COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

July 25, 2008

Appearances:

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

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

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

Beth Whalen . . . . . Eastern Regional Integrated
. . . . . Health Authority

Pamela Taylor. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

Mark Pike . . . . . NL Medical Association
Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)
Blair Pritchett. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

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LIST OF EXHIBITS

Exhibit P-2360 entered . . . . . Pg. 58
Exhibits P-2395 and P2396; P-2398 to P-2408; P-2426 to P-2428;
P-2439 and C-0183 . . . . . Pg. 244

TABLE OF CONTENTS

DR. FINBAR (BARRY) PATRICK GEOFFREY GALLAGHER - SWORN

Examination by Bernard Coffey, Q.C. . . . . Pgs. 4 - 182
Examination by Jennifer Newbury . . . . . Pgs. 182 - 184
Examination by Pamela Taylor . . . . . 185 - 191
Examination by Peter Browne . . . . . Pgs. 191 - 193
Examination by Madam Commissioner . . . . . Pgs. 193 - 199

DR. SUSHIL PARAI - SWORN
Examination by Bernard Coffey, Q.C. . . . . Pgs. 199 - 344

Certificate

Certificate

THE COMMISSIONER:
Q. Mr. Coffey?
COFFEY, Q.C.:
Q. Thank you, Commissioner. The next witness is Barry Gallagher, Dr. Barry Gallagher.
DR. BARRY GALLAGHER, SWORN, EXAMINATION BY BERNARD COFFEY, Q.C.
REGISTRAR:
Q. Would you please state and spell your name for the Commission?
DR. GALLAGHER:
A. My name is Finbar Patrick Geoffrey Gallagher. F-I-N-B-A-R P-A-T-R-I-C-K G-E-O-F-F-R-E-Y G-A-L-L-A-G-H-E-R.
REGISTRAR:
Q. Thank you.
COFFEY, Q.C.:
Q. And Doctor, I take it you go by the name Barry as your first name?
DR. GALLAGHER:
A. I do.
COFFEY, Q.C.:
Q. Okay. So if at some point throughout this I'm referring to you as Dr. Barry Gallagher, you know who I'm speaking of.

Page 5

DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, could you tell the Commissioner, give the Commissioner, please, an overview of your educational and professional background?
DR. GALLAGHER:
A. I obtained my medical degree from University College Dublin in Ireland in 1982 and I did my internship in Don Patrick in Northern Ireland in 1982 to 1983. I obtained a Master of Medical Science degree from University College Dublin between 1983 and 1984 and I then obtained a senior house officer position in the Regional Hospital Galway, Ireland from 1984 to 1986. Thereafter, I moved to Calgary, to the University of Calgary, where I did an anatomical pathology residency training program from 1986 to 1989 and that's when I finished my training.
COFFEY, Q.C.:
Q. Doctor, did you take the Canadian Fellowship exams?
DR. GALLAGHER:
A. I took the Fellowship of the Royal College of

Page 6

Physicians and Surgeons of Canada in 1989 in anatomical pathology and I took the American Board of Pathology exam in anatomic pathology in 1991.
COFFEY, Q.C.:
Q. Were you successful in those, Doctor?
DR. GALLAGHER:
A. Yes, I was.
COFFEY, Q.C.:
Q. Doctor, having completed your training then, I take it, in a formal sense, in a residency formal sense in 1989?
DR. GALLAGHER:
A. Yes, that's correct.
COFFEY, Q.C.:
Q. Where did you go from there, Doctor?
DR. GALLAGHER:
A. From there, I did a locum in St. Anthony in 1989 and thereafter, I did another locum in pathology in the Janeway Hospital in 1990, a further locum in Shaughnessy Hospital in Vancouver 1990 to '91, and after that, I took up a position as a staff pathologist at the Central Newfoundland Regional Health Centre in Grand Falls Windsor from 1991 until 1994.

Page 7

COFFEY, Q.C.:
Q. Take us on then, Doctor.
DR. GALLAGHER:
A. And after that, I did a locum again in St. Anthony at the end of 1994, and in approximately November, I think, 1994, I took up my position as staff pathologist at James Paton Memorial Hospital in Gander, where I have been since, apart from a leave of absence from December '05 to May '07 in Calgary, with Calgary Laboratory Services.
COFFEY, Q.C.:
Q. And Calgary Laboratory Services, what is that?
DR. GALLAGHER:
A. Calgary Laboratory Services is the organization that performs pathological testing for the City of Calgary.
COFFEY, Q.C.:
Q. And they perform it for all the hospitals in Calgary?
DR. GALLAGHER:
A. For all the hospitals in Calgary. It's one group of pathologists that performs all the pathology testing for the City.
COFFEY, Q.C.:

Page 8

Q. Are they stationed in different centres?
DR. GALLAGHER:
A. Yes, they're stationed in multiple hospitals and there was also a diagnostic services centre apart from the hospitals where I worked mainly.
COFFEY, Q.C.:
Q. And then in May of 2007, you returned to Gander?
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. Now Doctor, and I take it you're currently a staff pathologist in the hospital in Gander?
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, tell the Commissioner, I'll ask you first of all about the staffing levels in Gander over the years that you've been there. You've been there, I believe since, in effect, with the exception of the leave of absence, since 1994?
DR. GALLAGHER:
A. Yes.

Page 9

COFFEY, Q.C.:
Q. Since 1994, Doctor, how many pathologists does the hospital in Gander, I think that's the James Paton?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Is what it's called, the hospital?
DR. GALLAGHER:
A. James Paton Regional Health Centre now, James Paton Memorial Regional Health Centre.
COFFEY, Q.C.:
Q. I'll refer to it as the James Paton Hospital. Doctor, in the James Paton Hospital, during your time there, how many pathologist positions are assigned to the hospital or allocated to it?
DR. GALLAGHER:
A. Two.
COFFEY, Q.C.:
Q. And during your time there, how often have there been two pathologists on staff?
DR. GALLAGHER:
A. For most of the time, there have been two pathologists there. I would say there have

Page 10

been very short breaks really over that time in terms of the appointment of two pathologists. Obviously at some times, we would be down to one pathologist when the other pathologist would be away, but we've been relatively fortunate with staffing.
COFFEY, Q.C.:
Q. And I raise that in contradistinction to the situation that Dr. Dalton, Maurice Dalton--you would know of Dr. Dalton?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Has found himself in over the years. He's kind of, I gather from his evidence, he's kind of one--a year or pretty well, at a time, he'd have a two people and then one and then two, roughly, over the years.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. But Gander has not been in that position. As you say, you've been fortunate in that regard.
DR. GALLAGHER:
A. Yes.

Page 11

COFFEY, Q.C.:
Q. Doctor, when you arrived in Gander in 1994, were you the senior pathologist at the time or how did that work over the years?
DR. GALLAGHER:
A. Well, there was another pathologist working there when I arrived. That was Dr. Sangeeta Somers.
COFFEY, Q.C.:
Q. And how long did Dr. Somers -
DR. GALLAGHER:
A. She had been there since 1993, I believe.
COFFEY, Q.C.:
Q. And is she still there?
DR. GALLAGHER:
A. She is still there.
COFFEY, Q.C.:
Q. So between you, is there a senior position and a junior position or how does that work?
DR. GALLAGHER:
A. Yes, I became the senior pathologist there and in 1997, I believe, I was given the title of pathology director and I've been the senior pathologist ever since, apart from my leave of absence, when she assumed those duties.

Page 12

COFFEY, Q.C.:
Q. Doctor, while I'm on the topic, while you were away on your leave of absence, was there a replacement for you?
DR. GALLAGHER:
A. Yes, there was. Dr. Lawrence Lacey did a long locum while I was in Calgary.
COFFEY, Q.C.:
Q. Doctor, can you tell then the Commissioner, please, and perhaps beginning in 1994 and take us up to the present, the structure involving the pathology department, pathology lab, the clinical laboratory in fact for the hospital, could you just tell us about that?
DR. GALLAGHER:
A. Well, when I arrived in 1994, James Paton Memorial Hospital was under the Gander Regional and District Board and it remained under that Board from 1994 until 1998. In 1998, the Central East Health Care Institutions Board was formed and in 2005, the Central Regional Integrated Health Authority was formed. So in the original Gander and District Board, for all internal lab issues, we reported to the assistant executive

Page 13

director and for other issues of a medical nature, we, in practice, reported to the medical director.

COFFEY, Q.C.:

Q. Doctor, if I could, could you just move that just a little bit away from you? No, no, away from you. Thanks. And the situation even today is what, you report to whom?

DR. GALLAGHER:

A. We report to the person who has assumed the medical director's functions, who is the Vice President of Medical Affairs.

COFFEY, Q.C.:

Q. And that has been so since?

DR. GALLAGHER:

A. That has been so since 2005 when that position was created. Between 1998 and 2005, we reported to the Medical Director in practice for medical matters, although we also reported to the executive director and for purely laboratory concerns, we reported to the assistant executive director.

COFFEY, Q.C.:

Q. Okay, so perhaps then you could take us through then the--the assistant executive

Page 14

director was he or she a clinician?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. Okay, so this would be an administrative -

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. - concerns, I suppose, in terms of buying equipment?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Things like that.

DR. GALLAGHER:

A. Budgetary issues, staffing issues.

COFFEY, Q.C.:

Q. Between 1998 and 2005, the medical director was whom?

DR. GALLAGHER:

A. Dr. Peter Blackie.

COFFEY, Q.C.:

Q. And he was located where physically?

DR. GALLAGHER:

A. In James Paton in Gander.

Page 15

COFFEY, Q.C.:

Q. Whom did he report to?

DR. GALLAGHER:

A. He reported to Mr. David Lewis, the executive director.

COFFEY, Q.C.:

Q. Now since 2005, how has that worked?

DR. GALLAGHER:

A. Since 2005, the Vice President Medical Affairs reports to the CEO of the Regional Integrated Health Authority.

COFFEY, Q.C.:

Q. And so in 2005, the Vice President Medical Affairs was?

DR. GALLAGHER:

A. Dr. Larry Alteen.

COFFEY, Q.C.:

Q. So Dr. Alteen, in effect, his responsibility in his job function extended to Gander beginning in 2005?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. And before that, the medical director was Dr. -

Page 16

DR. GALLAGHER:

A. Dr. Blackie in Gander and Dr. Alteen in Grand Falls Windsor.

COFFEY, Q.C.:

Q. Now Doctor, in a practical sense, how much interaction would Dr. Blackie actually have with yourself? You're the head of the--on the ground, I take it, in the lab, the medical director of the lab, as it were. As a pathologist, how much actual interaction would you have with Dr. Blackie on medical matters?

DR. GALLAGHER:

A. Well, in a small hospital like Gander, you would interact or I would interact frequently with Dr. Blackie on a daily basis. One would see him almost daily, talk to him. So we interacted with him very frequently.

COFFEY, Q.C.:

Q. Now Doctor, throughout the period that you've been in Gander, what has been the relationship between the technologists and the pathologists, in a formal sense, in terms of who reports to whom or does either report to the other?

DR. GALLAGHER:

Page 17

A. The technologists report to the Director of Laboratory Services, and that has been the case since I arrived.

COFFEY, Q.C.:

Q. And it is still the case today?

DR. GALLAGHER:

A. Yes, they liaise with us, but they report-- their reporting structure is to the Director of Laboratory Services.

COFFEY, Q.C.:

Q. And liaise involves what sorts of things?

DR. GALLAGHER:

A. They discuss issues with us, of interest to us or of concern to us.

COFFEY, Q.C.:

Q. For example, I take it, the state of particular slides, whether or not to clarify something that you may have ordered, particular type of -

DR. GALLAGHER:

A. That's correct, yeah, that's right.

COFFEY, Q.C.:

Q. And would you have interaction then with the technologists frequently?

DR. GALLAGHER:

Page 18

A. We would have interaction with them every day.

COFFEY, Q.C.:

Q. Would that involve you actually attending in the part of the lab that they work in on a pretty well daily basis?

DR. GALLAGHER:

A. Yes, we would have to be in their area for our grossing activities and for any slides we would order extra stains on or deeper sections on, we would actually be in their area.

COFFEY, Q.C.:

Q. Doctor, could you describe for the Commissioner a typical day in your work life?

DR. GALLAGHER:

A. Well, I would arrive in the morning and first of all, I would consult my Meditech, see what Meditech messages I had, what e-mails I'd received, whether there were any phone messages for me, and deal with any administrative issues that had come up over the night. After that then, the slides would begin to arrive from the laboratory and I would start to look at the H & E slides and dictate my microscopic descriptions and diagnosis on these slides for the secretary to

Page 19

type. This would go on until lunch time and thereafter. I would order my deeper levels, extra stains, prepare cases to be sent out for consultation and perhaps, in some cases, I would then have to go back in the afternoon to the gross room to take further sections on cases that I was looking at in my microscopic description.

On the following day, I would do the gross examination. So we used to alternate. One day you would do a gross examination and the next day you would examine the cases you had cut on the previous day. Apart from that -

COFFEY, Q.C.:

Q. So I take it on the day that you were grossing, Dr. Somers would be in her office and on the day that you were in your office, Dr. Somers would be grossing?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. In that sense?

DR. GALLAGHER:

A. That's right.

Page 20

COFFEY, Q.C.:

Q. Okay.

DR. GALLAGHER:

A. And then apart from that, there would be meetings and various other issues to deal with on other parts of the lab that might arise or discussions with physicians that might come up to be dealt with as well.

COFFEY, Q.C.:

Q. Ask you about that, your interaction with the other non-pathologist doctors in the hospital, in what settings generally would that occur?

DR. GALLAGHER:

A. It would occur at coffee and at lunch time. It would occur when they would just come down to my office. The operating rooms are less than a minute's walk from the pathology department. So they would often come in and talk to me about any issues of concern they had.

COFFEY, Q.C.:

Q. Was there any formal regularly scheduled meetings, like rounds, as it were?

DR. GALLAGHER:

A. There are -

Page 21

COFFEY, Q.C.:
Q. That you would attend?
DR. GALLAGHER:
A. - morbidity mortality rounds that I have attended.
COFFEY, Q.C.:
Q. How frequent are they?
DR. GALLAGHER:
A. I'm not sure how frequent they are. I haven't attended one for some time. That's the only rounds that we have now. We used to have-- before I left for Calgary, I ran the medical staff rounds for many years in the hospital, and we would meet every Thursday to discuss cases and to lecture on subjects to the medical staff.
COFFEY, Q.C.:
Q. And that had been going on for how long? It went on until you left in 2005.
DR. GALLAGHER:
A. It actually was started by a predecessor of mine, so it was there when I arrived in 1994.
COFFEY, Q.C.:
Q. And you were expected, I take it, as part of your job or your job role, you were expected

Page 22

or at least you assumed you were expected to carry on in that regard?
DR. GALLAGHER:
A. I volunteered to do it.
COFFEY, Q.C.:
Q. So that would cover about seven years, seven to eight -- no, I apologize, eleven years approximately?
DR. GALLAGHER:
A. Yes, eleven years, yes.
COFFEY, Q.C.:
Q. Doctor, what would go on then in these sorts -- these weekly meetings?
DR. GALLAGHER:
A. Well, various aspects of clinical medicine would arise. It was -- varied between didactic type of session and discussions around particular cases, interesting cases that had occurred in the hospital.
COFFEY, Q.C.:
Q. And, Doctor, since your return, I'll ask you has it resumed since you returned?
DR. GALLAGHER:
A. No, it has not.
COFFEY, Q.C.:

Page 23

Q. And why is that?
DR. GALLAGHER:
A. I'm not sure really. We never got it running again.
COFFEY, Q.C.:
Q. Did you find -- from your perspective at the time, did you find them useful?
DR. GALLAGHER:
A. Yes, I did.
COFFEY, Q.C.:
Q. Why is that?
DR. GALLAGHER:
A. They gave me an exposure to other areas of medicine that I would not normally read about. I learned a lot about anesthesiology and gastroenterology and gynecology, which was actually quite useful for my practice, but it would be something that I wouldn't naturally read about myself.
COFFEY, Q.C.:
Q. And would you contribute comments from the pathologists perspective to the other physicians in the meetings?
DR. GALLAGHER:
A. Yes, I would.

Page 24

COFFEY, Q.C.:
Q. You would expect then that they would learn something about what you did?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. From time to time.
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. Doctor, over the years since 1994, has the laboratory in James Paton Hospital been involved in formal quality assurance function or role?
DR. GALLAGHER:
A. The quality assurance measures we have in place would comprise such things as the College of American Pathologist Performance Improvement Program, which we'd been involved in, I think, since 1995. We've also been involved in a limited internal review of our negative slides, that is our slides deemed to be normal, since 1995. So a certain number of cases are randomly reviewed each quarter that were considered to be normal by the

Page 25

pathologist originally.
COFFEY, Q.C.:
Q. And reviewed by whom?
DR. GALLAGHER:
A. Generally by the other pathologists internally. We also subscribed to journals and we have recently started attending the tumour board rounds of the Health Care Corporation on Wednesday mornings.
COFFEY, Q.C.:
Q. That's via video conference, I take it?
DR. GALLAGHER:
A. Via video conference. In 2008, we started sending a small number of cases that we deemed to be normal randomly to Dr. Dalton, and we also started sending mastectomy specimens with accillary dissections that we thought did not contain any evidence of malignancy to Dr. Carter for rechecking.
COFFEY, Q.C.:
Q. Anything else, Doctor?
DR. GALLAGHER:
A. We are all enrolled -- myself and Dr. Somers, and Dr. Abdullah were all fellows of the Royal College, and we were all enrolled in the

Page 26

MOCOMP Program, the Maintenance of Competence Program that the Royal College mandates now where one has to obtain 400 hours of continuing medical education in a cycle, which I believe is five years.
COFFEY, Q.C.:
Q. How long has that been in effect, Doctor?
DR. GALLAGHER:
A. That has been going on for about eight years, I think, seven or eight years. Now on top of that, there are other activities that enhance quality, although whether they would be defined as quality assurance, I'm not sure whether they would, such as we examined the consults we receive from many institutions, particularly St. John's and Halifax. We review the cases we send to them and see if there are discrepancies between our provisional diagnosis and the final diagnosis and attempt to learn from that. Almost every afternoon we discuss cases between ourselves and look to see if there are any issues that we did not consider on the cases. In addition, we have started a second review of malignancies this year where every malignancy

Page 27

is reviewed by a second pathologist, and that pathologist then signs off on the malignancy and that becomes part of the report that the second pathologist agrees with the first pathologist on the diagnosis of cancer. Our consultation process that used to be informal where we would just go back and forth to each other's offices with cases, we now document, we now have a sheet that we sign and we put in our diagnosis on the case.
COFFEY, Q.C.:
Q. And the purpose in doing that, the change in approach, the formalizing, why is that?
DR. GALLAGHER:
A. It's part of a trend towards more documentation.
COFFEY, Q.C.:
Q. Doctor, is the laboratory itself -- is there anything else, first of all, involving the pathologists directly?
DR. GALLAGHER:
A. Not that I can think of offhand, actually.
COFFEY, Q.C.:
Q. The laboratory, which involves, of course, the technologists as well, is the laboratory

Page 28

involved or has it been involved over the years in any external proficiency activities?
DR. GALLAGHER:
A. Yes, they have.
COFFEY, Q.C.:
Q. Okay, could you tell us -- tell the Commissioner, please, about that?
DR. GALLAGHER:
A. They're involved in the CAP testing proficiency program.
COFFEY, Q.C.:
Q. How long has that been going on?
DR. GALLAGHER:
A. That has been going on for many years. I can't tell you exactly. I think it certainly predates my arrival.
COFFEY, Q.C.:
Q. And the CAP is?
DR. GALLAGHER:
A. College of American Pathologists.
COFFEY, Q.C.:
Q. Not to be confused with the Canadian --
DR. GALLAGHER:
A. Canadian Association of Pathologists, that's right.

Page 29

COFFEY, Q.C.:
Q. But they've been involved in the College of American Pathologists Program predating your -- going back to the beginning of your time certainly?
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. Are they involved or have they been involved in anything else?
DR. GALLAGHER:
A. Well, we're involved in accreditation at the moment in the national accreditation process.
COFFEY, Q.C.:
Q. And that -- whose accreditation process is that?
DR. GALLAGHER:
A. There's a new body formed, a new Canadian accreditation structure formed, whose name I can't remember now, but we're involved in that and it's an ongoing process over the years. It used to be a -- I can't remember the name of the first organization, but it's a national body of accreditation now that looks at every aspect of the laboratory and accredits the

Page 30

laboratory.
COFFEY, Q.C.:
Q. And this has occurred since when?
DR. GALLAGHER:
A. This new accreditation -- we have undergone accreditation again periodically as part of the hospital accreditation for years.
COFFEY, Q.C.:
Q. Yes.
DR. GALLAGHER:
A. This new one, I think, is our first one and the process has just started. I think it's -- we're preparing for a two years process of accreditation.
COFFEY, Q.C.:
Q. So is this part of the Canadian Hospitals Accreditation?
DR. GALLAGHER:
A. Yes, it is.
COFFEY, Q.C.:
Q. Okay, this is part of that?
DR. GALLAGHER:
A. It is.
COFFEY, Q.C.:
Q. The Canadian Hospitals Accreditation Program,

Page 31

that one which James Paton certainly, I gather, would have been involved in over the years --
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Up until now, very recently, the laboratory aspect of the hospital was not involved directly in accreditation, was it?
DR. GALLAGHER:
A. It was involved just as part of the general hospital accreditation. So they would ask us for details of our QA and so on, but this is a much more in-depth assessment.
COFFEY, Q.C.:
Q. And this is a new initiative?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Anything else, Doctor, the laboratories and external proficiency --
DR. GALLAGHER:
A. Not that I can think of.
COMMISSIONER:
Q. Sorry, Mr. Coffey, but while I think of it, is

Page 32

there just the two of you still there, Doctor?
DR. GALLAGHER:
A. Yes.
COMMISSIONER:
Q. I didn't hear a third name creep in there.
DR. GALLAGHER:
A. Yes, Dr. Abdullah, Dr. Amid Abdullah, replaced Dr. Somers for three and a half years when she did a residency training program in New York from 1997 until 2001, and she finished an APCP Program in New York and came back then, and then he left when she came back.
COMMISSIONER:
Q. All right, thank you.
COFFEY, Q.C.:
Q. Doctor, the technologists, how many technologists work in the pathology side of the lab?
DR. GALLAGHER:
A. We have two full time equivalents, so that generally means two technologists who are occasionally replaced by another person when one is away.
COFFEY, Q.C.:
Q. And, Doctor, could you describe for the

Page 33

Commissioner the process involved in tissue fixation and tissue processing in the lab in James Paton?

DR. GALLAGHER:

A. Well, specimens are immediately immersed in formalin following their removal in the operating room endoscopy suite and day surgery, and in the clinics around the region, and they are sent then to the laboratory, and after that they are examined and sectioned.

COFFEY, Q.C.:

Q. So would that be the same day?

DR. GALLAGHER:

A. Depending on the specimen. It would be the same day for small specimens, and all of them would be opened on the same day. So if you took a small specimen like a biopsy of skin, it would come to the laboratory and it would be excisioned and then examined and sections would be taken and would be put into cassettes, and the cassettes would then be put on the processor overnight and slides would be stained and coverslipped and made the following morning.

COFFEY, Q.C.:

Page 34

Q. They're smaller?

DR. GALLAGHER:

A. Smaller specimens, yes.

COFFEY, Q.C.:

Q. How about larger, how are they handled?

DR. GALLAGHER:

A. The larger specimens would be opened and sliced, and depending whether they're hollow or solid organs, the approach would be somewhat different. If they were hollow --

COFFEY, Q.C.:

Q. Deal with breast for example.

DR. GALLAGHER:

A. Breast specimens would be removed from their containers and the dictating machine would then be turned on and they would be weighed and then examined in terms of their dimensions and consistency, and following the gross description, they would be bread loafed. That is they would be sliced transversely into thin slices, and then paper towels would be placed between these slices and the specimen would then be put back into a large bucket of formalin. Frequently the formalin would be replaced actually before it would be put back.

Page 35

It would be put back into this large bucket of formalin and left to fix overnight.

COFFEY, Q.C.:

Q. And that would have -- I take it that this bread loafing process would have occurred by what time of the day?

DR. GALLAGHER:

A. The bread loafing occurred at our gross examination which went on from 1 to 1:30 to approximately 3 p.m. each day.

COFFEY, Q.C.:

Q. So sometime by mid afternoon --

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. It would be completed, and it would be left then in formalin overnight?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. What then would happen?

DR. GALLAGHER:

A. The following afternoon, the --

COFFEY, Q.C.:

Q. While I'm on this topic, Doctor, because I

Page 36

take it the assignment of cases generally is you do it between yourself and Dr. Somers, for example, is whatever comes in that day you happen to be grossing, you end up doing?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. How does that work with respect to the larger specimens, for example, breast tissue that is left overnight to fix? Who's responsible for that case?

DR. GALLAGHER:

A. Once it's assigned to you, you do it.

COFFEY, Q.C.:

Q. Okay, perhaps you could tell -- so assigned to you in the sense of when it comes in, if you end up doing, if you do the bread loafing --

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Then the next day you're back at the grossing bench?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Page 37

Q. Okay.
DR. GALLAGHER:
A. It's your specimen from then on.
COFFEY, Q.C.:
Q. So although you wouldn't normally then be at the grossing bench the next day because that's not your turn --
DR. GALLAGHER:
A. That's right.
COFFEY, Q.C.:
Q. You would have to attend, make a point to do so?
DR. GALLAGHER:
A. That's correct, yes, usually. Sometimes if there was some reason you couldn't be there, the other pathologist might take the sections for you, but generally you would take the sections yourself.
COFFEY, Q.C.:
Q. I'm sorry, Doctor, interrupted you there. Being required then to return to the gross bench on your off day, as it were, what would then happen with respect to a breast tissue?
DR. GALLAGHER:
A. Well, again you would remove the specimen from

Page 38

the container and you would begin to take your sections with a scalpel. The example of a mastectomy specimen, you would take sections from the nipple, random sections from the quadrants, sections from a tumour or biopsy cavity site if it's there, and sections from any other suspicious area. Frequently after that then, I would say usually we would removed the accillary tail from the specimen if it's present and keep it for fixation for a following day in formalin and on the morning of the following day, on the morning of the Wednesday if we had started on Monday, we would put that specimen in acetic formalin and that makes the nodes, the lymph nodes, become whiter and more obvious, and we would then dissect those lymph nodes on that following afternoon of Wednesday.
COFFEY, Q.C.:
Q. So on the middle day, on the Tuesday in our example, having taken the sections, dissected the tissue, what would then happen to the tissue that you wanted to examine further?
DR. GALLAGHER:
A. We would make thin sections of the specimen

Page 39

that we wanted to look at, of the pieces of tissue we wanted to look at, and we would put them into perforated boxes called cassettes, and these would then be placed again in formalin awaiting the tissue processing stage. At 4:30, they would go into the tissue processor, and then they would go through a series of processes within the processor starting with more fixation for formalin actually at a slightly increased temperature to enhance the degree of fixation, and they would then be dehydrated in various stations of alcohol to remove the water. They would then be cleared by being exposed to xylene. They would then be infiltrated with wax and that's when the process would stop, around 5 a.m. and they would be removed then by the technologists who come on in the morning and put the waxed tissue specimen from the cassette into a mould that contains molten wax, and they cassette itself is broke in two, the top is taken off, and the specimen and the waxed mould is then stuck on the back of the cassette which is numbered with the patient's name. That then is put on a microtome which

Page 40

is a rotary slicer of tissue similar to a meat slicer in a delicatessen, basically, and it takes very thin sections of these wax blocks. A thin section of about three t five microns from this wax block is then floated in a bath and a slide numbered with the patient's name is put under the section and the section is put onto the glass slide and is then stained and coverslipped.
And that then is put on a microtone which is a rotary slicer of tissue, similar to a meat slicer in a delicatessen, basically, and it takes very thin sections of these wax blocks. A thin section of about three to five microns from this wax block is then floated in a bath and a slide numbered with the patient's name is put under the section and the section is put onto the glass slide and is then stained and coverslipped.
COFFEY, Q.C.:
Q. And it's stained H&E -
DR. GALLAGHER:
A. With H&E, hematoxylin and eosin.
COFFEY, Q.C.:
Q. So on that day then, the first slide, H&E

Page 41

slides are prepared, they would end up in your office?

DR. GALLAGHER:

A. Yes, they would end up in my office, starting at around 9:30 in the morning.

COFFEY, Q.C.:

Q. And that would be the morning they came off the tissue processor?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. So, Doctor, you would examine them and I take it note your observations at the time?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, in relation to breast tissue, breast cancer, the ordering of ER and PR, when would that occur?

DR. GALLAGHER:

A. That would occur after I had examined the whole case under the microscope and had made my diagnosis of invasive cancer. I would then select the block corresponding to a slide that had representative tumour that was well

Page 42

preserved on it and showed no evidence of necrosis on it. And it was representative of the tumour in general from the other slides.

COFFEY, Q.C.:

Q. What would then -- well, we'll get to what happened because I take it that changed over time, depending upon what time frame or what year in this time frame we'll be dealing with. I take it then that the block that you had selected would be sent somewhere for ER/PR IHC and processing?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. I'll concentrate then on what happened when it came back to you when we get to that stage of the process here. Doctor, who's responsible in James Paton for the maintenance of the tissue processor?

DR. GALLAGHER:

A. The technologists and their supervisors.

COFFEY, Q.C.:

Q. Doctor, do you know if there were any written policies over the years that they have, like protocols that they have to follow?

Page 43

DR. GALLAGHER:

A. Yes, there are.

COFFEY, Q.C.:

Q. And who's responsible for vetting them as to their appropriateness and making sure they're up to date?

DR. GALLAGHER:

A. The supervisors would be.

COFFEY, Q.C.:

Q. And that would be the technologist's supervisor?

DR. GALLAGHER:

A. Yes, and the technologists and he supervisor would be.

COFFEY, Q.C.:

Q. Would the -- have the pathologists over the years been consulted about those, would you be asked to review them?

DR. GALLAGHER:

A. We've discussed the processor and the processing techniques with them and the buying of a new processor, which occurred in 2003, I think. That's really --

COFFEY, Q.C.:

Q. The extent of your involvement.

Page 44

DR. GALLAGHER:

A. The extent of what we've done with that.

COFFEY, Q.C.:

Q. Doctor, for the pathologists, are there any written policies or procedures or protocols?

DR. GALLAGHER:

A. Yes, there are.

COFFEY, Q.C.:

Q. How long have they existed?

DR. GALLAGHER:

A. Well, most of our written policies on gross examination as policies are from this year. Prior to that, we relied on the policies written in Ackerman Surgical Pathology to guide us.

COFFEY, Q.C.:

Q. Now, Doctor, I'm going to ask you then to describe for the Commissioner, I'm going to particularly now focus on the ER and PR aspect of the matter. When you -

DR. GALLAGHER:

A. I'm sorry, I should add that in our histology manual, there are descriptions laid out for the pathologists on the gross examination of specimens that go back many years.

Page 45

COFFEY, Q.C.:
Q. In your histology manual.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. As opposed to--so that, this is what I was asking you about, so this histology written manual, that has existed for -
DR. GALLAGHER:
A. That has existed for many years.
COFFEY, Q.C.:
Q. And they do, you're pointing out that there is a policy there dealing with the grossing process?
DR. GALLAGHER:
A. Yes, there is, by the way, also a policy in the hospital dating back to 1992 that mandates that all specimens be placed in formalin following removal by the nurses in the OR and that's an OR policy.
COFFEY, Q.C.:
Q. Doctor, perhaps before I leave it now I'm on the topic, is there currently a policy in the hospital dealing with fixation?
DR. GALLAGHER:

Page 46

A. Yes, there is.
COFFEY, Q.C.:
Q. And how long has that existed and how, if at all, has it changed over the years?
DR. GALLAGHER:
A. Well, there were general policies as I've mentioned in the histology manual regarding formalin and the hazards of formalin and there existed a policy in the OR manual regarding how all specimens must be placed in formalin.
COFFEY, Q.C.:
Q. That's the 1992 one.
DR. GALLAGHER:
A. 1992 policy, but our policies became more explicit on formalin in '08, in this year.
COFFEY, Q.C.:
Q. And the policy, did you develop your own written policy or -
DR. GALLAGHER:
A. The first policy we were given from '08 was from Dr. Carter and we received a subsequent policy document from Dr. Denic.
COFFEY, Q.C.:
Q. Doctor, I'm going to take you back now to when you arrived in Gander, well perhaps even

Page 47

before I get to that, Doctor, in your training when you first were trained as a pathologist, I take it your training was in Calgary?
DR. GALLAGHER:
A. Yes, and in Galway.
COFFEY, Q.C.:
Q. Yes, it started in Ireland and continued in Calgary. Doctor, certainly in your days in Calgary, okay, what was utilized, what process was utilized at that time to attempt to determine the estrogen and progesterone presence in breast tissue or breast tumours?
DR. GALLAGHER:
A. I have no very clear recollection of that in Calgary. I do know in Galway previous to Calgary, we were doing the biochemical assay and we were phasing in ER/PR in Galway. In Calgary, I think we were doing ER/PR, but I have no clear recollection of that, ER/PR immunohistochemistry. I surmise that we were, but I can't remember whether we were or not.
COFFEY, Q.C.:
Q. I'll take you, fast forward as it were, skip in the intervening--well I'll ask you, during the intervening years, were you, before you

Page 48

ended up in Gander in 1994, were you exposed to ER/PR by the IHC method?
DR. GALLAGHER:
A. Not in my professional practice.
COFFEY, Q.C.:
Q. Then when you arrived in Gander, what was the situation in 1994?
DR. GALLAGHER:
A. The situation was that fresh tissue was frozen and sent to Dr. Prabhakaran at the Health Sciences Centre for a biochemical assay for a ligand binding assay. And formalin fixed tissue, it was required that estrogen and progesterone receptors be performed, was sent to Dr. Zayid in Halifax.
COFFEY, Q.C.:
Q. So why was the biochemical assay being done for ER/PR and you say as well they were utilizing Halifax for the IHC method?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Both going on at the one time?
DR. GALLAGHER:
A. No, well what would happen is on some cases

Page 49

one would receive fresh tissue. Now the practice of breast surgery has changed quite a bit since the 70s. It was common practice in the 70s and 80s to do frozen section examinations of breast prior to mastectomy, for example or definitive surgery on the day. So we would frequently receive breast tissue with obvious tumour within it and the tumours would be quite large in those days as well, because I think diagnosis wasn't as well refined on the radiology side. So we would frequently receive large tumours and we would do a frozen section on those tumours and confirm their malignancy and we would then have enough tumour tissue available to safely remove a cube of that tissue and sent it for biochemical assay without compromising the diagnosis and management of the specimen.

COFFEY, Q.C.:

Q. By the paraffin, H&E paraffin -

DR. GALLAGHER:

A. Yes, yes.

COFFEY, Q.C.:

Q. Preserved H&E slides?

DR. GALLAGHER:

Page 50

A. Yes, we could take a large block out of that specimen and still be confident we would make a diagnosis that was comprehensive and accurate on that specimen.

COFFEY, Q.C.:

Q. With what you had -

DR. GALLAGHER:

A. With what we had left, because we would not know what was in that cube other than what we had taken for frozen section.

COFFEY, Q.C.:

Q. So you would send, I take it, in those situations, Dr. Prabhakaran would receive a frozen tissue -

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. - for the biochemical assay determination of ER/PR levels.

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. And that--would that report actually come back to you?

DR. GALLAGHER:

Page 51

A. Yes.

COFFEY, Q.C.:

Q. The biochemical report?

DR. GALLAGHER:

A. Yes, it would.

COFFEY, Q.C.:

Q. And what would you do with the biochemical report?

DR. GALLAGHER:

A. We would send it to the physician.

COFFEY, Q.C.:

Q. Then the other situation, perhaps you can describe then when Halifax was utilized?

DR. GALLAGHER:

A. Well, more and more frequently we got small specimens of breast that contained small tumours. We began to see more needle localization specimens where a needle is placed beside a suspicious lesion and these lesions could be very small. One might have a tumour that was less than a centimetre across and it became increasingly difficult to remove a representative piece of this specimen without running the risk of removing important diagnostic material. So it became

Page 52

increasingly standard practice in pathology to put the suspicious area through in its entirety and then if a malignancy was discovered in that specimen, one would then have to send it for immunohistochemistry because the biochemical assay required fresh tissue. You could not do the biochemical assay on formalin fixed tissue.

COFFEY, Q.C.:

Q. So when you arrived in Gander, I take it this was the situation you found?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. In some particular patients, tumours were such that biochemical assay analysis was appropriate--was possible, not appropriate, and it was done.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And in those cases and I take it from what you've told us then as time went on, '94, '95, there were more and more cases that wasn't possible for and the IHC, ER/PR IHC method

Page 53

would have to be used for ER/PR?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And you would send it off to Halifax?
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. What was the situation, so you would send a block to Halifax with a request, I take it, that ER/PR be conducted.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. What would you get back from Halifax?
DR. GALLAGHER:
A. We would get back a report and the report would state that the receptors were positive or negative. They would use adjectives such as strongly or weakly positive.
COFFEY, Q.C.:
Q. Do you recall if at that time they were utilizing percentages?
DR. GALLAGHER:
A. No, they were not using percentages.

Page 54

COFFEY, Q.C.:
Q. And did you have any understanding about what strongly or weakly or moderately meant?
DR. GALLAGHER:
A. Not in terms of its significance for patient management.
COFFEY, Q.C.:
Q. Having received the written report, I'll ask you, would you receive the block back?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Did you receive the slides, do you recall?
DR. GALLAGHER:
A. I don't recall.
COFFEY, Q.C.:
Q. And I take it if the slides did come back, you wouldn't look at them -
DR. GALLAGHER:
A. I think we did eventually receive the slides back, actually, I think we did, sometime later.
COFFEY, Q.C.:
Q. Would you have examined them back in those days yourself when they came in from Halifax?

Page 55

DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. So I take it you had the report itself, Doctor.
DR. GALLAGHER:
A. No, sorry, the slides--I don't recall ever seeing those slides on those cases, I'm sorry, the ER/PR slides from Halifax, I don't think we did.
COFFEY, Q.C.:
Q. And you'd be relying upon the report from Halifax, the written report?
DR. GALLAGHER:
A. Yes, that's correct.
COFFEY, Q.C.:
Q. And who would you--what would you do with the report?
DR. GALLAGHER:
A. The report would go to all the physicians who were mentioned on the requisition.
COFFEY, Q.C.:
Q. Doctor, I'll ask you just to think about it for a second, do you ever recall being questioned by--because you had forwarded the

Page 56

report on, I take it?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. To the oncologist or the surgeon or both, for that matter.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Did you ever receive any--do you ever recall receiving any inquiries as to what was meant by strongly, weakly or moderately from the attending physicians?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. What then happened with respect to ER/PR then as we progress then?
DR. GALLAGHER:
A. Well, subsequent to this, I became aware of Dr. Khalifa in St. John's and the fact that he was interested in gynecological oncology and breast pathology and he also did several locums for us in Gander and we began to send more and more cases to him on gynecological

Page 57

pathology and on breast pathology. So we felt it nature to send him estrogen and progesterone receptor determinations as well.

COFFEY, Q.C.

Q. If we could, please--and in terms of the ER/PR by IHC method in St. John's, how did you become aware that it was even being done in St. John's? Do you recall -

DR. GALLAGHER:

A. No, I don't recall.

COFFEY, Q.C.

Q. Because I take it, originally when you're utilizing Halifax, you would have understood, I take it, at the time or did you understand at the time that it wasn't being done in St. John's?

DR. GALLAGHER:

A. Yes, we had to go to Halifax at that time.

COFFEY, Q.C.

Q. And you can't recall who first alerted you to the fact that Dr. Khalifa and St. John's are now involved in this?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.

Page 58

Q. But at some point you learned that they were and you started to send cases.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.

Q. If I could please, there is an exhibit that I do wish to--it'll come up later, Doctor, this particular exhibit. Commissioner, if I could, Exhibit P-2360, it's just a single exhibit for Dr. Gallagher.

THE COMMISSIONER:

Q. Entered.

EXHIBIT P-2360 MARKED AND ENTERED.

COFFEY, Q.C.

Q. And Doctor there has been many, many exhibits entered already, that's why there's only one through yourself. Entered, Commissioner? Thank you. P-1850. Now, Doctor, this is a memorandum, Health Care Corporation of St. John's dated February 16th, 1998. It's from Dr. Khalifa to all Newfoundland pathologists, and the subject is "Reporting of Estrogen and Progesterone Receptor Immunohistochemical Results." Now do you recall whether you ever received this?

Page 59

DR. GALLAGHER:

A. I did receive it.

COFFEY, Q.C.

Q. And at the time, Doctor, well first of all I'll ask you, had you had any understanding or sense that this initiative involving reporting by individual pathologists throughout the province was being planned?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.

Q. This was your first introduction to the idea that you would be asked--you and your fellow pathologists outside of St. John's and perhaps even within St. John's, outside Dr. Khalifa, in fact, were going to be asked to report your own ER/PR?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.

Q. Doctor, perhaps you could just take us through it then, you have, of course the mouse there if you wish, and I'll ask you your reaction to various parts of it and your reaction overall to the idea that you were henceforth report

Page 60

ER/PR.

DR. GALLAGHER:

A. Well, it was a very well written and comprehensive memo that explained what the process was going to be. I have said already that my professional practice did not include ER/PR assessment, but given that Dr. Khalifa felt we were fully capable of doing this, I was quite happy to proceed with it.

COFFEY, Q.C.

Q. When you look at, when you scroll to page 2, phase 2, and it indicates this phase involving each pathologist being asked to report results of his or her own cases, it's indicated by the brown staining of nuclei of the invasive neoplastic cells would start March 1, 1998. And he would mail you the positive controls whenever technically possible and he gives an assurance that he will review the positive controls in the lab and slides wouldn't go out to you unless adequate staining is noted in those positive controls. And he offers to be available to answer any questions or address any concerns.

Now Doctor, brown staining of nuclei of

Page 61

the invasive neoplastic cells, up to that point, were there any stains that you were interpreting that involved nuclei staining?

DR. GALLAGHER:

A. No. Obviously I'd seen some of these stains in the books and in my residency, not only ER/PR, but T67 and other stains, but I was not interpreting any of these stains on a regular basis.

COFFEY, Q.C.

Q. Nuclei staining.

DR. GALLAGHER:

A. Nuclear staining.

COFFEY, Q.C.

Q. The other staining, the stains you would be looking at would be cytoplasmic or membrane.

DR. GALLAGHER:

A. That's correct. On the rare occassion that I would interpret them myself.

COFFEY, Q.C.

Q. And just to give the Commissioner some sense, at that point, in early 1998, how many IHC stains would you order? I take it, the special stains--how often would you order special stains?

Page 62

DR. GALLAGHER:

A. Well, special chemical stains are ordered frequently within the laboratory. These would be things like PAS diastase, reticulin, those sorts of stains would be ordered within our laboratory.

COFFEY, Q.C.

Q. And produced within your laboratory?

DR. GALLAGHER:

A. And produced within our laboratory every week. Immunohistochemical stains, it's quite difficult to say how many we would produce a year or order a year. I would imagine we might order one or two a week. It might be something of that order.

COFFEY, Q.C.

Q. And this is at that point, of course, I'm talking about early 1998, late 1997, early 1998 in the lead up to this.

DR. GALLAGHER:

A. Yes, we might order one a week, one or two a week in that order or it might be less.

COFFEY, Q.C.

Q. And they would be performed at that time where?

Page 63

DR. GALLAGHER:

A. In St. John's.

COFFEY, Q.C.

Q. Was IHC staining ever done at James Paton?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.

Q. And, of course, up to this point these one or two IHC stains per week that you might order or would order in St. John's, of course, didn't involve the ER/PR which was being done in Halifax.

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.

Q. Doctor, now the positive controls that are referred to here, did you understand them to be positive external controls?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.

Q. What was your practice, what was your experience in terms of external controls generally?

DR. GALLAGHER:

Page 64

A. Well, external controls are used throughout the pathology laboratory. And they're important to ensure that a test is working. So, I knew of external controls for many areas of the lab.

COFFEY, Q.C.

Q. Doctor, such external, for example, positive controls, would they generally--would they be a yes or no, they stained or didn't or could they stain weakly or strongly?

DR. GALLAGHER:

A. There would be a range of acceptable staining.

COFFEY, Q.C.

Q. For external controls generally.

DR. GALLAGHER:

A. For external controls.

COFFEY, Q.C.

Q. Now, the positive controls referred to here for ER/PR, did you have any understanding or expectation as to whether or not a range of staining was acceptable?

DR. GALLAGHER:

A. I thought a range of staining was acceptable.

COFFEY, Q.C.

Q. Because that was consistent with the special

Page 65

stains?
DR. GALLAGHER:
A. That's consistent with pathology in general. One sees quite a bit of variety in staining in pathology.
COFFEY, Q.C.
Q. In particular I'm speaking of the external controls even. You can expect generally a fair amount of variability.
DR. GALLAGHER:
A. You can.
COFFEY, Q.C.
Q. The idea that, for example, the idea here that the external positive controls should, if they're working properly, should be staining significantly. There should be a significant portion of the external control stained, of its nuclei stained. The fact that that might be important wasn't really brought to your attention?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.
Q. Doctor, the assurance the Dr. Khalifa gave here, I will still be responsible for

Page 66

reviewing the positive controls here in our laboratory and the slides will not be mailed to you unless adequate staining is noted in the positive controls. What did you understand that from that and what, if any, influence did that then have upon your behaviour subsequently?
DR. GALLAGHER:
A. It certainly reassured me that the process would be closely monitored and in this case, would be reviewed by an expert. I drew considerable confidence from it.
COFFEY, Q.C.
Q. Doctor, up until this point in time you'd been utilizing Halifax, well to your knowledge, for about four years.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. Increasingly as time we on, as you indicated, more and more.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. But why did you--I'll ask your first of all,

Page 67

was the service that you were receiving from Halifax adequate?
DR. GALLAGHER:
A. Yes, it was.
COFFEY, Q.C.
Q. Why did you consider then switching to St. John's?
DR. GALLAGHER:
A. Well, firstly because it makes good medical sense for pathology cases to be reviewed in the same institution and dealt with in the same institution as the oncologists practice. It's common practice in many cancer centres for all pathology to be reviewed and often re-stained in the cancer centre where the treatment will take place. So, I felt it was better if, as far as possible, such testing could occur within our system because we obviously will have more control over the quality of that system than if it were done elsewhere. And there's less likely to be problem of opinions going back and forth between provinces. So, it made good medical sense from that point of view.
COFFEY, Q.C.

Page 68

Q. Yes, Dr. Khalifa was in St. John's and you understood, I take it, from you dealings with him that he was dealing with the cancer treatment centre here -
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. - and the oncologists.
DR. GALLAGHER:
A. He was an acknowledged expert in gynecological oncology and it made sense for him to be dealing with this test where he was right next to the oncologists and had a good working relationship with them.
COFFEY, Q.C.
Q. Now Doctor, -
THE COMMISSIONER:
Q. I'm sorry, Mr. Coffey, while this is just splitting through my bring, do I understand that there would be no oncologists based in Gander?
DR. GALLAGHER:
A. There are no oncologists based in Gander. They visit -
THE COMMISSIONER:

Page 69

Q. Periodically.
DR. GALLAGHER:
A. - from St. John's.
THE COMMISSIONER:
Q. Coming from the centre in St. John's?
DR. GALLAGHER:
A. They do.
COFFEY, Q.C.
Q. And then phase 3, he talks about the plan, discontinuance of the biochemical techniques. Doctor, it goes on to say, "attached please find a proposal for uniform reporting of ER/PR immunohistochemical staining. This proposal was discussed with many of my colleagues who mostly agree with its content and accept it as a policy. I encourage you to adopt the attached proposal in your reporting to maintain uniformity. It should be clearly stated this is only a proposal". And he points out there are considerable host of publications addressing this issue and he'd be glad to share the material he has.
And if we look at the third page, it is the actual proposal for uniform reporting of ER/PR immunohistochemical assessment, February

Page 70

1998. "The report on the hormone receptor status will have three components. The first component is a statement of whether the stain is positive or negative. Positivity is defined by nuclear staining detected any number of malignant cells. Second component is a rough estimate of the percentage of immuno-reactive cells in a section examined. This estimate could be in the form of a range or a fixed number and is listed in parenthesis".
Now, up to this point in time, Doctor, had you ever been involved in making rough estimate, rough or otherwise, of the percentage of immuno-reactive cells, in any sort of stains?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.
Q. This was something new that was being asked of you?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. And then the third component is a comment, it

Page 71

says, this comment dealing with the 1990 American Journal of Surgical Pathology article paper dealing with the 30 percent cutoff.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. Now, Doctor, in terms of this comment aspect, I'll ask you about this first, from your perspective as a pathologist, per se, did that make any difference to your practice, the cut off issue.
DR. GALLAGHER:
A. No, it did not make any difference to how I assessed the slide.
COFFEY, Q.C.
Q. And that's perhaps what I was getting at, whether you included it or not might be another issue, but in terms of how you assessed the slide, whether it was one percent, ten or 90 or 100 percent, what the cut off an oncologist might use was their concern.
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.

Page 72

Q. You were looking for this rough estimate or make this estimate and in some instances, I take it, it might be rough.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. How would you then--did you speak to anybody about how you should go about making this estimate, Doctor?
DR. GALLAGHER:
A. No, I consulted the textbooks and did some reading on it, but that's as far as I went in terms of my research.
COFFEY, Q.C.
Q. And how then did you approach it?
DR. GALLAGHER:
A. I would firstly examine the positive controls and check the number on the positive controls, make sure it matched with the slide in question. I would, of course, check the H & E slide that came back to make sure that this was the correct case and it was indeed invasive and to get a clear idea of where the invasive component was in the slide. I would then put the ER slide on the microscope stage

Page 73

on low power. And I would try to obtain a rough idea of how extensive the staining was. The brown nuclei would be in one area and the blue nuclei, which is basically how the other nuclei, the negative nuclei would look on the slide would be beside them. And I would get a rough idea from my 2 power lens which is actually a 20 magnification because you got a 2 power and a 10 power in the microscope. So, at 20 magnification I would get a rough idea of how many cells were staining. Perhaps I would say is it greater than half or less than half for starters? And if it's greater than half, is it more than 75 or less than 75? I would then go onto the higher powers by 10 which is by 100 and by 40 which is by 400, just to make sure that the staining was crisp and strong in the nuclei, that it was indeed nuclear staining and not cytoplasmic staining. And that I would clearly see where the tumour was in terms of the blue nuclei beside it, that these were, indeed, tumour nuclei that I was considering to be negative. And I would give then a rough estimate of the number of these nuclei, these malignant epithelial cell

Page 74

nuclei that were staining brown of the total malignant epithelial cell nuclei.

COFFEY, Q.C.

Q. I take it this approach, you arrived at having read the memo and read text and journals, would there have been articles at that time?

DR. GALLAGHER:

A. There would have been, yes.

COFFEY, Q.C.

Q. And then having arrived at a figure in your head, a number, I take it you would record that or have that recorded.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.

Q. And you'd go through the same process for the PR slide.

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.

Q. Doctor, then in terms of reporting it, what format did you use to report the ER/PR?

DR. GALLAGHER:

A. I reported it as shown in example one and two there. I would report the receptors as

Page 75

positive if there were any cells positive. So, I would say estrogen receptors positive bracket percentage of cells, progesterone receptors positive bracket percentage of cells. And I would not put in a comment. I did not put in a comment.

COFFEY, Q.C.

Q. And why is that, Doctor?

DR. GALLAGHER:

A. It was just my personal preference. I had read very little about ER/PR. I had a very limited understanding of it, but from my limited understanding, I felt that there was some divergence of opinion as to what a positive case would be among the oncologists in terms of treatment.

COFFEY, Q.C.

Q. You understood enough about it to realize that there might be differences of opinion with the oncologists.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.

Q. And so rather get into that, I take it, you chose or be asked about it even or insert

Page 76

yourself into that potential disagreement, you chose to put down what I see.

DR. GALLAGHER:

A. Yes, it was generally my policy not to put down comments from an academic paper on our reports in Gander. I generally did not do that. And I thought in this case as well, it was my feeling that I should leave it up to the oncologists to decide what a significant number was.

COFFEY, Q.C.

Q. Now, Doctor, having adopted that approach and I take it you began to order ER/PR stains from St. John's, you would get the slides and would report them.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.

Q. Examine them and report them in the way you've described. Did you ever get any questions back from the oncologists about that aspect of your reports?

DR. GALLAGHER:

A. No. I don't recall ever getting a question back from the oncologists about that.

Page 77

COFFEY, Q.C.
Q. About ER/PR.
DR. GALLAGHER:
A. About ER/PR.
COFFEY, Q.C.
Q. Doctor, you did refer to the fact that when you look at the external control slide, that you cross referenced it with the patient slide to make sure it was the right control slide for the right patient slide.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. What was it that you could--what allowed you to do that?
DR. GALLAGHER:
A. The surgical number was written the control slide.
COFFEY, Q.C.
Q. On the control slide.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. So, the control slide would be identified somehow about the control slide, control -

Page 78

DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. And a surgical number would be on it?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. And that surgical number would relate to the patient surgical number.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. Doctor, while I'm on the topic, over the years, approximately how many breast cancer patients, how many ER/PR analysis would be done annually or originating in Gander?
DR. GALLAGHER:
A. Approximately 20 per year.
COFFEY, Q.C.
Q. About one every two and a half weeks.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.
Q. And if it was operated on the basis of chance, I take it that you would then, if there is two

Page 79

of you there, you'd do ten a year.
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.
Q. Which would be less than one a month.
DR. GALLAGHER:
A. That's right.
COFFEY, Q.C.
Q. Doctor, while it's crossing my mind, the example, when we were talking about fixation, we used breast tissue as the example, you utilized, for example, Monday. If Monday was the day of the surgery, was breast surgery in Gander done on any particular day?
DR. GALLAGHER:
A. No, it was done on every day.
COFFEY, Q.C.
Q. So, what would happen if it was done on a Friday, how would this work?
DR. GALLAGHER:
A. Well, the specimen would be cut and would fix over the weekend.
COFFEY, Q.C.
Q. Okay. So, it would be cut, I take it, it would be breadloafed -

Page 80

DR. GALLAGHER:
A. It would be breadloafed and it would fix over the weekend.
COFFEY, Q.C.
Q. Would there ever be instances when breast surgery would occur and it would not be breadloafed on that day because breast surgery occurred later in the day.
DR. GALLAGHER:
A. I don't recall an instance, but that was always a hazard and we tried to avoid that happening by examining the OR sheet which we were given every day from the OR and discussing it with the technologists if there were any breast cases scheduled for the afternoon that might run later than they were present in the laboratory. So, if that happened, we would collect the specimens ourselves and cut them ourselves after the technologists left.
COFFEY, Q.C.
Q. Doctor, was that limited to breast specimens or was there -
DR. GALLAGHER:
A. No, that's for all specimens actually, for all

Page 81

specimens we would attempt to make sure the specimens were opened at the weekend and exposed to formalin.

COFFEY, Q.C.

Q. I take it then that if that occurred, like late in the week, it would be picked up in the process, wherever you were in the process of the following work day, the next work day.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.

Q. Which would be the next regularly scheduled work day, a Monday or a Tuesday depending on whether there was a long weekend.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.

Q. Okay. Doctor, in describing the process, analytic process involving ER/PR, you just went through, internal controls, okay, would you, back in 1998, would be looking for internal controls in relation to ER/PR?

DR. GALLAGHER:

A. My emphasis was on external controls. I was aware of the issue of internal controls, but I

Page 82

relied on the external controls. I did put my emphasis on the external controls.

COFFEY, Q.C.

Q. You say you were aware of it. How would you become aware of it?

DR. GALLAGHER:

A. Well, from my residency training, the issue of internal controls had been mentioned in immmunohistochemistry in general.

COFFEY, Q.C.:

Q. How about, in particular, in relation to ER/PR IHC testing for breast tissue and usage of internal controls there in a particular instance of that?

DR. GALLAGHER:

A. No, I was not aware of it as a particular issue in ER/PR.

COFFEY, Q.C.:

Q. So, Doctor, in 1998, I take it yourself and Dr. Somers -- Dr. Somers would have been away at that point?

DR. GALLAGHER:

A. Yes, Dr. Abdullah was --

COFFEY, Q.C.:

Q. Abdullah.

Page 83

DR. GALLAGHER:

A. Was present at that time.

COFFEY, Q.C.:

Q. And I take it from what you've described to the Commissioner so far, while Dr. Abdullah was there, you can just kind of substitute Dr. Abdullah's name for Dr. Somers.

