COMMISSION OF INQUIRY
ON HORMONE RECEPTOR TESTING

BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER

October 27, 2008

Appearances:

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

Rolf Pritchard. . . . . 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

Jennifer Newbury . . . . . Canadian Cancer Society (NL Division)

Blair Pritchett. . . . . Central, Western and Labrador-Grenfell
Regional Integrated Health Authorities

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DR. CLIVE WELLS - AFFIRMED - VIA VIDEOCONFERENCE

MS. LYNN WADE - SWORN

OCTOBER 27, 2008
THE COMMISSIONER:
Q. Please be seated. So we have contact, do we, Mr. Coffey?
COFFEY, Q.C.:
Q. Actually, Dr. Clive Wells was just seated there. I presume he's probably gone out of the room for a moment.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. Considering that he's anticipating possibly sitting for three hours straight, so -
THE COMMISSIONER:
Q. Good idea, in that case. All right. We'll just wait for his return.
COFFEY, Q.C.:
Q. What we'll do, Commissioner, to utilize the time for now, whenever we finish with Dr. Wells, I'm going to suggest that we take the lunch break at that point, and then I understand that Ms. Wade will be following then.
THE COMMISSIONER:
Q. Uh-hm.

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COFFEY, Q.C.:
Q. And we're going to continue on then until past what is the normal scheduled break time. You told counsel that last week.
THE COMMISSIONER:
Q. You mean, at the end of the day break time?
COFFEY, Q.C.:
Q. Yes, the end of the day break.
THE COMMISSIONER:
Q. Okay. Yes, I think that was clear from last week and since -
COFFEY, Q.C.:
Q. Mr. Simmons has advised Ms. Chaytor and I that, in fact, Ms. Wade will be here later on, actually in the morning too.
THE COMMISSIONER:
Q. Okay.
COFFEY, Q.C.:
Q. So she'll be here.
THE COMMISSIONER:
Q. Well, if -
MR. SIMMONS:
Q. In fact, if this goes quicker than anticipated, she's available to start -
COFFEY, Q.C.:

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Q. Even before then.
MR. SIMMONS:
Q. Before then.
THE COMMISSIONER:
Q. Okay then, all right. Well, we'll assess it when we're through with this particular witness. After that, we'll be happy. The picture quality is very nice, in any event, very nice blue chairs.
COFFEY, Q.C.:
Q. Good morning, doctor. Actually, good afternoon where you are, and you and I have, of course, spoken. I'm Bernard Coffey, but this is the first time we've seen each other. I have the Registrar here now and we're already convened, so the Registrar is going to have you affirmed.
DR. WELLS:
A. Okay.
DR. CLIVE WELLS (AFFIRMED) EXAMINATION BY BERNARD COFFEY, Q.C. - VIA VIDEOCONFERENCE
REGISTRAR:
Q. Would you please state and spell your complete name for the Commissioner?
DR. WELLS:

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A. Clive Alan Wells, that's C-L-I-V-E A-L-A-N W-E-L-L-S.
REGISTRAR:
Q. Thank you.
COFFEY, Q.C.:
Q. Doctor, I'm going to ask the Commissioner to enter a couple of exhibits. If you'll just bear with me for a moment. Commissioner, they are exhibits P-3630, 3631, 3632, 3633, 3634, 3635 and 3636.
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-3630 through P-3636
COFFEY, Q.C.:
Q. Now, doctor, you provided the Commission with a copy of your summary curriculum vitae and your detailed curriculum vitae this morning?
DR. WELLS:
A. Yes, that's correct.
COFFEY, Q.C.:
Q. And, doctor, would you please outline for the Commissioner, give us kind of a summary of your educational and professional background?
DR. WELLS:
A. Well, I was educated as a doctor at Cambridge

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University, and then trained as a pathologist initially in Oxford, and then subsequently took up a post which I still hold to this day at Sir Bartholomew Hospital, which is now Bart's and the London NHS Trust.
COFFEY, Q.C.:
Q. Doctor, what is your position there?
DR. WELLS:
A. I'm a consultant histopathologist with a special responsible for breast pathology.
COFFEY, Q.C.:
Q. And, doctor, you've been involved then as a-- in particular in breast pathology for how long?
DR. WELLS:
A. Since, I guess, about 1984.
COFFEY, Q.C.:
Q. And, doctor, I understand as well that you're involved with a european group?
DR. WELLS:
A. Yes, this is a European Commission funded body which oversees a number of aspects of pathology as related to breast cancer screening in Europe. It also advises on quality issues and is involved in writing

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guidelines.

COFFEY, Q.C.:

Q. Doctor, I understand as well that you're involved with the Royal College of Pathologists in relation to breast disease?

DR. WELLS:

A. Yes, in the National Coordinating Committee which is actually a breast screening funded body in the health service, but has the additional attachment to the Royal College of Pathologists, that's correct.

COFFEY, Q.C.:

Q. Now, doctor, could you please outline for the Commissioner, give her some sense from a European perspective, in particular the UK, during your career in relation to pathology generally in a particular breast pathology, how quality assurance has evolved over the years since the mid '80s?

DR. WELLS:

A. Right, when the NHS Breastscreening Program was set up with a quality aspect to it, because it was realized that the quality of pathological diagnosis is critical to the quality of the service, and so quality

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assurance was built into it. I think probably not initially right at the beginning in 1988, but certainly in 1989/1990 quality assurance was being set up.

COFFEY, Q.C.:

Q. And -

DR. WELLS:

A. And--sorry.

COFFEY, Q.C.:

Q. Doctor, we've heard--the Commission has heard a lot of references or quite a number of references to UK NEQAS.

DR. WELLS:

A. Yes, this is a body which is run from one of the London hospitals which is a non-for-profit company which operates to oversee the quality of immunocytochemistry staining amongst other things.

COFFEY, Q.C.:

Q. And I take it, doctor, that some of UK NEQAS work does involve aspects of breast pathology?

DR. WELLS:

A. Indeed. They run a number of modules, as they call them, for various technical aspects, estrogen/progesterone receptor, HER2 staining,

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and also FISH for HER2. That's Fluorescent In Situ Hybridization.

COFFEY, Q.C.:

Q. Doctor, can you tell us, please, about from your perspective in terms of the establishment of UK NEQAS, the time it was established, what perceived need was there that had to be addressed through UK NEQAS? What was the reason?

DR. WELLS:

A. That's a very good question. I'm not sure because I'm not directly involved with UK NEQAS, but it was recognized that the quality of immunostaining in general was critical, I think, when it--when it was introduced routinely into laboratories, and certainly there has been variable quality in the past. So I guess that that was the main driver for this.

COFFEY, Q.C.:

Q. Now -

DR. WELLS:

A. But the driver, I think, for the receptor estimations has been that there are laboratories that have not been performing as

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well as other laboratories in the UK, and so now it's a mandatory system.

COFFEY, Q.C.:

Q. And, doctor, when did it become mandatory in the UK, do you know?

DR. WELLS:

A. I'm not sure of the exact date, but it's certainly been for some years now.

COFFEY, Q.C.:

Q. Doctor, we have what is here Exhibit P-3635, which is a document which involves excerpts from the NHS Breastscreening Programs, the Third Edition of it, Guidelines for Pathology Reporting in Breast Cancer Screening, and a Second Edition of the Royal College of Pathologists, Minimum Dataset for Breast Cancer Histopathology.

DR. WELLS:

A. Yes, I have it here.

COFFEY, Q.C.:

Q. Now, doctor, I understand at least this version that we have was published in 2005. It's on the -

DR. WELLS:

A. Yeah, that's correct.

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COFFEY, Q.C.:
Q. Doctor, could you tell us, please, as you were involved as a consultant, amongst other doctors in relation to this, why there is a need for such--perceived to be a need for such a document to be published?
DR. WELLS:
A. This was commissioned by the NHS Breastscreening Program because of the perceived need for the pathology of the screening program to be as high a quality as possible. The success of the Breastscreening Program, I think, depends on the quality of the component parts and pathology is an essential one.
COFFEY, Q.C.:
Q. And -
DR. WELLS:
A. So this is actually an update of a previous pathology reporting booklet which was brought out, I think, in 1990 or around that time.
COFFEY, Q.C.:
Q. So it goes back well over a decade?
DR. WELLS:
A. Yes.

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COFFEY, Q.C.:
Q. Doctor, if you'll look at the Table of Contents which is the Roman Numeral III there at the bottom of the page -
DR. WELLS:
A. Yes.
COFFEY, Q.C.:
Q. There are--there's a description of the writing group, and there's a Preface?
DR. WELLS:
A. Yes.
COFFEY, Q.C.:
Q. And then there's a whole listing of specimen handling, surgical handling, laboratory handing, diagnostic localization biopsies, therapeutic wide local excisions, re-excision specimens, mastectomy specimens, pathological examinations of lymph nodes, NHSBSP histopathology reporting form, minimum dataset for breast cancer histopathology, recording basic information, and then it goes on at some length, I mean, it just kind of goes on and on, including to--in particular here--I'm just going to go to, if I could, paragraph 21 or section 21 which deals with--chapter 21 which

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deals with steroid receptors at page 86 and 87, and I'll be taking you to that, but as well--yes, as well, if I could, when you look at the appendices -
DR. WELLS:
A. Yes.
COFFEY, Q.C.:
Q. I apologize, I skipped past it there, here locally, and under the appendices there is Appendix 3, synoptic reports, and I'm going to ask you some questions about that, and Appendix 7, quality assurance for estrogen receptors and progesterone receptors.
DR. WELLS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, I take it then that this is a fairly comprehensive document, at least as of 2005?
DR. WELLS:
A. Yes, it was written to try to give pathologists guidance on how they should do various techniques and what they should do in their daily practice of reporting breast disease.
COFFEY, Q.C.:

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Q. Doctor, you did of course just then use the word "guidance", and I'm going to take you to the Preface, which is at page one. I'm not going to--there's an opening paragraph, and the second paragraph in the middle of the page says, "These guidelines aim to encourage the use of common terminology and definitions of breast disease and to standardize methods of classification of breast cancer", and -
DR. WELLS:
A. That's correct.
COFFEY, Q.C.:
Q. And then when we go to the next page, the first full paragraph begins by saying, "This document also serves to provide guidance for pathologists when participating in the UK external quality assurance scheme for breast screening histopathology". I wanted to ask you about the usage of the word "guidance" in this context.
DR. WELLS:
A. Yes, it's--it's not--it's not an absolutely mandatory document, but it is--it is regarded as being guidance for pathologists in how they should participate in the various programs and

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how they should also report breast disease. We don't want to absolutely discourage innovative things by saying, well, they're not in the guidelines, therefore, you can't do them. That's why these are guidelines and not mandatory requirements.

COFFEY, Q.C.:

Q. Doctor, if I could ask you first of all to, in fact, go to Appendix 3, which is at page 103, and locally it's page 17 in the exhibit here. It's page 17 in the exhibit itself.

DR. WELLS:

A. Right, I have it, yes, synoptic reports.

COFFEY, Q.C.:

Q. Appendix 3, synoptic reports, "The use of synoptic reports is helpful as these may act as aide-memoire for a complete dataset, an example format", and "example" is in bold print here, is shown on the next page, "Alternatively adaptations of the NHSBSP or the Royal College of Pathologists minimum dataset forms can be used". Now, Doctor, from your perspective, what is the purpose of synoptic reports, what do they achieve or potentially achieve?

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DR. WELLS:

A. Well, some people use them as an aid-memoire for making sure that they put in all the various important things which we have to put into the breast screening dataset into the breast screening computer, and that is used for audits and quality assurance purposes, and also for recording what the problem for the actual woman is.

COFFEY, Q.C.:

Q. Doctor, does -

DR. WELLS:

A. Many pathologist use -

COFFEY, Q.C.:

Q. Go ahead, doctor.

DR. WELLS:

A. Text reports rather than synoptic reports.

COFFEY, Q.C.:

Q. Is an advantage of the usage of a synoptic report that the person to whom it is sent, for example, the treating physician, that he or she knows exactly because of familiarity with the form where to look for particular results?

DR. WELLS:

A. That is one use of them. Not everybody uses them, but everybody tends to put a conclusion with the summary report at the end of the report.

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COFFEY, Q.C.:

Q. Now Doctor, if we could go then to paragraph or not paragraph, I suppose, chapter 21, which is at pages--begins at page 86 of the original document. It's page 13 of the exhibit.

DR. WELLS:

A. Yes.

COFFEY, Q.C.:

Q. And this is, of course, the section of the document dealing with steroid receptors, which is, I understand to be estrogen and progesterone receptors. Doctor, there is--I just want to take you through, just a little bit of this. It says recommendation--paragraph 21.1, recommendations for steroid receptor testing, and just spells out really what steroid receptor testing is meant to accomplish, and it concludes by saying "these guidelines have been formulated to give advice," presumably in that regard, and then 21.2, there's a heading principles, and then there's a subparagraph fixation, subparagraph

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methods, subparagraph controls, and then there's a larger paragraph, 21.3 scoring, 21.4 ductal carcinoma in situ. Testing predictive factors is 21.5.

DR. WELLS:

A. That's correct.

COFFEY, Q.C.:

Q. Now Doctor, the situation then in, I take it, in the UK is that using these as guidelines, pathologists who practice in this area are expected to know this and to at least govern themselves accordingly, knowing these are guidelines?

DR. WELLS:

A. Yes, that's correct. There's no policing of this system particularly but the participation in UK NEQAS is effectively a quality assurance backup to these documents.

COFFEY, Q.C.:

Q. Now Doctor, but there is, I take it, from your earlier comment, the potential for flexibility and innovation?

DR. WELLS:

A. I think there always has to be the potential for flexibility and these are minimum

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standards. They're not the Rolls Royce service that some laboratory do perform. Some laboratories will perform CISH (sic.) for example, rather than HER2 testing with immunocytochemistry and we don't want to discourage that.

COFFEY, Q.C.:

Q. Now Doctor, in relation to steroid receptors, I'm going to ask you then to turn to Appendix 7, which is at page 127 of the original document and it's at page 23 of the exhibit.

DR. WELLS:

A. Yes, I have that.

COFFEY, Q.C.:

Q. And this is titled "Quality Assurance for Estrogen Receptors and Progesterone Receptors" and the particular writing party here is described as a Dr. A. Rhodes and a Dr. B. Jasani.

DR. WELLS:

A. That's correct.

COFFEY, Q.C.:

Q. Do you know Dr. Rhodes?

DR. WELLS:

A. They are allied to UK NEQAS.

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COFFEY, Q.C.:

Q. And we understand that in 2000 and 2001, Dr. Rhodes and some colleagues published a series of articles dealing with the issue of quality assurance for estrogen and progesterone receptors.

DR. WELLS:

A. Yes, I believe that's correct. They have written a number of articles on immunohistochemistry over the past years and also produce a regular newsletter for UK NEQAS which has articles within it, and that can be found on the NEQAS website.

COFFEY, Q.C.:

Q. And in fact, Doctor, just here looking at this particular page, I take it that the second paragraph here dealing with "UK NEQAS ICC on a quarterly basis circulates to over 200 laboratories unstained formalin fixed and paraffin processed tissue sections from a composite block, comprising tissue fragments of known receptor content" and it goes on to talk about it from there, and talks about then the process that is followed by the participating laboratories, right here.

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DR. WELLS:

A. That's correct.

COFFEY, Q.C.:

Q. Doctor, in the UK, laboratories that perform or create ER and PR slides, are they required to comply with UK NEQAS guidelines?

DR. WELLS:

A. The pathology laboratories are visited by a company called CPA, Clinical Pathology Accreditation Limited, which requires that an appropriate quality assurance scheme for immunohistochemistry is followed by every laboratory before they will give accreditation to that laboratory.

COFFEY, Q.C.:

Q. And I take it that accreditation is necessary in order to continue to work in this area?

DR. WELLS:

A. It's certainly regarded as necessary by many of the people that send their tissue specimens to that particular laboratory, that's true.

COFFEY, Q.C.:

Q. Doctor, here, just looking down through this, further toward the bottom of the page there, there's a paragraph which deals with the

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scoring by participants who participate in the UK NEQAS process and including remedial measures if you score below a certain level. I take it that's a sort of -

DR. WELLS:

A. That's correct, yes.

COFFEY, Q.C.:

Q. And now, Doctor, if I could ask you to look then at Exhibit P-3631, which is an article from 2004, which yourself and -

DR. WELLS:

A. Yes.

COFFEY, Q.C.:

Q. - I understand you and a number of other authored.

DR. WELLS:

A. Yes, correct.

COFFEY, Q.C.:

Q. And Doctor, this European Working Group for Breastscreening Pathology, which I understand you're part of, could you tell--first of all, tell the Commissioner when you first got involved in this yourself, this European effort?

DR. WELLS:

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A. I was invited to participate in the group, I suppose it was about 1998. I can't remember exactly. And I became the Chairman in 2001, unfortunately due to the death of the previous chairman.

COFFEY, Q.C.:

Q. And Doctor, do you still hold that position?

DR. WELLS:

A. I do.

COFFEY, Q.C.:

Q. And I understand that there was a meeting, in fact, during the past week involving this group?

DR. WELLS:

A. That's correct, on Friday and Saturday we had a meeting in Utrecht in the Netherlands.

COFFEY, Q.C.:

Q. And Doctor, I'm going to take you to that in a little bit, but in looking at this publication in May of--I'm sorry, June, it was actually published online June 24th 2004. This is entitled "Consistency of Staining and Reporting of Estrogen Receptor Immunocytochemistry within the European Union: an Interlaboratory Study." Now Doctor, I

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wanted to ask you, in the period before this was published, why was it thought appropriate or necessary to conduct such a study?

DR. WELLS:

A. I think we were concerned in the European Working Group that the quality of testing of estrogen receptor was not really known throughout the European Group and throughout the European Union, and so a number of laboratories decided that we would get together and do the same sort of thing as UK NEQAS to see what the consistency throughout Europe was.

COFFEY, Q.C.:

Q. And Doctor, can you tell us please then when the actual distribution of, for example, the samples and so on occurred? I mean, this was published in 2004. What period would the actual study have involved?

DR. WELLS:

A. Yes, it was much earlier than that in fact, because the problem was that it was initiated by Professor Sloane, who unfortunately died in 2000, and it took us some time to get all the data back together to be able to publish this

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particular paper, and in fact, I think it was '99, because if you look at the number of the slides in Table 1 on page 122, or your page four, you will see they're all dated '97 and '98 at the end. So in fact, it was a study that was sometime in getting to publication.

COFFEY, Q.C.:

Q. So the actual study itself, the work that was being examined or the results that were being examined would have been '98, '99, 2000, that actual time frame?

DR. WELLS:

A. '99, 2000, yes.

COFFEY, Q.C.:

Q. And Doctor, what then, from your perspective, and you're one of the authors of this paper, what did the study find or show?

DR. WELLS:

A. Well, it showed that unfortunately it's a bit variable, even amongst the laboratories that were represented in this particular test. This was the--these were major laboratories within the EU, basically the laboratories represented by the members of the group.

COFFEY, Q.C.:

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Q. Yes, and this is--in terms of that, I wanted to have that brought out, you know, for the Commissioner that in fact here, people who were asked to stain and/or read slides were, in fact, the participants in the actual working group and they would all represent major laboratories in their home countries?

DR. WELLS:

A. That is correct. All the members of the group are nominated by either their screening organization or their colleges in the particular country as being breast experts.

COFFEY, Q.C.:

Q. Now Doctor, here, the abstract at page two of the exhibit, which is page 120 of the publication, says "to assess the variability of estrogen receptor ER testing using immunocytochemistry, centrally stained and unstained slides from breast cancers were circulated to the members of the European Working Group for breast screening pathology," which is the actual group itself, "who were asked to report on both slides. The results show that there was almost complete concordance among readers, kappa equals .95 in

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ER negative tumours on the stained slide and excellent concordance among readers, kappa equals .82, on the slides stained in each individual laboratory. Tumors showing strong positivity were reasonably well assessed, kappa .57 and .4 respectively, but there was less concordance in tumors with moderate and low levels of ER, especially when these were heterogeneous in their staining. Because of the variation, the working group recommends that laboratories performing these stains should take part in an external quality assurance scheme for immunocytochemistry, should include a tumor with low ER levels as a weak positive control and should audit the percentage positive tumors in their laboratory against the accepted norms annually. The Quick Score method of receptor assessment may also have too many categories for good concordance and grouping of these into fewer categories may remove some of the variation among laboratories."

Now I take it, Doctor, that the abstract is a summary of what was done and what the conclusions were?

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DR. WELLS:

A. That is correct.

COFFEY, Q.C.:

Q. Doctor, from your perspective as the chair of this group, I mean, what did you, yourself, take from this at the time?

DR. WELLS:

A. I think that it showed really that it wasn't as good as I'd expected. It was reasonable, but not--I would have expected major laboratories to have done better than this, and so it was important, I think, to bring this to the notice of the breast cancer community, and we haven't actually implemented any changes to the Quick Score method, but this did show that there was quite a bit of variability in the assessment of these slides. Bear in mind that this is actually different or slightly different to UK NEQAS in that this is also an assessment of pathologists' performance in reading the slides.

COFFEY, Q.C.:

Q. Yes.

DR. WELLS:

A. As well as the performance of the laboratory.

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COFFEY, Q.C.:

Q. And I take it, Doctor, that UK NEQAS actually concentrates on the performance of the laboratory, the technologists or technicians' work?

DR. WELLS:

A. That is correct. They have a small assessment of what the individual pathologist who's responsible for the immunocytochemistry service feels is the score on their own slide, but they don't actually circulate slides to pathologists for their scoring.

COFFEY, Q.C.:

Q. Doctor, if we could, please, ask you to--and this is under the discussion section of the paper, go to page 127 of the paper, which is page nine of the exhibit.

DR. WELLS:

A. Yes.

COFFEY, Q.C.:

Q. Actually, if I could, go back actually, Doctor, I apologize, to page six of the exhibit, page 124, to put it in context.

DR. WELLS:

A. Um-hm.

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COFFEY, Q.C.:

Q. Page six, there we are, bottom of the page there. Here, at the bottom of the page, and the text reads, "although ER staining has been included in the UK scheme recently," and that's citing footnote 16, and in terms of that, just to put that in context, we go to footnote 16 is at page ten of the exhibit, says "United Kingdom National Group for Breastscreening Pathology, 2001, Guidelines for Non-operative Diagnostic Procedures and Reporting of Breast Cancer Screening." So I take it it would have been around 2001 that they were -

DR. WELLS:

A. Yes, that's -

COFFEY, Q.C.:

Q. - at the time -

DR. WELLS:

A. That's true. I'm not sure exactly when NEQAS started the ER scheme, because I'm not directly involved in NEQAS itself.

COFFEY, Q.C.:

Q. It goes on "although ER staining has been included in the scheme, the scheme does not

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assess the variation in reading the slides and in determining the variation in positivity and negativity of the test. Many laboratories are still using the simple method of counting the percentage of positive cells, although the intensity of staining also appears to be important. In this regard, there is a necessity to standardize the quality of the staining technique and the assessment to ensure that the level of the receptors is consistently estimated, and indeed it is entirely possible that the response of some tumors with low Quick scores reported in the literature is due to the technical differences in the quality of the immunocytochemical staining."

So Doctor, what I wanted to ask you about is this, is that within the UK itself right now, what general reporting scheme is used, in terms of ER and PR?

DR. WELLS:

A. Most laboratories now use the Quick score method, but some use the H score and I think some still use the percentage score, but not many, most have gone over to a score based on

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both, both the intensity and the percentage.

COFFEY, Q.C.:

Q. And why is that, Doctor?

DR. WELLS:

A. I suppose it's because we recommended it.

COFFEY, Q.C.:

Q. And why did you recommend it?

DR. WELLS:

A. We recommended it because we felt that the likelihood of response was better assessed in the Allred papers where they described the Quick score, they stated off the top of my head, I believe that it was about 80 percent of women with strongly positive tumours would respond in some way to hormonal therapy and that women without any staining whatsoever would tend not to respond. And then there were variations in between.

COFFEY, Q.C.:

Q. Doctor, here at page 127 of the paper, the paper goes on to say, "The results of this circulation demonstrate that there is some variation in reporting of a level of ER positivity, but encouragingly the variation on the whole is very small for completely

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negative tumours, even when interlaboratory variation is taken into account. This means that a negative result may be generally relied upon for therapy, unlike some of the older biochemical results." And then it goes on to say, Doctor, that this means that a negative result may be generally relied upon for--I'm sorry--"similar reliability for ER negative and also for progesterone receptor negative results have also been demonstrated and a study performed in a number of pathology departments in Austria. Tumours with a high degree of tumor heterogeneity may cause problems in arriving at a consistent level of positivity, but this heterogeneity would also give rise to difficulties with biochemical methods, depending on which bit of the tumor is submitted for biochemical analysis." I take it, Doctor, at that point, this is really just a comparison between an IHC method and a biochemical method?

DR. WELLS:

A. That was originally, yes, it was at a time when certain laboratories or certain biochemists were still saying, well the

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biochemical method is good, why do you want to do it by immunohistochemistry. But there were many problems with biochemistry results in the past, and so we wished to promote around Europe the immunohistochemical method.

COFFEY, Q.C.:

Q. And, Doctor, here, if you go further down the page, and there are certain recommendations there in the middle paragraph which include taking part in external quality assurance approaches, that is certainly urged. You go on to say here "variation in the assessment of the Quick score is interesting in that there is poor concordance between observers and allocating a specific Quick score to tumors except in very strongly positive or completely negative tumors." And this suggests that the eight points for -

DR. WELLS:

A. Yes.

COFFEY, Q.C.:

Q. "We have too many categories for good interlaboratory concordance." And it goes on then to talk about perhaps using a modified Quick score. I wanted to ask you, Doctor,

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this, this reference to very strongly positive or completely negative tumors, I take it that generally if a tumor is--the underlying tissue is in fact very strongly positive or completely negative, that many labs in processing the slides and pathologists in interpreting it will get the results consistently?

DR. WELLS:

A. This is what the study suggested, yes. There were occasional tumors that were negative in one laboratory, with strong positivity in the rest of the laboratories, but there were very few.

COFFEY, Q.C.:

Q. And the more than--the problematic tumors are the ones in which category?

DR. WELLS:

A. Usually they're the ones with moderate to low levels of estrogen receptor.

COFFEY, Q.C.:

Q. And why is that, Doctor, from your experience?

DR. WELLS:

A. I would have said that mainly it's the sensitivity of the technique. If a laboratory

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is not staining tumors very well, then they may falsely report a low level receptor tumor as negative.

COFFEY, Q.C.:

Q. And here, Doctor -

DR. WELLS:

A. I think there's a picture in the publication demonstrating the one, the case that was the worse--that's your page 5 or our page 123.

COFFEY, Q.C.:

Q. That's correct, Doctor, it's here on the screen now and this is demonstrating, in fact -

DR. WELLS:

A. Figure 2.

COFFEY, Q.C.:

Q. Yes, it says, the caption reads "Medium-power view of a Liverpool-stained estrogen receptor positive slide"--and the case number is sited--"which had the worse inter observer concordance in reporting." I take it that's because it's -

DR. WELLS:

A. That's because the positive cells are rather heterogeneously distributed mostly towards the

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top right and somewhat negative towards the bottom left.

COFFEY, Q.C.:

Q. And this was a particular tissue sample then that was proved more problematic in being consistent, in terms of the lab's reporting on it?

DR. WELLS:

A. That is correct.

COFFEY, Q.C.:

Q. Doctor, we go to the page 127, the last paragraph of the paper, says, "In summary, the variation and assessment of receptor status among laboratories has two components, a technical variation and an interpretative variation. These variations are less pronounced in negative tumors and in strongly positive tumors, but significant variation is seen in tumors that express low or moderate levels of receptor. Technical external quality assessment schemes and inclusion of a weakly positive control may help reduce technical variation and guidelines on assessment on receptors may also help to reduce the interpretative variation."

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DR. WELLS:

A. That's correct.

COFFEY, Q.C.:

Q. Now, Doctor, in relation to that, we understand from what we've heard through various witnesses that the fixation process and the processing of tissue into paraffin blocks in considered very important to the reliability of ER and PR testing?

DR. WELLS:

A. That is correct. In fact, it states in the reporting document, your exhibit P-3635, that fixation is critical.

COFFEY, Q.C.:

Q. Yes. And I take it, Doctor, that if the fixation is--or the tissue processing for some reason or another is problematic, that subsequently it could be very difficult for a laboratory to actually perform a test that is truly representative of what the tissue state was originally?

DR. WELLS:

A. It may be very difficult, yes. Fixation is a problem in some laboratories, especially where tissue has to be transported some distance and

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if you've got a large volume of tissue, you need to deal with it in a certain way to make sure it fixes properly if it's going to be without sectioning for some time, especially over a weekend or something like that.

COFFEY, Q.C.:

Q. And, Doctor, while I had not intended to ask you but I will, now that you've raised it, how is that dealt with locally where you are?

DR. WELLS:

A. Well we do have a number of hospitals that send specimens to us and we try and get them there by dedicated transport as quickly as possible. But very occasionally we do have some fixation problems when specimens are done later on a Friday evening, so we've tried to avoid having the surgeons operate on breast cancer cases late on Friday evening.

COFFEY, Q.C.:

Q. And, Doctor, the Commissioner has heard evidence here locally that in fact, that's one of the things that has been done locally here to try to address just that problem. Doctor, I'm going to ask you if you could, please, to turn to Exhibit P-3632? And this is a

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spreadsheet that you prepared?

DR. WELLS:

A. Ah yes, yes, that's true. I don't know whether you've got the updated version that I sent this morning, you probably did.

