COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

September 2, 2008

Appearances:

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

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

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

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

Ches Crosbie, Q.C./
Laura Brocklehurst. . . . . Members of the Breast Cancer
. . . . . Testing Class Action
Mark Pike . . . . . NL Medical Association
Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
Blair Pritchett. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

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LIST OF EXHIBITS

TABLE OF CONTENTS

September 2, 2008

THE COMMISSIONER:

Q. Please be seated. Mr. Coffey?

COFFEY, Q.C.:

Q. Thank you, Commissioner. The next witness is Dr. Ford Elms.

DR. FORD ELMS (SWORN) EXAMINATION BY BERNARD COFFEY, Q.C.

REGISTRAR:

Q. Would you please state and spell your complete name for the Commission?

DR. ELMS:

A. Ford John Elms, F-O-R-D J-O-H-N E-L-M-S.

REGISTRAR:

Q. Thank you.

COFFEY, Q.C.:

Q. Commissioner, I have some new exhibits I'm going to ask that be entered, please. They are P-2300, 2301, 2302, 2303, 2305, 2306, 2308, as well as C-0173, C-0225, 0226, 0227 through C-0228.

THE COMMISSIONER:

Q. Entered.

EXHIBITS ENTERED AND MARKED P-2300 THROUGH P-2303

EXHIBITS ENTERED AND MARKED P-2305 AND P-2306

EXHIBIT ENTERED AND MARKED P-2308

Page 5

EXHIBIT ENTERED AND MARKED C-0173
EXHIBITS ENTERED AND MARKED C-0225 THROUGH C-0228
COFFEY, Q.C.:
Q. Thank you, Commissioner. Good morning, Dr. Elms.
DR. ELMS:
A. Good morning.
COFFEY, Q.C.:
Q. I'm going to ask, please, Registrar, if you could bring up Exhibit P-2308, please? And Doctor, there on the screen in front of you the exhibit is. That's your name, Ford Elms, and an education summary on page two of it, and community involvement on page three. Is this your CV, Doctor?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, could you please then give the Commissioner and overview of your educational and professional background?
THE COMMISSIONER:
Q. Dr. Elms, it's also in written form in the book, if you'd prefer to look at that.
DR. ELMS:

Page 6

A. Yes. I entered medical school at Memorial University in 1980 and completed the program there. I then did a rotating internship for one year. Then in June of 2005, I commenced work as a casualty officer in Carbonear Emergency Department.
COFFEY, Q.C.:
Q. I'm sorry, in?
DR. ELMS:
A. As a casualty officer.
COFFEY, Q.C.:
Q. In what year?
DR. ELMS:
A. In 1985 rather, sorry.
COFFEY, Q.C.:
Q. No, no, I was -
DR. ELMS:
A. I'm older than that.
COFFEY, Q.C.:
Q. Thanks, Doctor.
DR. ELMS:
A. After four months there, I went to work as a casualty officer in the emergency department at the Grace General Hospital. I was there for 22 months and then transferred back to

Page 7

Carbonear. In 1990, I then transferred to the emergency department of St. Clare's Hospital, and in 1996, I entered the pathology residency program at Memorial University. I studied there for four years and completed by licensing exams in 2001. In June of 2000, I commenced work as a staff pathologist at St. Clare's Hospital.
COFFEY, Q.C.:
Q. And are you still located there today?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, the licensing exams that you took in 2000-2001, which ones were they?
DR. ELMS:
A. They were the Royal College certification exams.
COFFEY, Q.C.:
Q. And the Canadian?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And your certification is in anatomic?
DR. ELMS:

Page 8

A. General pathology.
COFFEY, Q.C.:
Q. General pathology, okay. Now Doctor, could you give the Commissioner, please, an account of what, if any, exposure you had to immunohistochemistry during your medical school days, that would be back in the early '80s, your internship and then your residency as a pathologist in the latter part of the '90s?
DR. ELMS:
A. During medical school and my internship, I had no exposure to immunohistochemistry. I didn't encounter it until I began my residency and then we were studying immunohistochemistry from the point of view of the interpretation of panels of immunohistochemical stains in the diagnosis of difficult cases and in the course of that, during my residency, the testing for estrogen and progesterone receptors began.
COFFEY, Q.C.:
Q. Okay. This was while Dr. Khalifa was -
DR. ELMS:
A. Yes.
COFFEY, Q.C.:

Page 9

Q. - here in St. John's, and you would have been a pathology resident in St. John's during the period where the IHC approach to ER/PR determination was introduced?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. What do you recall, if anything, about your introduction to that?

DR. ELMS:

A. In the beginning, we were still doing the bioassay and then I became aware that we were introducing the immunohistochemical process and then it came on stream and it became a part of our assessment of breast cases.

COFFEY, Q.C.:

Q. And do you recall, Doctor, what that actually involved? I mean, you say exposure to, what made up the exposure? How were you exposed to you?

DR. ELMS:

A. Well, when we would get a breast case, initially we would be requested to do estrogen and progesterone receptors on a particular case. When we received the request, we would

Page 10

order it and then the slides would come back to the attending pathologist under whom I was working at the time, and we would then read those slides and report on them.

COFFEY, Q.C.:

Q. And I take it the attending pathologist would be whomever you were working for at the time?

DR. ELMS:

A. Whomever, yes.

COFFEY, Q.C.:

Q. And then, I take it then whatever you learned about it would be what the attending pathologist taught you?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Do you recall, Doctor--sorry about that, Doctor. Okay, Doctor, do you recall whether or not you were introduced to it at the time or learned anything at the time through reading?

DR. ELMS:

A. Yes, yes.

COFFEY, Q.C.:

Q. What sorts of things were available at that

Page 11

time and did you avail of?

DR. ELMS:

A. Most of what was available to me at the time was what was included in our pathologist textbooks.

COFFEY, Q.C.:

Q. And do you recall generally what that was?

DR. ELMS:

A. Again, it was to do with the interpretation of panels of stains in the diagnosis of disease.

COFFEY, Q.C.:

Q. Doctor, do you recall what it was, during your residency then, in relation to ER/PR IHC stains that you were taught to look for back then?

DR. ELMS:

A. We were taught to look for nuclear staining and to assess the intensity of the staining.

COFFEY, Q.C.:

Q. And what about the intensity, what were you taught about that?

DR. ELMS:

A. Basically that the intensity could vary, that some tumours would be weaker, that not the entirety of a tumour would stain.

Page 12

COFFEY, Q.C.:

Q. When you say intensity in this context, that means what?

DR. ELMS:

A. How dark the stain is basically. The indicator that we use is a brown dye and basically it's to do with how dark, how brown the nucleus looks.

COFFEY, Q.C.:

Q. Doctor, and then you said as well that so it might be--you've got to look at how brown, dark, the nuclear staining was?

DR. ELMS:

A. Um-hm.

COFFEY, Q.C.:

Q. For ER/PR. What about in terms of how much of the tumour stained, percentages?

DR. ELMS:

A. Just that it was variable, that various tumours could stain in various ways. I was aware that there were various--that there was debate as to what percentage of tumour cells would be considered to be a positive.

COFFEY, Q.C.:

Q. And what do you recall about that?

Page 13

DR. ELMS:
A. In the early days, I believe we were working with 30 percent.
COFFEY, Q.C.:
Q. And so that was, I take it, generally the approach at St. Clare's. Would you have done any time at the General Hospital?
DR. ELMS:
A. Oh yes, yeah.
COFFEY, Q.C.:
Q. And how about the Grace?
DR. ELMS:
A. Same, and the Grace as well, yes.
COFFEY, Q.C.:
Q. Was there anything written down as to this 30 percent figure?
DR. ELMS:
A. Not that I recall.
COFFEY, Q.C.:
Q. And when you say percentages, were there any other type of stains at the time that you were using or coming to a percentage determination of?
DR. ELMS:
A. No.

Page 14

COFFEY, Q.C.:
Q. This is kind of the only one in which you were called upon to actually come up with a percentage or a fraction?
DR. ELMS:
A. That's correct.
COFFEY, Q.C.:
Q. Were you taught anything else, to look for anything else at the time? We've heard a lot now about internal controls and the usage of internal controls for ER/PR. At that time, in the '90s, do you recall being made aware of that?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, again so the Commissioner can get some sense of this, you wrote your exams in 2000-2001?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall what, if any, part of the testing process involved testing of your knowledge of IHC?

Page 15

DR. ELMS:
A. In the--the exam is divided into several parts and one of those parts is a practical exam in which you're shown unknown slides. There may have been one at the time that we were required to look at.
COFFEY, Q.C.:
Q. There may have been one out of what?
DR. ELMS:
A. Out of 40.
COFFEY, Q.C.:
Q. Okay.
DR. ELMS:
A. But it was not a big, a large component of the exam.
COFFEY, Q.C.:
Q. Okay, that's the practical part of it. How about -
DR. ELMS:
A. Yes, or of the written.
COFFEY, Q.C.:
Q. Or the written. So if it was there at all, it was a very small part?
DR. ELMS:
A. Very small part.

Page 16

COFFEY, Q.C.:
Q. And I specify IHC, not particularly ER/PR.
DR. ELMS:
A. IHC in general.
COFFEY, Q.C.:
Q. IHC in general, and at that time, there would have been, I take it, many dozens of IHC tests?
DR. ELMS:
A. Oh yes.
COFFEY, Q.C.:
Q. Easily?
DR. ELMS:
A. Yeah, easily.
COFFEY, Q.C.:
Q. Doctor, while I'm on the topic, I take--and we will come to this, you are currently the director of immunohistochemistry for Eastern Health?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Are you involved in teaching residents?
DR. ELMS:
A. Yes.

Page 17

COFFEY, Q.C.:
Q. And you'd certainly be aware of what exposure they got to IHC generally?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. As of right now, as we speak, how much, to your knowledge, how much do the current exams, fellowship exams or examining process, test IHC?
DR. ELMS:
A. I don't know.
COFFEY, Q.C.:
Q. You don't know, okay. In terms of the residents' actual exposure to IHC though, how much do they have?
DR. ELMS:
A. IHC is relatively commonly done and in numerous instances, they will be--they will order immunohistochemical stains to help them in their assessment of a case.
COFFEY, Q.C.:
Q. Are they actually, to your knowledge, exposed though to what actually goes on in the lab, in terms of IHC?

Page 18

DR. ELMS:
A. Not at the present time.
COFFEY, Q.C.:
Q. Are there any plans to change that?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Okay. What are the plans in that regard?
DR. ELMS:
A. I'm currently developing a series of lectures, geared towards our technologists, of histology with relation to immunohistochemistry. So that in various types of tissues, we can discuss the types of antibodies that would be expected to stain and it's not merely a matter of staining. In many tissues, it's pattern of staining, actual area of staining. One of the big areas where that would be in lymph node, and so our technologists will need to know which areas of tissues would be expected to stain and we're also throwing that open to the residents.
COFFEY, Q.C.:
Q. You'll make it available?
DR. ELMS:

Page 19

A. Yes. Yes, we have a residents academic half day in pathology and the plan is to have these lectures as a portion of that.
COFFEY, Q.C.:
Q. And again, so the Commissioner has some understanding of what a residents' half day means, in a cycle of a week or a month, how much is that?
DR. ELMS:
A. The residents half day in pathology, what we refer to as RHDIP, which I believe has been mentioned here before -
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. - occurs on Friday mornings and our residents are relieved of their service duties to attend to academic issues. Usually that is in the context of lectures provided by various members of the staff.
COFFEY, Q.C.:
Q. So it would be once a week for a half day?
DR. ELMS:
A. Once a week.
COFFEY, Q.C.:

Page 20

Q. And as part of that process, these lectures would be offered and they'd be expected to attend them?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you have any estimate as to when that might come or be made available to the technologists and the residents?
DR. ELMS:
A. I hope to begin them next week.
COFFEY, Q.C.:
Q. And so I take it then, Doctor, this hadn't been done before, to your knowledge, in the program here?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, if we could, please, Registrar, I'm going to ask you to bring up Exhibit P-2300. Now Doctor, these are the minutes of a laboratory management committee meeting, number eight actually, of April 26, 2000, and you'll notice that you're present there, noted listed as present, as well as Dr. Cook and

Page 21

others, and at the bottom of the page, paragraph 8.4, "a list of new tests offered was presented." Look to the next page, they are indicated to be HER2/neu expression, FISH techniques, cytogenetics and auto antibodies to three different conditions. Doctor, was this--would this reflect the introduction of HER2/neu in St. John's around that time?

DR. ELMS:

A. I don't recall the exact discussion, but it would have been at least to inform the staff that this test was to be offered.

COFFEY, Q.C.:

Q. And Doctor, in terms of HER2/neu, at the time, were you involved in ordering and reporting HER2/neu cases?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Were you given any training in that regard?

DR. ELMS:

A. No, we were given information provided by the manufacturer.

COFFEY, Q.C.:

Q. That would be the manufacturer of the -

Page 22

DR. ELMS:

A. Of the antibody.

COFFEY, Q.C.:

Q. - of the antibody. And what sorts of information or what sort of information would that have been?

DR. ELMS:

A. HER2/neu is assessed on a scale of zero to three plus and so we were given information as to what appearance each of these stains would have, so we'd know what was considered to be a one plus or a two plus or a three plus.

COFFEY, Q.C.:

Q. And so I take it this would be textual information?

DR. ELMS:

A. Textual and visual.

COFFEY, Q.C.:

Q. Visual, okay.

DR. ELMS:

A. We had colour photographs as well.

COFFEY, Q.C.:

Q. Doctor, how did what happened in relation to HER2/neu, such as it was, you described, compare with what had happened with ER and PR stains several years before?

Page 23

DR. ELMS:

A. There was much more information provided as to interpretation, so that, as I said, we were given visual information, because the interpretation of HER2/neu is more complex than that of ER.

COFFEY, Q.C.:

Q. Exhibit P-1867, please. Doctor, these are-- this is a quality initiatives report for April 1st '99 through March 31st, 2000. It's prepared by Mr. Whalen and Dr. Cook and I just refer to it because--I'm sorry, at page 22, please. Go back here a bit. Actually, this is the one at page 19, begins the quality initiatives report for 2000 to 2001, executive summary, and at page 22 of the exhibit it's noted in passing that yourself and a number of other physicians have passed your exams. So you then, if I could, please, Exhibit P-0479, page eight, please? This is a listing of Eastern Health pathologists staff turnover. Look down at 3.02, Ford Elms is listed there. It's the second entry, June 1st, 2000.

DR. ELMS:

Page 24

A. Yes.

COFFEY, Q.C.:

Q. So that's when you actually started then or is that correct?

DR. ELMS:

A. I started on the 12th of June.

COFFEY, Q.C.:

Q. Okay, that's fine. It's close. Doctor, tell the Commissioner, please, then, in terms of ER and PR reporting, by the time you began in the middle of 2000 on staff at St. Clare's, I understand from evidence we've heard that ER/PR had already been utilized in St. John's really going back to 1997?

DR. ELMS:

A. Yes, that's true.

COFFEY, Q.C.:

Q. Through '98, '99 and 2000, in effect through most of your residency?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Before having a staff position, as a resident, would you actually report ER/PR results?

DR. ELMS:

Page 25

A. Not independently. I would see them--the process of residency training is a process of increasingly graded responsibility. I would see them and assess them and assess the case myself and then sign them out with my attending.

COFFEY, Q.C.:

Q. And Doctor, what was your approach or what were you taught in terms of--first of all, what were you taught, as opposed to your approach, what were you taught in terms of how it should be reported, ER and PR?

DR. ELMS:

A. That we reported positivity or negativity and that initially, as I said, there was considered a cut off of, I believe it was 30 percent.

COFFEY, Q.C.:

Q. So how would you have reported it?

DR. ELMS:

A. In those days, that it was positive or negative.

COFFEY, Q.C.:

Q. And you'd simply say ER is positive or negative and PR is positive or negative?

Page 26

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And wouldn't use a percentage?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. And in your own mind, it was--if it was 30 or less or less than 30, or do you recall?

DR. ELMS:

A. If it's less than 30.

COFFEY, Q.C.:

Q. Less than 30. So if you saw 30, 33 percent, say a third, then you would simply report it as positive?

DR. ELMS:

A. As positive.

COFFEY, Q.C.:

Q. Did you ever have, during your residency, any occasion to discuss or be questioned by any oncologists as to what you meant by positive?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. In fact, even after your residency?

Page 27

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Never actually had anybody come back and say "well, what do you mean by positive or negative?"

DR. ELMS:

A. No. No, I had no contact of that nature.

COFFEY, Q.C.:

Q. Doctor, this 30 percent, did that ever change, the approach to that?

DR. ELMS:

A. Yes, after I began work at St. Clare's, there was a debate--we became aware of debate as to exactly what constituted a positive. Was greater than 30 percent positive? Was greater than ten percent positive? Some were saying that any staining at all would be considered positive.

COFFEY, Q.C.:

Q. What do you recall then happened? In what context did that debate occur and what happened?

DR. ELMS:

A. We decided at the time that it would be

Page 28

prudent for us to report percentages and give that information to the oncologists and the oncologists could then decide.

COFFEY, Q.C.:

Q. Do you recall having any discussion with the oncologists about that?

DR. ELMS:

A. I didn't personally.

COFFEY, Q.C.:

Q. Were you told that anyone did?

DR. ELMS:

A. Not that I recall.

COFFEY, Q.C.:

Q. Do you recall who participated in this debate?

DR. ELMS:

A. It was within the staff at St. Clare's.

COFFEY, Q.C.:

Q. At the time?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And what--do you recall what era this would have been? It was after you became a staff person?

DR. ELMS:

Page 29

A. 2000 to 2001.
COFFEY, Q.C.:
Q. Okay, and at that time, the clinical chief was whom, do you recall?
DR. ELMS:
A. Clinical chief at that--I'm not sure if it was Dr. Haegert or Dr. Cook at that point.
COFFEY, Q.C.:
Q. Okay, depending upon which -
DR. ELMS:
A. Yeah.
COFFEY, Q.C.:
Q. - on which part of that period, it could be one or the other, and in any case, I take it the site chief though at St. Clare's would have been Dr. Cook?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, you have the advantage, of course, of having been a resident throughout the time when this was introduced, the first several years. When you were a resident, was there any understanding amongst the--that you could tell amongst the residents as to whether or

Page 30

not any, one or more pathologist staff members had any particular expertise in immunohistochemistry, kind of a go-to person?
DR. ELMS:
A. No. No, we had some--I recall we had one lecturing RHDIP from Dr. Khalifa about sort of the basic technique of how it was done, but -
COFFEY, Q.C.:
Q. How what was done?
DR. ELMS:
A. How the immunohistochemical test was performed.
COFFEY, Q.C.:
Q. Immunohistochemistry, period?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Not ER/PR?
DR. ELMS:
A. Not ER/PR specifically, no.
COFFEY, Q.C.:
Q. Okay.
DR. ELMS:
A. And there was no go-to person per se.
COFFEY, Q.C.:

Page 31

Q. We've seen memos involving Dr. Khalifa introducing or telling people that ER/PR IHC staining reporting by pathologists is going to be expected of them and explaining how it was to be done and so on. As a resident, did you see such memos?
DR. ELMS:
A. I don't recall.
COFFEY, Q.C.:
Q. And your recollection of being introduced to IHC was through the staff person or persons from time to time you were assigned to?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2301, please. Doctor, this is a--appear to be minutes of an OR practice meeting of November 29, 2001 and you're not present for it, but you are, if we go down the page, paragraph B, there's a reference to "Glenda requested site forms for specimen policy" and that lady would be Glenda Tapp. "Ford Elms, pathologist at St. Clare's, is currently reviewing the lab manual to verify if content is still accurate. Glenda will follow up with

Page 32

Dr. Elms." I refer you to this, Doctor, and there's a reference to Catherine Parnell out to the side, because I wanted to ask you were you ever involved in kind of examining manuals for St. Clare's?
DR. ELMS:
A. At the time that this occurred, I had, in discussions with Ms. Tapp, identified that we wanted to be sure that their copy of our policies was up to date and so Ms. Parnell was our lead technologist in our lab at the time and I asked her if she would provide that material to Ms. Tapp.
COFFEY, Q.C.:
Q. And what was the status of the written policies and procedures that existed at St. Clare's at the time, in terms of how current they were?
DR. ELMS:
A. In terms of how current they were, I'm not sure what the date was on them at the time.
COFFEY, Q.C.:
Q. So this would be in late--this is November 2001.
DR. ELMS:

Page 33

A. Yes.
COFFEY, Q.C.:
Q. The operating room personnel are looking to see if they have the latest version of what the pathology department's written policies and procedures were?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Presumably as they affected the OR?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall whether or not there was any such written policies in relation to immunohistochemistry?
DR. ELMS:
A. I don't believe there was.
COFFEY, Q.C.:
Q. And how up to date or otherwise the policies that did exist at the time were, you can't recall right now?
DR. ELMS:
A. I don't recall the dates.
COFFEY, Q.C.:

Page 34

Q. Was there anyone, that you could tell, at the time who was responsible for updating the written policies?
DR. ELMS:
A. My assumption was that it was a role of the technical management of the lab, but I had no specific indication as to who that was.
COFFEY, Q.C.:
Q. Were there any written policies and procedures for the pathologists at the time?
DR. ELMS:
A. I don't recall.
COFFEY, Q.C.:
Q. You don't recall there being any?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Now Doctor, in terms of written guides at the time, this would be late 2001, at St. Clare's, what would you use as a written aid or guide? What sorts of things?
DR. ELMS:
A. You mean in terms of grossing procedures and handling of specimens?
COFFEY, Q.C.:

Page 35

Q. Yes.
DR. ELMS:
A. There is a core textbook of anatomic pathology called--well, it's Ackerman's Surgical Pathology, and there's an extensive appendix in the back of Ackerman that was always stressed to us to be our guide for grossing, and so when we needed information as to how to prepare particular specimens, that was the reference we used.
COFFEY, Q.C.:
Q. And did Ackerman's provide any guidance as to how it should be, the format for reporting?
DR. ELMS:
A. No. Actually, I believe there were suggestions in another appendix in the textbook as to forms.
COFFEY, Q.C.:
Q. Now at St. Clare's at the time, was there any particular requirement for how you should report, for example, ER and PR?
DR. ELMS:
A. Other than what we've already addressed, no.
COFFEY, Q.C.:
Q. Which is the, as you said, the change in 2000

Page 36

to 2001, the decision to go to percentages?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, during your residency period, can you give us some estimate as to how many ER/PR cases you might have co-examined with an attending physician, an approximation as to how -
DR. ELMS:
A. I would say three maybe four a month.
COFFEY, Q.C.:
Q. And St. Clare's itself, I take it, there was a lot of breast surgery, comparatively speaking, going on at St. Clare's, compared to other sites?
DR. ELMS:
A. Yes, and that estimate is sort of based overall on my experience during my residency. I would have seen more at St. Clare's in the times I rotated through there.
COFFEY, Q.C.:
Q. So it would be three to four, on average, throughout the whole of your residency?
DR. ELMS:

Page 37

A. Yes.
COFFEY, Q.C.:
Q. Which would be 35 to 50 a year, depending up three to four a month?
DR. ELMS:
A. Depending on rotations. In each year, we would rotate through various areas so that you didn't spend an entire year at anatomic pathology, and where I was doing general pathology, six months of my total residency was outside of anatomic pathology entirely.
COFFEY, Q.C.:
Q. So for a particular period of time, you would have seen a lot or relatively speaking, frequently?
DR. ELMS:
A. Relatively speaking, yeah.
COFFEY, Q.C.:
Q. Frequently seeing ER/PR cases.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then for extended periods, you wouldn't see them at all probably?
DR. ELMS:

Page 38

A. Wouldn't see them at all.
COFFEY, Q.C.:
Q. Exhibit C-0225, please. Now Doctor, this is a matter of a surgical specimen number from 2001. You'll see that there.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And it's indicated to be received that would be August 14th, 2001, so it'll give you some sense of the time frame, and Doctor, what I'd do is just ask--take you to page two of the exhibit, addendum number one, okay. So I take it then, Doctor, and to put this in context for the Commissioner, perhaps you could just outline for us generally then, in terms of a breast case in 2001, how the report would get prepared, entered, addendums and so on, perhaps you could just take us through that?
DR. ELMS:
A. I don't recall if we were, at that time, ordering them routinely or if we were requested to order them by the oncologists. But in any event, the necessity for doing one, either as a request or as a routine, was

Page 39

there. We would order the stain. It did not preclude the initial sign out of the case, so oftentimes a case would be signed out with immunohistochemistry for ER/PR pending. Then when we would get the stains, we would assess the stains and report them.
COFFEY, Q.C.:
Q. And then in terms of signing out the case initially, I take it you would dictate what you saw?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And your views, interpretation of what you were seeing, and that would be entered. It would be reviewed and there's some kind of an electronic signature?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then if you wanted to add an addendum, could you just take the Commissioner through actually how is that done? What would happen?
DR. ELMS:
A. We would identify the case and specify that we

Page 40

were dictating an addendum on a particular case and then dictate the contents of the addendum. That would be entered in there as a specific field in the data entry program in which addenda are entered, and then the entered document, so to speak, would be brought back to us and we could review the addendum in the same way that you would review your original sign out, correct any errors and then apply an electronic signature.
COFFEY, Q.C.:
Q. And then if there was a second addendum, you'd dictate--in fact, this is another addendum and -
DR. ELMS:
A. The same process.
COFFEY, Q.C.:
Q. Same process would be repeated?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, in terms of pathology reports, can you tell the Commissioner, please, is there any particular methodology or practices to where an addendum ends up physically within the

Page 41

report?
DR. ELMS:
A. It ends up appended to the report. Generally they come, actually, before the rest of the report and in the case of an addendum the clinical will already have received the initial report, so all the other information is there is information the clinician already has. And the above that then occurs the addenda.
COFFEY, Q.C.:
Q. Yeah. At least your sense of it is is that the addenda would keep getting added to the front of the document, as it were?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you have any experience, though, with addenda or addendums being put kind of inserted halfway through or toward the end or -
DR. ELMS:
A. It's not something I've noticed, certainly not halfway through a report. It would either be at the beginning of it or at the end of it,

Page 42

but I haven't really -
COFFEY, Q.C.:
Q. You haven't actually kind of examined them to see -
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. - see what the result is. Just on that point, again, so the Commission have some sense of what it is you as a pathologist actually see, okay, you would initially dictate your report, the initial report?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. You would get kind of a draft, as it were, typed?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Would you get that in writing, like in paper or would you get that on a computer screen?
DR. ELMS:
A. That's on paper.
COFFEY, Q.C.:

Page 43

Q. And if it's satisfactory, you'd do what?
DR. ELMS:
A. If it was satisfactory, there is also a batch in the computer, so we get paper documents that we can review, however, they're also batched within the sign out program as a part of Meditech and so then we can sign them out in the computer at the time that we're reviewing them on paper.
COFFEY, Q.C.:
Q. So you look at the paper, that's fine, bring up that, scroll through or bring up that one and apply your electronic signature?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. If you want to make a change, what would happen?
DR. ELMS:
A. There's two ways we could do it. You could dictate and have the secretaries make the additions or you could do it yourself, you can enter into the actual program and do it yourself.
COFFEY, Q.C.:

Page 44

Q. And then, Doctor, when it comes time then, for example, in the ER/PR cases where you want to do an addendum, just use, for example, Addendum No. 1, the ER/PR results.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. You would dictate the fact that you're doing an addendum and whatever it was you wanted to say about the ER/PR?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And the tape would go away to be transcribed?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. When it would come back to you, what form would it be?
DR. ELMS:
A. In the same form that you see here on the screen, it would be ask I would expect a clinician to see it.
COFFEY, Q.C.:
Q. So it would be--the full report would be

Page 45

there, the body of the report?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Plus the addendum?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then if you were satisfied, you could enter, go into the computer and apply your electronic signature to the addendum?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then if there was a second addendum, when you dictated that, Addendum No. 1 and the report would show up?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. So whatever way in which they were being entered by whomever was doing the formatting, as it were, at some point it would cross, the paper version of it would cross your desk?
DR. ELMS:

Page 46

A. Yes.
COFFEY, Q.C.:
Q. Because this particular one, Doctor, certainly comports with your account of--you see page 4 there's the electronic signature, yourself, August 24th, 2001, and then the actual body of the report itself, including the pathology interpretation, gross and so on. And we go back and the second page of the exhibit we see Addendum No. 1. This is dated entered September 25th, 2001 at 1000 hours. And it's indicated to be addendum signed, signature on file by yourself, September 26th, 2001. And here's it's written "Immunohistochemical staining is negative for progesterone receptors. The immunohistochemical staining for estrogen receptors has been technically unsatisfactory on two occasions. A repeat attempt will be made and an addendum issued once this investigation has been performed." And this is September, 2001. And then we look up above, we see Addendum No. 2, October 10th, 2001, entered at 922 hours. And then it's written, "Immunohistochemical stains for estrogen and progesterone receptors are

Page 47

negative." Signed electronically by yourself, October 10th, 2001. Doctor, I'm not asking you to remember this particular case, per se, but a reference to here in the first addendum, "has been technically unsatisfactory on two occasions. A repeat attempt will be made." Doctor, can you tell us, please, about in 2001, at least, and perhaps before that, what your experience was with ER and PR slides here in St. John's?
DR. ELMS:
A. On occassion we would have slides that had technical difficulties, and those could be of a number of things. Sometimes there would be wrinkles in the slide, sometimes we would have what's referred to as knife chatter, which is when the--knife chatter, which is when the slide is being cut, the block vibrates against the microtome blade. In some instances tissue was boiling off slides. Those are, in the technical difficulties that I remember, those would be the ones that come to mind.
COFFEY, Q.C.:
Q. Idea of reporting just positive or negative here, this is your recollection of, at least

Page 48

as of the latter, well, two thirds of the way through 2001 you were still using positive and negative?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. At that point. Now, this particular case, Doctor, I have it here, it did end up, it's Addendum No. 4, actually, on the first page of it, indicates that this was, in fact, retested at--sent to Mount Sinai in probably 2006 and was retested and the estrogen and progesterone were reported as zero, zero percent, which had accorded with your record back in 2001. Doctor, these technical problems that you referred to in 2001, had the existed back into your days as a resident?
DR. ELMS:
A. I don't recall that being an issue during my residency.
COFFEY, Q.C.:
Q. Okay. Again now, again, with the benefit of looking at it from 2008 looking back, because you began your residency in 19 -
DR. ELMS:

Page 49

A. '96.
COFFEY, Q.C.:
Q. Six, so just before Dr. Khalifa got involved?
DR. ELMS:
A. Um-hm, yes.
COFFEY, Q.C.:
Q. Locally, with this process. With the benefit now of hindsight, can you think about kind of what changed over time, if anything, that you recall, like, in terms of technical problems and stuff, when you first became aware of them and how things developed?
DR. ELMS:
A. During those days there were periods in which we would have issues with, as I said, a slide in which the tissue had boiled off, for instance, or in which there was knife chatter. It seemed to me to be sporadic.
COFFEY, Q.C.:
Q. That was your -
DR. ELMS:
A. That was my feeling -
COFFEY, Q.C.:
Q. You don't have any real recollection of it during your residency, but certainly this is

Page 50

you're on the staff now for about a year and a half?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Just over a year, anyway, in, like, 2001?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And there were periods then, sporadically, where this would happen?
DR. ELMS:
A. An individual slide here and there.
COFFEY, Q.C.:
Q. Any other problems at the time that you noticed, that you were aware of?
DR. ELMS:
A. No. Those three were the common areas where you'd have a problem if you were going to have a problem.
COFFEY, Q.C.:
Q. And how were those problems addressed?
DR. ELMS:
A. I would--if there was--if I was satisfied that I could assess the slide, if, for instance, I

Page 51

had a small wrinkle on the edge and I was still able to assess the majority of the lesion, then I would accept that. If there was a problem that I felt compromised my interpretation, I'd reorder it and discuss it with the lead technologist at the time, which was Ms. Butler.
COFFEY, Q.C.:
Q. Do you recall having such discussions?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And what do you recall about them?
DR. ELMS:
A. Specifically it was in the context of slides in which the tissue had boiled off the slide, and I would call and discuss it with Ms. Butler and I was told that they were working on the problem, that they recognized it and were working on it to try to solve it.
COFFEY, Q.C.:
Q. Were you ever told what the result of that was?
DR. ELMS:
A. Not specifically.

Page 52

COFFEY, Q.C.:
Q. Of those inquiries, they were working on it?
DR. ELMS:
A. Yeah. No specifically. This was also a sporadic thing. I mean, if I had a problem with one slide, I'd be--it would be awhile before I'd see another slide with the same problem.
COFFEY, Q.C.:
Q. Do you ever recall there being a period or periods when there were problems with a number of slides during like a month or two, that you recall?
DR. ELMS:
A. No, not a prolonged thing with them, a multitude of cases, no.
COFFEY, Q.C.:
Q. Doctor, I'm just here while I'm on the topic, I notice here in Addendum No. 3 there's a reference to this case having been reviewed at the request of Dr. Bob Williams. But I'm just going to ask you, down below there's reference to infiltrating ductal carcinoma.
DR. ELMS:
A. Um-hm.