DR. GALLAGHER:

A. That's right.

COFFEY, Q.C.:

Q. When yourself and -- Dr. Abdullah was doing this as well?

DR. GALLAGHER:

A. He was.

COFFEY, Q.C.:

Q. The ER/PR. When that got up and running then in 1998, what if anything is your next memory then of ER/PR in terms of -- it was a routine thing?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Ordering it.

DR. GALLAGHER:

A. Well, we had no problem that we knew of for

Page 84

the subsequent years up until 2005.

COFFEY, Q.C.:

Q. If we could, please, Exhibit -- actually before I leave this, I'll ask you, Doctor, you did receive this memo. On this particular exhibit, Doctor, there is appended here, and I'm not necessarily suggesting it went to you, okay, back then, there's a document entitled "Immunohistochemical staining of steroid receptors, correlation with biochemistry. A report of our experience over a nine month period, January '97 to September '97", it spells it out, "concordance between immunohistochemistry results and biochemistry results", there are actually 19 of these cases here, and the Commissioner has seen this already, and just to get some sense, Doctor, when we look back at the beginning of this memo in the second paragraph, Dr. Khalifa had said, "Recent audits correlating IHC with biochemical results in selected specimens where both techniques had been running parallel, have shown high accuracy of the introduced IHC detection. Results of these audits have been discussed in several meetings

Page 85

and are available for review". So, Doctor, that actual document here at page four, did you ever receive a copy of that, do you recall?

DR. GALLAGHER:

A. No, I did not.

COFFEY, Q.C.:

Q. This did not actually accompany the memo itself.

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. It was -- I take it here, if one wanted to see the audit, one could ask for a copy?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. Exhibit P-0113, please. Doctor, this is a memorandum from Dr. Ejeckam, April 4th, 2003. It's addressed to pathologists, HSC, St. Clare's, and out of town hospitals, and he writes, "Please note that immunohistochemical stains with the following antibodies", and he lists eight of them and the last two are ER and PR, "have remained unreliable, erratic,

Page 86

and, therefore, unhelpful for diagnostic purposes. Consequent on the above, staining with these antibodies will stop forthwith until we can solve the reliability sensitivity and specificity", I think is what it should read, "problems. Efforts are underway and hopefully a solution will be found within the next four to six weeks. You will be duly informed when such stains can resume". Signed by Dr. Ejeckam, copied to Barry Dyer and all technical staff on immunohistochemistry. Doctor, in 2003, did you receive a copy of this?

DR. GALLAGHER:

A. No, I did not.

COFFEY, Q.C.:

Q. When did you first become aware of this and the 2003 Dr. Ejeckam memos, we're going to look at the next two as well -- when did you first become aware of their existence?

DR. GALLAGHER:

A. I think it was in 2007.

COFFEY, Q.C.:

Q. Doctor, page two of the Exhibit P-0113, the May 2nd, 2003, memo, I take it, Doctor -- this

Page 87

is the one where he begins by saying, "I'm glad to inform you we've rectified the difficulties related to the immunostain of ER/PR. Therefore, we can now resume regular requests for these antibody stains. I will, however, like to bring the following information to your attention", and he goes on for three pages. Did you receive a copy of this in 2003?

DR. GALLAGHER:

A. No, I did not.

COFFEY, Q.C.:

Q. When did you first become aware of this one?

DR. GALLAGHER:

A. Again in 2007.

COFFEY, Q.C.:

Q. Doctor, in 2007 - when did you first actually read it, do you recall?

DR. GALLAGHER:

A. It was late in 2007.

COFFEY, Q.C.:

Q. Now this particular document, the May 2nd one, Doctor Ejeckam does go on at some length about various aspects or potential aspects of estrogen receptors and progesterone receptor

Page 88

IHC testing, and beginning with, "Results of the immunostains may be affected by", and he talks about fixation issues, dehydration, tissue reprocessing, and he talks about optimal fixation times, 10 percent neutral buffer formalin, regularly checking and changing the grades of alcohol in the tissue processor, he indicates would eliminate inadequate tissue dehydration, ER/PR false negative results, increase in core biopsies or limit the request to excision biopsies, check normal breast acini in your sections as internal controls, this is a second level control, nuclear staining of normal breast tissue is heterogeneous and varies with menstrual cycle. He goes on at some length, and you have had a chance since to read this?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, would this have been of some assistance to you, do you believe, in 2003?

DR. GALLAGHER:

A. It's difficult to say looking back now. Most of this information which is very well put

Page 89

together here were things I was aware of at the time.

COFFEY, Q.C.:

Q. And, Doctor, he does in paragraph seven refer to ER positive tumours will tend to or be more likely than not to be positive for ER. He lists four of them and he has indicated he should have listed lobular as well as a fifth. He's told the Commissioner that. Would you have been aware of that?

DR. GALLAGHER:

A. I would have been aware that in general more well differentiated tumours tend to be estrogen receptor positive as a general principle.

COFFEY, Q.C.:

Q. In your practice over the years, would you have been alert to that when you were actually looking at individual cases because you would see only -- you'd only see about ten a year yourself.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Would you have --

Page 90

DR. GALLAGHER:

A. Well, the issue would be if you saw a negative lobular or tubular carcinoma, you'd have to consider whether it was one of the five or ten percent that should be negative when you're seeing so small a number. So it did not affect my practice.

COFFEY, Q.C.:

Q. Doctor, do you know if anyone in Gander received a copy of this memo, the April 4th one?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. I take it you made inquiries in that regard since?

DR. GALLAGHER:

A. No, I did not.

COFFEY, Q.C.:

Q. I take it your assumption would be, though, if it came, I would have seen it?

DR. GALLAGHER:

A. I would have -- I would have been told about it.

COFFEY, Q.C.:

Page 91

Q. Doctor, the reference here in paragraph three, the internal controls issues as being a second level control, were you aware of that and the potential importance of that, we are told at least by certain witnesses, to ER/PR IHC analysis?

DR. GALLAGHER:

A. I wasn't aware that it was so important. I mean, as I said, I thought it was something that was preferable to include if you could on a sample, but I did not regard it at the time as something that was absolutely vital to have on a case.

COFFEY, Q.C.:

Q. And to be fair here, what would you have -- if you had read this at the time, what would you have understood to be a second level control, the meaning of a second level control?

DR. GALLAGHER:

A. A back up control, I guess.

COFFEY, Q.C.:

Q. Because, like, reading the language that is there and comparing it to what you understand now that you just referred to as to the potential significance of internal controls,

Page 92

bearing in mind what you now understand and comparing that understanding to what is written there, would you have gotten your current understanding from what's written there now, do you think?

DR. GALLAGHER:

A. It's hard to say. Perhaps not. We've heard so much about internal controls over the last year that I think if this memo were written today, it would be more strongly emphasized.

COFFEY, Q.C.:

Q. You would think if you were to receive a memo like this today that was to be circulated --

DR. GALLAGHER:

A. Yes, a memo of this type would be.

COFFEY, Q.C.:

Q. So looking at that at the time, and again I appreciate you're saying it's difficult to know hat I would have done looking back in 2003, but it might not have leaped out at you at the time?

DR. GALLAGHER:

A. I don't think it would have, and there is one other thing on this memo, number two, item number two, I think, is a matter of some

Page 93

controversy.
COFFEY, Q.C.:
Q. Yes.
DR. GALLAGHER:
A. In the medical literature, from my limited reading.
COFFEY, Q.C.:
Q. And controversy even continuing to this day?
DR. GALLAGHER:
A. To this very day, yes.
COFFEY, Q.C.:
Q. Doctor, but in any case, I take it that the memo -- receiving the memo couldn't have hurt you back in 2003?
DR. GALLAGHER:
A. No, it's a well written memo, very well written memo.
COFFEY, Q.C.:
Q. Doctor, looking at the first page of the exhibit, would it have been of interest to you at the time in April of 2003 to have known that Dr. Ejeckam in St. John's was describing eight antibodies or the immunohistochemical stains with these eight antibodies were considered by him, anyway, or characterized by

Page 94

him as unreliable, erratic, and unhelpful for diagnostic purposes?
DR. GALLAGHER:
A. Yes, it would.
COFFEY, Q.C.:
Q. If you had received that back then, what do you think your reaction might have been?
DR. GALLAGHER:
A. I think I would have been concerned about the ER and PR, which was something that I was at the time quite confident about.
COFFEY, Q.C.:
Q. And might you have made inquiries of St. John's at the time, do you think?
DR. GALLAGHER:
A. It's possible for sure.
COFFEY, Q.C.:
Q. What's going on here?
DR. GALLAGHER:
A. Yes, what is it -- I might have sought some clarification of what this meant for me.
COFFEY, Q.C.:
Q. Doctor, at the time in terms of -- because up to that point you probably would have reported a case looking at your stats during the

Page 95

previous month. You know, on average you did about one a month?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Do you know whether -- a reported ER and PR case the previous month, might you have made inquiries about, well, what about the one I reported last month?
DR. GALLAGHER:
A. Yes, well, that would be reasonable to think about.
COFFEY, Q.C.:
Q. How about the other six stains that are listed there, would you be utilizing those at the time?
DR. GALLAGHER:
A. No, apart from the possible exception of CEA. The first stain is a keratin stain and it's used mainly in the diagnosis of prostatic carcinoma and we don't see urologic specimens in Grand Falls - in Gander. They see them in Grand Falls. The next four stains are lymphoid markers, and all cases suspicious for lymphoma in Gander are sent to St. John's.

Page 96

COFFEY, Q.C.:
Q. To be dealt with.
DR. GALLAGHER:
A. To be dealt with there, and they read the stains there themselves.
COFFEY, Q.C.:
Q. And that's been going on for many years, I take it?
DR. GALLAGHER:
A. For many years. Dr. Abdullah had an interest in hemapathology, so he would on occasion read some of the lymphoid markers himself, but apart from that that we'd been sending our lymph nodes that are suspicious for lymphoma or that have come up as abnormal on flow cytometry to St. John's for diagnosis, and they read the stains down there themselves. CEA, carcinoma embryonic antigen, is rarely used in my practice. I've rarely ordered it. I doubt if I order it once a year.
COFFEY, Q.C.:
Q. Okay, but the ER/PR, you would be ordering those about once a month?
DR. GALLAGHER:
A. Yes.

Page 97

COFFEY, Q.C.:
Q. Possibly once a month, and as you indicated, because you had no concerns at all about it?
DR. GALLAGHER:
A. That's right.
COFFEY, Q.C.:
Q. So you were quite comfortable, and to receive a memo from a doctor indicating a suspension of that testing and describing it as unreliable, erratic, and unhelpful, might have -- I don't want to overstate it, but it might have alarmed you?
DR. GALLAGHER:
A. It might have, yes.
COFFEY, Q.C.:
Q. Doctor, I take it then that in the spring of 2003, April, 2003, you've indicated you thought or understood that there were no problems with ER/PR that you were aware of, you were confident with it, that continued right up until 2005?
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. And your practice didn't change, what you

Page 98

described for the Commissioner, from '98 onward really?
DR. GALLAGHER:
A. It did not change.
COFFEY, Q.C.:
Q. Doctor Ejeckam, did you have any understanding as to who he was?
DR. GALLAGHER:
A. Not at the time. I knew he was a physician who had come from the Middle East to work in St. John's, and that's really all I knew.
COFFEY, Q.C.:
Q. Did you subsequently learn anything further about him as time went on, about his involvement in immunohistochemistry?
DR. GALLAGHER:
A. Not until after I came back from Calgary.
COFFEY, Q.C.:
Q. Okay, that was -- so that was even after May of '05, that's after -- it's, in fact, in 2007?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. When you became aware of Dr. Ejeckam's

Page 99

involvement in this whole matter?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And at the time -- in fact, you've indicated it was late '07 when you saw the memos?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. So that's when you would have learned about it?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Okay. I take it, Doctor, while we're on the topic, page five, June 19th, 2003, Dr. Ejeckam memo, was not addressed to you, so normally it wouldn't have come to you and you wouldn't have been aware of this back in 2003?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. You would have become aware of this in 2007?
DR. GALLAGHER:
A. This memo --

Page 100

COFFEY, Q.C.:
Q. And perhaps not even then.
DR. GALLAGHER:
A. I think I might have become aware of in 2008, actually.
COFFEY, Q.C.:
Q. Doctor, could you tell us, please -- actually, Commissioner, I'm going to move on now to the 2005. So we'll have the morning break, if we would, and we'll come back and continue, Doctor. Thank you.
COMMISSIONER:
Q. Take fifteen minutes.
(BREAK)
COMMISSIONER:
Q. Mr. Coffey.
COFFEY, Q.C.:
Q. Thank you, Commissioner. Doctor, in the period between 1998 and 2005, May, 2005, or June in your case, June, 2005, did you ever hear of any concerns being expressed about ER and PR staining in St. John's?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:

Page 101

Q. About IHC staining in general?
DR. GALLAGHER:
A. No, I did not.
COFFEY, Q.C.:
Q. Doctor, the matter that brings us here overall, when did you first become aware or hear about this and how, do you recall?
DR. GALLAGHER:
A. I recall several telephone conversations I had with Dr. Cook and Dr. Carter over the summer of 2005 regarding a problem with the Ventana machine and some problems with correlating that to the results on the DAKO machine.
COFFEY, Q.C.:
Q. Okay. If we could bring up Exhibit, please, P-0492? And Doctor, this is a memo to all laboratory directors beginning with Dr. Fontaine, and you're there, you're number four on the list. Actually it's Dr. F. Gallagher, which is I take it the initial of your proper first name.
DR. GALLAGHER:
A. That's correct, yes.
COFFEY, Q.C.:
Q. And it's dated June 14th, 2005. It's from Dr.

Page 102

Cook. It's re: estrogen and progesterone receptors and I want to ask you, did you receive a copy of this?
DR. GALLAGHER:
A. I don't know whether I did. I don't have a copy of it, but I know I discussed its contents at around this time with Dr. Cook.
COFFEY, Q.C.:
Q. And do you recall why or how it was you came to discuss this with Dr. Cook? Did he call you, you call him?
DR. GALLAGHER:
A. I think he called me.
COFFEY, Q.C.:
Q. And I take it just to talk to you generally about what was going on here?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall what he told you? This is looking for all your 2002 slides. I'm sorry, blocks, slides.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:

Page 103

Q. Reports.
DR. GALLAGHER:
A. Well, I don't recall in detail what he told me, but all I can remember is that there was an issue with the Ventana machine in that it was producing different results from the DAKO machine, and they wanted to check and see why this was. So they needed to review these cases to do so.
COFFEY, Q.C.:
Q. Now, so the idea that the--the assertion "we are aware of a number of negative estrogen and progesterone receptors that have converted on repeat testing with the Ventana," that's consistent with that, that the Ventana being utilized, for some reason, to retest earlier cases?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And was giving different results for some negatives?
DR. GALLAGHER:
A. My impression at the time was that this was a relatively limited problem involving the

Page 104

introduction of new technology.
COFFEY, Q.C.:
Q. And he refers to now, here, he says, it's the third line, this new Ventana system is fully automated, much more sensitive than the technique under the previous DAKO method. "Most of these false negatives have occurred during the year 2002." Did you have any understanding as to when the Ventana had been first come on stream in St. John's?
DR. GALLAGHER:
A. No, I did not know that.
COFFEY, Q.C.:
Q. Do you recall whether or not Dr. Cook said or told you why they were concentrating on 2002?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. At the time, Doctor, in your initial contact with Dr. Cook and then Dr. Carter, from your perspective in Gander, how much did this involve you and your institution?
DR. GALLAGHER:
A. Well, it involved a considerable number of cases potentially. We had never received a

Page 105

request like this before. So it was an unusual request.

COFFEY, Q.C.:

Q. And I appreciate that. How about implications or ramifications for your own 2002 cases? Did you have any sense at the time that there was a potential for Gander's 2002 ER and PR cases to convert upon retesting?

DR. GALLAGHER:

A. I did not think of that at the time. I was not alarmed at the time.

COFFEY, Q.C.:

Q. And that's what I'm--it was an unusual request, but it didn't alarm you?

DR. GALLAGHER:

A. No, I thought it was a machine related issue, involving the processor, and I was not alarmed at the time, but I was a little bit uncertain as to how we would go about gathering up all this material and sending it in.

COFFEY, Q.C.:

Q. Did you make any inquiries of Doctors Cook or Carter about what should be sent in? In particular, I'll try to assist you in that regard, Exhibit P-2360, please?

Page 106

DR. GALLAGHER:

A. Doctor, this is an e-mail of July 25th, 2005. It's from Dr. Carter, Beverley Carter, to yourself. She writes "1997-"--it 2204 and presumably it should be 2004 and you would have understood it that way, "ER negative, don't care about PR. ER/PR slides, controls and the H & E of that block, that block report. I'm looking at the logic, type, grade, internal controls, external controls, date of testing." Signed Beverley Carter. Because you had written to her an e-mail the day before, July 24th, saying "I just wanted to check again the criteria on the breast cancers that you want us to send to St. John's, January '97 to December 2004. ER and PR negative, both negative, block HE slide, ER/PR slides and report."

So Doctor, here, you're not certain you actually received the June 14th memo, but you may have, and in any case, you did discuss its subject matter with Dr. Cook?

DR. GALLAGHER:

A. Yes, and what happened between my first discussion with him and my e-mail, I honestly

Page 107

can't exactly recall, but I do know that I had subsequent conversations with one or both of them and the scope of the review expanded rapidly and it became obvious that this was a much more serious problem than I had first realized.

COFFEY, Q.C.:

Q. And you would have become aware of that during your conversations with Doctors Carter and Cook?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Because as best, and I stand to be corrected on this, but as best I can see in the material we've looked at to date, this is the first communication involving a pathologist outside St. John's, involving Doctors Carter and Cook, that suggests that a doctor outside St. John's was aware of the expanded scope, in the sense of--because the actual memo looking for your slides from '97 through 2004 doesn't come until September.

DR. GALLAGHER:

A. Yes.

Page 108

COFFEY, Q.C.:

Q. And you recall that?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. So by the end of July, well certainly by July 24th, because--or based upon your conversations with Doctors Cook and Carter, you had come to the understanding that they were looking for the--your material from January of '97 to December of '04?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And Doctor, in terms of the matter potentially being more serious, what had led you to that conclusion or thought or impression?

DR. GALLAGHER:

A. Well, from my conversations, I gathered the impression that this wasn't just a transition problem between the two machines involving a small number of cases. This was going to be a very wide ranging review of cases from across the province, and that this would obviously involve our cases and what we had done with

Page 109

those cases. So clearly, the scope of the review had changed.

COFFEY, Q.C.:

Q. If it wasn't a machine or solely a machine problem, switch over from one machine to the other, did you have any understanding of what it might involve, what it might be related to, if it wasn't machinery?

DR. GALLAGHER:

A. I had no clear understanding at the time what else it involved.

COFFEY, Q.C.:

Q. Doctor, up to this point, in June/July 2005, you would have, of course, known that over the years that Dr. Khalifa had long since left St. John's?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. He left St. John's in 1999, we understand. Doctor, what was your understanding about how the external controls were being handled for ER/PR related to his memo of February 1998, after he left? What was your understanding about what had happened?

Page 110

DR. GALLAGHER:

A. Well, I assumed the same practice had continued, that these were being checked before being released to us.

COFFEY, Q.C.:

Q. Doctor, when you would send--I take it then as time went on with ER/PR in '98, '99, we understand there were requisition forms used?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. To order ER/PR?

DR. GALLAGHER:

A. Yes, that's right.

COFFEY, Q.C.:

Q. And this form, kind of in a bundle of forms, was circulated out of St. John's?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. And you'd circle what you wanted, be filled in. Doctor, would you get the forms back?

DR. GALLAGHER:

A. Yes, with the case.

COFFEY, Q.C.:

Page 111

Q. Occasionally on the forms, would there be any reference to the controls being checked, do you know?

DR. GALLAGHER:

A. I don't recall that.

COFFEY, Q.C.:

Q. So you understood that they were being checked, if not by Dr. Khalifa, then by his successor?

DR. GALLAGHER:

A. I did, yes, or by somebody designated by them.

COFFEY, Q.C.:

Q. Would you always get an external control slide for ER and PR?

DR. GALLAGHER:

A. I only recall one instance when I didn't.

COFFEY, Q.C.:

Q. And because it stands out, I take it?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And what happened in that instance?

DR. GALLAGHER:

A. I phoned to ask for the controls and they sent it to me.

Page 112

COFFEY, Q.C.:

Q. Doctor, do you ever recall encountering any problems with the external control slides, from your perspective?

DR. GALLAGHER:

A. I did not encounter a problem with the controls.

COFFEY, Q.C.:

Q. How about ER and PR slides themselves?

DR. GALLAGHER:

A. I thought they were all adequate.

COFFEY, Q.C.:

Q. Did you ever request any to be rerun?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. So repeats, as it were.

DR. GALLAGHER:

A. I did not.

COFFEY, Q.C.:

Q. Now I take it, when the external control slides would come out from St. John's, and even on the time you looked for it, you would check them when they came?

DR. GALLAGHER:

Page 113

A. Yes.
COFFEY, Q.C.:
Q. You weren't just relying upon Dr. Khalifa's assurance?
DR. GALLAGHER:
A. No. No, I would check them.
COFFEY, Q.C.:
Q. And you don't--in your own case, you don't ever recall actually asking for a repeat?
DR. GALLAGHER:
A. No, I do not.
COFFEY, Q.C.:
Q. How about were you aware of whether or not Dr. Abdullah or Dr. Somers ever asked for a repeat, to your knowledge?
DR. GALLAGHER:
A. Not to my knowledge. I did not ask them, but not to my knowledge.
COFFEY, Q.C.:
Q. You don't recall -
DR. GALLAGHER:
A. They've never told me.
COFFEY, Q.C.:
Q. They never told you that.
DR. GALLAGHER:

Page 114

A. They never told me they had a problem or they had to request a repeat.
COFFEY, Q.C.:
Q. Doctor, just looking at your--or this exchange of e-mails, July 24th and 25th, what then happened? Because I mean, we've gone from 2002, the middle of June memo, June 14th memo, to at least in your e-mail exchange there with Dr. Carter by the end of July, we're into '97 to '04. Up to the end of July, had you gone looking for the 2002 patients?
DR. GALLAGHER:
A. I think we had barely started that. We had-- I'm not even sure whether we had done our searches or what we had done. We didn't have much of a sense of urgency about that issue, because it didn't seem like a very pressing matter.
COFFEY, Q.C.:
Q. And the impression, at least, you were left with was there was no urgency to get this done that week or the next?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:

Page 115

Q. And this would have been summer time with, I take it, reductions in staff, vacations and so on?
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. When you did become of the expanded scope of this and potential for it to be more serious, what then happened in terms of looking for patients' material?
DR. GALLAGHER:
A. We started a Meditech set of searches to try and identify everybody who might be affected.
COFFEY, Q.C.:
Q. Doctor, did you start that before September?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Okay, you were actually, having received this e-mail from--or having sent your--having talked to Dr. Carter -
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. - and confirmed something in writing with her

Page 116

in the e-mail -
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. - you then embarked upon this search?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Now could you tell the Commissioner then what challenges you faced at the time, if any, but how you went about it and what challenges you faced?
DR. GALLAGHER:
A. Well, we were fortunate that our Meditech system went online in 1995. So we didn't have to do any manual searching. But there were challenges in terms of how the reports were phrased and the terms used in the reports, which even though we were using the synoptic reporting of Dr. Khalifa, there were still some variations in the way we would report cases, some slight changes in terminology or words, and that could cause difficulties for capturing cases. Basically, we started by doing a search for breast, all breast cases

Page 117

within these years, and then we looked for breasts and carcinomas, and then we looked for breasts, carcinomas and hormone receptors, and then we saw how many of the first two groups might contain a few cases that the last group missed, and we compiled a list and then checked through the three lists we had, the three searches we had, to see that everybody was on it.

COFFEY, Q.C.:

Q. And having compiled then a list or a total, a full list that you were satisfied contained the patients, all the patients, what did you do then?

DR. GALLAGHER:

A. We then began to gather up the blocks and slides to be sent to St. John's.

COFFEY, Q.C.:

Q. Doctor, when you were made aware of the initial request involving 2002, did you pass that on to your superiors in the hospital?

DR. GALLAGHER:

A. No, I did not.

COFFEY, Q.C.:

Q. And I take it you didn't do so because you

Page 118

didn't see it as urgent or in fact all that significant at the time?

DR. GALLAGHER:

A. I did not appreciate its significance at the time.

COFFEY, Q.C.:

Q. How about when you got this, by the end of July when you realized that there was an expanded scope to this?

DR. GALLAGHER:

A. I believe we spoke to Dr. Alteen sometime in August or September, I'm not exactly sure when, but we spoke to him or communicated with him at some point over those two months.

COFFEY, Q.C.:

Q. And in terms of supplying or responding to the request from St. John's, which is evidenced in Exhibit P-3260, P-2360, it's at the top of the page there, the exhibit number.

DR. GALLAGHER:

A. Oh yeah.

COFFEY, Q.C.:

Q. Doctor, who was primarily responsible for doing that within your organization, for organizing it?

Page 119

DR. GALLAGHER:

A. For organizing the sending it, well, it was organized by--in terms of it being sent, by our pathology secretary. She would have sent the cases.

COFFEY, Q.C.:

Q. Okay. How about identifying them?

DR. GALLAGHER:

A. Myself and Dr. Somers and the technologists would identify the blocks and slides.

COFFEY, Q.C.:

Q. And I take it, identify the search criteria initially for Meditech?

DR. GALLAGHER:

A. The search criteria I decided, along with help from our information systems people.

COFFEY, Q.C.:

Q. So you did go to the IT technical folks?

DR. GALLAGHER:

A. Yes, I did. I did consult with the IT technical people.

COFFEY, Q.C.:

Q. And were they of any assistance?

DR. GALLAGHER:

A. They were.

Page 120

COFFEY, Q.C.:

Q. And Doctor, while I'm on the subject, of course, you'd be aware that there have been issues raised publicly and there's been evidence before this Commission concerning patients subsequently identified that were missed the first time round.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Has that occurred in your institution? Were there any patients missed?

DR. GALLAGHER:

A. It has.

COFFEY, Q.C.:

Q. And how--when were they identified and how did that come about?

DR. GALLAGHER:

A. In 2008, Grand Falls identified one case and then subsequently a second one, and our CEO, Karen McGrath, asked us to do another search to make sure we hadn't missed any. So we went back and did another search and we found a male with breast cancer and we realized that the first search had been restricted to

Page 121

females.
COFFEY, Q.C.:
Q. And that was utilizing the criteria initially?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Three categories were all limited initially to females?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Who fall into one of these three categories?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And I take it that--was that patient--in 2008, was that patient's tissue then analyzed?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And the patient notified?
DR. GALLAGHER:
A. The patient was deceased.
COFFEY, Q.C.:
Q. Deceased. Doctor, and in fact, there is the

Page 122

one patient and that's it?
DR. GALLAGHER:
A. That's it.
COFFEY, Q.C.:
Q. Doctor, having identified the patients in the summer and early fall of 2005, was there any problem in actually locating the blocks themselves and the slides?
DR. GALLAGHER:
A. Not too much of a problem. I mean, some of them are in different places, obviously going back that far, but we managed to locate them all eventually. We, of course, ran into some difficulties with that, but we managed to locate them in the end.
COFFEY, Q.C.:
Q. And they were then, i take it, packaged and sent off to St. John's?
DR. GALLAGHER:
A. Yes, they were packaged and sent off in several batches. We were talking to St. John's again subsequent to that, as to what they wanted, in terms of criteria. So they were packaged and sent off in, I think, three batches over the next two months.

Page 123

COFFEY, Q.C.:
Q. With a view to, I take it, just getting the process started?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, we understand that in August of 2005, at least in St. John's, ER/PR testing stopped, August 8th, August 9th, 2005. When did you first become aware of that?
DR. GALLAGHER:
A. Dr. Cook told me and I think I got a letter about that.
COFFEY, Q.C.:
Q. Okay, so -
DR. GALLAGHER:
A. A communication of some sort.
COFFEY, Q.C.:
Q. - you would have spoken to Dr. Cook?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Give you a heads up, as it were.
DR. GALLAGHER:
A. Yes.

Page 124

COFFEY, Q.C.:
Q. Okay, and could--throughout the summer of 2005 and in the fall of 2005, Doctor, other than Doctors Cook and Carter, were you speaking to any other pathologists in Newfoundland about this? Well, obviously Dr. Somers, and I appreciate that.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. But anybody, any of the other doctors?
DR. GALLAGHER:
A. I think I may have spoken to Dr. Dalton just casually about our concerns.
COFFEY, Q.C.:
Q. And at the time, what did you express to him about what concerns you had?
DR. GALLAGHER:
A. Well, just how large a review this was and how alarming it was at the time.
COFFEY, Q.C.:
Q. By that point, Doctor, did you have any understanding from St. John's, your communications with St. John's, about how many or the extent of the conversions that had

Page 125

occurred?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. Did you have any understanding, given any understanding as to the extent of the investigation that was going on in St. John's, and in fact, the nature of it?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. In terms of like the idea that in July, that Dr. Carter had planned to do a full review of all cases?
DR. GALLAGHER:
A. No, I did not know that.
COFFEY, Q.C.:
Q. Okay. Then what, Doctor, then did you learn about--when did you first--what did you understand by September was actually going to happen? What was your impression or understanding?
DR. GALLAGHER:
A. My understanding was that the cases would be sent to Mount Sinai for retesting and the

Page 126

cases would then come back to St. John's and decisions would be made regarding the management of the patients who converted.
COFFEY, Q.C.:
Q. And those decisions then would be communicated to whom? To the patients how? Would they come back through your hospital?
DR. GALLAGHER:
A. My understanding was--I'm not sure exactly when it occurred, but my understanding was that a panel would be set up that would deal with those issues.
COFFEY, Q.C.:
Q. So I take it initially, from your perspective, in late July, August and September of '05, the initial concern is identifying the patients and getting the material and getting it out to be retested?
DR. GALLAGHER:
A. Yes, exactly, we were just in a frantic rush to try and get all this material together and make sure it was correct, make sure we didn't miss anybody, and get it down to St. John's as soon as possible.
COFFEY, Q.C.:

Page 127

Q. Exhibit P-0590, please? Now Doctor, this is a memo of September 6th 2005. It's to all laboratory directors and you're listed there.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And you would have received this memo from Dr. Cook?
DR. GALLAGHER:
A. Yes. Yes, I did.
COFFEY, Q.C.:
Q. And in the meantime, you would have spoken with him in the intervening time period?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, Dr. Cook during those communications with you, told you anything about what he had--any of his observations up to late August, early September, observations concerning, for example, fixation issues?
DR. GALLAGHER:
A. Not to my recollection.
COFFEY, Q.C.:
Q. So if he had gleaned or come up with some

Page 128

information or come to some conclusions himself, he didn't pass those on to you at the time?
DR. GALLAGHER:
A. I don't recall if he did.
COFFEY, Q.C.:
Q. And do you think if in fact he had, like he had attributed some cause or causes to this that you would remember that?
DR. GALLAGHER:
A. Yeah, there was no forceful statement that fixation is a number one or big problem.
COFFEY, Q.C.:
Q. Is an issue. Or internal controls or usage or non-usage of internal controls?
DR. GALLAGHER:
A. No, the details on that, I don't recall as being said as an issue at that time.
COFFEY, Q.C.:
Q. And I'm going to suggest to you, Doctor, that if in fact it had been said to you or brought to your attention at the time in a context of everything that's happened here, bearing in mind what you were being asked to do at the time, you'd remember that?

Page 129

DR. GALLAGHER:
A. I think so, I think I would have.
COFFEY, Q.C.:
Q. Doctor, what then was happening, we looked through this, I'm just going to look to the second page, I'm sorry. On the second page, Dr. Cook says that "the Laboratory Medicine Program is currently undergoing a quality review process" and it says, "note the following changes, there's a hold on reporting of ER/PR by pathologists in St. John's, all current requests for ER/PR going to Mount Sinai for IHC processing, interpretation and reporting, you may elect to directly refer your ER and PR to Mount Sinai or to a laboratory of your choice." Did you take him up on that, Doctor?
DR. GALLAGHER:
A. Yes, yes, I did.
COFFEY, Q.C.:
Q. And you communicated with, I take it Dr. Brendan Mullen?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:

Page 130

Q. And the Commissioner has already seen a letter, a communication from Dr. Mullen to yourself?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And then you, I take it then on your current cases, on a go-forward basis, that's what was done with them?
DR. GALLAGHER:
A. Since that time they have all been sent to Mount Sinai.
COFFEY, Q.C.:
Q. While I'm on the topic, Doctor, that continues to this day?
DR. GALLAGHER:
A. It does.
COFFEY, Q.C.:
Q. Doctor, how has the service been?
DR. GALLAGHER:
A. We've been very happy with it.
COFFEY, Q.C.:
Q. Doctor, have you been invited at any time or your hospital, has it been invited at any time to resume using St. John's?

Page 131

DR. GALLAGHER:
A. Yes, I believe we were.
COFFEY, Q.C.:
Q. And do you recall when that was?
DR. GALLAGHER:
A. I think it might have been in '06 when I was away.
COFFEY, Q.C.:
Q. Okay, so you've learned of this since you came back.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. You were gone in fact, all of '06.
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. And you came back when in '07?
DR. GALLAGHER:
A. May 23rd.
COFFEY, Q.C.:
Q. Halfway through the--the day after the announcement of the Commission of Inquiry, as it turns out.
DR. GALLAGHER:

Page 132

A. Oh.
THE COMMISSIONER:
Q. We weren't the only ones that (inaudible).
COFFEY, Q.C.:
Q. But, Doctor, then and you've been practising, of course, for the past--resumed practice in Gander over the past year, in doing so.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Has any consideration been given during that time period to resuming utilization of St. John's for ER/PR testing?
DR. GALLAGHER:
A. Well we have considered it and I think we decided to stay with Mount Sinai for the present time. As I've said before, our preference long term would be for testing within the province because that's the best way to practice cancer care, to have all the tests done within the same system, that's the ideal way to do it. We knew that St. John's were very busy and they had a considerable shortfall in staff in the pathology side, so we felt that they were quite overburdened at

Page 133

that time and secondly, we felt we should wait until the inquiry was over.

COFFEY, Q.C.:

Q. By the time you arrived back on the scene and actually got back to work, the inquiry process had been announced and you understood that that would continue on and eventually, I don't know if you understood you would eventually be here, but you certainly understood that there would be a process and there'd be some result from it?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And the decision was made considering all aspects of the matter, including that you should wait to see how things turned out.

DR. GALLAGHER:

A. Exactly.

COFFEY, Q.C.:

Q. And, Doctor, meantime, returning then to the memo, and I will be coming back to the '07 events after you returned to work in Gander. Doctor, here the first bullet on the first page says "requesting you for all the ER

Page 134

negative cases and primary breast lesions, independent of PR status from May of '97 to March 31, '04." And you look at the last bullet on the first page, it then takes up the narrative, "All the ERs and PRs performed on the Ventana system from April 1, '04 to August 9, '05, would also be referred to Mount Sinai for retesting. You can also forward these cases to Barry Dyer." Well, sir, what did you understand then about what was going on here in terms of why the division, as of April 1, '04?

DR. GALLAGHER:

A. I didn't know at the time why that division occurred?

COFFEY, Q.C.:

Q. And in terms of the first bullet, I take it over this timeframe, May '97 to March 31, 2004, you're to go searching for all ER negative cases.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And then they're defined in a certain way here, in the second bullet. Did you make any

Page 135

inquiries about the basis for that definition?

DR. GALLAGHER:

A. No, I found out about the definition while we were undergoing our searches because we were pulling, all the negatives up to 30 percent, but I did not ask why. I just accepted that that had been defined in that way for some reason and I just pulled the cases.

COFFEY, Q.C.:

Q. Now here he says, as you have indicated, you were pulling all negatives, which is 30 or less, I take it.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Here, though, he says from January 1, '01 onward to the, I suppose to March 31, 2004, defined as ten percent or less. What about the cases in 2001 and 2001 and 2003 that were, for example, 20 percent? Would you have sent them into St. John's?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. So initially it was 30 and less, across the

Page 136

board, going back to Dr. Carter's e-mail exchange, and then when you go this memo from January 1, 2001 onward, only the ERs of 10 percent or less were sent?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. That's the way you, you filtered them out.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, what about the deceased patients, was any effort made at that point to identify the deceased and were they being sent to St. John's for retesting as well?

DR. GALLAGHER:

A. They were all sent.

COFFEY, Q.C.:

Q. Okay, in your case.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. You didn't distinguish between -

DR. GALLAGHER:

A. No. We saw this as a laboratory test, first

Page 137

of all, to determine the effectiveness of the test and the clinical implications and the treatment implications would be handled down the road.

COFFEY, Q.C.:

Q. Now, Doctor, at the time this was going on, you were engaged in this effort to identify the patients and to gather up the material to be sent, what was the situation in terms of whether or not the attending physicians were notified about the fact that this was even going on, the primary care physicians, you know what I'm getting at?

DR. GALLAGHER:

A. We did not notify them.

COFFEY, Q.C.:

Q. Were you asked not to or it didn't occur to you not to? Or it didn't occur to you to do so, I'm sorry.

DR. GALLAGHER:

A. I guess it did not occur to us to do so or for me to do so, I saw this as a province-wide review and I didn't feel that I had to do so at the time.

COFFEY, Q.C.:

Page 138

Q. Doctor, in terms of within your organization actually notifying patients, who was responsible as time went on for doing that?

DR. GALLAGHER:

A. That was handled by Dr. Alteen.

COFFEY, Q.C.:

Q. Okay, and we'll be hearing from Dr. Alteen eventually, so as a pathologist, you were not--you didn't see that as part of your mandate, nor were you asked to get involved in that.

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. The identification of all ERs and PRs from April 1, '04 to August 9, '05, which would include positives and negatives. Were they identified and sent to St. John's?

DR. GALLAGHER:

A. We only sent the negatives at that time.

COFFEY, Q.C.:

Q. Okay, why was that?

DR. GALLAGHER:

A. I think we misinterpreted the memo.

COFFEY, Q.C.:

Q. You assumed that it was the false negatives

Page 139

was what they were concerned about.

DR. GALLAGHER:

A. Yeah.

COFFEY, Q.C.:

Q. It's limited to negatives.

DR. GALLAGHER:

A. I guess we were so pre-occupied with the negatives from our previous communications with St. John's, that we thought it was only the negatives that they wanted.

COFFEY, Q.C.:

Q. And did you ever get any complaints from St. John's about not sending the positives?

DR. GALLAGHER:

A. No, we did not.

COFFEY, Q.C.:

Q. And the Commissioner has already heard that eventually it got limited to the negatives anyway, on the retesting, and you understood that, I take it as time went on.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. There's a reference then to what you should concentrate on, what particular periods. Did

Page 140

you follow that?

DR. GALLAGHER:

A. No, we just pulled everything.

COFFEY, Q.C.:

Q. There's a reference here to "we will return all blocks and slides as soon as possible". To this day, have you received the blocks and slides back?

DR. GALLAGHER:

A. I don't think we've received any of them back.

COFFEY, Q.C.:

Q. Doctor, what then happened in terms of your involvement and your lab's involvement as time went on then? You've identified the patients, gathered the material, sent it to St. John's, what then happened?

DR. GALLAGHER:

A. Well we had several discussions with administration about what was going to happen subsequently and the setting up of the panel that would decide on treatment of these patients, and how the patients were going to be informed. And after that, we basically waited for the results to come back.

COFFEY, Q.C.:

Page 141

Q. And when did they first come back, do you recall?
DR. GALLAGHER:
A. I believe they started coming back in February. The results, I believe, some of them were actually brought back to St. John's in November, but I think we first got our results in February.
COFFEY, Q.C.:
Q. Now, Doctor, were you aware in the fall of 2005 that there was a pathologist from British Columbia or at least a pathologist, an outside pathologist asked to come in and examine the situation in St. John's and a technologist from Toronto?
DR. GALLAGHER:
A. No, I was not aware.
COFFEY, Q.C.:
Q. As it turns out, Dr. Banerjee and Trish Wegrynowski.
DR. GALLAGHER:
A. Other than being told there was some sort of review here, I was not aware of anything in specific terms about that.
COFFEY, Q.C.:

Page 142

Q. And this, on the second page, you're referring to, in this sentence "The Laboratory Medicine Program for St. John's hospital is currently undergoing a quality review process."
DR. GALLAGHER:
A. I did not know who they were.
COFFEY, Q.C.:
Q. And that's as far as--as much as you knew about it?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And that's both in writing or verbally?
DR. GALLAGHER:
A. That's right.
COFFEY, Q.C.:
Q. When did you first hear that there was this external or there were these external reviews?
DR. GALLAGHER:
A. It would have been in '07. I think--yes, in '07, yes.
COFFEY, Q.C.:
Q. Doctor, what then happened, because I understand you left Gander when?
DR. GALLAGHER:

Page 143

A. I finished work near the end of November and I went to Calgary in December of '05.
COFFEY, Q.C.:
Q. Of '05. And you have told the Commissioner you understand that the results came back to--Gander's results on the retest came back in February of '06.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Did you keep in touch with the hospital in Gander as to what was going on with respect to this?
DR. GALLAGHER:
A. Occasionally I did, yes.
COFFEY, Q.C.:
Q. If I could, please, Exhibit P-0076 please? Now in your--well I'll ask you, Doctor, in your absence, who was in charge then of the lab from a pathologist perspective in Gander?
DR. GALLAGHER:
A. Dr. Somers.
COFFEY, Q.C.:
Q. And this is a memo, Doctor, of July 28th, 2005, it's not addressed to yourself. It's

Page 144

addressed to all pathologists and pathology residents in Eastern Health, okay. And the subject matter is "Re: optimal assessment and reporting of hormone receptor status in infiltrating carcinoma." And it's drafted with the signatures of Drs. Cook and Carter. There are nine numbered paragraphs and it begins by saying, "When ordering and reporting ER/PR status on infiltrating carcinoma of the breast"--and there's kind of a checklist, as it were of what to do and what to look for, and did you receive a copy of this?
DR. GALLAGHER:
A. No, I didn't.
COFFEY, Q.C.:
Q. Were you aware of it?
DR. GALLAGHER:
A. No, I was not aware of it. This is the first time I've seen it.
COFFEY, Q.C.:
Q. I'll ask you this, take your time, just glance down through it or read down through it. And at the time, bearing in mind the date of the memo, late July which is several days after your e-mail exchange with Dr. Carter, we

Page 145

looked at earlier, might this have been of some assistance to somebody such as yourself?

DR. GALLAGHER:

A. I think it would have been. Obviously the issue of internal controls in a subject like immunohistochemistry evolves and moves from being something that's debated and queried as to its validity in the early years, to being something that becomes more or less mandatory by this stage and this memo is quite explicit about how one should go through looking at these cases. I think it would have been useful.

COFFEY, Q.C.:

Q. And, Doctor, here--and in fact, to this day have you seen any memo like this, or even any one like this in the sense of kind of spelling this out?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. And do you think if Dr. Somers had received any such memo or one like it, that it would have been brought to your attention upon your return?

Page 146

DR. GALLAGHER:

A. I think so, it's a well written memo, very explicit.

COFFEY, Q.C.:

Q. It's succinct.

DR. GALLAGHER:

A. It is.

COFFEY, Q.C.:

Q. Doctor, and the general subject matter, as you've pointed out, the significance of internal controls, potential significance of internal controls and so on and these sorts of details, they did not come up during your conversations with Drs. Cook or Carter throughout 2005, that you recall?

DR. GALLAGHER:

A. Not in this fashion, I mean, it's really spelled out here.

COFFEY, Q.C.:

Q. Now, Doctor, while you were away, while you were in Calgary did you have--I have asked you whether or not you kept in touch, as it were, were you asked for any input while you were away?

DR. GALLAGHER:

Page 147

A. No, I was not.

COFFEY, Q.C.:

Q. Did you offer any?

DR. GALLAGHER:

A. No, I did not.

COFFEY, Q.C.:

Q. Have you since your return, have you become aware of the results for the James Paton Hospital, ER/PR retest results, have you become aware of them?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And have you kind of looked at them analyzed them?

DR. GALLAGHER:

A. I have looked at them, yes.

COFFEY, Q.C.:

Q. And what, if any, observations have you made? Of course, I don't want to talk about individual patients, but -

DR. GALLAGHER:

A. Well there were, of course, two sets of assessments made on the original slides and on the re-cut slides, so there were cases that

Page 148

were described as poorly fixed. In the re-cut slides, the incidents was 3.8 percent.

COFFEY, Q.C.:

Q. 3.8 percent were?

DR. GALLAGHER:

A. Poorly fixed.

COFFEY, Q.C.:

Q. Were described as poorly fixed, the block was poorly fixed.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And there were internal controls that were missing on some of the slides.

COFFEY, Q.C.:

Q. And in relation to some of those slides, the ones the internal controls were missing, did any of those fall under the category of conversions, that upon retest converted, do you recall?

DR. GALLAGHER:

A. I don't know.

COFFEY, Q.C.:

Q. And, Doctor, the idea or the observation that some of the original blocks did not contain

Page 149

tissue to be utilized as internal controls, were you surprised by that, bearing in mind what you've told us earlier today?

DR. GALLAGHER:

A. No, I was not.

COFFEY, Q.C.:

Q. Because you were not concentrating on that at the time?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. Any other observations, Doctor?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. Doctor, fixation or issues involving--potential issues involving fixation, okay, Doctor, were you aware of any--was any issues of fixation, were you aware of or were they brought to your attention prior to 2005?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. So it's really only since you returned to work in 2007.

Page 150

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. That it's become brought to your attention. So 3.8 percent, that's a calculation you've done yourself, I take it, is it?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. It's about--how many patients are we talking about in overall that were retested, because again, in terms of Gander you're only talking about 20 or so a year, so how many patients from Gander would have been retested?

DR. GALLAGHER:

A. 75 in total.

COFFEY, Q.C.:

Q. And so 4 percent of that is about what, 3 patients or so?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Quick calculation. Doctor, have you become aware of Dr. Banerjee's and Trish Wegrynowski's reports?

Page 151

DR. GALLAGHER:

A. I saw Dr. Banerjee's report on the inquiry website and I read Trish Wegrynowski's report last night.

COFFEY, Q.C.:

Q. Of course, Trish Wegrynowski's report you would have understood related to the St. John's laboratory?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. She certainly didn't visit Gander to your knowledge?

DR. GALLAGHER:

A. That's right.

COFFEY, Q.C.:

Q. I'll ask you first of all, in terms of Ms. Wegrynowski's report, did you look at both of them? Because there are two, there's--are you aware that there were two reports by Ms. Wegrynowski?

DR. GALLAGHER:

A. I looked at the second report because there was references to things that had not been followed up, so I think I saw the second

Page 152

report.

COFFEY, Q.C.:

Q. You would have read the 2006 report then. I'll bring it up, I believe it's -

DR. GALLAGHER:

A. Certainly I saw the second report, I'm not sure if I saw the first report as well.

COFFEY, Q.C.:

Q. P-0047, it's the second one--P-0048, and this, Doctor, this is the one you would have looked at last night?

DR. GALLAGHER:

A. Yes, that's it.

COFFEY, Q.C.:

Q. I take it, as you pointed out just now, you were looking at it, amongst other things, perhaps what had not yet been done from her perspective in the spring of '06.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, and of course, when we look through this, I'm not going to take you through this in detail, but when we read this, because the Commissioner has seen it already, there are

Page 153

references to this, of course, to her earlier report and what she found or said in her earlier report as well. Doctor, from your perspective what was your overall impression? Were you surprised.

DR. GALLAGHER:

A. Yes, I was somewhat surprised.

COFFEY, Q.C.:

Q. And why is that?

DR. GALLAGHER:

A. Well I'm not, certainly someone who is knowledgeable about immunohistochemistry at all, but there seemed to my inexpert eye to be a considerable number of deficiencies.

COFFEY, Q.C.:

Q. And I take it that during the period that you were utilizing the St. John's laboratory for IHC, from about '94 in the beginning until 2005, including to the time you left, November 2005, you were not aware of those sorts of deficiencies or at least alleged deficiencies?

DR. GALLAGHER:

A. No, I was not.

COFFEY, Q.C.:

Q. Doctor, on that topic because you've told the

Page 154

Commissioner, look, in the summer of '05, September of '05, we started to utilize Mount Sinai for ER/PR and I take it, HER2/neu as well?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. But you continued to utilize St. John's for IHC testing?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Were you made aware of any concerns or did you have any concerns, did it even occur to you that there might possibly be concerns about other IHC stains?

DR. GALLAGHER:

A. I haven't encountered any other problems. As I say, we don't see most of those stains ourselves that we order, so I have not encountered any cases that would suggest a problem.

COFFEY, Q.C.:

Q. But in terms of deficiencies at least, perceived deficiencies from Ms. Wegrynowski's

Page 155

report, based upon her report in relation to the lab, you were surprised by that?

DR. GALLAGHER:

A. I was somewhat surprised. I mean, I haven't read many of these reports and I'm sure most of them contain some deficiencies, so it would be difficult for me to say how deficient this report is, in that sense, or how unfavourable it is, but I was a little surprised.

COFFEY, Q.C.:

Q. And what I wanted to ask you about was during the fall of '05 after you'd gotten your blocks together and sent them on to St. John's, did you have any further conversations with Drs. Cook or Carter about this ER/PR matter before you left in November?

DR. GALLAGHER:

A. I probably did just, you know, asking them how things were going, when we might see our cases back, but I don't recall anything about specifics of this. It was more my own lab's work that I was focused on at this point.

COFFEY, Q.C.:

Q. And certainly, I take it from what you're telling us, you heard nothing from Drs. Cook

Page 156

or Carter about any perceived deficiencies or identified deficiencies in St. John's?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. Now you have indicated that you also saw Dr. Banerjee's report. Have you seen both of his reports?

DR. GALLAGHER:

A. I don't think so. I'm not sure if I have. I had a casual look at them on the website, and that's all I did.

COFFEY, Q.C.:

Q. P-0046, please. Doctor, this is the first of the reports. This the October -- that's the covering letter of October 17th, 2005, from Dr. Banerjee to Dr. Cook. The second page of the exhibit is a cover page of the report itself, dated October 17th, 2005, and when was it that you would have read this, Doctor, or looked at it?

DR. GALLAGHER:

A. In 2008 sometime.

COFFEY, Q.C.:

Q. Sometime on the website?

Page 157

DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And it is not that long, as reports go, you would agree, wouldn't you, the actual text is not very long?
DR. GALLAGHER:
A. That's correct.
COFFEY, Q.C.:
Q. And why was it that you went and looked for it, Doctor?
DR. GALLAGHER:
A. Well, I had heard so much talk about it as an important report.
COFFEY, Q.C.:
Q. And, Doctor, what were your thoughts or impressions, having read it?
DR. GALLAGHER:
A. That there were serious problems.
COFFEY, Q.C.:
Q. And I appreciate that at the time you would have understood reading this report, Dr. Banerjee was at the time focused on St. John's cases? You would have understood that from reading this report?

Page 158

DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Did his observations here have any implications from your perspective for your own hospital?
DR. GALLAGHER:
A. Well, certainly when any reference is made to poor fixation, negative internal controls, absent internal controls, one would pay attention particularly to poor fixation.
COFFEY, Q.C.:
Q. Doctor, having read that reference by Dr. Banerjee, and I appreciate he was making a comment in relation to St. John's cases, originated in St. John's, but as well you've indicated that you did calculate the number of cases out of Gander that were identified as having fixation issues, did you take any steps then in that regard to make any inquiries within your own hospital, take any steps to ensure that there would not be fixation problems or try to alleviate them?
DR. GALLAGHER:
A. Well, we adopted the recommendations of Dr. Carter's quality assurance document on breast reporting and grossing and fixation at the beginning of '07, and subsequently Dr. Denic sent us more material in the middle of '07 that we adopted, and, I guess, in relation to that, several things have been done. Firstly, the needle localization specimens of breast are one of the specimens most vulnerable to delayed fixation because they are not in formalin. They have to be x-rayed, and you can't send a specimen in formalin to the x-ray department and have people inhaling formalin fumes up there and so on in a mammography unit. So they are sent fresh to radiology and then they come back to pathology for grossing and immersion in formalin. So there's always a hazard that these cases may at some point be delayed. So we started in '08 a system whereby we asked the surgeons to write down the time they removed the specimen, and then we write down the time we receive the specimen back from mammography, and lastly we write down the time that the last block went into formalin. We try to keep the whole process under 30 minutes so that the last block to

Page 159

Page 160

enter formalin --
COFFEY, Q.C.:
Q. From block --
DR. GALLAGHER:
A. From the time it was removed from the patient --
COFFEY, Q.C.:
Q. In these needle --
DR. GALLAGHER:
A. In these needle localization boxes, is no more than 30 minutes. That's our goal, and we try to minimize it even further than that, but that's our maximum goal. In terms of under fixation, we are trying to cut the bread loafing segments as thin as possible. Historically, in the pathology literature, these specimens were cut at one to two centimetre thicknesses and Dr. Carter has recommended five millimetres. So we have tried to cut these breast specimens as thin as possible, though it is quite difficult with a fatty specimen sometimes to do that. In terms of over fixation, we have asked the surgeons not to do surgery on breast on Friday or on Thursday afternoon, so that biopsies,

Page 161

particularly core biopsies, will not be vulnerable to over fixation over the weekend. They would be some of the changes we've made very recently. Within the last week I have made inquiries about refrigeration in the OR. We do have a refrigerator in the OR in Gander, but it is used for drugs, and we don't know whether we can segment it so that we can put specimens in there if they cannot be immediately delivered to us. In the histology department, we have a small refrigerator which is large enough to take some large specimens, but we will probably need a larger one. We are undertaking from last week to refrigerate certainly all fresh specimens and all large specimens in the OR and in histology.

COFFEY, Q.C.:

Q. Doctor, in terms of the issue of choosing tissue with internal controls to ensure, if possible, that there is normal ductal epithelium present because, I take it, you're not reading ER/PR slides yourself right now?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Page 162

Q. Nor is Dr. Somers. It's being done in Mount Sinai, but in terms of the choice of blocks, this number three, really, in effect, would be your choice as to which blocks to use to send to Mount Sinai?

DR. GALLAGHER:

A. Sorry?

COFFEY, Q.C.:

Q. If I could, here right now Mount Sinai is currently doing ER and PR testing?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. But they are doing it, I take it, on the block that you or Dr. Somers chooses?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And, of course, in the choice of blocks now, what is your approach now?

DR. GALLAGHER:

A. We make sure we attempt, where possible, to find a block with internal controls.

COFFEY, Q.C.:

Q. Yes.

Page 163

DR. GALLAGHER:

A. Obviously, in some post-menopausal patients, it can be that there is no lobular tissue, normal lobular tissue, near the tumour, but we try, wherever possible, to include internal controls, and as far as I know every case that we have sent to them has had internal controls since we've started sending cases to them because it's being recorded.

COFFEY, Q.C.:

Q. I'm sorry, it's being --

DR. GALLAGHER:

A. I think it's being recorded on their reports.

COFFEY, Q.C.:

Q. On their reports themselves.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And these would be these two page reports you get back from Dr. Mullen?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, is there anything else in terms of this report?

