COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

October 7, 2008

Appearances:

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

Rolf Pritchard/Jackie Brazil, Q.C. . Her Majesty in Right of NL

Peter Browne, Q.C./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, Q.C. . . . . NL Medical Association
Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
Blair Pritchett. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

LIST OF EXHIBITS

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THE COMMISSIONER:
Q. Please be seated. Mr. Coffey?
COFFEY, Q.C.:
Q. The next witness, Commissioner, is Dr. Carolyn Morris-Larkin.
DR. CAROLYN MORRIS-LARKIN, AFFIRMED, EXAMINATION BY BERNARD COFFEY, Q.C.
REGISTRAR:
Q. Would you please state and spell your complete name for the Commission?
DR. MORRIS-LARKIN:
A. Carolyn Morris-Larkin, C-A-R-O-L-Y-N M-O-R-R-I-S hyphen L-A-R-K-I-N
REGISTRAR:
Q. Thank you.
COFFEY, Q.C.:
Q. Commissioner, there are some additional exhibits, please. They are exhibits P-3350, 3351, 3352, 3363 and 3364.
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-3350 THROUGH P-3352
EXHIBITS ENTERED AND MARKED P-3363 AND P-3364
COFFEY, Q.C.:
Q. Thank you, Commissioner. Exhibit, Registrar,

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when you're ready, Exhibit P-3363?
REGISTRAR:
Q. Is there another one?
COFFEY, Q.C.:
Q. Oh yes, there is another one. Yes, thank you very much. Exhibit P-3042 was referred to a previous witness. It had not been entered, although it certainly was referred to and on the screens here, and I would ask that that be entered as well. It was referred--previously referred to while Patricia Pilgrim was testifying, Commissioner, 3042.
THE COMMISSIONER:
Q. The Registrar sent me a note to that effect.
COFFEY, Q.C.:
Q. Oh yes.
THE COMMISSIONER:
Q. She's keeping track.
COFFEY, Q.C.:
Q. Oh yes.
THE COMMISSIONER:
Q. Thank you.
EXHIBIT ENTERED AND MARKED EXHIBIT P-3042
COFFEY, Q.C.:
Q. 3363, when you're ready, Commissioner,

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Registrar, please? Thank you. Dr. Larkin, I understand this is your curriculum vitae?
DR. MORRIS-LARKIN:
A. Yes, it is.
COFFEY, Q.C.:
Q. And Doctor, earlier this morning, you did point out that there was one typo you wanted to correct in it?
DR. MORRIS-LARKIN:
A. Yes, towards the end -
COFFEY, Q.C.:
Q. Okay, if I could, just a second, toward the end here, are we getting close there?
DR. MORRIS-LARKIN:
A. It's almost the last thing, I believe.
COFFEY, Q.C.:
Q. Okay, last thing on the page.
THE COMMISSIONER:
Q. You have a mouse in front of you which hopefully is working, if you want to control it yourself.
COFFEY, Q.C.:
Q. Yes, you go ahead.
DR. MORRIS-LARKIN:
A. The final entry there, acting co-chair, that's

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actually May 2008, not 2007.
COFFEY, Q.C.:
Q. Okay, acting co-chair, Pathology Quality Management Committee, Eastern Health, May 2008.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. To the current?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Okay, Doctor, I'm going to refer to you as Dr. Larkin, okay, if I could?
DR. MORRIS-LARKIN:
A. That's fine.
COFFEY, Q.C.:
Q. Dr. Larkin, could you give the Commissioner, please, then an overview of your educational and professional backgrounds?
DR. MORRIS-LARKIN:
A. I went to Memorial University and from a biochemistry background went into the medical school here. I graduated in 1984, did a rotating internship in St. John's and then

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went into the pathology residency training program from that. I did a year of pathology and decided to take a year to do some other--explore some other aspects of medicine. So I did some locums and then went back and finished the pathology residency training program in 1990.
COFFEY, Q.C.:
Q. That's here in St. John's?
DR. MORRIS-LARKIN:
A. In St. John's, yes. At that time then, I joined the Faculty of Medicine and the staff at what would have been the General Hospital as a faculty member and a staff pathologist, and I've been in that position ever since, with the changes of course to Health Care Corporation of St. John's and then Eastern Health.
COFFEY, Q.C.:
Q. And so you've worked at the General, I'll refer to it, the General Hospital site ever since?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:

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Q. And your positions at the General Hospital have been what?
DR. MORRIS-LARKIN:
A. For most of the time, it's been as a staff pathologist.
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. In recent years, I've taken on some administrative roles for Eastern Health. I'm currently the site chief for pathology at the Health Science and I've been involved recently in the Quality Management Program for pathology for Eastern Health and in the training of the pathologist assistants.
COFFEY, Q.C.:
Q. Yes, and Doctor, you've been site chief at the General Hospital site, I believe since 2006?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, are you also involved in training of residents?
DR. MORRIS-LARKIN:
A. Yes.

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COFFEY, Q.C.:
Q. Okay. Could you tell the Commissioner--I'm going to refer to some exhibits where it comes up from time to time, but could you tell the Commissioner about how--the nature of your involvement in training residents?
DR. MORRIS-LARKIN:
A. Well, in a teaching hospital setting, you always are interacting with the residents on a one-to-one basis. So I would be overseeing them as they learn how to gross specimens and then when they are learning how to diagnose the slides. So you know, just sort of an on-the-job training type of interaction. As well, there are more formal teaching sessions and there have been a variety of different formats over the years. We have what's called an academic half day for our pathology residents. So I would have regularly contributed there. As well, I would interact with them on a variety of the different rounds that we have that deal sometimes specifically with patients' cases and sometimes more academic related rounds that are something that probably they may do presentations, I may assist them with that.
COFFEY, Q.C.:
Q. Do you have closer involvement with teaching residents than other pathologists do?
DR. MORRIS-LARKIN:
A. It depends on the site we're talking about. I think certainly in St. John's, all of the pathologists have a great deal of interaction with the residents, so I don't think any more than any of my colleagues at Eastern Health, no.
COFFEY, Q.C.:
Q. And you're a member of the--have an appointment then with the Faculty of Medicine?
DR. MORRIS-LARKIN:
A. I am, yes.
COFFEY, Q.C.:
Q. Now if we could look, please, at Exhibit 2411 please, P-2411? Doctor, you'll see it there on the screen in front of you. It's a memorandum, August 21st, 1997 from Dr. Khalifa to a number of individuals including yourself?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:

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Q. See your own name there. The reference is "initiating ER/PR immunostaining of in-house cases" and he writes "this is a reminder that the initiation of ER/PR immunostaining of our in-house cases remains the responsibility of the pathologist who first makes the diagnosis of invasive mammary malignancy on the respective specimen. As you already know, this is done by filling in a request form and submitting it to our laboratory. Although currently ER/PR slides come to me for reporting, the procedure has to be initiated by the primary pathologist since I have no access to the case in question at the time when the diagnosis is being made." Now, Doctor, I refer to this because I want to ask you then, in your training in the late 80s really, in effect, most of your training -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. - as a resident would have been here in St. John's, how much, if any, exposure did you have to immunohistochemistry?
DR. MORRIS-LARKIN:

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A. Very little. Most of what I learned in immunohistochemistry would have been as a working pathologist.
COFFEY, Q.C.:
Q. Okay, in the years afterward?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And at this point, and this is in 1997, ER and PR status, I take it you would have been just aware that there was such a thing as ER/PR and biochemists were involved in it?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. That was the nature of it?
DR. MORRIS-LARKIN:
A. That was the nature of the test up to that time, yes.
COFFEY, Q.C.:
Q. And here, the Commissioner has heard evidence that by the middle of 1997, Dr. Khalifa was involved in testing for ER/PR by immunohistochemistry.
DR. MORRIS-LARKIN:

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A. Yes.
COFFEY, Q.C.:
Q. Paraffin blocks, and what do you recall about the introduction of that here in St. John's? And I'm going to be referring to you his memo in a moment, but by the time his memo comes along, February of '98, it's already agreed that it's going to happen.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. What do you recall about it?
DR. MORRIS-LARKIN:
A. Well, I think this was an initiative of Dr. Khalifa's. He had come from a training centre in the United States where they had already been making the move from the biochemical testing to doing IHC staining for ER/PR. He was, as far as I understood, familiar with that in his training and had discussed it with the then clinical chief, Dr. Haegert, and I think they agreed that this was an appropriate type of move. This was the trend and we should be looking into moving in that direction.

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COFFEY, Q.C.:
Q. And from your own perspective, as a staff pathologist at the General, now Dr. Khalifa was at the General Hospital?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. You would have kind of seen him on a-- certainly on a weekly basis around the -
DR. MORRIS-LARKIN:
A. On a daily basis, yes.
COFFEY, Q.C.:
Q. On a daily basis. At the time, Doctor--I'll ask the Registrar, please, if you could bring up, please, Exhibit P-1850? This is Dr. Khalifa's memo of February 16th, 1998 to all Newfoundland pathologists, which would, of course, included yourself. The reference is reporting of estrogen and progesterone receptor immunohistochemical results, and it says "as you all know, it has been suggested that assessment of ER/PR status in mammary invasive carcinomas be performed IHC on formalin fixed paraffin embedded tissues" and he goes on then to speak about it. The third

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paragraph, he says "as the technique was still in its introductory phase, phase one, I have been reporting results of the majority of cases to establish consistency and reproducible techniques" and then he refers to a more advanced stage of this pursuit, which is phase two, on the second page, "each pathologist will be asked to report results of his or her own cases as indicated by the brown staining of nuclei of the invasive neoplastic cells. That will start March 1, 1998, at which time the immunostained slides will be mailed back to you with positive controls whenever it is technically possible." And Doctor, up to this point, that's February and March of 1998, had you, in your practice, ever encountered having to look at nuclei staining, do you recall?
DR. MORRIS-LARKIN:
A. There -
COFFEY, Q.C.:
Q. How common was it to look at nuclei staining?
DR. MORRIS-LARKIN:
A. There are some stains that would have been available that do have some nuclear staining,

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but this was probably the--this was probably the most prominent at that time, that I can recall.

COFFEY, Q.C.:

Q. And was there any particular training that was made available for the pathologists at the General Hospital site, in relation to interpreting these stains?

DR. MORRIS-LARKIN:

A. There was no specific training. There were the general discussions in the run of a work day or, you know, during rounds, that kind of thing.

COFFEY, Q.C.:

Q. Doctor, did you have any misgivings at the time or reservations about getting involved in this?

DR. MORRIS-LARKIN:

A. I don't think so. I think I would have seen it as a part of the evolution of knowledge within a pathology department, something new that we had to learn about and carry on with.

COFFEY, Q.C.:

Q. Now here, in phase two, there's a reference to with positive controls. You'll see it in the

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fourth line there, "whenever it's technically possible" positive controls, and he says "I will still be responsible for reviewing the positive controls here in our lab" and we've heard evidence that that, in fact, refers to positive external controls.

DR. MORRIS-LARKIN:

A. It does, yes.

COFFEY, Q.C.:

Q. We've also heard evidence concerning internal control, internal controls, internal control tissue.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. In relation to ER/PR, were you aware of the usage at this time of internal controls where ER/PR was concerned?

DR. MORRIS-LARKIN:

A. As well as I can recall, there--I had an awareness that breast tissue might stain and I remember having discussions about do we even need external controls when, you know, there could be some internal control staining, but I came away from those discussions with a final

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conclusion that I couldn't rely on the ER/PR staining of internal controls. So I would not have focused on that. I would have focused on external controls.

COFFEY, Q.C.:

Q. I'm sorry, you came away with -

DR. MORRIS-LARKIN:

A. With an understanding that you couldn't always rely on the internal control expression of ER/PR.

COFFEY, Q.C.:

Q. And do you recall who that discussion would have been with at the time?

DR. MORRIS-LARKIN:

A. I don't remember specifically who it was, no.

COFFEY, Q.C.:

Q. At the time, in the General Hospital kind of pathologist's milieu in early--late '97, early '98, when this was starting to be reported by individual pathologists, was there much discussion about this?

DR. MORRIS-LARKIN:

A. No more than discussion about other things. I mean, there are always discussions about new things or particular cases, but I don't recall

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this standing out as being a huge issue.

COFFEY, Q.C.:

Q. Were there any demonstrations or seminars that you recall at the General, kind of double-headed microscope people looking at ER/PR slides?

DR. MORRIS-LARKIN:

A. Not specifically, not that I recall.

COFFEY, Q.C.:

Q. Doctor, here as well, there is a reference to, this paragraph here you see with the cursor, "attached please find a proposal for uniform reporting of ER/PR immunohistochemical staining. This proposal was discussed with many of my colleagues who mostly agree with its content and accepted it as a policy. I encourage you to adopt the attached proposal in your reporting to maintain uniformity"--I'm sorry, "as I encourage you to adopt it to maintain uniformity, it should be clearly stated that this is only a proposal" and he refers to "there is a considerable host of publications addressing this issue" and he's prepared to share any that you might request. First of all, did you ever take Dr. Khalifa up

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on his offer to share this host of publications?
DR. MORRIS-LARKIN:
A. I don't think I did, no.
COFFEY, Q.C.:
Q. Okay, and here, on page three of the exhibit, there's a proposal for uniformity in reporting the ER/PR immunohistochemical assessment, February '98, and this is spelled out. Now, I haven't asked you, perhaps I should, you would have received this memo, I take it, back in 1998?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Okay. This proposal for uniform reporting of ER/PR immunohistochemical assessment, did you adopt this reporting format?
DR. MORRIS-LARKIN:
A. Yes, I did.
COFFEY, Q.C.:
Q. Including the comment?
DR. MORRIS-LARKIN:
A. Yes, the rider.
COFFEY, Q.C.:

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Q. The rider here, down here in example two. Doctor, in terms of your own approach to reporting ER/PR, how long then did you maintain that reporting style for ER/PR, do you recall?
DR. MORRIS-LARKIN:
A. I don't recall exactly when the change occurred, but at some point in--you know, in the evolution of my own knowledge, I went from having an appreciation that the oncologists would treat cases that had staining of less than 30 percent and I think at that point, I simply stopped using the rider and just left the percent without any further comment.
COFFEY, Q.C.:
Q. Doctor, here, just look at this exhibit, the actual kind of original memo of February of 1998 is three pages long. On the fourth page of the exhibit now, there's "immunohistochemical staining of steroid receptors, correlation with biochemistry" and it's a report about experience over a nine-month period, January '97 to September '97. Do you ever recall seeing this?
DR. MORRIS-LARKIN:

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A. I don't remember seeing it, but I was aware that Dr. Khalifa had done such a review.
COFFEY, Q.C.:
Q. Okay. Now Doctor, at the time, and this would be, again, early in 1998, the site chief at the General was Dr. Khalifa?
DR. MORRIS-LARKIN:
A. Yes, it was.
COFFEY, Q.C.:
Q. And what was your understanding of his degree of knowledge about immunohistochemistry?
DR. MORRIS-LARKIN:
A. I remember him having been involved particularly in this and I don't know that I had an appreciation of any particular expertise in immunohistochemistry, but he was very well versed in quite a number of things and he had a different training background, so I did feel comfortable with what I thought he knew.
COFFEY, Q.C.:
Q. And Doctor, with respect then to this matter, I take it then in 1998, you began to report your own ER/PR cases?
DR. MORRIS-LARKIN:

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A. Yes.
COFFEY, Q.C.:
Q. And that would be--that continued on through '99, 2000 and really up until 2005?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Did you--I'm going to get to 2002 and 2003 in a moment, but prior to 2002, did you ever have any reason to doubt the validity of what you were seeing or any cause for concern about ER/PR?
DR. MORRIS-LARKIN:
A. Not specifically about ER/PR. I think that we had seen evolution of changes in our lab with, you know, general aspects of immunohistochemistry. We--and in 2002 -
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. 2002 you're asking specifically?
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. I don't recall there being anything specific

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about it, no.
COFFEY, Q.C.:
Q. About ER/PR. How about immunohistochemistry itself? Perhaps you could just tell the Commissioner about kind of, again, in the late '80s, there was very little of it.
DR. MORRIS-LARKIN:
A. Right.
COFFEY, Q.C.:
Q. Perhaps you can kind of bring us up through the '90s then, into the 2000's, as a pathologist here locally.
DR. MORRIS-LARKIN:
A. Well, it was something that was very much only developing throughout the '90s. There were new antibodies coming into our knowledge base on a regular basis and we were going, sometimes individuals going "oh, this sounds like a good antibody. We should probably get that" and the technologists would order them. So it wasn't--you know, it was quite ad hoc in the '90s as more and more information was being gathered. We had some pathologists who had more access to particular antibodies. One of our pathologists brought in some antibodies

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from a research lab that he had worked in and I think that when Dr. Khalifa came then in the late '90s, he kind of helped to organize what knowledge and what we had available in the lab so that he produced lists of -
COFFEY, Q.C.:
Q. Coming up with requisition forms.
DR. MORRIS-LARKIN:
A. With the requisition forms. Because before that, I think we were probably--we may not have even known all the antibodies that were potentially available to us at the time.
COFFEY, Q.C.:
Q. Within the lab itself?
DR. MORRIS-LARKIN:
A. Within the lab.
COFFEY, Q.C.:
Q. You might bring one in and somebody down the corridor might not realize you had and vice versa?
DR. MORRIS-LARKIN:
A. That's right.
COFFEY, Q.C.:
Q. Or even over at St. Clare's, they might have asked one to be brought in and it would be in

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the General Hospital IHC lab, but you wouldn't know it?
DR. MORRIS-LARKIN:
A. That's right.
COFFEY, Q.C.:
Q. Before Dr. Khalifa got involved in organizing it. Doctor, as an example of that, in the 1990s, if you asked, for example, if it was yourself, for example, and you asked--you saw something in an article and you wanted a particular antibody -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. - how would you go about getting it and then utilizing it?
DR. MORRIS-LARKIN:
A. I don't remember if I asked for any specific antibodies and actually received them. I do remember suggesting this may be a good antibody for us to have, and most of the time, it would probably be mentioned to one of the senior technologists or the then lab manager.
COFFEY, Q.C.:
Q. And then what would happen? That's yourself--

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some of your colleagues, like you've asked and somebody orders it, I take it. What happened then?
DR. MORRIS-LARKIN:
A. I think that--you know, I think that there were antibodies brought in. As I say, I don't remember if there was one specific antibody that I asked for that I got, but definitely antibodies were acquired based upon the requests from pathologists.
COFFEY, Q.C.:
Q. What was your understanding of what was happening then? I take it the antibody would come in -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. - in probably a liquid form, and what was your understanding then would happen between the time it was ordered and the time, for example, you saw a slide?
DR. MORRIS-LARKIN:
A. I really would have very little knowledge of what would happen beyond, you know, asking we should perhaps look into getting this

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antibody, but what would happen in the lab itself, I really wouldn't have that knowledge.

COFFEY, Q.C.:

Q. And what I'm getting at is in relation to, for example, how would you know then that a stained slide that you received in relation to a new antibody was appropriately stained or not?

DR. MORRIS-LARKIN:

A. Again, we would be looking at controls and it would be compared to controls. So that's--that would be my benchmark really.

COFFEY, Q.C.:

Q. And these would be these external controls?

DR. MORRIS-LARKIN:

A. Both external and internal, because if you were looking at a particular type of stain and you knew that there was a tissue within--a normal tissue within your section, then you would automatically be able to see, well, that's also staining.

COFFEY, Q.C.:

Q. Okay. But in terms of, for example, if the concentration of the antibody had to be adjusted potentially, in terms of the way it

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was being utilized in the lab here in St. John's, would you ever--were you ever involved in that?

DR. MORRIS-LARKIN:

A. I wasn't, no.

COFFEY, Q.C.:

Q. In terms of dilution rates or -

DR. MORRIS-LARKIN:

A. No.

COFFEY, Q.C.:

Q. - things like that. Did you have any understanding about ER/PR, that it involved antigen retrieval, compared to--you know, compared to other IHC stains?

DR. MORRIS-LARKIN:

A. Again, at some point, I became aware of the technique of antigen retrieval, that it was something that was being used by the technologists. I believe they were using it for a variety of antibodies, not just those against ER and PR. But beyond that, I really wouldn't know anything much.

COFFEY, Q.C.:

Q. Do you recall when that would have been?

DR. MORRIS-LARKIN:

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A. No.

COFFEY, Q.C.:

Q. On a topic that eventually you become much more involved in, okay, I'm going to refer you to an exhibit from years ago, Exhibit P-2539. Doctor, this is the agenda for a meeting of April 24th, 2001, at the General Hospital site. Look at the second page of the exhibit, you'll see your name listed as being present. It's the division of anatomical pathology, General Hospital site, minutes of a meeting of April 24th, 2001, and there are a number of topics discussed, but in particular of interest here now, paragraph 3.8, pathologist assistant. "There's been much discussion on this issue. However, Dr. Haegert will discuss with Dr. Williams in future. However, there is no money in the budget to fund this position. Dr. Sushil Parai will talk with Terry Gulliver, exploring the possibility of training two senior technologists for doing additional grossing." See that?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

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Q. Of course, you eventually end up involved years later with pathologists assistants. Doctor, the idea of utilizing pathologist assistants, when were you first introduced to that?

DR. MORRIS-LARKIN:

A. I think my first introduction to having someone other than a pathologist or a resident assist us at the gross bench actually came during Dr. Khalifa's time when he, in fact, trained some of the senior technologists to do very basic lab--some very basic assisting at the gross bench, so very small specimens where there was no examination, sectioning, selecting of blocks required. It was simply take the specimen from the specimen bottle, put it into the cassette and up until he had introduced that, that was a responsibility that was falling on residents and pathologists. So that would have been the first introduction to this concept, although at a very basic level, and I think that that was something that was becoming more widespread elsewhere in the province as well.

COFFEY, Q.C.:

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Q. Elsewhere in the country?
DR. MORRIS-LARKIN:
A. And elsewhere in the country. I think elsewhere in the country we knew about pathologist assistants.
COFFEY, Q.C.:
Q. Doctor -
DR. MORRIS-LARKIN:
A. And certainly in the United States we were aware.
COFFEY, Q.C.:
Q. And what's your recollection then how the local pathologists, how did they react to the idea of utilizing pathologist assistants?
DR. MORRIS-LARKIN:
A. The vast majority were all in favour. I think I heard one pathologist who was only briefly here voice some concern over it, but I think the overwhelming majority would be in favour of this.
COFFEY, Q.C.:
Q. And if we could, Exhibit P-2540? Doctor, page 2 again. These are minutes of a meeting of June 14, 2001. You'll see you're listed as present. It's the division of anatomical

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pathology. And in particular, paragraph 3.4, pathologist assistants. "Much"--this is a couple of months later, "Much discussion on this issue. It is unlikely that the corporation will fund for pathologist assistant. However, we have three senior technologists who will be willing to do additional grossing if their jobs were to be classified to a technologist three level. It is expected that we will know this information very soon." And they refer to some issues involving specimen labelling and handling. And, Doctor, I take it at this point in time, in the middle of 2001, you weren't involved in the pathologists assistants issue? You're attending these meetings where it's being discussed, but -
DR. MORRIS-LARKIN:
A. Only in this meeting kind of setting, yes.
COFFEY, Q.C.:
Q. Yes. And in terms of the idea of utilizing the three technologists, you know, if they were to get involved, you did not get involved at that time?
DR. MORRIS-LARKIN:

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A. I think that was more an administrative thing as a way to try and--to try and get around the fact that we were not being given an specific funding for pathologist assistants.
COFFEY, Q.C.:
Q. Here under 4.4 "ASCP Check Schedule", I'm sorry, "Check Sample" and can you tell us, please, well, it goes on to say, "The corporation has prescribed 2001 ASCP check samples as follows: Surgical Pathology I - exercises. Surgical Pathology II - 8 exercises. Cytopathology - 12 exercises. These are available in the reporting room. Check sample answer sheet has been circulated to all Pathologists and this can be completed at the end of the year for CME credit hours." Can you tell us, please, what, if any--well, first of all, what this involved, what this is speaking about?
DR. MORRIS-LARKIN:
A. There are several proficiency testing systems available and the one that we had subscribed to at the General Hospital was from the College of American Pathologists. The one that had been subscribed to at the Grace

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Hospital was the ASCP check sample. I was less familiar with this, but I think that with the merger, the closure of the Grace and then the transfer of several of the pathologists, they brought this particular set along with them, although I think it was very short lived. We probably only had this particular testing or this particular proficiency test exercise for about a year. I may be wrong on the exact number of dates. But we continued with the other one, which I'm more familiar with, which is the PIP type of proficiency testing. So this basically would involve case presentation with, I think the ASCP was always just kodachrome slides, so you'd have a case presentation, you'd have slides that were essentially photographs of, micro photographs of a case and then questions to answer on it.
COFFEY, Q.C.:
Q. Okay. And you otherwise yourself had been familiar with and involved in the CAP?
DR. MORRIS-LARKIN:
A. Yes. That's -
COFFEY, Q.C.:
Q. Project. Could you tell the Commissioner

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about when, your recollection is when you first got involved with that and how long it continued for?

DR. MORRIS-LARKIN:

A. I think we began subscribing to the CAP again around the time Dr. Khalifa was site chief. I believe it was '96 or '97. And we have subscribed to it ever since with perhaps one year there was a lapse in the subscription for some reason, I'm not entirely certain.

COFFEY, Q.C.:

Q. And what does that involve?

DR. MORRIS-LARKIN:

A. There are four sets per year sent out, which include usually about ten glass slides that are difficult cases and then a set of questions that go with it. And what you would do is review the slides, make your diagnosis based on the history provided and the slides- it was a multiple choice type of thing. And then there would be further multiple choice questions to allow you to deepen your knowledge. So essentially what we would do is we would all get this--or photocopies of this, the slides would be available, we would all

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review them and then we would get together on an assigned time and review it as a group, but by then everyone would have researched the answers, looked at the slides, kind of come together and then talk about, maybe argue back and forth over why I think it's diagnosis X and why you think it's diagnosis Y. And then we would get the answers to the questions.

COFFEY, Q.C.:

Q. And these would be generally complicated?

DR. MORRIS-LARKIN:

A. They're usually complicated cases.

COFFEY, Q.C.:

Q. Do you ever remember ER and PR slides being utilized in that, that you recall?

DR. MORRIS-LARKIN:

A. Not specifically, but it's possible there could have been because certainly with time there are more and more, more and more reference to immunohistochemistry. In that particular set we would not have received ER/PR slides, they were always H&E slides. We would have just been told what the results of the immunohistochemistry testing was in the little summary that goes with the slide.

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COFFEY, Q.C.:

Q. In order to allow you to continue on with your analysis of the H&E slides?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Okay. And these would not, though, involve any creation of local slides locally?

DR. MORRIS-LARKIN:

A. Not this particular -

COFFEY, Q.C.:

Q. Not that type?

DR. MORRIS-LARKIN:

A. No.

COFFEY, Q.C.:

Q. In your years there up until more recent, since 2005, prior to 2005 were you ever aware of, in the General Hospital site, where there was proficiency testing going on that required the creation of slides locally?

DR. MORRIS-LARKIN:

A. In terms of one of these organized -

COFFEY, Q.C.:

Q. Yes.

DR. MORRIS-LARKIN:

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A. CAPs?

COFFEY, Q.C.:

Q. Yes.

DR. MORRIS-LARKIN:

A. I'm not aware of it, no.

COFFEY, Q.C.:

Q. CAP or any other program, to your knowledge?

DR. MORRIS-LARKIN:

A. Or any other, no. But it may have happened without--I wouldn't have been in the knowledge loop for that.

COFFEY, Q.C.:

Q. And you were never asked to get involved, and that's what I'm getting at?

DR. MORRIS-LARKIN:

A. No.

COFFEY, Q.C.:

Q. Okay. If we could, finally, on this again, to put some of this in context for the Commissioner, 4.5 here, "Resident Training." It says that, this is June 14, 2001. "It is expected that one pathology resident will start as of July 1st, 2001. Dr. Robb has asked all staff to teach and train the resident in a positive way. This is a

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challenge for the program and therefore cooperation is highly appreciated." Now, Doctor, I take it then that residencies generally start the beginning of July?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. So this would be one pathology resident would be starting for the then, the then coming year?

DR. MORRIS-LARKIN:

A. And I think, I think, again, this has to be perhaps further explained.

COFFEY, Q.C.:

Q. Sure.

DR. MORRIS-LARKIN:

A. We went through a period of about four, maybe five, but I think four years where we had no pathology residents at all.

COFFEY, Q.C.:

Q. Yes. I was going to ask you about that, okay, this is a way of coming to that. Could you tell us, please, then about that? Like, you were trained here in the late '80s?

DR. MORRIS-LARKIN:

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A. Yes.

COFFEY, Q.C.:

Q. And what your recollection is of kind of the availability of residents in training here as time progressed?

DR. MORRIS-LARKIN:

A. I think that a major part of our problem has been, in fact -

COFFEY, Q.C.:

Q. If I could, just before, because I'm going to ask you about the why.

DR. MORRIS-LARKIN:

A. Okay.

COFFEY, Q.C.:

Q. Just the actual what happened, in the late '80s, like, how many would you have trained with, approximately, how many pathology residents in the late '80s?

DR. MORRIS-LARKIN:

A. There were usually seven to eight of us in the program. There was some turnover and, you know, people would not finish; people would come in, decide this wasn't for them. And that probably continued to the mid '90s.

COFFEY, Q.C.:

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Q. Okay.

DR. MORRIS-LARKIN:

A. We had a regular, a regular group of up to about eight residents.

COFFEY, Q.C.:

Q. A core group of about a half dozen and maybe a bit higher?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Okay. And then what happened then?

DR. MORRIS-LARKIN:

A. Many of our residents have come from international medical schools and that's common in pathology across North America. What we saw in the late '90s was a much tighter restriction on who was going to get in the residency programs based upon licensure. And I think that one of the big things that resulted here in Newfoundland was the restriction, the way the criteria were written, it very much limited the availability of the pool of people who we could draw from. In particular, the rules were such that someone who was trained as a pathologist who

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may not have been in any kind of clinical practice for several years because they had immigrated from their country of practice and were now working at whatever job they could to keep them sustained, were out of actual clinical practice for a longer period of time than the Newfoundland Medical Board would allow and as a result, they were not eligible for educational licence. That was a major reason why we had a significant drop in the number of residents.

COFFEY, Q.C.:

Q. Yes. Because -

DR. MORRIS-LARKIN:

A. To the point where we had none. And -

COFFEY, Q.C.:

Q. You were about to tell the Commissioner, I apologize, I interrupted you, you said for a period of about four or five years?

DR. MORRIS-LARKIN:

A. It happened for about four years. And it was, it was at the initiative of the late Dr. Robb, who invested a great deal of time with the Newfoundland Medical Board to try and define criteria that would be appropriate for

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pathologists who had lab exposure but yet didn't have the official clinical lab practice or the clinical kinds of practice that the Newfoundland Medical Board were looking for.

COFFEY, Q.C.:

Q. So I take it then in the turn of the century, 2000, 2001 Dr. Robb was able to -

DR. MORRIS-LARKIN:

A. He had been successful in trying to, you know, refine these particular requirements so that, you know, so that it made sense. And now our residency program is, you know, fairly well full again. And again, almost entirely of international medical graduates, although we do have a few Canadian graduates in the program.

COFFEY, Q.C.:

Q. So then beginning in the early 2000s, in effect, the residency program for pathologists here in St. John's began to slowly be built again?

DR. MORRIS-LARKIN:

A. It had to rebuild, yes. So we were used to doing things without residents for a period of time.

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COFFEY, Q.C.:

Q. And so in the late '90s, certainly, you would have been used to it because you had no residents?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. In the late '90s itself?

DR. MORRIS-LARKIN:

A. That's right.

COFFEY, Q.C.:

Q. And then even in the early 2000s you would have had relatively few residents to assist? For example, here -

DR. MORRIS-LARKIN:

A. It quickly, it quickly built up again.

COFFEY, Q.C.:

Q. Okay, in 2001, '01, '02 year, that school year, as it were.

DR. MORRIS-LARKIN:

A. Right.

COFFEY, Q.C.:

Q. Academic year, there would have been one, I take it?

DR. MORRIS-LARKIN:

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A. There was one starting, but--and I don't remember specifically who that was at that time, but I guess we got to a full kind of complement by 2002, 2003, because we graduated four people in 2006.

COFFEY, Q.C.:

Q. Okay. Doctor, I don't know how fair this question is, but do residents, being involved with pathology residents, does it increase the pathologists workload or decrease it or is it neutral in terms of your interaction with them?

DR. MORRIS-LARKIN:

A. It definitely increases a pathologist's workload. But there was some trade off in that there are certain things that then once you trained your resident to do, you could hand off to them. So things like the grossing, once they were trained, the autopsies, that kind of thing, so there's also a bit of a trade off, as well. It also keeps you on your toes and, you know, there's a great deal more educational aspect that has to be paid attention to so that there's probably more work in preparing rounds and

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presentations, you know, particularly the teaching at the academic half days, as I mentioned.

COFFEY, Q.C.:

Q. Exhibit C-0175, please? Actually, if I could, I apologize, C-0184, first of all. Doctor, this is a redacted pathology report. It's, you'll see here from the date, the specimen number is 02SU6969. It's indicated to be received May 16th, 2002. Go on to the second page of the exhibit, see your name there at the bottom. And then the third page here, at the very bottom of the page is addendum number one, entered July 10th, 2002. And you've written "Less than ten percent of the cells show positivity for estrogen receptors. This correlates with a negative estrogen receptor result." And "Approximately 25 percent of the cells are positive for progesterone receptors, MC." And that is actually signed electronically by yourself on July 10th, 2002. So that's July 10th, '02. Addendum number two reads, "Due to the" and this entered July 22nd and signed the same day by yourself, 2002. You wrote, "Due to the unavailability of a

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control the ER and PR were repeated. A difference is seen in the results as follows: Approximately 30 percent of the cells are positive for estrogen receptors, best considered a positive ER result. 50 percent are positive for PR receptors." Doctor, do you actually recall this case?

DR. MORRIS-LARKIN:

A. I don't recall this specific case, no.

COFFEY, Q.C.:

Q. Specific case. And then, Doctor, and I appreciate--again for the Commissioner's benefit, that you would report approximately how many cases a year, not just ER/PR, but how many cases a year would you report?

DR. MORRIS-LARKIN:

A. I would--well, I would report in all of my practice, because I don't do just surgical pathology.

COFFEY, Q.C.:

Q. Yes.

DR. MORRIS-LARKIN:

A. At that time I would have done cytology, bone marrows, peripheral bloods, approximately 2000 cases per year.

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COFFEY, Q.C.:

Q. Per year.

DR. MORRIS-LARKIN:

A. And less than one percent of that would be related to breast cancer.

COFFEY, Q.C.:

Q. And in this, in terms of that, because you'd been beginning in March of '98 would begin to report ER/PR?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. In breast cancer cases. Approximately how many breast cancer cases a year would you do, report?