COFFEY, Q.C.:

Q. October 27th, 2008.

DR. WELLS:

A. That would be today then.

COFFEY, Q.C.:

Q. Yes, that's the one we have, Doctor. Now, Doctor, this is entitled "ER EQA document provided by Dr. Clive Wells to the Commission of Inquiry on Hormone Receptor Testing." It's dated now, today's date and there's a listing of countries, a column of country names on the left-hand side and then a textual description to the right. I had asked--well I'll tell the Commissioner, I had asked, after I got in touch with you originally, if you would canvass you counterparts in Europe as to what if any EQA was being done in that particular country in relation to ER and PR. Could you just then take us as well through this, perhaps as an aid and tell the Commissioner,

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if you could, about what happened during the past three or four days in your meeting in Utrecht, in relation to this?

DR. WELLS:

A. Yes, we've been asked to produce for a body called EUSOMA which is the European Society of Mastology. We've been asked to produce a paper of guidance as to, guidance for quality assurance schemes. And we've been discussing, not only immunohistochemistry, but also reporting of histological sections as well. And we have not written the guidelines as yet, but essentially it was agreed that laboratories should participate in an EQA scheme for receptor testing. And that we would give recommendations as to schemes that we thought were acceptable in the various countries.

COFFEY, Q.C.:

Q. And that was or the discussion during the past several days, in fact, Friday and Saturday past.

DR. WELLS:

A. Friday and Saturday, yes. But we've had some correspondence about it before.

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COFFEY, Q.C.:

Q. And, Doctor, just looking at this particular exhibit here, I take it that this is the summary that you made and you've updated it over the past couple of days as to what the situation is in each of those listed countries?

DR. WELLS:

A. That's correct. There are a few missing which I note now, Ireland participated in a NEQAS scheme, the same as the UK, so they can be added to the list too.

COFFEY, Q.C.:

Q. And here, Doctor, and I take it, for example, I'll just use France as an example, there is-- it's the third entry, it's the AFAQAP scheme run by Strasbourg, a voluntary participation. I take it that the AFAQAP is the French equivalent of UK NEQAS?

DR. WELLS:

A. That's correct. They also do histopathology and diagnostic EQA.

COFFEY, Q.C.:

Q. So it involves an analysis of--or a judgment concerning the pathologist work itself.

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DR. WELLS:
A. That's correct.
COFFEY, Q.C.:
Q. And, Doctor, the fourth entry is the UK and you've pointed out this would cover not only the UK, but also the Republic of Ireland. NEQAS scheme, labs doing receptors should participate and should score at least 12 out of 18 for staining quality. 10 and 11 are regarded as borderline.
DR. WELLS:
A. That's correct.
COFFEY, Q.C.:
Q. I take it that that is -
DR. WELLS:
A. Yes, in fact it's the same as in the guidelines. I think 10 to 12 is regarded as borderline in the guidelines.
COFFEY, Q.C.:
Q. Yes, Doctor, in Appendix 7 of the guidelines at page 127 of P-3635--well actually page 23 of the exhibit, but if we look down towards the bottom of the page there -
DR. WELLS:
A. Yes, that's the more, the more detailed

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assessment of the scheme.
COFFEY, Q.C.:
Q. In effect, a passing and a borderline mark, as it were.
DR. WELLS:
A. Yes, that's correct.
COFFEY, Q.C.:
Q. And the borderline or below it would require remedial attention.
DR. WELLS:
A. Yes, NEQAS does send people out or have technologists go to the lab where NEQAS originates to try and help them. It's not a sort of punitive scheme, it's sort of attempting to raise the quality.
COFFEY, Q.C.:
Q. And if we could look back, please, at Exhibit P-3632 which is your spreadsheet.
DR. WELLS:
A. Yes.
COFFEY, Q.C.:
Q. Doctor, I note here that for example, I'll just pick Belgium and Portugal, you've noted both have no official scheme, and I take it that's no local official scheme.

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DR. WELLS:
A. Yeah, no national scheme is what I meant.
COFFEY, Q.C.:
Q. Yes, and you go on to say, "labs participate in UK NEQAS and in Belgium, as well as AFAQAP"--which will be the French national program, "et cetera, on a voluntary basis, and in Portugal, labs participate in UK NEQAS, et cetera, on a voluntary basis."
DR. WELLS:
A. Yes, that's correct. It won't be every laboratory and I think there is also a problem that UK NEQAS is pretty much, as far as I understand, reaching its capacity in terms of what it can provide in this respect.
COFFEY, Q.C.:
Q. And, Doctor, as well there's a reference to Sweden and Denmark to the NoriCQ scheme is used and in Denmark, some labs also participate in NEQAS and in Sweden, they also use Equalis Limited and KVAST, which I take it are two other such external quality assurance -
DR. WELLS:
A. Yes, the NordiCQ scheme is Danish, I believe

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and the--some Swedish laboratories participate in one of the other ones. I believe KVAST is the one that does receptor testing, but I would have to check that.
COFFEY, Q.C.:
Q. Now, Doctor, you've indicated that coming out of the past weekend's work that you've been asked to provide or produce a paper.
DR. WELLS:
A. That is correct.
COFFEY, Q.C.:
Q. And who would be involved in the production of that?
DR. WELLS:
A. This is the working group basically giving guidance for the members of EUSOMA and anybody else who cases to read it, about what they should do about quality assurance schemes and participation in such.
COFFEY, Q.C.:
Q. And, Doctor, do you have any--is there any estimate of when the paper might be ready for distribution?
DR. WELLS:
A. Oh, we've been asked to provide a draft to the

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board of EUSOMA by December, so the first draft we will be doing in the next few weeks.

COFFEY, Q.C.:

Q. Now, Doctor, I'm going to ask you to look at, please, Exhibit P-3634?

DR. WELLS:

A. Uh-hm.

COFFEY, Q.C.:

Q. This is a document entitled "Consensus Recommendations on Estrogen Receptor Testing and Breast Cancer by Immunohistochemistry". It's a review article -

DR. WELLS:

A. Yes.

COFFEY, Q.C.:

Q. See that here, and it's--there are a number of authors listed. It's, in effect--it finishes and concludes by saying, "And members of the Standardization Ad Hoc Consensus Committee", and it's noted here being received for publication, August 14th, 2008, accepted August 14th, 2008, and it's going to be published in the Applied Immunohistochemistry Molecular Morphology. I take it--we're advised it, in fact, is already available

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online, and it's going to be published, though, in 2008. We were provided it by Dr. David Dabbs, who has been here and testified before the Commissioner earlier. Doctor, have you had a chance--I provided this to you recently. Have you had a chance to look through this?

DR. WELLS:

A. I've had a chance to look through very briefly. I haven't seen this publication before, and actually it may very well be of some use to us when we come to produce our guidelines. I'm very grateful to you for bringing it to my attention.

COFFEY, Q.C.:

Q. Well, doctor, as it turned out, and I'm not surprised that you wouldn't have seen it yet because apparently it just--I gather it's probably just gone up on a website connected with the publisher.

DR. WELLS:

A. Yes.

COFFEY, Q.C.:

Q. But in the main, doctor, and what I wanted to ask you about is this, and you just made the

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comment that it may prove of some use to the group that you're working with, why is that, doctor, in terms of what sorts of things that are discussed in this that may be of some assistance?

DR. WELLS:

A. Well, there are a number of recommendations as to the technique. In fact, the publication that we're doing is not really dealing with the technique, it's dealing with whether you should or should not participate in EQA schemes and which EQA schemes you should participate in, and also if you are setting up an EQA scheme, what you should--what you should take into account, but it's obviously quite an interesting publication saying that the standardization of ER immunohistochemistry is essentially.

COFFEY, Q.C.:

Q. And I take it that certainly in terms--your own group, I take it, in terms of, certainly are urging its members to--member countries at least to adopt quality assurance approaches?

DR. WELLS:

A. That's correct.

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COFFEY, Q.C.:

Q. Doctor, the--if I could, please, doctor, I wanted to ask you about the idea of false negatives and false positives, but in relation to something that is in the paper from 2004.

DR. WELLS:

A. Uh-hm.

COFFEY, Q.C.:

Q. If we could look again, please, Registrar, at Exhibit P-3631, page 9 of the exhibit which is page 127 of the paper, doctor.

DR. WELLS:

A. Okay, I have it.

COFFEY, Q.C.:

Q. And here the second full paragraph on the left hand side beginning with the words, "The results do, however, indicate the need for some quality control of the technical aspects of immunocytochemical staining as well as guidance in the aspects of reporting of the stains. As Table 1 shows, there were a few "false negative" cases reported coming from eleven different laboratories, but there was one laboratory responsible for five of these false negatives".

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DR. WELLS:
A. That's correct.
COFFEY, Q.C.:
Q. And then it goes on to say, "To reduce or avoid such discrepancies, the working group recommends the laboratories performing ER and progesterone receptor tests for therapeutic reasons, take part in one of the circulations of quality assurance on immunohistochemistry such as NEQAS, and it is also helpful to include a composite block with a known positive, a known negative, and a very weakly positive tumour as a control with each run". Now, doctor, what I wanted to ask you about is this, the idea of or the notion of false negatives. From your perspective as a pathologist, breast pathologist, in relation to--and I'll just ask you about estrogen receptors at this point. What does a false negative in your world mean?
DR. WELLS:
A. Well, if it were combined with a false negative progesterone receptor or a poor progesterone receptor as well, then it would mean that the woman was not given Tamoxifen.

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However, if it was negative for estrogen receptor and positive for progesterone receptor, then certainly the laboratory would have a good look at that and she would be given Tamoxifen anyway, even if that was proved to be a true ER negative/PR positive tumour. Using both estrogen and progesterone receptor is helpful.
COFFEY, Q.C.:
Q. Doctor, from your perspective, what can contribute to a false negative result?
DR. WELLS:
A. Well, it can be fixation, it can be technical--usually it's not pathologist reporting because if there is staining, then the pathologist will see it, but technical aspects may be wrong dilution of antibody. There are a number of scenarios in the publications that you've shown here, especially in this new review article that goes into recommendations on fixation, recommendations on staining, etc. So it can be multi-factorial. It could be both fixation and technical problems.
COFFEY, Q.C.:
Q. Doctor, the idea of false positives in

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relation to ER/PR, because I do note that here you--even back as far as 2004, your group was saying it's helpful to include a composite block with a known positive, a known negative, and a very weakly positive tumour as a control with each run.
DR. WELLS:
A. Yes.
COFFEY, Q.C.:
Q. The known positive would be, of course, to ensure that you're not getting false negatives. A known negative, why would you include a known negative?
DR. WELLS:
A. Well, to make sure that you weren't getting some spurious staining. It's unusual to have false positive receptors, especially strongly positive tumours--sorry, negative tumours coming up as staining strongly positive. I don't recall ever having seen that, but certainly occasional negative tumours can have a blush of staining weakly to make them appear estrogen receptor positive if the technique is not standardized properly.
COFFEY, Q.C.:

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Q. I was going to ask you, doctor, what could cause that, what sorts of things could contribute to a false positive?
DR. WELLS:
A. Well, binding of the second antibody non-specifically is an issue in some laboratories, but that's generally less common now with the more modern techniques, and just general over strong antibodies. It's very--it's very unusual, I think, to get false positives. It's false negatives that one worries about more.
COFFEY, Q.C.:
Q. Just a moment, please, doctor.
DR. WELLS:
A. Uh-hm.
COFFEY, Q.C.:
Q. Doctor, they are the questions I have. There may be some questions from my colleagues here in the room, okay.
DR. WELLS:
A. Uh-hm.
THE COMMISSIONER:
Q. Mr. Pritchard, do you have any questions?
MR. PRITCHARD:

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Q. No, Commissioner, I don't. Thank you, Doctor, for your evidence.
THE COMMISSIONER:
Q. Mr. Simmons.
MR. SIMMONS:
Q. No, Commissioner, I have no questions either.
THE COMMISSIONER:
Q. Mr. Browne.
BROWNE, Q.C.:
Q. Just a couple questions.
THE COMMISSIONER:
Q. All right.
DR. CLIVE WELLS, EXAMINATION BY PETER BROWNE, Q.C. - VIA VIDEOCONFERENCE
BROWNE, Q.C.:
Q. Good afternoon, doctor. My name is Peter Browne. I represent a number of the individual physicians, pathologists and oncologists and surgeons who've been asked to testify before the inquiry. If I could, please, we heard recently--the Commissioner has heard from a number of witnesses, and recently as last week the Commissioner heard from a couple of gentlemen who were involved in going back and assisting the hospital,

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Eastern Health, in identifying patients and they talked to the Commissioner about some of the difficulties they had in trying to locate patients, and, in fact, they identified some patients, and some of the problems they identified was the number of hospitals here in Newfoundland were using different dictionaries, and I want to ask you about that issue because it is identified in the joint document, the NHS Breastscreening Program, and it's Appendix 10. It's the first time--one of the gentlemen, a Dr. Reza, had talked about SNOMED, and I want to ask you about that, and if you can tell us what you know about, tell the Commissioner what you know about that, and the usefulness of that from your experience?
DR. WELLS:
A. Yes, there are a number of coding systems that are in use in various countries. SNOMED is the most common, and it's a system of classification of disease pathology and also procedures and other things that can be translated into a code that's put onto a computer and then it's easily searchable.
BROWNE, Q.C.:

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Q. Right, and that would allow you that -
DR. WELLS:
A. All our -
BROWNE, Q.C.:
Q. Sorry, continue.
DR. WELLS:
A. Sorry, all of our cases are actually coded with the SNOMED code here in our hospital, and I think mainly throughout most of the United Kingdom and I'm sure that most laboratories use SNOMED coding.
BROWNE, Q.C.:
Q. Now just on that -
DR. WELLS:
A. If not all.
BROWNE, Q.C.:
Q. With that use of that SNOMED coding allow you to, that these gentlemen all talked about, you have the data, but then it's translating that data into information, useful information. Does SNOMED allow you to do that in terms of trying to identify if you were looking back at trends or anything like that, would that be a useful tool to have?
DR. WELLS:

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A. It's usually used to just computerize the diagnosis in terms of an easily searchable system. I don't think people put more than just the diagnosis onto SNOMED because otherwise that would take too long.
BROWNE, Q.C.:
Q. We've heard from Dr. Dabbs, as Mr. Coffey mentioned, about tracking of metrics and so on. Does your lab--are you familiar with that notion in terms of positivity rates and so on? Is that something that your institution does?
DR. WELLS:
A. We don't do it using any specific program as such, but we do have internal quality control looking at various aspects, and amongst those is the percentage of positivity that we are getting in our laboratory.
BROWNE, Q.C.:
Q. As well, doctor, just to--and I don't have the exhibit number, I just have the document itself. If you could turn to the NHSBSP document, page two.
DR. WELLS:
A. Uh-hm.
BROWNE, Q.C.:

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Q. Yes, 3635, we just -
DR. WELLS:
A. Yes.
BROWNE, Q.C.:
Q. If you want me to find it--I'll find that, sure.
THE COMMISSIONER:
Q. Mr. Browne, you'll have to tell him which page on his document?
BROWNE, Q.C.:
Q. I've actually told him on his document. It's just trying to find it for here.
THE COMMISSIONER:
Q. That's all right, page two.
DR. WELLS:
A. Yes, I have it.
BROWNE, Q.C.:
Q. You have it, doctor?
DR. WELLS:
A. Yes, I do.
BROWNE, Q.C.:
Q. This is sort of situations that these guidelines were put out, and I take it there's some discussion around issues that were encountered in respect to diagnostic

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consistency. So could you just talk to the Commissioner about what sort of--is this feedback from the profession as to difficulties encountered from pathologists with the guidelines?
DR. WELLS:
A. No, this is--these are four points that have been shown by the external quality assessment scheming diagnosis that we have in the UK. This where 15 cases are sent twice a year to all the pathologists reporting breast pathology in the UK, and they report them and send their reports back to the central coordinating office. The diagnosis is then compared against the norm and these are the four main situations that have been discovered from that particular scheme. It's not to do with immunohistochemistry testing.
BROWNE, Q.C.:
Q. Thank you, doctor, that's all the questions I have. Thank you, Commissioner.
THE COMMISSIONER:
Q. Mr. Pritchett.
MR. PRITCHETT:
Q. No questions, Commissioner.

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THE COMMISSIONER:
Q. Ms. Newbury.
MS NEWBURY:
Q. Yes, Madam Commissioner.
THE COMMISSIONER:
Q. Great timing on your part.
DR. CLIVE WELLS, EXAMINATION BY MS. JENNIFER NEWBURY - VIA VIDEOCONFERENCE
MS. NEWBURY:
Q. Thank you. Good afternoon, Dr. Wells. Jennifer Newbury, and I represent the Canadian Cancer Society, Newfoundland and Labrador Division.
DR. WELLS:
A. Good afternoon.
MS. NEWBURY:
Q. I wonder if you can advise if during a quality review you encountered slides that were inappropriately interpreted as positive due to over interpretation of background staining or cytoplasmic staining, what would you do to correct such a problem?
DR. WELLS:
A. I suppose we would ask the laboratory to retest.

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MS. NEWBURY:
Q. Okay, and in terms of trying on a go forward basis to modify different procedures, pre-analytic, analytic, or post analytic aspects of the testing, what would you look to specifically to hopefully avoid that type of an error in the future?
DR. WELLS:
A. Well, this is the a remit of UK NEQAS, which I'm not actually involved with.
MS. NEWBURY:
Q. Uh-hm.
DR. WELLS:
A. But as I understand it, they would then go look at the laboratory's procedures and invite the technologists to go to the hospital and see how they do it. I mean, in that way you can usually sort out, as far as I understand, most of the difficulties.
MS. NEWBURY:
Q. Okay. So there's no one particular thing that would have to be focused upon? You'd have to look at the procedures throughout all of the different aspects?
DR. WELLS:

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A. I think you'd have to look at certainly the procedure of testing. I don't think fixation is likely in my experience to have a great effect on false positives. It's more of an effect on false negatives.

MS. NEWBURY:

Q. Okay, so the -

DR. WELLS:

A. So I would--if I was looking, I would concentrate on the technical aspects.

MS. NEWBURY:

Q. And if during a quality assurance review, you had encountered slides that had false nuclear staining, what--and they had been inappropriately interpreted as a positive, what would you do to correct that sort of a problem?

DR. WELLS:

A. I'm sorry, I don't--false nuclear staining, you mean?

MS. NEWBURY:

Q. Yes, we've heard some evidence about as opposed to cytoplasmic staining, sometimes there might be procedures that cause false nuclear staining. Are you familiar with what

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any factors that might contribute to that?

DR. WELLS:

A. I'm not actually involved in the NEQAS assessment, so I have never come across that particular problem.

MS. NEWBURY:

Q. Okay, so you're aware of anything in the analytic or pre-analytic or post-analytic phase that might contribute to that?

DR. WELLS:

A. I think that's something you need to ask somebody that's involved in NEQAS.

MS. NEWBURY:

Q. Okay.

DR. WELLS:

A. Or one of the other schemes.

MS. NEWBURY:

Q. Okay, thank you. Those are all the questions, Dr. Wells.

THE COMMISSIONER:

Q. Mr. Crosbie.

CROSBIE, Q.C.:

Q. Thank you.

DR. CLIVE WELLS, EXAMINATION BY CHESLEY CROSBIE, Q.C. - VIA VIDEOCONFERENCE

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CROSBIE, Q.C.:

Q. Ches Crosbie, Dr. Wells. I represent some of the affected patients. I have a couple of questions for you. First of all, can you tell us--just confirm for us, was UK NEQAS available as an external proficiency testing method to a hospital here in Newfoundland in 1997?

DR. WELLS:

A. That's a good question. I'm not sure when they started taking international people on. I would suspect that it probably wasn't generally the case that they would have been taking international hospital referrals at that stage, but that's another question I think you would have to ask someone from NEQAS.

CROSBIE, Q.C.:

Q. Are you able to say whether any other external proficiency testing was--would have been available in '97 to a hospital in Canada, specifically Newfoundland?

DR. WELLS:

A. I think the schemes that are available in the United States and Canada, I'm not familiar

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with, apart from the College of American Pathology scheme which again I do not know whether that would have been open to a Canadian laboratory at that time.

CROSBIE, Q.C.:

Q. Positivity rates are used as a metric for quality assurance purposes. We've heard that from other witnesses. You would agree?

DR. WELLS:

A. Yes, that's correct.

CROSBIE, Q.C.:

Q. Is positivity calculated on the basis of ER only, not PR?

DR. WELLS:

A. Most laboratories--well, not all laboratories, but many laboratories did both ER and PR testing because the theoretical aspects are that to get progesterone receptor produced, you have to have a working estrogen receptor. So many laboratories will look at both receptors because in some ways it tells you a little bit more. It doesn't just tell you that estrogen receptor is there, it tells you that estrogen receptor is working.

CROSBIE, Q.C.:

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Q. I'm sorry, when you get a--by doing the PR assay or testing, and you get a positive -
DR. WELLS:
A. Uh-hm.
CROSBIE, Q.C.:
Q. Are you saying that tells you that the ER -
DR. WELLS:
A. You get a bit more -
CROSBIE, Q.C.:
Q. Just explain a little.
DR. WELLS:
A. Yeah, the biochemistry generally of progesterone receptor is that it needs a functioning estrogen receptor to be expressed. So the estrogen receptor has to be working for you to get progesterone receptor. That's the usually held belief amongst most biochemists and pathologists.
CROSBIE, Q.C.:
Q. My question was specifically on the periodic checks that it is recommended for a hospital to do on its positivity rate. Is that check performed only on ER or is it performed also on PR, or is it performed on them combined?
DR. WELLS:

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A. Well, these are generally internal audits and they're not specifically mandated exactly how you do it, but most laboratories, I think, would look at the percentage positivity of both estrogen and progesterone, but would not look at the combination, I don't think, because that would be a bit more work.
CROSBIE, Q.C.:
Q. What is the expected positivity rate?
DR. WELLS:
A. Well, around about 70 to 80 percent for estrogen receptor would be, I guess, an acceptable rate. It depends somewhat on your population, and if you have a screening program or don't have a screening program. The figures are very different for those two scenarios.
CROSBIE, Q.C.:
Q. When you say a screening program, are you talking about breast cancer screening with mammography?
DR. WELLS:
A. Yes, that's correct. You get more estrogen receptor positive tumours in a screening population than you do in a general

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population.
CROSBIE, Q.C.:
Q. Is that because earlier detection turns up, to put it in layman's terms, the smaller the tumour, the more likely it is positive?
DR. WELLS:
A. No, no, it's because the units without breast cancer screening programs have a different age distribution of the cancers, and more of the younger women have estrogen receptor negative tumours.
CROSBIE, Q.C.:
Q. Thank you. So just to be clear on this point, a lab would not add clinically negative results to clinically positive results to arrive at a positivity rate?
DR. WELLS:
A. Sorry, I'm not quite--I don't understand what you mean.
CROSBIE, Q.C.:
Q. Let me back up.
DR. WELLS:
A. A laboratory would not look at the general positivity for both the ER and PR together.
CROSBIE, Q.C.:

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Q. Perhaps I should give you a little background. The particular lab under consideration here, until a certain point in time, was using a cut of 30 percent, a cut point.
DR. WELLS:
A. Of positive cells?
CROSBIE, Q.C.:
Q. For ER.
DR. WELLS:
A. Of percentage positivity?
CROSBIE, Q.C.:
Q. Yes, for ER, and then it switched to using 10 percent?
DR. WELLS:
A. Then I may have misunderstood you.
CROSBIE, Q.C.:
Q. Then it switched to using 10 percent.
DR. WELLS:
A. I may have misunderstood you then. Yes, sorry, I understood you to mean in an internal audit, the percentage of tumours that were positive for estrogen receptor, but you mean the percentage of cells positive? A slight difference.
CROSBIE, Q.C.:

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Q. I'll give a little bit more explanation. The lab here was using a 30 percent cutoff until a certain stage, and then it switched to 10 percent.

DR. WELLS:

A. Yes.

CROSBIE, Q.C.:

Q. Now in calculating the positivity rate for quality assurance purposes as a metric, which we've been told by various people is a good idea to do periodically, would you add in the clinically negative results to the clinically positive results, bearing in mind you have these cut points, in order to arrive at the positivity rate?

DR. WELLS:

A. The laboratory was defining positivity, I presume, at 30 percent.

CROSBIE, Q.C.:

Q. Correct.

DR. WELLS:

A. At one point, and then changed to defining positivity at 10 percent of tumours positive. I would expect if you were defining tumours as positive at 30 percent, you would have a lot

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of supposedly negative tumours that were actually--would have been positive by the Quick Score Method or the H-Score Method that we use in the UK. If that's what you mean? Therefore, they would have had a lower percentage of tumours that were estrogen receptor positive.

CROSBIE, Q.C.:

Q. That's a--in that statement, you're being critical of adopting a 30 percent cutoff, I take it?

DR. WELLS:

A. It's not a cutoff that I would have adopted myself, but I'm not sure at which point this was adopted by the laboratory in question and I haven't seen the dates and the data on this.

CROSBIE, Q.C.:

Q. Yes. Again, I'm not sure if we're connecting on the intent of the question. In order to calculate your metric, your positivity rate, you got a distribution below your 30 percent or your ten percent cutoff. In other words, those are considered to be clinically negative. Do you follow me so far?

DR. WELLS:

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A. They're considered to be receptor negative on the test you mean?

CROSBIE, Q.C.:

Q. Yes.

DR. WELLS:

A. Yes, okay.

CROSBIE, Q.C.:

Q. Clinically negative, in other words, the assumption is that their results below 30 percent and then ten percent are not going to be treated. Follow?

DR. WELLS:

A. Right. In the past, many patients were treated, even with low levels of receptor.

CROSBIE, Q.C.:

Q. That may vary depending on -

DR. WELLS:

A. And even negative tumors were treated.

CROSBIE, Q.C.:

Q. That may vary depending on the attitude of the clinician admittedly?

DR. WELLS:

A. Indeed.

CROSBIE, Q.C.:

Q. Yes. Again though, my question is to arrive

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at your positivity rate, which is a quality check, do you add those clinically negative, below 30 and below ten, in other words that stain weakly, weak positives you could call them, into your above the cut point positives to get at your rate?

DR. WELLS:

A. I'm not quite sure what--I'm still not quite sure what you mean by this. If you have set a level of positivity at 30 percent, then your positivity--the number of tumors that were estrogen receptor positive in your laboratory over a year would be less obviously than a laboratory that was using ten percent as its cut off point. So I mean, they are adjudicating whether something is positive at a level of 30 percent or a level of ten percent or with us a Quick score value of three and above. Then we look at -

CROSBIE, Q.C.:

Q. Well, put it another way.

DR. WELLS:

A. - the number of tumors in a year that are estrogen receptor positive. So we say that of all our tumors that we had through the

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laboratory, 70 percent are estrogen receptor positive and that's the kind of range we would expect for our practice.

CROSBIE, Q.C.:

Q. Perhaps to put it another way, when calculating your positivity rate, you should reference the cut point in use at that period in time?

DR. WELLS:

A. I'm sure, yeah, that's absolutely true. You must take that into account.

CROSBIE, Q.C.:

Q. I'd like to ask you on another somewhat different subject. In 1997, was it generally accepted methodology to use trypsin for antigen retrieval for all antigens except ER/PR?

DR. WELLS:

A. Now that's a technical question which I suppose you ought to ask some of the technologists. I don't know whether trypsin was generally used in that procedure because I do not directly supervise the technical scheme, the technical production of antibody staining.

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CROSBIE, Q.C.:

Q. If you don't have this knowledge, then just tell us, but I'll ask my next question. By 1997, was the standard for doing ER/PR antigen retrieval not trypsin but moist heat?

DR. WELLS:

A. Certainly we were using pressure cooking ourselves and microwaving was certainly coming in at that point. I think I would have to look at the reference to pressure cooking to see when that was particularly used, but microwaving was a bit before that. I think it was around about that time, certainly, probably a bit before.

CROSBIE, Q.C.:

Q. And the technical term for this method of antigen retrieval is heat-induced epitome retrieval or HIER?

DR. WELLS:

A. That's one of the terms used, yes.

CROSBIE, Q.C.:

Q. And if HIER were in use, then trypsin would have no role or use whatsoever?

DR. WELLS:

A. As far as I understand it, yes, because they

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are two different methods of retrieving the same antigen. These are questions that actually a pathologist is less acquainted with than a histotechnologist.

CROSBIE, Q.C.:

Q. Thank you. A couple of things arising out of your testimony a little earlier. The article on consistency of staining makes the comment that variation is very small for completely negative tumors.

DR. WELLS:

A. That's correct. In general, that's another way of saying there were very few false positives.

CROSBIE, Q.C.:

Q. In making the recommendation, there's a recommendation there it seems to use a known negative/known positive and a very weakly positive as controls.

DR. WELLS:

A. Yes, there is. Not every laboratory does that, but it was our recommendation at the time, if you were having problems in your runs. I think also one thing that hasn't come out, in the paragraph after that, it says that

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assessment of internal controls within the same slide is necessary or is helpful.

CROSBIE, Q.C.:

Q. Yes.

DR. WELLS:

A. They're not always there, but that's a very good way of assessing whether the specimen is being stained correctly.

CROSBIE, Q.C.:

Q. These three things I just mentioned are external controls?

DR. WELLS:

A. Yes.

CROSBIE, Q.C.:

Q. The known negative, that's the patient's own tissue?

DR. WELLS:

A. No, these are control samples from other patients where you know that the estrogen receptor is negative on previous testing.

CROSBIE, Q.C.:

Q. I see. Do you use patient's own tissue from the patient specimen and simply not put the antibody on it?

DR. WELLS:

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A. Yes, well that is another form of control that is often--well, almost always performed, certainly performed in our laboratory.