Page 164

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. Doctor, have you received any communications from Mount Sinai about any concerns about the quality of the tissue or the blocks that you've been sending?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. Doctor, how much of what you've described for me now about the current practice, how much of this is reduced to writing -- reduced to writing? You've indicated, for example, that you received a written procedure outline from Dr. Carter?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. And then you've received a subsequent one from Dr. Denic?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Does your hospital have its own, or are you

Page 165

utilizing St. John's?
DR. GALLAGHER:
A. We're utilizing St. John's at present. We have taken this and adopted it as our policy. I mean, the recommendations of Dr. Denic have been distributed to myself and the other pathologists and they are in a binder in the pathology office as well, and they were approved for use in the gross room.
COFFEY, Q.C.:
Q. Doctor, in terms of creating written polices, procedures, and protocols, on a large scale, comprehensive ones, do you have the resources to do that in Gander?
DR. GALLAGHER:
A. We are very stretched to do that, and I think we need help from outside to do it.
COFFEY, Q.C.:
Q. Because we've heard -- Dr. Neil has been here and he works in Corner Brook. You know Paul Neil?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. And he has indicated to the Commissioner that

Page 166

-- he has more people working with him, but he has indicated that it would take him a considerable period of time, perhaps many months or a number of months just to do that, to be able to concentrate on it. I take it you'd be in the same position?
DR. GALLAGHER:
A. Yes. Dr. Dalton kindly lent us his quality assurance document several months ago and I've been attempting to adapt it for our hospital. We've already implemented some of those QA measures he has, but we haven't yet got it officially approved as policy, but even with Grand Falls and its greater capacity, I don't think we have enough ability within our region to produce all the documents necessary now, all the standard operating procedures necessary. I think it's a job that will require assistance at least from St. John's, and quite possibly from experts in Ontario and resource people in Ontario, and elsewhere, to get all these standard operating procedures done because there's a huge amount of work to do.
COFFEY, Q.C.:

Page 167

Q. Just a moment, please, Doctor. Exhibit P-2157, I think it is. That large document that takes several -- more than several seconds to open. Doctor, are you aware coming in here today of the fact that St. John's does have a relatively -- at least far more than they did in the past, written policies and procedures manual?
DR. GALLAGHER:
A. I saw this referred to in Dr. Dalton's testimony.
COFFEY, Q.C.:
Q. So you --
DR. GALLAGHER:
A. That's the first time I saw it. I mean, I saw it referenced. I didn't actually see the document.
COFFEY, Q.C.:
Q. As you can see, it is Exhibit P-2157, and it's there on our website, "our" in the sense of the Commission's website. Doctor, this is a Pathology Policies and Procedures Manual, Table of Contents, from Eastern Health, and pathology policies, there are a number of them. Seven listed there, and on the second

Page 168

page there's Pathology Policies and Procedures Manual, Table of Contents, and there's general information, specimen collecting and handling procedures, including fixation procedure, pathology specimen handling, and it goes on at some length, a number of them here; grossing procedures, routine and pathology assistants. I take it you would not have pathology assistants?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. But there are grossing procedures spelled out here, there are pathology technical and staining procedures, you can see there's, in effect, a page of them, and then there's a draft section of pathology quality management procedures, a draft section of pathology reporting procedures. I take it, IHC policies and procedures wouldn't be of any particular relevance to yourselves in Gander because you don't do that sort of testing, but -- and they have a number of those. So, Doctor -- there's one for as well human resources, pathology workstation duties. There are a list of forms

Page 169

as well, including pathology IHC forms. Doctor, this goes on for hundreds of pages, okay. I take it, preparing anything and even adapting something like this locally for yourself for your institution or even for yourself and Dr. Dalton's institutions, would require -- do you think you would have the resources to do that as it is right now or would you need outside help?

DR. GALLAGHER:

A. I don't think we would have the resources in Gander to do it. I just don't think we would.

COFFEY, Q.C.:

Q. And even bearing in mind what you know about Grand Falls Windsor even, even if you combined them, as a practical matter?

DR. GALLAGHER:

A. I don't think we would. I think this is challenging for St. John's to do.

COFFEY, Q.C.:

Q. Yes, I gather, from what we've heard. Because I take it, Doctor, too, even if one does have this as a template or as a model, you have to adapt it or adopt it if it's going to be realistic to your own situation?

Page 170

DR. GALLAGHER:

A. Yes, yes, but it's a lot easier to start with a standard and make changes that are within acceptable limits that are agreed that you can make. I think really, the laboratories should have one set of policies.

COFFEY, Q.C.:

Q. Laboratories, isn't it? You used the plural, didn't you?

DR. GALLAGHER:

A. Yes, I think that all the laboratories in the province should have one set of policies that are then adapted as according to size and need. I don't see why we should be developing separate policies in separate institutions really.

COFFEY, Q.C.:

Q. Have you expressed that view to others?

DR. GALLAGHER:

A. Yes, I have.

COFFEY, Q.C.:

Q. To whom?

DR. GALLAGHER:

A. I've expressed it just at the Newfoundland Association of Pathologists meetings.

Page 171

COFFEY, Q.C.:

Q. And what has the reaction been?

DR. GALLAGHER:

A. I think people have been generally favourable to it.

COFFEY, Q.C.:

Q. And from your perspective, at least, and I'm not asking you to speak for your health authority, but from your own perspective as an individual pathologist, you'd be prepared to become engaged in that sort of a process?

DR. GALLAGHER:

A. I'd be delighted to become engaged in it. I think it would be a big improvement, a big step forward.

COFFEY, Q.C.:

Q. And Doctor, I take it then, as you've indicated, you only became aware of this when Dr. Dalton testified, the existence of this at that time?

DR. GALLAGHER:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, I'm going to take you now to, if I could, your return to Newfoundland in May of

Page 172

2007.

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. May 23rd, I take it, is your first day back at work.

DR. GALLAGHER:

A. I think May 24th.

COFFEY, Q.C.:

Q. 24th, okay, you arrived back on the 23rd. The ER and PR matter, what then happened? I take it you're back, you're back at work as a pathologist in Gander. What, if any, involvement did you then have in it?

DR. GALLAGHER:

A. Basically, we were waiting for news about what was going to happen, and waiting to get some final determination on what exactly had caused the conversions.

COFFEY, Q.C.:

Q. Did you make any inquiries in that regard? Did you ever make--in the fall of 2005 or in fact, for that matter, while you were away in Calgary, and upon your return, did you ever ask anybody, in particular anybody in St.

Page 173

John's, about how did this happen, why did it happen?
DR. GALLAGHER:
A. I think I did, but I didn't record it and I don't recall exactly who I spoke to, but I know I was concerned about it. I was concerned to get news and see where we stood.
COFFEY, Q.C.:
Q. And do you recall what you were told or in terms of your impression you were left with? I understand you can't recall who told it to you, but what was your impression?
DR. GALLAGHER:
A. My impression was that I didn't really get a definite answer as to what had occurred.
COFFEY, Q.C.:
Q. For example, we've just looked at Dr. Banerjee's report and pointed out one, two, three, fixation, internal controls not staining, no internal controls, that sort of kind of succinct summary of potential problems, that wasn't -
DR. GALLAGHER:
A. It wasn't succinctly put like that, no.
COFFEY, Q.C.:

Page 174

Q. You've had the opportunity to look at Trish Wegrynowski's report, even up to as of last night.
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Those sorts of problems, was that brought to your attention at the time? Anybody articulate that?
DR. GALLAGHER:
A. No.
COFFEY, Q.C.:
Q. Doctor, we understand there was a teleconference that occurred involving people across the province, involving Vice President Medicals across the province, May 24th, 2007, which would have been, in effect, your first day back to work. Do you recall whether you participated in that?
DR. GALLAGHER:
A. I did not.
COFFEY, Q.C.:
Q. Were you aware that it was going on or did you become aware afterward that it had gone on?
DR. GALLAGHER:

Page 175

A. No, not until much later.
COFFEY, Q.C.:
Q. And do you recall what you were told much later about it?
DR. GALLAGHER:
A. No, I only became aware of it within the last month.
COFFEY, Q.C.:
Q. Okay, during--in relation to this Commission?
DR. GALLAGHER:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, the fixation policy that you received from Dr. Denic, do you recall when it was you received that?
DR. GALLAGHER:
A. I think it was in--it was e-mailed in May, I believe.
COFFEY, Q.C.:
Q. Okay.
DR. GALLAGHER:
A. I think it was.
COFFEY, Q.C.:
Q. And if there has been a subsequent one or one that perhaps may have been slightly amended

Page 176

since, you haven't received one since?
DR. GALLAGHER:
A. I only received one.
COFFEY, Q.C.:
Q. Okay, and now let's what I'll--that's the one in May of '07?
DR. GALLAGHER:
A. Yeah.
COFFEY, Q.C.:
Q. Here, Doctor, this is apparently the current fixation policy for Eastern Health. It's original approval date is February 4th, 2008, and the issuing authority is described as being Dr. Denic and Mr. Gulliver, Terry Gulliver. You would not have received a copy of this, I take it?
DR. GALLAGHER:
A. No, I did not.
COFFEY, Q.C.:
Q. Now a predecessor of it, you've indicated perhaps you did, but not this itself?
DR. GALLAGHER:
A. Yes, a short document.
COFFEY, Q.C.:
Q. This is actually the document itself. There's

Page 177

an overview, safety precautions, a policy, and a scope and a purpose and a procedure. There are certain supporting documents along with linkages to, in fact, what are listed as, if you look elsewhere in this overall P-2157, you'll see these linkages. These documents appear elsewhere here. So Doctor, you referred to the Newfoundland Association of Pathologists and you raising this recently, this topic about potentially having kind of a province wide approach to this.

DR. GALLAGHER:

A. I think I raised it last year, but it's an issue that's very much current anyway.

COFFEY, Q.C.:

Q. Is there--Doctor, when this was discussed at the Newfoundland Association of Pathologists level, is there any opposition voiced to this approach?

DR. GALLAGHER:

A. I don't think so.

COFFEY, Q.C.:

Q. From your perspective, if there is to be this--if such an initiative was to be pursued where or by whom or what group does that have to be

Page 178

pursued? Who's got to take the initiative here, from your perspective? Because I take it you don't have the--you just don't have the resources yourself.

DR. GALLAGHER:

A. Well, I mean, we certainly would be willing to play our part. We wouldn't want to see individuals in St. John's who are already extremely busy having to do all the work. We certainly would want to participate, but I think it's appropriate that this effort be headed by the tertiary care centre in the province, in association with experts from other provinces as well.

COFFEY, Q.C.:

Q. Doctor, are you aware that St. John's has--the laboratory in St. John's, Eastern Health's laboratory has or was visited in December of 2007 by QMPLS, which is an organization out of Ontario?

DR. GALLAGHER:

A. I read about it in the transcripts.

COFFEY, Q.C.:

Q. Okay, so you became aware of it through the Commission?

Page 179

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, are you aware of any initiatives involving QMPLS in Newfoundland?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. From your perspective, would it be of any benefit, do you think, for--if it could happen, for Gander's laboratory to be reviewed by an outside agency?

DR. GALLAGHER:

A. Yes, it would be.

COFFEY, Q.C.:

Q. I take it initially and then on a periodic basis?

DR. GALLAGHER:

A. Yes.

COFFEY, Q.C.:

Q. Are you aware of any organization or body that actually offers that service now in Canada?

DR. GALLAGHER:

A. Well, I believe QMPLS does it in Ontario.

COFFEY, Q.C.:

Page 180

Q. Ontario, yes.

DR. GALLAGHER:

A. And I don't know how further--they do it for other provinces as well.

COFFEY, Q.C.:

Q. But if they do, you're not--you have not made inquiries in that regard?

DR. GALLAGHER:

A. No.

COFFEY, Q.C.:

Q. Just a moment, please, Commissioner. Doctor, is there anything that we haven't covered that you think the Commissioner should be made aware of? Bearing in mind the--because you'd be familiar generally with the mandate of the Commission and the subject matter of what's being discussed here.

DR. GALLAGHER:

A. No, I don't think so. I think that's really it, and the last issue being among the most significant, looking to the future.

COFFEY, Q.C.:

Q. In terms of your idea, for example, that we have--if we're going to get involved and this is desirable from your perspective to have

Page 181

written policies, procedures, protocols, SOPs, to have all of that in place, it's going to require outside assistance, from your perspective?

DR. GALLAGHER:

A. Probably.

COFFEY, Q.C.:

Q. Yes, in the sense of locally?

DR. GALLAGHER:

A. Certainly in Gander, yes.

COFFEY, Q.C.:

Q. Yes, in Gander.

DR. GALLAGHER:

A. Certainly in Gander, yes.

COFFEY, Q.C.:

Q. They're the questions I have, Commissioner.

THE COMMISSIONER:

Q. Mr. Pritchard?

MR. PRITCHARD:

Q. Thank you, Commissioner. I don't have any questions for this witness. Thank you for your evidence, Doctor.

THE COMMISSIONER:

Q. Thank you. Ms. Whalen?

MS. WHALEN:

Page 182

Q. Commissioner, we have no questions.

THE COMMISSIONER:

Q. Mr. Pritchett?

MR. PRITCHETT:

Q. No questions, Commissioner. Thank you, Dr. Gallagher.

THE COMMISSIONER:

Q. One second, as she walks through the door. Ms. Newbury, do you have any questions for this witness?

DR. BARRY GALLAGHER, EXAMINATION BY MS. JENNIFER NEWBURY

MS. NEWBURY:

Q. Yes. Good afternoon, Dr. Gallagher. Jennifer Newbury for the Canadian Cancer Society, Newfoundland and Labrador Division. I just have a couple of questions for you this morning. First of all, I was wondering what is the practice of James Paton Memorial Hospital in terms of registering pathology reports with the Cancer Registry?

DR. GALLAGHER:

A. The reports are sent to our Cancer Clinic and they are electronically transmitted to the Cancer Registry.

MS. NEWBURY:

Page 183

Q. And how long has that practice been going on?

DR. GALLAGHER:

A. I believe it's been going on about five to eight years.

MS. NEWBURY:

Q. Okay, and with regard to breast cases, would those reports include ER/PR results?

DR. GALLAGHER:

A. They would, yes.

MS. NEWBURY:

Q. Okay, and when you were tasked with finding the ER/PR test results back in 2005, did you give any consideration to contacting the Cancer Registry as a double check on a list of patients who had ER/PR testing?

DR. GALLAGHER:

A. No, I did not.

MS. NEWBURY:

Q. Okay, and do you ever request information of that nature from the Cancer Registry?

DR. GALLAGHER:

A. I don't recall having done so.

MS. NEWBURY:

Q. Okay, and do you use the Cancer Registry for monitoring any trends or do you have your own

Page 184

system in place for monitoring trends at your hospital with the laboratory?

DR. GALLAGHER:

A. We haven't been using the Cancer Registry.

MS. NEWBURY:

Q. And you don't have any other system in place for monitoring trends?

DR. GALLAGHER:

A. Well, apart from keeping a track of the number of malignant neoplasms on our reports, no, we don't.

MS. NEWBURY:

Q. And is the fact that you have a relatively low number of patients, I guess, who might be subject to testing in your hospital, is that a reason for that or is there any other reason why you may not monitor trends on a regular basis?

DR. GALLAGHER:

A. No, we just don't do it in our laboratory.

MS. NEWBURY:

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

THE COMMISSIONER:

Q. Thank you. Ms. Taylor?

Page 185

DR. BARRY GALLAGHER, EXAMINATION BY MS. PAMELA TAYLOR
MS. TAYLOR:
Q. Good morning, Dr. Gallagher. My name is Pam Taylor. I'm here on behalf of the Breast Cancer Testing Class Action Group. Now I just have a couple of questions for you. The patient that was identified in 2008, the gentleman that's now deceased, do you have any idea if his family has been notified of the results or that he was in fact a patient that had been missed in the initial review of ER/PR testing?
DR. GALLAGHER:
A. Well, he was missed in the initial review, so his family would not have been informed.
MS. TAYLOR:
Q. No, but you said that he was identified in 2008.
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. And that -
DR. GALLAGHER:
A. He was already deceased at that time.
MS. TAYLOR:

Page 186

Q. Right, so were his tests reviewed at that time?
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. In 2008?
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. And they were analyzed?
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. Do you know if his family was notified in 2008?
DR. GALLAGHER:
A. No, I don't believe they were. The report was sent out to the physician, the amended report was sent to the physician, but the--and the case was sent to the NLCHI and that was what we did with that.
MS. TAYLOR:
Q. But as far as you're aware, the family hasn't been notified of the results?
DR. GALLAGHER:

Page 187

A. As far as I'm aware, I don't think the family have been notified.
MS. TAYLOR:
Q. Okay. Now another question that I had, you said that ER/PR testing is still being sent to Mount Sinai for your hospital?
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. And you said that you were invited or your hospital was invited some time back in 2006 to resume testing in St. John's. That was while you were gone?
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. And obviously at that time, a decision was made not to resume testing?
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. You became aware of that when you came back to Newfoundland in '07?
DR. GALLAGHER:
A. Yes.

Page 188

MS. TAYLOR:
Q. And again, there was no change made at that time, but there was some thought given to whether or not testing would resume in St. John's? I believe that's what you had indicated?
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. And you gave a couple of reasons as to why testing wouldn't be resuming in St. John's at that time.
DR. GALLAGHER:
A. Yes.
MS. TAYLOR:
Q. One was they were overburdened and shortage of staff. Now I presume that if they had issued an invitation for testing to resume in St. John's that, I'm going to suggest to you, they felt capable, even with, as you say, being overburdened or a shortage of staff, that they were capable of doing the testing. Would you agree with that statement?
DR. GALLAGHER:
A. That may be reasonable to say.

Page 189

MS. TAYLOR:
Q. And in terms of the other reason, you had said that you wanted to wait for the results of the Inquiry to see, I guess, what came from the Inquiry, before considering resuming testing. That would suggest to me that there were still some concerns in terms of the quality of testing that was being done in St. John's. Is that fair to say?
DR. GALLAGHER:
A. Well, there was uncertainty about the nature of the problem, I would say.
MS. TAYLOR:
Q. Well, if you haven't resumed retesting to this point, does that uncertainty still exist for you and your hospital?
DR. GALLAGHER:
A. I think it exists just in a general sense that I would like to see the findings of the Inquiry first.
MS. TAYLOR:
Q. And wouldn't that suggest then that there's some concerns with the current practices?
DR. GALLAGHER:
A. Well, I would -

Page 190

MS. TAYLOR:
Q. Are you just not aware of what they are?
DR. GALLAGHER:
A. I would say that I wouldn't like to prejudge what the Inquiry will find.
MS. TAYLOR:
Q. Okay. Because you did indicate that your preference would be for testing and in terms of cancer care, for those things to happen within the same site?
DR. GALLAGHER:
A. That's correct.
MS. TAYLOR:
Q. So that would be the preference?
DR. GALLAGHER:
A. That's correct, yes.
MS. TAYLOR:
Q. So at this point, there's no particular plan in terms of when testing might resume here in St. John's?
DR. GALLAGHER:
A. No.
MS. TAYLOR:
Q. That's all the questions I have. Thank you, Dr. Gallagher.

Page 191

THE COMMISSIONER:
Q. Mr. Pike?
MR. PIKE:
Q. Nothing for me, thank you.
THE COMMISSIONER:
Q. Mr. Browne?
DR. BARRY GALLAGHER, EXAMINATION BY MR. PETER BROWNE
MR. BROWNE:
Q. Thank you, Commissioner. Dr. Gallagher, just a couple of areas I want to cover with you. First of all, you had mentioned to Mr. Coffey that you returned to Newfoundland in May of 2007. We've heard evidence from other witnesses that in November of 2007, there was a teleconference, provincial wide teleconference where information was distributed to the outside hospitals. Did you participate in that teleconference?
DR. GALLAGHER:
A. No, I did not.
MR. BROWNE:
Q. And you were asked about the discovery of the male patient who was deceased in 2008. In terms of disclosure approaches, did I understand from your evidence earlier today

Page 192

that that would be handled by the VP of Medical Affairs, in terms of any patients that were discovered through this process?
DR. GALLAGHER:
A. Yes, it would.
MR. BROWNE:
Q. Okay. So that wouldn't be something that you would follow through on? That would be handled higher up in the institution?
DR. GALLAGHER:
A. Yes. Our administration is aware of the case.
MR. BROWNE:
Q. And lastly, Dr. Gallagher, the Commission does and is interested in hearing from those who come before it whether or not they have any statements, recommendations or comments to make, and I would invite you, if you do wish to make any comments or anything along those lines, to do so now.
DR. GALLAGHER:
A. Well, I'd like to thank Madam Commissioner and Commission co-counsel for giving me this opportunity to participate in this important process. I am certain that good things will come from this for health care in Newfoundland

Page 193

and across Canada.

MR. BROWNE:

Q. Thank you, Doctor. Mr. Coffey may have some follow up.

THE COMMISSIONER:

Q. Anything arising, Mr. Coffey?

COFFEY, Q.C.:

Q. No.

DR. BARRY GALLAGHER, EXAMINATION BY MADAM COMMISSIONER

THE COMMISSIONER:

Q. Dr. Gallagher, there was one thing you said earlier this morning which I'd just like you to expand on a little, if you can. It was around--it was concerning the period of time just after you had first been contacted about sending the blocks, and as I understood it, early, it was just limited to 2002. Your view was that they were dealing with the question of the transition from one piece of equipment to the other. My impression was that you saw this as just another resolving of the kind of problems that sometimes occur when you switch from one piece of equipment to another. Is that fair?

DR. GALLAGHER:

Page 194

A. Yes, although it was an unusual request. We'd never received a request quite like that to have so many cases sent, but it was quite a large project, but at the time, it didn't seem as if there were going to be serious implications from it.

THE COMMISSIONER:

Q. And then you got the call from Dr. Cook in the summer in which they were asking you to provide a much larger sample, and my note to myself was that you, in fact, spoke to Dr. Dalton, who is sort of just a little further down the road, and that you were concerned about how large it was and how alarming, and from that, I concluded that it wasn't just the size of it that you saw as being alarming. Now, perhaps I'm just making things out of something here, so I wanted to know, could you tell me whether you found it alarming because it was so big or was there something else about it that caused you to view it in that way?

DR. GALLAGHER:

A. I think, well, first of all, because it was so big and secondly, it may be something that

Page 195

should have dawned on me in the initial conversation with Dr. Cook, but I then realized how much it was going to involve our laboratory and our laboratory's work, that this could not just be a matter for the machine in St. John's really. It could not just be a transition issue. That this would be something that would involve a much more extensive examination.

THE COMMISSIONER:

Q. So was it at that point it dawned on you that you were looking at an inquiry by the laboratory system into things that were much wider than just the adjustment because we had a new machine?

DR. GALLAGHER:

A. Yes.

THE COMMISSIONER:

Q. They were looking for something else?

DR. GALLAGHER:

A. That thought did occur to me at that time, yes.

THE COMMISSIONER:

Q. And you didn't know what that thing was?

DR. GALLAGHER:

Page 196

A. No.

THE COMMISSIONER:

Q. And do I take it that at no point did anybody come back to you and say what that thing was?

DR. GALLAGHER:

A. Not explicitly. I mean, obviously when an issue like this comes up, there are certain things that can go wrong, but nobody at that time said to be "well, this is really what we think happened."

THE COMMISSIONER:

Q. Okay. Now just one other thing. I'm just wondering about how one feels when one is outside of Eastern Health area and you're practising, in large part with the aid of the tertiary care hospital, which is billed as that and which is the function that the current General Hospital provides. What is the relationship between you, as a pathologist operating in Gander, and that hospital, and I'm particularly concerned about the communications between the two groups. From your perspective, is it satisfactory? Do you hear enough about specimens of whatever kind you send and they send back to you? Do you

Page 197

get the turnaround fast enough? You probably want it immediately, but I mean, fast in the sense of do you get a reasonable turnaround? And do you, from your perspective, get enough comments from the tertiary care hospital about what they're seeing in terms of being of assistance to you in your practice in Gander?

DR. GALLAGHER:

A. Well, I think the turnaround time is reasonable, and I think the relationship with the pathologists in St. John's is excellent, in general, and I think they offer good leadership to us overall, and I think I'm optimistic about the future, as regards the leadership they will offer to us.

THE COMMISSIONER:

Q. Okay, and can we bring that back now once again to this, because the information that has thus far come to the Commission would indicate that there wasn't a lot of frank disclosure, if you will, between Eastern Health and those pathologists working outside about what they were finding in the process of examining this problem. Is that fair? Do you feel that they were providing you with the

Page 198

information that they could or were there other things that they could be doing to assist you to deal with the problem?

DR. GALLAGHER:

A. Well, I realize that they were constrained by various limitations when they weren't sure about what the problems were and I suppose, these reviews were confidential as well, so I realize that, you know, we probably couldn't be told about those. So I realize that they were working themselves in a difficult environment in that regard, and they mightn't be as forthcoming as they would usually be with us, because of the peculiar nature of this problem. Because usually we have a very good relationship with them, very open relationship and I think this was just such a complex problem that it was difficult to give us unequivocal answers about what was going on.

THE COMMISSIONER:

Q. And would you have liked to have gotten more information about what was going on, even if it maybe had to have a rider on it?

DR. GALLAGHER:

Page 199

A. Yes, I would have.

THE COMMISSIONER:

Q. Okay. Thank you. Thank you very much for your assistance in this process, Dr. Gallagher. We'll take the luncheon break and meet again at ten after two.

(LUNCH BREAK)

THE COMMISSIONER:

Q. Mr. Coffey.

COFFEY, Q.C.:

Q. The next witness is Dr. Sushil Parai.

DR. SUSHIL PARAI, SWORN, EXAMINATION BY BERNARD COFFEY, Q.C.

REGISTRAR:

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

DR. S. PARAI:

A. Sushil Parai, S-U-S-H-I-L P-A-R-A-I.

REGISTRAR:

Q. Thank you.

COFFEY, Q.C.:

Q. Good afternoon, Doctor. Doctor, can you outline for the Commissioner, please, in an overview way, your educational and professional background?

Page 200

DR. S. PARAI:

A. I was graduated in medicine with MBBS degree in 1973 from Dhaka University, Bangladesh. I did a year of internship, year of general practice, year of residency in general surgery. I started residency training in general pathology 1977 in Shiraz University, Iran.

COFFEY, Q.C.:

Q. In Iran?

DR. S. PARAI:

A. Yes. In 1979, I was offered a residency position at Dalhousie University, Halifax, and moved to Halifax in January 1980. I completed residency training in 1984. I am fellow of Royal College of Physicians and Surgeons of Canada. I was certified by the Royal College of Physicians and Surgeons of Canada in anatomical pathology, also by American Board of Pathology. I hold -

COFFEY, Q.C.:

Q. Doctor, when did you get the fellowships?

DR. S. PARAI:

A. Certification 1986 and fellowship, 1987.

COFFEY, Q.C.:

Page 201

Q. Okay, and that's the American and Canadian?
DR. S. PARAI:
A. American, 1991.
COFFEY, Q.C.:
Q. 1991?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Okay. Go ahead, Doctor, I'm sorry. So what did you--when you finished up with Dalhousie, what happened then?
DR. S. PARAI:
A. Well, I started working as a staff pathologist at the Yarmouth Regional Hospital, 1984 to '88.
COFFEY, Q.C.:
Q. I'm sorry, which hospital?
DR. S. PARAI:
A. Yarmouth.
COFFEY, Q.C.:
Q. Oh, Yarmouth?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Nova Scotia. I'm sorry, I just didn't under--

Page 202

didn't catch the Yarmouth. Go ahead.
DR. S. PARAI:
A. 1984 to 1988. In 1988, I moved to St. John's General Hospital as a staff pathologist and worked there five years. In 1991, I was given an award by the Canadian Cancer Society called Blair Award to pursue further training in cancer diagnosis, which I did, as a fellow at Ottawa Civic Hospital. In 1993, I was offered the position of Director of Laboratories at the Grace General Hospital and worked there in that position until October 1996. With the formation of Health Care Corporation in 1996, I was offered the position as site chief of anatomical pathology, Grace General Hospital, and I continued in that position until the closure of Grace Hospital in July 2000. In 2000, I was offered also a position at the General Hospital as site chief of anatomical pathology and at the closure of Grace Hospital, I moved to the General Hospital site.
I continued to work in that position until March 2005. With the formation of Eastern Health in April, I stepped down from

Page 203

that position and worked as a staff pathologist until October 2005. In 2005, I moved to Alberta with a position at the Red Deer Regional Hospital.
COFFEY, Q.C.:
Q. Red Deer?
DR. S. PARAI:
A. Red Deer.
COFFEY, Q.C.:
Q. Okay, go ahead.
DR. S. PARAI:
A. In Alberta, as staff pathologist, and worked there until December 2006. I returned to St. John's in January 2007 and working in the present position as a staff pathologist.
COFFEY, Q.C.:
Q. And you're located where, Doctor?
DR. S. PARAI:
A. At the General Hospital.
COFFEY, Q.C.:
Q. General Hospital.
DR. S. PARAI:
A. I'm a faculty with the Memorial University of Newfoundland, rank of clinical professor of pathology.

Page 204

COFFEY, Q.C.:
Q. So that kind of recounts your educational and your professional history. Doctor, to go back then, I take it that you went to the Grace Hospital here in St. John's in 1993?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. But I understand you to say that you had been in St. John's before that?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. I understood that correctly?
DR. S. PARAI:
A. Yeah, I came in '88, in May.
COFFEY, Q.C.:
Q. In May of '88.
DR. S. PARAI:
A. May 29th, 1988.
COFFEY, Q.C.:
Q. '88?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:

Page 205

Q. And from that point until when, you were--you left for a while in the early '90s? Did I understand you correctly? I was just trying to follow the chronology.

DR. S. PARAI:

A. Yes, I went for two years, sorry, two months at a fellowship training in Ottawa Civic Hospital.

COFFEY, Q.C.:

Q. Okay, so you spent two months in Ottawa?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And then following that, when you returned to St. John's, it was at the Grace Hospital?

DR. S. PARAI:

A. No, no, at the General.

COFFEY, Q.C.:

Q. The General?

DR. S. PARAI:

A. That was 1991 I went to the fellow. At that time, I was at the General Hospital.

COFFEY, Q.C.:

Q. So you were in the General Hospital from '88 through '91?

Page 206

DR. S. PARAI:

A. '93, yeah.

COFFEY, Q.C.:

Q. You did the two months in Ottawa. You returned to the General?

DR. S. PARAI:

A. Correct.

COFFEY, Q.C.:

Q. And you stayed there until you moved to the Grace?

DR. S. PARAI:

A. Correct.

COFFEY, Q.C.:

Q. In 1993?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Okay. Because when you had mentioned you had gone to Ottawa, I wasn't certain for how long, so that's what I was trying to figure out. Doctor, and if we could bring up then, please, Exhibit P1600? And this'll come up on the screen for you, Doctor, and if you do need to, Doctor, just to let you know, you'll see there, just below the screen, there's a mouse,

Page 207

one of these little scrolling devices, and you are able to, in fact, if you wish, to scroll up and down. The Commissioner has seen this page before, Doctor. It's a listing of pathologists, labelled Eastern Health Pathologist Staff Turnover, and it lists a number of different pathologists, you know, their start dates, their termination dates and in some cases, the comments of course, indicate why they had terminated their employment. There's retirement and another person was deceased. In terms of yourself, Doctor, you're listed here under 2.03, that's you, and what I want to draw to your attention, of course, they have you listed as starting June 2nd, 1993, and of course, there's no termination date. That continues. You're still there today. Doctor, so the actual start date for the predecessor organizations for Eastern Health for yourself -

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. - is in fact probably not correct. That's

Page 208

your most recent start with the Grace?

DR. S. PARAI:

A. It is not correct. I noticed this thing before. I reminded them that can you correct it.

COFFEY, Q.C.:

Q. And in fact, as you pointed out just now to the Commissioner, in terms of St. John's, in hospitals that are now part of Eastern Health, you, in fact, date back to 1988?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Okay, just I wanted to clarify that.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And give you an assurance that it would be brought to the Commissioner's attention, okay, that this is not necessarily correct, this listing, and in fact, in your case, it's not. Doctor, what I want to ask you about, in terms of just so the Commissioner has some sense of your career with the Health Care Corporation, in particular, okay, and I will be asking you

Page 209

as well in some more detail about your time at the Grace Hospital, but if we could bring up, please, Exhibit P-1868? Doctor, this is a letter January 14th, 2000. It's addressed to Dr. Donald Cook. It's from yourself. At the time, Dr. Cook is clinical chief acting in the Laboratory Medicine Program and it's from yourself. You, at that point, were the site chief of pathology at the Grace General and you here write--this is to acknowledge the receipt of Dr. Cook's letter of January 10th, 2000. "I do hereby accept the appointment of permanent site chief of anatomical pathology at the General Hospital site as of May 1, 2000." That's what you've indicated.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And I take it that you remained in that position in fact until March 31, 2005, as site chief?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, I'm going to refer to another document

Page 210

here, if I could. It's Exhibit P-0021. These are a series of Medical Advisory Committee minutes, okay, there's a whole grouping of them here for different dates, but if we could go to page 51, please? Doctor, this is the meeting minutes for October 12th, 2005 of the MAC, and most of it's redacted, but there is a leave of absence reference here, Dr. Sushil Parai, leave of absence from the Laboratory Medicine Program, Division of Anatomical Pathology, January 7th, 2006 to December 31, 2006. You had a leave of absence for certainly a year here, under the MAC.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Had you in fact actually left before January of '06?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Okay, and you've described for the Commissioner, you in fact left when?

DR. S. PARAI:

A. In middle of October, 17th. I was on annual

Page 211

leave and then -

COFFEY, Q.C.:

Q. Okay. So in practice, formally you were on leave from January 7th onward, leave in the sense of leave of absence.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. But in fact, you had vacation or annual leave time and you took that from mid October onward?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Okay. The point what I'm getting at is this, is that from October 17th, 2005 really until 2007, you weren't at work here in St. John's?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Okay, you were gone that whole October, the end of October, November and December of '05?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Page 212

Q. And if we could, please, Exhibit P-2112? Doctor, here, these are--it's the Division of Anatomical Pathology meeting, the minutes of January 10th, 2007. There are listed a number of individuals present, including yourself. You're right there, and there is, under call to order, the meeting was called to order by Doctor--or Dr. Denic welcomed Dr. Avis to his new position as Acting Chair Discipline of Laboratory Medicine, and also welcomed Dr., it would be Sushil Parai back to work at Eastern Health. So you were--this is your first kind of meeting, as it were, back in St. John's in '07?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, when did you begin as a site chief at the Grace Hospital?

DR. S. PARAI:

A. November 1st, 1996.

COFFEY, Q.C.:

Q. And had there been a site chief before that, do you know?

DR. S. PARAI:

Page 213

A. No, there was a new position created at the amalgamation with Corporation.
COFFEY, Q.C.:
Q. Okay, with the formation of the Health Care Corporation and the Grace becoming part of it?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. There is this new position created and you are appointed to it?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, had there been a comparable position to that before that?
DR. S. PARAI:
A. At the Grace?
COFFEY, Q.C.:
Q. Yes, in the sense of, you know, I appreciate as the site chief because it's a particular site.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Before that, the Grace had been an independent

Page 214

hospital.
DR. S. PARAI:
A. It is a different position I would say in a reduced capacity, reduced responsibility.
COFFEY, Q.C.:
Q. Okay, I'm going to ask you about that, if you could expand upon that then. There had been some kind of a medical director, I take it, before you were appointed site chief. The Grace Hospital had a person who was a medical director and had somebody, a pathologist who was in charge?
DR. S. PARAI:
A. I was the medical director, Director of Laboratory Medicine.
COFFEY, Q.C.:
Q. For the Grace?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Before the Health Care Corporation ever came along?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:

Page 215

Q. So I want to ask, so the Commissioner understands kind of the world in which you worked at the time, and how it evolved, that's why I'm asking you about it. Could you compare your position as the medical director in the Grace Hospital days, when it was a hospital by itself, to what happened when you became site chief, and how it changed? Perhaps you could tell the Commissioner about that?
DR. S. PARAI:
A. The designation was not medical director. It was Director of Laboratories.
COFFEY, Q.C.:
Q. Okay, I'll get the title right, okay, Director of Laboratories.
DR. S. PARAI:
A. Yeah, it is similar position.
COFFEY, Q.C.:
Q. As Director of Laboratories, what were you responsible for?
DR. S. PARAI:
A. It's a quality service for the laboratory and the administrative, as well as the service oriented service. It is 80 percent of the

Page 216

component, work component is clinical. 20 percent is administrative and supervising the medical or clinical supervision of the all division of laboratory medicine. There are four divisions before amalgamation and also clinical work sharing with the other fellow pathologists in the Department.
COFFEY, Q.C.:
Q. And about 80 percent of your time was supposed to be clinical work of your own?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And you had 20 percent of your time allotted to the administrative end of things?
DR. S. PARAI:
A. Right.
COFFEY, Q.C.:
Q. Doctor, in that position, who reported to you? What sorts of people reported to you?
DR. S. PARAI:
A. There are four other pathologists. We are a group of five pathologists. It's administratively four pathologists would be reporting to me.

Page 217

COFFEY, Q.C.:
Q. And that would just be pathologists reporting to you? How about the technologists, who did they report to, in the days before the Health Care Corporation?
DR. S. PARAI:
A. There was a manager, a technical manager. The technologists will be reportable to the manager of the lab.
COFFEY, Q.C.:
Q. And who did the manager report to?
DR. S. PARAI:
A. Manager would report to the medical director of hospital, and also to the laboratory director.
COFFEY, Q.C.:
Q. Which was?
DR. S. PARAI:
A. Myself.
COFFEY, Q.C.:
Q. That's what I'm getting at is that in those days, the senior technologist, the person in charge -- the technologist in charge of the technologists, the manager, he or she reported to you?

Page 218

DR. S. PARAI:
A. Yes, it was joint reporting to the medical director and laboratory director.
COFFEY, Q.C.:
Q. Who did you report to?
DR. S. PARAI:
A. To the medical director of the hospital.
COFFEY, Q.C.:
Q. So the manager reported to you and to the medical director. You reported to the medical director?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, in that capacity at the time, would you actually have any supervisory role over the technologists themselves? I appreciate not directly, but how about indirectly.
DR. S. PARAI:
A. There are some indirect supervision with the liaison with the manager of the lab in an advisory capacity.
COFFEY, Q.C.:
Q. And in what sorts of -- for what sorts of things did the manager of the laboratory report to you?

Page 219

DR. S. PARAI:
A. Clinical problem, troubleshooting, service all -- the lab has four division, not only pathology, cytology, biochemistry, hematology, transfusion, microbiology, any issue related to those divisions, reporting any error or any incidents report.
COFFEY, Q.C.:
Q. And they would end up -- the manager, if it involved the technologists, would end up coming to you about those things?
DR. S. PARAI:
A. Yes, we would consult, will discuss, and --
COFFEY, Q.C.:
Q. Just on that point, what I understand is that you, yourself, had the pathologists reporting to you, the other four pathologists who were there. The other divisions, who did they report to? If there were physicians, for example, in hematology, who would they report to?
DR. S. PARAI:
A. There is separate divisions. One of the pathologists was interested in one particular

Page 220

division, they will supervise those divisions with their experience and interest.
COFFEY, Q.C.:
Q. So as the laboratory director, were you responsible for, for example, hematology?
DR. S. PARAI:
A. Well, there was another pathology point person or designate to hematology division who had been working there 30 years with experience and expertise.
COFFEY, Q.C.:
Q. But if that person had a problem or concern of a clinical nature, would they come to you about it or could they come to you about it?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Because you were their supervisor?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. At least on paper, anyway, you were certainly their supervisor?
DR. S. PARAI:
A. Yes.

Page 221

COFFEY, Q.C.:
Q. Doctor, what then happened when you assumed the site chief's role? What were you responsible for then?
DR. S. PARAI:
A. Anatomical Pathology Division, and that consists of surgical pathology, autopsy service, and cytopathology.
COFFEY, Q.C.:
Q. How about hematology and biochemistry, and those other --
DR. S. PARAI:
A. With the restructuring of the Health Care Corporation, those divisions would be supervised by divisional chief at the General Hospital site. I want to correct it. Only surgical pathology and autopsy, cytopathology. There was another divisional chief at the General Hospital site.
COFFEY, Q.C.:
Q. So was there a divisional chief for surgical pathology or anatomical pathology?
DR. S. PARAI:
A. No, the same person. I was the --
COFFEY, Q.C.:

Page 222

Q. You were the site chief -- in the case of surgical and anatomical pathology upon the formation of the Health Care Corporation, it was the site chief who was responsible for the surgical pathology and anatomical pathology in a particular institution?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. But that was not true for the other departments, cytology, they were run as a division out of the General Hospital?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Hematology, same thing?
DR. S. PARAI:
A. Same.
COFFEY, Q.C.:
Q. Doctor, can you tell the Commissioner why that difference existed, why there was no divisional manager for anatomical pathology? Do you know why?
DR. S. PARAI:
A. Well, do I understand your question,

Page 223

divisional manager for the medical clinical services or technical services?
COFFEY, Q.C.:
Q. Clinical.
DR. S. PARAI:
A. Dr. Haegert was the clinical chief, and in a meeting he mentioned he will be the divisional chief of the anatomical pathology division and the site chief would be reportable to him.
COFFEY, Q.C.:
Q. In that capacity?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. So you assumed the site chief's role, and your understanding at the time was you were then responsible for what? How had things changed from one position to the next? In your world, how had they changed?
DR. S. PARAI:
A. I was only working clinical work at the anatomical pathology division meaning surgical and autopsy services, some cytology also, and administrative complement of that division, limited only one division.

Page 224

COFFEY, Q.C.:
Q. One division.
DR. S. PARAI:
A. Reduced position.
COFFEY, Q.C.:
Q. Before that, you'd been doing a number of different -- what ended up being a number of other divisions you had originally been responsible for?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Hematology and those others you've listed?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And that changed, it narrowed down to surgical pathology?
DR. S. PARAI:
A. And autopsy.
COFFEY, Q.C.:
Q. And autopsy?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:

Page 225

Q. Now, Doctor, in that capacity as site chief, who reported to you then in your capacity as site chief?

DR. S. PARAI:

A. The administrative role have changed with the creation of the new position and restructuring. I would not say the other pathologists was reportable to me. If you look at the by-law of the Health Care Corporation at that time, it was the divisional chief in charge of a division, and the clinical chief in charge of overall divisions. Now it was not clear to me at the time whether the other four pathologists in the hospital was reportable to me, but in practice, we have the same relationship, cordial relationship as before Health Care Corporation. There was no change of administrative structure unofficially, I will say. So it remained an unclear entity.

COFFEY, Q.C.:

Q. I take it, and not well defined? On paper, anyway, it wasn't a well defined relationship?

DR. S. PARAI:

A. Yes.

Page 226

COFFEY, Q.C.:

Q. Doctor, you remained in that capacity as site chief until 2000?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Was there ever a job description written up for the site chief at the Grace that you were aware of?

DR. S. PARAI:

A. I haven't received any.

COFFEY, Q.C.:

Q. And you weren't asked to prepare one yourself?

DR. S. PARAI:

A. No, I did not prepare myself.

COFFEY, Q.C.:

Q. You didn't prepare one and no one asked you to do it either, I take it?

DR. S. PARAI:

A. Well, I don't think I had authority to prepare myself a job description.

COFFEY, Q.C.:

Q. Doctor, when you assumed the role of site chief at the general hospital -- I just want to stay on this theme for a moment. Who had been the site chief at the General before you?

DR. S. PARAI:

A. Dr. Pat Wadden.

COFFEY, Q.C.:

Q. And before Dr. Wadden?

DR. S. PARAI:

A. Dr. Chittal.

COFFEY, Q.C.:

Q. And before that?

DR. S. PARAI:

A. Dr. Khalifa.

COFFEY, Q.C.:

Q. Doctor, we understand -- Dr. Khalifa was here yesterday and testified that he left in 1999, he left St. John's around May/June of 1999, and you took over in May of 2000. So about a year later.

DR. S. PARAI:

A. It was July, although my appointment is May 1st. Now that because of the delay of the closure of the Grace Hospital, and then I spoke with Don Cook and he said when the Grace closes, you go to the General Hospital site, so it is July, 2000.

COFFEY, Q.C.:

Page 227

Page 228

Q. In practice -- it was July before you arrived, actually arrived in the General Hospital itself?

DR. S. PARAI:

A. Right.

COFFEY, Q.C.:

Q. When you took that position, and we just looked at the letter where you accepted, it was in mid January of 2000 that you agreed that you would become site chief in the future of the General. Did you have any understanding -- first of all, did you see any job description at that time as to what your role would be?

DR. S. PARAI:

A. I have not received any job description.

COFFEY, Q.C.:

Q. Up until the time you resigned as site chief in 2005 at the General Hospital, was there ever a description in writing that you're aware of?

DR. S. PARAI:

A. Not that I am aware of.

DR. S. PARAI:

A. You've indicated that while you were site

Page 229

chief at the Grace that Dr. Haegert had a meeting and indicated that he would act as divisional chief for surgical - anatomical surgical pathology, and he was also the clinical chief of the day, I take it, Dr. Haegert at that time?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. As the site chief of the Grace, who did you report to? You reported to Dr. Haegert?

DR. S. PARAI:

A. To Dr. Haegert.

COFFEY, Q.C.:

Q. And in his capacity as clinical chief and divisional chief or just divisional chief?

DR. S. PARAI:

A. Both.

COFFEY, Q.C.:

Q. Can you tell the Commissioner, please, in your days as site chief at the Grace, how often, if at all, the site chiefs from the various sites would get together and meet?

DR. S. PARAI:

A. There was a monthly meeting in rotation with

Page 230

three sites, that is St. Clare, General, and Grace Hospital, and except the summer months. So there would be about eight to nine meeting a year.

COFFEY, Q.C.:

Q. And it rotated from one site to the next?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Your turn would come up to host it every third time?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, I take it that this goes back to the days of Dr. Khalifa's time when he was site chief?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And you were site chief, and Dr. Haegert was the clinical chief, and Dr. Cook was the site chief at St. Clare's?

DR. S. PARAI:

A. Yes.

Page 231

COFFEY, Q.C.:

Q. It goes back to that time. Doctor, that practice, how long did that continue for?

DR. S. PARAI:

A. Until Grace closed.

COFFEY, Q.C.:

Q. And then what happened?

DR. S. PARAI:

A. Then we --

COFFEY, Q.C.:

Q. Then you took over at the General.

DR. S. PARAI:

A. We had also same meeting or similar meeting between two sites, General and St. Clare's.

COFFEY, Q.C.:

Q. And it continued on then up until the time you left a site chief?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Now the purpose of those meetings from your perspective was what, the site chief's meetings?

DR. S. PARAI:

A. It's a communication, it was policy making, it

Page 232

was various issues arise in the division on both sides, and relayed to our site pathologists, and from them get feedback and make plan.

COFFEY, Q.C.:

Q. So it dealt with administrative and clinical issues from time to time?

DR. S. PARAI:

A. Both.

COFFEY, Q.C.:

Q. Doctor, at the Grace itself, the Grace Hospital itself, in your days as site chief, what quality assurance practises were there for surgical pathology at that time?

DR. S. PARAI:

A. We followed College of American Pathologists that was available at that time, but it was a partial implementation of that quality assurance program.

COFFEY, Q.C.:

Q. I'll come to that in a bit. We do have some documents that relate, at least at certain points, to the College of American Pathologists Program. Doctor, was there anything else that surgical pathology program

Page 233

at the Grace was involved in, any other external issues?

DR. S. PARAI:

A. We had American Society of Clinical Pathology checklist, which is CME Program. We sponsored that program. We had surgical pathology, cytopathology, program would come and we'll follow the direction and -- yes.

COFFEY, Q.C.:

Q. How about internal to the Grace itself, what was done in terms of quality assurance?

DR. S. PARAI:

A. Interdepartmental consultation. We had a good group of pathologists, well experienced and educated, working there a long time, and every day or almost every day we had regular multi (unintelligible) consultation, and we have several rounds we organized, a gynepath round, dermapath round, and so -- and formal and informal consultation in the department.

COFFEY, Q.C.:

Q. What about with respect to other non-pathologist clinicians, would there be any -- was there any formal or semi-formal interaction with them in terms of QA?

Page 234

DR. S. PARAI:

A. We had formal interaction, as I mentioned. The gynepathology round was quite popular. Every month we'll meet a number of dermatologists -- in town that time there are three dermatologists. We organize meeting, discuss four to six dermatological cases, both clinical and pathological, and come to a conclusion, consensus of opinion, some recommendations. That's one. The second thing was some gynepathological rounds.

COFFEY, Q.C.:

Q. I'm sorry, the what?

DR. S. PARAI:

A. Gynecological.

COFFEY, Q.C.:

Q. Okay.

DR. S. PARAI:

A. Gynecological rounds.

COFFEY, Q.C.:

Q. And anything else?

DR. S. PARAI:

A. We have got involved in the medical grand round of the Grace General Hospital. Pathologists would go there and there is some

Page 235

nephrology meeting. That's the clinical pathological correlation with the clinical medicine department.

COFFEY, Q.C.:

Q. At the Grace, was there any one individual responsible for quality assurance activities within the hospital?

DR. S. PARAI:

A. There was no such position in the hospital.

COFFEY, Q.C.:

Q. So no one individual position responsible?

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. What sorts of individuals spearheaded those activities?

DR. S. PARAI:

A. It's not only me. There were other pathologists that got involved into this rounds.

COFFEY, Q.C.:

Q. Doctor, the decision to close the Grace Hospital, how as that received by the staff at the Grace at the time? What's your memory of that, how did the staff feel about it, and the

Page 236

staff in the sense of the people working in the laboratory, the technologists that you were aware of, and your fellow pathologists, how did they feel about that at the time?

DR. S. PARAI:

A. It was a bad experience. A lot of technologists that had been working there a long time, they feel sad, some people are crying, disappointment, and all kinds of emotions at the Grace.

COFFEY, Q.C.:

Q. The pathologists, where were they -- were they divided up between St. Clare's and the General, or did you all end up in the one site?

DR. S. PARAI:

A. Divided between two.

COFFEY, Q.C.

Q. And how was that decided, do you recall?

DR. S. PARAI:

A. The principle was based on the workload, what percentage of the pathology work moved to the General Hospital and St. Clare and we have a rough estimate and, based on that, we are pathologists. We estimated at that time 60 to

Page 237

65 percent of the pathology workload moved to the General Hospital site, and the rest to the St. Clare's. So three pathologists moved to the General and to St. Clare.

COFFEY, Q.C.

Q. And it was split 3/2 - 60/40, in effect.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. And you were one of those who ended up at the General Hospital.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Now, Doctor, before I leave the topic of the Grace Hospital itself, was there breast surgery being performed at the Grace Hospital?

DR. S. PARAI:

A. Yes, but not many.

COFFEY, Q.C.

Q. I was going to ask you about that. In terms of within the St. John's area, where was the bulk of the breast surgery being done in the late 1990's?

DR. S. PARAI:

Page 238

A. St. Clare's site.

COFFEY, Q.C.

Q. And how would the volume of breast surgery at the Grace compare with the volume at St. Clare's?

DR. S. PARAI:

A. I can't recall the statistics now, but I would say we were doing 50 percent up there compared to St. Clare's doing.

COFFEY, Q.C.

Q. St. Clare's would be doing about double what you--the Grace was.

DR. S. PARAI:

A. Even more.

COFFEY, Q.C.

Q. Or perhaps more.

DR. S. PARAI:

A. More.

COFFEY, Q.C.

Q. And to put it another way, looking back to your days as site chief at the Grace, about how many breast cancer surgeries would be performed at the Grace per year. Roughly, about how many a year would you do?

DR. S. PARAI:

Page 239

A. I can't tell you the exact number.

COFFEY, Q.C.

Q. No, I appreciate that.

DR. S. PARAI:

A. Two to three hundred or more.

COFFEY, Q.C.

Q. Cases per year at the Grace itself?

DR. S. PARAI:

A. Yes, all the cancer.

COFFEY, Q.C.

Q. Cancer. Would that be breast cancer?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. And, Doctor, what was the situation then when you arrived at - and perhaps I'll back up a bit - when you came to Newfoundland back in 1988, okay - I believe that's when you arrived and started at the General Hospital. What was the situation at that point in terms of analysis of breast cancer--or breast tumours for estrogen receptors and progesterone receptors, ER and PR? What was the situation back in '88?

DR. S. PARAI:

Page 240

A. There was no--well, there was biochemical assay at that time.

COFFEY, Q.C.

Q. Okay.

DR. S. PARAI:

A. And a division of biochemistry, General Hospital site.

COFFEY, Q.C.

Q. And were pathologists involved in that aspect of the matter back then?

DR. S. PARAI:

A. No.

COFFEY, Q.C.

Q. What was your first exposure then to ER and PR because the biochemists were doing it in the meantime, I take it, when you were at the General, and when you moved over to the Grace the same thing applied, I take it.

DR. S. PARAI:

A. Initially, sometimes the surgeon will ask us to take a block and send it for biochemical assay to the General Hospital site, sometimes. Most of the time, they will choose a block in the operating room. Sometimes if the pathologist are at the operating room doing a

Page 241

frozen section for breast or are receiving a specimen, breast specimen, for cancer, surgeon will ask would we send a tissue for biochemical assay.

COFFEY, Q.C.

Q. I'm asking you about, not so much the biochemical as the ER and PR testing via paraffin blocks by HC. What was your first exposure to that?

DR. S. PARAI:

A. In 1997.

COFFEY, Q.C.

Q. And in what context did that occur?

DR. S. PARAI:

A. We had noticed that surgeons would call us to send a tissue block of cancer, breast cancer, to the Health Sciences for ER/PR receptor study.

COFFEY, Q.C.

Q. Receptor study?

DR. S. PARAI:

A. Receptor analysis or study.

COFFEY, Q.C.

Q. Okay, and, Doctor, while you were at the Grace, did the Grace Hospital ever deal with

Page 242

any other institution except the General Hospital in relation to ER and PR analysis.

DR. S. PARAI:

A. No.

COFFEY, Q.C.

Q. Okay, whatever ER and PR analysis was performed, whether biochemically or by IHC, it was done at the General Hospital, wherever it was done.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Doctor, could you tell the Commissioner, please, what you know about or what you recall about Dr. Khalifa's efforts to introduce the IHC method to ER and PR in St. John's? What do you recall about that?

DR. S. PARAI:

A. We had several meeting with Dr. Khalifa while--you know, the site chief at the General Hospital, regular meeting, and it was discussed to implementation of the IHC for breast ER/PR. The meeting went--several meeting we had and we needed some time to see the correlation between the biochemical assay

Page 243

as well as immunohistochemistry he was doing at the General Hospital site since '97, and when he came up with the study of good correlation and discussed at the site chief meeting with the presence of clinical chief, and we are in argument that maybe this is the way to go.

COFFEY, Q.C.

Q. And, Doctor, if I could, please - Commissioner, if I could, please, there are some new exhibits. I'm going to ask that they be entered. They are 2395 and 2396, 2398 through 2408 inclusive, and then 2426 through 2428 inclusive, and 2439, as well as a C-0183. Thank you. Doctor, I'm going to ask you to look at some exhibits now, Doctor. Registrar, Exhibit P-2395. Doctor, this is a letter from Dr. Khalifa, April 14, 1997, addressed to yourself, and he writes, "Enclosed please find a folder with copies of the specification sheets for all the immunoglobulins available in our laboratory. Please keep this folder in your department and make it available to all of your staff to help them place their orders. However, it is of note that few

Page 244

immunoglobulins are also available in our lab but yet missing from this folder, and these are" - and he lists them, and then he says, "I hope you find this folder to your satisfaction. Please do not hesitate to call with any further suggestions or remarks." Now, Doctor, as of April, 1997, where was the immunohistochemistry testing being performed in St. John's?

DR. S. PARAI:

A. At the General Hospital.

COFFEY, Q.C.

Q. Had, to your knowledge, there ever been any IHC work done at the Grace?

DR. S. PARAI:

A. We introduced a kit method only for limited number of antibodies, but in the introductory levels.

COFFEY, Q.C.

Q. And when had that been?

DR. S. PARAI:

A. I don't recall exactly, maybe '96.

COFFEY, Q.C.

Q. Okay, in the mid -

DR. S. PARAI:

Page 245

A. '96, in the mid time, yeah.
COFFEY, Q.C.
Q. In the mid-90's.
DR. S. PARAI:
A. '96.
COFFEY, Q.C.
Q. '96.
DR. S. PARAI:
A. Yeah.
COFFEY, Q.C.
Q. Why wasn't that pursued at the Grace, Doctor?
DR. S. PARAI:
A. We did not have enough big volume and we realized this was an introductory we tried to introduce in immunohistochemistry at the Grace. We tried with only preliminary--some common marker for cancer lymphoma and found we do not have enough resources, volume or experienced technologists dedicated, so we thought maybe it is not a good idea to continue, but it was only for a short time.
COFFEY, Q.C.
Q. And at that point, was there IHC testing being done at the General Hospital?
DR. S. PARAI:

Page 246

A. It was.
COFFEY, Q.C.
Q. And let me ask you about this. Was there ever any discussion about--after you kind of got introduced to it, or started to experiment with it, I take it, it's not a completely inaccurate word to say, "Well, we got some kits and we have a look and see how--whether we really want to get involved in this."
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. If that's what you're describing in 1996.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. Was there ever any discussion amongst the site chiefs, for example, and the clinical chief about - and you have having embarked on this initial effort - about, well, whether you should continue in it and, if not, it should be centralized in one location - for example, the General. Was that ever discussed?
DR. S. PARAI:
A. There was no discussion.

