COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 24, 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

Pamela Taylor. . . . . 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

THIS PAGE ONLY REVISED NOVEMBER 18, 2008

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Certificate

THE COMMISSIONER:
Q. Mr. Coffey.
COFFEY, Q.C.:
Q. Dr. Mahmoud Khalifa.
DR. MAHMOUND KHALIFA, AFFIRMED, EXAMINATION BY BERNARD COFFEY, Q.C.
REGISTRAR:
Q. Would you please state and spell your complete name for the Commission?
DR. KHALIFA:
A. My complete name is Mahmoud Abdelfattah Khalifa. First name is spelled Mahmoud, M-A-H-M-O-U-D. Last name Khalifa, K-H-A-L-I-F, as in Frank, A.
REGISTRAR:
Q. Thank you.
COFFEY, Q.C.:
Q. Good morning, Doctor.
DR. KHALIFA:
A. Good morning, sir.
COFFEY, Q.C.:
Q. Commissioner, I do have some new exhibits, please. They are exhibit numbers P-2410 through P-2425 inclusive. That's 2410 through 2425 inclusive.

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THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-2410 THROUGH P-2425
COFFEY, Q.C.:
Q. Thank you, Commissioner. If we could, please, Registrar--and I would point out, Commissioner, we're having some technical difficulty with the mice, electronic version that is, and I'm going to be relying upon the Registrar to scroll through documents this morning. Exhibit, please, P-2423? Now Doctor, I understand that this is a copy of your curriculum vitae?
DR. KHALIFA:
A. That is correct.
CHAYTOR, Q.C.:
Q. Doctor, I'm going to ask you, first of all, perhaps, if you could just give us a broad overview of your educational and professional background?
DR. KHALIFA:
A. Yes, thank you. I graduated from medical school in Cairo, Egypt in 1978. I have my Masters and PhD at the same university. I was awarded a Fullbright scholarship to study

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breast and gynecological pathology at the Armed Forces Institute of Pathology in Washington, D.C.. That was '87. I spent a few months there. After that, I was a research assistant at the University of Maryland in Baltimore. I did my anatomic pathology residency training at the University of Oklahoma between the years 1990 and '93. After that, I did a surgical pathology fellowship at George Washington University in Washington, D.C. I became a junior staff in Georgetown University for the year after, from '94 to '95. I was appointed as an assistant professor at Memorial University of Newfoundland and became a staff pathologist at the General Hospital in St. John's on April '95. In July '99, I moved as an associate professor at the University of Toronto, and a staff pathologist at Sunnybrook Hospital. I stayed there from '99 until 2003. In 2003, I went for a year as a staff pathologist at Northwest Medical Centre and Cancer Centre in Oklahoma City. Came back to Toronto in August 2004 and I remain there as the Director of Surgical Pathology, the Director of Oncology

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Quality Assurance Program, and currently, I am a professor at the University of Toronto.
COFFEY, Q.C.:
Q. Doctor, just looking at the first page of your curriculum vitae, which is there on the screen, you graduated, as you indicated, as a physician with a degree in medicine first in 1978 in Cairo, Egypt. Just so the Commissioner has some sense of this, would that be a degree at that time which would entitle you to practise medicine in Egypt in 1978?
DR. KHALIFA:
A. In order to practise medicine in Egypt, one needs a degree, a medical degree from a recognized university, plus a one-year of internship in a university hospital, after which one acquires a medical license, yes.
COFFEY, Q.C.:
Q. So Doctor, did you do that internship at that time?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Okay. So after you graduated in '78, you went

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on and did your internship?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Now as well then, you did refer to the fact that you have a Masters degree and PhD, and we look at the screen here, see you have a Masters degree in Pathology, November of 1982, and then a PhD degree in pathology, October of 1986. These degrees, I take it they are over and above the degree that you obtained that allowed you to practice medicine, these are Masters and PhDs over and above?
DR. KHALIFA:
A. Yes, these are requirements for staff because I was on the teaching staff in the same university and I was required to do these degrees.
COFFEY, Q.C.:
Q. Doctor, you've indicated that you were--so that in between then, when you were studying for the degrees of Masters of Pathology and PhD in Pathology, were you actually practising as a physician at the time?
DR. KHALIFA:

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A. Yes.
COFFEY, Q.C.:
Q. And that would be as, in effect, a staff pathologist?
DR. KHALIFA:
A. As a staff pathologist, yes.
COFFEY, Q.C.:
Q. What would be the difference, if any, between that sort of study and a residency, such as occurs in North America?
DR. KHALIFA:
A. North American residency training is known for being structured in terms of certain requirements a physician has to fulfil before they acquire--before they can sit for the certification exam. In the United States, that the Board, American Board, which I have. In Canada, it's the Royal College certification, which I also acquired in '95. In Egypt, at that time, there wasn't such a structured program. One would pursue a certain area of research in which I get my Masters and get exposed to a wide variety of pathology which doesn't necessarily have to meet certain structure.

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COFFEY, Q.C.:
Q. And so you did, in effect, in the academic world, a Masters and a PhD?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And you had already, as is pointed out here in this first page, under training intern, you had already done your rotating internship?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, then there's a reference, and you've already referred to this, to the--you were a Fullbright Research scholar between September 1987 and March of 1988 in the Armed Forces Institute of Pathology in Washington, D.C. So I take it, Doctor, that after you finished up your PhD in 1986, in Egypt, kind of the next step professionally was you became a Fullbright scholar in the U.S.? You had the scholarship, you had -
DR. KHALIFA:
A. The Fullbright Commission is a highly competitive student exchange program in the

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United States and the year when I applied in Egypt, there was 4,000 applicants in the country. All were PhD holders, and I was selected through a competition to go and study any area of research that the candidate chooses, and that was the privilege of the scholarship. I chose the Armed Forces. There was an eminent gynecological pathologist over there at that time, Dr. Henry J. Norris, who accepted to host me for that duration of time. We had research together and I participated in his signing out of complicated breast and gynecological cancer cases.
COFFEY, Q.C.:
Q. Doctor, out of the number of applicants at the time, as you indicated, you were successful. How many out of the 4,000 applicants, how many were chosen?
DR. KHALIFA:
A. I know that it was less than ten.
COFFEY, Q.C.:
Q. Doctor, following then the period you spent at the Armed Forces Institute of Pathology, there's an indication that--well, I'm going to ask you, where did you go from there, from the

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Armed Forces Institute?
DR. KHALIFA:
A. One of the requirements was for the fellow to go back to their home country to transfer the knowledge and technology they learned in the United States to their developing countries, and that's exactly what I did. I went back to Egypt. I wrote my experience in a book that was published and it was used for teaching. I continued to teach using the skills and knowledge I learned. More than a year later, another opportunity came up to go back to the States and as I said, to work in research at the University of Maryland in Baltimore, and I applied for that competition and I was granted the opportunity.
COFFEY, Q.C.:
Q. And what did you study or research in Maryland, the University of Maryland, do you recall?
DR. KHALIFA:
A. That was in an eye institute. I did eye research. It was mostly experimental on hamsters. We injected them with virus and we studied the lesions in their eyes, because the

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granting agency was an organization called Research to Prevent Blindness.

COFFEY, Q.C.:

Q. And then looking at your list of training here, Doctor, the next thing in the list here is you took up or enrolled in or became part of the anatomic pathology residency at the University of Oklahoma?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. In Oklahoma City. What type of a residency was that, the standard North American anatomic pathology residency?

DR. KHALIFA:

A. Yes, one of the reputable ones.

COFFEY, Q.C.:

Q. I understand you wrote and were certified by the American Board, if we turn to the second page, please, Registrar, top of the page, in June of 1994?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Then Doctor, I understand, if I recall your

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account properly, you ended up in Canada?

DR. KHALIFA:

A. After a year in George Washington University, a year at Georgetown University, I went to Canada, yes.

COFFEY, Q.C.:

Q. Okay, yes, so I want to ask you about that. What were you doing at George Washington University and then Georgetown?

DR. KHALIFA:

A. Georgetown, I was a surgical pathology fellow. A fellow is supposed to be a person with training more than a resident, but less than a staff, to acquire more specialized training and the chief of service at the time was one of another figure in gynecologic and breast pathology, Dr. Stephen Silverberg, under whom I trained for a year, and the training was broad surgical pathology, but was also focused on the art of inter-operative consultation, also known as frozen section. After a year, Georgetown University contacted me. They were interested in a junior staff.

COFFEY, Q.C.:

Q. So this was at George Washington, this year

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you just accounted for?

DR. KHALIFA:

A. The fellowship was at George Washington.

COFFEY, Q.C.:

Q. Yes, I'm sorry, go ahead, and then Georgetown, I'm sorry?

DR. KHALIFA:

A. Georgetown is another university in Washington, D.C. They needed a junior staff to help with the workload. I worked there as--they gave me a title of instructor. I was signing out cases independently at that point in time because I was Board certified.

COFFEY, Q.C.:

Q. And so you went to work at Georgetown?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. How long were you there for?

DR. KHALIFA:

A. I was there, my initial contract was for a year. In September of '94, I came to interview in St. John's at Memorial University. Early '95, the Chairman, Dr. Haegert, called me and told me that they

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needed me to come here in April. So I excused myself from Georgetown a couple of months earlier than my contract and they had no problem with that. They released me in April to come to St. John's.

COFFEY, Q.C.:

Q. Doctor, can you tell then the Commissioner, so you arrived in St. John's, when would that be?

DR. KHALIFA:

A. Sorry?

COFFEY, Q.C.:

Q. When did you arrive in St. John's? April of 1995?

DR. KHALIFA:

A. April '95.

COFFEY, Q.C.:

Q. Okay, and where were you--what were your positions at the time and where were you stationed? Which hospital were you at?

DR. KHALIFA:

A. My position at the time was assistant professor at Memorial University, with a teaching and academic mandate, and I was a staff pathologist at the General Hospital.

COFFEY, Q.C.:

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Q. What then happened, Doctor? So you were on the staff there. Did your status, first of all, at the University, ever change?
DR. KHALIFA:
A. My status with the University changed sometime in '98. Dr. Haegert agreed to apply on my behalf for what was known at the time as expedited promotion. I was promoted to an associate professor. I received a cross appointment at the Department of Gynecology and Obstetrics and I was offered a tenure status.
COFFEY, Q.C.:
Q. And then, Doctor, with respect to your work at the Health Sciences Centre, you were a staff pathologist initially. What then happened?
DR. KHALIFA:
A. What happened is sometime the following year--so I came here in April. In May of the same year, I successfully got the certification from the Royal College. So now I am certified by the Royal College as an anatomic pathologist and sometime in '96, somehow, I can't remember the exact date, but it was early '96 and the Chairman came to me with the

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current site chief to tell me that she decided to step down and they saw that I would be a good candidate for that position, and I accepted.
COFFEY, Q.C.:
Q. Who had been the site chief in the Health Sciences Centre when you arrived in St. John's? Who was that?
DR. KHALIFA:
A. That was Dr. Dzintra Fernandez.
COFFEY, Q.C.:
Q. And so by the beginning of '96, Dr. Fernandez was interested in stepping down from the site chief's position and Dr. Haegert approached you and said "will you take it on?" and you agreed to?
DR. KHALIFA:
A. Yes, sometime early '96.
COFFEY, Q.C.:
Q. What position did Dr. Haegert hold when you arrived in St. John's? What was his position? That would be David Haegert, I take it, and what was -
DR. KHALIFA:
A. That's David Haegert, and I'm sorry, I'm not

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really sure of the exact date. I just want to -
COFFEY, Q.C.:
Q. Okay. So what was Dr. Haegert's position when you arrived?
DR. KHALIFA:
A. Dr. Haegert was certainly the Chairman of the Department on the University side, and I understand that around that time an organization by the name Health Care Corporation of St. John's was born. I wasn't involved in that and I don't know when that entity was born, but Dr. Haegert also was the clinical chief of pathology in the Corporation.
COFFEY, Q.C.:
Q. At the time when you arrived in St. John's, as you pointed out, the Health Care Corporation of St. John's came into existence around that time. Other than being eventually employed in that structure, you weren't involved in the setting it up or anything like that?
DR. KHALIFA:
A. No.
COFFEY, Q.C.:

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Q. The other hospitals in St. John's at the time were which? Do you recall?
DR. KHALIFA:
A. Yes, there was St. Clare's Hospital. There was the Grace Hospital and there was the Janeway Hospital.
COFFEY, Q.C.:
Q. Now Doctor, I understand that you left St. John's in 1999?
DR. KHALIFA:
A. June '99.
COFFEY, Q.C.:
Q. June of '99, and you remained site chief up until that point?
DR. KHALIFA:
A. Up to that point, I was.
COFFEY, Q.C.:
Q. And when you left St. John's, the hospital structure was still--there was still the Grace Hospital, still existed, and St. Clare's still existed?
DR. KHALIFA:
A. Towards the end of my era, there was -- there were discussions about, I think, closing the Grace Hospital because I was engaged in

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meetings where we talked about what to do with the pathologists from Grace Hospital, who would join St. Clare's and who would join the Health Sciences Centre. So I know there was talk about the Grace Hospital closing.

COFFEY, Q.C.:

Q. And by the time you left, it was still - it still existed?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Now these other hospitals -- I take it as well the Janeway would have existed at that time?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. The time you left. In these other hospitals during your time as site chief at the Health Sciences Centre, were there site chiefs for the other hospitals too?

DR. KHALIFA:

A. Yes. Each site had its own chief, and Dr. Haegert was the clinical chief for the whole organization.

COFFEY, Q.C.:

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Q. Yes. So in your time, I take it at St. Clare's, and we've already heard -- Dr. Cook has already testified here. Dr. Cook would have been the site chief at St. Clare's.

DR. KHALIFA:

A. He was, yes.

COFFEY, Q.C.:

Q. And during your time, Dr. Parai, Sushil Parai, would have been the site chief at the Grace?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. Although I don't know that it's particularly germane to what the Commissioner has to deal with, who was the site chief at the Janeway, was that Dr. Pushpanathan?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, I'm going to ask you then, so the Commissioner gets some sense of the work environment of the day, okay, when you arrived in St. John's in 1995 and started as a staff pathologist, describe for the Commissioner what your typical work day would be as a staff

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pathologist when you first arrived?

DR. KHALIFA:

A. My typical work day would be come to the office in the early morning. The slides would come from the lab -- the slides would come from the lab late in the afternoon. They'd come, I would think, probably around one. So I get the slides and I sit with the resident to sign out the cases. The ones that can be signed out, I sign them out; the ones that need further investigation, I order the stains and what not. Sometimes if there's an autopsy, I think we took turn to perform autopsies. Some days I would be on call for frozen section examination, so I would have to cover the operating rooms, but then because we received the slides late in the day, of course, one cannot finish them, so the drag until the next day and that would be the first thing I would do the next day.

COFFEY, Q.C.:

Q. The next day.

DR. KHALIFA:

A. And so on. Many days, of course, when the school starts, we would be teaching, so we had

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that arm of our activity. I was particularly interested in research as part of my academic profile. I was engaged in several research projects. You get residents involved, train them to communicate with colleagues. After a while -- my interdepartmental consultation is a popular practice in pathology. My colleagues would bring cases to me to seek my opinion. Some cases, I seek opinion of my colleagues who had certain areas of expertise and interest. So that also was part of our work, exchange opinions and diagnosis. I respond to clinician's call when a clinician calls to ask about a case or a diagnosis. That's pretty much it.

COFFEY, Q.C.:

Q. Okay, and, Doctor, would you occasionally then -- we've heard references to doing grossing, okay, staff pathologists would be scheduled to be on the grossing bench every so often. Would that happen? What I'm getting at is this, you would get slides, how would it be determined which slide you would get?

DR. KHALIFA:

A. I wouldn't remember exactly how it worked, but

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it was known that "x" number of cases belong to this doctor or that doctor. Maybe it was weekly schedule, maybe it was daily, something like that, but going back to the first part of your question about grossing, most of the grossing at that time was done by residents. Sometimes for some scheduling issues, the resident would not be available, so the staff steps in and grosses.

COFFEY, Q.C.:

Q. Doctor, when you arrived in St. John's, what was the structure in terms of -- I'll deal, in particular, with this. Specimens such as, for example, breast tissue, in particular, mastectomy specimen, how would the fixation occur in relation to that, the bread loafing and so on which we've heard about? Would you be involved with that as a staff pathologist with a resident, would it sometimes vary? Could you tell us about that.

DR. KHALIFA:

A. As a staff pathologist, I understand the importance of proper fixation, proper handling -- I would rather call it proper handling because handling is a little bit more than

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fixation.

COFFEY, Q.C.:

Q. It's broader, yes.

DR. KHALIFA:

A. Proper handling of the specimen is absolutely critical. As a staff pathologist, I would instruct the residents how to do it, how I expect them to do it. If I see any problem, I would probably take that upon myself until I became a chief -- that changed a little bit, but at that point that's what I was doing.

COFFEY, Q.C.:

Q. That's what I asked you about, as a staff pathologist.

DR. KHALIFA:

A. As a staff pathologist.

COFFEY, Q.C.:

Q. You've indicated that certainly some time in '96, probably early '96, you became the site chief?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Could you tell the Commissioner then how your work pattern and what you ended up doing and a

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typical day evolved? How did that change over time? When you became site chief, what changed?

DR. KHALIFA:

A. By that time, remember I've been in the department for quite some time, so I could see things, I could see areas that could be improved. As we all know, any lab pathology anywhere in the world, any organization can -- there is room for improvement. So when I became the chief, I started tackling the areas that I thought needed to be improved a little bit; issues like standardization of reports, requesting special stains, policies -- we needed many, many policies about how to handle the work flow in the department. So it was that sort of thing. Administration is a constant thing. I tried to squeeze my work between administration.

COFFEY, Q.C.:

Q. That's your clinical work?

DR. KHALIFA:

A. That's my clinical work. Troubleshooting in the lab with residents, with staff, personality conflicts. I mean, it's a very

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wide range of activity.

COFFEY, Q.C.:

Q. As the site chief?

DR. KHALIFA:

A. As a site chief.

COFFEY, Q.C.:

Q. Doctor, how many pathologists do you recall were working at the General Hospital at the time on site? Do you recall approximately how many there were?

DR. KHALIFA:

A. I remember seven including myself, and including renowned neuropathologist at the time, and then you add to that the forensic pathologists, so that will be eight -- I apologize, maybe we were nine. Eight or nine maybe.

COFFEY, Q.C.:

Q. That was about it in the mid '90s when you first arrived?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Of course, this is before the Grace -- the number of pathologists at the Grace got

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redistributed when the Grace closed afterwards. So the numbers, I gather, have changed in the General Hospital over the years?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. But your recollection of it, and I notice -- you're just going to, I suspect, listing off initials.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And remembering who they were. The environment -- so the Commissioner has some sense of the environment from which you had come, and then coming to St. John's, the environment at Georgetown, for example, how many pathologists would have been working at Georgetown when you were there approximately? Again just a rough figure.

DR. KHALIFA:

A. Georgetown is one of the oldest universities in the country. It's a very well established program. We had probably, I would say, a

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dozen pathologists looking at doing clinical work and probably half a dozen doing research, R & D, and several PhD's. It was a much bigger scale operation.

COFFEY, Q.C.:

Q. How about George Washington?

DR. KHALIFA:

A. George Washington was more hands-on. Again I would say, including the (unintelligible) pathologists, including the neuropathologists, and dermapathologists, there's probably 15 or 16.

COFFEY, Q.C.:

Q. So it was again a larger operation?

DR. KHALIFA:

A. Oh, yes.

COFFEY, Q.C.:

Q. And the University of Oklahoma?

DR. KHALIFA:

A. The University of Oklahoma again is -- at that time, we had the largest molecular lab in the south. God knows how many researchers were there, so we had many researchers, many PhD's, but on the service side because we also had the VA Hospital and the Children's Hospital,

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again I would say probably 20.

COFFEY, Q.C.:

Q. So again a much larger --

DR. KHALIFA:

A. Probably 20, yeah, on the clinical.

COFFEY, Q.C.:

Q. A much larger operation clinically?

DR. KHALIFA:

A. Absolutely.

COFFEY, Q.C.:

Q. Doctor, you've indicated that when you arrived in St. John's, had worked for a while, and became site chief and as you've pointed out, of course, any organization can stand to be improved.

DR. KHALIFA:

A. Absolutely.

COFFEY, Q.C.:

Q. That's the nature of human activity. At the time, Doctor, when you took over as site chief here in St. John's, did you have any particular immediate goals, immediate in the sense of more important goals from your perspective?

DR. KHALIFA:

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A. As a staff pathologist?

COFFEY, Q.C.:

Q. As a site chief.

DR. KHALIFA:

A. As a site chief, immediate goals were to tighten up quality assurance a little bit. That needed some work.

COFFEY, Q.C.:

Q. And why was that, Doctor?

DR. KHALIFA:

A. Why?

COFFEY, Q.C.:

Q. Yes.

DR. KHALIFA:

A. Well --

COFFEY, Q.C.:

Q. I appreciate it's a desirable result.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. But, I mean, what in particular needed to be tightened up, I suppose is what I'm asking?

DR. KHALIFA:

A. Okay, for one thing, I thought that efficiency could increase to decrease stressed

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pathologist who were very stressed.
COFFEY, Q.C.:
Q. Perhaps you could tell the Commissioner about that, what you found in St. John's when you arrived?
DR. KHALIFA:
A. Pathologists were very stressed because of a variety of reasons. Do you want to get into that? It's a very long --
COFFEY, Q.C.:
Q. Right now while we're at it, yes.
DR. KHALIFA:
A. Okay, pathologists were stressed because for one thing I mentioned the slides would come out of the lab in the afternoon. Everywhere I worked, there was something called night shift where the technologists come at night. By 7 o'clock, the staff goes to the office and the slides are ready for them. So we start fresh -- after your morning coffee, full of energy, you start embarking on the slides. In St. John's, the slides come in the afternoon when you are tired, and, of course, the argument was, well, you're busy from the slides the day before, but still receiving the slides in the

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afternoon in my mind was not an optimal set up. That could improve maybe, and I was told I couldn't play with the shifts of the technologists because they belong to a union or something in the organization that I couldn't --
COFFEY, Q.C.:
Q. You couldn't change?
DR. KHALIFA:
A. I couldn't change. So, okay, another thing, just a simple thing, everywhere I worked before, specimens are divided into large and smalls, which means smalls would be something like colon biopsy. Large would be an excised whole colon. So obviously a clinician who did a biopsy, which is a small specimen, expects a diagnosis fast because the patient is coming and we need to decide what to do with that patient. The patient who had his or her colon removed, they knew why it was removed, so if that case delays 48 hours, it's not such a bad thing. So when I arrived, cases were not divided, and that was probably one of my very early -- in fact, I think I did that even before I became the site chief; who don't we

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divide the cases into small and large, or biopsies and larges, or priorities and routines. I think we ended up calling them priority and routine. So if you would imagine you show up in the office at 1 p.m. and you get two piles, biopsies and routines, I guess you know which ones to start with. You get your priorities out so at least the clinician will get their diagnosis. Things like that which I would probably call just streamlining the operation, that alleviated some of the stress. Decreased phone calls -- stress was coming from the fact that clinicians would send the specimens without adequate clinical history. Of course, the pathologist gets very stressed by that, so I started working formally and informally on improving communication and trying to be more social with the clinicians so they know our needs and things like that, show up more in their rounds, or just make your face a little bit -- so things like that to decrease the stress. I'm not sure if the stress was because of the complexity of cases or because of the total number of cases because if you compare the

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total number of cases at that time with the total number of cases I was doing at George Washington or Georgetown, it wasn't that much; if anything, it was actually less.
COFFEY, Q.C.:
Q. In St. John's.
DR. KHALIFA:
A. In St. John's at that time, the total number of cases per pathologist I would say was less. Complexity of cases was the same or probably less.
COFFEY, Q.C.:
Q. In St. John's.
DR. KHALIFA:
A. In St. John's, but yet pathologists in St. John's were which more stressed than any pathologists I worked with before.
COFFEY, Q.C.:
Q. In the other institutions in the US?
DR. KHALIFA:
A. In the other institutions. Scheduling, for example, I know that when you schedule people on -- well, some people like to be scheduled in weeks block or days blocks, so just put some structure into the operation, and the

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stress level was get down a little bit. I would like to believe that the stress level came down. I don't know if --

COFFEY, Q.C.:

Q. After you got involved.

DR. KHALIFA:

A. If you ask the pathologists, I hope they would say that.

COFFEY, Q.C.:

Q. So, Doctor, these were some administrative work flow aspects of the matter that you recognized because you came from a background outside other institutions and these were some things you wanted to, if you could, immediately address?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Some you could, some as you've indicated, rescheduling the technologists work was beyond your ability, you were told?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, at the time, and this is in the mid

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1990s, again to try and put this in perspective for the Commissioner, remuneration levels for pathologists in St. John's compared to elsewhere, like, money, the amount of income they were paid, how did they compare -- do you know was that a cause of concern to the pathologists at that time?

DR. KHALIFA:

A. Major.

COFFEY, Q.C.:

Q. Major?

DR. KHALIFA:

A. Major concern.

COFFEY, Q.C.:

Q. Could you tell the Commissioner what you recall about that in the time that you were here?

DR. KHALIFA:

A. When I came to St. John's, I was shocked by my salary and my take home money after tax. Of course, I was introduced to a new country, new system, that I didn't fully understand. My take home money would allow me as a staff pathologist to do less to my family than my take home money when I was a fellow back in

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DC.

COFFEY, Q.C.:

Q. A fellow --

DR. KHALIFA:

A. In surgical pathology back in DC.

COFFEY, Q.C.:

Q. Meaning below the level of a staff person?

DR. KHALIFA:

A. Well, a fellow is -- there's a huge difference in salary between a fellow and a staff, but by the time your take home -- at that time the sales tax in St. John's was like 19 percent or something like that. I had major difficulty. I personally had major financial difficulties when I arrived, but talking with people around me, everybody was I would say dissatisfied with the salary scale we were on. There was one particular pathologist who was obviously senior and very knowledgeable and was very proactive about this, and he talked and counselled me a lot to help me try to understand. I was -- up to the moment I left -- well, they talked about increasing salaries and things like that, but up to the moment I left, the salary scale in Newfoundland was

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significantly lower than any salary scale I was aware of. I remember one particular -- one particular incident which I think is significant, or at least it was significant at the time, when I got promoted from assistant professor to associate professor, that was a huge deal, it was a huge deal to be promoted in such a short time, and associate professor is a big title. So I got the first -- my first pay cheque after that, and the money wasn't different, and I said, well, okay, sometimes things drag a little bit, and I waited one more month and it wasn't different and I said, well, maybe they made a mistake. The next month it wasn't different. So I went back to the chair and said, David, what's going on here, I got promoted and my salary didn't change. He said, no, no, no, your salary has nothing to do with your academic rank. That was a shock to me and when I went back and I talked to my colleagues, and one senior pathologist said this is what I've been tell you all the time, there is no credit for your academic status, there's no credit for -- so there wasn't. Sorry, I did say there isn't

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-- I meant there wasn't, at the time there wasn't any -- there wasn't recognition for academic achievements and the overall salary scale was significantly lower than anybody else.

COFFEY, Q.C.:

Q. So, Doctor, and I take it that, as you've indicated to the Commissioner, that in discussing this with your colleagues, by the late 90s you were the site chief, in discussing it with your colleagues, the ones who worked for you, nominally at least reported to you, as site chief, they would report to you, they were dissatisfied with the relatively low incomes that they were being paid.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, the structure of the department at the time, I mean, as site chief, what were you responsible for in the sense of who reported to you and what parts of the lab were you, the clinical laboratory were you responsible for?

DR. KHALIFA:

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A. That wasn't really clarified to me. I wasn't presented with an organization structure. I wasn't given a job description. I wasn't told what the expectations were and I guess the impression at the time was it was understood, it was understood that Dr. Haegert was the clinical chief, so I reported to him. I did not make any significant decision without consulting with him. I would go to him as a resource, for guidance as to how to do things. Who would report to me? I don't think anybody reported to me or I didn't think people felt that they needed to report to me. The overall atmosphere was very collegial at that time, people were very friendly with each other. We were, at least as a group, we were tight. I would say I would make a suggestion and people would respectfully follow it or they may say, it will not work, let's do this. So things were run by, I don't know the word, collegial or -

COFFEY, Q.C.:

Q. Consensus.

DR. KHALIFA:

A. Consensus, exactly, collegial and then when I

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started making staff meeting with agendas and minutes and things like that to give it, again, a little bit of structure -

COFFEY, Q.C.:

Q. I'm going to be asking you about that, I'll be pursuing that a little bit more, Doctor. Within the laboratory, as I take it there's pathology is a division of the laboratory.

DR. KHALIFA:

A. Anatomic pathology.

COFFEY, Q.C.:

Q. Anatomic pathology, but there are other aspects of the laboratory, hematology, chemistry.

DR. KHALIFA:

A. Yes, Yes.

COFFEY, Q.C.:

Q. Did you have any involvement in those?

DR. KHALIFA:

A. No, I knew the directors, we have coffee and stuff together, but I had no expertise and I had nothing to do with it.

COFFEY, Q.C.:

Q. So the physicians who worked in hematology, they had their own structure, their own

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director.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Or site chief, whatever the title was. What about the technologists, how did the structure work with respect to the technologists?

DR. KHALIFA:

A. We had a group of technologists. We had two other, what you probably would call morgue assistants and they mostly worked with the, of course, they worked with the autopsy and they had close relationship with the chief medical examiner. So excluding these two individuals, we had a fine group of histotechnologists. We had a manager and I understand we had a lab manager who was, I guess the manager of all labs, so he was over our anatomic pathology lab manager.

COFFEY, Q.C.:

Q. Over the anatomic pathology--you had an anatomic pathology manager who reported to, you understood, to the lab manager period.

