PERRINE DUPONT SETTLEMENT CLAIMS OFFICE
ATTN: EDGAR C. GENTLE, CLAIMS ADMINISTRATOR
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September 1, 2011

VIA HAND DELIVERY

The Honorable Thomas A. Bedell
Circuit Judge of Harrison County
301 West Main Street, Room 321
Clarksburg, West Virginia 26301

Re: **Perrine, et al. v. DuPont, et al.; Civil Action No. 04-C-296-2 (Circuit Court of Harrison County, West Virginia) - (i) Claims Administrator's Preliminary CT Rule and Preliminary Medical Monitoring Budget Filing for Briefing by the Parties, as Contemplated in August 24, 2011 Claims Administrator's Supplemental Report to the Court and as Ordered By the Court on August 31, 2011; and (ii) Suggested Procedures for Requested Medical Monitoring Implementation Hearing; Our File No. 4609-1 {R}, 4609-1 {NN} and 4609-1 {GG-1}**

Dear Judge Bedell:

Your Claims Administrator submits the following, after considering the very helpful input of the Finance Committee and the Guardian Ad Litem for children:

I.
ENCLOSED SUBMISSION AND SUGGESTED BRIEFING SCHEDULE

In accordance with the Claims Administrator's Supplemental Report and proposed Order filed with the Court on August 24, 2011, and as ordered by the Court on August 31, 2011, we file herewith:

(a) Attachment I: Your Claims Administrator's preliminary proposed guidelines for the attending physician to consider in determining whether to diagnose a CT Scan for CT Scan eligible Medical Monitoring participating claimants (the "Preliminary CT Rule"), as contemplated in paragraph (c) of page two of the Parties' November 19, 2011 Settlement Memorandum of Understanding (the "MOU"). The Preliminary CT Rule takes into consideration and references DuPont's comments respecting a CT Rule that we received on August 29, 2011 and September 1, 2011,[1] and related discussions with DuPont attorney James B. Lees, Jr., Esq., and a written critique by Dr. Andrea H. McGuire, with the referenced documents being in Exhibit A to the Preliminary CT Rule submitted herewith; and

(b) Attachment II: A revised post-implementation date Preliminary Budget with respect to the Perrine DuPont Medical Monitoring Qualified Settlement (the "Medical Monitoring Fund"), for expenditures from November 1, 2011 through August 31, 2011 and totaling $4,509,348.55 (the "Preliminary Budget"). This is a revision to the Preliminary Budget filed with the Court on August 19, 2011, and, to the extent practicable, tries to accommodate the August 19, 2011, Budget Objection of DuPont (the "DuPont Objection"), and also takes into account our updated current projection that there will be 3,500 Medical Monitoring participating Claimants instead of the 3,000 we projected at August 19, 2011, due to the very large registration turn-out the last two weeks of August, with the registration deadline being August 31, 2011. As of midnight last night, we had received approximately 6,500 Registration Forms, with, as the Court knows, Claimants being able to select the Medical Monitoring Program or decline it, and with not all forms to be ultimately accepted. A materially accurate estimate of the number of Medical Monitoring participating Claimants should be provided with and be the basis for the October 10, 2011, Pre-Hearing Submission described below.

This number is computed as follows (as further discussed below):

1.	Column C of Budget in Attachment I (Medical Monitoring Implementation Budget without Incremental CT Scan Costs)	$2,407,835.93
2.	Column D of Budget in Attachment I (Incremental CT Scan Costs)	$2,128,037.19

[1]Today, DuPont, for the first time, has also provided a draft Claimant CT Scan Consent and Physician Diagnosis form. We are not asking for Court consideration of such a form at this time but will try to design a form in collaboration with the Finance Committee, and we will report to the Court when this process is completed.

3.	Less Bridge Funding (ultimate payment by new DuPont contribution or old DuPont contribution to be determined by the Court)	($ 26,524.57)
	DUPONT NEW CONTRIBUTION DUE BY OCTOBER 31, 2011 (RECOMMENDATION BY CLAIMS ADMINISTRATOR TO BE FINALIZED OCTOBER 10, 2011 AND PRIOR TO HEARING)	$4,509,348.55

We understand that DuPont may suggest that it directly fund the CT Scan component of the Medical Monitoring Program, as opposed to the Medical Monitoring Fund providing the funding. See September 1, 2011, Memorandum of Mr. Lees in Exhibit A to Attachment I. Note that DuPont in the Memo apparently agrees that this approach will not reduce Medicare and Medicaid exposure. We agree that this DuPont suggestion appears to have no bearing on Medicare and Medicaid. See August 30, 2011 Memorandum at the end of Attachment I as Exhibit H thereto.

This approach would give up the Settlement's and Medical Monitoring Fund's fiscal control of the CT Scan component of the Medical Monitoring Program. It also appears to contradict the terms of the MOU, which contemplates that DuPont will pay into the Settlement each year all Medical Monitoring funding. The Parties are invited to brief this issue if they care to do so, although your Claims Administrator considers it moot under the MOU:

> "After said enrollment period has expired, a Finance Committee comprised of representatives from class counsel, DuPont, and the Settlement Administrator shall be created for purposes of advising the Court on the structure and execution of the medical monitoring program. On an annual basis the Court, with the recommendation of the Finance Committee, shall direct DuPont to pay a sum certain that will be set aside for each such calendar year that reasonably secures such expenditures for each such calendar year."

MOU p. 2, paragraph b (emphasis added).

In considering the Preliminary CT Rule, the Parties and the Court may find footnote 66 on pp. 120-121 of the March 26, 2010 Decision of the West Virginia Supreme Court of Appeals helpful or not in this matter. In its September 1, 2011 Memorandum, DuPont questions the relevance of this footnote.

As contemplated by the MOU, the Preliminary Budget is to be funded by an additional DuPont contribution to the Medical Monitoring Fund on or before October 31, 2011 in the amount of the above $4,509,348.55, with this recommended contribution to be finalized in the Claims Administrator's October 10, 2011 Pre-Hearing Submission, and subject to a proposed hearing, as described below.

In an attempt to narrow the unresolved issues, the Preliminary Budget has been divided into the following two components:

(a) A separate Preliminary Budget component without CT Scans totaling $2,381,311.36 ($2,407,835.93 in Column C of Budget in Attachment I minus Bridge Funding of $26,524.57 for September and October 2011) that does not include the budget incremental costs of the CT Scan portion of the Medical Monitoring Plan for the budget period, in an attempt to reach closure with the Parties on this portion of the Preliminary Budget (the "Non-CT Scan Preliminary Budget"); and

(b) A separate Preliminary Budget component totaling $2,128,037.19 in Column D of Budget in Attachment I that only contains the Medical Monitoring Plan's budgeted incremental costs of conducting CT Scans for the budget period (the "CT Scan Incremental Cost Preliminary Budget").[2] Incremental costs are only included in this second component of the Preliminary Budget, based on the assumption that both Preliminary Budget components will be resolved and carried out in tandem, with all aspects of the Medical Monitoring Plan to timely begin on November 1, 2011.

If, however, the CT Scan component of the Medical Monitoring Plan is delayed by litigation, then,

(a) The Medical Monitoring Program, with the CT Scan portion delayed, may proceed under the Non-CT Scan Preliminary Budget described in Paragraph (a) above; but

(b) The CT Scan Incremental Cost Preliminary Budget will have to be materially increased, due to the cost savings that will not be realized if both components of the Medical Monitoring Program are not executed in tandem.

In reviewing the Preliminary Budget, the Court and the Parties may keep in mind that the proposed final version of (i) the September 1, 2011 through August 31, 2012, Perrine DuPont Property Remediation Qualified Settlement Fund (the "Remediation Fund") Budget; and (ii) the Medical Monitoring Fund September 1, 2011 through October 31, 2011 Budget (the "Bridge Funding") were filed with the court on August 19, 2011, (collectively the "Finalized Two Budgets") with the only unresolved issue respecting these Finalized Two Budgets being whether DuPont shall

[2]Guardian Ad Litem expenses are included for the reasons described in the August 31, 2011, Memorandum at the beginning of Attachment II, as the design and implementation of the CT Scan program will assist minor Claimants as they become CT Scan eligible adults. DuPont challenges the inclusion. See, September 1, 2011, Memorandum.

or shall not pay for the Bridge Funding with an additional contribution to the Medical Monitoring Fund. The Finalized Two Budgets were approved by the Court on August 31, 2011.

However, these Finalized Two Budgets, unaltered from the August 19, 2011 Claims Administrator's submission and now approved by the Court, are still included with the enclosed Preliminary Budget for the Medical Monitoring Fund from November 1, 2011 through August 31, 2012, to depict cost-sharing by the Finalized Two Budgets and the Preliminary Budget.

Input from the Parties respecting the Finalized Two Budgets is not being requested.

In accordance with the August 24, 2011, Supplemental Report and the subsequent August 31, 2011 Order, please consider this letter to recommend the following briefing schedule:

(a) Initial briefs and evidentiary submissions of the Parties respecting (a) the enclosed Preliminary CT Rule and Preliminary Budget (addressing the two budget components together and separately); and (b) the "Bridge Funding" and "Minor No-Inactive Claimant Rules" described in the August 24, 2011 Claims Administrator's Supplemental Report to be submitted to the Court and the Claims Administrator on September 21, 2011; and

(b) Reply briefs and evidentiary submissions of the Parties to be submitted on October 3, 2011.

Following the above briefing and evidentiary submissions, and in accordance with the August 24, 2011 Supplemental Report and the subsequent August 31, 2011 Order, your Claims Administrator then proposes to submit his final preliminary recommendations for a subsequent Court hearing respecting (i) the CT Rule; (II) the Preliminary Budget; (iii) the Bridge Funding; and (iv) the Minor No-Inactive Claimant Rules by October 10, 2011 (collectively the "Claims Administrator Pre-Hearing Submission"), and requesting a hearing on or about October 17, 2011 (the "Medical Monitoring Implementation Hearing").

