COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 2, 2008

Appearances:

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

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

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

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

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

LIST OF EXHIBITS

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COMMISSIONER:
Q. Mr. Coffey.
COFFEY, Q.C.:
Q. Good morning, Commissioner. The next witness, Commissioner, is Dr. Donald Cook.
DR. DONALD COOK (SWORN) EXAMINATION BY BERNARD COFFEY
REGISTRAR:
Q. And would you please state and spell your complete name for the Commission?
DR. COOK:
A. Donald Cook, D-o-n-a-l-d, C-o-o-k.
REGISTRAR:
Q. Thank you.
COFFEY, Q.C.:
Q. Commissioner, there are a number of exhibits that are proposed to ask--I'm going to ask to have entered. There are, Commission, beginning at 1854 through 1888, inclusive; and then 1890 through 1892, inclusive; 1894 through 1897, inclusive; 1899 through 1901, inclusive; 1903 through, I believe, 2136; and then 2138 through 2143. There's one I've skipped over there that's under review here, so.
COMMISSIONER:

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Q. All right.
COFFEY, Q.C.:
Q. We'll come back to that.
COMMISSIONER:
Q. Okay. Entered.
EXHIBITS P-1854 THROUGH P-1888, INCLUSIVE, ENTERED INTO EVIDENCE.
EXHIBITS P-1890 THROUGH P-1892, INCLUSIVE, ENTERED INTO EVIDENCE.
EXHIBITS P-1894 THROUGH P-1897, INCLUSIVE, ENTERED INTO EVIDENCE.
EXHIBITS P-1899 THROUGH P-1901, INCLUSIVE, ENTERED INTO EVIDENCE.
EXHIBITS P-1903 THROUGH P-2136, INCLUSIVE, ENTERED INTO EVIDENCE.
EXHIBITS P-2138 THROUGH P-2143, INCLUSIVE, ENTERED INTO EVIDENCE.
COFFEY, Q.C.:
Q. Thank you. If we could bring up, please, Exhibit 1854? And, Dr. Cook, I take it, this is a copy with some information redacted of your curriculum vitae?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:

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Q. Doctor, could you tell us, please, give the Commissioner a brief overview of your professional educational background and your professional background?
DR. COOK:
A. I obtained my MD from Memorial University in May of 1980. Following that I did a year rotating internship at Memorial, that was primarily centred on the three hospitals in the St. John's area which, at that time, the Grace, St. Clare's, General Hospital. Following that I entered into a general pathology training program at Memorial and that was a five and a half year program. That program included two and a half years training in anatomical pathology, six months training in biochemistry, six months training in microbiology, six months training in hematology, two months training in cytology and one months training in immunology. Following that I obtained, became a staff pathologist at St. Clare's Mercy Hospital commencing January 1st, 1986. Obtained certification in general pathology from the Royal College of Physicians and Surgeons of

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Canada as well as that American Board of Pathology in anatomic pathology. During most of that time at St. Clare's I was acting as a staff pathologist. That involved the interpretation of routine surgicals, autopsies, cytology cases and hematology cases. I served on a number of committees at that institution and later went on to serve on a number of committees at a provincial and national level. In regards to leadership roles, I became site chief at the St. Clare's institution in November of '96 and became acting clinical chief or interim clinical chief from July of '99 to July of 2000 and acting clinical chief and clinical chief from March of '02 to March of '06.
COFFEY, Q.C.:
Q. Doctor, at the--during the time that you were interim clinical chief, who had been the clinical chief for the Health Care Corporation at that time?
DR. COOK:
A. From the period of '97 to '99, you mean?
COFFEY, Q.C.:
Q. Yes.

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DR. COOK:
A. Dr. David Haegert.
COFFEY, Q.C.:
Q. And I take it then you were replacing Dr. Haegert while he was away for a year?
DR. COOK:
A. He was away for a year on sabbatical.
COFFEY, Q.C.:
Q. And then when he returned, he returned to his position as clinical chief at that point for a period of time and then Dr. Haegert, I take it, stepped down or left that position as clinical chief and you took over as acting?
DR. COOK:
A. That's correct. He came, resumed his position in July of, late July of 2000 until, I believe, March of '02.
COFFEY, Q.C.:
Q. Doctor, I want to--now, I gather, as well, you've been site chief at--is there such a thing as a site chief?
DR. COOK:
A. As a site chief, yes.
COFFEY, Q.C.:
Q. As well, in pathology. Could you tell the

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Commissioner, please, what it is--first of all, how long were you site chief at St. Clare's?

DR. COOK:

A. Since November of '96, I believe.

COFFEY, Q.C.:

Q. And are you still the site chief today?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Could you tell us, please, what the role of a site chief is?

DR. COOK:

A. The role of the site chief mainly is to act as a liaison between the pathologists on site at St. Clare's and the surgical and medical staff, as well as liaison with managerial staff in the OR and clinics and ambulatory care area. The site chief functions to make sure that there is adequate numbers of pathology personnel on site and to ensure that rotars are in place. These are scheduling rotars for covering OR and call issues. The site chief also oversees various educational activities that occurs on site, making sure

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that the rounds are instituted and that the rounds are sustained. There is also a role there in the undergraduate and post-graduate teaching programs. The site chief makes sure that in regard to post-graduates that they're involved in the on call rota, that they participate in rounds and teaching activities. The same goes true for undergraduates who go through that site doing elective operations. The site chief also ensures that there is a quality of medical reports on that site, looks at such things are turnaround times and outstanding reports as well as the content of the reports.

COFFEY, Q.C.:

Q. Doctor, and I appreciate you have also been the clinical chief and at times simultaneously the site chief and clinical chief?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Just on the aspect of the position involving the site chief, can you tell us, please, what, if any, interaction the site chief, and I appreciate you can't really interact with

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yourself while you're simultaneously holding both positions, but the interaction of a site chief when you were not the clinical chief, while you were site chief during the time that Dr. Haegert was clinical chief, could you tell us, please, what, if any, interaction a site chief would have with the clinical chief and, you know, the interaction or relationship between those two roles?

DR. COOK:

A. Well, the site chief would communicate with the clinical chief usually on a weekly basis, either through a telephone conversation or informal conversations, but more formally you would meet, say, once a month at the site chiefs and divisional managers' meeting. There may be other meetings that we had on the go, such as at the time we had an internal lab advisory committee. There my be participation of the site chiefs at the laboratory management committee level. There would be interaction at the various inter-hospital rounds that we had on the go. So there would be interaction between the various two individuals on a, usually on a weekly basis,

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informally, but formally at least once or twice a month.

COFFEY, Q.C.:

Q. And as site chief would the person, whomever he or she was, who performed the function of being site chief, in that capacity would the site chief report to the clinical chief?

DR. COOK:

A. Site chief would report to the clinical chief.

COFFEY, Q.C.:

Q. I take it you became site chief at St. Clare's in 1996, I think that's what you -

DR. COOK:

A. '96.

COFFEY, Q.C.:

Q. '96 or so, yeah. And that's around the time, I gather, that the Commission has heard evidence that really the Health Care Corporation of St. John's, around that time, '95, '96, really came into being itself?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, while you were site chief and before you became, during the period before you

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became interim clinical chief, while you were solely a site chief at St. Clare's, could you tell the Commissioner, please, what the structure of the lab at St. Clare's was in the sense of I take it there were technologists that worked there and pathologists, as well?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. In the lab. Approximately how many pathologists would have worked in the lab at the time?

DR. COOK:

A. You mean prior to the formation of Health Care Corporation of St. John's?

COFFEY, Q.C.:

Q. No. From the period, the first four years or so of the Health Care Corporation, in the late '90s, say, '95, '96 through 2000, approximately how many?

DR. COOK:

A. Four pathologists.

COFFEY, Q.C.:

Q. Four. And would that have included yourself as site chief?

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DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And how about technologists, how many were there have been?

DR. COOK:

A. We had four technologists and I guess one lab assistant at that particular time, or tech aid or whatever the designation was, so there'd be about five individuals within the histology lab at the St. Clare's site.

COFFEY, Q.C.:

Q. And within the histology lab?

DR. COOK:

A. That's right, in histology.

COFFEY, Q.C.:

Q. Doctor, who would the technologists in the histology lab report to?

DR. COOK:

A. They would report to the divisional manager.

COFFEY, Q.C.:

Q. And during that time frame do you recall who that was?

DR. COOK:

A. John Murphy.

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COFFEY, Q.C.:

Q. And was. Mr. Murphy division manager at the time, for that period, late '90s, was he on site?

DR. COOK:

A. He was on site. He would equal up his time between St. Clare's and the Grace. He was divisional manager for both the Grace and St. Clare's site.

COFFEY, Q.C.:

Q. Okay. And do you recall who he reported to?

DR. COOK:

A. He reported to the program director.

COFFEY, Q.C.:

Q. And in that period was?

DR. COOK:

A. Mr. Vern Whalen.

COFFEY, Q.C.:

Q. Okay. Do you recall where Mr. Whalen was situated?

DR. COOK:

A. His main base of operations was at the General Hospital.

COFFEY, Q.C.:

Q. Okay. So the technologists then during the

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time, say, the second half of the '90s, while you were site chief, during that time frame at St. Clare's, the technologists would not report to you then, I take it?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. So they had their own reporting stream through Mr. Murphy, through Mr. Whalen, that was one reporting stream?

DR. COOK:

A. That was the official reporting stream, yes.

COFFEY, Q.C.:

Q. Yes, okay. And the site chief with other staff pathologists, they reported to you?

DR. COOK:

A. They would report to me.

COFFEY, Q.C.:

Q. And you reported to the clinical chief?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Of the day, Dr. Haegert. And you say, I take it, that's the formal way they reported, I think you used the word on paper or formally

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that's the way the technologists work. In practice how did it work?

DR. COOK:

A. Usually at St. Clare's site there was a lot of interaction between the pathologists and the technologists, so if there were certain directions given to the technologists on what needed to be done with the various patient samples and whatnot, usually that direction came from the pathologists to the technologists.

COFFEY, Q.C.:

Q. And would that be directly from, like, an individual pathologist to particular technologists?

DR. COOK:

A. That could be, yes.

COFFEY, Q.C.:

Q. Or would it have to be funnelled through yourself as site chief or maybe -

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. - both?

DR. COOK:

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A. It could be both, something that could be funnelled through me or depending on the nature of the issue, something that could be dealt with directly between the individual pathologist and technologist.

COFFEY, Q.C.:

Q. Now, sir, I'd like to explore a bit further, then, the--as you assumed the role of interim clinical chief for year. And then I gather about approximately two years, 2000 and 2001, so about a year later, in '02 through '06 you were actually clinical chief?

DR. COOK:

A. From '02 to '06, that's correct.

COFFEY, Q.C.:

Q. So I'd like to explore that, the reporting mechanisms. In the period during which you were either interim clinical chief or acting or clinical chief, because it varied over time, could you tell the Commissioner what the role of the clinical chief was during your tenure?

DR. COOK:

A. Well, the clinical chief was responsible for running the, mainly the medical arm of the

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laboratory medicine program. The laboratory medicine program was divided into two arms, both the technical and the medical. The technical came under the program director and the medical primarily under the clinical chief. And I would report to the vice president of medical services at that time, and that would have been Dr. Robert Williams. The clinical chief, I guess the major role would be acting as a liaison with the various other entities that existed around the Health Care Corporation at that time, so I would interact a lot with the discipline chair. That was an individual who oversaw the university side of things. There would be interaction with clinical chiefs from the various other programs as well as sometimes discipline chairs from the other programs. There would be at times interactions between the Newfoundland and Labrador Medical Association on various issues. The clinical chief was responsible primarily for maintaining adequate numbers of pathologists on the various sites and involved quite extensive in recruitment and retention. I was

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also--you also made sure that pathologists were involved in various CME activities and tried to make sure that there was adequate funding for those CME activities. At the same time you were heavily involved in service activities. During my role as interim clinical chief, I still was involved in about 100 percent service load and -

COFFEY, Q.C.:

Q. Service load, that means actual clinical work as a pathologist?

DR. COOK:

A. That means the actual clinical work as a pathologist.

COFFEY, Q.C.:

Q. Sorry, go ahead.

DR. COOK:

A. And during my time period from '02 to '06 I was still involved in service work to the tune of about 50 to 70 percent. The remainder of time now, for the remainder of the time I was involved in various committees and these were clinical chief committees, medical advisory committees and various hospital committees as well as committees with university, residency

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training programs and College of the North Atlantic.

COFFEY, Q.C.:

Q. And as the clinical chief for the laboratory medicine program, okay, did that make you defacto a member of the MAC?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Okay. And from your perspective at the time as the clinical chief, what, if anything, did you see as your role in relation to the MAC?

DR. COOK:

A. Providing, acting as a liaison between that program and with that committee, providing that committee with information regarding activities as it relates to laboratory medicine program.

COFFEY, Q.C.:

Q. And as the clinical chief the relationship between yourself and the vice president of medical, which in your tenure was Dr. Williams?

DR. COOK:

A. That's correct.

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COFFEY, Q.C.:

Q. What was the--how much interaction would you have with Dr. Williams? Were there any--what, if any, committees were there? And how often did they meet?

DR. COOK:

A. Well, we usually meet on a regular basis with the leadership committee that was composed of Dr. Williams, myself, and the program director at the time.

COFFEY, Q.C.:

Q. That would be the leadership committee of the laboratory medicine program?

DR. COOK:

A. That's right.

COFFEY, Q.C.:

Q. We've heard of that.

DR. COOK:

A. With Dr. Williams, and that usually--we usually meet about once a month to discuss various issues surrounding the laboratory medicine program. Again, there was a much--a lot more informal interaction usually with phone calls, usually on a weekly basis, during that time period and attendance at other

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committee meetings, again such as MAC or clinical chiefs.

COFFEY, Q.C.:

Q. Doctor, I take you back now to the period when you were a site chief first, at St. Clare's. As site chief, how much or how, if any, if at all, did your occupying that role affect your clinical load as a pathologist?

DR. COOK:

A. Well -

COFFEY, Q.C.:

Q. Would you get any--only have to do so many cases compared--like was there any time allotted, getting at this kind of division of responsibility between the administrative work as the site chief and clinical work?

DR. COOK:

A. On paper, I was supposed to have 20 percent protected time.

COFFEY, Q.C.:

Q. Protected time.

DR. COOK:

A. To be involved in administrative activities. On a more realistic or actual--what actually happened, I was actually involved in 100

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percent service load.

COFFEY, Q.C.:

Q. And why was that? Why couldn't you use or get the 20 percent protected time?

DR. COOK:

A. Well, we were dealing with heavy service workloads, with not only just the service aspect, but you're involved in continuing medical education. You're involved in education activities, so were your other pathologists. They were also heavily involved in other committee meetings. The workloads were gradually increasing each year. There was involvement with undergraduate and post graduate teaching programs.

COFFEY, Q.C.:

Q. And I'll ask you about--the same question, but in relation to your period as clinical chief, either interim, acting or actual clinical chief, what was the situation there in terms of protected time and how did--versus clinical load and how did it work out in practice?

DR. COOK:

A. It was never really defined for me, in terms of here it is, you got 40-60 percent protected

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time to do or perform administrative activities. It was basically left up to the clinical chief, I suppose, as to what available time you could devote to administrative activities. So in my particular case, that varied from administration, anywhere from 30 to at times 50 percent on the average over that four-year period.

COFFEY, Q.C.:

Q. That's the four years from '02 through '06?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And there was never--your recollection is it was never actually spelled out on paper, that you can recall, you know, clinical chief, you know, 30 or 40 percent protected time or 50 percent protected time?

DR. COOK:

A. I can never remember seeing that figure.

COFFEY, Q.C.:

Q. Okay, but in practice, your recollection is that it would have varied, in your case, from about what to what, I'm sorry?

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DR. COOK:

A. Well, it would vary, again, taking the service load, anywhere from 50 to 70 percent in terms of administrative varied from 30 to 50 percent, depending on the various times of the years, the various months, weeks, whatever.

COFFEY, Q.C.:

Q. Now Doctor, you referred to the idea of one of the--certainly one of the functions, I gather, when you told the Commissioner of a clinical chief is to be involved in the recruiting?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. I take it that was a clinical chief's role, as opposed to a site chief's?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Could you tell the Commissioner, please, during your tenure as clinical chief in one form or another, in terms of recruitment of pathologists, how that occurred over the years and how, if any, if at all, it evolved over the years?

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DR. COOK:

A. Well, I certainly remember my interim year, between '99 and 2000, I remember when Dr. Haegert left for his sabbatical and was overseen with the task of clinical chief for that year. That year was particularly significant in that we--I had to recruit six laboratory physicians. Five of those were pathologists and one medical biochemist. That particular year, roughly each pathologist comprises about five percent of your manpower, so I had to recruit for that year, about 25 percent of the manpower in pathology and one medical biochemist. That was a pretty extensive undertaking during that particular year. Recruitment into Newfoundland hasn't always been easy and the retention is significantly more challenging. That particular year, I remember was a time that we got a new contract or just got a new contract between the Newfoundland and Labrador Medical Association and Government. So we were relatively in the middle of the pack in terms of where we stood in the Canadian perspective. That certainly helped in recruitment. The

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issue was that I couldn't get many in terms of whom had Canadian qualification. We relied an awful lot on what was known as the individuals with J1 Visas, pathologists who were trained down in the States, whose visas had expired and were looking -

COFFEY, Q.C.:

Q. I take it that J1 is a temporary training sort of visa that allows an non-American citizen to train in the U.S.?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. That was your understanding of it.

DR. COOK:

A. And when that visa runs out, then they have to leave the country.

COFFEY, Q.C.:

Q. Yes. I'm sorry, go ahead.

DR. COOK:

A. And so many of them look to Canada to come to establish the pathology practice and at that particular time, many of the provincial provinces had tight licensing restrictions. Now Newfoundland was one of the provinces that

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were attractive to the J1 Visas. So I was fortunate in that year in picking up, I think it was, three or four of the J1s and also fortunate that I had one or two of our own pathology residents who were finishing up their programs and managed to get them as staff pathologists. But even with that, it's still a significant amount of workload involved in recruiting. You can spend an extensive amount of time reviewing curriculum vitaes, going through the search process, going through the interview process, and I remember roughly we had about 16 or 17 applicants. So there's no shortage of applicants applying to the program. It's the competitiveness of the program that you also have to deal with.

COFFEY, Q.C.:

Q. And so that, in particular, stands out in terms of that one year that you were interim chief, '99 through 2000. What then happened after you took over then as acting and then finally actual clinical chief, that four-year period, in terms of recruitment, how did it work then?

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DR. COOK:

A. The first year, and since March of '02, I remember there was something in the order of three vacant positions that we had in the program. One of the significant vacant positions was our divisional chief for cytology. So I remember coming on and taking on that position of clinical chief that I had no divisional chief in that area, so I assumed responsibility for that particular division until I was able to recruit an individual. So not only was I wearing the site chief, clinical chief, but I was also divisional chief for cytology during that particular year.

As I said, there were about three vacant positions at that particular time. One of the first individuals I managed to recruit during that time was Dr. Gershon Ejeckam and he had been previously--had conversation with Dr. Dave Haegert. When Dr. Haegert stepped down, then I took over the recruitment process. The second pathologist that I was able to bring in with recruitment initiatives was, I believe, Dr. Dan Fontaine. He was a resident in

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Dalhousie, but he did an elective with our program prior to him coming to St. John's. And a third, I believe, and I'm not absolutely clear on that, but I think it was a Dr. Prakash Makarla, who was one of our J1 Visas from the United States.

COFFEY, Q.C.:

Q. And then as time went on, Doctor, during that four-year period, if you could just take--I'm not asking you to take us through every individual pathologist you attempted to recruit and were successful in recruiting or not, as the case might be, but over that four-year period from '02 to '06, what's your recollection of how the recruiting efforts went or were necessary as time went on?

DR. COOK:

A. Well, we fairly stabilized the manpower situation for a period of about '03 to halfway through '04. So that was a period that we had relative stability in the manpower situation. What was occurring was during the latter half of '04 and particularly through '05, that we were beginning to run into serious manpower problems and this occurred as a result of

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retirements. This also occurred as a result of career opportunities that individuals had and also there were areas on mainland Canada that were more attractive to pathologists practising in that particular area. So things started to become quite significant, I'd say around June or July of '05, when I realized that we were going to be in significant problems.

And things got particularly tough around April, November, December of '05 when again we've lost about, on the estimate, 25 to 30 percent of our pathologists, either through retirement or trans locations to other areas of Canada, and that was quite significant.

COFFEY, Q.C.:

Q. And Doctor, as the person, the clinical chief of the day, I take it trying to--or watching people--and I take it that you--the fact that somebody was leaving, retiring or leaving, would be communicated to you at some point?

DR. COOK:

A. Sometimes, yes; sometimes, no. There were very few individuals who would come to me and say "look, Dr. Cook, I'm thinking of leaving

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within the next two to three months. I'm just giving you the heads up, so you know, you can prepare for what's coming." Many times individuals have already made their plans. They would come in and say "here it is, Dr. Cook. I'm leaving in the next month or two. I've already signed a position with another institution." Now I would be given the heads up when I knew that somebody was retiring, but that was generally few and far between, but what I described to you previously is usually what happened in many circumstances.

COFFEY, Q.C.:

Q. Doctor, during that time period, in terms of the doctors who moved on, not so much the retirees as those who moved on to other places, did you have any understanding or views as to why they were leaving?

DR. COOK:

A. Well, to be honest with you, particularly when it came to the J1s, they saw Newfoundland as a holding area. This was a place where they can come, gain their experience, gain some knowledge, gain their confidence levels, and when better opportunities arose in other parts

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of Canada, they chose those opportunities to leave the province, and many of them had contacts and friends and relatives in mainland Canada, so they were quite well abreast of any developments happening in mainland Canada in terms of changes in licensing regulations and career opportunities in mainland Canada or vacant positions.

COFFEY, Q.C.:

Q. During the period from 2002 through 2006, while you were clinical chief, do you have any views as to whether or not the remuneration levels for pathologists here had any effect on people's willingness to stay?

DR. COOK:

A. I think it had an effect to a certain degree. We were one of the lowest paid pathologists in Canada.

COFFEY, Q.C.:

Q. Were you involved in any of the efforts during the period '02 to '06 to increase the remuneration for pathologists?

DR. COOK:

A. Mainly through my interaction with Dr. Bob Williams.

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COFFEY, Q.C.:

Q. I take it was Dr. Williams involved with some group or committee that was -

DR. COOK:

A. That's right, he would be involved in negotiations with Newfoundland and Labrador Medical Association and there would be, I would say, communication namely between him and the Deputy Minister of Health.

COFFEY, Q.C.:

Q. Now Doctor, your training in pathology, as a resident, goes back to around the--well, the first half of the 1980s, in effect.

DR. COOK:

A. I started around June of '81.

COFFEY, Q.C.:

Q. '81, so through '85-86, that time frame. Could you tell the Commissioner, please, at that time, how much, if any, training in immunohistochemistry there was for a pathologist in a Canadian residency program, at least the one you went through?

DR. COOK:

A. Well, immunohistochemistry was just starting in the residency program that I was involved

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at. Most of the stains were at the histochemical level and at the routine haematoxylin and eosin level. The stains that we dealt with, as residents, were few and far between. They were mainly used as an adjunct in helping us make a diagnosis, but they weren't the sole indicator. So the level was mainly at the area of interpretation, as opposed to technical know-how or troubleshooting. It was mainly at interpretative levels.

COFFEY, Q.C.:

Q. And that was as a resident?

DR. COOK:

A. As a resident.

COFFEY, Q.C.:

Q. Then as a staff person, I take it in mid 80s, as you've indicated, you became a staff member at St. Clare's. Were you ever part of Memorial University's medical program, in the sense of as a teacher?

DR. COOK:

A. Yes, I was.

COFFEY, Q.C.:

Q. Could you tell the Commissioner about that?

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DR. COOK:
A. I was clinical assistant lecturer at Memorial University and then that was upgraded to clinical or assistant professor at Memorial University of Newfoundland.
COFFEY, Q.C.:
Q. And what sort of responsibilities did those positions involve?
DR. COOK:
A. Those mainly involved responsibilities at the undergraduate and mainly at post graduate levels. Post graduate levels were involved in residency training programs which was involved in setting up the various rounds, making sure residents were involved in scheduling, making sure they were doing adequate numbers of surgical cytology, autopsy cases, meetings with other members of the discipline in regards to planning of the curriculum. We were also involved in undergraduate teaching programs, particularly medical students and setting up lecturers, rotations at the various hospitals, and tutorials.
COFFEY, Q.C.:
Q. And Doctor, are you still involved in that

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function with Memorial?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Memorial's medical school. You referred to the planning of the curriculum?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Would that be for undergraduates and graduate students?
DR. COOK:
A. Mostly graduates.
COFFEY, Q.C.:
Q. Graduates, and that's--and in that world, I take it, that's another name for graduates here are residents?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Okay, and you've been involved, in one form or another in that aspect of medical education really from the mid 80s until right up until now?
DR. COOK:

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A. That's correct.
COFFEY, Q.C.:
Q. Doctor, can you tell us, please, what--how much, if any, training that you're aware of, at least in terms of the curriculum, that a pathology resident would receive going through the pathology programs at Memorial University's medical school in terms of immunohistochemistry?
DR. COOK:
A. Again, only at the microscopic level, that would be mainly in the area of interpretation, determining what stains are best suited to make a particular diagnosis of a lesion, determining what part of, say of the cell would be staining with the cell, the cytoplasmic membrane, cytoplasm nucleus aspects of the cell. And determining what profile of antibodies immunohistochemical stains are best suited to diagnose that particular lesion, and that would be used in conjunction possibly with histochemical stains, your routine H&E's and at times, electron microscopy and or flocytometry or molecular genetics. So it was one component

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amongst many used to make diagnostic interpretations.
COFFEY, Q.C.:
Q. Has that changed over this, well I'll refer to it as just over a twenty-year period from the mid eighties to, say 2008?
DR. COOK:
A. It certainly changed in the utilization or the degree of immunohistochemistry. It's much more utilized today than it was, say my time period as a resident and early staff pathologist.
COFFEY, Q.C.:
Q. And you indicated at the microscopic level and the terms of different stains utilize different stainings of different parts of the cell, particular stains use--the staining should occur in particular parts of the cell, for example you refer to the nucleus cytoplasm and the membrane.
DR. COOK:
A. Right.
COFFEY, Q.C.:
Q. Different stainings. What about the idea of, because you referred to it just earlier, the

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idea of troubleshooting and the theory, the scientific theory behind immunohistochemistry. Would a medical resident in pathology be expected or be expected to know or even be exposed to that?

DR. COOK:

A. Most of the--in terms of troubleshooting, that was mainly at the technical end. The interpretive end was primarily the weight that was placed on residents. There would be an expectation that the resident would know the theory behind immunohistochemistry and the various pitfalls in immunohistochemistry, but primarily that would be used in interpretation and what battery of stains would be used to make interpretations in various lesions.

COFFEY, Q.C.:

Q. Do you know for example if a pathology resident, for example a Memorial University program, would ever actually be tested on their knowledge of the theory, the scientific theory behind IHC?

DR. COOK:

A. That I can't say for sure, that individual may or may not, again there were many others that

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involved in the examination of the residents, mainly at the discipline chair level and pathologists who are university academic pathologists, so I really can't comment on that.

COFFEY, Q.C.:

Q. And the same question in relation to the idea of, you know, use the word pitfalls or potential, problematic aspects of IHC procedures, do you know if pathology residents would be tested on that sort of knowledge?

DR. COOK:

A. In regards to interpretation, knowledge that, you know, a certain percentage of particular lesions may have a particular percentage of immuno reactive positivity. In regards that a particular stain may be present in more than one lesion; in regards that a particular lesion may have the unusual identification of a particular stain.

COFFEY, Q.C.:

Q. They would be expected to know that and be tested upon it?

DR. COOK:

A. They would be expected to know that in regards

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to the total interpretation of the lesion, taken into account again your hematoxylin eosin, your other histochemical stains and if necessary immunoperoxidase, flocytometry, that sort of thing. It would be used, not solely to make an interpretation, but as part of an overall plan, as part of an overall picture.

COFFEY, Q.C.:

Q. Doctor, I take it that as the, I gather that the number of IHC stains, for example in usage at the General Hospital site here in St. John's has changed significantly over the past 20 years?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. The amount of exposure to IHC, as a treatment or a clinical tool for pathology residents, I take it that has changed over time as well.

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, can you tell the Commissioner please what your exposure, for example in your own individual case to IHC has been over your

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career? Like, when were you first exposed to it and then how has that evolved over time?

DR. COOK:

A. Well I was first exposed to it, I'd say around the early eighties when, now IHC had been around for quite some time, but in terms of Memorial University, in terms of my experience with it, it gradually came on stream in the early mid eighties and it evolved slowly but steadily and there was quite a bit of reliance placed on our routine H&E stains, histochemical stains and electron microscopy. But more and more it became more prominent in the role of interpretations to the point that it almost became routine ordering immunohistochemistry on many lesions that we saw going through the institution.