CROSBIE, Q.C.:

Q. So are you assuming that you're doing that negative control as well, the patient's own tissue?

DR. WELLS:

A. All of our antibodies have that done, yes, in our particular laboratory and I assume that that is pretty much a standard procedure.

CROSBIE, Q.C.:

Q. So you're talking about actually doing two negative controls in this recommendation?

DR. WELLS:

A. We do, not for each--not for each test. The test would, in our laboratory, would consist of an estrogen receptor, a progesterone receptor on the patient's tissue and a negative control on the patient's tissue, and then included in the same run on the machine, a known positive and known negative. We don't actually use a weak positive ourselves at the moment.

CROSBIE, Q.C.:

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Q. That's what I was going to ask you. How strong a recommendation is the use of a weak positive?

DR. WELLS:

A. It's a very--I believe it's a very useful thing, but we're always up against cost restraints and many laboratories do not use this.

CROSBIE, Q.C.:

Q. So that's an evolving issue?

DR. WELLS:

A. It was a recommendation that we felt it was useful to make in this particular paper, but it hasn't been uniformly accepted.

CROSBIE, Q.C.:

Q. You were asked, sir, about the significance of false negatives, and your comment was that if the test result was ER false negative and PR false negative, then that would result in no prescription for Tamoxifen.

DR. WELLS:

A. It would nowadays in the UK, but previously, before about 2000, I guess most women with breast cancer were given Tamoxifen anyway because it was believed to be pretty much

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without side effects, so it was generally prescribed.

CROSBIE, Q.C.:

Q. Negative ER and positive PR you said would provoke the lab or the lab would have a good look. What do you mean by that? If you get a negative ER and a positive -

DR. WELLS:

A. They would retest the ER.

CROSBIE, Q.C.:

Q. That would make you wonder -

DR. WELLS:

A. To make sure that it -

CROSBIE, Q.C.:

Q. Sorry, go ahead.

DR. WELLS:

A. That should make you wonder whether the estrogen receptor test was working, especially if you had a lot of them. They're supposed to be less than two percent of all breast cancers have this particular profile and that is assumed to be due to an estrogen receptor that is structurally abnormal, so it's not recognized by the antibody, but actually working to produce the progesterone receptor.

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It's a very rare scenario. So if you had a lot of these, you would question, I think, your technique of estrogen receptor.

CROSBIE, Q.C.:

Q. If you did go back and were satisfied that you had a negative ER and a positive PR, your comment was that a woman would get Tamoxifen on the strength of that result?

DR. WELLS:

A. On the assumption that something was driving their progesterone receptor and that was likely to be estrogen receptor, even though we weren't able to demonstrate it.

CROSBIE, Q.C.:

Q. Is there any cut point below which--and I guess we're talking about standards today to start with. Positive PR would not result in a prescription of Tamoxifen? For example, 30.

DR. WELLS:

A. I think if it was very weak, under--we don't use the just percentage positivity. We use the Quick Score and if it was a progesterone receptor of three under the Quick Score, which is weak positivity in less than--actually, let me see, one to 12 percent of cells in the

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Quick Score, that would not generally be regarded as positive. The cut off levels for the Quick Score are very different to the cut off that was originally used, ten percent or 30 percent or whatever.

CROSBIE, Q.C.:

Q. Lastly, sir, just wanted to ask you about fixation. If fixation is poor, it's possible to lose the--to degrade the specimen to such an extent that you can't retrieve the ER or PR receptor sites. Is that right?

DR. WELLS:

A. That is correct.

CROSBIE, Q.C.:

Q. So if testing on such a specimen yielded a negative result for ER/PR, retesting that specimen or that tissue block would not yield the result that this original test was falsely negative, would it?

DR. WELLS:

A. Not usually, no, but if the technique was much more sensitive than the previous technique, I suppose theoretically, it could.

CROSBIE, Q.C.:

Q. That would be because the receptor sites were

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no longer there to retrieve because of the manner in which the tissue had been handled?

DR. WELLS:

A. What I meant by that was that it's possible that the first technique that was used that was negative was less sensitive than the new technique that was used and therefore, the previous test was stated to be negative when in fact there was a little bit of estrogen receptor there, albeit at a level not detected by the first technique, but detectable by the second technique.

CROSBIE, Q.C.:

Q. I understand, however, it is possible to have degraded the tissue so much that you can't retrieve the receptor?

DR. WELLS:

A. Yes, of course.

CROSBIE, Q.C.:

Q. And in fact, that would mean that the false negative rate, if one were doing a retrospective review, would be higher than what showed up in the statistics because you're not going to detect the false negative if it occurred pre-analytically?

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DR. WELLS:

A. I guess that could be true. I have no way of knowing how you would tell that.

CROSBIE, Q.C.:

Q. Thank you.

THE COMMISSIONER:

Q. Do you have anything arising, Mr. Coffey?

DR. CLIVE WELLS, RE-EXAMINATION BY BERNARD COFFEY, Q.C. - VIA VIDEOCONFERENCE

COFFEY, Q.C.:

Q. Yes, I do, Commissioner. Actually, Doctor, you--in response to some questions you were asked, you made reference to internal controls, which of course are referred to in the 2004 paper?

DR. WELLS:

A. That's correct.

COFFEY, Q.C.:

Q. And you indicated that, you described them as a very good way of assessing whether the tissue was staining appropriately?

DR. WELLS:

A. That's correct.

COFFEY, Q.C.:

Q. And Doctor, I wanted to ask you this. As a

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practising pathologist, in relation to ER and PR done by the IHC method, using paraffin blocks, how long have you known about the utilization of internal controls in that context?

DR. WELLS:

A. I guess for quite a long time. We always get our technical staff to report--they initially assess the positivity of the slides and then they give them to us, and they will write down internal controls present or internal controls not present. There are sometimes when you get a block of tissue, say if you only have a very limited core biopsy sample, where you may not have an internal control, but we do like to see them if they're there. It's a way of knowing that the techniques worked.

COFFEY, Q.C.:

Q. And Doctor, I take it then, in terms of your view that if at all possible that tissue that can act as an internal control be there and you'd actually examine it, if it was there, to satisfy yourself that it had stained appropriately. I take it that you've known about that, you say a long time. What are we

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talking about here, like decades?
DR. WELLS:
A. I suppose we've been reporting receptors for, golly, about 15 years.
COFFEY, Q.C.:
Q. 15 years.
DR. WELLS:
A. Regularly, I personally. So I guess about that sort of time.
COFFEY, Q.C.:
Q. And certainly since the early to mid 1990s?
DR. WELLS:
A. I guess that would be about right, yes.
COFFEY, Q.C.:
Q. Doctor, you also referred to, in terms of positivity statistics and presumably then, of course, one can also calculate a negative receptor rate as well in a population, you referred to the prevalence or lack thereof of breast screening in a population, having a potential effect on the statistics that might be forthcoming in relation to the positivity rates. Could you elaborate on that a bit for the Commissioner?
DR. WELLS:

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A. Yes. A laboratory that is involved in breast screening will have a higher percentage or estrogen receptor positive tumors because it will have a different age distribution of its breast cancer population because of picking up--in general, the estrogen receptor positive tumors are generally slower growing than the estrogen receptor negative ones, and so they're easier to pick up by breast cancer screening. Also, they're more common in the breast cancer screening age group, rather than in the younger age groups. So you would expect a hospital having a high breast cancer screening workload to have a higher percentage positivity of estrogen and progesterone receptor than one that doesn't have a program.
COFFEY, Q.C.:
Q. They're the questions I have.
DR. CLIVE WELLS, EXAMINATION BY MADAM COMMISSIONER - VIA VIDEOCONFERENCE
THE COMMISSIONER:
Q. Thank you, Mr. Coffey. Doctor, my name is Margaret Cameron. I'm the Commissioner for this Commission and I wanted to explore a little bit with you an answer that you gave to

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a question by Mr. Crosbie a few moments ago, which was directed to the explanation of the difference in test results on a first test and a second test when on the first occasion the patient might have been determined to be negative and on the second occasion positive, and you referred to more sensitive technique having been used on the second occasion as a possible explanation.
DR. WELLS:
A. Yes. I would have thought that as the testing has evolved, the sensitivity of the test has increased because of the use of the better antibodies and better techniques, and better antigen retrieval.
THE COMMISSIONER:
Q. Okay, what I'm wondering specifically is whether, if you assume optimal fixation and optimal processing in two laboratories which might use different antibodies because they have chosen for perhaps good reason to use one antibody in one laboratory and another, assume for the moment, both well recognized acceptable for use in this test. Would you expect that the results would be statistically

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different in those two laboratories, testing the same sample?
DR. WELLS:
A. No, I would expect that with good fixation and with good technique and with good antibodies, they should be identical.
THE COMMISSIONER:
Q. Okay.
DR. WELLS:
A. What I was talking about was the problems of a badly fixed tumor that was falsely reported as negative by a less sensitive technique could be picked up as positive by a more sensitive technique later on.
THE COMMISSIONER:
Q. And when you say less sensitive and more sensitive, is that a general statement about sensitivity or does that refer to the difference that is inherent in using different antibodies in the sense of in the fixation process could something happen which would cause what I would think of as the second stage, fixation being the first stage and the second stage of processing? Would one expect that a fixation problem might result in one

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process thereafter optimally done to make a difference? That's what I'm--I'm getting to the fixation end of it and what its effect could be, because you've said that if it's properly, optimally fixed and optimally processed, you would expect the same result. Now I'm looking to if it's not optimally fixed, but you use optimal processing on either side, could you expect a different result because of the problems with fixation?

DR. WELLS:

A. Yes, I was specifically thinking of fixation being the problem.

THE COMMISSIONER:

Q. Yes.

DR. WELLS:

A. In that if you've got a tumor that's poorly fixed, it's lost, say, 90 percent of its estrogen receptor activity.

THE COMMISSIONER:

Q. Um-hm.

DR. WELLS:

A. And then you stain that with a technique that's not particularly sensitive -

THE COMMISSIONER:

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Q. Okay.

DR. WELLS:

A. - you may not pick up the residual activity that is still there, but if you used a more sensitive technique, you may pick up that residual activity. Do you understand what I mean?

THE COMMISSIONER:

Q. I think I do, and that's just underlying again the point of how critical fixation is to the success of this particular test. Is that fair?

DR. WELLS:

A. That's correct.

THE COMMISSIONER:

Q. Yes, okay. Mr. Coffey, you're on your feet. Does that mean I raised a question with you?

DR. CLIVE WELLS, RE-EXAMINATION BY BERNARD COFFEY, Q.C. - VIA VIDEOCONFERENCE

COFFEY, Q.C.:

Q. Yes. If I could, Doctor, Commissioner and Doctor. Doctor, just to use a concrete example of what the Commissioner has been just asking you about, assuming the same block of tissue, okay, and whatever may have been done

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to the block before, the tissue and the block before, if it was well fixed, fine, but if it wasn't well--well, assume for the moment it was properly fixed, okay.

DR. WELLS:

A. Yes, okay.

COFFEY, Q.C.:

Q. And laboratory A processes a slide and the result is an ER of zero, or very low ER, zero or five or so, five percent.

DR. WELLS:

A. Yes.

COFFEY, Q.C.:

Q. Laboratory B takes the same block, processes it into slides using its own technique and reports the ER at 80 percent, what could account for that, assuming that the tissue was properly fixed in the first place?

DR. WELLS:

A. That would have to be a problem in the technique in the first laboratory.

COFFEY, Q.C.:

Q. Doctor, assuming for the moment that, again we have another block of tissue and this second block of tissue is poorly fixed, there are

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problems with its fixation, okay, laboratory A processes that block with its own technique and reports the ER at zero or very low, again, zero, two or five low. Laboratory B takes the same block using its technique and processes the block into a slide and again produces perhaps, I'll pick a figure of 60 to 70 percent, okay, what might account for that?

DR. WELLS:

A. Well, that could be the sensitivity of the test employed by--the first laboratory being less than the sensitivity of the test employed by the second laboratory, or it could be, as with a well fixed block, a problem with the first processing, the first testing.

COFFEY, Q.C.:

Q. The technique used by lab A?

DR. WELLS:

A. Yeah.

COFFEY, Q.C.:

Q. Problems in their--they haven't optimized their--potentially haven't optimized their technique?

DR. WELLS:

A. Yes, that's what this would suggest.

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COFFEY, Q.C.:
Q. Thank you, Commissioner.
THE COMMISSIONER:
Q. Thank you very much, Dr. Wells, for your contribution.
DR. WELLS:
A. Thank you.
THE COMMISSIONER:
Q. We very much appreciate your having cooperated with us in this matter. I know at times we've made strange demands at odd hours, at least in your part of the world. So we very much appreciate your participation. Thank you.
DR. WELLS:
A. You're welcome.
COFFEY, Q.C.:
Q. Thank you, Doctor.
DR. WELLS:
A. Thank you.
(LUNCH BREAK)
THE COMMISSIONER:
Q. Please be seated. Ms. Chaytor?
CHAYTOR, Q.C.:
Q. Good afternoon, Commissioner. The next witness is Lynn Wade.

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MS. LYNN WADE, SWORN, EXAMINATION BY SANDRA CHAYTOR, Q.C.
REGISTRAR:
Q. Would you please state and spell your complete name for the Commission?
MS. WADE:
A. Lynn Wade, L-Y-N-N W-A-D-E.
REGISTRAR:
Q. Thank you.
CHAYTOR, Q.C.:
Q. Good afternoon, Ms. Wade.
MS. WADE:
A. Good afternoon.
CHAYTOR, Q.C.:
Q. Commissioner, we have a number of new exhibits, please, that I'd ask to have entered, P-3585 to P-3629 inclusive and P-3637 to P-3644 inclusive, and P-3649 to P-3673 inclusive.
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-3585 THROUGH P- 3629
EXHIBITS ENTERED AND MARKED P-3637 THROUGH P- 3644
EXHIBITS ENTERED AND MARKED P-3649 THROUGH P- 3673
CHAYTOR, Q.C.:
Q. Registrar, if we could have, please, P-3585?

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Ms. Wade, this is a copy of your current CV and perhaps if you could take us through your educational and professional background?
MS. WADE:
A. Okay. I graduated with the certificate of Medical Lab Technology from the College of the North Atlantic, back then it was the College of Trades and Technology, and also achieved the CSMLS certification in 1977. I worked briefly in Labrador City and then in 1978 started work at the General Hospital. I completed a Bachelor of Technology at Memorial University in 2005. I was a technologist I in several different departments at the General Hospital, Tech II in the biochemistry division until 1997 when I became Client Services Manager for the Health Care Corporation, and in 2007, I was the--became the program manager for Safety and Quality, which I told today.
CHAYTOR, Q.C.:
Q. Okay, and what is a Bachelor of Technology?
MS. WADE:
A. Bachelor of Technology is a relatively new degree program that was developed with the University in conjunction with the College, in

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order for those people who have achieved technical diploma status to go on and achieve Bachelor status.
CHAYTOR, Q.C.:
Q. Okay, and your work as a technologist, you worked in biochemistry and cytology, microbiology. Did you have any experience in the pathology lab?
MS. WADE:
A. No.
CHAYTOR, Q.C.:
Q. Okay, and under your professional profile, Human Resources Management, you've written "encourages and facilitates continuing education opportunities for laboratory managers and staff."
MS. WADE:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And that was in your role as client services manager?
MS. WADE:
A. Well, I do that now.
CHAYTOR, Q.C.:
Q. And you still do that?

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MS. WADE:
A. Yes, certainly in my role as program manager for safety and quality, yes.
CHAYTOR, Q.C.:
Q. And that would include the technologists, I take it?
MS. WADE:
A. Yes.
CHAYTOR, Q.C.:
Q. And "performed performance appraisals and annual attendance reviews," is that -
MS. WADE:
A. That would have been as client services manager. I had approximately 100 staff reporting to me at that time and that was part of my duties as manager.
CHAYTOR, Q.C.:
Q. Okay, and you also had financial responsibilities as client services manager?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And changes management, "assists in training of laboratory staff for the purposes of policy and procedure writing." Perhaps you could

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tell the Commissioner what--is that your current position?
MS. WADE:
A. That will be my current position, yes.
CHAYTOR, Q.C.:
Q. Okay, and what is involved in that?
MS. WADE:
A. Well, basically now, I have the role of helping to facilitate all of the programs, the divisions within the program of lab medicine across Eastern Health, and help to facilitate the redevelopment of the policies and procedures in relation to the regionalization component, as well as the quality management processes. So they are now--I'm helping them to put them into new templates and standardize the formats, basically.
CHAYTOR, Q.C.:
Q. Yes, and we've seen a new manual. We refer to it here as P-2157, and that's just a little heads up to the Registrar, because it'll take her a while to bring that one up, but so that's the new manual, and you were assisting, I take it, in doing that, in bringing up or in developing that manual?

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MS. WADE:
A. I'm thinking this--I don't know which one this is. It's probably -
CHAYTOR, Q.C.:
Q. That's fine.
MS. WADE:
A. Oh, the pathology one, yes.
CHAYTOR, Q.C.:
Q. Yes, that's right.
MS. WADE:
A. Yes, so that's very--that's specific to the pathology division.
CHAYTOR, Q.C.:
Q. Yes.
MS. WADE:
A. And I have been helping with that really since last summer perhaps, yeah.
CHAYTOR, Q.C.:
Q. Okay, and you also say, under change management, "liaise with information management and technology department and participates on Meditech consolidation committee." Is that in your current role?
MS. WADE:
A. It is in my current role, but it also was part

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of my last role too, something that carried through and it's all part of helping to develop quality systems, certainly for communication, for the enhancement of availability of the policies and procedures on the intranet for staff across the region, because there are 17 sites and it is certainly beneficial if we can have them on an intranet system.
CHAYTOR, Q.C.:
Q. Okay, and Registrar, thank you for bringing it up. Maybe we could just diminish the window and go back to 3585 for a moment? Thank you. And "coordinated Medinet implementation for electronic transfer of laboratory data between regional laboratories and laboratories at the General site Eastern Health." When would this have been taking place and what exactly were you doing?
MS. WADE:
A. This is actually a link that provides for the electronic transfer of lab orders and results from one site to another and reverse. So basically, what this was was--it's probably three years maybe since we started the process

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and right now, we have the rural Avalon region and the Western region that are linked electronically so that there are no paper requisitions per se coming to us. The orders go directly from them into our system and our results go directly back to them, and it enhances the quality of reports and the turnaround time and reduces data entry errors that can happen to manual transfer.

CHAYTOR, Q.C.:

Q. Okay, and then under quality initiatives, "developed and conducted quality management workshop to introduce laboratory managers and senior technologists to quality management concepts." When would you have done this?

MS. WADE:

A. This was in February of 2008. That was following the completion of the regional lab safety manual that I worked on for several months prior to that, and then I hosted the workshop to get staff and managers from all the sites throughout the region together to talk about basically quality management and processes and procedures and then to introduce them to the safety manual for the region.

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CHAYTOR, Q.C.:

Q. Okay, and what types of quality management concepts would you have been introducing them to?

MS. WADE:

A. Basically about quality management, just explaining what quality management was, and then how to flow chart their processes so that they could identify any gaps in their procedure manuals that may be there now and introducing them to templates, standardized templates with standardized headers and explaining how they would adapt them to the individual labs.

CHAYTOR, Q.C.:

Q. And maybe then you could also educate us. What is quality management?

MS. WADE:

A. Okay. Quality management basically is a management approach that strives to meet our customers' satisfaction, and that would be physicians and patients and the public, through a continuous improvement initiative. So basically, we develop and monitor everything that we do so that we can continuously improve.

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CHAYTOR, Q.C.:

Q. Okay. So for example, the development of policies and procedures, seeing that they're revised and updated as needed?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. And seeing that they are also implemented?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. That's part of quality management?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. Okay, and then we have "developed and conducted workshop to introduce the regional laboratory safety program" and what is that? What's the regional laboratory safety program?

MS. WADE:

A. Well, the labs have--laboratories, by virtue of what they are and what we work with, can be very dangerous environment and so what we have done now is a regional policy manual that all

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labs in the region have to follow, but then they also have to customize it to their own site, so that they have to ensure that they have the procedures in place, for instance, for chemical spill clean up, specific to their labs and the kinds of equipment and the kinds of chemical that they would be using, for instance.

CHAYTOR, Q.C.:

Q. Okay, and "developed and conducted indicators workshop for laboratory managers and senior technologists." What do you mean by indicators?

MS. WADE:

A. Well, indicators really are a way of providing a snapshot of the quality for the lab, so it could be anything: looking at financial indicators, looking at how well we are within or not, within our budget; looking at quality of work life, you know, how many staff are injured in the workplace; looking at quality patient centred kinds of initiatives and indicators for that would be things like turnaround time and error rates and things like that.

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CHAYTOR, Q.C.:
Q. Okay, and "conducted quality rounds to educate laboratory staff regarding occurrences." What are quality rounds?
MS. WADE:
A. That's something that came as a result of--well, this first one actually was a result of an occurrence that we had in one of the labs and in conjunction with Ms. Predham at Quality and Risk Department, we conducted--we used that occurrence as an opportunity to educate staff about the importance of report, not only things when they happen, but the near misses and the kinds of things that--the oops moments that they may have in their everyday work that would provide opportunities to improve. So that quality round was a presentation and then a very general discussion with staff and management right across the region, and Heather and I did a couple of them and then I went out to the rest of the region and conducted them with staff.
CHAYTOR, Q.C.:
Q. And is that something then that you would do on a regular basis?

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MS. WADE:
A. That would be seen as part of my role as quality manager and I haven't been able to get out as much in the last few months, but certainly even--not only to do discussions around a specific occurrence, but to talk generally about other initiatives within quality management, like corrective actions and lots of things.
CHAYTOR, Q.C.:
Q. Yes, and the Commissioner has heard about, for example, tumor board rounds and those happen on a regular basis. So would quality rounds be something that you would have happen on, you know, a monthly or quarterly basis? Is that the intent or is this something -
MS. WADE:
A. There's no framework yet around the frequency. Certainly with 17 sites in the region, you know, to get out there on a frequent basis to every site is difficult, but the hope, certainly my goal would be to educate the staff in their own areas so that they can conduct these kinds of things, just in -
CHAYTOR, Q.C.:

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Q. On a regular basis.
MS. WADE:
A. - staff huddles and those kinds of things, yeah.
CHAYTOR, Q.C.:
Q. And that's something, Ms. Wade, you're responsible for quality throughout the entire region, in terms of you say 17 sites. So that would include acute care and long-term sites as well?
MS. WADE:
A. Well, my role with the lab program, the lab itself has 17 sites and they provide anything from sample collection only right to referral type testing, as at the Health Science Centre, so that's a lab site. As far as my role as program manager for quality and safety, it's a portfolio appointment and that is responsible for all of those programs in Dr. Howell's portfolio. So it includes diagnostic imaging and pharmacy and medical services, as well as lab.
CHAYTOR, Q.C.:
Q. Yes, okay. So the 17 sites, there are 17 labs throughout Eastern Health and -

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MS. WADE:
A. That this refers to.
CHAYTOR, Q.C.:
Q. - all of them would come under your portfolio?
MS. WADE:
A. Certainly.
CHAYTOR, Q.C.:
Q. Yes, okay, and you write here "communicates with internal and external stakeholders, including nursing staff, family physicians and other regional laboratories regarding laboratory policies and procedures." So I take it you have a liaison role?
MS. WADE:
A. Right.
CHAYTOR, Q.C.:
Q. And in terms of communicating with other regional laboratories, I take it that means Western, Central, Labrador Grenfell?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And so were you involved then in communicating with them regarding the new policies and procedures that are coming out of Eastern

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Health?
MS. WADE:
A. That's right, and generally, what I would do is anything that is new that I've been involved with, I would forward the information to the directors of those regions so that they could then disseminate it all throughout their region.
CHAYTOR, Q.C.:
Q. Yes, and I'll have a few more questions for you on that later on today. And then you "facilitate continuing education opportunities such as web-based presentation by CLMA and CLSI for laboratory personnel throughout the region."
MS. WADE:
A. Um-hm.
CHAYTOR, Q.C.:
Q. And "coordinate a pilot laboratory accreditation in 2007."
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. Okay, and then under interpersonal skills, you "advise Vice President Medical Services and

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Diagnostics regarding issues of quality and employee and patient safety for the portfolio," and I understand you report directly--in your current position, you report directly to Dr. Howell? Is that correct?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And then under committee participation, there's quite a number of committees listed there, which are relevant to the laboratory. Laboratory Quality Management Steering Committee, what's the role of that committee? Is that -
MS. WADE:
A. That is a very new committee of the lab. We just held one meeting so far, and basically it's the lab managers and the division chief, as well as myself, and the role of that committee will basically be to oversee quality management initiatives for the lab program. So the framework for that and the terms of reference have not been developed yet and we're in the process of formalizing that process.

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CHAYTOR, Q.C.:
Q. Okay, I'm sorry, and who chairs that committee?
MS. WADE:
A. I will be chairing that committee.
CHAYTOR, Q.C.:
Q. You're going to chair that committee?
MS. WADE:
A. Yes.
CHAYTOR, Q.C.:
Q. And then the Pathology Quality Management Committee, is that then a similar committee but it would just deal with the pathology section of the lab?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And who chairs that committee?
MS. WADE:
A. Dr. Lynn Morris-Larkin right now, and Bev Rowe, who is the quality coordinator for pathology.
CHAYTOR, Q.C.:
Q. Okay, and is that the committee that Dr. Bev Carter was involved with at some point?

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MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. Same committee. And then the Laboratory Leadership Committee, you sit on that committee?
MS. WADE:
A. I sit on that committee, yes.
CHAYTOR, Q.C.:
Q. And that's relatively new, I take it, in your new position?
MS. WADE:
A. Well, certainly for me, but that consists of Mr. Gulliver and Dr. Denic and Dr. Howell and Dr. Simon Avis.
CHAYTOR, Q.C.:
Q. And now yourself?
MS. WADE:
A. And myself, yeah.
CHAYTOR, Q.C.:
Q. Okay, and Laboratory Operating Room Quality Improvement Committee, is that a new committee?
MS. WADE:
A. That is actually. We've had two meetings and

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that was called at the request of the OR educators and their director, and basically consists of various people from the lab program, as well as from the OR, and it's a great venue to enhance quality initiatives, certainly for specimens that are coming from the OR to the lab, given that those samples are very precious samples and we want to make sure that we get it right the first time, from the time that they're taken out, and we see this as a good networking opportunity to communicate our policies and to get feedback from the people who would be using them.

CHAYTOR, Q.C.:

Q. So representatives of the perioperative program and the -

MS. WADE:

A. And the lab.

CHAYTOR, Q.C.:

Q. - laboratory medicine program sit on that committee?

MS. WADE:

A. That's right, yes.

CHAYTOR, Q.C.:

Q. Okay, and the purpose being to address any

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common issues that may arise?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. And to ensure, in particular, as you're saying, that specimens are handled appropriately and -

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. - in a timely manner as well?

MS. WADE:

A. Yeah.

CHAYTOR, Q.C.:

Q. And then you have Portfolio Safety and Quality Committee, Medical Services and Diagnostics. What's the mandate of that committee?

MS. WADE:

A. Well, that is the overall portfolio one chaired by Dr. Howell, and that consists of all the directors from his portfolio as well as some stakeholders from the surgery medicine program and users of our service, and I sit on that as the quality manager for his portfolio.

CHAYTOR, Q.C.:

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Q. And Laboratory Pan-Canadian Standards Group, Canada Health Infoway, what is that group?

MS. WADE:

A. That is a national group out of Canada Health Infoway that is developing standards for the electronic health record in relation to lab. So it talks about electronic transfer of lab data, a lot of IT-ish information and also to help the provinces to conform to a standard process so that eventually the lab components can be within the electronic health record.

CHAYTOR, Q.C.:

Q. Okay, and you've been part of both the Electronic Health Record Laboratory Advisory Committee of NLCHI and Clinical Meditech Consolidation Committee, Eastern Health?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. And how long has that committee been in existence?

MS. WADE:

A. The Clinical Consolidation Committee?

CHAYTOR, Q.C.:

Q. The Clinical Meditech Consolidation.

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MS. WADE:

A. The Meditech one is recently, probably in the last couple of months, and that is with a view to consolidating into one Meditech system for Eastern Health.

CHAYTOR, Q.C.:

Q. Okay. Your role as the manager of client services, what were your overall responsibilities in that position?

MS. WADE:

A. It was twofold. First off was the human resources component. I was responsible for all of the blood collection staff and the data entry staff in St. John's hospitals, and then there was the liaising kind of role that provided a link for other programs and other regions to communicate with the lab program within the Health Care Corp at one time and then Eastern Health.

CHAYTOR, Q.C.:

Q. And so when Eastern Health came on, your role as manager of client services was basically the same with Eastern Health?

MS. WADE:

A. That's right, and it was to try and expand,

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certainly in the regional component, to expand some of our policies around things like labelling of samples and specimen handling and acceptance and rejection criteria throughout the region, to standardize that component of safety.

CHAYTOR, Q.C.:

Q. Okay, and do you have any particular experience or expertise in quality or quality initiatives?

MS. WADE:

A. From my role in the client services program, I did--a lot of the occurrence reports for the lab came to me because I was that liaison person. So in that role, I did a lot of investigation or certainly follow up on any occurrences that might be something like a sample didn't arrive at the lab or they didn't get a report in a timely manner, things like that. So the processes for follow up became very familiar to me over the course of time, and I took an interest in quality management from early in my career. Anytime I went away to national conferences or had an opportunity to attend any lectures or workshops, those

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were the kinds of things that I would take.

