COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

October 15, 2008

Appearances:

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

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

Peter Browne, Q.C./Jane Hennebury . . . Doctors Kara Laing et al

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

Chesley Crosbie, Q.C.. . . . . Members of the Breast Cancer
. . . . . Testing Class Action

Mark Pike, Q.C. . . . . 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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THE COMMISSIONER:

Q. Please be seated. Mr. Browne.

MR. TERRY GULLIVER - EXAMINATION BY PETER BROWNE, Q.C.:

BROWNE, Q.C.:

Q. Good morning, Mr. Gulliver. Peter Browne. I represent a number of the individual physicians who have testified before the Commission. We met previously.

MR. GULLIVER:

A. Good morning, Mr. Browne.

BROWNE, Q.C.:

Q. I just want to clarify some of your answers to Ms. Chaytor's questions over the course of your testimony, and unfortunately I have to go back to the first day, but we'll try to move forward very quickly.

MR. GULLIVER:

A. It seems forever ago.

BROWNE, Q.C.:

Q. We'll try to move as quickly as we can here. You had mentioned to Ms. Chaytor that the training - I guess, the schooling program for lab technology is a three year diploma program followed by national certification exam, and that applies across - uniformly across the

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country, is that right?
MR. GULLIVER:
A. The national exam does.
BROWNE, Q.C.:
Q. The national exam.
MR. GULLIVER:
A. Training programs may differ from province to province, but you do have a national competency profile that each training program has to ensure the students follow that profile.
BROWNE, Q.C.:
Q. Okay. Now looking at - if you wish you could call it up, and that's Ms. Wegrynowski's first report, P-0047, but generally within that review of the lab, she mentions a number of things surrounding, I guess, the equipment and use of equipment by the technologists, and in particular the pipette calibration and accuracy, the use of, I think it's an NIST thermometer. Just dealing with those two pieces of equipment, is that something that you learn about in the program in terms of use of this equipment, and, I guess, accuracy of the equipment and so on.

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MR. GULLIVER:
A. The pipetters, you would learn how to use a pipetter in your training program.
BROWNE, Q.C.:
Q. Yes.
MR. GULLIVER:
A. But certainly the calibration of it or - and it's not the calibration of it, it's to verify that the calibration set by the manufacturer is still at that setting, whether it's a year later or two years later.
BROWNE, Q.C.:
Q. Right.
MR. GULLIVER:
A. That's really something that's a function of the biomedical engineering department.
BROWNE, Q.C.:
Q. Okay.
MR. GULLIVER:
A. Within your organization that's now who does that for us.
BROWNE, Q.C.:
Q. But in terms of recognizing, I guess, when - is that already set? Does the technologist have any involvement in recognizing when that

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needs to be done and the bio - is it the bio engineering, did you say?
MR. GULLIVER:
A. Yeah.
BROWNE, Q.C.:
Q. When they're contacted, or is it just set times when they come in?
MR. GULLIVER:
A. I think the protocol is to recalibrate once a year.
BROWNE, Q.C.:
Q. And thermometers as well?
MR. GULLIVER:
A. And the thermometers is the - NIST is an instrument that verifies that your thermometer is working properly. So, you know, the case where Ms. Wegrynowski had mentioned that was in the - for example, the Ventana platform, the procedures taking place inside the instrument at a certain temperature, and the instrument automatically sets itself in a program at that temperature, and she said what Mount Sinai uses, they actually put a thermometer inside the instrument and measure to make sure that the instrument is working

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properly and is really at that temperature. So if it's supposed to be at 37 celsius, they put a thermometer to measure that. What the NIST is then it's another calibration to make sure the thermometer you're using to measure the instrument is actually working properly.
BROWNE, Q.C.:
Q. So would these sorts of things -
MR. GULLIVER:
A. And that's not something that you learn in the general medical lab technology program.
BROWNE, Q.C.:
Q. Okay, and that's what I was coming back to. These sorts of things are, like, I guess, we've heard the term troubleshooting. Is that - would that canvas that, sort of checking instrumentation and so on, would that be troubleshooting?
MR. GULLIVER:
A. That's not really troubleshooting. That's your preventative maintenance kind of schedules.
BROWNE, Q.C.:
Q. Okay. The notion of troubleshooting in the lab, is that again something that is canvassed

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in either the national certification examination or in the training program, the three year training program?

MR. GULLIVER:

A. Troubleshooting, yes, it is. It's covered off, but troubleshooting in a general sense within medical laboratory technology, i.e. it could be troubleshooting in a biochemistry environment, a pathology environment, microbiology environment, but how to troubleshoot specific instances within any certain test, that really is learning on the job.

BROWNE, Q.C.:

Q. But the theory, the notion that it's necessary to -

MR. GULLIVER:

A. The theory behind it, yes.

BROWNE, Q.C.:

Q. Now in terms of going back to the instrumentation, such as pipettes, thermometers, and then, I guess, add to that slides and pH meters, those sorts of pieces of equipment, in your lab or in the lab at the Health Sciences Complex, who would have been

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responsible for ordering that type of equipment?

MR. GULLIVER:

A. For ordering it?

BROWNE, Q.C.:

Q. Yes, selection of a particular piece of equipment?

MR. GULLIVER:

A. They're basic lab equipment. They'd be at the division manager's level.

BROWNE, Q.C.:

Q. And you had mentioned in your - you became - I guess you went into management in 1987?

MR. GULLIVER:

A. Yes.

BROWNE, Q.C.:

Q. You became the divisional manager at that point?

MR. GULLIVER:

A. Pathology supervisor.

BROWNE, Q.C.:

Q. Pathology supervisor, and I was unclear, at the point that you made that transition, there was some IHC being performed. I think you'd mentioned Dr. Wang and Dr. Chittal were doing

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some of it at that point?

MR. GULLIVER:

A. For about three or four years at that point.

BROWNE, Q.C.:

Q. I was unclear. Were the - we've heard various evolutions of the IHC up to now the Ventana. Were kits being used at the time you were doing IHC?

MR. GULLIVER:

A. No.

BROWNE, Q.C.:

Q. Were either Dr. Chittal or Dr. Wang doing any type of antigen retrieval?

MR. GULLIVER:

A. No, antigen retrieval wasn't even invented then.

BROWNE, Q.C.:

Q. Okay, so the antibodies that they were using didn't require antigen retrieval?

MR. GULLIVER:

A. No.

BROWNE, Q.C.:

Q. Now you had - when you became manager, was there any requirement upon you, or supervisor at that point, to assess - I think we've heard

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that Ms. Butler and Ms. Welsh were trained to do IHC and brought in. Did you supervise and train both of these individuals in terms of their knowledge of - I guess, test their knowledge of IHC before they went on the bench?

MR. GULLIVER:

A. I don't think I would say that it was just myself who trained them. I certainly helped, and, you know, passed along any material that I had. I did submit during my testimony that 20 page basic theory lecture that Mary and Peggy would have done and who had a copy of it. We did have a basic theory handbook that we used that was supplied by one of the companies. We had a textbook by Sternberger that we used at the bench, and again, you know, Dr. Chittal was there and he also would have been good assistance with Mary and Peggy.

BROWNE, Q.C.:

Q. Uh-hm.

MR. GULLIVER:

A. And mostly on the troubleshooting side, you know, that would read the slides.

BROWNE, Q.C.:

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Q. You mentioned as well, I guess, that Mr. Hewlett who testified here, he had been at and did some presentations?

MR. GULLIVER:

A. In 1986, we had - our professional association, we had our national week long congress being hosted in St. John's, and a part of that - and it's a combination of workshops, lectures, to cover all disciplines in laboratories. It's a combination of a trade show with the new technology, like your basic overall congress, and during that time Mr. Hewlett did a one day workshop and we used the lab at the medical school to do that.

BROWNE, Q.C.:

Q. And were these in IHC?

MR. GULLIVER:

A. It was just when IHC - again back in 1986, it would have been a one day workshop in basic theory and principles in IHC, and then talking about your PAP procedure, policies procedure.

BROWNE, Q.C.:

Q. You mentioned in 2001 he was back again?

MR. GULLIVER:

A. Again we had our national congress here again

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in 2001, and we're here again next year, 2009.

BROWNE, Q.C.:

Q. In terms of - we've heard a lot about issues surrounding fixation and so on. If technologists noted problems with fixation, would it be incumbent on them to report if they saw a regular problem with fixation coming from specimens? Would it be incumbent upon them to bring that to the attention of the manager and/or the program director at an point?

MR. GULLIVER:

A. They wouldn't bring it to the program director. I mean, it's operations within the pathology division.

BROWNE, Q.C.:

Q. Right, so presumably if there was a noticeable problem, they would bring it to the manager and the manager would, if felt -

MR. GULLIVER:

A. In pathology, would go to the site chief.

BROWNE, Q.C.:

Q. Site chief.

MR. GULLIVER:

A. Yeah.

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BROWNE, Q.C.:

Q. So just going back, if the technologists noted that, would their line of communication be to the manager, though, in terms of getting something rectified?

MR. GULLIVER:

A. It would, yes.

BROWNE, Q.C.:

Q. Okay, and then presumably the manager would then, if they could not resolve it directly with pathologists, go to the site chief and/or the clinical chief to get that resolved?

MR. GULLIVER:

A. Yes.

BROWNE, Q.C.:

Q. Was there ever any point prior to 2005 issues brought to your attention, either as the manager or the program director, from technologists surrounding fixation?

MR. GULLIVER:

A. At the Health Sciences site, which is my home base, I don't remember any instances. At St. Clare's site, I certainly was made aware of some issues up at St. Clare's.

BROWNE, Q.C.:

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Q. And were those followed up?

MR. GULLIVER:

A. Yes.

BROWNE, Q.C.:

Q. How were they followed up?

MR. GULLIVER:

A. It was pretty well just in basic discussions with the site chief at St. Clare's that there seems to be an issue at St. Clare's with specimens that were not being fixed properly for either two reasons; that the specimen initially was not left in formalin long enough, or when it was grossed, the tissue was too thick to go into the cassette and - because consequently, I was made aware - I was actually the division manager for pathology at Health Sciences/Janeway, and I worked fairly closely with John Murphy, the manager of pathology at the Grace/St. Clare's, and the issue was the amount of reprocessing that the technologists at St. Clare's had to carry out primarily because the tissue was not fixed properly from the beginning at the gross bench.

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Q. Do you remember when that was, Mr. Gulliver?
MR. GULLIVER:
A. It was over a period of - a fairly lengthy period. I would say probably '98, '99, 2000, during that time frame.
BROWNE, Q.C.:
Q. Was there any thought given to sending a memo to - like, something like along the lines of Dr. Ejeckam from sort of the technology side saying, look, could you please pay attention to these issues?
MR. GULLIVER:
A. I never wrote one. It was brought to the attention - at the time, only the pathologists did the grossing. It was brought to the attention of the site chief and brought to the attention of the pathologists at St. Clare's, and other than that, that's where it went.
BROWNE, Q.C.:
Q. Would the notion - again this is probably with hindsight. Given the high turnovers that were occurring, I guess, at both sites, would there be some benefit to having that type of memo distributed if you're seeing things from the technologists point of view, communicated back

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to the pathologist side, again along the lines of Dr. Ejeckam?
MR. GULLIVER:
A. I know, and you mentioned the high turnover, but at St. Clare's site there really wasn't a high turnover at that time. They had a stable group of pathologists there, and it was shortly after the Grace - then the Grace closed, and pathologists from the Grace moved to St. Clare's, and obviously in hindsight, such a memo like Dr. Ejeckam did in 2003 would have been appropriate in '97/'98, but again that would have to come from the site chief or clinical chief.
BROWNE, Q.C.:
Q. It's not something you would see coming from the technologist side?
MR. GULLIVER:
A. No.
BROWNE, Q.C.:
Q. Just to - you mentioned you had professional experience and knowledge through CMLS which is your, I guess, professional organization, national professional organization, and you, I think, testified - I think the first day you

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testified, that you'd learned a lot around management and administration of laboratories. Did I understand that that was mostly talking to your colleagues and dealing with colleagues from Alberta and Ontario primarily?
MR. GULLIVER:
A. Not really, no, it was just a combination of multiple things. When I was elected president of the CSMLS, at the time it was CSLT, Canadian Society for Laboratory Technologists, and a part of our role of being on the Board of Directors and being in the what we call the presidential chain where I was vice president for a year, president elect, president, and past president, for example, you know, they sent me to Ottawa to do two days training in communications in dealing with media. They sent me for a week to the Banff School of Management, sort of like an executive leadership kind of training to help you with dealing with board issues and governance issues, like, those kinds of things. I mean, all of that is knowledge that you gain. Certainly, I mean it does help you back in the workplace.

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BROWNE, Q.C.:
Q. You were obviously in most organizations in the executive stream for a number of years. So what years were you actually in that sort of -
MR. GULLIVER:
A. 1995, I was vice president; 1996, president elect; 1997, I was president; 1998, past president.
BROWNE, Q.C.:
Q. So 1995 to 1998.
MR. GULLIVER:
A. And before I took that leap, I had been several years on our national public relations committee, you know, where you talked about your profession. Before that, I was on our exam panels, so I've been multiple roles within the organization.
BROWNE, Q.C.:
Q. Okay. In sort of that environment in speaking and dealing with your colleagues at that national level, were there any occasions where you discussed or learned about how labs are set up in other parts of the country?
MR. GULLIVER:

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A. It all depends what your definition of set up is.

BROWNE, Q.C.:

Q. Well, I guess, in terms of lab structure, management, and those sorts of things, the notion, say, for instance, of having a lead technologist for IHC, for example?

MR. GULLIVER:

A. Not - no, not that kind of detail, no.

BROWNE, Q.C.:

Q. What about in the area of quality control and quality assurance, again were there any sort of discussions surrounding how things were set up internally or externally within these labs?

MR. GULLIVER:

A. No. Most discussion would be more the big picture for the profession across the country, you know, more talking about accreditation and those licensing - those kinds of issues.

BROWNE, Q.C.:

Q. What about in terms of advances in the profession, say, for histology, IHC, as it was expanding because this was a period where this was expanding quite - we've heard from a number of witnesses.

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MR. GULLIVER:

A. Those kinds of things are what you would probably see at our national congress or if you went to an international conference.

BROWNE, Q.C.:

Q. But nothing -

MR. GULLIVER:

A. Not through the professional association work, no.

BROWNE, Q.C.:

Q. Now you had spent a bit of time, and Ms. Chaytor spent a bit of time exploring with you the set up of the Meditech system, and I understand it was introduced initially in 1987?

MR. GULLIVER:

A. At the Health Sciences, yes.

BROWNE, Q.C.:

Q. And you stated I think the first day that the technical staff were more inclined to use the system as opposed to physicians?

MR. GULLIVER:

A. True.

BROWNE, Q.C.:

Q. We had learned from one of the technologists,

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I think it was Ms. Butler, about her reluctance towards computers and so on. Were the technicians given - the technologists, excuse me, given any courses in introduction to computers because, I guess, they both are required to use the computer for both the DAKO system when it came in, and also the Meditech system?

MR. GULLIVER:

A. Well, basic computer training is something that's offered all the time through the Health Care Corporation of St. John's, even now with Eastern Health, so employees can avail of your basic computer skills. To go back to '87 when Meditech came in, I mean, it was not just the technologists, it was myself as a manager who had to learn, you know, say, computer skills, in particular the Meditech system. So we did have - I think we might have been six months or eight months where we had the test system at the work bench with all the terminals for people to learn and use before we actually went to a live - to a live date.

BROWNE, Q.C.:

Q. Were, I guess, individuals such as

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technologists who were required to use both Meditech and later on computer systems such as the DAKO, were they required as part of their job to take computer courses to expand their knowledge?

MR. GULLIVER:

A. Well, there is no computer course in Meditech that there are - IM & T does have a training room and they do have staff who do provide basic computer training to all new staff.

BROWNE, Q.C.:

Q. Okay.

MR. GULLIVER:

A. To go through that process. The DAKO computer that was a PCU, the person who came in and set up the initial instrument who was in St. John's, I don't know, might have been three, four, or five days, did the basic computer set up with Mary and Peggy.

BROWNE, Q.C.:

Q. And I presume would be available for any questions on a regular basis? Was there a hotline to DAKO?

MR. GULLIVER:

A. Yes, it was a toll free number.

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BROWNE, Q.C.:
Q. Now as well around the DAKO system, you had mentioned that there was some - and I think you clarified this yesterday, some difficulties standardizing the format and the content. Did I understand Dr. Khalifa back in 1998 introduced synoptic reporting in pathology?
MR. GULLIVER:
A. I really can't answer that question. I just made the statement that Dr. Khalifa's reporting was pretty well standard throughout the whole time that I read his reports.
BROWNE, Q.C.:
Q. And your comment about standardizing the content, was that in relation to the fact that pathologists reported the ER/PR in different fashions, and, therefore, it was hard to sort of when you're going back doing searched in 2005 to locate all this information, is that -
MR. GULLIVER:
A. Yes, a fair assessment. They reported in different fashion and they also reported in different parts of the report. Some people had an addendum, some people did their

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interpretation under the pathological interpretation. We had another one that was called diagnosis. Some had it as part of their tumour summary. There was also no standard place on the report where you could find that information.
BROWNE, Q.C.:
Q. In terms of searching for that information, was that difficult? I mean, could you key the word in "estrogen" or "ER", and "progesterone" and "PR" and get that information back? Was the Meditech set up for that?
MR. GULLIVER:
A. Yes, it is, but Meditech would come back and give you that key word in any single report, but when you're doing the Meditech search, it also asks you "and where in the report will I find that key word", will I find it under diagnosis, will I find it under the - it's called data section, will I find it under interpretation, will I find it under addendum, will I find it under tumour summary. So again it just makes the - it just complicates it a little bit more.
BROWNE, Q.C.:

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Q. When Meditech was set up, and I gather it was integrated in 1999, all the systems, did I understand that correctly from you?
MR. GULLIVER:
A. Yes, when St. John's went to one -
BROWNE, Q.C.:
Q. One system.
MR. GULLIVER:
A. - one database, pretty well one system.
BROWNE, Q.C.:
Q. Right, because, I mean, I view that sort of, that issue, broader than just ER/PR. Was Meditech consulted as to sort of the best use and most efficient use of how items could be searched within a pathology report?
MR. GULLIVER:
A. I think by that time, the people who were using the system, Meditech system, at all sites had a fairly good knowledge in how to search the Meditech system for pathology.
BROWNE, Q.C.:
Q. My question was more designed towards was Meditech brought in to look at the current system, say in 1999, when all the systems were being--because, I think, it was recognized

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that different set ups existed at the various hospitals. For instance, there was different dictionaries at St. Clare's than there was at Health Sciences. Were they brought in and sort of said, "okay, now we're going to integrate. Can we look at a most efficient use in making sure that this does work uniformly?"
MR. GULLIVER:
A. No, they weren't brought in, but we weren't upgrading the Meditech system. I mean, the Meditech system, it's pretty well how you decide to operate the system and there's where your differences is come in in dictionaries.
When we did the consolidation of Meditech, the consolidation wasn't really taking Meditech from the Grace and St. Clare's and Janeway and Health Sciences and making it one. It was taking the Health Sciences current Meditech system and expanding that to include the Grace, St. Clare's and Janeway. What we did within Lab Medicine, in all parts of lab, not just pathology, we worked for almost a year in looking at the standard operations of Meditech at each site and how

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could we agree upon a standard set of dictionary or template for the city-wide computer system.

For example, one of the things that we did talk about was just the basic standard report format of how a pathology report would look when it went back to a physician, and we didn't get agreement on that. That ended up St. Clare's wanted to have their own report format and the Health Sciences continued to use the one that was in existence for the ten years prior. So there's the standard operations that went on.

BROWNE, Q.C.:

Q. So that happened internally? Meditech or their representatives weren't sort of brought in to sort of consult with you as to the best way to approach this and to come up with a solution that would work well for all sites? Is that right? They weren't sort of consulted as to -

MR. GULLIVER:

A. No.

BROWNE, Q.C.:

Q. Whose decision would that have been, to sort

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of bring them in, if that was viewed as a positive thing?

MR. GULLIVER:

A. Well, it would have been a combination of IM & T, because the consolidation was taking place for Meditech. The lab information system was one component of Meditech, so it would have been an IM & T broader decision for the organization. But again, you know, I don't know what you would need Meditech for because we weren't changing our Meditech system at all. It was for the different groups to come to a decision on how are you going to use and operate Meditech.

BROWNE, Q.C.:

Q. So from your -

MR. GULLIVER:

A. Within existing mainframe, the existing that was already there. The dictionaries are all hard coded. It's the test names you put in there and how you want to use them that you have to agree about.

BROWNE, Q.C.:

Q. So what I understand is you're saying, from your perspective, all it would require is a

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data input? It would not require their expertise to sort of -

MR. GULLIVER:

A. Not, no.

BROWNE, Q.C.:

Q. Registrar, P-1889, please? Mr. Gulliver, this exhibit was shown to you by Ms. Chaytor, and it's the letter, and I think you said you don't recall receiving this letter from Dr. Khalifa in 1997. I just want to go over a couple of comments that Dr. Khalifa made here and just ask you for your feedback. The third line here says--this is, again, you're quite familiar with this letter. You've seen it previously. It mentions, Dr. Khalifa mentions "you knew this" and this is referring now to the ER/PR kit which had been consumed the previous week. "You knew this and you were trying to use a detection system in combination with an old primary antibody that the lab had for some time. This combination did not work," and then he says he called you, but the two points I wanted to sort of draw your attention to is one, "new detection system in combination with an old primary

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antibody," and then two, his comment that "any trial of a new technique need to be done in parallel with a well-established one before a switch could be safely made."

Were you aware of the significance of what Dr. Khalifa was saying to you about using an old antibody with a new detection kit?

MR. GULLIVER:

A. Again, you know, I don't ever remember receiving this memo, you know, 11 years ago, and I really can't give you anything more than I've already testified because I don't remember even discussing this with Dr. Khalifa.

BROWNE, Q.C.:

Q. Putting aside--and I recognize that, the notion of what he's talking about here, you know, an old primary antibody with a new detection kit, do you realize the significance of what he's talking about here, this notion of a problem -

MR. GULLIVER:

A. I certainly do now, yes.

BROWNE, Q.C.:

Q. Okay, and in fact, if we look at Ms.

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Wegrynowski's report, she talks about that whole notion as well, the use of validating and optimizing and making sure that there's a parallel testing. That's a critical value in IHC, is it not?

MR. GULLIVER:

A. Well, Trish is talking about parallel testing. If you're going to switch, say, from DAKO to Ventana or you're going to switch antibodies to do validation.

BROWNE, Q.C.:

Q. Right.

MR. GULLIVER:

A. Dr. Khalifa is talking about moving from a biochemistry, biochemical assay to an IHC assay. So it's a difference there.

BROWNE, Q.C.:

Q. Okay, so you view this as making a switch. I read this as one kit to another kit using the old antibody from an old kit with a new detection system. You don't view it that way?

MR. GULLIVER:

A. When he's talking about here, "any trial with new technique needs to be done in parallel with a well-established one -

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BROWNE, Q.C.:

Q. Um-hm.

MR. GULLIVER:

A. - before a switch can be safely made." By this point in time, we have no established method, except for the biochemical assay in chemistry.

BROWNE, Q.C.:

Q. Okay. But going back to the previous comment, "new detection system in combination with an old primary antibody." Ms. Wegrynowski talks about the importance of making sure that the -

MR. GULLIVER:

A. Yes, I have to agree with it, yes.

BROWNE, Q.C.:

Q. Now another area I was unclear on, Mr. Gulliver, is you had mentioned on several occasion to Ms. Chaytor that your understanding of the reporting of ER/PR was that a negative result was zero, zero. That was negative to you. Did I capture that correctly?

MR. GULLIVER:

A. Zero, zero is negative.

BROWNE, Q.C.:

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Q. Yes, it was a negative. Now in 1997/1998, there were a number of meetings where Dr. Khalifa, I guess, introduced the notion of making the switch over from biochemical assay to immunohistochemistry reporting for IHC, and there was a number of discussions surrounding, I guess, how that would occur and reporting and how it would be reported. Do you recall attending those meetings?

MR. GULLIVER:

A. I don't remember attending specific meetings. It might have been just things in discussion with Dr. Khalifa.

BROWNE, Q.C.:

Q. Right. There were a number of site chief meetings and I can take you through them. I have one, two, three, four, five, between 1997 and 1998 where you were in attendance and this issue was discussed and including the 30 percent cut off. Do you recall anything from those meetings about that discussion, how the 30 percent cut off was arrived at, the discussions between St. Clare's and the Health Sciences Centre?

MR. GULLIVER:

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A. I don't offhand right now, anything specific -

BROWNE, Q.C.:

Q. But you -

MR. GULLIVER:

A. - discussion there.

BROWNE, Q.C.:

Q. - you wouldn't have remembered that from when this came up in 2005, being at those meetings, the information that was disseminated among the pathologists where you were there?

MR. GULLIVER:

A. If you have to show me the minutes -

BROWNE, Q.C.:

Q. Okay, sure. Well then, let's start with the first and that's May 13, 1997, and that's P-2351. Oh, sorry, maybe--let me just see. No, that can't be right. Let me try, sorry, Registrar, 1856. Yes, okay. My apologies, Mr. Gulliver. And you'll see, right there. Now just to go back, those in attendance, you'll see you're listed.

MR. GULLIVER:

A. Yeah, I see that, yeah.

BROWNE, Q.C.:

Q. Okay, and that's May 13, 1997, and then you'll

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see there's an extensive minute there about Dr. Khalifa reporting to the committee about his correlation and then about how results are reported and that there will be a consensus among pathologists. "Such a meeting will be held in June" and then it was agreed to, so that "individual pathologists reporting these receptors and need for standardized criteria to determine what is positive and negative." Again, does this -

MR. GULLIVER:

A. I can't--I don't remember this -

BROWNE, Q.C.:

Q. So you don't remember being at -

MR. GULLIVER:

A. - discussion from ten years ago, no.

BROWNE, Q.C.:

Q. And then P-1857, again, I think you're there present. This is in June of 1997. You're listed as being present again, and there's further discussion surrounding the reporting of ER/PR. Again, no recollection about the discussions at this meeting either, Mr. Gulliver?

MR. GULLIVER:

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A. No.

BROWNE, Q.C.:

Q. Just take a moment, sorry, and I'll just -

MR. GULLIVER:

A. I'm reading other -

BROWNE, Q.C.:

Q. Yes, and I apologize. It's 3.4 there.

MR. GULLIVER:

A. - other parts of the minutes here to see if there's something else.

BROWNE, Q.C.:

Q. Yes, if anything around that would refresh.

MR. GULLIVER:

A. Yeah.

BROWNE, Q.C.:

Q. By all means then, use the mouse, if you wish, to just -

MR. GULLIVER:

A. Again, this one here, I'm not in attendance? Yes.

BROWNE, Q.C.:

Q. This is--okay, you're not there, okay. Then let's, if we could, move to P-2413? Now would you receive minutes nonetheless as being the manager?

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MR. GULLIVER:

A. Sometimes, but I can't say all the time.

BROWNE, Q.C.:

Q. Okay. This is now December 17th, sorry, 16th, 1997, and you'll see here again, I thought there was a reference here. Let me just--I must have missed that, sorry. Item number three, yes, okay. Item number three here. Sorry, it wasn't headed--"steroid receptors assessment and paraffin sections. Dr. Khalifa discussed the issue further and suggested pathologists start reporting their own cases. A suggestion was made that Dr. Khalifa write up a proposal with criteria cut off values distributed to various pathologists and ask them for their feedback." Does this -

MR. GULLIVER:

A. I do remember it being, at some point, where they were discussing, you know, where all the other pathologists now will start doing their own interpretation.

BROWNE, Q.C.:

Q. Do you recall--and we'll go to the next, I think it's 2416, which is the January meeting, and I understand from--I stand to be

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corrected--I think you are present at this one. This meeting, this was a meeting Dr. Khalifa actually made a draft proposal and it was distributed at this meeting about the reporting and how it would be reported and 30 percent cut off was used. Do you recall that, ever seeing that proposal or in fact, later on the final version of that, at any of these meetings?

MR. GULLIVER:

A. I don't remember seeing it at the meeting, no, but I do remember, you know, at this time, you know, Dr. Khalifa who had been doing pretty well most of the ER/PR interpretations, that you know, I guess we're getting to that literature suggests 30 percent.

BROWNE, Q.C.:

Q. Right.

MR. GULLIVER:

A. I mean, that's Dr. Khalifa is the one that had suggested that, yes.

BROWNE, Q.C.:

Q. Right. So you were--I guess that's what I'm trying to understand here now. You were familiar about that discussion around it

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being, the 30 percent being the cut off as being a correlation to negative in biochemical assay?

MR. GULLIVER:

A. Yes.

BROWNE, Q.C.:

Q. So you do recall that being discussed around that time?

MR. GULLIVER:

A. Yeah. Exactly which meeting, you know, or which time frame, I can't tell you exactly.

BROWNE, Q.C.:

Q. Sure, no, and I appreciate, there were a number--as I've taken you through here, and there are a number of others, but I guess my question goes back to your understanding of zero, zero being negative. This seems to be somewhat at odds with what was being discussed around this time among the pathologists with the 30 percent.

MR. GULLIVER:

A. The 30 percent was a cut off that they were talking about for that the oncologists would use. I mean, I'm going back to a zero, zero, a lab test. If there's no staining, it's

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negative. If there is staining, well, it's positive. It's trying to decide what percentage of tumour cells are positive.

BROWNE, Q.C.:

Q. Right, and you understood that that, that all that sort of discussion that had occurred previously, despite, I guess, what you had learned in terms of the basic lab training of zero means negative, you were familiar with what discussions had occurred in 1997/1998?

MR. GULLIVER:

A. I was familiar with Dr. Khalifa was talking about the 30 percent was a correlation to the biochemical assay.

BROWNE, Q.C.:

Q. And there are others there as well where this is all discussed, but thank you, Mr. Gulliver, I think you've clarified that for me. Now Ms. Chaytor asked you about the position of the quality management manager position and I think you had said you had raised this with Dr. Williams around 2001/2002. When the external reviewers were here, did this ever come up about the notion of having a quality position within the lab, either with Dr.

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Banerjee or Dr. Wegrynowski or Ms. Wegrynowski?

MR. GULLIVER:

A. A quality manager?

BROWNE, Q.C.:

Q. Yes, or having someone in the lab responsible for quality.

MR. GULLIVER:

A. Do you mean in the lab or in pathology lab?

BROWNE, Q.C.:

Q. Well, in the pathology lab or in the lab itself, either.

MR. GULLIVER:

A. Because our quality manager, you know, it's for the whole Laboratory Medicine program.

BROWNE, Q.C.:

Q. Right, right.

MR. GULLIVER:

A. It's not just for pathology.

BROWNE, Q.C.:

Q. Sure. Did that whole notion ever come up with either of the reviewers?

MR. GULLIVER:

A. Not as a dedicated quality manager, but we had talked about a technologist being dedicated

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for quality in pathology.

BROWNE, Q.C.:

Q. And did you discuss with either of the reviewers about your sort of previous thoughts along that line in previous years to management?

MR. GULLIVER:

A. I don't--well, I didn't have a lot of discussions with them. I mean, they were in for a very set time and they had--you know, they had, I guess, a job to perform, to do their review. So I mean, we didn't discuss all aspects. It was -

BROWNE, Q.C.:

Q. Or did you point out to them, "look, I have been trying to sort of get quality position here in the lab for a number of years, but just haven't been successful"?

MR. GULLIVER:

A. I think with Trish, both myself and Mr. Dyer, and we pointed out a significant number of things that we would hope that she would include in her final report.

BROWNE, Q.C.:

Q. Did you specifically say "look, we have been

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trying to do this for years, but we weren't successful"?

MR. GULLIVER:

A. I may have. I may not have. I can't tell you.

BROWNE, Q.C.:

Q. We've heard as well, Mr. Gulliver, about, I guess, from actually Mr. Green when he testified, the different types of slides that were being used for--at St. Clare's and the Health Sciences and that he, as we understand it, had been at St. Clare's, transferred over after Ms. Welsh had left over at the Health Sciences, and he recognized when he was over at the Health Sciences being trained in for -

MR. GULLIVER:

A. Ken was there with Ms. Welsh.

BROWNE, Q.C.:

Q. Right.

MR. GULLIVER:

A. Les Simms moved over when Ms. Welsh left.

BROWNE, Q.C.:

Q. Right. That the Health Sciences were using special slides for IHC where St. Clare's slides were, I guess, normal adalin slides

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were being used and that he recognized there as a result that it could probably cause more background staining. Was there--who would have been--again, to come back to my previous question to you. Who would have been responsible for ordering slides for, I guess, at that point, the Health Care Corporation?

MR. GULLIVER:

A. No, at that point, it's St. Clare's has a separate manager. For most years, it was John Murphy. And again, I can't answer your question because, you know, I don't know about the bench level operations at St. Clare's pathology and St. Clare's pathology or the bench level operations of chemistry in Carbonear. That question needs to go to the technologists or, I guess, to the division manager.

BROWNE, Q.C.:

Q. Right, but I guess my question is more directed at the fact that Health Sciences Centre is the referral lab for IHC for the province, okay, and obviously there was some recognition, from what Mr. Green was saying, that special slides were needed for IHC. Was

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that communicated out to the other labs in the province?

MR. GULLIVER:

A. I don't know what he means by special slides. I know the IHC, at some point, I don't know which company, they came out with another slide, I think it was called Histogrip. They were more expensive than your regular slides used every day. And what that did was create a positive charge in your slide and it helped keep your tissue on the slide. I don't think it had anything to do with background staining. But then, most labs who were sending their blocks, they would send their blocks to the Health Sciences. The Health Sciences would actually cut the slides on those slides. So if Corner Brook wanted an IHC test done, they just sent the paraffin block in and if there's 20 slides to be created, the lab at the Health Sciences created the slides, and I'm kind of thinking, again I can't be 100 percent sure, Mr. Browne, I know that at one--I think St. Clare's used to cut--the techs at St. Clare's used to cut their own blocks and just send the unstained

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slides to Health Sciences, and I think Mr. Dyer stopped that practice when he became the manager for the city and just told St. Clare's to send your blocks as anybody else, and let the Health Sciences Lab cut your blocks, because the slides were at the Health Sciences.

BROWNE, Q.C.:

Q. Okay, and that would have occurred for all labs around the province?

MR. GULLIVER:

A. Yes.

BROWNE, Q.C.:

Q. The procedure would be that they would send in the blocks so they would be cut -

MR. GULLIVER:

A. Yes.

BROWNE, Q.C.:

Q. So the same uniform slide would be -

MR. GULLIVER:

A. Slides would be used, yeah.

BROWNE, Q.C.:

Q. We've also heard about the use of formalin and, I guess, as I understand it, 2003, there was a switch from in-house preparation to the

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commercial use of formalin. Was there a particular--at least while you were a manager, presumably this was occurring, it would be bulk formalin would be purchased and then mixed in house, and we heard from Mr. Hewlett and Mr. Parks about sort of the steps that are necessary to making your in-house preparation. Was there a procedure in place, a documented procedure in place for mixing in-house formalin while you were the manager?