COFFEY, Q.C.:

Q. Where were the IHC staining processes performed at that time, in the eighties?

DR. COOK:

A. In the eighties mainly at the General Hospital, but I think the Grace were doing some IHC staining and I think we did some at St. Clare's and that was probably later in the

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80's for St. Clare's.
COFFEY, Q.C.:
Q. And we'll go through the 90's, how did it evolve then in terms of what sites were doing what?
DR. COOK:
A. Still basic staining at St. Clare's and the Grace. I can't really say for sure what was happening at the Grace. I know that at St. Clare's we were just getting into the use of some of the kits, using some of the basic stains, but most of the immunohistochemistry was taking place at the General Hospital site.
COFFEY, Q.C.:
Q. And why was that?
DR. COOK:
A. I guess it's regarded at the site that was tertiary care site, it was the site that had the most concentration of technologists and historically it is a site that had taken in samples and specimens from other areas of the province.
COFFEY, Q.C.:
Q. And was there anything in particular or unique about IHC that caused the performing of--or

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the utilization of those stains increasingly be concentrated at the General site?
DR. COOK:
A. I guess the General had the greatest number of technologists and it was an area there that probably, I would say in terms of the province had the most expertise and various aspects of laboratory medicine.
COFFEY, Q.C.:
Q. Doctor, when you took over or you became site chief of St. Clare's at around 1996, you told the Commissioner, what, if any, involvement would you have in IHC staining at that point?
DR. COOK:
A. Very little.
COFFEY, Q.C.:
Q. Okay, and the very little, what if any did that involve?
DR. COOK:
A. That involved mainly interpretations.
COFFEY, Q.C.:
Q. Okay, the interpret--you would order--so how did that work? Could you tell the Commissioner, please, for example, you got a-- I don't know, you have a particular tissue

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sample come to you -
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And then if you wanted an IHC stain done, how would that work?
DR. COOK:
A. Well I would look at it first, I mean obviously you had to pay great reliance and attention on your hematoxylin and eosin stains. You would go through a number of differential diagnosis in your mind as to what the possible interpretation or final interpretation could be, so you could again order your histochemical stains, what you may order could be a battery of IHC stains or maybe just one or two that helped to confirm what you're thinking at the interpretative level. Now, depending on the time on which we're talking about, again we were just doing a few stains at St. Clare's, but if I wanted to order stains that came from the Health Sciences I would sign out a particular requisition and on the requisition, if I remember, were the stains that were available,

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so we would circle or mark or indicate the stains. Those would be--that requisition would be forwarded over to the General Hospital site and at that particular time, depending on where the blocks were located, the paraffin block, on which the tissue was embedded, would also be forwarded over to the General Hospital site where the staining process would be performed. The slides then would be forwarded back to St. Clare's for interpretation.
COFFEY, Q.C.:
Q. Doctor, and I take it then that as time went on and there were more and more IHC stains available, particularly at the General Hospital site, if as a practising pathologist at St. Clare's, if you wanted a particular IHC stain done, you'd check it off on the form, indicate it on the form, someone would arrange for the particular block or you might even identify the block in the form that you wanted it done on.
DR. COOK:
A. Oh the block would be identified in the form.
COFFEY, Q.C.:

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Q. And the block and the form would go over and the slide would be prepared and it would end up back on your desk?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, now the preparation of the blocks, okay, for example at St. Clare's in the 1990's, were the blocks, paraffin blocks actually prepared on the St. Clare's site in the 1990's?
DR. COOK:
A. In the 1990's they were.
COFFEY, Q.C.:
Q. Has that ever changed since?
DR. COOK:
A. During the '90's or -
COFFEY, Q.C.:
Q. Or since--well I never know what to call the 2000's, as it were, the first ten years.
DR. COOK:
A. That changed in May of '05 when we centralized the technical services at the General Hospital, but up until that time, the preparation of the blocks were performed at

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St. Clare's.
COFFEY, Q.C.:
Q. And that process then, so up until May of 2005, that process involved what? Could you just describe for the Commissioner what would happen? I take it a surgeon would take tissue from a patient and it would end up down in the pathology lab. How would it work then?
DR. COOK:
A. Well, let's say a biopsy was excised from the patient in the OR. that biopsy would be placed in a container or formalin, usually you make sure there's adequate amounts of formalin to completely immerse and cover that biopsy. That container then would be forwarded at that time to our frozen section room. It would have been picked up by the hospital porter, along with numerous other specimens at designated times during the day. That would then be forwarded to the lab at St. Clare's. Once in the lab, that would be registered or accessioned, you have to make sure that that container was appropriately labelled, both on a container and accompanied by the requisition. The accessioning would take

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place in the computer system and it could be a variety of people who are involved in that time period actually entering the specimen into the system, it would be a technologist or a lab aid and eventually it came under one of our secretaries or data entry operators. So once those cases were accessioned, they were given a surgical number, a special designate number and that number was then placed on the specimen container and on the lab requisition which held also the name and the various other demographics of the patient. There would be certain times of the day that then the pathologist would be called in to do a gross examination specimen and then to do the proper sectioning. Now on major specimens or large organs that came up from the OR through the portering system, the pathologist would be called in by the technologist to do what we know as slicing or bread loafing of the specimen or to open up the specimen to allow for formalin penetration and permeation. Depending on the type of specimen that was there, there would be fixation period of anywhere of 24 to 48 hours, again, depending

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on the specimen. Smaller specimens, the--they would be processed roughly the same day they came into the lab; however, you would require a time period of at least maybe six to seven hours before those specimens would be sectioned. So once they're sectioned and the appropriate tissue taken by the pathologist, the pathologist would place the tissue into the paraffin block. The paraffin block again would be placed in formalin fixation for added fixation time. Later on the tissue would be put into a processor and that's a process that involves the removal or dehydration of water from the tissue and that's a process that involved the tissue going through various gradients of alcohol and cylene preparation. That process, I think, would take place overnight. The next day the tissue would have been taken out of the processor and then embedded it in paraffin wax. The idea of the paraffin is to provide a supporting matrix for the tissue and the entire specimen in the paraffin block. Following that, once the paraffin hardened and solidified, the tissue would then go through a sectioning process

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where the paraffin block would be placed in a microtome and sections would be cut and placed in a bath. The sections would be cut to the thickness of approximately three to four or five microns, depending on the tissue involved. Once the sections were then cut, the individual sections were placed on a glass slide and it would then go through a staining process, usually with the hematoxylin and eosin and eventually we obtained automatic stainers that provided the stain for the H&E. Once the staining process was then done, a cover slipping process would take place. The completed slides then would be then forwarded to the pathologist once the labelling process has taken place and there's correlation between the slide, the surgical number and the requisition. So what the pathologist would receive then for interpretation would be their slides of the case and the requisitions and surgical numbers and various demographic information.

COFFEY, Q.C.:

Q. Doctor, at St. Clare's while you were site chief, was there ever--were there ever any

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written protocols for this process you've just described?

DR. COOK:

A. There may have been technical protocols which I wouldn't have been too involved in, but there were no written protocols for the fixation process. We did have a manual, an old manual at that time which was then forwarded to the OR and nursing people regarding the amount of formalin that would be submitted in the various containers.

COFFEY, Q.C.:

Q. I'm sorry, when would that have been?

DR. COOK:

A. I think that was occurring as early as the 1970s.

COFFEY, Q.C.:

Q. And do you know if there was such a written protocol in place, for example, from 1997 through 2005?

DR. COOK:

A. In regards to the fixation?

COFFEY, Q.C.:

Q. Yes.

DR. COOK:

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A. No.

COFFEY, Q.C.:

Q. No. Well, with respect to the amount of formalin that would be required for certain type of specimens.

DR. COOK:

A. Not in the lab, but there still probably could have been still existing at the ward, nursing ward level and at the OR level.

COFFEY, Q.C.:

Q. But that would be something one would have to ask the peri-operative program, I take it?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, you've referred to tissue processors, the idea of reprocessing, what is that?

DR. COOK:

A. Reprocessing would take place, that if I got the slide and let's say I was not happy with the quality of the slide or had problems with the nuclear features, the nuclei would become hazy or fuzzy, I would ask the technologist to do a reprocessing technique. And that basically would involve the remounting of the

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paraffin block, resubmission of the tissue through the processor and then re-imbedding of the tissue into the paraffin and solidification and then staining.

COFFEY, Q.C.:

Q. Are there any potential complications or problems associated with the reprocessing process?

DR. COOK:

A. There's a possibility that it may interfere with certain stains, certain histochemical stains. That's always a possibility.

COFFEY, Q.C.:

Q. And would that also apply to immunohistochemical stains as well?

DR. COOK:

A. It could.

COFFEY, Q.C.:

Q. Doctor, what would be the root cause or causes that would contribute to the necessity or the need for reprocessing? I appreciate what you see on the slide and from your perspective as a pathologist, you need it reprocessed, but what would have caused the problem in the first place?

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DR. COOK:
A. Again, if there hasn't been significant dehydration of the tissue through the processor.
COFFEY, Q.C.:
Q. The tissue processor itself.
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. In other words, if there has been some problematic aspect of the tissue in question going through the tissue processor and you've referred to in adequate dehydration -
DR. COOK:
A. Or there may have been a step or hasn't gone through the correct grading of alcohol. I mean, we go through various grades of alcohol, 90, 70 , 80 percent. If something was missed in that type of process -
COFFEY, Q.C.:
Q. And this again involves the tissue processing itself, the tissue processor?
DR. COOK:
A. That's my understanding, yes.
COFFEY, Q.C.:

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Q. Doctor, was there any way, as a practising pathologist that you'd be able to ascertain what, if any, negative effects reprocessing might have on particular IHC stains or histology stains?
DR. COOK:
A. It's a bit rough on the antigen that excites. So, if you go through reprocessing of the tissue through, again through a number of times, a number of episodes. It could reduce the number of antigen excites that are available for attachment by the primary antibody.
COFFEY, Q.C.:
Q. It might affect your ability to visualize, for the process to visualize for you, looking through a scope.
DR. COOK:
A. It could or it may not. I mean, there's very little, from what I understand, written in the literature on the effect of reprocessing itself and how that affects IHC.
COFFEY, Q.C.:
Q. Is reprocessing as a process, is it desirable or not, all things being equal?

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DR. COOK:
A. Oh, you wouldn't want to reprocess. If you can reduce the amount of reprocessing, that's what you would want.
COFFEY, Q.C.:
Q. Doctor, do you know at St. Clare's, during your time as site chief there, whether anyone ever kept track of the amount of tissue that was required to be reprocessed?
DR. COOK:
A. The actual numbers of cases?
COFFEY, Q.C.:
Q. Yes, number of cases, like the overall percentage of cases that might have to be reprocessed?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Doctor, the Commissioner has heard evidence related to fixation problems. Like, the idea that, from a pathologist perspective, able to look at a tissue on a slide or slides and at times problems with the fixation process can be apparent.
DR. COOK:

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A. Yes.
COFFEY, Q.C.:
Q. What is your experience with that, I mean, throughout your career in terms of when in your career would you have learned about it? What would have been apparent, you know, what would it all mean? What, if anything, would you do about it?
DR. COOK:
A. Fixation was always an issue that you always had to keep in the back of your mind. You're, always when you look at a slide, look at the general quality of the slide, making sure there were no folds or there were no bubbles or that the tissue was clear and crisp when it came to immunohistochemistry. Fixation was always something in the back of your mind that you would look at, but by and large, from what I saw at St. Clare's there would have been relatively small numbers of cases that you would see fixation issues. For the most part, what we saw or what was acceptable to us was acceptable quality of the slides, apart from the, you know, portions of tissue that were missing or holes or whatever which you see in

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any other lab.
COFFEY, Q.C.:
Q. Do you recall in your period as site chief at St. Clare's, whether or not you ever made any inquiries in relation to fixation concerns? Did you ever complain about fixation problems?
DR. COOK:
A. Not in regards to fixation concerns. There would be concerns about, again, mostly the concerns that I had to deal with were turnaround times, getting the actual slides to the pathologist, but generally speaking, very few concerns regarding the actual quality of the slides.
COFFEY, Q.C.:
Q. And Doctor, how about complaints to yourself as site chief from other pathologists?
DR. COOK:
A. Mainly again regarding turnaround times.
COFFEY, Q.C.:
Q. And what did that involve?
DR. COOK:
A. Oh, this would involve the, again, how many technologists that we would have available on site, the increasing workload and the ability

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of the technologists to keep up with the workload. So, when you would fix and gross and submit your various portions of the specimen for your paraffin block process, you would certainly hope, once you obtain that specimen, to obtain your slides within a 24-hour period. Over that time period from St. Clare's during--particularly during '97 and even times prior to '97, we had trouble with actually attaining slides within a 24 to 48 period. It wouldn't be unusual to get a slide say in 72 hours or even 4 days later. That would have an affect then on being able to get a report out within an acceptable turnaround time.
COFFEY, Q.C.:
Q. And get the slides from whom, in this context?
DR. COOK:
A. Oh, from our technologists.
COFFEY, Q.C.:
Q. Technologists on the site, on your own site at St. Clare's.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:

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Q. I've asked you about any complaints about fixation. How about complaints related to processing? Now, you've indicated that at times you would have to ask for a slide or a particular block to be reprocessed. How common was that -
DR. COOK:
A. That was -
COFFEY, Q.C.:
Q. - or uncommon as the case might be.
DR. COOK:
A. Fairly--uncommon.
COFFEY, Q.C.:
Q. Do you know if any record was kept at all, any records were kept of that? For example, how would you know if a particular block had been reprocessed?
DR. COOK:
A. I wouldn't know. The only time a block would be reprocessed is if I asked for it to be reprocessed.
COFFEY, Q.C.:
Q. Would any record be kept of the fact that you had asked?
DR. COOK:

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A. That I would ask? No.
COFFEY, Q.C.:
Q. Now, Doctor, I take it then in your period before you became clinical chief interim and then acting in defacto clinical chief, or des jurai (phonetic), I should use phase that, actual clinical chief. As site chief of St. Clare's, when you're in that role alone, I take it you didn't have a whole lot to do with IHC itself, the actual process, you would order a stain and you'd look at a slide?
DR. COOK:
A. That's basically it, yeah.
COFFEY, Q.C.:
Q. And IHC at that time was, looking back on it, if you had to kind of point out somebody who was responsible for IHC as an overall process, who would you have pointed to?
DR. COOK:
A. During 2002?
COFFEY, Q.C.:
Q. Well, up to 2002, up to that point.
DR. COOK:
A. Well, in the early days I would say it was Dr. Sash Chittal in the '80s, late '80s, early

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'90s. Then during that time period, around '96 to '99 it was Dr. Mahmoud Khalifa. We had no one from that time period, around 2000 to 2003 actually overseeing the immunohistochemistry. That role or overseeing of the role generally would fall in the hands of the site chief.

COFFEY, Q.C.:

Q. The site chief in this context would be the site chief of the General Hospital?

DR. COOK:

A. The General Hospital.

COFFEY, Q.C.:

Q. Okay. And who was the site chief in that time frame?

DR. COOK:

A. During that time period for a period of time there was Dr. Sash Chittal, Dr. Patricia Wadden and Dr. Sushil Parai.

COFFEY, Q.C.:

Q. Okay. And what happened then in 2003?

DR. COOK:

A. 2003, well, after I recruited Dr. Ejeckam and he came in 2002, he expressed an interest overseeing the immunohistochemistry.

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COFFEY, Q.C.:

Q. And then he was there until, well, through '05 into '06, I take it?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And we'll be dealing more with that as we go on. Then, Doctor, up to the time Dr. Ejeckam arrived and expressed an interest in IHC, okay, because by then you would have already been--you were clinical chief by that point?

DR. COOK:

A. Since March, yeah.

COFFEY, Q.C.:

Q. Yes. And you had been clinical chief, so you'd been clinical chief from March of '02 on?

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. And you'd been clinical chief for a year back in '99 through 2000?

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

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Q. Before Dr. Ejeckam arrived and after Dr. Khalifa left, during that hiatus, as the clinical chief if someone at the time had asked you about IHC, I take it in theory you would have been responsible because whoever was responsible would report to you as clinical chief?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. How much actual involvement did you have in IHC during that time?

DR. COOK:

A. Apart from interpretations, very little.

COFFEY, Q.C.:

Q. And is somebody had asked you about it then you would actually point to Khalifa in his day.

DR. COOK:

A. Khalifa in his day.

COFFEY, Q.C.:

Q. The site chief of the General Hospital, whoever he or she was at the time. And then finally when Doctor Ejeckam came along, Doctor Ejeckam.

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DR. COOK:

A. Doctor Ejeckam.

COFFEY, Q.C.:

Q. I'm going to ask, please, during the period when you would just be involved in IHC processes by way of ordering an IHC stain and then interpreting the slide, how would you go about learning what to look for a particular stain? How would you even know that a particular stain existed. And if so then, how to utilize it.

DR. COOK:

A. Well, I mean, it would depend on the lesion involved. If I'm looking at an undifferentiated carcinoma, I know I would order a battery of stains to look whether there's lymphoepithelial or a lymphoreticular or a menschel lesion. So, that knowledge was there in determining the type of stains that I would order. So, for lymphomas I would order a battery of stains to, you know, help me sub-classify certain lesions along with flocytometry or whatnot, but it would depend on the type of lesion I was looking at, forming a differential diagnosis, I would

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determine a batter of stains.
COFFEY, Q.C.:
Q. For example, in the early 1990s, how would you know which new stains there were? How would you become aware of -
DR. COOK:
A. I would phone--in the early ’90s?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. Could be conversations what Doctor Chittal at that particular time or it would be conversation with the discipline chair because we had a university component there. The university people would be involved in bringing in new peroxidase stains. There would be conversations with the various chief tech or the divisional manager at that time, at the General Hospital, as to what stains are available. And I can’t remember, there may have been a list sent out--you can obtain a list sent out with the various stains that were available at the General Hospital.
COFFEY, Q.C.:
Q. And then, what about the utilization of the

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stains because I take it, different stains, if they’re working properly, stained potentially different parts of the cell depending on the stain you’re talking about; some stain the nucleus, some stain the cytoplasm, some stain the membrane. Okay. How would you know if it was a new stain? How would you know what part of the cell to be looking for and what to be looking for?
DR. COOK:
A. That would depend on your reading standard textbooks at that time. Ackerman was a standard textbook that we used, so we would obtain information from that. Later on new textbooks such as Dabbs came out which would highlight what particular type or what particular aspect of the cell would be highlighted by the stain.
COFFEY, Q.C.:
Q. If we could, please, Registrar, P-1855. Doctor, here this is a two-page exhibit. It’s a letter dated April 10, 1997. It’s addressed to yourself. It’s from Mahmoud. And who is Mahmoud?
DR. COOK:

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A. Doctor Mahmoud Khalifa. He was a site chief and staff pathologist at St. Clare’s. I believe he came in ’96 until ’99.
COFFEY, Q.C.:
Q. And, I’m sorry, he was at which site?
DR. COOK:
A. Sorry, General Hospital.
COFFEY, Q.C.:
Q. General Hospital. And you believe he came in 19 -
DR. COOK:
A. I think he came in ’96.
COFFEY, Q.C.:
Q. - 96. Now, was Doctor Khalifa, as I’ll refer to him, did he ever become a site chief at the General?
DR. COOK:
A. Yes, he did.
COFFEY, Q.C.:
Q. Was that early on in his tenure, do you recall?
DR. COOK:
A. I can’t remember exactly when he became site chief. I can’t give you the specific date.
COFFEY, Q.C.:

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Q. And if he was the site chief throughout the, around the time or just after he arrived in St. John’s until the time he left, I take it that you and he then would generally be corresponding, you’d be the site chief at St. Clare’s and he would have been the site chief at the General, for much of that period in the late ’90s.
DR. COOK:
A. Yes, we generally have correspondence usually in a formal manner at the site chiefs and divisional managers meeting.
COFFEY, Q.C.:
Q. But you were both--he was site chief on one site; you were on the other?
DR. COOK:
A. That’s correct.
COFFEY, Q.C.:
Q. Okay. Doctor Khalifa says, "Here’s a summary of the few cases where we managed to have simultaneous immuno and biochem assessment of ER/PR. If we follow the suggested cutoff line of 30 percent on immuno to achieve the highest possible correlation of the bio, you can see that we seem to be doing very well. The very

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first case, 97-1400 which will be considered at ER positive by immuno was, in fact, negative by bio. 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 would appreciate your thoughts on this, of course, your efforts to provide the parallel biochemical studies are extremely viable. Let me know if you have any further suggestions to make this task more valid and effective. Also, let me know of any possible correlation with Mayo. Yours truly".

And if we could just look, Doctor, the second page, correlation of biochemistry, there are four cases involved here, immunohistochemistry on the left and biochemistry results on the right. Doctor, up to that point in time, biochemistry, it's involvement for ER and PR, can you tell the Commissioner please about what, if anything pathologist had to do with ER and PR up to this point?

DR. COOK:

A. Well, up to this point, prior to '97, '98, we performed what is known as the Ligand Binding

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Assay on breast tissue with carcinomas. And that would involve--and I go back to what I did at St. Clare's--when the breast tissue was removed from the patient, this would be put in a submitting container and we would be notified by the OR that there was a breast ready for submission for biochemical analysis for ER and PR . So, we would be called down from the lab to go down to the OR and actually take a portion of the tumor and submit that into liquid nitrogen, rapid freezing of the tumor. And that would then be submitted over to the General Hospital for analysis by the biochemical assay.

COFFEY, Q.C.:

Q. You'd actually be called to the OR and excise a piece of the tumor.

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And then put it in liquid nitrogen and then it would be transported in the liquid nitrogen over to the General for biochemical assay. And the report on the biochemical assay results would go to whom? Would that come to

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a pathologist?

DR. COOK:

A. It varied. There were, I think, about four reports generated at that time, four copies. One report might stay in the lab itself; another copy, hard copy, would be going to the physician; a third copy may go to the chart; and it's possible, if I recollect properly that another copy may go to myself or to someone at the St. Clare's.

COFFEY, Q.C.:

Q. Doctor, who would be responsible at the time for ordering the ER/PR biochemical assay? Would a pathologist order that test or would the surgeon or someone else?

DR. COOK:

A. I can tell you what I did at St. Clare's. I would order the test.

COFFEY, Q.C.:

Q. So, at what stage then in the process would you come to order the biochemical test?

DR. COOK:

A. Oh, almost instantly. As soon as I was notified from the OR, go down and take the tissue, I would order a requisition.

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COFFEY, Q.C.:

Q. And the biochemical assay results would come from the General Hospital lab from biochem -

DR. COOK:

A. From biochemistry lab.

COFFEY, Q.C.:

Q. - lab. And other than perhaps getting a copy of the report, would you have any further involvement in the ER/PR aspect of the matter at that time?

DR. COOK:

A. What I would do initially is incorporate the copy of that report into our pathology report because over--you just didn't know over a time period over the next five, ten or fifteen years where that hard copy of that report would go. So, if incorporated it into your computer system, the hospital information system, you certainly felt a comfort level that that information would be maintained for ten, fifteen or twenty year period.

COFFEY, Q.C.:

Q. So, the biochemistry lab generated a report on the biochemical assay.

DR. COOK:

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A. Um-hm.
COFFEY, Q.C.:
Q. They wouldn't actually enter that into the Meditec system.
DR. COOK:
A. They mightn't, no. Now, I could be wrong on that, but I mean, I can't be absolutely sure, but that hard copies, at that time, were sent in a number of different directions.
COFFEY, Q.C.:
Q. And it was your practice as the pathologist for that particular case, when you got the biochemical assay report, to dictate that into the Meditec system.
DR. COOK:
A. I would dictate into Meditec. Now, for me--I can't say whether that happened with every other pathologist in the system.
COFFEY, Q.C.:
Q. I take it then that there was no hard and fast rule about that, at the time?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Now, looking at this -

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THE COMMISSIONER:
Q. I just want to make sure I understand. Do I take it then in the days when you sent it off for biochemical assay, you didn't really have to exercise your professional judgment except at the OR where you chose the sample to go in the -
DR. COOK:
A. I would take the sample -
THE COMMISSIONER:
Q. - in relation to that particular -
DR. COOK:
A. I would look at the specimen, section it, look at the lesion, make sure that the area I took was actually the lesion in question, make sure it was tumor for the most part.
THE COMMISSIONER:
Q. Yes.
DR. COOK:
A. And then submit that in liquid nitrogen.
THE COMMISSIONER:
Q. Um-hm. After that you got numbers back from the biochemistry lab in the General Hospital?
DR. COOK:
A. That's right.

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THE COMMISSIONER:
Q. And that's as far as you were required to act professionally, as it were? I mean, it didn't require your professional judgment except to the point that you, before you put it into the liquid nitrogen, does that make sense?
DR. COOK:
A. That's correct, yes.
THE COMMISSIONER:
Q. Yes, okay.
COFFEY, Q.C.:
Q. And then when the numbers came back from the biochemistry lab, in your own case you might dictate them into the Meditec system, but you wouldn't have to make any professional judgment about them--the Commissioner is asking you about.
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Whatever the number was, you -
DR. COOK:
A. The number was there and it would say either negative or equivocal or positive. And there would be a range of numbers given there to

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show where the number you got from the test result fit in with the various ranges.
COFFEY, Q.C.:
Q. Yes. In fact, just on that point, looking at page two of Exhibit P-1855, I take it here that biochemical reporting -
DR. COOK:
A. Yes, those are the ranges.
COFFEY, Q.C.:
Q. That's the ranges, zero to three, negative; three to twenty, equivocal; and greater than twenty, positive.
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. That would be the sort of range that you're talking about in the biochemical reporting system.
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Thanks. Now, Doctor, could you tell the Commissioner then, what was going on here then in April of 1997, as we're talking here now about immuno assessment of ER/PR in the first

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sentence, what was going on?
DR. COOK:
A. Well, Doctor Khalifa wanted to transfer the interpretations, performance of ER/PR from the biochemical assay to immunoperoxidase. And he felt that this was a standard, that this was a trend that was taking place across North America. And he felt that we should be doing the same in St. John's.
COFFEY, Q.C.:
Q. And did you have any discussions with him about this before April 10, 1997?
DR. COOK:
A. I may have. I can't remember exact discussions, but I could have.
COFFEY, Q.C.:
Q. He concludes this letter by saying, "I would appreciate your thoughts on this. Or course, your efforts to provide the parallel biochemical studies are extremely valuable". Do you recall what, if any, involvement you had in providing the parallel biochemical studies?
DR. COOK:
A. Well, I may have been running nine or ten

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cases at St. Clare's where our samples--and this was at the time when the biochemistry was still on the go. I would forward the breast samples to the General Hospital. I think I remember at that time taking the paraffin block, the actual tissue itself and sending it down to the Mayo clinic for correlations.
COFFEY, Q.C.:
Q. And what was the Mayo clinic doing with it?
DR. COOK:
A. They were doing immunoperoxidase staining on the paraffin block and I would fill out a Mayo requisition, send that down along with the paraffin block to the Mayo and ask them for their interpretation.
COFFEY, Q.C.:
Q. Using the paraffin block and IHC as the process -
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. - in that particular patients tissue sample and you compared it--when you got the result from the Mayo clinic, you would have compared that to what?

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DR. COOK:
A. Compare it to the biochemical assay.
COFFEY, Q.C.:
Q. Why were you doing that?
DR. COOK:
A. It was just another check in my mind to see--i was using the Mayo as a reference lab to compare their performance with our performance.
COFFEY, Q.C.:
Q. "Our performance", who's the "our" in this context?
DR. COOK:
A. The General Hospital.
COFFEY, Q.C.:
Q. Is it the biochemical -
DR. COOK:
A. The biochemical and also the immunohistochemical.
COFFEY, Q.C.:
Q. That Doctor Khalifa was also, by this time, had started to utilize?
DR. COOK:
A. He was doing a correlation between our bioassay and the result of the

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immunohistochemistry.
COFFEY, Q.C.:
Q. So, Doctor, what happened then with that process as time went on? Did you continue to utilize the Mayo for a period of time in it correlation effort?
DR. COOK:
A. I believe. I think, as I said earlier, around ten cases I may have sent down to look at the correlations.
COFFEY, Q.C.:
Q. And do you recall were any records kept of that afterward?
DR. COOK:
A. No, the records that I kept were handwritten records that I was just confirming with Doctor Khalifa.
COFFEY, Q.C.
Q. What was the overall result of that? How did what Doctor Khalifa, his IHC results in St. John's compare to the Mayo clinics results in IHC in biochemical assay?
DR. COOK:
A. Generally good, although there were a couple

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of discrepancies that I noted between the Mayo and our results.

COFFEY, Q.C.:

Q. Did you take that up with anyone at the time?

DR. COOK:

A. I did.

COFFEY, Q.C.:

Q. And with whom?

DR. COOK:

A. Dr. Khalifa.

COFFEY, Q.C.:

Q. And what, if anything, became of that?

DR. COOK:

A. Well, that was taken up at one meeting of the site chiefs and divisional managers and this was probably near sometime in 1998 when we talked about releasing the tests to the pathologists for reporting and there was concern over the cutoff points that we would use to determine whether a test would be positive or negative.

COFFEY, Q.C.:

Q. So Doctor, I take it at the time, 1997, Dr. Khalifa was investigating the possibility really in effect here of utilizing paraffin

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block IHC process to perform ER and PR tests within the province?

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. That was in substitution for the biochemical assay?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. The decision at the time as to whether or not to go ahead with that, to switch over to the IHC process from the biochemical assay, whose decision was it at the time? Who had the authority at the time to do that?

DR. COOK:

A. The authority to do that would have come, I would say, from the clinical chief of the day.

COFFEY, Q.C.:

Q. And do you recall who the clinical chief was?

DR. COOK:

A. That was Dr. David Haegert.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1856? Now Doctor, this is--these are the minutes of the

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anatomy pathology site chiefs and divisional managers meeting, May 13th, 1997. Present are yourself, Dr. Khalifa, Dr. Parai, Dr. Pushpanathan, Mr. Gulliver and Mr. Murphy, and apologies from Dr. Haegert. So at the time, Doctor, circa 1997, you were site chief at St. Clare's, Dr. Khalifa at the General, Dr. Parai?

DR. COOK:

A. At the Grace.

COFFEY, Q.C.:

Q. Dr. Pushpanathan?

DR. COOK:

A. She was site chief at the Janeway.

COFFEY, Q.C.:

Q. Janeway, and Mr. Gulliver, at that time?

DR. COOK:

A. He was a divisional manager at the General Hospital and the Janeway sites.

COFFEY, Q.C.:

Q. Okay, and Mr. Murphy was the divisional manager, I take it, for the Grace and St. Clare's?

DR. COOK:

A. That's correct.

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COFFEY, Q.C.:

Q. And Dr. Haegert would have been the clinical chief of the day?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. If we could, please, Doctor, here on page three of those minutes, and paragraph labelled A there, new business.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. It says "ER and PR immunoperoxidase receptors. Dr. Khalifa reported to the committee that there is good correlation between a 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 was 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 is a need for

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standardized criteria 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 is agreed to maintain the status quo. Dr. Cook also recognized the amount of hard work that Dr. Khalifa has put into this project."

Doctor, can you tell us, please, what was going on here at that point in time? This is May of '97.

DR. COOK:

A. Well, if I remember correctly, pathologists, not only at St. Clare's but the Grace, and I think even at the General Hospital, still wanted to have the ability to report their own estrogen receptors reports. The concern -

COFFEY, Q.C.:

Q. Up to that point, they wouldn't have been doing so?

DR. COOK:

A. No, but this was immunohistochemical stain and

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they still wanted to report on that stain.

