SIMMONS:

Q. Right. So even if you had two slides prepared with exactly the same technical process, if they went to two different pathologists to be read at two different times, you could still have some variation in the results?

DR. EJECKAM:

A. Yes, yes.

MR. SIMMONS:

Q. Yes, okay. Thank you very much, Dr. Ejeckam, I don't have anything else for you.

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DR. EJECKAM:

A. Thank you.

THE COMMISSIONER:

Q. Thank you, Mr. Simmons. Ms. O'Dea?

MS. O'DEA:

Q. We have no questions, Commissioner.

THE COMMISSIONER:

Q. Ms. Newbury?

MS. NEWBURY:

Q. I don't have any questions.

THE COMMISSIONER:

Q. Mr. Crosbie?

DR. GERSHON EJECKAM, EXAMINATION BY CHESLEY CROSBIE, Q.C.

CROSBIE, Q.C.:

Q. Thank you, Dr. Ejeckam. I had an opportunity to introduce myself a little earlier when you first took the stand and I represent the members of the Breast Cancer Testing Class Action. So thank you for your long journey here to give evidence.

I'd first like you to address something that Mr. Simmons was just asking you about actually a few minutes ago, which is the antigen retrieval stage of the process, and would it be fair to say that this is

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identified in the literature as being an area of trouble and possibly an area that can produce erratic results, the antigen retrieval stage?

DR. EJECKAM:

A. I wouldn't characterize it that way. Antigen retrieval has been described as the one most important procedure in antigen antibody stain, but not an area of problem. If it's properly done, especially if it's computerized--if it's automated, there shouldn't be any problem there.

CROSBIE, Q.C.:

Q. If it's properly done, which of course would -

DR. EJECKAM:

A. Unless it is automated. You have an automated machine, and then you time it, then it should be one of the most important, because let me explain a little bit. With fixation problem was a problem initially and a lot of things in the literature about poor fixation, over fixation, that we keep saying. Now it's been shown that if you have proper antigen retrieval, then you override any kind of problem with fixation. So it is the most, one

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most important step that needs to be taken before the antigen antibody reaction takes place. But, and that is why, I think, there's improvement in the methodology where instead of doing manual boiling or microwave heating, it moved on to automation. So that you can now decide that you're going to be ten minutes for this antigen and then program it and it will take ten minutes.

CROSBIE, Q.C.:

Q. Just to take things one step at a time, sir, when you were questioned by Mr. Coffey, I understand you to explain that the formalin fixation binds the estrogen and progesterone receptors together and this therefore masks the receptor sites.

DR. EJECKAM:

A. Formalin fixation could mask receptor sites.

CROSBIE, Q.C.:

Q. And these receptor sites are antigens because you are using an antibody to attach to the antigens, right?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

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Q. This is in elementary terms now, and this is the process that we refer to as antigen retrieval?
DR. EJECKAM:
A. No.
CROSBIE, Q.C.:
Q. Could you explain that?
DR. EJECKAM:
A. Antigen retrieval is when--well, you know, fixation will mask the antigens and then you don't react it with antibody until you've done antigen retrieval. So what you do is either we boil it or put it in a microwave so that the heat effect will now rearrange the protein. When you fix tissue, the proteins are sort of bound and then that binding of proteins in the cell may mask the sites of antigenic activity. But when you heat it in a certain solution, it has been shown--used trial and error before they arrived at this--that this heating, antigen retrieval heat-induced will now rearrange the protein in a way that those sites are now exposed. Then when you finish that, the next thing then is to add the antibody which will now go and

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attach to those exposed sites.
CROSBIE, Q.C.:
Q. You mentioned, I guess, there are methods, several different methods that could be used for accomplishing the unmasking?
DR. EJECKAM:
A. Yes.
CROSBIE, Q.C.:
Q. Trypsin is one that's been used?
DR. EJECKAM:
A. We don't--well, trypsin, yeah, trypsin was used back sometime ago when we were doing mainly immunoflourescent and I think Professor Kwan, who was chairman at Memorial, worked on this. In fact, he published a lot on this. You can use trypsin to digest the tissue and they make more antigens available. But for immunohistochemistry nowadays, I'm not aware that we're using trypsin at all.
CROSBIE, Q.C.:
Q. And it was not being used then when you intervened in 2003?
DR. EJECKAM:
A. No, we were not using trypsin.
CROSBIE, Q.C.:

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Q. You can use heat; you can use microwave ovens, water baths and maybe variations beyond that?
DR. EJECKAM:
A. We used microwave or heating in a pressured environment. I'm not aware of a water bath method. I'm not aware that we ever used that.
CROSBIE, Q.C.:
Q. So what exactly were they doing when you intervened in the lab in 2003? Which of these methods were they using again?
DR. EJECKAM:
A. I think they were boiling them.
CROSBIE, Q.C.:
Q. And you say this would be--so is that a water bath method?
DR. EJECKAM:
A. No, not water bath. Well, if you water bath--what I'm saying, we have water bath in histopathology, it's a floatation water bath which is just at 42 degrees. We use it for when you cut section to lay out the section. That's different.
CROSBIE, Q.C.:
Q. Yes.
DR. EJECKAM:

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A. But when you talk about heating under like using a pressure cooker is--it's not a water bath by name, unless that's what they called it, but we won't call it water bath. You heat it under pressure, vacuum pressure at times, or you use microwave to be able to mask the sites.
CROSBIE, Q.C.:
Q. So the--I think you referred to it as a boiling method?
DR. EJECKAM:
A. Yeah, well basically.
CROSBIE, Q.C.:
Q. Basically. This is under pressure, is it?
DR. EJECKAM:
A. Yeah.
CROSBIE, Q.C.:
Q. So this is a heat under pressure method?
DR. EJECKAM:
A. Yes.
CROSBIE, Q.C.:
Q. Is that technically how you'd describe it?
DR. EJECKAM:
A. I would describe it as heating under pressure, you know, pressure cooker. So I mean, we use

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pressure cooker to do this and pressure cooker, my impression that is whatever is being boiled is under pressure.