CHAYTOR, Q.C.:

Q. And we see, of course, under your continuing education a number of seminars?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. That you've attended in 2007/2008, in particular. Perhaps we could have, please, Registrar, P-3588, and this is a job description it looks like what was posted for your current position, and it indicates that it's Medical Services Diagnostics Program Manager, Safety and Quality Management, reporting to the VP Medical Services, "shall be accountable for developing, coordinating comprehensive quality management program within the portfolio, and you have regional responsibility regarding quality issues. The Safety Quality Manager will work in close liaison with directors, clinical chiefs, discipline chair, managers, as well as the other quality team leaders. The initial focus will be on the laboratory medicine program and will expand to other programs/departments

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within the portfolio. The candidate will develop, implement, and coordinate a comprehensive quality management program for laboratory medicine and safety plan for the program, which would include meeting all safety legislation and CSMLS safety guidelines, liaise with quality and systems improvement department regarding patient safety risk management issues", and does that basically capture what, in fact, then you are doing?

MS. WADE:

A. That's right, yeah.

CHAYTOR, Q.C.:

Q. And having to--your initial focus be on the laboratory medicine program. Why do you understand to be the case, why is that your initial focus, and what portion of your time is dedicated to the laboratory medicine program?

MS. WADE:

A. Well, this position was not created until March of 2007. I didn't take the position until close to the summer. We were then two years into this investigation, and it was seen

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that we needed to enhance our policies and procedures, and certainly given the regionalization of lab medicine. It was a daunting task to be done without someone being able to oversee it.

CHAYTOR, Q.C.:

Q. Okay, and you're accountable for developing and coordinating a comprehensive quality management program, and so far to date has that happened or is it still in the works?

MS. WADE:

A. Oh, it's--it's very much in the works. Obviously, there's been a lot of emphasis on the pathology division over the last couple of years, and I've spent a lot of my time assisting them in redeveloping their procedures and policies. I have done some other lab, general lab policies, around more administrative kinds of things, and recently we regionalized and rolled out the laboratory mislabelled specimen policy for the region and communicated that to all regions in the province because being a referral centre here in this site, in St. John's site, we had to ensure that, and also a policy around specimen

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acceptance and rejection criteria.
CHAYTOR, Q.C.:
Q. Okay, and I take it then this is a new initiative, there was no quality management program beforehand?
MS. WADE:
A. Well, all of the labs in all of their own legacy boards had various dates of policies and procedures, but what we're doing now is consolidating where they can be, enhancing where we need it, and standardizing it all throughout.
CHAYTOR, Q.C.:
Q. And you're also responsible it says here for quality issues throughout the region. How do you go about doing that aspect of your job in terms of your liaison with the other hospitals that come under Eastern Health's umbrella?
MS. WADE:
A. I have a pretty close relationship with all of the managers for all of the divisions, and then the three site managers in rural Avalon and the two Peninsulas areas. I meet with them, certainly in the manager's group, and then every day I have communication with at

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least one of them on some issue or initiative that we're working on, and also being very cognizant of where I'm coming from, my career was always in St. John's. We have to be very aware that we have a regional responsibility and to ensure that anything that's put in place by the lab program can be followed in all areas, not just the urban labs. So we have that role in the urban dynamic that we have to ensure that we cover off as well.
CHAYTOR, Q.C.:
Q. So, for example, if in Carbonear, if Dr. Baker had an issue in Carbonear in the lab, a quality issue were to arise, would he contact you or somebody--you'd expect someone from the lab to contact you?
MS. WADE:
A. Yeah, typically what would happen is because I have a close relationship with Ms. Browne, who is the manager out there, typically issues within her site will be dealt with by her. If Dr. Baker had an issue, he would go to her, and if they felt that it was something that needed escalation or a little more work, then they would contact me and I would help them to

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work on those.
CHAYTOR, Q.C.:
Q. And do they have representation on the committees that we looked at, some or all of the committees?
MS. WADE:
A. Well, on the Lab Management Committee, their manager sits on the Lab Managers Committee, and then also the pathology--one of the pathology technologists liaises with us as well from Carbonear.
CHAYTOR, Q.C.:
Q. If we could have, please, P-3586, and this is a position description for your job and it's marked in draft. Has it been finalized?
MS. WADE:
A. Pardon? Sorry.
CHAYTOR, Q.C.:
Q. That's okay, sorry, has--your job description, has this been finalized?
MS. WADE:
A. No, I'm still waiting to get some feedback from Classification people, and it is a work in progress. It's only been a year since I started this position, so to get down on paper

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now to try to frame it up. So it's close, though.
CHAYTOR, Q.C.:
Q. So this is your draft of what you see yourself doing?
MS. WADE:
A. This is--I drafted it and it's been vetted to Dr. Howell already once, yeah.
CHAYTOR, Q.C.:
Q. And under Quality Management, this position is accountable for ensuring the development, organization, evaluation, and improvement of quality management systems for the programs in the portfolio?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And, of course, one of those programs being the laboratory medicine?
MS. WADE:
A. Right.
CHAYTOR, Q.C.:
Q. And then the nature and scope, it's quite detailed what you've set out here in terms of the nature and scope of your position, and you

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indicate, "Safety and Quality Management Program is a new program implemented in July of 2007", and reporting--the incumbent advises the VP Medical on aspects of patient and employee safety and quality management related to the programs. "The Program Manager receives documents and follows up on reports and orders issues to the departments in the portfolio by the inspectors from the Department of Government Services". That's Occupational Health and Safety?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. And you're responsible for ensuring that the programs develop a quality management system, including policies and procedures that are in compliance with applicable standards, regulatory body requirements, and government legislation and guidelines, and you provide direction and support to the lab for the purpose of planning and developing their quality management system safety programs and provide guidance and training to staff that are responsible for writing policies and

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procedures in their departments, responsible for facilitating training of portfolio management and employees regarding safety programs and quality management systems, and ensuring promotion of policies and procedures to other programs and external stakeholders, such as community physicians and other regional health authorities as required. So I take it if there's anything in the way of a policy and procedure that needs to be communicated outside of Eastern Health, you're responsible for facilitating that as well?

MS. WADE:

A. I would certainly recommend that it would be shared, yes.

CHAYTOR, Q.C.:

Q. And you're responsible for overseeing the development of key indicators by the programs, and monitoring the effectiveness and quality of the services--sorry, for the purpose of monitoring the effectiveness and quality of services and ensures continuous quality improvement initiatives are undertaken based on indicator measurements, satisfaction--survey results and occurrence reporting.

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What's involved in that? Perhaps you could just give us some practical or an example as to what would that involve?

MS. WADE:

A. You've heard about one of the initiatives, I guess, in determining indicators of quality. We've talked about proficiency testing and those kinds of things, and we've been looking at the overall reporting or results of proficiency testing for the labs throughout the region, all labs, not just pathology certainly, and basically looking at ways to measure how well we're doing, and how we are perceived by our stakeholders and users, such as clinicians and patients.

CHAYTOR, Q.C.:

Q. Okay. How do you go about monitoring whether or not policies and procedures, once adopted, that they're, in fact, being followed?

MS. WADE:

A. Well, part of the--part of the procedure for putting out a new policy is to ensure that there is a cover sheet that goes with it, basically, a sign off sheet. So people who are responsible for following it must read it

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and indicate that they have, and then we maintain the document as a control document that says that they--so by people signing off that they had read a policy, then they're accountable to follow that policy.

CHAYTOR, Q.C.:

Q. So that indicates that they have read it and are aware of it and informed?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. Then is there any checks or balances to follow up to see, in fact, that they are following the policies? Is there anything in terms of the implementation of the policy, is there any checks that can be made or are to be made?

MS. WADE:

A. There are types of audits and checks, even if the--we have a policy around monitoring temperature dependent equipment, and one of the audits to ensure that that policy is being followed is that we can go at any point in time and look at their temperature charts, for instance, and if there are gaps in that or if there are temperature failures, what were the

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corrective actions that were taken and ensuring that they are following. So that's-- you know, you have to--we have to build in indicators or audits for determining compliance.

CHAYTOR, Q.C.:

Q. And that's still in the works, I take it?

MS. WADE:

A. Some of it is in place. So certainly, you know, for some policies--the new policies that are going out, I know certainly in pathology, for instance, that binder does have a sign-off sheet in there.

CHAYTOR, Q.C.:

Q. So that people know--acknowledge they've read them?

MS. WADE:

A. Exactly, yeah.

CHAYTOR, Q.C.:

Q. And what about then what's built in in terms of an audit function to check whether or not the policies or procedures are being followed?

MS. WADE:

A. And again things like audit sheets for monitoring temperature control is one, or

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daily maintenance procedure check-offs for equipment, there's policies around ensuring that the equipment is maintained. So the managers really need to be checking the maintenance manuals to make sure that they have been checked off, and that they are being followed as they are set out.

CHAYTOR, Q.C.:

Q. So then that becomes the managers--that's part of the managers function then to do that?

MS. WADE:

A. Certainly, yes, the managers or the designate. It could be a senior technologist in the department who would be doing certain aspects of it, and in my role, I certainly know that the managers are challenged with everything day to day, and there does need to be accountability on the part of all technologists to ensure that they're following the guidelines and policies and day to day operation procedures. So one of the things that I recommend to managers is that they build daily tasks relating to compliance for safety and quality in every work bench, so that it becomes inherent as part of the job

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and it's not something else they have to do, it's just part of what you do.

CHAYTOR, Q.C.:

Q. Part of what they do when they sit down to do their job every day?

MS. WADE:

A. Exactly, that's right.

CHAYTOR, Q.C.:

Q. And at your level then, you work with them to make sure they have the appropriate policies and procedures in place, and then assist them in how--in different ways in which they can go about ensuring compliance?

MS. WADE:

A. That's right, yeah.

CHAYTOR, Q.C.:

Q. Okay. You write on the third page of the exhibit the major challenges faced by yourself "are facilitating change management to enhance the quality and a patient and employee safety culture". What are you referring to there?

MS. WADE:

A. The intricacies, I guess, of quality management, there's a lot of detail associated with it, you know, and really paying attention

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to all the details in combination will provide you with a better enhanced quality program for anything that we do, and putting in place all of the documentation of what we do. So technologists on a day to day basis will run quality control on their analyzers before they run their thousands of patient samples, and if the quality control, for instance, is not working on a particular analyte, then there are a number of steps that they would take to fix that before they will run anything. Technologists always did that. I guess, what we are enhancing now is the documentation of that even further than saying that we did it and checking off on a checklist that it was done, but if it didn't work, then what else did you do, and that was also done. So that-- the change around that is helping people to understand the importance of documenting every single detail of what they do. So that's-- that's a change because in the busyness of the environment and the workload that some areas face. Right now it's seen as something else, you know, it's the "Lynn" file and it's a challenge, but, you know, I'm getting--I'm

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making inroads.
CHAYTOR, Q.C.:
Q. And, "Planning, revising, communicating, and implementing standardized policies and procedures across 17 sites to meet the needs of the users, both in urban and rural", and we've touched on that briefly?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. "Fostering a team approach to continuous quality improvement in the programs of the portfolio", how is that a challenge and how do you go about addressing that?
MS. WADE:
A. I would like to see the lab as part of the whole process around anything involving the lab. So just because the lab is not the one that writes the requisition or orders the test, we have to ensure that physicians have the information or that nurses have the information to make the right decisions about what to order and what kind of sample is appropriate to be sending, and to give us the information on the requisitions. So while we

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are not at that front end, we have to ensure that they have the information. So that's all part of fostering this team approach to the front end, the pre-analysis component. Obviously, then within the lab, many people in the lab programs are involved with the sample, getting them ready for testing, and actually testing, and then the reporting of them, so -
CHAYTOR, Q.C.:
Q. Okay.
MS. WADE:
A. That's what I mean by that.
CHAYTOR, Q.C.:
Q. Okay, and then under your--we've talked about your committee involvement, and under your specific accountability, advising Dr. Howell on aspects of safety and quality relevant to the programs in his portfolio, providing leadership and guidance to the programs for the development, auditing, and review of quality management systems.
MS. WADE:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. And again we've just spoken briefly on the

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auditing and how you've -
MS. WADE:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Of assistance in that regard.
MS. WADE:
A. Yes.
CHAYTOR, Q.C.:
Q. "Collaborates with managers and staff in the development of policies and procedures for the program. Collaborates with management and staff to development orientation training, continuing education and competency assessment tools for the programs", and what have you done in terms of that for the laboratory medicine program?
MS. WADE:
A. A lot of my original--the early stages, I guess, has been around the safety program, ensuring that all staff are educated in WHMIS education, again the workshop around quality management, introducing that certainly to the senior staff, the leaders of the various sites and divisions. The competency assessment tool is--is not necessarily a new tool. There are

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lots of ways to assess competency, and most of the divisions have checklists that when people come in to start work, there is a list of things that they will have to know before they could be considered trained. Some areas are more developed than others. Something--areas like transfusion medicine, as a result of the initiatives that came out of the Krever Inquiry a number of years ago, there are a lot of standards and guidelines around transfusion medicine relating to labs. So they're probably a little more advanced in some areas. We hope to be able to develop some competency assessment tools that are a little more generic and can be used anywhere. You just--you just frame them around actual duties and responsibilities in the various divisions.
CHAYTOR, Q.C.:
Q. And what credentials are currently required to work as a laboratory technologist at Eastern Health?
MS. WADE:
A. Lab technologists must be CSMLS eligible.
CHAYTOR, Q.C.:
Q. And is there anything in place stipulating

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what credentials a laboratory technologist is required to have before they are permitted to work within the IHC component of the program?

MS. WADE:

A. At this point in time, they must be a CSMLS certified lab technologist.

CHAYTOR, Q.C.:

Q. And is there any requirement for any competency assessment or testing?

MS. WADE:

A. That's pretty specific to the pathology division, and Mr. Dyer could probably answer that better than I could.

CHAYTOR, Q.C.:

Q. So in terms of, would you expect if there were to have something like that develop, that you would be of assistance in doing that?

MS. WADE:

A. Certainly with, most of the work benches now, I do know in pathology do have kind of a checklist of duties and responsibilities, so that would be the kind of thing that, you know, if you have a checklist of things that you have to do, then it stands to reason you have to know how to do them before you can

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start to work there.

CHAYTOR, Q.C.:

Q. And have you been asked to do anything in terms of looking at a competency assessment for laboratory technologists?

MS. WADE:

A. Overall at this point I'm just starting to do some research around what is out there and what other jurisdictions are doing with respect to competency assessments. We have some things that are available as little quizzes, that kind of thing. I'm more inclined to go with peer to peer assessments and those kind of things, as opposed to making them very intimidating kind of things, you know, something that could be used in peer reviews, that kind of thing within their own divisions.

CHAYTOR, Q.C.:

Q. So I just want to be clear, have you been asked to look into that or this is something that you -

MS. WADE:

A. It is part of a Quality Management Program that there be competency assessment for

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personnel, so that's part of the whole policy around, the people within the lab.

CHAYTOR, Q.C.:

Q. And has there been anything put in place to date to your knowledge?

MS. WADE:

A. Not completed, no, because--it's certainly something that I'm working on for the program, the overall policies that there need to be competency assessment tools and each division will have to develop what is appropriate for them.

CHAYTOR, Q.C.:

Q. Right, and that's something I believe was raised back in 2005 by Ms. Wegrynowski was the first time that we've seen it raised here.

But you are now working on coming up with some assessment tools, competency assessment tools.

MS. WADE:

A. Yes.

CHAYTOR, Q.C.:

Q. And that would include the IHC technologists?

MS. WADE:

A. It would be every employee within the lab.

CHAYTOR, Q.C.:

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Q. And is there any policy which requires the type and duration of an orientation process that a new hire, in terms of a technologist, would be required to meet to be able to work in the IHC portion of the lab?

MS. WADE:

A. I'm not aware of the specifics of IHC.

CHAYTOR, Q.C.:

Q. And do you know whether or not there's any plan to develop such a policy? Has anyone approached you -

MS. WADE:

A. There will be a lab program policy that discusses the need for adequate and appropriate orientation, training and continuing education and competency assessment. So the lab program will develop--or I will be developing the lab programs policy, certainly in conjunction with all the managers, but then every division and site will have to personalize it to their area because everywhere it is different, so you have to ensure that the tools that are developed will work.

CHAYTOR, Q.C.:

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Q. And have you had any discussions with anyone, whether the director of the program or the clinical chief about the requirement for lab technologists to pursue a certain level of continuing education?

MS. WADE:

A. Yes, I have always, as a technologist long before I was ever in this role, felt that continuing education is certainly an individual responsibility to make sure that you are aware and educated around the advances of our profession, I mean, lab technology has come leaps and bounds since I started and it's even faster with--these days, so continuing education I have discussed with Dr. Denic certainly and he's been very supportive of any initiatives that we have undertaken to enhance this, so in recent months we have provided web based kinds of education sessions where staff can attend at a computer. Just recently we had one out of clinical--I think it was out of Maryland General Hospital. There are a number of on-line opportunities and certainly because of where we are located, it can be very cost prohibitive to, for people to go away and one

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or two at a time is going to take a long time for everybody to go, so we find that--I'm finding that there is a lot of opportunity on the web now.

CHAYTOR, Q.C.:

Q. Yes.

MS. WADE:

A. So that's what we're looking to facilitate.

CHAYTOR, Q.C.:

Q. And is there an additional designation that a technologist can acquire beyond an RT? Is there an advanced registered technologist?

MS. WADE:

A. There is an advanced registration, there's not necessarily a requirement for that. A lot of people who have achieved the registered technologists certification and designation through the CSMLS have done so of their own volition as a personal development piece, but--and also now with the Bachelor of Technology, a number of people throughout the region are challenging the Bachelor of Technology degree program.

CHAYTOR, Q.C.:

Q. And in doing an ART, can that be done in

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specific areas of expertise, like microbiology or pathology?

MS. WADE:

A. The advance certification, there is a general one, but then most people tend to select the discipline specific, such as microbiology or pathology. Microbiology seems to be the most common one that I am aware of.

CHAYTOR, Q.C.:

Q. And has there been any discussion within Eastern Health as to, for example, technologists that ultimately come to work in IHC, we understand have been fairly senior people. Has there been any discussion as to whether or not there should be an ART pursued that may be of assistance to them?

MS. WADE:

A. I'm not aware of that discussion, although I do know that they're looking at the possibility of some specific certification maybe in immunohistochemistry. That may be offered, certainly not in--I don't think there's anything offered in Canada, but there are through various other agencies.

CHAYTOR, Q.C.:

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Q. Okay, and we've heard that the medical laboratory technologists are not a regulated profession in this province. Have you been involved over the years in trying to have laboratory technologists regulated?

MS. WADE:

A. Yes, back in the early '90s I was involved in the first committee, I guess, out of the society to put together a presentation or a brief to government with a view of having this profession licensed in the province. We had a very unfortunate incident back in the late '70s that we really felt should have been a driving force towards regulating the profession and to this day, it is still not licensed.

CHAYTOR, Q.C.:

Q. And why are you a proponent of regulation? What benefit do you see coming out of that?

MS. WADE:

A. Well obviously the very overriding principle is public safety, but I believe that public safety then is not only just enhanced by confidence, I guess, in the knowledge that the people who are working and doing lab testing

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are competent and trained and accountable for the result that they do and also I believe that with regulation comes an accountability on the technologists to continuing education and ensuring that they enhance their training as well.

CHAYTOR, Q.C.:

Q. So to renew your license on an annual basis, you'd have to show that you met certain continuing requirements.

MS. WADE:

A. Exactly.

CHAYTOR, Q.C.:

Q. So why hasn't it happened? You've been at this a long time trying to have it happen, what obstacles have you encountered along the way?

MS. WADE:

A. Back, after we made the initial presentation, of course, back then there was a number of government changes of government and you know, I think in 2001 another group of us met with some people at the Department of Labour, I think it was, it was involved with regulation of professions and there was a white paper

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that had been put out on regulating of numerous professions. So we submitted a response to that, answered all the questions and again, in the throes of government bureaucracy, I guess, in all of the changes that went on, it never was received by whoever was supposed to get it. So our latest information now is that 2006 the provincial society resubmitted an updated response to the white paper and the last correspondence was last October, 2007 that it was now on the table. Prior to that, correspondence was that it was not a priority at this time and that was back in early 2000.

CHAYTOR, Q.C.:

Q. Two thousand and -

MS. WADE:

A. Back earlier in 2000, so after 2001 -

CHAYTOR, Q.C.:

Q. So was it in 2005 you had a response on that?

MS. WADE:

A. I can't recall the dates now, but in 2007 the last response was last October that it was being discussed and they had hoped that it would be on the fall sitting or the next

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sitting of the House, so--but I haven't heard of anything further from that.

CHAYTOR, Q.C.:

Q. And then if we could just look back at this exhibit, it also indicates that you are to assist the portfolio programs in preparation for accreditation an we understand that that lab is now going to be in the next accreditation round, the lab will be part of that, and so what is it that you are tasked with doing to prepare the Laboratory Medicine Program for accreditation?

MS. WADE:

A. Well certainly out of the accreditation pilot that we participated in in 2007, we received a number of recommendations and have been working to meet those and part of that is the development of a Quality Management Program, but that basically is in compliance with the ISO 15189 standard for medical laboratories. So the accreditation, if we meet the standard for ISO, we will meet the accreditation anyway, so my role now has been--it's all around the developing of a Quality Management Program.

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CHAYTOR, Q.C.:

Q. If we could have, please, Commissioner, P-0697? And this is a meeting of the Laboratory Program, Divisional Managers, back in, I believe it's March 4th, 1997. And on page 2, there's "an internal advisory committee referred to under QI issues for the Laboratory Program has been set up and the first meeting held. The membership is as follows:"--and we'll see that you're there in your role as manager of client services at the time. "The membership will rotate and the terms of reference are being established. Divisional subcommittees will be set up and will report back to the IAC, which will probably meet every second month. And the IAC will report once a year to the senior advisory committee." What do you recall about this committee, its mandate and did the terms of reference ever get established? Did they ever get off the ground? I realize it's over ten years ago.

MS. WADE:

A. That was right after the beginning of Health Care Corporation and the--oh my, I recall meetings, internal advisory committee meetings

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and presenting at that--presented at that committee would be thing like external proficiency testing reports and any complaints and occurrence that may have occurred throughout the program.

CHAYTOR, Q.C.:

Q. Okay.

MS. WADE:

A. I don't recall the specifics around terms of reference or anything now, it's quite a while ago.

CHAYTOR, Q.C.:

Q. Okay, and if we could have then, please, P-2537? I'll bring you forward three years to see if your memory gets better. September 20th, 2000, this is a meeting of the Laboratory Management Committee and you're indicated to be in attendance and on page 2, under QI activities, "The most recent copies of the following activities were reviewed, proficiency reports, human resource indicators instance reports, there are no proficiency surveys for pathology and cytology." So who attending the meeting would be giving this? Would this be part of your job as the manager

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of Client Services?

MS. WADE:

A. No, not then in 2000. I was manager of Client Services at that time.

CHAYTOR, Q.C.:

Q. Yes.

MS. WADE:

A. And that was just part of--the lab management committee at that time consisted of the managers and the chief, so the QI activities then were tabled as information.

CHAYTOR, Q.C.:

Q. And so it wasn't part of your job to track whether or not there were proficiency surveys being done in any particular area?

MS. WADE:

A. No.

CHAYTOR, Q.C.:

Q. For example, were you aware whether or not there was--had you heard prior to all of this coming up in 2005 that there was no external proficiency testing for the IHC portion of the lab?

MS. WADE:

A. No, I didn't.

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CHAYTOR, Q.C.:

Q. And if we could have, please, P-1900 please? And I think this again is the Laboratory Management Committee, you're not in attendance, you're absent and on page 2 there's a reference of "Notification of laboratory error (written policy) this has been completed by Lynn Wade." And again, this is back 3 more years, along life's way, November 20th, 2003. What was your involvement at that time in completing a notification of laboratory error policy?

MS. WADE:

A. I'm sorry, Ms. Chaytor, but this is -

CHAYTOR, Q.C.:

Q. You're drawing a blank.

MS. WADE:

A. It totally escapes me right now.

CHAYTOR, Q.C.:

Q. If we could look at P-3637 please? This is a very recent policy called Pathology Error Disclosure and this one is quite recent, approved July 28th, 2008, effective September 15th, 2008. Would that be a pathology error disclosure, would that be similar to what a

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notification of lab error policy may have been, a similar sort of thing as this?

MS. WADE:

A. In this one here, if I could just go down -

CHAYTOR, Q.C.:

Q. Sure, yes, take the mouse.

MS. WADE:

A. See if I can--that policy is a policy specific for the pathology division and explains how any error may be detected and that they have to be reported to the chief, the site chief, certainly if there are pathology reporting errors and just looking to see -

CHAYTOR, Q.C.:

Q. So the other one may have been broader for lab errors overall for the entire program?

MS. WADE:

A. That one is specific for pathology.

CHAYTOR, Q.C.:

Q. This one.

MS. WADE:

A. Yes, yeah, for the lab, I'm in the process of writing a policy called corrected report, so that if there's something picked up in reviews, certainly something like this, it

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would apply to this kind of policy. Pathology and a couple of other divisions have much more narrative kinds of reports and the errors would be picked up on quality reviews to, the random reviews that would be done within their division.

CHAYTOR, Q.C.:

Q. So you don't have any specific recollection of what the notification of lab error policy that you would have worked on back in 2003, you don't have any -

MS. WADE:

A. Right off the top of my head, I can't even -

CHAYTOR, Q.C.:

Q. And in going through all the reviewing and revising of policies for the lab, you didn't come across such a policy?

MS. WADE:

A. Not specific, no.

CHAYTOR, Q.C.:

Q. Since we -

THE COMMISSIONER:

Q. I'm sorry, I wasn't sure that I understood the nature of this particular policy, did you say it related to the pathology division or

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related to the pathologists?

MS. WADE:

A. This is the pathology division, so it could be relating to--it is the report that it's referring to, so any errors that are picked up may be on random review or if there was an error picked up as a result of maybe a correlation of a final pathology verses the frozen section, something like that, anything that requires a change in the report, the final report would have to follow this-

THE COMMISSIONER:

Q. Follow this process, okay.

MS. WADE:

A. That's very specific to the pathology.

THE COMMISSIONER:

Q. All right, thank you.

CHAYTOR, Q.C.:

Q. And maybe then I will continue then, I have a few questions for you on this policy, so while we have it up, it says that "Eastern Health Pathology Division adheres to the Quality Management Department policies regarding error reporting and disclosure. Errors or possible errors found by QMP personnel or

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pathologists"--so that would be yourself -

MS. WADE:

A. That should be pathology quality management group, right.

CHAYTOR, Q.C.:

Q. So yourself or anyone working with you or your group or a pathologist?

MS. WADE:

A. Pathology has a quality management committee specific for pathology.

CHAYTOR, Q.C.:

Q. Which you sit on?

MS. WADE:

A. I do sit on that. The reviews of pathology reports would be undertaken by Ms. Bev Rowe who is the quality co-ordinator technologist.

CHAYTOR, Q.C.:

Q. And notes "when performing an audit or case review" so if errors or possible errors are picked up on an audit or case review -

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. And they could be minor or they could be of major significance, "any significant error or

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discrepancy that has an effect on patient care must be brought to the immediate attention of the site chief and/or clinic chief". And C, "Definitions of errors of clinical significance", where would we find that, the definition of clinical significance?

MS. WADE:

A. Is that at the bottom of this? Usually--yeah, at the bottom of this policy there's a definition section, definitions and acronyms.

CHAYTOR, Q.C.:

Q. Under that, yes, okay.

MS. WADE:

A. So they have clinical--errors of clinical significance and--which would be, but not limited to those various type.

CHAYTOR, Q.C.:

Q. Okay, thank you. And the purpose it indicates is "to ensure all pathology errors or possible errors are discovered, investigated, documented, corrected and reported appropriately to assure adequate patient care." And then if the error is determined to be of clinical significance, it is to be reported immediately, as it said, prior to,

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and also "report the error to the QI risk manager and complete an occurrence report form."

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. So even if you're going through pathology reports afterwards for an audit, it's intended that an occurrence report would be completed.

MS. WADE:

A. Yes, that's right.

THE COMMISSIONER:

Q. And the QI risk manager referred to here is?

MS. WADE:

A. Pardon?

THE COMMISSIONER:

Q. Who would be the QI risk manager referred to there?

MS. WADE:

A. The manager--well, that probably could say consultant, so it could be for the lab, it has been Ms. Janet Laidley is who we were report directly to for -

THE COMMISSIONER:

Q. In the division under Ms. Predham?

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MS. WADE:

A. Under Ms. Predham or the director now is Pam Elliott.

THE COMMISSIONER:

Q. Yes, all right, thank you.

CHAYTOR, Q.C.:

Q. Okay, and this goes on to allow then the original pathologists to have some input into whether or not they agree with the new diagnosis. At the bottom here it says, "The pathology department and the responsible clinician will consult with the quality and risk management department if a disclosure to a patient is to be made." Would there ever be a situation where an error has been determined of clinical significance that disclosure to a patient would not be made?

MS. WADE:

A. Not that I'm aware of.

CHAYTOR, Q.C.:

Q. And then "if the error is determined to be of no clinical significance, the case will be reviewed by QMP department"--and QMP department -

MS. WADE:

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A. Is a pathology Quality Management Committee.

CHAYTOR, Q.C.:

Q. That's the committee?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. "With site chief or clinical and the error will be documented in QMP records for analysis as accumulated data may suggest, practice pattern improvements and an amended report will not be issued for an error of no clinical significance." First of all, who keeps track of the QMP records and who would then do the analysis?

