

1 A P P E A R A N C E S :

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MEMBERS PRESENT:

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4 ANAD RAO, CHAIRMAN
THOMAS E. JOHNSON, MEMBER
5 NICHOLAS J. MELAS, MEMBER

6

7 CHARLES MATOESIAN

8 Illinois Environmental Protection Agency

9

HODGE DWYER ZEMAN
10 BY: MS. KATHERINE D. HODGE
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11 Post Office Box 5776
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12 (217) 523-4900

13 On behalf of Abbott Laboratories;

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1 making in this rulemaking as she owns a small
2 amount of stock in Abbott and also has close
3 family members who are employed by Abbott.
4 Would you like to make any remarks at this
5 point, Mr. Melas?

6 MEMBER MELAS: Nothing else but to
7 welcome you all here. It will be a pleasure
8 listening to the answers to the pre-filed
9 questions.

10 MS. CROWLEY: Today we're holding the
11 first and only hearing currently scheduled in
12 this rule making. I see that there are no
13 members of the public present so I will cut
14 short the introductory remarks that we
15 usually make a little bit.

16 The proceeding is governed by the
17 Board's procedural rules. All information
18 that is relevant and not repetitious is
19 admitted into the record. The Board makes
20 its rulings on the basis of its sworn and
21 transcribed records. So the hearing officer
22 will be asked to swear in the witnesses. I
23 also want to remind you that any questions
24 that may be posed today by any member of the

1 Board or staff are intended solely to develop
2 a complete and clear record for the Board and
3 are not intended to reflect any prejudgment
4 of the proposal.

5 The hearing today will consider
6 both the technical justification of the
7 proposal, as well as any economic impact of
8 the proposed rules as required by Section
9 27-B of the Environmental Protection Act. On
10 October 18, 2007 the Board requested The
11 Department of Commerce and Economic
12 Opportunity to conduct an economic impact
13 study. That department has not responded to
14 this request or pre-filed a study within the
15 45-day period the Act provides, so the Board
16 will be basing its decision on the economic
17 information that is provided today and in any
18 post-hearing comments. The Board has
19 received pre-filed testimony in this
20 proceeding only from the two witnesses from
21 Abbott. We also have some pre-filed
22 questions that were developed by the Board
23 and given to the parties on March 4, 2008.
24 So we will begin, I think, by asking the

1 attorneys to introduce themselves and then we
2 will turn the proceedings over to Ms. Hodge
3 for Abbott.

4 MS. HODGE: Thank you very much. Good
5 afternoon, everyone. Thank you for allowing
6 us to come here today to present support for
7 our proposal. My name is Katherine Hodge,
8 H-O-D-G-E, and I'm with the Hodge Dwyer
9 Zeeman here today representing Abbott
10 Laboratories.

11 MR. MATOESIAN: Good afternoon. I'm
12 Charlie Matoesian. I'm with the Illinois
13 Environmental Protection agency. I'm hearing
14 appearing for the agency, although we are not
15 part of the filing per se.

16 MS. HODGE: Also present with me today
17 on behalf of Abbott Labs is Mr. Steve
18 Ziesmann, right here. He is the senior
19 counsel for legal and regulatory compliance
20 for Abbott. Diane Beno, to my immediate
21 left. She is the manager of Abbott's
22 operations in building AB16, some of which
23 are the topic for this proceeding. Mr. Bob
24 Wells to her left, and Bob is the air manager

1 for environmental support in Abbott's global
2 environmental health and safety department
3 and then Mr. Keith Marhafka, and he is the
4 environmental health and safety manager for
5 building AB16.

6 MS. CROWLEY: I'm sorry, I didn't
7 catch the first and last names, if we could
8 say them again.

9 MS. HODGE: Steven Ziesmann,
10 Z-I-E-S-M-A-N-N. Diane Beno. Robert Wells.
11 You have that, and Mr. Keith Marhafka, M-A-R-
12 H-A-F-K-A.

13 MS. CROWLEY: Thank you.

14 MS. HODGE: And I have just a short
15 opening statement to make, and then we'll
16 move on to our two witnesses for today.

17 Abbott owns a pharmaceutical
18 manufacturing building located at 100 Abbott
19 Park Road in Unincorporated Lake County in
20 Libertyville Township, Illinois. Abbott
21 produces a number of pharmaceutical products
22 at this facility. And these operations are
23 subject to 35 Illinois Administrative Code,
24 Subpart-T, Pharmaceutical Manufacturing. As

1 it is currently written, Subpart-T, and in
2 particular section 218.480(b) contains
3 certain exemptions that are applicable to
4 Abbott's air suspension of coater dryers,
5 fluid bed dryers, tunnel dryers, and
6 accelacotas, a-c-c-e-l-a-c-o-t-a-s, located
7 in building AB16 of the facility.

8 Today through our testimony and in
9 response to questions, we intend to
10 demonstrate that Abbott's proposal to amend
11 these site specific exceptions will, one,
12 allow Abbott to use the combined actual
13 emissions from its effective tunnel bed
14 dryers and fluid bed dryers to determine the
15 applicability of Subpart-T to these units;
16 and, two, decrease the overall VOM emissions
17 that would be allowed below the level of
18 historical actual emissions from the tunnel
19 dryers and fluid bed dryers as a group
20 relating to the 35 Illinois Administrative
21 Code, Section 218.480(b), the VOM exemption,
22 while at the same time increasing operational
23 flexibility by allowing preferential use of
24 the more efficient dryer or dryers for a

1 particular manufacturing campaign.