II.
SUGGESTED MEDICAL MONITORING IMPLEMENTATION HEARING PROCEDURE

Your Claims Administrator respectfully makes the following procedural suggestions.

First, your Claims Administrator would provide testimony concerning the Claims Administrator Pre-Hearing Submission, and would answer any questions from the Parties or the

Court. As a neutral, I would be sponsored by outside Counsel not representing any Party in the case. Your Claims Administrator may also engage a neutral expert to testify about the CT Rule.

Second, the Parties would then be invited to provide arguments and evidence in connection with the Pre-Hearing Submission or any other matters they and the Court deem relevant. The Claims Administrator, as a neutral, would not ask any questions of Counsel or Party witnesses.

With this letter, we are requesting the Parties to comment on these suggested procedures.

We would like to thank the Finance Committee and the Guardian Ad Litem for their hard work in providing thoughtful input in the design of the enclosed materials.

Thank you for the Court's consideration.

Yours very truly,

Edgar C. Gentle, III
Claims Administrator

ECGIII/alw
Enclosures

cc: (with enclosures)(by e-mail)(confidential)
Stephanie D. Thacker, Esq., DuPont Representative on the Settlement Finance Committee
Virginia Buchanan, Esq., Plaintiff Class Representative on the Finance Committee
Meredith McCarthy, Esq., Guardian Ad Litem for Children
Clerk of Court of Harrison County, West Virginia, for filing (via hand delivery)
Terry D. Turner, Jr., Esq.
Diandra S. Debrosse, Esq.
Katherine A. Harbison, Esq.
Paige F. Osborn, Esq.
Michael A. Jacks, Esq.
William S. ("Buddy") Cox, Esq.
J. Keith Givens, Esq.
McDavid Flowers, Esq.
Farrest Taylor, Esq.
Ned McWilliams, Esq.
Perry B. Jones, Esq.
Angela Mason, Esq.

cc: (continued)
Mr. Don Brandt
Ms. Pat Gagne
James B. Lees, Jr., Esq.
Leigh Anne Hodge, Esq., Outside Counsel for Claims Administrator

I. PRELIMINARY CT RULE AND MEMORANDUM ON MEDICARE AND MEDICAID

September 1, 2011
Claims Administrator
Preliminary CT Rule for Briefing

THE PERRINE MEDICAL MONITORING PROGRAM, A PRODUCT OF THE PERRINE DUPONT SETTLEMENT

CT SCAN UTILIZATION GUIDELINES

FOR MEDICAL MONITORING BEGINNING NOVEMBER 1, 2011

These CT Scan Utilization Guidelines, which will be updated every 2 years based upon the state of scientific research respecting radiology and input from the Program's Medical Advisory Committee, is to be utilized by the examining physician in carrying out Step 3 of the CT Scan Utilization Protocols in Exhibit 1 for a Medical Monitoring participating Claimant who is CT Scan eligible, with eligibility to be determined in accordance with Dr. Brookshire's Report.

I. PREFACE

The proposed guidelines address the position that CT Scans should be allowed for any and all claimants due to their exposure. Furthermore, they address prior suggestions that we attempt to quantify the approximate number of CT Scans which may occur as a result of Medical Monitoring.

The most recent scientific trial involving the benefit of CT Scans in the early detection of lung cancer[1] qualifies its finding of a 20% decrease in mortality by stating that the current data alone is insufficient to fully inform a decision to unilaterally recommend CT Scans to a high risk population. Similarly, the Lung Cancer Alliance states that all "...those at high risk for lung cancer should speak with their doctors about the risks and benefits of screening...".

As suggested in the below guidelines, after a review of the Claimant's history and exposure, the examining physician will determine whether to recommend a CT Scan for the Claimant as being medically necessary. No definitive determination is recommended for all CT Scan eligible Medical Monitoring Participating Claimants at this time. The NCI Division of Cancer Prevention, the Lung Cancer Alliance, the National Institute for Occupational Safety and Health of the Department of Health and Human Services Centers for Disease Control and Prevention, and the National Institute of Health appear to agree with this approach.

We note that DuPont is in agreement with our position. Specifically, in the Memorandum of James B. Lees, Jr., Esq., Counsel for DuPont, of August 29, 2011, which is in Exhibit A, DuPont states:

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[1]National Lung Screening Trial Research Team; Reduced Lung Cancer Mortality with Low-Dose Computed Tomographic Screening, N Engl J Med 2011; 365:395-409, August 4, 2011, in Exhibit B.

"The words "medically necessary" were inserted to preclude the lawyers and the Court from attempting to interfere with the medical judgments made by competent physicians. The words "medically necessary" were used to make absolutely sure that decisions in the future are being made by physicians and not pursuant to some lawyer-created criteria."

We agree. In sum, the examining physician is to decide whether to recommend a CT Scan for a given claimant, as reflected in the guidelines recommended below.

We understand that Mr. Lees has also suggested linking putative disease with cadmium, arsenic, zinc and lead exposure resulting from the former zinc smelter, prior to having a CT scan. To the extent contemplated in the Settlement, we try to accommodate this suggestion in Section 3b of the below guidelines, giving weight to additional exposure, and in Paragraph 6, as described below. However, medical screening is just that, an examination for disease. Often, the etiology (cause) of disease is unknown and debatable. See, for example, respecting cancer, The Emperor of All Maladies, by Siddhartha Mukherjee. To apply a more wooden exposure rule, other than the agreed "relevant to possible exposure to heavy metal contamination" term in the November 19, 2011, Settlement Memorandum of Understanding (the "MOU") by removing the term "possible", as apparently suggested by Mr. Lees, may remove the very "physician decisions" he advocates in the above quote, and was therefore rejected by your Claims Administrator as possibly medically ethically improper.

On September 1, 2011, we received a second Memorandum from Mr. Lees in Exhibit A, which suggests edits to the guidelines in paragraphs 2 and 3 of the Memorandum.

We agree with the substance of paragraph 2, that there should be CT Scan diagnosis and consent documentation. As to consent documentation, the Court on August 31, 2011, has already ordered it. See August 19, 2011 CT Scan Protocols approved by the Court at paragraph 6 that are Exhibit 1 hereto. We have added language to CT Scan Guidelines paragraph 6 stating that the diagnosis will also be documented. However, DuPont's suggestion in the Memo that these forms be collected by the Claims Office before a CT Scan is authorized as opposed to carrying out the CT Scan as soon as practicable, may have a chilling effect on this component of Medical Monitoring.

We do not agree with Memo paragraph 3 suggesting that the physician find the disease to be "related to" and not "relevant to possible exposure to heavy metal contamination" (the MOU standard), for the reasons stated above. We do agree to include the specific MOU standard on this issue. See revised Paragraph 6 of the CT Scan Guidelines.

We also received an August 19, 2011 letter, also in Exhibit A, from Dr. Andrea H. McGuire, who was asked by CTIA, the Medical Monitoring Plan's Third Party Administrator, to critique an earlier draft of these guidelines, which are not materially different from these guidelines. In response to Dr. McGuire's comments which are critical of the guidelines, and recommend that all eligible Claimants be provided a CT Scan, we note that although Dr. McGuire correctly notes that the reports cited in the guidelines describe Scans other than chest CT Scans, the following issues remain: (1) exposure to CT Scan radiation must be justified and weighted against a benefit to the Claimant; and

(2) we are unaware of evidence that CT scanning of all Claimants would result in a decrease in cancer mortality rates. Furthermore, as noted in these guidelines, recent publications from leading medical authorities establish that no medical authority recommends CT chest scanning of an entire at risk population absent additional research.

A revised protocol is in Section IV of this memorandum and follows an analysis of where current medical and research organizations stand with regard to CT chest scans.

II. SCIENTIFIC BACKGROUND

According to the USFDA Center for Devices and Radiological Health[2], medical professional societies have not endorsed CT scanning for individuals without symptoms, and CT screening of high-risk individuals for specific diseases such as lung cancer are currently being studied. The FDA maintains the position that CT Scans and radiography imaging are to be used *in the diagnosis of syptomatic people*.

As discussed in the American College of Radiology Practice Guideline for the Performance of Pediatric and Adult Chest Radiography[3], the "ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in the light of the circumstances presented." That said, the below CT Scan Guidelines provide that the proper indications and contraindications that are relevant to this matter, which may establish a need for a CT Scan, and which are:

1. Evaluation of signs and symptoms potentially related to the respiratory and cardiovascular system; and
2. Compliance with governmental regulations that may indicate chest radiography (e.g., surveillance PA x-rays for active TB or occupational lung disease).

With regard to total-body CT scanning, the American College of Radiology Board of Chancellors issued the following statement[4]:

> The American College of Radiology (ACR), at this time, does not believe there is sufficient evidence to justify recommending total body computed (CT) screening for patients with no symptoms or a family history suggesting disease.

Robert Smith, Director of cancer screening at the American Cancer Society, says that his organization also discourages full-body scanning CT exams[5].

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[2]See Publication of USFDA in **Exhibit C**: http://www.pueblo.gsa.gov/cic_text/health/fullbody-ctscan/

[3]ACR Practice Guideline, attached as **Exhibit D**.

[4]American College of Radiology (2002, September). Statement on CT Screening Exams. Retrieved March 6, 2006 from http://www.acr.org/s_acr/doc.asp?TrackID=&SID=a&DID=16014&CID, attached as **Exhibit E**.

[5]Please see American Medical News article of September 3, 2011 in **Exhibit E**.