MS. WADE:

A. Bev Rowe, who is the quality co-ordinator technologist, she is responsible for doing numerous audits, one of them being a review, random review of reports and retains all the documents for that, and presents any analysis to the Quality Management Committee for pathology.

CHAYTOR, Q.C.:

Q. Okay, and in this particular situation if it's not of any clinical significance, it doesn't

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get reported to the risk manager?

MS. WADE:

A. No, but we would--I would still recommend that there would be an occurrence form because obviously it's an opportunity to -

CHAYTOR, Q.C.:

Q. For them to do some tracking as well.

MS. WADE:

A. To do some tracking, yes.

CHAYTOR, Q.C.:

Q. And that's not though what it says here, it's different than the requirement -

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. - for an occurrence report is mandatory if it's of clinical significance, but it appears when I read this that it just stays basically within the labs -

MS. WADE:

A. They would know that they--yeah, they would have to make the occurrence report for the clinically significant one, but typically again, in the quality management office of pathology, she is documenting and tracking all

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of these as well.
CHAYTOR, Q.C.:
Q. And if we--and "no amended report will be issued for an error of no clinical significance", and so if we think about the ER/PR situation, if a patient had had an ER of zero and a PR of, say, 80 originally and then on--and nonetheless was treated with Tamoxifen because they were treated on their PR status, if that patient then, if there were a repeat then for whatever reason of that test and it was found that the ER status changed, PR stayed the same, and that particular situation might not have any clinical significance because the patient's treatment would not have changed, but under this policy would you nonetheless expect an amended report to be filed?
MS. WADE:
A. But you are saying that the results changed?
CHAYTOR, Q.C.:
Q. If the test result changed but it didn't change the treatment for the patient.
MS. WADE:
A. But in the lab, the lab is not responsible for

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the treatment, so in that case, I would consider that to be a clinically significant change in report.
CHAYTOR, Q.C.:
Q. Okay, so that would then come under the, something of clinical significance and this procedure would be followed?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. Okay. If we could have then, please, P-3617? And this is a meeting then of September 27th, 2005 and you are in attendance at this, it's the laboratory divisional managers' meeting. And if we look at page 3, Medinet update. "Lynn indicated that most of the bugs have been ironed out with Carbonear and it is working well. Gander is next to come on line and Lynn go out for a site visit probably in early November. Corner Brook and Grand Falls will then follow and Jim will check the IT regarding the purchase of necessary software for Clarenville and Burin." And what's that about, what particular -
MS. WADE:

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A. That again goes back to that Medinet which is the electronic link of orders and reports. Pathology is not involved in that and it's core lab results and orders.
CHAYTOR, Q.C.:
Q. Okay. "And hard copies of reports, Lynn stated that reports are now being reported directly to Corner Brook and this is working well. This can be set up for other regions as well." Did that involve the pathology lab at all?
MS. WADE:
A. I don't think pathology reports--they generally go out from the stenos and are mailed directly to the physicians.
CHAYTOR, Q.C.:
Q. If we could have, please, P-2654?
THE COMMISSIONER:
Q. Why would that be dealt with differently? Why would it be different because it's pathology?
MS. WADE:
A. Because the core lab has, we print batches of reports every day and mail them or batch print them directly to the site. Pathology reports are transcribed by a different group and they

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print them as they do them, as they are completed and then they are submitted to be mailed directly. So they go directly to the ordering physician or the surgeon. So we don't just print pathology reports out in Corner Brook, we would send those back to the ordering physician if they ordered a pathology report.
THE COMMISSIONER:
Q. Or there are, as I understand it, there are occasions when a pathology lab in Corner Brook would be sending to St. John's a specimen asking the St. John's lab do some thing that they weren't able to do in pathology in Corner Brook.
MS. WADE:
A. That's right, yes, but we don't have the link between the pathology module and the direct reporting, printing of reports. We set that up for the high volume bulk reporting of routine lab testing. But the pathology reports are mailed or delivered -
THE COMMISSIONER:
Q. As they say "snail mail".
MS. WADE:

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A. To the physician.
THE COMMISSIONER:
Q. Snail mail by a month, as I understand it.
MS. WADE:
A. That's right.
THE COMMISSIONER:
Q. Thank you.
CHAYTOR, Q.C.:
Q. This is September 15th, 2006, meeting of Laboratory Medicine Program and on page 3, referred to again, "Mr. Gulliver informed the new accreditation process will now include specific laboratory standards. Eastern Health will take part in the 2007 pre-formal accreditation and Lynn Wade, client service manager will serve as the point person for the lab." So I take it you were involved in the, what's referred to as the pre-formal accreditation that took place in 2007?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And what was your involvement in that and what did you understand happen in terms of the overview of the lab?

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MS. WADE:
A. It was certainly a comprehensive overview, it introduced us to standards that were very specific to labs which were not in the previous accreditations that I had been involved with. My role in this was as a team leader for one of three lab committee teams looking at specific groups of standards and then as a liaison with the surveyors when they came.
CHAYTOR, Q.C.:
Q. And if we could look, please, at P-2422? And this is June 21st, 2007 meeting of Laboratory Medicine Program and you are in attendance at this meeting, as you've indicated this is the new Laboratory Medicine Leadership Team.
MS. WADE:
A. That's the leadership group, yes.
CHAYTOR, Q.C.:
Q. Which now includes yourself. And you're welcomed to the meeting and I take it this is the first time in attending, you're there in your new role as quality manager. "After some discussion it was agreed that Lynn would attend all of the monthly leadership meetings

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to discuss quality issues which will be first on the agenda"--and it's not necessary then for you to stay for the remainder of the agenda items. "Discussion in regards to Lynn's role and interaction with the lab program, Terry indicated the laboratory needs to put real resources into the program to assist Lynn in developing a Quality Management Program that includes risk management, patient safety, workplace safety and accreditation and Mr. Gulliver informed he will be assigning a .5 FTE in peninsulas that will be dedicated for that region and also a .5 FTE in rural Avalon. Mr. Gulliver indicated he would like to assign the current FTE in pathology to work with Lynn for that division and he was assigning a .5 Clerk IV to support the Quality Management Program and he's working with other divisions to determine if we can re-allocate staff resources to be part of this program." And there is some discussion about your need for office space. So, Ms. Wade, were those resources assigned to you?
MS. WADE:
A. There are additional resources within the

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program; however, they are also assigned to--some of them are assigned to transfusion medicine safety and right now a lot of the work is related to transfusion safety and I'm not involved directly in that. They have a transfusion safety committee. Another aspect of those .5 FTEs is the safety program and dealing with compliance to directives and orders from the Department of Government Services Occupational Health and Safety Division, so to date, there is not a lot of support, human resources support, for this.
CHAYTOR, Q.C.:
Q. So you ran into some challenges in completing your work because of lack of resources?
MS. WADE:
A. Yes, certainly within most of the other areas, pathology is the exception. They have a dedicated resource to quality management, a full FTE and they have some clerical support.
CHAYTOR, Q.C.:
Q. So the pathology lab is adequately resourced in terms of your job and what your mandate is, but in other areas of the Laboratory Medicine Program it's been somewhat of a challenge?

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MS. WADE:
A. It is, yes.
THE COMMISSIONER:
Q. How does that work between you and the person within pathology who has the role? What is the relationship between you and -
MS. WADE:
A. Well she is a lab technologist who is responsible for redeveloping their policy and procedures and performing various audits for quality assurance and it may be around random reviews of pathology reports, it may be auditing the requirements for temperature dependant equipment monitoring, various things like that. So she developed the indicators for the pathology divisions, specifically. We have a very close working relationship.
THE COMMISSIONER:
Q. So if you have a staff which you could distribute to the various sections of a laboratory -
MS. WADE:
A. That's right.
THE COMMISSIONER:
Q. That would probably be a way one might

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anticipate it would go, there would be somebody responsible for division reporting up to you?
MS. WADE:
A. Oh, definitely.
THE COMMISSIONER:
Q. Except in this case, it's only been established in pathology?
MS. WADE:
A. Yes, yeah. The efforts are there in some divisions, in spite of the lack of resources, but it is a challenge because it's something else that they have to do, and while the staff--there are a number of champions in all of the divisions, you know, staff are very eager to work on this, but, you know, in reality it's very difficult given that patient samples still have to be tested and there is day to day workload, so -
THE COMMISSIONER:
Q. Okay, thank you.
CHAYTOR, Q.C.:
Q. Ms. Wade, what is the importance and purpose of a quality management program?
MS. WADE:

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A. Well, again it is to ensure continuous quality improvement for all of the testing and the processes that are performed within the lab.
CHAYTOR, Q.C.:
Q. And part of doing that, would that be to eliminate any variation in processes?
MS. WADE:
A. Part of that would be to eliminate variation through standardizing procedures. That certainly helps to eliminate variation. Staff know exactly what they are to do in given circumstances. Also external proficiency testing provides an opportunity to educate staff, not only on how well they perform in relation to their peer organizations, but also to learn how to do things better to enhance the result that they put out. So there are many aspects of quality management that enhance improvement.
CHAYTOR, Q.C.:
Q. And so would--all other programs within Eastern Health would have quality management programs? So if you go to the perioperative program, for example, would they have a quality management program or committee?

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MS. WADE:
A. I can't speak to how they are set up or how they are developed, but certainly from the Clinical and Laboratory Standards Institute, CLSI, there is a document that is called quality systems for health care, and it is around the quality management framework. So there is a general overall document that the CLSI has published, and in conjunction with that, they also have a document for implementing a quality system in a laboratory. So that is the overriding document that I refer to.
CHAYTOR, Q.C.:
Q. And I take it that's been around for quite some time, is it?
MS. WADE:
A. The CLSI has been around in other formats for quite a while. They've developed a number of standards for the labs, everything from Vena puncture to various types of testing, lab information systems, all kinds of standards, and certainly in my former job as Client Services Manager I referred to those many times. If we had occurrences around Vena

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puncture issues, we would refer to those kinds of standards.

CHAYTOR, Q.C.:

Q. Okay, and the quality management program that you're now working towards having implemented for laboratory medicine, that is new in June of 2007, the summer of 2007?

MS. WADE:

A. That's what we're implementing, but it is in compliance with ISO 15189.

CHAYTOR, Q.C.:

Q. And what's that?

MS. WADE:

A. That is the standard for medical laboratories.

CHAYTOR, Q.C.:

Q. Okay, and how long has that--has that standard been around a while?

MS. WADE:

A. Well, the ISO standard, I think is 2003, and it was adapted for the Canadian environment by the CSA. So we have a document now, I think from 2004, for laboratories in Canada, and basically it advocates for quality management system across the continuum of laboratory services.

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CHAYTOR, Q.C.:

Q. Okay. If we could have, please, P-3588, page three of this document is terms of reference for the Quality Management Program Committee for Anatomic Pathology, and that's one of the committees that you mentioned earlier in going through your CV. "The Pathology Quality Management Program Committee will incorporate quality control and quality assurance principles and functions within its services, and it will develop, implement, and coordinate quality processes within pathology services that include pre-analytic, analytic, and post-analytic phases", and there's a number of functions, including identify and review current policies, procedures, and standards; developing and reviewing annually quality assurance protocols, including standardized policy and procedures; advising and ensuring education of pathology staff on present and new policies and procedure, and it goes on for nine different functions. Were you involved then in drafting the terms of reference for this committee?

MS. WADE:

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A. Not in the initial one because I was not part of the first number of meetings. It was only after--I think in July that I sat on that committee.

CHAYTOR, Q.C.:

Q. July of 2007 -

MS. WADE:

A. And we have--we have finalized that, the terms of reference.

CHAYTOR, Q.C.:

Q. This is now finalized?

MS. WADE:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay, because it's still in draft form here.

MS. WADE:

A. That one is, but it is -

CHAYTOR, Q.C.:

Q. It's finalized.

MS. WADE:

A. It is approved, yes.

CHAYTOR, Q.C.:

Q. And do you recall is the final version quite similar to this or are there any -

MS. WADE:

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A. Yeah, it is.

CHAYTOR, Q.C.:

Q. Any significant changes.

MS. WADE:

A. Quite similar to that, yeah.

CHAYTOR, Q.C.:

Q. Quite similar, okay, and you started sitting on that committee, July, 2007, is that correct? Around then?

MS. WADE:

A. Around that time.

CHAYTOR, Q.C.:

Q. That's fine, that's fine. It's a fairly new committee, I take it?

MS. WADE:

A. Yes.

CHAYTOR, Q.C.:

Q. And this committee came into existence some time in 2007, is that correct?

MS. WADE:

A. I'm not quite sure when they started meeting, but I know that there were several attempts to draft the terms of reference, and it wasn't until after--I know it was after I started to participate in the committee that the terms of

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reference were finalized.
CHAYTOR, Q.C.:
Q. And what was the problem with that, why did it take so long to even come up with the terms of reference for the committee?
MS. WADE:
A. Well, certainly from the first meeting that I attended, there seemed to be some conflict in the committee and the purpose of the committee, I guess, and I attended that committee having just come from a conference to discuss quality management, so I basically presented my views about what I saw being the purpose of that kind of committee, and certainly the function that are outlined there was in my line of thinking, but there had been some conflict at the time, and following that committee, Dr. Carter resigned and Dr. Lynn Morris-Larkin subsequently took over as the clinical representative on that committee.
CHAYTOR, Q.C.:
Q. So you attended your first meeting of this committee in maybe June of 2007 or thereabouts?
MS. WADE:

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A. That's right.
CHAYTOR, Q.C.:
Q. And did you have any sense that there was conflict within the committee prior to going to that first meeting, were you invited to go there because of some input that you could bring to the committee?
MS. WADE:
A. Well, I think that I was just--had just recently been appointed as Program Manager for Quality and Safety, and I would be sitting on that committee as--certainly as a support, if not all the time, but I--you hear through the grapevine of rumblings, but other than that, it wasn't until I got to that committee and I heard what people had to say, and I could sense that there had been conflict, and I could see from looking at old drafts and new drafts in coming up with a final terms of reference that there were some differences of opinion.
CHAYTOR, Q.C.:
Q. They weren't getting down to the work of the committee because the committee couldn't decide what the work was?

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MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. What, in fact, they were mandated to do?
MS. WADE:
A. There was conflict over who should be doing what, and what they should be doing at all.
CHAYTOR, Q.C.:
Q. Okay, and--so this involved Dr. Carter and her views as to the mandate of the committee, or what she understood to be the mandate of the committee?
MS. WADE:
A. Yes.
CHAYTOR, Q.C.:
Q. Okay, and what do you recall about that, what direction did Dr. Carter see this committee going?
MS. WADE:
A. Well, certainly to develop a quality program structure you need to have--redevelop or create your policies and your processes and procedure, and ensure that you have all of those, do your gap analysis and ensure that all of those are in place, and then you need

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to put in place your monitoring activities to ensure that those policies and procedures; number one, that they are working; number two, that people are complying with them. So I saw the cart getting before the horse sort of, and while Dr. Carter was doing great work with doing some quality audits and things like that, we had to ensure that everything was in place on the front end, and that we weren't just doing audits for the sake of auditing. We had to know that the way things were being done was correct and appropriate, and then what we measured was also appropriate. So there was just some conflict, and I don't know that in time they may have been resolved, but we had to get--we had to get to the beginning before we could build on it.
CHAYTOR, Q.C.:
Q. And so did you speak then at that meeting and say what you thought your views were in terms of the cart going before the horse, that you can't be doing your monitoring or your auditing before you figure out what exactly this is?
MS. WADE:

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A. Exactly.
CHAYTOR, Q.C.:
Q. And you said that at the meeting?
MS. WADE:
A. I did, yes.
CHAYTOR, Q.C.:
Q. And what happened at the meeting?
MS. WADE:
A. Well, Dr. Carter felt that that wasn't her role there, and she left the meeting.
CHAYTOR, Q.C.:
Q. And I take it after that she resigned from the meeting (sic.)?
MS. WADE:
A. Yes.
CHAYTOR, Q.C.:
Q. And who then took up the responsibility for doing the work that Dr. Carter was doing in terms of tracking outcomes and that piece of the work?
MS. WADE:
A. Well, the coordinator, the technologist coordinator was still the person who was running the audits and providing the data. So that was still being done throughout all of

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this. Dr. Denic certainly took a role in reviewing anything that came from that, and then eventually Dr. Lynn Morris-Larkin sits on the committee. So what happens now is that any audits or data that has been collated, is brought to the committee for review. So it's all of the committee because it's technologists, as well as pathologist assistants, as well as pathologists that are involved in all of the processes, so it stands to reason that they would be the most appropriate people to review them.
CHAYTOR, Q.C.:
Q. Okay, and we see here then on the membership of the committee, it refers to pathology quality management officer, a Lab Tech III, pathology laboratory technologist II, clinical chief, site chiefs. So that would include Dr. Lynn Morris-Larkin, and clinical chief, Dr. Denic, pathology division manager, and I take it that's Mr. Dyer, Barry Dyer?
MS. WADE:
A. Yes, or his alternate.
CHAYTOR, Q.C.:
Q. And program manager, safety and quality of

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management, medical services and diagnostics. That's yourself?
MS. WADE:
A. That's me.
CHAYTOR, Q.C.:
Q. And secretary. Dr. Ford Elms, in his role as Director--Medical Director for IHC, does he sit on this committee?
MS. WADE:
A. No, not on the regular committee, but we have invited, for instance, Ms. Jane Gamberg, who is the technical director for IHC lab, to come if there were issues or if there was proficiency testing reports that we wanted her to review, and any time that we have on our agenda items that are relevant to specific areas, PAs, or IHC, then those people would be invited to come and speak to that.
CHAYTOR, Q.C.:
Q. And this includes, if we look at the functions, includes reviewing all incidents, occurrences, within the department, make appropriate recommendations, and assist with implementation?
MS. WADE:

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A. That's right.
CHAYTOR, Q.C.:
Q. So all--would all occurrence reports then come to this committee for review?
MS. WADE:
A. That's right. So any occurrence reports that are given to the manager in the course of the month, then copies should come to this committee.
CHAYTOR, Q.C.:
Q. And do you know has that happened yet, has the committee actually sat down and reviewed all occurrence reports?
MS. WADE:
A. I don't recall seeing any specific recently, not recently, no.
CHAYTOR, Q.C.:
Q. At any point--well, since the summer of 2007 you've sat on the committee. How often does this committee meet?
MS. WADE:
A. We do have monthly meetings scheduled. Certainly we've been challenged throughout the last year to get a quorum on times because of the fact that we've had people who have been

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involved with the Commission of Inquiry and other issues ongoing in the lab that they've not been available for meetings, but generally the meetings are held on a monthly basis.

CHAYTOR, Q.C.:

Q. And when is the last time this committee met?

MS. WADE:

A. Just a couple of weeks ago, I believe.

CHAYTOR, Q.C.:

Q. And when would it have most recently met prior to that?

MS. WADE:

A. I think it was two months ago. We had several people on vacation, so -

CHAYTOR, Q.C.:

Q. Yes. It also indicates that, "To facilitate, support, and ensure auditing of ongoing training of all personnel within the pathology department", and I take it that includes technologists, pathologists, pathology assistants, everybody?

MS. WADE:

A. That's right, "And ensure all qualified personnel are trained on appropriate equipment prior to use, provide tools to audit the

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process". Has the committee been involved in anything along those lines so far?

MS. WADE:

A. There are workstation check tool that basically provide people who are training new personnel with a checklist now at every workstation. So if you're doing embedding, there are things you have to know about embedding and there are things you have to know about the microtomy section. I have seen some of those checklists, but they're all very specific to pathology. I certainly don't get involved with their day to day operations for sure.

CHAYTOR, Q.C.:

Q. So when I'm thinking, like, well, how is that happening, how on a practical basis this committee does that, you're saying that, well, the tools that you're aware of are checklists, for example?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. Where the person actually doing then the task would check it off. So this committee has

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been involved in coming up with checklists?

MS. WADE:

A. Well, the people who are on the committee, the core of that committee are pathology division participants. So they are the people who are best going to know their processes and their procedures, and ensure that--they are generally the senior people. The quality coordinator, Bev Rowe, is overseeing the development of a lot of the day to day operational kinds of checklists and training tools.

CHAYTOR, Q.C.:

Q. And validate--number seven is, "Validate all equipment and procedures used within the department through evidence based research and auditing process". For example, the Commission has heard about two new tissue processors that came into the lab. Would this committee have been involved in the validation of the equipment, that equipment, and the procedures for its use?

MS. WADE:

A. Not so much the committee being involved in it. However, ensuring that there are

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processes in place and procedures that people would have to follow, procedures for using the equipment and to make sure that they are trained, that there are training opportunities for the staff.

CHAYTOR, Q.C.:

Q. And then referral of issues, there's, "Items from the quality management program committee for anatomic pathology will be brought forward to the VP of Diagnostic and Medical Services when there's no resolution after a three month period or unless it's considered urgent". So I take it there's an option to engage Dr. Howell if need be?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. And do you know has that ever happened, has there ever been any need to bring Dr. Howell in on an issue?

MS. WADE:

A. Not specifically anything in particular, not since my involvement, anyway.

CHAYTOR, Q.C.:

Q. And if we could have, please, 2128. I believe

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this was the next meeting after--actually, I don't know, did we look at--yes, no, 2122, sorry. 2121, sorry, my fault. That's better, June 6th, 2007, we understand this to be, Pathology Quality Management Committee, and you are in attendance at this meeting, and Dr. Carter is still there at this point, and refers to under introduction, "B. Carter opens with an introduction to the QMP Department, as we had some new committee members. It was discussed that Terry Gulliver become a consultant or ad hoc member, as opposed to a full time committee member. There was an intense dialogue regarding the roles of individual members and the focus and direction of the committee". Would this be the committee meeting that you're recalling?

MS. WADE:

A. That would be the meeting, yes.

CHAYTOR, Q.C.:

Q. So that's the intense dialogue that you recall?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

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Q. Okay, and then if we look please at 2128, and this appears to be the next meeting of this committee. It's July 18th, 2007, and now Dr. Denic is in attendance and Dr. Carter, I take it, has resigned, and you're in attendance at this point in time. How did then the committee progress after that, from July 18th onwards? Has the committee--how active has the committee been in terms of achieving what it set out to do?

MS. WADE:

A. I certainly feel that they've made a lot of progress. There's been a lot of procedure and policy development been undertaken and finalized. Certainly the meetings that I attend now, it certainly seems to be positive and successful.

CHAYTOR, Q.C.:

Q. And if we could look at, please, P-3593? And this is an e-mail from Mr. Gulliver to yourself, July 24th, 2007, and he's forwarding on to you an e-mail that he had sent to Dr. Reza of the same date, and basically this outlines a summary of the process used by him and Mr. Dyer to select patients back in 2005

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for retesting at Mount Sinai, and why is this being forwarded on to you in July of 2007?

MS. WADE:

A. Ms. Chaytor, I don't recall ever seeing it, but obviously it must have been on my e-mail, but I don't recall seeing it. I know that during that period and long before that, that Mr. Gulliver and Mr. Dyer were putting in countless hours tabulating numerous reports and I guess as I took on the role of safety and quality, it was seen that I should be aware of the processes that they were going through. So that's the only purpose for that. I certainly had no involvement in the ER/PR investigation per se.

CHAYTOR, Q.C.:

Q. Okay, and there's a Post-it here, guide on how spreadsheets were created. Is that your Post-it note or your note?

MS. WADE:

A. No, that looks like Mr. Gulliver's writing.

CHAYTOR, Q.C.:

Q. Okay, and if we could have, please, P-3589? We understand this is an on-site consultation by QMP-LS which took place in December of

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2007, and were you involved in that process?

MS. WADE:

A. Yes. They asked me to gather the information and submit it to QMP-LS prior to their coming in to do the review of the lab in December.

CHAYTOR, Q.C.:

Q. Okay, and then it says "the person completing this pro-forma is Lynn Wade," yourself as program manager, safety and quality, December 4th 2007, and then it goes on for quite some length, in terms of a questionnaire that you had to fill out, and how would you have been able to fill out this information?

MS. WADE:

A. I would have consulted with probably, if I recall, Ken Green in the lab, he was very involved in that area at the time, for anything specific to IHC, and Mr. Dyer then overall for pathology.

CHAYTOR, Q.C.:

Q. Okay, and if we look then at page five, for example, it says "does the histotechnical staff perform duties other than histology testing?" and you've circled yes. "If yes, what other duties? Assist pathologists with

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frozen section, retrieve biopsies from DI for kidney, prepare biopsies, muscle, kidney, for immunofluorescent stains, assist physician with fine needle aspirations, grossing all specimens." And then if we come down to the bottom, "is the immunohistochemistry staff specifically trained in these techniques? Yes. Does the immunochemistry staff perform duties other than IHC testing? Yes. If yes, what other duties? As noted above."

So was it your understanding, in December 2007, or leading up to the assessment in December '07, that the IHC technologists were involved in all these other duties?

MS. WADE:

A. It's my understanding that some of them were still involved with the kidney biopsies and assisting with frozen sections, yes.

CHAYTOR, Q.C.:

Q. And "the immunohistochemistry staff specifically trained in these techniques?" and you've said yes. And what information would you have had made available to you as to what their specific training might be?

MS. WADE:

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A. I'm looking at the duties up above. Are we talking about IHC specifically or are we talking -

CHAYTOR, Q.C.:

Q. If we could look at--perhaps this'll be of assistance to you, page 14 of the exhibit. Actually, I believe it may start with page 13.

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. And there's lists of, for example, this is -

MS. WADE:

A. Yeah, yes, I recall.

CHAYTOR, Q.C.:

Q. - pertaining to Mr. Green. So were you provided with -

MS. WADE:

A. These lists.

CHAYTOR, Q.C.:

Q. - what they've done in terms of continuing education?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. Okay, and that, so this would be the source,

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whatever is indicated on these forms for continuing education?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. Okay, and if we could go back then, please, to page five? Actually move on then to page six. Under laboratory organization structure, "is there a laboratory management committee with responsibility for histotechnology?" and you've said yes, and which committee would that be?

MS. WADE:

A. The specific one for histotechnology would be their manager and their technologists, but if they're talking about the quality management committee, it could be that. I can't -

CHAYTOR, Q.C.:

Q. So is there a specific committee for histotechnology?

MS. WADE:

A. The lab management committee with Mr. Dyer sitting on the management--you know, on the-- as a manager would be responsible for the histotechnology overall.

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CHAYTOR, Q.C.:

Q. So I take it that's no different than the biochemistry or whatever area of the lab?

MS. WADE:

A. That would -

CHAYTOR, Q.C.:

Q. There's no specific committee?

MS. WADE:

A. The lab management committee would, with Mr. Dyer responsible for histotechnology specifically.

CHAYTOR, Q.C.:

Q. Okay. There's no specific committee for histotechnology?

MS. WADE:

A. Not a management committee -

CHAYTOR, Q.C.:

Q. No specific laboratory management -

MS. WADE:

A. - other than the quality management committee, that's all.

CHAYTOR, Q.C.:

Q. And that's not specific for histotechnology? What I'm wondering is is there a committee--we know of a number of committees, but this

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caught my eye because I thought, well, there's a specific committee for histotechnology, a specific lab management committee.

MS. WADE:

A. No, the lab management committee itself is responsible for all divisions, not specifically for histotechnology, but then for the quality management piece, we have a specific pathology quality management committee, and that consists of managers and technologists.

CHAYTOR, Q.C.:

Q. Yes, for all of pathology.

MS. WADE:

A. For all of pathology, which is histotechnology.

CHAYTOR, Q.C.:

Q. Okay, and included under that then would be IHC again?

MS. WADE:

A. They would, right, yes.

CHAYTOR, Q.C.:

Q. "Are there meetings of the histotechnology staff to make recommendations regarding the service?" and you say yes.

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MS. WADE:

A. And again, that's something that would come out of quality management, but then individual staff, division staff meetings, I would see this kind of initiative happening.

CHAYTOR, Q.C.:

Q. And are you aware of any meetings of the staff where recommendations have come forward regarding the service?

MS. WADE:

A. I'm not, no. I wouldn't be involved in their regular staff meetings.

CHAYTOR, Q.C.:

Q. And nothing in that regard was brought to your attention to enable you to be able to answer this particular question?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. "In addition to the laboratory director, does the laboratory have a physician or allied health professional specializing in immunohistochemistry available?" and you've indicated yes, and that's Dr. Elms?

MS. WADE:

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A. That's right.

CHAYTOR, Q.C.:

Q. And "is there a mechanism by which the consultants recommendations are received, reviewed and implemented as appropriate?" and you've said yes, and what is that mechanism?

MS. WADE:

A. Typically, the quality management committee. This is very specific to pathology and more so to immunohistochemistry and Dr. Elms, Dr. Denic and the technologists within that section of pathology would be reviewing any recommendation and making appropriate action, taking appropriate actions.

CHAYTOR, Q.C.:

Q. And I take it that means a mechanism for this particular consult that was taking place?

MS. WADE:

A. Yes, that's right.

CHAYTOR, Q.C.:

Q. And were you involved in that at the end of the day? Were you involved in putting together a spreadsheet regarding the recommendations that came out of the QMP-LS report in December 2007?

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MS. WADE:

A. The only thing I did was take the recommendations and put them into a spreadsheet, as opposed to having a very narrative document. So from my perspective, I have absolutely no expertise in immunohistochemistry and certainly could not respond to specific recommendations relating to that service.