Page 53

COFFEY, Q.C.:
Q. And we've seen references at times, pathologists use the word "invasive". Is there any difference between infiltrating and invasive?
DR. ELMS:
A. No. I would use them synonymously.
COFFEY, Q.C.:
Q. Synonymously. Doctor, here, Doctor, looking at Addendum 1 on this particular exhibit C-0225, page 2 of the exhibit, when you would dictate this addendum and then sign it out, this particular one, September 26th, 2001, asserting that "has been technically unsatisfactory on two occasions. A repeat attempt will be made." Do you ever recall getting any inquiries from oncologists about this?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Like, expressions of concern or -
DR. ELMS:
A. No.
COFFEY, Q.C.:

Page 54

Q. You're fairly--you're fairly emphatic about that. You'd recall, in fact, if there were such instances?
DR. ELMS:
A. If there were such instances, I'd recall it, I would expect to.
COFFEY, Q.C.:
Q. Were you ever asked by oncologists to do a repeat?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. ER/PR?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall the first such time you were asked to do that?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Do you recall how often you were asked?
DR. ELMS:
A. Rarely.
COFFEY, Q.C.:

Page 55

Q. And do you recall what, if any, the circumstances were, what sorts of things would occassion it?
DR. ELMS:
A. You mean specifically to review the estrogen and progesterone receptor?
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. I know I was asked to repeat them on occassion. There's a couple of instances as a result of the Inquiry that I now can speak to, but to remember overall, no, I don't recall the exact issues.
COFFEY, Q.C.:
Q. Okay. And we'll be speaking about Ms. Deane's case.
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And one or two others. But--because the documents refer to cases at times. But other than those specific instances, again, so the Commissioner have some sense of it, your recollection of how often this would happen,

Page 56

like, in the run of a year how often do you think you might have been asked to repeat ER/PR by an oncologist?
DR. ELMS:
A. Perhaps a couple of times a year. I don't remember it being a prominent occurrence.
COFFEY, Q.C.:
Q. And again, to put this in context, Doctor, in the course of a year, you would report how many cases, not ER/PRs, just how many cases, period?
DR. ELMS:
A. At most 50.
COFFEY, Q.C.:
Q. Fifty a year?
DR. ELMS:
A. At most.
COFFEY, Q.C.:
Q. ER/PR?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. No, but say how many IHC cases would you report a year at -
DR. ELMS:

Page 57

A. IHC cases overall?
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. It's very difficult to say. I'd order, I'd say, probably between a third or more of my cases. Most of what we see is biopsies. It's not all that common to have to do immunohistochemistry on many biopsy cases. So a third, I would say, would be an upper estimate of the numbers that I had to order.
COFFEY, Q.C.:
Q. And how many would you do a year, a third of what? Again, rough figures, how many--I'm just trying to get some sense of -
DR. ELMS:
A. I do, I guess, between 1500 and 2000 cases a year.
COFFEY, Q.C.:
Q. So about a third of them might involve IHC?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And again, I'm not holding you to, obviously, to this, because you're doing this arithmetic,

Page 58

obviously, just thinking about it now. But maybe a couple of times a year you might be asked to repeat an ER/PR by an oncologist?
DR. ELMS:
A. At most.
COFFEY, Q.C.:
Q. At most. How about repeating other types of IHC tests?
DR. ELMS:
A. You mean would I be requested to do it or would -
COFFEY, Q.C.:
Q. Yeah, requested -
DR. ELMS:
A. - I take it upon myself?
COFFEY, Q.C.:
Q. - as opposed to you doing it, taking it upon yourself?
DR. ELMS:
A. I don't recall ever being asked to repeat a test that wasn't ER/PR.
COFFEY, Q.C.:
Q. So what IHC repeats there were for ER/PR -
DR. ELMS:
A. It's not entirely true to say that. I wasn't

Page 59

requested to -
COFFEY, Q.C.:
Q. Oh, requested.
DR. ELMS:
A. - I would occasionally order one myself if I had a technical problem with a particular slide.
COFFEY, Q.C.:
Q. And as an example we just looked at then?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. That would be a repeat?
DR. ELMS:
A. Yeah.
COFFEY, Q.C.:
Q. Doctor, did you ever receive or become aware of any complaints by oncologists about IHC tests?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Or expressions of concern about--by them about, you know, the quality or the results or -

Page 60

DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. In situations where you would be asked to repeat the ER/PR, in those relatively few cases, was it explained to you why that was they wanted it repeated?
DR. ELMS:
A. I don't recall specifically.
COFFEY, Q.C.:
Q. All right. So just from your perspective someone would ask and -
DR. ELMS:
A. Yeah, it--I don't recall being given specific reasons.
COFFEY, Q.C.:
Q. Doctor, in terms of requesting an initial ER/PR case, leaving aside whether it's repeated or not, right, just an initial case, what actually did that involve by you, what did you actually physically have to do?
DR. ELMS:
A. It would involve identifying a tissue block and then I would fill out a requisition form for it. That form up until our labs were

Page 61

consolidated, that form would go up to our lab and the block would be cut in our lab and sent to the Health Sciences. After it was--after services were consolidated the request would be faxed to the Health Sciences and staff at the Health Sciences would then obtain the block and carry out the stain and transfer the stain back to me.

COFFEY, Q.C.:

Q. Transfer the stained slides?

DR. ELMS:

A. The slides, yes.

COFFEY, Q.C.:

Q. And you would examine them and report?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And if a physician or when a physician would ask you to repeat an ER/PR, what would that actually involve then, what would you have to do?

DR. ELMS:

A. It would involve the same process. Usually I would order it on the same block.

COFFEY, Q.C.:

Page 62

Q. Um-hm. Any particular reason for that at the time?

DR. ELMS:

A. No, just that that block was already on site at Health Sciences, in all likelihood, and more accessible.

COFFEY, Q.C.:

Q. And would you have to fill out a requisition form?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-2149? Now, Doctor, these are a whole series of--I take it these are the sorts of requisition forms you've been speaking of?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. The particular wording of ones may have changed from time to time, I take it, as it revised?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Page 63

Q. But if we could look, please, at Exhibit P-2149, page 32? Doctor, this is one filled out in your handwriting?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Is surgical No. SS5577-02. The date is 2002, July, '07, 26. And here circled is estrogen and progesterone receptors?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. So I take it would circle that, fill out the top part of the form and circle this?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. If we look please, at page 38? Doctor, this is the same surgical pathology number. It's on block A. The one we were just looking at is block A, as well. Go back, the date is again the same at the top. But if you go down through this, at the bottom, hysto tech initially is P. Welsh, they completed July 30th, I believe, '02. And then there's an "M. Butler, Please repeat ER/PR August 28th, '02."

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Would this--whose handwriting would that be, do you know?

DR. ELMS:

A. I'm not sure. It doesn't look like mine.

COFFEY, Q.C.:

Q. And so that's, that particular block apparently, the ER/PR got repeated on. If we could go back, if we could just go back, please, to page 32, you'll see that's the same one, the page we just looked at before, it's block A. If you look, please, at, I'm just going to go to page 34, same exhibit. And this is for block SS-5464-02, it's for July 25th, '02, a special procedure request form. It's block J, it's yourself and Dr. Elms, that would be your handwriting, I take it, up there?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Estrogen/progesterone receptors are circled

Page 65

and filled out as P. Welsh, July 30th, '02. Go to page 36 of the same exhibit. That's the same surgical block number, SS-5464-02, July 25, '02, block J, yourself. And this one again is P. Welsh, July 30th, 02, M. Butler, "Please repeat ER/PR, August 28th, '02." If we go back, please--so that appears again to be a repeat?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. One for July 25th, one for July 26th. If we go back, please, to page 35? Actually, I'll go back--sorry. Page 35. This is a special procedure request form SS5481-02, block D. It's yourself. It's dated July 24, 2002. This is your handwriting up here?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Again, estrogen/progesterone receptors are circled. And it's P. Welsh, July 30th, '02. If we go to page 37 of the same exhibit, P-2149, we'll see that's the same surgical number, SS541-02, block D. It's your name.

Page 66

July 24th, '02. Again, this one is P. Welsh, July 30th, '02. M. Butler, "Please repeat ER/PR, August 28th, '02." Doctor, this is in the summer of 2002 and it appears that on three different days you made three different requests for three different patients for ER/PR and three of them ended up getting repeated, at least sometime in August, 2002. Was there anything in particular in the summer of 2002 that you recall about that was problematic?

DR. ELMS:

A. Not that I recall.

COFFEY, Q.C.:

Q. Now, Doctor, at that point in time, this would be the summer of 2002, in examining in ER and PR patients' slides, what would you be looking for?

DR. ELMS:

A. Nuclear positivity and the external control and the amount of tumour that was staining positive.

COFFEY, Q.C.:

Q. The percentage?

DR. ELMS:

Page 67

A. Yes.

COFFEY, Q.C.:

Q. If it was positive, if it was nuclear staining, the percentage?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And in the external control you'd be looking for what?

DR. ELMS:

A. I would be looking for positivity of the stain in the cells, I expected--I expect it would be staining, and no staining or very weak staining, at most, in other tissues, no staining, preferably.

COFFEY, Q.C.:

Q. Sorry?

DR. ELMS:

A. If you have a piece of tissue in which there is tumour or other breast tissue and then other besides breast, ductal tissue, I would expect there to be staining in the ductal tissue, but I wouldn't expect there to be staining in the remainder. So I wouldn't expect, for instance, blood vessel cells to be

Page 68

staining.

COFFEY, Q.C.:

Q. Now at that time were you thinking of internal controls at that point in ER/PR in the summer of 2002?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. In terms of external controls, what would you be looking for in the external controls?

DR. ELMS:

A. If I see breast duct tissue, I would expect that to be staining, if there was breast -

COFFEY, Q.C.:

Q. In the external control slide?

DR. ELMS:

A. - in the external control. If there was tumour, I'd expect the tumour to be staining.

COFFEY, Q.C.:

Q. And staining how?

DR. ELMS:

A. Again, nuclear staining.

COFFEY, Q.C.:

Q. And any particular amount of staining or like percentages, high percentage, low percentage?

Page 69

DR. ELMS:
A. No, I wouldn't be assessing percentages on control.
COFFEY, Q.C.:
Q. Would you be--I appreciate you wouldn't be assessing or making a percentage call, but would you be looking to see if it was strongly stained, moderately stained, weakly stained or would any staining suffice?
DR. ELMS:
A. You want at least moderate staining.
COFFEY, Q.C.:
Q. Now if we look at the same exhibit, P-2149, and look at page 41, now this is immunoperoxidase request form. It's surgical number happens to be SS5754-02. It's for September 9th, 2002. You're the pathologist. Ductal carcinoma is the diagnosis. And this would be your handwriting, I take it, here?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And it's dated completed is September 12th, '02 by Ms. Butler. And it's indicated to be somebody's handwritten "rush" there. But the

Page 70

top of the page says, "ER control weak but working." See that?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you know whose handwriting that is?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, at that point in time, this would be September, 2002, like the middle of '02, June, July, August, September, '02, would you actually see the external control slides?
DR. ELMS:
A. Not necessarily. There was--I can't speak to dates, but there was a period when we were not receiving external controls; the external controls would be reviewed at the Health Sciences before the slides were released.
COFFEY, Q.C.:
Q. And then how would you know that they were being looked at and someone was determining them to be satisfactory, how would that be communicated to you?
DR. ELMS:

Page 71

A. When we get our slides back, we would get a copy of the form that you see there and the technologist's signature would be indicated at the bottom.
COFFEY, Q.C.:
Q. And you understood that to be what?
DR. ELMS:
A. That the controls had been checked.
COFFEY, Q.C.:
Q. And checked by, do you have any understanding about who would have checked them?
DR. ELMS:
A. There were various people, as I remember. I believe at one point Dr. Robb was looking at them. But I was also of the understanding that there were technologists who were reading them.
COFFEY, Q.C.:
Q. Do you recall who gave you that understanding?
DR. ELMS:
A. No, not specifically.
COFFEY, Q.C.:
Q. Do you have any understanding about whether or not technologists were trained to read external control slides for ER/PR?

Page 72

DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Who would be--from your perspective at the time, who would have been responsible for determining whether or not they should be reading them at all?
DR. ELMS:
A. The laboratory director.
COFFEY, Q.C.:
Q. You don't recall who gave you the understanding but certainly at one point you felt or understood that the technologists at the General Hospital were reading the external controls for ER/PR?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And were noting?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. That they were satisfactory?
DR. ELMS:
A. Yes.

Page 73

COFFEY, Q.C.:
Q. Doctor, a reference to "ER control weak but working", now at that time in 2002 what would you have understood that to mean?
DR. ELMS:
A. That the control stain was paler than, or pale, at least, but that it had been assessed as being satisfactory.
COFFEY, Q.C.:
Q. Doctor, would you at the time or did you at the time have any concern that if that was so, that a tumour that was, in fact, positive, patient's tumour that was, in fact, positive but weakly positive, like not very strongly positive for ER, might not stain? Whatever had caused the external control to stain weakly, whatever process, part of the process that caused that to happen might also have a negative influence on the outcome?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. It didn't occur to you at the time?
DR. ELMS:
A. No.

Page 74

COFFEY, Q.C.:
Q. Do you recall whether that was ever discussed amongst the pathologists?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. So from your perspective at the time, I take it, Doctor, it would be fair to say that, look, if the form came back and said the external controls were working, then from your perspective and understanding, that would suffice?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Here when we look at this particular page, there's no reference to the PR control at all?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. So what would you have understood about the PR control?
DR. ELMS:
A. That it had been read as well.
COFFEY, Q.C.:

Page 75

Q. So no reference at all meant--if I have the slides, the patient slides in my hands --
DR. ELMS:
A. I'm assuming that the technologists have read them and rather than not being done, that the PR was not --deemed worthy of comment.
COFFEY, Q.C.:
Q. Doctor, knowing what you do now in 2008 with reference to ER control weak but working, would that cause you concern now?
DR. ELMS:
A. It would certainly make me want to look at the slide and see what they meant by weak.
COFFEY, Q.C.:
Q. Yes, and I'll be discussing more with you now about what you've learned in the intervening time. Again I take it that in the middle of 2002, we looked at those three just a little while ago in July, into August, 2002, and now this one in September, 2002. At the time, did you have any unease or misgivings at all about reporting ER/PR?
DR. ELMS:
A. You mean in general?
COFFEY, Q.C.:

Page 76

Q. Yes.
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And you weren't made aware by anybody else of any?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Exhibit P-2173, please. Doctor, this is a series of immunoperoxidase request forms for 2003, and I'll be taking you to some of them. I'm going to ask you now about Dr. Ejeckam, okay. We understand that he came to St. John's in 2002.
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. When did you first meet him?
DR. ELMS:
A. Upon his arrival.
COFFEY, Q.C.:
Q. And, Doctor, in the summer and fall of 2002, particularly the fall of 2002--I take it in the summer, they would be relatively short,

Page 77

people on holidays, relatively short staffed, but in the fall of 2002, how much or how often would the pathologists at St. Clare's get together with the pathologists at the General Hospital?

DR. ELMS:

A. We got together at our departmental meetings. I'm not sure how frequently they were taking place in the fall of 2002.

COFFEY, Q.C.:

Q. And from time to time, looking back on it now, how often did you get together. I appreciate that in any particular month, you might not know, but generally what has been the practise over the years.

DR. ELMS:

A. Monthly or bi-monthly.

COFFEY, Q.C.:

Q. There would be a meeting, and would it be at one site or the other?

DR. ELMS:

A. Generally at the Health Sciences.

COFFEY, Q.C.:

Q. How long would the meetings run?

DR. ELMS:

Page 78

A. A couple of hours.

COFFEY, Q.C.:

Q. What sorts of things would be discussed?

DR. ELMS:

A. The running of the department, issues to do with training of the residents.

COFFEY, Q.C.:

Q. How about cases or problems with --

DR. ELMS:

A. Not at those meetings, no.

COFFEY, Q.C.:

Q. Were there meetings where cases would be discussed or problems with the technical process?

DR. ELMS:

A. At St. Clare's we have a difficult case round every week in which people have cases that they're not sure about and want to share with their colleagues. We also have a consultation process whereby we can circulate slides through the department, but difficult cases in that way would often be brought to our difficult case rounds at a multi-head microscope where all of us would sit and review specific cases.

Page 79

COFFEY, Q.C.:

Q. And that sort of process, did you ever attend that at the General Hospital?

DR. ELMS:

A. When I was a resident.

COFFEY, Q.C.:

Q. Okay, back in your residency days, but after the residency?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Now, Doctor, here on page five of the Exhibit P-2173, this is SS9015-02, March 18th, '03. In fact, it's a case for Dr. Denic, but ER/PR is requested and there are two signatures, Mr. Green and Ms. Butler, two different dates, March 21st, 2003; April 28, 2003, checked by Dr. Ejeckam. Here at the top, though, it has noted Dr. Elms has ER/PR control. Then page seven of the same exhibit, SS2190-03, March 26th '03, and again this particular one has written on it, "Dr. Elms has ER/PR control" and we can look through it there. I'll just take you to one more, page nine of the Exhibit, SS2345-03, March 31st, '03, "Dr. Elms

Page 80

has ER/PR controls". This sort of reference to you having the controls, what would that be about?

DR. ELMS:

A. By that time the controls were being sent to us. Dr. Ejeckam was checking them and was sending them to us, and they would be put on one of the trays of slides that was being sent back to St. Clare's. There was no specific attempt to send them to me as opposed to anyone else.

COFFEY, Q.C.:

Q. Oh, okay, it just happened at the time that you were the one who had obtained them?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, how were you able then to look at the control slides, ER external control slide and a PR external control slide, and relate it to particular cases?

DR. ELMS:

A. My understanding was that the control that was being done was a batch control, so that you had a batch of ER/PRs being done and one slide

Page 81

of known staining characteristics was included with that batch as a control.

COFFEY, Q.C.:

Q. How were you able to tell, for example, if three different cases came back to St. Clare's?

DR. ELMS:

A. Because that slide was being sent with that batch. I assume that they were all done on the same run.

COFFEY, Q.C.:

Q. Was there anything about the external control slide itself, anything written on it that would lead you to--to play detective, as it were, and go back and relate it?

DR. ELMS:

A. Not at the time.

COFFEY, Q.C.:

Q. At that time, no.

DR. ELMS:

A. Not that I recall, no.

COFFEY, Q.C.:

Q. So if you wanted to actually determine conclusively from your perspective that a particular external control slide was run with

Page 82

a particular patient slide, what would you have to have done?

DR. ELMS:

A. I would have to call the technologist and ask.

COFFEY, Q.C.:

Q. Look at Exhibit P-0113, please. Doctor, this is Dr. Ejeckam's memo of April 4th, 2003, to pathologists at the Health Sciences Centre, St. Clare's, and out of town hospitals. The subject is immunohistochemical stains, and the Commissioner has seen this before. This is the one that reads, "Kindly note that immunohistochemical stains with the following antibodies", and it lists a number of them, the last two are ER and PR, "have remained unreliable, erratic, and, therefore, unhelpful for diagnostic purposes. Consequent on the above, staining with these antibodies will stop forthwith until we can solve their reliability, sensitivity, and specificity", I suspect it should read, "problems. Efforts are underway and hopefully a solution will be found within the next four to six weeks. You will be duly informed when such stains can resume", and it's signed by Dr. Ejeckam and

Page 83

copied to Barry Dyer and all technical staff, Immunohistochemistry. Doctor, when did you first become aware of the subject matter of this?

DR. ELMS:

A. At the point of that memo.

COFFEY, Q.C.:

Q. So before that, were you alerted at all to any problems or concerns about ER/PR stains, or the other six stains for that matter?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Or IHC stains generally?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. And when you received this, did you discuss it with anybody at the time, do you recall?

DR. ELMS:

A. Not that I recall.

COFFEY, Q.C.:

Q. Did you ask any questions of anybody, what's this all about?

DR. ELMS:

Page 84

A. No.

COFFEY, Q.C.:

Q. At the time you would have been at St. Clare's, that would be April, 2003.

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. How many pathologists would there have been at St. Clare's at the time, do you think?

DR. ELMS:

A. Six.

COFFEY, Q.C.:

Q. Including yourself?

DR. ELMS:

A. Including myself.

COFFEY, Q.C.:

Q. Dr. Cook would be the site chief?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. He was also the clinical chief?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Dr. Denic?

Page 85

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Who else, do you recall?
DR. ELMS:
A. Dr. Cook, Dr. Denic, myself, Dr. Vaze, I believe Dr. Gorechi was there at the time, and Dr. Wadwa.
THE COMMISSIONER:
Q. Excuse me, Mr. Coffey. Do I take it, Dr. Elms, from your answer to Mr. Coffey's question that when you received this memo, up until that point you had no reason to believe, as Dr. Ejeckam has said, that the stains were unreliable and erratic?
DR. ELMS:
A. That's correct.
THE COMMISSIONER:
Q. So nothing in your practise had led you to that conclusion?
DR. ELMS:
A. That's correct.
COFFEY, Q.C.:
Q. No discussion amongst the pathologists that you recall about that?

Page 86

DR. ELMS:
A. Not that I recall. We have a very collegial environment at St. Clare's. I'm sure there must have been some sort of discussion, but nothing that I recall specifically.
COFFEY, Q.C.:
Q. Now these other stains referred to as CK34, CD3, CD5, CD20, CD79, and CEA, in relation to them, upon being told that they were unreliable, erratic, unhelpful, had you been using those stains or would you have been using those stains?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Before that?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. So to be told that presumably they're so unreliable that he's shutting down the processing for a while, you at the time had no concerns, though, about it?
DR. ELMS:
A. Not--no, no. Each of those stains is used as a part of a panel of investigating a tumour.
COFFEY, Q.C.:
Q. And what significance, if any, would that have?
DR. ELMS:
A. For instance--well, let's look, for instance, at the Cds. These are all stains that are used in the investigation of lymphoma. CD3 and CD5 are T cell markers. We do use other T cell markers besides those. CD20 and CD 79A are B cell markers and again we use others. Lymphoma is also assessed by means of another process called flocytometry, and in some instances those same antibodies would be looked at. In other cases, there would be other specific antibodies done on the flocytometry.
COFFEY, Q.C.:
Q. That's the lymphomas?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The other --
DR. ELMS:
A. The CEA again is a epithelial marker and it's

Page 87

Page 88

used as one of a battery of epithelial markers, so that if I was looking at a tumour, I wouldn't rely solely on my CEA, and the same occurs with the 34 BE12.
COFFEY, Q.C.:
Q. If, though, the CEA or the CK34, if it's part of a battery, at times presumably it could be the swing vote, as it were, on the battery? Do you understand what I'm talking about?
DR. ELMS:
A. I understand what you're saying. No, I wouldn't say it would be a swing vote. It's one part of a series of components used in the assessment of a case.
COFFEY, Q.C.:
Q. Now with respect to the six stains, other than ER/PR, do you know what, if anything, happened in relation to that?
DR. ELMS:
A. My understanding was that the problem was corrected and the staining was brought back on line.
COFFEY, Q.C.:
Q. Do you recall who advised you of that, and how you became aware of it?

Page 89

DR. ELMS:
A. Not off the top of my head. I would assume it was Dr. Ejeckam.
COFFEY, Q.C.:
Q. And ER and PR, what about them? They're not part of a battery of tests, I take it?
DR. ELMS:
A. No, they're not. However, Dr. Ejeckam was looking into the situation, so I assume that he had the situation under control.
COFFEY, Q.C.:
Q. So, Doctor, at the time, do you recall any discussion at all about this subject matter amongst the pathologists at St. Clare's?
DR. ELMS:
A. Not that I recall.
COFFEY, Q.C.:
Q. Page two of the Exhibit is a memo of May 2nd, 2003, from Dr. Ejeckam. Again it's to the same group of pathologists, and the subject matter is ER/PR immunohistochemical stains, and he informs all of you that he had rectified the difficulties and you can now resume regular requests for these antibody stains. "I will, however, like to bring the

Page 90

following information to your attention", and he goes on at some length about aspects of the ER/PR staining process. Do you recall receiving this?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall whether there was any discussion by you with anybody or anything you overheard by others involving this memo, any talk about this?
DR. ELMS:
A. I don't recall specific discussions.
COFFEY, Q.C.:
Q. How about generally?
DR. ELMS:
A. Generally, yes, I would think we talked about it.
COFFEY, Q.C.:
Q. And in what context, do you recall?
DR. ELMS:
A. That the staining had been problematic and was now resolved and that there were issues in the memo that we should pay attention to.
COFFEY, Q.C.:

Page 91

Q. What sorts of issues were they?
DR. ELMS:
A. Well, the kinds of issues you just mentioned to do with fixation and the various other elements of the report, the stuff that he's bringing to our attention.
COFFEY, Q.C.:
Q. And do you recall--what, if anything, do you recall was actually done, that you were made aware of was being done to actually address, for example, the fixation issues?
DR. ELMS:
A. I don't recall anything being done from that. I read that there was a caution that these things can be a problem, but I don't take from that that there was identified specifically a problem.
COFFEY, Q.C.:
Q. So as far as you knew or were aware, having received this memo, at least at St. Clare's as far as you knew, other than read the memo and discuss it in a general manner?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:

Page 92

Q. No actual steps taken?
DR. ELMS:
A. Not that I was made aware of, not that I recall in any event.
COFFEY, Q.C.:
Q. Paragraph three on the second page of the memo refers to internal controls. Is this the first time that you had become aware of this in the context of the ER/PR?
DR. ELMS:
A. I would think yes, yes, it was around that time I became aware of it.
COFFEY, Q.C.:
Q. And what, if anything, did that cause you to do?
DR. ELMS:
A. It caused me to look at the internal controls, as he says there, as a second level control.
COFFEY, Q.C.:
Q. And for what purpose then, what process did you -- you hadn't been going through that process before because you hadn't been aware of the necessity, but beginning at this point in time, what would you do then?
DR. ELMS:

Page 93

A. Again as a second level control, I would either have seen the control, the external control myself or had been made aware that it had been checked, and then in the course of examining my slide, I would look at it to see if there was staining in normal duct tissue.

COFFEY, Q.C.:

Q. And if there wasn't?

DR. ELMS:

A. If there wasn't, it would be a concern certainly, but there are cases in which normal ducts can be negative, so one case like that would not spur my attention.

COFFEY, Q.C.:

Q. If the--the tumour, I take it, stained?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And the normal tissue didn't stain, you'd be somewhat comfortable with that?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. With the tumour staining, anyway, with the external control staining?

Page 94

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. If the external control stained, but the tumour didn't stain, and the normal tissue didn't stain, would you have a concern?

DR. ELMS:

A. In an isolated instance, it would be something to bear in mind, but I wouldn't look at an isolated instance as being significant enough to negate the case.

COFFEY, Q.C.:

Q. Would you make any note on the reports or report you did?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Did you ever make any inquiries, do you recall?

DR. ELMS:

A. I don't recall having had an opportunity to.

COFFEY, Q.C.:

Q. Doctor, with reference to paragraph five to the reporting of ER/PR, and there's different percentages you'll see; five, ten, and one

Page 95

percent, and this consensus statement of November 1st to the 3rd, 2002, National Institute of Health. Now by May of 2003, what was your practise in terms of reporting ER and PR?

DR. ELMS:

A. As a general rule, to report percentages.

COFFEY, Q.C.:

Q. Did you have any understanding as to what the cutoff, as it were, was for positivity?

DR. ELMS:

A. That there was a debate that overall my assumption was that 10 percent was being considered as a cutoff, however, I was also aware that on the horizon was, as you see in number three there, the idea that 1 percent might well be a cutoff.

COFFEY, Q.C.:

Q. Do you recall any particular debate, for example, or discussion with the oncologist about this?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. So any discussion that did occur would have

Page 96

been within the pathology circles?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. If at the time you were reporting simply something as positive or negative for 2002/2003, if you reported something as negative, what was the cutoff you were using at the time yourself?

DR. ELMS:

A. In that instance, I would be--that would be negative, I would see no staining.

COFFEY, Q.C.:

Q. So you had gone to the percentage yourself?

DR. ELMS:

A. Yes, in general.

COFFEY, Q.C.:

Q. By that point, and if, however, you didn't use a percentage in that time period, if we examined all the cases you reported, and you used the word negative?

DR. ELMS:

A. That meant no staining.

COFFEY, Q.C.:

Q. No staining. The 10 percent wouldn't have

Page 97

figured into your calculation?
DR. ELMS:
A. No, no.
COFFEY, Q.C.:
Q. Unlike back in your early days when you would actually do the arithmetic in your head and if it was under 30, it was --
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. It was determined negative. Doctor, paragraph seven is ER positive tumours, and got a list of them there, and Dr. Ejeckam has, in fact, told us that lobular should have been included in that list.
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. Before receiving this memo in May of 2003, were you aware that certain types of breast tumours would tend to be statistically ER positive?
DR. ELMS:
A. No.
COFFEY, Q.C.:

Page 98

Q. You weren't--did you make any inquiries yourself at that time, having received this memo, as to how often, what percentages one might expect positivity in?
DR. ELMS:
A. You mean to look at actual numbers of how many tubulars I'd expect?
COFFEY, Q.C.:
Q. Sure.
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Having received this, did that information then have any influence upon your approach to looking at the slides?
DR. ELMS:
A. It was a piece of information that I would keep in my mind. I don't see many tubular carcinomas, or papillaries for that matter, but it was certainly information that I would have been aware of.
COFFEY, Q.C.:
Q. And then were you aware or had you been aware--I take it you hadn't been aware then, I take it, that lobular invasive ER negative tumours

Page 99

could be relatively unusual?
DR. ELMS:
A. I hadn't been up to this point, no.
COFFEY, Q.C.:
Q. You had not been?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Up to this point. In fact, it's not mentioned here, so even having read this, you wouldn't have been aware of that.
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And you didn't go and look further?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. When did you first become aware that lobular invasives --
DR. ELMS:
A. Lobular invasive? I believe it was around when Dr. Carter started with us.
COFFEY, Q.C.:
Q. Do you recall what year that was?

Page 100

DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. I take it whenever she showed up, I take it on the permanent staff at St. Clare's?
DR. ELMS:
A. Yes, yeah, exactly.
COFFEY, Q.C.:
Q. You would have become aware of that. In what context then would you have become aware of it?
DR. ELMS:
A. Just in informal discussions with Dr. Carter. When she came as a breast pathologist, she was very interested in our breast service, and we all saw her as a source of information. So in informal discussions with Dr. Carter, subjects like this would come up.
COFFEY, Q.C.:
Q. I take it before she arrived on the staff, there was no one there who you would think of as a breast pathologist in the way you did her?
DR. ELMS:
A. No, there wasn't.

Page 101

COFFEY, Q.C.:
Q. Had there been anyone during your time in St. John's in the General Hospital site, or the Grace, for that matter, whom you would have thought of as a breast pathologist?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, before I go to the June 19, 2003, memo from Dr. Ejeckam to Mr. Gulliver at page five of P-0113, just on the issue of specialization which breast pathology is on my mind, during your residency and then in the first--in the years since really, in terms of specialization amongst pathologists in St. John's, how many pathologists would you describe as being specialized?
DR. ELMS:
A. Dr. Robb had an interest in lymphoma and molecular genetics. I know Dr. Wadden had a special interest in dermapathology, but in terms of people who were actually sub-specialized pathologists, Dr. Khalifa had a sub-specialty in gynepathology, but none functioned specifically as that. We were all

Page 102

general pathologists, so to speak, in terms of our assessment of cases.
COFFEY, Q.C.:
Q. I take it some pathologists, though, would do a particular type of work more than others would?
DR. ELMS:
A. Would have a greater interest in it. They certainly wouldn't-- their case loads would not reflect that. They would still receive cases the way all of us did. However, if, for instance, I had a problem with a skin case, I would be more inclined to ask Dr. Wadden's opinion.
COFFEY, Q.C.:
Q. Okay. During your period in St. John's as a pathologist dating back to your residency days and continuing on, do you ever recall any effort or efforts throughout that time period, now more than a decade, to move towards specialization?
DR. ELMS:
A. It was --
COFFEY, Q.C.:
Q. Or sub-specialization.

Page 103

DR. ELMS:
A. It was discussed and considered. Most of my time, the atmosphere that I understand it was about getting people, rather than getting specific people.
COFFEY, Q.C.:
Q. I take it there just wasn't sufficient personnel?
DR. ELMS:
A. There wasn't sufficient-- yeah, it was of that nature.
COFFEY, Q.C.:
Q. After Dr. Carter arrived, we're aware--we've seen a document where there's a reference to Dr. Fontaine having raised at the General Hospital the idea of her looking at all ER/PR slides?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Did that ever come up at St. Clare's, do you know?
DR. ELMS:
A. I remember there was discussion about her sub-specializing in breast and what form that

Page 104

would take. It wasn't--as I remember, it wasn't considered feasible for her to just solely see breast cases, but I remember there being discussion as to how her expertise would be utilized.
COFFEY, Q.C.:
Q. And the discussion, did it get any further than being talked about, do you recall? I appreciate in '05 onward, we'll come to that.
DR. ELMS:
A. At the time, I'm not sure. I know she was receiving consultations from outside the city.
COFFEY, Q.C.:
Q. The idea that she might, even without reporting them, look at all ER/PR slides, do you recall that ever being raised with you?
DR. ELMS:
A. I don't recall that.
COFFEY, Q.C.:
Q. In that case, she would have ended up looking at some of your slides in that context if that had happened.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:

Page 105

Q. You don't recall that ever being raised?
DR. ELMS:
A. I don't recall, no.
COFFEY, Q.C.:
Q. Looking at the June 19, 2003, memo of Dr. Ejeckam to Mr. Gulliver, this is not addressed to yourself.
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. It's to Mr. Gulliver. It's on the-- the last page of the memo, it's copied to Dr. Robb, Dr. Cook, Dr. Parai, and Barry Dyer. Could you tell me, please, Doctor, were you made aware of the existence of this memo in 2003?
DR. ELMS:
A. Not that I remember, no.
COFFEY, Q.C.:
Q. You've seen it since, I take it, the subject matter, this is one where Dr. Ejeckam, he concludes the first paragraph by saying, "Despite the fact that the problem seems to have been arrested, which is the erratic results of immunostains, the state of immunostaining at the General Hospital,

Page 106

Department of Laboratory Medicine and Pathology, is still unsatisfactory".
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And he goes on at some length about that?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Okay. In fact, the end of paragraph three on the second page of the memo, he says, "To do less would simply become a gamble where you may win or lose. This, obviously, will spell disaster".
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. And the memo is written with that sort of tone at times in it. Do you recall the concerns or the nature of these concerns about the future of immunohistochemistry being discussed in 2003?
DR. ELMS:
A. I wasn't involved in discussions that I recall.