MR. GULLIVER:

A. Yes, yeah.

BROWNE, Q.C.:

Q. Was there--and we also heard about the importance of measuring the pH and so on. Was all this set out in some sort of policy or protocol for -

MR. GULLIVER:

A. For the making of your ten percent buffered formalin?

BROWNE, Q.C.:

Q. Yes.

MR. GULLIVER:

A. There was a set procedure, you know. It's pretty well a mixture of two different

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powders, a mixture of your concentrated formaldehyde and then added to--basically to water.

BROWNE, Q.C.:

Q. What were the two powders that were used, do you know?

MR. GULLIVER:

A. Well, I haven't done it in 20 years. I'm thinking sodium--sodium monobasic and sodium phosphate dibasic. And again, you know, what you have in your textbook is that your target is pretty well a pH around seven. So the text book would tell you to get a pH of seven using 20 litres of water, you had to add I think it was two litres of concentrated formaldehyde. You had to add then so many grams mixed in water, premixed in water, of one powder and the second one, you added all three together and then that would give you your neutral ten percent buffered formalin.

BROWNE, Q.C.:

Q. And then was that--was there sort of a set process in place to measure the pH of the formalin?

MR. GULLIVER:

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A. I don't think we ever measured it, no, but the formula that was given you by the textbook was for 7.0 pH.

BROWNE, Q.C.:

Q. Around 2003 as well, and you spoke to this on a number of questions from Ms. Chaytor about the centralization of lab services, and this had been--I think you indicated had been an issue or at least on the table for discussion since 1998 and then when Mr. Dyer became manager in 2000, 2003, the issue was brought forth once again.

MR. GULLIVER:

A. I'm assuming you mean centralization of pathology services.

BROWNE, Q.C.:

Q. Yes, yes, and that's one of the--one clarification I want to--when you say centralization of pathology services, as a layperson, am I understanding that that, you mean both the technology side and the pathologist side being moved to one site or are you just talking about the technology side?

MR. GULLIVER:

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A. The original '98 was to have one lab for the city of St. John's.

BROWNE, Q.C.:

Q. Right, but pathologists would remain on both sites. Is that -

MR. GULLIVER:

A. No.

BROWNE, Q.C.:

Q. No.

MR. GULLIVER:

A. Originally in '98, the discussion was the Grace Hospital was closing, the Janeway was closing. The Lab Medicine program had made a decision to have--to consolidate and have one microbiology lab for the City of St. John's, and again, there was a proposal put forward to have one pathology lab for the City of St. John's.

BROWNE, Q.C.:

Q. I guess both then and in 2003, where was it envisioned that the pathologists would end up at the Health Sciences? I understand now that they still can't move because of--even though that's desirable, they still can't move because of space issues. How was that sort of

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envisaged?
MR. GULLIVER:
A. Well, the Grace had not closed. The Janeway had not closed. There were plans ongoing to renovate the space at the Health Sciences, and it would have been pretty well an issue where you may have moved one service out of St. Clare's and moved something out of the Health Sciences to go to St. Clare's in order to accommodate like a pathology consolidation.
BROWNE, Q.C.:
Q. Was there sort of a set plan as to how all that would occur?
MR. GULLIVER:
A. Back in 1998?
BROWNE, Q.C.:
Q. Or in 2003 even.
MR. GULLIVER:
A. In 2003/2004 when it was being discussed, well, we had not gotten to the planning stages with Facilities Management because we didn't have agreement to even go that far.
BROWNE, Q.C.:
Q. Okay, and just dealing with that point, do you recall some of the--you mentioned one of the--

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from your perspective, there was, you felt Dr. Cook, there was a cultural concern about what would happen to St. Clare's and there were rumours around that time that St. Clare's would move--sorry, would close. Was there any--do you recall any discussions with Dr. Cook about concerns over having quality assurance issues about transportation of specimens?
MR. GULLIVER:
A. I think that was one of Dr. Cook's issues where if we did move parts of pathology services, it would require specimens from St. Clare's having to be transported across the city.
BROWNE, Q.C.:
Q. Right.
MR. GULLIVER:
A. To be processed, embedded, cut and stained at the Health Sciences and then slides returned over there for interpretation.
BROWNE, Q.C.:
Q. And in fact, did Dr. Cook ask for and receive a quality initiatives review of that whole scheme to make sure that that was what -

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MR. GULLIVER:
A. Well that was more of a risk management assessment.
BROWNE, Q.C.:
Q. Right.
MR. GULLIVER:
A. To ensure that that would not be an issue.
BROWNE, Q.C.:
Q. Did Dr. Cook also raise issues about sort of how surgery would interface with pathology, given that there was a large degree of surgery still occurring at St. Clare's if that were to occur as well?
MR. GULLIVER:
A. Well obviously, I mean, as I testified at some point, myself and Dr. Cook met with George Tilley, the CEO; Dr. Bob Williams, and these are some of the concerns Dr. Cook was putting forward of why we should not move services from St. Clare's and obviously to allay some of those concerns, we had engaged both risk management, like Heather Predham and we had engaged management engineering to do sort of an operations review and again, you know, one of Dr. Cook's concerns was the transport of

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specimens across the city of St. John's. And another issue was about having on-site pathologists with surgeons.
BROWNE, Q.C.:
Q. And that was the importance of having frozen sections and doing frozen sections and so on, in consult in terms of -
MR. GULLIVER:
A. I don't know about the frozen sections, but again, you know, across the country there are multiple, multiple organizations who have moved to one pathology lab for the city and pathologists would then, on an out-call basis, go back to a certain site to do an on-site frozen section. And, you know, I have to say that while, you know, Dr. Cook did have his concerns about, you know, transporting specimens across the city, however, you know, he put a process in place where we transport specimens to Dynacare in Ottawa every day. So on one side he was against sending specimens from St. Clare's to Health Sciences and then on the other side, you know, we're sending specimens on an average of 500 a month to Dynacare in Ottawa for pathologist

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interpretation.
BROWNE, Q.C.:
Q. No, but coming back to Dr. Cook's concerns, once he had those reviews done, did he not agree with the proposal once those reviews were conducted? And in fact, we saw documentation--the Commission has seen documentation where he in fact went to the MAC and -
MR. GULLIVER:
A. That was like in 2005. Once the reviews were done, we met with George Tilley and Dr. Williams and there was no decision from executive to go ahead and do a consolidation of pathology. I think that might be May '04 and at some point after that, we do move the technical component from pathology to the Health Sciences and consolidate that component.
BROWNE, Q.C.:
Q. As I understand, there's still not available--there's no space available to bring pathologists over to the -
MR. GULLIVER:
A. We now have detailed plans in place, as you

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are probably well aware, with facilities management now to do the physical construction to accommodate that move. But again, I mean, and I've said this to Ms. Chaytor, you know, I know Dr. Cook for a long time was against the pathology consolidation, but I really believe that, you know, Dr. Cook was concerned about St. Clare's--St. Clare's hospital, as were many physicians at St. Clare's in that, you know, you pull out pathology, what's going to go next, you know, then goes DI, then goes something else and then what is left at St. Clare's as a, you know, as a physical building or as a full hospital operation and that's really where I believe his biggest concern was.
BROWNE, Q.C.:
Q. And that was where I think he testified that he wanted a strategic plan overall in terms of what was going to happen, do you recollect -
MR. GULLIVER:
A. I think he wanted a plan for, you know, health care services for the city of St. John's, not just labs.
BROWNE, Q.C.:

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Q. Sure. Now you were shown as well Dr. Ejeckam's memos both for April, May and June of 2003. You testified yesterday you weren't made aware of the first two, the April and May, but if we look at both of those documents, not necessary, you will see that Mr. Dyer was copied on both of those.
MR. GULLIVER:
A. I think he copied--he addressed it to a number of people, pathologists -
BROWNE, Q.C.:
Q. Right, pathologists and technical staff and cc'd to Mr. Dyer and technologists.
MR. GULLIVER:
A. - and I think he cc'd the technologists and Mr. Dyer, yes.
BROWNE, Q.C.:
Q. So in terms of your order of command, Mr. Dyer would have had the responsibility to bring that to your attention.
MR. GULLIVER:
A. Or Dr. Cook as the clinical chief on the leadership team with him.
BROWNE, Q.C.:
Q. But in terms of direct, in terms of the sort

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of set up, Mr. Dyer would have been -
MR. GULLIVER:
A. Reported directly to me, yes.
BROWNE, Q.C.:
Q. And again, I don't necessarily wish--if you wish, you can bring up the memo, but in the June 19th, 2003 memo, Ms. Chaytor went through that extensively with you. I got the sense that Dr. Ejeckam was also suggesting that or recommending that technologists be given time and resources to learn more. Did you get that sense from reading that June 19th, 2003 memo?
MR. GULLIVER:
A. No, I got the sense from him talking directly.
BROWNE, Q.C.:
Q. Either way, it was clear from Dr. Ejeckam's point of view that technology should be given time and resources to learn more about IHC and -
MR. GULLIVER:
A. He wanted to free up some of their duties, even though we didn't have the workload to support three fulltime techs in IHC. What he was saying was that he wanted them to have time to be able to spend fulltime in IHC and

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give them the opportunity if they wanted to learn more. And I think Dr. Ejeckam wanted to teach them more and I think what he wanted to teach them was to start reading things in a microscope and start reading control slides, so that they would be able to troubleshoot anything at that end, as opposed to on the pathologist end.

BROWNE, Q.C.:

Q. And in terms of that, just sort of from the technologist's point of view, after receiving this letter from your discussions with Dr. Ejeckam, did you give thought to sort of-- we've heard, the Commissioner has heard the notion of protected time and so on, of giving the technologists protected time and access to journals and subscriptions to journals, to learn more about IHC and the theory of IHC as a result of what Dr. Ejeckam suggested in 2003?

MR. GULLIVER:

A. Well Dr. Ejeckam never ever came back with any kind of outline or plan of this is the kinds of things he would like the technologists to learn.

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BROWNE, Q.C.:

Q. Could you not have done that on your own without talking to and in terms of saying, well Dr. Ejeckam -

MR. GULLIVER:

A. Again, I'm not the manager over there, I mean, I'm the director.

BROWNE, Q.C.:

Q. Okay, so that would have been the manager's responsibility to go to him and say, okay, can you show me what journals, can you show me where they can -

MR. GULLIVER:

A. Yes.

BROWNE, Q.C.:

Q. Was there any discussion about sort of going to Dr. Ejeckam and sitting down with him and organizing that type of plan?

MR. GULLIVER:

A. Dr. Ejeckam sat in my office with myself and Mr. Dyer and we talked about the whole memo and Dr. Ejeckam pretty--his thing was, he wanted the technologists to have more time in the IHC lab so he could spend time with them and he could actually teach them new skills in

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IHC. He didn't talk about the technologists getting more basic training in IHC theory. He talked about him wanting to have time to spend with the technologists.

BROWNE, Q.C.:

Q. But putting aside Dr. Ejeckam's own initiatives, what about from your end in terms of either you or Mr. Dyer looking at this and saying, okay, well what can we do to sort of escalate the knowledge of our technologists, either with protected time, with journals, like a journal club, interactions with colleagues and we saw from Ms. Wegrynowski's report the ability to interact with their peers in other institutions to learn -

MR. GULLIVER:

A. That would have to be outside Newfoundland because they're the only ones in Newfoundland doing the testing.

BROWNE, Q.C.:

Q. Sure, I appreciate that, but that whole notion is taking upon yourselves to sort of look at organizing a plan, independent of what Dr. Ejeckam was saying, for technologists?

MR. GULLIVER:

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A. No, I mean, if Dr. Ejeckam would have done an assessment, he'd be able to bring something forward, it certainly would have been supported by myself and Mr. Dyer.

BROWNE, Q.C.:

Q. We saw as well around this time, the letter that was sent to Ms. Butler and Mr. Dyer from the DAKO representative and if you wish, you can refer to it, it's Exhibit P-2155. Was there any thought, again on the technologist side because we've heard from Mr. Hewlett and Mr. Parks about this, the notion that communicating that information in a similar memo to lab directors around the island--from the technology side, putting aside what Dr. Ejeckam is doing, because I understood from Mr. Parks and Mr. Hewlett as well independent of the pathologist's role in fixation that technologists also have a role in sort of recognizing and looking at blocks and looking at slides and communication back to the pathologist. Was there any thought sort of communicating that information, where you're again, the referral centre, to other labs around the island, that information piece?

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MR. GULLIVER:
A. You mean this letter from DAKO?
BROWNE, Q.C.:
Q. And, well also saying the notion of, I think he talks about here in terms of to get some guidelines from other hospitals, going out and getting information from them. Do you see that there?
MR. GULLIVER:
A. I know, they're suggesting that we, as in the Health Sciences, as in the IHC lab -
BROWNE, Q.C.:
Q. Uh-hm.
MR. GULLIVER:
A. - should provide guidelines to the other hospitals.
BROWNE, Q.C.:
Q. Right.
MR. GULLIVER:
A. In how to fix and how to properly fix their specimens and Dr. Ejeckam did that.
BROWNE, Q.C.:
Q. Okay, but what about in terms of commun--he sent it to pathologists, but what about that sort of closing the loop from your side as the

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technical arm of this whole process, to your colleagues around the island, again emphasizing that information?
MR. GULLIVER:
A. Well I guess Dr. Ejeckam didn't even give me a copy as a director sitting in the lab with him, so you're saying to me I should have sent this memo then to other administrative directors in the province?
BROWNE, Q.C.:
Q. No, no, what I'm saying is the information-- Mr. Dyer got Dr. Ejeckam's two memos. Mr. Dyer also got this information from DAKO. Was there any thought given to sort of communicating again or reinforcing what Dr. Ejeckam had said in his memos from the technical side, where you're -
MR. GULLIVER:
A. Well I think when I seen Dr. Ejeckam's second memo, I mean, he sent it to all pathologists, you know, and it was an excellent memo and he outlines the importance of fixation and gives him proper protocols and interpretation guidelines, I don't know how receiving something else from the manager or from

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technologists was going to do anything different.
BROWNE, Q.C.:
Q. You were shown a memo that you wrote to Dr. Williams in 2004 following the accreditation that occurred, I think it's P-3113 and I just--yes, the second sentence here, "We also voluntarily participated in multiple proficiency testing programs from outside agencies that assess our accuracy and quality of testing." What multiple proficiency testing programs are you referring to there, Mr. Gulliver?
MR. GULLIVER:
A. Again, this is writing from me, as director of Laboratory Medicine -
BROWNE, Q.C.:
Q. Yes.
MR. GULLIVER:
A. At this point in time, we are enrolled in external proficiency testing, as we are now for IHC in particular, that was taking place in, for example, tissue transplantation, flow cytometry, biochemical genetics, most parts of biochemistry, hematology, coagulation, even in

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pathology at that time we were enrolled in CAP and ASAP, but it was more from a pathologist side.
BROWNE, Q.C.:
Q. Right.
MR. GULLIVER:
A. As you know now, we're enrolled in external proficiency testing that assesses both the technical and the clinical side of IHC testing. At this point in time, lab medicine had enrolled in external proficiency testing for years.
BROWNE, Q.C.:
Q. But I guess, in terms of this statement, it's a general statement, there's no limitations on it when you're writing this to Dr. Williams. Should that have, again, recognizing it's hindsight, should you have not indicated with the exception of the technology side of the Lab Medicine Program?
MR. GULLIVER:
A. No, because most of the other external proficiency testing is the technology side in chemistry and hematology and genetics and -
BROWNE, Q.C.:

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Q. I'm sorry, for IHC, that limitation should have been, because it wasn't occurring at that point in time.

MR. GULLIVER:

A. Well at this point in time we don't have external proficiency testing in the renal lab or IHC--I mean, there's other parts of the program that we don't have external proficiency testing in.

BROWNE, Q.C.:

Q. Okay, so there's no indication here as to what ones you are in and what ones you are not in, what programs are in -

MR. GULLIVER:

A. In this memo here, no. There isn't a detailed list of here's what we participated in or here is what we don't participate in.

BROWNE, Q.C.:

Q. And then finally, Mr. Gulliver -

MR. GULLIVER:

A. And most is from CAP.

BROWNE, Q.C.:

Q. Right. You were asked about the meeting of August 1st, 2005 and the discussion that occurred between yourself and Mr. Dyer and Dr.

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Carter.

MR. GULLIVER:

A. Well Mr. Dyer didn't really speak at all.

BROWNE, Q.C.:

Q. Okay. At that meeting, was there a representative--I think Ms. Bonnell who was the communications officer for Eastern Health at that time, was she present at that meeting? Do you recall her being there?

MR. GULLIVER:

A. I would assume so, I can't tell you for sure.

BROWNE, Q.C.:

Q. Do you recall--I guess my question more specifically in terms of do you recall at that meeting was there any discussion about--and the Commissioner has seen draft press releases and so on, do you recall any discussion about the wording of a draft press release?

MR. GULLIVER:

A. At that particular meeting? No, I don't. I'm not saying that we didn't, but you know, there's so many meetings in that time frame.

BROWNE, Q.C.:

Q. Dr. Carter has testified that one of the things that sort of concerned her at the

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meeting and why she voiced her opinion was that there was a discussion around that time or during that meeting about what information should go in a draft press release and she was concerned about your use of the term sensitivity--of the Ventana machine being more sensitive than the DAKO machine and so on and the implications that that may mean to the public. Do you recall any discussion around that and her challenging on that?

MR. GULLIVER:

A. I think I can remember something like that, I don't know if she challenged on it. I think I was being asked at the time for basic information about the Ventana, you know, system and that was one of the things that when the Ventana system was implemented, that it was more sensitive than using the old DAKO autostainer.

BROWNE, Q.C.:

Q. Okay. And that would have been your sort of input to, I guess, that whole discussion.

MR. GULLIVER:

A. It would have been a part of my input, yes.

BROWNE, Q.C.:

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Q. Mr. Gulliver, thank you very much.

MR. GULLIVER:

A. You're welcome.

THE COMMISSIONER:

Q. Thank you, Mr. Browne.

BROWNE, Q.C.:

Q. Thank you, Commissioner.

THE COMMISSIONER:

Q. Ms. Newbury? I'm assuming you're still of the same position?

MR. PRITCHETT:

Q. I am Commissioner.

THE COMMISSIONER:

Q. All right, thank you.

MR. TERRY GULLIVER, EXAMINATION BY MS. JENNIFER NEWBURY

MS. NEWBURY:

Q. Good morning, Mr. Gulliver.

MR. GULLIVER:

A. Good morning.

MS. NEWBURY:

Q. Jennifer Newbury for the Canadian Cancer Society, Newfoundland and Labrador division. Mr. Gulliver, yesterday you were asked if you were aware in July or August of 2005 when you were gathering together information for

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retesting, if anyone is going to try and figure out what happened and that's with respect to the ER/PR test results, and you responded that you would assume at some point that would be a focus that you would need to work on, but at that point in time, which is July and August, 2005, all you were focused on was trying to identify patients who could be retested and who could be offered hormone therapy. Can you recall any time between July or August, 2005 and up until the spring of 2007 when the Inquiry was called, were you asked by anyone within Eastern Health to retain or collect all documentation regarding ER/PR, whether it's e-mails or letters or policies or articles or educational documents, manuals, et cetera, for the purposes of any such investigation or review or whatever that you had contemplated might very well happen?

MR. GULLIVER:

A. And you're saying up until July '07?

MS. NEWBURY:

Q. Any time between the summer of 2005 when, at that point in time you were focusing on collecting results for testing.

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MR. GULLIVER:

A. I don't remember ever being asked to specifically, you know, collect every piece of document that you have to go to this group who are going to start assessing to try to determine, you know, what went wrong or why the results changed.

MS. NEWBURY:

Q. Okay.

MR. GULLIVER:

A. I mean, certainly, being involved in meetings after meetings after meetings, after meetings, I mean, certainly there was discussion about, well, what could have went wrong, what could have happened? Why would results change like this and I mean, you've heard through all this inquiry the multiple scenarios that could be a possibility in, you know, leading to a changed result.

MS. NEWBURY:

Q. Right, and I guess the focus of my question was the mechanics of trying to answer those questions and whether -

MR. GULLIVER:

A. And I was never asked that, no.

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MS. NEWBURY:

Q. You were never asked by anyone to do that specifically or generally, if not said it to someone, to at the very least make sure that you don't discard any relative documentation or to-

MR. GULLIVER:

A. But you're asking me by an Eastern Health person.

MS. NEWBURY:

Q. By anyone within Eastern Health and how about outside Eastern Health?

MR. GULLIVER:

A. Well we were asked that by -

MS. NEWBURY:

Q. For the Class Action.

MR. GULLIVER:

A. Yes.

MS. NEWBURY:

Q. And on your own initiative did you ever, say back in July or August of 2005, when you had it in your mind that at some point, you know, this is something that we will probably focus on, did you take your own initiative to speak to people who you are responsible for

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supervising to make sure that as soon as you have an e-mail or an article or anything here that relates to ER/PR, please don't discard it? Did you take that initiative yourself?

MR. GULLIVER:

A. I don't remember specifically telling people don't throw anything away, no.

MS. NEWBURY:

Q. Okay. And you're in a transition here between Eastern Health and developing new policies, discarding, I guess, or replacing Health Care Corporation policies with Eastern Health policies, so that wasn't a concern of yours.

MR. GULLIVER:

A. No.

MS. NEWBURY:

Q. And is there any reason why you didn't think that that might be something more of looking into, just for the purposes of your Laboratory Medicine Program that you're the director of?

MR. GULLIVER:

A. When it comes to the policies?

MS. NEWBURY:

Q. Anything that relates to the ER/PR. You know you've got an issue here, you know, that right

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now, July, August, 2005, you're focusing on retesting, but at some point we might want to try and put our heads together and figure out what's going on. I'm just wondering whether you focused on that, I guess, somewhat of an administrative task -

MR. GULLIVER:

A. At that point in time, no, not at that point in time.

MS. NEWBURY:

Q. Mr. Gulliver, yesterday you had indicated when asked about the changed test results between 1997 and 2005, and in particular your response to or your contribution to an article by Carolyn Stokes in October of 2005 and you indicated that it's your belief today that in the eight-year time frame that almost 3000 patients were originally tested and assessed for treatment for hormone therapy and that three years later, after going through thousands of hours of work to identify review patients, have patients retested that could be affected, we now know that approximately 300 patient's results have changed and a lessor number than that had to require a treatment

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change. So based on your original approximately 3000 patients, 90 percent of the patients were done correctly right from the beginning. Now, of those 3000 test results, how many were actually retested?

MR. GULLIVER:

A. I think you've seen documentation, there's about a little over a thousand, about one third.

MS. NEWBURY:

Q. So the other approximately 2000 were not retested?

MR. GULLIVER:

A. And as you know, they weren't retested because they were deemed to be positive, therefore, they would have been a candidate for hormone therapy.

MS. NEWBURY:

Q. Okay, but in terms of saying that those, all 3000 tests or 90 percent of the 3000 were done correctly right from the beginning, how can you be confident that those other 2000 were done correctly from the beginning?

MR. GULLIVER:

A. Well I trust the opinion of the oncologist.

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MS. NEWBURY:

Q. And what opinion is that?

MR. GULLIVER:

A. That, you know, they told us that if patients were positive, then you can make the assumption that those patients were either offered hormone therapy or on hormone therapy.

MS. NEWBURY:

Q. Okay, but in terms of whether or not the positive test result is a correct result for that patient -

MR. GULLIVER:

A. Well that's a different matter, I mean, I know where -

MS. NEWBURY:

Q. But I guess what you said yesterday and I guess the general concept that was covered off by you in your contribution to the article written by Carolyn Stokes is that 3000 patients were tested over that eight-year time frame and 90 percent of those patients were done correctly right from the beginning. So it's a positive assertion that those 2000 patients results that were never retested are correct and I'm just wondering what basis do

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you have to say that they were correct?

MR. GULLIVER:

A. Well I think we've seen enough submissions through the inquiry and enough evidence since then that, you know, the issue with this test is the false negatives. You know, certainly there's documentation that there could be anywhere from, you know, up to three percent false positives. I think through all this review there's been a documented, you know, a handful of patients who were originally called positive who are now being treated as a negative, you know. It's been five or six or seven, so and listen to the oncologists that, you know, patients who were originally positive were either offered or on hormone therapy, I think the issue is the false negatives, not the false positives.

MS. NEWBURY:

Q. So that's your understanding and nothing over the last three years has changed your mind that there is no issue with those 2000 test results that were not redone?

MR. GULLIVER:

A. And I think Eastern Health has made that

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determination also.
MS. NEWBURY:
Q. Okay, and have you been involved in meetings where that's been determined?
MR. GULLIVER:
A. I was at meetings with, you know, Eastern Health officials and oncologists and pathologists and executive, you know, in talking about should we go back and retest all the positives.
MS. NEWBURY:
Q. And who generally was at those meetings?
MR. GULLIVER:
A. At some of those meetings was Kara Laing, Joy McCarthy from the oncologist side; Dr. Denic, Dr. Cook, Pat Pilgrim, Dr. Howell, you know, myself and Heather Predham, you know, it's been -
MS. NEWBURY:
Q. Those are the main players.
MR. GULLIVER:
A. The main players we'll say, yes.
MS. NEWBURY:
Q. And you've indicated that in the last three years thousands of hours of work were actually

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spent reviewing the results of ER and I assume the positive test results, but was there any portion of time spent reviewing the--or sorry, the ER negative results, but was a portion of that thousand of hours of work actually spent reviewing the ER positive test results?
MR. GULLIVER:
A. No, a portion of time was reviewing the actual pathology reports where a patient was reported as positive and to ensure that, you know, if they're deemed positive, that they are positive. There was not a lot of time in ensuring the patients who were called positive are still positive, with the exception of doing some retesting to confirm that a patient who was positive was still retested positive.
MS. NEWBURY:
Q. So essentially once the report was identified to be a positive test result for ER, then that was put aside and that was the end of the inquiry for those particular results?
MR. GULLIVER:
A. For individual patients, yes, but as a positive group, there were some samples retested and confirmed positive that they were

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positive originally and retested positive just to kind of, you know, sort of put that aside.
THE COMMISSIONER:
Q. My understanding up to point had been that there were some people in the positive group who, at their request, were retested.
MR. GULLIVER:
A. And there has been some of those, yes.
THE COMMISSIONER:
Q. And there were some people who one might, depending on your point of view, put in the positive group because they might have been viewed as weak expressers and therefore, somebody would have decided they were appropriate to be testing, but are you suggesting that there was another group of people who nobody would be worried about in terms of whether or not their category is genuinely positive, who you would have at randomly rechecked?
MR. GULLIVER:
A. There was a group in the summer of '05, there were some patients who had tested positive, were sent off for retest and they were confirmed positive.

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MS. NEWBURY:
Q. Perhaps I could bring up Exhibit P-1402 please? This is an e-mail, you were shown this in the last day or so, Mr. Gulliver.
MR. GULLIVER:
A. I don't know if I've seen that one, Ms. Newbury.
MS. NEWBURY:
Q. Actually down here there's an embedded message, October 26, 2006. It was sent from Oscar Howell to a number of people, including yourself and there was the original one from Heather Predham to a group, including yourself, and that's dated October 26th. And in the first paragraph there, it states--a person's name has been redacted, "was diagnosed with breast cancer in 1999. Her original ER/PR was 30 and 40 percent. Upon retesting, her ER/PR was zero zero. This was rechecked twice by Mount Sinai and still no staining was revealed. The original slides were assessed by pathology and it was found that the original interpretation was accurate. She was one of the four patients that we classified as retro converters; in other

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words, she originally stained positive but now was coming back negative, the opposite of our concern." Now are these the patients that you were just mentioning had been tested in the summer of 2005 for whatever reason?

MR. GULLIVER:

A. No, I don't think so.

MS. NEWBURY:

Q. Okay, so there was another group of patients retested then?

MR. GULLIVER:

A. I think Dr. Carter had selected some positive patients, I think mostly from the Ventana system and had them retested just to be confirmed positive because there was some discussion in the summer of '05 about are we getting too many positives off the Ventana system? Is it too sensitive?

MS. NEWBURY:

Q. And where were they retested?

MR. GULLIVER:

A. I think she sent them to the Mount Sinai and they were done as like consults.

MS. NEWBURY:

Q. Okay, and what was your understanding as to

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the results of those?

MR. GULLIVER:

A. That they were confirmed positive.

MS. NEWBURY:

Q. Okay. If I could bring up Exhibit P-0125, page 42 please? This is a document that was prepared by Eastern Health for the Department of Health and Community Services in November of 2006, November 23rd. And this has, it's called "ER/PR case analysis" and has a breakdown of some numbers and are you familiar generally with the information in this particular document?

MR. GULLIVER:

A. I wasn't involved in that and I didn't see the document.

MS. NEWBURY:

Q. Okay, but are you familiar with the content of it, the numbers, the general types of -

MR. GULLIVER:

A. I guess in general, yes.

MS. NEWBURY:

Q. And if you note there under the first group, the third bullet, there is a statement that "there are confirmed positive results

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numbering 12" and down below, "originally had a degree of ER positivity, but on retesting was negative", that's down under the change in results section. And those are the only references there to positive test results that are specifically broken down, so that would be four, plus the 12 is 16. So 12 were confirmed positive. Now do you know if Dr. Carter's information would likely have been included in this?

MR. GULLIVER:

A. I don't think it is, Ms. Newbury. I think these are--this is an assessment of the patients that were sent off in the retesting. I think what Dr. Carter had done was just to have some positive cases from Ventana system confirmed positive by Mount Sinai.

MS. NEWBURY:

Q. So you think that that would have been excluded from -

MR. GULLIVER:

A. And they would not have been part of the retesting--they would be excluded from this, yes.

MS. NEWBURY:

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Q. And if any of the preliminary results retested under the guidance of Dr. Carter had resulted in changes, would that be included in this breakdown of numbers generally speaking?

MR. GULLIVER:

A. You're saying if those positive Ventanas had to come back as negative?

MS. NEWBURY:

Q. If any results came back, because Dr. Carter wasn't only sending up positives, she was sending up a selection of results and this was before sort of the mass retesting.

MR. GULLIVER:

A. Right.

MS. NEWBURY:

Q. I'm just wondering if any of those other results would be reflected in these numbers?

MR. GULLIVER:

A. I would think the ones that she sent off in 2002 would be in these numbers.

MS. NEWBURY:

Q. In 2002?

MR. GULLIVER:

A. Like Dr. Carter had organized about 60 cases from 2002 that were sent off, those numbers,

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I'm assuming would be reflected in this total number.
MS. NEWBURY:
Q. So you think there's a separate group of numbers -
MR. GULLIVER:
A. That were Ventana positive and then confirmed as positive.
MS. NEWBURY:
Q. And Mr. Gulliver -
MR. GULLIVER:
A. And there were, you know, another dozen cases I think we sent out to Montreal to try and correlate and confirming, I mean, those numbers would not be here in this retest.
MS. NEWBURY:
Q. And why is that?
MR. GULLIVER:
A. Because they were not being done to retest the patient, they were being done to compare systems.
MS. NEWBURY:
Q. Sort of quality assurance with the systems?
MR. GULLIVER:
A. Pretty well, yeah.