III. CT SCANS IN HIGH RISK POPULATIONS: THE MOST RECENT STUDY AND WHAT IT MEANS

The National Lung Screening Trial (NLST) described in Exhibit B was a randomized trial of screening with the use of low-dose CT as compared screening with the use of chest radiography, and was an effort of the Lung Screening Study (LSS), administered by the NCI Division of Cancer Prevention, and the American College of Radiology Imaging Network (ACRIN), and sponsored by the NCI Division of Cancer Treatment and Diagnosis, Cancer Imaging Program.

The NCI Division of Cancer Prevention conducted the NLST, a randomized controlled trial designed to determine whether screening with LDCT can reduce lung cancer mortality among persons at elevated risks for cancer. The study consisted of more than 50,000 individuals, ages 55 to 74 years with a history of smoking at least 30-pack years. Participants were randomly assigned to receive either three annual Cat Scans or three annual chest x-rays.

In the NLST[6], a 20.0% decrease in mortality from lung cancer was observed in the low-dose CT group as compared with the radiography group[7]. Despite this finding, the National Lung Screening Trial Research team went on to say:

> Although some agencies and organizations are contemplating the establishment of lung-cancer screening recommendations on the basis of the findings of the NLST, the current NLST data alone, are in our opinion, insufficient to fully inform such important decisions....
>
> The reduction in lung-cancer mortality must be weighed against the harms from positive screening results and over[-]diagnosis, as well as costs...
>
> Other strategies for early detection of cancer... may one day help select persons who are best suited for low-dose CT screening tests who should undergo more rigorous diagnostic evaluation.

As further noted by Dr. Simome Tramma, MD, MS, Eileen Storey, MD, MPH, Douglas B. Trout, MD, MHS, and Marie Haring Sweeney, Ph, MPH of the National Institute for Occupational Safety and Health of the Department of Health and Human Services Centers for Disease Control and

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[6] Another large ongoing study is the Ducth-Belgian randomized lung cancer screening trial (NELSON). The NELSON trial is investigating whether the 16-detector multislice computed tomography screening will decrease lung cancer mortality compared to no screening. This trial started in August 2003 and is expected to be completed in December 2015. It is expected to include 15, 600 participants. The participants will receive CT screenings or usual care.

[7] *Id.*

Prevention in their NIOSH Science Blog (discussing the breadth of the NLST), attached hereto as Exhibit F[8]:

> "In the occupational setting, there are a number of agents associated with lung cancer. However, the excess risks for lung cancer associated with these occupational exposures vary depending on the actual exposures. Consideration of the use of any screening test in occupationally exposed groups requires a careful assessment of the risk of a given condition. The risk of lung cancer from a specific exposure will directly affect the likelihood that a positive screening test for lung cancer will actually be evidence that the cancer exists. In other words, high risk for lung cancer in the NSLT trial due to a long history of heavy smoking made it more likely that a "positive" funding on a low-dose CT Scan was in fact a lung cancer. The benefit of screening for lung cancer with low-dose CT cannot be easily estimated for populations with risk profiles that are different from those of the NLST participants."

The National Institute for Health states that "[d]ecisions to recommend screening for a population should be based upon the highest possible level of evidence of population benefit from clinical trials."

The Lung Cancer Alliance states its position with regard to lung cancer screening as follows:

> "Lung Cancer Alliance (LCA) has consistently maintained that those at high risk for lung cancer should speak with their doctors about the risks and benefits of screening. Those at risk include smokers and former smokers, first degree relatives of people diagnosed with lung cancer and those with prolonged exposure to radon, asbestos, Agent Orange, radioactive materials and other lung carcinogens. If the decision is made to undergo screening by computed tomography (CT), the scan should only be done at a site which has experience in screening for lung cancer and which follows a lung cancer screening protocol based on best published practices, such as the International Early Lung Cancer Action Program (I-ELCAP) protocol[9]." Emphases Added.

LCA Position on Lung Cancer Screening is attached as Exhibit E.

As noted in the conclusion of the LCA's position statement "[t]hose at high risk for lung cancer and their primary care doctors need to be fully informed in order to reach a decision on screening appropriate to each individual case."

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[8] National Institute of Health, Screening in the Dark: Ethical Considerations of Providing Screening Tests to Individuals When Evidence is Insufficient to Support Screening Populations, A, J Bioeth. 2009 April; 9(4):3-14, in Exhibit F.

[9] The above mentioned International Early Lung Cancer Action Program protocol, dated July 1, 2011, is attached hereto as Exhibit G, and was pioneered and developed over the past 17 years by the International Lung Cancer Action Program, and deals with research concerning the efficacy of CT scans in asymptomatic high risk individuals.

See also Radiation Dose Associated with Common Completed Tomography Examinations and the Associated Lifetime Attributable Risk of Cancer, Rebecca Smith-Bindman, MD, Archives of Internal Medicine, Vol. 169 No. 22., Dec 14/28, 2009 in Exhibit F; Lung CT scan for cancer: Should you be screened?, Mayo Clinic, mayoclinic.com/health/lung-ct-scan/CA0086/MET in Exhibit G.

In designing the guidelines and carrying out the CT Scan portion of the Medical Monitoring Program, Medicare and Medicaid issues should be considered. Please refer to the Memorandum in Exhibit H, expressing the opinion that these issues should not impact how the Medical Monitoring Program is funded.

Footnote 66 to the West Virginia Supreme Court of Appeals March 26, 2010 Decision might also be considered.

IV. THE CT SCAN GUIDELINES (THE "CT RULE")

In light of the above, and current research regarding the signs and symptoms associated with cancer, the below guidelines are recommended:

1. These rules shall be re-evaluated every two years based upon scientific developments in radiology, and following consultation with the Medical Advisory Committee.

2. CT Scan eligible Claimants are described in Dr. Brookshire's Report.

3. During the CT-Scan eligible Claimant's initial medical monitoring visit with the examining physician, the examining physician will:

    a. Take the Claimant's vital signs;
    b. Conduct a general health interview which shall include the number of years the Claimant has lived in the Class Area in Exhibit 2, with greater weight being given to:
        i. Zone 1 Claimants who have lived in the Class Area for 2 years or more;
        ii. Zone 2 Claimants who have lived in Class Area for 6 years or more; and
        iii. Zone 3 Claimants who have lived in the Class Area of concern for 10 years or more);

    c. Review the Claimant's prior medical record (necessary to determine propensity for cancer); and

    d. Ensure that all female Claimants receive a pregnancy exam.

4. The Claimant will have paragraph C on page 2 of the Memorandum of Understanding in Exhibit 3 read to him or her by the examining physician or will be provided a copy to read.

5. The examining physician will ensure informed consent. Specifically, the examining physician will explain the nature of the radiological imaging, that the results may not be definitive, there may be false outcomes, and that there is a risk associated with radiological imaging and CT Scans specifically.

6. After a review of the Claimant's vital signs, general health interview, and prior medical history, the examining physician will, in his discretion, make a determination on whether to recommend a CT Scan for the Claimant as being medically necessary and relevant to possible exposure to heavy metals (cadmium, arsenic, lead or zinc) contamination (which will be documented by the examining physician with a signed form provided).

7. Factors which satisfy medical necessity include:

   (1) **Signs and Symptoms**, including but not limited to, paraneoplastic syndromes (production of hormone like symptoms from the tumor cells), unexplained weight loss, fever, fatigue, pain, persistent coughing or hoarseness, hemoptysis, unusual bleeding or discharge, dysphagia, persistent shortness of breath, thickening or lumps in the body, hyper pigmentation, jaundice, shoulder pain (Pancoast's Syndrome), pneumonia, persistent headaches, and/or other medical signs and symptoms which are widely accepted in the medical community as potential indicators of cancer.

   AND/OR

   (2) **Medical history** (including known diagnoses).

8. The lowest possible radiation dose consistent with acceptable diagnostic image quality should be used.

9. The care provider shall not bill Medicaid, Medicare and/or any other third party for the services outlined in these guidelines under any circumstances.

EXHIBITS TO CT SCAN UTILIZATION GUIDELINES

EXHIBIT	DESCRIPTION
1	CT Scan Utilization Protocols
2	Class Area Map
3	Paragraph C, page 2, of Memorandum of Understanding
A	James B. Lees, Jr., Esq., August 29, 2011 and September 1, 2011 Memoranda, and August 19, 2011 letter from Dr. Andrea H. McGuire
B	N. Eng. J. Med. 2011; 365: 395-409, August 4, 2011
C	Publication of USFDA
D	ACR Practice Guideline
E	American College of Radiology September 2002 Statement on CT Screening Exams
F	NIH Publications, J Bioeth. 2009 April; 9(4):3-14
G	Early Lung Cancer Program Protocol dated July 1, 2011
H	August 30, 2011, Memorandum Re DuPont: CT Scans and Medicare

Exhibit 1

CT Scan Utilization Protocols

CT SCAN UTILIZATION PROTOCOLS

1. CT Scan eligible claimants are described in Dr. Brookshire's report.

2. At the initial medical monitoring testing visit, the attending physician will take the CT scan eligible claimant's vital signs and conduct a general health interview of the claimant.

3. After examining the claimant, the examining physician will make a determination on whether to recommend a CT scan for the claimant as being diagnostically medically necessary based on the CT Scan Utilization Guidelines to be developed by the Claims Administrator and to be ultimately determined by the Court.