Page 107

COFFEY, Q.C.:
Q. You didn't become --
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Like, over at St. Clare's sitting around at times --
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Having a chat about --
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Ejeckam's concerns.
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Okay. Doctor, here when we look at the last page of this, we see it's copied to Dr. Cook as clinical chief, and site chief, St. Clare's, Dr. Parai as the site chief, and Barry Dyer, the manager of histopathology. IHC, from your perspective being a staff pathologist at St. Clare's at the time, June,

Page 108

2003, who would you have seen a responsible for IHC?
DR. ELMS:
A. Dr. Ejeckam.
COFFEY, Q.C.:
Q. Was your-- when would he first then, from your perspective, have become responsible for it?
DR. ELMS:
A. I'm not sure as to the exact date when he became the one with oversight of the immunohistochemistry procedures.
COFFEY, Q.C.:
Q. Do you recall who first advised you of that?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And the manner in which you first became aware of that --
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. He was the go to person, as it were?
DR. ELMS:
A. Yes, I'm not sure when that occurred.
COFFEY, Q.C.:

Page 109

Q. Did you ever have occasion to speak to Dr. Ejeckam about--you know, in 2002, 2003, 2004, about a particular problem or problems with IHC yourself?
DR. ELMS:
A. Not that I recall.
COFFEY, Q.C.:
Q. So then, Doctor, after the suspension of the ER/PR testing in 2003 and its resumption of the same effectively a month later, your own practise then would have changed in the context of you looking for internal control?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In terms of looking for staining in that, and anything else?
DR. ELMS:
A. I would have been more conscious of the issues that he discussed.
COFFEY, Q.C.:
Q. Particularly --
DR. ELMS:
A. That he brought to our attention.
COFFEY, Q.C.:

Page 110

Q. The fixation issue?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Related issues, and processing issues. In terms of oversight then for ER/PR from that point on, did you have any understanding about anyone who was responsible for it in a general way?
DR. ELMS:
A. In a general way, I knew that Dr. Ejeckam was the physician with oversight, and I assumed as well that our laboratory manager was also involved in the process and that it was a shared oversight between the two of them.
COFFEY, Q.C.:
Q. And the manager here is?
DR. ELMS:
A. Mr. Dyer--well, Mr. Dyer and Mr. Gulliver.
COFFEY, Q.C.:
Q. Exhibit P-2173, please, page 11, please. Doctor, this is immunoperoxidase request form, SS2033-03, March 19th, 2003. The pathologist is yourself and --
DR. ELMS:

Page 111

A. Chai. That's one of our residents.
COFFEY, Q.C.:
Q. Resident, and this would be an example of, I take it, a resident being involved?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In the process, and this then--your handwriting here?
DR. ELMS:
A. No, that would be Chai's.
COFFEY, Q.C.:
Q. The resident.
DR. ELMS:
A. The resident's, yes.
COFFEY, Q.C.:
Q. So March 19th, 2003, it would have been--the ER/PR was ordered, we see that here, and then date completed, April 28th '03, M. Butler, checked by Dr. Ejeckam. In this context, "checked by Dr. Ejeckam" would have been interpreted by you as what?
DR. ELMS:
A. That he had reviewed the controls.
COFFEY, Q.C.:

Page 112

Q. Page 15 of the same exhibit is surgical number SS8560-02. It's March 12, '03. See here?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. This would be your handwriting?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Blocks B and --
DR. ELMS:
A. E.
COFFEY, Q.C.:
Q. E, Elms, ER/PR testing, signed by Ms. Butler, May 2nd '03, checked by Dr. Ejeckam. I take it the same significance?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In other words, checked by him. Here, Doctor, this seemingly spans the time that the suspension occurred. This would be March 12th '03 would be when it was ordered, see that?
DR. ELMS:
A. Uh-hm.

Page 113

COFFEY, Q.C.:
Q. It's reported May 2nd '03.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And April 4th '03 is the date that memo --
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Announcing the suspension of ER/PR testing was sent around. Was there any particular--I'll just bring you to one other one, page 22 of the same exhibit. It's SS1549-03, and the date is 03/03, hard to tell what the final figure is, March, 2003. It's your handwriting, isn't it?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Block 3E, ER/PR, and M. Butler, May 2nd '03, checked by Dr. Ejeckam.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. So, Doctor, during the time period that the

Page 114

testing was suspended, you apparently had some ER/PR cases outstanding or being done?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Was there anything in particular done at that time frame when these cases came back or finally reported, were they handled in any particular way, do you recall?
DR. ELMS:
A. Not that I --
COFFEY, Q.C.:
Q. Having received the memos.
DR. ELMS:
A. Not that I recall. I mean, I received things, checked by Dr. Ejeckam.
COFFEY, Q.C.:
Q. Now in the same exhibit, P-2173, if we could go, please, to page 56. This is immunoperoxidase request form, SS5231-02, it's Block 6C. The pathologist is indicated to be yourself. It's dated May 23rd '03, and the block itself is an '02 block, and written here is "Repeat" ER/PR, requested by Dr. Zaidi, and ER/PR is the test, M. Butler, May 29th, '03.

Page 115

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall what this was about?
DR. ELMS:
A. I know I had been requested to repeat the test by Dr. Zaidi. As to why, I'm not sure.
COFFEY, Q.C.:
Q. Would you have made any inquiries at the time, do you recall?
DR. ELMS:
A. I would assume, yes. I mean, he would have either called or sent a requisition asking for it, and if I talked to him on the phone, I'm sure I asked what the problem was originally, but I don't recall this particular case specifically.
THE COMMISSIONER:
Q. Mr. Coffey, wherever you can find an appropriate place to take the morning break.
COFFEY, Q.C.:
Q. That'll be fine, Commissioner, right now, thank you.
THE COMMISSIONER:
COFFEY, Q.C.:

Page 116

Q. Take fifteen minutes.
(RECESS)
THE COMMISSIONER:
Q. Mr. Coffey.
CROSBIE, Q.C.:
Q. Commissioner, I'd like to introduce Laura Brocklehurst from my office. She'll be here off and on over the next few weeks.
THE COMMISSIONER:
Q. Thank you, Mr. Crosbie. Welcome, Ms. Brocklehurst.
MS. BROCKLEHURST:
Q. Thank you.
COFFEY, Q.C.:
Q. Bring up, Registrar, please, Exhibit P-2407, page 72, please. Doctor, this is a surgical pathology #5903-01. The date would be 2001, probably September 24th, it's hard to know. Looking down below, the date is at the bottom right hand side of that page indicates it probably is September 24th, 09/24. It's Block 1E. The pathologist is indicated to be F. Elms, and do you recognize the handwriting?
DR. ELMS:
A. That's mine.

Page 117

COFFEY, Q.C.:
Q. And here under comments-- well, first of all, M. Butler, date completed, September 28th '01, and then M. Butler, October 4th '01, Dr. K. Laurence is referred to, and it's written here, "Please repeat ER again, stain totally negative in non-neoplastic breast tissue".
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Whose handwriting is this?
DR. ELMS:
A. That's mine.
COFFEY, Q.C.:
Q. What would this be referring to?
DR. ELMS:
A. I had--I had a case in which I obviously had a problem and felt that the negative staining was not acceptable.
COFFEY, Q.C.:
Q. So non-neoplastic breast tissue --
DR. ELMS:
A. That would be normal breast tissue.
COFFEY, Q.C.:
Q. And suggesting that you had concerns about it

Page 118

being normal breast tissue?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Normal in the sense of not cancerous?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Being totally negative?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And why would you have been concerned about that at the time?
DR. ELMS:
A. I would have to see the slide to be able to say what it was that specifically tweaked me to that one.
COFFEY, Q.C.:
Q. Because at that time, and again this would be September/October, 2001, you have indicated you weren't in particular looking to see whether internal controls were staining or not?
DR. ELMS:

Page 119

A. Not formally, no.
COFFEY, Q.C.:
Q. Not formally. Formally, in the sense of, I take it, just not doing it in the sense of kind of every case like you would now --
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. If you were doing it now, you'd --
DR. ELMS:
A. Just not doing it every case, exactly.
COFFEY, Q.C.:
Q. But at that time, I mean, in relation to this particular case, anyway, something must have caused you to --
DR. ELMS:
A. For some reason, it must have stood out, yes.
COFFEY, Q.C.:
Q. But you can't recall now why in particular this was?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Have you made any effort to ascertain why it was?

Page 120

DR. ELMS:
A. I beg your pardon?
COFFEY, Q.C.:
Q. Have you made any effort since to ascertain, like, knowing that you were going to be coming and testifying?
DR. ELMS:
A. I didn't know about this particular case.
COFFEY, Q.C.:
Q. Oh! If we could look, please, at Exhibit P-2302. Doctor, this is a Physician Services Liaison Committee minutes of March 15th, 2005. It's a record of decisions, it's styled. There are a number in attendance. You're listed as one of the guests, yourself, Dr. Denic, Dr. Fontaine, and Dr. Jenkins by phone, and Juanita Barrett. There's paragraph four, presentation discussion relating to pathology issues?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Nash Denic, Dan Fontaine, Ford Elms, provided issues aging workforce, retirements, recruitment and retention. L. Bryant to

Page 121

forward a copy of the presentation from the co-chairs to the medical directors in medicine for review and feedback?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Do you recall, Doctor, what this was about? This would be the spring, March of '05--well, winter of 2005, actually.

DR. ELMS:

A. This was one phase of a period when we were attempting to bring to government issues of concerns that we had with regard to recruitment and retention of pathologists. At the time, we were the lowest paid in the country, and it had been difficult for quite some time to--not so much to recruit people, but certainly to retain them, and whatever difficulties that were there in recruitment were magnified by the difficulties in retention, and we had gone through various routes through the NLMA. I had earlier to this been on the Salaried Physician's Negotiating Committee, and the issue was one that the committee had been putting forward to

Page 122

government in negotiations. This was an attempt to clarify the issue for various parties involved, and if you go back to the attendees, you've got members from the Department of Health and Community Services, Dr. Jenkins specifically is a Medical Director in Corner Brook, so we were trying to impress upon the various governing bodies that this was an issue, and we were warning that in the near future there would be a crunch in pathology manpower.

COFFEY, Q.C.:

Q. And has that come to fruition?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. You were doing so--this is a presentation of March 15, 2005, so I take it that this was not the first time that this had been voiced?

DR. ELMS:

A. No, it wasn't.

COFFEY, Q.C.:

Q. It was recognized that it was going to be a problem?

DR. ELMS:

Page 123

A. Yes.

COFFEY, Q.C.:

Q. There were concerns expressed about it increasingly as time went on?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And finally there have been problems.

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. This is, in fact--as it turns out, I take it, this is actually a month before--I won't say to the day, but pretty well a month before Peggy Dean's case was identified?

DR. ELMS:

A. Somewhere in that vicinity.

COFFEY, Q.C.:

Q. We'll see that in a moment. Exhibit C-0173, please. Doctor, this is a special procedure request form. This is one of those immunohistochemistry forms. This particular one is for SS4884-02. It's dated June 26th, 2002. Block--what would that have been?

DR. ELMS:

Page 124

A. Block X and Block AA.

COFFEY, Q.C.:

Q. Block X and AA, and the patient's name is Margaret Dean, the pathologist, and it's lobular carcinoma. I take it that this is your handwriting?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. The request is for ER and PR?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And it's indicated to be date completed by P. Welsh, July 4th '02?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. If we could look, please, at Exhibit C-0156. These are some pathology reports for Ms. Deane's case. In particular, Doctor, if you could look, please, at page two. First of all, go back to page one, I'm sorry. It's for specimen #02 SS484, which would be the same number we just looked at on the requisition

Page 125

form?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And it's indicated to be received June 21st '02. Doctor, the significance of that is what, what does that mean in this context here?
DR. ELMS:
A. What do you mean, the --
COFFEY, Q.C.:
Q. Received that date.
DR. ELMS:
A. That is the date that the specimen was received in the laboratory.
COFFEY, Q.C.:
Q. And here there's a comment, "Case was verbally discussed by phone with Dr. David Pace, Wednesday, June 26th, 2002, at 4:15 p.m". I take it that that would be some note that you would have made at the time?
DR. ELMS:
A. Yes, some discussion that I would have had with Dr. Pace.
COFFEY, Q.C.:
Q. Just to record that, in fact, you had talked

Page 126

to him about it?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Okay. If we go to the second page of the exhibit, pathological interpretation, and you have an interpretation here. Doctor, here under "Mass right breast, excisional biopsy", you've got "invasive lobular carcinoma".
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Widespread lobular carcinoma in situ.
DR. ELMS:
A. In situ.
COFFEY, Q.C.:
Q. And you go on from there, and you finally note by saying, "Please see tumour summary", which is, I take it, the detailed --
DR. ELMS:
A. The detailed --
COFFEY, Q.C.:
Q. Analysis.
DR. ELMS:
A. List you see just below it.

Page 127

COFFEY, Q.C.:
Q. Sure, and here, Doctor, overall, I take it, this was characterized by yourself as an infiltrating lobular carcinoma?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then Addendum #1, and above that on the page, it's indicated to be entered July 8th, 2002, and signed electronically on July 10th '02 by yourself, immunohistochemical staining for estrogen and progesterone receptors shows weak staining for progesterone receptors in less than 10 percent of lesional cells, negative staining for estrogen receptors.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then, Doctor, above that, Addendum 2, which is entered August 21st '02, and signed out the same day when we look at the next page, there's a HER2/neu status?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:

Page 128

Q. So, Doctor, I take it then that in 2002, at least in respect of that surgical specimen number, SS484, you would have looked at it for diagnosis purposes?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Pathological interpretation, and recorded your observations, ordered the ER/PR test, and reported it?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. As indicated here in Addendum #1, and then later the same summer, reported the HER2/neu?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, can you tell us, please, after that when you next recall hearing about Peggy Deane or being involved?
DR. ELMS:
A. It was when I was contacted to repeat her estrogen receptor.
COFFEY, Q.C.:

Page 129

Q. And that would be in 2005 as we'll see in a moment. Do you recall who contacted you?
DR. ELMS:
A. I believe it was Dr. McCarthy or Dr. Laing.
COFFEY, Q.C.:
Q. And do you recall the circumstances?
DR. ELMS:
A. At that point, Ms. Deane had had several courses of chemotherapy and the oncologists were concerned-- just to be sure, just to leave on stone unturned, Ms. Deane was a young woman with young children, and having gone through several courses of chemotherapy, they were considering that there was very little else that could be done, and they wanted to, as I say, make sure there was no stone unturned and that there was no possibility they could give the woman Tamoxifen at that point.
COFFEY, Q.C.:
Q. That was the way it was explained to you?
DR. ELMS:
A. That was the way it was explained to me.
COFFEY, Q.C.:
Q. Was there any discussion about invasive

Page 130

lobular and whether it should or shouldn't be positive or negative at that time?
DR. ELMS:
A. Not on my first contact that I recall, no.
COFFEY, Q.C.:
Q. So you had a contact, and it was your first contact that caused you to do the retest?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. So you got this explanation, we'd like you to check again?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. If you would.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. So what did you do?
DR. ELMS:
A. I reviewed the case to identify an appropriate block and then ordered the estrogen and progesterone receptor testing.
COFFEY, Q.C.:

Page 131

Q. And then what happened, Doctor?
DR. ELMS:
A. I got the slide back and it was positive. So I immediately telephoned, again I believe it was Dr. Rorke at that time to let him know the result while I had the slide on my stage. I knew they were waiting for it and I knew the significance of it. So I called him right away to let him know.
COFFEY, Q.C.:
Q. And why Dr. Rorke, do you recall?
DR. ELMS:
A. I believe his name had been given to me, that Dr. McCarthy was to be out of town or something of that nature. It was a--I was told he would be the one to call.
COFFEY, Q.C.:
Q. And so while you still had it there, as you say, on your stage, on the microscope in fact?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. You called Dr. Rorke?
DR. ELMS:
A. Yes.

Page 132

COFFEY, Q.C.:
Q. And told him what?
DR. ELMS:
A. That this woman's repeat test was positive.
COFFEY, Q.C.:
Q. And did he say anything at the time?
DR. ELMS:
A. I recall expressing a certain amount of relief that now at least there was something that they could do for this woman.
COFFEY, Q.C.:
Q. And was that you expressed that or him or both?
DR. ELMS:
A. Him, and myself as well. It was the--but he was the one who said "we can now look at giving Ms. Deane Tamoxifen."
COFFEY, Q.C.:
Q. And okay then, then what happened, Doctor, in terms of Ms. Deane, in terms of your involvement?
DR. ELMS:
A. That was the end of my involvement.
COFFEY, Q.C.:
Q. Did you speak to anyone else about it at that

Page 133

time?
DR. ELMS:
A. I don't recall. I may have spoken to Dr. McCarthy a couple of days later, but I don't recall that for sure.
COFFEY, Q.C.:
Q. How about any other pathologists?
DR. ELMS:
A. I then went to my supervisor, Dr. Cook, and informed him that this situation had occurred.
COFFEY, Q.C.:
Q. And what did you tell him had happened?
DR. ELMS:
A. That an isolated estrogen receptor case had been originally reported negative, stained negative, and was now staining positive, and that this might result in a complaint on this particular case.
COFFEY, Q.C.:
Q. And why did you--why might it result in a complaint?
DR. ELMS:
A. Well, Ms. Deane had originally been told she was negative and had now been through several courses of chemotherapy and now our test was

Page 134

coming up positive.
COFFEY, Q.C.:
Q. Doctor, do you recall how long it was between the time you first looked at the new slide, the new ER and PR slides and phoned Dr. Rorke, I appreciate you got Dr. Rorke on the phone right away -
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. - how long passed before you told Dr. Cook about this?
DR. ELMS:
A. It was within 24 hours. If I remember correctly, it was the same afternoon.
COFFEY, Q.C.:
Q. And why were you concerned to tell him right away?
DR. ELMS:
A. Because he was site chief and I believe at the time he may have been clinical chief, and I felt he needed to know.
COFFEY, Q.C.:
Q. Doctor, at the time, was there any adverse event form or anything similar to that filled

Page 135

out in relation to this?
DR. ELMS:
A. I don't recall.
COFFEY, Q.C.:
Q. Okay. I take it, it didn't cross your mind at the time to do that?
DR. ELMS:
A. Not at the time.
COFFEY, Q.C.:
Q. When you spoke to Dr. Cook about it, what was his reaction?
DR. ELMS:
A. He appreciated letting me know. I mean, if he was going--if a patient was going to call him to discuss the issue, it would be important for him to know what the issue was, so he was appreciative that I had brought it to his attention.
COFFEY, Q.C.:
Q. Now had you known who Ms. Deane was before? Did you know her otherwise then?
DR. ELMS:
A. Not outside. I knew who she was, by virtue of her name and having gone through the medical system here in terms of training, but I'd

Page 136

never spoken to her.
COFFEY, Q.C.:
Q. So you didn't know her in a personal way at all?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And Doctor, did you speak then to--well, you'd spoken to Dr. Rorke and Dr. Cook, I believe that same day, certainly Dr. Rorke that day and Dr. Cook within, if not that day, certainly early the next?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Within 24 hours, Dr. Cook to tell him about it, and you may have spoken to Dr. McCarthy or Dr. Laing within a couple of days?
DR. ELMS:
A. Within a couple of days, yeah.
COFFEY, Q.C.:
Q. Can't really recall. Doctor, you've indicated that the first time you spoke with, whether it was Dr. McCarthy or Laing asked you about the retesting or doing the retesting, that the

Page 137

invasive lobular aspect of the matter didn't come up at that time?

DR. ELMS:

A. At that time, that I recall.

COFFEY, Q.C.:

Q. Yes. But how about afterward?

DR. ELMS:

A. Yes, in--as I said, I recall speaking to either Dr. McCarthy or Dr. Laing subsequently and yes, then I was informed that it had been reviewed and they were somewhat surprised that a lobular had been negative.

COFFEY, Q.C.:

Q. They were?

DR. ELMS:

A. Yes, the people who did the review.

COFFEY, Q.C.:

Q. Okay, so they--what were you told about the review?

DR. ELMS:

A. That it had been seen, I believe, at the Mayo Clinic and that they had agreed that it was a lobular and that they were--they had expected that a lobular carcinoma would likely be positive.

Page 138

COFFEY, Q.C.:

Q. Now at that time, was that news to you, at that time?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. That was new to you?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Had you passed that on--did you pass that on to Dr. Cook, do you know, at that point?

DR. ELMS:

A. I don't recall.

COFFEY, Q.C.:

Q. Having been told that, lobular invasive, it would be unusual that it would be ER negative, did that cause you to reflect upon any earlier cases that you might have had?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. In terms of reevaluating earlier cases?

DR. ELMS:

A. No.

Page 139

COFFEY, Q.C.:

Q. Did you speak to anyone else at St. Clare's or the General about this?

DR. ELMS:

A. Not that I recall.

COFFEY, Q.C.:

Q. Now Doctor, were you ever asked to reexamine Ms. Deane's case in relation to whether or not it was in fact a lobular?

DR. ELMS:

A. Was I ever asked to?

COFFEY, Q.C.:

Q. Yes.

DR. ELMS:

A. No, not that I recall.

COFFEY, Q.C.:

Q. Did you ever do so?

DR. ELMS:

A. At the time, yes.

COFFEY, Q.C.:

Q. Okay, and so when was it that you did that?

DR. ELMS:

A. It was at around the time that I was--within, you know, two days or three, certainly within the week, of having received the stain that

Page 140

was now positive.

COFFEY, Q.C.:

Q. The ER stain that was positive, you went back and looked then? Within a week of that, you went back and looked at her case?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And to determine whether or not, from your perspective, it was lobular?

DR. ELMS:

A. Yes, yes, if I had experts at the Mayo Clinic telling me it was, then I wanted to go back and see what they were telling me.

COFFEY, Q.C.:

Q. And the reference to the Mayo Clinic and experts had been either Dr. McCarthy or Dr. Laing?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Certainly you hadn't called the Mayo Clinic yourself about it?

DR. ELMS:

A. No.

Page 141

COFFEY, Q.C.:
Q. What did you find when you reexamined it, from your perspective?
DR. ELMS:
A. That it had the architecture of a lobular carcinoma, that as I had noted in my microscopy there were areas that had a more ductal appearance, but that overall it looked like a lobular carcinoma.
COFFEY, Q.C.:
Q. Lobular, and you had been told that the Mayo had said it was a lobular too?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. So in effect, that was--in effect, you were confirming in your own mind what the Mayo had already confirmed you had said.
DR. ELMS:
A. What the Mayo had already confirmed and to see what those ductal areas were, how prominent they were, so that in future, how much would I--how much weight would I put on those kinds of cell groupings.
COFFEY, Q.C.:

Page 142

Q. Did you ever tell anyone that this was not a lobular but a ductal cancer? Have you ever told anyone that?
DR. ELMS:
A. At the time?
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. Not that I recall.
COFFEY, Q.C.:
Q. How about since?
DR. ELMS:
A. I know in the course of preparing for this, I had originally remembered that I called it ductal, but I see from the report that I called it lobular.
COFFEY, Q.C.:
Q. I'm sorry?
DR. ELMS:
A. In terms, in preparing for this, for to come here to address the Commission, I of course have been thinking about the case and my initial memory was that I had called it ductal on my diagnosis, but I see that I didn't. That was just a memory three years after the

Page 143

fact.
COFFEY, Q.C.:
Q. Okay, and in fact, throughout all of this, you've examined now, before today, in preparing to come here today, you've examined what you have available to you about Ms. Deane's case?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In terms of her pathology reports and so on?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And other than this reference to ductal, appearance of some minor aspects of it, and it's spelled out in your report, okay -
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. - in terms of your own view of this though, documentary wise, it's always been lobular, according to the reports?
DR. ELMS:
A. According to the reports.

Page 144

COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. Not a classic lobular, but a lobular with ductal areas.
COFFEY, Q.C.:
Q. Did you tell Dr. Laing--ever speak to Dr. Laing about reexamining the slides?
DR. ELMS:
A. I don't recall.
COFFEY, Q.C.:
Q. In terms of whether they were lobular or ductal?
DR. ELMS:
A. Oh no, I don't recall ever speaking to her about that.
COFFEY, Q.C.:
Q. How about Dr. McCarthy?
DR. ELMS:
A. Again, I don't recall speaking to them about that.
COFFEY, Q.C.:
Q. Doctor, if we could look, please, at Exhibit C-0167? Now Doctor, this is a discharge summary for Ms. Deane. It's dated--the

Page 145

discharge--well, the admission date is April 12th, 2005. The discharge date is April 20th, 2005. Dr. Stewart Rorke is the attending physician, and under history of present illness, second paragraph says "repeat testing of her ER/PR receptor status has changed the status to ER/PR positive." I note she was started on treatment with Tamoxifen and given other treatment which is spelled out there. Doctor, do you recall the actual date that you called Dr. Rorke or contacted Dr. Rorke?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Okay. Based upon this, it would suggest, I take it, it was some--certainly on or before April 20th.

DR. ELMS:

A. Definitely, yes.

COFFEY, Q.C.:

Q. Yes, sometime. Now when you--on the retest in 2005, I take it the ER and PR were both positive?

DR. ELMS:

A. As I remember. I would have to see my

Page 146

addendum.

COFFEY, Q.C.:

Q. Sure, and I'll be showing you that just now momentarily. Well, I'll do that now. Exhibit C-0156, please, page one. That's the same surgical number there, Doctor, and the addendum number three entered May 31st, '05 at 15:28 hours. It reads "immunohistochemical staining for ER and PR has been repeated on this tissue using Ventana automated system. Stains for both receptors are positive" and it's signed out yourself the same day.

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, can you tell us, please, why it wasn't until May 31st that this was entered?

DR. ELMS:

A. I'm not exactly sure as to the reason. I had--I knew that Doctor--that the clinicians had the information about Ms. Deane and that they were working on it, but as to the reason why it took so long to get that done, I don't recall.

COFFEY, Q.C.:

Page 147

Q. Exhibit C-0168, please. Doctor, do you recall--the percentages are not there on that one.

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Notice that?

DR. ELMS:

A. Yeah.

COFFEY, Q.C.:

Q. Do you recall roughly what the percentages were?

DR. ELMS:

A. No, not at the time.

COFFEY, Q.C.:

Q. Were they strongly positive, do you know?

DR. ELMS:

A. Again, I don't recall. If I called it positive, I wouldn't have been questioning in my own mind whether or not to call it positive.

COFFEY, Q.C.:

Q. Are you able to tell us why you didn't have the percentages there?

DR. ELMS:

Page 148

A. No, not at the time.

COFFEY, Q.C.:

Q. Because your practice had been, for some period of time, reporting -

DR. ELMS:

A. Had been, as a general rule, yes, to report percentages.

COFFEY, Q.C.:

Q. Doctor, this is--again, this is for Ms. Deane and it's a progress note of May 3rd, 2005, medical oncology clinic. There's part of it--now normally you wouldn't see these progress notes, I take it, in your practice?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. And here, in the second paragraph, I'm just going to read you a portion of it and then ask you a question about it. Dr. Laing has written "when I had sent an e-mail to Dr. Clifford Hudis in the United States asking him if he had any trials that Peggy might be eligible for, he commented that it would be unusual for a lobular carcinoma to be ER/PR negative. For this reason, I had asked for

Page 149

her pathology to be reviewed and interestingly, it came back saying it was a ductal cancer, but when they did stain her for ER/PR, it was positive for both. Because of this, we started Peggy on Tamoxifen as she still had evidence of an estradiol at a level which would put her in a pre-menopausal range" and it goes on from there. "She has been tolerating the Tamoxifen well with no difficulties." This is dictated May 3rd, 2005 and typed May 13th.

Now Doctor, did you ever tell, that you can recall, anyone that this was a ductal cancer?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Have you ever become aware that, at least in St. John's, that it has been determined to be a ductal cancer?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Okay. Now Doctor, having spoken with Dr. Rorke and then Dr. Cook and one or perhaps

Page 150

both of Doctors McCarthy and Laing in the aftermath, immediate aftermath of the positive results, did you have any further involvement with Ms. Deane's case?

DR. ELMS:

A. Not that I recall, no.

COFFEY, Q.C.:

Q. I take it in May, we've gone through that, you dictated the Meditec addendum three.

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. But other than that?

DR. ELMS:

A. Not that I recall.

COFFEY, Q.C.:

Q. Okay, and in relation to this whole ER/PR matter that brings us here now, you'd first become aware of this change for Ms. Deane in April of '05.

DR. ELMS:

A. Um-hm.

COFFEY, Q.C.:

Q. When did you next become aware of investigations going on into ER/PR?

Page 151

DR. ELMS:

A. It was over the course of the following weeks subsequent to that. My understanding was that one of the oncologists remembered a small number of other cases that they had been concerned about and that these cases were looked into and then that other cases were being looked into and the situation developed over a matter of weeks, but I wasn't directly involved with any of those.

COFFEY, Q.C.:

Q. And how were you made aware that even that was going on?

DR. ELMS:

A. Within the department it was, it became known.

COFFEY, Q.C.:

Q. Because Dr. Cook, who was the clinical chief and site chief, was within the small, the same area of the building as you were anyway?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And what then happened, Doctor, in terms of-- at least as best you can recall, in terms of what you knew about what was going on?

Page 152

DR. ELMS:

A. I knew that Dr. Cook was looking into the matter, that other cases were being found that had originally been called negative and were now being called positive, and then I became aware that it had been decided to stop testing and that a more formal review would be done.

COFFEY, Q.C.:

Q. Doctor, in terms of Ms. Deane's case, did you look at the original ER/PR slides?

DR. ELMS:

A. At the time, yes.

COFFEY, Q.C.:

Q. And do you recall how they appeared at the time?

DR. ELMS:

A. No, I don't recall now. I know they were negative.

COFFEY, Q.C.:

Q. Negative, and when you looked, at the time when you reexamined, got the positive results back, you would have looked at the original slides?

