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| <p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">July 2, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. Commission Co-counsel Sandra Chaytor, Q.C./Mandy Woodland Commission Co-counsel</p> <p>Rolf Pritchard/Jackie Brazil Her Majesty in Right of NL</p> <p>Peter Browne/Jane Hennebury Doctors Kara Laing et al</p> <p>Daniel Simmons Eastern Regional Integrated Health Authority</p> <p>Ches Crosbie, Q.C. Members of the Breast Cancer Testing Class Action</p> <p>Mark Pike NL Medical Association</p> <p>Jennifer Newbury Canadian Cancer Society (NL Division)</p> <p>David Eaton/ Blair Pritchett. Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p> | <p style="text-align: center;">LIST OF EXHIBITS</p> <p>EXHIBITS P-1854 THROUGH P-1888, INCLUSIVE Pg. 5 EXHIBITS P-1890 THROUGH P-1892, INCLUSIVE Pg. 5 EXHIBITS P-1894 THROUGH P-1897, INCLUSIVE Pg. 5 EXHIBITS P-1899 THROUGH P-1901, INCLUSIVE Pg. 5 EXHIBITS P-1903 THROUGH P-2136, INCLUSIVE Pg. 5 EXHIBITS P-2138 THROUGH P-2143, INCLUSIVE Pg. 5</p> |
| <p style="text-align: center;">TABLE OF CONTENTS</p> <p>DOCTOR DONALD COOK - SWORN</p> <p>Examination by Bernard Coffey, Q.C. Pgs. 4 - 348</p> <p>Certificate</p> | <p style="text-align: right;">Page 4</p> <p>1 COMMISSIONER: 2 Q. Mr. Coffey. 3 COFFEY, Q.C.: 4 Q. Good morning, Commissioner. The next witness, 5 Commissioner, is Dr. Donald Cook. 6 DR. DONALD COOK (SWORN) EXAMINATION BY BERNARD COFFEY 7 REGISTRAR: 8 Q. And would you please state and spell your 9 complete name for the Commission? 10 DR. COOK: 11 A. Donald Cook, D-o-n-a-l-d, C-o-o-k. 12 REGISTRAR: 13 Q. Thank you. 14 COFFEY, Q.C.: 15 Q. Commissioner, there are a number of exhibits 16 that are proposed to ask--I'm going to ask to 17 have entered. There are, Commission, 18 beginning at 1854 through 1888, inclusive; and 19 then 1890 through 1892, inclusive; 1894 20 through 1897, inclusive; 1899 through 1901, 21 inclusive; 1903 through, I believe, 2136; and 22 then 2138 through 2143. There's one I've 23 skipped over there that's under review here, 24 so. 25 COMMISSIONER:</p> |

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1 Q. All right.
 2 COFFEY, Q.C.:
 3 Q. We'll come back to that.
 4 COMMISSIONER:
 5 Q. Okay. Entered.
 6 EXHIBITS P-1854 THROUGH P-1888, INCLUSIVE, ENTERED INTO
 7 EVIDENCE.
 8 EXHIBITS P-1890 THROUGH P-1892, INCLUSIVE, ENTERED INTO
 9 EVIDENCE.
 10 EXHIBITS P-1894 THROUGH P-1897, INCLUSIVE, ENTERED INTO
 11 EVIDENCE.
 12 EXHIBITS P-1899 THROUGH P-1901, INCLUSIVE, ENTERED INTO
 13 EVIDENCE.
 14 EXHIBITS P-1903 THROUGH P-2136, INCLUSIVE, ENTERED INTO
 15 EVIDENCE.
 16 EXHIBITS P-2138 THROUGH P-2143, INCLUSIVE, ENTERED INTO
 17 EVIDENCE.
 18 COFFEY, Q.C.:
 19 Q. Thank you. If we could bring up, please,
 20 Exhibit 1854? And, Dr. Cook, I take it, this
 21 is a copy with some information redacted of
 22 your curriculum vitae?
 23 DR. COOK:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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

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1 Canada as well as that American Board of
 2 Pathology in anatomic pathology. During most
 3 of that time at St. Clare's I was acting as a
 4 staff pathologist. That involved the
 5 interpretation of routine surgicals,
 6 autopsies, cytology cases and hematology
 7 cases. I served on a number of committees at
 8 that institution and later went on to serve on
 9 a number of committees at a provincial and
 10 national level. In regards to leadership
 11 roles, I became site chief at the St. Clare's
 12 institution in November of '96 and became
 13 acting clinical chief or interim clinical
 14 chief from July of '99 to July of 2000 and
 15 acting clinical chief and clinical chief from
 16 March of '02 to March of '06.
 17 COFFEY, Q.C.:
 18 Q. Doctor, at the--during the time that you were
 19 interim clinical chief, who had been the
 20 clinical chief for the Health Care Corporation
 21 at that time?
 22 DR. COOK:
 23 A. From the period of '97 to '99, you mean?
 24 COFFEY, Q.C.:
 25 Q. Yes.

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1 DR. COOK:
 2 A. Dr. David Haegert.
 3 COFFEY, Q.C.:
 4 Q. And I take it then you were replacing Dr.
 5 Haegert while he was away for a year?
 6 DR. COOK:
 7 A. He was away for a year on sabbatical.
 8 COFFEY, Q.C.:
 9 Q. And then when he returned, he returned to his
 10 position as clinical chief at that point for a
 11 period of time and then Dr. Haegert, I take
 12 it, stepped down or left that position as
 13 clinical chief and you took over as acting?
 14 DR. COOK:
 15 A. That's correct. He came, resumed his position
 16 in July of, late July of 2000 until, I
 17 believe, March of '02.
 18 COFFEY, Q.C.:
 19 Q. Doctor, I want to--now, I gather, as well,
 20 you've been site chief at--is there such a
 21 thing as a site chief?
 22 DR. COOK:
 23 A. As a site chief, yes.
 24 COFFEY, Q.C.:
 25 Q. As well, in pathology. Could you tell the

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1 Commissioner, please, what it is--first of
 2 all, how long were you site chief at St.
 3 Clare's?
 4 DR. COOK:
 5 A. Since November of '96, I believe.
 6 COFFEY, Q.C.:
 7 Q. And are you still the site chief today?
 8 DR. COOK:
 9 A. That's correct.
 10 COFFEY, Q.C.:
 11 Q. Could you tell us, please, what the role of a
 12 site chief is?
 13 DR. COOK:
 14 A. The role of the site chief mainly is to act as
 15 a liaison between the pathologists on site at
 16 St. Clare's and the surgical and medical
 17 staff, as well as liaison with managerial
 18 staff in the OR and clinics and ambulatory
 19 care area. The site chief functions to make
 20 sure that there is adequate numbers of
 21 pathology personnel on site and to ensure that
 22 rotars are in place. These are scheduling
 23 rotars for covering OR and call issues. The
 24 site chief also oversees various educational
 25 activities that occurs on site, making sure

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1 that the rounds are instituted and that the
 2 rounds are sustained. There is also a role
 3 there in the undergraduate and post-graduate
 4 teaching programs. The site chief makes sure
 5 that in regard to post-graduates that they're
 6 involved in the on call rota, that they
 7 participate in rounds and teaching activities.
 8 The same goes true for undergraduates who go
 9 through that site doing elective operations.
 10 The site chief also ensures that there is a
 11 quality of medical reports on that site, looks
 12 at such things are turnaround times and
 13 outstanding reports as well as the content of
 14 the reports.
 15 COFFEY, Q.C.:
 16 Q. Doctor, and I appreciate you have also been
 17 the clinical chief and at times simultaneously
 18 the site chief and clinical chief?
 19 DR. COOK:
 20 A. That's correct.
 21 COFFEY, Q.C.:
 22 Q. Just on the aspect of the position involving
 23 the site chief, can you tell us, please, what,
 24 if any, interaction the site chief, and I
 25 appreciate you can't really interact with

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1 yourself while you're simultaneously holding
 2 both positions, but the interaction of a site
 3 chief when you were not the clinical chief,
 4 while you were site chief during the time that
 5 Dr. Haegert was clinical chief, could you tell
 6 us, please, what, if any, interaction a site
 7 chief would have with the clinical chief and,
 8 you know, the interaction or relationship
 9 between those two roles?
 10 DR. COOK:
 11 A. Well, the site chief would communicate with
 12 the clinical chief usually on a weekly basis,
 13 either through a telephone conversation or
 14 informal conversations, but more formally you
 15 would meet, say, once a month at the site
 16 chiefs and divisional managers' meeting.
 17 There may be other meetings that we had on the
 18 go, such as at the time we had an internal lab
 19 advisory committee. There my be participation
 20 of the site chiefs at the laboratory
 21 management committee level. There would be
 22 interaction at the various inter-hospital
 23 rounds that we had on the go. So there would
 24 be interaction between the various two
 25 individuals on a, usually on a weekly basis,

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1 informally, but formally at least once or
 2 twice a month.
 3 COFFEY, Q.C.:
 4 Q. And as site chief would the person, whomever
 5 he or she was, who performed the function of
 6 being site chief, in that capacity would the
 7 site chief report to the clinical chief?
 8 DR. COOK:
 9 A. Site chief would report to the clinical chief.
 10 COFFEY, Q.C.:
 11 Q. I take it you became site chief at St. Clare's
 12 in 1996, I think that's what you -
 13 DR. COOK:
 14 A. '96.
 15 COFFEY, Q.C.:
 16 Q. '96 or so, yeah. And that's around the time,
 17 I gather, that the Commission has heard
 18 evidence that really the Health Care
 19 Corporation of St. John's, around that time,
 20 '95, '96, really came into being itself?
 21 DR. COOK:
 22 A. That's correct.
 23 COFFEY, Q.C.:
 24 Q. Doctor, while you were site chief and before
 25 you became, during the period before you

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1 became interim clinical chief, while you were
 2 solely a site chief at St. Clare's, could you
 3 tell the Commissioner, please, what the
 4 structure of the lab at St. Clare's was in the
 5 sense of I take it there were technologists
 6 that worked there and pathologists, as well?
 7 DR. COOK:
 8 A. That's correct.
 9 COFFEY, Q.C.:
 10 Q. In the lab. Approximately how many
 11 pathologists would have worked in the lab at
 12 the time?
 13 DR. COOK:
 14 A. You mean prior to the formation of Health Care
 15 Corporation of St. John's?
 16 COFFEY, Q.C.:
 17 Q. No. From the period, the first four years or
 18 so of the Health Care Corporation, in the late
 19 '90s, say, '95, '96 through 2000,
 20 approximately how many?
 21 DR. COOK:
 22 A. Four pathologists.
 23 COFFEY, Q.C.:
 24 Q. Four. And would that have included yourself
 25 as site chief?

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1 DR. COOK:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. And how about technologists, how many were
 5 there have been?
 6 DR. COOK:
 7 A. We had four technologists and I guess one lab
 8 assistant at that particular time, or tech aid
 9 or whatever the designation was, so there'd be
 10 about five individuals within the histology
 11 lab at the St. Clare's site.
 12 COFFEY, Q.C.:
 13 Q. And within the histology lab?
 14 DR. COOK:
 15 A. That's right, in histology.
 16 COFFEY, Q.C.:
 17 Q. Doctor, who would the technologists in the
 18 histology lab report to?
 19 DR. COOK:
 20 A. They would report to the divisional manager.
 21 COFFEY, Q.C.:
 22 Q. And during that time frame do you recall who
 23 that was?
 24 DR. COOK:
 25 A. John Murphy.

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1 COFFEY, Q.C.:
 2 Q. And was Mr. Murphy division manager at the
 3 time, for that period, late '90s, was he on
 4 site?
 5 DR. COOK:
 6 A. He was on site. He would equal up his time
 7 between St. Clare's and the Grace. He was
 8 divisional manager for both the Grace and St.
 9 Clare's site.
 10 COFFEY, Q.C.:
 11 Q. Okay. And do you recall who he reported to?
 12 DR. COOK:
 13 A. He reported to the program director.
 14 COFFEY, Q.C.:
 15 Q. And in that period was?
 16 DR. COOK:
 17 A. Mr. Vern Whalen.
 18 COFFEY, Q.C.:
 19 Q. Okay. Do you recall where Mr. Whalen was
 20 situated?
 21 DR. COOK:
 22 A. His main base of operations was at the General
 23 Hospital.
 24 COFFEY, Q.C.:
 25 Q. Okay. So the technologists then during the

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1 time, say, the second half of the '90s, while
 2 you were site chief, during that time frame at
 3 St. Clare's, the technologists would not
 4 report to you then, I take it?
 5 DR. COOK:
 6 A. That's correct.
 7 COFFEY, Q.C.:
 8 Q. So they had their own reporting stream through
 9 Mr. Murphy, through Mr. Whalen, that was one
 10 reporting stream?
 11 DR. COOK:
 12 A. That was the official reporting stream, yes.
 13 COFFEY, Q.C.:
 14 Q. Yes, okay. And the site chief with other
 15 staff pathologists, they reported to you?
 16 DR. COOK:
 17 A. They would report to me.
 18 COFFEY, Q.C.:
 19 Q. And you reported to the clinical chief?
 20 DR. COOK:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. Of the day, Dr. Haegert. And you say, I take
 24 it, that's the formal way they reported, I
 25 think you used the word on paper or formally

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1 that's the way the technologists work. In
 2 practice how did it work?
 3 DR. COOK:
 4 A. Usually at St. Clare's site there was a lot of
 5 interaction between the pathologists and the
 6 technologists, so if there were certain
 7 directions given to the technologists on what
 8 needed to be done with the various patient
 9 samples and whatnot, usually that direction
 10 came from the pathologists to the
 11 technologists.
 12 COFFEY, Q.C.:
 13 Q. And would that be directly from, like, an
 14 individual pathologist to particular
 15 technologists?
 16 DR. COOK:
 17 A. That could be, yes.
 18 COFFEY, Q.C.:
 19 Q. Or would it have to be funnelled through
 20 yourself as site chief or maybe -
 21 DR. COOK:
 22 A. No.
 23 COFFEY, Q.C.:
 24 Q. - both?
 25 DR. COOK:

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1 A. It could be both, something that could be
 2 funnelled through me or depending on the
 3 nature of the issue, something that could be
 4 dealt with directly between the individual
 5 pathologist and technologist.
 6 COFFEY, Q.C.:
 7 Q. Now, sir, I'd like to explore a bit further,
 8 then, the--as you assumed the role of interim
 9 clinical chief for year. And then I gather
 10 about approximately two years, 2000 and 2001,
 11 so about a year later, in '02 through '06 you
 12 were actually clinical chief?
 13 DR. COOK:
 14 A. From '02 to '06, that's correct.
 15 COFFEY, Q.C.:
 16 Q. So I'd like to explore that, the reporting
 17 mechanisms. In the period during which you
 18 were either interim clinical chief or acting
 19 or clinical chief, because it varied over
 20 time, could you tell the Commissioner what the
 21 role of the clinical chief was during your
 22 tenure?
 23 DR. COOK:
 24 A. Well, the clinical chief was responsible for
 25 running the, mainly the medical arm of the

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1 laboratory medicine program. The laboratory
 2 medicine program was divided into two arms,
 3 both the technical and the medical. The
 4 technical came under the program director and
 5 the medical primarily under the clinical
 6 chief. And I would report to the vice
 7 president of medical services at that time,
 8 and that would have been Dr. Robert Williams.
 9 The clinical chief, I guess the major role
 10 would be acting as a liaison with the various
 11 other entities that existed around the Health
 12 Care Corporation at that time, so I would
 13 interact a lot with the discipline chair.
 14 That was an individual who oversaw the
 15 university side of things. There would be
 16 interaction with clinical chiefs from the
 17 various other programs as well as sometimes
 18 discipline chairs from the other programs.
 19 There would be at times interactions between
 20 the Newfoundland and Labrador Medical
 21 Association on various issues. The clinical
 22 chief was responsible primarily for
 23 maintaining adequate numbers of pathologists
 24 on the various sites and involved quite
 25 extensive in recruitment and retention. I was

Page 20

1 also--you also made sure that pathologists
 2 were involved in various CME activities and
 3 tried to make sure that there was adequate
 4 funding for those CME activities. At the same
 5 time you were heavily involved in service
 6 activities. During my role as interim
 7 clinical chief, I still was involved in about
 8 100 percent service load and -
 9 COFFEY, Q.C.:
 10 Q. Service load, that means actual clinical work
 11 as a pathologist?
 12 DR. COOK:
 13 A. That means the actual clinical work as a
 14 pathologist.
 15 COFFEY, Q.C.:
 16 Q. Sorry, go ahead.
 17 DR. COOK:
 18 A. And during my time period from '02 to '06 I
 19 was still involved in service work to the tune
 20 of about 50 to 70 percent. The remainder of
 21 time now, for the remainder of the time I was
 22 involved in various committees and these were
 23 clinical chief committees, medical advisory
 24 committees and various hospital committees as
 25 well as committees with university, residency

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1 training programs and College of the North
 2 Atlantic.
 3 COFFEY, Q.C.:
 4 Q. And as the clinical chief for the laboratory
 5 medicine program, okay, did that make you
 6 defacto a member of the MAC?
 7 DR. COOK:
 8 A. That's correct.
 9 COFFEY, Q.C.:
 10 Q. Okay. And from your perspective at the time
 11 as the clinical chief, what, if anything, did
 12 you see as your role in relation to the MAC?
 13 DR. COOK:
 14 A. Providing, acting as a liaison between that
 15 program and with that committee, providing
 16 that committee with information regarding
 17 activities as it relates to laboratory
 18 medicine program.
 19 COFFEY, Q.C.:
 20 Q. And as the clinical chief the relationship
 21 between yourself and the vice president of
 22 medical, which in your tenure was Dr.
 23 Williams?
 24 DR. COOK:
 25 A. That's correct.

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1 COFFEY, Q.C.:
 2 Q. What was the--how much interaction would you
 3 have with Dr. Williams? Were there any--what,
 4 if any, committees were there? And how often
 5 did they meet?
 6 DR. COOK:
 7 A. Well, we usually meet on a regular basis with
 8 the leadership committee that was composed of
 9 Dr. Williams, myself, and the program director
 10 at the time.
 11 COFFEY, Q.C.:
 12 Q. That would be the leadership committee of the
 13 laboratory medicine program?
 14 DR. COOK:
 15 A. That's right.
 16 COFFEY, Q.C.:
 17 Q. We've heard of that.
 18 DR. COOK:
 19 A. With Dr. Williams, and that usually--we
 20 usually meet about once a month to discuss
 21 various issues surrounding the laboratory
 22 medicine program. Again, there was a much--a
 23 lot more informal interaction usually with
 24 phone calls, usually on a weekly basis, during
 25 that time period and attendance at other

Page 23

1 committee meetings, again such as MAC or
 2 clinical chiefs.
 3 COFFEY, Q.C.:
 4 Q. Doctor, I take you back now to the period when
 5 you were a site chief first, at St. Clare's.
 6 As site chief, how much or how, if any, if at
 7 all, did your occupying that role affect your
 8 clinical load as a pathologist?
 9 DR. COOK:
 10 A. Well -
 11 COFFEY, Q.C.:
 12 Q. Would you get any--only have to do so many
 13 cases compared--like was there any time
 14 allotted, getting at this kind of division of
 15 responsibility between the administrative work
 16 as the site chief and clinical work?
 17 DR. COOK:
 18 A. On paper, I was supposed to have 20 percent
 19 protected time.
 20 COFFEY, Q.C.:
 21 Q. Protected time.
 22 DR. COOK:
 23 A. To be involved in administrative activities.
 24 On a more realistic or actual--what actually
 25 happened, I was actually involved in 100

Page 24

1 percent service load.
 2 COFFEY, Q.C.:
 3 Q. And why was that? Why couldn't you use or get
 4 the 20 percent protected time?
 5 DR. COOK:
 6 A. Well, we were dealing with heavy service
 7 workloads, with not only just the service
 8 aspect, but you're involved in continuing
 9 medical education. You're involved in
 10 education activities, so were your other
 11 pathologists. They were also heavily involved
 12 in other committee meetings. The workloads
 13 were gradually increasing each year. There
 14 was involvement with undergraduate and post
 15 graduate teaching programs.
 16 COFFEY, Q.C.:
 17 Q. And I'll ask you about--the same question, but
 18 in relation to your period as clinical chief,
 19 either interim, acting or actual clinical
 20 chief, what was the situation there in terms
 21 of protected time and how did--versus clinical
 22 load and how did it work out in practice?
 23 DR. COOK:
 24 A. It was never really defined for me, in terms
 25 of here it is, you got 40-60 percent protected

Page 25

1 time to do or perform administrative
 2 activities. It was basically left up to the
 3 clinical chief, I suppose, as to what
 4 available time you could devote to
 5 administrative activities. So in my
 6 particular case, that varied from
 7 administration, anywhere from 30 to at times
 8 50 percent on the average over that four-year
 9 period.
 10 COFFEY, Q.C.:
 11 Q. That's the four years from '02 through '06?
 12 DR. COOK:
 13 A. That's correct.
 14 COFFEY, Q.C.:
 15 Q. And there was never--your recollection is it
 16 was never actually spelled out on paper, that
 17 you can recall, you know, clinical chief, you
 18 know, 30 or 40 percent protected time or 50
 19 percent protected time?
 20 DR. COOK:
 21 A. I can never remember seeing that figure.
 22 COFFEY, Q.C.:
 23 Q. Okay, but in practice, your recollection is
 24 that it would have varied, in your case, from
 25 about what to what, I'm sorry?

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1 DR. COOK:
 2 A. Well, it would vary, again, taking the service
 3 load, anywhere from 50 to 70 percent in terms
 4 of administrative varied from 30 to 50
 5 percent, depending on the various times of the
 6 years, the various months, weeks, whatever.
 7 COFFEY, Q.C.:
 8 Q. Now Doctor, you referred to the idea of one of
 9 the--certainly one of the functions, I gather,
 10 when you told the Commissioner of a clinical
 11 chief is to be involved in the recruiting?
 12 DR. COOK:
 13 A. That's correct.
 14 COFFEY, Q.C.:
 15 Q. I take it that was a clinical chief's role, as
 16 opposed to a site chief's?
 17 DR. COOK:
 18 A. That's correct.
 19 COFFEY, Q.C.:
 20 Q. Could you tell the Commissioner, please,
 21 during your tenure as clinical chief in one
 22 form or another, in terms of recruitment of
 23 pathologists, how that occurred over the years
 24 and how, if any, if at all, it evolved over
 25 the years?

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1 DR. COOK:
 2 A. Well, I certainly remember my interim year,
 3 between '99 and 2000, I remember when Dr.
 4 Haegert left for his sabbatical and was
 5 overseen with the task of clinical chief for
 6 that year. That year was particularly
 7 significant in that we--I had to recruit six
 8 laboratory physicians. Five of those were
 9 pathologists and one medical biochemist. That
 10 particular year, roughly each pathologist
 11 comprises about five percent of your manpower,
 12 so I had to recruit for that year, about 25
 13 percent of the manpower in pathology and one
 14 medical biochemist. That was a pretty
 15 extensive undertaking during that particular
 16 year. Recruitment into Newfoundland hasn't
 17 always been easy and the retention is
 18 significantly more challenging. That
 19 particular year, I remember was a time that we
 20 got a new contract or just got a new contract
 21 between the Newfoundland and Labrador Medical
 22 Association and Government. So we were
 23 relatively in the middle of the pack in terms
 24 of where we stood in the Canadian perspective.
 25 That certainly helped in recruitment. The

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1 issue was that I couldn't get many in terms of
 2 whom had Canadian qualification. We relied an
 3 awful lot on what was known as the individuals
 4 with J1 Visas, pathologists who were trained
 5 down in the States, whose visas had expired
 6 and were looking -
 7 COFFEY, Q.C.:
 8 Q. I take it that J1 is a temporary training sort
 9 of visa that allows a non-American citizen to
 10 train in the U.S.?
 11 DR. COOK:
 12 A. That's correct.
 13 COFFEY, Q.C.:
 14 Q. That was your understanding of it.
 15 DR. COOK:
 16 A. And when that visa runs out, then they have to
 17 leave the country.
 18 COFFEY, Q.C.:
 19 Q. Yes. I'm sorry, go ahead.
 20 DR. COOK:
 21 A. And so many of them look to Canada to come to
 22 establish the pathology practice and at that
 23 particular time, many of the provincial
 24 provinces had tight licensing restrictions.
 25 Now Newfoundland was one of the provinces that

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

18 COFFEY, Q.C.:
 19 Q. And so that, in particular, stands out in
 20 terms of that one year that you were interim
 21 chief, '99 through 2000. What then happened
 22 after you took over then as acting and then
 23 finally actual clinical chief, that four-year
 24 period, in terms of recruitment, how did it
 25 work then?

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1 DR. COOK:
 2 A. The first year, and since March of '02, I
 3 remember there was something in the order of
 4 three vacant positions that we had in the
 5 program. One of the significant vacant
 6 positions was our divisional chief for
 7 cytology. So I remember coming on and taking
 8 on that position of clinical chief that I had
 9 no divisional chief in that area, so I assumed
 10 responsibility for that particular division
 11 until I was able to recruit an individual. So
 12 not only was I wearing the site chief,
 13 clinical chief, but I was also divisional
 14 chief for cytology during that particular
 15 year.
 16 As I said, there were about three vacant
 17 positions at that particular time. One of the
 18 first individuals I managed to recruit during
 19 that time was Dr. Gershon Ejeckam and he had
 20 been previously--had conversation with Dr.
 21 Dave Haegert. When Dr. Haegert stepped down,
 22 then I took over the recruitment process. The
 23 second pathologist that I was able to bring in
 24 with recruitment initiatives was, I believe,
 25 Dr. Dan Fontaine. He was a resident in

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

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

17 DR. COOK:
 18 A. Well, we fairly stabilized the manpower
 19 situation for a period of about '03 to halfway
 20 through '04. So that was a period that we had
 21 relative stability in the manpower situation.
 22 What was occurring was during the latter half
 23 of '04 and particularly through '05, that we
 24 were beginning to run into serious manpower
 25 problems and this occurred as a result of

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1 retirements. This also occurred as a result
 2 of career opportunities that individuals had
 3 and also there were areas on mainland Canada
 4 that were more attractive to pathologists
 5 practising in that particular area. So things
 6 started to become quite significant, I'd say
 7 around June or July of '05, when I realized
 8 that we were going to be in significant
 9 problems.
 10 And things got particularly tough around
 11 April, November, December of '05 when again
 12 we've lost about, on the estimate, 25 to 30
 13 percent of our pathologists, either through
 14 retirement or trans locations to other areas
 15 of Canada, and that was quite significant.

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

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

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1 within the next two to three months. I'm just
 2 giving you the heads up, so you know, you can
 3 prepare for what's coming." Many times
 4 individuals have already made their plans.
 5 They would come in and say "here it is, Dr.
 6 Cook. I'm leaving in the next month or two.
 7 I've already signed a position with another
 8 institution." Now I would be given the heads
 9 up when I knew that somebody was retiring, but
 10 that was generally few and far between, but
 11 what I described to you previously is usually
 12 what happened in many circumstances.
 13 COFFEY, Q.C.:
 14 Q. Doctor, during that time period, in terms of
 15 the doctors who moved on, not so much the
 16 retirees as those who moved on to other
 17 places, did you have any understanding or
 18 views as to why they were leaving?
 19 DR. COOK:
 20 A. Well, to be honest with you, particularly when
 21 it came to the J1s, they saw Newfoundland as a
 22 holding area. This was a place where they can
 23 come, gain their experience, gain some
 24 knowledge, gain their confidence levels, and
 25 when better opportunities arose in other parts

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1 of Canada, they chose those opportunities to
 2 leave the province, and many of them had
 3 contacts and friends and relatives in mainland
 4 Canada, so they were quite well abreast of any
 5 developments happening in mainland Canada in
 6 terms of changes in licensing regulations and
 7 career opportunities in mainland Canada or
 8 vacant positions.
 9 COFFEY, Q.C.:
 10 Q. During the period from 2002 through 2006,
 11 while you were clinical chief, do you have any
 12 views as to whether or not the remuneration
 13 levels for pathologists here had any effect on
 14 people's willingness to stay?
 15 DR. COOK:
 16 A. I think it had an effect to a certain degree.
 17 We were one of the lowest paid pathologists in
 18 Canada.
 19 COFFEY, Q.C.:
 20 Q. Were you involved in any of the efforts during
 21 the period '02 to '06 to increase the
 22 remuneration for pathologists?
 23 DR. COOK:
 24 A. Mainly through my interaction with Dr. Bob
 25 Williams.

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1 COFFEY, Q.C.:
 2 Q. I take it was Dr. Williams involved with some
 3 group or committee that was -
 4 DR. COOK:
 5 A. That's right, he would be involved in
 6 negotiations with Newfoundland and Labrador
 7 Medical Association and there would be, I
 8 would say, communication namely between him
 9 and the Deputy Minister of Health.
 10 COFFEY, Q.C.:
 11 Q. Now Doctor, your training in pathology, as a
 12 resident, goes back to around the--well, the
 13 first half of the 1980s, in effect.
 14 DR. COOK:
 15 A. I started around June of '81.
 16 COFFEY, Q.C.:
 17 Q. '81, so through '85-86, that time frame.
 18 Could you tell the Commissioner, please, at
 19 that time, how much, if any, training in
 20 immunohistochemistry there was for a
 21 pathologist in a Canadian residency program,
 22 at least the one you went through?
 23 DR. COOK:
 24 A. Well, immunohistochemistry was just starting
 25 in the residency program that I was involved

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1 at. Most of the stains were at the
 2 histochemical level and at the routine
 3 haematoxylin and eosin level. The stains that
 4 we dealt with, as residents, were few and far
 5 between. They were mainly used as an adjunct
 6 in helping us make a diagnosis, but they
 7 weren't the sole indicator. So the level was
 8 mainly at the area of interpretation, as
 9 opposed to technical know-how or
 10 troubleshooting. It was mainly at
 11 interpretative levels.
 12 COFFEY, Q.C.:
 13 Q. And that was as a resident?
 14 DR. COOK:
 15 A. As a resident.
 16 COFFEY, Q.C.:
 17 Q. Then as a staff person, I take it in mid 80s,
 18 as you've indicated, you became a staff member
 19 at St. Clare's. Were you ever part of
 20 Memorial University's medical program, in the
 21 sense of as a teacher?
 22 DR. COOK:
 23 A. Yes, I was.
 24 COFFEY, Q.C.:
 25 Q. Could you tell the Commissioner about that?

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1 DR. COOK:
 2 A. I was clinical assistant lecturer at Memorial
 3 University and then that was upgraded to
 4 clinical or assistant professor at Memorial
 5 University of Newfoundland.
 6 COFFEY, Q.C.:
 7 Q. And what sort of responsibilities did those
 8 positions involve?
 9 DR. COOK:
 10 A. Those mainly involved responsibilities at the
 11 undergraduate and mainly at post graduate
 12 levels. Post graduate levels were involved in
 13 residency training programs which was involved
 14 in setting up the various rounds, making sure
 15 residents were involved in scheduling, making
 16 sure they were doing adequate numbers of
 17 surgical cytology, autopsy cases, meetings
 18 with other members of the discipline in
 19 regards to planning of the curriculum. We
 20 were also involved in undergraduate teaching
 21 programs, particularly medical students and
 22 setting up lecturers, rotations at the various
 23 hospitals, and tutorials.
 24 COFFEY, Q.C.:
 25 Q. And Doctor, are you still involved in that

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1 function with Memorial?
 2 DR. COOK:
 3 A. That's correct.
 4 COFFEY, Q.C.:
 5 Q. Memorial's medical school. You referred to
 6 the planning of the curriculum?
 7 DR. COOK:
 8 A. Um-hm.
 9 COFFEY, Q.C.:
 10 Q. Would that be for undergraduates and graduate
 11 students?
 12 DR. COOK:
 13 A. Mostly graduates.
 14 COFFEY, Q.C.:
 15 Q. Graduates, and that's--and in that world, I
 16 take it, that's another name for graduates
 17 here are residents?
 18 DR. COOK:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. Okay, and you've been involved, in one form or
 22 another in that aspect of medical education
 23 really from the mid 80s until right up until
 24 now?
 25 DR. COOK:

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1 A. That's correct.
 2 COFFEY, Q.C.:
 3 Q. Doctor, can you tell us, please, what--how
 4 much, if any, training that you're aware of,
 5 at least in terms of the curriculum, that a
 6 pathology resident would receive going through
 7 the pathology programs at Memorial
 8 University's medical school in terms of
 9 immunohistochemistry?
 10 DR. COOK:
 11 A. Again, only at the microscopic level, that
 12 would be mainly in the area of interpretation,
 13 determining what stains are best suited to
 14 make a particular diagnosis of a lesion,
 15 determining what part of, say of the cell
 16 would be staining with the cell, the
 17 cytoplasmic membrane, cytoplasm nucleus
 18 aspects of the cell. And determining what
 19 profile of antibodies immunohistochemical
 20 stains are best suited to diagnose that
 21 particular lesion, and that would be used in
 22 conjunction possibly with histochemical
 23 stains, your routine H&E's and at times,
 24 electron microscopy and or floctometry or
 25 molecular genetics. So it was one component

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1 amongst many used to make diagnostic
 2 interpretations.
 3 COFFEY, Q.C.:
 4 Q. Has that changed over this, well I'll refer to
 5 it as just over a twenty-year period from the
 6 mid eighties to, say 2008?
 7 DR. COOK:
 8 A. It certainly changed in the utilization or the
 9 degree of immunohistochemistry. It's much
 10 more utilized today than it was, say my time
 11 period as a resident and early staff
 12 pathologist.
 13 COFFEY, Q.C.:
 14 Q. And you indicated at the microscopic level and
 15 the terms of different stains utilize
 16 different stainings of different parts of the
 17 cell, particular stains use--the staining
 18 should occur in particular parts of the cell,
 19 for example you refer to the nucleus cytoplasm
 20 and the membrane.
 21 DR. COOK:
 22 A. Right.
 23 COFFEY, Q.C.:
 24 Q. Different stainings. What about the idea of,
 25 because you referred to it just earlier, the

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1 idea of troubleshooting and the theory, the
 2 scientific theory behind immunohistochemistry.
 3 Would a medical resident in pathology be
 4 expected or be expected to know or even be
 5 exposed to that?
 6 DR. COOK:
 7 A. Most of the--in terms of troubleshooting, that
 8 was mainly at the technical end. The
 9 interpretive end was primarily the weight that
 10 was placed on residents. There would be an
 11 expectation that the resident would know the
 12 theory behind immunohistochemistry and the
 13 various pitfalls in immunohistochemistry, but
 14 primarily that would be used in interpretation
 15 and what battery of stains would be used to
 16 make interpretations in various lesions.
 17 COFFEY, Q.C.:
 18 Q. Do you know for example if a pathology
 19 resident, for example a Memorial University
 20 program, would ever actually be tested on
 21 their knowledge of the theory, the scientific
 22 theory behind IHC?
 23 DR. COOK:
 24 A. That I can't say for sure, that individual may
 25 or may not, again there were many others that

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1 involved in the examination of the residents,
 2 mainly at the discipline chair level and
 3 pathologists who are university academic
 4 pathologists, so I really can't comment on
 5 that.
 6 COFFEY, Q.C.:
 7 Q. And the same question in relation to the idea
 8 of, you know, use the word pitfalls or
 9 potential, problematic aspects of IHC
 10 procedures, do you know if pathology residents
 11 would be tested on that sort of knowledge?
 12 DR. COOK:
 13 A. In regards to interpretation, knowledge that,
 14 you know, a certain percentage of particular
 15 lesions may have a particular percentage of
 16 immuno reactive positivity. In regards that a
 17 particular stain may be present in more than
 18 one lesion; in regards that a particular
 19 lesion may have the unusual identification of
 20 a particular stain.
 21 COFFEY, Q.C.:
 22 Q. They would be expected to know that and be
 23 tested upon it?
 24 DR. COOK:
 25 A. They would be expected to know that in regards

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1 to the total interpretation of the lesion,
 2 taken into account again your hematoxylin
 3 eosin, your other histochemical stains and if
 4 necessary immunoperoxidase, floctometry, that
 5 sort of thing. It would be used, not solely
 6 to make an interpretation, but as part of an
 7 overall plan, as part of an overall picture.
 8 COFFEY, Q.C.:
 9 Q. Doctor, I take it that as the, I gather that
 10 the number of IHC stains, for example in usage
 11 at the General Hospital site here in St.
 12 John's has changed significantly over the past
 13 20 years?
 14 DR. COOK:
 15 A. That's correct.
 16 COFFEY, Q.C.:
 17 Q. The amount of exposure to IHC, as a treatment
 18 or a clinical tool for pathology residents, I
 19 take it that has changed over time as well.
 20 DR. COOK:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. Doctor, can you tell the Commissioner please
 24 what your exposure, for example in your own
 25 individual case to IHC has been over your

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1 career? Like, when were you first exposed to
 2 it and then how has that evolved over time?
 3 DR. COOK:
 4 A. Well I was first exposed to it, I'd say around
 5 the early eighties when, now IHC had been
 6 around for quite some time, but in terms of
 7 Memorial University, in terms of my experience
 8 with it, it gradually came on stream in the
 9 early mid eighties and it evolved slowly but
 10 steadily and there was quite a bit of reliance
 11 placed on our routine H&E stains,
 12 histochemical stains and electron microscopy.
 13 But more and more it became more prominent in
 14 the role of interpretations to the point that
 15 it almost became routine ordering
 16 immunohistochemistry on many lesions that we
 17 saw going through the institution.
 18 COFFEY, Q.C.:
 19 Q. Where were the IHC staining processes
 20 performed at that time, in the eighties?
 21 DR. COOK:
 22 A. In the eighties mainly at the General
 23 Hospital, but I think the Grace were doing
 24 some IHC staining and I think we did some at
 25 St. Clare's and that was probably later in the

