

<p style="text-align: center;">COMMISSION OF INQUIRY ON HORMONE RECEPTOR TESTING</p> <p style="text-align: center;">BEFORE THE HONOURABLE JUSTICE CAMERON - COMMISSIONER</p> <p style="text-align: center;">October 27, 2008</p> <p>Appearances:</p> <p>Bernard Coffey, Q.C. Commission Co-counsel Sandra Chaytor, Q.C. Commission Co-counsel</p> <p>Rolf Pritchard. Her Majesty in Right of NL</p> <p>Peter Browne, Q.C./Jane Hennebury . . . Doctors Kara Laing et al</p> <p>Daniel Simmons Eastern Regional Integrated Health Authority</p> <p>Chesley Crosbie, Q.C... Members of the Breast Cancer Testing Class Action</p> <p>Jennifer Newbury Canadian Cancer Society (NL Division)</p> <p>Blair Pritchett. Central, Western and Labrador-Grenfell Regional Integrated Health Authorities</p>	<p style="text-align: center;">LIST OF EXHIBITS</p> <p>EXHIBITS P-3630 through P-3636 Pg. 7</p> <p>EXHIBITS P-3585 THROUGH P-3629 Pg. 98</p> <p>EXHIBITS P-3637 THROUGH P-3644 Pg. 98</p> <p>EXHIBITS P-3649 THROUGH P-3673 Pg. 98</p> <p>EXHIBITS P-3674 AND P-3675 Pg. 219</p>
<p style="text-align: center;">TABLE OF CONTENTS</p> <p>DR. CLIVE WELLS - AFFIRMED - VIA VIDEOCONFERENCE</p> <p>Examination by Bernard Coffey, Q.C. Pgs. 6 - 57 Examination by Peter Browne, Q.C. Pgs. 57 - 63 Examination by Jennifer Newbury Pgs. 63 - 66 Examination by Chesley Crosbie, Q.C. Pgs. 66 - 87 Re-examination by Bernard Coffey, Q.C. Pgs. 87 - 90 Examination by Madam Commissioner Pgs. 90 - 94 Re-examination by Bernard Coffey, Q.C. Pgs. 94 - 98</p> <p>MS. LYNN WADE - SWORN</p> <p>Examination by Sandra Chaytor, Q.C. Pgs. 98 - 307 Examination by Jennifer Newbury Pgs. 307 - 321 Examination by Daniel Simmons Pgs. 321 - 325</p> <p>Discussion Pgs. 325 - 327</p> <p>Certificate</p>	<p style="text-align: right;">Page 4</p> <p>1 OCTOBER 27, 2008</p> <p>2 THE COMMISSIONER:</p> <p>3 Q. Please be seated. So we have contact, do we,</p> <p>4 Mr. Coffey?</p> <p>5 COFFEY, Q.C.:</p> <p>6 Q. Actually, Dr. Clive Wells was just seated</p> <p>7 there. I presume he's probably gone out of</p> <p>8 the room for a moment.</p> <p>9 THE COMMISSIONER:</p> <p>10 Q. Okay.</p> <p>11 COFFEY, Q.C.:</p> <p>12 Q. Considering that he's anticipating possibly</p> <p>13 sitting for three hours straight, so -</p> <p>14 THE COMMISSIONER:</p> <p>15 Q. Good idea, in that case. All right. We'll</p> <p>16 just wait for his return.</p> <p>17 COFFEY, Q.C.:</p> <p>18 Q. What we'll do, Commissioner, to utilize the</p> <p>19 time for now, whenever we finish with Dr.</p> <p>20 Wells, I'm going to suggest that we take the</p> <p>21 lunch break at that point, and then I</p> <p>22 understand that Ms. Wade will be following</p> <p>23 then.</p> <p>24 THE COMMISSIONER:</p> <p>25 Q. Uh-hm.</p>

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1 COFFEY, Q.C.:

2 Q. And we're going to continue on then until past

3 what is the normal scheduled break time. You

4 told counsel that last week.

5 THE COMMISSIONER:

6 Q. You mean, at the end of the day break time?

7 COFFEY, Q.C.:

8 Q. Yes, the end of the day break.

9 THE COMMISSIONER:

10 Q. Okay. Yes, I think that was clear from last

11 week and since -

12 COFFEY, Q.C.:

13 Q. Mr. Simmons has advised Ms. Chaytor and I

14 that, in fact, Ms. Wade will be here later on,

15 actually in the morning too.

16 THE COMMISSIONER:

17 Q. Okay.

18 COFFEY, Q.C.:

19 Q. So she'll be here.

20 THE COMMISSIONER:

21 Q. Well, if -

22 MR. SIMMONS:

23 Q. In fact, if this goes quicker than

24 anticipated, she's available to start -

25 COFFEY, Q.C.:

Page 6

1 Q. Even before then.

2 MR. SIMMONS:

3 Q. Before then.

4 THE COMMISSIONER:

5 Q. Okay then, all right. Well, we'll assess it

6 when we're through with this particular

7 witness. After that, we'll be happy. The

8 picture quality is very nice, in any event,

9 very nice blue chairs.

10 COFFEY, Q.C.:

11 Q. Good morning, doctor. Actually, good

12 afternoon where you are, and you and I have,

13 of course, spoken. I'm Bernard Coffey, but

14 this is the first time we've seen each other.

15 I have the Registrar here now and we're

16 already convened, so the Registrar is going to

17 have you affirmed.

18 DR. WELLS:

19 A. Okay.

20 DR. CLIVE WELLS (AFFIRMED) EXAMINATION BY BERNARD COFFEY,

21 Q.C. - VIA VIDEOCONFERENCE

22 REGISTRAR:

23 Q. Would you please state and spell your complete

24 name for the Commissioner?

25 DR. WELLS:

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1 A. Clive Alan Wells, that's C-L-I-V-E A-L-A-N

2 W-E-L-L-S.

3 REGISTRAR:

4 Q. Thank you.

5 COFFEY, Q.C.:

6 Q. Doctor, I'm going to ask the Commissioner to

7 enter a couple of exhibits. If you'll just

8 bear with me for a moment. Commissioner, they

9 are exhibits P-3630, 3631, 3632, 3633, 3634,

10 3635 and 3636.

11 THE COMMISSIONER:

12 Q. Entered.

13 EXHIBITS ENTERED AND MARKED P-3630 through P-3636

14 COFFEY, Q.C.:

15 Q. Now, doctor, you provided the Commission with

16 a copy of your summary curriculum vitae and

17 your detailed curriculum vitae this morning?

18 DR. WELLS:

19 A. Yes, that's correct.

20 COFFEY, Q.C.:

21 Q. And, doctor, would you please outline for the

22 Commissioner, give us kind of a summary of

23 your educational and professional background?

24 DR. WELLS:

25 A. Well, I was educated as a doctor at Cambridge

Page 8

1 University, and then trained as a pathologist

2 initially in Oxford, and then subsequently

3 took up a post which I still hold to this day

4 at Sir Bartholomew Hospital, which is now

5 Bart's and the London NHS Trust.

6 COFFEY, Q.C.:

7 Q. Doctor, what is your position there?

8 DR. WELLS:

9 A. I'm a consultant histopathologist with a

10 special responsible for breast pathology.

11 COFFEY, Q.C.:

12 Q. And, doctor, you've been involved then as a--

13 in particular in breast pathology for how

14 long?

15 DR. WELLS:

16 A. Since, I guess, about 1984.

17 COFFEY, Q.C.:

18 Q. And, doctor, I understand as well that you're

19 involved with a european group?

20 DR. WELLS:

21 A. Yes, this is a European Commission funded body

22 which oversees a number of aspects of

23 pathology as related to breast cancer

24 screening in Europe. It also advises on

25 quality issues and is involved in writing

Page 9

1 guidelines.

2 COFFEY, Q.C.:

3 Q. Doctor, I understand as well that you're

4 involved with the Royal College of

5 Pathologists in relation to breast disease?

6 DR. WELLS:

7 A. Yes, in the National Coordinating Committee

8 which is actually a breast screening funded

9 body in the health service, but has the

10 additional attachment to the Royal College of

11 Pathologists, that's correct.

12 COFFEY, Q.C.:

13 Q. Now, doctor, could you please outline for the

14 Commissioner, give her some sense from a

15 European perspective, in particular the UK,

16 during your career in relation to pathology

17 generally in a particular breast pathology,

18 how quality assurance has evolved over the

19 years since the mid '80s?

20 DR. WELLS:

21 A. Right, when the NHS Breastscreening Program

22 was set up with a quality aspect to it,

23 because it was realized that the quality of

24 pathological diagnosis is critical to the

25 quality of the service, and so quality

Page 10

1 assurance was built into it. I think probably

2 not initially right at the beginning in 1988,

3 but certainly in 1989/1990 quality assurance

4 was being set up.

5 COFFEY, Q.C.:

6 Q. And -

7 DR. WELLS:

8 A. And--sorry.

9 COFFEY, Q.C.:

10 Q. Doctor, we've heard--the Commission has heard

11 a lot of references or quite a number of

12 references to UK NEQAS.

13 DR. WELLS:

14 A. Yes, this is a body which is run from one of

15 the London hospitals which is a non-for-profit

16 company which operates to oversee the quality

17 of immunocytochemistry staining amongst other

18 things.

19 COFFEY, Q.C.:

20 Q. And I take it, doctor, that some of UK NEQAS

21 work does involve aspects of breast pathology?

22 DR. WELLS:

23 A. Indeed. They run a number of modules, as they

24 call them, for various technical aspects,

25 estrogen/progesterone receptor, HER2 staining,

Page 11

1 and also FISH for HER2. That's Fluorescent In

2 Situ Hybridization.

3 COFFEY, Q.C.:

4 Q. Doctor, can you tell us, please, about from

5 your perspective in terms of the establishment

6 of UK NEQAS, the time it was established, what

7 perceived need was there that had to be

8 addressed through UK NEQAS? What was the

9 reason?

10 DR. WELLS:

11 A. That's a very good question. I'm not sure

12 because I'm not directly involved with UK

13 NEQAS, but it was recognized that the quality

14 of immunostaining in general was critical, I

15 think, when it--when it was introduced

16 routinely into laboratories, and certainly

17 there has been variable quality in the past.

18 So I guess that that was the main driver for

19 this.

20 COFFEY, Q.C.:

21 Q. Now -

22 DR. WELLS:

23 A. But the driver, I think, for the receptor

24 estimations has been that there are

25 laboratories that have not been performing as

Page 12

1 well as other laboratories in the UK, and so

2 now it's a mandatory system.

3 COFFEY, Q.C.:

4 Q. And, doctor, when did it become mandatory in

5 the UK, do you know?

6 DR. WELLS:

7 A. I'm not sure of the exact date, but it's

8 certainly been for some years now.

9 COFFEY, Q.C.:

10 Q. Doctor, we have what is here Exhibit P-3635,

11 which is a document which involves excerpts

12 from the NHS Breastscreening Programs, the

13 Third Edition of it, Guidelines for Pathology

14 Reporting in Breast Cancer Screening, and a

15 Second Edition of the Royal College of

16 Pathologists, Minimum Dataset for Breast

17 Cancer Histopathology.

18 DR. WELLS:

19 A. Yes, I have it here.

20 COFFEY, Q.C.:

21 Q. Now, doctor, I understand at least this

22 version that we have was published in 2005.

23 It's on the -

24 DR. WELLS:

25 A. Yeah, that's correct.

Page 13

1 COFFEY, Q.C.:

2 Q. Doctor, could you tell us, please, as you were

3 involved as a consultant, amongst other

4 doctors in relation to this, why there is a

5 need for such--perceived to be a need for such

6 a document to be published?

7 DR. WELLS:

8 A. This was commissioned by the NHS

9 Breastscreening Program because of the

10 perceived need for the pathology of the

11 screening program to be as high a quality as

12 possible. The success of the Breastscreening

13 Program, I think, depends on the quality of

14 the component parts and pathology is an

15 essential one.

16 COFFEY, Q.C.:

17 Q. And -

18 DR. WELLS:

19 A. So this is actually an update of a previous

20 pathology reporting booklet which was brought

21 out, I think, in 1990 or around that time.

22 COFFEY, Q.C.:

23 Q. So it goes back well over a decade?

24 DR. WELLS:

25 A. Yes.

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1 COFFEY, Q.C.:

2 Q. Doctor, if you'll look at the Table of

3 Contents which is the Roman Numeral III there

4 at the bottom of the page -

5 DR. WELLS:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. There are--there's a description of the

9 writing group, and there's a Preface?

10 DR. WELLS:

11 A. Yes.

12 COFFEY, Q.C.:

13 Q. And then there's a whole listing of specimen

14 handling, surgical handling, laboratory

15 handling, diagnostic localization biopsies,

16 therapeutic wide local excisions, re-excision

17 specimens, mastectomy specimens, pathological

18 examinations of lymph nodes, NHSBSP

19 histopathology reporting form, minimum dataset

20 for breast cancer histopathology, recording

21 basic information, and then it goes on at some

22 length, I mean, it just kind of goes on and

23 on, including to--in particular here--I'm just

24 going to go to, if I could, paragraph 21 or

25 section 21 which deals with--chapter 21 which

Page 15

1 deals with steroid receptors at page 86 and

2 87, and I'll be taking you to that, but as

3 well--yes, as well, if I could, when you look

4 at the appendices -

5 DR. WELLS:

6 A. Yes.

7 COFFEY, Q.C.:

8 Q. I apologize, I skipped past it there, here

9 locally, and under the appendices there is

10 Appendix 3, synoptic reports, and I'm going to

11 ask you some questions about that, and

12 Appendix 7, quality assurance for estrogen

13 receptors and progesterone receptors.

14 DR. WELLS:

15 A. Yes.

16 COFFEY, Q.C.:

17 Q. Doctor, I take it then that this is a fairly

18 comprehensive document, at least as of 2005?

19 DR. WELLS:

20 A. Yes, it was written to try to give

21 pathologists guidance on how they should do

22 various techniques and what they should do in

23 their daily practice of reporting breast

24 disease.

25 COFFEY, Q.C.:

Page 16

1 Q. Doctor, you did of course just then use the

2 word "guidance", and I'm going to take you to

3 the Preface, which is at page one. I'm not

4 going to--there's an opening paragraph, and

5 the second paragraph in the middle of the page

6 says, "These guidelines aim to encourage the

7 use of common terminology and definitions of

8 breast disease and to standardize methods of

9 classification of breast cancer", and -

10 DR. WELLS:

11 A. That's correct.

12 COFFEY, Q.C.:

13 Q. And then when we go to the next page, the

14 first full paragraph begins by saying, "This

15 document also serves to provide guidance for

16 pathologists when participating in the UK

17 external quality assurance scheme for breast

18 screening histopathology". I wanted to ask

19 you about the usage of the word "guidance" in

20 this context.

21 DR. WELLS:

22 A. Yes, it's--it's not--it's not an absolutely

23 mandatory document, but it is--it is regarded

24 as being guidance for pathologists in how they

25 should participate in the various programs and

Page 17

1 how they should also report breast disease.
 2 We don't want to absolutely discourage
 3 innovative things by saying, well, they're not
 4 in the guidelines, therefore, you can't do
 5 them. That's why these are guidelines and not
 6 mandatory requirements.
 7 COFFEY, Q.C.:
 8 Q. Doctor, if I could ask you first of all to, in
 9 fact, go to Appendix 3, which is at page 103,
 10 and locally it's page 17 in the exhibit here.
 11 It's page 17 in the exhibit itself.
 12 DR. WELLS:
 13 A. Right, I have it, yes, synoptic reports.
 14 COFFEY, Q.C.:
 15 Q. Appendix 3, synoptic reports, "The use of
 16 synoptic reports is helpful as these may act
 17 as aide-memoire for a complete dataset, an
 18 example format", and "example" is in bold
 19 print here, is shown on the next page,
 20 "Alternatively adaptations of the NHSBSP or
 21 the Royal College of Pathologists minimum
 22 dataset forms can be used". Now, Doctor, from
 23 your perspective, what is the purpose of
 24 synoptic reports, what do they achieve or
 25 potentially achieve?

Page 18

1 DR. WELLS:
 2 A. Well, some people use them as an aid-memoire
 3 for making sure that they put in all the
 4 various important things which we have to put
 5 into the breast screening dataset into the
 6 breast screening computer, and that is used
 7 for audits and quality assurance purposes, and
 8 also for recording what the problem for the
 9 actual woman is.
 10 COFFEY, Q.C.:
 11 Q. Doctor, does -
 12 DR. WELLS:
 13 A. Many pathologist use -
 14 COFFEY, Q.C.:
 15 Q. Go ahead, doctor.
 16 DR. WELLS:
 17 A. Text reports rather than synoptic reports.
 18 COFFEY, Q.C.:
 19 Q. Is an advantage of the usage of a synoptic
 20 report that the person to whom it is sent, for
 21 example, the treating physician, that he or
 22 she knows exactly because of familiarity with
 23 the form where to look for particular results?
 24 DR. WELLS:
 25 A. That is one use of them. Not everybody uses

Page 19

1 them, but everybody tends to put a conclusion
 2 with the summary report at the end of the
 3 report.
 4 COFFEY, Q.C.:
 5 Q. Now Doctor, if we could go then to paragraph
 6 or not paragraph, I suppose, chapter 21, which
 7 is at pages--begins at page 86 of the original
 8 document. It's page 13 of the exhibit.
 9 DR. WELLS:
 10 A. Yes.
 11 COFFEY, Q.C.:
 12 Q. And this is, of course, the section of the
 13 document dealing with steroid receptors, which
 14 is, I understand to be estrogen and
 15 progesterone receptors. Doctor, there is--I
 16 just want to take you through, just a little
 17 bit of this. It says recommendation--
 18 paragraph 21.1, recommendations for steroid
 19 receptor testing, and just spells out really
 20 what steroid receptor testing is meant to
 21 accomplish, and it concludes by saying "these
 22 guidelines have been formulated to give
 23 advice," presumably in that regard, and then
 24 21.2, there's a heading principles, and then
 25 there's a subparagraph fixation, subparagraph

Page 20

1 methods, subparagraph controls, and then
 2 there's a larger paragraph, 21.3 scoring, 21.4
 3 ductal carcinoma in situ. Testing predictive
 4 factors is 21.5.
 5 DR. WELLS:
 6 A. That's correct.
 7 COFFEY, Q.C.:
 8 Q. Now Doctor, the situation then in, I take it,
 9 in the UK is that using these as guidelines,
 10 pathologists who practice in this area are
 11 expected to know this and to at least govern
 12 themselves accordingly, knowing these are
 13 guidelines?
 14 DR. WELLS:
 15 A. Yes, that's correct. There's no policing of
 16 this system particularly but the participation
 17 in UK NEQAS is effectively a quality assurance
 18 backup to these documents.
 19 COFFEY, Q.C.:
 20 Q. Now Doctor, but there is, I take it, from your
 21 earlier comment, the potential for flexibility
 22 and innovation?
 23 DR. WELLS:
 24 A. I think there always has to be the potential
 25 for flexibility and these are minimum

Page 21

1 standards. They're not the Rolls Royce
 2 service that some laboratory do perform. Some
 3 laboratories will perform CISH (sic.) for
 4 example, rather than HER2 testing with
 5 immunocytochemistry and we don't want to
 6 discourage that.
 7 COFFEY, Q.C.:
 8 Q. Now Doctor, in relation to steroid receptors,
 9 I'm going to ask you then to turn to Appendix
 10 7, which is at page 127 of the original
 11 document and it's at page 23 of the exhibit.
 12 DR. WELLS:
 13 A. Yes, I have that.
 14 COFFEY, Q.C.:
 15 Q. And this is titled "Quality Assurance for
 16 Estrogen Receptors and Progesterone Receptors"
 17 and the particular writing party here is
 18 described as a Dr. A. Rhodes and a Dr. B.
 19 Jasani.
 20 DR. WELLS:
 21 A. That's correct.
 22 COFFEY, Q.C.:
 23 Q. Do you know Dr. Rhodes?
 24 DR. WELLS:
 25 A. They are allied to UK NEQAS.

Page 22

1 COFFEY, Q.C.:
 2 Q. And we understand that in 2000 and 2001, Dr.
 3 Rhodes and some colleagues published a series
 4 of articles dealing with the issue of quality
 5 assurance for estrogen and progesterone
 6 receptors.
 7 DR. WELLS:
 8 A. Yes, I believe that's correct. They have
 9 written a number of articles on
 10 immunohistochemistry over the past years and
 11 also produce a regular newsletter for UK NEQAS
 12 which has articles within it, and that can be
 13 found on the NEQAS website.
 14 COFFEY, Q.C.:
 15 Q. And in fact, Doctor, just here looking at this
 16 particular page, I take it that the second
 17 paragraph here dealing with "UK NEQAS ICC on a
 18 quarterly basis circulates to over 200
 19 laboratories unstained formalin fixed and
 20 paraffin processed tissue sections from a
 21 composite block, comprising tissue fragments
 22 of known receptor content" and it goes on to
 23 talk about it from there, and talks about then
 24 the process that is followed by the
 25 participating laboratories, right here.

Page 23

1 DR. WELLS:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. Doctor, in the UK, laboratories that perform
 5 or create ER and PR slides, are they required
 6 to comply with UK NEQAS guidelines?
 7 DR. WELLS:
 8 A. The pathology laboratories are visited by a
 9 company called CPA, Clinical Pathology
 10 Accreditation Limited, which requires that an
 11 appropriate quality assurance scheme for
 12 immunohistochemistry is followed by every
 13 laboratory before they will give accreditation
 14 to that laboratory.
 15 COFFEY, Q.C.:
 16 Q. And I take it that accreditation is necessary
 17 in order to continue to work in this area?
 18 DR. WELLS:
 19 A. It's certainly regarded as necessary by many
 20 of the people that send their tissue specimens
 21 to that particular laboratory, that's true.
 22 COFFEY, Q.C.:
 23 Q. Doctor, here, just looking down through this,
 24 further toward the bottom of the page there,
 25 there's a paragraph which deals with the

Page 24

1 scoring by participants who participate in the
 2 UK NEQAS process and including remedial
 3 measures if you score below a certain level.
 4 I take it that's a sort of -
 5 DR. WELLS:
 6 A. That's correct, yes.
 7 COFFEY, Q.C.:
 8 Q. And now, Doctor, if I could ask you to look
 9 then at Exhibit P-3631, which is an article
 10 from 2004, which yourself and -
 11 DR. WELLS:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. - I understand you and a number of other
 15 authored.
 16 DR. WELLS:
 17 A. Yes, correct.
 18 COFFEY, Q.C.:
 19 Q. And Doctor, this European Working Group for
 20 Breast Screening Pathology, which I understand
 21 you're part of, could you tell--first of all,
 22 tell the Commissioner when you first got
 23 involved in this yourself, this European
 24 effort?
 25 DR. WELLS:

Page 25

1 A. I was invited to participate in the group, I
 2 suppose it was about 1998. I can't remember
 3 exactly. And I became the Chairman in 2001,
 4 unfortunately due to the death of the previous
 5 chairman.
 6 COFFEY, Q.C.:
 7 Q. And Doctor, do you still hold that position?
 8 DR. WELLS:
 9 A. I do.
 10 COFFEY, Q.C.:
 11 Q. And I understand that there was a meeting, in
 12 fact, during the past week involving this
 13 group?
 14 DR. WELLS:
 15 A. That's correct, on Friday and Saturday we had
 16 a meeting in Utrecht in the Netherlands.
 17 COFFEY, Q.C.:
 18 Q. And Doctor, I'm going to take you to that in a
 19 little bit, but in looking at this publication
 20 in May of--I'm sorry, June, it was actually
 21 published online June 24th 2004. This is
 22 entitled "Consistency of Staining and
 23 Reporting of Estrogen Receptor
 24 Immunocytochemistry within the European Union:
 25 an Interlaboratory Study." Now Doctor, I

Page 26

1 wanted to ask you, in the period before this
 2 was published, why was it thought appropriate
 3 or necessary to conduct such a study?
 4 DR. WELLS:
 5 A. I think we were concerned in the European
 6 Working Group that the quality of testing of
 7 estrogen receptor was not really known
 8 throughout the European Group and throughout
 9 the European Union, and so a number of
 10 laboratories decided that we would get
 11 together and do the same sort of thing as UK
 12 NEQAS to see what the consistency throughout
 13 Europe was.
 14 COFFEY, Q.C.:
 15 Q. And Doctor, can you tell us please then when
 16 the actual distribution of, for example, the
 17 samples and so on occurred? I mean, this was
 18 published in 2004. What period would the
 19 actual study have involved?
 20 DR. WELLS:
 21 A. Yes, it was much earlier than that in fact,
 22 because the problem was that it was initiated
 23 by Professor Sloane, who unfortunately died in
 24 2000, and it took us some time to get all the
 25 data back together to be able to publish this

Page 27

1 particular paper, and in fact, I think it was
 2 '99, because if you look at the number of the
 3 slides in Table 1 on page 122, or your page
 4 four, you will see they're all dated '97 and
 5 '98 at the end. So in fact, it was a study
 6 that was sometime in getting to publication.
 7 COFFEY, Q.C.:
 8 Q. So the actual study itself, the work that was
 9 being examined or the results that were being
 10 examined would have been '98, '99, 2000, that
 11 actual time frame?
 12 DR. WELLS:
 13 A. '99, 2000, yes.
 14 COFFEY, Q.C.:
 15 Q. And Doctor, what then, from your perspective,
 16 and you're one of the authors of this paper,
 17 what did the study find or show?
 18 DR. WELLS:
 19 A. Well, it showed that unfortunately it's a bit
 20 variable, even amongst the laboratories that
 21 were represented in this particular test.
 22 This was the--these were major laboratories
 23 within the EU, basically the laboratories
 24 represented by the members of the group.
 25 COFFEY, Q.C.:

Page 28

1 Q. Yes, and this is--in terms of that, I wanted
 2 to have that brought out, you know, for the
 3 Commissioner that in fact here, people who
 4 were asked to stain and/or read slides were,
 5 in fact, the participants in the actual
 6 working group and they would all represent
 7 major laboratories in their home countries?
 8 DR. WELLS:
 9 A. That is correct. All the members of the group
 10 are nominated by either their screening
 11 organization or their colleges in the
 12 particular country as being breast experts.
 13 COFFEY, Q.C.:
 14 Q. Now Doctor, here, the abstract at page two of
 15 the exhibit, which is page 120 of the
 16 publication, says "to assess the variability
 17 of estrogen receptor ER testing using
 18 immunocytochemistry, centrally stained and
 19 unstained slides from breast cancers were
 20 circulated to the members of the European
 21 Working Group for breast screening pathology,"
 22 which is the actual group itself, "who were
 23 asked to report on both slides. The results
 24 show that there was almost complete
 25 concordance among readers, kappa equals .95 in

Page 29	Page 31
<p>1 ER negative tumours on the stained slide and 2 excellent concordance among readers, kappa 3 equals .82, on the slides stained in each 4 individual laboratory. Tumors showing strong 5 positivity were reasonably well assessed, 6 kappa .57 and .4 respectively, but there was 7 less concordance in tumors with moderate and 8 low levels of ER, especially when these were 9 heterogeneous in their staining. Because of 10 the variation, the working group recommends 11 that laboratories performing these stains 12 should take part in an external quality 13 assurance scheme for immunocytochemistry, 14 should include a tumor with low ER levels as a 15 weak positive control and should audit the 16 percentage positive tumors in their laboratory 17 against the accepted norms annually. The 18 Quick Score method of receptor assessment may 19 also have too many categories for good 20 concordance and grouping of these into fewer 21 categories may remove some of the variation 22 among laboratories." 23 Now I take it, Doctor, that the abstract 24 is a summary of what was done and what the 25 conclusions were?</p>	<p>1 COFFEY, Q.C.: 2 Q. And I take it, Doctor, that UK NEQAS actually 3 concentrates on the performance of the 4 laboratory, the technologists or technicians' 5 work? 6 DR. WELLS: 7 A. That is correct. They have a small assessment 8 of what the individual pathologist who's 9 responsible for the immunocytochemistry 10 service feels is the score on their own slide, 11 but they don't actually circulate slides to 12 pathologists for their scoring. 13 COFFEY, Q.C.: 14 Q. Doctor, if we could, please, ask you to--and 15 this is under the discussion section of the 16 paper, go to page 127 of the paper, which is 17 page nine of the exhibit. 18 DR. WELLS: 19 A. Yes. 20 COFFEY, Q.C.: 21 Q. Actually, if I could, go back actually, 22 Doctor, I apologize, to page six of the 23 exhibit, page 124, to put it in context. 24 DR. WELLS: 25 A. Um-hm.</p>
Page 30	Page 32
<p>1 DR. WELLS: 2 A. That is correct. 3 COFFEY, Q.C.: 4 Q. Doctor, from your perspective as the chair of 5 this group, I mean, what did you, yourself, 6 take from this at the time? 7 DR. WELLS: 8 A. I think that it showed really that it wasn't 9 as good as I'd expected. It was reasonable, 10 but not--I would have expected major 11 laboratories to have done better than this, 12 and so it was important, I think, to bring 13 this to the notice of the breast cancer 14 community, and we haven't actually implemented 15 any changes to the Quick Score method, but 16 this did show that there was quite a bit of 17 variability in the assessment of these slides. 18 Bear in mind that this is actually different 19 or slightly different to UK NEQAS in that this 20 is also an assessment of pathologists' 21 performance in reading the slides. 22 COFFEY, Q.C.: 23 Q. Yes. 24 DR. WELLS: 25 A. As well as the performance of the laboratory.</p>	<p>1 COFFEY, Q.C.: 2 Q. Page six, there we are, bottom of the page 3 there. Here, at the bottom of the page, and 4 the text reads, "although ER staining has been 5 included in the UK scheme recently," and 6 that's citing footnote 16, and in terms of 7 that, just to put that in context, we go to 8 footnote 16 is at page ten of the exhibit, 9 says "United Kingdom National Group for 10 Breast Screening Pathology, 2001, Guidelines 11 for Non-operative Diagnostic Procedures and 12 Reporting of Breast Cancer Screening." So I 13 take it it would have been around 2001 that 14 they were - 15 DR. WELLS: 16 A. Yes, that's - 17 COFFEY, Q.C.: 18 Q. - at the time - 19 DR. WELLS: 20 A. That's true. I'm not sure exactly when NEQAS 21 started the ER scheme, because I'm not 22 directly involved in NEQAS itself. 23 COFFEY, Q.C.: 24 Q. It goes on "although ER staining has been 25 included in the scheme, the scheme does not</p>

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1 assess the variation in reading the slides and
 2 in determining the variation in positivity and
 3 negativity of the test. Many laboratories are
 4 still using the simple method of counting the
 5 percentage of positive cells, although the
 6 intensity of staining also appears to be
 7 important. In this regard, there is a
 8 necessity to standardize the quality of the
 9 staining technique and the assessment to
 10 ensure that the level of the receptors is
 11 consistently estimated, and indeed it is
 12 entirely possible that the response of some
 13 tumors with low Quick scores reported in the
 14 literature is due to the technical differences
 15 in the quality of the immunocytochemical
 16 staining."
 17 So Doctor, what I wanted to ask you about
 18 is this, is that within the UK itself right
 19 now, what general reporting scheme is used, in
 20 terms of ER and PR?
 21 DR. WELLS:
 22 A. Most laboratories now use the Quick score
 23 method, but some use the H score and I think
 24 some still use the percentage score, but not
 25 many, most have gone over to a score based on

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1 both, both the intensity and the percentage.
 2 COFFEY, Q.C.:
 3 Q. And why is that, Doctor?
 4 DR. WELLS:
 5 A. I suppose it's because we recommended it.
 6 COFFEY, Q.C.:
 7 Q. And why did you recommend it?
 8 DR. WELLS:
 9 A. We recommended it because we felt that the
 10 likelihood of response was better assessed in
 11 the Allred papers where they described the
 12 Quick score, they stated off the top of my
 13 head, I believe that it was about 80 percent
 14 of women with strongly positive tumours would
 15 respond in some way to hormonal therapy and
 16 that women without any staining whatsoever
 17 would tend not to respond. And then there
 18 were variations in between.
 19 COFFEY, Q.C.:
 20 Q. Doctor, here at page 127 of the paper, the
 21 paper goes on to say, "The results of this
 22 circulation demonstrate that there is some
 23 variation in reporting of a level of ER
 24 positivity, but encouragingly the variation on
 25 the whole is very small for completely

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1 negative tumours, even when interlaboratory
 2 variation is taken into account. This means
 3 that a negative result may be generally relied
 4 upon for therapy, unlike some of the older
 5 biochemical results." And then it goes on to
 6 say, Doctor, that this means that a negative
 7 result may be generally relied upon for--I'm
 8 sorry--"similar reliability for ER negative
 9 and also for progesterone receptor negative
 10 results have also been demonstrated and a
 11 study performed in a number of pathology
 12 departments in Austria. Tumours with a high
 13 degree of tumor heterogeneity may cause
 14 problems in arriving at a consistent level of
 15 positivity, but this heterogeneity would also
 16 give rise to difficulties with biochemical
 17 methods, depending on which bit of the tumor
 18 is submitted for biochemical analysis." I
 19 take it, Doctor, at that point, this is really
 20 just a comparison between an IHC method and a
 21 biochemical method?
 22 DR. WELLS:
 23 A. That was originally, yes, it was at a time
 24 when certain laboratories or certain
 25 biochemists were still saying, well the

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1 biochemical method is good, why do you want to
 2 do it by immunohistochemistry. But there were
 3 many problems with biochemistry results in the
 4 past, and so we wished to promote around
 5 Europe the immunohistochemical method.
 6 COFFEY, Q.C.:
 7 Q. And, Doctor, here, if you go further down the
 8 page, and there are certain recommendations
 9 there in the middle paragraph which include
 10 taking part in external quality assurance
 11 approaches, that is certainly urged. You go
 12 on to say here "variation in the assessment of
 13 the Quick score is interesting in that there
 14 is poor concordance between observers and
 15 allocating a specific Quick score to tumors
 16 except in very strongly positive or completely
 17 negative tumors." And this suggests that the
 18 eight points for -
 19 DR. WELLS:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. "We have too many categories for good
 23 interlaboratory concordance." And it goes on
 24 then to talk about perhaps using a modified
 25 Quick score. I wanted to ask you, Doctor,

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1 this, this reference to very strongly positive
 2 or completely negative tumors, I take it that
 3 generally if a tumor is--the underlying tissue
 4 is in fact very strongly positive or
 5 completely negative, that many labs in
 6 processing the slides and pathologists in
 7 interpreting it will get the results
 8 consistently?
 9 DR. WELLS:
 10 A. This is what the study suggested, yes. There
 11 were occasional tumors that were negative in
 12 one laboratory, with strong positivity in the
 13 rest of the laboratories, but there were very
 14 few.
 15 COFFEY, Q.C.:
 16 Q. And the more than--the problematic tumors are
 17 the ones in which category?
 18 DR. WELLS:
 19 A. Usually they're the ones with moderate to low
 20 levels of estrogen receptor.
 21 COFFEY, Q.C.:
 22 Q. And why is that, Doctor, from your experience?
 23 DR. WELLS:
 24 A. I would have said that mainly it's the
 25 sensitivity of the technique. If a laboratory

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1 is not staining tumors very well, then they
 2 may falsely report a low level receptor tumor
 3 as negative.
 4 COFFEY, Q.C.:
 5 Q. And here, Doctor -
 6 DR. WELLS:
 7 A. I think there's a picture in the publication
 8 demonstrating the one, the case that was the
 9 worse--that's your page 5 or our page 123.
 10 COFFEY, Q.C.:
 11 Q. That's correct, Doctor, it's here on the
 12 screen now and this is demonstrating, in fact
 13 -
 14 DR. WELLS:
 15 A. Figure 2.
 16 COFFEY, Q.C.:
 17 Q. Yes, it says, the caption reads "Medium-power
 18 view of a Liverpool-stained estrogen receptor
 19 positive slide"--and the case number is sited-
 20 -"which had the worse inter observer
 21 concordance in reporting." I take it that's
 22 because it's -
 23 DR. WELLS:
 24 A. That's because the positive cells are rather
 25 heterogeneously distributed mostly towards the

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1 top right and somewhat negative towards the
 2 bottom left.
 3 COFFEY, Q.C.:
 4 Q. And this was a particular tissue sample then
 5 that was proved more problematic in being
 6 consistent, in terms of the lab's reporting on
 7 it?
 8 DR. WELLS:
 9 A. That is correct.
 10 COFFEY, Q.C.:
 11 Q. Doctor, we go to the page 127, the last
 12 paragraph of the paper, says, "In summary, the
 13 variation and assessment of receptor status
 14 among laboratories has two components, a
 15 technical variation and an interpretative
 16 variation. These variations are less
 17 pronounced in negative tumors and in strongly
 18 positive tumors, but significant variation is
 19 seen in tumors that express low or moderate
 20 levels of receptor. Technical external
 21 quality assessment schemes and inclusion of a
 22 weakly positive control may help reduce
 23 technical variation and guidelines on
 24 assessment on receptors may also help to
 25 reduce the interpretative variation."