CROSBIE, Q.C.:

Q. Did you personally actually observe the method being used by the techs -

DR. EJECKAM:

A. No.

CROSBIE, Q.C.:

Q. - at the time of your intervention?

DR. EJECKAM:

A. No.

CROSBIE, Q.C.:

Q. So when you'd give us that description of what they were doing, what's the basis for you to say that?

DR. EJECKAM:

A. That is a standard and I understand they were doing, and I did ask them what method. I know they don't have microwave at that time. They were--I wasn't aware they were using microwave in the laboratory.

CROSBIE, Q.C.:

Q. So, I'm sorry, I'm not clear. Did you say you asked them what they were doing in this

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connection?

DR. EJECKAM:

A. I don't remember going to say "what are you using for heat? What are you using for that?" What I remember that they would tell me they were--during this discussion, that they are doing boil--kind of the retrieval is by heating, and I know they didn't have microwave at that time.

CROSBIE, Q.C.:

Q. Okay, you know that much, all right. So you assumed they--you assumed they were using a method of pressure heating?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. And you said boiling?

DR. EJECKAM:

A. Pardon?

CROSBIE, Q.C.:

Q. Pressure heating/boiling, I think you used the word?

DR. EJECKAM:

A. Yes, yes.

CROSBIE, Q.C.:

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Q. So you're constructing what was going on rather than speaking to your actual observation of what exactly the techs were actually doing?

DR. EJECKAM:

A. What the techs did were technical work that I didn't have anything to do with.

CROSBIE, Q.C.:

Q. Sure.

DR. EJECKAM:

A. And I'm not supposed to actually do it. So what they did was their job.

CROSBIE, Q.C.:

Q. Yes.

DR. EJECKAM:

A. And produced material for me to evaluate.

CROSBIE, Q.C.:

Q. Okay. Are there potential weaknesses in the system that you described of applying heat or that you understood that they were using?

DR. EJECKAM:

A. The potential problem would be if one was to boil it for ten minutes and boil it for six minutes or if you're going to boil it for ten minutes and did it for less, then you are now

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not using what you can are the optimum time in for it. That's what I see as the possible potential danger there. That's why automation has removed that manual step.

CROSBIE, Q.C.:

Q. I think you described--again, you have to forgive me if it's a--you'll no doubt appreciate that it's somewhat technical for, well, everyone in the room except yourself, I guess, or maybe one or two observers, but I understood you to explain that when you were doing your troubleshooting--and is that a reasonable description of what your assignment was, troubleshooting?

DR. EJECKAM:

A. Yeah, in a way, yes.

CROSBIE, Q.C.:

Q. When you were doing your troubleshooting, you experimented with various numbers of minutes, five, ten, I don't know, eight, six, whatever.

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. Trying to refine the length of time that was optimal for getting the result you wanted in

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relation to crisp, getting a crisp staining in a positive control. Is that -

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. - a fair summary?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. A control meaning something which is a known quantity which ought to behave in an expected manner. You know how it's going to behave if it's dealt with appropriately.

DR. EJECKAM:

A. Control for me in this situation is a tissue that possesses the antigen that I'm staining for, and that if I do the stain, it should be positive. That's what I call a positive control.

CROSBIE, Q.C.:

Q. And as we've just seen, in 2003, in the circumstances at hand, this was a manual technique?

DR. EJECKAM:

A. Yeah, it was semi-automated.

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CROSBIE, Q.C.:

Q. And we've just heard from you that the Ventana machine has taken the manual human element out of this and now does that part of the process automatically?

DR. EJECKAM:

A. The antigen retrieval, I believe, is incorporated in the new machine, the Ventana machine. So all they needed to do, I believe--I didn't do it myself, but what they needed to do would be to cue in the number of minutes they wanted antigen retrieval to take place.

CROSBIE, Q.C.:

Q. Indeed, and that's what I understand. A manual technique, if not performed properly, can lead to false negatives, particularly if the receptors are not plentiful in the tissue?

DR. EJECKAM:

A. Can you say that again, please?

CROSBIE, Q.C.:

Q. A manual technique -

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. - if it's not done in an appropriate manner, can lead to a false negative, particularly if you have few receptors in the tissue you're looking at?

DR. EJECKAM:

A. It's possible. It is possible.

CROSBIE, Q.C.:

Q. And I was going to suggest to you that literature identifies antigen retrieval as a common source of false negatives.

DR. EJECKAM:

A. I don't know which literature that is, but as far as I can tell, antigen retrieval, done properly, is a good--very important step and factor in getting appropriate result.

CROSBIE, Q.C.:

Q. I'd like to talk for a moment now about antibody strengths and concentrations. So if you don't use the proper concentration of antibody, this can also lead to false negatives? Is that correct?

DR. EJECKAM:

A. It is possible.

CROSBIE, Q.C.:

Q. Can you just explain to the Commission how you--what is the process by which you reach optimal concentration of antibodies so that you can achieve good, crisp staining?

DR. EJECKAM:

A. What we did, Commissioner, is that first of all I will discuss with the technologist what dilution that they are using. And I don't remember the figures off head now, but they would tell me, for instance, primary antibody, if it is it be diluted, is one in 100 or one in 50. Then what we will do if we were having problem with that particular stain is to now say let us try one in 20, one in 30, one in 50, one in 70 or one in 100. So we'll now cover, below and above that recommended or whatever that they were using. Then when we run this test, we then examine this and see which of these dilutions with the antigen retrieval and the whole test completed, that has given the best stain, what I call the best stain. Immunohistochemistry we talk about the noise and signal. The signal here is what we are looking for the antigen, antibody reaction. The noise is the background stain, what has no background as possible. And if the background is clean and no background

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staining and then the antigen we are looking for is there and stains, then that will then compare against subjective. Now to say one in 60 is better than one in 70, we'll now say, okay, that's what we're going to be using as dilution for that particular antibody.