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1 80's for St. Clare's.
 2 COFFEY, Q.C.:
 3 Q. And we'll go through the 90's, how did it
 4 evolve then in terms of what sites were doing
 5 what?
 6 DR. COOK:
 7 A. Still basic staining at St. Clare's and the
 8 Grace. I can't really say for sure what was
 9 happening at the Grace. I know that at St.
 10 Clare's we were just getting into the use of
 11 some of the kits, using some of the basic
 12 stains, but most of the immunohistochemistry
 13 was taking place at the General Hospital site.
 14 COFFEY, Q.C.:
 15 Q. And why was that?
 16 DR. COOK:
 17 A. I guess it's regarded at the site that was
 18 tertiary care site, it was the site that had
 19 the most concentration of technologists and
 20 historically it is a site that had taken in
 21 samples and specimens from other areas of the
 22 province.
 23 COFFEY, Q.C.:
 24 Q. And was there anything in particular or unique
 25 about IHC that caused the performing of--or

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1 the utilization of those stains increasingly
 2 be concentrated at the General site?
 3 DR. COOK:
 4 A. I guess the General had the greatest number of
 5 technologists and it was an area there that
 6 probably, I would say in terms of the province
 7 had the most expertise and various aspects of
 8 laboratory medicine.
 9 COFFEY, Q.C.:
 10 Q. Doctor, when you took over or you became site
 11 chief of St. Clare's at around 1996, you told
 12 the Commissioner, what, if any, involvement
 13 would you have in IHC staining at that point?
 14 DR. COOK:
 15 A. Very little.
 16 COFFEY, Q.C.:
 17 Q. Okay, and the very little, what if any did
 18 that involve?
 19 DR. COOK:
 20 A. That involved mainly interpretations.
 21 COFFEY, Q.C.:
 22 Q. Okay, the interpret--you would order--so how
 23 did that work? Could you tell the
 24 Commissioner, please, for example, you got a--
 25 I don't know, you have a particular tissue

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

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1 so we would circle or mark or indicate the
 2 stains. Those would be--that requisition
 3 would be forwarded over to the General
 4 Hospital site and at that particular time,
 5 depending on where the blocks were located,
 6 the paraffin block, on which the tissue was
 7 embedded, would also be forwarded over to the
 8 General Hospital site where the staining
 9 process would be performed. The slides then
 10 would be forwarded back to St. Clare's for
 11 interpretation.
 12 COFFEY, Q.C.:
 13 Q. Doctor, and I take it then that as time went
 14 on and there were more and more IHC stains
 15 available, particularly at the General
 16 Hospital site, if as a practising pathologist
 17 at St. Clare's, if you wanted a particular IHC
 18 stain done, you'd check it off on the form,
 19 indicate it on the form, someone would arrange
 20 for the particular block or you might even
 21 identify the block in the form that you wanted
 22 it done on.
 23 DR. COOK:
 24 A. Oh the block would be identified in the form.
 25 COFFEY, Q.C.:

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1 Q. And the block and the form would go over and
 2 the slide would be prepared and it would end
 3 up back on your desk?
 4 DR. COOK:
 5 A. That's correct.
 6 COFFEY, Q.C.:
 7 Q. Doctor, now the preparation of the blocks,
 8 okay, for example at St. Clare's in the
 9 1990's, were the blocks, paraffin blocks
 10 actually prepared on the St. Clare's site in
 11 the 1990's?
 12 DR. COOK:
 13 A. In the 1990's they were.
 14 COFFEY, Q.C.:
 15 Q. Has that ever changed since?
 16 DR. COOK:
 17 A. During the '90's or -
 18 COFFEY, Q.C.:
 19 Q. Or since--well I never know what to call the
 20 2000's, as it were, the first ten years.
 21 DR. COOK:
 22 A. That changed in May of '05 when we centralized
 23 the technical services at the General
 24 Hospital, but up until that time, the
 25 preparation of the blocks were performed at

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1 St. Clare's.
 2 COFFEY, Q.C.:
 3 Q. And that process then, so up until May of
 4 2005, that process involved what? Could you
 5 just describe for the Commissioner what would
 6 happen? I take it a surgeon would take tissue
 7 from a patient and it would end up down in the
 8 pathology lab. How would it work then?
 9 DR. COOK:
 10 A. Well, let's say a biopsy was excised from the
 11 patient in the OR. that biopsy would be placed
 12 in a container or formalin, usually you make
 13 sure there's adequate amounts of formalin to
 14 completely immerse and cover that biopsy.
 15 That container then would be forwarded at that
 16 time to our frozen section room. It would
 17 have been picked up by the hospital porter,
 18 along with numerous other specimens at
 19 designated times during the day. That would
 20 then be forwarded to the lab at St. Clare's.
 21 Once in the lab, that would be registered or
 22 accessioned, you have to make sure that that
 23 container was appropriately labelled, both on
 24 a container and accompanied by the
 25 requisition. The accessioning would take

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

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

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1 where the paraffin block would be placed in a
 2 microtome and sections would be cut and placed
 3 in a bath. The sections would be cut to the
 4 thickness of approximately three to four or
 5 five microns, depending on the tissue
 6 involved. Once the sections were then cut,
 7 the individual sections were placed on a glass
 8 slide and it would then go through a staining
 9 process, usually with the hematoxylin and
 10 eosin and eventually we obtained automatic
 11 stainers that provided the stain for the H&E.
 12 Once the staining process was then done, a
 13 cover slipping process would take place. The
 14 completed slides then would be then forwarded
 15 to the pathologist once the labelling process
 16 has taken place and there's correlation
 17 between the slide, the surgical number and the
 18 requisition. So what the pathologist would
 19 receive then for interpretation would be their
 20 slides of the case and the requisitions and
 21 surgical numbers and various demographic
 22 information.
 23 COFFEY, Q.C.:
 24 Q. Doctor, at St. Clare's while you were site
 25 chief, was there ever--were there ever any

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1 written protocols for this process you've just
 2 described?
 3 DR. COOK:
 4 A. There may have been technical protocols which
 5 I wouldn't have been too involved in, but
 6 there were no written protocols for the
 7 fixation process. We did have a manual, an
 8 old manual at that time which was then
 9 forwarded to the OR and nursing people
 10 regarding the amount of formalin that would be
 11 submitted in the various containers.
 12 COFFEY, Q.C.:
 13 Q. I'm sorry, when would that have been?
 14 DR. COOK:
 15 A. I think that was occurring as early as the
 16 1970s.
 17 COFFEY, Q.C.:
 18 Q. And do you know if there was such a written
 19 protocol in place, for example, from 1997
 20 through 2005?
 21 DR. COOK:
 22 A. In regards to the fixation?
 23 COFFEY, Q.C.:
 24 Q. Yes.
 25 DR. COOK:

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1 A. No.
 2 COFFEY, Q.C.:
 3 Q. No. Well, with respect to the amount of
 4 formalin that would be required for certain
 5 type of specimens.
 6 DR. COOK:
 7 A. Not in the lab, but there still probably could
 8 have been still existing at the ward, nursing
 9 ward level and at the OR level.
 10 COFFEY, Q.C.:
 11 Q. But that would be something one would have to
 12 ask the peri-operative program, I take it?
 13 DR. COOK:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. Doctor, you've referred to tissue processors,
 17 the idea of reprocessing, what is that?
 18 DR. COOK:
 19 A. Reprocessing would take place, that if I got
 20 the slide and let's say I was not happy with
 21 the quality of the slide or had problems with
 22 the nuclear features, the nuclei would become
 23 hazy or fuzzy, I would ask the technologist to
 24 do a reprocessing technique. And that
 25 basically would involve the remounting of the

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1 paraffin block, resubmission of the tissue
 2 through the processor and then re-embedding of
 3 the tissue into the paraffin and
 4 solidification and then staining.
 5 COFFEY, Q.C.:
 6 Q. Are there any potential complications or
 7 problems associated with the reprocessing
 8 process?
 9 DR. COOK:
 10 A. There's a possibility that it may interfere
 11 with certain stains, certain histochemical
 12 stains. That's always a possibility.
 13 COFFEY, Q.C.:
 14 Q. And would that also apply to
 15 immunohistochemical stains as well?
 16 DR. COOK:
 17 A. It could.
 18 COFFEY, Q.C.:
 19 Q. Doctor, what would be the root cause or causes
 20 that would contribute to the necessity or the
 21 need for reprocessing? I appreciate what you
 22 see on the slide and from your perspective as
 23 a pathologist, you need it reprocessed, but
 24 what would have caused the problem in the
 25 first place?

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1 DR. COOK:
 2 A. Again, if there hasn't been significant
 3 dehydration of the tissue through the
 4 processor.
 5 COFFEY, Q.C.:
 6 Q. The tissue processor itself.
 7 DR. COOK:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. In other words, if there has been some
 11 problematic aspect of the tissue in question
 12 going through the tissue processor and you've
 13 referred to in adequate dehydration -
 14 DR. COOK:
 15 A. Or there may have been a step or hasn't gone
 16 through the correct grading of alcohol. I
 17 mean, we go through various grades of alcohol,
 18 90, 70, 80 percent. If something was missed
 19 in that type of process -
 20 COFFEY, Q.C.:
 21 Q. And this again involves the tissue processing
 22 itself, the tissue processor?
 23 DR. COOK:
 24 A. That's my understanding, yes.
 25 COFFEY, Q.C.:

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1 Q. Doctor, was there any way, as a practising
 2 pathologist that you'd be able to ascertain
 3 what, if any, negative effects reprocessing
 4 might have on particular IHC stains or
 5 histology stains?
 6 DR. COOK:
 7 A. It's a bit rough on the antigen that excites.
 8 So, if you go through reprocessing of the
 9 tissue through, again through a number of
 10 times, a number of episodes. It could reduce
 11 the number of antigen excites that are
 12 available for attachment by the primary
 13 antibody.
 14 COFFEY, Q.C.:
 15 Q. It might affect your ability to visualize, for
 16 the process to visualize for you, looking
 17 through a scope.
 18 DR. COOK:
 19 A. It could or it may not. I mean, there's very
 20 little, from what I understand, written in the
 21 literature on the effect of reprocessing
 22 itself and how that affects IHC.
 23 COFFEY, Q.C.:
 24 Q. Is reprocessing as a process, is it desirable
 25 or not, all things being equal?

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1 DR. COOK:
 2 A. Oh, you wouldn't want to reprocess. If you
 3 can reduce the amount of reprocessing, that's
 4 what you would want.
 5 COFFEY, Q.C.:
 6 Q. Doctor, do you know at St. Clare's, during
 7 your time as site chief there, whether anyone
 8 ever kept track of the amount of tissue that
 9 was required to be reprocessed?
 10 DR. COOK:
 11 A. The actual numbers of cases?
 12 COFFEY, Q.C.:
 13 Q. Yes, number of cases, like the overall
 14 percentage of cases that might have to be
 15 reprocessed?
 16 DR. COOK:
 17 A. No.
 18 COFFEY, Q.C.:
 19 Q. Doctor, the Commissioner has heard evidence
 20 related to fixation problems. Like, the idea
 21 that, from a pathologist perspective, able to
 22 look at a tissue on a slide or slides and at
 23 times problems with the fixation process can
 24 be apparent.
 25 DR. COOK:

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

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1 any other lab.
 2 COFFEY, Q.C.:
 3 Q. Do you recall in your period as site chief at
 4 St. Clare's, whether or not you ever made any
 5 inquiries in relation to fixation concerns?
 6 Did you ever complain about fixation problems?
 7 DR. COOK:
 8 A. Not in regards to fixation concerns. There
 9 would be concerns about, again, mostly the
 10 concerns that I had to deal with were
 11 turnaround times, getting the actual slides to
 12 the pathologist, but generally speaking, very
 13 few concerns regarding the actual quality of
 14 the slides.
 15 COFFEY, Q.C.:
 16 Q. And Doctor, how about complaints to yourself
 17 as site chief from other pathologists?
 18 DR. COOK:
 19 A. Mainly again regarding turnaround times.
 20 COFFEY, Q.C.:
 21 Q. And what did that involve?
 22 DR. COOK:
 23 A. Oh, this would involve the, again, how many
 24 technologists that we would have available on
 25 site, the increasing workload and the ability

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

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1 Q. I've asked you about any complaints about
 2 fixation. How about complaints related to
 3 processing? Now, you've indicated that at
 4 times you would have to ask for a slide or a
 5 particular block to be reprocessed. How
 6 common was that -
 7 DR. COOK:
 8 A. That was -
 9 COFFEY, Q.C.:
 10 Q. - or uncommon as the case might be.
 11 DR. COOK:
 12 A. Fairly--uncommon.
 13 COFFEY, Q.C.:
 14 Q. Do you know if any record was kept at all, any
 15 records were kept of that? For example, how
 16 would you know if a particular block had been
 17 reprocessed?
 18 DR. COOK:
 19 A. I wouldn't know. The only time a block would
 20 be reprocessed is if I asked for it to be
 21 reprocessed.
 22 COFFEY, Q.C.:
 23 Q. Would any record be kept of the fact that you
 24 had asked?
 25 DR. COOK:

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

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|---|--|
| <p>1 '90s. Then during that time period, around 2 '96 to '99 it was Dr. Mahmoud Khalifa. We had 3 no one from that time period, around 2000 to 4 2003 actually overseeing the 5 immunohistochemistry. That role or overseeing 6 of the role generally would fall in the hands 7 of the site chief.</p> <p>8 COFFEY, Q.C.: 9 Q. The site chief in this context would be the 10 site chief of the General Hospital?</p> <p>11 DR. COOK: 12 A. The General Hospital.</p> <p>13 COFFEY, Q.C.: 14 Q. Okay. And who was the site chief in that time 15 frame?</p> <p>16 DR. COOK: 17 A. During that time period for a period of time 18 there was Dr. Sash Chittal, Dr. Patricia 19 Wadden and Dr. Sushil Parai.</p> <p>20 COFFEY, Q.C.: 21 Q. Okay. And what happened then in 2003?</p> <p>22 DR. COOK: 23 A. 2003, well, after I recruited Dr. Ejeckam and 24 he came in 2002, he expressed an interest 25 overseeing the immunohistochemistry.</p> | <p>1 Q. Before Dr. Ejeckam arrived and after Dr. 2 Khalifa left, during that hiatus, as the 3 clinical chief if someone at the time had 4 asked you about IHC, I take it in theory you 5 would have been responsible because whoever 6 was responsible would report to you as 7 clinical chief?</p> <p>8 DR. COOK: 9 A. Yes.</p> <p>10 COFFEY, Q.C.: 11 Q. How much actual involvement did you have in 12 IHC during that time?</p> <p>13 DR. COOK: 14 A. Apart from interpretations, very little.</p> <p>15 COFFEY, Q.C.: 16 Q. And is somebody had asked you about it then 17 you would actually point to Khalifa in his 18 day.</p> <p>19 DR. COOK: 20 A. Khalifa in his day.</p> <p>21 COFFEY, Q.C.: 22 Q. The site chief of the General Hospital, 23 whoever he or she was at the time. And then 24 finally when Doctor Ejeckam came along, Doctor 25 Ejeckam.</p> |
| <p style="text-align: right;">Page 66</p> <p>1 COFFEY, Q.C.: 2 Q. And then he was there until, well, through '05 3 into '06, I take it?</p> <p>4 DR. COOK: 5 A. That's correct.</p> <p>6 COFFEY, Q.C.: 7 Q. And we'll be dealing more with that as we go 8 on. Then, Doctor, up to the time Dr. Ejeckam 9 arrived and expressed an interest in IHC, 10 okay, because by then you would have already 11 been--you were clinical chief by that point?</p> <p>12 DR. COOK: 13 A. Since March, yeah.</p> <p>14 COFFEY, Q.C.: 15 Q. Yes. And you had been clinical chief, so 16 you'd been clinical chief from March of '02 17 on?</p> <p>18 DR. COOK: 19 A. Um-hm.</p> <p>20 COFFEY, Q.C.: 21 Q. And you'd been clinical chief for a year back 22 in '99 through 2000?</p> <p>23 DR. COOK: 24 A. Um-hm.</p> <p>25 COFFEY, Q.C.:</p> | <p style="text-align: right;">Page 68</p> <p>1 DR. COOK: 2 A. Doctor Ejeckam.</p> <p>3 COFFEY, Q.C.: 4 Q. I'm going to ask, please, during the period 5 when you would just be involved in IHC 6 processes by way of ordering an IHC stain and 7 then interpreting the slide, how would you go 8 about learning what to look for a particular 9 stain? How would you even know that a 10 particular stain existed. And if so then, how 11 to utilize it.</p> <p>12 DR. COOK: 13 A. Well, I mean, it would depend on the lesion 14 involved. If I'm looking at an 15 undifferentiated carcinoma, I know I would 16 order a battery of stains to look whether 17 there's lymphoepithelial or a lymphoreticular 18 or a menschel lesion. So, that knowledge was 19 there in determining the type of stains that I 20 would order. So, for lymphomas I would order 21 a battery of stains to, you know, help me sub- 22 classify certain lesions along with 23 floctometry or whatnot, but it would depend 24 on the type of lesion I was looking at, 25 forming a differential diagnosis, I would</p> |

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1 determine a batter of stains.
 2 COFFEY, Q.C.:
 3 Q. For example, in the early 1990s, how would you
 4 know which new stains there were? How would
 5 you become aware of -
 6 DR. COOK:
 7 A. I would phone--in the early '90s?
 8 COFFEY, Q.C.:
 9 Q. Yes.
 10 DR. COOK:
 11 A. Could be conversations what Doctor Chittal at
 12 that particular time or it would be
 13 conversation with the discipline chair because
 14 we had a university component there. The
 15 university people would be involved in
 16 bringing in new peroxidase stains. There
 17 would be conversations with the various chief
 18 tech or the divisional manager at that time,
 19 at the General Hospital, as to what stains are
 20 available. And I can't remember, there may
 21 have been a list sent out--you can obtain a
 22 list sent out with the various stains that
 23 were available at the General Hospital.
 24 COFFEY, Q.C.:
 25 Q. And then, what about the utilization of the

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

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1 A. Doctor Mahmoud Khalifa. He was a site chief
 2 and staff pathologist at St. Clare's. I
 3 believe he came in '96 until '99.
 4 COFFEY, Q.C.:
 5 Q. And, I'm sorry, he was at which site?
 6 DR. COOK:
 7 A. Sorry, General Hospital.
 8 COFFEY, Q.C.:
 9 Q. General Hospital. And you believe he came in
 10 19 -
 11 DR. COOK:
 12 A. I think he came in '96.
 13 COFFEY, Q.C.:
 14 Q. - 96. Now, was Doctor Khalifa, as I'll refer
 15 to him, did he ever become a site chief at the
 16 General?
 17 DR. COOK:
 18 A. Yes, he did.
 19 COFFEY, Q.C.:
 20 Q. Was that early on in his tenure, do you
 21 recall?
 22 DR. COOK:
 23 A. I can't remember exactly when he became site
 24 chief. I can't give you the specific date.
 25 COFFEY, Q.C.:

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

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1 first case, 97-1400 which will be considered
 2 at ER positive by immuno was, in fact,
 3 negative by bio. Of course, the number of
 4 cases is still too low to come to a final
 5 conclusion, but I think overall we are not
 6 doing bad. I would appreciate your thoughts
 7 on this, of course, your efforts to provide
 8 the parallel biochemical studies are extremely
 9 viable. Let me know if you have any further
 10 suggestions to make this task more valid and
 11 effective. Also, let me know of any possible
 12 correlation with Mayo. Yours truly".
 13 And if we could just look, Doctor, the
 14 second page, correlation of biochemistry,
 15 there are four cases involved here,
 16 immunohistochemistry on the left and
 17 biochemistry results on the right. Doctor, up
 18 to that point in time, biochemistry, it's
 19 involvement for ER and PR, can you tell the
 20 Commissioner please about what, if anything
 21 pathologist had to do with ER and PR up to
 22 this point?
 23 DR. COOK:
 24 A. Well, up to this point, prior to '97, '98, we
 25 performed what is known as the Ligand Binding

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1 Assay on breast tissue with carcinomas. And
 2 that would involve--and I go back to what I
 3 did at St. Clare's--when the breast tissue was
 4 removed from the patient, this would be put in
 5 a submitting container and we would be
 6 notified by the OR that there was a breast
 7 ready for submission for biochemical analysis
 8 for ER and PR. So, we would be called down
 9 from the lab to go down to the OR and actually
 10 take a portion of the tumor and submit that
 11 into liquid nitrogen, rapid freezing of the
 12 tumor. And that would then be submitted over
 13 to the General Hospital for analysis by the
 14 biochemical assay.
 15 COFFEY, Q.C.:
 16 Q. You'd actually be called to the OR and excise
 17 a piece of the tumor.
 18 DR. COOK:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. And then put it in liquid nitrogen and then it
 22 would be transported in the liquid nitrogen
 23 over to the General for biochemical assay.
 24 And the report on the biochemical assay
 25 results would go to whom? Would that come to

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1 a pathologist?
 2 DR. COOK:
 3 A. It varied. There were, I think, about four
 4 reports generated at that time, four copies.
 5 One report might stay in the lab itself;
 6 another copy, hard copy, would be going to the
 7 physician; a third copy may go to the chart;
 8 and it's possible, if I recollect properly
 9 that another copy may go to myself or to
 10 someone at the St. Clare's.
 11 COFFEY, Q.C.:
 12 Q. Doctor, who would be responsible at the time
 13 for ordering the ER/PR biochemical assay?
 14 Would a pathologist order that test or would
 15 the surgeon or someone else?
 16 DR. COOK:
 17 A. I can tell you what I did at St. Clare's. I
 18 would order the test.
 19 COFFEY, Q.C.:
 20 Q. So, at what stage then in the process would
 21 you come to order the biochemical test?
 22 DR. COOK:
 23 A. Oh, almost instantly. As soon as I was
 24 notified from the OR, go down and take the
 25 tissue, I would order a requisition.

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1 COFFEY, Q.C.:
 2 Q. And the biochemical assay results would come
 3 from the General Hospital lab from biochem -
 4 DR. COOK:
 5 A. From biochemistry lab.
 6 COFFEY, Q.C.:
 7 Q. - lab. And other than perhaps getting a copy
 8 of the report, would you have any further
 9 involvement in the ER/PR aspect of the matter
 10 at that time?
 11 DR. COOK:
 12 A. What I would do initially is incorporate the
 13 copy of that report into our pathology report
 14 because over--you just didn't know over a time
 15 period over the next five, ten or fifteen
 16 years where that hard copy of that report
 17 would go. So, if incorporated it into your
 18 computer system, the hospital information
 19 system, you certainly felt a comfort level
 20 that that information would be maintained for
 21 ten, fifteen or twenty year period.
 22 COFFEY, Q.C.:
 23 Q. So, the biochemistry lab generated a report on
 24 the biochemical assay.
 25 DR. COOK:

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1 A. Um-hm.
 2 COFFEY, Q.C.:
 3 Q. They wouldn't actually enter that into the
 4 Meditec system.
 5 DR. COOK:
 6 A. They mightn't, no. Now, I could be wrong on
 7 that, but I mean, I can't be absolutely sure,
 8 but that hard copies, at that time, were sent
 9 in a number of different directions.
 10 COFFEY, Q.C.:
 11 Q. And it was your practice as the pathologist
 12 for that particular case, when you got the
 13 biochemical assay report, to dictate that into
 14 the Meditec system.
 15 DR. COOK:
 16 A. I would dictate into Meditec. Now, for me--I
 17 can't say whether that happened with every
 18 other pathologist in the system.
 19 COFFEY, Q.C.:
 20 Q. I take it then that there was no hard and fast
 21 rule about that, at the time?
 22 DR. COOK:
 23 A. No.
 24 COFFEY, Q.C.:
 25 Q. Now, looking at this -

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1 THE COMMISSIONER:
 2 Q. I just want to make sure I understand. Do I
 3 take it then in the days when you sent it off
 4 for biochemical assay, you didn't really have
 5 to exercise your professional judgment except
 6 at the OR where you chose the sample to go in
 7 the -
 8 DR. COOK:
 9 A. I would take the sample -
 10 THE COMMISSIONER:
 11 Q. - in relation to that particular -
 12 DR. COOK:
 13 A. I would look at the specimen, section it, look
 14 at the lesion, make sure that the area I took
 15 was actually the lesion in question, make sure
 16 it was tumor for the most part.
 17 THE COMMISSIONER:
 18 Q. Yes.
 19 DR. COOK:
 20 A. And then submit that in liquid nitrogen.
 21 THE COMMISSIONER:
 22 Q. Um-hm. After that you got numbers back from
 23 the biochemistry lab in the General Hospital?
 24 DR. COOK:
 25 A. That's right.

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1 THE COMMISSIONER:
 2 Q. And that's as far as you were required to act
 3 professionally, as it were? I mean, it didn't
 4 require your professional judgment except to
 5 the point that you, before you put it into the
 6 liquid nitrogen, does that make sense?
 7 DR. COOK:
 8 A. That's correct, yes.
 9 THE COMMISSIONER:
 10 Q. Yes, okay.
 11 COFFEY, Q.C.:
 12 Q. And then when the numbers came back from the
 13 biochemistry lab, in your own case you might
 14 dictate them into the Meditec system, but you
 15 wouldn't have to make any professional
 16 judgment about them--the Commissioner is
 17 asking you about.
 18 DR. COOK:
 19 A. No.
 20 COFFEY, Q.C.:
 21 Q. Whatever the number was, you -
 22 DR. COOK:
 23 A. The number was there and it would say either
 24 negative or equivocal or positive. And there
 25 would be a range of numbers given there to

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1 show where the number you got from the test
 2 result fit in with the various ranges.
 3 COFFEY, Q.C.:
 4 Q. Yes. In fact, just on that point, looking at
 5 page two of Exhibit P-1855, I take it here
 6 that biochemical reporting -
 7 DR. COOK:
 8 A. Yes, those are the ranges.
 9 COFFEY, Q.C.:
 10 Q. That's the ranges, zero to three, negative;
 11 three to twenty, equivocal; and greater than
 12 twenty, positive.
 13 DR. COOK:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. That would be the sort of range that you're
 17 talking about in the biochemical reporting
 18 system.
 19 DR. COOK:
 20 A. That's correct.
 21 COFFEY, Q.C.:
 22 Q. Thanks. Now, Doctor, could you tell the
 23 Commissioner then, what was going on here then
 24 in April of 1997, as we're talking here now
 25 about immuno assessment of ER/PR in the first

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

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1 cases at St. Clare's where our samples--and
 2 this was at the time when the biochemistry was
 3 still on the go. I would forward the breast
 4 samples to the General Hospital. I think I
 5 remember at that time taking the paraffin
 6 block, the actual tissue itself and sending it
 7 down to the Mayo clinic for correlations.
 8 COFFEY, Q.C.:
 9 Q. And what was the Mayo clinic doing with it?
 10 DR. COOK:
 11 A. They were doing immunoperoxidase staining on
 12 the paraffin block and I would fill out a Mayo
 13 requisition, send that down along with the
 14 paraffin block to the Mayo and ask them for
 15 their interpretation.
 16 COFFEY, Q.C.:
 17 Q. Using the paraffin block and IHC as the
 18 process -
 19 DR. COOK:
 20 A. That's correct.
 21 COFFEY, Q.C.:
 22 Q. - in that particular patients tissue sample
 23 and you compared it--when you got the result
 24 from the Mayo clinic, you would have compared
 25 that to what?

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1 DR. COOK:
 2 A. Compare it to the biochemical assay.
 3 COFFEY, Q.C.:
 4 Q. Why were you doing that?
 5 DR. COOK:
 6 A. It was just another check in my mind to see--i
 7 was using the Mayo as a reference lab to
 8 compare their performance with our
 9 performance.
 10 COFFEY, Q.C.:
 11 Q. "Our performance", who's the "our" in this
 12 context?
 13 DR. COOK:
 14 A. The General Hospital.
 15 COFFEY, Q.C.:
 16 Q. Is it the biochemical -
 17 DR. COOK:
 18 A. The biochemical and also the
 19 immunohistochemical.
 20 COFFEY, Q.C.:
 21 Q. That Doctor Khalifa was also, by this time,
 22 had started to utilize?
 23 DR. COOK:
 24 A. He was doing a correlation between our
 25 bioassay and the result of the

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1 immunohistochemistry.
 2 COFFEY, Q.C.:
 3 Q. So, Doctor, what happened then with that
 4 process as time went on? Did you continue to
 5 utilize the Mayo for a period of time in it
 6 correlation effort?
 7 DR. COOK:
 8 A. I believe. I think, as I said earlier, around
 9 ten cases I may have sent down to look at the
 10 correlations.
 11 COFFEY, Q.C.:
 12 Q. And do you recall were any records kept of
 13 that afterward?
 14 DR. COOK:
 15 A. No, the records that I kept were handwritten
 16 records that I was just confirming with Doctor
 17 Khalifa.
 18 COFFEY, Q.C.:
 19 Q. What was the overall result of that? How did
 20 what Doctor Khalifa, his IHC results in St.
 21 John's compare to the Mayo clinics results in
 22 IHC in biochemical assay?
 23 DR. COOK:
 24 A. Generally good, although there were a couple

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1 of discrepancies that I noted between the Mayo
 2 and our results.
 3 COFFEY, Q.C.:
 4 Q. Did you take that up with anyone at the time?
 5 DR. COOK:
 6 A. I did.
 7 COFFEY, Q.C.:
 8 Q. And with whom?
 9 DR. COOK:
 10 A. Dr. Khalifa.
 11 COFFEY, Q.C.:
 12 Q. And what, if anything, became of that?
 13 DR. COOK:
 14 A. Well, that was taken up at one meeting of the
 15 site chiefs and divisional managers and this
 16 was probably near sometime in 1998 when we
 17 talked about releasing the tests to the
 18 pathologists for reporting and there was
 19 concern over the cutoff points that we would
 20 use to determine whether a test would be
 21 positive or negative.
 22 COFFEY, Q.C.:
 23 Q. So Doctor, I take it at the time, 1997, Dr.
 24 Khalifa was investigating the possibility
 25 really in effect here of utilizing paraffin

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1 block IHC process to perform ER and PR tests
 2 within the province?
 3 DR. COOK:
 4 A. Um-hm.
 5 COFFEY, Q.C.:
 6 Q. That was in substitution for the biochemical
 7 assay?
 8 DR. COOK:
 9 A. That's correct.
 10 COFFEY, Q.C.:
 11 Q. The decision at the time as to whether or not
 12 to go ahead with that, to switch over to the
 13 IHC process from the biochemical assay, whose
 14 decision was it at the time? Who had the
 15 authority at the time to do that?
 16 DR. COOK:
 17 A. The authority to do that would have come, I
 18 would say, from the clinical chief of the day.
 19 COFFEY, Q.C.:
 20 Q. And do you recall who the clinical chief was?
 21 DR. COOK:
 22 A. That was Dr. David Haegert.
 23 COFFEY, Q.C.:
 24 Q. If we could, please, Exhibit P-1856? Now
 25 Doctor, this is--these are the minutes of the

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1 anatomy pathology site chiefs and divisional
 2 managers meeting, May 13th, 1997. Present are
 3 yourself, Dr. Khalifa, Dr. Parai, Dr.
 4 Pushpanathan, Mr. Gulliver and Mr. Murphy, and
 5 apologies from Dr. Haegert. So at the time,
 6 Doctor, circa 1997, you were site chief at St.
 7 Clare's, Dr. Khalifa at the General, Dr.
 8 Parai?
 9 DR. COOK:
 10 A. At the Grace.
 11 COFFEY, Q.C.:
 12 Q. Dr. Pushpanathan?
 13 DR. COOK:
 14 A. She was site chief at the Janeway.
 15 COFFEY, Q.C.:
 16 Q. Janeway, and Mr. Gulliver, at that time?
 17 DR. COOK:
 18 A. He was a divisional manager at the General
 19 Hospital and the Janeway sites.
 20 COFFEY, Q.C.:
 21 Q. Okay, and Mr. Murphy was the divisional
 22 manager, I take it, for the Grace and St.
 23 Clare's?
 24 DR. COOK:
 25 A. That's correct.

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1 COFFEY, Q.C.:
 2 Q. And Dr. Haegert would have been the clinical
 3 chief of the day?
 4 DR. COOK:
 5 A. That's correct.
 6 COFFEY, Q.C.:
 7 Q. If we could, please, Doctor, here on page
 8 three of those minutes, and paragraph labelled
 9 A there, new business.
 10 DR. COOK:
 11 A. Um-hm.
 12 COFFEY, Q.C.:
 13 Q. It says "ER and PR immunoperoxidase receptors.
 14 Dr. Khalifa reported to the committee that
 15 there is good correlation between a
 16 biochemical assay and immunoperoxidase
 17 staining for breast receptors. It appears
 18 that the time may be right to implement the
 19 immunoperoxidase breast receptors corporate
 20 wide. Dr. Cook stated that there was a
 21 concern amongst the pathologists at St.
 22 Clare's that they should be the ones reporting
 23 the breast receptors. Discussion then arose
 24 that if individual pathologists are reporting
 25 these receptors, then there is a need for

| Page 89 | Page 91 |
|--|---|
| <p>1 standardized criteria to determine what is 2 regarded as receptor positive and negative. 3 There was also discussion as to how the Mayo 4 Clinic reports its receptors. It was decided 5 that this issue should be brought to a 6 discipline meeting to get a consensus among 7 pathologists. Hopefully such a meeting will 8 be held in June. Until then, it is agreed to 9 maintain the status quo. Dr. Cook also 10 recognized the amount of hard work that Dr. 11 Khalifa has put into this project." 12 Doctor, can you tell us, please, what was 13 going on here at that point in time? This is 14 May of '97. 15 DR. COOK: 16 A. Well, if I remember correctly, pathologists, 17 not only at St. Clare's but the Grace, and I 18 think even at the General Hospital, still 19 wanted to have the ability to report their own 20 estrogen receptors reports. The concern - 21 COFFEY, Q.C.: 22 Q. Up to that point, they wouldn't have been 23 doing so? 24 DR. COOK: 25 A. No, but this was immunohistochemical stain and</p> | <p>1 A. That's correct. 2 COFFEY, Q.C.: 3 Q. Because by then, I take it, there was more or 4 less--IHC service was more or less centralized 5 at the General? 6 DR. COOK: 7 A. Yes, at that time. 8 COFFEY, Q.C.: 9 Q. And that had been the practice, leaving ER/PR 10 completely out of it, you know, as an issue 11 because you weren't doing IHC stains for ER/PR 12 up to this point in time. 13 DR. COOK: 14 A. Right. 15 COFFEY, Q.C.: 16 Q. So leaving ER/PR out of it, all IHC stains 17 were reported by whatever pathologist ordered 18 it in the first place? 19 DR. COOK: 20 A. They wouldn't be reported on an individual 21 basis. In other words, let's say I'm out in 22 Corner Brook. 23 COFFEY, Q.C.: 24 Q. Sure. 25 DR. COOK:</p> |
| Page 90 | Page 92 |
| <p>1 they still wanted to report on that stain. 2 COFFEY, Q.C.: 3 Q. Okay, so just so the Commissioner is clear on 4 that, so up to that point, immunohistochemical 5 stains, whatever they might be were reported 6 by - 7 DR. COOK: 8 A. Were reported or interpreted by - 9 COFFEY, Q.C.: 10 Q. - pathologists at whatever site ordered it? 11 DR. COOK: 12 A. That's correct. 13 COFFEY, Q.C.: 14 Q. The ordering pathologist, and so the 15 Commissioner is clear on this, so that would 16 have been true for St. Clare's, the Grace, to 17 your knowledge, I suppose, Corner Brook, Grand 18 Falls, whoever ordered the IHC stain. 19 DR. COOK: 20 A. Would be interpreted by the pathologist who 21 had ordered it from the respective site. 22 COFFEY, Q.C.: 23 Q. Yes, and the slide itself would be prepared at 24 the General? 25 DR. COOK:</p> | <p>1 A. And I have, say, an undifferentiated tumor. 2 So I might order an LCA or a cytokeratin or an 3 EMA or whatever it is. That block would come 4 in from that tumor to the General Hospital. 5 Stains would be performed and the stains would 6 be sent back to me, say, if I were generated 7 from Corner Brook. Now I wouldn't report-- 8 issue a separate report on the EMA or the 9 cytokeratin or the LCA. I would use that in 10 making an interpretation on the lesion in 11 question. You understand? 12 COFFEY, Q.C.: 13 Q. Yes, so you would be the one interpreting 14 those particular slides? 15 DR. COOK: 16 A. I would be interpreting, but I wouldn't issue 17 a separate report on each of those stains. 18 COFFEY, Q.C.: 19 Q. I appreciate the distinction there, but you 20 would be the one looking at the slides, the 21 three or four slides for that particular 22 purpose, each with a different stain on it, 23 and drawing your own conclusions about what 24 interpretation to give them and what the 25 overall result was?</p> |

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1 DR. COOK:
 2 A. Yeah.
 3 COFFEY, Q.C.:
 4 Q. From a diagnostic perspective.
 5 DR. COOK:
 6 A. So they would be used in conjunction, say,
 7 with the H & E stain and any histochemical
 8 stains or any other procedures that I would
 9 do.
 10 COFFEY, Q.C.:
 11 Q. And what you're saying "Mr. Coffey, it
 12 wouldn't necessarily mean though, in fact
 13 might not at all involve me actually saying
 14 what a particular stain, my interpretation of
 15 that individual stain was"?
 16 DR. COOK:
 17 A. It may in the body of the report. Like I
 18 could say LCA positive or negative or EMA
 19 positive or negative, but I would take all
 20 those positives and negatives and put them
 21 together along with the H & E and any other
 22 testing that I would do to make an
 23 interpretation.
 24 THE COMMISSIONER:
 25 Q. So okay, just to make sure I understand.