DR. MORRIS-LARKIN:

A. Again, to try and give you a number would be impossible, but probably one every few weeks, maybe. You know, no more than that.

COFFEY, Q.C.:

Q. One a month?

DR. MORRIS-LARKIN:

A. One to two a month, maximum.

COFFEY, Q.C.:

Q. Maximum?

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DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. In a typical year?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And I take it that you caught whatever breast cancer cases you did on your rotation at the General Hospital, that's, in effect?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. The way it would work?

DR. MORRIS-LARKIN:

A. Yes. We would, you know, we would be assigned cases and whatever particular rota we were using at a given time, the cases that came out, the slides that came out, they were our cases.

COFFEY, Q.C.:

Q. Now, Doctor, here, looking at this, this addendum number one, addendum number two, can you tell the Commissioner what appears from, you know, looking at what's written here, what

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appears to have happened?

DR. MORRIS-LARKIN:

A. I think what would have happened is I would have signed the case based upon the H&E slides so that the bulk of the information would have been available and I would have provided that for the clinician and then would have ordered the ER and PR. Reading the addendum number one, that would have, at that time, fallen into my 30 percent cutoff that I would have been using. And I can see I've done a modification of the rider. I probably didn't have the exact thing in front of me and we didn't have it as a canned text, but the -

COFFEY, Q.C.:

Q. So this -

DR. MORRIS-LARKIN:

A. Basically I was referring to that rider less than 30 percent would correlate with a negative estrogen result on biochemistry.

COFFEY, Q.C.:

Q. So this -

DR. MORRIS-LARKIN:

A. So that's -

COFFEY, Q.C.:

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Q. This sentence was a reference to what would otherwise have been the rider -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. - if you had it in front of you? So you were still utilizing the rider at this point in time?
DR. MORRIS-LARKIN:
A. Yes, I was.
COFFEY, Q.C.:
Q. That mind set. And I'm sorry, go ahead, Doctor?
DR. MORRIS-LARKIN:
A. So addendum number two where I say "Due to unavailability of a control, the ER and PR were repeated." I would have, at that time, been looking at the controls myself. I would have wanted to see the control, and if for whatever reason it hadn't been provided to me and where that would have fallen into that interpreted as negative range from a clinical point of view, I would have wanted to see a control with it, so the only way I could deal with it was to repeat the entire thing and

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have the control to compare it to.
COFFEY, Q.C.:
Q. It's apparent then, I take it, that you did reorder the test?
DR. MORRIS-LARKIN:
A. And I did repeat that stain with the control and with that result and my interpretation.
COFFEY, Q.C.:
Q. Now, the unavailability of a control, this would be an external control?
DR. MORRIS-LARKIN:
A. That would have been the external control.
COFFEY, Q.C.:
Q. External controls.
DR. MORRIS-LARKIN:
A. At that time I would have been referring to, yes.
COFFEY, Q.C.:
Q. Doctor, why would you report addendum number one, a case like here, without having seen the external controls?
DR. MORRIS-LARKIN:
A. Perhaps because I did see that, you know, there was a positive stain there and I don't know what the clinicians were actually doing,

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even though I know we were referencing this 30 percent. You know, if you were to take all the other--if the clinicians were to take all the other aspects, whether or not they would utilize it--specifically why I sent it out, I don't know. Maybe I just dictated it and said, well, you know, I really shouldn't do that, the better practice would be for me to get the control, and I'd already signed it. That's the only explanation I can give you.
COFFEY, Q.C.:
Q. Okay, you'd already kind of gone through the process -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And thought, in effect -
DR. MORRIS-LARKIN:
A. Because this would have been electronic signature and -
COFFEY, Q.C.:
Q. Entered it and signed it off the same day, in fact.
DR. MORRIS-LARKIN:
A. And said, and, you know, something in my head

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said, well, you know, you really should make sure you see that control, and that was the best way to do it then was to repeat it.
COFFEY, Q.C.:
Q. Doctor, did that cause you any concern when on the repeat it went from less than ten, the ER went from less than ten to 30?
DR. MORRIS-LARKIN:
A. I don't remember noting that specific case. I mean, it caused me concern enough to make sure that it was reported and that the oncologist had that kind of information. But again, we were--I was just trying to report what I had there and I didn't know exactly how they were going to utilize the percentages.
COFFEY, Q.C.:
Q. And you've said here, "Best considered a positive ER control." I'm sorry, "Best considered a positive ER result" here in addendum number two, the second -
DR. MORRIS-LARKIN:
A. Yes, and that's a reflection of the agonizing that I certainly did over is it less than 30 percent or more than 30 percent. I might call something 25 percent, my colleague might call

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it 35 percent.
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. And these were the kinds of things that we, you know, certainly I agonized over.
COFFEY, Q.C.:
Q. And "Best considered a positive ER result" would be in keeping with this comment of Dr. Khalifa had utilized -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. - back in '98, you're still thinking in that mode, thinking about this?
DR. MORRIS-LARKIN:
A. I was still thinking in terms of the reference to the biochemical assay.
COFFEY, Q.C.:
Q. And if you say agonizing over it, thinking well, I'm saying 30, you would have understood that a colleague might say 20, 25, 35, 40, depending upon who the colleague was?
DR. MORRIS-LARKIN:
A. Yes, and, I mean, this was always an issue

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with this 30 percent cutoff because it sounds so quantitative when, in fact, it's not. It's really a subjective judgment call. And it's always difficult. There are other areas of pathology where you see this kind of percenting, and it's always associated with the same kind of semi-quantitative judgment call that you try your best to be as accurate on as possible.
COFFEY, Q.C.:
Q. Would you have brought this, at the time, to the attention of anyone else, the fact it had gone from, well, in effect, ten, less than ten to 30 ER and from 25 PR to 50 PR?
DR. MORRIS-LARKIN:
A. I don't think I did.
COFFEY, Q.C.:
Q. And at the time no particular significance to you?
DR. MORRIS-LARKIN:
A. Other than again there's always some degree of variation.
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:

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A. And we always, we always have a spectrum of expectation. And I don't recall this standing out as something that I did anything about.
COFFEY, Q.C.:
Q. Now, Doctor, this happens to be around the time that--in terms of the timing, that Peggy Deane, July of 2002 is when Peggy Deane's initially ER/PR testing was done. It didn't involve yourself, but it was done around the same time.
DR. MORRIS-LARKIN:
A. Okay.
COFFEY, Q.C.:
Q. In the summer of 2002, and I appreciate you referred here to the unavailability of a control as being the reason why you reordered the test, were there any concerns that you were aware of amongst pathologists about the ER/PR testing?
DR. MORRIS-LARKIN:
A. I don't remember anything being expressed, and as far as the unavailability of a control, I may have had a note that said this is with Dr. "X" and then Dr. "X" had already looked at it and filed it, so -

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COFFEY, Q.C.:
Q. What was the practice in relation to that in terms of the - at that time in the middle of 2002 about the availability of external controls for yourself at the General Hospital?
DR. MORRIS-LARKIN:
A. I think at that time we were, for the most part, receiving a control with our slides, but sometimes there would be just one control within the department, and that's when you would get the note that said, you know, doctor so and so has the control.
COFFEY, Q.C.:
Q. Was there any communication within the department at the time at the General Hospital about, like, Dr. "X" actually having examined the control and satisfied him or herself that it was working, and then communicating that to everybody else?
DR. MORRIS-LARKIN:
A. I don't think that was the system that was in place. I think the system that - my appreciation of the system was I had to look at my own control.
COFFEY, Q.C.:

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Q. And then - I take it then even preparing addendum number one, looking at the slides initially, you'd be looking for, well, where are the external controls?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And if they were already filed away, why wouldn't you just go get them or have somebody go get them for you?

DR. MORRIS-LARKIN:

A. I don't know what the exact - what the exact thing was. It may have been filed with their case, and - I don't know exactly what happened in that particular one.

COFFEY, Q.C.:

Q. Okay. Was it a common problem?

DR. MORRIS-LARKIN:

A. I don't think so.

COFFEY, Q.C.:

Q. Controls not being available.

DR. MORRIS-LARKIN:

A. No, I don't think so.

COFFEY, Q.C.:

Q. Exhibit P-3350. I apologize - Exhibit P-2426,

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page three, please. Doctor, these are - page three are minutes of site chiefs and divisional managers of April 24th, '02. Drs. Cook, Parai and there, and Barry Dyer. In paragraph 3.1, there's a reference to quality control and quality assurance program, "A draft has been circulated. Some of the items of this draft were discussed in the meeting of November, however, it was felt that this draft proposal be reviewed by the site chiefs and divisional manager and their edited opinion will be discussed in the next meeting". I take it then, Doctor - I appreciate you wouldn't have been at this meeting, but as of April, 2002, there was a recognition locally that there were concerns about quality control and quality assurance programs, whether or not they existed, and if so, whether they were sufficient?

DR. MORRIS-LARKIN:

A. I think that's true. There have always been some quality control activities in place as well as quality assurance activities, and this was an attempt to take it to the next level of putting it into a more organized program that

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could be better monitored and managed.

COFFEY, Q.C.:

Q. Page seven, please, Registrar. This is minutes of a meeting of February 17th '03, the same group of people, three of those individuals, but under 3.1 again, quality assurance program, "Dr. Parai informed that he's prepared another draft on quality assurance. The typing is not yet complete. He will circulate it as soon as typing is complete. There will be a second document that will be reviewed in the next meeting before final approval". So I take it then, Doctor, going into early 2003, this was still going on, efforts in this regard?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. From your perspective as a practising pathologist here in St. John's at the General Hospital, in relation to organizing QA and QC, who's responsible for ensuring that such a program existed and was implemented?

DR. MORRIS-LARKIN:

A. I think the - I think the responsibility was

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the management team and I think that's what this reflects as their recognition of the need to have this in a more organized manner.

COFFEY, Q.C.:

Q. If I could, please, Registrar, page 10, same exhibit. Here there's a Division of Anatomical Pathology pathologists meeting at the General Hospital site, March 4, '03. You're not listed as in attendance for that particular day, but when we go to the next page, 4.2, QA Program, "The draft policy has been circulated to all the pathologists for review and revision". So I take it there was by the beginning of 2003 at least a draft policy?

DR. MORRIS-LARKIN:

A. There was a - there was something circulated, yes.

COFFEY, Q.C.:

Q. What's your memory of how far they got with that at the time?

DR. MORRIS-LARKIN:

A. I don't think they got much further than that at that time because again it was one of many things that the leadership team were trying to

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deal with, and like many things, would get a certain amount of attention, and then something else would perhaps be more pressing.

COFFEY, Q.C.:

Q. Here at page 14 of the same exhibit, May 1st, 2003, meeting of pathologists at the General Hospital site. You're noted as being absent, but I take it you would have eventually gotten the minutes?

DR. MORRIS-LARKIN:

A. I would have gotten the minutes, yes.

COFFEY, Q.C.:

Q. Here in Paragraph 3.2, there's a QA Program, "A draft proposal of this program has been circulated previously. There's been a few comments by some staff to make some changes, which will be done. In addition, the issue of cancer diagnosis by a second pathologist was discussed in detail. It was decided that all the difficult and problematic cases like prostatic needle biopsies, lymph node, gastric, and lung biopsies, the opinion of a second pathologist would be included in the microscopic description. This will be incorporated in large specimens as well. At

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the present moment, there is no way to put the signature of a second pathologist in the Meditech System". I take it this was an effort at the time to move ahead with this?

DR. MORRIS-LARKIN:

A. Yes, there were a lot of discussions. This was something that was being done at other sites and I think Dr. Ejeckam had experience with this kind of practice, but it wasn't again in any kind of formalized way that we could put - I would look at one case and then give it to my colleague and both of us would be able to officially sign it. So as a fall back, I think, what would happen is you would - if you wanted somebody's support on a case, you would have them sign an internal consult form.

COFFEY, Q.C.:

Q. Here looking at page 20 of the same exhibit, to follow through on this, again there's another pathologist meeting and the minutes of September 24th, 2003, at the General Hospital site. Again you're not noted to be present, but you would have been still employed there at the time, I take it. 3.2, QA Program, "The final QA program will be completed soon after

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a final meeting with Dr. Cook and Barry Dyer. However, the present practice of mentioning the name of the consulting pathologist in the microscopic description will continue". So that was the way around that?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. If we could, page 22, same exhibit, paragraph - this is December 18th, 2003, minutes of a meeting at the General Hospital amongst pathologists - well, this is amongst the site chiefs actually. 3.1, Quality Assurance Program, "The draft quality assurance program has been reviewed and revised". It's still in draft form trying to be finalized. What were the problems with finalizing it, do you recall?

DR. MORRIS-LARKIN:

A. I wouldn't have been involved with that particular aspect, no.

COFFEY, Q.C.:

Q. I suppose what I'm trying to ask you in terms of as a staff pathologist, do you recall any resistance from the staff pathologist's

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perspective?

DR. MORRIS-LARKIN:

A. I don't think so.

COFFEY, Q.C.:

Q. I'm not suggesting there was, I'm just -

DR. MORRIS-LARKIN:

A. No.

COFFEY, Q.C.:

Q. Asking about it. Doctor, in the meantime, you have mentioned Dr. Ejeckam, okay.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. If we could look, please, at Exhibit P-0113. Doctor, this is a series of memos. This one is April 4th, 2003, a memo from Dr. Ejeckam to pathologists, HSC, which would be the General. The Commissioner has seen this on numerous occasions now. Did you receive a copy of this?

DR. MORRIS-LARKIN:

A. Yes, I did.

COFFEY, Q.C.:

Q. And what - first of all, did you have any inkling before receiving this that there was a

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problem with IHC stains?
DR. MORRIS-LARKIN:
A. Not specifically any particular stains, no. I think we always - we were always working towards reducing variability and getting rid of background. Those were - those were things that were part of the evolution of IHC stains in the lab.
COFFEY, Q.C.:
Q. Prior to this, was there a discussion amongst the group of pathologists at the General?
DR. MORRIS-LARKIN:
A. There may have been some discussion at some of the rounds. That still happens. You know, if we have a particular stain that we say, you know, this one is not looking at bright or as distinct as I would like, maybe it's not what I remember from a few months ago, that kind of discussion does go on at the rounds and that's the place where we kind of pick up on other people having any particular issues with something.
COFFEY, Q.C.:
Q. Doctor, we understand Dr. Khalifa, I believe, left in 1999, if I recall correctly, and now

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we understand that Dr. Ejeckam showed up in September, 2002.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. In between those two times, in between Dr. Khalifa leaving and Dr. Ejeckam coming to the General Hospital, who, if anyone, did you associate amongst the pathologists with immunohistochemistry?
DR. MORRIS-LARKIN:
A. No one.
COFFEY, Q.C.:
Q. There was no one particular pathologist who kind of owned it, as it were, or took responsibility, or you would have thought at the time, well, if there's a problem with IHC, I'll talk to Dr. So and So?
DR. MORRIS-LARKIN:
A. No, if I had a problem, I went to the technologists.
COFFEY, Q.C.:
Q. Perhaps you can tell the Commissioner then about that, how did that work?
DR. MORRIS-LARKIN:

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A. Again it would be part of everyday work in a pathology lab, whether you were having problems with perhaps a couple of H & E stains were not quite the usual, or if we needed to cut deeper into a tissue, those are normal things, and if there was too much background in an immunohistochemical stain, I would go to the technologists and say I'm seeing this, and to let them know about it.
COFFEY, Q.C.:
Q. Here having received this memo of April 4th, 2003, what, if anything, was your reaction, your own reaction?
DR. MORRIS-LARKIN:
A. I don't remember exactly, but I think I would have seen that as, well, the variation is beyond our acceptable limits, and I thought it was a very positive thing that Dr. Ejeckam was in place and he was able to focus on the troubleshooting and we did greatly appreciate the efforts of Dr. Ejeckam working with the technologists. I think that it really worked towards quality improvement.
COFFEY, Q.C.:
Q. At the time you understood he was doing what

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in relation to these eight stains?
DR. MORRIS-LARKIN:
A. Specifically, I didn't know, other than -
COFFEY, Q.C.:
Q. Okay.
DR. MORRIS-LARKIN:
A. You know, other than he's saying, "I see there's a problem and I'm going to try to figure it out for you".
COFFEY, Q.C.:
Q. Having been told eight stains including ER and PR have remained unreliable, erratic, and, therefore, unhelpful for diagnostic purposes, at the time did that cause you to have any concerns about any ER/PR slides that you had already reported?
DR. MORRIS-LARKIN:
A. Not specifically.
COFFEY, Q.C.:
Q. Okay, do you recall any discussion at all about that amongst pathologists?
DR. MORRIS-LARKIN:
A. No, not specifically, no.
COFFEY, Q.C.:
Q. Do you recall if, in fact - do you recall any

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discussion you yourself had with anyone else about this?

DR. MORRIS-LARKIN:

A. Again it would have been in general terms about, you know, Dr. Ejeckam is looking into this and it's great that we've got him there to help sort this out for us, to have somebody focused. He had - you know, it was obvious to us that he had both an interest and a greater deal of knowledge than most of us had, certainly than I had.

COFFEY, Q.C.:

Q. And Exhibit C-175. If we could, please, perhaps we could go back to P-0113, I apologize. Here, Doctor, the second page of this, I take it - so you're told that ER/PR and these other six stains are shut down for now?

DR. MORRIS-LARKIN:

A. Right.

COFFEY, Q.C.:

Q. He'll get back to you. This is the May 2nd, 2003, memo from Dr. Ejeckam again to yourself and others. You would have received this as well?

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DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And it says, "I am glad to inform you we have rectified the difficulties related to the immunostaining of ER/PR. Therefore, we can now resume regular requests for these antibody stains. I will, however, like to bring the following information to you attention", and then he goes on at some length, three pages about ER and PR, and different aspects of ER/PR and immunohistochemistry. Doctor, at the time you received the May 2nd memo, 2003, was some of this news to you at the time?

DR. MORRIS-LARKIN:

A. I think perhaps the tissue reprocessing was not something I knew much about.

COFFEY, Q.C.:

Q. Yes.

DR. MORRIS-LARKIN:

A. Certainly - yes, certainly under fixation, I would have appreciated. Over fixation, I was not aware that that would interfere with the ER/PR. So that would have been new to me.

COFFEY, Q.C.:

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Q. And how about delayed fixation?

DR. MORRIS-LARKIN:

A. Oh, definitely, I would have known that, yes.

COFFEY, Q.C.:

Q. And uneven fixation?

DR. MORRIS-LARKIN:

A. Again I would put that all into the under fixation or inadequate type of fixation category.

COFFEY, Q.C.:

Q. Doctor, at that time in May of 2003, from your perspective, who was responsible for ensuring fixation was appropriately carried out?

DR. MORRIS-LARKIN:

A. Well, I think that fixation is something that has a responsibility - the responsibility for fixation crosses a number of disciplines. Certainly we had no control over specimens before they come to us, so there is a responsibility of the people collecting the specimen to make sure that there is an appropriate amount of fixative required, and from within the lab then, it would be my responsibility as a pathologist or the pathology resident who was on to make sure

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that specimens were appropriately handled once they were received in the lab to ensure proper fixation, to not put the specimen blocks onto the processor before they were adequately fixed. So that would have been within our responsibility.

COFFEY, Q.C.:

Q. And did you ever have occasion to complain to the perioperative program about fixation issues?

DR. MORRIS-LARKIN:

A. I did not specifically have that kind of role. I know Dr. Khalifa had spent a great deal of time working with people in the OR at the General Hospital during his time to try and establish the best possible transport. There were often issues with, you know, who's responsible, the porters and that kind of thing, getting specimens from the OR to the lab. From my point of view, if I had a case that was under fixed or if there was some reason there had been a delay, I would include it in my report and that would be the feedback to the surgeon, and that was how I would have seen my role.

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COFFEY, Q.C.:
Q. And inadequate tissue dehydration, I take it, would be the technologists?
DR. MORRIS-LARKIN:
A. That would be a processing technologist issue.
COFFEY, Q.C.:
Q. Tissue reprocessing?
DR. MORRIS-LARKIN:
A. Again it wasn't something I was exposed to.
COFFEY, Q.C.:
Q. And talking about optimal fixation time for immunostains, 18 to 24 hours, 10 percent neutral buffer formalin, was that news to you at the time in terms of the time frames?
DR. MORRIS-LARKIN:
A. No, I don't think so.
COFFEY, Q.C.:
Q. You would have understood that?
DR. MORRIS-LARKIN:
A. I think adequate - again I would put it in the adequate fixation type of category.
COFFEY, Q.C.:
Q. And were there any actual rules at the time, policies, or guidelines in force within the General Hospital site?

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DR. MORRIS-LARKIN:
A. There were general practises, I would have to say, not written policies or procedures, but there was, you know, kind of a standard of practice that you did these things, you attended to the specimens, you appropriately opened or sliced specimens that needed to be fixed, and you didn't put the blocks on before they were ready. If you handled a specimen after some degree of fixation, you will have the option to put the blocks in a container of formalin and then you would tell the technologist leave this again overnight and put it on tomorrow. So that was kind of standards of practice.
COFFEY, Q.C.:
Q. Now, Doctor, here in paragraph two, the reference to ER/PR false negative results, increase in core biopsies. Therefore, where possible, restrict requests for ER/PR to excision biopsies. Whether that's correct or not is another issue, but at the time would that have been news to you?
DR. MORRIS-LARKIN:
A. At the time that would have been news to me,

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yes.
COFFEY, Q.C.:
Q. And, "Check normal breast acini in your sections as internal controls. This is a second level control. Nuclear staining in normal breast tissue is heterogeneous and varies with menstrual cycle". Now you've referred to the fact that you, in fact, were somewhat aware of this even in the early days?
DR. MORRIS-LARKIN:
A. I was, although that was not what I was using as my control reference.
COFFEY, Q.C.:
Q. Did this cause you to change your practice at all, being told this in 2003?
DR. MORRIS-LARKIN:
A. I don't - I think it may have heightened my awareness of a specimen perhaps if I saw something that was totally blank. It may have, but I honestly don't remember specifically.
COFFEY, Q.C.:
Q. Paragraph four, "Carcinoma of the breast, most PR positive tumours are also ER positive", however, he's got a 10 percent of PR positive

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tumours are ER negative, and I appreciate he's saying this in 2003.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Like, 90 percent -- only 10 percent of all tumours would be PR positive, ER negative. Was that news to you at the time?
DR. MORRIS-LARKIN:
A. That was. I did not have an appreciation of the PR usually being ER positive because, in fact, I had reported PR positive cases with ER negative results.
COFFEY, Q.C.:
Q. Did this cause you to change your approach in any way?
DR. MORRIS-LARKIN:
A. Again specifically affecting any case, I don't remember, no.
COFFEY, Q.C.:
Q. And then, "The reporting of ER/PR, certain formulae are in the literature", and he refers to the formulae, including the November 1 to 3 consensus statement of 2000. Did this change your reporting style, Doctor?

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DR. MORRIS-LARKIN:
A. At some point, and I don't know if it was with this or with further discussions with Dr. Carter later, I dropped the comment regarding the biochemistry. I think most of the time - I think probably always, but most of the time I certainly remember reporting percents anyway, and then it was, I thought, what the oncologists would do with that was within their purview.
COFFEY, Q.C.:
Q. Paragraph six refers to cytoplasmic staining, all of it in ER/PR immunostains are to be considered as negative. What's contained in paragraph six, was that news to you at the time?
DR. MORRIS-LARKIN:
A. The variability and intensity wasn't. I think the cytoplasmic staining was something that was often a little bit confusing. It wasn't clear perhaps until this that there were other things that could be contributing to the cytoplasmic staining. I often just considered it as background.
COFFEY, Q.C.:

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Q. Background, and he refers to certain tumours as being ER positive tumours. He lists four of them and he's told us, in fact, there should have been a fifth.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Lobular. Were you aware of these before -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. As being ER positive?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. You were already aware, and lobular as well?
DR. MORRIS-LARKIN:
A. No, I would not have. I was not aware at that time, and I think it was in discussions again with Dr. Carter following the index case that that's when I became aware of the very high frequency I should be expecting positivity in the lobular cases.
COFFEY, Q.C.:
Q. And that would have been in 2005, that

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discussion?
DR. MORRIS-LARKIN:
A. That was 2005, yes.
COFFEY, Q.C.:
Q. You would have been aware of this before, though, at the time you received this in '03, certainly these four?
DR. MORRIS-LARKIN:
A. Not specifically, but again I think it was more tied into number eight where these things, certainly the papillary and the tubular are better differentiated, so within that concept of a better differentiated tumour, more likely to express ER/PR. I think I had that concept.
COFFEY, Q.C.:
Q. Did that ever cause you any idea that some tumours are very much more apt to be positive for ER than others? Did that ever cause you - when you would get something and look at a slide, to think, well, wait now, it's a particular type of tumour, yet I'm not seeing any ER staining?
DR. MORRIS-LARKIN:
A. Again with - I can't recall if I had a tubular

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carcinoma that was negative, so I can't really speak to that.
COFFEY, Q.C.:
Q. Okay. Doctor, if we could look, please, at now then - well, finally, while I'm at it, this page five of the June 19th, 2003, memo from Terry Gulliver - I'm sorry, to Terry Gulliver from Dr. Ejeckam. The Commissioner has seen this on a number of occasions. It was not copied - sent nor copied to you.
DR. MORRIS-LARKIN:
A. No, it wasn't.
COFFEY, Q.C.:
Q. Were you aware of this?
DR. MORRIS-LARKIN:
A. No.
COFFEY, Q.C.:
Q. Not only the memo - you would be aware of it now, but you weren't aware of it back in '03?
DR. MORRIS-LARKIN:
A. No, I was aware of some of the efforts and some of the things that are mentioned here that Dr. Ejeckam was striving for, but not specifically this memo.
COFFEY, Q.C.:

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Q. And here in paragraph six, see this line, "Diagnosis based on inappropriate immunostaining 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 unreliable and erratic immunohistochemical procedures in our laboratory". I appreciate you didn't see this, but was that notion, were you aware of the idea that Dr. Ejeckam felt that way in 2003?

DR. MORRIS-LARKIN:

A. I don't think he had voiced that specifically to me. I did not have a conversation that I recall.

COFFEY, Q.C.:

Q. How about concerns, like, within the lab itself amongst pathologists? This expresses some fairly - at least in writing, some fairly grave concern.

DR. MORRIS-LARKIN:

A. Yes. I think that this - again I can't really tell you what Dr. Ejeckam was thinking, but -

COFFEY, Q.C.:

Q. I'm asking amongst the pathologist as a rule?

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DR. MORRIS-LARKIN:

A. And I don't remember this, you know, this being discussed amongst the pathologists in this sort of way. We're always striving to see improvements and we were seeing Dr. Ejeckam as the lead person who was working with the technologists to do that.

COFFEY, Q.C.:

Q. C-175, please. Doctor, this is a pathology report. The specimen number is 03SU4821. It's received March 31, 2003, which I take it is the day that the pathology lab would have received the specimen?

DR. MORRIS-LARKIN:

A. That's correct.

COFFEY, Q.C.:

Q. And this is - you can see here is a case of yours, and at the bottom of the second page, addendum number one, entered May 6th, 2003, and you'll see the addendum is signed the same day by yourself, and you begin by saying, "The stains have been delayed due to unavailability in the lab. When compared to controls, the specimen is negative for HER2/neu, ER and PR", and then you go on to speak about the HER2/neu scoring, okay?

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DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And then here, addendum number two, which is entered May 9th, 2003, and it's signed by yourself the same day, you've written, "The ER and PR were repeated due to quality assurance issues. The repeated stains show the following; ER positive in 80 percent of the cells, PR positive in 10 percent of the cells. This replaces the previous report. Phoned the Cancer Clinic voice mail on May 9th '03". Doctor, can you tell us then what this was about?

DR. MORRIS-LARKIN:

A. I don't recall the specific case. The timing of it would suggest that in the first addendum, I had requested the ER/PR stain, and that was when Dr. Ejeckam was working on the issue, so I didn't have it until some weeks later.

COFFEY, Q.C.:

Q. When we look back, you would have received this, just to put this in context for the Commissioner, this particular one was received, surgical specimen, March 31 '03. You got the memo of April 4th, 2003, several days later, so you would have known, okay, he's shut it down for now.

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DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And then presumably some time after that, after May 2nd, '03 when he sent you a memo saying it's up and running again, you would have received the ER/PR slides?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. So go ahead, I'm sorry.

DR. MORRIS-LARKIN:

A. So it looks - as I read this, it looks as though I did get a set of slides very shortly after and I reported them, as you see here, and at that time I reported them as negative.

COFFEY, Q.C.:

Q. Right, and then what happened?

DR. MORRIS-LARKIN:

A. I don't know. There are two possibilities

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because within a few days there is the addendum that states that it was repeated due to quality assurance issues. I don't know if that was a quality issue that I was after detecting in my own case and saying I don't feel quite right about this, maybe I better - maybe I'd better repeat it, or if it was something that was triggered by the lab itself, given the timing.

COFFEY, Q.C.:

Q. Here you did repeat the ER and PR. You did not repeat the HER2/neu. At least there's no indication it was repeated.

DR. MORRIS-LARKIN:

A. I don't have a record of it there, no.

COFFEY, Q.C.:

Q. There's no indication here in the records. So within three days of having reported after the resumption of testing in May of '03, then three days - you've had a requisition completed again, reordered, the test is back and you've got the slides, and you're entering it. We can see that here.

DR. MORRIS-LARKIN:

A. Yes.

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COFFEY, Q.C.:

Q. And you've taken - you've been careful to note that you actually did phone the Cancer Clinic presumably to tell them that ignore the first results, there's a new one?

DR. MORRIS-LARKIN:

A. Because there was a significant change.

COFFEY, Q.C.:

Q. Did you tell anybody else about this?

DR. MORRIS-LARKIN:

A. Given the timing of it, I may have spoken to Dr. Ejeckam, but I honestly don't remember if I did.

COFFEY, Q.C.:

Q. Do you recall - you phoned the Cancer Clinic and left a voice mail, you've noted here. You would have left that for whom?

DR. MORRIS-LARKIN:

A. At that time, I don't know which -

COFFEY, Q.C.:

Q. Would it be an oncologist you'd be looking for?

DR. MORRIS-LARKIN:

A. It may have been one of the oncologists. I may have known which oncologist was involved,

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or I may have phoned the Cancer Clinic in general because I wasn't - perhaps I had phoned the surgeon and they had said, well, they've gone to the Cancer Clinic and I didn't know which oncologist, so I may have left it to the general Cancer Clinic voice mail.

COFFEY, Q.C.:

Q. Do you recall -

DR. MORRIS-LARKIN:

A. If I said I phoned to the Cancer Clinic, most likely I left it to a general Cancer Clinic voice mail and that I didn't know which oncologist was dealing with the patient.

COFFEY, Q.C.:

Q. Doctor, do you recall getting any feedback from this?

DR. MORRIS-LARKIN:

A. I don't recall, no.

COFFEY, Q.C.:

Q. And you've certainly just acknowledged that going from - when compared to controls, because you've noted here in addendum one, when compared to controls, which would be external controls?

DR. MORRIS-LARKIN:

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A. At that time I still was probably referring to external controls. It was in that time frame, I think.

COFFEY, Q.C.:

Q. And the specimen is negative for ER and PR. At that time, by the middle of 2003, when you referred to a specimen being negative for ER and PR, that meant what?

DR. MORRIS-LARKIN:

A. It's totally negative.

COFFEY, Q.C.:

Q. Like zeros?

DR. MORRIS-LARKIN:

A. Zeros, yes.

COFFEY, Q.C.:

Q. And then within three days, you're saying the ER is 80 percent and the PR is 10 percent. You say you may have spoken to Dr. Ejeckam about it. Do you recall letting the clinical chief know? This could potentially affect the patient's care, you'd be the first to acknowledge that.

DR. MORRIS-LARKIN:

A. Well, I would have thought that I was impacting the patient's care in a positive

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way.
COFFEY, Q.C.:
Q. Oh, yes.
DR. MORRIS-LARKIN:
A. By making sure that the treating physician had this report. I don't think I would have brought it to the clinical chief. If I brought it to anyone, I would have brought it to Dr. Ejeckam because I would have seen this as something that he would have been delegated by the clinical chief to deal with.
COFFEY, Q.C.:
Q. And the idea how could something go from zero to 80 in three days, was that pursued, do you know?
DR. MORRIS-LARKIN:
A. Again it was around the time where he was looking into the issue, so I would have seen it within that kind of context.
COFFEY, Q.C.:
Q. And the idea that presumably the first set of slides that you used for addendum number one were kind of the newly improved version in terms of the process -
DR. MORRIS-LARKIN:

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A. I can't say that for certain because I don't know exactly what happened there, was this - did the lab release slides that they knew - sorry, I should say it that way, did the lab release slides that were part of this investigation, and then say, well, actually we have a better set for you. I honestly don't remember.
COFFEY, Q.C.:
Q. In terms of how you came to reorder the test, you have no recollection of that?
DR. MORRIS-LARKIN:
A. No.
COFFEY, Q.C.:
Q. Do you know if - did you discuss it with any of your other colleagues, do you recall?
DR. MORRIS-LARKIN:
A. I don't think so. If I spoke with anyone, it would have been Dr. Ejeckam.
COFFEY, Q.C.:
Q. At the time, did you complete an occurrence report?
DR. MORRIS-LARKIN:
A. I don't think I would have, no. I would have seen this within - a change within something

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in daily practice. I mean, we do see these kinds of changes. When we're looking into case, we repeat stains, we get deeper sections, we get additional levels, and sometimes that does - that does bring us to a specific conclusion. So I would have seen it within that kind of realm of practice that I was doing.
COFFEY, Q.C.:
Q. If we could look, please, at exhibit - I take it then that your understanding at the time was this would not require an occurrence report?
DR. MORRIS-LARKIN:
A. I wouldn't have thought it did, no.
COFFEY, Q.C.:
Q. How about today?
DR. MORRIS-LARKIN:
A. I would - today I would see it as what I would refer to as an internal lab occurrence. I think that it's something that needs to be reported within the lab, and to investigate and implement corrective action.
COFFEY, Q.C.:
Q. The idea, for example, because you have - this

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sort of circumstances involved you communicating with in this context the Cancer Clinic?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. So if this was to happen tomorrow, you reported something and then three days later, for whatever reason, you had had the test rerun and had to contact the Cancer Clinic and say ignore that, this is a completely different result, and under the current occurrence reporting regime, would that require an occurrence report, or would it remain internal to the lab?
DR. MORRIS-LARKIN:
A. I don't think that this would require, from my understanding, an occurrence report, and we do fill out lots of occurrence reports. Again this would have been something within the - working towards the best result type of practice.
COFFEY, Q.C.:
Q. So why would it not - if, for example, there wasn't three days between them, but, say,

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three weeks between the two of them, would that require an occurrence report, or three months?