DR. ELMS:

A. Yes.

Page 153

COFFEY, Q.C.:
Q. And you do recall now, looking back on it, that it confirmed for you that they were negative, the slides were negative?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. It wasn't kind of like "I didn't see something." You confirmed it was -
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. - "what I saw as a negative originally, I still see as negative."
DR. ELMS:
A. I still see as negative.
COFFEY, Q.C.:
Q. Do you know whether--did you make any observation as to whether or not there was any internal control tissue?
DR. ELMS:
A. Not at the time.
COFFEY, Q.C.:
Q. Doctor, then could you take the Commissioner then through the ER/PR matter then as it

Page 154

developed? We're into the middle of 2005. You understand there's a more formal review, as you put it, going on.
DR. ELMS:
A. Well, I was only peripherally aware of what was happening. I knew that Dr. Cook and lab management were reviewing cases and that originally there were a couple of cases that had been identified by a particular oncologist as something that they'd always thought was kind of puzzling, was the way I understood it, and that when those two cases were looked into, then other cases came to light and over the course of a couple of weeks, the situation developed and I'm not sure as to how or when the decision was made to formalize the process or what formalities that entailed.
COFFEY, Q.C.:
Q. And then, I take it, you understood that there was a full scale review going on.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Or some kind of a large review going on, and we understand that in the summer of 2005, the

Page 155

middle of the summer, the ER/PR testing was suspended locally?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, just look--how did you become aware they were suspended locally? Who made you aware of that?
DR. ELMS:
A. I don't recall specifically. It may have been Dr. Cook.
COFFEY, Q.C.:
Q. Look at Exhibit C-0156, please. Doctor, here this is this addendum number three for Ms. Deane. You do conclude here by saying "using Ventana automated system."
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Why the reference to that?
DR. ELMS:
A. I'm not sure. That wasn't a part of my usual reporting at that time. I can't say.
COFFEY, Q.C.:
Q. At the time, when this first happened, you got

Page 156

the positive slides in front of you and the earlier ones were negative, did you make any inquiries or conduct any investigations as to how that could have happened?
DR. ELMS:
A. No, not at the time.
COFFEY, Q.C.:
Q. And how about afterward?
DR. ELMS:
A. No, because very shortly there afterward, it became obvious that the laboratory administration was looking into the issue.
COFFEY, Q.C.:
Q. Did you ever attribute the change yourself to the changeover using from one--from the DAKO to the Ventana system?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. You never, in your mind?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. What then happened, Doctor? The testing was suspended locally. What next, in terms of

Page 157

your recollection now, looking back on it, as a staff pathologist?
DR. ELMS:
A. I remember that there were meetings and there was a panel set up and a procedure started to investigate these cases to decide how far back to look and to look at disclosing to the patients what had happened.
COFFEY, Q.C.:
Q. Did you have any input into any of that?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. You were just kind of aware generally?
DR. ELMS:
A. I was aware that it was going on.
COFFEY, Q.C.:
Q. Were you ever formally made aware or in a semiformal way made aware of it, in terms of, "look, we're having a meeting. Doctor, would you like to come--we expect everybody to be there and we'll tell them kind of the status, updates from time to time"?
DR. ELMS:
A. I believe there were, there was a meeting, but

Page 158

I don't recall exactly, but I believe there was a meeting in which we were informed.
COFFEY, Q.C.:
Q. Doctor, did you become aware that the retesting was going on at Mount Sinai?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. How about any outside consultants or experts coming in, did you become aware of that?
DR. ELMS:
A. I knew that Dr. Banerjee was coming to review the lab.
COFFEY, Q.C.:
Q. And how about, well as it turns out, it's Trish Wegrynowski.
DR. ELMS:
A. Trish Wegrynowski as well, yes.
COFFEY, Q.C.:
Q. You became aware that both of them were -
DR. ELMS:
A. Both of them were coming, yes.
COFFEY, Q.C.:
Q. Had you known Dr. Banerjee before?
DR. ELMS:

Page 159

A. No.
COFFEY, Q.C.:
Q. How about Ms. Wegrynowski?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. What was your understanding as to what the purpose of their investigations were?
DR. ELMS:
A. That they were looking at the running of our lab as a means of trying to find out what had happened.
COFFEY, Q.C.:
Q. Now we've heard from Dr. Carter, who was a colleague of yours at St. Clare's.
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. At this point in time, in 2005. And she's told the Commissioner about investigation she conducted in the summer of 2005 into this matter.
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:

Page 160

Q. Were you aware that she was doing that?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. So if you weren't aware she was doing it, I take it you weren't aware that she discontinued doing it?
DR. ELMS:
A. No, I wasn't.
COFFEY, Q.C.:
Q. Doctor, when did you first become aware that Dr. Carter had in fact begun to undertake investigation?
DR. ELMS:
A. Sometime during the course of that or just after her finishing it, but it was a very informal understanding. I was peripheral to the whole process. I wasn't involved in looking into the lab and that nature. So what I found out, I would have found out from discussions, informal talks in the corridor.
COFFEY, Q.C.:
Q. Now were you aware that Dr. Banerjee, were you aware when he was in St. John's?
DR. ELMS:

Page 161

A. Yes.
COFFEY, Q.C.:
Q. Did you have any interaction with him yourself?
DR. ELMS:
A. I don't recall speaking to him.
COFFEY, Q.C.:
Q. How about Ms. Wegrynowski?
DR. ELMS:
A. No, I didn't speak with her.
COFFEY, Q.C.:
Q. The results of their investigations, when did you first become aware of those?
DR. ELMS:
A. When they were received, I was aware that they had received a document.
COFFEY, Q.C.:
Q. You were aware. When did you first become aware of the contents?
DR. ELMS:
A. Subsequent to my taking up my position as medical director.
COFFEY, Q.C.:
Q. Okay, which would be in 2006?
DR. ELMS:

Page 162

A. Which would have been in 2006.
COFFEY, Q.C.:
Q. So before that -
DR. ELMS:
A. So it was sometime after May of 2006.
COFFEY, Q.C.:
Q. So in the intervening time period, you weren't aware of -
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. - weren't told what Dr. Banerjee had found or Ms. Wegrynowski had found?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Just one moment, please, Commissioner. Doctor, there were a couple--before I go on then to your time as assistant director and then director of IHC, there are a couple of matters that I do wish to look at. If we could look at, please, Exhibit--and this is going back to 2003, C-0226 please?
COFFEY, Q.C.:
Q. ... Doctor, this is a immunoperoxidase request

Page 163

form, page 1, it's for SS1044-03, it's February 17th, 2003. It's for yourself, Dr. Elms. 1-E is the block. ER/PR there. And completed, February 21, '03 by Ms. Welsh. On the second page you'll see that that's the surgical number?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. '03, SS1044. And go to the next page, actually, the fourth in the exhibit. Addendum No. 1 is you, on appears to be March 4th, '03 reporting in Addendum 1, immunohistochemical staining for estrogen and progesterone receptors is negative?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then if we look at the page before, which is Addendum No. 2, it's March 26, 2003 it's entered. And it says, you've written, "I have received a request from Dr. Kara Laing to review this case to clarify lymph node status and ER/PR status." And you go on to speak about your reexamination. But on the top of

Page 164

the fourth page of the exhibit, said, "Further estrogen and progesterone receptors have been reviewed in both cases." And including SS1044-03. And you note in the earlier case, SS1103 ER/PR are both weakly positive and the later case, 1044-03, ER and PR are both negative. "It's worth noting that the areas of DCIS in 1044-03 are positive for estrogen receptors. Overall, given that the metastatic lesion is weakly ER/PR positive, this interpreted as the tumour having ER/PR receptor positivity. Discrepancy on the later case is possibly on the basis of weak presence of estrogen and progesterone receptors overall in the tumour with the possible existence of hormone receptor negative clone within the slide tested in the latter case." Doctor, I take it this is one of those cases where you're requested by an oncologist to review the ER/PR status?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And this again is just before the suspension of--well, the April 4th memo -

Page 165

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. - of 2003 of Dr. Ejeckam? I appreciate here you were finally reporting this as ER/PR receptor positivity?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. I think is your final conclusion here. Do you recall this case?
DR. ELMS:
A. Not specifically, but I have had occassion to go over this report.
COFFEY, Q.C.:
Q. Okay. And do you recall why it was that Dr. Laing requested you to review it?
DR. ELMS:
A. This case, this patient had originally had a biopsy of an axillary lymph node which showed a metastatic carcinoma and that had been originally reported as weakly positive. Then she proceeded to have a definitive procedure done on that lesion in her breast, so it was removed, and when that was stained for

Page 166

estrogen and progesterone receptors, that was negative. So that prompted Dr. Laing to ask for a review as to why these two pieces of tissue from the patient should have a different result.
COFFEY, Q.C.:
Q. In fact, probably from the same tumour, in fact?
DR. ELMS:
A. From the same tumour, yes, one would assume, yes.
COFFEY, Q.C.:
Q. Sure. And the explanation was what, in layman's terms?
DR. ELMS:
A. In layman's terms, when a particular tissue becomes malignant, there are several changes that occur to the DNA, the governing material, if you will, of that cell that allow it to be malignant, so that the development of malignancy isn't a single hit event. And when a cell become malignant, all of its daughter cells, so to speak, as it divides and then as they divide will all have the same appearance as the original cell. Now, you can appreciate

Page 167

that over the course of this time, evolution being what it is, DNA damage will continue to occur in the daughters so that you, over time, in any tumour, can get a situation in which a more aggressive or a less well differentiated clone will occur and that clone may well then go on to multiply and to dominate the tumour. So it could be a case in this instance that the tumour was originally ER positive but that a more aggressive or a different, anyway, ER negative clone arose and then dominated the original tumour after it had already metastasized to the lymph node. Within tumours we will see that, as well. That's part of the reason I think why you will see a breast tumour that is not 100 percent, some of those cells simply do not have the receptor there of a different Clone.
THE COMMISSIONER:
Q. Dr. Elms, just to make sure I understood that, so the explanation is that in the process of the cells changing, one should not assume that the--all of the cancer which results in the end has precisely the same structure because the mutating cells can mutate to something

Page 168

different?
DR. ELMS:
A. That's correct.
THE COMMISSIONER:
Q. Is that sum and substance of it?
DR. ELMS:
A. Yes.
THE COMMISSIONER:
Q. Okay. So you will get, within a massive cancer, perhaps, conflicting results on a test which is designed to look for a specific thing like ER/PR because some of those cells, in fact, will have it and some won't, some having mutated, depending on which was first?
DR. ELMS:
A. Yes.
THE COMMISSIONER:
Q. Okay, thank you.
COFFEY, Q.C.:
Q. Did you discuss this case with anyone, do you recall, other than perhaps Dr.--obviously you communicated with Dr. Laing through Meditech, certainly?
DR. ELMS:
A. Yes.

Page 169

COFFEY, Q.C.:
Q. But did you discuss it with any pathologists, do you know?
DR. ELMS:
A. Not that I recall.
COFFEY, Q.C.:
Q. And the fact that you were advised the next month, in April of 2003, that the ER/PR stains were thought to erratic and so on and so forth? You remember we looked at the memo?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Dr. Ejeckam's memo. You didn't connect the two, possibly?
DR. ELMS:
A. I didn't connect the two.
COFFEY, Q.C.:
Q. I'm not saying they're necessarily connected at all, but -
DR. ELMS:
A. No, I didn't -
COFFEY, Q.C.:
Q. - but you didn't at the time?
DR. ELMS:

Page 170

A. No.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-2173? Now, Doctor, we saw this--I apologize. Page 56. Doctor, we looked at this earlier today, this is this May 23rd, 2003 form, immunoperoxidase request form, one referring to repeat ER/PR requested by Dr. Zaidi. And if we could bring up, please, Exhibit C-0174? That surgical number on that form, Doctor, was SS5231-02. And if we look here at page 1 of C-0174, you'll see that this is the pathology report for that same surgical number?
DR. ELMS:
A. Yes. This is--yes.
COFFEY, Q.C.:
Q. Yes, you can flip back if you like, but that's the one where you hand wrote, "Requested by Dr. Zaidi."
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Repeat. And here, this particular case, if we look through the third page at the comment at the bottom, you have a comment and then you

Page 171

say, you conclude that page by saying, "To that end, immunohistochemical staining will be performed and an addendum issued once these studies have been received."
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And this was under your original report?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. I take it, you can look back, the first copy?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Okay. And then we go to the fourth page of the exhibit, this case is originally signed out July 25th, '02. See that?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Signature on file. And then there are the various addendums. And this is one of the reasons I was asking you about the addendums is here they're at the end, you'll see?

Page 172

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. At least the way this one is printed out. Addendum No. 1 is July 31st, '02. And you refer to immunohistochemical staining for CK7. And then addendum No. 2, August 29th, 2002, "Immunohistochemical staining for progesterone receptors is positive in approximately 15 percent of lesional cells. Immunochemical staining for estrogen receptors is negative."
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And it's signed out by yourself, August 29th, '02. And then addendum No. 3, which is entered June 11th, '03 and signed out by yourself the same day. It says, "At the request of Dr. Zaidi immunohistochemical staining for estrogen and progesterone receptors has been repeated. Estrogen receptors show faint positivity in approximately 10 to 15 percent of lesional cells. Progesterone receptors are unequivocally positive in approximately 75

Page 173

percent of lesional cells. So here when we look at addendums 1--I'm sorry, 2 and 3, estrogen is gone from negative to 10 to 15 percent and progesterone has gone from 15 to 75? See that?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Do you recall how it was or why it was that Dr. Zaidi asked you to do the repeat?

DR. ELMS:

A. No.

COFFEY, Q.C.:

Q. Now, Doctor, we've heard, the Commissioner has heard the word "conversion" used at times here. I appreciate that that may not be a precise term, perhaps more a term of art, but would this be a conversion?

DR. ELMS:

A. Yes, it would certainly be a case of if we're defining conversion as a case that was originally negative and is now testing positive, then, yes.

COFFEY, Q.C.:

Q. And I appreciate it goes from negative. And

Page 174

in this context under addendum 2, negative would be zero, I take it, at that point in time?

DR. ELMS:

A. Zero, yes.

COFFEY, Q.C.:

Q. In August 29th, '02?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And would it have been zero, negative or less than 10, negative?

DR. ELMS:

A. I would say it would be zero, negative.

COFFEY, Q.C.:

Q. Negative. And 15 percent, the PR, all the way to 75?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And certainly that's a significant shift?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. In your world it would be. 15, to 75, you

Page 175

might quibble about 15 to 20, 15 to 25?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. But 15 to 75, this is a big shift?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And even from zero, negative or zero, to 10 to 15 -

DR. ELMS:

A. Ten to fifteen.

COFFEY, Q.C.:

Q. - that would be something that would stand out, wouldn't it?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. In your world?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Did you report this to anyone other than Dr. Zaidi?

DR. ELMS:

Page 176

A. I'm not sure. I don't recall specifically.

COFFEY, Q.C.:

Q. Do you recall, did you--so you don't recall--well, you would have spoke to Dr. Zaidi now, obviously?

DR. ELMS:

A. Um-hm.

COFFEY, Q.C.:

Q. But how about other pathologists, including Dr. Cook, for example?

DR. ELMS:

A. I don't recall.

COFFEY, Q.C.:

Q. Like in Ms. Deane's case where certainly you spoke to the oncologist right away?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And then told Dr. Cook, in effect, right away?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. You don't recall in 2003 whether or not you did or didn't?

DR. ELMS:

Page 177

A. No.
COFFEY, Q.C.:
Q. If you did at the time, who would you have spoken to?
DR. ELMS:
A. It would have been Dr. Cook.
COFFEY, Q.C.:
Q. And to the effect to tell him what, that you'd had a -
DR. ELMS:
A. That I had a case like this that originally had been tested negative and was now testing positive.
COFFEY, Q.C.:
Q. Was there an incident report filed on this adverse event?
DR. ELMS:
A. Not that I recall.
COFFEY, Q.C.:
Q. And, Doctor, this was at a time you're reporting your June 11th, 2003, see that?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. "Entered and reported". And you had been

Page 178

requested back on May 23rd--well, that's the date of the request form, you've dated it-- Exhibit P-2173, page 56. You had just gotten Dr. Ejeckam's memo in April suspending the testing and May restarting it?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And now had a case here where there had been a retest at the end of May and early June which had converted. It didn't occur to you, well, maybe I should go back in a more general way?
DR. ELMS:
A. Not in a more general way, no.
COFFEY, Q.C.:
Q. If we could, one other exhibit, C-0228, please? Dr. Vaze worked where?
DR. ELMS:
A. Dr. Vaze.
COFFEY, Q.C.:
Q. Vaze, I'm sorry.
DR. ELMS:
A. She worked at St. Clare's, as well.
COFFEY, Q.C.:
Q. Worked at St. Clare's. As well, this is a

Page 179

four-page exhibit. The immunoperoxidase request form is February 10th, 2003, it's for Dr. Vaze. And it's completed, indicated to be completed February 14, 2003 by Ken Green. If we look at the next page, I apologize, go back one. That is for surgical pathology No. SS960-03, block 1-G. Go to the second page of the exhibit is the pathology report. Again, that's the surgical pathology No. is 03-SS960. And when one goes to the fourth page of the exhibit under addendum No. 1, it's dated March 17th, '03, addendum 1 entered the same day and signed off the same day. Estrogen and progesterone, immunoperoxidase method, "ER occasional positive cells less than one percent. PR 15 percent positivity. No controls available." And then addendum No. 2, entered May 28th, 2003 and signed off the same day by Dr. Vaze. "As requested," she writes, "As requested, repeat," and that's underlined "estrogen and progesterone receptors by immunoperoxidase staining. Estrogen receptors 40 percent positivity. Progesterone receptors, 73 percent positivity. Controls positive." Doctor, were you made aware that--

Page 180

of this case where Dr. Vaze apparently had a conversion, as well, around the same time?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. In the context of within St. Clare's itself?
DR. ELMS:
A. No, I didn't, I didn't know about this case.
COFFEY, Q.C.:
Q. Doctor, if we could look, please, at Exhibit P-2076? This is a letter of April 24, 2006 addressed to yourself at St. Clare's, it's from Dr. Nash Denic, copied to a number of individuals, five of whom are physicians. And Dr. Denic, it's "Re appointment of assistant director of immunohistochemistry department, St. John's hospitals, Eastern Health." Dr. Denic writes, "As per our discussion it gives me great pleasure to appoint you as Assistant Director of Immunohistochemistry Department, Laboratory Medicine, St. John's hospitals, Eastern Health. Your appointment has been endorsed by the laboratory medicine leadership team. Along with Dr. Dan Fontaine, Director of Immunohistochemistry Department you will

Page 181

take on an assumed responsibility for the services provided with a goal of achieving excellence in the field of immunohistochemistry. Sincerely yours." I take it that this is the beginning of your appointment or involvement with immunohistochemistry you referred to earlier?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Doctor. Doctor, do you recall how it was that you came to be approached about this?

DR. ELMS:

A. Dr. Denic asked me.

COFFEY, Q.C.:

Q. Okay. And do you recall the context in which that happened?

DR. ELMS:

A. I'm not sure that I was aware that it was one of the recommendations from Dr. Banerjee, but I do know that Dr. Denic felt that it was necessary to have a medical director of immunohistochemistry.

COFFEY, Q.C.:

Q. And initially that appointment letter here on

Page 182

the screen Dan Fontaine, Dr. Fontaine is going to be the director and you're going to be the assistant director, at least initially?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. What was the purpose of having a director and assistant director?

DR. ELMS:

A. We were based at two different sites. Immunohistochemistry is at Health Sciences and I'm based at St. Clare's. I felt, personally, that it would be advisable to have someone at Health Sciences who could handles sort of day-to-day issues in the running of the lab and I felt it feasible, as well, to have two of us, one handling the more technical issues and the other handling the more administrative type of issues. And I felt far more comfortable handling the technological side.

COFFEY, Q.C.:

Q. And so from the outset in terms of your involvement, Dr. Denic approached you about it, you thought about it and said yes, you understood there would be a director and an

Page 183

assistant director?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. One at the General Hospital, one at St. Clare's?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And there'd be administrative duties, functions, necessarily?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. But as well, technical and you were signing on for the technical?

DR. ELMS:

A. For the most part, yes.

COFFEY, Q.C.:

Q. That summarizes it, I take it?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, had you had any training before this in this particular area?

Page 184

DR. ELMS:

A. Other than what we've discussed earlier, no.

COFFEY, Q.C.:

Q. Okay. And what did you understand or were you given to understand would happen if you took this on?

DR. ELMS:

A. That I would be expected to build expertise. I was quite clear that I needed some start-up time to be able to familiarize myself with the technology and a part of that was a two-week preceptorship at PhenoPath Laboratories in Seattle.

COFFEY, Q.C.:

Q. Now, Doctor, if we could, Exhibit P-0277, please? Now, Doctor, this is, well, this particular document is entitled "Recommendations, Immunohistochemistry Service spreadsheet, Dr. D. Banerjee, Trish Wegrynowski." Updated April 25, '06. Compiled December 16th, '05. And it's updated, as indicated, April 25th, which just happens to be the day after the letter is sent to you.

DR. ELMS:

Page 185

A. Yes.
COFFEY, Q.C.:
Q. Notifying you you're the assistant director. Doctor, when you look at this, there are 30 recommendations. See that, spreadsheet, in fact, 18 on the first, then we go on--on the first page and then--I apologize. Yes, 30, numbers up to 30, including the first two pages. If you look at the next page of the exhibit, page 3, you'll notice it's the same heading except it's updated June 30th, '06?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The reference to December is gone, the top right-hand side. And now page 4, continues on into page 5, we're up to 52 recommendations?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, I'm going to ask you, at the time that you agreed to take this on had you even see the lists of these recommendations?
DR. ELMS:
A. No.

Page 186

COFFEY, Q.C.:
Q. That's the first sheet?
DR. ELMS:
A. Either sheet.
COFFEY, Q.C.:
Q. Either sheet?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And you had not seen Dr. Banerjee's report or reports?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And you had not seen Trish Wegrynowski's report or reports at that point?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, were you given to understand before you agreed to take this on, given any understanding about what the status of IHC was?
DR. ELMS:
A. Other than the kind of general information

Page 187

we've already discussed, no. I knew we'd been reviewed, but that was the extent of it.
COFFEY, Q.C.:
Q. When did you then first received a list of recommendations?
DR. ELMS:
A. It was shortly thereafter. It would, I guess, have been in June because I remember the 52 recommendations.
COFFEY, Q.C.:
Q. By the time, certainly by the--your recollection is, look, when I really got myself immersed in this, you're saying, Mr. Coffey, by that point it was up to 52?
DR. ELMS:
A. By that point it was up to 52.
COFFEY, Q.C.:
Q. Yeah. And if we could look, please, at Exhibit P-1754? Doctor, these are handwritten notes dated June 30th, 2006. And that just happens to be the--that's the same date as that list of recommendations, 52 we just saw, updated June 30th, '06?
DR. ELMS:
A. Yeah.

Page 188

COFFEY, Q.C.:
Q. And this is indicated to be a Friday. Present are a number of individuals, Drs. Cooks, Morris-Larkin, Denic, yourself, Markarla, Carter, Williams and other individuals, non-physicians. And it's re reimplementation of ER/PR testing. And then there's some remarks attributed to Nash Denic and to yourself and so on and to Dr. Williams, Dr. Markarla. So, Doctor, do you recall attending this meeting, the June 30th?
DR. ELMS:
A. It doesn't come to my mind. I mean -
COFFEY, Q.C.:
Q. Okay, I'll look at some, I'll take you to some of the notes and maybe that might help refresh your memory. It indicates that, or attributes to "Dr. Nash Denic gave overview of immunohistochemitry. Dr. Gown, Dr. Banerjee, Trish Wegrynowski. Most of recommendations have been handled." It goes on from there, and then to yourself it attributes--actually, yes, the second remark to--or third remark under Dr. Denic, "Consultants middle of pack in North American practice."

Page 189

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Listed here. And do you remember being told that?
DR. ELMS:
A. I remember it being said. I don't remember exactly when.
COFFEY, Q.C.:
Q. And then attributed to yourself is the remark or remarks, "Can't afford to be average. Must have comparable." And it says "Pre-analytic fixation, can't have specimen in formalin more than 24 hours." Something "situation".
UNKNOWN SPEAKER:
Q. "Block selection."
DR. ELMS:
A. "Block selection."
COFFEY, Q.C.:
Q. "Block selection" thank you, is the second thing, and then "Analytic, running out of test itself, validity issue over reproducibility, no global standardization" and then that is continued on, "validity of antibody is issue." See that there? I say continued, there's kind

Page 190

of an arrow down here.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. I appreciate these are not your notes.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And it says, "Post analytic interpretation, three people will read the ER and PRs"?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then it goes on to attribute other remarks to Dr. Denic and Dr. Carter?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Does that help you?
DR. ELMS:
A. Not really. I don't really recall the actual meeting itself.
COFFEY, Q.C.:
Q. Would it be at a time early in your involvement then in the -

Page 191

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. As IHC director?
DR. ELMS:
A. Definitely.
COFFEY, Q.C.:
Q. Exhibit P-2303, please? Now, Doctor, before I go into this, which is your trip to PhenoPath, as the assistant director you were reporting to whom?
DR. ELMS:
A. Dr. Denic.
COFFEY, Q.C.:
Q. The clinical chief?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then I take it as director when that happened, it was the same thing?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. When did you become the director?
DR. ELMS:

Page 192

A. It was at--there was another change in the meantime.
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. Dr. Fontaine found that he was unable to continue and Dr. Prakash Markarla was on staff with us at the time and I approach Prakash to see if he would fill into that role and he agreed.
COFFEY, Q.C.:
Q. To the director's role?
DR. ELMS:
A. To the--yes.
COFFEY, Q.C.:
Q. On site at that -
DR. ELMS:
A. If you--we didn't see it as necessarily being a subordination between the two of us.
COFFEY, Q.C.:
Q. Yes. I wanted to clarify that. Because it's not--the usage of the word "director" and "assistant director" here, those words -
DR. ELMS:
A. Yeah, I would say more co-director than

Page 193

assistant director.
COFFEY, Q.C.:
Q. Okay.
DR. ELMS:
A. However, not too long after that, I'm not sure what the date of that particular letter is, but certainly by the end of 2006 Dr. Markarla has left, as well, which meant that I then became director.
COFFEY, Q.C.:
Q. And is there an assistant director?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. So you not only had to take on the technical, but as well the administrative end of it?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Here, this is an e-mail from Harriet Childs to Dr. Denic, June 7th, 2006. The subject is PhenoPath visit. And after identifying herself as the preceptorship coordinator of PhenoPath Laboratories, she says you are--that would be Dr. Denic's e-mail to Dr. Gown

Page 194

regarding Dr. Ford Elms' visit to PhenoPath was forwarded to her for follow-up, "Based on our pathologists availability, we would recommend Dr. Elms visit for two weeks from October 23rd to November 3rd, 2006. If you are unavailable during this time period, please provide alternate dates in October." And it goes on to talk about how the expenses will be covered. Doctor, did you actually attend?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And during the October 23rd to November 3rd?
DR. ELMS:
A. During that period, yes.
COFFEY, Q.C.:
Q. And what then was the purpose, your understanding of the purpose of you going there, what were you supposed to learn and what happened?
DR. ELMS:
A. To observe the running of an immunohistochemistry lab. I wanted to look at technical aspects, I also wanted to look at

Page 195

their means of interpretation, how they went about the process of interpreting their immunostains.
COFFEY, Q.C.:
Q. Doctor, why PhenoPath?
DR. ELMS:
A. We had had contact with Dr. Gown. Dr. Denic knew Dr. Gown and approached him and said "He will take you if you want to go."
COFFEY, Q.C.:
Q. Now, in that--in your world, world of pathology in North America, for example, the idea of being exposed to immunohistochemistry laboratory and being trained, as it were, to become a director or assistant director, is there any formal way of doing that that you're aware of?
DR. ELMS:
A. There are some very, very few post-graduate positions. The majority of such as there are are generally within the context of lymphoma. So if you're going to sub-specialize in hematopathology, there are centres in which there'll be a fairly heavy wait to immunohistochemistry, but that then is to the

Page 196

immunohistochemistry of lymphoma. There are a vanishingly rare number of fellowship positions that I'm aware of that's specifically looking into immunohistochemistry.
COFFEY, Q.C.:
Q. And again, what sort of numbers would you be talking?
DR. ELMS:
A. Well, I briefly--I did a very sort of superficial on-line search awhile ago and I found one in North America.
COFFEY, Q.C.:
Q. Okay, and where was that?
DR. ELMS:
A. That was in PhenoPath. There was--there may be another one in Florida, but I can't speak to that for sure.
COFFEY, Q.C.:
Q. And you did this search when?
DR. ELMS:
A. Oh, several months ago.
COFFEY, Q.C.:
Q. And those one or two positions in North America, Doctor, are they post--what type of

Page 197

post-graduate work are they?
DR. ELMS:
A. They would be fellowship positions.
COFFEY, Q.C.:
Q. Fellowship positions.
DR. ELMS:
A. So they would be positions you would enter into after you'd finished a residency.
COFFEY, Q.C.:
Q. You'd be a pathologist?
DR. ELMS:
A. So you'd be a practising pathologist and then -
COFFEY, Q.C.:
Q. And kind of like becoming a breast pathologist, a fellowship -
DR. ELMS:
A. Exactly.
COFFEY, Q.C.:
Q. - you spend a year or so or a portion of a year doing a fellowship?
DR. ELMS:
A. Exactly.
THE COMMISSIONER:
Q. Mr. Coffey, it's near to the luncheon break so

Page 198

wherever you can find a convenient spot.
COFFEY, Q.C.:
Q. Doctor, can you tell us, please, then, what it was that you--you know, how it went out there, who were you exposed to and -
DR. ELMS:
A. It was very productive, very informative. I would go in in the mornings and review the day's controls with the technologists and discuss issues with the running of their machines. They use a DAKO semi-automated platform, which is different from ours, but the basic idea is still the same. And PhenoPath is a referral centre, so they don't handle wet specimens; they receive tissue from other centres. Sometimes they'll receive blocks to do immunostains on themselves. And in other instances they will just receive immunostains that have been sent from somewhere else. As the referring clinician sees fit they will also send the H and E slides and the pathologists at PhenoPath are then asked to give their opinion on these particular cases. And so the cases are allotted out just as they would be in a

Page 199

regular pathology lab and every day they have difficult case sign-out rounds and so the pathology staff that's there will meet and discuss cases. There's generally a senior technologist in attendance.
COFFEY, Q.C.:
Q. During those?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Rounds. Anything else that you recall and figure that you -
DR. ELMS:
A. That was--there was one day of they do an academic half day quarterly and I was fortunate enough to be there for one of them.
COFFEY, Q.C.:
Q. So the purpose then in you going there was to be exposed to a large-scale immunohistochemistry service?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And how that would be run?
DR. ELMS:

Page 200

A. Yes.
COFFEY, Q.C.:
Q. Were you given any materials, written materials in that regard?
DR. ELMS:
A. Written materials, I was given some brochures about the activities that PhenoPath is doing. They're also a research lab; they develop and validate antibodies, as well, plus they're doing a great deal of research into the applications of immunohistochemistry, so I was given access to most of their publications.
COFFEY, Q.C.:
Q. And how about written policies and procedures?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. You didn't have access to them?
DR. ELMS:
A. No, at the time.
COFFEY, Q.C.:
Q. Have you since asked them for them?
DR. ELMS:
A. Asked them for theirs, no.
COFFEY, Q.C.:

Page 201

Q. So, Doctor, then I take then for two weeks, which would be, I take it, two five-day periods?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Monday to Friday, perhaps eight hours a day?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Or so, you went as an observer?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In effect, to see how their lab was operated?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Would you have taken notes or anything on that at the time?
DR. ELMS:
A. On certain, certain issues, but not to any great extent.
COFFEY, Q.C.:
Q. And in terms of the aspect of their lab, we've

Page 202

just seen notes there, pre-analytic and analytic, post-analytic?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. What aspect of their work really would you have seen, would you have seen really very much of the pre-analytic at all?
DR. ELMS:
A. Not of the pre-analytic. And as a matter of fact, most of the pre-analytic would have been done outside of their centre, anyway.
COFFEY, Q.C.:
Q. Outside. For the reasons you just referred to?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Before it became--the specimens become blocks?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. So it would be the production of slides, you would have seen that?
DR. ELMS:

Page 203

A. Yes.
COFFEY, Q.C.:
Q. And the processing of the slides?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And witnessed the interpretation of them?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Thank you, Commissioner.
THE COMMISSIONER:
Q. All right, then, we'll take a luncheon break and meet again at 2:05. Thank you.
(LUNCH BREAK)
THE COMMISSIONER:
Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Good afternoon, Doctor. Doctor, when you visited PhenoPath Laboratories, first of all could--in the fall of 2006, where is that located?
DR. ELMS:
A. That's in Seattle, Washington.
COFFEY, Q.C.:

Page 204

Q. And were you, in fact, at the time given any particular training in respect of particular antibodies?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Okay, so it was again a more general approach?
DR. ELMS:
A. It was a more general approach.
COFFEY, Q.C.:
Q. Exhibit P-2386, please? I take it then, Doctor, by the time you'd come back from Seattle in the fall of 2006 that you were the director?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Yes, and--of IHC. Now, this, Doctor, is a memo April 17th, 2006 sent by Dr. Ejeckam. And he was still in St. John's in April of 2006. And it's to all pathologists, oncologists, pathology residents and immunohistochemistry technologists, Health Sciences and St. Clare's sites. It's copied to a number of individuals. And this would

Page 205

have been a week before you were appointed assistant director. But it says, "The Ventana Medical System will sponsor a medical session on breast panel markers and role of VIAS Image Analysis and grading of breast panel markers. Please see attached schedule. You are all encouraged to attend and hopefully have all your questions answered. Yours sincerely, Dr. Gershon Ejeckam, Interim Director of Immunohistochemistry Laboratory." Doctor, what, if anything, do you recall about this VIAS system?

DR. ELMS:

A. The VIAS system is an image analyzer in which you scan in the slide that you wish to analyze and then the computer system basically analyzes it in itself, it also draws in boundaries and gives you an idea of the percentage of what's considered positive. You have to select the areas you want the machine to analyze.

COFFEY, Q.C.:

Q. And I take it that that can be time intensive at times?

DR. ELMS:

Page 206

A. Yes, it could be.

COFFEY, Q.C.:

Q. Doctor, did you, at the time in 2006, gain any experience utilizing the machine?

DR. ELMS:

A. Yes, there was a session where we were shown how it was used and what it could do.

COFFEY, Q.C.:

Q. Did you actually then, as it were, experiment with it?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. What was your reaction to it?

DR. ELMS:

A. I thought it was a very interesting piece of technology.

COFFEY, Q.C.:

Q. And to call it very interesting means what?

DR. ELMS:

A. Well, I'm interested in technological things, I'm something of a tech nerd, as I think a lot of us are in pathology. We were looking at purchasing the machine at the time and as medical director of immunohistochemistry, I

Page 207

mean, in late 2006, it became--it fell to me to make the decision.

COFFEY, Q.C.:

Q. What decision was made and why?

DR. ELMS:

A. I decided at the time that we wouldn't purchase the VIAS but that we would revisit it at a later date.

COFFEY, Q.C.:

Q. Has it been revisited to date?

DR. ELMS:

A. Not yet.

COFFEY, Q.C.:

Q. And why was it deferred, as it were, at that point, put off -

DR. ELMS:

A. I had been provided with the names of people in the United States who were using it by Ventana themselves and discussed it with them and they each--they all felt that while it gave them the ability to produce a more complete report none of the people that I talked to felt that they gained any increase in detection of positivity over what would have been done had they been a small group of

Page 208

people reading all of these results. Furthermore, at that time it was only being used for ER/PR and HER2/neu with an eye to expanding it as this kind of testing for purposes of treatment becomes available. So I felt at the time there were more pressing issues facing us in terms of addressing issues within the lab and that it would perhaps be best for us to deal with those issues first, deal with the recommendations in the Banerjee inquiry and then revisit the issue of the VIAS.

COFFEY, Q.C.:

Q. And has it gotten any further than that?

DR. ELMS:

A. Not at this point, no.

COFFEY, Q.C.:

Q. Exhibit P-1754? Now, Doctor, these are these notes of June 30th, 2006, what we looked at earlier today. Midway down or just past the midway point on the first page there's a note, "Bev has written a fixation protocol to be sent out to other centres."