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MS. NEWBURY:
Q. And are there records available of that? Perhaps I've seen them, I'm not--I don't have a clear understanding of what you're talking about.
MR. GULLIVER:
A. I think Ms. Predham may have those.
MS. NEWBURY:
Q. Okay. Mr. Gulliver, as director of the Laboratory Medicine Program, do you have access to all of the test results that were obtained as part of the retesting program in Mount Sinai or as part of Dr. Carter's own, I guess, comparison of the system?
MR. GULLIVER:
A. The actual results?
MS. NEWBURY:
Q. Yes.
MR. GULLIVER:
A. I didn't have the results as it was ongoing.
MS. NEWBURY:
Q. But you have access to it.
MR. GULLIVER:
A. Right now those results are in the database.
MS. NEWBURY:

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Q. The NLCHI database?
MR. GULLIVER:
A. The NLCHI database.
MS. NEWBURY:
Q. But prior to that, prior to NLCHI's involvement, would you have had access, as the director of the Laboratory Medicine Program to these results? If you wanted to look at those for any reason to do your own analysis or what have you?
MR. GULLIVER:
A. If I wanted to get them, I would be able to get them, yes.
MS. NEWBURY:
Q. Okay, you're permitted access to that, is my question.
MR. GULLIVER:
A. Yes.
MS. NEWBURY:
Q. And you can physically, from a practical sense, you can log into a system and get it or make a request to get access to that information. Mr. Gulliver, do you today have your own idea as to the number of retro conversions and that's the term that was used

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in the e-mail from Heather Predham, do you know today how many retro conversions, whether it was part of Dr. Carter's assessment or the official retesting program at Mount Sinai -
MR. GULLIVER:
A. I can't give you an exact number, Ms. Newbury. I mean, I know originally there were four that were confirmed that were originally called positive for whatever reason, whether it was actually a true positive, whether it was a mis-call originally and now retested and came back as zero zero as a negative, and my best estimate would be that there's less than ten.
MS. NEWBURY:
Q. And you're alluding to there the different reasons why a test result might have been called positive and now is being called negative, so there could be an actual technical issue which gives a true false positive, is that something that you're familiar with?
MR. GULLIVER:
A. It could be that or it could be a misinterpretation.
MS. NEWBURY:

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Q. Okay, and have you ever compiled a list of all retro conversions?
MR. GULLIVER:
A. I have not, no.
MS. NEWBURY:
Q. Okay, and has anyone in the lab, such as Mr Dyer compiled such a list?
MR. GULLIVER:
A. Not to my knowledge, Barry hasn't no. I don't know if the pathologists have.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. Dr. Denic would be the best one to answer that.
MS. NEWBURY:
Q. Okay, now Dr. Denic does not appear to have done so. Do you know if anyone else in Eastern Health has prepared such a list?
MR. GULLIVER:
A. My best guess would be Ms. Predham.
MS. NEWBURY:
Q. Your guess, so that means you have no idea of whether she has or hasn't, is that correct?
MR. GULLIVER:

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A. I can't tell you for sure, but I think she would be the best person to ask.
MS. NEWBURY:
Q. Okay. So she hasn't come to you for any information or any input on how to go about doing this? You don't have any reason to believe that she's done it?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. And why have you not compared or compiled such a list of retro converters?
MR. GULLIVER:
A. I think that, I mean, that's more of a clinical issue, you know, someone like Dr. Denic, our clinical chief, would be something he would want to undertake and, you know, and review the original slides and compare them to the retest slides.
MS. NEWBURY:
Q. And you don't see that, as a director of the Laboratory Medicine Program, that you would have any role in helping to gather together the information?
MR. GULLIVER:

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A. I think that Dr. Denic would ask Barry Dyer something like that, to help him organize and pull blocks of slides and do those basic things.
MS. NEWBURY:
Q. And are you aware of whether Dr. Denic has asked Barry Dyer to assist in that regard?
MR. GULLIVER:
A. I know that Dr. Denic has reviewed some retro converters.
MS. NEWBURY:
Q. But in terms of actually compiling a list of all of the retro converters?
MR. GULLIVER:
A. I can't tell you for sure if he has or has not.
MS. NEWBURY:
Q. And if Dr. Denic had taken it upon himself to compile such a list of retro converters, would you anticipate receiving a copy of that list?
MR. GULLIVER:
A. I would think that he would keep me informed, yes.
MS. NEWBURY:
Q. Okay, and would that be of any value or

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benefit to you as the director, either you or perhaps Mr. Dyer?
MR. GULLIVER:
A. Well I think the benefit would be, number one, how many do you have, so you know, if you--I mean, we know we have documented less than ten out of, you know, so we're talking out of 2000 patients approximately, that you know, the 2000 patients who were deemed to be positive and have not been retested, so within that group, you know, for whatever reason, we've identified that there may be ten or less than ten who have converted from a positive, whether it was a misinterpretation, whether it was a technical false positive and now they're retested negative. So you're talking about less than one percent of that total. If, so if Dr. Denic compiled a list, you know, and that list, Ms. Newbury, was like 200. I think then, you know, yes, that's something that you really want to be interested in if the numbers were something like that.
MS. NEWBURY:
Q. Okay, and is that because if you take 200 and divide that by 2000, which are the approximate

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total of -
MR. GULLIVER:
A. It's 10 percent.
MS. NEWBURY:
Q. Ten percent, and ten percent for you would be a concern, would it?
MR. GULLIVER:
A. It would be, yes.
MS. NEWBURY:
Q. Okay. Now you're assuming that the 2000 test results that haven't been retested are all accurate?
MR. GULLIVER:
A. I have to say yes.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. As many other people are, yes.
MS. NEWBURY:
Q. Okay. Now the document right here shows some results. Now unfortunately it appears from your understanding that Dr. Carter's information is not there, but based on this information, you have four out of sixteen positive test results that converted upon

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retesting. That's 25 percent.
MR. GULLIVER:
A. I know when I see this, it's reviewing 763 cases.
MS. NEWBURY:
Q. Right.
MR. GULLIVER:
A. And within that 763 cases, four of them have been confirmed as a retro converter.
MS. NEWBURY:
Q. Yeah, but 763, those are - you know, the large bulk of that would be negative results. So a negative test result for ER doesn't tell you anything about a PR test or a positive test result for ER. So wouldn't you have to look at the actual total number of positive test results to see how are we doing here, how are we doing with conversions of positive test results?
MR. GULLIVER:
A. Of false positives?
MS. NEWBURY:
Q. Exactly.
MR. GULLIVER:
A. I know, and you've heard experts testify that

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the expected false positive rate would be anywhere from 1 to 3 percent.
MS. NEWBURY:
Q. Very rare, I think, was your evidence yesterday, that experts said it would be very rare to get a false positive, but my question is here you have only retested, according to this particular document, a total of sixteen positive test results, you haven't retested the approximately 2000 others that didn't get into part of this retesting program. You've only retested sixteen in total. Four of those have converted. That's not a particularly good success rate if you compare it with what the experts expected, which is one to three or very rare, and I'm just wondering whether that has caused you to delve into that issue any further than that?
MR. GULLIVER:
A. It has not, no.
MS. NEWBURY:
Q. Okay, so it doesn't concern you that the expectations of the experts has not been borne out by what's being shown here?
MR. GULLIVER:

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A. I think I'd be more concerned if our oncologists were concerned.
MS. NEWBURY:
Q. Okay. Now you haven't compiled a list of the actual retro conversions, so you can't say today here's a list, here are the exact number, your understanding is that it's fewer than ten?
MR. GULLIVER:
A. Yes.
MS. NEWBURY:
Q. And is it your understanding that that's the same information that the oncologists would have that they're relying upon to decide whether or not we should be concerned about this?
MR. GULLIVER:
A. No. Even before retesting started, you know, the oncologists had no concern about the patients who were already called positive.
MS. NEWBURY:
Q. And in that case, the retesting program started because of an ER negative test result that converted?
MR. GULLIVER:

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A. Yes.
MS. NEWBURY:
Q. But once it was discovered that we're actually getting more positive test results that are converting to negative than would be expected, based on what the experts say, did that cause you to say, well, we should gather together all of the information, all of the data on these conversions, to make sure that the oncologists are aware of that before they decide, listen, we shouldn't be worried about this? I'm just wondering whether you've actually gathered together the data for that?
MR. GULLIVER:
A. I have not personally, no.
MS. NEWBURY:
Q. Or thought about doing it?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. And you don't know that anyone else has?
MR. GULLIVER:
A. I think you should ask Ms. Predham.
MS. NEWBURY:
Q. And I will do that, I'm sure, but I'm just

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wondering about your particular role there as the director of the laboratory medicine program. On that issue of what the experts have told you to expect, 1 to 3 percent, what experts specifically are you talking about?
MR. GULLIVER:
A. Well, I think we've seen through literature, through literature researches -
MS. NEWBURY:
Q. I'm just wondering what your understanding at the time. I know there's a lot of information from the literature, but prior to, say, the inquiry and all of the evidence that came out there, what was your understanding from 2005, 2006, early 2007, as to what experts - which experts would have expected very rare or 1 to 3 percent?
MR. GULLIVER:
A. I spoke to an expert who's involved with the class action, so I can't really disclose anything there.
MS. NEWBURY:
Q. Okay, I don't want to go there. Is there anyone else that you spoke to, any other - the reviewers that were here, or anyone that you

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might know through your association, any colleagues across the country?
MR. GULLIVER:
A. I'm just thinking in general within the lab profession that, you know, false positives is not something that you see.
MS. NEWBURY:
Q. That you're not supposed to see?
MR. GULLIVER:
A. It's very rare.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. Very rare.
MS. NEWBURY:
Q. And if it turns out that there are more instances of that, of retro conversions, which contradicts what's expected by the literature and by the experts, would that cause you a concern?
MR. GULLIVER:
A. Certainly would. As I mentioned earlier - I think what you need to be concerned with is what is the reason for a false positive, why was something called positive originally and

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now why is it retesting and there's no staining.
MS. NEWBURY:
Q. And what are the things that you would look for to try to ascertain what the reasons are for false positives?
MR. GULLIVER:
A. I think there's two things you would have to look at; was the actual test procedure - you know, was the antibody being used - was it being used too strongly, therefore, you're giving an awful lot of background staining that could be misread.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. Or is it simply that the pathologist who read the original slide misinterpreted plasmic staining for nuclear staining and called it positive.
MS. NEWBURY:
Q. Are you aware of any other possible causes, such as over antigen retrieval?
MR. GULLIVER:
A. I would think that's the two main - the two

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main causes.
MS. NEWBURY:
Q. Dr. Laing gave some evidence on her knowledge of the data relating to the retro conversions, and she was shown two particular lists that contained some information about original results and retest results. If I could bring up Exhibit 1373, please.
THE COMMISSIONER:
Q. What was that number, please?
MS. NEWBURY:
Q. 1373, please. So this was a list, and you're neither the sender nor recipient of this document. It's called "Retro List", and it was sent from Heather Predham to Dr. Denic and Kara is referenced, Kara Laing is referenced in the body of the e-mail here, and attached to that are lists of several original and Mount Sinai retest results. Are you familiar with the information in that chart that's shown there?
MR. GULLIVER:
A. I'm not, no.
MS. NEWBURY:
Q. You're not.

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MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. Okay, so you don't recognize anything about that particular group, not the e-mail itself because I know that you weren't a recipient of that?
MR. GULLIVER:
A. Not that group as a group. You know, individually, if these patients were - if Heather came across these patients, you know, she may ask me to do some further documentation to ensure the Meditech system, that what the original results were and those kinds of things, but I've not been involved in this small list of patients here, Ms. Newbury.
MS. NEWBURY:
Q. Okay, and there's a larger list which contains this information and some additional information at Exhibit P-2642, and this was from Heather Predham to Dr. Denic, and Dr. Laing was familiar with this as well, and attached - I wonder if we can reverse the orientation. There we go. Are you familiar with the information in this?

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MR. GULLIVER:
A. I'm not, no.
MS. NEWBURY:
Q. Okay, and in terms of - you indicated that there were initially four retro converters that you were aware of, and you still think that there's a documented group of fewer than ten?
MR. GULLIVER:
A. That's to the best of my knowledge.
MS. NEWBURY:
Q. That's your best guesstimate.
MR. GULLIVER:
A. Yes.
MS. NEWBURY:
Q. You don't have a -
MR. GULLIVER:
A. I know it's not 50, 60, 70, or 100, you know, it's in that number range.
MS. NEWBURY:
Q. And how is retro converter defined in terms of coming up with that particular figure, the four or whatever figure now, less than 10 percent?
MR. GULLIVER:

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A. I don't - and I even hate the term "retro converter".
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. Whoever invented that term internally -
MS. NEWBURY:
Q. I think someone at Eastern Health can take credit for that.
MR. GULLIVER:
A. I know they did - as a retro converter, you know, a patient converted.
MS. NEWBURY:
Q. Right.
MR. GULLIVER:
A. Whether it was from positive to negative or negative to positive.
MS. NEWBURY:
Q. And I think the purpose was to try to distinguish.
MR. GULLIVER:
A. To try to distinguish that these are patients who originally -
MS. NEWBURY:
Q. For simplicity sake.

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MR. GULLIVER:
A. Yeah.
MS. NEWBURY:
Q. I guess you can call it false positives as well.
MR. GULLIVER:
A. Yeah.
MS. NEWBURY:
Q. Do you know of that collection of four or whatever number it is less than ten now that it might be, would that include the results of a specimen for a deceased patient whose results changed?
MR. GULLIVER:
A. I'm assuming it would because we've had all the deceased patients now retested.
MS. NEWBURY:
Q. Okay, but in terms of the -
MR. GULLIVER:
A. But the original four, by that time we had not retested the deceased patients because the original four I knew by, I would say, sometime in '07, and I think those four were documented before the deceased patients were sent off for retesting.

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MS. NEWBURY:
Q. It was Ms. Pilgrim's evidence just in the last couple of weeks, I think, late September, early October, that she's now aware of four retro converters. Are you - would that be something that's consistent with your understanding or not, based perhaps on new information about the results -
MR. GULLIVER:
A. I knew some time in '07, again through the other process.
MS. NEWBURY:
Q. Yeah. This has nothing to do with what you were doing on a day to day basis?
MR. GULLIVER:
A. Right.
MS. NEWBURY:
Q. Coming up with these figures.
MR. GULLIVER:
A. Right.
MS. NEWBURY:
Q. So you heard the number from someone?
MR. GULLIVER:
A. Yes.
MS. NEWBURY:

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Q. But you don't know for sure how that number was derived by the person using the figure, whether they included the deceased patients or not?
MR. GULLIVER:
A. When I first heard the four, I heard it from somebody on the class action side of it, so I, you know -
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. But after that number is when we sent off the deceased patients for retesting.
MS. NEWBURY:
Q. So if the official number now is still four, do you know if that would include the results of deceased patients or not?
MR. GULLIVER:
A. I don't know if the official number - what the official number is.
MS. NEWBURY:
Q. And would the figure for the number of retro conversions of a test result include a situation where there was a change from a positive result to a negative result, but

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there was no recommended treatment change by a physician or the review panel?
MR. GULLIVER:
A. I wouldn't know that.
MS. NEWBURY:
Q. Okay, and do you know if a retro conversion would include a situation where you have an ER negative/PR positive test result, but upon retesting it was determined to be ER and PR negative, would that be included in the group of retro converters?
MR. GULLIVER:
A. I don't think so.
MS. NEWBURY:
Q. And why is that?
MR. GULLIVER:
A. Because I think the focus was more on the ER.
MS. NEWBURY:
Q. Okay. From your perspective, and keeping in mind that the oncologists involved are probably focused on trying to find out whether or not there should be a change of treatment for patients who are now living, but your perspective is different, I take it, as the director of the laboratory medicine program,

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you're dealing with the day to day events happening in the lab -

MR. GULLIVER:

A. You mean during '05?

MS. NEWBURY:

Q. Any time, 2005, 2006, 2007, today?

MR. GULLIVER:

A. My perspective is different how?

MS. NEWBURY:

Q. Your focus is broader, I would assume, than on just whether or not a living patient needs a change of treatment?

MR. GULLIVER:

A. I don't get what you want to ask me.

MS. NEWBURY:

Q. Let me ask the question another way. Would it be of interest to you that a specimen for a deceased patient changed from a positive result to a negative result?

MR. GULLIVER:

A. It certainly would be of interest to me, but I think it would be more important to the oncologist.

MS. NEWBURY:

Q. And why is it more important to the

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oncologist?

MR. GULLIVER:

A. Well, I think the oncologist would like to know that if they had a patient that they were treating for a various number of years, and now they discover that patient retested negative, you know, and that patient probably should not have been on hormone therapy.

MS. NEWBURY:

Q. And how about a retro conversion of a test result where ultimately there was no recommended treatment change by either a physician or the physician review panel. So there was a positive test result, say, 30/40 and it changed to 0/0, but fortunately for whatever reason the patient had received the correct treatment from the outset based on the results being 0/0.

MR. GULLIVER:

A. So they didn't get hormone therapy?

MS. NEWBURY:

Q. Right. Is that of interest to you as the director of the laboratory medicine program?

MR. GULLIVER:

A. I think - yes, it would be.

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MS. NEWBURY:

Q. Okay.

MR. GULLIVER:

A. Anybody involved in this.

MS. NEWBURY:

Q. And if a test result was originally ER negative and PR positive, but that converts to 0/0, is that of interest to you as the director of the laboratory medicine program?

MR. GULLIVER:

A. Again anybody who's involved in this, those would be of interest to us, yes.

MS. NEWBURY:

Q. And your particular interest would be to do what? How is that of interest to you?

MR. GULLIVER:

A. Well, I think it's - through all this here, I think it's also an interest in to look at individual cases.

MS. NEWBURY:

Q. But in terms of assessing potential problem areas or quality areas in the laboratory medicine program, would it be of interest to you to gather up and add up the numbers into those categories?

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MR. GULLIVER:

A. It would give us statistics, add up those categories, and compare them to what you would expect in the literature or expect in the world now.

MS. NEWBURY:

Q. Okay, and you've had no reason to date to compile such a list that would include retro conversions for deceased patients or patients -

MR. GULLIVER:

A. I haven't, no.

MS. NEWBURY:

Q. Do you have any plans to do that?

MR. GULLIVER:

A. I don't think I do individually, but I think that once this piece of the inquiry is over, you know, as you heard Ms. Pilgrim testify, Eastern Health, I think, will be able to start focusing on reviewing the events of the past three years.

MS. NEWBURY:

Q. Okay. Dr. Laing was asked about some information about retro conversions that were not on those two lists that I showed you, 1373

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and 2642, and the information is contained in a document P-0720. This is an e-mail. Again you did not - you're not named here as a recipient of the e-mail, and it is information that was provided to Mark Quinn following a request for information, access to information request, and it contains several - quite a number of pages of information by columns indicating the original ER, the original PR, the Mount Sinai ER, and the Mount Sinai PR. Are you generally familiar with the layout of this, the data contained -

MR. GULLIVER:

A. Not really, no, no.

MS. NEWBURY:

Q. Did you ever do a similar analysis of comparing the original test results, whether they were positive, negative, with the Mount Sinai test results?

MR. GULLIVER:

A. In -

MS. NEWBURY:

Q. In an organized fashion like this prior to the NLCHI involvement?

MR. GULLIVER:

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A. Prior to NLCHI, no.

MS. NEWBURY:

Q. And why is that?

MR. GULLIVER:

A. I just didn't have time.

MS. NEWBURY:

Q. Did you think it was important and didn't have time?

MR. GULLIVER:

A. I knew that, you know, NLCHI was coming in, it started in July '07.

MS. NEWBURY:

Q. But prior to that, you had no knowledge that NLCHI would be involved until, I think, somewhere around June or July of 2007.

MR. GULLIVER:

A. Certainly prior to that time, I had interest in things like, well, of the totals that were retested, you know, how many - how many came back with a changed result. I would have interest in the origin of the original specimen.

MS. NEWBURY:

Q. Uh-hm.

MR. GULLIVER:

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A. Was it a specimen that originated in St. Clare's, Health Sciences, Corner Brook. I would have interest in the total numbers that were sent off from the nine different pathology labs in the province. I would have interest in, you know, pathologists or groups of pathologists -

MS. NEWBURY:

Q. Right.

MR. GULLIVER:

A. Who may be interpreting them.

MS. NEWBURY:

Q. And year by year analysis, would that be of interest to you?

MR. GULLIVER:

A. Yes, it would be.

MS. NEWBURY:

Q. Yeah.

MR. GULLIVER:

A. But that's certainly something that by July '07, you know, we just did not have the time or the resources to be able to start doing that, and, you know, when NLCHI then was seconded and we knew that would be a piece of the outcome from NLCHI.

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MS. NEWBURY:

Q. Did you ever express that view to anyone else that this will be a worthwhile exercise?

MR. GULLIVER:

A. I certainly have, yes.

MS. NEWBURY:

Q. And to whom did you express that?

MR. GULLIVER:

A. I think in general to again the same people that you've heard over and over who were actively involved in this here. Again they're all in the same boat that I was in, you know, you're doing this - this file along with the rest of your job. I think that it's something that Eastern Health had talked about, you know, talking about engaging, like, even researchers to do some kind of analysis and summary of all this here.

MS. NEWBURY:

Q. But even something less sophisticated than having perhaps statisticians or epidemiologists involved, just for your own review - you don't think you had any time just to add to your tables. You already had tables, I think, by year that you and Mr. Dyer

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prepared, just to add in the results for the Mount Sinai ER and PR?
MR. GULLIVER:
A. I know, but that would have meant reviewing another thousand patients and then reviewing them and putting them into specific categories. So it's a patient from Western Memorial, Gander, Grand Falls, Carbonear, Clarenville, Health Sciences, Grace, St. Clare's, St. Anthony. There would have been another table then which pathologist did the original interpretation, you know, the time frame that the testing was done, broken down by year, so it's -
MS. NEWBURY:
Q. Now a couple of those categories -
MR. GULLIVER:
A. It's a significant amount of work.
MS. NEWBURY:
Q. Yes, no doubt it will be, but a couple of those tables already existed by year and by region, isn't that correct?
MR. GULLIVER:
A. Not - only in numbers, but not broken down by patient results.

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MS. NEWBURY:
Q. Okay, so you didn't have separate tables -
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. For sending off for retesting purposes? I had understood that that was -
MR. GULLIVER:
A. No, no, we had - for the regions, yes.
MS. NEWBURY:
Q. Yes, for the regions.
MR. GULLIVER:
A. Yes.
MS. NEWBURY:
Q. Okay, and how about St. John's, would you have -
MR. GULLIVER:
A. And for St. John's, they were for St. John's patients.
MS. NEWBURY:
Q. Okay, and that wasn't broken down by year, was it?
MR. GULLIVER:
A. It was broken down by year, and then you could go to the spreadsheet to see what the original

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site, like, where the patient had their primary surgery.
MS. NEWBURY:
Q. Okay, but at the very least you did have some tables, not as organized or sophisticated -
MR. GULLIVER:
A. Yes.
MS. NEWBURY:
Q. As having pathologists or sites in St. John's even, but you did have some tables there?
MR. GULLIVER:
A. Some.
MS. NEWBURY:
Q. Now, Mr. Gulliver, there's some information here on Exhibit 720 which is something that you're not familiar with, but I wanted to bring to your attention some results here, and line 20 has two entries, which I assume would be for the same patient, although I'm really not sure, and one of the results was a negative ER, 75 PR, and retesting it went to 2 and 0, and I couldn't locate that on either P-2642 or 1373, which were the lists that Dr. Laing was aware of.
MR. GULLIVER:

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A. Okay.
MS. NEWBURY:
Q. And would you have any explanation for why that would not be on her lists?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. Were you even aware of this type of a result, this particular - did anyone ever bring to your attention, gee, this is unusual, we have a result that was negative for ER, 75 for PR, and then it converted to 2 and 0?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. No one ever brought that to your attention?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. Line 61, we have a result - again there are several entries there, but the third line for 61 -
MR. GULLIVER:
A. And I'm thinking - this must be the same patient retested more than once or more than

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one block, I'm assuming.
MS. NEWBURY:
Q. Yeah, unfortunately there's not - this was done for Mr. Quinn, so it's not as elaborate as having surgical numbers.
MR. GULLIVER:
A. Yeah.
MS. NEWBURY:
Q. Those types of information. So this is - or even whether this was done over several. Unfortunately, that information is not there, but the third line for 61, we've got a 0 ER, 50/60 PR, 0 and 0, and I couldn't locate that on the table that Dr. Laing was working with.
MR. GULLIVER:
A. And again I wouldn't know.
MS. NEWBURY:
Q. And no one ever brought that to your attention?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. Would that have been of interest to you?
MR. GULLIVER:
A. This particular case, or do you mean in

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general?
MS. NEWBURY:
Q. Just the very fact that you've got that conversion. I mean, you've indicated that it was your understanding that a conversion from a positive result to a negative result would be very rare. Was there ever any understanding that it would be different for PR?
MR. GULLIVER:
A. Well, and again I think, you know, we were told by the oncologists that the ER was the more critical one to focus on.
MS. NEWBURY:
Q. Do you know whether or not they would have treated a patient who was -
MR. GULLIVER:
A. I don't know that. I mean -
MS. NEWBURY:
Q. And just in terms of the - and again there is some evidence that they did, in fact, treat these patients as positive. That was a general practice.
MR. GULLIVER:
A. You mean if they were ER negative, PR

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positive?
MS. NEWBURY:
Q. Yes.
MR. GULLIVER:
A. I don't know if that was - I think you heard individual oncologists apply that differently.
MS. NEWBURY:
Q. I think the evidence of Dr. McCarthy, that was a prevalent practice, and she's been here, that she was aware of anyway. So certainly some did, if not all. And that was never ever brought to your attention at any time throughout this process or is that--did you just hear that for the first time after the Inquiry started?
MR. GULLIVER:
A. Hear what? That something was a zero ER and positive PR -
MS. NEWBURY:
Q. Yes.
MR. GULLIVER:
A. - and then was a zero, zero?
MS. NEWBURY:
Q. And then a patient who's a zero ER but a positive PR might be treated with hormone

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therapy?
MR. GULLIVER:
A. Oh no, I heard that before the Inquiry started.
MS. NEWBURY:
Q. Oh, okay. So you were aware of that.
MR. GULLIVER:
A. At some meeting where we were there with the oncologists.
MS. NEWBURY:
Q. Okay, I had misunderstood when you said that.
MR. GULLIVER:
A. I even heard--I heard Dr. Kwan say that people who were zero, zero, he treated them with hormone therapy. He looked at the clinical--the age of the woman, the clinical history. So he stated that early on.
MS. NEWBURY:
Q. Right, but did he make any comment about how common it was for oncologists to treat -
MR. GULLIVER:
A. He did not say that, no.
MS. NEWBURY:
Q. Okay. Would it concern you that you've got conversions? Like today, if you went into

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your lab and you were told by Mr. Dyer that "well, we've got this result." It was zero ER, 50-60 PR and the patient requested a retest or the pathologist or oncologist requested a repeat and now the results are zero, zero. What would you do if you encountered that?

MR. GULLIVER:

A. Would it concern me today?

MS. NEWBURY:

Q. Yes.

MR. GULLIVER:

A. Certainly would.

MS. NEWBURY:

Q. Okay, and would it have concerned you in 2005 or 2006?

MR. GULLIVER:

A. Well, certainly it would, yes.

MS. NEWBURY:

Q. Okay, and do you know if anyone else within your lab would also be cognizant of that as a concern, Mr. Dyer or the other lab technologists?

MR. GULLIVER:

A. Well, I think Dr. Ford Elms, the director of

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the lab, would be the main concern.

MS. NEWBURY:

Q. Okay. So if you came across a result like that now, you would bring it to Dr. Elms' attention?

MR. GULLIVER:

A. Well, I wouldn't come across a result like that. I mean -

MS. NEWBURY:

Q. Well, what if you happened to, for some reason? If Mr. Dyer -

MR. GULLIVER:

A. Well, I would bring it to Dr. Denic, the clinical chief.

MS. NEWBURY:

Q. Okay, and he would bring it to Dr. Elms?

MR. GULLIVER:

A. Yes, or to Ford, either, whoever I could get hold of first.

MS. NEWBURY:

Q. Okay.

MR. GULLIVER:

A. Pretty well.

MS. NEWBURY:

Q. And there are a number of others, I'm not

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going to bring you through all of them. Now we have a result here, line 717, negative for ER, greater than 60 for PR and zero, zero for the Mount Sinai retest results.

MR. GULLIVER:

A. You know, and again, I mean, I haven't seen this here, in this--you know, like this here laid out.

MS. NEWBURY:

Q. Sure, and then we've got another one, line 767, negative, 40-50 for PR and then zero, zero for ER and PR upon retesting, and 827, we've got one entry, negative for ER, 60-70 for PR, and then we have zero and zero for retesting, and now these are separate and above from those that are acknowledged to be retro converters on the list that Dr. Laing had seen. So is this new information for you today? Did you have any idea that there is other information out there which suggests that there's been a retro conversion? And I don't think there's an explanation for that.

MR. GULLIVER:

A. I think they based the retro conversion based upon the negative ER.

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MS. NEWBURY:

Q. Okay. So if there's a conversion from a PR result to a ER negative result -

MR. GULLIVER:

A. I don't think they call that a retro converter. I can't be 100 percent sure. Again, you know, Ms. Predham was involved with this here with the oncologists and you know, she would be the more accurate person to answer that.

MS. NEWBURY:

Q. And I believe if we go to--if we could bring up 1373 again, please? Now this list actually has a couple of instances there where there's a negative result for ER and a 50-60 for PR. So they do appear to be, and I think it's consistent with Dr. Laing's testimony, that that would be considered a retro converter.

MR. GULLIVER:

A. Again, I can't answer that question.

MS. NEWBURY:

Q. So there's no sort of--you're not on the same page here with the oncologists, are you?

MR. GULLIVER:

A. No.

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MS. NEWBURY:
Q. In terms of what would be considered a retro converter?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. And no one has ever brought to your attention that there's a potential issue here with PRs that are converting to zeros?
MR. GULLIVER:
A. No.
THE COMMISSIONER:
Q. Ms. Newbury, it's around the time for the morning break (inaudible).
MS. NEWBURY:
Q. Okay. Well, this is probably a good place to break.
THE COMMISSIONER:
Q. All right. We'll take the morning break.
(BREAK)
THE COMMISSIONER:
Q. Please be seated. Ms. Newbury.
MS. NEWBURY:
Q. Mr. Gulliver, I just showed you a few entries in the data that was given to Mark Quinn at P-

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0720, please, and you indicated that those were--you noted that those were PR conversions. They weren't ER conversions, and perhaps that may have been a reason why it wasn't brought to your attention. Is that -
MR. GULLIVER:
A. Quite possible, yes.
MS. NEWBURY:
Q. Okay. There are some other retro conversions that are not on either of Dr. Laing's lists that she was familiar with, the two that I showed you just before the break. If we go to line 132 of Exhibit P-0720? We have an entry, line 132, original ER and PR ten and ten and Mount Sinai zero and zero, and there are several other similar entries. 239, we've got a ten ten and zero zero, and the same thing at line 413. Actually, there is a ten, ten and less than one and zero, upon retesting. And line 804, we have ten ten going to zero zero, line 804. Also, line 778, there's a 10 to 20 for ER and 40 to 50 for PR and that converts to zero, zero. And line 520, there is a result 40 for ER, zero for PR and that converts to five and zero. And line 615,

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that's a 20 for ER, zero for PR and then zero, zero upon retesting at Mount Sinai, and then back at the beginning of the document, line 68, we have a 20 ER, zero PR and that converts to zero, zero upon retesting at Mount Sinai.
These numbers that I've just shown you, on the longer of the two exhibits that I showed to you this morning that Dr. Laing was familiar with, there was one instance of a ten, ten converting to zero, zero. There was only one instance of that, whereas in this document here, there are a total of four, and the other conversions that I just showed you, the 40, zero to five, zero, 10-20, 40-50 to zero, zero, 20 zero to zero, zero, two instances of those, they were not on the list that Dr. Laing had been shown and was familiar with.
So there appears to be here, in addition to the PR retro conversions, a number of other ER retro conversions. That would be, you know, what you might glean from the numbers there, and are you familiar with all of these different instances of apparent retro conversions?

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MR. GULLIVER:
A. Not individually, but I think first of all, you have to ask what were the oncologists and Ms. Predham's definition of a retro converter, and to my knowledge, they categorize people as a retro converter as people who had a treatment change in reverse.
MS. NEWBURY:
Q. Right, so they had been given hormone therapy and perhaps they ought not to have -
MR. GULLIVER:
A. Based upon the original test results, and what -
MS. NEWBURY:
Q. Now before the break--sorry, before the break, you weren't aware of that. I had asked you that question. Is that something that you learned in between or -
MR. GULLIVER:
A. You asked me what--sorry?
MS. NEWBURY:
Q. I had asked you if you understood what their definition was of retro conversion.
MR. GULLIVER:
A. I don't remember you asking me that question.

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MS. NEWBURY:
Q. Okay. So is that something that just came to your mind then, that that's what they would have included as a retro conversion?
MR. GULLIVER:
A. To my knowledge, that's what they were--the retro conversions were based upon treatment, but all what you showed--what we're not seeing here though in this table, Ms. Newbury, is the ones that you're highlighting certainly on paper could look like it was ten and ten and came back zero and zero, and why was not that considered a retro converter. What we're missing here is the time frame of the original test. I'm assuming that most, as you've shown me, ten, ten, zero, zero, were probably done in the '97 to 2000 time frame where the treatment side was--it was less than 30 they considered as negative and didn't offer treatment. But on a retesting, it came back ten, ten, zero, zero, so it probably didn't effect a treatment change.
MS. NEWBURY:
Q. So that's a possible explanation, but do you actually know that that's the case?

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MR. GULLIVER:
A. I can't tell you 100 percent, no, but I mean, that's from--you're asking me my opinion and that's the best opinion I can give you.
MS. NEWBURY:
Q. Okay, and it is your understanding that the treatment--whether or not there was a change of treatment is what would determine who would be placed on the list of retro conversions?
MR. GULLIVER:
A. To the best of my knowledge, yes.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. Again, you know, Ms. Predham, who is up after me, would be probably the best person to ask that question.
MS. NEWBURY:
Q. From your own perspective, considering that you're the director of Laboratory Medicine, and recognizing that the standards have changed over the years, that a ten now is typically treated as positive--that's evidence that we've heard from any oncologist, in fact sometimes less than that--is it of interest to

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you to get to the root of that problem, to find out why are there conversions from ten to zero? Whether it's a zero ten to a zero, zero or a ten, ten to zero, zero.
MR. GULLIVER:
A. Well, again, I think you've heard it could be multiple factors that could be involved in a reason for a change like that.
MS. NEWBURY:
Q. Yes, and I'm wondering if you're interested in finding out what those multiple factors are in these particular instances.
MR. GULLIVER:
A. I'll have to say yes.
MS. NEWBURY:
Q. Okay, and given that Ms. Predham might have been focused on the actual treatment, in terms of her role there, do you see that your interest might be a little broader than that? Your interest might be more on what does this tell us mechanically about what's happening or technically in the lab from a day-to-day basis?
MR. GULLIVER:
A. Well, I think both technically and from a

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pathologist's perspective also. I mean, the lab is just not the pathologists or just the technologists. I mean, it's a group effort.
MS. NEWBURY:
Q. Okay, and in light of these various numbers that I've shown you and regardless of whether there's a change of treatment, from your perspective, would you still say that there are only four or fewer than ten retro conversions? Do you have any--has this cast any doubt on your conclusion about that?
MR. GULLIVER:
A. I don't think so. I think that, again, the best of my knowledge that there's been a few number of patients who were on hormone therapy. On retesting they had to come off hormone therapy.
MS. NEWBURY:
Q. Okay. So in your mind, not just in Ms. Predham's mind, but in your mind, if a person was not initially treated with hormone therapy, whether it was 1998 or 2002, even if their results ended up, upon retesting, being a zero, zero result, you do not consider that a retro conversion?

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MR. GULLIVER:
A. So originally, what was the original result?
MS. NEWBURY:
Q. Well, I've shown you a number. You've got a negative ER, 40-50 PR.
MR. GULLIVER:
A. And that patient -
MS. NEWBURY:
Q. Going to zero, zero.
MR. GULLIVER:
A. And the patient was not treated, based upon that?
MS. NEWBURY:
Q. Well, I have no idea. I'm just wondering, from your perspective, would you consider that to be a retro conversion or would you need to know whether that person was initially treated or not?
MR. GULLIVER:
A. I think you'd need to know what the treatment was also.
MS. NEWBURY:
Q. And say if you have a 40 ER and a zero PR converting to five and zero.
MR. GULLIVER:

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A. I would call that a retro converter, in my lingo. But then you'd need to know how the patient was affected by it.
MS. NEWBURY:
Q. Okay, and say a patient was determined to be ten ER and ten PR in 2004, which is well after the change in cut off, would you consider that to be a retro conversion or would you need to know whether or not there's been a change of treatment?
MR. GULLIVER:
A. In 2004, the patient was originally tested ten, ten and then retested zero, zero?
MS. NEWBURY:
Q. Converts to zero, zero, and I don't have any idea because I don't have information about when these were done, but say that happened.
MR. GULLIVER:
A. And I can't--I can't say at all because I don't have it either.
MS. NEWBURY:
Q. No, and you haven't compiled your own list of that?
MR. GULLIVER:
A. No, no.