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1 DR. WELLS:
 2 A. That's correct.
 3 COFFEY, Q.C.:
 4 Q. Now, Doctor, in relation to that, we
 5 understand from what we've heard through
 6 various witnesses that the fixation process
 7 and the processing of tissue into paraffin
 8 blocks in considered very important to the
 9 reliability of ER and PR testing?
 10 DR. WELLS:
 11 A. That is correct. In fact, it states in the
 12 reporting document, your exhibit P-3635, that
 13 fixation is critical.
 14 COFFEY, Q.C.:
 15 Q. Yes. And I take it, Doctor, that if the
 16 fixation is--or the tissue processing for some
 17 reason or another is problematic, that
 18 subsequently it could be very difficult for a
 19 laboratory to actually perform a test that is
 20 truly representative of what the tissue state
 21 was originally?
 22 DR. WELLS:
 23 A. It may be very difficult, yes. Fixation is a
 24 problem in some laboratories, especially where
 25 tissue has to be transported some distance and

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1 if you've got a large volume of tissue, you
 2 need to deal with it in a certain way to make
 3 sure it fixes properly if it's going to be
 4 without sectioning for some time, especially
 5 over a weekend or something like that.
 6 COFFEY, Q.C.:
 7 Q. And, Doctor, while I had not intended to ask
 8 you but I will, now that you've raised it, how
 9 is that dealt with locally where you are?
 10 DR. WELLS:
 11 A. Well we do have a number of hospitals that
 12 send specimens to us and we try and get them
 13 there by dedicated transport as quickly as
 14 possible. But very occasionally we do have
 15 some fixation problems when specimens are done
 16 later on a Friday evening, so we've tried to
 17 avoid having the surgeons operate on breast
 18 cancer cases late on Friday evening.
 19 COFFEY, Q.C.:
 20 Q. And, Doctor, the Commissioner has heard
 21 evidence here locally that in fact, that's one
 22 of the things that has been done locally here
 23 to try to address just that problem. Doctor,
 24 I'm going to ask you if you could, please, to
 25 turn to Exhibit P-3632? And this is a

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1 spreadsheet that you prepared?
 2 DR. WELLS:
 3 A. Ah yes, yes, that's true. I don't know
 4 whether you've got the updated version that I
 5 sent this morning, you probably did.
 6 COFFEY, Q.C.:
 7 Q. October 27th, 2008.
 8 DR. WELLS:
 9 A. That would be today then.
 10 COFFEY, Q.C.:
 11 Q. Yes, that's the one we have, Doctor. Now,
 12 Doctor, this is entitled "ER EQA document
 13 provided by Dr. Clive Wells to the Commission
 14 of Inquiry on Hormone Receptor Testing." It's
 15 dated now, today's date and there's a listing
 16 of countries, a column of country names on the
 17 left-hand side and then a textual description
 18 to the right. I had asked--well I'll tell the
 19 Commissioner, I had asked, after I got in
 20 touch with you originally, if you would
 21 canvass you counterparts in Europe as to what
 22 if any EQA was being done in that particular
 23 country in relation to ER and PR. Could you
 24 just then take us as well through this,
 25 perhaps as an aid and tell the Commissioner,

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1 if you could, about what happened during the
 2 past three or four days in your meeting in
 3 Utrecht, in relation to this?
 4 DR. WELLS:
 5 A. Yes, we've been asked to produce for a body
 6 called EUSOMA which is the European Society of
 7 Mastology. We've been asked to produce a
 8 paper of guidance as to, guidance for quality
 9 assurance schemes. And we've been discussing,
 10 not only immunohistochemistry, but also
 11 reporting of histological sections as well.
 12 And we have not written the guidelines as yet,
 13 but essentially it was agreed that
 14 laboratories should participate in an EQA
 15 scheme for receptor testing. And that we
 16 would give recommendations as to schemes that
 17 we thought were acceptable in the various
 18 countries.
 19 COFFEY, Q.C.:
 20 Q. And that was or the discussion during the past
 21 several days, in fact, Friday and Saturday
 22 past.
 23 DR. WELLS:
 24 A. Friday and Saturday, yes. But we've had some
 25 correspondence about it before.

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1 COFFEY, Q.C.:
 2 Q. And, Doctor, just looking at this particular
 3 exhibit here, I take it that this is the
 4 summary that you made and you've updated it
 5 over the past couple of days as to what the
 6 situation is in each of those listed
 7 countries?
 8 DR. WELLS:
 9 A. That's correct. There are a few missing which
 10 I note now, Ireland participated in a NEQAS
 11 scheme, the same as the UK, so they can be
 12 added to the list too.
 13 COFFEY, Q.C.:
 14 Q. And here, Doctor, and I take it, for example,
 15 I'll just use France as an example, there is--
 16 it's the third entry, it's the AFAQAP scheme
 17 run by Strasbourg, a voluntary participation.
 18 I take it that the AFAQAP is the French
 19 equivalent of UK NEQAS?
 20 DR. WELLS:
 21 A. That's correct. They also do histopathology
 22 and diagnostic EQA.
 23 COFFEY, Q.C.:
 24 Q. So it involves an analysis of--or a judgment
 25 concerning the pathologist work itself.

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

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1 assessment of the scheme.
 2 COFFEY, Q.C.:
 3 Q. In effect, a passing and a borderline mark, as
 4 it were.
 5 DR. WELLS:
 6 A. Yes, that's correct.
 7 COFFEY, Q.C.:
 8 Q. And the borderline or below it would require
 9 remedial attention.
 10 DR. WELLS:
 11 A. Yes, NEQAS does send people out or have
 12 technologists go to the lab where NEQAS
 13 originates to try and help them. It's not a
 14 sort of punitive scheme, it's sort of
 15 attempting to raise the quality.
 16 COFFEY, Q.C.:
 17 Q. And if we could look back, please, at Exhibit
 18 P-3632 which is your spreadsheet.
 19 DR. WELLS:
 20 A. Yes.
 21 COFFEY, Q.C.:
 22 Q. Doctor, I note here that for example, I'll
 23 just pick Belgium and Portugal, you've noted
 24 both have no official scheme, and I take it
 25 that's no local official scheme.

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1 DR. WELLS:
 2 A. Yeah, no national scheme is what I meant.
 3 COFFEY, Q.C.:
 4 Q. Yes, and you go on to say, "labs participate
 5 in UK NEQAS and in Belgium, as well as
 6 AFAQAP"--which will be the French national
 7 program, "et cetera, on a voluntary basis, and
 8 in Portugal, labs participate in UK NEQAS, et
 9 cetera, on a voluntary basis."
 10 DR. WELLS:
 11 A. Yes, that's correct. It won't be every
 12 laboratory and I think there is also a problem
 13 that UK NEQAS is pretty much, as far as I
 14 understand, reaching its capacity in terms of
 15 what it can provide in this respect.
 16 COFFEY, Q.C.:
 17 Q. And, Doctor, as well there's a reference to
 18 Sweden and Denmark to the NordicQ scheme is
 19 used and in Denmark, some labs also
 20 participate in NEQAS and in Sweden, they also
 21 use Equalis Limited and KVASt, which I take it
 22 are two other such external quality assurance
 23 -
 24 DR. WELLS:
 25 A. Yes, the NordicQ scheme is Danish, I believe

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1 and the--some Swedish laboratories participate
 2 in one of the other ones. I believe KVASt is
 3 the one that does receptor testing, but I
 4 would have to check that.
 5 COFFEY, Q.C.:
 6 Q. Now, Doctor, you've indicated that coming out
 7 of the past weekend's work that you've been
 8 asked to provide or produce a paper.
 9 DR. WELLS:
 10 A. That is correct.
 11 COFFEY, Q.C.:
 12 Q. And who would be involved in the production of
 13 that?
 14 DR. WELLS:
 15 A. This is the working group basically giving
 16 guidance for the members of EUSOMA and anybody
 17 else who cases to read it, about what they
 18 should do about quality assurance schemes and
 19 participation in such.
 20 COFFEY, Q.C.:
 21 Q. And, Doctor, do you have any--is there any
 22 estimate of when the paper might be ready for
 23 distribution?
 24 DR. WELLS:
 25 A. Oh, we've been asked to provide a draft to the

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1 board of EUSOMA by December, so the first
 2 draft we will be doing in the next few weeks.
 3 COFFEY, Q.C.:
 4 Q. Now, Doctor, I'm going to ask you to look at,
 5 please, Exhibit P-3634?
 6 DR. WELLS:
 7 A. Uh-hm.
 8 COFFEY, Q.C.:
 9 Q. This is a document entitled "Consensus
 10 Recommendations on Estrogen Receptor Testing
 11 and Breast Cancer by Immunohistochemistry".
 12 It's a review article -
 13 DR. WELLS:
 14 A. Yes.
 15 COFFEY, Q.C.:
 16 Q. See that here, and it's--there are a number of
 17 authors listed. It's, in effect--it finishes
 18 and concludes by saying, "And members of the
 19 Standardization Ad Hoc Consensus Committee",
 20 and it's noted here being received for
 21 publication, August 14th, 2008, accepted
 22 August 14th, 2008, and it's going to be
 23 published in the Applied Immunohistochemistry
 24 Molecular Morphology. I take it--we're
 25 advised it, in fact, is already available

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1 online, and it's going to be published,
 2 though, in 2008. We were provided it by Dr.
 3 David Dabbs, who has been here and testified
 4 before the Commissioner earlier. Doctor, have
 5 you had a chance--I provided this to you
 6 recently. Have you had a chance to look
 7 through this?
 8 DR. WELLS:
 9 A. I've had a chance to look through very
 10 briefly. I haven't seen this publication
 11 before, and actually it may very well be of
 12 some use to us when we come to produce our
 13 guidelines. I'm very grateful to you for
 14 bringing it to my attention.
 15 COFFEY, Q.C.:
 16 Q. Well, doctor, as it turned out, and I'm not
 17 surprised that you wouldn't have seen it yet
 18 because apparently it just--I gather it's
 19 probably just gone up on a website connected
 20 with the publisher.
 21 DR. WELLS:
 22 A. Yes.
 23 COFFEY, Q.C.:
 24 Q. But in the main, doctor, and what I wanted to
 25 ask you about is this, and you just made the

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1 comment that it may prove of some use to the
 2 group that you're working with, why is that,
 3 doctor, in terms of what sorts of things that
 4 are discussed in this that may be of some
 5 assistance?
 6 DR. WELLS:
 7 A. Well, there are a number of recommendations as
 8 to the technique. In fact, the publication
 9 that we're doing is not really dealing with
 10 the technique, it's dealing with whether you
 11 should or should not participate in EQA
 12 schemes and which EQA schemes you should
 13 participate in, and also if you are setting up
 14 an EQA scheme, what you should--what you
 15 should take into account, but it's obviously
 16 quite an interesting publication saying that
 17 the standardization of ER immunohistochemistry
 18 is essentially.
 19 COFFEY, Q.C.:
 20 Q. And I take it that certainly in terms--your
 21 own group, I take it, in terms of, certainly
 22 are urging its members to--member countries at
 23 least to adopt quality assurance approaches?
 24 DR. WELLS:
 25 A. That's correct.

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1 COFFEY, Q.C.:
 2 Q. Doctor, the--if I could, please, doctor, I
 3 wanted to ask you about the idea of false
 4 negatives and false positives, but in relation
 5 to something that is in the paper from 2004.
 6 DR. WELLS:
 7 A. Uh-hm.
 8 COFFEY, Q.C.:
 9 Q. If we could look again, please, Registrar, at
 10 Exhibit P-3631, page 9 of the exhibit which is
 11 page 127 of the paper, doctor.
 12 DR. WELLS:
 13 A. Okay, I have it.
 14 COFFEY, Q.C.:
 15 Q. And here the second full paragraph on the left
 16 hand side beginning with the words, "The
 17 results do, however, indicate the need for
 18 some quality control of the technical aspects
 19 of immunocytochemical staining as well as
 20 guidance in the aspects of reporting of the
 21 stains. As Table 1 shows, there were a few
 22 "false negative" cases reported coming from
 23 eleven different laboratories, but there was
 24 one laboratory responsible for five of these
 25 false negatives".

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

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

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

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1 Q. I was going to ask you, doctor, what could
 2 cause that, what sorts of things could
 3 contribute to a false positive?
 4 DR. WELLS:
 5 A. Well, binding of the second antibody non-
 6 specifically is an issue in some laboratories,
 7 but that's generally less common now with the
 8 more modern techniques, and just general over
 9 strong antibodies. It's very--it's very
 10 unusual, I think, to get false positives.
 11 It's false negatives that one worries about
 12 more.
 13 COFFEY, Q.C.:
 14 Q. Just a moment, please, doctor.
 15 DR. WELLS:
 16 A. Uh-hm.
 17 COFFEY, Q.C.:
 18 Q. Doctor, they are the questions I have. There
 19 may be some questions from my colleagues here
 20 in the room, okay.
 21 DR. WELLS:
 22 A. Uh-hm.
 23 THE COMMISSIONER:
 24 Q. Mr. Pritchard, do you have any questions?
 25 MR. PRITCHARD:

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1 Q. No, Commissioner, I don't. Thank you, Doctor,
 2 for your evidence.
 3 THE COMMISSIONER:
 4 Q. Mr. Simmons.
 5 MR. SIMMONS:
 6 Q. No, Commissioner, I have no questions either.
 7 THE COMMISSIONER:
 8 Q. Mr. Browne.
 9 BROWNE, Q.C.:
 10 Q. Just a couple questions.
 11 THE COMMISSIONER:
 12 Q. All right.
 13 DR. CLIVE WELLS, EXAMINATION BY PETER BROWNE, Q.C. - VIA
 14 VIDEOCONFERENCE
 15 BROWNE, Q.C.:
 16 Q. Good afternoon, doctor. My name is Peter
 17 Browne. I represent a number of the
 18 individual physicians, pathologists and
 19 oncologists and surgeons who've been asked to
 20 testify before the inquiry. If I could,
 21 please, we heard recently--the Commissioner
 22 has heard from a number of witnesses, and
 23 recently as last week the Commissioner heard
 24 from a couple of gentlemen who were involved
 25 in going back and assisting the hospital,

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1 Eastern Health, in identifying patients and
 2 they talked to the Commissioner about some of
 3 the difficulties they had in trying to locate
 4 patients, and, in fact, they identified some
 5 patients, and some of the problems they
 6 identified was the number of hospitals here in
 7 Newfoundland were using different
 8 dictionaries, and I want to ask you about that
 9 issue because it is identified in the joint
 10 document, the NHS Breast Screening Program, and
 11 it's Appendix 10. It's the first time--one of
 12 the gentlemen, a Dr. Reza, had talked about
 13 SNOMED, and I want to ask you about that, and
 14 if you can tell us what you know about, tell
 15 the Commissioner what you know about that, and
 16 the usefulness of that from your experience?
 17 DR. WELLS:
 18 A. Yes, there are a number of coding systems that
 19 are in use in various countries. SNOMED is
 20 the most common, and it's a system of
 21 classification of disease pathology and also
 22 procedures and other things that can be
 23 translated into a code that's put onto a
 24 computer and then it's easily searchable.
 25 BROWNE, Q.C.:

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1 Q. Right, and that would allow you that -
 2 DR. WELLS:
 3 A. All our -
 4 BROWNE, Q.C.:
 5 Q. Sorry, continue.
 6 DR. WELLS:
 7 A. Sorry, all of our cases are actually coded
 8 with the SNOMED code here in our hospital, and
 9 I think mainly throughout most of the United
 10 Kingdom and I'm sure that most laboratories
 11 use SNOMED coding.
 12 BROWNE, Q.C.:
 13 Q. Now just on that -
 14 DR. WELLS:
 15 A. If not all.
 16 BROWNE, Q.C.:
 17 Q. With that use of that SNOMED coding allow you
 18 to, that these gentlemen all talked about, you
 19 have the data, but then it's translating that
 20 data into information, useful information.
 21 Does SNOMED allow you to do that in terms of
 22 trying to identify if you were looking back at
 23 trends or anything like that, would that be a
 24 useful tool to have?
 25 DR. WELLS:

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

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1 Q. Yes, 3635, we just -
 2 DR. WELLS:
 3 A. Yes.
 4 BROWNE, Q.C.:
 5 Q. If you want me to find it--I'll find that,
 6 sure.
 7 THE COMMISSIONER:
 8 Q. Mr. Browne, you'll have to tell him which page
 9 on his document?
 10 BROWNE, Q.C.:
 11 Q. I've actually told him on his document. It's
 12 just trying to find it for here.
 13 THE COMMISSIONER:
 14 Q. That's all right, page two.
 15 DR. WELLS:
 16 A. Yes, I have it.
 17 BROWNE, Q.C.:
 18 Q. You have it, doctor?
 19 DR. WELLS:
 20 A. Yes, I do.
 21 BROWNE, Q.C.:
 22 Q. This is sort of situations that these
 23 guidelines were put out, and I take it there's
 24 some discussion around issues that were
 25 encountered in respect to diagnostic

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

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1 THE COMMISSIONER:
 2 Q. Ms. Newbury.
 3 MS NEWBURY:
 4 Q. Yes, Madam Commissioner.
 5 THE COMMISSIONER:
 6 Q. Great timing on your part.
 7 DR. CLIVE WELLS, EXAMINATION BY MS. JENNIFER NEWBURY -
 8 VIA VIDEOCONFERENCE
 9 MS. NEWBURY:
 10 Q. Thank you. Good afternoon, Dr. Wells.
 11 Jennifer Newbury, and I represent the Canadian
 12 Cancer Society, Newfoundland and Labrador
 13 Division.
 14 DR. WELLS:
 15 A. Good afternoon.
 16 MS. NEWBURY:
 17 Q. I wonder if you can advise if during a quality
 18 review you encountered slides that were
 19 inappropriately interpreted as positive due to
 20 over interpretation of background staining or
 21 cytoplasmic staining, what would you do to
 22 correct such a problem?
 23 DR. WELLS:
 24 A. I suppose we would ask the laboratory to
 25 retest.

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1 MS. NEWBURY:
 2 Q. Okay, and in terms of trying on a go forward
 3 basis to modify different procedures, pre-
 4 analytic, analytic, or post analytic aspects
 5 of the testing, what would you look to
 6 specifically to hopefully avoid that type of
 7 an error in the future?
 8 DR. WELLS:
 9 A. Well, this is the a remit of UK NEQAS, which
 10 I'm not actually involved with.
 11 MS. NEWBURY:
 12 Q. Uh-hm.
 13 DR. WELLS:
 14 A. But as I understand it, they would then go
 15 look at the laboratory's procedures and invite
 16 the technologists to go to the hospital and
 17 see how they do it. I mean, in that way you
 18 can usually sort out, as far as I understand,
 19 most of the difficulties.
 20 MS. NEWBURY:
 21 Q. Okay. So there's no one particular thing that
 22 would have to be focused upon? You'd have to
 23 look at the procedures throughout all of the
 24 different aspects?
 25 DR. WELLS:

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1 A. I think you'd have to look at certainly the
 2 procedure of testing. I don't think fixation
 3 is likely in my experience to have a great
 4 effect on false positives. It's more of an
 5 effect on false negatives.
 6 MS. NEWBURY:
 7 Q. Okay, so the -
 8 DR. WELLS:
 9 A. So I would--if I was looking, I would
 10 concentrate on the technical aspects.
 11 MS. NEWBURY:
 12 Q. And if during a quality assurance review, you
 13 had encountered slides that had false nuclear
 14 staining, what--and they had been
 15 inappropriately interpreted as a positive,
 16 what would you do to correct that sort of a
 17 problem?
 18 DR. WELLS:
 19 A. I'm sorry, I don't--false nuclear staining,
 20 you mean?
 21 MS. NEWBURY:
 22 Q. Yes, we've heard some evidence about as
 23 opposed to cytoplasmic staining, sometimes
 24 there might be procedures that cause false
 25 nuclear staining. Are you familiar with what

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1 any factors that might contribute to that?
 2 DR. WELLS:
 3 A. I'm not actually involved in the NEQAS
 4 assessment, so I have never come across that
 5 particular problem.
 6 MS. NEWBURY:
 7 Q. Okay, so you're aware of anything in the
 8 analytic or pre-analytic or post-analytic
 9 phase that might contribute to that?
 10 DR. WELLS:
 11 A. I think that's something you need to ask
 12 somebody that's involved in NEQAS.
 13 MS. NEWBURY:
 14 Q. Okay.
 15 DR. WELLS:
 16 A. Or one of the other schemes.
 17 MS. NEWBURY:
 18 Q. Okay, thank you. Those are all the questions,
 19 Dr. Wells.
 20 THE COMMISSIONER:
 21 Q. Mr. Crosbie.
 22 CROSBIE, Q.C.:
 23 Q. Thank you.
 24 DR. CLIVE WELLS, EXAMINATION BY CHESLEY CROSBIE, Q.C. -
 25 VIA VIDEOCONFERENCE

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1 CROSBIE, Q.C.:
 2 Q. Ches Crosbie, Dr. Wells. I represent some of
 3 the affected patients. I have a couple of
 4 questions for you. First of all, can you tell
 5 us--just confirm for us, was UK NEQAS
 6 available as an external proficiency testing
 7 method to a hospital here in Newfoundland in
 8 1997?
 9 DR. WELLS:
 10 A. That's a good question. I'm not sure when
 11 they started taking international people on.
 12 I would suspect that it probably wasn't
 13 generally the case that they would have been
 14 taking international hospital referrals at
 15 that stage, but that's another question I
 16 think you would have to ask someone from
 17 NEQAS.
 18 CROSBIE, Q.C.:
 19 Q. Are you able to say whether any other external
 20 proficiency testing was--would have been
 21 available in '97 to a hospital in Canada,
 22 specifically Newfoundland?
 23 DR. WELLS:
 24 A. I think the schemes that are available in the
 25 United States and Canada, I'm not familiar

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1 with, apart from the College of American
 2 Pathology scheme which again I do not know
 3 whether that would have been open to a
 4 Canadian laboratory at that time.
 5 CROSBIE, Q.C.:
 6 Q. Positivity rates are used as a metric for
 7 quality assurance purposes. We've heard that
 8 from other witnesses. You would agree?
 9 DR. WELLS:
 10 A. Yes, that's correct.
 11 CROSBIE, Q.C.:
 12 Q. Is positivity calculated on the basis of ER
 13 only, not PR?
 14 DR. WELLS:
 15 A. Most laboratories--well, not all laboratories,
 16 but many laboratories did both ER and PR
 17 testing because the theoretical aspects are
 18 that to get progesterone receptor produced,
 19 you have to have a working estrogen receptor.
 20 So many laboratories will look at both
 21 receptors because in some ways it tells you a
 22 little bit more. It doesn't just tell you
 23 that estrogen receptor is there, it tells you
 24 that estrogen receptor is working.
 25 CROSBIE, Q.C.:

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1 Q. I'm sorry, when you get a--by doing the PR
 2 assay or testing, and you get a positive -
 3 DR. WELLS:
 4 A. Uh-hm.
 5 CROSBIE, Q.C.:
 6 Q. Are you saying that tells you that the ER -
 7 DR. WELLS:
 8 A. You get a bit more -
 9 CROSBIE, Q.C.:
 10 Q. Just explain a little.
 11 DR. WELLS:
 12 A. Yeah, the biochemistry generally of
 13 progesterone receptor is that it needs a
 14 functioning estrogen receptor to be expressed.
 15 So the estrogen receptor has to be working for
 16 you to get progesterone receptor. That's the
 17 usually held belief amongst most biochemists
 18 and pathologists.
 19 CROSBIE, Q.C.:
 20 Q. My question was specifically on the periodic
 21 checks that it is recommended for a hospital
 22 to do on its positivity rate. Is that check
 23 performed only on ER or is it performed also
 24 on PR, or is it performed on them combined?
 25 DR. WELLS:

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

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1 population.
 2 CROSBIE, Q.C.:
 3 Q. Is that because earlier detection turns up, to
 4 put it in layman's terms, the smaller the
 5 tumour, the more likely it is positive?
 6 DR. WELLS:
 7 A. No, no, it's because the units without breast
 8 cancer screening programs have a different age
 9 distribution of the cancers, and more of the
 10 younger women have estrogen receptor negative
 11 tumours.
 12 CROSBIE, Q.C.:
 13 Q. Thank you. So just to be clear on this point,
 14 a lab would not add clinically negative
 15 results to clinically positive results to
 16 arrive at a positivity rate?
 17 DR. WELLS:
 18 A. Sorry, I'm not quite--I don't understand what
 19 you mean.
 20 CROSBIE, Q.C.:
 21 Q. Let me back up.
 22 DR. WELLS:
 23 A. A laboratory would not look at the general
 24 positivity for both the ER and PR together.
 25 CROSBIE, Q.C.:

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1 Q. Perhaps I should give you a little background.
 2 The particular lab under consideration here,
 3 until a certain point in time, was using a cut
 4 of 30 percent, a cut point.
 5 DR. WELLS:
 6 A. Of positive cells?
 7 CROSBIE, Q.C.:
 8 Q. For ER.
 9 DR. WELLS:
 10 A. Of percentage positivity?
 11 CROSBIE, Q.C.:
 12 Q. Yes, for ER, and then it switched to using 10
 13 percent?
 14 DR. WELLS:
 15 A. Then I may have misunderstood you.
 16 CROSBIE, Q.C.:
 17 Q. Then it switched to using 10 percent.
 18 DR. WELLS:
 19 A. I may have misunderstood you then. Yes,
 20 sorry, I understood you to mean in an internal
 21 audit, the percentage of tumours that were
 22 positive for estrogen receptor, but you mean
 23 the percentage of cells positive? A slight
 24 difference.
 25 CROSBIE, Q.C.:

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1 Q. I'll give a little bit more explanation. The
 2 lab here was using a 30 percent cutoff until a
 3 certain stage, and then it switched to 10
 4 percent.
 5 DR. WELLS:
 6 A. Yes.
 7 CROSBIE, Q.C.:
 8 Q. Now in calculating the positivity rate for
 9 quality assurance purposes as a metric, which
 10 we've been told by various people is a good
 11 idea to do periodically, would you add in the
 12 clinically negative results to the clinically
 13 positive results, bearing in mind you have
 14 these cut points, in order to arrive at the
 15 positivity rate?
 16 DR. WELLS:
 17 A. The laboratory was defining positivity, I
 18 presume, at 30 percent.
 19 CROSBIE, Q.C.:
 20 Q. Correct.
 21 DR. WELLS:
 22 A. At one point, and then changed to defining
 23 positivity at 10 percent of tumours positive.
 24 I would expect if you were defining tumours as
 25 positive at 30 percent, you would have a lot

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1 of supposedly negative tumours that were
 2 actually--would have been positive by the
 3 Quick Score Method or the H-Score Method that
 4 we use in the UK. If that's what you mean?
 5 Therefore, they would have had a lower
 6 percentage of tumours that were estrogen
 7 receptor positive.
 8 CROSBIE, Q.C.:
 9 Q. That's a--in that statement, you're being
 10 critical of adopting a 30 percent cutoff, I
 11 take it?
 12 DR. WELLS:
 13 A. It's not a cutoff that I would have adopted
 14 myself, but I'm not sure at which point this
 15 was adopted by the laboratory in question and
 16 I haven't seen the dates and the data on this.
 17 CROSBIE, Q.C.:
 18 Q. Yes. Again, I'm not sure if we're connecting
 19 on the intent of the question. In order to
 20 calculate your metric, your positivity rate,
 21 you got a distribution below your 30 percent
 22 or your ten percent cutoff. In other words,
 23 those are considered to be clinically
 24 negative. Do you follow me so far?
 25 DR. WELLS:

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1 A. They're considered to be receptor negative on
 2 the test you mean?
 3 CROSBIE, Q.C.:
 4 Q. Yes.
 5 DR. WELLS:
 6 A. Yes, okay.
 7 CROSBIE, Q.C.:
 8 Q. Clinically negative, in other words, the
 9 assumption is that their results below 30
 10 percent and then ten percent are not going to
 11 be treated. Follow?
 12 DR. WELLS:
 13 A. Right. In the past, many patients were
 14 treated, even with low levels of receptor.
 15 CROSBIE, Q.C.:
 16 Q. That may vary depending on -
 17 DR. WELLS:
 18 A. And even negative tumors were treated.
 19 CROSBIE, Q.C.:
 20 Q. That may vary depending on the attitude of the
 21 clinician admittedly?
 22 DR. WELLS:
 23 A. Indeed.
 24 CROSBIE, Q.C.:
 25 Q. Yes. Again though, my question is to arrive

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1 at your positivity rate, which is a quality
 2 check, do you add those clinically negative,
 3 below 30 and below ten, in other words that
 4 stain weakly, weak positives you could call
 5 them, into your above the cut point positives
 6 to get at your rate?
 7 DR. WELLS:
 8 A. I'm not quite sure what--I'm still not quite
 9 sure what you mean by this. If you have set a
 10 level of positivity at 30 percent, then your
 11 positivity--the number of tumors that were
 12 estrogen receptor positive in your laboratory
 13 over a year would be less obviously than a
 14 laboratory that was using ten percent as its
 15 cut off point. So I mean, they are
 16 adjudicating whether something is positive at
 17 a level of 30 percent or a level of ten
 18 percent or with us a Quick score value of
 19 three and above. Then we look at -
 20 CROSBIE, Q.C.:
 21 Q. Well, put it another way.
 22 DR. WELLS:
 23 A. - the number of tumors in a year that are
 24 estrogen receptor positive. So we say that of
 25 all our tumors that we had through the

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1 laboratory, 70 percent are estrogen receptor
 2 positive and that's the kind of range we would
 3 expect for our practice.
 4 CROSBIE, Q.C.:
 5 Q. Perhaps to put it another way, when
 6 calculating your positivity rate, you should
 7 reference the cut point in use at that period
 8 in time?
 9 DR. WELLS:
 10 A. I'm sure, yeah, that's absolutely true. You
 11 must take that into account.
 12 CROSBIE, Q.C.:
 13 Q. I'd like to ask you on another somewhat
 14 different subject. In 1997, was it generally
 15 accepted methodology to use trypsin for
 16 antigen retrieval for all antigens except
 17 ER/PR?
 18 DR. WELLS:
 19 A. Now that's a technical question which I
 20 suppose you ought to ask some of the
 21 technologists. I don't know whether trypsin
 22 was generally used in that procedure because I
 23 do not directly supervise the technical
 24 scheme, the technical production of antibody
 25 staining.