COFFEY, Q.C.:

Q. Okay, so just so the Commissioner is clear on that, so up to that point, immunohistochemical stains, whatever they might be were reported by -

DR. COOK:

A. Were reported or interpreted by -

COFFEY, Q.C.:

Q. - pathologists at whatever site ordered it?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. The ordering pathologist, and so the Commissioner is clear on this, so that would have been true for St. Clare's, the Grace, to your knowledge, I suppose, Corner Brook, Grand Falls, whoever ordered the IHC stain.

DR. COOK:

A. Would be interpreted by the pathologist who had ordered it from the respective site.

COFFEY, Q.C.:

Q. Yes, and the slide itself would be prepared at the General?

DR. COOK:

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A. That's correct.

COFFEY, Q.C.:

Q. Because by then, I take it, there was more or less--IHC service was more or less centralized at the General?

DR. COOK:

A. Yes, at that time.

COFFEY, Q.C.:

Q. And that had been the practice, leaving ER/PR completely out of it, you know, as an issue because you weren't doing IHC stains for ER/PR up to this point in time.

DR. COOK:

A. Right.

COFFEY, Q.C.:

Q. So leaving ER/PR out of it, all IHC stains were reported by whatever pathologist ordered it in the first place?

DR. COOK:

A. They wouldn't be reported on an individual basis. In other words, let's say I'm out in Corner Brook.

COFFEY, Q.C.:

Q. Sure.

DR. COOK:

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A. And I have, say, an undifferentiated tumor. So I might order an LCA or a cytokeratin or an EMA or whatever it is. That block would come in from that tumor to the General Hospital. Stains would be performed and the stains would be sent back to me, say, if I were generated from Corner Brook. Now I wouldn't report--issue a separate report on the EMA or the cytokeratin or the LCA. I would use that in making an interpretation on the lesion in question. You understand?

COFFEY, Q.C.:

Q. Yes, so you would be the one interpreting those particular slides?

DR. COOK:

A. I would be interpreting, but I wouldn't issue a separate report on each of those stains.

COFFEY, Q.C.:

Q. I appreciate the distinction there, but you would be the one looking at the slides, the three or four slides for that particular purpose, each with a different stain on it, and drawing your own conclusions about what interpretation to give them and what the overall result was?

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DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. From a diagnostic perspective.
DR. COOK:
A. So they would be used in conjunction, say, with the H & E stain and any histochemical stains or any other procedures that I would do.
COFFEY, Q.C.:
Q. And what you're saying "Mr. Coffey, it wouldn't necessarily mean though, in fact might not at all involve me actually saying what a particular stain, my interpretation of that individual stain was"?
DR. COOK:
A. It may in the body of the report. Like I could say LCA positive or negative or EMA positive or negative, but I would take all those positives and negatives and put them together along with the H & E and any other testing that I would do to make an interpretation.
THE COMMISSIONER:
Q. So okay, just to make sure I understand.

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You're in a situation where you've been asked to give your opinion on a diagnosis of a particular kind of cancer, say. So you decide that you want a range of things done in order to come to that opinion. One of those might be an IHC stain. You would send the block to the General. It would be processed, comes back to you. Then you, along with all the other things, would use the IHC component to come to an opinion as to the particular diagnosis?
DR. COOK:
A. That's right.
THE COMMISSIONER:
Q. Okay, and you might or might not, in the body of the--in your comments, refer to your interpretation of the IHC stain?
DR. COOK:
A. Well, I would--yeah, me, as a pathologist, I would. I would say, say, you know, an LCA stain shows whatever it is positivity or an EMA stain shows positive immunoreactivity. So looking at those individual stains, I would say that I would make an interpretation on each of those individual stains in the

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microscopic description.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. So then here, Doctor, in the fifth line, it says "Dr. Cook stated that there's a concern among the pathologists at St. Clare's that they should be the ones reporting the breast receptors."
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Now I think you've--you were about to, you were elaborating on that saying well, it says at St. Clare's, but you understood that that was a wider concern?
DR. COOK:
A. That was a wider concern. My understanding that the pathologist at the Grace also wanted to report on their own stains because they reviewed it as being a part of their own case.
COFFEY, Q.C.:
Q. And in this context, reporting the breast receptors would be reporting breast receptors results from an IHC stain and IHC stains are

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things that pathologists deal with?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. So that would be the idea that -
DR. COOK:
A. Yes, they looked at it as an IHC stain. If it's coming from my case, it should be reported for whatever pathologist that originated from.
COFFEY, Q.C.:
Q. I'm sorry, Doctor, you were about to--you said well, that's--that happened, that was one aspect of the matter and -
DR. COOK:
A. And then there was another aspect.
COFFEY, Q.C.:
Q. Yes, about standardization and so on, it's referred to here. Can you elaborate now on this?
DR. COOK:
A. Well, again, when Khalifa was getting ready to release the stain, the IHC stain for ER and PR, there was discussion on the need for standardization of reports. That was one

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thing. The concern I had was the cut off points, and I suppose this was a concern going back about a year or so and it started when I was at a Canadian Association of Pathologists Annual Meeting in Vancouver and I think that was around '97, and one of the conferences that I attended, there was discussion on ER and PR, not in regards to the performance or evaluation of the test, but to what we would use as cut off points, whether it would be 30 percent or 20 percent or whatever. And I remember there being a fairly heated discussion between pathologists and oncologists over what would you use as a cut off, whether you accept the 30 percent or the 20 percent, and there was no consensus of agreement as to what that cut off point would be. So I left that meeting beginning, for the first time, to realize that there is no consensus on cut off points, certainly in parts of Canada and the United States.

Now in regard to what was happening at the Mayo Clinic, because as I mentioned earlier in my testimony, I did notice some discrepancies between the Mayo reports and the

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biochemical report. When we investigated further as to what the Mayo was doing, they were issuing their immunoperoxidase reports or ER/PR reports on the fact that the stain is either reported as positive or negative, and there was no value given.

COFFEY, Q.C.:

Q. I'm sorry, who was doing this?

DR. COOK:

A. This was the Mayo Clinic.

COFFEY, Q.C.:

Q. Okay.

DR. COOK:

A. So when we checked at that time, I think one of our pathologists, Dr. Miriam Griffin, who was on staff at St. Clare's, she spoke to an individual or mostly assume that was a pathologist at Mayo Clinic stating that they would report if they see one stain positive, one cell positive, and so if there was one or two cells positive, then they would report the ER and PR as being positive. So that was a significant variation in the use of cut off points, what was happening in North America.

COFFEY, Q.C.:

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Q. And you came to that view why? Why was that a -

DR. COOK:

A. Well, because if we were using a cut off at 30 percent at say the General Hospital and you compare that to a Mayo Clinic report, you know, and you consider that all things are being equal, let's say you had a stain performed say both at the General and at the Mayo Clinic and both came back, say, the ER/PR status of 15 percent. We would have called it negative and the Mayo would have called it positive.

COFFEY, Q.C.:

Q. You say "we would have called it negative," say the 15 at the time, who's the we in this context at that point?

DR. COOK:

A. General Hospital or St. Clare's and the Grace.

COFFEY, Q.C.:

Q. And why do you say "we would have called it negative" at that time?

DR. COOK:

A. Because Dr. Khalifa wanted to use a cut off of 30 percent.

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COFFEY, Q.C.:

Q. And did he explain to you why that was so?

DR. COOK:

A. That was in relation to an article, I think, from the American Journal of Pathology, around 1990, that correlated the 30 percent with a negative result on the biochemical assay.

COFFEY, Q.C.:

Q. Doctor, I'm going to go, please, to Exhibit P-1857? In the minutes we just looked at, there was a reference to the fact that it would come up the next month in June. This is an agenda for the division of anatomical pathology. The agenda is addressed to a number of individuals, including yourself, and it's for a June 17th, 1997 meeting. You'll note here, Doctor, under 2 CER, business arising, ER and PR receptors, immunoperoxidase staining is referenced there, and then page two of the exhibit are the actual minutes of that meeting.

I'll take you, Doctor, to paragraph 3.4. It's "ER and PR receptor interpretation. This was discussed in detail. The majority of pathologists at St. Clare's, as well as the

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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 the next paragraph as well relates to immunoperoxidase staining, 3.5. "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 these slides. Dr. S. Parai mentioned whether this turnaround time could be reduced by doing the immunoperoxidase staining on a daily basis instead of twice a week, which is presently being done." And go on to talk about workload.

Doctor, here, first of all, the immunoperoxidase staining and the idea that it was being done twice a week as opposed to daily, I take it this was being done at the General Hospital?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And is that consistent with your understanding

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at the time, they were batching, as it were, the immunoperoxidase stains?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. At that period, 19--this is the middle of 1997, did you have any understanding about whether there were particular technologists doing this IHC staining?

DR. COOK:

A. In '97, I think I would have, yes. There were--the IHC was assigned to--I think there were two technologists at the time.

COFFEY, Q.C.:

Q. Do you recall either of their names?

DR. COOK:

A. Peggy Walsh, I believe, and Mary Butler.

COFFEY, Q.C.:

Q. And then paragraph 3.4 which notes this was discussed in detail, and it refers to "the majority of pathologists in St. Clare's and the Grace want to interpret their own cases with control slides." Now the control slides here are what? What types of control slides are we talking about?

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DR. COOK:

A. These were tissue that was stained. This was not the test tissue, but tissue that was obtained from patients previously diagnosed with breast cancer and correlated with the bioassay result and these controls would be stained with the ER and PR immunoperoxidase stains and then submitted with the test tissue.

COFFEY, Q.C.:

Q. And the purpose of utilizing such slides is what?

DR. COOK:

A. To make sure that the staining process worked.

COFFEY, Q.C.:

Q. And these, would they be referred to or could they be characterized as external control slides?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Do you recall, I take it that you've indicated they would be--you expected them to stain, so they'd be positive external controls?

DR. COOK:

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A. Positive external controls.

COFFEY, Q.C.:

Q. At that time, in the middle of '97 was there any utilization of negative external controls?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. And it goes on to say "Dr. Khalifa has agreed to provide a number of cases to the Grace for them to review."

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. St. Clare's is notable by its omission here in the sense that he doesn't refer to that. Why would that be, why would the Grace be getting slides to review and not St. Clare's at this point?

DR. COOK:

A. I guess we were reviewing the Mayo Clinic slides and getting accustomed to the stain.

COFFEY, Q.C.:

Q. Can you recall, Doctor, then, how that worked, how are people being educated, as it were, concerning what these slides should look like

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if properly stained?
DR. COOK:
A. They were educated. There was no service being given to pathologists as a group. They were expected to know which part of the slide or which part of the cell would be picked up by the stain, so that was on their own endeavour at that time.
COFFEY, Q.C.:
Q. And so there was no in-service for the pathologists at St. Clare's, if there was, you would have been aware of it as the site chief?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And there was not?
DR. COOK:
A. I mean -
COFFEY, Q.C.:
Q. And there was not such a -
DR. COOK:
A. No.
COMMISSIONER:
Q. Do I take it from your remark earlier they were expected to know the part that should

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stain?
DR. COOK:
A. Yeah.
COMMISSIONER:
Q. That effectively you were expected to consult the appropriate literature to determine that or did everybody assume you would have known that from your prior education?
DR. COOK:
A. You were expected to know that and to look into the literature.
COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. Doctor, and what slides would there have been available at St. Clare's in May and June and July of '97, how many slides and from where?
DR. COOK:
A. The only ones I can remember are the ones we received from the Mayo Clinic, that was before the start-up of the biochemical--excuse me, the immunohistochemical staining.
COMMISSIONER:
Q. Now, Mr. Coffey, wherever you can find a convenient place, we'll take the morning

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break.
COFFEY, Q.C.:
Q. And, Doctor, in June of 1997 apparently this had been discussed at a meeting, just look over here, those present were Dr. S. Parai, Dr. Khalifa, yourself and Mr. Murphy. I take it, Doctor, that, you know, the idea that Dr. Khalifa here would provide a number of cases to review them to be familiar with positive and negative results, do you recall whether there was any kind of extended discussion on this whole idea of how do you tell it's positive, how do you tell it's negative, what do you look for?
DR. COOK:
A. No. That was Khalifa felt that that was the part of an individual--or individual pathologist to know that information.
COFFEY, Q.C.:
Q. Now, these particular types of slides for ER/PR you referred to percentages?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Thirty, twenty, one cell in the Mayo Clinic's

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case. At that time was there any other sort of interpretation process the pathologists went through where they would be utilizing percentages? Like, 30 percent, I take it, is 30 percent of tumor cells are staining in the nuclei 30 or more, or more than 30. That suggested you actually had to do a calculation of some sort? Is it 50, is it 70, is it 100, is it 20. So do you recall whether there was any other sort of slides that you had to do, just kind of arithmetic calculation?
DR. COOK:
A. You mean at that time?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. In any other immunohistochemical stain?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. In 1997?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:

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A. I can't recall.
COFFEY, Q.C.:
Q. Nothing jumps out to you in terms of -
DR. COOK:
A. Percentages of stains or cells of stain, no, not in 1997.
COFFEY, Q.C.:
Q. So this would have been, that aspect of the matter would have been novel or new?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. I take it that if it was novel for yourself as a practising pathologist here in St. John's, would you have understood it was novel perhaps for anyone else who had the similar experience to yours?
DR. COOK:
A. I would say, possibly with the exception of Khalifa.
COFFEY, Q.C.:
Q. And why Khalifa, why would he be an exception?
DR. COOK:
A. Well, he seemed to be the--he's the lead pathologist in this endeavour and I would say

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the one most conversed with introducing the IH stain for ER and PR.
COFFEY, Q.C.:
Q. Doctor, that's, of course, this is the middle of 1997. We are now about at the midway point of 2008. If such a, I'll refer to as kind of a newer, novel aspect of one's professional existence, for example, in this context in '97 doing this percentage calculation and how you would do that actually under a microscope, how you might physically go about it and the mental processes used, if something similar, like in a new format was to come along now in 2008 and it was new, it was new to pathology, it was certainly new to pathology in St. John's, would there now be any in-service?
DR. COOK:
A. Oh, I would say now there would be an in-service, yes.
COFFEY, Q.C.:
Q. Thank you, Commissioner, we'll break.
COMMISSIONER:
Q. Sure, we'll take the morning break.
(RECESS)
COMMISSIONER:

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Q. Please be seated. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Doctor, if we could, please, Registrar, Exhibit P-1858? Doctor, this is a letter of June 18th, 1997, it's to Sushil Parai from Dr. Khalifa, it's copied to Dr. Haegert and yourself. And I just bring it up here because it refers to, Dr. Khalifa writes to Dr. Parai noting an earlier conversation and says, "You filled in an immuno request for two cases that you were complaining about." And he goes on to say, "The stains were completed June 5th, '97. I'm attaching a copy of the request forms for these two cases that show the histochem," histochemistry, presumably. He has signed a completion of the procedure on June 5, '97. "I think you may be experiencing problems with the transportation system and 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." Doctor, was there, like, in that time frame and afterward, a concern

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about turnaround times involving the immunohistochemistry lab?
DR. COOK:
A. Oh, it was a continual issue.
COFFEY, Q.C.:
Q. And can you tell the Commissioner about that, what--as it evolved over time and why it was a continuing issue?
DR. COOK:
A. Well, we had centralized the immunohistochemistry service at the General Hospital site. And -
COFFEY, Q.C.:
Q. Do you remember when that had occurred by?
DR. COOK:
A. That had occurred around '97, '98. And the idea of that was to enhance getting into the whole idea of sub-specialization, having a specialized group of histo techs performing the immunohistochemistry as opposed to shifting it around to the different hospitals. So that was an effort to try to sub-specialize and gain and area of expertise in one site. The, in regards to the turnaround times, that because particularly problematic on many

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occasions. A pathologist would, let's say a pathologist was on call for that particular day, would receive a specimen, section it and submit the blocks for slides. If you were doing that, say, on a Monday, you may not get your H & E slides possibly until Wednesday, but if you ordered your H & E or you got your slides and ordered immuno, it could be another two to three or four days before you got the immunohistochemistry slides, so that meant, basically, that you had a turnaround time of six to seven days before you were able to complete that report. The issue became particularly problematic when the patient came in to the clinic and both the physician and the patient were looking for the report and the first people they would call regarding the report would be ourselves and the lab and we would get queries from the clinics as to the status of the pathology reports. So not only did that create problems with the attending physician and patients and also created problems with ourselves in that inefficiency creates more inefficiency. If you're getting increasing phone calls from the clinics and

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whatnot, that meant that you had to stop your flow of work and go back and look at the original case and try to figure out what was the delay in reporting of that case. So that was a particular issue of concern around that time and it had been for many years. What we were dealing with basically were resource issues. The volumes of the work was steadily increasing, however, we weren't able to keep up with the demand in terms of increasing resources, both financial and human resources. So I think basically that was the root of the problem there.

COFFEY, Q.C.:

Q. Now, Doctor, in terms of resources, were there complaints about lack of resources at that time?

DR. COOK:

A. Pretty much. I remember -

COFFEY, Q.C.:

Q. By whom to whom?

DR. COOK:

A. There would be complaints over lack of resources from ourselves coming to Mr. Gulliver at the time, Dr. Haegert at the time.

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I remember there were issues from the technologists' point of view. I guess they were reporting to their own manager regarding the lack of human resources and dealing with the increased workload.

COFFEY, Q.C.:

Q. Exhibit P-1859? Doctor, this is the minutes of a meeting of October 8th, 1997, it's the site chief/divisional manager's meeting. Yourself, Dr. Haegert, Dr. Khalifa, Dr. Parai, Dr. Pushpanathan and Mr. Murphy are present, noted to be present. And in terms of business arising, paragraph 3 there, it says, "Case referral policies. Dr. Khalifa inquired about the policies adopted in the various sites regarding referring slides for outside review."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. "It was pointed out that no clear policies are in place for sending slides to an outside institute. After a lengthy discussion Dr. Khalifa was asked to draft policies regarding outside referral of cases as well as internal

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consultations."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Now, what was that about?

DR. COOK:

A. Well, basically we wanted to develop a uniform process how to deal, say, with outside consultations. Let's say a patient was referred to Princess Margaret in Toronto and there was a request from Princess Margaret to review our slides. That was a fairly normal procedure that if the patient, say, went up for radiation or chemotherapy treatments in regards of cancer, that there was always a second review of the original histology to confirm the original interpretation of the pathologist. So we wanted to develop a standardized policy as to what you send up. I mean, obviously the original slides would have to go, but what would you do with the paraffin blocks, would you send up all the paraffin blocks or a representative portion of the paraffin blocks and along with the various pathology reports? So we wanted to develop a

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standardized procedure on what would be sent up and what would remain behind.

COFFEY, Q.C.:

Q. And so this was outside review in the sense of outside the province?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. In this context.

DR. COOK:

A. Or it could be in the province. Let's say you had a pathologist in Corner Brook who may want to review a particular case, say, in St. John's. The patient was having surgery in Corner Brook, so he or she might want to review that particular case.

COFFEY, Q.C.:

Q. And this related then to the whole idea of the Health Care Corporation of St. John's sending its slides, whether to Corner Brook or Toronto or wherever else, have some policy in place that would be uniform across the -

DR. COOK:

A. Uniform policy, yeah.

COFFEY, Q.C.:

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Q. New business, at paragraph 1, "Dr. Khalifa presented results of an audit of steroid receptors in 19 breast cancer cases correlating immunohistochemistry and biochemical assays." The typed version is "Dr. D. Cook" and somebody has handwritten "Dr. Parai," "recommended that the Health Care Corporation continue performing the immunohistochemical test and encouraging"--I'm sorry, "and encouraged doing them on endometrial carcinomas. He also mentioned that Dr. Thain"?

DR. COOK:

A. Yeah, that individual was an oncologist at the time.

COFFEY, Q.C.:

Q. I'm sorry?

DR. COOK:

A. He was an oncologist here at the time.

COFFEY, Q.C.:

Q. "He also mentioned that Dr. Thain, at the cancer clinic, still prefers to see the biochemical assay done. Standardization of reporting of results of the bio"--of the, I'm sorry, "immunohistochemical assay also seem to

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be a problem. Dr. Khalifa was asked to call upon other Canadian medical centres, Toronto General, to inquire about their protocols. Dr. Khalifa action. He was also asked to seek feedback from the cancer clinic staff. Dr. Khalifa." So, Doctor, I take it then in terms of the fall of 1997, early October, 1997, the idea of moving ahead with, or at least the process of trying to decide whether to go with the IHC testing for ER and PR was well in progress here by this point?

DR. COOK:

A. It was moving ahead.

COFFEY, Q.C.:

Q. If we could please, exhibit P-1860. Now this is a memorandum of December 15th, 1997 and page one of it is giving notice of a site chief's meeting. If we go to page two of the exhibit, the minutes of a meeting of December 16th, 1997, site chief/divisional managers. You are present, as well as a number of other physicians and two technologists. Now, Doctor, here it notes at the top of the page here, you amended the last paragraph of the first page of the previous meetings minutes,

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of course, to substitute Dr. Parai's name for yourself. What was it Dr. Parai was recommending here?

DR. COOK:

A. Just recommended the performance of histochemical tests and encouraged in doing them on endometrial carcinomas. I can't remember the exact discussions surrounding that.

COFFEY, Q.C.:

Q. Okay, so that had nothing to do with ER and PR itself?

DR. COOK:

A. I don't believe.

COFFEY, Q.C.:

Q. That you recall. And then under "Business Arising", it's noted here in the first paragraph "Laboratory utilization and anatomic pathology. Dr. Cook was the divisional representative in the Laboratory Utilization Committee. A meeting of this committee took place where the following topics were discussed" and it lists a number of them.

DR. COOK:

A. Uh-hm.

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COFFEY, Q.C.:
Q. Doctor, what was this Laboratory Utilization Committee about?
DR. COOK:
A. Well I was looking at the most effective way we can use our resources, the thinking at the time with program management that if we could effectively save money within the program and not compromise our service, that we can use the savings to be redirected towards such initiatives as CME activities, conferences and whatnot, so if we, for instance just to give an example, let's look a the position, say ordering serum B12 or folic acid levels and a lot of that was being ordered over the year, we could work on ways to educate the physicians to only order them on specific cases or to try to reduce that without jeopardizing clinical care, that we may take those cost savings and redirect them elsewhere in the program.
COFFEY, Q.C.:
Q. And more efficient utilization of the resources, I take it was the committee's mandate?

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DR. COOK:
A. That's what we were hoping to achieve, yes.
COFFEY, Q.C.:
Q. Where possible. The paragraph two is a reference to turn-around time at St. Clare's site. "Dr. Cook indicated the processing of some specimens, particularly needle localization of breast biopsies takes a necessary long time. Preparation of slides may take six to seven days from grossing the specimen, while some re-cuts may take as long as nine to ten days. Both pathologists and surgeons have expressed their concerns about this issue. Mr. Murphy acknowledged the problem and suggested a low number of histotechnologists as being its atiology." So I take it, Doctor, this does relate to the-- some of the turn-around times?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Paragraph three here says "steroid receptors assessment in paraffin sections, Dr. Khalifa discussed this issue further and suggested pathologists start reporting their own cases.

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A suggestion was made that Dr. Khalifa write up a proposal with the criteria (cut-off values) distribute it to the various pathologists and ask them for their feedback." Now, Doctor, up to this point do you recall whether or not ER and PR results were being reported?
DR. COOK:
A. Up to this -
COFFEY, Q.C.:
Q. Other than biochemical.
DR. COOK:
A. To my knowledge it was only biochemical, but I can't be absolutely sure of that.
COFFEY, Q.C.:
Q. I'm sorry, and so what was envisaged here then?
DR. COOK:
A. Getting into standardization of reporting.
COFFEY, Q.C.:
Q. And this would be reporting by each individual pathologist, I take it?
DR. COOK:
A. That's right.
COFFEY, Q.C.:

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Q. Was there, at the time any idea of, you know, whether or not individual pathologists should report their own ER and PR results using the IHC method, was there ever any discussion about the pros and cons of that or any pros and cons involved in having individual pathologist do it, as opposed to having one or two do it?
DR. COOK:
A. I can't remember much discussion around that, I think there was a lot of pressure, from what I remember of--I was getting from individual pathologists, particularly at St. Clare's that they wanted to look at all aspects of their case and that included ER and PR. To the best of my recollection that's about the only discussion that I can remember at that time.
COFFEY, Q.C.:
Q. So they were pushing to report their own cases for ER and PR and anything else related to the case?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Certainly involving IHC stains. And from the

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other side, I take it the idea of perhaps limiting it one or--one individual or a small number of individuals that wasn't discussed, at least that you can recall?

DR. COOK:

A. No, because at that time our whole thinking at the time was one of general assign-out in all aspects of pathology.

COFFEY, Q.C.:

Q. The idea of specialization or subspecialization, in that timeframe, this would be the latter part of 1997, had that taken hold at all in St. John's?

DR. COOK:

A. No, it hadn't taken hold, but that didn't mean that we had some discussions regarding that. And -

COFFEY, Q.C.:

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

DR. COOK:

A. Well I remember a meeting that we had with Dr. Haegert and I believe Sushil Parai was there or Dr. Parai was there and myself, and you have to look at what was happening across

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Canada at that particular time. Health care budgets not only health care but education budgets were being slashed by many governments throughout the country and we weren't immuned here in this particular province. And I can remember hospitals being closed in major cities across Canada and physicians and even some pathologists actually being unemployed, and it was around that particular time period that there was a tremendous reduction in the financing to the health care system in the country. So we looked at that situation and we said there may be an opportunity here if we can certainly stabilize the pathology population in the province, that we can move towards subspecialization. Our greatest fear was that if we began a process of subspecialization and we lost stability in our manpower, we were--had a mindset that if we create a subspecialization that that would have a negative impact on patient care, if we lost subspecialized groups or key people in certain areas. So our thinking was that generalized sign out worked well in the 70's and the 80's and early mid 90's, but we need

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to move toward subspecialization if we could stabilize the manpower situation. So we talked about that at that particular meeting and we saw this opportunity as what was happening in mainland Canada, possibly as an opportunity to help stabilize the situation in Newfoundland. And at that time we had been extremely lucky in not losing positions in the province and that was through efforts that we had with the Newfoundland and Labrador Medical Association and dialogue with government.

COFFEY, Q.C.:

Q. Now, Doctor, Dr. Khalifa, I'll be referring to him in the next couple of exhibits, and I have, we have already this morning, do you recall the events or any events leading up to the recruitment of Dr. Khalifa?

DR. COOK:

A. I can't remember per se, I was not in the leadership position at that time, but I remember our director of laboratories, Dr. John Williams who was then director of St. Clare's, looking at Dr. Khalifa's curriculum vitae and it was a very impressive curriculum vitae and I always remember Dr. Williams

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saying to me if we recruit Dr. Khalifa, I'm sure he will only be around for a year or two.

COFFEY, Q.C.:

Q. And why is that? What did you understand -

DR. COOK:

A. The way I understand it, here was an impressive individual with an impressive curriculum vitae that looking at our past history, we were able to recruit good people. The challenges that we had were able to retain them and once positions began opening up, particularly in mainland Canada, particularly in the Toronto area, we were losing many of our capable people, highly trained and highly respected people to mainland centres, mainly in Toronto and Toronto area, Calgary, Vancouver, so we had to deal with, you know, that factor on many occasions.

COFFEY, Q.C.:

Q. Exhibit P-1861 please? Doctor, this is an agenda for a meeting of February 12th, 1998. It's the division of anatomical pathology meeting of site chiefs and divisional managers and here under "business arising" paragraph 2B, "ER and PR reporting", Doctor, do you

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recognize the handwriting on this?
DR. COOK:
A. Yeah, that's my handwriting.
COFFEY, Q.C.:
Q. Now what's after the ER and PR reporting, do you recognize what that is?
DR. COOK:
A. Looks like the word "past", so we must have been discussing the format of the reporting.
COFFEY, Q.C.:
Q. If I could, please, the second page of the exhibit, second through the fourth page are the actual minutes themselves. Under "Business Arising" yourself and Dr. Haegert, Dr. Khalifa and Dr. Parai are noted to be present. Paragraph 3.2 "ER and PR reporting, Dr. Khalifa will write to Dr. Prabhakaran asking him to discontinue the biochemical ER and PR assay as of March 1, 1998." And is that your handwriting then, you've written something there?
DR. COOK:
A. Yeah, "every pathologist will sign out cases after transitionary period, will talk to Dr. Prabhakaran."

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COFFEY, Q.C.:
Q. And who was going to talk to him, do you recall? Was that you or was that Dr. Khalifa?
DR. COOK:
A. That sounds like that may have been me.
COFFEY, Q.C.:
Q. Okay, and where was, I take it he was a biochemist?
DR. COOK:
A. He was a medical biochemist.
COFFEY, Q.C.:
Q. Medical biochemist located where, what site?
DR. COOK:
A. At the General Hospital site.
COFFEY, Q.C.:
Q. And here I take it would be to tell him that after a particular point in time it wouldn't be necessary for him to--he wouldn't be asked anymore to do a biochemical assay?
DR. COOK:
A. Probably to firm up the exact date that this would be stopped, I would say in terms of receiving official notification to stop the biochemical assay, that that would have to come from Dr. Haegert or Mr. Vern Whalen who

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was the program director at that time.
THE COMMISSIONER:
Q. Dr. Cook, do I take it that up to this point there had been a period of both testing using both methods?
DR. COOK:
A. Yes, I think you can say that. I don't think it was being reported by pathologists at St. Clare's or the Grace, but it may have been reported by Dr. Khalifa at the General Hospital, so there may be reports from both the biochemical assay and the immunohistochemical stain going out on the patient's charts.
THE COMMISSIONER:
Q. Okay, thank you.
COFFEY, Q.C.:
Q. Exhibit P-1862 please? Now this is a memorandum of March 13th, 1998. It's from Dr. Khalifa to a number of individuals, including yourself and one of the agenda items is follow up on ER/PR reporting and if we could, please, here at page 2, the exhibit is a memorandum of March 16th, 1998 from Dr. Khalifa again to yourself and others, it was indicated planned

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having a site chief's meeting on March 19th and under "Amended Agenda Items" it's a follow up on ER/PR reporting and there's a dash "-settled and a run on Fridays." What is this "run on Fridays" refer to?
DR. COOK:
A. I can't say for sure, Mr. Coffey, all I can say is we're probably just getting into determining what was the best day to batch these cases. I mean, I really can't comment on thought processes around that particular statement.
COFFEY, Q.C.:
Q. And the third paragraph refers to, third line, I'm sorry, "procedure for adding new antibodies for existing panel." You have an arrow "update list of immunos, newsletter."
DR. COOK:
A. "That new antibodies are circulated, what antibodies are useful for what?" So this is getting into a form drawn up to identify what antibodies are available in the division and circulating these to the pathologist.
COFFEY, Q.C.:
Q. Now, Doctor, the third page of the exhibit and

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this is the minutes of a meeting of March 19th, 1998. Present are yourself and a number of other individuals, including Dr. Haegert, Dr. Khalifa, Dr. Parai and there's a note here, Dr. Khalifa amended paragraph 3.2 of the previous meeting's minutes, it should read "Dr. Khalifa will transfer the responsibility, reporting of results of immunohistochemical staining of ER/PR to the respective pathologist on March 1, 1998. (Dr. Prabhakaran will be contacted at a later stage and asked to discontinue the biochemical assays.)" And that amendment was accepted by those present here. And then under "Business Arising" paragraph one indicates "Dr. Khalifa updated the committee about the current stage of ER/PR reporting by the requesting pathologist. The transition was going smooth. Dr. Cook made very positive remarks about the role played by Dr. Khalifa in this regard. Dr. Cook suggested two changes to the outside case referral policy. Dr. Khalifa informed members of the committee that following the adoption of the last two recommendations from Dr. Cook, the policy will be ready for

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submission to a legal counsellor" and that's, I take it, this outside referral case issue. And he goes on to say "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 to our existing panel. Members of the committee agree that such requests be submitted to the respective site chief, who in turn brings them to the committee. These requests are to be studied in light of the support of evidence, years utilization and budgetary feasibility. Final decisions are to be made jointly by members of the committee." Now, this committee is which committee here?