2 The proposed amendment also will
3 not impose any new control requirements on
4 any other source other than Abbott's
5 facility. The proposed amendment will not
6 result in any increase in emissions. First
7 before offering testimony in support of our
8 proposal, I would like to address a matter
9 raised in the hearing officer order dated
10 January 31, 2008. As you know, Ms. Crowley
11 requested Abbott to address economic and
12 budgetary effects, issues associated with our
13 proposal. In that regard, the proposed rule
14 if adopted by the Board apply only to
15 specific emission units within Abbott's
16 facility, and again the proposed rule will
17 allow for increased operational flexibility
18 at Abbott's facility which in turn will
19 result in more efficient and cost effective
20 production of pharmaceutical products.
21 Moreover the proposal will not impose any new
22 requirements upon the Illinois EPA, so there
23 will be no budgetary effect. In light of the
24 limited and site specific nature of the

1 proceeding and the information set forth in
2 Abbott's proposal and the testimony to be
3 presented today in answers to questions,
4 Abbott believes there's sufficient
5 information in this record for the Board to
6 make an analysis of the economic and
7 budgetary effects of the proposal. However,
8 Abbott would be happy to answer any questions
9 the Board may have on this topic.

10 Abbott will present two witnesses
11 today, and first Ms. Diane Beno. She is the
12 plant manager of the portion of the Abbott
13 facility internally known as Building AB16.
14 Ms. Beno will provide information about the
15 processes carried out in Building AB16 and
16 the products manufactured at that location.
17 Mr. Robert Wells is the air manager for
18 environmental support in Abbott's Global and
19 Environmental Health and Safety Department,
20 and he will testify as to the technical
21 description of the process and dryers at
22 issue in this rulemaking. He will also
23 discuss the current rule and explain how it
24 causes inefficiencies in the operations, and

1 then he will discuss the methods Abbott has
2 utilized in an attempt to alleviate those
3 inefficiencies. Finally, Mr. Wells will
4 discuss the emissions from the effected
5 dryers from both a historical and prospective
6 perspective. The testimony of these two
7 witnesses also will demonstrate that Abbott
8 has worked closely with the Illinois EPA and
9 the US EPA on this issue over the course of
10 several years. We thank both the Illinois
11 EPA and the US EPA for working with us in
12 trying to resolve this issue and we
13 appreciate Illinois EPA's participation here
14 today.

15 As set forth in Abbott's proposal
16 that was filed with the Board on September 4,
17 2007, Abbott's testimony today will focus on
18 the concept called the "Source Specific
19 Emissions Cap EIP." Abbott included a full
20 copy of the US EPA guidance document entitled
21 "Improving Air Quality With Economic
22 Incentives Program," and that was included as
23 Exhibit 2 to our initial proposal. The EIP
24 guidance provides direction on a number of

1 types of EIPs, including the source specific
2 emission caps. The EIP guidance provides
3 that there are fundamental principles that
4 must be included in every EIP; number one,
5 integrity; number two, equity; and three,
6 environmental benefit. All EIP's must
7 contain four elements that compose the
8 integrity principle: Surplus, quantifiable,
9 enforceable and permanent. Second, with
10 regard to the equity principle, all EIP's
11 must contain an element of general equity.
12 Finally as noted, all EIP's must demonstrate
13 environmental benefit.

14 A source specific emissions cap
15 EIP allows a specified stationary source or a
16 limited group of sources that are subject to
17 a rate based emission limit to meet that
18 requirement by accepting a mass based
19 emission limit or cap rather than complying
20 directly with the rate based limit. The US
21 EPA's stated goal for this type of EIP is
22 compliance flexibility. Abbott in
23 consultation with both the Illinois EPA and
24 the US EPA relied upon and followed this

1 federal guidance in formulating its proposal.
2 Mr. Wells will provide additional detail in
3 how Abbott's proposal is consistent with the
4 Federal guidance for source specific
5 emissions cap EIP's.

6 With that, if there are no
7 questions, I would like to move ahead with
8 the testimony of Ms. Diane Beno and Mr. Bob
9 Wells. And Ms. Beno is going to, her
10 testimony is short and she would like to go
11 ahead and read that into the record. Bob's
12 testimony, we're happy to enter into the
13 record as if read, but he would like to offer
14 a summary, and we'll be happy to move to
15 Board questions or, you know, to agency
16 questions as appropriate.

17 MS. CROWLEY: Can we go off the record
18 for a one moment.

19 (Discussion off the record, after
20 which the following proceedings
21 were had:)

22 MS. CROWLEY: Go back on the record.
23 We discussed briefly entering some of the
24 exhibits to the original proposal as hearing

1 exhibits just to keep the record tidy. So
2 the first Exhibit will be Exhibit 1, which is
3 an aerial photograph of Abbott Park and
4 vicinity in Libertyville Township and is so
5 labeled. The second will be the US EPA
6 document that is entitled "Improving Air
7 Quality With Economic Incentive Programs"
8 prepared by the United States Environmental
9 Protection Agency, dated January 2001, and
10 that is EPA document number EPA-452/R-01-001.
11 And then finally, the third exhibit is
12 Exhibit 3 entitled "Revised Exhibit 3," dated
13 2-29-08 entitled "Historical VOM Air
14 Emissions From Tunnel Dryers And Fluid Bed
15 Dryers At The Abbott Park Facility." For the
16 record this is slightly revised from the copy
17 that was attached as Exhibit 3 to Abbott's
18 original September 4th proposal. So those
19 are marked and entered into the record as
20 exhibits.

21 Now you may proceed.

22 MS. HODGE: Thank you. I do have
23 extra copies of this pre-filed testimony here
24 today, but I'm assuming everyone has a copy.

1 With that, I think we're ready to move ahead
2 with Ms. Beno. And I'm not sure how you want
3 to handle the --

4 MS. CROWLEY: I'm sorry, I didn't
5 quite hear that.

6 MS. HODGE: I think we're ready to
7 move forward.

8 MS. CROWLEY: Yes, go ahead.

9 (WITNESSES SWORN.)

10 DIANE BENO

11 Having been first duly sworn, was examined and
12 testified as follows:

13 BY MS. BENO:

14 Thank you for the opportunity to
15 speak here today. My name is Diane Beno. I am the
16 plant manager of the portion of the Abbott
17 Laboratories facility internally known as AB16. The
18 operations contained in AB16 produce intermediate
19 and final product formulations including liquids,
20 tablets, capsules packaged in bottles and blister
21 formats. The general process flow includes receipt
22 of raw materials, weighing of ingredients, massing
23 and granulation of ingredients, coating tablets or
24 particles, printing symbols onto tablets and

1 packaging finished products for distribution.