Page 247

COFFEY, Q.C.
Q. I take it, you just -
DR. S. PARAI:
A. There was no, I will say, organized discussion.
COFFEY, Q.C.
Q. Yes.
DR. S. PARAI:
A. No discussion in a meeting but General Hospital was doing immunohistochemistry long before '97.
COFFEY, Q.C.
Q. And having experimented with it or tried it at least o see if you would want to get involved, the decision was made by yourself and perhaps the other pathologists in the Grace that, no, we will not continue with this.
DR. S. PARAI:
A. It was our joint effort.
COFFEY, Q.C.
Q. Yes.
DR. S. PARAI:
A. Joint decision by all the pathologists.
DR. S. PARAI:
A. And, Doctor, if we could, please - Registrar,

Page 248

Exhibit P-1856. These are the minutes of an anatomic pathology site chiefs' meeting and divisional managers' meeting of May 13, 1997. Happens to be being held at St. Clare's. Present were Drs. Cook, Khalifa, yourself, Dr. Pushpanathan, Mr. Gulliver and Mr. Murphy, and it notes "The minutes of the December 3, 1996 meeting" - so that would have been five months earlier - "were accepted by Dr. Khalifa" so, apparently, this had perhaps been the first meeting in five months at that point. Doctor, just so you're aware, the last page of these minutes - and we looked at this yesterday - there's a note that "it was agreed to hold these meetings once a month." So, certainly, as of May 1997, the decision was made to henceforth hold them on a monthly basis?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. Doctor, on the third page here there's a reference to new business, ER and PR immunoperoxidase receptors, and so Dr. Khalifa reported to the committee that there's good correlation between a biochemical assay and

Page 249

immunoperoxidase staining for breast receptors. So, Doctor, as of May 1997 you would have been aware that Dr. Khalifa was involved in this effort to introduce IHC ER/PR testing. He had been involved for some time.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Had he ever involved you or the Grace in it in the sense of ask you for any blocks or for biochemical results or anything like that, do you recall?

DR. S. PARAI:

A. No.

COFFEY, Q.C.

Q. Here, Doctor, it's noted that--in the third line, Doctor, in the minutes note, "It appears that the time may be right to implement the immunoperoxidase, breast receptors, corporate-wide, which would be across the Health Care Corporation. "Dr. Cook stated that there's a concern among the pathologists at St. Clare's that they be the ones reporting the breast receptors. Discussion then arose that if individual pathologists are reporting these

Page 250

receptors, then there's a need for standardized criteria to determine what is required"--I'm sorry, "what is regarded as receptor positive and negative," and there's a reference to also discussions to how the Mayo Clinic reports its receptors. It was decided that this issue should be brought to a discipline meeting to get a consensus amongst pathologists and, hopefully, that meeting would be held in June. In the meantime, the status quo would be maintained." Now, Doctor, now did the discussion, if there was one, occur at the Grace Hospital concerning whether or not individual pathologists there or a group would get involved in reporting ER/PR?

DR. S. PARAI:

A. After this meeting, I discussed this issue with our pathologist at the Grace Hospital and asked their opinion, what would you prefer to do.

COFFEY, Q.C.

Q. And what was the result of that, Doctor?

DR. S. PARAI:

A. The majority wanted to report themselves.

COFFEY, Q.C.

Page 251

Q. Now, Doctor, had you had yourself any prior experience with ER/PR IHC testing?

DR. S. PARAI:

A. No.

COFFEY, Q.C.

Q. And to your knowledge, had the other pathologists at the Grace had any such experience?

DR. S. PARAI:

A. I will say, no.

COFFEY, Q.C.

Q. At least that you were aware of at the time.

DR. S. PARAI:

A. I was not aware, yeah.

COFFEY, Q.C.

Q. Exhibit P-1857. Doctor, these are the minutes of a meeting, Page 2, on June 17, 1997. It's a similar meeting and it's indicated you were present and, looking at the third page of the exhibit, the second page of the minutes under Paragraph 3.4 - "ER and PR Receptor Interpretation - this was discussed in detail. The majority of pathologists at St. Clare's, as well as the Grace Hospital, would like to interpret their own cases with control slides,

Page 252

and Dr. Khalifa has agreed to provide a number of cases to the Grace Hospital to review them to be familiar with the positive and negative results." Now, Doctor, the purpose of Dr. Khalifa providing such cases was what?

DR. S. PARAI:

A. To educate us for our learning, to be familiar with the staining and then the positive and negative -

COFFEY, Q.C.:

Q. Did you understand at the time that there might be anything different or new about the ER and PR IHC process, compared to other IHC stains.

DR. S. PARAI:

A. I was not aware of.

COFFEY, Q.C.:

Q. That there might be anything different about these?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Now, Doctor, up to this point, at the Grace were pathologists ordering IHC stains from the General?

Page 253

DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Other types of IHC stains.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And were you reporting your own slides or own stains at that time?
DR. S. PARAI:
A. Not at this time, no.
COFFEY, Q.C.:
Q. Not the ER/PR now, I'm asking about just any other IHC stain.
DR. S. PARAI:
A. Yes, we were reporting.
COFFEY, Q.C.:
Q. The others?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. If you ordered an IHC stain, the General produced the slides and they would come back to the Grace and you would read the slides and report them?

Page 254

DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And I appreciate this is not ER/PR at this point because that's in the future. Doctor, you've indicated, I think you use the word-- and in fact, the notes note here, the minutes note that it's the majority. At the Grace hospital, was there any reservations expressed by any of the pathologists about getting involved in this?
DR. S. PARAI:
A. There were some concerns expressed by some pathologists that we are not familiar with the ER/PR immunostain and so, there were some concerns expressed how compatible we are, so there are some concerns.
COFFEY, Q.C.:
Q. And I take it that is, perhaps, one of the reasons or one of the things that gave rise to Dr. Khalifa's (phonetic) agreement to provide a number of cases to the Grace, to review them so you would be familiar with them.
DR. S. PARAI:
A. Yes.

Page 255

COFFEY, Q.C.:
Q. If we could, Exhibit P-2397? And, Doctor, this is a letter of September 23rd, 1997, the minutes we just looked at were June 17th. Here, Dr. Khalifa writes to you in your capacity, I gather as your capacity of site chief and says, "As per our last meeting, I am submitting ten cases of invasive mammary carcinoma stained with antibodies against estrogen and progesterone receptors. I am also enclosing a list of my assessments of these cases." And he continues, "I am seriously considering referring the stained slides to the requesting pathologist for this test without reporting them. I have discussed this issue with Dr. Haegert and I would like to discuss it further in one of our future meetings. I will appreciate a return of the slides when you are done with them because I am going to circulate this collection among all pathologists who frequently request this test. I am looking forward to meeting with you and please accept my best regards." So this, I take it, Doctor, was the covering letter sending over the slides that Dr.

Page 256

Khalifa had agreed to send over to the Grace?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. What happened at the Grace with respect to those slides in the sense of were they circulated?
DR. S. PARAI:
A. Yes, circulated. We looked at them individually and also the group on our multi-headed scope, we discussed which one you think positive, which one negative and with any disagreement and we studied that group of slides quite awhile, maybe a week and then returned to him.
COFFEY, Q.C.:
Q. And was it discussed, did you make any further inquiries to familiarize yourself with this process?
DR. S. PARAI:
A. We looked at the available literature at that time, textbook to try to find out more information, learn ourself how it looks like and what is the pitfalls. Yes, we took effort ourselves.

Page 257

COFFEY, Q.C.:
Q. And, Doctor, at the time what do you recall about what was available, at least in your search at the time you found available in textbooks and in journals, concerning this at that time?
DR. S. PARAI:
A. Not much on textbook, but there was something of a level on the journal, current journals.
COFFEY, Q.C.:
Q. Articles, I take it, dealing with these techniques or this particular technique.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Do you recall at the time what, if anything, you learned at the time about the pitfalls or potential pitfalls at that time?
DR. S. PARAI:
A. So far I recall of this immunohistochemistry has some pitfalls and problem of false negative result was quite common and that was a big pitfall and also the procedure itself was complicated and complex.
COFFEY, Q.C.:

Page 258

Q. And do you recall learning at that time about what might cause false negatives?
DR. S. PARAI:
A. There were various issues discussed in some journal, what I recall, is that the methodology itself has some problem, any concentration only is problem and -
COFFEY, Q.C.:
Q. I'm sorry, the concentration?
DR. S. PARAI:
A. The concentration of these antibodies and then, only a few, not many I could recall.
COFFEY, Q.C.:
Q. Now, but you do recall that there were certainly some.
DR. S. PARAI:
A. There was.
COFFEY, Q.C.:
Q. Doctor, at the time you would have been familiar, of course, from your training as a pathologist with the idea of external positive controls?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:

Page 259

Q. And you understood at the time that external positive controls were required in this process.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. How about internal controls or the usage of normal epithelium for internal controls in ER/PR?
DR. S. PARAI:
A. I was not aware at that time.
COFFEY, Q.C.:
Q. When did you, looking back on it now, when did you first become aware of that?
DR. S. PARAI:
A. I would say in 2000, 2002, '03. I don't know the exact time, but after several years, a few years.
COFFEY, Q.C.:
Q. Do you recall what brought it to your attention, like why was it that you became aware of it, do you recall that? I appreciate you might never remember exactly when, but do you recall the circumstances in which it kind of came home to you that internal controls may

Page 260

be of some significance here?
DR. S. PARAI:
A. I can't recall exactly the date, I used to go to every year to convention, pathology convention, there has been some presentation, some poster session (phonetic) and some article in journal.
COFFEY, Q.C.:
Q. And at some point you became aware--now, what did you understand was the significance or potential significance of internal controls in this area.
DR. S. PARAI:
A. If I recall there are some recommendation of internal control, but it was not anything absolute I could think of, like it must be there.
COFFEY, Q.C.:
Q. And the advantages, perhaps of them being there, you became aware of them, the potential advantages of utilizing internal controls?
DR. S. PARAI:
A. Similar.
COFFEY, Q.C.:
Q. Yes. And now, Doctor, after you had received

Page 261

these grouping of ten slides from Dr. Khalifa, had the chance as a group to study them, as individuals and as a group and done the research you did, were there any reservations after that amongst the pathologists at the Grace about getting involved in this?

DR. S. PARAI:

A. Not much, we thought we would give it a try. If we are not comfortable, Khalifa was there, we could go and review with him.

COFFEY, Q.C.:

Q. Exhibit P-1859? Now, Doctor, these are the minutes of the site chiefs' divisional manager meeting of October 8th, '97. Under "New Business" paragraph one, notes "Dr. Khalifa presented results of an audit of steroid receptors of 19 breast cancer cases correlating immunohistochemistry and biochemical assays." It's typed, but apparently it was agreed afterward that it was Dr. Parai, that would be yourself, "recommended that the Health Care Corporation continue performing immunohistochemical tests and encourage doing them on endometrial carcinomas. He also mentioned that Dr. Thain,

Page 262

the Cancer Clinic still prefers to see the biochemical assay done. Standardization of reporting the results of the immunohistochemical assay also seemed to be a problem. Dr. Khalifa was asked to call upon other Canadian medical centres and the Toronto General to inquire about their protocols. He was also asked to check, receive feedback from the cancer clinic staff." Again, that's something he was going to do. Now, Doctor, this analysis of 19 cases, this audit of 19 cases was shown to yourselves in the site chief's meeting, do you recall that?

DR. S. PARAI:

A. I don't recall any audit of any result there but, so far I recall, that, yes, he mentioned the audit has been done and there is a good correlation, but if the 19 case side by side, I don't recall them. There might be, but I don't recall.

COFFEY, Q.C.

Q. And if it's possible and, if it was--in any case, I take it, that Dr. Khalifa was telling you, look, he had done this audit. Yes, these are the results and they're satisfactory.

Page 263

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. At that time, your view was that you were prepared to accept his word for it in any case.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. You would. Doctor - and just looking at that Page 2 that's there on the screen - it says "Dr. Khalifa action, Dr. Khalifa action." So from your perspective as the site chief at the Grace, who was spearheading this and responsible for it at that time?

DR. S. PARAI:

A. I would say Dr. Khalifa.

THE COMMISSIONER:

Q. Mr. Coffey, maybe this would be good spot to take the afternoon break.

COFFEY, Q.C.

Q. Thank you, sure. Perhaps we'll take it now then, Commissioner. Thank you.

(OFF RECORD)

THE COMMISSIONER:

Page 264

Q. Mr. Coffey.

COFFEY, Q.C.

Q. Thank you, Commissioner. Registrar, Exhibit P-1850, please. Doctor, this is a memo of February 16, 1998, from Dr. Khalifa to all Newfoundland pathologists, and the subject is "Reporting of Estrogen and Progesterone Receptor Immunohistochemical Results," and this is the one where he announces that, "Henceforth, starting March 1, 1998, individual pathologists throughout the province would be expected to--asked and expected to report their own ER/PR results."

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. You remember getting this?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. And I take it, Doctor, that this stage--the idea of actually sending out such a memo as of mid-February 1998, this had been agreed by the site chiefs in St. John's and the clinical chief.

Page 265

DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. Here on the second page, the second-last paragraph says, "Attached please find a proposal for uniform reporting of ER immunohistochemical staining," and he concludes by saying, "As you already know, there's a considerable host of publications addressing this issue. I'm glad to share any of the material I have already have with you, and I would extremely appreciate your feedback on this matter. And, Doctor, to your knowledge, did anyone at the Grace Hospital that you're aware of ever go looking for other materials from Dr. Khalifa?
DR. S. PARAI:
A. I am not aware.
COFFEY, Q.C.
Q. If they did, you didn't -
DR. S. PARAI:
A. I was not aware.
COFFEY, Q.C.
Q. It wasn't brought to your attention, and the actual proposal itself - there is a draft

Page 266

proposal - the Commissioner saw it yesterday, actually, in January of '98. Do you know if the final proposal - this is the final version - were you asked to review the draft, do you recall?
DR. S. PARAI:
A. No, I was not.
COFFEY, Q.C.
Q. Okay, you got the final version of it and -
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. And this would have been distributed to the pathologist at the Grace Hospital.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. Doctor, here--it's the back here, Page 2. "Each pathologist will be asked to report results of his or her own cases indicated by the brown staining of nuclei of the invasive neoplastic cells." Now up to this point--up to that point in time, were there any other stains - IHC or other stains - that you were aware of that relied upon nuclei staining, up

Page 267

to that point that you were dealing with.
DR. S. PARAI:
A. No.
COFFEY, Q.C.
Q. So this would be the first time you would have been involved with nuclei staining.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. And at the time that you were sent over those 10 cases - you recall we looked at that earlier - the letter, the cover letter where Dr. Khalifa sent you those slides from 10 cases.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. At that time and reviewing the literature at the time, you would have become aware that it was nuclei staining.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. Which is, I take it, different than cytoplasmic and membrane staining.

Page 268

DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. Here, Doctor, as well, if we get through the phase, we go to the--in Paragraph 2 of the Proposal For Uniform Reporting on Page 3 of the memo, it reads, "The second component is a rough estimate of the percentage of immuno reactive cells in the section examined. This estimate could be in the form of a range or a fixed number and is listed in parentheses." Were there any other stains up to that point in time as a pathologist that you had been dealing with that involved such an approach as involving making an estimate or a rough estimate of a percentage of staining.
DR. S. PARAI:
A. No, I was not aware.
COFFEY, Q.C.
Q. Okay, this is the first again--your first exposure to that aspect of ER/PR IHC.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. So I asked you earlier, Doctor - and we had

Page 269

discussed this outside the break, in fact, momentarily - I asked you earlier this afternoon if there was anything about ER/PR IHC, and you had indicated, no, and I take it, in principle that is still the case. It involves antigen retrieval.

DR. S. PARAI:

A. Well, I was answering the -

COFFEY, Q.C.

Q. Yes.

DR. S. PARAI:

A. The principle of the test.

COFFEY, Q.C.

Q. Yes.

DR. S. PARAI:

A. Whether it is antigen, antibody, it look like this one.

COFFEY, Q.C.

Q. Yes.

DR. S. PARAI:

A. But not interpretation.

COFFEY, Q.C.

Q. Yes.

DR. S. PARAI:

A. There is a difference.

Page 270

COFFEY, Q.C.

Q. yes.

DR. S. PARAI:

A. The difference is the nucleus strain, ER/PR.

COFFEY, Q.C.

Q. Yes.

DR. S. PARAI:

A. In contrast to the other stains, cytoplastic or membraneous stain.

COFFEY, Q.C.

Q. That's one difference, and this usage of an estimate, I take it, is that different?

DR. S. PARAI:

A. It is. It is estimate. Other stain we call positive or negative.

COFFEY, Q.C.

Q. Yes. It's yes or no.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. That sort of an approach.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Positive, negative, yes, no, as opposed to

Page 271

here in ER/PR IHC stains - you actually have to go further, if there's anything there that's positive, and then go beyond that, as Dr. Khalifa points out here, and make it an estimate of the percentage.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. And that's different too, I take it.

DR. S. PARAI:

A. It is.

COFFEY, Q.C.

Q. Doctor, the third paragraph here on this page, Page 3, refers to his suggestion or proposal-- or suggestion, usage of a comment and, see, that's--the third component is a comment regarding only ER, not PR, and this is the comment that would refer to the 1990 study.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Or paper. What was the approach at the Grace? Well, first of all, I'll back up a bit. Did the Grace accept this proposal?

DR. S. PARAI:

Page 272

A. We did not have any formal meeting at the Grace Hospital to accept this proposal. It came as a memo, and they learned from the pathologists how they used reporting.

COFFEY, Q.C.

Q. Yes.

DR. S. PARAI:

A. These examples.

COFFEY, Q.C.

Q. To your knowledge, did they utilize the approach that Dr. Khalifa suggested? They did.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. And was the usage of this sort of a comment in the case where the staining was between one and thirty? Were those sorts of comments, do you know, used by the pathologists at the Grace for any period of time?

DR. S. PARAI:

A. Well there often is discussion of shall we put this comment along with the report or put percentage? Now I think it--I can't answer, because it may vary from pathologist to

Page 273

pathologist. They may not use this comment.
COFFEY, Q.C.:
Q. On that point, I was going to ask you, was there any, at that time, in the late 1990s, while you were site chief, was there any standardized reporting approach at the Grace Hospital in pathology?
DR. S. PARAI:
A. No, we did not.
COFFEY, Q.C.:
Q. So each pathologist reported his or her own cases on the basis of their training and their understanding from time to time?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. What was your own approach, Doctor, to this?
DR. S. PARAI:
A. I followed this protocol.
COFFEY, Q.C.:
Q. Now Doctor, if we could, while we have this up here, Doctor, because we referred to it earlier, page four and five of this particular exhibit, in fact, four, five and actually six of this particular exhibit, four is

Page 274

immunohistochemical staining of steroid receptors, correlation with biochemistry, and it's the second page of it, you'll notice that the ER results, ER/PR results are on one side and the biochemical assay results are on the other, left and right-hand sides respectively, and then there's two tables summarizing the estrogen receptor, progesterone receptor results, and the comments section and then two footnotes. This is, in fact, I gather from Dr. Khalifa's evidence yesterday, this is this audit that we saw referred to earlier?
DR. S. PARAI:
A. I would think so.
COFFEY, Q.C.:
Q. And even now looking at it now, you don't recall ever seeing it?
DR. S. PARAI:
A. I don't recall.
COFFEY, Q.C.:
Q. Doctor, if you could tell us then, how then did the introduction of this at the Grace go, ER/PR, IHC?
DR. S. PARAI:
A. You mean what we did after that?

Page 275

COFFEY, Q.C.:
Q. Well, you know, what you did and how it went, from your perspective, as a site chief?
DR. S. PARAI:
A. What I recall is that even after his memo that the individual pathologists will report as of March 1998, we continued to send block to him for reporting. I believe he did for a while and then slowly we started reporting ourselves.
COFFEY, Q.C.:
Q. So you're telling the Commissioner, even though it says March 1, 1998, everybody will report their own, it's your recollection that, in fact, it wasn't necessarily like March 1 or March 2nd or 3rd that you or your fellow pathologists at the Grace actually reported your own cases? It came in over time.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Is that what your memory of it is?
DR. S. PARAI:
A. Yeah, that's -
COFFEY, Q.C.:

Page 276

Q. Initially even, Dr. Khalifa was continuing to do the reporting himself?
DR. S. PARAI:
A. I believe so.
COFFEY, Q.C.:
Q. Okay, and in terms of when any individual pathologist started to report their own cases, you could check that simply by looking at all the old pathology reports?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. That would be the way, one way to do it?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, before we leave this exhibit, under Phase II, page two, in the middle of the paragraph, Dr. Khalifa writes, "with each run, I will still be responsible for reviewing the positive controls here in our laboratory and the slides will not be mailed to you unless adequate staining is noted in the positive controls." And in fact, I should back up a bit. The second sentence he had written "this

Page 277

phase will start March 1/98, at which time your immuno stained slides will be mailed back to you with positive controls whenever it is technically possible," and then he continues, with each run, he'd be responsible for ensuring the positive controls worked, and he wouldn't mail them out unless they did. You interpreted these positive controls to be external controls?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And Doctor, what was your understanding then in 1998, when this process started, you know, and the Grace was going to report its own cases, as to how the external control slides would be handled? What was your understanding?

DR. S. PARAI:

A. My understanding was that it will be kept at the General Hospital site and if we request them and they may send it to us, but we have to return after we finish our study.

COFFEY, Q.C.:

Q. And Doctor, did you have the understanding

Page 278

that you wouldn't get the patient slides in the first place, the ER/PR slides unless Dr. Khalifa had looked at the positive--the external positive controls?

DR. S. PARAI:

A. Yes, that was the understanding, yes.

COFFEY, Q.C.:

Q. That was your understanding?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. You wouldn't even get the patient slides unless he had looked at the controls and was satisfied, the external controls?

DR. S. PARAI:

A. That was my understanding.

COFFEY, Q.C.:

Q. And if you wanted to see the external control yourself, control slides yourself, you'd have to ask for them?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. What then developed? What was your practice in that regard?

Page 279

DR. S. PARAI:

A. I recall initially I used to ask control. As you know, we had only ten cases we reviewed among pathologists and that was about a few months earlier. So initially, I recall we asked control from time to time. Not only me, other pathologists, and after sometimes when we are familiar with the positive or external control, we were comfortable to report ourselves.

COFFEY, Q.C.:

Q. Okay, and so as time went on then, for example, in early 1999, within--after a year had passed, for example, and you ordered an ER/PR for a patient, say in the beginning of 1999, I'll just pick that as a time frame, you would fill out a requisition form?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And the block would go with the requisition form over to St. Clare's, I'm sorry, over to the General Hospital?

DR. S. PARAI:

A. Yes.

Page 280

COFFEY, Q.C.:

Q. And they would prepare the slides, ER and PR slides?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And the slides would come back to you, or would come to you?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Would the external control slides, at that point, be coming to you?

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. And how would you know that they had been--the external control slide had worked or the ER control, external control and the PR external control had worked?

DR. S. PARAI:

A. My understanding was that one of the pathologists, Dr. Khalifa, was looking at them.

COFFEY, Q.C.:

Page 281

Q. And you wouldn't get the patient slides unless the external control slides were okay?
DR. S. PARAI:
A. That was my understanding.
COFFEY, Q.C.:
Q. And then as time went on, would you ask to see the external control slides or would you just rely upon the fact that they'd been looked at?
DR. S. PARAI:
A. As I said, initially, occasionally, I recall I did, but not later on.
COFFEY, Q.C.:
Q. As time went on, you were satisfied that, based upon your experience then and his assurance that the external controls would be looked at?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. You were prepared then to interpret the patient slides?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Did you make any observation about that

Page 282

practice, how your fellow pathologists at the Grace handled that? Were they doing the same thing you were?
DR. S. PARAI:
A. They were doing this--well, I can't tell for them, but so far I understand is that they--that was the understanding. Initially they wanted to see control themselves, which was not--we had to request, so after sometimes, they started reporting themselves.
COFFEY, Q.C.:
Q. Doctor, if we could look, please, at Exhibit P-1862? Doctor, here again, these are minutes of a site chief divisional managers meeting of March 19th, 1998, and it's noted under business arising that Dr. Khalifa updated the committee--I apologize, I got to go to page two. It's actually page three. These are the minutes. Under business arising, "Dr. Khalifa updated the committee about the current stage of ER/PR reporting by the requesting pathologists. The transition was going smooth. Dr. Cook made very positive remarks about the role played by Dr. Khalifa in this regard." So Doctor, I appreciate that this is

Page 283

now--well, in fact, it's more than ten years ago now, looking back on it. Did the transition, or looking back on it now, your memory of it, how did the transition go? Was it, from your perspective, at that time, smooth from the biochemical assay to the ER/PR IHC?
DR. S. PARAI:
A. Initially, we got some phone call from the oncologist or radiation oncologist that they still wanted biochemical assay. They saw the new IHC. They had little bit of reservation about the tissue. I can't explain why, but they wanted also biochemical assay side by side with the tissue immunohistochemistry.
COFFEY, Q.C.:
Q. The oncologists did?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. So initially, the oncologists, at least that you were dealing with, wanted to see the ER/PR IHC results side by side with the biochemical assay results? They wanted both results?
DR. S. PARAI:

Page 284

A. I think so, yes.
COFFEY, Q.C.:
Q. And you've indicated that they didn't explain why, they just wanted to see both?
DR. S. PARAI:
A. No.
COFFEY, Q.C.:
Q. What then happened as time went on?
DR. S. PARAI:
A. Well, then I did not--after sometimes--well, what I say to oncologists that I'll mention these things to Dr. Khalifa, but if you have any concern, you have to talk to the clinical chief of the program.
COFFEY, Q.C.:
Q. And then what happened?
DR. S. PARAI:
A. I did not hear anything from this issue any more.
COFFEY, Q.C.:
Q. And was it your understanding the biochemical assay process ended in 1998?
DR. S. PARAI:
A. It ended. What time, I don't recall, but that was a time there was a move to stop it, but

Page 285

when, I can't--I don't know.
COFFEY, Q.C.:
Q. Now Doctor, what then happened then Doctor, as '98 became 1999, okay, and the Grace is about to close as we get into 2000, to your knowledge, were you aware of any problems with ER/PR IHC process? Were you made aware of any at the time?
DR. S. PARAI:
A. I was not aware of any problem.
COFFEY, Q.C.:
Q. And at the time, as a practising pathologist, you would have from time to time reported your own individual case?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And were you comfortable at the time in doing so?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And no concerns were brought to your attention at that time about that?
DR. S. PARAI:

Page 286

A. No.
COFFEY, Q.C.:
Q. Doctor, if we look again at P-1868? Appreciate, Doctor, we looked at this earlier, but it was mid January 2000 that you agreed to accept the appointment as the permanent site chief at the General Hospital effective, you thought, May 1st at that time?
DR. S. PARAI:
A. Yes, but that was changed to July.
COFFEY, Q.C.:
Q. Sure, and you've told us about that. What I wanted to ask you about here is this, there's a certain amount of lead time here, I take it, that you understood at the time "in four months or five or six months, I will be the site chief at the General. I, Dr. Parai, would be."
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. What did you understand, when you accepted the position, was going to be your role at the General as site chief? What was expected of a site chief at the General Hospital?

Page 287

DR. S. PARAI:
A. I was expecting a similar job as I was doing at the Grace Hospital, maybe in a greater role because more manpower, it's a bigger lab, and more involved at the General.
COFFEY, Q.C.:
Q. More involved in what sense?
DR. S. PARAI:
A. I had to be more involved at the General Hospital. It would be, with the merger of the labs, significant increase of the workload, manpower, and this kind of -
COFFEY, Q.C.:
Q. Now in terms of the things you would be responsible for, for example, we've looked at these various memos and minutes of meetings involving Dr. Khalifa and in particular, Dr. Khalifa was involved in IHC. We just looked at the ER/PR in particular. And did you understand, at the time, that Dr. Khalifa, as the site chief, was involved with the IHC end of the lab at the General Hospital, actively involved with it?
DR. S. PARAI:
A. That was--from his memo, that appear he was,

Page 288

but I didn't know what, in practice, I can't confirm.
COFFEY, Q.C.:
Q. Did you expect that you would then be involved? I appreciate you weren't replacing Dr. Khalifa directly. He had been gone for a while, but you were going to be occupying that position.
DR. S. PARAI:
A. This was a grey period, more than one year. Khalifa left in end of June '99.
COFFEY, Q.C.:
Q. Yes.
DR. S. PARAI:
A. Now I'll be going there after a year, in between there are two other site chiefs, Dr. Chittal and Dr. Wadden. So I was--I knew them, so I did not know what kind of role they had as the acting site chiefs, and what would be my job description, I was not sure.
COFFEY, Q.C.:
Q. Okay. So you accepted the job without really knowing necessarily exactly what you were getting yourself into?
DR. S. PARAI:

Page 289

A. Well, I knew -
COFFEY, Q.C.:
Q. In the sense of day to day?
DR. S. PARAI:
A. Well, I knew what would be my role there, but not everything. It was not clear.
COFFEY, Q.C.:
Q. Now Doctor, what did you find then when you arrived as the site chief?
DR. S. PARAI:
A. The workload increased significantly at the General Hospital. As I mentioned before that the 70 percent of the pathology workload moved to the General Hospital. Before July 2000, Grace had the largest pathology lab in the province. We processed 13,000 surgical specimens and at the General, 10,000. St. Clare, maybe around 6,000. So the almost seven to eight thousand specimens of the Grace Hospital moved to the General Hospital site. We got the corresponding service also moved to the General. So workload increased dramatically within a short period of time.
COFFEY, Q.C.:
Q. To about how many a year? How many surgical

Page 290

specimens a year, roughly?
DR. S. PARAI:
A. 17 to 18 thousand, from 10,000. There would be 65 to 70 specimen compared to 45 to 50 a day. So although pathologists also moved, technologists also moved, renovation still going on at the General Hospital, not completed, pathologist office were not ready. There was a facility problem for the lab tech who moved there. So these are the few facility management issue are there and -
COFFEY, Q.C.:
Q. They were some of the practical problems you faced initially?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, I'll show you another document, please, Registrar, Exhibit P-1867? Doctor, this is a document entitled Laboratory Medicine Program, Health Care Corporation of St. John's, Quality Initiatives Report. It's for the period April 1, 1999 to March 31, 2000, okay, which of course, March 31, 2000 is just several months before you take over as

Page 291

site chief at the General, okay. This was submitted by Vern Whelan, who was the program director of the day, and Dr. Cook, the clinical chief at the time, the acting clinical chief. On page three of the exhibit, under executive summary, there's a report for that period and executive summary, I just wanted to ask you about a couple of comments in it. It notes, in the last paragraph, on the first page here, "resignations were received during the year from Dr. -
DR. S. PARAI:
A. Prabhakaran.
COFFEY, Q.C.:
Q. - Prabhakaran and chief of biochemistry, Dr. Khalifa, the site chief anatomical pathology, and Dr. McIntosh, the chief of cytology. Dr. Randell was appointed chief of biochemistry. Dr. P. Wadden, site chief acting of anatomical pathology until April 30th. You were identified here, Dr. Parai is going to be the permanent site chief for the General Hospital, effective May 1, 2001, and the chief of cytology is still vacant. "Division of anatomical pathology received resignations

Page 292

from six pathologists, approximately half of the total pathologists manpower. All positions have been successfully filled."
THE COMMISSIONER:
Q. One third.
COFFEY, Q.C.:
Q. I apologize, one half, and you're correct, certainly, Commissioner, one third. Now Doctor, I take it then by the time you took over as site chief, according to this anyway, of a couple of months before this, you took over as site chief, all the positions were filled, pathologists positions were filled, there was still a chief of cytology not in place, but there were a number of new people, I take it, in positions?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. So Doctor, I want to ask you to, looking back on that now, what, if any, effect did that have at the time, I mean, this change in personnel? I mean, because it's a significant change. If a third of your personnel changed, that's got to be a significant number turning

Page 293

over in this context. So what, if any, as the new site chief, with all these new staff -

DR. S. PARAI:

A. Well, it required a lot of work to do. The new people come in, we needed to orient them with the new work flow and I was moving to a new site, also needed to orient and familiar with these personnel and facilities, but I knew that place before. I worked at the General Hospital five years or seven years ago, so I knew the place. I knew pathologist staff, technical staff.

COFFEY, Q.C.:

Q. And you would have known the pathologists that accompanied you from the Grace?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And the technologists?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. That came over from the Grace. Doctor, when you arrived then as the site chief and kind of got settled, as it were, and the immediate

Page 294

practical problems you've described addressed, the immunohistochemistry end of the lab at that time, who from your perspective was responsible for that at the time?

DR. S. PARAI:

A. I was not aware of any particular person responsible, but I knew Dr. Chittal had interest in immunohistochemistry. He was the founding pathologist of immunohistochemistry lab early 90s, so he had keen interest. Now what I understood also that Dr. Wadden was looking, as acting site chief, she was also looking at the lab overall, and so I was assuming that I would be doing the similar things.

COFFEY, Q.C.:

Q. And did you get involved in that?

DR. S. PARAI:

A. Well, I got involved in all areas of the lab.

COFFEY, Q.C.:

Q. How much involvement did you have in the IHC aspect of it?

DR. S. PARAI:

A. How much means what percentage of my workload?

COFFEY, Q.C.:

Page 295

Q. Not so much percentage as the nature of what you -- and perhaps the percentage of your workload, and as well the nature of your involvement?

DR. S. PARAI:

A. I can't say any percentage, but I was - I was looking after all lab as a whole, and the amount of time needed for any particular issue.

COFFEY, Q.C.:

Q. Initially in 2000, were there any problems brought to your attention in relation to IHC, any -- and I appreciate there might have been from time to time a particular -- you ran out of a particular stain or whatever, but I'm talking about more general problems or concerns.

DR. S. PARAI:

A. Well, the IHC lab was -- there were two senior technologists. They are quite knowledgeable. I knew them before. When I came back, they were quite -- not only knowledgeable, quite good, experienced, and very reliable, and it was the technical manager or the division manager was Terry Gulliver. He had been there

Page 296

a long time, quite capable and experienced technologists, so it was looked after well, in my opinion.

COFFEY, Q.C.:

Q. The two technologists would be Peggy Welsh and Mary Butler?

DR. S. PARAI:

A. Right.

COFFEY, Q.C.:

Q. In terms of from the pathologist end, okay, as pathologist, was there any particular pathologist who would be seen as the -- a phrase we've seen referred to in some of the documents as a "point person" or the resource person for immunohistochemistry. In that time when you came over as site chief, was there anyone who filled that role?

DR. S. PARAI:

A. There was no official point person or resource person so for I know of.

COFFEY, Q.C.:

Q. Yes.

DR. S. PARAI:

A. I was not aware.

COFFEY, Q.C.:

Page 297

Q. And there wasn't -- after you became site chief at least in the first year or two you were there, there was no particular person appointed resource person or a point person for IHC?

DR. S. PARAI:

A. Right.

COFFEY, Q.C.:

Q. Exhibit P-1874, please -- actually, if we could, please, I apologize, Commissioner, Exhibit P-2399. Doctor, this is an agenda, February 21st, 2001, Division of Anatomical Pathologist meeting, General Hospital site, and it's an agenda, and then we look at the second page of the exhibit, these are the actual minutes of that meeting. It's minutes of meeting, February 21st, 2001, and paragraph 4.7 which is on page three of the exhibit, there are a couple of things here I wanted to ask you about, Doctor. Paragraph 4.6, first of all, pathologist assistant or assistants, Dr. D. Haegert, which would be Dave Haegert, "Will discuss with Dr. Williams the possibility of recruiting two pathologist assistants in the future". So this is back as

Page 298

far ago as the beginning of 2001, pathology assistants.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Who at first raised that, the idea of utilizing pathologist assistants, do you recall that?

DR. S. PARAI:

A. Well, I was one of the proponents. Even when I was at the Grace Hospital, I was trying to recruit pathologist assistant at the Grace General Hospital, and there were funding problem, basically, that the reason I could not do that. I trained one of the technologist who did grossing for us for a short period of time, but he left. There was another technologist at the Grace Hospital, well qualified with a Bachelor of Science degree, and she was interested to do pathologist assistant job, but we could not do that because of the funding problem. So these issues of pathologist assistant dates back to 1998/1997 from Grace Hospital, and when I moved to the General Hospital site, I

Page 299

discussed with the pathologists formally and informally and approached Dr. Haegert that we require pathologist assistant at the site.

COFFEY, Q.C.:

Q. So was Dr. Haegert, do you recall, was he a proponent, was he in favour of pathology assistants?

DR. S. PARAI:

A. I read that statement, yes.

COFFEY, Q.C.:

Q. And how about Dr. Robb, was he -- how did he feel about it?

DR. S. PARAI:

A. Yes, he was also supportive of pathologist assistant.

COFFEY, Q.C.:

Q. Now Dr. Cook had been the clinical chief, acting clinical chief from '99 to 2000, but he was the site chief at St. Clare's anyway during your time as site chief at the Grace. Do you know how Dr. Cook felt or how did he feel about pathology assistants?

DR. S. PARAI:

A. I do not recall.

COFFEY, Q.C.:

Page 300

Q. You don't recall that.

DR. S. PARAI:

A. I don't recall.

COFFEY, Q.C.:

Q. Certainly yourself, Dr Haegert, and Dr. Robb were in favour of it?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And even after you came on as site chief, you were in favour of it, said you were, but it didn't go anywhere, I take it, because there was no money?

DR. S. PARAI:

A. That's my understanding.

COFFEY, Q.C.:

Q. Here as well, Doctor, paragraph 4.7 says, "Immunoperoxidase quality control, a survey has been undergoing for the quality control of the immunoperoxidase staining". It goes on to say, "This will also be discussed in the site chiefs meetings to inform the pathologist at St. Clare's Hospital. A follow up will be given later on". Doctor, because, of course, this particular meeting is of the pathologist

Page 301

at the General Hospital, and amongst those listed as present is Dr. Haegert, a number of others, and yourself. Doctor, do you recall what that was about? This is February 21st, 2001.

DR. S. PARAI:

A. So far I recall is I believe our division manager, Mr. Gulliver, was circulating a number of stain slide with control to the pathologists. It is, in general, all immunohistochemistry, and wanted to track back from the pathologist how are the quality of the stains.

COFFEY, Q.C.:

Q. Do you recall whether or not there had been any other such survey before this of IHC stains?

DR. S. PARAI:

A. I don't recall. I was not aware.

COFFEY, Q.C.:

Q. If there was, you weren't aware of it?

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. And do you know what had occasioned or why

Page 302

this had come about?

DR. S. PARAI:

A. I don't recall was there anything. I don't recall.

COFFEY, Q.C.:

Q. Exhibit P-1874. Now, Doctor, here is the next day, February 22nd, 2001, and these are the minutes of meeting of site chiefs and divisional managers. You're listed here as the chair. I take it at that time you would be the chair because it was in your -- the meeting was probably at the General Hospital.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. And Dr. Haegert is present, Dr. Cook, Mr. Gulliver, Mr. Murphy, and here in paragraph 4.2, quality control of immunoperoxidase staining, "There's been a study going on, the quality of the immunoperoxidase staining for both sites. It is agreed the control for immunoperoxidase staining be run for every batch. The pathologist will check the control slide before sending the slide to the other site. Dr. S. Parai", that will be yourself,

Page 303

"has agreed to do this. In case he is not available, another pathologist will be looking at the control", and then they talk about a particular substance as being a positive control or a mesothelioma. Anyway, "it is agreed that this antibody is needed in our panel and Mr. Gulliver has agreed to order antibodies as soon as possible". Now, Doctor, this having been raised at the General Hospital meeting and it came up at the site chief's divisional managers meeting the next day, what was the outcome of this study, do you recall?

DR. S. PARAI:

A. It was good. We were satisfied with the immunostains. Many of the pathologists thought it was good. That was the survey -- outcome of the survey.

COFFEY, Q.C.:

Q. Were there any complaints, do you recall?

DR. S. PARAI:

A. There was the -- the ER/PR issue was also raised. I think that's the only thing I could think of, whether it is working well or not, but as a whole, it was all right. It was --

Page 304

everybody -- what we got feedback from the pathologists at the General Hospital site, they all were satisfied.

COFFEY, Q.C.:

Q. What was the concern about ER and PR?

DR. S. PARAI:

A. I don't recall specifically any complaint, but -- I don't recall.

COFFEY, Q.C.:

Q. Now here there is a reference to a pathologist will check the control slide before sending the slide to the other site, and you have agreed, that's Dr. Parai has agreed to do this, and in case you're not available, of course, somebody else will have to do it?

DR. S. PARAI:

A. That always has been the practice, yes.

COFFEY, Q.C.:

Q. Now this is the control slide for which stains?

DR. S. PARAI:

A. For all the stains.

COFFEY, Q.C.:

Q. All stains?

DR. S. PARAI:

Page 305

A. Yes.
COFFEY, Q.C.:
Q. And that would be ER and PR and any other type of stain as well?
DR. S. PARAI:
A. Yes, most of our work was lymphoma sarcoma, also ER/PR, yes.
COFFEY, Q.C.:
Q. So the external control slides for not only ER and PR stains were being read by the site chief, yourself, according to this, this is the agreement, but --
DR. S. PARAI:
A. There was --
COFFEY, Q.C.:
Q. The other external control slides for other stains as well?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And why was this -- why did they have to discuss this at this point in time? This is February, 2001. Why was there a discussion about the control slides, do you recall?
DR. S. PARAI:

Page 306

A. I don't recall.
COFFEY, Q.C.:
Q. I take it, though, that you do have some recollection that there was something said or concerns raised about estrogen and progesterone stains?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. If we could, please, Exhibit P-1876. Now here, Doctor, this is the minutes of a meeting of site chiefs and divisional managers of April 25th, 2001. Present are Drs. Cook, Parai, Haegert, and Mr. Gulliver, and Mr. Murphy. The minutes of the previous meeting of February 22nd were approved by Dr. S. Parai and seconded by Mr. Terry Gulliver and then under business arising, paragraph two, "Quality control of immunoperoxidase staining. Generally the immunos appear to be very good. There appears to be some problems with the estrogen and progesterone receptors. The positive controls are checked daily by a pathologist. However, these need to be documented. Dr. Parai will follow up on this.

Page 307

Note is also made of heavy utilization of immuno services and the high volumes encountered". Now, Doctor, in relation then to this -- firstly it says that immunos generally appear to be very good, some problems with the estrogen and progesterone receptors. Now this -- we looked at February. This is now April. We looked at the minutes of February 22nd. This is two months later in April. There had been this survey talked about in the February meeting, that there was a survey ongoing. Now in April 25th, I gather the survey was probably concluded because there is an assertion here at this site chief's meeting that the immunos appear to be very good, is your recollection of it, "but there appears to be some problems with estrogen and progesterone receptors". Doctor, who would have brought the nature of the problems with estrogen and progesterone receptors to this committee?
DR. S. PARAI:
A. I don't recall who did.
COFFEY, Q.C.:
Q. So you --

Page 308

DR. S. PARAI:
A. One of -- either me, Dr. Cook, or Dr. Haegert, one of us.
COFFEY, Q.C.:
Q. Was this then --
DR. S. PARAI:
A. Or another pathologist. I don't recall who brought it. I don't think a name was mentioned. It could be any pathologist at either site. I don't recall.
COFFEY, Q.C.:
Q. Was this -- in April of 2001, the idea or understanding that, look, we've done a survey of immunos, everybody is satisfied with the immunos generally, but there are concerns about the ER and PR stains, was that generally understood amongst the pathologists do you think at the time? Not only by yourselves, the three guys who are in charge, Dr. Haegert, Dr. Cook, and yourself, but the others?
DR. S. PARAI:
A. I can't answer that. I was not -- I can't answer.
COFFEY, Q.C.:
Q. Yourself, though, you did understand that

Page 309

there was -- at least some people were concerned about it?

DR. S. PARAI:

A. Yes, well, the staining, so far I recall, whether it is weak positive or positive, that was the thing. Now the intensity of the staining of the nuclei when we grade it, so sometimes we thought maybe it is positive, weak positive, moderate. These are the -- this is what I recall, but if it was a negative stain, I think there was no problem to determine negative.

COFFEY, Q.C.:

Q. Doctor, do you know if any inquiries -- any further inquiries were made to address this, what is asserted here to be some problems with the estrogen and progesterone receptors? Do you know if any inquiries were made as to, well, what's this about, what can we do about it?

DR. S. PARAI:

A. So far I recall, there was not many inquiry after some time we followed the control, and satisfied it was working well.

COFFEY, Q.C.:

Page 310

Q. Doctor, another aspect of this matter, the reference at the bottom of this page under new business, terminology of estrogen and progesterone reports, "Mr. Gulliver will a canned text for reporting of estrogen and progesterone receptors. Information for this will be obtained from Dr. Parai", and presumably you are the Dr. Parai here. Do you recall what this was about?

DR. S. PARAI:

A. Yes, this is the memo of Dr. Khalifa. Mr. Terry Gulliver wanted that memo.

COFFEY, Q.C.:

Q. That's the February 16th, 1998 memo.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Go ahead.

DR. S. PARAI:

A. So far I recall, I gave it to him.

COFFEY, Q.C.:

Q. What was the purpose or your understanding of the purpose of Mr. Gulliver developing a canned text?

DR. S. PARAI:

Page 311

A. For standardized reporting.

COFFEY, Q.C.:

Q. Was there a concern about a lack of standardized reporting at that time?

DR. S. PARAI:

A. I don't recall. We are following the memo of Dr. Khalifa, same protocol. I believe most of us have.

COFFEY, Q.C.:

Q. Doctor, was there any -- were there any checks being made or any reviews being done to see how many of you were following his memo?

DR. S. PARAI:

A. No, I was not aware.

COFFEY, Q.C.:

Q. Was there at the time any discussion about any problems that a lack of standardization might cause in the future?

DR. S. PARAI:

A. There was no such discussion. We wanted the canned text so that it is also easy to report. What happened before this, we had to dictate all those paragraphs, one to three, in the memo. We have to dictate the comment as well. So there is a lot of secretarial work

Page 312

involved. With canned text, it is automatically there, you only put the number percentage to facilitate some of the secretarial work.

COFFEY, Q.C.:

Q. Doctor, what do you recall about how far that effort by Mr. Gulliver got in developing a canned text?

DR. S. PARAI:

A. So far I recall, it was done later on, but exact date, I am not -- I don't recall.

COFFEY, Q.C.:

Q. And was it done before 2005, do you think?

DR. S. PARAI:

A. I can't answer.

COFFEY, Q.C.:

Q. You don't know. We'll ask Mr. Gulliver about that. As well here looking at the minutes of -- it's the same meeting, Doctor. There's a reference to updating the immunoperoxidase form in paragraph 10 on page three of the memo, and under paragraph 12, again you referred to this earlier, "Pathologists offices. Dr. Parai reported that providing new offices for pathologists at the General

Page 313

site continues to be a problem. There is no firm date on completion. Pathologists now occupying offices at the new Janeway site will soon have to vacate them. Mr. Gulliver reported the renovations are currently underway and hopefully this issue will soon be addressed", and there's continuing discussion with facilities management concerning this. So, Doctor, as of April, 2001, the problems with office space that you had encountered in June or July of 2000 still existed, at least for some of the pathologists?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, reference there to -- just go back before we leave it, under paragraph -- business arising, paragraph two on page one, "Positive controls are checked daily by a pathologist". Now at that point, this is early 2001, what was the practice in terms of checking positive controls at the General Hospital site for IHC, how was that being handled?

DR. S. PARAI:

Page 314

A. Can I --

COFFEY, Q.C.:

Q. At the General Hospital site by early 2001 --

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. What was the practice in terms of pathologists checking the external positive controls?

DR. S. PARAI:

A. When the immunostain run is done, the control will be initially checked by the technologist at the lab, pass the line of control check, and then would be brought to -- in our reporting room in a tray slide and put to a particular box for controls. So the pathologist, either me or another pathologist on call in my absence, will go -- usually it is ready in the afternoon, will check the control and if they are satisfactory, will just inform the technologist at the lab that they're okay. That was the system there.

COFFEY, Q.C.:

Q. And here it goes on to say, "However, these need to be documented". So at that point if you checked the controls, for example, for ER

Page 315

and PR stains, okay, yourself, and it was -- as the site chief, you had seen it as your responsibility to do, but if you're absent, somebody else would have to do it in your absence -- am I correct on that?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Was this being documented in any way?

DR. S. PARAI:

A. There was no form at the box, but I would go and say, Mary, that it is okay.

COFFEY, Q.C.:

Q. Do you know if it was being recorded in any way by Peggy or Mary?

DR. S. PARAI:

A. I think it would be. That was my understanding.

COFFEY, Q.C.:

Q. Do you know what they recorded it on?

DR. S. PARAI:

A. There will be a -- there will be some form, requisition form, a particular control, either lymphoma or sarcoma or ER/PR in this particular case. They will put some note,

Page 316

either a tick mark or some "N" word.

COFFEY, Q.C.:

Q. Did you keep any record of the fact that you had approved of or had found to be -- particular positive controls to be adequate? Would you keep any record yourself?

DR. S. PARAI:

A. No, that was not the practice.

COFFEY, Q.C.:

Q. After this meeting of April 25th, 2001, do you know if any efforts were made to document the fact that the positive controls were okay?

DR. S. PARAI:

A. I don't recall.

COFFEY, Q.C.:

Q. So it does indicate that you were to follow up on this. Do you know if any such record exists of the controls being documented that you're aware of?

DR. S. PARAI:

A. Well, after some time, after we followed up sometimes and found there was no problem with the control of ER/PR or other immunostains, and then every time there was a batch run, I would call another pathologist to tell or

Page 317

inform the technologists at the immunohistochemistry lab and other pathologists will -- I did not have any document myself.

COFFEY, Q.C.:

Q. Okay, you didn't keep any documentation. As far as you knew, the other pathologists didn't document this?

DR. S. PARAI:

A. I can't answer that. I was not --

COFFEY, Q.C.:

Q. Certainly you didn't do it and you weren't aware of anybody else doing it?

DR. S. PARAI:

A. It might be somebody may have.

COFFEY, Q.C.:

Q. They may have, but you're not aware of it. If they did, you're not aware of it?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Okay. Doctor, at the General, if for some reason you wanted to see a control slide for a slide that had been done six months before, I'll just pick an example, six months before,

Page 318

at the General Hospital, how would you go about getting the control slide?

DR. S. PARAI:

A. I will ask the technologist that I want this control and there is a file system and report filed for the controls as well as the slides, and they will bring it to us.

COFFEY, Q.C.

Q. And I take it, if somebody outside St. John's who had ER and PR slides sent to them, or in fact somebody at the General Hospital - I'm sorry, St. Clare's - wanted to see the external controls in that sort of a situation, they'd have to send it to--if you had not already sent them a copy of the control slides or their own control slides, you'd have to dig them out and have them sent out.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Now, Doctor, in terms of ER and PR external control slides, when you examined them, what were you looking for?

DR. S. PARAI:

A. Nucleus, positive nucleus stain. It is a

Page 319

brown stain, diffused and granular, brown-black stain. Sometimes you also call grease stain. So it would be in the nuclei, particular anatomical location of the cell.

COFFEY, Q.C.

Q. Doctor, if I could, please, while we're in that timeframe, Exhibit P-2400. Doctor, these are Laboratory Management Committee minutes of February 28, 2001. There are a number of people present. There are your regrets from yourself at this particular meeting but, I take it, that you would get the minutes of the meeting at the next meeting. They would be distributed.

DR. S. PARAI:

A. I would think so, yes.

COFFEY, Q.C.

Q. Just a particular thing in this meeting, doctor, there's a reference here to business arising, proficiency programs, Atlantic Canada, awaiting Dr. Whiffen. So I take it, that there was at that point - and this is early '01, 2001 - there were inquiries being made about proficiency programs at the time.

DR. S. PARAI:

Page 320

A. Yes.

COFFEY, Q.C.

Q. As well here, Doctor, there's QI activities, "Latest external CAP," C-A-P, "proficiency reports presented. Excellent reports for all divisions and latest immunology t-cells sub-set reports excellent." To recall what these - these are College of American Pathologists proficiency reports?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.

Q. Was your anatomical pathology division participating in that? This is as of -

DR. S. PARAI:

A. This is a clinical lab here. It is talking about hemotology. They are -

COFFEY, Q.C.

Q. Yes, it's - I'm sorry, go ahead.

DR. S. PARAI:

A. Yeah, the proficiency test of the hemotology is completely different, in my understanding, than anatomical pathology.

COFFEY, Q.C.

Q. Okay, so this was hemotology.

Page 321

DR. S. PARAI:
A. Hemotology.
COFFEY, Q.C.
Q. Okay.
DR. S. PARAI:
A. However, (unintelligible) portion we had College of American Pathologists, it's called a PIP, Performance Improvement Program, subscribed and also American Society of Clinical Pathologists, samples subscribed.
COFFEY, Q.C.
Q. Did any of those processes at the time involve or necessarily involve any consideration or analysis of IHC staining?
DR. S. PARAI:
A. Some of the cases would be IHC stain, yes.
COFFEY, Q.C.
Q. IHC stains.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.
Q. Would they necessarily involve ER and PR stains?
DR. S. PARAI:
A. I don't recall.

Page 322

COFFEY, Q.C.
Q. I take it, it might vary from year to year.
DR. S. PARAI:
A. It does.
COFFEY, Q.C.
Q. So some years you might be looked at in terms of your ER and PR stains and your analysis of them, but other years--and in any particular year you might be by the CAP process.
DR. S. PARAI:
A. Well, I can't confirm what year it was so -
COFFEY, Q.C.
Q. Yes. Some years though, you might. Some years you might not.
DR. S. PARAI:
A. Or it may not, whenever it was, discussed, yeah.
COFFEY, Q.C.
Q. Okay.
DR. S. PARAI:
A. Right.
COFFEY, Q.C.
Q. Exhibit P-1877, please. And, Doctor, these are minutes of a meeting of site chiefs and divisional managers, June 26, 2000, but this

Page 323

is the agenda for June 26, 2001. Just look at the minutes there - June 26, 2001. Present are yourself, Dr. Cook and Dr. Haegert, and here, Doctor, under Paragraph 3.2, "Business Arising," refer to an expression "ER and PR control," and it reads, "The controls for all these immunostaining are checked by the site chief or by on-call pathologists when site chief is not available. So do you recall why it was that this would have come up again in June?
DR. S. PARAI:
A. This is the follow-up of the previous meeting. As you recall, in the previous meeting there are something discussed to follow up. So I was giving a follow-up that this is checked and we did not see any problem.
COFFEY, Q.C.
Q. Doctor, here as well under "New Business," Paragraph 4, "Quality Assurance for Anatomical Pathology, Pathologist Review. This meeting is dedicated for the above items and the following points are discussed," and there are a number of points. A system review - it says, "This system review is not in place and

Page 324

will be discussed in the next meeting for possible implementation. A pathology report review by system by a committee." So, I take it, there was no such system review in place at that time.
DR. S. PARAI:
A. System review means any organ system like a breast cancer or colon cancer or lymphoma, the body organ system, at that time we are--this is the time we are developing a quality assurance program. I recall as soon as I came into General Hospital, there was no definite--well there was fragmented--we are doing quality assurance side by side, in the meantime, we are trying to develop a program suitable for our organization for corporate-wide policy.
COFFEY, Q.C.:
Q. And this is part of the process of trying to develop that?
DR. S. PARAI:
A. Yes. At this point, this is June 2001, there was a draft program was already being developed, it was not me along with other site chief and the manager and this particular

Page 325

meeting we are reviewing those draft, how far we are doing and how far we have to go and what we are lacking, so as I say, you see that it was exclusively dedicated to review the process.

COFFEY, Q.C.:

Q. This particular meeting itself?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. To see where you were at that point in time?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Now, Doctor, did the effort continue afterward?

DR. S. PARAI:

A. It did.

COFFEY, Q.C.:

Q. I take it that in once sense it's continued to this day?

DR. S. PARAI:

A. Well I can't answer that.

COFFEY, Q.C.:

Q. But in terms of while you were site chief,

Page 326

I'll ask you that.