DR. COOK:

A. I think that refers to the site chief's, maybe, committee.

COFFEY, Q.C.:

Q. Now, Doctor, at that point in time the idea of now moving from the biochemical assay in early 1998 for ER/PR to the IHC method of getting an ER and PR result, the impetus behind that move had been which individual?

DR. COOK:

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A. Dr. Khalifa.

COFFEY, Q.C.:

Q. Do you recall whether there was any objection by anyone?

DR. COOK:

A. You mean from biochemical assay to immunohistochemical stain?

COFFEY, Q.C.:

Q. Or by the pathologist or anyone that you recall. I'm not suggesting there was, I'm just asking you.

DR. COOK:

A. I can't remember.

COFFEY, Q.C.:

Q. How about reservations? Anybody express any reservations about it?

DR. COOK:

A. Not to me, except in regard to the cut off point.

COFFEY, Q.C.:

Q. Yes, and I'm going to get to that in a moment now. But the idea and I appreciate that, the cut-off point and there was a discussion about that, you've referred, alluded to that already and talked about it already and I'll take you

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through that a bit more.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. But the underlying notion of moving to IHC though, that was it, that was where we locally were going with it.

DR. COOK:

A. Yeah, I can't remember anybody objecting to that.

COFFEY, Q.C.:

Q. Now, Doctor, if we could, please, before we get into the actual discussion with you about that, about the cut-offs, Exhibit P-1863, please? This is, under "site chief's meeting an anatomical pathology, Health Care Corporation, April 22nd, 1998." And here under paragraph B, "Business Arising", there's a heading "Adding new immunoperoxidase stains to existing panel." And he says, "Dr. Griffin's letter was submitted at the committee. After some discussion was agreed to acquire the immunoperoxidase stains, CD5, CD10, Cyclin D1 and Calretinin. In regards to the rapid immuno staining technique, it was

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agreed that the current procedure employed by the General Hospital site appears adequate. Currently the DAKO envisaged system is employed which is a two-step method giving comparable results to the rapid immuno staining technique outlined in Dr. Griffin's letter." Now this DAKO envisaged system, what does that involve?

DR. COOK:

A. I think that refers to the detection system that was being used at the time and it's a semi-automated procedure.

COFFEY, Q.C.:

Q. And was that new, do you know here, locally?

DR. COOK:

A. I believe it was, I can't tell you the exact date that that was brought in.

COFFEY, Q.C.:

Q. Now, Doctor, here looking at--paragraph (f) is entitled "Estrogen Receptors. Dr. Cook wondered about the rider in the case where estrogen receptors stained less than 30 percent of the cells. Dr. Khalifa informed him that this rider is a recommendation only and is not part of the formal policy regarding

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the reporting of breast receptors." Now, Doctor, do you recall what that was about?

DR. COOK:

A. Again, that's concerning a discussion regarding the cut off point. I had concerns about using that cut off point of 30 percent in the reports and I felt that no statement about cut off points should be made in the report when you consider what we were starting to find out about the variation cut off points across the country and the United States and the debate about that, I felt it would be better off to leave the issue of the cut-off point out of the report and make that--give that decision to the oncologists whether to treat or not.

COFFEY, Q.C.:

Q. If we could, please Registrar, Exhibit P-1287? Now, Doctor, here beginning at page two of this exhibit is a memorandum from Dr. Khalifa to all Newfoundland pathologists, February 16th, 1998. The reference is "reporting of estrogen and progesterone receptor immunohistochemical results" and then that goes on then for three pages, page two, three

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and four of the exhibit. I take it, Doctor, that if we just look here, the second page of this memo, Dr. Khalifa writes "Attached please find a proposal for uniform reporting of ER/PR immunohistochemical staining. This proposal was discussed with many of my colleagues who mostly agreed 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 a proposal, as you already know, there is a considerable list of publications addressing this issue. I will be glad to share any of the material I already have with you and I would extremely appreciate your feedback on this matter." And then if we go to the next page, it's entitled "Proposal for uniformed reporting of the ER/PR immunohistochemical assessment, February 8th, 1998." And it's paragraphs one, two, three and then some examples, example one and example two. Doctor Khalifa's suggestion here is that the report on the hormone receptor status will have three components. One, the first component is a statement of whether this

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stain is "positive" or "negative", positivity is defined by nuclear staining detected in any number of malignant cells. The second component is a rough estimate of the percentage of immuno reactive cells in a section examined. This estimate could be in a form of a range or a fixed number and is parentheses. Number three, the third component is a comment regarding only ER (and not PR) immuno activity and is only to be included in the report if a small percentage of neoplastic cells (one to thirty percent) is positive." The comment reads, "evidence from the available literature indicates that estrogen receptors immuno activity detected in less than 30 percent of neoplastic cells would most likely correspond to a negative result of biochemical assay of the same specimen. Citing the American Journal of Surgical Pathology, 14:121 and 127, 1990." So I take it that that's the kind of comment or the comment you had concerns about.

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

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Q. And as he had pointed out in his memo here, in February of 1998, this was just a suggestion, I think the Doctor had said here, "this is only a proposal" and you had then spoken to Dr. Khalifa and expressed your concerns and your approach was -

DR. COOK:

A. I didn't want that last statement included in the reports.

COFFEY, Q.C.:

Q. You had concerns about perhaps its continued applicability?

DR. COOK:

A. Well, I mean, it was such a dynamic situation that was happening across North America in terms of ER/PR, particularly in terms of where the cut-off was because we appeared to be all over the map and my feeling on it is we state whether we do see positive or negative staining and if we see positive staining, give the percentage of cells that are positive and then let the oncologist decide based on that percentage of cells whether to go ahead and treat or not.

COFFEY, Q.C.:

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Q. And then, Doctor, on that when we're looking at it, here in the examples that Dr. Khalifa's put forward a third page of his memo, it's page four of the exhibit. In effect, I take it you were in agreement kind of with example one, as it were.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. That would be fine, and example two really would be the same, except you would leave out the "please see comment" and you would leave out the comment itself?

DR. COOK:

A. That's what I wanted.

COFFEY, Q.C.:

Q. Because you wanted just estrogen receptors, if there was anything one or greater in percentages, you would have positive and then a percentage; and if it was negative, for example in example two here, you'd have progesterone receptors, you'd put in negative?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

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Q. And would you put in zero percent?

DR. COOK:

A. I may or may not have. For me, negative means zero. That's my interpretation of negative.

COFFEY, Q.C.:

Q. Now, Doctor, in that regard, what approach was adopted at St. Clare's when you were the site chief, do you know?

DR. COOK:

A. When I was site chief, I told them to follow example one. I did not want the line or comment made about the 30 percent cut off to be included in the reporting of the ER's and PR's.

COFFEY, Q.C.:

Q. And do you know what, in that regard, happened elsewhere in Newfoundland, outside of St. Clare's?

DR. COOK:

A. I didn't know--I know now, but that would have been up for individual directors and pathologists to decide the format they were going to take.

COFFEY, Q.C.:

Q. And you now know what?

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DR. COOK:

A. I know now they use example number two.

COFFEY, Q.C.:

Q. And was it uniformly used or was it used some places and not others or -

DR. COOK:

A. Used in some places, not others. I think it was used in the majority of centres throughout Newfoundland.

COFFEY, Q.C.:

Q. They would add the comment.

DR. COOK:

A. They would add that comment, yeah.

COFFEY, Q.C.:

Q. Now, Doctor, what about the idea of, I appreciate you said well I use example one, but in example one here, there's no negative. When you would report either estrogen receptors or progesterone receptors or both as negative, do you know whether or not you use zero percent any of the time, some of the time, none of the time or do you know?

DR. COOK:

A. It could have been some of the time, I can't be--I wouldn't say that I used zero percent

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all of the time, but there may have been some reports that I would say zero percentage or just reports that went up just as negative.

COFFEY, Q.C.:

Q. Doctor, would there be anything in a pathology report, if you used just the word "negative" okay, if that was all you used and you didn't use zero percent, would there be any way of a reader of that report telling that you meant zero percent?

DR. COOK:

A. Not unless I stated that in the micro. I mean, I could say in the micro that evaluation of the ER and PR shows zero percent of cells, other than that, negative would mean negative.

COFFEY, Q.C.:

Q. And I take it then these reports in the main were done for whom? Who would be relying upon them?

DR. COOK:

A. For the oncologist and there were also surgeons who were in the area of oncology as well.

COFFEY, Q.C.:

Q. So would a surgeon or an oncologist reading a

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report that, for example, just said positive and I appreciate you would use a percentage, but for--I'll deal with yourself first, you use the word "positive" and a percentage, one or the other -

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Then the oncologists or the surgeon go look at the figure, 20, 30, 40, and they'd know what you meant?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Positive and a percentage. In reports that just said positive, would they have any way of telling what the percentage was?

DR. COOK:

A. Not unless it was stated in the microscopic.

COFFEY, Q.C.:

Q. I take it that there was no hard and fast rule everywhere throughout the province or even within your own hospital?

DR. COOK:

A. Well, there was a hard and fast rule. This

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was in regards to the standardization of the report, but there was no hard and fast rule whether to use example one or two.

COFFEY, Q.C.:

Q. Now if there are, for example, if we were to look at a number of pathology reports from the period say 1998 through 2005, and a number of them just say positive, they don't say--there's no percentage. I take it that then, unless there's something else spelled out somewhere in the report, there'd be no way of knowing -

DR. COOK:

A. There'd be no way, that's correct.

COFFEY, Q.C.:

Q. - of how, what percentage meant positive?

DR. COOK:

A. That could be, again, someone could state positive--if they were using example number two, positive would mean greater than 30 percent, if they were thinking along that lines.

THE COMMISSIONER:

Q. When you say if they were using example number two, you mean example number two with the

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additional wording on the bottom?

DR. COOK:

A. With the additional wording. They may just say positive, but they could be looking at the fact that they're thinking positive greater than 30 percent.

THE COMMISSIONER:

Q. Yes.

COFFEY, Q.C.:

Q. Positive and then if they said they had the comment there, well you could--and they've cross-referenced the comment?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Then that reader would know that it's 30 or higher or more than 30?

DR. COOK:

A. That's right, that positive could be 35 percent or it could be 90 percent.

COFFEY, Q.C.:

Q. Doctor, and I appreciate that you were, in 1998, you were--your dealings with Dr. Khalifa concerning this whole issue about the comment, okay, and whether it should or shouldn't be

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included in reports and whether it was policy or his was simply advice or policy, your discussion with him regarding that would have occurred in what time frame?

DR. COOK:

A. It would have occurred prior to that, sometime during early '98.

COFFEY, Q.C.:

Q. You've indicated that there was--your approach was the one that you wanted adopted at St. Clare's. Did you ever actually--was there ever a written policy to that effect circulated at St. Clare's?

DR. COOK:

A. No, I just told the pathologists, well, we had that proposal and I just told them to follow example one, not to include cut offs.

COFFEY, Q.C.:

Q. Now if a new pathologist came along after that, how would he or she know what the policy was?

DR. COOK:

A. I would tell them in regards to estrogen receptors, not to use the cut offs.

COFFEY, Q.C.:

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Q. How would you know to do that, in the sense of -

DR. COOK:

A. This would sometimes come up at our various rounds about--that I came across a case that we were discussing in which that comment was used, I would quickly tell them to avoid using that comment.

COFFEY, Q.C.:

Q. Doctor, from the time then that yourself, as a pathologist in Newfoundland, began to report your own ER and PR cases, IHC cases, up until May of 2005, do you recall any discussions with oncologists or surgeons about the idea of positive and negative and cut offs?

DR. COOK:

A. Not from my aspect.

COFFEY, Q.C.:

Q. No one ever came to you and said "well, what do you mean? Don, what do you mean by negative?" If, for example, you just used negative and didn't use zero.

DR. COOK:

A. No one came to me.

COFFEY, Q.C.:

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Q. Now Doctor, while we're looking at this memo, at the time when this was circulated, I take it in February of 1998, do you recall whether there was any discussion about it, other than the comment--discussion about the adding or not adding that comment? I take it there were no in-services in relation to this that you're aware of?

DR. COOK:

A. Not that I'm aware of.

COFFEY, Q.C.:

Q. And caucusing about it or anything like that?

DR. COOK:

A. Not that I'm aware of.

COFFEY, Q.C.:

Q. So just the memo came out and you had a discussion with Dr. Khalifa and made your own views known internally within St. Clare's as to how it would be reported?

DR. COOK:

A. That's right.

COFFEY, Q.C.:

Q. And other than that, ER and PR IHC ordering and reporting interpretations and so on, just went right on?

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DR. COOK:

A. That's correct.

THE COMMISSIONER:

Q. Dr. Cook, at the time, would--and frankly, perhaps now, I don't know necessarily where the oncologists are located, except there seem to be a large number on the site of the Health Science Complex, but would the oncologists you would be dealing with be in St. Clare's or would you be primarily communicating with surgeons in St. Clare's and oncologists at Health Sciences or in the Cancer Clinic or whatever?

DR. COOK:

A. I would be primarily communicating with our surgeons on site at St. Clare's and if there was any calls concerning issues surrounding a pathology report, a particular oncologist would call me concerning a particular interest or a particular point. So up until that time, I don't believe that there was any sort of mass interaction between pathologists and oncologists at that point in time.

THE COMMISSIONER:

Q. Okay.

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DR. COOK:
A. Except at scattered rounds, medical pathology rounds or grand medical rounds, that sort of thing.
THE COMMISSIONER:
Q. And would those oncologists be primarily at St. Clare's?
DR. COOK:
A. No, they would be at the Cancer Centre, which was attached to the General Hospital.
THE COMMISSIONER:
Q. So as a general rule, is it safe to assume that normally you would communicate with the surgeon who had done the surgery and the information from the pathologist got through the Cancer Centre through that person's chart having been transferred over to that site?
DR. COOK:
A. That's a fair assessment to make. Most of-- any, 95 percent of all communication that I had regarding pathology reports or queries were with the attending surgeon.
THE COMMISSIONER:
Q. Okay.
DR. COOK:

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A. And then who would forward that information then to the Cancer Centre.
THE COMMISSIONER:
Q. Okay, thank you.
COFFEY, Q.C.:
Q. Looking at the first page of Dr. Khalifa's February 16th 1998 memo, the third paragraph says "as the technique was still in its introductory phase, phase one, I have been reporting results of the majority of cases to establish consistency and reproducible techniques. 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 are probably ready to move into the next two and final phases."
So in terms of the idea that Dr. Khalifa, for a while, was reporting all such cases, do you recall -
DR. COOK:
A. That was a--I didn't realize he was doing that at the time. I knew he was obviously evaluating and looking at the stain, but I did not have recollection that he was actually

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reporting that and entering it into the system.
COFFEY, Q.C.:
Q. And phase two is described here as "each pathologist will be asked to report results of his or her own case as indicated by the brown staining of nuclei of the invasive neoplastic cells. This phase will start March 1, 1998, at which time your immunostained slides will be mailed back to you with positive controls wherever 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 would be more than glad to continue being available to answer any questions and address concerns."
And then there's a reference to "the division of medical biochemistry will be addressed to officially discontinue performing steroid assessment by biochemical techniques."

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And Doctor, looking at phase two in that paragraph, up to that point in time, which would be February/March 1998, how many IHC stains involved the staining of nuclei of the cells, of the tumor cells?
DR. COOK:
A. I can't give you an exact number.
COFFEY, Q.C.:
Q. Were there many at that time?
DR. COOK:
A. Most of them, I believe, were cytoplasmic stains.
COFFEY, Q.C.:
Q. Cytoplasmic, which is non -
DR. COOK:
A. Non-nuclear.
COFFEY, Q.C.:
Q. - the area around the nucleus?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. So at that point, in terms of ER and PR IHC testing, as best you can recall, at least locally, this is probably the first such stains that involved percentages?

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DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And it was--or involved nuclei staining and there weren't a lot of nuclei stains being used at the time?
DR. COOK:
A. Again, I can't be sure on that.
COFFEY, Q.C.:
Q. Yes, I appreciate that. Who would, in fact, know that, do you know? Who might be the repository of that kind of knowledge at the time?
DR. COOK:
A. I guess Dr. Khalifa.
COFFEY, Q.C.:
Q. Khalifa, okay, and he goes on to say, in the beginning, "Starting March 1, 1998, the immunostained slides will be mailed back to you," that would be to the ordering physician, "with positive controls." What type of positive controls were they?
DR. COOK:
A. These were the external positive controls.
COFFEY, Q.C.:

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Q. And he goes on to say "with each run, I will still be responsible for reviewing the positive controls here in our laboratory," which would be, I take it, the General Hospital?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. "And the slides will not be mailed to you unless adequate staining is noted in the positive controls." So at that time, again beginning in March and April of 1998, was St. Clare's getting positive control stain slides back?
DR. COOK:
A. Yes, we were.
COFFEY, Q.C.:
Q. Did that ever change?
DR. COOK:
A. No, I think for the most part, we got our controls.
COFFEY, Q.C.:
Q. The purpose of you getting the controls or the controls being sent to you and you looking at them was what?

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DR. COOK:
A. To make sure the stain was working.
COFFEY, Q.C.:
Q. And I take it if the external positive control, in your view, didn't stain, then the test would have to be redone?
DR. COOK:
A. That's right.
THE COMMISSIONER:
Q. Are we talking about a positive controls per batch or are we talking about one per--when you're talking about a positive control, would you look for an external positive control in respect of--I'm sorry, I should start at a earlier point. Are you talking about external positive controls on the same slide or are you talking about external positive controls under different--on a different slide?
DR. COOK:
A. On a different slide. These would be--a control would be run with a batch or a run.
THE COMMISSIONER:
Q. Okay, so with a group of slides, you would get a slide on which there was an external positive control?

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DR. COOK:
A. Yeah, there was an external positive control for ER and PR, so there'd be two slides with a batch or run of slides that were submitted to St. Clare's.
THE COMMISSIONER:
Q. So presumably all your batches would be done at once, as opposed to doing--unless they were going to run extra positive controls. I'm just thinking if they had them coming in from Western Newfoundland and were running Western Newfoundland at the same time as they were running yours--well, perhaps they did, and they would do two separate slides or four for controls.
DR. COOK:
A. I can't be sure on that.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. Doctor, how would you know like sitting in St. Clare's when the ER and PR slides came back, in 1998, or came over across St. John's to you and control slides came, how would you know which control slide related to which patient

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slides?
DR. COOK:
A. I wouldn't. These were ER and PR control slides that were related to the whole batch, because the controls -
COFFEY, Q.C.:
Q. Well, how would you know what was in each batch? That's what I'm getting at.
DR. COOK:
A. You mean -
COFFEY, Q.C.:
Q. For example, in any one day, say you had--I don't know, I'll just pick a number, say St. Clare's had three ER and three PR slides, three separate patients, one for each patient, one ER for each patient, one PR for each patient, come over from the General Hospital, how many external controls would you expect?
DR. COOK:
A. It would be only one set of external controls.
COFFEY, Q.C.:
Q. One for ER and one for PR?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:

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Q. For that particular run or batch. How would you then know, for example, after you'd looked at them and they were filed away, if you had to go back and look again, how would you know which control slide was which patient slide? How were they cross-referenced, if at all?
DR. COOK:
A. You might have the date on it or you may have a surgical number on it, but that wasn't consistent. What I did, when I got an ER and PR case, and usually on the requisition, it would state on what particular pathologist got the controls. So if I got an ER and PR, before I reported, I would go to that particular pathologist and track down where the ER and PR control was.
COFFEY, Q.C.:
Q. And have him or her, I take it, send you the slides?
DR. COOK:
A. Yes, or I would look at them directly in their office.
COFFEY, Q.C.:
Q. Sure.
DR. COOK:

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A. Just to verify that they worked.
COFFEY, Q.C.:
Q. Now Doctor, here, there's no reference here to--in the paragraph phase two, nor in fact on the next page under the heading or the text, the report on hormone receptor status who have three components, there's no reference here to internal controls. See that?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. The idea of an internal control for patient tissue, tumor tissue or related to tumor tissue of a patient, in March and April of 1997, the idea of internal controls, would you have been familiar with that at that time?
DR. COOK:
A. No, that was never discussed in any of the meetings.
COFFEY, Q.C.:
Q. When did you first become aware of that in relation to ER and PR testing?
DR. COOK:
A. I would say probably around 2000, 2001.
COFFEY, Q.C.:

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Q. And do you recall how it was you became aware of it?
DR. COOK:
A. In my reading of a textbook or it could have been reading some of the journals.
COFFEY, Q.C.:
Q. And do you recall, like, at the time, because by then you would have been reporting your own breast cancer ER/PR cases for about two years?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. By 2000. And the idea of internal controls, what did you glean from your reading at the time as to their importance or significance or lack thereof, what did you understand that -
DR. COOK:
A. Just another component you should use and evaluate in the ER and PR stain.
COFFEY, Q.C.:
Q. Having learned that at the time did you distribute that information to anyone?
DR. COOK:
A. No, that was just part of my reading.
COFFEY, Q.C.:

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Q. And at that point in time would you have understood, or would you have had any reason to believe at that point in time that the other pathologists, for example, at St. Clare's would have been aware of the potential need for internal controls?

DR. COOK:

A. Not at that time, no.

COFFEY, Q.C.:

Q. Do you know when internal controls, the information concerning that was generally distributed amongst pathologists for the first time?

DR. COOK:

A. Oh, 2003.

COFFEY, Q.C.:

Q. And that would be with Dr. Ejeckam?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. In 2000 when you came across the reference to internal controls in ER and PR testing, IHC testing, Doctor, do you recall the time was that--and I appreciate it was new to you, but was that actually new information at the time?

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DR. COOK:

A. I can't say whether it was new information. Was it widely-distributed information, I don't think so because any time we would read about new IHC testing, it was always about the interpretation of that testing and the application of an immunohistochemical test in terms of using that test to make a diagnosis of a particular lesion. Most of the reading that I centred around at that time commented very little, if none at all, about identifying internal controls. It was always about here's a new antibody that's out or new immunohistochemical stain that's out, here's how it can use you to help make a diagnosis or an interpretation of a particular lesion.

COFFEY, Q.C.:

Q. Now, Doctor, at the time this memo, in February of 1998, February 16th, 1998, would this have been, like, kind of the first general information bulletin, as it were, to all pathologists in Newfoundland that, look, in terms of ER and PR, beginning in a couple, by then a couple of weeks time you're going to be on your own doing this in the sense of if

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you order the test, the slides will go back to you. Dr. Khalifa does say he's available, he does offer himself up as available. He says in the second page of his memo, the last sentence, "I will be glad to share any of the material I already have with you. I would extremely appreciate your feedback on this matter." I take it then, Doctor, that other than this memo, were you aware--and your conversation with Dr. Khalifa about not adding the word, the comment that he suggested, were you aware of any other discussion at all amongst the pathology community at that time about ER and PR?

DR. COOK:

A. None that comes to mind.

COFFEY, Q.C.:

Q. Exhibit P-1864, please? Now, Doctor, this is a letter of December 9th, 1998 addressed to yourself as the site chief at St. Clare's. It's from Dr. Khalifa. He says, "Dr. Maghfoor, of our cancer clinic, has asked me to look into the above cited case. Apparently the patient's tumor was reported by our biochemical laboratory to be ER negative. It

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also seems that your laboratory," which would be Dr. Cook's, I presume, St. Clare's, "has submitted a portion of the tumor for immunohistochemical assessment." And it's, I take it, the 1996 case, if we could see this here. "And was reported as ER positive." as per Dr. Maghfoor. "Since the immunohistochemistry was not done in our laboratory I thought I would have very little to do with this case. I ask could you please address Dr. Maghfoor's questions?" He's copied it to Dr. Maghfoor. Do you recall this, Doctor?

DR. COOK:

A. I vaguely recall it. I can't remember all the details surrounding that.

COFFEY, Q.C.:

Q. And what do you recall about it?

DR. COOK:

A. It may have been, again, in relation to the cutoff. I may have reported the case saying it was positive at, say, five percent or ten percent, whereas the biochemical assay would have reported as negative. That's about all I can generally recollect about that.

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COFFEY, Q.C.:
Q. And in terms of "Your lab has submitted a portion of the tumor," which would be, I take it, from St. Clare's?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. Who would have had the--or request the IHC assessment to do be done. And from your perspective you, if it was, for example, 20 percent, you would simply have said -
DR. COOK:
A. Positive 20 percent.
COFFEY, Q.C.:
Q. - 20 percent. And that might not then have met the biochemical cutoff for positivity?
DR. COOK:
A. It's possible, yes.
COFFEY, Q.C.:
Q. And that could account for the difference in biochemical assay, reporting it as equivocal or negative?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:

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Q. Doctor, during this time period which is, like, throughout '98, into '99, into 2000, was there ever any expression of concern, do you recall, about fixation and inadequacies in fixation or tissue processing potentially affecting ER and PR results?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-1870? And, Doctor, this is a memo to provincial laboratory directors, program director of laboratory medicine program and divisional managers from yourself. You're the acting clinical chief at this point?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. April 27th, 2000. The subject is HER2/neu Expression. And notes here, "Effective April 1, 2000, pathologists at the Health Care Corporation of St. John's had begun reporting on HER2/neu overexpression." And "HER2/neu overexpression will only be reported following a request from oncology." And you note, "We

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are using the DAKO kit, which has been approved by FDA and Health Canada." You go on to talk about the grading system and so on. You continue by saying, "We will be able to perform HER2/neu immunoperoxidase stains on paraffin blocks on cases referred in. Once the stains are completed both the paraffin blocks and the slides, it will be referred back to your hospital. At this point in time reporting of HER2/neu overexpression will be the responsibility of the pathologist who ordered the stain. It is also recommended that for evaluation of breast biopsies for HER2/neu overexpression, the biopsies should be fixed overnight for at least 18 hours."
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. "If you have any other questions concerning this, please feel free to call me." Signed, "Donald Cook." And, Doctor, the second page of this is a text which has a heading "Staining and Intensity Score, Staining Pattern and HER2 Overexpression Assessment." The text reads, "Health Care Corporation of

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St. John's uses the interpretation guidelines recommended by the DAKO Herceptest, which is the FDA and CSA approved testing method for HER2/neu overexpression. The guidelines are as follows." Now, Doctor, was this the beginning of reporting of HER2/neu locally?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And was there any other educational efforts made, preparatory efforts made in relation to having pathologists do this reporting other than this?
DR. COOK:
A. That's--yes, there was preparation made in regard to the HER2/neu.
COFFEY, Q.C.:
Q. Do you recall what that was in terms of -
DR. COOK:
A. That was an in-service that was given to all of our pathologists at the Health Care Corporation of St. John's. It was around October of '99 that we had a meeting, about 18 individuals attended that meeting with representatives from the DAKO company as well

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as, I believe, our program manager at that time to go over how to report the HER2/neu.

COFFEY, Q.C.:

Q. And they, I take it, were the locals Health Care Corporation -

DR. COOK:

A. These were the local pathologists, yeah.

COFFEY, Q.C.:

Q. Pathologists. How about outside St. John's, outside the Health Care -

DR. COOK:

A. No. That would have been I regarded as the responsibility of the director of labs at that time in each of the hospitals.

COFFEY, Q.C.:

Q. The local pathologist, whoever was in charge in a particular location outside the city?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And in terms of that, Doctor, just so the Commissioner is clear on that, I take it by this point you were acting clinical chief?

DR. COOK:

A. Um-hm.

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COFFEY, Q.C.:

Q. At this particular point in time. From a strictly legalistic perspective I take it you would have no authority over people in Grand Falls or, like pathologists in Grand Falls or Corner Brook or Clarenville or St. Anthony?

DR. COOK:

A. No. I would just be strictly overseeing the pathologists at the General, Health Sciences, the General, the St. Clare's and Grace.

COFFEY, Q.C.:

Q. And why was it seen to be desirable or necessary, for that matter, to have an in-service for HER/2 neu -

DR. COOK:

A. Because -

COFFEY, Q.C.:

Q. - in the fall of '99?

DR. COOK:

A. Yeah. I wanted them, all the pathologists to become familiar with how to report the case.

COFFEY, Q.C.:

Q. And was it--how to report, what does that entail or -

DR. COOK:

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A. Well, if you're using zero, what does that mean, if you're using one plus, what does that mean, two plus and three plus.

COFFEY, Q.C.:

Q. And what about actually looking at the slides themselves?

DR. COOK:

A. That's correct, to actually interpret that this is a cytoplasmic stain.

COFFEY, Q.C.:

Q. Okay, so this in-service educational effort involved actual viewing of slides, talking about them, explaining the thought process that go -

DR. COOK:

A. Showing photographs on the screen, that sort of thing. There were hand outs circulated from DAKO Industries with microscopic presentations showing the different intensity of the stain and how to grade it.

COFFEY, Q.C.:

Q. Why was that felt to be necessary for HER2/neu?

DR. COOK:

A. Well, it was much more complex stain than the

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ER and PR, which just relied on nuclear staining. We were getting into cytoplasmic staining and where there was partial or incomplete staining, various percentages of the stain, so it was a more complex stain to interpret than the ER and PR.