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1 CROSBIE, Q.C.:
 2 Q. If you don't have this knowledge, then just
 3 tell us, but I'll ask my next question. By
 4 1997, was the standard for doing ER/PR antigen
 5 retrieval not trypsin but moist heat?
 6 DR. WELLS:
 7 A. Certainly we were using pressure cooking
 8 ourselves and microwaving was certainly coming
 9 in at that point. I think I would have to look
 10 at the reference to pressure cooking to see
 11 when that was particularly used, but
 12 microwaving was a bit before that. I think it
 13 was around about that time, certainly,
 14 probably a bit before.
 15 CROSBIE, Q.C.:
 16 Q. And the technical term for this method of
 17 antigen retrieval is heat-induced epitome
 18 retrieval or HIER?
 19 DR. WELLS:
 20 A. That's one of the terms used, yes.
 21 CROSBIE, Q.C.:
 22 Q. And if HIER were in use, then trypsin would
 23 have no role or use whatsoever?
 24 DR. WELLS:
 25 A. As far as I understand it, yes, because they

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1 are two different methods of retrieving the
 2 same antigen. These are questions that
 3 actually a pathologist is less acquainted with
 4 than a histotechnologist.
 5 CROSBIE, Q.C.:
 6 Q. Thank you. A couple of things arising out of
 7 your testimony a little earlier. The article
 8 on consistency of staining makes the comment
 9 that variation is very small for completely
 10 negative tumors.
 11 DR. WELLS:
 12 A. That's correct. In general, that's another
 13 way of saying there were very few false
 14 positives.
 15 CROSBIE, Q.C.:
 16 Q. In making the recommendation, there's a
 17 recommendation there it seems to use a known
 18 negative/known positive and a very weakly
 19 positive as controls.
 20 DR. WELLS:
 21 A. Yes, there is. Not every laboratory does
 22 that, but it was our recommendation at the
 23 time, if you were having problems in your
 24 runs. I think also one thing that hasn't come
 25 out, in the paragraph after that, it says that

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1 assessment of internal controls within the
 2 same slide is necessary or is helpful.
 3 CROSBIE, Q.C.:
 4 Q. Yes.
 5 DR. WELLS:
 6 A. They're not always there, but that's a very
 7 good way of assessing whether the specimen is
 8 being stained correctly.
 9 CROSBIE, Q.C.:
 10 Q. These three things I just mentioned are
 11 external controls?
 12 DR. WELLS:
 13 A. Yes.
 14 CROSBIE, Q.C.:
 15 Q. The known negative, that's the patient's own
 16 tissue?
 17 DR. WELLS:
 18 A. No, these are control samples from other
 19 patients where you know that the estrogen
 20 receptor is negative on previous testing.
 21 CROSBIE, Q.C.:
 22 Q. I see. Do you use patient's own tissue from
 23 the patient specimen and simply not put the
 24 antibody on it?
 25 DR. WELLS:

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1 A. Yes, well that is another form of control that
 2 is often--well, almost always performed,
 3 certainly performed in our laboratory.
 4 CROSBIE, Q.C.:
 5 Q. So are you assuming that you're doing that
 6 negative control as well, the patient's own
 7 tissue?
 8 DR. WELLS:
 9 A. All of our antibodies have that done, yes, in
 10 our particular laboratory and I assume that
 11 that is pretty much a standard procedure.
 12 CROSBIE, Q.C.:
 13 Q. So you're talking about actually doing two
 14 negative controls in this recommendation?
 15 DR. WELLS:
 16 A. We do, not for each--not for each test. The
 17 test would, in our laboratory, would consist
 18 of an estrogen receptor, a progesterone
 19 receptor on the patient's tissue and a
 20 negative control on the patient's tissue, and
 21 then included in the same run on the machine,
 22 a known positive and known negative. We don't
 23 actually use a weak positive ourselves at the
 24 moment.
 25 CROSBIE, Q.C.:

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1 Q. That's what I was going to ask you. How
 2 strong a recommendation is the use of a weak
 3 positive?
 4 DR. WELLS:
 5 A. It's a very--I believe it's a very useful
 6 thing, but we're always up against cost
 7 restraints and many laboratories do not use
 8 this.
 9 CROSBIE, Q.C.:
 10 Q. So that's an evolving issue?
 11 DR. WELLS:
 12 A. It was a recommendation that we felt it was
 13 useful to make in this particular paper, but
 14 it hasn't been uniformly accepted.
 15 CROSBIE, Q.C.:
 16 Q. You were asked, sir, about the significance of
 17 false negatives, and your comment was that if
 18 the test result was ER false negative and PR
 19 false negative, then that would result in no
 20 prescription for Tamoxifen.
 21 DR. WELLS:
 22 A. It would nowadays in the UK, but previously,
 23 before about 2000, I guess most women with
 24 breast cancer were given Tamoxifen anyway
 25 because it was believed to be pretty much

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1 without side effects, so it was generally
 2 prescribed.
 3 CROSBIE, Q.C.:
 4 Q. Negative ER and positive PR you said would
 5 provoke the lab or the lab would have a good
 6 look. What do you mean by that? If you get a
 7 negative ER and a positive -
 8 DR. WELLS:
 9 A. They would retest the ER.
 10 CROSBIE, Q.C.:
 11 Q. That would make you wonder -
 12 DR. WELLS:
 13 A. To make sure that it -
 14 CROSBIE, Q.C.:
 15 Q. Sorry, go ahead.
 16 DR. WELLS:
 17 A. That should make you wonder whether the
 18 estrogen receptor test was working, especially
 19 if you had a lot of them. They're supposed to
 20 be less than two percent of all breast cancers
 21 have this particular profile and that is
 22 assumed to be due to an estrogen receptor that
 23 is structurally abnormal, so it's not
 24 recognized by the antibody, but actually
 25 working to produce the progesterone receptor.

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1 It's a very rare scenario. So if you had a
 2 lot of these, you would question, I think,
 3 your technique of estrogen receptor.
 4 CROSBIE, Q.C.:
 5 Q. If you did go back and were satisfied that you
 6 had a negative ER and a positive PR, your
 7 comment was that a woman would get Tamoxifen
 8 on the strength of that result?
 9 DR. WELLS:
 10 A. On the assumption that something was driving
 11 their progesterone receptor and that was
 12 likely to be estrogen receptor, even though we
 13 weren't able to demonstrate it.
 14 CROSBIE, Q.C.:
 15 Q. Is there any cut point below which--and I
 16 guess we're talking about standards today to
 17 start with. Positive PR would not result in a
 18 prescription of Tamoxifen? For example, 30.
 19 DR. WELLS:
 20 A. I think if it was very weak, under--we don't
 21 use the just percentage positivity. We use
 22 the Quick Score and if it was a progesterone
 23 receptor of three under the Quick Score, which
 24 is weak positivity in less than--actually, let
 25 me see, one to 12 percent of cells in the

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1 Quick Score, that would not generally be
 2 regarded as positive. The cut off levels for
 3 the Quick Score are very different to the cut
 4 off that was originally used, ten percent or
 5 30 percent or whatever.
 6 CROSBIE, Q.C.:
 7 Q. Lastly, sir, just wanted to ask you about
 8 fixation. If fixation is poor, it's possible
 9 to lose the--to degrade the specimen to such
 10 an extent that you can't retrieve the ER or PR
 11 receptor sites. Is that right?
 12 DR. WELLS:
 13 A. That is correct.
 14 CROSBIE, Q.C.:
 15 Q. So if testing on such a specimen yielded a
 16 negative result for ER/PR, retesting that
 17 specimen or that tissue block would not yield
 18 the result that this original test was falsely
 19 negative, would it?
 20 DR. WELLS:
 21 A. Not usually, no, but if the technique was much
 22 more sensitive than the previous technique, I
 23 suppose theoretically, it could.
 24 CROSBIE, Q.C.:
 25 Q. That would be because the receptor sites were

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1 no longer there to retrieve because of the
 2 manner in which the tissue had been handled?
 3 DR. WELLS:
 4 A. What I meant by that was that it's possible
 5 that the first technique that was used that
 6 was negative was less sensitive than the new
 7 technique that was used and therefore, the
 8 previous test was stated to be negative when
 9 in fact there was a little bit of estrogen
 10 receptor there, albeit at a level not detected
 11 by the first technique, but detectable by the
 12 second technique.
 13 CROSBIE, Q.C.:
 14 Q. I understand, however, it is possible to have
 15 degraded the tissue so much that you can't
 16 retrieve the receptor?
 17 DR. WELLS:
 18 A. Yes, of course.
 19 CROSBIE, Q.C.:
 20 Q. And in fact, that would mean that the false
 21 negative rate, if one were doing a
 22 retrospective review, would be higher than
 23 what showed up in the statistics because
 24 you're not going to detect the false negative
 25 if it occurred pre-analytically?

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1 DR. WELLS:
 2 A. I guess that could be true. I have no way of
 3 knowing how you would tell that.
 4 CROSBIE, Q.C.:
 5 Q. Thank you.
 6 THE COMMISSIONER:
 7 Q. Do you have anything arising, Mr. Coffey?
 8 DR. CLIVE WELLS, RE-EXAMINATION BY BERNARD COFFEY, Q.C. -
 9 VIA VIDEOCONFERENCE
 10 COFFEY, Q.C.:
 11 Q. Yes, I do, Commissioner. Actually, Doctor,
 12 you--in response to some questions you were
 13 asked, you made reference to internal
 14 controls, which of course are referred to in
 15 the 2004 paper?
 16 DR. WELLS:
 17 A. That's correct.
 18 COFFEY, Q.C.:
 19 Q. And you indicated that, you described them as
 20 a very good way of assessing whether the
 21 tissue was staining appropriately?
 22 DR. WELLS:
 23 A. That's correct.
 24 COFFEY, Q.C.:
 25 Q. And Doctor, I wanted to ask you this. As a

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1 practising pathologist, in relation to ER and
 2 PR done by the IHC method, using paraffin
 3 blocks, how long have you known about the
 4 utilization of internal controls in that
 5 context?
 6 DR. WELLS:
 7 A. I guess for quite a long time. We always get
 8 our technical staff to report--they initially
 9 assess the positivity of the slides and then
 10 they give them to us, and they will write down
 11 internal controls present or internal controls
 12 not present. There are sometimes when you get
 13 a block of tissue, say if you only have a very
 14 limited core biopsy sample, where you may not
 15 have an internal control, but we do like to
 16 see them if they're there. It's a way of
 17 knowing that the techniques worked.
 18 COFFEY, Q.C.:
 19 Q. And Doctor, I take it then, in terms of your
 20 view that if at all possible that tissue that
 21 can act as an internal control be there and
 22 you'd actually examine it, if it was there, to
 23 satisfy yourself that it had stained
 24 appropriately. I take it that you've known
 25 about that, you say a long time. What are we

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1 talking about here, like decades?
 2 DR. WELLS:
 3 A. I suppose we've been reporting receptors for,
 4 golly, about 15 years.
 5 COFFEY, Q.C.:
 6 Q. 15 years.
 7 DR. WELLS:
 8 A. Regularly, I personally. So I guess about
 9 that sort of time.
 10 COFFEY, Q.C.:
 11 Q. And certainly since the early to mid 1990s?
 12 DR. WELLS:
 13 A. I guess that would be about right, yes.
 14 COFFEY, Q.C.:
 15 Q. Doctor, you also referred to, in terms of
 16 positivity statistics and presumably then, of
 17 course, one can also calculate a negative
 18 receptor rate as well in a population, you
 19 referred to the prevalence or lack thereof of
 20 breast screening in a population, having a
 21 potential effect on the statistics that might
 22 be forthcoming in relation to the positivity
 23 rates. Could you elaborate on that a bit for
 24 the Commissioner?
 25 DR. WELLS:

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

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

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1 different in those two laboratories, testing
 2 the same sample?
 3 DR. WELLS:
 4 A. No, I would expect that with good fixation and
 5 with good technique and with good antibodies,
 6 they should be identical.
 7 THE COMMISSIONER:
 8 Q. Okay.
 9 DR. WELLS:
 10 A. What I was talking about was the problems of a
 11 badly fixed tumor that was falsely reported as
 12 negative by a less sensitive technique could
 13 be picked up as positive by a more sensitive
 14 technique later on.
 15 THE COMMISSIONER:
 16 Q. And when you say less sensitive and more
 17 sensitive, is that a general statement about
 18 sensitivity or does that refer to the
 19 difference that is inherent in using different
 20 antibodies in the sense of in the fixation
 21 process could something happen which would
 22 cause what I would think of as the second
 23 stage, fixation being the first stage and the
 24 second stage of processing? Would one expect
 25 that a fixation problem might result in one

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1 process thereafter optimally done to make a
 2 difference? That's what I'm--I'm getting to
 3 the fixation end of it and what its effect
 4 could be, because you've said that if it's
 5 properly, optimally fixed and optimally
 6 processed, you would expect the same result.
 7 Now I'm looking to if it's not optimally
 8 fixed, but you use optimal processing on
 9 either side, could you expect a different
 10 result because of the problems with fixation?
 11 DR. WELLS:
 12 A. Yes, I was specifically thinking of fixation
 13 being the problem.
 14 THE COMMISSIONER:
 15 Q. Yes.
 16 DR. WELLS:
 17 A. In that if you've got a tumor that's poorly
 18 fixed, it's lost, say, 90 percent of its
 19 estrogen receptor activity.
 20 THE COMMISSIONER:
 21 Q. Um-hm.
 22 DR. WELLS:
 23 A. And then you stain that with a technique
 24 that's not particularly sensitive -
 25 THE COMMISSIONER:

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1 Q. Okay.
 2 DR. WELLS:
 3 A. - you may not pick up the residual activity
 4 that is still there, but if you used a more
 5 sensitive technique, you may pick up that
 6 residual activity. Do you understand what I
 7 mean?
 8 THE COMMISSIONER:
 9 Q. I think I do, and that's just underlying again
 10 the point of how critical fixation is to the
 11 success of this particular test. Is that
 12 fair?
 13 DR. WELLS:
 14 A. That's correct.
 15 THE COMMISSIONER:
 16 Q. Yes, okay. Mr. Coffey, you're on your feet.
 17 Does that mean I raised a question with you?
 18 DR. CLIVE WELLS, RE-EXAMINATION BY BERNARD COFFEY, Q.C. -
 19 VIA VIDEOCONFERENCE
 20 COFFEY, Q.C.:
 21 Q. Yes. If I could, Doctor, Commissioner and
 22 Doctor. Doctor, just to use a concrete
 23 example of what the Commissioner has been just
 24 asking you about, assuming the same block of
 25 tissue, okay, and whatever may have been done

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1 to the block before, the tissue and the block
 2 before, if it was well fixed, fine, but if it
 3 wasn't well--well, assume for the moment it
 4 was properly fixed, okay.
 5 DR. WELLS:
 6 A. Yes, okay.
 7 COFFEY, Q.C.:
 8 Q. And laboratory A processes a slide and the
 9 result is an ER of zero, or very low ER, zero
 10 or five or so, five percent.
 11 DR. WELLS:
 12 A. Yes.
 13 COFFEY, Q.C.:
 14 Q. Laboratory B takes the same block, processes
 15 it into slides using its own technique and
 16 reports the ER at 80 percent, what could
 17 account for that, assuming that the tissue was
 18 properly fixed in the first place?
 19 DR. WELLS:
 20 A. That would have to be a problem in the
 21 technique in the first laboratory.
 22 COFFEY, Q.C.:
 23 Q. Doctor, assuming for the moment that, again we
 24 have another block of tissue and this second
 25 block of tissue is poorly fixed, there are

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1 problems with its fixation, okay, laboratory A
 2 processes that block with its own technique
 3 and reports the ER at zero or very low, again,
 4 zero, two or five low. Laboratory B takes the
 5 same block using its technique and processes
 6 the block into a slide and again produces
 7 perhaps, I'll pick a figure of 60 to 70
 8 percent, okay, what might account for that?
 9 DR. WELLS:
 10 A. Well, that could be the sensitivity of the
 11 test employed by--the first laboratory being
 12 less than the sensitivity of the test employed
 13 by the second laboratory, or it could be, as
 14 with a well fixed block, a problem with the
 15 first processing, the first testing.
 16 COFFEY, Q.C.:
 17 Q. The technique used by lab A?
 18 DR. WELLS:
 19 A. Yeah.
 20 COFFEY, Q.C.:
 21 Q. Problems in their--they haven't optimized
 22 their--potentially haven't optimized their
 23 technique?
 24 DR. WELLS:
 25 A. Yes, that's what this would suggest.

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1 COFFEY, Q.C.:

2 Q. Thank you, Commissioner.

3 THE COMMISSIONER:

4 Q. Thank you very much, Dr. Wells, for your

5 contribution.

6 DR. WELLS:

7 A. Thank you.

8 THE COMMISSIONER:

9 Q. We very much appreciate your having cooperated

10 with us in this matter. I know at times we've

11 made strange demands at odd hours, at least in

12 your part of the world. So we very much

13 appreciate your participation. Thank you.

14 DR. WELLS:

15 A. You're welcome.

16 COFFEY, Q.C.:

17 Q. Thank you, Doctor.

18 DR. WELLS:

19 A. Thank you.

20 (LUNCH BREAK)

21 THE COMMISSIONER:

22 Q. Please be seated. Ms. Chaytor?

23 CHAYTOR, Q.C.:

24 Q. Good afternoon, Commissioner. The next

25 witness is Lynn Wade.

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1 MS. LYNN WADE, SWORN, EXAMINATION BY SANDRA CHAYTOR, Q.C.

2 REGISTRAR:

3 Q. Would you please state and spell your complete

4 name for the Commission?

5 MS. WADE:

6 A. Lynn Wade, L-Y-N-N W-A-D-E.

7 REGISTRAR:

8 Q. Thank you.

9 CHAYTOR, Q.C.:

10 Q. Good afternoon, Ms. Wade.

11 MS. WADE:

12 A. Good afternoon.

13 CHAYTOR, Q.C.:

14 Q. Commissioner, we have a number of new

15 exhibits, please, that I'd ask to have

16 entered, P-3585 to P-3629 inclusive and P-3637

17 to P-3644 inclusive, and P-3649 to P-3673

18 inclusive.

19 THE COMMISSIONER:

20 Q. Entered.

21 EXHIBITS ENTERED AND MARKED P-3585 THROUGH P- 3629

22 EXHIBITS ENTERED AND MARKED P-3637 THROUGH P- 3644

23 EXHIBITS ENTERED AND MARKED P-3649 THROUGH P- 3673

24 CHAYTOR, Q.C.:

25 Q. Registrar, if we could have, please, P-3585?

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1 Ms. Wade, this is a copy of your current CV

2 and perhaps if you could take us through your

3 educational and professional background?

4 MS. WADE:

5 A. Okay. I graduated with the certificate of

6 Medical Lab Technology from the College of the

7 North Atlantic, back then it was the College

8 of Trades and Technology, and also achieved

9 the CSMLS certification in 1977. I worked

10 briefly in Labrador City and then in 1978

11 started work at the General Hospital. I

12 completed a Bachelor of Technology at Memorial

13 University in 2005. I was a technologist I in

14 several different departments at the General

15 Hospital, Tech II in the biochemistry division

16 until 1997 when I became Client Services

17 Manager for the Health Care Corporation, and

18 in 2007, I was the--became the program manager

19 for Safety and Quality, which I told today.

20 CHAYTOR, Q.C.:

21 Q. Okay, and what is a Bachelor of Technology?

22 MS. WADE:

23 A. Bachelor of Technology is a relatively new

24 degree program that was developed with the

25 University in conjunction with the College, in

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1 order for those people who have achieved

2 technical diploma status to go on and achieve

3 Bachelor status.

4 CHAYTOR, Q.C.:

5 Q. Okay, and your work as a technologist, you

6 worked in biochemistry and cytology,

7 microbiology. Did you have any experience in

8 the pathology lab?

9 MS. WADE:

10 A. No.

11 CHAYTOR, Q.C.:

12 Q. Okay, and under your professional profile,

13 Human Resources Management, you've written

14 "encourages and facilitates continuing

15 education opportunities for laboratory

16 managers and staff."

17 MS. WADE:

18 A. Um-hm.

19 CHAYTOR, Q.C.:

20 Q. And that was in your role as client services

21 manager?

22 MS. WADE:

23 A. Well, I do that now.

24 CHAYTOR, Q.C.:

25 Q. And you still do that?

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1 MS. WADE:
 2 A. Yes, certainly in my role as program manager
 3 for safety and quality, yes.
 4 CHAYTOR, Q.C.:
 5 Q. And that would include the technologists, I
 6 take it?
 7 MS. WADE:
 8 A. Yes.
 9 CHAYTOR, Q.C.:
 10 Q. And "performed performance appraisals and
 11 annual attendance reviews," is that -
 12 MS. WADE:
 13 A. That would have been as client services
 14 manager. I had approximately 100 staff
 15 reporting to me at that time and that was part
 16 of my duties as manager.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, and you also had financial
 19 responsibilities as client services manager?
 20 MS. WADE:
 21 A. That's right.
 22 CHAYTOR, Q.C.:
 23 Q. And changes management, "assists in training
 24 of laboratory staff for the purposes of policy
 25 and procedure writing." Perhaps you could

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

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1 MS. WADE:
 2 A. I'm thinking this--I don't know which one this
 3 is. It's probably -
 4 CHAYTOR, Q.C.:
 5 Q. That's fine.
 6 MS. WADE:
 7 A. Oh, the pathology one, yes.
 8 CHAYTOR, Q.C.:
 9 Q. Yes, that's right.
 10 MS. WADE:
 11 A. Yes, so that's very--that's specific to the
 12 pathology division.
 13 CHAYTOR, Q.C.:
 14 Q. Yes.
 15 MS. WADE:
 16 A. And I have been helping with that really since
 17 last summer perhaps, yeah.
 18 CHAYTOR, Q.C.:
 19 Q. Okay, and you also say, under change
 20 management, "liaise with information
 21 management and technology department and
 22 participates on Meditech consolidation
 23 committee." Is that in your current role?
 24 MS. WADE:
 25 A. It is in my current role, but it also was part

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

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1 and right now, we have the rural Avalon region
 2 and the Western region that are linked
 3 electronically so that there are no paper
 4 requisitions per se coming to us. The orders
 5 go directly from them into our system and our
 6 results go directly back to them, and it
 7 enhances the quality of reports and the
 8 turnaround time and reduces data entry errors
 9 that can happen to manual transfer.
 10 CHAYTOR, Q.C.:
 11 Q. Okay, and then under quality initiatives,
 12 "developed and conducted quality management
 13 workshop to introduce laboratory managers and
 14 senior technologists to quality management
 15 concepts." When would you have done this?
 16 MS. WADE:
 17 A. This was in February of 2008. That was
 18 following the completion of the regional lab
 19 safety manual that I worked on for several
 20 months prior to that, and then I hosted the
 21 workshop to get staff and managers from all
 22 the sites throughout the region together to
 23 talk about basically quality management and
 24 processes and procedures and then to introduce
 25 them to the safety manual for the region.

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1 CHAYTOR, Q.C.:
 2 Q. Okay, and what types of quality management
 3 concepts would you have been introducing them
 4 to?
 5 MS. WADE:
 6 A. Basically about quality management, just
 7 explaining what quality management was, and
 8 then how to flow chart their processes so that
 9 they could identify any gaps in their
 10 procedure manuals that may be there now and
 11 introducing them to templates, standardized
 12 templates with standardized headers and
 13 explaining how they would adapt them to the
 14 individual labs.
 15 CHAYTOR, Q.C.:
 16 Q. And maybe then you could also educate us.
 17 What is quality management?
 18 MS. WADE:
 19 A. Okay. Quality management basically is a
 20 management approach that strives to meet our
 21 customers' satisfaction, and that would be
 22 physicians and patients and the public,
 23 through a continuous improvement initiative.
 24 So basically, we develop and monitor
 25 everything that we do so that we can

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1 continuously improve.
 2 CHAYTOR, Q.C.:
 3 Q. Okay. So for example, the development of
 4 policies and procedures, seeing that they're
 5 revised and updated as needed?
 6 MS. WADE:
 7 A. That's right.
 8 CHAYTOR, Q.C.:
 9 Q. And seeing that they are also implemented?
 10 MS. WADE:
 11 A. That's right.
 12 CHAYTOR, Q.C.:
 13 Q. That's part of quality management?
 14 MS. WADE:
 15 A. That's right.
 16 CHAYTOR, Q.C.:
 17 Q. Okay, and then we have "developed and
 18 conducted workshop to introduce the regional
 19 laboratory safety program" and what is that?
 20 What's the regional laboratory safety program?
 21 MS. WADE:
 22 A. Well, the labs have--laboratories, by virtue
 23 of what they are and what we work with, can be
 24 very dangerous environment and so what we have
 25 done now is a regional policy manual that all

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1 labs in the region have to follow, but then
 2 they also have to customize it to their own
 3 site, so that they have to ensure that they
 4 have the procedures in place, for instance,
 5 for chemical spill clean up, specific to their
 6 labs and the kinds of equipment and the kinds
 7 of chemical that they would be using, for
 8 instance.
 9 CHAYTOR, Q.C.:
 10 Q. Okay, and "developed and conducted indicators
 11 workshop for laboratory managers and senior
 12 technologists." What do you mean by
 13 indicators?
 14 MS. WADE:
 15 A. Well, indicators really are a way of providing
 16 a snapshot of the quality for the lab, so it
 17 could be anything: looking at financial
 18 indicators, looking at how well we are within
 19 or not, within our budget; looking at quality
 20 of work life, you know, how many staff are
 21 injured in the workplace; looking at quality
 22 patient centred kinds of initiatives and
 23 indicators for that would be things like
 24 turnaround time and error rates and things
 25 like that.

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1 CHAYTOR, Q.C.:

2 Q. Okay, and "conducted quality rounds to educate

3 laboratory staff regarding occurrences." What

4 are quality rounds?

5 MS. WADE:

6 A. That's something that came as a result of--

7 well, this first one actually was a result of

8 an occurrence that we had in one of the labs

9 and in conjunction with Ms. Predham at Quality

10 and Risk Department, we conducted--we used

11 that occurrence as an opportunity to educate

12 staff about the importance of report, not only

13 things when they happen, but the near misses

14 and the kinds of things that--the oops moments

15 that they may have in their everyday work that

16 would provide opportunities to improve. So

17 that quality round was a presentation and then

18 a very general discussion with staff and

19 management right across the region, and

20 Heather and I did a couple of them and then I

21 went out to the rest of the region and

22 conducted them with staff.

23 CHAYTOR, Q.C.:

24 Q. And is that something then that you would do

25 on a regular basis?

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1 MS. WADE:

2 A. That would be seen as part of my role as

3 quality manager and I haven't been able to get

4 out as much in the last few months, but

5 certainly even--not only to do discussions

6 around a specific occurrence, but to talk

7 generally about other initiatives within

8 quality management, like corrective actions

9 and lots of things.

10 CHAYTOR, Q.C.:

11 Q. Yes, and the Commissioner has heard about, for

12 example, tumor board rounds and those happen

13 on a regular basis. So would quality rounds

14 be something that you would have happen on,

15 you know, a monthly or quarterly basis? Is

16 that the intent or is this something -

17 MS. WADE:

18 A. There's no framework yet around the frequency.

19 Certainly with 17 sites in the region, you

20 know, to get out there on a frequent basis to

21 every site is difficult, but the hope,

22 certainly my goal would be to educate the

23 staff in their own areas so that they can

24 conduct these kinds of things, just in -

25 CHAYTOR, Q.C.:

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1 Q. On a regular basis.

2 MS. WADE:

3 A. - staff huddles and those kinds of things,

4 yeah.

5 CHAYTOR, Q.C.:

6 Q. And that's something, Ms. Wade, you're

7 responsible for quality throughout the entire

8 region, in terms of you say 17 sites. So that

9 would include acute care and long-term sites

10 as well?

11 MS. WADE:

12 A. Well, my role with the lab program, the lab

13 itself has 17 sites and they provide anything

14 from sample collection only right to referral

15 type testing, as at the Health Science Centre,

16 so that's a lab site. As far as my role as

17 program manager for quality and safety, it's a

18 portfolio appointment and that is responsible

19 for all of those programs in Dr. Howell's

20 portfolio. So it includes diagnostic imaging

21 and pharmacy and medical services, as well as

22 lab.

23 CHAYTOR, Q.C.:

24 Q. Yes, okay. So the 17 sites, there are 17 labs

25 throughout Eastern Health and -

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1 MS. WADE:

2 A. That this refers to.

3 CHAYTOR, Q.C.:

4 Q. - all of them would come under your portfolio?

5 MS. WADE:

6 A. Certainly.

7 CHAYTOR, Q.C.:

8 Q. Yes, okay, and you write here "communicates

9 with internal and external stakeholders,

10 including nursing staff, family physicians and

11 other regional laboratories regarding

12 laboratory policies and procedures." So I take

13 it you have a liaison role?

14 MS. WADE:

15 A. Right.

16 CHAYTOR, Q.C.:

17 Q. And in terms of communicating with other

18 regional laboratories, I take it that means

19 Western, Central, Labrador Grenfell?

20 MS. WADE:

21 A. That's right.

22 CHAYTOR, Q.C.:

23 Q. And so were you involved then in communicating

24 with them regarding the new policies and

25 procedures that are coming out of Eastern

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1 Health?

2 MS. WADE:

3 A. That's right, and generally, what I would do

4 is anything that is new that I've been

5 involved with, I would forward the information

6 to the directors of those regions so that they

7 could then disseminate it all throughout their

8 region.

9 CHAYTOR, Q.C.:

10 Q. Yes, and I'll have a few more questions for

11 you on that later on today. And then you

12 "facilitate continuing education opportunities

13 such as web-based presentation by CLMA and

14 CLSI for laboratory personnel throughout the

15 region."

16 MS. WADE:

17 A. Um-hm.

18 CHAYTOR, Q.C.:

19 Q. And "coordinate a pilot laboratory

20 accreditation in 2007."

21 MS. WADE:

22 A. That's right.

23 CHAYTOR, Q.C.:

24 Q. Okay, and then under interpersonal skills, you

25 "advise Vice President Medical Services and

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1 Diagnostics regarding issues of quality and

2 employee and patient safety for the

3 portfolio," and I understand you report

4 directly--in your current position, you report

5 directly to Dr. Howell? Is that correct?

6 MS. WADE:

7 A. That's right.

8 CHAYTOR, Q.C.:

9 Q. And then under committee participation,

10 there's quite a number of committees listed

11 there, which are relevant to the laboratory.

12 Laboratory Quality Management Steering

13 Committee, what's the role of that committee?

14 Is that -

15 MS. WADE:

16 A. That is a very new committee of the lab. We

17 just held one meeting so far, and basically

18 it's the lab managers and the division chief,

19 as well as myself, and the role of that

20 committee will basically be to oversee quality

21 management initiatives for the lab program.

22 So the framework for that and the terms of

23 reference have not been developed yet and

24 we're in the process of formalizing that

25 process.

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1 CHAYTOR, Q.C.:

2 Q. Okay, I'm sorry, and who chairs that

3 committee?

4 MS. WADE:

5 A. I will be chairing that committee.

6 CHAYTOR, Q.C.:

7 Q. You're going to chair that committee?

8 MS. WADE:

9 A. Yes.

10 CHAYTOR, Q.C.:

11 Q. And then the Pathology Quality Management

12 Committee, is that then a similar committee

13 but it would just deal with the pathology

14 section of the lab?

15 MS. WADE:

16 A. That's right.

17 CHAYTOR, Q.C.:

18 Q. And who chairs that committee?

19 MS. WADE:

20 A. Dr. Lynn Morris-Larkin right now, and Bev

21 Rowe, who is the quality coordinator for

22 pathology.

23 CHAYTOR, Q.C.:

24 Q. Okay, and is that the committee that Dr. Bev

25 Carter was involved with at some point?

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1 MS. WADE:

2 A. That's right.

3 CHAYTOR, Q.C.:

4 Q. Same committee. And then the Laboratory

5 Leadership Committee, you sit on that

6 committee?

7 MS. WADE:

8 A. I sit on that committee, yes.

9 CHAYTOR, Q.C.:

10 Q. And that's relatively new, I take it, in your

11 new position?