DR. ELMS:

A. Yes.

Page 209

COFFEY, Q.C.:
Q. Do you have any knowledge as to when that happened, if it did happen, when it happened?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And in terms of the idea of distributing a fixation protocol to other centres?
DR. ELMS:
A. I knew it was being done and it was being sent to other boards on the island.
COFFEY, Q.C.:
Q. Who would be responsible within your organization for distributing it?
DR. ELMS:
A. Dr. Carter and Dr. Denic.
COFFEY, Q.C.:
Q. Exhibit P-0076, please? And, Doctor, these are just several things, documents I'm going to take you to now, the one I just looked at and this one because I want to get some, Commissioner to get some sense of what was happening when you, in practice, took over in a practical way as the director, what you were aware of up to that point. This is a memo, I

Page 210

should point out to you or show you, Doctor, that on the second page the space for Doctors Cook and Beverley Carter's signature, but we don't have a signed copy, if there is one. It's dated July 28th, 2005, it's to all pathologists and pathology residents in the Department of Pathology, St. John's hospitals, Eastern Health. It's from Doctors Cook and Carter. It's "Re optimal assessment and reporting of hormone receptor status in infiltrating carcinoma." And it begins by saying, "When ordering and reporting ER/PR status on infiltrating carcinoma of the breast," and it goes one, two, three, four, five, six, seven, eight through nine. And I'll just take you to the first couple. "Select a block that contains infiltrating carcinoma and normal and/or benign breast epithelium. (2) When reporting always check internal and external controls." And it goes on from there in a fairly detailed form. Do you recall seeing this in the summer of 2005?
DR. ELMS:
A. Not specifically, no.
COFFEY, Q.C.:

Page 211

Q. How about generally, was it discussed, do you know?
DR. ELMS:
A. Generally, definitely, yes, it did. I mean, the points that I'm reading in it now are things that would have been, we would have been dealing with it around that time.
COFFEY, Q.C.:
Q. Now, Doctor, as a staff pathologist in the summer of 2005, you know, what was your reaction to this overall, this whole, by then there was a mass retesting, in effect, started or planned?
DR. ELMS:
A. That, well, I was upset that this was going on in our lab. I was upset for what it would mean for patient care, not only for those patients that were affected, but for what it would mean for general confidence in the system. At the time I don't believe that there was much public awareness but there was also the understanding that the public was going to have to be made aware and that disclosure was necessary. So those were my biggest concerns.

Page 212

COFFEY, Q.C.:
Q. Doctor, then as a staff pathologist, and I appreciate it was in April of 2006, effectively eight or nine--almost actually a year after you'd first spoken about Ms. Deane's case, that you became assistant director of IHC. But before you became assistant director how informed were you kept as to what was going on in terms of the investigation?
DR. ELMS:
A. I knew that it was going on, I knew that over the course of weeks to months after the initial case that the review had been extended on at least two occasions, if not more, to cover a certain amount of time. And I was perfectly aware that the lab was being reviewed, these types of things, and that there were meetings ongoing to discuss what the impact would be for individual patients and to review individual patient cases and then contact them.
COFFEY, Q.C.:
Q. In terms of how about as a pathologist, as a member of the staff, were you in a periodic

Page 213

way or any routine fashion, kept apprised of what was going on? In any systematic way?

DR. ELMS:

A. Not in any systematic way.

COFFEY, Q.C.:

Q. Looking back on that now, you know, if someone was to consult you about it, if someone else had a problem elsewhere and was to consult you about it, do you think that that sort of approach-- would you advocate that sort of approach or would you advocate the pathologists being kept apprised from time to time?

DR. ELMS:

A. Yes, I would. I would think that as a situation like this developed, that there should be a specific group of people who are dealing with the issue, and who would, as necessary, apprise the staff pathologist as to any impact it might have on their current practise. There would come a point in which I would think people should at least be made aware of how far it impacted their practise, how many of the cases were actually theirs, but to--I would think it would be more

Page 214

appropriate to have a smaller group of people who were dealing with these issues.

COFFEY, Q.C.:

Q. And actually to manage the issue.

DR. ELMS:

A. To manage the issue.

COFFEY, Q.C.:

Q. Dealing with it, but from time to time keep people apprised of it?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. As to what they found. Doctor, on that latter point, the one about being told what the impact was for your own patients, have you ever been told that?

DR. ELMS:

A. Yes, yes.

COFFEY, Q.C.:

Q. When did that occur?

DR. ELMS:

A. It was well into it because we needed to know how many were--I mean, the retesting had to be done before we could know how many of our cases were involved with this.

Page 215

COFFEY, Q.C.:

Q. Oh, yes.

DR. ELMS:

A. So it was well into the process of retesting.

COFFEY, Q.C.:

Q. Do you recall when?

DR. ELMS:

A. No, not specifically.

COFFEY, Q.C.:

Q. At the time the inquiry was announced in May of 2007, had you--at that point, did you know how many of your patients were impacted?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. You had been told before that?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Were you told in your capacity or did you learn in your capacity as the Director of Immunohistochemistry, or as a pathologist generally?

DR. ELMS:

A. As a pathologist.

Page 216

COFFEY, Q.C.:

Q. General staff pathologist.

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Do you recall who informed you and how you were informed?

DR. ELMS:

A. Dr. Denic.

COFFEY, Q.C.:

Q. Was it you individually or a group and you could ask him?

DR. ELMS:

A. It was me individually.

COFFEY, Q.C.:

Q. Did you approach him or him --

DR. ELMS:

A. It was in the context of a conversation we were having and we were talking about how extensive it was, and he said, well, you know, here are your numbers.

COFFEY, Q.C.:

Q. Okay. You did have some cases that did convert?

DR. ELMS:

Page 217

A. Yes.
COFFEY, Q.C.:
Q. Doctor, I appreciate now, of course--I gather, as the Director, you've become much more aware of immunohistochemistry as a field?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Looking back on it, from your perspective, are you able to attribute any reason or reasons as to why there might have been conversions in individual cases that you were involved in?
DR. ELMS:
A. I have felt that individual errors at a given time, or individual conversions at a given time, could be based on a number of issues, and that it probably wasn't a single issue overriding.
COFFEY, Q.C.:
Q. For example, examples such as what sorts of things?
DR. ELMS:
A. Such as fixation, for instance, and antigen retrieval. There may have been issues with temperatures, with ph's, and many of these

Page 218

tests. ER isn't as susceptible as some, but many of these tests are quite sensitive to minor changes in their environment.
COFFEY, Q.C.:
Q. And for any one patient's circumstances, it's your view that there might be one or more of those factors came into play in that individual patient's case?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, have you given any thought to whether or not it's possible to actually ascertain at this point in time for any one case what factor or factors might have played a part?
DR. ELMS:
A. I'm not sure at this point that it might be specifically. We can know the actual quality of the slides themselves, but my understanding, not having gone back and looked, my understanding is that the documentation isn't necessarily always there as to the exact path of the material through the laboratory.
COFFEY, Q.C.:

Page 219

Q. And that would be from the technologist end, I take it, in terms of the processing of the slides?
DR. ELMS:
A. In terms of the processing, yes.
COFFEY, Q.C.:
Q. So is that answer then to the effect that, no, you don't think it would be possible, in fact, now, in at least an overall manner to do so?
DR. ELMS:
A. I think it would be a very big job. It would require a review of all those cases, and I think in some instances we may not be able to tell.
COFFEY, Q.C.:
Q. If, for example, it was an antigen retrieval problem or issue in a particular case?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. As opposed to a fixation issue, as opposed to both of them?
DR. ELMS:
A. Or a temperature issue, or a length of time with the antibody on the--on the tissue

Page 220

itself.
COFFEY, Q.C.:
Q. Doctor, while Exhibit P-0076 is on the screen there in front of you, I appreciate this was - is dated, anyway, July 28th, 2005. Doctor, knowing what you do now, would a memo such as this have been of benefit to have had back in--well, in fact, in your residency days?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Or anything if it developed over time, something -- one of these arose afterward.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. It's certainly a detailed memo as to what to look out for.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In your experience, Doctor, and your training in the late 90s, and then practising in the 2000's here in St. John's, did you ever receive any sort of memo like this for any

Page 221

other stain?
DR. ELMS:
A. Any other stain, no.
COFFEY, Q.C.:
Q. How about since then? I'm not suggesting you even did receive this one, but--like, this kind of detailed memo about a particular stain or stains?
DR. ELMS:
A. No, no, not that I recall.
COFFEY, Q.C.:
Q. Do you have any thoughts as to whether or not it might be of benefit to a pathologist?
DR. ELMS:
A. For the majority of our stains, probably not, because as I say, the majority of our stains are investigative and are used in the diagnostic process and are used as part of a panel. However, estrogen receptor was the first, HER2/neu was next, and now we're gradually getting more and more antibodies developed as single point tests used in the guiding of treatment, and that puts a very different impact on what it is you're doing with your antibodies. So in that instance,

Page 222

yes, that would certainly be of value.
COFFEY, Q.C.:
Q. Right now with the resources that you have available to you locally, are there sufficient resources to actually then produce such for those sorts of stains, those stains that fall into that category you just described? Do you have the resources available to you to have someone on the staff there produce such a memo?
DR. ELMS:
A. Such a memo?
COFFEY, Q.C.:
Q. Like, an instructive memo?
DR. ELMS:
A. Not really. Administrative support is not prominent, with the result that the production of such a memo would--it would require me to find someone, which is usually the case.
COFFEY, Q.C.:
Q. And, I take it as well, either you would have to prepare the memo yourself or deputize or could you haul some other pathologist into doing it?
DR. ELMS:

Page 223

A. Yes.
COFFEY, Q.C.:
Q. Researching it and doing it?
DR. ELMS:
A. I could do that. I would end up typing it up myself.
COFFEY, Q.C.:
Q. But it is something that--I take it your time might be better spent doing other things than typing up a memo?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2467, please. Doctor, as you're going to see now, this is an e-mail from Heather Predham to Pam Elliott and Patricia Pilgrim. The subject is ER/PR, the date is November 19th, 2006, and she begins by saying, "I met with Bev Carter, Ford Elms, Don Cook, Nash Denic, and Susan Bonnell, on Friday afternoon. We reviewed the presentation from Monday, and it's very good and comprehensive. As always, Bev's comments in the meeting were a bit alarmist in nature, but she is only speaking about ER testing at the

Page 224

presentation", and they go on here to talk about the summary document of the reviewer's recommendations and the lab's actions, and it hadn't been updated since June of 2006, that would be. Doctor, I take it that you were involved in this meeting and the preparation for these November 2006 presentations to the executive and to the medical staff?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. What was the nature of your involvement?
DR. ELMS:
A. I was there to explain the science behind immunohistochemistry, how the test was carried out.
COFFEY, Q.C.:
Q. And who had asked you to do that?
DR. ELMS:
A. I believe it was Dr. Denic.
COFFEY, Q.C.:
Q. I'm sorry, Doctor --
DR. ELMS:
A. Denic.
COFFEY, Q.C.:

Page 225

Q. Denic. The idea--from your perspective--"Bev Carter's comments in the meeting, a bit alarmist". From your perspective, had you found Bev Carter to be alarmist, at least that you would conclude that she was alarmist?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Did anyone ever express to you that she was alarmist, that you recall?
DR. ELMS:
A. Not that I recall.
COFFEY, Q.C.:
Q. If we could look, please, at Exhibit P-1425. Doctor, this is, I believe, a PowerPoint presentation. It goes on for quite a number of pages, but the first of them is--the first slide is immunohistochemistry, Dr. Ford Elms, and then it goes on from there, immunohistochemistry microscopy requires cellular constituents be made visible, and it goes on from there. This, I take it, is your slide presentation?
DR. ELMS:
A. Yes.

Page 226

COFFEY, Q.C.:
Q. Or at least a portion of it, and the purpose of this slide presentation was what?
DR. ELMS:
A. It was to inform the clinicians--this was just before the announcement was made that there had been the problem in our lab, and the purpose of this was to inform the clinicians - well, to give them a background as to the technology, to inform them what had gone on, what measures had been taken up until that point, and to update their knowledge or refresh their knowledge on the issues of ER/PR testing.
COFFEY, Q.C.:
Q. And then from your perspective, this was geared to what, what sort of an audience?
DR. ELMS:
A. It was geared to the clinicians, the surgeons, and the oncologists who had been dealing with breast cancer patients.
COFFEY, Q.C.:
Q. Did you participate in the presentation?
DR. ELMS:
A. Yes.

Page 227

COFFEY, Q.C.:
Q. Did you make a presentation to anyone else?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. How about the executive?
DR. ELMS:
A. No, there was a meeting the following day, but I didn't attend that meeting.
COFFEY, Q.C.:
Q. Do you know if your part of the presentation was given to the administration?
DR. ELMS:
A. I don't know.
COFFEY, Q.C.:
Q. Doctor, I'm here leafing through it, and we're at page 28 of the exhibit. It says, "In summary", and then it goes on. Page 29 of the exhibit is "Pitfalls in ER testing" by Dr. Bev Carter.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, the information, for example, contained here in pages one through 28 of this

Page 228

exhibit --
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. Prior to becoming assistant director, had you been aware of that, those sorts of things?
DR. ELMS:
A. Somewhat more generally, more superficially than that.
COFFEY, Q.C.:
Q. Okay. So I'll ask you then in terms of--when had you emersed yourself or began to really immerse yourself in this, and what process did you use?
DR. ELMS:
A. It was in May of 2006. When I was asked to take over the running of the lab, as I said, my first task was to educate myself to get myself up and running. I read textbooks and and reviewed the literature, and then went into phenopath.
COFFEY, Q.C.:
Q. When you read textbooks, they would be textbooks on what?
DR. ELMS:

Page 229

A. On immunohistochemistry, as a sub-area of pathology.
COFFEY, Q.C.:
Q. Do you recall any particular text you read?
DR. ELMS:
A. Dabbs was the most prominent one.
COFFEY, Q.C.:
Q. That would be David Dabbs?
DR. ELMS:
A. David Dabbs.
COFFEY, Q.C.:
Q. And his textbook deals with immunohistochemistry generally, not just breast?
DR. ELMS:
A. Yeah, yes, that's correct.
COFFEY, Q.C.:
Q. All the different aspects of IHC?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. At least there are quite a number of them spelled out in the text.
DR. ELMS:
A. Yes.

Page 230

COFFEY, Q.C.:
Q. Doctor, when you gave your presentation in November of 2006 to your colleagues, do you recall being questioned or asked questions?
DR. ELMS:
A. I may have been asked a couple, but I think most of the questions were directed at Dr. Carter, Dr. Denic, and Dr. Cook.
COFFEY, Q.C.:
Q. Have you ever--have you provided any other presentations other than that one?
DR. ELMS:
A. You mean, in general?
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. I provided a presentation to the media that was associated with this inquiry at their request just to--again, it was a very similar presentation, to inform them of the nature of the test and what the technology was they were hearing.
COFFEY, Q.C.:
Q. Do you recall when that was?
DR. ELMS:

Page 231

A. June of this year, I believe.
COFFEY, Q.C.:
Q. So June of 2008?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The media, you just alluded to the fact that in -- just before this went public, which would have been the December 11, 2006, media, technical media briefing, you weren't involved in that, I take it?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. If we could look, please, at Exhibit P-1602. I apologize, P-2108. Doctor, these are the Minutes of an Executive Management meeting held November 21st, 2006, in Conference Room C of the corporate office in St. John's. Present are a number of the executive, they're spelled out there. Guests for the ER/PR presentation, you're listed fifth down.
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:

Page 232

Q. As being from Laboratory Medicine, and then the actual presentations themselves are indicated to be presentation ER/PR, Dr. Denic's presentation, and Dr. Kara Laing's presentation is referred to below that.
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. So I take it that you did not actually give a presentation?
DR. ELMS:
A. No, I don't recall this. Is this on the day after the previous presentation?
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. No, I wasn't --
COFFEY, Q.C.:
Q. Day after or day before, depending on--day after.
DR. ELMS:
A. Day after. No, I didn't --
COFFEY, Q.C.:
Q. You certainly don't recall.
DR. ELMS:

Page 233

A. No.
COFFEY, Q.C.:
Q. If you were there, you don't have any recollection of it at all.
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, by this point in time, anyway, by the time you briefed your colleagues in November, 2006, clinicians, did you have any understanding by that point as to what the cause or causes of the problem had been?
DR. ELMS:
A. I knew that there had been identified issues of fixation, but other than that, I wasn't aware of -- I'm trying to remember when it was I got the recommendations from the Banerjee inquiry. I knew what was on those recommendations.
COFFEY, Q.C.:
Q. But other than the recommendations, how about the reports themselves?
DR. ELMS:
A. I had been shown portions of the reports.
COFFEY, Q.C.:

Page 234

Q. Do you recall when that was and by whom?
DR. ELMS:
A. It was by Dr. Denic and it was sometime over the course of that fall.
COFFEY, Q.C.:
Q. The fall of 2006?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Before the actual presentation to your colleagues?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The slide show?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. P-0046, please. Doctor, this is the cover letter of October 17, 2005, for Dr. Banerjee's first report.
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. October 17th, 2005, and then the headings are

Page 235

background, incident problem case, review of cases, literature review of Dako vs. Ventana immunostainer performance, literature review about the effects of formalin fixation on ER immunostaining, choice of antibody, interlaboratory variability, conclusions about the reason for test failure, and then other system flaws observed, and recommendations. Do you recall what portions of this you were shown?
DR. ELMS:
A. If you'll go back up --
COFFEY, Q.C.:
Q. Sure.
DR. ELMS:
A. The issue of choice of antibody was one. If we can come back down.
COFFEY, Q.C.:
Q. Sure, choice of antibody which is there on page four, yes.
DR. ELMS:
A. Choice of antibody, and the issue of fixation, and I believe we went through the conclusions about reasons for test failure and other reasons.

Page 236

COFFEY, Q.C.:
Q. It would be the choice of antibody, SP1 vs. ID5, and conclusions about the reasons for test failure, and it's numbered 1 to 4, and then 6 and 7.
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. And other system flaws observed, 1 through 7.
DR. ELMS:
A. Yes, and they were--I considered those to be a part of the recommendations, the spreadsheet that I had.
COFFEY, Q.C.:
Q. Sure. So, Doctor, when you became aware and were exposed to these in the fall of 2006, those portions of Dr. Banerjee's report, I take it your conclusion was that it certainly wasn't the Dako System or the Ventana System per se?
DR. ELMS:
A. Certainly.
COFFEY, Q.C.:
Q. And you had no reason to believe, as you pointed out earlier today, that it was ever

Page 237

that yourself?
DR. ELMS:
A. No, no.
COFFEY, Q.C.:
Q. And this would just confirm for you it wasn't?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In fact, the laboratory you visited in Seattle, Dr. Gown's used the Dako autostainer?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The problems with tissue fixation, he refers here to inadequate attention being paid by grossing pathologists to the thickness of tissue slices?
DR. ELMS:
A. Uh-hm.
COFFEY, Q.C.:
Q. Quality and adequacy of fixation, and there's no standardized fixation protocol. Doctor, the idea of thickness of tissue slices, and quality and adequacy of fixation, when you first saw this report, was that the first time

Page 238

that you became aware that the thickness, for example, of the tissue slices was a concern?
DR. ELMS:
A. Was it a concern in this instance, or was it something to be paid attention to when you're grossing a case?
DR. ELMS:
A. Well, both, actually.
DR. ELMS:
A. No. Issues of tissue thickness was something I was made aware of during my residency.
COFFEY, Q.C.:
Q. Which is for the cassettes, I take it?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. But how about in relation in particular to ER/PR?
DR. ELMS:
A. In relation to ER/PR, I don't recall if that was the first time. I'm certainly aware of it now, but if that was the first time that I was made aware of it, I can't say.
COFFEY, Q.C.:
Q. And if you were made aware of it before this

Page 239

point when you were first shown portions of this report by Dr. Denic, it would have been in the context of someone making a comment generally?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. As opposed to in a more formal way.
DR. ELMS:
A. And there were very few comments made. I don't recall informal comments being made on what was in the document.
COFFEY, Q.C.:
Q. And inadequate or no attention is being paid by the reporting pathologist to the status of internal controls, inappropriately exclusive reliance on external positive controls. Now, Doctor, from your perspective again looking back on your own practise, had that been a-- had you fallen into that category?
DR. ELMS:
A. In the period of the review, yes.
COFFEY, Q.C.:
Q. And Doctor, we did look at that handwritten note that we saw there earlier today. I'll

Page 240

just -
DR. ELMS:
A. Yes, I remember the one.
COFFEY, Q.C.:
Q. Remember that, take you there. Anyway, it's the one dealing with non-neoplastic -
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. - cells and them not being stained, which in effect is internal controls.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And that was back in 2001?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Are you able, and upon reflecting upon it, are you able to -
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. - help the Commissioner in that regard, as to why that would have been on your mind at that

Page 241

particular point in 2001?
DR. ELMS:
A. I'm not sure why at that time I felt obliged to make a comment on a form. In any event, it's not a common thing for me to do. Sometimes, if I'm say--you know, I want to say "there's holes in this piece, do another one," but I'm not sure why I wrote that.
COFFEY, Q.C.:
Q. It was in the context of you asking that it be repeated.
DR. ELMS:
A. That it be repeated, yes.
COFFEY, Q.C.:
Q. And you were explaining why, because the internal controls didn't stain.
DR. ELMS:
A. Yes. What I can say is that it was a reason why I wanted it done. It certainly wasn't that I was paying attention any more to internal controls than--like I said, I'm not sure why it was I wrote that comment.
THE COMMISSIONER:
Q. Dr. Elms, doesn't the comment indicate that in the context of an ER/PR test, you are saying

Page 242

the absence of the appropriate response on the internal control has caused you to want that repeated?
DR. ELMS:
A. I'm not sure that that's the case in this instance. I know that I made that comment, but I'm not sure why it was that I ordered that test.
COFFEY, Q.C.:
Q. Can you think of any other reason why?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Other than the one the Commissioner has -
DR. ELMS:
A. No, I've thought about it. It certainly at that time would not have spurred me to reorder the test. It would have been almost as an add-on to say "I want this repeated, and besides, this is the case in this instance." I'm not sure what other issues there were in that case.
THE COMMISSIONER:
Q. But did I misunderstand you? I had understood you to say that at that point, you were not

Page 243

looking for internal controls?
DR. ELMS:
A. At that point, I wasn't.
THE COMMISSIONER:
Q. So for a reason that you don't know, or you now can't remember, when ordering a retest, you indicated the absence of the appropriate result on internal control?
DR. ELMS:
A. Yes.
THE COMMISSIONER:
Q. Although you don't normally look for it. It's an odd sequence.
DR. ELMS:
A. I appreciate that. As I say, I'm not sure what I was looking at at the time in that particular case. I know in those days, absence of an internal control would not have triggered me to -
THE COMMISSIONER:
Q. To order a repeat.
DR. ELMS:
A. - to reorder the test. So I'm not sure as to why I put that there. I'm assuming I ordered the test for another reason.

Page 244

THE COMMISSIONER:
Q. Okay, which you didn't put on the form.
DR. ELMS:
A. That wasn't there, yes. I'm not sure why.
COFFEY, Q.C.:
Q. Doctor, in doing a presentation for your colleagues in November of 2006, for the clinicians, I take it the presentation, you have understood, would have gone to pathologists as well? I mean, there would have been medical staff generally there?
DR. ELMS:
A. Yes, yes, I would have expected pathologists to have been in the room.
COFFEY, Q.C.:
Q. Doctor, were you ever asked for your input or did you ever give any input as to, from your perspective, what should or shouldn't be talked about or could or couldn't be talked about, in the sense of, for example, the reasons for test failure, to quote Dr. Banerjee?
DR. ELMS:
A. I understood that at the time we were treating the Banerjee report as a protected document

Page 245

and that as a result of that, that was not something to be addressed. I don't recall if I was formally told that. I do know that when I was first introduced to the Banerjee report, I was told that it was a confidential document.

COFFEY, Q.C.:

Q. To which you were provided some access?

DR. ELMS:

A. Some access.

COFFEY, Q.C.:

Q. And were given a copy?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. How about Trish Wegrynowski's reports?

DR. ELMS:

A. Very similar. I mean, the spreadsheet which I was provided was a summary of both of them and again, there were portions of the report. As I needed clarification, I felt, on the spreadsheet material, there was portions that I was read.

COFFEY, Q.C.:

Q. Of Ms. Wegrynowski's report?

Page 246

DR. ELMS:

A. Ms. Wegrynowski's report, yes.

COFFEY, Q.C.:

Q. And that would be of both the original and subsequent reports in both cases, do you think?

DR. ELMS:

A. Yes, I believe so.

COFFEY, Q.C.:

Q. By the fall of '06, both reports had been in at least for five or six months?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. The second report from each?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, again, as the then director, in the fall of 2006, and preparing to talk to your colleagues about this matter, did the inability to actually kind of talk frankly about what was in those reports, openly, frankly about what was in them? Would that, in any way, inhibit or did it in any way

Page 247

inhibit your ability or the discussion generally?

DR. ELMS:

A. No, not my ability. I was talking about how the test is done.

COFFEY, Q.C.:

Q. Okay, as a theoretical structure?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. How about--but you would have sat through the presentations of others, Dr. Carter, Dr. Denic's -

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Dr. Howell's presentations?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. As a staff pathologist at the time, was there talk amongst the staff pathologists in St. John's about what happened here, why did it happen? Like I'm trying to get for the Commissioner some sense of, you know, as the

Page 248

people actually doing the work, how they felt about it.

DR. ELMS:

A. I think what was felt was that there was a group of people that was looking into this and that would identify the problems and fix them. People were wondering. People had their own speculations as to what might have gone wrong. But that was the level of the discussion.

COFFEY, Q.C.:

Q. If we could look, please, at Exhibit P-1602? Now Doctor, here, this is a document, it's undated, the source was Terry Gulliver. It's entitled "major changes improvements for the IHC lab." Technology is there. Training is there. You're referenced in the last bullet of the training, planning to send you to Dr. Gown's lab for training. Staffing has approval for four pathologist assistants. I take it that that, the idea of pathologist assistants, we understand, we've heard here at the Commission, that that had been going on for years, had been talked about.

DR. ELMS:

A. Had been talked about, yes.

Page 249

COFFEY, Q.C.:
Q. Talked about. From your perspective, had you been in favour of it or against it?
DR. ELMS:
A. Very much in favour of it.
COFFEY, Q.C.:
Q. What was your understanding, if any, as to why it hadn't happened before this?
DR. ELMS:
A. My understanding was that it was an issue of funding.
COFFEY, Q.C.:
Q. Approval for one QA tech. Had there been any QA techs before this?
DR. ELMS:
A. Not that I was aware of.
COFFEY, Q.C.:
Q. Approval for Dr. Carter part time QA pathologist. Had there been any full or part-time QA pathologist before this?
DR. ELMS:
A. At times during the course of my training and my employment there, yes, there had been. Dr. Miriam Griffin at St. Clare's was one who I remember who was doing QA.

Page 250

COFFEY, Q.C.:
Q. And do you recall what time period that was?
DR. ELMS:
A. That would have been '96 up until she left in, I believe, 1999.
COFFEY, Q.C.:
Q. And after she left?
DR. ELMS:
A. I'm not sure that anyone was doing it then.
COFFEY, Q.C.:
Q. And to your knowledge, was anyone doing it at the General Hospital, that you were aware of?
DR. ELMS:
A. Not to my knowledge.
COFFEY, Q.C.:
Q. Now it refers to enrolled in CAP, College of American Pathologists?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Had that been going on before?
DR. ELMS:
A. Yes, we had had--we get quarterly reviews in which we're send slides and photographs of slides with cases that are circulated to the

Page 251

individual pathologists and we assess them and submit them back as a proficiency test.
COFFEY, Q.C.:
Q. Had that ever involved IHC testing, do you know?
DR. ELMS:
A. It would depend on the cases. We're given a certain number of cases and in some instances, there may be an IHC, but it's not a prominent feature of the modules that we were using.
COFFEY, Q.C.:
Q. From CAP?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. How about then enrolled in the UK, that would be NEQAS?
DR. ELMS:
A. That would be NEQAS.
COFFEY, Q.C.:
Q. And this was new, I take it?
DR. ELMS:
A. This was new.
COFFEY, Q.C.:
Q. Go back, please, to Exhibit P-2108? Page two,

Page 252

Doctor, this is minutes of executive management meeting of November 21/06. The second page, it's noted here "quality and risk management are confident that the appropriate processes are in place. Heather Predham advised that there are some recommendations from the review that have yet to be implemented. It is important to ensure the quality assurance monitoring processes are in place and can be sustained and monitored into the future. Documentation is of paramount importance and must be monitored and reviewed." And then it concludes by saying, "the director and clinical chief are directly accountable for the laboratory," and "Dr. Howell agreed to develop a proposal re: the leadership component for further discussion at executive." Now the director in this context would be?
DR. ELMS:
A. That would be the laboratory director.
COFFEY, Q.C.:
Q. Mr. Gulliver?
DR. ELMS:
A. Yes.

Page 253

COFFEY, Q.C.:
Q. And not yourself as IHC?
DR. ELMS:
A. Not myself.
COFFEY, Q.C.:
Q. The reference to "documentation is of paramount importance and must be monitored and reviewed," what was the state, in November of 2006, of the development of documentation in the lab or the labs in St. John's?
DR. ELMS:
A. The state, it was being developed. We were, at that point, I believe there was documentation ongoing on the machinery, the maintenance of the machinery, the various temperatures and pH's, and we were also retaining documents of our proficiency testing and these types of things.
COFFEY, Q.C.:
Q. Compared to, for example, what exists today?
DR. ELMS:
A. It was in the process of being developed. It wasn't as extensive as now.
COFFEY, Q.C.:
Q. And was this the beginning of it then in the

Page 254

fall of 2006?
DR. ELMS:
A. It had been ongoing that it had been developed, so that when I came to this and began inquiring, some of it was already being done.
COFFEY, Q.C.:
Q. Who had done the initial work?
DR. ELMS:
A. Mr. Gulliver and Mr. Dyer, I had assumed.
COFFEY, Q.C.:
Q. Doctor, here, as well, in this particular page, there's a reference in the third last bullet to "the organization needs to establish a date when it will return to 'testing mode' and returning to testing mode requires the confidence," it should be, I suppose, "of the oncologists and medical staff." Then there's reference to extending the ER/PR testing at Mount Sinai for another month, and then "the MAC is a key group that confidence will need to be restored," or the confidence of which, I presume it means, will need to be restored. Now the MAC, as the director of immunohistochemistry, have you ever addressed

Page 255

the MAC in relation to this?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Have you ever been asked to?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. That's up to the day today?
DR. ELMS:
A. Up to today.
COFFEY, Q.C.:
Q. Would you be prepared to address them, if they asked?
DR. ELMS:
A. If they asked, yes.
COFFEY, Q.C.:
Q. I take it, in the course of your presentation to your colleagues in November 2006 that some people in the audience were probably members of the MAC itself?
DR. ELMS:
A. Yes, I would assume, yes.
COFFEY, Q.C.:
Q. As is Dr. Denic?

Page 256

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2175, page seven, please. This is a document, page seven of it is entitled "immunohistochemistry laboratory management and staff." It lists a number of laboratory medicine program leadership, Dr. Denic, Mr. Gulliver and Ms. Wade. Pathology division leadership, Dr. Morris-Larkin, Mr. Barry Dyer and Ms. Catherine Parnell, and then the immunohistochemistry section, technical staff, are yourself as clinical director immunohistochemistry and at the time, Mr. Green, Mr. Simms, Ms. Rowe and Ms. Voisey. Doctor, who are the current staff of the immunohistochemistry section?
DR. ELMS:
A. There's myself, Mr. Ken Green, Ms. Kim Voisey, Ms. Jane Gamberg and we have another technologist just starting now, Mr. Lloyd Mushreau.
THE COMMISSIONER:
Q. I'm sorry, what was that last name?
DR. ELMS:

Page 257

A. Lloyd Mushreau.
THE COMMISSIONER:
Q. Mushreau?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Could you spell that, please?
DR. ELMS:
A. Not sure exactly how. I believe it ends in R-E-A-U, M-U-S-H-R-E-A-U.
COFFEY, Q.C.:
Q. Doctor, what, if any, training did the technologists receive?
DR. ELMS:
A. They had gone to--I know Mr. Green and Mr. Simms did some training at Ventana. They had also gone off to Jewish General. Ms. Rowe and Ms. Voisey had also done likewise. Mr. Mushreau has not been sent off, but we are undertaking his training within the laboratory.
COFFEY, Q.C.:
Q. Who would be doing the training?
DR. ELMS:
A. That would be myself and Mr. Green.

Page 258

COFFEY, Q.C.:
Q. And you say, I'm sorry, the middle two, Ms. Rowe and Ms. Voisey?
DR. ELMS:
A. Ms. Voisey, they also went away for seminars.
COFFEY, Q.C.:
Q. With whom?
DR. ELMS:
A. I'm not sure. I believe it was with Ventana, but I'm not 100 percent sure of that.
COFFEY, Q.C.:
Q. Have they been to Montreal, Jewish General?
DR. ELMS:
A. I don't know.
COFFEY, Q.C.:
Q. Okay. Is there any particular certification that technologists receive as IHC technologists?
DR. ELMS:
A. Not that I'm aware of. They do training and the training itself, the individual seminars are documented.
COFFEY, Q.C.:
Q. Yes, and so in terms of that, is there a syllabus for them or a plan for how they're to be trained?