COFFEY, Q.C.:

Q. Why was it more complex?

DR. COOK:

A. Because of the cytoplasmic staining and trying to determine whether there was a mild or moderate degree of staining there.

COFFEY, Q.C.:

Q. I take it the idea of using a percentage or arriving at a percentage, that was consistent with ER/PR?

DR. COOK:

A. Well, that was one thing, the percentage. But then evaluating that cytoplasmic stain, whether it was a complete membrane staining and the intensity of the stain.

COFFEY, Q.C.:

Q. So the idea, the fact that or the characteristic in HER2/neu that you would have to or a pathologist would have to offer an

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opinion or interpretation as to intensity levels -
DR. COOK:
A. Intensity levels and whether that membrane staining is complete or not and what percentage of cells are involved.
COFFEY, Q.C.:
Q. Okay. So the percentage issue would be -
DR. COOK:
A. Still there.
COFFEY, Q.C.:
Q. Still there, but it was there for ER/PR, as well?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Would I be correct on that?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. Okay. But the distinguishing feature of HER2/neu was involved an assessment of intensity?
DR. COOK:
A. Intensity, the degree of membraneous staining

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and the percentage of cells that are stained.
COFFEY, Q.C.:
Q. So is it membranes, it's a membrane stain, not--is it cytoplasmic staining, as well?
DR. COOK:
A. Mainly cytoplasmic stain--sorry, membrane stain.
COFFEY, Q.C.:
Q. Yes, okay. So it's membrane staining?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. And as in ER/PR in contradistinction to nuclei staining?
DR. COOK:
A. Nuclear staining.
COFFEY, Q.C.:
Q. Nuclear staining. And the membrane is the outside of the cell?
DR. COOK:
A. That's the cell boundary.
COFFEY, Q.C.:
Q. Boundary as opposed to the nucleus, within the cell. So -
DR. COOK:

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A. And the cytoplasm.
COFFEY, Q.C.:
Q. And the cytoplasm. But in terms of the staining for HER2/neu, cytoplasm wouldn't figure into it, would it?
DR. COOK:
A. That's right.
COFFEY, Q.C.:
Q. So the chief difference, would it be fair to say, that really the chief difference other than if membrane equals nucleus in the sense of one has to be stained in one context, one in another?
DR. COOK:
A. In terms of the ER and PR it's nuclear, in terms of the HER2/neu it would be cytoplasmic membrane.
COFFEY, Q.C.:
Q. And percentages calculation had to be done?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. In both instances. The chief difference would be then this assessment of intensity?
DR. COOK:

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A. Intensity is a factor, yes, and whether that membraneous staining is complete or incomplete.
COFFEY, Q.C.:
Q. Okay.
DR. COOK:
A. So there's another factor there.
COFFEY, Q.C.:
Q. Complete or incomplete and if so, what percentage of overall cells?
DR. COOK:
A. So the percentage would weigh into it.
COMMISSIONER:
Q. Just a curiosity level, I'm sure it has nothing to do with anything, but presumably you could get a slide where the intensity would vary across the slide or would you expect that the intensity would be consistent? I'm just wondering how you get a percentage if intensity is different in different parts of the slide?
DR. COOK:
A. The HER2/neu, the intensity tends to be fairly homogenous across the slide.
COMMISSIONER:

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Q. Okay.
DR. COOK:
A. But that's not an absolute. I mean, you can't say that with 100 percent certainty. But if you got a strong positive, three plus, you would get strong membraneous staining right across the slide.
COFFEY, Q.C.:
Q. So, Doctor, ER/PR then, and I'll use the phrase, in effect was rolled out in early ' 98 across the province?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. And without any in-service?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. While HER2/neu was rolled out in early 2000 with an in-service in late '99?
DR. COOK:
A. Right. Or it was, came on stream April, 2000.
COFFEY, Q.C.:
Q. Yes, rolled out in the sense of you're here advising everybody from now on this is what

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we'll be doing. Did anyone at the time remark upon the different approaches to using an in-service for one process then after the other?
DR. COOK:
A. No. The only remark I received was people were happy that I conducted an in-service on the HER2/neu.
COFFEY, Q.C.:
Q. Oh, yes.
DR. COOK:
A. But that's, there were no remarks about in-service for ER and PR.
COFFEY, Q.C.:
Q. Or the lack thereof now that we've got our HER2/neu in-service?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. Okay. Doctor, here looking at this, there's a reference here to "It is also recommended that for evaluation of breast biopsies the biopsies should be fixed overnight for at least 18 hours."
DR. COOK:
A. Um-hm.

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COFFEY, Q.C.:
Q. Where did that information come from?
DR. COOK:
A. That came from the DAKO company itself. There were DAKO representatives at that in-service.
COFFEY, Q.C.:
Q. Was there any explanation at the time as to why that was so?
DR. COOK:
A. No, that was their recommendation.
COMMISSIONER:
Q. Mr. Coffey, wherever you can find a place, we'll break for lunch.
COFFEY, Q.C.:
Q. Doctor, if we could look, please, at Exhibit P-1874? So, Doctor, by this point in time, that's April of 2000, I'm sorry?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. You were acting clinical chief. Where was Dr. Khalifa at that point?
DR. COOK:
A. He had left the province, I think it was April or May of '99.

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COFFEY, Q.C.:
Q. So by that point he would have been gone for approximately a year?
DR. COOK:
A. That's right.
COFFEY, Q.C.:
Q. If we look here, these are minutes of a meeting of site chiefs, division managers, division of anatomical pathology, February 22nd, 2001. You're listed as one of the attendees. And paragraph 4.2 under "New Business" "Quality control of immunoperoxidase staining."
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. "There has been a study going on the quality of the immunoperoxidase staining for both sites. It is agreed the control for immunoperoxidase staining be run for every batch. A pathologist will check the control slide before sending the slide to the other site. Dr. S. Parai has agreed to do this. In case he is not available another pathologist will be looking at the control." And it goes

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on to talk about another particular antibody. Do you recall what this was about, Doctor, this study?

DR. COOK:

A. I don't even know if that study went ahead or it certainly didn't involve the pathologists at St. Clare's. It seemed to me to be centralized at the General Hospital and I never did get the results of that study.

COFFEY, Q.C.:

Q. Do you know what had occasioned the study, I mean, the need for it or the view that it might be a good idea?

DR. COOK:

A. It may have been something that, well, an evaluation, but I have no recollection of what triggered that or ignited that.

COFFEY, Q.C.:

Q. And because he refers to both sites. See that?

DR. COOK:

A. Yeah.

COFFEY, Q.C.:

Q. Which both sites would this be?

DR. COOK:

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A. It was not St. Clare's unless it was the General, and by that time the Grace was closed, but definitely it didn't involve St. Clare's.

COFFEY, Q.C.:

Q. If we could, please, Exhibit P-1876? That was February of 2001. This is the minutes of a meeting of site chiefs and divisional managers, division of pathology, Wednesday, April 25th, 2001. Present are yourself and a number of others, including Dr. Parai and Haegert. Doctor Sushil Parai, I take it, would have been site chief of -

DR. COOK:

A. The General.

COFFEY, Q.C.:

Q. The General by then. And you would be of St. Clare's?

DR. COOK:

A. St. Clare's. Dr. Haegert is back at this point?

DR. COOK:

A. As clinical chief.

COFFEY, Q.C.:

Q. As clinical chief. And under "Business

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Arising" paragraph 2 there's a heading "Quality Control of Immunoperoxidase Staining." "Generally the immunos appear to be very good. There appears to be some problems with the estrogen and progesterone receptors. The positive controls are checked daily by a pathologist, however these need to be documented. Dr. Parai will follow up on this. Note is also made of heavy utilization of immuno services and the high volumes encountered."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Do you recall what this was about, because this again refers to the quality of immunostaining?

DR. COOK:

A. Well the only recollection that I had was I may have brought that up at that meeting, again, regarding the turnaround times for ER and PR. They were always getting constant concerns from the pathologists regarding the turnaround times for the ERs and PRs, getting calls from the clinics and from surgeons

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looking for ER and PR reports., So the only thing I can recollect about that particular statement is that problems concerning the turnaround times for the ERs and PRs. I can't recollect any problems regarding quality.

COFFEY, Q.C.:

Q. That is the quality of the stain?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. The stain on the slides themselves. So you would attribute this comment here to a turnaround time issue as opposed to a quality of stain with the ER and PR stains?

DR. COOK:

A. Yes, that's how I interpret that. And my recollection seems to tend towards that.

COFFEY, Q.C.:

Q. Commissioner, if we could take this up then after lunch? Thank you.

COMMISSIONER:

Q. Sure. We'll meet again at ten after two.

(LUNCH BREAK)

COMMISSIONER:

Q. Mr. Coffey.

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COFFEY, Q.C.:
Q. Thank you, Commissioner. Registrar, Exhibit, yes, 1876 is there, thank you. Now, Doctor, there's a reference here under "New Business", this is the April 25th, 2001 site chiefs and divisional managers' memo. Under "New Business" paragraph 1, "Control documentation and registration of slides from site to site within the corporation." It says, "Dr. Haegert will issue a memo to all pathologists. The slides being returned to the respective sites should be sent directly to pathology labs to be filed by the technologist. Slides should not be return to pathologist's offices. Note, when slides are received and returned, it should be documented in the computer." What was this about, Doctor?
DR. COOK:
A. Again, there was--there may have been issues when slides were returned, say, from a site on Corner Brook, gone directly to a pathologist's office and not being registered. So in order to properly document the, say, the return of slides from another site, the slides should go directly to a secretary or technologist to

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document receipt of those slides.
COFFEY, Q.C.:
Q. Okay. I take it this is related to documenting, keeping track of where particular, like, items were such as particular slides?
DR. COOK:
A. That's right. So you know, it wouldn't bypass the registration process to say that the slides had been returned. So it's just to keep a handle on documentation of slides.
COFFEY, Q.C.:
Q. Paragraph 2 refers to terminology of estrogen and progesterone reports. It says, "Mr. Gulliver will develop and canned text for reporting of estrogen and progesterone receptors. Information for this will be obtained from Dr. Parai. What was this about, Doctor?
DR. COOK:
A. I would assume that that's a--that's referring to Dr. Khalifa's canned text that Dr. Parai would have and the copy of that text would be incorporated into the computer, so a pathologist reading an ER and PR report, that

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canned text would already be in the system.
COFFEY, Q.C.:
Q. And would it--as Dr. Khalifa, by that point in time, would have been gone for approximately two years, if he left in early '99?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. A canned text here, would it relate to his or would it just be--what is a canned text? Perhaps you could explain that to the Commissioner, what is -
DR. COOK:
A. A canned text is a stated term that's already in the computer system, so all you would have to do, if you say that the estrogen receptor was either positive or negative, you can just dictate into your microphone or your dictaphone and that would be automatically incorporated into a canned text that's already in the system.
COFFEY, Q.C.:
Q. Do you know if the canned text for reporting of estrogen and progesterone receptors was ever subsequently developed?

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DR. COOK:
A. I don't know. I can't say for sure, but that's the assumption I would make looking at that.
COFFEY, Q.C.:
Q. Do you know if the reports that you did after April, 2001, did they have a canned text when you actually saw the reports?
DR. COOK:
A. Not for St. Clare's, no. We would actually dictate that report into the dictaphone and transcribed by the secretary.
COMMISSIONER:
Q. So this would be some kind of a voice recognition?
DR. COOK:
A. No, no, Commissioner. It would be a standardized text that's in the system. So all I would need to say is ER positive, say, at 80 percent and that whole format would automatically come up on the screen and the secretary would punch in those numbers and positivity.
COMMISSIONER:
Q. Oh, okay. Yeah, it's a kind of a form?
DR. COOK:

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A. It's a form for--it's much like our synoptic reporting that we later get into that you have the format already in the system.

COMMISSIONER:

Q. Yeah, okay. Thank you.

COFFEY, Q.C.:

Q. And when the transcriber heard your voice refer to certain words, they'd know that that's what I'm to plug in the values here, as it were?

DR. COOK:

A. They would go back to the canned text and put that in.

COFFEY, Q.C.:

Q. Yes. Here on page the next page, page 2 of the exhibit under paragraph 3 there's a HER2 expression. And the text says, "Some discussion centred around the predictive value of the current HER2/neu kit provided by the DAKO company and whether we need to implement the FISH as confirmatory test. The issue as to whether we can provide FISH as an alternative depends on approval on two technologists positions. We will obtain some literature on this matter." What was that

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about, Doctor?

DR. COOK:

A. I would think that's getting into the possibility of false positives being documented, not only by the HER2/neu kit, but by the HER2/neu immunoperoxidase stain. That's a concern that was being generated, not only by DAKO, but by the medical community throughout Canada and United States. Now, in regards to the FISH, there were guidelines that came out from the Canadian Consensus Guidelines on HER2/neu that recommended that for all two plus results on the HER2/neu that there be a reflex testing for FISH. And we implemented that, I believe, in April or May of 2001 by sending cases up to Sunnybrook.

COFFEY, Q.C.:

Q. I'm sorry, so they would be sent to Sunnybrook for?

DR. COOK:

A. FISH testing.

COFFEY, Q.C.:

Q. FISh testing.

DR. COOK:

A. And confirmation.

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COFFEY, Q.C.:

Q. Now, the reference here to "depends on approval on two new technologists' positions," what was that about?

DR. COOK:

A. It refers to setting up the florescent in situ hybridization ourselves here in St. John's, but that would be dependent on the acquisition of two new technologist positions. It was a resource issue.

COFFEY, Q.C.:

Q. And do you know whether those two technologist, new positions were ever created at that time?

DR. COOK:

A. No, I don't think we were able to get the funding for those new positions.

COFFEY, Q.C.:

Q. Exhibit P-1877, please? Sir, this is, again, an agenda for a meeting of June 26th, 2001. And under "New Business" there's a quality assurance program for anatomical pathology/pathologists review. See that there?

DR. COOK:

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A. Um-hm.

COFFEY, Q.C.:

Q. And we go to the second page of the exhibit, these are the minutes of meeting, site chiefs and divisional managers, June 26th, 2001. Yourself, Dr. Parai and Dr. Haegert are present. And under "Business Arising" paragraph 3.2, "HER2 Expression ER and PR control" the text reads, "The controls for all these immunostaining are checked by the site chief or by on call pathologist when site chief is not available." What was the concern here, what was that about?

DR. COOK:

A. That may have been addressed by me to make sure that there was somebody checking the controls and documenting the controls before those tests are released.

COFFEY, Q.C.:

Q. Do you know if at this point, this would be June, late June, 2001, if there was a situation that developed where the external control slides were not being distributed?

DR. COOK:

A. I may have. That may have been a case where

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some external control slides were submitted to St. Clare's and it may have been a case where I was looking for them, can't find them, and may express concern about that.

COFFEY, Q.C.:

Q. On the next page under "New Business" there's a heading, "Quality Assurance Program for Anatomical Pathology/Pathologist's Review." And the text goes on to say, "This meeting is dedicated for the above items and the following points are discussed." And paragraph 1, "System review. This system review is not in place. It will be discussed in the next meeting for possible implementation of pathology report review by system via committee." What was that about, Doctor?

DR. COOK:

A. I'm trying to remember exactly, Mr. Coffey. It may have been looking at trying to get a system in place to review pathology reports by systems, either look periodic review of something like a GI system or a pulmonary system and see how well the reporting is working by pathologists. So it's trying to

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get in a system of auditing to review the quality reports.

COFFEY, Q.C.:

Q. So up to this point in time, June of 2001, was there such a system in place?

DR. COOK:

A. There was a system in a way in that there was a review at various rounds of various pathology reports. These could occur at various inter-hospital rounds or could occur by individual pathologists reviewing a particular case that came to attention; it could be review of a, say, a metastatic lesion, that someone may go back two or three years ago to review our primary lesion to correlate the histologies between primary and current lesions.

COFFEY, Q.C.:

Q. And I take it, though, that sort of thing is is as happens as opposed to systematically going about -

DR. COOK:

A. Well, that has happened and has happened for many years. Pathologists on a routine basis go back and review reports.

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COFFEY, Q.C.:

Q. As of June, 2001 was there any systematic way, though, in terms of the overall system in place that provided that occasionally, for example, like just yourself, for example, your cases or certain of your cases would come up for review just systematically?

DR. COOK:

A. It could. If, for instance, I go into a case and at that time I believe we had the hospital information systems in place, computer systems in place that if I'm reviewing, say, a superficial gastric biopsy or something, I would get a printout of all previous reports on that patient, so if there was a concern, I would go in and review those cases. But that would have been basically in an individual case setting or it could come up at rounds.

COFFEY, Q.C.:

Q. So here what was being contemplated here then, because the statement, "This system review is not in place"?

DR. COOK:

A. This would have been random reviews.

COFFEY, Q.C.:

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Q. Okay. In some sort of systematic fashion?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. "Canned Text", paragraph 4, there's a reference to "There is partial implementation of canned text at the General Hospital site for ER?PR and HER2/neu expression. It is important to use standard specimen grossing and reporting."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. So I take it where this refers to "at the General Hospital site" for those three stains, the ER/PR and HER2/neu expression, I take it that there was no such implementation of canned text at St. Clare's at that point?

DR. COOK:

A. There would have been or there certainly would have been, I think, for HER2/neu, it would not be for ER and PR, but I can't say for sure at that point in time, Mr. Coffey.

COFFEY, Q.C.:

Q. It refers to "It is important to use standard

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specimen grossing and reporting."
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. What is "standard specimen grossing"?
DR. COOK:
A. It means that every pathologist would gross the specimen in a standard way, that there's be no deviation from one pathologist to another.
COFFEY, Q.C.:
Q. And were there any protocols or understandings in place in that regard?
DR. COOK:
A. At St. Clare's we used a standard textbook, Ackerman Surgical Pathology of which at the end of the book there was a protocol for the standard grossing of specimens.
COFFEY, Q.C.:
Q. And do you know what was being used at the General Hospital at the time?
DR. COOK:
A. I don't know.
COFFEY, Q.C.:
Q. And to use standard specimen grossing. And, I

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take it, and standard specimen reporting?
DR. COOK:
A. Yeah. That would be getting into synoptic reporting, T and M (phonetic) classifications and whatnot, so if you have, say, a diagnosis of tumor, there would be a standardized way of reporting that using synoptic reports.
COFFEY, Q.C.:
Q. And at that time, June, 2001, was synoptic reporting in place at St. Clare's?
DR. COOK:
A. Yes, it was.
COFFEY, Q.C.:
Q. How long had it been in place?
DR. COOK:
A. Since 1998.
COFFEY, Q.C.:
Q. And was that either across the board for all pathology or -
DR. COOK:
A. All pathologists in the division of anatomical pathology.
COFFEY, Q.C.:
Q. Used synoptic reporting for every type of case?

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DR. COOK:
A. That's correct, we would use it for lung, breast, gastrointestinal tumors, genital, urinary, so standardized reporting using that synoptic report.
COFFEY, Q.C.:
Q. And what, if any, advantage is there to the utilization of synoptic reporting?
DR. COOK:
A. Well, it provides sort of a checklist in a way in that pathologists will record on a checklist pertinent information needed by surgeons or oncologists to carry out treatments.
COFFEY, Q.C.:
Q. And the requirement that a certain type of synoptic reporting be use at St. Clare's beginning in 1998, who implemented that?
DR. COOK:
A. I would have done that.
COFFEY, Q.C.:
Q. And was there any written guidelines to that effect?
DR. COOK:
A. No. That came out of site chiefs and

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divisional meetings that we would have had with myself and Dr. Khalifa and Haegert as well as Dr. Parai to implement that throughout the whole system.
COFFEY, Q.C.:
Q. And do you know what was being done, you know, circa June, 2001 at the General Hospital in that regard?
DR. COOK:
A. They would have used synoptic reporting, as well.
COFFEY, Q.C.:
Q. The synoptic reporting used at St. Clare's and at the General at the time, were they identical?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. So the same system was being used?
DR. COOK:
A. That's right.
COFFEY, Q.C.:
Q. In terms of other than the coming up at rounds or being talked about, was there any actual kind of, you know, if a new pathologist came

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on site, came to work at the Health Care Corporation, would there be any manual that he or she could be pointed to?

DR. COOK:

A. No. They would be pointed to, again, in my case, at the St. Clare's using the Ackerman text and a listing of various synoptic reports that would be given to them. And the same would occur at the General Hospital site or whatever standard manual they would use.

COMMISSIONER:

Q. Sorry, Dr. Cook, did you say the author of the text was Ackerman?

DR. COOK:

A. Commissioner, Ackerman, yeah, A-c-k-e-r-m-a-n.

COMMISSIONER:

Q. Thank you.

COFFEY, Q.C.:

Q. Now, Doctor, in June of 2001, this quality assurance program for anatomical pathology/pathologists review.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Prior to this, was there a quality assurance

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program for anatomical pathology?

DR. COOK:

A. There were quality assurance activities, but not a coordinated program where we would have a designated pathologist overseeing all quality assurance activities. There were quite a number of quality assurance activities, but not a designated individual assessing those, other than site chiefs.

COFFEY, Q.C.:

Q. And Doctor, whose idea was the establishment of a quality assurance program at that time, do you recall?

DR. COOK:

A. At this particular time, 2001?

COFFEY, Q.C.:

Q. Yes.

DR. COOK:

A. I can't say who in particular came up with it. It may have been a consensus opinion amongst the site chiefs and clinical chief.

COFFEY, Q.C.:

Q. And who was responsible, at that time, for coordinating or running the quality assurance program?

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DR. COOK:

A. Well, that would have been, overall, the clinical chief.

COFFEY, Q.C.:

Q. That would be Dr. Haegert at this point?

DR. COOK:

A. Yeah.

COFFEY, Q.C.:

Q. If we could, please, Exhibit--if I could just go back one, please, to P-1876, and Doctor, here, on page three of this, these are minutes of April 25th, 2001, site chiefs, divisional managers meeting. Here, looking at paragraph 10, "updating the immunoperoxidase form. The immunoperoxidase forms are in the process of being updated to accommodate new additions to the profile" and you had suggested a particular one be added, okay.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. I'm just going to ask then, please, that Exhibit P-1886 be brought up, Registrar, please? Now this is a form Health Care Corporation of St. John's, entitled

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immunoperoxidase request form. There's some redaction occurred in this, in the form. The date it's completed is January 30th, I believe, 2003.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. And at the bottom, there's some handwriting there, "received January 31, 2003."

DR. COOK:

A. Right.

COFFEY, Q.C.:

Q. Whose handwriting is that, do you know?

DR. COOK:

A. That's mine.

COFFEY, Q.C.:

Q. Yours, so that little note that you received the form or received that date is yours.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. PR equals negative, ER equals negative.

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

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Q. Would that be your handwriting?
DR. COOK:
A. That's my handwriting.
COFFEY, Q.C.:
Q. And up here on the top right-hand side, this handwriting here, whose is that?
DR. COOK:
A. That's mine.
COFFEY, Q.C.:
Q. Yours, okay. That's in the first block, Commissioner, for the record. And written up here is "ER/PR, controls are okay. Checked by Dr. Chittal."
DR. COOK:
A. Right.
COFFEY, Q.C.:
Q. Is that your handwriting?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Okay, so could you just tell then--and I use this as an example, kind of circa January 2003, how, for example, estrogen and progesterone receptors, which I take it is this area right here, on this form circled

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carcinoma.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. How this sort of form was used.
DR. COOK:
A. Well, the form is used, I mean, I would highlight what I would order, in terms of immunoperoxidase stains. What I wanted the site chief to do at the General Hospital, if for any reason that the external controls were--could not be sent over to the St. Clare's site, that before any of those batch tests are released that we would have a system in place where the external ER and PR controls would be reviewed and documented by a staff pathologist, just reenforcing what we had, in terms of documentation.
COFFEY, Q.C.:
Q. And so this handwriting up here, what did that signify to you when you received the form?
DR. COOK:
A. That signified that the external controls were reviewed, that they were satisfactory and the batch could be released.

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COFFEY, Q.C.:
Q. Now here, Doctor, just to--so the Commissioner understands at least what the practice was in January of 2003 -
THE COMMISSIONER:
Q. The batch could be released meaning they could send them out from the Health Science or the batch could be released meaning they could be released to pathologists within St. Clare's?
DR. COOK:
A. They could be released to pathologists in St. Clare's and released to pathologists outside the General Hospital. So I wanted those controls to be reviewed and documented before anything is released outside of that General Hospital lab.
THE COMMISSIONER:
Q. So the doctor listed up here would be within the Health Science?
DR. COOK:
A. That's correct.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. So this is obviously a preprinted form, I

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guess one can see that, I take it.
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. And in fact, the minutes we just looked at a moment ago of a meeting just in April of 2001 had referred to the fact that there were new additions to the profile, so this form would be revised from time to time to add -
DR. COOK:
A. Yes, that's correct.
COFFEY, Q.C.:
Q. - the stains available, and so this is a breast cancer case. So you would have filled out the top part of this yourself with a surgical pathology number, the block number, you would specify the block. Your own name, as the pathologist, the diagnosis or DD -
DR. COOK:
A. Differential diagnosis.
COFFEY, Q.C.:
Q. - differential diagnosis, breast carcinoma. The date, January 28th '03, the name of the patient an the MCP number of the patient?
DR. COOK:

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A. That's correct.
COFFEY, Q.C.:
Q. And then you would come down and for a breast cancer, under carcinoma, the stain you'd be looking for here, antibodies would be estrogen and progesterone receptors, and you'd just circle it?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, I take it then that that form, so filled out up to that point, would go off? You'd send it off with the block or the technologist at St. Clare's would find the block, take the form and -
DR. COOK:
A. Yes, I would fill it out and give it to our technologists, who would then find the block and forward the block and the requisition to the General Hospital.
COFFEY, Q.C.:
Q. Now Doctor, here, you've specified block 3C. What process would you go through to identify block 3C?
DR. COOK:

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A. Well, the actual surgical pathology number and block number would be on the paraffin block itself. So these paraffin blocks would be stored. That requisition would be given to a technologist or to a lab aide who would go and retrieve that paraffin block from the archival process or the storage system.
COFFEY, Q.C.:
Q. Why would you say 3C as opposed to 3B or -
DR. COOK:
A. Because I would be--well, in a case like this, we may have three blocks from the same tumor, so I would go through the histological slides and pick out an appropriate block to be used for ER and PR testing or slide.
COFFEY, Q.C.:
Q. And in that time, January of 2003, what criteria would you be utilizing to determine which block, which was the most appropriate block?
DR. COOK:
A. In '03, I would be looking for the presence of an adequate amount of tumor, looking to see how differentiated it was, looking for the presence of external control tissue, looking

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to see if there -
COFFEY, Q.C.:
Q. I'm sorry, what -
DR. COOK:
A. Breast tissue adjacent to the tumor.
COFFEY, Q.C.:
Q. That would be internal control?
DR. COOK:
A. I'm sorry, internal control tissue. Looking for how well the tumor is differentiated and overall histological preparation of the slide.
COFFEY, Q.C.:
Q. Now Doctor, you've indicated that it was in 2000 that you came across an article or a reference in a text that brought to your attention the idea of utilizing an internal control for ER and PR analysis. Before you came across that article in 2000, would you have made any effort in picking out the blocks or, you know, the block for a patient to be looking for normal tissue?
DR. COOK:
A. Probably not. My emphasis would have been on the state of the tumor itself. I would have been placing a lot of emphasis on how well

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preserved the tissue is, looking for the histological features of, you know, tubular formation, mycotic activity, that sort of thing. So most of my emphasis would be on the histological characteristics of the tumor.
COFFEY, Q.C.:
Q. And then after becoming aware, I take it, of the desirability of utilizing an internal control, you would then have, from that point on -
DR. COOK:
A. Well, it would have changed my practice, I mean, to incorporate that.
COFFEY, Q.C.:
Q. Here, Doctor, so you send it off to the General Hospital. This is Ken Green, I take it?
DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. The histotech, and the date completed January 30, 2003. That signified, I take it, that Mr. Green had processed or prepared the slide?
DR. COOK:
A. Right.

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COFFEY, Q.C.:
Q. And the date he had done so, he'd concluded it by January 30th, 2003.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. So it came back. You'd mark on it received and the date?
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. January 31st, and the PR and ER, PR negative, ER negative, why would you have marked that on the requisition form, on the req request form?
DR. COOK:
A. Because when I'm transcribing or dictating into the system and I do get the report back, because sometimes the report may not come back until 24 or 48 hours, I would obviously forget the result that I transcribed into the system. So I would use that as a reminder to again verify the result that I recorded into the dictating system and compare those results that I've documented on the requisition. So as a safeguard.

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COFFEY, Q.C.:
Q. Doctor, in that regard, I take it here, because it says negative and negative, in your world at the time, January 2003, what did that mean about percentages?
DR. COOK:
A. There was no percentage, absolutely negative.
COFFEY, Q.C.:
Q. That would be zero, zero then?
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. If in a form that say there was an ER and PR were positive, would you also--you'd note the fact that it was positive?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. Would you also note on this form the percentage?
DR. COOK:
A. I would.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-0113, please? Now Doctor, you've referred to Dr. Ejeckam having arrived, I believe, in 2002.
DR. COOK:
A. September of 2002.
COFFEY, Q.C.:
Q. Where was he stationed?
DR. COOK:
A. Previously in Dohar, Qatar.
COFFEY, Q.C.:
Q. And within St. John's, he was located at which hospital?
DR. COOK:
A. At the General Hospital site.
COFFEY, Q.C.:
Q. How did you become aware of his interest in immunohistochemistry?
DR. COOK:
A. Well, he previously practised pathology in St.--at the Grace Hospital in the mid 80s and at that time, he played a role in bringing in immunohistochemistry into the Grace Hospital. So he had an interest in immunohistochemistry.
COFFEY, Q.C.:
Q. And you'd known that back in the 80s, I take it?
DR. COOK:

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A. I would have known that when I was resident.
COFFEY, Q.C.:
Q. Yes, okay. Go ahead. I'm sorry, go ahead.
DR. COOK:
A. So basically, I was looking for someone to take a leading role in immunohistochemistry and also to take a leading role in other aspects of pathology as well, and -
COFFEY, Q.C.:
Q. Such as?
DR. COOK:
A. Sitting on various committees.
COFFEY, Q.C.:
Q. And what types of committees, do you recall in particular?
DR. COOK:
A. There was a surgical pathology review committee that I was interested in having an experienced pathologist sit on and take the lead role in.
COFFEY, Q.C.:
Q. And where had your interest in that--when had that first arisen, Doctor?
DR. COOK:
A. Well, that was first arisen while I was acting

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clinical chief back in ’99 and near the end of that term, and that arose mainly because prior to ’95/96, each of our hospitals were separate institutions and each had their own separate committees. After ’95/96, there was a complete reorganization of the health care system and some of those committees needed to be reactivated. One of the committees that was fairly active in each of the hospitals was a tissue audit committee. So I was looking -

COFFEY, Q.C.:

Q. And that was back, I take it, before the Health Care Corporation came into existence?

DR. COOK:

A. That’s correct. These were in each of the hospitals prior to ’95/96. So near the end of my term in 2000, I had set up a terms of reference for this committee and was looking for someone to take it over. At that time, I had a pathologist in mind who was willing to take on that committee, but like many times, things happen, that pathologist left the province to go to the mainland, and at that time, Dr. Haegert came on as clinical chief. So I asked Dr. Haegert would he pursue the

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surgical pathology review committee to try to set up an auditing process. That, for some reason, didn’t happen and when I became clinical chief in 2002, I was looking at setting up a process where we would have an auditing committee in place, and Ejeckam came to mind because of his experience. So I asked him would he chair this committee.