12 MS. WADE:

13 A. Well, certainly for me, but that consists of

14 Mr. Gulliver and Dr. Denic and Dr. Howell and

15 Dr. Simon Avis.

16 CHAYTOR, Q.C.:

17 Q. And now yourself?

18 MS. WADE:

19 A. And myself, yeah.

20 CHAYTOR, Q.C.:

21 Q. Okay, and Laboratory Operating Room Quality

22 Improvement Committee, is that a new

23 committee?

24 MS. WADE:

25 A. That is actually. We've had two meetings and

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1 that was called at the request of the OR
 2 educators and their director, and basically
 3 consists of various people from the lab
 4 program, as well as from the OR, and it's a
 5 great venue to enhance quality initiatives,
 6 certainly for specimens that are coming from
 7 the OR to the lab, given that those samples
 8 are very precious samples and we want to make
 9 sure that we get it right the first time, from
 10 the time that they're taken out, and we see
 11 this as a good networking opportunity to
 12 communicate our policies and to get feedback
 13 from the people who would be using them.
 14 CHAYTOR, Q.C.:
 15 Q. So representatives of the perioperative
 16 program and the -
 17 MS. WADE:
 18 A. And the lab.
 19 CHAYTOR, Q.C.:
 20 Q. - laboratory medicine program sit on that
 21 committee?
 22 MS. WADE:
 23 A. That's right, yes.
 24 CHAYTOR, Q.C.:
 25 Q. Okay, and the purpose being to address any

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1 common issues that may arise?
 2 MS. WADE:
 3 A. That's right.
 4 CHAYTOR, Q.C.:
 5 Q. And to ensure, in particular, as you're
 6 saying, that specimens are handled
 7 appropriately and -
 8 MS. WADE:
 9 A. That's right.
 10 CHAYTOR, Q.C.:
 11 Q. - in a timely manner as well?
 12 MS. WADE:
 13 A. Yeah.
 14 CHAYTOR, Q.C.:
 15 Q. And then you have Portfolio Safety and Quality
 16 Committee, Medical Services and Diagnostics.
 17 What's the mandate of that committee?
 18 MS. WADE:
 19 A. Well, that is the overall portfolio one
 20 chaired by Dr. Howell, and that consists of
 21 all the directors from his portfolio as well
 22 as some stakeholders from the surgery medicine
 23 program and users of our service, and I sit on
 24 that as the quality manager for his portfolio.
 25 CHAYTOR, Q.C.:

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1 Q. And Laboratory Pan-Canadian Standards Group,
 2 Canada Health Infoway, what is that group?
 3 MS. WADE:
 4 A. That is a national group out of Canada Health
 5 Infoway that is developing standards for the
 6 electronic health record in relation to lab.
 7 So it talks about electronic transfer of lab
 8 data, a lot of IT-ish information and also to
 9 help the provinces to conform to a standard
 10 process so that eventually the lab components
 11 can be within the electronic health record.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and you've been part of both the
 14 Electronic Health Record Laboratory Advisory
 15 Committee of NLCHI and Clinical Meditech
 16 Consolidation Committee, Eastern Health?
 17 MS. WADE:
 18 A. That's right.
 19 CHAYTOR, Q.C.:
 20 Q. And how long has that committee been in
 21 existence?
 22 MS. WADE:
 23 A. The Clinical Consolidation Committee?
 24 CHAYTOR, Q.C.:
 25 Q. The Clinical Meditech Consolidation.

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1 MS. WADE:
 2 A. The Meditech one is recently, probably in the
 3 last couple of months, and that is with a view
 4 to consolidating into one Meditech system for
 5 Eastern Health.
 6 CHAYTOR, Q.C.:
 7 Q. Okay. Your role as the manager of client
 8 services, what were your overall
 9 responsibilities in that position?
 10 MS. WADE:
 11 A. It was twofold. First off was the human
 12 resources component. I was responsible for
 13 all of the blood collection staff and the data
 14 entry staff in St. John's hospitals, and then
 15 there was the liaising kind of role that
 16 provided a link for other programs and other
 17 regions to communicate with the lab program
 18 within the Health Care Corp at one time and
 19 then Eastern Health.
 20 CHAYTOR, Q.C.:
 21 Q. And so when Eastern Health came on, your role
 22 as manager of client services was basically
 23 the same with Eastern Health?
 24 MS. WADE:
 25 A. That's right, and it was to try and expand,

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1 certainly in the regional component, to expand
 2 some of our policies around things like
 3 labelling of samples and specimen handling and
 4 acceptance and rejection criteria throughout
 5 the region, to standardize that component of
 6 safety.
 7 CHAYTOR, Q.C.:
 8 Q. Okay, and do you have any particular
 9 experience or expertise in quality or quality
 10 initiatives?
 11 MS. WADE:
 12 A. From my role in the client services program, I
 13 did--a lot of the occurrence reports for the
 14 lab came to me because I was that liaison
 15 person. So in that role, I did a lot of
 16 investigation or certainly follow up on any
 17 occurrences that might be something like a
 18 sample didn't arrive at the lab or they didn't
 19 get a report in a timely manner, things like
 20 that. So the processes for follow up became
 21 very familiar to me over the course of time,
 22 and I took an interest in quality management
 23 from early in my career. Anytime I went away
 24 to national conferences or had an opportunity
 25 to attend any lectures or workshops, those

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1 were the kinds of things that I would take.
 2 CHAYTOR, Q.C.:
 3 Q. And we see, of course, under your continuing
 4 education a number of seminars?
 5 MS. WADE:
 6 A. Right.
 7 CHAYTOR, Q.C.:
 8 Q. That you've attended in 2007/2008, in
 9 particular. Perhaps we could have, please,
 10 Registrar, P-3588, and this is a job
 11 description it looks like what was posted for
 12 your current position, and it indicates that
 13 it's Medical Services Diagnostics Program
 14 Manager, Safety and Quality Management,
 15 reporting to the VP Medical Services, "shall
 16 be accountable for developing, coordinating
 17 comprehensive quality management program
 18 within the portfolio, and you have regional
 19 responsibility regarding quality issues. The
 20 Safety Quality Manager will work in close
 21 liaison with directors, clinical chiefs,
 22 discipline chair, managers, as well as the
 23 other quality team leaders. The initial focus
 24 will be on the laboratory medicine program and
 25 will expand to other programs/departments

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1 within the portfolio. The candidate will
 2 develop, implement, and coordinate a
 3 comprehensive quality management program for
 4 laboratory medicine and safety plan for the
 5 program, which would include meeting all
 6 safety legislation and CSMLS safety
 7 guidelines, liaise with quality and systems
 8 improvement department regarding patient
 9 safety risk management issues", and does that
 10 basically capture what, in fact, then you are
 11 doing?
 12 MS. WADE:
 13 A. That's right, yeah.
 14 CHAYTOR, Q.C.:
 15 Q. And having to--your initial focus be on the
 16 laboratory medicine program. Why do you
 17 understand to be the case, why is that your
 18 initial focus, and what portion of your time
 19 is dedicated to the laboratory medicine
 20 program?
 21 MS. WADE:
 22 A. Well, this position was not created until
 23 March of 2007. I didn't take the position
 24 until close to the summer. We were then two
 25 years into this investigation, and it was seen

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1 that we needed to enhance our policies and
 2 procedures, and certainly given the
 3 regionalization of lab medicine. It was a
 4 daunting task to be done without someone being
 5 able to oversee it.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, and you're accountable for developing
 8 and coordinating a comprehensive quality
 9 management program, and so far to date has
 10 that happened or is it still in the works?
 11 MS. WADE:
 12 A. Oh, it's--it's very much in the works.
 13 Obviously, there's been a lot of emphasis on
 14 the pathology division over the last couple of
 15 years, and I've spent a lot of my time
 16 assisting them in redeveloping their
 17 procedures and policies. I have done some
 18 other lab, general lab policies, around more
 19 administrative kinds of things, and recently
 20 we regionalized and rolled out the laboratory
 21 mislabelled specimen policy for the region and
 22 communicated that to all regions in the
 23 province because being a referral centre here
 24 in this site, in St. John's site, we had to
 25 ensure that, and also a policy around specimen

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

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

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1 work on those.
 2 CHAYTOR, Q.C.:
 3 Q. And do they have representation on the
 4 committees that we looked at, some or all of
 5 the committees?
 6 MS. WADE:
 7 A. Well, on the Lab Management Committee, their
 8 manager sits on the Lab Managers Committee,
 9 and then also the pathology--one of the
 10 pathology technologists liaises with us as
 11 well from Carbonear.
 12 CHAYTOR, Q.C.:
 13 Q. If we could have, please, P-3586, and this is
 14 a position description for your job and it's
 15 marked in draft. Has it been finalized?
 16 MS. WADE:
 17 A. Pardon? Sorry.
 18 CHAYTOR, Q.C.:
 19 Q. That's okay, sorry, has--your job description,
 20 has this been finalized?
 21 MS. WADE:
 22 A. No, I'm still waiting to get some feedback
 23 from Classification people, and it is a work
 24 in progress. It's only been a year since I
 25 started this position, so to get down on paper

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1 now to try to frame it up. So it's close,
 2 though.
 3 CHAYTOR, Q.C.:
 4 Q. So this is your draft of what you see yourself
 5 doing?
 6 MS. WADE:
 7 A. This is--I drafted it and it's been vetted to
 8 Dr. Howell already once, yeah.
 9 CHAYTOR, Q.C.:
 10 Q. And under Quality Management, this position is
 11 accountable for ensuring the development,
 12 organization, evaluation, and improvement of
 13 quality management systems for the programs in
 14 the portfolio?
 15 MS. WADE:
 16 A. That's right.
 17 CHAYTOR, Q.C.:
 18 Q. And, of course, one of those programs being
 19 the laboratory medicine?
 20 MS. WADE:
 21 A. Right.
 22 CHAYTOR, Q.C.:
 23 Q. And then the nature and scope, it's quite
 24 detailed what you've set out here in terms of
 25 the nature and scope of your position, and you

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1 indicate, "Safety and Quality Management
 2 Program is a new program implemented in July
 3 of 2007", and reporting--the incumbent advises
 4 the VP Medical on aspects of patient and
 5 employee safety and quality management related
 6 to the programs. "The Program Manager
 7 receives documents and follows up on reports
 8 and orders issues to the departments in the
 9 portfolio by the inspectors from the
 10 Department of Government Services". That's
 11 Occupational Health and Safety?
 12 MS. WADE:
 13 A. That's right.
 14 CHAYTOR, Q.C.:
 15 Q. And you're responsible for ensuring that the
 16 programs develop a quality management system,
 17 including policies and procedures that are in
 18 compliance with applicable standards,
 19 regulatory body requirements, and government
 20 legislation and guidelines, and you provide
 21 direction and support to the lab for the
 22 purpose of planning and developing their
 23 quality management system safety programs and
 24 provide guidance and training to staff that
 25 are responsible for writing policies and

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1 procedures in their departments, responsible
 2 for facilitating training of portfolio
 3 management and employees regarding safety
 4 programs and quality management systems, and
 5 ensuring promotion of policies and procedures
 6 to other programs and external stakeholders,
 7 such as community physicians and other
 8 regional health authorities as required. So I
 9 take it if there's anything in the way of a
 10 policy and procedure that needs to be
 11 communicated outside of Eastern Health, you're
 12 responsible for facilitating that as well?
 13 MS. WADE:
 14 A. I would certainly recommend that it would be
 15 shared, yes.
 16 CHAYTOR, Q.C.:
 17 Q. And you're responsible for overseeing the
 18 development of key indicators by the programs,
 19 and monitoring the effectiveness and quality
 20 of the services--sorry, for the purpose of
 21 monitoring the effectiveness and quality of
 22 services and ensures continuous quality
 23 improvement initiatives are undertaken based
 24 on indicator measurements, satisfaction--
 25 survey results and occurrence reporting.

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1 What's involved in that? Perhaps you could
 2 just give us some practical or an example as
 3 to what would that involve?
 4 MS. WADE:
 5 A. You've heard about one of the initiatives, I
 6 guess, in determining indicators of quality.
 7 We've talked about proficiency testing and
 8 those kinds of things, and we've been looking
 9 at the overall reporting or results of
 10 proficiency testing for the labs throughout
 11 the region, all labs, not just pathology
 12 certainly, and basically looking at ways to
 13 measure how well we're doing, and how we are
 14 perceived by our stakeholders and users, such
 15 as clinicians and patients.
 16 CHAYTOR, Q.C.:
 17 Q. Okay. How do you go about monitoring whether
 18 or not policies and procedures, once adopted,
 19 that they're, in fact, being followed?
 20 MS. WADE:
 21 A. Well, part of the--part of the procedure for
 22 putting out a new policy is to ensure that
 23 there is a cover sheet that goes with it,
 24 basically, a sign off sheet. So people who
 25 are responsible for following it must read it

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1 and indicate that they have, and then we
 2 maintain the document as a control document
 3 that says that they--so by people signing off
 4 that they had read a policy, then they're
 5 accountable to follow that policy.
 6 CHAYTOR, Q.C.:
 7 Q. So that indicates that they have read it and
 8 are aware of it and informed?
 9 MS. WADE:
 10 A. That's right.
 11 CHAYTOR, Q.C.:
 12 Q. Then is there any checks or balances to follow
 13 up to see, in fact, that they are following
 14 the policies? Is there anything in terms of
 15 the implementation of the policy, is there any
 16 checks that can be made or are to be made?
 17 MS. WADE:
 18 A. There are types of audits and checks, even if
 19 the--we have a policy around monitoring
 20 temperature dependent equipment, and one of
 21 the audits to ensure that that policy is being
 22 followed is that we can go at any point in
 23 time and look at their temperature charts, for
 24 instance, and if there are gaps in that or if
 25 there are temperature failures, what were the

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1 corrective actions that were taken and
 2 ensuring that they are following. So that's--
 3 you know, you have to--we have to build in
 4 indicators or audits for determining
 5 compliance.
 6 CHAYTOR, Q.C.:
 7 Q. And that's still in the works, I take it?
 8 MS. WADE:
 9 A. Some of it is in place. So certainly, you
 10 know, for some policies--the new policies that
 11 are going out, I know certainly in pathology,
 12 for instance, that binder does have a sign-off
 13 sheet in there.
 14 CHAYTOR, Q.C.:
 15 Q. So that people know--acknowledge they've read
 16 them?
 17 MS. WADE:
 18 A. Exactly, yeah.
 19 CHAYTOR, Q.C.:
 20 Q. And what about then what's built in in terms
 21 of an audit function to check whether or not
 22 the policies or procedures are being followed?
 23 MS. WADE:
 24 A. And again things like audit sheets for
 25 monitoring temperature control is one, or

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1 daily maintenance procedure check-offs for
 2 equipment, there's policies around ensuring
 3 that the equipment is maintained. So the
 4 managers really need to be checking the
 5 maintenance manuals to make sure that they
 6 have been checked off, and that they are being
 7 followed as they are set out.
 8 CHAYTOR, Q.C.:
 9 Q. So then that becomes the managers--that's part
 10 of the managers function then to do that?
 11 MS. WADE:
 12 A. Certainly, yes, the managers or the designate.
 13 It could be a senior technologist in the
 14 department who would be doing certain aspects
 15 of it, and in my role, I certainly know that
 16 the managers are challenged with everything
 17 day to day, and there does need to be
 18 accountability on the part of all
 19 technologists to ensure that they're following
 20 the guidelines and policies and day to day
 21 operation procedures. So one of the things
 22 that I recommend to managers is that they
 23 build daily tasks relating to compliance for
 24 safety and quality in every work bench, so
 25 that it becomes inherent as part of the job

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1 and it's not something else they have to do,
 2 it's just part of what you do.
 3 CHAYTOR, Q.C.:
 4 Q. Part of what they do when they sit down to do
 5 their job every day?
 6 MS. WADE:
 7 A. Exactly, that's right.
 8 CHAYTOR, Q.C.:
 9 Q. And at your level then, you work with them to
 10 make sure they have the appropriate policies
 11 and procedures in place, and then assist them
 12 in how--in different ways in which they can go
 13 about ensuring compliance?
 14 MS. WADE:
 15 A. That's right, yeah.
 16 CHAYTOR, Q.C.:
 17 Q. Okay. You write on the third page of the
 18 exhibit the major challenges faced by yourself
 19 "are facilitating change management to enhance
 20 the quality and a patient and employee safety
 21 culture". What are you referring to there?
 22 MS. WADE:
 23 A. The intricacies, I guess, of quality
 24 management, there's a lot of detail associated
 25 with it, you know, and really paying attention

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

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

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1 are not at that front end, we have to ensure
 2 that they have the information. So that's all
 3 part of fostering this team approach to the
 4 front end, the pre-analysis component.
 5 Obviously, then within the lab, many people in
 6 the lab programs are involved with the sample,
 7 getting them ready for testing, and actually
 8 testing, and then the reporting of them, so -
 9 CHAYTOR, Q.C.:
 10 Q. Okay.
 11 MS. WADE:
 12 A. That's what I mean by that.
 13 CHAYTOR, Q.C.:
 14 Q. Okay, and then under your--we've talked about
 15 your committee involvement, and under your
 16 specific accountability, advising Dr. Howell
 17 on aspects of safety and quality relevant to
 18 the programs in his portfolio, providing
 19 leadership and guidance to the programs for
 20 the development, auditing, and review of
 21 quality management systems.
 22 MS. WADE:
 23 A. Uh-hm.
 24 CHAYTOR, Q.C.:
 25 Q. And again we've just spoken briefly on the

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1 auditing and how you've -
 2 MS. WADE:
 3 A. Uh-hm.
 4 CHAYTOR, Q.C.:
 5 Q. Of assistance in that regard.
 6 MS. WADE:
 7 A. Yes.
 8 CHAYTOR, Q.C.:
 9 Q. "Collaborates with managers and staff in the
 10 development of policies and procedures for the
 11 program. Collaborates with management and
 12 staff to development orientation training,
 13 continuing education and competency assessment
 14 tools for the programs", and what have you
 15 done in terms of that for the laboratory
 16 medicine program?
 17 MS. WADE:
 18 A. A lot of my original--the early stages, I
 19 guess, has been around the safety program,
 20 ensuring that all staff are educated in WHMIS
 21 education, again the workshop around quality
 22 management, introducing that certainly to the
 23 senior staff, the leaders of the various sites
 24 and divisions. The competency assessment tool
 25 is--is not necessarily a new tool. There are

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

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1 what credentials a laboratory technologist is
 2 required to have before they are permitted to
 3 work within the IHC component of the program?
 4 MS. WADE:
 5 A. At this point in time, they must be a CSMLS
 6 certified lab technologist.
 7 CHAYTOR, Q.C.:
 8 Q. And is there any requirement for any
 9 competency assessment or testing?
 10 MS. WADE:
 11 A. That's pretty specific to the pathology
 12 division, and Mr. Dyer could probably answer
 13 that better than I could.
 14 CHAYTOR, Q.C.:
 15 Q. So in terms of, would you expect if there were
 16 to have something like that develop, that you
 17 would be of assistance in doing that?
 18 MS. WADE:
 19 A. Certainly with, most of the work benches now,
 20 I do know in pathology do have kind of a
 21 checklist of duties and responsibilities, so
 22 that would be the kind of thing that, you
 23 know, if you have a checklist of things that
 24 you have to do, then it stands to reason you
 25 have to know how to do them before you can

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1 start to work there.
 2 CHAYTOR, Q.C.:
 3 Q. And have you been asked to do anything in
 4 terms of looking at a competency assessment
 5 for laboratory technologists?
 6 MS. WADE:
 7 A. Overall at this point I'm just starting to do
 8 some research around what is out there and
 9 what other jurisdictions are doing with
 10 respect to competency assessments. We have
 11 some things that are available as little
 12 quizzes, that kind of thing. I'm more
 13 inclined to go with peer to peer assessments
 14 and those kind of things, as opposed to making
 15 them very intimidating kind of things, you
 16 know, something that could be used in peer
 17 reviews, that kind of thing within their own
 18 divisions.
 19 CHAYTOR, Q.C.:
 20 Q. So I just want to be clear, have you been
 21 asked to look into that or this is something
 22 that you -
 23 MS. WADE:
 24 A. It is part of a Quality Management Program
 25 that there be competency assessment for

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1 personnel, so that's part of the whole policy
 2 around, the people within the lab.
 3 CHAYTOR, Q.C.:
 4 Q. And has there been anything put in place to
 5 date to your knowledge?
 6 MS. WADE:
 7 A. Not completed, no, because--it's certainly
 8 something that I'm working on for the program,
 9 the overall policies that there need to be
 10 competency assessment tools and each division
 11 will have to develop what is appropriate for
 12 them.
 13 CHAYTOR, Q.C.:
 14 Q. Right, and that's something I believe was
 15 raised back in 2005 by Ms. Wegrynowski was the
 16 first time that we've seen it raised here.
 17 But you are now working on coming up with some
 18 assessment tools, competency assessment tools.
 19 MS. WADE:
 20 A. Yes.
 21 CHAYTOR, Q.C.:
 22 Q. And that would include the IHC technologists?
 23 MS. WADE:
 24 A. It would be every employee within the lab.
 25 CHAYTOR, Q.C.:

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1 Q. And is there any policy which requires the
 2 type and duration of an orientation process
 3 that a new hire, in terms of a technologist,
 4 would be required to meet to be able to work
 5 in the IHC portion of the lab?
 6 MS. WADE:
 7 A. I'm not aware of the specifics of IHC.
 8 CHAYTOR, Q.C.:
 9 Q. And do you know whether or not there's any
 10 plan to develop such a policy? Has anyone
 11 approached you -
 12 MS. WADE:
 13 A. There will be a lab program policy that
 14 discusses the need for adequate and
 15 appropriate orientation, training and
 16 continuing education and competency
 17 assessment. So the lab program will develop--
 18 or I will be developing the lab programs
 19 policy, certainly in conjunction with all the
 20 managers, but then every division and site
 21 will have to personalize it to their area
 22 because everywhere it is different, so you
 23 have to ensure that the tools that are
 24 developed will work.
 25 CHAYTOR, Q.C.:

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1 Q. And have you had any discussions with anyone,
 2 whether the director of the program or the
 3 clinical chief about the requirement for lab
 4 technologists to pursue a certain level of
 5 continuing education?
 6 MS. WADE:
 7 A. Yes, I have always, as a technologist long
 8 before I was ever in this role, felt that
 9 continuing education is certainly an
 10 individual responsibility to make sure that
 11 you are aware and educated around the advances
 12 of our profession, I mean, lab technology has
 13 come leaps and bounds since I started and it's
 14 even faster with--these days, so continuing
 15 education I have discussed with Dr. Denic
 16 certainly and he's been very supportive of any
 17 initiatives that we have undertaken to enhance
 18 this, so in recent months we have provided web
 19 based kinds of education sessions where staff
 20 can attend at a computer. Just recently we
 21 had one out of clinical--I think it was out of
 22 Maryland General Hospital. There are a number
 23 of on-line opportunities and certainly because
 24 of where we are located, it can be very cost
 25 prohibitive to, for people to go away and one

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1 or two at a time is going to take a long time
 2 for everybody to go, so we find that--I'm
 3 finding that there is a lot of opportunity on
 4 the web now.
 5 CHAYTOR, Q.C.:
 6 Q. Yes.
 7 MS. WADE:
 8 A. So that's what we're looking to facilitate.
 9 CHAYTOR, Q.C.:
 10 Q. And is there an additional designation that a
 11 technologist can acquire beyond an RT? Is
 12 there an advanced registered technologist?
 13 MS. WADE:
 14 A. There is an advanced registration, there's not
 15 necessarily a requirement for that. A lot of
 16 people who have achieved the registered
 17 technologists certification and designation
 18 through the CSMLS have done so of their own
 19 volition as a personal development piece, but--
 20 -and also now with the Bachelor of Technology,
 21 a number of people throughout the region are
 22 challenging the Bachelor of Technology degree
 23 program.
 24 CHAYTOR, Q.C.:
 25 Q. And in doing an ART, can that be done in

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1 specific areas of expertise, like microbiology
 2 or pathology?
 3 MS. WADE:
 4 A. The advance certification, there is a general
 5 one, but then most people tend to select the
 6 discipline specific, such as microbiology or
 7 pathology. Microbiology seems to be the most
 8 common one that I am aware of.
 9 CHAYTOR, Q.C.:
 10 Q. And has there been any discussion within
 11 Eastern Health as to, for example,
 12 technologists that ultimately come to work in
 13 IHC, we understand have been fairly senior
 14 people. Has there been any discussion as to
 15 whether or not there should be an ART pursued
 16 that may be of assistance to them?
 17 MS. WADE:
 18 A. I'm not aware of that discussion, although I
 19 do know that they're looking at the
 20 possibility of some specific certification
 21 maybe in immunohistochemistry. That may be
 22 offered, certainly not in--I don't think
 23 there's anything offered in Canada, but there
 24 are through various other agencies.
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and we've heard that the medical
 2 laboratory technologists are not a regulated
 3 profession in this province. Have you been
 4 involved over the years in trying to have
 5 laboratory technologists regulated?
 6 MS. WADE:
 7 A. Yes, back in the early '90s I was involved in
 8 the first committee, I guess, out of the
 9 society to put together a presentation or a
 10 brief to government with a view of having this
 11 profession licensed in the province. We had a
 12 very unfortunate incident back in the late
 13 '70s that we really felt should have been a
 14 driving force towards regulating the
 15 profession and to this day, it is still not
 16 licensed.
 17 CHAYTOR, Q.C.:
 18 Q. And why are you a proponent of regulation?
 19 What benefit do you see coming out of that?
 20 MS. WADE:
 21 A. Well obviously the very overriding principle
 22 is public safety, but I believe that public
 23 safety then is not only just enhanced by
 24 confidence, I guess, in the knowledge that the
 25 people who are working and doing lab testing

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1 are competent and trained and accountable for
 2 the result that they do and also I believe
 3 that with regulation comes an accountability
 4 on the technologists to continuing education
 5 and ensuring that they enhance their training
 6 as well.
 7 CHAYTOR, Q.C.:
 8 Q. So to renew your license on an annual basis,
 9 you'd have to show that you met certain
 10 continuing requirements.
 11 MS. WADE:
 12 A. Exactly.
 13 CHAYTOR, Q.C.:
 14 Q. So why hasn't it happened? You've been at
 15 this a long time trying to have it happen,
 16 what obstacles have you encountered along the
 17 way?
 18 MS. WADE:
 19 A. Back, after we made the initial presentation,
 20 of course, back then there was a number of
 21 government changes of government and you know,
 22 I think in 2001 another group of us met with
 23 some people at the Department of Labour, I
 24 think it was, it was involved with regulation
 25 of professions and there was a white paper

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1 that had been put out on regulating of
 2 numerous professions. So we submitted a
 3 response to that, answered all the questions
 4 and again, in the throes of government
 5 bureaucracy, I guess, in all of the changes
 6 that went on, it never was received by whoever
 7 was supposed to get it. So our latest
 8 information now is that 2006 the provincial
 9 society resubmitted an updated response to the
 10 white paper and the last correspondence was
 11 last October, 2007 that it was now on the
 12 table. Prior to that, correspondence was that
 13 it was not a priority at this time and that
 14 was back in early 2000.
 15 CHAYTOR, Q.C.:
 16 Q. Two thousand and -
 17 MS. WADE:
 18 A. Back earlier in 2000, so after 2001 -
 19 CHAYTOR, Q.C.:
 20 Q. So was it in 2005 you had a response on that?
 21 MS. WADE:
 22 A. I can't recall the dates now, but in 2007 the
 23 last response was last October that it was
 24 being discussed and they had hoped that it
 25 would be on the fall sitting or the next

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1 sitting of the House, so--but I haven't heard
 2 of anything further from that.
 3 CHAYTOR, Q.C.:
 4 Q. And then if we could just look back at this
 5 exhibit, it also indicates that you are to
 6 assist the portfolio programs in preparation
 7 for accreditation and we understand that that
 8 lab is now going to be in the next
 9 accreditation round, the lab will be part of
 10 that, and so what is it that you are tasked
 11 with doing to prepare the Laboratory Medicine
 12 Program for accreditation?
 13 MS. WADE:
 14 A. Well certainly out of the accreditation pilot
 15 that we participated in in 2007, we received a
 16 number of recommendations and have been
 17 working to meet those and part of that is the
 18 development of a Quality Management Program,
 19 but that basically is in compliance with the
 20 ISO 15189 standard for medical laboratories.
 21 So the accreditation, if we meet the standard
 22 for ISO, we will meet the accreditation
 23 anyway, so my role now has been--it's all
 24 around the developing of a Quality Management
 25 Program.

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1 CHAYTOR, Q.C.:
 2 Q. If we could have, please, Commissioner, P-
 3 0697? And this is a meeting of the Laboratory
 4 Program, Divisional Managers, back in, I
 5 believe it's March 4th, 1997. And on page 2,
 6 there's "an internal advisory committee
 7 referred to under QI issues for the Laboratory
 8 Program has been set up and the first meeting
 9 held. The membership is as follows:"--and
 10 we'll see that you're there in your role as
 11 manager of client services at the time. "The
 12 membership will rotate and the terms of
 13 reference are being established. Divisional
 14 subcommittees will be set up and will report
 15 back to the IAC, which will probably meet
 16 every second month. And the IAC will report
 17 once a year to the senior advisory committee."
 18 What do you recall about this committee, its
 19 mandate and did the terms of reference ever
 20 get established? Did they ever get off the
 21 ground? I realize it's over ten years ago.
 22 MS. WADE:
 23 A. That was right after the beginning of Health
 24 Care Corporation and the--oh my, I recall
 25 meetings, internal advisory committee meetings

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1 and presenting at that--presented at that
 2 committee would be thing like external
 3 proficiency testing reports and any complaints
 4 and occurrence that may have occurred
 5 throughout the program.
 6 CHAYTOR, Q.C.:
 7 Q. Okay.
 8 MS. WADE:
 9 A. I don't recall the specifics around terms of
 10 reference or anything now, it's quite a while
 11 ago.
 12 CHAYTOR, Q.C.:
 13 Q. Okay, and if we could have then, please, P-
 14 2537? I'll bring you forward three years to
 15 see if your memory gets better. September
 16 20th, 2000, this is a meeting of the
 17 Laboratory Management Committee and you're
 18 indicated to be in attendance and on page 2,
 19 under QI activities, "The most recent copies
 20 of the following activities were reviewed,
 21 proficiency reports, human resource indicators
 22 instance reports, there are no proficiency
 23 surveys for pathology and cytology." So who
 24 attending the meeting would be giving this?
 25 Would this be part of your job as the manager

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1 of Client Services?
 2 MS. WADE:
 3 A. No, not then in 2000. I was manager of Client
 4 Services at that time.
 5 CHAYTOR, Q.C.:
 6 Q. Yes.
 7 MS. WADE:
 8 A. And that was just part of--the lab management
 9 committee at that time consisted of the
 10 managers and the chief, so the QI activities
 11 then were tabled as information.
 12 CHAYTOR, Q.C.:
 13 Q. And so it wasn't part of your job to track
 14 whether or not there were proficiency surveys
 15 being done in any particular area?
 16 MS. WADE:
 17 A. No.
 18 CHAYTOR, Q.C.:
 19 Q. For example, were you aware whether or not
 20 there was--had you heard prior to all of this
 21 coming up in 2005 that there was no external
 22 proficiency testing for the IHC portion of the
 23 lab?
 24 MS. WADE:
 25 A. No, I didn't.