DR. KHALIFA:

A. That's what I assumed, yes.

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COFFEY, Q.C.:
Q. And do you recall who the anatomic pathology manager was?
DR. KHALIFA:
A. Yes, it was Mr. Terry Gulliver.
COFFEY, Q.C.:
Q. And so Mr. Gulliver then would have had a number of histotechnologists reporting to him at the time.
DR. KHALIFA:
A. Yeah.
COFFEY, Q.C.:
Q. Doctor, when you arrived, well as a staff pathologist, were the technologists reporting to you? Would they report to you or would they report to Mr. Gulliver?
DR. KHALIFA:
A. I'm not sure if I understand the word "report". If you mean if they want vacation or overtime or -
COFFEY, Q.C.:
Q. Yes, talk about that.
DR. KHALIFA:
A. - things of that nature, I had nothing to do with that. I knew nothing about that.

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COFFEY, Q.C.:
Q. That was presumably Mr. Gulliver's problem, as it were.
DR. KHALIFA:
A. Probably, yes.
COFFEY, Q.C.:
Q. How about, but you've pointed out there's a distinction between administrative function and how about from a clinical sense, like in terms of involving particular slides or stains or whatever, would they be involved with you?
DR. KHALIFA:
A. As a staff pathologist?
COFFEY, Q.C.:
Q. Yes.
DR. KHALIFA:
A. As a staff pathologist the pathologist would order the stain, would say I want such and such antibody or such and such stain on such and such block. They present that to the technologist, the technologist would prepare the slide and bring them back to the pathologist. Sometimes if the pathologist doesn't like the stain or something is wrong with it, they take it back to the technologist

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and say "why don't you do this" and "let us repeat it" or "why did this happen", stuff like that. So that's, again, that's not a reporting system, I guess it's a supervisory role, rather than a reporting role.
COFFEY, Q.C.:
Q. And then as a site chief, what was your interaction then with technologists as a group and the manager of the technologists, how did that work during your days as site chief?
DR. KHALIFA:
A. Now as a site chief, as I said, I had a priority kind of, priority list in my head and I wanted to change things a little bit. So at that point, I had to interact more with the technologists. For example, I just want to give you one example. When I started, I think, I think, if my memory is not failing me, when I started, the technologists would write the number of the case by a diamond pen on the glass slide, and we did that in the old country. In North America, people didn't do that any more. It's just so time consuming and it's not practical. So I told them to-- why don't we start putting labels on the

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slide, something of that nature. So I guess, someone purchased the labels and they changed it. The pathologists wanted to change the protocol from getting three levels or five levels on a liver biopsy to only three levels. So I would go to the technologists and say "guys, let us stop doing five levels. Let's do three levels," things like that. So I was a little bit more involved in their work.
COFFEY, Q.C.:
Q. Doctor, during your days as the site chief with the Health Sciences site, the General Hospital site, the reporting lines, such as they were, was there--who did Terry Gulliver report to? Do you recall the man or person in Terry Gulliver's position reported to--the anatomic pathology manager reported to the clinical laboratory manager, which you just described. You, as the site chief, would report to the clinical chief, Dr. Haegert. So was there a division between the clinicians and the technologists, in terms of who they reported to?
DR. KHALIFA:
A. I guess in the way you put it, yes, I reported

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to Dr. Haegert and Mr. Gulliver probably reported to Vern?

COFFEY, Q.C.:

Q. Vern?

DR. KHALIFA:

A. Whelan.

COFFEY, Q.C.:

Q. Vern Whelan, yes, go ahead.

DR. KHALIFA:

A. I think that was the manager.

COFFEY, Q.C.:

Q. Clinical laboratory manager, yes.

DR. KHALIFA:

A. Yeah.

COFFEY, Q.C.:

Q. And they then reported to the Vice President Medical probably, in its time?

DR. KHALIFA:

A. I wouldn't know that. I didn't know.

COFFEY, Q.C.:

Q. You wouldn't know. Even that was beyond your -

DR. KHALIFA:

A. No, no, that was behind my--I don't know.

COFFEY, Q.C.:

Q. Doctor, just another aspect of this matter,

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perhaps to give, again, the Commissioner some sense of what the environment in which you first arrived and then what you--your approach to possibly changing it. Doctor, I understand that you were involved--for example, you referred to the fact pathologists would order particular stains or antibodies for particular blocks, right, you recall just described that?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. What was the situation when you first arrived in St. John's in terms of that and then how did it change over time?

DR. KHALIFA:

A. Well, this was, for example, this is one of the early things that I noticed. The way it was done, a pathologist sitting in his or her office wanted to request a special stain, so they have to physically walk down the hall, go to the lab and there was a log, like one big list on one page, one piece of paper, so they write down the case number and they write down the stain and the block. The next doctor comes and writes this and so forth and so

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forth, and I think the technologists, they will go down the list. When they finish one, they cross it off or something like that. That was in direct contrast to what I was trained to in the United States, because I know that we shouldn't include different patients' information on the same page. So I asked if we can develop what is called a requisition form, and then my colleagues said "go ahead." So I sat on my computer and I developed a very simplistic form with all the stains and the antibodies available, with a spot for the pathologist to write down the block and the case number and they would hand over that stain--that sheet, requisition to the lab. That will allow better checking down of their workload. When they are done with the stain, they put their notes on the form. So now we have a record that actually the stain was done. This was very useful because we printed these in books and we dispatched them to other pathologists in Newfoundland. So now when they need a stain, they send the block with the form and they tick on the antibody or the stain they wanted. Of course,

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the criticism to a system like that would be if you tell the pathologist all the stains we have, then the pathologist is going to tick as many as they want and -

COFFEY, Q.C.:

Q. Perhaps unnecessarily in some cases?

DR. KHALIFA:

A. Exactly. Which takes us to a whole different issue here, which is lab utilization. We were not in that position yet to collect data and monitor, I mean, in Sunnybrook, I do that, but because the system is old. Here the system was new at the time, so and I said, but you know, let us just have everything on the form and then we can probably later on, monitor who is abusing the system or whatever. There wasn't really, I mean, something like that, that was one of the things that I implemented and of course, pathologists will go to meetings and read literature and they read about a new stain or a new antibody, they call me. So we add to that list, so that list kept growing.

COFFEY, Q.C.:

Q. And the requisitions would change accordingly

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over, from time to time?
DR. KHALIFA:
A. Yes, I think I was in the habit of printing the date on the right upper corner of the form, where the form was updated and if you go back to the records, you will see that that form went through evolution.
COFFEY, Q.C.:
Q. Doctor, on that point, the idea for example there were these stains available, now I'll just ask you about this, the immunohistochemistry, when you arrived in St. John's, where was immunohistochemistry staining being performed?
DR. KHALIFA:
A. Well, okay, so now in the anatomic pathology lab, you have the regular H&E, you have special stains which are just regular histochemistry and then you have immunohistochemistry.
COFFEY, Q.C.:
Q. Yes.
DR. KHALIFA:
A. Immunohistochemistry uses antibodies and immunology principles. The lab was up and

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running, I was actually, if anything, I was really impressed by the number of antibodies available, the quality of work done.
COFFEY, Q.C.:
Q. In IHC at the time?
DR. KHALIFA:
A. Yeah, in immunohistochemistry at that time. The lab was up and running and in fact, I was very impressed to know that this was the only lab--up to the time when I left, it was the only lab in the whole province who performs this service, so this was a high volume, high volume lab and it was functioning.
COFFEY, Q.C.:
Q. Now, Doctor, when you arrived as a staff pathologist and looking around you, you understood who amongst the pathologists was responsible for the IHC end of the lab? And, for that matter, for the histology and the H&E end of it, who was the pathologist who was responsible for that?
DR. KHALIFA:
A. Well Dr. Ferandez was the site chief.
COFFEY, Q.C.:
Q. I take it, it was the site chief from your

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perspective?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. That was your understanding?
DR. KHALIFA:
A. That was my understanding.
COFFEY, Q.C.:
Q. Yeah, because I ask you about it because there was no formal description of what the site chief's role was?
DR. KHALIFA:
A. No, up to the time I became a site chief, there wasn't a job description.
COFFEY, Q.C.:
Q. But you would have understood, as a staff pathologist, that well Dr. Fernandez is the site chief.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Therefore, she is responsible for the clinical aspects of the pathology end of the lab, the H&E staining, the histology staining, special stains and the IHC staining?

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DR. KHALIFA:
A. Well, you can put it this way, but as a staff pathologist, when I had problems with the lab or a stain didn't work, I would go to the lab, so I did not interact with her at that time as the person responsible for seeing to it that things are done in a certain way. I think that was probably her role, but I'm not sure if people acted this way in the lab.
COFFEY, Q.C.:
Q. When you became site chief, okay, I take it that you did interact because you got involved to the extent of even deciding, well, we'll use particular types of requisition forms and so on.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. So as a site chief, certainly you were involved in that end of it.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. How was, during the time you were site chief, Doctor, how was the laboratory physically laid

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out in terms of H&E staining, special staining and IHC staining? How was that, do you recall physically how they were--were they all kind of lumped in together or were they, IHC at one end, histology at another, do you recall how that was laid out?

DR. KHALIFA:

A. There was an open concept area where all the histotechnologists worked in the same area. I would say probably immunohistochemistry was on one bench with the stainer and the microtones and the regular histology was on another end, but it was all in one place.

COFFEY, Q.C.:

Q. Were there any particular technologists, histotechnologists assigned to doing the IHC work at the time?

DR. KHALIFA:

A. At the time and up to when I left, there were two particular histotechnologists doing immunohistochemistry, yes.

COFFEY, Q.C.:

Q. And that would be, in your day, Peggy Welsh was one.

DR. KHALIFA:

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A. Yes.

COFFEY, Q.C.:

Q. And Mary Butler?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. Were you involved in any way in training them?

DR. KHALIFA:

A. Four-month training or in-service?

COFFEY, Q.C.:

Q. Yes, well, formal first.

DR. KHALIFA:

A. No.

COFFEY, Q.C.:

Q. Okay, how about in-service.

DR. KHALIFA:

A. No. I was involved with them in troubleshooting and just explaining things as we go.

COFFEY, Q.C.:

Q. Doctor, in giving the Commissioner some sense of this, if we could bring up, please, Page 28--or go to Page 28 of this document, Registrar. That's of your CV. Doctor, on this page under the heading, "Local Lectures"

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- you see that there? - the second bullet is "Med-path rounds every other Wednesday at Memorial University, September '95 to September '96," and then "Surgical pathology rounds, Department of Pathology, Memorial University every Tuesday." Okay?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Could you please tell the Commissioner then, during your days of site chief at the Health Sciences Center here in St. John's, how that aspect of your job worked? I mean, how did you organize that? Was it there when you arrived? Did you reorganize it? Did you institute anything, because I do understand that there were certainly rounds, teaching rounds and otherwise, and perhaps you could tell the Commissioner about that.

DR. KHALIFA:

A. Med-path rounds were probably multidisciplinary rounds that--I think they were there before I arrived and I just participated in them, but it came clear to me soon that the department needed communication.

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The staff needed to communication to work together and, again, because of my background, everywhere I worked before there were set time where all members of the department come around what we call a multi-headed microscope, so all pathologists will be looking at the same slide at the same time. It's a good forum for quality assurance because one pathologist will be presenting a case and say - I know it happened to me. I would present a case and say, "I think this is an example of this entity," and one of the staff would say, "I'm not sure. It looks like probably it could be that, and why don't you do this stain or do this or that," and then I go back and I take their advice and I like to give them follow-up in the following week. I would say, "You know what, I almost missed the boat on this one." So I decided to have a Tuesday round at noon. It became like our religion to come around the microscope, all the staff, and so it served communications so at least each one of us knows what others are doing and how would we diagnose such a case. It was a very good forum to quality--to QA every other's--

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our work. Each one would bring cases and discuss them, difficult ones. It was a good forum to get second opinion, and it was an excellent forum for residents to learn and, of course, my kind of hidden objective of that was at least to have a certain percentage of our cases that were documented to have more than one set of eyes look at it to ensure correct diagnosis, and during my tenure in the four years I think we met around the microscope more than a hundred times and we discussed probably more than 800 cases. So for whatever it's worth, one can at least now say these 800-plus cases were discussed in a group format and they were offered--they were difficult. Obviously, otherwise, they wouldn't show up in this forum, and they were offered the collective diagnosis of everybody around the microscope at the time.

COFFEY, Q.C.:

Q. Doctor, were there notes or minutes kept of these, or any kind of record kept of these meetings, do you recall?

DR. KHALIFA:

A. I know that towards the end of my time I wrote

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a letter to Dr. Haegert to summarize this experience and mention that the attendance was--at least three pathologists were sitting in every one of these sessions. I would have to wonder if I had these figures--so I probably have a record, or probably there was a record of these cases somewhere in the system.

COFFEY, Q.C.:

Q. And so after four years when you are now able almost a decade later to say, "Well, there were about 800 cases that we looked at and a 100 meetings," in order to keep track of the fact that there were upwards of a 100 meetings, you have to have been track of the meetings, I take it.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Some record was being kept.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, you've also indicated that - and you referred to this earlier - that when you

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arrived in St. John's that you wanted to--or saw the need to more formalize certain aspects of the way pathology was carried on in St. John's. For example, I think you referred to having meetings, having agendas for meetings, things like that. How did you go about doing that?

DR. KHALIFA:

A. I just used commonsense and used some of my previous experience, with the understanding that it was kind of on-the-go process. In other words, you would only face--you would only know of an issue when it happens, and I can give you many examples. At one point in time, I realized that--like I would ask for a case, and I'd find out that it was sent to Dr. so and so for consultation, and I would say, "Who authorized this?" They would say, "Nobody." So I said, "So are you telling me that anybody can call up the lab and say I want my cases--I am Joe Smith and I want to send my cases to Mayo Clinic for a second opinion, and you just send it out?" "Yeah, that's pretty much what we do." So that was an immediate area that obviously needed some

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interference. So we sat down. We wrote a policy about how to release cases and someone has to sign for the case, and so things like that.

COFFEY, Q.C.:

Q. You create a record that this is going -

DR. KHALIFA:

A. This is to create a record for--and when did the case left the department? When did it arrive, and where did it go to because, again, in other places - as a matter of fact, before the case leaves the department, it needs a second look and that is another layer of quality assurance. I mean, you talk about random review of diagnosis. If we just have a policy that every - and it doesn't have to be a different pathologist. The same pathologist can look at the same slides--because, you know, on a different day you may have a fresher look at it. So I said, "Please, guys, before you release a case, have a second look at it and authorize. Just authorize that the case will go, will leave the department." We keep track which cases left the department, where did they go to, and when did they come

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back and, more importantly, what was the outside diagnosis, and that was another layer of quality assurance because now if the case is reviewed--if my case is reviewed in John Hopkins, I pretty much would like to know what the John Hopkins' guys called it. I mean, if they agreed, that's fine. If they disagreed, I would like to know why.

COFFEY, Q.C.:

Q. Doctor, in relation to that, I take it then, you would expect that that would be recorded eventually on the patient's chart and you, as the original pathologist, would like to know what John Hopkins said.

DR. KHALIFA:

A. Absolutely.

COFFEY, Q.C.:

Q. Found its way into the chart.

DR. KHALIFA:

A. Absolutely

COFFEY, Q.C.:

Q. Doctor, just as an aside here, during these Tuesday surgical pathology rounds -

DR. KHALIFA:

A. Yes.

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COFFEY, Q.C.:

Q. Where you've indicated perhaps upwards of 800 cases would have been discussed, do you know if the fact that each of these patient's cases was being discussed in that context? Would it have been recorded on the patient's chart?

DR. KHALIFA:

A. Okay. If you look at any quality assurance program, it has different components and one of the components is called prospective review. A prospective review means a case is being reviewed before the report goes out. So at the end the patient's chart will have a report saying that this is what it is, but in the department we know that this case has been reviewed by so and so and, believe it or not, that by itself became a problem because, again, the pathologist would say, "I showed the case to Dr. K and he agreed on it," and, again, according to what I know in pathology, you can't mention someone else's name on the report unless that person was given the opportunity to review the case in its totality, so that needed a policy. We sat down. We said, "Guys, you can only mention

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someone's name on your report if that person reviewed the case it its entirely as if it was his or hers." If the other person reviewed only part of the case and gave an informal opinion, that shouldn't be on the report but should be kept in internal record," and then we said, "Okay, how are we going to keep internal record?" So I developed another forum, which is the consultation forum. So my colleague brings a case to me and says, "What do you think of this slide," and we'll have a forum and I will say, "I think Slide B shows cancer" and I sign. So now it is on record that I only saw Slide B and my opinion of Slide B that it is cancer, so things of that sort.

COFFEY, Q.C.:

Q. And why I'm canvassing this - and we'll see some of this in some of the minutes of meetings I'm going to take you through, Doctor, is to give the Commissioner some sense of--I take it then, would it be fair to say, Doctor, that documenting things and having structures in place, acknowledge structures in place, guidelines, protocols, approaches and

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formalizing them with something, that when you took over as site chief there was a lot of that to be done in St. John's.

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. That's not unfair to make that -

DR. KHALIFA:

A. No, that's a very fair statement.

COFFEY, Q.C.:

Q. And I gather, Doctor, that that sort of a process, even in a very old and established institute, is an ongoing process. In a place like Sunnybrook, for example, where you work now, even that would be still an ongoing process. There's still changes.

DR. KHALIFA:

A. Yes, no matter how many issues we see and no matter how much experience we gather, we still get surprised.

COFFEY, Q.C.:

Q. Doctor, up to the point where you left in early 1999, how far had that aspect of the matter evolved or progressed? You've been site chief from the beginning of '96, really,

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to the beginning of '99. So over the three years, compared to a place like Sunnybrook which is a much older institution, how far had St. John's evolved, from your perspective?

DR. KHALIFA:

A. It evolved a lot. It evolved a lot. Due to the keenness of members of the department on the technical side and the clinical side, people knew the issues. People wholeheartedly wanted to improve and, if they found a little bit of leadership, that was very helpful, was very collegial and the department evolved a lot.

COFFEY, Q.C.:

Q. And from your perspective at the time you left, did it have a ways yet though to go?

DR. KHALIFA:

A. I would say by the time I left, if you talk about the structure and the quality assurance program in the department, it was acceptable but, as I said, every place can improve and it needed a lot to improve.

COFFEY, Q.C.:

Q. Doctor, in that regard, is it your experience that at times such improvements require

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financial resources, more money. If you're going to accomplish certain things, you need more money to do it.

DR. KHALIFA:

A. Absolutely. Absolutely. My four years in St. John's were not what you would describe as the years of plenty. I don't recall having plenty of anything except the number of cases. I mean, you need benchmarks, right? I mean, if you want to compare that to Sunnybrook or you want to compare it to UHN or Hopkins, we have a whole team. We have a whole quality assurance section team.

COFFEY, Q.C.:

Q. In Sunnybrook, for example.

DR. KHALIFA:

A. In Sunnybrook. I mean, in Sunnybrook, if I want to figure out how many frozen sections went wrong last month, it takes a click on the button - and I am not kidding - it takes a click on the button or a phone call because we have one person in the department who does nothing but collecting data for me. I ask her, "Tell me what went wrong. Collect this." So that's like--right there, you need

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personnel. You need computer system. The computer system at the time - and I still don't know what system is employed today - but the computer system, if I remember, was Meditec and people in the field know that Meditec is a very good, robust system but not necessarily very quality assurance friendly. The way it pulls out management reports, quality assurance reports, there are better systems if that's what you want to do, and that's very expensive. I mean, you talk to other places in the country who are trying--or at least in our province in Ontario, trying to meet the standards by Cancer Care Ontario, and hospitals are struggling with their resources because these things are very expensive. So I'm not sure if I'm answering your question but -

COFFEY, Q.C.:

Q. I think you are, Doctor.

DR. KHALIFA:

A. But in St. John's there were many constraints. Money was probably the most important, not to underestimate other elements, which is what I would call culture elements, because if you

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talk about the safety culture that we all embrace today, that needs systemic work by the leadership on developing the safety culture, the non-punitive culture that will host learning and encourage disclosure. The culture needs work as well. So it's not all money. Money is very important and probably is the most important piece during that time, but culture needed some work as well.

COFFEY, Q.C.:

Q. I take it, to evolve toward a culture where - blame, I'll use that word.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Was less emphasized and more disclosure was encouraged.

DR. KHALIFA:

A. That's the safety culture we like to see.

COFFEY, Q.C.:

Q. Safety culture, yes, and what you found in St. John's throughout the late 1990's was--there was room for improvement in that regard.

DR. KHALIFA:

A. Well, we have to remember that the landmark

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report by the Institute of Medicine "To Ere Is Human," came in 2000. So there's a revolution in the whole North America about patient safety, and it wasn't unique to St. John's at the time. The defensiveness and the fear of blame was not unique to St. John's.

COFFEY, Q.C.:

Q. Yes, your point is well taken, Doctor, is that by looking--you're saying, "Look, Mr. Coffey, looking back from the perspective of 2008, the culture that existed in St. John's and elsewhere in the late 1990's could have been improved in terms of safety, patient safety."

DR. KHALIFA:

A. Yes. Yes.

COFFEY, Q.C.:

Q. And the major impetus, from your perspective, began around the year 2000.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. North American wide anyway.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

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Q. Doctor, to give the Commissioner some sense of the work environment in the late 1990's - and I'm going to go on then to ER/PR, in particular - and IHC format that came out of usage in the late 1990's in St. John's, you've indicated that you--after you got settled in St. John's, over time then you began to be consulted by your fellow pathologists at times on particular cases.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. As time went on, how did that develop? How did that evolve? Did you get more and more such consultations and did it evolve outside St. John's? Could you tell the Commissioner about that?

DR. KHALIFA:

A. Yes. There was - because at that time the department did not sub-specialize formally. Each one had a little piece of expertise. One particular pathologists was interested in skin pathology. Another was interested in lymphoma. I just happened to be interested in gastrointestinal tract. Gynaecology was by

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virtue of formal training, and breast pathology, and at that time I also had interest in prostate pathology. It just covered a wider range. So more pathologists would come to me for second opinion and everybody was consulting with everybody, and that evolved. Also, because I need to mention that in many cancer centers there is a policy called pathology review or cancer review. Cancer reviews mean that a patient is referred to one cancer center. Say, they are going to Sloan Kettering in New York. The oncologist in Sloan Kettering would like their own pathologist to tell them about the tumour. So it's not an unusual practice for Sloan Kettering to call St. John's and say, "Send the slides to us so we can review it by our own pathologists." Any cancer center does that, and there are several reasons. I mean, there's literature about why this is a safer practice. In St. John's we had the cancer center, we had a very active oncology group and there was nobody really formally reviewing their cases. They gained trust in me. They valued my opinion, so they started asking me

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to review cases. So cases coming from Gander, Grand Falls, they would come to me and I would write my report and I'd talk to the oncologist in the cancer center. Of course, physically, we are close. If they have a problem, they can call me rather than calling the original pathologist. My sense at the time was pathologists in the community liked my diagnoses, liked my services because it added another layer of quality assurance to them, so we built that relationship of trust between our department and myself and the cancer center.

COFFEY, Q.C.:

Q. And that involved you too being consulted by pathologists from outside St. John's a well.

DR. KHALIFA:

A. And that also was going on. Even without having a formal cancer review, a pathologist in the community outside St. John's would send me their case and say, "What do you think of this" or "What do I need to do with this?" That was going on all the time.

COFFEY, Q.C.:

Q. Now, Doctor, before I leave that aspect of the

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matter, that, I take--the General Hospital was a tertiary care center.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And was performing that function for the province. These consultations from outside St. John's or even, I suppose, within St. John's -

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Across town.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. By other pathologists. Were you paid in any way extra for that? Would you paid for doing that extra because I - was that extra work for you and, if so, were you paid for it?

DR. KHALIFA:

A. That was extra work. I would estimate that as probably - we can go back to the numbers - but I would estimate that as probably .2 or .3 FTE at the time, but the answer to your question

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is, no. I was not compensated for this service.

COFFEY, Q.C.:

Q. So .2 to .3, that's two-tenths or three-tenths of a full-time equivalent.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. That kind of consultation work amounted to--from looking back on it, it was between 20 and 30 percent of your work.

DR. KHALIFA:

A. Yes. Yeah, but I was still performing my work as a staff pathologist as well.

COFFEY, Q.C.:

Q. Your own work, yes. It was the equivalent of doing 20 or 30 percent of a full-time position.

DR. KHALIFA:

A. Yes, on top of my work.

COFFEY, Q.C.:

Q. Did you ever take that up with anybody, the fact that you weren't being compensated for that?

DR. KHALIFA:

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A. Again, I was coming at the time from a system where pathologists billed for their services, in the States, so I went to my chief and I asked him if - well, honestly, I thought that this was in the system. I thought that I was doing this and I was compensated and, again, when I noticed that I wasn't compensated, I went and asked him--I said, "Listen, I'm doing all these things and the cancer center is not paying me for this. Are they going to pay?" He said, "Well, we didn't really have this situation before, but let me talk to some people," and he talked to some people in the senior leadership and came back to me and he said, "You know what, they don't think that you need to be compensated for this. This should be part of your work. You don't have to do it. I'm not going to force you to do it, but you can continue to do it." And I told him that this is an unbelievable service for the patients and for our residents because, obviously, cases that come for consultation are the difficult ones. Those are the ones that the residents like to see and like to learn from and, if we can do a

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better service for our patients, we can't deny that. So we made a decision, a collective decision between the two of us that this service is going to continue and we will not bring it up again.

COFFEY, Q.C.:

Q. And the clinical chief at this point is Dave Haegert.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. All right, Commissioner, it would be an appropriate time to take a break now.

DR. KHALIFA:

A. Good.

COFFEY, Q.C.:

Q. Thank you, Doctor.

(OFF RECORD)

THE COMMISSIONER:

Q. Mr. Coffey, before you begin, I'm told that the mice are now working but that the system reveals that there is a laptop with a Blue Tooth operational. So if that happens to be your laptop, could you disable the Blue Tooth so that we don't have any further problems

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with our mice. I won't make you stay after school if you don't fess up or anything like that. I'd just ask you to disable it. Thank you.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Commissioner, there are three other exhibits which I will be referring the Doctor to. They're C exhibits. They're C-0185, 0186 and 0187. I'll be coming to those eventually.

THE COMMISSIONER:

Q. 0185, 86, and 87 entered.

EXHIBITS ENTERED AND MARKED C-0185 THROUGH C-0187

COFFEY, Q.C.:

Q. Thank you. Now Doctor, you would, of course, Doctor, I gather, be aware of the--generally aware of the mandate of the Commissioner is to look into the ER/PR retesting matter and the changes that have occurred upon retesting, at least for some patients tissue samples. I'm going to ask you, Doctor, about IHC testing, and in particular, ER/PR and what you found when you arrived in St. John's and then have you tell the Commissioner about how that evolved during your time here. Perhaps you

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could tell us then when you arrived in St. John's, estrogen receptors and progesterone receptors, how were they being tested for for breast cancer in St. John's when you arrived?

DR. KHALIFA:

A. At the time, in '95, estrogen receptors was tested by what was known at the time as biochemical assay. The biochemical assay means that the surgeon excises the tumour and a fresh piece of the tumour is cut using just the naked eye exams, which means that someone assumes that this is the tumour and they take a piece and they send it directly from the OR to the chemistry lab. So it doesn't come to pathology at all. That little piece is removed from the OR to the chemistry lab and they take the tissue and they form what is known as an emulsion, which is converting the tissue into just a group of cells, and they test them through their procedure and their results are released by biochemistry. I think they had three categories, negative, equivocal and positive, depending on the level of expression. At the same time, on the other end, the surgeon sends the rest of the

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specimen to pathology. So pathology technically was not involved at all in ER/PR.

By the mid '90s, going into the late '90s, most North American institutions moved away from that technique for a variety of reasons. It was seen as a crude technique. It mixes benign with malignant cells. We are not sure that we are actually analysing tumour. Several issues with that procedure, and everybody was moving into immunohistochemistry. Probably by 1990, '92, in Oklahoma City, I remember the technology was being introduced, the immunohistochemistry, but was kind of primitive. It was done on frozen sections. So this is when pathology received now the specimen. They prepare a frozen section, which is a fresh section, and then they process the specimen after that. That one frozen section is done by immunohistochemistry.

By later on, '94, when I was at George Washington, they were doing it by regular immunohistochemistry on paraffin-fixed,

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formalin fixed, paraffin embedded tissue. Same thing with '95 in Georgetown, and I was under the impression, at the time, that probably everybody was about then doing immunohistochemistry. I came to St. John's and again, I found that they were still doing it by biochemical assay. I saw that this was suboptimal. I started again talking to people and my leadership, Dr. Haegert, supported the initiative. We brought the director of biochemistry on board, a medical director, Dr. Prabhakaran. He came on board. We started working on how to introduce the test, and through the period of time, the test was introduced.

COFFEY, Q.C.:

Q. So how did you go about doing it then, Doctor, the introduction? What happened before initially? You've talked to the biochemist?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And you've talked to Dr. Haegert?

DR. KHALIFA:

A. Yes.

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COFFEY, Q.C.:
Q. So how did you go about it then?
DR. KHALIFA:
A. So the immunohistochemistry lab was up and running and this was just one more antibody that they can work with. The recipes were already there. The procedure was there. We had the personnel. So I didn't think that this was going to represent a big burden on our lab. We developed a program, a three-phase program, with the priority at making sure that the result we released by immunohistochemistry will be comparable to what would have otherwise been produced by the biochemical assay. The logic behind that was for the patient in Newfoundland at the time, her option was the biochemical assay, and everybody was comfortable with that and clinicians were treating patients based on that. So if I can adopt this new technique to produce similarly reliable results, then that was the goal.