2 Over the course of a year we

3 produce many different products in building AB16.

4 For example, we produce products that treat diseases

5 in the field of neuroscience such as epilepsy and

6 bipolar disorder. We make anti-viral products for

7 the treatment of AIDS. We manufacture products to

8 fight infection. We package products that help

9 patients achieve healthy cholesterol levels and

10 products that improve the lives of people with

11 rheumaty arthritis, psoriasis and Crohn's disease.

12 We manufacture our products using batch production

13 processes. In batch production all of the

14 processing equipment in a process train, including

15 the dryers, manufactures one product at a time.

16 Each batch is completed before the manufacture of

17 the next batch begins. In a typical process, the

18 active and inactive ingredients are combined with

19 the liquid in a process called massing. The massing

20 process forms uniform granules. The wet granules

21 are dried in tunnel dryers or in fluid bed dryers

22 and then further processed into tablets or capsules.

23 The massing fluid which is typically either water or

24 ethanol is evaporated from the solid material in the

1 drying step. If an organic solvent is volatilized
2 from the dryer, it is emitted to the ambient air as
3 VOM or VOC. The quantity of VOM emissions will vary
4 for different products and is calculated from the
5 quantity of VOM added to the mixture and loss
6 factors defined for the dryers and specified in the
7 Clean Air Act Permitting Program permit for the
8 facility. It's also important to note that the
9 organic solvent currently used in granulation and
10 dried from the granulated mixtures in building AB16
11 is ethanol. Ethanol is a VOM, but it's not
12 considered a Hazardous Air Pollutant or HAP. The
13 proposed site specific amendment will have no impact
14 on HAP emissions.

15 Abbott's proposed site specific
16 amendment for building AB16 covers four tunnel
17 dryers and three fluid bed dryers. One additional
18 fluid bed dryer located in building AB16 is used
19 exclusively for research and development and is not
20 involved in the normal operating processes in
21 building AB16; therefore our proposed amendment does
22 not include that dryer. The tunnel dryers and fluid
23 bed dryers operate on different principles. We have
24 some diagrams here to help explain this point, so

1 I'll go ahead and pass these out. I think this will
2 help us make a point. I think this will be helpful
3 as we get into the pre-filed questions later on. So
4 as I stated --

5 MS. CROWLEY: Just one moment. I'd
6 like to mark this as Exhibit 4, if you have
7 no objection, and it's a single-page document
8 with a heading "Granulation Process Fluid Bed
9 Drawing." Thank you. Go ahead.

10 MS. BENO: The tunnel dryers and fluid
11 bed dryers operator on different principles.
12 In the use of tunnel dryers depicted on the
13 lower half of the exhibit, materials are
14 spread on trays and placed in a warming
15 chamber or tunnel that circulates warm air
16 over and under the trays. As shown in the
17 upper portion of the diagram, a fluid bed
18 dryer is a large vertical cylindrical shaped
19 vessel with a diffuser that blows warm air up
20 from the bottom of the vessel. The wet
21 intermediate granules are loaded into the
22 dryer, and flow upward suspended in a warm
23 air stream.

24 Abbott has increased its use of

1 fluid air dryers for recently developed
2 products because they are more efficient and
3 produce a more uniform product than the
4 tunnel dryers. Abbott anticipates increased
5 use of water for massing fluid in future
6 products, and Abbott expects that this
7 preferential use of fluid bed dryers and
8 water based products will continue. That is,
9 many new products are expected to use fluid
10 bed dryers and water based formulations,
11 while older products continue to be
12 manufactured using tunnel dryers.

13 Batches of specific products are
14 typically manufactured using either one or
15 more tunnel dryers or one or more fluid bed
16 dryers, but not both because the technologies
17 are not interchangeable. Individual dryers
18 of the same type can typically be used in
19 combination or interchangeably in many cases,
20 but specific dryers are preferable for
21 combining with other equipment in a process
22 train to manufacture certain products from an
23 operational efficiency standpoint.

24 Abbott manufactures its batch

1 processes whereby each manufacturing process
2 train and its associated equipment, including
3 the dryers, produces one product at a time in
4 fixed batch sizes. Process trains are
5 designed to accommodate batches of different
6 scales with some for large batches and some
7 for small batches. Therefore, the scale of a
8 given batch plays an important role in
9 determining which of the dryers will be most
10 efficient. Additionally, in accordance with
11 the U.S. Food and Drug Administration current
12 good manufacturing processes, extensive
13 equipment cleaning is required between
14 batches of different products, resulting in
15 up to three days of lost production time.
16 Therefore Abbott uses a campaign strategy to
17 continue running batches of the same product
18 consecutively in the process train to
19 minimize this cleaning time.

20 As currently written 218.480(b)
21 effectively defines a 12 month total VOM
22 limit on each individual dryer. This can
23 limit Abbott's ability to schedule the
24 campaigns of certain products to maximize the

1 efficiency of the processes. In other words,
2 to insure compliance with the current 12
3 month VOM limit on each dryer for a
4 particular batch, Abbott may be required to
5 utilize a dryer with a low VOM emissions
6 during the last 12 months, instead of using
7 the dryer that is most efficient from a
8 production scale standpoint. Such selection
9 of dryers is based only on the amount of VOM
10 that has been emitted from an individual
11 dryer during the preceding 12 months is an
12 inefficient approach to the scheduling of
13 Abbott's equipment and resources.

14 Additionally, the dryer selected for a given
15 campaign also depends on dryer availability
16 and other factors. For example, one dryer
17 may be temporarily out of use to allow for
18 cleaning or for unscheduled maintenance
19 requirements; therefore the standards as
20 currently defined can result in wasted
21 resources by requiring Abbott to dry a small
22 batch of our product in our large scale
23 process train to maintain our equipment
24 specific VOM limits. Total annual emissions

1 from a dryer result in a quantity of organic
2 solvent removed from the different products
3 processed in a dryer over a 12-month rolling
4 period. The material is processed in a
5 number of individual campaigns for particular
6 products each consisting of multiple
7 individual batches. The assignment of a
8 campaign of a particular product to one or
9 more dryers involves a number of operating
10 factors, such as the scale and equipment
11 availability that contribute to the
12 efficiency of manufacturing. The VOM
13 emission threshold effectively acts as an
14 overriding factor that can force a particular
15 production campaign with VOM emissions to be
16 scheduled using equipment that has low enough
17 recent emissions to avoid exceeding a dryer's
18 threshold, but that may not otherwise be the
19 optimal or most efficient equipment for the
20 campaign. This scheduling shift increases
21 the operational cost, but results in no
22 environmental benefit because the actual
23 emissions will be the same as if the campaign
24 would have used the optimal equipment.