CHAYTOR, Q.C.:

Q. But you were involved in the creation of a spreadsheet for the recommendations coming out of this process?

MS. WADE:

A. Just recently to give Dr. Denic something a little easier to read on a day-to-day basis, if he wanted to monitor it.

CHAYTOR, Q.C.:

Q. And I don't think we have that, so that's something you just recently completed?

MS. WADE:

A. It is recent.

CHAYTOR, Q.C.:

Q. Like how recent?

MS. WADE:

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A. Maybe within the last month or so.
CHAYTOR, Q.C.:
Q. And this though took place in December 2007?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. So it's almost a year later, ten months certainly.
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And there's just a spreadsheet being made from those recommendations?
MS. WADE:
A. Well, it basically is so that I would have--we would have something as an easier document to see what recommendations were made out of QMP-LS, what recommendations came from the other reviews that were done and where the labs were in relation to all of those.
CHAYTOR, Q.C.:
Q. And in creating that spreadsheet in the past month, were you able to determine whether all the recommendations from the QMP-LS assessment in December 2007 had now been implemented?

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MS. WADE:
A. Some of them I couldn't speak to because it's very specific to immunohistochemistry.
CHAYTOR, Q.C.:
Q. So are there things that have not yet been implemented?
MS. WADE:
A. I can't tell you for sure.
CHAYTOR, Q.C.:
Q. So does this spreadsheet have like a column where you would indicate completed or in progress, such as we've seen for the other?
MS. WADE:
A. Yes, but I couldn't complete that.
CHAYTOR, Q.C.:
Q. Right, but in preparing it and putting the information onto the spreadsheet, were there areas left vacant or indicating that it's still ongoing or things not completed?
MS. WADE:
A. Well, certainly all procedures and policies are continuously being reviewed and revised and even today, something that was written last May would have--could have -
CHAYTOR, Q.C.:

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Q. And those, of course, would have to be ongoing?
MS. WADE:
A. That's right, and those are ongoing procedures. In immunohistochemistry, simply because of the Commission, I guess, and I have been more aware of what's happening in that area, there are quite a few procedures that have been developed and continue to be developed for that area.
CHAYTOR, Q.C.:
Q. Perhaps the best way for us to get the answer then is if you could provide us with a copy of your work on that spreadsheet?
MS. WADE:
A. Sure.
CHAYTOR, Q.C.:
Q. That would be great. And then on page seven, in filling out here under manuals, user manual, "is there a manual regarding specimen collection and handling instructions available in all specimen collecting areas within the institution?" and there's no answer completed to this section. "Does the manual include instructions for patient sample

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identification?" and what you've written in here is "nursing manual protocols. Lab is developing a user guide" and is that the--is the user guide the manual of policies and procedures that we have here, the 2157 document? Is that what you're referring to?
MS. WADE:
A. For that specifically to IHC and pathology would be the tissue handling protocols and procedures that have been developed.
CHAYTOR, Q.C.:
Q. Yes, for example, it refers to instructions for proper labelling and fixation of specimens. So what you're referring to in writing this in here -
MS. WADE:
A. They would be specific, yeah.
CHAYTOR, Q.C.:
Q. That is--that's what you're referring to?
MS. WADE:
A. Yes, and they have all been communicated to the ORs and the various users, yeah.
CHAYTOR, Q.C.:
Q. So in December of '07, that manual was under development?

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MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And you do--you note then under procedure manual for histotechnology, in particular, "are all tests and procedures performed within histology documented in the manual? Yes." And "is there a procedure for validating new methods, reagents, instruments? Are all procedures used based on published reference methods?" and you've got yes to those, and then your comment is "the lab program is currently developing quality management program reviewing" I take P and P is policies and procedures?
MS. WADE:
A. Policies and procedures.
CHAYTOR, Q.C.:
Q. And that was the status as of December 2007?
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And since then, a lot of those policies and procedures we see were signed off in February/March 2008, in that time period.

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MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. Okay.
MS. WADE:
A. I think it's important to note that a lot of these policies and procedures, or certainly the procedures that they followed in the lab, they didn't become new procedures. It was a standardized formatting of what was currently being done.
CHAYTOR, Q.C.:
Q. And if we look at page eight, there's a list of questions here. "Is there a written policy designating minimum fixation duration requirements for specimens requiring IHC testing, for example, breast tumors? Yes. Are tissue processing reagents replenished or changed on a regular basis? Yes. Are tissue processors logs detailing these steps maintained? Yes. Are daily embedding logs provided and maintained?" and then you have "worksheets" written there. What were you indicating there?
MS. WADE:

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A. They have--when they go to do the tissue embedding, they have worksheets of the samples that they would be embedding, so that they would know what to look for when they take them out of the processor.
CHAYTOR, Q.C.:
Q. And "are the routinely stained slides checked against the embedding log? Yes." And who would have provided you with the answers to enable you to fill this out?
MS. WADE:
A. Technologists working in the area, for the most part.
CHAYTOR, Q.C.:
Q. And "is there documentation to indicate automated instruments were evaluated and validated prior to being placed into use?" and how would you answer--how would you be able to answer yes to that? What did you do to ensure that to be the case?
MS. WADE:
A. For that specifically, I would have deferred to the manager at the time to answer the question.
CHAYTOR, Q.C.:

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Q. So you didn't answer that? Mr. Dyer answered yes?
MS. WADE:
A. They would have to, yeah. I'm trying to think now, December 2007, yes, Mr. Dyer was -
CHAYTOR, Q.C.:
Q. It refers to here the Ventana, for example, two years in use and tissue processing. There were two at that point, 10 and 15 years, it says.
MS. WADE:
A. That's right. They have new ones since then, but those processors were in place at that time.
CHAYTOR, Q.C.:
Q. So prior to answering yes to this, did you see any documentation to indicate that the instruments were evaluated and validated prior to being put into use?
MS. WADE:
A. I don't recall seeing it.
CHAYTOR, Q.C.:
Q. And is that something you think you would recall? Is it that you don't recall or you didn't see it?

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MS. WADE:
A. I don't recall seeing it.
CHAYTOR, Q.C.:
Q. "Does the laboratory have sufficient and appropriately maintained equipment to provide the expected level of histology and immunohistochemistry service (workload and test menu)?" and you say yes, and what would you have done to satisfy yourself that the answer to that question is yes?
MS. WADE:
A. The manager would have to indicate that they had the right amount of equipment and they had appropriate equipment and that it was of a suitable quality to provide their service.
CHAYTOR, Q.C.:
Q. So what was the purpose in having you fill out this particular form, as opposed to Mr. Dyer?
MS. WADE:
A. I think at that time Mr. Dyer was very tied up with the whole investigation and at that time that these people were coming in, it happened very quickly, I think, and I, being quality person, I get deferred to for a lot of those kinds of things.

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CHAYTOR, Q.C.:
Q. And I'm sorry, Mr. Dyer was tied up in the investigation of what?
MS. WADE:
A. Well, at that time, I know that they were still doing a lot of investigation on the ER/PR reports and things like that, so at that point in time, on that day that they needed that document, perhaps he wasn't around.
CHAYTOR, Q.C.:
Q. In December of 2007, there was -
MS. WADE:
A. At that day, yeah.
CHAYTOR, Q.C.:
Q. - ongoing investigation?
MS. WADE:
A. It was--I found out about it probably the day of or day before and that form had to be completed because they were coming in fairly quickly after that form was completed.
CHAYTOR, Q.C.:
Q. And if he wasn't available then for you to consult, where did you get your information?
MS. WADE:
A. I would have the senior staff, people like

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maybe Mary Butler at the time. Ken Green certainly was--because I know I had to go to him to get any information about immunohistochemistry. He was the senior person in that area at the time.
CHAYTOR, Q.C.:
Q. And what investigation on the ER/PR issue did you understand was still ongoing in December of 2007?
MS. WADE:
A. Other--all I know is that there were--there was always issues that they were dealing with on a day-to-day basis, but I didn't work next door to them any more, so--but I do know that they were -
CHAYTOR, Q.C.:
Q. An investigation that involved the lab manager, Mr. Dyer?
MS. WADE:
A. If it was to do with the--anything to do with ER/PR, but again, you know, I can only speak to my memory of this, and it is a bit foggy. I just remember getting this form and I do--seeing it, I remember completing it.
THE COMMISSIONER:

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Q. Ms. Chaytor, wherever you can find a spot, we'll take the break.
CHAYTOR, Q.C.:
Q. Okay, thank you. Under record keeping, "is a patient index maintained for easy retrieval of information?" and then you've written "LIS" and yes. First of all, remind us what LIS is?
MS. WADE:
A. That's the lab information system.
CHAYTOR, Q.C.:
Q. And what is--what patient index is maintained for easy retrieval of information?
MS. WADE:
A. That would basically be the lab information system with the patient registrations.
CHAYTOR, Q.C.:
Q. And is that anything different than would have been in place, say, in 2005?
MS. WADE:
A. Not really. We still have--in 2005, we had--I'm just trying to think. 2005, we had one lab information system for St. John's. We still have three lab information systems in Eastern Health.
CHAYTOR, Q.C.:

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Q. And you also go on to answer here, "are control slides retained in a separate file?" and you indicate "IHC control is on the patient slide" at that point, so the answer to that would be no.
MS. WADE:
A. Um-hm.
CHAYTOR, Q.C.:
Q. "Are IHC evaluation records and validation slides retained for at least 20 years?" and you say "yes, currently lab is ten years old, retaining records." What lab is currently ten years old?
MS. WADE:
A. The immunohistochemistry section, so this is information that I would have from the people in immunohistochemistry lab. So obviously we are retaining the records, but we're not--that section is not 20 years old.
CHAYTOR, Q.C.:
Q. So did you understand that the IHC portion of the lab came into existence in 19 -

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Q. - in 1997?
MS. WADE:
A. That would be my understanding.
CHAYTOR, Q.C.:
Q. And that there was no IHC prior to 1997?
MS. WADE:
A. That's correct.
CHAYTOR, Q.C.:
Q. And who told you that?
MS. WADE:
A. Pardon?
CHAYTOR, Q.C.:
Q. And who would have been your source of that information?
MS. WADE:
A. Maybe Mr. Gulliver.
CHAYTOR, Q.C.:
Q. And so, and the retaining records, so what you're saying is that they would have records for ten years, not 20, because they've only been in existence for ten years?
MS. WADE:
A. That's right, whatever they have, they retain. Well, the LIS system maintains all of the records.

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CHAYTOR, Q.C.:
Q. Perhaps then we'll take a break there, please, Commissioner.
THE COMMISSIONER:
Q. All right then, we'll take the afternoon break.
(BREAK)
THE COMMISSIONER:
Q. Please be seated. Ms. Chaytor?
CHAYTOR, Q.C.:
Q. Thank you, Commissioner. There are two new exhibits, please, that I would ask to have entered. P-3674 and P-3675.
THE COMMISSIONER:
Q. Entered.
EXHIBITS ENTERED AND MARKED P-3674 AND P-3675
CHAYTOR, Q.C.:
Q. If we look back then at P-3589, before we broke, and under quality assurance, there's a couple of questions that you filled in here as well. "Are there procedures for the processing of external quality assessment samples and a review of EQA reports?" and you've indicated yes, and Ms. Wade, what is that? What are the procedures for the

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processing of EQA?
MS. WADE:
A. For the external quality assessment?
CHAYTOR, Q.C.:
Q. Yes. The reports come back to the pathology, the manager. I'm not quite sure who they come back to initially, but for the IHC component, Dr. Elms and the technical director, Ms. Gamberg, reviews the external proficiency reports. She does a little collated summary of the report and shares it with the technologists in the area and Dr. Elms, of course.
CHAYTOR, Q.C.:
Q. And where does her assessment then go or her report? Does that get--is there a committee responsible for that?
MS. WADE:
A. All of the external proficiency testing for pathology and any--just like any occurrences or any other activities, audit, are to go to the quality management committee. So the external proficiency report summary will also go there.
CHAYTOR, Q.C.:

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Q. Okay, and "is there documentation of corrective action or QC records and EQA reviews?" and you've indicated yes. So in December 2007, you would have seen documentation of corrective actions?
MS. WADE:
A. Yes, because by then, they did have--back then, they did have corrective action sheets and also the external proficiency testing reports were all available.
CHAYTOR, Q.C.:
Q. Okay, and under quality control, 10.1, internal quality control, "is there a written system in operation to routinely detect clerical errors, significant analytical errors and unusual laboratory results?" and you didn't fill that part in, and why not?
MS. WADE:
A. Now that I'm looking at it, I would, in that case, the corrective action procedures and processes are all part of that whole system and then the regular audits of pathology reports would pick up any clerical errors and those kinds of things.
CHAYTOR, Q.C.:

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Q. Was there a corrective actions procedure in place as of December 2007?
MS. WADE:
A. I'm trying to think. I know that they have their corrective actions logs and part of their procedures that they document whatever they do to make changes.
CHAYTOR, Q.C.:
Q. Now, but did they have that in place back then?
MS. WADE:
A. I seem to recall that they did have corrective action logs.
CHAYTOR, Q.C.:
Q. And whether or not there was procedure or policy in place at the time, do you know?
MS. WADE:
A. I can't remember.
CHAYTOR, Q.C.:
Q. And if we look then at page ten of this document, under histotechnology quality control, "are tests and control slides reviewed by a senior technologist before being sent to the pathologist?" and you've indicated yes. What did you understand to be the role

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of the technologist in terms of reviewing tests and control slides?
MS. WADE:
A. I would interpret that to mean that they would have reviewed to make sure that they were of adequate quality for a pathologist to interpret.
CHAYTOR, Q.C.:
Q. And "are new lots of all IHC reagents tested in parallel with existing reagents on validated control material before being put in use?" and you say yes. "Are there records of these parallel tests maintained?" and you haven't completed that. Did you see any documented evidence or records of such parallel tests?
MS. WADE:
A. I understand from--and again, I don't work in the area, I just understand from discussions with those who do that in the immunohistochemistry, as in any other lab, if you're introducing a change to your processes, you have to validate it and run it parallel to your current processes.
CHAYTOR, Q.C.:

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Q. And your answer to that being yes, who would have provided you with that information?
MS. WADE:
A. Mr. Green, I think.
CHAYTOR, Q.C.:
Q. And in terms of records of those parallel tests, did you see any records, and if you had, would you have completed this?
MS. WADE:
A. I did not, no.
CHAYTOR, Q.C.:
Q. You didn't see any records?
MS. WADE:
A. I didn't see any.
CHAYTOR, Q.C.:
Q. The last question here is "are positivity/negativity rates for ER/PR and HER2/neu tests maintained?" and you've circled yes. Who is maintaining those rates, positivity and negativity rates for ER/PR?
MS. WADE:
A. My understanding that it would be the breast people, the people involved with the breast group.
CHAYTOR, Q.C.:

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Q. Okay. Have you ever seen any such records?
MS. WADE:
A. I do not, no.
CHAYTOR, Q.C.:
Q. And to this date, have you ever seen any positivity or negativity rates for ER/PR?
MS. WADE:
A. No, I have not.
CHAYTOR, Q.C.:
Q. And you understand who is keeping track of that? I realize right now the test is not running, but up in December 2007, it would have been, and had been since February of '07.
MS. WADE:
A. My understanding, it would have been the breast group because they were the ones who would be reviewing and documenting anything relating to breast pathology.
CHAYTOR, Q.C.:
Q. And do you mean the Breast Disease Site Group when you say the breast group?
MS. WADE:
A. The breast group that I understood it to be at that time would have been Dr. Carter and Dr. Cook.

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CHAYTOR, Q.C.:
Q. And would that be part of your role or would you have any involvement in that to--if there's to be any kind of tracking or metrics kept, do you have a role in that, to see what might be appropriate for the program and that they do have the appropriate mechanisms in place to be carrying out that function?
MS. WADE:
A. It's certainly not my role to determine what needs to be measured and documented in the specific divisions. I have no expertise in most of it. So I certainly would not be able to speak to what they should be reviewing and what is appropriate for the various test procedures, but I do see my role in ensuring that we have a policy developed that would ensure corrective actions are undertaken and that there is auditing and monitoring to ensure that the procedures are followed and that there are appropriate results being obtained. So every division is going to have to ensure that they have those processes in place.
CHAYTOR, Q.C.:

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Q. Yes, and then after they've made a decision to have such processes in place, what systems are put in place to make sure that's happening, that the positivity, for example, or negativity rates are being tracked?
MS. WADE:
A. That would be something I would see that could be reported to the quality management committee for pathology. I have not seen -
CHAYTOR, Q.C.:
Q. And you sit on that committee?
MS. WADE:
A. I sit on that committee, yes. I have not seen that at that committee.
CHAYTOR, Q.C.:
Q. Okay, and in filling out yes here, how were you able to answer yes? Who gave you that answer?
MS. WADE:
A. In speaking to anybody involved in immunohistochemistry that they--I can only assume now that I was told that it was the breast group, because as I expounded on the next section that the breast group oversees the quality and documentation for that tissue

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type, including positive and negative rates.
CHAYTOR, Q.C.:
Q. Yes, and so in terms of filling it out though, you didn't see any documentation and somebody would have given you this information?
MS. WADE:
A. They would have given me the information, yes.
CHAYTOR, Q.C.:
Q. If we could look, please, at P-3600? And this appears to be results from NEQAS, from the external proficiency testing on July 30th, 2008, and it's indicated here "ER NEQAS and then ER in-house." So I understand this to be the NEQAS provided slide and then the in-house provided slide. The first slide, our mark, and this I understand, if we look up here, might explain it a bit better. "NEQAS provided three slides, one for ER and one for BCL-2 and BCL-6. We were also requested to provide three in-house slides with our current control samples stained for same three stains. Then four assessors marked each of the six slides by giving each a score of one to five. The four scores were then added together for maximum marks, so the highest you can get is

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20. We scored the six slides before they were shipped, giving each a mark of 20. A summary of these results is given below." And who would prepare this document?

MS. WADE:

A. Ms. Gamberg.

CHAYTOR, Q.C.:

Q. So this is her report?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. That then goes to the quality management committee?

MS. WADE:

A. That then goes to Dr. Elms who reviews it.

CHAYTOR, Q.C.:

Q. And it gets ultimately brought to the pathology quality management committee?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. Okay, and so would you have seen this at the quality management committee?

MS. WADE:

A. Yes, I have.

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CHAYTOR, Q.C.:

Q. And then for the ER NEQAS, our mark was 20. So I take it it was a 20 given by Eastern Health to themselves on the ER NEQAS slide?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. And the assessors then, the mark was 18, and in-house, it was our mark was again a 20 and it was a 12 given by the assessors.

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. And it says "more tumor nuclei could be demonstrated. Stain intensity could be stronger."

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. And then Eastern Health's response to NEQAS run number 82, "we received a low score on our in-house slide. However, since our score on the NEQAS slide is very good, we know that our staining protocol is appropriate and the problem must be with the tissue." What--

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"NEQAS returned the slide, so we reviewed them and Ford agreed," Dr. Elms agreed, "that our slide looks more like a two plus than a three plus. We need to watch this in the future." And do you recall any discussion about that?

MS. WADE:

A. Not in particular, no, no discussion, other than that I took this to mean that they've taken what they've learned from the assessors and on reviewing the slide, agreed that they probably scored them too high, and that is exactly what you want to get from external proficiency testing, so that you can improve your service, and that's one of the components or one of the purposes of doing it external proficiency testing.

CHAYTOR, Q.C.:

Q. Okay, and we understood from Dr. Wells' evidence this morning, you want to--the 12 out of 20, that's the least, that's the minimum requirement?

MS. WADE:

A. That's the least, that's right.

CHAYTOR, Q.C.:

Q. That you want to have.

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MS. WADE:

A. Yes.

CHAYTOR, Q.C.:

Q. That's the least?

MS. WADE:

A. Yeah.

CHAYTOR, Q.C.:

Q. Anything below that is then cause for, I guess, some serious concern in terms of a borderline result.

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. So in terms of the idea then, and I understand this is not within your expertise, but I'm just wondering if there was any follow up then by the pathology quality management committee, in terms of "the problem must be with the tissue." Did that raise any concern? What problems would there be, because of course by July 2008, there's been a lot of concern, I would suggest to you, about fixation, for example?

MS. WADE:

A. Um-hm.

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CHAYTOR, Q.C.:
Q. And appropriate processing and the pre-analytical phase for preparing tissue for ER/PR, and so I'm just wondering if there was any discussion or follow up on that, if there were--if it was indicated a problem must be with the tissue?
MS. WADE:
A. I do know that the histology section of the lab that does the pre-analytic functions prior to the samples getting to the immunohistochemistry also participate in external proficiency testing that assesses the quality of fixation, microtomy of the cutting and the staining, and there have been no issues with the fixation. So I seem to recall Ms. Gamberg saying something about the problem with the tissue not necessarily meaning fixation. It may not have been an in-house--might not have been the most appropriate one to select to use and it could have been that was the problem, as opposed to a problem with the tissue in of itself.
CHAYTOR, Q.C.:
Q. So do you know if there was any investigation

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carried out to determine what the problem was with the tissue?
MS. WADE:
A. It's my understanding that this is Ms. Gamberg's area and that she takes all reports and does her investigation. I don't know what the follow up has been on this one at this point.
CHAYTOR, Q.C.:
Q. Would that come back to your quality management committee?
MS. WADE:
A. They should come back to the quality committee.
CHAYTOR, Q.C.:
Q. And there hasn't been anything back since?
MS. WADE:
A. No, I haven't seen a report.
CHAYTOR, Q.C.:
Q. Since July?
MS. WADE:
A. Follow up, no.
THE COMMISSIONER:
Q. How long has there been this external proficiency testing in respect of the

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histology section? That would be going on for how long?
MS. WADE:
A. I am not sure if they only started that just in 2005 or if they had been doing it all along. I don't know. I was not involved.
CHAYTOR, Q.C.:
Q. And at the end it says "no corrective action is required." What do you understand that to mean, in her report?
MS. WADE:
A. In that the report of itself didn't mean that they had to go back and review their protocol or change anything in the way they were doing it, because they knew that the protocol worked based on the NEQAS slide, results of the NEQAS slide.
CHAYTOR, Q.C.:
Q. So but you did understand there would have been further questions asked as to what the problem would be with the tissue?
MS. WADE:
A. Right.
CHAYTOR, Q.C.:
Q. And you're expecting to hear back on that?

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MS. WADE:
A. Yeah.
CHAYTOR, Q.C.:
Q. At some point, okay. I'd just like to turn now then and talk to you a bit about your involvement with the policies and procedures document that we have here. First of all, perhaps you could just tell the Commissioner, when you took on the role in the summer of 2007, what was the status or stage of written policies and procedures for the pathology portion of the laboratory medicine program?
MS. WADE:
A. They were in various stages of write. Some of them were done, completed, others were in draft. Ms. Parnell was the quality management coordinator in pathology at the time. I know she was off for a period of time and so there was a period of time when she was not available to do any of the work. As a result, I assisted those in the pathology, immunohistochemistry section to get some of their procedures down in the standardized template. So I would have Mr. Green come and sit with me and bring me his documents and I

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would get them formatted for him in a standard template.

CHAYTOR, Q.C.:

Q. And were there any particular obstacles or challenges that you encountered then in the development of the policy and procedure manual?

MS. WADE:

A. The challenge again is trying to get the work done off the corner of your desk, and the people who are best to write the procedures that they do every day are those who are actually doing them, and obviously with the workload that they have, they can't just leave it and say, well, I'm going to do policies and procedures today because there is work to be done. So often it was on their breaks, or I would hold them over after their work day and we'd get some work done, or I would go out looking for the information and get it drafted and bring it back so that they could do the reviews, at least get things done in a format that we were going to move forward with. So the biggest challenge again is the human resources around having the people that can

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just be dedicated to get this done, and once it's done, it's a maintenance issue as opposed to--and a continuous process.

CHAYTOR, Q.C.:

Q. And how is that going to work then in terms of--because it's a living document, it has to be revised, it has to be updated, it has to be reviewed periodically.

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. And so who's going to be responsible for doing that?

MS. WADE:

A. Well, again, you know, my role is to ensure that there are reviews done. All of our documents have dates on them. They're active effective dates, so a year from that they're expected to be at least reviewed, and again if there were issues, they would be revised at appropriate times, anyway. The human--the Department--the lab program has been challenged for a long time with human resources because the workload continues to increase. It's an 8 percent increase year

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over year for the last two years, and the expertise required to do this, not everybody is going to have the knowledge or the understanding of writing policies and procedures. So it is always going to be the most knowledgeable people in the department, who at this time generally are the more senior staff. So I know that the Lab Medicine Program has applied--well, has certainly identified the need for additional resources to--put specifically to quality management initiative in their budget for this new fiscal year. So there is some hope that we will get additional resources, but given that this is something that there is no choice, this has to happen, we have to find a way; I don't know how, but it is a challenge.

CHAYTOR, Q.C.:

Q. And it's still in the works as to how that will happen?

MS. WADE:

A. Oh, certainly, definitely.

CHAYTOR, Q.C.:

Q. And how important is it to--how importance is the performance of preventative maintenance to

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your equipment in a laboratory to ongoing quality control in the lab?

MS. WADE:

A. Well, preventative maintenance is one aspect of quality assurance. It's one thing that we do, the control specific to the test, but you have to ensure that the--in pathology, you have to ensure that the temperatures of the water baths are adequate, that the temperature of the fridges are maintained, the paraffin wax is maintained, and that the equipment is maintained as it should be.

CHAYTOR, Q.C.:

Q. So it's one of many things that you have to be doing?

MS. WADE:

A. It's one of many -

CHAYTOR, Q.C.:

Q. On a daily, weekly, or monthly -

MS. WADE:

A. Assurance activities.

MS. WADE:

A. - basis.

MS. WADE:

A. That's right.

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CHAYTOR, Q.C.:
Q. According to the particular procedure?
MS. WADE:
A. Right.
CHAYTOR, Q.C.:
Q. And if we could look then, please, at P-2157. This is the one that we had up before, but it's not up any more. Perhaps then while we're waiting for the document to come up, this is the pathology policy and procedure manual?
MS. WADE:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. How are the policies and procedures distributed, first of all, within the laboratory medicine program itself?
MS. WADE:
A. There are various levels of policies, as you've heard.
CHAYTOR, Q.C.:
Q. Yes. Perhaps you could tell the Commissioner about that, about the different levels of policies?
MS. WADE:

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A. Well, we have a policy framework was that developed by the corporate strategy and research division, and that framework outlines four levels for policy development. Level 1 is organizational, Level 2 is the next level, so that would be something from the Vice President level, say, and then the program specific policies are Level 3's, and those are the ones that I am most involved with. The Level 4 policies are very specific to divisions and how they do their business.
CHAYTOR, Q.C.:
Q. Yes. So once a policy then is signed off regardless of what level signed off, how would the staff then become aware of the existence of a policy?
MS. WADE:
A. Again, you know, it is a challenge given our diverse communications processes that we have because we have the three Meditech systems that have an e-mail system for staff, so in all the various regions, former regions, they have their own Meditech system. Then we also have the Outlook e-mail. Typically what happens, if it's a Level 2 policy, the

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direction or the communication comes from Corporate Strategy and Planning because they get the policies loaded to the intranet and send the information out to all management that these policies are now in effect and that they're available for their staff. From the lab program specific one, the Level 3's, the ones that I have done, I finish them--once they're signed off, I communicate to all of the division managers across the region, and then they disseminate that information in their systems to their own employees. We also now have all policies as they're being written are uploaded to the Eastern Health Intranet, so we at least have a quasi-electronic method, but at least staff that have the PCs in their areas can access the policies that are most current now on the Intranet.
CHAYTOR, Q.C.:
Q. Okay.
MS. WADE:
A. We don't have procedures yet on the Intranet.
CHAYTOR, Q.C.:
Q. Procedures aren't there yet.
MS. WADE:

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A. No.
CHAYTOR, Q.C.:
Q. Just your policies?
MS. WADE:
A. Just the policies.
CHAYTOR, Q.C.:
Q. And what about then, for example, this manual that we've now brought up here, and you'll see pathology procedures, page three, pathology policies procedures manual, table of contents, and then there's quite a number. How were the staff apprised of the existence of--this was a fairly new manual, and you'll see the number of--number of them, for example, on page nine, the fixation policy came into effect--well, the effective date is not indicated, but it's been approved as of February 4th, 2008, and then on page 13, we have tissues for gross examination only came into effect January 21st, 2006, so how did the staff become aware that all these policies, this manual now exists with all of this information?
MS. WADE:
A. Again it is the responsibility of the manager to communicate within their division for new

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policies and procedures. The binders are--you know, they're green, they're easy to identify in a shelf of black binders, and there is a signoff procedure. Staff are made aware of it. Pathology is challenged with continuous new people coming in and--on any given day, there may be a temporary employee in there, that might not know the binder was put there yesterday or that there was something new, but the communication is a challenge, but it is the responsibility of the managers to ensure that their staff know where the binder is and that they read off and sign off any new procedures.

CHAYTOR, Q.C.:

Q. So there's physically a binder kept at the various workstations?

MS. WADE:

A. There is a single binder in the main histology lab, there is one in immunohistochemistry, there is one at St. Clare's, there is one in Burin, one in Clarenville, there's one in all sites.

CHAYTOR, Q.C.:

Q. And a new staff member then coming into the

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lab, into the pathology section, then they'd be responsible for having to read through the manual?

MS. WADE:

A. That's right. Well, typically what they're doing now is training people as they come in. If they're being trained to work in pathology for all of the various aspects of the work, then they will be trained in embedding, and trained in microtomy, and trained in staining, and as they get trained, they're being shown the new--you know, the procedures and the policies, and eventually they have the whole binder that they will recognize then as being a whole--binder for the whole of the division.

CHAYTOR, Q.C.:

Q. So what happens if there's a change? You know, there's a change for some reason, IHC problem report form, I'll just pick that one how is the staff then made aware that that has changed and how does the change get put into the binder? How does it logistically happen?