CROSBIE, Q.C.:

Q. So I guess you described a process of experimentation against a known positive control to arrive at the ideal solution?

DR. EJECKAM:

A. Yes, that's what is done in titration of antibodies, that's what should be done for even new antibodies purchased before you put them in the system.

CROSBIE, Q.C.:

Q. Sir, you've told us that you yourself use as a reference the DABBS textbook, Diagnostic Immunohistochemistry?

DR. EJECKAM:

A. Yeah, I use that.

CROSBIE, Q.C.:

Q. Yes. Mr. Pike just joked with me a moment ago that he had a pile of, what is it, Dummies Guides to Leadership -

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MR. PIKE:

Q. (Inaudible).

CROSBIE, Q.C.:

Q. He couldn't find one on diagnostic immunohistochemistry, so I had to go directly to the source. So this, of course, you would recognize?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. As the DABBS textbook?

DR. EJECKAM:

A. Yeah, yeah.

CROSBIE, Q.C.:

Q. And what I've placed in front of the witness is the 2002 edition. And there's a copy of the few pages I was to refer to at Exhibit 1569. Perhaps you could bring that up?

REGISTRAR:

Q. We have a request for it has to be entered.

CROSBIE, Q.C.:

Q. Oh, okay.

REGISTRAR:

Q. That wasn't entered yet, Mr. Crosbie.

CROSBIE, Q.C.:

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Q. Yes.

COMMISSIONER:

Q. And what was the number again, please, Mr. Crosbie?

CROSBIE, Q.C.:

Q. P-1569, it's an excerpt from this textbook.

COMMISSIONER:

Q. 1569, all right. Enter than.

EXHIBIT ENTERED AND MARKED P-1569.

CROSBIE, Q.C.:

Q. And on the second page you can see that it's copyright 2002? It's toward the bottom of the page.

DR. EJECKAM:

A. Yeah.

CROSBIE, Q.C.:

Q. It's one of these multiple author textbooks. And we haven't copied it, but actually if you look on the inside of the cover, coincidentally, I think you'll see there's a date stamp by the library at the medical school as to when they received that copy.

DR. EJECKAM:

A. 2003.

CROSBIE, Q.C.:

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Q. What date exactly?

DR. EJECKAM:

A. "Health Sciences Library, 2003, March 21."

CROSBIE, Q.C.:

Q. March 21. So I guess we could say that this textbook was actually available in the library at the time you were intervening and suspending the processes that were concerned with IHC in early 2003?

DR. EJECKAM:

A. Well, if that's the date they have there, then it obviously must have been there.

CROSBIE, Q.C.:

Q. It seems that it was.

DR. EJECKAM:

A. Pardon?

CROSBIE, Q.C.:

Q. It seems that it was there, right?

DR. EJECKAM:

A. Yeah, all I'm saying, if that's the date on the book.

CROSBIE, Q.C.:

Q. Yes.

DR. EJECKAM:

A. That means they date stamp it, so I assume if

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they stamped it, then that must have been there by 2003, March.

CROSBIE, Q.C.:

Q. It seems pretty logical. Can you turn to or can we turn to on the screen page 17? And there's a paragraph there about quality control, that's the third page in, it's page 3 of the exhibit. As defined by the College of American Pathologists and they appear, to my mind, as a lay reader of this, to distinguish here between quality control and quality assurance. And it seems the quality assurance is a larger more inclusive concept and quality control is somewhat more specific. And I'm not going to sort of drone through the entire paragraph, but almost--but the paragraph down to the final sentence which starts in this section is basically DABBS and Company's definition of quality control. And I'm going to let you take your time and read that.

DR. EJECKAM:

A. The first sentence on quality controls in it.

CROSBIE, Q.C.:

Q. I'm sorry?

DR. EJECKAM:

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A. I just want to be sure where you're -

CROSBIE, Q.C.:

Q. It begins, "Quality control as defined by the College" -

DR. EJECKAM:

A. "As defined by"--yeah, okay, I see that.

CROSBIE, Q.C.:

Q. And then it ends, "Daily records of control results are maintained and corrective actions are undertaken and documented when results are unacceptable."

DR. EJECKAM:

A. I need to see a better way to read it now. I want to know exactly where you are, sir.

COMMISSIONER:

Q. If you'd prefer to look at the paper copy, if it's easier to read.

DR. EJECKAM:

A. What page?

CROSBIE, Q.C.:

Q. Page 17, sir.

COMMISSIONER:

Q. Page 17.

DR. EJECKAM:

A. Okay.

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COMMISSIONER:

Q. It may be easier that way.

DR. EJECKAM:

A. Okay, I read it.

CROSBIE, Q.C.:

Q. Thank you. As a general statement does it appear to be a reasonable statement about quality control in this context?

DR. EJECKAM:

A. I think so.

CROSBIE, Q.C.:

Q. And it says "Specifically, as it pertains to IHC quality control standards address and define each step of the total IHC test, including tissue procurement, fixation, processing, sectioning, staining and finally the interpretation and reporting of the staining results." It goes on, "As part of a laboratory's quality control program, all steps of the test are described separately and parameters of each step are established and monitored in order to ensure consistency of performance and reproducibility of results." Where he's saying there "As part of a laboratory's quality control program all steps

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of the test are described separately," is that basically the operations manual that we've heard reference to?

DR. EJECKAM:

A. Yes, all these, these steps would appear in the operationing manual for the immunohistochemistry.

CROSBIE, Q.C.:

Q. Did I understand you to suggest a little earlier this afternoon that a knowledgable person could derive from the DABBS textbook itself enough information to put together, together with, perhaps, manufacturer's literature, depending on what machinery they're using, an operations manual?

DR. EJECKAM:

A. It's not what I said. I said that you'll get information from the index medicals, there are several articles published, that and including information from a textbook like, DABBS, will enable you and not just anybody, you have to be a pathologist or a technologist who is dealing with the immunohistochemistry, will enable you to write a manual. And I did mention too that we have manual from College

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of American Pathologists dealing with anatomic pathology and some of the information there were taken to formulate the manual.