DR. S. PARAI:

A. Yes, it did.

COFFEY, Q.C.:

Q. It continued while you were site chief.

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. Doctor, what were the challenges in pursuing this, if any? What were the challenges you faced at the time in terms of resources -

DR. S. PARAI:

A. We, I can give you follow up now on what happened at the end, we developed at least four, five version, I have not same version, the first version we did at every six months, three months and so, and there was another program we are just editing and circulating to pathologists, so it went many months, few years and continue to be revised.

COFFEY, Q.C.:

Q. And why did it take, I take it by the time you ended your term as site chief, it still wasn't finalized, am I correct on that?

DR. S. PARAI:

Page 327

A. You are correct. What happened is that we have all this program are circulated to the pathologists on both sides and managers, so we got a lot of feedback, we have to accommodate all the opinions, some of them we could not, some of them we did. So this process continued. In the meantime, we are not sitting idle, we have not forgotten that we have a responsibility for the quality assurance that was going on and that was the rough guideline, unofficial guideline. If you can see from this minute that we are doing quality assurance program as part of this guideline, although it was in a draft form.

COFFEY, Q.C.:

Q. And it being in a draft form, was it actually being followed? Was any particular draft of this being followed from time to time?

DR. S. PARAI:

A. Yeah, initially we started with College of American Pathologist guideline and this program was big, very big program, it involved lot of resources, lot of manpower and funding to implement. Then we devised, I thought -

COFFEY, Q.C.:

Page 328

Q. So were you able to utilize that?

DR. S. PARAI:

A. At that point we are not, so Dr. Haegert has a lot of input -

COFFEY, Q.C.:

Q. That's what I was going to ask you, why weren't you able to at that time?

DR. S. PARAI:

A. Unfortunately I don't have that draft copy with me now and it is lot of involvement, it is a big program and require a lot of resource funding.

COFFEY, Q.C.:

Q. It required a lot of resource funding?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. That you didn't have at the time?

DR. S. PARAI:

A. No. We discussed many meetings, we thought let's try to edit some of this stain, what is suitable in our--for our organization without compromising quality of our service, that was our goal.

COFFEY, Q.C.:

Page 329

Q. And so, this process continued during your time as the site chief at the General.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Did it ever get finalized?
DR. S. PARAI:
A. Well I can't answer there, what happened, we have a version completed end of 2004 and around that time, Dr. Carter became the chairman of the quality assurance program, so I handed over to her to follow up on that.
COFFEY, Q.C.:
Q. Okay, and I'll be coming back to that later on because there are references in the documents to that, Dr. Carter's involvement in '04, but what I'm getting at here is what was passed--what she got involved in in 2004, had started at least in 2001 and even before that time, QA.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And you were making the efforts as you could.
DR. S. PARAI:

Page 330

A. That is correct.
COFFEY, Q.C.:
Q. Doctor, here, just looking at this, canned text, paragraph 4.4, "there's partial implementation of canned text at the General Hospital site for ER/PR and HER2/neu expression. It is important to use standard specimen, grossing and reporting." Do you recall--well, first of all, do you recall why there was only partial implementation?
DR. S. PARAI:
A. I don't recall what was all about here, but partially it mean that they believe some, I think some of the pathologists are not using the full canned text, like what are you think, maybe comment, that's all I can think of.
COFFEY, Q.C.:
Q. Did you have any understanding about whether or not canned text such as it was being used at the General, I take it it was not being used at the St. Clare's?
DR. S. PARAI:
A. I can't answer that.
COFFEY, Q.C.:
Q. You can't answer it. Although it did come up

Page 331

at the site chief's meeting, so Dr. Cook would have been there at this meeting.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And this reference is only to the General Hospital site?
DR. S. PARAI:
A. No, I would say it is a site chief meeting, is it not?
COFFEY, Q.C.:
Q. Yes, so Dr. Cook would be there, but this particular reference here in the minutes is only to the General Hospital, do you see that?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. At the General Hospital site.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. It also goes on to say, "It is important to use standard specimen grossing and reporting." Now what does that sentence relate to?
DR. S. PARAI:

Page 332

A. Well I think it is quoting a different, what should have been a different paragraph. We discussed the surgical specimen, grossing, reviewing, examination and reporting and that's what it says.
COFFEY, Q.C.:
Q. And why was it, and I appreciate it shouldn't have come under the heading "canned text", it should have had its own heading.
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. But why was it thought to be important to use standard specimen grossing and reporting?
DR. S. PARAI:
A. So far I recall, I think this discussion was in reference to context of the breast, breast cancer, breast tumour, I think that's what I recall, that's why I put together so that it makes sense.
COFFEY, Q.C.:
Q. And it was in relation to that that the reference to it being important to use standard specimen grossing and reporting in relation to breast cancer, but why was that

Page 333

thought to be important as of June, 2001?
DR. S. PARAI:
A. The new standardized grossing and reporting system was coming, all over the country in the major centre mainly, so we thought we should follow the standard guidelines as it was used by the other major centre.
COFFEY, Q.C.:
Q. And were these standard guidelines, were these circulated at the General Hospital, do you know?
DR. S. PARAI:
A. I don't recall.
COFFEY, Q.C.:
Q. Here as well, under paragraph 6, there's a reference to performance improvement program, institutional case review A) American College of Pathologists material will be used as well as American Society of Clinical Pathologists check sample review. Now had they been used before this point, do you recall?
DR. S. PARAI:
A. It was used, American Society of Clinical Pathologists check sample was reviewed by our group.

Page 334

COFFEY, Q.C.:
Q. Was that being used before June of '01?
DR. S. PARAI:
A. Yes, yes, but the American College of Pathologist performance improvement program, we subscribe from 2001.
COFFEY, Q.C.:
Q. Okay, so that was the time it was implemented?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Here as well, Doctor, while we're on the topic, paragraph 4.7, quality control rounds. They're described as interdepartmental rounds, intradepartmental round, interhospital rounds, intradepartmental consultation and external consultation. Now the first two are described as being presently in place at both sites, in the first instance, and "this has been in place at both sites," right here in paragraphs A and B?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. I take it this was just a summary then of the

Page 335

current state of affairs?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. These reference in paragraph C to interhospital rounds -
DR. S. PARAI:
A. Yeah, these are the -
COFFEY, Q.C.:
Q. Go ahead, Doctor.
DR. S. PARAI:
A. These are the round organized one month by the St. Clare, the other month by the General Hospital alternatively, where we discuss a number of difficult interesting and complex cases. The slide would be previously circulated among the pathologists and resident at both sites and in a particular, usually Friday morning, these meeting will hold one or the other site and those cases will be discussed in depth with new information.
COFFEY, Q.C.:
Q. Here, Doctor, under paragraph D, "intradepartmental consultation, this has been going on at both the sites. However, St.

Page 336

Clare's Hospital has proper documentation of consultation. At the General Hospital site, documentation is not done all the time." What does that relate to?
DR. S. PARAI:
A. This is the consultation would be given one pathologist to another to have a second opinion about some interesting difficult cases, and there are the standard form that once you submit this case to another pathologist should be filled properly and documented and the review diagnosis of the second pathologist will be documented and saved.
COFFEY, Q.C.:
Q. And was that done then?
DR. S. PARAI:
A. As I say, at that time, some pathologists did. Some of our documents are there, but other pathologists would not document, just ask verbal opinion.
COFFEY, Q.C.:
Q. Did that change at the General, is what I'm asking you?
DR. S. PARAI:

Page 337

A. It changed at some point, slowly, but the process was going on regularly.

COFFEY, Q.C.:

Q. Exhibit P-1890? Here, Doctor, these are the Laboratory Management Committee minutes of March 13th, 2003. Present are a number of--actually, Dr. Cook and Dr. Whitman and Dr. Randell and Robb and Dr. Hutchinson and a number of other individuals, regrets from yourself and two others, but I take it you would have eventually received these minutes. In particular, I wanted to ask you about one thing on page two. Under paragraph three, new business, quality assurance. "Dr. Hutchinson discussed quality assurance for the laboratory program. He indicated that in Ontario, there is an interprovincial working group for microbiology. Dr. Hutchinson has concerns that if our program were required to be licensed through accreditation, such as the Ontario QMPLS program, that we may not be successful. Terry indicated that today there is no legislation requiring laboratories in Newfoundland to be accredited and/or licensed through such a program. General discussion

Page 338

took place in regards to an overall laboratory quality assurance program. It was suggested that this should be a goal for the next several years and the laboratory program should have a quality officer," okay?

DR. S. PARAI:

A. Yes.

COFFEY, Q.C.:

Q. So, and of course, we've moved ahead now. Before we've been looking at--the last minutes we looked at were 2001, June 2001. This is now March 2003. Doctor, I take it then that this effort to establish laboratory quality assurance program, as of March 2003, was still thought to be perhaps lacking, according to this, in the sense of it hadn't gone far enough?

DR. S. PARAI:

A. What I can speak for our side of the anatomical pathology division, we are not lagging behind. We are going along with the par with the other labs in the country. I was familiar what was going on in Ontario, in Alberta, or Nova Scotia. We are at par.

COFFEY, Q.C.:

Page 339

Q. And you're saying if Dr. Hutchinson had a concern about microbiology, then that didn't involve you?

DR. S. PARAI:

A. No.

COFFEY, Q.C.:

Q. From your perspective, in terms of anatomical pathology and surgical pathology, you felt that you were keeping up with what was going on elsewhere in the country?

DR. S. PARAI:

A. I would say we are ahead of many other hospital or corporation in anatomical division.

COFFEY, Q.C.:

Q. Did you ever make any inquiries of QMPLS, the program, in 2003, for example, here?

DR. S. PARAI:

A. No. No, I did not.

COFFEY, Q.C.:

Q. As to what they might--their standards might be for surgical and anatomical pathology?

DR. S. PARAI:

A. I knew they had a program, but I did not inquire. This inquiry from another

Page 340

pathologist friend in Ontario.

COFFEY, Q.C.:

Q. I'm sorry?

DR. S. PARAI:

A. I inquired from a pathologist friend, but not the officials of this program.

COFFEY, Q.C.:

Q. Is there any reason why you didn't make any inquiries of QMPLS?

DR. S. PARAI:

A. My understanding, there was no surgical pathology program at that time. That was my understanding.

COFFEY, Q.C.:

Q. Was there any surgical pathology program at that time available anywhere in the country?

DR. S. PARAI:

A. I could not answer.

COFFEY, Q.C.:

Q. Was there any that you were aware of?

DR. S. PARAI:

A. I was not aware of that.

COFFEY, Q.C.:

Q. Okay, and you were making inquiries?

DR. S. PARAI:

Page 341

A. Yes.
COFFEY, Q.C.:
Q. Doctor, here, the reference to "the laboratory program should have a quality officer," see that?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. What, if anything, was then done about that?
DR. S. PARAI:
A. I don't know anything. I don't know. I can't answer that.
COFFEY, Q.C.:
Q. Okay.
DR. S. PARAI:
A. We wanted a quality control manager for the pathology lab because that's one of the resources we require to adapt our program, but not successful, was not successful to get a quality control manager.
COFFEY, Q.C.:
Q. And when was it you first went looking for one?
DR. S. PARAI:
A. 2001.

Page 342

COFFEY, Q.C.:
Q. Okay, back in 2001?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. Back with those minutes, around that time we just looked at, in June of 2001?
DR. S. PARAI:
A. Yes.
COFFEY, Q.C.:
Q. And the reason you were given for not providing one was what?
DR. S. PARAI:
A. I would say funding.
COFFEY, Q.C.:
Q. Whose decision would that have been, from your perspective? How far up would that have -
DR. S. PARAI:
A. I can't answer that question. I would approach to the clinical chief.
COFFEY, Q.C.:
Q. Did he--by 2003, that would have been Don Cook. Did he support the request?
DR. S. PARAI:
A. I can't answer that.

Page 343

COFFEY, Q.C.:
Q. Okay. So you requested it of Dr. Cook?
DR. S. PARAI:
A. Well, request, not in writing, but always discussion came of the quality control issue. He knew that one of the recommendations, who is going to do that, is quality control manager.
COFFEY, Q.C.:
Q. Okay.
THE COMMISSIONER:
Q. Mr. Coffey, we'll take the break whenever you find a spot.
COFFEY, Q.C.:
Q. Okay. If I could, Commissioner, if I could just--perhaps this would be a good time to break, Commissioner, because I'm going to go on to a particular document and it's got a number of pages in it. So we'll meet again -
THE COMMISSIONER:
Q. Monday morning.
COFFEY, Q.C.:
Q. Monday morning, we'll be continuing with Dr. Parai and then continuing on when he finishes with Dr. Carter. I've discussed that with Mr.

Page 344

Browne already.
THE COMMISSIONER:
Q. All right. Thank you very much. We'll meet then at 9:30 on Monday morning. Administration has asked me to let you know that they have an envelope for you before you leave. Thank you.

CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 25th day of July, A.D., 2008 before the Honourable Justice Margaret A. Cameron, Commissioner, at the Commission of Inquiry, St. John's, Newfoundland and Labrador and was transcribed by me to the best of my ability by means of a sound apparatus.

Dated at St. John's, Newfoundland and Labrador this 25th day of July, A.D., 2008

Judy Moss

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& [3] 18:23 72:20 106:8

-'-

'01 [3] 135:16 319:23 334:2
'03 [1] 259:16
'04 [7] 108:11 114:10 134:3,6,12 138:15 329:16
'05 [11] 7:10 98:20 126:15 134:7 138:15 143:2,4 154:1,2 155:12 211:22
'06 [5] 131:6,14 143:7 152:18 210:18
'07 [11] 7:10 99:6 131:18 133:22 142:20,21 159:3 159:4 176:6 187:23 212:14
'08 [3] 46:15,20 159:18
'88 [6] 201:15 204:16,18 204:22 205:24 239:24
'90s [1] 205:2
'91 [2] 6:22 205:25
'93 [1] 206:2
'94 [2] 52:23 153:18
'95 [1] 52:23
'96 [4] 244:22 245:1,5,7
'97 [11] 84:12,12 106:16 107:22 108:11 114:9 134:2,18 243:2 247:11 261:14
'98 [4] 98:1 110:7 266:2 285:4
'99 [3] 110:7 288:11 299:18

-any [1] 127:19
-if [1] 177:24
-you [2] 138:9 242:20

-1-

1 [13] 35:9 60:16 134:6 134:11 135:16 136:3 138:15 209:14 264:10 275:13,15 290:23 291:23
1/98 [1] 277:1
10 [7] 73:9,15 88:5 136:3 267:11,13 312:21
10,000 [2] 289:17 290:3
100 [2] 71:20 73:16
10th [2] 209:11 212:4
12 [1] 312:22
12th [1] 210:6
13 [1] 248:3
13,000 [1] 289:16
13th [1] 337:6
14 [1] 243:18
14th [4] 101:25 106:20 114:7 209:4
16 [1] 264:5
16th [2] 58:20 310:14
17 [2] 251:17 290:3
17th [5] 156:16,19 210:25 211:16 255:4
18 [2] 3:1 290:3
182 [2] 2:3,4
184 [1] 2:4
185 [1] 2:5
19 [5] 84:15 261:17 262:11,11,18
191 [2] 2:5,6
193 [2] 2:6,7
1973 [1] 200:3
1977 [1] 200:7
1979 [1] 200:12
1980 [1] 200:14
1982 [2] 5:9,11
1983 [2] 5:11,13
1984 [5] 5:13,16 200:15 201:14 202:3
1986 [3] 5:16,19 200:24
1987 [1] 200:24
1988 [5] 202:3,3 204:20 208:10 239:18
1989 [4] 5:19 6:1,12,19
199 [2] 2:7,9
1990 [4] 6:20,22 71:1 271:18
1990's [1] 237:24
1990s [1] 273:4
1991 [6] 6:4,25 201:3,5 202:5 205:21
1992 [3] 45:17 46:12,14
1993 [5] 11:12 202:9 204:5 206:14 207:16
1994 [13] 6:25 7:5,6 8:23 9:2 11:2 12:10,16,19 21:22 24:11 48:1,7
1995 [3] 24:20,23 116:15
1996 [5] 202:12,13 212:21 246:13 248:7
1997 [12] 11:22 32:10 62:18 106:4 241:11 243:18 244:7 248:3,16 249:2 251:17 255:3
1998 [24] 12:19,20 13:17 14:18 58:20 60:16 61:22 62:18,19 70:1 81:21 82:19 83:17 100:19 109:23 264:5,10,23 275:7 275:13 277:14 282:15 284:22 310:14
1998/1997 [1] 298:24
1999 [7] 109:20 227:14 227:15 279:13,16 285:4 290:23
19th [2] 99:16 282:15
1:30 [1] 35:9
1st [3] 212:21 227:20 286:8

-2-

2 [8] 60:11,12 73:7,9 251:17 263:11 266:18 268:5
2.03 [1] 207:13
20 [7] 73:8,10 78:18 135:20 150:13 216:1,14
2000 [19] 202:17,18 209:4 209:12,15 226:3 227:16 227:24 228:9 259:16 285:5 286:5 289:14 290:24,24 295:11 299:18 313:11 322:25
2001 [30] 32:10 135:19 135:19 136:3 291:23 297:12,17 298:1 301:5 302:7 305:23 306:13 308:12 313:9,21 314:3 316:10 319:9,23 323:1,2 324:22 329:19 333:1 334:6 338:11,11 341:25 342:2,7
2002 [10] 102:21 104:8 104:15 105:5,7 114:7,11 117:20 193:17 259:16
2003 [20] 43:22 85:19 86:12,18,25 87:9 88:22 92:20 93:14,21 97:17,17 99:16,19 135:19 337:6 338:12,14 339:17 342:22
2004 [7] 106:5,16 107:22 134:19 135:17 329:9,18
2005 [43] 12:21 13:16,17 14:18 15:7,9,13,20 21:19 84:1 97:21 100:9,19,19 100:20 101:11,25 106:2 109:13 122:6 123:7,9 124:2,3 127:2 141:11 143:25 146:15 149:20 153:19,20 156:16,19 172:22 183:12 202:24 203:2,2 209:20 210:6 211:16 228:19 312:13
2006 [5] 152:3 187:11 203:13 210:11,12
2007 [16] 8:8 86:22 87:15 87:17,20 98:21 99:23 149:25 172:1 174:16 178:19 191:13,14 203:14 211:17 212:4
2008 [15] 1:4 3:1 25:13 100:4 120:19 121:16 156:23 176:12 185:7,18 186:6,15 191:23 345:5 345:12
2157 [1] 167:2
21st [3] 297:12,17 301:4
2204 [1] 106:4
22nd [3] 302:7 306:16 307:9
2395 [1] 243:12
2396 [1] 243:12
2398 [1] 243:12
23rd [4] 131:20 172:5,10 255:3
2408 [1] 243:13
2426 [1] 243:13
2428 [1] 243:14
2439 [1] 243:14
244 [1] 3:5
24th [6] 106:13 108:7 114:5 172:8,10 174:16
25 [1] 1:4
25th [7] 106:2 114:5 306:13 307:12 316:10 345:5,12
26 [3] 322:25 323:1,2
28 [1] 319:9
28th [1] 143:24
29th [1] 204:20
2nd [4] 86:25 87:22 207:16 275:16

-3-

3 [6] 35:10 69:9 150:18 248:7 268:6 271:14
3.2 [1] 323:4
3.4 [1] 251:21
3.8 [3] 148:2,4 150:5
3/2 [1] 237:6
30 [7] 71:3 135:5,11,25 159:25 160:11 220:9
30th [1] 291:20
31 [7] 134:3,18 135:17 209:20 210:11 290:23,24
344 [1] 2:9
3rd [1] 275:16

-4-

4 [3] 2:3 150:18 323:20
4.2 [1] 302:18
4.4 [1] 330:4
4.6 [1] 297:20
4.7 [3] 297:18 300:17 334:13
40 [1] 73:16
400 [2] 26:3 73:16
45 [1] 290:4
4:30 [1] 39:6
4th [3] 85:19 90:10 176:12

-5-

5 [1] 39:16
50 [2] 238:8 290:4
51 [1] 210:5
58 [1] 3:3

-6-

6 [1] 333:15
6,000 [1] 289:18
60 [1] 236:25
60/40 [1] 237:6
65 [2] 237:1 290:4
6th [1] 127:2

-7-

70 [2] 289:13 290:4
70s [2] 49:3,4
75 [3] 73:14,14 150:16
7th [2] 210:11 211:4

-8-

80 [2] 215:25 216:9
80s [1] 49:4
8th [2] 123:9 261:14

-9-

9 [2] 134:7 138:15
90 [1] 71:20
90s [1] 294:10
9:30 [2] 41:5 344:4
9th [1] 123:9

-A-

A.D [2] 345:5,12
a.m [1] 39:17
Abdullah [9] 25:24 32:7 32:7 82:23,25 83:5,11 96:10 113:14
Abdullah's [1] 83:7
ability [2] 166:15 345:9
able [4] 166:5 207:2 328:1,7
abnormal [1] 96:15
above [2] 86:2 323:22
absence [11] 7:9 8:22 11:25 12:3 143:19 210:8 210:9,12 211:5 314:17 315:5
absent [2] 158:10 315:3
absolute [1] 260:16
absolutely [1] 91:12
academic [1] 76:5
accept [7] 69:15 209:12 255:23 263:5 271:24 272:2 286:6
acceptable [4] 64:12,21 64:23 170:4
accepted [5] 135:6 228:8 248:9 286:22 288:22
accillary [2] 25:17 38:9
accommodate [1] 327:4
accompanied [1] 293:15
accompany [1] 85:8
according [4] 170:13 292:10 305:11 338:15
accreditation [14] 29:12 29:13,15,19,24 30:5,6,7 30:14,17,25 31:9,12 337:20
accredited [1] 337:24
accredits [1] 29:25
accuracy [1] 84:23
accurate [1] 50:4
acetic [1] 38:14
acini [1] 88:12
Ackerman [1] 44:14

acknowledge [1] 209:10
acknowledged [1] 68:10
act [1] 229:2
acting [7] 209:6 212:9 288:19 291:4,19 294:12 299:18
action [4] 1:13 185:5 263:12,12
actively [1] 287:22
activities [6] 18:8 26:11 28:2 235:6,16 320:3
actual [8] 16:10 69:24 85:2 107:21 157:5 207:19 265:25 297:16
adapt [3] 166:10 169:24 341:18
adapted [1] 170:13
adapting [1] 169:4
add [1] 44:22
addition [1] 26:24
address [2] 60:23 309:15
addressed [8] 85:20 99:17 143:25 144:1 209:4 243:18 294:1 313:7
addressing [2] 69:21 265:10
adequate [6] 60:21 66:3 67:2 112:11 276:23 316:5
adjectives [1] 53:19
adjustment [1] 195:14
administration [3] 140:19 192:11 344:5
administrative [9] 14:5 18:20 215:24 216:2,15 223:24 225:5,19 232:6
administratively [1] 216:24
adopt [2] 69:16 169:24
adopted [4] 76:12 158:25 159:5 165:4
advantages [2] 260:19 260:21
advisory [2] 210:2 218:22
affairs [5] 13:12 15:9,14 192:2 335:1
affect [1] 90:7
affected [2] 88:2 115:13
afternoon [12] 19:5 26:21 35:12,23 38:18 80:16 160:25 182:13 199:22 263:20 269:3 314:18
afterward [3] 174:24 261:20 325:16
again [20] 7:4 23:4 30:6 37:25 39:4 87:15 92:17 106:14 122:22 150:12 188:2 197:18 199:6 262:9 268:20 282:13 286:3 312:22 323:10 343:19
against [1] 255:9
agency [1] 179:12
agenda [3] 297:11,14 323:1
ago [4] 166:9 283:2 293:11 298:1
agree [3] 69:15 157:5 188:23
agreed [14] 170:4 228:9 248:14 252:1 256:1 261:20 264:23 286:5 302:21 303:1,6,7 304:13 304:13
agreement [2] 254:21 305:12
agrees [1] 27:4
ahead [8] 201:9 202:1 203:10 310:18 320:19 335:10 338:9 339:12
aid [1] 196:15
al [1] 1:9
alarm [1] 105:14
alarmed [3] 97:12 105:11,17
alarming [4] 124:20 194:14,16,19
Alberta [3] 203:3,12 338:24
alcohol [2] 39:13 88:7
alert [1] 89:18
alerted [1] 57:20
alleged [1] 153:21
alleviate [1] 158:23
allocated [1] 9:17
allotted [1] 216:14
allowed [1] 77:14
almost [4] 16:16 26:20 233:16 289:18
along [7] 119:15 177:3 192:18 214:22 272:23 324:24 338:21
Alteen [6] 15:16,18 16:2 118:11 138:5,7
alternate [1] 19:10
alternatively [1] 335:14
always [5] 80:11 111:13 159:16 304:17 343:4
amalgamation [2] 213:2 216:5
amended [2] 175:25 186:18
American [19] 6:2 24:18 28:20 29:3 71:2 200:19 201:1,3 232:16,23 233:4 320:8 321:7,9 327:21 333:17,19,23 334:4
Amid [1] 32:7
among [6] 75:15 180:20 249:22 255:20 279:4 335:17
amongst [6] 152:16 246:17 250:8 261:5 301:1 308:17
amount [4] 65:9 166:23 286:14 295:8
analysis [10] 52:16 78:15 91:6 239:21 241:22 242:2 242:6 262:11 321:14 322:7
analytic [1] 81:19
analyzed [3] 121:17 147:14 186:10
anatomic [2] 6:3 248:2
anatomical [28] 5:18 6:2 200:19 202:15,19 209:13 210:10 212:3 221:6,22 222:2,5,22 223:8,22 229:3 291:16,19,25 297:12 319:4 320:13,23 323:20 338:20 339:7,13 339:22
anesthesiology [1] 23:15
announced [1] 133:6
announcement [1] 131:23
announces [1] 264:9
annual [2] 210:25 211:9
annually [1] 78:16
answer [15] 60:23 173:15 272:24 308:22,23 312:15 317:10 325:23 329:8 330:23,25 340:18 341:12 342:19,25
answering [1] 269:8
answers [1] 198:19
Anthony [2] 6:18 7:5
antibodies [8] 85:23 86:3 93:23,24 244:17 255:9 258:11 303:8
antibody [3] 87:5 269:16 303:6
antigen [3] 96:18 269:6 269:16
anyway [8] 93:25 139:19 177:14 220:22 225:23 292:10 299:19 303:5
apart [8] 7:9 8:5 11:24 19:13 20:4 95:18 96:13 184:9
APCP [1] 32:10
apologize [4] 22:7 282:17 292:7 297:10
apparatus [1] 345:10
appear [5] 177:7 287:25 306:20 307:5,15
Appearances [1] 1:5
appended [1] 84:6
applied [1] 240:18
appointed [4] 213:10 214:9 291:18 297:4
appointment [4] 10:2 209:12 227:19 286:6
appreciate [18] 92:18 105:4 118:4 124:7 157:21 158:14 213:19 218:17 239:3 254:4 255:18 259:22 265:12 282:25 286:4 288:5 295:13 332:7
approach [15] 27:13 34:9 72:15 74:4 76:12 162:20 177:11,19 268:14 270:21 271:22 272:11 273:6,17 342:20
approached [1] 299:2
approaches [1] 191:24
appropriate [3] 52:17 52:17 178:11
appropriateness [1] 43:5
approval [1] 176:12
approved [4] 165:9 166:13 306:16 316:4
April [19] 85:19 90:10 93:21 97:17 134:6,11 138:15 202:25 243:18 244:7 290:23 291:20 306:13 307:8,10,12 308:12 313:9 316:10
area [8] 18:7,10 38:7 52:2 73:3 196:14 237:22 260:12
areas [4] 23:13 64:4 191:10 294:19
argument [1] 243:6
arise [3] 20:6 22:16 232:1
arising [7] 193:6 282:16 282:19 306:18 313:18 319:20 323:5
arose [1] 249:24
arrival [1] 28:16
arrive [2] 18:15,22
arrived [18] 11:2,7 12:16 17:3 21:22 46:25 48:6 52:10 74:4,10 133:4 172:10 228:1,2 239:16 239:18 289:9 293:24
article [2] 71:2 260:7
articles [2] 74:6 257:11
articulate [1] 174:9
aspect [9] 29:25 31:8 44:19 71:7 76:21 240:9 268:21 294:22 310:1
aspects [4] 22:15 87:24 87:24 133:16
assay [22] 47:16 48:11 48:12,17 49:17 50:18 52:6,8,16 240:2,22 241:4 242:25 248:25 262:2,4 274:5 283:6,11,14,24 284:22
assays [1] 261:19
asserted [1] 309:16
assertion [2] 103:11 307:14
assessed [2] 71:14,19
assessment [4] 31:14 60:7 69:25 144:3
assessments [2] 147:24 255:11
assigned [3] 9:16 36:13 36:15
assignment [1] 36:1
assist [2] 105:24 198:3
assistance [7] 88:22 119:23 145:2 166:19 181:3 197:7 199:4
assistant [9] 12:25 13:22 13:25 297:21 298:12,21 298:23 299:3,15
assistants [8] 168:7,9 297:21,25 298:2,7 299:7 299:22
association [6] 1:14 28:24 170:25 177:8,17 178:13
assumed [8] 11:25 13:10 22:1 110:2 138:25 221:2 223:15 226:23
assuming [1] 294:14
assumption [1] 90:20
assurance [24] 24:13,16 26:13 60:19 65:24 113:4 159:1 166:9 208:18 232:13,19 233:11 235:6 281:15 323:20 324:11,14 327:10,13 329:11 337:14 337:15 338:2,14
Atlantic [1] 319:20
attached [3] 69:11,17 265:5
attempt [4] 26:20 47:10 81:1 162:22
attempting [1] 166:10
attend [2] 21:2 37:11
attended [2] 21:5,10
attending [4] 18:3 25:7 56:13 137:10
attention [14] 65:20 87:7 128:22 145:24 149:20 150:4 158:11 174:8 207:15 208:19 259:21 265:24 285:23 295:12
attributed [1] 128:8
audit [7] 85:14 261:16 262:11,15,17,24 274:12
audits [2] 84:20,25
August [8] 118:12 123:7 123:9,9 126:15 127:19 134:6 138:15
Authorities [1] 1:17
authority [6] 1:11 12:22 15:11 171:9 176:13 226:20
automated [1] 104:5
automatically [1] 312:2
autopsy [5] 221:7,17 223:23 224:20,22
available [14] 49:15 60:23 85:1 232:17 243:21 243:23 244:1 256:21 257:3,4 303:2 304:14 323:9 340:16
average [1] 95:1
Avis [1] 212:8
avoid [1] 80:11
awaiting [2] 39:5 319:21
award [2] 202:6,7
aware [89] 56:20 57:7 81:25 82:4,5,16 86:17 86:20 87:13 89:1,10,12 91:3,8 97:19 98:25 99:19

99:23 100:4 101:6 103:12 107:8,20 113:13 117:19 120:3 123:10 141:10,17 141:23 144:16,18 147:8 147:10 149:18,19 150:24 151:20 153:20 154:13 167:4 171:18 174:23,24 175:6 178:16,24 179:4 179:21 180:14 186:23 187:1,22 190:2 192:11 226:9 228:21,23 236:3 248:12 249:3 251:12,14 252:16 259:11,14,22 260:9,20 265:15,18,22 266:25 267:19 268:18 285:6,7,10 294:6 296:24 301:19,21 311:14 316:19 317:13,17,18 340:20,22
away [10] 10:5 12:3 13:6 13:6 32:23 82:20 131:7 146:20,24 172:23
awhile [1] 256:14

-B-

B [1] 334:21
Bachelor [1] 298:19
background [2] 5:6 199:25
bad [1] 236:6
Banerjee [4] 141:19 156:17 157:23 158:14
Banerjee's [4] 150:24 151:2 156:7 173:18
Bangladesh [1] 200:3
barely [1] 114:13
Barry [12] 2:2 4:5,5,6 4:18,24 86:10 134:9 182:11 185:1 191:7 193:9
based [7] 68:20,23 108:7 155:1 236:21,24 281:14
basis [10] 16:15 18:5 61:9 78:24 130:8 135:1 179:17 184:18 248:17 273:12
batch [2] 302:23 316:24
batches [2] 122:21,25
bath [2] 40:5,16
bearing [6] 92:1 128:23 144:23 149:2 169:14 180:14
became [18] 11:21 46:14 51:22,25 56:20 98:25 107:4 171:18 175:6 178:24 187:22 215:8 259:21 260:9,20 285:4 297:1 329:10
become [22] 38:15 57:7 82:5 86:17,20 87:13 99:23 100:4 101:6 107:8 115:7 123:10 147:7,10 150:4,23 171:11,13 174:24 228:10 259:14 267:19
becomes [2] 27:3 145:9
becoming [1] 213:5
began [4] 51:17 56:24 76:13 117:16
begin [3] 18:22 38:1 212:18
beginning [10] 12:10 15:20 29:4 84:18 88:1 101:17 153:18 159:3 279:15 298:1
begins [2] 87:1 144:8
behalf [1] 185:4
behaviour [1] 66:7
behind [1] 338:21
below [1] 206:25
bench [3] 36:22 37:6,22
benefit [1] 179:10
Bernard [5] 1:6 2:3,9 4:6 199:12
beside [3] 51:19 73:6,21
best [5] 107:14,15 132:19 255:23 345:9
Beth [1] 1:10
better [1] 67:17
between [26] 5:13 11:18 13:17 14:18 16:21 22:16 26:18,21 34:22 36:2 67:23 84:13 100:19 106:24 108:21 136:23 196:19,22 197:21 231:14 236:13,17 242:25 248:25 272:17 288:16
Beverley [2] 106:3,11
beyond [1] 271:3
big [10] 128:12 171:14,14 194:20,25 245:13 257:23 327:22,22 328:11
bigger [1] 287:4
billed [1] 196:16
binder [1] 165:7
binding [1] 48:12
biochemical [27] 47:16 48:11,17 49:17 50:18 51:3,7 52:6,7,16 69:10 84:21 240:1,21 241:4,7 242:25 248:25 249:11 261:19 262:2 274:5 283:6 283:11,14,23 284:21
biochemically [1] 242:7
biochemistry [8] 84:10 84:14 219:5 221:10 240:6 274:2 291:15,18
biochemists [1] 240:15
biopsies [4] 88:10,11 160:25 161:1
biopsy [2] 33:17 38:5
bit [9] 13:6 49:3 65:4 105:18 232:21 239:17 271:23 276:25 283:12
black [1] 319:2
Blackie [5] 14:21 16:2,6 16:11,15
Blair [2] 1:16 202:7
block [21] 40:5,15 41:24 42:9 50:1 53:10 54:9 106:8,8,17 148:8 159:23 159:25 160:3 162:14,23 240:21,23 241:16 275:7 279:21
blocks [17] 40:3,14 102:22 117:16 119:10 122:7 140:6,7 148:25 155:12 162:2,4,19 164:6 193:16 241:8 249:10
blue [2] 73:4,21
board [8] 6:3 12:18,19 12:21,24 25:8 136:1 200:19
body [4] 29:18,24 179:21 324:9
books [1] 61:6
bottom [1] 310:2
box [2] 314:15 315:11
boxes [2] 39:3 160:10
bracket [2] 75:3,4
Brazil [1] 1:8
bread [5] 34:19 35:5,8 36:17 160:14
breadloafed [3] 79:25 80:2,7
break [8] 100:9,14 199:5 199:7 263:20 269:1 343:12,17
breaks [1] 10:1
breast [57] 1:12 34:12 34:14 36:9 37:23 41:17 41:17 47:12,12 49:2,5,7 51:16 56:23 57:1 78:14 79:11,13 80:5,7,15,22 82:12 88:12,14 106:14 116:25,25 120:24 134:1 144:10 159:1,7 160:20 160:24 183:6 185:4 237:16,23 238:3,22 239:11,21,21 241:1,2,16 242:23 249:1,19,23 261:17 324:8 332:17,17 332:18,25
breasts [2] 117:2,3
Brendan [1] 129:22
bring [8] 68:19 87:6 101:15 152:4 197:17 206:21 209:2 318:7
brings [1] 101:5
British [1] 141:11
broke [1] 39:21
Brook [1] 165:20
brought [16] 65:19 128:21 141:6 145:24 149:20 150:4 174:7 208:19 250:7 259:20 265:24 285:23 295:12 307:19 308:8 314:13
brown [7] 60:15,25 73:3 74:1 266:21 319:1,1
Browne [9] 2:6 191:6,7 191:8,21 192:6,12 193:2 344:1
Browne/Jane [1] 1:9
bucket [2] 34:23 35:1
Budgetary [1] 14:16
buffer [1] 88:6
bulk [1] 237:23
bullet [4] 133:24 134:4 134:17,25
bundle [1] 110:16
business [11] 248:22 261:15 282:16,19 306:18 310:3 313:18 319:19 323:4,19 337:14
busy [2] 132:23 178:9
Butler [1] 296:6
buying [2] 14:9 43:21
by-law [1] 225:9

-C-

C [1] 335:5
C-0183 [2] 3:5 243:14
C-A-P [1] 320:4
calculate [1] 158:17
calculation [2] 150:5,23
Calgary [21] 5:16,17 7:10,11,13,15,17,20,22 12:7 21:12 47:3,8,9,15 47:16,18 98:17 143:2 146:21 172:24
Cameron [2] 1:3 345:6
Canada [6] 6:1 179:22 193:1 200:17,18 319:21
Canadian [11] 1:15 5:22 28:22,24 29:18 30:16,25 182:14 201:1 202:6 262:6
cancer [39] 1:12,15 27:5 41:18,23 67:13,15 68:3 78:14 120:24 132:20 182:14,20,22,24 183:14 183:20,24 184:4 185:5 190:9 202:6,8 238:22 239:9,11,11,21 241:2,16 241:16 245:17 261:17 262:1,9 324:8,8 332:18 332:25
cancers [1] 106:15
canned [10] 310:5,24 311:21 312:1,8 330:3,5 330:15,19 332:8
cannot [1] 161:9
CAP [4] 28:9,18 320:4 322:9
capable [4] 60:8 188:20 188:22 296:1
capacity [11] 166:14 214:4 218:15,22 223:11 225:1,2 226:2 229:15 255:6,6
capturing [1] 116:24
carcinoma [6] 90:3 95:21 96:18 144:5,9 255:9
carcinomas [3] 117:2,3 261:25
care [23] 12:20 25:8 58:19 106:7 132:20 137:12 178:12 190:9 192:25 196:16 197:5 202:13 208:24 213:4 214:21 217:5 221:13 222:3 225:9,17 249:20 261:22 290:21
career [1] 208:24
carry [1] 22:2
Carter [24] 25:19 46:21 101:10 104:20 105:23 106:3,3,11 107:9,18 108:8 114:9 115:21 124:4 125:13 144:6,25 146:14 155:15 156:1 160:18 164:16 329:10 343:25
Carter's [3] 136:1 159:1 329:16
case [35] 17:3,5 27:10 36:11 41:22 66:10 72:22 75:15 76:7 91:13 93:12 94:25 95:7 100:20 106:21 110:24 113:8 120:19 136:19 163:6 186:20 192:11 208:21 222:1 262:18,23 263:6 269:5 272:17 285:14 303:1 304:14 315:25 333:17 336:10
cases [84] 19:3,4,7,12 21:15 22:18,18 24:24 25:14 26:17,21,23 27:8 36:1 48:25 52:22,24 55:8 56:25 58:2 60:14 67:10 80:15 84:15 89:19 95:24 103:9,17 104:25 105:5,7 108:22,23,25 109:1 116:22,24,25 117:5 119:5 125:14,24 126:1 130:8 134:1,9,20 135:8,19 145:12 147:25 154:21 155:19 157:24 158:15,18 159:17 163:8 183:6 194:3 207:9 234:7 239:7 251:25 252:2,5 254:22 255:8,12 261:17 262:11,12 266:20 267:11,14 273:12 275:18 276:7 277:16 279:3 321:16 335:16,20 336:9
cassette [3] 39:20,21,24
cassettes [3] 33:21,21 39:3
casual [1] 156:11
casually [1] 124:14
catch [1] 202:1
categories [2] 121:7,12
category [1] 148:18
caused [2] 172:18 194:21
causes [1] 128:8
cavity [1] 38:6
CEA [2] 95:18 96:18
cell [3] 73:25 74:2 319:4
cells [11] 60:16 61:1 70:6 70:8,15 73:11 75:1,3,5 266:22 268:9
centimetre [2] 51:21 160:18
Central [4] 1:16 6:24 12:20,22
centralized [1] 246:22
centre [11] 6:24 8:5 9:10 9:11 48:11 67:15 68:4 69:5 178:12 333:5,7
centres [3] 8:1 67:13

262:6
CEO [2] 15:10 120:20
certain [10] 24:23 91:5 106:19 134:24 177:3 192:24 196:7 206:19 232:22 286:14
certainly [24] 28:15 29:5 31:1 47:8 66:9 108:6 133:9 151:12 152:6 153:11 155:24 158:8 161:15 178:6,10 181:10 181:14 210:13 220:22 248:15 258:15 292:8 300:5 317:12
Certificate [3] 2:10,11 345:1
Certification [1] 200:24
certified [1] 200:17
certify [1] 345:2
chair [3] 212:9 302:10 302:11
chairman [1] 329:11
challenges [5] 116:10 116:11,17 326:9,10
challenging [1] 169:19
chance [3] 78:24 88:17 261:2
change [8] 27:12 97:25 98:4 188:2 225:18 292:22 292:24 336:23
changed [12] 42:6 46:4 49:2 109:2 215:8 223:17 223:19 224:17 225:5 286:10 292:24 337:1
changes [4] 116:22 129:10 161:3 170:3
changing [1] 88:7
characterized [1] 93:25
charge [7] 143:19 214:12 217:23,23 225:11,12 308:19
Chaytor [1] 1:7
check [16] 72:18,20 88:11 103:7 106:14 112:24 113:6 183:14 262:8 276:8 302:23 304:11 314:12,18 333:20,24
checked [10] 110:3 111:2 111:8 117:7 306:23 313:19 314:11,25 323:7 323:16
checking [3] 88:6 313:22 314:8
checklist [2] 144:10 233:5
checks [1] 311:10
chemical [1] 62:2
chief [95] 202:14,19 209:6,9,13,21 212:18,23 213:20 214:9 215:8 221:15,18,21 222:1,4 223:6,8,9 225:1,3,11,12 226:3,8,24 227:1 228:10 228:18 229:1,3,5,10,15 229:16,16,21 230:17,21 230:22,23 231:17 232:12 238:21 242:20 243:4,5 246:18 255:7 263:13 264:25 273:5 275:3 282:14 284:14 286:7,17 286:24,25 287:21 289:9 291:1,4,5,15,16,17,18 291:19,22,23 292:10,12 292:14 293:2,24 294:12 296:16 297:2 299:17,18 299:19,20 300:10 305:11 315:2 323:8,9 324:25 325:25 326:5,23 329:2 331:9 342:20
chief's [7] 221:3 223:15 231:22 262:13 303:11 307:15 331:1
chiefs [9] 229:22 246:18 264:24 288:16,19 300:22 302:8 306:12 322:24
chiefs' [2] 248:2 261:13
Chittal [3] 227:7 288:17 294:7
choice [4] 129:16 162:2 162:4,19
choose [1] 240:23
chooses [1] 162:15
choosing [1] 161:18
chose [2] 75:25 76:2
chronology [1] 205:4
circle [1] 110:21
circulate [1] 255:20
circulated [7] 92:13 110:17 256:7,9 327:2 333:10 335:17
circulating [2] 301:8 326:18
circumstances [1] 259:24
City [2] 7:17,24
Civic [2] 202:9 205:7
Clare [5] 230:1 236:23 237:4 289:18 335:13
Clare's [18] 85:21 230:23 231:14 236:13 237:3 238:1,5,9,11 248:4 249:22 251:23 279:22 299:19 300:23 318:12 330:21 336:1
clarification [1] 94:21
clarify [2] 17:17 208:14
Class [2] 1:13 185:5
clear [6] 47:14,19 72:23 109:10 225:13 289:6
cleared [1] 39:14
clearly [3] 69:18 73:20 109:1
clinic [4] 182:22 250:6 262:1,9
clinical [37] 12:13 22:15 137:2 203:24 209:6 216:1 216:3,6,10 219:3 220:13 223:1,4,6,21 225:12 229:5,15 230:22 232:6 233:4 234:8 235:1,2 243:5 246:18 264:24 284:13 291:4,5 299:17 299:18 320:16 321:10 333:19,23 342:20
clinician [1] 14:1
clinicians [1] 233:23
clinics [1] 33:8
close [2] 235:22 285:5
closed [1] 231:5
closely [1] 66:10
closes [1] 227:23
closure [3] 202:17,20 227:21
CME [1] 233:5
co-counsel [3] 1:6,7 192:22
coffee [1] 20:14
Coffey [1004] 1:6 2:3,9 4:2,3,7,17,22 5:3,21 6:5 6:9,15 7:1,12,18,25 8:7 8:12,17 9:1,7,12,20 10:7 10:13,21 11:1,9,13,17 12:1,8 13:4,13,23 14:4,8 14:13,17,22 15:1,6,12 15:17,23 16:4,18 17:4 17:10,15,22 18:2,11 19:15,22 20:1,9,21 21:1 21:6,17,23 22:5,11,20 22:25 23:5,10,20 24:1,6 24:10 25:2,10,20 26:6 27:11,17,23 28:5,11,17 28:21 29:1,8,14 30:2,8 30:15,20,24 31:6,15,19 31:25 32:15,24 33:11,25 34:4,11 35:3,11,15,20 35:24 36:7,14,20,25 37:4 37:10,19 38:19 40:20,24 41:6,11,16 42:4,14,22 43:3,9,15,24 44:3,8,16 45:1,5,11,21 46:2,11,16 46:23 47:6,22 48:5,16 48:22 49:19,23 50:5,11 50:17,22 51:2,6,11 52:9 52:14,21 53:4,8,14,21 54:1,7,12,16,23 55:3,11 55:16,22 56:4,9,16 57:4 57:11,19,25 58:5,14 59:3 59:11,20 60:10 61:10,14 61:20 62:7,16,23 63:3,7 63:15,21 64:6,13,17,24 65:6,12,23 66:13,19,24 67:5,25 68:7,15,18 69:8 70:19,24 71:6,15,25 72:6 72:14 74:3,9,15,20 75:7 75:17,23 76:11,18 77:1 77:5,13,19,23 78:3,7,12 78:19,23 79:4,8,17,23 80:4,21 81:4,11,17 82:3 82:10,18,24 83:3,10,15 83:22 84:2 85:7,12,17 86:16,23 87:12,16,21 88:20 89:3,16,24 90:8 90:14,19,25 91:14,21 92:11,16 93:2,7,11,18 94:5,12,17,22 95:5,13 96:1,6,21 97:1,6,15,24 98:5,12,18,24 99:4,9,14 99:22 100:1,6,16,17,25 101:4,14,24 102:8,14,19 102:25 103:10,20 104:2 104:13,18 105:3,12,21 107:7,13 108:1,5,14 109:3,12,19 110:5,11,15 110:20,25 111:6,12,17 111:21 112:1,8,12,16,20 113:2,7,12,19,23 114:3 114:19,25 115:6,14,18 115:24 116:4,8 117:10 117:18,24 118:6,15,22 119:6,11,17,22 120:1,10 120:15 121:2,6,11,15,20 121:24 122:4,16 123:1,6 123:14,18,22 124:1,10 124:15,21 125:4,11,17 126:4,13,25 127:6,11,16 127:24 128:6,13,19 129:3 129:20,25 130:6,13,18 130:22 131:3,8,13,17,21 132:4,10 133:3,14,20 134:16,23 135:9,15,24 136:7,11,18,22 137:5,16 137:25 138:6,13,20,24 139:4,11,16,23 140:4,11 140:25 141:9,18,25 142:7 142:12,16,22 143:3,10 143:16,23 144:15,20 145:14,21 146:4,8,19 147:2,6,13,18 148:3,7 148:12,15,23 149:6,11 149:15,23 150:3,9,17,22 151:5,11,16 152:2,8,14 152:21 153:8,15,24 154:7 154:12,23 155:10,23 156:5,13,24 157:3,9,15 157:20 158:3,12 160:2,7 161:17,25 162:8,13,18 162:24 163:10,14,18,23 164:3,10,19,24 165:10 165:18,24 166:25 167:12 167:18 168:12 169:13,20 170:7,17,21 171:1,6,16 171:23 172:4,9,20 173:8 173:16,25 174:6,12,22 175:2,8,12,19,23 176:4 176:9,19,24 177:15,22 178:15,23 179:3,8,15,20 179:25 180:5,10,22 181:7 181:11,15 191:11 193:3 193:6,7 199:9,10,12,21 200:9,21,25 201:4,8,16 201:20,24 203:5,9,16,20 204:1,8,13,17,21,25 205:9,13,18,23 206:3,8 206:13,17 207:24 208:6 208:13,17 209:18,24 210:16,21 211:2,8,14,20 211:25 212:17,22 213:3 213:8,13,18,24 214:5,16 214:20,25 215:14,19 216:8,13,18 217:1,10,16 217:20 218:4,8,14,23 219:9,15 220:3,11,17,21 221:1,9,20,25 222:9,15 222:19 223:3,10,14 224:1 224:5,12,16,21,25 225:21 226:1,6,12,16,22 227:4 227:8,12,25 228:6,17 229:9,14,19 230:5,9,14 230:20 231:1,6,10,15,20 232:5,10,20 233:9,21 234:12,16,20 235:4,10 235:14,21 236:11,18 237:5,9,14,20 238:2,10 238:15,19 239:2,6,10,14 240:3,8,13 241:5,12,19 241:23 242:5,12 243:8 244:12,19,23 245:2,6,10 245:22 246:2,12,16 247:1 247:6,12,20 248:20 249:8 249:15 250:21,25 251:5 251:11,15 252:10,17,22 253:3,7,12,17,21 254:3 254:18 255:1 256:4,16 257:1,10,15,25 258:8,13 258:18,25 259:6,12,19 260:8,18,24 261:11 262:21 263:3,9,19,21 264:1,2,16,20 265:3,19 265:23 266:8,12,17 267:4 267:9,17,23 268:3,19,24 269:9,13,18,22 270:1,5 270:10,16,20,24 271:8 271:12,21 272:5,9,15 273:2,10,16,20 274:15 274:20 275:1,11,21,25 276:5,12,16 277:12,24 278:7,11,17,23 279:11 279:20 280:1,6,11,16,25 281:5,12,19,24 282:11 283:16,20 284:2,7,15,20 285:2,11,17,22 286:2,11 286:21 287:6,13 288:3 288:12,21 289:2,7,24 290:12,17 291:14 292:6 292:19 293:13,18,22 294:16,20,25 295:10 296:4,9,21,25 297:8 298:5 299:4,10,16,25 300:4,9,16 301:14,20,24 302:5,15 303:19 304:4,9 304:18,23 305:2,8,15,20 306:2,9 307:24 308:4,11 308:24 309:13,25 310:13 310:17,21 311:2,9,15 312:5,12,16 313:15 314:2 314:6,22 315:8,13,19 316:2,9,15 317:5,11,16 317:21 318:8,20 319:5 319:17 320:2,12,18,24 321:3,11,17,21 322:1,5 322:12,18,22 323:18 324:18 325:6,10,14,19 325:24 326:4,8,21 327:15 327:25 328:5,13,17,25 329:5,13,23 330:2,17,24 331:5,11,17,21 332:6,12 332:21 333:8,14 334:1,7 334:11,24 335:4,9,22 336:15,22 337:3 338:8 338:25 339:6,15,20 340:2 340:7,14,19,23 341:2,8 341:13,21 342:1,5,10,15 342:21 343:1,9,12,14,22
colleagues [1] 69:14
collect [1] 80:18
collecting [1] 168:3
collection [1] 255:20
College [17] 5:9,12,25 24:18 25:25 26:2 28:20 29:2 200:16,17 232:16 232:23 320:8 321:7 327:20 333:17 334:4
colon [1] 324:8
Columbia [1] 141:12
combined [1] 169:15
comfortable [4] 97:7