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1 You're in a situation where you've been asked
 2 to give your opinion on a diagnosis of a
 3 particular kind of cancer, say. So you decide
 4 that you want a range of things done in order
 5 to come to that opinion. One of those might
 6 be an IHC stain. You would send the block to
 7 the General. It would be processed, comes
 8 back to you. Then you, along with all the
 9 other things, would use the IHC component to
 10 come to an opinion as to the particular
 11 diagnosis?
 12 DR. COOK:
 13 A. That's right.
 14 THE COMMISSIONER:
 15 Q. Okay, and you might or might not, in the body
 16 of the--in your comments, refer to your
 17 interpretation of the IHC stain?
 18 DR. COOK:
 19 A. Well, I would--yeah, me, as a pathologist, I
 20 would. I would say, say, you know, an LCA
 21 stain shows whatever it is positivity or an
 22 EMA stain shows positive immunoreactivity. So
 23 looking at those individual stains, I would
 24 say that I would make an interpretation on
 25 each of those individual stains in the

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1 microscopic description.
 2 THE COMMISSIONER:
 3 Q. Okay.
 4 COFFEY, Q.C.:
 5 Q. So then here, Doctor, in the fifth line, it
 6 says "Dr. Cook stated that there's a concern
 7 among the pathologists at St. Clare's that
 8 they should be the ones reporting the breast
 9 receptors."
 10 DR. COOK:
 11 A. Um-hm.
 12 COFFEY, Q.C.:
 13 Q. Now I think you've--you were about to, you
 14 were elaborating on that saying well, it says
 15 at St. Clare's, but you understood that that
 16 was a wider concern?
 17 DR. COOK:
 18 A. That was a wider concern. My understanding
 19 that the pathologist at the Grace also wanted
 20 to report on their own stains because they
 21 reviewed it as being a part of their own case.
 22 COFFEY, Q.C.:
 23 Q. And in this context, reporting the breast
 24 receptors would be reporting breast receptors
 25 results from an IHC stain and IHC stains are

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1 things that pathologists deal with?
 2 DR. COOK:
 3 A. That's correct.
 4 COFFEY, Q.C.:
 5 Q. So that would be the idea that -
 6 DR. COOK:
 7 A. Yes, they looked at it as an IHC stain. If
 8 it's coming from my case, it should be
 9 reported for whatever pathologist that
 10 originated from.
 11 COFFEY, Q.C.:
 12 Q. I'm sorry, Doctor, you were about to--you said
 13 well, that's--that happened, that was one
 14 aspect of the matter and -
 15 DR. COOK:
 16 A. And then there was another aspect.
 17 COFFEY, Q.C.:
 18 Q. Yes, about standardization and so on, it's
 19 referred to here. Can you elaborate now on
 20 this?
 21 DR. COOK:
 22 A. Well, again, when Khalifa was getting ready to
 23 release the stain, the IHC stain for ER and
 24 PR, there was discussion on the need for
 25 standardization of reports. That was one

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1 thing. The concern I had was the cut off
 2 points, and I suppose this was a concern going
 3 back about a year or so and it started when I
 4 was at a Canadian Association of Pathologists
 5 Annual Meeting in Vancouver and I think that
 6 was around '97, and one of the conferences
 7 that I attended, there was discussion on ER
 8 and PR, not in regards to the performance or
 9 evaluation of the test, but to what we would
 10 use as cut off points, whether it would be 30
 11 percent or 20 percent or whatever. And I
 12 remember there being a fairly heated
 13 discussion between pathologists and
 14 oncologists over what would you use as a cut
 15 off, whether you accept the 30 percent or the
 16 20 percent, and there was no consensus of
 17 agreement as to what that cut off point would
 18 be. So I left that meeting beginning, for the
 19 first time, to realize that there is no
 20 consensus on cut off points, certainly in
 21 parts of Canada and the United States.
 22 Now in regard to what was happening at
 23 the Mayo Clinic, because as I mentioned
 24 earlier in my testimony, I did notice some
 25 discrepancies between the Mayo reports and the

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1 biochemical report. When we investigated
 2 further as to what the Mayo was doing, they
 3 were issuing their immunoperoxidase reports or
 4 ER/PR reports on the fact that the stain is
 5 either reported as positive or negative, and
 6 there was no value given.
 7 COFFEY, Q.C.:
 8 Q. I'm sorry, who was doing this?
 9 DR. COOK:
 10 A. This was the Mayo Clinic.
 11 COFFEY, Q.C.:
 12 Q. Okay.
 13 DR. COOK:
 14 A. So when we checked at that time, I think one
 15 of our pathologists, Dr. Miriam Griffin, who
 16 was on staff at St. Clare's, she spoke to an
 17 individual or mostly assume that was a
 18 pathologist at Mayo Clinic stating that they
 19 would report if they see one stain positive,
 20 one cell positive, and so if there was one or
 21 two cells positive, then they would report the
 22 ER and PR as being positive. So that was a
 23 significant variation in the use of cut off
 24 points, what was happening in North America.
 25 COFFEY, Q.C.:

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1 Q. And you came to that view why? Why was that a
 2 -
 3 DR. COOK:
 4 A. Well, because if we were using a cut off at 30
 5 percent at say the General Hospital and you
 6 compare that to a Mayo Clinic report, you
 7 know, and you consider that all things are
 8 being equal, let's say you had a stain
 9 performed say both at the General and at the
 10 Mayo Clinic and both came back, say, the ER/PR
 11 status of 15 percent. We would have called it
 12 negative and the Mayo would have called it
 13 positive.
 14 COFFEY, Q.C.:
 15 Q. You say "we would have called it negative,"
 16 say the 15 at the time, who's the we in this
 17 context at that point?
 18 DR. COOK:
 19 A. General Hospital or St. Clare's and the Grace.
 20 COFFEY, Q.C.:
 21 Q. And why do you say "we would have called it
 22 negative" at that time?
 23 DR. COOK:
 24 A. Because Dr. Khalifa wanted to use a cut off of
 25 30 percent.

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1 COFFEY, Q.C.:
 2 Q. And did he explain to you why that was so?
 3 DR. COOK:
 4 A. That was in relation to an article, I think,
 5 from the American Journal of Pathology, around
 6 1990, that correlated the 30 percent with a
 7 negative result on the biochemical assay.
 8 COFFEY, Q.C.:
 9 Q. Doctor, I'm going to go, please, to Exhibit P-
 10 1857? In the minutes we just looked at, there
 11 was a reference to the fact that it would come
 12 up the next month in June. This is an agenda
 13 for the division of anatomical pathology. The
 14 agenda is addressed to a number of
 15 individuals, including yourself, and it's for
 16 a June 17th, 1997 meeting. You'll note here,
 17 Doctor, under 2 CER, business arising, ER and
 18 PR receptors, immunoperoxidase staining is
 19 referenced there, and then page two of the
 20 exhibit are the actual minutes of that
 21 meeting.
 22 I'll take you, Doctor, to paragraph 3.4.
 23 It's "ER and PR receptor interpretation. This
 24 was discussed in detail. The majority of
 25 pathologists at St. Clare's, as well as the

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1 Grace Hospital, would like to interpret their
 2 own cases with control slides. Dr. Khalifa
 3 has agreed to provide a number of cases to the
 4 Grace Hospital to review them to be familiar
 5 with the positive and negative results." And
 6 the next paragraph as well relates to
 7 immunoperoxidase staining, 3.5. "The
 8 turnaround time of immunoperoxidase staining
 9 takes at least one week or more from the time
 10 of sending the block and the time of receiving
 11 these slides. Dr. S. Parai mentioned whether
 12 this turnaround time could be reduced by doing
 13 the immunoperoxidase staining on a daily basis
 14 instead of twice a week, which is presently
 15 being done." And go on to talk about
 16 workload.
 17 Doctor, here, first of all, the
 18 immunoperoxidase staining and the idea that it
 19 was being done twice a week as opposed to
 20 daily, I take it this was being done at the
 21 General Hospital?
 22 DR. COOK:
 23 A. That's correct.
 24 COFFEY, Q.C.:
 25 Q. And is that consistent with your understanding

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1 at the time, they were batching, as it were,
 2 the immunoperoxidase stains?
 3 DR. COOK:
 4 A. That's correct.
 5 COFFEY, Q.C.:
 6 Q. At that period, 19--this is the middle of
 7 1997, did you have any understanding about
 8 whether there were particular technologists
 9 doing this IHC staining?
 10 DR. COOK:
 11 A. In '97, I think I would have, yes. There
 12 were--the IHC was assigned to--I think there
 13 were two technologists at the time.
 14 COFFEY, Q.C.:
 15 Q. Do you recall either of their names?
 16 DR. COOK:
 17 A. Peggy Walsh, I believe, and Mary Butler.
 18 COFFEY, Q.C.:
 19 Q. And then paragraph 3.4 which notes this was
 20 discussed in detail, and it refers to "the
 21 majority of pathologists in St. Clare's and
 22 the Grace want to interpret their own cases
 23 with control slides." Now the control slides
 24 here are what? What types of control slides
 25 are we talking about?

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1 DR. COOK:
 2 A. These were tissue that was stained. This was
 3 not the test tissue, but tissue that was
 4 obtained from patients previously diagnosed
 5 with breast cancer and correlated with the
 6 bioassay result and these controls would be
 7 stained with the ER and PR immunoperoxidase
 8 stains and then submitted with the test
 9 tissue.
 10 COFFEY, Q.C.:
 11 Q. And the purpose of utilizing such slides is
 12 what?
 13 DR. COOK:
 14 A. To make sure that the staining process worked.
 15 COFFEY, Q.C.:
 16 Q. And these, would they be referred to or could
 17 they be characterized as external control
 18 slides?
 19 DR. COOK:
 20 A. That's correct.
 21 COFFEY, Q.C.:
 22 Q. Do you recall, I take it that you've indicated
 23 they would be--you expected them to stain, so
 24 they'd be positive external controls?
 25 DR. COOK:

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1 A. Positive external controls.
 2 COFFEY, Q.C.:
 3 Q. At that time, in the middle of '97 was there
 4 any utilization of negative external controls?
 5 DR. COOK:
 6 A. No.
 7 COFFEY, Q.C.:
 8 Q. And it goes on to say "Dr. Khalifa has agreed
 9 to provide a number of cases to the Grace for
 10 them to review."
 11 DR. COOK:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. St. Clare's is notable by its omission here in
 15 the sense that he doesn't refer to that. Why
 16 would that be, why would the Grace be getting
 17 slides to review and not St. Clare's at this
 18 point?
 19 DR. COOK:
 20 A. I guess we were reviewing the Mayo Clinic
 21 slides and getting accustomed to the stain.
 22 COFFEY, Q.C.:
 23 Q. Can you recall, Doctor, then, how that worked,
 24 how are people being educated, as it were,
 25 concerning what these slides should look like

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1 if properly stained?
 2 DR. COOK:
 3 A. They were educated. There was no service
 4 being given to pathologists as a group. They
 5 were expected to know which part of the slide
 6 or which part of the cell would be picked up
 7 by the stain, so that was on their own
 8 endeavour at that time.
 9 COFFEY, Q.C.:
 10 Q. And so there was no in-service for the
 11 pathologists at St. Clare's, if there was, you
 12 would have been aware of it as the site chief?
 13 DR. COOK:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. And there was not?
 17 DR. COOK:
 18 A. I mean -
 19 COFFEY, Q.C.:
 20 Q. And there was not such a -
 21 DR. COOK:
 22 A. No.
 23 COMMISSIONER:
 24 Q. Do I take it from your remark earlier they
 25 were expected to know the part that should

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1 stain?
 2 DR. COOK:
 3 A. Yeah.
 4 COMMISSIONER:
 5 Q. That effectively you were expected to consult
 6 the appropriate literature to determine that
 7 or did everybody assume you would have known
 8 that from your prior education?
 9 DR. COOK:
 10 A. You were expected to know that and to look
 11 into the literature.
 12 COMMISSIONER:
 13 Q. Okay.
 14 COFFEY, Q.C.:
 15 Q. Doctor, and what slides would there have been
 16 available at St. Clare's in May and June and
 17 July of '97, how many slides and from where?
 18 DR. COOK:
 19 A. The only ones I can remember are the ones we
 20 received from the Mayo Clinic, that was before
 21 the start-up of the biochemical--excuse me,
 22 the immunohistochemical staining.
 23 COMMISSIONER:
 24 Q. Now, Mr. Coffey, wherever you can find a
 25 convenient place, we'll take the morning

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

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1 case. At that time was there any other sort
 2 of interpretation process the pathologists
 3 went through where they would be utilizing
 4 percentages? Like, 30 percent, I take it, is
 5 30 percent of tumor cells are staining in the
 6 nuclei 30 or more, or more than 30. That
 7 suggested you actually had to do a calculation
 8 of some sort? Is it 50, is it 70, is it 100,
 9 is it 20. So do you recall whether there was
 10 any other sort of slides that you had to do,
 11 just kind of arithmetic calculation?
 12 DR. COOK:
 13 A. You mean at that time?
 14 COFFEY, Q.C.:
 15 Q. Yes.
 16 DR. COOK:
 17 A. In any other immunohistochemical stain?
 18 COFFEY, Q.C.:
 19 Q. Yes.
 20 DR. COOK:
 21 A. In 1997?
 22 COFFEY, Q.C.:
 23 Q. Yes.
 24 DR. COOK:

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1 A. I can't recall.
 2 COFFEY, Q.C.:
 3 Q. Nothing jumps out to you in terms of -
 4 DR. COOK:
 5 A. Percentages of stains or cells of stain, no,
 6 not in 1997.
 7 COFFEY, Q.C.:
 8 Q. So this would have been, that aspect of the
 9 matter would have been novel or new?
 10 DR. COOK:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. I take it that if it was novel for yourself as
 14 a practising pathologist here in St. John's,
 15 would you have understood it was novel perhaps
 16 for anyone else who had the similar experience
 17 to yours?
 18 DR. COOK:
 19 A. I would say, possibly with the exception of
 20 Khalifa.
 21 COFFEY, Q.C.:
 22 Q. And why Khalifa, why would he be an exception?
 23 DR. COOK:
 24 A. Well, he seemed to be the--he's the lead
 25 pathologist in this endeavour and I would say

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1 the one most conversed with introducing the IH
 2 stain for ER and PR.
 3 COFFEY, Q.C.:
 4 Q. Doctor, that's, of course, this is the middle
 5 of 1997. We are now about at the midway point
 6 of 2008. If such a, I'll refer to as kind of
 7 a newer, novel aspect of one's professional
 8 existence, for example, in this context in '97
 9 doing this percentage calculation and how you
 10 would do that actually under a microscope, how
 11 you might physically go about it and the
 12 mental processes used, if something similar,
 13 like in a new format was to come along now in
 14 2008 and it was new, it was new to pathology,
 15 it was certainly new to pathology in St.
 16 John's, would there now be any in-service?
 17 DR. COOK:
 18 A. Oh, I would say now there would be an in-
 19 service, yes.
 20 COFFEY, Q.C.:
 21 Q. Thank you, Commissioner, we'll break.
 22 COMMISSIONER:
 23 Q. Sure, we'll take the morning break.
 24 (RECESS)
 25 COMMISSIONER:

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1 Q. Please be seated. Mr. Coffey.
 2 COFFEY, Q.C.:
 3 Q. Thank you, Commissioner. Doctor, if we could,
 4 please, Registrar, Exhibit P-1858? Doctor,
 5 this is a letter of June 18th, 1997, it's to
 6 Sushil Parai from Dr. Khalifa, it's copied to
 7 Dr. Haegert and yourself. And I just bring it
 8 up here because it refers to, Dr. Khalifa
 9 writes to Dr. Parai noting an earlier
 10 conversation and says, "You filled in an
 11 immuno request for two cases that you were
 12 complaining about." And he goes on to say,
 13 "The stains were completed June 5th, '97. I'm
 14 attaching a copy of the request forms for
 15 these two cases that show the histochem,"
 16 histochemistry, presumably. He has signed a
 17 completion of the procedure on June 5, '97.
 18 "I think you may be experiencing problems with
 19 the transportation system and you may want to
 20 discuss this issue a little further in one of
 21 the department meetings. As for the work in
 22 our immunohistochemistry lab, I think it is
 23 being done within the time limits we've agreed
 24 upon in the past." Doctor, was there, like,
 25 in that time frame and afterward, a concern

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1 about turnaround times involving the
 2 immunohistochemistry lab?
 3 DR. COOK:
 4 A. Oh, it was a continual issue.
 5 COFFEY, Q.C.:
 6 Q. And can you tell the Commissioner about that,
 7 what--as it evolved over time and why it was a
 8 continuing issue?
 9 DR. COOK:
 10 A. Well, we had centralized the
 11 immunohistochemistry service at the General
 12 Hospital site. And -
 13 COFFEY, Q.C.:
 14 Q. Do you remember when that had occurred by?
 15 DR. COOK:
 16 A. That had occurred around '97, '98. And the
 17 idea of that was to enhance getting into the
 18 whole idea of sub-specialization, having a
 19 specialized group of histo techs performing
 20 the immunohistochemistry as opposed to
 21 shifting it around to the different hospitals.
 22 So that was an effort to try to sub-specialize
 23 and gain an area of expertise in one site.
 24 The, in regards to the turnaround times, that
 25 because particularly problematic on many

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

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1 whatnot, that meant that you had to stop your
 2 flow of work and go back and look at the
 3 original case and try to figure out what was
 4 the delay in reporting of that case. So that
 5 was a particular issue of concern around that
 6 time and it had been for many years. What we
 7 were dealing with basically were resource
 8 issues. The volumes of the work was steadily
 9 increasing, however, we weren't able to keep
 10 up with the demand in terms of increasing
 11 resources, both financial and human resources.
 12 So I think basically that was the root of the
 13 problem there.
 14 COFFEY, Q.C.:
 15 Q. Now, Doctor, in terms of resources, were there
 16 complaints about lack of resources at that
 17 time?
 18 DR. COOK:
 19 A. Pretty much. I remember -
 20 COFFEY, Q.C.:
 21 Q. By whom to whom?
 22 DR. COOK:
 23 A. There would be complaints over lack of
 24 resources from ourselves coming to Mr.
 25 Gulliver at the time, Dr. Haegert at the time.

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1 I remember there were issues from the
 2 technologists' point of view. I guess they
 3 were reporting to their own manager regarding
 4 the lack of human resources and dealing with
 5 the increased workload.
 6 COFFEY, Q.C.:
 7 Q. Exhibit P-1859? Doctor, this is the minutes
 8 of a meeting of October 8th, 1997, it's the
 9 site chief/divisional manager's meeting.
 10 Yourself, Dr. Haegert, Dr. Khalifa, Dr. Parai,
 11 Dr. Pushpanathan and Mr. Murphy are present,
 12 noted to be present. And in terms of business
 13 arising, paragraph 3 there, it says, "Case
 14 referral policies. Dr. Khalifa inquired about
 15 the policies adopted in the various sites
 16 regarding referring slides for outside
 17 review."
 18 DR. COOK:
 19 A. Um-hm.
 20 COFFEY, Q.C.:
 21 Q. "It was pointed out that no clear policies are
 22 in place for sending slides to an outside
 23 institute. After a lengthy discussion Dr.
 24 Khalifa was asked to draft policies regarding
 25 outside referral of cases as well as internal

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1 consultations."
 2 DR. COOK:
 3 A. Um-hm.
 4 COFFEY, Q.C.:
 5 Q. Now, what was that about?
 6 DR. COOK:
 7 A. Well, basically we wanted to develop a uniform
 8 process how to deal, say, with outside
 9 consultations. Let's say a patient was
 10 referred to Princess Margaret in Toronto and
 11 there was a request from Princess Margaret to
 12 review our slides. That was a fairly normal
 13 procedure that if the patient, say, went up
 14 for radiation or chemotherapy treatments in
 15 regards of cancer, that there was always a
 16 second review of the original histology to
 17 confirm the original interpretation of the
 18 pathologist. So we wanted to develop a
 19 standardized policy as to what you send up. I
 20 mean, obviously the original slides would have
 21 to go, but what would you do with the paraffin
 22 blocks, would you send up all the paraffin
 23 blocks or a representative portion of the
 24 paraffin blocks and along with the various
 25 pathology reports? So we wanted to develop a

| | |
|--|---|
| Page 117 | Page 119 |
| <p>1 standardized procedure on what would be sent 2 up and what would remain behind. 3 COFFEY, Q.C.: 4 Q. And so this was outside review in the sense of 5 outside the province? 6 DR. COOK: 7 A. That's correct. 8 COFFEY, Q.C.: 9 Q. In this context. 10 DR. COOK: 11 A. Or it could be in the province. Let's say you 12 had a pathologist in Corner Brook who may want 13 to review a particular case, say, in St. 14 John's. The patient was having surgery in 15 Corner Brook, so he or she might want to 16 review that particular case. 17 COFFEY, Q.C.: 18 Q. And this related then to the whole idea of the 19 Health Care Corporation of St. John's sending 20 its slides, whether to Corner Brook or Toronto 21 or wherever else, have some policy in place 22 that would be uniform across the - 23 DR. COOK: 24 A. Uniform policy, yeah. 25 COFFEY, Q.C.:</p> | <p>1 be a problem. Dr. Khalifa was asked to call 2 upon other Canadian medical centres, Toronto 3 General, to inquire about their protocols. 4 Dr. Khalifa action. He was also asked to seek 5 feedback from the cancer clinic staff. Dr. 6 Khalifa." So, Doctor, I take it then in terms 7 of the fall of 1997, early October, 1997, the 8 idea of moving ahead with, or at least the 9 process of trying to decide whether to go with 10 the IHC testing for ER and PR was well in 11 progress here by this point? 12 DR. COOK: 13 A. It was moving ahead. 14 COFFEY, Q.C.: 15 Q. If we could please, exhibit P-1860. Now this 16 is a memorandum of December 15th, 1997 and 17 page one of it is giving notice of a site 18 chief's meeting. If we go to page two of the 19 exhibit, the minutes of a meeting of December 20 16th, 1997, site chief/divisional managers. 21 You are present, as well as a number of other 22 physicians and two technologists. Now, 23 Doctor, here it notes at the top of the page 24 here, you amended the last paragraph of the 25 first page of the previous meetings minutes,</p> |
| Page 118 | Page 120 |
| <p>1 Q. New business, at paragraph 1, "Dr. Khalifa 2 presented results of an audit of steroid 3 receptors in 19 breast cancer cases 4 correlating immunohistochemistry and 5 biochemical assays." The typed version is 6 "Dr. D. Cook" and somebody has handwritten 7 "Dr. Parai," "recommended that the Health Care 8 Corporation continue performing the 9 immunohistochemical test and encouraging"--I'm 10 sorry, "and encouraged doing them on 11 endometrial carcinomas. He also mentioned 12 that Dr. Thain"? 13 DR. COOK: 14 A. Yeah, that individual was an oncologist at the 15 time. 16 COFFEY, Q.C.: 17 Q. I'm sorry? 18 DR. COOK: 19 A. He was an oncologist here at the time. 20 COFFEY, Q.C.: 21 Q. "He also mentioned that Dr. Thain, at the 22 cancer clinic, still prefers to see the 23 biochemical assay done. Standardization of 24 reporting of results of the bio"--of the, I'm 25 sorry, "immunohistochemical assay also seem to</p> | <p>1 of course, to substitute Dr. Parai's name for 2 yourself. What was it Dr. Parai was 3 recommending here? 4 DR. COOK: 5 A. Just recommended the performance of 6 histochemical tests and encouraged in doing 7 them on endometrial carcinomas. I can't 8 remember the exact discussions surrounding 9 that. 10 COFFEY, Q.C.: 11 Q. Okay, so that had nothing to do with ER and PR 12 itself? 13 DR. COOK: 14 A. I don't believe. 15 COFFEY, Q.C.: 16 Q. That you recall. And then under "Business 17 Arising", it's noted here in the first 18 paragraph "Laboratory utilization and anatomic 19 pathology. Dr. Cook was the divisional 20 representative in the Laboratory Utilization 21 Committee. A meeting of this committee took 22 place where the following topics were 23 discussed" and it lists a number of them. 24 DR. COOK: 25 A. Uh-hm.</p> |

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1 COFFEY, Q.C.:

2 Q. Doctor, what was this Laboratory Utilization

3 Committee about?

4 DR. COOK:

5 A. Well I was looking at the most effective way

6 we can use our resources, the thinking at the

7 time with program management that if we could

8 effectively save money within the program and

9 not compromise our service, that we can use

10 the savings to be redirected towards such

11 initiatives as CME activities, conferences and

12 whatnot, so if we, for instance just to give

13 an example, let's look at the position, say

14 ordering serum B12 or folic acid levels and a

15 lot of that was being ordered over the year,

16 we could work on ways to educate the

17 physicians to only order them on specific

18 cases or to try to reduce that without

19 jeopardizing clinical care, that we may take

20 those cost savings and redirect them elsewhere

21 in the program.

22 COFFEY, Q.C.:

23 Q. And more efficient utilization of the

24 resources, I take it was the committee's

25 mandate?

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1 DR. COOK:

2 A. That's what we were hoping to achieve, yes.

3 COFFEY, Q.C.:

4 Q. Where possible. The paragraph two is a

5 reference to turn-around time at St. Clare's

6 site. "Dr. Cook indicated the processing of

7 some specimens, particularly needle

8 localization of breast biopsies takes a

9 necessary long time. Preparation of slides

10 may take six to seven days from grossing the

11 specimen, while some re-cuts may take as long

12 as nine to ten days. Both pathologists and

13 surgeons have expressed their concerns about

14 this issue. Mr. Murphy acknowledged the

15 problem and suggested a low number of

16 histotechnologists as being its atiology." So

17 I take it, Doctor, this does relate to the--

18 some of the turn-around times?

19 DR. COOK:

20 A. That's correct.

21 COFFEY, Q.C.:

22 Q. Paragraph three here says "steroid receptors

23 assessment in paraffin sections, Dr. Khalifa

24 discussed this issue further and suggested

25 pathologists start reporting their own cases.

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1 A suggestion was made that Dr. Khalifa write

2 up a proposal with the criteria (cut-off

3 values) distribute it to the various

4 pathologists and ask them for their feedback."

5 Now, Doctor, up to this point do you recall

6 whether or not ER and PR results were being

7 reported?

8 DR. COOK:

9 A. Up to this -

10 COFFEY, Q.C.:

11 Q. Other than biochemical.

12 DR. COOK:

13 A. To my knowledge it was only biochemical, but I

14 can't be absolutely sure of that.

15 COFFEY, Q.C.:

16 Q. I'm sorry, and so what was envisaged here

17 then?

18 DR. COOK:

19 A. Getting into standardization of reporting.

20 COFFEY, Q.C.:

21 Q. And this would be reporting by each individual

22 pathologist, I take it?

23 DR. COOK:

24 A. That's right.

25 COFFEY, Q.C.:

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1 Q. Was there, at the time any idea of, you know,

2 whether or not individual pathologists should

3 report their own ER and PR results using the

4 IHC method, was there ever any discussion

5 about the pros and cons of that or any pros

6 and cons involved in having individual

7 pathologist do it, as opposed to having one or

8 two do it?

9 DR. COOK:

10 A. I can't remember much discussion around that,

11 I think there was a lot of pressure, from what

12 I remember of--I was getting from individual

13 pathologists, particularly at St. Clare's that

14 they wanted to look at all aspects of their

15 case and that included ER and PR. To the best

16 of my recollection that's about the only

17 discussion that I can remember at that time.

18 COFFEY, Q.C.:

19 Q. So they were pushing to report their own cases

20 for ER and PR and anything else related to the

21 case?

22 DR. COOK:

23 A. That's correct.

24 COFFEY, Q.C.:

25 Q. Certainly involving IHC stains. And from the

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1 other side, I take it the idea of perhaps
 2 limiting it one or--one individual or a small
 3 number of individuals that wasn't discussed,
 4 at least that you can recall?
 5 DR. COOK:
 6 A. No, because at that time our whole thinking at
 7 the time was one of general assign-out in all
 8 aspects of pathology.
 9 COFFEY, Q.C.:
 10 Q. The idea of specialization or
 11 subspecialization, in that timeframe, this
 12 would be the latter part of 1997, had that
 13 taken hold at all in St. John's?
 14 DR. COOK:
 15 A. No, it hadn't taken hold, but that didn't mean
 16 that we had some discussions regarding that.
 17 And -
 18 COFFEY, Q.C.:
 19 Q. Could you tell the Commissioner what you
 20 recall about that?
 21 DR. COOK:
 22 A. Well I remember a meeting that we had with Dr.
 23 Haegert and I believe Sushil Parai was there
 24 or Dr. Parai was there and myself, and you
 25 have to look at what was happening across

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

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1 to move toward subspecialization if we could
 2 stabilize the manpower situation. So we
 3 talked about that at that particular meeting
 4 and we saw this opportunity as what was
 5 happening in mainland Canada, possibly as an
 6 opportunity to help stabilize the situation in
 7 Newfoundland. And at that time we had been
 8 extremely lucky in not losing positions in the
 9 province and that was through efforts that we
 10 had with the Newfoundland and Labrador Medical
 11 Association and dialogue with government.
 12 COFFEY, Q.C.:
 13 Q. Now, Doctor, Dr. Khalifa, I'll be referring to
 14 him in the next couple of exhibits, and I
 15 have, we have already this morning, do you
 16 recall the events or any events leading up to
 17 the recruitment of Dr. Khalifa?
 18 DR. COOK:
 19 A. I can't remember per se, I was not in the
 20 leadership position at that time, but I
 21 remember our director of laboratories, Dr.
 22 John Williams who was then director of St.
 23 Clare's, looking at Dr. Khalifa's curriculum
 24 vitae and it was a very impressive curriculum
 25 vitae and I always remember Dr. Williams

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1 saying to me if we recruit Dr. Khalifa, I'm
 2 sure he will only be around for a year or two.
 3 COFFEY, Q.C.:
 4 Q. And why is that? What did you understand -
 5 DR. COOK:
 6 A. The way I understand it, here was an
 7 impressive individual with an impressive
 8 curriculum vitae that looking at our past
 9 history, we were able to recruit good people.
 10 The challenges that we had were able to retain
 11 them and once positions began opening up,
 12 particularly in mainland Canada, particularly
 13 in the Toronto area, we were losing many of
 14 our capable people, highly trained and highly
 15 respected people to mainland centres, mainly
 16 in Toronto and Toronto area, Calgary,
 17 Vancouver, so we had to deal with, you know,
 18 that factor on many occasions.
 19 COFFEY, Q.C.:
 20 Q. Exhibit P-1861 please? Doctor, this is an
 21 agenda for a meeting of February 12th, 1998.
 22 It's the division of anatomical pathology
 23 meeting of site chiefs and divisional managers
 24 and here under "business arising" paragraph
 25 2B, "ER and PR reporting", Doctor, do you

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1 recognize the handwriting on this?

2 DR. COOK:

3 A. Yeah, that's my handwriting.

4 COFFEY, Q.C.:

5 Q. Now what's after the ER and PR reporting, do

6 you recognize what that is?

7 DR. COOK:

8 A. Looks like the word "past", so we must have

9 been discussing the format of the reporting.

10 COFFEY, Q.C.:

11 Q. If I could, please, the second page of the

12 exhibit, second through the fourth page are

13 the actual minutes themselves. Under

14 "Business Arising" yourself and Dr. Haegert,

15 Dr. Khalifa and Dr. Parai are noted to be

16 present. Paragraph 3.2 "ER and PR reporting,

17 Dr. Khalifa will write to Dr. Prabhakaran

18 asking him to discontinue the biochemical ER

19 and PR assay as of March 1, 1998." And is

20 that your handwriting then, you've written

21 something there?

22 DR. COOK:

23 A. Yeah, "every pathologist will sign out cases

24 after transitional period, will talk to Dr.

25 Prabhakaran."

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1 COFFEY, Q.C.:

2 Q. And who was going to talk to him, do you

3 recall? Was that you or was that Dr. Khalifa?

4 DR. COOK:

5 A. That sounds like that may have been me.

6 COFFEY, Q.C.:

7 Q. Okay, and where was, I take it he was a

8 biochemist?

9 DR. COOK:

10 A. He was a medical biochemist.

11 COFFEY, Q.C.:

12 Q. Medical biochemist located where, what site?

13 DR. COOK:

14 A. At the General Hospital site.

15 COFFEY, Q.C.:

16 Q. And here I take it would be to tell him that

17 after a particular point in time it wouldn't

18 be necessary for him to--he wouldn't be asked

19 anymore to do a biochemical assay?

20 DR. COOK:

21 A. Probably to firm up the exact date that this

22 would be stopped, I would say in terms of

23 receiving official notification to stop the

24 biochemical assay, that that would have to

25 come from Dr. Haegert or Mr. Vern Whalen who

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1 was the program director at that time.

2 THE COMMISSIONER:

3 Q. Dr. Cook, do I take it that up to this point

4 there had been a period of both testing using

5 both methods?

6 DR. COOK:

7 A. Yes, I think you can say that. I don't think

8 it was being reported by pathologists at St.

9 Clare's or the Grace, but it may have been

10 reported by Dr. Khalifa at the General

11 Hospital, so there may be reports from both

12 the biochemical assay and the

13 immunohistochemical stain going out on the

14 patient's charts.

15 THE COMMISSIONER:

16 Q. Okay, thank you.

17 COFFEY, Q.C.:

18 Q. Exhibit P-1862 please? Now this is a

19 memorandum of March 13th, 1998. It's from Dr.

20 Khalifa to a number of individuals, including

21 yourself and one of the agenda items is follow

22 up on ER/PR reporting and if we could, please,

23 here at page 2, the exhibit is a memorandum of

24 March 16th, 1998 from Dr. Khalifa again to

25 yourself and others, it was indicated planned

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1 having a site chief's meeting on March 19th

2 and under "Amended Agenda Items" it's a follow

3 up on ER/PR reporting and there's a dash "-

4 settled and a run on Fridays." What is this

5 "run on Fridays" refer to?

6 DR. COOK:

7 A. I can't say for sure, Mr. Coffey, all I can

8 say is we're probably just getting into

9 determining what was the best day to batch

10 these cases. I mean, I really can't comment

11 on thought processes around that particular

12 statement.

13 COFFEY, Q.C.:

14 Q. And the third paragraph refers to, third line,

15 I'm sorry, "procedure for adding new

16 antibodies for existing panel." You have an

17 arrow "update list of immunos, newsletter."

18 DR. COOK:

19 A. "That new antibodies are circulated, what

20 antibodies are useful for what?" So this is

21 getting into a form drawn up to identify what

22 antibodies are available in the division and

23 circulating these to the pathologist.