So we started talking about purchasing antibodies and of course, there were a variety of antibodies available in the market,

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different clones. Some companies included their antibody in what we call a kit, which includes other chemicals for treatment. So we started working with those, maybe purchased a couple of samples, experiment with them, working on the titration, getting the concentration right, getting the testing conditions up to meeting the specification of the manufacturer. All of that was happening in parallel with the biochemical assay. The biochemical assay, we decided early on that we were not going to stop that unless we are fully comfortable with the immunohistochemistry.

So the biochemical assay was going in parallel and we were experimenting, and then we decided to start doing the test on real cases. Doing the test on real cases, Dr. Haegert's view was "why don't you read the slides for now until we are satisfied with the procedure." So I continued reading the slides, which means now that the case, they are still doing the biochemical assay. We are getting the tissue. We are making our sections. We are staining them for ER/PR and

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the slides come to me and I report them. We continued doing that from sometime early in '97 until probably early '98. When we--and during that, of course, there was discussions with pathologists. I was showing the slides in the Tuesday noon conference. We were talking with pathologists at St. Clare's, at the Grace Hospital. So we had a whole year to discuss the issue.
COFFEY, Q.C.:
Q. Doctor -
DR. KHALIFA:
A. Clinicians at that time were receiving two reports now. They are receiving the biochemistry report and they were receiving my report on the immunohistochemistry. The group of pathologists at St. Clare's, certainly they were doing more breast cases. They were more involved in breast pathology, and they didn't mind--in fact, they wanted to start seeing their own cases. They didn't think that--okay, so you got the technique going on. You got the slides going on. We need to start getting our own slides. We need to read our own cases and -

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COFFEY, Q.C.:
Q. Read the ER/PR?
DR. KHALIFA:
A. I'm talking about the ER/PR.
COFFEY, Q.C.:
Q. Yes, go ahead, Doctor.
DR. KHALIFA:
A. So until when we went to the second phase of this experiment, or of this procedure, correlating the results, I think we started talking about now sending back the slides to the respective pathologists to read them, because remember, at that time, we were doing this service for all other antibodies. The pathologist sends the block, we do the antibody, and then we send the slide to them. So we started to do the same with ER/PR. We said "guys, now you are going to start receiving your own slides for reporting." A lot of discussion went on around that. A lot of discussion about how are we going to report them, the standardization, how do we--what format, what controls are we getting, a lot of discussion, and the logistics, how are you going to send the slides and obviously this

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was a new thing for everybody and in reality, the only new thing about ER/PR at the time was the fact that this antibody stains the nuclei. All the other antibodies known at the time were staining the cytoplasm. So the pathologist just needed to be reminded to look at the nuclei and any pathologist, at that time, by going to meetings and reading literature, they knew what ER/PR is about.

So we went through this phase and then ultimately, after they started receiving the slides, after everybody was comfortable, we decided to pull the plug on the biochemical assay later on, and that technique stopped completely.

COFFEY, Q.C.:

Q. Now Doctor, you've indicated that ER and PR IHC method involved staining of nuclei, and that was different than other types of IHC stains?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Which are cytoplasmic or membrane?

DR. KHALIFA:

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A. Yes.

COFFEY, Q.C.:

Q. In terms of the ER and PR IHC method within the laboratory itself, in terms of producing the slides, was there anything different about that, involving in particular antigen retrieval, that aspect of the matter, compared to other IHC stains?

DR. KHALIFA:

A. It needed antigen retrieval.

COFFEY, Q.C.:

Q. Yes.

DR. KHALIFA:

A. Other antibodies needed antigen retrieval too.

COFFEY, Q.C.:

Q. We are advised, we understand that it involved heating the slides, considerably heating the slides, like to -

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. - in effect, I won't say boiling them, but certainly coming close to boiling them.

DR. KHALIFA:

A. Yes.

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COFFEY, Q.C.:

Q. That sort of a process involving IHC, how many stains at that time were using heat induced retrieval?

DR. KHALIFA:

A. I wouldn't be able to know that.

COFFEY, Q.C.:

Q. Do you recall, was that--within the laboratory itself, was that something new at the time, do you recall, like the idea that boiling the slides, I use the phrase advisedly. I don't mean to actually boil them, but significantly -

DR. KHALIFA:

A. Heating.

COFFEY, Q.C.:

Q. - heating the slides, was that common at the time, do you know, or was it -

DR. KHALIFA:

A. I wouldn't remember that. I don't know.

COFFEY, Q.C.:

Q. Now Doctor, at the time, you indicated that you would have had to choose, of course, between the various antibodies that were available for ER and PR. There were more--

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there's more than one antibody available for each. How would you go about doing that? How would you decide on which antibody to use?

DR. KHALIFA:

A. You look at the literature. You see what clone is more popular. Of course, there is the finance part, which one comes in a kit and which ones we can use our own solutions. There are several factors, and when we started, we started with different antibodies to try them. Like any experiment in the lab, you try several antibodies until you are happy with one vendor, and you go for it.

COFFEY, Q.C.:

Q. And Doctor, when you first got involved in this in St. John's, there were kits involved. I take it each individual patient's tissue involved the usage of a kit?

DR. KHALIFA:

A. Some companies marketed their antibody in kits, in the kit format.

COFFEY, Q.C.:

Q. The one that was finally decided upon or chosen in St. John's, it wasn't in kit form, was it?

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DR. KHALIFA:
A. I would suspect no, because kits are very expensive.
COFFEY, Q.C.:
Q. We've heard about a DAKO auto stainer.
DR. KHALIFA:
A. Okay.
COFFEY, Q.C.:
Q. Are you familiar with the DAKO machine that they used in St. John's in the late 1990s?
DR. KHALIFA:
A. I don't know exact the specifics of the machine, but I am familiar with DAKO machines.
COFFEY, Q.C.:
Q. Doctor then, I'll come back then. So in deciding to go ahead with or get involved in ER/PR IHC staining in St. John's, you had to choose the clone? Choose amongst a number of clones. You would have indicated--you indicated you would have looked at a number of different ones, tried them. Finances would be of interest, the form they came in.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:

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Q. Kit or otherwise. We understand that the dilutions can be different, depending upon the clone, and in fact depending upon the location?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Were you involved in that, deciding what the dilution should be in St. John's?
DR. KHALIFA:
A. Yes. Dilution would be different. As you know, the antibody comes with a specification sheet. The manufacturer advises you the temperature, advises you how to do the recipes, sort of a cooking recipe.
COFFEY, Q.C.:
Q. Yes.
DR. KHALIFA:
A. So if they say you can use one to 100 concentration, we try that and it is still negative and now, remember, we are running the biochemistry in parallel. We want to hit the same, the consistent result. So if the biochemistry is saying this case is negative and we are getting it positive, so probably we

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are using too much concentration. We want to get to the biochemistry, and we had external controls of known positive cases that we used. So we had few tools to work with to adjust the concentration and the temperature and all the testing conditions of the lab.
COFFEY, Q.C.:
Q. As I indicated, as well then the testing, the heating conditions, and particularly the time period, the duration of the heating, I take it could change?
DR. KHALIFA:
A. Exactly, and even the time of the antibody and do you put it at room temperature, higher, lower, ten minutes, a whole day.
COFFEY, Q.C.:
Q. All of that had to be addressed at the time?
DR. KHALIFA:
A. Of course.
COFFEY, Q.C.:
Q. Were there any records kept of that at the time, that whole process?
DR. KHALIFA:
A. I was doing this with technologists and I would give her advice and I would look at the

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slides with her and she would keep record as Khalifa said this or said that, and bring it back and actually, I remember the slides would come labelled with different--so I would get different slides on the tray with different concentrations. So I have the chance to look at them. Okay, we pick that concentration because the one before were too faint or the one after were too concentrated. So that stuff should have stayed in the lab.
COFFEY, Q.C.:
Q. So Doctor, I take it then, in getting involved in this, having chosen the clone or at least narrowed down the clones, you looked at and experimented with different dilutions?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Comparing it all the time to known positives?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And the biochemistry?
DR. KHALIFA:
A. Yes.

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COFFEY, Q.C.:
Q. Biochemical results. Different heating times, antigen exposure times?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Clone exposure times and so on, you would have gone through that whole process?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. From your perspective. Had you ever done anything like that before, like that kind of a process?
DR. KHALIFA:
A. Experimental. Remember before that, I wasn't playing that role in any other hospital, but I was a researcher, I was -- as a resident in Oklahoma, I was probably the very first resident to acquire a university research grant. I had my own technologist at the time, a PhD student, to run different antibodies, and by the time I came to St. John's I already had publications on Her-2-neu, EGFR, P53. in other tumours, in female genital tract cancer.

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So every time we -- Her-2-neu antibodies in the early 90s was experimental, so we had to do that same thing, experimentation, and even in St. John's the late Dr. Robb was interested in research and he and I would meet and talk about certain projects, and get new antibodies, and when I started in St. John's the university gave me SEED grant of $10,000.00 that I used to purchase antibodies and me and Des Robb would sit and experiment with the antibodies. So that is kind of like a normal procedure for any antibody -- any new antibody.
COFFEY, Q.C.:
Q. In fact, were you tomorrow or the next day to be ordering an antibody, for example, at Sunnybrook, if you're involved in that end of it at Sunnybrook, does that same sort of process go on even today if there's a new antibody comes into the lab?
DR. KHALIFA:
A. In most -- to the best of my knowledge, in most tertiary care academic medical centres in North America, immunohistochemistry has a different -- falls under anatomic pathology,

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but it's a different department. In our place in Sunnybrook, we have a director of immunohistochemistry, we have a senior tech, we have a group of techs, we have -- in many places they have RD people. We don't have an RD person, but -- so in Sunnybrook, if I want a new antibody, I would contact so and so and tell her that why don't we buy this antibody, and she will go through all that.
COFFEY, Q.C.:
Q. But the process, your understanding that she goes through in a general way would be the same one you went through back in the 90s in St. John's?
DR. KHALIFA:
A. Yes, sir.
COFFEY, Q.C.:
Q. There's a suggested approach by the manufacturer, and you set out to test is that going to work here in my institution?
DR. KHALIFA:
A. Yes, because what the manufacturer says on the spec sheet -- again just like a cooking recipe someone can give you to cook and you try it and it just doesn't taste right. So just

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because the manufacturer says that this is the way to do it doesn't necessarily guarantee that it works every time under those conditions.
COFFEY, Q.C.:
Q. Doctor, if we could, please, while we're on the topic, if we could look at P-2423, please, and page 28, please. Again on the same page under local lectures, the fifth bullet, see that? It's "Significance of ER/PR and breast cancer. A presentation at the Newfoundland Cancer Treatment and Research Foundation, Continuing Medical Education Program, March, 1997". So I take it, Doctor, that you were involved enough in the ER/PR to have given a lecture here in St. John's in 1997 involving ER/PR?
DR. KHALIFA:
A. Well, I was trying to get the word out that we are doing this, and that was one of many endeavours. I remember even calling the Evening Telegram at the time. I knew that there was someone who writes a health related column, and I called her, I left messages on her voice mail, and after several unsuccessful

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attempts, she finally -- I finally got hold of her and I told her, listen, there is something called immunohistochemistry and ER/PR, and we are introducing this and it's going to be very useful for patients in Newfoundland, and she told me that's probably not something that people are interested to read about. So I wouldn't -- at that time I wouldn't have missed a chance to get the word out to as many people as possible that this is a better technology and we are embarking on it.

COFFEY, Q.C.:

Q. Doctor, this lecture at the Cancer Centre, the Newfoundland Cancer Treatment and Research Foundation Centre, do you recall who the audience was, not necessarily individuals, but who is your audience, who was your lecture directed at, do you recall? Were they oncologists, pathologists, a mixture, technologists?

DR. KHALIFA:

A. I would probably assume it was residents, pathology residents, pathologists, oncologists, breast surgeons, and some of the health care providers around this area.

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COFFEY, Q.C.:

Q. Could we just go back one page. Doctor, there is invited lectures on the page before, page 27 of your CV. Look down through it, the third bullet, "National Society for Histotechnology annual meeting, two workshops. Staining estrogen and progesterone receptors, and beyond the -- how do you pronounce that?

DR. KHALIFA:

A. The Feulgen. Okay, there was -- the histotechnologists annual meetings in North America, they invite speakers to talk to histotechnologists, and one particular organization was interested in ER/PR and interested in Feulgen reaction. Feulgen reaction at that time was a special stain that stains nuclei, and for the machine to be able to read and assess how much DMA is in the nucleus, for something not related to breast cancer, anyways, but it was used in breast cancer also at the time. So they invited me to go there and give a workshop and a presentation on the theoretical aspect of ER/PR so that histotechnologists will understand what the stain means. That was

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kind of, I would describe, as a successful -- actually it was a very successful presentation, they liked it, and then they invited me the next year in their next meeting, it was in Salt Lake City, again they loved it, so I was invited again to give the same talk in -- yeah, somewhere on the east coast, in Rhode Island.

COFFEY, Q.C.:

Q. Providence, Rhode Island?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, why I ask about this now is that -- so this did not involve breast cancer per se?

DR. KHALIFA:

A. Well, the primary reason for ER/PR was breast cancer.

COFFEY, Q.C.:

Q. But it did relate to the staining of estrogen and progesterone receptors, so you were asked on a number of occasions in the last 1990s to go and talk to histotechnologists in the US about the theoretical aspects?

DR. KHALIFA:

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A. The theoretical background of the stain, yes.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1889. Doctor, this is a letter dated March 12th, 1997. It's from yourself and it's copied to Dr. Haegert and Mr. Whelan, Vern Whelan, and it's a letter addressed to Terry Gulliver, and you write, "The ER/PR kit we have tried, and which offered us very good and reliable results, has been totally consumed by late last week, Thursday, February 20th. You knew this and you were trying to use a new detection system in combination with an old primary antibody that the laboratory had for some time. This combination did not work. I called you on Monday morning at the Janeway Hospital site, told you were having an emergency situation, any trial of a new technique needs to be done in parallel with a well established one before a switch could be safely made. I thought I conveyed to you this message clearly and asked you to replace the ER/PR kit as soon as possible. This was an emergency situation because at the time we had two cases referred from Corner Brook and one in-house case from

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1996 which we're waiting for this test to be reliably performed. As of now the kit has not arrived and I was told that you are out of town. Ordering such a kit in a timely fashion was vital and a follow up on the order was even more crucial. Mr. Gulliver, I do not think you fully appreciate the delicacy of this test, its clinical consequences, and the overall emotional charge in the public regarding this very sensitive procedure. I'm also uncertain whether our service is being run as smoothly as it should. The medical legal implications of delaying this test are huge, and I want to clearly document my concerns at this time. You willingly have put me in a situation where I have to explain to other physicians why our results are being delayed. I do not want to be responsible for this. I'm also have a very difficult time communicating with you basically because you are either out of town, on another site, or extremely busy within this site. I would have expected you to approach this issue with more precision since Monday morning, as you had told me, and even more not to have allowed the

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first kit to be consumed without obtaining a replacement in a timely manner". Now, Doctor, this is early 1997, and I take it this reference then to the kits here would suggest that at that point the kit process was still being used and you're at the stage where you're involved in trying to do this comparison?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Parallel testing. Doctor, I have this here and refer you to it because I want to ask you just generally about it. How, if at all, does this reflect the relationship between yourself as a site chief, and Mr. Gulliver as the manager of anatomical pathology in terms of spheres of influence? He obviously had to order the kit.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. You're complaining he hasn't done so.

DR. KHALIFA:

A. Yes.

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COFFEY, Q.C.:

Q. So could you tell the Commissioner, please, what, if any, problems that division of responsibility had for you at the time?

DR. KHALIFA:

A. Well, the issue here is two-fold. One is changing the procedure without doing the necessary required testing and getting me involved, and the other one was not ordering it in a timely fashion.

COFFEY, Q.C.:

Q. So we'll deal with the first one then, and then we'll go to the second, okay.

DR. KHALIFA:

A. Okay, but to answer your question about my relationship with Mr. Gulliver, Mr. Gulliver was a very busy man, he had to juggle many responsibilities. There were issues with the other labs in the city, and I think they were talking about closing the Grace and maybe even merging St. Clare's, I don't know, and he was -- at that time he was the president of the national consortium organization for histotechnologists. So he had the national role, he had the local role, he had a

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province-wide role. He was very busy. I was having communication problems with him, not to be reflected in any negative way on him and his dedication to the place. I had no doubt at all that everybody was coming to the lab trying to do the best job they can, and I had no concerns about that whatsoever. It's just the dynamics of the place at that time, it was very stressful time, cutting jobs and straining people -- people were very stressed. We were almost like chasing ourselves. You are trying to relieve stress on one hand, and then you are hit by something else that increases the level of stress again and he was just not available.

COFFEY, Q.C.:

Q. And, in particular, you're, I take it, admonishing him or asking, if not admonishing him, please don't let us run out of kits?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. First of all, this shouldn't have happened in the first place.

DR. KHALIFA:

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A. Yes.
COFFEY, Q.C.:
Q. And I, Dr. Khalifa, having brought it to your attention, I would have expected you to have actually ordered it?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. But as well, though, you refer to him having -- as you pointed out, there's two aspects to this. The other part of it is using a particular kit with an old primary antibody without consulting yourself. Could you tell us, please, what potential effects that had, negative effects that had on your approach?
DR. KHALIFA:
A. I think it's an example of a communication breakdown. Obviously with him, and his obligations and responsibility to be physically responsible, he would rather use our local recipe with just the antibody rather than the kit because it's cheaper. I thought that I should have been part of that decision.
COFFEY, Q.C.:
Q. You pointed out here, this combination did not

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work, in the fourth line there?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. So the -- this particular thing, I take it, that was addressed, was it, this usage of in future -- was that a problem afterwards, using old primary antibodies?
DR. KHALIFA:
A. I know that we tried different combination of things and colouring solutions and things, and remember here you are on one hand trying to optimize the technique and on the other hand -- and the industry is moving on, they keep developing new technologies, and I remember even we had to move to a better, a more sensitive staining mix - I forget what it was, but, I mean, it's a constant challenge to keep up to date with the industry and to run a reliable lab on the other hand. With all the finances involved, it's not easy.
COFFEY, Q.C.:
Q. You do begin the second paragraph here by saying, "Mr. Gulliver, I do not think you fully appreciate the delicacy of this test,

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its clinical consequences, and the overall emotional charge in the public regarding this very sensitive procedure". This procedure, the ER/PR kit, of course, related to breast cancer?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. That, I take it, is the last part of what you're referring to here, this involves breast cancer and you should be -- this is important -- it's important, period, but it's important in a public sense?
DR. KHALIFA:
A. Yes, ER/PR at that time was solely done for breast cancer.
COFFEY, Q.C.:
Q. And you refer to the delicacy of the test. What does that involve?
DR. KHALIFA:
A. The delicacy of the test is -- it's obvious. Well, for one thing, you are running a test that has a gold standard. Remember the gold standard at the time was the biochemical assay. For other antibodies that we introduce

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in the lab, there is no gold standard. So in other words, if it works or it doesn't work, you wouldn't be able to tell, but here I have this gold standard and my diagnosis has always to meet one of these three categories; negative, equivocal, or positive. So there's this monitoring aspect on the one hand. On the other hand, it has a prognostic value which means what to tell the patient about the likelihood of recurrence, and then it has a third dimension, which is therapy. At that time, I think the rationale was to give a certain drug known as Tamoxifen to ER positive patients to prevent or -- to delay the recurrence or to prevent the recurrence. So here you are running a lab test that has a prognostic significance, it has a therapeutic significance, it has a gold standard to compare it with, and it is technically, as any other immunohistochemistry, technically sensitive; sensitive to heating time, antibody dilution, all the other factors we talked about, and it serves a disease that could potentially be lethal. So it's a serious matter.

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COFFEY, Q.C.:
Q. Did Mr. Gulliver ever speak to you about this afterward, do you recall?
DR. KHALIFA:
A. I don't recall a meeting or a formal setting where the issue was discussed, but probably we bumped into each other in the hall and talked about it.
COFFEY, Q.C.:
Q. Did that sort of problem in relation to ER/PR arise again, do you recall, your problem with not having the material there?
DR. KHALIFA:
A. Not to my memory, no. There were other issues, but not the fact that the antibody ran out and we didn't have it.
COFFEY, Q.C.:
Q. What were those -- what were -- if there were other issues involving ER and PR, what were they, do you recall?
DR. KHALIFA:
A. Well, yes, you will get -- you will get a case that the pathologist forgot to order ER/PR because remember before that, pathologists were not involved, when the case goes to the

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chemistry, pathologists had nothing to do with it.
COFFEY, Q.C.:
Q. Pathologists didn't order the ER/PR?
DR. KHALIFA:
A. They didn't order the tests.
COFFEY, Q.C.:
Q. In those days, who was actually doing the ordering of the tests?
DR. KHALIFA:
A. Well, as in any lab, the pathologist who looks at the case -- because here you have a patient, they removed a mass from the patient, they don't know if it's benign or malignant, so the pathologist decides that this is cancer. So the pathologist is the first gate keeper, if you will, is the first person to identify cancer in that patient, so and the patient will have a whole collection of blocks, some of them are benign, some of them are malignant and some of them are in between. So the pathologist looks at the block and chooses the best block to present cancer and then orders the lab through my requisition form to perform the test. So if a pathologist

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is busy or distracted, they make a diagnosis of cancer and they forget to order the ER/PR, then it will never be done. The next thing I get is a phone call from an oncologist saying, well, what's going on, I received this case of cancer, the patient is coming to my office tomorrow or whatever or the patient is here and I don't have ER and PR on her. I go to the computer and it wasn't ordered, so I have to run to the pathologist and say, would you please choose a block and then they order--so that was an ongoing thing, which is understandable in any lab you're introducing a new procedure, people are bound to forget.
COFFEY, Q.C.:
Q. So this wasn't so much--this didn't involve the technologists, this was your fellow pathologists because the fact that they were under the new regime, which I'll be getting to in a moment, they were going to have to order the ER/PR.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And at times, at least in the early years,

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while you were still here in St. John's, at times they forgot to do so?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And a complaint about that would come to you?
DR. KHALIFA:
A. And remember, everybody was doing breast, so you have like six or seven people, it's not like a selected group who does breast.
COFFEY, Q.C.:
Q. Yes. If we could, please, Exhibit P-1855? This is a letter dated April 10th, 1997 to Dr. Cook from yourself. You write "Here's a summary of a few cases where we managed to have simultaneous immuno and biochem assessment of ER/PR. If we follow the suggested cut-off line of 30 percent on immuno to achieve the highest possible correlation with the bio, you can see we seem to be doing very well. The very first case, '97 1400, which would be considered as ER positive by immuno was in fact negative by bio. Of course, the number of cases is still too low to come to final conclusion, but I think

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overall we are not doing bad. I would appreciate your thoughts on this. Of course your efforts to provide the parallel biochemical studies are extremely valuable. Let me know if you have any further suggestion as to make this task more valid and effective. Also let me know of any possible correlation with Mayo." So what was going on here, Doctor, at this point, in early '97? And just so you can see, Doctor, the second page of the exhibit is a document "Correlation with biochemistry, biochemical reporting, 0 to 3, negative; 3 to 20 equivocal; and greater than 20 positive. I take it they are biochemical numbers? And then you have immunohistochemistry number, the results, biochemistry number and the results. So what was going on here, Doctor, overall with this letter to Dr. Cook and the attachment? At what stage was the process at the time?

DR. KHALIFA:

A. Dr. Cook at the time was the site chief at St. Clare's Hospital, again, this was a very active group in breast--actually, they had more breast cancer than we did at the Health

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Sciences Centre. They were very knowledgeable, they were up to date with the literature and I counselled with them a lot on the fine details of ER/PR testing. And I wanted to present to him the very small collection--can we go to the second page please?

COFFEY, Q.C.:

Q. We surely can, Doctor.

DR. KHALIFA:

A. Yeah, what's happening here is we, because the literature at the time was--people believed at the time that a case would be, if 30 percent of malignant cells are positive, then that case would be positive by biochemical assay, so remember here I'm dealing with an oncologist and I'm thinking if the oncologist was used to seeing results in the biochemical assay and now they are seeing immunohistochemical assay, they will ask themselves how can I translate these results to the old system? And the conventional thinking at the time was 30 percent. If 30 percent of the malignant cells were positive on immunohistochemistry, the biochemical assay

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would have been positive. Again, at that time, Tamoxifen was known to be a tricky drug because it delays--its effect on breast cells is that it delays its progression to cancer, so in other words, if a patient had breast cancer, was removed and turned out to be ER positive, if that patient receives Tamoxifen, then her chances for survival are higher or her chances for recurrence are lower, but the flip side of that coin is that Tamoxifen induces or pushes uterine endometrial cells in the uterus to become malignant, so you are giving a patient a drug to delay her breast cancer on the one hand, but you are encouraging her uterine cancer on the other. So unless the patient is going to really benefit from the Tamoxifen in preventing her breast cancer, she really doesn't need that drug because it will increase her risk for uterine cancer. That was the conventional wisdom at the time. Of course, then they came back and they said, well don't give Tamoxifen for more than five years. Well, five years is enough already, you've stimulated the uterus so much that now, after five years, you're

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really pushing the envelop, pushing your luck. And then in, I think in 2003, maybe 2004, they came up with another drug known as Femara and Femara is superior to Tamoxifen in the fact that it does the same effect on breast, but doesn't carry the risk for endometrial cancer. Well, of course, it's nice now to look retrospectively through the time ball, but at the time we only had Tamoxifen. People were very nervous about Tamoxifen. Yes, Tamoxifen gives hope to breast cancer survivors, but puts them at high risk for endometrial cancer. Well you can argue and say what about the patient who had her uterus already removed for another reason, then maybe she's not at the risk for uterine cancer. So these decisions, obviously, are not made at our level, it is made at the oncologist's level, they see the patient, they knew them, they know what's best for them. My job, as I saw it, was to communicate to the clinician, the oncologist a message that is clear and is meaningful is their head to try to translate that to the old biochemical testing. So, we played a little bit with the 30 percent thing and we were

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talking about it, whether we should, we should use it or not use it and how do we word the report and things of that nature.

COFFEY, Q.C.:

Q. And I'll be getting to that, so at this point--because all of that discussion with Dr. Cook, in particular, occurs in early '98. In early '97, you, I take it, were still into this simultaneous immuno and biochemical assessment of ER/PR and the first paragraph concludes with, "Of course, the number of cases is still too low to come to a final conclusion, but I think overall we are not doing bad. I will appreciate your thoughts on this." That will be Don Cook's thoughts. Don would have been, Don Cook would have been the site chief at St. Clare's at the time?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. So at the time you were inviting his input into this?

DR. KHALIFA:

A. All the time.

COFFEY, Q.C.:

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Q. And in particular, his hospital, the hospital he worked in was the one with the most breast cancer patients?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. And you say that is, of course, your efforts, that would be Don Cook's efforts to provide the parallel biochemical studies are extremely valuable. Do you recall what -

DR. KHALIFA:

A. No, "of course, your efforts to provide the parallel biochemical study are extremely valuable", I don't know what that means.

COFFEY, Q.C.:

Q. Was he identifying patients that in fact had had biochemical -

DR. KHALIFA:

A. Yeah.

COFFEY, Q.C.:

Q. At St. Clare's done -

DR. KHALIFA:

A. And maybe the biochemical result will go directly to St. Clare's, so I maybe had no access to this or--and I think they were also

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at the time sending some cases to Mayo Clinic. So we wanted feedback, I wanted feedback from him as to how are the cases being tested in Mayo Clinic compared to our stain, just to make it a tight case.

COFFEY, Q.C.:

Q. And, if we could, please Registrar, Exhibit P-1857? Now, Doctor, the first page of this is an agenda, it's a notice of a meeting, Division of Anatomical Pathology, Health Care Corporation of St. John's, there are a number of individuals--it's addressed to a number of individuals, including Dr. Haegert and Dr. Cook, Dr. Pushpanathan, Mr. Gulliver, Mr. Murphy. John Murphy was who, do you recall? Who was John Murphy, do you recall?

DR. KHALIFA:

A. I'm sorry, I'm sorry.

COFFEY, Q.C.:

Q. It's from, now this is, in fact, it's addressed to yourself. It's from Dr. Parai who is the site chief, I take it, at the Grace at the time. And June 17th, 1997 is the date of the meeting. It's going to be at the Grace and there's an agenda here spelled out,

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including "Business Arising". Paragraph C is "ER and PR receptors, immunoperoxidase staining." So, I take it, Doctor, that--I'm going to ask you about this, the idea of having kind of a formal meeting with an agenda, notice of meeting and agenda, had that existed when you arrived in St. John's for this sort of -

DR. KHALIFA:

A. I don't recall, I don't recall it.

COFFEY, Q.C.:

Q. But certainly by this point in time, that is June of '97, the idea that you would be advised of a meeting as a site chief, invited to a meeting at another site, that there would be a formal agenda, minutes kept, that was certainly established by the middle of 1997?

DR. KHALIFA:

A. I was quite uptight about this.

COFFEY, Q.C.:

Q. Okay, why was that?

DR. KHALIFA:

A. Because I believe in documentation and I wanted to build structure in the process.

COFFEY, Q.C.:

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Q. Certainly by this point in time, the middle of '97, there's structure, there's an agenda, a written agenda, there's minutes being kept and in fact when we look, we'll see that the minutes were being approved, okay. If we could, please Registrar, before I go to the June one, if we could go back--I want to look, please, at Exhibit P-1856. Now, Doctor, this particular one is for the minutes of the anatomic pathology site chiefs and divisional managers' meeting of the month before, May 13th, 1997. It was held at St. Clare's Hospital. A number of people present: Drs. Cook, Khalifa, Parai, Pushpanathan, Mr. Gulliver, Mr. Murphy--Dr. Haegert wasn't present. Now something here I want to ask you about, this is May 13th, it says "The minutes of the December 3rd, 1996 meeting were accepted by Dr. Khalifa." Doctor, apparently the last meeting had been in December 3rd, 1996 and now there's one May 13th, 1997, which is about five months later. Was that the frequency with which these sorts of meeting occurred?