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1 CHAYTOR, Q.C.:
 2 Q. And if we could have, please, P-1900 please?
 3 And I think this again is the Laboratory
 4 Management Committee, you're not in
 5 attendance, you're absent and on page 2
 6 there's a reference of "Notification of
 7 laboratory error (written policy) this has
 8 been completed by Lynn Wade." And again, this
 9 is back 3 more years, along life's way,
 10 November 20th, 2003. What was your
 11 involvement at that time in completing a
 12 notification of laboratory error policy?
 13 MS. WADE:
 14 A. I'm sorry, Ms. Chaytor, but this is -
 15 CHAYTOR, Q.C.:
 16 Q. You're drawing a blank.
 17 MS. WADE:
 18 A. It totally escapes me right now.
 19 CHAYTOR, Q.C.:
 20 Q. If we could look at P-3637 please? This is a
 21 very recent policy called Pathology Error
 22 Disclosure and this one is quite recent,
 23 approved July 28th, 2008, effective September
 24 15th, 2008. Would that be a pathology error
 25 disclosure, would that be similar to what a

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1 notification of lab error policy may have
 2 been, a similar sort of thing as this?
 3 MS. WADE:
 4 A. In this one here, if I could just go down -
 5 CHAYTOR, Q.C.:
 6 Q. Sure, yes, take the mouse.
 7 MS. WADE:
 8 A. See if I can--that policy is a policy specific
 9 for the pathology division and explains how
 10 any error may be detected and that they have
 11 to be reported to the chief, the site chief,
 12 certainly if there are pathology reporting
 13 errors and just looking to see -
 14 CHAYTOR, Q.C.:
 15 Q. So the other one may have been broader for lab
 16 errors overall for the entire program?
 17 MS. WADE:
 18 A. That one is specific for pathology.
 19 CHAYTOR, Q.C.:
 20 Q. This one.
 21 MS. WADE:
 22 A. Yes, yeah, for the lab, I'm in the process of
 23 writing a policy called corrected report, so
 24 that if there's something picked up in
 25 reviews, certainly something like this, it

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1 would apply to this kind of policy. Pathology
 2 and a couple of other divisions have much more
 3 narrative kinds of reports and the errors
 4 would be picked up on quality reviews to, the
 5 random reviews that would be done within their
 6 division.
 7 CHAYTOR, Q.C.:
 8 Q. So you don't have any specific recollection of
 9 what the notification of lab error policy that
 10 you would have worked on back in 2003, you
 11 don't have any -
 12 MS. WADE:
 13 A. Right off the top of my head, I can't even -
 14 CHAYTOR, Q.C.:
 15 Q. And in going through all the reviewing and
 16 revising of policies for the lab, you didn't
 17 come across such a policy?
 18 MS. WADE:
 19 A. Not specific, no.
 20 CHAYTOR, Q.C.:
 21 Q. Since we -
 22 THE COMMISSIONER:
 23 Q. I'm sorry, I wasn't sure that I understood the
 24 nature of this particular policy, did you say
 25 it related to the pathology division or

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1 related to the pathologists?
 2 MS. WADE:
 3 A. This is the pathology division, so it could be
 4 relating to--it is the report that it's
 5 referring to, so any errors that are picked up
 6 may be on random review or if there was an
 7 error picked up as a result of maybe a
 8 correlation of a final pathology verses the
 9 frozen section, something like that, anything
 10 that requires a change in the report, the
 11 final report would have to follow this-
 12 THE COMMISSIONER:
 13 Q. Follow this process, okay.
 14 MS. WADE:
 15 A. That's very specific to the pathology.
 16 THE COMMISSIONER:
 17 Q. All right, thank you.
 18 CHAYTOR, Q.C.:
 19 Q. And maybe then I will continue then, I have a
 20 few questions for you on this policy, so while
 21 we have it up, it says that "Eastern Health
 22 Pathology Division adheres to the Quality
 23 Management Department policies regarding error
 24 reporting and disclosure. Errors or possible
 25 errors found by QMP personnel or

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1 pathologists"--so that would be yourself -
 2 MS. WADE:
 3 A. That should be pathology quality management
 4 group, right.
 5 CHAYTOR, Q.C.:
 6 Q. So yourself or anyone working with you or your
 7 group or a pathologist?
 8 MS. WADE:
 9 A. Pathology has a quality management committee
 10 specific for pathology.
 11 CHAYTOR, Q.C.:
 12 Q. Which you sit on?
 13 MS. WADE:
 14 A. I do sit on that. The reviews of pathology
 15 reports would be undertaken by Ms. Bev Rowe
 16 who is the quality co-ordinator technologist.
 17 CHAYTOR, Q.C.:
 18 Q. And notes "when performing an audit or case
 19 review" so if errors or possible errors are
 20 picked up on an audit or case review -
 21 MS. WADE:
 22 A. Right.
 23 CHAYTOR, Q.C.:
 24 Q. And they could be minor or they could be of
 25 major significance, "any significant error or

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1 discrepancy that has an effect on patient care
 2 must be brought to the immediate attention of
 3 the site chief and/or clinic chief". And C,
 4 "Definitions of errors of clinical
 5 significance", where would we find that, the
 6 definition of clinical significance?
 7 MS. WADE:
 8 A. Is that at the bottom of this? Usually--yeah,
 9 at the bottom of this policy there's a
 10 definition section, definitions and acronyms.
 11 CHAYTOR, Q.C.:
 12 Q. Under that, yes, okay.
 13 MS. WADE:
 14 A. So they have clinical--errors of clinical
 15 significance and--which would be, but not
 16 limited to those various type.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, thank you. And the purpose it indicates
 19 is "to ensure all pathology errors or possible
 20 errors are discovered, investigated,
 21 documented, corrected and reported
 22 appropriately to assure adequate patient
 23 care." And then if the error is determined to
 24 be of clinical significance, it is to be
 25 reported immediately, as it said, prior to,

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1 and also "report the error to the QI risk
 2 manager and complete an occurrence report
 3 form."
 4 MS. WADE:
 5 A. That's right.
 6 CHAYTOR, Q.C.:
 7 Q. So even if you're going through pathology
 8 reports afterwards for an audit, it's intended
 9 that an occurrence report would be completed.
 10 MS. WADE:
 11 A. Yes, that's right.
 12 THE COMMISSIONER:
 13 Q. And the QI risk manager referred to here is?
 14 MS. WADE:
 15 A. Pardon?
 16 THE COMMISSIONER:
 17 Q. Who would be the QI risk manager referred to
 18 there?
 19 MS. WADE:
 20 A. The manager--well, that probably could say
 21 consultant, so it could be for the lab, it has
 22 been Ms. Janet Laidley is who we were report
 23 directly to for -
 24 THE COMMISSIONER:
 25 Q. In the division under Ms. Predham?

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1 MS. WADE:
 2 A. Under Ms. Predham or the director now is Pam
 3 Elliott.
 4 THE COMMISSIONER:
 5 Q. Yes, all right, thank you.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, and this goes on to allow then the
 8 original pathologists to have some input into
 9 whether or not they agree with the new
 10 diagnosis. At the bottom here it says, "The
 11 pathology department and the responsible
 12 clinician will consult with the quality and
 13 risk management department if a disclosure to
 14 a patient is to be made." Would there ever be
 15 a situation where an error has been determined
 16 of clinical significance that disclosure to a
 17 patient would not be made?
 18 MS. WADE:
 19 A. Not that I'm aware of.
 20 CHAYTOR, Q.C.:
 21 Q. And then "if the error is determined to be of
 22 no clinical significance, the case will be
 23 reviewed by QMP department"--and QMP
 24 department -
 25 MS. WADE:

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1 A. Is a pathology Quality Management Committee.
 2 CHAYTOR, Q.C.:
 3 Q. That's the committee?
 4 MS. WADE:
 5 A. Right.
 6 CHAYTOR, Q.C.:
 7 Q. "With site chief or clinical and the error
 8 will be documented in QMP records for analysis
 9 as accumulated data may suggest, practice
 10 pattern improvements and an amended report
 11 will not be issued for an error of no clinical
 12 significance." First of all, who keeps track
 13 of the QMP records and who would then do the
 14 analysis?
 15 MS. WADE:
 16 A. Bev Rowe, who is the quality co-ordinator
 17 technologist, she is responsible for doing
 18 numerous audits, one of them being a review,
 19 random review of reports and retains all the
 20 documents for that, and presents any analysis
 21 to the Quality Management Committee for
 22 pathology.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, and in this particular situation if it's
 25 not of any clinical significance, it doesn't

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1 get reported to the risk manager?
 2 MS. WADE:
 3 A. No, but we would--I would still recommend that
 4 there would be an occurrence form because
 5 obviously it's an opportunity to -
 6 CHAYTOR, Q.C.:
 7 Q. For them to do some tracking as well.
 8 MS. WADE:
 9 A. To do some tracking, yes.
 10 CHAYTOR, Q.C.:
 11 Q. And that's not though what it says here, it's
 12 different than the requirement -
 13 MS. WADE:
 14 A. That's right.
 15 CHAYTOR, Q.C.:
 16 Q. - for an occurrence report is mandatory if
 17 it's of clinical significance, but it appears
 18 when I read this that it just stays basically
 19 within the labs -
 20 MS. WADE:
 21 A. They would know that they--yeah, they would
 22 have to make the occurrence report for the
 23 clinically significant one, but typically
 24 again, in the quality management office of
 25 pathology, she is documenting and tracking all

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1 of these as well.

2 CHAYTOR, Q.C.:

3 Q. And if we--and "no amended report will be

4 issued for an error of no clinical

5 significance", and so if we think about the

6 ER/PR situation, if a patient had had an ER of

7 zero and a PR of, say, 80 originally and then

8 on--and nonetheless was treated with Tamoxifen

9 because they were treated on their PR status,

10 if that patient then, if there were a repeat

11 then for whatever reason of that test and it

12 was found that the ER status changed, PR

13 stayed the same, and that particular situation

14 might not have any clinical significance

15 because the patient's treatment would not have

16 changed, but under this policy would you

17 nonetheless expect an amended report to be

18 filed?

19 MS. WADE:

20 A. But you are saying that the results changed?

21 CHAYTOR, Q.C.:

22 Q. If the test result changed but it didn't

23 change the treatment for the patient.

24 MS. WADE:

25 A. But in the lab, the lab is not responsible for

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1 the treatment, so in that case, I would

2 consider that to be a clinically significant

3 change in report.

4 CHAYTOR, Q.C.:

5 Q. Okay, so that would then come under the,

6 something of clinical significance and this

7 procedure would be followed?

8 MS. WADE:

9 A. That's right.

10 CHAYTOR, Q.C.:

11 Q. Okay. If we could have then, please, P-3617?

12 And this is a meeting then of September 27th,

13 2005 and you are in attendance at this, it's

14 the laboratory divisional managers' meeting.

15 And if we look at page 3, Medinet update.

16 "Lynn indicated that most of the bugs have

17 been ironed out with Carbonear and it is

18 working well. Gander is next to come on line

19 and Lynn go out for a site visit probably in

20 early November. Corner Brook and Grand Falls

21 will then follow and Jim will check the IT

22 regarding the purchase of necessary software

23 for Clarenville and Burin." And what's that

24 about, what particular -

25 MS. WADE:

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1 A. That again goes back to that Medinet which is

2 the electronic link of orders and reports.

3 Pathology is not involved in that and it's

4 core lab results and orders.

5 CHAYTOR, Q.C.:

6 Q. Okay. "And hard copies of reports, Lynn

7 stated that reports are now being reported

8 directly to Corner Brook and this is working

9 well. This can be set up for other regions as

10 well." Did that involve the pathology lab at

11 all?

12 MS. WADE:

13 A. I don't think pathology reports--they

14 generally go out from the stenos and are

15 mailed directly to the physicians.

16 CHAYTOR, Q.C.:

17 Q. If we could have, please, P-2654?

18 THE COMMISSIONER:

19 Q. Why would that be dealt with differently? Why

20 would it be different because it's pathology?

21 MS. WADE:

22 A. Because the core lab has, we print batches of

23 reports every day and mail them or batch print

24 them directly to the site. Pathology reports

25 are transcribed by a different group and they

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1 print them as they do them, as they are

2 completed and then they are submitted to be

3 mailed directly. So they go directly to the

4 ordering physician or the surgeon. So we

5 don't just print pathology reports out in

6 Corner Brook, we would send those back to the

7 ordering physician if they ordered a pathology

8 report.

9 THE COMMISSIONER:

10 Q. Or there are, as I understand it, there are

11 occasions when a pathology lab in Corner Brook

12 would be sending to St. John's a specimen

13 asking the St. John's lab do some thing that

14 they weren't able to do in pathology in Corner

15 Brook.

16 MS. WADE:

17 A. That's right, yes, but we don't have the link

18 between the pathology module and the direct

19 reporting, printing of reports. We set that

20 up for the high volume bulk reporting of

21 routine lab testing. But the pathology

22 reports are mailed or delivered -

23 THE COMMISSIONER:

24 Q. As they say "snail mail".

25 MS. WADE:

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

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

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1 to discuss quality issues which will be first
 2 on the agenda"--and it's not necessary then
 3 for you to stay for the remainder of the
 4 agenda items. "Discussion in regards to
 5 Lynn's role and interaction with the lab
 6 program, Terry indicated the laboratory needs
 7 to put real resources into the program to
 8 assist Lynn in developing a Quality Management
 9 Program that includes risk management, patient
 10 safety, workplace safety and accreditation and
 11 Mr. Gulliver informed he will be assigning a
 12 .5 FTE in peninsulas that will be dedicated
 13 for that region and also a .5 FTE in rural
 14 Avalon. Mr. Gulliver indicated he would like
 15 to assign the current FTE in pathology to work
 16 with Lynn for that division and he was
 17 assigning a .5 Clerk IV to support the Quality
 18 Management Program and he's working with other
 19 divisions to determine if we can re-allocate
 20 staff resources to be part of this program."
 21 And there is some discussion about your need
 22 for office space. So, Ms. Wade, were those
 23 resources assigned to you?
 24 MS. WADE:
 25 A. There are additional resources within the

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

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1 MS. WADE:
 2 A. It is, yes.
 3 THE COMMISSIONER:
 4 Q. How does that work between you and the person
 5 within pathology who has the role? What is
 6 the relationship between you and -
 7 MS. WADE:
 8 A. Well she is a lab technologist who is
 9 responsible for redeveloping their policy and
 10 procedures and performing various audits for
 11 quality assurance and it may be around random
 12 reviews of pathology reports, it may be
 13 auditing the requirements for temperature
 14 dependant equipment monitoring, various things
 15 like that. So she developed the indicators
 16 for the pathology divisions, specifically. We
 17 have a very close working relationship.
 18 THE COMMISSIONER:
 19 Q. So if you have a staff which you could
 20 distribute to the various sections of a
 21 laboratory -
 22 MS. WADE:
 23 A. That's right.
 24 THE COMMISSIONER:
 25 Q. That would probably be a way one might

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1 anticipate it would go, there would be
 2 somebody responsible for division reporting up
 3 to you?
 4 MS. WADE:
 5 A. Oh, definitely.
 6 THE COMMISSIONER:
 7 Q. Except in this case, it's only been
 8 established in pathology?
 9 MS. WADE:
 10 A. Yes, yeah. The efforts are there in some
 11 divisions, in spite of the lack of resources,
 12 but it is a challenge because it's something
 13 else that they have to do, and while the
 14 staff--there are a number of champions in all
 15 of the divisions, you know, staff are very
 16 eager to work on this, but, you know, in
 17 reality it's very difficult given that patient
 18 samples still have to be tested and there is
 19 day to day workload, so -
 20 THE COMMISSIONER:
 21 Q. Okay, thank you.
 22 CHAYTOR, Q.C.:
 23 Q. Ms. Wade, what is the importance and purpose
 24 of a quality management program?
 25 MS. WADE:

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

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

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1 puncture issues, we would refer to those kinds
 2 of standards.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, and the quality management program that
 5 you're now working towards having implemented
 6 for laboratory medicine, that is new in June
 7 of 2007, the summer of 2007?
 8 MS. WADE:
 9 A. That's what we're implementing, but it is in
 10 compliance with ISO 15189.
 11 CHAYTOR, Q.C.:
 12 Q. And what's that?
 13 MS. WADE:
 14 A. That is the standard for medical laboratories.
 15 CHAYTOR, Q.C.:
 16 Q. Okay, and how long has that--has that standard
 17 been around a while?
 18 MS. WADE:
 19 A. Well, the ISO standard, I think is 2003, and
 20 it was adapted for the Canadian environment by
 21 the CSA. So we have a document now, I think
 22 from 2004, for laboratories in Canada, and
 23 basically it advocates for quality management
 24 system across the continuum of laboratory
 25 services.

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1 CHAYTOR, Q.C.:
 2 Q. Okay. If we could have, please, P-3588, page
 3 three of this document is terms of reference
 4 for the Quality Management Program Committee
 5 for Anatomic Pathology, and that's one of the
 6 committees that you mentioned earlier in going
 7 through your CV. "The Pathology Quality
 8 Management Program Committee will incorporate
 9 quality control and quality assurance
 10 principles and functions within its services,
 11 and it will develop, implement, and coordinate
 12 quality processes within pathology services
 13 that include pre-analytic, analytic, and post-
 14 analytic phases", and there's a number of
 15 functions, including identify and review
 16 current policies, procedures, and standards;
 17 developing and reviewing annually quality
 18 assurance protocols, including standardized
 19 policy and procedures; advising and ensuring
 20 education of pathology staff on present and
 21 new policies and procedure, and it goes on for
 22 nine different functions. Were you involved
 23 then in drafting the terms of reference for
 24 this committee?
 25 MS. WADE:

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1 A. Not in the initial one because I was not part
 2 of the first number of meetings. It was only
 3 after--I think in July that I sat on that
 4 committee.
 5 CHAYTOR, Q.C.:
 6 Q. July of 2007 -
 7 MS. WADE:
 8 A. And we have--we have finalized that, the terms
 9 of reference.
 10 CHAYTOR, Q.C.:
 11 Q. This is now finalized?
 12 MS. WADE:
 13 A. Yes.
 14 CHAYTOR, Q.C.:
 15 Q. Okay, because it's still in draft form here.
 16 MS. WADE:
 17 A. That one is, but it is -
 18 CHAYTOR, Q.C.:
 19 Q. It's finalized.
 20 MS. WADE:
 21 A. It is approved, yes.
 22 CHAYTOR, Q.C.:
 23 Q. And do you recall is the final version quite
 24 similar to this or are there any -
 25 MS. WADE:

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1 A. Yeah, it is.
 2 CHAYTOR, Q.C.:
 3 Q. Any significant changes.
 4 MS. WADE:
 5 A. Quite similar to that, yeah.
 6 CHAYTOR, Q.C.:
 7 Q. Quite similar, okay, and you started sitting
 8 on that committee, July, 2007, is that
 9 correct? Around then?
 10 MS. WADE:
 11 A. Around that time.
 12 CHAYTOR, Q.C.:
 13 Q. That's fine, that's fine. It's a fairly new
 14 committee, I take it?
 15 MS. WADE:
 16 A. Yes.
 17 CHAYTOR, Q.C.:
 18 Q. And this committee came into existence some
 19 time in 2007, is that correct?
 20 MS. WADE:
 21 A. I'm not quite sure when they started meeting,
 22 but I know that there were several attempts to
 23 draft the terms of reference, and it wasn't
 24 until after--I know it was after I started to
 25 participate in the committee that the terms of

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1 reference were finalized.
 2 CHAYTOR, Q.C.:
 3 Q. And what was the problem with that, why did it
 4 take so long to even come up with the terms of
 5 reference for the committee?
 6 MS. WADE:
 7 A. Well, certainly from the first meeting that I
 8 attended, there seemed to be some conflict in
 9 the committee and the purpose of the
 10 committee, I guess, and I attended that
 11 committee having just come from a conference
 12 to discuss quality management, so I basically
 13 presented my views about what I saw being the
 14 purpose of that kind of committee, and
 15 certainly the function that are outlined there
 16 was in my line of thinking, but there had been
 17 some conflict at the time, and following that
 18 committee, Dr. Carter resigned and Dr. Lynn
 19 Morris-Larkin subsequently took over as the
 20 clinical representative on that committee.
 21 CHAYTOR, Q.C.:
 22 Q. So you attended your first meeting of this
 23 committee in maybe June of 2007 or
 24 thereabouts?
 25 MS. WADE:

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

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1 MS. WADE:
 2 A. That's right.
 3 CHAYTOR, Q.C.:
 4 Q. What, in fact, they were mandated to do?
 5 MS. WADE:
 6 A. There was conflict over who should be doing
 7 what, and what they should be doing at all.
 8 CHAYTOR, Q.C.:
 9 Q. Okay, and--so this involved Dr. Carter and her
 10 views as to the mandate of the committee, or
 11 what she understood to be the mandate of the
 12 committee?
 13 MS. WADE:
 14 A. Yes.
 15 CHAYTOR, Q.C.:
 16 Q. Okay, and what do you recall about that, what
 17 direction did Dr. Carter see this committee
 18 going?
 19 MS. WADE:
 20 A. Well, certainly to develop a quality program
 21 structure you need to have--redevelop or
 22 create your policies and your processes and
 23 procedure, and ensure that you have all of
 24 those, do your gap analysis and ensure that
 25 all of those are in place, and then you need

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

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1 A. Exactly.
 2 CHAYTOR, Q.C.:
 3 Q. And you said that at the meeting?
 4 MS. WADE:
 5 A. I did, yes.
 6 CHAYTOR, Q.C.:
 7 Q. And what happened at the meeting?
 8 MS. WADE:
 9 A. Well, Dr. Carter felt that that wasn't her
 10 role there, and she left the meeting.
 11 CHAYTOR, Q.C.:
 12 Q. And I take it after that she resigned from the
 13 meeting (sic.)?
 14 MS. WADE:
 15 A. Yes.
 16 CHAYTOR, Q.C.:
 17 Q. And who then took up the responsibility for
 18 doing the work that Dr. Carter was doing in
 19 terms of tracking outcomes and that piece of
 20 the work?
 21 MS. WADE:
 22 A. Well, the coordinator, the technologist
 23 coordinator was still the person who was
 24 running the audits and providing the data. So
 25 that was still being done throughout all of

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

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1 management, medical services and diagnostics.
 2 That's yourself?
 3 MS. WADE:
 4 A. That's me.
 5 CHAYTOR, Q.C.:
 6 Q. And secretary. Dr. Ford Elms, in his role as
 7 Director--Medical Director for IHC, does he
 8 sit on this committee?
 9 MS. WADE:
 10 A. No, not on the regular committee, but we have
 11 invited, for instance, Ms. Jane Gamberg, who
 12 is the technical director for IHC lab, to come
 13 if there were issues or if there was
 14 proficiency testing reports that we wanted her
 15 to review, and any time that we have on our
 16 agenda items that are relevant to specific
 17 areas, PAS, or IHC, then those people would be
 18 invited to come and speak to that.
 19 CHAYTOR, Q.C.:
 20 Q. And this includes, if we look at the
 21 functions, includes reviewing all incidents,
 22 occurrences, within the department, make
 23 appropriate recommendations, and assist with
 24 implementation?
 25 MS. WADE:

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1 A. That's right.
 2 CHAYTOR, Q.C.:
 3 Q. So all--would all occurrence reports then come
 4 to this committee for review?
 5 MS. WADE:
 6 A. That's right. So any occurrence reports that
 7 are given to the manager in the course of the
 8 month, then copies should come to this
 9 committee.
 10 CHAYTOR, Q.C.:
 11 Q. And do you know has that happened yet, has the
 12 committee actually sat down and reviewed all
 13 occurrence reports?
 14 MS. WADE:
 15 A. I don't recall seeing any specific recently,
 16 not recently, no.
 17 CHAYTOR, Q.C.:
 18 Q. At any point--well, since the summer of 2007
 19 you've sat on the committee. How often does
 20 this committee meet?
 21 MS. WADE:
 22 A. We do have monthly meetings scheduled.
 23 Certainly we've been challenged throughout the
 24 last year to get a quorum on times because of
 25 the fact that we've had people who have been

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1 involved with the Commission of Inquiry and
 2 other issues ongoing in the lab that they've
 3 not been available for meetings, but generally
 4 the meetings are held on a monthly basis.
 5 CHAYTOR, Q.C.:
 6 Q. And when is the last time this committee met?
 7 MS. WADE:
 8 A. Just a couple of weeks ago, I believe.
 9 CHAYTOR, Q.C.:
 10 Q. And when would it have most recently met prior
 11 to that?
 12 MS. WADE:
 13 A. I think it was two months ago. We had several
 14 people on vacation, so -
 15 CHAYTOR, Q.C.:
 16 Q. Yes. It also indicates that, "To facilitate,
 17 support, and ensure auditing of ongoing
 18 training of all personnel within the pathology
 19 department", and I take it that includes
 20 technologists, pathologists, pathology
 21 assistants, everybody?
 22 MS. WADE:
 23 A. That's right, "And ensure all qualified
 24 personnel are trained on appropriate equipment
 25 prior to use, provide tools to audit the

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1 process". Has the committee been involved in
 2 anything along those lines so far?
 3 MS. WADE:
 4 A. There are workstation check tool that
 5 basically provide people who are training new
 6 personnel with a checklist now at every
 7 workstation. So if you're doing embedding,
 8 there are things you have to know about
 9 embedding and there are things you have to
 10 know about the microtomy section. I have seen
 11 some of those checklists, but they're all very
 12 specific to pathology. I certainly don't get
 13 involved with their day to day operations for
 14 sure.
 15 CHAYTOR, Q.C.:
 16 Q. So when I'm thinking, like, well, how is that
 17 happening, how on a practical basis this
 18 committee does that, you're saying that, well,
 19 the tools that you're aware of are checklists,
 20 for example?
 21 MS. WADE:
 22 A. That's right.
 23 CHAYTOR, Q.C.:
 24 Q. Where the person actually doing then the task
 25 would check it off. So this committee has

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1 been involved in coming up with checklists?
 2 MS. WADE:
 3 A. Well, the people who are on the committee, the
 4 core of that committee are pathology division
 5 participants. So they are the people who are
 6 best going to know their processes and their
 7 procedures, and ensure that--they are
 8 generally the senior people. The quality
 9 coordinator, Bev Rowe, is overseeing the
 10 development of a lot of the day to day
 11 operational kinds of checklists and training
 12 tools.
 13 CHAYTOR, Q.C.:
 14 Q. And validate--number seven is, "Validate all
 15 equipment and procedures used within the
 16 department through evidence based research and
 17 auditing process". For example, the
 18 Commission has heard about two new tissue
 19 processors that came into the lab. Would this
 20 committee have been involved in the validation
 21 of the equipment, that equipment, and the
 22 procedures for its use?
 23 MS. WADE:
 24 A. Not so much the committee being involved in
 25 it. However, ensuring that there are

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1 processes in place and procedures that people
 2 would have to follow, procedures for using the
 3 equipment and to make sure that they are
 4 trained, that there are training opportunities
 5 for the staff.
 6 CHAYTOR, Q.C.:
 7 Q. And then referral of issues, there's, "Items
 8 from the quality management program committee
 9 for anatomic pathology will be brought forward
 10 to the VP of Diagnostic and Medical Services
 11 when there's no resolution after a three month
 12 period or unless it's considered urgent". So
 13 I take it there's an option to engage Dr.
 14 Howell if need be?
 15 MS. WADE:
 16 A. That's right.
 17 CHAYTOR, Q.C.:
 18 Q. And do you know has that ever happened, has
 19 there ever been any need to bring Dr. Howell
 20 in on an issue?
 21 MS. WADE:
 22 A. Not specifically anything in particular, not
 23 since my involvement, anyway.
 24 CHAYTOR, Q.C.:
 25 Q. And if we could have, please, 2128. I believe

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1 this was the next meeting after--actually, I
 2 don't know, did we look at--yes, no, 2122,
 3 sorry. 2121, sorry, my fault. That's better,
 4 June 6th, 2007, we understand this to be,
 5 Pathology Quality Management Committee, and
 6 you are in attendance at this meeting, and Dr.
 7 Carter is still there at this point, and
 8 refers to under introduction, "B. Carter opens
 9 with an introduction to the QMP Department, as
 10 we had some new committee members. It was
 11 discussed that Terry Gulliver become a
 12 consultant or ad hoc member, as opposed to a
 13 full time committee member. There was an
 14 intense dialogue regarding the roles of
 15 individual members and the focus and direction
 16 of the committee". Would this be the
 17 committee meeting that you're recalling?
 18 MS. WADE:
 19 A. That would be the meeting, yes.
 20 CHAYTOR, Q.C.:
 21 Q. So that's the intense dialogue that you
 22 recall?
 23 MS. WADE:
 24 A. Right.
 25 CHAYTOR, Q.C.:

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1 Q. Okay, and then if we look please at 2128, and
 2 this appears to be the next meeting of this
 3 committee. It's July 18th, 2007, and now Dr.
 4 Denic is in attendance and Dr. Carter, I take
 5 it, has resigned, and you're in attendance at
 6 this point in time. How did then the
 7 committee progress after that, from July 18th
 8 onwards? Has the committee--how active has
 9 the committee been in terms of achieving what
 10 it set out to do?
 11 MS. WADE:
 12 A. I certainly feel that they've made a lot of
 13 progress. There's been a lot of procedure and
 14 policy development been undertaken and
 15 finalized. Certainly the meetings that I
 16 attend now, it certainly seems to be positive
 17 and successful.
 18 CHAYTOR, Q.C.:
 19 Q. And if we could look at, please, P-3593? And
 20 this is an e-mail from Mr. Gulliver to
 21 yourself, July 24th, 2007, and he's forwarding
 22 on to you an e-mail that he had sent to Dr.
 23 Reza of the same date, and basically this
 24 outlines a summary of the process used by him
 25 and Mr. Dyer to select patients back in 2005

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1 for retesting at Mount Sinai, and why is this
 2 being forwarded on to you in July of 2007?
 3 MS. WADE:
 4 A. Ms. Chaytor, I don't recall ever seeing it,
 5 but obviously it must have been on my e-mail,
 6 but I don't recall seeing it. I know that
 7 during that period and long before that, that
 8 Mr. Gulliver and Mr. Dyer were putting in
 9 countless hours tabulating numerous reports
 10 and I guess as I took on the role of safety
 11 and quality, it was seen that I should be
 12 aware of the processes that they were going
 13 through. So that's the only purpose for that.
 14 I certainly had no involvement in the ER/PR
 15 investigation per se.
 16 CHAYTOR, Q.C.:
 17 Q. Okay, and there's a Post-it here, guide on how
 18 spreadsheets were created. Is that your Post-
 19 it note or your note?
 20 MS. WADE:
 21 A. No, that looks like Mr. Gulliver's writing.
 22 CHAYTOR, Q.C.:
 23 Q. Okay, and if we could have, please, P-3589?
 24 We understand this is an on-site consultation
 25 by QMP-LS which took place in December of

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1 2007, and were you involved in that process?
 2 MS. WADE:
 3 A. Yes. They asked me to gather the information
 4 and submit it to QMP-LS prior to their coming
 5 in to do the review of the lab in December.
 6 CHAYTOR, Q.C.:
 7 Q. Okay, and then it says "the person completing
 8 this pro-forma is Lynn Wade," yourself as
 9 program manager, safety and quality, December
 10 4th 2007, and then it goes on for quite some
 11 length, in terms of a questionnaire that you
 12 had to fill out, and how would you have been
 13 able to fill out this information?
 14 MS. WADE:
 15 A. I would have consulted with probably, if I
 16 recall, Ken Green in the lab, he was very
 17 involved in that area at the time, for
 18 anything specific to IHC, and Mr. Dyer then
 19 overall for pathology.
 20 CHAYTOR, Q.C.:
 21 Q. Okay, and if we look then at page five, for
 22 example, it says "does the histotechnical
 23 staff perform duties other than histology
 24 testing?" and you've circled yes. "If yes,
 25 what other duties? Assist pathologists with

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1 frozen section, retrieve biopsies from DI for
 2 kidney, prepare biopsies, muscle, kidney, for
 3 immunofluorescent stains, assist physician
 4 with fine needle aspirations, grossing all
 5 specimens." And then if we come down to the
 6 bottom, "is the immunohistochemistry staff
 7 specifically trained in these techniques?
 8 Yes. Does the immunochemistry staff perform
 9 duties other than IHC testing? Yes. If yes,
 10 what other duties? As noted above."
 11 So was it your understanding, in December
 12 2007, or leading up to the assessment in
 13 December '07, that the IHC technologists were
 14 involved in all these other duties?
 15 MS. WADE:
 16 A. It's my understanding that some of them were
 17 still involved with the kidney biopsies and
 18 assisting with frozen sections, yes.
 19 CHAYTOR, Q.C.:
 20 Q. And "the immunohistochemistry staff
 21 specifically trained in these techniques?" and
 22 you've said yes. And what information would
 23 you have had made available to you as to what
 24 their specific training might be?
 25 MS. WADE:

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1 A. I'm looking at the duties up above. Are we
 2 talking about IHC specifically or are we
 3 talking -
 4 CHAYTOR, Q.C.:
 5 Q. If we could look at--perhaps this'll be of
 6 assistance to you, page 14 of the exhibit.
 7 Actually, I believe it may start with page 13.
 8 MS. WADE:
 9 A. Right.
 10 CHAYTOR, Q.C.:
 11 Q. And there's lists of, for example, this is -
 12 MS. WADE:
 13 A. Yeah, yes, I recall.
 14 CHAYTOR, Q.C.:
 15 Q. - pertaining to Mr. Green. So were you
 16 provided with -
 17 MS. WADE:
 18 A. These lists.
 19 CHAYTOR, Q.C.:
 20 Q. - what they've done in terms of continuing
 21 education?
 22 MS. WADE:
 23 A. That's right.
 24 CHAYTOR, Q.C.:
 25 Q. Okay, and that, so this would be the source,

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1 whatever is indicated on these forms for
 2 continuing education?
 3 MS. WADE:
 4 A. Right.
 5 CHAYTOR, Q.C.:
 6 Q. Okay, and if we could go back then, please, to
 7 page five? Actually move on then to page six.
 8 Under laboratory organization structure, "is
 9 there a laboratory management committee with
 10 responsibility for histotechnology?" and
 11 you've said yes, and which committee would
 12 that be?
 13 MS. WADE:
 14 A. The specific one for histotechnology would be
 15 their manager and their technologists, but if
 16 they're talking about the quality management
 17 committee, it could be that. I can't -
 18 CHAYTOR, Q.C.:
 19 Q. So is there a specific committee for
 20 histotechnology?
 21 MS. WADE:
 22 A. The lab management committee with Mr. Dyer
 23 sitting on the management--you know, on the--
 24 as a manager would be responsible for the
 25 histotechnology overall.