DR. MORRIS-LARKIN:

A. In months, it would I think for sure.

COFFEY, Q.C.:

Q. Why is that?

DR. MORRIS-LARKIN:

A. Well, I think it would depend on the circumstances. Again it's a little out of context and I'm not sure what would - why we would end up doing something like that, other than what we've already been through with the ER/PR retesting. So it's - so that would be a little bit different. I think, you know, depending on how it was identified that you needed to repeat the test months later.

THE COMMISSIONER:

Q. Referencing the occurrence report, is it something having to do with a change in the patient's status or treatment, or - I'm not sure I'm getting why the time makes the difference between the decision to have an occurrence report.

DR. MORRIS-LARKIN:

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A. The occurrence reporting system is corporate wide, and it involves then sending notification to the quality initiatives people, and the kinds of things that would trigger is anything that may potentially interfere with patient care. So if you have mislabelled specimens, if you have inappropriately labelled specimens, that's the kind of thing which I see a number of occurrence reports filled out, and there are a things that occur within the lab that occasionally we would send an occurrence form for. If there is a mislabelled block, that kind of thing, that has any potential impact on a patient's care, again the purpose of it being part of a quality - overall quality management and making people aware of the kinds of events that can occur and getting feedback then to try and prevent those kinds of events, and heighten the vigilance to prevent them.

COFFEY, Q.C.:

Q. And going from zero to 80?

DR. MORRIS-LARKIN:

A. Again in this setting, I would have seen it

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within the context of Dr. Ejeckam has been looking at the ER/PR, you know, we know he's been dealing with an issue and it's related to that, and that's how I would have interpreted that.

THE COMMISSIONER:

Q. So if there had been no Dr. Ejeckam memo, would it have been something that would have been reported?

DR. MORRIS-LARKIN:

A. Again -

THE COMMISSIONER:

Q. Was it because Dr. Ejeckam was already working on it and you say the problem as being identified, or that you did not see this as something that potentially might interfere with a patient's care?

DR. MORRIS-LARKIN:

A. Well, it was within a few days, and I - again at that time, I would have been working within trying to get the best result out, and that would have been my focus. So I would not have - I would have not seen this as something I would fill an occurrence report out on, no.

COFFEY, Q.C.:

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Q. C-184. Doctor, this is 2002 pathology report, July of '02, a report we looked at earlier. I take it this - is this the sort of thing that back in 2002, because Dr. Ejeckam is not involved at this point, he's not even at the General, going from an ER negative result to - as you point out, this correlates a negative ER result to a 30 percent PR - ER result, I'm sorry, best considered a positive ER result. Would that be the sort of thing that would occasion an occurrence report?

DR. MORRIS-LARKIN:

A. Again it wasn't something that I would have thought required an occurrence report, no.

COFFEY, Q.C.:

Q. Although it could have ramifications at the time for patient care? In fact, as you say, that's probably the reason you redid the test.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. No controls, negative.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

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Q. You're uncomfortable and then you redo it and it's positive.
DR. MORRIS-LARKIN:
A. Because it would have made the difference in whether or not--in the choice of treatment they were going to make.
COFFEY, Q.C.:
Q. Yes. I take it today then, if you reported a result and then had occasion to have a retest done and the retest results, to your knowledge, might occasion a change in treatment choice, would that have -
DR. MORRIS-LARKIN:
A. We have had--you know, there are cases where under--particularly under quality assurance types of audits that we do, we've had changes in diagnosis and those do trigger occurrence reports.
COFFEY, Q.C.:
Q. Now, if we could look, please, at Exhibit P-2426? And Doctor, before I get--I'll take you--if I could go to page 29, please? We go to this, then I take it, Doctor, after Dr. Ejeckam's May 2nd, 2003 memo and that pathology report we looked at involving May

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6th and May 9th, we just looked at just then, after that, in terms of ER/PR, do you recall anything else coming up about ER/PR or did it just continue on, in terms of your reporting your cases in a routine fashion?
DR. MORRIS-LARKIN:
A. In that 2003?
COFFEY, Q.C.:
Q. In 2003, yes, '03/04.
DR. MORRIS-LARKIN:
A. Things just continued on.
COFFEY, Q.C.:
Q. If we could up C-0174 please? Just before I go to 2004, I want to--C-0174 please. Now Doctor, this does not involve yourself. It's a pathology report. Does not involve a patient of yours, but you'll note here, the specimen number is 02SS5231, received July 5th '02, back in July of 2002. It's a report by Dr. Elms and here, he had reported the case originally, entered it and reported it on August 29th, 2002, reporting ER as negative and PR as 15--approximately 15 percent of lesional cells, and then addendum number three, entered June 11th, 2003 and signed the

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same day, he says "at the request of Dr. Zaidi, IHC staining for estrogen and progesterone receptors has been repeated. ER receptors show faint positivity in approximately 10 to 15 percent of lesional cells. Progesterone receptors are unequivocally positive in approximately 75 percent of lesional cells." I appreciate Dr. Elms, at the time, was at St. Clare's and you were at the General.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. But again, the idea that a retest would be done in June of '03, had one done in May of '03, there was no talk generally amongst the pathologists about--well, we--you know, you had had one redone, results changed, zero to 80. He had had one redone after a year, zero to 10 to 15.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Which we understand would have clinical significance. There was no talk amongst the

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pathologists when you got together about, you know, the fact that "Ejeckam's been here and has reinstituted this and we're getting--some of us are getting changed results"?
DR. MORRIS-LARKIN:
A. I don't recall there being any discussion.
COFFEY, Q.C.:
Q. I apologize, I was at 2426. Doctor, this is--these are minutes of a QC/QA meeting at the Health Care Corporation of St. John's, November 9th '04. Again, you're not listed as being one of those present, but paragraph two, "two aspects of the QC/QA committee mandate were briefly introduced" and paragraph three, "within the department, two aspects of QA/QC will be begun by anatomical pathologists. These are the intradepartmental consultation review and frozen section review," and it goes on to talk about it from there. Doctor, if I could, please--just a moment, Commissioner. You've referred already to Dr. Carter. You know Dr. Carter certainly.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:

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Q. Dr. Carter showed up in the early 2000s, here in St. John's, in terms of she came to St. Clare's on staff.
DR. MORRIS-LARKIN:
A. I think in 2003, she did some locums.
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. At the General Hospital site, and then St. Clare's.
COFFEY, Q.C.:
Q. Did you have any understanding about whether she had any particular training in relation to breast cancer or breast pathology, I'm sorry?
DR. MORRIS-LARKIN:
A. Yes, I knew she had done the year's fellowship, I believe, in Nashville.
COFFEY, Q.C.:
Q. And could you tell us please then about this QA/QC initiative, that I gather Dr. Carter in particular was involved in in 2004, what you recall about that?
DR. MORRIS-LARKIN:
A. I don't know much about the details. I knew that there was a QA committee and that Dr.

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Carter and Dr. Ejeckam were both involved.
COFFEY, Q.C.:
Q. And do you recall when this was first raised, the idea that there--did you have any concerns or was that later?
DR. MORRIS-LARKIN:
A. I'm not sure what you're asking.
COFFEY, Q.C.:
Q. Okay, I'll come back to that. If I could, please, P-1908, page two? 1908. I'm sorry, 1908, apologize. These are minutes of a meeting of March 2nd, 2004, Dr. Larkin. You're noted to be present. It's a pathologists meeting at the General Hospital. Under 3.3, specimen grossing, it says "some changes of specimen grossing will start effective March 1/04, mainly of the large specimens. This will allow overnight fixation and processing the day of grossing. Pathologists are asked to process all specimens on the same day or next morning to keep the work flow updated." Do you recall what this was about or what change is implemented?
DR. MORRIS-LARKIN:

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A. Well, I think we were always undergoing or always looking at how best to address the work flow. We had made a number of changes in how we scheduled ourselves and residents over the years. I think this specifically is referring to the timing of getting pathology specimens, the appropriate timing for getting pathology specimens onto the processor in such a way that things were adequately fixed, but things were not overly delayed. So again, trying to find that right balance. One of the issues that often would come up is if my day to attend gross specimens was today, but I've got meetings and teaching and other things that interfere, then I may spill my work over into the next day and there's only so much available space and that last line refers to that, "to process all specimens on the same day or the next morning to keep the work flow updated," so we weren't all, you know, vying for the same limited space at the same time.
COFFEY, Q.C.:
Q. Okay, and if we could look at 2406, please, 2406, page three? Actually, I'll go back to page one, to put it in context for you. Just

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leave it there, please. These are minutes of a pathologist meeting, group of pathologists meeting at the General Hospital, September 1/04. You're noted to be present. Doctor, here on paragraph 3.6, "HER2/neu, ER and PR immunostaining." It notes "Dr. D. Fontaine did mention that Dr. Bev Carter would like to review all the new HER2/neu, ER and PR immunostaining before returning to the reporting pathologist. Some members of the division expressed that this is unnecessary and they will continue reporting their own cases." Now this is September of '04, Doctor. Do you recall what this was about?
DR. MORRIS-LARKIN:
A. I do recall this meeting and my recollection is that the main concern expressed by pathologists, including myself, was losing the experience in any aspect of pathology. We have some subspecialization and we knew what it was like when our renal pathologist or our neuropathologist went away, and we hadn't seen a case for a period of time. We also knew that with the frequent turnover of people that this was something we couldn't afford to do

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was to lose any broad skills that we had. So my recollection was it was more about the concern of losing skills than about Dr. Carter looking at anything specific, and in fact, certainly I frequently sent Dr. Carter cases. I knew of her expertise and I often asked her questions and she was always very happy to even take the case and say "I'll take it and sign it out."

COFFEY, Q.C.:

Q. Doctor, then in relation to what brings us here today in particular, the ER/PR matter, when did you first become aware of it, as an issue?

DR. MORRIS-LARKIN:

A. That this was a bigger issue?

COFFEY, Q.C.:

Q. Yes, or an issue at all, first of all.

DR. MORRIS-LARKIN:

A. In the summer of 2005, I believe.

COFFEY, Q.C.:

Q. An issue at all.

DR. MORRIS-LARKIN:

A. Yes, in the summer of 2005.

COFFEY, Q.C.:

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Q. Okay. What do you recall about that?

DR. MORRIS-LARKIN:

A. At that time, I recall hearing some discussion about the particular case that we call the index case now. Of course, many of us were familiar with Dr. Deane, although we may not have known him personally, and so--and he was quite free in discussing it, from what I understand. So we were aware that that case had happened and that that had triggered a relook at what's going on with regards to specifically then the lobular carcinoma cases, I think, were the things that Dr. McCarthy and Dr. Carter had been most addressing, and from that then, I was aware that Dr. Carter was after doing some repeats. I didn't know the details of it, and then we had a meeting with Dr. Cook and Dr. Carter, basically summarizing what they knew to that point and giving us an outline of what was happening and where things were going.

COFFEY, Q.C.:

Q. Where was that meeting?

DR. MORRIS-LARKIN:

A. I believe that meeting was at the Health Science.

COFFEY, Q.C.:

Q. And you recall Dr. Cook and Carter being there and you understood that they were telling you what we found to date, as it were?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, what do you recall about what they told you?

DR. MORRIS-LARKIN:

A. Well, some of the things that I've just outlined really and that I believe mainly Bev, but had repeated a number of cases and looked at the stains on a number of cases and within our lab, we had seen the cases that had been previously negative, she now, on the repeats, had positive results.

COFFEY, Q.C.:

Q. Did she tell you anything else about observations she had made about the quality of the slides?

DR. MORRIS-LARKIN:

A. I think there were some general discussions. Whether they were specifically at that meeting

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or in the, you know, obviously numerous conversations that occurred during that time.

COFFEY, Q.C.:

Q. And at the time, Doctor, as a staff pathologist, did you think to go look at any of your earlier cases yourself?

DR. MORRIS-LARKIN:

A. Well, at that time, I don't think I would have even known how to do it, other than to do a computer search of all breast cases. It would have been very cumbersome and at that time, we also had to continue on with the everyday work. So I wouldn't have had the time to try and do that kind of search, or the computer skills really to be able to search that out.

COFFEY, Q.C.:

Q. Mr. Simmons, earlier this morning, you gave me an exhibit number.

MR. SIMMONS:

Q. I think it was 0076.

COFFEY, Q.C.:

Q. 0076. Thank you very much. P-0076, please. Yes, you have a good memory, Mr. Simmons. This is a memo of July 28th, 2005. It's from Doctors Cook and Carter to all pathologists

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and pathology residents in the St. John's Eastern Hospitals of Eastern Health. The subject is optimal assessment and reporting of hormone receptor status in infiltrating carcinoma, and it goes on, it's in effect a nine-point process to achieving optimal assessment in reporting of hormone receptor status. Doctor, did you receive a copy of this?

DR. MORRIS-LARKIN:

A. Yes, I did.

COFFEY, Q.C.:

Q. And would have been just on July 28th or shortly thereafter?

DR. MORRIS-LARKIN:

A. In that time frame, yes.

COFFEY, Q.C.:

Q. And what, if anything, did you understand about the purpose for which this was sent to you?

DR. MORRIS-LARKIN:

A. I think it was again to try and--to standardize things, to kind of building on what Dr. Ejeckam had sent out previously, a little bit more concise, a little bit clearer,

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easier to follow and just, you know, the things that we could reference when we did report ER/PR.

COFFEY, Q.C.:

Q. Now Doctor, I take it at the time you received this, it was still anticipated that you would be reporting cases at that point?

DR. MORRIS-LARKIN:

A. It was anticipated, yes.

COFFEY, Q.C.:

Q. Still that you would continue on?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. I gather things changed just after this, but -

DR. MORRIS-LARKIN:

A. Very shortly after.

COFFEY, Q.C.:

Q. Doctor, at the time, did you have any understanding about what kind of review Dr. Carter had been involved in in the second half of July?

DR. MORRIS-LARKIN:

A. Not specifically, other than that she had--I think I knew that she had looked at some of

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the old slides and that she had repeated stains on some of these cases.

COFFEY, Q.C.:

Q. Did you know anything--and I appreciate the retesting, you had been told that a number of them had changed results.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. How about her observations concerning the old slides or the original slides?

DR. MORRIS-LARKIN:

A. I know that she had--these were archival slides. I don't know how far she had gone back. I know she expressed concerns about a number of things -

COFFEY, Q.C.:

Q. Do you recall -

DR. MORRIS-LARKIN:

A. - with regards to the slides. She mentioned of the things that we've talked about with regards to internal controls, with tissue staining on the slides, you know, with holes in the slides. I think those kinds of things probably were mentioned.

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COFFEY, Q.C.:

Q. And this would be during this meeting that her and Dr. Cook had with a group of pathologists?

DR. MORRIS-LARKIN:

A. I believe during that meeting and around that time. I can't zone in specifically on when, but you know, within that context.

COFFEY, Q.C.:

Q. And here's where I'm getting at, Doctor. As a pathologist at the time at the General Hospital, okay, and I appreciate Doctors Cook and Carter were at St. Clare's, based at St. Clare's?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. But at the end of July, early August, you were aware that Dr. Carter had been conducting some kind of a review, looking at old slides, original slides, and she'd been doing some retesting?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. You knew that a number of the retest results

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involved conversions, what we now call conversions?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And she had noted a number of problems with, from her perspective, the original slides.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Fixation issues, holes in tissue, internal controls not there, internal controls there and not stained.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And the significance of that potentially.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And she communicated that, with Dr. Cook's knowledge, to the pathologists at the General Hospital?
DR. MORRIS-LARKIN:
A. Again, I do -

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COFFEY, Q.C.:
Q. And freely?
DR. MORRIS-LARKIN:
A. I do think it was at a meeting, although there was so much happened at that time that it's hard to be certain.
COFFEY, Q.C.:
Q. But you your -
DR. MORRIS-LARKIN:
A. But there was an effort made on their part to let the people at the General Hospital site know what was going on because we didn't really, the same way that people at St. Clare's probably knew, just because of the proximity.
COFFEY, Q.C.:
Q. Doctor, so I take it then that by the time you'd learned what Dr. Carter, at least in her view, had concluded, to whatever extent she had conducted this review, did you have an understanding then that the problem or problems were not related to a change from one piece of equipment to another?
DR. MORRIS-LARKIN:
A. In all honesty, at that time, I did think that

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the change in equipment had a role to play.
COFFEY, Q.C.:
Q. Did you?
DR. MORRIS-LARKIN:
A. We had seen, in probably the couple of years prior to that, slides that were crisper where, you know, it was easier to read. You weren't struggling with background and I had seen what I thought was quality improvement. Whether it was due to a change in the machine, whether it was due to the efforts of Dr. Ejeckam or a combination, I don't know, but I certainly did see a difference.
COFFEY, Q.C.:
Q. And when she told you--not you in particular, but you, as a group, that internal controls, there was a problem with internal controls in the earlier--in the years gone by -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. - with fixation issues?
DR. MORRIS-LARKIN:
A. I don't remember if fixation was--yes, I do think she referred to fixation at the time as

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well, and that would have been--she would have been the one during that conversation that I first learned about over fixation in a real significant way. I know it was mentioned in Dr. Ejeckam's memo as well, but I think it was a particular issue for Dr. Carter.
COFFEY, Q.C.:
Q. Exhibit P-1994, 1994.
THE COMMISSIONER:
Q. Where you can find a spot, Mr. Coffey, we'll take the morning break.
COFFEY, Q.C.:
Q. Okay, Commissioner. Doctor, this is a meeting, notes of a meeting of August 5th, 2005 involving Dr. Fontaine, yourself and a number of others listed here. Dr. Cook is there. It's a meeting of pathologists. Do you recall this meeting?
DR. MORRIS-LARKIN:
A. Yes, I do.
COFFEY, Q.C.:
Q. Do you know anything about who typed this up?
DR. MORRIS-LARKIN:
A. I'm fairly certain it was me. I couldn't find the record on my computer, but it has my style

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and it's the kind of thing that I--it has my style of writing and it's the kind of thing I would have done to sort of help crystallize things for Dr. Cook, because of course, he was at the General site and--sorry, at the St. Clare's site and we were talking at the General site, and it sort of reflected the kinds of communications and the level of anxiety, I think, that was going on that he may not have been seeing and we wanted to try and put it into some form for him.

COFFEY, Q.C.:

Q. So you believe that it's likely, more likely than not, you typed this for the purpose of as an agenda as it were, in the sense of setting out the nature of the concerns for Dr. Cook?

DR. MORRIS-LARKIN:

A. Well, I think I did it as trying to crystallize -

COFFEY, Q.C.:

Q. Crystallize, I -

DR. MORRIS-LARKIN:

A. - some of those, some of the things that -

COFFEY, Q.C.:

Q. Before the meeting -

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DR. MORRIS-LARKIN:

A. - had been expressed, before the meeting, or between--I think we had had two meetings. I think there had been one where we first learned about the issue and then there was a great deal of discussion and various things were being said and it was, again, a time of very high emotional activity, and so I thought it was most effective to put a few things to paper for Dr. Cook.

COFFEY, Q.C.:

Q. After the break, Commissioner, thank you.

THE COMMISSIONER:

Q. Take 15 minutes.

(BREAK)

THE COMMISSIONER:

Q. Mr. Coffey.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Exhibit P-1994, please? 1994. Doctor, just to go down through this briefly, you begin by saying "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 then

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"important features of the ongoing process should include: cooperation, transparency, communication, dissemination of information as the process evolves, avoidance of fingerpointing to either individuals or a group of individuals and 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." Which ongoing study was that?

DR. MORRIS-LARKIN:

A. I think that that was referring to what Dr. Carter wanted to do with regards to looking further into the previous cases.

COFFEY, Q.C.:

Q. And referring to "if the purpose is to compare methods," compare what sorts of methods?

DR. MORRIS-LARKIN:

A. Again, at that time, I would have very much seen it as an evolving methodology issue that we had changed what we were doing and we had seen an improvement as a result.

COFFEY, Q.C.:

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Q. And changed what we are--changed when?

DR. MORRIS-LARKIN:

A. Well, again, at some point with the change in the machine.

COFFEY, Q.C.:

Q. Okay.

DR. MORRIS-LARKIN:

A. You know, to me, that did play a factor in the timing of this.

COFFEY, Q.C.:

Q. Now here too, Doctor, the fourth bullet above says "dissemination of information as the process evolves," that fourth bullet.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Up to that point, and this is early August 2005, how much, if any, information were staff pathologists getting concerning what was going on?

DR. MORRIS-LARKIN:

A. I don't think there was anything formal, because you know, I think that Dr. Carter and Dr. Cook were doing the best they could to deal with the issue and they were probably,

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you know, very, very busy with that, but you hear bits of information and then that gets distorted.

COFFEY, Q.C.:

Q. Yes.

DR. MORRIS-LARKIN:

A. So it was a matter of looking for--you know, looking to find out what was going on and know that what was being said was what was actually happening, not, you know, the rumour mill kind of thing.

COFFEY, Q.C.:

Q. And Doctor, now around this time, in fact, the decision was made to have the samples going back over years retested at Mount Sinai. It was around this point, okay, in fact probably actually a day or two before, but it's not referred to here.

DR. MORRIS-LARKIN:

A. Okay.

COFFEY, Q.C.:

Q. And when did you first become aware that Mount Sinai was using a DAKO machine to do the retesting?

DR. MORRIS-LARKIN:

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A. Oh, it probably would have been sometime later, much later.

COFFEY, Q.C.:

Q. Much later, okay. Here, you say "if the purpose is to compare methods, then the following are important features: assume pathologist reported the original test correctly." Now why would one assume that if under the newer and better machine, as it were, which you understood, was producing a different result?

DR. MORRIS-LARKIN:

A. Well, I think what that's referring to is again, it's if the purpose is to compare methods, then you shouldn't be looking at the variable--the other variable of the pathologist. That was a separate issue, and if the purpose was to compare methods, then to compare how we reported on one method versus how you reported on another.

COFFEY, Q.C.:

Q. What was the reaction amongst pathologists then to being told about Dr. Carter's observations about fixation, poor fixation or fixation issues, you know, internal controls

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not having been chosen, not having been included, not having stained, which presumably are comments directed at pathologist issues themselves, what was the reaction amongst pathologists?

DR. MORRIS-LARKIN:

A. I think that the pathologists probably--or I think that what I heard then was concern, you know. For me, I would have said "well, my goodness, did I do things the right way?" I would have been second guessing, questioning myself and thinking "how did I do it?" and you know, what impact would it have had, and I think that that's probably fair to say that many of the other pathologists were going through that same kind of mental exercise.

COFFEY, Q.C.:

Q. Doctor, when did you first hear that Dr. Carter had removed herself from this review process?

DR. MORRIS-LARKIN:

A. The exact timing, I don't remember. I do remember her saying it to me that, you know, "I've quit."

COFFEY, Q.C.:

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Q. Did she tell you why?

DR. MORRIS-LARKIN:

A. I think, and I don't want to misquote her, but I think that she felt that she couldn't get a resolution with the way some people in the group were wanting to approach this and the way she felt it should be approached. The bottom line that I come away with is she felt that the lab shouldn't investigate itself, that somebody else should do it. So that's what I think -

COFFEY, Q.C.:

Q. That was your understanding.

DR. MORRIS-LARKIN:

A. I remember her, you know, being the main issue for her.

COFFEY, Q.C.:

Q. Here, this is circled with--kind of over here to the side, would that be something you'd have done?

DR. MORRIS-LARKIN:

A. No. This has Dr. Cook's writing on it.

COFFEY, Q.C.:

Q. Yes.

DR. MORRIS-LARKIN:

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A. So I think he probably would have provided that and he may have done that.
COFFEY, Q.C.:
Q. "Persons conducting the study do not need to know which pathologist signed the report originally." Why is that?
DR. MORRIS-LARKIN:
A. Well, at that time, again, we were looking at it, you know--I was looking at it, as a pathologist, looking at comparing methods. We'd seen improvements. I had certainly attributed to an improvement in method, and I didn't think that it was necessary for an individual to introduce any--for one person to introduce bias into it, and I felt that that was potentially what could happen if--I mean, people being people, you go in with preformed notions of things. So I just thought that, you know, in the interest of being unbiased, that that was the kind of thing that should be done.
COFFEY, Q.C.:
Q. It says "anything else is an audit of individual pathologists, and if that is the aim, this is not the proper procedure for an

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audit of pathologists performance." What would be the proper procedure?
DR. MORRIS-LARKIN:
A. Well, the proper procedure would be, you know, again in relation to the kind of quality assurance principles that we see, you don't do retrospective--at this time, we'd not seen the kind of retrospective review of archival material that we've seen in recent years. So this was totally a foreign concept. What we were familiar with, in terms of auditing pathologists, would be, first of all, the kind of auditing we do ourselves by sharing our cases at rounds, by getting external consults and, you know, comparing what we thought with an external consultant and the kind of one percent audit or two percent whatever a department chooses of random review of cases and other things that are done within a time frame that's usually within a few months of when a pathologist signs a case. So it's a different sort of--totally different sort of approach.
COFFEY, Q.C.:
Q. Did this have anything to do with peer review,

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formal peer review?
DR. MORRIS-LARKIN:
A. This thing specifically?
COFFEY, Q.C.:
Q. Yes, like the reference to proper procedure, were you thinking of peer review?
DR. MORRIS-LARKIN:
A. Well, any of these kind of quality assurance activities I would consider peer review, yes.
COFFEY, Q.C.:
Q. And there was a formalized procedure for that, you would have been aware of that?
DR. MORRIS-LARKIN:
A. At this time?
COFFEY, Q.C.:
Q. Would you have been aware that there was a formal procedure in existence at the General Hospital concerning peer review?
DR. MORRIS-LARKIN:
A. That, I don't think I was aware that that kind of thing existed. That's a different issue from what I'm referring to here.
COFFEY, Q.C.:
Q. Okay, and then you go on to talk about "we should not be working in a culture where

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pathologists feel they are being criticized for past performances, avoid generalized statements such as," and there are a number of them attributed here. "These statements, as well as loud discussions around the issue in corridors of high public traffic are threatening and demoralizing." Now Doctor, does this accurately reflect kind of the feeling amongst the pathologists at the General Hospital at the time?
DR. MORRIS-LARKIN:
A. It accurately reflects my feeling and at least several of the pathologists who I had conversations with at that time, yes.
COFFEY, Q.C.:
Q. Okay, and there's a final reference to a pathologists outside the Health Care Corporation, which would be outside St. John's in particular.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And you assert that they need to be informed and told about it and reassured about the process that's going to happen, thinking about

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your colleagues outside.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. What was the result of this meeting?
DR. MORRIS-LARKIN:
A. I think Dr. Cook was very receptive to the points, some of the points that were brought to him. He appreciated that this was, you know, a very big issue for all of us and that we were concerned and I think that he took this and did his best, you know, to incorporate some of our suggestions in the proceedings that followed.
COFFEY, Q.C.:
Q. Exhibit P-1953? Some minutes of a meeting of pathologists at the General Hospital site, October 4th, 2005. You'll note you're there, Doctor. Here in paragraph 3.2, update on ER/PR status, reads "as all are aware, the media has gotten a hold of this issue. We are still in the process of determining how extensive this problem is. In view of this discussion with Dr. Cook, he has appointed Dr. Bev Carter as the point person for HER2/neu

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testing. With this in mind, there was some sentiment from the pathologists that Dr. Carter should review all breast cases with a back up person to cover in her absence. A letter to this effect will be sent to Dr. Cook stating the opinion of the pathologists at this site," which would be the General Hospital, "and this will be discussed with Dr. Carter as well." So I take it, Doctor, here that in light of what--the circumstances that existed in October 2005, things had changed. The view of having Dr. Carter look at all cases since September of '04, the breast cases, people were content to have her look at them?
DR. MORRIS-LARKIN:
A. I think that this reflects the sentiment that many of us were feeling that this was, of course, a very sensitive issue and that there were areas of expertise that Dr. Carter could contribute, especially now where we were going with the retesting that was being done of Mount Sinai.
COFFEY, Q.C.:
Q. Here, Doctor, 3.3, update on pathology

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assistants. "In view of the problems outlined in 3.2, there has been a decision that there will be pathology assistants made available to standardize the gross room. The pathologists expressed concerns about the qualifications of these individuals. A letter to Dr. Cook with copies to Doctors Williams and--I'm sorry, Dr. Williams and Terry Gulliver, will be sent outlining qualifications of these individuals as well as training expectations." Doctor, I take it then that there was a linkage between finally getting pathology assistants and the problem in the middle of '05?
DR. MORRIS-LARKIN:
A. Absolutely.
COFFEY, Q.C.:
Q. Yes, and the idea that there are concerns being expressed about the qualifications of these individuals and standardizing the gross room, okay, I take it that the advantage of having pathology assistants, a limited group in terms of standardization is what?
DR. MORRIS-LARKIN:
A. The advantage?
COFFEY, Q.C.:

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Q. Yes.
DR. MORRIS-LARKIN:
A. Again, if you have a group of people who develop a special--you know, develop expertise which we would anticipate pathologists assistants would, then you're more likely to have standard standardized approaches to everything.
COFFEY, Q.C.:
Q. Had there been a--bearing in--at the time when pathologists generally were doing their own grossing, each pathologist was doing his or her own and residents might be assisting -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. - was there a lack of standardization in that regard?
DR. MORRIS-LARKIN:
A. There were no standard written procedures, other than the references that we would refer to. There was, I'm sure you've heard about the Acerman Surgical Pathology book.
COFFEY, Q.C.:
Q. Yes.

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DR. MORRIS-LARKIN:
A. At this time, we had in the department a copy of the Lester Approach to Surgical Pathology, which has a great deal of detailed grossing procedures, but that had just probably come into the department around that time. So there were references, but there was no one procedure that -
COFFEY, Q.C.:
Q. Everybody agreed to.
DR. MORRIS-LARKIN:
A. - everyone specifically followed. You know, in general, most things were done the same way, I think it's fair to say.
COFFEY, Q.C.:
Q. And, Doctor, the reference to expressed concerns about the qualifications of these individuals who have become pathology assistants, I understand that you became very involved in that afterward?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. In the early days in October of '05, was there anything really known in St. John's about how

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a pathology assistant would be trained?
DR. MORRIS-LARKIN:
A. At that time, no, and I think that's what that statement reflects.
COFFEY, Q.C.:
Q. Okay. Doctor, the next page, paragraph 4.2, "Resident reporting of cases. Dr. Morris-Larkin brought it to the attention of the group that residents are typing cases on their own without the use of the secretarial pool. This has created confusion as there is generally several reports included in the chart as to which the staff pathologist may have difficulty identifying which is the most recent. From this, it was agreed that the policy on resident reporting of cases should be done through the secretaries, and the autopsy should be dictated at time of autopsy. There needs to be strict enforcing of policies as well as standardization of the grossing approach to be used by residents". I take it, Doctor, that you were complaining about variability across the system?
DR. MORRIS-LARKIN:
A. Yes.

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COFFEY, Q.C.:
Q. Here -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And wanted it addressed?
DR. MORRIS-LARKIN:
A. I think there are two separate issues in there. The first was specifically with regards to autopsy files, and then the second was with regards to the grossing to be used by the residents. It was an important part of residents training that we were trying to all do things the same way as well, so that the residents would be consistently trained.
COFFEY, Q.C.:
Q. As opposed to being with you one day, and being trained in a particular way -
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And then next week potentially being with another pathologist and being trained in respect of the same procedure to do something in a different manner? That's what you're

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getting at, is it?
DR. MORRIS-LARKIN:
A. In part, but there are always some variations on a theme that are acceptable, but then the more we tried to standardize, the better it would be for the residents training. That's what that's referring to.
COFFEY, Q.C.:
Q. The idea of having difficulty finding something in a particular part of a pathology report, confusion, generally several reports, staff pathologists may have difficulty identifying which is the most recent. Is that a problem?
DR. MORRIS-LARKIN:
A. I believe -
COFFEY, Q.C.:
Q. Or has it been a problem in the past?
DR. MORRIS-LARKIN:
A. I believe that this specifically is referring to the autopsy report and the files, and having the most current version of the autopsy report in work and draft form in the file.
COFFEY, Q.C.:
Q. How about within pathology reports, not

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autopsy, but pathology reports, for example, the ER and PR and breast cancer cases, we've seen examples of it, addendum are all over - potentially all over the place, and sometimes inserted right in the middle of other text?

DR. MORRIS-LARKIN:

A. And that, I think, is something that has been resolved. Whenever I see an addendum now, my expectation is an addendum should always be up front because then when a report comes out, if you just have the report up front, the clinician is going to look at it and say, well, I already saw that, they're not going to be flipping through to find any addendums whereas the way that repots are generated now, the paper is such that the most recent addendum is at the top of the page on the front page.

COFFEY, Q.C.:

Q. And even ones we looked at earlier this morning didn't have that?

DR. MORRIS-LARKIN:

A. Yes, and we don't see them like that now.

COFFEY, Q.C.:

Q. And that has occurred since 2005, I take it,

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that difference in approach?

DR. MORRIS-LARKIN:

A. I'm not sure when that particular change occurred. That was - it was sort of a managerial organizational thing.

COFFEY, Q.C.:

Q. Exhibit P-1957. Doctor, this is one of a couple of exhibits involving Dr. Banerjee's report of October 17th, 2005, external quality review of immunohistochemical service. Doctor, when did you first see a copy of this report?

DR. MORRIS-LARKIN:

A. When it was posted on the Commission website.

COFFEY, Q.C.:

Q. That would be in 2008?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. 2008.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Had you ever asked for it before that?

DR. MORRIS-LARKIN:

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A. I don't think I ever asked for it. I think I alluded to it, you know, what is this repot, what is it, where is it, that kind of thing, but, no, I never asked for it.

COFFEY, Q.C.:

Q. What exposure, if any, had you had to it or its contents?

DR. MORRIS-LARKIN:

A. The only exposure I had to it was in the fall or early winter of 2007 when Dr. Denic was discussing the Eastern Health's concern about this being a peer review report, and he read one or two points from it. That's the only time - I believe it was presented to the pathologists at a period before, but I was away at that time.

COFFEY, Q.C.:

Q. Doctor, if we could just look at - you've had an opportunity since its gone on the website, anyway, to look at this?

DR. MORRIS-LARKIN:

A. Yes, I have.

COFFEY, Q.C.:

Q. Doctor, here under review of cases, page four of the exhibit, Dr. Banerjee talks about poor

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fixation, negative internal controls, and absent internal controls.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. These are the same subject matters that, in fact, Dr. Carter had referred to -

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Back in the middle of '05, hadn't she?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And here under the heading, conclusions about the reasons for test failure, "Is the DAKO System faulty", he says no. "The Ventana System too sensitive", and he says "no evidence that it produces false positive results". Was this the first time when you read this that you learned that?

DR. MORRIS-LARKIN:

A. No, because I think that that discussion would have been happening - you know, in particular, Dr. Carter had referred to the fact that DAKO

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had been used in other places and she did not feel that that was the issue.

COFFEY, Q.C.:

Q. And the problem with tissue fixation, and he goes on to talk about that.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. But again in the context here, "Inadequate attention paid by the grossing pathologist to the thickness of tissue slices, quality and adequacy of fixation, no standardized fixation protocol everyone adheres to", was that something that Dr. Carter, in effect, was speaking about in the middle of 2005?