24 COFFEY, Q.C.:

25 Q. Now, Doctor, the third page of the exhibit and

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1 this is the minutes of a meeting of March
 2 19th, 1998. Present are yourself and a number
 3 of other individuals, including Dr. Haegert,
 4 Dr. Khalifa, Dr. Parai and there's a note
 5 here, Dr. Khalifa amended paragraph 3.2 of the
 6 previous meeting's minutes, it should read
 7 "Dr. Khalifa will transfer the responsibility,
 8 reporting of results of immunohistochemical
 9 staining of ER/PR to the respective
 10 pathologist on March 1, 1998. (Dr.
 11 Prabhakaran will be contacted at a later stage
 12 and asked to discontinue the biochemical
 13 assays.)" And that amendment was accepted by
 14 those present here. And then under "Business
 15 Arising" paragraph one indicates "Dr. Khalifa
 16 updated the committee about the current stage
 17 of ER/PR reporting by the requesting
 18 pathologist. The transition was going smooth.
 19 Dr. Cook made very positive remarks about the
 20 role played by Dr. Khalifa in this regard.
 21 Dr. Cook suggested two changes to the outside
 22 case referral policy. Dr. Khalifa informed
 23 members of the committee that following the
 24 adoption of the last two recommendations from
 25 Dr. Cook, the policy will be ready for

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1 submission to a legal counsellor" and that's,
 2 I take it, this outside referral case issue.
 3 And he goes on to say "Dr. Khalifa suggested
 4 that a system be in place for members of the
 5 committee to study requests submitted from
 6 various staff members for the addition of new
 7 antibodies to our existing panel. Members of
 8 the committee agree that such requests be
 9 submitted to the respective site chief, who in
 10 turn brings them to the committee. These
 11 requests are to be studied in light of the
 12 support of evidence, years utilization and
 13 budgetary feasibility. Final decisions are to
 14 be made jointly by members of the committee."
 15 Now, this committee is which committee here?
 16 DR. COOK:
 17 A. I think that refers to the site chief's,
 18 maybe, committee.
 19 COFFEY, Q.C.:
 20 Q. Now, Doctor, at that point in time the idea of
 21 now moving from the biochemical assay in early
 22 1998 for ER/PR to the IHC method of getting an
 23 ER and PR result, the impetus behind that move
 24 had been which individual?
 25 DR. COOK:

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1 A. Dr. Khalifa.
 2 COFFEY, Q.C.:
 3 Q. Do you recall whether there was any objection
 4 by anyone?
 5 DR. COOK:
 6 A. You mean from biochemical assay to
 7 immunohistochemical stain?
 8 COFFEY, Q.C.:
 9 Q. Or by the pathologist or anyone that you
 10 recall. I'm not suggesting there was, I'm
 11 just asking you.
 12 DR. COOK:
 13 A. I can't remember.
 14 COFFEY, Q.C.:
 15 Q. How about reservations? Anybody express any
 16 reservations about it?
 17 DR. COOK:
 18 A. Not to me, except in regard to the cut off
 19 point.
 20 COFFEY, Q.C.:
 21 Q. Yes, and I'm going to get to that in a moment
 22 now. But the idea and I appreciate that, the
 23 cut-off point and there was a discussion about
 24 that, you've referred, alluded to that already
 25 and talked about it already and I'll take you

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1 through that a bit more.
 2 DR. COOK:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. But the underlying notion of moving to IHC
 6 though, that was it, that was where we locally
 7 were going with it.
 8 DR. COOK:
 9 A. Yeah, I can't remember anybody objecting to
 10 that.
 11 COFFEY, Q.C.:
 12 Q. Now, Doctor, if we could, please, before we
 13 get into the actual discussion with you about
 14 that, about the cut-offs, Exhibit P-1863,
 15 please? This is, under "site chief's meeting
 16 an anatomical pathology, Health Care
 17 Corporation, April 22nd, 1998." And here
 18 under paragraph B, "Business Arising", there's
 19 a heading "Adding new immunoperoxidase stains
 20 to existing panel." And he says, "Dr.
 21 Griffin's letter was submitted at the
 22 committee. After some discussion was agreed
 23 to acquire the immunoperoxidase stains, CD5,
 24 CD10, Cyclin D1 and Calretinin. In regards to
 25 the rapid immuno staining technique, it was

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1 agreed that the current procedure employed by
 2 the General Hospital site appears adequate.
 3 Currently the DAKO envisaged system is
 4 employed which is a two-step method giving
 5 comparable results to the rapid immuno
 6 staining technique outlined in Dr. Griffin's
 7 letter." Now this DAKO envisaged system, what
 8 does that involve?
 9 DR. COOK:
 10 A. I think that refers to the detection system
 11 that was being used at the time and it's a
 12 semi-automated procedure.
 13 COFFEY, Q.C.:
 14 Q. And was that new, do you know here, locally?
 15 DR. COOK:
 16 A. I believe it was, I can't tell you the exact
 17 date that that was brought in.
 18 COFFEY, Q.C.:
 19 Q. Now, Doctor, here looking at--paragraph (f) is
 20 entitled "Estrogen Receptors. Dr. Cook
 21 wondered about the rider in the case where
 22 estrogen receptors stained less than 30
 23 percent of the cells. Dr. Khalifa informed
 24 him that this rider is a recommendation only
 25 and is not part of the formal policy regarding

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1 the reporting of breast receptors." Now,
 2 Doctor, do you recall what that was about?
 3 DR. COOK:
 4 A. Again, that's concerning a discussion
 5 regarding the cut off point. I had concerns
 6 about using that cut off point of 30 percent
 7 in the reports and I felt that no statement
 8 about cut off points should be made in the
 9 report when you consider what we were starting
 10 to find out about the variation cut off points
 11 across the country and the United States and
 12 the debate about that, I felt it would be
 13 better off to leave the issue of the cut-off
 14 point out of the report and make that--give
 15 that decision to the oncologists whether to
 16 treat or not.
 17 COFFEY, Q.C.:
 18 Q. If we could, please Registrar, Exhibit P-1287?
 19 Now, Doctor, here beginning at page two of
 20 this exhibit is a memorandum from Dr. Khalifa
 21 to all Newfoundland pathologists, February
 22 16th, 1998. The reference is "reporting of
 23 estrogen and progesterone receptor
 24 immunohistochemical results" and then that
 25 goes on then for three pages, page two, three

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1 and four of the exhibit. I take it, Doctor,
 2 that if we just look here, the second page of
 3 this memo, Dr. Khalifa writes "Attached please
 4 find a proposal for uniform reporting of ER/PR
 5 immunohistochemical staining. This proposal
 6 was discussed with many of my colleagues who
 7 mostly agreed with its content and accepted it
 8 as a policy. As I encourage you to adopt the
 9 attached proposal in your reporting to
 10 maintain uniformity, it should be clearly
 11 stated that this is only a proposal, as you
 12 already know, there is a considerable list of
 13 publications addressing this issue. I will
 14 be glad to share any of the material I already
 15 have with you and I would extremely appreciate
 16 your feedback on this matter." And then if we
 17 go to the next page, it's entitled "Proposal
 18 for uniformed reporting of the ER/PR
 19 immunohistochemical assessment, February 8th,
 20 1998." And it's paragraphs one, two, three
 21 and then some examples, example one and
 22 example two. Doctor Khalifa's suggestion here
 23 is that the report on the hormone receptor
 24 status will have three components. One, the
 25 first component is a statement of whether this

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1 stain is "positive" or "negative", positivity
 2 is defined by nuclear staining detected in any
 3 number of malignant cells. The second
 4 component is a rough estimate of the
 5 percentage of immuno reactive cells in a
 6 section examined. This estimate could be in a
 7 form of a range or a fixed number and is
 8 in parentheses. Number three, the third
 9 component is a comment regarding only ER (and
 10 not PR) immuno activity and is only to be
 11 included in the report if a small percentage
 12 of neoplastic cells (one to thirty percent) is
 13 positive." The comment reads, "evidence from
 14 the available literature indicates that
 15 estrogen receptors immuno activity detected in
 16 less than 30 percent of neoplastic cells would
 17 most likely correspond to a negative result of
 18 biochemical assay of the same specimen.
 19 Citing the American Journal of Surgical
 20 Pathology, 14:121 and 127, 1990." So I take
 21 it that that's the kind of comment or the
 22 comment you had concerns about.
 23 DR. COOK:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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1 Q. And as he had pointed out in his memo here, in
 2 February of 1998, this was just a suggestion,
 3 I think the Doctor had said here, "this is
 4 only a proposal" and you had then spoken to
 5 Dr. Khalifa and expressed your concerns and
 6 your approach was -
 7 DR. COOK:
 8 A. I didn't want that last statement included in
 9 the reports.
 10 COFFEY, Q.C.:
 11 Q. You had concerns about perhaps its continued
 12 applicability?
 13 DR. COOK:
 14 A. Well, I mean, it was such a dynamic situation
 15 that was happening across North America in
 16 terms of ER/PR, particularly in terms of where
 17 the cut-off was because we appeared to be all
 18 over the map and my feeling on it is we state
 19 whether we do see positive or negative
 20 staining and if we see positive staining, give
 21 the percentage of cells that are positive and
 22 then let the oncologist decide based on that
 23 percentage of cells whether to go ahead and
 24 treat or not.
 25 COFFEY, Q.C.:

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1 Q. And then, Doctor, on that when we're looking
 2 at it, here in the examples that Dr. Khalifa's
 3 put forward a third page of his memo, it's
 4 page four of the exhibit. In effect, I take
 5 it you were in agreement kind of with example
 6 one, as it were.
 7 DR. COOK:
 8 A. Yes.
 9 COFFEY, Q.C.:
 10 Q. That would be fine, and example two really
 11 would be the same, except you would leave out
 12 the "please see comment" and you would leave
 13 out the comment itself?
 14 DR. COOK:
 15 A. That's what I wanted.
 16 COFFEY, Q.C.:
 17 Q. Because you wanted just estrogen receptors, if
 18 there was anything one or greater in
 19 percentages, you would have positive and then
 20 a percentage; and if it was negative, for
 21 example in example two here, you'd have
 22 progesterone receptors, you'd put in negative?
 23 DR. COOK:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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1 Q. And would you put in zero percent?
 2 DR. COOK:
 3 A. I may or may not have. For me, negative means
 4 zero. That's my interpretation of negative.
 5 COFFEY, Q.C.:
 6 Q. Now, Doctor, in that regard, what approach was
 7 adopted at St. Clare's when you were the site
 8 chief, do you know?
 9 DR. COOK:
 10 A. When I was site chief, I told them to follow
 11 example one. I did not want the line or
 12 comment made about the 30 percent cut off to
 13 be included in the reporting of the ER's and
 14 PR's.
 15 COFFEY, Q.C.:
 16 Q. And do you know what, in that regard, happened
 17 elsewhere in Newfoundland, outside of St.
 18 Clare's?
 19 DR. COOK:
 20 A. I didn't know--I know now, but that would have
 21 been up for individual directors and
 22 pathologists to decide the format they were
 23 going to take.
 24 COFFEY, Q.C.:
 25 Q. And you now know what?

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1 DR. COOK:
 2 A. I know now they use example number two.
 3 COFFEY, Q.C.:
 4 Q. And was it uniformly used or was it used some
 5 places and not others or -
 6 DR. COOK:
 7 A. Used in some places, not others. I think it
 8 was used in the majority of centres throughout
 9 Newfoundland.
 10 COFFEY, Q.C.:
 11 Q. They would add the comment.
 12 DR. COOK:
 13 A. They would add that comment, yeah.
 14 COFFEY, Q.C.:
 15 Q. Now, Doctor, what about the idea of, I
 16 appreciate you said well I use example one,
 17 but in example one here, there's no negative.
 18 When you would report either estrogen
 19 receptors or progesterone receptors or both as
 20 negative, do you know whether or not you use
 21 zero percent any of the time, some of the
 22 time, none of the time or do you know?
 23 DR. COOK:
 24 A. It could have been some of the time, I can't
 25 be--I wouldn't say that I used zero percent

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1 all of the time, but there may have been some
 2 reports that I would say zero percentage or
 3 just reports that went up just as negative.
 4 COFFEY, Q.C.:
 5 Q. Doctor, would there be anything in a pathology
 6 report, if you used just the word "negative"
 7 okay, if that was all you used and you didn't
 8 use zero percent, would there be any way of a
 9 reader of that report telling that you meant
 10 zero percent?
 11 DR. COOK:
 12 A. Not unless I stated that in the micro. I
 13 mean, I could say in the micro that evaluation
 14 of the ER and PR shows zero percent of cells,
 15 other than that, negative would mean negative.
 16 COFFEY, Q.C.:
 17 Q. And I take it then these reports in the main
 18 were done for whom? Who would be relying upon
 19 them?
 20 DR. COOK:
 21 A. For the oncologist and there were also
 22 surgeons who were in the area of oncology as
 23 well.
 24 COFFEY, Q.C.:
 25 Q. So would a surgeon or an oncologist reading a

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1 report that, for example, just said positive
 2 and I appreciate you would use a percentage,
 3 but for--I'll deal with yourself first, you
 4 use the word "positive" and a percentage, one
 5 or the other -
 6 DR. COOK:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. Then the oncologists or the surgeon go look at
 10 the figure, 20, 30, 40, and they'd know what
 11 you meant?
 12 DR. COOK:
 13 A. Yes.
 14 COFFEY, Q.C.:
 15 Q. Positive and a percentage. In reports that
 16 just said positive, would they have any way of
 17 telling what the percentage was?
 18 DR. COOK:
 19 A. Not unless it was stated in the microscopic.
 20 COFFEY, Q.C.:
 21 Q. I take it that there was no hard and fast rule
 22 everywhere throughout the province or even
 23 within your own hospital?
 24 DR. COOK:
 25 A. Well, there was a hard and fast rule. This

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1 was in regards to the standardization of the
 2 report, but there was no hard and fast rule
 3 whether to use example one or two.
 4 COFFEY, Q.C.:
 5 Q. Now if there are, for example, if we were to
 6 look at a number of pathology reports from the
 7 period say 1998 through 2005, and a number of
 8 them just say positive, they don't say--
 9 there's no percentage. I take it that then,
 10 unless there's something else spelled out
 11 somewhere in the report, there'd be no way of
 12 knowing -
 13 DR. COOK:
 14 A. There'd be no way, that's correct.
 15 COFFEY, Q.C.:
 16 Q. - of how, what percentage meant positive?
 17 DR. COOK:
 18 A. That could be, again, someone could state
 19 positive--if they were using example number
 20 two, positive would mean greater than 30
 21 percent, if they were thinking along that
 22 lines.
 23 THE COMMISSIONER:
 24 Q. When you say if they were using example number
 25 two, you mean example number two with the

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1 additional wording on the bottom?
 2 DR. COOK:
 3 A. With the additional wording. They may just
 4 say positive, but they could be looking at the
 5 fact that they're thinking positive greater
 6 than 30 percent.
 7 THE COMMISSIONER:
 8 Q. Yes.
 9 COFFEY, Q.C.:
 10 Q. Positive and then if they said they had the
 11 comment there, well you could--and they've
 12 cross-referenced the comment?
 13 DR. COOK:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. Then that reader would know that it's 30 or
 17 higher or more than 30?
 18 DR. COOK:
 19 A. That's right, that positive could be 35
 20 percent or it could be 90 percent.
 21 COFFEY, Q.C.:
 22 Q. Doctor, and I appreciate that you were, in
 23 1998, you were--your dealings with Dr. Khalifa
 24 concerning this whole issue about the comment,
 25 okay, and whether it should or shouldn't be

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1 included in reports and whether it was policy
 2 or his was simply advice or policy, your
 3 discussion with him regarding that would have
 4 occurred in what time frame?
 5 DR. COOK:
 6 A. It would have occurred prior to that, sometime
 7 during early '98.
 8 COFFEY, Q.C.:
 9 Q. You've indicated that there was--your approach
 10 was the one that you wanted adopted at St.
 11 Clare's. Did you ever actually--was there
 12 ever a written policy to that effect
 13 circulated at St. Clare's?
 14 DR. COOK:
 15 A. No, I just told the pathologists, well, we had
 16 that proposal and I just told them to follow
 17 example one, not to include cut offs.
 18 COFFEY, Q.C.:
 19 Q. Now if a new pathologist came along after
 20 that, how would he or she know what the policy
 21 was?
 22 DR. COOK:
 23 A. I would tell them in regards to estrogen
 24 receptors, not to use the cut offs.
 25 COFFEY, Q.C.:

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1 Q. How would you know to do that, in the sense of
 2 -
 3 DR. COOK:
 4 A. This would sometimes come up at our various
 5 rounds about--that I came across a case that
 6 we were discussing in which that comment was
 7 used, I would quickly tell them to avoid using
 8 that comment.
 9 COFFEY, Q.C.:
 10 Q. Doctor, from the time then that yourself, as a
 11 pathologist in Newfoundland, began to report
 12 your own ER and PR cases, IHC cases, up until
 13 May of 2005, do you recall any discussions
 14 with oncologists or surgeons about the idea of
 15 positive and negative and cut offs?
 16 DR. COOK:
 17 A. Not from my aspect.
 18 COFFEY, Q.C.:
 19 Q. No one ever came to you and said "well, what
 20 do you mean? Don, what do you mean by
 21 negative?" If, for example, you just used
 22 negative and didn't use zero.
 23 DR. COOK:
 24 A. No one came to me.
 25 COFFEY, Q.C.:

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1 Q. Now Doctor, while we're looking at this memo,
 2 at the time when this was circulated, I take
 3 it in February of 1998, do you recall whether
 4 there was any discussion about it, other than
 5 the comment--discussion about the adding or
 6 not adding that comment? I take it there were
 7 no in-services in relation to this that you're
 8 aware of?
 9 DR. COOK:
 10 A. Not that I'm aware of.
 11 COFFEY, Q.C.:
 12 Q. And caucusing about it or anything like that?
 13 DR. COOK:
 14 A. Not that I'm aware of.
 15 COFFEY, Q.C.:
 16 Q. So just the memo came out and you had a
 17 discussion with Dr. Khalifa and made your own
 18 views known internally within St. Clare's as
 19 to how it would be reported?
 20 DR. COOK:
 21 A. That's right.
 22 COFFEY, Q.C.:
 23 Q. And other than that, ER and PR IHC ordering
 24 and reporting interpretations and so on, just
 25 went right on?

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1 DR. COOK:
 2 A. That's correct.
 3 THE COMMISSIONER:
 4 Q. Dr. Cook, at the time, would--and frankly,
 5 perhaps now, I don't know necessarily where
 6 the oncologists are located, except there seem
 7 to be a large number on the site of the Health
 8 Science Complex, but would the oncologists you
 9 would be dealing with be in St. Clare's or
 10 would you be primarily communicating with
 11 surgeons in St. Clare's and oncologists at
 12 Health Sciences or in the Cancer Clinic or
 13 whatever?
 14 DR. COOK:
 15 A. I would be primarily communicating with our
 16 surgeons on site at St. Clare's and if there
 17 was any calls concerning issues surrounding a
 18 pathology report, a particular oncologist
 19 would call me concerning a particular interest
 20 or a particular point. So up until that time,
 21 I don't believe that there was any sort of
 22 mass interaction between pathologists and
 23 oncologists at that point in time.
 24 THE COMMISSIONER:
 25 Q. Okay.

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1 DR. COOK:
 2 A. Except at scattered rounds, medical pathology
 3 rounds or grand medical rounds, that sort of
 4 thing.
 5 THE COMMISSIONER:
 6 Q. And would those oncologists be primarily at
 7 St. Clare's?
 8 DR. COOK:
 9 A. No, they would be at the Cancer Centre, which
 10 was attached to the General Hospital.
 11 THE COMMISSIONER:
 12 Q. So as a general rule, is it safe to assume
 13 that normally you would communicate with the
 14 surgeon who had done the surgery and the
 15 information from the pathologist got through
 16 the Cancer Centre through that person's chart
 17 having been transferred over to that site?
 18 DR. COOK:
 19 A. That's a fair assessment to make. Most of--
 20 any, 95 percent of all communication that I
 21 had regarding pathology reports or queries
 22 were with the attending surgeon.
 23 THE COMMISSIONER:
 24 Q. Okay.
 25 DR. COOK:

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1 A. And then who would forward that information
 2 then to the Cancer Centre.
 3 THE COMMISSIONER:
 4 Q. Okay, thank you.
 5 COFFEY, Q.C.:
 6 Q. Looking at the first page of Dr. Khalifa's
 7 February 16th 1998 memo, the third paragraph
 8 says "as the technique was still in its
 9 introductory phase, phase one, I have been
 10 reporting results of the majority of cases to
 11 establish consistency and reproducible
 12 techniques. As we have come to a more
 13 advanced stage of this pursuit where this test
 14 could be done with a relatively high
 15 efficiency and reliability, I came to believe
 16 that we are probably ready to move into the
 17 next two and final phases."
 18 So in terms of the idea that Dr. Khalifa,
 19 for a while, was reporting all such cases, do
 20 you recall -
 21 DR. COOK:
 22 A. That was a--I didn't realize he was doing that
 23 at the time. I knew he was obviously
 24 evaluating and looking at the stain, but I did
 25 not have recollection that he was actually

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1 reporting that and entering it into the
 2 system.
 3 COFFEY, Q.C.:
 4 Q. And phase two is described here as "each
 5 pathologist will be asked to report results of
 6 his or her own case as indicated by the brown
 7 staining of nuclei of the invasive neoplastic
 8 cells. This phase will start March 1, 1998,
 9 at which time your immunostained slides will
 10 be mailed back to you with positive controls
 11 wherever it is technically possible. With
 12 each run, I will still be responsible for
 13 reviewing the positive controls here in our
 14 laboratory and the slides will not be mailed
 15 to you unless adequate staining is noted in
 16 the positive controls. As we are all
 17 interested in making this transition as smooth
 18 as possible, I would be more than glad to
 19 continue being available to answer any
 20 questions and address concerns."
 21 And then there's a reference to "the
 22 division of medical biochemistry will be
 23 addressed to officially discontinue performing
 24 steroid assessment by biochemical techniques."

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1 And Doctor, looking at phase two in that
 2 paragraph, up to that point in time, which
 3 would be February/March 1998, how many IHC
 4 stains involved the staining of nuclei of the
 5 cells, of the tumor cells?
 6 DR. COOK:
 7 A. I can't give you an exact number.
 8 COFFEY, Q.C.:
 9 Q. Were there many at that time?
 10 DR. COOK:
 11 A. Most of them, I believe, were cytoplasmic
 12 stains.
 13 COFFEY, Q.C.:
 14 Q. Cytoplasmic, which is non -
 15 DR. COOK:
 16 A. Non-nuclear.
 17 COFFEY, Q.C.:
 18 Q. - the area around the nucleus?
 19 DR. COOK:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. So at that point, in terms of ER and PR IHC
 23 testing, as best you can recall, at least
 24 locally, this is probably the first such
 25 stains that involved percentages?

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1 DR. COOK:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. And it was--or involved nuclei staining and
 5 there weren't a lot of nuclei stains being
 6 used at the time?
 7 DR. COOK:
 8 A. Again, I can't be sure on that.
 9 COFFEY, Q.C.:
 10 Q. Yes, I appreciate that. Who would, in fact,
 11 know that, do you know? Who might be the
 12 repository of that kind of knowledge at the
 13 time?
 14 DR. COOK:
 15 A. I guess Dr. Khalifa.
 16 COFFEY, Q.C.:
 17 Q. Khalifa, okay, and he goes on to say, in the
 18 beginning, "Starting March 1, 1998, the
 19 immunostained slides will be mailed back to
 20 you," that would be to the ordering physician,
 21 "with positive controls." What type of
 22 positive controls were they?
 23 DR. COOK:
 24 A. These were the external positive controls.
 25 COFFEY, Q.C.:

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1 Q. And he goes on to say "with each run, I will
 2 still be responsible for reviewing the
 3 positive controls here in our laboratory,"
 4 which would be, I take it, the General
 5 Hospital?
 6 DR. COOK:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. "And the slides will not be mailed to you
 10 unless adequate staining is noted in the
 11 positive controls." So at that time, again
 12 beginning in March and April of 1998, was St.
 13 Clare's getting positive control stain slides
 14 back?
 15 DR. COOK:
 16 A. Yes, we were.
 17 COFFEY, Q.C.:
 18 Q. Did that ever change?
 19 DR. COOK:
 20 A. No, I think for the most part, we got our
 21 controls.
 22 COFFEY, Q.C.:
 23 Q. The purpose of you getting the controls or the
 24 controls being sent to you and you looking at
 25 them was what?

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1 DR. COOK:
 2 A. To make sure the stain was working.
 3 COFFEY, Q.C.:
 4 Q. And I take it if the external positive
 5 control, in your view, didn't stain, then the
 6 test would have to be redone?
 7 DR. COOK:
 8 A. That's right.
 9 THE COMMISSIONER:
 10 Q. Are we talking about a positive controls per
 11 batch or are we talking about one per--when
 12 you're talking about a positive control, would
 13 you look for an external positive control in
 14 respect of--I'm sorry, I should start at a
 15 earlier point. Are you talking about external
 16 positive controls on the same slide or are you
 17 talking about external positive controls under
 18 different--on a different slide?
 19 DR. COOK:
 20 A. On a different slide. These would be--a
 21 control would be run with a batch or a run.
 22 THE COMMISSIONER:
 23 Q. Okay, so with a group of slides, you would get
 24 a slide on which there was an external
 25 positive control?

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

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1 slides?

2 DR. COOK:

3 A. I wouldn't. These were ER and PR control

4 slides that were related to the whole batch,

5 because the controls -

6 COFFEY, Q.C.:

7 Q. Well, how would you know what was in each

8 batch? That's what I'm getting at.

9 DR. COOK:

10 A. You mean -

11 COFFEY, Q.C.:

12 Q. For example, in any one day, say you had--I

13 don't know, I'll just pick a number, say St.

14 Clare's had three ER and three PR slides,

15 three separate patients, one for each patient,

16 one ER for each patient, one PR for each

17 patient, come over from the General Hospital,

18 how many external controls would you expect?

19 DR. COOK:

20 A. It would be only one set of external controls.

21 COFFEY, Q.C.:

22 Q. One for ER and one for PR?

23 DR. COOK:

24 A. That's correct.

25 COFFEY, Q.C.:

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1 Q. For that particular run or batch. How would

2 you then know, for example, after you'd looked

3 at them and they were filed away, if you had

4 to go back and look again, how would you know

5 which control slide was which patient slide?

6 How were they cross-referenced, if at all?

7 DR. COOK:

8 A. You might have the date on it or you may have

9 a surgical number on it, but that wasn't

10 consistent. What I did, when I got an ER and

11 PR case, and usually on the requisition, it

12 would state on what particular pathologist got

13 the controls. So if I got an ER and PR,

14 before I reported, I would go to that

15 particular pathologist and track down where

16 the ER and PR control was.

17 COFFEY, Q.C.:

18 Q. And have him or her, I take it, send you the

19 slides?

20 DR. COOK:

21 A. Yes, or I would look at them directly in their

22 office.

23 COFFEY, Q.C.:

24 Q. Sure.

25 DR. COOK:

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1 A. Just to verify that they worked.

2 COFFEY, Q.C.:

3 Q. Now Doctor, here, there's no reference here

4 to--in the paragraph phase two, nor in fact on

5 the next page under the heading or the text,

6 the report on hormone receptor status who have

7 three components, there's no reference here to

8 internal controls. See that?

9 DR. COOK:

10 A. That's correct.

11 COFFEY, Q.C.:

12 Q. The idea of an internal control for patient

13 tissue, tumor tissue or related to tumor

14 tissue of a patient, in March and April of

15 1997, the idea of internal controls, would you

16 have been familiar with that at that time?

17 DR. COOK:

18 A. No, that was never discussed in any of the

19 meetings.

20 COFFEY, Q.C.:

21 Q. When did you first become aware of that in

22 relation to ER and PR testing?

23 DR. COOK:

24 A. I would say probably around 2000, 2001.

25 COFFEY, Q.C.:

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1 Q. And do you recall how it was you became aware

2 of it?

3 DR. COOK:

4 A. In my reading of a textbook or it could have

5 been reading some of the journals.

6 COFFEY, Q.C.:

7 Q. And do you recall, like, at the time, because

8 by then you would have been reporting your own

9 breast cancer ER/PR cases for about two years?

10 DR. COOK:

11 A. Um-hm.

12 COFFEY, Q.C.:

13 Q. By 2000. And the idea of internal controls,

14 what did you glean from your reading at the

15 time as to their importance or significance or

16 lack thereof, what did you understand that -

17 DR. COOK:

18 A. Just another component you should use and

19 evaluate in the ER and PR stain.

20 COFFEY, Q.C.:

21 Q. Having learned that at the time did you

22 distribute that information to anyone?

23 DR. COOK:

24 A. No, that was just part of my reading.

25 COFFEY, Q.C.:

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1 Q. And at that point in time would you have
 2 understood, or would you have had any reason
 3 to believe at that point in time that the
 4 other pathologists, for example, at St.
 5 Clare's would have been aware of the potential
 6 need for internal controls?
 7 DR. COOK:
 8 A. Not at that time, no.
 9 COFFEY, Q.C.:
 10 Q. Do you know when internal controls, the
 11 information concerning that was generally
 12 distributed amongst pathologists for the first
 13 time?
 14 DR. COOK:
 15 A. Oh, 2003.
 16 COFFEY, Q.C.:
 17 Q. And that would be with Dr. Ejeckam?
 18 DR. COOK:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. In 2000 when you came across the reference to
 22 internal controls in ER and PR testing, IHC
 23 testing, Doctor, do you recall the time was
 24 that--and I appreciate it was new to you, but
 25 was that actually new information at the time?

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1 DR. COOK:
 2 A. I can't say whether it was new information.
 3 Was it widely-distributed information, I don't
 4 think so because any time we would read about
 5 new IHC testing, it was always about the
 6 interpretation of that testing and the
 7 application of an immunohistochemical test in
 8 terms of using that test to make a diagnosis
 9 of a particular lesion. Most of the reading
 10 that I centred around at that time commented
 11 very little, if none at all, about identifying
 12 internal controls. It was always about here's
 13 a new antibody that's out or new
 14 immunohistochemical stain that's out, here's
 15 how it can use you to help make a diagnosis or
 16 an interpretation of a particular lesion.
 17 COFFEY, Q.C.:
 18 Q. Now, Doctor, at the time this memo, in
 19 February of 1998, February 16th, 1998, would
 20 this have been, like, kind of the first
 21 general information bulletin, as it were, to
 22 all pathologists in Newfoundland that, look,
 23 in terms of ER and PR, beginning in a couple,
 24 by then a couple of weeks time you're going to
 25 be on your own doing this in the sense of if

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1 you order the test, the slides will go back to
 2 you. Dr. Khalifa does say he's available, he
 3 does offer himself up as available. He says
 4 in the second page of his memo, the last
 5 sentence, "I will be glad to share any of the
 6 material I already have with you. I would
 7 extremely appreciate your feedback on this
 8 matter." I take it then, Doctor, that other
 9 than this memo, were you aware--and your
 10 conversation with Dr. Khalifa about not adding
 11 the word, the comment that he suggested, were
 12 you aware of any other discussion at all
 13 amongst the pathology community at that time
 14 about ER and PR?
 15 DR. COOK:
 16 A. None that comes to mind.
 17 COFFEY, Q.C.:
 18 Q. Exhibit P-1864, please? Now, Doctor, this is
 19 a letter of December 9th, 1998 addressed to
 20 yourself as the site chief at St. Clare's.
 21 It's from Dr. Khalifa. He says, "Dr.
 22 Maghfoor, of our cancer clinic, has asked me
 23 to look into the above cited case. Apparently
 24 the patient's tumor was reported by our
 25 biochemical laboratory to be ER negative. It

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1 also seems that your laboratory," which would
 2 be Dr. Cook's, I presume, St. Clare's, "has
 3 submitted a portion of the tumor for
 4 immunohistochemical assessment." And it's, I
 5 take it, the 1996 case, if we could see this
 6 here. "And was reported as ER positive." as
 7 per Dr. Maghfoor. "Since the
 8 immunohistochemistry was not done in our
 9 laboratory I thought I would have very little
 10 to do with this case. I ask could you please
 11 address Dr. Maghfoor's questions?" He's
 12 copied it to Dr. Maghfoor. Do you recall
 13 this, Doctor?
 14 DR. COOK:
 15 A. I vaguely recall it. I can't remember all the
 16 details surrounding that.
 17 COFFEY, Q.C.:
 18 Q. And what do you recall about it?
 19 DR. COOK:
 20 A. It may have been, again, in relation to the
 21 cutoff. I may have reported the case saying
 22 it was positive at, say, five percent or ten
 23 percent, whereas the biochemical assay would
 24 have reported as negative. That's about all I
 25 can generally recollect about that.

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1 COFFEY, Q.C.:

2 Q. And in terms of "Your lab has submitted a

3 portion of the tumor," which would be, I take

4 it, from St. Clare's?

5 DR. COOK:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. Who would have had the--or request the IHC

9 assessment to do be done. And from your

10 perspective you, if it was, for example, 20

11 percent, you would simply have said -

12 DR. COOK:

13 A. Positive 20 percent.

14 COFFEY, Q.C.:

15 Q. - 20 percent. And that might not then have

16 met the biochemical cutoff for positivity?

17 DR. COOK:

18 A. It's possible, yes.

19 COFFEY, Q.C.:

20 Q. And that could account for the difference in

21 biochemical assay, reporting it as equivocal

22 or negative?

23 DR. COOK:

24 A. That's correct.

25 COFFEY, Q.C.:

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1 Q. Doctor, during this time period which is,

2 like, throughout '98, into '99, into 2000, was

3 there ever any expression of concern, do you

4 recall, about fixation and inadequacies in

5 fixation or tissue processing potentially

6 affecting ER and PR results?

7 DR. COOK:

8 A. No.

9 COFFEY, Q.C.:

10 Q. If we could, please, Exhibit P-1870? And,

11 Doctor, this is a memo to provincial

12 laboratory directors, program director of

13 laboratory medicine program and divisional

14 managers from yourself. You're the acting

15 clinical chief at this point?

16 DR. COOK:

17 A. Um-hm.

18 COFFEY, Q.C.:

19 Q. April 27th, 2000. The subject is HER2/neu

20 Expression. And notes here, "Effective April

21 1, 2000, pathologists at the Health Care

22 Corporation of St. John's had begun reporting

23 on HER2/neu overexpression." And "HER2/neu

24 overexpression will only be reported following

25 a request from oncology." And you note, "We

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1 are using the DAKO kit, which has been

2 approved by FDA and Health Canada." You go on

3 to talk about the grading system and so on.

4 You continue by saying, "We will be able to

5 perform HER2/neu immunoperoxidase stains on

6 paraffin blocks on cases referred in. Once

7 the stains are completed both the paraffin

8 blocks and the slides, it will be referred

9 back to your hospital. At this point in time

10 reporting of HER2/neu overexpression will be

11 the responsibility of the pathologist who

12 ordered the stain. It is also recommended

13 that for evaluation of breast biopsies for

14 HER2/neu overexpression, the biopsies should

15 be fixed overnight for at least 18 hours."

16 DR. COOK:

17 A. Um-hm.

18 COFFEY, Q.C.:

19 Q. "If you have any other questions concerning

20 this, please feel free to call me." Signed,

21 "Donald Cook." And, Doctor, the second page

22 of this is a text which has a heading

23 "Staining and Intensity Score, Staining

24 Pattern and HER2 Overexpression Assessment."

25 The text reads, "Health Care Corporation of

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1 St. John's uses the interpretation guidelines

2 recommended by the DAKO Herceptest, which is

3 the FDA and CSA approved testing method for

4 HER2/neu overexpression. The guidelines are

5 as follows." Now, Doctor, was this the

6 beginning of reporting of HER2/neu locally?

7 DR. COOK:

8 A. Yes.

9 COFFEY, Q.C.:

10 Q. And was there any other educational efforts

11 made, preparatory efforts made in relation to

12 having pathologists do this reporting other

13 than this?

14 DR. COOK:

15 A. That's--yes, there was preparation made in

16 regard to the HER2/neu.

17 COFFEY, Q.C.:

18 Q. Do you recall what that was in terms of -

19 DR. COOK:

20 A. That was an in-service that was given to all

21 of our pathologists at the Health Care

22 Corporation of St. John's. It was around

23 October of '99 that we had a meeting, about 18

24 individuals attended that meeting with

25 representatives from the DAKO company as well

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1 as, I believe, our program manager at that
 2 time to go over how to report the HER2/neu.
 3 COFFEY, Q.C.:
 4 Q. And they, I take it, were the locals Health
 5 Care Corporation -
 6 DR. COOK:
 7 A. These were the local pathologists, yeah.
 8 COFFEY, Q.C.:
 9 Q. Pathologists. How about outside St. John's,
 10 outside the Health Care -
 11 DR. COOK:
 12 A. No. That would have been I regarded as the
 13 responsibility of the director of labs at that
 14 time in each of the hospitals.
 15 COFFEY, Q.C.:
 16 Q. The local pathologist, whoever was in charge
 17 in a particular location outside the city?
 18 DR. COOK:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. And in terms of that, Doctor, just so the
 22 Commissioner is clear on that, I take it by
 23 this point you were acting clinical chief?
 24 DR. COOK:
 25 A. Um-hm.

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1 COFFEY, Q.C.:
 2 Q. At this particular point in time. From a
 3 strictly legalistic perspective I take it you
 4 would have no authority over people in Grand
 5 Falls or, like pathologists in Grand Falls or
 6 Corner Brook or Clarenville or St. Anthony?
 7 DR. COOK:
 8 A. No. I would just be strictly overseeing the
 9 pathologists at the General, Health Sciences,
 10 the General, the St. Clare's and Grace.
 11 COFFEY, Q.C.:
 12 Q. And why was it seen to be desirable or
 13 necessary, for that matter, to have an in-
 14 service for HER/2 neu -
 15 DR. COOK:
 16 A. Because -
 17 COFFEY, Q.C.:
 18 Q. - in the fall of '99?
 19 DR. COOK:
 20 A. Yeah. I wanted them, all the pathologists to
 21 become familiar with how to report the case.
 22 COFFEY, Q.C.:
 23 Q. And was it--how to report, what does that
 24 entail or -
 25 DR. COOK:

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1 A. Well, if you're using zero, what does that
 2 mean, if you're using one plus, what does that
 3 mean, two plus and three plus.
 4 COFFEY, Q.C.:
 5 Q. And what about actually looking at the slides
 6 themselves?
 7 DR. COOK:
 8 A. That's correct, to actually interpret that
 9 this is a cytoplasmic stain.
 10 COFFEY, Q.C.:
 11 Q. Okay, so this in-service educational effort
 12 involved actual viewing of slides, talking
 13 about them, explaining the thought process
 14 that go -
 15 DR. COOK:
 16 A. Showing photographs on the screen, that sort
 17 of thing. There were hand outs circulated
 18 from DAKO Industries with microscopic
 19 presentations showing the different intensity
 20 of the stain and how to grade it.
 21 COFFEY, Q.C.:
 22 Q. Why was that felt to be necessary for
 23 HER2/neu?
 24 DR. COOK:
 25 A. Well, it was much more complex stain than the

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1 ER and PR, which just relied on nuclear
 2 staining. We were getting into cytoplasmic
 3 staining and where there was partial or
 4 incomplete staining, various percentages of
 5 the stain, so it was a more complex stain to
 6 interpret than the ER and PR.
 7 COFFEY, Q.C.:
 8 Q. Why was it more complex?
 9 DR. COOK:
 10 A. Because of the cytoplasmic staining and trying
 11 to determine whether there was a mild or
 12 moderate degree of staining there.
 13 COFFEY, Q.C.:
 14 Q. I take it the idea of using a percentage or
 15 arriving at a percentage, that was consistent
 16 with ER/PR?
 17 DR. COOK:
 18 A. Well, that was one thing, the percentage. But
 19 then evaluating that cytoplasmic stain,
 20 whether it was a complete membrane staining
 21 and the intensity of the stain.
 22 COFFEY, Q.C.:
 23 Q. So the idea, the fact that or the
 24 characteristic in HER2/neu that you would have
 25 to or a pathologist would have to offer an

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1 opinion or interpretation as to intensity
 2 levels -
 3 DR. COOK:
 4 A. Intensity levels and whether that membrane
 5 staining is complete or not and what
 6 percentage of cells are involved.
 7 COFFEY, Q.C.:
 8 Q. Okay. So the percentage issue would be -
 9 DR. COOK:
 10 A. Still there.
 11 COFFEY, Q.C.:
 12 Q. Still there, but it was there for ER/PR, as
 13 well?
 14 DR. COOK:
 15 A. Um-hm.
 16 COFFEY, Q.C.:
 17 Q. Would I be correct on that?
 18 DR. COOK:
 19 A. Yes.
 20 COFFEY, Q.C.:
 21 Q. Okay. But the distinguishing feature of
 22 HER2/neu was involved an assessment of
 23 intensity?
 24 DR. COOK:
 25 A. Intensity, the degree of membraneous staining

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1 and the percentage of cells that are stained.
 2 COFFEY, Q.C.:
 3 Q. So is it membranes, it's a membrane stain,
 4 not--is it cytoplasmic staining, as well?
 5 DR. COOK:
 6 A. Mainly cytoplasmic stain--sorry, membrane
 7 stain.
 8 COFFEY, Q.C.:
 9 Q. Yes, okay. So it's membrane staining?
 10 DR. COOK:
 11 A. Um-hm.
 12 COFFEY, Q.C.:
 13 Q. And as in ER/PR in contradistinction to nuclei
 14 staining?
 15 DR. COOK:
 16 A. Nuclear staining.
 17 COFFEY, Q.C.:
 18 Q. Nuclear staining. And the membrane is the
 19 outside of the cell?
 20 DR. COOK:
 21 A. That's the cell boundary.
 22 COFFEY, Q.C.:
 23 Q. Boundary as opposed to the nucleus, within the
 24 cell. So -
 25 DR. COOK:

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1 A. And the cytoplasm.
 2 COFFEY, Q.C.:
 3 Q. And the cytoplasm. But in terms of the
 4 staining for HER2/neu, cytoplasm wouldn't
 5 figure into it, would it?
 6 DR. COOK:
 7 A. That's right.
 8 COFFEY, Q.C.:
 9 Q. So the chief difference, would it be fair to
 10 say, that really the chief difference other
 11 than if membrane equals nucleus in the sense
 12 of one has to be stained in one context, one
 13 in another?
 14 DR. COOK:
 15 A. In terms of the ER and PR it's nuclear, in
 16 terms of the HER2/neu it would be cytoplasmic
 17 membrane.
 18 COFFEY, Q.C.:
 19 Q. And percentages calculation had to be done?
 20 DR. COOK:
 21 A. Um-hm.
 22 COFFEY, Q.C.:
 23 Q. In both instances. The chief difference would
 24 be then this assessment of intensity?
 25 DR. COOK:

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1 A. Intensity is a factor, yes, and whether that
 2 membraneous staining is complete or
 3 incomplete.
 4 COFFEY, Q.C.:
 5 Q. Okay.
 6 DR. COOK:
 7 A. So there's another factor there.
 8 COFFEY, Q.C.:
 9 Q. Complete or incomplete and if so, what
 10 percentage of overall cells?
 11 DR. COOK:
 12 A. So the percentage would weigh into it.
 13 COMMISSIONER:
 14 Q. Just a curiosity level, I'm sure it has
 15 nothing to do with anything, but presumably
 16 you could get a slide where the intensity
 17 would vary across the slide or would you
 18 expect that the intensity would be consistent?
 19 I'm just wondering how you get a percentage if
 20 intensity is different in different parts of
 21 the slide?
 22 DR. COOK:
 23 A. The HER2/neu, the intensity tends to be fairly
 24 homogenous across the slide.
 25 COMMISSIONER:

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1 Q. Okay.