261:9 279:9 285:18
coming [8] 69:5 133:22 141:4 167:4 219:12 280:13 329:14 333:4
comment [14] 70:25 71:1 71:7 75:5,6 158:15 271:15,16,18 272:16,23 273:1 311:24 330:16
comments [9] 23:21 76:5 192:16,18 197:5 207:9 272:18 274:9 291:8
Commission [15] 1:1,6 1:7 4:10 120:5 131:23 175:9 178:25 180:16 192:13,22 197:19 199:16 345:4,7
Commission's [1] 167:21
Commissioner [92] 1:3 2:7 4:1,4 5:4,5 8:18 12:9 18:13 28:7 31:24 32:4 32:13 33:1 44:18 58:8 58:11,17 61:21 68:17,25 69:4 83:5 84:16 89:9 98:1 100:8,12,15,18 116:9 130:1 132:2 139:17 143:4 152:25 154:1 165:25 180:11,13 181:16 181:17,20,23 182:1,2,5 182:7 184:24 191:1,5,9 192:21 193:5,9,10 194:7 195:10,18,23 196:2,11 197:16 198:21 199:2,8 199:23 207:3 208:8,23 210:23 215:1,9 222:20 229:20 242:13 243:10 263:18,23,25 264:3 266:1 275:12 292:4,8 297:10 343:11,15,17,20 344:2 345:7
Commissioner's [1] 208:19
committee [8] 210:2 248:24 282:17,20 307:21 319:8 324:3 337:5
common [4] 49:3 67:13 245:17 257:22
communicated [3] 118:13 126:5 129:21
communication [4] 107:17 123:17 130:2 231:25
communications [5] 124:24 127:17 139:8 164:4 196:22
comparable [1] 213:14
compare [2] 215:5 238:4
compared [3] 238:8 252:13 290:4
comparing [2] 91:23 92:2
compatible [1] 254:16
Competence [1] 26:1
compiled [2] 117:6,11
complaint [1] 304:7
complaints [2] 139:12 303:20
complement [1] 223:24
complete [1] 199:15
completed [5] 6:10 35:16 200:14 290:8 329:9
completely [2] 246:6 320:22
completion [1] 313:2
complex [3] 198:18 257:24 335:15
complicated [1] 257:24
component [8] 70:3,6 70:25 72:24 216:1,1 268:7 271:16
components [1] 70:2
comprehensive [3] 50:3 60:4 165:13
comprise [1] 24:17
compromising [2] 49:17 328:23
concentrate [3] 42:15 139:25 166:5
concentrating [2] 104:15 149:7
concentration [3] 258:7 258:9,11
concern [10] 17:14 20:19 71:22 126:16 220:12 249:22 284:13 304:5 311:3 339:2
concerned [7] 94:9 139:1 173:6,7 194:13 196:21 309:2
concerning [6] 120:5 127:20 193:14 250:13 257:5 313:8
concerns [21] 13:21 14:9 60:24 97:3 100:21 124:14 124:17 154:13,14,15 164:5 189:7,23 254:13 254:16,17 285:23 295:17 306:5 308:15 337:18
concluded [2] 194:15 307:13
concludes [1] 265:8
conclusion [2] 108:17 234:9
conclusions [1] 128:1
concordance [1] 84:13
conducted [1] 53:11
conference [2] 25:11,13
confidence [1] 66:12
confident [3] 50:2 94:11 97:20
confidential [1] 198:8
confirm [3] 49:14 288:2 322:11
confirmed [1] 115:25
confused [1] 28:22
consensus [2] 234:9 250:8
Consequent [1] 86:2
consider [3] 26:23 67:6 90:4
considerable [7] 66:12 69:20 104:24 132:23 153:14 166:3 265:9
consideration [3] 132:11 183:13 321:13
considered [3] 24:25 93:25 132:15
considering [4] 73:23 133:15 189:5 255:13
consistency [1] 34:18
consistent [3] 64:25 65:3 103:15
consists [1] 221:7
constrained [1] 198:5
consult [3] 18:16 119:20 219:14
consultation [10] 19:4 27:6 233:13,17,20 334:16 334:17 335:24 336:2,6
consulted [2] 43:17 72:11
consults [1] 26:15
contact [1] 104:19
contacted [1] 193:15
contacting [1] 183:13
contain [4] 25:18 117:5 148:25 155:6
contained [2] 51:16 117:12
container [1] 38:1
containers [1] 34:15
contains [1] 39:20
content [1] 69:15
contents [4] 2:1 102:7 167:23 168:2
context [4] 128:22 241:13 293:1 332:17
continue [9] 100:10 133:7 231:3 245:21 246:21 247:17 261:23 325:15 326:20
continued [12] 47:7 97:20 110:3 154:8 202:16 202:23 231:16 275:7 325:20 326:5 327:7 329:1
continues [5] 130:14 207:17 255:12 277:4 313:1
continuing [6] 26:4 93:8 276:1 313:7 343:23,24
contradistinction [1] 10:8
contrast [1] 270:8
contribute [1] 23:21
control [65] 65:17 67:19 77:7,9,17,20,24,25,25 88:14 91:3,17,18,20 111:13 112:3,21 251:25 260:15 277:16 278:18,19 279:2,6,9 280:12,18,19 280:19,20 281:2,7 282:8 300:18,19 301:9 302:18 302:21,23 303:3,5 304:11 304:19 305:9,16,24 306:19 309:23 314:10,12 314:19 315:23 316:23 317:23 318:2,5,15,16,22 323:6 334:13 341:16,20 343:5,7
controls [82] 60:17,20 60:22 63:16,18,23 64:1 64:4,8,14,16,18 65:8,14 66:1,4 72:17,18 81:20 81:22,24,25 82:1,2,8,13 88:13 91:2,25 92:8 106:7 106:10,10 109:22 111:2 111:24 112:7 128:14,15 145:5 146:11,12 148:13 148:17 149:1 158:9,10 161:19 162:23 163:6,7 173:19,20 258:22 259:2 259:7,8,25 260:11,21 276:21,24 277:3,6,8,9 278:4,13,14 281:15 306:23 313:19,22 314:8 314:15,25 316:5,12,18 318:6,13 323:6
controversy [2] 93:1,8
convention [2] 260:4,5
conversation [1] 195:2
conversations [7] 101:9 107:2,9 108:8,19 146:14 155:14
conversions [3] 124:25 148:19 172:19
convert [1] 105:8
converted [3] 103:13 126:3 148:19
Cook [44] 101:10 102:1 102:7,10 104:14,20 105:22 106:22 107:10,18 108:8 123:12,19 124:4 127:8,17 129:7 144:6 146:14 155:15,25 156:17 194:8 195:2 209:5,6 227:22 230:22 248:5 249:21 282:23 291:3 299:17,21 302:16 306:13 308:2,20 323:3 331:1,12 337:7 342:23 343:2
Cook's [1] 209:11
copied [1] 86:10
copies [1] 243:20
copy [11] 85:3,14 86:12 87:8 90:10 102:3,6 144:12 176:15 318:15 328:9
cordial [1] 225:17
core [2] 88:10 161:1
Corner [1] 165:20
corporate [2] 249:19 324:16
corporation [16] 25:9 58:19 202:13 208:24 213:2,5 214:21 217:5 221:14 222:3 225:10,18 249:21 261:22 290:21 339:13
correct [48] 6:14 8:11,16 15:22 17:21 24:9 29:7 36:24 37:14 41:10 50:21 53:7 55:15 59:19 61:18 63:14 71:24 72:22 74:19 79:3 85:16 97:23 101:23 110:19 115:5 126:22 131:16 136:6 149:10 154:6 157:8 161:24 171:22 190:12,16 206:7 206:12 207:25 208:3,4 208:20 221:16 292:7 315:5 326:24 327:1 330:1 345:3
corrected [1] 107:14
correctly [2] 204:14 205:3
correlating [3] 84:20 101:12 261:18
correlation [7] 84:10 235:2 242:25 243:4 248:25 262:18 274:2
corresponding [2] 41:24 289:21
country [4] 333:4 338:22 339:10 340:16
couple [7] 182:16 185:6 188:10 191:10 291:8 292:11 297:19
course [24] 27:24 59:22 62:17 63:8,10 72:20 109:14 120:3 122:13 132:6 147:20,23 151:6 152:22 153:1 162:19 207:9,15,16 258:20 290:24 300:24 304:15 338:9
cover [4] 22:6 156:18 191:10 267:12
covered [1] 180:12
covering [2] 156:16 255:24
coverslipped [3] 33:23 40:9,19
created [3] 13:17 213:1 213:9
creating [1] 165:11
creation [1] 225:6
creep [1] 32:5
crisp [1] 73:17
criteria [6] 106:14 119:12,15 121:3 122:23 250:2
cross [1] 77:8
crossing [1] 79:9
crying [1] 236:9
cube [2] 49:16 50:9
current [11] 92:4 129:12 130:7 164:12 176:10 177:14 189:23 196:18 257:9 282:20 335:1
cut [9] 19:13 71:10,21 79:21,24 80:19 160:14 160:17,20
cutoff [1] 71:3
cycle [2] 26:4 88:16
cytology [6] 219:5 222:11 223:23 291:17,24 292:14
cytometry [1] 96:16
cytopathology [3] 221:8 221:17 233:7

cytoplasmic [3] 61:16 73:19 267:25
cytoplastic [1] 270:8

-D-

D [2] 297:22 335:23
daily [5] 16:15,16 18:5 306:23 313:19
DAKO [3] 101:13 103:6 104:6
Dalhousie [2] 200:13 201:10
Dalton [8] 10:9,9,10 25:15 124:13 166:8 171:19 194:12
Dalton's [2] 167:10 169:6
date [11] 43:6 106:11 107:16 144:23 176:12 207:17,19 208:10 260:3 312:11 313:2
dated [4] 58:20 101:25 156:19 345:11
dates [4] 207:8,8 210:4 298:23
dating [1] 45:17
Dave [1] 297:22
David [1] 15:4
dawned [2] 195:1,11
days [11] 47:8 49:9 54:25 144:24 215:6 217:4,22 229:21 230:16 232:12 238:21
deal [6] 18:19 20:5 34:12 126:11 198:3 241:25
dealing [12] 42:8 45:13 45:24 68:3,12 71:1,3 193:18 257:11 267:1 268:14 283:22
dealings [1] 68:2
dealt [5] 20:8 67:11 96:2 96:4 232:6
debated [1] 145:7
deceased [8] 121:23,25 136:12,14 185:8,24 191:23 207:12
December [9] 7:10 106:16 108:11 143:2 178:18 203:13 210:11 211:22 248:7
decide [2] 76:9 140:21
decided [4] 119:15 132:16 236:19 250:6
decision [7] 133:15 187:17 235:22 247:15,23 248:16 342:16
decisions [2] 126:2,5
dedicated [3] 245:19 323:22 325:4
deemed [2] 24:22 25:14
deeper [2] 18:9 19:2
Deer [3] 203:4,6,8
deficiencies [8] 153:14 153:21,21 154:24,25 155:6 156:1,2
deficient [1] 155:7
defined [7] 26:13 70:5 134:24 135:7,18 225:22 225:23
definite [2] 173:15 324:12
definition [2] 135:1,3
definitive [1] 49:6
degree [5] 5:8,12 39:11 200:2 298:20
dehydrated [1] 39:12
dehydration [2] 88:3,9
delay [1] 227:20
delayed [2] 159:9,18
delicatessen [2] 40:2,12
delighted [1] 171:13
delivered [1] 161:10
Denic [7] 46:22 159:3 164:21 165:5 175:14 176:14 212:8
department [8] 12:12 20:18 159:12 161:11 216:7 233:20 235:3 243:23
departments [1] 222:11
depending [4] 33:14 34:8 42:7 81:13
depth [1] 335:21
dermapath [1] 233:19
dermatological [1] 234:7
dermatologists [2] 234:5,6
describe [4] 18:12 32:25 44:18 51:13
described [11] 76:20 83:4 98:1 148:1,8 164:11 176:13 210:22 294:1 334:14,17
describing [4] 81:18 93:22 97:9 246:13
description [8] 19:8 34:19 226:7,21 228:13 228:16,20 288:20
descriptions [2] 18:24 44:23
designate [1] 220:8
designated [1] 111:11
designation [1] 215:12
desirable [1] 180:25
detail [4] 103:3 152:24 209:1 251:22
details [3] 31:13 128:17 146:13
detected [1] 70:5
detection [1] 84:24
determination [2] 50:18 172:18
determinations [1] 57:3
determine [4] 47:11 137:1 250:2 309:12
develop [3] 46:17 324:15 324:20
developed [3] 278:24 324:24 326:14
developing [4] 170:14 310:23 312:7 324:10
devices [1] 207:1
devised [1] 327:24
Dhaka [1] 200:3
diagnosis [13] 18:25 26:19,19 27:5,10 41:23 49:10,18 50:3 95:20 96:16 202:8 336:12
diagnostic [4] 8:4 51:25 86:1 94:2
diastase [1] 62:4
dictate [3] 18:24 311:22 311:24
dictating [1] 34:15
didactic [1] 22:17
difference [6] 71:10,13 222:21 269:25 270:4,11
differences [1] 75:19
different [17] 8:1 34:10 103:6,21 122:11 207:7 210:4 214:3 224:7 252:12 252:18 267:24 270:12 271:9 320:22 332:1,2
differentiated [1] 89:13
difficult [10] 51:22 62:12 88:24 92:18 155:7 160:21 198:11,18 335:15 336:8
difficulties [3] 87:3 116:23 122:14
diffused [1] 319:1
dig [1] 318:16
dimensions [1] 34:17
direction [1] 233:8
directly [5] 27:20 31:9 129:14 218:18 288:6
director [32] 11:23 13:1 13:3,18,20,22 14:1,18 15:5,24 16:9 17:1,8 202:10 214:8,11,14,14 215:5,12,13,15,20 217:13 217:15 218:3,3,7,10,11 220:4 291:3
director's [1] 13:11
directors [2] 101:17 127:3
disagreement [2] 76:1 256:13
disappointment [1] 236:9
discipline [2] 212:9 250:8
disclosure [2] 191:24 197:21
discontinuance [1] 69:10
discovered [2] 52:4 192:3
discovery [1] 191:22
discrepancies [1] 26:18
discuss [11] 17:13 21:14 26:21 102:10 106:21 219:14 234:7 255:17 297:23 305:22 335:14
discussed [27] 43:20 69:14 84:25 102:6 177:16 180:17 242:22 243:4 246:23 250:17 251:22 255:15 256:11,17 258:4 269:1 299:1 300:21 322:16 323:15,23 324:1 328:20 332:3 335:21 337:15 343:25
discussing [1] 80:14
discussion [16] 106:25 246:4,17,25 247:5,9 249:24 250:12 272:22 305:23 311:16,20 313:7 332:16 337:25 343:5
discussions [4] 20:7 22:17 140:18 250:5
dissect [1] 38:17
dissected [1] 38:21
dissections [1] 25:17
distinguish [1] 136:23
distributed [4] 165:6 191:17 266:13 319:14
District [2] 12:18,24
divergence [1] 75:14
divided [2] 236:13,17
division [27] 1:15 134:11 134:14 182:15 210:10 212:2 216:4 219:4 220:1 220:8 221:6 222:12 223:8 223:22,24,25 224:2 225:11 232:1 240:6 291:24 295:24 297:12 301:7 320:13 338:20 339:14
divisional [17] 221:15 221:18,21 222:22 223:1 223:7 225:11 229:3,16 229:16 248:3 261:13 282:14 302:9 303:11 306:12 322:25
divisions [9] 216:5 219:7 219:19,24 220:1 221:14 224:8 225:13 320:6
doctor [298] 4:18 5:4,22 6:6,10,16 7:2 8:13,18 9:2 9:14 11:2 12:2,9 13:5 16:5,19 18:12 22:12,21 24:11 25:21 26:7 27:18 31:20 32:1,16,25 35:25 37:20 41:12,17 42:17,23 44:4,17 45:22 46:24 47:1 47:8 55:5,23 58:7,15,18 59:4,21 60:25 63:16 64:7 65:24 66:14 68:16 69:11 70:12 71:7 72:9 74:21 75:8 76:12 77:6 78:13 79:9 80:22 81:18 82:19 84:4,6,17 85:1,18 86:12 86:24,25 87:17,23 88:21 89:4 90:9 91:1 93:12,19 94:23 97:8,16 98:6 99:15 100:7,11,18 101:5,16 104:19 106:2,19 107:19 108:15 109:13,21 110:6 110:22 112:2 114:4 115:15 117:19 118:23 120:2 121:25 122:5 123:7 124:3,22 125:18 127:1 127:17 128:20 129:4,17 130:14,19,23 132:5 133:21,24 136:12 137:6 138:1 140:12 141:10 142:23 143:18,24 145:15 146:9,20 148:24 149:12 149:16,18 150:23 152:10 152:22 153:3,25 156:14 156:20 157:11,16 158:13 161:18 163:24 164:4,11 165:11 167:1,4,21 168:23 169:2,22 171:17,24 174:13 175:13 176:10 177:7,16 178:16 179:4 180:11 181:22 193:3 199:22,22 200:22 201:9 203:17 204:3 206:21,23 206:24 207:4,13,18 208:22 209:3,25 210:5 212:2,8,18 213:14 216:19 218:15 221:2 222:20 225:1 226:2,23 227:13 230:15 231:2 232:11,24 235:22 237:15 239:15 241:24 242:13 243:9,15 243:16,17 244:7 245:11 247:25 248:11,21 249:2 249:16,17 250:11,22 251:1,16 252:4,23 254:5 255:2,24 257:2 258:19 260:25 261:12 262:10 263:10 264:4,21 265:13 266:18 268:4,25 271:13 273:17,21,22 274:21 276:17 277:13,25 282:12 282:13,25 285:3,3 286:3 286:4 289:8 290:18,19 292:9,20 293:23 297:11 297:20 300:17,24 301:3 302:6 303:8 306:11 307:3 307:18 309:14 310:1 311:10 312:6,19 313:9 313:16 317:22 318:21 319:6,7,19 320:3 322:23 323:4,19 325:15 326:9 330:3 334:12 335:10,23 337:4 338:12 341:3
doctors [8] 1:9 20:11 105:22 107:9,18 108:8 124:4,11
document [19] 27:8 46:22 84:8 85:2 87:22 159:1 166:9 167:2,17 176:23,25 209:25 290:18 290:20 316:11 317:4,8 336:20 343:18
documentation [4] 27:16 317:6 336:1,3
documented [6] 306:25 314:24 315:9 316:18 336:12,13
documents [7] 166:16 177:3,6 232:22 296:14 329:15 336:19
doesn't [1] 107:22
Don [3] 5:10 227:22 342:22
Donald [1] 209:5

done [46] 44:2 48:17 52:18 57:7,15 63:4,11 67:20 78:16 79:14,16,18 92:19 108:25 114:14,15 114:21 130:9 132:21 150:6 152:17 159:6 162:1 166:23 183:22 189:8 233:11 237:23 242:8,9 244:14 245:24 255:19 261:3 262:2,17,24 308:13 311:11 312:10,13 314:10 317:24 336:3,16 341:9
door [1] 182:8
double [2] 183:14 238:11
doubt [1] 96:20
down [16] 10:4 20:15 76:2,5 96:17 126:23 137:3 144:22,22 159:19 159:21,23 194:13 202:25 207:3 224:17
Dr [1284] 2:2,8 4:5,6,11 4:20,24 5:1,7,24 6:7,13 6:17 7:3,14,21 8:2,10,15 8:24 9:5,9,18,23 10:9,10 10:11,19,24 11:5,7,10 11:11,15,20 12:5,6,15 13:9,15 14:2,6,11,15,20 14:21,24 15:3,8,15,16 15:18,21,24 16:1,2,2,6 16:11,12,15,25 17:6,12 17:20,25 18:6,14 19:17 19:19,20,24 20:3,13,24 21:3,8,20 22:3,9,14,23 23:2,8,12,24 24:4,8,15 25:4,12,15,18,22,23,24 26:8 27:14,21 28:3,8,13 28:19,23 29:6,11,17 30:4 30:10,18,22 31:4,10,17 31:22 32:2,6,7,7,8,19 33:4,13 34:2,6,13 35:7 35:13,18,22 36:2,5,12 36:18,23 37:2,8,13,24 38:24 40:22 41:3,9,14 41:20 42:12,20 43:1,7 43:12,19 44:1,6,10,21 45:3,9,15,25 46:5,13,19 46:21,22 47:4,13 48:3,8 48:10,15,20,24 49:21,25 50:7,13,15,20,25 51:4,9 51:14 52:12,19 53:2,6 53:12,16,24 54:4,10,14 54:19 55:1,6,14,19 56:2 56:7,14,19,21 57:9,17 57:21,23 58:3,10,21 59:1 59:9,15,18 60:2,7 61:4 61:12,17 62:1,9,20 63:1 63:5,13,19,25 64:11,15 64:22 65:2,10,21,24 66:8 66:17,22 67:3,8 68:1,5,9 68:22 69:2,6 70:17,22 71:4,12,23 72:4,10,16 74:7,13,18,23 75:9,21 76:3,16,23 77:3,11,16 77:21 78:1,5,10,17,21 79:2,6,15,20 80:1,9,24 81:9,15,23 82:6,15,20 82:20,22,23 83:1,5,6,7,8 83:11,13,20,24 84:19 85:5,10,15,19 86:10,14 86:18,21 87:10,14,19 88:18,23 89:11,22 90:1 90:12,17,22 91:7,19 92:6 92:14,22 93:4,9,15,22 94:3,8,15,19 95:3,10,17 96:3,9,10,24 97:4,13,22 98:3,8,16,22,25 99:2,7 99:12,16,20,24 100:3,23 101:2,8,10,10,17,19,22 101:25 102:4,7,10,12,17 102:23 103:2,18,23 104:11,14,16,20,20,23 105:9,15 106:1,3,22,23 107:11,24 108:3,12,18 109:9,15,17 110:1,9,13 110:18,23 111:4,8,10,15 111:19,23 112:5,10,14 112:18,25 113:3,5,10,13 113:14,16,21,25 114:9 114:12,23 115:4,11,16 115:21,22 116:2,6,13,20 117:15,22 118:3,10,11 118:20 119:1,8,9,14,19 119:24 120:8,13,18 121:4 121:9,13,18,22 122:2,9 122:19 123:4,11,12,16 123:19,20,24 124:6,8,12 124:13,18 125:2,9,13,15 125:23 126:8,19 127:4,7 127:9,14,17,22 128:4,10 128:16 129:1,7,18,21,23 130:2,4,10,16,20 131:1 131:5,11,15,19,25 132:8 132:14 133:12,18 134:13 134:21 135:2,13,22 136:1 136:5,9,16,20,24 137:14 137:20 138:4,5,7,11,18 138:22 139:2,6,14,21 140:2,9,17 141:3,16,19 141:21 142:5,10,14,19 142:25 143:8,14,21,22 144:13,17,25 145:3,19 145:22 146:1,6,16,25 147:4,11,16,22 148:5,10 148:21 149:4,9,13,21 150:1,7,15,20,24 151:1 151:2,9,14,22 152:5,12 152:19 153:6,10,22 154:5 154:10,17 155:3,17 156:3 156:6,9,17,17,22 157:1 157:7,12,18,22 158:1,7 158:13,24,25 159:3 160:4 160:9,18 161:23 162:1,6 162:11,15,16,21 163:1 163:12,16,20,21 164:1,8 164:16,17,21,22 165:2,5 165:15,19,22 166:7,8 167:9,10,14 168:10 169:6 169:10,17 170:1,10,19 170:23 171:3,12,19,21 172:2,7,15 173:3,13,17 173:23 174:4,10,20,25 175:5,10,14,16,21 176:2 176:7,14,17,22 177:12 177:20 178:5,21 179:1,6 179:13,18,23 180:2,8,18 181:5,9,13 182:5,11,13 182:21 183:2,8,16,21 184:3,8,19 185:1,3,13 185:19,23 186:3,7,11,16 186:25 187:7,14,19,24 188:7,13,24 189:10,17 189:24 190:3,11,15,21 190:25 191:7,9,19 192:4 192:10,13,20 193:9,11 193:25 194:8,11,23 195:2 195:16,20,25 196:5 197:8 198:4,25 199:4,11,12,17 200:1,11,23 201:2,6,12 201:18,22 202:2 203:7 203:11,18,22 204:6,11 204:15,19,23 205:5,11 205:16,20 206:1,6,11,15 207:22 208:2,11,15 209:5 209:6,11,16,22 210:8,14 210:19,24 211:6,12,18 211:23 212:8,8,10,15,20 212:25 213:6,11,16,22 214:2,13,18,23 215:11 215:17,22 216:11,16,21 217:6,12,18 218:1,6,12 218:19 219:2,13,23 220:6 220:15,19,24 221:5,12 221:23 222:7,13,17,24 223:5,6,12,20 224:3,10 224:14,19,23 225:4,24 226:4,10,14,19 227:2,3 227:5,6,7,10,11,13,18 228:4,15,22,24 229:1,5 229:7,11,12,13,17,24 230:7,12,16,18,21,22,24 231:4,8,12,18,24 232:8 232:15 233:3,12 234:1 234:14,18,22 235:8,12 235:17 236:5,16,20 237:7 237:12,18,25 238:6,13 238:17,25 239:4,8,12,25 240:5,11,19 241:10,14 241:21 242:3,10,15,18 242:19 243:18 244:10,15 244:21,25 245:4,8,12,25 246:10,14,24 247:3,8,18 247:22,24 248:5,9,18,23 249:3,6,13,21 250:16,23 251:3,9,13 252:1,4,6,15 252:20 253:1,5,10,15,19 254:1,12,21,24 255:5,16 255:25 256:2,8,20 257:7 257:13,19 258:3,10,16 258:23 259:4,10,15 260:2 260:13,22 261:1,7,15,21 261:25 262:5,14,23 263:1 263:7,12,12,16,17 264:5 264:14,18 265:1,16,17 265:21 266:6,10,15 267:2 267:7,13,15,21 268:1,17 268:22 269:7,11,15,20 269:24 270:3,7,13,18,22 271:4,6,10,19,25 272:7 272:11,13,21 273:8,14 273:18 274:11,13,18,24 275:4,19,23 276:1,3,10 276:14,19 277:10,19 278:2,5,9,15,21 279:1 279:18,24 280:4,9,14,21 280:23 281:3,9,17,22 282:4,16,19,23,24 283:8 283:18,25 284:5,9,12,17 284:23 285:9,15,20,25 286:9,17,19 287:1,8,17 287:17,20,24 288:6,9,14 288:16,17,25 289:4,10 290:2,15 291:3,11,12,15 291:17,17,19,21 292:17 293:3,16,20 294:5,7,11 294:18,23 295:5,18 296:7 296:18,23 297:6,22,23 298:3,9 299:2,5,8,11,13 299:17,21,23 300:2,5,5 300:7,14 301:2,6,18,22 302:2,13,16,16,25 303:14 303:21 304:6,13,16,21 304:25 305:5,13,18,25 306:7,16,25 307:22 308:1 308:2,2,6,19,20,21 309:3 309:21 310:7,8,10,11,15 310:19,25 311:5,7,13,19 312:9,14,24 313:13,25 314:4,9 315:6,10,16,21 316:7,13,20 317:9,14,19 318:3,18,24 319:15,21 319:25 320:10,15,20 321:1,5,15,19,24 322:3 322:10,15,20 323:3,3,12 324:6,21 325:8,12,17,22 326:2,6,12,25 327:19 328:2,3,8,15,19 329:3,7 329:10,16,21,25 330:11 330:22 331:1,3,8,12,15 331:19,25 332:10,15 333:2,12,22 334:3,9,22 335:2,7,11 336:5,17,25 337:7,7,7,8,14,18 338:6 338:18 339:1,4,11,18,23 340:4,10,17,21,25 341:6 341:10,15,24 342:3,8,13 342:18,24 343:2,3,23,25
draft [10] 168:17,18 265:25 266:4 324:23 325:1 327:14,16,17 328:9
drafted [1] 144:5
dramatically [1] 289:23
draw [1] 207:14
drew [1] 66:11
Drs [6] 144:6 146:14 155:14,25 248:5 306:13
drugs [1] 161:7
Dublin [2] 5:9,13
ductal [1] 161:20
duly [1] 86:8
during [15] 9:14,21 47:24 94:25 104:8 107:8 127:17 132:11 146:13 153:16 155:11 175:9 291:11 299:20 329:1
duties [2] 11:25 168:25
Dyer [2] 86:10 134:9

-E-

E [3] 18:23 72:20 106:8
e-mail [8] 106:2,12,25 114:8 115:20 116:1 136:1 144:25
e-mailed [1] 175:17
e-mails [2] 18:17 114:5
early [13] 61:22 62:18,18 122:6 127:20 145:8 193:17 205:2 279:13 294:10 313:21 314:3 319:23
easier [1] 170:2
East [2] 12:20 98:10
Eastern [12] 1:10 144:2 167:23 176:11 178:17 196:14 197:21 202:25 207:5,20 208:9 212:11
easy [1] 311:21
edit [1] 328:21
editing [1] 326:18
educate [1] 252:7
educated [1] 233:15
education [1] 26:4
educational [3] 5:6 199:24 204:2
effect [8] 8:21 15:18 26:7 162:3 168:16 174:17 237:6 292:21
effective [2] 286:7 291:23
effectiveness [1] 137:1
effort [10] 136:13 137:7 178:11 246:20 247:19 249:4 256:24 312:7 325:15 338:13
efforts [4] 86:6 242:15 316:11 329:24
eight [9] 22:7 26:9,10 85:24 93:23,24 183:4 230:3 289:19
either [7] 16:23 226:18 308:2,10 314:16 315:23 316:1
Ejeckam [7] 85:19 86:10 86:18 87:23 93:22 98:6 99:16
Ejeckam's [1] 98:25
elect [1] 129:14
electronically [1] 182:23
eleven [2] 22:7,10
eliminate [1] 88:8
elsewhere [5] 67:21 166:21 177:5,7 339:10
embarked [2] 116:5 246:19
embryonic [1] 96:18
emotions [1] 236:10
emphasis [2] 81:24 82:2
emphasized [1] 92:10
employment [1] 207:11
Enclosed [1] 243:19
enclosing [1] 255:11
encounter [1] 112:6
encountered [4] 154:18 154:21 307:3 313:10
encountering [1] 112:2
encourage [2] 69:16 261:24
end [22] 7:5 36:4,17 41:1 41:4 108:6 114:9,10 118:7 122:15 143:1 211:22 216:15 219:10,11 236:14 287:21 288:11 294:2 296:10 326:14 329:9
ended [6] 48:1 224:7 237:10 284:22,24 326:23
endometrial [1] 261:24
endoscopy [1] 33:7
engaged [3] 137:7

171:11,13
enhance [2] 26:11 39:11
enrolled [2] 25:23,25
ensure [3] 64:3 158:22 161:19
ensuring [1] 277:6
enter [1] 160:1
entered [6] 3:3 58:12,13 58:16,17 243:12
entirety [1] 52:3
entitled [2] 84:8 290:20
entity [1] 225:20
envelope [1] 344:6
environment [1] 198:12
eosin [1] 40:23
epithelial [2] 73:25 74:2
epithelium [2] 161:21 259:8
equipment [3] 14:10 193:19,23
equivalents [1] 32:20
ER [43] 41:18 44:19 72:25 85:24 89:5,6 94:10 95:6 100:21 105:7 106:6 106:16 111:14 112:9 129:15 133:25 134:19 162:10 172:11 239:23 240:14 241:7 242:2,6,16 248:22 251:21 252:13 265:6 271:17 274:4 280:2 280:18 304:5 305:3,9 308:16 314:25 318:10,21 321:22 322:7 323:5
ER/PR [85] 42:10 47:17 47:18,19 48:2,18 50:19 52:25 53:1,11 55:9 56:17 57:5 59:17 60:1,7 61:7 63:11 64:19 69:12,25 74:22 75:11 76:13 77:2 77:4 78:15 81:19,22 82:11,17 83:16,18 87:4 88:9 91:5 96:22 97:19 106:7,18 109:23 110:7 110:12 123:8 129:11,12 132:13 144:9 147:9 154:3 155:15 161:22 183:7,12 183:15 185:11 187:5 241:17 242:23 249:4 250:15 251:2 253:13 254:4,15 259:9 264:13 268:21 269:3 270:4 271:1 274:4,23 278:2 279:15 282:21 283:6,22 285:7 287:19 303:22 305:7 315:24 316:23 330:6
erratic [3] 85:25 94:1 97:10
error [1] 219:7
ERs [3] 134:5 136:3 138:14
establish [1] 338:13
estimate [15] 70:7,9,14 72:1,2,9 73:24 236:24 268:8,10,15,16 270:12 270:14 271:5
estimated [1] 236:25
estrogen [21] 47:11 48:13 57:2 58:22 75:2 87:25 89:14 102:1 103:12 239:22 255:10 264:7 274:8 306:5,22 307:6,18 307:20 309:17 310:3,5
et [1] 1:9
events [1] 133:23
eventually [7] 54:20 122:13 133:7,8 138:8 139:18 337:11
everybody [5] 115:13 117:8 275:13 304:1 308:14
evidence [8] 10:15 25:18 42:1 120:5 181:22 191:13 191:25 274:11
evidenced [1] 118:17
evolved [1] 215:3
evolves [1] 145:6
exact [3] 239:1 259:17 312:11
exactly [12] 28:15 107:1 118:12 126:9,20 133:19 172:18 173:5 244:22 259:23 260:3 288:23
exam [1] 6:3
examination [19] 2:3,4 2:5,6,7,9 4:6 19:10,11 35:9 44:12,24 182:11 185:1 191:7 193:9 195:9 199:12 332:4
examinations [1] 49:5
examine [6] 19:12 38:23 41:12 72:17 76:19 141:13
examined [9] 26:14 33:10,19 34:17 41:21 54:24 70:8 268:9 318:22
examining [2] 80:12 197:24
example [28] 17:16 34:12 36:3,9 38:2,21 49:6 64:7 65:13 74:24 79:10,11,12 127:21 135:20 164:14 173:17 180:23 219:21 220:5 246:18,22 279:13,14 287:15 314:25 317:25 339:17
examples [1] 272:8
exams [1] 5:23
excellent [3] 197:11 320:5,7
except [2] 230:2 242:1
exception [2] 8:22 95:18
exchange [4] 114:4,8 136:2 144:25
excision [1] 88:11
excisioned [1] 33:19
exclusively [1] 325:4
executive [7] 12:25 13:20,22,25 15:4 291:6 291:7
exhibit [46] 3:3 58:6,8,9 58:9,13 84:3,6 85:18 86:24 93:20 101:15 105:25 118:18,19 127:1 143:17 156:18 167:1,19 206:22 209:3 210:1 212:1 243:17 248:1 251:16,20 255:2 261:12 264:3 273:24,25 276:17 282:12 290:19 291:5 297:9,11 297:15,18 302:6 306:10 319:7 322:23 337:4
exhibits [5] 3:2,4 58:15 243:11,16
exist [1] 189:15
existed [7] 44:9 45:8,10 46:3,9 222:21 313:11
existence [2] 86:20 171:19
exists [2] 189:18 316:18
expand [2] 193:13 214:7
expanded [4] 107:3,20 115:7 118:9
expect [3] 24:2 65:8 288:4
expectation [1] 64:20
expected [6] 21:24,25 22:1 264:12,13 286:24
expecting [1] 287:2
experience [8] 63:23 84:11 220:2,9 236:6 251:2,8 281:14
experienced [4] 233:14 245:19 295:23 296:1
experiment [1] 246:5
experimented [1] 247:13
expert [2] 66:11 68:10
expertise [1] 220:10
experts [2] 166:20 178:13
explain [2] 283:13 284:3
explained [1] 60:4
explicit [3] 46:15 145:10 146:3
explicitly [1] 196:6
exposed [3] 39:14 48:1 81:3
exposure [4] 23:13 240:14 241:9 268:21
express [1] 124:16
expressed [6] 100:21 170:18,24 254:9,13,16
expression [2] 323:5 330:7
extended [1] 15:19
extensive [2] 73:2 195:9
extent [4] 43:25 44:2 124:25 125:6
external [46] 28:2 31:21 63:18,23 64:1,4,7,14,16 65:7,14,17 77:7 81:24 82:1,2 106:10 109:22 111:13 112:3,21 142:18 142:18 233:2 258:21 259:1 277:9,16 278:4,14 278:18 279:8 280:12,18 280:19,19 281:2,7,15 305:9,16 314:8 318:13 318:21 320:4 334:16
extra [2] 18:9 19:3
extremely [2] 178:9 265:12
eye [1] 153:13

-F-

F [1] 101:19
F-I-N-B-A-R [1] 4:13
faced [4] 116:10,12 290:14 326:11
facilitate [1] 312:3
facilities [2] 293:8 313:8
facility [2] 290:9,11
fact [42] 12:13 56:21 57:21 59:16 65:18 77:6 98:20 99:5 118:1 121:25 125:8 128:7,21 131:14 137:11 145:15 167:5 172:23 177:4 184:13 185:10 194:11 207:2,25 208:7,10,21 209:20 210:17,23 211:9 254:7 269:1 273:24 274:10 275:15 276:24 281:8 283:1 316:3,12 318:11
faculty [1] 203:23
fair [5] 65:9 91:15 189:9 193:24 197:24
fall [7] 121:12 122:6 124:3 141:10 148:18 155:12 172:22
Falls [7] 6:25 16:3 95:22 95:23 120:19 166:14 169:15
false [5] 88:9 104:7 138:25 257:21 258:2
familiar [9] 180:15 252:3,7 254:14,23 258:20 279:8 293:7 338:23
familiarize [1] 256:18
family [5] 185:9,15 186:14,23 187:1
far [26] 67:17 72:12 83:5 122:12 142:8 163:6 167:6 186:23 187:1 197:19 257:20 262:16 282:6 298:1 301:7 309:4,22 310:20 312:6,10 317:7 325:1,2 332:16 338:16 342:17
fashion [1] 146:17
fast [3] 47:23 197:1,2
fatty [1] 160:22
favour [3] 299:6 300:6 300:11
favourable [1] 171:4
February [19] 58:20 69:25 109:23 141:5,8 143:7 176:12 264:5 297:12,17 301:4 302:7 305:23 306:16 307:7,9 307:11 310:14 319:9
feedback [5] 232:3 262:8 265:12 304:1 327:4
feeling [1] 76:8
feels [1] 196:13
fellow [8] 59:13 200:15 202:8 205:21 216:6 236:3 275:16 282:1
fellows [1] 25:24
fellowship [4] 5:22,25 200:24 205:7
fellowships [1] 200:22
felt [9] 57:1 60:8 67:16 75:13 132:25 133:1 188:20 299:21 339:8
females [2] 121:1,8
few [7] 117:5 243:25 258:12 259:17 279:4 290:10 326:19
fifteen [1] 100:13
fifth [1] 89:8
figure [2] 74:10 206:20
file [1] 318:5
filed [1] 318:6
fill [1] 279:17
filled [6] 110:21 292:3 292:13,13 296:17 336:11
filtered [1] 136:8
final [5] 26:19 172:18 266:3,3,9
finalized [2] 326:24 329:6
Finbar [2] 2:2 4:12
finding [2] 183:11 197:23
findings [1] 189:19
finish [1] 277:23
finished [4] 5:20 32:10 143:1 201:10
finishes [1] 343:24
firm [1] 313:2
first [73] 4:19 8:19 18:15 27:4,19 29:23 30:11 40:25 46:20 47:2 57:20 59:4,12 66:25 70:2 71:8 86:17,20 87:13,17 93:19 95:19 101:6,21 104:10 106:24 107:5,16 117:4 120:7,25 123:10 125:19 133:24,24 134:4,17 136:25 141:1,7 142:17 144:18 151:17 152:7 156:14 167:15 172:5 174:17 182:17 189:20 191:11 193:15 194:24 212:12 228:12 240:14 241:8 248:10 259:14 267:5 268:20,20 271:23 278:2 291:10 297:2,20 298:6 326:16 330:9 334:17,19 341:22
firstly [4] 67:9 72:17 159:6 307:4
five [16] 26:5 40:4,14 90:4 99:16 160:19 183:3 202:5 216:23 248:8,11 273:23,24 286:16 293:10 326:15
fix [4] 35:2 36:10 79:21

80:2
fixation [26] 33:2 38:10 39:9,11 45:24 79:10 88:3 88:5 127:21 128:12 149:16,17,19 158:9,11 158:19,22 159:2,9 160:14 160:23 161:2 168:4 173:19 175:13 176:11
fixed [8] 48:12 52:8 70:10 148:1,6,8,9 268:11
floated [2] 40:5,15
flow [2] 96:15 293:6
focus [1] 44:19
focused [2] 155:22 157:23
folder [4] 243:20,22 244:2,4
folks [1] 119:18
follow [13] 42:25 140:1 192:8 193:4 205:4 233:8 300:23 306:25 316:16 323:15 326:13 329:12 333:6
follow-up [2] 323:13,16
followed [7] 151:25 232:16 273:19 309:23 316:21 327:17,18
following [17] 19:9 33:6 33:24 34:18 35:23 38:11 38:12,17 45:19 81:8 85:23 87:6 129:10 205:14 311:6,12 323:23
Fontaine [1] 101:18
footnotes [1] 274:10
forceful [1] 128:11
foregoing [1] 345:2
forgotten [1] 327:8
form [12] 70:9 110:16 268:10 279:17,22 312:21 315:11,22,23 327:14,16 336:9
formal [9] 6:11,12 16:22 20:22 24:13 233:19,24 234:2 272:1
formalin [24] 33:6 34:24 34:24 35:2,17 38:11,14 39:5,9 45:18 46:8,8,10 46:15 48:12 52:8 81:3 88:6 159:10,11,12,16,24 160:1
formalizing [1] 27:13
formally [2] 211:3 299:1
format [1] 74:22
formation [4] 202:13 202:24 213:4 222:3
formed [4] 12:21,23 29:18,19
forms [6] 110:8,16,22 111:1 168:25 169:1
forth [2] 27:7 67:22
forthcoming [1] 198:13
forthwith [1] 86:3
fortunate [3] 10:6,23 116:14
forward [4] 47:23 134:8 171:15 255:22
forwarded [1] 55:25
found [11] 10:14 52:11 86:7 120:23 135:3 153:2 194:19 245:17 257:4 316:4,22
founding [1] 294:9
four [18] 66:16 85:2 86:8 89:7 95:23 101:18 216:5 216:22,24 219:4,18 225:14 234:7 273:23,24 273:25 286:15 326:15
fragmented [1] 324:13
frame [3] 42:7,8 279:16
frank [1] 197:20
frantic [1] 126:20
frequent [2] 21:7,9
frequently [10] 16:14 16:17 17:24 34:24 38:7 49:7,12 51:15 62:3 255:21
fresh [5] 48:9 49:1 52:6 159:14 161:15
Friday [3] 79:19 160:24 335:19
friend [2] 340:1,5
frozen [6] 48:9 49:4,13 50:10,14 241:1
full [4] 32:20 117:12 125:13 330:15
fully [2] 60:8 104:4
fumes [1] 159:13
function [3] 15:19 24:13 196:17
functions [1] 13:11
funding [6] 298:13,22 327:23 328:12,14 342:14
future [7] 180:21 197:14 228:10 254:5 255:17 297:25 311:18

-G-

G-A-L-L-A-G-H-E-R [1] 4:14
G-E-O-F-F-R-E-Y [1] 4:13
Gallagher [615] 2:2 4:5 4:5,6,11,12,20,24 5:1,7 5:24 6:7,13,17 7:3,14,21 8:2,10,15,24 9:5,9,18,23 10:11,19,24 11:5,11,15 11:20 12:5,15 13:9,15 14:2,6,11,15,20,24 15:3 15:8,15,21 16:1,12,25 17:6,12,20,25 18:6,14 19:20,24 20:3,13,24 21:3 21:8,20 22:3,9,14,23 23:2,8,12,24 24:4,8,15 25:4,12,22 26:8 27:14 27:21 28:3,8,13,19,23 29:6,11,17 30:4,10,18 30:22 31:4,10,17,22 32:2 32:6,19 33:4,13 34:2,6 34:13 35:7,13,18,22 36:5 36:12,18,23 37:2,8,13 37:24 38:24 40:22 41:3 41:9,14,20 42:12,20 43:1 43:7,12,19 44:1,6,10,21 45:3,9,15,25 46:5,13,19 47:4,13 48:3,8,20,24 49:21,25 50:7,15,20,25 51:4,9,14 52:12,19 53:2 53:6,12,16,24 54:4,10 54:14,19 55:1,6,14,19 56:2,7,14,19 57:9,17,23 58:3,10 59:1,9,18 60:2 61:4,12,17 62:1,9,20 63:1,5,13,19,25 64:11 64:15,22 65:2,10,21 66:8 66:17,22 67:3,8 68:5,9 68:22 69:2,6 70:17,22 71:4,12,23 72:4,10,16 74:7,13,18,23 75:9,21 76:3,16,23 77:3,11,16 77:21 78:1,5,10,17,21 79:2,6,15,20 80:1,9,24 81:9,15,23 82:6,15,22 83:1,8,13,20,24 85:5,10 85:15 86:14,21 87:10,14 87:19 88:18,23 89:11,22 90:1,12,17,22 91:7,19 92:6,14,22 93:4,9,15 94:3,8,15,19 95:3,10,17 96:3,9,24 97:4,13,22 98:3,8,16,22 99:2,7,12 99:20,24 100:3,23 101:2 101:8,19,22 102:4,12,17 102:23 103:2,18,23 104:11,16,23 105:9,15 106:1,23 107:11,24 108:3 108:12,18 109:9,17 110:1 110:9,13,18,23 111:4,10 111:15,19,23 112:5,10 112:14,18,25 113:5,10 113:16,21,25 114:12,23 115:4,11,16,22 116:2,6 116:13 117:15,22 118:3 118:10,20 119:1,8,14,19 119:24 120:8,13,18 121:4 121:9,13,18,22 122:2,9 122:19 123:4,11,16,20 123:24 124:8,12,18 125:2 125:9,15,23 126:8,19 127:4,9,14,22 128:4,10 128:16 129:1,18,23 130:4 130:10,16,20 131:1,5,11 131:15,19,25 132:8,14 133:12,18 134:13,21 135:2,13,22 136:5,9,16 136:20,24 137:14,20 138:4,11,18,22 139:2,6 139:14,21 140:2,9,17 141:3,16,21 142:5,10,14 142:19,25 143:8,14,21 144:13,17 145:3,19 146:1 146:6,16,25 147:4,11,16 147:22 148:5,10,21 149:4 149:9,13,21 150:1,7,15 150:20 151:1,9,14,22 152:5,12,19 153:6,10,22 154:5,10,17 155:3,17 156:3,9,22 157:1,7,12 157:18 158:1,7,24 160:4 160:9 161:23 162:6,11 162:16,21 163:1,12,16 163:21 164:1,8,17,22 165:2,15,22 166:7 167:9 167:14 168:10 169:10,17 170:1,10,19,23 171:3,12 171:21 172:2,7,15 173:3 173:13,23 174:4,10,20 174:25 175:5,10,16,21 176:2,7,17,22 177:12,20 178:5,21 179:1,6,13,18 179:23 180:2,8,18 181:5 181:9,13 182:6,11,13,21 183:2,8,16,21 184:3,8 184:19 185:1,3,13,19,23 186:3,7,11,16,25 187:7 187:14,19,24 188:7,13 188:24 189:10,17,24 190:3,11,15,21,25 191:7 191:9,19 192:4,10,13,20 193:9,11,25 194:23 195:16,20,25 196:5 197:8 198:4,25 199:5
Galway [4] 5:15 47:5,15 47:17
Gander [47] 7:8 8:9,14 8:20 9:3 10:22 11:2 12:17,23 14:25 15:19 16:2,13,20 46:25 48:1,6 52:10 56:24 68:21,23 76:6 78:16 79:14 90:9 95:22,25 104:21 132:7 133:23 142:24 143:12,20 150:12,14 151:12 158:18 161:6 165:14 168:21 169:12 172:13 181:10,12 181:14 196:20 197:7
Gander's [3] 105:7 143:6 179:11
gastroenterology [1] 23:16
gather [8] 10:15 31:2 117:16 137:8 169:21 255:6 274:10 307:12
gathered [2] 108:19 140:15
gathering [1] 105:19
general [108] 31:11 42:3 46:6 65:3 82:9 89:12,14 101:1 146:9 168:2 189:18 196:18 197:12 200:4,5,7 202:4,11,15,19,21 203:19 203:21 205:17,19,22,24 206:5 209:9,14 221:15 221:19 222:12 226:24 227:1,23 228:2,11,19 230:1 231:11,14 234:24 236:14,23 237:2,4,11 239:19 240:6,17,22 242:1 242:8,20 243:2 244:11 245:24 246:23 247:9 252:25 253:22 262:7 277:21 279:23 286:7,17 286:24,25 287:5,9,22 289:12,14,17,20,22 290:7 291:1,22 293:10 295:16 297:13 298:13,25 301:1 301:10 302:12 303:9 304:2 312:25 313:22 314:3 317:22 318:1,11 324:12 329:2 330:5,20 331:6,14,18 333:10 335:13 336:2,23 337:25
generally [18] 20:12 25:5 32:21 36:1 37:17 63:24 64:8,14 65:8 76:4,6 102:15 171:4 180:15 306:20 307:5 308:15,16
gentleman [1] 185:8
Geoffrey [2] 2:2 4:12
given [11] 11:22 46:20 60:7 80:13 125:5 132:11 188:3 202:5 300:24 336:6 342:11
giving [3] 103:21 192:22 323:16
glad [3] 69:22 87:2 265:10
glance [1] 144:21
glass [2] 40:8,18
gleaned [1] 127:25
go-forward [1] 130:8
goal [4] 160:11,13 328:24 338:3
goes [10] 69:11 87:7 88:16 168:5 169:2 230:15 231:2 300:20 314:23 331:22
gone [9] 114:6,10 131:14 174:24 187:13 206:19 211:21 288:6 338:16
good [22] 67:9,23 68:13 182:13 185:3 192:24 197:12 198:16 199:22 233:13 243:3 245:20 248:24 262:17 263:19 295:23 303:15,17 306:20 307:5,16 343:16
Grace [84] 202:11,15,17 202:20 204:4 205:15 206:10 208:1 209:2,9 212:19 213:5,17,25 214:10,17 215:6 226:8 227:21,22 229:1,10,21 230:2 231:5 232:11,11 233:1,10 234:24 235:5 235:22,24 236:10 237:16 237:17 238:4,12,21,23 239:7 240:17 241:25,25 244:14 245:11,16 247:16 249:9 250:13,18 251:7 251:24 252:2,23 253:24 254:8,22 256:1,5 261:6 263:14 265:14 266:14 271:22,24 272:2,20 273:6 274:22 275:17 277:15 282:2 285:4 287:3 289:15 289:19 293:15,23 298:11 298:12,18,24 299:20
grade [2] 106:10 309:7
grades [1] 88:7
graduated [1] 200:2
grand [8] 6:25 16:2 95:22,23 120:19 166:14 169:15 234:23
granular [1] 319:1
grease [1] 319:2
greater [4] 73:12,13 166:14 287:3
grey [1] 288:10
gross [9] 19:6,10,11 34:18 35:8 37:21 44:11 44:24 165:9
grossing [18] 18:8 19:17

19:19 36:4,21 37:6 45:13 159:2,15 168:6,13 298:16 330:8 331:23 332:3,14 332:24 333:3
ground [1] 16:8
group [13] 7:23 117:5 177:25 185:5 216:23 233:14 250:15 256:10,13 261:2,3 333:25 337:17
grouping [2] 210:3 261:1
groups [2] 117:4 196:22
guess [6] 91:20 137:21 139:7 159:5 184:14 189:4
guide [1] 44:15
guideline [4] 327:11,11 327:14,21
guidelines [2] 333:6,9
Gulliver [15] 176:14,15 248:6 295:25 301:8 302:17 303:7 306:14,17 310:4,12,23 312:7,17 313:4
guys [1] 308:19
gynecological [5] 56:22 56:25 68:10 234:15,19
gynecology [1] 23:16
gynepath [1] 233:18
gynepathological [1] 234:11
gynepathology [1] 234:3

-H-

H [3] 18:23 72:20 106:8
H&E [5] 40:21,23,25 49:20,24
Haegert [19] 223:6 229:1 229:6,11,13 230:21 255:16 297:22,22 299:2 299:5 300:5 301:2 302:16 306:14 308:2,19 323:3 328:3
half [7] 32:8 73:12,13,14 78:20 292:1,7
Halfway [1] 131:22
Halifax [17] 26:16 48:15 48:19 51:13 53:5,10,15 54:25 55:9,13 57:13,18 63:12 66:15 67:2 200:13 200:14
handed [1] 329:12
handled [9] 34:5 109:22 137:3 138:5 192:1,9 277:17 282:2 313:24
handling [2] 168:3,5
happening [2] 80:12 129:4
happy [2] 60:9 130:21
hard [1] 92:7
hat [1] 92:19
hazard [2] 80:11 159:17
hazards [1] 46:8
HC [1] 241:8
he'd [3] 10:16 69:21 277:5
head [2] 16:7 74:11
headed [2] 178:12 256:11
heading [2] 332:8,9
heads [1] 123:23
health [36] 1:11,17 6:24 9:10,11 12:20,22 15:11 25:8 48:10 58:19 144:2 167:23 171:8 176:11 192:25 196:14 197:22 202:13,25 207:5,20 208:9 208:24 212:12 213:4 214:21 217:4 221:13 222:3 225:9,17 241:17 249:20 261:22 290:21
Health's [1] 178:17
hear [6] 32:5 100:21 101:7 142:17 196:24 284:18
heard [8] 92:7 139:17 155:25 157:13 165:19 169:21 191:13 345:5
hearing [2] 138:7 192:14
heavy [1] 307:1
held [2] 248:4 250:10
help [4] 119:15 165:17 169:9 243:24
hemapathology [1] 96:11
hematology [7] 219:5 219:21 220:5,8 221:10 222:16 224:13
hematoxylin [1] 40:23
hemotology [4] 320:17 320:21,25 321:2
henceforth [3] 59:25 248:17 264:10
Hennebury [1] 1:9
HER2/neu [2] 154:3 330:6
hereby [2] 209:12 345:2
hesitate [1] 244:5
heterogeneous [1] 88:15
high [2] 84:23 307:2
higher [2] 73:15 192:9
himself [4] 10:14 96:12 128:2 276:2
histology [6] 44:22 45:2 45:7 46:7 161:10,16
Historically [1] 160:16
history [1] 204:3
hold [5] 129:10 200:20 248:14,17 335:19
hollow [2] 34:8,10
home [1] 259:25
honestly [1] 106:25
Honourable [2] 1:3 345:6
hope [1] 244:4
hopefully [3] 86:7 250:9 313:6
hormone [5] 1:2 70:1 117:3 144:4 345:4
hospital [148] 5:15 6:20 6:21 7:8 8:14 9:3,8,13 9:14,16 12:13,17 16:13 20:11 21:13 22:19 24:12 30:7 31:8,12 45:17,24 117:21 126:7 130:24 142:3 143:11 147:9 158:6 158:21 164:25 166:10 182:19 184:2,15 187:6 187:11 189:16 196:16,18 196:20 197:5 201:14,17 202:4,9,11,15,17,19,21 202:21 203:4,19,21 204:5 205:8,15,22,24 209:2,14 212:19 214:1,10 215:6,7 217:14 218:7 221:16,19 222:12 225:15 226:24 227:21,23 228:2,19 230:2 232:12 234:24 235:7,9 235:23 236:23 237:2,11 237:16,17 239:19 240:7 240:22 241:25 242:2,8 242:21 243:2 244:11 245:24 247:10 250:13,18 251:24 252:2 254:9 265:14 266:14 272:2 273:7 277:21 279:23 286:7,25 287:3,10,22 289:12,14,20,20 290:7 291:22 293:10 297:13 298:11,13,18,24,25 300:23 301:1 302:12 303:10 304:2 313:23 314:3 318:1,11 324:12 330:6 331:7,14,18 333:10 335:14 336:1,2 339:13
hospitals [9] 7:19,22 8:3 8:5 30:16,25 85:21 191:17 208:9
host [3] 69:20 230:10 265:9
hours [1] 26:3
house [1] 5:14
HSC [1] 85:20
huge [1] 166:23
human [1] 168:24
hundred [1] 239:5
hundreds [1] 169:2
hurt [1] 93:13
Hutchinson [4] 337:8 337:14,18 339:1

-I-

idea [18] 59:12,25 65:13 65:13 72:23 73:2,7,10 103:11 125:12 148:24 180:23 185:9 245:20 258:21 264:22 298:6 308:12
ideal [1] 132:22
identification [1] 138:14
identified [12] 77:24 120:6,16,19 122:5 138:17 140:14 156:2 158:18 185:7,17 291:21
identify [5] 115:13 119:10,12 136:13 137:7
identifying [2] 119:7 126:16
idle [1] 327:8
IHC [54] 42:10 48:2,19 52:25,25 57:6 61:22 63:4 63:9 82:12 84:20,24 88:1 91:5 101:1 129:13 153:18 154:9,16 168:19 169:1 242:7,16,22 244:14 245:23 249:4 251:2 252:13,13,24 253:4,14 253:22 266:24 268:21 269:4 271:1 274:23 283:7 283:12,23 285:7 287:18 287:21 294:21 295:12,19 297:5 301:16 313:23 321:14,16,18
II [1] 276:18
imagine [1] 62:13
immediate [1] 293:25
immediately [3] 33:5 161:10 197:2
immersed [1] 33:5
immersion [1] 159:16
immmunohistochemistry [1] 82:9
immuno [3] 268:8 277:2 307:2
immuno-reactive [2] 70:8,15
immunoglobulins [2] 243:21 244:1
immunohistochemical [12] 58:23 62:11 69:13 69:25 84:9 85:22 93:23 261:23 262:4 264:8 265:7 274:1
immunohistochemistry [20] 47:20 52:5 84:14 86:11 98:15 145:6 153:12 243:1 244:8 245:15 247:10 257:20 261:18 283:15 294:2,8,9 296:15 301:11 317:2
immunology [1] 320:6
immunoperoxidase [10] 248:23 249:1,19 300:18,20 302:18,20,22 306:19 312:20
immunos [5] 306:20 307:4,15 308:14,15
immunostain [3] 87:3 254:15 314:10
immunostaining [1] 323:7
immunostains [3] 88:2 303:16 316:23
implement [2] 249:18 327:24
implementation [5] 232:18 242:22 324:2 330:5,10
implemented [2] 166:11 334:8
implications [5] 105:4 137:2,3 158:5 194:6
importance [1] 91:4
important [11] 51:24 64:3 65:19 91:8 157:14 192:23 330:7 331:22 332:13,23 333:1
impression [10] 103:24 108:17,20 114:20 125:21 153:4 173:10,12,14 193:20
impressions [1] 157:17
improvement [5] 24:19 171:14 321:8 333:16 334:5
in-depth [1] 31:14
inaccurate [1] 246:7
inadequate [1] 88:9
inaudible [1] 132:3
incidents [2] 148:2 219:8
include [5] 60:6 91:10 138:16 163:5 183:7
included [1] 71:17
including [5] 133:16 153:19 168:4 169:1 212:5
inclusive [2] 243:13,14
increase [2] 88:10 287:11
increased [3] 39:10 289:11,22
increasingly [3] 51:22 52:1 66:20
indeed [3] 72:22 73:18 73:22
independent [2] 134:2 213:25
indicate [4] 190:7 197:20 207:10 316:16
indicated [25] 60:14 66:20 89:7 97:2,17 99:5 135:10 156:6 158:17 164:14 165:25 166:2 171:18 176:20 188:6 209:15 228:25 229:2 251:18 254:6 266:20 269:4 284:3 337:16,22
indicates [2] 60:12 88:8
indicating [1] 97:8
indirect [1] 218:20
indirectly [1] 218:18
individual [12] 59:7 89:19 147:21 171:10 235:5,11 249:25 250:14 264:11 275:6 276:6 285:14
individually [1] 256:10
individuals [5] 178:8 212:5 235:15 261:3 337:9
inexpert [1] 153:13
infiltrated [1] 39:15
infiltrating [2] 144:5,9
influence [1] 66:6
inform [4] 87:2 300:22 314:20 317:1
informal [2] 27:6 233:20
informally [1] 299:2

information [13] 87:7 88:25 119:16 128:1 168:3 183:19 191:16 197:18 198:1,23 256:23 310:6 335:21
informed [3] 86:9 140:23 185:15
inhaling [1] 159:12
initial [8] 101:20 104:19 117:20 126:16 185:11,14 195:1 246:20
initiative [4] 31:16 59:6 177:24 178:1
initiatives [2] 179:4 290:22
input [2] 146:23 328:4
inquire [2] 262:7 339:25
inquired [1] 340:5
inquiries [18] 56:11 90:15 94:13 95:8 105:22 135:1 158:20 161:5 172:21 180:7 256:18 309:14,15,18 319:23 339:16 340:9,24
inquiry [14] 1:1 131:23 133:2,5 151:2 189:4,5 189:20 190:5 195:12 309:22 339:25 345:4,7
insert [1] 75:25
instance [5] 80:10 82:14 111:16,22 334:19
instances [2] 72:2 80:5
institution [8] 67:11,12 104:22 120:11 169:5 192:9 222:6 242:1
institutional [1] 333:17
institutions [4] 12:21 26:15 169:6 170:15
Integrated [4] 1:10,17 12:22 15:10
intensity [1] 309:6
interact [2] 16:14,14
interacted [1] 16:17
interaction [7] 16:6,10 17:23 18:1 20:10 233:25 234:2
interdepartmental [2] 233:13 334:14
interest [6] 17:13 93:20 96:10 220:2 294:8,10
interested [4] 56:22 192:14 219:25 298:20
interesting [3] 22:18 335:15 336:8
interhospital [2] 334:15 335:6
internal [35] 12:24 24:21 81:20,22,25 82:8,13 88:13 91:2,25 92:8 106:10 128:14,15 145:5 146:11,12 148:13,17 149:1 158:9,10 161:19 162:23 163:5,7 173:19 173:20 233:10 259:7,8 259:25 260:11,15,21
internally [1] 25:6
internship [2] 5:10 200:4
interpret [3] 61:19 251:25 281:20
interpretation [3] 129:13 251:22 269:21
interpreted [1] 277:8
interpreting [2] 61:3,8
interprovincial [1] 337:17
interrupted [1] 37:20
intervening [3] 47:24 47:25 127:13
intradepartmental [3] 334:15,16 335:24
introduce [3] 242:15 245:15 249:4
introduced [3] 84:24 244:16 246:5
introduction [3] 59:12 104:1 274:22
introductory [2] 244:17 245:14
invasive [7] 41:23 60:15 61:1 72:23,24 255:8 266:21
investigation [1] 125:7
invitation [1] 188:18
invite [1] 192:17
invited [4] 130:23,24 187:10,11
involve [11] 18:3 63:11 104:22 108:25 109:7 195:3,8 321:12,13,22 339:3
involved [49] 24:13,19 24:21 28:1,1,9 29:2,9,9 29:12,20 31:2,8,11 33:1 57:22 61:3 70:13 104:24 109:11 138:10 180:24 219:11 233:1 234:23 235:19 240:9 246:9 247:14 249:4,5,9 250:15 254:11 261:6 267:6 268:14 287:5,7,9,18,21 287:23 288:5 294:17,19 312:1 327:22 329:18
involvement [10] 43:25 98:15 99:1 140:13,13 172:14 294:21 295:4 328:10 329:16
involves [3] 17:11 27:24 269:6
involving [18] 12:11 27:19 59:6 60:12 81:19 103:25 105:17 107:17,18 108:21 117:20 149:16,17 174:14,15 179:5 268:15 287:17
Iran [2] 200:8,10
Ireland [4] 5:9,10,15 47:7
issue [29] 69:21 71:11,18 81:25 82:7,17 90:2 103:5 105:16 114:16 128:14,18 145:5 161:18 177:14 180:20 195:7 196:7 219:6 250:7,17 255:16 265:10 284:18 290:11 295:9 303:22 313:6 343:5
issued [1] 188:17
issues [23] 12:24 13:1 14:16,16 17:13 18:20 20:5,19 26:22 88:3 91:2 120:4 126:12 127:21 149:16,17,18 158:19 232:1,7 233:2 258:4 298:23
issuing [1] 176:13
it'll [1] 58:7
item [1] 92:24
items [1] 323:22
itself [18] 27:18 39:21 55:4 85:9 156:19 176:21 176:25 215:7 228:3 232:11,12 233:10 237:16 239:7 257:23 258:6 265:25 325:7