COFFEY, Q.C.:

Q. Now Doctor, you took over as acting chief when in 2002?

DR. COOK:

A. Acting chief?

COFFEY, Q.C.:

Q. Yes.

DR. COOK:

A. In March of ’02.

COFFEY, Q.C.:

Q. Okay, and Dr. Ejeckam arrived in the fall of 2002?

DR. COOK:

A. He arrived in September of ’02.

COFFEY, Q.C.:

Q. So the purpose of the surgical pathology review committee, I take it it was

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established?

DR. COOK:

A. It was established in ’03.

COFFEY, Q.C.:

Q. It’s purpose was what?

DR. COOK:

A. Well, the purpose was--one of the things that I was frustrated as clinical chief is that how were we, particularly in regards to division of anatomical pathology, were performing in regards to our reports. Were we providing the type of information that an oncologist needed to be able to act on their patient’s treatment regimes? How were the reports, in terms of completeness? How, overall, did the clinicians appreciate the work being produced in terms of the quality of the work being produced, and at the same time, look--provide a mechanism whereby pathologists can also evaluate the work of clinicians, in terms of the type of information that would be sent down to them, how the various organs would be sent down, in terms of them, in terms of the state of the organs. So I wanted a committee that would have sort of have eyes and ears for

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the laboratory medicine program. But I wanted to go a little bit beyond that and just auditing, but identify any issues of concern outside of the tissue auditing process that clinicians would have with the division of anatomical pathology.

When I approached Ejeckam regarding this, we talked quite a bit about quality assurance activities. Dr. Ejeckam was willing to take on this committee, provided it had a bit of teeth, and to give this committee some teeth, we both agreed the best way to do it would be to have the committee report directly to the Vice President Medical Services.

COFFEY, Q.C.:

Q. In this context, that would be Dr. Williams?

DR. COOK:

A. That would be Dr. Williams.

COFFEY, Q.C.:

Q. And did Dr. Williams agree with that?

DR. COOK:

A. He did.

COFFEY, Q.C.:

Q. And what’s--up to that point, what sorts of quality assurance activities was the

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pathologist in the lab involved in at that time?

DR. COOK:

A. Well we were involved in proficiency testing with the College of American Pathology Performance Improvement Program, both in anatomical pathology and in cytology. We were involved in proficiency testing program with the American Society of Clinical Pathologists. At that time we were involved in the Mocan (phonetic) process with the Royal College of Physicians and Surgeons of Canada, whereby we had to document the number of hours, we attended CME activities, such as conferences, rounds, there had to be documentation of journals, documentation of education, teaching and research. There would be, again, documentation of proficiency testing program, such as the ASCP program. There would be a whole host of rounds which were quality rounds, such as lymphoma consensus rounds, slide review rounds, quality control rounds, medical pathology rounds, grand medical rounds, there would be rounds regarding tumor board rounds, chest board rounds, there would

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be rounds with our radiologists in terms of correlations of our breast pathology with our radiology reports, so there was a whole hose of rounds taking place, as well as the process of interdepartmental consultations which were documented and extradepartment reviews, such as reviews to such institutions as the Mayo Clinic, AFIP, and the BC Cancer Agency. So this is just--I don't know if I included everything in the quality assurance activities, but this is just an indication of the amount of quality assurance that was going on in the program.

COFFEY, Q.C.:

Q. How much, if any of that, related to immunohistochemistry?

DR. COOK:

A. A lot of it would have related to immunohistochemistry because we would have relied on immunohistochemistry to aid in the interpretation of our cases. For example, if we had a case that we discussed at quality control rounds and was reviewed by four or five pathologists and we couldn't come up with a consensus opinion, that case would be

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referred to a major centre, such as the Mayor Clinic or the Armed Forces Institute of Pathology in the United States or the B.C. Cancer Agency whereby all pertinent histology, including special stains as well as IHC stains, would be forwarded to that institution for a second opinion and review.

COFFEY, Q.C.:

Q. Was there any external proficiency testing going on?

DR. COOK:

A. There was external proficiency testing going on for pathology interpretation, but not specifically for immunohistochemistry.

COFFEY, Q.C.:

Q. So immunohistochemistry there was no external proficiency testing going on?

DR. COOK:

A. Not at that time.

COFFEY, Q.C.:

Q. When did that start?

DR. COOK:

A. That started, I believe around the fall of '05.

COFFEY, Q.C.:

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Q. Now, Doctor, you spoke to Dr. Ejeckam about getting involved in this review committee, Surgical Pathology Review Committee, you spoke to Dr. Williams and he was supportive, I take it?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. If we could, I'm just looking--we have here on the screen exhibit P-0113, page one. Doctor, this is a memo, the Commissioner has seen it before, to pathologists in the Health Sciences Centre, St. Clare's and out of town hospitals. It's from Dr. Ejeckam. Subject is immunohistochemical stains, it's dated April 4, 2003 and it's copied to Barry Dyer and all technical staff on immunohistochemistry. And, Doctor, at the time in 2003, your office was where?

DR. COOK:

A. At St. Clare's.

COFFEY, Q.C.:

Q. The first notice that you had that there was a concern about immunohistochemistry stains, those particular antibodies and there are

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eight of them listed there, did you have any heads up that this was going to come to you?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. Doctor, prior to April 2003, like in the six or seven month period before that when Dr. Ejeckam first arrived, the first seven months after he arrived in St. John's, September of '02, were there--what, if any, circumstances were there in which pathologists from the St. Clare's and the General Hospital would end up meeting as a group?

DR. COOK:

A. Would end up meeting in a group at various discipline meetings, various interhospital rounds, there may be interaction at tumor board rounds for some pathologists from St. Clare's going over there, but usually at the level of discipline meetings and various rounds.

COFFEY, Q.C.:

Q. Now in this Dr. Ejeckam lists eight stains, two of them--the last two are ER and PR and he says "have remained unreliable, erratic and

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therefore unhelpful for diagnostic purposes."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Had you had any inkling at all that that was Dr. Ejeckam's view in the beginning of April? Like before that, was there any lead up to this at all that you were aware of?

DR. COOK:

A. There was no lead up to it, as I said before, Mr. Coffey, many times we would send out cases for review to major reference centres which include immunoperoxidase stains or paraffin blocks and these reports would come back without any comment about the quality of the stains.

COFFEY, Q.C.:

Q. So up until you received--you did receive this memo, I take it on April 4th or shortly thereafter, 2003?

DR. COOK:

A. I did.

COFFEY, Q.C.:

Q. Up to that point, no one had brought to your attention, at least the notion or idea that at

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least some stains, eight of them, these particular eight ones or some subset of the eight stains or any other stains, for that matter, were unreliable, erratic and unhelpful?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. So if there was concern amongst--or one or more pathologists about it, no one had voiced it to you?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Having received this, Doctor, what, if anything, did you do?

DR. COOK:

A. Well I was going to phone Dr. Ejeckam, I was a little bit irritated that I had received this memo without any consultations prior to that, but I looked at this at the time as a quality assurance activity. Here was somebody that I had put in place to oversee the IHC and had taken steps to stop the staining and was acting as a circuit breaker in the system.

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So, in many respects I got a comfort level out of this in that now I had somebody overseeing and monitoring the IHC.

COFFEY, Q.C.:

Q. Which means, I take it your answer then, though, you didn't actually contact Dr. Ejeckam about it?

DR. COOK:

A. No, I gave him the ball and let him run with it.

COFFEY, Q.C.:

Q. Did you speak to anyone else about it?

DR. COOK:

A. I did speak to Dr. Desmond Robb in a telephone conversation concerning another issue and I did bring up the issue of Ejeckam's letter. Dr. Robb is a discipline chair with our university program and expressed to him any concerns that he had with the stains previously.

COFFEY, Q.C.:

Q. I'm sorry, what?

DR. COOK:

A. And expressed--and asked him if there was any concerns that he had with the previous

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staining.
COFFEY, Q.C.:
Q. And what was Dr. Robb's response?
DR. COOK:
A. No. Now thinking back at this time, Mr. Coffey, I was also thinking back to any issues or trying to think of any issue that had come up at tumor boards and also an issue that had taken place with the Cleveland Medical Clinic back in around 2000, 2001.
COFFEY, Q.C.:
Q. I'm sorry, I didn't hear the last part.
DR. COOK:
A. The Cleveland Medical Clinic.
COFFEY, Q.C.:
Q. Oh yes, okay, and what happened in respect to the Cleveland Medical Clinic?
DR. COOK:
A. Well back in 2000, 2001, we had a shortage of oncologists here in the province and as a result of that, our patients were sent out for treatment at the Cleveland Medical Clinic. Along with these patients there was a review of all histology at that time. Quite a number of these patients were breast cancer patients,

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so when they went to the Cleveland Medical Clinic, they--all histology concerning the cancer patients was reviewed by the Cleveland Medical pathologists and this included review of all H&E slides and if there was any receptor staining at that time, they would be reviewed as well.
COFFEY, Q.C.:
Q. What, if anything, did that have to do with the memo in April of -
DR. COOK:
A. Well it gave me a certain comfort level and at that time, 2000, 2001, that served as a quality assurance activity and there was nothing that came out of that review.
COFFEY, Q.C.:
Q. Do you know how many such patients had their slides sent to Cleveland?
DR. COOK:
A. I believe something around the order of 30 or 33 cases.
COFFEY, Q.C.:
Q. And would that be from what, what location?
DR. COOK:
A. Throughout Newfoundland.

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COFFEY, Q.C.:
Q. Do you know if the ER/PR slides went?
DR. COOK:
A. There were ER and PR slides, I understand.
COFFEY, Q.C.:
Q. The H&E slides?
DR. COOK:
A. And H&E slides, yes.
COFFEY, Q.C.:
Q. Have you checked that since?
DR. COOK:
A. I have not, but that was the information that I knew at that particular time.
COFFEY, Q.C.:
Q. So, Doctor, you were clinical chief on April-- in April of 2003 for the Health Care Corporation of St. John's, did you communicate--well you talked to Dr. Robb -
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. And I gather only Dr. Robb about this?
DR. COOK:
A. At this particular time.
COFFEY, Q.C.:

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Q. Subsequently, when did you next speak to anybody about this?
DR. COOK:
A. I spoke to Dr. Ejeckam in June of '03.
COFFEY, Q.C.:
Q. Okay, and I'll come to that in a moment. These other stains, I take it four of them are related to lymphomas?
DR. COOK:
A. Yes, the CD3, 5, 20 and 79A.
COFFEY, Q.C.:
Q. And CEA is used for what?
DR. COOK:
A. Well that's a marker that can be used to identify epithelial lesions, it's so--it's pretty nonspecific that it's hardly ever used anymore.
COFFEY, Q.C.:
Q. How about in 2003, was it being utilized at the time?
DR. COOK:
A. It may have been utilized as part of a panel in work up of a tumor.
COFFEY, Q.C.:
Q. And CK34?

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DR. COOK:
A. C34, that's used in prostrate and it could be used in other epithelial tumors as well, as part of a panel.
COFFEY, Q.C.:
Q. So, Doctor, having been told as clinical chief by, I gather Dr. Ejeckam, you understood by this point, April of 2003, that Dr. Ejeckam had what kind of experience with IHC? You understood in the mid 80's and I appreciate the Grace, but how about afterward?
DR. COOK:
A. Well he was obviously a well read individual, but in terms of practical experience, he probably had more than any of us had at that time.
COFFEY, Q.C.:
Q. And you understood that based upon what?
DR. COOK:
A. Based on a discussion with him that I had at the time of the surgical pathology review, setting up the Surgical Pathology Review Committee and his expressed interest in setting up the or overseeing the IHC.
COFFEY, Q.C.:

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Q. Had he spoken to you at that point about his experiences in Dohar?
DR. COOK:
A. At that point prior to that memo?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Okay, so you didn't know that he had been involved with, like for more than a decade with the immunohistochemistry lab?
DR. COOK:
A. Not in Dohar, but since his involvement at Grace, yes, but not specifically in a Dohar situation.
COFFEY, Q.C.:
Q. Because the Grace would be the mid 80's.
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. This is now 2002, '03 roughly.
DR. COOK:
A. That's correct.
COFFEY, Q.C.:

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Q. In between, like the period in the 1990's?
DR. COOK:
A. No, we didn't discuss that.
COFFEY, Q.C.:
Q. Doctor, who, other than pathologists set out here, Barry Dyer is down here at the bottom here, all technical staff, you would have understood that to be who?
DR. COOK:
A. These would have been the technologists themselves involved in the staining of IHC.
COFFEY, Q.C.:
Q. And the pathologists, well the HSC would be the General Hospital, St. Clare's and out of town hospitals, what, if anything, did you believe at the time about how widely distributed this was?
DR. COOK:
A. This would have been widely distributed throughout the province.
COFFEY, Q.C.:
Q. At the time in April, 2003, did you understand or have any understanding about whether or not Dr. Williams would have seen this?
DR. COOK:

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A. No, he wouldn't have.
COFFEY, Q.C.:
Q. So it would have gone as far as--as high as yourself, as clinical chief.
DR. COOK:
A. And myself and Dr. Desmond Robb.
COFFEY, Q.C.:
Q. And the assertion that those eight stains are unreliable, erratic and therefore unhelpful for diagnostic purposes, didn't involve any more inquiries by yourself as to what was meant by that? How extensive any such unreliability was, what it might all mean?
DR. COOK:
A. Well, up to that time, I mean, we looked at this as being in the world of immunohistochemistry. At that time, immunohistochemical stains can vary from day to day, can vary in intensity, can vary in staining characteristics. So, we looked at immunohistochemistry as a variable event.
COFFEY, Q.C.:
Q. And you would have attributed or did attribute such variability to what?
DR. COOK:

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A. Well, the fact that you're dealing with a process that's very manual oriented, if it's about a 40 or 50 step process in the staining of immunohistochemistry, there's a lot of variables in regards to the preparation of the tissue, the processing, the stain itself, the interpretation. So, there was a lot of variability there in the production of that slide.

COFFEY, Q.C.:

Q. Did you ever ascertain what efforts were underway to find a solution?

DR. COOK:

A. Not at that time? That was, like I said, I left that to Doctor Ejeckam.

COFFEY, Q.C.:

Q. At the time, Doctor Ejeckam, in relation to immunohistochemistry had what, if any, titles?

DR. COOK:

A. He didn't have a title per se other than I looked at him as a resource person for immunohistochemistry.

COFFEY, Q.C.:

Q. What about other physicians, would they have had any--other pathologists, I mean, for

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example, whose Doctor Ejeckam's or if you're sitting in Grand Falls or Corner Brook or for that matter, in St. Clare's and you're not Doctor Cook -

DR. COOK:

A. Well, Doctor Ejeckam, I mean, what we did in those days is that pathologists who had an interest in particular aspects of pathology would take the lead in either issuing protocols or providing information for pathologists. We have, say, pathologists such as our new pathologists in breast pathology. Doctor Carter would come in, even though she wouldn't have any particular title, people would recognize her as being a resource person in breast pathology. Someone would see another pathologist as being a resource person in dermatology. So, that wouldn't be unusual.

COFFEY, Q.C.:

Q. And I appreciate you saw Doctor Ejeckam as a resource person in immunohistochemistry, but what, if any, reason would anyone else view him--why would anyone else view him in that regard?

DR. COOK:

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A. Again, probably common knowledge around at that particular time. I mean, pathologists tend to talk to each other. So, I mean, it wouldn't have raised any concerns; here was a pathologist taking a lead in something, a pathologist showing an interest in something and acting on it.

COFFEY, Q.C.:

Q. Could Exhibit P-0904 please. This is an agenda for a surgical pathology review committee meeting scheduled for April 15, 2003. It's copied to Doctor Williams and Doctor Cook, yourself. The agenda is called to order and business arising. And the Terms of Reference, paragraph 2.1, are spelled out here. And they include standardized reporting of pathology specimens; performing tissue audits on surgical specimens; forum for interesting and/or difficult cases; chaired by a pathologist; meet once every two months; and the committee would report directly to the vice-president of medical affairs and make recommendations if necessary. So, this agenda, would you have approved of this?

DR. COOK:

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A. Yes.

COFFEY, Q.C.:

Q. Please, Exhibit P-1572. Thank you, Registrar. These are the minute of the meeting of April 15, 2003 of the surgical pathology review committee. Doctor Ejeckam is present as chairman; Doctor Babcock was a surgeon?

DR. COOK:

A. No, he's a radiologist.

COFFEY, Q.C.:

Q. Radiologist, I apologize. Dr. Dawson?

DR. COOK:

A. Gyne oncologist, I believe.

COFFEY, Q.C.:

Q. Dr. M. Parai?

DR. COOK:

A. Pathologist.

COFFEY, Q.C.:

Q. Dr. J. Siddiqui?

DR. COOK:

A. Medical oncologist.

COFFEY, Q.C.:

Q. Dr. Thavanathan?

DR. COOK:

A. General surgeon.

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COFFEY, Q.C.:
Q. And Dr. Kwan?
DR. COOK:
A. Surgeon oncology.
COFFEY, Q.C.:
Q. This is noted, "call to order. The first meeting of the surgical pathology review committee was called to order by Dr. Ejeckam" and under the paragraph 2.1 (a) standardized reporting of pathology specimens. It notes there "Dr. Ejeckam asked the members for input for standardized reporting of pathology specimens. After much discussion, it was agreed that ER and PR receptors be done automatically on breast surgery cases. Since HER2/neu testing is expensive, only done when requested. It was suggested it should be performed automatically on patients with a past history of carcinoma of the breast." Now sir, the reference in the second sentence there to "after much discussion, it was agreed that ER and PR receptors be done automatically on breast surgery cases." As of April 2003, what was the situation in that regard?
DR. COOK:

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A. It was always done automatically on breast cases.
COFFEY, Q.C.:
Q. So these minutes, at some point, would have come to yourself?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. At some point later. Did you question that as to why there would be an assertion--if it was always being done, why would it be agreed that ER/PR receptors be done automatically?
DR. COOK:
A. No one ever questioned it. I mean, you know, our practice was, both at the General and hospital sites that whenever you got a breast cancer, one of the things that you do is order an ER and PR, unless come--unless there was discussion at that meeting that there was concern by oncologists that this wasn't done.
COFFEY, Q.C.:
Q. At that--the notion that it, for some cases, perhaps wasn't being done or automatically ordered, had that come to your attention before this?

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DR. COOK:
A. Not before that.
COFFEY, Q.C.:
Q. How about subsequently?
DR. COOK:
A. After, it did.
COFFEY, Q.C.:
Q. Okay. Could you tell the Commissioner about that?
DR. COOK:
A. I received a phone call from one of our oncologists letting me know that there were some cases that ER and PRs were not done automatically on breast cancers.
COFFEY, Q.C.:
Q. And what, if anything, did you do then?
DR. COOK:
A. Well, I sent out a memo to all pathologists, I think that was some time in 2004, stating that as a reminder that this should be done.
COFFEY, Q.C.:
Q. Doctor, here in the same April 15th minutes, paragraph 3.1 under new business, "ER and PR receptors. Dr. G. Ejeckam stated that ER and PR receptors are not being performed for the

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next six weeks due to a technical problem. If a solution cannot be found, these tests will be sent outside St. John's. He stated it is being considered to send one or two technologists to Halifax or Toronto for training." Doctor, the idea of--well, the idea that it was ER and PR receptors are not going to be performed for about six weeks, that wouldn't have been--by the time these minutes came along to you, that wouldn't be new to you, because you would have gotten the April 4th memo?
DR. COOK:
A. Right.
COFFEY, Q.C.:
Q. Okay. The idea tough that Dr. Ejeckam states here, he stated "it is being considered to send one or two technologists to Halifax or Toronto for training" in relation to ER and PR receptors, which is what this paragraph anyway is about, did--when you got these minutes, well had that come to your attention by the time you got these minutes?
DR. COOK:
A. I looked at that and I mean that's something

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that would come under the program director and a divisional manager.

COFFEY, Q.C.:

Q. Which would be who in this context?

DR. COOK:

A. Mr. Terry Gulliver and Mr. Barry Dyer, who was--Barry Dyer for the divisional manager for pathology.

COFFEY, Q.C.:

Q. So you saw that as their--to arrange such a thing, if necessary, would be their function?

DR. COOK:

A. If Dr. Ejeckam recommended that to be done, that would be under them.

COFFEY, Q.C.:

Q. Did you ever take that matter up with Mr. Gulliver or Mr. Dyer?

DR. COOK:

A. Not at that time, no.

COFFEY, Q.C.:

Q. At some point in time?

DR. COOK:

A. At some point in time I did, yeah.

COFFEY, Q.C.:

Q. When was that?

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DR. COOK:

A. That was around June of ’03, I believe.

COFFEY, Q.C.:

Q. So about two months after this?

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Did you speak to Dr. Ejeckam about it at the time?

DR. COOK:

A. No, I did not.

COFFEY, Q.C.:

Q. Exhibit P-0113, please? This is page two is a memo of May 2nd, 2003, again to pathologists in the Health Sciences Centre, St. Clare’s and out-of-town hospitals from Dr. Ejeckam. The subject here is ER/PR immunohistochemical stains, and on page four, his signature appears there. It’s copied to the site chief in the Health Sciences Centre and St. Clare’s. In this context, that would be yourself at St. Clare’s?

DR. COOK:

A. Right.

COFFEY, Q.C.:

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Q. Site chief, and the site chief at the Health Sciences Centre at the time would be Dr. Parai?

DR. COOK:

A. Parai.

COFFEY, Q.C.:

Q. S. Parai, and Barry Dyer and the technical staff on immunohistochemistry. Now sir, here he opens by saying "I’m glad to inform you that we have rectified the difficulties related to the immunostain of ER/PR. Therefore we can now resume regular requests for these antibody stains. I will, however, like to bring the following information to your attention" and then there are a number of paragraphs, the first of them dealing with or specifying or stating that "results of the immunostains may be affected by various types of problems with fixation, delayed, over and under and uneven tissue dehydration and tissue reprocessing." References to the necessity for the optimal fixation time to be 18 to 24 hours in ten percent neutral buffered formalin, underlined, and it goes on at some length then, this memo does, including at

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paragraph three, referring to normal breast tissue as internal controls, the second level control. Doctor, when you got this memo, well other than being advised first of all--well, first of all, did you know this memo was coming? I’ll ask you that.

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. To be advised that they’ve rectified the difficulties related to the immunostain of ER/PR, did you ever make any inquiries as to what was rectified?

DR. COOK:

A. Not at that time, no.

COFFEY, Q.C.:

Q. When did you do so then?

DR. COOK:

A. I did so in June of ’03.

COFFEY, Q.C.:

Q. Did you speak to anyone else about this when you first received it?

DR. COOK:

A. No.

COFFEY, Q.C.:

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Q. The information contained in this memo relating to estrogen receptor and progesterone receptor testing generally, was any of this new to you at that time?
DR. COOK:
A. Overall covered most of my knowledge. There was information there on the cutoff point for the NIH which was interesting to note.
COFFEY, Q.C.:
Q. That's at paragraph five, I take it?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. Had you known of that before that time?
DR. COOK:
A. No, that was the first time I seen that type of reference, in particular, to the National Institute of Health.
COFFEY, Q.C.:
Q. The idea that, paragraph 7 for example, ER positive tumors -
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. - and he lists four there.

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DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Had you been aware of that before that time?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And, in fact, is there another one that's missing from that?
DR. COOK:
A. There's two that's missing from that. There lobular and carcinomas in male breast.
COFFEY, Q.C.:
Q. Doctor, having received this memo, did you do anything? You didn't speak to anybody about it. Did you make any inquiries yourself of the literature or text?
DR. COOK:
A. No, I thought it was a good memo submitted for information purposes and that was sort of the thing I was looking at people to take the initiative in and forward that type of information to pathologists across the system.
COFFEY, Q.C.:
Q. Did you make any inquiries at the time--and

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you say pathologists across the system, would that be across the Health Care Corporation or across the Island and Labrador for that matter?
DR. COOK:
A. Well, I looked primarily at the Health Care Corporation.
COFFEY, Q.C.:
Q. Did you make any inquiries as to whether or not pathologists outside St. John's all received this?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Whose job, if anyone's or responsibility, if anyone's, was it to ensure that if it's addressed to out of town pathologists and out of town hospitals that it actually went out to the pathologists and out of town hospitals?
DR. COOK:
A. I guess it would be our hospital mailing system to make sure that the memo was delivered to pathologists in those particular areas. I -
COFFEY, Q.C.:

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Q. The contents--sorry, Doctor, go ahead.
DR. COOK:
A. I can't tell you the specific individual who'd be responsible for that in the mailing system, but that would be the area that I would suspect to have, you know, control and authority over it.
COFFEY, Q.C.:
Q. Doctor, in terms of the contents of the May 2, 2003 memo, did you take any issue with any of the contents of it?
DR. COOK:
A. No, thought it was a good memo.
COFFEY, Q.C.:
Q. Now Doctor, at that point in time, May of 2003 with the resumption of ER and PR staining in St. John's, what, if any, quality assurance measures were in place to ER and PR stains?
DR. COOK:
A. None in particular for ER and PR.
COFFEY, Q.C.:
Q. I take it whatever measures there were for IHC staining generally -
DR. COOK:
A. Yes, they would be looked, the ER and PR would

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be looked at as a total package. I mean, if there was a case that was referred for outside consultation that involved review of the slides, the ER and PR would be part of that overall package and review.

COFFEY, Q.C.:

Q. But a case with ER and PR slides does not fall into that group of cases referred outside then. No one else outside would ever come to look at the slides?

DR. COOK:

A. Could come look at those slides if there was a review within the department. If for whatever reason a pathologist wanted to review an original case, it could be reviewed by another pathologist within the same institution.

COFFEY, Q.C.:

Q. Doctor -

COMMISSIONER:

Q. Sorry, would you run that past me again. Are you saying that it would be normal for one pathologist to review another pathologist's-- slides having been read by another pathologist or is it just in the context of that person's cancer having reoccurred and an effective new

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case comes along?

DR. COOK:

A. Commissioner, that would be the case. I mean, if there was a metastatic lesion, say, that was in a lung or the liver, the pathologists received that liver and they knew that the patient had a previous breast cancer, they would go back and review the original histology and do comparisons with the histology from the primary metastatic lesion.

COMMISSIONER:

Q. Is that for the purpose of determining whether it's really same cancer or another cancer or is it -

DR. COOK:

A. Oh, that's for the purpose of determining the correlation to make sure that what you have in the lung or the live arose from the breast.

COMMISSIONER:

Q. Yes, okay.

COFFEY, Q.C.:

Q. It wouldn't necessarily be looking back at the original ER/PR slides?

DR. COOK:

A. They would not necessarily, no.

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COFFEY, Q.C.:

Q. Now Doctor, in the same exhibit, P-0113, page five, there's a memo from Terry Gulliver, I'm sorry, to Terry Gulliver from Doctor Ejeckam. The subject is immunohistochemical stains at the Health Sciences Centre, June 19, 2003. And Doctor Ejeckam opens by saying, "the following persistent erratic results of immuno stains in our laboratory. I accepted to work closely with the technical staff in order to rectify this problem, despite the fact that that the problem seems to have been arrested, the state of immuno stain at the General Hospital, Department of Laboratory Medicine and Pathology is still unsatisfactory". And then the doctor goes on to explain why he takes that view, over the next three pages, six numbered paragraphs and he concludes with the comment, "I therefore advise that you kindly take a hard look at the above and then commit the necessary resources, human and financial, to this special all important and only service in the Province of Newfoundland". Now, it's copied to Doctor Desmond Robb as the discipline chair of laboratory medicine;

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yourself as clinical chief and site chief of St. Clare's; Doctor S. Parai, the site chief; and Barry Dyer, manager of histopathology. Now, did you speak to anyone about this memo?

DR. COOK:

A. I spoke to Doctor Ejeckam.

COFFEY, Q.C.:

Q. And what, if anything, was said?

DR. COOK:

A. Well, when I went in to speak to him, I inquired as to, first of all, what do we do in terms of the rectification of the stain. We talked about the pH levels, the antibody concentrations, the incubation times, but that was only a small portion of the actual discussion. What came out of that discussion and what I read out of that discussion or that memo was the overall theme of that memo. There was a concern about the resources that we had available at the General Hospital and also issues regarding the management structure at that particular time. There was frustration in trying to get things done, according to Doctor Ejeckam, particularly with the managers.

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COFFEY, Q.C.:
Q. What managers?
DR. COOK:
A. I believe he mentioned Mr. Dyer and Mr. Gulliver.
COFFEY, Q.C.:
Q. Did he elaborate on that?
DR. COOK:
A. Well, there was a specific example he gave to me regarding trying to get some secretarial work done regarding minutes for a surgical pathology review committee, approached a particular secretary and there was an issue whether that should be done or not. That particular secretary approached, I think, Mr. Dyer who agreed that those minutes shouldn't be typed. That was just an example of dealing with frustrations in the system overall and he related that particularly to his frustrations and IHC.
COFFEY, Q.C.:
Q. So, I take it, the overall message, both in the memo and in your meeting with him was that he was not happy with the then current state of affairs.