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MS. NEWBURY:
Q. Okay. But would you consider at ten, ten converting to zero, zero, if it happened in 2004, as an example, after the change of cut off, would you consider that to be retro conversion?
MR. GULLIVER:
A. I would consider it to be a false positive.
MS. NEWBURY:
Q. A false positive, okay.
MR. GULLIVER:
A. Whether it affected a patient treatment, I wouldn't know.
MS. NEWBURY:
Q. Okay. So that's--those are two separate issues?
MR. GULLIVER:
A. Yeah.
MS. NEWBURY:
Q. So, and you've mentioned earlier that you don't like the term retro conversion. Let me ask this question. If all of those numbers--would you consider those to be all false positives, the ones that I showed you? I mean, just looking at the numbers. Perhaps

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there's a typographical error there, but if those numbers are accurate, would you consider those to be false positives?
MR. GULLIVER:
A. So you're saying the one that, for example, that you see number 70 or something, it was ten, ten and was zero, zero?
MS. NEWBURY:
Q. Ten, ten, zero, zero or -
MR. GULLIVER:
A. Would I consider it to be a false positive?
MS. NEWBURY:
Q. Yes.
MR. GULLIVER:
A. I would have to say yes.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. But then, you'd need to know why was it -
MS. NEWBURY:
Q. I understand. I'm focusing, I guess, on your perspective. Whether or not it impacted a patient's treatment, that would be another issue.
MR. GULLIVER:

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A. Right.
MS. NEWBURY:
Q. But I'm focusing on your role, running a lab, the director of lab -
MR. GULLIVER:
A. From a lab perspective, I would have to consider that to be a false positive.
MS. NEWBURY:
Q. Okay, and how about negative 75 and converting to two, zero? Would you consider that to be a false positive?
MR. GULLIVER:
A. Negative and 75 for PR?
MS. NEWBURY:
Q. Yes.
MR. GULLIVER:
A. And on retesting it's two percent?
MS. NEWBURY:
Q. And zero.
MR. GULLIVER:
A. And zero percent?
MS. NEWBURY:
Q. Yes.
MR. GULLIVER:
A. That would be--again, that's one of those grey

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ones.
MS. NEWBURY:
Q. Okay, and is that because the two is not zero?
MR. GULLIVER:
A. I don't know.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. You know, two percent.
MS. NEWBURY:
Q. Okay. So zero ER and 50 to 60 PR converting to zero, zero?
MR. GULLIVER:
A. I would have to say it's a false positive.
MS. NEWBURY:
Q. False positive, okay. So perhaps there's a difference in terminology between what Ms. Predham is using and others are using.
MR. GULLIVER:
A. It could be, yeah.
MS. NEWBURY:
Q. Refer to retro conversion, you prefer the term false positive?
MR. GULLIVER:
A. Yes, yeah.

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MS. NEWBURY:
Q. Okay. So looking at the two lists that Dr. Laing was familiar with, as well as the information that I read out to you this morning, there would appear to be a number of false positives there, and a greater number than for retro conversions.
MR. GULLIVER:
A. I would have to say yes.
MS. NEWBURY:
Q. Okay, and is that of any concern to you?
MR. GULLIVER:
A. I think it only--it becomes a concern when you know how is the patient affected or how is the treatment, based upon that.
MS. NEWBURY:
Q. Is it a concern that you're having such a high frequency of these false positives, from a technical perspective?
MR. GULLIVER:
A. Again, I have not yet seen a full review of all the testing to be able to tell us this was the number of cases that tested false positive.
MS. NEWBURY:

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Q. Okay. So you can't rule out whether or not there is a concern, but you can't say there is one?
MR. GULLIVER:
A. I can't say that there is one or I can't say there is not one.
MS. NEWBURY:
Q. And that's primarily because you haven't actually seen the full list of false positives?
MR. GULLIVER:
A. Right.
MS. NEWBURY:
Q. Do you know if Dr. Denic would be aware of the number of false positives?
MR. GULLIVER:
A. I don't know.
MS. NEWBURY:
Q. And his evidence was that he had reviewed four slides that were from the retro converters and perhaps he was using the term in the same way that you were. Were you aware of Dr. Denic conducting a review of any other of these false positives that may not be--may not have had an impact on patient treatment?

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MR. GULLIVER:
A. No, I'm not.
MS. NEWBURY:
Q. Okay. If Dr. Laing was not actually aware of the frequency of the false positives here, and if she were focusing, for example, on retro conversions or false positives that had an impact upon patient treatment, for example, of patients who were living as opposed to any deceased patients, would it be of concern to you that you're relying upon oncologists to say "oh, there's no concern with the positive test results"? That perhaps she didn't have a full picture of what was going on in the lab?
MR. GULLIVER:
A. Again, I don't know what Dr. Laing's full picture is or isn't.
MS. NEWBURY:
Q. Okay, and to this day, you don't know what her understanding was?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. And is that of a concern to you, that you don't know what information Dr. Laing had?

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You're relying upon her to say whether there is or is not a concern, but you don't know what -
MR. GULLIVER:
A. I'm just relying upon her and her oncologists.
MS. NEWBURY:
Q. Right.
MR. GULLIVER:
A. And it's not just myself, it's the whole laboratory and Eastern Health, that you know, when the oncologists say that they don't have--they have very little concern, no concern about the patients who originally tested positive, you know, I have to take them for their opinion.
MS. NEWBURY:
Q. Right, but when they did come across false positives for patients that were living, I believe it was her evidence that they would refer them to a panel and in some instances, if there was--if they have been treated with hormone therapy from the beginning, they would be taken off that hormone therapy. So it seems that that would be a concern if that were to occur?

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MR. GULLIVER:
A. Yes.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. And to date, as far as I know, again I'll tell you that to verify that, you know, those numbers have been very, very small.
MS. NEWBURY:
Q. Right, but you don't know though how many numbers of false positives there are in total and how many of them have been reviewed by the oncologists? I mean, Dr. Laing, I've showed you -
MR. GULLIVER:
A. I don't know the full total number, no.
MS. NEWBURY:
Q. Right, and I've showed you a number of bits of data that Dr. Laing wasn't familiar with. She was familiar with two lists of retro converters and she had some recollection of having some of those panelled, but she wasn't able to explain a number of these other entries from Exhibit P-0720.
MR. GULLIVER:

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A. And I can't explain them either.
MS. NEWBURY:
Q. Mr. Gulliver, in your e-mail to Reza on July 24th, 2007, in which you summarize the guidelines and the process used to select patients for retesting, you stated at the end of the document--I could bring this up for your information, P-2129 please? Okay, this is the document. I think you were shown this yesterday. It's July 24th, 2007, and I wanted to refer you to the end of the document here, item ten, and then the last paragraph. It states that "once results started to come back, they were reviewed by our pathologists and then the new results from Mount Sinai were added to the patient's original report in our LIS Meditech system, and a new report generated with both the original and new results. Barry and I had very little involvement after results came back. The pathologists, oncologists, QI department, communications department, handles this phase of the process."
Mr. Gulliver, was that division of duties and I guess your lack of involvement after the

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results came back, was that something that was, you know, by design? Was there a meeting to discuss the allocation of who does what when the results come back?

MR. GULLIVER:

A. I don't think there was a--there was no meeting. I think it just evolved.

MS. NEWBURY:

Q. Okay.

MR. GULLIVER:

A. Again, what I'm indicating there, once the results came back and were verified, the laboratory's responsibility, particularly mine and Mr. Dyer's and the staff, was to ensure that the new results were put into the computer system so it's documented and recorded. The last piece here for Reza is talking about then the implications of those new results. That was dealt with by those people, either the oncologists in speaking to patients or assessing treatment or the QI department, communications in the patient disclosure, contacting patients and that whole piece of it.

MS. NEWBURY:

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Q. And so in terms of the mechanics of you, of entering the results into the LIS Meditech system, who did that? Who sat down at the system and -

MR. GULLIVER:

A. Most often, early on, mostly it was Dr. Cook's secretary.

MS. NEWBURY:

Q. Okay.

MR. GULLIVER:

A. Who would input information. I know Mr. Dyer did some. I know Mary Butler, the senior tech, that was part of her role to ensure that new results would go into the computer system, that a new number was created to document receiving back from Mount Sinai and that reports were printed off by the secretary and then, you know, distributed.

MS. NEWBURY:

Q. So there's a combination of people involved with that?

MR. GULLIVER:

A. A combination, yes.

MS. NEWBURY:

Q. Was there any thought given to asking that

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person to also, aside from entering it into the Meditech system, adding it to the tables that you and Mr. Dyer had?

MR. GULLIVER:

A. No.

MS. NEWBURY:

Q. And why not?

MR. GULLIVER:

A. Well, what would enter in the table would be the actual results.

MS. NEWBURY:

Q. Yes.

MR. GULLIVER:

A. New results.

MS. NEWBURY:

Q. Yes.

MR. GULLIVER:

A. Dr. Cook was doing that piece of it. He was adding the results to -

MS. NEWBURY:

Q. To the Meditech?

MR. GULLIVER:

A. No, he was adding results to the spreadsheets, so he would know here are the results of the patients and he was tracking that there in

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conjunction with Heather Predham.

MS. NEWBURY:

Q. Okay, and was that side by side with the original results?

MR. GULLIVER:

A. In most cases, as far as I know, yes.

MS. NEWBURY:

Q. Okay, and have you seen those results?

MR. GULLIVER:

A. I have not seen a full list of them, no.

MS. NEWBURY:

Q. Okay, and is there any reason why you haven't?

MR. GULLIVER:

A. Nothing in particular.

MS. NEWBURY:

Q. Okay, and -

MR. GULLIVER:

A. That's been--was handled by the clinical side.

MS. NEWBURY:

Q. And what format was Dr. Cook using for those tables?

MR. GULLIVER:

A. The spreadsheets which I've shown that I've created.

MS. NEWBURY:

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Q. Okay, that you provided to him.
MR. GULLIVER:
A. They were copied and he had a copy of those, and there was a place on those spreadsheets left for the results from Mount Sinai to be entered in there.
MS. NEWBURY:
Q. Okay, and it's your understanding that those were all completed, were they?
MR. GULLIVER:
A. To the best of my knowledge.
MS. NEWBURY:
Q. Okay, and so earlier today, I was trying to find out if there had been a comparison done of the original and the Mount Sinai test results, and you thought it would be interesting to do, to have some information to look for trends perhaps in the years or the pathologists.
MR. GULLIVER:
A. But those spreadsheets doesn't have complete information.
MS. NEWBURY:
Q. No, what does it have?
MR. GULLIVER:

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A. Again, you've seen them. It has the basis patient demographic. It has the original result and that's all I had.
MS. NEWBURY:
Q. Okay. So it's not broken down by year?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. And you had some other sheets broken down by year and by region.
MR. GULLIVER:
A. No, no, the spreadsheets are broken down by year.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. But then on those spreadsheets, there is not documentation, complete documentation of what block was originally tested, what block was retested. You know, so it's not a complete-- it's not complete enough to do a full set of data analysis of them. I think we're at that point now with, you know, NLCHI being involved, that those are the kinds of things that we can now perform.

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MS. NEWBURY:
Q. And you never thought to ask Dr. Cook to have access to at least the incomplete documents that he had, just for some--to see if you can glean anything from that, for your perspective?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. Now Mr. Gulliver, as a program director for the laboratory medicine program, was there an opportunity for you to have input into decisions by Eastern Health about the retesting plan for the ER and PR issues, particularly as they might relate to the laboratory medicine program?
MR. GULLIVER:
A. I would say yes.
MS. NEWBURY:
Q. Okay. Were there ever any limits placed upon your participation or your input?
MR. GULLIVER:
A. I don't think I've seen a list of things that I can't do. I think we all accepted here's the piece of it that, you know, that I can

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help with or that I can do.
MS. NEWBURY:
Q. And so no one ever said, well, this is going to be your role and only your role and don't stray from that? You could have, if you wanted to, for example, suggest looking at PR retro conversions or doing an analysis of the results to compare, you know, what happened by pathologists or breaking down by pathologists or regions?
MR. GULLIVER:
A. But I think we're only at that point now that we can do that.
MS. NEWBURY:
Q. Okay, and is that something that you'd ever suggested before?
MR. GULLIVER:
A. Again, as I said to you earlier, that before NLCHI got involved, those are some of the basic things that we did talk about and some of the things that we could look back and review, and you know, who would we get to do this kind of analysis and kind of review and before, I think, there was any kind of decision made, you know, NLCHI then got

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involved and we all felt that once that exercise was completed, that Eastern Health would now be in a position to do some data analysis.

MS. NEWBURY:

Q. Okay, and is it your understanding that Eastern Health would intend to look at the retro conversions, whether they're PR retro conversions or retro conversions for deceased patients?

MR. GULLIVER:

A. I just think that they would look at retro conversions.

MS. NEWBURY:

Q. But retro conversions by Ms. Predham's definition or retro conversions or false positives?

MR. GULLIVER:

A. I don't know. I think that we would have to do both. In my opinion -

MS. NEWBURY:

Q. That's your opinion.

MR. GULLIVER:

A. - I think if the retro converters are being classified as that because they had a

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treatment change, that that's one piece, and I think I would be more interested in looking at a false positive rate.

MS. NEWBURY:

Q. Have you ever expressed that opinion to anyone before, within Eastern Health?

MR. GULLIVER:

A. I would say yes, yeah.

MS. NEWBURY:

Q. And do you know who and when?

MR. GULLIVER:

A. I don't know when. I think some of these things are, you know, we discuss on a regular basis. On a weekly basis, we have, you know, what we call our ER/PR meeting. Those kinds of things would come up.

MS. NEWBURY:

Q. Okay. Just a couple of documents I wanted to ask you to explain, if you can. P-3107, please? Okay, this is a document sent by you to Ms. Predham, January 28th, 2008, so earlier this year, and it attaches some ER/PR statistics, and in the top two headings there, you've got a heading for DAKO and a heading for Ventana. So would it be correct to assume

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that the information in this table here would be the rates prior to any retesting at Mount Sinai?

MR. GULLIVER:

A. Oh yes.

MS. NEWBURY:

Q. Okay, these haven't been readjusted?

MR. GULLIVER:

A. No.

MS. NEWBURY:

Q. Okay.

MR. GULLIVER:

A. This is an exercise that confirmed with Reza through NLCHI in all parts of this whole ER/PR testing to kind of finalize those numbers.

MS. NEWBURY:

Q. Okay, and has tried to make sure that the data is accurate essentially?

MR. GULLIVER:

A. Yeah.

MS. NEWBURY:

Q. Okay, and does this include only the non--does this include any non-breast primaries?

MR. GULLIVER:

A. I can't say 100 percent, but it's pretty well

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part of our exercise was to make sure we removed any of those non-breast primaries.

MS. NEWBURY:

Q. Okay. So the intention was not to include non-breast primaries in this table?

MR. GULLIVER:

A. Exactly, yeah.

MS. NEWBURY:

Q. And in this table, there's references to positive negative rates and got several categories here on the left-hand side, the left-hand column. When you're talking about positive here, are you referring to ER only? So would that include ER positive, PR positive, ER negative, PR--or ER positive, PR negative?

MR. GULLIVER:

A. If it--say it again.

MS. NEWBURY:

Q. Let's put it this way, if you had an ER negative, PR positive test -

MR. GULLIVER:

A. I would call that a weak positive.

MS. NEWBURY:

Q. That would be called a weak positive.

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MR. GULLIVER:
A. In that category, yes.
MS. NEWBURY:
Q. So that would all be -
MR. GULLIVER:
A. The ones where you see strong positive, all those would be a positive result for both ER and PR. The weak positives may have had, you know, a low positive for ER and it could be five percent ER, 90 percent PR. I would call that a weak positive.
MS. NEWBURY:
Q. Say you had, and I'll refer to a couple of the examples that I showed you earlier, a negative ER and a 40-50 PR or a negative ER and a 60-70 PR?
MR. GULLIVER:
A. That would be weak positive.
MS. NEWBURY:
Q. Okay. So even if the PR is quite high, if the ER is negative, you call it a weak -
MR. GULLIVER:
A. Right.
MS. NEWBURY:
Q. Okay, thank you.

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MR. GULLIVER:
A. Again, and this is just for an overview and assessment from a lab perspective that, you know, what percentage of cases had some degree of positivity reported on them.
MS. NEWBURY:
Q. Okay, and when you talk generally about your positivity rates, you've mentioned that you were interested in finding out what the positivity rates are for year to year, so that positivity rate would include ER negatives, PR positives?
MR. GULLIVER:
A. Yes.
MS. NEWBURY:
Q. Because you had categorized them as weak positives?
MR. GULLIVER:
A. Right.
MS. NEWBURY:
Q. Okay. Have you ever prepared a similar table that has the adjusted positivity rates?
MR. GULLIVER:
A. No.
MS. NEWBURY:

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Q. And looking at the results there for 2004, you have a positivity rate of 89 percent and then that's for the DAKO machine, so -
MR. GULLIVER:
A. Again, but that's just--that's for three months.
MS. NEWBURY:
Q. Right.
MR. GULLIVER:
A. January, February, March.
MS. NEWBURY:
Q. So it's a small sample size.
MR. GULLIVER:
A. Very small sample size.
MS. NEWBURY:
Q. And then you have the Ventana, you have 86 for all three or for two of those periods of time. So April 4th to March 5th, 2005.
MR. GULLIVER:
A. That's for like a year and three or four months under Ventana.
MS. NEWBURY:
Q. Okay. So it's 86 percent for those two years?
MR. GULLIVER:
A. And again, it's still not--still, I mean,

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that's one of the things too that we had talked about with doing all this exercise is that, you know, when you have such a small sample size, you know, five or six or seven or eight patients one way or the other, it could make a big difference in your percentages.
MS. NEWBURY:
Q. Sure. Do you have any idea how many would be in say that period, April '04 to March '05?
MR. GULLIVER:
A. April, it tells you right here.
MS. NEWBURY:
Q. It's 119 at--okay, 119. So you consider that too small -
MR. GULLIVER:
A. There's 139 with results. So the percentages you see below are based upon the ones we have documented results that we know we can categorize them as positive or negative, weak positive. So the sample size there was 139.
MS. NEWBURY:
Q. Oh yes, I see, it's a third.
MR. GULLIVER:
A. The total Ventana is 198.
MS. NEWBURY:

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Q. Okay.
MR. GULLIVER:
A. So when you see a positivity rate of 86 percent on 198, again, you change five or six patients and it could drop down to 80 percent.
MS. NEWBURY:
Q. Now 189 is a bit of a larger sample size though than some of the others, like the 42 for 2004 on DAKO is pretty small.
MR. GULLIVER:
A. And that's for the first three--the last three months of DAKO.
MS. NEWBURY:
Q. Until the Ventana was put in.
MR. GULLIVER:
A. First three months of the year, yes. But even if you see anything in any kind of like surveys, you know, really a sample size less than 400 is something that really could have a significant plus or minus.
MS. NEWBURY:
Q. So looking here though at the total test performed for each of those years, they're all less than 400.

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MR. GULLIVER:
A. With results.
MS. NEWBURY:
Q. With results. So are you saying that there's no information -
MR. GULLIVER:
A. With results, I mean, I don't know the numbers of positives and weak positive negatives that were interpreted outside St. John's. These are strictly for St. John's numbers.
MS. NEWBURY:
Q. Right, so the only information you have is about what happened in St. John's?
MR. GULLIVER:
A. Right.
MS. NEWBURY:
Q. But are you concerned though that they're all under 400, in terms of sample size?
MR. GULLIVER:
A. Well I think then that's why on the bottom you do sort of a total test with results that you look at, you know, the whole big picture. There are 1,529 St. John's patients with results documented and of that total, there were 77 percent reported with positive

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staining and 23 percent that were reported with negative staining.
MS. NEWBURY:
Q. But do you think there's any value in looking at this year by year? I guess the question is if you found a particularly high or a particularly low rate for positivity in any given year, you had a small sample size in any given year -
MR. GULLIVER:
A. Well, I can--I mentioned this the other day. If you look at this table and the two years that really would look at--well, accepting it at face value, the two years that you would look in here would be 2000 and 2002.
MS. NEWBURY:
Q. And that's because there are 68 and 70 -
MR. GULLIVER:
A. And you look at there, that's the highest years that we have the highest percentage of negatives, of zero, zeros.
MS. NEWBURY:
Q. Right, but do you still see value in looking at that on a year-by-year basis, notwithstanding your small sample size?

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MR. GULLIVER:
A. I think so, yes.
MS. NEWBURY:
Q. Okay, and looking at the Ventana results, and even the result for 2004, even though it's a small sample size, would that have to be adjusted to take into account your Mount Sinai retest results?
MR. GULLIVER:
A. Well, there's no retest results added in here.
MS. NEWBURY:
Q. No, I know, but if you were to look at--now to look back on what was your real positivity rate, would you not have to adjust it to take into account what happened at Mount Sinai?
MR. GULLIVER:
A. That has not been done.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. But however, I mean, if you're asking so for example, if you're talking about the first three months of 2004?
MS. NEWBURY:
Q. Yes, just looking at the Ventana years, for

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example, you've got--that's a fairly large sample size.
MR. GULLIVER:
A. Okay, and again, I mean, for the years under Ventana, you know, and the ones that were retested were all the negatives, as you're well aware.
MS. NEWBURY:
Q. Right.
MR. GULLIVER:
A. So here, for the total for Ventana, during that time frame, there are 28 samples that were tested as negative, negative and I don't think any of them were converted.
MS. NEWBURY:
Q. But the information here would be with regard to all of the results that were done for that particular year?
MR. GULLIVER:
A. For the year. So for Ventana, the statistic wouldn't change because there are--we didn't have any confirmed conversions of a negative, negative Ventana and restained positive at Mount Sinai.
MS. NEWBURY:

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Q. There were no conversions?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. Okay, and is that the same for 2005?
MR. GULLIVER:
A. Well, the Ventana is all 2005, for all of Ventana.
MS. NEWBURY:
Q. You've got two different periods of time here, sorry.
MR. GULLIVER:
A. From April '04, because see, when I first did this here, it was the fiscal year up to April '04 to March '05 when we stopped--stopped DAKO, I did a full year of Ventana, get a full year statistics. Then I added on April, March (sic), June, July when we stopped testing.
MS. NEWBURY:
Q. Okay.
MR. GULLIVER:
A. But for the Ventana period -
MS. NEWBURY:
Q. The entire period, from April 2004 to July 31st 2005, there was not -

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MR. GULLIVER:
A. Right, to my knowledge, from what I've seen -
MS. NEWBURY:
Q. - there was not one single conversion?
MR. GULLIVER:
A. - we haven't seen one conversion from the Ventana.
MS. NEWBURY:
Q. Okay. So you wouldn't then have to adjust your positivity rate then?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. There's no data that would suggest that?
MR. GULLIVER:
A. No.
MS. NEWBURY:
Q. Okay, and -
MR. GULLIVER:
A. And if it went back to '97, you know, the numbers of negatives that were retested that converted to--you know, came back as a positive, again, it was a very low number, so it wouldn't--the positivity rate may go up three or four percent in '97.

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MS. NEWBURY:
Q. One more document, just if you can briefly explain what it is, P-3215, please? I'm not sure if you're familiar with this particular document. You're not a recipient here of the document. It was sent from Deborah Gregory to Paula Dillon and copied to Pat Pilgrim, is one of the people, what she received. And this is a draft document for internal review purposes only, and I believe this was prepared by NLCHI, and given that you were having some interaction with NLCHI in terms of getting the data together, would you be able to comment on what this particular table is about? Is this something that you're familiar with?
MR. GULLIVER:
A. Well, I mean, again, I mean I can't give you--I think NLCHI people are going to come and testify.
MS. NEWBURY:
Q. Okay, so you don't have any--you can't speak to this at all?
MR. GULLIVER:
A. Well, I mean, because this is just one table. There's multiple tables.

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MS. NEWBURY:
Q. Sure, okay.
MR. GULLIVER:
A. And again, when you go through them, they're doing analysis based upon if something was one percent staining positive, if that was considered a positive, or ten percent or higher or 30 percent or higher.
MS. NEWBURY:
Q. Okay. Thank you, Mr. Gulliver. Those are all the questions.
MR. GULLIVER:
A. You're welcome.
THE COMMISSIONER:
Q. Mr. Crosbie.
MR. TERRY GULLIVER, EXAMINATION BY CHESLEY CROSBIE, Q.C.
CROSBIE, Q.C.:
Q. One moment, Commissioner, figure out a way to re-rig so that I can see my notes better. It may work for Ms. Chaytor very well, but not for me.
THE COMMISSIONER:
Q. I learned long ago not to comment on Ms. Chaytor's size, Mr. Coffey. It's a very dangerous thing to do.

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CROSBIE, Q.C.:
Q. Well, it seems to work for Mr. Coffey as well, but not for me.
THE COMMISSIONER:
Q. Okay.
CROSBIE, Q.C.:
Q. Thanks, Mr. Gulliver. We've met before, and as you know, I'm the class counsel for members of the Breast Cancer Testing Class Action and we have standing here. I'd like to take a step back, a step back to 1997, and just look at the overall setting at that time when the decision was being taken to establish ER/PR testing in a different section of the lab than it had been done before, and what I'm referring to there, I guess, is the fact that there was a technique called enzyme immuno assay or EIA which was conducted in the biochemistry section of the lab for the detection of positive ER and PR status in cancer patients. Am I correct so far?
MR. GULLIVER:
A. Yes, that's correct.
CROSBIE, Q.C.:
Q. And this technique involved taking fresh

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frozen - frozen tissue, and creating an emulsion out of it and using equipment, I won't try to describe because I don't understand, to get a count on the presence of positive staining in this emulsion, is that roughly true as well?
MR. GULLIVER:
A. I think, or the amount of estrogen in the emulsion.
CROSBIE, Q.C.:
Q. Uh-hm.
MR. GULLIVER:
A. It's not a staining then, it's a measurement.
CROSBIE, Q.C.:
Q. Okay. Now again this was conducted in - this was a biochemical procedure and it wasn't done in histology?
MR. GULLIVER:
A. Correct.
CROSBIE, Q.C.:
Q. It was done in biochemistry, whereas in histology there was at that time, 1997, and had been for a number of years going back to the 80s, I believe, tumours were being assessed or tested for staining purposes, and

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the results of that were being used by pathologists to refine their diagnoses, and these tumours might be lung, they might be brain, they might be other things. That's roughly correct again?
MR. GULLIVER:
A. For the IHC testing at that time?
CROSBIE, Q.C.:
Q. IHC testing was done -
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. In histology for a number of years.
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. This again being in 1997. So that if we contrast it to the - as I understand it now, the pathologists had nothing to do with the enzyme immuno assay testing performed over in the chemistry section, they weren't involved in signing out reports or interpreting the results of that testing at all, is that correct?
MR. GULLIVER:

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A. They didn't interpret the result, but again, I mean, that patient who would have had a sample of a tumour submitted to biochemistry, then would have had their primary breast surgery done and the pathologist would have then seen the patient's tissue after the biochemical assay was performed, but they were not involved in interpreting the assay in biochemistry.

CROSBIE, Q.C.:

Q. Right, but they did do, of course, their usual histological diagnosis?

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. However, in terms of the assay, they weren't involved in the interpretation of reporting of that?

MR. GULLIVER:

A. Not to my knowledge, no.

CROSBIE, Q.C.:

Q. Yeah, they had nothing to do with that per se. That was done for the benefit, well, of the patient, but for the oncologist who is managing the case and treating?

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MR. GULLIVER:

A. To the best of my knowledge.

CROSBIE, Q.C.:

Q. The assay was done -

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. That was for the oncologist?

MR. GULLIVER:

A. Yeah.

CROSBIE, Q.C.:

Q. Whereas tumour antigens in IHC done in histology at this time were done for the pathologist?

MR. GULLIVER:

A. Well, the pathologists interpreted it, but still being performed for the final benefit of the oncologist.

CROSBIE, Q.C.:

Q. Well, my information is that it was done for the pathologist for diagnostic purposes to assist them in refining their diagnosis, but that the IHC testing being done in 1997 in histology was not - was not basically being used for treatment of patients, it wasn't

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being used for - it wasn't being relied on by oncologists for therapeutic purposes.

MR. GULLIVER:

A. You mean, IHC overall, or ER/PR testing, in particular?

CROSBIE, Q.C.:

Q. No, we're talking about a time before ER/PR.

MR. GULLIVER:

A. Okay, so before ER/PR -

CROSBIE, Q.C.:

Q. Yes.

MR. GULLIVER:

A. The pathologist would order based upon their type of case, type of tumour, type of tissue, they would request the technologists to perform a certain number of IHC antibodies and, you know, they were using that strictly in their own aid in interpretation of the patient case.

CROSBIE, Q.C.:

Q. That's what I understand.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. However it was not being relied on for

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therapeutic purposes by the oncologist?

MR. GULLIVER:

A. To the best of my knowledge, also that's correct.

CROSBIE, Q.C.:

Q. Which, of course, is something dramatically different about ER/PR testing?

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. So just to get that picture, up until '97 when ER/PR was commenced as a test or as a stain done in histology, what histology was doing with stains was being done for the diagnosis or diagnostic purposes of the pathologist, not for the therapeutic purposes of the oncologist?

MR. GULLIVER:

A. To the best of my knowledge, yes.

CROSBIE, Q.C.:

Q. That's what I understand. So that when ER/PR testing was moved over as an IHC procedure to histology, that's something that made that task unique, the fact that it was being done not just for diagnosis but also for therapy?

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MR. GULLIVER:
A. Correct.
CROSBIE, Q.C.:
Q. And, of course, if you got the test wrong, then the risk was the patient could be deprived or hormone therapy?
MR. GULLIVER:
A. It all depends on what your definition is of getting the test wrong. You mean if the test was performed incorrectly or do you mean it was not interpreted correctly or -
CROSBIE, Q.C.:
Q. If it yielded an incorrect result for whatever reason, it could have therapeutic implications?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. One of which is that a patient might not get hormone therapy?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. So in 1997 we have, I think, Dr. Haegert was the clinical chief; Dr. Khalifa was the site

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chief; Vern Whelan was the program director, am I right?
MR. GULLIVER:
A. Uh-hm.
CROSBIE, Q.C.:
Q. And you, sir, was the supervisor or manager of histology, the histology lab, with its - can we call it a subsection, IHC section?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. Okay, and you explained earlier in your testimony that at this time in 1997, you'd been off the bench in histology for about ten years or more even, is that right?
MR. GULLIVER:
A. Yeah.
CROSBIE, Q.C.:
Q. And you had to rely on Mary Butler and Peggy Welsh to perform procedures, including the IHC procedures, in an adequate fashion?
MR. GULLIVER:
A. And they had been doing them for a number of years by this time.
CROSBIE, Q.C.:

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Q. And you also testified that you had the utmost confidence in both of those techs?
MR. GULLIVER:
A. I thought they were both two good very technologists.
CROSBIE, Q.C.:
Q. Can you explain, sir, what were your responsibilities as the supervisor of anatomical pathology in relation to IHC testing?
MR. GULLIVER:
A. Overall for IHC testing? I guess, my primary role was to ensure that obviously we had the financial resources to maintain that section of our pathology laboratory. You know, if there were new antibodies that were being added to the list of antibodies, to ensure that those things got - that we had the money for those. I was also responsible, I guess, responsible for the staff who were performing the testing, responsible for the administrative functions for the lab, you know, general - what you would expect the supervisor to be responsible for.
CROSBIE, Q.C.:

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Q. Can we say that you are responsible for the quality of the output of the lab?
MR. GULLIVER:
A. I really can't agree with that statement.
CROSBIE, Q.C.:
Q. Can you explain that?
MR. GULLIVER:
A. Because I think the way, you know, laboratory medicine - the practice of laboratory medicine, in particular in pathology, it really is a - it's a combined effort between the technical side and clinical side. I think that the overall quality for the laboratory would be a joint responsibility for administrative side and the clinical side, however, the assessment of the quality is really - was the primary function of the pathologists, and, you know, the technologists relied upon that feedback from the pathologists to assess the outcome or output from all the slides. Whether it was an H & E slide or an IHC slide, they still relied upon the pathologist's feedback.
CROSBIE, Q.C.:
Q. The clinical side would have to rely on the

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manager of the lab to ensure that the technical things that were required to be done in order to get a quality output were done and were done right, though?

MR. GULLIVER:

A. That's correct.

CROSBIE, Q.C.:

Q. And what you're explaining is that there had to be an interaction between the clinical side and the technical side to ensure that that objective of good quality product was continuously being met?

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. And you're saying that it was a shared responsibility?

MR. GULLIVER:

A. I mean, certainly - I mean, ti can't be all left to the clinical side nor the administrative side, I mean, it has to be a shared dual responsibility.

CROSBIE, Q.C.:

Q. And, I guess, we could say that as director of the - manager of the histology lab, you would

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be responsible for development of new procedures and the deletion of old ones?

MR. GULLIVER:

A. Not necessarily, no.

CROSBIE, Q.C.:

Q. How so?

MR. GULLIVER:

A. Well, for example, a new procedure, we would add a new procedure at the request and approval of the pathologists. Again if the new procedure was added, you know, they would verify this is the outcome of the procedure, review the slides to make sure it's what they were - that it was satisfactory, and then that new procedure would become a part of the daily routine.

CROSBIE, Q.C.:

Q. Well, you explained before that if there was to be something new done, you had to ensure that you had the financial resources in place to do it right. Didn't you just explain that?

MR. GULLIVER:

A. Part of my responsibility is to ensure that we have the resources, yes.

CROSBIE, Q.C.:

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Q. Registrar, could we bring up Document P-1889, please. My up and down control doesn't seem to be working here. We'll probably see the full letter on the screen. Thank you. So this was sent - it appears sent to you in March, 1997, but you've told us - or February. I think there was a March date on it as well. Yes, March 12th. In any event, that's the time period, and I think you've explained to the Commissioner that as far as you can ascertain you did not receive this?

MR. GULLIVER:

A. I couldn't say that I could or I could not. When I was shown this, you know, in preparation for the Commission of Inquiry, you know, my opinion was I was reading it for the first time, but I really can't say that I did not get that ten years ago or did I get it ten years ago.

CROSBIE, Q.C.:

Q. You don't have a recollection of it, though?

MR. GULLIVER:

A. No.

CROSBIE, Q.C.:

Q. And I think it's not in your own personal file

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or the files that -

MR. GULLIVER:

A. We couldn't find it, no.

CROSBIE, Q.C.:

Q. Yes.

MR. GULLIVER:

A. And I think when I asked - I think it was something that was an e-mail that Dr. Khalifa had composed on his computer system, and again they couldn't verify if it was even sent.

CROSBIE, Q.C.:

Q. I'm not sure where you're getting that it's an e-mail because, to me, it looks very much like it has the form of a letter.

MR. GULLIVER:

A. That's just what I was told. I mean, that's -

CROSBIE, Q.C.:

Q. "Dear Mr. Gulliver", and, you know, it doesn't have any e-mail address on it, and then down at the bottom, it has a signature line, yours, where there would normally be a signature placed in it, but, anyway, the point I want to get to, there in the second paragraph, you see where he says, "Mr. Gulliver, I do not think you fully appreciate the delicacy of this

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test, its clinical consequences, and the overall emotional charge in the public regarding this very sensitive procedure". Whether you received this or not, or recall receiving this or not, did Dr. Khalifa and you have a conversation along those lines about any concern that he harboured that you didn't appreciate the delicacy of the test?

MR. GULLIVER:

A. Again, not to my knowledge.

CROSBIE, Q.C.:

Q. Is that something that you think you would remember?

MR. GULLIVER:

A. And again that's what I had said when I read this, that, you know, when I'm reading this here - you know, Dr. Khalifa and I had a fantastic relationship, and I was thinking, well, you know, if Dr. Khalifa said this and sent it to me, it's something that I would have remembered, but I can't say that I did.