DR. MORRIS-LARKIN:

A. I do think she referred to issues of tissue fixation being reflected on the slides that she had seen, yes.

COFFEY, Q.C.:

Q. And where she got down to, though, that you should be doing breadloafing at 10 millimetres or whatever, in fact, she may have -

DR. MORRIS-LARKIN:

A. I think that was something that was so widely

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known for so long, that would have been the practice.

COFFEY, Q.C.:

Q. Okay, that was already known.

DR. MORRIS-LARKIN:

A. Yeah.

COFFEY, Q.C.:

Q. So he's just making the observation, though, that in his view, anyway, inadequate attention is being paid to actually getting it down to the required maximum size. You were aware there was no standardized fixation protocol everyone adheres to?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. You were aware of that before. "Inadequate or no attention is paid by the reporting pathologist to the status of internal controls". Well, that, in fact, repeats what we --

DR. MORRIS-LARKIN:

A. These were things that we had already been talking about with Dr. Carter and Dr. Cook.

COFFEY, Q.C.:

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Q. Paragraph six is the same thing.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Internal controls, and better education was required for all concerned.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. In his view. That wouldn't have been news to you, I take it?

DR. MORRIS-LARKIN:

A. No.

COFFEY, Q.C.:

Q. Certainly by the time you met on August 5th, 2005, that list of concerns of yours, the idea that everybody concerned should know more about this and should be better educated about it, you were all very aware of that?

DR. MORRIS-LARKIN:

A. Yes, yes.

COFFEY, Q.C.:

Q. Doctor, you would have been aware that Dr. Banerjee was here in 2005?

DR. MORRIS-LARKIN:

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A. I did not know until he had come and gone.

COFFEY, Q.C.:

Q. Okay, I appreciate that.

DR. MORRIS-LARKIN:

A. But I was aware that he had been in, yes.

COFFEY, Q.C.:

Q. Doctor, now having had a chance to look at this in 2008, would it have been of some assistance to yourself to actually have seen this in 2005?

DR. MORRIS-LARKIN:

A. To have seen this?

COFFEY, Q.C.:

Q. To actually have it spelled out in this way, yes, in late 2005?

DR. MORRIS-LARKIN:

A. I don't think that there's anything in this that we didn't already address in numerous meetings, general discussions, one on one discussions with each other.

COFFEY, Q.C.:

Q. Would there have been any advantage, though, to actually having it spelled out by someone, an outsider in writing, recorder and seen, and you can sit and read it and think about it?

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DR. MORRIS-LARKIN:
A. Again, you know, it does put things - all the things that we've talked about into one document, which makes it easier to refer to.
COFFEY, Q.C.:
Q. Doctor, the idea that you wouldn't be given a copy of it, why wouldn't you be given - what was your understanding about why you didn't get a copy of that report?
DR. MORRIS-LARKIN:
A. I was not really aware of the actual process that had gone on at all. It was my understanding when it became an issue last year that it was seen as a peer review process, and I accepted that as it was described. I think many of the recommendations had been taken and implemented.
COFFEY, Q.C.:
Q. Would it have made any difference in this whole process to have someone from the outside come in and give his observations, even if they just reinforced what the internal investigator had found?
DR. MORRIS-LARKIN:

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A. Yes.
COFFEY, Q.C.:
Q. It helps, doesn't it?
DR. MORRIS-LARKIN:
A. It does.
COFFEY, Q.C.:
Q. To have somebody from outside?
DR. MORRIS-LARKIN:
A. Oh, yes.
COFFEY, Q.C.:
Q. Exhibit P-2068. Doctor, this is minutes of a discipline laboratory medicine meeting of March 28th, 2006. You'll note you're there. It's at the General Hospital, and under new business, I'm going to take you to that in a moment, but we understand from other evidence that by January, and certainly into February of 2006, the great bulk of retest results were back from Mount Sinai?
DR. MORRIS-LARKIN:
A. I honestly don't know much about the timing.
COFFEY, Q.C.:
Q. Okay.
DR. MORRIS-LARKIN:
A. And the return of any of that.

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COFFEY, Q.C.:
Q. That's what I was going to ask you about. We know because of exhibits and witnesses. When did you first become aware of when the bulk of the retesting was over, when and how?
DR. MORRIS-LARKIN:
A. I think I was less aware of when it was over than, you know, the fact that it was taking so long to get it done, that, you know, Dr. Cook was struggling with the issues with the Mount Sinai group and they're overworked, they're backlogged, so I was aware of that. Beyond that, I don't know when the bulk of it was finished.
COFFEY, Q.C.:
Q. So you weren't, as a member of the staff at the Health Sciences Centre, kind of kept apprised from time to time by the management?
DR. MORRIS-LARKIN:
A. No.
COFFEY, Q.C.:
Q. As to what the status is now?
DR. MORRIS-LARKIN:
A. No.
COFFEY, Q.C.:

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Q. I take it, did that in any way contribute to rumours about what the results might be, or speculation about what the results were?
DR. MORRIS-LARKIN:
A. I think, you know, there were occasional questions, but we also appreciated that their hands were tied and they couldn't really give us a comprehensive picture of what was happening because they didn't have the results themselves.
COFFEY, Q.C.:
Q. Did you - were you ever told, have you ever been told to this day how many of your own cases were retested?
DR. MORRIS-LARKIN:
A. I have been told that I can inquire to whatever information Drs. Cook and Denic have, but that's beyond - I mean, we know that the database is now beyond that, but that's all they have access to, and I am able to ask them and have spoken to Dr. Denic about it.
COFFEY, Q.C.:
Q. When were you first told that that was available to you?
DR. MORRIS-LARKIN:

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A. I think that very early on Dr. Cook always made it clear that if you want to find out, I will certainly make this available to you. I think he had a huge - an overwhelming management issue to try and deal with, so I don't think any of us expected him to start feeding back to us. I think the onus was on us to go to him.

COFFEY, Q.C.:

Q. On the retesting when the retests came back, they came back in spreadsheets in the main, okay, I'll tell you that.

DR. MORRIS-LARKIN:

A. Uh-hm.

COFFEY, Q.C.:

Q. The evidence indicates that Dr. Cook would then generate - at least in the early days it was Dr. Cook, and then Dr. Denic would generate in St. John's an addendum.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. If it was you patient, did you get a copy of the addendum?

DR. MORRIS-LARKIN:

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A. No, I didn't.

COFFEY, Q.C.:

Q. Should you have, do you think?

DR. MORRIS-LARKIN:

A. At that time, I don't think we really thought about it. I don't remember really thinking about it. I think it could have been useful, but I don't think it was something that we had an issue with, and I don't remember if it was ever discussed or a decision made to do it or not do it, and it's quite possible that it could have been discussed.

COFFEY, Q.C.:

Q. Doctor, here under quality assurance, new business, quality assurance, is a reference to this is a changeover, in effect, from Dr. Denic to Dr. Cook as clinical chief, and it goes on, "Implementation of the new quality assurance program was discussed at length. Dr. Beverley Carter will act as manager of the new quality management program for the pathology department. There will be a technical member and a clerical member on the team. Dr. Carter will act independently and answer to quality management team. This is

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supported by Dr. Williams, VP of Quality, Diagnostics, and Medical Services. Dr. Morris-Larkin expressed concern about being audited", and then notes, "Dr. Denic stated that random slides will be audited. Dr. Carter says the random cases will be picked by the technologists who is working with the quality management program. Dr. Morris-Larkin expressed the feeling that one pathologist should not do all of the auditing. Dr. Denic also stated that there will be policies put in place regarding the auditing. Dr. Cook stated there was no QA committee before November of '04. Dr. Mathieson said it was not a good policy to have the QA committee report to anybody but the clinical chief, who would then report to Eastern Heath. Dr. Denic informed the group that Eastern Health will have regional managers for QA who will be involved with our managers, and Dr. Morris-Larkin offered to help with the QA", and then it goes on from there. Doctor, I wanted to review that with you to ask you what your concerns were about being audited, and then before the meeting ends, you've offered to get involved.

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So could you tell the Commissioner about that?

DR. MORRIS-LARKIN:

A. Well, again the minutes are being taken by a secretary who's recording things, and the whole context of the discussion, I think, is around how should we do this, we want to make sure we do it in an appropriate manner, we want to - again really echoing some of the things I had written in the notes from that August 5th meeting in '05. So it was the same kind of concerns that we do this in a way that is - you know, in a culture of quality that is a blameless kind of culture, you're much more likely to have successful auditing and attention to patient related events that are significant, and that's the kind of thing that I would have been referring to there. As well, I would have had a concern that if one person does all the auditing and that person leaves, then this activity falls by the wayside again, and I think that it's very important to have a structure in place that - I think that's probably what I was referring to there, have a structure in place that was not dependent upon an individual who was doing

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the bulk of the work, but would be sustainable after that individual left, and as well, I didn't think that one person should be burdened with all that work.

COFFEY, Q.C.:

Q. Here, Doctor, on page three of the exhibit is a reference to pathology assistants. "Dr. Denic stated some people have been interviewed for the pathology assistants. One with experience is starting on Monday", and this is March 28th, the date of the meeting. "Manuals and policies will be developed for the pathology assistants. They will be trained according to the standards in the United States. Four pathology assistants will be trained at the same time". Now to help put this in context for the Commissioner, if we could look, please, at Exhibit P-2092. This is a laboratory program two year operational plan from April of '06 to March of '08, and the division is pathology. "Priority issues/focus area, integrated clinical system, regional policies and procedures", and there's a detailed activity plan. In particular, could we go, please, Registrar, to page six.

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The operational goal there is by March of '08, lab medicine will review present staff capacity and determine efficiencies, realignments, and appropriate skill mix and use of staff resources. You will note there under directors, operational objective number three, identify and implement staff efficiencies, and then under actions required, how resources - you see, Doctor, right there, it says, "Pathologist sub-specialty, organ site tumour leader, lab flow for technical and professional duties, pathologists assistants", and, of course, your name appears out here under "delegated to responsibility". Doctor, the pathologist assistants, I take it, ended up being yours?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. April '06 to March of '08, and here in this context, which one of - pathologist sub-specialty, or the organ site tumour leader, or both of them that - and the lab flow?

DR. MORRIS-LARKIN:

A. I think both mine and Dr. Denic's name are

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there because we would be - that would be a pathologist related issue.

COFFEY, Q.C.:

Q. The sub-specialty.

DR. MORRIS-LARKIN:

A. Developing sub-specialty groups essentially.

COFFEY, Q.C.:

Q. And there's a reference down below to electronic test ordering. Yourself and Mr. Dyer.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Trying to develop that, and I think it that's to avoid the paper requisitions?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And transcription services, yourself, Dr. Cook, and Mr. Dyer, I take it. That had been a problem for years?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. I haven't taken you through the minutes, but

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from time to time backlogs in transcription would have been a problem?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, if we go then, please, to Exhibit P-3364. I want to ask you - this is May 2nd '06, a letter appointing you - it's addressed to you, appointing you as site chief physician at the General Hospital site. It's from Dr. Denic, and as well May 11th, 2006, page three, is a letter from Dr. Williams thanking you for having agreed to accept the site chief's role. Two questions. One, why did you agree at that point in time to become the site chief?

DR. MORRIS-LARKIN:

A. There was a need. It had to be filled.

COFFEY, Q.C.:

Q. Number two, Doctor, taking on the responsibility for the pathology assistants, why did you do that?

DR. MORRIS-LARKIN:

A. Again, I think that within that realm of site chief being responsible for the grossing room and, you know, the overall pathology

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activities, I felt that that was a reasonable thing to try and, you know, take that on from a co-ordinating point of view. I also had a fair bit of experience in teaching both undergraduates and pathology residents, so I felt that it was something that I could try and approach.

COFFEY, Q.C.:

Q. Now, Doctor, here in this letter to yourself of May 2nd, 2006, it says, "Listed below are the duties which you should assume in your position as site chief." And then it goes on, 1 through 12. Did you have any input into what was contained in numbers 1 to 12?

DR. MORRIS-LARKIN:

A. I did from the point of view of discussing it with Dr. Denic when he gave it to me, we sort of fleshed out one or two points in particular, because at this time the Quality Management Program was just fledgling, but was certainly up and running--off to a running start with Dr. Carter and Ms. Parnell and he mentions, you know, the quality assurance there, so we needed to kind of more clearly define what were my roles and what were her

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roles in this. But otherwise I think, you know, Dr. Denic had looked at what it was he saw I was doing and what was needed to be done and I pretty much agreed with what he had there.

COFFEY, Q.C.:

Q. Now, Doctor, you are still a staff pathologist II, in the sense you still do staff pathologist work.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. How much of your time beginning in May of '06, in terms of workload, was made available to you to carry out your site chief's role compared to your staff pathologist role?

DR. MORRIS-LARKIN:

A. Well certainly Dr. Denic indicated to me that I should try and reduce some of my clinical workload from the point of view of receiving cases. The reality of that is that a lot of times when things get down to a crunch, it's often the site chief who actually has to take on the extra work. But he did make it clear to me that I would be expected to reduce my

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clinical workload and I did do that.

COFFEY, Q.C.:

Q. And was there any percentage talked about or proportions or -

DR. MORRIS-LARKIN:

A. The percentages are, you know, the percentages are nice numbers of paper, but in reality it's very hard to actually apply percentages. I also had to balance my obligations to Memorial University and, you know, it was clear from the Dean that I was expected to spend a certain amount of my time in a week at activities that related specifically to the medical school and undergraduate programs.

COFFEY, Q.C.:

Q. And in the undergraduate programs, because here, looking through this, I don't think the undergraduate medical program is referred to here.

DR. MORRIS-LARKIN:

A. No, because this would be specifically an Eastern Health issue.

COFFEY, Q.C.:

Q. Which is the rounds and -

DR. MORRIS-LARKIN:

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A. Yes.

COFFEY, Q.C.:

Q. And he says, "on site, along with"--paragraph 10 here, "Responsible for maintenance of all teaching rounds and same day (phonetic) activity on site, along with the education component of medical students and residents visiting that particular site." So I take it whatever is going on site, yes, but if you had to go and give a lecture somewhere, that -

DR. MORRIS-LARKIN:

A. That's a separate issue.

COFFEY, Q.C.:

Q. - would have been a separate issue entirely.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Is there a percentage of time on paper even, allotted to the site chief role and your division of responsibility with Memorial University?

DR. MORRIS-LARKIN:

A. The percentages that are allotted really mostly relate to the site chief and well major administrative activities, being, I think

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about 20 percent of a work week, so point two of your time, roughly. In the big picture for me, what would have been expected at this time, I would have had a 80 percent commitment to Eastern Health, my time being given to them or basically I guess, you know, compensated for by them to Memorial University for my time and then I would receive appropriate compensation. So the organizational structure is that I was expected to do 80 percent of the work of a fulltime hospital pathologist in prior to taking this one. Now within that 80 percent, because I was now taking on this major administrative role, I would be expected to reduce the clinical workload to 60 percent.

COFFEY, Q.C.:

Q. Sixty out of a hundred?

DR. MORRIS-LARKIN:

A. Of one hundred and then I went further because within months, there was so much work to be done, I think it was actually last summer I changed my arrangement with Eastern Health so that, because I was doing so much work for them, I actually reduced it to 60 percent, so that now my work structure is, I am supposed

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to do 60 percent of what a hospital pathologist does. I did that because I needed to feel I could justify reducing my clinical workload even further because of the overwhelming administrative responsibilities that I was carrying.

THE COMMISSIONER:

Q. So that's 20 percent site chief work, 20 percent to MUN and then 60 percent to your normal duties?

DR. MORRIS-LARKIN:

A. No, essentially it doesn't really work--it doesn't actually add up to a hundred percent, there's always a problem, but essentially I am 60 percent Eastern Health and within that 20 percent supposedly is to my site chief duty.

COFFEY, Q.C.:

Q. Twenty of the 60.

THE COMMISSIONER:

Q. Is it 20 percent of 60 or 20 percent of a hundred would be the site chief?

DR. MORRIS-LARKIN:

A. And that's where the numbers really--they just don't jive.

THE COMMISSIONER:

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Q. So you should be 40 percent to MUN?

DR. MORRIS-LARKIN:

A. In rough terms and that was what I was aiming for because I had, you know, direction from the Dean that essentially a day and a half of my work week should be devoted to Faculty of Medicine duties, so -

COFFEY, Q.C.:

Q. Teaching undergraduates, graduates -

DR. MORRIS-LARKIN:

A. Teaching undergraduates the research projects, administrative things related, I don't do as much administrative things related to undergrad now. I did that in the past and I've replaced that with the Eastern Health administrative responsibilities.

COFFEY, Q.C.:

Q. And, Doctor, you've been in that position now for, well it's coming on to two and a half years?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Is there enough time in a week to do it?

DR. MORRIS-LARKIN:

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A. No.

COFFEY, Q.C.:

Q. There's not. Has the shortage of pathologists locally had contributed to the lack of time in a week to get it done?

DR. MORRIS-LARKIN:

A. It has because not only the shortage, the shortage contributes in one way, even though we have found an outlet source for some cases in that we refer them to the Dynacare lab in Ottawa, that in itself creates administrative work for me because I basically triage and I'm the stop gap (phonetic), so that, you know, I try and keep anything that's going to be more significantly sensitive, time sensitive and things like that, within house. As well, what we send to Dynacare are really the smaller, simpler cases and the proportion for all the pathologists who are here in Eastern Health, the proportion of difficult cases to simple cases has gotten off balance as a result. The other thing is with the frequent turn over, there are more people that have to be oriented and with staff coming out of residency programs and we've had more of those than we

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had staff that had been around for five or ten years, then they need, they need somebody they can go to because we do frequently show our cases, it's an important part of our quality practice. So then the few more senior people who are left around do a lot more of reviewing cases with the newer staff members.

COFFEY, Q.C.:

Q. Doctor, I ask you to think about this for a moment, if the pathology positions in St. John's were fully staffed, if they were, okay.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Would there still be enough time in a normal work week for you to get what's expected of you done, within a normal work week?

DR. MORRIS-LARKIN:

A. At this point, still maybe not, it two years I think it might be different because as you can well imagine, there's a great deal of more administrative issues going on at this time because of the great number of changes that have occurred at this time.

COFFEY, Q.C.:

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Q. Including, and we're going to look at this in a moment, the whole issue around written procedures and protocols -

DR. MORRIS-LARKIN:

A. That's correct.

COFFEY, Q.C.:

Q. - which is a whole time consuming issue in itself.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And you anticipate that over the next couple of years at least that will be more or less-- it won't end, but the bulk of it will be done.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. That's one of the things you're getting at here?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-0022? Page 29? Doctor, these are MAC minutes of, this particular page of May 10th, 2006, do you see

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that?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And it's got an announcement, I take it, of the MAC that you now site chief.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Dr. Denic is reporting back to them. "Dr. Makarla is taking on the role of director of immunohistochemistry and Dr. Ford Elms is appointed assistant director of immunohistochemistry and Dr. Beverley Carter has agreed to take on the leadership role for QA of the Laboratory Medicine Program." Now, just to branch out from that, you are still in your job as site chief.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Dr. MaKarla has gone, has moved on?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

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Q. Doctor Elms has come in here and testified as his role as, well, initially assistant and then finally director of immunohistochemistry.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. I'm going to ask you about that, what is the relationship between yourself as site chief at the General and Dr. Elms as the director of immunohistochemistry, how does that work?

DR. MORRIS-LARKIN:

A. Dr. Elms spends--Dr. Elms is based at St. Clare's but he spends a great deal of time at the Health Science. I see him almost every day. Sometimes he pops into my office; sometimes I see him because I pop into the immunohistochemistry lab. So we frequently talk about what's going on in the lab, the general changes that have occurred and the current practices within the lab. As well, when we have any particular issue, I usually bring it--if I have an issue, I would bring it both to the technologists and I would let Dr. Elms know about it. And the situation has been such that there's feedback, so there is a

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great deal of discussion goes back and forth.

COFFEY, Q.C.:

Q. In your position as site chief, does he report to you?

DR. MORRIS-LARKIN:

A. No, no. Dr. Elm's site chief would be based at St. Clare's.

COFFEY, Q.C.:

Q. No, but the site for IHC is actually in the General.

DR. MORRIS-LARKIN:

A. And no, he does not report to me, he would report to, I presume Dr. Denic as clinical chief.

COFFEY, Q.C.:

Q. Dr. Denic as clinical chief, even in relation to his capacity of director of immunohistochemistry?

DR. MORRIS-LARKIN:

A. I would see him, you know, I would see us as laterally related.

COFFEY, Q.C.:

Q. "Dr. Carter has agreed to take on the leadership role for QA of the Laboratory Medicine Program." Now Dr. Carter, of course,

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has testified here and she certainly--and the documents bear this out, she initially got involved in this QA matter. Who is doing that role right now from a pathologist end?

DR. MORRIS-LARKIN:

A. That would be me.

COFFEY, Q.C.:

Q. Okay, and when did you begin that?

DR. MORRIS-LARKIN:

A. Well Dr. Carter had taken a great deal of initiative and had set up a good foundation in the Quality Assurance Program, Quality Management Program really, and with that, she managed to get funding for a permanent person who is taken from the technical group, so that now we've got a structure in place that we have a pathology quality management co-ordinator. So the bulk of this -

COFFEY, Q.C.:

Q. And who is that?

DR. MORRIS-LARKIN:

A. Currently it's Ms. Bev Rowe.

COFFEY, Q.C.:

Q. And before that?

DR. MORRIS-LARKIN:

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A. It was Catherine Parnell.

COFFEY, Q.C.:

Q. Okay.

DR. MORRIS-LARKIN:

A. So Dr. Carter got that in place and then I believe it was last summer she decided to move away from this role and what we had in place at that time was basically a Quality Management Program Committee which was comprised of a number of people, including the co-ordinator, a co-chair that would have been filled by Dr. Carter for a brief period of time and then a number of other significant stakeholders, such as the site chiefs, representation from the technical lab, representation from the pathologist assistants and then ad hoc members, such as people from immunohistochemistry. So for about maybe 8 months, it functioned as a committee, but with the expected retirement of Ms. Parnell, I thought that, you know, it was necessary to have somebody who was going to be at least a resource person for her successor. So I volunteered for six months to fill that role to allow Dr. Denic some time to try and find

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somebody to take it on a permanent basis. He had been trying previously, but had been unsuccessful in recruiting somebody to take up that particular responsibility.

COFFEY, Q.C.:

Q. So when did that six months begin?

DR. MORRIS-LARKIN:

A. That began in May.

COFFEY, Q.C.:

Q. Of?

DR. MORRIS-LARKIN:

A. Of 2008.

COFFEY, Q.C.:

Q. And I take it their activities are ongoing?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. That group's activities.

DR. MORRIS-LARKIN:

A. Yes, and Ms. Rowe has just come into it, so it has taken her a few months to get up to speed, but I think that, you know, things are progressing very well.

COFFEY, Q.C.:

Q. Exhibit P-3351 please? Doctor, this is a

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series of e-mails, it's a confirmation of a meeting and in fact, it was to occur later on in June of 2006. This first e-mail here is from Terry Gulliver to Denise Dunn, June 20th, '06. It's "RE: ER/PR retesting". Mr. Gulliver writes, "Shouldn't Doctor Lynn Morris-Larkin be there. She is the new site chief for the Health Sciences Centre." Apparently they just missed you in the send out of the e-mail below about the confirmation of the meeting of June 30th, at the lab conference room at St. Clare's. Now we understand from documentation that we have otherwise seen, that this related to the idea of discussing the potential for resuming ER/PR testing in St. John's.

DR. MORRIS-LARKIN:

A. Uh-hm.

COFFEY, Q.C.:

Q. Did you attend that June 30th meeting, do you recall?

DR. MORRIS-LARKIN:

A. No, I did not.

COFFEY, Q.C.:

Q. And do you recall why not?

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DR. MORRIS-LARKIN:

A. In all honesty, I don't even recall the communication at all, although there's a note there that says I'm on service that day, but would try to switch. So perhaps someone had called me about it, but I don't think I heard anything subsequent to that.

COFFEY, Q.C.:

Q. And, Doctor, I raise this here because I wanted to ask you about this whole ER/PR matter, up to that point in time until you became site chief, I take it your involvement with ER/PR was just simply as an observer, as a staff pathologist?

DR. MORRIS-LARKIN:

A. That's correct.

COFFEY, Q.C.:

Q. Having become site chief and this would have invited you to an actual meeting when ER/PR, the nitty gritty of it, retesting, was going to be discussed, did you ever then get involved in the kind of nitty gritty of the matter?

DR. MORRIS-LARKIN:

A. No, by that time I think that the group had

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been organized, things had been going ahead. Doctor Carter and Doctor Cook, I believe, were mostly dealing with the reports that came back, so I wasn't involved at all.

COFFEY, Q.C.:

Q. And have you ever been, in fact, to this day?

DR. MORRIS-LARKIN:

A. No, no.

COFFEY, Q.C.:

Q. Exhibit P-1616? Now, Doctor, what I want to look at is here on the second page, it's a spreadsheet where Dr. Banerjee and Trish Wegrynowski's recommendations for IHC, updated June 30th, '06, and here, Doctor, under recommendation No. 31. "SOPs for accessioning, grossing and fixation" being recommended by Trish Wegrynowski and agree with, yes, and your name is listed amongst those--Dr. Dyer, yourself and Dr. Carter are working on, September '06 to March '08, so I take it that it had begun by then -

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. - the process. And 32 says, "SOPs and

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performance evaluation of PAs documented", see that?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And it's yourself and Mr. Dyer, March of '08.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. I take it you had signed on in effect to be involved with the PAs?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And again, why was it you agreed--who asked you to do that and why did you agree -

DR. MORRIS-LARKIN:

A. Dr. Denic would have asked me as clinical chief.

COFFEY, Q.C.:

Q. And was this before you became site chief?

DR. MORRIS-LARKIN:

A. It was at the same time.

COFFEY, Q.C.:

Q. At the same time, obviously it was part of it.

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DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2106? These are the minutes of the site chief's meeting in November 6, '06, at St. Clare's, you're present, Dr. Denic, Dr. Cook and Mr. Dyer, under the heading "New Business a) Pathologist Assistants." It reads, "Dr. Morris-Larkin circulated drafts on pathology assistant training and the role of pathologists as mentors and supervisors to the PAs. This is to be reviewed by the site chiefs who will provide comments and feedback on this document. Formal PA teaching sessions have been set up by Drs. Wadden and Morris-Larkin. Dr. Morris-Larkin will work in developing an evaluation process for PAs, once PA training is complete. A log will be signed by the various site group pathologists, this is currently under development and an ITER type process will have to be developed to monitor their training and development. The goal is to eventually formulate a gross manual for PAs based on evidenced based literature." Now, Doctor, I take it that's kind of a

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snapshot as of November 6th as to where you were with this, yourself?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. How did you go about, because PAs locally, I take it, were new. How did you go about organizing it?
DR. MORRIS-LARKIN:
A. Well I wasn't involved in the initial hiring of the people who would eventually become our pathology assistants.
COFFEY, Q.C.:
Q. Who did that?
DR. MORRIS-LARKIN:
A. Dr. Fontaine and I think Mr. Dyer had the most input, I'm not sure if Dr. Cook had any input into it, he may have. And so by the time I had agreed to sign on, we were well into that process of having people who were going to be coming into the system. And we had two-- people of two different backgrounds. We had laboratory technologists with absolutely no training in pathology assisting at all, but who had a background in pathology, so they had

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been at the gross bench assisting a pathologist during their work, so they were familiar with many of the things. And then the other individual who came in who was also a laboratory assistant, had worked as a laboratory technologist, had also worked as a pathologist assistant in Ontario for a period of time, so she was kind of at an intermediate level of training. And then by August, we acquired a trained pathologist assistant from Ontario. She was an individual who would be identified as the lead pathologist assistant and that was very important for us because she could be at the gross bench much more readily than a pathologist, although we would, you know, have a major role in training the pathologist assistants, she could be there to co-ordinate things, to help them through the smaller issues and to contribute to the training as well.
COFFEY, Q.C.:
Q. And how would you go about getting kind of a syllabus, as it were?
DR. MORRIS-LARKIN:
A. Well, what I did was I did some looking on the

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internet, essentially, looked at some websites in the United States where they have accredited pathologists assistant training programs, the kinds of things that they were doing, what they were looking for and I also spoke to some people. I happened to be on a social visit in Ontario so I went to see Dr. Khalifa and we had a chat because they had a well-developed pathologists assistant group. You know, they had some six or seven. So I spoke with him about how he had gone about or how they went about training because they have a fair amount of turnover because a number of their pathologists assistants were, in fact, previously training pathologists and some of them had come here to our residency program, so there was a connection there.
COFFEY, Q.C.:
Q. Previously pathologists, foreign -
DR. MORRIS-LARKIN:
A. Pathologists, yeah, international medical graduates who had been pathologists elsewhere and were in between finding positions as pathology residents to retrain. So, you know, I had a relationship with Dr. Khalifa and we

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talked about some of the issues and how to go about this and he gave me some advice.

COFFEY, Q.C.:

Q. Is there -

DR. MORRIS-LARKIN:

A. And -

COFFEY, Q.C.:

Q. I'm sorry, I apologize, go ahead, Doctor.

DR. MORRIS-LARKIN:

A. So when I came back, I started to try and write up a draft that in some ways gave me an idea of what to do, you know, to keep me on a track of how should we go about this because this was entirely a new thing. We didn't have any kind of formal accredited approved program, but we wanted to try and work towards something that was comparable to such a thing.

COFFEY, Q.C.:

Q. And, Doctor, what's an ITER?

DR. MORRIS-LARKIN:

A. An ITER is an In-Training Evaluation Report, I think. It's actually something that we have for residency programs so that when a resident rotates to one of our sites, we would complete one of these. And it has a number of, a

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number of items on it that reflect the residents' training and their achievement of the goals of training. And we decided that it would be appropriate to try and work towards something like that for our pathologists assistants in training, as well.

COFFEY, Q.C.:

Q. Doctor, I mean, do you have, as it were, a filing cabinet or part of a filing cabinet that has the records, like, related to pathology assistants?

DR. MORRIS-LARKIN:

A. Yes, I do.

COFFEY, Q.C.:

Q. You do, in terms of from the beginning, kind of how, it started and how it's evolved and where it is now?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. You do. And is there a training program for pathology assistants in Canada?

DR. MORRIS-LARKIN:

A. There is one training program in Canada in Winnipeg. I'm not sure what their

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accreditation, what their accrediting body is or at what level, whether it's baccalaureate or a master's, but that is the only, you know, official training program, as such. And they do require university credit hours as well as some of the things that we are doing, you know, with the on bench training, the regular seminars, the attendance at rounds and so on.

COFFEY, Q.C.:

Q. And so in effect you had to set up, figure out what the program should contain, set up your own syllabus and start?

DR. MORRIS-LARKIN:

A. Yes. And in the beginning it was done rather ad hoc. I mean, we looked at--I looked at training pathologists assistants as doing a role that pathologists did, so I would see them as, in many ways, doing the kinds of things we would train the pathology residents to do, but recognizing that they had a different level of knowledge. They would not have had the anatomy training or the same, quite the same level of--or certainly not the clinical level of knowledge, so we wanted to try and incorporate that kind of thing into

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our training sessions.

COFFEY, Q.C.:

Q. Did you consult with any actual formal program about it? I appreciate you -

DR. MORRIS-LARKIN:

A. I did not.

COFFEY, Q.C.:

Q. You did not?

DR. MORRIS-LARKIN:

A. No, other than to see what was available on line.

COFFEY, Q.C.:

Q. Yeah, not the American programs -

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. - nor Winnipeg?

DR. MORRIS-LARKIN:

A. Not, and I've only recently learned about the Winnipeg program being formal, so I've not spoken to them formally, no.

COFFEY, Q.C.:

Q. And how long are the programs in Winnipeg or the United States, the formal programs?

DR. MORRIS-LARKIN:

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A. I believe that they're between 18 and 22 months, and I'm not sure which ones are which. There are only five or six in the United States and then the one in Canada.
COFFEY, Q.C.:
Q. Do you know how much--what the qualifications are to get into them?
DR. MORRIS-LARKIN:
A. In the United States it's more often a baccalaureate undergraduate degree required, and five of their six programs are actually master's levels programs. In Winnipeg -
COFFEY, Q.C.:
Q. You have to have a master's to get into it or you -
DR. MORRIS-LARKIN:
A. No, no, you have to have -
COFFEY, Q.C.:
Q. - do a master's degree?
DR. MORRIS-LARKIN:
A. You have a master's level degree when you complete it.
COFFEY, Q.C.:
Q. Okay.
DR. MORRIS-LARKIN:

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A. But you would need an undergraduate degree. In Winnipeg I'm not sure exactly what their requirements are, but I did think it was a baccalaureate or equivalent sometimes comes into the qualification, and very often the equivalent would be accepted as a registered laboratory technologist, which is where the bulk of pathologists assistants who are practising in Canada have come from, that route.
COFFEY, Q.C.:
Q. And, Doctor, in relation to that, I take it then in the United States, anyway, the programs you've looked at or inquired about, they are based in teaching hospitals, university centres, that sort of thing, is that the kind of thing?
DR. MORRIS-LARKIN:
A. I think so.
COFFEY, Q.C.:
Q. If you're giving out master's degrees and -
DR. MORRIS-LARKIN:
A. Yes, I would think so, but I'm -
COFFEY, Q.C.:
Q. You're not certain of that?

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DR. MORRIS-LARKIN:
A. I'm not certain.
COFFEY, Q.C.:
Q. Has any thought ever been given to actually training, having people from here trying to attend, you know, graduate from such programs in the United States or Winnipeg, for that matter, and come here?
DR. MORRIS-LARKIN:
A. I don't think, I don't think that there was-there have been formal discussions. I think it's been thrown about as one of those wish things that, you know, it would be nice if, but I don't think it's entirely practical, in all honesty. There are limited numbers of programs available; the entry would be limited. And I think that we've done what most of Canada has done, and that is take these individuals and do our best to train them to the kind of standards that we want to achieve.
COFFEY, Q.C.:
Q. And, Doctor, here if we could look at Exhibit P-2109? This it the minutes of a meeting of site chiefs, December 5th, '06 at the--you're

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there along with Doctors Cook and Denic, Pirzada and Mr. Dyer. "Pathology Assistants" paragraph 1, "The pathology assistants will be trained on grossing bowel specimens by Dr. Morris-Larkin in the month of December. Commencing in the new year the St. Clare's group will do formal training in lung, stomach, breast and ENT. Dr. Morris-Larkin will organize the schedule. Some of the group felt strongly that a quiz would be appropriate for a pathology assistants. This will tentatively be set for April and will consist of short answer questions." I take it the "some of the group" is the group of pathologists, I take it?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Here. About the quiz. And I want to--and the reference to the quiz here I wanted to ask you about: Is there any formal testing procedure that has been used to determine whether or not a particular pathology assistant is kind of finished their training, as it were, in the sense of in a formal way?