1 In order to assure Abbott's Lake
2 County manufacturing facilities remain
3 competitive with our national and global
4 competitors Abbott must continually seek ways
5 of making our manufacturing operations more
6 efficient. The scheduling inefficiency
7 created by Subpart-T was identified as one
8 area where improvements in efficiency could
9 be made and is the basis for the proposed
10 amendment. This seems particularly
11 appropriate as the business costs created by
12 this efficiency results in no environmental
13 benefit. The most efficient method to
14 manufacture Abbott's products in AB16 would
15 be to use the dryer that is best suited to
16 the requirements of the production schedule
17 and scale, regardless of the amount of VOM
18 that has been emitted from that dryer in the
19 past 12 months. Provided that the combined
20 VOM emissions from all of the dryers are less
21 than the combined amount allowed under
22 section 218.480(b), this method of operation
23 would not require an increase in allowable
24 VOM emissions from the facility. In fact,

1 the proposed amendment would provide Abbott
2 improved production flexibility to utilize
3 the most efficient dryers for a given product
4 while significantly lowering the total
5 allowed VOM emissions for all of the dryers
6 combined.

7 Thank you. I'll be happy to
8 answer any questions.

9 MS. HODGE: Shall we move on to Bob.
10 Why don't you go through a summary of your
11 testimony, and then we'll be happy to turn to
12 the Board's questions well.

13 MS. CROWLEY: That's certainly
14 acceptable.

15 MR. WELLS: I am going to attempt to
16 summarize my testimony in a shorter summary
17 than the actual testimony. My name is a
18 Robert Wells. I'm air manager for
19 Environmental Support in Abbott's Global EHS
20 Department. I've been assisting the EHS
21 staff with regulatory statutes with our
22 proposal, and I'm going to touch on some of
23 the technical points that relate to why we
24 proposed what we did and where we see that

1 we're consistent with the approaches that
2 we've proposed.

3 The concern today is for
4 provisions applicable to seven of the Abbott
5 parking units, four tunnel dryers and three
6 fluid bed dryers. Subpart-T requires VOM
7 controls for tunnel dryers and fluid bed
8 dryers if their annual emissions exceed
9 seven-and-a-half tons per year for an
10 individual tunnel dryer and five tons per
11 year for individual fluid bed dryers. The
12 seven units therefore have a total potential
13 emissions without control of 45 tons per
14 year. Because of the cost associated with
15 VOM control for this type of equipment, it is
16 impractical to add control. So effectively
17 the limits before control is required act as
18 upper limits on the air emissions from the
19 seven units. The actual emissions from these
20 units vary year to year based on the quantity
21 of production and based on the different
22 materials produced. In recent years the
23 tunnel dryer emissions have varied from
24 six-tenths of a ton to 5.6 per year, each

1 year. Fluid bed dryer emissions have varied
2 from .1 tons to 3.9 tons per year each where
3 the units have been operating. And you can
4 see from Exhibit 3 that's where those numbers
5 came from, although they were not in my
6 pre-filed testimony.

7 Abbott sought solutions to
8 eliminate manufacturing constraints that
9 effected the efficiency of the overall
10 operation, and two options were initially
11 considered. One be would be to request an
12 increase in the threshold that would have to
13 be exceeded before control were required, and
14 the second would be to refine Subpart-T so
15 that the individual unit control would be
16 applied as a group to the combined emissions
17 of the combined allowed emissions of the
18 seven dryers. We evaluated the alternatives,
19 and we did some analysis that demonstrated to
20 us that it would be justifiable to increase
21 the limit for each dryer, that the cost of
22 control was such that at the levels that the
23 threshold of requiring control and at higher
24 levels, that the cost would be beyond

1 reasonably available control technology or
2 RACT.

3 Considering the combined emission
4 controlled threshold, we determined that the
5 flexibility that we were looking for would
6 fit well within that so that there was -- we
7 could go forward with that program without
8 increasing the allowable emissions from the
9 units. We discussed these alternatives with
10 Illinois EPA and later with both IEPA and US
11 EPA through our attorneys Hodge Dwyer Zeeman.
12 And IEPA and US EPA identified a third
13 alternative that was preferable to them and
14 that was a source specific emission cap,
15 SSEC, under US EPA's economic incentive
16 program or EIP. The source specific emission
17 cap would allow us to combine our future
18 emission limits for all the dryers but set to
19 a limit below the historical actual emissions
20 rather than the previously allowable
21 emissions or emissions allowable without
22 control. The historical emissions could be
23 based on a concept called baseline actual
24 emissions defined as the highest two year

1 period in the last ten years. I know there
2 was some confusion about that following my
3 filing of the pre-filed testimony and we're
4 prepared to answer that question in detail
5 when we go through the prepared questions.
6 This is a change from the original definition
7 of historical actual emissions that the US
8 EPA included in their 2001 guidance. Abbott
9 reviewed the actual emissions that we've had
10 from the dryers in the most recent ten years,
11 and we identified the maximum two-year period
12 with emissions of 22.9 tons per year in 1999
13 and 2000. As I'll discuss later, a reduction
14 of ten percent of that level is applied to
15 insure environmental benefit and that results
16 in an emission limit for the seven units of
17 20.6 tons per year. This restriction would
18 be less than half of the 45 ton per year
19 effective limit that now applies to the seven
20 units taken together. This significantly
21 lower allowable limit though is acceptable to
22 Abbott's anticipated business and meets our
23 needs for flexibility.