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1 CHAYTOR, Q.C.:
 2 Q. So I take it that's no different than the
 3 biochemistry or whatever area of the lab?
 4 MS. WADE:
 5 A. That would -
 6 CHAYTOR, Q.C.:
 7 Q. There's no specific committee?
 8 MS. WADE:
 9 A. The lab management committee would, with Mr.
 10 Dyer responsible for histotechnology
 11 specifically.
 12 CHAYTOR, Q.C.:
 13 Q. Okay. There's no specific committee for
 14 histotechnology?
 15 MS. WADE:
 16 A. Not a management committee -
 17 CHAYTOR, Q.C.:
 18 Q. No specific laboratory management -
 19 MS. WADE:
 20 A. - other than the quality management committee,
 21 that's all.
 22 CHAYTOR, Q.C.:
 23 Q. And that's not specific for histotechnology?
 24 What I'm wondering is is there a committee--we
 25 know of a number of committees, but this

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1 caught my eye because I thought, well, there's
 2 a specific committee for histotechnology, a
 3 specific lab management committee.
 4 MS. WADE:
 5 A. No, the lab management committee itself is
 6 responsible for all divisions, not
 7 specifically for histotechnology, but then for
 8 the quality management piece, we have a
 9 specific pathology quality management
 10 committee, and that consists of managers and
 11 technologists.
 12 CHAYTOR, Q.C.:
 13 Q. Yes, for all of pathology.
 14 MS. WADE:
 15 A. For all of pathology, which is
 16 histotechnology.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, and included under that then would be
 19 IHC again?
 20 MS. WADE:
 21 A. They would, right, yes.
 22 CHAYTOR, Q.C.:
 23 Q. "Are there meetings of the histotechnology
 24 staff to make recommendations regarding the
 25 service?" and you say yes.

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1 MS. WADE:
 2 A. And again, that's something that would come
 3 out of quality management, but then individual
 4 staff, division staff meetings, I would see
 5 this kind of initiative happening.
 6 CHAYTOR, Q.C.:
 7 Q. And are you aware of any meetings of the staff
 8 where recommendations have come forward
 9 regarding the service?
 10 MS. WADE:
 11 A. I'm not, no. I wouldn't be involved in their
 12 regular staff meetings.
 13 CHAYTOR, Q.C.:
 14 Q. And nothing in that regard was brought to your
 15 attention to enable you to be able to answer
 16 this particular question?
 17 MS. WADE:
 18 A. That's right.
 19 CHAYTOR, Q.C.:
 20 Q. "In addition to the laboratory director, does
 21 the laboratory have a physician or allied
 22 health professional specializing in
 23 immunohistochemistry available?" and you've
 24 indicated yes, and that's Dr. Elms?
 25 MS. WADE:

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1 A. That's right.
 2 CHAYTOR, Q.C.:
 3 Q. And "is there a mechanism by which the
 4 consultants recommendations are received,
 5 reviewed and implemented as appropriate?" and
 6 you've said yes, and what is that mechanism?
 7 MS. WADE:
 8 A. Typically, the quality management committee.
 9 This is very specific to pathology and more so
 10 to immunohistochemistry and Dr. Elms, Dr.
 11 Denic and the technologists within that
 12 section of pathology would be reviewing any
 13 recommendation and making appropriate action,
 14 taking appropriate actions.
 15 CHAYTOR, Q.C.:
 16 Q. And I take it that means a mechanism for this
 17 particular consult that was taking place?
 18 MS. WADE:
 19 A. Yes, that's right.
 20 CHAYTOR, Q.C.:
 21 Q. And were you involved in that at the end of
 22 the day? Were you involved in putting
 23 together a spreadsheet regarding the
 24 recommendations that came out of the QMP-LS
 25 report in December 2007?

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1 MS. WADE:
 2 A. The only thing I did was take the
 3 recommendations and put them into a
 4 spreadsheet, as opposed to having a very
 5 narrative document. So from my perspective, I
 6 have absolutely no expertise in
 7 immunohistochemistry and certainly could not
 8 respond to specific recommendations relating
 9 to that service.
 10 CHAYTOR, Q.C.:
 11 Q. But you were involved in the creation of a
 12 spreadsheet for the recommendations coming out
 13 of this process?
 14 MS. WADE:
 15 A. Just recently to give Dr. Denic something a
 16 little easier to read on a day-to-day basis,
 17 if he wanted to monitor it.
 18 CHAYTOR, Q.C.:
 19 Q. And I don't think we have that, so that's
 20 something you just recently completed?
 21 MS. WADE:
 22 A. It is recent.
 23 CHAYTOR, Q.C.:
 24 Q. Like how recent?
 25 MS. WADE:

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1 A. Maybe within the last month or so.
 2 CHAYTOR, Q.C.:
 3 Q. And this though took place in December 2007?
 4 MS. WADE:
 5 A. That's right.
 6 CHAYTOR, Q.C.:
 7 Q. So it's almost a year later, ten months
 8 certainly.
 9 MS. WADE:
 10 A. That's right.
 11 CHAYTOR, Q.C.:
 12 Q. And there's just a spreadsheet being made from
 13 those recommendations?
 14 MS. WADE:
 15 A. Well, it basically is so that I would have--we
 16 would have something as an easier document to
 17 see what recommendations were made out of QMP-
 18 LS, what recommendations came from the other
 19 reviews that were done and where the labs were
 20 in relation to all of those.
 21 CHAYTOR, Q.C.:
 22 Q. And in creating that spreadsheet in the past
 23 month, were you able to determine whether all
 24 the recommendations from the QMP-LS assessment
 25 in December 2007 had now been implemented?

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1 MS. WADE:
 2 A. Some of them I couldn't speak to because it's
 3 very specific to immunohistochemistry.
 4 CHAYTOR, Q.C.:
 5 Q. So are there things that have not yet been
 6 implemented?
 7 MS. WADE:
 8 A. I can't tell you for sure.
 9 CHAYTOR, Q.C.:
 10 Q. So does this spreadsheet have like a column
 11 where you would indicate completed or in
 12 progress, such as we've seen for the other?
 13 MS. WADE:
 14 A. Yes, but I couldn't complete that.
 15 CHAYTOR, Q.C.:
 16 Q. Right, but in preparing it and putting the
 17 information onto the spreadsheet, were there
 18 areas left vacant or indicating that it's
 19 still ongoing or things not completed?
 20 MS. WADE:
 21 A. Well, certainly all procedures and policies
 22 are continuously being reviewed and revised
 23 and even today, something that was written
 24 last May would have--could have -
 25 CHAYTOR, Q.C.:

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1 Q. And those, of course, would have to be
 2 ongoing?
 3 MS. WADE:
 4 A. That's right, and those are ongoing
 5 procedures. In immunohistochemistry, simply
 6 because of the Commission, I guess, and I have
 7 been more aware of what's happening in that
 8 area, there are quite a few procedures that
 9 have been developed and continue to be
 10 developed for that area.
 11 CHAYTOR, Q.C.:
 12 Q. Perhaps the best way for us to get the answer
 13 then is if you could provide us with a copy of
 14 your work on that spreadsheet?
 15 MS. WADE:
 16 A. Sure.
 17 CHAYTOR, Q.C.:
 18 Q. That would be great. And then on page seven,
 19 in filling out here under manuals, user
 20 manual, "is there a manual regarding specimen
 21 collection and handling instructions available
 22 in all specimen collecting areas within the
 23 institution?" and there's no answer completed
 24 to this section. "Does the manual include
 25 instructions for patient sample

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1 identification?" and what you've written in
 2 here is "nursing manual protocols. Lab is
 3 developing a user guide" and is that the--is
 4 the user guide the manual of policies and
 5 procedures that we have here, the 2157
 6 document? Is that what you're referring to?
 7 MS. WADE:
 8 A. For that specifically to IHC and pathology
 9 would be the tissue handling protocols and
 10 procedures that have been developed.
 11 CHAYTOR, Q.C.:
 12 Q. Yes, for example, it refers to instructions
 13 for proper labelling and fixation of
 14 specimens. So what you're referring to in
 15 writing this in here -
 16 MS. WADE:
 17 A. They would be specific, yeah.
 18 CHAYTOR, Q.C.:
 19 Q. That is--that's what you're referring to?
 20 MS. WADE:
 21 A. Yes, and they have all been communicated to
 22 the ORs and the various users, yeah.
 23 CHAYTOR, Q.C.:
 24 Q. So in December of '07, that manual was under
 25 development?

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1 MS. WADE:
 2 A. That's right.
 3 CHAYTOR, Q.C.:
 4 Q. And you do--you note then under procedure
 5 manual for histotechnology, in particular,
 6 "are all tests and procedures performed within
 7 histology documented in the manual? Yes."
 8 And "is there a procedure for validating new
 9 methods, reagents, instruments? Are all
 10 procedures used based on published reference
 11 methods?" and you've got yes to those, and
 12 then your comment is "the lab program is
 13 currently developing quality management
 14 program reviewing" I take P and P is policies
 15 and procedures?
 16 MS. WADE:
 17 A. Policies and procedures.
 18 CHAYTOR, Q.C.:
 19 Q. And that was the status as of December 2007?
 20 MS. WADE:
 21 A. That's right.
 22 CHAYTOR, Q.C.:
 23 Q. And since then, a lot of those policies and
 24 procedures we see were signed off in
 25 February/March 2008, in that time period.

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

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1 A. They have--when they go to do the tissue
 2 embedding, they have worksheets of the samples
 3 that they would be embedding, so that they
 4 would know what to look for when they take
 5 them out of the processor.
 6 CHAYTOR, Q.C.:
 7 Q. And "are the routinely stained slides checked
 8 against the embedding log? Yes." And who
 9 would have provided you with the answers to
 10 enable you to fill this out?
 11 MS. WADE:
 12 A. Technologists working in the area, for the
 13 most part.
 14 CHAYTOR, Q.C.:
 15 Q. And "is there documentation to indicate
 16 automated instruments were evaluated and
 17 validated prior to being placed into use?" and
 18 how would you answer--how would you be able to
 19 answer yes to that? What did you do to ensure
 20 that to be the case?
 21 MS. WADE:
 22 A. For that specifically, I would have deferred
 23 to the manager at the time to answer the
 24 question.
 25 CHAYTOR, Q.C.:

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1 Q. So you didn't answer that? Mr. Dyer answered
 2 yes?
 3 MS. WADE:
 4 A. They would have to, yeah. I'm trying to think
 5 now, December 2007, yes, Mr. Dyer was -
 6 CHAYTOR, Q.C.:
 7 Q. It refers to here the Ventana, for example,
 8 two years in use and tissue processing. There
 9 were two at that point, 10 and 15 years, it
 10 says.
 11 MS. WADE:
 12 A. That's right. They have new ones since then,
 13 but those processors were in place at that
 14 time.
 15 CHAYTOR, Q.C.:
 16 Q. So prior to answering yes to this, did you see
 17 any documentation to indicate that the
 18 instruments were evaluated and validated prior
 19 to being put into use?
 20 MS. WADE:
 21 A. I don't recall seeing it.
 22 CHAYTOR, Q.C.:
 23 Q. And is that something you think you would
 24 recall? Is it that you don't recall or you
 25 didn't see it?

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

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1 CHAYTOR, Q.C.:
 2 Q. And I'm sorry, Mr. Dyer was tied up in the
 3 investigation of what?
 4 MS. WADE:
 5 A. Well, at that time, I know that they were
 6 still doing a lot of investigation on the
 7 ER/PR reports and things like that, so at that
 8 point in time, on that day that they needed
 9 that document, perhaps he wasn't around.
 10 CHAYTOR, Q.C.:
 11 Q. In December of 2007, there was -
 12 MS. WADE:
 13 A. At that day, yeah.
 14 CHAYTOR, Q.C.:
 15 Q. - ongoing investigation?
 16 MS. WADE:
 17 A. It was--I found out about it probably the day
 18 of or day before and that form had to be
 19 completed because they were coming in fairly
 20 quickly after that form was completed.
 21 CHAYTOR, Q.C.:
 22 Q. And if he wasn't available then for you to
 23 consult, where did you get your information?
 24 MS. WADE:
 25 A. I would have the senior staff, people like

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

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1 Q. Ms. Chaytor, wherever you can find a spot,
 2 we'll take the break.
 3 CHAYTOR, Q.C.:
 4 Q. Okay, thank you. Under record keeping, "is a
 5 patient index maintained for easy retrieval of
 6 information?" and then you've written "LIS"
 7 and yes. First of all, remind us what LIS is?
 8 MS. WADE:
 9 A. That's the lab information system.
 10 CHAYTOR, Q.C.:
 11 Q. And what is--what patient index is maintained
 12 for easy retrieval of information?
 13 MS. WADE:
 14 A. That would basically be the lab information
 15 system with the patient registrations.
 16 CHAYTOR, Q.C.:
 17 Q. And is that anything different than would have
 18 been in place, say, in 2005?
 19 MS. WADE:
 20 A. Not really. We still have--in 2005, we had--
 21 I'm just trying to think. 2005, we had one
 22 lab information system for St. John's. We
 23 still have three lab information systems in
 24 Eastern Health.
 25 CHAYTOR, Q.C.:

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1 Q. And you also go on to answer here, "are
 2 control slides retained in a separate file?"
 3 and you indicate "IHC control is on the
 4 patient slide" at that point, so the answer to
 5 that would be no.
 6 MS. WADE:
 7 A. Um-hm.
 8 CHAYTOR, Q.C.:
 9 Q. "Are IHC evaluation records and validation
 10 slides retained for at least 20 years?" and
 11 you say "yes, currently lab is ten years old,
 12 retaining records." What lab is currently ten
 13 years old?
 14 MS. WADE:
 15 A. The immunohistochemistry section, so this is
 16 information that I would have from the people
 17 in immunohistochemistry lab. So obviously we
 18 are retaining the records, but we're not--that
 19 section is not 20 years old.
 20 CHAYTOR, Q.C.:
 21 Q. So did you understand that the IHC portion of
 22 the lab came into existence in 19 -
 23 MS. WADE:
 24 A. That's my understanding, yes.
 25 CHAYTOR, Q.C.:

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1 Q. - in 1997?
 2 MS. WADE:
 3 A. That would be my understanding.
 4 CHAYTOR, Q.C.:
 5 Q. And that there was no IHC prior to 1997?
 6 MS. WADE:
 7 A. That's correct.
 8 CHAYTOR, Q.C.:
 9 Q. And who told you that?
 10 MS. WADE:
 11 A. Pardon?
 12 CHAYTOR, Q.C.:
 13 Q. And who would have been your source of that
 14 information?
 15 MS. WADE:
 16 A. Maybe Mr. Gulliver.
 17 CHAYTOR, Q.C.:
 18 Q. And so, and the retaining records, so what
 19 you're saying is that they would have records
 20 for ten years, not 20, because they've only
 21 been in existence for ten years?
 22 MS. WADE:
 23 A. That's right, whatever they have, they retain.
 24 Well, the LIS system maintains all of the
 25 records.

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1 CHAYTOR, Q.C.:
 2 Q. Perhaps then we'll take a break there, please,
 3 Commissioner.
 4 THE COMMISSIONER:
 5 Q. All right then, we'll take the afternoon
 6 break.
 7 (BREAK)
 8 THE COMMISSIONER:
 9 Q. Please be seated. Ms. Chaytor?
 10 CHAYTOR, Q.C.:
 11 Q. Thank you, Commissioner. There are two new
 12 exhibits, please, that I would ask to have
 13 entered. P-3674 and P-3675.
 14 THE COMMISSIONER:
 15 Q. Entered.
 16 EXHIBITS ENTERED AND MARKED P-3674 AND P-3675
 17 CHAYTOR, Q.C.:
 18 Q. If we look back then at P-3589, before we
 19 broke, and under quality assurance, there's a
 20 couple of questions that you filled in here as
 21 well. "Are there procedures for the
 22 processing of external quality assessment
 23 samples and a review of EQA reports?" and
 24 you've indicated yes, and Ms. Wade, what is
 25 that? What are the procedures for the

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1 processing of EQA?
 2 MS. WADE:
 3 A. For the external quality assessment?
 4 CHAYTOR, Q.C.:
 5 Q. Yes. The reports come back to the pathology,
 6 the manager. I'm not quite sure who they come
 7 back to initially, but for the IHC component,
 8 Dr. Elms and the technical director, Ms.
 9 Gamberg, reviews the external proficiency
 10 reports. She does a little collated summary
 11 of the report and shares it with the
 12 technologists in the area and Dr. Elms, of
 13 course.
 14 CHAYTOR, Q.C.:
 15 Q. And where does her assessment then go or her
 16 report? Does that get--is there a committee
 17 responsible for that?
 18 MS. WADE:
 19 A. All of the external proficiency testing for
 20 pathology and any--just like any occurrences
 21 or any other activities, audit, are to go to
 22 the quality management committee. So the
 23 external proficiency report summary will also
 24 go there.
 25 CHAYTOR, Q.C.:

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

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1 Q. Was there a corrective actions procedure in
 2 place as of December 2007?
 3 MS. WADE:
 4 A. I'm trying to think. I know that they have
 5 their corrective actions logs and part of
 6 their procedures that they document whatever
 7 they do to make changes.
 8 CHAYTOR, Q.C.:
 9 Q. Now, but did they have that in place back
 10 then?
 11 MS. WADE:
 12 A. I seem to recall that they did have corrective
 13 action logs.
 14 CHAYTOR, Q.C.:
 15 Q. And whether or not there was procedure or
 16 policy in place at the time, do you know?
 17 MS. WADE:
 18 A. I can't remember.
 19 CHAYTOR, Q.C.:
 20 Q. And if we look then at page ten of this
 21 document, under histotechnology quality
 22 control, "are tests and control slides
 23 reviewed by a senior technologist before being
 24 sent to the pathologist?" and you've indicated
 25 yes. What did you understand to be the role

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

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1 Q. And your answer to that being yes, who would
 2 have provided you with that information?
 3 MS. WADE:
 4 A. Mr. Green, I think.
 5 CHAYTOR, Q.C.:
 6 Q. And in terms of records of those parallel
 7 tests, did you see any records, and if you
 8 had, would you have completed this?
 9 MS. WADE:
 10 A. I did not, no.
 11 CHAYTOR, Q.C.:
 12 Q. You didn't see any records?
 13 MS. WADE:
 14 A. I didn't see any.
 15 CHAYTOR, Q.C.:
 16 Q. The last question here is "are
 17 positivity/negativity rates for ER/PR and
 18 HER2/neu tests maintained?" and you've circled
 19 yes. Who is maintaining those rates,
 20 positivity and negativity rates for ER/PR?
 21 MS. WADE:
 22 A. My understanding that it would be the breast
 23 people, the people involved with the breast
 24 group.
 25 CHAYTOR, Q.C.:

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1 Q. Okay. Have you ever seen any such records?
 2 MS. WADE:
 3 A. I do not, no.
 4 CHAYTOR, Q.C.:
 5 Q. And to this date, have you ever seen any
 6 positivity or negativity rates for ER/PR?
 7 MS. WADE:
 8 A. No, I have not.
 9 CHAYTOR, Q.C.:
 10 Q. And you understand who is keeping track of
 11 that? I realize right now the test is not
 12 running, but up in December 2007, it would
 13 have been, and had been since February of '07.
 14 MS. WADE:
 15 A. My understanding, it would have been the
 16 breast group because they were the ones who
 17 would be reviewing and documenting anything
 18 relating to breast pathology.
 19 CHAYTOR, Q.C.:
 20 Q. And do you mean the Breast Disease Site Group
 21 when you say the breast group?
 22 MS. WADE:
 23 A. The breast group that I understood it to be at
 24 that time would have been Dr. Carter and Dr.
 25 Cook.

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1 CHAYTOR, Q.C.:
 2 Q. And would that be part of your role or would
 3 you have any involvement in that to--if
 4 there's to be any kind of tracking or metrics
 5 kept, do you have a role in that, to see what
 6 might be appropriate for the program and that
 7 they do have the appropriate mechanisms in
 8 place to be carrying out that function?
 9 MS. WADE:
 10 A. It's certainly not my role to determine what
 11 needs to be measured and documented in the
 12 specific divisions. I have no expertise in
 13 most of it. So I certainly would not be able
 14 to speak to what they should be reviewing and
 15 what is appropriate for the various test
 16 procedures, but I do see my role in ensuring
 17 that we have a policy developed that would
 18 ensure corrective actions are undertaken and
 19 that there is auditing and monitoring to
 20 ensure that the procedures are followed and
 21 that there are appropriate results being
 22 obtained. So every division is going to have
 23 to ensure that they have those processes in
 24 place.
 25 CHAYTOR, Q.C.:

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1 Q. Yes, and then after they've made a decision to
 2 have such processes in place, what systems are
 3 put in place to make sure that's happening,
 4 that the positivity, for example, or
 5 negativity rates are being tracked?
 6 MS. WADE:
 7 A. That would be something I would see that could
 8 be reported to the quality management
 9 committee for pathology. I have not seen -
 10 CHAYTOR, Q.C.:
 11 Q. And you sit on that committee?
 12 MS. WADE:
 13 A. I sit on that committee, yes. I have not seen
 14 that at that committee.
 15 CHAYTOR, Q.C.:
 16 Q. Okay, and in filling out yes here, how were
 17 you able to answer yes? Who gave you that
 18 answer?
 19 MS. WADE:
 20 A. In speaking to anybody involved in
 21 immunohistochemistry that they--I can only
 22 assume now that I was told that it was the
 23 breast group, because as I expounded on the
 24 next section that the breast group oversees
 25 the quality and documentation for that tissue

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1 type, including positive and negative rates.
 2 CHAYTOR, Q.C.:
 3 Q. Yes, and so in terms of filling it out though,
 4 you didn't see any documentation and somebody
 5 would have given you this information?
 6 MS. WADE:
 7 A. They would have given me the information, yes.
 8 CHAYTOR, Q.C.:
 9 Q. If we could look, please, at P-3600? And this
 10 appears to be results from NEQAS, from the
 11 external proficiency testing on July 30th,
 12 2008, and it's indicated here "ER NEQAS and
 13 then ER in-house." So I understand this to be
 14 the NEQAS provided slide and then the in-house
 15 provided slide. The first slide, our mark,
 16 and this I understand, if we look up here,
 17 might explain it a bit better. "NEQAS
 18 provided three slides, one for ER and one for
 19 BCL-2 and BCL-6. We were also requested to
 20 provide three in-house slides with our current
 21 control samples stained for same three stains.
 22 Then four assessors marked each of the six
 23 slides by giving each a score of one to five.
 24 The four scores were then added together for
 25 maximum marks, so the highest you can get is

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1 20. We scored the six slides before they were
 2 shipped, giving each a mark of 20. A summary
 3 of these results is given below." And who
 4 would prepare this document?
 5 MS. WADE:
 6 A. Ms. Gamberg.
 7 CHAYTOR, Q.C.:
 8 Q. So this is her report?
 9 MS. WADE:
 10 A. That's right.
 11 CHAYTOR, Q.C.:
 12 Q. That then goes to the quality management
 13 committee?
 14 MS. WADE:
 15 A. That then goes to Dr. Elms who reviews it.
 16 CHAYTOR, Q.C.:
 17 Q. And it gets ultimately brought to the
 18 pathology quality management committee?
 19 MS. WADE:
 20 A. That's right.
 21 CHAYTOR, Q.C.:
 22 Q. Okay, and so would you have seen this at the
 23 quality management committee?
 24 MS. WADE:
 25 A. Yes, I have.

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1 CHAYTOR, Q.C.:
 2 Q. And then for the ER NEQAS, our mark was 20.
 3 So I take it it was a 20 given by Eastern
 4 Health to themselves on the ER NEQAS slide?
 5 MS. WADE:
 6 A. Right.
 7 CHAYTOR, Q.C.:
 8 Q. And the assessors then, the mark was 18, and
 9 in-house, it was our mark was again a 20 and
 10 it was a 12 given by the assessors.
 11 MS. WADE:
 12 A. Right.
 13 CHAYTOR, Q.C.:
 14 Q. And it says "more tumor nuclei could be
 15 demonstrated. Stain intensity could be
 16 stronger."
 17 MS. WADE:
 18 A. Right.
 19 CHAYTOR, Q.C.:
 20 Q. And then Eastern Health's response to NEQAS
 21 run number 82, "we received a low score on our
 22 in-house slide. However, since our score on
 23 the NEQAS slide is very good, we know that our
 24 staining protocol is appropriate and the
 25 problem must be with the tissue." What--

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1 "NEQAS returned the slide, so we reviewed them
 2 and Ford agreed," Dr. Elms agreed, "that our
 3 slide looks more like a two plus than a three
 4 plus. We need to watch this in the future."
 5 And do you recall any discussion about that?
 6 MS. WADE:
 7 A. Not in particular, no, no discussion, other
 8 than that I took this to mean that they've
 9 taken what they've learned from the assessors
 10 and on reviewing the slide, agreed that they
 11 probably scored them too high, and that is
 12 exactly what you want to get from external
 13 proficiency testing, so that you can improve
 14 your service, and that's one of the components
 15 or one of the purposes of doing it external
 16 proficiency testing.
 17 CHAYTOR, Q.C.:
 18 Q. Okay, and we understood from Dr. Wells'
 19 evidence this morning, you want to--the 12 out
 20 of 20, that's the least, that's the minimum
 21 requirement?
 22 MS. WADE:
 23 A. That's the least, that's right.
 24 CHAYTOR, Q.C.:
 25 Q. That you want to have.

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1 MS. WADE:
 2 A. Yes.
 3 CHAYTOR, Q.C.:
 4 Q. That's the least?
 5 MS. WADE:
 6 A. Yeah.
 7 CHAYTOR, Q.C.:
 8 Q. Anything below that is then cause for, I
 9 guess, some serious concern in terms of a
 10 borderline result.
 11 MS. WADE:
 12 A. Right.
 13 CHAYTOR, Q.C.:
 14 Q. So in terms of the idea then, and I understand
 15 this is not within your expertise, but I'm
 16 just wondering if there was any follow up then
 17 by the pathology quality management committee,
 18 in terms of "the problem must be with the
 19 tissue." Did that raise any concern? What
 20 problems would there be, because of course by
 21 July 2008, there's been a lot of concern, I
 22 would suggest to you, about fixation, for
 23 example?
 24 MS. WADE:
 25 A. Um-hm.

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1 CHAYTOR, Q.C.:

2 Q. And appropriate processing and the pre-

3 analytical phase for preparing tissue for

4 ER/PR, and so I'm just wondering if there was

5 any discussion or follow up on that, if there

6 were--if it was indicated a problem must be

7 with the tissue?

8 MS. WADE:

9 A. I do know that the histology section of the

10 lab that does the pre-analytic functions prior

11 to the samples getting to the

12 immunohistochemistry also participate in

13 external proficiency testing that assesses the

14 quality of fixation, microtomy of the cutting

15 and the staining, and there have been no

16 issues with the fixation. So I seem to recall

17 Ms. Gamberg saying something about the problem

18 with the tissue not necessarily meaning

19 fixation. It may not have been an in-house--

20 might not have been the most appropriate one

21 to select to use and it could have been that

22 was the problem, as opposed to a problem with

23 the tissue in of itself.

24 CHAYTOR, Q.C.:

25 Q. So do you know if there was any investigation

Page 234

1 carried out to determine what the problem was

2 with the tissue?

3 MS. WADE:

4 A. It's my understanding that this is Ms.

5 Gamberg's area and that she takes all reports

6 and does her investigation. I don't know what

7 the follow up has been on this one at this

8 point.

9 CHAYTOR, Q.C.:

10 Q. Would that come back to your quality

11 management committee?

12 MS. WADE:

13 A. They should come back to the quality

14 committee.

15 CHAYTOR, Q.C.:

16 Q. And there hasn't been anything back since?

17 MS. WADE:

18 A. No, I haven't seen a report.

19 CHAYTOR, Q.C.:

20 Q. Since July?

21 MS. WADE:

22 A. Follow up, no.

23 THE COMMISSIONER:

24 Q. How long has there been this external

25 proficiency testing in respect of the

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1 histology section? That would be going on for

2 how long?

3 MS. WADE:

4 A. I am not sure if they only started that just

5 in 2005 or if they had been doing it all

6 along. I don't know. I was not involved.

7 CHAYTOR, Q.C.:

8 Q. And at the end it says "no corrective action

9 is required." What do you understand that to

10 mean, in her report?

11 MS. WADE:

12 A. In that the report of itself didn't mean that

13 they had to go back and review their protocol

14 or change anything in the way they were doing

15 it, because they knew that the protocol worked

16 based on the NEQAS slide, results of the NEQAS

17 slide.

18 CHAYTOR, Q.C.:

19 Q. So but you did understand there would have

20 been further questions asked as to what the

21 problem would be with the tissue?

22 MS. WADE:

23 A. Right.

24 CHAYTOR, Q.C.:

25 Q. And you're expecting to hear back on that?

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1 MS. WADE:

2 A. Yeah.

3 CHAYTOR, Q.C.:

4 Q. At some point, okay. I'd just like to turn

5 now then and talk to you a bit about your

6 involvement with the policies and procedures

7 document that we have here. First of all,

8 perhaps you could just tell the Commissioner,

9 when you took on the role in the summer of

10 2007, what was the status or stage of written

11 policies and procedures for the pathology

12 portion of the laboratory medicine program?

13 MS. WADE:

14 A. They were in various stages of write. Some of

15 them were done, completed, others were in

16 draft. Ms. Parnell was the quality management

17 coordinator in pathology at the time. I know

18 she was off for a period of time and so there

19 was a period of time when she was not

20 available to do any of the work. As a result,

21 I assisted those in the pathology,

22 immunohistochemistry section to get some of

23 their procedures down in the standardized

24 template. So I would have Mr. Green come and

25 sit with me and bring me his documents and I

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1 would get them formatted for him in a standard
 2 template.
 3 CHAYTOR, Q.C.:
 4 Q. And were there any particular obstacles or
 5 challenges that you encountered then in the
 6 development of the policy and procedure
 7 manual?
 8 MS. WADE:
 9 A. The challenge again is trying to get the work
 10 done off the corner of your desk, and the
 11 people who are best to write the procedures
 12 that they do every day are those who are
 13 actually doing them, and obviously with the
 14 workload that they have, they can't just leave
 15 it and say, well, I'm going to do policies and
 16 procedures today because there is work to be
 17 done. So often it was on their breaks, or I
 18 would hold them over after their work day and
 19 we'd get some work done, or I would go out
 20 looking for the information and get it drafted
 21 and bring it back so that they could do the
 22 reviews, at least get things done in a format
 23 that we were going to move forward with. So
 24 the biggest challenge again is the human
 25 resources around having the people that can

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1 just be dedicated to get this done, and once
 2 it's done, it's a maintenance issue as opposed
 3 to--and a continuous process.
 4 CHAYTOR, Q.C.:
 5 Q. And how is that going to work then in terms
 6 of--because it's a living document, it has to
 7 be revised, it has to be updated, it has to be
 8 reviewed periodically.
 9 MS. WADE:
 10 A. That's right.
 11 CHAYTOR, Q.C.:
 12 Q. And so who's going to be responsible for doing
 13 that?
 14 MS. WADE:
 15 A. Well, again, you know, my role is to ensure
 16 that there are reviews done. All of our
 17 documents have dates on them. They're active
 18 effective dates, so a year from that they're
 19 expected to be at least reviewed, and again if
 20 there were issues, they would be revised at
 21 appropriate times, anyway. The human--the
 22 Department--the lab program has been
 23 challenged for a long time with human
 24 resources because the workload continues to
 25 increase. It's an 8 percent increase year

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1 over year for the last two years, and the
 2 expertise required to do this, not everybody
 3 is going to have the knowledge or the
 4 understanding of writing policies and
 5 procedures. So it is always going to be the
 6 most knowledgeable people in the department,
 7 who at this time generally are the more senior
 8 staff. So I know that the Lab Medicine
 9 Program has applied--well, has certainly
 10 identified the need for additional resources
 11 to--put specifically to quality management
 12 initiative in their budget for this new fiscal
 13 year. So there is some hope that we will get
 14 additional resources, but given that this is
 15 something that there is no choice, this has to
 16 happen, we have to find a way; I don't know
 17 how, but it is a challenge.
 18 CHAYTOR, Q.C.:
 19 Q. And it's still in the works as to how that
 20 will happen?
 21 MS. WADE:
 22 A. Oh, certainly, definitely.
 23 CHAYTOR, Q.C.:
 24 Q. And how important is it to--how importance is
 25 the performance of preventative maintenance to

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1 your equipment in a laboratory to ongoing
 2 quality control in the lab?
 3 MS. WADE:
 4 A. Well, preventative maintenance is one aspect
 5 of quality assurance. It's one thing that we
 6 do, the control specific to the test, but you
 7 have to ensure that the--in pathology, you
 8 have to ensure that the temperatures of the
 9 water baths are adequate, that the temperature
 10 of the fridges are maintained, the paraffin
 11 wax is maintained, and that the equipment is
 12 maintained as it should be.
 13 CHAYTOR, Q.C.:
 14 Q. So it's one of many things that you have to be
 15 doing?
 16 MS. WADE:
 17 A. It's one of many -
 18 CHAYTOR, Q.C.:
 19 Q. On a daily, weekly, or monthly -
 20 MS. WADE:
 21 A. Assurance activities.
 22 MS. WADE:
 23 A. - basis.
 24 MS. WADE:
 25 A. That's right.