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DR. MORRIS-LARKIN:
A. No, there isn't. We did talk about it and, you know, a number of people said it would be a good idea and we discussed it with the pathologists assistants that this may be coming. But to try and actually write appropriate formal examinations is yet another challenge on top of everything else that we were trying to do. So, in effect, the training has been really very much the evaluation of performance of the pathologists assistants. And that's done on a daily basis, you know, in terms of reviewing the reports that--basically they generate a part of our pathology report now when they do their duties of grossing.
COFFEY, Q.C.:
Q. If we could, Exhibit P-2115? Doctor, here this is a site chiefs meeting minutes of March 27th, 2007. You're there. "Pathology Assistants" paragraph 1, "Jessica Swain reported on issues regarding the pathologists assistants. Shift assignments are in place at the Health Sciences Complex and is working well. Pathologists assistants in training

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have been successfully accepting increased responsibility at that site. At the St. Clare's site it is expected that two big specimens per day would be appropriate. Issues regarding one pathologists assistant were discussed and this is documented in another separate letter. Pathologists assistants are working on templates. Training education log is now in placed and they are required to have supervision and sign off on five examples of significant large specimens. Implementation of review of large specimens by the pathologist with the pathology assistants and residents on site will begin. Dr. Morris-Larkin reported an audit of the workload for the PAs at the Health Sciences Centre and St. Clare's and this is approximately equal. The fixation rule was discussed. Sign out of a policy regarding this is pending. It was agreed by the group that punch biopsies would be inked." So I take it, Doctor, this is kind of a snapshot as of March, '07 as to where the teaching of the PAs was?
DR. MORRIS-LARKIN:
A. That's correct.

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COFFEY, Q.C.:
Q. This is--Doctor, is there any one in Canada that you would be able to go to, that you're aware of, you know, with the records of what is being done with the pathology assistants here in terms of their training and ask somebody to review them and say, well, you know, somebody who would know, make an informed comment, to say, well, yes, Dr. Larkin, if that is being done, if this is--they've been trained in this way and they've achieved this much that from, you know, my perspective as kind of an outsider, that this is sufficient?
DR. MORRIS-LARKIN:
A. Again, are you talking about like a formal accrediting body?
COFFEY, Q.C.:
Q. Yes, accrediting body or, you know, somebody who, for example, at some of these centres that do have a formal training process?
DR. MORRIS-LARKIN:
A. Well, the only centre that does have the formal training process is in Winnipeg. Ms. Swain, who is mentioned here, is our lead

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pathologists assistant and she does have communication with this director of the pathologists assistants in Winnipeg, so we have an avenue for communication there. There is no formal accrediting body, although there is now a section within the Canadian Association of Pathologists that is dedicated to pathologists assistants and we may see formal accreditation and certification down the road. Within the United States there is an accrediting body and certification and, in fact, Ms. Swain has passed and is certified in the American, the American Society of Clinical Pathologists in that section, so that's as far as we have right now. But again, I think with time--this is still something that's very much an evolution in all of Canada. We will have a body probably in the section of the CAP, the Canadian Association of Pathologists to go to.
COFFEY, Q.C.:
Q. And, Doctor, here, if I could, Exhibit P-2132? These are minutes of a site chiefs meeting of October 5th, 2007. Paragraph 2.1 "Pathologists Assistants." There's a note here, "The need for formal evaluation of

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pathologists assistants was discussed. Currently it is done in pre-style format but there is a move to have a more formal checklist for the in training PAs with a view to using a similar checklist in yearly evaluations. Suggestions were made and Dr. Larkin will put these into a form." And "The impact of the colon tumour bank collection on the pathologists assistants' workload was discussed. There is a perceived need to define the daily workload. Both site chiefs will continue to monitor the situation with a view to further discussion. A congenial and collegial relationship between pathology assistants, residents and staff is encouraged. Note is made of the new challenge of training residents on grossing in the current era of pathologists assistants. This will be referred to the anatomic residency training committee for further discussion." What is that--I take it the first paragraph just simply deals with the idea of kind of formalizing the -

DR. MORRIS-LARKIN:

A. Yes. I think that's "free-style format."

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COFFEY, Q.C.:

Q. "Free-style," yeah, "format." As opposed to using a formal checklist for the training?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And yearly evaluations. But in terms of the relationship then between pathologists, residents and pathology assistants in teaching grossing, how has that worked itself out?

DR. MORRIS-LARKIN:

A. It's working itself out. We still have, we still have issues that we deal with on a regular basis. One of our biggest challenges which is noted at the end of the paragraph is finding the right balance between getting the residents exposed enough to this activity and getting-while the pathologists assistants need to be exposed to develop their expertise. But that's something that we constantly address on a regular basis at just about every meeting that either pathologists assistants or residents are discussed. And I think that we do have, at this point I think--I'm not sure of the date of this, but right now there's a

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very good working relationship. The pathologists assistants frequently, if they're doing something that's not necessarily assigned to a resident, they will give them a call and say, you know, you should see this, this is a very interesting specimen. They work with them to divide up the work appropriately so that the residents get exposed to certain types of specimens. They ask each other questions. And then there are regular rounds; every morning we have a gross bench round, essentially, at both sites so that it's the responsibility of the pathologist on call for that day to check in with the pathologists assistant, see what the gross specimens are, review them, have any discussions. And that becomes both a practical round as well as an educational round for the pathologists assistants.

COFFEY, Q.C.:

Q. If we could, Exhibit 2112, 2-1-1-2? These are the minutes of a division of anatomic pathology meeting of January 10th, 2007. You're present. It's at the General Hospital site. And here under "Resident Teaching and

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Sign-out" there's a reference to "There seems to be some problems with resident training. With more pathologists retiring or leaving there's a shortage of staff for teaching and the interest in rounds had dwindled. Residents are upset with this and also the availability of staff for signing out cases. Also cases being sent to Dynacare seem to taking away cases of interest. All gastric biopsies and skin were being sent, but this will be tailored by Dr. Cook and Dr. Larkin. The possibility of a resident shadowing one pathologist for full week was considered as this should allow exposure to a variety of cases." So, Doctor, I take it then that--because this is not the only reference to concerns about residency training?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. I take it then for a period of time because of the shortage of pathologists, the Commissioner has heard about that, that there just weren't enough staff pathologists to spend enough time with residents from the residents'

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perspective?
DR. MORRIS-LARKIN:
A. That is a part of it. As well, because we have been sending these cases away, there are a lot of common type specimens that the residents weren't getting exposed to and we had to try and find some way to make sure that there was a balance there, that we didn't overdo it by sending all of these, you know, common variety cases out and then the residents, our residents, what we were finding were getting a great deal of exposure to the complex things but were less exposed to the more common variety things that you would expect to see in the day-to-day practice, again, because of the, you know, the issues that are prevailing.
COFFEY, Q.C.:
Q. Here, Doctor, at page 5 of the same exhibit there's a reference to "Dr. Morris-Larkin asked that the pathologists make time for pathologists assistants, particularly grossing unusual specimens." So this back again, this is the beginning of '07. Did you find that the pathologists, because you were asking

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here, did they, in fact, cooperate?
DR. MORRIS-LARKIN:
A. I think that the pathologists spend a lot of time with the pathologists assistants and, in fact, some of the pathologists who've joined us from other programs are impressed by just how much teaching our residents do get. But there are two sides to the coin -
COFFEY, Q.C.:
Q. That's residents. This is the pathologists assistants, too, in this case.
DR. MORRIS-LARKIN:
A. Oh, I'm sorry.
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. Oh, the pathologists assistants.
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. Sorry. And again, I think the same kind of thing does happen. It's very easy to say, well, we've got these pathologist assistants and so they're doing the work. And we had to always be vigilant of ourselves and remember

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that we are training them to do the work and we need to interact. So again, with regards to that, I think the same thing, we do spend a lot of time with the pathologists assistants at the grossing, at the gross rounds, I should say, and perhaps more, it would be fair to say we're very much available to them and I think they've learned, they've learned to avail of that. I believe in the beginning they weren't sure should I call somebody or I feel bad calling you, and we've kind of gotten over that kind of hump and that everyone knows that we're working together. And, you know, we try and check in on them and they try and call us and don't hesitate, in fact, to call us now when there's anything that they want to learn about or ask a question about.
COFFEY, Q.C.:
Q. And current gross, breast specimens are being grossed by whom?
DR. MORRIS-LARKIN:
A. The pathologists assistants.
COFFEY, Q.C.:
Q. And where?
DR. MORRIS-LARKIN:

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A. The majority of them are done at St. Clare's, but if one comes at the Health Science, I believe it's still grossed there.
COFFEY, Q.C.:
Q. And current who are the pathologists responsible for breast pathology?
DR. MORRIS-LARKIN:
A. Dr. Nick Makretsov who has just joined us since July.
COFFEY, Q.C.:
Q. Yes. And do any other pathologists really do any amount of breast pathology?
DR. MORRIS-LARKIN:
A. None at the Health Science. There have--I'm not quite sure, I really couldn't speak to how they organize things at St. Clare's. But certainly there have been recent times when there was nobody of the former established breast group to sign things out, and I think it was necessary for other pathologists to sign breast cases then. I'm not sure what their organization is over there, but Dr. Makretsov does do the bulk of it.
COFFEY, Q.C.:
Q. If we could, Exhibit P-2112, 2112? Page 3.

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Doctor, this meeting, minutes of a meeting of January 10th, 2007. It's kind of a group meeting at the General Hospital site. I notice here under seven, "Quality Management Program." "Quality management is in the process of creating a book of policy and procedures for pathology." And it goes on to talk at some length of various aspects of it and other things involving the quality management program. So I take it was in the beginning of '07, really, that at least the pathologists generally at the General Hospital were being told that this process is under way?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And it's, I take it it's still going on?

DR. MORRIS-LARKIN:

A. It is. And it is the type of process that will always go on.

COFFEY, Q.C.:

Q. But in terms of kind of the bulk, because I take it there was initially you had to restart from scratch?

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DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Including formatting and sign off authorities and so on?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. The intention right now is to create such policies and procedures for what, for what group, for the entire clinical laboratory, for the pathology end of the laboratory, what?

DR. MORRIS-LARKIN:

A. The intention, and Ms. Lynn Wade could speak better to this as the person responsible for quality in the lab is to have policy manuals for each of the different clinical labs. And there are -

COFFEY, Q.C.:

Q. Microbiology, for example?

DR. MORRIS-LARKIN:

A. Right. So that would not come under our umbrella here. The quality management program referred to here is specifically the one for pathology and the policy and procedures that

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we have focused on are specifically for pathology. Occasionally there may be a procedure that relates to sending a specimen to one of the other labs, but not overseeing those labs.

COFFEY, Q.C.:

Q. And how far as you along in that process in terms of policies and procedures for pathology?

DR. MORRIS-LARKIN:

A. I think that we're after making a great deal of progress. There are still, you know, every now and then I think, well, we should have a policy on this or somebody says we need a procedure on that. There are definitely, there are definitely a number of gaps to be filled, but there's a great deal, great deal of work already accomplished.

COFFEY, Q.C.:

Q. Okay.

COMMISSIONER:

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

COFFEY, Q.C.:

Q. Commissioner, perhaps we could break and I'll

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come back and finish up in about ten minutes or so.

COMMISSIONER:

Q. All right. We'll meet at 2:15.

(LUNCH BREAK)

THE COMMISSIONER:

Q. Please be seated. Mr. Coffey.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Exhibit P-2674, 2674? Doctor, this is a site chief meeting, May 15th, 2007. The attendees are there, including yourself and paragraph 2.0 says "delivery of service during summer 2007. Dr. Morris-Larkin reported that due to severe reduction in pathology manpower levels, it will be extremely difficult to provide an adequate service during the months of July, August and early September 2007" and you go on to talk--it goes on then to talk about the details of it, and it ends that paragraph by saying "it is also noted that due to the anticipated shortage of pathology assistants during the summer months, the pathologists may be expected to take up grossings which will certainly worsen an already critical

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situation." I appreciate this is a summer ago.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Just over a year ago, but Doctor, what I wanted to ask you about is this, I take it that this severe reduction in pathology manpower that's referred to here, did that really become acute then in the summer of '07?

DR. MORRIS-LARKIN:

A. I can't remember specifically the summer, but there certainly--I mean, it's been an acute problem for quite some time and that has been exacerbated during periods of time when particularly people go on vacation.

COFFEY, Q.C.:

Q. What's the situation right now, Doctor?

DR. MORRIS-LARKIN:

A. At the Health Science right now, we have, I believe, four vacancies available or four vacancies, and at St. Clare's, there's one.

COFFEY, Q.C.:

Q. So four in how many positions?

DR. MORRIS-LARKIN:

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A. For the Health Science, and I'm including the person who is now leaving in November, not counting any vacation, there should be 11 and of that, we cover the cytology lab and coverage for flow cytometry and some hematology lab coverage for bone marrows.

COFFEY, Q.C.:

Q. So there are 11 positions?

DR. MORRIS-LARKIN:

A. 11 positions.

COFFEY, Q.C.:

Q. For staff pathologists. Does that include yourself?

DR. MORRIS-LARKIN:

A. Historically.

COFFEY, Q.C.:

Q. Does that include yourself?

DR. MORRIS-LARKIN:

A. Yes, historically have there been 11 positions.

COFFEY, Q.C.:

Q. And as you sit here right now, there are four vacant positions or three and soon to be one -

DR. MORRIS-LARKIN:

A. Three and soon to be four.

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COFFEY, Q.C.:

Q. A fourth person is leaving in November?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. And in terms of recruitment, I take it that's Dr. Denic's primary responsibility?

DR. MORRIS-LARKIN:

A. It is, but we have essentially a perpetual recruitment committee. I've been on a committee for recruiting pathologists since before Dr. Ejeckam came, probably in 1998/99, and we just reform on a regular basis.

COFFEY, Q.C.:

Q. Okay. Doctor, as of right now, again because I expect you'll be the last pathologist possibly that will testify here, at least from Eastern Health, what's the current expectation in terms of being able to fill the positions?

DR. MORRIS-LARKIN:

A. I think that Dr. Denic probably referred to this. I know that we have one person who is-- we've been trying to schedule for an interview. I know that he has a number of applications that we've not yet met to review

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because there have been a number of other activities obviously going on.

COFFEY, Q.C.:

Q. So in terms of having a full roster, as it were, as of right now, there's no kind of actual time that you could point to in an objective way and say "we'll have -

DR. MORRIS-LARKIN:

A. I don't see it any time soon, no.

COFFEY, Q.C.:

Q. And in the meantime, I take it that other than extra work being done by the pathologists who are there, some work is being sent out to like organizations such as Dynacare?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. Here, Doctor, and again, bearing in mind this is May of '07, a year ago, pathology assistants, paragraph six, there's a reference here to "training has started on our new pathology assistant. However, this means that time is currently taken away from service in order to help with the new pathology assistant." This is singular, one person

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training?
DR. MORRIS-LARKIN:
A. Yes, because we had one person come in to training much later than the others.
COFFEY, Q.C.:
Q. And it goes on "there is also a concern that pathology assistants are getting different directions from different pathologists leading to confusion and poor communication. Daily conferences are being held between the pathologists and pathology assistants." I take it this was one of those glitches, as it were, you had to overcome?
DR. MORRIS-LARKIN:
A. That's right. It's, you know, I like it a little bit differently than you like it, but both are acceptable ways and what we were striving for was to have one way so that the pathologist assistant didn't have to do it-- you know, didn't have to figure out who's going to get this specimen, so I can do it to make them happy.
COFFEY, Q.C.:
Q. Here, at paragraph eight, is dealing with residents. "Dr. Larkin has expressed strong

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concerns over the level of residents training. It is felt the program may not be able to sustain residency training. There are issues over cases currently going to Dynacare that residents are not seeing," and that's the sort of--you've alluded to that earlier.
DR. MORRIS-LARKIN:
A. We've heard that before.
COFFEY, Q.C.:
Q. How has that turned out so far, Doctor, in terms of your concerns at the time, in the level of training of residents?
DR. MORRIS-LARKIN:
A. I think with regards to the Dynacare issue, basically that mostly falls to me to try and pull back specimens that we triage to make sure that the residents get a good cross-section and otherwise, we still have a burdened group of staff pathologists who are doing their best to maintain residency teaching and are doing quite a bit, but it is taking a toll.
COFFEY, Q.C.:
Q. Exhibit P-2121? And Doctor, I'm going to show you a short series of exhibits dealing with

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policies and procedures. This is June 6th, 2007. These are the minutes of a Pathology Quality Management Committee, of which you're a member.
DR. MORRIS-LARKIN:
A. I think that would have been the first meeting I attended.
COFFEY, Q.C.:
Q. Yes, and introduction, Dr. Carter opens with an introduction to QMP department as we get some new committee members. It was discussed that Terry Gulliver become a consultant or ad hoc member as opposed to a full-time committee member. There was intense dialogue regarding the roles of individual members and the focus and direction of the committee. I take it this is the beginnings of the committee, certainly from your perspective?
DR. MORRIS-LARKIN:
A. From my perspective. I think that there was a smaller committee that had been meeting, but they had decided to expand the group in terms of the resources and input.
COFFEY, Q.C.:
Q. And here, under policy and procedure

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implementation development, "the following policies and procedures will need to be distributed for the appropriate people to review and comment. The committee will await feedback before passing any policy procedure," and there are four listed here, and well actually four, but there's a number on the next page too. So there were a number that existed, but they had to be vetted, as it were, throughout the organization?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. In looking for--vetted in the sense of -
DR. MORRIS-LARKIN:
A. Looking for input. Again, things are much more effective if the people who are doing the work have some input into the development of these procedures and that was what that kind of thing was trying to address.
COFFEY, Q.C.:
Q. 2128, please, 2128? These are the minutes of a pathology quality management committee meeting of July 18th, 2007, about a month later. Again, you're present, and again, to

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give the Commissioner some sense of this, "business arising, policy and procedure implementation development. Dr. Larkin presented three procedures that have been 'peer reviewed' and returned to her for committee approval," and there are three listed.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. "It was decided that upon signing, the originals stay in QMP office in a binder appropriately labelled. Eventually they will be accessible online. Once approved and in place, and in-service should be planned for educational and clarification purposes" and it goes on to say "after creation and peer review of a procedure, all comments will then be forwarded for further debate at the site chiefs meeting. Questions arose regarding authorizing signatures and policy levels. It was discussed and agreed that four policies would be signed by the site chief," which would be yourself, "and division manager, Doctors Larkin, Cook and Mr. Dyer. Level

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three policies will be signed by the clinical chief and program director." That's Dr. Denic and Mr. Gulliver. Now Doctor, I wanted to ask you about what happens then once a policy or procedure is actually finally signed off, issued, completely put in place. What then happens?

DR. MORRIS-LARKIN:

A. At that point, right now, our policy and procedure manual is being managed by the quality management program coordinator and so she would, once something is approved, she would make sure that the binders that have been distributed--because I think the Commission has a binder which is in a number of places within the organization now, so that once its been approved, then it would be distributed and put into that binder as an accepted policy. What we're still trying to develop is a way in which we can make sure that everybody to whom they're relevant can be made aware that these things are in existence, that we now have a new policy or a new procedure and that they will sign off that they have in fact read them. So that's

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something that's still under development. The other thing that's happening is the Eastern Health site or Eastern Health has an intranet website and Ms. Wade has been instrumental in getting things organized there so that all of our approved policies, not our procedures, but our policies are uploaded to this site and we're working on getting that available to as many people as possible. There are some limits with information technology and so on, but the goal would be I could go into my office and--right now, I can, as of last week, click on the icon, go to the website, find all the policies, not only for me but for elsewhere in the organization. So that's something that's become online, I guess, now.

COFFEY, Q.C.:

Q. In terms of--and the procedures though are not yet online?

DR. MORRIS-LARKIN:

A. No, procedures are not on that website and I don't know if they will be, although we've had discussions about how to deal with procedures. I'm not quite sure where we are with that at the moment.

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COFFEY, Q.C.:

Q. Doctor, in terms of yourself as the site chief, I take it you're site chief for the pathologists?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. How about the pathology assistants?

DR. MORRIS-LARKIN:

A. And--well, the pathology assistants have--they kind of straddle a line. For various administrative managerial issues, they would go to the laboratory manager. For anything related to the medical function of their work, they would go--first, the pathologists assistants would go to the lead pathologist assistant, who would come to me, and all of them essentially know that they can come to me about issues.

COFFEY, Q.C.:

Q. Doctor, in terms of these policies and procedures, and you refer to signing off, the process of kind of implementing a sign off approach?

DR. MORRIS-LARKIN:

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A. Yes.
COFFEY, Q.C.:
Q. How far has that advanced?
DR. MORRIS-LARKIN:
A. I believe within the organization of the pathologists, we've not gotten very far with that yet. The pathologists are all aware, they know where the binder is, they've been notified and encouraged to go and read it, and they've been notified that it's available on the internet, but they don't yet have those - the sites available. The pathologists assistants have also been informed of the same things, but we've not got the sign up, but most certainly I think most of the things the pathology assistants have read. I don't know where we are with the pathologists reading them yet.
COFFEY, Q.C.:
Q. That's what I was going to ask you, as of yet you haven't kind of gone around and said, well, look, in two months time or a months time, I want your certification on each sheet that you've read all the ones that we are going to review.

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DR. MORRIS-LARKIN:
A. We are going there, but we're not there yet, and many of these things that would have been vetted through have - people are aware of them because they would have seen them in draft form of some sort. They just don't - they may not have looked at the final draft yet.
COFFEY, Q.C.:
Q. Exhibit P-2131, please. This is again a pathology quality management committee meeting minutes of September 19th, 2007. You're present and here under business arising, "Discussion began regarding review of the following; fixation, pathology tissue handling", and it goes on, "tissues for gross examination only", and there's another one there as well. "It is recommended a policy or procedure sent for peer review not have changes made until the committee approves them. Sheets with comments and signatures with each policy/procedure should be brought to the meetings and discussed". Doctor, I take it then that it was only in September of 2007 that the actual document dealing with fixation and pathology tissue handling, and

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tissues for gross examination only was being dealt with?
DR. MORRIS-LARKIN:
A. It had been circulating for some time. I think that preceded this, but I can't tell you exactly when.
COFFEY, Q.C.:
Q. And there was one that had been distributed on May 31st, 2007, by Dr. Denic to all pathologists in Newfoundland. One of the policies dealt with fixation?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. And you would have received that?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. So that's the - at least "a" one that had been out there?
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. From the middle of 2007.
DR. MORRIS-LARKIN:

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A. Yes.
COFFEY, Q.C.:
Q. Here, Doctor, if we could, Exhibit P-3352. These are minutes of a site chiefs meeting on November 7th, 2007. You're present, as well as Drs. Denic and Cook. Fixation policy, paragraph one, "It is agreed that the OR will need to document the time when tissue was initially submitted in formalin. This will be incorporated into the fixation policy. The PAs will need to document the day of processing as well. Dr. Denic will also liaison with Dr. Howell regarding this. A copy of the fixation policy will be forwarded by Dr. Denic to the clinics and the OR once the policy is finalized". Now, Doctor, here in relation to dealing with the perioperative program, are you involved in particularly in dealing with that in terms of fixation policy or is that Dr. Denic, as the Clinical Chief, or Dr. Howell, as the VP Medical?
DR. MORRIS-LARKIN:
A. At this time it would have been both, I think, Dr. Denic and Dr. Howell. I wasn't involved at that time. I am involved now in a

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committee that deals with perioperative issues in relation to the lab specifically, so I would be involved with any issues that arose now.

COFFEY, Q.C.:

Q. And when did that start, Doctor?

DR. MORRIS-LARKIN:

A. The first meeting was last week.

COFFEY, Q.C.:

Q. Last?

DR. MORRIS-LARKIN:

A. Last week.

COFFEY, Q.C.:

Q. Last week, and who's on that group - in that group?

DR. MORRIS-LARKIN:

A. Ms. Tracey, Maria Tracey, I believe, chairs it, and I'm not sure how it came about, it probably actually - I should say the first meeting I attended was last week. I think there was a meeting before that and I was invited to join afterwards. We have our quality management coordinator, Ms. Bev Rowe. There are several - I believe there are clinical educators from the perioperative

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program, and I'm not sure if we're at an ad hoc or a definite involvement of other lab representatives, but there is an awareness that there are other labs, like the cytology lab, the microbiology lab, with whom the perioperative program want to have communication, so that's - those terms of reference and the exact membership, I think, is still being developed.

COFFEY, Q.C.:

Q. Exhibit P-2132, please, 2132. Thank you. These are the minutes of a site chiefs meeting of October 5th, 2007. Again, Doctor, you're present, along with your compatriots, and we've looked at that paragraph 2.1, pathology assistants already, but down below here, there's a reference to 2.2, accreditation, "Dr. Denic informed the group that the review by the accreditors was generally positive, with small negative, such as the need for emergency showers in lab locations. The reviewer's assessment of the ER/PR handling was also positive". There's a reference to 2.3, "OLA laboratory accreditation. Mr. Greg", and that would be Flynn, Dr. Greg

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Flynn, actually -

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. "Will be promoting the OLA laboratory accreditation service at a meeting on Wednesday, October 10th. The group will compare this to that of the CCHSA". Now, Doctor, as the site chief for the General Hospital, what is your understanding about the difference between a CCHSA involvement in its accreditation process in September of 2007 with respect to the lab versus or in comparison to that of the QMPLS in December of '07?

DR. MORRIS-LARKIN:

A. I think at that time this was one of the objectives was to see how they actually compared. My understanding - I was fairly peripherally involved in this activity, but my understanding was that the CCHSA was a more general overview of the lab, and the QMPLS, as part of the OLA laboratory accreditation program, was much more detailed. So it looked into much finer detail, and it was the one

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that we actually found the most productive because you're asked for the various procedures or you're asked for documentation of various sorts, and we found that that was really what we wanted because you - it's both a learning activity as well as an accrediting activity.

COFFEY, Q.C.:

Q. Exhibit P-2390. Doctor, this is a letter written to Terry Gulliver, program director, laboratory medicine. It's from - it's actually three pages long. It's from yourself, copied to quite a number of people. I take it these are - well, Dr. Denic is readily apparent, and Mr. Dyer. The other individuals listed here.

DR. MORRIS-LARKIN:

A. Mr. Gerry McLean was in a managerial or an acting managerial role, I think probably at the time this was written, so I would have included him in the information. Ms. Swain, pathologist assistant. At this time, Ms. Searle and Ms. Milley would have completed, I think, the 18 months. That was what they were initially told would be their probation

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period, and Ms. Bouzanne was under that 18 month time period. So this was written as a summary and an outline of where we had gone with the pathologist assistants, and I believe one of the main reasons, aside from providing a letter for the people who had completed their 18 months, was to give support to their reclassification. They're still being classified as laboratory technologists, and we really wanted to have a recognition of their role as being unique from laboratory technologists.

COFFEY, Q.C.:

Q. And it's written to Mr. Gulliver because that's an administrative aspect?

DR. MORRIS-LARKIN:

A. I would have written it to him as the program director.

COFFEY, Q.C.:

Q. Now, Doctor, in terms of the training of pathology assistants, there are currently how many pathology assistants in St. John's?

DR. MORRIS-LARKIN:

A. There are currently four.

COFFEY, Q.C.:

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Q. And they are located where?

DR. MORRIS-LARKIN:

A. They rotate through both sites, and it's one of the jobs of the lead pathologist assistant is to ensure that there is coverage at both sites. So she does scheduling.

COFFEY, Q.C.:

Q. That's spelled out in your letter, the scheduling and all that is, yes.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. So there are three at the General and one at St. Clare's?

DR. MORRIS-LARKIN:

A. When we're full - when they're all there and not away on leave or whatever, what usually happens is there's one and a half at St. Clare's. By that, I mean there's one person posted there for probably weeks to months at a time, and then one of the other people rotates back and forth between the two sites. So she'll spend three days - usually it's Ms. Swain, will spend three days at the Health Science site and two days at St. Clare's.

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COFFEY, Q.C.:

Q. And keeps her kind of --

DR. MORRIS-LARKIN:

A. Trying to keep a balance in the workload because there's too much for one pathologist assistant to do at St. Clare's.

COFFEY, Q.C.:

Q. And here, Doctor, just looking at the third page of the exhibit, you've written, "The pathology assistant position is not a natural progression from a laboratory technologist. In both Canada and the United States, there is a requirement for additional training usually in the range of 18 to 24 months beyond a primary diploma. Many pathology assistants have not come from a technologist background, but have a Bachelor of Science. In the United States, pathology assistants training programs are considered master level programs", and I point out you've told the Commissioner that.

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. "Pathology assistants have a unique knowledge and skillset with significant and direct

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responsibility in patient care. For these reasons, we need to see that the classification of pathology assistants with certification for the different levels of responsibility within the classification separate from that of laboratory technologists". Now, Doctor, where has this gone? Have you gotten any response to this and what's the status?

DR. MORRIS-LARKIN:

A. I don't expect any response. It was written, from my point of view, for information purposes. From Mr. Gulliver, I believe it would have went to whatever - and I honestly don't know what the route is, whatever route they would have had to take to look at this issue of reclassifying and creating - within the lab union section that they're in, creating this new group to be recognized, pathology assistants, and that would involvement government and union people. Beyond that, I couldn't tell you.

COFFEY, Q.C.:

Q. And so you haven't heard anything further back about it?

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DR. MORRIS-LARKIN:
A. I have heard that - you know, just by word of mouth from one of the pathologist assistants that their application has been rejected.
COFFEY, Q.C.:
Q. So they are currently classified and paid as what?
DR. MORRIS-LARKIN:
A. As laboratory technologists.
COFFEY, Q.C.:
Q. And whatever level -
DR. MORRIS-LARKIN:
A. At whatever level - I believe, and I could be corrected on this, I believe that the pathologist assistants are considered - they start at Laboratory Tech II and Tech III, maybe Tech IV. I honestly - I'm not sure of the -- you would need to ask somebody else.
COFFEY, Q.C.:
Q. Okay, Mr. Gulliver would know.
DR. MORRIS-LARKIN:
A. Yes.
COFFEY, Q.C.:
Q. Mr. Gulliver would know about that?
DR. MORRIS-LARKIN:

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A. I would think so, yes.
COFFEY, Q.C.:
Q. Now on this point, you're writing this letter as of the end of - May 23rd, 2008. I'm not going to take you through it, but you have set out here - you said, "Within the lab, this is a unique group with specific duties which were formerly the responsibility of pathologists. This includes", and you list them all off.
DR. MORRIS-LARKIN:
A. Uh-hm.
COFFEY, Q.C.:
Q. Headings and descriptions. At the time, the descriptions here, did they accurately encompass what you understood pathology assistants were doing at the time?
DR. MORRIS-LARKIN:
A. Yes, yes.
COFFEY, Q.C.:
Q. I take it this was an attempt to be relatively comprehensive?
DR. MORRIS-LARKIN:
A. This was, yes.
COFFEY, Q.C.:
Q. Has anything changed since? Is there anything

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that you would now delete or add?
DR. MORRIS-LARKIN:
A. As new duties?
COFFEY, Q.C.:
Q. Yes.
DR. MORRIS-LARKIN:
A. I think that, you know, they are still--as many people in medical fields are learning new things all the time, so the big thing that would stand out is their role in the autopsy performance. We've had limited opportunity to training them to do the autopsies the way a pathology--a pathologist would do, for example, but that is where we're going and with time, we will get there. So this is something we have started, but we've only--we're only in the very preliminary stages of it.
THE COMMISSIONER:
Q. Any questions?
COFFEY, Q.C.:
Q. Thank you, Commissioner, thank you, Doctor. There may be--I understand there are some more questions from others.
MR. PRITCHARD:

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Q. Thank you, Commissioner. I don't have any questions for this witness, thank you.
THE COMMISSIONER:
Q. Mr. Simmons?
MR. SIMMONS:
DR. CAROLYN MORRIS-LARKIN, EXAMINATION BY MR. DAN SIMMONS
MR. SIMMONS:
Q. Good afternoon, Dr. Morris-Larkin. I have only one thing to ask you about. You gave some evidence this morning when you were looking at some of the pathology reports from back in 2002 and 2003 where there were some changed results, and you were asked about whether occurrence reports were something that would be filed there. And I understood you to say that today that sort of thing would be reviewed as an internal lab occurrence?
DR. MORRIS-LARKIN:
A. I think it would depend--each one of these would be individual case dependent in determining what really is an adverse event and I think that's probably where it may have gotten a little confused this morning. Depending on what the issue is, if there's a significant change in a report, so if I had

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for some reason an opportunity to review a previous one of my reports or someone else's or I gained new information and there was a significant discrepancy in what I had said before, then that would be something that could potentially be filed as an occurrence report and we have seen that happen within the lab. So one example that stands out is during our quality assurance activity, you would identify something that perhaps someone hadn't seen and it would be appropriate then to file an occurrence report on that. The other issue, I think, was related specifically to something that might change within the context of me trying to do the best I could with a pathology report. The example, of course, which is given it was ER/PR and I don't deal with ER/PR anymore. But I think in that particular example, that's the kind of thing that we hope with the Quality Management Program we will see more identified as an internal occurrence because it would be much more relevant to us to be able to track that kind of thing. So for instance, if there's some significant discrepancy in one of the

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stains when you order a repeat test, you would bring that to the immunohistochemistry lab, they have corrective action logs and things like that. So that's the kind of thing I would think would be much more relevant within the lab itself, because when we talk about occurrence reports, as you are referring to, we're talking about corporate wide and things go way up the level, and in terms of, you know, going to quality risk and initiatives management, it's something that they may not be as effective in dealing with as we would be in the lab, so it's like there are two different levels of occurrence reporting.

MR. SIMMONS:

Q. Right. In the current Quality Management Program, is there a particular--are you aware of a particular policy or procedure now in place for dealing with corrective action logs and these internal measures you're talking about?

DR. MORRIS-LARKIN:

A. There are--it depends on which level you're speaking of again, there is one for the corporate wide for the quality initiatives and

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the occurrence reports, the ones that go to them. There is also a general lab policy on occurrence reporting. We have not gotten one, I don't think--I could be corrected.

MR. SIMMONS:

Q. Well, I'll show you one.

DR. MORRIS-LARKIN:

A. In the pathology specifically about how we do that.

MR. SIMMONS:

Q. I'll just show you one, Exhibit P-2157 please? And if you could go to page 177, it's a big file, so it takes a little while to open. Is it going to open? The particular policy I am going to refer you to, when we get to see it, is one entitled "Correction actions for IHC Occurrences".

DR. MORRIS-LARKIN:

A. Yes, I'm aware of that.

MR. SIMMONS:

Q. That's one that you are aware of, is it?

DR. MORRIS-LARKIN:

A. Yes.

MR. SIMMONS:

Q. Is that the sort of policy that you would be

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referring to when you were talking about the internal occurrence reporting within the lab?

DR. MORRIS-LARKIN:

A. That kind of level of reporting, yes. It's a direct feedback and it addresses the issues much more timely and more directly.