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DR. COOK:
A. That's correct.
COFFEY, Q.C.:
Q. Did you speak to anyone about that?
DR. COOK:
A. I did.
COFFEY, Q.C.:
Q. Who did you speak to?
DR. COOK:
A. I spoke to Mr. Terry Gulliver immediately after a meeting.
COFFEY, Q.C.:
Q. Did you speak to anyone else?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Okay. Why didn't you speak to anyone else?
DR. COOK:
A. Well, after speaking to Mr. Gulliver, I felt that the measures would be taken to improve the situation and move ahead. And I looked at this as a go forward basis.
COFFEY, Q.C.:
Q. Did you speak to Doctor Williams about this?
DR. COOK:

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A. I did not, at the time. I looked at this as an internal laboratory issue.
COFFEY, Q.C.:
Q. Why would that, even if it's an internal laboratory issue, why wouldn't you bring it to Doctor Williams' attention?
DR. COOK:
A. Well, I think Doctor Williams at the time, I don't think he was available. I think he was off sick leave at that particular time.
COFFEY, Q.C.:
Q. And he was back about 10 weeks later.
DR. COOK:
A. In September.
COFFEY, Q.C.:
Q. Yes. So, you didn't raise it with him then either?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Could you tell us please then what it was-- what you can recall of your conversation with Mr. Gulliver?
DR. COOK:
A. Well, I said to Mr. Gulliver that Doctor

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Ejeckam is getting frustrated, there are certain movements that he wants to or certain initiatives that he wants to place in immunohistochemistry. There was concern over the actual location of IHC. There was concern over the ability to centralize and specialize technologists in that particular area. So, Mr. Gulliver had the copies of those memos and agreed and I agreed that he would work together with Doctor Ejeckam to rectify the situation.
COFFEY, Q.C.:
Q. Did you ever take this up with anybody afterward?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Why not?
DR. COOK:
A. Well, I felt they were moving ahead. I was monitoring the situation. I knew eventually that the IHC had been moved out of the general histology lab into the hormonal assay lab, into a separate area. Mr. Gulliver was making moves to do as much as he can with

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specializing the text in that particular area in IHC. Later on that year Mr. Dyer informed me of the intent to purchase a new Ventana automated system for IHC. So, movement was being made to rectify what was outlined in that memo.

COFFEY, Q.C.:

Q. I appreciate that, but why wouldn't you have spoken to Doctor Ejeckam about it afterward?

DR. COOK:

A. Because I felt that an agreement or an understanding had been made with Mr. Gulliver to address his concerns.

COMMISSIONER:

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

COFFEY, Q.C.:

Q. Okay, thank you. Now, did you ever speak with Doctor Robb about this after the June 19 memo?

DR. COOK:

A. No, I didn't.

COFFEY, Q.C.:

Q. Doctor Parai?

DR. COOK:

A. No.

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COFFEY, Q.C.:

Q. Mr. Dyer?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. By the time you received the June 19th, 2003 memo did it ever cross your mind that there might be a concern about the validity of the test using these eight stains, the results, test results?

DR. COOK:

A. No, it did not.

COFFEY, Q.C.:

Q. Now with hindsight do you have any thoughts on that, as to why that was so?

DR. COOK:

A. Well, like I said before, when it came to the other tests, when you look at stains such as CD3, CD5, CD10, whatever, they're used in conjunction as part of a panel with other stains and you use those in conjunction with your routine H & E or histological examination. In terms of the lymphomas, we don't make a diagnosis of lymphomas alone based on the results of one or two

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immunoperoxidase stains, we use a battery of stains along with our flow cytometry and molecular genetics. So there was a variety of criteria that we look at to make a diagnosis of malignancy, not just based on one or two stains that may be erratic or unhelpful. We look at the histology, we look at histochemical stains and molecular. There's other parameters that we look at as opposed to just looking at one or two stains.

COFFEY, Q.C.:

Q. Now, that's true for those other six stains, but for ER and PR that's not true, is it?

DR. COOK:

A. Well, for ER and PR I thought back, as I previously said, to the Cleveland situation and what if anything was coming out from tumor boards.

COFFEY, Q.C.:

Q. So it did--you at the time thought of Cleveland, it crossed your mind at the time, didn't it, that there might be some question about the validity of what was going on here before Dr. Ejeckam inserted himself?

DR. COOK:

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A. Well, I mean, if there had to been any issue with the ER and PR slides, I mean, my understanding or my hope was that it would have been picked up in that review.

COFFEY, Q.C.:

Q. And if it wasn't picked up in Cleveland, for whatever reason, you know, the idea that there might be something to pick up did cross your mind, otherwise you'd never have thought of Cleveland, would you?

DR. COOK:

A. No, I wouldn't say that, Mr. Coffey. You know, it--when I read that memo first, you know, I thought back to the Cleveland situation and was there anything that had come out of that situation that would have been cause for concern.

COFFEY, Q.C.:

Q. Why would you have thought Cleveland would have brought it to your attention at all?

DR. COOK:

A. Well, I mean, they're outside pathologists, they're reviewing our cases, I mean, you have a duty and an obligation if you do see a difference of opinion from a referring

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pathologist, that that would be recorded on the their report. And it is common courtesy to notify the original pathology of any change in interpretation of your histological slides or status.

COMMISSIONER:

Q. Sorry, I just wanted to clarify something regarding the Cleveland, which I just went back to my note and I didn't note down if you did say it. You said, I believe, that you sent 30 to 33 cases to Cleveland?

DR. COOK:

A. Approximately. That was my understanding, Commissioner, at that particular time.

COMMISSIONER:

Q. And were they all of the same nature or were they of varying types of cases?

DR. COOK:

A. Varying types of breast carcinomas.

COMMISSIONER:

Q. Okay.

COFFEY, Q.C.:

Q. Have you ever gone back to check what the status was of those Cleveland cases?

DR. COOK:

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A. I have.

COFFEY, Q.C.:

Q. When was that and what did you find?

DR. COOK:

A. Well, what I found was there were 35 or 36 cases there of which there were about, I believe, four or five ER and PR stains and they showed a good correlation, I believe with the exception of one.

COFFEY, Q.C.:

Q. So, wait now, so out of the 35 or so, 33, five of them involved ER and PR?

DR. COOK:

A. That's my understanding.

COFFEY, Q.C.:

Q. Okay, so there was only actually--so Cleveland only saw, would have only seen five ER slides and five PR slides?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And did you check those particular patients' files?

DR. COOK:

A. I didn't check them all. I checked the ones

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that were related to St. Clare's.

COFFEY, Q.C.:

Q. Okay. And how many of those were, I'm sorry, were related to St. Clare's?

DR. COOK:

A. There would have been maybe three or four, I understand.

COFFEY, Q.C.:

Q. Out of the five?

DR. COOK:

A. Out of the five.

COFFEY, Q.C.:

Q. And the ones at St. Clare's, what did you find?

DR. COOK:

A. I found good correlations with the results that we had submitted with Cleveland had found.

COFFEY, Q.C.:

Q. When you say good correlation, correlation of what?

DR. COOK:

A. That it was positive or negative.

COFFEY, Q.C.:

Q. So your understanding was Cleveland had redone

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the ER and redone the PR?

DR. COOK:

A. Oh, they didn't redo it, they looked at our slides.

COFFEY, Q.C.:

Q. Okay.

DR. COOK:

A. So the original slides were sent down and reviewed by the Cleveland pathologists, all the histology and all the ER and PR slides themselves.

COFFEY, Q.C.:

Q. Do you know if the control slides were sent?

DR. COOK:

A. I can't be sure on that. There may have been control slides sent with the case.

COFFEY, Q.C.:

Q. Now you say that there was correlation except for one case?

DR. COOK:

A. There was one case, I believe, that there was a variation in the percentage.

COFFEY, Q.C.:

Q. Do you recall how much the variation was?

DR. COOK:

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A. The variation, I think we had reported 60 percent where the variation was probably around 40 percent for the Cleveland pathologist.
COFFEY, Q.C.:
Q. So when they said 40, you said 60 or they said 20 and you said 60?
DR. COOK:
A. We'd say 60, they said 40.
COFFEY, Q.C.:
Q. Oh, 40, okay. And so that's the one case that had the variance?
DR. COOK:
A. As far as I can remember.
COFFEY, Q.C.:
Q. When was it that you checked that, Doctor?
DR. COOK:
A. That particular recheck was around a few months ago.
COFFEY, Q.C.:
Q. Okay, so that's since the Commission of Inquiry was established?
DR. COOK:
A. Yeah.
COFFEY, Q.C.:

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Q. Can you tell us why you did that then?
DR. COOK:
A. Well, because I thought about the situation when this came up, what in actual fact happened in the Cleveland situation. I mean, I knew we had a few cases with St. Clare's and there were other cases from elsewhere across the province, so I was interested in the overall outcome and interpretation of that.
COFFEY, Q.C.:
Q. And so, Doctor, until then several months ago when you actually went and looked at the Cleveland cases, at least the ones at St. Clare's, you've indicated, when you checked, you found that about five or so out of the 33 had ER and PR slides sent to -
DR. COOK:
A. Approximately that.
COFFEY, Q.C.:
Q. Okay. So the other, well, doing the arithmetic, the other 28 didn't?
DR. COOK:
A. As far as I know.
COFFEY, Q.C.:
Q. And are you able to tell the Commissioner why

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the other 28 wouldn't have had the slides sent?
DR. COOK:
A. The other 28 wouldn't have ER and PRs?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. They may be metastatic deposits or they may be cases where there would have been needle cores, that there wouldn't be ERs and PRs ordered on that.
COFFEY, Q.C.:
Q. Thank you, Commissioner.
COMMISSIONER:
Q. We'll take the afternoon break.
(RECESS)
COMMISSIONER:
Q. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Dr. Cook, you've indicated that in the practice of pathology, certainly in dealing with stains, they will-- it's not unusual to see them vary from day to day?
DR. COOK:

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A. That's correct.
COFFEY, Q.C.:
Q. What is it about them that varies, what are we talking about here?
DR. COOK:
A. There may be the intensity of the stain, you might get varying shades, or like we were talking about, immunohistochemistry, varying shades of brown, from low, moderate, to high intensity, so there may be a difference in intensity of staining from cell to cell or even from slide to slide or even if you stain the stain from one day to the next, you may see variation in intensity.
COFFEY, Q.C.:
Q. Okay. Doctor, if we just look back, please, at Exhibit P-0113, which is there? I'm going to take you back to page 1 of the exhibit, the April 4th, 2003 memo.
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. The immunohistochemical stains for those particular antibodies, there are eight, "Have remained unreliable, erratic and therefore

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unhelpful for diagnostic purposes." Now, when you received this, of course, you would have been one of the utilizers of the slides, you were one of the people at whom this memo is directed?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Had you noticed before or up to April, 2003 that the slides, IHC slides you were receiving were unreliable or erratic?

DR. COOK:

A. I mean, not specifically into regard to that, but overall in terms of immunohistochemistry, I mean, that's something that's not unusual in terms of variability and variability in staining from one case to another. I mean, in terms of general--in terms of general knowledge of pathology and discussion around immunohistochemical stains by pathologists.

COFFEY, Q.C.:

Q. And, sir, when we go to page 2 of the exhibit, which is the May 2nd, 2003 memo, Dr. Ejeckam opens by saying, "I'm glad to inform you that we have rectified the difficulties related to

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the immunostain of ER/PR."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Did you notice any difference after May 2nd, 2003 in the ER/PR slides?

DR. COOK:

A. I mean, to be honest with you, I didn't see that much of a difference.

COFFEY, Q.C.:

Q. So you never did take it up with Dr. Ejeckam, I take it, as to, well, what was all that about, I don't see a whole lot of difference, if any, and back in April you had stopped the ER and PR staining and now you're saying, now you, Dr. Ejeckam, are saying that you've rectified the difficulty?

DR. COOK:

A. Well, Mr. Coffey, beauty lies in the eyes of the beholder. I mean, there are some pathologists who would review one stain with a certain appreciation in quality and another pathologist who would look at the same stain and view it as something else.

COFFEY, Q.C.:

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Q. In the sense of unsatisfactory, perhaps?

DR. COOK:

A. Well, one individual may think the stain is crisp and adequate, another individual may think it's under stained, another individual may think it's over stained.

COFFEY, Q.C.:

Q. I take it then that in terms of at least you're speaking for yourself, you didn't notice any particular difference at the time?

DR. COOK:

A. And I didn't notice any great difference in the stains.

COFFEY, Q.C.:

Q. Doctor, if we could, please, yes, this May 2nd, 2003 memo ends with a comment, the sentence, "We are working on the remaining antibodies and hopefully all normal immunostains will resume soon." Did you ever make any inquiries about that?

DR. COOK:

A. No, I did not. I mean, as I said before, I gave Ejeckam the ball and let him run with it. Any time that we needed any extra stains or that were off line or whatever, we could

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easily refer these stains out to another institution.

COFFEY, Q.C.:

Q. Now, do you know if in 2003 any of the eight stains or patients who needed the results of any of those eight stains did have their samples sent out?

DR. COOK:

A. Not that I'm aware of.

COFFEY, Q.C.:

Q. Was there any difference other than the staining or did you even--or did you notice any difference in the staining at all?

DR. COOK:

A. I mean, as I said before, Mr. Coffey, I didn't see a great deal of difference in the stains.

COFFEY, Q.C.:

Q. Okay. Anything other than the stains, the fact that there was staining at all?

DR. COOK:

A. Well how would I -

COFFEY, Q.C.:

Q. For example, if, for example, if there was a problem, as it turns out, I gather, with hindsight now that perhaps some things were

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not staining and they should have been, then there's an absence of staining is what I'm getting at here.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Doctor, I take it then that overall you didn't see any difference at all, staining or otherwise?

DR. COOK:

A. Personally, no.

COFFEY, Q.C.:

Q. Okay. Looking at page 5 of the exhibit, the June 19th, 2003 memo, the second page of it, the end of paragraph 3. On June 19th Dr. Ejeckam had written "To do less will simply become a gamble where you may win or lose. This obviously will spell disaster." I appreciate you took this up with Mr. Gulliver.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. But that sort of a statement by a pathologist whom you'd given, you'd given his head and let him run with it, that sort of an assertion in

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writing by him over his signature, this wasn't, didn't occassion you bringing this to Dr. Williams' attention, discussing it?

DR. COOK:

A. No, because I had made the discussion with Mr. Gulliver and was satisfied that Mr. Gulliver was going to address Dr. Ejeckam's concerns.

COFFEY, Q.C.:

Q. What, if anything, would have had to have happen in order for you to have discussed it with Dr. Williams?

DR. COOK:

A. Well, if Mr. Gulliver wasn't acting on it, if we had an indication that a patient had received a wrong result or there was evidence of an index case or conversion, I would have acted on it.

COFFEY, Q.C.:

Q. Now, Doctor, I take it that for an index case or involving a conversion, which I take it is someone who's had, in this context, perhaps, a negative result, ER/PR result first and then on retest a positive result, I take that requires that there at least be a retesting, at least one retest to give you a different

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result?

DR. COOK:

A. Could be a retest in the system, yes.

COFFEY, Q.C.:

Q. In the context at the time, in 2003, did it ever cross your mind that perhaps we should retest at least a couple of these to see what -

DR. COOK:

A. No, Mr. Coffey, I never had any indication or concerns from anyone. There was no concerns from those attending tumor boards. And again, I go back to the Cleveland situation, there's no concerns that came out of that. There was nothing there to indicate to go ahead and do a review.

COFFEY, Q.C.:

Q. You know, in terms of Cleveland at the time, I take it, that you had no idea in 2003 as to how many ER and PR tests actually went to Cleveland?

DR. COOK:

A. I mean -

COFFEY, Q.C.:

Q. You were thinking -

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DR. COOK:

A. I was thinking at St. Clare's.

COFFEY, Q.C.:

Q. Yes. But you didn't know how many actually had gone to Cleveland, did you?

DR. COOK:

A. Well, province wide? No, not at that time in Cleveland, when I'm thinking back in 2003.

COFFEY, Q.C.:

Q. If we could, please, just a moment, Commissioner. If we could, please, Registrar, Exhibit P-1398? Doctor, do you recognize the handwriting here?

DR. COOK:

A. That's my handwriting.

COFFEY, Q.C.:

Q. Okay. It says "Spoke to Dr. Ejeckam with Terry Gulliver morning of March 7th, 2006 re the hold on certain stains in 2003. I asked him," that would be you, "asked him," Dr. Ejeckam, "what he meant by erratic. Dr. Ejeckam reported that it meant some stains worked some days and didn't work on others. I asked him if he should have recommended a review of stains at that time. He replied to

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me that it wasn't his place to initiate or recommend a review."

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Now, how did this come up on March 7th, 2006?

DR. COOK:

A. Well, again, you're thinking back, you know, you're looking at the current situation and you're thinking back in your mind is there anything you missed, is there anything you should have done at that particular time, you know, looking back at hindsight. And that was a question asked in that regard.

COFFEY, Q.C.:

Q. So why was it on March 7th, 2006, you went to Dr. Ejeckam to ask him about the idea of retesting in '03?

DR. COOK:

A. Well, we were in a--we had just gone through a major event, a major situation, and again -

COFFEY, Q.C.:

Q. Why did it take until March 7th, 2006 for you to raise that with him?

DR. COOK:

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A. Well, because I had no reason to think, in 2003, that we needed to go back to do a review. There was nothing in 2003 -

COFFEY, Q.C.:

Q. I'm asking between May of 2005, which we're about to get to, and March 2006, why did it take ten months for you to ask Dr. Ejeckam that question?

DR. COOK:

A. Well, because I'm going through, in my mind, if there's something that we had missed, something that had indicated that we should have done a review earlier.

COFFEY, Q.C.:

Q. Now the idea that Dr. Ejeckam, you know, had been involved in a--use the word "erratic" in a memo in 2003, you would have been aware of that in the middle of 2005. That memo was kicking around -

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. - at that time, so I'm asking you why did it take, you know, nine or ten months for you to approach Dr. Ejeckam about this?

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DR. COOK:

A. Well, because you have to look at the situation at the time and around when we're doing this review, we were going full blast, concentrating all our resources on the ER and PR. I mean, we certainly didn't have time to think about taking on another review or even contemplating it at that time.

COFFEY, Q.C.:

Q. So when he told you, on March 7th, 2006, that some stains worked some days and didn't work on others, that meant what to you? You understood what? That they literally did not work?

DR. COOK:

A. No, I mean, that again, it could be variation in the staining based on a highly manual technique.

COFFEY, Q.C.:

Q. Did you explore that with him?

DR. COOK:

A. No, I didn't.

COFFEY, Q.C.:

Q. And when you asked him should he have recommended a review of stains at that time,

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in '03, and he told you that it wasn't his place to initiate or recommend a review, did you speak to him about that? Take any issue with that?

DR. COOK:

A. Well, I thought if he knew something there, when he stopped it, and again he compared the new staining with the previous staining when he came in 2002, if he had thought that there was a reason to go back and do a review, I thought he would have--he should have made a recommendation.

COFFEY, Q.C.:

Q. So you thought, in 2006, March 2006, that Dr. Ejeckam, in 2003, should have recommended not only stopping the stains, restarting them, but also a review?

DR. COOK:

A. If he had knowledge that, you know, the stains were of significant calibre, the staining was of significant degree, had he had any indications or any concerns, I felt then that he should have made a recommendation, if there was any concerns regarding patient care.

COFFEY, Q.C.:

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Q. At the time, having received the April 4th memo by early 2006, had it crossed your mind that perhaps, as the clinical chief, you should have taken it upon yourself?
DR. COOK:
A. As clinical chief, I would have acted on recommendations from individuals, highly trained individuals, such as Ejeckam. I certainly had no indication back in 2003 that we had any issues concerning patient care.
COFFEY, Q.C.:
Q. Well, what would have--what would you have had to have been told, in what sort of language would it have to have been expressed to you in 2003 for you to have understood there was an issue of patient care?
DR. COOK:
A. If someone was able to demonstrate to me there was a change in the stain or a result that affected treatment outcome or a treatment regime in a patient, I would have begun an investigation.
COFFEY, Q.C.:
Q. I take it if somebody had actually done a retest and had a conversion?

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DR. COOK:
A. If somebody had done a retest and had a conversion, then we would have started a process.
COFFEY, Q.C.:
Q. So absent that, absent such a situation, absent a conversion, is there any other situation in which you would have done a review?
DR. COOK:
A. If someone was able to demonstrate a trend, for instance, that we had a trend in overcalling a particular lesion or a trend in under calling, we would have certainly done a preliminary review.
COFFEY, Q.C.:
Q. That would require, of course, somebody to actually look at the statistics too, wouldn't it?
DR. COOK:
A. Not necessarily, somebody sees a trend in something, I mean, they get concerned about something, they'll go ahead and start reviewing cases.
COFFEY, Q.C.:

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Q. Was there anyone keeping track of trends in 2003, do you know?
DR. COOK:
A. In regards to what?
COFFEY, Q.C.:
Q. Well, you mentioned it as a trend. I'm just asking you. You said if someone saw a trend in the calling of particular--over calling or under calling certain types of lesions. Was there anyone actually keeping track of trends, do you know?
DR. COOK:
A. No, there wasn't.
COFFEY, Q.C.:
Q. Exhibit P-0907, please? Now Doctor, this is a memo of September 30th, 2000--I apologize, that's the wrong page. Actually, it's the page--it's the September 30, 2003 memo to Dr. Williams from Dr. Ejeckam, sending Dr. Williams a copy of the surgical pathology review committee meeting minutes and the second page of that are the minutes of committees meeting of September 23rd 2003 and in business arising, there's a reference to paragraph--in 2.1, estrogen and progesterone

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status. Dr. Ejeckam stated the technical problem with staining for ER and PR stains has been solved. Doctor, would a copy of this, these minutes have come to you?
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. And in reference to "the technical problem with staining for ER and PR stains has been solved," you would have read that?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. What would you have understood by it?
DR. COOK:
A. Well, again, as I understood from talking to him in June of '03, there would be an issue regarding a number of things, at the analytical aspect of it, in terms of the pHs and incubation times of the staining procedure, that sort of thing.
COFFEY, Q.C.:
Q. Did you ask--this was this conversation you had in June of '03 with Dr. Ejeckam, did you ask Dr. Ejeckam what, if anything, that all

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meant, in the sense of titration, incubation times and stuff, what the possible effects could be if, for example, the titration was off?

DR. COOK:

A. No, I didn't.

COFFEY, Q.C.:

Q. The antigen retrieval time was off?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. What effect it could have on the result?

DR. COOK:

A. No, because I looked at the overall quality of the staining that I saw before his intervention and the staining after his intervention, and as I said before, I didn't see much difference in the stains.

COFFEY, Q.C.:

Q. Doctor, did you have any understanding, in 2003, that there was a possibility that one or more of those things, alone or in combination, could result in there being no staining when there should have been some staining?

DR. COOK:

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A. Not in 2003.

COFFEY, Q.C.:

Q. In 2003, did you make any efforts, do any research yourself in relation to immunohistochemistry?

DR. COOK:

A. Nothing more than my standard knowledge, no.

COFFEY, Q.C.:

Q. Now Doctor, you've referred to the fact that in 2000, you'd come across a reference to utilizing internal controls for ER and PR testing.

DR. COOK:

A. Um-hm.

COFFEY, Q.C.:

Q. Why had you--was that just by chance you came across that?

DR. COOK:

A. Yeah, I mean it would have been an article in a text book I believe that, I mean, I may have been reading up on something or other, or it could have been at my office just doing some general reading.

COFFEY, Q.C.:

Q. Do you recall--why is it you recall it was

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2000?

DR. COOK:

A. It was roughly, I remember, the time that we were closing the Grace and doing the move that I remember a lot of things going on at that time regarding the close of the Grace and reading that particular article.

COFFEY, Q.C.:

Q. Why--I mean, you must read--in your job, you must read an awful lot of articles.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Is there any particular reason that that, the year, and you associate it with the closing of the Grace and the time frame, why that stands out?

DR. COOK:

A. No, just the way that I remember reading that particular article and concentrating more on internal controls and that was about the same year that we were making the big move at the Grace.

COFFEY, Q.C.:

Q. Was there any discussion between yourself and

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other pathologists about internal controls?

DR. COOK:

A. No.

COFFEY, Q.C.:

Q. The June 19th memo does refer to--in 2003, does refer to the idea of litigation, correct?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Litigation in this context would certainly involve aspects of patient care, wouldn't it?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. So Dr. Ejeckam's June 19th, 2003 memo certainly raised issues of--or related to patient care potentially?

DR. COOK:

A. That could happen on down the road if you didn't make improvements now, making now means 2003.

COFFEY, Q.C.:

Q. And in the context, because there had been changes you had understood between April and June -

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DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. - of ’03, you’d understood that, so I take it the idea that potentially patient care might have been at risk before April, it didn’t occur to you?
DR. COOK:
A. No. Again, I get back to what I saw as the quality of the stains before April and after April.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-1913? This is a site chiefs and divisional managers minutes of a meeting of March 31st, 2004. Present are yourself, Dr. Parai, and Dr. Robb. If we could, please, looking at paragraph four, new business, on page two of the exhibit, under "4.2. New Technology. The immunoperoxidase stainer appears to be working generally well. However, there continues to be some problems with estrogen and progesterone receptors," and you’ve signed these particular minutes.
DR. COOK:
A. Um-hm.

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COFFEY, Q.C.:
Q. As the clinical chief. Do you recall what the problems were in March of 2004 that continue with estrogen and progesterone receptors?
DR. COOK:
A. Well, the only thing I could recollect was at the time, we were bringing in a new Ventana system and speaking to Dr. Robb, there was validation of the Ventana system by our technical people and there seemed to be some issues with the validation process with estrogen and progesterone receptors and that they would be corrected in a week’s time or a few days.
COFFEY, Q.C.:
Q. Did you ever follow up on that?
DR. COOK:
A. No, I didn’t. I just looked at that as a validation process.
COFFEY, Q.C.:
Q. So Doctor, I take it, what would the point be of bringing it to your attention if you were never going to follow up on it?
DR. COOK:
A. Well, it’s something that I would have asked

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Dr. Parai and Dr. Robb is "how well is the new Ventana system working?" and "when can we expect to get it up online?"
COFFEY, Q.C.:
Q. Yes, and you’re told about some problems, continue to be some problems with estrogen and progesterone receptors.
DR. COOK:
A. Yeah.
COFFEY, Q.C.:
Q. I take it, was there any system in place for this to kind of come around again to be brought to your attention for you to make inquiries further about it?
DR. COOK:
A. No, I mean, that the issue of the equipment coming on line and the validation would be in the hands of the technical aspect of the program.
COFFEY, Q.C.:
Q. Who was supposed to be doing the validation at this point?
DR. COOK:
A. That would be Mr. Gulliver and Mr. Dyer.
COFFEY, Q.C.:

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Q. They would be doing a validation of ER and PR stains?
DR. COOK:
A. Well, all the stains with the Ventana system.
COFFEY, Q.C.:
Q. So what was it they were supposed to be doing with that?
DR. COOK:
A. Well, if you have a negative ER and PR stain and you run it through the Ventana system, it should come out negative under the new system. A known negative being run through should come out negative. A known positive that’s run through should come out positive.
COFFEY, Q.C.:
Q. And that was being evaluated, you understood, by the technologists?
DR. COOK:
A. Yes, that’s correct.
COFFEY, Q.C.:
Q. So what was your understanding about technologists were to do what? Were they involved in the controls at all?
DR. COOK:
A. They would be involved in taking a positive

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control and running it through the machine and make sure we get a positive result.

COFFEY, Q.C.:

Q. How about reading the controls?

DR. COOK:

A. The reading of the controls would be done by the pathologists.

COFFEY, Q.C.:

Q. So at that point, at this point in time, March of 2004, who, if any, pathologist was responsible for IHC?

DR. COOK:

A. Well, that would have been--to oversee the IHC it still would be Dr. Ejeckam overseeing it.

COFFEY, Q.C.:

Q. And was there anything in writing at that point in time, in early 2004, to that effect?

DR. COOK:

A. No.

THE COMMISSIONER:

Q. I'm sorry, I wasn't sure I understood that, Dr. Cook. When the Ventana was being brought into operation and you were, in effect, testing it.

DR. COOK:

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A. Yes, Commissioner.

THE COMMISSIONER:

Q. What I understood you to be saying is that part of the method of testing the Ventana would be to run known results, as it were, through the system. i.e. you would have a negative stain or a positive--something you knew would become negative or positive, if properly processed?

DR. COOK:

A. That's correct.

THE COMMISSIONER:

Q. Run it through the machine and then have it read. Were you saying that it was Mr. Gulliver and Mr. Dyer who would determine was it positive or negative or would Dr. Ejeckam being doing that?

DR. COOK:

A. It could be Dr. Ejeckam or any one of the pathologists that Mr. Dyer or Mr. Gulliver brought the slides to read.

THE COMMISSIONER:

Q. Okay. So they would run the process in the same way that the technicians, the technologists would normally run if either the

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DAKO or the Ventana system were normally--in normal operation, but when it came to the point of deciding whether or not the result was as anticipated, they would be expected to take that slide to a pathologist, Dr. Ejeckam or one of the other pathologists?

DR. COOK:

A. Yeah, they would take it to them and the pathologist would give an opinion on that side and that would be used by our technical people.

THE COMMISSIONER:

Q. Okay, thank you.

COFFEY, Q.C.:

Q. Doctor, here--the word used here is "there continues to be some problems", had there been--the reference to "continuous", when did these problems with the estrogen and progesterone receptors begun, this is March of '04.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. When had they begun?

DR. COOK:

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A. The problems that came to light were around May of '05.

COFFEY, Q.C.:

Q. I appreciate that, but this stated here and we just look at here, that 4.2, right there, "However, there continues to be some problems with estrogen and progesterone receptors."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. The word "continuous" suggests that it had been going on, sort of forever, as it were or it had stopped at some point or begun at some point, continuous, do you recall?

DR. COOK:

A. My recollection of that, again, concerns the validation process that was going on. I mean, that's to the best of my knowledge.

COFFEY, Q.C.:

Q. So if we could please then, Exhibit P-1876 please? These are these site chief's and divisional manager's minutes, April 25, 2001, business arising, paragraph two. "Quality control of immunoperoxidase staining. Generally the immunos appear to be very good,

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there appears to be some problems with the estrogen and progesterone receptors."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. "The positive controls are checked daily by a pathologist; however, these need to be documented." So there's a reference here to "appears to be some problems with the estrogen and progesterone receptors, April, 2001."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. If we can look, please, at Exhibit P-0113, page one. It's the April 4, 2003 memo from Dr. Ejeckam.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. The ER and PR, amongst other stains, are described as having remained unreliable, erratic and therefore unhelpful for diagnostic purposes.