24 Abbott considered the requirements

1 of the EIP program in going forward with this
2 in order to define our conformance with the
3 three general principles for an EIP,
4 integrity, equity and environmental benefit.
5 Integrity, the integrity principle focuses on
6 the emission reductions themselves and
7 requires them to be surplus, bonafiable,
8 enforceable and permanent. This proposal
9 satisfies those conditions. The emissions
10 are surplus because our future allowable
11 emissions will be below past baseline
12 emissions for the dryers. Our emissions are
13 quantifiable because the VOM emissions can be
14 readily calculated from process record
15 keeping as established in the facility's
16 title five permit. The limits are
17 enforceable because they will be included in
18 Illinois's state implementation plan and also
19 in our Title V permit for Abbott Park and
20 they are permanent for the same reason. They
21 will be established as continuing limits on
22 our operations.

23 The proposed program satisfies the
24 equity principle because it involves only

1 emissions at one facility. There is no
2 instance of relative increases and decreases
3 that must be balanced against one another.
4 The program satisfies the environmental
5 benefit principle because future emissions
6 will be reduced by ten percent below our
7 baseline actual emissions.

8 So in summary, the proposal limits
9 our maximum future allowable emissions to a
10 level below what we historically had really
11 in the course of the variations in our
12 manufacturing, but it will give us the
13 flexibility to operate more efficiently.

14 Thank you. I'll be happy to
15 answer any further questions.

16 MS. HODGE: Thank you very much.
17 We're ready to move on to the Board's
18 questions unless counsel for Illinois EPA has
19 anything now?

20 MS. CROWLEY: If we could first mark
21 as Exhibit No. 5, the pre-filed testimony
22 submitted by Mr. Wells on February 22nd, as
23 I'm sure he would like the complete testimony
24 included in this record.

1 MS. HODGE: Yes, he would.

2 MS. CROWLEY: We will do that.

3 MS. HODGE: Now, we'll turn to the
4 questions of the Board that were included in
5 the hearing officer order dated March 4,
6 2008.

7 MS. CROWLEY: And let's mark that as
8 Exhibit 8.

9 MS. HODGE: And we're not going to
10 read the questions. We'll just go straight
11 to the answers, if that's acceptable.

12 MS. CROWLEY: Unless you are more
13 comfortable having us read the questions, we
14 can dispense with that.

15 MS. HODGE: Okay. Then we'll probably
16 answer the questions certainly in order. And
17 No. 1, we'll start with --

18 MR. WELLS: Question 1-A refers to
19 whether the economic feasibility for the
20 original rule making still applies? The
21 answer to that is yes. As a part of this
22 process we analyzed the cost of control using
23 a methodology developed by the United States
24 EPA for what's referred to as BACT analysis,

1 Best Available Controlled Technology, and
2 using this analysis we found that the cost of
3 control was continued to be significantly in
4 excess of what's normally considered
5 reasonably available control technology. So
6 essentially the economics have not changed.
7 And as to question 1-B, there have been no
8 fundamental changes in emission control
9 technology that would be applicable to the
10 facility since that original rule making. So
11 what we were looking at were the same control
12 technologies that were considered at that
13 time.

14 MEMBER RAO: We're fine with that.

15 MS. HODGE: Thank you. And let's move
16 on to the Board's question No. 2 dealing with
17 emission trends.

18 MS. BENO: Okay. 2-A is in regard to
19 the lower actual emissions since 2000.
20 That's due to many factors. For example,
21 pharmaceutical manufacturing business
22 activity is highly variable year over year.
23 The types of products that we produce in a
24 given year can vary based on a number of

1 market factors and patient demand. So
2 therefore, as I stated in the testimony,
3 different products emit different levels of
4 VOM. So product mix is a primary factor in
5 regard to the variability of our emissions.

6 MEMBER RAO: Has there been any change
7 in terms of production itself because when we
8 look at this, we see some variation but there
9 is also a significant, you know, reduction in
10 VOM emissions since 2000?

11 MS. BENO: As stated in the testimony
12 many new products where possible utilize
13 water based massing fluid, and so we make an
14 attempt using water instead of ethanol or
15 other VOM. So therefore the new products
16 that have been introduced to the facility
17 typically have used water based solvents.

18 MEMBER JOHNSON: And there's no VOM
19 produced when you use water as a fluid?

20 MS. BENO: No, no.

21 MEMBER RAO: Do you anticipate VOM
22 emissions to increase over time?

23 MS. BENO: We don't anticipate them to
24 increase over time.

1 MEMBER MELAS: I have a question. You
2 stated earlier that the fluid bed drying is a
3 more efficient way of doing it. Do you
4 contemplate over the course of time now that
5 you will be phasing out the tunnel drying
6 equipment and concentrate on buying or
7 purchasing new fluid drying equipment?

8 MS. BENO: No, that's not currently
9 the plan. In fact, the products that we
10 manufacture in the tunnel dryers, we will
11 continue to manufacture those in the tunnel
12 dryers. To switch between the technologies
13 can have an impact on the safety or efficacy
14 of the drug product. So it would require a
15 lengthy amount of process development and
16 studies potentially, even clinical trials, so
17 that is the lengthy FDA process I referred
18 to.

19 MEMBER MELAS: You say there is a
20 one-on-one relationship to the type of
21 product to the type of dryer?

22 MS. BENO: Yes, absolutely.

23 MEMBER JOHNSON: Let me ask then.
24 There is then in your mind a potential any

1 way that your company will begin some time in
2 the future to manufacture products that
3 either can't use the water as a massing fluid
4 and have to use ethanol; there is a potential
5 that you'll get back up to VOM rates
6 comparable to what they were in '99 and 2000?

7 MS. BENO: I wouldn't rule it out. It
8 certainly wouldn't be our intent, but I
9 wouldn't rule out the possibility.

10 I'll move on to B?

11 MS. HODGE: Yes.

12 MS. BENO: B is in regard to tunnel
13 dryer number four specifically, and in
14 Exhibit 3 it was noted that there was no VOM
15 from tunnel dryer three since 2005, and based
16 on Abbott's production needs, tunnel dryer
17 No. 4 has not been in use since 2005.
18 However, it remains fully validated and
19 maintained and available for use should
20 production needs demand. So it serves us as
21 a back up in the event that one of the other
22 tunnel dryers would become unavailable for
23 use.