2 DR. COOK:

3 A. But that's not an absolute. I mean, you can't

4 say that with 100 percent certainty. But if

5 you got a strong positive, three plus, you

6 would get strong membranous staining right

7 across the slide.

8 COFFEY, Q.C.:

9 Q. So, Doctor, ER/PR then, and I'll use the

10 phrase, in effect was rolled out in early ' 98

11 across the province?

12 DR. COOK:

13 A. Um-hm.

14 COFFEY, Q.C.:

15 Q. And without any in-service?

16 DR. COOK:

17 A. Um-hm.

18 COFFEY, Q.C.:

19 Q. While HER2/neu was rolled out in early 2000

20 with an in-service in late '99?

21 DR. COOK:

22 A. Right. Or it was, came on stream April, 2000.

23 COFFEY, Q.C.:

24 Q. Yes, rolled out in the sense of you're here

25 advising everybody from now on this is what

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1 we'll be doing. Did anyone at the time remark

2 upon the different approaches to using an in-

3 service for one process then after the other?

4 DR. COOK:

5 A. No. The only remark I received was people

6 were happy that I conducted an in-service on

7 the HER2/neu.

8 COFFEY, Q.C.:

9 Q. Oh, yes.

10 DR. COOK:

11 A. But that's, there were no remarks about in-

12 service for ER and PR.

13 COFFEY, Q.C.:

14 Q. Or the lack thereof now that we've got our

15 HER2/neu in-service?

16 DR. COOK:

17 A. Yes.

18 COFFEY, Q.C.:

19 Q. Okay. Doctor, here looking at this, there's a

20 reference here to "It is also recommended that

21 for evaluation of breast biopsies the biopsies

22 should be fixed overnight for at least 18

23 hours."

24 DR. COOK:

25 A. Um-hm.

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1 COFFEY, Q.C.:

2 Q. Where did that information come from?

3 DR. COOK:

4 A. That came from the DAKO company itself. There

5 were DAKO representatives at that in-service.

6 COFFEY, Q.C.:

7 Q. Was there any explanation at the time as to

8 why that was so?

9 DR. COOK:

10 A. No, that was their recommendation.

11 COMMISSIONER:

12 Q. Mr. Coffey, wherever you can find a place,

13 we'll break for lunch.

14 COFFEY, Q.C.:

15 Q. Doctor, if we could look, please, at Exhibit

16 P-1874? So, Doctor, by this point in time,

17 that's April of 2000, I'm sorry?

18 DR. COOK:

19 A. Um-hm.

20 COFFEY, Q.C.:

21 Q. You were acting clinical chief. Where was Dr.

22 Khalifa at that point?

23 DR. COOK:

24 A. He had left the province, I think it was April

25 or May of '99.

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1 COFFEY, Q.C.:

2 Q. So by that point he would have been gone for

3 approximately a year?

4 DR. COOK:

5 A. That's right.

6 COFFEY, Q.C.:

7 Q. If we look here, these are minutes of a

8 meeting of site chiefs, division managers,

9 division of anatomical pathology, February

10 22nd, 2001. You're listed as one of the

11 attendees. And paragraph 4.2 under "New

12 Business" "Quality control of immunoperoxidase

13 staining."

14 DR. COOK:

15 A. Um-hm.

16 COFFEY, Q.C.:

17 Q. "There has been a study going on the quality

18 of the immunoperoxidase staining for both

19 sites. It is agreed the control for

20 immunoperoxidase staining be run for every

21 batch. A pathologist will check the control

22 slide before sending the slide to the other

23 site. Dr. S. Parai has agreed to do this. In

24 case he is not available another pathologist

25 will be looking at the control." And it goes

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1 on to talk about another particular antibody.
 2 Do you recall what this was about, Doctor,
 3 this study?
 4 DR. COOK:
 5 A. I don't even know if that study went ahead or
 6 it certainly didn't involve the pathologists
 7 at St. Clare's. It seemed to me to be
 8 centralized at the General Hospital and I
 9 never did get the results of that study.
 10 COFFEY, Q.C.:
 11 Q. Do you know what had occasioned the study, I
 12 mean, the need for it or the view that it
 13 might be a good idea?
 14 DR. COOK:
 15 A. It may have been something that, well, an
 16 evaluation, but I have no recollection of what
 17 triggered that or ignited that.
 18 COFFEY, Q.C.:
 19 Q. And because he refers to both sites. See
 20 that?
 21 DR. COOK:
 22 A. Yeah.
 23 COFFEY, Q.C.:
 24 Q. Which both sites would this be?
 25 DR. COOK:

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1 A. It was not St. Clare's unless it was the
 2 General, and by that time the Grace was
 3 closed, but definitely it didn't involve St.
 4 Clare's.
 5 COFFEY, Q.C.:
 6 Q. If we could, please, Exhibit P-1876? That was
 7 February of 2001. This is the minutes of a
 8 meeting of site chiefs and divisional
 9 managers, division of pathology, Wednesday,
 10 April 25th, 2001. Present are yourself and a
 11 number of others, including Dr. Parai and
 12 Haegert. Doctor Sushil Parai, I take it,
 13 would have been site chief of -
 14 DR. COOK:
 15 A. The General.
 16 COFFEY, Q.C.:
 17 Q. The General by then. And you would be of St.
 18 Clare's?
 19 DR. COOK:
 20 A. St. Clare's. Dr. Haegert is back at this
 21 point?
 22 DR. COOK:
 23 A. As clinical chief.
 24 COFFEY, Q.C.:
 25 Q. As clinical chief. And under "Business

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1 Arising" paragraph 2 there's a heading
 2 "Quality Control of Immunoperoxidase
 3 Staining." "Generally the immunos appear to
 4 be very good. There appears to be some
 5 problems with the estrogen and progesterone
 6 receptors. The positive controls are checked
 7 daily by a pathologist, however these need to
 8 be documented. Dr. Parai will follow up on
 9 this. Note is also made of heavy utilization
 10 of immuno services and the high volumes
 11 encountered."
 12 DR. COOK:
 13 A. Um-hm.
 14 COFFEY, Q.C.:
 15 Q. Do you recall what this was about, because
 16 this again refers to the quality of
 17 immunostaining?
 18 DR. COOK:
 19 A. Well the only recollection that I had was I
 20 may have brought that up at that meeting,
 21 again, regarding the turnaround times for ER
 22 and PR. They were always getting constant
 23 concerns from the pathologists regarding the
 24 turnaround times for the ERs and PRs, getting
 25 calls from the clinics and from surgeons

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1 looking for ER and PR reports., So the only
 2 thing I can recollect about that particular
 3 statement is that problems concerning the
 4 turnaround times for the ERs and PRs. I can't
 5 recollect any problems regarding quality.
 6 COFFEY, Q.C.:
 7 Q. That is the quality of the stain?
 8 DR. COOK:
 9 A. Yes.
 10 COFFEY, Q.C.:
 11 Q. The stain on the slides themselves. So you
 12 would attribute this comment here to a
 13 turnaround time issue as opposed to a quality
 14 of stain with the ER and PR stains?
 15 DR. COOK:
 16 A. Yes, that's how I interpret that. And my
 17 recollection seems to tend towards that.
 18 COFFEY, Q.C.:
 19 Q. Commissioner, if we could take this up then
 20 after lunch? Thank you.
 21 COMMISSIONER:
 22 Q. Sure. We'll meet again at ten after two.
 23 (LUNCH BREAK)
 24 COMMISSIONER:
 25 Q. Mr. Coffey.

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1 COFFEY, Q.C.:

2 Q. Thank you, Commissioner. Registrar, Exhibit,

3 yes, 1876 is there, thank you. Now, Doctor,

4 there's a reference here under "New Business",

5 this is the April 25th, 2001 site chiefs and

6 divisional managers' memo. Under "New

7 Business" paragraph 1, "Control documentation

8 and registration of slides from site to site

9 within the corporation." It says, "Dr.

10 Haegert will issue a memo to all pathologists.

11 The slides being returned to the respective

12 sites should be sent directly to pathology

13 labs to be filed by the technologist. Slides

14 should not be return to pathologist's offices.

15 Note, when slides are received and returned,

16 it should be documented in the computer."

17 What was this about, Doctor?

18 DR. COOK:

19 A. Again, there was--there may have been issues

20 when slides were returned, say, from a site on

21 Corner Brook, gone directly to a pathologist's

22 office and not being registered. So in order

23 to properly document the, say, the return of

24 slides from another site, the slides should go

25 directly to a secretary or technologist to

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1 document receipt of those slides.

2 COFFEY, Q.C.:

3 Q. Okay. I take it this is related to

4 documenting, keeping track of where

5 particular, like, items were such as

6 particular slides?

7 DR. COOK:

8 A. That's right. So you know, it wouldn't bypass

9 the registration process to say that the

10 slides had been returned. So it's just to

11 keep a handle on documentation of slides.

12 COFFEY, Q.C.:

13 Q. Paragraph 2 refers to terminology of estrogen

14 and progesterone reports. It says, "Mr.

15 Gulliver will develop and canned text for

16 reporting of estrogen and progesterone

17 receptors. Information for this will be

18 obtained from Dr. Parai. What was this about,

19 Doctor?

20 DR. COOK:

21 A. I would assume that that's a--that's referring

22 to Dr. Khalifa's canned text that Dr. Parai

23 would have and the copy of that text would be

24 incorporated into the computer, so a

25 pathologist reading an ER and PR report, that

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1 canned text would already be in the system.

2 COFFEY, Q.C.:

3 Q. And would it--as Dr. Khalifa, by that point in

4 time, would have been gone for approximately

5 two years, if he left in early '99?

6 DR. COOK:

7 A. Um-hm.

8 COFFEY, Q.C.:

9 Q. A canned text here, would it relate to his or

10 would it just be--what is a canned text?

11 Perhaps you could explain that to the

12 Commissioner, what is -

13 DR. COOK:

14 A. A canned text is a stated term that's already

15 in the computer system, so all you would have

16 to do, if you say that the estrogen receptor

17 was either positive or negative, you can just

18 dictate into your microphone or your

19 dictaphone and that would be automatically

20 incorporated into a canned text that's already

21 in the system.

22 COFFEY, Q.C.:

23 Q. Do you know if the canned text for reporting

24 of estrogen and progesterone receptors was

25 ever subsequently developed?

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1 DR. COOK:

2 A. I don't know. I can't say for sure, but that's

3 the assumption I would make looking at that.

4 COFFEY, Q.C.:

5 Q. Do you know if the reports that you did after

6 April, 2001, did they have a canned text when

7 you actually saw the reports?

8 DR. COOK:

9 A. Not for St. Clare's, no. We would actually

10 dictate that report into the dictaphone and

11 transcribed by the secretary.

12 COMMISSIONER:

13 Q. So this would be some kind of a voice

14 recognition?

15 DR. COOK:

16 A. No, no, Commissioner. It would be a

17 standardized text that's in the system. So

18 all I would need to say is ER positive, say,

19 at 80 percent and that whole format would

20 automatically come up on the screen and the

21 secretary would punch in those numbers and

22 positivity.

23 COMMISSIONER:

24 Q. Oh, okay. Yeah, it's a kind of a form?

25 DR. COOK:

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1 A. It's a form for--it's much like our synoptic
 2 reporting that we later get into that you have
 3 the format already in the system.
 4 COMMISSIONER:
 5 Q. Yeah, okay. Thank you.
 6 COFFEY, Q.C.:
 7 Q. And when the transcriber heard your voice
 8 refer to certain words, they'd know that
 9 that's what I'm to plug in the values here, as
 10 it were?
 11 DR. COOK:
 12 A. They would go back to the canned text and put
 13 that in.
 14 COFFEY, Q.C.:
 15 Q. Yes. Here on page the next page, page 2 of
 16 the exhibit under paragraph 3 there's a HER2
 17 expression. And the text says, "Some
 18 discussion centred around the predictive value
 19 of the current HER2/neu kit provided by the
 20 DAKO company and whether we need to implement
 21 the FISH as confirmatory test. The issue as
 22 to whether we can provide FISH as an
 23 alternative depends on approval on two
 24 technologists positions. We will obtain some
 25 literature on this matter." What was that

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1 about, Doctor?
 2 DR. COOK:
 3 A. I would think that's getting into the
 4 possibility of false positives being
 5 documented, not only by the HER2/neu kit, but
 6 by the HER2/neu immunoperoxidase stain.
 7 That's a concern that was being generated, not
 8 only by DAKO, but by the medical community
 9 throughout Canada and United States. Now, in
 10 regards to the FISH, there were guidelines
 11 that came out from the Canadian Consensus
 12 Guidelines on HER2/neu that recommended that
 13 for all two plus results on the HER2/neu that
 14 there be a reflex testing for FISH. And we
 15 implemented that, I believe, in April or May
 16 of 2001 by sending cases up to Sunnybrook.
 17 COFFEY, Q.C.:
 18 Q. I'm sorry, so they would be sent to Sunnybrook
 19 for?
 20 DR. COOK:
 21 A. FISH testing.
 22 COFFEY, Q.C.:
 23 Q. FISH testing.
 24 DR. COOK:
 25 A. And confirmation.

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1 COFFEY, Q.C.:
 2 Q. Now, the reference here to "depends on
 3 approval on two new technologists' positions,"
 4 what was that about?
 5 DR. COOK:
 6 A. It refers to setting up the florescent in situ
 7 hybridization ourselves here in St. John's,
 8 but that would be dependent on the acquisition
 9 of two new technologist positions. It was a
 10 resource issue.
 11 COFFEY, Q.C.:
 12 Q. And do you know whether those two
 13 technologist, new positions were ever created
 14 at that time?
 15 DR. COOK:
 16 A. No, I don't think we were able to get the
 17 funding for those new positions.
 18 COFFEY, Q.C.:
 19 Q. Exhibit P-1877, please? Sir, this is, again,
 20 an agenda for a meeting of June 26th, 2001.
 21 And under "New Business" there's a quality
 22 assurance program for anatomical
 23 pathology/pathologists review. See that
 24 there?
 25 DR. COOK:

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1 A. Um-hm.
 2 COFFEY, Q.C.:
 3 Q. And we go to the second page of the exhibit,
 4 these are the minutes of meeting, site chiefs
 5 and divisional managers, June 26th, 2001.
 6 Yourself, Dr. Parai and Dr. Haegert are
 7 present. And under "Business Arising"
 8 paragraph 3.2, "HER2 Expression ER and PR
 9 control" the text reads, "The controls for all
 10 these immunostaining are checked by the site
 11 chief or by on call pathologist when site
 12 chief is not available." What was the concern
 13 here, what was that about?
 14 DR. COOK:
 15 A. That may have been addressed by me to make
 16 sure that there was somebody checking the
 17 controls and documenting the controls before
 18 those tests are released.
 19 COFFEY, Q.C.:
 20 Q. Do you know if at this point, this would be
 21 June, late June, 2001, if there was a
 22 situation that developed where the external
 23 control slides were not being distributed?
 24 DR. COOK:
 25 A. I may have. That may have been a case where

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1 some external control slides were submitted to
 2 St. Clare's and it may have been a case where
 3 I was looking for them, can't find them, and
 4 may express concern about that.
 5 COFFEY, Q.C.:
 6 Q. On the next page under "New Business" there's
 7 a heading, "Quality Assurance Program for
 8 Anatomical Pathology/Pathologist's Review."
 9 And the text goes on to say, "This meeting is
 10 dedicated for the above items and the
 11 following points are discussed." And
 12 paragraph 1, "System review. This system
 13 review is not in place. It will be discussed
 14 in the next meeting for possible
 15 implementation of pathology report review by
 16 system via committee." What was that about,
 17 Doctor?
 18 DR. COOK:
 19 A. I'm trying to remember exactly, Mr. Coffey.
 20 It may have been looking at trying to get a
 21 system in place to review pathology reports by
 22 systems, either look periodic review of
 23 something like a GI system or a pulmonary
 24 system and see how well the reporting is
 25 working by pathologists. So it's trying to

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1 get in a system of auditing to review the
 2 quality reports.
 3 COFFEY, Q.C.:
 4 Q. So up to this point in time, June of 2001, was
 5 there such a system in place?
 6 DR. COOK:
 7 A. There was a system in a way in that there was
 8 a review at various rounds of various
 9 pathology reports. These could occur at
 10 various inter-hospital rounds or could occur
 11 by individual pathologists reviewing a
 12 particular case that came to attention; it
 13 could be review of a, say, a metastatic
 14 lesion, that someone may go back two or three
 15 years ago to review our primary lesion to
 16 correlate the histologies between primary and
 17 current lesions.
 18 COFFEY, Q.C.:
 19 Q. And I take it, though, that sort of thing is
 20 is as happens as opposed to systematically
 21 going about -
 22 DR. COOK:
 23 A. Well, that has happened and has happened for
 24 many years. Pathologists on a routine basis
 25 go back and review reports.

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1 COFFEY, Q.C.:
 2 Q. As of June, 2001 was there any systematic way,
 3 though, in terms of the overall system in
 4 place that provided that occasionally, for
 5 example, like just yourself, for example, your
 6 cases or certain of your cases would come up
 7 for review just systematically?
 8 DR. COOK:
 9 A. It could. If, for instance, I go into a case
 10 and at that time I believe we had the hospital
 11 information systems in place, computer systems
 12 in place that if I'm reviewing, say, a
 13 superficial gastric biopsy or something, I
 14 would get a printout of all previous reports
 15 on that patient, so if there was a concern, I
 16 would go in and review those cases. But that
 17 would have been basically in an individual
 18 case setting or it could come up at rounds.
 19 COFFEY, Q.C.:
 20 Q. So here what was being contemplated here then,
 21 because the statement, "This system review is
 22 not in place"?
 23 DR. COOK:
 24 A. This would have been random reviews.
 25 COFFEY, Q.C.:

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1 Q. Okay. In some sort of systematic fashion?
 2 DR. COOK:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. "Canned Text", paragraph 4, there's a
 6 reference to "There is partial implementation
 7 of canned text at the General Hospital site
 8 for ER/PR and HER2/neu expression. It is
 9 important to use standard specimen grossing
 10 and reporting."
 11 DR. COOK:
 12 A. Um-hm.
 13 COFFEY, Q.C.:
 14 Q. So I take it where this refers to "at the
 15 General Hospital site" for those three stains,
 16 the ER/PR and HER2/neu expression, I take it
 17 that there was no such implementation of
 18 canned text at St. Clare's at that point?
 19 DR. COOK:
 20 A. There would have been or there certainly would
 21 have been, I think, for HER2/neu, it would not
 22 be for ER and PR, but I can't say for sure at
 23 that point in time, Mr. Coffey.
 24 COFFEY, Q.C.:
 25 Q. It refers to "It is important to use standard

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1 specimen grossing and reporting."
 2 DR. COOK:
 3 A. Um-hm.
 4 COFFEY, Q.C.:
 5 Q. What is "standard specimen grossing"?
 6 DR. COOK:
 7 A. It means that every pathologist would gross
 8 the specimen in a standard way, that there's
 9 be no deviation from one pathologist to
 10 another.
 11 COFFEY, Q.C.:
 12 Q. And were there any protocols or understandings
 13 in place in that regard?
 14 DR. COOK:
 15 A. At St. Clare's we used a standard textbook,
 16 Ackerman Surgical Pathology of which at the
 17 end of the book there was a protocol for the
 18 standard grossing of specimens.
 19 COFFEY, Q.C.:
 20 Q. And do you know what was being used at the
 21 General Hospital at the time?
 22 DR. COOK:
 23 A. I don't know.
 24 COFFEY, Q.C.:
 25 Q. And to use standard specimen grossing. And, I

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1 take it, and standard specimen reporting?
 2 DR. COOK:
 3 A. Yeah. That would be getting into synoptic
 4 reporting, T and M (phonetic) classifications
 5 and whatnot, so if you have, say, a diagnosis
 6 of tumor, there would be a standardized way of
 7 reporting that using synoptic reports.
 8 COFFEY, Q.C.:
 9 Q. And at that time, June, 2001, was synoptic
 10 reporting in place at St. Clare's?
 11 DR. COOK:
 12 A. Yes, it was.
 13 COFFEY, Q.C.:
 14 Q. How long had it been in place?
 15 DR. COOK:
 16 A. Since 1998.
 17 COFFEY, Q.C.:
 18 Q. And was that either across the board for all
 19 pathology or -
 20 DR. COOK:
 21 A. All pathologists in the division of anatomical
 22 pathology.
 23 COFFEY, Q.C.:
 24 Q. Used synoptic reporting for every type of
 25 case?

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1 DR. COOK:
 2 A. That's correct, we would use it for lung,
 3 breast, gastrointestinal tumors, genital,
 4 urinary, so standardized reporting using that
 5 synoptic report.
 6 COFFEY, Q.C.:
 7 Q. And what, if any, advantage is there to the
 8 utilization of synoptic reporting?
 9 DR. COOK:
 10 A. Well, it provides sort of a checklist in a way
 11 in that pathologists will record on a
 12 checklist pertinent information needed by
 13 surgeons or oncologists to carry out
 14 treatments.
 15 COFFEY, Q.C.:
 16 Q. And the requirement that a certain type of
 17 synoptic reporting be use at St. Clare's
 18 beginning in 1998, who implemented that?
 19 DR. COOK:
 20 A. I would have done that.
 21 COFFEY, Q.C.:
 22 Q. And was there any written guidelines to that
 23 effect?
 24 DR. COOK:
 25 A. No. That came out of site chiefs and

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1 divisional meetings that we would have had
 2 with myself and Dr. Khalifa and Haegert as
 3 well as Dr. Parai to implement that throughout
 4 the whole system.
 5 COFFEY, Q.C.:
 6 Q. And do you know what was being done, you know,
 7 circa June, 2001 at the General Hospital in
 8 that regard?
 9 DR. COOK:
 10 A. They would have used synoptic reporting, as
 11 well.
 12 COFFEY, Q.C.:
 13 Q. The synoptic reporting used at St. Clare's and
 14 at the General at the time, were they
 15 identical?
 16 DR. COOK:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. So the same system was being used?
 20 DR. COOK:
 21 A. That's right.
 22 COFFEY, Q.C.:
 23 Q. In terms of other than the coming up at rounds
 24 or being talked about, was there any actual
 25 kind of, you know, if a new pathologist came

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1 on site, came to work at the Health Care
 2 Corporation, would there be any manual that he
 3 or she could be pointed to?
 4 DR. COOK:
 5 A. No. They would be pointed to, again, in my
 6 case, at the St. Clare's using the Ackerman
 7 text and a listing of various synoptic reports
 8 that would be given to them. And the same
 9 would occur at the General Hospital site or
 10 whatever standard manual they would use.
 11 COMMISSIONER:
 12 Q. Sorry, Dr. Cook, did you say the author of the
 13 text was Ackerman?
 14 DR. COOK:
 15 A. Commissioner, Ackerman, yeah, A-c-k-e-r-m-a-n.
 16 COMMISSIONER:
 17 Q. Thank you.
 18 COFFEY, Q.C.:
 19 Q. Now, Doctor, in June of 2001, this quality
 20 assurance program for anatomical
 21 pathology/pathologists review.
 22 DR. COOK:
 23 A. Um-hm.
 24 COFFEY, Q.C.:
 25 Q. Prior to this, was there a quality assurance

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1 program for anatomical pathology?
 2 DR. COOK:
 3 A. There were quality assurance activities, but
 4 not a coordinated program where we would have
 5 a designated pathologist overseeing all
 6 quality assurance activities. There were
 7 quite a number of quality assurance
 8 activities, but not a designated individual
 9 assessing those, other than site chiefs.
 10 COFFEY, Q.C.:
 11 Q. And Doctor, whose idea was the establishment
 12 of a quality assurance program at that time,
 13 do you recall?
 14 DR. COOK:
 15 A. At this particular time, 2001?
 16 COFFEY, Q.C.:
 17 Q. Yes.
 18 DR. COOK:
 19 A. I can't say who in particular came up with it.
 20 It may have been a consensus opinion amongst
 21 the site chiefs and clinical chief.
 22 COFFEY, Q.C.:
 23 Q. And who was responsible, at that time, for
 24 coordinating or running the quality assurance
 25 program?

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1 DR. COOK:
 2 A. Well, that would have been, overall, the
 3 clinical chief.
 4 COFFEY, Q.C.:
 5 Q. That would be Dr. Haegert at this point?
 6 DR. COOK:
 7 A. Yeah.
 8 COFFEY, Q.C.:
 9 Q. If we could, please, Exhibit--if I could just
 10 go back one, please, to P-1876, and Doctor,
 11 here, on page three of this, these are minutes
 12 of April 25th, 2001, site chiefs, divisional
 13 managers meeting. Here, looking at paragraph
 14 10, "updating the immunoperoxidase form. The
 15 immunoperoxidase forms are in the process of
 16 being updated to accommodate new additions to
 17 the profile" and you had suggested a
 18 particular one be added, okay.
 19 DR. COOK:
 20 A. Um-hm.
 21 COFFEY, Q.C.:
 22 Q. I'm just going to ask then, please, that
 23 Exhibit P-1886 be brought up, Registrar,
 24 please? Now this is a form Health Care
 25 Corporation of St. John's, entitled

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1 immunoperoxidase request form. There's some
 2 redaction occurred in this, in the form. The
 3 date it's completed is January 30th, I
 4 believe, 2003.
 5 DR. COOK:
 6 A. Um-hm.
 7 COFFEY, Q.C.:
 8 Q. And at the bottom, there's some handwriting
 9 there, "received January 31, 2003."
 10 DR. COOK:
 11 A. Right.
 12 COFFEY, Q.C.:
 13 Q. Whose handwriting is that, do you know?
 14 DR. COOK:
 15 A. That's mine.
 16 COFFEY, Q.C.:
 17 Q. Yours, so that little note that you received
 18 the form or received that date is yours.
 19 DR. COOK:
 20 A. Um-hm.
 21 COFFEY, Q.C.:
 22 Q. PR equals negative, ER equals negative.
 23 DR. COOK:
 24 A. That's correct.
 25 COFFEY, Q.C.:

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1 Q. Would that be your handwriting?
 2 DR. COOK:
 3 A. That's my handwriting.
 4 COFFEY, Q.C.:
 5 Q. And up here on the top right-hand side, this
 6 handwriting here, whose is that?
 7 DR. COOK:
 8 A. That's mine.
 9 COFFEY, Q.C.:
 10 Q. Yours, okay. That's in the first block,
 11 Commissioner, for the record. And written up
 12 here is "ER/PR, controls are okay. Checked by
 13 Dr. Chittal."
 14 DR. COOK:
 15 A. Right.
 16 COFFEY, Q.C.:
 17 Q. Is that your handwriting?
 18 DR. COOK:
 19 A. No.
 20 COFFEY, Q.C.:
 21 Q. Okay, so could you just tell then--and I use
 22 this as an example, kind of circa January
 23 2003, how, for example, estrogen and
 24 progesterone receptors, which I take it is
 25 this area right here, on this form circled

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1 carcinoma.
 2 DR. COOK:
 3 A. Um-hm.
 4 COFFEY, Q.C.:
 5 Q. How this sort of form was used.
 6 DR. COOK:
 7 A. Well, the form is used, I mean, I would
 8 highlight what I would order, in terms of
 9 immunoperoxidase stains. What I wanted the
 10 site chief to do at the General Hospital, if
 11 for any reason that the external controls
 12 were--could not be sent over to the St.
 13 Clare's site, that before any of those batch
 14 tests are released that we would have a system
 15 in place where the external ER and PR controls
 16 would be reviewed and documented by a staff
 17 pathologist, just reenforcing what we had, in
 18 terms of documentation.
 19 COFFEY, Q.C.:
 20 Q. And so this handwriting up here, what did that
 21 signify to you when you received the form?
 22 DR. COOK:
 23 A. That signified that the external controls were
 24 reviewed, that they were satisfactory and the
 25 batch could be released.

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1 COFFEY, Q.C.:
 2 Q. Now here, Doctor, just to--so the Commissioner
 3 understands at least what the practice was in
 4 January of 2003 -
 5 THE COMMISSIONER:
 6 Q. The batch could be released meaning they could
 7 send them out from the Health Science or the
 8 batch could be released meaning they could be
 9 released to pathologists within St. Clare's?
 10 DR. COOK:
 11 A. They could be released to pathologists in St.
 12 Clare's and released to pathologists outside
 13 the General Hospital. So I wanted those
 14 controls to be reviewed and documented before
 15 anything is released outside of that General
 16 Hospital lab.
 17 THE COMMISSIONER:
 18 Q. So the doctor listed up here would be within
 19 the Health Science?
 20 DR. COOK:
 21 A. That's correct.
 22 THE COMMISSIONER:
 23 Q. Okay.
 24 COFFEY, Q.C.:
 25 Q. So this is obviously a preprinted form, I

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1 guess one can see that, I take it.
 2 DR. COOK:
 3 A. Yeah.
 4 COFFEY, Q.C.:
 5 Q. And in fact, the minutes we just looked at a
 6 moment ago of a meeting just in April of 2001
 7 had referred to the fact that there were new
 8 additions to the profile, so this form would
 9 be revised from time to time to add -
 10 DR. COOK:
 11 A. Yes, that's correct.
 12 COFFEY, Q.C.:
 13 Q. - the stains available, and so this is a
 14 breast cancer case. So you would have filled
 15 out the top part of this yourself with a
 16 surgical pathology number, the block number,
 17 you would specify the block. Your own name,
 18 as the pathologist, the diagnosis or DD -
 19 DR. COOK:
 20 A. Differential diagnosis.
 21 COFFEY, Q.C.:
 22 Q. - differential diagnosis, breast carcinoma.
 23 The date, January 28th '03, the name of the
 24 patient an the MCP number of the patient?
 25 DR. COOK:

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1 A. That's correct.
 2 COFFEY, Q.C.:
 3 Q. And then you would come down and for a breast
 4 cancer, under carcinoma, the stain you'd be
 5 looking for here, antibodies would be estrogen
 6 and progesterone receptors, and you'd just
 7 circle it?
 8 DR. COOK:
 9 A. That's correct.
 10 COFFEY, Q.C.:
 11 Q. Doctor, I take it then that that form, so
 12 filled out up to that point, would go off?
 13 You'd send it off with the block or the
 14 technologist at St. Clare's would find the
 15 block, take the form and -
 16 DR. COOK:
 17 A. Yes, I would fill it out and give it to our
 18 technologists, who would then find the block
 19 and forward the block and the requisition to
 20 the General Hospital.
 21 COFFEY, Q.C.:
 22 Q. Now Doctor, here, you've specified block 3C.
 23 What process would you go through to identify
 24 block 3C?
 25 DR. COOK:

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

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1 to see if there -
 2 COFFEY, Q.C.:
 3 Q. I'm sorry, what -
 4 DR. COOK:
 5 A. Breast tissue adjacent to the tumor.
 6 COFFEY, Q.C.:
 7 Q. That would be internal control?
 8 DR. COOK:
 9 A. I'm sorry, internal control tissue. Looking
 10 for how well the tumor is differentiated and
 11 overall histological preparation of the slide.
 12 COFFEY, Q.C.:
 13 Q. Now Doctor, you've indicated that it was in
 14 2000 that you came across an article or a
 15 reference in a text that brought to your
 16 attention the idea of utilizing an internal
 17 control for ER and PR analysis. Before you
 18 came across that article in 2000, would you
 19 have made any effort in picking out the blocks
 20 or, you know, the block for a patient to be
 21 looking for normal tissue?
 22 DR. COOK:
 23 A. Probably not. My emphasis would have been on
 24 the state of the tumor itself. I would have
 25 been placing a lot of emphasis on how well

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1 preserved the tissue is, looking for the
 2 histological features of, you know, tubular
 3 formation, mycotic activity, that sort of
 4 thing. So most of my emphasis would be on the
 5 histological characteristics of the tumor.
 6 COFFEY, Q.C.:
 7 Q. And then after becoming aware, I take it, of
 8 the desirability of utilizing an internal
 9 control, you would then have, from that point
 10 on -
 11 DR. COOK:
 12 A. Well, it would have changed my practice, I
 13 mean, to incorporate that.
 14 COFFEY, Q.C.:
 15 Q. Here, Doctor, so you send it off to the
 16 General Hospital. This is Ken Green, I take
 17 it?
 18 DR. COOK:
 19 A. That's correct.
 20 COFFEY, Q.C.:
 21 Q. The histotech, and the date completed January
 22 30, 2003. That signified, I take it, that Mr.
 23 Green had processed or prepared the slide?
 24 DR. COOK:
 25 A. Right.

| | |
|---|--|
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| <p>1 COFFEY, Q.C.:</p> <p>2 Q. And the date he had done so, he'd concluded it</p> <p>3 by January 30th, 2003.</p> <p>4 DR. COOK:</p> <p>5 A. Um-hm.</p> <p>6 COFFEY, Q.C.:</p> <p>7 Q. So it came back. You'd mark on it received</p> <p>8 and the date?</p> <p>9 DR. COOK:</p> <p>10 A. Yeah.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. January 31st, and the PR and ER, PR negative,</p> <p>13 ER negative, why would you have marked that on</p> <p>14 the requisition form, on the req request form?</p> <p>15 DR. COOK:</p> <p>16 A. Because when I'm transcribing or dictating</p> <p>17 into the system and I do get the report back,</p> <p>18 because sometimes the report may not come back</p> <p>19 until 24 or 48 hours, I would obviously forget</p> <p>20 the result that I transcribed into the system.</p> <p>21 So I would use that as a reminder to again</p> <p>22 verify the result that I recorded into the</p> <p>23 dictating system and compare those results</p> <p>24 that I've documented on the requisition. So</p> <p>25 as a safeguard.</p> | <p>1 having arrived, I believe, in 2002.</p> <p>2 DR. COOK:</p> <p>3 A. September of 2002.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Where was he stationed?</p> <p>6 DR. COOK:</p> <p>7 A. Previously in Dohar, Qatar.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. And within St. John's, he was located at which</p> <p>10 hospital?</p> <p>11 DR. COOK:</p> <p>12 A. At the General Hospital site.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. How did you become aware of his interest in</p> <p>15 immunohistochemistry?</p> <p>16 DR. COOK:</p> <p>17 A. Well, he previously practised pathology in</p> <p>18 St.--at the Grace Hospital in the mid 80s and</p> <p>19 at that time, he played a role in bringing in</p> <p>20 immunohistochemistry into the Grace Hospital.</p> <p>21 So he had an interest in immunohistochemistry.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. And you'd known that back in the 80s, I take</p> <p>24 it?</p> <p>25 DR. COOK:</p> |
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| <p>1 COFFEY, Q.C.:</p> <p>2 Q. Doctor, in that regard, I take it here,</p> <p>3 because it says negative and negative, in your</p> <p>4 world at the time, January 2003, what did that</p> <p>5 mean about percentages?</p> <p>6 DR. COOK:</p> <p>7 A. There was no percentage, absolutely negative.</p> <p>8 COFFEY, Q.C.:</p> <p>9 Q. That would be zero, zero then?</p> <p>10 DR. COOK:</p> <p>11 A. Yeah.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. If in a form that say there was an ER and PR</p> <p>14 were positive, would you also--you'd note the</p> <p>15 fact that it was positive?</p> <p>16 DR. COOK:</p> <p>17 A. Um-hm.</p> <p>18 COFFEY, Q.C.:</p> <p>19 Q. Would you also note on this form the</p> <p>20 percentage?</p> <p>21 DR. COOK:</p> <p>22 A. I would.</p> <p>23 COFFEY, Q.C.:</p> <p>24 Q. If we could, please, Exhibit P-0113, please?</p> <p>25 Now Doctor, you've referred to Dr. Ejeckam</p> | <p>1 A. I would have known that when I was resident.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. Yes, okay. Go ahead. I'm sorry, go ahead.</p> <p>4 DR. COOK:</p> <p>5 A. So basically, I was looking for someone to</p> <p>6 take a leading role in immunohistochemistry</p> <p>7 and also to take a leading role in other</p> <p>8 aspects of pathology as well, and -</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Such as?</p> <p>11 DR. COOK:</p> <p>12 A. Sitting on various committees.</p> <p>13 COFFEY, Q.C.:</p> <p>14 Q. And what types of committees, do you recall in</p> <p>15 particular?</p> <p>16 DR. COOK:</p> <p>17 A. There was a surgical pathology review</p> <p>18 committee that I was interested in having an</p> <p>19 experienced pathologist sit on and take the</p> <p>20 lead role in.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. And where had your interest in that--when had</p> <p>23 that first arisen, Doctor?</p> <p>24 DR. COOK:</p> <p>25 A. Well, that was first arisen while I was acting</p> |

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1 clinical chief back in '99 and near the end of
 2 that term, and that arose mainly because prior
 3 to '95/96, each of our hospitals were separate
 4 institutions and each had their own separate
 5 committees. After '95/96, there was a
 6 complete reorganization of the health care
 7 system and some of those committees needed to
 8 be reactivated. One of the committees that
 9 was fairly active in each of the hospitals was
 10 a tissue audit committee. So I was looking -
 11 COFFEY, Q.C.:
 12 Q. And that was back, I take it, before the
 13 Health Care Corporation came into existence?
 14 DR. COOK:
 15 A. That's correct. These were in each of the
 16 hospitals prior to '95/96. So near the end of
 17 my term in 2000, I had set up a terms of
 18 reference for this committee and was looking
 19 for someone to take it over. At that time, I
 20 had a pathologist in mind who was willing to
 21 take on that committee, but like many times,
 22 things happen, that pathologist left the
 23 province to go to the mainland, and at that
 24 time, Dr. Haegert came on as clinical chief.
 25 So I asked Dr. Haegert would he pursue the