CROSBIE, Q.C.:

Q. Well, thanks for correcting that. So the DABBS text in front of you, together with other published sources and sources available from pathologic organizations?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. Could be accessed to put together an operating manual for any given lab for doing IHC?

DR. EJECKAM:

A. Yes, I believe so.

CROSBIE, Q.C.:

Q. And you told us, as well, that you offered or, in fact, gave a copy, I think, was it, of your own operating manual from your hospital in the Middle East to the site chief?

DR. EJECKAM:

A. What I gave was my manual for anatomic pathology, not for IHC. So you have the manual for doing anatomic pathology with ordinary processing; we have manual for IHC.

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I didn't give them IHC manual. What I give to Dr. Parai, the site chief, was manual for anatomic pathology which the general processing and producing of slides and everything that goes with it, that's what I give him.

CROSBIE, Q.C.:

Q. Would that be of assistance to him and others in putting together the operations manual for doing IHC?

DR. EJECKAM:

A. It could be because I have said that information there, a block is a block, tissue is tissue, procurement of a tissue before IHC will be the same procurement for anatomic pathology. So that might help up to a point, but they needed to look at immunohistochemistry material before it could be completed.

CROSBIE, Q.C.:

Q. Is the operations manual something that you would expect each lab to do an original work product for? In other words, I'm trying to think of this in terms of labs would have variations in the equipment they use, in the

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antibodies they use, in how they optimize various aspects of the procedure and this being a sensitive sort of procedure might well vary from one lab to another, so what you'd expect the lab to do is to put together its own original work product of -

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. Long question with a simple answer. So it's not a matter of just calling Doha and saying courier over a copy of our own manual, that would be of limited use, perhaps, to another lab. They should really do the work themselves to put together and document their own processes which are optimal for them, is that the idea?

DR. EJECKAM:

A. The idea is that you don't want to invent the wheel. If somebody has a manual that has been prepared, it could assist you preparing yours. And no one is suggesting that you just lift the manual from Lab A and drop it on Lab B and use that same manual. But if you--a lot of preambles and preliminaries you have to write

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in a manual, you could use a manual that has already been prepared as a help to you. But you needed to sit down and do your own because the machine may be different, the materials may be different, so you cannot superimpose one on the other. But if you have already prepared manual, you can even see the format, you can see the format, that could help you if you didn't know what to do from the beginning; the format would be a help.

CROSBIE, Q.C.:

Q. Is there any question that a lab should have such a manual?

DR. EJECKAM:

A. A laboratory should have a manual. That's a standard thing. But a number of laboratories may not have this, they may have what I call cardex where the procedure for each test, the techs will write them on a small cardex and file them. Now, the problem with that sometimes may get lost or a new person comes, he doesn't know where to find them. That's why laboratories are encouraged to prepare manual, bind them so a new person comes, you hand over this manual, the person can go

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through it and see what is there and what is going on.

CROSBIE, Q.C.:

Q. In 2003, to your knowledge, was our lab using a cardex system?

DR. EJECKAM:

A. I know they have where they do methodology on a kind of cardex system. I didn't see any manual when I arrived.

CROSBIE, Q.C.:

Q. Excuse me, I just want to be clear about that. Were they following a cardex system as you've just described it?

DR. EJECKAM:

A. They were following a system where they wrote down their methodologies on paper or cardex or whatever you call it, they would choose to call it. But I describe it was a cardex system where it's not a booklet, it's not a bound manual, but you have the methods written out in small cardex and filed, so that if you want to do Test A, you go there and pick it and see the method there.

CROSBIE, Q.C.:

Q. I see. So are you telling us as a fact that

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that was the system for documentation?

DR. EJECKAM:

A. That's my understanding of the system because I didn't see any manual when I came, so that was my understanding. And I would go into the lab and talk about writing on a piece of paper, of small paper that, you know, this may--you know, have to keep them carefully. But I do know that when you look at their shelf they have where they file the methods they are using for their staining.

CROSBIE, Q.C.:

Q. They did have places where they filed away their methods?

DR. EJECKAM:

A. Yes, yes, I believe that, yes.

CROSBIE, Q.C.:

Q. You believe that, but did you observe that personally?

DR. EJECKAM:

A. When I--yeah, I saw those.

CROSBIE, Q.C.:

Q. You did?

DR. EJECKAM:

A. Yes.

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CROSBIE, Q.C.:

Q. Because I haven't seen any of this. I've looked through a lot of materials here, and maybe I missed it, but that's something we're going to have perhaps have a look for. In any event, you thought that having a manual was a superior way to do it?

DR. EJECKAM:

A. Well, it's a better way to keep records.

CROSBIE, Q.C.:

Q. Okay. Can we go to Exhibit P-1604? And I think Mr. Coffey entered this earlier this afternoon. And if we look at those present at this meeting, sir, it's said to be a meeting, in handwriting here, regarding update on implementation of ER/PR, February 8th, 2006. Present, D. Cook and then next is listed yourself. I believe that's your name, Dr. Ejeckam?

DR. EJECKAM:

A. Yeah.

CROSBIE, Q.C.:

Q. You agree? And if we look at the first paragraph, Mr. Coffey looked at other paragraphs, I am taking from this that the two

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persons mentioned, I think, Ken Green and it may be Mary Young, I'm not sure, but these would--irrespective of the names, that doesn't matter so much, they would appear to be technical people who had been sent away for training?

DR. EJECKAM:

A. Yeah, Ken went to Montreal.

CROSBIE, Q.C.:

Q. Yeah. It says Montreal Jewish General?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. Ken, yes, it would seem, and the other person went to Mount Sinai. And Ken brought back information for--or from Montreal on types of antibodies used and problems, is that how you'd read that?

DR. EJECKAM:

A. I think "protocoled."

CROSBIE, Q.C.:

Q. "And protocoled" sorry. Mary brought back or brought forth issue on QA. She brought back document on PAs. What would PA stand for?