24 MEMBER RAO: Since the emissions for

1 all these dryers that you have listed in
2 revised Exhibit 3 are significantly lower
3 than the applicable limits, does Abbott have
4 enough flexibility under the current rule
5 itself or do you need to have the combined
6 limit to provide you that flexibility?

7 MS. BENO: We believe we need the
8 combined limit to provide flexibility.

9 MEMBER RAO: Can you explain a little
10 more why, if you don't have enough
11 flexibility under the current rule?

12 MS. BENO: It's based on the highly
13 variable nature of the product mix in the
14 facility. So in the event we were to run
15 more or some the products that have an
16 ethanol based mass in fluid, it would prevent
17 us from using the most effective and
18 efficient equipment.

19 MEMBER RAO: Have you had that kind of
20 situation in the past?

21 MS. BENO: What specific situation?

22 MEMBER RAO: Where you were not able
23 to use whatever dryer you wanted to under the
24 current rules.

1 MS. BENO: It's become very close.

2 MEMBER RAO: Looking at this data that
3 you have provided, fluid bed dryer 3
4 obviously could be the one which is kind of
5 closer to its limit?

6 MS. BENO: Right.

7 MEMBER RAO: Is that a situation where
8 you see and you'd need to use another dryer
9 similar to that again?

10 MS. BENO: Yes, absolutely. Fluid bed
11 dryer 3 in Exhibit 3, as you noted, has
12 reached 3.9 in recent years which approaches
13 our current limit.

14 MEMBER RAO: Thank you.

15 MS. HODGE: Let's move on to the
16 questions in the Board's order relating to
17 the pre-filed testimony of Ms. Beno, and
18 question No. 1.

19 MS. BENO: This is in regard to the
20 type of organic massing fluid that we
21 currently use, and ethanol has been the only
22 organic massing fluid that we've used in
23 building AB16 during the ten-year period
24 under review for this proposal. I do want to

1 note that prior to late 2002 the type of
2 ethanol used was denatured ethanol which
3 contains a small percentage of methanol as
4 the denaturant, but since late 2002 we've
5 converted to all beverage grade ethanol which
6 does not contain methanol as the denaturant.

7 MS. HODGE: Question number two?

8 MS. BENO: Again, number two is in
9 regards for the basis for choosing the
10 massing fluid, and the choice of massing
11 fluid is dependent on the particular
12 properties of a product. For example, the
13 relative solubility of the product in either
14 water or ethanol plays a key role in
15 determining which solvent will be required
16 for the massing fluid. So it's really
17 related to the various properties of the
18 product we're intending to manufacture
19 whether or not water is an option for us or
20 not.

21 MEMBER RAO: So it's got nothing to do
22 with the type of dryer you are using; it's
23 all the product you are manufacturing?

24 MS. BENO: No, either can be used in

1 either dryer. Water or ethanol can be used
2 in either drying technology.

3 MS. HODGE: Question number three?

4 MS. BENO: No. 3, this is in regard to
5 increased use of fluid bed dryers and water
6 for massing fluid. Abbott does in fact
7 expect there will be an increased mass for
8 water in new products as I indicated. It's
9 not practical to change the ethanol based
10 processes to a water based process because of
11 the FDA considerations that I indicated
12 before had the opportunity to influence the
13 safety and efficacy of the product. But we
14 do consider the type of massing fluid as we
15 developed new products with a preference to
16 using water. So accordingly we expect there
17 will be an increased use of water for the
18 massing fluid for new products. Questions
19 there?

20 B, this is in regard to the use of
21 water to avoid VOM emissions. And in fact
22 VOM emission avoidance is one of several
23 factors that we consider as one of the
24 benefits resulting from increased use of

1 water for the massing fluid. Other benefits
2 include increased raw material costs, reduced
3 worker exposure to organic materials in the
4 work place and improved safety due to
5 reduction of flammable solvents.

6 In regard to C, water based
7 products are preferable for a number of
8 reasons. As described previously, they are
9 preferable because they don't contribute to
10 VOM emissions, reduced raw material costs,
11 reduced worker exposure and improve overall
12 safety to the facility. Those were similar
13 questions.

14 In regard to the fluid bed dryers
15 being more efficient, it's mainly related to
16 the way they operate. If you refer to the
17 diagram, you can see in a fluid bed dryer,
18 individual granules, very small pieces of the
19 product are airborne in the warm air stream
20 and the air moves around freely on all
21 surfaces of the particle or granule drying
22 the drying process. This results in a much
23 more even drying process and higher quality
24 end product because of the evenness of the

1 drying. Tunnel dryers on the other hand are
2 like cookie sheets in an oven. You hand-load
3 the material onto the cookie sheet, onto the
4 big rack, push the rack into the tunnel dryer
5 and it's exposed to air movement in the
6 tunnel. What can happen in a tunnel dryer
7 similar to in baking, you could have parts of
8 the cookie that are more done than other
9 parts of the cookie. Whereas in the fluid
10 bed drying technology, a smaller portion of
11 the product is exposed to the warm air across
12 the entire surface. So it makes for a much
13 more uniform drying process which makes the
14 downstream processing much easier.

15 MEMBER RAO: I think you answered 4B
16 already.

17 MS. BENO: Yes, yes. Thank you.

18 MS. HODGE: Number five?

19 MS. BENO: Selection of the dryers.
20 One example of the inefficiencies created by
21 the current rule is that the most
22 appropriately sized equipment may not be
23 chosen. As I mentioned in the testimony, we
24 have small scale process trains and large

1 scale process trains. Now, in the event that
2 the small scale process train would be
3 approaching its limit, we may be forced to
4 use the large scale process train to process
5 smaller batches than would normally be
6 processed in that particular process train.
7 So that is the main consideration in regards
8 to inefficiency of the scheduling that could
9 be influenced by the current rule. It's much
10 like flying a plane half full or running a
11 dishwasher half full, you are not utilizing
12 the full capacity of the equipment in that
13 particular area.