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1 surgical pathology review committee to try to
 2 set up an auditing process. That, for some
 3 reason, didn't happen and when I became
 4 clinical chief in 2002, I was looking at
 5 setting up a process where we would have an
 6 auditing committee in place, and Ejeckam came
 7 to mind because of his experience. So I asked
 8 him would he chair this committee.
 9 COFFEY, Q.C.:
 10 Q. Now Doctor, you took over as acting chief when
 11 in 2002?
 12 DR. COOK:
 13 A. Acting chief?
 14 COFFEY, Q.C.:
 15 Q. Yes.
 16 DR. COOK:
 17 A. In March of '02.
 18 COFFEY, Q.C.:
 19 Q. Okay, and Dr. Ejeckam arrived in the fall of
 20 2002?
 21 DR. COOK:
 22 A. He arrived in September of '02.
 23 COFFEY, Q.C.:
 24 Q. So the purpose of the surgical pathology
 25 review committee, I take it it was

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1 established?
 2 DR. COOK:
 3 A. It was established in '03.
 4 COFFEY, Q.C.:
 5 Q. It's purpose was what?
 6 DR. COOK:
 7 A. Well, the purpose was--one of the things that
 8 I was frustrated as clinical chief is that how
 9 were we, particularly in regards to division
 10 of anatomical pathology, were performing in
 11 regards to our reports. Were we providing the
 12 type of information that an oncologist needed
 13 to be able to act on their patient's treatment
 14 regimes? How were the reports, in terms of
 15 completeness? How, overall, did the
 16 clinicians appreciate the work being produced
 17 in terms of the quality of the work being
 18 produced, and at the same time, look--provide
 19 a mechanism whereby pathologists can also
 20 evaluate the work of clinicians, in terms of
 21 the type of information that would be sent
 22 down to them, how the various organs would be
 23 sent down, in terms of them, in terms of the
 24 state of the organs. So I wanted a committee
 25 that would have sort of have eyes and ears for

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1 the laboratory medicine program. But I wanted
 2 to go a little bit beyond that and just
 3 auditing, but identify any issues of concern
 4 outside of the tissue auditing process that
 5 clinicians would have with the division of
 6 anatomical pathology.
 7 When I approached Ejeckam regarding this,
 8 we talked quite a bit about quality assurance
 9 activities. Dr. Ejeckam was willing to take
 10 on this committee, provided it had a bit of
 11 teeth, and to give this committee some teeth,
 12 we both agreed the best way to do it would be
 13 to have the committee report directly to the
 14 Vice President Medical Services.
 15 COFFEY, Q.C.:
 16 Q. In this context, that would be Dr. Williams?
 17 DR. COOK:
 18 A. That would be Dr. Williams.
 19 COFFEY, Q.C.:
 20 Q. And did Dr. Williams agree with that?
 21 DR. COOK:
 22 A. He did.
 23 COFFEY, Q.C.:
 24 Q. And what's--up to that point, what sorts of
 25 quality assurance activities was the

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1 pathologist in the lab involved in at that
 2 time?
 3 DR. COOK:
 4 A. Well we were involved in proficiency testing
 5 with the College of American Pathology
 6 Performance Improvement Program, both in
 7 anatomical pathology and in cytology. We were
 8 involved in proficiency testing program with
 9 the American Society of Clinical Pathologists.
 10 At that time we were involved in the Mocan
 11 (phonetic) process with the Royal College of
 12 Physicians and Surgeons of Canada, whereby we
 13 had to document the number of hours, we
 14 attended CME activities, such as conferences,
 15 rounds, there had to be documentation of
 16 journals, documentation of education, teaching
 17 and research. There would be, again,
 18 documentation of proficiency testing program,
 19 such as the ASCP program. There would be a
 20 whole host of rounds which were quality
 21 rounds, such as lymphoma consensus rounds,
 22 slide review rounds, quality control rounds,
 23 medical pathology rounds, grand medical
 24 rounds, there would be rounds regarding tumor
 25 board rounds, chest board rounds, there would

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1 be rounds with our radiologists in terms of
 2 correlations of our breast pathology with our
 3 radiology reports, so there was a whole hose
 4 of rounds taking place, as well as the process
 5 of interdepartmental consultations which were
 6 documented and extradepartment reviews, such
 7 as reviews to such institutions as the Mayo
 8 Clinic, AFIP, and the BC Cancer Agency. So
 9 this is just--I don't know if I included
 10 everything in the quality assurance
 11 activities, but this is just an indication of
 12 the amount of quality assurance that was going
 13 on in the program.
 14 COFFEY, Q.C.:
 15 Q. How much, if any of that, related to
 16 immunohistochemistry?
 17 DR. COOK:
 18 A. A lot of it would have related to
 19 immunohistochemistry because we would have
 20 relied on immunohistochemistry to aid in the
 21 interpretation of our cases. For example, if
 22 we had a case that we discussed at quality
 23 control rounds and was reviewed by four or
 24 five pathologists and we couldn't come up with
 25 a consensus opinion, that case would be

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1 referred to a major centre, such as the Mayor
 2 Clinic or the Armed Forces Institute of
 3 Pathology in the United States or the B.C.
 4 Cancer Agency whereby all pertinent histology,
 5 including special stains as well as IHC
 6 stains, would be forwarded to that institution
 7 for a second opinion and review.
 8 COFFEY, Q.C.:
 9 Q. Was there any external proficiency testing
 10 going on?
 11 DR. COOK:
 12 A. There was external proficiency testing going
 13 on for pathology interpretation, but not
 14 specifically for immunohistochemistry.
 15 COFFEY, Q.C.:
 16 Q. So immunohistochemistry there was no external
 17 proficiency testing going on?
 18 DR. COOK:
 19 A. Not at that time.
 20 COFFEY, Q.C.:
 21 Q. When did that start?
 22 DR. COOK:
 23 A. That started, I believe around the fall of
 24 '05.
 25 COFFEY, Q.C.:

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1 Q. Now, Doctor, you spoke to Dr. Ejeckam about
 2 getting involved in this review committee,
 3 Surgical Pathology Review Committee, you spoke
 4 to Dr. Williams and he was supportive, I take
 5 it?
 6 DR. COOK:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. If we could, I'm just looking--we have here on
 10 the screen exhibit P-0113, page one. Doctor,
 11 this is a memo, the Commissioner has seen it
 12 before, to pathologists in the Health Sciences
 13 Centre, St. Clare's and out of town hospitals.
 14 It's from Dr. Ejeckam. Subject is
 15 immunohistochemical stains, it's dated April
 16 4, 2003 and it's copied to Barry Dyer and all
 17 technical staff on immunohistochemistry. And,
 18 Doctor, at the time in 2003, your office was
 19 where?
 20 DR. COOK:
 21 A. At St. Clare's.
 22 COFFEY, Q.C.:
 23 Q. The first notice that you had that there was a
 24 concern about immunohistochemistry stains,
 25 those particular antibodies and there are

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1 eight of them listed there, did you have any
 2 heads up that this was going to come to you?
 3 DR. COOK:
 4 A. No.
 5 COFFEY, Q.C.:
 6 Q. Doctor, prior to April 2003, like in the six
 7 or seven month period before that when Dr.
 8 Ejeckam first arrived, the first seven months
 9 after he arrived in St. John's, September of
 10 '02, were there--what, if any, circumstances
 11 were there in which pathologists from the St.
 12 Clare's and the General Hospital would end up
 13 meeting as a group?
 14 DR. COOK:
 15 A. Would end up meeting in a group at various
 16 discipline meetings, various interhospital
 17 rounds, there may be interaction at tumor
 18 board rounds for some pathologists from St.
 19 Clare's going over there, but usually at the
 20 level of discipline meetings and various
 21 rounds.
 22 COFFEY, Q.C.:
 23 Q. Now in this Dr. Ejeckam lists eight stains,
 24 two of them--the last two are ER and PR and he
 25 says "have remained unreliable, erratic and

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1 therefore unhelpful for diagnostic purposes."
 2 DR. COOK:
 3 A. Uh-hm.
 4 COFFEY, Q.C.:
 5 Q. Had you had any inkling at all that that was
 6 Dr. Ejeckam's view in the beginning of April?
 7 Like before that, was there any lead up to
 8 this at all that you were aware of?
 9 DR. COOK:
 10 A. There was no lead up to it, as I said before,
 11 Mr. Coffey, many times we would send out cases
 12 for review to major reference centres which
 13 include immunoperoxidase stains or paraffin
 14 blocks and these reports would come back
 15 without any comment about the quality of the
 16 stains.
 17 COFFEY, Q.C.:
 18 Q. So up until you received--you did receive this
 19 memo, I take it on April 4th or shortly
 20 thereafter, 2003?
 21 DR. COOK:
 22 A. I did.
 23 COFFEY, Q.C.:
 24 Q. Up to that point, no one had brought to your
 25 attention, at least the notion or idea that at

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1 least some stains, eight of them, these
 2 particular eight ones or some subset of the
 3 eight stains or any other stains, for that
 4 matter, were unreliable, erratic and
 5 unhelpful?
 6 DR. COOK:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. So if there was concern amongst--or one or
 10 more pathologists about it, no one had voiced
 11 it to you?
 12 DR. COOK:
 13 A. That's correct.
 14 COFFEY, Q.C.:
 15 Q. Having received this, Doctor, what, if
 16 anything, did you do?
 17 DR. COOK:
 18 A. Well I was going to phone Dr. Ejeckam, I was a
 19 little bit irritated that I had received this
 20 memo without any consultations prior to that,
 21 but I looked at this at the time as a quality
 22 assurance activity. Here was somebody that I
 23 had put in place to oversee the IHC and had
 24 taken steps to stop the staining and was
 25 acting as a circuit breaker in the system.

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1 So, in many respects I got a comfort level out
 2 of this in that now I had somebody overseeing
 3 and monitoring the IHC.
 4 COFFEY, Q.C.:
 5 Q. Which means, I take it your answer then,
 6 though, you didn't actually contact Dr.
 7 Ejeckam about it?
 8 DR. COOK:
 9 A. No, I gave him the ball and let him run with
 10 it.
 11 COFFEY, Q.C.:
 12 Q. Did you speak to anyone else about it?
 13 DR. COOK:
 14 A. I did speak to Dr. Desmond Robb in a telephone
 15 conversation concerning another issue and I
 16 did bring up the issue of Ejeckam's letter.
 17 Dr. Robb is a discipline chair with our
 18 university program and expressed to him any
 19 concerns that he had with the stains
 20 previously.
 21 COFFEY, Q.C.:
 22 Q. I'm sorry, what?
 23 DR. COOK:
 24 A. And expressed--and asked him if there was any
 25 concerns that he had with the previous

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1 staining.
 2 COFFEY, Q.C.:
 3 Q. And what was Dr. Robb's response?
 4 DR. COOK:
 5 A. No. Now thinking back at this time, Mr.
 6 Coffey, I was also thinking back to any issues
 7 or trying to think of any issue that had come
 8 up at tumor boards and also an issue that had
 9 taken place with the Cleveland Medical Clinic
 10 back in around 2000, 2001.
 11 COFFEY, Q.C.:
 12 Q. I'm sorry, I didn't hear the last part.
 13 DR. COOK:
 14 A. The Cleveland Medical Clinic.
 15 COFFEY, Q.C.:
 16 Q. Oh yes, okay, and what happened in respect to
 17 the Cleveland Medical Clinic?
 18 DR. COOK:
 19 A. Well back in 2000, 2001, we had a shortage of
 20 oncologists here in the province and as a
 21 result of that, our patients were sent out for
 22 treatment at the Cleveland Medical Clinic.
 23 Along with these patients there was a review
 24 of all histology at that time. Quite a number
 25 of these patients were breast cancer patients,

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1 so when they went to the Cleveland Medical
 2 Clinic, they--all histology concerning the
 3 cancer patients was reviewed by the Cleveland
 4 Medical pathologists and this included review
 5 of all H&E slides and if there was any
 6 receptor staining at that time, they would be
 7 reviewed as well.
 8 COFFEY, Q.C.:
 9 Q. What, if anything, did that have to do with
 10 the memo in April of -
 11 DR. COOK:
 12 A. Well it gave me a certain comfort level and at
 13 that time, 2000, 2001, that served as a
 14 quality assurance activity and there was
 15 nothing that came out of that review.
 16 COFFEY, Q.C.:
 17 Q. Do you know how many such patients had their
 18 slides sent to Cleveland?
 19 DR. COOK:
 20 A. I believe something around the order of 30 or
 21 33 cases.
 22 COFFEY, Q.C.:
 23 Q. And would that be from what, what location?
 24 DR. COOK:
 25 A. Throughout Newfoundland.

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1 COFFEY, Q.C.:
 2 Q. Do you know if the ER/PR slides went?
 3 DR. COOK:
 4 A. There were ER and PR slides, I understand.
 5 COFFEY, Q.C.:
 6 Q. The H&E slides?
 7 DR. COOK:
 8 A. And H&E slides, yes.
 9 COFFEY, Q.C.:
 10 Q. Have you checked that since?
 11 DR. COOK:
 12 A. I have not, but that was the information that
 13 I knew at that particular time.
 14 COFFEY, Q.C.:
 15 Q. So, Doctor, you were clinical chief on April--
 16 in April of 2003 for the Health Care
 17 Corporation of St. John's, did you
 18 communicate--well you talked to Dr. Robb -
 19 DR. COOK:
 20 A. Uh-hm.
 21 COFFEY, Q.C.:
 22 Q. And I gather only Dr. Robb about this?
 23 DR. COOK:
 24 A. At this particular time.
 25 COFFEY, Q.C.:

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1 Q. Subsequently, when did you next speak to
 2 anybody about this?
 3 DR. COOK:
 4 A. I spoke to Dr. Ejeckam in June of '03.
 5 COFFEY, Q.C.:
 6 Q. Okay, and I'll come to that in a moment.
 7 These other stains, I take it four of them are
 8 related to lymphomas?
 9 DR. COOK:
 10 A. Yes, the CD3, 5, 20 and 79A.
 11 COFFEY, Q.C.:
 12 Q. And CEA is used for what?
 13 DR. COOK:
 14 A. Well that's a marker that can be used to
 15 identify epithelial lesions, it's so--it's
 16 pretty nonspecific that it's hardly ever used
 17 anymore.
 18 COFFEY, Q.C.:
 19 Q. How about in 2003, was it being utilized at
 20 the time?
 21 DR. COOK:
 22 A. It may have been utilized as part of a panel
 23 in work up of a tumor.
 24 COFFEY, Q.C.:
 25 Q. And CK34?

| | |
|--|---|
| Page 237 | Page 239 |
| <p>1 DR. COOK:</p> <p>2 A. C34, that's used in prostate and it could be</p> <p>3 used in other epithelial tumors as well, as</p> <p>4 part of a panel.</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. So, Doctor, having been told as clinical chief</p> <p>7 by, I gather Dr. Ejeckam, you understood by</p> <p>8 this point, April of 2003, that Dr. Ejeckam</p> <p>9 had what kind of experience with IHC? You</p> <p>10 understood in the mid 80's and I appreciate</p> <p>11 the Grace, but how about afterward?</p> <p>12 DR. COOK:</p> <p>13 A. Well he was obviously a well read individual,</p> <p>14 but in terms of practical experience, he</p> <p>15 probably had more than any of us had at that</p> <p>16 time.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. And you understood that based upon what?</p> <p>19 DR. COOK:</p> <p>20 A. Based on a discussion with him that I had at</p> <p>21 the time of the surgical pathology review,</p> <p>22 setting up the Surgical Pathology Review</p> <p>23 Committee and his expressed interest in</p> <p>24 setting up the or overseeing the IHC.</p> <p>25 COFFEY, Q.C.:</p> | <p>1 Q. In between, like the period in the 1990's?</p> <p>2 DR. COOK:</p> <p>3 A. No, we didn't discuss that.</p> <p>4 COFFEY, Q.C.:</p> <p>5 Q. Doctor, who, other than pathologists set out</p> <p>6 here, Barry Dyer is down here at the bottom</p> <p>7 here, all technical staff, you would have</p> <p>8 understood that to be who?</p> <p>9 DR. COOK:</p> <p>10 A. These would have been the technologists</p> <p>11 themselves involved in the staining of IHC.</p> <p>12 COFFEY, Q.C.:</p> <p>13 Q. And the pathologists, well the HSC would be</p> <p>14 the General Hospital, St. Clare's and out of</p> <p>15 town hospitals, what, if anything, did you</p> <p>16 believe at the time about how widely</p> <p>17 distributed this was?</p> <p>18 DR. COOK:</p> <p>19 A. This would have been widely distributed</p> <p>20 throughout the province.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. At the time in April, 2003, did you understand</p> <p>23 or have any understanding about whether or not</p> <p>24 Dr. Williams would have seen this?</p> <p>25 DR. COOK:</p> |
| Page 238 | Page 240 |
| <p>1 Q. Had he spoken to you at that point about his</p> <p>2 experiences in Dohar?</p> <p>3 DR. COOK:</p> <p>4 A. At that point prior to that memo?</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Yes.</p> <p>7 DR. COOK:</p> <p>8 A. No.</p> <p>9 COFFEY, Q.C.:</p> <p>10 Q. Okay, so you didn't know that he had been</p> <p>11 involved with, like for more than a decade</p> <p>12 with the immunohistochemistry lab?</p> <p>13 DR. COOK:</p> <p>14 A. Not in Dohar, but since his involvement at</p> <p>15 Grace, yes, but not specifically in a Dohar</p> <p>16 situation.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. Because the Grace would be the mid 80's.</p> <p>19 DR. COOK:</p> <p>20 A. Yes.</p> <p>21 COFFEY, Q.C.:</p> <p>22 Q. This is now 2002, '03 roughly.</p> <p>23 DR. COOK:</p> <p>24 A. That's correct.</p> <p>25 COFFEY, Q.C.:</p> | <p>1 A. No, he wouldn't have.</p> <p>2 COFFEY, Q.C.:</p> <p>3 Q. So it would have gone as far as--as high as</p> <p>4 yourself, as clinical chief.</p> <p>5 DR. COOK:</p> <p>6 A. And myself and Dr. Desmond Robb.</p> <p>7 COFFEY, Q.C.:</p> <p>8 Q. And the assertion that those eight stains are</p> <p>9 unreliable, erratic and therefore unhelpful</p> <p>10 for diagnostic purposes, didn't involve any</p> <p>11 more inquiries by yourself as to what was</p> <p>12 meant by that? How extensive any such</p> <p>13 unreliability was, what it might all mean?</p> <p>14 DR. COOK:</p> <p>15 A. Well, up to that time, I mean, we looked at</p> <p>16 this as being in the world of</p> <p>17 immunohistochemistry. At that time,</p> <p>18 immunohistochemical stains can vary from day</p> <p>19 to day, can vary in intensity, can vary in</p> <p>20 staining characteristics. So, we looked at</p> <p>21 immunohistochemistry as a variable event.</p> <p>22 COFFEY, Q.C.:</p> <p>23 Q. And you would have attributed or did attribute</p> <p>24 such variability to what?</p> <p>25 DR. COOK:</p> |

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1 A. Well, the fact that you're dealing with a
 2 process that's very manual oriented, if it's
 3 about a 40 or 50 step process in the staining
 4 of immunohistochemistry, there's a lot of
 5 variables in regards to the preparation of the
 6 tissue, the processing, the stain itself, the
 7 interpretation. So, there was a lot of
 8 variability there in the production of that
 9 slide.
 10 COFFEY, Q.C.:
 11 Q. Did you ever ascertain what efforts were
 12 underway to find a solution?
 13 DR. COOK:
 14 A. Not at that time? That was, like I said, I
 15 left that to Doctor Ejeckam.
 16 COFFEY, Q.C.:
 17 Q. At the time, Doctor Ejeckam, in relation to
 18 immunohistochemistry had what, if any, titles?
 19 DR. COOK:
 20 A. He didn't have a title per se other than I
 21 looked at him as a resource person for
 22 immunohistochemistry.
 23 COFFEY, Q.C.:
 24 Q. What about other physicians, would they have
 25 had any--other pathologists, I mean, for

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1 example, whose Doctor Ejeckam's or if you're
 2 sitting in Grand Falls or Corner Brook or for
 3 that matter, in St. Clare's and you're not
 4 Doctor Cook -
 5 DR. COOK:
 6 A. Well, Doctor Ejeckam, I mean, what we did in
 7 those days is that pathologists who had an
 8 interest in particular aspects of pathology
 9 would take the lead in either issuing
 10 protocols or providing information for
 11 pathologists. We have, say, pathologists such
 12 as our new pathologists in breast pathology.
 13 Doctor Carter would come in, even though she
 14 wouldn't have any particular title, people
 15 would recognize her as being a resource person
 16 in breast pathology. Someone would see
 17 another pathologist as being a resource person
 18 in dermatology. So, that wouldn't be unusual.
 19 COFFEY, Q.C.:
 20 Q. And I appreciate you saw Doctor Ejeckam as a
 21 resource person in immunohistochemistry, but
 22 what, if any, reason would anyone else view
 23 him--why would anyone else view him in that
 24 regard?
 25 DR. COOK:

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1 A. Again, probably common knowledge around at
 2 that particular time. I mean, pathologists
 3 tend to talk to each other. So, I mean, it
 4 wouldn't have raised any concerns; here was a
 5 pathologist taking a lead in something, a
 6 pathologist showing an interest in something
 7 and acting on it.
 8 COFFEY, Q.C.:
 9 Q. Could Exhibit P-0904 please. This is an
 10 agenda for a surgical pathology review
 11 committee meeting scheduled for April 15,
 12 2003. It's copied to Doctor Williams and
 13 Doctor Cook, yourself. The agenda is called
 14 to order and business arising. And the Terms
 15 of Reference, paragraph 2.1, are spelled out
 16 here. And they include standardized reporting
 17 of pathology specimens; performing tissue
 18 audits on surgical specimens; forum for
 19 interesting and/or difficult cases; chaired by
 20 a pathologist; meet once every two months; and
 21 the committee would report directly to the
 22 vice-president of medical affairs and make
 23 recommendations if necessary. So, this
 24 agenda, would you have approved of this?
 25 DR. COOK:

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1 A. Yes.
 2 COFFEY, Q.C.:
 3 Q. Please, Exhibit P-1572. Thank you, Registrar.
 4 These are the minute of the meeting of April
 5 15, 2003 of the surgical pathology review
 6 committee. Doctor Ejeckam is present as
 7 chairman; Doctor Babcock was a surgeon?
 8 DR. COOK:
 9 A. No, he's a radiologist.
 10 COFFEY, Q.C.:
 11 Q. Radiologist, I apologize. Dr. Dawson?
 12 DR. COOK:
 13 A. Gyne oncologist, I believe.
 14 COFFEY, Q.C.:
 15 Q. Dr. M. Parai?
 16 DR. COOK:
 17 A. Pathologist.
 18 COFFEY, Q.C.:
 19 Q. Dr. J. Siddiqui?
 20 DR. COOK:
 21 A. Medical oncologist.
 22 COFFEY, Q.C.:
 23 Q. Dr. Thavanathan?
 24 DR. COOK:
 25 A. General surgeon.

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1 COFFEY, Q.C.:

2 Q. And Dr. Kwan?

3 DR. COOK:

4 A. Surgeon oncology.

5 COFFEY, Q.C.:

6 Q. This is noted, "call to order. The first

7 meeting of the surgical pathology review

8 committee was called to order by Dr. Ejeckam"

9 and under the paragraph 2.1 (a) standardized

10 reporting of pathology specimens. It notes

11 there "Dr. Ejeckam asked the members for input

12 for standardized reporting of pathology

13 specimens. After much discussion, it was

14 agreed that ER and PR receptors be done

15 automatically on breast surgery cases. Since

16 HER2/neu testing is expensive, only done when

17 requested. It was suggested it should be

18 performed automatically on patients with a

19 past history of carcinoma of the breast." Now

20 sir, the reference in the second sentence

21 there to "after much discussion, it was agreed

22 that ER and PR receptors be done automatically

23 on breast surgery cases." As of April 2003,

24 what was the situation in that regard?

25 DR. COOK:

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1 A. It was always done automatically on breast

2 cases.

3 COFFEY, Q.C.:

4 Q. So these minutes, at some point, would have

5 come to yourself?

6 DR. COOK:

7 A. Yes.

8 COFFEY, Q.C.:

9 Q. At some point later. Did you question that as

10 to why there would be an assertion--if it was

11 always being done, why would it be agreed that

12 ER/PR receptors be done automatically?

13 DR. COOK:

14 A. No one ever questioned it. I mean, you know,

15 our practice was, both at the General and

16 hospital sites that whenever you got a breast

17 cancer, one of the things that you do is order

18 an ER and PR, unless come--unless there was

19 discussion at that meeting that there was

20 concern by oncologists that this wasn't done.

21 COFFEY, Q.C.:

22 Q. At that--the notion that it, for some cases,

23 perhaps wasn't being done or automatically

24 ordered, had that come to your attention

25 before this?

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1 DR. COOK:

2 A. Not before that.

3 COFFEY, Q.C.:

4 Q. How about subsequently?

5 DR. COOK:

6 A. After, it did.

7 COFFEY, Q.C.:

8 Q. Okay. Could you tell the Commissioner about

9 that?

10 DR. COOK:

11 A. I received a phone call from one of our

12 oncologists letting me know that there were

13 some cases that ER and PRs were not done

14 automatically on breast cancers.

15 COFFEY, Q.C.:

16 Q. And what, if anything, did you do then?

17 DR. COOK:

18 A. Well, I sent out a memo to all pathologists, I

19 think that was some time in 2004, stating that

20 as a reminder that this should be done.

21 COFFEY, Q.C.:

22 Q. Doctor, here in the same April 15th minutes,

23 paragraph 3.1 under new business, "ER and PR

24 receptors. Dr. G. Ejeckam stated that ER and

25 PR receptors are not being performed for the

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1 next six weeks due to a technical problem. If

2 a solution cannot be found, these tests will

3 be sent outside St. John's. He stated it is

4 being considered to send one or two

5 technologists to Halifax or Toronto for

6 training." Doctor, the idea of--well, the

7 idea that it was ER and PR receptors are not

8 going to be performed for about six weeks,

9 that wouldn't have been--by the time these

10 minutes came along to you, that wouldn't be

11 new to you, because you would have gotten the

12 April 4th memo?

13 DR. COOK:

14 A. Right.

15 COFFEY, Q.C.:

16 Q. Okay. The idea though that Dr. Ejeckam states

17 here, he stated "it is being considered to

18 send one or two technologists to Halifax or

19 Toronto for training" in relation to ER and PR

20 receptors, which is what this paragraph anyway

21 is about, did--when you got these minutes,

22 well had that come to your attention by the

23 time you got these minutes?

24 DR. COOK:

25 A. I looked at that and I mean that's something

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1 that would come under the program director and
 2 a divisional manager.
 3 COFFEY, Q.C.:
 4 Q. Which would be who in this context?
 5 DR. COOK:
 6 A. Mr. Terry Gulliver and Mr. Barry Dyer, who
 7 was--Barry Dyer for the divisional manager for
 8 pathology.
 9 COFFEY, Q.C.:
 10 Q. So you saw that as their--to arrange such a
 11 thing, if necessary, would be their function?
 12 DR. COOK:
 13 A. If Dr. Ejeckam recommended that to be done,
 14 that would be under them.
 15 COFFEY, Q.C.:
 16 Q. Did you ever take that matter up with Mr.
 17 Gulliver or Mr. Dyer?
 18 DR. COOK:
 19 A. Not at that time, no.
 20 COFFEY, Q.C.:
 21 Q. At some point in time?
 22 DR. COOK:
 23 A. At some point in time I did, yeah.
 24 COFFEY, Q.C.:
 25 Q. When was that?

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1 DR. COOK:
 2 A. That was around June of '03, I believe.
 3 COFFEY, Q.C.:
 4 Q. So about two months after this?
 5 DR. COOK:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. Did you speak to Dr. Ejeckam about it at the
 9 time?
 10 DR. COOK:
 11 A. No, I did not.
 12 COFFEY, Q.C.:
 13 Q. Exhibit P-0113, please? This is page two is a
 14 memo of May 2nd, 2003, again to pathologists
 15 in the Health Sciences Centre, St. Clare's and
 16 out-of-town hospitals from Dr. Ejeckam. The
 17 subject here is ER/PR immunohistochemical
 18 stains, and on page four, his signature
 19 appears there. It's copied to the site chief
 20 in the Health Sciences Centre and St. Clare's.
 21 In this context, that would be yourself at St.
 22 Clare's?
 23 DR. COOK:
 24 A. Right.
 25 COFFEY, Q.C.:

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1 Q. Site chief, and the site chief at the Health
 2 Sciences Centre at the time would be Dr.
 3 Parai?
 4 DR. COOK:
 5 A. Parai.
 6 COFFEY, Q.C.:
 7 Q. S. Parai, and Barry Dyer and the technical
 8 staff on immunohistochemistry. Now sir, here
 9 he opens by saying "I'm glad to inform you
 10 that we have rectified the difficulties
 11 related to the immunostain of ER/PR.
 12 Therefore we can now resume regular requests
 13 for these antibody stains. I will, however,
 14 like to bring the following information to
 15 your attention" and then there are a number of
 16 paragraphs, the first of them dealing with or
 17 specifying or stating that "results of the
 18 immunostains may be affected by various types
 19 of problems with fixation, delayed, over and
 20 under and uneven tissue dehydration and tissue
 21 reprocessing." References to the necessity
 22 for the optimal fixation time to be 18 to 24
 23 hours in ten percent neutral buffered
 24 formalin, underlined, and it goes on at some
 25 length then, this memo does, including at

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1 paragraph three, referring to normal breast
 2 tissue as internal controls, the second level
 3 control. Doctor, when you got this memo, well
 4 other than being advised first of all--well,
 5 first of all, did you know this memo was
 6 coming? I'll ask you that.
 7 DR. COOK:
 8 A. No.
 9 COFFEY, Q.C.:
 10 Q. To be advised that they've rectified the
 11 difficulties related to the immunostain of
 12 ER/PR, did you ever make any inquiries as to
 13 what was rectified?
 14 DR. COOK:
 15 A. Not at that time, no.
 16 COFFEY, Q.C.:
 17 Q. When did you do so then?
 18 DR. COOK:
 19 A. I did so in June of '03.
 20 COFFEY, Q.C.:
 21 Q. Did you speak to anyone else about this when
 22 you first received it?
 23 DR. COOK:
 24 A. No.
 25 COFFEY, Q.C.:

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1 Q. The information contained in this memo
 2 relating to estrogen receptor and
 3 progesterone receptor testing generally, was
 4 any of this new to you at that time?
 5 DR. COOK:
 6 A. Overall covered most of my knowledge. There
 7 was information there on the cutoff point for
 8 the NIH which was interesting to note.
 9 COFFEY, Q.C.:
 10 Q. That's at paragraph five, I take it?
 11 DR. COOK:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Had you known of that before that time?
 15 DR. COOK:
 16 A. No, that was the first time I seen that type
 17 of reference, in particular, to the National
 18 Institute of Health.
 19 COFFEY, Q.C.:
 20 Q. The idea that, paragraph 7 for example, ER
 21 positive tumors -
 22 DR. COOK:
 23 A. Um-hm.
 24 COFFEY, Q.C.:
 25 Q. - and he lists four there.

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1 DR. COOK:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. Had you been aware of that before that time?
 5 DR. COOK:
 6 A. Yes.
 7 COFFEY, Q.C.:
 8 Q. And, in fact, is there another one that's
 9 missing from that?
 10 DR. COOK:
 11 A. There's two that's missing from that. There
 12 lobular and carcinomas in male breast.
 13 COFFEY, Q.C.:
 14 Q. Doctor, having received this memo, did you do
 15 anything? You didn't speak to anybody about
 16 it. Did you make any inquiries yourself of
 17 the literature or text?
 18 DR. COOK:
 19 A. No, I thought it was a good memo submitted for
 20 information purposes and that was sort of the
 21 thing I was looking at people to take the
 22 initiative in and forward that type of
 23 information to pathologists across the system.
 24 COFFEY, Q.C.:
 25 Q. Did you make any inquiries at the time--and

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1 you say pathologists across the system, would
 2 that be across the Health Care Corporation or
 3 across the Island and Labrador for that
 4 matter?
 5 DR. COOK:
 6 A. Well, I looked primarily at the Health Care
 7 Corporation.
 8 COFFEY, Q.C.:
 9 Q. Did you make any inquiries as to whether or
 10 not pathologists outside St. John's all
 11 received this?
 12 DR. COOK:
 13 A. No.
 14 COFFEY, Q.C.:
 15 Q. Whose job, if anyone's or responsibility, if
 16 anyone's, was it to ensure that if it's
 17 addressed to out of town pathologists and out
 18 of town hospitals that it actually went out to
 19 the pathologists and out of town hospitals?
 20 DR. COOK:
 21 A. I guess it would be our hospital mailing
 22 system to make sure that the memo was
 23 delivered to pathologists in those particular
 24 areas. I -
 25 COFFEY, Q.C.:

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1 Q. The contents--sorry, Doctor, go ahead.
 2 DR. COOK:
 3 A. I can't tell you the specific individual who'd
 4 be responsible for that in the mailing system,
 5 but that would be the area that I would
 6 suspect to have, you know, control and
 7 authority over it.
 8 COFFEY, Q.C.:
 9 Q. Doctor, in terms of the contents of the May 2,
 10 2003 memo, did you take any issue with any of
 11 the contents of it?
 12 DR. COOK:
 13 A. No, thought it was a good memo.
 14 COFFEY, Q.C.:
 15 Q. Now Doctor, at that point in time, May of 2003
 16 with the resumption of ER and PR staining in
 17 St. John's, what, if any, quality assurance
 18 measures were in place to ER and PR stains?
 19 DR. COOK:
 20 A. None in particular for ER and PR.
 21 COFFEY, Q.C.:
 22 Q. I take it whatever measures there were for IHC
 23 staining generally -
 24 DR. COOK:
 25 A. Yes, they would be looked, the ER and PR would

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1 be looked at as a total package. I mean, if
 2 there was a case that was referred for outside
 3 consultation that involved review of the
 4 slides, the ER and PR would be part of that
 5 overall package and review.
 6 COFFEY, Q.C.:
 7 Q. But a case with ER and PR slides does not fall
 8 into that group of cases referred outside
 9 then. No one else outside would ever come to
 10 look at the slides?
 11 DR. COOK:
 12 A. Could come look at those slides if there was a
 13 review within the department. If for whatever
 14 reason a pathologist wanted to review an
 15 original case, it could be reviewed by another
 16 pathologist within the same institution.
 17 COFFEY, Q.C.:
 18 Q. Doctor -
 19 COMMISSIONER:
 20 Q. Sorry, would you run that past me again. Are
 21 you saying that it would be normal for one
 22 pathologist to review another pathologist's--
 23 slides having been read by another pathologist
 24 or is it just in the context of that person's
 25 cancer having reoccurred and an effective new

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1 case comes along?
 2 DR. COOK:
 3 A. Commissioner, that would be the case. I mean,
 4 if there was a metastatic lesion, say, that
 5 was in a lung or the liver, the pathologists
 6 received that liver and they knew that the
 7 patient had a previous breast cancer, they
 8 would go back and review the original
 9 histology and do comparisons with the
 10 histology from the primary metastatic lesion.
 11 COMMISSIONER:
 12 Q. Is that for the purpose of determining whether
 13 it's really same cancer or another cancer or
 14 is it -
 15 DR. COOK:
 16 A. Oh, that's for the purpose of determining the
 17 correlation to make sure that what you have in
 18 the lung or the live arose from the breast.
 19 COMMISSIONER:
 20 Q. Yes, okay.
 21 COFFEY, Q.C.:
 22 Q. It wouldn't necessarily be looking back at the
 23 original ER/PR slides?
 24 DR. COOK:
 25 A. They would not necessarily, no.

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

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1 yourself as clinical chief and site chief of
 2 St. Clare's; Doctor S. Parai, the site chief;
 3 and Barry Dyer, manager of histopathology.
 4 Now, did you speak to anyone about this memo?
 5 DR. COOK:
 6 A. I spoke to Doctor Ejeckam.
 7 COFFEY, Q.C.:
 8 Q. And what, if anything, was said?
 9 DR. COOK:
 10 A. Well, when I went in to speak to him, I
 11 inquired as to, first of all, what do we do in
 12 terms of the rectification of the stain. We
 13 talked about the pH levels, the antibody
 14 concentrations, the incubation times, but that
 15 was only a small portion of the actual
 16 discussion. What came out of that discussion
 17 and what I read out of that discussion or that
 18 memo was the overall theme of that memo.
 19 There was a concern about the resources that
 20 we had available at the General Hospital and
 21 also issues regarding the management structure
 22 at that particular time. There was
 23 frustration in trying to get things done,
 24 according to Doctor Ejeckam, particularly with
 25 the managers.

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1 COFFEY, Q.C.:

2 Q. What managers?

3 DR. COOK:

4 A. I believe he mentioned Mr. Dyer and Mr.

5 Gulliver.

6 COFFEY, Q.C.:

7 Q. Did he elaborate on that?

8 DR. COOK:

9 A. Well, there was a specific example he gave to

10 me regarding trying to get some secretarial

11 work done regarding minutes for a surgical

12 pathology review committee, approached a

13 particular secretary and there was an issue

14 whether that should be done or not. That

15 particular secretary approached, I think, Mr.

16 Dyer who agreed that those minutes shouldn't

17 be typed. That was just an example of dealing

18 with frustrations in the system overall and he

19 related that particularly to his frustrations

20 and IHC.

21 COFFEY, Q.C.:

22 Q. So, I take it, the overall message, both in

23 the memo and in your meeting with him was that

24 he was not happy with the then current state

25 of affairs.

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1 DR. COOK:

2 A. That's correct.

3 COFFEY, Q.C.:

4 Q. Did you speak to anyone about that?

5 DR. COOK:

6 A. I did.

7 COFFEY, Q.C.:

8 Q. Who did you speak to?

9 DR. COOK:

10 A. I spoke to Mr. Terry Gulliver immediately

11 after a meeting.