MR. SIMMONS:

Q. Good. Thank you very much, that's all I have for you.

THE COMMISSIONER:

Q. Is this the one you're referring to, Mr. Simmons?

MR. SIMMONS:

Q. Yes, it is, it's on the screen there now.

THE COMMISSIONER:

Q. All right, thank you. Mr. Pritchett?

MR. PRITCHETT:

Q. No questions.

THE COMMISSIONER:

Q. Ms. Newbury?

DR. CAROLYN MORRIS-LARKIN, EXAMINATION BY MS. JENNIFER NEWBURY

MS. NEWBURY:

Q. Good afternoon, Dr. Larkin. My name is Jennifer Newbury and I represent the

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Newfoundland and Labrador division of the Canadian Cancer Society. And I want to pick up where Mr. Simmons left off and I was just wondering if you are familiar with the concept of a near miss, in terms of policies and procedures at Eastern Health?

DR. MORRIS-LARKIN:

A. I am familiar with the concept, yes.

MS. NEWBURY:

Q. And just in terms of the application of that concept and perhaps what we can do is bring up Exhibit P-0057 please, because this specifically refers to the near miss. And as I understand it, these are the procedures, policies that are currently in place for 2007.

DR. MORRIS-LARKIN:

A. This is the quality and risk management which is a level above.

MS. NEWBURY:

Q. Right.

DR. MORRIS-LARKIN:

A. This is for Eastern Health.

MS. NEWBURY:

Q. So that's the corporate why, as opposed to something particular to Eastern or to the

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pathology lab in particular.

DR. MORRIS-LARKIN:

A. That's correct.

MS. NEWBURY:

Q. And on page 5 of the exhibit, there are several references in this policy which relates to occurrence reporting to near miss, is that the concept that you're familiar with?

DR. MORRIS-LARKIN:

A. I would probably have to read it again.

MS. NEWBURY:

Q. Okay, well what I can do, I'll read down to the overview, which is on page 1 of the policy and just looking up above, it's, the original approval date was August 28th, 2007. And under the second paragraph of the heading, "Overview", it indicates that "the occurrence reporting system facilitates the identification, monitoring and analysis of adverse events, sentinel events, hazards, incidents and near misses. Occurrence reporting is not designed to place blame on individuals." And near miss is referenced several times there, but there is a definition on page 10 of the document. And in the first

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row there, near miss is defined as "an event or circumstance which has the potential to cause serious physical or psychological injury, unexpected death or significant property damage, but did not actualize due to chance, corrective action and/or timely intervention." And I'm just wondering whether there would be any role for this type of a policy, even though it's a corporate wide policy to apply to the two situations, if they were to happen again, relating to the pathology reports that were shown at Exhibit C-0184 and C-0175 and I can bring those up, if you want.

DR. MORRIS-LARKIN:

A. I can certainly see where that could play a role and this is something, you know, in terms of defining a near miss, this is something that I think that within the Quality Management Program is on our radar to try and address, would the specific report that you referred to this morning, where it was negative and it changed to positive, within, again at that time would have been within my concept of working of that case. In today's

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event, for Dr. Makretsov in particular who would be reporting them, I wouldn't be reporting them, would such an event qualify as a near miss? And I think that within the Quality Management Program, these are the kinds of things that we would be looking at in terms of addressing so that we're clear on what does actually qualify, you know, as these particular types of events.

MS. NEWBURY:

Q. Right.

DR. MORRIS-LARKIN:

A. For a pathologist in another type of stain where it may also impact upon my final decision on what this, what this was diagnostically but has different implications because it doesn't necessarily relate to the very specific treatment that you see with the ER/PR, then we would need to define it for that as well.

MS. NEWBURY:

Q. Right.

DR. MORRIS-LARKIN:

A. So there's a broad number of things that go on in the lab that we would need to, you know,

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address and say, well does this qualify as a near miss and I can certainly see that the case you're suggesting might fit into that category.

MS. NEWBURY:

Q. Right, okay, so you're talking then the fact that some types of stains may not be used for--specifically for decisions that might relate to patient care, so you might have to draw the line between those two?

DR. MORRIS-LARKIN:

A. No, it's not that, it's how you utilize the stains. For the ER and PR, it's very specifically treatment directed and there are more and more of those coming on, so if you're ER positive, then you would be a candidate for Tamoxifen. For most of the stains that we use, it's one of several stains in a panel that may sway my diagnosis in one way or another, so they could have an impact on what my diagnosis would be and then what the patient's treatment would be. But it's a bit more layered and more complex. The ER is a little bit more straightforward there.

MS. NEWBURY:

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Q. Yes, and we have heard other evidence on that point, that other types of stains are not quite the same as ER/PR in terms of the reliance placed on that to make decisions pertaining to patient care. Just, I think you mentioned earlier this morning you were comparing a situation where you might have a mislabelled specimen and say you came across a situation where there were a mislabelled specimen and again, just to make an analogy here, if the problem had been detected in time, that it didn't interfere with patient care, however it was, you know, if it hadn't been caught, it would have been a significant issue for that particular patient. In that situation would this type of a report be used?

DR. MORRIS-LARKIN:

A. Oh yes, that would be a near miss, that would be a very clearly a near miss to me then, that would have an occurrence report done.

MS. NEWBURY:

Q. And are there any immediate plans to try to develop more concrete guidelines as to how to deal with the types of situations that, you know, arose with the two exhibits, C-0184 and

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C-0175 for the benefit of pathologists?

DR. MORRIS-LARKIN:

A. There are discussions at the Quality Management Program level of closing the various loops on corrective actions, yes.

MS. NEWBURY:

Q. Okay. Dr. Larkin, in your role now with the quality assurance of the Laboratory Medicine Program that you recently took over from Dr. Carter, which I believe is a temporary, you've taken it over for a temporary period of time. Is there any monitoring of, for example, positivity rates or the ER/PR rates and as compared with what might be expected based upon literature?

DR. MORRIS-LARKIN:

A. From the Quality Management Program view itself, we have not any data on that yet. I do think that there is, within house of that specific laboratory, that there is--and attention being paid to that, but in terms of tracking trends which is something we know we want to get to, we have not gotten there yet. But specifically within the lab itself, their awareness, I think you would probably need to

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address somebody, you know, who works with that on a daily basis.

MS. NEWBURY:

Q. Okay.

DR. MORRIS-LARKIN:

A. Because I think they've done a tremendous amount with regards to those kinds of issue and I'm not sure yet what is available there.

MS. NEWBURY:

Q. Okay, and from your role as a pathologist and particularly with your involvement in that, is that something that you planned to delve into in the future, looking at positivity rates and to develop guidelines as to what might be done if there's any deviation from those expected rates.

DR. MORRIS-LARKIN:

A. Again, I think that that's within the overview of the Quality Management Program as something that will need to be done.

MS. NEWBURY:

Q. Okay. Thank you, those are all the questions I have, Dr. Larkin.

THE COMMISSIONER:

Q. Mr. Crosbie?

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CROSBIE, Q.C.:
Q. Thank you.
DR. CAROLYN MORRIS-LARKIN, EXAMINATION BY CHESLEY CROSBIE, Q.C.
CROSBIE, Q.C.:
Q. Thank you. Good afternoon. Ches Crosbie, we met at break time.
DR. MORRIS-LARKIN:
A. Yes.
CROSBIE, Q.C.:
Q. Perhaps we could start by bringing back the Ejeckam memorandum document, 113 please? We looked at this a little bit earlier.
DR. MORRIS-LARKIN:
A. Yes.
CROSBIE, Q.C.:
Q. And we see there in that first paragraph, it's a short memo and it starts out, "Kindly note that the immunohistochemical stains with the following antibodies"--and it lists off a bunch there. There are six antibodies before he gets to ER and PR, correct?
DR. MORRIS-LARKIN:
A. Yes.
CROSBIE, Q.C.:

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Q. And those would be looked upon by you and I think you touched by pathologists, so I think you've touched on it just a moment ago with Ms. Newbury as diagnostic stains for the pathologist's purposes, is that right?
DR. MORRIS-LARKIN:
A. I would look upon those as stains which contributed to a diagnosis, so that in any of these stains of the six that you referred to, they would be perhaps one of a half a dozen or a dozen stains that I would use and then from looking at what we call a panel of stains in addition to your opinion on the H&E, they would contribute to a final diagnosis.
CROSBIE, Q.C.:
Q. The ones under ER/PR are not directly relevant to prognosis, are they?
DR. MORRIS-LARKIN:
A. Only relevant in terms of helping you make the diagnosis, so again, it's within that setting of using the information you get from the stain to determine what your diagnosis is. There are other immunohistochemical stains not mentioned here that we do in other settings that may have prognostic implications.

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CROSBIE, Q.C.:
Q. These ones we're looking at here, though, are primarily for the pathologist to refine the diagnosis, that's the logical diagnosis?
DR. MORRIS-LARKIN:
A. That's correct.
CROSBIE, Q.C.:
Q. ER/PR, however, is different from that because it has a prognostic application, obviously, doesn't it?
DR. MORRIS-LARKIN:
A. Yes.
CROSBIE, Q.C.:
Q. And a therapeutic application?
DR. MORRIS-LARKIN:
A. Yes.
CROSBIE, Q.C.:
Q. So to that extent ER/PR is a unique stain compared to those others mentioned by Dr. Ejeckam?
DR. MORRIS-LARKIN:
A. Yes.
CROSBIE, Q.C.:
Q. Uniquely important, in fact.
DR. MORRIS-LARKIN:

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A. Unique--they're all important.
CROSBIE, Q.C.:
Q. In the case that Mr. Coffey looked at with you from July 2000, I believe it was document number 184, we need not refer to it now, unless you wish to, you mentioned that there is no control available, but it seems like you read the slide originally without the control, is that right?
DR. MORRIS-LARKIN:
A. If that's the way I reported it, what I would have done is I looked at it and I didn't see the control and for that reason went and repeated everything with the control.
CROSBIE, Q.C.:
Q. Yes, well you added an addendum and there is number one and number two, so you must have dictated the initial -
DR. MORRIS-LARKIN:
A. I would have dictated it without the control and for some reason, and I don't know why that was, but recognized that I do need to have the control and then went through the further exercise.
CROSBIE, Q.C.:

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Q. But at the point of dictation you dictated it and left the matter as a finished case?

DR. MORRIS-LARKIN:

A. I dictated it, other than that, I can't tell you anything more. I don't remember the specific case and I don't know the sequence, I don't recall the sequence of events that triggered me to go further there.

CROSBIE, Q.C.:

Q. But it presents itself as an addendum No. 1 or it ended up being addendum 1 I think it's called, as a finished case at that point, right?

DR. MORRIS-LARKIN:

A. It presents it as finished to that point in time.

CROSBIE, Q.C.:

Q. And you had either second thoughts or something happened to make you go back to it and you did, you did go back.

DR. MORRIS-LARKIN:

A. Yes, I did.

CROSBIE, Q.C.:

Q. Are you familiar with the substance of Dr. Dabbs' testimony that we heard here two or

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three weeks ago?

DR. MORRIS-LARKIN:

A. Not the details, no, I've seen maybe a small amount of what he had stated, but I didn't read the transcriptions in detail and I wasn't here at the time.

CROSBIE, Q.C.:

Q. I see. I know you're busy and we've heard how busy you are, but it may--many of us would commend that as worthwhile reading, I suspect. In any event, amongst the many things he said was that positive and negative and internal controls are all mandatory and you understand that to be best practice at this point in time?

DR. MORRIS-LARKIN:

A. Yes, I do.

CROSBIE, Q.C.:

Q. In fact, in the case that we're now referring to, the July, 2002 case that you went back to with the control, it seems that the control did have a dramatic impact on case interpretation?

DR. MORRIS-LARKIN:

A. It did.

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CROSBIE, Q.C.:

Q. Which I guess is an illustration of why people like Dabbs say that the presence of controls are mandatory.

DR. MORRIS-LARKIN:

A. And in essence, that's what I followed. By the time I completed the case with the addendums, that was where I was going with that.

CROSBIE, Q.C.:

Q. Were there any other occasions, Doctor, on which you reported without the control?

DR. MORRIS-LARKIN:

A. No, it was not my practice and that's why you would have seen that addendum. It was my practice to look for the controls--unless they were being reported by somebody else because we know for a time period it was.

CROSBIE, Q.C.:

Q. So initially when this program was set up, we've heard that Dr. Khalifa was the resource person to whom you and other pathologists looked.

DR. MORRIS-LARKIN:

A. Yes, that's true.

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CROSBIE, Q.C.:

Q. He seemed to have the most experience, round experience with labs elsewhere, I think in the United States, he mentioned.

DR. MORRIS-LARKIN:

A. Yes.

CROSBIE, Q.C.:

Q. More experience than anyone else in 1997 or 1998 or in fact until Dr. Ejeckam came later.

DR. MORRIS-LARKIN:

A. I think that's probably correct to assume. He certainly had more experience than I did and I looked--I looked to him as a resource person.

CROSBIE, Q.C.:

Q. You, yourself, had no formal training in reading this kind of stain, the ER/PR nuclear stain?

DR. MORRIS-LARKIN:

A. No, my training was at a time when this was just something that was coming on board, so most of what I would have learned, I would have learned as a practising pathologist.

CROSBIE, Q.C.:

Q. Would that be a true statement of the other people practising in your group here in St.

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John's, say, at the time in '97, '98?
DR. MORRIS-LARKIN:
A. It would depend upon the timing and it would depend upon the place in which they practised. For example, Dr. Khalifa had trained in a place where there was more availability to learn this information and when he came here, I learned from him.
CROSBIE, Q.C.:
Q. We've seen a good deal of documentation, including the sort of foundational document on which Dr. Khalifa established the immunohistochemical program for ER/PR, including a reference to literature. And I think that was looked at a little earlier today as well. And we've also seen documents from, for example, the summer of 2005, it's only a short document, but it's one in which Dr. Carter and Dr. Cook, for example, set out in list form, very shortly, here are the things that it is mandatory to be looking for when you're reading these slides and giving an opinion.
DR. MORRIS-LARKIN:
A. Yes.

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CROSBIE, Q.C.:
Q. You remember that one from, I think, August 2005?
DR. MORRIS-LARKIN:
A. Oh yes, yes.
CROSBIE, Q.C.:
Q. And it talked about, you've got to have this control, you got to have that control and so on. There's no document like that made available to the practising pathologists back in '97 or '98, was there?
DR. MORRIS-LARKIN:
A. No, the document that I would have referred to in '97 was that memo from Dr. Khalifa with recommendations on the way to report.
CROSBIE, Q.C.:
Q. The way to report, but in fact he didn't spell out the kind of controls that were mandatory, did he?
DR. MORRIS-LARKIN:
A. The controls that he refers to here are the external controls. And he does state that they are there and he was looking at them and eventually, they would be issued to us. I believe that's how the document was drawn up.

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CROSBIE, Q.C.:
Q. Anything mentioned about external negative controls?
DR. MORRIS-LARKIN:
A. I don't believe in that document.
CROSBIE, Q.C.:
Q. Well internal controls?
DR. MORRIS-LARKIN:
A. I don't believe it's in that document.
CROSBIE, Q.C.:
Q. One of the reasons you gave the Commission for why the decision was taken not to concentrate the reading of this test in the hands of the limited number of people, is that we, pathologists generally, didn't want to lose our skills, is that correct?
DR. MORRIS-LARKIN:
A. I think that in the context of that particular meeting, what we were seeing, what was being discussed was, you know, this was one of the things that we do and if you just take it and one person does it, then who will do it in their absence, so it was in that context at that time, the same kind of thing that we see in other areas of subspecialty practice and we

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had experience with what happens when you have subspecialty practice; it's a double-edge sword. It definitely is a very good thing, but it also, in a place like this where there's a high turn over, it also has very negative impact because suddenly there's nobody left with the skills to look at a particular area and you have a void, and that was the context in which that conversation in that meeting would have taken place, I think.
CROSBIE, Q.C.:
Q. So I understand two things are going on: one is the concern that if you lose somebody with a subspecialty skill or a specialized skill, whether it's by reason of someone going on vacation or perhaps more of a concern, leaving altogether, then you got a void and there's no one there to do that job, that's one concern.
DR. MORRIS-LARKIN:
A. That's one concern.
CROSBIE, Q.C.:
Q. But the other one I understood separately, perhaps, is that--or perhaps it's not separate, but people wanted to maintain their skills in an overall sense, including in that

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area.
DR. MORRIS-LARKIN:
A. And you're right, it's not separate, it's all part of the same kind of concept that we would have.
CROSBIE, Q.C.:
Q. Well, there was a third alternative, wasn't there, to sub-specialization here, to everybody reading it here, it could have been referred out?
DR. MORRIS-LARKIN:
A. And eventually that is what had to happen when we were left the spring with nobody to read ER and PR.
CROSBIE, Q.C.:
Q. So with no formal training, learning on the job, as you did without - with, can we agree, limited guidance on how to do it from Dr. Khalifa?
DR. MORRIS-LARKIN:
A. Limited guidance, but some guidance.
CROSBIE, Q.C.:
Q. Did you feel confident you had the skills to do this properly?
DR. MORRIS-LARKIN:

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A. I would have seen this within the context of everything that I do and everything that I've learned on the job. I learn all the time in my practice. It's the nature of our practice, so we're always faced with new things. There are - not only are new things from a new technology or a new available technology point of view, but things that are rare or uncommon that we've not encountered before. So I think I would have seen it within that context, this is something that's being done across North America, it's being introduced here as something that our lab should be doing, and I would have felt that it was something I was supposed to be doing.
CROSBIE, Q.C.:
Q. I guess we can all understand that. Maybe I can ask you, looking back on it now in retrospect knowing, in fact, what you know now about the sensitivity of this procedure, do you think that you were over confident?
DR. MORRIS-LARKIN:
A. I don't think I was over confident. I think I had the same level of confidence that any one of us had. It was something new, it was

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something that we were learning, and there is always - there is always a learning curve where you start out being uncertain, and then you gain knowledge. We practice that way all the time. It's the nature of medicine. It's the hard part of the nature of medicine.
CROSBIE, Q.C.:
Q. So you'd do this again the same way?
DR. MORRIS-LARKIN:
A. If I'm introduced to something new. I deal with this all the time. I have to learn new things. I have to learn and practice new things.
CROSBIE, Q.C.:
Q. But you - even knowing all you know today, you put this IHC testing and the reading of these slides in a category of something new, I can handle it, we can all handle it, I'd do it the same way?
DR. MORRIS-LARKIN:
A. I'm not sure what you're asking me beyond what I've said, that I need to learn things all the time.
CROSBIE, Q.C.:
Q. You made mention of a learning curve. I

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suppose that curve started in 1997, is that the start point?
DR. MORRIS-LARKIN:
A. For the ER/PR?
CROSBIE, Q.C.:
Q. Yeah.
DR. MORRIS-LARKIN:
A. I think that's fair to say.
CROSBIE, Q.C.:
Q. For the lab here, in general, is that fair to say, as well as the pathologists?
DR. MORRIS-LARKIN:
A. I can't really speak for the lab.
CROSBIE, Q.C.:
Q. When did the end of the learning curve arrive?
DR. MORRIS-LARKIN:
A. I don't think you ever at the end of a learning curve.
CROSBIE, Q.C.:
Q. So you're still working on that?
DR. MORRIS-LARKIN:
A. Always. Always will be.
CROSBIE, Q.C.:
Q. So what I can get out of - what I thought you'd tell me, I must say to you, is that you

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went into this in '97 and '98, in that time period, without knowing adequately the sensitivity of the procedure, and remember, for example, the necessity of closing down the lab for a period in 2003, there are a lot of things the pathologists here didn't understand about it, but you wouldn't agree that - you wouldn't agree with me that if you had your time back, you probably would have done it differently?

DR. MORRIS-LARKIN:

A. You're asking me about something that we see with hindsight now.

CROSBIE, Q.C.:

Q. Exactly.

DR. MORRIS-LARKIN:

A. And we always -

CROSBIE, Q.C.:

Q. I did ask you about hindsight.

DR. MORRIS-LARKIN:

A. And we always do look back on anything with hindsight as there are things that if we knew, would contribute or would make a change. I mean, there's no denying that kind of thing. That's - again that's the way we learn, that's

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the way we practice, that's the way we live.

CROSBIE, Q.C.:

Q. Can you tell the Commissioner is there anything important missing from the way the program was established in '97, '98 time period that wasn't done and that should have been done?

DR. MORRIS-LARKIN:

A. I can't speak to the technical aspect. I think that probably a more formal in-service. if such a thing were to be introduced today, I can tell you that we have a pathology update meeting that covers technical issues, that covers pathologist issues, and it's the kind of thing that this would have been presented, it's the kind of forum where this kind of thing could have been presented in a more formal teaching sort of way. I think we would have benefited from something like that, yes.

CROSBIE, Q.C.:

Q. Well, what about a document that you could call a feasibility analysis, I suppose, that sets out the human and financial resources that were going to be needed by the institution in order to do the service up to

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the standard to which it deserved to be done? We don't see anything like that in front of us hailing from '97 or '98, do we?

DR. MORRIS-LARKIN:

A. And that's not something I would have known anything about. As a practising staff pathologist and a faculty member, that's not where my focus or my - any kind of knowledge of expertise would be.

CROSBIE, Q.C.:

Q. It's more a management function?

DR. MORRIS-LARKIN:

A. It would be, yes.

CROSBIE, Q.C.:

Q. In your notes of perhaps 1994, the Exhibit 1994, these are notes of August 5th, 2005, that you typed yourself?

DR. MORRIS-LARKIN:

A. I believe I'm the one who typed this, yes.

CROSBIE, Q.C.:

Q. The impulse behind this, I gather, is what you described, I think you mentioned to an earlier question here today, as the idea of the blameless culture?

DR. MORRIS-LARKIN:

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A. Yes.

CROSBIE, Q.C.:

Q. Does this discuss the concept of accountability anywhere, this document you typed?

DR. MORRIS-LARKIN:

A. This wasn't meant to be a comprehensive document. This was probably done a half hour before we went in to meet with Dr. Cook. It's something that again I did more for his benefit, and for the pathologists who had been dealing with the emotional fallout of knowing that a major event had happened in the lab, and it was something that we had to address. So it's not meant to be a comprehensive document. So if anything is missing, it's not by - you know, it's not because it should have been there, it was just basically me putting down the thoughts and the thoughts of other people around me.

CROSBIE, Q.C.:

Q. You mentioned earlier that the document we now know as the Banerjee report -

DR. MORRIS-LARKIN:

A. Yes.

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CROSBIE, Q.C.:
Q. You just assumed that that was a peer review report, and pretty much thought nothing more about it, didn't ask to see it for that reason?
DR. MORRIS-LARKIN:
A. I think, you know, in terms of what I knew about the Banerjee report, again that's something that occurred over time. I think what we've - you know, what I knew was that Dr. Banerjee had been in and had done a report. I happened to be away at the time that the report was read, so I was not even - I don't think I was even aware that it was read until much, much later. I knew that it was referred to. I knew that Dr. Cook had been trying to implement recommendations made from it, and I saw that within the purview of the leadership team and I was - I was not gone - I did not go beyond that, no.
CROSBIE, Q.C.:
Q. So if there were a peer review report, you wouldn't expect to be brought into the loop and shown a copy?
DR. MORRIS-LARKIN:

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A. You know, in all honestly, I never even heard about the issue of peer review until it became an issue for this Commission.
CROSBIE, Q.C.:
Q. You knew there was a report?
DR. MORRIS-LARKIN:
A. I think I knew Dr. Banerjee had written a report, I knew it had gone to Dr. Cook, and this whole focus on this being a peer review report was not something that I really had much thought on. It wasn't -
CROSBIE, Q.C.:
Q. Because I thought earlier your explanation for not making inquiries about the document was that it was a peer review and, therefore, not properly something you should be informed about?
DR. MORRIS-LARKIN:
A. No, that wasn't - I apologize if I misled you there because that wasn't even on my radar of - the peer review report.
CROSBIE, Q.C.:
Q. Because I was going to ask you, which of your peers did you think the report was about.
DR. MORRIS-LARKIN:

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A. Yeah, it was only when it became an issue for this Commission that I even really became aware of the whole issue of, this is peer review, and how people were trying to deal with it. I knew that Dr. Banerjee had reported his findings to Dr. Cook, and Dr. Cook was doing his best to implement it.
CROSBIE, Q.C.:
Q. However, you were a member of the team and you were aware, I'm sure, that there was a significant failure in this testing that had extended over a period of years?
DR. MORRIS-LARKIN:
A. I knew that there was something that had happened and that there had been changed results and we were trying to address it in a number of ways, both in terms of trying to find whose results had changed so that - in particular, what I understood was that the focus was to provide treatment options for any women to whom it may still benefit. That was far and away the main focus of everything that was going on in the lab. I also was aware that Dr. Cook had taken the initiative to say, well, you know, why is this happening let's

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look to outside sources to give us some advice, and that's how I saw it.
CROSBIE, Q.C.:
Q. No doubt there may be some people who think it's rather extraordinary that as a staff pathologist in that lab faced with an error of some magnitude extending over a period of years that you did not exert yourself to be better informed about the causes as to how that had happened?
DR. MORRIS-LARKIN:
A. But I think we were learning about the causes as to how that had happened because Dr. Cook was sharing information, Dr. Carter was sharing information, and we were seeing changes happen as a result of recommendations from this report.
CROSBIE, Q.C.:
Q. Except they certainly didn't share the report?
DR. MORRIS-LARKIN:
A. No.
CROSBIE, Q.C.:
Q. My final question is who, if anyone, do you understand has publicly taken responsibility for these testing failures in the lab?

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DR. MORRIS-LARKIN:
A. I think that all of us take responsibility. I don't know that there's any public - I've not heard of anything publicly, but I think that every one of us, and I should only speak for myself, I certainly think that we all - I take responsibility for any cases that I would have been involved in. I think that's something that is a general accepted thing. You know, we're all working toward the best result we can get, and if somehow we didn't get the best result, then we all have to take a role in taking the responsibility.
CROSBIE, Q.C.:
Q. Thank you.
THE COMMISSIONER:
Q. Mr. Pike.
PIKE, Q.C.:
Q. No questions. Thank you very much.
THE COMMISSIONER:
Q. Mr. Browne.
DR. CAROLYN MORRIS-LARKIN, EXAMINATION BY PETER BROWNE, Q.C.
BROWNE, Q.C.:
Q. Good afternoon, Dr. Morris-Larkin. I just

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have a couple of areas I want to cover off with you. The first one is a short area. Mr. Coffey was asking you about the current situation in terms of pathologist ratio and I think in the course of that exchange, you had mentioned about 4 out of 11 at the Health Sciences, and you were about to say there was one in relation to St. Clare's, but I don't think you completed that answer. Is there a -
DR. MORRIS-LARKIN:
A. There is a vacancy at St. Clare's.
BROWNE, Q.C.:
Q. Vacancy, so in fact, there are now five vacancies?
DR. MORRIS-LARKIN:
A. There are five within the City.
BROWNE, Q.C.:
Q. Now I want to go back and just sort of just cover off another short area and that is this questioning about the peer review report and what Mr. Coffey just asked you a moment ago. Do I understand your evidence in summary is that the information--you've now read the reports, the contents of the reports, the focus of Dr. Banerjee's points with regard to

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fixation, internal controls, the absence of internal controls, all that information. That information was translated to you through Dr. Carter and through Dr. Cook fairly early on in this whole process? Is that fair?
DR. MORRIS-LARKIN:
A. Yes, that's true.
BROWNE, Q.C.:
Q. And you saw the changes--putting aside whether or not you saw that report or read that report, you saw those changes happening over the course of time as a result of those observations, both--and just so we're clear, the observations in Dr. Banerjee's report are consistent with what you were told by Dr. Cook and Dr. Carter?
DR. MORRIS-LARKIN:
A. Yes, they are.
BROWNE, Q.C.:
Q. And then the recommendations that he's made, you saw happening over the course of time?
DR. MORRIS-LARKIN:
A. Yes.
BROWNE, Q.C.:
Q. Okay. Now the last area which you were asked

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about by Mr. Coffey and Mr. Simmons and Ms. Newbury is the quality assurance and how that, I guess, developed over the course of time within the pathology side of the lab. We've seen a number of documents, number of minutes, site chief minutes and so on, where there are initiatives going back as far as 2001 within the pathology department, various areas where QA was identified and there was some development to move towards developing a handbook and so on. Was there--we've heard evidence as well about cutbacks. Did cutbacks ever affect how--because I think you mentioned in your evidence about we had not gotten to that level where you are now with the quality management program, and that's where you were intending on going, I take it? Is that where all this initiative was going?
DR. MORRIS-LARKIN:
A. I wasn't involved in the initiative in 2001.
BROWNE, Q.C.:
Q. Right.
DR. MORRIS-LARKIN:
A. But I think that is--I think that reflects where it was going. There's quality control

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which is one level. There's quality assurance which is another and then there's the quality management which is a higher level that starts to loop it all together, because if--you know, that's where you get the things that have been referred to, like the trends. That's where you pick up the more repetitive errors that may be occurring. So the quality management program, we weren't anywhere near that, but I think that's where they wanted to go and one of the things that Dr. Carter managed to do was impress upon senior executive that that needs resourcing.

BROWNE, Q.C.:

Q. Okay, and in the early days, was resourcing available and were there cutbacks in any of these sort of quality areas as a result of lack of resources?

DR. MORRIS-LARKIN:

A. There were definitely things lost during the cutbacks. There were a large number of journals that circulated through the Department, pretty much all of which were cut with budget cuts. There were teleconferences from the American Society of Clinical

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Pathologists which happened on a regular basis. Those were cut. We were discouraged from sending things for external consult because we have to pay quite a lot of money for these external consults and although it was acceptable to send things, it had to be vetted within the department before it was sent out and you kind of had to justify it.

BROWNE, Q.C.:

Q. And then Mr. Simmons and Ms. Newbury showed you, I guess, the lab policy and the corporate policy, and you talked about that. Do you see the--and perhaps you could speak to this, the role of the current quality management program looping into the overall corporate policy for quality assurance and adverse events and I just want to sort of ask you about the importance of having data in order to do that and tracking trends as you mentioned a minute ago.

DR. MORRIS-LARKIN:

A. Yeah. I think that that's a huge part of what the quality management program will want to do. Again, the resources are limited and we've been working or, you know, before my

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involvement, they have been working on a large number of things and have made a great deal of progress. Those are, I think, within the scope of future plans.

BROWNE, Q.C.:

Q. Okay. So you see the quality management program looping into the corporate wide, and what sort of things do you view in terms of -

THE COMMISSIONER:

Q. I don't want to interrupt, but you're going to have to explain looping.

BROWNE, Q.C.:

Q. Oh, I'm sorry, connecting information and what sort of information do you--you talked, I think, Dr. Morris-Larkin talked, you talked about sort of the information within the lab itself. How do you--is there any information you would see going to sort of the corporate higher up?

DR. MORRIS-LARKIN:

A. Well, I think if the quality management program were to detect things like a major trend that might have a negative impact, then that's something that would definitely be communicated to the quality risk management

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group. I think that's the kind of--is that the kind of thing you're referring to perhaps?

BROWNE, Q.C.:

Q. Well, I'm just sort of thinking that would be--would that be an issue you would see?

DR. MORRIS-LARKIN:

A. Oh, I think that that would--you know, again, you try and connect all the dots and close the circuit so that things are not just hanging out there meaning nothing. It's only when you connect it all together that these things really mean something.

BROWNE, Q.C.:

Q. And obviously in terms of we've heard several witnesses talk about metrics. Dr. Dabbs talked about tracking metrics and looking for trends and so on. Obviously in order to do all this, you would have to have a good data collection system in place?

DR. MORRIS-LARKIN:

A. That's right.

BROWNE, Q.C.:

Q. Now Doctor, I understand you have a statement that you would like to make this afternoon. That's all the questions I have for you.

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DR. MORRIS-LARKIN:

A. I thank the Commission for the opportunity to speak here today. As a result of the Inquiry into Hormone Receptor Testing, I have seen a significant commitment to resourcing the laboratories which has led to a number of long overdue changes resulting in quality improvement. This includes a team of pathologists assistants who ensure the standardized handling of specimens and allow the pathologists time to focus on the microscopic aspect of diagnosis. As well, the permanent assignment of lab technologists to the immunohistochemistry lab along with the acquisition of a PhD scientist in this lab has resulted in a developing expertise that allows for troubleshooting and will allow for future development initiatives. As well, there is now funding for a structured quality management program which is essential in the delivery of a quality lab service. Thank you.

BROWNE, Q.C.:

Q. Dr. Morris-Larkin, I think Mr. Coffey does have one question or one area to cover with you. Thank you. Thank you, Commissioner.

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THE COMMISSIONER:

Q. Mr. Coffey.

DR. CAROLYN MORRIS-LARKIN, RE-EXAMINATION BY BERNARD COFFEY, Q.C.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Mr. Browne just asked you, Doctor, about metrics and tracking and you need computer programs and systems to do that. I appreciate that up until--well, since May of this year that ER/PR has not been done at the General Hospital site.

DR. MORRIS-LARKIN:

A. I may be wrong, I think it was briefly done, but had to be suspended again because there was nobody to report it.

COFFEY, Q.C.:

Q. I appreciate that, beginning--we've heard evidence that up until--it was being done up until May?

DR. MORRIS-LARKIN:

A. Yes.

COFFEY, Q.C.:

Q. From really February of '07 to -

DR. MORRIS-LARKIN:

A. And I don't believe it has restarted.

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COFFEY, Q.C.:

Q. Okay. Doctor, do you know if anyone--you're the site chief there involved in this quality management groups. Do you know if anyone was actually keeping track of the ER/PR stats trends during the period that it was reinstituted in St. John's?

DR. MORRIS-LARKIN:

A. That's not something I could speak to. I don't know anything about it.

COFFEY, Q.C.:

Q. Who would be -

DR. MORRIS-LARKIN:

A. Either Dr. Cook, Dr. Carter or possibly Dr. Elms.

COFFEY, Q.C.:

Q. Thank you. Thank you, Commissioner.

THE COMMISSIONER:

Q. Thank you. Thank you very much, Dr. Morris-Larkin for adding your perspective to this rather large issue. I do appreciate you coming.

DR. MORRIS-LARKIN:

A. Thank you.

THE COMMISSIONER:

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Q. Mr. Coffey, I suggest we take the afternoon break -

COFFEY, Q.C.:

Q. Ms. Chaytor.

THE COMMISSIONER:

Q. I'm sorry, Ms. Chaytor, might I suggest we take the afternoon break so that we're not going to interrupt the witness five or ten minutes into this presentation.

(BREAK)

THE COMMISSIONER:

Q. Please be seated. Ms. Chaytor.

MR. TERRY GULLIVER, EXAMINATION BY SANDRA CHAYTOR, Q.C. (CONT'D)

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. We're continuing with the evidence of Mr. Gulliver, and there are a few new exhibits that I'd ask please to have entered. P-3113 to P-3118 inclusive.