DR. KHALIFA:

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A. Well, remember, at the time I was very keen on having regular staff meeting at the Health Sciences Centre, this is what I kind of controlled and had more influence. Then we had this other forum where the site chiefs from the three hospitals met. These meetings were less regular and probably you're showing that it was almost quarterly, right, so they were probably quarterly.

COFFEY, Q.C.:

Q. And again, to give the Commissioner some sense of the environment, if you look at page 2 of this, paragraph C, "Status of pathology specimen forms." It says, "It was agreed that the pathology specimen forms from the Grace will serve as a standardized form for the Laboratory Program. Dr. Haegert will be asked to write letters to Rosemary Barrington, Program Director and Marie Tracey, Program Director for the Operative Program, advising them that this is now laboratory policy." So I take it at this point they were just within the Health Care Corporation of St. John's getting around to standardizing the pathology forms, that was the status.

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DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Looking at page 3 of this exhibit, it's under "New Business: ER and PR immunoperoxidase receptors." And I take it this would probably by new business for the committee, this committee as a group because you were already involved in the ER/PR itself.

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. It says, "Dr. Khalifa reported to the committee that there is good correlation between the biochemical assay and immunoperoxidase staining for breast receptors. It appears that the time may be right to implement the immunoperoxidase breast receptors corporate wide. Dr. Cook stated that there is a concern amongst the pathologists at St. Clare's that they should be the ones reporting the breast receptors. Discussion then arose that if individual pathologists are reporting these receptors, then there's a need for standardized criteria

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to determine what is regarded as receptor positive and negative. There was also discussion as to how the Mayo Clinic reports its receptors. It was decided that this issue should be brought to a discipline meeting to get a consensus among pathologists. Hopefully such a meeting will be held in June. Until then, it was agreed to maintain a status quo. Dr. Cook also recognized the amount of hard work that Dr. Khalifa had put into this project." I take it, Doctor, that at the time, up to this point, you were reporting the ER/PR IHC results? If they were being reported at all, you were reporting them?

DR. KHALIFA:

A. Throughout the entire '97, I was reporting them. But here I'm reading time to implement the immunohisto staining corporate wide, so I'm not sure if this means that up to that moment I was only doing it in the Health Sciences Centre, maybe. I think that might be an indication that probably cases from St. Clare's were done on case-by-case basis.

COFFEY, Q.C.:

Q. It's possible you, at this point in time, as

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of the middle of 1997, were still not doing all the ER/PR IHC testing.

DR. KHALIFA:

A. I guess that's what I'm trying to say.

COFFEY, Q.C.:

Q. And Dr. Cook stated "There is a concern among the pathologists at St. Clare's that they should be the ones reporting the breast receptors", so what I wanted to ask you about is this, so is Dr. Cook then, in the middle of 1997, at this meeting, asserted, that look, the pathologists at his institution were interested in reporting their own ER/PR IHC cases?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. It wasn't you going out and foisting it upon them, it was they invited this?

DR. KHALIFA:

A. Absolutely, yes.

COFFEY, Q.C.:

Q. The reference to, "If individual pathologists are reporting these receptors, then there's a need for standardized criteria to determine

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what is regarded as positive and negative", and talking about how the Mayo Clinic did it at the time. So I take it then the whole idea of how this would be reported was going to be investigated here?

DR. KHALIFA:

A. Yes, because up to that moment, remember I was kind of doing this on my own using what I learned in Washington, and again in Washington, you have the east coast, you have the Mayo Clinic, you have MD Anderson, you have UCLA, so you have different camps and everybody was doing it differently, and just because I was using -- even if you go back to the record, you see the language I was using. For example, the St. Clare's group didn't like certain words I was using like mild, moderate, and severe, something like that, and they wanted to delete that. So we started deleting this and so we started playing with the words in such a way that everybody would be comfortable and I would go and say, can you live with this, because the idea was not necessarily for me or for "x" to be happy, but to be consistent. That was very important.

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The oncologist doesn't need to be confused when they receive a report from Health Sciences Centre, Grace, or St. Clare's.

COFFEY, Q.C.:

Q. And if we look at page four of this exhibit under "See other business", just again the timing of these meetings and to place, "It is agreed to hold these meetings once a month and to rotate the meetings throughout the various sites". So I take it as of this point, May of '97, the idea of having it monthly is perhaps where this begins?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. If we could go back then to Exhibit P-1857, which is that June 17th, 1997 meeting. The agenda, "ER/PR receptors, immunoperoxidase staining", I referred you to that earlier. These are the actual minutes, page two. Dr. Parai, Khalifa, and Cook are present, apologies from certain others. If you look at paragraph 3.4 on page three, ER and PR receptor interpretation, it says, "This was discussed in detail. The majority of

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pathologists at St. Clare's as well as the Grace Hospital would like to interpret their own cases with control slides. Dr. Khalifa has agreed to provide a number of cases to the Grace Hospital to review them to be familiar with the positive and negative results", and I'm going to come back to paragraph 3.5, but just looking back here at those present, so Dr. Parai is here at this meeting, he's the site chief from the Grace, and presumably he is the one who is saying or communicating to yourself that, "as well the Grace Hospital would like to interpret their own cases". So Dr. Parai is weighing in saying --

DR. KHALIFA:

A. Yes, yes.

COFFEY, Q.C.:

Q. We want to do what St. Clare's has suggested, which is they want to read their own cases?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And you're going to provide a number of cases to them to be familiar with positive and negative results. Why would that be necessary

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at the time, Doctor?
DR. KHALIFA:
A. At that time, I think the St. Clare's group did not feel that they needed to familiarize themselves with the stain because they were up to date with the literature and what not. The Grace group, maybe they felt that they need to look at examples, so I recall collecting some examples, putting them in a list and send it to the Grace Hospital for the pathologists to look at them to see -- to get their feedback as to whether they are comfortable reporting them or not.
COFFEY, Q.C.:
Q. Look to, Doctor, paragraph 3.5 of the June 17th, 1997, minutes, immunoperoxidase staining, "The turnaround time of immunoperoxidase staining takes at least one week or more from the time of sending the block and the time of receiving the slides. Dr. Parai mentioned whether this turnaround time could be reduced by doing immunoperoxidase staining on a daily basis instead of twice a week which is presently being done". Do you recall what that was

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about, Doctor?
DR. KHALIFA:
A. Yes. You asked an earlier question about whether we encountered problems in immunohistochemistry, and I mentioned some examples. I mentioned example of a pathologist forgetting to order the stain, but this was another example where, in this case, the stain was requested but the lab is not releasing--is not doing the test at the speed that the pathologist expects, so this is not an uncommon issue. Of course, we have to prioritize the work. A pathologist from Corner Brook or St. Clare's or Grace sending a case, they want the result now. They want the result yesterday and I understand that, but when it arrives to Health Science Center, again we are the only lab producing this technique and we have so many stains and things had to be prioritized according to our own local schedule, not to start making mistakes. So there was a constant theme, again because we don't have many histotechnologists. We have very limited resources and, of course, everybody wants

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their cases to be done first. That is very natural, and you just have to, you know, explain to people why cases are taking that long and many times we run into a special situation where, say, for example, the patient is leaving town and they want to take their slides or whatnot, then we may want to bump one case for compassionate circumstances, but that's usual.
COFFEY, Q.C.:
Q. Here you noted that--you mean immunoperoxidase staining was being done twice a week at that point, apparently, so they were being grouped and done on particular days.
DR. KHALIFA:
A. Exactly, yes.
COFFEY, Q.C.:
Q. I take it, they couldn't be done daily because you didn't have the resources to do it.
COFFEY, Q.C.:
Q. We didn't have resources for that. Would that have been explained to Dr. Parai at the time?
DR. KHALIFA:
A. Of course.
COFFEY, Q.C.:

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Q. Exhibit P-1858, please. That meeting was June 17th. This is a letter of June 18, 1997. It's from yourself to Dr. Parai at the Grace, and you've copied it to Dr. Haegert and Dr. Cook and you write, "This is a follow-up on our conversation in the site chiefs' meeting yesterday and the phone conversation early this morning. You filled in the immuno requests for the two cases you were complaining about" - and you name them, or the numbers - "and the stains were completed on June 5, '97, which is a Thursday. I'm enclosing copies of the requests forms for these two cases to show that the histotech signed the completion of the procedure on June 5, 1997. I think you maybe" - that is "you," Dr. Pari - "may be experiencing problems with the transportation system. You may want to discuss this issue a little further in one of the department meetings. As for the work in our immunohistochemistry lab, I think it is being done within the time limits we've agreed upon in the past." I take it, you left the meeting and made inquiries about whatever Dr. Parai was complaining about, and particular

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cases.
DR. KHALIFA:
A. Was this subsequent to the previous -
COFFEY, Q.C.:
Q. Yes, this is the day after.
DR. KHALIFA:
A. Okay. Okay, so here's the situation, which again is very common because many things can go wrong in a process like that.
COFFEY, Q.C.:
Q. Doctor, in terms of the transportation system -
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. That's what I wanted to ask you about. Did you actually have any control over the transportation system?
DR. KHALIFA:
A. I had no idea even who was transporting the slides. I had no idea.
COFFEY, Q.C.:
Q. And so as site chief at the General, I take it then, Dr. Parai, presumably, would have had no more control over the transportation system.

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He'd have to make inquiries and see if he could get it.
DR. KHALIFA:
A. Well, I don't think so. As a site chief on the other end, he probably wasn't involved in transportation. What happened here was he requested the slides on June 2nd and he probably received the slides on June 7 or 8, so he said it took too long but, if we finish them on June 5th, then the slides were delayed in transition. Who was managing the transportation system, I don't know.
COFFEY, Q.C.:
Q. What I want to get at is that the site chief, I take it, wasn't managing the transport system, from your perspective.
DR. KHALIFA:
A. No.
COFFEY, Q.C.:
Q. That what I want to ask you about, and whoever was managing it, was it outside your area of control?
DR. KHALIFA:
A. Outside my domain, yes.
COFFEY, Q.C.:

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Q. Exhibit P-2411, please, and, Doctor, this is on August 21, 1997, a memorandum from yourself to Drs. Chittal, Fernandez, Haegert, MacIntosh, Morris-Larking, Robb and Wadden, and would all these be doctors at the time pathologists at the General Hospital?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And the reference is "Initiate ER/PR immunostaining of the in-house cases." You're right, this is a reminder that the initiation of the ER/PR immunostaining of our in-house cases remains the responsibility of the pathologist who first makes the diagnosis of invasive mammary malignancy on the respected specimen. As you already know, this is done by filling in a request form and submitting it to our laboratory. Although, currently, ER/PR slides come to me for reporting, the procedure has to be initiated by the primary pathologist. Since I have no access to the case in question at the time the diagnosis is being made, I thank you for paying extra attention to this matter." I take it, Doctor,

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this relates to this whole issue you referred to earlier about pathologists now ordering ER/PR for their patients.
DR. KHALIFA:
A. And they just forget it.
COFFEY, Q.C.:
Q. This is a reminder, a friendly reminder.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Exhibit P-2397, please. Doctor, this is a letter of September 23, 1997, from yourself to Dr. Sushil Parai.
REGISTRAR:
Q. Excuse me, Mr. Coffey, that's an exhibit from Dr. Wayne Lucus, so it's not an exhibit yet. We could have it entered and -
COFFEY, Q.C.:
Q. If we could.
REGISTRAR:
Q. I'll arrange to have it switched.
COFFEY, Q.C.:
Q. Thank you.
THE COMMISSIONER:
Q. And the number again is?

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COFFEY, Q.C.:
Q. She's keeping us on our toes, record-keeping.
REGISTRAR:
Q. P-2397 entered.
COFFEY, Q.C.:
Q. I suspect it was for Dr. Parai, actually, but he was supposed to testify before you were - the scheduling. So, Doctor, you've written to Dr. Parai on September 23, '97, and you write, "As per our last meeting, I am submitting 10 cases of invasive mammary carcinoma stained with antibodies against estrogen or progesterone receptors. I'm also enclosing a list of my assessments of these cases. I am seriously considering referring the stained slides to the requesting pathologist for this test without reporting them. I have discussed this issue with Dr. Haegert and I would like to discuss it further in one of our future meetings. I will appreciate your return of the slides when you are done with them because I'm going to circulate this collection among all pathologists who frequently request this test. I look forward to meeting with you, and please accept my best regards, signed" - and

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we look at this--if we could, Doctor - it's not part of the same exhibit because it came to us as a separate page - but Exhibit P-2410. Is that available to me? Thank you, Registrar. Doctor, this is listed as a document entitled "Estrogen and Progesterone Receptors. It's with your name. There are case numbers. There are 10 of them, all 1997 cases and estrogen receptors and the classification of them, and progesterone receptors and the classification, strongly positive and you have a percentage or moderately positive and weakly positive with a percentage, and negative and that here. If we could go back, please, to Exhibit P-2397 - so, Doctor, I take it, that the reference in the minutes we looked at from June 17 to - you would send slides representative of the group up to Dr. Parai?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. The pathologist at the Grace.
DR. KHALIFA:
A. Yes.

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COFFEY, Q.C.:
Q. This would be your letter doing so in September.
DR. KHALIFA:
A. Exactly.
COFFEY, Q.C.:
Q. And the purpose was to let them become familiar with it.
DR. KHALIFA:
A. Exactly, and to know if they have issues with it or if they were not prepared to take it on.
COFFEY, Q.C.:
Q. Did you ever hear anything from the doctors at the Grace after you sent the slides up about concerns they had about taking it on.
DR. KHALIFA:
A. No.
COFFEY, Q.C.:
Q. Did you ever hear at anytime from them or from the doctors at St. Clare's about any concerns they had about taking this on.
DR. KHALIFA:
A. No, I never did.
COFFEY, Q.C.:
Q. Now while I'm on the topic, Doctor, because

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we'll get to this eventually because it's rolled out across Newfoundland, did you ever concerns expressed by any pathologists in Newfoundland and Labrador about taking this on?
DR. KHALIFA:
A. No, I didn't hear concerns. As I say, these pathologists were consulting with me on regular basis so I wouldn't be surprised if at one point they sent a case back and they said, "What about this, what about that?" but I did not get any formal or informal complaint or concern about taking on this process.
COFFEY, Q.C.:
Q. Thank you, Doctor.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, here you do refer to--you conclude by saying "I will appreciate your return of the slides when you are done with them because I'm going to circulate this collection among all pathologists who frequently request this test." Who would that be in this context?
DR. KHALIFA:

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A. I guess the intention was to circulate these to other pathologists in the province outside St. John's who would eventually be reporting their own cases.

COFFEY, Q.C.:

Q. Did that ever happen, do you know?

DR. KHALIFA:

A. I don't recall if this happened. No, I don't recall if it happened or if it was requested.

COFFEY, Q.C.:

Q. If you had ever received--if you can't recall it, you can't, but if you had ever received a request like you had from Dr. Parai to get a representative sample from any pathologist throughout the province, would you have sent them?

DR. KHALIFA:

A. Absolutely. The collection was ready to go and it was packaged with diagnoses.

COFFEY, Q.C.:

Q. Exhibit P-1859, please. Now, Doctor, these are the site chiefs', divisional managers' minutes of meeting, October 8, 1997. Present are Drs. Cook, Haegert, yourself, Parai, Pushpanathan, and Mr. Murphy, and regrets from

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Mr. Gulliver, and there's a note here even. "The minutes of the previous meeting were accepted by a motion from Dr. Cook, seconded by Dr. Khalifa." So it was even that formal in the sense of you -

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. The formalities even were being attended to.

DR. KHALIFA:

A. Yes, we tried.

COFFEY, Q.C.:

Q. Yes. Here, Doctor, under "New Business," it reads, "Dr. Khalifa presented results of an audit of steroid receptors of 19 breast cancer cases, correlating immunohistochemistry and biochemical assays." It's typed here, "Dr. D. Cook," but then it's handwritten, "Dr. Parai," and I'll come to that eventually. "I recommended that the Health Care Corporation continue performing the immunohistochemical tests and encourage doing them on endometrial carcinomas." He also mentioned Dr. Thain. "The cancer clinic still prefers to see a biochemical assay done. Standardization of

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reporting the result of the immunohistochemical assay also seem to be a problem. Dr. Khalifa was asked to call upon other Canadian medical centers, Toronto General, to inquire about their protocols. (Dr. Khalifa action) He was also asked to seek feedback from the cancer clinic staff. (Dr. Khalifa action)" So, Doctor, here then in early October of 1997, you had provided the meeting with an audit, as it were, or results of an audit - ask, please, that we bring up Exhibit P-1850 - and I'll be getting to the first four pages of this shortly, Doctor, but here on Page 4 and 5--Page 4 is entitled - well, it's the General Hospital, Division of Anatomic Pathology - Immunohistochemical Staining of Steroid Receptors, Correlation with Biochemistry. "A report of our experience over a nine-month period, January '97 to September '97 by Drs. M. Khalifa and C. Pugh?"

DR. KHALIFA:

A. Pugh.

DR. KHALIFA:

A. Pugh, I'm sorry. Who is Dr. Pugh?

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DR. KHALIFA:

A. Dr. Pugh was a resident at the time in pathology.

COFFEY, Q.C.:

Q. Okay, and is this the--or would this be the results of an - I referred to it in the minutes - results of an audit of steroid receptors of 19 cases?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. This is his audit, as it were, and you got "immunohistochemical reporting less than 30 negative, greater than 30 positive for--and biochemical reporting 0-3 negative, 3- 20 equivocal and greater than 20 positive." I should have said, immunohistochemical reporting is actually less than 30 percent, greater than 30 percent, and you've noted here for statistical purposes, equivocal cases are considered as negative--first statistical analysis, I'm sorry. Now, Doctor, what was this about? Perhaps you could just explain to the Commissioner what was going on here?

DR. KHALIFA:

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A. If you allow me to bring this in context a little bit -

COFFEY, Q.C.:

Q. Yes.

DR. KHALIFA:

A. Remember, all that time patients were actually managed based on the biochemical assays. The oncologists were getting the biochemical assays and treating their patients accordingly. So all of this, again, is internal correlation and optimization of the procedure. So I've been doing this now for about nine months and people are anxious. They want to start reporting their cases, and so I think it was time to put together some sort of a record of how are we doing. So Dr. Pugh--we were supposed to mentor residents for research projects and QA is my area. I told him, "Why don't we do this? I mean, people are waiting for something like that." So we collected the records. We collected cases and we put together this series of cases to show how our results by immunohistochemistry correlate to the ones by biochemistry, and at that time I was using the conventional wisdom

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of using 30 percent of malignant cells as a cut-off time, again, to put the brakes on giving Tamoxifen that they didn't need - and the literature was supportive of this at the time - while giving Tamoxifen to only patients who would benefit from it. So if you go through the audit, you can see the correlation and the results were satisfactory and, as you saw, I presented that in the site chiefs' meeting.

COFFEY, Q.C.:

Q. Back to 14, under the heading "100 percent concordant cases, agreement in both receptors".

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. If you count them up, there are 14 of those.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And on the second page, or page five of the exhibit, it's 50 percent concordant cases, agreement in only one receptor. So it was 14 out of the 19 concordant in both?

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DR. KHALIFA:

A. In both.

COFFEY, Q.C.:

Q. And five of the cases, there was concordant in one receptor. Doctor, would the fact that there was not concordance or absolute concordance across the 19 cases, would that be a matter of concern?

DR. KHALIFA:

A. Well, remember we do ER/PR, but what the clinicians really like to hear is the ER because ER is the one that Tamoxifen deals with. PR is a complementary receptor and it just tells something about how the tumour is likely to behave. PR does not, in fact, management. So if you really want to look at correlation, you really are -- you should really be focusing on ER, but, I mean, this is a semi-scientific document, and I wanted to be as accurate as possible, so I didn't -- I looked at ER and PR separately, and if you look at the results, the first three cases of the five cases, the ER corresponded correctly.

COFFEY, Q.C.:

Q. Yes, the first ER is negative?

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DR. KHALIFA:

A. Negative.

COFFEY, Q.C.:

Q. And biochemical is --

DR. KHALIFA:

A. Negative, positive, positive, positive, positive.

COFFEY, Q.C.:

Q. And then the last two, the ER under the IHC method is determined to be positive and it's equivocal under the -- it was equivocal under the biochemical approach?

DR. KHALIFA:

A. Yes, the case number, 1400, you can see that we would have called it positive, but the biochemistry would have called it equivocal, which for statistical analysis it was included as negative. So that was considered as discrepancy. It was only that one last case that would have probably been called by biochemistry positive, but the immunohistochemistry was negative.

COFFEY, Q.C.:

Q. Now, Doctor, were you familiar at the time with any studies comparing the ER/PR IHC

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testing with biochemical assay results, like large scale studies?

DR. KHALIFA:

A. At that time, the literature -- yes, there were studies of that nature.

COFFEY, Q.C.:

Q. And in such studies, would there ever be -- over a large sampling, would there ever be 100 percent concurrence?

DR. KHALIFA:

A. I'm yet to see something in medicine that is 100 percent.

COFFEY, Q.C.:

Q. So if we could, please, look at page six of this exhibit, because this continues on. You've got here tables, estrogen and progesterone, the actual numbers of positives and negatives and so on as we look down through it. Under comments you've got, "When the cut off point is set at 30 percent in immunohistochemical reporting, testing for estrogen receptors has a sensitivity of 88 percent and a specificity if 90 percent. Analysis of all 19 cases, results of similar studies for estrogen receptors [in a much

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larger series of cases] showed sensitivity of 76 percent and a specificity of 82 percent, and you've got a -- there's a footnote here, number 1, and references. You've actually referenced a paper, a 1990 paper. I take it this is a larger scale study, this one here?

DR. KHALIFA:

A. It was one of the larger studies. This is the most prestigious journal in pathology, the American Journal of Surgical Pathology.

COFFEY, Q.C.:

Q. And that, I take it, where the 76 and 82 percent figures came from?

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, you also go on to note here under comments, "When the cut off point is set at 30 percent in immunohistochemical reporting, testing for progesterone receptors has a sensitivity of 86 percent and a specificity of 80 percent. Only 17 cases reported", and you go on to say, "Discrepancies in estrogen receptors, where it's only noted in two of 19 cases, while that of progesterone receptors

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was in three of 17 cases. For reporting estrogen receptors in a quantitative format, percentage of positive cells might be a good practice since it was shown to have a predictive value as a prognostic indicator", and there's a footnote, number 2, and you have the citation there from the American Journal of Clinical Pathology, 1994 study?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, these three pages, I take it, were the -- you would have presented that to that meeting in October of '97?

DR. KHALIFA:

A. It was presented to the site chiefs, it was presented locally --

COFFEY, Q.C.:

Q. Go ahead, Doctor, presented locally.

DR. KHALIFA:

A. It was presented locally in the Health Sciences Centre.

COFFEY, Q.C.:

Q. And your purpose in doing so was what, preparing this and presenting it was what?

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DR. KHALIFA:

A. I wanted to -- I wanted to document where we stood at the time. I wanted to assure myself that we are probably on the right track. I wanted to raise awareness of the issue.

COFFEY, Q.C.:

Q. Doctor, with that sort of a sample size, would that be statistically significant? Was that sufficiently large to be statistically significant, do you think?

DR. KHALIFA:

A. Remember here I was not validating a test. ER/PR in immunohistochemistry was a well documented procedure. In fact, I wouldn't -- I would be interested to see who else did what we did. If, say, a cancer centre in Vermont or a cancer centre in Idaho, or Saskatchewan, wanted to adopt immunohistochemistry, they would probably purchase the kit and start using it because that's a valid kit, it is certified, it is licensed, at least in the States -- they don't really have to do any correlation. For me, just because I wanted to be sure and I wanted to make sure that our oncologists are comfortable, our staff is

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comfortable, I took it upon myself for a year and three months, so that's 15 months, to go through this exercise and just move very slowly to make sure that everybody is comfortable.

COFFEY, Q.C.:

Q. So it wasn't done -- the study was not done with a view to having it published?

DR. KHALIFA:

A. Oh, no.

COFFEY, Q.C.:

Q. For example, that kind of --

DR. KHALIFA:

A. And publication -- the first publication by O'Keane, they had much, much bigger series, and they established the technique.

COFFEY, Q.C.:

Q. So it wasn't so much to prove that the technique works, so much as it was -- in fact, it wasn't to do that at all, it was to see if locally we're on the right track here?

DR. KHALIFA:

A. Exactly, and it is comparable to all conditions in Newfoundland, yes.

COMMISSIONER:

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Q. Mr. Coffey, when it's convenient to break.

COFFEY, Q.C.:

Q. Thank you. Doctor, the reference here -- if we could back, please, to Exhibit P-1859, please. Doctor, here in paragraph under "New Business", and I read this earlier. As it turns out, it's not Dr. Cook, it's Dr. Parai recommended the Health Care Corporation continue performing IHC tests, and he also mentioned, Dr. Thain, the Cancer Clinic, still prefers to see the biochemical assay done. Who is the "he" here, is that you or Dr. Parai, do you know?

DR. KHALIFA:

A. No. I would say this was Dr. Parai.

COFFEY, Q.C.:

Q. Okay, and --

DR. KHALIFA:

A. Excuse me, I'm not sure because Dr. Thain was in the Cancer Centre, and probably I was more in a closer contact with him, so I'm not sure.

COFFEY, Q.C.:

Q. Doctor, it says, he also mentioned -- okay, biochemical assay done. So the biochemical assay, as you pointed out to the Commissioner,

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at this point in October of '97 was still being done?

DR. KHALIFA:

A. Oh, yes.

COFFEY, Q.C.:

Q. And your understanding was at this point in time, the fall of '97, that that was the result that the oncologists and surgeons were still relying upon?

DR. KHALIFA:

A. That was my understanding, yes.

COFFEY, Q.C.:

Q. That although you were having the slides -- in fact, going back to your memo in August of '97 to your fellow pathologists in the General Hospital, you and your fellow pathologists were ordering ER/PR IHC tests?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Slides were all coming to you?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. You were reading them?

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DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. You were actually reporting it in the sense of recording it in Meditec?

DR. KHALIFA:

A. That is correct.

COFFEY, Q.C.:

Q. But it wasn't being relied upon by the oncologists because biochemical was still going on?

DR. KHALIFA:

A. Well, the oncologists would receive both of them, yes, but they were not told at the time that the biochemical assay would stop. They were still getting them.

COFFEY, Q.C.:

Q. So looking at -- if we could, please, and I'll just go back to 1850, please, page four. For example, these here, if we were to go find, for example, the patient with surgical number 97-1932 and look at their chart in Meditec or the patient's chart overall, we'd probably find not only a report from you with ER/PR, but we'd also find a biochemical assay report?

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DR. KHALIFA:
A. Exactly.
COFFEY, Q.C.:
Q. Okay, and one final point, if I could just push it a little bit, Commissioner, go back to 1859, please. Here, Doctor, the reference to standardization of reporting the results of the immunohistochemical assay also seemed to be a problem and you're asked to call upon other Canadian centres to inquire about how they're reporting of their protocols and to seek feedback from the Cancer Clinic staff, which would be the oncologists, I take it. So what happened with that, Doctor, this -- your inquiries in Toronto General and locally?
DR. KHALIFA:
A. So this is the time when the pathologists started to say should we use strongly positive, moderately positive, and weakly positive, should we mention the percentage of malignant cells, should we use the 50 percent disclaimer, issues of that nature about how to formulate a report that would be consistent and reproducible among all members of the department. So I was asked to call and I

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called around. I communicated with the Cancer Clinic people, the oncologists, to see their preference, does it matter to you, because I think the push was to drop the moderate, strong, and weak, and just give the percentage. So I had to clear things of that nature with our oncologists, would that be okay with you, how are people doing it in the States or in places like University of Toronto. So I did these investigations and I went back to the group, and as you see how the process evolved, you can see that we drafted another protocol and then we drafted a final one, so there was --
COFFEY, Q.C.:
Q. We'll come to that after lunch.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. So you did -- you made your inquiries?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And had discussions locally and we'll come back to that after lunch.

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DR. KHALIFA:
A. That's correct.
COFFEY, Q.C.:
Q. Thank you, Doctor. Thank you, Commissioner.
COMMISSIONER:
Q. We'll meet again at ten after two. Thank you.
(BREAK)
COMMISSIONER:
Q. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Registrar, if we could, please, Exhibit P-1860. Actually, instead because I'll use one that's not marked up, Exhibit P-2412, please. Doctor Khalifa, this is a memorandum dated December 15th, '97. It's from yourself to Drs. Cook, Haegert, Parai, and Pushpanathan, Mr. Gulliver, and Mr. Murphy, notice of a site chiefs meeting. This a meeting planned December 16th, 1997. The agenda is set out there. I'll take you down through that -- number three, follow up on steroid receptors assessment and paraffin blocks. If we could go, please, to Exhibit P-2413, please, which is the actual minutes of that December 16th meeting. Present are -- of

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course, there's yourself, Dr. Parai, Dr. Cook, and Dr. Haegert, and Mr. Gulliver and Mr. Murphy, and just as -- just so the Commissioner again will have some appreciation for the tone and tenor perhaps of the meetings at times, Dr. D. Cook amended the last paragraph of the first page of the previous meeting's minutes. The second sentence of this paragraph should read, "Dr. S. Parai recommended that the Health Care Corporation continue performing the immunohistochemical tests and encouraged doing them on endometrial carcinomas". A motion from Dr. S. Parai, seconded by Mr. Murphy, accepted the minutes of the previous meeting. So that we saw just before lunch that it was typed Dr. Cook, handwritten Dr. Parai.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. So this was, as best I suppose as was possible at the time, was being attended to in detail. On this, Doctor, a couple of different things. Here there's -- in paragraph two there's a reference to turnaround time at St. Clare's

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site, and they talk about that in the minutes here, but midway through the paragraph it says, "Mr. Murphy acknowledged the problem -- well, actually the sentence before that, "Both pathologists and surgeons have expressed their concerns about this issue", and it has to do with the turnaround times for slides, and "Mr. Murphy acknowledged the problem and suggested that the low number of histotechnologists as being idealogy". I want to ask you about that, Doctor. The staffing levels of histotechnologists at the time, how were they at the time? I mean, were there -- Mr. Murphy, according to this, didn't seem to think there were enough.