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1 CHAYTOR, Q.C.:

2 Q. According to the particular procedure?

3 MS. WADE:

4 A. Right.

5 CHAYTOR, Q.C.:

6 Q. And if we could look then, please, at P-2157.

7 This is the one that we had up before, but

8 it's not up any more. Perhaps then while

9 we're waiting for the document to come up,

10 this is the pathology policy and procedure

11 manual?

12 MS. WADE:

13 A. Uh-hm.

14 CHAYTOR, Q.C.:

15 Q. How are the policies and procedures

16 distributed, first of all, within the

17 laboratory medicine program itself?

18 MS. WADE:

19 A. There are various levels of policies, as

20 you've heard.

21 CHAYTOR, Q.C.:

22 Q. Yes. Perhaps you could tell the Commissioner

23 about that, about the different levels of

24 policies?

25 MS. WADE:

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1 A. Well, we have a policy framework was that

2 developed by the corporate strategy and

3 research division, and that framework outlines

4 four levels for policy development. Level 1

5 is organizational, Level 2 is the next level,

6 so that would be something from the Vice

7 President level, say, and then the program

8 specific policies are Level 3's, and those are

9 the ones that I am most involved with. The

10 Level 4 policies are very specific to

11 divisions and how they do their business.

12 CHAYTOR, Q.C.:

13 Q. Yes. So once a policy then is signed off

14 regardless of what level signed off, how would

15 the staff then become aware of the existence

16 of a policy?

17 MS. WADE:

18 A. Again, you know, it is a challenge given our

19 diverse communications processes that we have

20 because we have the three Meditech systems

21 that have an e-mail system for staff, so in

22 all the various regions, former regions, they

23 have their own Meditech system. Then we also

24 have the Outlook e-mail. Typically what

25 happens, if it's a Level 2 policy, the

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1 direction or the communication comes from

2 Corporate Strategy and Planning because they

3 get the policies loaded to the intranet and

4 send the information out to all management

5 that these policies are now in effect and that

6 they're available for their staff. From the

7 lab program specific one, the Level 3's, the

8 ones that I have done, I finish them--once

9 they're signed off, I communicate to all of

10 the division managers across the region, and

11 then they disseminate that information in

12 their systems to their own employees. We also

13 now have all policies as they're being written

14 are uploaded to the Eastern Health Intranet,

15 so we at least have a quasi-electronic method,

16 but at least staff that have the PCs in their

17 areas can access the policies that are most

18 current now on the Intranet.

19 CHAYTOR, Q.C.:

20 Q. Okay.

21 MS. WADE:

22 A. We don't have procedures yet on the Intranet.

23 CHAYTOR, Q.C.:

24 Q. Procedures aren't there yet.

25 MS. WADE:

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1 A. No.

2 CHAYTOR, Q.C.:

3 Q. Just your policies?

4 MS. WADE:

5 A. Just the policies.

6 CHAYTOR, Q.C.:

7 Q. And what about then, for example, this manual

8 that we've now brought up here, and you'll see

9 pathology procedures, page three, pathology

10 policies procedures manual, table of contents,

11 and then there's quite a number. How were the

12 staff apprised of the existence of--this was a

13 fairly new manual, and you'll see the number

14 of--number of them, for example, on page nine,

15 the fixation policy came into effect--well,

16 the effective date is not indicated, but it's

17 been approved as of February 4th, 2008, and

18 then on page 13, we have tissues for gross

19 examination only came into effect January

20 21st, 2006, so how did the staff become aware

21 that all these policies, this manual now

22 exists with all of this information?

23 MS. WADE:

24 A. Again it is the responsibility of the manager

25 to communicate within their division for new

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1 policies and procedures. The binders are--you
 2 know, they're green, they're easy to identify
 3 in a shelf of black binders, and there is a
 4 signoff procedure. Staff are made aware of
 5 it. Pathology is challenged with continuous
 6 new people coming in and--on any given day,
 7 there may be a temporary employee in there,
 8 that might not know the binder was put there
 9 yesterday or that there was something new, but
 10 the communication is a challenge, but it is
 11 the responsibility of the managers to ensure
 12 that their staff know where the binder is and
 13 that they read off and sign off any new
 14 procedures.
 15 CHAYTOR, Q.C.:
 16 Q. So there's physically a binder kept at the
 17 various workstations?
 18 MS. WADE:
 19 A. There is a single binder in the main histology
 20 lab, there is one in immunohistochemistry,
 21 there is one at St. Clare's, there is one in
 22 Burin, one in Clarenville, there's one in all
 23 sites.
 24 CHAYTOR, Q.C.:
 25 Q. And a new staff member then coming into the

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1 lab, into the pathology section, then they'd
 2 be responsible for having to read through the
 3 manual?
 4 MS. WADE:
 5 A. That's right. Well, typically what they're
 6 doing now is training people as they come in.
 7 If they're being trained to work in pathology
 8 for all of the various aspects of the work,
 9 then they will be trained in embedding, and
 10 trained in microtomy, and trained in staining,
 11 and as they get trained, they're being shown
 12 the new--you know, the procedures and the
 13 policies, and eventually they have the whole
 14 binder that they will recognize then as being
 15 a whole--binder for the whole of the division.
 16 CHAYTOR, Q.C.:
 17 Q. So what happens if there's a change? You
 18 know, there's a change for some reason, IHC
 19 problem report form, I'll just pick that one
 20 how is the staff then made aware that that has
 21 changed and how does the change get put into
 22 the binder? How does it logistically happen?
 23 MS. WADE:
 24 A. For pathology, the coordinator for pathology
 25 management, Bev Rowe, is responsible for

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1 maintaining and updating any of the policies
 2 and procedures for the pathology division. So
 3 she communicates to the manager that this is
 4 ready and here's your copy, make sure it goes
 5 in each of the binders that you have in your
 6 areas.
 7 CHAYTOR, Q.C.:
 8 Q. And there's no--there's no other electronic
 9 way of, for example, communicating with the
 10 staff to let them know?
 11 MS. WADE:
 12 A. Other than an e-mail on the system, you know.
 13 That's one of the disadvantages of not having
 14 an electronic document system, which is
 15 certainly on my wishlist for the labs for the
 16 region. With 17 sites, and every site having
 17 very specific procedures, having something
 18 that is electronic, the document software
 19 system actually do the tracking and the
 20 maintaining and they send the messages to all
 21 the users. So this system will certainly be
 22 an advantage for the labs to have, and it's
 23 something that's going to have to happen in
 24 order for the lab to ensure that we have
 25 consistency of practice from one division to

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1 another and one site to another.
 2 CHAYTOR, Q.C.:
 3 Q. And were you involved in any workshops to
 4 introduce the staff involved with the policies
 5 and procedures, the new policies and
 6 procedures?
 7 MS. WADE:
 8 A. I was involved with the whole workshop on
 9 quality management, and attending that were
 10 the managers as well as their senior staff,
 11 and those are the kinds of things that we
 12 discussed about development of policies and
 13 procedures and how you need to document and
 14 sign off on those.
 15 CHAYTOR, Q.C.:
 16 Q. So there was no actual getting the staff
 17 together, for example, for an information
 18 session to say we now have this new manual,
 19 here it is, and let's go through some of -
 20 MS. WADE:
 21 A. I'm not sure pathology did that particular--
 22 anything particular for their division, no.
 23 CHAYTOR, Q.C.:
 24 Q. You weren't involved with that?
 25 MS. WADE:

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1 A. No, I wouldn't be involved in the individual
 2 divisions.
 3 CHAYTOR, Q.C.:
 4 Q. We'll see, for example, on page seven of the
 5 exhibit, most of those that are listed there
 6 are all still noted to be in draft form.
 7 Coming down you'll see "in draft" after a fair
 8 number of those particular policies on that
 9 page. How much progress has been made?
 10 MS. WADE:
 11 A. A lot of those policies that--or procedures
 12 really that are in draft are actually the way
 13 they're doing their business today. A lot of
 14 them were prepared and getting finalized in
 15 their electronic format in order to be printed
 16 for signing. So at the time that these were
 17 presented, we had not--the coordinator had not
 18 been able to get either Mr. Dyer or Dr. Denic,
 19 whoever was required was required to get them
 20 signed off. So I suggested that they present
 21 these as drafts even though--because they
 22 haven't been signed off, but a lot of them are
 23 as they do their business today.
 24 CHAYTOR, Q.C.:
 25 Q. So this was an enormous amount of work in

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1 terms of getting these policies and procedures
 2 in place?
 3 MS. WADE:
 4 A. It is a huge amount of work, and given that
 5 there is a table of contents, you can see the
 6 vast amount of work that is there, I mean, and
 7 that's just for one division.
 8 CHAYTOR, Q.C.:
 9 Q. So, Ms. Wade, is wasn't a situation where--
 10 when we go back to page one of this and it's
 11 the pathology policies and procedures manual,
 12 it wasn't a situation when you walked in to
 13 your job in the summer of 2007 where there was
 14 such a policy and procedure manual in
 15 existence, and it was just a matter of going
 16 through it and updating it, or putting it in a
 17 particular format. This was--most of these
 18 policies and procedures were being created for
 19 the first time?
 20 MS. WADE:
 21 A. Some of them were. Some of them were
 22 procedures that they were already following,
 23 but--for instance, a lot of the staining
 24 procedures were in a binder in an old format,
 25 typed format. Sometimes they may be right

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1 directly from a reference document, a
 2 reference manual, or a reference textbook that
 3 they were following as the best practice
 4 procedure, just not typed in a format as we
 5 have here today.
 6 CHAYTOR, Q.C.:
 7 Q. And was there any evidence of any--I hear what
 8 you're saying, that was true of some of them,
 9 but in terms of the volume of policies and
 10 procedures that we see here -
 11 MS. WADE:
 12 A. Not as comprehensive as it is now, no.
 13 CHAYTOR, Q.C.:
 14 Q. And the majority--there were no policies and
 15 procedures, regardless of format, the policies
 16 and procedures, these are new, the majority of
 17 those in terms of -
 18 MS. WADE:
 19 A. I can't imagine any lab being able to work
 20 without a procedure manual of some kind.
 21 CHAYTOR, Q.C.:
 22 Q. Did you see it?
 23 MS. WADE:
 24 A. Oh, I have seen them, yes, and in the course
 25 of preparing for accreditation, I had--you

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1 know, I had binders upon binders of
 2 procedures, and they were -
 3 CHAYTOR, Q.C.:
 4 Q. For the pathology and IHC lab, in particular,
 5 that we're talking about?
 6 MS. WADE:
 7 A. And pathology--for IHC, I don't recall
 8 specific--you know, I know stains, and I know
 9 that they have binders for various protocols,
 10 but again a lot of what they followed was
 11 specific from the manual that they were using,
 12 not a format that makes it their own, let's
 13 say.
 14 CHAYTOR, Q.C.:
 15 Q. I just want to be clear on that.
 16 THE COMMISSIONER:
 17 Q. You're talking about the manufacturer's
 18 document?
 19 MS. WADE:
 20 A. Could be, yes.
 21 THE COMMISSIONER:
 22 Q. Is that what you're talking about?
 23 MS. WADE:
 24 A. Yes, and in often cases, exactly how the
 25 procedure is written today for the tissue

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1 processor, will be as directed by the
 2 procedure manual, but they will take the
 3 component that they would use on a day to day
 4 basis and put it to a format that staff would
 5 be--it would be a quicker reference than going
 6 to a manual.
 7 CHAYTOR, Q.C.:
 8 Q. And, though, standard operating procedure for
 9 the particular lab in question?
 10 MS. WADE:
 11 A. Right.
 12 CHAYTOR, Q.C.:
 13 Q. In terms of any evidence as to what did exist,
 14 was there any evidence as to when it had last
 15 been reviewed or updated?
 16 MS. WADE:
 17 A. No.
 18 CHAYTOR, Q.C.:
 19 Q. And if we look at, please, page nine,
 20 Registrar, fixation policy, and again it
 21 doesn't say an effective date, but it does say
 22 an approval date of February 4th, 2008, and
 23 this policy has come up before here at the
 24 Commission, and we understand that it was some
 25 time in the making in terms of it coming up

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1 and finally having an approval date of
 2 February 4th, 2008?
 3 MS. WADE:
 4 A. Right.
 5 CHAYTOR, Q.C.:
 6 Q. Because, of course, the issue of fixation was
 7 something that was brought up by Dr. Cook in
 8 the summer of 2005 as an issue, and then, of
 9 course, again by the external reviewers. What
 10 difficulties are you aware of that were
 11 encountered in developing this policy and
 12 finally having it adopted?
 13 MS. WADE:
 14 A. I'm not--I don't think that there was
 15 difficulty in the policy itself, the how they
 16 should be handling the tissue. I think that
 17 they had plenty of evidence to give them
 18 information to make the policy. The difficulty
 19 came about as a result of the introduction of
 20 the policy framework for Eastern Health. So
 21 now we had to go back and revisit the policy
 22 in this format and the signatories of it, and
 23 again I was in this role for about six or
 24 seven months at that point in time. I know
 25 that the fixation policy had been drafted and

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1 sent in an old format out to the regions and
 2 Dr. Denic had communicated that to the various
 3 pathologists around the province. After the
 4 policy framework came out, there was some
 5 discussion around issuing authority and who
 6 were we going to have sign it off, and all of
 7 that, and at the end of the day I felt that
 8 fixation is a pathology concern, pathologists
 9 are the best to know about it, and the
 10 pathologists should it off. So at the end of
 11 the day, it became a policy that we kept for
 12 the pathology division, and communicated it to
 13 all of those entities that would use that--
 14 would use fixative. So it was signed at the
 15 end of the day by Dr. Denic and Mr. Gulliver,
 16 and disseminated to all of the regional
 17 directors out in all of the regional health
 18 authorities and to all of the lab, to the ORS,
 19 across the province.
 20 CHAYTOR, Q.C.:
 21 Q. And we know, of course, this one is deemed to
 22 be a Level 4. So a Level 4 means that it's
 23 mandatory across all departments if it's a
 24 Level 4?
 25 MS. WADE:

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1 A. The Level 4 is the pathology policy.
 2 CHAYTOR, Q.C.:
 3 Q. Okay.
 4 MS. WADE:
 5 A. The pathology division creates that policy and
 6 it's about their specimens. So that's why I
 7 recommended that it be maintained as a
 8 pathology policy as opposed to a Level 2
 9 policy or a Level 3, because it is specific to
 10 the specimens that are handled in that
 11 department.
 12 CHAYTOR, Q.C.:
 13 Q. So if it's Level 2, then it goes beyond the
 14 borders of just the Laboratory Medicine
 15 Program?
 16 MS. WADE:
 17 A. It would be signed typically by--a Level 2
 18 would be signed off by Dr. Howell, but--I
 19 discussed with Dr. Denic, and in discussions
 20 with Dr. Howell, I felt that this was a very
 21 technical policy very specific to the quality
 22 of tissues that were coming to that
 23 department, and it was important that Dr.
 24 Denic sign this off as opposed to Dr. Howell.
 25 CHAYTOR, Q.C.:

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1 Q. We had seen a version at one point where it
 2 was for Dr. Howell's signature.
 3 MS. WADE:
 4 A. Exactly, that's right.
 5 CHAYTOR, Q.C.:
 6 Q. Okay, but wouldn't this be--isn't it important
 7 that--it stretches beyond, obviously, just the
 8 lab.
 9 MS. WADE:
 10 A. That's right, and that -
 11 CHAYTOR, Q.C.:
 12 Q. It deals with perioperative program as well.
 13 MS. WADE:
 14 A. That's right.
 15 CHAYTOR, Q.C.:
 16 Q. And how they have to handle the specimen?
 17 MS. WADE:
 18 A. That's right, and that's how you engage your
 19 stakeholders. So the stakeholders are engaged
 20 in either to develop it to ensure that they
 21 can comply with the requirement, and/or the
 22 implementation of it.
 23 CHAYTOR, Q.C.:
 24 Q. Okay, but it being a lab policy as opposed to
 25 something that's going to also apply to the

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

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1 ensure that they understand that the quality
 2 of the sample that they send it, whether it be
 3 a blood sample, or a tissue sample, has to
 4 meet certain criteria. Because that policy
 5 overrides all of the lab program, it is a
 6 Level 3. This here is specific to tissues
 7 that come to the pathology lab, however, we
 8 need to ensure that the people who are going
 9 to put the tissue in fixative are aware of its
 10 existence and the importance of maintaining
 11 fixation.
 12 CHAYTOR, Q.C.:
 13 Q. So then, for example, we have linkages here of
 14 fixation procedure for OR and clinic staff.
 15 MS. WADE:
 16 A. That's right.
 17 CHAYTOR, Q.C.:
 18 Q. So they would have their own -
 19 MS. WADE:
 20 A. That's right.
 21 CHAYTOR, Q.C.:
 22 Q. Their own policies.
 23 MS. WADE:
 24 A. That's right, they have all the tissue
 25 handling procedures for their areas.

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

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

15 CHAYTOR, Q.C.:

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

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

6 MS. WADE:

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

10 CHAYTOR, Q.C.:

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

15 MS. WADE:

16 A. The newer one.

17 CHAYTOR, Q.C.:

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

20 MS. WADE:

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

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

11 CHAYTOR, Q.C.:

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

14 MS. WADE:

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

19 CHAYTOR, Q.C.:

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

22 MS. WADE:

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

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

3 CHAYTOR, Q.C.:

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

7 MS. WADE:

8 A. No.

9 CHAYTOR, Q.C.:

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

12 MS. WADE:

13 A. No.

14 CHAYTOR, Q.C.:

15 Q. So no feedback along those lines?

16 MS. WADE:

17 A. No difficulty, no.

18 CHAYTOR, Q.C.:

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

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1 handling procedures and fixation policy for
 2 use in the ORs. These should be put into a
 3 binder for laboratory procedures in the ORs at
 4 St. Clare's and the Health Sciences Centre. If
 5 you would like an in-service for staff at the
 6 OR regarding these documents, please contact
 7 Catherine Parnell". So you're sending along
 8 quite a number of the pathology or lab
 9 policies which have been signed off on at this
 10 point in time?
 11 MS. WADE:
 12 A. That's right.
 13 CHAYTOR, Q.C.:
 14 Q. And is this the first time those policies
 15 would have been then provided to Ms. Tracey?
 16 MS. WADE:
 17 A. I can't speak to that. I wouldn't know.
 18 CHAYTOR, Q.C.:
 19 Q. Or otherwise given to the perioperative
 20 program?
 21 MS. WADE:
 22 A. I don't know if they had anything in the past
 23 in other formats.
 24 CHAYTOR, Q.C.:
 25 Q. Yes, whether or not they had--you're saying

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1 these should be put into a binder. Whether or
 2 not--you're not instructing her, well, look,
 3 update your binder, take out the old ones,
 4 these are the new ones. It's not that
 5 situation?
 6 MS. WADE:
 7 A. No, because I--I do know from our newly formed
 8 OR Quality Committee that they do have a
 9 procedure binder for labs or protocols that
 10 they follow in the OR. My instruction for
 11 this, this is very specific to the lab, and I
 12 just wanted to keep them to whatever your
 13 processes are.
 14 CHAYTOR, Q.C.:
 15 Q. Yes, but you're not telling her to update her
 16 -
 17 MS. WADE:
 18 A. No.
 19 CHAYTOR, Q.C.:
 20 Q. Not telling her to update the binder, so -
 21 MS. WADE:
 22 A. Because -
 23 CHAYTOR, Q.C.:
 24 Q. I assume you wouldn't have -
 25 MS. WADE:

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1 A. No, because I don't know if she had one.
 2 CHAYTOR, Q.C.:
 3 Q. Yes, okay, so you don't know whether or not
 4 they had similar policies?
 5 MS. WADE:
 6 A. Right.
 7 CHAYTOR, Q.C.:
 8 Q. That these were just replacing or not.
 9 MS. WADE:
 10 A. Right.
 11 CHAYTOR, Q.C.:
 12 Q. And wouldn't that be important, though, to
 13 know in terms of you're not just going to be
 14 sending up policies which might conflict with
 15 other policies that are already in existence,
 16 for example?
 17 MS. WADE:
 18 A. Well, the fact that these are new tissue
 19 handling policies, I would think that anybody
 20 who was--if they had any other policies and
 21 protocols in place, they would have to ensure
 22 that they either comply with these or else not
 23 use them any more.
 24 CHAYTOR, Q.C.:
 25 Q. And you've offered an in-service. So I take

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1 it this is something new, this is not just a
 2 matter of updating -
 3 MS. WADE:
 4 A. I do know that Ms. Parnell did an in-service
 5 with St. Clare's. I don't know when she did
 6 them, but she had done one, and I do know that
 7 there has been one at the Health Science done
 8 specifically with these.
 9 CHAYTOR, Q.C.:
 10 Q. For the perioperative, you mean, program?
 11 MS. WADE:
 12 A. Yes.
 13 CHAYTOR, Q.C.:
 14 Q. So they took advantage of that and took you up
 15 on your suggestion for an in-service?
 16 MS. WADE:
 17 A. Yes.
 18 CHAYTOR, Q.C.:
 19 Q. Okay. So I take it, this was fairly--this was
 20 new information for them?
 21 MS. WADE:
 22 A. It was certainly more comprehensive probably
 23 than what they had, yeah.
 24 CHAYTOR, Q.C.:
 25 Q. If they had anything?

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1 MS. WADE:
 2 A. If they had, and I can't say if they did or
 3 not.
 4 CHAYTOR, Q.C.:
 5 Q. Okay, and how would they then--who looks after
 6 ensuring that they're kept up to date. So, for
 7 example, if your policy is up for review or
 8 revision next February, who ensures then any
 9 revisions that are made then get distributed
 10 to the regions and also internally within
 11 Eastern Health to other programs that may need
 12 to know about the revision?
 13 MS. WADE:
 14 A. Well, again our communication is difficult,
 15 but the route that we would take for the other
 16 regions would be to the directors of the labs
 17 in those regions, and then within our own--for
 18 Eastern Health, they would be communicated to
 19 the lab managers--certainly the site managers
 20 for outside the city, the pathology managers
 21 are involved with these, and then in the case
 22 of pathology specimen policies, they would be
 23 communicated to the ORS, and not only in this
 24 case, but in--in the case of some procedures,
 25 they may require information in ambulatory

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

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

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

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

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1 thing different is the name of the equipment.
 2 They all have fridges and water baths and a
 3 lot of equipment to maintain. So the
 4 documentation is going to be the same.
 5 CHAYTOR, Q.C.:
 6 Q. And the tissue processors -
 7 MS. WADE:
 8 A. Right.
 9 CHAYTOR, Q.C.:
 10 Q. That's peculiar to histology?
 11 MS. WADE:
 12 A. That's right, yeah.
 13 CHAYTOR, Q.C.:
 14 Q. So, for example, when you sat down to do this,
 15 it's not like you just pulled, well, the old
 16 policy and started to revise it or update it?
 17 MS. WADE:
 18 A. No.
 19 CHAYTOR, Q.C.:
 20 Q. There was no such -
 21 MS. WADE:
 22 A. That's right.
 23 CHAYTOR, Q.C.:
 24 Q. There was no such policy in existence?
 25 MS. WADE:

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1 A. Not--no.
 2 CHAYTOR, Q.C.:
 3 Q. You created this yourself?
 4 MS. WADE:
 5 A. Right, and that's based in part as well by
 6 standards from the Clinical and Laboratory
 7 Standards Institute guidelines and -
 8 CHAYTOR, Q.C.:
 9 Q. You looked at the--you got assistance from
 10 that?
 11 MS. WADE:
 12 A. I have that manual, yes.
 13 CHAYTOR, Q.C.:
 14 Q. For example, if we look at water baths and,
 15 "The temperature of the water bath will be
 16 dependent upon procedure requirements, and
 17 while the bath is in operation, use a
 18 thermometer calibrated to an NIST traceable
 19 thermometer, measure the temperature of the
 20 water bath, record the temperature daily on
 21 temperature record sheets". Who then after--
 22 so you've got your policy now put on paper,
 23 and it's been signed off on. Who then ensures
 24 that that, in fact, happens?
 25 MS. WADE:

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

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1 the machine, Section 6, care of the
 2 instrument, and Section 7, troubleshooting".
 3 So then where would--where would the person
 4 reading this, such as myself right now, where
 5 would you go to find out, well, what's the
 6 maintenance procedure?
 7 MS. WADE:
 8 A. In the Tissue Tek Processor Manual that's in
 9 the room where the tissue processor is.
 10 CHAYTOR, Q.C.:
 11 Q. So you would then go to the actual operating
 12 manual -
 13 MS. WADE:
 14 A. For--yeah, for more in depth maintenance, yes.
 15 CHAYTOR, Q.C.:
 16 Q. And look it up.
 17 MS. WADE:
 18 A. Right.
 19 CHAYTOR, Q.C.:
 20 Q. Okay. In terms of--there's also procedures
 21 and policies that are here for corrective
 22 actions, and the accumulation of any
 23 corrective actions. Where is that data going?
 24 Who is accumulating that data and what purpose
 25 is it being used for?

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1 MS. WADE:
 2 A. Again it's an audit kind of process, so that
 3 if there are corrective action sheets and
 4 logs, part of the audit and the quality
 5 assurance audit that are being done, Ms. Rowe
 6 would, for example, take the corrective action
 7 sheet to ensure that that was being followed
 8 properly. Again it is the manager's
 9 responsibility to ensure that staff undertake
 10 corrective action, and that they are
 11 documented prior to the next step of their
 12 procedures.
 13 CHAYTOR, Q.C.:
 14 Q. And if we could look at page 178, please.
 15 This is the corrective action for IHC
 16 occurrences, and I believe you drafted this as
 17 well. Yes, and this one as well is February
 18 29th, 2008. The policy is, "All issues
 19 regarding quality of IHC staining and all
 20 corrective actions undertaken must be
 21 documented", and there's an indication here
 22 that the following steps must be followed to
 23 ensure appropriate and adequate documentation
 24 of corrective actions; the person identifying
 25 the issue must enter the issue into the record

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1 of quality issues form and corrective actions
 2 logbook with the following information, and
 3 then the logbook is reviewed at least monthly
 4 by the clinical director, IHC laboratory. So
 5 Dr. Elms is in that position. Is this
 6 information then, the logbook, is that kept in
 7 an electronic format?
 8 MS. WADE:
 9 A. No, not that I'm aware of.
 10 CHAYTOR, Q.C.:
 11 Q. So in terms of somebody being able to do an
 12 easy search on the information, there's
 13 nothing set up to allow that to happen?
 14 MS. WADE:
 15 A. Not that I'm aware of. Most of them, if you
 16 seen the corrective action sheets, they're
 17 basically a spreadsheet manual format. Some
 18 departments do have some electronic--it
 19 depends on the expertise in the department to
 20 develop them.
 21 CHAYTOR, Q.C.:
 22 Q. And is there anyone in quality or in a quality
 23 position involved in the analysing of
 24 information such as information that would
 25 come out of a corrective actions logbook?

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1 MS. WADE:
 2 A. Specifically, I can't speak to, other than
 3 that in every section, certainly in this
 4 section, immunohistochemistry, the people who
 5 know the processes would be the best to
 6 identify whether or not the corrective action
 7 was appropriate, and if there was a trend;
 8 however, I would see the role of the quality
 9 coordinator to track the trend specifically as
 10 a quality assurance indicator, let's say.
 11 CHAYTOR, Q.C.:
 12 Q. And Ms. Wade, you were involved in, or you're
 13 listed as the author anyhow on a number of
 14 those, under what circumstances were you
 15 involved as opposed to, as you were saying
 16 earlier, the person who is actually doing the
 17 job is the best person to be doing it.
 18 MS. WADE:
 19 A. Right, well to write the policies in most
 20 instances, I had somebody with me that said I
 21 need a policy on this, so I would write what I
 22 perceived to be what the statement was that
 23 they had to do, but as far as the procedure, I
 24 would need them to tell me the kinds of things
 25 that would be on the corrective action log and

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

12 CHAYTOR, Q.C.:

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

21 MS. WADE:

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

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

5 CHAYTOR, Q.C.:

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

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1 processor." And so there's a lot of detail on
 2 what these all--this on is in May of 2008 and
 3 I think all of them are around the early part
 4 of 2008. And in that respect, Ms. Wade, most
 5 of the policies and procedures that we looked
 6 at, a lot of the ones that I brought you to
 7 specifically yourself, February, 2008, March,
 8 2008 and some of these are May, the ER/PR
 9 testing had resumed in February, 2007 and
 10 those policies and procedures weren't
 11 completed until at least after the testing had
 12 resumed. What in the meantime was in place
 13 prior to the testing being allowed to resume
 14 in February, 2007?

15 MS. WADE:

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

18 CHAYTOR, Q.C.:

19 Q. In February, 2007.

20 MS. WADE:

21 A. Yeah.

22 CHAYTOR, Q.C.:

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

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1 MS. WADE:

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

9 CHAYTOR, Q.C.:

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

18 MS. WADE:

19 A. Again, I don't know.

20 CHAYTOR, Q.C.:

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

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1 regarding the VIP5 tissue processor and
 2 excessive xylene fumes. And are you aware of
 3 what caused Mr. Simpson to write this report?
 4 MS. WADE:
 5 A. Yes, I am.
 6 CHAYTOR, Q.C.:
 7 Q. And Mr.--you'll see Mr. Simpson found here
 8 ultimately that the charcoal filter had not
 9 been replaced since March, 2008. Charcoal
 10 filters are recommended to be replaced every
 11 20 processing runs as it becomes saturated
 12 with xylene molecules and fume control waters
 13 not being replaced daily. There were
 14 deficiencies discovered, obviously, in the
 15 maintenance of the tissue processors in
 16 question and I'm wondering how could that be
 17 in light of the policies and procedures that
 18 are now in place?
 19 MS. WADE:
 20 A. Again, this is very specific to the histology
 21 section of the lab and I certainly can't speak
 22 to the installation and training and any of
 23 the processes that were brought in, I would
 24 not be involved in anything at that level.
 25 CHAYTOR, Q.C.:

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1 Q. And in terms, though, and it says here, for
 2 example, "the lab had two new charcoal filters
 3 on hand which were replaced during the
 4 warranty inspection. Laboratory was found not
 5 following the recommended maintenance for
 6 charcoal exchange every 20 runs and
 7 replacement of fume control every run." And,
 8 for example, even the policy that I took you
 9 to that you, yourself had drafted and
 10 directing that people refer to the manual.
 11 Has there been any inquiries made as to there
 12 is a policy in place, there's procedure in
 13 place, how is it that it wasn't being
 14 followed?
 15 MS. WADE:
 16 A. Well certainly since this there were questions
 17 asked because it became known. One of the
 18 things that I did to ensure that the
 19 procedures get followed appropriately is that
 20 the log sheets that they have are accurate.
 21 And if the log sheet has any handwriting on it
 22 that may deface what the intent is, that could
 23 cause someone not to follow a proper process,
 24 so I instructed the acting manager to ensure
 25 that the document that he has in place is one

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1 that is not defaced and that staff are aware
 2 that they're not to write on it, other than to
 3 log in or out that they have done the work.
 4 CHAYTOR, Q.C.:
 5 Q. And who is that, who is the acting manager?
 6 MS. WADE:
 7 A. Mr. Gerry McLean.
 8 CHAYTOR, Q.C.:
 9 Q. He's acting manager for which?
 10 MS. WADE:
 11 A. In pathology.
 12 CHAYTOR, Q.C.:
 13 Q. Where is Mr. Dyer?
 14 MS. WADE:
 15 A. I don't know what other role Mr. Dyer is
 16 involved in at this moment.
 17 CHAYTOR, Q.C.:
 18 Q. He also found, "the fume control water is
 19 recommended to be changed on a daily or every
 20 run basis. The laboratory is therefore
 21 advised to revise their SOP to reflect the
 22 charcoal and fume control water maintenance
 23 for optimal fume management." And I'm
 24 wondering have the SOPs been revised to your
 25 knowledge?