CROSBIE, Q.C.:

Q. Doesn't stand out?

MR. GULLIVER:

A. It doesn't stand out, no.

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CROSBIE, Q.C.:

Q. Do you agree or disagree with me when he says, "I do not think you fully appreciate the delicacy of the test".

MR. GULLIVER:

A. I think I testified that I certainly think at that time when this test was being implemented by Dr. Khalifa, and he was working with Dr. Prabhakaran in biochemistry, that my knowledge of the test at that time, certainly this would be - that would be accurate.

CROSBIE, Q.C.:

Q. So you had a learning curve ahead of you?

MR. GULLIVER:

A. And I think as many of our pathologists did also. I mean, this is a new test coming into - it's not just a new procedure, it's a whole new test coming into the laboratory.

CROSBIE, Q.C.:

Q. Can you say approximately when you became aware Dr. Khalifa was planning this, this new test?

MR. GULLIVER:

A. I would - I can't tell you the exact time frame, Mr. Crosbie. I know there was

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discussions between himself and, I guess, Dr. Haegert, and the biochemistry people, and I think that was going on for a few months before we even - the staff even started testing anything. So I would say maybe late '96, you know, like, to this time frame, '97.

CROSBIE, Q.C.:

Q. And you and Dr. Khalifa were present in various committee meetings where discussion of this took place during 1997/1998?

MR. GULLIVER:

A. Well - well, whether it's the implementation or whether now it's been implemented and Dr. Khalifa is giving updates on it, I think.

CROSBIE, Q.C.:

Q. How close would you say you were to Dr. Khalifa during the process of developing the test?

MR. GULLIVER:

A. You mean, was I involved - was I actively involved in developing the test?

CROSBIE, Q.C.:

Q. However you wish to describe it.

MR. GULLIVER:

A. I wasn't involved at all in the actual

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development of the test. I mean, he worked specifically with the biochemistry people and, in particular - in the pathology lab, he worked with the pathologists, but in particular he worked with Mary and Peggy, the two technologists.

CROSBIE, Q.C.:

Q. Did Dr. Khalifa give you any what you describe as education in the new test?

MR. GULLIVER:

A. I don't remember Dr. Khalifa sitting me down and giving me a lecture. I just know in general discussions over a period of time, you know, that we knew this test was being used for hormone therapy.

CROSBIE, Q.C.:

Q. Something I left out of the overall picture that perhaps help pull it together. We mentioned that when the ER/PR procedure or test was being performed by biochemistry by the EIA, or the enzyme immuno assay, this was being done on frozen sections and did not involve paraffinized blocks of tissue?

MR. GULLIVER:

A. It was done on fresh tissue, and then it was

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snap frozen, I think.
CROSBIE, Q.C.:
Q. Yeah, so I guess a big part of the rationale for moving the location within the laboratory structure of the ER/PR test to histochemistry is the fact that it was now to be done on paraffinized blocks of tissue?
MR. GULLIVER:
A. Right, and, therefore, then you had a permanent block and permanent slide.
CROSBIE, Q.C.:
Q. Yeah, superior in many ways to the previous method of emulsifying?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. But it's in histology where they dealt with tissue in paraffinized blocks?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. And were already doing the tumour markers that we spoke of before. You mentioned that Dr. Khalifa worked with the techs?
MR. GULLIVER:

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A. Yes.
CROSBIE, Q.C.:
Q. Can you describe to what extent or what that involved, are you able to tell us?
MR. GULLIVER:
A. I really can't tell you to the extent. I mean, I just know that he worked really well with the technologists. I know Mary and Peggy had the utmost respect for Dr. Khalifa. I think they appreciated any advice or involvement he had with them, but, you know, I can't give you a detailed outline.
CROSBIE, Q.C.:
Q. You can't give a detailed description?
MR. GULLIVER:
A. No, no.
CROSBIE, Q.C.:
Q. Okay. Sir, you said that you had no active role in setting up or supervising these tests for the ER/PR, in particular. Therefore, we must infer that it was Dr. Khalifa who set up and supervised the test.
MR. GULLIVER:
A. Dr. Khalifa set up and supervised the actual performance of it, and then, you know, it was

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his assessment of reviewing the quality of the slides being produced by Mary and Peggy, and, you know, if he decided to use this antibody dilution or those kinds of variables - my role would have been to ensure, you know, that we have resources on hand to buy the reagents and buy kits. I had discussions with - you know, at the time Vern Whelan was our program director. We did - I mean, the most expensive piece of doing this testing was do you have the equipment and staff in place. It's adding two new antibodies to the current list of antibodies you already perform in your laboratory, and I know I spoke to Dr. Haegert and to Vern Whelan to say that while in my estimate adding these two antibodies to the IHC part of the laboratory, and the additional work involved, would probably have cost - I think it was, like, 10 or 20,000 dollars per year, and, you know, I had asked Mr. Whelan then, he should transfer - if biochemistry is going to stop performing the testing, you know, whatever money they had in their operations budget should be transferred over to the pathology budget to cover off our extra

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expense for the operations side of the testing. I mean, that would have been more my involvement with Dr. Khalifa as opposed to being on the bench overseeing the staff.
CROSBIE, Q.C.:
Q. And the assumption you made as manager is that no other financial resources were going to be required in order to do this test to an appropriate standard than the transfer of the 20,000 or so from the chemistry side?
MR. GULLIVER:
A. Biochemistry.
CROSBIE, Q.C.:
Q. That was your assumption?
MR. GULLIVER:
A. Well, it's my assumption, and it was in talking to Dr. Khalifa and looking at, you know, what would be the cost of the reagents to start up, how many tests do you expect to perform on a yearly basis, and then multiply it by the number of patients that we're going to be testing. We already had two technologists in the laboratory that were doing IHC testing for a number of years, so those same two staff, you know, would perform

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the testing. You know, we had Dr. Khalifa on staff who was going to do the clinical side, so I didn't see other parts of the resources required to start this test up.

CROSBIE, Q.C.:

Q. It wasn't assumed, for example, that any of the techs would need to be sent out for training to another institution?

MR. GULLIVER:

A. Dr. Khalifa never assessed that, and never asked for that, and I think you've heard him testify that when he came to St. John's, he was fairly impressed with the amount of IHC testing taking place and the quality of the work and the technologists. If Dr. Khalifa had suggested it or asked for it, I'm sure funding would have been found for it.

CROSBIE, Q.C.:

Q. We've talked about your responsibility for quality of output and that it's an interaction with the clinical side to achieve that, right, but as manager, you would be responsible as well for documenting the processes followed in the lab, is that right, for the documentation of it?

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MR. GULLIVER:

A. No, I mean the staff, you know, had to document, you know, what they were doing and it all depends what documentation that you are referring to. If it's documenting the fact that we have a patient and here's a test performed and here's the results on the patient, those things are documented, you know, that's a part of the lab function.

CROSBIE, Q.C.:

Q. Yes, but if you're the supervisor, then it falls to you, the responsibility falls to you to ensure that the techs are actually doing that, right?

MR. GULLIVER:

A. I guess ultimately, yes.

CROSBIE, Q.C.:

Q. Well that's your job as manager.

MR. GULLIVER:

A. A part of my role, yes.

CROSBIE, Q.C.:

Q. You're responsible for those techs doing their jobs right which includes documenting they're doing their jobs right.

MR. GULLIVER:

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A. I think people have to take responsibility for their own job also.

CROSBIE, Q.C.:

Q. Yet there's a manager responsible to ensure that they are doing so. And in histology, that was you.

MR. GULLIVER:

A. Yes, I was the manager but I don't think I can be, you know, watching over the shoulder of 25 or 30 staff every day, I mean staff worked different schedules, you know. You also have to assume that staff are going to accept their responsibility and perform their role as what they're supposed to do.

CROSBIE, Q.C.:

Q. Ultimately as manager the bucks stops with you; you're the manager.

MR. GULLIVER:

A. I guess if you apply that line of thinking, ultimately I guess it rests with the CEO, I mean because the manager responds--is responsible to somebody else, then that person is responsible to somebody else. I mean, that's how a organization works.

CROSBIE, Q.C.:

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Q. Sir, I thought I was attempting to establish a fairly uncontroversial proposition, which is that the manager is responsible for the quality of the work of the people who work under him., the manager of histology lab responsible for the techs in this case?

MR. GULLIVER:

A. I know and the pathology lab structure had both an administrative and clinical structure, so it would be a joint responsibility and accountability for the quality of the work produced in the laboratory.

CROSBIE, Q.C.:

Q. I wonder if I gave the Registrar this reference here, I'm looking for the October 9th, 2008 testimony of Dr. Torlakovic and I may or may not have given you that, Registrar, sorry, I missed that one. It takes a little longer if you don't put them on alert that you're looking for a transcript, you see, page 181 is what I'm looking for. Thanks. So you can see in the lead up to these questions on page 181, we--there's information provided, we assume that there's about 14,000 immunohistochemical tests performed per year

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by your institution?
MR. GULLIVER:
A. I think there's--slides.
CROSBIE, Q.C.:
Q. Slides.
MR. GULLIVER:
A. That would be total slides, that would include patient slides, control slides, the whole total.
CROSBIE, Q.C.:
Q. Uh-hm, and about 350 ER/PR.
MR. GULLIVER:
A. I think that's correct, yes.
CROSBIE, Q.C.:
Q. Yes. So then she wanted to know what the volumes were because I was asking this doctor from Saskatchewan, this pathologist, for her feelings as to what the duties of a pathologist who--should there be a pathologist responsible to assist in ER/PR IHC testing and that sort of thing, and she gives an answer here starting at line 20, I think you can see it there. You can move that up and down to suit yourself as well, sir, I think you have a mouse. And the first one is, she feels that

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where there is volume enough, you should have a designated specialist to dedicate part of his or her time for immunohistochemistry laboratory work alone. You would agree with that, I guess?
MR. GULLIVER:
A. She's talking about a pathologist there, I think.
CROSBIE, Q.C.:
Q. She is, yes.
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. You agree with that?
MR. GULLIVER:
A. Sure.
CROSBIE, Q.C.:
Q. And down on page 181, you can move it down if you wish, around line 5.
THE COMMISSIONER:
Q. 181, line 5?
CROSBIE, Q.C.:
Q. Yes.
THE COMMISSIONER:
Q. Thank you.

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CROSBIE, Q.C.:
Q. Sorry, I meant 181, I apologize.
THE COMMISSIONER:
Q. Okay.
CROSBIE, Q.C.:
Q. Line 5, she's saying "The pathologist would have to closely interact on a daily basis with an expert technologist who is in charge of immunohistochemistry." So the first part of that, do you agree that there should be close interaction on a daily basis with a pathologist?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. And do you agree there should be an expert technologistin charge of immunohistochemistry?
MR. GULLIVER:
A. I think there needs to a technologist, that's their primary function, I mean, it all depends on what your definition of an expert technologist is.
CROSBIE, Q.C.:
Q. Well just going from that idea, somebody who

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has some level of expertise in the process, was there such a person at your lab in '97, '98, '99?
MR. GULLIVER:
A. I would have to say that both Peggy Welsh and Mary Butler have been performing these procedures for ten years and I would say that Peggy was probably more knowledgeable for IHC testing and she was more the lead person for IHC.
CROSBIE, Q.C.:
Q. And when Dr. Khalifa was present, which was up until I believe--do you know the month in 1999? Was it summer or fall -
MR. GULLIVER:
A. I think it might have been June, June of '99 when he left.
CROSBIE, Q.C.:
Q. In '99, so in the period when he was there, did he interact on a daily basis with Peggy Welsh or anyone else?
MR. GULLIVER:
A. I don't know on a daily basis. I would have to say, though, on a very frequently basis.
CROSBIE, Q.C.:

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Q. And if you could then go to page 183, which is back up and around line 10, Dr. Torlakovic is saying "The pathologist would be in charge of making sure that daily quality control systems are functioning correctly and there is participation in standard quality assurance programs and would be touching base with other pathologists to make sure that unusual results are being reported or communicated." Now, first of all to take the first of that, in the period of Dr. Khalifa in respect to ER/PR testing, what were the quality control systems?

MR. GULLIVER:

A. Well the quality control system was the technologist, as you've heard, would run a known positive control with, you know, with the ER and the PR, so a positive ER, a positive PR, those controls would be read by Dr. Khalifa to verify the quality of the controls and to make sure the quality of the staining and then any feedback back to the laboratory.

CROSBIE, Q.C.:

Q. That was the quality control system. The

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positive external control?

MR. GULLIVER:

A. Well some of the daily quality control system, I think she's referring to there the controls, the control slides.

CROSBIE, Q.C.:

Q. Okay, well I asked you what were the daily quality control systems is the word she uses here and you're referring to the slides, the external positive control slides, yes.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. Is there anything else you'd have? What other quality controls -

MR. GULLIVER:

A. Well I guess then having a pathologist review the slides to ensure that the procedure is working fine.

CROSBIE, Q.C.:

Q. The patient slides that were to be interpreted?

MR. GULLIVER:

A. And the control slides.

CROSBIE, Q.C.:

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Q. Along with the control slides.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. That was the quality control.

MR. GULLIVER:

A. For that particular procedure.

CROSBIE, Q.C.:

Q. Uh-hm. Now, participation I think we know in standard quality assurance programs that was a little bit of an issue because there wasn't any, was there?

MR. GULLIVER:

A. In what kind of quality assurance programs? You mean external proficiency testing programs or -

CROSBIE, Q.C.:

Q. Well to take that as an example, yes.

MR. GULLIVER:

A. Well at that point in time in pathology, the pathologists were enrolled in external proficiency in getting samples in to do interpretations and get assessment on it. There was no external proficiency testing in particular for the IHC part of the pathology

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lab.

CROSBIE, Q.C.:

Q. Do you mean it wasn't available or you just didn't have it in that lab?

MR. GULLIVER:

A. I don't think either, we didn't have it and I don't think in '97 it was available. I would have thought that if it was available, that would have been something that Dr. Khalifa probably would have been aware of and probably would have requested.

CROSBIE, Q.C.:

Q. Okay, but you don't know.

MR. GULLIVER:

A. I can't say for sure, no.

CROSBIE, Q.C.:

Q. You can't say that the UK system of external proficiency testing was not available in '97? You don't know that?

MR. GULLIVER:

A. I can't say if it was or if it was not.

CROSBIE, Q.C.:

Q. Okay.

MR. GULLIVER:

A. And I don't know what time it came in because

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Dr. Ejeckam who came with us in 2003, it wasn't until 2005 that he suggests that we should enrole in UK NEQAS, so I don't know when that program was -

CROSBIE, Q.C.:

Q. You don't know, so that's the answer.

MR. GULLIVER:

A. No.

CROSBIE, Q.C.:

Q. As the lab manager, did you have responsibility for training of techs?

MR. GULLIVER:

A. Not training directly, no.

CROSBIE, Q.C.:

Q. Did you have responsibility to ensure that they were adequately trained to the tasks they were doing?

MR. GULLIVER:

A. Pretty well yes, I mean it all depends, you know, as you realize pathology is a process, you're talking about technologists performing the functions in the pre-analytical part of pathology, they do the embedding of blocks, the cutting of blocks, the routine staining, the histochemicalstaining,

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immunohistochemical stainings, so what you pretty well rely upon is that you have your other technologists and senior technologists to assist and train new staff into those functions.

CROSBIE, Q.C.:

Q. And you had responsibility for budgeting, for staffing, staffing levels.

MR. GULLIVER:

A. Issues and -

CROSBIE, Q.C.:

Q. Dealing with unions, purchasing reagents and other things.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. All that. When we looked, might have been yesterday, at the Wegrynowski report, there was a recommendation in there, she used the word or the term "medical section head" to be designated. That was one of the recommendations. And so in my understanding, I guess this would be the pathologist who we've just read, Dr. Torlakovic's testimony, would be the daily contact person resource -

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MR. GULLIVER:

A. For the IHC.

CROSBIE, Q.C.:

Q. For IHC.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. That's what she's calling the medical section head. Is that a position which is being created or recognized at this point in time?

MR. GULLIVER:

A. Well it's Dr. Ford Elms.

CROSBIE, Q.C.:

Q. So he's doing that function?

MR. GULLIVER:

A. Yes, but I think he's officially called the director of IHC lab.

CROSBIE, Q.C.:

Q. Director.

MR. GULLIVER:

A. I don't think it's called medical section head.

CROSBIE, Q.C.:

Q. Okay, same thing though, you would think.

MR. GULLIVER:

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A. Yes.

CROSBIE, Q.C.:

Q. And so that, although there is no title or described function of director or medical section head, Dr. Khalifa effectively functioned in that role, that's more or less what you've told us.

MR. GULLIVER:

A. I'd have to say, yes.

CROSBIE, Q.C.:

Q. And then Dr. Khalifa leaves in June, 1999, who was in place as site chief, was Dr. Wadden acting for a period of time?

MR. GULLIVER:

A. I think Dr. Wadden might have been--that was a very, very short time.

CROSBIE, Q.C.:

Q. Very short time.

MR. GULLIVER:

A. Primarily it was Dr. Sushil Parai who was appointed site chief of the Health Sciences.

CROSBIE, Q.C.:

Q. What I'm getting at is Dr. Wadden didn't really assert herself to have an effect or play a role in IHC testing?

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MR. GULLIVER:
A. No.
CROSBIE, Q.C.:
Q. So really we go from Dr. Khalifa at the end of June '99 to Dr. Parai and he takes over whatever the function was that Dr. Khalifa was performing.
MR. GULLIVER:
A. As site chief.
CROSBIE, Q.C.:
Q. As site chief. However, we've heard, I think as well, that Dr. Parai didn't have an interest or, well an interest in IHC testing and that his role was pretty much limited to reading the control slides, is that about right?
MR. GULLIVER:
A. That's for a time period, yes.
CROSBIE, Q.C.:
Q. Well, he would be the site chief up to March 2005 is what I have here.
MR. GULLIVER:
A. No, I mean a time period where it was Dr. Parai who was then reading the control slides from the IHC lab and then at some point, that

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changed and the individual pathologist at the Health Sciences were then, they were all taking on a part of that responsibility.
CROSBIE, Q.C.:
Q. So what else did Dr. Parai do? He didn't do as much as Dr. Khalifa did in terms of having interaction with IHC, did he?
MR. GULLIVER:
A. Not to my knowledge.
CROSBIE, Q.C.:
Q. In fact, he had very little interaction with the lab, is that correct?
MR. GULLIVER:
A. With the IHC lab?
CROSBIE, Q.C.:
Q. Yes.
MR. GULLIVER:
A. I think after Dr. Khalifa left, I think Peggy or Mary probably were interactive with Dr. Chittal who was a pathologist on staff for a long time and he did have a fair bit of IHC experience and interest.
CROSBIE, Q.C.:
Q. And Dr. Chittal, when did he leave the scene?
MR. GULLIVER:

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A. Dr. Chittal retired maybe--might be two years now.
CROSBIE, Q.C.:
Q. So are you saying to the Commission here that Dr. Chittal filled the role of giving daily interaction and guidance to laboratory staff?
MR. GULLIVER:
A. He certainly didn't fill the role Dr. Khalifa left, but in the absence of Dr. Khalifa, I think that's the pathologist--and Dr. Chittal was at the Health Sciences maybe since 1981/'82 and I think that's the clinical person who Mary and Peggy probably went to looking for any questions or guidance or--because they already had an established relationship working together as technologist, pathologist since the early '80's.
CROSBIE, Q.C.:
Q. Dr. Khalifa had a formal position of site chief.
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. Dr. Parai had the formal position of site chief.

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MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. Dr. Chittal had no position as site chief.
MR. GULLIVER:
A. At some point Dr. Chittal is our site chief for a small--for again, a short period of time, Mr. Crosbie.
CROSBIE, Q.C.:
Q. Can you say when?
MR. GULLIVER:
A. I can't tell you the exact time frame, you know.
CROSBIE, Q.C.:
Q. Is it within the 1997 through 2005 time period?
MR. GULLIVER:
A. No, I don't think so.
CROSBIE, Q.C.:
Q. So he did not hold a formal position of site chief during that period.
MR. GULLIVER:
A. No.
CROSBIE, Q.C.:
Q. He did not hold the position such as medical

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director or medical section head during that period in relation to the IHC lab?

MR. GULLIVER:

A. Well there was no position as such during that time frame regardless.

CROSBIE, Q.C.:

Q. Correct. So you're saying that informally this gentleman gave some assistance to the techs on a periodic basis?

MR. GULLIVER:

A. Pretty well, yes.

CROSBIE, Q.C.:

Q. Something which Dr. Parai, as site chief, didn't do?

MR. GULLIVER:

A. I don't think so, no.

CROSBIE, Q.C.:

Q. Now you were the lab manager until, right from the beginning of '97 to October, 2001.

MR. GULLIVER:

A. 2001.

CROSBIE, Q.C.:

Q. And then Mr. Dyer took over from you.

MR. GULLIVER:

A. A few months afterwards, yes.

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CROSBIE, Q.C.:

Q. The majority of the period then, from 1997 to 2005, you were the lab manager?

MR. GULLIVER:

A. It was about half, I guess.

CROSBIE, Q.C.:

Q. A bit more than half.

MR. GULLIVER:

A. To 2005?

CROSBIE, Q.C.:

Q. October 2001, we're talking about '97, '98, '99, 2000.

MR. GULLIVER:

A. From '97 to '01, I was the only manager.

CROSBIE, Q.C.:

Q. Pardon?

MR. GULLIVER:

A. From '97 to October, 2001, all that time frame I was the pathology manager.

CROSBIE, Q.C.:

Q. Exactly, so that's four and almost five years. Almost five years from '97 to October -

MR. GULLIVER:

A. Well it was March '97 to October '01, so it's four years and a bit, whatever, maybe, yes.

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CROSBIE, Q.C.:

Q. Four and a half years and then Mr. Dyer took over. So Dr. Ejeckam, we've heard, came on the scene and he became the resource person for people who had questions or issues in the lab, but he didn't come on the scene until, what is it, September 2000?

MR. GULLIVER:

A. No, I think he comes in late 2002, I think.

CROSBIE, Q.C.:

Q. Perhaps Ms. Chaytor knows. Okay, so late 2002 it is, Dr. Ejeckam comes on the scene.

MR. GULLIVER:

A. Uh-hm.

CROSBIE, Q.C.:

Q. So what I'm getting from this is that from the time Dr. Khalifa leaves in June '99 to the time Dr. Ejeckam comes on the scene in September, 2002, with the exception of the gentleman you mentioned who hasn't appeared o the record here all that much, no one was doing the job of daily interacting with the techs to help them with any problems they were having in performing their ER/PR IHC procedure?

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MR. GULLIVER:

A. Well I think and your answer is right and I think that, you know, if there was a problem encountered by the technologists, they would informally go to Dr. Chittal.

THE COMMISSIONER:

Q. Mr. Crosbie, when there's a convenient spot, we'll break for the luncheon break.

CROSBIE, Q.C.:

Q. Thanks for the reminder. As you've noticed with lawyers before, they tend to forget what time it is.

THE COMMISSIONER:

Q. Uh-hm.

CROSBIE, Q.C.:

Q. Thank you. Well I have some other things to ask about and we'll do that after lunch at what time, Commissioner?

THE COMMISSIONER:

Q. At 2:15.

(ADJOURNED FOR LUNCH)

THE COMMISSIONER:

Q. Please be seated. Mr. Crosbie?

CROSBIE, Q.C.:

Q. Thank you, Commissioner. I'd like to talk,

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Mr. Gulliver, about antigen retrieval and in simple terms what we are trying to accomplish here is to use--if we have a method for uncovering the cross linkages that obscure the antigen sites to which we want our antibodies to bind and then be visible under the microscope as brown dots, simplistic, but that's about the right idea?

MR. GULLIVER:

A. Correct.

CROSBIE, Q.C.:

Q. And so to achieve antigen retrieval or to reveal these antigen sites or these receptor sites, the method that we've been talking about most of the time here is heat, the use of heat.

MR. GULLIVER:

A. A part of it is using heat.

CROSBIE, Q.C.:

Q. There are other methods though and Trypsin would be an example?

MR. GULLIVER:

A. Trypsin is used also at the front end of IHC testing, but not as a part of antigen retrieval for the ER/PR.

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CROSBIE, Q.C.:

Q. Just explain what Trypsin is?

MR. GULLIVER:

A. You're getting to technical terms there now that are not at my level.

CROSBIE, Q.C.:

Q. Well why, they're certainly not at our level either, I guess, if you're--we're not looking for an ultra technical description, just what it does and what it's used for.

MR. GULLIVER:

A. Trypsin is used as a, I think it's used as a protein digestion that it kind of, you apply to the slides and it, say in simple terms, kind of sucks out the things that you don't want staining.

CROSBIE, Q.C.:

Q. It's used a part of the peroxidase, anti-peroxidase method?

MR. GULLIVER:

A. Procedure, yes.

CROSBIE, Q.C.:

Q. Procedure. It can be used in ER/PR testing process?

MR. GULLIVER:

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A. I think it can, yes.

CROSBIE, Q.C.:

Q. So a couple of times--more than a couple of times, numerous times you've made reference to boiling on a hot plate, for example, I've made a note here "manually take your slides and put them on a hot plate and boil them." And you said that a couple of times.

MR. GULLIVER:

A. And what I'm meaning there is that you actually take the substrate buffer that you're using, that you're boiling to a certain temperature, which is in like a pyrex dish, then your slides go in that dish which is on the hot plate.

CROSBIE, Q.C.:

Q. So it's not like a pot with the slides in it on a hot plate, it's something like a coplin jar in the solution in the pot on a hot plate, is that what you mean?

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. Can I have brought up document P-0565 please? And there, probably in the third paragraph

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there, at the time you're talking about '97, so you're giving a history now in this document to Dr. Williams and you're saying "1997 switched to ER/PR testing from biochemical assay, which involved freezing tumour tissue, mashing tissue, that assay for ER/PR" and that's what we talked about a little bit before lunch. Then you go on to say "At the time, immunohistochemistry method gave better results than the old biochemical assay. The new method involved a manual procedure to boil slides in a solution on a hot plate to unmask as best possible antigen sites in the patient's tissue." And so there you are again describing what was done in our lab here commencing in 1997, this time describing it in writing to Dr. Williams.

MR. GULLIVER:

A. Just the basic outline of what was done, yes.

CROSBIE, Q.C.:

Q. Just the basics. And Ms. Chaytor, I have here, asked you "At some time did St. John's use other than a hot plate?" And your answer was "No."

MR. GULLIVER:

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A. Well, because you can use--I've learned since then you can--people do use pressure cookers and people do use microwave ovens to heat the substrate solution. We always use the hot plate and then at some point, I think DAKO came out then with like a waterbath that you could use to heat up your substrate solution.

CROSBIE, Q.C.:

Q. Did you adopt the waterbath technique at some point?

MR. GULLIVER:

A. Well it's not a technique, it's just replacing the hot plate.

CROSBIE, Q.C.:

Q. But did you?

MR. GULLIVER:

A. Yes, we did.

CROSBIE, Q.C.:

Q. Can I have document P-3050? You'll see on the top left there, "Source is Eastern Health, source, Terry Gulliver. It's a protocol sheet for high temperature epitope unmasking." Do you recognize this document?

MR. GULLIVER:

A. Well I gather the document is from the

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laboratory.

CROSBIE, Q.C.:

Q. You're named as the source.

MR. GULLIVER:

A. I gathered them from the pathology lab and provided all documents for ER/PR to the inquiry.

CROSBIE, Q.C.:

Q. Do you know what this designation, volume 14, page 188 is over there in the top right?

MR. SIMMONS:

Q. Commissioner, the same question about that Mr. Gulliver wouldn't know the answer, that's just the indexing method used by us as we produce the documents to the Commission, so that just indicates the volume of production and page numbering of the production.

CROSBIE, Q.C.:

Q. Well there's the answer. You can--or I can, go over to the second page. There's your pressure cooker mentioned there, item A, autoclave. There seems to be a microwave oven method and then they have here at C, hot water bath method and there under hot water bath on page 2 of the exhibit, DAKO is saying "set up

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a hot water bath, 95 to 99 degrees C by placing water into a large vessel, such as a kitchen pot on a hot plate." Is that effectively the protocol that your lab was following?

MR. GULLIVER:

A. To the best of my knowledge, yes. And I think they used to use, like, you know, a Corning, you know, the plain glass Corning dish.

CROSBIE, Q.C.:

Q. Uh-hm, rather than the kitchen pot, you mean?

MR. GULLIVER:

A. Yeah.

CROSBIE, Q.C.:

Q. When it's put that way, it sounds a bit crude to the layperson, you would agree?

MR. GULLIVER:

A. Yeah.

CROSBIE, Q.C.:

Q. Okay. Hot plates and kitchen pots. But you said at some point you switched to, I guess what they describe on the first page, the pressure cooker?

MR. GULLIVER:

A. No, we never ever switched to pressure cooker.

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CROSBIE, Q.C.:

Q. Okay, what would you call it then, a waterbath?

MR. GULLIVER:

A. Yes, when they were first doing this testing, in order to heat the substrate solution, it was boiled on a hot plate. At some point DAKO did come out with like a waterbath you could use in place of that.

CROSBIE, Q.C.:

Q. I think I may be able to help -

MR. GULLIVER:

A. But we never ever used a pressure cooker method or a microwave oven method.

CROSBIE, Q.C.:

Q. I might be able to help you if we go to Exhibit P-2888? And we go along to page 3 of that. Now this doesn't seem to be the document I was looking for, actually, Mr. Gulliver. What I thought I had there was and I believe it's here in the documents somewhere, is the acquisition of a waterbath by the lab was acquired on October 27, 1999, would that seem about right?

MR. GULLIVER:

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A. That got to be, yeah, I think so.
CROSBIE, Q.C.:
Q. And in fact, it seems that you were given the waterbath by DAKO, after all, I guess, you were spending a lot of money with DAKO.
MR. GULLIVER:
A. Probably, yeah.
CROSBIE, Q.C.:
Q. So they sort of threw that in and do you think then that from around that period, late '99 you started using a waterbath method?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. As opposed to the cruder sounding hot plate.
MR. GULLIVER:
A. By using a hot plate with a kitchen pot.
CROSBIE, Q.C.:
Q. Kitchen pot, yes, okay. Can we now go to Document 1853, and I'm interested in page two, please. As you can see, sir, these are answers to interrogatories, and the question three appears there, "Please attach a copy of the bench manual for the DAKO system, specifically written methodology on antigen

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retrieval controls, negative and positive, etc", and then if we carry on over, are those your initials at the top of page six?
MR. GULLIVER:
A. Yes, it is.
CROSBIE, Q.C.:
Q. That's TR for Terry Gulliver?
MR. GULLIVER:
A. TG.
CROSBIE, Q.C.:
Q. Yes, sorry, it is TG. It reads like TR, but that's your initial. You have marked there, that's your handwriting, "Immunoperoxidase, step by step procedure".
MR. GULLIVER:
A. Correct.
CROSBIE, Q.C.:
Q. And if we go down there, we can see - see the word "trypsin" in Item 2 there under procedure?
MR. GULLIVER:
A. Yeah.
CROSBIE, Q.C.:
Q. And I think it appears there as well above, appears a second time. Just check it against

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my paper copy. Under day two, it says - there's the word "trypsin" again, which you mentioned to us a little while ago. So why did you - first of all, these interrogatories were addressed to Ms. Predham, as you remember, but she obviously required the assistance of other people and on this occasion, you, to answer the interrogatories accurately and correctly.
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. So the question that this was meant to answer was, "Attach a copy of the bench manual for the DAKO system, specifically written methodology on antigen retrieval controls, negative and positive, etc". My question is why did you give us the immunoperoxidase step by step procedure using trypsin?
MR. GULLIVER:
A. Is there anything else attached to this?
CROSBIE, Q.C.:
Q. Yes, feel free to have a look. There's a fe more pages in the attachment.
MR. GULLIVER:

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A. Well, I guess this is the procedure that was used, the protocol for IHC testing. The antigen retrieval process is applied specifically for ER/PR before the slides even get to the actual IHC procedure. So the trypsin is added, and it's not added to all antibodies, it's added to some antibodies during the actual step by step procedure.
CROSBIE, Q.C.:
Q. I'm sorry, is this being done at a certain point in time and not at another point in time?
MR. GULLIVER:
A. Yeah.
CROSBIE, Q.C.:
Q. And when was it abandoned?
MR. GULLIVER:
A. Oh, the trypsin was not abandoned. At some point in time -
CROSBIE, Q.C.:
Q. For ER/PR testing now specifically?
MR. GULLIVER:
A. I can't answer that question. I mean, I've never done an ER/PR test. I can tell you some basic answers to some of the questions here,

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but, you know, if you want to get into more technical detail, you'll have to speak to the technologists who are actually performing the test.

CROSBIE, Q.C.:

Q. So, in fact, you can't tell us whether trypsin is still in use, or in use up to when the testing was being performed?

MR. GULLIVER:

A. Trypsin is used still for some antibodies, even in the Ventana system.

CROSBIE, Q.C.:

Q. But you can't tell us whether it was being used for ER/PR testing?

MR. GULLIVER:

A. I can't tell you definitively right now, no. So what you have here, the first couple of pages, Mr. Crosbie, is the actual step by step procedure for doing IHC antibodies. The ER/PR antigen retrieval is applied before the slides get to this part of the procedure. What you're seeing here next is the - it's just documentation from the manufacturer that this is the DAKO retrieval solution that's used for antigen retrieval.

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CROSBIE, Q.C.:

Q. And also you've got isolated there with your own markings, DAKO antigen retrieval, step by step?

MR. GULLIVER:

A. And this is the procedure for the antigen retrieval piece, yes.

CROSBIE, Q.C.:

Q. And it mentions waterbath specifically?

MR. GULLIVER:

A. Uh-hm.

CROSBIE, Q.C.:

Q. So I would have guessed that after you were given the waterbath in late 1999, you adopted what's set out there, recommended procedure, waterbath?

MR. GULLIVER:

A. But this procedure is still the same whether you're using a waterbath or using a hot plate or a kitchen pot. It's still the same procedure. You still have to use our pH solution, you still have to dewax your slides and rehydrate your tissue sections, you still got to immerse them into the retrieval solution.

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CROSBIE, Q.C.:

Q. So your evidence is you were using trypsin, as described in the step by step procedure at page six, and the recommended waterbath?

MR. GULLIVER:

A. But trypsin is not used - trypsin is not used as an antigen retrieval for ER/PR antibodies. Trypsin is used for - is applied to most antibodies for IHC testing.

CROSBIE, Q.C.:

Q. One final thing before we leave page nine - by all means, have a look, but if you -

MR. GULLIVER:

A. I'm still scrolling - do you want me to scroll back?

CROSBIE, Q.C.:

Q. Page nine, when you're ready. Just one more thing, a few lines into that paragraph that you have marked off, it says, "Heat waterbath to 95/99 centigrade. Do not boil". Any particular significance to that advice?