DR. KHALIFA:

A. So Mr. Murphy --

COFFEY, Q.C.:

Q. Mr. Murphy was in charge of --

DR. KHALIFA:

A. In charge of the Health Sciences Centre or at St. Clare's?

COFFEY, Q.C.:

Q. Frankly, I -- St. Clare's. Yes, St. Clare's. So the staffing levels of histotechnologists

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at the General Hospital, do you recall, from your perspective, were they sufficient or not? Perhaps that's unfair. Was there a problem at times with the staffing levels of histotechnologists, were there enough of them to go around?

DR. KHALIFA:

A. At that time the lab in the Health Sciences Centre was separate from St. Clare's.

COFFEY, Q.C.:

Q. Yes.

DR. KHALIFA:

A. So assessing the workload in the Health Sciences Centre, I would say the lab was understaffed.

COFFEY, Q.C.:

Q. Understaffed?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Apparently Mr. Murphy thought the same problem existed at St. Clare's too.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

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Q. Paragraph three here, Steroid receptors assessment and paraffin sections, "Dr. Khalifa discussed this issue further and suggested the pathologists start reporting their own cases. A suggestion was made that Dr. Khalifa write up a proposal with the criteria [cut off values] distributed to the various pathologists and ask them for their feedback. The meeting adjourned". If we could look, please, at Exhibit P-2414. It's a document here and your name is to the top right hand side. The document is entitled proposal for uniform reporting of ER/PR immunohistochemical assessment, January, 1998, and then the text is introduction and there are three bullets, three paragraphs. So this would be something you prepared?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. This would be that draft, I take it, referred to in the minutes we just looked at. If we could have, please, Exhibit P-2415. This is another document again with your name on the top right hand side entitled "Proposal for

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uniform reporting of ER/PR immunohistochemical assessment", January, 1998, first draft, and it says, "The report on the hormone receptor status will have three components", and you spell out here paragraphs one, two, and three, and then there are examples, example one, and example two. I take it, Doctor, this is your first draft of what turns out to be your February memo?

DR. KHALIFA:

A. That was one of the drafts that we were working on, and it was distributed to members of the staff for feedback.

COFFEY, Q.C.:

Q. And do you recall, Doctor, what the reaction was to the draft generally?

DR. KHALIFA:

A. So now by this time you can see that the words "strongly, moderately, and weakly", were omitted, so we are just using the positive and negative. At this stage, we included the percentage of malignant cells positive, and at that stage there was a comment to follow cases with less than 30 percent positivity to link in the clinician's mind our report, our

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current report, with the previous technology that they were used to.

COFFEY, Q.C.:

Q. And so this was distributed, and as you pointed out, the usage of the words "strong, weak", in terms of describing positivity have been omitted by this point. What was the general reaction, and I appreciate we're going to come to the issue about the comment.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. We'll come to that in a little bit, but generally the reaction to this was what?

DR. KHALIFA:

A. It was almost agreed upon.

COFFEY, Q.C.:

Q. Exhibit P-2416, please. Doctor, these are minutes of a site chiefs/divisional managers anatomical pathology meeting of January 8th, '98. Present are Drs. Cook, Haegert, yourself, and Parai, Mr. Gulliver and Mr. Murphy are there, and, Doctor, before we get to paragraph two which deals with breast receptors immunoperoxidase technique, under

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agenda item #1, outside referral policy --

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. I take it that this -- if we look through the minutes here, I'm not going to take you through them in detail, but this refers to dealing with this issue of outside consultation which you mentioned this morning as a matter that had to be addressed at one point. I'll just let you look down through it.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And so it was at this point -- if it hadn't been already dealt with before, at least started to be addressed before, you're in the process at this point of addressing this issue about how outside consults will be dealt with and kept track of?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Paragraph two, breast receptors

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immunoperoxidase technique, it reads, "It is agreed that there is no longer a need for evaluation of the breast receptors by the bio-assay technique. It was also agreed that in regards to reporting of the breast receptors via the immunoperoxidase technique, that individual pathologists could report these results. It is agreed that the estrogen and progesterone stains will be recorded as negative or positive with percentage of positivity given. It is also agreed that a rider will be given with the report, the exact wording of which is to be developed by Dr. Khalifa".

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. So I take it then, Doctor, that they're going to move into the next phase of this, which is to have individual pathologists throughout the province report their own cases?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Now, Doctor, I just -- here looking at this,

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it says, of course, "It is agreed", and I take it that would be it is agreed by Drs. Cook, Haegert, Khalifa, and Parai, who are the site chiefs for the Health Care Corporation of St. John's?

DR. KHALIFA:

A. That is correct, and each chief brought in the consensus view of his/her own staff.

COFFEY, Q.C.:

Q. Doctor, because we will see a memo in a moment that is addressed by yourself to all pathologists in Newfoundland, I want to ask you what had been the status up to this point in time, January of 1998 about ER and PR, for example, for Corner Brook or for Grand Falls, or Gander, how did that work?

DR. KHALIFA:

A. They were sending the block, the chosen block on their site, with the requisition. I would do the stain, I would report it, and they will get the report.

COFFEY, Q.C.:

Q. And before you arrived -- when you first arrived in Newfoundland, before your arrival, what was your understanding about what had

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been the ER and PR, how had those tests been done, or did you have any understanding?
DR. KHALIFA:
A. That's a good question, but -- I didn't know. I didn't know how it was handled.
COFFEY, Q.C.:
Q. You just knew that locally in St. John's it was biochemical assay?
DR. KHALIFA:
A. That's correct.
COFFEY, Q.C.:
Q. And it was being done locally by a physician at the General Hospital?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Biochemist. The centres outside St. John's, the medical centres outside St. John's, but within the province, were they asked about ER/PR IHC testing in terms of their views as to whether or not they should be reporting? Like, pathologists in Corner Brook, were they ever canvassed about whether they wanted to get involved in reporting their own cases?
DR. KHALIFA:

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A. Again I wouldn't remember a formal communication as a letter I received from any of my colleagues outside St. John's, and I don't recall an incident where there was some sort of anxiety or disagreement about it. I know we talked about it because I was on the phone with these colleagues regularly. I actually visited their labs on multiple occasions and worked for them. So at that point, the level of camaraderie and the level of collegiality between me and the pathologist in the periphery was sufficient to make me believe that if they are uncomfortable, they would not be shy to talk about it, they wouldn't be intimidated or uncomfortable at all.
COFFEY, Q.C.:
Q. And no one did complain or raise concerns about it with you?
DR. KHALIFA:
A. No.
COFFEY, Q.C.:
Q. Exhibit P-1861, please. Doctor, the first page of this is the agenda for a meeting scheduled for February 12th, 1998, and the

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second item under business arising is, "ER and PR reporting". Go to page two of the exhibit, these are the minutes themselves of that meeting of February 12th, and again it's Drs. Cook, Haegert, Khalifa, and Parai present, as well as Mr. Gulliver and Mr. Murphy. When we look at paragraph 3.2, ER and PR reporting, it reads, "Dr. Khalifa will write to -- I always have difficulty with -- the biochemist's name?
DR. KHALIFA:
A. Prabhakaran.
COFFEY, Q.C.:
Q. I apologize, "To Prabhakaran asking him to discontinue the biochemical ER and PR assay as of February 1, 1998".
DR. KHALIFA:
A. March.
COFFEY, Q.C.:
Q. I apologize, March 1, 1998, thank you, and here we understand these are Dr. Cook's handwriting, he's written March 1, 1998, "Every pathologist will sign out cases. After transition period, will talk to Prabhakaran". So I take it then as of the end of the meeting of February 12th, 1998, Doctor, in terms of

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this ER/PR IHC testing, if you're going to be writing to the biochemist asking him to discontinue it as of March 1 --
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. That the die is cast, as it were, we're moving ahead with this?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-1850. Doctor, this is a memo of February 16th, 1998, from yourself to all Newfoundland pathologists. The reference is reporting of estrogen and progesterone receptor immunohistochemical results, and -- now the Commissioner has seen this before because it's been referred to other pathologists who received it years ago. Doctor, you'll note in the second paragraph here, "The Division of Pathology, St. John's, has been employing this technology for over a year. Recent audits correlating IHC with biochemical results in selected specimens where both techniques have been run in

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parallel have shown high accuracy of the introduced IHC detection. Results of these audits have been discussed at several meetings and are available for review". So you're advising really all pathologists that if you want to see the results to date --

DR. KHALIFA:

A. They are welcome to ask for it, yes.

COFFEY, Q.C.:

Q. And did anyone ever ask to see them, do you recall?

DR. KHALIFA:

A. No.

COFFEY, Q.C.:

Q. And it goes on, "As this technique was still in its introductory phase, Phase I, I've been reporting results of the majority of cases to establish consistency and reproducible techniques. As we have come to a more advanced stage of this pursuit where this test could be done with a relatively high efficiency and reliability, I came to believe that we're probably ready to move into the next two and final phases". Doctor, just on that, you do say here, "I've been reporting

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the results of the majority of cases". So it is possible that you did not actually report all of the original cases? If we were to go back and look at all the pathology reports, there might be some up to that point reported by local pathologists?

DR. KHALIFA:

A. As I mentioned before, I happen to know that pathologists in St. Clare's Hospital were sending their cases to Mayo Clinic. So they would send the block to Mayo Clinic, Mayo Clinic send them back their report. So I couldn't claim at this point that I was -- or that the Health Sciences Centre was doing ER/PR for everybody because I knew that there are cases that were going outside of this domain.

COFFEY, Q.C.:

Q. And on page two of this exhibit, Phase II, you write, "Each pathologist will be asked to report results of his or her own case, as indicated by the brown staining of nucelli of the invasive neoplastic cells. This phase will start March 1, 1998, at which time your immunostain slides will be mailed back to you

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with positive controls whenever it is technically possible. With each run, I will still be responsible for reviewing the positive controls here in our laboratory, and the slides will not be mailed to you unless adequate staining is noted in the positive controls. As we are all interested in making this transition as smooth as possible, I will be more than glad to continue being available to answer any questions and address concerns". Now, Doctor, I have a couple of questions on this Phase II reference. Where you say, "will be mailed back to you with positive controls whenever it is technically possible", what type of positive controls are you speaking of there?

DR. KHALIFA:

A. Positive controls were what we call external controls and these were known cases to be positive that we use to make sure that the run actually worked.

COFFEY, Q.C.:

Q. And why would you -- why did you say whenever it is technically possible?

DR. KHALIFA:

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A. The reason for that is as a standard procedure in labs, you would run a positive control with every run. So if we have ten cases in the Health Sciences Centre, we do one positive stain and we all see them at the Health Sciences Centre, but since we are doing it to other hospitals as well, then the logic would say you need to do a positive control to be dispatched with the slides back to each of these pathologists, which means that with every run we will do more than one positive control, and that was not always possible. Because of again resources and financial reasons, we were told that we probably can do one positive control for every run. So in the site chief meeting, we struggled a lot with this idea. Some of the pathologists were not comfortable with it from St. Clare's, they wanted to get the positive control themselves and they said, well, if we have one positive control, they said, well, then you send it to us and then when we are done with it, we will start sending around. So that would be like one positive control circulating across the island and by the time that slide circulates,

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another batch comes and then we will start to get confused and the slides will be broken and -- that wasn't really practical. We asked can we get two positive controls, so one can stay with us and one goes to St. Clare's, and then why would we give St. Clare's preferential treatment, and so there was a lot of discussion around this and we tried to be reasonable and realistic about it, and the lab was only prepared to one positive control. So I said, guys, I've been doing this for a year, would you trust me if I look at the positive control and the consensus was, we trust you, so my vow to them was I will not send you the slides unless I am comfortable and convinced that it actually worked. So I would look at the positive control and am comfortable with it, and then I would tell Mary or whoever was doing it, okay, dispatch the slides, so they will send them to the respective pathologists.

COFFEY, Q.C.:

Q. And while you remained in St. John's as the site chief, the positive external controls for the ER and PR slides, were you reading all of the positive external controls?

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DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And was it being signified in any way that you were doing that, like documented in any way?

DR. KHALIFA:

A. I was -- I would be in my office. The technologist brings a bunch of slides, I will look at them and I say, well, it's faint, let's repeat it, let's do this, let's do that, and at the end I would say, okay, send them. So I probably would check on the requisition and give her back the paperwork and the slides and she goes back to the lab.

COFFEY, Q.C.:

Q. So if it's recorded at all, it would be on the requisition form?

DR. KHALIFA:

A. I would probably say so.

COFFEY, Q.C.:

Q. And the understanding you had, certainly after having discussed it with people, and sending out this memo, recording it and writing the understanding you had with the pathologists throughout the province was if there's an

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ER/PR slides from a patient coming back to you, if you -- they will not leave the lab unless "I have examined the external positive control and I'm satisfied that the control is positive, it's good to send you the patient tissue".

DR. KHALIFA:

A. Absolutely, and if the pathologist wanted to see that positive control, by all means I would send it.

COFFEY, Q.C.:

Q. Now, Doctor, you also say here that -- you referred to, "Unless adequate staining is noted in the positive controls", and you just referred to weak staining just then in passing, you said if the external control came and you looked at it and you said, well, it might have to be redone, you were giving an example --

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. What in this context -- what in the context of external positive controls does adequate staining in the positive controls mean? Why

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do you refer to adequate?

DR. KHALIFA:

A. Well, the positive staining -- the positive control, the positive external control would be a known case, so you got a block with lots of cells, you want to make sure that -- I know the case after looking at the slide many times, so every time it is cut, it becomes like reading the palm of my own hand. So I know the case. Let us say I would see staining on only half of the slide or there's discrepancy between the periphery and the centre, or some of the nuclei are faint, some are dark --

COFFEY, Q.C.:

Q. Which hadn't been there when you'd seen it for the first ten or fifteen or twenty times?

DR. KHALIFA:

A. Yes, exactly, so I have the image printed in my head. So I would -- I know what adequate staining is. So does every other pathologist. So if you show the slide to any pathologist, they will tell you this is adequate or not.

COFFEY, Q.C.:

Q. And if the external control was not adequately

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stained --
DR. KHALIFA:
A. We would repeat. I would like also to look at the cases. At that point, I wasn't looking at the actual cases case by case. I would look at them also because if you are going to make a judgment of this -- in this context, you want to use several parameters because sometimes what if the positive control didn't work and all the other cases worked, so maybe the problem now isn't the control, maybe we need to get another control. So you really want to be as comprehensive as you can, but I must say at this point I wasn't looking at every case.
COFFEY, Q.C.:
Q. Every --
DR. KHALIFA:
A. Every patient case. I would look at the positive control and may pick up selected cases to make sure that, you know, things are making sense, so to speak.
COFFEY, Q.C.:
Q. But the external control --
DR. KHALIFA:

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A. It had to work, it had to work.
COFFEY, Q.C.:
Q. You conclude this Phase II reference by saying, "As we are all interested in making this transition as smooth as possible, I'll be more than glad to continue being available to answer any questions and address concerns". I think you told us this morning when we referred to this that the doctors may have called you about individual cases to talk about, but in terms of the overall scheme of things, the overall approach to doing this, having them report their own cases, there were no general concerns raised with you?
DR. KHALIFA:
A. No.
COFFEY, Q.C.:
Q. And Phase III, here you're advising all pathologists in the province that Division of Medical Biochemistry at the General Hospital will be addressed to officially discontinue performing steroid assessment by biochemical techniques. So I take it then that this ended -- you did talk to --
DR. KHALIFA:

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A. At that point there was no proposed date, and I think it dragged a little bit even more. We were not really in a hurry to do this, just drag a little bit. So I think the biochemistry dragged a little bit even after that date.
COFFEY, Q.C.:
Q. I take it that would have allowed then the doctors outside your own institution, the General Hospital, to get their own slides, to report their own cases?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And simultaneously have the biochemical assays still coming in, the results coming in?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. So they would be going parallel for a while?
DR. KHALIFA:
A. If they notice anything that they are not comfortable with, I wanted to give them a window to --
COFFEY, Q.C.:

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Q. To raise concerns?
DR. KHALIFA:
A. Yes, to raise concerns, yes.
COFFEY, Q.C.:
Q. And you conclude, Doctor, by saying, "Attached please find a proposal for uniform reporting of ER/PR immunohistochemical staining. This proposal was discussed with many of my colleagues who mostly agree with its content and accepted it as a policy. As I encourage you to adopt the attached proposal in your reporting to maintain uniformity, it should be clearly stated that this is only proposal. As you already know, there is a considerable host of publications addressing this issue. I'll be glad to share any of the material I already have with you, and I would extremely appreciate your feedback on this matter". Did you get any requests for copies of publications in relation to this matter?
DR. KHALIFA:
A. You mean someone requested?
COFFEY, Q.C.:
Q. Yes.
DR. KHALIFA:

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A. No, I did not get requests, but I want to emphasize the issue that I didn't want this memo to be considered as a policy or a guideline, or anything like that. I was in no position to make province-wide guidelines or demand on my colleagues outside our hospital. The pathologists at the General Hospital adopted this as a policy, adopted my memo as a policy, but I wanted to make it very clear that I was not making a policy because I was fully aware that (a) I have no authority to do such a thing, I am not a provincial accrediting agent, and there is no uniformity across the globe, even within the same country. Different medical centres were using different format. So I wasn't going to try to push this one format as a policy.

COFFEY, Q.C.:

Q. You do refer, Doctor, "I encourage you to adopt the attached proposal in your reporting to maintain uniformity". I take it the advantage of maintaining uniformity in reporting is what, Doctor?

DR. KHALIFA:

A. You want the oncologist to get used to the way

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things are being reported, so they don't get confused.

COFFEY, Q.C.:

Q. Page three of this exhibit, Doctor, is entitled "Proposal for uniform reporting of ER/PR immunohistochemical assessment, February, 1998". I take it this is the last version of that proposal?

DR. KHALIFA:

A. This is the final.

COFFEY, Q.C.:

Q. And you have, "Report on hormone receptor status will have three components. The first component is a statement of whether the stain is positive or negative. Positivity is defined by nuclear staining detected in any number of malignant cells". I take it, Doctor, does that mean that if there's any positivity at all, one percent --

DR. KHALIFA:

A. That is very clear here, one percent counts as positive and in the example -- in the example given, number two, that case was reported as positive with a percentage of one to five percent.

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COFFEY, Q.C.:

Q. And you write in paragraph two, "The second component is a rough estimate of the percentage of immuno reactive cells in a section examined. This estimate could be in the form of a range or a fixed number and is listed in parenthesis", and when we look at these examples, this is -- as you point out, the one you -- you use ranges generally, 70 to 80 percent, 80 to 90 percent, in example one. Example two, one to five percent, and a single number for zero.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Zero percent.

DR. KHALIFA:

A. Because remember these are eyeballing. We didn't have computers. Some centres now have computers to read this.

COFFEY, Q.C.:

Q. But at the time, it would be the estimate by the viewer?

DR. KHALIFA:

A. Yes.

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COFFEY, Q.C.:

Q. And in some cases, you envisaged that doctors might use a particular number or might use a range?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Paragraph three you've written, Doctor, "The third component is a comment regarding only ER [and not PR] immuno reactivity, and is only to be included in the report if a small percentage of neoplastic cells [1 to 30 percent] is positive". The comment reads, "Evidence from the available literature indicates that estrogen receptors immuno reactivity detected in less than 30 percent of neoplastic cells would most likely correspond to a negative result in a biochemical assay of the same specimen. American Journal of Pathology, 1990, Volume 14, pages 121 to 127".

DR. KHALIFA:

A. That's correct.

COFFEY, Q.C.:

Q. End quote. Now, Doctor, what was your purpose in adding the comment or suggesting this

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comment be added?
DR. KHALIFA:
A. My purpose is because at that time there was literature to correlate, to close the loop in the oncologist's head about how to translate the report they receive now with the results of the test before, that a case like that would -- say, five percent, if you would have done biochemical assay on that same tumour, probably it would have been reported as negative, and that has nothing to do with whether the patient receives Tamoxifen or not because the decision to give Tamoxifen or not is solely in the hand of the oncologist who would make their assessment based on their entire evaluation of the case and probably by looking at the percentages. For one patient, 5 percent positivity is good enough to give Tamoxifen; for another patient maybe with -- I don't know, for another patient with a different clinical setting, maybe 10 percent will not be enough. So that is their decision, that is not our role.
COFFEY, Q.C.:
Q. And here, Doctor, in the examples, and I take

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it these are just examples, but the first of them, estrogen receptors positive, 70 to 80 percent of cells, and then progesterone receptors, positive, 80 to 90 percent of cells, so that would be the suggested approach if you were reporting both as positive, or, in fact, even say, for example, estrogen receptors was positive and progesterone receptors here was negative --
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Zero percent of cells.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. It would be -- that would be the approach. If one leaves out the reference to the comment here at the bottom, just the comment is not there, in effect there's not really any difference between the reporting formats from examples one to two, are there?
DR. KHALIFA:
A. No, the difference is that in example two, the number of positive cells for ER was very

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small.
COFFEY, Q.C.:
Q. One to five percent.
DR. KHALIFA:
A. So if that case was done by biochemistry, probably it would have been negative.
COFFEY, Q.C.:
Q. In terms of this, Doctor, and reading it, the only usage of the word "negative" here amongst the text for the examples themselves, is when you get down to zero percent?
DR. KHALIFA:
A. That is correct. So one percent is a positive case.
COFFEY, Q.C.:
Q. Just, for example, here --
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. One to five percent. Even if you had just said here one percent --
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. That would still have been positive?

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DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. In the -- in the text itself, and then there's this cross reference, please see comment.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And then in the comment, the only reference to negative would be in relation to a biochemical assay?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, after this went out and during the time then you spent in St. John's up until 1999, did you ever get any questions from oncologists about what was meant by the wording in the reports that you did?
DR. KHALIFA:
A. No, I don't recall, and again I just want to put things in context. That was the time when the biochemical assay was still kind of alive because I bet you now if you go to one of our residents now in Memorial or in Toronto and

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ask them about biochemical assay, they wouldn't have any idea. In that sense, that comment today probably is meaningless.

COFFEY, Q.C.:

Q. If it was -- if somebody was to now -- for example, if you had a resident when you returned to Toronto in your work next week --

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And somebody for some reason pulled up an old case, a pathology report, you wouldn't be surprised to have a resident come along and ask you what does this mean?

DR. KHALIFA:

A. Yes, they will clearly understand, well, this was probably the transition where people were moving away for biochemical assays.

COFFEY, Q.C.:

Q. Exhibit P-1862, please. Now, Doctor, this is -- the first page is a memorandum of March 13th, '98, dealing with a site scheduling -- scheduling of a site chief's meeting of March 19th, 1998, and the agenda items; one, follow up on ER/PR reporting, and the memo is from

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yourself. Page two is just a marked up copy of the same memo, and page three of this exhibit, Doctor, is a -- actually is minutes of a meeting of March 19th, 1998, dated up here in the top right hand corner, March 25th, 1998, so presumably it was typed after the meeting itself. Present are Drs. Cook, Haegert, Khalifa, Parai, and again Mr. Gulliver and Mr. Murphy. It notes here, "Dr. Khalifa amended paragraph 3.2 of the previous meeting minutes. It should read Dr. Khalifa will transfer the responsibility of reporting the results of the immunohistochemical staining of ER/PR to the respective pathologists on March 1, 1998. Dr. Prabhakaran will be contacted at a later date and asked to discontinue the biochemical assays". A motion from Mr. Gulliver, seconded by Dr. Cook, accepted the minutes of the previous meeting, and then under business arising, it's noted, "Dr. Khalifa updated the committee about the current stage of ER/PR reporting by the requesting pathologists. The transition was going smooth. Dr. Cook made very positive remarks about the role played by

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Dr. Khalifa in this regard". It goes on from there. If we could look, please, at Exhibit P-1863. Doctor, these are minutes of a meeting of April 22nd, 1998, site chief's meeting, notes the minutes of the March 19th meeting, 1998, were accepted, and seconded, and then under business arising, additional new immunoperoxidase stains to existing panel, there's a reference to a letter from Dr. Griffin being submitted to the committee, and after some discussion, it was agreed to acquire the immunoperoxidase stains and it lists four of them, actually. It continues on, "In regards to the rapid immunostaining technique, it was agreed that the current procedure employed by the General Hospital site appears adequate. Currently the DAKO EnVisage System is employed, which is a two step method, giving comparable results to the rapid immunostaining technique outlined in Dr. Griffin's letter". So Doctor, do you recall what this was about?

DR. KHALIFA:

A. I wouldn't recall this particular thing. Of course, I can relate to what is being said

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here, but this was a theme by this one pathologist who was active in going to meetings and talking to people outside St. John's, and that was useful to bring in views from outside, but probably the problem here was that she gets these ideas and she gets these views, and she was kind of under the impression that she can cal up -- she was stationed at St. Clare's Hospital. She would cal up the lab in St. John's in the General Hospital and tell them do this, or buy this antibody, or switch to this technique, do this or do that, which is by-passing me because I thought that was -- my role was to prioritize things and make sure that -- I mean, I thought I was looking at the bigger picture than what she was at the time, and so -- because if you go back to the minute of the previous meeting, I was actually starting to talk to people about developing a policy about how should we request new antibody or define a protocol, and here we go again the following meeting, we are still talking about this. We were trying to address her concerns and trying to accommodate her request as much as we can.

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COFFEY, Q.C.:
Q. So Doctor, in terms of the reference to the rapid immunostaining technique, I take it the consensus amongst the group of you at the time, the site chiefs was, and including the clinical chief, that the current procedure employed at the General Hospital site appeared adequate?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. In terms of immunostaining techniques?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. If we could, just on that point, Exhibit P-1862, please. Doctor, paragraph three here. I take it, "Dr. Khalifa suggested that a system be in place for members of the committee to study requests submitted from various staff members for the addition of new antibodies". Doctor, just on that point, if new antibodies were ordered, when they were ordered, what if anything was done in terms of bringing the antibody on line in the sense of

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--
DR. KHALIFA:
A. Same what we did with ER/PR with exception of the correlation, as I said, because we didn't have gold standard, but during this time many, many antibody--if you look at our requisition form, when I first developed it and after four years and you see how it grew--it grew tremendously.
COFFEY, Q.C.:
Q. And so the process then, while you were the site chief for--well, what developed here was that the group the site chiefs had to approve of -
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. The purchase of an antibody, a new antibody, and when it was brought in your understanding was what in terms of it being optimized? What was going on?
DR. KHALIFA:
A. We would go through the same thing. We will try different concentrations, different titrations and -

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COFFEY, Q.C.:
Q. And who was overseeing that for each new antibody?
DR. KHALIFA:
A. I was.
COFFEY, Q.C.:
Q. Okay, site chief that was.
DR. KHALIFA:
A. As a site chief, yes.
COFFEY, Q.C.:
Q. If we could go back, please, to Exhibit P-1863. I was going to bring you to - thank you - Page 2. There's these April 22, 1998, minutes. Doctor, Paragraph "F" reads, "Estrogen receptors, Dr. Cook wondered about the rider in the case. Where estrogen receptors are stained less than 30 percent of its cells, Dr. Khalifa informed him that this rider is a recommendation only and is not part of the formal policy regarding the reporting of breast receptors." I take it, that Dr. Cook wanted to drop the account.
DR. KHALIFA:
A. Certainly, this was the view of the pathologist at St. Clare's and, again,

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everybody was free to do what they wanted to do as long as they saw it as within the standard of care at the time.
COFFEY, Q.C.:
Q. Exhibit P-2417, please. Doctor, this is a memorandum of November 10, 1998, from yourself to a number of physicians. These are all pathologists at the General Hospital, I take it, the list there.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. It's a divisional meeting. You're advising them about a meeting on Thursday, November 12th, that would be. Under "Agenda," the third item is "ER/PR immunohistochemistry requests." And Exhibit P-2418, please, and these are minutes, Doctor, of a meeting of November 12, 1998, at the General Hospital site. Again, the physicians are listed as in attendance, including yourself, and under Paragraph 2, flagging breast cancer cases, "Members of the committee agreed to receive a note from the secretaries with every breast cancer case as a reminder for the submission

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of a ER/PR request. This process will be triggered by dictating a microscopic description or diagnosis." So I take it, that this is again -

DR. KHALIFA:

A. So we are still struggling with this, yeah.

COFFEY, Q.C.:

Q. Struggling, trying to make sure that it's always requested.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. For every breast cancer. Now, Doctor, Exhibit P-2347, please - 2347 - and, Doctor, this is a letter from the Central Newfoundland Regional Health Center, November 13, 1998, addressed to yourself and the patient's name. Personal information is redacted. Dr. Dalton writes, "Enclosed is a block and slide on the above-mentioned lady for ER/PR evaluation. Thanking you in advance, and return of block and slide at your earliest convenience will be greatly appreciated." I take it, Doctor, that this is the sort of letter you would get with--at least in the early days, for ER/PR?