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1 MS. WADE:
 2 A. I know that Ms. Rowe is working of revising
 3 the tissue processor schedule procedure and
 4 anything else related to tissue processing
 5 that had to be changed.
 6 CHAYTOR, Q.C.:
 7 Q. And I just want to understand this as an
 8 example, not as to how the process would work
 9 in terms of--because there has been a lot of
 10 processes put in place, obviously, in terms of
 11 the quality management program and I'm just
 12 wondering how this type of issue could be
 13 detected without external people having to
 14 come in to detect that there's a problem. So
 15 on a go-forward basis, when an issue such as
 16 this would arise, how the processes are now in
 17 place at Eastern Health that they can be
 18 picked up internally so that there's not
 19 someone else having to come through the door,
 20 an external review, to determine this. What
 21 is now in place to ensure that Eastern Health
 22 will pick up on these issues internally?
 23 MS. WADE:
 24 A. Again, the managers need to ensure, the
 25 manager needs to ensure that the processes for

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1 the staff are in place. Following that, to
 2 ensure that the processes and procedures are
 3 followed, there needs to be routine regular
 4 audits and those audits would be done by the
 5 quality management technologist, as I
 6 mentioned before.
 7 CHAYTOR, Q.C.:
 8 Q. And if we could have, please, P-3119? And
 9 this is a report which was done by Mr. Bryan
 10 Hewlett and Mr. Bill Parks and have you seen
 11 this document?
 12 MS. WADE:
 13 A. Yes, I have.
 14 CHAYTOR, Q.C.:
 15 Q. And I just want to bring you to page 6 of this
 16 document about the manuals and documentation
 17 and he's referring to the new policy and
 18 procedure manual that we know as P-2157,
 19 "there is evidence of the use of the new
 20 procedures at the St. Clare's Mercy site. The
 21 staff at this site is aware of the new manual
 22 and have been reading and signing off on
 23 relevant sections. They have also
 24 demonstrated their knowledge through
 25 application of several situations during our

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1 visits to the site. Unfortunately the
 2 majority of bench staff at the Health Centre
 3 site appears to be uninformed of the existence
 4 of this new document. A staff in-service
 5 education session regarding reading and
 6 signing off of the new relevant manual
 7 sections is strongly suggested." And I'm
 8 wondering, Ms. Wade, has anything been done to
 9 address that?
 10 MS. WADE:
 11 A. I do know that the binder is in the pathology
 12 lab and I do know that staff are told and have
 13 been told that they have to read it and sign
 14 it off. I have been in the lab when that has
 15 actually been taking place. I have witnessed
 16 staff reading the manual, so I find that
 17 statement quite alarming that people don't
 18 know.
 19 CHAYTOR, Q.C.:
 20 Q. So you take issue with that statement?
 21 MS. WADE:
 22 A. He said the majority of bench staff and all I
 23 can say is that I do know, I've heard the
 24 manager state that staff have been told about
 25 it and that there is a process for them to do

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1 it and I have seen it myself, so whoever they
 2 spoke to that day might have been just that
 3 day, you know, I can't answer the question
 4 other than I know that it's supposed to be
 5 done.
 6 CHAYTOR, Q.C.:
 7 Q. And Ms. Wade, you told us earlier that the
 8 staff would have been asked to sign off, so
 9 did you see evidence that the staff had signed
 10 off indicating that they had read the manual?
 11 MS. WADE:
 12 A. That they had? I witnessed an employee at the
 13 bench with the manual, with the sign off
 14 sheet.
 15 CHAYTOR, Q.C.:
 16 Q. And when was that?
 17 MS. WADE:
 18 A. That was right around that day, very close to
 19 that because that's why I find it so amazing.
 20 CHAYTOR, Q.C.:
 21 Q. And perhaps after that day?
 22 MS. WADE:
 23 A. It could have been, but I do know, at the
 24 quality management committee meeting, perhaps
 25 two or three, maybe a couple of months ago,

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1 Mr. McLean had stated that he has specifically
 2 said to staff that, you know, if they come
 3 looking for time off, he said, well if you
 4 haven't got the policy manual read, you can't
 5 go, so you can have your time off after you
 6 read it. So I know that it's a very--there is
 7 heightened awareness of the need for this.
 8 CHAYTOR, Q.C.:
 9 Q. Particularly in light, I guess of this report?
 10 MS. WADE:
 11 A. Well now certainly, but even before that.
 12 CHAYTOR, Q.C.:
 13 Q. So my question is, Ms. Wade, have you seen any
 14 documented evidence that all the staff that
 15 need to know about these manuals have signed
 16 off indicating that they are aware and are
 17 informed?
 18 MS. WADE:
 19 A. I would not see documentation that every
 20 employee, no.
 21 CHAYTOR, Q.C.:
 22 Q. Have you seen any documentation to support
 23 that they in fact have signed off, that they
 24 are aware of the existence -
 25 MS. WADE:

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

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

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

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

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1 the lab." And I had taken you through the
 2 corrective actions policy that we referred to
 3 a few moments ago, so is there anything that's
 4 being done in terms of tightening up this
 5 aspect?
 6 MS. WADE:
 7 A. I can't speak specifically to the pathology
 8 section.
 9 CHAYTOR, Q.C.:
 10 Q. So what, if any, action is taking place to
 11 ensure that the corrective actions information
 12 is being correlated, analyzed and then used in
 13 a QA processing function?
 14 MS. WADE:
 15 A. Well, certainly if--following this, I would
 16 expect that a review of how they're handling
 17 corrective action and what they're going to do
 18 to improve that process would be undertaken.
 19 CHAYTOR, Q.C.:
 20 Q. See, what I'm reading here, and it appears
 21 that the policy is in place. There's a
 22 corrective actions policy. There's a log to
 23 be kept and Dr. Elms is accumulating, for IHC
 24 anyhow, there's that, and I'm just wondering
 25 is there--is it a situation where the policy

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1 is in place but the practice hasn't caught up
 2 yet with the policy?
 3 MS. WADE:
 4 A. That could be. Now I read this as the main
 5 histology lab and not immunohistochemistry, so
 6 I know that Ms. Gamberg, in
 7 immunohistochemistry, is involved with
 8 corrective actions and processes around that
 9 section. So I'm not sure what they are
 10 referring to specifically.
 11 CHAYTOR, Q.C.:
 12 Q. Okay, and of course, it would be equally
 13 important for histology to have the same -
 14 MS. WADE:
 15 A. Exactly.
 16 CHAYTOR, Q.C.:
 17 Q. - processes in place and procedures and
 18 policies in place regarding this.
 19 MS. WADE:
 20 A. Yeah.
 21 CHAYTOR, Q.C.:
 22 Q. And the IHC lab depends on the histology lab
 23 to get their portion right along the way.
 24 MS. WADE:
 25 A. Yeah.

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1 CHAYTOR, Q.C.:
 2 Q. And page ten then of this document, and he
 3 refers here to "we also observed pockets of
 4 corrective actions being taken and documented
 5 based on the results of the QC, but there is
 6 some disconnection of the information on its
 7 use in total quality improvement of the
 8 overall product of the laboratory. There has
 9 been a real effort in areas of the laboratory
 10 to determine what the current patterns of
 11 practice and implementation of these
 12 practices. Fixation time and tissue sample
 13 thickness is one of the most obvious," he
 14 refers to. "The disconnection of the
 15 information and the need for corrective action
 16 is most likely due to the instability and
 17 movement of staff in and out of the histology
 18 lab. Staff are being trained on specific
 19 benches to get the most productivity out of
 20 their efforts without knowledge of the whole
 21 process and this has been happening for years
 22 and has resulted in inability to use all the
 23 information being collected."
 24 And in terms of that being an issue, in
 25 terms of your role in the training and the

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1 ongoing education of the staff, have you given
 2 any thought as to how this issue may be
 3 corrected?
 4 MS. WADE:
 5 A. Well, if you read the next section, they talk
 6 about the new training that's undergoing now
 7 with new full-time employees, that they
 8 started their training at the front end and
 9 will go through the training in a logical
 10 sequential format. So that certainly is an
 11 enhancement to the training process for those
 12 employees. Again, with regard to the issue of
 13 temporary staff and the in and out continued
 14 flux of staff, unfortunately that has been a
 15 problem with the lab program throughout, in
 16 that there is not enough redundancy built into
 17 staffing levels to ensure that we don't have
 18 to bring in a casual employee when someone is
 19 off, and that is the world in which we have
 20 worked for a number of years. We just have
 21 enough people to do the work and then we're
 22 challenged even then.
 23 CHAYTOR, Q.C.:
 24 Q. And I take it then you agree with their
 25 comments about the importance of that for a

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1 total quality management? It says here "we
 2 firmly believe that if staffing can be
 3 stabilized and the right people are recruited
 4 and retained in permanent positions, the lab
 5 will be able to develop a whole picture
 6 approach to total quality management."
 7 MS. WADE:
 8 A. Yes, certainly. You know, we are still
 9 challenged by following a collective
 10 agreement. We have a lot of issues that, you
 11 know, are certainly aspects of the collective
 12 agreement that you have to adhere to.
 13 CHAYTOR, Q.C.:
 14 Q. And how does that impede you? How does that--
 15 how is that a factor?
 16 MS. WADE:
 17 A. Well, employees have a right to move from job
 18 to job. In Eastern Health, one of the
 19 policies that was put in place a few years ago
 20 to try and stabilize our work force was that
 21 we limited the transfer temporarily--the
 22 temporary transfer of permanent employees into
 23 temporary positions, so that you would limit
 24 the amount of training. Because if you can
 25 imagine, you have a job that's vacant due to a

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1 long-term sick leave or a maternity leave, for
 2 instance, and that job has to be filled for a
 3 year, the training that takes place is quite
 4 comprehensive. It takes quite a while to
 5 train someone, to bring them up to speed. You
 6 may never in a year, and so if you allow staff
 7 who are in a permanent job in biochemistry to
 8 go temporarily for a year to pathology, while
 9 that is good for their professional
 10 development, it's not necessarily good for the
 11 program at that time, because then you have
 12 the training of that person, then you got to
 13 backfill of that other one, and then it's a
 14 snowball effect. So a number of years ago, we
 15 put a policy--well, basically, we followed the
 16 collective agreement to the letter in saying
 17 that it was the employer's prerogative
 18 basically to say whether or not we would allow
 19 this to happen. So what we've done is limited
 20 the ability to permanent employees to move
 21 temporarily. So that helped to stabilize us to
 22 some degree.
 23 But in pathology, we have seen an
 24 increase of staffing for various reasons.
 25 We've seen retirement, so turnover inherent in

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1 that, and we have summer breaks and vacations
 2 whereby you fill with casual staff and
 3 temporary employees. So we still are not able
 4 to stabilize our work force, and then you are
 5 also bound by the collective agreement,
 6 seniority clauses and various aspects of that.
 7 So we have--as managers, there are challenges
 8 with maintaining a stable work force because
 9 if somebody doesn't like where they are or if
 10 for whatever reason of professional
 11 development they choose to go learn something
 12 else, we don't really have any way of telling
 13 them "no, you can't go" if there is a vacancy
 14 and they're trained and qualified at the basic
 15 level.
 16 CHAYTOR, Q.C.:
 17 Q. And in terms of someone to be trained and
 18 qualified, I asked you earlier today, in
 19 particular for a job in the IHC lab, the
 20 training and qualifications, is it any
 21 different than what would be required anywhere
 22 else within the pathology lab?
 23 MS. WADE:
 24 A. Well, typically the immunohistochemistry is a
 25 section of pathology. So the people who are

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1 working there have experience of years in
 2 pathology division itself. So they know--they
 3 have experience in the front end, the whole
 4 pre-analysis piece and the microtomy and the
 5 staining, the embedding and the cutting, all
 6 of those processes prior to
 7 immunohistochemistry.
 8 CHAYTOR, Q.C.:
 9 Q. If we could have, please, P-3598?
 10 THE COMMISSIONER:
 11 Q. So are you saying that problem does not exist
 12 in IHC?
 13 MS. WADE:
 14 A. Does not?
 15 THE COMMISSIONER:
 16 Q. Yes.
 17 MS. WADE:
 18 A. I can't say that it does not exist. It's just
 19 that the manager does have the ability to
 20 take--they would take--if a position came up
 21 in immunohistochemistry, they would expect
 22 that they would fill it with someone with
 23 experience at least in pathology. They
 24 wouldn't just take somebody out of another
 25 section, because the manager would reorganize

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1 their staffing so that the most experienced
 2 person goes where they're required most.
 3 THE COMMISSIONER:
 4 Q. So it's done on the basis -
 5 MS. WADE:
 6 A. And they would bring a new person -
 7 THE COMMISSIONER:
 8 Q. - of IHC being part of pathology and therefore
 9 you switch around within pathology?
 10 MS. WADE:
 11 A. You would move, yes.
 12 THE COMMISSIONER:
 13 Q. You don't actually have to go outside of
 14 pathology to find somebody?
 15 MS. WADE:
 16 A. Right, right, yeah.
 17 THE COMMISSIONER:
 18 Q. All right.
 19 CHAYTOR, Q.C.:
 20 Q. And Ms. Wade, do you know what this document
 21 is?
 22 MS. WADE:
 23 A. I believe it's some external proficiency
 24 testing. I saw it in a presentation, but as
 25 for interpretation, I really can't interpret

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1 it.
 2 CHAYTOR, Q.C.:
 3 Q. Okay. It appears down at the bottom, there's
 4 a small key and the red stands for positive,
 5 white is negative and then yellow, sample
 6 unsuitable for evaluation, i.e. fallen off or
 7 no tumor. Is this Eastern Health's data, do
 8 you know?
 9 MR. SIMMONS:
 10 Q. These are ones that were identified, I think--
 11 not these particular documents, but Ms.
 12 Torlakovic spoke about these as coming from
 13 the CIQC.
 14 CHAYTOR, Q.C.:
 15 Q. Okay, great, thank you. Thank you, Ms. Wade.
 16 Those are my questions. Perhaps some of my
 17 colleagues will have questions for you too.
 18 MS. WADE:
 19 A. Thank you.
 20 THE COMMISSIONER:
 21 Q. Mr. Pritchard?
 22 MR. PRITCHARD:
 23 Q. Thank you, Commissioner. I have no questions.
 24 Thank you for your evidence, Ms. Wade.
 25 MS. HENNEBURY:

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1 Q. I have no questions.
 2 THE COMMISSIONER:
 3 Q. You've been abandoned by Mr. Browne, have you?
 4 MS. HENNEBURY:
 5 Q. I have.
 6 THE COMMISSIONER:
 7 Q. Mr. Pritchett?
 8 MR. PRITCHETT:
 9 Q. No questions, Commissioner, thank you.
 10 THE COMMISSIONER:
 11 Q. Ms. Newbury?
 12 MS. LYNN WADE, EXAMINATION BY MS. JENNIFER NEWBURY
 13 MS. NEWBURY:
 14 Q. Just a couple. Good afternoon, Ms. Wade. My
 15 name is Jennifer Newbury and I represent the
 16 Newfoundland and Labrador division of the
 17 Canadian Cancer Society, and I just wanted to
 18 ask for some clarification on a reference you
 19 made this afternoon to ISO. I think the
 20 standard was 15189?
 21 MS. WADE:
 22 A. Um-hm.
 23 MS. NEWBURY:
 24 Q. Okay, and can you advise if there are any
 25 current plans to obtain ISO certification

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1 pursuant to that particular ISO standard?
 2 MS. WADE:
 3 A. The Accreditation Canada, accreditation for
 4 labs, which is new, was mandatory for all
 5 health care organizations in Canada that are
 6 not currently accredited otherwise -
 7 MS. NEWBURY:
 8 Q. Okay.
 9 MS. WADE:
 10 A. - for the lab, the ISO--the Accreditation
 11 Canada Lab Standards is done in collaboration
 12 with the Canadian Standards Association which
 13 oversees the Canadian version of the ISO
 14 15189.
 15 MS. NEWBURY:
 16 Q. Okay. I thought I had heard your evidence
 17 that accreditation wouldn't be necessary if
 18 the lab is determined to meet the ISO 15189
 19 standards. Did I understand that?
 20 MS. WADE:
 21 A. If the lab were to be accredited by some body
 22 that was ISO 1--following 15189 standards,
 23 then they would not be required to go through
 24 the Accreditation Canada standard because
 25 they've already met them. So there are

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1 provinces in the country that have additional
 2 accreditation processes.
 3 MS. NEWBURY:
 4 Q. Right, such as Ontario, I think.
 5 MS. WADE:
 6 A. That's right.
 7 MS. NEWBURY:
 8 Q. One of the examples there, and just so I'm
 9 clear, I want to be clear, because I
 10 understand that there are a number of
 11 different types of organizations and groups
 12 that can certify or accredit an organization
 13 such as a health care organization to meet the
 14 standards of ISO, such as ISO 15189. Is it
 15 your understanding that the Accreditation
 16 Canada organization will actually come to the
 17 lab and certify that it has met all of those
 18 stringent requirements or whatever the
 19 requirements are of ISO 15189?
 20 MS. WADE:
 21 A. Accreditation Canada is using those standards
 22 in their -
 23 MS. NEWBURY:
 24 Q. Okay.
 25 MS. WADE:

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1 A. - used them in their standard development.
 2 MS. NEWBURY:
 3 Q. Okay.
 4 MS. WADE:
 5 A. I do know that QMPLS in Ontario specifically
 6 uses 15189 and their audit process follows the
 7 15189 standard.
 8 MS. NEWBURY:
 9 Q. Okay. So your understanding then is that
 10 Accreditation Canada has taken, I guess, as
 11 its background information, the ISO standards?
 12 MS. WADE:
 13 A. That's right.
 14 MS. NEWBURY:
 15 Q. And whether or not it's identical, you're not
 16 clear. Is that correct, or do you think it is
 17 identical to the ISO standards?
 18 MS. WADE:
 19 A. I don't think it's identical, but you know, I
 20 haven't read--I've read the documents, but I
 21 haven't done a real correlation.
 22 MS. NEWBURY:
 23 Q. Okay, and it's your understanding that the
 24 accreditation has been done in accordance with
 25 whatever Accreditation Canada has decided

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1 would be appropriate?
 2 MS. WADE:
 3 A. Well, in our labs, at this point in time, we
 4 went through the pilot accreditation in 2007,
 5 which was the last year that the pilot was
 6 undertaken for Accreditation Canada. So now,
 7 for our next accreditation, our laboratories
 8 will have to meet those standards in order for
 9 Eastern Health to become a certified--an
 10 accredited entity.
 11 MS. NEWBURY:
 12 Q. Okay. So hopefully at the end of that, when
 13 it's no longer just a pilot project and -
 14 MS. WADE:
 15 A. Exactly, it's no longer a pilot.
 16 MS. NEWBURY:
 17 Q. - then you meet standards that are perhaps
 18 similar to, if not identical to, the ISO
 19 standards?
 20 MS. WADE:
 21 A. That's right.
 22 MS. NEWBURY:
 23 Q. Okay. I understand that the College of
 24 American Pathologists actually has its own
 25 accreditation program which seeks to certify a

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1 health organization as having met those
 2 particular standards, the ISO 15189, and I
 3 understand that the College of American
 4 Pathologists has some quality programs that
 5 Eastern Health participates in. Have you ever
 6 heard any discussion about perhaps relying
 7 upon the College of American Pathologists
 8 program to certify according to ISO 15189?
 9 MS. WADE:
 10 A. I have not heard of discussions around the CAP
 11 in particular.
 12 MS. NEWBURY:
 13 Q. Okay.
 14 MS. WADE:
 15 A. Accreditation. However, we have had
 16 discussions with QMPLS just to get a sense of
 17 their processes and what kind of service they
 18 offer, with a view to perhaps in the future
 19 going through that kind of a process, whether
 20 it's QMPLS or CAP or some other provincial
 21 scheme, but that would have to come as a
 22 directive, I think, from the provincial
 23 government that they would recognize that that
 24 accreditation would be satisfactory for labs
 25 in our province.

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1 MS. NEWBURY:
 2 Q. Okay, and just--I just want to clarify what
 3 exactly that particular standard relates to,
 4 and I just did a quick website search and
 5 found this description. I just wanted you to
 6 confirm whether or not that that seems
 7 consistent with your understanding of it, and
 8 it basically--it's the ISO 15189 for the year
 9 2003. I think it's been updated since, but
 10 for 2003 it basically describes it as being
 11 "medical laboratories particular requirements
 12 for quality and competence."
 13 MS. WADE:
 14 A. That's right.
 15 MS. NEWBURY:
 16 Q. And it specifies "the quality management
 17 system requirements particular to medical
 18 laboratories."
 19 MS. WADE:
 20 A. That's right.
 21 MS. NEWBURY:
 22 Q. That's generally it?
 23 MS. WADE:
 24 A. That is, yes.
 25 MS. NEWBURY:

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1 Q. Okay. Thank you, and I just have one other
 2 quick question in relation to the occurrence
 3 reporting. If I could bring up Exhibit P-
 4 3620, please? And I'm not sure now if you--
 5 okay, this is a document, I'm not sure if you
 6 answered any questions on that today. I may
 7 have missed it if you have, and this is to
 8 program directors from Janet Laidley, Quality
 9 and Clinical Safety Leaders. Are you familiar
 10 with this particular document?
 11 MS. WADE:
 12 A. Wait now, I'll move it along there.
 13 MS. NEWBURY:
 14 Q. And you can go through it with the mouse.
 15 MS. WADE:
 16 A. Yes.
 17 MS. NEWBURY:
 18 Q. Okay, and what policy of Eastern Health is
 19 this occurrence reporting document produced
 20 pursuant to, I guess?
 21 MS. WADE:
 22 A. I would think it would be the quality and risk
 23 framework.
 24 MS. NEWBURY:
 25 Q. Okay. And is that a corporate wide -

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1 MS. WADE:
 2 A. That's a--Eastern Health has a quality and
 3 risk framework, yes.
 4 MS. NEWBURY:
 5 Q. Okay.
 6 MS. WADE:
 7 A. But in the past, the Health Care Corporation
 8 of St. John's had these kinds of reports.
 9 MS. NEWBURY:
 10 Q. Okay. The legacy organizations. And I note
 11 on page four of this particular document and
 12 I'll just--there we go--page four here on the
 13 bottom, it has a division for pathology.
 14 Let's try page five. Yes, here we go. So,
 15 the division and it has the lab pathology and
 16 then there are a number of different entries
 17 for reports. And I'm just wondering, on the
 18 left hand side, for example, there's, in a
 19 bold print, under treatment/test specimen,
 20 there's a description that's labelled specimen
 21 and then there are a number of entries below
 22 that. And if we go over onto the next page,
 23 actually perhaps--this is a different
 24 department, but I'm going to go back to page
 25 four because I think it has some interesting

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1 descriptions here. It has descriptions such
 2 as "lost specimen", here in bold print. And
 3 then down towards the bottom of the page,
 4 "analysis not done". Are those standard types
 5 of descriptions for the purposes of occurrence
 6 reporting?
 7 MS. WADE:
 8 A. Yes, on the occurrence reports that we use
 9 now, it's a two or three copy report and there
 10 are sections for various kinds of incidents or
 11 occurrences. And one of them, under specimen
 12 test results would be analysis not done, wrong
 13 kind of sample, might be various things. And
 14 in some instances, the lab will fill what was
 15 a little more appropriate for its documents.
 16 MS. NEWBURY:
 17 Q. So, it can elaborate on it, but basically -
 18 MS. WADE:
 19 A. Yes, that's right -
 20 MS. NEWBURY:
 21 Q. - categories, types of occurrences are given.
 22 MS. WADE:
 23 A. Yes, and dealing with specimens. So, the
 24 document is a bit cumbersome at this point,
 25 but Eastern Health is in the process of

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1 rolling out a new, piloting a new electronic
 2 occurrence management system which will enable
 3 much better tracking, much better
 4 documentation in compliance with documents.
 5 It will be easier to use at the touch of a
 6 mouse and a PC.
 7 MS. NEWBURY:
 8 Q. Yes. And Ms. Predham has given us some
 9 evidence, I think, on that plan.
 10 MS. WADE:
 11 A. Right.
 12 MS. NEWBURY:
 13 Q. And I'm just thinking, up until that new
 14 system is launched, are there any headings or
 15 categories that would cover off something like
 16 a test procedure that was done using an
 17 incorrect dilution or they were missing
 18 controls in the particular test procedure.
 19 MS. WADE:
 20 A. Not on the form in any checklist, but what
 21 would happen is there would be a narrative,
 22 descriptive entered in the narrative section
 23 that would highlight the specific issue.
 24 MS. NEWBURY:
 25 Q. So, would that come under--I notice there that

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1 there's a couple of headings in bold that just
 2 says "other" -
 3 MS. WADE:
 4 A. Well, down in Quality and Risk, they may chose
 5 to collate it as a specimen issue under other
 6 or it may be something that they could flag it
 7 to more specifically.
 8 MS. NEWBURY:
 9 Q. Okay, there might be more general category.
 10 MS. WADE:
 11 A. Yes.
 12 MS. NEWBURY:
 13 Q. And I guess I asked the question because it
 14 seems that a lot of these, just looking at
 15 this report in its entirety, there seems to be
 16 a lot that seem more like administrative type
 17 errors, like missing labels or things like
 18 that, as opposed to the technical, something
 19 like using an improper dilution or something
 20 more technical in nature. And I was wondering
 21 if it was intended that that would be covered
 22 off in this type of a report here.
 23 MS. WADE:
 24 A. Well, you see, most--the technical kinds of
 25 things would often be dealt with under the

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1 corrective action logs and what they would do.
 2 So, for instance, a technologist is running
 3 quality controls on a major analyzer in a lab
 4 and noted a quality control failure of one
 5 particular test, analyte, before they would
 6 test any patient, they would go through a
 7 series of steps to determine what the problem
 8 was and they would document that. That's part
 9 of the day-to-day operations of the lab. The
 10 occurrence report would probably be used if it
 11 got outside of the lab and there were some
 12 adverse event or opportunity for an adverse
 13 event to a patient, then we would document
 14 that as something that got outside of our
 15 control and we had to backtrack now and start
 16 to see how that happened.
 17 MS. NEWBURY:
 18 Q. So, just for clarification, if a lab report
 19 was generated even though there was an
 20 incorrect dilution used, for example, in a
 21 test procedure, and then the test had to be
 22 re-done, would you expect that sort of
 23 situation to be reflected in this kind of a
 24 document, the second quarter occurrences
 25 summary?

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1 MS. WADE:
 2 A. If a report left a lab, yes, and it was picked
 3 up by some clinician and was identified--
 4 should be identified as an occurrence.
 5 MS. NEWBURY:
 6 Q. And you said a potential for an adverse event,
 7 is that a near miss?
 8 MS. WADE:
 9 A. It could be a near miss.
 10 MS. NEWBURY:
 11 Q. Okay. Thank you very much. Those are all my
 12 questions.
 13 THE COMMISSIONER:
 14 Q. Thank you. I saw Mr. Crosbie here a moment
 15 ago.
 16 MS. NEWBURY:
 17 Q. Mr. Crosbie advises that he has no questions.
 18 THE COMMISSIONER:
 19 Q. Okay, thank you. Mr. Simmons.
 20 MS. LYNN WADE, EXAMINATION BY MR. DANIEL SIMMONS
 21 MR. SIMMONS:
 22 Q. Ms. Wade, we'll get you out of here before
 23 6:00. I just have -
 24 THE COMMISSIONER:
 25 Q. Promises, promises, Mr. Simmons.

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1 MR. SIMMONS:
 2 Q. - very specific things and they're very direct
 3 and very short. Ms. Chaytor asked you if you
 4 were able to say whether all the policies and
 5 procedures relating to the ER and PR testing
 6 were now done and in place and I understood
 7 you to say that you couldn't necessarily say
 8 that. My question is, are you aware of any
 9 policy and procedures for ER and PR testing
 10 that are outstanding? Are there any that you
 11 know of that are outstanding, that haven't
 12 been addressed?
 13 MS. WADE:
 14 A. Again, I don't know.
 15 MR. SIMMONS:
 16 Q. There's none that you know of that are
 17 outstanding.
 18 MS. WADE:
 19 A. Not that I'm aware of. I know that certainly
 20 IHC gets high priority in the pathology lab,
 21 so -
 22 MR. SIMMONS:
 23 Q. Ms. Chaytor showed you one of the reports from
 24 UK NEQAS, I think the one from this last
 25 summer, can I have P-3595, please. First of

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1 all, do you recognize what this particular
 2 report is, this document?
 3 MS. WADE:
 4 A. Yes, I do.
 5 MR. SIMMONS:
 6 Q. And what is it?
 7 MS. WADE:
 8 A. Basically it's a summary of some indicators
 9 for anatomic pathology for 2007/2008. It just
 10 demonstrates the kinds of some random reviews,
 11 correlations and quality assurance activities
 12 that are undertaken in pathology.
 13 MR. SIMMONS:
 14 Q. Who is it prepared by and where does it go?
 15 MS. WADE:
 16 A. Some of the indicators such as the cases
 17 referred for Dynacare, other--those very
 18 specific pathology ones would have been
 19 prepared by Ms. Catherine Parnell at that time
 20 and the table, I put it together in a table
 21 format.
 22 MR. SIMMONS:
 23 Q. And the report is prepared for presentation
 24 where or to whom?
 25 MS. WADE:

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1 A. We will be preparing and we do prepare them
 2 for Dr. Howell to present as a, at the
 3 portfolio committee and then also for the
 4 regional quality council annually.
 5 MR. SIMMONS:
 6 Q. Can I have page seven please, there's a table
 7 here, it's under a heading, "United Kingdom
 8 National External Quality Assessment Scheme UK
 9 NEQAS", results for ER and PR. And is this a
 10 table listing the results for the four rounds
 11 of proficiency testing before the one that you
 12 looked at earlier?
 13 MS. WADE:
 14 A. Right.
 15 MR. SIMMONS:
 16 Q. And if we look at this, it appears that the ER
 17 scores out of a maximum of 20 were 16 in 2005;
 18 16 in 2006; 20 for the second one in 2006; and
 19 18 in 2007.
 20 MS. WADE:
 21 A. That's right.
 22 MR. SIMMONS:
 23 Q. And for the PR they were 16, 14 and 16.
 24 MS. WADE:
 25 A. That's right.

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1 MR. SIMMONS:
 2 Q. Okay. You answered a fair number of questions
 3 on the form that was filled out for QMPLS
 4 before they came in and did their review in
 5 December of 2007. And you had experience with
 6 other accreditations and so on, as well.
 7 MS. WADE:
 8 A. Yes.
 9 MR. SIMMONS:
 10 Q. Is that a common type of approach for
 11 accreditors to us, to have certain information
 12 prepared or forms filled out and submitted
 13 before they -
 14 MS. WADE:
 15 A. Yeah, that's right. Certainly, when I was
 16 doing--I was doing the same kind of form for
 17 the accreditation Canada pilot, just gathering
 18 information about the organization so that the
 19 surveyors will have background about the
 20 organization, the kind of testing procedures
 21 that are handled.
 22 MR. SIMMONS:
 23 Q. And are you able to tell me how much
 24 accreditors or reviewers normally use those
 25 forms, whether they accept those things at

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1 face value or whether they do any of their own
 2 verification to check the things that are -
 3 MS. WADE:
 4 A. Well, when they come in to the organization,
 5 they look for evidence based on the standards
 6 and kinds of audits that they are doing. So,
 7 they would look for evidence that the
 8 procedures were there or any indicators that
 9 were relevant, they would look for.
 10 MR. SIMMONS:
 11 Q. So, in your experience, when they come in,
 12 they will actually look to see if the answers
 13 they've been given can be backed up by the
 14 evidence that they see when they get there.
 15 MS. WADE:
 16 A. Exactly.
 17 MR. SIMMONS:
 18 Q. Okay. Now, I thought I had one more, but it
 19 looks like I don't. Thank you very much.
 20 That's all I have.
 21 MS. WADE:
 22 A. Thank you.
 23 THE COMMISSIONER:
 24 Q. You kept your promise, Mr. Simmons. Anything
 25 arising, Ms. Chaytor?

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1 CHAYTOR, Q.C.:
 2 Q. Nothing arising, Commissioner.
 3 THE COMMISSIONER:
 4 Q. Why are you on your feet, Mr. Coffey?
 5 COFFEY, Q.C.:
 6 Q. Commissioner--I'm sorry, Ms. Wade, this has
 7 nothing at all to do with yourself.
 8 Commissioner, I did want, as it just turns
 9 out, Dr. Denic happens to be in the room, the
 10 back of the room. I did want to advise you
 11 that the matter of the, if you recall, there
 12 was a discussion about the ethics consult
 13 meeting of June '06 and whether or not Dr.
 14 Denic might be asked a further question
 15 concerning one aspect of what was said, I
 16 believe, in the meeting.
 17 THE COMMISSIONER:
 18 Q. Um-hm.
 19 COFFEY, Q.C.:
 20 Q. In any case, I will not be--just to advise
 21 you, Commissioner, we will not be pursuing
 22 that further.
 23 THE COMMISSIONER:
 24 Q. So, I can tell Ms. Wade that she's been
 25 released, with my appreciation for your having

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1 come and contributed to us. And Dr. Denic, it
 2 appears that you will not be called back.
 3 DR. DENIC:
 4 Q. (Inaudible).
 5 THE COMMISSIONER:
 6 Q. Two with one blow this after. Counsel,
 7 however, the good news for you is that
 8 apparently administration has an envelope for
 9 you before you leave today. Your up again,
 10 Mr. Coffey?
 11 COFFEY, Q.C.:
 12 Q. No, no.
 13 THE COMMISSIONER:
 14 Q. Thank you again, Ms. Wade.
 15 MS. WADE:
 16 A. Thank you.
 17 THE COMMISSIONER:
 18 Q. 9:30 in the morning.
 19 Upon conclusion at 5:55 p.m.

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1 CERTIFICATE
 2 I, Judy Moss, hereby certify that the foregoing is
 3 a true and correct transcript in the matter of the
 4 Commission of Inquiry on Hormone Receptor Testing,
 5 heard on the 27th day of October, A.D., 2008 before
 6 the Honourable Justice Margaret A. Cameron,
 7 Commissioner, at the Commission of Inquiry, St.
 8 John's, Newfoundland and Labrador and was
 9 transcribed by me to the best of my ability by
 10 means of a sound apparatus.
 11 Dated at St. John's, Newfoundland and Labrador
 12 this 27th day of October, A.D., 2008
 13 Judy Moss

Inquiry on Hormone Receptor Testing

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