Page 259

DR. ELMS:
A. We are in the process of developing a syllabus now for Mr. Mushreau and for future. I would not see us as being the sole trainers of our technologists all the same. I would like to see a continuance of this training outside of our department.
COFFEY, Q.C.:
Q. Have there inquiries been made of other bodies, educational bodies or other institutions?
DR. ELMS:
A. We have subscribed to a series of online seminars by CSMLS or rather, I should say, MSH, and these are quite valuable actually for our technologists.
COFFEY, Q.C.:
Q. Who is responsible, in an administrative sense, for their training?
DR. ELMS:
A. The laboratory director.
COFFEY, Q.C.:
Q. That would be Mr. -
DR. ELMS:

Page 260

A. So Mr. Dyer and Mr. Gulliver.
COFFEY, Q.C.:
Q. I take it you're consulted about it?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In your capacity as--you wouldn't see yourself as responsible for it, but you would be consulted about it?
DR. ELMS:
A. Consulted about it.
COFFEY, Q.C.:
Q. Have input.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2112. Doctor, this is a division of anatomic pathology meeting, January 10th, 2007. Present are yourself and a number of other pathologists listed there. The new business begins with subspecialty task groups, paragraph Roman numeral two, paragraph one. "These groups were explained by Dr. Nash Denic. So far the two most urgent groups, breast and genitourinary have met. The breast

Page 261

group has their mandate and terms of reference done. The terms of reference have been passed to all pathologists for their information." Doctor, what do you recall this was about, this subspecialty task group?

DR. ELMS:

A. This was in response to recommendations from the Banerjee review or Dr. Banerjee and Ms. Wegrynowski's review. The issue of subspecialty sign out in pathology is coming more to the fore within the field of pathology in any event and we decided that in response to these recommendations, we should attempt, as best we can, to set up subspecialty groups and breast, of course, was quite important, because breast is one of the few areas up until now where we have a single test that determines treatment. Genitourinary was another one that was seen as priority.

COFFEY, Q.C.:

Q. And in a general way, where does it stand right now?

DR. ELMS:

A. We still have our genitourinary group. Our numbers have dwindled to the point where we

Page 262

haven't been able to maintain groups and the most obvious is our breast group.

COFFEY, Q.C.:

Q. And this group would be, I take it, of pathologists, I take it, in this context?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. The third paragraph refers to Dr. Denic having spoken to Dr. Howell to try to get funding for training in these subspecialties. I appreciate this was January of '07 and it is now September of '08. What's the situation been with respect to, for example, funding for training for subspecialties?

DR. ELMS:

A. I know, Dr. Afrouzian went for a short period to Calgary. We also have a resident who is interested in doing a subspecialty fellowship and I know arrangements are--people are attempting to make arrangements for him to have funding. I'm not sure if they've been successful as yet.

COFFEY, Q.C.:

Q. For example, in terms of a breast group, the

Page 263

group had been made of Dr. Cook, Dr. Carter -

DR. ELMS:

A. And Dr. Naghibi.

COFFEY, Q.C.:

Q. And Dr. Carter just left?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Dr. Cook is off on leave?

DR. ELMS:

A. Yes. Dr. Naghibi was the first. She left over a year ago, and which reduced the group down to two, and then Dr. Carter went--Dr. Cook went on leave, bringing the group down to one, and then when Dr. Carter resigned, we had no one.

COFFEY, Q.C.:

Q. Doctor, do you know if any particular funding was spent for training for the people in that group, that you're aware of?

DR. ELMS:

A. Not that I'm aware of.

COFFEY, Q.C.:

Q. Now this next paragraph refers to resident teaching and sign out. Won't take you through

Page 264

that in detail, but as it is here, as part of the exhibit, are there problems with resident teaching, because of the staffing levels?

DR. ELMS:

A. I know it can be difficult to fulfil responsibilities in terms of teaching at rounds in this type of area. I'm not aware that there's a problem with RHADIP and residents are still assigned to individual pathologists for the sign--assigned to individual pathologists for the signing out of cases, so that they still get cases to assess and then review with an attending physician prior to sign out.

COFFEY, Q.C.:

Q. Now there is a reference in this paragraph to cases being sent to Dynacare.

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. What's the current situation?

DR. ELMS:

A. That's still going on.

COFFEY, Q.C.:

Q. I take it does it vary from time, month to

Page 265

month or time to time?
DR. ELMS:
A. It varies from month to month, depending on the numbers, but our numbers have been very low since the beginning of May.
COFFEY, Q.C.:
Q. Numbers being sent?
DR. ELMS:
A. Numbers of pathologists.
COFFEY, Q.C.:
Q. Yes, okay. So you would expect the volume going to Dynacare has been higher in the past four months?
DR. ELMS:
A. In the past four months, yes.
COFFEY, Q.C.:
Q. Is there any particular cases that are sent?
DR. ELMS:
A. I know the cases are triaged at Health Sciences prior to being assigned, so that the material all comes in and then at the Health Sciences, a decision is made. I believe Dr. Morris-Larkin has a list of the cases she sends, but I'm not sure what the content of that list is.

Page 266

COFFEY, Q.C.:
Q. Doctor, we've heard reference to a breast pathologist, a new breast pathologist. What's the person's name?
DR. ELMS:
A. That's Dr. Nikita MaKretzov. He is just returned from Great Britain. His background is in breast research and he has taken over, at this point, reading the breast cases and he has agreed to be a core of the reconstituted breast group, when we get back to having that done and reinstituting breast testing.
COFFEY, Q.C.:
Q. And has he started here in St. John's?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. When was that?
DR. ELMS:
A. In July.
COFFEY, Q.C.:
Q. Of this year?
DR. ELMS:
A. Of this year.
COFFEY, Q.C.:

Page 267

Q. Doctor, on the bottom of the third page of Exhibit P-2112, under the heading "seven quality management program" it says "quality management is in the process of creating a book of policy and procedures for pathology."
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. I take it this is January 2007. So that was then ongoing?
DR. ELMS:
A. Yes, ongoing.
COFFEY, Q.C.:
Q. Has progress been made in that regard?
DR. ELMS:
A. Yes, yes, we have developed policies and as we know, it's a continually growing document.
COFFEY, Q.C.:
Q. The next page, page four, under the conclusion at paragraph seven, it says "Dr. Ford Elms is the new director of immunohistochemistry. He will work on validation of estrogen/progesterone and HER2/neu staining. The next stains to be looked at are CD20 and CD117 for prostate." So as of January 2007, I

Page 268

don't know if you were really new new then, but you had become director in the fall of 2006. "Working on validation of estrogen and progesterone and HER2/neu staining." Did you do so?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And what did that involve?
DR. ELMS:
A. The first part of the process is to determine basically what your recipe is, what your protocol for the carrying out of the test is. In that instance, we would--we take a breast, a piece of breast tissue with known staining qualities and every antibody comes with manufacturer's recommendations as to how you do the test, but that can only ever be a recommendation. Immunohistochemistry requires that you know what you're doing in your own lab. So we would take, as a start, and this was something I read in several areas really. You take as a start the variables that you can manipulate. We, on our machine, can manipulate the antibody incubation time, which

Page 269

is the time the antibody is exposed to the tissue, and we can manipulate the antigen retrieval, both in terms of the type of antigen retrieval used and the duration. The easiest and well, the most easily manipulable is the antibody incubation time. We get an antibody that has a recommended incubation time and we will run five slides going down and above at two-minute intervals. We would then assess those slides and based on the results of that, decide where we go from there. We may well find an acceptable protocol then. We may need to alter our incubation time further. We may need to introduce or change in some fashion or take away our antigen retrieval and this applies to any antibody. Once that process has been done and we know what our protocol is, we then need to run a series of slides, again of known result, so that we can show that we can reliably reproduce them. So that process needed to go on for estrogen and progesterone and then subsequent to that, we started the validation of HER2/neu.

COFFEY, Q.C.:

Page 270

Q. So the estrogen and progesterone, when was that done, the validation?

DR. ELMS:

A. That was done late January, early February of 2007.

COFFEY, Q.C.:

Q. And were records kept of that?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And do they still exist?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And when you say records, I take it that would be the actual slides?

DR. ELMS:

A. The slides and the run sheets.

COFFEY, Q.C.:

Q. That produce those particular slides?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, who would have examined the slides themselves, as to determining which was the optimum?

DR. ELMS:

A. Myself and Mr. Green.

COFFEY, Q.C.:

Q. And this would be for ER/PR?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Do you have any particular training in that regard yourself?

DR. ELMS:

A. Other than what I picked up in the course of my self education and my perceptorship, no.

COFFEY, Q.C.:

Q. Now in terms of control tissue, I take it then when you were looking at these slides trying to determine which was the optimum recipe, as it were, to use that word, how would you have picked the blocks? What criteria would be used to pick those and then to know what you were actually looking for, what the block should look like?

DR. ELMS:

A. I would have to search back through the records to identify blocks and they would

Page 271

Page 272

already have been stained for estrogen, and so I would know what the original result was, and then, I would have to pull the case numbers and look at the slides and examine them and then select an appropriate block and it's not sufficient to use one block from one case. You need to get one block from many cases.

COFFEY, Q.C.:

Q. Yes, and how--I take it then, how would you know then what the slide should look like?

DR. ELMS:

A. They had been tested previously. We used slides that had been tested at Mount Sinai.

COFFEY, Q.C.:

Q. I'm sorry, you used?

DR. ELMS:

A. We used tissue that had been tested at Mount Sinai.

COFFEY, Q.C.:

Q. Okay, the blocks that had ended up at Mount Sinai?

DR. ELMS:

A. The cases that had ended up at Mount Sinai.

COFFEY, Q.C.:

Q. Cases, and so some of those cases, you would

Page 273

at least have Mount Sinai's results?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The block that they had tested.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Would you have the actual slides themselves?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. You would have a report on a block, on a slide on a block done at Mount Sinai?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And then you would utilize the same case, a case, that case, and pick another suitable block?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Create your own slide?
DR. ELMS:

Page 274

A. Yes.
COFFEY, Q.C.:
Q. Or slides, series of slides?
DR. ELMS:
A. Series of slides, yes.
COFFEY, Q.C.:
Q. And using different antigen retrieval times and so on, as you've described?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Different recipes as it were?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And would look at the slides and determine--how would you determine which was the best recipe?
DR. ELMS:
A. Well, if you know, for instance, that you have 40 percent intense staining in your case, you would--I would look at that first. Then I need to--it's not a matter merely of saying do I get positive or negative. I also need to know specificity. Is there background

Page 275

staining? Is there other extraneous staining? And if that is the case, as sometimes happens, then you need to do something to deal with that. It may be biotin staining, in which you'd need the block, overall now not necessarily just with ER. You'd need to know if you need to block it with biotin for instance. You may have to turn up or turn down your antigen retrieval. You may have to alter the antibody incubation time, depending on what you see.
COFFEY, Q.C.:
Q. And what you see, I take it, is you have to have some idea first of all of what perhaps I should be seeing?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Anticipate I should be seeing.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And what you should be seeing in this particular instance, in the early 2007, was a function of what Mount Sinai had reported

Page 276

these cases as?
DR. ELMS:
A. Yes.
THE COMMISSIONER:
Q. Dr. Elms, is this whole process like a house of cards, it all depends on the validity of what was done before?
DR. ELMS:
A. Yes, I would say. Yes, I mean, we -
THE COMMISSIONER:
Q. It seems to me the descriptions I get are we use known quantities for the purpose of determining what we use now.
DR. ELMS:
A. Yes.
THE COMMISSIONER:
Q. But you must go on the assumption that the known quantities in fact are valid?
DR. ELMS:
A. Yes.
THE COMMISSIONER:
Q. And Dr. Khalifa comes in and describes how he set this up originally and he goes back to the results that they would have gotten in terms of his use of certain criteria, when they were

Page 277

using the old bioassay method.
DR. ELMS:
A. Yes.
THE COMMISSIONER:
Q. So it seems like it's all built on the assumption that at every step along the way, things were done properly.
DR. ELMS:
A. That's correct. The issue of standardization in immunohistochemistry worldwide has been debated and looked at for years. In Great Britain, they've been working for at least ten years on that. One of the problems, and we keep saying there's no gold standard. One of the problems is that it's not like a blood test. If you, for instance, want to have a standardized glucose test, you can take blood samples from 1,000 or 2,000 or whatever people, pool them all and then that can be used as your standard across the country. You can't do that with a small portion of tissue. Various techniques have been discussed as to how to do it. What seems to be most up and coming now is the issue of tissue micro rays, which is a methodology that's being used in

Page 278

B.C., and in that, you have very small portions of tissue, numerous portions of tissue mounted on the same slide, and that is where the B.C. group is going. But the issue of how you standardize immunohistochemistry is still being discussed and worked on.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. Doctor, I take it then, in doing this, going through this validation process for ER and PR in early 2007, had you ever been through such a validation process before yourself?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. So this was your first time out?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And the approach to be utilized you obtained from where?
DR. ELMS:
A. I received--I read some documents from Dr. Gown's lab and also from a lab in Dallas, and

Page 279

there is some information available in textbooks. There is not a specific standard procedure for doing this. Every lab has manifestations anyway of the basic principles.
COFFEY, Q.C.:
Q. But there's no one template, I take it?
DR. ELMS:
A. There's no one absolute template, no.
COFFEY, Q.C.:
Q. Now Doctor, the kind of outline then for the recipe was gotten from where? I use the word "recipe".
DR. ELMS:
A. The outline comes with the antibody itself. When we receive the antibody from the vendor, they have recommendations as to how to perform the test.
COFFEY, Q.C.:
Q. And this antibody at the time was being provided by whom? Who was the manufacturer?
DR. ELMS:
A. We have several manufacturers. We got some from Ventana. We use some--most of the ones are from Ventana, but some are from Celmarque, some are from DAKO, and some are produced by

Page 280

other organizations but sold, by other companies but sold through Ventana as well.
COFFEY, Q.C.:
Q. The ER and PR at the time, beginning of 2007?
DR. ELMS:
A. At the time, they were Ventana antibodies.
COFFEY, Q.C.:
Q. They come, I take it, prediluted?
DR. ELMS:
A. Prediluted.
COFFEY, Q.C.:
Q. At that point, do you recall what they were at the time?
DR. ELMS:
A. Our ER antibody at the time was 6F11 or 4B5. I keep getting confused between that and the--there was an awful lot of HER2/neu testing at the same time, and I don't recall the name of what was then our PR antibody. We changed it quite a while ago.
COFFEY, Q.C.:
Q. So in effect, you were getting the antibody--you had a Ventana machine?
DR. ELMS:
A. Yes.

Page 281

COFFEY, Q.C.:
Q. You had Ventana supplied antibodies?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. They supplied the formula?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Recipe, as it were?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The approach protocol, and you then experimented with that, within certain limits?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. To get what you thought was an optimum result?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Based upon a report for that particular patient?
DR. ELMS:

Page 282

A. For that particular patient.
COFFEY, Q.C.:
Q. That you had received from Mount Sinai?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2114. Now this is February 8th, 2007. It's a letter to Dr. Carter as leader of the breast pathology subspecialty task group. It's re: ER/PR and HER2/neu reporting. It's from Dr.--just on the second page, Doctor, it's from Dr. Denic.
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. It's copied to a number of individuals, including yourself, and who is the third doctor?
DR. ELMS:
A. Dr. Afrouzian, Dr. Marjan Afrouzian.
COFFEY, Q.C.:
Q. And who is that in this context?
DR. ELMS:
A. She's one of our staff pathologists at St. Clare's.

Page 283

COFFEY, Q.C.:
Q. Any particular reason she was listed here at the time, that you're aware?
DR. ELMS:
A. I'm not sure.
COFFEY, Q.C.:
Q. And he informs Dr. Carter that "after a period of 18 months, we are reinstating IHC testing for ER/PR and HER2/neu. I was given assurance by the director of immunohistochemisty department, Dr. Ford Elms, that the immunohistochemistry service has met all the requirements to continue aforementioned tests. The reporting of ER/PR and HER2/neu should come into effect immediately, according to the approved (standardized) protocols." Now Doctor, these approved standardized protocols, approved by whom?
DR. ELMS:
A. Me.
COFFEY, Q.C.:
Q. And standardized?
DR. ELMS:
A. He's referring to the validation process.
COFFEY, Q.C.:

Page 284

Q. And it's ER and PR and we do understand that it did start then in February of 2007.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. How about the HER2/neu?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And why is that?
DR. ELMS:
A. HER2/neu is a very delicate antibody, is probably the best, but I hesitate to use the word "sensitive" because that has specific meaning. HER2/neu is quite susceptible to a number of small variations in environment. It remains as yet one of the--well, remains the only antibody for which we have formal recommendations as to how you validate it and control it, and those recommendations became law in the United States in February, but they're still recommendations in this country. It requires -
COFFEY, Q.C.:
Q. Recommendations by whom?

Page 285

DR. ELMS:
A. They were put out originally by the CAP ASCO, the College of American Pathologists and American Society of Clinical Oncologists and then adopted by the Canadian working group in Toronto, and they make specific recommendations as to fixation, time and fixation, how many cases need to be done in order to validate the case. They recommend a minimum number of cases that should be read a year, and how controls should be done as the tests are made, and they're quite stringent. As I say, it's the only antibody for which we have any kind of recommendation specific as to how to validate and control them.
COFFEY, Q.C.:
Q. As to how to validate?
DR. ELMS:
A. As to how to validate them.
COFFEY, Q.C.:
Q. Period?
DR. ELMS:
A. Period.
COFFEY, Q.C.:
Q. And you, I take it, in Canada, there are still

Page 286

a number of IHC stains available, commercially available is what, pushing 200?
DR. ELMS:
A. Pushing 200.
COFFEY, Q.C.:
Q. And this is the only--HER2/neu is the only one?
DR. ELMS:
A. Yes, and we had significant problems with validating them with regards to background staining and we tried several--two antibodies at least before we arrived at SP3 and we were able to validate that. I had it validated, reviewed the material with Dr. Carter. She felt the stain was too weak, so we went back and revalidated at a more intense level, and in discussions with laboratory technologists, chief technologists in other labs, the recommendations are that you have a positive control and a negative control, but when you discuss this with other technologists, what you always hear is that "yes, but it's your equivocals that are the problem." HER2 is graded on a scale of zero to three. Zero and one plus staining have specific definitions

Page 287

and they're considered zero. Three plus staining also has a specific--as does two plus, of course, has specific definitions, and a three plus is a three. But a two plus is considered equivocal and must then reflex to FISH, which is a different technology. There's another kind of equivocal and that is you have to run two antibodies on HER2/neu, not just one. You use a sensitive one and a specific one. The other kind of equivocal is if there is a discrepancy between your sensitive and your specific and that also has to reflex to FISH. We don't have access to FISH in our lab and most of our equivocals are of the latter kind, where there's a discrepancy between the two antibodies, and so as a result of that, until I was able to get a good equivocal control, I wasn't comfortable turning on the testing of HER2/neu. We were getting it done at Mount Sinai and I felt it would be best for us to continue with that until such time as we had adequate controls.
COFFEY, Q.C.:
Q. You say adequate controls, why weren't you able to get adequate controls?

Page 288

DR. ELMS:
A. Because most of our equivocals are not of the two plus equivocal. They're of the discrepant equivocal.
COFFEY, Q.C.:
Q. And are you aware of why that would be so?
DR. ELMS:
A. Other than just that it--I know that that's a problem across the board. I've been talking to various people in various other hospitals and they have a similar problem. Not quite as acute as ours, but they do have a problem.
COFFEY, Q.C.:
Q. And this sort of problem can be caused by what?
DR. ELMS:
A. Well, it's just the rarity of two plus stains. It's not that there's something wrong with your test. It's that the equivocal HER2's can be difficult to find within your community.
COFFEY, Q.C.:
Q. I was thinking about the contradictory results between the two different stains.
DR. ELMS:
A. On the contradictory, that has to do with the

Page 289

nature of the stains themselves. We run two antibodies. One is a polyclonal and the other is a monoclonal. A polyclonal antibody is more sensitive, which is to say it'll pick up more--it will stain more things. It will rule out more false negatives, so to speak. A sensitive will stain--or a specific stain rather, will stain less frequently, but it will be more specific to the--if it's there, you're more sure that it's there. So basically a sensitive stain rules out the false negatives and the positive--or a specific rules out the false negatives. So that if you have a very sensitive stain, it is possible in your staining that you're getting staining that may well be specific to the area where you expect to see it, but it's not 100 percent sure that it's actually staining the antibody you're looking for. That is more of an acute situation with HER2. So you then do your monoclonal and then if your monoclonal as well stains, then you can be reasonably sure. If you do have a discrepancy between them, that may be an equivocal that you need to go to FISH for, and then when your FISH result

Page 290

comes back, it's of a different nature.

COFFEY, Q.C.:

Q. But you indicated discrepancy is more common here, you've noticed?

DR. ELMS:

A. I wouldn't say that it is more common here, but it is common that, I mean, every technologist that you talk to will tell you that true equivocal HER2s are rare. You can buy cell line controls which are produced bodies of cells, produced within a lab, and that are optimized to show particular levels of staining. We could use those as controls but they are not optimal controls by virtue of the fact that they're not tissue from your own lab that have been through your own particular processes, and the general wisdom in immunohistochemistry is that the better control is always the control that's been subject to what you would expect all of your tissue to be subject to in your lab.

COFFEY, Q.C.:

Q. Doctor, while we're on the idea of, well, some of the testing, HER2/neu testing is being done at Mount Sinai, had been up to this point,

Page 291

anyway.

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And continued to be. The ER/PR testing, why not just leave it to Mount Sinai, because I gather since May of this year, since Dr. Carter announced that she was going, that ER/PR testing in St. John's was suspended?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Well, first of all I'll ask you, why was that?

DR. ELMS:

A. Why was it suspended?

DR. ELMS:

A. Because we no longer had a breast subspeciality group that would be able to, as a small group, would be able to sign out all of our breast cases.

COFFEY, Q.C.:

Q. And I take it that arrangements were made with Mount Sinai for them to then, at least for a period of time, continue to do or do ER/PR?

DR. ELMS:

Page 292

A. Yes.

COFFEY, Q.C.:

Q. And the HER2/neu they were doing anyway?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, why not just simply have Mount Sinai do the ER/PR or their equivalent, Mount Sinai or another laboratory?

DR. ELMS:

A. Well, within the organization I think it was felt that, I mean, it's important to provide services for patients and this, has now become a pretty standard service in the treatment of breast cancer patients and we should be offering it. So that was the idea, that if we're going to be running an immunohistochemistry lab and if we're going to be treating breast cancer patients, we feel a need to provide the service of ER/PR testing.

COFFEY, Q.C.:

Q. Are there any other ramifications of not providing it?

DR. ELMS:

A. Well, we would be relying on an external lab.

Page 293

Cost factors would certainly be involved, time factors, as well, and you're relying on a lab, you're not doing the test yourself, you're relying on someone else's results.

COFFEY, Q.C.:

Q. Would it have any affect on accreditation?

DR. ELMS:

A. I'm not sure at this Time.

COMMISSIONER:

Q. Mr. Coffey, wherever you can find a convenient spot, we'll take the afternoon break.

COFFEY, Q.C.:

Q. Doctor, just looking to the next page of this February 8th letter it says, Dr. Denic concludes by saying "I also expect that your group should monitor and take an active role in QA of these tests with certain number of cases as decided by this group to be sent to an outside institution such as Mount Sinai for validation." I take it this is a kind of a random sampling, as it were?

DR. ELMS:

A. Um-hm.

COFFEY, Q.C.:

Q. Have them checked?

Page 294

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. Was that done?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. And what were the results?

DR. ELMS:

A. We had good correlation. I kept--the logbook was maintained by Dr. Carter and I kept in close contact with her and she never felt there was any significant issues.

COFFEY, Q.C.:

Q. So what does that, in fact, mean?

DR. ELMS:

A. Well, I believe that our correlation was three to four percent discrepancy between us and Mount Sinai.

COFFEY, Q.C.:

Q. Three to four percent in the sense of, like, 40 to 45, is that--or three to four -

DR. ELMS:

A. Oh, no, no. What I'm saying is of the cases that were sent, three to four percent -

Page 295

COFFEY, Q.C.:

Q. Of the ER/PR cases?

DR. ELMS:

A. Yes, were discrepant.

COFFEY, Q.C.:

Q. Were discrepant. And discrepant in this context would be defined as what?

DR. ELMS:

A. We called it positive, they called it negative; we called it negative, they called it positive.

COFFEY, Q.C.:

Q. And in this context calling it positive means what in this context?

DR. ELMS:

A. That we reported positivity in ten percent--it was never an issue that you had debate over whether they called it 12 and we called it eight.

COFFEY, Q.C.:

Q. Okay, so what I'm getting at is positivity defined here in a clinical oncology sense is ten percent or was it positivity, they called it zero, Mount Sinai did, and St. John's called it, I don't know, 10, 20, 30?

Page 296

DR. ELMS:

A. Or vice versa.

COFFEY, Q.C.:

Q. Or vice versa?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. That's the discrepancy you're talking about here?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. For the discrepant cases were there any inquiries made as to why they were discrepant?

DR. ELMS:

A. We reviewed the material, we reviewed the cases and reviewed back through the documentation of the quality initiatives or quality management material that was looked at. But three to four percent is not outside of what one would expect as a discrepancy between labs.

COFFEY, Q.C.:

Q. What would, in that regard, what would one expect?

Page 297

DR. ELMS:
A. Three to five.
COFFEY, Q.C.:
Q. Three to five percent?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And that figure comes from where?
DR. ELMS:
A. Various quoted sources.
COFFEY, Q.C.:
Q. I'm sorry, various?
DR. ELMS:
A. Various quoted sources. You can find it in textbooks.
COFFEY, Q.C.:
Q. Thank you, Commissioner, break.
COMMISSIONER:
Q. All right, we'll take the afternoon break.
(RECESS)
COMMISSIONER:
Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Now, Registrar, Exhibit P-2114, please? This is a letter of

Page 298

February 8th, 2007 from Dr. Denic to Dr. Carter, copied to yourself, Doctor. Doctor, so I take it then what's reflected here in the first paragraph is that you had assured Dr. Denic that the requirements to begin, at least, ER and PR reporting in the sense of at least producing the slides here in St. John's, you were satisfied that it was appropriate?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. It could be done?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Appropriately and safely?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, did anyone check your work in that regard?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. To your knowledge had ER and PR stains ever

Page 299

been validated before that in St. John's, to your knowledge?
DR. ELMS:
A. Not to my knowledge.
COFFEY, Q.C.:
Q. How about any other IHC stain?
DR. ELMS:
A. No, to my knowledge.
COFFEY, Q.C.:
Q. Doctor, just before we broke you indicated that there was on these cases that were referred out for QA to Mount Sinai, they would be ER/PR cases, some of them?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Approximately how many would that involve?
DR. ELMS:
A. I don't remember the exact number. I know we were sending approximately 20 percent.
COFFEY, Q.C.:
Q. Okay. And so and it was about a four percent discrepancy?
DR. ELMS:
A. Yes.

Page 300

COFFEY, Q.C.:
Q. Well, our of 100 cases that would be four or about one in 25?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In effect. Doctor, in those instances where that happened and what, if anything, was done then in terms of for that particular patient?
DR. ELMS:
A. We'd review the case. But that level of disagreement between labs is not unacceptable, that's what we would understand. So we would review the case, we would see if we agreed, and then decide from there. But it wouldn't necessarily treat--trigger a retest elsewhere that that--that's within the working parameters.
COFFEY, Q.C.:
Q. From lab to lab?
DR. ELMS:
A. From lab to lab.
COFFEY, Q.C.:
Q. Involving inter-lab variability, I take it?
DR. ELMS:

Page 301

A. Yes.
COFFEY, Q.C.:
Q. Sort of that phrase?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, but for the individual patient, I take it, if St. John's reviewed its--the material it had for that particular patient, that there was discordant result with Mount Sinai in the current cases?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And the local result, if you were satisfied that, yeah, we'll go, we'll accept Mount Sinai's, I take it the patients' oncologists would be told accordingly or do I have that right or wrong?
DR. ELMS:
A. We weren't doing these retests from a point of view of clinical treatment, we were doing this from a point of view of quality assurance, to monitor our results in correlation to someone else's. So it's not to say that if we say

Page 302

positive and Mount Sinai says negative, that we or Mount Sinai are necessarily wrong, it's to be sure that we are within that same parameters of concordance with other labs.
COFFEY, Q.C.:
Q. And on that point, like, the idea of random testing for QA purposes, which is what you're describing here, as within medicine does that involve clinical, potentially clinical ramifications for the patients or how does that work?
DR. ELMS:
A. I not understanding -
COFFEY, Q.C.:
Q. Well, for example, if you look at a case and you say, well, say, one in 25 you have a different result?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And you look at it and you think, well, no, our result, we're satisfied our result is appropriate?
DR. ELMS:
A. Um-hm.

Page 303

COFFEY, Q.C.:
Q. Would you communicate that to Mount Sinai or -
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Okay. How about if you looked at your case and it had been reported already?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. To the patient, the patients' oncologist and upon reconsideration you thought, no, Mount Sinai had got this--you know, this result was probably not appropriate or wrong internal result, what would happen then for that patient?
DR. ELMS:
A. It would depend on what we're talking about in terms of our result not being appropriate. As I say, we're doing this -- we're not doing this to identify specific problems with an individual case. We're doing this to see what our trends are over time, but if you would look back and see -- for instance, if we looked back and saw that our slide had been

Page 304

misinterpreted or that there was an obvious issue with the staining, then you would have to be concerned about that particular case. I'm not aware that that happened in this instance.
COFFEY, Q.C.:
Q. But those sorts of factors, you look back on your original slides and it was obvious to you that it was inappropriately reported?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Interpreted?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Well, then --
DR. ELMS:
A. You'd have an obligation to repeat the test. I don't think that I would necessarily go on Mount Sinai's result as it stood. I would repeat the test myself and then make a decision.
COFFEY, Q.C.:
Q. And I take it then, does this generally

Page 305

describe the approach to QA processes?
DR. ELMS:
A. Yes, that's the way I --
COFFEY, Q.C.:
Q. They're not done for clinical purposes per se for individual patients.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. It might be, though, that a patient is clinically affected by it depending upon the reasons upon investigation as to why there's a discrepancy?
DR. ELMS:
A. Possibly, possibly.
COFFEY, Q.C.:
Q. Exhibit P-1114. I apologize, Exhibit P-2304 first. Doctor, these are minutes of a Laboratory Medicine Program meeting of April 10th, 2007. Dr. Howell, Denic, and Mr. Gulliver are present. On page two, paragraph five, ER/PR HER2 receptors, it says, "Dr. Denic gave an update on ER/PR, and informed the lab has reinstated testing and it is going well. Dr. Denic also informed that we are

Page 306

doing comparison testing with Mount Sinai in regards to HER2 testing. Terry will arrange a meeting with Dr. Denic, Dr. Elms, and Barry Dyer, to review roles and responsibilities for the immunohistochemistry lab". Doctor, do you know if such a meeting occurred?
DR. ELMS:
A. Yes, we did.
COFFEY, Q.C.:
Q. Do you recall when that was and who was there?
DR. ELMS:
A. I'm not sure. I remember a meeting with myself, Dr. Dyer, and Mr. Gulliver, and Dr. Denic.
COFFEY, Q.C.:
Q. And it was about the roles and responsibilities for the IHC lab?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And what was the outcome of that?
DR. ELMS:
A. My understanding was that I was to be more concerned with the medical/clinical aspects of the running of the lab, that is to say with

Page 307

the approval of new antibodies, with the recommendation of antibody panels, with the interpretation of difficult cases.
COFFEY, Q.C.:
Q. In contra-distinction to?
DR. ELMS:
A. In contra-distinction to issues like staffing, payroll, maintenance of the machines, these types of things.
COFFEY, Q.C.:
Q. And who had that responsibility?
DR. ELMS:
A. Mr. Gulliver and Mr. Dyer.
COFFEY, Q.C.:
Q. Is that really any different than it had been before?
DR. ELMS:
A. No, no.
COFFEY, Q.C.:
Q. Before, in the sense of before 2005?
DR. ELMS:
A. I can't speak to what happened before 2005.
COFFEY, Q.C.:
Q. Sure, but as a pathologist looking back on it now, is it really any different for the --

Page 308

whoever the pathologist, with their individual case, they'd be responsible for reporting and interpretation of a difficult case, and staffing, and IHC, and machinery and so on was the --
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. -- technologist problem.
DR. ELMS:
A. Yes. Individual pathologists, of course, were still to be responsible for reporting their own immuno.
COFFEY, Q.C.:
Q. As the Director then, you were responsible for exactly what?
DR. ELMS:
A. For the approval of new antibodies, the retirement of old antibodies, the recommendation of panels for investigation.
COFFEY, Q.C.:
Q. Could you just explain that to the Commissioner?
DR. ELMS:
A. Well, for instance, if you are investigating a

Page 309

biopsy of prostate and you're looking for prostate carcinoma, there are specific stains that you would do.

COFFEY, Q.C.:

Q. That would be a panel of stain?

DR. ELMS:

A. That would be a panel of stains, and you wouldn't only do just the one, to rely on the one. So you could recommend not just -- most pathologists would sort of have an idea what their stains were going to be. However, as new antibodies come on line to be introduced into a panel, as new understandings of how to approach diagnosis come about, it would be up to me to recommend that to my colleagues.