12 COFFEY, Q.C.:

13 Q. Did you speak to anyone else?

14 DR. COOK:

15 A. No.

16 COFFEY, Q.C.:

17 Q. Okay. Why didn't you speak to anyone else?

18 DR. COOK:

19 A. Well, after speaking to Mr. Gulliver, I felt

20 that the measures would be taken to improve

21 the situation and move ahead. And I looked at

22 this as a go forward basis.

23 COFFEY, Q.C.:

24 Q. Did you speak to Doctor Williams about this?

25 DR. COOK:

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1 A. I did not, at the time. I looked at this as

2 an internal laboratory issue.

3 COFFEY, Q.C.:

4 Q. Why would that, even if it's an internal

5 laboratory issue, why wouldn't you bring it to

6 Doctor Williams' attention?

7 DR. COOK:

8 A. Well, I think Doctor Williams at the time, I

9 don't think he was available. I think he was

10 off sick leave at that particular time.

11 COFFEY, Q.C.:

12 Q. And he was back about 10 weeks later.

13 DR. COOK:

14 A. In September.

15 COFFEY, Q.C.:

16 Q. Yes. So, you didn't raise it with him then

17 either?

18 DR. COOK:

19 A. No.

20 COFFEY, Q.C.:

21 Q. Could you tell us please then what it was--

22 what you can recall of your conversation with

23 Mr. Gulliver?

24 DR. COOK:

25 A. Well, I said to Mr. Gulliver that Doctor

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1 Ejeckam is getting frustrated, there are

2 certain movements that he wants to or certain

3 initiatives that he wants to place in

4 immunohistochemistry. There was concern over

5 the actual location of IHC. There was concern

6 over the ability to centralize and specialize

7 technologists in that particular area. So,

8 Mr. Gulliver had the copies of those memos and

9 agreed and I agreed that he would work

10 together with Doctor Ejeckam to rectify the

11 situation.

12 COFFEY, Q.C.:

13 Q. Did you ever take this up with anybody

14 afterward?

15 DR. COOK:

16 A. No.

17 COFFEY, Q.C.:

18 Q. Why not?

19 DR. COOK:

20 A. Well, I felt they were moving ahead. I was

21 monitoring the situation. I knew eventually

22 that the IHC had been moved out of the general

23 histology lab into the hormonal assay lab,

24 into a separate area. Mr. Gulliver was making

25 moves to do as much as he can with

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1 specializing the text in that particular area
 2 in IHC. Later on that year Mr. Dyer informed
 3 me of the intent to purchase a new Ventana
 4 automated system for IHC. So, movement was
 5 being made to rectify what was outlined in
 6 that memo.
 7 COFFEY, Q.C.:
 8 Q. I appreciate that, but why wouldn't you have
 9 spoken to Doctor Ejeckam about it afterward?
 10 DR. COOK:
 11 A. Because I felt that an agreement or an
 12 understanding had been made with Mr. Gulliver
 13 to address his concerns.
 14 COMMISSIONER:
 15 Q. Mr. Coffey, wherever you can find a good spot,
 16 we'll break for the afternoon break.
 17 COFFEY, Q.C.:
 18 Q. Okay, thank you. Now, did you ever speak with
 19 Doctor Robb about this after the June 19 memo?
 20 DR. COOK:
 21 A. No, I didn't.
 22 COFFEY, Q.C.:
 23 Q. Doctor Parai?
 24 DR. COOK:
 25 A. No.

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1 COFFEY, Q.C.:
 2 Q. Mr. Dyer?
 3 DR. COOK:
 4 A. No.
 5 COFFEY, Q.C.:
 6 Q. By the time you received the June 19th, 2003
 7 memo did it ever cross your mind that there
 8 might be a concern about the validity of the
 9 test using these eight stains, the results,
 10 test results?
 11 DR. COOK:
 12 A. No, it did not.
 13 COFFEY, Q.C.:
 14 Q. Now with hindsight do you have any thoughts on
 15 that, as to why that was so?
 16 DR. COOK:
 17 A. Well, like I said before, when it came to the
 18 other tests, when you look at stains such as
 19 CD3, CD5, CD10, whatever, they're used in
 20 conjunction as part of a panel with other
 21 stains and you use those in conjunction with
 22 your routine H & E or histological
 23 examination. In terms of the lymphomas, we
 24 don't make a diagnosis of lymphomas alone
 25 based on the results of one or two

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1 immunoperoxidase stains, we use a battery of
 2 stains along with our flow cytometry and
 3 molecular genetics. So there was a variety of
 4 criteria that we look at to make a diagnosis
 5 of malignancy, not just based on one or two
 6 stains that may be erratic or unhelpful. We
 7 look at the histology, we look at
 8 histochemical stains and molecular. There's
 9 other parameters that we look at as opposed to
 10 just looking at one or two stains.
 11 COFFEY, Q.C.:
 12 Q. Now, that's true for those other six stains,
 13 but for ER and PR that's not true, is it?
 14 DR. COOK:
 15 A. Well, for ER and PR I thought back, as I
 16 previously said, to the Cleveland situation
 17 and what if anything was coming out from tumor
 18 boards.
 19 COFFEY, Q.C.:
 20 Q. So it did--you at the time thought of
 21 Cleveland, it crossed your mind at the time,
 22 didn't it, that there might be some question
 23 about the validity of what was going on here
 24 before Dr. Ejeckam inserted himself?
 25 DR. COOK:

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1 A. Well, I mean, if there had to be any issue
 2 with the ER and PR slides, I mean, my
 3 understanding or my hope was that it would
 4 have been picked up in that review.
 5 COFFEY, Q.C.:
 6 Q. And if it wasn't picked up in Cleveland, for
 7 whatever reason, you know, the idea that there
 8 might be something to pick up did cross your
 9 mind, otherwise you'd never have thought of
 10 Cleveland, would you?
 11 DR. COOK:
 12 A. No, I wouldn't say that, Mr. Coffey. You
 13 know, it--when I read that memo first, you
 14 know, I thought back to the Cleveland
 15 situation and was there anything that had come
 16 out of that situation that would have been
 17 cause for concern.
 18 COFFEY, Q.C.:
 19 Q. Why would you have thought Cleveland would
 20 have brought it to your attention at all?
 21 DR. COOK:
 22 A. Well, I mean, they're outside pathologists,
 23 they're reviewing our cases, I mean, you have
 24 a duty and an obligation if you do see a
 25 difference of opinion from a referring

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1 pathologist, that that would be recorded on
 2 the their report. And it is common courtesy
 3 to notify the original pathology of any change
 4 in interpretation of your histological slides
 5 or status.
 6 COMMISSIONER:
 7 Q. Sorry, I just wanted to clarify something
 8 regarding the Cleveland, which I just went
 9 back to my note and I didn't note down if you
 10 did say it. You said, I believe, that you
 11 sent 30 to 33 cases to Cleveland?
 12 DR. COOK:
 13 A. Approximately. That was my understanding,
 14 Commissioner, at that particular time.
 15 COMMISSIONER:
 16 Q. And were they all of the same nature or were
 17 they of varying types of cases?
 18 DR. COOK:
 19 A. Varying types of breast carcinomas.
 20 COMMISSIONER:
 21 Q. Okay.
 22 COFFEY, Q.C.:
 23 Q. Have you ever gone back to check what the
 24 status was of those Cleveland cases?
 25 DR. COOK:

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1 A. I have.
 2 COFFEY, Q.C.:
 3 Q. When was that and what did you find?
 4 DR. COOK:
 5 A. Well, what I found was there were 35 or 36
 6 cases there of which there were about, I
 7 believe, four or five ER and PR stains and
 8 they showed a good correlation, I believe with
 9 the exception of one.
 10 COFFEY, Q.C.:
 11 Q. So, wait now, so out of the 35 or so, 33, five
 12 of them involved ER and PR?
 13 DR. COOK:
 14 A. That's my understanding.
 15 COFFEY, Q.C.:
 16 Q. Okay, so there was only actually--so Cleveland
 17 only saw, would have only seen five ER slides
 18 and five PR slides?
 19 DR. COOK:
 20 A. That's correct.
 21 COFFEY, Q.C.:
 22 Q. And did you check those particular patients'
 23 files?
 24 DR. COOK:
 25 A. I didn't check them all. I checked the ones

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1 that were related to St. Clare's.
 2 COFFEY, Q.C.:
 3 Q. Okay. And how many of those were, I'm sorry,
 4 were related to St. Clare's?
 5 DR. COOK:
 6 A. There would have been maybe three or four, I
 7 understand.
 8 COFFEY, Q.C.:
 9 Q. Out of the five?
 10 DR. COOK:
 11 A. Out of the five.
 12 COFFEY, Q.C.:
 13 Q. And the ones at St. Clare's, what did you
 14 find?
 15 DR. COOK:
 16 A. I found good correlations with the results
 17 that we had submitted with Cleveland had
 18 found.
 19 COFFEY, Q.C.:
 20 Q. When you say good correlation, correlation of
 21 what?
 22 DR. COOK:
 23 A. That it was positive or negative.
 24 COFFEY, Q.C.:
 25 Q. So your understanding was Cleveland had redone

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1 the ER and redone the PR?
 2 DR. COOK:
 3 A. Oh, they didn't redo it, they looked at our
 4 slides.
 5 COFFEY, Q.C.:
 6 Q. Okay.
 7 DR. COOK:
 8 A. So the original slides were sent down and
 9 reviewed by the Cleveland pathologists, all
 10 the histology and all the ER and PR slides
 11 themselves.
 12 COFFEY, Q.C.:
 13 Q. Do you know if the control slides were sent?
 14 DR. COOK:
 15 A. I can't be sure on that. There may have been
 16 control slides sent with the case.
 17 COFFEY, Q.C.:
 18 Q. Now you say that there was correlation except
 19 for one case?
 20 DR. COOK:
 21 A. There was one case, I believe, that there was
 22 a variation in the percentage.
 23 COFFEY, Q.C.:
 24 Q. Do you recall how much the variation was?
 25 DR. COOK:

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1 A. The variation, I think we had reported 60
 2 percent where the variation was probably
 3 around 40 percent for the Cleveland
 4 pathologist.
 5 COFFEY, Q.C.:
 6 Q. So when they said 40, you said 60 or they said
 7 20 and you said 60?
 8 DR. COOK:
 9 A. We'd say 60, they said 40.
 10 COFFEY, Q.C.:
 11 Q. Oh, 40, okay. And so that's the one case that
 12 had the variance?
 13 DR. COOK:
 14 A. As far as I can remember.
 15 COFFEY, Q.C.:
 16 Q. When was it that you checked that, Doctor?
 17 DR. COOK:
 18 A. That particular recheck was around a few
 19 months ago.
 20 COFFEY, Q.C.:
 21 Q. Okay, so that's since the Commission of
 22 Inquiry was established?
 23 DR. COOK:
 24 A. Yeah.
 25 COFFEY, Q.C.:

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

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1 the other 28 wouldn't have had the slides
 2 sent?
 3 DR. COOK:
 4 A. The other 28 wouldn't have ER and PRs?
 5 COFFEY, Q.C.:
 6 Q. Yes.
 7 DR. COOK:
 8 A. They may be metastatic deposits or they may be
 9 cases where there would have been needle
 10 cores, that there wouldn't be ERs and PRs
 11 ordered on that.
 12 COFFEY, Q.C.:
 13 Q. Thank you, Commissioner.
 14 COMMISSIONER:
 15 Q. We'll take the afternoon break.
 16 (RECESS)
 17 COMMISSIONER:
 18 Q. Mr. Coffey.
 19 COFFEY, Q.C.:
 20 Q. Thank you, Commissioner. Dr. Cook, you've
 21 indicated that in the practice of pathology,
 22 certainly in dealing with stains, they will--
 23 it's not unusual to see them vary from day to
 24 day?
 25 DR. COOK:

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

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1 unhelpful for diagnostic purposes." Now, when
 2 you received this, of course, you would have
 3 been one of the utilizers of the slides, you
 4 were one of the people at whom this memo is
 5 directed?
 6 DR. COOK:
 7 A. That's correct.
 8 COFFEY, Q.C.:
 9 Q. Had you noticed before or up to April, 2003
 10 that the slides, IHC slides you were receiving
 11 were unreliable or erratic?
 12 DR. COOK:
 13 A. I mean, not specifically into regard to that,
 14 but overall in terms of immunohistochemistry,
 15 I mean, that's something that's not unusual in
 16 terms of variability and variability in
 17 staining from one case to another. I mean, in
 18 terms of general--in terms of general
 19 knowledge of pathology and discussion around
 20 immunohistochemical stains by pathologists.
 21 COFFEY, Q.C.:
 22 Q. And, sir, when we go to page 2 of the exhibit,
 23 which is the May 2nd, 2003 memo, Dr. Ejeckam
 24 opens by saying, "I'm glad to inform you that
 25 we have rectified the difficulties related to

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1 the immunostain of ER/PR."
 2 DR. COOK:
 3 A. Um-hm.
 4 COFFEY, Q.C.:
 5 Q. Did you notice any difference after May 2nd,
 6 2003 in the ER/PR slides?
 7 DR. COOK:
 8 A. I mean, to be honest with you, I didn't see
 9 that much of a difference.
 10 COFFEY, Q.C.:
 11 Q. So you never did take it up with Dr. Ejeckam,
 12 I take it, as to, well, what was all that
 13 about, I don't see a whole lot of difference,
 14 if any, and back in April you had stopped the
 15 ER and PR staining and now you're saying, now
 16 you, Dr. Ejeckam, are saying that you've
 17 rectified the difficulty?
 18 DR. COOK:
 19 A. Well, Mr. Coffey, beauty lies in the eyes of
 20 the beholder. I mean, there are some
 21 pathologists who would review one stain with a
 22 certain appreciation in quality and another
 23 pathologist who would look at the same stain
 24 and view it as something else.
 25 COFFEY, Q.C.:

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1 Q. In the sense of unsatisfactory, perhaps?
 2 DR. COOK:
 3 A. Well, one individual may think the stain is
 4 crisp and adequate, another individual may
 5 think it's under stained, another individual
 6 may think it's over stained.
 7 COFFEY, Q.C.:
 8 Q. I take it then that in terms of at least
 9 you're speaking for yourself, you didn't
 10 notice any particular difference at the time?
 11 DR. COOK:
 12 A. And I didn't notice any great difference in
 13 the stains.
 14 COFFEY, Q.C.:
 15 Q. Doctor, if we could, please, yes, this May
 16 2nd, 2003 memo ends with a comment, the
 17 sentence, "We are working on the remaining
 18 antibodies and hopefully all normal
 19 immunostains will resume soon." Did you ever
 20 make any inquiries about that?
 21 DR. COOK:
 22 A. No, I did not. I mean, as I said before, I
 23 gave Ejeckam the ball and let him run with it.
 24 Any time that we needed any extra stains or
 25 that were off line or whatever, we could

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1 easily refer these stains out to another
 2 institution.
 3 COFFEY, Q.C.:
 4 Q. Now, do you know if in 2003 any of the eight
 5 stains or patients who needed the results of
 6 any of those eight stains did have their
 7 samples sent out?
 8 DR. COOK:
 9 A. Not that I'm aware of.
 10 COFFEY, Q.C.:
 11 Q. Was there any difference other than the
 12 staining or did you even--or did you notice
 13 any difference in the staining at all?
 14 DR. COOK:
 15 A. I mean, as I said before, Mr. Coffey, I didn't
 16 see a great deal of difference in the stains.
 17 COFFEY, Q.C.:
 18 Q. Okay. Anything other than the stains, the
 19 fact that there was staining at all?
 20 DR. COOK:
 21 A. Well how would I -
 22 COFFEY, Q.C.:
 23 Q. For example, if, for example, if there was a
 24 problem, as it turns out, I gather, with
 25 hindsight now that perhaps some things were

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1 not staining and they should have been, then
 2 there's an absence of staining is what I'm
 3 getting at here.
 4 DR. COOK:
 5 A. Um-hm.
 6 COFFEY, Q.C.:
 7 Q. Doctor, I take it then that overall you didn't
 8 see any difference at all, staining or
 9 otherwise?
 10 DR. COOK:
 11 A. Personally, no.
 12 COFFEY, Q.C.:
 13 Q. Okay. Looking at page 5 of the exhibit, the
 14 June 19th, 2003 memo, the second page of it,
 15 the end of paragraph 3. On June 19th Dr.
 16 Ejeckam had written "To do less will simply
 17 become a gamble where you may win or lose.
 18 This obviously will spell disaster." I
 19 appreciate you took this up with Mr. Gulliver.
 20 DR. COOK:
 21 A. Um-hm.
 22 COFFEY, Q.C.:
 23 Q. But that sort of a statement by a pathologist
 24 whom you'd given, you'd given his head and let
 25 him run with it, that sort of an assertion in

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1 writing by him over his signature, this
 2 wasn't, didn't occasion you bringing this to
 3 Dr. Williams' attention, discussing it?
 4 DR. COOK:
 5 A. No, because I had made the discussion with Mr.
 6 Gulliver and was satisfied that Mr. Gulliver
 7 was going to address Dr. Ejeckam's concerns.
 8 COFFEY, Q.C.:
 9 Q. What, if anything, would have had to have
 10 happen in order for you to have discussed it
 11 with Dr. Williams?
 12 DR. COOK:
 13 A. Well, if Mr. Gulliver wasn't acting on it, if
 14 we had an indication that a patient had
 15 received a wrong result or there was evidence
 16 of an index case or conversion, I would have
 17 acted on it.
 18 COFFEY, Q.C.:
 19 Q. Now, Doctor, I take it that for an index case
 20 or involving a conversion, which I take it is
 21 someone who's had, in this context, perhaps, a
 22 negative result, ER/PR result first and then
 23 on retest a positive result, I take that
 24 requires that there at least be a retesting,
 25 at least one retest to give you a different

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1 result?
 2 DR. COOK:
 3 A. Could be a retest in the system, yes.
 4 COFFEY, Q.C.:
 5 Q. In the context at the time, in 2003, did it
 6 ever cross your mind that perhaps we should
 7 retest at least a couple of these to see what
 8 -
 9 DR. COOK:
 10 A. No, Mr. Coffey, I never had any indication or
 11 concerns from anyone. There was no concerns
 12 from those attending tumor boards. And again,
 13 I go back to the Cleveland situation, there's
 14 no concerns that came out of that. There was
 15 nothing there to indicate to go ahead and do a
 16 review.
 17 COFFEY, Q.C.:
 18 Q. You know, in terms of Cleveland at the time, I
 19 take it, that you had no idea in 2003 as to
 20 how many ER and PR tests actually went to
 21 Cleveland?
 22 DR. COOK:
 23 A. I mean -
 24 COFFEY, Q.C.:
 25 Q. You were thinking -

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1 DR. COOK:
 2 A. I was thinking at St. Clare's.
 3 COFFEY, Q.C.:
 4 Q. Yes. But you didn't know how many actually
 5 had gone to Cleveland, did you?
 6 DR. COOK:
 7 A. Well, province wide? No, not at that time in
 8 Cleveland, when I'm thinking back in 2003.
 9 COFFEY, Q.C.:
 10 Q. If we could, please, just a moment,
 11 Commissioner. If we could, please, Registrar,
 12 Exhibit P-1398? Doctor, do you recognize the
 13 handwriting here?
 14 DR. COOK:
 15 A. That's my handwriting.
 16 COFFEY, Q.C.:
 17 Q. Okay. It says "Spoke to Dr. Ejeckam with
 18 Terry Gulliver morning of March 7th, 2006 re
 19 the hold on certain stains in 2003. I asked
 20 him," that would be you, "asked him," Dr.
 21 Ejeckam, "what he meant by erratic. Dr.
 22 Ejeckam reported that it meant some stains
 23 worked some days and didn't work on others. I
 24 asked him if he should have recommended a
 25 review of stains at that time. He replied to

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1 me that it wasn't his place to initiate or
 2 recommend a review."
 3 DR. COOK:
 4 A. Um-hm.
 5 COFFEY, Q.C.:
 6 Q. Now, how did this come up on March 7th, 2006?
 7 DR. COOK:
 8 A. Well, again, you're thinking back, you know,
 9 you're looking at the current situation and
 10 you're thinking back in your mind is there
 11 anything you missed, is there anything you
 12 should have done at that particular time, you
 13 know, looking back at hindsight. And that was
 14 a question asked in that regard.
 15 COFFEY, Q.C.:
 16 Q. So why was it on March 7th, 2006, you went to
 17 Dr. Ejeckam to ask him about the idea of
 18 retesting in '03?
 19 DR. COOK:
 20 A. Well, we were in a--we had just gone through a
 21 major event, a major situation, and again -
 22 COFFEY, Q.C.:
 23 Q. Why did it take until March 7th, 2006 for you
 24 to raise that with him?
 25 DR. COOK:

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1 A. Well, because I had no reason to think, in
 2 2003, that we needed to go back to do a
 3 review. There was nothing in 2003 -
 4 COFFEY, Q.C.:
 5 Q. I'm asking between May of 2005, which we're
 6 about to get to, and March 2006, why did it
 7 take ten months for you to ask Dr. Ejeckam
 8 that question?
 9 DR. COOK:
 10 A. Well, because I'm going through, in my mind,
 11 if there's something that we had missed,
 12 something that had indicated that we should
 13 have done a review earlier.
 14 COFFEY, Q.C.:
 15 Q. Now the idea that Dr. Ejeckam, you know, had
 16 been involved in a--use the word "erratic" in
 17 a memo in 2003, you would have been aware of
 18 that in the middle of 2005. That memo was
 19 kicking around -
 20 DR. COOK:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. - at that time, so I'm asking you why did it
 24 take, you know, nine or ten months for you to
 25 approach Dr. Ejeckam about this?

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1 DR. COOK:
 2 A. Well, because you have to look at the
 3 situation at the time and around when we're
 4 doing this review, we were going full blast,
 5 concentrating all our resources on the ER and
 6 PR. I mean, we certainly didn't have time to
 7 think about taking on another review or even
 8 contemplating it at that time.
 9 COFFEY, Q.C.:
 10 Q. So when he told you, on March 7th, 2006, that
 11 some stains worked some days and didn't work
 12 on others, that meant what to you? You
 13 understood what? That they literally did not
 14 work?
 15 DR. COOK:
 16 A. No, I mean, that again, it could be variation
 17 in the staining based on a highly manual
 18 technique.
 19 COFFEY, Q.C.:
 20 Q. Did you explore that with him?
 21 DR. COOK:
 22 A. No, I didn't.
 23 COFFEY, Q.C.:
 24 Q. And when you asked him should he have
 25 recommended a review of stains at that time,

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1 in '03, and he told you that it wasn't his
 2 place to initiate or recommend a review, did
 3 you speak to him about that? Take any issue
 4 with that?
 5 DR. COOK:
 6 A. Well, I thought if he knew something there,
 7 when he stopped it, and again he compared the
 8 new staining with the previous staining when
 9 he came in 2002, if he had thought that there
 10 was a reason to go back and do a review, I
 11 thought he would have--he should have made a
 12 recommendation.
 13 COFFEY, Q.C.:
 14 Q. So you thought, in 2006, March 2006, that Dr.
 15 Ejeckam, in 2003, should have recommended not
 16 only stopping the stains, restarting them, but
 17 also a review?
 18 DR. COOK:
 19 A. If he had knowledge that, you know, the stains
 20 were of significant calibre, the staining was
 21 of significant degree, had he had any
 22 indications or any concerns, I felt then that
 23 he should have made a recommendation, if there
 24 was any concerns regarding patient care.
 25 COFFEY, Q.C.:

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1 Q. At the time, having received the April 4th
 2 memo by early 2006, had it crossed your mind
 3 that perhaps, as the clinical chief, you
 4 should have taken it upon yourself?
 5 DR. COOK:
 6 A. As clinical chief, I would have acted on
 7 recommendations from individuals, highly
 8 trained individuals, such as Ejeckam. I
 9 certainly had no indication back in 2003 that
 10 we had any issues concerning patient care.
 11 COFFEY, Q.C.:
 12 Q. Well, what would have--what would you have had
 13 to have been told, in what sort of language
 14 would it have to have been expressed to you in
 15 2003 for you to have understood there was an
 16 issue of patient care?
 17 DR. COOK:
 18 A. If someone was able to demonstrate to me there
 19 was a change in the stain or a result that
 20 affected treatment outcome or a treatment
 21 regime in a patient, I would have begun an
 22 investigation.
 23 COFFEY, Q.C.:
 24 Q. I take it if somebody had actually done a
 25 retest and had a conversion?

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1 DR. COOK:
 2 A. If somebody had done a retest and had a
 3 conversion, then we would have started a
 4 process.
 5 COFFEY, Q.C.:
 6 Q. So absent that, absent such a situation,
 7 absent a conversion, is there any other
 8 situation in which you would have done a
 9 review?
 10 DR. COOK:
 11 A. If someone was able to demonstrate a trend,
 12 for instance, that we had a trend in
 13 overcalling a particular lesion or a trend in
 14 under calling, we would have certainly done a
 15 preliminary review.
 16 COFFEY, Q.C.:
 17 Q. That would require, of course, somebody to
 18 actually look at the statistics too, wouldn't
 19 it?
 20 DR. COOK:
 21 A. Not necessarily, somebody sees a trend in
 22 something, I mean, they get concerned about
 23 something, they'll go ahead and start
 24 reviewing cases.
 25 COFFEY, Q.C.:

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1 Q. Was there anyone keeping track of trends in
 2 2003, do you know?
 3 DR. COOK:
 4 A. In regards to what?
 5 COFFEY, Q.C.:
 6 Q. Well, you mentioned it as a trend. I'm just
 7 asking you. You said if someone saw a trend
 8 in the calling of particular--over calling or
 9 under calling certain types of lesions. Was
 10 there anyone actually keeping track of trends,
 11 do you know?
 12 DR. COOK:
 13 A. No, there wasn't.
 14 COFFEY, Q.C.:
 15 Q. Exhibit P-0907, please? Now Doctor, this is a
 16 memo of September 30th, 2000--I apologize,
 17 that's the wrong page. Actually, it's the
 18 page--it's the September 30, 2003 memo to Dr.
 19 Williams from Dr. Ejeckam, sending Dr.
 20 Williams a copy of the surgical pathology
 21 review committee meeting minutes and the
 22 second page of that are the minutes of
 23 committees meeting of September 23rd 2003 and
 24 in business arising, there's a reference to
 25 paragraph--in 2.1, estrogen and progesterone

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1 status. Dr. Ejeckam stated the technical
 2 problem with staining for ER and PR stains has
 3 been solved. Doctor, would a copy of this,
 4 these minutes have come to you?
 5 DR. COOK:
 6 A. Yeah.
 7 COFFEY, Q.C.:
 8 Q. And in reference to "the technical problem
 9 with staining for ER and PR stains has been
 10 solved," you would have read that?
 11 DR. COOK:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. What would you have understood by it?
 15 DR. COOK:
 16 A. Well, again, as I understood from talking to
 17 him in June of '03, there would be an issue
 18 regarding a number of things, at the
 19 analytical aspect of it, in terms of the pHs
 20 and incubation times of the staining
 21 procedure, that sort of thing.
 22 COFFEY, Q.C.:
 23 Q. Did you ask--this was this conversation you
 24 had in June of '03 with Dr. Ejeckam, did you
 25 ask Dr. Ejeckam what, if anything, that all

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1 meant, in the sense of titration, incubation
 2 times and stuff, what the possible effects
 3 could be if, for example, the titration was
 4 off?
 5 DR. COOK:
 6 A. No, I didn't.
 7 COFFEY, Q.C.:
 8 Q. The antigen retrieval time was off?
 9 DR. COOK:
 10 A. No.
 11 COFFEY, Q.C.:
 12 Q. What effect it could have on the result?
 13 DR. COOK:
 14 A. No, because I looked at the overall quality of
 15 the staining that I saw before his
 16 intervention and the staining after his
 17 intervention, and as I said before, I didn't
 18 see much difference in the stains.
 19 COFFEY, Q.C.:
 20 Q. Doctor, did you have any understanding, in
 21 2003, that there was a possibility that one or
 22 more of those things, alone or in combination,
 23 could result in there being no staining when
 24 there should have been some staining?
 25 DR. COOK:

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1 A. Not in 2003.
 2 COFFEY, Q.C.:
 3 Q. In 2003, did you make any efforts, do any
 4 research yourself in relation to
 5 immunohistochemistry?
 6 DR. COOK:
 7 A. Nothing more than my standard knowledge, no.
 8 COFFEY, Q.C.:
 9 Q. Now Doctor, you've referred to the fact that
 10 in 2000, you'd come across a reference to
 11 utilizing internal controls for ER and PR
 12 testing.
 13 DR. COOK:
 14 A. Um-hm.
 15 COFFEY, Q.C.:
 16 Q. Why had you--was that just by chance you came
 17 across that?
 18 DR. COOK:
 19 A. Yeah, I mean it would have been an article in
 20 a text book I believe that, I mean, I may have
 21 been reading up on something or other, or it
 22 could have been at my office just doing some
 23 general reading.
 24 COFFEY, Q.C.:
 25 Q. Do you recall--why is it you recall it was

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1 2000?
 2 DR. COOK:
 3 A. It was roughly, I remember, the time that we
 4 were closing the Grace and doing the move that
 5 I remember a lot of things going on at that
 6 time regarding the close of the Grace and
 7 reading that particular article.
 8 COFFEY, Q.C.:
 9 Q. Why--I mean, you must read--in your job, you
 10 must read an awful lot of articles.
 11 DR. COOK:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Is there any particular reason that that, the
 15 year, and you associate it with the closing of
 16 the Grace and the time frame, why that stands
 17 out?
 18 DR. COOK:
 19 A. No, just the way that I remember reading that
 20 particular article and concentrating more on
 21 internal controls and that was about the same
 22 year that we were making the big move at the
 23 Grace.
 24 COFFEY, Q.C.:
 25 Q. Was there any discussion between yourself and

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1 other pathologists about internal controls?
 2 DR. COOK:
 3 A. No.
 4 COFFEY, Q.C.:
 5 Q. The June 19th memo does refer to--in 2003,
 6 does refer to the idea of litigation, correct?
 7 DR. COOK:
 8 A. That's correct.
 9 COFFEY, Q.C.:
 10 Q. Litigation in this context would certainly
 11 involve aspects of patient care, wouldn't it?
 12 DR. COOK:
 13 A. That's correct.
 14 COFFEY, Q.C.:
 15 Q. So Dr. Ejeckam's June 19th, 2003 memo
 16 certainly raised issues of--or related to
 17 patient care potentially?
 18 DR. COOK:
 19 A. That could happen on down the road if you
 20 didn't make improvements now, making now means
 21 2003.
 22 COFFEY, Q.C.:
 23 Q. And in the context, because there had been
 24 changes you had understood between April and
 25 June -

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1 DR. COOK:
 2 A. Um-hm.
 3 COFFEY, Q.C.:
 4 Q. - of '03, you'd understood that, so I take it
 5 the idea that potentially patient care might
 6 have been at risk before April, it didn't
 7 occur to you?
 8 DR. COOK:
 9 A. No. Again, I get back to what I saw as the
 10 quality of the stains before April and after
 11 April.
 12 COFFEY, Q.C.:
 13 Q. If we could, please, Exhibit P-1913? This is
 14 a site chiefs and divisional managers minutes
 15 of a meeting of March 31st, 2004. Present are
 16 yourself, Dr. Parai, and Dr. Robb. If we
 17 could, please, looking at paragraph four, new
 18 business, on page two of the exhibit, under
 19 "4.2. New Technology. The immunoperoxidase
 20 stainer appears to be working generally well.
 21 However, there continues to be some problems
 22 with estrogen and progesterone receptors," and
 23 you've signed these particular minutes.
 24 DR. COOK:
 25 A. Um-hm.

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1 COFFEY, Q.C.:
 2 Q. As the clinical chief. Do you recall what the
 3 problems were in March of 2004 that continue
 4 with estrogen and progesterone receptors?
 5 DR. COOK:
 6 A. Well, the only thing I could recollect was at
 7 the time, we were bringing in a new Ventana
 8 system and speaking to Dr. Robb, there was
 9 validation of the Ventana system by our
 10 technical people and there seemed to be some
 11 issues with the validation process with
 12 estrogen and progesterone receptors and that
 13 they would be corrected in a week's time or a
 14 few days.
 15 COFFEY, Q.C.:
 16 Q. Did you ever follow up on that?
 17 DR. COOK:
 18 A. No, I didn't. I just looked at that as a
 19 validation process.
 20 COFFEY, Q.C.:
 21 Q. So Doctor, I take it, what would the point be
 22 of bringing it to your attention if you were
 23 never going to follow up on it?
 24 DR. COOK:
 25 A. Well, it's something that I would have asked

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1 Dr. Parai and Dr. Robb is "how well is the new
 2 Ventana system working?" and "when can we
 3 expect to get it up online?"
 4 COFFEY, Q.C.:
 5 Q. Yes, and you're told about some problems,
 6 continue to be some problems with estrogen and
 7 progesterone receptors.
 8 DR. COOK:
 9 A. Yeah.
 10 COFFEY, Q.C.:
 11 Q. I take it, was there any system in place for
 12 this to kind of come around again to be
 13 brought to your attention for you to make
 14 inquiries further about it?
 15 DR. COOK:
 16 A. No, I mean, that the issue of the equipment
 17 coming on line and the validation would be in
 18 the hands of the technical aspect of the
 19 program.
 20 COFFEY, Q.C.:
 21 Q. Who was supposed to be doing the validation at
 22 this point?
 23 DR. COOK:
 24 A. That would be Mr. Gulliver and Mr. Dyer.
 25 COFFEY, Q.C.:

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1 Q. They would be doing a validation of ER and PR
 2 stains?
 3 DR. COOK:
 4 A. Well, all the stains with the Ventana system.
 5 COFFEY, Q.C.:
 6 Q. So what was it they were supposed to be doing
 7 with that?
 8 DR. COOK:
 9 A. Well, if you have a negative ER and PR stain
 10 and you run it through the Ventana system, it
 11 should come out negative under the new system.
 12 A known negative being run through should come
 13 out negative. A known positive that's run
 14 through should come out positive.
 15 COFFEY, Q.C.:
 16 Q. And that was being evaluated, you understood,
 17 by the technologists?
 18 DR. COOK:
 19 A. Yes, that's correct.
 20 COFFEY, Q.C.:
 21 Q. So what was your understanding about
 22 technologists were to do what? Were they
 23 involved in the controls at all?
 24 DR. COOK:
 25 A. They would be involved in taking a positive

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1 control and running it through the machine and
 2 make sure we get a positive result.
 3 COFFEY, Q.C.:
 4 Q. How about reading the controls?
 5 DR. COOK:
 6 A. The reading of the controls would be done by
 7 the pathologists.
 8 COFFEY, Q.C.:
 9 Q. So at that point, at this point in time, March
 10 of 2004, who, if any, pathologist was
 11 responsible for IHC?
 12 DR. COOK:
 13 A. Well, that would have been--to oversee the IHC
 14 it still would be Dr. Ejeckam overseeing it.
 15 COFFEY, Q.C.:
 16 Q. And was there anything in writing at that
 17 point in time, in early 2004, to that effect?
 18 DR. COOK:
 19 A. No.
 20 THE COMMISSIONER:
 21 Q. I'm sorry, I wasn't sure I understood that,
 22 Dr. Cook. When the Ventana was being brought
 23 into operation and you were, in effect,
 24 testing it.
 25 DR. COOK:

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1 A. Yes, Commissioner.
 2 THE COMMISSIONER:
 3 Q. What I understood you to be saying is that
 4 part of the method of testing the Ventana
 5 would be to run known results, as it were,
 6 through the system. i.e. you would have a
 7 negative stain or a positive--something you
 8 knew would become negative or positive, if
 9 properly processed?
 10 DR. COOK:
 11 A. That's correct.
 12 THE COMMISSIONER:
 13 Q. Run it through the machine and then have it
 14 read. Were you saying that it was Mr.
 15 Gulliver and Mr. Dyer who would determine was
 16 it positive or negative or would Dr. Ejeckam
 17 being doing that?
 18 DR. COOK:
 19 A. It could be Dr. Ejeckam or any one of the
 20 pathologists that Mr. Dyer or Mr. Gulliver
 21 brought the slides to read.
 22 THE COMMISSIONER:
 23 Q. Okay. So they would run the process in the
 24 same way that the technicians, the
 25 technologists would normally run if either the

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1 DAKO or the Ventana system were normally--in
 2 normal operation, but when it came to the
 3 point of deciding whether or not the result
 4 was as anticipated, they would be expected to
 5 take that slide to a pathologist, Dr. Ejeckam
 6 or one of the other pathologists?
 7 DR. COOK:
 8 A. Yeah, they would take it to them and the
 9 pathologist would give an opinion on that side
 10 and that would be used by our technical
 11 people.
 12 THE COMMISSIONER:
 13 Q. Okay, thank you.
 14 COFFEY, Q.C.:
 15 Q. Doctor, here--the word used here is "there
 16 continues to be some problems", had there
 17 been--the reference to "continuous", when did
 18 these problems with the estrogen and
 19 progesterone receptors begun, this is March of
 20 '04.
 21 DR. COOK:
 22 A. Uh-hm.
 23 COFFEY, Q.C.:
 24 Q. When had they begun?
 25 DR. COOK:

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1 A. The problems that came to light were around
 2 May of '05.
 3 COFFEY, Q.C.:
 4 Q. I appreciate that, but this stated here and we
 5 just look at here, that 4.2, right there,
 6 "However, there continues to be some problems
 7 with estrogen and progesterone receptors."
 8 DR. COOK:
 9 A. Uh-hm.
 10 COFFEY, Q.C.:
 11 Q. The word "continuous" suggests that it had
 12 been going on, sort of forever, as it were or
 13 it had stopped at some point or begun at some
 14 point, continuous, do you recall?
 15 DR. COOK:
 16 A. My recollection of that, again, concerns the
 17 validation process that was going on. I mean,
 18 that's to the best of my knowledge.
 19 COFFEY, Q.C.:
 20 Q. So if we could please then, Exhibit P-1876
 21 please? These are these site chief's and
 22 divisional manager's minutes, April 25, 2001,
 23 business arising, paragraph two. "Quality
 24 control of immunoperoxidase staining.
 25 Generally the immunos appear to be very good,

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1 there appears to be some problems with the
 2 estrogen and progesterone receptors."
 3 DR. COOK:
 4 A. Uh-hm.
 5 COFFEY, Q.C.:
 6 Q. "The positive controls are checked daily by a
 7 pathologist; however, these need to be
 8 documented." So there's a reference here to
 9 "appears to be some problems with the estrogen
 10 and progesterone receptors, April, 2001."
 11 DR. COOK:
 12 A. Uh-hm.
 13 COFFEY, Q.C.:
 14 Q. If we can look, please, at Exhibit P-0113,
 15 page one. It's the April 4, 2003 memo from
 16 Dr. Ejeckam.
 17 DR. COOK:
 18 A. Uh-hm.
 19 COFFEY, Q.C.:
 20 Q. The ER and PR, amongst other stains, are
 21 described as having remained unreliable,
 22 erratic and therefore unhelpful for diagnostic
 23 purposes.
 24 DR. COOK:
 25 A. Uh-hm.