DR. EJECKAM:

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A. Maybe pathologist assistant.
CROSBIE, Q.C.:
Q. I think it's probably something else, but it may come to us. "And fixation protocols. Mary was not allowed to bring back documents on immunoperoxidase protocols from Mount Sinai. Both agreed on the need for documentation of activities in the lab and the establishment of manuals." And we've just seen, I think, that you fully endorse that?
DR. EJECKAM:
A. Yeah.
CROSBIE, Q.C.:
Q. But it's also, I guess, of some slight interest to note that Mount Sinai didn't want to just give out some of their protocols for people to bring back to this institution.
DR. EJECKAM:
A. I remember Mary did say they refused to let her take their manual.
CROSBIE, Q.C.:
Q. And that's what's written here. Sir, if you go to page 2 of that, if I could ask the Registrar to go to page 2? This follows on as part of the same exhibit, although it's not

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perhaps totally on topic to what we have just been talking about, but it's a note of March 6th, 2006. And I make it that this would be handwriting of Dr. Cook. Are you able to say whether that's so or not?
DR. EJECKAM:
A. No, I cannot.
CROSBIE, Q.C.:
Q. Well, maybe.
DR. EJECKAM:
A. Maybe, yes.
CROSBIE, Q.C.:
Q. We'll find out in due course. So here it says, "Spoke to Dr. Nabbibi" (phonetic), is that the way to pronounce that, Nagihiby?
DR. EJECKAM:
A. Probably.
CROSBIE, Q.C.:
Q. Yes. "B.B. Nagihiby about why Clarenville discontinued ER/PR slides," I think the words is. "Dr. Nagihiby replied, 'this was due to poor quality and to lack of external controls' plus the fact they were paying for this." I guess that adds insult to injury. Were you aware of the situation with Clarenville?

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DR. EJECKAM:
A. No.
CROSBIE, Q.C.:
Q. You weren't aware of the situation with Clarenville in 2003?
DR. EJECKAM:
A. No.
CROSBIE, Q.C.:
Q. Or even in 2006?
DR. EJECKAM:
A. Clarenville in particular, no, I was not--I'm not aware of any problem that they have, in particular.
CROSBIE, Q.C.
Q. Were you aware that there were surgeons who, from before the year 2000, had insisted that all of their specimens be sent out of province for reading, their tumor specimens or suspected tumor specimens?
DR. EJECKAM:
A. I'm not aware of that. I came in 2002 and I'm not aware that the surgeons would want the pathologists to read their cases.
CROSBIE, Q.C.
Q. When it was discussed, you told us about

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yesterday, at a meeting of pathologists, if I understood this correctly, that basically it would be a good idea and you either volunteered or it was thought that you had the necessary skill, knowledge and background to be, as Dr. Cook later refers to you, our point man to go in and tidy a few things up about IHC. Was that a discussion solely amongst pathologists or was there any input from, for example, oncologists?
DR. EJECKAM:
A. No, I didn't see any oncologists on this issue. They didn't know me and there was no way for them to contribute to this discussion unless somebody told them. I'm not aware of any oncologists on board with the decision.
CROSBIE, Q.C.
Q. I realize you are here for a relatively number of years, sir. Did you pick up from oncologists, during your stay at the Health Sciences more recently, any sense of dissatisfaction with the quality of the IHC service or any other aspect of quality in the lab?
DR. EJECKAM:

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A. I'm not aware of any of the oncologists, they didn't tell me about any poor quality work that was coming from the laboratory. I'm not aware of that. They usually--well, the laboratory has tumor board, we have the oncologists and the pathologists and other clinicians will have meetings and I attended a couple of times and I didn't hear about poor job by the lab. We have lymphoma rounds, sometimes the pathologist--not only lymphoma hematology rounds where the tumor, hematological tumor would be discussed and I didn't hear of anything like that. If they existed, it didn't come to my notice.

CROSBIE, Q.C.

Q. Registrar, could you bring up P-0554? This document is dated August 8th, '05 and we've had it described for us and Mr. Tilley has been asked about it and identified this -

THE COMMISSIONER:

Q. (Inaudible).

CROSBIE, Q.C.

Q. I'm corrected that it's August 8--or 5.

THE COMMISSIONER:

Q. You said 8.

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CROSBIE, Q.C.

Q. Okay. I'll give it to you, Mr. Coffey, I'm not going to argue over that.

COFFEY, Q.C.

Q. Mr. Crosbie, this is the meeting of August 5 because Ottenheimer, Abbott, Hennessey and Stephanie were there, I take it Mr. Pritchard is, in fact, indicating that's his understanding.

CROSBIE, Q.C.

Q. Okay. I don't want to distort anybody's chronology, but the date is not of such great interest to me right at the moment, as if you go about two-thirds or three quarters of the way down the page, you'll see the word "boiling". Can you see that word there?

DR. EJECKAM:

A. Yeah, yes, I see it.

CROSBIE, Q.C.

Q. There it is, the cursor is by the word there "boiling", so Mr. Tilley's understanding was that the process involved boiling of tissue samples. And we could see this in various places in the documentation, but for example, if we go to P-1469, page two, these are

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briefing notes and it represents what the Department of Health was being told about the problems of the time. We go over to page two under the work "background" first bullet, "prior to April 2004 DAKO testing technique was used at Eastern Health's laboratories which required the manual boiling of tissue samples" and so there's the reference to boiling again. And the next exhibit, I believe Mr. Coffey entered this as 1605. Perhaps I should explain the providence of the document to you, Doctor. I mentioned before that I'm counsel to members of a certain class action.

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.

Q. And in the process of that, a bit more than a year ago we asked one of the witness for Eastern Health, what's called an interrogatory which is a question, in a formal sense. And what we asked for was that she append to her answers to interrogatories the, I think we used the term, bench manual. Would you understand bench manual in this context to be

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the same thing as the operation's manual?

DR. EJECKAM:

A. Probably, yeah, depends on what word you use to describe it.

CROSBIE, Q.C.