14 MR. RAO: In this regard, I didn't see
15 any information about the drying capacity of
16 these dryers. Are they all about the same or
17 each dryer is different.

18 MS. BENO: It has to do with the
19 processing suits that they are in. We have
20 one dryer in one processing suit, and we have
21 two dryers in another processing suit.
22 That's our large scale processing train
23 versus our small scale processing train. As
24 I mentioned, you can only run one product in

1 a process train at any given time.

2 MEMBER RAO: Thank you.

3 MS. BENO: So there was one final
4 question regarding how we select which dryer
5 to use for a given campaign. And the
6 selection of dryers is mainly based on the
7 technology first. As I mentioned there is a
8 one to one relationship of which product goes
9 in which type of technology. Meaning a
10 tunnel dryer or a fluid bed dryer. The
11 second consideration would be the scale,
12 whether it's a large scale batch or a small
13 scale batch, and then the third consideration
14 is general availability; do we have more
15 products running in one size suit than the
16 other or is one of the suits down for
17 maintenance or cleaning. So those are the
18 critical factors that we consider when
19 scheduling the production in the dryers.

20 MEMBER RAO: Thank you.

21 MEMBER JOHNSON: The amount of VOM
22 produced is dependent upon the amount of
23 ethanol, use not on your choice of which
24 drying --

1 MS. BENO: Absolutely because we're
2 going to be drying to the specification of
3 the product so we'll always be drying off the
4 same amount of VOM for a given product for a
5 given batch.

6 MS. HODGE: Thank you. Anything else?

7 MS. CROWLEY: Mr. Matoesian, have you
8 had any questions?

9 MR. MATOESIAN: No, not so far.

10 MS. CROWLEY: I've been keeping an eye
11 on you, but I just wanted to state it for the
12 record.

13 MS. HODGE: Let's move on to the
14 questions of the pre-filed testimony of
15 Mr. Wells.

16 MR. WELLS: I talked briefly earlier
17 about the two-year period. What has happened
18 is that there has been a change in philosophy
19 on the conceptual level in US EPA's
20 application of historical emissions.

21 The definition of historical
22 actual emissions that appears in the 2001
23 guidelines, the US EPA developed is the same
24 as the concept in prevention of significant

1 deterioration, PSD, or non-attainment new
2 source review, netting that US EPA has
3 previously used and what was in place at the
4 time; that is , the two years immediately
5 preceding the action or another two year
6 period, if it's determined to be more
7 representative. There's been a lot of
8 problems historically in the determination of
9 whether a particular period is
10 representative, and the US EPA in 2002
11 changed the definition of actual emissions.
12 They defined a term "baseline actual
13 emissions" for the PSD and the non-attainment
14 new source review program. And what they
15 said was that you can use any 24-month period
16 in the preceding ten years. That assures
17 that you can look back far enough to see a
18 representative business cycle so that you can
19 see the periods when your normal fluctuation
20 of business would result in relatively higher
21 emissions. But at the same time it gives a
22 simple concrete basis to make that decision.
23 That was originally suggested to us in the
24 conversations that our attorneys had with

1 IEPA and with US EPA. That was the
2 recommended interpretation at the time, and
3 as we understand it, US EPA guidance is now,
4 their guideline on the EIP process, which is
5 not a regulation. It is guidance, is being
6 interpreted differently to allow the use of
7 that two-year period as far back as ten
8 years. I'll also point you to the revised
9 Exhibit 3. If you notice, 1999 and 2000 were
10 the highest years. 1998 was actually lower
11 than the emissions in either 1999 or 2000.
12 So it is in fact a peak that we are talking
13 about rather than just a continuing decline.

14 MEMBER RAO: And, Mr. Wells, do you
15 have any specific US EPA publication or
16 memorandum that talks about this change in
17 their policy?

18 MR. WELLS: Well, the baseline actual
19 emissions were established in a federal
20 register notice amending the PSR rules at 67
21 Federal Register 80.186.

22 MEMBER JOHNSON: We, as good corporate
23 citizens, it's to your benefit to keep your
24 VOM emissions as low as possible, but what

1 you want to be able to do, at least I take it
2 is, that the demand for whatever product you
3 are producing in 1999 and 2000 were to return
4 and you had to use the same drying system or
5 use the ethanol rather than water on that to
6 develop that or make that particular product,
7 you want to be covered so that you can do
8 that and fulfill the demand. And that's why
9 even though these VOM emissions are at least
10 twice as much as the next five years, that's
11 why you want to have that set as your
12 baseline?

13 MR. WELLS: Exactly.

14 MS. HODGE: And, again, just to note
15 for the record, that historical baseline is
16 being reduced by ten percent, you know, in
17 the limit that we're requesting.

18 MEMBER JOHNSON: And in fact, the
19 reduction from what it is now is
20 significantly more than that. If you ran all
21 of your dryers at capacity, you would produce
22 45 tons, and this site specific rule as
23 proposed reduces that by over 30 tons, right?

24 MEMBER RAO: Half.

1 MR. WELLS: Over half, a little over
2 half.

3 MEMBER RAO: Thank you.

4 MR. WELLS: Question two, I think it
5 kind of follows question one.

6 MS. HODGE: We're good there. Shall
7 we move on the economic incentive program
8 guidance? Question No. 1. And this is
9 something that we thought might be more
10 properly addressed to the Illinois EPA.

11 MR. MATOESIAN: That's fine. Charles
12 Matoesian speaking. With me today I have
13 Mr. Yoginder Mohajan (Phonetic), who is an
14 engineer with the Illinois Environmental
15 Protection Agency, he is here to answer some
16 questions from the board. He is currently in
17 the air quality planning section of the
18 Bureau of Air and has prepared some answers
19 for these questions.

20 MS. CROWLEY: Would you swear him in?

21 YOGINDER MAHAJAN

22 having been first duly sworn, was examined and
23 testified as follows:

24 Question No. 1 on page three, the

1 guidance states that the guidance applies if
2 state applies --

3 MS. CROWLEY: Off the record.

4 (Discussion off the record.)