COFFEY, Q.C.:

Q. In your role as --

COMMISSIONER:

Q. If you made no recommendations to the panel for a particular type of cancer, is that an indication of what's being offered in the lab?

DR. ELMS:

A. Yes.

COMMISSIONER:

Q. Which you were in before that?

Page 310

DR. ELMS:

A. Yes.

COMMISSIONER:

Q. Or would a particular pathologist who might like -- or find informative another test which you did not include, could they get that done within the lab, or would it not be offered?

DR. ELMS:

A. If we offered it within the lab, yes, they could get it done even if it wasn't something I might have recommended. If it was to be outside, we would have to make recommendations to -- make arrangements to have it done.

COMMISSIONER:

Q. Uh-hm, but they're free to do that?

DR. ELMS:

A. Oh, yes.

COFFEY, Q.C.:

Q. Doctor, were there any problems then encountered in re-instituting ER/PR?

DR. ELMS:

A. No, no, we were able to get it validated and on line.

COFFEY, Q.C.:

Q. Doctor, what about the other regions within the province, the other health authorities, were they invited to participate with St. John's?

Page 311

DR. ELMS:

A. The initial -- it was initially offered just within Eastern Health, and subsequent to that, I believe some medical directors have felt that they were quite satisfied with the service they were being provided with Mount Sinai and they continued with that.

COFFEY, Q.C.:

Q. And to this day, how has that worked, has it changed in any way?

DR. ELMS:

A. I believe Corner Brook is still sending their ER/PR to Mount Sinai.

COFFEY, Q.C.:

Q. What I'm asking about really is in terms of their involvement with St. John's. Have they been approached since to --

DR. ELMS:

A. I don't know if they've been approached since.

COFFEY, Q.C.:

Q. Certainly not by you anyway?

DR. ELMS:

Page 312

A. No.

COFFEY, Q.C.:

Q. Have you discussed with any of the pathologists in the other regions as to their views on this?

DR. ELMS:

A. Their views on having testing done -- I had early on in this process discussions with Dr. Neil in Corner Brook, and as I said, he was quite satisfied with the service they were getting, and at that time had no intent to change from Mount Sinai back to Eastern Health.

COFFEY, Q.C.:

Q. Did he express any concerns about utilizing St. John's?

DR. ELMS:

A. Just given what had happened, he preferred to stay with Mount Sinai in the interim.

COFFEY, Q.C.:

Q. Exhibit P-0050, please. Doctor, this is one of those spreadsheets. This one is dated April 26th, 2007, recommendations. See that?

DR. ELMS:

A. Yes.

Page 313

COFFEY, Q.C.:
Q. And it's 0052. It's updated April 26/07. Doctor, do you recall how it was that this came to be produced at that date?
DR. ELMS:
A. That this came to be produced at that date?
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. We had -- I had been suing this as my template for measures that I wanted to take in the lab, so it was updated to sort of keep it up to date as to what had been actually done, what was ongoing, what had yet to be done.
COFFEY, Q.C.:
Q. Okay. Was it updated at your request?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. It wasn't.
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, we understand that ER/PR matter became a matter of a large public issue in May of

Page 314

2007?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. You would be aware of that. Had you been aware of the media briefing in December of '06?
DR. ELMS:
A. Yes, yes.
COFFEY, Q.C.:
Q. Had you been asked for any input into it yourself?
DR. ELMS:
A. No, no, I wasn't in town at that point.
COFFEY, Q.C.:
Q. And then when this became an issue in May of 2007, how did you become aware of it, that it was an issue in the way it became?
DR. ELMS:
A. I knew that it was going to be announced, and, I mean, I knew that it had been an issue, I knew that there had been -- up until that point, that the issue had been looked into and that retesting had been done.
COFFEY, Q.C.:

Page 315

Q. You're thinking of December of '06. I'm thinking about May of '07 when it became a big controversy in the province, not so much the press conference, as it was talked about in the media, it was talked about in the House of Assembly.
DR. ELMS:
A. Well, I think -- what question are you asking?
COFFEY, Q.C.:
Q. I'm asking you at the time were you aware that there was a blow up, as it were, at the time?
DR. ELMS:
A. I knew that it would become an issue. I mean, obviously, this is something that was going to cause a great deal of concern to a large number of people. So it wasn't surprising to me.
COFFEY, Q.C.:
Q. Exhibit P-0114. Doctor, this is a document that's typed. It says, "Feedback from immunohistochemistry technologists", dated May 29th, 2007. The first bullet is, "Expressed concerns related to coordination of quality assurance activities for entire immunohistochemical service. Vast majority of

Page 316

IHC SOP's not signed off. ER/PR had been completed. No knowledge or feedback re; external proficiency testing, no knowledge of overall action plan or status of same, recommended training for technologists to read controls has not occurred. Overall feeling that QA activities for ER/PR are in place, but not for the remaining IHC service", and then there's another bullet, "Expressed concerns regarding communication; requests for project type work are coming from numerous sources, i.e. clinical chief, IHC chief, without explanation or knowledge of manager, requests for documentation are coming in without knowledge of manager, ER/PR retesting restarted without knowledge of manager, manager informed by technologists after the fact". Now, Doctor, first of all, were you aware that feedback was being sought from immunohistochemistry technologists in late May of '07?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Were you made aware of what's referred to

Page 317

here?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. When did you first become aware that at least in May of 2007 this reports that these are the technologists concerns?
DR. ELMS:
A. During the course of the inquiry.
COFFEY, Q.C.:
Q. Okay, at some point in the --
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. In the interviews or at some point in time, anyway, you became aware of this?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, can I ask you then, from your perspective as the Director of Immunohistochemistry, whose responsibility at least as of May, 2007, up to that point, had it been to deal with the technologists in this regard?

Page 318

DR. ELMS:
A. Mr. Gulliver and Mr. Dyer.
COFFEY, Q.C.:
Q. Did any of the technologists ever complain to you about the matter --
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. These matters?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. And in that regard, Doctor, how much time as the Director do you get to spend in the General Hospital in the IHC part of the lab?
DR. ELMS:
A. I spend roughly two hours a day.
COFFEY, Q.C.:
Q. And what, if any, adjustments are made in the rest of your pathology workload to allow that?
DR. ELMS:
A. As Dr. Denic has been able to do so, I have had my workload reduced, but that has not always been -- for the most part, that hasn't been possible.

Page 319

COFFEY, Q.C.:
Q. You've generally been carrying your share of the full time equivalent load?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. As a staff pathologist and also doing this daily visit to the IHC part of the lab?
DR. ELMS:
A. Yes, and since May it's become far more acute.
COFFEY, Q.C.:
Q. May of this year?
DR. ELMS:
A. Of this year.
COFFEY, Q.C.:
Q. And I take it that's because of the shortage of pathologists?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, since becoming aware of this document and the things referred to in it since the inquiry process started, have you made any inquiries to ascertain whether these have been addressed?

Page 320

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And what have you found?
DR. ELMS:
A. Some of them have. We have consolidated our process of reviewing our external proficiency testing, and we always discussed them as they came in, but now we discuss the actual results in tabulated form. "The recommended training for technologists to read controls" has been ongoing. That's part of what I go to the Health Sciences every day for, actually, is to read the controls with the technologists prior to release of the cases, and again, as I say, now in the fall I'll be formalizing that more with a series of lectures. "The overall feeling that QA activities for ER/PR are in place, but not for the remaining IHC service", we are developing our control bank and my understanding is that the total quality initiatives is -- that that may be a feeling, but it's not necessarily a reality, promoting QA activities for IHC. "Request for project type work coming from numerous sources", I'm

Page 321

assuming that refers to validations and the running of the lab. That has certainly been tightened up. "Request for documentation coming in without knowledge of the manager", I'm not sure what that refers to. I mean, what kind of documentation we're talking about.

COFFEY, Q.C.:

Q. And the ER/PR retesting?

DR. ELMS:

A. The ER/PR retesting was started. I informed my supervisor, Dr. Denic at the time, that we were ready to restart.

COFFEY, Q.C.:

Q. And if Mr. Dyer didn't know, then you had anticipated, I take it, Dr. Denic would pass that on?

DR. ELMS:

A. I had anticipated he would pass that on.

COFFEY, Q.C.:

Q. Doctor, in terms of QA activities for ER and PR, I take it they are in place from your perspective?

DR. ELMS:

A. Yes.

Page 322

COFFEY, Q.C.:

Q. And they are what?

DR. ELMS:

A. Pardon?

COFFEY, Q.C.:

Q. They are what?

DR. ELMS:

A. Again the usual monitoring of our machines, the retesting, the performance of our controls, and the retesting we just referred to earlier.

COFFEY, Q.C.:

Q. Retesting at Mount Sinai?

DR. ELMS:

A. Yeah, the sending away of a larger percentage than recommended, actually, of cases for retesting.

COFFEY, Q.C.:

Q. And how about other stains?

DR. ELMS:

A. That work is ongoing. We have had to build up a control bank and we are still building that up. We do provide a control with every slide, and as I say, the slides are reviewed by myself before they go out, and the remaining

Page 323

activities, I'm not exactly sure what QA is doing, but we need to -- that's an area where we're still working.

COFFEY, Q.C.:

Q. So from your perspective in terms of the ER/PR, you've described those?

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. For the other stains, are there any other stains?

DR. ELMS:

A. The other stains are in development.

COFFEY, Q.C.:

Q. That's in development process?

DR. ELMS:

A. Yes. As I said, we still haven't been sending out a proportion of our other stains, and we are also involved in -- as I said, we're also involved in proficiency testing, and that proficiency testing program, they don't only relate to ER/PR and HER2. CIQC so far has -- we have done -- we do several other spot check stains with our NEQAS, and our CAP, and the QMPLS programs.

Page 324

COFFEY, Q.C.:

Q. And how about validation of all these other stains?

DR. ELMS:

A. The validation is an ongoing process as well. We're working on validating them now.

COFFEY, Q.C.:

Q. Is there any particular master list, like, how many are you through, how many have you got to go, and I appreciate there will always be new stains?

DR. ELMS:

A. We should have -- we do have a list of our signed off protocols.

COFFEY, Q.C.:

Q. For individual stains?

DR. ELMS:

A. For individual stains.

COFFEY, Q.C.:

Q. Can you give us a ballpark figure as to how many have been validated?

DR. ELMS:

A. Ten to fifteen. That's very ballpark.

COFFEY, Q.C.:

Q. And I appreciate it's a ballpark figure, but

Page 325

ER and PR, the two of those --
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And they were the first two?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2130, please. Actually, I'm sorry, 2272. Doctor, this is -- the first page is a fax coversheet to Paul Neil, but attached to it is an e-mail from Dr. Nash Denic, with a memorandum below it of May 31st, 2007, to pathologists in Newfoundland and Labrador. It's from him and Dr. Carter. He refers to -- it says, "Please find enclosed a number of evidence-based policies in current use at the St. John's hospitals of Eastern Health", and it goes on from there. He continues on at the second page, page 2 of 3 of this, saying, "I'm inviting all lab directors to pay us a visit and view the IHC lab", and he goes on to talk about that, and suggestions can be forwarded to him and/or Dr. Ford Elms. Doctor, to your knowledge, did any of your colleagues across

Page 326

the province take you up on this offer?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. They haven't been to visit the lab, at least that you're aware of?
DR. ELMS:
A. Not that I'm aware of.
COFFEY, Q.C.:
Q. Have you been consulted by any of your colleagues across the province about this?
DR. ELMS:
A. About?
COFFEY, Q.C.:
Q. IHC service, and generally what the status is?
DR. ELMS:
A. Not in general. I have been consulted about particular cases, but not IHC in general.
COFFEY, Q.C.:
Q. How about your colleagues in St. John's? Particular cases, I take it, but --
DR. ELMS:
A. Again particular cases.
COFFEY, Q.C.:
Q. How about in terms of the lab service overall,

Page 327

IHC?
DR. ELMS:
A. Yes, I mean, we discuss it informally. I have not had any formal request or concerns about particular issues.
COFFEY, Q.C.:
Q. Here at the top of this second page at the e-mail he says, "At this visit you can get familiarized with issues and recommendations by external reviewers and the accomplishments of the IHC lab pertaining to ER/PR testing and reporting". So the issues and recommendations by external reviewers, have you ever been asked by any of your colleagues across the province as to what they were?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. For example, the issues?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. This particular exhibit, fourth page of it, and this was faxed out to Dr. Neil as apparently this had been missed and the e-mail

Page 328

sent out to him, he's told us. This particular one, breast needle core biopsy standardized reporting, there's this one, and there were a number of others went out at that time. Were you aware that these were being sent out in May of 2007?
DR. ELMS:
A. I'd need to see the --
COFFEY, Q.C.:
Q. Sure.
DR. ELMS:
A. I know that they were -- that our fixation policy was being sent out, but I'm not sure --
COFFEY, Q.C.:
Q. Okay, that's -- so you were aware that that was -- made aware that was going out?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And your understanding of the purpose in doing so was what?
DR. ELMS:
A. Was to bring greater standardization to the process across the province.
COFFEY, Q.C.:

Page 329

Q. In terms of that fixation policy, I take it that wasn't limited to ER and PR breast tissue?
DR. ELMS:
A. No, that was limited to -- that was how to fix tissue.
COFFEY, Q.C.:
Q. Period?
DR. ELMS:
A. Period.
COFFEY, Q.C.:
Q. And fixation of tissue, period, as it were, could influence all these other stains potentially?
DR. ELMS:
A. Potentially.
COFFEY, Q.C.:
Q. So it was felt important at the time to have that distributed?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Province-wide, because all the other -- even if ER/PR was being done elsewhere at Mount Sinai, all the other IHC stains were being

Page 330

done in St. John's?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. With the exception of HER2/neu?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2130, please. Thank you. Doctor, these are minutes of a joint laboratory medicine discipline and program meeting of September 13, 2007, and there are a number of individuals present, including yourself. Dr. Denic, in the first paragraph, stated that the goal is to have monthly meetings, and he passed out a schedule for these meetings, and do you recall what this was about, Doctor, in terms of your involvement, not this particular meeting so much as the purpose of this group?
DR. ELMS:
A. This is a meeting of our discipline, the laboratory medicine discipline, just for us to get together to discuss, as a body, the issues going on within the lab.
COFFEY, Q.C.:

Page 331

Q. And have these meetings continued?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And how frequently do they?
DR. ELMS:
A. Not monthly, unfortunately, especially most recently, but we do have these meetings, and Dr. Denic convenes them as we can have them.
COFFEY, Q.C.:
Q. Sure. Subspecialty task groups, paragraph seven, says, "It is expected from the members of subspecialty groups to start working on terms of reference for each group, which will be presented at the next meeting. In the future, all pathologists will be involved in QA/QC of the surgical pathology reports. A letter in this regard was passed out to the pathologists". Doctor, talking about subspecialities, would IHC be considered a subspecialty?
DR. ELMS:
A. Not in this context.
COFFEY, Q.C.:
Q. In this context.

Page 332

DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Exhibit P-2306. This is a joint laboratory medicine discipline and program meeting of October 11, 2007, and you're present. Paragraph eight reads, "IHC report. Dr. F. Elms reported that ER/PR and HER2/neu testing has been validated for new antibodies being used for testing at present, SP3 and AO485. Soon this test will be conducted on site. Prostate related antibodies are next to be validated". Doctor, we spoke earlier about ER and PR being validated, and I take it that that was the validation that had occurred early in '07?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. The HER2/neu testing, had that, in fact, from your perspective, been validated locally?
DR. ELMS:
A. Yes, it had been validated by that point.
COFFEY, Q.C.:
Q. And these two new antibodies, they relate to

Page 333

what?
DR. ELMS:
A. They are the HER2/neu antibodies. The SP3 is the monoclonal, the specific one, and the AO485 is the polyclonal.
COFFEY, Q.C.:
Q. And HER2/neu did not start here again?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. For the reasons you've enunciated earlier?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-0051, please. Doctor, this is a report from QMPLS. It's on site consultation report for Newfoundland, date and time of on site consultation is December 7, 2007, and the name of the laboratory is the immunopathology laboratory at Eastern Health.
COFFEY, Q.C.:
Q. Uh-hm, yes.
COFFEY, Q.C.:
Q. Doctor, you would have received a copy of this?

Page 334

DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Can you tell us, please, or give us your observations in relation to this? Do you recall when you received it and what your observations were?
DR. ELMS:
A. I received it early in January, I believe it was, of this year, and I received a copy through Dr. Denic. It was quite valuable, it was actually quite reassuring that we had -- we had come a good way with regard to this. It was very heartening for our technologists as well that they had -- that all of us together had worked to bring the lab up to the position that it was. They felt that -- QMPLS felt that we were certainly in the middle of the pack, and made some very, very good comments about our status, and some good recommendations as to how to proceed, most of which we were already in the process of bringing on.
COFFEY, Q.C.:
Q. Now having read this, how about in terms of distance to go to things to do?

Page 335

DR. ELMS:
A. We still need to -- we still needed to work on our SOP's, we still needed to work on our -- to tighten up our control procedures, and we certainly need to work on communication within our department.
COFFEY, Q.C.:
Q. Deal with the last first, communications within the department --
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. What did --
DR. ELMS:
A. Well, for me that meant communication between myself and the technological management of the lab, Mr. Dyer and Mr. Gulliver.
COFFEY, Q.C.:
Q. And what, if anything, have you done in that regard?
DR. ELMS:
A. We have -- we've worked at being more -- we still haven't formalized meetings and this type of thing, added to which Mr. Dyer has been off for several months, but we are in

Page 336

close communication.
COFFEY, Q.C.:
Q. Communication -- I'm sorry, the other two were?
DR. ELMS:
A. We need to -- we're working still on tightening up our control procedures.
COFFEY, Q.C.:
Q. And what does that mean, tightening up controls?
DR. ELMS:
A. Well, what I mean by that is we're working at developing a control bank because that was the recommendation made earlier, and dealing with some of the logistics of how we run our controls. We have -- also as I said, we're tightening up our documentation and our SOP's specifically, which is an ongoing process, anyway.
COFFEY, Q.C.:
Q. QMPLS were in St. John's in early December of 2007, December 7th, in particular. The actual number of SOP's that have been signed off were very few, I take it?
DR. ELMS:

Page 337

A. There were very few at that point, yes.
COFFEY, Q.C.:
Q. Very few at that point, and some of them at the time existed in draft form?
DR. ELMS:
A. In draft form.
COFFEY, Q.C.:
Q. The bulk of them had been prepared or created when?
DR. ELMS:
A. Last fall around -- between September and November of 2007.
COFFEY, Q.C.:
Q. And you had become aware that QMPLS was coming when, when did you first become aware that they were --
DR. ELMS:
A. Again the course of -- when Dr. Denic arranged it, he had contacted me and let me know.
COFFEY, Q.C.:
Q. Has any list of recommendations been made, like a spreadsheet list made in relation to this report?
DR. ELMS:
A. Not in relation to that report.

Page 338

COFFEY, Q.C.:
Q. Any reason why not?
DR. ELMS:
A. Largely as a result of time and ability to do so.
COFFEY, Q.C.:
Q. If you could look, please, at Exhibit P-2305. This is an e-mail -- it's actually several e-mails, but there's one of January 14th, 2008, at the bottom of the page there to Dr. Denic from Brenda Todd at QMPLS, advising Dr. Denic that the report is attached, the report we just looked at, and then Dr. Denic on January 15th forwarded it to a number of individuals, including yourself, and then on January 15th at 12:49 p.m., you wrote to Dr. Denic as follows, "I've read the report and will make a more detailed analysis and comments on it shortly. At this time, I note some very helpful recommendations as to how we can fine tune our documentation of times and fixation, et cetera. Further, they suggest we use controls of varying fixation times for at least specimens reflect varying times tissue spends in formalin when it is referred in from

Page 339

outside centres. We've already begun this process for breast tissue. As you are aware, we are working on a system of controls to be done and held in our lab for review". Signed, Ford Elms. Now, Doctor, was there any further detailed analysis?
DR. ELMS:
A. I did discuss the report with Dr. Denic in detail.
COFFEY, Q.C.:
Q. Was it ever reduced to writing, any further analysis?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. To your knowledge, has there been by you or anyone else?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Do you know how far along you are in terms of implementing the recommendations that are in the report?
DR. ELMS:
A. We have -- as I mentioned in that letter, we

Page 340

have worked at developing control tissues for breast tissue based on different times and fixation in formalin, and we are still working on a control bank. We're coming along very well now with that. One of the great benefits of that is that we have hired Ms. Gamberg, who has looked after a lot of those issues.
COFFEY, Q.C.:
Q. She was retained or brought in when?
DR. ELMS:
A. I believe it was February or March of this year.
COFFEY, Q.C.:
Q. How about any other recommendations there, and there are a number of them?
DR. ELMS:
A. I'd have to look down through them to --
COFFEY, Q.C.:
Q. And I appreciate that, and we can go through it kind of line for line, or paragraph to paragraph, sorry, and at times line for line.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. But in terms of systematically going through

Page 341

and, as it were, extracting a recommendation, what could be said to be a recommendation and putting it kind of number one, number two, number three, listing out however many there are --

DR. ELMS:

A. We haven't systematically done that, no.

COFFEY, Q.C.:

Q. I'll just pick one, as an example, page four - if we could go back, please, to P-0051, page four, under "Documentation/recording keeping", and "we recommend that Ventana data backups be performed on a daily or weekly basis to protect the integrity of the Ventana System information. Please see Section 9.0 for quality control recommendations". Do you know, for example, if data backups --

DR. ELMS:

A. That one hasn't been done. To do that wipes the material off the machine and we found that that wasn't feasible for us. We're still doing our six month backups.

COFFEY, Q.C.:

Q. I take it that's using a zip drive?

DR. ELMS:

Page 342

A. Yes.

COFFEY, Q.C.:

Q. Is there any reason that couldn't be done using a zip drive daily?

DR. ELMS:

A. As I say, it takes the information off the machine from a day-to-day basis, so it makes it more difficult for us to be able to compare from day to day.

COFFEY, Q.C.:

Q. So in making a backup, you take all --

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. The process takes the information off the Ventana computer?

DR. ELMS:

A. Yes, that's what I've been advised by my tech staff.

COFFEY, Q.C.:

Q. Doctor, do you think it might be worthwhile to actually have someone make a listing of all what could be made recommendations?

DR. ELMS:

A. Definitely.

Page 343

COFFEY, Q.C.:

Q. And then you could kind of check them off or at least make a note as to where -

DR. ELMS:

A. Yes.

COFFEY, Q.C.:

Q. - as a group you are. Exhibit P-2157? This is a large document, yes. Sorry. Thank you, Registrar. Doctor, this is a document, "Pathology Policies and Procedures Manual, Table of Contents." The first page here is "Pathology policies," and there are a list of them there. There's seven, I think, here on this page. And then the pathology procedures begin at page 2 of the document. And the table of contents continues on the third page and so on. Doctor, I'm going to take you through to, if I could, please, page 201? Doctor, this particular one is entitled "Pathology Procedure" the second is "Anatomic Pathology/Immunohistochemistry" and there's a number associated with it titled "Immunohistochemistry Stain Process Flow Chart." Issuing authority is yourself?

DR. ELMS:

Page 344

A. Um-hm.

COFFEY, Q.C.:

Q. And the signature is March 17th, 2008. The author is Ken Green and the issue date is March 19th, 2008 and date effective, March 19th, 2008. And there's a space for revision dates?

DR. ELMS:

A. Yeah.

COFFEY, Q.C.:

Q. And, Doctor, if you can just--the next page is noted to be left blank intentionally. And then page 203 of the exhibit is titled "Ancillary Products, Records" and again, its issuing authority is yourself. And then as we go through, on page 205 again there's another entitled "Ordering Class Slides" and issuing authority is yourself. The author is Ken Green. I could take you through a number of them here. I just collected them here at the end of the book that's there in front of you. Doctor, how is it that you--how is it determined that you are the issuing authority and Mr. Green is the author and what process is utilized for this?

Page 345

DR. ELMS:
A. When it became--well, when I was told I was required to write the SOPs, there's a significant number of SOPs that relate to the technological running of the test, the running of the machines, this type of thing. Mr. Green is my lead tech and he has been an invaluable aid in this. He actually compiled most of the SOPs, especially the ones to do with the technological aspects. We were then--these were written out in rough form by hand. We then submitted them to Ms. Wade, who passed them on to Quality Assurance. And I guess my name is there as issuing authority because I'm the medical director of immunohistochemistry.
COFFEY, Q.C.:
Q. So you would perhaps see them in draft form?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Handwritten form and get a typed version and say, okay, I'm satisfied with that and signify that and -
DR. ELMS:
A. Yes.

Page 346

COFFEY, Q.C.:
Q. - and then it would be approved?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And issued. And if we look, in fact, this particular one is March 17th, 2008. And then page 203, it's issued and you're the issuing authority, March 17th, 2008. Page 205, same thing, different pathology procedure. Page 207, same thing, you're the issuing authority, March 17th and it's a different title or aspect of the matter. And we go on through, there's another one at page 209 of the exhibit issued by yourself March 17, 2008. And page 211 of the exhibit the same thing. There are quite a number of them.
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. March 17, 2008. Is there any particular reason why it was March 17, 2008 that a group of them got issued?
DR. ELMS:
A. Mr. Green was compiling them over the course of time and it's quite conceivable that they were submitted to QA all at the same time.

Page 347

COFFEY, Q.C.:
Q. And, Doctor, currently, I take it, and we referred to this earlier, that ER and PR reporting is not going on in St. John's?
DR. ELMS:
A. Not since the beginning of May.
COFFEY, Q.C.:
Q. Not since the beginning--since May of 2008?
DR. ELMS:
A. Of 2008.
COFFEY, Q.C.:
Q. What is the plan right now?
DR. ELMS:
A. The plan is to return to ER/PR testing when the situation permits. That would require reconstituting our breast group, so we would need to find--Dr. Makretzov has agreed to be the core. We would need to find another two people, at most, to function as a breast group. It will also require revalidation of the antibody.
COFFEY, Q.C.:
Q. And why is that?

Page 348

DR. ELMS:
A. Because over time antibody specificity can drift. If you're running daily controls and you're reading daily controls, you can pick it up before it becomes significant, so you can see, for instance, your stain weakening if you're seeing the same control tissue every day. We have not been doing that now since May, so therefore I would need to--I wouldn't be comfortable without going back and revalidating it because I don't know what drift may or may not have occurred in the course of that time.
COFFEY, Q.C.:
Q. And what would cause such drift or could cause such drift?
DR. ELMS:
A. It has to do with degradation of the antibody over time. It's a protein product and it would gradually break down.
COFFEY, Q.C.:
Q. Okay, the actual--the chemical?
DR. ELMS:
A. Yeah.
COFFEY, Q.C.:

Page 349

Q. Or chemicals in the liquid form?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-1840? How long, Doctor, would validation take?
DR. ELMS:
A. Revalidation of this nature might take me a week.
COFFEY, Q.C.:
Q. And, Doctor, this is a letter of April 14th, 2008, it's addressed to myself as Commission co-counsel. It's from Dr. Mullen, Brendan Mullen. And he had examined a number of individual original slides, ER/PR slides. Have you seen this? Take your time, Doctor, I'll just bring it back up and just -
DR. ELMS:
A. I believe this was entered into evidence previous in the Inquiry?
COFFEY, Q.C.:
Q. Yes, oh, yes.
DR. ELMS:
A. So I would--I saw it over the course of that.
COFFEY, Q.C.:

Page 350

Q. And at the bottom of the first page he says, "To summarize my observations, the overwhelming majority of cases had one or more of the following problems: (1) Poor fixation or processing resulting in incomplete tissue sections; loss of the internal structure of the nucleus; and staining restricted to the periphery of the slide." And he goes on from there, talks about exploding sections and so on. Her refers to hollow nuclei as the second issue and the third issue, staining restricted to the periphery. He in paragraph 2 refers to the absence of internal controls, that would be for any particular slide or slides. And negative internal controls where the tissue was, normal tissue was present but not stained, or stained very weakly. And stain deposit obscuring morphology and external controls and them being inconsistent both between slides and within slides, some had barely stained. And then discrepancy between internal and external controls, and he found that only in one or two--of the--two of the 539 cases he had reviewed. Now, Doctor, when you had a chance to review this, did you have

Page 351

any thoughts or observations on this, what Dr. Mullen reported as, at least in his view in terms of looking at these 539 cases that go back to the--there are a portion of the case during the time period?
DR. ELMS:
A. I'm not sure -
COFFEY, Q.C.:
Q. Did you have any thought at the time in terms of, well, did you take any issue with anything?
DR. ELMS:
A. Did I take issue with anything?
COFFEY, Q.C.:
Q. Yes.
DR. ELMS:
A. I certainly didn't--I wasn't aware that to say that the overwhelming majority of issue was to do with anything specific. As I say, I had seen my own cases, but I was looking at the results of someone who had looked at, you know, the majority of the cases across the--across our organization.
COFFEY, Q.C.:
Q. The fact that, for example, internal controls

Page 352

might be there but not stained, be negative, in your own individual case for a period of time you had not been even aware to have internal controls?
DR. ELMS:
A. Exactly, exactly.
COFFEY, Q.C.:
Q. So that wouldn't be--if they weren't stained, you wouldn't be surprised by it?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Or the fact that there wasn't any internal control tissue there?
DR. ELMS:
A. Again, no, I wouldn't be surprised.
COFFEY, Q.C.:
Q. You wouldn't be surprised by that. Doctor, the idea of, the issue of fixation itself and the various problems that can have for ER and PR staining, you know, knowing what you do now, what if any steps, you know, in your position have you taken to address that?
DR. ELMS:
A. Well, personally I haven't taken steps, but

Page 353

our -
COFFEY, Q.C.:
Q. Or what are you aware of?
DR. ELMS:
A. - department has. So that we now have a fixation policy, we document the time that the tissue goes in formalin, we document the time that it--or we document, rather, when it arrives in the lab. In the case of specimens like breast, for instance, they're brought to us fresh, the times are documented, the tissue is incised and fixed properly. So, I mean, the issue of fixation, to my way of thinking now, is--has been dealt with.
COFFEY, Q.C.:
Q. Have there been any concerns expressed to you about fixation or tissue processing since you took over as director?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. In terms of current cases?
DR. ELMS:
A. In terms of current cases, no.
COFFEY, Q.C.:

Page 354

Q. Nothing brought to your attention?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. Doctor, one final point, if we could. Again, please, at Exhibit C-0174? Doctor, this is the case involving a request by Dr. Zaidi I showed you earlier.
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And, you know, this change in result which is reflected here between addendum 2 and addendum 3 that occurred in 2002, 2003, as you can see there, are you able to tell the Commissioner why it was that in 2005 you brought the matter to the attention of Dr. Cook, the conversion for Peggy Deane, and as best you can recall, and if you don't recall bringing it to his attention in '03, why that was?
DR. ELMS:
A. I may have, I may not have, I'm not have; I'm not sure. I reported it to the clinician involved. As I say, I'm not sure that I didn't do that, didn't report it to Dr. Cook,

Page 355

but I have no recollection of having done so.
COFFEY, Q.C.:
Q. Doctor, in that regard, you know, here in 2005, just thinking about it now in terms of Peggy Deane, you reported it to, well, Dr. Rorke?
DR. ELMS:
A. Um-hm.
COFFEY, Q.C.:
Q. And Dr. Cook?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. And from your perspective now, as a staff pathologist at the time, throughout '05, was there any immediate steps taken to do any retesting of anyone else in April of 2005?
DR. ELMS:
A. When -
COFFEY, Q.C.:
Q. I mean by yourself?
DR. ELMS:
A. When I--I didn't take any steps to retest my cases, no.
COFFEY, Q.C.:

Page 356

Q. And to your knowledge did anyone?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. In your department?
DR. ELMS:
A. No.
COFFEY, Q.C.:
Q. So as you described to the Commissioner earlier today, it was when the oncologists began to come forward with a case or two afterward?
DR. ELMS:
A. Yes, there was -
COFFEY, Q.C.:
Q. Expressions of concern?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. That that resulted in them individual cases being retested and then more and more?
DR. ELMS:
A. Yes.
COFFEY, Q.C.:
Q. Okay. Thank you, Commissioner. Thank you,

Page 357

Doctor.
THE COMMISSIONER:
Q. Mr. Pritchard, do you have any questions of this witness?
MR. PRITCHARD:
Q. No, Commissioner, I don't have any questions of this witness. Thank you, Doctor.
THE COMMISSIONER:
Q. Mr. Simmons?
MR. SIMMONS:
Q. I have a few questions, Madam Commissioner. I wonder at this point if either counsel know and they may or may not, if Dr. Elms is coming back tomorrow anyway?
THE COMMISSIONER:
Q. Well, we'll find out how many others would wish to question him. Do you have any idea how long you might need?
MR. SIMMONS:
Q. Maybe 15 or 20 minutes.
THE COMMISSIONER:
Q. All right.
MR. SIMMONS:
Q. We need to reflect on it (inaudible).
THE COMMISSIONER:

Page 358

Q. Oh, you're always holding out these carrots to me. Now, oh, Mr. Pritchett?
MR. PRITCHETT:
Q. We have no questions of this witness, thank you.
THE COMMISSIONER:
Q. Are you going to have any questions, Ms. Newbury?
MS. NEWBURY:
Q. I don't think so.
MR. PIKE:
Q. No questions.
THE COMMISSIONER:
Q. No questions. Do you have any questions, Mr. Brocklehurst?
MS. BROCKLEHURST:
Q. Just a couple.
THE COMMISSIONER:
Q. Just a couple?
MS. BROCKLEHURST:
Q. Yes.
THE COMMISSIONER:
Q. Mr. Browne, do you want to weigh in on a length of time?
MR. BROWNE:

Page 359

Q. At this point I just have a couple of questions, I would say about five to ten minutes, but it may expand or shorten, depending on the questions they'll be asking. So I don't anticipate -
THE COMMISSIONER:
Q. We're looking at being able to finish by about 5:00 and I don't know, but I don't imagine our witness would relish coming back tomorrow if he doesn't have to.
MR. SIMMONS:
Q. I have my doubts.
THE COMMISSIONER:
Q. Have I read that correctly?
DR. ELMS:
A. You've read that very correctly.
THE COMMISSIONER:
Q. Okay. Mr. Simmons.
MR. SIMMONS:
Q. This may, in fact, mean I'll be shorter rather than longer, Dr. Elms. Dr. Elms, as you know, I'm Dan Simmons, I'm the lawyer here for Eastern Health. I wonder if maybe you could describe for me a little bit more about what it is you do as the director of

Page 360

immunohistochemistry, a bit of a description of what it means hands on to be in that position, the type of function you carry out, the type of tasks that you do in that position?
DR. ELMS:
A. Well, what I have been doing largely has been I've had a much more hands-on role with the validation process than I had originally anticipated and I also read the controls and assess the tissue. Also, I look at difficult cases as a sort of a consultant role for other pathologists; I've received requests from other pathologists to assess their cases. And keep abreast of the literature, assess the need for new antibodies, the introduction of new antibodies, getting them validated.
MR. SIMMONS:
Q. Okay. How closely do you work with the technologists, the technical staff in the immunohistochemistry lab?
DR. ELMS:
A. Quite closely. We, as I say, we spend upwards of two hours a day every day. We read the controls, we discuss the cases. If there's

Page 361

proficiency testing material to be read, we go through that.