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1 COFFEY, Q.C.:
 2 Q. Did you ever have any understanding as to how
 3 long the remained was there?
 4 DR. COOK:
 5 A. No, Mr. Coffey.
 6 COFFEY, Q.C.:
 7 Q. Okay, and exhibit P-1913, March 31st, 2004,
 8 paragraph 4.2. "The immunoperoxidase stain
 9 appears to be working generally well, however
 10 there continues to be some problems with
 11 estrogen and progesterone receptors."
 12 DR. COOK:
 13 A. Uh-hm.
 14 COFFEY, Q.C.:
 15 Q. So in '01, the spring of '01 and the spring of
 16 '03, and now the spring of '04, there are
 17 references in the minutes to problems with ER
 18 and PR.
 19 DR. COOK:
 20 A. If we're talking about new technology, what I
 21 believe we were talking about at that time was
 22 the issue of validation.
 23 COFFEY, Q.C.:
 24 Q. Yes, and validation, there was something wrong
 25 with the new system or the old one?

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1 DR. COOK:
 2 A. I would interpret the new system.
 3 COFFEY, Q.C.:
 4 Q. Something wrong with the new system.
 5 DR. COOK:
 6 A. Right, they're into the process of validating
 7 it.
 8 COFFEY, Q.C.:
 9 Q. And if there was a problem with the new
 10 system, if indeed there was, you don't know
 11 whether that was so or not, and if they fixed
 12 it or not, you don't know?
 13 DR. COOK:
 14 A. No, I put my reliance on them. These are
 15 trained professional people to deal with--if
 16 there's a validity problem or whatever problem
 17 was with the technology, to deal with it.
 18 COFFEY, Q.C.:
 19 Q. And in this context, the "they" is Mr. Dyer
 20 and Mr. Gulliver in March of '04.
 21 DR. COOK:
 22 A. Yes, yes.
 23 COFFEY, Q.C.:
 24 Q. If we could please, Exhibit P-1393? This,
 25 Doctor, are the minutes of a meeting,

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1 September 1st, 2004 of a division of
 2 anatomical pathology, pathologist meeting,
 3 General Hospital site. Present are Drs.
 4 Fernandez, Robb, Ejeckam, M. Parai, Wadden,
 5 Pirzada, Chittal, Morris-Larkin, Fontaine and
 6 Chittal, Parai. And paragraph 3.6, "Business
 7 Arising" says, "It's HER2/neu, ER and PR
 8 immunostaining. Dr. D. Fontaine did mention
 9 that Dr. B. Carter would like to review all
 10 the new HER2/neu ER and PR staining before
 11 returning to the reporting pathologist. Some
 12 members of the division expressed that this is
 13 unnecessary and they will continue reporting
 14 their own cases." Doctor, I take it that by
 15 September 2004, Dr. Beverley Carter had joined
 16 the Health Care Corporation?
 17 DR. COOK:
 18 A. That's correct.
 19 COFFEY, Q.C.:
 20 Q. And in fact, she was located at what site?
 21 DR. COOK:
 22 A. At St. Clare's.
 23 COFFEY, Q.C.:
 24 Q. And her office was located where in relation
 25 to yours?

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|--|---|
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| <p>1 DR. COOK: 2 A. Next to mine. 3 COFFEY, Q.C.: 4 Q. Were you aware of this request by Dr. Carter? 5 DR. COOK: 6 A. I was aware that we discussed the situation of 7 maintaining her level of confidence and 8 competency in breast pathology. If she was 9 coming here, she would want to see as many 10 breast cases as possible. I can't remember 11 discussing the issue of ER and PR in 12 particular. 13 COFFEY, Q.C.: 14 Q. Did you ever become aware of this request and 15 the reaction that's recorded here to it? 16 DR. COOK: 17 A. I'm not aware of that, Mr. Coffey. 18 COFFEY, Q.C.: 19 Q. So you were aware of it before today, I take 20 it? Were you aware that this existed before 21 today, these minutes? 22 DR. COOK: 23 A. You mean today? 24 COFFEY, Q.C.: 25 Q. Yes.</p> | <p>1 Carter at the time back when she first came to 2 St. John's and had, you know, the office next 3 to yourself, and the topic got raised about, 4 well, she'd like to keep her skills sharp or 5 sharper by looking at more cases, okay, which 6 is I gather what you had just referred to. 7 DR. COOK: 8 A. Uh-hm. 9 COFFEY, Q.C.: 10 Q. At the time that happened, Doctor, what was 11 your understanding about her intention in that 12 regard? Was she going to report all these 13 cases or was she just going to look at the 14 slides? 15 DR. COOK: 16 A. Well they all had already been reported, there 17 was no need to go ahead and issue an addendum 18 report, it was basically to review the slides 19 and to keep her skill set intact, so it was--I 20 can't remember any discussion where she was 21 going to issue any addendum report or put her 22 signature to the existing reports. 23 COFFEY, Q.C.: 24 Q. And the idea, when she discussed it with you, 25 the idea that she might want to just examine</p> |
| Page 310 | Page 312 |
| <p>1 DR. COOK: 2 A. I'm aware of it now. 3 COFFEY, Q.C.: 4 Q. So when did you first become aware of this? 5 DR. COOK: 6 A. When I was reviewing the various documents in 7 preparation for the Commission of Inquiry. 8 COFFEY, Q.C.: 9 Q. Okay, so that's what I'm getting at, Doctor, 10 so in 2004 and '05 when the ER/PR matter, you 11 really got involved in it in 2005, it was only 12 after the Commission of Inquiry was 13 established that and in looking through the 14 documentation that any one ever or you noticed 15 that in '04, this matter had been raised? 16 DR. COOK: 17 A. That's right. 18 COFFEY, Q.C.: 19 Q. That Dr. Carter had requested this and no one, 20 you weren't aware of a request in that regard, 21 nor of the apparent rejection of it. 22 DR. COOK: 23 A. No, I was unaware of that. 24 COFFEY, Q.C.: 25 Q. Doctor, when you discussed the matter with Dr.</p> | <p>1 like larger groups of slides for her own 2 purposes, you know, to keep her skill set up 3 or sharp, did you have any problem with that? 4 DR. COOK: 5 A. No. 6 COFFEY, Q.C.: 7 Q. Did any other pathologist ever ask you to do 8 that? 9 DR. COOK: 10 A. I can't recollect anybody asking me to do 11 that. 12 COFFEY, Q.C.: 13 Q. Did you say now, looking at this, page three 14 of P-1393, as the clinical chief at the time, 15 I appreciate you've told us no one approached 16 you about it, or spoke to you about this, 17 about the expression of views by apparently 18 other pathologists, as the clinical chief at 19 the time, would you have had any concern about 20 Dr. Carter looking at such slides and just for 21 her own purposes? 22 DR. COOK: 23 A. No. 24 COFFEY, Q.C.: 25 Q. Would you understand any reluctance by the</p> |

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

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

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

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1 ever--this memo, did the issue ever come up
 2 again?
 3 DR. COOK:
 4 A. No.
 5 COFFEY, Q.C.:
 6 Q. Now, Doctor, the training of technologists in
 7 relation to IHC stains, whose responsibility
 8 was that during the tenure of yourself?
 9 DR. COOK:
 10 A. Well the training of technologists comes under
 11 the control of the program director and the
 12 divisional manager.
 13 COFFEY, Q.C.:
 14 Q. Okay, and if, for example, the HER2/neu stains
 15 or stain, okay, you recall you looked at a
 16 memo of April 2000 in that regard?
 17 DR. COOK:
 18 A. Uh-hm, yes.
 19 COFFEY, Q.C.:
 20 Q. When that stain was first utilized in St.
 21 John's in 2000, was there any training of
 22 technologists in '99 and 2000 for it?
 23 DR. COOK:
 24 A. What happened in '99 and 2000, that being a
 25 kit, they had to follow the instructions of

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1 the manufacturer to the "T".
 2 COFFEY, Q.C.:
 3 Q. I'm sorry, they had to what?
 4 DR. COOK:
 5 A. Follow the instructions of the manufacturer
 6 exactly as specified in the manufacturer's
 7 instructions.
 8 COFFEY, Q.C.:
 9 Q. Now in relation to estrogen receptors and
 10 progesterone receptors tests, what, if any,
 11 instructions were they to follow in doing an
 12 ER and PR stain? Where would you find the
 13 instructions for that?
 14 DR. COOK:
 15 A. Well they would have had information available
 16 in their lab that could be a manual or it
 17 could be some sort of documentation that they
 18 would have.
 19 COFFEY, Q.C.:
 20 Q. Did you know whether or not that they did have
 21 any?
 22 DR. COOK:
 23 A. I didn't go that far, I mean, that would be
 24 under the medical--the technical aspect, the
 25 program director and the divisional manager.

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1 COFFEY, Q.C.:
 2 Q. So the procedure, for example for processing
 3 an estrogen receptor stain, a particular
 4 estrogen receptor stain and a particular PR
 5 stain, the protocol that he followed--well
 6 first of all, whether or not there was a
 7 protocol, whose responsibility was it to
 8 ensure that there was a written protocol?
 9 DR. COOK:
 10 A. The program director.
 11 COFFEY, Q.C.:
 12 Q. And would the pathologist be at all involved
 13 in approving such a protocol?
 14 DR. COOK:
 15 A. Not in our system, no.
 16 COFFEY, Q.C.:
 17 Q. What, if at any point or when, if at any
 18 point, would pathologists get involved?
 19 DR. COOK:
 20 A. Pathologists would get involved in the
 21 interpretation of the slide, the issuing of a
 22 pathology report and the documentation of
 23 their signature to the pathology report.
 24 COFFEY, Q.C.:
 25 Q. Well with respect to the interpretation of the

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1 slide, I take it that if there was a problem
 2 in the slide preparation protocol or procedure
 3 or both, when would that become apparent to
 4 the pathologist?
 5 DR. COOK:
 6 A. If the pathologist identified a problem with
 7 the slide itself, if there were folding of the
 8 slide or folding of the tissue, bubbles in the
 9 tissue, stain that he felt it didn't work,
 10 then he or she has a choice of not signing
 11 that case out.
 12 COFFEY, Q.C.:
 13 Q. Okay, so you refuse to sign and then what
 14 happens?
 15 DR. COOK:
 16 A. Then you would notify the divisional manager
 17 of the problem with the stain or the quality
 18 of the slide.
 19 COFFEY, Q.C.:
 20 Q. And then what was to happen?
 21 DR. COOK:
 22 A. Well the divisional manager should go back and
 23 review his processes and protocols.
 24 COFFEY, Q.C.:
 25 Q. So there would be no role for the pathologist

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1 in that process at all, is that what you're
 2 telling us?
 3 DR. COOK:
 4 A. In the technical aspect, no.
 5 COFFEY, Q.C.:
 6 Q. How about, for example, the dilution
 7 procedures, the amount of dilutions, the
 8 amount of antigen retrieval heating time, all
 9 those--the intricate steps involved. Would a
 10 pathologist be involved in any of that?
 11 DR. COOK:
 12 A. Not normally.
 13 COFFEY, Q.C.:
 14 Q. I appreciate not normally, but in terms of
 15 optimizing it.
 16 DR. COOK:
 17 A. Optimizing, no, I mean, I would see that as a
 18 technical function.
 19 COFFEY, Q.C.:
 20 Q. So in St. John's, Newfoundland--well I'll just
 21 ask, has that ever changed? Has your view in
 22 that regard ever changed?
 23 DR. COOK:
 24 A. In terms of the proper optimization of the
 25 antibody, the incubation temperatures?

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1 COFFEY, Q.C.:

2 Q. And the involvement of a pathologist in same?

3 DR. COOK:

4 A. Well it has changed since our issue, our index

5 case but prior to that, no, I would have saw

6 that as a technical function.

7 COFFEY, Q.C.:

8 Q. So as the clinical chief of the day and the

9 site chief at St. Clare's going back to the

10 mid 90's, it was your understanding that in

11 getting the stain right, as it were, getting

12 the staining process right for IHC, was

13 entirely within the purview of the

14 technologist?

15 DR. COOK:

16 A. That's the way I look at it.

17 COFFEY, Q.C.:

18 Q. Do you know whether or not that was true at

19 other hospitals or other health authorities,

20 like outside of Newfoundland?

21 DR. COOK:

22 A. I don't know for sure, Mr. Coffey.

23 COFFEY, Q.C.:

24 Q. And why was Dr. Ejeckam involved in 2003?

25 DR. COOK:

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1 A. Dr. Ejeckam was involved in 2003 to be used as

2 a resource person if there were questions

3 about the staining, whether staining was too

4 intense or too light or whatever, that he

5 would be used as a go-between between the

6 pathologist and the technologist.

7 COFFEY, Q.C.:

8 Q. And his function as a go-between was what?

9 DR. COOK:

10 A. To act as liaison, to communicate concerns

11 with pathologists to our technical people.

12 And to express and to take an interest in the

13 end quality of the slide.

14 COFFEY, Q.C.:

15 Q. And I'm just trying to get some sense from

16 your perspective as the clinical chief and his

17 as the liaison person.

18 DR. COOK:

19 A. Uh-hm.

20 COFFEY, Q.C.:

21 Q. That your understanding of his role was that

22 he would be a go-between between the

23 technologist or technologists who were

24 actually doing the manipulation.

25 DR. COOK:

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1 A. Uh-hm

2 COFFEY, Q.C.:

3 Q. The heating, the dilution and whatever other

4 procedures are required, the liaison between

5 them doing that and other pathologists,

6 himself and others -

7 DR. COOK:

8 A. Yes.

9 COFFEY, Q.C.:

10 Q. And his role was what?

11 DR. COOK:

12 A. Again, I mean, if I had a concern with the

13 quality of the stain in terms of it being over

14 stained or under stained, I would pick up the

15 phone, get his opinion on a particular case,

16 send the slide over and see what would need to

17 be done, or get his opinion on whether the

18 staining was adequate or not.

19 COFFEY, Q.C.:

20 Q. And if it was inadequate in his view, what

21 then would happen?

22 DR. COOK:

23 A. Then he would go to the divisional manager or

24 could speak directly to the technologist.

25 COFFEY, Q.C.:

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1 Q. And your understanding was what, if any,

2 authority did Dr. Ejeckam have?

3 DR. COOK:

4 A. He didn't have the direct authority to make

5 the change, he would make a recommendation.

6 COFFEY, Q.C.:

7 Q. To?

8 DR. COOK:

9 A. To a divisional manager or to a technologist.

10 COFFEY, Q.C.:

11 Q. So that before Dr. Ejeckam arrived in

12 September of 2002, who, if anyone, was

13 performing that function after Dr. Khalifa

14 left?

15 DR. COOK:

16 A. No one directly but that control of the IHC

17 being part of the histology lab would follow

18 under the site chief.

19 COFFEY, Q.C.:

20 Q. Which would be Dr. Parai?

21 DR. COOK:

22 A. Yes.

23 COFFEY, Q.C.:

24 Q. In this context, since 2000 anyway or after

25 2000. So, you know, between 2000 and 2002

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1 when Dr. Ejeckam arrived, how much involvement
 2 did Dr. Parai have to your knowledge in the
 3 IHC end of things?
 4 DR. COOK:
 5 A. He wouldn't have the involvement at the
 6 technical end. Where his involvement would be
 7 would be looking at things such as turn-around
 8 times, which would be a big thing with the
 9 immunohistochemistry and making sure the
 10 slides are delivered properly to the
 11 pathologist.
 12 COFFEY, Q.C.:
 13 Q. The administrative end of it, but he didn't--
 14 he wasn't involved like--what was the
 15 difference between him and Dr. Ejeckam's
 16 involvement, that's what I'm trying to
 17 ascertain?
 18 DR. COOK:
 19 A. Yeah, well Dr. Ejeckam had a more active
 20 interest in immunohistochemistry, so he would
 21 have gone further with it than Dr. Parai in
 22 becoming more involved in the process.
 23 COFFEY, Q.C.:
 24 Q. And you've indicated that after Dr. Ejeckam
 25 showed up, if you had a concern about a

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1 particular slide or slides, you might send
 2 them over to him and ask his opinion of them?
 3 DR. COOK:
 4 A. Yes, I would do that.
 5 COFFEY, Q.C.:
 6 Q. Was there any one pathologist around before
 7 Dr. Ejeckam showed up who fulfilled or could
 8 fulfil the same role?
 9 DR. COOK:
 10 A. Not until there was Dr. Khalifa and prior to
 11 that, Dr. Chittal had the same interest in
 12 IHC.
 13 COFFEY, Q.C.:
 14 Q. So after Dr. Khalifa left in the late 90's,
 15 between then and Dr. Ejeckam, there was no
 16 one, there was no go-to pathologist, as it
 17 were, in IHC.
 18 DR. COOK:
 19 A. Except for the site chief. The site chief
 20 would assume that role.
 21 COFFEY, Q.C.:
 22 Q. And I appreciate Dr. Parai, Sushil Parai I
 23 take it would assume the role, but how much
 24 actual involvement compared to Dr. Ejeckam did
 25 Dr. Parai have? Again, I'm trying to get for

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1 the Commissioner some sense of what was going
 2 on?
 3 DR. COOK:
 4 A. He wouldn't have the same involvement, I mean,
 5 unless Dr. Parai had a special interest, he
 6 had additional training or he read around the
 7 subject, I mean, he wouldn't have the same
 8 degree of involvement as Dr. Ejeckam.
 9 THE COMMISSIONER:
 10 Q. So are you saying that while, because of Dr.
 11 Ejeckam's special interest in the subject, you
 12 might have, for example, consulted him
 13 regarding a particular slide you were
 14 concerned about, you would not likely do that
 15 with Dr. Parai, whereas if you had a question
 16 about whether you were getting the slides on
 17 time and that kind of thing, you would have
 18 gone to Dr. Parai?
 19 DR. COOK:
 20 A. Yeah, the more administrative function of it I
 21 would have gone to Dr. Parai; in regards to
 22 Dr. Ejeckam, I would have called him about,
 23 again the quality of the staining, whether
 24 something--is it normal to have this
 25 particular type of intensity stain in such and

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1 such a malignancy or if it's a stain being
 2 positive in certain condition, so I would have
 3 used him as a resource in that case, as
 4 opposed to Dr. Parai who would I would expect
 5 to have more of an administrative function.
 6 THE COMMISSIONER:
 7 Q. Okay.
 8 COFFEY, Q.C.:
 9 Q. Exhibit P-1868 please? And this is a letter
 10 of January 14th, 2000. It's from Dr. Sushil
 11 Parai to yourself, as the then acting clinical
 12 chief. And he concludes by saying, "I do
 13 hereby accept the appointment of permanent
 14 site chief of anatomical pathology to the
 15 General Hospital as of May 1, 2000."
 16 DR. COOK:
 17 A. Uh-hm.
 18 COFFEY, Q.C.:
 19 Q. So he was there then. Looking at page two of
 20 the exhibit, you've noted here "received
 21 February 8th, 2005"?
 22 DR. COOK:
 23 A. Uh-hm.
 24 COFFEY, Q.C.:
 25 Q. Or the letter itself is, I take it that's a

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1 typo probably, February 4, 2004 -
 2 DR. COOK:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. It's probably 2005 because if we look at the
 6 text, Dr. Parai notes, concludes "I wish to
 7 inform you that I do not wish to reapply for
 8 the renewal of the posted site chief General
 9 Hospital at the end of my term, 31st of March,
 10 2005."
 11 DR. COOK:
 12 A. Uh-hm.
 13 COFFEY, Q.C.:
 14 Q. So, Dr. Parai was the site chief between--at
 15 the General Hospital from May 2000 until March
 16 31st, 2005.
 17 DR. COOK:
 18 A. That's correct.
 19 COFFEY, Q.C.:
 20 Q. What was your understanding of then if,
 21 because his--the last several years of his
 22 role as site chief of the general hospital,
 23 overlap with Dr. Ejeckam's period from
 24 September 2002, really and I take it Dr.
 25 Ejeckam was there through the beginning of

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1 '06.
 2 DR. COOK:
 3 A. Yes.
 4 COFFEY, Q.C.:
 5 Q. So, the fall of '02, all of '03, all of '04
 6 and the beginning of '05, Dr. Parai was the
 7 site chief.
 8 DR. COOK:
 9 A. Uh-hm.
 10 COFFEY, Q.C.:
 11 Q. At the General Hospital. Dr. Ejeckam was the
 12 staff pathologist there with an interest in
 13 IHC.
 14 DR. COOK:
 15 A. Uh-hm.
 16 COFFEY, Q.C.:
 17 Q. Who then, from your perspective as clinical
 18 chief, was actually responsible in that
 19 overlapping period, September '02 to March of
 20 '05, who was responsible for the IHC lab, from
 21 a pathologist perspective?
 22 DR. COOK:
 23 A. Well that's difficult to say, who is
 24 responsible for the IHC lab comes under the
 25 program director in terms of the technical

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1 component of it, right. Now who is
 2 responsible for the overall interpretation of
 3 the slides, rests with the individual
 4 pathologist.
 5 COFFEY, Q.C.:
 6 Q. And what about in terms of the role that Dr.
 7 Parai, before Dr. Ejeckam showed up, the role
 8 that he had with the IHC lab and then Dr.
 9 Ejeckam's role -
 10 DR. COOK:
 11 A. Uh-hm.
 12 COFFEY, Q.C.:
 13 Q. Did you ever make any inquiries of those two
 14 gentlemen as to how they were interacting in
 15 relation to the IHC lab?
 16 DR. COOK:
 17 A. No, because those individuals are both
 18 professionals and I would make the assumption
 19 that they would come to a mutual agreement,
 20 that's what we do as professionals.
 21 COFFEY, Q.C.:
 22 Q. So, Doctor, then I take it then until or prior
 23 to May, 2005, that responsibility from your
 24 perspective for the staining and the IHC end
 25 of the lab was primarily the responsibility of

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1 the technologist?
 2 DR. COOK:
 3 A. The technical aspect, yes, right.
 4 COFFEY, Q.C.:
 5 Q. And the only aspect the pathologists were
 6 involved with was the interpretation of the
 7 slides?
 8 DR. COOK:
 9 A. They would take responsibility in signing out
 10 the case and putting their signature to the
 11 report.
 12 THE COMMISSIONER:
 13 Q. I'm sorry, when you say signing of the case,
 14 what exactly does that mean?
 15 DR. COOK:
 16 A. Commissioner, to sign out the case, your
 17 signature goes on the bottom of that report.
 18 THE COMMISSIONER:
 19 Q. But you said two things, signing of the case
 20 and doing a report, they're not different?
 21 DR. COOK:
 22 A. Same thing, I mean, you would, the pathologist
 23 would do up the report, dictate his report
 24 which include the results of IHC, make the
 25 interpretation and sign out the case.

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1 THE COMMISSIONER:
 2 Q. Meaning sign the report?
 3 DR. COOK:
 4 A. Sign out, yeah, that's what I mean, sign the
 5 report.
 6 THE COMMISSIONER:
 7 Q. Okay, thank you.
 8 COFFEY, Q.C.:
 9 Q. Doctor, who then was responsible for
 10 addressing any concerns about fixation of the
 11 tissue, the quality of a fixation of a tissue?
 12 Who is responsible for dealing with that or
 13 addressing any concerns in that regard? First
 14 of all, raising any concerns in that regard.
 15 DR. COOK:
 16 A. The individual pathologist.
 17 COFFEY, Q.C.:
 18 Q. And that would become apparent to the
 19 individual pathologist when in the process?
 20 DR. COOK:
 21 A. When they're looking under the microscope.
 22 COFFEY, Q.C.:
 23 Q. After the slide was prepared, I take it?
 24 DR. COOK:
 25 A. Yes.

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1 COFFEY, Q.C.:
 2 Q. And what, if anything, was the individual
 3 pathologist expected to do?
 4 DR. COOK:
 5 A. Well the individual pathologist would be
 6 responsible for handling his or her own
 7 grossing at that particular time and they
 8 would go back and look at their own procedure,
 9 make sure that the specimen was adequately
 10 sliced at the particular time, make sure that
 11 there was an adequate amount of formalin in
 12 the specimen, make sure it wasn't left in
 13 formalin for too long. So a lot of it rests
 14 with the individual pathologist to go back and
 15 look at his or her methodology in performing
 16 the grossing technique on the specimen.
 17 COFFEY, Q.C.:
 18 Q. Now in relation to breast tissue and breast
 19 tumors and estrogen receptors and progesterone
 20 receptors and just breast tumors in general,
 21 how was a pathologist supposed to know how to
 22 gross the tissue?
 23 DR. COOK:
 24 A. Because that's an inherent part of our
 25 training as residents. We have books as I

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1 said. Acumen is a good source of information
 2 that comes from. The residents are supervised
 3 by the staff. So that's something that's
 4 engrained in pathologists from the initial
 5 days of their training.
 6 COFFEY, Q.C.:
 7 Q. And with respect to breast tissue during your
 8 time, has that ever changed?
 9 DR. COOK:
 10 A. Breast tissue in my time?
 11 COFFEY, Q.C.:
 12 Q. Yes.
 13 DR. COOK:
 14 A. We always made sure that the tissue was
 15 submitted from the OR to the lab in a
 16 reasonable period of time. Once you received
 17 it, you made sure that that specimen was bread
 18 loafed. You made sure that -
 19 COFFEY, Q.C.:
 20 Q. Bread loafed how?
 21 DR. COOK:
 22 A. Slicing.
 23 COFFEY, Q.C.:
 24 Q. I appreciate that, but like any particular
 25 thickness?

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1 DR. COOK:
 2 A. Six-seven millimetres and the -
 3 COFFEY, Q.C.:
 4 Q. Has that changed over time?
 5 DR. COOK:
 6 A. Well, it's down to five or four millimetres.
 7 COFFEY, Q.C.:
 8 Q. And what was it when you started? What was
 9 the recommended, do you recall?
 10 DR. COOK:
 11 A. The recommended, I think, was around six or
 12 seven millimetres, if I remember.
 13 COFFEY, Q.C.:
 14 Q. Okay, and--okay, so was there any time frame
 15 involved, any recommended times by which the
 16 grossing was supposed to have occurred?
 17 DR. COOK:
 18 A. The grossing, when the specimen came up from
 19 the OR, you were notified by the technologist
 20 that we had this specimen here. They notified
 21 you immediately and you went in immediately
 22 and you did your slicing. Slices were
 23 separated by gauze tissue.
 24 COFFEY, Q.C.:
 25 Q. Doctor, well, we heard--the Commissioner has

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1 heard a certain amount of evidence about
 2 fixation issues involving tissue, breast
 3 tissue in St. John's and elsewhere.
 4 DR. COOK:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. Okay. If this was--that approach, you know,
 8 utilizing the procedures you've referred to
 9 was actually followed, would you be able to
 10 explain then why there might be problems with
 11 fixation?
 12 DR. COOK:
 13 A. It depends on how many times a year or how
 14 many times a month you would see an actual
 15 breast lesion. It gets back to the way we
 16 have our general assign out. You look at St.
 17 Clare's, for instance, there may be something
 18 like, I don't know, 100-120 cases per year or
 19 220 cases per year. That would translate into
 20 maybe two or maybe three cases per month per
 21 pathologist. So are you seeing a good
 22 representation of breast cases per month? I
 23 mean, you may see one one week and another one
 24 another two weeks. So if you're only seeing
 25 one or two a month, you may not see a trend.

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1 COFFEY, Q.C.:
 2 Q. I appreciate that. What I'm getting at,
 3 Doctor, is not so much whether you would have
 4 seen a trend in fixation issues. If fixation
 5 protocol is standardized for breast tissue,
 6 and going back certainly to your training
 7 days, which would be the early 80s, and that
 8 hasn't really materially changed until now,
 9 okay, do you know if that protocol was being
 10 followed at St. Clare's, systematically
 11 followed?
 12 DR. COOK:
 13 A. I believe so.
 14 COFFEY, Q.C.:
 15 Q. Was there any written protocol to that effect?
 16 DR. COOK:
 17 A. No, that protocol lay in, again, our standard
 18 textbooks.
 19 COFFEY, Q.C.:
 20 Q. Is there any way or anything that you can
 21 think of then that you could offer the
 22 Commissioner to explain why there might then,
 23 if people know this protocol, because that's
 24 the standard way things are done, and to your
 25 knowledge, as far as you know, it was being

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1 done at St. Clare's, if that is so, can you
 2 offer any explanation as to why then, despite
 3 that, there might be fixation problems in the
 4 tissue?
 5 DR. COOK:
 6 A. The only thing I could speculate, if tissue
 7 was left overnight in a submitting container,
 8 say down in the OR or over the weekend without
 9 it being sectioned.
 10 COFFEY, Q.C.:
 11 Q. And how could that come about?
 12 DR. COOK:
 13 A. It would come about if there was a surgical
 14 procedure that's taking place after hours.
 15 Specimen is put in a submitting container and
 16 the lab not notified.
 17 COFFEY, Q.C.:
 18 Q. And so this would be, in that context, I take
 19 it that would be on the OR staff?
 20 DR. COOK:
 21 A. The OR staff would make sure, yes, they would
 22 make sure that the specimen has an adequate
 23 amount of formalin in it, and I mean adequate
 24 amount, about ten times volume to the volume
 25 of a specimen.

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1 COFFEY, Q.C.:
 2 Q. I appreciate that, but I'm talking about
 3 notification of the lab.
 4 DR. COOK:
 5 A. Notification of the lab would be made by the
 6 OR.
 7 COFFEY, Q.C.:
 8 Q. So that if the OR chose not to notify the lab,
 9 in this context, the breast specimen could do
 10 what, sit in a container of formalin overnight
 11 ungressed?
 12 DR. COOK:
 13 A. That's correct.
 14 COFFEY, Q.C.:
 15 Q. At room temperature presumably, that would be
 16 accurate, would it?
 17 DR. COOK:
 18 A. That's correct.
 19 COFFEY, Q.C.:
 20 Q. Or even over the weekend?
 21 DR. COOK:
 22 A. That's correct.
 23 COFFEY, Q.C.:
 24 Q. In a container of formalin at room temperature
 25 in the OR?

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1 DR. COOK:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. When did you first become aware that that was
 5 a distinct possibility?
 6 DR. COOK:
 7 A. Following the review of the ER and PR.
 8 COFFEY, Q.C.:
 9 Q. So in the beginning of 2005?
 10 DR. COOK:
 11 A. Yes.
 12 COFFEY, Q.C.:
 13 Q. I'm sorry, the middle of 2005, I apologize.
 14 So before that, the idea that the specimens
 15 might have been sitting up there--a specimen
 16 might have been sitting up there all weekend
 17 in the OR or at least overnight in the OR in
 18 formalin had not come to your attention?
 19 DR. COOK:
 20 A. No, the issue surrounding it had not come to
 21 my attention.
 22 COFFEY, Q.C.:
 23 Q. Well, had the fact that it was occurring, were
 24 you aware of that?
 25 DR. COOK:

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1 A. I was aware of cases that were occurring, but
 2 not aware, totally aware of the significance
 3 of that.
 4 COFFEY, Q.C.:
 5 Q. Okay. When did you become aware of the
 6 potential significance of that?
 7 DR. COOK:
 8 A. When I was doing the ER and PR review.
 9 COFFEY, Q.C.:
 10 Q. Okay. And that would be in the middle of
 11 2005, May and June, beginning May, June, July?
 12 DR. COOK:
 13 A. Well, throughout, I mean, my knowledge was
 14 evolving throughout the period of--since 2005.
 15 COFFEY, Q.C.:
 16 Q. And what, if anything, did you become aware of
 17 then that you had not been aware of before in
 18 that regard?
 19 DR. COOK:
 20 A. In that regard it's when I began investigating
 21 or looking into the ER and PR issue the effect
 22 that fixation could have on the tissue
 23 immunoperoxidase staining.
 24 COFFEY, Q.C.:
 25 Q. And what did you learn at that time?

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1 DR. COOK:
 2 A. That there could be a component there, that
 3 could be the fixation of the tissue could,
 4 could affect the result.
 5 COFFEY, Q.C.:
 6 Q. In what way?
 7 DR. COOK:
 8 A. The result that you get from IHC staining.
 9 COFFEY, Q.C.:
 10 Q. In the sense, but affected how, like, I
 11 appreciate it could affect the result?
 12 DR. COOK:
 13 A. You may get under staining.
 14 COFFEY, Q.C.:
 15 Q. Yes, under or over staining, I don't know, I'm
 16 just asking you what -
 17 DR. COOK:
 18 A. Get under staining, but again, it depends on
 19 the strength of your stain itself and the
 20 technical procedures.
 21 COMMISSIONER:
 22 Q. Mr. Coffey, it's getting close to -
 23 COFFEY, Q.C.:
 24 Q. Thank you. So and you only became aware of
 25 that, though, in May of 2005 or thereafter?

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1 DR. COOK:
 2 A. That's when I became aware of it.
 3 COFFEY, Q.C.:
 4 Q. Was that information already available in the
 5 sense of if you'd gone looking for it before
 6 May of 2005, was that readily ascertainable?
 7 DR. COOK:
 8 A. I would imagine it is.
 9 COFFEY, Q.C.:
 10 Q. Doctor, as a practising pathologist, clinical,
 11 clinician, what is it about what you see on a
 12 slide that makes you aware that there's a
 13 fixation issue with the tissue, what do you
 14 see that causes you to come to that
 15 conclusion?
 16 DR. COOK:
 17 A. Well, you may see retraction of the cytoplasm
 18 from the cytoplasmic membrane, some of the
 19 nuclei may become small and pyknotic, some of
 20 them may become, have a dusky appearance, a
 21 boggy appearance, so there may be issue there
 22 that you would be concerned about fixation
 23 issues.
 24 COFFEY, Q.C.:
 25 Q. And you had been aware of that, those sorts of

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1 factors for how long?
 2 DR. COOK:
 3 A. Oh, I mean, I would see variable amounts of
 4 that, those sort of changes, I guess, for a
 5 number of years.
 6 COFFEY, Q.C.:
 7 Q. Going back to, I take it, your training days
 8 and then afterward at various times?
 9 DR. COOK:
 10 A. Various times.
 11 COFFEY, Q.C.:
 12 Q. In particular in relation to breast tissue,
 13 when did you become aware of that as a
 14 concern?
 15 DR. COOK:
 16 A. Well, I became aware of that as a concern when
 17 I did the review.
 18 COFFEY, Q.C.:
 19 Q. And that's the 2005 matter?
 20 DR. COOK:
 21 A. Yes.
 22 COFFEY, Q.C.:
 23 Q. Doctor, you have referred to the fact that you
 24 became aware of the idea of internal controls
 25 for ER and PR tests or stains in 2000?

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1 DR. COOK:
 2 A. Yes.
 3 COFFEY, Q.C.:
 4 Q. Having become so aware, did you ever afterward
 5 have a case or cases where you had internal
 6 control tissue there and it did not stain?
 7 DR. COOK:
 8 A. I can't recollect specifically. I mean, I
 9 would look for the internal control to make
 10 sure it would stain, but I can't remember
 11 earlier whether the internal control didn't
 12 stain.
 13 COFFEY, Q.C.:
 14 Q. I appreciate, after 2000, though, after you
 15 were aware, certainly aware of it, like in
 16 2001, '02, '03, do you recall whether you were
 17 encountering cases of your own where you were
 18 looking for an internal control tissue, you
 19 saw it?
 20 DR. COOK:
 21 A. Um-hm.
 22 COFFEY, Q.C.:
 23 Q. But it was not staining or it had not -
 24 DR. COOK:
 25 A. I can't recollect, Mr. Coffey.

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1 COFFEY, Q.C.:
 2 Q. Okay. Did you ever order or reorder any ER
 3 and PR tests?
 4 DR. COOK:
 5 A. Yes.
 6 COFFEY, Q.C.:
 7 Q. And going back to what time?
 8 DR. COOK:
 9 A. Oh, I can't remember. I mean, I wouldn't be
 10 able to give you a specific date.
 11 COFFEY, Q.C.:
 12 Q. And why would you have reordered an ER and PR,
 13 or PR test?
 14 DR. COOK:
 15 A. Mostly it had to do with how the tissue was
 16 laid out, whether there was folding of the
 17 tissue, there was bubbling in the tissue,
 18 there was fragmentation of the tissue.
 19 COFFEY, Q.C.:
 20 Q. So it had to do with how the tissue was lying
 21 on the slide?
 22 DR. COOK:
 23 A. Yes.
 24 COFFEY, Q.C.:
 25 Q. What about in terms of reordering it because

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1 of problems with the controls?
 2 DR. COOK:
 3 A. I can't recollect that I reordered because of
 4 problems with the controls.
 5 COFFEY, Q.C.:
 6 Q. Continue, Commission, the morning, please.
 7 Thank you.
 8 COMMISSIONER:
 9 Q. 9:30, thank you.
 10 Upon conclusion.

CERTIFICATE

1
2 I, Judy Moss, hereby certify that the foregoing is
3 a true and correct transcript in the matter of the
4 Commission of Inquiry on Hormone Receptor Testing,
5 heard on the 2nd day of July, A.D., 2008 before the
6 Honourable Justice Margaret A. Cameron,
7 Commissioner, at the Commission of Inquiry, St.
8 John's, Newfoundland and Labrador and was
9 transcribed by me to the best of my ability by
10 means of a sound apparatus.
11 Dated at St. John's, Newfoundland and Labrador
12 this 2nd day of July, A.D., 2008
13 Judy Moss

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