4. The claimant can accept or decline the recommendation for a CT scan.

5. Prior to agreeing to a CT scan, a claimant will be told by the physician the benefits and risks of a CT scan.

6. Claimants agreeing to a CT scan shall sign a standard CT scan release.

Exhibit 2

Class Area Map

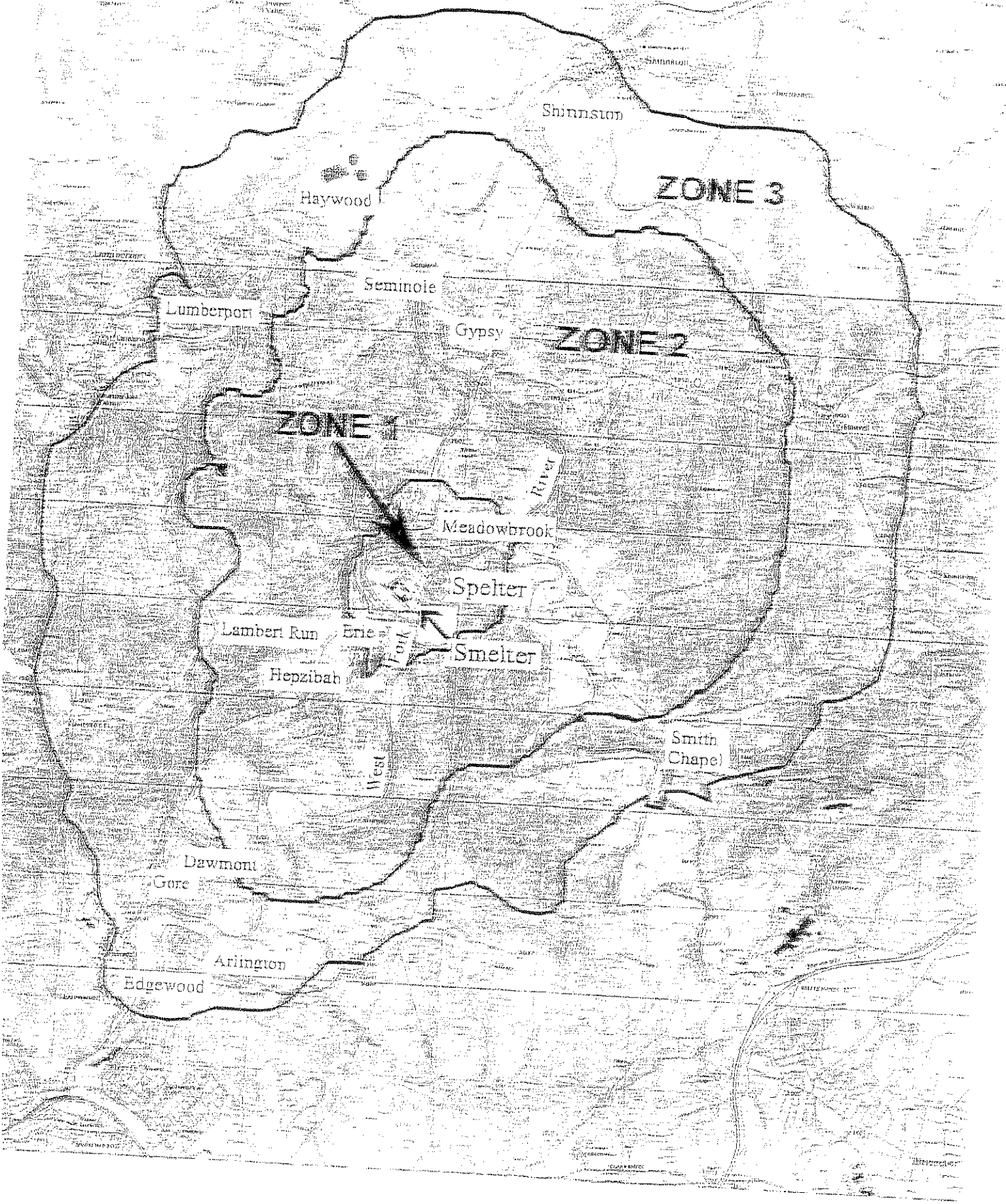

ZONE 3
ZONE 2
ZONE 1
Shinnston
Haywood
Seminole
Lumberport
Gypsy
River
Meadowbrook
Spelter
Lambert Run
Erie
Fork
Smelter
Hepzibah
West
Smith
Chapel
Dawmont
Gore
Arlington
Edgewood

Exhibit 3

Paragraph C, page 2, of Memorandum of Understanding

c. The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT scans shall be performed as part of the medical monitoring program. The Defendant does agree to provide CT scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation.

Exhibit A

James B. Lees, Jr., Esq., August 29, 2011 and September 1, 2011 Memoranda, and August 19, 2011 letter from Dr. Andrea H. McGuire

MEMORANDUM

TO: Edgar C. Gentle, III, Esq,

FROM: DuPont by James B. Lees Jr. Esq.

DATE: August 29, 2011

RE: Draft CT Scan Utilization Guidelines

Dear Ed

As per your Memorandum dated August 18, 2011 I have been asked by DuPont to step back into this matter for the purpose of helping you deal with the issue of CT scans as they relate to the settlement of this litigation. As the principal attorney who negotiated this settlement with counsel for the plaintiffs and having spent many hours discussing this very subject matter with Ed Hill, then counsel for the plaintiffs, DuPont believed I was in a better position to address this matter with you.

First let me set forth what I hope we do agree upon:

1. There are no Medicare issues relevant to this subject matter. There are no prior created Medicare liens at issue and there will be no future Medicare liens created by the operation of the settlement agreement as it relates to CT scans. DuPont is the primary payor of all services covered under the settlement agreement, and absent a mistaken billing by a physician to Medicare there should be no claims or submissions made to Medicare by any physician or claimant in this matter nor should there be any Medicare liens created. I am not sure how this issue arose but I believe we are in complete agreement with you that Medicare is not relevant to this matter.
2. DuPont is the primary payor for any CT scans that are provided to class members pursuant to the settlement agreement. Whether DuPont pays any such invoices directly upon receipt of an appropriate invoice or whether you pay such invoices from monies deposited with you in advance is an issue still undecided. However it is clear that DuPont is obligated under the settlement agreement and will pay the cost of CT scans covered under the settlement agreement.
3. The settlement agreement changed the original Court Order relevant to medical monitoring in that the settlement agreement removes routine CT scans for screening purposes as part of the medical monitoring program. This of course was the subject of much negotiation among the parties, some of which you and the Court were parties to at the mediation which resulted in the settlement of this matter. All parties agreed that CT scans would not be routinely performed on class members as a screening tool, and

this agreement was specifically referenced in paragraph 3(c) of the agreement so as to remove screening CT scans as part of the medical monitoring program.

Hopefully these are three points in which you and I agree. I can tell you that I was somewhat taken back by some written comments by the current representative for the class members to the extent that she expressed surprise that CT scans were not part of the medical monitoring screening process in the settlement. This is the very issue that was negotiated by the parties and was an absolute condition precedent for DuPont to enter into the settlement agreement for a number of reasons, not the least of which is accurately referenced in your draft guidelines that the FDA states that CT scans are to be used for the diagnosis of illness and disease in symptomatic people and not as a tool used to screen non-symptomatic people for possible medical problems.

Ct scans pursuant to the settlement agreement are to be used when a physician determines that a patient (or in this case a class member) likely has a disease or medical condition that is related to exposure to heavy metal exposure and that a CT scan is medically necessary as a "diagnostic" tool to rule in or rule out the disease. In such a case DuPont under the terms of the settlement agreement stands ready and willing to pay for that diagnostic test to confirm the presence or absence of the heavy metal-related disease in the class member. This is precisely what was discussed in the settlement negotiations, and it is precisely what is set forth in the settlement agreement.

The question then becomes what if anything is necessary to be done by you to make sure this provision of the settlement agreement is carried out in an organized fashion. Most importantly in my view one of the main purposes of addressing this issue in advance of the commencement of the medical monitoring program is to develop a way in which to insure that physicians that order such CT scans for the reasons stated above:

a. Notify your office in some manner as to the conclusions they have reached about a given class member and their determination for the need to do the diagnostic CT scan to rule in or rule out the disease.
b. Bill the correct party.....or more precisely know that they are not to bill Medicare.

These are two relevant issues that need addressed by you in advance of the commencement of the program, and DuPont is certainly amenable to working with you to create some method or system for insuring that these matters are addressed.

Where I believe you and I may disagree is the need for your office to attempt to set out "Guidelines" that in my opinion cross the line from administering a program to one of attempting to dictate how the practice of medicine is carried out. I do think we need to be very careful in this area for a number of reasons, not the least of which is that I do not want your office or DuPont in any way named as a defendant in a medical malpractice case sometime in the future because you or DuPont interfered with a competent physician's judgment as to when a diagnostic CT scan is needed to rule in or rule out a disease thought to be related to the heavy metal exposure relevant in this litigation.

I believe is it a mistake to attempt in any written document to set out "signs and symptoms" that attempt to give competent physicians instructions on how to practice medicine. This is not

our role in this matter, and the language of the settlement agreement was drafted specifically to keep the lawyers and administrators out of the business of practicing medicine. Since you do have counsel available to you I would urge you to discuss this issue with counsel, particularly with respect to the issue of setting out specific criteria for physicians to use in determining how to best manage and treat those class members that come before them. I foresee you being dragged into future medical negligence litigation needlessly by taking this approach.

As an alternative I believe the settlement agreement is crystal clear on this matter and should govern when CT scans are ordered and when they are not ordered. The settlement agreement specifically states CT scans are to be used only as part of a diagnostic process. That is why the word "diagnostically" was inserted in paragraph 3(c) of the settlement so as to make clear that CT scans would only be ordered consistent with the FDA mandates as part of a diagnostic process to rule in or rule out a disease.

The words "medically necessary" were inserted to preclude the lawyers and the Court from attempting to interfere with the medical judgments made by competent physicians. The words "medically necessary" were used to make absolutely sure that decisions in the future are being made by physicians and not pursuant to some lawyer-created criteria.

And of course the words "relevant to the heavy metal contamination at issue in this litigation" were inserted to make it clear that DuPont pays only for diagnostic CT scans that are related to ruling in or ruling out a disease related to the heavy metal exposure. Otherwise DuPont would end up paying for CT scans for suspected lung cancers and other diseases that are related to cigarette smoking, life styles, and or simply genetic disease processes.