MR. GULLIVER:

A. Well, I mean, they always told the staff that you don't allow your retrieval solution to boil, which is a much higher temperature than

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that.

CROSBIE, Q.C.:

Q. Well, some of us may be struck by the fact that you repeatedly referred to boiling.

MR. GULLIVER:

A. Oh, I think you're just taking things too literally. What is meant is that instead of putting your solution on a hot plate and then you turn it up and let it boil and bubble, and then wait for it to cool down to 95/99, you actually apply a more even heat until the solution reaches up to 95/99 degree temperature.

CROSBIE, Q.C.:

Q. When the - well, it's called kitchen pot and hot plate method was being used, did you - you were ten years off the bench at that point in time in '97. Did you work with the techs to see how they were performing that part of the procedure?

MR. GULLIVER:

A. I didn't work with the techs to see it, but, I mean, I was in the lab enough to see the times when they were doing the procedure, yes.

CROSBIE, Q.C.:

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Q. Do you know how they controlled for the temperature to make sure -
MR. GULLIVER:
A. With a thermometer.
CROSBIE, Q.C.:
Q. The slides were not in a solution which boiled?
MR. GULLIVER:
A. They had a thermometer in it, like, a thermometer.
CROSBIE, Q.C.:
Q. In which?
MR. GULLIVER:
A. Into the solution.
CROSBIE, Q.C.:
Q. In the solution in which the slides were placed?
MR. GULLIVER:
A. Exactly. To make sure it's at 95/99 degrees, there was a thermometer placed into it so they know when it reached up to that range.
CROSBIE, Q.C.:
Q. And they'd keep it at that range for how long?
MR. GULLIVER:
A. Well, the time was 20 minutes that they used

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to incubate for.
CROSBIE, Q.C.:
Q. And you know this, though, not from having watched them do it, or taken them through the process of doing it, you know that from what's set out here?
MR. GULLIVER:
A. No, I know that from speaking to the technologists and I know that enough times over the years that just by chance I might have been out in the lab when they were doing their procedure to verify that.
CROSBIE, Q.C.:
Q. How was the twenty minutes timed for?
MR. GULLIVER:
A. How was it timed?
CROSBIE, Q.C.:
Q. Uh-hm.
MR. GULLIVER:
A. It was - in all parts of pathology, there's multiple different stains that are performed and different timings for different solutions, whether it's an IHC test, histochemical test, or an H & E stain, and they use multiple timers. So you have a lab timer clock that

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you set your time for twenty minutes, and then when the time is up, the buzzer goes off, you take your things out, and do the next - enter the next step.
CROSBIE, Q.C.:
Q. I guess in lay terms, an alarm clock?
MR. GULLIVER:
A. Pretty well, yeah.
CROSBIE, Q.C.:
Q. A timer that would make an audible noise and you'd know your time was up?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. And you saw that, did you?
MR. GULLIVER:
A. Hundreds of times.
CROSBIE, Q.C.:
Q. Was it always used?
MR. GULLIVER:
A. To my knowledge, yes.
CROSBIE, Q.C.:
Q. Of course, you didn't see this procedure done every time it was done?
MR. GULLIVER:

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A. Obviously not, no, but my experience with the technologists is they had a procedure to follow and that's the procedure they followed. Again whether it's an ER/PR or an H & E stain, that's the procedure that you follow.
CROSBIE, Q.C.:
Q. Document 1889, please. We looked at this before. That's the Dr. Khalifa letter which you don't recall receiving, and, of course, we looked at the part where it says, "I do not think you appreciate the delicacy of this test", and I think you told us that at the outset you may not have, but you learned, is that true?
MR. GULLIVER:
A. I think we all learned, yes. This was a new test that was being introduced, and Dr. Khalifa was pretty well the only - even the only pathologist that had knowledge about this test.
CROSBIE, Q.C.:
Q. Was it a delicate test?
MR. GULLIVER:
A. I think you have to say yes.
CROSBIE, Q.C.:

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Q. Did Dr. Khalifa know you were using trypsin as part of your technique?
MR. GULLIVER:
A. Yes. I can't tell you if trypsin was used for ER/PR. Again I know some antibodies, you use trypsin digestion, other ones you don't.
CROSBIE, Q.C.:
Q. So you're not sure whether trypsin was used for ER/PR?
MR. GULLIVER:
A. I can't tell you that. I mean, I didn't do the procedure. I certainly can find out and provide information to the Commission.
CROSBIE, Q.C.:
Q. So, Mr. Gulliver, your evidence is that you've learned, as everyone does, and I guess by the end of the period to 2005, you knew an awful lot more about the delicacy of this procedure than you did at the outset?
MR. GULLIVER:
A. Sure.
CROSBIE, Q.C.:
Q. You had a good understanding of the procedure by 2005?
MR. GULLIVER:

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A. Yes.
CROSBIE, Q.C.:
Q. That, however, does not seem to be the opinion of Dr. Carter, does it? Dr. Carter was a pathologist with special expertise in breast cancer.
MR. GULLIVER:
A. And that's her opinion, yes.
CROSBIE, Q.C.:
Q. And she thought you did not have a good understanding of ER/PR testing, as we see at the letter at 0079, and here in the second paragraph she says that, "Mr. Terry Gulliver and Mr. Barry Dyer do not have a good understanding of the limitations of automated immunohistochemistry, etc".
MR. GULLIVER:
A. But she's talking about the Ventana system here now. She's not talking about ER/PR testing in general. Dr. Carter was not in favour of the Ventana system of automation.
CROSBIE, Q.C.:
Q. Okay, in the first paragraph she talks about organizational role in the investigation of the problems with ER/PR testing from '97 to

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2004, and the planning of solutions to the current issues discovered with the Ventana automated system. She seems to be looking at both things.
MR. GULLIVER:
A. No, specifically here she's talking about she believed that automation had limitations, and that's exactly what she's saying there, that she doesn't think that we have a good understanding of the limitations of automated immunohistochemistry.
CROSBIE, Q.C.:
Q. Okay, so you would limit that statement to an understanding of the Ventana automated system, not the ER/PR testing generally?
MR. GULLIVER:
A. Exact - well, she doesn't say there "ER/PR testing".
CROSBIE, Q.C.:
Q. She goes on to say, "Rigorous clinical and technical validation of antibodies against ER and PR and establishment of reliable and reproducible means of providing ER/PR results to our patients using the substantial published peer review" and then continuous

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monitoring of immunohistochemical testing protocol. All that's not limited just to the Ventana machine surely?
MR. GULLIVER:
A. No, but what she's referring there, by August 1st, '05, since the Ventana system had been in, Dr. Ejeckam is the director of IHC lab, Dr. Ejeckam is the one that validated the antibodies for ER/PR that we were using, so that was all done under Dr. Ejeckam's guidance.
CROSBIE, Q.C.:
Q. So, sir, your evidence is that her intent here was to say that you didn't have a good understanding of the Ventana automated system?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. I'd like to go to Document 2095, page 13. I guess this was advice to Mr. Tilley from Dr. Williams, who in turn would be relying on people in pathology and in the lab, and presumably yourself, for the statement at the bottom of the page, "It has been determined that positive controls were conducted every

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day as part of the quality assurance process within the lab". Were you the source of that information?

MR. GULLIVER:

A. I could be.

CROSBIE, Q.C.:

Q. And that's what you believe today?

MR. GULLIVER:

A. I believe what today?

CROSBIE, Q.C.:

Q. Positive controls were conducted every day?

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. And these were controls that weren't run necessarily with each patient slide. They were run with a batch, right?

MR. GULLIVER:

A. They were run--there were known positive controls run every single time the ER procedure was performed. Sometimes there may be four patient cases in the run with a PR control, ER control. Other times, there were, depending on the pathologist who was interpreting, other times there might have

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been four patient cases in the batch and four ER controls and four PR controls. It depended on how many pathologists were doing the interpretation afterwards. But controls were run every single time.

CROSBIE, Q.C.:

Q. I thought that you explained earlier in your testimony that there might only be one control per batch, even if there were -

MR. GULLIVER:

A. There were times like that, yes.

CROSBIE, Q.C.:

Q. Yes.

MR. GULLIVER:

A. Yeah, but there was a control run every time.

CROSBIE, Q.C.:

Q. Okay. That's the positive external control?

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. And did your lab run negative controls every day?

MR. GULLIVER:

A. No, we did not.

CROSBIE, Q.C.:

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Q. Because you can't run more--or rather one per batch as you might be able to do with a positive control, can you? With negative controls, you have to run one per patient sample.

MR. GULLIVER:

A. I think that would be the ideal scenario.

CROSBIE, Q.C.:

Q. Is it more than the ideal scenario? Isn't the point that it's the patient's own tissue?

MR. GULLIVER:

A. That's a part of the negative control, yes. Again, you're asking me questions that really need to be answered by a pathologist.

CROSBIE, Q.C.:

Q. Well, I think we're interested, sir, in knowing just how much you did understand about this procedure. So with the negative control, how is that treated differently than the patient's specimen which it is intended to be read for ER/PR status? What's different about the negative?

MR. GULLIVER:

A. The negative control, when you are applying the particular antibody that you're trying to

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uncover, investigate, like ER, at that stage of the procedure, you don't apply any antibody. It's almost like applying a placebo, we'd say. But you still treat the negative slide in all the same other steps of the procedure.

CROSBIE, Q.C.:

Q. Same in all other respects, except it doesn't get the antibody?

MR. GULLIVER:

A. Correct.

CROSBIE, Q.C.:

Q. And it's to control for what?

MR. GULLIVER:

A. I think it's mostly used to control when you're looking at--if you have a positive external control, you have the patient's own tissue and the negative control that the negative control would assist in identifying background staining or excessive background staining.

CROSBIE, Q.C.:

Q. So the theory of it, I guess, is that it would prevent false positives?

MR. GULLIVER:

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A. I don't know if it would prevent false positives. I think that it would help reduce false positives.
CROSBIE, Q.C.:
Q. Ideally prevent them, but certainly reduce them?
MR. GULLIVER:
A. Yeah.
CROSBIE, Q.C.:
Q. Can you explain why negative controls were not run on a regular basis?
MR. GULLIVER:
A. The decision to use--what controls were run, it was made by a pathologist. Whether it's made by the site chief, whether it's made by the director of that part of the lab, you know, it's not a technologist's decision. It's not an administrative decision. Nobody had requested to run negative controls with every antibody.
CROSBIE, Q.C.:
Q. So your evidence to the Commission then is that this was not a technology decision, not a lab manager decision? It was done under direction of the pathologists and that the

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decision not to run negative controls, you're not responsible for that decision?
MR. GULLIVER:
A. No.
CROSBIE, Q.C.:
Q. You agree, your evidence is that you were not responsible for that decision?
MR. GULLIVER:
A. Right, that was not my decision to make.
CROSBIE, Q.C.:
Q. Did you know there was an issue about negative controls or even that it's a decision had to be made?
MR. GULLIVER:
A. I don't think there was ever really much discussion over negative controls.
CROSBIE, Q.C.:
Q. Was there any?
MR. GULLIVER:
A. During this time frame, Mr. Crosbie, I don't remember any specific discussion about, you know, running negative controls with ER/PR or any other IHC antibodies.
CROSBIE, Q.C.:
Q. Was this a case of not running negative

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controls in order to save money?
MR. GULLIVER:
A. Not to my knowledge, no.
CROSBIE, Q.C.:
Q. Could we go to document 3114, please, page 29? This is a DAKO handbook you provided over the weekend. Not this weekend, but the one before. You see that title there, controls?
MR. GULLIVER:
A. Positive and negative controls, yes.
CROSBIE, Q.C.:
Q. Can you do us the service of reading the first sentence?
MR. GULLIVER:
A. "Positive and negative controls must be processed alongside with the unknown to assure the accuracy of the results in any stain technique," and this is 1983.
CROSBIE, Q.C.:
Q. Yes. In fact, if we go to page four, that's a long way back, we'll go there.
THE COMMISSIONER:
Q. Do you want four? The Registrar could get that.
CROSBIE, Q.C.:

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Q. Yes, that's going to be faster than if I turn to it. Down at the foot.
THE COMMISSIONER:
Q. The foot of the page, thank you.
CROSBIE, Q.C.:
Q. We see copyright 1983 by DAKO Corporation, suggesting that this direction or knowledge about the importance of negative controls goes back quite a ways.
MR. GULLIVER:
A. Um-hm. Again, you know, negative controls are used to help assess background staining. Over the years, this procedure, this test and the advances made in this test has drastically reduced background staining in patient slides. So the requirement for negative controls, if you check most labs in North America, most labs don't run negative controls, as this has advanced. If you actually go read this manual, back when we first started doing this procedure, I used to apply glue to glass slides to try to keep the tissue on, and that glue would produce a lot of background staining. So back in the early 80s, it was more important to run negative controls just

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for the background staining.
When I first started doing this procedure with Dr. Wang, I used to run negative controls for the first antibodies. What I would have to do, I would actually have to go and collect blood samples from volunteers in the lab and centrifuge that blood and take the person's serum, separate it out and add that serum to a phosphate buffered saline and that was my placebo that I used to run a negative control with Dr. Wang. But we did that only for a short period of time, and -

CROSBIE, Q.C.:

Q. Can I just extract a point here? Are you saying that it was more important in an earlier period, in the '80s, to be running negative controls and it became less important later?

MR. GULLIVER:

A. No, it became more important when you're running prognostic markers like ER/PR, but for general IHC staining, the negative control is used to look at the amount of background staining that may be present in that particular slide.

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CROSBIE, Q.C.:

Q. Now did you just say that most labs don't use negative controls?

MR. GULLIVER:

A. To my knowledge, a lot of labs do not use-- don't run negative controls with all their IHC testing.

CROSBIE, Q.C.:

Q. What about ER/PR?

MR. GULLIVER:

A. I can't tell you specifically what every lab is doing for ER/PR, if they're running both positive and negative controls, and have always been running positive and negative controls.

CROSBIE, Q.C.:

Q. You think there are some credible labs that don't use negative controls, today, for ER/PR?

MR. GULLIVER:

A. I would submit that you'll probably find that, yes.

CROSBIE, Q.C.:

Q. Can we go to the Predham answer to interrogatories 1852, please? This is a different answer. This is a different

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interrogatory and a different answer from the one we just looked at, and specifically page six, please? Question 17 on page six. And so question 17 asked "please provide a copy of the bench procedure for antigen retrieval during the use of the DAKO system" and if we could then go to page nine, thank you, Registrar, we see there a spec sheet.

MR. GULLIVER:

A. That looks like it's the ER spec sheet, the clone.

CROSBIE, Q.C.:

Q. I just have to find my marked up copy. Give me a moment, please. Down at the bottom of page nine, I'm going to read a sentence there. It's like three from the bottom. It says "there are no obvious signs to indicate instability of this product. Therefore, positive and negative controls should be run simultaneously with patient specimens," and I'm going to guess that's your writing at the top of the page.

MR. GULLIVER:

A. That's not my writing, no.

CROSBIE, Q.C.:

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Q. Do you know whose writing it is?

MR. GULLIVER:

A. It looks like to me it's either Mary Butler--I think Mary Butler.

CROSBIE, Q.C.:

Q. And did you assist Ms. Predham in giving the answer to this question, "please provide a copy of the bench procedure for antigen retrieval during the use of the DAKO system"?

MR. GULLIVER:

A. I think I supplied a--I gave as much information to Ms. Bussey.

CROSBIE, Q.C.:

Q. And the answer is "please see the bench procedures for certain clones," and then as part of the appendix to all that, we have the spec sheet from DAKO and the statement "positive and negative controls should be run simultaneously with patient specimens." That's not really an equivocal statement, is it?

MR. GULLIVER:

A. That's their recommendation.

CROSBIE, Q.C.:

Q. It is their recommendation, isn't it?

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MR. GULLIVER:
A. Yeah, and I will submit to you that if the pathologists want negative controls, they would have been run. But no pathologist ever asked to start running negative controls for IHC testing until recently we're now doing negative controls.
CROSBIE, Q.C.:
Q. Whose files were these documents in that are appended here? Were they in any pathologists' files?
MR. GULLIVER:
A. These were -
CROSBIE, Q.C.:
Q. Or were they in your files?
MR. GULLIVER:
A. They weren't in my files, no. I retrieved them. I asked the pathology staff to please gather any documentation. If I got requests either from, you know, our lawyer's office, I gathered them up and sent them down to Ms. Bussey.
CROSBIE, Q.C.:
Q. Is this spec sheet intended for the pathologist or for the technologist and lab

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manager?
MR. GULLIVER:
A. It's certainly intended for both. There's information here that applies to both clinical and technical.
CROSBIE, Q.C.:
Q. Does it imply that negative controls were mandatory?
MR. GULLIVER:
A. It says that they're recommended.
CROSBIE, Q.C.:
Q. If the purpose of negative controls was to eliminate or reduce the presence of false positive readings -
MR. GULLIVER:
A. Which is the background staining, yes.
CROSBIE, Q.C.:
Q. Yes. Does that absence of negative controls increase the risk of having false positives?
MR. GULLIVER:
A. Again, I think you got to ask the pathologists that question.
CROSBIE, Q.C.:
Q. Could we go to document 3108, page two? This document was prepared by you, sir. It's a

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spreadsheet prepared by you?
MR. GULLIVER:
A. Mostly along the way, yes.
CROSBIE, Q.C.:
Q. And it's entitled "ER/PR technical positive negative rate for St. John's specimens." What do you mean by technical?
MR. GULLIVER:
A. Technical means if there's something reported as being positive. So it's not zero, zero. Someone says it's two percent, five percent, 90 percent, 100 percent, that there is positive staining detected within the tissue.
CROSBIE, Q.C.:
Q. So what does this table assist us in arriving at by way of the positivity rate for the total DAKO period? What do you say it is?
MR. GULLIVER:
A. From a lab perspective, we're saying there there was 74 percent of the total cases that were reported as positive staining and 26 percent were reported with zero, zero staining.
CROSBIE, Q.C.:
Q. Okay, and now you qualify that by saying "from

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a lab perspective." Just explain that.
MR. GULLIVER:
A. Well, if you have, you know, a slide that comes from the pathology lab and the pathologist reads the slide and they assign the case out and says that the tumour cells are five percent positive for ER/PR or 25 percent positive or 75 percent or 100 percent, they are saying that there's a portion of that slide is positive.
CROSBIE, Q.C.:
Q. So in arriving at that 74 percent positivity rate, you're excluding all the clinically negative slides?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. And you think that's the proper way to arrive at the positivity rate?
MR. GULLIVER:
A. I don't think that there's any proper way and I think if you search the world, you're probably not going to find any agreement on what you should categorize as a positive lab result or a negative lab result.

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CROSBIE, Q.C.:
Q. Well, sir, it sure does produce a different result, I suggest to you, when you include the--when you exclude, rather, the clinically negative and if you go to that column, total DAKO, over toward the right, rather, you count down three lines, you got 53 percent, and I suggest to you that that's the true positivity rate for the total DAKO period.
MR. GULLIVER:
A. That's 53 percent of what we call strong positive.
CROSBIE, Q.C.:
Q. And that's the most appropriate way of doing the calculation is your evidence? That's what you feel is most appropriate way? The way that arrives at 74 percent, that's the most appropriate way?
MR. GULLIVER:
A. No, that's why I have three different figures here. When this was being done along the way within Eastern Health, there was still no agreement upon between the lab side and the oncologists side of what really constituted a positive or a negative. We heard people say

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that anything above one percent should be considered positive. So that's why I made three separate categories, so we could make that determination. What percentage were strong positives, there's no dispute. They're positive, positive, positive. What numbers and percentage would fall into that, the clinical definition and what ones were the true zero, zeros, the true negatives, and if you look at that figure, you can see there's a--you just showed the total, 53 percent were strongly positive. 19 percent were reported with a degree with positivity and there were 28 percent that were reported with no staining whatsoever.
CROSBIE, Q.C.:
Q. Can we go to document 3100, please, Registrar? It's an e-mail on October '07 from you to Dr. Howell and some others, and it's about the Peninsula results and you say "please find attached a table of the Peninsulas' patients who originally tested at MSH from 1999-2005" and that must mean Mount Sinai, correct?
MR. GULLIVER:
A. Yes.

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CROSBIE, Q.C.:
Q. "I read each hard copy of reports and then logged them the same as we did two years ago." Then you say "positive, weak positive and negative, no staining, the positive negative rate overall is excellent," and if we look down to the table, which is page two, we see a 78.3 percent positivity rate, which in fact is excellent, isn't it?
MR. GULLIVER:
A. Um-hm.
CROSBIE, Q.C.:
Q. However, you--did you ever meet with Dr. Gown?
MR. GULLIVER:
A. I never met with him. I was in a room where he was there.
MR. SIMMONS:
Q. Excuse me, I think there's nowhere in this report any questions concerning the content from Dr. Gown, I believe that's a matter that we haven't (inaudible).
THE COMMISSIONER:
Q. Whether he met with him or not surely isn't the question, and so far Mr. Crosbie hasn't trespassed into anything that could be

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classified as solicitor-client privilege, I don't think.
MR. SIMMONS:
Q. (Inaudible).
CROSBIE, Q.C.:
Q. Well, I don't need a reminder because--maybe my friend needs a reminder that Dr. Gown swore an affidavit, and in that affidavit, he quoted a 74 percent positivity rate. We can look at the affidavit, if you wish. I'm just--I'm suggesting that must have come from you.
MR. GULLIVER:
A. I think that came probably from some of those tables that I was asked to produce and update over the period of time.
CROSBIE, Q.C.:
Q. So you feel that information must have come from you, 74 percent?
MR. GULLIVER:
A. I don't know must have. I didn't give it to him directly, but whoever gave it to him probably used that as a source for their estimation.
CROSBIE, Q.C.:
Q. Why did you use a different method of

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calculating the positivity rate for Clarenville than you did for St. John's?

MR. GULLIVER:

A. How is there a different method? I got positives, the weak positives and then the zero, the negative no staining.

CROSBIE, Q.C.:

Q. All right, let's put it this way, if we follow the same method you followed at Exhibit 3100 for Clarenville, who we know was sending their--past a certain point, their material out to Mount Sinai, we get 78.3 percent positivity. That's obvious. If we follow the same methodology for St. John's, we get 53 percent positivity, the same methodology.

MR. GULLIVER:

A. Again, this is a total of 112 specimens. The numbers here is a total of 143 cases that were reviewed for Peninsulas.

CROSBIE, Q.C.:

Q. Yes. So that's not big enough to have a--run a valid estimate of positivity rates?

MR. GULLIVER:

A. I don't know that, but I didn't do this to determine the positive, negative rates for

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Clarenville. That's not why this was done.

CROSBIE, Q.C.:

Q. Okay. Well, we just take the same methodology which yields 78.3 percent and we do it with St. John's and it yields 53 percent. We're agreed on that?

MR. GULLIVER:

A. The strong positives, yes.

CROSBIE, Q.C.:

Q. Yet 53 percent doesn't find its way into Dr. Gown's affidavit. It's 74 percent.

MR. GULLIVER:

A. Again, I did not give him anything directly.

CROSBIE, Q.C.:

Q. Never met with him?

MR. GULLIVER:

A. I was in a room where he was in attendance. I never met with him individually, separately, no.

CROSBIE, Q.C.:

Q. Suggest to you that the Clarenville positivity rates are a reasonable control for positivity in St. John's, done at Mount Sinai.

THE COMMISSIONER:

Q. I'm sorry, the question, I didn't understand

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the question, Mr. Crosbie.

CROSBIE, Q.C.:

Q. I'm suggesting to the witness that this positivity result for Clarenville is a reasonable control for what was being done in St. John's at the same point in time.

MR. GULLIVER:

A. I don't understand.

THE COMMISSIONER:

Q. Control or comparable?

CROSBIE, Q.C.:

Q. Pardon me?

THE COMMISSIONER:

Q. I mean, in the--I think it's the use of the word "control" that I'm having trouble with.

CROSBIE, Q.C.:

Q. Well -

THE COMMISSIONER:

Q. Are you suggesting they should have had the same -

CROSBIE, Q.C.:

Q. For the same reason that you keep tabs on your positivity rate, it's a metric that tells you whether you're conforming to established expectations in your outcomes. So sir, I'm

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simply suggesting that this is an interesting and valid control against what was going on at your lab in St. John's.

MR. GULLIVER:

A. Well, you haven't even asked me why I even did this.

CROSBIE, Q.C.:

Q. Can you answer the question, please?

MR. GULLIVER:

A. I can't answer your question because you're assuming--I think you're trying to infer that this was done to compare the St. John's testing to a pool of results that we could access in Clarenville that were done at Mount Sinai and compare the two from St. John's to Clarenville.

CROSBIE, Q.C.:

Q. During the same time period, yes.

MR. GULLIVER:

A. This was done just quite recently, the Clarenville ones. Long after all of our retesting was completed.

CROSBIE, Q.C.:

Q. Would you go back to page one there? What you're saying there is these were tested at

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Mount Sinai from 1999 to 2005.
MR. GULLIVER:
A. Right, but I did this in October of 2007, long after our retesting was pretty well completed at Mount Sinai. This was not done to compare St. John's results to somehow Mount Sinai results.
CROSBIE, Q.C.:
Q. No, it doesn't matter why you did it. I'm saying there's the data. When we compare the two, for the same--more or less the same periods, your calculations yield, done by the same methodology, 53 percent positivity in St. John's, and yet in Clarenville, sending their specimens to Mount Sinai, they got 78 percent.
MR. GULLIVER:
A. On 143 samples over almost six years. But the main reason why we did this here was that every patient with a test performed in Newfoundland had the review done to see if they should be retested at Mount Sinai, and the assumption was made that the patients who resided on the Clarenville domain and had been tested at Mount Sinai from '99 up until this point in time, that the assumption was that

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any negative patients there could not retest positive and should those patients be given the same review as all the other patients in Newfoundland. It had nothing to do with trying to compare positive rates to what was found in St. John's.
CROSBIE, Q.C.:
Q. That may be so. Could the reason for the difference in performance on this metric, positivity rates, be poor quality tissue preparation and lack of controls?
MR. GULLIVER:
A. Lack of controls at St. John's? I don't think so. Controls were run every time in St. John's, but it certainly could be due to--partly due to tissue preparation. I mean, that's obviously one of the factors that could affect the outcome.
CROSBIE, Q.C.:
Q. Could we go to 2141, please? And I read there, March 6th, 2006. Now this is a note by Dr. Cook but he's speaking to Dr. Naghibi why Clarenville discontinued ER/PR slides. She replied "it was due to poor quality and to lack of external controls." That's what they

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thought in Clarenville.
MR. GULLIVER:
A. And plus, they were paying for this.
CROSBIE, Q.C.:
Q. That's what they thought in Clarenville.
MR. GULLIVER:
A. And I think that was during a time after Dr. Khalifa stopped all the interpretations. There were control slides that were run and the control slide was being read and verified pathologists in St. John's and then cases--then the slides were--the patient slides were sent out to around the region. That went on for a small time frame before control slides were done for every pathologist that were outside St. John's interpreting.
CROSBIE, Q.C.:
Q. I put it to you that this suggests that positive controls were not being conducted every day.
MR. GULLIVER:
A. Well, I'm telling you that's not correct.
CROSBIE, Q.C.:
Q. Thank you. Now could we have the testimony of Dr. O'Malley? It's June 23, 2008, page 179.

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REGISTRAR:
Q. June 23rd?
CROSBIE, Q.C.:
Q. That's what my note says, June 23rd. And page 179. Let's see if we are where I think we are. Yes. Could you just read that passage, roughly lines one to 17 at the top of page 179? Just read it to yourself.
MR. GULLIVER:
A. On the right-hand side?
CROSBIE, Q.C.:
Q. On the right-hand side, that's page 179. Just read it to yourself. Whenever you're ready, sir.
MR. GULLIVER:
A. Go ahead.
CROSBIE, Q.C.:
Q. So the first point I'd extract out of that is "a good control should catch problems in the preparation of specimens." Nothing controversial about that.
MR. GULLIVER:
A. And I don't know if he means the internal or external control.
CROSBIE, Q.C.:

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Q. The second point is that "the effectiveness of controls depends on having a senior, experienced technologist or pathologist to oversee the technical steps." Anything controversial about that?
MR. GULLIVER:
A. No.
CROSBIE, Q.C.:
Q. So if she's describing, it's she, is describing a critical function in ensuring a quality test, senior supervision and oversight.
MR. GULLIVER:
A. Yeah.
CROSBIE, Q.C.:
Q. And on the technical side, you said that the persons performing that critical function in the period from 1997 to 2005 were who again?
MR. GULLIVER:
A. Well, from 1987 up until -
CROSBIE, Q.C.:
Q. '97.
MR. GULLIVER:
A. But from '87, Mary Butler and Peggy Welsh are doing IHC testing. Then they're the two ten

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years later who start doing the ER/PR testing with Dr. Khalifa. They continue that up until Mr. Ken Green, who was 25 years in pathology at St. Clare's. He moves in as a third technologist in the IHC lab. Ms. Welsh resigns and she moves to Nova Scotia and then the next senior pathology technologist, Mr. Les Simms, was then moved into that part of the laboratory.
CROSBIE, Q.C.:
Q. And you as manager were responsible to ensure that they were doing that function that Dr. O'Malley describes here?
MR. GULLIVER:
A. I was the manager up until 2001 when Mary and Peggy were both there as technologists.
CROSBIE, Q.C.:
Q. And in the period until 2001, the answer then would be "yes"?
MR. GULLIVER:
A. Up until 2001?
CROSBIE, Q.C.:
Q. When you moved? The answer then would be "yes"?
MR. GULLIVER:

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A. I was the manager then, yes.
CROSBIE, Q.C.:
Q. And you were responsible to ensure that these people were doing - were performing that critical function?
MR. GULLIVER:
A. And to the best of my knowledge, they performed that function.
CROSBIE, Q.C.:
Q. Your answer then is "yes"?
MR. GULLIVER:
A. The technologists?
CROSBIE, Q.C.:
Q. No, no, I asked you, you were responsible as manager?
MR. GULLIVER:
A. well, at that time I'm managing pathology, blood collection, immunology. I probably got 75 staff, and I said to you earlier I cannot be behind staff shoulders 24 hours a day, 7 days a week. There's a point where you have trained staff where you expect that they will perform their job as they're supposed to.
CROSBIE, Q.C.:
Q. So is the answer then that no one was

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exercising managerial oversight over their fulfilment of those responsibilities?
MR. GULLIVER:
A. No, that's not the answer.
CROSBIE, Q.C.:
Q. Then is the answer that sometimes you did and sometimes you didn't?
MR. GULLIVER:
A. No, I think the answer is that people work, they do their jobs, they work independently in a lot of these parts of the laboratories. If they needed guidance or assistance, they would go to the pathologist if it's a clinical issue. If they needed guidance or assistance for an administrative issue, then they would go to their direct manager, and at that point in time it would be me.
CROSBIE, Q.C.:
Q. So the system was if they had a problem, they should come to somebody else?
MR. GULLIVER:
A. If they had a problem that they needed assistance with, then they would go seek guidance.
CROSBIE, Q.C.:

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Q. And if they had a problem and didn't know it, then I guess they wouldn't go and seek guidance?

MR. GULLIVER:

A. Well, if they had a problem and didn't know it, that problem should show up in the end product, which is the slide, and then the pathologist would still read every single slide and sign it out and verify it, so they would pick up a problem.

CROSBIE, Q.C.:

Q. Looking at line 15 on page 181, "So if it turns out that an institution was not getting reliable reading of the patient's tissue sample, it stands to reason we should look for problems with the controls", and she says, "Definitely, yes". Do you agree, disagree?

MR. GULLIVER:

A. I never heard her testimony, or don't know how this is all framed here, but certainly with that simple statement, I would have to say yes. I'm thinking she's wanting to talk about the internal patient's control. She's talking about reading the patient's tissue sample.

CROSBIE, Q.C.:

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Q. Could we go to the testimony of Dr. Cook, July 7th, 2008, page 218. What I'm asking Dr. Cook about right there in that paragraph starting around line six -

MR. GULLIVER:

A. Over on page 218?

CROSBIE, Q.C.:

Q. Right. There was testimony from a Dr. Mullen from Mount Sinai earlier, and he looked at his data and he - depending on what values you use for clinically positive/clinically negative, then his positivity rate for the material he had processed on behalf of Eastern Health here would vary between 46.3 and 53.7 percent positivity rate, and I was putting that to Dr. Cook, and Dr. Cook, you might see at 219, page 219, "No, it's more - it's in the range of 70 to 67 percent - 67 to 70 percent positivity, 30 to 33 percent negative". He's disagreeing, in other words, and I'm suggesting it would look like he's getting that information from you?

MR. GULLIVER:

A. I have never said directly to Dr. Cook - again you've seen multiple times where that spreadsheet was updated. You've seen the template, and I mean, Dr. Cook would have a copy of it and he could use it as he - and that's his opinion.

CROSBIE, Q.C.:

Q. Do you have a view, Mr. Gulliver, on who's correct, Dr. Mullen or Dr. Cook? Was it more in the area of 50 percent or 30 percent?

MR. GULLIVER:

A. About positive cases?

CROSBIE, Q.C.:

Q. Well, 30 percent would refer to the negative rate.

MR. GULLIVER:

A. I think that our negative rate is closer to the 30 percent.

CROSBIE, Q.C.:

Q. So what is the - you're program director now. What is the laboratory's position on the positivity rate for the period of the DAKO machine, what is your position?

MR. GULLIVER:

A. I don't think Eastern Health has a position on that.

CROSBIE, Q.C.:

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Q. All this time later?

MR. GULLIVER:

A. Are you asking my opinion or are you asking what's Eastern Health's position on the overall positivity rate?

CROSBIE, Q.C.:

A. Well, both. If your opinion is different from something you know to be the official view of Eastern Health, you can let us know about it, but let's come back to your answer, you're not sure that Eastern Health has a position on what its positivity rate was during the relevant period?

MR. GULLIVER:

A. I don't think Eastern Health has done an official release of data to say here was the official positivity rate. Again you're going back to a debate that's been going on for a long time, not just in Eastern Health, across a lot of labs, in what really is the definition of a positive, what's a positive, what's a negative.