Q. Okay. Well, what we got back was the DAKO manufacturer's literature which you see before you and if you go to page two of that, you see it has the DAKO logo there on the top of the page. And if go down, there's some handwriting in the left hand margin. And you'll see there the initials "TG" inside a circle on the left hand lower side?

DR. EJECKAM:

A. Yeah.

CROSBIE, Q.C.

Q. I'm assuming those initials are those of Terry Gulliver, but in due course, I suppose we'll have that confirmed.

DR. EJECKAM:

A. I have no way of knowing that.

CROSBIE, Q.C.

Q. Pardon me?

DR. EJECKAM:

A. I said I have no way of knowing whose initials

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those are.
CROSBIE, Q.C.
Q. Okay. Well, we'll proceed on that assumption for the time being and what it appears he's marked there is "DAKO antigen retrieval, step by step". So, I guess he intends us to understand from that that the procedure he's outlined there with his marking is the procedure that this lab was following. That's what I understand. So, do you have any comment on that so far?
DR. EJECKAM:
A. No.
CROSBIE, Q.C.
Q. Okay. If we look at, under "recommended procedure, water bath", number one is "fill coplin jar or other suitable container with sufficient quantity of diluted target retrieval solution, et cetera. Place container in water bath. Heat water bath to 95 - 99 degrees centigrade (do not boil)". This is the manufacturers literature as far as we can tell, is that right?
DR. EJECKAM:
A. I don't know that. I mean, what you showed

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me, you have logo of DAKO on top of it, but I don't know that this is -
CROSBIE, Q.C.
Q. Just scroll up again, please, Registrar. And an address.
DR. EJECKAM:
A. Okay, fine.
CROSBIE, Q.C.
Q. Someone may correct us, but by appearances and I guess I can advise you that it was given to us by Ms. Heather Predham whose name you heard before -
DR. EJECKAM:
A. Yes.
CROSBIE, Q.C.
Q. - as an attachment to a sworn set of answers in a court process. This is what was offered to us as their bench manual. And it appears to be a manufacturer's document. In any event, if I'm wrong in all that, I'm sure I'll be corrected. But what I ask your reaction to is the manufacturer's instruction there that we just read, "do not boil".
MR. BROWN:
Q. Excuse me, I'm not sure, this is not a

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question for Dr. Ejeckam. Dr. Ejeckam is not, at least by his evidence in part has not held himself out to be an expert in this area, it's purely a technical phase of questioning, now I mean, obviously it's there, what it is, but if Mr. Crosbie is attempting to ask what appears to be opinion evidence on something he's not qualified on, I caution--I just raise it at this point.
THE COMMISSIONER:
Q. Mr. Crosbie?
CROSBIE, Q.C.
Q. The witness seems very capable of saying whether or not he's in a position to offer any comment on the question.
DR. EJECKAM:
A. You see, what--well, in terms of bench manual, bench manual should be prepared by the laboratory, not--shouldn't substitute the manufacturers manual with it, I mean, information with it. And that's what we saying, okay, but in terms of do not boil or boil somewhere, somebody write boiling, when you say heat up to 99 degrees, boils at probably 100, right. So, somebody who is not

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a technical person may assume that if you heat, it's going to boil. So, it is--I don't know what--I mean, when they said, I mean, say "do not boil", so I would assume that my technologists that are doing this, follow the instruction. Now, if somebody and I (unintelligible) down wants to describe this and say boiling, I don't take it that it was boiling good unless he has an understanding of what was going on.
CROSBIE, Q.C.
Q. Sir, let me just be clear on this, as someone with expertise in IHC procedures would you or would you not see boiling the specimen as creating a problem?
DR. EJECKAM:
A. If the instruction says do not boil, then we don't boil it, but you have to raise that temperature to 99 degrees maximum.
CROSBIE, Q.C.
Q. What happens if you raise it to 100, what's the risk then?
DR. EJECKAM:
A. For them to boil.
CROSBIE, Q.C.:

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Q. And what would that do?
DR. EJECKAM:
A. I don't know because I have not experimented on that, I don't know what will happen. If you, a retrieval will cause--I know that retrieval time will cause what should be negative to start being positive. We've seen that when you leave the tissue a longer time than necessary in the antigen retrieval solution and heat it for a longer period of time, then you start to find that some of the cells that are supposed to be negative, start showing positivity. Now when you have that, then of course, you have to ask yourself why I did like that, and then you now have to check your time and check what you've done.
CROSBIE, Q.C.:
Q. Well I guess, you know, to put it in layman's terms, if you take protein and you heat it too much or for too long, you cook it. So in a loose way, could you cook the specimens and render them useless for interpretation?
DR. EJECKAM:
A. It's possible, that's what I'm saying, if you overheat it or if you leave it for longer

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period than necessary, then you'll start getting spurious results, it may be a result that you don't want. No more tissues--the example is this, no more tissue should not be positive for Her2/neu, but if you heat it, if you leave it for too long in the antigen retrieval solution and heat it at high temperatures, you'll start seeing dots being positive and that is wrong, but when you see it, then you tell yourself this is not a proper result.
THE COMMISSIONER:
Q. Sorry, Mr. Crosbie, two points. Are you saying that if in fact it was either over heated or heated too long, there would be indications of that on the slide?
DR. EJECKAM:
A. Yeah, they may be false positive.
THE COMMISSIONER:
Q. But how do you know it's a false positive?
DR. EJECKAM:
A. Her2/neu, an example, is not supposed to be seen in normal breast ducts, so when you stain it and you see normal breast or staining with Her2/neu, then it's (unintelligible) stain,

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there's something wrong, it is not supposed to happen that way.
CROSBIE, Q.C.:
Q. That's your internal control.
DR. EJECKAM:
A. Yes.
CROSBIE, Q.C.:
Q. Which you say is critical.
DR. EJECKAM:
A. Yes, I say that, yes.
CROSBIE, Q.C.:
Q. But apparently from what we've seen, not always used here.
DR. EJECKAM:
A. That's an individual problem for individual pathologists or those who look at it, it is not a problem of the laboratory. The staining has been done by the laboratory and someone is looking at it, so if you send out or an in-house pathologist looks at it, it's for him or her to identify this.
CROSBIE, Q.C.:
Q. Just on that same theme about temperature, can we bring up P-0047 and start with the cover, it's the Wegrynowski report from the fall of