-J-

James [15] 7:7 9:4,10,10 9:13,14 12:16 14:25 24:12 31:1 33:3 42:18 63:4 147:8 182:18
Janeway [2] 6:20 313:3
January [16] 84:12 106:16 108:11 135:16 136:3 200:14 203:14 209:4,11 210:11,17 211:4 212:4 228:9 266:2 286:5
Jennifer [4] 1:15 2:4 182:11,13
job [12] 15:19 21:25,25 166:18 226:7,21 228:13 228:16 287:2 288:20,22 298:21
John's [95] 26:16 56:21 57:6,8,16,21 58:20 59:14 59:15 63:2,10 67:7 68:1 69:3,5 76:14 93:22 94:14 95:25 96:16 98:11 100:22 104:10 106:16 107:18,19 109:16,20 110:17 112:22 117:17 118:17 122:18,22 123:8 124:23,24 125:7 126:1,23 129:11 130:25 132:13,22 135:21 136:15 138:17 139:9,13 140:15 141:6,14 142:3 151:8 153:17 154:8 155:13 156:2 157:23 158:15,16 165:1,3 166:19 167:5 169:19 173:1 178:8,16 178:17 187:12 188:5,11 188:19 189:8 190:20 195:6 197:11 202:3 203:14 204:5,10 205:15 208:8 211:17 212:13 227:15 237:22 242:16 244:9 264:24 290:22 318:9 345:8,11
joint [3] 218:2 247:19,23
journal [4] 71:2 257:9 258:5 260:7
journals [4] 25:6 74:5 257:5,9
Judy [2] 345:2,13
July [22] 1:4 106:2,13 108:6,6 114:5,9,10 118:8 125:12 126:15 143:24 144:24 202:17 227:19,24 228:1 286:10 289:14 313:11 345:5,12
June [22] 99:16 100:20 100:20 101:25 106:20 114:7,7 207:16 250:10 251:17 255:4 288:11 313:11 322:25 323:1,2 323:11 324:22 333:1 334:2 338:11 342:7
June/July [1] 109:13
junior [1] 11:19
Justice [2] 1:3 345:6

-K-

Kara [1] 1:9
Karen [1] 120:21
keen [1] 294:10
keep [7] 38:10 143:11 159:24 243:22 316:3,6 317:6
keeping [2] 184:9 339:9
kept [2] 146:22 277:20
keratin [1] 95:19
Khalifa [52] 56:21 57:21 58:21 59:15 60:7 65:24 68:1 84:19 109:15 111:8 116:20 227:11,13 242:19 243:18 248:5,9,23 249:3 252:1,5 255:5 256:1 261:1,9,15 262:5,23 263:12,12,17 264:5 265:16 267:13 271:4 272:11 276:1,19 278:3 280:23 282:16,19,24 284:12 287:17,18,20 288:6,11 291:16 310:11 311:7
Khalifa's [5] 113:3 230:16 242:15 254:21 274:11
kind [20] 10:15,15 83:6 110:16 144:10 145:17 147:14 173:21 177:10 193:21 196:24 204:2 212:12 214:8 215:2 246:4 259:24 287:12 288:18 293:24
kindly [1] 166:8
kinds [1] 236:9
kit [1] 244:16
kits [1] 246:8
knew [17] 64:4 83:25 98:9,11 132:22 142:8 288:17 289:1,5 293:9,11 293:11 294:7 295:21 317:7 339:24 343:6
knowing [1] 288:23
knowledge [10] 66:15 113:15,17,18 151:13 244:13 251:6 265:14 272:10 285:6
knowledgeable [3] 153:12 295:20,22
known [3] 93:21 109:14 293:14

-L-

lab [31] 12:12,24 16:8,9 18:4 20:6 32:18 33:2 60:20 64:5 143:20 155:2 217:9 218:21 219:4 244:1 287:4,22 289:15 290:9 294:2,10,13,19 295:7,19 314:12,20 317:2 320:16 341:17
lab's [2] 140:13 155:21
labelled [1] 207:5
laboratories [9] 31:20 170:5,8,11 202:10 215:13 215:16,20 337:23
laboratory [60] 7:11,13 7:15 12:13 13:21 17:2,9 18:22 24:12 27:18,24,25 29:25 30:1 31:7 33:9,18 62:3,6,8,10 64:2 66:2 80:17 101:17 127:3 129:7 129:16 136:25 142:2 151:8 153:17 178:17,18 179:11 184:2,20 195:4 195:13 209:7 210:9 212:10 214:15 215:23 216:4 217:14 218:3,25 220:4 236:2 243:22 276:21 290:20 319:8 337:5,15 338:1,4,13 341:3
laboratory's [1] 195:4
Labrador [3] 182:15 345:8,11
Labrador-Grenfell [1] 1:16
labs [2] 287:11 338:22
Lacey [1] 12:6
lack [2] 311:3,17
lacking [2] 325:3 338:15
lagging [1] 338:21
laid [1] 44:23
Laing [1] 1:9
language [1] 91:22
large [14] 34:23 35:1 49:9 49:12 50:1 124:19 161:12 161:12,15 165:12 167:2 194:4,14 196:15
larger [5] 34:5,7 36:8 161:13 194:10
largest [1] 289:15
Larry [1] 15:16
last [19] 85:24 92:8 95:9 117:5 134:3 151:4 152:11 159:23,25 161:4,14 174:2 175:6 177:13 180:20 248:12 255:7 291:9 338:10
lastly [2] 159:22 192:13
late [9] 62:18 81:6 87:20 99:6 126:15 127:19

144:24 237:24 273:4
latest [2] 320:4,6
Lawrence [1] 12:6
lead [2] 62:19 286:14
leadership [2] 197:13 197:15
leaped [1] 92:20
learn [5] 24:2 26:20 98:13 125:18 256:23
learned [6] 23:15 58:1 99:10 131:9 257:17 272:3
learning [2] 252:7 258:1
least [22] 22:1 91:5 114:8 114:20 123:8 141:12 153:21 154:24 166:19 167:6 171:7 220:22 232:22 247:14 251:12 257:3 283:21 297:2 309:1 313:11 326:14 329:19
leave [19] 7:9 8:22 11:24 12:3 45:22 76:8 84:4 210:8,9,12 211:1,4,4,5,9 237:15 276:17 313:17 344:7
lecture [1] 21:15
led [1] 108:16
left [25] 21:12,19 32:12 35:2,16 36:10 50:8 80:20 109:15,20,24 114:20 142:24 153:19 155:16 173:10 205:2 210:17,23 227:14,15 231:17 274:6 288:11 298:17
legislation [1] 337:23
length [3] 87:23 88:16 168:6
lens [1] 73:7
lent [1] 166:8
lesion [1] 51:19
lesions [2] 51:20 134:1
less [12] 20:16 51:21 62:22 67:21 73:12,14 79:5 135:12,18,25 136:4 145:9
letter [11] 123:12 130:2 156:16 209:4,11 228:8 243:17 255:3,25 267:12 267:12
level [6] 88:13 91:3,17 91:18 177:18 257:9
levels [4] 8:19 19:2 50:19 244:18
Lewis [1] 15:4
liaise [2] 17:7,11
liaison [1] 218:21
licensed [2] 337:20,24
life [1] 18:13
ligand [1] 48:12
liked [1] 198:22
likely [2] 67:21 89:6
limit [1] 88:11
limitations [1] 198:6
limited [12] 24:21 75:12 75:13 80:22 93:5 103:25 121:7 139:5,18 193:17 223:25 244:16
limits [1] 170:4
line [3] 104:4 249:17 314:12
lines [1] 192:19
linkages [2] 177:4,6
list [8] 3:2 101:19 117:6 117:11,12 168:25 183:14 255:11
listed [13] 70:10 89:8 95:14 127:3 167:25 177:4 207:13,15 212:4 224:13 268:11 301:2 302:9
listing [2] 207:4 208:21
lists [5] 85:24 89:7 117:7 207:6 244:3
literature [4] 93:5 160:16 256:21 267:18
loafed [1] 34:19
loafing [4] 35:5,8 36:17 160:15
lobular [4] 89:8 90:3 163:3,4
localization [3] 51:18 159:7 160:10
locally [2] 169:4 181:8
locate [2] 122:12,15
located [2] 14:23 203:17
locating [1] 122:7
location [2] 246:22 319:4
locum [5] 6:18,19,21 7:4 12:7
locums [1] 56:24
logic [1] 106:9
look [30] 18:23 26:22 39:1,2 54:18 60:11 69:23 73:5 77:7 84:18 86:19 129:5 134:3 144:11 151:18 152:22 154:1 156:11 174:1 177:5 225:9 243:16 246:8 262:24 269:16 282:12 286:3 297:14 308:13 323:1
looked [32] 107:16 112:23 117:1,2 129:4 145:1 147:14,17 151:23 152:10 156:21 157:10 173:17 228:8 248:13 255:4 256:9,21 267:11 278:3,13 281:8,16 286:4 287:15,18 296:2 307:7,8 322:6 338:11 342:7
looking [43] 19:7 61:16 72:1 81:21 88:24 89:19 92:17,19 93:19 94:25 102:21 106:9 107:21 108:10 114:4,11 115:9 145:11 152:16 180:21 195:12,19 238:20 251:19 255:22 259:13 263:10 265:15 274:16 276:8 280:23 283:2,3 292:20 294:12,13 295:7 303:2 312:18 318:23 330:3 338:10 341:22
looks [2] 29:24 256:23
low [2] 73:1 184:13
lunch [3] 19:1 20:14 199:7
luncheon [1] 199:5
lymph [3] 38:15,17 96:14
lymphoid [2] 95:24 96:12
lymphoma [6] 95:25 96:14 245:17 305:6 315:24 324:8

-M-

MAC [2] 210:7,13
machine [11] 34:15 101:12,13 103:5,7 105:16 109:4,4,5 195:6,15
machinery [1] 109:8
machines [1] 108:21
Madam [3] 2:7 192:21 193:9
magnification [2] 73:8 73:10
mail [2] 60:17 277:7
mailed [3] 66:2 276:22 277:2
maintain [1] 69:18
maintained [1] 250:11
maintenance [2] 26:1 42:18
Majesty [1] 1:8
major [2] 333:5,7
majority [3] 250:24 251:23 254:8
makes [3] 38:15 67:9 332:20
male [2] 120:24 191:23
malignancies [1] 26:25
malignancy [5] 25:18 26:25 27:2 49:14 52:3
malignant [4] 70:6 73:25 74:2 184:10
mammary [1] 255:8
mammography [2] 159:13,22
managed [2] 122:12,14
management [8] 49:18 54:6 126:3 168:17 290:11 313:8 319:8 337:5
manager [20] 217:7,7,9 217:11,13,24 218:9,21 218:25 219:10 222:22 223:1 261:13 295:24,25 301:8 324:25 341:16,20 343:8
managers [6] 282:14 302:9 303:11 306:12 322:25 327:3
managers' [1] 248:3
mandate [2] 138:9 180:15
mandates [2] 26:2 45:17
mandatory [1] 145:9
manpower [4] 287:4,12 292:2 327:23
manual [9] 44:23 45:2,8 46:7,9 116:16 167:8,22 168:2
March [18] 60:16 134:3 134:18 135:17 202:24 209:20 264:10 275:7,13 275:15,16 277:1 282:15 290:23,24 337:6 338:12 338:14
Margaret [1] 345:6
mark [2] 1:14 316:1
MARKED [1] 58:13
marker [1] 245:17
markers [2] 95:24 96:12
Mary [3] 296:6 315:12 315:15
mastectomy [3] 25:16 38:3 49:5
Master [1] 5:11
matched [1] 72:19
material [13] 51:25 69:22 105:20 107:15 108:10 115:10 126:17,21 137:8 140:15 159:4 265:11 333:18
materials [1] 265:16
matter [21] 44:20 56:6 92:25 99:1 101:5 106:22 108:15 114:18 133:16 144:3 146:9 155:15 169:16 172:11,23 180:16 195:5 240:10 265:13 310:1 345:3
matters [2] 13:19 16:11
Maurice [1] 10:9
maximum [1] 160:13
may [47] 7:10 8:8 17:18 86:25 87:22 88:2 98:19 100:19 106:21 124:13 129:14 131:20 134:2,18 159:17 171:25 172:5,8 174:16 175:17,25 176:6 184:17 188:25 191:12 193:3 194:25 204:16,18 204:20 209:14 227:16,19 248:3,16 249:2,18 259:25 272:25 273:1 277:22 286:8 291:23 317:15,17 322:16 337:21
May/June [1] 227:15
Mayo [1] 250:5
MBBS [1] 200:2
McGrath [1] 120:21
McIntosh [1] 291:17
mean [14] 91:9 114:6 122:10 146:17 155:4 165:5 167:15 178:6 196:6 197:2 274:25 292:22,23 330:13
meaning [2] 91:18 223:22
means [4] 32:21 294:24 324:7 345:10
meant [3] 54:3 56:11 94:21
meantime [6] 127:12 133:21 240:16 250:10 324:15 327:7
measures [2] 24:16 166:12
meat [2] 40:1,12
medical [37] 1:14 5:8,12 13:1,3,11,12,18,19 14:18 15:9,13,24 16:8,11 21:12 21:16 26:4 67:9,23 93:5 192:2 210:2 214:8,10,14 215:5,12 216:3 217:13 218:2,7,10,10 223:1 234:23 262:6
Medicals [1] 174:16
medicine [12] 22:15 23:14 129:7 142:2 200:2 209:7 210:10 212:10 214:15 216:4 235:3 290:21
Meditech [5] 18:16,17 115:12 116:14 119:13
meet [6] 21:14 199:6 229:23 234:4 343:19 344:3
meeting [62] 210:6 212:3 212:7,13 223:7 229:2,25 230:3 231:13,13 234:6 235:1 242:19,21,23,24 243:5 247:9 248:2,3,8 248:11 250:8,9,17 251:17 251:18 255:7,22 261:14 262:13 272:1 282:14 297:13,16,17 300:25 302:8,12 303:10,11 306:11,15 307:11,15 312:19 316:10 319:11,13 319:13,18 322:24 323:13 323:14,21 324:1 325:1,7 331:1,2,9 335:19
meetings [13] 20:5,23 22:13 23:23 84:25 170:25 231:21,23 248:15 255:18 287:16 300:22 328:20
Members [1] 1:12
membrane [2] 61:16 267:25
membraneous [1] 270:9
memo [48] 60:4 74:5 84:5 84:19 85:8 86:25 90:10 92:9,12,15,24 93:13,13 93:16,17 97:8 99:17,25 101:16 106:20 107:21 109:23 114:7,7 127:2,7 133:22 136:2 138:23 143:24 144:24 145:10,16 145:23 146:2 264:4,22 268:7 272:3 275:5 287:25 310:11,12,14 311:6,12 311:24 312:22
memorandum [2] 58:19 85:19
Memorial [5] 7:8 9:11 12:17 182:18 203:23
memory [4] 83:17 235:24 275:22 283:4
memos [3] 86:18 99:6 287:16

menstrual [1] 88:16
mention [1] 284:11
mentioned [11] 46:7 55:21 82:8 191:11 206:18 223:7 234:2 261:25 262:16 289:12 308:9
merger [1] 287:10
mesothelioma [1] 303:5
messages [2] 18:17,19
method [7] 48:2,19 52:25 57:6 104:6 242:16 244:16
methodology [1] 258:6
microbiology [3] 219:6 337:18 339:2
microns [2] 40:4,15
microscope [3] 41:22 72:25 73:9
microscopic [2] 18:24 19:7
microtome [1] 39:25
microtone [1] 40:10
mid [6] 35:12 211:10 228:9 244:24 245:1 286:5
mid-90's [1] 245:3
mid-February [1] 264:23
middle [6] 38:20 98:10 114:7 159:4 210:25 276:18
might [49] 20:6,7 37:16 51:20 62:14,14,21,22 63:9 65:18 71:17,21 72:3 75:19 80:16 92:20 94:7 94:13,20 95:7 97:10,11 97:14 100:4 109:7,7 115:13 117:5 131:6 145:1 154:15 155:19 184:14 190:19 252:12,18 258:2 259:23 262:19 295:13 311:17 317:15 322:2,6,9 322:13,14 339:21,21
mightn't [1] 198:12
millimetres [1] 160:19
mind [7] 79:9 92:1 128:24 144:23 149:2 169:14 180:14
mine [1] 21:22
minimize [1] 160:12
minute [1] 327:12
minute's [1] 20:17
minutes [34] 100:13 159:25 160:11 210:3,6 212:3 248:1,7,13 249:17 251:16,20 254:7 255:4 261:13 282:13,19 287:16 297:16,16 302:8 306:11 306:15 307:8 312:18 319:8,12 322:24 323:2 331:13 337:5,11 338:10 342:6
misinterpreted [1] 138:23
miss [1] 126:23
missed [6] 117:6 120:7 120:12,22 185:11,14
missing [3] 148:14,17 244:2
MOCOMP [1] 26:1
model [1] 169:23
moderate [1] 309:9
moderately [2] 54:3 56:12
molten [1] 39:20
moment [4] 29:13 167:1 180:11 226:25
momentarily [1] 269:2
Monday [7] 38:13 79:12 79:12 81:13 343:21,23 344:4
money [1] 300:13
monitor [1] 184:17
monitored [1] 66:10
monitoring [3] 183:25 184:1,7
month [13] 79:5 84:11 95:1,2,7,9 96:23 97:2 175:7 234:4 248:15 335:12,13
monthly [2] 229:25 248:17
months [22] 118:14 122:25 166:4,4,9 205:6 205:10 206:4 230:2 248:8 248:11 279:5 286:16,16 290:25 292:11 307:9 317:24,25 326:16,17,19
morbidity [1] 21:4
morning [15] 18:15 33:24 38:11,12 39:18 41:5,7 100:9 182:17 185:3 193:12 335:19 343:21,23 344:4
mornings [1] 25:9
mortality [1] 21:4
Moss [2] 345:2,13
most [13] 9:24 44:11 88:24 104:7 154:19 155:5 159:8 180:20 208:1 210:7 240:23 305:6 311:7
mostly [1] 69:15
mould [2] 39:20,23
Mount [12] 125:25 129:12,15 130:12 132:16 134:7 154:2 162:1,5,9 164:5 187:6
mouse [2] 59:22 206:25
move [3] 13:5 100:8 284:25
moved [18] 5:16 200:14 202:3,21 203:3 206:9 236:22 237:1,3 240:17 289:13,20,21 290:5,6,10 298:25 338:9
moves [1] 145:6
moving [1] 293:6
Ms [41] 151:17,20 154:25 181:24,25 182:9,11,12 182:25 183:5,10,18,23 184:5,12,21,25 185:1,2 185:16,21,25 186:5,9,13 186:22 187:3,9,16,21 188:1,9,15 189:1,13,21 190:1,6,13,17,23
Mullen [3] 129:22 130:2 163:20
multi [2] 233:16 256:10
multiple [1] 8:3
Murphy [3] 248:6 302:17 306:15
must [2] 46:10 260:16

-N-

N [1] 316:1
name [15] 4:9,12,18,19 29:19,22 32:5 39:25 40:6 40:17 83:7 101:21 185:3 199:16 308:8
narrative [1] 134:5
narrowed [1] 224:17
national [2] 29:13,23
naturally [1] 23:18
nature [10] 13:2 57:2 125:8 183:20 189:11 198:14 220:13 295:1,3 307:19
near [2] 143:1 163:4
necessarily [6] 84:7 208:20 275:15 288:23 321:13,22
necessary [2] 166:16,18
necrosis [1] 42:2
need [8] 161:13 165:17 169:9 170:14 206:23 250:1 306:24 314:24
needed [6] 103:8 242:24 293:5,7 295:8 303:6
needle [5] 51:17,18 159:7 160:8,10
negative [24] 24:22 53:19 70:4 73:5,23 88:10 90:2,5 103:12 106:6,17 106:17 134:1,20 158:9 250:4 252:3,9 256:12 257:22 270:15,25 309:10 309:12
negatives [12] 103:22 104:7 135:5,11 138:16 138:19,25 139:5,8,10,18 258:2
Neil [2] 165:19,21
neoplasms [1] 184:10
neoplastic [3] 60:16 61:1 266:22
nephrology [1] 235:1
neutral [1] 88:5
never [7] 23:3 104:25 113:22,24 114:1 194:2 259:23
new [34] 29:18,18 30:5 30:11 31:16 32:9,11 43:22 70:20 104:1,4 195:15 212:9 213:1,9 225:6 243:11 248:22 252:12 261:14 283:12 292:15 293:2,2,5,6,7 310:2 312:25 313:3 323:19 333:3 335:21 337:13
Newbury [14] 1:15 2:4 182:9,11,12,14,25 183:5 183:10,18,23 184:5,12 184:21
Newfoundland [18] 6:24 58:21 124:5 170:24 171:25 177:8,17 179:5 182:15 187:23 191:12 192:25 203:24 239:17 264:6 337:24 345:8,11
news [2] 172:16 173:7
next [21] 4:4 19:12 36:21 37:6 68:12 81:8,12 83:17 86:8,19 95:23 114:22 122:25 199:11 223:18 230:6 302:6 303:11 319:13 324:1 338:3
night [4] 18:21 151:4 152:11 174:3
nine [3] 84:11 144:7 230:3
nipple [1] 38:4
NL [3] 1:8,14,15
NLCHI [1] 186:20
nobody [1] 196:8
nodes [4] 38:15,15,17 96:14
non [1] 233:22
non-pathologist [1] 20:11
non-usage [1] 128:15
nor [2] 138:10 162:1
normal [8] 24:23,25 25:15 88:12,14 161:20 163:4 259:8
normally [3] 23:14 37:5 99:17
Northern [1] 5:10
note [11] 41:13 85:22 129:9 194:10 243:25 248:14 249:17 254:7,8 307:1 315:25
noted [5] 60:21 66:3 249:16 276:23 282:15
notes [4] 248:7 254:7 261:15 291:9
nothing [2] 155:25 191:4
notice [1] 274:3
noticed [2] 208:3 241:15
notified [6] 121:21 137:11 185:9 186:14,24 187:2
notify [1] 137:15
notifying [1] 138:2
Nova [2] 201:25 338:24
November [9] 3:1 7:6 141:7 143:1 153:19 155:16 191:14 211:22 212:21
now [126] 8:13 9:10 15:7 16:5,19 21:11 26:2,10 27:8,9 29:20,24 31:7 44:17,19 45:22 46:24 49:1 57:22 58:18,24 60:25 63:16 64:18 68:16 70:12 71:7 76:12 87:4 87:22 88:24 91:24 92:1 92:5 100:8 103:11 104:3 112:21 116:9 127:1 135:10 137:6 141:10 143:18 146:20 152:15 156:6 161:22 162:9,19 162:20 164:12 166:16 169:8 171:24 176:5,20 179:22 185:5,8 187:4 188:17 192:19 194:17 196:12 197:17 208:7,9 225:1,13 227:20 231:21 237:15 238:7 243:16 244:7 250:11,12 251:1 252:4,23 253:13 258:14 259:13 260:9,25 261:12 262:10 263:22 266:22 272:24 273:21 274:16,16 283:1,2,3 285:3 287:14 288:15 289:8 292:8,21 294:10 299:17 302:6 303:8 304:10,19 306:10 307:3,7,8,12 309:6 313:2 313:20 318:21 325:15 326:13 328:10 331:24 333:20 334:17 338:9,12
nuclear [4] 61:13 70:5 73:19 88:14
nuclei [21] 60:15,25 61:3 61:11 65:18 73:3,4,5,5 73:18,21,22,25 74:1,2 266:21,25 267:6,20 309:7 319:3
nucleus [3] 270:4 318:25 318:25
number [51] 24:23 25:14 70:6,10 72:18 73:24 74:11 76:10 77:17 78:4 78:8,9 90:6 92:24,25 101:18 103:12 104:24 108:22 118:19 128:12 153:14 158:17 162:3 166:4 167:24 168:6,23 184:9,14 207:7 212:4 224:6,7 234:4 239:1 244:17 252:1 254:22 268:11 292:15,25 301:2 301:9 312:2 319:9 323:24 335:15 337:6,9 343:19
numbered [4] 39:24 40:6,16 144:7
nurses [1] 45:19

-O-

o [1] 247:14
observation [2] 148:24 281:25
observations [6] 41:13 127:19,20 147:19 149:12 158:4
obtain [2] 26:3 73:1
obtained [4] 5:8,11,14 310:7
obvious [3] 38:16 49:8 107:4

obviously [10] 10:3 61:5 67:19 108:24 122:11 124:6 145:4 163:2 187:17 196:6
occasion [1] 96:11
occasionally [4] 32:22 111:1 143:15 281:10
occasioned [1] 301:25
occassion [1] 61:18
occupying [2] 288:7 313:3
occur [15] 20:12,14,15 41:19,21 67:18 80:6 137:17,18,21 154:14 193:22 195:21 241:13 250:13
occurred [14] 22:19 30:3 35:5,8 43:22 80:8 81:5 104:7 120:11 125:1 126:10 134:15 173:15 174:14
October [12] 156:15,16 156:19 202:12 203:2 210:6,25 211:10,16,21 211:22 261:14
off [11] 27:2 37:22 39:22 41:7 53:5 71:11,21 122:18,20,24 263:24
offer [3] 147:3 197:12,15
offered [4] 200:12 202:9 202:14,18
offers [2] 60:22 179:22
offhand [1] 27:22
office [8] 19:17,18 20:16 41:2,4 165:8 290:8 313:10
officer [3] 5:14 338:5 341:4
offices [4] 27:8 312:24 312:25 313:3
official [1] 296:19
officially [1] 166:13
officials [1] 340:6
often [6] 9:21 20:18 61:24 67:14 229:21 272:22
old [1] 276:9
on-call [1] 323:8
once [8] 36:13 96:20,23 97:2 197:17 248:15 325:20 336:10
oncologist [4] 56:5 71:21 283:10,10
oncologists [13] 67:12 68:8,13,20,23 75:15,20 76:9,21,25 283:17,21 284:11
oncology [2] 56:22 68:11
one [122] 7:22 10:4,16,17 16:15 19:11 21:10 26:3 30:11,11 31:1 32:23 46:12 48:23 49:1 51:20 52:4 58:16 62:14,21,21 63:8 65:4 71:19 73:3 74:24 78:20 79:5 85:13 85:14 87:1,13,22 90:4 90:11 92:23 95:2,8 107:2 109:5 111:16 120:19,20 121:12 122:1 128:12 145:11,17,23 152:9,10 158:10 159:8 160:17 161:13 164:20 168:24 169:22 170:6,12 173:18 175:24,24 176:1,3,5 182:8 188:16 193:11,19 193:23 196:12,13,13 207:1 219:24,25 223:18 223:25 224:2 226:13,17 226:17 230:6 234:10 235:5,11 236:14 237:10 246:22 250:12 254:19,20 255:17 256:11,12 261:15 264:9 269:17 270:11 272:17 274:4 276:13 280:22 288:10 292:5,7,8 298:10,15 308:2,3 311:23 313:18 335:12,19 336:6 337:12 341:17,23 342:12 343:6
ones [4] 132:3 148:17 165:13 249:23
ongoing [2] 29:21 307:12
online [1] 116:15
Ontario [9] 166:20,21 178:20 179:24 180:1 337:16,21 338:23 340:1
onto [3] 40:8,18 73:15
onward [5] 98:2 135:17 136:3 211:4,11
open [2] 167:4 198:16
opened [3] 33:16 34:7 81:2
operated [1] 78:24
operating [7] 20:16 33:7 166:17,22 196:20 240:24 240:25
opinion [7] 75:14,19 234:9 250:19 296:3 336:8 336:21
opinions [2] 67:22 327:5
opportunity [2] 174:1 192:23
opposed [2] 45:6 270:25
opposition [1] 177:18
optimal [2] 88:5 144:3
optimistic [1] 197:14
order [18] 18:9 19:2 61:23,24 62:13,14,15,21 62:22 63:9,10 76:13 96:20 110:12 154:20 212:7,7 303:7
ordered [6] 17:18 62:2,5 96:19 253:22 279:14
ordering [5] 41:18 83:23 96:22 144:8 252:24
orders [1] 243:24
organ [2] 324:7,9
organization [8] 7:16 29:23 118:24 138:1 178:19 179:21 324:16 328:22
organizations [1] 207:20
organize [1] 234:6
organized [4] 119:3 233:18 247:4 335:12
organizing [2] 118:25 119:2
organs [1] 34:9
orient [2] 293:5,7
oriented [1] 215:25
original [4] 12:23 147:24 148:25 176:12
originally [3] 25:1 57:12 224:8
originated [1] 158:16
originating [1] 78:16
otherwise [1] 70:14
Ottawa [5] 202:9 205:7 205:10 206:4,19
ourself [1] 256:23
ourselves [7] 26:21 80:19,19 154:20 256:25 275:10 279:10
outcome [2] 303:12,18
outline [2] 164:15 199:23
outside [14] 59:14,15 107:17,19 141:12 165:17 169:9 179:12 181:3 191:17 196:14 197:22 269:1 318:9
overall [9] 59:24 101:6 150:11 153:4 177:5 197:13 225:12 294:13 338:1
overburdened [3] 132:25 188:16,21
overnight [4] 33:22 35:2 35:17 36:10
overstate [1] 97:11
overview [3] 5:5 177:1 199:24
own [27] 46:17 59:17 60:14 105:5 113:8 155:21 158:6,21 164:25 169:25 171:9 183:25 216:10 251:25 253:8,8 264:13 266:20 273:11,17 275:14 275:18 276:7 277:15 285:14 318:16 332:9

-P-

P [2] 167:1 291:19
P-0021 [1] 210:1
P-0046 [1] 156:14
P-0047 [1] 152:9
P-0048 [1] 152:9
P-0076 [1] 143:17
P-0113 [2] 85:18 86:24
P-0492 [1] 101:16
P-0590 [1] 127:1
P-1850 [2] 58:18 264:4
P-1856 [1] 248:1
P-1857 [1] 251:16
P-1859 [1] 261:12
P-1862 [1] 282:13
P-1867 [1] 290:19
P-1868 [2] 209:3 286:3
P-1874 [2] 297:9 302:6
P-1876 [1] 306:10
P-1877 [1] 322:23
P-1890 [1] 337:4
P-2112 [1] 212:1
P-2157 [2] 167:19 177:5
P-2360 [5] 3:3 58:9,13 105:25 118:18
P-2395 [2] 3:4 243:17
P-2397 [1] 255:2
P-2398 [1] 3:4
P-2399 [1] 297:11
P-2400 [1] 319:7
P-2408 [1] 3:4
P-2426 [1] 3:4
P-2428 [1] 3:4
P-2439 [1] 3:5
P-3260 [1] 118:18
P-A-R-A-I [1] 199:18
P-A-T-R-I-C-K [1] 4:13
p.m [1] 35:10
P1600 [1] 206:22
P2396 [1] 3:4
packaged [3] 122:17,20 122:24
page [44] 3:1 60:11 69:23 85:2 86:24 93:19 99:16 118:19 129:6,6 133:25 134:4 142:1 156:17,18 163:19 168:1,16 207:4 210:5 248:12,21 251:17 251:19,20 263:11 265:4 266:18 268:6 271:13,14 273:23 274:3 276:18 282:17,18 291:5,10 297:15,18 310:2 312:21 313:18 337:13
pages [3] 87:8 169:2 343:19
Pam [1] 185:3
Pamela [3] 1:12 2:5 185:1
panel [3] 126:11 140:20 303:7
paper [6] 34:21 71:3 76:5 220:22 225:22 271:22
par [2] 338:22,24
paraffin [3] 49:20,20 241:8
paragraph [28] 84:19 89:4 91:1 251:21 261:15 265:5 268:5 271:13 276:19 291:9 297:17,20 300:17 302:17 306:18 312:21,22 313:17,18 323:4,20 330:4 332:2 333:15 334:13 335:5,23 337:13
paragraphs [3] 144:7 311:23 334:20
Parai [453] 2:8 199:11 199:12,17,18 200:1,11 200:23 201:2,6,12,18,22 202:2 203:7,11,18,22 204:6,11,15,19,23 205:5 205:11,16,20 206:1,6,11 206:15 207:22 208:2,11 208:15 209:16,22 210:9 210:14,19,24 211:6,12 211:18,23 212:11,15,20 212:25 213:6,11,16,22 214:2,13,18,23 215:11 215:17,22 216:11,16,21 217:6,12,18 218:1,6,12 218:19 219:2,13,23 220:6 220:15,19,24 221:5,12 221:23 222:7,13,17,24 223:5,12,20 224:3,10,14 224:19,23 225:4,24 226:4 226:10,14,19 227:2,6,10 227:18 228:4,15,22,24 229:7,12,17,24 230:7,12 230:18,24 231:4,8,12,18 231:24 232:8,15 233:3 233:12 234:1,14,18,22 235:8,12,17 236:5,16,20 237:7,12,18,25 238:6,13 238:17,25 239:4,8,12,25 240:5,11,19 241:10,14 241:21 242:3,10,18 244:10,15,21,25 245:4,8 245:12,25 246:10,14,24 247:3,8,18,22,24 248:18 249:6,13 250:16,23 251:3 251:9,13 252:6,15,20 253:1,5,10,15,19 254:1 254:12,24 256:2,8,20 257:7,13,19 258:3,10,16 258:23 259:4,10,15 260:2 260:13,22 261:7,21 262:14 263:1,7,16 264:14 264:18 265:1,17,21 266:6 266:10,15 267:2,7,15,21 268:1,17,22 269:7,11,15 269:20,24 270:3,7,13,18 270:22 271:6,10,19,25 272:7,13,21 273:8,14,18 274:13,18,24 275:4,19 275:23 276:3,10,14 277:10,19 278:5,9,15,21 279:1,18,24 280:4,9,14 280:21 281:3,9,17,22 282:4 283:8,18,25 284:5 284:9,17,23 285:9,15,20 285:25 286:9,17,19 287:1 287:8,24 288:9,14,25 289:4,10 290:2,15 291:12 291:21 292:17 293:3,16 293:20 294:5,18,23 295:5 295:18 296:7,18,23 297:6 298:3,9 299:8,13,23 300:2,7,14 301:6,18,22 302:2,13,25 303:14,21 304:6,13,16,21,25 305:5 305:13,18,25 306:7,14 306:16,25 307:22 308:1 308:6,21 309:3,21 310:7 310:8,10,15,19,25 311:5 311:13,19 312:9,14,24 313:13,25 314:4,9 315:6 315:10,16,21 316:7,13 316:20 317:9,14,19 318:3 318:18,24 319:15,25 320:10,15,20 321:1,5,15

321:19,24 322:3,10,15 322:20 323:12 324:6,21 325:8,12,17,22 326:2,6 326:12,25 327:19 328:2 328:8,15,19 329:3,7,21 329:25 330:11,22 331:3 331:8,15,19,25 332:10 332:15 333:2,12,22 334:3 334:9,22 335:2,7,11 336:5,17,25 338:6,18 339:4,11,18,23 340:4,10 340:17,21,25 341:6,10 341:15,24 342:3,8,13,18 342:24 343:3,24
parallel [1] 84:23
parentheses [1] 268:11
parenthesis [1] 70:11
part [15] 18:4 21:24 27:3 27:15 30:6,16,21 31:11 138:9 178:7 196:15 208:9 213:5 324:19 327:13
partial [3] 232:18 330:4 330:10
partially [1] 330:13
participate [3] 178:10 191:18 192:23
participated [1] 174:19
participating [1] 320:14
particular [49] 17:17,19 22:18 52:15 58:8 65:7 79:14 82:11,13,16 84:5 87:22 105:24 139:25 168:20 172:25 190:18 208:25 213:20 219:25 222:6 257:12 273:23,25 287:17,19 294:6 295:8 295:14,15 296:11 297:3 300:25 303:4 314:15 315:23,25 316:5 319:4 319:11,18 322:8 324:25 325:7 327:17 331:13 335:18 337:12 343:18
particularly [5] 26:16 44:19 158:11 161:1 196:21
parts [2] 20:6 59:24
PAS [1] 62:4
pass [3] 117:20 128:2 314:12
passed [2] 279:14 329:17
past [3] 132:6,7 167:7
Pat [1] 227:3
pathological [3] 7:16 234:8 235:2
pathologist [86] 6:23 7:7 8:14 9:15 10:4,5 11:3,6 11:21,24 16:10 24:18 25:1 27:1,2,4,5 37:16 47:2 60:13 71:9 107:17 138:8 141:11,12,13 143:20 171:10 172:13 196:19 201:13 202:4 203:2,12,15 207:6 214:11 233:23 240:25 250:18 255:14 258:21 266:14,19 268:13 272:25 273:1,11 276:7 285:12 290:8 293:11 294:9 296:10,11 296:12 297:13,21,24 298:7,12,21,23 299:3,14 300:22,25 301:12 302:23 303:2 304:10 306:24 308:7,9 313:20 314:16 314:16 316:25 323:21 327:21 334:5 336:7,11 336:13 340:1,5
pathologists [105] 7:23 9:2,22,25 10:3 16:22 23:22 25:5 27:20 28:20 28:24 29:3 43:16 44:4 44:24 58:21 59:7,14 85:20 124:5 129:11 144:1 165:7 170:25 177:9,17 197:11,22 207:5,7 216:7 216:22,23,24 217:2 219:17,18,25 225:8,14 232:3,16,24 233:14 234:25 235:19 236:3,12 236:25 237:3 240:9 247:16,23 249:22,25 250:9,14 251:7,23 252:24 254:10,14 255:21 261:5 264:6,11 272:4,19 275:6 275:17 279:4,7 280:23 282:1,22 290:5 292:1,2 292:13 293:14 299:1 301:10 303:16 304:2 308:17 312:23,25 313:2 313:12 314:7 317:3,7 320:8 321:7,10 323:8 326:19 327:3 330:14 333:18,19,24 335:17 336:18,20
pathology [94] 5:18 6:2 6:3,3,20 7:24 11:23 12:12,12 20:17 32:17 44:14 52:1 56:23 57:1,1 64:2 65:3,5 67:10,14 71:2 119:4 132:24 144:1 159:15 160:16 165:8 167:22,24 168:1,5,7,8 168:14,17,18,24 169:1 182:19 200:7,19,20 202:15,20 203:25 209:9 209:13 210:11 212:3 219:5 220:7 221:6,7,17 221:22,22 222:2,5,5,22 223:8,22 224:18 229:4 232:14,25 233:4,6 236:22 237:1 248:2 260:4 273:7 276:9 289:13,15 291:16 291:20,25 298:1 299:6 299:22 320:13,23 323:21 324:2 338:20 339:8,8,22 340:12,15 341:17
patient [17] 54:5 77:8,10 78:9 121:16,21,23 122:1 160:5 185:7,10 191:23 278:1,12 279:15 281:1 281:21
patient's [4] 39:24 40:6 40:16 121:17
patients [25] 52:15 78:15 114:11 117:13,13 120:6 120:12 122:5 126:3,6,16 136:12 137:8 138:2 140:14,22,22 147:21 150:10,13,19 163:2 183:15 184:14 192:2
patients' [1] 115:10
Paton [15] 7:8 9:4,10,11 9:13,14 12:16 14:25 24:12 31:1 33:3 42:18 63:4 147:8 182:18
Patrick [3] 2:2 4:12 5:10
Paul [1] 165:20
pay [1] 158:10
peculiar [1] 198:14
Peggy [2] 296:5 315:15
people [15] 10:17 119:16 119:21 159:12 166:1,21 171:4 174:14 216:20 236:1,8 292:15 293:5 309:1 319:10
per [6] 63:9 71:9 78:18 238:23 239:7 255:7
perceived [2] 154:25 156:1
percent [20] 71:3,20,20 88:5 90:5 135:5,18,20 136:4 148:2,4 150:5,18 215:25 216:2,9,14 237:1 238:8 289:13
percentage [14] 70:7,15 75:3,4 236:22 268:8,16 271:5 272:24 294:24 295:1,2,6 312:3
percentages [2] 53:23 53:25
perforated [1] 39:3
perform [1] 7:19
performance [4] 24:18 321:8 333:16 334:5
performed [7] 48:14 62:24 134:5 237:17 238:23 242:7 244:8
performing [1] 261:23
performs [2] 7:16,23
perhaps [29] 12:10 13:24 19:4 36:15 45:22 46:25 51:12 59:14,21 71:16 73:11 92:7 100:2 152:17 166:3 175:25 176:21 194:17 215:9 238:16 239:16 247:15 248:10 254:19 260:19 263:22 295:2 338:15 343:16
period [14] 16:19 84:12 100:19 127:13 132:12 153:16 166:3 193:14 272:20 288:10 289:23 290:23 291:7 298:17
periodic [1] 179:16
periodically [2] 30:6 69:1
periods [1] 139:25
permanent [3] 209:13 286:6 291:22
person [16] 13:10 32:22 207:12 214:10 217:22 220:7,12 221:24 294:6 296:14,15,19,20 297:3,4 297:4
personal [1] 75:10
personnel [3] 292:23,24 293:8
perspective [26] 23:6 23:22 71:9 104:21 112:4 126:14 143:20 152:18 153:4 158:5 171:7,9 177:23 178:2 179:9 180:25 181:4 196:23 197:4 231:22 263:13 275:3 283:5 294:3 339:7 342:17
Peter [4] 1:9 2:6 14:21 191:7
Pg [2] 3:3,5
Pgs [5] 2:3,4,6,7,9
phase [6] 60:12,12 69:9 268:5 276:18 277:1
phasing [1] 47:17
phone [2] 18:18 283:9
phoned [1] 111:24
phonetic [2] 254:21 260:6
phrase [1] 296:13
phrased [1] 116:18
physically [1] 14:23
physician [4] 51:10 98:9 186:18,19
physicians [10] 6:1 20:7 23:23 55:20 56:13 137:10 137:12 200:16,18 219:20
pick [2] 279:16 317:25
picked [1] 81:6
piece [3] 51:23 193:19 193:23
pieces [1] 39:1
Pike [3] 1:14 191:2,3
PIP [1] 321:8
pitfall [1] 257:23
pitfalls [4] 256:24 257:17 257:18,21
place [15] 24:17 67:16 181:2 184:1,6 243:24 278:2 292:15 293:9,11 323:25 324:4 334:18,20 338:1
placed [5] 34:21 39:4 45:18 46:10 51:19
places [1] 122:11
plan [3] 69:9 190:18 232:4
planned [2] 59:8 125:13
play [1] 178:7
played [1] 282:24
plural [1] 170:8
point [51] 4:23 37:11 58:1 61:2,22 62:17 63:8 66:14 67:24 70:12 82:21 94:24 109:13 118:14 124:22 136:13 155:22 159:17 189:15 190:18 195:11 196:3 205:1 209:8 211:15 219:16 220:7 239:20 245:23 248:11 252:23 254:5 260:9 266:22,23 267:1 268:12 273:3 280:13 296:14,19 297:4 305:22 313:20 314:24 319:22 324:22 325:11 328:3 333:21 337:1
pointed [4] 146:10 152:15 173:18 208:7
pointing [1] 45:12
points [5] 69:20 232:23 271:4 323:23,24
polices [1] 165:11
policies [16] 42:24 44:5 44:11,12,13 46:6,14 167:7,22,24 168:1,19 170:6,12,15 181:1
policy [19] 45:13,16,20 45:23 46:9,14,17,18,20 46:22 69:16 76:4 165:4 166:13 175:13 176:11 177:1 231:25 324:17
poor [2] 158:9,11
poorly [4] 148:1,6,8,9
popular [1] 234:3
portion [2] 65:17 321:6
position [35] 5:14 6:23 7:7 10:22 11:18,19 13:16 166:6 200:13 202:10,12 202:14,16,18,23 203:1,3 203:15 209:20 212:9 213:1,9,14 214:3 215:5 215:18 216:19 223:18 224:4 225:6 228:7 235:9 235:11 286:23 288:8
positions [5] 9:16 292:3 292:12,13,16
positive [53] 53:18,20 60:17,19,22 63:16,18 64:7,18 65:14 66:1,4 70:4 72:17,18 75:1,1,2,4 75:15 89:5,6,14 250:4 252:3,8 256:12 258:21 259:2 270:15,25 271:3 276:21,23 277:3,6,8 278:3,4 279:8 282:23 303:4 306:23 309:5,5,8 309:9 313:19,22 314:8 316:5,12 318:25
positives [2] 138:16 139:13
Positivity [1] 70:4
possibility [1] 297:24
possible [17] 52:17,25 60:18 67:17 94:16 95:18 126:24 140:6 160:15,21 161:20 162:22 163:5 262:22 277:4 303:8 324:2
possibly [3] 97:2 154:15 166:20
post-menopausal [1] 163:2
poster [1] 260:6
potential [12] 76:1 87:24 91:4,25 105:7 115:8 146:11 149:17 173:21 257:18 260:11,20
potentially [3] 104:25 108:15 177:10
power [4] 73:1,7,9,9

powers [1] 73:15
PR [38] 41:18 44:19 74:17 85:25 94:10 95:6 100:22 105:7 106:7,17 111:14 112:9 129:15 134:2 162:10 172:11 239:23 240:14 241:7 242:2,6,16 248:22 251:21 252:13 271:17 280:2,19 304:5 305:3,10 308:16 315:1 318:10,21 321:22 322:7 323:5
Prabhakaran [4] 48:10 50:13 291:13,15
practical [4] 16:5 169:16 290:13 294:1
practice [35] 13:2,18 23:17 48:4 49:2,3 52:1 60:6 63:22 67:12,13 71:10 89:17 90:7 96:19 97:25 110:2 132:6,20 164:12 182:18 183:1 197:7 200:5 211:3 225:16 228:1 231:3 278:24 282:1 288:1 304:17 313:21 314:7 316:8
practices [1] 189:23
practises [1] 232:13
practising [3] 132:5 196:15 285:12
pre-occupied [1] 139:7
precautions [1] 177:1
predates [1] 28:16
predating [1] 29:3
predecessor [3] 21:21 176:20 207:19
prefer [1] 250:19
preferable [1] 91:10
preference [4] 75:10 132:18 190:8,14
prefers [1] 262:1
prejudge [1] 190:4
preliminary [1] 245:16
prepare [6] 19:3 226:13 226:15,17,20 280:2
prepared [4] 41:1 171:10 263:5 281:20
preparing [2] 30:13 169:3
presence [2] 47:12 243:5
present [17] 12:11 38:10 80:17 83:2 132:17 161:21 165:3 203:15 212:5 248:5 251:19 301:2 302:16 306:13 319:10 323:2 337:6
presentation [1] 260:5
presented [2] 261:16 320:5
presently [1] 334:18
preserved [2] 42:1 49:24
President [4] 13:12 15:9 15:13 174:15
pressing [1] 114:17
presumably [2] 106:5 310:8
presume [1] 188:17
pretty [2] 10:16 18:5
previous [9] 19:13 47:15 95:1,7 104:6 139:8 306:15 323:13,14
previously [1] 335:16
primarily [1] 118:23
primary [2] 134:1 137:12
principle [4] 89:15 236:21 269:5,12
Pritchard [2] 181:18,19
Pritchard/Jackie [1] 1:8
Pritchett [3] 1:16 182:3 182:4
problem [32] 67:22 83:25 101:11 103:25 107:5 108:21 109:5 112:6 114:1 122:7,10 128:12 154:22 189:12 197:24 198:3,15,18 219:3 220:12 257:21 258:6,7 262:5 285:10 290:9 298:14,22 309:11 313:1 316:22 323:17
problems [23] 86:6 97:19 101:12 112:3 154:18 157:19 158:23 173:22 174:7 193:22 198:7 285:6 290:13 294:1 295:11,16 306:21 307:6 307:17,20 309:16 311:17 313:9
procedure [4] 164:15 168:4 177:2 257:23
procedures [15] 44:5 165:12 166:17,22 167:7 167:22 168:1,4,7,13,15 168:18,19,20 181:1
proceed [1] 60:9
process [42] 27:6 29:13 29:15,21 30:12,13 33:1 35:5 39:16 42:17 45:14 47:9 60:5 66:9 74:16 81:7,7,18,19 123:3 129:9 133:5,10 142:4 159:24 171:11 192:3,24 197:23 199:4 252:13 256:19 259:3 277:14 284:22 285:7 322:9 324:19 325:5 327:6 329:1 337:2
processed [1] 289:16
processes [2] 39:8 321:12
processing [5] 33:2 39:5 42:11 43:21 129:13
processor [9] 33:22 39:7 39:8 41:8 42:19 43:20 43:22 88:8 105:17
produce [2] 62:12 166:16
produced [3] 62:8,10 253:23
producing [1] 103:6
professional [5] 5:6 48:4 60:6 199:25 204:3
professor [1] 203:24
proficiency [8] 28:2,10 31:21 319:20,24 320:4,9 320:21
progesterone [20] 47:11 48:14 57:3 58:23 75:3 87:25 102:1 103:13 239:22 255:10 264:7 274:8 306:6,22 307:6,18 307:20 309:17 310:4,6
program [49] 5:19 24:19 26:1,2 28:10 29:3 30:25 32:9,11 129:8 142:3 209:7 210:10 232:19,24 232:25 233:5,6,7 284:14 290:21 291:2 321:8 324:11,15,23 326:18 327:2,13,22,22 328:11 329:11 333:16 334:5 337:16,19,21,25 338:2,4 338:14 339:17,24 340:6 340:12,15 341:4,18
programs [2] 319:20,24
progress [1] 56:18
project [1] 194:4
proper [2] 101:20 336:1
properly [2] 65:15 336:11
proponent [1] 299:6
proponents [1] 298:10
proposal [13] 69:12,13 69:17,19,24 265:6,25 266:1,3 268:6 271:14,24 272:2
prostatic [1] 95:20
protocol [2] 273:19 311:7
protocols [5] 42:25 44:5 165:12 181:1 262:7
provide [3] 194:10 252:1 254:21
provides [1] 196:18
providing [4] 197:25 252:5 312:24 342:12
province [10] 59:8 108:24 132:19 170:12 174:15,16 177:11 178:13 264:12 289:16
province-wide [1] 137:22
provinces [3] 67:23 178:14 180:4
provincial [1] 191:15
provisional [1] 26:19
PRs [2] 134:5 138:14
publications [2] 69:21 265:9
publicly [1] 120:4
pulled [2] 135:8 140:3
pulling [2] 135:5,11
purely [1] 13:20
purpose [6] 27:12 177:2 231:21 252:4 310:22,23
purposes [2] 86:2 94:2
pursue [1] 202:7
pursued [3] 177:24 178:1 245:11
pursuing [1] 326:9
Pushpanathan [1] 248:6
put [32] 27:9 33:20,21 34:23,25 35:1 38:14 39:2 39:19,25 40:7,8,10,17 40:18 52:2 72:25 75:5,6 76:2,4 82:1 88:25 161:8 173:24 238:20 272:22,23 312:2 314:14 315:25 332:19