CROSBIE, Q.C.:

Q. And so you can't give us the position of Eastern Health on that question?

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MR. GULLIVER:
A. I can't, no.
CROSBIE, Q.C.:
Q. Thank you. I'd like to go back to these Ejeckam memos, 113, page 5. I'm just looking for my paper copy because I have it marked. Yes, it's page 5 of 113. So just to pick a few things out of there we can note - now, first of all, this is the third memorandum, June 19th, 2003. The earlier one, which you can look at if you want to, but you've probably seen it lots of times, it's at page one, and it's April of 2003. That's the first one and it was addressed to pathologists and Barry Dyer, and all technical staff on immunohistochemistry.
MR. GULLIVER:
A. It's addressed to pathologists across the province, and it's cc'd to --
CROSBIE, Q.C.:
Q. CC'd, yeah.
MR. GULLIVER:
A. To Barry and the technical staff in the IHC lab.
CROSBIE, Q.C.:

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Q. So your evidence would be that this wasn't sent to you and it didn't find its way into your hands?
MR. GULLIVER:
A. I found out from Mr. Dyer after the fact, after testing had been stopped.
CROSBIE, Q.C.:
Q. So then if we go to the next one, we see May 2nd, 2003. This one is to pathologists -
MR. GULLIVER:
A. It's the same group as the other one, and I think it's CC'd to Mr. Dyer and technical staff.
CROSBIE, Q.C.:
Q. Yes, same as before. So that's why I'm going to ask you why the difference when we get to June? That's addressed to you.
MR. GULLIVER:
A. Again I've said in my testimony with Ms. Chaytor that - and this takes place - it's seven weeks after he puts testing back in place. I had met Dr. Ejeckam over in the lab corridor and I had said to him that if there's anything else that he views in the IHC part of our lab, you know, put it in writing and send

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it to me, and that's why - and there's been some dispute over did I even ask him to do that, and, you know, my point is I'm the only one who gets addressed this one. He doesn't send the memo shutting down testing, he doesn't send me the memo putting testing back in place, but he - I'm the only one who he's addressed this to, and he copies the clinical chief, and I think Dr. Robb, but he addressed this one specifically to me because I asked him any else with the lab, put it in writing, and then we sat down and we talked about it.
CROSBIE, Q.C.:
Q. Could it be because you had budgetary responsibility?
MR. GULLIVER:
A. I think that's a part of my role, yes.
CROSBIE, Q.C.:
Q. Well, let's look at what he's saying here. Paragraph one, he's talking about physical location. Paragraph three, he's talking about the need for a dedicated staff. Over on page two down toward the bottom of the paragraph, he's talking about to do less would become a gamble where you may win or lose?

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MR. GULLIVER:
A. Uh-hm.
CROSBIE, Q.C.:
Q. And talks about spelling disaster, and bottom of page - paragraph four, he talks about an activity being identified as special and unique and requiring financing and staffing. At paragraph six -
MR. GULLIVER:
A. The next paragraph he compliments our existing staff.
CROSBIE, Q.C.:
Q. Yes, he does, and in paragraph six, he speaks of diagnosis and so on, jeopardizing patient care, and at the bottom he says, "Therefore, advise you kindly take a hard look and then commit the necessary resources, human and financial, to this special all important and only service", and you described for us earlier how your responsibility had to do with budgeting and making sure that what was being done was adequately budgeted for?
MR. GULLIVER:
A. That's a part of my overall responsibility as the program director.

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CROSBIE, Q.C.:
Q. Sir, we know that this didn't find its way to Dr. Williams, did it?
MR. GULLIVER:
A. Not to my knowledge, no.
CROSBIE, Q.C.:
Q. Until much later.
MR. GULLIVER:
A. Yeah.
CROSBIE, Q.C.:
Q. If human and financial resources had to be committed, that by itself would mean that this would have to go to Dr. Williams?
MR. GULLIVER:
A. If we had to find - if we had to ask for new resources or additional resources.
CROSBIE, Q.C.:
Q. When I read this, it sure looks to me like Dr. Ejeckam thinks that necessary human and financial resources be committed, meaning new ones. You had a different view?
MR. GULLIVER:
A. No, I sat down with Dr. Ejeckam and we discussed all parts of this here, and I've testified, as you probably read or heard, what

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we did in response to this here for Dr. Ejeckam. It was physically moving the staff and the lab into its own dedicated space, which did not require new additional resources. We took the current staff that were working in the IHC lab with Dr. Ejeckam. He wanted them to be full time in the lab to spend more time with him for training and read, as he says - as he outlines there. I think Mr. Dyer took one of the technologists from St. Clare's, moved them over to Health Sciences to train them in to do the small grossing to replace part of the work these people were doing, and then the advancement in the new technology, new equipment to help with workload and productivity and volumes, I've already testified we had enough money in our operating budget to be able to go out and acquire the Ventana system within existing resources. So I didn't need to go to Dr. Williams to look for new resources for this here.
CROSBIE, Q.C.:
Q. Commissioner, I'll no longer be critical of Ms. Chaytor for going longer than her

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estimated time. I still have a fair amount of material here.
THE COMMISSIONER:
Q. Do you want to take the afternoon break?
CROSBIE, Q.C.:
Q. Probably a good place.
(BREAK)
THE COMMISSIONER:
Q. Please be seated. Mr. Crosbie.
CROSBIE, Q.C.:
Q. Thanks. Registrar, could we have Dr. Cook's testimony, July 2nd, 2008, page 262. What I'm asking Dr. Cook about there is the follow-up to the Ejeckam memorandum, and as we've just seen, the memorandum in June addressed to you had recommendations for various forms of action, Mr. Gulliver, including mention of resources that should be committed, and so I'm just going to ask you to have a look at Dr. Cook's account. You can take your mouse there if you would, and go from page 262 to 265. Read that to yourself, and when you're through I'm going to ask you if his account squares with your recollection of how this transpired. I might have said I asked the questions, but

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it's obviously Mr. Coffey.
MR. GULLIVER:
A. You want me to go to the end of 265?
CROSBIE, Q.C.:
Q. Well, 265 is probably - that tells the story.
MR. GULLIVER:
A. Okay.
CROSBIE, Q.C.:
Q. And you notice at line 11, 265, Dr. Cook - well, he was asked just before that why he wouldn't have spoken to Dr. Ejeckam about it. He said, "Because I felt an agreement or understanding had been made with Mr. Gulliver to address his concerns". First of all, can you tell the Commissioner whether this seems like a fair account of what transpired in relation to whatever meeting you had about Dr. Cook and the question of following up on Dr. Ejeckam's concerns?
MR. GULLIVER:
A. I think that's a fair account, that after Dr. Ejeckam and I and Barry had met in my office and talked about, you know, June 19th memo, and the things that we could do, the time frame that it would take, I think Dr. Cook and

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I just spoke about it, and I let Dr. Cook know what we had talked about, and I think this is a fairly accurate account of what transpired.

CROSBIE, Q.C.:

Q. So what I get out of that is that the follow-up was informal in the sense there's nothing in writing?

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. Was there further oral communication between you and Dr. Cook on the response to Dr. Ejeckam's concerns?

MR. GULLIVER:

A. Not specifically. I just think that over a time period, I think that both Dr. Cook and I saw that, you know, the laboratory itself was moving into its own space, knew that Mr. Dyer had start putting a process in place to retrain other techs in pathology to take over the grossing function that the IHC techs were taking, thereby freeing them up to have more time down in the IHC lab, and I think that Dr. Cook knew - and this happened in late June. Again it's during the summer period with

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vacations and things, and then I think in September Mr. Dyer starts writing the tender to go out to the marketplace looking for a new system.

CROSBIE, Q.C.:

Q. But there's no oral communication about the progress of this between you and Cook, is there?

MR. GULLIVER:

A. I don't think we had a separate meeting about it, just thinking in just talking -

CROSBIE, Q.C.:

Q. Oral communication.

MR. GULLIVER:

A. In speaking to Dr. Cook, yes.

CROSBIE, Q.C.:

Q. You did speak to him about the progress of these matters?

MR. GULLIVER:

A. To my knowledge, yes.

CROSBIE, Q.C.:

Q. Okay, nothing in writing, though, is there?

MR. GULLIVER:

A. No.

CROSBIE, Q.C.:

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Q. There's no actual appraisal of what would be acted on and what would not be acted on?

MR. GULLIVER:

A. In relation to what we could do?

CROSBIE, Q.C.:

Q. In relation to what Dr. Ejeckam set out as being his concerns.

MR. GULLIVER:

A. Well the concerns were the space, the staffing being dedicated and then to address the workload volumes and productivity.

CROSBIE, Q.C.:

Q. There was no budget drawn up because you didn't see those issues or any other issues raised by Ejeckam as requiring a commitment of fresh resources.

MR. GULLIVER:

A. It didn't seem to be at the time, no.

CROSBIE, Q.C.:

Q. And overall, you and Dr. Cook regarded the issues raised by Dr. Ejeckam as among a host of other issues of similar importance facing the lab, the lab program?

MR. GULLIVER:

A. I would say yes.

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CROSBIE, Q.C.:

Q. And the Ejeckam issues deserved no special attention and no documentation of a special nature and no special reporting?

MR. GULLIVER:

A. I think they required the attention that we gave them in talking to Dr. Ejeckam. Dr. Ejeckam seen the physical things that were taking place and, you know, what we committed to, it actually all took place.

CROSBIE, Q.C.:

Q. In your opinion, did Dr. Cook provide appropriate leadership on the Ejeckam issues?

MR. GULLIVER:

A. I really don't think I could answer that. I think that from my perspective, what was in my realm of responsibility, talking about the space, staff and equipment, that I think I responded appropriately, along with Mr. Dyer in conjunction with Dr. Ejeckam and Dr. Cook was well aware of the things that were taking place.

CROSBIE, Q.C.:

Q. I'd like to turn now to the question of some statistics and I mentioned earlier about the

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Gown affidavit and that's found at P-0375, page 2 if the Registrar can take us there, please? And page 2, paragraph 6, and that's the reference there, "In reviewing the generic data presented to me, it appeared that the ER positivity rate was in the range of 65 to 75 percent for breast cancers analyzed at the laboratory during the time the DAKO instrument was employed. I have been advised that the seven year average was 74 percent ER positivity." And that information would seem to be in sync with what you developed in your spreadsheets?

MR. GULLIVER:

A. Probably, yes.

CROSBIE, Q.C.:

Q. Could we now bring up Exhibit P-1841? This is explained in the footnotes, Mr. Gulliver. It was prepared by Dr. Hutton and it's based on information contained in those interrogatories, the documents which we looked at a little earlier. And it's simply a matter of taking numbers and doing a little math on them and arriving at percentages, and you'll see in that top table there where Dr. Hutton

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simply takes total test, total positives and any of us could take the same information from the Predham answers to interrogatories and do the same calculations. We come up with a calculation of a false negative rate and percentage terms, and for the period in the top table, the period when the DAKO autostainer was in use, the statistical performance shows a 44 percent false negative rate. Are you in any position to dispute that?

MR. GULLIVER:

A. I'm really in no position to either agree or disagree. This is the first time I've seen this kind of analysis.

CROSBIE, Q.C.:

Q. Have you calculated the false negative rate?

MR. GULLIVER:

A. No, I have not.

CROSBIE, Q.C.:

Q. Nobody asked you to do that?

MR. GULLIVER:

A. I think that's a part of what NLCHI has been working on and doing some analyses.

CROSBIE, Q.C.:

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Q. So that was left for NLCHI to do.

MR. GULLIVER:

A. And I guess it looks like to me if you're using the clinical guidelines as to what's a negative and positive for this table, on the bottom it says "30 percent cut off and 10 percent".

CROSBIE, Q.C.:

Q. Yes. Clinically negative. I want to come back to--so just to get that clear now, Eastern Health as far as you're aware doesn't have a calculation or an official position on what a false negative rate was.

MR. GULLIVER:

A. No, I think that NLCHI is doing some of that analyses in the database and I think they're doing it, Mr. Crosbie, based upon a one percent positivity, which would be, you know, a positive result, but at one percent, ten percent, 30 percent, looking at different cut offs.

CROSBIE, Q.C.:

Q. Well I'm sure that will be revealed to us all in good time. I want to come to your--when you were talking to Ms. Chaytor and it was in

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relation to this NTV story from October 13th, 2005, you know the one that talked about new technology with more accurate results and 90 to 95 percent of patients won't be affected and all testing would be complete in a month, that one?

MR. GULLIVER:

A. Yeah.

CROSBIE, Q.C.:

Q. You adopted the approach of talking about 3000 patients, meaning, I guess, 3000 patients who had been, on whom this test had been run in the period '97 through 2005.

MR. GULLIVER:

A. Well I think at that time, but that time, I think that's October '05, I think that the day that we had available at that time was that I had seen through the computer searches that we searched for ER/PR tests and there were approximately 3000 tests that were performed.

CROSBIE, Q.C.:

Q. Uh-hm. How does that relate to what we looked at in Exhibit P-3107 this morning at page 2 where the number 2700 and 26 appears?

MR. GULLIVER:

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A. Again, this here has been refined many times, this is dated January of '08, I think, over three years later. And by this time we've gone back through all the reports and verified and patients who had ER/PR tests performed that weren't on the primary breast cancers were removed from the--from numbers.

CROSBIE, Q.C.:

Q. Uh-hm, so you know, are we talking about twenty seven hundred and something patients?

MR. GULLIVER:

A. Who have ER/PR for primary breast cancer. But in October '05, at that point in time, we wouldn't be at this with that final number, it was an approximate number of 3000 patients who had an ER/PR test performed.

CROSBIE, Q.C.:

Q. All right.

THE COMMISSIONER:

Q. For whatever reason.

MR. GULLIVER:

A. For whatever reason, yes.

CROSBIE, Q.C.:

Q. And do I get that there may be another hundred who had the test for tumours of unknown

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primary origin?

MR. GULLIVER:

A. Could be more than that, a bit more than that, yes.

CROSBIE, Q.C.:

Q. How many?

MR. GULLIVER:

A. I can't tell you an exact number, but I mean, it's somewhere between this number and 3000. It could be 150, it could be 175.

CROSBIE, Q.C.:

Q. Okay. And do you know what the current estimate of the number of patients tested false positive is now?

MR. GULLIVER:

A. No, I don't.

CROSBIE, Q.C.:

Q. That we get from NLCHI, does 386 mean anything to you?

MR. GULLIVER:

A. No.

CROSBIE, Q.C.:

Q. It doesn't. So from your experience, though, you told Ms. Chaytor that you thought that certainly ten percent or less of the patients

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who were tested during this period were affected, that's how you put it.

MR. GULLIVER:

A. That would be affected by this whole retest process.

CROSBIE, Q.C.:

Q. Uh-hm. Yet the patient group who stood to be most affected would be the ones who tested negative during the period, wouldn't they?

MR. GULLIVER:

A. They would be, yes.

CROSBIE, Q.C.:

Q. There's something I don't understand here, so I'm going to ask you to try and enlighten me. I'm not sure if I picked up that there are patients you discovered going through your--through Meditech and through the pathology reports, there were patients for whom ER/PR had not been requisitioned, do I understand that to be the case?

MR. GULLIVER:

A. They were not ordered in the Meditech system, yes.

CROSBIE, Q.C.:

Q. They were not ordered.

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MR. GULLIVER:

A. Yeah.

CROSBIE, Q.C.:

Q. And therefore not done?

MR. GULLIVER:

A. Oh they were done. So what would happen, Mr. Crosbie, the pathologists who were in the reporting room most of times doing their readings, they would fill out a manual IHC requisition form and then that form would go to the technologist to perform the testing, but then the technologist would do the data entry and put their request in the computer system on behalf of the pathologist to say Dr. So and So wants an ER/PR on this patient. And they would go and physically order the test in the computer system and then when the slides were completed, they would go back and say and they're now complete and done and bring them back. We came across, you know, there were a handful of situations where that function was not completed by the technologist and again, over the almost 3000 total ER/PR tests done, I think we came across eight or nine or ten cases where the paper requisition wasn't

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transcribed into the computer record.
CROSBIE, Q.C.:
Q. Uh-hm. But you could discover a result because the testing was done.
MR. GULLIVER:
A. The testing was done and the pathologist had put the result into the computer system--in the patient's report.
CROSBIE, Q.C.:
Q. So there was a result there to be looked at?
MR. GULLIVER:
A. Yes.
CROSBIE, Q.C.:
Q. Okay, so that actually didn't result in any distortion of anything, it was just a matter of maybe, well it's just a matter of finding out what the result as entered by the pathologist was?
MR. GULLIVER:
A. Right.
CROSBIE, Q.C.:
Q. Then was there a category of patients for whom ER/PR was requisitioned but there was no test or no report and--or have I got that wrong. Is that the same thing you just described to

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me?
MR. GULLIVER:
A. No, and there were, I think there might have been two or three cases in total, Mr. Crosbie, where in reading all the reports, we came across where there was an ER/PR ordered in the system, but in reading through the whole pathologist report, there was no indication of a result on the patient's report.
CROSBIE, Q.C.:
Q. It either hadn't been done or it hadn't been reported?
MR. GULLIVER:
A. One or the other.
CROSBIE, Q.C.:
Q. Yeah, and that's maybe two or three?
MR. GULLIVER:
A. I think there's only two or three cases, yes.
CROSBIE, Q.C.:
Q. And so what was done with those? You went and sent those to Mount Sinai, I guess.
MR. GULLIVER:
A. And they were gone back, checked and reviewed and then if they had to be retested, were retested, yes.

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CROSBIE, Q.C.:
Q. Well it wouldn't be a retest because you couldn't figure out if it had been tested already.
MR. GULLIVER:
A. I think when we went through them, there were original slides, but there was no result documented into the computer system.
CROSBIE, Q.C.:
Q. So did someone read the slide before the block or whatever was sent to Mount Sinai?
MR. GULLIVER:
A. I don't know what Dr. Cook or Dr. Fontaine did with the -
CROSBIE, Q.C.:
Q. Yeah, this may be a small effect, but I'm guessing that the two or three people for whom no result could be found, either not reported or because the test was not done, well they can't show up in the false negative rate because there's no -
MR. GULLIVER:
A. I know and that was so small that really it's not going to change significantly anything on these spreadsheets here.

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CROSBIE, Q.C.:
Q. However, I suppose they could have been deprived of an opportunity for a therapy that otherwise might have been offered to them.
MR. GULLIVER:
A. And again, I mean that's certainly a possibility, yes.
CROSBIE, Q.C.:
Q. One might want to ask--this is outside your scope, I suppose, one might want to ask the oncologist how it didn't get noticed. Dr. Ejeckam, when we looked--I don't know if you saw this, it's still up here--no it's not still up there.
MR. GULLIVER:
A. I think you had something, you had a statistic when, after Dr. Ejeckam's intervention in 2003.
CROSBIE, Q.C.:
Q. Yeah, Dr. Ejeckam's table there. Just briefly, just for the sake do you have any idea about this, Dr. Ejeckam seemed to have improved the positivity rate in the wake of his interjection or his intervention, but not the false negative rate. I'm just wondering

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if you had any suggestion as to why that would be?

MR. GULLIVER:

A. It really--I really can't comment on that.

CROSBIE, Q.C.:

Q. Okay. Now if I could ask you about standard operating procedure manuals, you know who I mean by Dr. Dabbs?

MR. GULLIVER:

A. I know he was here, I didn't hear his testimony but I know he was here.

CROSBIE, Q.C.:

Q. Eminent authority in lab medicine, pathology, IHC testing and so forth. Anyway, you've heard of him, right?

MR. GULLIVER:

A. I've heard of him, yes.

CROSBIE, Q.C.:

Q. And you know he testified here.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. So, sir, when you were lab manager, there was no SOP in the sense that the witnesses we've heard here have described it, there's no SOP

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for ER/PR testing, was there?

MR. GULLIVER:

A. Well, you've seen what we submitted is that we had a procedure and multiple procedures, but they certainly were not to the level of what Trish would have expected to see and that's well documented now.

CROSBIE, Q.C.:

Q. They were manufacturer specs and procedures marked up by you in your handwriting, and maybe others?

MR. GULLIVER:

A. Well they were marked up by me after the fact in submitting them to the Inquiry.

CROSBIE, Q.C.:

Q. Okay. So you didn't see a need for an SOP?

MR. GULLIVER:

A. No, I've never said that.

CROSBIE, Q.C.:

Q. You didn't have one.

MR. GULLIVER:

A. Well we did have an operating procedure and protocols, we didn't have them in a format and a template as I've testified that Trish would expect in Mount Sinai, that one would expect

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if you were going through an accreditation process like the QMPLS process in Ontario and we didn't have them in formats like the Clinical Lab Standard Institute from the United States, as what Trish had recommended. And when you're able to have those in those templates, you know, you're able to have them signed off by the signing authorities, you have to put a date there when they must be reviewed over a certain period of time -

CROSBIE, Q.C.:

Q. This is what we've heard.

MR. GULLIVER:

A. And those are things that we did not do. I mean, that's well--we've acknowledged that.

CROSBIE, Q.C.:

Q. At the time you thought what you had was enough?

MR. GULLIVER:

A. At the time I thought what we had was enough for the staff to perform the procedure correctly. We were following the protocols and again, we relied heavily upon the pathologists' feedback and their interpretation.

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CROSBIE, Q.C.:

Q. Dr. Dabbs told the Inquiry that the absence of an SOP in the sense we're talking about, is a recipe for disaster. In retrospect, do you agree?

MR. GULLIVER:

A. I think in retrospect there's a lot of things we had absent.

CROSBIE, Q.C.:

Q. That you rather you'd have.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. That might have made for a better quality test.

MR. GULLIVER:

A. I think that would have made for minimizing the risk or chance of reducing our false negatives because you're going to have false negatives. We obviously had more false negatives than you would see in most other major teaching labs.

CROSBIE, Q.C.:

Q. And NLCHI will tell us exactly how many that was. Madam Registrar, could I ask you to go

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to Dr. Cook's transcript again, page 232? Here, Dr. Cook is being asked by Mr. Coffey, it's between pages 232 and 236, about cost benefit analysis. Because we remember that you and Dr. Cook signed, as co-authors, a proposal in October, 2005 and you were taken through that in the last few days.

MR. GULLIVER:

A. Yes.

CROSBIE, Q.C.:

Q. Which came up with a budget and you defined a goal and the goal was to provide an equivalent ER/PR and immunohistochemical testing service, equivalent to that of the reference lab in Mount Sinai, that was your goal?

MR. GULLIVER:

A. And that submission was more to do with the resources required to work towards that goal.

CROSBIE, Q.C.:

Q. Right. There's a budget in there too, $282,000 is what you estimated at the time and I think you said it's actually turned out to cost more.

MR. GULLIVER:

A. I think we spent more than that, yes.

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CROSBIE, Q.C.:

Q. So your initial thought that reallocating $20,000 or thereabouts from the biochemical laboratory in 1997, that turned out not to be a correct assumption.

MR. GULLIVER:

A. At the time it was the right assumption, that's how much money was required to start performing the ER/PR procedure in that IHC lab under the guidance of Dr. Khalifa.

CROSBIE, Q.C.:

Q. To what standard?

MR. GULLIVER:

A. Well what you see in 2005 is really a report that addresses the pathology laboratory overall, where a new resources where we now have approval to create pathologist assistants, i.e. we take technologists and train them up to do the grossing, that was a large chunk of the new resources required for that report. We also asked for, I think a fulltime med lab assistant and those things were to address other parts of the pathology lab. We asked for dedicated funding for education for the staff in IHC for pathology.

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But at the time, Mr. Crosbie, '97, you know, we looked at what resources were required to actually perform the testing. There was no thought given to well let's now, because we're doing ER/PR testing, let's now hire pathology assistants, let's now put in this or this. I mean, it wasn't thought of back then.

CROSBIE, Q.C.:

Q. Well with the luxury of hindsight, it might seem to some people that the question should have been asked what resources, human and financial, were going to be required to do this testing service in the new manner, moving it from biochemistry over to histology, to an acceptable standard. And if the answer was that the authorities in the organization were not prepared to fund those resources, then it shouldn't have been done.

MR. GULLIVER:

A. Well I'm saying to you what was done, the authorities in the organization were not asked for additional resources. Dr. Khalifa worked with Dr. Prabhakaran in biochemistry. It was moving a testing methodology from biochemistry to pathology to another part of the

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laboratory, and we already had two technologists who were skilled in doing IHC testing. The biggest obstacle would have been having a pathologist with the expertise to interpret the testing. And we had that, we now had that pathologist on site in St. John's, Dr. Khalifa and the resources required was the actual operation's money to order the supplies and reagents in order to add that to the existing pool of antibodies that was taking place in the pathology lab.

CROSBIE, Q.C.:

Q. So a lot of the difference, by the time you got to 2005, October, and signed that joint proposal with a budget with Dr. Cook, is that you knew a lot more about what was required to do this right, than you did in 1997?

MR. GULLIVER:

A. I think we realized in 2005 that a large segment of an issue, as we've talked about the possibility of specimens being not fixed properly or grossed properly and if the thickness of the tissue submitted is not proper, that by 2005, we're at a position where we realize we need to have a dedicated

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core team of people to do all the surgical grossing, and that would require the additional hire of four new staff and training of those four staff. I mean, what else we've learned since 2005 is obviously we wholeheartedly agree with all the recommendations from Ms. Wegrynowski and from Dr. Banerjee, you know, is the documentation of all the work processes in pathology, including technical and clinical. We've also learned that we started this test with Dr. Khalifa, who in my opinion was an expert in breast pathology in this field, and we now have gone back to that process where we have a dedicated team of pathologists ensuring that they are reading all of those slides.

CROSBIE, Q.C.:

Q. There is no defined objective back in 1997, was there, nothing set down in writing?

MR. GULLIVER:

A. To my knowledge, I don't remember Dr. Khalifa doing anything in writing as an objective. I just think it was something that he worked with, the biochemistry staff and our clinical chief at the time and the program director and

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came forward and said that there was a new way to do this test, it would mean that there would be a permanent record kept, where it was done in pathology on a paraffin block and a glass slide. It also meant the patients didn't have to go through a lumpectomy to get a sample for chemistry, it could be done using a biopsy, so it was much more less intervention.

CROSBIE, Q.C.:

Q. And I think we understand the reasons why this was considered to be a good shift, but what I'm saying is there is no defined objective, in terms of quality or standard for this testing to meet, no institution was referenced, like Mount Sinai and there is no budget drawn up for the resources needed to achieve that objective. And I think the answer to that is quite obviously, yes, there was no such thing.

MR. GULLIVER:

A. Well, the budget piece was done, that I had submitted an official request to Mr. Whelan to say that in our estimation it will cost $20,000.00 additional to perform this testing

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in pathology, and my recommendation would - was that resources that were currently used in chemistry to perform the test, to switch those resources to the pathology budget. The other piece of it, Mr. Crosbie, to my knowledge, was not done, but I think that Dr. Khalifa should be asked that question.

CROSBIE, Q.C.:

Q. Indeed, and the $20,000.00 was estimated and sought at the time when your understanding of the test was much more in its beginning stages than it became?

MR. GULLIVER:

A. No, at that time I knew how much it was going to cost because Dr. Khalifa - we had gotten the cost from DAKO to purchase reagents and Dr. Khalifa had given an estimate of how many patients we expect to do a year, and we estimated it was going to cost on average about $100.00 per patient, and he figured it would be about 200 cases done a year, times 100 was $20,000.00.

CROSBIE, Q.C.:

Q. Could we bring up Dr. Cook, page 303 to 304.

REGISTRAR:

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Q. I think you're looking for July 7th.
CROSBIE, Q.C.:
Q. Yeah, it's not the right date. Thank you, by the way for straightening this out. I think the Registrar was concerned it was about to topple over.
THE COMMISSIONER:
Q. We're very conscious of quality control, Mr. Crosbie.
CROSBIE, Q.C.:
Q. And health and life safety. So is this what we're looking for? Okay, so right about line 11, page 303 and then just over to 304.
MR. GULLIVER:
A. Start reading page 303?
CROSBIE, Q.C.:
Q. Yes. You see there that Dr. Cook is saying that we were in reality nothing more than a glorified community lab. As a lab man, could we have your comment on that?
MR. GULLIVER:
A. Well, I think Dr. Cook is actually stating that, I think, in retrospect, and I think Dr. Cook is probably talking about, in particular, the pathology department. I don't think that

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he's talking about the lab medicine program. I think he's talking about pathology, in particular, and I guess by the time Don gives his testimony this summer, you know, we've seen that as a university teaching hospital, when it came to our pathology department, and you look at our practises - for example, pathologist assistants, you know, most major tertiary care hospitals, teaching hospitals in the country, had long ago had pathologist assistants that would assist the pathologists and do - standardize the fixation, grossing, and those practices. Most university teaching hospitals in this country would have had dedicated technologists and managers that oversaw quality management for laboratory services.
CROSBIE, Q.C.:
Q. These things were missing back in the period?
MR. GULLIVER:
A. Well, they're missing up until just recently, and I think that's - what Dr. Cook is referring to, I certainly - when you look at other parts of our laboratory medicine program, I think, you know, our biochemistry

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division and other divisions may take exception to that assessment that they're a community lab and not a university teaching lab.
CROSBIE, Q.C.:
Q. Sir, let me put something to you. In ER/PR testing, the lab could have performed to the standard of Mount Sinai if the service had been established on sound principles and adequately resourced from the start. Do you agree?
MR. GULLIVER:
A. I think from the start it was sound principles because I think that we had the luxury of having Dr. Khalifa here to put that testing in place, we had the luxury of him reviewing the control slides, and we had the luxury of him pretty well doing almost all the interpretations, and we had the resources at the time to perform the testing. We didn't have the resources at the time to have a level of documentation of what we see today.
CROSBIE, Q.C.:
Q. That's your comment?
MR. GULLIVER:

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A. I think that's - well, you've asked for my opinion and that's how I feel.
CROSBIE, Q.C.:
Q. If the service could not be established with adequate resources, it should have been referred out.
MR. GULLIVER:
A. And I submit to you that when the service was started with Dr. Khalifa, we had adequate resources to perform the testing and do the interpretations.
CROSBIE, Q.C.:
Q. Including the human resources in the form of expertise on the bench?
MR. GULLIVER:
A. Well, the two technologists had been - had ten years experience in IHC testing, and you've heard Dr. Khalifa who came in from Sunnybrook and testified. He said when he first came to St. John's and he had come from Washington, DC, and other large centres, he said that he was impressed with the level and quality of service from the technologists in the IHC lab.
CROSBIE, Q.C.:
Q. And he must have been of the view that your

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staff in the lab adequately understood the delicacy of the test?

MR. GULLIVER:

A. Again you'll have to ask Dr. Khalifa that.

CROSBIE, Q.C.:

Q. Lastly, Rosalind Jardine testified here in April. She was one of the patients who testified initially. I spoke to her myself last week, I met with her, and she continues well, you may be pleased to know, Commissioner, although she - and she knew at that time that she'd had a recurrence. She's in her 50s, and she believes that she should have been on Tamoxifen several years before it was offered. In relation to ER/PR testing problems, what if any personal responsibility do you take for that?

MR. SIMMONS:

Q. Commissioner, I don't think that's a fair question for Mr. Gulliver. It's not grounded in any particular evidence (inaudible). The analysis is just an open ended question. I don't think it's fair that now Mr. Gulliver has to respond to -

CROSBIE, Q.C.:

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Q. I'm attempting to give the question of responsibility a human face, Commissioner, and that's somebody who testified here back six months ago. My suggestion is that the patient population whose lives are involved in this would like to hear from the responsible persons in Eastern Health whether and to what extent they accept responsibility for what these patients have had to endure.

MR. SIMMONS:

Q. Commissioner, there's been many witnesses from Eastern Health that Mr. Crosbie has had the opportunity to ask such questions to, if he wanted to depose them, the proper position would have been to depose them to someone like the CEO or people in authority to speak up now within the organization. He hasn't chosen to address other witnesses from Eastern Health in this way. And I don't think he should now be put in a position - Mr. Gulliver shouldn't be put in a position to have to take that kind of burden and responsibility upon himself to answer that question.

THE COMMISSIONER:

Q. Your question again was?

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CROSBIE, Q.C.:

Q. My question is what, if any, personal responsibility do you take for the women who feel that they should have had therapy earlier than they have. He can answer or not.

THE COMMISSIONER:

Q. Are you saying he can answer or not? You're giving the witness an opportunity to answer the question if he wishes, is that the idea?

CROSBIE, Q.C.:

Q. Yes, I can hardly - I'm not going to beat him around the head if he doesn't want to answer that.

MR. SIMMONS:

Q. Well, Commissioner, even doing that is putting the weight on Mr. Gulliver to decide whether he feels the pressure to address a question like that. Personal responsibility is not within the mandate of really of what the Commission is all about. It's getting -

THE COMMISSIONER:

Q. It is true that I'm not to determine any personal liability in respect of any particular person, as Mr. Crosbie knows all too well. The question of liability is -

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CROSBIE, Q.C.:

Q. Well, strike the word "personal".

THE COMMISSIONER:

Q. Is to be determined elsewhere, but what you are - if you are giving this witness an opportunity to comment on a personal level about the circumstances of the patients, then I'm prepared to let him comment if he wishes to do so. He does not have, however, to - he's not obliged to do so. So do you understand what's happened?

MR. GULLIVER:

A. I do, and I think my answer would be that my closing statement will probably answer that.

THE COMMISSIONER:

Q. Okay. So it appears, Mr. Crosbie, that there will be an answer. Mr. Simmons.

MR. SIMMONS:

Q. Thank you, Commissioner.

THE COMMISSIONER:

Q. Mr. Simmons, do you want that left as it is? Are you prepared to enter into this dangerous ground?

MR. SIMMONS:

Q. I think the quality assurance manager has

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addressed it satisfactorily. I won't be long, Commissioner. Mr. Gulliver, you'll be happy to know I won't be very long either.

MR. TERRY GULLIVER - EXAMINATION BY MR. DAN SIMMONS

MR. SIMMONS:

Q. I just had actually one very specific thing to ask you about. I'd like to have Exhibit P-1373 again, please. This is one that Ms. Newbury showed you, and it's an e-mail message from Heather Predham to a number of people, not to you, on May 18th, 2006, and there was a table attached to it here. You'd said you weren't familiar with the particular message. In the text of it, Ms. Predham says that "Kara", and that would be Dr. Laing, the oncologist, "and I reviewed the retrolist and here is the final list that will need to be reviewed", and attached to it there is a table which has, I think, eight separate lines there for separate entries. I'm going to ask you just to presume that the four that were ultimately identified as the retro converters are included on these listed here.

MR. GULLIVER:

A. I think they are, yes.

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MR. SIMMONS:

Q. And you'll see that there's an original ER result, an original PR, a Mount Sinai ER, and a Mount Sinai PR, and if we look at the first entry across, the name and the specimen numbers and the RS numbers are all blocked out. I'm going to ask you to assume that the first line there has a specimen number for 1999.

MR. GULLIVER:

A. I was just going to ask that question, what year are these from?

MR. SIMMONS:

Q. Assume the first one is from 1999. The original ER of 25 to 30, would that specimen have met the criteria for retesting of negatives?

MR. GULLIVER:

A. Yes.

MR. SIMMONS:

Q. Okay, and -

MR. GULLIVER:

A. Again I had testified that anything we seen close to even the 25 to 30, even, say, 25 to 35, that those patients were all put on the

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spreadsheet to be reviewed for retesting.