MS. WADE:

A. For pathology, the coordinator for pathology management, Bev Rowe, is responsible for

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maintaining and updating any of the policies and procedures for the pathology division. So she communicates to the manager that this is ready and here's your copy, make sure it goes in each of the binders that you have in your areas.

CHAYTOR, Q.C.:

Q. And there's no--there's no other electronic way of, for example, communicating with the staff to let them know?

MS. WADE:

A. Other than an e-mail on the system, you know. That's one of the disadvantages of not having an electronic document system, which is certainly on my wishlist for the labs for the region. With 17 sites, and every site having very specific procedures, having something that is electronic, the document software system actually do the tracking and the maintaining and they send the messages to all the users. So this system will certainly be an advantage for the labs to have, and it's something that's going to have to happen in order for the lab to ensure that we have consistency of practice from one division to

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another and one site to another.

CHAYTOR, Q.C.:

Q. And were you involved in any workshops to introduce the staff involved with the policies and procedures, the new policies and procedures?

MS. WADE:

A. I was involved with the whole workshop on quality management, and attending that were the managers as well as their senior staff, and those are the kinds of things that we discussed about development of policies and procedures and how you need to document and sign off on those.

CHAYTOR, Q.C.:

Q. So there was no actual getting the staff together, for example, for an information session to say we now have this new manual, here it is, and let's go through some of -

MS. WADE:

A. I'm not sure pathology did that particular--anything particular for their division, no.

CHAYTOR, Q.C.:

Q. You weren't involved with that?

MS. WADE:

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A. No, I wouldn't be involved in the individual divisions.

CHAYTOR, Q.C.:

Q. We'll see, for example, on page seven of the exhibit, most of those that are listed there are all still noted to be in draft form. Coming down you'll see "in draft" after a fair number of those particular policies on that page. How much progress has been made?

MS. WADE:

A. A lot of those policies that--or procedures really that are in draft are actually the way they're doing their business today. A lot of them were prepared and getting finalized in their electronic format in order to be printed for signing. So at the time that these were presented, we had not--the coordinator had not been able to get either Mr. Dyer or Dr. Denic, whoever was required was required to get them signed off. So I suggested that they present these as drafts even though--because they haven't been signed off, but a lot of them are as they do their business today.

CHAYTOR, Q.C.:

Q. So this was an enormous amount of work in

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terms of getting these policies and procedures in place?

MS. WADE:

A. It is a huge amount of work, and given that there is a table of contents, you can see the vast amount of work that is there, I mean, and that's just for one division.

CHAYTOR, Q.C.:

Q. So, Ms. Wade, is wasn't a situation where--when we go back to page one of this and it's the pathology policies and procedures manual, it wasn't a situation when you walked in to your job in the summer of 2007 where there was such a policy and procedure manual in existence, and it was just a matter of going through it and updating it, or putting it in a particular format. This was--most of these policies and procedures were being created for the first time?

MS. WADE:

A. Some of them were. Some of them were procedures that they were already following, but--for instance, a lot of the staining procedures were in a binder in an old format, typed format. Sometimes they may be right

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directly from a reference document, a reference manual, or a reference textbook that they were following as the best practice procedure, just not typed in a format as we have here today.

CHAYTOR, Q.C.:

Q. And was there any evidence of any--I hear what you're saying, that was true of some of them, but in terms of the volume of policies and procedures that we see here -

MS. WADE:

A. Not as comprehensive as it is now, no.

CHAYTOR, Q.C.:

Q. And the majority--there were no policies and procedures, regardless of format, the policies and procedures, these are new, the majority of those in terms of -

MS. WADE:

A. I can't imagine any lab being able to work without a procedure manual of some kind.

CHAYTOR, Q.C.:

Q. Did you see it?

MS. WADE:

A. Oh, I have seen them, yes, and in the course of preparing for accreditation, I had--you

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know, I had binders upon binders of procedures, and they were -

CHAYTOR, Q.C.:

Q. For the pathology and IHC lab, in particular, that we're talking about?

MS. WADE:

A. And pathology--for IHC, I don't recall specific--you know, I know stains, and I know that they have binders for various protocols, but again a lot of what they followed was specific from the manual that they were using, not a format that makes it their own, let's say.

CHAYTOR, Q.C.:

Q. I just want to be clear on that.

THE COMMISSIONER:

Q. You're talking about the manufacturer's document?

MS. WADE:

A. Could be, yes.

THE COMMISSIONER:

Q. Is that what you're talking about?

MS. WADE:

A. Yes, and in often cases, exactly how the procedure is written today for the tissue

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processor, will be as directed by the procedure manual, but they will take the component that they would use on a day to day basis and put it to a format that staff would be--it would be a quicker reference than going to a manual.

CHAYTOR, Q.C.:

Q. And, though, standard operating procedure for the particular lab in question?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. In terms of any evidence as to what did exist, was there any evidence as to when it had last been reviewed or updated?

MS. WADE:

A. No.

CHAYTOR, Q.C.:

Q. And if we look at, please, page nine, Registrar, fixation policy, and again it doesn't say an effective date, but it does say an approval date of February 4th, 2008, and this policy has come up before here at the Commission, and we understand that it was some time in the making in terms of it coming up

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and finally having an approval date of February 4th, 2008?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. Because, of course, the issue of fixation was something that was brought up by Dr. Cook in the summer of 2005 as an issue, and then, of course, again by the external reviewers. What difficulties are you aware of that were encountered in developing this policy and finally having it adopted?

MS. WADE:

A. I'm not--I don't think that there was difficulty in the policy itself, the how they should be handling the tissue. I think that they had plenty of evidence to give them information to make the policy. The difficulty came about as a result of the introduction of the policy framework for Eastern Health. So now we had to go back and revisit the policy in this format and the signatories of it, and again I was in this role for about six or seven months at that point in time. I know that the fixation policy had been drafted and

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sent in an old format out to the regions and Dr. Denic had communicated that to the various pathologists around the province. After the policy framework came out, there was some discussion around issuing authority and who were we going to have sign it off, and all of that, and at the end of the day I felt that fixation is a pathology concern, pathologists are the best to know about it, and the pathologists should it off. So at the end of the day, it became a policy that we kept for the pathology division, and communicated it to all of those entities that would use that--would use fixative. So it was signed at the end of the day by Dr. Denic and Mr. Gulliver, and disseminated to all of the regional directors out in all of the regional health authorities and to all of the lab, to the ORs, across the province.

CHAYTOR, Q.C.:

Q. And we know, of course, this one is deemed to be a Level 4. So a Level 4 means that it's mandatory across all departments if it's a Level 4?

MS. WADE:

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A. The Level 4 is the pathology policy.

CHAYTOR, Q.C.:

Q. Okay.

MS. WADE:

A. The pathology division creates that policy and it's about their specimens. So that's why I recommended that it be maintained as a pathology policy as opposed to a Level 2 policy or a Level 3, because it is specific to the specimens that are handled in that department.

CHAYTOR, Q.C.:

Q. So if it's Level 2, then it goes beyond the borders of just the Laboratory Medicine Program?

MS. WADE:

A. It would be signed typically by--a Level 2 would be signed off by Dr. Howell, but--I discussed with Dr. Denic, and in discussions with Dr. Howell, I felt that this was a very technical policy very specific to the quality of tissues that were coming to that department, and it was important that Dr. Denic sign this off as opposed to Dr. Howell.

CHAYTOR, Q.C.:

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Q. We had seen a version at one point where it was for Dr. Howell's signature.
MS. WADE:
A. Exactly, that's right.
CHAYTOR, Q.C.:
Q. Okay, but wouldn't this be--isn't it important that--it stretches beyond, obviously, just the lab.
MS. WADE:
A. That's right, and that -
CHAYTOR, Q.C.:
Q. It deals with perioperative program as well.
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. And how they have to handle the specimen?
MS. WADE:
A. That's right, and that's how you engage your stakeholders. So the stakeholders are engaged in either to develop it to ensure that they can comply with the requirement, and/or the implementation of it.
CHAYTOR, Q.C.:
Q. Okay, but it being a lab policy as opposed to something that's going to also apply to the

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perioperative, would the perioperative have to still follow this as being -
MS. WADE:
A. They are following it, yes, and we communicated that for them, along with handling of tissue--procedures for handling of various tissue that go into the fixative. So all of the tissue handling procedures are also separate from this policy.
CHAYTOR, Q.C.:
Q. Okay. So I guess I'm just trying to figure when would it be--when would it be warranted to make it a Level 2 policy, or a level that is mandatory on all departments to follow, because fixation is something that I did--I understood did cross all sections?
MS. WADE:
A. Yes, but a lot of--we have a lot of policies in the lab. For instance, a new regional policy on specimen acceptance and rejection is a lab program policy at Level 3. It provides guidance for the technologists who are handling samples, whether it's pathology or chemistry, however, we also engage our stakeholders and users of lab services to

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ensure that they understand that the quality of the sample that they send it, whether it be a blood sample, or a tissue sample, has to meet certain criteria. Because that policy overrides all of the lab program, it is a Level 3. This here is specific to tissues that come to the pathology lab, however, we need to ensure that the people who are going to put the tissue in fixative are aware of its existence and the importance of maintaining fixation.
CHAYTOR, Q.C.:
Q. So then, for example, we have linkages here of fixation procedure for OR and clinic staff.
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. So they would have their own -
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. Their own policies.
MS. WADE:
A. That's right, they have all the tissue handling procedures for their areas.

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CHAYTOR, Q.C.:
Q. If we could have, please, P-2131, and this is September 19th, 2007, a meeting of Pathology Quality Management Committee, and you're absent on this particular occasion. Business arising, "Discussion began regarding review of the following; fixation pathology tissue handling, submission of pathology specimen tissue to microbiology, tissues for gross examination only. It was recommended that a procedure policy sent for peer review not have changes made until the committee approves them. Sheets with comments and signatures with each policy procedure should be brought to the meetings and discussed". Then there's policy and procedure implementation and development, "Following are to be sent for Level 3 signing", and it goes on from there. So I take it, as of September 19th, 2007, there was still review happening of the fixation and pathology tissue handling, those particular policies were still being worked on at that point in time?
MS. WADE:
A. Yeah, that's right, and what happened

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certainly if they're pathology policies, they created a process for review by pathologists within the program as well, certainly in Eastern Health, so that it wasn't only Dr. Cook or Dr. Morris-Larkin who were saying what the policy should be, but ensuring that the other pathologists had input, and then sending it to other pathologists throughout the province as well to get their feedback to ensure that if Eastern Health was going to have a policy, that the others were going to be able to comply with it, and if there were issues, that they would address it at the front end before the policy was sent out.

CHAYTOR, Q.C.:

Q. And if we could have, please, P-3607, and this is an e-mail from yourself to a number of people in other health regions and it's dated February 19th, 2008. "Attached is the Eastern Health fixation policy that was communicated to your pathologists by Dr. Denic, Clinical Chief, in May of 2007. The attached is revised in format/template, and it's basically the same information. Please ensure that this information is disseminated to the pathology

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department and the OR who may have specimens that are sent for analysis to Eastern Health labs". So I take it you're involved here in getting this information out to the other regions?

MS. WADE:

A. I did, yes, because I know who these directors are. I just happened to have that communication.

CHAYTOR, Q.C.:

Q. And what went out in May of '07, though--we've just looked at minutes of a meeting in September of '07 where fixation policy and procedure is still being worked on.

MS. WADE:

A. The newer one.

CHAYTOR, Q.C.:

Q. So what were you made aware of had been distributed in May of 2007?

MS. WADE:

A. They were some that Ms. Parnell had formatted in the beginning days of when she took over it as coordinator for quality management committee for pathology. So they had their policies and whatever in another template, and

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in, I think it was January or February of--I can't recall if it was 2007 or--it was probably 2007, but there was a policy framework, the Eastern Health policy framework, was rolled out, and then, of course, I became--came on the scene and I felt then whatever policies we had in place, we had to start from scratch and ensure that they were put into the policy framework that was already developed.

CHAYTOR, Q.C.:

Q. Okay. Did you receive any feedback from any of the regions once you sent out this policy?

MS. WADE:

A. I--not then. Those were--they were signed off policies at that point in time. We would have had any feedback from pathologists prior to that.

CHAYTOR, Q.C.:

Q. And what type of feedback had you already received then?

MS. WADE:

A. Just reiterating the requirement that the tissue be breadloafed in the case of large samples, and things that would be included in

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the actual specific tissue handling as opposed to the fixation itself.

CHAYTOR, Q.C.:

Q. I just want to be clear on that. So did anyone indicate that they would have any difficulty -

MS. WADE:

A. No.

CHAYTOR, Q.C.:

Q. Being able to meet what Eastern Health was proposing?

MS. WADE:

A. No.

CHAYTOR, Q.C.:

Q. So no feedback along those lines?

MS. WADE:

A. No difficulty, no.

CHAYTOR, Q.C.:

Q. Okay. If we could look at P-3608, please, and this is an e-mail then of March 19th, 2008, to Maria Tracey, and she's been along already to give her evidence, and we understand here to be the perioperative program--with the perioperative program, and you're saying, "Maria, attached are pathology specimen

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handling procedures and fixation policy for use in the ORs. These should be put into a binder for laboratory procedures in the ORs at St. Clare's and the Health Sciences Centre. If you would like an in-service for staff at the OR regarding these documents, please contact Catherine Parnell". So you're sending along quite a number of the pathology or lab policies which have been signed off on at this point in time?

MS. WADE:

A. That's right.

CHAYTOR, Q.C.:

Q. And is this the first time those policies would have been then provided to Ms. Tracey?

MS. WADE:

A. I can't speak to that. I wouldn't know.

CHAYTOR, Q.C.:

Q. Or otherwise given to the perioperative program?

MS. WADE:

A. I don't know if they had anything in the past in other formats.

CHAYTOR, Q.C.:

Q. Yes, whether or not they had--you're saying

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these should be put into a binder. Whether or not--you're not instructing her, well, look, update your binder, take out the old ones, these are the new ones. It's not that situation?

MS. WADE:

A. No, because I--I do know from our newly formed OR Quality Committee that they do have a procedure binder for labs or protocols that they follow in the OR. My instruction for this, this is very specific to the lab, and I just wanted to keep them to whatever your processes are.

CHAYTOR, Q.C.:

Q. Yes, but you're not telling her to update her -

MS. WADE:

A. No.

CHAYTOR, Q.C.:

Q. Not telling her to update the binder, so -

MS. WADE:

A. Because -

CHAYTOR, Q.C.:

Q. I assume you wouldn't have -

MS. WADE:

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A. No, because I don't know if she had one.

CHAYTOR, Q.C.:

Q. Yes, okay, so you don't know whether or not they had similar policies?

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. That these were just replacing or not.

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. And wouldn't that be important, though, to know in terms of you're not just going to be sending up policies which might conflict with other policies that are already in existence, for example?

MS. WADE:

A. Well, the fact that these are new tissue handling policies, I would think that anybody who was--if they had any other policies and protocols in place, they would have to ensure that they either comply with these or else not use them any more.

CHAYTOR, Q.C.:

Q. And you've offered an in-service. So I take

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it this is something new, this is not just a matter of updating -

MS. WADE:

A. I do know that Ms. Parnell did an in-service with St. Clare's. I don't know when she did them, but she had done one, and I do know that there has been one at the Health Science done specifically with these.

CHAYTOR, Q.C.:

Q. For the perioperative, you mean, program?

MS. WADE:

A. Yes.

CHAYTOR, Q.C.:

Q. So they took advantage of that and took you up on your suggestion for an in-service?

MS. WADE:

A. Yes.

CHAYTOR, Q.C.:

Q. Okay. So I take it, this was fairly--this was new information for them?

MS. WADE:

A. It was certainly more comprehensive probably than what they had, yeah.

CHAYTOR, Q.C.:

Q. If they had anything?

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MS. WADE:
A. If they had, and I can't say if they did or not.
CHAYTOR, Q.C.:
Q. Okay, and how would they then--who looks after ensuring that they're kept up to date. So, for example, if your policy is up for review or revision next February, who ensures then any revisions that are made then get distributed to the regions and also internally within Eastern Health to other programs that may need to know about the revision?
MS. WADE:
A. Well, again our communication is difficult, but the route that we would take for the other regions would be to the directors of the labs in those regions, and then within our own--for Eastern Health, they would be communicated to the lab managers--certainly the site managers for outside the city, the pathology managers are involved with these, and then in the case of pathology specimen policies, they would be communicated to the ORs, and not only in this case, but in--in the case of some procedures, they may require information in ambulatory

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care. So we have to ensure that the communication is sent out to the appropriate people.
CHAYTOR, Q.C.:
Q. And if we could look, please, 2157, at page 25. This particular policy, reporting consultative opinions, you are the author of this particular policy, and it indicates here that, "The department recommends that all pathologists actively take part in a referral practice as this is the best interest of patients, good continuing medical education and good practice. The final pathology report should then include any consultative opinions". For example, a number of these policies including this one--well, the date is obviously not right in terms of its coming up for review on February 29th, 2009.
MS. WADE:
A. Yes.
CHAYTOR, Q.C.:
Q. And that wouldn't be right, because we already had a leap year this year.
MS. WADE:
A. That's right.

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CHAYTOR, Q.C.:
Q. But a number of them, because they were all brought in around the same time, next February and March is going to be a very busy time again in terms of having to review through, for example then, the next one. They're all coming up for review around the same time.
MS. WADE:
A. Uh-hm.
CHAYTOR, Q.C.:
Q. Has there been any provision made as to how that could happen, or whether or not there should be a staggering by, you know, a month or so, or two months for -
MS. WADE:
A. Right. I would expect that these policies, certainly the newest ones with those dates, they would start probably reviewing any time from here on, and--so that we don't have hundreds all at the same time, and again some of them are being looked at--if something comes up, they might get reviewed in advance of the date, anyway.
CHAYTOR, Q.C.:
Q. And what's the purpose of this policy, the

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reporting consultative opinions?
MS. WADE:
A. Often pathologists may consult with another pathologist, or they may refer specimen tissue samples out to other jurisdictions for opinions, and this policy ensures that--instructs pathologists that if they do that, that they have to state on the final pathology report whether or not there was any consultative opinion. It just makes for--it's a quality assurance component really.
CHAYTOR, Q.C.:
Q. Okay, and then on page 27, you're also indicated to be the author of this particular policy and it's monitoring temperature dependent equipment, and obviously all pathology laboratory temperature dependent equipment must be monitored and the documentation of all checks and corrective actions must be retained, and it goes on for some length in terms of refrigerators, water baths, tissue processors, and your paraffin dispenser. How did you go about--the incubation oven. How did you go about--not being familiar with this particular area, how

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did you accumulate all this information?
MS. WADE:
A. Well, there's a lot of literature out there about monitoring of equipment. There are labs across the country that already have policies and procedures written, so we certainly referenced or discussed with them what their practices are, and for--I had worked in a lab for many years prior to being a manager and was certainly well aware that you need to know if your fridge is maintained, and you need to know if your water bath is the right temperature, so this puts on paper that you do it and document it more so. It's not that it was never done, it was the documentation that this enhanced.
CHAYTOR, Q.C.:
Q. So when you sat down to do this, and whether or not it was ever done or not, I guess, you're not able to say because you didn't--you've never worked in the pathology lab.
MS. WADE:
A. Not in pathology, but this is a policy that will actually be rolled across the whole region for all of the labs because the only

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thing different is the name of the equipment. They all have fridges and water baths and a lot of equipment to maintain. So the documentation is going to be the same.
CHAYTOR, Q.C.:
Q. And the tissue processors -
MS. WADE:
A. Right.
CHAYTOR, Q.C.:
Q. That's peculiar to histology?
MS. WADE:
A. That's right, yeah.
CHAYTOR, Q.C.:
Q. So, for example, when you sat down to do this, it's not like you just pulled, well, the old policy and started to revise it or update it?
MS. WADE:
A. No.
CHAYTOR, Q.C.:
Q. There was no such -
MS. WADE:
A. That's right.
CHAYTOR, Q.C.:
Q. There was no such policy in existence?
MS. WADE:

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A. Not--no.
CHAYTOR, Q.C.:
Q. You created this yourself?
MS. WADE:
A. Right, and that's based in part as well by standards from the Clinical and Laboratory Standards Institute guidelines and -
CHAYTOR, Q.C.:
Q. You looked at the--you got assistance from that?
MS. WADE:
A. I have that manual, yes.
CHAYTOR, Q.C.:
Q. For example, if we look at water baths and, "The temperature of the water bath will be dependent upon procedure requirements, and while the bath is in operation, use a thermometer calibrated to an NIST traceable thermometer, measure the temperature of the water bath, record the temperature daily on temperature record sheets". Who then after--so you've got your policy now put on paper, and it's been signed off on. Who then ensures that that, in fact, happens?
MS. WADE:

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A. The managers of the division is responsible for ensuring that there's a process in place. Whether they delegate that to someone else or not, but it's their responsibility to ensure that there are recordkeeping documents.
CHAYTOR, Q.C.:
Q. And again the tissue processors temperature and the maintenance of the temperature record sheets, and then where does this go--do all the records get--does all the documentation get accumulated and does somebody then use it for any kind of QA purpose?
MS. WADE:
A. The--I just know from speaking with Ms. Rowe, the pathology quality management, that she will do random audits. She will call over to the lab and say send me over last month's temperature chart for XYZ equipment, and she will audit that to ensure that there was compliance, and if there wasn't, to tell them it had to be done.
CHAYTOR, Q.C.:
Q. And under the tissue processors under maintenance, "For the maintenance procedures, see operating manual, tissue processing VIP,

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the machine, Section 6, care of the instrument, and Section 7, troubleshooting". So then where would--where would the person reading this, such as myself right now, where would you go to find out, well, what's the maintenance procedure?

MS. WADE:

A. In the Tissue Tek Processor Manual that's in the room where the tissue processor is.

CHAYTOR, Q.C.:

Q. So you would then go to the actual operating manual -

MS. WADE:

A. For--yeah, for more in depth maintenance, yes.

CHAYTOR, Q.C.:

Q. And look it up.

MS. WADE:

A. Right.

CHAYTOR, Q.C.:

Q. Okay. In terms of--there's also procedures and policies that are here for corrective actions, and the accumulation of any corrective actions. Where is that data going? Who is accumulating that data and what purpose is it being used for?

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MS. WADE:

A. Again it's an audit kind of process, so that if there are corrective action sheets and logs, part of the audit and the quality assurance audit that are being done, Ms. Rowe would, for example, take the corrective action sheet to ensure that that was being followed properly. Again it is the manager's responsibility to ensure that staff undertake corrective action, and that they are documented prior to the next step of their procedures.

CHAYTOR, Q.C.:

Q. And if we could look at page 178, please. This is the corrective action for IHC occurrences, and I believe you drafted this as well. Yes, and this one as well is February 29th, 2008. The policy is, "All issues regarding quality of IHC staining and all corrective actions undertaken must be documented", and there's an indication here that the following steps must be followed to ensure appropriate and adequate documentation of corrective actions; the person identifying the issue must enter the issue into the record

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of quality issues form and corrective actions logbook with the following information, and then the logbook is reviewed at least monthly by the clinical director, IHC laboratory. So Dr. Elms is in that position. Is this information then, the logbook, is that kept in an electronic format?

MS. WADE:

A. No, not that I'm aware of.

CHAYTOR, Q.C.:

Q. So in terms of somebody being able to do an easy search on the information, there's nothing set up to allow that to happen?

MS. WADE:

A. Not that I'm aware of. Most of them, if you seen the corrective action sheets, they're basically a spreadsheet manual format. Some departments do have some electronic--it depends on the expertise in the department to develop them.

CHAYTOR, Q.C.:

Q. And is there anyone in quality or in a quality position involved in the analysing of information such as information that would come out of a corrective actions logbook?

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MS. WADE:

A. Specifically, I can't speak to, other than that in every section, certainly in this section, immunohistochemistry, the people who know the processes would be the best to identify whether or not the corrective action was appropriate, and if there was a trend; however, I would see the role of the quality coordinator to track the trend specifically as a quality assurance indicator, let's say.

CHAYTOR, Q.C.:

Q. And Ms. Wade, you were involved in, or you're listed as the author anyhow on a number of those, under what circumstances were you involved as opposed to, as you were saying earlier, the person who is actually doing the job is the best person to be doing it.

MS. WADE:

A. Right, well to write the policies in most instances, I had somebody with me that said I need a policy on this, so I would write what I perceived to be what the statement was that they had to do, but as far as the procedure, I would need them to tell me the kinds of things that would be on the corrective action log and

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they would have to read that policy and give me feedback because, again, all I could do is write it and the office of responsibility, you can see there the pathology immunohistochemistry section, so they would be giving feedback to say that this is satisfactory or we need another step in our procedure or we should enhance it or take out something. So my role in that was to facilitate them getting their policy written because the support was not there.

CHAYTOR, Q.C.:

Q. Okay, so in terms of a monitoring function to oversee or ensure that these policies and procedures, there's a lot of work gone into them, so in terms of any monitoring in place, to make sure that the staff are in fact following the procedures and the policies, what you're saying is well that's the manager's job. The manager -

MS. WADE:

A. It is the manager's job to put the processes in place to ensure that the policies are being followed and that procedures are being followed. As far as audits, in the case of

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pathology they do have a dedicated person to pull a sheet and do an audit to ensure that it was done for a month, whatever month they're going to look at, random audits.

CHAYTOR, Q.C.:

Q. If we could look at page 127, please, of this document? And these, I understand, to be procedure section and this is the procedure for the routine operation and the Tissue Tek VIP5 and this was issued by Barry Dyer as the pathology manager and drafted, it appears, by Ms. Parnell and this procedure provides instructions for the routine operation of the Tissue Tek VIP5. And then if we look at 129, it's the VIP5 tissue processor reagent preparation and change schedules. And again, it's Mr. Dyer and authored by Catherine Parnell and there's some detail then in terms of the procedure. And then on 131, "troubleshooting for tissue processing, a list of potential processing problems and their possible causes and solutions" is listed out there. And 133 again, issued by Mr. Dyer, drafted this time by Mr. Green and determining specific gravity of alcohols for a tissue

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processor." And so there's a lot of detail on what these all--this on is in May of 2008 and I think all of them are around the early part of 2008. And in that respect, Ms. Wade, most of the policies and procedures that we looked at, a lot of the ones that I brought you to specifically yourself, February, 2008, March, 2008 and some of these are May, the ER/PR testing had resumed in February, 2007 and those policies and procedures weren't completed until at least after the testing had resumed. What in the meantime was in place prior to the testing being allowed to resume in February, 2007?

MS. WADE:

A. I'm sorry, I can't answer that. I certainly had no involvement in -

CHAYTOR, Q.C.:

Q. In February, 2007.

MS. WADE:

A. Yeah.

CHAYTOR, Q.C.:

Q. And are all the policies and procedures now in place and finalized which might relate to ER/PR testing?

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MS. WADE:

A. And again, I'm certainly not the best person to answer to something that's as specific as immunohistochemistry. I do know that there are a lot of policies and procedures in place and again, the living document as you said and there would be changes on a routine regular basis to--so it would never be final.

CHAYTOR, Q.C.:

Q. Yes, I'm just wondering, though, I realize they'll have to be updated, a go-forward basis as things change and new technology comes on or better procedures are determined, but I'm just wondering if everything now is in place that needs to be in place in terms of a policy or a procedure for carrying out hormone receptor testing?

MS. WADE:

A. Again, I don't know.

CHAYTOR, Q.C.:

Q. Okay, and if we could have, please, P-3038? And this is a report, it's quite recent, I believe just last month and it's by a Jamie Simpson on the second page here, field service engineer for Somagen Diagnostics. And it's

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regarding the VIP5 tissue processor and excessive xylene fumes. And are you aware of what caused Mr. Simpson to write this report?

MS. WADE:

A. Yes, I am.

CHAYTOR, Q.C.:

Q. And Mr.--you'll see Mr. Simpson found here ultimately that the charcoal filter had not been replaced since March, 2008. Charcoal filters are recommended to be replaced every 20 processing runs as it becomes saturated with xylene molecules and fume control waters not being replaced daily. There were deficiencies discovered, obviously, in the maintenance of the tissue processors in question and I'm wondering how could that be in light of the policies and procedures that are now in place?

MS. WADE:

A. Again, this is very specific to the histology section of the lab and I certainly can't speak to the installation and training and any of the processes that were brought in, I would not be involved in anything at that level.

CHAYTOR, Q.C.:

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Q. And in terms, though, and it says here, for example, "the lab had two new charcoal filters on hand which were replaced during the warranty inspection. Laboratory was found not following the recommended maintenance for charcoal exchange every 20 runs and replacement of fume control every run." And, for example, even the policy that I took you to that you, yourself had drafted and directing that people refer to the manual. Has there been any inquiries made as to there is a policy is place, there's procedure in place, how is it that it wasn't being followed?

MS. WADE:

A. Well certainly since this there were questions asked because it became known. One of the things that I did to ensure that the procedures get followed appropriately is that the log sheets that they have are accurate. And if the log sheet has any handwriting on it that may deface what the intent is, that could cause someone not to follow a proper process, so I instructed the acting manager to ensure that the document that he has in place is one

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that is not defaced and that staff are aware that they're not to write on it, other than to log in or out that they have done the work.

CHAYTOR, Q.C.:

Q. And who is that, who is the acting manager?

MS. WADE:

A. Mr. Gerry McLean.

CHAYTOR, Q.C.:

Q. He's acting manager for which?

MS. WADE:

A. In pathology.

CHAYTOR, Q.C.:

Q. Where is Mr. Dyer?

MS. WADE:

A. I don't know what other role Mr. Dyer is involved in at this moment.

CHAYTOR, Q.C.:

Q. He also found, "the fume control water is recommended to be changed on a daily or every run basis. The laboratory is therefore advised to revise their SOP to reflect the charcoal and fume control water maintenance for optimal fume management." And I'm wondering have the SOPs been revised to your knowledge?