I believe the language of the settlement agreement is very precise and very clear on this subject. I however am cognizant of the fact that physicians need to be aware of the fact that they can order diagnostic CT scans in certain circumstances and that the CT scans will be paid for by DuPont. It is therefore my suggestion that in lieu of "Guidelines" or any attempt to set forth medical symptomology or medical "triggers" you simply communicate to all physicians involved in medical monitoring the following information:

1. CT scans for screening purposes will not be paid for under the medical monitoring program.
2. Ct scans will be paid for under this program if you as the physician determine:
   a. A class member, based upon testing and examination, most likely has a disease.
   b. The disease is most likely related to heavy metal exposure from three heavy metals: arsenic, cadmium, or lead.
   c. You as the medical professional have determined that a diagnostic CT scan is medically necessary to rule in or rule out the disease in the class member.
3. In the event you make such a medical judgment simply submit your findings and conclusions to my office (deleting of course patient identification) together with your order for a CT scan.
4. Do not under any circumstances bill or invoice Medicare, Medicaid, or any other third-party provider for these CT scans. My office will handle all billing and payment.

This is essentially the information that we believe should be given to the physicians as the program commences. We are of course open to discussion as to whether DuPont needs to

deposit some monies into an account in advance of the program to pay invoices for any such diagnostic CT scans and, if so, how much. I believe the best practice is to simply have DuPont pay for the CT scans if and when they are ordered but this is something we are certainly willing to work with you on.

Because Ct scans are not parts of routine screening in the medical monitoring program but will only be ordered to rule in or rule out a disease that a physician believes is related to the heavy metal exposure we do not believe any monies for the non-screening CT scans should be included in the medical monitoring budget. DuPont agreed to pay for these limited CT scans as part of a diagnostic process if needed and not as part of any broad-based medical monitoring screening program. DuPont would be amenable to depositing advance monies with you in an escrow account that was designated specifically for these diagnostic CT scans so long as these monies were segregated from the overall medical monitoring budget if you were not satisfied with DuPont's ability and willingness to pay for these CT scans as they are ordered.

I do think we need some certification or document by the physician delivered to you that provides that a CT scan is being ordered for the purpose set forth in the settlement agreement (and provided to them by you at the commencement of the program). In order to protect DuPont's due process rights we do need some method to insure that the parameters of the settlement agreement are being met and not abused by physicians when ordering diagnostic CT scans.

If you need any additional input or information from me please let me know.

Memo: September 1, 2011

To: Edgar C. Gentle III, Esq.

Fr: Jim Lees, Counsel for DuPont

Re: Proposed Letter to Judge Bedell regarding CT Scans

Pursuant to your request in your memorandum of August 30, 2011 to counsel for DuPont I am submitting DuPont's written comments regarding your proposed letter to Judge Bedell as well as your proposed attached submission to the Court. I also am attaching a draft informed consent document which I believe will satisfy both the need for informed consent by a claimant in those situations where a physician is recommending a CT scan as well as some modicum of due process to DuPont to insure that the physician has complied with the relevant language of the settlement Memorandum of Understanding.

In short DuPont makes the following comments about your proposed letter to Judge Bedell as well as the proposed CT Guidelines and the CT Utilization Protocols:

1. We agree with your counsel's memorandum that the Medicare issue is a non-issue in this matter.
2. Under the CT Scan Utilization Protocols we ask that you add a paragraph 7 that reads: "Physicians ordering a CT scan for a claimant shall verify in writing their medical findings consistent with the CT Scan Utilization Guidelines. Both the CT scan Informed Consent form executed by the Claimant and the CT scan Verification executed by the physician shall be submitted to the Settlement Claim Office at the time any such CT scan is ordered."
3. Under paragraph 6 of the CT Scan Utilization Guidelines (as set forth in your proposed attached submission to the Court) we ask that the following language be added to the end of this paragraph so as to comply with the settlement agreement as between the parties:
   ...as being medically necessary "**to diagnose a disease or serious condition that is related to exposure to arsenic, cadmium, or lead.**"
4. We ask that you delete costs included in any budgeted estimate for CT scans that are related to the Guardian Ad Litem. Only claimants over the age of 35 are eligible for consideration of a CT scan for diagnostic purposes. The only relevance for participation of the Guardian Ad Litem in this issue is claimants who have been declared legally incompetent. DuPont believes that number is two.
5. We ask that rather than include proposed estimated costs of CT Scans in the Medical Monitoring Budget you simply invoice DuPont for any CT Scans approved by your office at the time of your approval. We believe any attempt by you to "pre-judge" the need or frequency of diagnostic decisions made by competent physicians is improper and ill-

advised and will potentially impact upon the medical decisions made by such physicians. Creating in essence a "pot of money" that is available to pay for a certain discretionary test has in the past led in some situations to abuse of medical decision-making. Your office is not equipped to monitor the use of this "pre-paid" diagnostic procedure in any meaningful manner, and the lessons learned in the past from similar Worker's Compensation systems has led to a much more constrained and cautious approach in dealing with these type issues. DuPont certainly has the ability to pay invoices in a timely fashion for CT Scans approved by your office, and we urge you to reconsider your proposal to simply create a new or additional "pot of money" for the sole purpose of paying for approved CT scans in a timely manner. Of all the services being provided to claimants by DuPont this limited service should be strictly on a pay-as-you-go basis.

6. In the event you persist in your effort to create an advance source of monies from which to pay approved CT scans we respectfully note that a sum of $100,000 should be more than sufficient to cover these limited situations, with said sum being replenished on a regular basis as the need arises. We also would then urge you to amend your letter to Judge Bedell as a middle ground approach on this subject to include the following language in place of your proposed language:
   "As contemplated by the MOU, the Preliminary Budget is to be funded by an additional DuPont contribution to the Medical Monitoring Fund. Because of the uncertainty associated with the frequency in which physicians will order CT scans, DuPont has proposed to provide initial funding of up to $100,000 (the "CT Fund") to provide a source for payment of approved CT scans and has agreed to replenish the CT Fund on a monthly basis as part of the process for the approval of the bills of the Claims Administrator. The Claims Administrator agrees with this proposed modification of the budgeting process for the initial payment of approved CT scans. Once the Claims Administrator, the TPA and the parties have experience with the implementation of the Medical Monitoring program, including the frequency with which CT scans are ordered, the Claims Administrator reserves the right to recommend to the Court that funding for CT scans be included as part of the annual budgeting process."
7. We note that your reference to Footnote 66 of the Supreme Court opinion in your Memorandum to the Court is noteworthy in that DuPont specifically negotiated the Memorandum of Understanding to exclude routine CT scans for screening purposes with that Footnote partially in mind. To the extent you were citing to it in support of the proposition that the language in that Footnote is relevant in light of the agreed-upon settlement of the parties in this matter we respectively disagree with your conclusion.

In summary we believe all parties including DuPont are working in good faith to resolve this matter in a reasonable and timely fashion and we appreciate your efforts to date in this matter.

August 19, 2011

Edgar C. Gentle, III, Esq.

Special Master

Perrine Medical Monitoring Plan, Product of the Perrine DuPont Settlement

Dear Mr. Gentle,

I am a medical consultant with experience in academics, private practice and Medical Management. My education includes a BS in Chemistry, a Medical Doctorate and an MBA. I have additional training in Nuclear Medicine with Board Certification. I have research experience with over 30 publications and a book chapter and over 10 years of experience in reviewing medical claims for medical appropriateness based on medical literature.

I have been asked to review the CT Scan Utilization Guidelines dated November 1, 2011. There are also several Exhibits that are referenced that I have reviewed including:

- Exhibit 1-CT Scan Utilization Protocols
- Exhibit 2-Class Area Map
- Exhibit 3-Paragraph C, page 2, of Memorandum of Understanding
- Exhibit A-Publication of USFDA
- Exhibit B-ACR Practice Guidelines
- Exhibit C-American College of Radiology September 2002 Statement on CT Screening Exams

In my review, I note many inconsistencies related to the information provided and the question at hand.

The first referenced publication under background in the Utilization guidelines is the Publication of the USFDA. First, this publication relates to Whole Body CT scanning in a normal population. It is my understanding that we are addressing Chest CT Scanning in high risk populations and not whole body scanning in normal populations; therefore this article is not applicable. It also is dated March 2003-

more than 8 years ago and is not up to date with the medical literature especially the recent New England Journal article published August 4, 2011 titled, "Reducing Lung-Cancer Mortality with Low-Dose Computed Tomography Screening". Additionally, the article does reference, "that CT screening of high-risk individuals for specific diseases such as lung cancer or colon cancer is currently being studied, but results are not yet available". The study they are referencing is the National Lung Screening Trial (NLST). The data from this study is what the New England Journal article is based on. Therefore, it is my opinion that this reference has no standing because it is addressing a different modality (whole body CT scanning versus specific areas), is outdated and even references that studies are coming in the future that are now available.

The next reference is to Exhibit B-the ACR Practice guideline. The practice guidelines included are for the performance of pediatric and adult chest radiography which is a Chest x-ray. I understood the matter we were discussing is CT scanning in high risk individuals and therefore

an article on Chest x-rays would be a completely different modality and certainly not applicable to this question. The practice guideline is out of date with the most recent medical literature cited in 2005 and the guideline revised in 2006. The other practice guideline in the exhibit was ACR practice guideline for performing FDG-PET/CT in Oncology. An FDG PET/CT utilizes positron emission tomography to assess metabolic activity in different tumors using flourodeoxyglucose, a radioactive sugar. The CT in PET/CT refers to the anatomic registration portion of the metabolic study and again is a completely different modality than CT scanning in high-risk lung cancers. These guidelines are dated 2007 and are therefore dated in this continually evolving field.