5 MS. CROWLEY: Go back on the record.

6 MR. MAHAJAN: The answer to the
7 question, I spoke with the US EPA, Mr. Steve
8 Rosenthal. He told me that the option of the
9 EIP is not required. It is recommended. It
10 is nice if you have it adopted, but it's not
11 required and the agency's intention is not to
12 adopt it. It will deal with it on a case by
13 case basis.

14 Question No. 2, yes, the agency
15 has discussed this with the US EPA and
16 confirmed that this amendment is consistent
17 with the EIP guidelines.

18 No. 3, yes. And question No. 3B
19 is also no. Regarding emissions being
20 surplus is there any concern? No we don't
21 have any concern. It's discussed with the US
22 EPA, and they said that it is consistent with
23 the EIP guidelines.

24 MEMBER RAO: Thank you.

1 MS. HODGE: Do you have any other
2 questions?

3 MEMBER RAO: There was one question
4 about the proposed amendment.

5 MS. HODGE: We're ready to move to
6 that.

7 MEMBER RAO: No follow-ups.

8 MS. CROWLEY: Do you have any
9 follow-ups for this.

10 MS. HODGE: No. So we'll move on to
11 the question on the proposed amendments,
12 question No. 1.

13 MR. WELLS: Yes. The only concern
14 that we had with the specification of the
15 equipment was that we not specify that --
16 28.480(b) now covers the entire facility,
17 more than just building AB16. We would not
18 have a problem if the specification were made
19 on the SSEC that we've been discussing today.
20 As far as specifically 218.480(b)(4), as far
21 as the general applicability of 218.480(b),
22 it's our understanding that still applies to
23 the facility, and it is possible that we
24 might find the need to install a fluid bed

1 dryer in another building for a totally
2 unrelated manufacturing process.

3 MEMBER RAO: You are comfortable with
4 the way the rule is proposed now?

5 MR. WELLS: That's correct.

6 MEMBER RAO: I think that question was
7 triggered because the way 218.480(b) is now
8 currently written, Abbott's name is not
9 mentioned in that section at all. And I know
10 it's highly unlikely that somebody else would
11 set up shop with four dryers and give them
12 names and take advantage of this rule, but in
13 most of our site specific rules we have the
14 name of the company involved in it. So I
15 just wanted to know what your thoughts were
16 on it.

17 MR. WELLS: In terms of identifying
18 the company, I don't think we have any
19 objection to it. The drafting of the
20 original rule was before my time. I'm not
21 sure where the language came from, but that
22 wouldn't be a problem. Again, the only thing
23 we wanted to be sure was that it wasn't
24 defined specifically to cover building AB16,

1 just to allow us the same flexibility in the
2 future.

3 MEMBER RAO: Okay.

4 MEMBER JOHNSON: The road is named
5 after you so --

6 MEMBER RAO: Thank you very much.

7 MS. HODGE: Thank you.

8 We have one more issue that we'd
9 like to address, and this deals with a
10 request that has been made by US EPA through
11 the Illinois EPA, and they had asked if we
12 could submit to them some of the supporting
13 emission calculations for the baseline years,
14 1999 and 2000. We've talked with IEPA about
15 how the emissions are calculated and US EPA
16 wants a little bit more information. We are
17 currently preparing that, and we will submit
18 additional information in response to that
19 request subject to CBI, confidential business
20 information requirements on that. So that
21 will be forthcoming, and I understand from
22 talking with counsel for IEPA, that you would
23 like to have some of that in this board's
24 record, that IEPA would like to have some of

1 that in the Board's record.

2 MS. CROWLEY: I understand that.
3 Please if any of it is confidential business
4 information or trade secrets, that when it is
5 submitted that it is properly submitted with
6 a redacted copy, as well as the copy that you
7 would like to have protected so that there
8 isn't any problem with that.

9 MS. HODGE: We can do that, and we
10 will work with IEPA and Mr. Steve Rosenthal
11 at US EPA to make sure that everyone is
12 comfortable with what we submit.

13 With that, I don't have anything
14 else.

15 MR. MATOESIAN: We have nothing.

16 MS. CROWLEY: One little left over bit
17 was the motion to file the amendment, Exhibit
18 3, and the motion to amend the proposal
19 specifically as it regards proposed
20 218.480(b)(4) to reflect the change to the 90
21 percent baseline calculations. Do you have
22 any objection to that?

23 MR. MATOESIAN: No.

24 MS. CROWLEY: Thank you. That motion

1 then is granted. Let's go off the record for
2 a moment.

3 (Discussion off the record.)

4 MS. CROWLEY: Back on the record. We
5 have had a brief discussion about what would
6 be a reasonable post-hearing comment period.
7 We have chosen May 1st as the close comment
8 period date subject to an extension if
9 necessary to allow completion of data
10 gathering for US EPA or if any other person
11 needs additional time. We specifically do
12 request that the agency file, even if short,
13 some comment on this record indicating their
14 view of whether this rule should or should
15 not be granted. If there is nothing else --

16 MR. MATOESIAN: We can say, the Agency
17 can state that it supports the petition.

18 MS. CROWLEY: Okay, fine. If there's
19 nothing else then, I thank you all for your
20 participation. The Board again thanks Abbott
21 for its patience in bearing with our
22 scheduling problems. We will try to render a
23 decision in an expedited fashion once the
24 record is closed. Again, thank you all very

1 much.

2 STATE OF ILLINOIS)
3) SS.
4 COUNTY OF COOK)

5 I, DENISE ANDRAS, being a Certified
6 Shorthand Reporter doing business in the City of Des
7 Plaines, Illinois, County of Cook, certify that I
8 reported in shorthand the proceedings had at the
9 foregoing hearing of the above-entitled cause. And
10 I certify that the foregoing is a true and correct
11 transcript of all my shorthand notes so taken as
12 aforesaid and contains all the proceedings had at
13 the said meeting of the above-entitled cause.

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DENISE Andras, CSR
CSR NO. 084-003437