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2005. Doctor, you can see the title of the document, "Quality Review" and who prepared it, it's dated November 9th, 2005 and she's a pathology consultant. Can we go then to page 11, exhibit, page 11. Item 17 says, "Guarantee pipette and temperature accuracy and calibration." Then drop down to the third paragraph from the top, "A standard thermometric device or referenced thermometer, NIST certified or guaranteed by manufacturer to meet NIST standards is to be available to check thermometers used on all temperature controlled instruments. Digital temperature readings do no suffice and thermometer's readings are to be recorded." So I infer from the fact that this is listed as a recommendation that what is said should be happening was in fact not happening at the time the investigator or report, Wegrynowski, did her investigation. Does that seem reasonable?
DR. EJECKAM:
A. This is the first time I'm seeing this report and so, talking generally if somebody made a recommendation, one would assume that a

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recommendation was in existence, but this is the first time I'm seeing it and this is a technical issue with a technical lab technologists, I have no, as a pathologist or even any of my colleagues anything to do with this aspect of the work.

CROSBIE, Q.C.:

Q. And in fact, it was brought up by somebody who, I understand, is not a pathologist herself, but has relevant expertise as a laboratory specialist who knows about how this--who knows the technical side of how IHC should be done, and I believe she works or did work out of Mount Sinai. So you're saying in effect that this is not the sort of thing that would normally be a matter for you attention?

DR. EJECKAM:

A. I wouldn't be involved with this. This is something for the technologist to take care of.

CROSBIE, Q.C.:

Q. At page nine, if I could ask that we go to that? Again, we see here "documentation in general is deficient. Key areas identified in IHC" and the first bullet "no test procedure

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manual, including standard operating procedures," and of course, we've been talking about that, haven't we? And so you and she would seem to agree on the need for that?

DR. EJECKAM:

A. Yeah, yes.

CROSBIE, Q.C.:

Q. And there's mention at Pipette, four dots down, and thermometer calibration of accuracy. That seemed to be an issue. And then we see a note at the bottom of the page under recommendations, and it says "the Ventana Benchmark operator's manual was available at the workbench. It is an acceptable component of the overall IHC departmental procedures, but does not replace a procedure manual," and I take it you would agree with that?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. Could I ask the Registrar to now bring up document 0561, and we're looking for item four. So this is from August 2005 from Dr. Cook, and what caught my eye here, and just ask you about this, is the statement "ER

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negative being defined as ten percent or less." In your memoranda from 2003, we've seen more than once, you made reference to a consensus statement from, I think, late 2000. Do I have that right?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. In which the consensus was that one percent or greater should be considered to be positive. Do I have that right?

DR. EJECKAM:

A. The consensus says one percent or less is a condition that may warrant treatment of the patient. A patient may be exposed to anti-estrogen. Now -

CROSBIE, Q.C.:

Q. Sorry, one percent or greater, would it not be, presence of positive staining?

DR. EJECKAM:

A. Now if--well, the consensus would say the positivity of the cells, whether it is one percent or less, may be a condition where a patient may be exposed to anti-estrogen. Now laboratories will set their standard. That's

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why when they report it out, they report percentages. The oncologist will then determine what he wants to use. Ten percent that was put in here is not universally used. When you look at the consensus opinion, a lot of people may use less percentage.

CROSBIE, Q.C.:

Q. I'm just wondering, and there may well be an explanation for this, but why, in the face of a consensus statement of considerable authority that you yourself quoted several years before in 2003, is Dr. Cook laying down ten percent? Can you explain that?

DR. EJECKAM:

A. I think he is the one to explain that. I cannot explain that, why he--I mean, this--what I'm just saying that laboratories and oncology determine their cutoffs. So if this is the agreed cutoff with the oncologists, then that's--as clinical chief, that's why he put this on paper.

CROSBIE, Q.C.:

Q. That's what you got to -

DR. EJECKAM:

A. So that's -

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CROSBIE, Q.C.:
Q. That's what you have a clinical chief for, I guess.
DR. EJECKAM:
A. Well, he has to make decisions.
MR. SIMMONS:
Q. Excuse me, Commissioner, I don't think this is a memo that Dr. Ejeckam was familiar with and may not have taken time to review it carefully, but my understanding of the use of the ten percent here was in selecting samples to be retested. It's not a statement that this is the cutoff. I think that this was the criteria--this is establishing a criteria that was used to select samples to be sent on for retesting.
THE COMMISSIONER:
Q. Mr. Crosbie.
CROSBIE, Q.C.:
Q. May I have a moment to read it?
THE COMMISSIONER:
Q. Yes, of course.
CROSBIE, Q.C.:
Q. Well, if Mr. Simmons is correct in that statement, why would you select the ten

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percent cutoff to assist you in determining which specimens ought to be retested?
THE COMMISSIONER:
Q. Wait now. Was this witness involved in retesting choices?
DR. EJECKAM:
A. I was not involved in -
CROSBIE, Q.C.:
Q. Well, I guess I'm asking, if he can, to explain why--I mean, I'm juxtaposing, Commissioner, obviously the consensus statement from several years before with this use of ten percent, and if you can enlighten us as to why ten percent is pertinent at this point in time, please do. If you can't, we'll have to hear it from Dr. Cook.
DR. EJECKAM:
A. I can't. I can't make any comment on this issue. I cannot clarify that, why that was put down there.
THE COMMISSIONER:
Q. Something you said though interests me. Did I take it from what you said that the business of the percentage is the call of the oncologist, in any event?