The CT scan guidelines that are quoted I believe are taken from the chest radiography practice guidelines and therefore are not applicable to another modality and neither is the reference to the American College of Radiology Board of Chancellors issued statement since it is referencing total body computed (CT) screening for patients with no

symptoms or a family history suggesting disease and we are addressing a different modality CT Scanning of the chest in patients with a high risk of cancer related to their exposure to the heavy metal contamination at issue in this litigation.

The guidelines that are listed (II. Guidelines, Page 2) are said to be based on these references that I have discussed above and therefore to base the guidelines on references about different tests than the one we are interested in and with medical references that are very out dated is not appropriate.

It is by opinion that according to the paragraph c, page 2 of the Memorandum of Understanding that was included as exhibit 3, CT scans should be provided as diagnostically medically necessary because of the high risk of the possible exposure to the heavy metal contamination at issue in this litigation. I base this on the August 4th 2011 article from the New England Journal "Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening" based on

the National Lung Screening Trial (NLST). This article relates directly to this issue because it addresses a large population (53,454) that is at similar high risk of lung cancer (30 pack year history of smoking) to your patients with heavy metal exposure as noted in Exhibit 2-Class Area Maps. The mortality in these similar at risk individuals was 20% less if they had CT scans than if just chest x-ray surveillance. This article is up to date and particularly on point to this situation. It is my opinion that because of this study all participants should have a CT Scan as part of their surveillance because it is medically necessary in a high risk population with possible exposure to heavy metal contaminants.

9/19/11

Andrea H McGuire, MD, MBA

Exhibit B

N. Eng. J. Med. 2011; 365: 395-409, August 4, 2011

ORIGINAL ARTICLE

Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team

N Engl J Med 2011; 365:395-409 | August 4, 2011

Comments open through August 10, 2011

Lung cancer is an aggressive and heterogeneous disease.[1,2] Advances in surgical, radiotherapeutic, and chemotherapeutic approaches have been made, but the long-term survival rate remains low.[3] After the Surgeon General's 1964 report on smoking and health, mortality from lung cancer among men peaked and then fell; among women, the peak occurred later and a slight decline has occurred more recently.[4] Even though the rate of heavy smoking continues to decline in the United States,[5] 94 million current or former smokers remain at elevated risk for the disease,[6] and lung cancer remains the leading cause of death from cancer in this country.[3] The prevalence of smoking is substantially higher in developing countries than in the United States, and the worldwide burden of lung cancer is projected to rise considerably during the coming years.[7]

Although effective mass screening of high-risk groups could potentially be of benefit, randomized trials of screening with the use of chest radiography with or without cytologic analysis of sputum specimens have shown no reduction in lung-cancer mortality.[8] Molecular markers in blood, sputum,

and bronchial brushings have been studied but are currently unsuitable for clinical application.[6] Advances in multidetector computed tomography (CT), however, have made high-resolution volumetric imaging possible in a single breath hold at acceptable levels of radiation exposure,[9] allowing its use for certain lung-specific applications. Several observational studies have shown that low-dose helical CT of the lung detects more nodules and lung cancers, including early-stage cancers, than does chest radiography.[6] Therefore, the National Cancer Institute (NCI) funded the National Lung Screening Trial (NLST), a randomized trial, to determine whether screening with low-dose CT, as compared with chest radiography, would reduce mortality from lung cancer among high-risk persons. The NLST was initiated in 2002.[10] In October 2010, the available data showed that there was a significant reduction with low-dose CT screening in the rates of both death from lung cancer and death from any cause. We report here the findings of the NLST, including the performance characteristics of the screening techniques, the approaches used for and the results of diagnostic evaluation of positive screening results, the characteristics of the lung-cancer cases, and mortality. A comprehensive description of the design and operations of the trial, including the collection of the data and the acquisition variables of the screening techniques, has been published previously.[10]

METHODS

Trial Oversight

The NLST, a randomized trial of screening with the use of low-dose CT as compared with screening with the use of chest radiography, was a collaborative effort of the Lung Screening Study (LSS), administered by the NCI Division of Cancer Prevention, and the American College of Radiology Imaging Network (ACRIN), sponsored by the NCI Division of Cancer Treatment and Diagnosis, Cancer Imaging Program. Chest radiography was chosen as the screening method for the control group because radiographic screening was being compared with community care (care that a participant usually receives) in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial (ClinicalTrials.gov number, NCT00002540).[11] The NLST was approved by the institutional review board at each of the 33 participating medical institutions. The study was conducted in accordance with the protocol; both the protocol and the

statistical analysis plan are available with the full text of this article at NEJM.org.

Participants

We enrolled participants from August 2002 through April 2004; screening took place from August 2002 through September 2007. Participants were followed for events that occurred through December 31, 2009 (Fig. 1 in the Supplementary Appendix, available at NEJM.org).

Eligible participants were between 55 and 74 years of age at the time of randomization, had a history of cigarette smoking of at least 30 pack-years, and, if former smokers, had quit within the previous 15 years. Persons who had previously received a diagnosis of lung cancer, had undergone chest CT within 18 months before enrollment, had hemoptysis, or had an unexplained weight loss of more than 6.8 kg (15 lb) in the preceding year were excluded. A total of 53,454 persons were enrolled; 26,722 were randomly assigned to screening with low-dose CT and 26,732 to screening with chest radiography. Previously published articles describing the NLST[10,12] reported an enrollment of 53,456 participants (26,723 in the low-dose CT group and 26,733 in the radiography group). The number of enrolled persons is now reduced by 2 owing to the discovery of the duplicate randomization of 2 participants.

Participants were enrolled at 1 of the 10 LSS or 23 ACRIN centers. Before randomization, each participant provided written informed consent. After the participants underwent randomization, they completed a questionnaire that covered many topics, including demographic characteristics and smoking behavior. The ACRIN centers collected additional data for planned analyses of cost-effectiveness, quality of life, and smoking cessation. Participants at 15 ACRIN centers were also asked to provide serial blood, sputum, and urine specimens. Lung-cancer and other tissue specimens were obtained at both the ACRIN and LSS centers and were used to construct tissue microarrays. All biospecimens are available to researchers through a peer-review process.

Screening

Participants were invited to undergo three screenings (T0, T1, and T2) at 1-year intervals, with the first screening (T0) performed soon after the time of randomization. Participants in whom lung cancer was diagnosed were not

offered subsequent screening tests. The number of lung-cancer screening tests that were performed outside the NLST was estimated through self-administered questionnaires that were mailed to a random subgroup of approximately 500 participants from LSS centers annually. Sample sizes were selected to yield a standard error of 0.025 for the estimate of the proportion of participants undergoing lung-cancer screening tests outside the NLST in each group. For participants from ACRIN centers, information on CT examinations or chest radiography performed outside the trial was obtained, but no data were gathered on whether the examinations were performed as screening tests.

All screening examinations were performed in accordance with a standard protocol, developed by medical physicists associated with the trial, that specified acceptable characteristics of the machine and acquisition variables.[10,13,14] All low-dose CT scans were acquired with the use of multidetector scanners with a minimum of four channels. The acquisition variables were chosen to reduce exposure to an average effective dose of 1.5 mSv. The average effective dose with diagnostic chest CT varies widely but is approximately 8 mSv.[10,13,14] Chest radiographs were obtained with the use of either screen-film radiography or digital equipment. All the machines used for screening met the technical standards of the American College of Radiology.[10] The use of new equipment was allowed after certification by medical physicists.

NLST radiologists and radiologic technologists were certified by appropriate agencies or boards and completed training in image acquisition; radiologists also completed training in image quality and standardized image interpretation. Images were interpreted first in isolation and then in comparison with available historical images and images from prior NLST screening examinations. The comparative interpretations were used to determine the outcome of the examination. Low-dose CT scans that revealed any noncalcified nodule measuring at least 4 mm in any diameter and radiographic images that revealed any noncalcified nodule or mass were classified as positive, "suspicious for" lung cancer. Other abnormalities such as adenopathy or effusion could be classified as a positive result as well. Abnormalities suggesting clinically significant conditions other than lung cancer also were noted, as were minor abnormalities. At the third round of screening (T2), abnormalities suspicious

for lung cancer that were stable across the three rounds could, according to the protocol, be classified as minor abnormalities rather than positive results.

Results and recommendations from the interpreting radiologist were reported in writing to the participant and his or her health care provider within 4 weeks after the examination. Since there was no standardized, scientifically validated approach to the evaluation of nodules, trial radiologists developed guidelines for diagnostic follow-up, but no specific evaluation approach was mandated.

Medical-Record Abstraction

Medical records documenting diagnostic evaluation procedures and any associated complications were obtained for participants who had positive screening tests and for participants in whom lung cancer was diagnosed. Pathology and tumor-staging reports and records of operative procedures and initial treatment were also obtained for participants with lung cancer. Pathology reports were obtained for other reported cancers to exclude the possibility that such tumors represented lung metastases. Histologic features of the lung cancer were coded according to the *International Classification of Diseases for Oncology, 3rd Edition* (ICD-O-3),[15] and the disease stage was determined according to the sixth edition of the *Cancer Staging Manual* of the American Joint Committee on Cancer.[16] At ACRIN sites, additional medical records were also obtained for a number of substudies, including studies of health care utilization and cost-effectiveness.[10]

Vital Status

Participants completed a questionnaire regarding vital status either annually (LSS participants) or semiannually (ACRIN participants). The names and Social Security numbers of participants who were lost to follow-up were submitted to the National Death Index to ascertain probable vital status. Death certificates were obtained for participants who were known to have died. An end-point verification team determined whether the cause of death was lung cancer. Although a distinction was made between a death caused by lung cancer and a death that resulted from the diagnostic evaluation for or treatment of lung cancer, the deaths from the latter causes were counted as lung-cancer deaths in the primary end-point analysis. The

members of the team were not aware of the group assignments (see Section 2 in the Supplementary Appendix).