THE COMMISSIONER:

Q. Entered.

EXHIBITS ENTERED AND MARKED P-3113 THROUGH P-3118 INCLUSIVE

CHAYTOR, Q.C.:

Q. Thank you, and if I could have, please,

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Registrar, P-0901. I believe we were on page six of this document when we broke last day, Mr. Gulliver, and if we come down to the bottom of page six, you're referring to a recommendation again from the Hay report, and you write "this recommendation appears to be a trade off for three technologist FTEs to be replaced with three pathology assistants. While having three pathology assistants will be beneficial in reducing pathologists workload, it would have an increased financial implication on the division as pathology assistants are paid much more in Canada than technologists. What we have already implemented in pathology at the General site is that we have trained technologists to do more than 50 percent of grossing of surgical specimen which is part of the work of the pathology assistant. It is important to note that this additional work assigned to our technologist twos also reduces their unit producing time. Also at the General site are two autopsy technicians, go far beyond their scope of duties in performing post mortems to the point that by and large the pathologists

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have to spend less time performing this function. Please see my plan for reductions of FTEs in anatomical pathology as outlined earlier in the report."

So Mr. Gulliver, I take it the Hay report had recommended pathology assistants? Is that correct?

MR. GULLIVER:

A. It was a part of, like I said, Dr. Manley's, I think his recommendations.

CHAYTOR, Q.C.:

Q. And what was your response in terms of that? Were you suggesting that it not be pathology assistants because of the additional cost of pathology assistants?

MR. GULLIVER:

A. Oh no, certainly not. Realize the Hay report, as I mentioned in my testimony Friday, was really a cost cutting measure within the laboratory and other parts of the health care system. I'm indicating there that, I guess, to sum up the Hay recommendation about this piece, Ms. Chaytor, on one side they were saying we should reduce staff in one part of our lab and use that money, I guess, to create

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three new positions for PAs. The position at the time within the divisions who would lose those staffing was that we need new money for three PAs and still keep the three positions in the other parts of the lab that they were recommending to cut. I'm indicating here then to Dr. Williams that pathology assistants are generally paid higher than general technologists, so it would also be an increase in our cost that they're higher salaried.

CHAYTOR, Q.C.:

Q. And overall then, your comments "at the end of the day, the total impact of staff reductions over the next year or so on the Laboratory Medicine Program is as follows:" and under the division of pathology, it's one full-time equivalent position, and ultimately I believe you told us last day that is what happened. Basically, the equivalent of -

MR. GULLIVER:

A. There was the two half times made into one and reducing the worked overtime hours.

CHAYTOR, Q.C.:

Q. Mr. Gulliver, last day too, you indicated that there had been a written protocol for IHC

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testing, and I believe you thought that document was something in 1985-1986 time frame?

MR. GULLIVER:

A. Around that time frame, yes.

CHAYTOR, Q.C.:

Q. And if we could just bring up, please, P-2156? I just want to clarify -

THE COMMISSIONER:

Q. Just before you go to that, on this same point, do I take it from the evidence that I've just heard from the last witness that, in fact, the PAs are still being paid as technologists?

MR. GULLIVER:

A. That's not 100 percent factual.

THE COMMISSIONER:

Q. Okay. So you might as well tell me what the-- since you're nearer to them, why don't you tell me what their--what's happened?

MR. GULLIVER:

A. What happened, once the PA positions were created internally in Eastern Health, we assigned a salary scale, an expected salary scale to those new positions, and then we had

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to go through a formal classification process within Eastern Health and it goes to Treasury Board. The recommendation that we made, Justice Cameron, to Treasury Board was to create a new classification within the NAPE (unintelligible) union agreement and to call them pathologists assistants, because within the NAPE (unintelligible) agreement, there is no classification as such. It's just med-lab assistant, lab technician, medical lab technologist one, two, three and four. And what came back from Treasury Board, they took--they made our lead PA, you just seen Jessica Swain, a technologist four, which is the highest ranking salary scale in the current union agreement, and the other three PAs, they made them lab technologist threes.

THE COMMISSIONER:

Q. Okay.

MR. GULLIVER:

A. So they're really called a lab technologist three or a lab technologist four.

THE COMMISSIONER:

Q. So they, in effect, recognized that the work they were doing -

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MR. GULLIVER:

A. Is of a higher classification, higher pay.

THE COMMISSIONER:

Q. Except they didn't create a new classification called -

MR. GULLIVER:

A. Right.

THE COMMISSIONER:

Q. - pathologist assistants?

MR. GULLIVER:

A. Right, and then we're appealing that decision, and what we got back from the--I don't know what his title is, that classification pay, the chief officer and I actually spoke to him on the phone, he called me, was that they don't have the authority to create a new classification in the agreement. It has to go through Government legislation, and we're waiting for an appeal answer to come back and still we're hoping to get a new classification created.

THE COMMISSIONER:

Q. So your point about it costing more money has in fact come through to this other process?

MR. GULLIVER:

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A. Yes.

THE COMMISSIONER:

Q. All right, thank you.

CHAYTOR, Q.C.:

Q. Thank you. P-2156, please? And I just want to confirm Mr. Gulliver, is this the document that you were referring to last day when you said there was a written protocol for IHC?

MR. GULLIVER:

A. Yes. This is the procedure.

CHAYTOR, Q.C.:

Q. Yes.

MR. GULLIVER:

A. This is your step-by-step procedure to prepare the slides and stain the slides.

CHAYTOR, Q.C.:

Q. And Ms. Welsh was aware of that. She went through that in her evidence as well.

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. And if we could have then, please, P-3116? And these are the number of new exhibits that we've just entered today, and I understand, Mr. Gulliver, perhaps you can tell us, this is

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3116, for example, and if we could also bring up 3117, please, Registrar, and then 3118 and 3114. And finally, 3115. And, Mr. Gulliver, these are a number of new exhibits that we've just received. And perhaps you can tell the Commissioner where those documents were located at this time?

MR. GULLIVER:

A. Well, actually, I located them over the weekend, over the weekend. And to be honest with you, it was your questioning of me on Friday afternoon about a particular--I had asked you about Dr. Ejeckam's--sorry, Dr. Khalifa's letter to me in '97, did we ever receive documentation, that I received it. And you asked me the question, well, am I the type of person to sort of throw things away or do I keep things, and I general answered, and I generally don't, that I'm not the type to keep things around for a long time. And over the weekend when I was in, I was thinking that, like, Mr. Dyer, our current pathology manager for the last six, seven years, he occupies my old office when I was the pathology manager and -

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CHAYTOR, Q.C.:
Q. So back in pre 2001 days?
MR. GULLIVER:
A. Pre 2001 days.
CHAYTOR, Q.C.:
Q. Okay.
MR. GULLIVER:
A. And I just thought, I just thought, I wondered if Barry ever went through any of my old files and discarded everything or kept things. So I went back to my old office in my original, some of my filing cabinets and sure enough there were still some old, you know, file folders and I looked through them all and I came across one where I had titled it, "Immuno Lectures." Because I knew back in the mid '80s to late '80s, some of this here are lectures I gave to Mary and Peggy and to our pathology residents, both on the theory of behind immunohistochemistry testing and talking about the fixation and proper fixation in pathology in general.
CHAYTOR, Q.C.:
Q. Okay.
MR. GULLIVER:

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A. And that's how I came about to get them.
CHAYTOR, Q.C.:
Q. Okay. So it was found in a filing cabinet, I take it, in Mr. Dyer's current office which you vacated sometime around 2001?
MR. GULLIVER:
A. Yeah.
CHAYTOR, Q.C.:
Q. And that's where those documents -
COMMISSIONER:
Q. When did you say those lectures would have been given?
MR. GULLIVER:
A. I used to give those, Justice Cameron, in, like, the mid '80s when we first started doing the testing, when Mary and Peggy would have taken over the testing when I became manager. And actually, at CONA, which is now CONA, the training program for medical lab technologists you've heard through other various witnesses that this is not something that is taught in the three-year training program. And back in the mid to late '80s and maybe even up to the early '90s I was asked to go do a lecture to the third-year students and this was the

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lecture I gave, talking about immunohistochemistry and the theory and principles.
CHAYTOR, Q.C.:
Q. Okay. And if we could have, please, 3116? So, for example, this document, perhaps you could tell us what this document is? Would this be your notes from the lectures you would have given in that time frame, the mid 1980s?
MR. GULLIVER:
A. Well, this would be sort of, this is a copy of--and you see up in the corner, one, two, three, four, five, I mean, back in those days we had, you know, overhead projectors, so this would have been the typed copy that we would use for overhead projection.
CHAYTOR, Q.C.:
Q. Okay. And so these are your notes of a lecture you would have given around that time period?
MR. GULLIVER:
A. And certainly. I mean, and most of this information, Ms. Chaytor, would have been, you know, that strictly is just a photocopy take from our handbook.

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CHAYTOR, Q.C.:
Q. Okay.
MR. GULLIVER:
A. Talking about the theory behind some of the testing. At the time there were three different methods you could use, the direct method, indirect and then the peroxidase method for paraffin sections.
CHAYTOR, Q.C.:
Q. Okay. And if we could look at 3117, please? And this one is indicated to be seminars for first-year residents in pathology. So is this also a seminar you would have given for the residents?
MR. GULLIVER:
A. Yeah. And on multiple occasions, you know, not -
CHAYTOR, Q.C.:
Q. For residents going through pathology?
MR. GULLIVER:
A. Who are now new residents in training in pathology. And we used-before the residents, when they first came into the pathology program, you know, and pretty well I think it was every Friday, they were assigned people to

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do lectures. And this would have been their, part of their introduction to learning on the gross bench of about fixation, the importance of fixation in grossing. And then we talked about once specimens are fixed and grossed, the technical process the specimens would go through on routine pathology, the embedding, the cutting, the staining and-to create a H&E slide.

CHAYTOR, Q.C.:

Q. Right. And you write here, for example, "It is essential that fixation is effective and the appropriate fixative is used." "The amount of fixative should be about 15 times the volume of tissue to be fixed and tissue should never be more than three to five millimetres in thickness."

MR. GULLIVER:

A. And we would emphasize that. It's also really important on the thickness of the sections they're going to submit into the block to make a paraffin block.

CHAYTOR, Q.C.:

Q. Yes. And, Mr. Gulliver, whose responsibility would it be then to follow up with the

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residents to see whether or not they are following those recommendations?

MR. GULLIVER:

A. It would be the pathologists.

CHAYTOR, Q.C.:

Q. And if we could look at, please, P-3114? And perhaps you could identify this document for us?

MR. GULLIVER:

A. Again, it was in that folder that I had titled, "Immuno Lecture." A lot of the basic information that I would use to put together the overhead presentation, I would use this manual here.

CHAYTOR, Q.C.:

Q. Yes.

MR. GULLIVER:

A. Along with some information from our book at the time was called Sternberger who wrote the book on IHC.

CHAYTOR, Q.C.:

Q. So, for example, if we look at page 10, please, Registrar, of this document, this is one of the overheads from your presentation?

MR. GULLIVER:

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A. I probably just photocopied it from the manual just to make it easier.

CHAYTOR, Q.C.:

Q. Okay. And so and I believe this is dated, I'm not sure this one actually has a -

MR. GULLIVER:

A. I think it's '83 or '84.

CHAYTOR, Q.C.:

Q. 1983 or '84, yes. So it's around that time period?

MR. GULLIVER:

A. Yeah.

CHAYTOR, Q.C.:

Q. Okay. Then if we could look at--so again, this would be used by yourself. And there's another article in there, I won't take you to it, but 3115 is the article by Mr. Kurt Davis. And that's something else, I take it, you used -

MR. GULLIVER:

A. That came from a different source.

CHAYTOR, Q.C.:

Q. Okay. You used that, though, as a resource for putting together your lectures or notes, is that right?

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MR. GULLIVER:

A. No. This here is talking about accreditation, standards in Canada from a professional association perspective in 1998.

CHAYTOR, Q.C.:

Q. Okay, so that's something you had in the same folder, but it's for a different -

MR. GULLIVER:

A. No, no, no, no, different folder. This was not from my old folder. This just came in to me in the last week.

CHAYTOR, Q.C.:

Q. Oh, okay. This is something new?

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, all right. I'm sorry, go ahead and explain.

MR. GULLIVER:

A. It's something that I knew, at this time I was sitting on the national board of directors for CSMLS.

CHAYTOR, Q.C.:

Q. Yes.

MR. GULLIVER:

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A. Mr. Davis was our, at the time, assistant executive director. And from a national professional association perspective, you know, this is late ’90s. After CCHSA pretty well -

CHAYTOR, Q.C.:

Q. 1998 and the other -

MR. GULLIVER:

A. Yes, pretty well when they stopped doing sort of an in depth lab accreditation, it’s kind of post Krever Inquiry, and this was sort of a position paper from our national perspective for the lack of Canadian accreditation standards for labs.

CHAYTOR, Q.C.:

Q. And you just received this in the past -

MR. GULLIVER:

A. Just a few days ago I asked Mr. Davis to e-mail me that.

CHAYTOR, Q.C.:

Q. Okay.

MR. GULLIVER:

A. Because I knew this had been done like a long time ago from my professional volunteer work.

CHAYTOR, Q.C.:

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Q. So before that you didn’t have this article in your possession -

MR. GULLIVER:

A. No.

CHAYTOR, Q.C.:

Q. - and you weren’t aware of its contents?

MR. GULLIVER:

A. No, no.

CHAYTOR, Q.C.:

Q. Okay. And if we could look at, please, P-3118? And can you identify this document, please, for the Commissioner?

MR. GULLIVER:

A. I submitted it, Ms. Chaytor, because that was in my folder that I had just titled, like, "Immuno Lectures." And I really cannot, you know, swear to you where I got this document originally. I’m kind of leaning towards it’s something that maybe Dr. Khalifa might have passed on to me when the ER/PR testing was being set up. So this is in the same folder, but the earlier lectures are probably from ’85, ’86, ’87. This is probably ’97, ’98.

CHAYTOR, Q.C.:

Q. It’s later, yes. And it has reference to

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estrogen receptor. For example, there’s a section on that. So you’re thinking this may have been around the time Dr. Khalifa was setting up -

MR. GULLIVER:

A. That’s just my best estimate, yeah.

CHAYTOR, Q.C.:

Q. And do you recall whether or not you ever used any of the information in this for lectures for anybody?

MR. GULLIVER:

A. No, I did not. I know that much.

CHAYTOR, Q.C.:

Q. Okay, thank you. And if we could look, please, at P-1879? And this is an e-mail from yourself to all staff laboratory medicine program. And it concerns the HAY report or the HAY operational review, it’s referred to here. March 27th, 2002. And it’s written for, it says at the top "For Mr. Donald Cook" from yourself. But then it is a memo, it appears, to go to all of the staff. So did this, in fact, go out to all of the staff, do you know?

MR. GULLIVER:

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A. Yes, I’m sure it did, yes.

CHAYTOR, Q.C.:

Q. Okay. And you write at the beginning "You have been aware for some time now that the HAY Management Group have been conducting an operational review of the Health Care Corporation of St. John’s. Of course, the laboratory program has been part of the review and I met with all of our division managers today and gave them as much information as I have to date on the lab’s response to this review. Tomorrow all managers are meeting with corporate team and will be given a broader briefing on the review." Let me just scroll down here a bit. "In case of number two and the really important one, we scored much lower than in 2000." And you’ll see number two is "Worked hours per patient care work unit. Basically how productive we are. But upon closer analysis of the HAY charts and figures I discovered that they have made a mistake and misinterpreted some of our workload units and therefore did not include them in our patient care workload statistics." And you’ve spoken about that last day when we

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were here. "I quickly pointed this out to our VP and corporate team and, in fact, produced the corrected version of our worked hours per patient care workload unit. It has been a battle, to say the least, in getting our corrected stats included in the final HAY report as was released today. Thanks to the support of corporate team, the HAY Group has acknowledged that they may have made an error in the lab stats." So I take it from that, Mr. Gulliver, that the corporate team, the Health Care Corporation team, were supportive of your efforts in this regard. But who was then--why was it a battle, who was the battle with to try and have your revised information included?

MR. GULLIVER:

A. Oh, the battle was with the HAY people themselves.

CHAYTOR, Q.C.:

Q. And what was the resistance, what was the nature of the resistance?

MR. GULLIVER:

A. I don't know 100 percent sure what the resistance was. I mean, they came in, they

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pretty well asked for copies of, like, yearly statistics, workload units, number of patients, number of tests, the volumes for all of our divisions. They pulled statistics from our financial data on the financial side of our system. I don't think that we had within at the time Health Care Corporation--that the statistics they had gathered from our financial reporting side matched up the actual real data that was taking place on a monthly basis in the laboratory program. And I think--yeah, so the battle was with the HAY Group in trying to make them understand this is how we capture our workload and these are the true statistics. Because they were removing several million workload units from their overall data, because they were saying it wasn't patient care units, it was other things. And, you know, this is very ironic. Sunday I worked all day because we had to prepare this year's budget submission and in a part of my briefing notes, in requesting new staff for the lab program, I was given the 2007 HAY national benchmarking for productivity for our lab and we score in the

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top five percent in the country in for productivity and efficiency.

CHAYTOR, Q.C.:

Q. Okay. And you go on with this memo and you say, "I would like to make it clear to all staff that even though I have made it clear to corporate team that the HAY report is not a true reflection of our program's productivity, there are, however, areas of the program that even with the corrected stats need to be addressed to improve the productivity and to meet the national benchmarking standards." What are you referring to there?

MR. GULLIVER:

A. Well, as you seen in my earlier, perhaps submission, that the HAY group, you know, they didn't just look at laboratory medicine, they looked at anatomical pathology, they looked at what they call the main lab or core lab, they looked at microbiology, so they broke down different parts of our program. And so that's what I'm saying there, that overall our lab medicine program was actually performing fairly well, but there were parts within the program that were not, at that time, meeting

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the national benchmarking for productivity by HAY.

CHAYTOR, Q.C.:

Q. And then on the top of the next page "Also, I would like to point out that our program will improve our operational efficiency in the coming months and into next year with new equipment and new technology in several areas of the program, along with reorganizing some of the ways that we process and test specimens." And my question for you on that: this is March of 2002, did any of that have to do with how you would be doing things in the IHC lab?

MR. GULLIVER:

A. No, that had nothing there. This was strictly to do with mainly our core lab services. We were bringing in front end, what we call front-end automation for the pre-analytical preparation of the thousands of blood samples we receive every day. It was going to automate that process.

CHAYTOR, Q.C.:

Q. Okay. So nothing to do with any new tissue processors or -

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MR. GULLIVER:
A. No, no.
CHAYTOR, Q.C.:
Q. - anything like that, okay. And you write that, "I'm confident we will meet the targets of the HAY report in those parts of the lab that need to be addressed in the coming months and into next year. It is my opinion that this can be achieved with very little direct impact on our staff. However, as we move toward new"--I'm sorry, "move forward with new equipment, changes in operational practice, etcetera, then we will need the full support of all of you to ensure that in each case it will be a smooth transition leading us to an improved quality of service and more importantly, keeping us one of the leaders in laboratory medicine in Canada." And, Mr. Gulliver, what data did you have or what reference did you have to believe that you were one of the leaders in laboratory medicine in Canada?
MR. GULLIVER:
A. And right here, Ms. Chaytor, I'm more referring to the technology side of our

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operations. For example, in the part before we talked about some of our new equipment. We were like one of the, I think number four or number five in Canada to implement pre-analytical automation in our front-end processing, say, of the thousands of blood tubes received every day. At that point we were installing new automated analyzers in biochemistry, in hematology and other--across the program. So I'm referring there that, yeah, the leaders in Canada, really, at that time, and I still believe today, that from a technology side and the equipment that we have to operate with, we pretty well are at the--you know, one of the leaders in the country.
CHAYTOR, Q.C.:
Q. In terms of the acquisition of the equipment?
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. And if we could have, please -
MR. GULLIVER:
A. And you know, in the--I wrote this e-mail to all staff at a time where everybody in the organization, in particular in the laboratory,

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everyone were really worried about job cuts and job losses. There were all kinds of rumours going throughout the organization for weeks and months leading up to this. And I felt it was important to make sure all staff were well informed of, you know, what the HAY report may have impacted upon the lab program and really to kind of reassure them that whatever cuts we'd have to make, we will do it as in so as a painless manner as possible.
CHAYTOR, Q.C.:
Q. Yes. And before then we leave it, your assertion here that you're confident you will meet the targets of the HAY report in the parts of the lab you indicate that needed to be addressed, what happened overall looking at--were you able to meet the targets of the HAY report and, if so, what, if any, impact overall did this have on your laboratory medicine program?
MR. GULLIVER:
A. Well, it certainly, it all depends what the division that we're looking at.
CHAYTOR, Q.C.:
Q. Well, particularly at the pathology division.

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MR. GULLIVER:
A. Actually, pathology, there was very little.
CHAYTOR, Q.C.:
Q. Very little impact?
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. Was the one person that you talked about?
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay.
MR. GULLIVER:
A. Pathology at that time, if you look at, this is strictly workload statistics, an analysis on productivity is not measuring or assessing anything to do with quality in the lab. At the time our pathology division was performing pretty close to what the recommended national benchmark was for the HAY Group.
CHAYTOR, Q.C.:
Q. And is it--I'm just thinking, though, when you do your budget, you do a budget overall for your whole program. And I'm just wondering if there was other impact because of what had to

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happen in other areas if that then left you in a situation where there may not have been funds that could have otherwise been diverted, for example, to pathology?

MR. GULLIVER:

A. Yes, certainly at this time--I don't know if you mean within the lab program or you mean within the health care system?

CHAYTOR, Q.C.:

Q. Well, I heard what your answer is, that really overall the HAY report probably didn't have a direct impact on pathology. And I'm wondering, well, indirectly did it impact because of cutbacks or other limits that were placed on you regarding your overall program?

MR. GULLIVER:

A. I have to say yes. You know, even though the HAY report didn't impact pathology a great deal, other parts of our program we did reduce staffing. For example, microbiology, we consolidated our microbiology lab to one lab for the City of St. John's. By doing that we reduced our staffing by four FTEs. And in a normal program management the way you're supposed to operate within your program, if

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you can reduce or find savings in one part of one division, you really should have the flexibility to be able to take that money and move it from microbiology division and move it over to other parts within your own program. And certainly, under the environment that we were operating at this point in time that just didn't happen. Savings were made in divisions overall in the lab and you weren't allowed to reinvest it in other parts of your lab; you just lost the funding.

CHAYTOR, Q.C.:

Q. Okay. And if we could have then, please, P-1867? And this is a quality initiatives report for the laboratory medicine program. And it's from April 1st, 1999 through to March 31st, 2000. And it's submitted to--submitted by, sorry, Mr. Whelan and Mr., or Dr. Cook as the clinical chief. And this is before you took over as director, obviously. And I think we actually looked at this one maybe last time. If we could look at--yes, it's page 33, if we could have, please? Don't want to go back in time, want to keep going forward. Here we go. This is a similar report. This

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one is for April 1st, 2001 to March 31st, 2002. That's better. And this one is, in fact, submitted by you. And who would you then make this quality initiatives report to?

MR. GULLIVER:

A. This was something that every program is required to submit on an annual basis. It would go to your VP and then the VP brought it up to our executive, I guess, and I guess it went to the Board Quality group.

CHAYTOR, Q.C.:

Q. Okay, and you summarized your year throughout your document and you break down the seven divisions -

MR. GULLIVER:

A. Well, really it's been about four or five months, I think, I've been director.

CHAYTOR, Q.C.:

Q. I'm sorry, is it? Yes.

MR. GULLIVER:

A. It begins April 1st, 2001 to March 31st '02. I became director in October '01.

CHAYTOR, Q.C.:

Q. Right.

MR. GULLIVER:

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A. So this is my first four or five months on the job.

CHAYTOR, Q.C.:

Q. But it's a year for the whole -

MR. GULLIVER:

A. But you have to submit a physical year report, yeah.

CHAYTOR, Q.C.:

Q. Yes, okay, and you had been the director, as you say, for since October of '01?

MR. GULLIVER:

A. Yeah.

CHAYTOR, Q.C.:

Q. So for the last quarter, all right, and the approximate--you say the breakdown of the seven divisions and approximate percentage of each division is allocated and the anatomical pathology would take up ten percent of your budget.

MR. GULLIVER:

A. The program budget, yes.

CHAYTOR, Q.C.:

Q. Your program budget, yes, and the first challenge of the year was April 1st, 2001 and that was the strike of the NAPE employees.

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Then at the top of page 35, "after several years of planning, the Janeway Child Health Centre moved in May of 2001, and therefore all laboratory services from the former Janeway site were brought into the General site." And then we have the reference to the program leadership change in September 2001 with yourself taking over from Mr. Whelan, and "in addition, a number of management positions were made redundant. The above changes resulted in the program reducing from nine division managers to seven in each division, and each division manager now has corporate wide responsibilities." So I take it it was not only a reduction in the number of division managers, but the scope of their responsibilities increased?

MR. GULLIVER:

A. Became corporate wide, yes.

CHAYTOR, Q.C.:

Q. And then "early 2002, the director received the report from the Hay management group" and we've talked about that and the challenges that that put forward for you. And then, you write, at the bottom here, "the following

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outlines two of the areas of the program that have significant challenges or changes in the past year" and then you list those, and there's challenges then. You list the strike, the consolidation of services, the change in the program management, dealing with labour management issues, keeping abreast of new technology equipment, the Hay report and CCHSA. Is that accreditation?

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. Was there accreditation in this year for the lab?

MR. GULLIVER:

A. I think there probably would have been. That might have been the cycle that CCHSA were probably in.

CHAYTOR, Q.C.:

Q. And would the lab have been part of that, part of the accreditation process for the hospital?

MR. GULLIVER:

A. It would have been a part of the--well, it's a part of the CCHSA process at that time that they followed. You really wouldn't be able to

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call it a lab accreditation process.

CHAYTOR, Q.C.:

Q. And why not? It was on a superficial level, I take it?

MR. GULLIVER:

A. Very, very superficial, yes, yeah.

CHAYTOR, Q.C.:

Q. Okay, and under the achievements then, it does refer to successful accreditation, but again, you're saying that wouldn't have been anything in depth?

MR. GULLIVER:

A. We certainly passed what they came in to review.

CHAYTOR, Q.C.:

Q. And what would it entail? What exactly would they do at that point in time, in terms -

MR. GULLIVER:

A. At that point in time, CCHSA had moved--and again, the document I submitted there for '98, from our professional association, really that's the concern from a lab professional perspective in the country is that CCHSA moved to these new what they called AIM standards and coming to assess, you know, hospital

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systems, and in that new process, pretty well when the reviewers came in, you know, they spent a bit of time with the director or the director walked them around the various labs. They had kind of a look and see and they just, you know, made a statement that, you know, "your lab seems to be equivalent to others in the country." There were very, very few standards that you kind of had to assess before the reviewers came, that you had to implement afterwards. What they relied upon in this process that there were several care teams in the organization. There was a medicine care, pediatric care team, acute care team and all the other parts of the clinical side of the hospital system, and in those care teams, the reviewers would ask them "so how do you find lab services?" or "how do you find diagnostic imaging services?" and that's really how they -

CHAYTOR, Q.C.:

Q. And that's it?

MR. GULLIVER:

A. That's pretty well how they assessed the lab services.

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CHAYTOR, Q.C.:
Q. And I take it at that point in time then, if there were any--there didn't appear to have been any major complaints about the lab that had been brought forward by the clinical teams?
MR. GULLIVER:
A. No.
CHAYTOR, Q.C.:
Q. Or the people who were providing information to the accreditors. Did that change in terms of the way in which CCHSA did accreditations then throughout--this is 2001 into '02 and -
MR. GULLIVER:
A. And they came back, I think it was 2004, you know, because it's -
CHAYTOR, Q.C.:
Q. And was it the same process?
MR. GULLIVER:
A. - sort of a three-year cycle. Well, we're still following the same--pretty well the same process.
CHAYTOR, Q.C.:
Q. Okay.
MR. GULLIVER:

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A. It wasn't much different than the one in 2000 or 2001 and I think the one before that, and you know, to just expand, if we go back further, the CCHSA used to do what we felt like was a good job in doing accreditation process for medical laboratories in Canada. In the early '90s when they decided to really not--and it's not just lab, it was diagnostic imaging is included also. When they changed their focus more on the clinical team kind of focus, that's really how QMPLS evolved in Ontario. Because there was no Canadian conjoint health accreditation any more, Ontario decided, as a government, to implement their own lab accreditation program for Ontario.
CHAYTOR, Q.C.:
Q. Something more was needed?
MR. GULLIVER:
A. Yes, and then Alberta followed suit after Ontario.
CHAYTOR, Q.C.:
Q. Okay, and so in terms of what was happening here with respect to the lab services, it was a little more than really window dressing in

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terms of what review your lab would have received?
MR. GULLIVER:
A. In my opinion, yes, yeah.
CHAYTOR, Q.C.:
Q. Okay. Overall, I'm looking, this is your first year, the first quarter of your year and it appears that it was somewhat of a challenging year. You had a strike, the Hay report to deal with, changing--the Janeway moved and you--well, you had to consolidate those services from the Janeway and the change you took on, your own position as well, in that time period. So I take it it was a bit of a challenging year that year for the lab medicine program.
MR. GULLIVER:
A. And I would say every year since has probably--you'd probably find something else to say for every year. But certainly as my first year as the program director was a--I mean, it was a very challenging year, I mean, for major issues that we had to deal with.
CHAYTOR, Q.C.:
Q. Yes, okay, and if we could look then, please,

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at P-0903? And this is a letter, October 11th, 2002 written to Dr. Cook by Dr. Williams and this is Dr. Cook being appointed as the clinical chief. So I take it that happened about a year after you came into your position?
MR. GULLIVER:
A. Dr. Haegert, who had been away on sabbatical and Dr. Cook was acting clinical chief for a while. I don't know the exact time frame, but Dr. Haegert did come back when I was appointed the new director and worked with--you know, worked with him for a while, and he decided to go back to McGill in Montreal.
CHAYTOR, Q.C.:
Q. Okay.
MR. GULLIVER:
A. And then Dr. Cook was appointed as the new clinical chief.
CHAYTOR, Q.C.:
Q. Okay, and Dr. Williams writes to Dr. Cook in the middle of page two of our exhibit, "you will be required to work closely with the program director, Mr. Terry Gulliver, in providing overall clinical direction to the

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Laboratory Medicine Program and working with Mr. Gulliver in broad administrative leadership as a member of the leadership team. This will include the main elements captured on the attached generic job description of clinical chief." So I take it that would have been the same relationship that you would have had with Dr. Haegert prior to Dr. Cook?

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. And overall, Mr. Gulliver, in terms of how that worked within your laboratory medicine program, in terms of you working with the clinical chief, how did it unfold itself? Did you work well together? Did the program management structure work within the laboratory medicine program or did you encounter any challenges along the way?

MR. GULLIVER:

A. You mean with Dr. Haegert or Dr. Cook or both?

CHAYTOR, Q.C.:

Q. Well, I guess you had a very brief period of time, your first year though would have been with Dr. Haegert, and if there is a

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difference, by all means, if it's--you know, if there is a difference between your experience with both individuals. But I'm just wondering how it worked in terms of what was envisioned by Dr. Williams here, in terms of the clinical chief providing overall clinical direction and both of you working together in broad administrative leadership positions?

MR. GULLIVER:

A. I have to say, I mean, when I was the first--went to work at the Health Sciences in 1980s as a medical lab technologist, I think Dr. Cook might have been '81/82 where he became--he was in the pathology residency training program. So I mean, I've known Dr. Cook very well since 1981/82 and you know, both he and I ended up being the leadership team for Lab Medicine and I've always worked well with him and whenever I had any issue, when I was a part of the group, myself and Dr. Williams interviewed for that position. So I was a part of the group who decided or chose Dr. Cook as the successful candidate for our clinical chief. The only difference between

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Dr. Cook and Dr. Haegert, and it wasn't a--sorry, not a difference, Dr. Cook was at St. Clare's and you know, for years prior, the clinical chief used to be at the--was at the Health Sciences where the program director was physically located. So you had a much more closer working relationship physically. But Dr. Cook decided to remain at St. Clare's where he had been since, I think, the early--since he graduated, and I was physically at the Health Sciences. But you know, we met regularly. We met monthly with Dr. Williams.

CHAYTOR, Q.C.:

Q. So from your point of view, the structure with program management with the two arms, as such, worked well and there was no difficulties encountered along the way?

MR. GULLIVER:

A. Well, I can't say there's no difficulties. I mean, you're working together and you're in a very dynamic environment. You're working in an environment where you're undergoing significant challenges and significant changes, not just to the medical laboratories, but to the physical buildings in the city. We

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had just gone through, you know, the closure of the Grace Hospital, the closure of the Janeway Hospital, and even after those two facilities closed, there was still a lot of rumours, and might even exist today, that there was talks that even St. Clare's was going to close. So again, I mean, look at the environment that we worked in, I thought that we worked really well together.

CHAYTOR, Q.C.:

Q. And if we could have then, please, P-2945? And this is a meeting of the laboratory division managers, February 12th 2003, and you're in attendance, along with Mr. Dyer and Lynn Wade, and a number of others, and then on page two of this document, under your budget at this point in time, and again, it's now February, actually it's up to December 2002, but you're 128,000 over budget to December 2002, and you had met with Sharon Lehr and outlined the unexpected expenses incurred by the Laboratory Medicine Program, and you were asking all divisions to keep tight control on their budget, and this would be the budget for 2002/03, and I think when Dr. Williams was

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here, he said that--or made a comment to the effect that he doesn't think, after the Hay report, that you were able to balance your budget at any point after that.

MR. GULLIVER:

A. Still haven't.

CHAYTOR, Q.C.:

Q. And that's a fair statement, I take it?

MR. GULLIVER:

A. Yeah, you might see another 50 minutes, copies of minutes here, either at the division managers level or our -

CHAYTOR, Q.C.:

Q. Certainly doesn't get any better.

MR. GULLIVER:

A. No.

CHAYTOR, Q.C.:

Q. The numbers get much worse.

MR. GULLIVER:

A. Yeah.

CHAYTOR, Q.C.:

Q. Yes.

MR. GULLIVER:

A. And that doesn't directly reflect--you know, it's not a full picture. While our program

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has yet to meet our budget targets, you know, laboratory services is the most utilized service in the health care system, believe it or not. We do over ten million tests a year and we respond to what physicians require. So it's very, very hard to budget laboratory medicine because you don't know if last year we did 1,000 bone marrows and it cost $1,000 each, and that's the kind of range that a bone marrow would cost for full investigation for genetics, we don't know this year if we're going to get 2,000, 1500, or 1200. It all depends on how the service grows. So trying to budget at the beginning of the year for lab service is really difficult and trying to project your growth this year or the new tests coming online and those kinds of things.

CHAYTOR, Q.C.:

Q. Okay. If we could have, please, P-1887? And Mr. Gulliver, this is a letter that was written to you by Mr. Dyer of February 17th, 2003 and he writes to you regarding some concerns with interactions that he had with Dr. Cook.