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DR. KHALIFA:

A. Well, by '99--'98, the requisition form for ordering antibodies was in place for many years, so we used to print these in books and send them to the pathologists. So maybe Dr. Dalton on that day, he ran out of the requisition forms so he sent the block with a letter rather than a form. Yes, we used to get things like that and this would be my handwriting, yes.

COFFEY, Q.C.:

Q. Yes, it says, "Please send back to Grand Falls," and there are your initials here at the bottom. So after a case would be done -

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. You would send it back and send a covering letter with this letter with your note on it. This would be an instruction to the staff.

DR. KHALIFA:

A. "M.B." is Mary Butler.

COFFEY, Q.C.:

Q. Yes, which would indicate, I take it, the date she would have processed.

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DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Or finished the slides.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And you would be instructing that they be sent back.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. In this context, would the slides--why would you put this on it? Would you have actually seen the slides, do you think?

DR. KHALIFA:

A. I would have seen the control.

COFFEY, Q.C.:

Q. Control.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And then you might endorse something like this on it.

DR. KHALIFA:

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A. Yes.

COFFEY, Q.C.:

Q. This would be an instruction to Ms. Butler to forward it on.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. If we could look, at Exhibit P-2152, please. Now, Doctor, this is a requisition form. It's dated probably June 2nd - I apologize. I'm looking at the wrong page. Yes, there we are. It's Page 7, Commissioner. Here, Doctor, in fact, you are the pathologist here. Your name is listed there. It's a date. You can see it's June because it's dated here June 5, 1998, signed by Ms. Welsh, and this is an example of your requisition form.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And used in June of 1998. Doctor, what I wanted to ask you about is, on the other side of this - you see this is obviously a computer printout. "Immunohistochemical Report 6/05/98" to be, I understand, June 5, '98, and

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patients--well, the name is not listed there but there's a case number, and note here the case number is S1778-98, Central Newfoundland Health, and if we look back at the page before, 1778-98, that would be the year 1998, and the surgical pathology number - that was 1778. Now there's another surgical pathology number here.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. At the bottom of the page.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And it's S4598-98.

DR. KHALIFA:

A. Yes sir.

COFFEY, Q.C.:

Q. And I take it, one of these would be the surgical number for outside St. John's, and this is the St. John's number.

DR. KHALIFA:

A. Yes, it's easy because now we are in June '98.

COFFEY, Q.C.:

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Q. Yes.

DR. KHALIFA:

A. In the Health Sciences Center we got between eleven and twelve thousand cases a year, so by June it's logic to be in the 5000 range, which is down--or 4000 range, but the outside hospital is a smaller lab so they have lower number of cases, so that was the number for Central Newfoundland.

COFFEY, Q.C.:

Q. Oh, the technician is listed to be Peggy and the doctor is yourself here. The institution is listed up here in the top, right-hand corner and there's a slide number, 19 and 20. The antibody estrogen receptor, 1 to 50, and this would be what, 30 minutes? Well, first of all, I'll ask you, are you familiar with this form, Doctor? When you were in St. John's, were these types of forms being utilized?

DR. KHALIFA:

A. I'm not familiar with this form, actually. I don't even know how it was generated.

COFFEY, Q.C.:

Q. So this is not something that you would--in your work as a pathologist, you wouldn't come across this.

DR. KHALIFA:

A. Okay.

COFFEY, Q.C.:

Q. You don't recall ever coming across this sort of form.

DR. KHALIFA:

A. No.

COFFEY, Q.C.:

Q. Okay. Oh, that's why I wanted to ask you about it. Your name is listed there on it.

DR. KHALIFA:

A. Yeah.

COFFEY, Q.C.:

Q. And I thought I would ask you. Exhibit P-2424, please. Doctor, this is from the Peninsula's Health Care Corporation. It's November 20, 1998. It's a letter from--Dr. Bibi she's referred to here locally. It's addressed to yourself, and she asks, "Please perform estrogen and progesterone receptors on the enclosed paraffin block and then return the block to that institution," and, I take it, that's your initial probably there.

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DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, while you were site chief in St. John's, was Clarenville's hospital, which is - because this is in Clarenville.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Was Clarenville utilizing St. John's for ER/PR while you were site chief?

DR. KHALIFA:

A. That is my impression, yes.

COFFEY, Q.C.:

Q. Did anyone ever make you aware while you were site chief - I'm not suggesting that it happened, but I'm asking you - while you were site chief in St. John's, did anyone ever make you aware that Clarenville was going to discontinue using St. John's?

DR. KHALIFA:

A. No.

COFFEY, Q.C.:

Q. Doctor, if I could please, Exhibit P-2419? Doctor, just--this is just an excerpt from a

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report in the late 1990s, we obtained it from Mr. Gulliver. It's a report he prepared, but other significant achievements are, and I just note in the third bullet here that Dr. Khalifa was named professor of the year for MUN Medical School. And I looked at your CV, I take it that on a couple of occasions, at least in St. John's while you were here, you were--you did receive that award?

DR. KHALIFA:

A. Well, the first one was this one and the second one they gave me the award after I went to Sunnybrook. They were so kind to me to give me the award, even after I left the university.

COFFEY, Q.C.:

Q. Doctor, if we could, please Registrar, Exhibit P-2420? This is again minutes of a meeting of a Division of Anatomical Pathology, April 20th, 1999. Present are Dr. Chittal, Ferandez, Haegert, Khalifa, MacIntosh, Morris-Larkin, Robb, and Wadden. A couple of different things here I wanted to ask you about, the group, with the exception of Dr. Robb, was called--who was called to the OR,

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Dr. Robb was called away, group posed for a picture. So I take it at this point in time, were you getting ready to leave? This is April of -

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. '99. And under paragraph 2, there's a summer workload schedule. It says you asked members of the group to consider their respective summer holiday schedule in advance to allow for developing a fair schedule, despite the anticipated shortage in staff. Doctor, was the idea that there would be shortages in pathologist staff in the summer, was that routine or was that particular to this year?

DR. KHALIFA:

A. I can't exactly recall the specifics of this summer, but having people away in summer is not unusual. I know that one staff during my time went on sabbatical to France, so we went down one pathologist for a very long time. I think around that time Dr. MacIntosh was also leaving, so we were going to--we were anticipating shortage.

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COFFEY, Q.C.:

Q. The second page of this exhibit, there's a reference to new site chief. "A discussion took place around this topic with the intention of not reaching a decision, but rather voicing out opinions. Dr. Khalifa presented to members of the group of summary of chores he carried out during his served period. He also presented some figures to summarize workload in various sites within the Health Care Corporation. A long discussion took place, some of its highlights are summarized below. And Dr. Chittal had an opinion as to the strategy that should be utilized in terms of combining the chair and site chief roles in one individual. Dr. Ferandez said she wasn't going to be come site chief again -

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Because she had been your predecessor. Dr. Robb made a comment about collegiality and avoiding conflicts within the discipline and Dr. Haegert pointed out some of the options,

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including rotating responsibilities among various staff and so on, not having a site chief and other possibilities. Now, Doctor, if I could refer you please to Exhibit P-1989--I'm sorry, 1898? Because that was a meeting of April 20th. This document is, your name on the top left-hand side, dated April 19th, 1999. "Some of my chores as a site chief, 1996 to 1999." I take it this is a document you prepared and presented at that meeting on April 20th?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Now, Doctor, you left, I gather in June of 1999.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Up to the point when you left St. John's, were you debriefed in any way, other than perhaps providing this as a summary of your duties? Were you debriefed by any one?

DR. KHALIFA:

A. No.

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COFFEY, Q.C.:
Q. Doctor, within St. John's at the time, within the General Hospital, how generally understood was it amongst the pathologists that you were reading the controls for ER/PR?
DR. KHALIFA:
A. Everybody knew that, that was a fact.
COFFEY, Q.C.:
Q. So that if you were not going to be there in July, I take it everyone, from your perspective, knew that if that was going to b done, someone would have to take over that role?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Had that been attended to up to the time you left?
DR. KHALIFA:
A. Sorry?
COFFEY, Q.C.:
Q. Had that been attended to in the sense of had your replacement -
DR. KHALIFA:
A. Not to the best of my knowledge.

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COFFEY, Q.C.:
Q. Now, Doctor, here in the rules here, scheduling, responding to clinician's calls, 3) responding to technical problems in laboratory (preparing controls for immunohistochemistry), troubleshooting with failed tests, supporting staff personality conflicts, et cetera." So, where IHC was concerned, I take it that as a site chief, if the pathologists had a concern, they would come to you about IHC?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. If the technologists had a concern, they would come to you?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And if there was a concern from somebody outside about IHC -
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. They would come to you?

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DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. "Through organizing a request for sending cases out, Tuesday conference is a tool for the limited QA we have." And I'm going to ask you now, what QA existed at the time? This is paragraph four--I'm sorry, paragraph five. And you've referred to this earlier today.
DR. KHALIFA:
A. Tuesday rounds were one example of QA. QA was other initiatives included, for example, correlating the frozen section diagnosis with the final diagnosis and again, that wasn't going on before my time, but I asked people to--because the frozen section diagnosis is an interoperative consultation which could be less than complete, so when the case is finalized, the pathologist has to correlate the final diagnosis and reconcile any differences with the diagnosis given during the interoperative consultation. Collating the outside opinions on our cases when they go for consultation and come back, keeping track of diagnostic errors, there was some activity

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but I wouldn't describe it as a full-fledged program.
COFFEY, Q.C.:
Q. And why wasn't there a full-fledged program? It may be self-evident to you, Doctor, I have to ask you why wasn't there at the time?
DR. KHALIFA:
A. I'm not sure if I understand your question. Are you saying why was this my assessment or why wasn't it in place?
COFFEY, Q.C.:
Q. Why wasn't it in place?
DR. KHALIFA:
A. It wasn't in place because quality assurance is almost a department by itself. You need-- first of all, you need resources, you need the right computer people, you need the right trained people with the mindset of quality assurance and then you need to build a culture and I worked on the culture, but of course, we were not there and we are not going to be there in this generation, that's the report of the Institute of Medicine. They clearly say that the culture of safety is not going to be accomplished in our time, probably the hope is

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in the next generation where we can openly talk about errors in a non-blame culture so we can learn from our mistakes. But we worked a lot on that in the Health Sciences Centre to get a little bit out of the sensitivity. It is granted that nobody likes to be called wrong, but we just have to live with the fact that sometimes we are wrong and we have to learn from this. So there's a lot more than the computer, the resources, the personnel. You need the culture, and you need the time, you need the dedication, you need the understanding, you need the leadership. Only when you are at that level and then you have audits and you have numbers and you have reports and, like in Sunnybrook now, I am committed to releasing quarterly reports with all the new misses and errors and all of that has to be in the open and has to be reported regularly, monitored regularly. Unless you get to that point, I don't think I would call this a full-fledged quality assurance program. I'm not even happy with our quality assurance program, but that's a different topic. We need a time. I guess I'm saying that the

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reason it was not there is because we needed time, we needed resources, we needed dedication.

COFFEY, Q.C.:

Q. Doctor, were the other pathologists around you, particularly the other clinical chiefs--the clinical chief and the other site chiefs in your day, were they aware of this? Were they aware of the state of the QA and the fact that a lot of work was required? From your perspective, I mean was it something they were aware--were they as seemingly aware of it as you were?

DR. KHALIFA:

A. Yes, they were.

COFFEY, Q.C.:

Q. Was there any external proficiency testing going on at the time during your time as site chief?

DR. KHALIFA:

A. Very good point, very good point, because I think this is a very, very essential element that is missing, I guess this is why we are here today. No, the answer is no.

COFFEY, Q.C.:

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Q. Were there programs that were available to be enrolled in at that time?

DR. KHALIFA:

A. There were programs, I am aware of programs in the United States, they would not be applicable to the environment here in St. John's. If there was, if there were accrediting agency for the laboratories in St. John's, in Newfoundland, that would have made our life much easier.

COFFEY, Q.C.:

Q. And so in the late 1990s, while you were site chief in St. John's, the clinical laboratory, at least the anatomical pathology end of it was not involved in external proficiency testing at the time, during your day?

DR. KHALIFA:

A. No.

COFFEY, Q.C.:

Q. And were there any Canadian programs that you were aware of at that time?

DR. KHALIFA:

A. Any Canadian programs?

COFFEY, Q.C.:

Q. Yes.

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DR. KHALIFA:

A. No, at that time I wasn't aware of the QMPLS or any of these programs, no.

COFFEY, Q.C.:

Q. And the American programs that you just referred to, you were aware of, you couldn't enroll in them from here? You said they wouldn't be applicable to a place like St. John's?

DR. KHALIFA:

A. It wouldn't be applicable, it wouldn't be fair, no.

COFFEY, Q.C.:

Q. When you say it "wouldn't be fair" why is that?

DR. KHALIFA:

A. Because of the philosophy, the programs in the States are so medical legally oriented, very turn around time oriented. Turn-around time is very important, reimbursement issues are very important and they govern the whole program. To try to apply that, I mean, I was a member of the accrediting team from the College of American Pathologists who went to accredit some of the labs in Toronto, like the

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Mount Sinai Hospital, I signed off that. And only very few labs in Canada can meet this standard and they do it for certain reasons as well. If you are accredited by the College of American Pathology, so your lab probably can receive grants for American agencies, and things like that, so there is an advantage. But I did not think that Newfoundland needs this kind of thing. We just need something practical and applicable to our situation.

COFFEY, Q.C.:

Q. If I could, please, Exhibit P-2421? This is a letter of April 28th, 1999, Doctor. It's from yourself, it's to Dr. Haegert. This, I take it, Doctor, is a letter where you're recounting or summarizing for Dr. Haegert the experience you had had with these Tuesday meetings.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And you note that 105--this dates back to February of 1996, referring to a memorandum of that time, beginning a new weekly surgical pathology conference, and "105 of these

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sessions are well documented in my files with more than 780 cases discussed. There are 3.2 staff pathologists per session." So I take it you were even keeping track of how many pathologists were showing up from time to time.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And, Doctor, at the time did anyone ask you, within the time you were leaving St. John's, did anyone ask you like to leave them a copy of your records in that regard? Like, you obviously had been keeping track of it.

DR. KHALIFA:

A. Yes. No one asked me.

COFFEY, Q.C.:

Q. Exhibit P-1867 please? Doctor, I'm just going to refer to page--this is a quality initiatives report of 1999 to 2000, but on page 3 of it, there's a reference in the last paragraph of that page, page 3 of the exhibit, Resignations were received during the year from Dr. Prabhakaran, Chief of Biochemistry; yourself, as site chief at the General

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Hospital and Dr. MacIntosh, the Chief of Cytology. There are references to replacements, Dr. Wadden replaced you as site chief acting. Dr. S. Parai was going to become the permanent site chief, effective May 1, 2000. Cytology chief was still vacant, the Division of Anatomical Pathology received resignations from six pathologists, approximately a third of the total pathologists manpower. All positions have been successfully filled. So I take it, Doctor, that that suggests there was a fair amount of turn over in that year involving pathologists?

DR. KHALIFA:

A. Yes, during my four years in St. John's, nobody left the department.

COFFEY, Q.C.:

Q. During?

DR. KHALIFA:

A. My four years. When I was in St. John's, there was no turn over, but this happened, I guess, towards the end.

COFFEY, Q.C.:

Q. Because, well this covers the period, when we

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look back, Doctor, this covers the period April 1, '99, so this covers the period really just a month, within a month or two of you leaving, to about ten months after you left.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. So if there was that kind of turn over and it's your recollection that that occurred after, must have occurred after you left St. John's.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. I have a couple of exhibits I wanted to show you before we break for the afternoon. C0185 please? And these next three exhibits, Commissioner, are just simple--this would be examples of pathology reports, completed by Dr. Khalifa. This is a 1997 report, Doctor, here signed yourself, November 3rd, '97 and you report that hormone receptor status, estrogen receptor strongly positive, 70 to 80 percent of cells; progesterone receptors strongly positive, 80 to 90 percent of cells.

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At the bottom here you write, Doctor, "Immunohistochemical assessment for estrogen and progesterone receptors was performed on the formalin and fixed paraffin embedded tissue submitted. Appropriate positive controls were obtained." What types of controls were you referring to there?

DR. KHALIFA:

A. This particular part of the report was not necessarily accepted by other pathologists, some pathologists did not feel that they need to document something of this nature, so I wouldn't be surprised if you go back and look at their reports, and again, as I say, this was not standardized, but at least where I came from, pathologists always documented positive controls and that is referring to the positive external control.

COFFEY, Q.C.:

Q. External controls. And, Doctor, I'm going to ask you about, while I'm on this now, internal controls, positive internal controls or internal controls, first of all, internal control tissue for ER and PR. Were you familiar with that idea, the idea of utilizing

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normal tissue for internal controls?

DR. KHALIFA:

A. Sure.

COFFEY, Q.C.:

Q. When had you first been introduced to that in relation to, well generally first of all I'll ask you?

DR. KHALIFA:

A. Internal control is not a unique concept for ER/PR. With every immunostain, some of the normal or the native tissue elements could be positive for the antibody that you are using and therefore, when you see them, that adds another layer of comfort that the antibody worked.

COFFEY, Q.C.:

Q. So at this point in time, in 1997, would you have been, by this point in time, in ER/PR, when you got involved in ER/PR, IHC testing, when you would look at a patient slide, would you be looking for internal controls?

DR. KHALIFA:

A. Well if the second, if the second stain has tumour and normal or non-tumour tissue next to it, then you throw the antibody, it stains

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some of the native elements and maybe or maybe not, some of the tumour. So when we saw that in the native tissue, we talked about it in Tuesdays rounds, we showed it to the residents and kind of, like you say, ah ha, see, the internal control, the antibody worked, so that concept was known.

COFFEY, Q.C.:

Q. It was known. And known to you to the extent that you were actually teaching it to your residents?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, in relation to ER and PR, I understand that they--we've heard evidence here to suggest that internal controls exists for other stains, but they can play a particular importance when you're dealing with ER and PR IHC testing? I'm not a physician, we just heard references to that.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. They can be very important. If you found back

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in '97, '98, were looking at tissue, breast tissue, normal tissue I'll refer to it, and it did not stain positive, what, if anything, would you do then? If the external control worked, first of all, you were satisfied the external control worked and then you were looking at a patient's tissue slide and there was normal tissue there and there was tumour there and the internal control did not stain, what would be your thought process? What was your approach at the time?

DR. KHALIFA:

A. Well if the internal control did not stain, but the tumour is positive, then the tumour is positive. If the internal control is negative and the tumour is negative, then it could be that the internal control is negative, that is acceptable, or it could be maybe something was wrong with the technique, maybe we didn't use the right concentration or the machine--something went wrong, but if the positive control is positive, then we know the machine was okay, the process was okay. Then the problem now is in the tissue. Then maybe the problem was with fixation of the tissue, so a

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negative control, a negative internal control with a positive external control and a negative tumour, maybe important, maybe important in tumours that are known to be ER positive, like tubular carcinoma, for example. So if I have a tubular carcinoma that is negative and the internal control is negative and the external control is positive, then I may wonder and say maybe there was a problem with fixation. But, having said that, internal controls do not tell the full story because we know that internal control, i.e. the normal non-tumour tissue in the female breast expresses estrogen receptors to different degrees during the menstrual cycle and different parts of the breast and different elements of the normal breast may express different levels of estrogen receptors. So when the internal control is negative, that does not equate to problem, it may suggest a problem, but it does not equal-- it's not equal to a problem.

COFFEY, Q.C.:

Q. Faced with that situation, like looking back on it, what would your thought process be,

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it's potentially a problem, I take it, so you would make inquiries? I take it that would -

DR. KHALIFA:

A. I would inquire, I would inquire.

COFFEY, Q.C.:

Q. Might you have the block run again, like do the test again?

DR. KHALIFA:

A. Yeah, let's do it again.

COFFEY, Q.C.:

Q. That's one possibility.

DR. KHALIFA:

A. Yes, but that, again, is not the end of the story because I was in the hotel yesterday and I was presented by my counsel with some report and I looked at some spreadsheet and in the spreadsheet, I could find about 41 cases with internal control that is negative and the tumour was called negative in Newfoundland, but was retested in another hospital and it was still negative. So it was negative here, when it was retested it was still negative and the internal control is negative. So what does that say? It says that probably it is acceptable to accept a negative internal

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control or are we saying that all 41 cases had fixation problem? If you accept that possibility that all 41 cases had fixation problem, then you go back to the same spreadsheet and you find about 5 other cases with internal control negative, the tumour was called negative in Newfoundland, but after repeated it, it became positive. So, okay, you have cases here with negative internal control and the tumour could be negative and on retesting, becomes positive; or the tumour is negative on retesting, still negative. So what is the negative internal control telling me? Probably not much in that setting.

COFFEY, Q.C.:

Q. If, Doctor, under that scenario in Newfoundland it was the internal control was viewed, there was internal control tissue there and it was viewed to be negative and the tumour was reported historically years ago as negative, as well, and upon retest it was reported as negative, the Mount Sinai reported it as negative, but Mount Sinai reported the internal control as positive, present and stained, would that suggest--and it happens to

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be the same block, that would suggest, I take it that while they got the result right the first time by calling it negative, but that was so despite the fact that the internal control didn't stain.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. It just happened to be negative, it ended up negative but upon retest in '05 or '06 in Mount Sinai, that the internal control did stain.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Which would make you more comfortable?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. I take it then from your perspective, back in '97 or today for that matter, that in looking at a slide and the external control is positive, you look at the slide, and the internal control is positive but the tumour is negative, you're comfortable to say, well

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that's a negative tumour? That gives you the degree of comfort then?

DR. KHALIFA:

A. Even if it was known to be one type of a tumour that is supposed to be ER positive, yes.

THE COMMISSIONER:

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

COFFEY, Q.C.:

Q. Commissioner, if I could, just before we break, Exhibit P-0186?

THE COMMISSIONER:

Q. 186 or C.

COFFEY, Q.C.:

Q. I apologize, C-0186, I apologize. Doctor, this is another pathology report. It's prepared by yourself, it's November 3rd, '97 and it happens to be signed out the same day actually by yourself. And here, Doctor, under diagnosis, you've got "steroid receptor status and here estrogen receptor is minimally positive, less than 5 percent of the invasive neoplastic cells, progesterone receptor is moderately positive, 50 to 60 percent of the

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invasive neoplastic cells" and then you've added here "The Comment", which I take it is because it's less than 30, is that the reason for the comment?

DR. KHALIFA:

A. (No audible response).

COFFEY, Q.C.:

Q. Doctor, here I noticed that you've gone to minimally positive and moderately positive, do you notice that?

DR. KHALIFA:

A. Well that was before, before we agreed to abandon this language.

COFFEY, Q.C.:

Q. Yes. Because before on the one we just looked at, it was strongly positive, strongly positive.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. And eventually after your memo in February, you would have adopted the new approach.

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

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Q. Break, Commissioner, thank you.

THE COMMISSIONER:

Q. Take the afternoon break.

(RECESS)

THE COMMISSIONER:

Q. Please be seated. Mr. Coffey.

COFFEY, Q.C.:

Q. Thank you, Commissioner. Doctor, I'm going to ask you to look at a couple of different memos, they are after your time, but I'm going to ask you to look at them and just comment on them. P--113 please? And I say after your time, after your time in St. John's?

DR. KHALIFA:

A. Yes.

COFFEY, Q.C.:

Q. Now, Doctor, this is a memo from--thank you. April 4th, 2003, it's addressed to pathologists in HSC and St. Clare's and out-of-town hospitals. It's from a Dr. Gershon Ejeckam. Subject is "Immunohistochemical Stains" and he writes to them at the time, "Please note the immunohistochemical stains with the following antibodies"--and there are eight of them listed, ER and PR and the two

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last ones--"have remained unreliable, erratic and therefore, unhelpful for diagnostic purposes. Consequent on the above, staining with the above antibodies will stop forthwith until we can solve the reliability, sensitivity and specificity problems. Efforts are underway and hopefully a solution will be found within the next four to six weeks." Now, Doctor, in your time as site chief, okay, do you--were you ever in a position that you felt that the immunohistochemical stains with any antibodies, those eight or any others for that matter, were unreliable, erratic and unhelpful for diagnostic purposes?

DR. KHALIFA:

A. No.

COFFEY, Q.C.:

Q. Page 2 of the same exhibit, Doctor, is a memo of May 2nd, 2003, it's again to the same group of pathologists, it's from the same doctor, Doctor Ejeckam. Subject is "ER/PR immunohistochemical stains." May 2, 2003, he writes, "I'm glad to inform you that we have rectified the difficulties related to the immunostain of ER/PR; therefore, we can now

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resume regular requests for these antibody stains. I will, however, like to bring the following information to your attention"--and then there's "results of the immunostains may be affected by and he lists A to F, A through D are fixation issues, E is dehydration and F is tissue reprocessing. There's a discussion of using 10 percent buffered formalin, neutral buffered formalin and 18 to 24 hours as being the optimal fixation time for immunostains. And then he talks about the possibility of ER/PR false negative results, increases in core biopsies, talks about utilization of internal controls using normal breast tissue as a second level of control. He talks about how often or the likelihood of PR tumours, positive tumours being ER negative, as being less than 10 percent or 10 percent or so. He talks about different reporting formula, cut-off points in the literature and refers to a 2000 National Institute of Health Consensus Statement. He notes a higher staining intensity does not reflect better results and he notes that cytoplasmic staining for ER/PR is considered negative. Notes ER positive

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tumours are of particular types and Dr. Ejeckam has told the Commissioner he should have included lobular in this listing. And as well, he notes that no nuclear grade tumours are usually positive for ER and PR. This is being described as an instructive memo to pathologists throughout Newfoundland by Dr. Ejeckam in 2003. Doctor, back in 1998, did it cross your mind at the time that, you know, you might send out a memo like this about ER and PR?

DR. KHALIFA:

A. Well two thoughts probably come to mind when I'm looking at this note, remember, this is 2003, so by that time, we came to know much more about breast cancer and ER/PR than we knew then, for example, how sensitive this test to fixation was not clear back then.

COFFEY, Q.C.:

Q. Back in '97, '98.

DR. KHALIFA:

A. Yes, '97, '98. The issue of internal controls as an additional layer for validation, that was not available to us in '97, '98. So many of the content of this very useful memo were

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things that evolved, not only in Newfoundland, but in our knowledge of breast cancer in general, that is the first thought. The second thought is memos of this nature can act as a double edge sword and why is that? Because if I send a memo like this or any kind of informative memo of that nature, I carry the risk that someone will take it as inclusive--as comprehensive, for example, you said he omitted to mention lobular carcinoma, then well someone will say, I didn't know, he didn't say, I am not a textbook. I am not a textbook. This stuff is in textbook by then, by '99, by '98, this stuff was already in textbook.

COFFEY, Q.C.:

Q. So I take it it was in textbooks our journals, the more cutting edge, leading edge parts of this, the internal controls and fixation, the particular susceptibility -

DR. KHALIFA:

A. That stuff started to trickle in papers in 2000. We didn't know that stuff but if you open a text book that was available to our residents, for example, in 1998, the text book

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talks about ER/PR. It was there - what tumours are likely to be positive - and that's maybe not internal control business. It was in there, but other things, so I'm not sure and I accept views here. If someone tells me that pathologists need memos of that nature, I can see the value of that but I don't like to take the risk of showing myself in a light that's probably bigger than I am and, as I said, many of these pathologists - when I used to go to Boston to meetings, I meet some of the Newfoundland pathologists there. I mean, some of them were cutting edge than I was. I don't know.

MR. COFFEY:

Q. So at the time, I take it, Doctor, it didn't occur to you to do it although your memo does refer to the fact that you were available. You made yourself available.

DR. KHALIFA:

A. I preferred to keep myself at that position. I am a resource. I will do everything in my capacity to help any colleague, any patient but not more than that.

MR. COFFEY:

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Q. And if I could, please, Exhibit P-2423 - if we could look, please, at Page 7 under your CV, Doctor. It's page "Clinical Practice Interests." The third bullet is "Standardization of Reporting in an Anatomic Pathology." Now if we could just go back - it's an interest of yours - and back to Page 4. The last entry under "Honours and Awards" on that particular page is "Cancer Quality Council of Ontario and Canadian Cancer Society, Ontario Division, Quality Award, November 2006 for leadership and improving the quality of cancer pathology reporting." I take it, Doctor, that you have some interest.

DR. KHALIFA:

A. Deep interest.

MR. COFFEY:

Q. And why is there a necessity for attention to be paid to that, from your perspective?

DR. KHALIFA:

A. Quality control.

MR. COFFEY:

Q. And in fact, in particular, this is cancer pathology reporting itself and I -

DR. KHALIFA:

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A. Oh, standardized reporting.

MR. COFFEY:

Q. Standardized reporting, and I appreciate assurance quality control is something that's of interest to you as well.

DR. KHALIFA:

A. Yes.

MR. COFFEY:

Q. And, in particular, I'm going to ask you right now about the standardized reporting that -

DR. KHALIFA:

A. Yes, standardized reporting simply means that for every tumour, the pathologist will have a set of questions to answer, whether they are present or not or--we call them parameters. So if a tumour exhibits certain characteristics, the tradition before was that pathologists only mentioned what they see, which means that they leave the oncologists with the question mark about other things that are not in the report. Does that mean that you didn't look for them, or did you look for them but they were not there, and as the science of oncology became more complicated with the introduction of new treatment

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modality, medical oncologists and using drugs, new drugs every day, radiation oncologists, they are basing very fine decisions on the fine details of the diagnosis pathologists mention in their report. So it became apparent that the pathology community needed a standardized set of questions or parameters to answer for every given tumour. When I came to Newfoundland, people had different ideas but there was no structure in place to standardize our reporting. In George Washington, they adopted what was called at the time tumour summary, and I started talking to my colleagues. They accepted my suggestion. I developed forms for the common disease sides - stomach, colon, breast, lung, the common disease sides - with the list and the options. Of course, this was very rudimentary. Of course, now these things are on computer with drop-down menus and it's very, very sophisticated but at that time we just had checklists on paper. We printed them in booklets. We distributed them to all pathologists in the island so they can use them. I had a set meeting with - I apologize,

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I'm missing the name of the chief in the cancer center. I would meet with him regularly in the presence of the CEO--or the President of the cancer clinic at the time. She was there, and we go the list and I ask him if he wants to add or delete, so this was even a customized list. Again, because some of my colleagues were supportive - some were not - I decided to scan the environment in Canada, and we had the lead article published in the Canadian literature questioning all chiefs across the country who was using and who was not using standardized reporting, and we published this. It's a Canadian publication, and we concluded that most medical centers at the time have some form of standardized reporting. So that was my contribution here in Newfoundland.