Statistical Analysis

The primary analysis was a comparison of lung-cancer mortality between the two screening groups, according to the intention-to-screen principle. We estimated that the study would have 90% power to detect a 21% decrease in mortality from lung cancer in the low-dose CT group, as compared with the radiography group. Secondary analyses compared the rate of death from any cause and the incidence of lung cancer in the two groups.

Event rates were defined as the ratio of the number of events to the person-years at risk for the event. For the incidence of lung cancer, person-years were measured from the time of randomization to the date of diagnosis of lung cancer, death, or censoring of data (whichever came first); for the rates of death, person-years were measured from the time of randomization to the date of death or censoring of data (whichever came first). The latest date for the censoring of data on incidence of lung cancer and on death from any cause was December 31, 2009; the latest date for the censoring of data on death from lung cancer for the purpose of the primary end-point analysis was January 15, 2009. The earlier censoring date for death from lung cancer was established to allow adequate time for the review process for deaths to be performed to the same, thorough extent in each group. We calculated the confidence intervals for incidence ratios assuming a Poisson distribution for the number of events and a normal distribution of the logarithm of the ratio, using asymptotic methods. We calculated the confidence intervals for mortality ratios with the weighted method that was used to monitor the primary end point of the trial,[17] which allows for a varying rate ratio and is adjusted for the design. The number needed to screen to prevent one death from lung cancer was estimated as the reciprocal of the reduction in the absolute risk of death from lung cancer in one group as compared with the other, among participants who had at least one screening test. The analyses were performed with the use of SAS/STAT[18] and R[19] statistical packages.

Interim analyses were performed to monitor the primary end point for efficacy and futility. The analyses involved the use of a weighted log-rank statistic, with weights increasing linearly from no weight at randomization to

full weight at 4 years and thereafter. Efficacy and futility boundaries were built on the Lan–DeMets approach with an O'Brien–Fleming spending function.[20] Interim analyses were performed annually from 2006 through 2009 and semiannually in 2010.

An independent data and safety monitoring board met every 6 months and reviewed the accumulating data. On October 20, 2010, the board determined that a definitive result had been reached for the primary end point of the trial and recommended that the results be reported.[21] The board's decision took into consideration that the efficacy boundary for the primary end point had been crossed and that there was no evidence of unforeseen screening effects that warranted acting contrary to the trial's prespecified monitoring plan. The NCI director accepted the recommendation of the data and safety monitoring board, and the trial results were announced on November 4, 2010.

RESULTS

Characteristics of the Participants

The demographic characteristics and smoking history of the participants were virtually identical in the two groups (Table 1). As compared with respondents to a 2002–2004 U.S. Census survey of tobacco use[22] who met the NLST eligibility criteria for age and smoking history, NLST participants were younger, had a higher level of education, and were more likely to be former smokers.[12] As of December 31, 2009, vital status was known for 97% of the participants in the low-dose CT group and 96% of those in the radiography group. The median duration of follow-up was 6.5 years, with a maximum duration of 7.4 years in each group.

TABLE 1

Selected Baseline Characteristics of the Study Participants.

Adherence to Screening

The rate of adherence to the screening protocol across the three rounds was high: 95% in the low-dose CT group and 93% in the radiography group. Among LSS participants in the radiography group, the average annual rate of helical CT screening outside the NLST during the screening

phase of the trial was 4.3%, which was well below the 10.0% rate estimated in the trial power calculations.

Results of Screening

In all three rounds, there was a substantially higher rate of positive screening tests in the low-dose CT group than in the radiography group (T0, 27.3% vs. 9.2%; T1, 27.9% vs. 6.2%; and T2, 16.8% vs. 5.0%) (Table 2). The rate of positive tests in both groups was noticeably lower at T2 than at T0 or T1 because the NLST protocol allowed tests showing abnormalities at T2 that were suspicious for cancer but were stable across all three rounds to be categorized as negative with minor abnormalities. During the screening phase of the trial, 39.1% of the participants in the low-dose CT group and 16.0% of those in the radiography group had at least one positive screening result. The percentage of all screening tests that identified a clinically significant abnormality other than an abnormality suspicious for lung cancer was more than three times as high in the low-dose CT group as in the radiography group (7.5% vs. 2.1%).

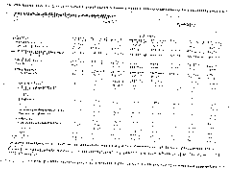
TABLE 2

Results of Three Rounds of Screening.

Follow-up of Positive Results

More than 90% of the positive screening tests in the first round of screening (T0) led to a diagnostic evaluation (Table 3). Lower rates of follow-up were seen at later rounds. The diagnostic evaluation most often consisted of further imaging, and invasive procedures were performed infrequently. Across the three rounds, 96.4% of the positive results in the low-dose CT group and 94.5% of those in the radiography group were false positive results. These percentages varied little by round. Of the total number of low-dose CT screening tests in the three rounds, 24.2% were classified as positive and 23.3% had false positive results; of the total number of radiographic screening tests in the three rounds, 6.9% were classified as positive and 6.5% had false positive results.

TABLE 3



Diagnostic Follow-up of Positive Screening Results in the Three Screening Rounds.

Adverse Events

Adverse events from the actual screening examinations were few and minor. The rates of complications after a diagnostic evaluation procedure for a positive screening test (listed by category in Table 1 in the Supplementary Appendix) were low; the rate of at least one complication was 1.4% in the low-dose CT group and 1.6% in the radiography group (Table 4). A total of 0.06% of the positive screening tests in the low-dose CT group that did not result in a diagnosis of lung cancer and 11.2% of those that did result in a diagnosis of lung cancer were associated with a major complication after an invasive procedure; the corresponding percentages in the radiography group were 0.02% and 8.2%. The frequency of major complications varied according to the type of invasive procedure. A total of 16 participants in the low-dose CT group (10 of whom had lung cancer) and 10 in the radiography group (all of whom had lung cancer) died within 60 days after an invasive diagnostic procedure. Although it is not known whether the complications from the diagnostic procedure caused the deaths, the low frequency of death within 60 days after the procedure suggests that death as a result of the diagnostic evaluation of positive screening tests is a rare occurrence.

TABLE 4

Complications after the Most Invasive Screening-Related Diagnostic Evaluation Procedure, According to Lung-Cancer Status.

Incidence, Characteristics, and Treatment of Lung Cancers

A total of 1060 lung cancers (645 per 100,000 person-years) were diagnosed in the low-dose CT group, as compared with 941 (572 per 100,000 person-years) in the radiography group (rate ratio, 1.13; 95% confidence interval [CI], 1.03 to 1.23). In the low-dose CT group, 649 cancers were diagnosed after a positive screening test, 44 after a negative screening test, and 367 among participants who either missed the screening or received the diagnosis after their trial screening phase was over (Table 5). In the radiography group, 279 cancers were diagnosed after a positive screening test, 137 after a negative screening test, and 525 among participants who either missed the screening or received the diagnosis after their trial screening phase was over. Figure 1A shows the cumulative number of lung cancers through

TABLE 5

Stage and Histologic Type

December 31, 2009, according to the screening group. Detailed calculations of sensitivity, specificity, positive predictive value, and negative predictive value are not reported here.

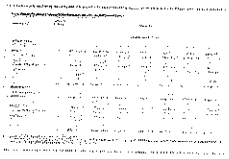
of Lung Cancers in the Two Screening Groups, According to the Result of Screening.

In each group, the percentage of stage IA and stage IB lung cancers was highest among cancers that were diagnosed after a positive screening test (Table 5). Fewer stage IV cancers were seen in the low-dose CT group than in the radiography group at the second and third screening rounds (Table 2 in the Supplementary Appendix). Low-dose CT screening identified a preponderance of adenocarcinomas, including bronchioloalveolar carcinomas. Although the use of the term bronchioloalveolar carcinoma is no longer recommended,[23] while the NLST was ongoing, the term was used to denote in situ, minimally invasive, or invasive adenocarcinoma, lepidic predominant (i.e., neoplastic cell growth restricted to preexisting alveolar structure). In both groups, many adenocarcinomas and squamous-cell carcinomas were detected at either stage I or stage II, although the stage distribution was more favorable in the low-dose CT group than in the radiography group (Table 6). Small-cell lung cancers were, in general, not detected at early stages by either low-dose CT or radiography. A total of 92.5% of stage IA and stage IB cancers in the low-dose CT group and 87.5% of those in the radiography group were treated with surgery alone or surgery combined with chemotherapy, radiation therapy, or both (Table 3 in the Supplementary Appendix).

FIGURE 1

Cumulative Numbers of Lung Cancers and of Deaths from Lung Cancer.

TABLE 6



Histologic Type of Lung Cancers in the Two Screening Groups, According to Tumor Stage.

Lung-Cancer–Specific Mortality

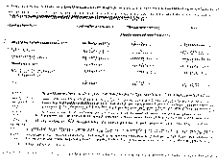
After the accrual of 144,103 person-years in the low-dose CT group and 143,368 person-years in the radiography group, 356 and 443 deaths from lung cancer in the two groups, respectively, had occurred, corresponding to rates of death from lung cancer of 247 and 309 deaths per 100,000 person-years, respectively, and a relative reduction in the rate of death from lung cancer with low-dose CT screening of 20.0% (95% CI, 6.8 to 26.7; P=0.004). Figure 1B shows the cumulative number of deaths

from lung cancer in the two screening groups through January 15, 2009. When only participants who underwent at least one screening test were included, there were 346 deaths from lung cancer among 26,455 participants in the low-dose CT group and 425 deaths among 26,232 participants in the radiography group. The number needed to screen with low-dose CT to prevent one death from lung cancer was 320.