MR. SIMMONS:

Q. Okay. We know that the historical structure in the lab has had the technologists reporting in a formal way to the pathology manager who reports to the program director. How--does that still work the same way now or have you taken on some role where you have a role in actually instructing or directing the activities of the technologists in the IHC lab?

DR. ELMS:

A. In terms of, for instance, doing the validations, I have some role, yes. We still have a parallel structure and we're working still at deciding where it is I fit into that structure. Ideally I'd be, I would assume, at much the level of Mr. Dyer in the clinical wing, so to speak, of the management of the IHC lab.

MR. SIMMONS:

Q. Okay. I take it that when you assumed the position as director of immunohistochemistry, the precise details of what that position was

Page 362

going to involve may not have been well defined at that point?

DR. ELMS:

A. That's correct.

MR. SIMMONS:

Q. And has it been a process as time has gone on of working out how this position fits within the structure and what's the best way to make it work?

DR. ELMS:

A. That is correct.

MR. SIMMONS:

Q. Okay. And what has your experience been in the position in regards to dealing with the technologists and the other managers in the system?

DR. ELMS:

A. It's been very good, actually, the technologists and I work very closely together.

MR. SIMMONS:

Q. Um-hm.

DR. ELMS:

A. And as things have improved, they have taken on a more active role in the performance of

Page 363

tests, in the identification of cases, these types of things. So that, for instance, the reading of the controls, as I say, I've been going over the workhorse controls with them. We read our controls on a daily basis. And as they have become familiar, we're still not at a stage where it's routine that I have designated a technologist to read the controls and send them out, but I'm becoming more and more confident that they're able to do that because they can--they are able to identify things much better now, they take a more, more hands-on control.

MR. SIMMONS:

Q. Right. There's been recommendations that come out of the external review reports from, among other things, saying that the technologists have a role in reading controls, and we know that historically it has been the pathologists here who have reviewed the external controls and have looked at the internal controls on slides here. Can you tell me are there any particular advantages or disadvantages to having the technologists involved in the review and the reading of the controls, where

Page 364

do you see that?

DR. ELMS:

A. In terms of the running of the lab, it's very advantageous because the accepted wisdom sort of within immunohistochemistry now is that the controls should be read by the medical director or the medical director's designate.

MR. SIMMONS:

Q. Um-hm.

DR. ELMS:

A. And so the idea behind that is that there should be two people. If the medical director is away, if, God forbid, the medical director is ill, there is someone else who can do it, and so it's always good to have these skills among more than one person in your lab. So there is that benefit to doing that. And that would be the main thing is the sort of a diversification of ability.

MR. SIMMONS:

Q. Where do you see the technologists role in reading the controls going, how do you see it developing here, will it displace the pathologist's role in reviewing controls or will that continue?

Page 365

DR. ELMS:
A. I would--not so much displace. I know, for instance, in PhenoPath it pretty much had displaces and it was the senior techs who read them. In the lab now I would see it being a joint effort.
MR. SIMMONS:
Q. Um-hm.
DR. ELMS:
A. I certainly would not want to have a situation where the technologists were letting go all the controls, and I didn't see them, just because as I said, in immunohistochemistry the general wisdom is that that shouldn't happen. But, I would be very comfortable with, for instance, once I have gone through the histologic processes of them and the techs feel comfortable and we have certified in some fashion their ability to do it, with letting them on a, you know, with them on a day-to-day basis signing out individual cases if need be. But I certainly wouldn't see it as them totally usurping my role as the person who reads the controls.
MR. SIMMONS:

Page 366

Q. Right, okay. You mentioned Ms. Gamberg as being someone that knew in the immunohistochemistry service since you have--and she's joined it since you've become the director, I believe?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. Yes. Is there a title for her position now, because I--there may not be.
DR. ELMS:
A. We've mooted the title of technical director, but we don't really have a title for her, as yet.
MR. SIMMONS:
Q. Right. And what's her background and qualifications?
DR. ELMS:
A. Her background is in immunology and she has a great deal of experience in quality assurance.
MR. SIMMONS:
Q. Um-hm.
DR. ELMS:
A. And so it was for those two areas of expertise that I was most interested in having her.

Page 367

MR. SIMMONS:
Q. Right. What role is she playing now in the IHC lab?
DR. ELMS:
A. She has been working at developing our control bank. She has taken over from Mr. Green the performance of the validations, the identification of the validation tissue. Prior to her coming on stream myself and Mr. Green would have to search for the cases and that necessarily takes time from both of us; she now does that, prepares the slides, and when we--as we're doing our validation runs, it's she that works through them and then brings them to me and we go over them together.
MR. SIMMONS:
Q. Her position is an additional position in the IHC lab?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. In addition to the technologists who were there when you took up your director position, correct?

Page 368

DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And does she have to perform any duties outside the IHC service?
DR. ELMS:
A. No.
MR. SIMMONS:
Q. No. So she is dedicated to the IHC service. And is she a laboratory technologist herself?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. Yes. In addition to having a background in immunology and I believe she has a PhD in -
DR. ELMS:
A. Immunology.
MR. SIMMONS:
Q. In that area, okay. And who is it that primarily directs her work?
DR. ELMS:
A. That would be me.
MR. SIMMONS:
Q. And how has that been working out?
DR. ELMS:

Page 369

A. Very well.
MR. SIMMONS:
Q. Now you've described the current process for antibody validation and if I understand what you said, Ms. Gamberg is now going to play a role in that, and you've also mentioned current--the proficiency testing programs and I believe you mentioned four.
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. One is the CAP program that has been in place for some time?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. If I understand correctly, that's a program where the--is it the College of American Pathologists operates it?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And they will send a case consisting of a number of slides which are to be reviewed and interpreted and reported on by the

Page 370

pathologists?
DR. ELMS:
A. Yes, a number of cases.
MR. SIMMONS:
Q. Okay, and the UK NEQAS program we have heard about here before.
DR. ELMS:
A. Um-hm.
MR. SIMMONS:
Q. And if I understand correctly, in that program, they will send the laboratory a slide, slides that have been prepared by them for staining and they will also send, I believe, tissue samples for slides to be prepared?
DR. ELMS:
A. No, they send slides prepared by them.
MR. SIMMONS:
Q. Yes.
DR. ELMS:
A. And then we prepare equivalent slides from our own in-house tissue.
MR. SIMMONS:
Q. Okay. So there is a NEQAS prepared slide and an in-house slide as part of that program.

Page 371

DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And the ER/PR, two of the antibodies for which Eastern Health participates in the UK NEQAS program, I believe?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And other antibodies as well?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. Okay, and how often are their submissions to the UK NEQAS program?
DR. ELMS:
A. Quarterly.
MR. SIMMONS:
Q. And do you play any role in monitoring the results of that, that program?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And what has your experience been with the results for ER/PR testing from the UK NEQAS

Page 372

program?
DR. ELMS:
A. They've been quite--we have, at times, received full scores.
MR. SIMMONS:
Q. Okay. You mentioned also CIQC.
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And I believe that is a relatively new program?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. Is that fully implemented yet or is that still in the development stages?
DR. ELMS:
A. It's at the transition stage between that. They've had three runs now. We have taken part in the last two.
MR. SIMMONS:
Q. And who is running that program or sponsoring it?
DR. ELMS:
A. That's run in B.C. at the B.C. Cancer Agency.

Page 373

MR. SIMMONS:
Q. Can you tell me how that proficiency testing program is working so far? What comprises it?
DR. ELMS:
A. We receive a tissue micro ray slide from CIQC. That is a specific technology in which small portions of tissue are cut from a block and these are all then embedded in a single block and they're embedded in an array in order. That slide is sent to us and then we stain it. We're then given a little template, a map, so that the way that the--it's done in a rectangle, but there's a gap in the top left corner, so you know that the piece of tissue immediately to the left of it is zero. That's the benchmark.
MR. SIMMONS:
Q. So you know which way is up.
DR. ELMS:
A. And you know which way is up, and then the next one over from that is number one, two, three, four and along and we're given a map, so to speak, with that and we grade each of these portions of tissue and then we send it to CIQC and they review it, and they have an

Page 374

online resource where we can see our slides, a micro photograph of our slides, and compare them with the micro photographs of other slides from other labs taking part in the program, and we also get what's called a garrattogram and that is a two by two lay out, a table, in which each lab has a column and then each row coming down is a specific case that was on the slide. And so we have a list of all the labs across the country with all the case--that take part in the program, with all the cases that are being tested at that time, and then in the case of ER, it's colour coded so that a red means positive. So if we called it positive, we'd have a red for that particular case. And the advantage of doing it that way is that you can by eye then compare yourself to other labs across the country. So that if you--you can see how high the concordance is all across the country and where our lab sits in relation to others. So if in each one you see that you're getting a--you're saying negative when someone else is getting positive, then you know that you're doing something--that there's something going

Page 375

on. If however you have concordance with other labs, then you're standardized with regard to the other labs.
MR. SIMMONS:
Q. Okay, and has there been a run for ER and PR in the CIQC program?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And how has--do you know how well your lab has done?
DR. ELMS:
A. We've done well.
MR. SIMMONS:
Q. So that's the CAP proficiency testing, UK NEQAS, CIQC and there's also, I believe, proficiency testing offered by the QMPLS program from Ontario, isn't it?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. And how does that work?
DR. ELMS:
A. That is they send us slides and we--in much the same way as UK NEQAS. They send us a

Page 376

slide and we provide a slide of our own in-house material. We stain it and submit it back to them and then they assess our staining and we're presented back with a report that gives a very detailed list of the various aspects of the slide that they look at and what our score is. We're given what the maximum score is and what the average score is on those that took part, and then in each area, the score is summarized into a final score and then there's an overall final score and we can also again visually access that online.
MR. SIMMONS:
Q. Okay, and in addition to all that, you've also told us that approximately 20 percent of the ER/PR slides that have been produced here, those specimens have also been sent to Mount Sinai for them to retest for comparison purposes?
DR. ELMS:
A. Yes.
MR. SIMMONS:
Q. You were asked some questions about technologists training in IHC and you told us,

Page 377

as we've heard elsewhere, that Mr. Green, for example, went to Montreal General or Jewish General, I believe.

DR. ELMS:

A. Jewish General.

MR. SIMMONS:

Q. For a couple weeks, and that some of the technologists have been to the Ventana facility, I believe in Arizona.

DR. ELMS:

A. Yes.

MR. SIMMONS:

Q. Where they've done some training as well. Do you know if there is anything like a school anywhere that a technologist can go to to learn IHC training?

DR. ELMS:

A. Not that I know of.

MR. SIMMONS:

Q. Have you ever heard of any such thing being available, being possible to do that?

DR. ELMS:

A. No.

MR. SIMMONS:

Q. Are you aware of any types of training

Page 378

specific to performing IHC that would be available for technologists, other than the types of opportunities that have been taken advantage of here?

DR. ELMS:

A. Well, as I said, we also subscribe to online seminars and there are also conferences going on yearly. Our technologists are going off to a conference later this month actually and we have obtained funding for that.

MR. SIMMONS:

Q. Is there anything else though that you're aware of that would be a good opportunity for them, another -

DR. ELMS:

A. Not that I'm aware of.

MR. SIMMONS:

Q. Okay. Do you know if there's any formal certifications of any sort available for technologists for IHC?

DR. ELMS:

A. Again, not that I'm aware of.

MR. SIMMONS:

Q. Your office is currently located where?

DR. ELMS:

Page 379

A. At St. Clare's.

MR. SIMMONS:

Q. Is there a plan for that to change?

DR. ELMS:

A. Yes.

MR. SIMMONS:

Q. And you are moving to Health Science Centre?

DR. ELMS:

A. Yes.

MR. SIMMONS:

Q. And do you know when that's planned to take place?

DR. ELMS:

A. I hope to move later on this month.

MR. SIMMONS:

Q. Okay. Will that in any way help facilitate your role as director of immunohistochemistry?

DR. ELMS:

A. Greatly.

MR. SIMMONS:

Q. Has there been any kind of impediment preventing you from moving before this?

DR. ELMS:

A. Lack of space. There haven't been offices that I would be able to avail of.

Page 380

MR. SIMMONS:

Q. Now you have reviewed the external review reports that were prepared by Dr. Banerjee and Ms. Wegrynowski, and the QMP-LS report from December of 2007 and all the recommendations contained in those reports, I believe?

DR. ELMS:

A. Yes.

MR. SIMMONS:

Q. Okay. As director of immunohistochemistry, have you been specifically charged in any general way with the implementation of all those recommendations or has your role been narrower?

DR. ELMS:

A. My role has been narrower. As I said, some of the recommendations to do with documentation of the running of the machines were in place when I started.

MR. SIMMONS:

Q. Yes. Are you aware of any significant initiatives yet to be taken or yet to be tackled coming out of any of those reports?

DR. ELMS:

A. Significant initiatives, no.

Page 381

MR. SIMMONS:
Q. Okay. Now there's probably always room for growth and improvement in a service like this, in a technological scientific based service. Are there any areas, are there any things that you would still like to see done that would improve your ability to do your job or the lab's ability to deliver quality, reliable IHC testing?
DR. ELMS:
A. I would like to see a greater emphasis put on administrative support. As it stands now, I do not have a secretary. I do not have a filing cabinet and no place to file anything. When there are memos to be done, I either type them myself or someone is found to do it. In the purpose of typing memos, that's not such a bad things, but when you're talking about the collating of this kind of quality assurance data and the documentation and validations, that becomes--it's not satisfactory to have one person today and another person tomorrow. You need someone who knows what--who understands what the material is.
MR. SIMMONS:

Page 382

Q. Yes. You've been in, I'll say, the system here now for ten years or more. Is the lack of that sort of administrative support something unique to pathology or the laboratory or is that more common in your experience through the health care system?
DR. ELMS:
A. My only experience outside of this was in working as an emergency physician and the general attitude as an emergency physician is that you're an independent contractor. So it wasn't expected that there would be any of that kind of administrative support. You would provide that on your own. So I can't say what goes on in other departments other than pathology.
MR. SIMMONS:
Q. Okay. It's 5:00. Thank you very much, Dr. Elms.
DR. ELMS:
A. Thank you.
THE COMMISSIONER:
Q. Mr. Pritchett, are you of the same position, no questions?
MR. PRITCHETT:

Page 383

Q. I am, Commissioner, thank you.
THE COMMISSIONER:
Q. Ms. Newbury?
MS. NEWBURY:
Q. I just have a couple questions.
DR. FORD ELMS, EXAMINATION BY MS. JENNIFER NEWBURY
MS. NEWBURY:
Q. Good afternoon, Dr. Elms. Jennifer Newbury for the Canadian Cancer Society, Newfoundland and Labrador Division. I just wanted to ask you a couple of questions about a couple of the pathology reports that you've been shown earlier today, starting with C-0174, please. This is the repeat test requested by Dr. Zaidi, and as we've gone through that earlier today, there have been a change in results from 2002 to 2003, and you've indicated that you can't recall whether or not this had been reported to anyone at the time, as you did with Ms. Deane's case when you reported it to Dr. Cook, and I'm just wondering if you would have expected that some record would have been kept if you had made such a formal report or an informal report to anyone, such as Dr. Cook?

Page 384

DR. ELMS:
A. No, not as a matter of routine.
MS. NEWBURY:
Q. Okay, and why not?
DR. ELMS:
A. I would have reported this--had I reported it, and as I say, I don't recall doing so, but I would have reported it to Dr. Cook. I'm not sure what he would have done as a report. I certainly wouldn't have at the time expected to have done so.
MS. NEWBURY:
Q. And you're not aware then of any protocols or any requirements that are placed upon a person to whom you're reporting to make a note of it?
DR. ELMS:
A. Not at the time, no.
MS. NEWBURY:
Q. Okay, and if you encountered such a situation today, how would you address that, in terms of any reporting protocols?
DR. ELMS:
A. Knowing what I know now?
MS. NEWBURY:
Q. Yes.

Page 385

DR. ELMS:
A. I would very much document it, yes, and look into the situation.
MS. NEWBURY:
Q. Okay, and are there any formal procedures in place that you know that you would go to this procedure or that procedure to follow or would you just -
DR. ELMS:
A. Not that I know of right now.
MS. NEWBURY:
Q. Okay. But you would make sure that you had it documented?
DR. ELMS:
A. Yes.
MS. NEWBURY:
Q. And you had reported it to someone?
DR. ELMS:
A. Yes.
MS. NEWBURY:
Q. And if I could have Exhibit C-0156, please? And this is the pathology reports related to Peggy Deane, and you may want to refer to that. You'd indicated earlier this morning that you had, subsequent to the retesting with

Page 386

the different results for ER/PR, you went back to verify the diagnosis that you had given, the lobular carcinoma, and that was a couple of days after.
DR. ELMS:
A. Yes.
MS. NEWBURY:
Q. Is that recorded anywhere here in this document?
DR. ELMS:
A. No.
MS. NEWBURY:
Q. Okay, and why not?
DR. ELMS:
A. I went back as an educational measure, more than anything. I wanted to see what I had done and what I had said and compare it to what I had been told, Sloan Kettering had said.
MS. NEWBURY:
Q. Okay, and if you were to do that again today, for example, even if it is just for your own educational purposes, would you make a record of that anywhere?
DR. ELMS:

Page 387

A. I might make a record for my own sake. I don't think I'd make a record for the patient's chart.
MS. NEWBURY:
Q. Okay. There's no requirement that you're aware of?
DR. ELMS:
A. No.
MS. NEWBURY:
Q. And would it be beneficial, do you think, to report it on a report, to say that it's been double checked?
DR. ELMS:
A. In this kind of instance, I would think the patient would know that it had been checked elsewhere and would know that result. If I was to review that case, I would think one of two things, either I would agree with my original assessment or that I would agree with the other one. I'm not sure that that would be of benefit, but it's not for me to second guess what's beneficial to the patient, in terms of what the patient would understand. But I'm not sure that would not simply add to the confusion, especially if I disagreed. I

Page 388

mean, if you have Sloan Kettering saying we think one thing and I say something else and then put my foot down and say "no, I'm right," I can't see that being beneficial for a patient.
MS. NEWBURY:
Q. What about to just provide the information and even if you personally can't resolve that issue, at least then the patient or her treating clinicians would know that?
DR. ELMS:
A. Well again, if I have already made an opinion on the case and now an expert has disagreed with my opinion, I'm not sure that it would benefit for -
MS. NEWBURY:
Q. If you had disagreed with your original opinion, do you think that would be of any value?
DR. ELMS:
A. Yes, I mean, it would be worthwhile, I guess, for the patient to know that. As it stands, there's really no protocol whereby we do that.
MS. NEWBURY:
Q. Now in this case here, I think with Ms.

Page 389

Deane's reports, it turns out that the diagnosis from the retest was the same as your original one. It was still lobular carcinoma. I just want to make sure.

DR. ELMS:

A. That was my understanding.

MS. NEWBURY:

Q. Okay, and you had put in some comments about some features of ductal carcinoma as well, but essentially it was still considered lobular carcinoma, as far as you know?

DR. ELMS:

A. That was my understanding.

MS. NEWBURY:

Q. Okay. It's also noted there that there was a reference that you had a discussion with Dr. David Pace. This was early, back in June of 2002.

DR. ELMS:

A. Yes.

MS. NEWBURY:

Q. So before any of the retesting was done, and this morning you'd indicated that you had actually called Dr. Rorke immediately when you still had the specimen on the slide, to let

Page 390

him know of the new ER/PR results.

DR. ELMS:

A. Yes.

MS. NEWBURY:

Q. Is that recorded anywhere here in this report?

DR. ELMS:

A. No.

MS. NEWBURY:

Q. Okay, and in this case, the actual written diagnosis wasn't made until May 31st, as indicated -

DR. ELMS:

A. The actual written documentation of what I had found on the ER/PR retest, no, it wasn't.

MS. NEWBURY:

Q. Okay, and why not have recorded your call to Dr. Rorke, even if you didn't go into the detail there?

DR. ELMS:

A. The original phone call with Dr. Pace was probably on the basis of the patient in the clinic awaiting the result and we would document that. If there was going to be a delay in us signing out the case, we would document that we had called them. But in this

Page 391

instance, as I said, the case had been dealt with and I was content that the oncologist dealing with Ms. Deane knew the result and would act on it. So it was--that was what was most important for me, was that they knew it and could act on it, because I knew they were waiting for the material.

MS. NEWBURY:

Q. Okay. So if you had a situation today where you had done a retest for whatever reason, and didn't get around to providing a written report until some weeks after, would you -

DR. ELMS:

A. Yes.

MS. NEWBURY:

Q. - proceed in the same manner or would you write a note?

DR. ELMS:

A. I would document that, at this point.

MS. NEWBURY:

Q. Thank you, Dr. Elms. Those are all the questions I have.

THE COMMISSIONER:

Q. Mr. Pike, you're still of the same view?

MR. PIKE:

Page 392

Q. No questions. Thank you.

THE COMMISSIONER:

Q. All right. Ms. Brocklehurst?

DR. FORD ELMS, EXAMINATION BY MS. LAURA BROCKLEHURST

MS. BROCKLEHURST:

Q. Thank you. Good afternoon, Dr. Elms. I'm Laura Brocklehurst with Ches Crosbie, here on behalf of the class members. Can I get document C-0174, please? Perfect. I know you had said earlier that you can't recall if you'd actually reported this conversion or not. Is there any reason that you can remember that you would have reported it or conversely, any reason that you would not have reported it?

DR. ELMS:

A. I would have wanted to make my supervisor aware that this had happened in the lab, in the same spirit that I had reported Ms. Deane's changed tests.

MS. BROCKLEHURST:

Q. Okay. So you did think it was important to let somebody know?

DR. ELMS:

A. Yes.

Page 393

MS. BROCKLEHURST:
Q. Okay. Did you have an obligation to report it or is it just something you thought was important to do?
DR. ELMS:
A. I'm not sure that I would have had an obligation, but I would have felt it important to do it.
MS. BROCKLEHURST:
Q. Was there a database being kept of the conversions, do you know?
DR. ELMS:
A. No.
MS. BROCKLEHURST:
Q. There wasn't?
DR. ELMS:
A. No, not that I know of.
MS. BROCKLEHURST:
Q. Okay. So how would a conversion rate have been known or would there have been any way to know?
DR. ELMS:
A. At that point?
MS. BROCKLEHURST:
Q. Yes.

Page 394

DR. ELMS:
A. I'm not sure that there would have been.
MS. BROCKLEHURST:
Q. There wouldn't have been, okay. This case, I believe--am I able to scroll down here?
THE COMMISSIONER:
Q. Yes, you should be able to.
MS. BROCKLEHURST:
Q. This case, I believe, went to about a 10 to 15 percent ER and 75 percent PR. I think we saw that somewhere.
DR. ELMS:
A. Something of that nature.
MS. BROCKLEHURST:
Q. I thought I saw that here somewhere earlier. What page, I'm not sure.
THE COMMISSIONER:
Q. There you go.
DR. ELMS:
A. Here we are.
MS. BROCKLEHURST:
Q. Perfect. Was there a pattern of high PRs and low ERs correlating with each other, and is that normal to have such high numbers for the PR and such low numbers for the ER?

Page 395

DR. ELMS:
A. Are you asking me is it usual to expect -
MS. BROCKLEHURST:
Q. Yes.
DR. ELMS:
A. No, I'm not aware of any pattern that would exist with that.
MS. BROCKLEHURST:
Q. Okay. So there's no actual pattern of separate cases around this time that would have had similar numbers?
DR. ELMS:
A. Not that I'm aware of.
MS. BROCKLEHURST:
Q. Okay. Is there anyone who would have been in a position to notice such a pattern? Like is there any one person who would have been seeing several conversions who would have been able to notice pattern?
DR. ELMS:
A. No, not that I'm aware of.
MS. BROCKLEHURST:
Q. Okay, and can I get document C-0228, please? Dr. Vaze, is that how you pronounce that?
DR. ELMS:

Page 396

A. Vaze.
MS. BROCKLEHURST:
Q. Vaze, okay. You said earlier that you were unaware of his conversion at the time?
DR. ELMS:
A. As far as I'm aware of.
MS. BROCKLEHURST:
Q. Okay. So it seems like, you know, independent or individual doctors weren't communicating with each other about mistakes, or I think adverse events they were called, when they occurred. So again, I guess there was no way then for any one person to know what a conversion rate would have been?
DR. ELMS:
A. That's correct.
MS. BROCKLEHURST:
Q. Okay. Okay, I just wanted to clarify that. And back to Exhibit C-0156, please? Peggy Deane, perfect. Was there anything specific or unique to Peggy Deane's case that would have caused you to look back again at her diagnosis once there was a conversion?
DR. ELMS:
A. Nothing specific.

Page 397

MS. BROCKLEHURST:
Q. Okay. So there was nothing special about her case as opposed to -
DR. ELMS:
A. No.
MS. BROCKLEHURST:
Q. - I think there was one other unnamed conversion we saw earlier. There's nothing special about hers that would have triggered it?
DR. ELMS:
A. No.
MS. BROCKLEHURST:
Q. So do you know why it was that you would have looked into hers?
DR. ELMS:
A. Well, I mean, I reviewed her case when I was asked to repeat the stain and then compared the stains when I got the positive back, but that's--I mean, you'd do that with any case that that kind of a situation exists in, and it certainly wasn't the case that that case, that one case spurred me to go back and look at others. I reported that to my supervisor who then discussed it with the oncologists and

Page 398

then over the course of those discussions, the situation developed.
MS. BROCKLEHURST:
Q. Okay. So there was nothing special about this one case.
DR. ELMS:
A. No.
MS. BROCKLEHURST:
Q. It was just the beginning. Okay, that's all I have. Thank you.
THE COMMISSIONER:
Q. Thank you. Mr. Browne?
DR. FORD ELMS, EXAMINATION BY MR. PETER BROWNE
MR. BROWNE:
Q. Thank you, Commissioner. We're drawing to a close, Dr. Elms. Just a couple of questions I want to cover off with you. First of all, I want to go back to some questions Mr. Coffey asked you fairly early on in this morning's session and it had to do with, I guess some technically unsatisfactory slides that you recognized back in either 2001, 2002, in that time frame.
DR. ELMS:
A. Yes.

Page 399

MR. BROWNE:
Q. And I think you answered that on occasion you noticed a couple of difficulties or problems with slides and those included wrinkles, knife, was it chatter?
DR. ELMS:
A. Knife chatter, yes.
MR. BROWNE:
Q. Okay, and then the last item was tissue boiling off the slides.
DR. ELMS:
A. Yes.
MR. BROWNE:
Q. Do you ever recall with regard to the last issue, tissue boiling off the slides, did you ever recall speaking with any of the lead techs, I think at that time it would have been either Ms. Butler or Ms. Walsh, about that issue and do you recall any response from them as to what steps they may have been taking?
DR. ELMS:
A. Yes, in those instances, I would have called. I called Ms. Butler and spoke with her on a couple of occasions about this issue and she informed me that it was an issue that was

Page 400

recognized, and I was certainly given the impression that others had said similar, and they were trying to solve the issue and were taking various steps to correct it, using positive slides, various other steps, and that they were looking into it.
MR. BROWNE:
Q. So one of the steps they were looking into, is it what we've heard about this previously, positively charged slides?
DR. ELMS:
A. Yes.
MR. BROWNE:
Q. As a matter of fact, and I know this is a difficult exhibit to call up, Registrar, but I'll ask Dr. Elms if he recalls seeing this. It's P-2151 and that's the 300 page policy manual that you were shown here this afternoon.
DR. ELMS:
A. Uh-hm.
MR. BROWNE:
Q. I think among that, there was a policy, I think at pages somewhere between pages 201 and 203, addressing positively charged slides.

Page 401

Can you indicate the significance of positively charged slides in IHC generally to the Commissioner, please?

DR. ELMS:

A. They increase adherence of tissue, so the tissue will stay on better, will adhere better to the glass slide.

MR. BROWNE:

Q. Okay, it's not that necessary, I think we saw it there, is it 205? Maybe we could just go to 205? Yes, right here. Doctor, in fact, page 205, there's a reference there to 25 by 77 superfrost slides positively charged.

DR. ELMS:

A. Yes.

MR. BROWNE:

Q. So there is in fact a policy for that purpose because of its relevance to IHC.

DR. ELMS:

A. Yes.

MR. BROWNE:

Q. Okay. Now as well, Mr. Coffey and the Commissioner asked you, I think on a couple of occasions about--if we could, Registrar, go to P-2407, page 72 and I think you recall this

Page 402

comment, Dr. Elms, that you made a reference to totally negative staining in the neoplastic tissue. And I think you answered the Commissioner this afternoon that you felt the request for the repeat was for something other than the absence of staining of an internal control.

DR. ELMS:

A. Yes.

MR. BROWNE:

Q. Could this be related to the boiling off of tissue?

DR. ELMS:

A. Yes.

MR. BROWNE:

Q. And what--could you explain that further how that would be relevant to your comment?

DR. ELMS:

A. It could very well be that, I mean there were cases where tissue would boil off the slides, it could very well be that all that remained adherent was normal tissue and that the statement was more one of all I've got is normal tissue and that even hasn't stained.

MR. BROWNE:

Page 403

Q. And then lastly, Dr. Elms, you were shown two reports, C-174 and I think we've gone over that just recently with Ms. Newbury and with Ms. Brocklehurst and in comparison to Ms. Deane, which was C-156. Now, both were repeats. In once case it was Dr. Zaidi and in the second, I guess, it was either Dr. McCarthy, Dr. Laing who communicated that to you. Was there--do you recall, was there any clinical significance discussed with you or when you related the results, I'm talking about Ms. Deane now, to Dr. Rorke -

DR. ELMS:

A. Uh-hm.

MR. BROWNE:

Q. Do you recall whether there was any discussion around any clinical significance to the new result, the repeat result, did Dr. Rorke mention that there was significance to the patient because of this change?

DR. ELMS:

A. That she would now be able to be treated with Tamoxifen.

MR. BROWNE:

Q. Right. In terms of the repeat with Dr. Zaidi,

Page 404

do you recall if there was any such discussion in that respect?

DR. ELMS:

A. No.

MR. BROWNE:

Q. So there was a difference in terms of what information you received back from the oncologist from Ms. Deane, verses what you received back from Dr. Zaidi?

DR. ELMS:

A. Yes.

MR. BROWNE:

Q. And there was, from the information you received from Dr. Rorke, some clinical significance to the repeat result?

DR. ELMS:

A. Yes.

MR. BROWNE:

Q. That's all the questions I have, Commissioner. The only other area, Dr. Elms, is that the Commissioner--we invite witnesses at this time if they want to make any comments or recommendations or any observations to the Commissioner, then this is your opportunity.

DR. ELMS:

Page 405

A. None at this time, just thank you very much for enabling me to make my testimony. I look forward to your report, Madam Commissioner.

THE COMMISSIONER:

Q. Thank you.

MR. BROWNE:

Q. Mr. Coffey may have some -

THE COMMISSIONER:

Q. Do you have anything arising, Mr. Coffey?

COFFEY, Q.C.:

Q. No, Commissioner, thank you.

MR. BROWNE:

Q. Commissioner, do you have any questions for -

THE COMMISSIONER:

Q. I don't.

MR. BROWNE:

Q. Oh good.

THE COMMISSIONER:

Q. Yes, you'll be terribly glad to learn. I do thank you, Dr. Elms for assisting us. It's not easy to be the first up on the first school day, so I do appreciate your coming along and taking that role for us. For counsel, I wish to advise that administration says that there's a CD for you before you

Page 406

leave today, just so that you can feel like you're really back -

MR. BROWNE:

Q. Homework on the first day of school.

THE COMMISSIONER:

Q. Homework on the first day, exactly. Thank you all, we'll meet again at 9:30 in the morning.

Page 407

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 2nd day of September, 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 2nd day of September, A.D., 2008

Judy Moss

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