MR. SIMMONS:

Q. Right, and the second entry there, assume as well that the second entry is from the period prior to the year 2000.

MR. GULLIVER:

A. So that would be retested, yes.

MR. SIMMONS:

Q. That one has an original ER of 30. So that would be considered a clinical negative and selected for retesting?

MR. GULLIVER:

A. Yes.

MR. SIMMONS:

Q. And the remaining entries there are either negative 10 or WP, and do you know what WP would indicate?

MR. GULLIVER:

A. Well, that means it would have said a weak positive would have been the interpretation in the patient's report.

MR. SIMMONS:

Q. So all of these entries here, would these all have met the criteria for selection for retesting at Mount Sinai?

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MR. GULLIVER:

A. Yes.

MR. SIMMONS:

Q. And would any of them have been considered positives, which would have been excluded from the retesting?

MR. GULLIVER:

A. No, no.

MR. SIMMONS:

Q. Okay. So - and in these particular cases, these tests then were reported by Mount Sinai as having an ER and PR of zero or very low numbers?

MR. GULLIVER:

A. Uh-hm.

MR. SIMMONS:

Q. Now aside from any cases where there is no order entered for a test, can we safely say that all cases like these where the original ER fell within the testing criteria were selected for retesting and have been retested?

MR. GULLIVER:

A. Yes, every one.

MR. SIMMONS:

Q. So there would be no other similar cases that

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we're aware of that we could locate?
MR. GULLIVER:
A. No.
MR. SIMMONS:
Q. That need to be retested, okay. Now another example here, if we look at the third line, there's one there from Carbonear which had an original ER negative and an original PR of 50 to 60, and that original PR, 50 to 60, would be above the - if the cutoff were being applied to it, that would be considered a positive result, correct?
MR. GULLIVER:
A. For PR.
MR. SIMMONS:
Q. For PR.
MR. GULLIVER:
A. Yes.
MR. SIMMONS:
Q. And but since the ER is negative, then that was -
MR. GULLIVER:
A. Was an automatic retest.
MR. SIMMONS:
Q. Selected for retesting.

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MR. GULLIVER:
A. Yeah.
MR. SIMMONS:
Q. Okay. So among all the tests that were identified and reviewed for retesting, are there any cases where there was a negative ER and a PR that was 30 or higher which were excluded from retesting?
MR. GULLIVER:
A. No, none.
MR. SIMMONS:
Q. No. So every case that falls into that category has been retested, and if any of those were to have changed to negative/negative on retesting, we would be aware of them?
MR. GULLIVER:
A. Yes.
MR. SIMMONS:
Q. Okay. Now Mr. Gulliver, I understand you do have a statement that you would like to make.
MR. GULLIVER:
A. Finally, after all these days.
MR. SIMMONS:
Q. This is your opportunity.

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MR. GULLIVER:
A. Thank you. It's a short statement. Over these past few days, and months, the Commission has heard from various witnesses, including myself, regarding the years of cost cutting and downsizing that impacted laboratory medicine. The laboratory, in my opinion, has for years been viewed as a call centre within the health care system, and in difficult financial times, the laboratory was required to reduce expenditures. This inquiry has put the laboratory and the health care system in general under the microscope. The laboratory, I feel, is now viewed as a value centre and not a call centre, as we are now recognized for the critical role we play in patient care. Eastern Health laboratories, with its 500 staff, produce over 10 million results every year that physicians and patients rely upon for diagnosis, prognosis, treatment, and preventive care. Even though the laboratory and health care in general underwent many years of downsizing and reduced budgets, I feel that every technologist, pathologist, manager, oncologist,

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administrator, came to work every day and did their best to serve our patients. However, at times our best was not good enough for some of our patients, and when I say patients, that includes my family, your families, co-workers and my friends. The list of approximately 1000 patients that I helped organize for retesting was not just a list of names. The list included friends of mine and staff. During this review process, I lost a very dear friend of mine, she was 40 years old, due to breast cancer. In the summer of 2005 when the decision was made to review and retest all patients that tested negative, I was in full support because as a laboratory professional, I felt a duty to do anything I possibly could to help serve our patients. However, at that time I never realized the full magnitude of the issue and the enormous amount of time it was going to take. Myself, my manager, technologists, and pathologists were focused on reviewing, identifying, and getting samples organized for retesting. Now three years later, after much anguish by many of the patient and their families affected by the

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retesting, and after thousands of additional hours of work by our laboratory staff and others, the work still continues. You have heard through this inquiry that much good as come from this. You have heard that our laboratory today has improved tissue fixation and tissue preparation.

MR. GULLIVER:

A. .... You have heard that our laboratory has improved its testing and the documentation of the testing. You have heard that our laboratory has improved its reporting and interpretation of this testing and you have also heard that our oncologists have improved the clinical treatment based upon this testing.

All of the above would not be possible without the support of Government, Eastern Health and the new resources that have been added to the laboratory and other parts of the health care system, and this support must continue.

We, in the laboratory, and all parts of

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the health care system that are involved in breast cancer testing and treatment, have gained a huge amount of knowledge through this whole process. When I started my testimony here, it was Canadian Patient Safety Week and this year's theme is knowledge is the best medicine. My hope and my vision is that the knowledge gained through the past three years, and in particular, the knowledge gained from this Commission of Inquiry, is truly used to ensure that Eastern Health's laboratory will be recognized as a leader within Canada. I hope that our laboratory will be given the resources to do so and I feel that we have dedicated and qualified technologists and pathologists and support staff to help us achieve that goal.

In closing, I would like to thank you, Madam Justice Cameron and her counsel for the opportunity to speak at this Inquiry and more importantly, for the very professional manner in which you have treated all laboratory staff who have been called to testify. Thank you.

MR. SIMMONS:

Q. Thank you, Mr. Gulliver. I don't have any

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other questions, Commissioner.

THE COMMISSIONER:

Q. Do you have anything arising, Ms. Chaytor?

MR. TERRY GULLIVER, EXAMINATION BY SANDRA CHAYTOR, Q.C.

CHAYTOR, Q.C.:

Q. Just one. I don't know if you can see me or not, but hopefully you can hear me. This arose out of a question, Mr. Gulliver, that Mr. Crosbie asked you, and Registrar, if we could have, please, P-1852? In asking about the standard operating procedures at the time, I think it's at page nine of this exhibit, and you were brought to this exhibit which was filed as part of the appendix to the answers to interrogatories at the time, and I believe you are indicating that this would be the standard operating procedures that the staff, the technologists, would have been using in performing the ER/PR tests throughout the period that the DAKO machine was used?

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and I understood you to say to Mr. Crosbie that you did have a procedure and this

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is your procedure, but not to the level -

MR. GULLIVER:

A. This is the antibody specification sheet you're showing here.

CHAYTOR, Q.C.:

Q. Yes, on this page. I think page six, Registrar, it begins? Unfortunately, my mouse--oh, here it is, okay. Maybe it's page--here we go. Well, we saw it in one of the exhibits.

MR. GULLIVER:

A. Yes.

CHAYTOR, Q.C.:

Q. It was the -

MR. GULLIVER:

A. The actual step-by-step procedure.

CHAYTOR, Q.C.:

Q. Yes, the step by step, and then it was the specification sheet, and I just understood you to say that you had a procedure in place, while it might not have been to the standard that Trish Wegrynowski would have expected, that you did have a procedure in place, and I think you said it may not have been to the level she expected or the format that she was

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expecting?
MR. GULLIVER:
A. That's correct.
CHAYTOR, Q.C.:
Q. And my question is, Mr. Gulliver, are you telling the Commissioner that there was a standardized and consistent procedure in place for the testing of ER/PR throughout the entire time period that was followed by the technologists consistently, rigidly throughout the entire period?
MR. GULLIVER:
A. Yes, and that's my firm belief.
CHAYTOR, Q.C.:
Q. And do you know whether or not all of the technologists utilized the same antibody dilution?
MR. GULLIVER:
A. That I can't verify, I mean -
CHAYTOR, Q.C.:
Q. Wouldn't that be part of your standard operating procedure?
MR. GULLIVER:
A. That would be part of the protocol.
CHAYTOR, Q.C.:

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Q. Yes.
MR. GULLIVER:
A. And the validation process of what antibody dilution to use, and I would be aware that at different times, you could use different antibody dilutions if the lot number changed or those kinds of things, and that's something, as you're well aware, you do during the validation or revalidation.
CHAYTOR, Q.C.:
Q. But would you expect that the--whichever technologist was doing the procedure would use the same dilution of antibody?
MR. GULLIVER:
A. Oh, I'm sorry, so if the recommended dilution was, say, one of 50?
CHAYTOR, Q.C.:
Q. Yes, that whether it's Peggy Welsh doing the test or Mary Butler doing the test -
MR. GULLIVER:
A. Irregardless, it would be done one of 50 every time.
CHAYTOR, Q.C.:
Q. Right. Do you know whether or not that was the case, that your technologists were all

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using the same antibody dilution at whatever that was for any particular time period?
MR. GULLIVER:
A. I can't guarantee you 100 percent, but to the best of my knowledge, the answer would be yes.
CHAYTOR, Q.C.:
Q. Do you know whether or not they were all utilizing the same incubation periods?
MR. GULLIVER:
A. To the best of my knowledge, yes.
CHAYTOR, Q.C.:
Q. Okay, and if they were to have told the Commissioner otherwise, you'd be unaware of that? If Mary was using -
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. - a different dilution at a particular period in time than -
MR. GULLIVER:
A. And I'd be unaware and surprised.
CHAYTOR, Q.C.:
Q. You'd be surprised. And are you aware of any documentation--for example, this is written here, July 14th, 2003, one out of 20. Are you

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aware of, if we pick another date, we could say July 2nd 2002, which I believe is the date that Peggy Deane's test was carried out, is there any documentation that would tell us what your standard operating procedure was on that date?
MR. GULLIVER:
A. Well, it would be the same procedure as what we submitted to you.
CHAYTOR, Q.C.:
Q. And what would the dilution of the antibody be -
MR. GULLIVER:
A. I can't tell you what the dilution would be.
CHAYTOR, Q.C.:
Q. - or what the incubation period that the technologists were using?
MR. GULLIVER:
A. But generally, the technologists would write the dilution on the sheets and on the actual bottle that they were using.
CHAYTOR, Q.C.:
Q. And what about the incubation period?
MR. GULLIVER:
A. And that's set out in the procedure.

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CHAYTOR, Q.C.:
Q. Well, it gives an optimal period in the procedure, in the spec sheet. Is that what you're referring to?
MR. GULLIVER:
A. Yes.
CHAYTOR, Q.C.:
Q. But whether or not -
MR. GULLIVER:
A. I think they always used 30 minutes, but I can't be 100 percent sure.
CHAYTOR, Q.C.:
Q. Thank you, that's it, Commissioner.
THE COMMISSIONER:
Q. Thank you. Thank you, Mr. Gulliver. I'm sure it's been a long few days.
MR. GULLIVER:
A. It has, yes.
THE COMMISSIONER:
Q. Spread out over weeks. I do appreciate your contribution. Thank you very much.
MR. GULLIVER:
A. Thank you so much.
THE COMMISSIONER:
Q. Ms. Chaytor, it's late in the day, but is the

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next witness here?
CHAYTOR, Q.C.:
Q. I believe she is.
THE COMMISSIONER:
Q. Let's--my suggestion is that we carry on until five and let's get over the introduction and let her get sworn in and have the--we'll return that to the comfort level for Ms. Chaytor. Thank you very much, gentlemen.
CHAYTOR, Q.C.:
Q. Thank you.
THE COMMISSIONER:
Q. Now Ms. Chaytor.
CHAYTOR, Q.C.:
Q. Commissioner, the next witness is Heather Predham.
MS. HEATHER PREDHAM, SWORN, EXAMINATION BY SANDRA CHAYTOR, Q.C.
REGISTRAR:
Q. Would you please state and spell your complete name for the Commission?
MS. PREDHAM:
A. Heather Predham, H-E-A-T-H-E-R P-R-E-D-H-A-M.
REGISTRAR:
Q. Thank you.

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CHAYTOR, Q.C.:
Q. Good afternoon, Ms. Predham.
MS. PREDHAM:
A. Good afternoon.
CHAYTOR, Q.C.:
Q. And thank you for your patience.
MS. PREDHAM:
A. No problem.
CHAYTOR, Q.C.:
Q. We have a number of new exhibits that I would ask, please, to have entered this afternoon, Commissioner, and it's actually quite a number, so that might eat up all of our time. I hope not. Okay, so we have P-2939 through to P-2944 inclusive, P-2948, P-2949, P- 2951 through to P-2957 inclusive, P-2960, P- 2965 through to P-2973 inclusive, P-2979 through to P-2981 inclusive, P-2983 through to P- 3003 inclusive, P-3005 through to P-3029 inclusive, P-3031 through to P-3035 inclusive, P-3037, P-3040, P-3041, P-3043 through to P- 3048 inclusive, P-3049--no, I'm sorry, not P-3049. P-3052 through to P-3054 inclusive, P-3056, P-3059 through to P-3073 inclusive, P-3075, P-3078, P-3370 through to P-3380 inclusive, P-

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3382 through P-3385 inclusive, P-3387 through to P-3410, P-3413 through P-3415 inclusive, P-3417, P-3418, P-3420 through to P-3462 inclusive and then we have four C exhibits, C-0264, C-0265, C-0273 and C-0274. Is that it, Registrar?
REGISTRAR:
Q. Yes.
CHAYTOR, Q.C.:
Q. Thank you.
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-2939 THROUGH P- 2944
EXHIBITS ENTERED AND MARKED P-2948 AND P-2949
EXHIBITS ENTERED AND MARKED P-2951 THROUGH P- 2957
EXHIBIT ENTERED AND MARKED P-2960
EXHIBITS ENTERED AND MARKED P-2965 THROUGH P- 2973
EXHIBITS ENTERED AND MARKED P-2979 THROUGH P- 2981
EXHIBITS ENTERED AND MARKED P-2983 THROUGH P- 3003
EXHIBITS ENTERED AND MARKED P-3005 THROUGH P- 3029
EXHIBITS ENTERED AND MARKED P-3031 THROUGH P- 3035
EXHIBIT ENTERED AND MARKED P-3037
EXHIBITS ENTERED AND MARKED P-3040 AND P-3041
EXHIBITS ENTERED AND MARKED P-3043 THROUGH P- 3048
EXHIBITS ENTERED AND MARKED P-3052 THROUGH P- 3054

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EXHIBIT ENTERED AND MARKED P-3056
EXHIBITS ENTERED AND MARKED P-3059 THROUGH P-3073
EXHIBIT ENTERED AND MARKED P-3075
EXHIBIT ENTERED AND MARKED P-3078
EXHIBITS ENTERED AND MARKED P-3370 THROUGH P-3380
EXHIBITS ENTERED AND MARKED P-3382 THROUGH P-3385
EXHIBITS ENTERED AND MARKED P-3387 THROUGH P-3410
EXHIBITS ENTERED AND MARKED P-3413 THROUGH P-3415
EXHIBITS ENTERED AND MARKED P-3417 THROUGH P-3418
EXHIBITS ENTERED AND MARKED P-3420 THROUGH P-3462
EXHIBITS ENTERED AND MARKED C-0264 AND C-0265
EXHIBITS ENTERED AND MARKED C-0273 AND C-0274

CHAYTOR, Q.C.:

Q. Thank you, Commissioner. Ms. Predham, perhaps you can begin by telling us about yourself, your educational and professional background.

MS. PREDHAM:

A. I graduated from Memorial University in 1986 with a Bachelor of Nursing. I then was employed as a psychiatric nurse at the Waterford Hospital until--as a front-line psychiatric nurse until 1993. At that time, I worked with the medical department in quality, in that area, until 1994, and then I had the position as quality care coordinator at the

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Waterford Hospital, and I had that position until 1996 when I became quality facilitator with the Health Care Corporation. And I had that position until 1998, when I became the risk manager with the Health Care Corporation and I continued on with that until 2004, when I became acting director of the Quality and System Improvement Department, and I held that position until 2005, towards the end of 2005, I was the manager of Quality and Risk Management, and then became the Risk Management Consultant, Assistant Director, which I am now.

CHAYTOR, Q.C.:

Q. Okay, and I'm just going to ask you then to take us through what all of those various titles might mean. I think we could probably figure out the front-line psychiatric nurse.

MS. PREDHAM:

A. Okay.

CHAYTOR, Q.C.:

Q. And that's not necessarily relevant to what we're doing here. I take it though at that time period, when you worked at the Waterford, were you a colleague of Peter Dawe at that

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point? Did you get to know Mr. Dawe?

MS. PREDHAM:

A. Yes, for a period of time he was a social service worker, I believe, and he worked on the unit that I worked on at that time.

CHAYTOR, Q.C.:

Q. Okay, and then while you're still at the Waterford, from 1993 to 1994, what was your position at that period?

MS. PREDHAM:

A. In 1993, I was a medical resource person and that's a title they--I was almost an administrative support person with the physicians. I helped develop audits, developed policies, write their policy and procedure manual, that type of administrative support, and I did that for just over a year.

CHAYTOR, Q.C.:

Q. And other than your BN, do you have any other educational or continuing education courses?

MS. PREDHAM:

A. In '93 or '94 actually I think it was, I did the Canadian Hospital Association year-long program in quality management, and I did some graduate courses in nursing and then in 2004,

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I started my Masters in Community Health. So I had the course work for that done. I still have my thesis to finish.

CHAYTOR, Q.C.:

Q. Okay, and in 19--the course you did, the year-long course in 1994 in, was it quality management you said?

MS. PREDHAM:

A. Quality management.

CHAYTOR, Q.C.:

Q. Quality management. Was that a correspondence course?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, and who offered that course?

MS. PREDHAM:

A. Canadian Hospital Association.

CHAYTOR, Q.C.:

Q. Okay, and what would that course involve?

MS. PREDHAM:

A. Well, that covered over the basis premises of quality management, you know, CQI, TQ and the history of it and also covered off components on risk management, utilization management,

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consumer feedback, a comprehensive course in quality management.

CHAYTOR, Q.C.:

Q. Okay, so basically the fundamentals of quality management?

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. Okay, and what types of things, for example, would you--what would you learn through that? Like what does it mean for us lay people, what is quality management basically?

MS. PREDHAM:

A. Do you want to know what is quality management -

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. - or what I learned?

CHAYTOR, Q.C.:

Q. It's different, is it? Okay. Well tell us then, what are the fundamentals of quality management?

MS. PREDHAM:

A. I guess the history of it, how it started off

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with quality assurance, basic quality assurance, would be auditing and just the auditing functions that are in a hospital, and of course, the focus of it all was hospital based and the other premises are taken from a lot of work by Edward Demmings, who was an engineer in the automobile industry. So he developed TQM, which is total quality management or CQI, which is continuous quality improvement. So the concept there was that you take your audits, you build on the quality assurance activities, but you go into this continuous quality improvement of plan, do, check, act cycle. So you would go into that--it's a continuous quality improvement, I guess, is what I'm trying to say, and that you would plan what you were doing. You would measure, you would--and you'd keep going. You keep evaluating there. So that's the basic premises that you would learn.

Then they would teach you the different tools. So you'd learn how to do a process improvement team, how to document using flow charts, how to document using a fish bone diagram, a pareto chart, and then you would

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also learn about risk management, how to investigate an incident, how to utilize occurrence reporting, so the tools that you would use in each of those.

Since then, of course, there are other tools that have been taken from engineering, such as root cause analysis and a failure mode effects analysis. So I've done courses in those as well.

CHAYTOR, Q.C.:

Q. In root cause analysis and failure mode analysis as well?

MS. PREDHAM:

A. Failure mode effects analysis.

CHAYTOR, Q.C.:

Q. Effects analysis, okay. And is quality management then different in the health care setting than it would be in, for example, as you've given the engineering setting? Is there any difference in quality management?

MS. PREDHAM:

A. There is--well, it's a slight difference. It's more with risk management is the bigger difference, but in quality management, there is a difference because it's more--in more

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industries, it's more structured and it's the same every day or you have that more regulated environment. In hospitals, you tend to have a lot of activity and a lot of fluctuating activity, I guess, is a term that I'd like to use. It is never the same twice. So you may do something one day, but something subtle will change to that. So there's nuances that make it different than another type of industry. If you're in a more manufacturing type industry, it's more stagnant. It's the same type of thing day in and day out.

CHAYTOR, Q.C.:

Q. Okay, and I'll come back probably, leave that for now and come back because I would like to explore a little bit more with you as to, you know, what root cause analysis is and the other things.

MS. PREDHAM:

A. Sure.

CHAYTOR, Q.C.:

Q. So right now, I'd just like to explore your background. So you have a BN and you've done this one-year correspondence course in quality management.

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MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you've done other courses you've said along the way which included courses that taught you about root cause analysis. Your background then in moving to Eastern Health in 1994 or moving to the -
MS. PREDHAM:
A. Health Care Corporation.
CHAYTOR, Q.C.:
Q. - Health Care Corporation at that time, in 1994, and your position at that time was quality facilitator? Is that correct?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And what did that involve, to be a quality facilitator at Health Care Corp?
MS. PREDHAM:
A. The quality facilitator role was a support role to the programs. We had--when Health Care Corporation was set up, they went into program management. So each of the quality facilitators were linked to a series of

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programs, a group of programs, and supported them in developing their goals, their objectives, their indicators, and we were all just moving into this process. So one of the big things we spent a lot of time on were developing indicators in which they could monitor, not the routine things that traditionally areas have monitored, but things that we can focus in on to improve. So you know, you'd sit down and you'd look at turnaround times, wait lists, you know, these types of things, trying to get the information for them.
CHAYTOR, Q.C.:
Q. Would you be involved in any education of the frontline staff as to what it means to have quality control and quality assurance in place?
MS. PREDHAM:
A. Yes, we did. We had a day-long session on quality and quality improvement and that was broken out into six sessions, I think, on what is quality, team work, consumer feedback, utilization management, some of the tools that you can use.

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CHAYTOR, Q.C.:
Q. And were you responsible for the laboratory medicine program? Was that one of the programs you were responsible for?
MS. PREDHAM:
A. Yes, I think, in the beginning, I think in 1996 I was linked to that.
CHAYTOR, Q.C.:
Q. Okay, and for how long? From 1996 until when?
MS. PREDHAM:
A. I think I was only linked with that program for about a year.
CHAYTOR, Q.C.:
Q. So, perhaps up until 1997?
MS. PREDHAM:
A. Sometime in 1997.
CHAYTOR, Q.C.:
Q. Sometime in 1997, okay. And do you know then who took over after--so there are different quality facilitators, I take it, assigned to different programs.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And do you know who took over then in 1997?

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MS. PREDHAM:
A. I'm not sure. I know later in 1998 after Nancy Parsons started, she had the lab program. I can remember that.
CHAYTOR, Q.C.:
Q. Yes and I believe she's told us about that.
MS. PREDHAM:
A. Yes, but I can't remember, and it may be that I had it until she started in '98.
CHAYTOR, Q.C.:
Q. Okay. And before I move then into your period of time as risk manager and then onto acting director, you education--you said that you're still working on your Masters degree.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And what exactly is it that you're--what is it that you're doing your Masters--it's a nursing Masters, I take it?
MS. PREDHAM:
A. No, it's in Community Health actually.
CHAYTOR, Q.C.:
Q. Oh, Community Health, okay.
MS. PREDHAM:

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A. Yes.
CHAYTOR, Q.C.:
Q. And is that at all involved in risk management or quality management?
MS. PREDHAM:
A. No, but it's much linked to it because you're learning about qualitative research. You're doing epidemiology and biostats. So, it has a lot of--I found it to be a better fit for what I was actually working at than when I started doing the nursing degree.
CHAYTOR, Q.C.:
Q. Okay. And does it involve patient safety at all?
MS. PREDHAM:
A. Well, that's a focus of what my thesis is going to be because that's my focus of things. So, projects that I've done as I've went through that, I've used that as my focus.
CHAYTOR, Q.C.:
Q. And so it is something that fits with what you're doing in your day-to-day work.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:

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Q. And so then after--well, the quality initiatives portfolio that you had and again remind me, that's 1994 -
MS. PREDHAM:
A. 1996.
CHAYTOR, Q.C.:
Q. '96 through to -
MS. PREDHAM:
A. '98 I became Risk Manager.
CHAYTOR, Q.C.:
Q. '98, okay. And what does it mean then, what's the difference in moving then into Risk Manager itself? What were your duties and responsibilities in 1998 when you took that on?
MS. PREDHAM:
A. Well, as a quality facilitator, you're linked with the program, so you're involved. You screen the occurrence reporting and you're involved with investigation of incidences, but when you move into the risk manager position, you're responsible for occurrence reporting. So, you're responsible to make sure staff are educated and that the program works, that the form needs to be updated or whatever. So,

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you're responsible for co-ordinating that entire program, getting the reports back to the program. You're also responsible for investigating the complaint, liaisoning with insurer, with legal counsel.
CHAYTOR, Q.C.:
Q. And that's as the risk manager.
MS. PREDHAM:
A. As the risk manager.
CHAYTOR, Q.C.:
Q. Okay.
MS. PREDHAM:
A. As a quality facilitator you could also end up linking with the legal counsel, but usually the contact goes through the risk manager.
CHAYTOR, Q.C.:
Q. Okay. So, you do do investigations of occurrences or incidences?
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. And you say you make sure that staff are educated and when you say the staff, do you mean the staff within the quality initiatives department or the staff actually out in the

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programs doing the frontline work?
MS. PREDHAM:
A. Oh no, we do--I've done education sessions on occurrence reporting to--I don't know how many staff, but also on different consent policies, you know, where you go around doing in-services on consent. And those types of issues that are higher risk, I guess, types of procedures then, that's what you would educate staff on.
CHAYTOR, Q.C.:
Q. Okay. So, staff would include anyone who worked within -
MS. PREDHAM:
A. Frontline staff.
CHAYTOR, Q.C.:
Q. - any frontline. Would it also include the physicians?
MS. PREDHAM:
A. At times, depending on the issue. It usually would be a special session for physicians or we'd work in something, probably with a VP medical or with clinical chief. We'd work around some way to get that information to them.

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CHAYTOR, Q.C.:
Q. Okay. And in this time period, in the late 1990's, how well informed were the staff in terms of quality initiatives?
MS. PREDHAM:
A. From '96 to '98 we did a lot of education for staff because although there was a quality person in each of the legacy boards up to that point, their roles were quite different. At the Waterford my role, majority of my role was responding to patient complaints. So, although I was following up on occurrence reports and that type of thing, that was the primary focus of my role. So, if frontline staff in the mental health program saw me, that's what they would think first and the same with the different legacy organizations. So, we had to do a lot of education on what type of thing that quality initiatives would do. But the other thing that's very important for frontline staff to know what we're doing is because we can't be everywhere. We have to rely on them to tell us what's happening out there.
CHAYTOR, Q.C.:

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Q. And to feel comfortable in telling you.
MS. PREDHAM:
A. Exactly.
CHAYTOR, Q.C.:
Q. Feel comfortable in reporting an incident or something they see as being dangerous or less than optimal.
MS. PREDHAM:
A. Exactly. And when we came together as the Health Care Corporation, we--two of the previous sites had very punitive form of occurrence reporting. So, that was another challenge that we had to deal with. So, we had to get that message across that occurrence reporting is non punitive, but we also had to, I guess, walk the walk, for the better way of putting it. We had to go through that process and say that, you know, you are not getting in trouble because you filled these out. So, we had to get examples and show them how this is so beneficial to us. These are the things that we've learned from occurrence reporting. If nobody reported this, we wouldn't know about it; we wouldn't be able to deal with it. So, it was really important to get that

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message out there.
CHAYTOR, Q.C.:
Q. So, I guess in getting the report, not only would you investigate that particular incident and look for whatever may have contributed to the incident, would you then keep track and keep that in some sort of database or otherwise keep it so that you could follow any trends of similar instances that may arise?
MS. PREDHAM:
A. Yes, and that was a big challenge when we first started. We were doing it manually when we first started. So, tallying up to, I think it was--we were probably getting 3 to 4000 occurrence reports a year. So, internally, our IT department was able to do a front end reporting mechanism. So, the quality facilitators would take the occurrence reports, we'd code them and then enter it all into this database. But then we had to download the information into Excel and format it into a report to quarterly get back to the programs to say these are the types of things that you're reporting. So beyond the individual follow up for occurrences, we had

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to do this trending as well.
CHAYTOR, Q.C.:
Q. Okay, and then you'd give feedback on a quarterly basis to the various programs.
MS. PREDHAM:
A. Yes.
CHAYTOR, Q.C.:
Q. For anything that you were seeing in terms of trends or types of incidences that were being -
MS. PREDHAM:
A. Well they give a summary of all their occurrences, so they would say over this quarter you had these many medication occurrences, these many files, this many property loss, you know, that type of thing. And then annually we would do that as well.
CHAYTOR, Q.C.:
Q. And if there is anything that you saw or that caused you concern that there was a trend, well whose attention would you then bring that to?
MS. PREDHAM:
A. Well it would depend on the type of occurrence. If it was anything--we had one

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trend that we picked up fairly quickly with a certain type of suction machine that we had and we had to get a large group of people, because that was throughout the organization, but it was because we were trending the occurrences that we picked up that we had an issue, because we had an issue in DI, diagnostic imaging, we had an issue on a surgery floor, we had an issue on the medicine floor and we had an issue in critical care. So they were very similar and because they were similar, we picked up that trend and then it was a very broad base group that had to get together to deal with that.

CHAYTOR, Q.C.:

Q. And then you were able to track it back to the -

MS. PREDHAM:

A. It was the--fundamentally it was a new suction device that we were using and the way that it had a backflow valve in it. The way we were using it was causing this problem and an interruption in the suction, so we actually had to cancel the tender with this one and go back to another version that we were using

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because to change practice, it would have been too difficult to ensure that that machine could keep working.

CHAYTOR, Q.C.:

Q. And so that's a good concrete example of how somebody filling out the occurrence report and having it come to a centralized location and having the trends followed, could then pick up on the issues and enhance patient care and safety.

MS. PREDHAM:

A. Exactly.

CHAYTOR, Q.C.:

Q. First of all I should ask you, where were you when you first came over to Health Care Corporation in 1996, where were you physically located?

MS. PREDHAM:

A. At that time our department centrally had an office at St. Clare's, but each of the quality facilitators had two offices, so I had an office at the Waterford and an office at St. Clare's because I was--we had a transition period going in through the Health Care Corporation where the programs had not been

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established yet, but the quality initiatives department had, so when we originally started, we were linked to sites. So I was linked to the St. Clare's site and the Waterford site. Another quality facilitator was linked to the Health Sciences site and the Grace and another one was the Janeway and somewhere else--I can't think of where else it was. But we had a central office then at St. Clare's.

CHAYTOR, Q.C.:

Q. Okay, and when you became risk manager, where were you physically then located?

MS. PREDHAM:

A. Well coincidentally, just when I became risk manager, we moved our entire office at the Waterford, so I was at the Waterford site.

CHAYTOR, Q.C.:

Q. Okay, and you remained then in the risk management position from 1998 until 2004, is that correct.

MS. PREDHAM:

A. 2004.

CHAYTOR, Q.C.:

Q. And then you became acting director--what was the name of your title?

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MS. PREDHAM:

A. Well again, coincidentally, our department changed just before I became acting director and we merged with the Management and Engineering Department. In Quality Initiatives, besides the quality facilitator, utilization manager and the director, we also had an infection control division reported to us, so when we became Quality and Systems Improvement, we had three divisions, so our department changed slightly and became--we had a management engineering division, the quality and risk management division and infection control division.

CHAYTOR, Q.C.:

Q. And that was as of 2004?

MS. PREDHAM:

A. 2004.

CHAYTOR, Q.C.:

Q. And that continued until when?

MS. PREDHAM:

A. That continued until, I think in the summer of 2005, management engineering reported to planning and research with the formation of Eastern Health, they moved over there.

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Infection control has just now become a division of their own with their own director.

CHAYTOR, Q.C.:

Q. And so then you remained in your acting director capacity until when?

MS. PREDHAM:

A. October of 2005.

CHAYTOR, Q.C.:

Q. October of 2005. And then in October, 2005, you became -

MS. PREDHAM:

A. I went back to the manager of quality and risk, which was--it was the risk manager position, I guess, but because we changed at that time to the three division format of our department, it was the manager of quality and risk, so the quality facilitators reported to the previous position of a risk manager.

CHAYTOR, Q.C.:

Q. So in 1998 when you were risk manager, the quality facilitators were reporting -

MS. PREDHAM:

A. No, they were reporting to the director.

CHAYTOR, Q.C.:

Q. They were reporting to the director, not to you.

MS. PREDHAM:

A. No.

CHAYTOR, Q.C.:

Q. And when you became the manager of quality and risk in the fall of 2005, then the quality facilitators were reporting to you?

MS. PREDHAM:

A. Yes.

THE COMMISSIONER:

Q. Wait now, what was your title in 2004? I thought you became acting director of quality and risk management.

MS. PREDHAM:

A. Of quality and system improvement.

THE COMMISSIONER:

Q. Quality and system, oh, sorry. But then in 2005, you were manager of quality and risk management.

MS. PREDHAM:

A. Quality and risk management. That was a division in the quality and system improvement department.

THE COMMISSIONER:

Q. Okay.

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CHAYTOR, Q.C.:

Q. So when you became the manager of quality and risk in the fall of 2005, was that in essence the same position that you held as risk manager?

MS. PREDHAM:

A. Other than the quality facilitators reported to me, it was.

CHAYTOR, Q.C.:

Q. So you had all the same duties in terms of making sure the staff were educated, making sure that incidents were being reported, liaisoning with the insurer or lawyers and investigating incidents, all of those same duties, plus then you had the quality facilitators reporting to you?

MS. PREDHAM:

A. Yes.

CHAYTOR, Q.C.:

Q. And that's the position that you still hold?

MS. PREDHAM:

A. No. Sorry.

CHAYTOR, Q.C.:

Q. Do you have a C.V.?

MS. PREDHAM:

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A. Yes, I do.

CHAYTOR, Q.C.:

Q. We have a C.V. okay.

MS. PREDHAM:

A. In June of 2006, because see, we were becoming Eastern Health--I was acting director until Pam Elliott started as director of quality and risk management.

CHAYTOR, Q.C.:

Q. Yes.

MS. PREDHAM:

A. And that was October 31st, 2005. So after that, we didn't have a structure for a department, so I had to go back to my old position which had changed, slightly different position. So then when the department positions got developed, then I became the risk management consultant and assistant director. So after Ms. Elliott started, the whole department changed because it was a regional department then.

CHAYTOR, Q.C.:

Q. Okay, and perhaps then what we can do, Commissioner, is we'll find the C.V. and if we could take it up from there tomorrow and you

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could tell us about how the department changed when Ms. Elliott came along into the position.

THE COMMISSIONER:

Q. All right. I'm sorry we were so late getting on with you, but I felt it was worthwhile using this half hour to try and straighten out your history. Thank you. 9:30 in the morning.

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CERTIFICATE

I, Judy Moss, hereby certify that the foregoing is a true and correct transcript in the matter of the Commission of Inquiry on Hormone Receptor Testing, heard on the 15th day of October, 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 15th day of October, A.D., 2008

Judy Moss

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