MR. GULLIVER:

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A. Um-hm.

CHAYTOR, Q.C.:

Q. And I won't take you through it all. I take it you're familiar with this letter or do you need -

MR. GULLIVER:

A. Well, I've become more familiar with it.

CHAYTOR, Q.C.:

Q. - do you need me to take you through it? Okay, I'll take you through it then, okay. So he writes to you saying "I'm writing this letter with apprehension and concern to discuss the treatment of one's self during two interactions with Dr. Donald Cook. Mr. Gulliver, being my supervisor and next line of communication, and it is necessary for you to be informed in writing" and he goes on to talk about what the first encounter involved and "it happened on February 12th, 2003 when I approached Mr. Cook's secretary to arrange a meeting with him to brief him on changes I planned to make to anatomical pathology. I discussed the corporate wide recall we would use to laboratory assistants from the Health Sciences Centre and one laboratory technician

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from St. Clare's, as well as the transfer of a technologist two from St. Clare's to the Health Science for training with an eventual lateral transfer to an upcoming vacant technologist two position" and he goes on to say that he has an encounter, they have a debate, was slightly uneasy. "One phrase I found quite unsettling was and I quote 'heads are going to roll over this, if things do not work out'" and he interpreted that as a threat to his position as manager, and he says that he verbally informed you of that.

And then the second encounter occurred February 14th '03 and he describes he was "having a staff meeting with St. Clare's pathology department to inform them of the changes pertaining to the corporate wide recall and the training and eventual lateral transfer of the technologist two position when Dr. Cook came in. I was sitting at the back of the laboratory and he stopped at the front. He pointed his forefinger directly at me and said, I quote, 'you.' He then pointed at the door and, I quote, 'I want to see you right now.'" and he goes on to say how he found that

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to be degrading and disrespectful and asks you to investigate as per the harassment in the workplace policy, and he also requests to have--"I request to have a meeting with St. Clare's pathology staff, myself and Mr. Gulliver, to discuss the management of anatomical pathology."

So Mr. Gulliver, what--do you recall this now, and what do you recall about this?

MR. GULLIVER:

A. I mean, I certainly recall the event when it happened and I certainly recall receiving this letter from Mr. Dyer at the time.

CHAYTOR, Q.C.:

Q. So you recall Mr. Dyer coming to you -

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. - after the first encounter and speaking to you about it?

MR. GULLIVER:

A. Certainly.

CHAYTOR, Q.C.:

Q. Okay, and what did you, as a manager or as his direct superior, what did you do about this?

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MR. GULLIVER:

A. Well, within--of all the things you just read, there are multiple issues in there. You know, it's one, it's about how Mr. Dyer felt he was being treated by our clinical chief. Number two, it's talking about specific issues within the anatomic pathology department as a whole, and it's talking about specific issues that relate to St. Clare's pathology lab. So there's--I can't answer them all in the same context.

CHAYTOR, Q.C.:

Q. Well, take your time and tell us what you did about it.

MR. GULLIVER:

A. Well, I guess maybe we'll start from, you know, Mr. Dyer's concern first. I mean, Barry came to me and informed me of these instances and I think, you know, my response to Barry was to calm him down and to tell him that, you know, I would speak to Dr. Cook about Dr. Cook's behaviour and you know, his--and at the back end of Barry's letter, he talks about there is corporate policy that talks about workplace harassment, personal harassment and

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it certainly applies to every employee in the Health Care Corporation. It doesn't make no difference if you're a director, if you're a doctor, a CEO or a staff person. Everyone is treated fairly. So I did speak to Barry. I did speak to Dr. Cook. I did not write Dr. Cook formally about this here. We just talked about it. I know at the time, and I guess, Dr. Cook's behaviour, while at this time was certainly unacceptable, I really think that you need to put some timing and context around the issues that were being discussed that, in my opinion, you know, led Dr. Cook to exhibit this behaviour. You will find no documents after this here of anything of this sort between Dr. Cook or Mr. Dyer or myself.

CHAYTOR, Q.C.:

Q. So I take it this was something unusual for you to have to deal with, in terms of behaviour by a pathologist towards a technical staff or technical manager?

MR. GULLIVER:

A. Rarely. I mean, it happened, yes, over my career. It's happened, you know, less than--count him on the toes and one hand. But I

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think, if you really put--to frame this in the time frame, this was leading up to--I've been director for a year, is leading up to for several months before March of 2003, I had been working with the division managers and division chiefs and Dr. Cook as clinical chief. We were getting ready to have a comprehensive three-year--putting together a three-year plan for lab services for the City of St. John's, partly in response to the Hay report, to look at the long term implications from Hay report and the long term objectives that we would like to achieve, and certainly in the environment that we're in a cost cutting environment. We had, just prior to this here, you know, reduced staffing and all those kinds of things, and at this time, Barry Dyer, who was the pathology manager, was--during the planning day, was going to present what he felt him and the site chiefs would be the division for pathology for the City of St. John's, and the recommendation was going to be to have one pathology lab for the City of St. John's. We had visited that exact scenario in 1998 before the Grace closed and before the

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Janeway closed when I was pathology manager, Mr. Whelan was director, and Dr. Haegert was clinical chief, that if we're going to close the Grace and close the Janeway, the Microbiology Division had put forward that at some point they think it would be best to operate with one lab in the city of St. John's. Pathology, it didn't work out in '98, it didn't get approval, and Mr. Dyer is really resurrecting that recommendation from five years earlier that maybe this is the time now that we should be looking at pooling all of our resources, both technical, clinical, and equipment, and operating under like one roof, one umbrella. So I think this is the context of when these events happened. In preparation for the planning day, Mr. Dyer was talking to staff and getting feedback about how do you think this could work out, what kinds of things do we need to do and put plans in place before it could happen, and this is the events around where Dr. Cook is talking about heads are going to roll over this if this doesn't work out. This means about closing the lab at St. Clare's for pathology.

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CHAYTOR, Q.C.:

Q. And the Technologist II position, that was vacant, and it was - it was contemplated somebody would be transferred from St. Clare's to the Health Science. Was that Les Simms?

MR. GULLIVER:

A. I think this might be Les Simms because Peggy Welsh by this time has informed us that she's going to resign, and move away to Nova Scotia, and Les was the senior technologist in pathology in the city, so he would be the one that would go into the IHC lab and begin that training. You know, again I really - you need to put yourself in our shoes back in 2003 and understand the environment that all of us were working in and the pressure that we're under, and, you know - obviously you're probably going to ask me more down the road about this whole consolidation and where it is today. You know, I was certainly, as director, in favour of having one pathology lab for the city of St. John's. I felt, you know, when you can have all your expertise under one roof, under one leadership, I think it provides for a much better service. However,

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you know, put yourself in Dr. Cook's shoes, he's been a practising pathologist at St. Clare's since the early 80s. We know he's an extremely dedicated laboratory physician, and that's the facility and site, that's his home, and, you know, you're talking about physically uprooting his whole home and his pathologists over there to a whole new facility. So it's not - it's a huge issue.

CHAYTOR, Q.C.:

Q. So he was resistant to that idea and that was the issue that -

MR. GULLIVER:

A. Certainly was, yes.

CHAYTOR, Q.C.:

Q. Underlying tension that you saw coming out of this.

MR. GULLIVER:

A. Yeah.

CHAYTOR, Q.C.:

Q. And when you went to speak to Dr. Cook about it then back in February of 2003, is that what he articulated to you?

MR. GULLIVER:

A. Exactly, and, obviously, Dr. Cook apologized,

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and, I mean, this is not his normal behaviour. I just took it as it was a one time incident and nothing ever happened again. So we just moved on from it.

CHAYTOR, Q.C.:

Q. And did Dr. Cook articulate to you any other reasons, apart from the comfort level of being within your own institution? Was there anything else articulate to you, as the program director, as to why he was resistant to consolidation?

MR. GULLIVER:

A. At this point in time, probably not. This is before our full planning day and before the full scope of what the plans are for the next three years for lab services. At some point, maybe it's a year or so later than this, you know, myself and Dr. Cook, we meet with the executive team and we talk about this pathology consolidation. I think you'll see more articulated there.

CHAYTOR, Q.C.:

Q. Yes.

MR. GULLIVER:

A. From Dr. Cook than at this point in time.

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CHAYTOR, Q.C.:
Q. Yes, so he did have other reasons apart from his affinity for St. Clare's? He had other reasons?
MR. GULLIVER:
A. I certainly believe so. I mean, you know, my experience with Don from, I guess, 1981 or 1982, when he was a resident, you know, Dr. Cook, he said what he felt and I operate the same way. There are times over many issues where you're not going to agree upon every single issue, and you try to find consensus and you try to implement what you think is the best. I don't think Don's resistance was simply because physically moving the pathology lab out of St. Clare's. I really believe, and again Dr. Cook testified here for several days, I don't know what he said, but Ms. Chaytor, I really believe it was kind of big picture stuff. You know, there were still at this time - the HAY group came in, the Grace was closed by government, the Janeway was closed, there were a lot of rumours flying around that maybe they're going to close St. Clare's next, and, you know, when you start

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pulling out services one by one, what is St. Clare's going to be left with, and I really think that's probably what Dr. Cook - I think it's more than just laboratory issues. I think it was more of a St. Clare's health care issue type of thing.
CHAYTOR, Q.C.:
Q. And is there anything else then around this time period or around this - I take it it was resolved to everybody's satisfaction?
MR. GULLIVER:
A. I certainly feel it was, yes.
CHAYTOR, Q.C.:
Q. And didn't impact then on a go forward basis the relationship between Dr. Cook or Mr. Dyer or their ability to work together?
MR. GULLIVER:
A. Nothing that I ever seen.
CHAYTOR, Q.C.:
Q. And nothing else that got brought to your attention as Mr. Dyer's supervisor?
MR. GULLIVER:
A. No, no.
CHAYTOR, Q.C.:
Q. And if we could have, please, P-1890, and this

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is another laboratory management committee meeting, and this one is March 13th, 2003, and Dr. Cook is in attendance, as is yourself, Ms. Wade, and Mr. Dyer.
MR. GULLIVER:
A. Yeah, and this is a group that Dr. Cook set up where it's a combination of the administrative part of the program and the divisional chiefs clinical side where it's pretty well more information exchange, keep everyone up to date what's going on in the program.
CHAYTOR, Q.C.:
Q. And that was an initiative of Dr. Cook?
MR. GULLIVER:
A. Yeah.
CHAYTOR, Q.C.:
Q. So you hadn't been doing that before he became clinical chief?
MR. GULLIVER:
A. We used to do it, I think, Ms. Chaytor, like, before when Vern Whelan and Dr. Haegert were the former director and clinical chief. We did have - not regular meetings, we did have occasional meetings with the management side and the clinical side as the full group. In

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the program structure that evolved from the Health Care Corporation, it was pretty well the leadership team of the lab, the director, the clinical chief, you met monthly with your VP and you kind of keep the big picture things in place.
CHAYTOR, Q.C.:
Q. And the other - who would Dr. Hutchinson be?
MR. GULLIVER:
A. Jim is our microbiologist, and he's in charge of infection control. Dr. Whitman would be our divisional chief for hematology. I'm sure Cindy's name is there.
CHAYTOR, Q.C.:
Q. And Dr. Parai is absent.
MR. GULLIVER:
A. Sushil was the site chief for pathology, Health Sciences, at the time.
CHAYTOR, Q.C.:
Q. Okay, and again under budget on page two, "The laboratory budget is over by 144,000 to the end of February. Terry feels that we are doing a reasonably good job in managing our compensation budgets. Terry also pointed out that much of the over expenditure is due to

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staff benefits, retro pay, and the increased regular pay associated with reclassifications and doctor's salaries. Terry indicated that the laboratory program budget for 2003/2004 will be reduced by 135,000 if we don't meet our 2002/2003 commitment. However, the planned 100,000 reduction for 2003/2004 will not take place". What's that all about?

MR. GULLIVER:

A. I can't tell you specifics, you know, from - I mean, you'll see every month in all of our meetings we're talking about budget.

CHAYTOR, Q.C.:

Q. Yes.

MR. GULLIVER:

A. This is sort of our post HAY, you know, that there was a certain level of reductions that was expected for the lab medicine program, and it was pretty well if we didn't meet those targets, that our budget would be reduced further in the next fiscal year to make up for what we didn't make up for in 2002/2003. That's pretty well the theme behind it.

CHAYTOR, Q.C.:

Q. Okay, that's what's happening. Under new

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business under quality assurance, "Dr. Hutchinson discussed quality assurance for the laboratory program. He indicated that in Ontario, there is an inter-provincial working group for microbiology. Dr. Hutchinson has concerns that if our program were required to be licensed through accreditation, such as the Ontario QMPLS program, that we may not be successful. Terry indicated that to date there is no legislation requiring laboratories in Newfoundland to be accredited and/or licensed through such a program. General discussion took place in regards to an overall laboratory quality assurance program. It was suggested that this should be a goal for the next several years and the laboratory program should have a quality officer". So in this time period now, Mr. Gulliver, and the issue of quality assurance coming up, and Dr. Hutchinson indicating that he had concerns that the program wouldn't be able to meet something such as a review by QMPLS, as was taking place by this point in time in Ontario, and this being discussed, what do you remember about that?

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MR. GULLIVER:

A. Well, first of all, Jim is talking about microbiology, in particular.

CHAYTOR, Q.C.:

Q. Is he, or is he talking about -

MR. GULLIVER:

A. No, no, 100 percent, he was talking about microbiology. Dr. Whitman, whether it was this meeting or other, you know, Cindy expressed concerns too about hematology, which includes blood banking, you know, all the post Krever Inquiry issues, and that, you know, we all knew within the lab in Newfoundland, you know, we don't have - there is no accreditation program, there is no licensing required for labs to practise in this province. I don't think it's fair to say it's a gap in our service that we recognize within the program. However, I don't know if it was recognized above us within the program.

CHAYTOR, Q.C.:

Q. And what's indicated here to be your contribution to the discussion, your indication that, well, there's no legislation requiring labs in Newfoundland to be

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accredited or licensed, were you saying that in terms of, you know, that you thought it was a good idea that that would happen?

MR. GULLIVER:

A. Oh, my God, yes, certainly. I mean, I submitted a document this morning from 1998. At the time, I'm on our national Board of Directors from a professional perspective, not my workplace perspective, but from the professional perspective, and I certainly was aware of the lack of standardization - you've heard lots about lack of standards in testing protocols, but there's no standard for - there is no standard where every lab in this country must achieve in order to receive a stamp of approval to say that you can now go ahead and practise laboratory medicine.

CHAYTOR, Q.C.:

Q. Did you have any reason to think - you said Dr. Hutchinson would have been specifically referring to microbiology, but did you have any reason to think that it would have been anything different for the pathology portion of the lab?

MR. GULLIVER:

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A. In which way?
CHAYTOR, Q.C.:
Q. His concerns that if the program had to meet such standards as QMPLS would stipulate, that microbiology, you're saying, is what he's referring to?
MR. GULLIVER:
A. He was, yes.
CHAYTOR, Q.C.:
Q. Okay. It says the program. So he's referring to microbiology. Do you have any reason to believe that it would have been any different for your pathology division?
MR. GULLIVER:
A. Probably no different for chemistry, cytology, or genetics either.
CHAYTOR, Q.C.:
Q. All of them would have had difficulty meeting?
MR. GULLIVER:
A. I would feel so, yes.
CHAYTOR, Q.C.:
Q. Meeting the standards of QMPLS?
MR. GULLIVER:
A. Yeah.
CHAYTOR, Q.C.:

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Q. General discussion it says did take place in that time period about an overall laboratory quality assurance program. So it seems that the discussion did become broader in terms of looking at such a program for the overall board?
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. Overall program, sorry, and there's indication that discussion about a quality officer comes up at that point in time?
MR. GULLIVER:
A. Yeah.
CHAYTOR, Q.C.:
Q. Whatever happened to that idea?
MR. GULLIVER:
A. Well, again, and we're in the time frame, Ms. Chaytor, where as a program we're actively putting together sort of a comprehensive three year plan for lab services where each division will partake in, and each division would submit objectives and goals for their division. For the program, and I think through that process, you know, we had talked

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about looking to see if we can get a full time manager for quality services. As you're aware, we got approval in 2007, July.
CHAYTOR, Q.C.:
Q. Yes, and - but was it ever in your three year plan - would we be able to see anywhere in your three year plan then on a go forward basis that you're looking for a quality officer?
MR. GULLIVER:
A. Again that's probably 100 pages or more. I don't remember everything that's in it. However -
CHAYTOR, Q.C.:
Q. Do you remember ever putting that forward?
MR. GULLIVER:
A. I can't remember specifically a quality manager within the three year plan because the three year plan is mostly based by division, by division, by division, by division. However - I think this is March, 2003. I know before this here that, you know - between I'm appointed director and between this time frame that we're talking about within the lab program, you know, I had already been turned

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down for reassigning my management money for quality person, and now we're trying to implement post HAY in cutting even more. Sometimes you reached a point where you just knew it was a waste of time to put something forward.
CHAYTOR, Q.C.:
Q. Mr. Gulliver, you did say in answering my questions on this that you got it - within your laboratory medicine program, you understood that you needed this, but you didn't think that people above you understood or got it. Who are you referring to?
MR. GULLIVER:
A. I'm not referring to one individual.
CHAYTOR, Q.C.:
Q. Well, who within the structure, or what positions?
MR. GULLIVER:
A. I know at some point later on, you know, I do express my concerns of, you know, the environment that we practice in in Newfoundland is not like Ontario or Alberta where they are very much more regulated and accreditated to Dr. Williams. Dr. Williams

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brought my concerns to the executive team, and this may be somewhere in the beginnings of it, and again I'm going to go back to what I said my first day of testifying on Friday, that it's particular culture that within the health care system, the cultural setup and organization of the health care system, the laboratory is physically located in the bottom of the building, and the laboratory a lot of times is the last one that people think about.

CHAYTOR, Q.C.:

Q. And also you stated that you didn't think it would have been any different for any of your divisions; microbiology pathology, chemistry, wherever, in terms of being able to meet QMPLS standards?

MR. GULLIVER:

A. At this time - no, that's not accurate.

CHAYTOR, Q.C.:

Q. Okay.

MR. GULLIVER:

A. I think, yes, for most divisions, however, in blood banking, because it was most Krever Inquiry, you know, there were national standards put in place, came out federally

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that all provincial governments agreed to. Certainly by this time our blood banking part of the laboratory is very heavily regulated.

CHAYTOR, Q.C.:

Q. Because they've just been through an inquiry.

MR. GULLIVER:

A. Yeah.

CHAYTOR, Q.C.:

Q. Why wouldn't the rest of your - why wouldn't the rest of your divisions have been able to meet the standards of QMPLS?

MR. GULLIVER:

A. And again - well, you're using a very broad term too, the standards of QMPLS. You really have to be more specific because -

CHAYTOR, Q.C.:

Q. Well, to be able to go through -

MR. GULLIVER:

A. They're not going to come in and assess the quality of every single division. QMPLS, by and large, are coming in to view your level of documentation, are you SOPs in place, are they updated, are they audited, are they regularly maintained and monitored. Certainly within all parts of our program you will find, even

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at this time, that part of the daily practice of lab medicine, you incorporate quality control material, whether it's a positive side in IHC or whether it's a commercially purchased quality control sera to do I & R testing, or cholesterol, or glucose testing. I mean, that stuff takes place every day. This is more big picture stuff looking - comparing our laboratories to the rest of the country really, that, you know, are we following the same standards and are we held to the same standard as what a lab would be in Ontario or Alberta, who I know through my professional experience were under much different regulations and accreditation processes.

CHAYTOR, Q.C.:

Q. So it's because they would have already been subjected to having to go through stringent regulations and through -

MR. GULLIVER:

A. They had been by this time for about eight or nine years.

CHAYTOR, Q.C.:

Q. So at this point in time then, and this is

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March of 2003, would you be aware then that there weren't standard operating procedures in the pathology lab at this point in time that would be able to meet the standards of QMPLS?

MR. GULLIVER:

A. Well, certainly every lab had operating procedures and they had protocols that you had to follow. I mean, the key word there is standard and were they in a standard template or standard format, the answer would be no, and the template format would include procedures being signed off by authorities and having a regular date on them when they need to be rechecked and reviewed to update. That certainly wasn't in place.

CHAYTOR, Q.C.:

Q. And those things would have been required to be able to -

MR. GULLIVER:

A. And those things certainly would be required if we were in Ontario or Alberta.

CHAYTOR, Q.C.:

Q. And the importance of having them standardized and having them updated on a regular basis, you would have been aware of the importance of

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that, I take it, in 2003?
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. I'm going to talk a little bit now about Dr. Ejeckam.
THE COMMISSIONER:
Q. Just before you leave the standards business, I'm not sure what message I'm getting from you, Mr. Gulliver. Are you suggesting that, you said every lab had operating procedures, but you acknowledge that there were things lacking in your laboratories that would be required, you would expect, by organizations such as QMPLS who might be doing reviews of laboratories in Ontario where certain standards have been required for a period of time. Are you suggesting that your operating procedures were sufficient that you really didn't need the other--what's your, I'm getting a mixed message, I think, from you about the necessity of this kind of review or what it accomplishes. Are you in favour of, for example, requiring your laboratory to come up to the kinds of standards that we would

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anticipate that somebody like QMPLS would require?
MR. GULLIVER:
A. Oh a hundred percent, yes.
THE COMMISSIONER:
Q. Okay, and are you suggesting that your laboratory would have come up to those standards had they come in earlier?
MR. GULLIVER:
A. No, you mean if QMPLS had to come in in 2003?
THE COMMISSIONER:
Q. Yes.
MR. GULLIVER:
A. I think what you're seeing in Ms. Wegrynowski's report in 2005, you probably would have found in 2003 also.
THE COMMISSIONER:
Q. Okay.
MR. GULLIVER:
A. And I guess I'm trying to--maybe I'm trying to over explain, our laboratories had operating procedures, so there's your method, there's your procedure where the technologist or staff would know, here's the procedure you follow performing this particular, it could be a

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stain in pathology, it could be cholesterol test over in chemistry.
THE COMMISSIONER:
Q. Uh-hm.
MR. GULLIVER:
A. What we were really lacking is we had no set of templates for things to be written in a standard format; therefore, could lead to misinterpretations if it's not written in a standard format. We had no authority who signed and authorized that this is the operating procedure or this is the policy, whether it's for pathology or chemistry or the Laboratory Medicine Program overall, and there was no review pros. built in to say, well, we've been using this procedure now for five years, is it time to review and update and see if something new or something has changed. And that's only a part of what we say the standard operating procedures, that's the whole format and template and having a document and process in place to update and review. Standard also means that the people performing the procedure are interpreting a policy, are doing it in a standardized format

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and you have to make sure. In order to ensure or minimize that risk, it's must better to have things written and presented in a consistent format, as opposed to this procedure manual looks this way, this procedure looks over this way and this procedure looks over this way. You -
THE COMMISSIONER:
Q. Well it seems to me in what you are now saying is that you recognize the desirability of establishing proper procedures and policies within your lab and ensuring that they are current and regularly reviewed.
MR. GULLIVER:
A. Yes, all labs, not just pathology.
THE COMMISSIONER:
Q. Yes, no, no, I'm not suggesting that--we are concentrating on pathology, but that logic would not be limited to pathology.
MR. GULLIVER:
A. Yeah.
THE COMMISSIONER:
Q. Okay, thank you.
CHAYTOR, Q.C.:
Q. So you recognize the importance of it, why

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didn't it happen? Why wasn't it done?
MR. GULLIVER:
A. I knew you were going to ask that question next. Again, I'm going to go back to the timeframe. You have heard from Dr. Lynn Morris-Larkin just this morning, today, and many other witnesses of, you know, the huge advances we made in our documentation, in not just writing SOPs and policies and having them in proper formats, in nice books and they're available on the internet, on the website for staff to review. All of that has happened because we have resources and dedicated people to do it. It's pretty well impossible and I'm going to have to say impossible five years ago in this environment that we had to work under, under the pressures that we're under for cost cutting and on top of that, the demands on the physician side and the population side for increased services, increased testing, new genetics testing to be developed for the province. I mean, that's the dynamics of working in the laboratory and really the staff and physicians who work in a laboratory, it was challenging enough just to come to work

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and get the work done that needed to be done for patient care today and get the results out. It really--we neither had the resources to start looking at the documentation and the auditing and those pieces of a full quality management program. We ran lots of quality control, but there certainly was no full quality management program.
CHAYTOR, Q.C.:
Q. And in terms of the importance that you appreciated, the importance of this piece, was that articulated to your superiors, the importance of having appropriate resources and funding for those initiatives?
MR. GULLIVER:
A. I don't know if you'll find, you know, written submission by me, in particular, but certainly, yes, I mean, this was certainly brought up the line by myself to my VP. I don't know how much further Dr. Williams would have brought it and I think Dr. Williams was pretty well in favour of such a program for Newfoundland, you know, I had made contact with QMPLS and asked them about their programs they have in Ontario, could they send me

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documentation on the kinds of things that would do if they came into a laboratory to do an accreditation and a review. I know by sometime in 2004, I think after our next CCHSA, you know accreditation, you know, I expressed my concerns to Dr. Williams that really, you know, it's a piece of paper but it really doesn't mean anything.
CHAYTOR, Q.C.:
Q. Yes, in terms of what happened in, I think that's late, maybe November 2004 in terms of -
MR. GULLIVER:
A. Which is the year after this here.
CHAYTOR, Q.C.:
Q. The window dressing accreditation that you go through again.
MR. GULLIVER:
A. Yes, but this is not something that was discussed at this particular meeting and then you never heard about it anymore.
CHAYTOR, Q.C.:
Q. Right.
MR. GULLIVER:
A. You know, this was certainly something that we talked about within the program.

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CHAYTOR, Q.C.:
Q. So it's an ongoing issue of concern within your program and it is something that you are having that discussion with Dr. Williams about the importance.
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. And the importance in terms of how it may impact on patient care, was that clearly appreciated and articulated to Dr. Williams?
MR. GULLIVER:
A. I have to say no.
CHAYTOR, Q.C.:
Q. And why not?
MR. GULLIVER:
A. I don't think myself and Dr. Cook, you know, warned Dr. Williams that patient care could be affected if, you know, if we don't have a regulated laboratory in Newfoundland similar to Ontario -
CHAYTOR, Q.C.:
Q. Or a Quality Assurance Program.
MR. GULLIVER:
A. Or Quality Assurance Program where we can

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stand up to the standard of Ontario, I don't think we directly linked it to say, you know, patient care can be affected. And I don't think we said that, Ms. Chaytor, because, you know, I have spent my whole career in medical laboratory and that's all we do is patient care. You know, do I have to say to the vice-president and executive team that, you know, medical laboratory, every test we perform could affect patient care. It could affect the prognosis, it could affect someone's treatment, it could affect--just preventative medicine, people just having their routine cholesterol done. So, you know, that's all we do is patient care, but I can't say to you I gave or Dr. Cook gave him something to say and here's warnings about patient care if we don't have a full Quality Management Program.

CHAYTOR, Q.C.:

Q. Could we have, please, P-3113? I'm going to skip ahead here in time, Mr. Gulliver, this is a memo that you wrote following the accreditation of 2004 to Dr. Williams. And you say, "Following our"--and I believe this to be, I think it's maybe December 8, 2004?

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MR. GULLIVER:

A. December, yeah.

CHAYTOR, Q.C.:

Q. "Following our recent meeting in regards to the accreditation process involving laboratory medicine, please find attached a copy of the survey guidelines for the accreditors and a copy of the pre-survey questionnaire for laboratory services. As I indicated at our meeting, I felt the surveyor of the Laboratory Program was very impressed with our services and facilities. The surveyor basically toured St. Clare's and the Health Science's laboratories and asked very few questions. The current accreditation standards under the AIMS system, relies on the clinical team's input to help assess laboratory services, in addition to the on-site visit. While the survey process is, in my opinion, of less detail than prior surveys in regards to laboratory services, I still feel that it was a useful exercise. For your information, the Laboratory Program also participates in accreditation for the Resident Training Program by the Royal College of Physicians and

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the College of the North Atlantic and Michener Institute for Medical Laboratory Technologists Clinical Training. In addition to the laboratories successfully completing all of the above formal accreditation processes, we also voluntarily participate in multiple proficiency testing programs from outside agencies that assess our accuracy and quality of testing. While there is no legislation in Newfoundland requiring medical laboratories to be licensed, we voluntarily adhere to international standards of practice, as outlined by the NCCLS and also national standards established by the CSMLS." And first of all, Mr. Gulliver, perhaps you can tell us what is the NCCLS?

MR. GULLIVER:

A. Oh, that's the National Conjoint Committee on Laboratory Standards.

CHAYTOR, Q.C.:

Q. And the CSMLS, if you can remind us what that is?

MR. GULLIVER:

A. Canadian Society for Medical Laboratory Signs, that's our national, professional certifying

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body.

CHAYTOR, Q.C.:

Q. And Mr. Gulliver, you think Dr. Williams, reading this, would walk away with any concern that perhaps your laboratory is lacking in any way in terms of its quality assurance measures.

MR. GULLIVER:

A. I don't know what he walked away with, but this was an outcome of discussion with myself and him and Dr. Cook where I'm expressing to Dr. Williams that we just finished our accreditation. I know there are accreditors that said the laboratory passed accreditation and, you know, I'm pretty well relaying to him that, but you realize the accreditation is pretty well, they come in, they talk to me for half a day, walked around the labs, they said hello to a few staff, looked around that pretty well was the accreditation process. With the exception of before they arrived, there was some basic questions we had to answer, the lab services, which is the pre-site visit. From that discussion, Dr. Williams asked, well, does the lab

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participate--does anybody from outside come in and review our lab for any reason? And I said, well, yes, you know, we do have a full accreditated pathology training program and during their cycle, the Royal College of Physicians come in and they do review the lab, but they're not reviewing the lab in what you perceive reviewing the lab. They're reviewing what we have in place for the training program for residents. The other two is, sort of, CONA, the ongoing accreditation we do with them for training of medical lab technologists and the other one is the Michener Institute in Toronto. We send two lab technologists every year to the Michener Institute for genetics training. It's a two year program, post appellant program. And we were, during their process, they came in to assess our genetics laboratory to ensure that we can provide clinical training to students in that program

CHAYTOR, Q.C.:

Q. What was the purpose of this memo? Why did you write this to Dr. Williams?

MR. GULLIVER:

A. I think for two reasons; one to make sure he

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understood that the current laboratory accreditation process really is not an accreditation similar to what the rest of the country, what most provinces in the rest of the country were being held up to. And I think around this point, I may have made inquiries to QMPLS to see, with the view, at some point, if we could actually, sort of, like, get a contract with them, where we could second them to do an accreditation review process for--at the time, Health Care Corporation.

THE COMMISSIONER:

Q. Your purpose in writing this memo was to convey to Dr. Williams the limitations in the -

MR. GULLIVER:

A. Well, I have conveyed that in speaking to him in our meeting.

THE COMMISSIONER:

Q. Yes, and they you follow it up with this. Was that the way I understand it happened? The sequence, you had a discussion with Dr. Williams about the process and then you follow it up with this memo?

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MR. GULLIVER:

A. Well, he asked me could I do up a memo that would include anything that the laboratory participates in, any kind of accreditation process. And this is pretty well--well, we do CCHSA, but I'm putting a bit more into this, say, well, it's useful, but it's not really the best and here's other things that we participate it. He didn't ask me to do a memo to express my direct concern about lack of accreditation for labs in Newfoundland, in particular, Health Care Corporation.

THE COMMISSIONER:

Q. But you're telling us that you did do that in -

MR. GULLIVER:

A. In our meetings.

THE COMMISSIONER:

Q. - your meetings.

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. So, in your meeting, you expressed those concerns and then he asked you to do a memo outlining what, in fact, you do do in the way

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of -

MR. GULLIVER:

A. In the absence of, really, in the absence of having no real accreditation process, what does the laboratory participate in? Who comes in to review the lab?

CHAYTOR, Q.C.:

Q. And you weren't asked to articulate, in writing, any of your concerns about what else should be happening or any of the shortcomings in what, in fact, was happening?

MR. GULLIVER:

A. No, not from writing. We talked about it in our monthly meetings and regular meetings. And you know, I think I was the one who told Dr. Williams that, you know, like Ontario does have standards and they have QMPLS. And I think he asked me to make contact to investigate and give him information on what is QMPLS.

CHAYTOR, Q.C.:

Q. And why wouldn't that be in writing as well?

MR. GULLIVER:

A. At this point in time?

CHAYTOR, Q.C.:

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Q. Yes.
MR. GULLIVER:
A. No, I think that comes after.
CHAYTOR, Q.C.:
Q. When I read this, I was left, you know, everything is good, there's nothing lacking and I mean, you end, in your last paragraph with, in addition to the laboratory successfully completing all of the above -
MR. GULLIVER:
A. But those accreditation--but these three accreditation processes are training programs. They're not coming into assess the quality of your work or do you have SOPs or policies written. They're saying that you have a clinical--the scope of practice is enough that you can train pathology residents, general registered technologists and genetics technologists. They're not an accreditation process to review your policy manuals or documentation.
CHAYTOR, Q.C.:
Q. But that was discussed with Dr. Williams in the meeting prior to you writing this memo?
MR. GULLIVER:

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A. No, what was discussed with him was in particular the CCHSA accreditation.
CHAYTOR, Q.C.:
Q. But did you also discuss with him the fact that there are other things out there for other provinces, but that's nowhere near what's happening with this accreditation process that we're going through.
MR. GULLIVER:
A. Yes, I did.
CHAYTOR, Q.C.:
Q. And that you have concerns as to what, in fact, is not being reviewed externally?
MR. GULLIVER:
A. I guess I'd let him be aware, he's my VP that while this is the accreditation that we're undergoing with CCHSA, it really is not a full accreditation process and that our province has no legislation requiring us to do any kind of accreditation as Ontario and Alberta has legislation requiring labs to be, not just accredited, labs had to be licensed and through that process in Ontario, Alberta, you had to be licensed, every staff member and technologist and physician has got to

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participate in so many continuing education hours over a three year period and you've got to prove that to the licensing process. So, that's the things I was making him be aware of.
THE COMMISSIONER:
Q. Ms. Chaytor, it's past the -
CHAYTOR, Q.C.:
Q. Thank you, I'll take up with--start the part on Dr. Ejeckam tomorrow then.
THE COMMISSIONER:
Q. All right. A couple of administration points, I'm advised that there is a package for all counsel before you leave. I'm sure there will be somebody near to the door, if not at the door to provide that for you, and I'm advised by counsel for the Commission also that you're being very co-operative and agreeing to have an extra long session tomorrow, so that we can hopefully keep to our schedule for this week. I thank you all for your co-operation in that respect. 9:30 in the morning, 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 7th day of October, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.
Dated at St. John's, Newfoundland and Labrador this 7th day of October, A.D., 2008
Judy Moss

-E-

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