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MS. WADE:

A. I know that Ms. Rowe is working of revising the tissue processor schedule procedure and anything else related to tissue processing that had to be changed.

CHAYTOR, Q.C.:

Q. And I just want to understand this as an example, not as to how the process would work in terms of--because there has been a lot of processes put in place, obviously, in terms of the quality management program and I'm just wondering how this type of issue could be detected without external people having to come in to detect that there's a problem. So on a go-forward basis, when an issue such as this would arise, how the processes are now in place at Eastern Health that they can be picked up internally so that there's not someone else having to come through the door, an external review, to determine this. What is now in place to ensure that Eastern Health will pick up on these issues internally?

MS. WADE:

A. Again, the managers need to ensure, the manager needs to ensure that the processes for

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the staff are in place. Following that, to ensure that the processes and procedures are followed, there needs to be routine regular audits and those audits would be done by the quality management technologist, as I mentioned before.

CHAYTOR, Q.C.:

Q. And if we could have, please, P-3119? And this is a report which was done by Mr. Bryan Hewlett and Mr. Bill Parks and have you seen this document?

MS. WADE:

A. Yes, I have.

CHAYTOR, Q.C.:

Q. And I just want to bring you to page 6 of this document about the manuals and documentation and he's referring to the new policy and procedure manual that we know as P-2157, "there is evidence of the use of the new procedures at the St. Clare's Mercy site. The staff at this site is aware of the new manual and have been reading and signing off on relevant sections. They have also demonstrated their knowledge through application of several situations during our

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visits to the site. Unfortunately the majority of bench staff at the Health Centre site appears to be uninformed of the existence of this new document. A staff in-service education session regarding reading and signing off of the new relevant manual sections is strongly suggested." And I'm wondering, Ms. Wade, has anything been done to address that?

MS. WADE:

A. I do know that the binder is in the pathology lab and I do know that staff are told and have been told that they have to read it and sign it off. I have been in the lab when that has actually been taking place. I have witnessed staff reading the manual, so I find that statement quite alarming that people don't know.

CHAYTOR, Q.C.:

Q. So you take issue with that statement?

MS. WADE:

A. He said the majority of bench staff and all I can say is that I do know, I've heard the manager state that staff have been told about it and that there is a process for them to do

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it and I have seen it myself, so whoever they spoke to that day might have been just that day, you know, I can't answer the question other than I know that it's supposed to be done.

CHAYTOR, Q.C.:

Q. And Ms. Wade, you told us earlier that the staff would have been asked to sign off, so did you see evidence that the staff had signed off indicating that they had read the manual?

MS. WADE:

A. That they had? I witnessed an employee at the bench with the manual, with the sign off sheet.

CHAYTOR, Q.C.:

Q. And when was that?

MS. WADE:

A. That was right around that day, very close to that because that's why I find it so amazing.

CHAYTOR, Q.C.:

Q. And perhaps after that day?

MS. WADE:

A. It could have been, but I do know, at the quality management committee meeting, perhaps two or three, maybe a couple of months ago,

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Mr. McLean had stated that he has specifically said to staff that, you know, if they come looking for time off, he said, well if you haven't got the policy manual read, you can't go, so you can have your time off after you read it. So I know that it's a very--there is heightened awareness of the need for this.

CHAYTOR, Q.C.:

Q. Particularly in light, I guess of this report?

MS. WADE:

A. Well now certainly, but even before that.

CHAYTOR, Q.C.:

Q. So my question is, Ms. Wade, have you seen any documented evidence that all the staff that need to know about these manuals have signed off indicating that they are aware and are informed?

MS. WADE:

A. I would not see documentation that every employee, no.

CHAYTOR, Q.C.:

Q. Have you seen any documentation to support that they in fact have signed off, that they are aware of the existence -

MS. WADE:

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A. I have seen procedure manuals with the sign off sheet with names on them.
CHAYTOR, Q.C.:
Q. And did you do anything to investigate whether or not it was all the staff or what other staff still need to be informed about the manual and its contents?
MS. WADE:
A. Not specific to this, but I have mentioned to Dr. Howell and Dr. Denic that I certainly see it as my role to go out and educate staff more about quality management and the processes around ensuring that policies and procedures become routine documents for them. And documentation more so than the reading of it, but that you have ensured that your manager knows that you've read it.
CHAYTOR, Q.C.:
Q. And the sign off sheet, is it specific to a particular policy or procedure, because--not the entire manual because I would take it there are certain, there's only certain policies or procedures would pertain to a particular technologist's line of work?
MS. WADE:

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A. That's right. Typically when a new procedure or policy goes out, then a sign off sheet specific to that will be put with it.
CHAYTOR, Q.C.:
Q. So has there been a--this is recommending a staff in-service session regarding the reading and sign off for the new relevant sections is strongly suggested, so is there anything in the works to have that done or to address this?
MS. WADE:
A. I can't speak specifically to pathology, but I know from my perspective it's certainly a highlight that I will be addressing in the overview of quality management for staff.
CHAYTOR, Q.C.:
Q. Yes, and that's one of the things that falls within your mandate?
MS. WADE:
A. Yes, it does.
CHAYTOR, Q.C.:
Q. So do you keep then records of each sign off sheet, so every time -
MS. WADE:
A. The managers retain the document in their

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department for their staff.
CHAYTOR, Q.C.:
Q. Okay, and how long are they maintained then?
MS. WADE:
A. As long as those policies and procedures are in place, they need to retain their documents.
CHAYTOR, Q.C.:
Q. Until it's revised, I take it.
MS. WADE:
A. Until it's revised again, but the old ones, you'd still retain them.
CHAYTOR, Q.C.:
Q. You'd still keep it, okay, yes, all right. And if we could look then further down on the same document, Mr. Hewlett and Mr. Parks notes that "there are sign off sheets at many of the workstations assigning ownership and responsibility for the tasks. Where possible the specific case numbers are also listed. Corrective action record sheets are in use in the block sorting area and in special stains. One of the most important QC checks in histology occurs at the H&E staining bench. The size and blocks should be brought together for comparison after staining to ensure that a

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complete section of the correct tissue is on the slide. This QC check is not being performed and documented at this time." And in terms of any follow up with respect to that particular issue, are you able to say what's been done?
MS. WADE:
A. I know that there are random checks as part of their quality control or quality assurance for that section of the lab, but exactly what their processes are, I'm not aware of it. I do know that Ms. Rowe is well aware of it and will likely do an audit of that area.
CHAYTOR, Q.C.:
Q. And the last paragraph on that page, "there is evidence of troubleshooting with small isolated corrective actions taking place, but an overall QA use of the QC information being produced is not evident. This valuable information is being collected but needs to be used to take corrective actions throughout the process. In order to reduce the occurrence, the QA processing of the QC information, the troubleshooting and the ultimate corrective action need to be assigned to a position in

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the lab." And I had taken you through the corrective actions policy that we referred to a few moments ago, so is there anything that's being done in terms of tightening up this aspect?

MS. WADE:

A. I can't speak specifically to the pathology section.

CHAYTOR, Q.C.:

Q. So what, if any, action is taking place to ensure that the corrective actions information is being correlated, analyzed and then used in a QA processing function?

MS. WADE:

A. Well, certainly if--following this, I would expect that a review of how they're handling corrective action and what they're going to do to improve that process would be undertaken.

CHAYTOR, Q.C.:

Q. See, what I'm reading here, and it appears that the policy is in place. There's a corrective actions policy. There's a log to be kept and Dr. Elms is accumulating, for IHC anyhow, there's that, and I'm just wondering is there--is it a situation where the policy

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is in place but the practice hasn't caught up yet with the policy?

MS. WADE:

A. That could be. Now I read this as the main histology lab and not immunohistochemistry, so I know that Ms. Gamberg, in immunohistochemistry, is involved with corrective actions and processes around that section. So I'm not sure what they are referring to specifically.

CHAYTOR, Q.C.:

Q. Okay, and of course, it would be equally important for histology to have the same -

MS. WADE:

A. Exactly.

CHAYTOR, Q.C.:

Q. - processes in place and procedures and policies in place regarding this.

MS. WADE:

A. Yeah.

CHAYTOR, Q.C.:

Q. And the IHC lab depends on the histology lab to get their portion right along the way.

MS. WADE:

A. Yeah.

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CHAYTOR, Q.C.:

Q. And page ten then of this document, and he refers here to "we also observed pockets of corrective actions being taken and documented based on the results of the QC, but there is some disconnection of the information on its use in total quality improvement of the overall product of the laboratory. There has been a real effort in areas of the laboratory to determine what the current patterns of practice and implementation of these practices. Fixation time and tissue sample thickness is one of the most obvious," he refers to. "The disconnection of the information and the need for corrective action is most likely due to the instability and movement of staff in and out of the histology lab. Staff are being trained on specific benches to get the most productivity out of their efforts without knowledge of the whole process and this has been happening for years and has resulted in inability to use all the information being collected."

And in terms of that being an issue, in terms of your role in the training and the

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ongoing education of the staff, have you given any thought as to how this issue may be corrected?

MS. WADE:

A. Well, if you read the next section, they talk about the new training that's undergoing now with new full-time employees, that they started their training at the front end and will go through the training in a logical sequential format. So that certainly is an enhancement to the training process for those employees. Again, with regard to the issue of temporary staff and the in and out continued flux of staff, unfortunately that has been a problem with the lab program throughout, in that there is not enough redundancy built into staffing levels to ensure that we don't have to bring in a casual employee when someone is off, and that is the world in which we have worked for a number of years. We just have enough people to do the work and then we're challenged even then.

CHAYTOR, Q.C.:

Q. And I take it then you agree with their comments about the importance of that for a

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total quality management? It says here "we firmly believe that if staffing can be stabilized and the right people are recruited and retained in permanent positions, the lab will be able to develop a whole picture approach to total quality management."

MS. WADE:

A. Yes, certainly. You know, we are still challenged by following a collective agreement. We have a lot of issues that, you know, are certainly aspects of the collective agreement that you have to adhere to.

CHAYTOR, Q.C.:

Q. And how does that impede you? How does that--how is that a factor?

MS. WADE:

A. Well, employees have a right to move from job to job. In Eastern Health, one of the policies that was put in place a few years ago to try and stabilize our work force was that we limited the transfer temporarily--the temporary transfer of permanent employees into temporary positions, so that you would limit the amount of training. Because if you can imagine, you have a job that's vacant due to a

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long-term sick leave or a maternity leave, for instance, and that job has to be filled for a year, the training that takes place is quite comprehensive. It takes quite a while to train someone, to bring them up to speed. You may never in a year, and so if you allow staff who are in a permanent job in biochemistry to go temporarily for a year to pathology, while that is good for their professional development, it's not necessarily good for the program at that time, because then you have the training of that person, then you got to backfill of that other one, and then it's a snowball effect. So a number of years ago, we put a policy--well, basically, we followed the collective agreement to the letter in saying that it was the employer's prerogative basically to say whether or not we would allow this to happen. So what we've done is limited the ability to permanent employees to move temporarily. So that helped to stabilize us to some degree.

But in pathology, we have seen an increase of staffing for various reasons. We've seen retirement, so turnover inherent in

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that, and we have summer breaks and vacations whereby you fill with casual staff and temporary employees. So we still are not able to stabilize our work force, and then you are also bound by the collective agreement, seniority clauses and various aspects of that. So we have--as managers, there are challenges with maintaining a stable work force because if somebody doesn't like where they are or if for whatever reason of professional development they choose to go learn something else, we don't really have any way of telling them "no, you can't go" if there is a vacancy and they're trained and qualified at the basic level.

CHAYTOR, Q.C.:

Q. And in terms of someone to be trained and qualified, I asked you earlier today, in particular for a job in the IHC lab, the training and qualifications, is it any different than what would be required anywhere else within the pathology lab?

MS. WADE:

A. Well, typically the immunohistochemistry is a section of pathology. So the people who are

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working there have experience of years in pathology division itself. So they know--they have experience in the front end, the whole pre-analysis piece and the microtomy and the staining, the embedding and the cutting, all of those processes prior to immunohistochemistry.

CHAYTOR, Q.C.:

Q. If we could have, please, P-3598?

THE COMMISSIONER:

Q. So are you saying that problem does not exist in IHC?

MS. WADE:

A. Does not?

THE COMMISSIONER:

Q. Yes.

MS. WADE:

A. I can't say that it does not exist. It's just that the manager does have the ability to take--they would take--if a position came up in immunohistochemistry, they would expect that they would fill it with someone with experience at least in pathology. They wouldn't just take somebody out of another section, because the manager would reorganize

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their staffing so that the most experienced person goes where they're required most.

THE COMMISSIONER:

Q. So it's done on the basis -

MS. WADE:

A. And they would bring a new person -

THE COMMISSIONER:

Q. - of IHC being part of pathology and therefore you switch around within pathology?

MS. WADE:

A. You would move, yes.

THE COMMISSIONER:

Q. You don't actually have to go outside of pathology to find somebody?

MS. WADE:

A. Right, right, yeah.

THE COMMISSIONER:

Q. All right.

CHAYTOR, Q.C.:

Q. And Ms. Wade, do you know what this document is?

MS. WADE:

A. I believe it's some external proficiency testing. I saw it in a presentation, but as for interpretation, I really can't interpret

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it.

CHAYTOR, Q.C.:

Q. Okay. It appears down at the bottom, there's a small key and the red stands for positive, white is negative and then yellow, sample unsuitable for evaluation, i.e. fallen off or no tumor. Is this Eastern Health's data, do you know?

MR. SIMMONS:

Q. These are ones that were identified, I think-- not these particular documents, but Ms. Torlakovic spoke about these as coming from the CIQC.

CHAYTOR, Q.C.:

Q. Okay, great, thank you. Thank you, Ms. Wade. Those are my questions. Perhaps some of my colleagues will have questions for you too.

MS. WADE:

A. Thank you.

THE COMMISSIONER:

Q. Mr. Pritchard?

MR. PRITCHARD:

Q. Thank you, Commissioner. I have no questions. Thank you for your evidence, Ms. Wade.

MS. HENNEBURY:

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Q. I have no questions.

THE COMMISSIONER:

Q. You've been abandoned by Mr. Browne, have you?

MS. HENNEBURY:

Q. I have.

THE COMMISSIONER:

Q. Mr. Pritchett?

MR. PRITCHETT:

Q. No questions, Commissioner, thank you.

THE COMMISSIONER:

Q. Ms. Newbury?

MS. LYNN WADE, EXAMINATION BY MS. JENNIFER NEWBURY

MS. NEWBURY:

Q. Just a couple. Good afternoon, Ms. Wade. My name is Jennifer Newbury and I represent the Newfoundland and Labrador division of the Canadian Cancer Society, and I just wanted to ask for some clarification on a reference you made this afternoon to ISO. I think the standard was 15189?

MS. WADE:

A. Um-hm.

MS. NEWBURY:

Q. Okay, and can you advise if there are any current plans to obtain ISO certification

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pursuant to that particular ISO standard?

MS. WADE:

A. The Accreditation Canada, accreditation for labs, which is new, was mandatory for all health care organizations in Canada that are not currently accredited otherwise -

MS. NEWBURY:

Q. Okay.

MS. WADE:

A. - for the lab, the ISO--the Accreditation Canada Lab Standards is done in collaboration with the Canadian Standards Association which oversees the Canadian version of the ISO 15189.

MS. NEWBURY:

Q. Okay. I thought I had heard your evidence that accreditation wouldn't be necessary if the lab is determined to meet the ISO 15189 standards. Did I understand that?

MS. WADE:

A. If the lab were to be accredited by some body that was ISO 1--following 15189 standards, then they would not be required to go through the Accreditation Canada standard because they've already met them. So there are

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provinces in the country that have additional accreditation processes.

MS. NEWBURY:

Q. Right, such as Ontario, I think.

MS. WADE:

A. That's right.

MS. NEWBURY:

Q. One of the examples there, and just so I'm clear, I want to be clear, because I understand that there are a number of different types of organizations and groups that can certify or accredit an organization such as a health care organization to meet the standards of ISO, such as ISO 15189. Is it your understanding that the Accreditation Canada organization will actually come to the lab and certify that it has met all of those stringent requirements or whatever the requirements are of ISO 15189?

MS. WADE:

A. Accreditation Canada is using those standards in their -

MS. NEWBURY:

Q. Okay.

MS. WADE:

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A. - used them in their standard development.

MS. NEWBURY:

Q. Okay.

MS. WADE:

A. I do know that QMPLS in Ontario specifically uses 15189 and their audit process follows the 15189 standard.

MS. NEWBURY:

Q. Okay. So your understanding then is that Accreditation Canada has taken, I guess, as its background information, the ISO standards?

MS. WADE:

A. That's right.

MS. NEWBURY:

Q. And whether or not it's identical, you're not clear. Is that correct, or do you think it is identical to the ISO standards?

MS. WADE:

A. I don't think it's identical, but you know, I haven't read--I've read the documents, but I haven't done a real correlation.

MS. NEWBURY:

Q. Okay, and it's your understanding that the accreditation has been done in accordance with whatever Accreditation Canada has decided

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would be appropriate?

MS. WADE:

A. Well, in our labs, at this point in time, we went through the pilot accreditation in 2007, which was the last year that the pilot was undertaken for Accreditation Canada. So now, for our next accreditation, our laboratories will have to meet those standards in order for Eastern Health to become a certified--an accredited entity.

MS. NEWBURY:

Q. Okay. So hopefully at the end of that, when it's no longer just a pilot project and -

MS. WADE:

A. Exactly, it's no longer a pilot.

MS. NEWBURY:

Q. - then you meet standards that are perhaps similar to, if not identical to, the ISO standards?

MS. WADE:

A. That's right.

MS. NEWBURY:

Q. Okay. I understand that the College of American Pathologists actually has its own accreditation program which seeks to certify a

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health organization as having met those particular standards, the ISO 15189, and I understand that the College of American Pathologists has some quality programs that Eastern Health participates in. Have you ever heard any discussion about perhaps relying upon the College of American Pathologists program to certify according to ISO 15189?

MS. WADE:

A. I have not heard of discussions around the CAP in particular.

MS. NEWBURY:

Q. Okay.

MS. WADE:

A. Accreditation. However, we have had discussions with QMPLS just to get a sense of their processes and what kind of service they offer, with a view to perhaps in the future going through that kind of a process, whether it's QMPLS or CAP or some other provincial scheme, but that would have to come as a directive, I think, from the provincial government that they would recognize that that accreditation would be satisfactory for labs in our province.

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MS. NEWBURY:
Q. Okay, and just--I just want to clarify what exactly that particular standard relates to, and I just did a quick website search and found this description. I just wanted you to confirm whether or not that that seems consistent with your understanding of it, and it basically--it's the ISO 15189 for the year 2003. I think it's been updated since, but for 2003 it basically describes it as being "medical laboratories particular requirements for quality and competence."
MS. WADE:
A. That's right.
MS. NEWBURY:
Q. And it specifies "the quality management system requirements particular to medical laboratories."
MS. WADE:
A. That's right.
MS. NEWBURY:
Q. That's generally it?
MS. WADE:
A. That is, yes.
MS. NEWBURY:

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Q. Okay. Thank you, and I just have one other quick question in relation to the occurrence reporting. If I could bring up Exhibit P-3620, please? And I'm not sure now if you--okay, this is a document, I'm not sure if you answered any questions on that today. I may have missed it if you have, and this is to program directors from Janet Laidley, Quality and Clinical Safety Leaders. Are you familiar with this particular document?
MS. WADE:
A. Wait now, I'll move it along there.
MS. NEWBURY:
Q. And you can go through it with the mouse.
MS. WADE:
A. Yes.
MS. NEWBURY:
Q. Okay, and what policy of Eastern Health is this occurrence reporting document produced pursuant to, I guess?
MS. WADE:
A. I would think it would be the quality and risk framework.
MS. NEWBURY:
Q. Okay. And is that a corporate wide -

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MS. WADE:
A. That's a--Eastern Health has a quality and risk framework, yes.
MS. NEWBURY:
Q. Okay.
MS. WADE:
A. But in the past, the Health Care Corporation of St. John's had these kinds of reports.
MS. NEWBURY:
Q. Okay. The legacy organizations. And I note on page four of this particular document and I'll just--there we go--page four here on the bottom, it has a division for pathology. Let's try page five. Yes, here we go. So, the division and it has the lab pathology and then there are a number of different entries for reports. And I'm just wondering, on the left hand side, for example, there's, in a bold print, under treatment/test specimen, there's a description that's labelled specimen and then there are a number of entries below that. And if we go over onto the next page, actually perhaps--this is a different department, but I'm going to go back to page four because I think it has some interesting

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descriptions here. It has descriptions such as "lost specimen", here in bold print. And then down towards the bottom of the page, "analysis not done". Are those standard types of descriptions for the purposes of occurrence reporting?
MS. WADE:
A. Yes, on the occurrence reports that we use now, it's a two or three copy report and there are sections for various kinds of incidents or occurrences. And one of them, under specimen test results would be analysis not done, wrong kind of sample, might be various things. And in some instances, the lab will fill what was a little more appropriate for its documents.
MS. NEWBURY:
Q. So, it can elaborate on it, but basically -
MS. WADE:
A. Yes, that's right -
MS. NEWBURY:
Q. - categories, types of occurrences are given.
MS. WADE:
A. Yes, and dealing with specimens. So, the document is a bit cumbersome at this point, but Eastern Health is in the process of

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rolling out a new, piloting a new electronic occurrence management system which will enable much better tracking, much better documentation in compliance with documents. It will be easier to use at the touch of a mouse and a PC.

MS. NEWBURY:

Q. Yes. And Ms. Predham has given us some evidence, I think, on that plan.

MS. WADE:

A. Right.

MS. NEWBURY:

Q. And I'm just thinking, up until that new system is launched, are there any headings or categories that would cover off something like a test procedure that was done using an incorrect dilution or they were missing controls in the particular test procedure.

MS. WADE:

A. Not on the form in any checklist, but what would happen is there would be a narrative, descriptive entered in the narrative section that would highlight the specific issue.

MS. NEWBURY:

Q. So, would that come under--I notice there that

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there's a couple of headings in bold that just says "other" -

MS. WADE:

A. Well, down in Quality and Risk, they may chose to collate it as a specimen issue under other or it may be something that they could flag it to more specifically.

MS. NEWBURY:

Q. Okay, there might be more general category.

MS. WADE:

A. Yes.

MS. NEWBURY:

Q. And I guess I asked the question because it seems that a lot of these, just looking at this report in its entirety, there seems to be a lot that seem more like administrative type errors, like missing labels or things like that, as opposed to the technical, something like using an improper dilution or something more technical in nature. And I was wondering if it was intended that that would be covered off in this type of a report here.

MS. WADE:

A. Well, you see, most--the technical kinds of things would often be dealt with under the

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corrective action logs and what they would do. So, for instance, a technologist is running quality controls on a major analyzer in a lab and noted a quality control failure of one particular test, analyte, before they would test any patient, they would go through a series of steps to determine what the problem was and they would document that. That's part of the day-to-day operations of the lab. The occurrence report would probably be used if it got outside of the lab and there were some adverse event or opportunity for an adverse event to a patient, then we would document that as something that got outside of our control and we had to backtrack now and start to see how that happened.

MS. NEWBURY:

Q. So, just for clarification, if a lab report was generated even though there was an incorrect dilution used, for example, in a test procedure, and then the test had to be re-done, would you expect that sort of situation to be reflected in this kind of a document, the second quarter occurrences summary?

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MS. WADE:

A. If a report left a lab, yes, and it was picked up by some clinician and was identified--should be identified as an occurrence.

MS. NEWBURY:

Q. And you said a potential for an adverse event, is that a near miss?

MS. WADE:

A. It could be a near miss.

MS. NEWBURY:

Q. Okay. Thank you very much. Those are all my questions.

THE COMMISSIONER:

Q. Thank you. I saw Mr. Crosbie here a moment ago.

MS. NEWBURY:

Q. Mr. Crosbie advises that he has no questions.

THE COMMISSIONER:

Q. Okay, thank you. Mr. Simmons.

MS. LYNN WADE, EXAMINATION BY MR. DANIEL SIMMONS

MR. SIMMONS:

Q. Ms. Wade, we'll get you out of here before 6:00. I just have -

THE COMMISSIONER:

Q. Promises, promises, Mr. Simmons.

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MR. SIMMONS:
Q. - very specific things and they're very direct and very short. Ms. Chaytor asked you if you were able to say whether all the policies and procedures relating to the ER and PR testing were now done and in place and I understood you to say that you couldn't necessarily say that. My question is, are you aware of any policy and procedures for ER and PR testing that are outstanding? Are there any that you know of that are outstanding, that haven't been addressed?
MS. WADE:
A. Again, I don't know.
MR. SIMMONS:
Q. There's none that you know of that are outstanding.
MS. WADE:
A. Not that I'm aware of. I know that certainly IHC gets high priority in the pathology lab, so -
MR. SIMMONS:
Q. Ms. Chaytor showed you one of the reports from UK NEQAS, I think the one from this last summer, can I have P-3595, please. First of

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all, do you recognize what this particular report is, this document?
MS. WADE:
A. Yes, I do.
MR. SIMMONS:
Q. And what is it?
MS. WADE:
A. Basically it's a summary of some indicators for anatomic pathology for 2007/2008. It just demonstrates the kinds of some random reviews, correlations and quality assurance activities that are undertaken in pathology.
MR. SIMMONS:
Q. Who is it prepared by and where does it go?
MS. WADE:
A. Some of the indicators such as the cases referred for Dynacare, other--those very specific pathology ones would have been prepared by Ms. Catherine Parnell at that time and the table, I put it together in a table format.
MR. SIMMONS:
Q. And the report is prepared for presentation where or to whom?
MS. WADE:

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A. We will be preparing and we do prepare them for Dr. Howell to present as a, at the portfolio committee and then also for the regional quality council annually.
MR. SIMMONS:
Q. Can I have page seven please, there's a table here, it's under a heading, "United Kingdom National External Quality Assessment Scheme UK NEQAS", results for ER and PR. And is this a table listing the results for the four rounds of proficiency testing before the one that you looked at earlier?
MS. WADE:
A. Right.
MR. SIMMONS:
Q. And if we look at this, it appears that the ER scores out of a maximum of 20 were 16 in 2005; 16 in 2006; 20 for the second one in 2006; and 18 in 2007.
MS. WADE:
A. That's right.
MR. SIMMONS:
Q. And for the PR they were 16, 14 and 16.
MS. WADE:
A. That's right.

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MR. SIMMONS:
Q. Okay. You answered a fair number of questions on the form that was filled out for QMPLS before they came in and did their review in December of 2007. And you had experience with other accreditations and so on, as well.
MS. WADE:
A. Yes.
MR. SIMMONS:
Q. Is that a common type of approach for accreditors to us, to have certain information prepared or forms filled out and submitted before they -
MS. WADE:
A. Yeah, that's right. Certainly, when I was doing--I was doing the same kind of form for the accreditation Canada pilot, just gathering information about the organization so that the surveyors will have background about the organization, the kind of testing procedures that are handled.
MR. SIMMONS:
Q. And are you able to tell me how much accreditors or reviewers normally use those forms, whether they accept those things at

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face value or whether they do any of their own verification to check the things that are -

MS. WADE:

A. Well, when they come in to the organization, they look for evidence based on the standards and kinds of audits that they are doing. So, they would look for evidence that the procedures were there or any indicators that were relevant, they would look for.

MR. SIMMONS:

Q. So, in your experience, when they come in, they will actually look to see if the answers they've been given can be backed up by the evidence that they see when they get there.

MS. WADE:

A. Exactly.

MR. SIMMONS:

Q. Okay. Now, I thought I had one more, but it looks like I don't. Thank you very much. That's all I have.

MS. WADE:

A. Thank you.

THE COMMISSIONER:

Q. You kept your promise, Mr. Simmons. Anything arising, Ms. Chaytor?

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CHAYTOR, Q.C.:

Q. Nothing arising, Commissioner.

THE COMMISSIONER:

Q. Why are you on your feet, Mr. Coffey?

COFFEY, Q.C.:

Q. Commissioner--I'm sorry, Ms. Wade, this has nothing at all to do with yourself. Commissioner, I did want, as it just turns out, Dr. Denic happens to be in the room, the back of the room. I did want to advise you that the matter of the, if you recall, there was a discussion about the ethics consult meeting of June '06 and whether or not Dr. Denic might be asked a further question concerning one aspect of what was said, I believe, in the meeting.

THE COMMISSIONER:

Q. Um-hm.

COFFEY, Q.C.:

Q. In any case, I will not be--just to advise you, Commissioner, we will not be pursuing that further.

THE COMMISSIONER:

Q. So, I can tell Ms. Wade that she's been released, with my appreciation for your having

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come and contributed to us. And Dr. Denic, it appears that you will not be called back.

DR. DENIC:

Q. (Inaudible).

THE COMMISSIONER:

Q. Two with one blow this after. Counsel, however, the good news for you is that apparently administration has an envelope for you before you leave today. Your up again, Mr. Coffey?

COFFEY, Q.C.:

Q. No, no.

THE COMMISSIONER:

Q. Thank you again, Ms. Wade.

MS. WADE:

A. Thank you.

THE COMMISSIONER:

Q. 9:30 in the morning.

Upon conclusion at 5:55 p.m.

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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 27th 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 27th day of October, A.D., 2008

Judy Moss