MR. COFFEY:

Q. Doctor, I take it, that you've been gone from here now for--getting close to a decade, but you still have an interest in it and, I take it, that from your perspective the field of pathology could use more standardized reporting, more discussion about it and

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agreement on it because it makes things more predictable for people reading the reports.

DR. KHALIFA:

A. Yes. It's better, more efficient communication.

MR. COFFEY:

Q. Doctor, I'm going to ask you now about - you're aware, course, that there was retesting done at Mount Sinai in 2005, 2006 of blocks from throughout Newfoundland between '97 and 2005. You're aware that there were a number of conversions. You would be aware that--conversions in the sense of things that were originally reported as negative, Mount Sinai reported them as positive.

DR. KHALIFA:

A. That is one type of conversion.

MR. COFFEY:

Q. Yes, conversion, and I appreciate there's others that--you can get into conversions in relation to cut-off points changing even if there was 20 percent--repeats as 20 percent. Depending upon where the cut-off point is, it may convert on that basis alone because the cut-off point has gone lower.

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DR. KHALIFA:

A. And can convert from positive to negative.

MR. COFFEY:

Q. Yes. In terms, Doctor, of--in the main, you understand that most of the conversions in Newfoundland from Mount Sinai throughout this whole process have been from negative--ER negative to ER positive, the conversions that have occurred. You understand that. Doctor, if some of them date back to - in fact, cases that you called years ago--okay, you reported on in 1997, 1998 - if some of your original cases did convert, do you have any thoughts as to why that might be so in the sense of why a case that you reported, for example, in 1997 as zero ER, might be reported - I'll just pick a figure - as 40 percent positive by Mount Sinai or 50 percent positive by Mount Sinai in 2005. What could account for that?

DR. KHALIFA:

A. Well, before we look at data of this nature we have to standardize the process so we would have to ask if the same clone of antibody was used, if the same concentration, same time, same stainer, same methodology. So we have to ensure that the methodology is the same.

MR. COFFEY:

Q. Why is that?

DR. KHALIFA:

A. Because we know that - I'll just give you an example. You saw my CV. You saw the papers I published, and the manuscripts, and if you--not even my work, but the work of others - if you open any pathology journal and you look at any published research in immunohistochemistry, you go to the section called Material and Methods and you see that the authors have to detail the procedure, the temperature, the concentration, everything, and the clone - everything in their material and method. The message here is that this is the research. These are our findings. If you want to get these findings, you have to follow this recipe. In other words, if you follow a different recipe you will get different results. So the first question would be - and I didn't see the details of that, but I'm sure it has been taken in consideration, were the procedures, including every fine detail, the same--that would be critical.

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MR. COFFEY:

Q. And, Doctor, if an ER test was run on a block in 1997 in St. John's -

DR. KHALIFA:

A. Sorry?

MR. COFFEY:

Q. If it was an ER -

DR. KHALIFA:

A. If it was negative?

MR. COFFEY:

Q. No, it was run on a block in St. John's and it was negative in 1997 and using a particular clone, whatever the clone was of the day, utilizing St. John's, and the same block was run in 2005 or 2006 or even now in 2008 in Sunnybrook in your institution, and using a different clone because the clones have changed over the years, I take it, would you expect to get a significant positive result from that same block or would you expect to get a negative result? Would the changing in clone itself account for the difference between, for example, zero and 70 or 80 percent? Would the change in clone alone do that?

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DR. KHALIFA:
A. Yeah, it wouldn't surprise me if it does that.
MR. COFFEY:
Q. Okay, and why is that?
DR. KHALIFA:
A. Because we know that clones have different sensitivity and certain clones come with kids that make them more sensitive with different methodology for antigen retrieval, so it's a different test.
MR. COFFEY:
Q. Okay. Doctor, we have heard, okay, that Dr. Ejeckam - you saw that memo of April where he stopped testing for awhile ER/PR and he started it again. You saw the second memo, and we understand that he--they changed. They kept the same clone but changed the dilution rates--or dilution proportions. Could changing the dilution--could that account for a block going from negative to positive, the same block.
DR. KHALIFA:
A. I would probably assume yes. Yes.
MR. COFFEY:
Q. And why is that? I take it, because -

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DR. KHALIFA:
A. Because you are adding more--the antibody is like the eyes that see the antigens so you're basically adding more eyes. You're more likely to see the antigen.
MR. COFFEY:
Q. Doctor, while you were the site chief at the General Hospital here in St. John's, did you notice any particular problems with fixation of tissue? I appreciate there'll be a sample from time to time is poorly fixed.
DR. KHALIFA:
A. Yes.
MR. COFFEY:
Q. But I'm talking more generally.
DR. KHALIFA:
A. Fixation of tissue and relation between fixation and immunohistochemistry is a problem in every pathology lab and it's a problem with every organ, basically. So it was an issue. It was an issue, and the issue is when the organ is removed--when the tumour or the organ is removed from the patient, it has to go to formalin within a certain time. It has to be sliced in a certain way and, if the organ is

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hollow like a uterus or a stomach, it needs to be open so the inside is exposed to formalin. Again, at that time, remember Newfoundland did not have what we call pathologists assistants or PA's, so residents had to do that, or staff. How can we do that, and the buckets come from the OR with the organs and someone has to add formalin and open the - I got a bench and I put it in a strategic location in the room in the lab where residents, in order to get out of their office to go to Tim Horton on the first floor, they have to pass through that so I told them, "Guys, you are not getting coffee without sticking your neck to make sure that the buckets have enough formalin and they have been cut and stuff" like--it became like a tradition. It's not an assembly line. It's not like if you're not on call that day I have nothing to do with the cases. These are our patients. These are our cases. Just cut them. So did that help? It helped. Did we eliminate the problem? I wouldn't say we did. We had cases coming from Labrador City on Friday night by plane, who knows what happened to the specimen when it

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was in Labrador City. We get cases that were cut in different hospitals. We know nothing about their processing and their procedures. We ourselves, we didn't have SOP's. We did the best we can.
MR. COFFEY:
Q. Yes.
DR. KHALIFA:
A. But it is a problem.
MR. COFFEY:
Q. Doctor, at the time, I take it, you would recognize when you see a slide, based upon your training and experience, that it might be apparent on the slide--the fixation problem might be apparent from what you're even seeing.
DR. KHALIFA:
A. It could be.
MR. COFFEY:
Q. It could.
DR. KHALIFA:
A. It could be.
MR. COFFEY:
Q. And sometimes it's not.
DR. KHALIFA:

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A. Yes.
MR. COFFEY:
Q. There's a problem there but it's not apparent visually.
DR. KHALIFA:
A. Yes.
MR. COFFEY:
Q. Doctor, I will ask you this, if you had a concern or misgivings about making a call on an ER/PR, for example, in a breast cancer case, based upon the fact that you just weren't satisfied that you could reliably do so, what would you do? Would you make kind of--make a guess at it anyway or would you actually just say, "No, I can't. I can't report this."
DR. KHALIFA:
A. No, I can't report it. I would repeat it or choose another block.
MR. COFFEY:
Q. And if, ultimately, it couldn't be reported, that's what would end up, I take it, on the report.
DR. KHALIFA:
A. What goes in the report has to be something

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that I am confident that it was truthful to the best of my knowledge.
MR. COFFEY:
Q. Doctor, you have indicated that there was no SOP's, for example, at the time. Why was that?
DR. KHALIFA:
A. I don't know why is that. I guess you can ask Mr. Gulliver about this or someone who was in management. I don't know. I don't write SOPs. I don't know.
COFFEY, Q.C.:
Q. And I take it as well, there were no SOPs as well for pathologists either?
DR. KHALIFA:
A. I didn't see them.
COFFEY, Q.C.:
Q. Yes, and I just have a couple of other questions. When you were dealing with the technologists, the histotechnologists in St. John's, did you ever give them any training?
DR. KHALIFA:
A. My experience with the two technologists who were running the tests, that they were comfortable with the test. They were doing

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immunohistochemistry for probably some time before I even arrived. I did not feel the need that they needed formal training. If I felt that they needed formal training, probably I wouldn't have given them myself because I am not qualified to do that. I would probably have sent them somewhere. But, the interactions we had, my suggestions, my discussions showed me that they were competent and I wasn't concerned.
COFFEY, Q.C.:
Q. Doctor, back in your time as site chief, speaking of QA, was any thought given to sending random samples out to be looked at elsewhere?
DR. KHALIFA:
A. You're talking about what is known as random reviews?
COFFEY, Q.C.:
Q. Yes.
DR. KHALIFA:
A. There are different ways of doing random reviews. One of them is, as you said, sending slides outside. We were not at that level, no. That didn't happen. Neither we sent

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cases outside nor did we randomly review them internally.
COFFEY, Q.C.:
Q. Okay. Doctor, just one point. You did indicate that on at least three occasions, you spoke in the U.S. to--and I referred you to it earlier, to the workshops involving staining. Remember that?
DR. KHALIFA:
A. Surgical?
COFFEY, Q.C.:
Q. The National Society of Histochemistry?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. National Society for Histotechnology.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Did you ever give that talk to the technologists in St. John's?
DR. KHALIFA:
A. No.
COFFEY, Q.C.:
Q. Why not?

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DR. KHALIFA:
A. This was a theoretical talk. I didn't feel--I didn't see the need for it. I didn't see that they needed it. Obviously hospitals who send their histotechnologists to this meeting, they felt the need for that, for their own histotechnologists, but I didn't see the need for that.
COFFEY, Q.C.:
Q. I take it that was because it was a more--it was a higher theoretical plane than would be of use here in St. John's?
DR. KHALIFA:
A. I wouldn't say higher. It was a theoretical background that probably is needed in R & D labs or some--but the histotechnologists we had on site were doing a fine job.
COFFEY, Q.C.:
Q. Doctor, you are the director of oncology quality assurance program at Sunnybrook?
DR. KHALIFA:
A. That's correct.
COFFEY, Q.C.:
Q. What is the mandate of that program, mind telling us that?

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DR. KHALIFA:
A. This program started in 2004. It was created and I became the director of that program to liaison between our cancer centre and the surgeons and pathology to address the issues in proof communication and tighten quality assurance in respect to cancer surgery.
COFFEY, Q.C.:
Q. And Doctor, one final question I have for you is this, because of course you did move on from Newfoundland in 1999, Doctor, but you had stayed--you had been here for four years at that point, approximately four years?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. And I'm going to ask you, is there any particular thing or things that caused you to move on at the time? Because I don't mind telling you, Dr. Cook said, has told the Commissioner that at the time, before you ever showed up here, okay, that there was talk here locally that they thought of you as a good catch, as it were, in the sense of you were going to--they were looking forward to your

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coming here in 1995/96, okay, 1995.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. So I'm just asking you, you were here for four years and you described the environment you were in, the challenges.
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. Can you tell us, please, then -
DR. KHALIFA:
A. Well, you know, decisions like that take place because of different groups of forces. There are pulling forces and pushing forces. Pulling forces are obvious family reasons and opportunities for the children and things of that nature and community and social. Pushing forces mostly were in the fact that I did not feel that my compensation was adequate. I had certain encounters that, at the personal level, that showed me that maybe probably people didn't see me the way I saw myself or the way I thought I was seen. I had one particular incident where my mother had--so

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there was a group of issues, but my mother had recurrence of her breast cancer. She did not have an MCP number. She wasn't a Canadian citizen at the time. She needed radiation as a life saving measure. She's in coma right now as we speak, so.
COFFEY, Q.C.:
Q. She's ill, I take it, yes. Doctor, I take it, because you've--we've spoken about this before, you and I have.
DR. KHALIFA:
A. Yes, anyway, I'm sorry for that, but as a life saving, she was treated at the Cancer Centre, very good oncologist took care of her and she wasn't covered by MCP and at the end of her treatment, the treatment was fantastic. She survived that. I don't know if she survives today, but she survived that time. And at the end, I received a huge bill from Cancer Centre. I went to the CEO of the Cancer Centre. I told her, "listen, can you give me a break here, a professional courtesy?" She said "no." I said "listen, I've been doing all this for four years. I've been reviewing all your cases. I did not receive

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compensation for that." I mean, I carried more than two or point two or point three FTE work, more than anybody, and I did all that, just give me a break, any break. No, and I didn't get any break. So I wasn't sure why was that.

COFFEY, Q.C.:

Q. I take it that that did not entice you to stay. I won't say it pushed you out of here, but didn't entice you to stay.

DR. KHALIFA:

A. No, no, no, no, I mean, people don't leave because of these things, but it's the little things that accumulate over time that makes you wonder if you are valued, if people are listening to what I'm saying. I annoyed so many people with my quality assurance initiative. Nobody likes quality assurance, but, and people cooperated with me and some people resisted me and it was time to move on.

COFFEY, Q.C.:

Q. Commissioner, they're the questions I have. Thank you.

THE COMMISSIONER:

Q. Thank you. Mr. Pritchard?

MR. PRITCHARD:

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Q. Thank you, Commissioner. I don't have any questions for this witness. Dr. Khalifa, thank you.

DR. KHALIFA:

A. Thank you.

THE COMMISSIONER:

Q. Mr. Simmons.

DR. MAHMOUD KHALIFA, EXAMINATION BY MR. DANIEL SIMMONS

MR. SIMMONS:

Q. Thank you, Commissioner. Good afternoon, Dr. Khalifa. Only a few questions for you. You've told us a certain amount about the manner of reporting ER/PR results and some efforts that you made to make some suggestions when you instituted the testing here in 1998 about a suggested manner in which they could be reported, but that you left it to the professional discretion of individual pathologists to determine whether they would adopt that or not.

DR. KHALIFA:

A. Yes.

MR. SIMMONS:

Q. Is there now, where you practice in Ontario, any set standard for how an ER/PR test is to

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be reported, a standard that applies across institutions? Is there one way in which it is to be done, even now?

DR. KHALIFA:

A. Yes. This is an initiative by Cancer Care Ontario. Of course in Sunnybrook, we have a subspecialized pathology practice, so only a selected groups do selected sites. Breast is only signed out by a certain group of pathologists and there are--there is a consensus about how the reports should look like and there are strictly followed guidelines and they consistently report in this way. Cases for ER/PR come from other hospitals to our medical centre or goes centralized in certain areas, in certain labs, so that they are consistently reported.

MR. SIMMONS:

Q. The Cancer Care Ontario guidelines for reporting ER/PR is that something that was in place when you went to Ontario in 1999 or has that--is that a development that has happened since then?

DR. KHALIFA:

A. Well, when I left St. John's and went to

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Sunnybrook, I wasn't hired as a breast pathologist. We did everything for about a year or so and then after that, we became subspecialized, but I moved away from breast significantly, so I wouldn't be able to answer that question.

MR. SIMMONS:

Q. Do you know if it is part of the Cancer Care Ontario reporting guidelines now that internal controls must be reported on as part of the reporting?

DR. KHALIFA:

A. I asked our expert pathology, breast pathology about that and she said no, and the reason they don't do it, it's not a requirement. It's not required by CCO, by Cancer Care Ontario. It's not required by the College of American Pathologists, for a variety of reasons. One is that if you put focus on internal control, then what about the other controls? Are we going to report all controls? It is useful, but only in certain cases. It is not the magic bullet. As I demonstrated earlier that it could be negative and still the case is kosher. So the answer

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is no, internal control is not one of the required parameters in breast pathology.

MR. SIMMONS:

Q. Okay. When you were in Newfoundland, up until 1999, you did see and report quite a few number of cases while you were here and for a while, initially, you were the only pathologist who was reporting the ER/PR cases done by the IHC method here?

DR. KHALIFA:

A. That's correct.

MR. SIMMONS:

Q. And during that time period in particular, you saw the positive control slides?

DR. KHALIFA:

A. Yes.

MR. SIMMONS:

Q. And do I understand that you continued to see every positive control slide up until the time you left in 1999?

DR. KHALIFA:

A. That's correct.

MR. SIMMONS:

Q. Yes, okay. Now did the technologists have any role then in reviewing the positive controls?

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DR. KHALIFA:

A. No. No, they look at the slide when it leaves the lab. If they see brown colour, brown stain, that's good enough.

MR. SIMMONS:

Q. Beyond that, did you have any expectation for the technologists to be able to read and interpret the controls, for example, to determine whether the staining was in the nucleus, as opposed to the cytoplasm in the cell?

DR. KHALIFA:

A. No, I didn't expect this from them.

MR. SIMMONS:

Q. Okay. Of all those cases that you saw and reported on, did you see any trend or pattern from the slides themselves that would have suggested that there was any problem with tissue handling that would have affected the reliability of the ER/PR results that you reported on?

DR. KHALIFA:

A. No.

MR. SIMMONS:

Q. So even though you were aware that there may

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have been some inconsistencies in the handling of tissue at different times, you weren't seeing any trends or problems in the slides that were resulting from those tissues?

DR. KHALIFA:

A. Well, this is a two-folded question. I did not notice trends. There was no trend, but remember, the issues that were shown in the memo before, the fixation, the sensitivity of fixation, under fixation, over fixation, inconsistent fixation, the issue of internal control, these things were not available. We didn't know these things at the time. So I didn't know if these things were impacting the stain or not, but I didn't see a problem, and remember, at that time, all what we were trying to do is to make sure that our immunohistochemical result matches the biochemical result.

MR. SIMMONS:

Q. Right, okay. Do you recall how or when you first learned that here in Newfoundland Eastern Health, successor to the Health Care Corporation, was undertaking a fairly large scale retesting of these ER/PR results from

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back as early as 1997?

DR. KHALIFA:

A. Probably 2005, 2006.

MR. SIMMONS:

Q. Okay. Are you aware of anything similar to that having been undertaken in any other hospitals in Canada or in North America?

DR. KHALIFA:

A. Never.

MR. SIMMONS:

Q. Did you have any particular reaction when you heard that it was being done here, any views concerning that?

DR. KHALIFA:

A. My reaction was probably similar to any of my colleagues who heard about that, "oh my God," that's the reaction, oh my God, what would happen if you take blocks from any hospital in North America, anywhere, choose the best, finest, institution you can think of. Take blocks ten years ago. Send them to another place to be tested under--in a different environment, even if you tried to imitate or match the specifics. Oh my God, I don't know. I don't know what will happen.

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MR. SIMMONS:
Q. Okay. One other point. In Ontario, we've heard that there is a program, QMPLS is the acronym, I believe.
DR. KHALIFA:
A. Yes.
MR. SIMMONS:
Q. Quality Management Program for Laboratory Services, and we understand that that provides a mandatory accreditation -
DR. KHALIFA:
A. Yes.
MR. SIMMONS:
Q. - for medical laboratories in Ontario.
DR. KHALIFA:
A. Yes.
MR. SIMMONS:
Q. I presume that you've had some experience with accreditation reviews at Sunnybrook?
DR. KHALIFA:
A. Yes, of course.
MR. SIMMONS:
Q. And I wonder if you would have any insight or comments for us on what the benefits might be for such a mandatory accreditation program for

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hospital laboratory services?
DR. KHALIFA:
A. Yes, it is my personal opinion and my strong belief that this probably would have--would be the most useful outcome from an endeavour such as this one, because I worked in this system enough to know how easy it is to have a checklist of things to follow and we all know that we can forget things. I mean, just because everything looks okay in this room doesn't mean that everything is actually done properly, but if I have a checklist to go over it and check the wires and check the microphone and everything, and then I can--I will be in a better position at least to say that I am giving reliable results. So accreditation programs, accreditation programs, accreditation programs, I think this is crucial.
MR. SIMMONS:
Q. Thank you very much, Dr. Khalifa.
THE COMMISSIONER:
Q. Thank you, Mr. Simmons. Mr. Pritchett?
MR. PRITCHETT:
Q. No questions, Commissioner.

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THE COMMISSIONER:
Q. Ms. Newbury?
DR. MAHMOUD KHALIFA, EXAMINATION BY MS. JENNIFER NEWBURY
MS. NEWBURY:
Q. Good afternoon, Dr. Khalifa. My name is Jennifer Newbury and I represent the Canadian Cancer Society, Newfoundland and Labrador Division. I have a few questions for you, starting with your interest in quality assurance, and I was wondering if you could explain what role, if any, monitoring of trends in a pathology lab, monitoring of test results plays in quality assurance? Is there any connection between the two?
DR. KHALIFA:
A. Regarding ER/PR or -
MS. NEWBURY:
Q. Just generally speaking.
DR. KHALIFA:
A. Generally speaking, yes. It is very useful, and I do that to monitor quality indicators and quality indicators should be designed in such a way to be sensitive to pick up areas that we know are likely to be trouble areas, and I do that regularly and if we see a trend,

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we try to troubleshoot or try to do a root analysis for the problem. I guess you are asking why is this important. It is important because it can pick up a potential problem before it actually happens.
MS. NEWBURY:
Q. And if you can extrapolate that to ER/PR or immunohistochemical testing -
DR. KHALIFA:
A. Yes.
MS. NEWBURY:
Q. - how would you apply those sorts of processes to ER/PR testing?
DR. KHALIFA:
A. Okay, so now we have a program, we have a test. We can start doing audits, just like the audit that we saw before. We can start putting audits and collect all different parameters that we think are important. Like for example, now in Sunnybrook, because this is a very hot topic, now when the case is received and it is put in formalin, it is reported when it went in formalin and when it is processed, it is reported when it is processed. So now we know how many hours did

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a specimen stay in formalin and stuff like that. Then you have a program, you can start developing the parameters and you monitor them on monthly or quarterly basis and collect data and draw graphs and work with it.

MS. NEWBURY:

Q. Okay, and I understand generally, from your various experiences in the United States and in Canada and Egypt, I guess, that there were varying degrees of sophistication of labs, depending on the size of the lab, the number of pathologists, the resources available, you know, whether or not the lab is affiliated with a teaching institution, a university. Are there any minimum requirements for monitoring? We can all strive, I guess, to have Sunnybrook's program.

DR. KHALIFA:

A. Yes.

MS. NEWBURY:

Q. And you indicated the ideal situation is to have a full blown quality assurance department dedicated to that, but what minimum requirements would you see for ER/PR testing?

DR. KHALIFA:

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A. So the minimum requirements, we will go back to the issue of accreditation program. An accreditation program will tell us what are the minimum requirements that are needed and then we will try to meet that, if not to exceed them. As I said, I've been away from breast for some time now, so I don't--I wouldn't really know now what are the minimum requirement for a QA program in ER/PR.

MS. NEWBURY:

Q. Okay, and if you were to go look for one, if you wanted to make a recommendation to some institution, where would you go to get that information? What body or individual would you look to?

DR. KHALIFA:

A. Again, this is something that I personally have very strong opinions about it, having been through Newfoundland and learned about the geography, the culture. I personally think it is dangerous to import quality assurance parameters or programs from other jurisdictions. You can use them to build on them, but I think quality assurance programs should always be custom made, should always be

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home recipes, and by home I mean province wide recipe, done by people who know the issues of the place.

MS. NEWBURY:

Q. Sure. So tailored to the geography and the population and the facilities?

DR. KHALIFA:

A. Of course, of course, with consultation with lawyers, the standard of care, experts. You get all the pieces together, but then at the end, what actually applies is what you design, based on the needs of your community.

MS. NEWBURY:

Q. And what role would a cancer registry have in your work, in terms of monitoring trends and dealing with quality assurance? Do you have any views on how a cancer registry might be of some benefit?

DR. KHALIFA:

A. You are almost talking now about the ultimate, like the Cadillac of all things. The ultimate goal is to have a central cancer registry and in Ontario, we are still working on that. Importing data, there is a system of staging now called collaborative staging. Very, very

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few places in North America has it. We are hoping that Ontario would be one of them by 2010 or 2011. In systems like this, the data warehouse receives data from all cancer systems, from radiology, from pathology, from biochemistry, from surgeons, from everything, pools in a central warehouse where people, experts will do data mining for quality assurance, for trend observation, for research, for translational research, health care research. So of course, when you have centralized data collected in such a way, someone can mine the data and pull out reports to notice those trends we are talking about.

MS. NEWBURY:

Q. Right, and if you were in charge of quality assurance at a pathology lab, would you have access--would you expect to have access to that information so that you can, you know, see if there's anything pertinent to your particular role?

DR. KHALIFA:

A. This is what Cancer Care Ontario is taking leadership in. When we started asking pathologists to follow the standardized

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reporting and do all these things, some of the pathologists said, "well, what's in it for me? If I'm going to give you all this data, what am I getting back?" and then CCO created a web-based system called I-Port in which health care providers now can go back and pull reports that are useful to them. If you want to monitor age for breast cancer, colon cancer, any report, you pull from pull-down menu, you choose the variables and you design your curve and here you go. So of course, it is still preliminary. I mean, this is only a two-year old program, but programs like this, yes, you have a central warehouse, but the health care providers can retrieve reports from the database.

MS. NEWBURY:

Q. Okay, and I'm going to bring up an Exhibit P-2416, just to help jog your memory. I want to ask you what was happening in St. John's when you were here, in terms of cancer registry, and on page two of this document, this is a January 8th, 1998 meeting, Anatomical Pathology Site Chief Divisional Managers meeting, and there's a note here, item number

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four, demographic information on pathology reports. "Dr. Cook presented a letter from Susan Ryan from the Cancer Registry. In the letter, she requested that pathology reports include pertinent demographic information, such as patient's address, city, town, etcetera. This information is currently supplied on pathology reports from the Grace site. Following a discussion at the meeting, it was felt that this information should not be supplied on pathology reports from the General Hospital and St. Clare's site. It was felt if this information is required, it should be obtained from the last attending or family physician. This information will continue on pathology reports from the Grace, mainly due to the fact that this information is entered at the time of patient registration on admission," and Dr. Cook was to write Susan Ryan regarding this. Do you have any recollection of this? I believe you were at that meeting.

DR. KHALIFA:

A. No, I don't recall this particular incident.

MS. NEWBURY:

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Q. And it seems to be just the demographic information, as opposed to pathology reports, the results themselves that are at issue here.

DR. KHALIFA:

A. Yeah, this issue falls under standardized, even the reports between the three hospitals.

MS. NEWBURY:

Q. Sure.

DR. KHALIFA:

A. If you look at the report from Grace Hospital at that time, you will see more information than the one from St. Clare's and General. We were trying to, as much as possible, to make them uniform.

MS. NEWBURY:

Q. Notwithstanding this, do you think that all pathology reports from the General Hospital and St. Clare's site were nonetheless being forwarded on to the Registry, albeit not with some of this demographic information?

DR. KHALIFA:

A. Yes.

MS. NEWBURY:

Q. And do you know if, at any point in time, even though it may not have been as advanced as

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what's happening now in Ontario, would there be access to that information to look for any trends? Was there any value in what was being sent to the Cancer Registry or was the Registry in such a state that it could be accessed by a pathologist with an interest in seeing what's going on in the lab?

DR. KHALIFA:

A. We are required by CCO standard, we have to have this information in the report. It's not a choice. It's not a matter of choice.

MS. NEWBURY:

Q. But I guess my question relates back to your time here in St. John's. Did you, as a pathologist, ever access that information for your own information? Did you ever contact the Cancer Registry to see, you know, curious in what's happening with these types of results? Was it actually a useable tool for you as a pathologist?

DR. KHALIFA:

A. It is useable for someone who is conducting a research project. Of course, if we want to do a project, we have to submit a proposal to the ethics committee, it's called the IRB, the

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Institutional Review Board, to approve the study and to tell us what we can and what we cannot do, and then when we have this approval, we may contact Cancer Care, the cancer centre and tell them we need to look at the files of these patients or things like that. So yes, they would provide us with data.

MS. NEWBURY:

Q. Okay, from a research point of view?

DR. KHALIFA:

A. For research.

MS. NEWBURY:

Q. I'll give an example, just to be more pointed in my question. Now you were reading all of the slides here, so you would have a good handle on the types of cancers, breast cancers that were being diagnosed and the ER/PR results. But if the reading of the slides were spread out amongst all of the pathologists in Newfoundland, as an example, and you wanted to find out if there are any trends here, in terms of the types of cancer, like tubular, which you would expect statistically speaking to be positive, ER

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positive as opposed to ER negative, would you have been able to access the registry at that time to get a list of all of those results so that you can eyeball and then see does this look right or, you know, should I -

DR. KHALIFA:

A. No.

MS. NEWBURY:

Q. You couldn't have?

DR. KHALIFA:

A. No, I couldn't.

MS. NEWBURY:

Q. Okay, and that's something that you could now do in Ontario? Is that something that you're working towards or that now exists in Ontario?

DR. KHALIFA:

A. In Ontario, some hospitals share the same network of computer information, but when they developed the data warehouse, it was a high level. It was administrative database. You can not go to the specifics of the patient. You can go, I think, as down as the level of the region, but not the hospital and not the patient.

MS. NEWBURY:

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Q. Okay. That's in Ontario?