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DR. EJECKAM:
A. It is the business agreed between the oncologist and the laboratory if they want to set a percentage.
THE COMMISSIONER:
Q. Yes.
DR. EJECKAM:
A. But there should be a meeting to agree what percentage to be decided as positive or negative.
THE COMMISSIONER:
Q. Okay.
DR. EJECKAM:
A. But some laboratories will just report the percentage they have and then let the oncologist decide what he decides as what to take as a cutoff to treat his patient. The pathologist has no hand, no input in that, that aspect of it.
THE COMMISSIONER:
Q. Okay. So the decision as to what percentage would e a cutoff for the purpose of treatment is that of the oncologist?
DR. EJECKAM:
A. Oncologist, yes.

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THE COMMISSIONER:
Q. There may be times when of the laboratory or the pathologists, as a group, and the oncologists will say "for the purposes of our organization, this is the percentage which shall be used, and if I say positive, I mean that percentage or greater"?
DR. EJECKAM:
A. Yes, yes.
THE COMMISSIONER:
Q. But if they don't do that, then you would expect, would you, that the pathologist would give a percentage so that the oncologist receiving it knows what the percentage is?
DR. EJECKAM:
A. That's exactly what I mean.
THE COMMISSIONER:
Q. Okay. Sorry, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Thank you, Commissioner. Near the beginning of your evidence yesterday, Mr. Coffey asked you, and the discussion appears around page 279 of the transcript that's already been prepared, some brief questions about keeping track of ER and PR positivity rates, and you

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started by saying "I don't understand the question," but I was left somewhat unclear on your attitude toward that, because you ended up saying that yes, you could get the statistics on them if you wished and they could be in the computer. You could get copies.

What I'm getting at, and I think Mr. Coffey was getting at, is this: is it a useful quality assurance device or quality control device, as the case may be, to periodically look at your positivity rates in a given lab to see if they measure up to an expected rate of positivity, if everything is working reasonably well?

DR. EJECKAM:

A. I think in the process of quality assurance that may be something that would be done periodically, maybe quarterly or yearly or half yearly, but it's not something you're going to be doing on a daily basis or routine basis.

CROSBIE, Q.C.:

Q. In your lab back in the Middle East, in Doha, is that something that you did periodically,

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look at your positivity rates?

DR. EJECKAM:

A. Actually, we didn't do that.

CROSBIE, Q.C.:

Q. You did not do that?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. Do you think it's a reasonable thing to do?

DR. EJECKAM:

A. I think you could add that to quality assurance program.

CROSBIE, Q.C.:

Q. Can you tell us, and if you can't then you can't, but is there an accepted percentage, if you were to look at positivity versus negativity rates in a lab, is there a benchmark rate that you should be measuring yourself against?

DR. EJECKAM:

A. Well, there are a number of information in the literature where there's calibrator comparisons, and there's variation from 70 to 80 percent. Some laboratories will give that. So it's a question of where you stand with

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that kind of field. If that's what you believe you want to do, then you compare yourself to such percentages. If you look at the literature, there's so many articles that will compare laboratory percentages of equipment percentages, DAKO against Ventana, and my understanding that you have a range sometimes, some going from 60 to 80 percent, in terms of positivity, but there may be some variation, laboratory variation that may make one to be higher and the other to be lower.

CROSBIE, Q.C.:

Q. Can you tell us, sir, if a lab had a rate of positivity of 65 percent, would that generally be considered to be sound and acceptable?

DR. EJECKAM:

A. I would think it's on the low side. From 70 up, I would think falls within the generally accepted, 70-75 to 80-85. It depends on the laboratory you are evaluating. The British have evaluated several calibrator laboratory work and I think most of the evaluation for calibrator came from either UK or Europe and they have--there's quite a range between one laboratory and the other. So I think most

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important thing here is if you are able to satisfy that the work you're doing in your laboratory is--you're following the proper methodology, then if you have a low percentage or high percentage, I'm not sure that is of critical importance, other than you're looking at--you know, if you're sure that your methodology is right. I don't know if I made myself clear or not.

CROSBIE, Q.C.:

Q. I guess if I under--tell me if I've got this right or not. It is a quality assurance measure that a lab might look at. You appear to feel that it's not obligatory, all the more so if you're satisfied with your other measurements and assurances of quality, such as the presence of the controls that you were describing earlier?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. That's a fair statement?

DR. EJECKAM:

A. Yeah.

CROSBIE, Q.C.:

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Q. Would the expected or desired positivity rate vary according to cut point?

DR. EJECKAM:

A. Well, yeah. If you have a cutoff point of ten percent and someone has a cutoff of 30 percent, then they're going to vary. So that's one of the things you'd want to compare and you have to ensure that all the laboratories you are going to compare have the same cutoff, about the same range of cutoff, so that you can have a proper comparison.

CROSBIE, Q.C.:

Q. So what effect would it have to include clinically negative if you're using a 30 percent cutoff in the positivity rate? What effect would that have?

DR. EJECKAM:

A. I don't understand the question.

CROSBIE, Q.C.:

Q. Well, let me lead it with--put it to you this way. You're telling us that the cutoff point used by the lab will have an effect on how you do the calculation or will have an effect on the calculation of positivity rate. Is that correct?

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DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. So you have to be aware of the cutoff point in use at any given period of time when you're making that calculation?

DR. EJECKAM:

A. Yes.

CROSBIE, Q.C.:

Q. Commissioner, I may have one half hour more of questioning, and I see that it's now ten to five.

THE COMMISSIONER:

Q. Okay. We'll break for the day. Let's do the round, because we have another witness scheduled for the morning. Mr. Pike?

MR. PIKE:

Q. No questions for me, thank you.

THE COMMISSIONER:

Q. Would you care to estimate, Mr. Browne?

MR. BROWNE:

Q. Currently, I would think 15 minutes, half hour tops.

THE COMMISSIONER:

Q. Okay. Well, we'll schedule the witness in in the morning accordingly. Thank you. 9:30, thank you.

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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 4th day of June, 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 4th day of June, A.D., 2008

Judy Moss

-B-

-C-

-M-

-Q-

-S-