-Q-

Q.C [994] 1:6,7 2:3,9 4:3 4:7,17,22 5:3,21 6:5,9 6:15 7:1,12,18,25 8:7,12 8:17 9:1,7,12,20 10:7,13 10:21 11:1,9,13,17 12:1 12:8 13:4,13,23 14:4,8 14:13,17,22 15:1,6,12 15:17,23 16:4,18 17:4 17:10,15,22 18:2,11 19:15,22 20:1,9,21 21:1 21:6,17,23 22:5,11,20 22:25 23:5,10,20 24:1,6 24:10 25:2,10,20 26:6 27:11,17,23 28:5,11,17 28:21 29:1,8,14 30:2,8 30:15,20,24 31:6,15,19 32:15,24 33:11,25 34:4 34:11 35:3,11,15,20,24 36:7,14,20,25 37:4,10 37:19 38:19 40:20,24 41:6,11,16 42:4,14,22 43:3,9,15,24 44:3,8,16 45:1,5,11,21 46:2,11,16 46:23 47:6,22 48:5,16 48:22 49:19,23 50:5,11 50:17,22 51:2,6,11 52:9 52:14,21 53:4,8,14,21 54:1,7,12,16,23 55:3,11 55:16,22 56:4,9,16 57:4 57:11,19,25 58:5,14 59:3 59:11,20 60:10 61:10,14 61:20 62:7,16,23 63:3,7 63:15,21 64:6,13,17,24 65:6,12,23 66:13,19,24 67:5,25 68:7,15 69:8 70:19,24 71:6,15,25 72:6 72:14 74:3,9,15,20 75:7 75:17,23 76:11,18 77:1 77:5,13,19,23 78:3,7,12 78:19,23 79:4,8,17,23 80:4,21 81:4,11,17 82:3 82:10,18,24 83:3,10,15 83:22 84:2 85:7,12,17 86:16,23 87:12,16,21 88:20 89:3,16,24 90:8 90:14,19,25 91:14,21 92:11,16 93:2,7,11,18 94:5,12,17,22 95:5,13 96:1,6,21 97:1,6,15,24 98:5,12,18,24 99:4,9,14 99:22 100:1,6,17,25 101:4,14,24 102:8,14,19 102:25 103:10,20 104:2 104:13,18 105:3,12,21 107:7,13 108:1,5,14 109:3,12,19 110:5,11,15 110:20,25 111:6,12,17 111:21 112:1,8,12,16,20 113:2,7,12,19,23 114:3 114:19,25 115:6,14,18 115:24 116:4,8 117:10 117:18,24 118:6,15,22 119:6,11,17,22 120:1,10 120:15 121:2,6,11,15,20 121:24 122:4,16 123:1,6 123:14,18,22 124:1,10 124:15,21 125:4,11,17 126:4,13,25 127:6,11,16 127:24 128:6,13,19 129:3 129:20,25 130:6,13,18 130:22 131:3,8,13,17,21 132:4,10 133:3,14,20 134:16,23 135:9,15,24 136:7,11,18,22 137:5,16 137:25 138:6,13,20,24 139:4,11,16,23 140:4,11 140:25 141:9,18,25 142:7 142:12,16,22 143:3,10 143:16,23 144:15,20 145:14,21 146:4,8,19 147:2,6,13,18 148:3,7 148:12,15,23 149:6,11 149:15,23 150:3,9,17,22 151:5,11,16 152:2,8,14 152:21 153:8,15,24 154:7 154:12,23 155:10,23 156:5,13,24 157:3,9,15 157:20 158:3,12 160:2,7 161:17,25 162:8,13,18 162:24 163:10,14,18,23 164:3,10,19,24 165:10 165:18,24 166:25 167:12 167:18 168:12 169:13,20 170:7,17,21 171:1,6,16 171:23 172:4,9,20 173:8 173:16,25 174:6,12,22 175:2,8,12,19,23 176:4 176:9,19,24 177:15,22 178:15,23 179:3,8,15,20 179:25 180:5,10,22 181:7 181:11,15 193:7 199:10 199:13,21 200:9,21,25 201:4,8,16,20,24 203:5 203:9,16,20 204:1,8,13 204:17,21,25 205:9,13 205:18,23 206:3,8,13,17 207:24 208:6,13,17 209:18,24 210:16,21 211:2,8,14,20,25 212:17 212:22 213:3,8,13,18,24 214:5,16,20,25 215:14 215:19 216:8,13,18 217:1 217:10,16,20 218:4,8,14 218:23 219:9,15 220:3 220:11,17,21 221:1,9,20 221:25 222:9,15,19 223:3 223:10,14 224:1,5,12,16 224:21,25 225:21 226:1 226:6,12,16,22 227:4,8 227:12,25 228:6,17 229:9 229:14,19 230:5,9,14,20 231:1,6,10,15,20 232:5 232:10,20 233:9,21 234:12,16,20 235:4,10 235:14,21 236:11,18 237:5,9,14,20 238:2,10 238:15,19 239:2,6,10,14 240:3,8,13 241:5,12,19

241:23 242:5,12 243:8 244:12,19,23 245:2,6,10 245:22 246:2,12,16 247:1 247:6,12,20 248:20 249:8 249:15 250:21,25 251:5 251:11,15 252:10,17,22 253:3,7,12,17,21 254:3 254:18 255:1 256:4,16 257:1,10,15,25 258:8,13 258:18,25 259:6,12,19 260:8,18,24 261:11 262:21 263:3,9,21 264:2 264:16,20 265:3,19,23 266:8,12,17 267:4,9,17 267:23 268:3,19,24 269:9 269:13,18,22 270:1,5,10 270:16,20,24 271:8,12 271:21 272:5,9,15 273:2 273:10,16,20 274:15,20 275:1,11,21,25 276:5,12 276:16 277:12,24 278:7 278:11,17,23 279:11,20 280:1,6,11,16,25 281:5 281:12,19,24 282:11 283:16,20 284:2,7,15,20 285:2,11,17,22 286:2,11 286:21 287:6,13 288:3 288:12,21 289:2,7,24 290:12,17 291:14 292:6 292:19 293:13,18,22 294:16,20,25 295:10 296:4,9,21,25 297:8 298:5 299:4,10,16,25 300:4,9,16 301:14,20,24 302:5,15 303:19 304:4,9 304:18,23 305:2,8,15,20 306:2,9 307:24 308:4,11 308:24 309:13,25 310:13 310:17,21 311:2,9,15 312:5,12,16 313:15 314:2 314:6,22 315:8,13,19 316:2,9,15 317:5,11,16 317:21 318:8,20 319:5 319:17 320:2,12,18,24 321:3,11,17,21 322:1,5 322:12,18,22 323:18 324:18 325:6,10,14,19 325:24 326:4,8,21 327:15 327:25 328:5,13,17,25 329:5,13,23 330:2,17,24 331:5,11,17,21 332:6,12 332:21 333:8,14 334:1,7 334:11,24 335:4,9,22 336:15,22 337:3 338:8 338:25 339:6,15,20 340:2 340:7,14,19,23 341:2,8 341:13,21 342:1,5,10,15 342:21 343:1,9,14,22

QA [4] 31:13 166:11 233:25 329:20

QI [1] 320:3

QMPLS [6] 178:19 179:5,24 337:21 339:16 340:9

quadrants [1] 38:5

qualified [1] 298:19

quality [42] 24:13,16 26:12,13 67:20 129:8 142:4 159:1 164:6 166:8 168:17 189:7 215:23 232:13,18 233:11 235:6 290:22 300:18,19 301:12 302:18,20 306:19 323:20 324:10,14 327:9,13 328:23 329:11 334:13 337:14,15 338:2,5,13 341:4,16,20 343:5,7

quarter [1] 24:24

queried [1] 145:7

questioned [1] 55:25

questions [11] 60:23 76:20 181:16,21 182:1,5 182:9,16 184:22 185:6 190:24

Quick [1] 150:23

quite [21] 23:17 49:2,9 60:9 62:11 65:4 94:11 97:7 132:25 145:10 160:21 166:20 194:2,3 234:3 256:14 257:22 295:20,22,22 296:1

quo [1] 250:11

quoting [1] 332:1

-R-

radiation [1] 283:10

radiology [2] 49:11 159:14

raise [1] 10:8

raised [6] 120:4 177:13 298:6 303:9,23 306:5

raising [1] 177:9

ramifications [1] 105:5

ran [3] 21:12 122:13 295:14

Randell [2] 291:18 337:8

random [1] 38:4

randomly [2] 24:24 25:15

range [5] 64:12,20,23 70:9 268:10

ranging [1] 108:23

rank [1] 203:24

rapidly [1] 107:4

rare [1] 61:18

rarely [2] 96:18,19

rather [1] 75:24

re [3] 67:14 102:1 144:3

re-cut [2] 147:25 148:1

reaction [4] 59:23,24 94:7 171:2

reactive [1] 268:9

read [24] 23:14,19 74:5,5 75:11 86:6 87:18 88:17 91:16 96:4,11,17 144:22 151:3 152:3,24 155:5 156:20 157:17 158:13 178:22 253:24 299:9 305:10

reading [6] 72:12 91:22 93:6 157:22,25 161:22

reads [2] 268:7 323:6

ready [2] 290:8 314:18

realistic [1] 169:25

realize [4] 75:18 198:5,9 198:10

realized [5] 107:6 118:8 120:24 195:3 245:14

really [18] 10:1 23:3 43:23 65:19 98:2,11 146:17 149:24 162:3 170:5,16 173:14 180:19 195:6 196:9 211:16 246:9 288:22

reason [10] 37:15 103:16 135:8 184:16,16 189:2 298:14 317:23 340:8 342:11

reasonable [4] 95:11 188:25 197:3,10

reasons [2] 188:10 254:20

reassured [1] 66:9

receipt [1] 209:11

receive [20] 26:15 49:1,7 49:12 50:13 54:9,13,20 56:10 59:2 84:5 85:3 86:12 87:8 92:12 97:7 102:3 144:12 159:21 262:8

received [29] 18:18 46:21 54:8 58:25 90:10 94:6 104:25 106:20 115:19 127:7 140:7,10 145:22 164:4,15,20 175:13,15 176:1,3,15 194:2 226:11 228:16 235:23 260:25 291:11,25 337:11

receiving [4] 56:11 67:1 93:13 241:1

recent [2] 84:20 208:1

recently [4] 25:7 31:7 161:4 177:9

receptor [16] 1:2 57:3 58:23 70:1 87:25 89:14 144:4 241:17,20,22 250:4 251:21 264:8 274:8,8 345:4

receptors [27] 48:14 53:18 74:25 75:2,4 84:10 87:25 102:2 103:13 117:3 239:22,23 248:23 249:2 249:19,24 250:1,6 255:10 261:17 274:2 306:22 307:7,18,21 309:17 310:6

rechecking [1] 25:19

recollection [6] 47:14 47:19 127:23 275:14 306:4 307:16

recommendation [1] 260:14

recommendations [5] 158:25 165:5 192:16 234:10 343:6

recommended [2] 160:19 261:22

record [6] 74:11 173:4 263:24 316:3,6,17

recorded [5] 74:12 163:9 163:13 315:14,20

recounts [1] 204:2

recruit [1] 298:12

recruiting [1] 297:24

rectified [1] 87:2

Red [3] 203:3,6,8

redacted [1] 210:7

reduced [5] 164:13,13 214:4,4 224:4

reductions [1] 115:2

refer [7] 9:13 77:6 89:4 129:14 209:25 271:18 323:5

reference [21] 91:1 111:2 139:24 140:5 158:8 158:13 210:8 248:22 250:5 304:10 310:2 312:20 313:16 319:19 331:6,13 332:17,23 333:16 335:5 341:3

referenced [2] 77:8 167:16

references [3] 151:24 153:1 329:15

referred [10] 63:17 64:18 91:24 134:7 167:10 177:8 273:22 274:12 296:13 312:23

referring [3] 4:24 142:1 255:13

refers [2] 104:3 271:14

refined [1] 49:11

refrigerate [1] 161:14

refrigeration [1] 161:5

refrigerator [2] 161:6 161:11

regard [12] 10:23 22:2 90:15 91:11 105:25 158:20 172:21 180:7 183:6 198:12 278:25 282:25

regarded [1] 250:3

regarding [5] 46:7,9 101:11 126:2 271:17

regards [3] 197:14 255:23 338:1

region [2] 33:8 166:15

Regional [11] 1:10,17 5:15 6:24 9:10,11 12:18 12:22 15:10 201:14 203:4

registering [1] 182:19

Registrar [8] 4:8,15 199:14,19 243:16 247:25 264:3 290:19

Registry [6] 182:20,24 183:14,20,24 184:4

regrets [2] 319:10 337:9

regular [5] 61:8 87:4 184:17 233:16 242:21

regularly [4] 20:22 81:12 88:6 337:2

relate [4] 78:8 232:22 331:24 336:4

related [6] 87:3 105:16 109:7,23 151:7 219:6

relation [13] 41:17 81:22 82:11 148:16 155:1 158:15 159:5 175:9 242:2 295:12 307:3 332:22,25

relationship [9] 16:20 68:14 196:19 197:10 198:16,17 225:16,17,23

relatively [4] 10:6 103:25 167:6 184:13

relayed [1] 232:2

released [1] 110:4

relevance [1] 168:21

reliability [1] 86:4

reliable [1] 295:23

relied [3] 44:13 82:1 266:25

rely [1] 281:8

relying [2] 55:12 113:3

remained [5] 12:18 85:25 209:19 225:20 226:2

remarks [2] 244:6 282:23

remember [8] 29:20,22 47:21 103:4 128:9,25 259:23 264:17

reminded [1] 208:4

removal [2] 33:6 45:19

remove [4] 37:25 39:13 49:16 51:22

removed [5] 34:14 38:9 39:17 159:20 160:5

removing [1] 51:24

renovation [1] 290:6

renovations [1] 313:5

repeat [4] 103:14 113:9 113:15 114:2

repeats [1] 112:17

replaced [3] 32:7,22 34:25

replacement [1] 12:4

replacing [1] 288:5

report [79] 13:8,10 15:2 16:23 17:1,7 27:3 50:23 51:3,8 53:17,17 54:8 55:4,12,13,18,20 56:1 59:16,25 60:13 70:1 74:22,25 76:15,19 84:11 106:9,18 116:21 151:2,3 151:6,18,23 152:1,3,6,7 153:2,3 155:1,1,8 156:7 156:18 157:14,22,25 163:25 173:18 174:2 186:17,18 217:4,11,13 218:5 219:1,8,20,21 229:11 250:24 253:25 264:13 266:19 272:23 275:6,14 276:7 277:15 279:9 290:22 291:6 311:21 318:5 324:2

reportable [4] 217:8 223:9 225:8,15

reported [23] 12:25 13:2 13:18,19,21 15:4 74:24 94:24 95:6,9 216:19,20 217:24 218:9,10 225:2 229:11 248:24 273:11 275:17 285:13 312:24

313:5
reporting [46] 17:8 58:22 59:6 69:12,17,24 74:21 116:20 129:10,14 144:4,8 159:2 168:19 216:25 217:2 218:2 219:7 219:17 249:23,25 250:15 253:8,16 255:15 262:3 264:7 265:6 268:6 272:4 273:6 275:8,9 276:2 282:10,21 310:5 311:1,4 314:14 330:8 331:23 332:4,14,24 333:3
reports [27] 15:10 16:23 76:6,22 103:1 116:17,18 150:25 151:20 155:5 156:8,15 157:4 163:13 163:15,19 182:20,22 183:7 184:10 250:6 276:9 310:4 320:5,5,7,9
representative [3] 41:25 42:2 51:23
reprocessing [1] 88:4
request [17] 53:10 88:11 105:1,2,14 112:13 114:2 117:20 118:17 183:19 194:1,2 255:21 277:21 282:9 342:23 343:4
requested [1] 343:2
requesting [3] 133:25 255:14 282:21
requests [2] 87:5 129:12
require [6] 166:19 169:7 181:3 299:3 328:11 341:18
required [8] 37:21 48:13 52:6 250:3 259:2 293:4 328:14 337:19
requiring [1] 337:23
requisition [5] 55:21 110:8 279:17,21 315:23
rerun [1] 112:13
research [2] 72:13 261:4
reservation [1] 283:12
reservations [2] 254:9 261:4
residency [9] 5:18 6:11 32:9 61:6 82:7 200:5,6 200:12,15
resident [1] 335:17
residents [1] 144:2
resignations [2] 291:10 291:25
resigned [1] 228:18
resolving [1] 193:21
resource [6] 166:21 296:14,19 297:4 328:11 328:14
resources [9] 165:13 168:24 169:8,11 178:4 245:18 326:11 327:23 341:18
respect [6] 36:8 37:23 56:17 143:12 233:22 256:5
respectively [1] 274:6
responding [1] 118:16
responsibility [4] 15:18 214:4 315:3 327:9
responsible [20] 36:10 42:17 43:4 65:25 118:23 138:3 215:21 220:5 221:4 222:4 223:17 224:9 235:6 235:11 263:15 276:20 277:5 287:15 294:4,7
rest [1] 237:2
restricted [1] 120:25
restructuring [2] 221:13 225:7
result [4] 133:10 250:22 257:22 262:15
results [38] 58:24 60:13 84:14,15,21,24 88:1,10 101:13 103:6,21 140:24 141:5,8 143:5,6 147:8,9 183:7,12 185:10 186:24 189:3 249:11 252:4 261:16 262:3,25 264:8 264:13 266:20 274:4,4,5 274:9 283:23,24,24
resume [8] 86:9 87:4 130:25 187:12,18 188:4 188:18 190:19
resumed [3] 22:22 132:6 189:14
resuming [3] 132:12 188:11 189:5
retest [4] 103:16 143:6 147:9 148:19
retested [3] 126:18 150:11,14
retesting [6] 105:8 125:25 134:8 136:15 139:19 189:14
reticulin [1] 62:4
retirement [1] 207:11
retrieval [1] 269:6
return [9] 22:21 37:21 140:5 145:25 147:7 171:25 172:24 255:18 277:23
returned [9] 8:8 22:22 133:23 149:24 191:12 203:13 205:14 206:5 256:15
returning [1] 133:21
review [32] 24:21 26:17 26:24 43:18 60:19 85:1 103:8 107:3 108:23 109:2 124:19 125:13 129:9 137:23 141:23 142:4 185:11,14 252:2 254:22 261:10 266:4 323:21,24 323:25 324:3,4,7 325:4 333:17,20 336:12
reviewed [10] 24:24 25:3 27:1 66:11 67:10,14 179:11 186:1 279:3 333:24
reviewing [5] 66:1 267:18 276:20 325:1 332:4
reviews [3] 142:18 198:8 311:11
revised [2] 3:1 326:20
rider [1] 198:24
right [31] 1:8 17:21 19:25 28:25 32:14 37:9 68:12 77:9,10 79:7 83:9 97:5 97:21 110:14 142:15 151:15 161:22 162:9 169:8 186:1 212:6 215:15 216:17 228:5 249:18 296:8 297:7 303:25 322:21 334:20 344:3
right-hand [1] 274:6
rise [1] 254:20
risk [1] 51:24
road [2] 137:4 194:13
Robb [3] 299:11 300:5 337:8
role [14] 21:25 24:14 218:16 221:3 223:15 225:5 226:23 228:14 282:24 286:23 287:3 288:18 289:5 296:17
Rolf [1] 1:8
room [6] 19:6 33:7 165:9 240:24,25 314:14
rooms [1] 20:16
rotary [2] 40:1,11
rotated [1] 230:6
rotation [1] 229:25
rough [13] 70:7,13,14 72:1,3 73:2,7,10,24 236:24 268:8,15 327:11
roughly [3] 10:18 238:23 290:1
round [7] 120:7 233:18 233:19 234:3,24 334:15 335:12
rounds [13] 20:23 21:4 21:11,13 25:8 233:18 234:11,19 235:20 334:13 334:14,15 335:6
routine [2] 83:18 168:7
Royal [5] 5:25 25:24 26:2 200:16,17
run [7] 80:16 222:11 276:19 277:5 302:22 314:10 316:24
running [4] 23:3 51:24 83:16 84:22
rush [1] 126:20

-S-

S [437] 199:17 200:1,11 200:23 201:2,6,12,18,22 202:2 203:7,11,18,22 204:6,11,15,19,23 205:5 205:11,16,20 206:1,6,11 206:15 207:22 208:2,11 208:15 209:16,22 210:14 210:19,24 211:6,12,18 211:23 212:15,20,25 213:6,11,16,22 214:2,13 214:18,23 215:11,17,22 216:11,16,21 217:6,12 217:18 218:1,6,12,19 219:2,13,23 220:6,15,19 220:24 221:5,12,23 222:7 222:13,17,24 223:5,12 223:20 224:3,10,14,19 224:23 225:4,24 226:4 226:10,14,19 227:2,6,10 227:18 228:4,15,22,24 229:7,12,17,24 230:7,12 230:18,24 231:4,8,12,18 231:24 232:8,15 233:3 233:12 234:1,14,18,22 235:8,12,17 236:5,16,20 237:7,12,18,25 238:6,13 238:17,25 239:4,8,12,25 240:5,11,19 241:10,14 241:21 242:3,10,18 244:10,15,21,25 245:4,8 245:12,25 246:10,14,24 247:3,8,18,22,24 248:18 249:6,13 250:16,23 251:3 251:9,13 252:6,15,20 253:1,5,10,15,19 254:1 254:12,24 256:2,8,20 257:7,13,19 258:3,10,16 258:23 259:4,10,15 260:2 260:13,22 261:7 262:14 263:1,7,16 264:14,18 265:1,17,21 266:6,10,15 267:2,7,15,21 268:1,17 268:22 269:7,11,15,20 269:24 270:3,7,13,18,22 271:6,10,19,25 272:7,13 272:21 273:8,14,18 274:13,18,24 275:4,19 275:23 276:3,10,14 277:10,19 278:5,9,15,21 279:1,18,24 280:4,9,14 280:21 281:3,9,17,22 282:4 283:8,18,25 284:5 284:9,17,23 285:9,15,20 285:25 286:9,19 287:1,8 287:24 288:9,14,25 289:4 289:10 290:2,15 291:12 292:17 293:3,16,20 294:5 294:18,23 295:5,18 296:7 296:18,23 297:6 298:3,9 299:8,13,23 300:2,7,14 301:6,18,22 302:2,13,25 303:14,21 304:6,16,21 304:25 305:5,13,18,25 306:7,16 307:22 308:1,6 308:21 309:3,21 310:10 310:15,19,25 311:5,13 311:19 312:9,14 313:13 313:25 314:4,9 315:6,10 315:16,21 316:7,13,20 317:9,14,19 318:3,18,24 319:15,25 320:10,15,20 321:1,5,15,19,24 322:3 322:10,15,20 323:12 324:6,21 325:8,12,17,22 326:2,6,12,25 327:19 328:2,8,15,19 329:3,7 329:21,25 330:11,22 331:3,8,15,19,25 332:10 332:15 333:2,12,22 334:3 334:9,22 335:2,7,11 336:5,17,25 338:6,18 339:4,11,18,23 340:4,10 340:17,21,25 341:6,10 341:15,24 342:3,8,13,18 342:24 343:3
S-U-S-H-I-L [1] 199:18
sad [1] 236:8
safely [1] 49:15
safety [1] 177:1
sample [4] 91:11 194:10 333:20,24
samples [1] 321:10
Sandra [1] 1:7
Sangeeta [1] 11:7
sarcoma [2] 305:6 315:24
satisfaction [1] 244:5
satisfactory [3] 196:23 262:25 314:19
satisfied [7] 117:12 278:14 281:13 303:15 304:3 308:14 309:24
saved [1] 336:14
saw [18] 90:2 99:6 117:4 136:25 137:22 151:2,25 152:6,7 156:6 167:10,15 167:15 193:20 194:16 266:1 274:12 283:11
says [16] 71:1 104:3 129:7,9 133:25 135:10 135:16 244:3 255:7 263:11 265:5 275:13 300:17 307:4 323:25 332:5
scale [1] 165:12
scalpel [1] 38:2
scene [1] 133:4
scheduled [3] 20:22 80:15 81:12
Science [2] 5:12 298:19
Sciences [2] 48:11 241:17
scope [7] 107:3,20 109:1 115:7 118:9 177:2 256:11
Scotia [2] 201:25 338:24
screen [3] 206:23,25 263:11
scroll [2] 60:11 207:2
scrolling [1] 207:1
se [1] 71:9
search [8] 116:5,25 119:12,15 120:21,23,25 257:4
searches [4] 114:15 115:12 117:8 135:4
searching [2] 116:16 134:19
second [31] 26:24 27:1,4 55:24 70:6 84:19 88:13 91:2,17,18 120:20 129:6 129:6 134:25 142:1 151:23,25 152:6,9 156:17 167:25 182:8 234:10 251:20 265:4 268:7 274:3 276:25 297:15 336:7,13
second-last [1] 265:4
seconded [1] 306:17
secondly [2] 133:1 194:25
seconds [1] 167:3

secretarial [2] 311:25 312:4
secretary [2] 18:25 119:4
section [15] 40:4,7,7,14 40:17,17 49:4,13 50:10 70:8 168:17,18 241:1 268:9 274:9
sectioned [1] 33:10
sections [15] 18:9 19:6 33:19 37:16,18 38:2,3,4 38:5,6,21,25 40:3,13 88:12
see [50] 16:16 18:16 26:17 26:22 51:17 73:20 76:2 85:13 89:20,20 95:21,22 103:7 107:15 117:8 118:1 133:17 138:9 154:19 155:19 167:16,19 168:15 170:14 173:7 177:6 178:7 189:4,19 206:24 228:12 242:24 246:8 247:14 262:1 271:15 278:18 281:6 282:8 283:22 284:4 311:11 317:23 318:12 323:17 325:3,11 327:12 331:14 341:4
seeing [4] 55:8 90:6 197:6 274:17
seem [2] 114:17 194:4
sees [1] 65:4
segment [1] 161:8
segments [1] 160:15
select [1] 41:24
selected [2] 42:10 84:21
semi-formal [1] 233:24
send [22] 26:17 50:12 51:10 52:5 53:5,9 56:24 57:2 58:2 106:15 110:6 159:11 162:4 196:25,25 240:21 241:3,16 256:1 275:7 277:22 318:14
sending [13] 25:14,16 96:13 105:20 119:2 139:13 163:8 164:7 193:16 255:25 264:22 302:24 304:11
senior [7] 5:14 11:3,18 11:21,23 217:22 295:19
sense [32] 6:11,12 16:5 16:22 19:23 36:16 59:6 61:21 67:10,24 68:11 84:17 105:6 107:20 114:16 145:17 155:8 167:20 181:8 189:18 197:3 208:23 211:5 213:19 236:1 249:10 256:6 287:7 289:3 325:20 332:20 338:16
sensitive [1] 104:5
sensitivity [1] 86:4
sent [41] 19:3 33:9 42:10 48:10,14 49:16 95:25 105:23 111:24 115:20 117:17 119:3,4 122:18 122:20,24 125:25 130:11 135:20 136:4,14,17 137:9 138:17,19 140:15 155:13 159:4,14 163:7 182:22 186:18,19,20 187:5 194:3 267:10,13 318:10,15,17
sentence [3] 142:2 276:25 331:24
separate [3] 170:15,15 219:24
September [10] 84:12 107:23 115:15 118:12 125:20 126:15 127:2,20 154:2 255:3
series [2] 39:8 210:2
serious [5] 107:5 108:16 115:8 157:19 194:5
seriously [1] 255:13
service [10] 67:1 130:19 179:22 215:23,24,25 219:3 221:8 289:21 328:23
services [10] 7:11,13,15 8:4 17:2,9 223:2,2,23 307:2
session [2] 22:17 260:6
set [5] 115:12 126:11 170:6,12 320:7
sets [1] 147:23
setting [1] 140:20
settings [1] 20:12
settled [1] 293:25
seven [7] 22:6,6 26:10 89:4 167:25 289:19 293:10
several [16] 56:23 84:25 101:9 122:21 140:18 144:24 159:6 166:9 167:3 167:3 233:18 242:19,23 259:17 290:25 338:4
shall [1] 272:22
share [2] 69:22 265:10
sharing [1] 216:6
Shaughnessy [1] 6:21
sheet [2] 27:9 80:12
sheets [1] 243:21
Shiraz [1] 200:7
short [5] 10:1 176:23 245:21 289:23 298:17
shortage [2] 188:16,21
shortfall [1] 132:24
show [1] 290:18
showed [1] 42:1
shown [3] 74:24 84:23 262:12
side [13] 32:17 49:11 132:24 262:18,18 274:4 283:14,15,23,23 324:14 324:14 338:19
sides [3] 232:2 274:6 327:3
sign [1] 27:9
signatures [1] 144:6
Signed [2] 86:9 106:11
significance [8] 54:5 91:25 118:4 146:10,11 260:1,10,11
significant [7] 65:16 76:9 118:2 180:21 287:11 292:23,25
significantly [2] 65:16 289:11
signs [1] 27:2
similar [8] 40:1,11 215:18 231:13 251:18 260:23 287:2 294:14
simply [1] 276:8
Sinai [12] 125:25 129:13 129:15 130:12 132:16 134:7 154:3 162:2,5,9 164:5 187:6
single [1] 58:9
site [120] 38:6 190:10 202:14,19,22 209:8,13 209:14,20 212:18,23 213:20,21 214:9 215:8 221:3,16,19 222:1,4 223:9,15 225:1,3 226:2 226:8,23 227:1,23 228:10 228:18,25 229:10,21,22 230:6,16,21,22 231:17 231:22 232:2,12 236:15 237:2 238:1,21 240:7,22 242:20 243:2,4 246:17 248:2 255:6 261:13 262:12 263:13 264:24 273:5 275:3 277:21 282:14 286:6,17,24,25 287:21 288:16,19 289:9 289:20 291:1,16,19,22 292:10,12 293:2,7,24 294:12 296:16 297:1,13 298:25 299:3,19,20 300:10,21 302:8,25 303:10 304:2,12 305:10 306:12 307:14 308:10 313:1,3,23 314:3 315:2 322:24 323:7,8 324:24 325:25 326:5,23 329:2 330:6 331:1,7,9,18 335:20 336:2
sites [8] 229:22 230:1 231:14 302:21 334:18,20 335:18,25
sitting [1] 327:8
situation [14] 10:9 13:7 48:7,9 51:12 52:11 53:9 137:9 141:14 169:25 239:15,20,23 318:13
situations [1] 50:13
six [9] 86:8 95:14 234:7 273:24 286:16 292:1 317:24,25 326:16
size [2] 170:13 194:16
skin [1] 33:17
skip [1] 47:23
sliced [2] 34:8,20
slicer [4] 40:1,2,11,12
slices [2] 34:21,22
slide [36] 40:6,8,16,18 40:25 41:24 71:14,19 72:19,21,24,25 73:6 74:17 77:7,8,9,10,18,20 77:24,25 106:17 111:13 280:18 301:9 302:24,24 304:11,12,19 314:14 317:23,24 318:2 335:16
slides [73] 17:17 18:8,21 18:23,25 24:22,22 33:22 41:1 42:3 49:24 54:13 54:17,20 55:7,8,9 60:20 66:2 76:14 102:21,22 106:7,18 107:22 112:3,9 112:22 117:17 119:10 122:8 140:6,8 147:24,25 148:2,14,16 161:22 251:25 253:8,23,24 255:14,19,25 256:6,14 261:1 267:13 276:22 277:2,16 278:1,2,12,19 280:2,3,7,12 281:1,2,7 281:21 305:9,16,24 318:6 318:10,15,16,22
slight [1] 116:22
slightly [2] 39:10 175:25
slowly [2] 275:9 337:1
small [10] 16:13 25:14 33:15,17 51:15,16,20 90:6 108:22 161:11
smaller [2] 34:1,3
smooth [2] 282:23 283:6
Society [7] 1:15 182:14 202:6 233:4 321:9 333:19 333:23
solely [1] 109:4
solid [1] 34:9
solution [1] 86:7
solve [1] 86:4
someone [1] 153:11
Somers [17] 11:8,10 19:17,19 25:23 32:8 36:2 82:20,20 83:7 113:14 119:9 124:6 143:22 145:22 162:1,15
sometime [5] 35:12 54:21 118:11 156:23,25
sometimes [12] 37:14 160:22 193:22 240:20,22 240:24 279:7 282:9 284:10 309:8 316:22 319:2
somewhat [3] 34:10 153:7 155:4
somewhere [1] 42:10
soon [6] 126:24 140:6 303:8 313:4,6 324:11
SOPs [1] 181:1
sorry [22] 31:25 37:20 44:22 55:7,8 68:18 102:21 129:6 137:19 162:7 163:11 201:9,17 201:25 205:6 234:13 250:3 258:9 279:22 318:12 320:19 340:3
sort [10] 70:16 123:17 141:22 168:22 171:11 173:20 194:12 270:21 272:16 318:13
sorts [11] 17:11 22:12 62:5 146:12 153:20 174:7 216:20 218:24,24 235:15 272:18
sought [1] 94:20
sound [1] 345:10
space [1] 313:10
speak [3] 72:7 171:8 338:19
speaking [3] 4:25 65:7 124:4
spearheaded [1] 235:15
spearheading [1] 263:14
special [4] 61:24,25 62:2 64:25
specific [1] 141:24
specifically [1] 304:7
specification [1] 243:20
specificity [1] 86:5
specifics [1] 155:21
specimen [31] 33:14,17 34:22 37:3,25 38:3,9,14 38:25 39:19,22 49:18 50:2,4 51:23 52:4 79:21 159:11,20,21 160:22 168:3,5 241:2,2 290:4 330:8 331:23 332:3,14 332:24
specimens [31] 25:16 33:5,15 34:3,7,14 36:9 44:25 45:18 46:10 51:16 51:18 80:18,22,25 81:1 81:2 84:21 95:21 159:7 159:8 160:17,20 161:9 161:12,15,16 196:24 289:17,19 290:1
spell [2] 4:9 199:15
spelled [2] 146:18 168:13
spelling [1] 145:17
spells [1] 84:13
spent [1] 205:10
split [1] 237:6
splitting [1] 68:19
spoke [5] 118:11,13 173:5 194:11 227:22
spoken [3] 123:19 124:13 127:12
sponsored [1] 233:5
spot [2] 263:19 343:13
spring [2] 97:16 152:18
St [120] 6:18 7:4 26:16 56:21 57:6,8,15,21 58:19 59:14,15 63:2,10 67:6 68:1 69:3,5 76:14 85:20 93:22 94:13 95:25 96:16 98:11 100:22 104:10 106:15 107:18,19 109:15 109:20 110:17 112:22 117:17 118:17 122:18,21 123:8 124:23,24 125:7 126:1,23 129:11 130:25 132:12,22 135:21 136:14 138:17 139:9,12 140:15 141:6,14 142:3 151:7 153:17 154:8 155:13 156:2 157:23 158:15,16 165:1,3 166:19 167:5 169:19 172:25 178:8,16 178:17 187:12 188:4,11

188:18 189:8 190:20 195:6 197:11 202:3 203:13 204:5,10 205:15 208:8 211:17 212:13 227:15 230:1,23 231:14 236:13,23 237:3,4,22 238:1,4,9,11 242:16 244:9 248:4 249:22 251:23 264:24 279:22 289:17 290:22 299:19 300:23 318:9,12 330:21 335:13,25 345:7,11
staff [25] 6:23 7:7 8:14 9:22 21:13,16 86:11 115:2 132:24 188:17,21 201:13 202:4 203:1,12 203:15 207:6 235:23,25 236:1 243:24 262:9 293:2 293:12,12
staffing [3] 8:19 10:6 14:16
stage [6] 39:5 42:16 72:25 145:10 264:21 282:20
stain [18] 64:10 70:3 95:19,19 253:14,22 270:9 270:14 295:15 301:9 305:4 309:11 318:25 319:1,2,3 321:16 328:21
stained [11] 33:23 40:8 40:19,21 64:9 65:17,18 67:15 255:9,13 277:2
staining [49] 60:15,21 60:25 61:3,11,13,15 63:4 64:12,21,23 65:4,15 66:3 69:13 70:5 73:2,11,17 73:19,19 74:1 84:9 86:2 88:14 100:22 101:1 168:15 173:20 249:1 252:8 265:7 266:21,25 267:6,20,25 268:16 272:17 274:1 276:23 300:20 302:19,20,22 306:19 309:4,7 321:14
stains [49] 18:9 19:3 61:2 61:5,7,8,15,23,24,25 62:2,5,11 63:9 65:1 70:16 76:13 85:23 86:9 87:5 93:24 95:14,23 96:5 96:17 154:16,19 252:14 252:24 253:4,9 266:24 266:24 268:12 270:8 271:1 301:13,17 304:20 304:22,24 305:10,17 306:6 308:16 315:1 321:18,23 322:7
stand [1] 107:14
standard [11] 52:1 166:17,22 170:3 330:7 331:23 332:14,24 333:6 333:9 336:9
standardization [2] 262:2 311:17
standardized [5] 250:2 273:6 311:1,4 333:3
standards [1] 339:21
stands [1] 111:18
start [8] 18:23 60:16 115:15 170:2 207:8,19 208:1 277:1
started [27] 21:21 25:7 25:13,16 26:24 30:12 38:13 47:7 58:2 114:13 115:12 116:24 123:3 141:4 154:2 159:18 163:8 200:6 201:13 239:19 246:5 275:9 276:7 277:14 282:10 327:20 329:18
starters [1] 73:13
starting [4] 39:9 41:4 207:16 264:10
state [5] 4:9 17:16 53:18 199:15 335:1
statement [4] 70:3 128:11 188:23 299:9
statements [1] 192:16
stationed [2] 8:1,3
stations [1] 39:12
statistics [1] 238:7
stats [1] 94:25
status [5] 70:2 134:2 144:4,9 250:11
stay [2] 132:16 226:25
stayed [1] 206:9
step [1] 171:15
stepped [1] 202:25
steps [2] 158:19,21
steroid [3] 84:9 261:16 274:1
still [21] 11:14,16 17:5 32:1 50:2 65:25 116:20 187:5 189:6,15 207:18 262:1 269:5 276:20 283:11 290:6 291:24 292:14 313:11 326:23 338:14
stood [1] 173:7
stop [3] 39:16 86:3 284:25
stopped [1] 123:8
strain [1] 270:4
stream [1] 104:10
stretched [1] 165:16
strong [1] 73:18
strongly [5] 53:20 54:3 56:12 64:10 92:10
structure [4] 12:11 17:8 29:19 225:19
stuck [1] 39:23
studied [1] 256:13
study [9] 241:18,20,22 243:3 261:2 271:18 277:23 302:19 303:12
sub [1] 320:6
subject [9] 58:22 106:22 120:2 144:3 145:5 146:9 180:16 184:15 264:6
subjects [1] 21:15
submit [1] 336:10
submitted [1] 291:2
submitting [1] 255:8
subscribe [1] 334:6
subscribed [3] 25:6 321:9,10
subsequent [7] 46:21 56:20 84:1 107:2 122:22 164:20 175:24
subsequently [6] 66:7 98:13 120:6,20 140:20 159:3
substance [1] 303:4
substitute [1] 83:6
successful [4] 6:6 337:22 341:19,19
successfully [1] 292:3
successor [1] 111:9
succinct [2] 146:5 173:21
succinctly [1] 173:24
such [23] 24:17 26:14 52:15 53:19 64:7 67:17 86:9 145:2,23 177:24 198:17 235:9 251:7 252:5 264:22 268:14 301:16 311:20 316:17 324:4 330:19 337:20,25
suggest [5] 128:20 154:21 188:19 189:6,22
suggested [2] 272:11 338:2
suggesting [1] 84:7
suggestion [2] 271:14 271:15
suggestions [1] 244:6
suggests [1] 107:19
suitable [2] 324:16 328:22
suite [1] 33:7
summarizing [1] 274:7
summary [4] 173:21 291:6,7 334:25
summer [7] 101:10 115:1 122:6 124:2 154:1 194:9 230:2
superiors [1] 117:21
supervise [1] 220:1
supervised [1] 221:15
supervising [1] 216:2
supervision [2] 216:3 218:20
supervisor [4] 43:11,13 220:18,23
supervisors [2] 42:21 43:8
supervisory [1] 218:16
supplying [1] 118:16
support [1] 342:23
supporting [1] 177:3
supportive [1] 299:14
suppose [3] 14:9 135:17 198:7
supposed [1] 216:9
surgeon [3] 56:5 240:20 241:2
surgeons [6] 6:1 159:19 160:23 200:16,18 241:15
surgeries [1] 238:22
surgery [12] 33:8 49:2,6 79:13,13 80:6,7 160:24 200:6 237:17,23 238:3
surgical [25] 44:14 71:2 77:17 78:4,8,9 221:7,17 221:21 222:2,5 223:22 224:17 229:3,4 232:14 232:25 233:6 289:16,25 332:3 339:8,22 340:11 340:15
surmise [1] 47:20
surprised [6] 149:2 153:5,7 155:2,4,9
survey [8] 300:18 301:16 303:17,18 307:10,12,13 308:13
Sushil [6] 2:8 199:11,12 199:18 210:8 212:11
suspension [1] 97:8
suspicious [5] 38:7 51:19 52:2 95:24 96:14
switch [2] 109:5 193:22
switching [1] 67:6
SWORN [4] 2:2,8 4:6 199:12
synoptic [1] 116:19
system [20] 67:18,20 104:4 116:15 132:21 134:6 159:18 184:1,6 195:13 314:21 318:5 323:24,25 324:3,4,7,7,9 333:4
systems [1] 119:16

-T-

t [1] 40:4
t-cells [1] 320:6
T67 [1] 61:7
Table [3] 2:1 167:23 168:2
tables [1] 274:7
tail [1] 38:9
takes [4] 40:3,13 134:4 167:3
talks [3] 69:9 88:3,4
tasked [1] 183:11
Taylor [28] 1:12 2:5 184:25 185:1,2,4,16,21 185:25 186:5,9,13,22 187:3,9,16,21 188:1,9 188:15 189:1,13,21 190:1 190:6,13,17,23
tech [1] 290:9
technical [8] 86:11 119:18,21 168:14 217:7 223:2 293:12 295:24
technically [2] 60:18 277:4
technique [2] 104:6 257:12
techniques [4] 43:21 69:10 84:22 257:12
technologist [8] 141:14 217:22,23 298:16,18 314:11,20 318:4
technologist's [1] 43:10
technologists [27] 16:21 17:1,24 27:25 32:16,17 32:21 39:18 42:21 43:13 80:14,20 119:9 217:3,8 217:24 218:17 219:11 236:2,7 245:19 290:6 293:19 295:20 296:2,5 317:1
technology [1] 104:1
teleconference [4] 174:14 191:15,16,18
telephone [1] 101:9
telling [3] 155:25 262:23 275:12
temperature [1] 39:10
template [1] 169:23
ten [10] 71:20 79:1 89:20 90:4 135:18 199:6 255:8 261:1 279:3 283:1
tend [2] 89:5,13
term [2] 132:18 326:23
terminated [1] 207:10
termination [2] 207:8 207:17
terminology [2] 116:22 310:3
terms [65] 10:2 14:9 16:22 34:17 54:5 57:5 63:23 71:7,18 72:13 73:21 74:21 75:16 83:18 94:23 108:15 115:9 116:17,18 118:16 119:3 122:23 125:12 134:11,17 137:9 138:1 140:12 141:24 150:12 151:17 154:24 160:13,22 161:18 162:2 163:24 165:11 173:10 180:23 182:19 189:2,7 190:8,19 191:24 192:2 197:6 207:12 208:8 208:22 233:11,25 237:21 239:20 276:6 287:14 296:10 313:21 314:7 318:21 322:6 325:25 326:11 339:7
Terry [5] 176:14 295:25 306:17 310:12 337:22
tertiary [3] 178:12 196:16 197:5
test [9] 64:3 68:12 136:25 137:2 183:12 255:15,22 269:12 320:21
testified [2] 171:19 227:14
testimony [1] 167:11
testing [38] 1:2,13 7:17 7:24 28:9 67:17 82:12 88:1 97:9 103:14 106:11 123:8 132:13,18 154:9 162:10 168:22 183:15 184:15 185:5,12 187:5 187:12,18 188:4,11,18 188:22 189:5,8 190:8,19 241:7 244:8 245:23 249:5 251:2 345:4

tests [3] 132:21 186:1 261:23
text [12] 74:5 157:5 310:5 310:24 311:21 312:1,8 330:4,5,15,19 332:8
textbook [2] 256:22 257:8
textbooks [2] 72:11 257:5
Thain [1] 261:25
thank [26] 4:4,16 32:14 58:18 100:11,18 181:20 181:21,24 182:5 184:22 184:25 190:24 191:4,9 192:21 193:3 199:3,3,20 243:15 263:22,23 264:3 344:3,7
Thanks [1] 13:7
theme [1] 226:25
themselves [10] 96:5,17 112:9 122:8 163:15 198:11 218:17 250:24 282:8,10
there'd [1] 133:10
thereafter [3] 5:16 6:19 19:2
therefore [2] 86:1 87:4
they've [2] 29:2 113:22
thicknesses [1] 160:18
thin [8] 34:20 38:25 40:3 40:4,13,14 160:15,20
third [13] 32:5 69:23 70:25 104:4 230:10 248:21 249:16 251:19 271:13,16 292:5,8,24
thirty [1] 272:18
this'll [1] 206:22
thought [22] 25:17 64:23 76:7 91:9 97:18 105:16 108:17 112:11 139:9 188:3 195:21 245:20 261:8 286:8 303:17 309:8 327:24 328:20 332:13 333:1,5 338:15
thoughts [1] 157:16
thousand [2] 289:19 290:3
three [25] 32:8 40:4,14 70:2 87:8 91:1 117:7,8 121:7,12 122:24 162:3 173:19 230:1 234:6 237:3 239:5 282:18 291:5 297:18 308:19 311:23 312:21 326:17 337:13
through [28] 13:25 39:7 52:2 58:17 59:21 68:19 74:16 81:20 107:22 117:7 126:7 129:5 131:22 144:22,22 145:11 152:22 152:23 178:24 182:8 192:3,8 205:25 243:13 243:13 268:4 337:20,25
throughout [7] 4:23 16:19 59:7 64:1 124:2 146:15 264:11
Thursday [2] 21:14 160:25
tick [1] 316:1
timeframe [2] 134:18 319:7
times [2] 10:3 88:5
tissue [41] 33:1,2 36:9 37:23 38:22,23 39:2,5,6 39:19 40:1,11 41:8,17 42:19 47:12 48:9,13 49:1 49:7,15,16 50:14 52:7,8 79:11 82:12 88:4,7,9,15 121:17 149:1 161:19 163:3,4 164:6 241:3,16 283:13,15
title [2] 11:22 215:15
today [9] 13:8 17:5 92:10 92:13 149:3 167:5 191:25 207:18 337:22
together [5] 89:1 126:21 155:13 229:23 332:19
too [3] 122:10 169:22 271:9
took [13] 5:25 6:2,22 7:6 33:17 211:10 227:16 228:7 231:11 256:24 292:9,11 338:1
top [3] 26:10 39:22 118:18
topic [10] 12:2 35:25 45:23 78:13 99:16 130:14 153:25 177:10 237:15 334:13
Toronto [2] 141:15 262:6
total [4] 74:1 117:11 150:16 292:2
touch [2] 143:11 146:22
towards [1] 27:15
towels [1] 34:21
town [2] 85:21 234:5
track [2] 184:9 301:11
trained [2] 47:2 298:15
training [13] 5:18,20 6:10 32:9 47:1,3 82:7 200:6,15 202:7 205:7 258:20 273:12
transcribed [1] 345:9
transcript [1] 345:3
transcripts [1] 178:22
transfusion [1] 219:6
transition [6] 108:20 193:19 195:7 282:22 283:3,4
transmitted [1] 182:23
transversely [1] 34:20
tray [1] 314:14
treatment [5] 67:16 68:4 75:16 137:3 140:21
trend [1] 27:15
trends [4] 183:25 184:1 184:7,17
tried [5] 80:11 160:20 245:14,16 247:13
Trish [5] 141:19 150:24 151:3,6 174:1
troubleshooting [1] 219:3
true [2] 222:10 345:3
try [11] 73:1 105:24 115:12 126:21 158:23 159:24 160:11 163:5 256:22 261:8 328:21
trying [6] 160:14 205:3 206:20 298:11 324:15,19
tubular [1] 90:3
Tuesday [2] 38:20 81:13
tumour [11] 25:8 38:5 41:25 42:3 49:8,15 51:21 73:20,22 163:4 332:18
tumours [9] 47:12 49:8 49:12,13 51:17 52:15 89:5,13 239:21
turn [2] 37:7 230:10
turnaround [3] 197:1,3 197:9
turned [2] 34:16 133:17
turning [1] 292:25
Turnover [1] 207:6
turns [2] 131:24 141:19
two [56] 9:19,22,24 10:2 10:17,17 30:13 32:1,20 32:21 39:21 62:14,21 63:9 74:24 78:20,25 85:24 86:19,24 92:24,25 108:21 117:4 118:14 122:25 147:23 151:19,20 160:17 163:19 173:18 196:22 199:6 205:6,6,10 206:4 231:14 236:17 239:5 274:7,9 276:18 282:18 288:16 295:19 296:5 297:2,24 306:18 307:9 313:18 334:17 337:10,13
type [6] 17:19 19:1 22:17 92:15 106:9 305:3
typed [1] 261:19
types [1] 253:4
typical [1] 18:13

-U-

uncertain [1] 105:18
uncertainty [2] 189:11 189:15
unclear [1] 225:20
under [29] 12:17,19 40:7 40:17 41:22 104:6 148:18 159:25 160:13 201:25 207:13 210:13 212:6 251:20 261:14 276:17 282:15,19 291:6 306:18 310:2 312:22 313:17 323:4,19 332:8 333:15 335:23 337:13
undergoing [4] 129:8 135:4 142:4 300:19
undergone [1] 30:5
understand [27] 57:14 63:17 66:5 68:19 91:23 92:1 109:20 110:8 123:7 125:20 134:10 142:24 143:5 173:11 174:13 191:25 204:9 205:3 219:16 222:25 227:13 252:11 260:10 282:6 286:22 287:20 308:25
understands [1] 215:2
understood [20] 57:13 68:2 75:18 91:17 97:18 106:6 111:7 133:6,8,9 139:19 151:7 157:22,24 193:16 204:14 259:1 286:15 294:11 308:17
undertaking [1] 161:14
underway [2] 86:6 313:6
unequivocal [1] 198:19
unfavourable [1] 155:8
Unfortunately [1] 328:9
unhelpful [3] 86:1 94:1 97:10
uniform [4] 69:12,24 265:6 268:6
uniformity [1] 69:18
unintelligible [2] 233:17 321:6
unit [1] 159:14
University [7] 5:8,12 5:17 200:3,7,13 203:23
unless [7] 60:21 66:3 276:22 277:7 278:2,13 281:1
unofficial [1] 327:11
unofficially [1] 225:19
unreliable [3] 85:25 94:1 97:10
unusual [3] 105:2,13 194:1
up [86] 6:23 7:7 12:11 18:20 20:7 31:7 36:4,17 41:1,4 43:6 48:1 58:7 61:1 62:19 63:8 66:14 70:12 76:8 81:6 83:16 84:1 91:20 94:23 96:15 97:21 101:15 105:19 109:13 114:10 117:16 123:23 126:11 127:19,25 129:17 134:4 135:5 137:8 140:20 146:13 151:25 152:4 159:13 174:2 192:9 193:4 196:7 201:10 206:21,22 207:3 209:2 219:10,11 224:7 226:7 228:18 230:10 231:16 236:13,14 237:10 238:8 239:16 243:3 252:23 266:22,22,25 268:12 271:23 273:21 276:24 300:23 303:10 306:25 316:16,21 323:10,15 326:13 329:12 330:25 339:9 342:17
updated [2] 282:16,20
updating [1] 312:20
urgency [2] 114:16,21
urgent [1] 118:1
urologic [1] 95:21
usage [6] 82:12 128:14 259:7 270:11 271:15 272:16
used [24] 19:10 21:11 27:6 29:22 53:1 64:1 79:11 95:20 96:19 110:8 116:18 161:7 170:8 260:3 272:4,19 279:2 330:19 330:21 333:6,18,20,23 334:2
useful [3] 23:7,17 145:13
using [5] 53:25 116:19 130:25 184:4 330:14
usually [6] 37:14 38:8 198:13,15 314:17 335:18
utilization [2] 132:12 307:1
utilize [4] 154:2,8 272:10 328:1
utilized [6] 47:9,10 51:13 79:12 103:16 149:1
utilizing [11] 48:19 53:23 57:13 66:15 95:15 121:3 153:17 165:1,3 260:21 298:7

-V-

vacant [1] 291:24
vacate [1] 313:4
vacation [1] 211:9
vacations [1] 115:2
validity [1] 145:8
Vancouver [1] 6:22
variability [1] 65:9
variations [1] 116:21
varied [1] 22:16
varies [1] 88:15
variety [1] 65:4
various [10] 20:5 22:15 39:12 59:24 87:24 198:6 229:22 232:1 258:4 287:16
vary [2] 272:25 322:2
Ventana [7] 101:11 103:5,14,15 104:4,9 134:6
verbal [1] 336:21
verbally [1] 142:13
Vern [1] 291:2
version [6] 266:3,9 326:15,15,16 329:9
vetting [1] 43:4
via [3] 25:11,13 241:7
Vice [4] 13:11 15:9,13 174:15
video [2] 25:11,13
view [6] 67:24 123:2 170:18 193:17 194:21 263:4
visit [2] 68:24 151:12
visited [1] 178:18
vital [1] 91:12
voiced [1] 177:18
volume [4] 238:3,4 245:13,18

volumes [1] 307:2
volunteered [1] 22:4
VP [1] 192:1
vulnerable [2] 159:8 161:2

-W-

Wadden [5] 227:3,5 288:17 291:19 294:11
wait [3] 133:1,17 189:3
waited [1] 140:24
waiting [2] 172:16,17
walk [1] 20:17
walks [1] 182:8
water [1] 39:13
wax [6] 39:15,21 40:3,5 40:13,15
waxed [2] 39:19,23
weak [2] 309:5,9
weakly [4] 53:20 54:3 56:12 64:10
website [5] 151:3 156:11 156:25 167:20,21
Wednesday [3] 25:9 38:13,18
week [10] 62:10,14,21,22 63:9 81:6 114:22 161:4 161:14 256:14
weekend [5] 79:22 80:3 81:2,14 161:2
weekly [1] 22:13
weeks [2] 78:20 86:8
Wegrynowski [2] 141:20 151:21
Wegrynowski's [6] 150:25 151:3,6,18 154:25 174:2
weighed [1] 34:16
welcomed [2] 212:8,10
Welsh [1] 296:5
Western [1] 1:16
Whalen [3] 1:10 181:24 181:25
Whelan [1] 291:2
whereby [1] 159:19
wherever [3] 81:7 163:5 242:8
Whiffen [1] 319:21
whiter [1] 38:16
Whitman [1] 337:7
whole [7] 41:22 99:1 159:24 210:3 211:21 295:7 303:25
wide [5] 108:23 177:11 191:15 249:20 324:17
wider [1] 195:14
Williams [1] 297:23
willing [1] 178:6
Windsor [3] 6:25 16:3 169:15
wish [4] 58:7 59:23 192:17 207:2
within [24] 39:8 49:8 59:15 62:3,5,8,10 67:18 86:7 117:1 118:24 132:19 132:21 138:1 158:21 161:4 166:15 170:3 175:6 190:10 235:7 237:22 279:13 289:23
without [5] 49:17 51:24 255:15 288:22 328:22
witness [4] 4:4 181:21 182:10 199:11
witnesses [2] 91:5 191:14
wondering [2] 182:17 196:13
word [4] 246:7 254:6 263:5 316:1
words [1] 116:23
worked [11] 8:5 15:7 202:5,11 203:1,12 215:3 277:6 280:18,20 293:9
workload [8] 236:21 237:1 287:11 289:11,13 289:22 294:24 295:3
works [1] 165:20
workstation [1] 168:25
world [2] 215:2 223:18
write [4] 159:19,21,22 209:10
writes [5] 85:22 106:4 243:19 255:5 276:19
writing [6] 115:25 142:13 164:13,14 228:20 343:4
written [23] 42:23 44:5 44:11,14 45:7 46:18 54:8 55:13 60:3 77:17 92:3,4 92:9 93:16,17 106:12 146:2 164:15 165:11 167:7 181:1 226:7 276:25
wrong [1] 196:8

-X-

x-ray [1] 159:11
x-rayed [1] 159:10
xylene [1] 39:14

-Y-

Yarmouth [4] 201:14 201:19,21 202:1
year [37] 10:16 26:25 42:8 44:12 46:15 62:13 62:13 78:18 79:1 89:20 92:9 96:20 104:8 132:7 150:13 177:13 200:4,4,5 210:13 227:17 230:4 238:23,24 239:7 260:4 279:13 288:10,15 289:25 290:1 291:11 297:2 322:2 322:2,9,11
years [49] 8:20 10:14,18 11:4 21:13 22:6,7,10 24:11 26:5,9,10 28:2,14 29:21 30:7,13 31:3 32:8 42:24 43:17 44:25 45:10 46:4 47:25 66:16 78:14 84:1 89:17 96:7,10 109:15 117:1 145:8 183:4 202:5 205:6 220:9 259:17 259:18 283:1 293:10,10 322:6,8,13,14 326:20 338:4
yesterday [4] 227:14 248:13 266:1 274:11
yet [3] 152:17 166:12 244:2
York [2] 32:9,11
yourself [45] 16:7 36:2 37:18 54:25 58:17 76:1 82:19 83:11 89:21 106:4 130:3 143:25 145:2 150:6 161:22 169:5,6 178:4 207:12,20 209:5,8 212:5 219:17 226:13 243:19 247:15 248:5 251:1 256:18 261:21 278:19,19 288:24 300:5 301:3 302:25 305:11 308:20,25 315:1 316:6 319:11 323:3 337:10
yourselves [3] 168:21 262:12 308:18

-Z-

Zayid [1] 48:15

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**** [1] 79:21