DR. KHALIFA:

A. In Ontario, that's right.

MS. NEWBURY:

Q. And in terms of monitoring those types of trends, was there anything being done in St. John's at that time in terms of ER/PR testing, not using the cancer registry, but just keeping a track of it? Now, I realize you were doing -

DR. KHALIFA:

A. Not until I left, no.

MS. NEWBURY:

Q. Okay. You've mentioned your interest in patient having a safety culture and promoting, I think, the reporting of any problems, near misses, et cetera with a view to promoting patient safety. And I'm just wondering if you could explain how, first of all, what do you mean by blame, you wanted to take the blame out, I think, in -

DR. KHALIFA:

A. Yes.

MS. NEWBURY:

Q. - order to promote safety. What do you mean

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by blame? What types of blame are you talking about?

DR. KHALIFA:

A. It is something that is inherent in the medical community, the way we studied medicine and the way we see ourselves and the society sees doctors. There is some belief that we are error free or we are expected to be error free. And because of that, this means that if I made an error, I will be--actually there's literature about this, what kind of emotions does a physician feel when he or she is confronted by their own error? You get, I think the highest emotion was shame, self doubt and very, very negative emotions. I think there were four or five of them. So, now what we are trying to say is that the problem with that is because I didn't talk about it, my colleagues didn't learn from it and even I, myself, didn't reflect positively on it, so probably I am going to do the same problem again, mistake again and my colleagues are going to do it again. That's very expensive. And, of course, we are talking about error in a very general sense because

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not every error is an adverse event. Adverse events are events that hurt patients, but error could be just a very simple error that does not result in an adverse event. So, the non-blame culture is a culture where people can sit around the table and talk freely about their near misses or their slips. And as I always tease my colleagues, I say, we need to have a party at the end of the year where we sit around the table and say, what did I do today to make my practice safer? If I can say one thing, if I can say one problem, one error I made and then the next guy goes and the next guy goes, then we are learning from each other. I cannot do that if as soon as I speak someone will point the finger at me and starting blaming me. So, blame stops me from doing that. So, if we get blame out of the picture a little bit and deal openly with issues, then we may actually learn something.

MS. NEWBURY:

Q. And in terms of that sort of a culture and the ability of patients and the public to be confident that their safety is being assured, how is that accomplished? How do you make

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sure that the public and the patients who might see this as taking out accountability, how can you assure them that their safety will be taken care of?

DR. KHALIFA:

A. Well, we need to gain trust of patients because patients come to physicians with a trust by their titles and their qualifications, but we need to gain the patients trust. And we gain patients trust by consist delivery of high quality health care and when something goes wrong, we just have to be open about it. And, I guess, disclosure, if patients are comfortable with the disclosure in the community, then they will have trust in the system.

MS. NEWBURY:

Q. Okay. So, you would see that if there are problems, that you would have to communicate that with the patients, be open and -

DR. KHALIFA:

A. In the right context.

MS. NEWBURY:

Q. I'd like to refer to exhibit P-1850 please. This the memo which you outlined the review

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of, I think you've attached a review of 19 cases. That was over a nine month period. At the top of page four, nine month period, January 1997 to September 1997 and you've indicated, I think, in your evidence this morning that you consider this to be a semi-scientific document. And you explained that this wasn't a full blown study.

DR. KHALIFA:

A. No, because we continued to look at slides until March of the next year. So, the total number of cases was much more than this.

MS. NEWBURY:

Q. Was higher than this, okay. The 19 cases over this nine month period, would that have been all of the tests for which ER/PR testing was done?

DR. KHALIFA:

A. As I said, I knew that some of the cases from St. Clare's hospital probably were sent to Mayo Clinic, but if your question is whether this is the total number done in our lab or not, I probably would have to go back to the files and track them down.

MS. NEWBURY:

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Q. Perhaps if I asked the question this way, was an effort made to pick out particularly difficult cases or were you trying to do a random sample of whatever tests came through the door?

DR. KHALIFA:

A. No, audits of that nature have to be either random or consecutive. We cannot pick up cases and do an audit.

MS. NEWBURY:

Q. And do you think this was probably the consecutive type of a study?

DR. KHALIFA:

A. I would assume that these were consecutive cases. Can you kindly scroll down the number and see if it is logic or not.

MS. NEWBURY:

Q. I'm not even sure that they're all listed in the same numerical order there.

DR. KHALIFA:

A. It's interesting, the numbers are not in an ascending order. So, okay, so we went probably from 2100 to 5500, that's about a total of 3000 cases. In 3000 cases you get 20 cases, that probably sounds okay, that sounds

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like consecutive numbers.
MS. NEWBURY:
Q. Okay, but either way it would have been one or the other, in your view.
DR. KHALIFA:
A. If it wasn't consecutive, it had to be random.
MS. NEWBURY:
Q. Okay. And were the 19 of these tests here all performed under the same circumstances?
DR. KHALIFA:
A. Yes.
MS. NEWBURY:
Q. Okay. You used the same kit for all 19?
DR. KHALIFA:
A. Yes.
MS. NEWBURY:
Q. And there was no tweaking of any of the steps -
DR. KHALIFA:
A. No, the tweaking part was before we starting doing the tests.
MS. NEWBURY:
Q. Okay. So, any of the tweaking you did before and this would have been all identical.
DR. KHALIFA:

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A. Yes, I didn't report that tweaking part.
MS. NEWBURY:
Q. Okay. And were you the only pathologist reading the slides produced through this study?
DR. KHALIFA:
A. Yes.
MS. NEWBURY:
Q. Okay. And there's no second pathologist or resident involved in rereading those slides just to -
DR. KHALIFA:
A. Just retrieving the slides and looking at them and learning from them, yes.
MS. NEWBURY:
Q. Okay, but not in a formal way of recording results.
DR. KHALIFA:
A. No.
MS. NEWBURY:
Q. And at the time that you read the slides from the ER/PR testing through the IHC method, would you have been aware of the results from the biochemical assay method?
DR. KHALIFA:

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A. I would like to say yes, I had to -
MS. NEWBURY:
Q. Before you read the slides. I guess the question I'm asking is whether or not this would have been done, I think it's called a blind study, that you would not know what the results are to try to keep any potential bias out of the study.
DR. KHALIFA:
A. Okay. I understand the question. This was not a study, this was an audit, these were actual patients. So, in other words, if you look at any of these cases, this case was reported with the purpose of serving the patient. I was serving the patient. I wasn't doing a research study. So, in order to serve the patient, I wanted to, in my mind, make sure that I'm signing an accurate report. And I would do whatever it takes to make the report accurate, even if I look at the biochemical assay. So, if I look at the biochemical assay and I look at my slide and I see that it was positive here and I'm looking at positive then, I'm comfortable with it. If it is positive and I'm calling it negative,

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maybe I have to repeat it. So, these were real cases. I had to deliver accurate diagnosis.
MS. NEWBURY:
Q. Okay. At the time you put your signature on the report, I can see that, but would you have at least tested yourself just to see if you would come up with the same results before looking at the biochemical assay? Is that something you might have considered or would you -
DR. KHALIFA:
A. No, no.
MS. NEWBURY:
Q. - have taken all information available to -
DR. KHALIFA:
A. No, I wanted full information.
MS. NEWBURY:
Q. And how about the individual doing the biochemical assay procedure. Would that person have known about you results at the time?
DR. KHALIFA:
A. No, the biochemical assay, my understanding was -

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MS. NEWBURY:
Q. That would have been done first, would it?
DR. KHALIFA:
A. - was done by a machine.
MS. NEWBURY:
Q. Okay.
DR. KHALIFA:
A. There's very little human influence on them.
MS. NEWBURY:
Q. So you always had the biochemical assay results before?
DR. KHALIFA:
A. Yes.
MS. NEWBURY:
Q. Okay, and you've indicated that you weren't validating the test procedure, due to the fact that you were relying upon a certified kit, which you understood to be valid?
DR. KHALIFA:
A. Yes.
MS. NEWBURY:
Q. Okay, and would you have expected that the validation of the kit itself by the manufacturer would have been put through a more rigorous analysis, a full blown

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scientific study?
DR. KHALIFA:
A. Oh yes, oh yes.
MS. NEWBURY:
Q. Okay, and just generally speaking, what types of steps would the manufacturer have completed in validating the kit?
DR. KHALIFA:
A. Well, with every specification sheet you get from the manufacturer, there is a list of references and they tell you exactly what studies use this clone and these are very, very well structured programs.
MS. NEWBURY:
Q. If a decision was made to do the immunohistochemical testing for ER/PR without the benefit of a kit, what type of exercise would you go through to ensure that the test procedures were valid?
DR. KHALIFA:
A. If I didn't have a kit, I'm just doing the antibody and using my own reagents?
MS. NEWBURY:
Q. Yes, without the benefit of the sheets that you were just talking about with all of the

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research protocols.
DR. KHALIFA:
A. Yes.
MS. NEWBURY:
Q. Would you ever have a kit--sorry, would you ever have a situation where you have a kit, but you have information from manufacturers? I'm just wondering, you know, how does a kit make it different, in terms of your ability to forego a more scientific study, compared to not having a kit when you do ER/PR testing?
DR. KHALIFA:
A. When we don't have the kit, we purchase the antibody and the manufacturer will say use this solution and this other solutions before you add the antibody, and after you add the antibody, there is a secondary antibody and so you get these elements of the recipe, ingredients, from different vendors, and so you shop around. You get the cheapest around and then you get this one antibody from that one manufacturer. Of course the kits sells itself by saying, you know, what I'm going to save you from shopping around for all ingredients. I'm going to put them altogether

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in one box, just open the box and add--and it is expensive, and at that time, and up to to date, if you compare the data from different national studies, you're comparing antibodies that come individually and antibodies that come in kits, you will not find any superiority linked to any of them. The issue here is what has been approved. Which one has been approved? And to my knowledge none of them were approved because the--and by approved, I mean FDA approved. Well first of all, you can argue about the value of FDA approval if you are not practising in the States, why are we looking for FDA approval? Should we have a Canadian agency that approves kits and antibodies and drugs, that is not a question for me to answer. But, for example, when in December of '98 when the FDA approved HER2/neu kits, then now that is the kit that is approved by FDA. Then anybody who uses a different kit of different antibody carries the risk of producing inaccurate results because, hey, this is the only one that is approved by FDA. I don't think, at least at that time, I didn't know of a FDA approved

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antibody or a kit for ER/PR. Of course, if there was such a thing, well, maybe that was the one that we should use, but I wasn't aware of any. But again, even if there was, the issue would be how much weight are you going to give to a FDA approval if you're not practising in the States.

MS. NEWBURY:

Q. But when you mention that the kit was certified, certified by the manufacturer or -

DR. KHALIFA:

A. That's what I meant.

MS. NEWBURY:

Q. Okay, and do you have the same sort of certification from the manufacturer when you're not using a kit and when you're just using antibodies?

DR. KHALIFA:

A. Yes, before they release the antibody, they run rigorous testing on it and they wouldn't release it unless they have validated it. And still, if you use it and you have problems with it, we can ship it back to the manufacturer and say this lot so and so is just not working and they replace it.

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MS. NEWBURY:

Q. And the fact that you have a kit with all the ingredients for your recipe, does that mean that you don't have to do as rigorous a test when you're trying to validate a procedure for ER/PR testing?

DR. KHALIFA:

A. No, I would still do the same, if you are talking about the correlation?

MS. NEWBURY:

Q. Yes.

DR. KHALIFA:

A. I would still do the correlation because remember, the correlation was done to make people comfortable that we are giving our patients similar service to the one that they were given under the old system.

MS. NEWBURY:

Q. But would the correlation have any additional requirements, given that you're not using a kit?

DR. KHALIFA:

A. No.

MS. NEWBURY:

Q. So it would be the same type of study that you would -

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DR. KHALIFA:

A. I would have done the same.

MS. NEWBURY:

Q. And there's no special consideration given what you've described to be the delegacy of this particular test, ER/PR testing using prognosis, that's using prognosis in a therapeutic role?

DR. KHALIFA:

A. No, because the manufacturer of an antibody guarantees reliable results. I mean, all of these manufacturers guarantee reliable results.

MS. NEWBURY:

Q. They've got a range of procedures though and you've indicated that they do change from, you know, in an institution you may not follow the recipe exactly, you still have to make sure that it's right for your particular circumstance?

DR. KHALIFA:

A. Yes, yes.

MS. NEWBURY:

Q. And is the manufacturer responsible for that

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or is that something that the hospital -

DR. KHALIFA:

A. Well, as I said, it's within a range, so they say from five to ten minutes, you can use the ten minutes, you use the five minutes, sometimes when the section is cut a little bit thicker, maybe you need to change the dilution a little bit, so it's again, like a cook recipe, you have to play a little bit. There's a range, we shouldn't exceed the range, but we can play within the range.

MS. NEWBURY:

Q. Just a quick question about the surgical pathology rounds on Tuesdays and you've indicated, I think that during this parallel study or the parallel review of the biochemical assay and the immunohistochemical testing for ER/PR, that you had reviewed some cases under the multi-headed microscope?

DR. KHALIFA:

A. Some of them, yes.

MS. NEWBURY:

Q. Some of them, okay, and which pathologists generally attended those rounds?

DR. KHALIFA:

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A. The pathologists in the Health Sciences Centre and the residents and as my farewell letter says, the attendance was at the average of 3.2, including myself, so that means that there was at least two other pathologists sitting at the microscope with me.

MS. NEWBURY:

Q. Were pathologists from other hospitals in the St. John's area aware of this and invited to attend?

DR. KHALIFA:

A. Oh of course they were aware of it, I don't recall them attending, but we may have had an occasional pathologist from another city who happened to be in St. John's and pops in and looks at slides with us.

MS. NEWBURY:

Q. That was the next question, I was wondering whether people from other parts of the province were aware of it and invited to attend?

DR. KHALIFA:

A. I recall at least a couple of incidents where some of our colleagues and friends came with us, but everybody knew about these rounds.

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MS. NEWBURY:

Q. Okay, and they certainly were welcome to attend if they so wanted to.

DR. KHALIFA:

A. Absolutely, absolutely.

MS. NEWBURY:

Q. Thank you very much, Dr. Khalifa, those are my questions.

DR. KHALIFA:

A. Thank you.

THE COMMISSIONER:

Q. Ms. Taylor?

DOCTOR MAHMOUD KHALIFA, EXAMINATION BY MS. PAMELA TAYLOR

MS. TAYLOR:

Q. Good afternoon, Dr. Khalifa. My name is Pay Taylor, I'm here on behalf of the Breast Cancer Testing Class Action Group. I just have a few questions for you. When, near the beginning of your testimony when you were talking about the ER/PR procedure in IHC actually being brought in back in 1997, and I think that Mr. Coffey asked you some questions about whether or not, you know, there was any examination then of the financial resources that might be needed or any sort of analysis

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at that time. And I think what you indicated was that you had talked to biochemistry, IHC was up and running at that time and this was just one more antibody that would be used or utilized within the IHC lab, is that a fair summarization of what you said?

DR. KHALIFA:

A. Yeah, it wasn't rocket science, it was just one more antibody added to our portfolio.

MS. TAYLOR:

Q. So there wouldn't have needed to be any type of analysis in terms of moving a procedure from one department of biochemistry to IHC, different people doing a procedure, whether or not they had proper training, the proper level of knowledge, if there was any equipment that was needed, those sorts of things, that wouldn't have to be examined at that time?

DR. KHALIFA:

A. As I indicated, the antibody for estrogen and progesterone receptors was just one more antibody, they were doing antibodies for a variety of antigens for different tumours and different situations, so that was just one antibody that comes with its recipe. Its

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recipe was very comparable to the recipe employed in other antibodies. No, it did not need any additional resource or personnel or anything like that.

MS. TAYLOR:

Q. Another question that I had had to do with the DAKO autostainer, now this might not be something that you can answer. There's a little bit of confusion, I think, over when the actual DAKO autostainer was brought in and was being used in the lab. We have seen a contract that shows that it was executed in May of 1998. Do you know when the DAKO autostainer would have been brought in and when it was in use in the lab?

DR. KHALIFA:

A. I wouldn't remember, I'm sorry, I wouldn't remember. I wasn't really involved in the process and that was happening in the lab and so I wouldn't remember.

MS. TAYLOR:

Q. And I just want to go back for one moment to P-1850 Registrar? I know you've been asked a number of questions about the series that was run, the audit that was done. Now the purpose

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of the audit again was to compare the two methods, the biochemical assay method verses the IHC method to ensure that the results were comparable.

DR. KHALIFA:

A. Comparable, yes.

MS. TAYLOR:

Q. So the total number of cases that were run in, I guess the side-by-side series were 19?

DR. KHALIFA:

A. In this audit they were 19, yes.

MS. TAYLOR:

Q. Was there any other audits?

DR. KHALIFA:

A. No, I was doing this on an ongoing basis. I kept doing it until the end of March, until March '98, and I continued the correlation on a case-by-base basis.

MS. TAYLOR:

Q. You continued doing that, but it wasn't necessarily documented in this way, is that what you're indicating?

DR. KHALIFA:

A. No, no, we did not generate another audit.

MS. TAYLOR:

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Q. Okay, and so the purpose of this, even though you were correlating the other cases, the purpose of doing this in this way, documenting this in this way was for what purpose?

DR. KHALIFA:

A. I wanted to document how we were doing, comparing our results to the biochemical assay so that pathologists, clinicians and everybody involved would feel comfortable that we can move in this direction.

MS. TAYLOR:

Q. And documenting the 19 cases in this way, you felt that that was enough, in terms of documenting the comparison between the two methods to, I'm going to use the word "validate" I know that's been used in a different way, but to sort of validate the difference between the two procedures, to provide a comfort level to these other professionals that you're talking about.

DR. KHALIFA:

A. It certainly was my impression that everybody was fine with it, if one of my colleagues or an oncologist or anybody would come back and say, you know what, why don't we keep doing

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this for another year, I would have done it for another year, but the colleagues in St. Clare's wanted to get custody of their cases, they wanted to take their cases for reporting, the Grace Hospital, as you saw in one of the minutes, wanted to take their cases, people were comfortable, there wasn't any undue anxiety around the procedure that would require extending and as you saw in one of the minutes that there was no timeline, I mean, we did not start this with pressure to end in a certain point. If someone wanted to expand this for one more year, I would have done it for another year.

MS. TAYLOR:

Q. So in terms of documenting a sample size for statistical reliability confirming between the two methods, that's not something that you were trying to achieve with this audit?

DR. KHALIFA:

A. As I said earlier, and we can go around and ask other medical centres when did they implement immunohistochemistry and what did they do, and I bet you many places would say we bought the kit, we started using it. Why

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trouble correlating with the biochemistry? I mean, this is a valid test, has been tested by the manufacturer and has been tested in many studies. You can pull out an article and see what clone they used, okay, give satisfactory results, I am going to use that clone. And that was customary at the time. Really the audit was on top and above of any endeavour to make people comfortable with this procedure.

MS. TAYLOR:

Q. Okay, thank you, that's all the questions I have.

THE COMMISSIONER:

Q. Thank you. Mr. Pike?

MR. PIKE:

Q. I have no questions, thank you.

THE COMMISSIONER:

Q. Mr. Browne?

DR. MAHMOUD KHALIFA, EXAMINATION BY MR. PETER BROWNE

MR. BROWNE:

Q. Dr. Khalifa, good afternoon. I just have a couple of questions for you and actually I'll just leave off where Ms. Taylor finished questioning you and it's Exhibit P-1850, just to sort of summarize your evidence in respect

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of what you were doing here, Doctor, you were correlating two test results, the estrogen progesterone receptor testing through the IHC method with the biochemical assay method, both results were measuring the same. This understanding was based on literature where large studies were done to say what was necessary and how this would correlate. So you used that literature to sort of basically perform an audit, not a scientific study -

DR. KHALIFA:

A. Yes.

MR. BROWNE:

Q. This is not a scientific study.

DR. KHALIFA:

A. Yes.

MR. BROWNE:

Q. So all that had been already done in the literature prior to all this, correct?

DR. KHALIFA:

A. Exactly, and that one reference I gave was the one that had the largest series for correlation.

MR. BROWNE:

Q. Right, and that was referenced in one of your

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--

DR. KHALIFA:

A. In this memo.

MR. BROWNE:

Q. In this --

DR. KHALIFA:

A. At the bottom of this audit.

COMMISSIONER:

Q. Just to make sure I understand, my conclusion from what I've heard today was that you looked at the studies as to what the correlation should be, and then you looked at the results of these 19 tests to see whether or not you fell within the parameters of what you anticipated based on the studies?

DR. KHALIFA:

A. That's correct.

COMMISSIONER:

Q. And what you found was consistent with the studies, in your view?

DR. KHALIFA:

A. That's correct.

MR. BROWNE:

Q. And I'm -- Commissioner, it's the O'Keane study which is cited at the bottom.

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COMMISSIONER:

Q. Yes, uh-hm. So that was the basis on which you felt that you could say to pathologists, and particularly oncologists who would be looking at this method for the first time because they would be accustomed to having the results of another kind of test, to say this is really -- this is how you transfer the knowledge you already have to this new IHC method?

DR. KHALIFA:

A. That's correct.

COMMISSIONER:

Q. Is that the whole purpose?

DR. KHALIFA:

A. That's correct.

COMMISSIONER:

Q. Okay.

MR. BROWNE:

Q. So continuing education for your colleagues on this transfer?

DR. KHALIFA:

A. Yes.

MR. BROWNE:

Q. Doctor, you had mentioned, and it's very

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evident from some of your answers your passion for quality assurance, and it would seem throughout your curriculum vitae your efforts -- endeavours in that direction beginning here in Newfoundland and carrying on to Toronto. I just want to touch on you mentioned you're a member of or were a member of the College of American Pathologists, Quality Assurance Accreditation Committee, did I capture that correctly?

DR. KHALIFA:

A. Yes.

MR. BROWNE:

Q. And one of the hospitals was Mount Sinai, which you certified under that program, and one of the factors -- did I understand it correctly, one of the factors that allowed that to happen -- you talked about sort of that that could not necessarily apply across the country, but one of the factors that was critical to that certification was the fact that Mount Sinai had very large research capabilities and very large funding?

DR. KHALIFA:

A. I wouldn't know the background as to why these

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sorts of certification by the College of the American Pathology, but I can tell you that certification by the College of American Pathology is a very prestigious status, and certainly labs like Mount Sinai lab is a very -- I mean, this is cutting edge, this is -- this is state of the art laboratory, and I was very impressed to see their work, very, very high quality. So it is a very prestigious status to say I am certified by the College of American Pathologists. I was just saying that seeking certification by the College of American Pathologists is not only a feather in your hat to say, look at me, how prestigious I am, it actually gives you credibility if you want to apply for grants from the United States -- like, Sunnybrook, for example, is not, and my personal position is that I didn't think that we needed that.

MR. BROWNE:

Q. So it is important if you're going to do research in the United States to have that certification?

DR. KHALIFA:

A. It is very useful, yes.

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MR. BROWNE:

Q. And you'd mentioned in one of your answers to -- I'm not sure if it was Mr. Coffey's question or one of other counsel, about the notion of an agency for labs, and I didn't quite get --

DR. KHALIFA:

A. Sorry, again please.

MR. BROWNE:

Q. You mentioned about having an agency for labs, and I'm not quite sure what -- if you completed that thought or not.

DR. KHALIFA:

A. Agency?

MR. BROWNE:

Q. For quality assurance for labs.

DR. KHALIFA:

A. Accreditation agency?

MR. BROWNE:

Q. Accreditation agency.

DR. KHALIFA:

A. Yes, or a program just like QMPLS. QMPLS came to Sunnybrook to inspect us. They passed us on certain things and did not pass some other labs on other things. We had to fix them, or

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they had to fix them, and we reapplied, and we were granted, but it was a stressful process, but extremely useful, extremely practical to get ann accrediting organization or body to go through the lab -- beforehand they give you a checklist of things that need to be in your lab, and you make sure you have them, of course, over many years, and then when the inspection date comes, they come and they inspect you and they certify you.

MR. BROWNE:

Q. Now is that mostly in relation to the technical component of the lab as opposed to sort of the interpretative pathology component, or is it both?

DR. KHALIFA:

A. Accreditation programs are mostly on the technical side.

MR. BROWNE:

Q. We heard -- Mr. Coffey asked you about synoptic reporting, and I just want to just canvas that for a minute. You were -- and we'll probably hear from another witness tomorrow about the introduction of synoptic reporting here in Newfoundland, and how you

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mentioned this afternoon how you sort of interfaced with the Cancer Clinic to do a checklist.

DR. KHALIFA:

A. Yes.

MR. BROWNE:

Q. And there are two types of reporting, I understand, in pathology. There is the narrative form.

DR. KHALIFA:

A. Yes.

MR. BROWNE:

Q. And then synoptic form?

DR. KHALIFA:

A. Yes.

MR. BROWNE:

Q. And there seems -- is there more of a move now towards synoptic reporting because of the importance to other specialties in trying to make sure that important information is transmitted to clinicians?

DR. KHALIFA:

A. Yes, indeed. The narrative report, when you read the narrative report, you may miss some of the parameters, some of the parameters may

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be missing and you wouldn't even know they were missing. So the step better than the narrative report which I was trying to implement here in Newfoundland, and I'm sure it is going on, what is called semi-synoptic. The semi-synoptic means you have the parameters, the variables, and the pathologist report. Each one, through their own language, for example, tumour type, and I would say that tumour type is tubular or lobular, something like that. So these are semi-synoptic. The true synoptic report which is now being implemented is you have the parameter, and then you can not free text -- you can not free text the variable, you have to choose from a drop down menu. So you're only presented by, say, six options, six names to call that tumour.

MR. BROWNE:

Q. Uh-hm.

DR. KHALIFA:

A. And, of course, these are developed -- we are following the College of American Pathologist checklist which is the most robust well studied evidence-based checklist available.

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There are several other systems. The College of American Pathologist is comprehensive, it's evidence-based, it's adopted by many accrediting agencies in the United States, and they give you, say, six or eight options, eight names. Then you have to choose one of them, so forth, and so forth, and so forth. So that does not only guarantee that the parameters are all included, but it guarantees standardized nomenclature and standardized language in the way we express our report.

MR. BROWNE:

Q. And just to -- you were shown your curriculum vitae, and the reference to your 2006 award for quality of cancer pathology reporting. Is that an area that this award focused on, your efforts there?

DR. KHALIFA:

A. My award was focused on three pillars, and that was one of them.

MR. BROWNE:

Q. What were the other two?

DR. KHALIFA:

A. The other two were creating an non-punitive culture in pathology which is on a website -- I think the website is where my CV -- it's in the Registry of Improved Medical Practice by the Ministry of Health in Ontario. They used what happened in Sunnybrook as a model that is used on their website for people around the world to see it and see how can that improve patient quality. The third parameter was our effort in making sure that every colon cancer is excised with 12 lymph nodes. So that's a surgical -that's a clinical parameter and a pathology parameter to make sure that patients of colon cancer are properly staged.

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MR. BROWNE:

Q. And that's one of your areas of special practice?

DR. KHALIFA:

A. That also is one of my sub-specialties, yes.

MR. BROWNE:

Q. Dr. Khalifa, you'll be glad to know I have one last question. That is, do you have any statements or recommendations you'd like to make to the Commission?

DR. KHALIFA:

A. I would like to make a brief statement, if you'll allow me. First, I want to thank the Commissioner and I want to thank people of Newfoundland for giving me the opportunity to be part of this endeavour. This is a very delicate issue we are dealing with here, and I am hoping and pleading to the public and the media to respect the delicacy of this situation and to treat it with sensitivity and objectiveness. I also want to mention that the pathology community in Ontario and across the country -- I was in Vancouver last month in the Canadian Partnership Against Cancer, the CPAC, spoke to pathologists from across the country. Everybody is watching what's happening here in Newfoundland very closely. It is very useful -- it's a very useful learning experience for everybody, and nobody has any doubt whatsoever that something very positive, extremely positive is going to come out of this endeavour, not only for Newfoundland, but for pathology and health care professionals across the country. Thank you very much.

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MR. BROWNE:

Q. Thank you, Commissioner.

COMMISSIONER:

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Q. Mr. Coffey, do you have any arising?
DR. MAHMOUD KHALIFA - EXAMINATION BY BERNARD COFFEY, Q.C.
COFFEY, Q.C.:
Q. Doctor, I have just one question. You were asked -- you made reference, I believe, in response to a question from Ms. Newbury, you referred to QMPLS, and, of course, that's in Ontario, a group, and their jurisdiction in a legal sense is limited to Ontario, I gather?
DR. KHALIFA:
A. Yes.
COFFEY, Q.C.:
Q. I think you indicated that if there was something like QMPLS or its equivalent nationally, that that might be from your perspective useful, and, in fact, I believe you indicated perhaps might have been helped to have -- if not prevent it, at least identify earlier any problems that there might have been in the laboratory here?
DR. KHALIFA:
A. Yes, sir.
COFFEY, Q.C.:
Q. So it is your view, I take it, that such a body, if it could exist or could be created,

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would be useful throughout Canada to provide such a service everywhere in this country?
DR. KHALIFA:
A. My personal view would be a national body with appropriate delegation to provincial bodies.
COFFEY, Q.C.:
Q. That would carry out that sort of function within their particular geographic location?
DR. KHALIFA:
A. Exactly, to deal with the fine details of each province.
COFFEY, Q.C.;
Q. Thank you, Commissioner. Thank you very much, Doctor?
DR. KHALIFA:
A. Thank you.
COMMISSIONER:
Q. Doctor, I'm afraid we kept you a little longer than we had anticipated. We very much appreciate your having come from Ontario to assist us with this, and the task, as you've noted, one that is a long one and is important not only to us, but I believe to people in the other parts of the country, and we're certainly very much aware of that. Thank you

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very much.
DR. KHALIFA:
A. Thank you.
COMMISSIONER:
Q. 9:30 in the morning.

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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 24th day of July, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.
Dated at St. John's, Newfoundland and Labrador this 24th day of July, A.D., 2008
Judy Moss

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