DR. COOK:

A. Uh-hm.

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COFFEY, Q.C.:

Q. Did you ever have any understanding as to how long the remained was there?

DR. COOK:

A. No, Mr. Coffey.

COFFEY, Q.C.:

Q. Okay, and exhibit P-1913, March 31st, 2004, paragraph 4.2. "The immunoperoxidase stain appears to be working generally well, however there continues to be some problems with estrogen and progesterone receptors."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. So in '01, the spring of '01 and the spring of '03, and now the spring of '04, there are references in the minutes to problems with ER and PR.

DR. COOK:

A. If we're talking about new technology, what I believe we were talking about at that time was the issue of validation.

COFFEY, Q.C.:

Q. Yes, and validation, there was something wrong with the new system or the old one?

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DR. COOK:

A. I would interpret the new system.

COFFEY, Q.C.:

Q. Something wrong with the new system.

DR. COOK:

A. Right, they're into the process of validating it.

COFFEY, Q.C.:

Q. And if there was a problem with the new system, if indeed there was, you don't know whether that was so or not, and if they fixed it or not, you don't know?

DR. COOK:

A. No, I put my reliance on them. These are trained professional people to deal with--if there's a validity problem or whatever problem was with the technology, to deal with it.

COFFEY, Q.C.:

Q. And in this context, the "they" is Mr. Dyer and Mr. Gulliver in March of '04.

DR. COOK:

A. Yes, yes.

COFFEY, Q.C.:

Q. If we could please, Exhibit P-1393? This, Doctor, are the minutes of a meeting,

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September 1st, 2004 of a division of anatomical pathology, pathologist meeting, General Hospital site. Present are Drs. Fernandez, Robb, Ejeckam, M. Parai, Wadden, Pirzada, Chittal, Morris-Larkin, Fontaine and Chittal, Parai. And paragraph 3.6, "Business Arising" says, "It's HER2/neu, ER and PR immunostaining. Dr. D. Fontaine did mention that Dr. B. Carter would like to review all the new HER2/neu ER and PR staining before returning to the reporting pathologist. Some members of the division expressed that this is unnecessary and they will continue reporting their own cases." Doctor, I take it that by September 2004, Dr. Beverley Carter had joined the Health Care Corporation?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. And in fact, she was located at what site?

DR. COOK:

A. At. St. Clare's.

COFFEY, Q.C.:

Q. And her office was located where in relation to yours?

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DR. COOK:
A. Next to mine.
COFFEY, Q.C.:
Q. Were you aware of this request by Dr. Carter?
DR. COOK:
A. I was aware that we discussed the situation of maintaining her level of confidence and competency in breast pathology. If she was coming here, she would want to see as many breast cases as possible. I can't remember discussing the issue of ER and PR in particular.
COFFEY, Q.C.:
Q. Did you ever become aware of this request and the reaction that's recorded here to it?
DR. COOK:
A. I'm not aware of that, Mr. Coffey.
COFFEY, Q.C.:
Q. So you were aware of it before today, I take it? Were you aware that this existed before today, these minutes?
DR. COOK:
A. You mean today?
COFFEY, Q.C.:
Q. Yes.

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DR. COOK:
A. I'm aware of it now.
COFFEY, Q.C.:
Q. So when did you first become aware of this?
DR. COOK:
A. When I was reviewing the various documents in preparation for the Commission of Inquiry.
COFFEY, Q.C.:
Q. Okay, so that's what I'm getting at, Doctor, so in 2004 and '05 when the ER/PR matter, you really got involved in it in 2005, it was only after the Commission of Inquiry was established that and in looking through the documentation that any one ever or you noticed that in '04, this matter had been raised?
DR. COOK:
A. That's right.
COFFEY, Q.C.:
Q. That Dr. Carter had requested this and no one, you weren't aware of a request in that regard, nor of the apparent rejection of it.
DR. COOK:
A. No, I was unaware of that.
COFFEY, Q.C.:
Q. Doctor, when you discussed the matter with Dr.

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Carter at the time back when she first came to St. John's and had, you know, the office next to yourself, and the topic got raised about, well, she'd like to keep her skills sharp or sharper by looking at more cases, okay, which is I gather what you had just referred to.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. At the time that happened, Doctor, what was your understanding about her intention in that regard? Was she going to report all these cases or was she just going to look at the slides?
DR. COOK:
A. Well they all had already been reported, there was no need to go ahead and issue an addendum report, it was basically to review the slides and to keep her skill set intact, so it was--I can't remember any discussion where she was going to issue any addendum report or put her signature to the existing reports.
COFFEY, Q.C.:
Q. And the idea, when she discussed it with you, the idea that she might want to just examine

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like larger groups of slides for her own purposes, you know, to keep her skill set up or sharp, did you have any problem with that?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Did any other pathologist ever ask you to do that?
DR. COOK:
A. I can't recollect anybody asking me to do that.
COFFEY, Q.C.:
Q. Did you say now, looking at this, page three of P-1393, as the clinical chief at the time, I appreciate you've told us no one approached you about it, or spoke to you about this, about the expression of views by apparently other pathologists, as the clinical chief at the time, would you have had any concern about Dr. Carter looking at such slides and just for her own purposes?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Would you understand any reluctance by the

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reporting pathologists?
DR. COOK:
A. I can't see why not, I mean, I wouldn't have an issue if Dr. Carter wanted to come in and review some of my slides, I mean, I wouldn't have an issue with it.
COFFEY, Q.C.:
Q. Do you know whether or not she ever did so at St. Clare's? Because all of these doctors I just listed off there at the beginning of this, are all, I gather, General Hospital pathologists, if we can look back at it to give you some comfort here, Doctor, there on page one, Fernandez, Robb, Ejeckam, Parai, Wadden, Pirzada, Chittal, Morris-Larkin, Fontaine and Parai were all General Hospital pathologists?
DR. COOK:
A. That's correct, yes.
COFFEY, Q.C.:
Q. Do you know if Dr. Carter ever conducted any such review of the ER/PR and HER2/neu slides at St. Clare's?
DR. COOK:
A. I can't recollect her doing that.

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COFFEY, Q.C.:
Q. If she wanted to do it at St. Clare's, what would have been required for her to do it?
DR. COOK:
A. She would have asked me, she would have gotten my blessing and I would have helped her in any way she wanted it done.
COFFEY, Q.C.:
Q. Exhibit P-1918 please? And, Doctor, this is a memo to all pathologists in the Laboratory Medicine Program, the Health Care Corporation of St. John's, October 7th, 2004 from yourself, three estrogen and progesterone receptors, you write "I would like to remind everyone that estrogen and progesterone receptors should be ordered automatically on all excisional biopsies, lumpectomy and mastectomy specimens demonstrating infiltrating carcinomas. It has come to my attention that these receptors have not been ordered on a number of cases. I would appreciate your co-operation in this matter. Sincerely yours, Donald Cook." And then there's a handwritten note here, do you recognize that handwriting?

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DR. COOK:
A. I think that's my secretary's handwriting.
COFFEY, Q.C.:
Q. "Given to all pathologists, St. Clare's and faxed to Jennifer for Health Science's Centre, Pathology, October 7th, '04."
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. Why or how did you come to write this memo?
DR. COOK:
A. Well one of the oncologists, Joy McCarthy, phoned me and said she had an issue with pathologists not automatically ordering ER's and PR's on their breast cancers, and I said, well, I'll issue a memo and send it out and keep me updated on the ordering aspect.
COFFEY, Q.C.:
Q. Did you ever make any inquiries as to why some pathologists were apparently not routinely ordering it?
DR. COOK:
A. Some would just forget to order it.
COFFEY, Q.C.:
Q. After you sent out the memo, did the issue

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ever--this memo, did the issue ever come up again?
DR. COOK:
A. No.
COFFEY, Q.C.:
Q. Now, Doctor, the training of technologists in relation to IHC stains, whose responsibility was that during the tenure of yourself?
DR. COOK:
A. Well the training of technologists comes under the control of the program director and the divisional manager.
COFFEY, Q.C.:
Q. Okay, and if, for example, the HER2/neu stains or stain, okay, you recall you looked at a memo of April 2000 in that regard?
DR. COOK:
A. Uh-hm, yes.
COFFEY, Q.C.:
Q. When that stain was first utilized in St. John's in 2000, was there any training of technologists in '99 and 2000 for it?
DR. COOK:
A. What happened in '99 and 2000, that being a kit, they had to follow the instructions of

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the manufacturer to the "T".
COFFEY, Q.C.:
Q. I'm sorry, they had to what?
DR. COOK:
A. Follow the instructions of the manufacturer exactly as specified in the manufacturer's instructions.
COFFEY, Q.C.:
Q. Now in relation to estrogen receptors and progesterone receptors tests, what, if any, instructions were they to follow in doing an ER and PR stain? Where would you find the instructions for that?
DR. COOK:
A. Well they would have had information available in their lab that could be a manual or it could be some sort of documentation that they would have.
COFFEY, Q.C.:
Q. Did you know whether or not that they did have any?
DR. COOK:
A. I didn't go that far, I mean, that would be under the medical--the technical aspect, the program director and the divisional manager.

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COFFEY, Q.C.:
Q. So the procedure, for example for processing an estrogen receptor stain, a particular estrogen receptor stain and a particular PR stain, the protocol that he followed--well first of all, whether or not there was a protocol, whose responsibility was it to ensure that there was a written protocol?
DR. COOK:
A. The program director.
COFFEY, Q.C.:
Q. And would the pathologist be at all involved in approving such a protocol?
DR. COOK:
A. Not in our system, no.
COFFEY, Q.C.:
Q. What, if at any point or when, if at any point, would pathologists get involved?
DR. COOK:
A. Pathologists would get involved in the interpretation of the slide, the issuing of a pathology report and the documentation of their signature to the pathology report.
COFFEY, Q.C.:
Q. Well with respect to the interpretation of the

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slide, I take it that if there was a problem in the slide preparation protocol or procedure or both, when would that become apparent to the pathologist?
DR. COOK:
A. If the pathologist identified a problem with the slide itself, if there were folding of the slide or folding of the tissue, bubbles in the tissue, stain that he felt it didn't work, then he or she has a choice of not signing that case out.
COFFEY, Q.C.:
Q. Okay, so you refuse to sign and then what happens?
DR. COOK:
A. Then you would notify the divisional manager of the problem with the stain or the quality of the slide.
COFFEY, Q.C.:
Q. And then what was to happen?
DR. COOK:
A. Well the divisional manager should go back and review his processes and protocols.
COFFEY, Q.C.:
Q. So there would be no role for the pathologist

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in that process at all, is that what you're telling us?
DR. COOK:
A. In the technical aspect, no.
COFFEY, Q.C.:
Q. How about, for example, the dilution procedures, the amount of dilutions, the amount of antigen retrieval heating time, all those--the intricate steps involved. Would a pathologist be involved in any of that?
DR. COOK:
A. Not normally.
COFFEY, Q.C.:
Q. I appreciate not normally, but in terms of optimizing it.
DR. COOK:
A. Optimizing, no, I mean, I would see that as a technical function.
COFFEY, Q.C.:
Q. So in St. John's, Newfoundland--well I'll just ask, has that ever changed? Has your view in that regard ever changed?
DR. COOK:
A. In terms of the proper optimization of the antibody, the incubation temperatures?

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COFFEY, Q.C.:
Q. And the involvement of a pathologist in same?
DR. COOK:
A. Well it has changed since our issue, our index case but prior to that, no, I would have saw that as a technical function.
COFFEY, Q.C.:
Q. So as the clinical chief of the day and the site chief at St. Clare's going back to the mid 90's, it was your understanding that in getting the stain right, as it were, getting the staining process right for IHC, was entirely within the purview of the technologist?
DR. COOK:
A. That's the way I look at it.
COFFEY, Q.C.:
Q. Do you know whether or not that was true at other hospitals or other health authorities, like outside of Newfoundland?
DR. COOK:
A. I don't know for sure, Mr. Coffey.
COFFEY, Q.C.:
Q. And why was Dr. Ejeckam involved in 2003?
DR. COOK:

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A. Dr. Ejeckam was involved in 2003 to be used as a resource person if there were questions about the staining, whether staining was too intense or too light or whatever, that he would be used as a go-between between the pathologist and the technologist.
COFFEY, Q.C.:
Q. And his function as a go-between was what?
DR. COOK:
A. To act as liaison, to communicate concerns with pathologists to our technical people. And to express and to take an interest in the end quality of the slide.
COFFEY, Q.C.:
Q. And I'm just trying to get some sense from your perspective as the clinical chief and his as the liaison person.
DR. COOK:
A. Uh-hm.
COFFEY, Q.C.:
Q. That your understanding of his role was that he would be a go-between between the technologist or technologists who were actually doing the manipulation.
DR. COOK:

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A. Uh-hm
COFFEY, Q.C.:
Q. The heating, the dilution and whatever other procedures are required, the liaison between them doing that and other pathologists, himself and others -
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And his role was what?
DR. COOK:
A. Again, I mean, if I had a concern with the quality of the stain in terms of it being over stained or under stained, I would pick up the phone, get his opinion on a particular case, send the slide over and see what would need to be done, or get his opinion on whether the staining was adequate or not.
COFFEY, Q.C.:
Q. And if it was inadequate in his view, what then would happen?
DR. COOK:
A. Then he would go to the divisional manager or could speak directly to the technologist.
COFFEY, Q.C.:

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Q. And your understanding was what, if any, authority did Dr. Ejeckam have?
DR. COOK:
A. He didn't have the direct authority to make the change, he would make a recommendation.
COFFEY, Q.C.:
Q. To?
DR. COOK:
A. To a divisional manager or to a technologist.
COFFEY, Q.C.:
Q. So that before Dr. Ejeckam arrived in September of 2002, who, if anyone, was performing that function after Dr. Khalifa left?
DR. COOK:
A. No one directly but that control of the IHC being part of the histology lab would follow under the site chief.
COFFEY, Q.C.:
Q. Which would be Dr. Parai?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. In this context, since 2000 anyway or after 2000. So, you know, between 2000 and 2002

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when Dr. Ejeckam arrived, how much involvement did Dr. Parai have to your knowledge in the IHC end of things?

DR. COOK:

A. He wouldn't have the involvement at the technical end. Where his involvement would be would be looking at things such as turn-around times, which would be a big thing with the immunohistochemistry and making sure the slides are delivered properly to the pathologist.

COFFEY, Q.C.:

Q. The administrative end of it, but he didn't-- he wasn't involved like--what was the difference between him and Dr. Ejeckam's involvement, that's what I'm trying to ascertain?

DR. COOK:

A. Yeah, well Dr. Ejeckam had a more active interest in immunohistochemistry, so he would have gone further with it than Dr. Parai in becoming more involved in the process.

COFFEY, Q.C.:

Q. And you've indicated that after Dr. Ejeckam showed up, if you had a concern about a

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particular slide or slides, you might send them over to him and ask his opinion of them?

DR. COOK:

A. Yes, I would do that.

COFFEY, Q.C.:

Q. Was there any one pathologist around before Dr. Ejeckam showed up who fulfilled or could fulfil the same role?

DR. COOK:

A. Not until there was Dr. Khalifa and prior to that, Dr. Chittal had the same interest in IHC.

COFFEY, Q.C.:

Q. So after Dr. Khalifa left in the late 90's, between then and Dr. Ejeckam, there was no one, there was no go-to pathologist, as it were, in IHC.

DR. COOK:

A. Except for the site chief. The site chief would assume that role.

COFFEY, Q.C.:

Q. And I appreciate Dr. Parai, Sushil Parai I take it would assume the role, but how much actual involvement compared to Dr. Ejeckam did Dr. Parai have? Again, I'm trying to get for

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the Commissioner some sense of what was going on?

DR. COOK:

A. He wouldn't have the same involvement, I mean, unless Dr. Parai had a special interest, he had additional training or he read around the subject, I mean, he wouldn't have the same degree of involvement as Dr. Ejeckam.

THE COMMISSIONER:

Q. So are you saying that while, because of Dr. Ejeckam's special interest in the subject, you might have, for example, consulted him regarding a particular slide you were concerned about, you would not likely do that with Dr. Parai, whereas if you had a question about whether you were getting the slides on time and that kind of thing, you would have gone to Dr. Parai?

DR. COOK:

A. Yeah, the more administrative function of it I would have gone to Dr. Parai; in regards to Dr. Ejeckam, I would have called him about, again the quality of the staining, whether something--is it normal to have this particular type of intensity stain in such and

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such a malignancy or if it's a stain being positive in certain condition, so I would have used him as a resource in that case, as opposed to Dr. Parai who would I would expect to have more of an administrative function.

THE COMMISSIONER:

Q. Okay.

COFFEY, Q.C.:

Q. Exhibit P-1868 please? And this is a letter of January 14th, 2000. It's from Dr. Sushil Parai to yourself, as the then acting clinical chief. And he concludes by saying, "I do hereby accept the appointment of permanent site chief of anatomical pathology to the General Hospital as of May 1, 2000."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. So he was there then. Looking at page two of the exhibit, you've noted here "received February 8th, 2005"?

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Or the letter itself is, I take it that's a

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typo probably, February 4, 2004 -

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. It's probably 2005 because if we look at the text, Dr. Parai notes, concludes "I wish to inform you that I do not wish to reapply for the renewal of the posted site chief General Hospital at the end of my term, 31st of March, 2005."

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. So, Dr. Parai was the site chief between--at the General Hospital from May 2000 until March 31st, 2005.

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. What was your understanding of then if, because his--the last several years of his role as site chief of the general hospital, overlap with Dr. Ejeckam's period from September 2002, really and I take it Dr. Ejeckam was there through the beginning of

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'06.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. So, the fall of '02, all of '03, all of '04 and the beginning of '05, Dr. Parai was the site chief.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. At the General Hospital. Dr. Ejeckam was the staff pathologist there with an interest in IHC.

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Who then, from your perspective as clinical chief, was actually responsible in that overlapping period, September '02 to March of '05, who was responsible for the IHC lab, from a pathologist perspective?

DR. COOK:

A. Well that's difficult to say, who is responsible for the IHC lab comes under the program director in terms of the technical

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component of it, right. Now who is responsible for the overall interpretation of the slides, rests with the individual pathologist.

COFFEY, Q.C.:

Q. And what about in terms of the role that Dr. Parai, before Dr. Ejeckam showed up, the role that he had with the IHC lab and then Dr. Ejeckam's role -

DR. COOK:

A. Uh-hm.

COFFEY, Q.C.:

Q. Did you ever make any inquiries of those two gentlemen as to how they were interacting in relation to the IHC lab?

DR. COOK:

A. No, because those individuals are both professionals and I would make the assumption that they would come to a mutual agreement, that's what we do as professionals.

COFFEY, Q.C.:

Q. So, Doctor, then I take it then until or prior to May, 2005, that responsibility from your perspective for the staining and the IHC end of the lab was primarily the responsibility of

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the technologist?

DR. COOK:

A. The technical aspect, yes, right.

COFFEY, Q.C.:

Q. And the only aspect the pathologists were involved with was the interpretation of the slides?

DR. COOK:

A. They would take responsibility in signing out the case and putting their signature to the report.

THE COMMISSIONER:

Q. I'm sorry, when you say signing of the case, what exactly does that mean?

DR. COOK:

A. Commissioner, to sign out the case, your signature goes on the bottom of that report.

THE COMMISSIONER:

Q. But you said two things, signing of the case and doing a report, they're not different?

DR. COOK:

A. Same thing, I mean, you would, the pathologist would do up the report, dictate his report which include the results of IHC, make the interpretation and sign out the case.

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THE COMMISSIONER:
Q. Meaning sign the report?
DR. COOK:
A. Sign out, yeah, that's what I mean, sign the report.
THE COMMISSIONER:
Q. Okay, thank you.
COFFEY, Q.C.:
Q. Doctor, who then was responsible for addressing any concerns about fixation of the tissue, the quality of a fixation of a tissue? Who is responsible for dealing with that or addressing any concerns in that regard? First of all, raising any concerns in that regard.
DR. COOK:
A. The individual pathologist.
COFFEY, Q.C.:
Q. And that would become apparent to the individual pathologist when in the process?
DR. COOK:
A. When they're looking under the microscope.
COFFEY, Q.C.:
Q. After the slide was prepared, I take it?
DR. COOK:
A. Yes.

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COFFEY, Q.C.:
Q. And what, if anything, was the individual pathologist expected to do?
DR. COOK:
A. Well the individual pathologist would be responsible for handling his or her own grossing at that particular time and they would go back and look at their own procedure, make sure that the specimen was adequately sliced at the particular time, make sure that there was an adequate amount of formalin in the specimen, make sure it wasn't left in formalin for too long. So a lot of it rests with the individual pathologist to go back and look at his or her methodology in performing the grossing technique on the specimen.
COFFEY, Q.C.:
Q. Now in relation to breast tissue and breast tumors and estrogen receptors and progesterone receptors and just breast tumors in general, how was a pathologist supposed to know how to gross the tissue?
DR. COOK:
A. Because that's an inherent part of our training as residents. We have books as I said. Acumen is a good source of information that comes from. The residents are supervised by the staff. So that's something that's engrained in pathologists from the initial days of their training.

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COFFEY, Q.C.:
Q. And with respect to breast tissue during your time, has that ever changed?
DR. COOK:
A. Breast tissue in my time?
COFFEY, Q.C.:
Q. Yes.
DR. COOK:
A. We always made sure that the tissue was submitted from the OR to the lab in a reasonable period of time. Once you received it, you made sure that that specimen was bread loafed. You made sure that -
COFFEY, Q.C.:
Q. Bread loafed how?
DR. COOK:
A. Slicing.
COFFEY, Q.C.:
Q. I appreciate that, but like any particular thickness?

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DR. COOK:
A. Six-seven millimetres and the -
COFFEY, Q.C.:
Q. Has that changed over time?
DR. COOK:
A. Well, it's down to five or four millimetres.
COFFEY, Q.C.:
Q. And what was it when you started? What was the recommended, do you recall?
DR. COOK:
A. The recommended, I think, was around six or seven millimetres, if I remember.
COFFEY, Q.C.:
Q. Okay, and--okay, so was there any time frame involved, any recommended times by which the grossing was supposed to have occurred?
DR. COOK:
A. The grossing, when the specimen came up from the OR, you were notified by the technologist that we had this specimen here. They notified you immediately and you went in immediately and you did your slicing. Slices were separated by gauze tissue.
COFFEY, Q.C.:
Q. Doctor, well, we heard--the Commissioner has

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heard a certain amount of evidence about fixation issues involving tissue, breast tissue in St. John's and elsewhere.

DR. COOK:

A. Yes.

COFFEY, Q.C.:

Q. Okay. If this was--that approach, you know, utilizing the procedures you've referred to was actually followed, would you be able to explain then why there might be problems with fixation?

DR. COOK:

A. It depends on how many times a year or how many times a month you would see an actual breast lesion. It gets back to the way we have our general assign out. You look at St. Clare's, for instance, there may be something like, I don't know, 100-120 cases per year or 220 cases per year. That would translate into maybe two or maybe three cases per month per pathologist. So are you seeing a good representation of breast cases per month? I mean, you may see one one week and another one another two weeks. So if you're only seeing one or two a month, you may not see a trend.

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COFFEY, Q.C.:

Q. I appreciate that. What I'm getting at, Doctor, is not so much whether you would have seen a trend in fixation issues. If fixation protocol is standardized for breast tissue, and going back certainly to your training days, which would be the early 80s, and that hasn't really materially changed until now, okay, do you know if that protocol was being followed at St. Clare's, systematically followed?

DR. COOK:

A. I believe so.

COFFEY, Q.C.:

Q. Was there any written protocol to that effect?

DR. COOK:

A. No, that protocol lay in, again, our standard textbooks.

COFFEY, Q.C.:

Q. Is there any way or anything that you can think of then that you could offer the Commissioner to explain why there might then, if people know this protocol, because that's the standard way things are done, and to your knowledge, as far as you know, it was being done at St. Clare's, if that is so, can you offer any explanation as to why then, despite that, there might be fixation problems in the tissue?

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DR. COOK:

A. The only thing I could speculate, if tissue was left overnight in a submitting container, say down in the OR or over the weekend without it being sectioned.

COFFEY, Q.C.:

Q. And how could that come about?

DR. COOK:

A. It would come about if there was a surgical procedure that's taking place after hours. Specimen is put in a submitting container and the lab not notified.

COFFEY, Q.C.:

Q. And so this would be, in that context, I take it that would be on the OR staff?

DR. COOK:

A. The OR staff would make sure, yes, they would make sure that the specimen has an adequate amount of formalin in it, and I mean adequate amount, about ten times volume to the volume of a specimen.

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COFFEY, Q.C.:

Q. I appreciate that, but I'm talking about notification of the lab.

DR. COOK:

A. Notification of the lab would be made by the OR.

COFFEY, Q.C.:

Q. So that if the OR chose not to notify the lab, in this context, the breast specimen could do what, sit in a container of formalin overnight ungrossed?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. At room temperature presumably, that would be accurate, would it?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. Or even over the weekend?

DR. COOK:

A. That's correct.

COFFEY, Q.C.:

Q. In a container of formalin at room temperature in the OR?

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DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. When did you first become aware that that was a distinct possibility?
DR. COOK:
A. Following the review of the ER and PR.
COFFEY, Q.C.:
Q. So in the beginning of 2005?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. I'm sorry, the middle of 2005, I apologize. So before that, the idea that the specimens might have been sitting up there--a specimen might have been sitting up there all weekend in the OR or at least overnight in the OR in formalin had not come to your attention?
DR. COOK:
A. No, the issue surrounding it had not come to my attention.
COFFEY, Q.C.:
Q. Well, had the fact that it was occuring, were you aware of that?
DR. COOK:

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A. I was aware of cases that were occuring, but not aware, totally aware of the significance of that.
COFFEY, Q.C.:
Q. Okay. When did you become aware of the potential significance of that?
DR. COOK:
A. When I was doing the ER and PR review.
COFFEY, Q.C.:
Q. Okay. And that would be in the middle of 2005, May and June, beginning May, June, July?
DR. COOK:
A. Well, throughout, I mean, my knowledge was evolving throughout the period of--since 2005.
COFFEY, Q.C.:
Q. And what, if anything, did you become aware of then that you had not been aware of before in that regard?
DR. COOK:
A. In that regard it's when I began investigating or looking into the ER and PR issue the effect that fixation could have on the tissue immunoperoxidase staining.
COFFEY, Q.C.:
Q. And what did you learn at that time?

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DR. COOK:
A. That there could be a component there, that could be the fixation of the tissue could, could affect the result.
COFFEY, Q.C.:
Q. In what way?
DR. COOK:
A. The result that you get from IHC staining.
COFFEY, Q.C.:
Q. In the sense, but affected how, like, I appreciate it could affect the result?
DR. COOK:
A. You may get under staining.
COFFEY, Q.C.:
Q. Yes, under or over staining, I don't know, I'm just asking you what -
DR. COOK:
A. Get under staining, but again, it depends on the strength of your stain itself and the technical procedures.
COMMISSIONER:
Q. Mr. Coffey, it's getting close to -
COFFEY, Q.C.:
Q. Thank you. So and you only became aware of that, though, in May of 2005 or thereafter?

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DR. COOK:
A. That's when I became aware of it.
COFFEY, Q.C.:
Q. Was that information already available in the sense of if you'd gone looking for it before May of 2005, was that readily ascertainable?
DR. COOK:
A. I would imagine it is.
COFFEY, Q.C.:
Q. Doctor, as a practising pathologist, clinical, clinician, what is it about what you see on a slide that makes you aware that there's a fixation issue with the tissue, what do you see that causes you to come to that conclusion?
DR. COOK:
A. Well, you may see retraction of the cytoplasm from the cytoplasmic membrane, some of the nuclei may become small and pyknotic, some of them may become, have a dusky appearance, a boggy appearance, so there may be issue there that you would be concerned about fixation issues.
COFFEY, Q.C.:
Q. And you had been aware of that, those sorts of

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factors for how long?
DR. COOK:
A. Oh, I mean, I would see variable amounts of that, those sort of changes, I guess, for a number of years.
COFFEY, Q.C.:
Q. Going back to, I take it, your training days and then afterward at various times?
DR. COOK:
A. Various times.
COFFEY, Q.C.:
Q. In particular in relation to breast tissue, when did you become aware of that as a concern?
DR. COOK:
A. Well, I became aware of that as a concern when I did the review.
COFFEY, Q.C.:
Q. And that's the 2005 matter?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, you have referred to the fact that you became aware of the idea of internal controls for ER and PR tests or stains in 2000?

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DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. Having become so aware, did you ever afterward have a case or cases where you had internal control tissue there and it did not stain?
DR. COOK:
A. I can't recollect specifically. I mean, I would look for the internal control to make sure it would stain, but I can't remember earlier whether the internal control didn't stain.
COFFEY, Q.C.:
Q. I appreciate, after 2000, though, after you were aware, certainly aware of it, like in 2001, '02, '03, do you recall whether you were encountering cases of your own where you were looking for an internal control tissue, you saw it?
DR. COOK:
A. Um-hm.
COFFEY, Q.C.:
Q. But it was not staining or it had not -
DR. COOK:
A. I can't recollect, Mr. Coffey.

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COFFEY, Q.C.:
Q. Okay. Did you ever order or reorder any ER and PR tests?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. And going back to what time?
DR. COOK:
A. Oh, I can't remember. I mean, I wouldn't be able to give you a specific date.
COFFEY, Q.C.:
Q. And why would you have reordered an ER and PR, or PR test?
DR. COOK:
A. Mostly it had to do with how the tissue was laid out, whether there was folding of the tissue, there was bubbling in the tissue, there was fragmentation of the tissue.
COFFEY, Q.C.:
Q. So it had to do with how the tissue was lying on the slide?
DR. COOK:
A. Yes.
COFFEY, Q.C.:
Q. What about in terms of reordering it because

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of problems with the controls?
DR. COOK:
A. I can't recollect that I reordered because of problems with the controls.
COFFEY, Q.C.:
Q. Continue, Commission, the morning, please. Thank you.
COMMISSIONER:
Q. 9:30, thank you.
Upon conclusion.

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 2nd day of 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 2nd day of July, A.D., 2008

Judy Moss

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