Overall Mortality

There were 1877 deaths in the low-dose CT group, as compared with 2000 deaths in the radiography group, representing a significant reduction with low-dose CT screening of 6.7% (95% CI, 1.2 to 13.6) in the rate of death from any cause (P=0.02). We were unable to obtain the death certificates for two of the participants in the radiography group who died, but the occurrence of death was confirmed through a review by the end-point verification team. Although lung cancer accounted for 24.1% of all the deaths in the trial, 60.3% of the excess deaths in the radiography group were due to lung cancer (Table 7). When deaths from lung cancer were excluded from the comparison, the reduction in overall mortality with the use of low-dose CT dropped to 3.2% and was not significant (P=0.28).

TABLE 7



Cause of Death on the Death Certificate, According to Screening Group.

DISCUSSION

In the NLST, a 20.0% decrease in mortality from lung cancer was observed in the low-dose CT group as compared with the radiography group. The rate of positive results was higher with low-dose CT screening than with radiographic screening by a factor of more than 3, and low-dose CT screening was associated with a high rate of false positive results; however, the vast majority of false positive results were probably due to the presence of benign intrapulmonary lymph nodes or noncalcified granulomas, as confirmed noninvasively by the stability of the findings on follow-up CT scans. Complications from invasive diagnostic evaluation procedures were uncommon, with death or severe complications occurring only rarely, particularly among participants who did not have lung cancer. The decrease in the rate of death from any cause with the use of low-dose CT screening suggests that such screening is not, on the whole, deleterious.

A high rate of adherence to the screening, low rates of lung-cancer screening outside the NLST, and thorough ascertainment of lung cancers and deaths contributed to the success of the NLST. Moreover, because there was no mandated diagnostic evaluation algorithm, the follow-up of positive screening tests reflected the practice patterns at the participating medical centers. A multidisciplinary team ensured that all aspects of the NLST were conducted rigorously.

There are several limitations of the NLST. First, as is possible in any clinical study, the findings may be affected by the "healthy-volunteer" effect, which can bias results such that they are more favorable than those that will be observed when the intervention is implemented in the community.[24] The role of this bias in our results cannot be ascertained at this time. Second, the scanners that are currently used are technologically more advanced than those that were used in the trial. This difference may mean that screening with today's scanners will result in a larger reduction in the rate of death from lung cancer than was observed in the NLST; however, the ability to detect more abnormalities may result only in higher rates of false positive results.[25] Third, the NLST was conducted at a variety of medical institutions, many of which are recognized for their expertise in radiology and in the diagnosis and treatment of cancer. It is possible that community facilities will be less prepared to undertake screening programs and the medical care that must be associated with them. For example, one of the most important factors determining the success of screening will be the mortality associated with surgical resection, which was much lower in the NLST than has been reported previously in the general U.S. population (1% vs. 4%).[26] Finally, the reduction in the rate of death from lung cancer associated with an ongoing low-dose CT screening program was not estimated in the NLST and may be larger than the 20% reduction observed with only three rounds of screening.

Radiographic screening rather than community care (care that a participant usually receives) was chosen as the comparator in the NLST because radiographic screening was being evaluated in the PLCO trial at the time the NLST was designed.[11] The designers of the NLST reasoned that if the PLCO trial were to show a reduction in lung-cancer mortality with radiographic screening, a trial of low-dose CT screening in which a community-care group was the control would be of less value, since the

standard of care would have become screening with chest radiography. Nevertheless, the choice of radiography precludes a direct comparison of low-dose CT with community care. Analysis of the subgroup of PLCO participants who met the NLST criteria for age and smoking history indicated that radiography, as compared with community care, does not reduce mortality from lung cancer.[27] Therefore, a similar reduction in lung-cancer mortality would probably have been observed in the NLST if community care had been chosen instead for the control group.

In addition to the high rate of false positive results, two other potentially harmful effects of low-dose CT screening must be mentioned. Overdiagnosis, a major source of controversy surrounding low-dose CT lung-cancer screening, results from the detection of cancers that never would have become symptomatic.[28] Although additional follow-up would be necessary to measure the magnitude of overdiagnosis in the NLST, a comparison of the number of cancers diagnosed in the two trial groups suggests that the magnitude of overdiagnosis with low-dose CT as compared with radiographic screening is not large. The other harmful effect, the association of low-dose CT with the development of radiation-induced cancers, could not be measured directly, is a long-term phenomenon, and must be assessed in future analyses.[29]

A number of smaller, randomized trials of low-dose CT screening are under way in Europe.[30-36] Because none of these trials have sufficient statistical power to detect a reduction in lung-cancer mortality of the magnitude seen in the NLST, it is expected that meta-analyses of the findings from these trials will be performed. The European studies are gathering types of data that were not collected by the NLST and will be able to address additional questions about low-dose CT screening, including the best strategies for the management of nodules observed with screening.[37]

The observation that low-dose CT screening can reduce the rate of death from lung cancer has generated many questions. Will populations with risk profiles that are different from those of the NLST participants benefit? Are less frequent screening regimens equally effective? For how long should screening continue? Would the use of different criteria for a positive screening result, such as a larger nodule diameter, still result in a benefit? It is unlikely that large, definitive, randomized trials will be undertaken to

answer these questions, but modeling and microsimulation can be used to address them. Although some agencies and organizations are contemplating the establishment of lung-cancer screening recommendations on the basis of the findings of the NLST, the current NLST data alone are, in our opinion, insufficient to fully inform such important decisions.

Before public policy recommendations are crafted, the cost-effectiveness of low-dose CT screening must be rigorously analyzed. The reduction in lung-cancer mortality must be weighed against the harms from positive screening results and overdiagnosis, as well as the costs. The cost component of low-dose CT screening includes not only the screening examination itself but also the diagnostic follow-up and treatment. The benefits, harms, and costs of screening will all depend on the way in which low-dose CT screening is implemented, specifically in regard to the eligibility criteria, screening frequency, interpretation threshold, diagnostic follow-up, and treatment. For example, although there are currently only about 7 million persons in the United States who would meet the eligibility criteria for the NLST, there are 94 million current or former smokers6 and many more with secondhand exposure to smoke or other risk factors. The cost-effectiveness of low-dose CT screening must also be considered in the context of competing interventions, particularly smoking cessation. NLST investigators are currently analyzing the quality-of-life effects, costs, and cost-effectiveness of screening in the NLST and are planning collaborations with the Cancer Intervention and Surveillance Modeling Network to investigate the potential effect of low-dose CT screening in a wide range of scenarios.

Other strategies for early detection of lung cancer — in particular, molecular markers in blood, sputum, and urine, which can be studied in specimens that were obtained as part of ACRIN's NLST activities and are available to the research community — may one day help select persons who are best suited for low-dose CT screening or identify persons with positive low-dose CT screening tests who should undergo more rigorous diagnostic evaluation.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

The members of the writing team (who are listed in the Appendix) assume responsibility for the integrity of the article.

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We thank the trial participants for their contributions in making this trial possible.

SOURCE INFORMATION

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A complete list of members of the National Lung Screening Trial research team is provided in the Supplementary Appendix, available at NEJM.org.

Appendix

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Exhibit C

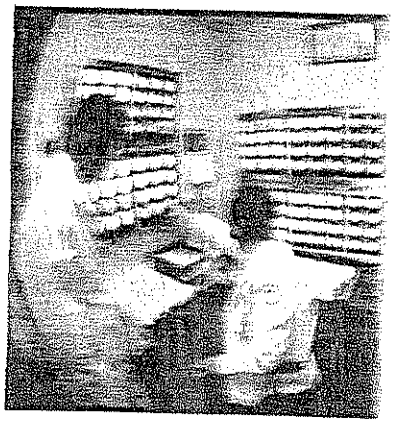
Publication of USFDA

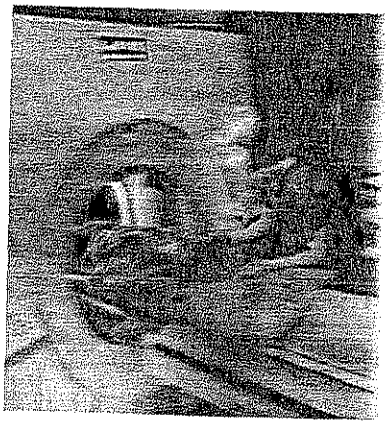
FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Home | What is CT? | What are the Radiation Risks From CT? | Should I get "whole body" CT? | How does FDA regulate CT? | Other Resources | Radiation Quantities and Units | Contact Us

Brochure: Full-Body CT Scans *What You Need to Know*





Using a technology that "takes a look" at people's insides and promises early warnings of cancer, cardiac disease, and other abnormalities, clinics and medical imaging facilities nationwide are touting a new service for health-conscious people: "Whole-body CT screening." This typically involves scanning the body from the chin to below the hips with a form of X-ray imaging that produces cross-sectional images.

The technology used is called "X-ray computed tomography" (CT), sometimes referred to as "computerized axial tomography" (CAT). A

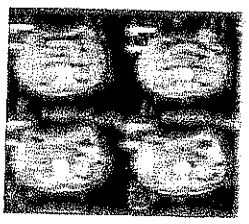
number of different types of X-ray CT systems are being promoted for various types of screening. For example, "multi-slice" CT (MSCT) and "electron beam" CT (EBCT) - also called "electron beam tomography" (EBT) - are X-ray CT systems that produce images rapidly and are often promoted for screening the buildup of calcium in arteries of the heart.

CT, MSCT and EBCT all use X-rays to produce images representing "slices" of the body - like the slices of a loaf of bread. Each image slice corresponds to a wafer-thin section which can be viewed to reveal body structures in great detail.

CT is recognized as an invaluable medical tool for the diagnosis of disease, trauma, or abnormality in patients with signs or symptoms of disease. It's also used for planning, guiding, and monitoring therapy. What's new is that CT is being marketed as a preventive or proactive health care measure to healthy individuals who have no symptoms of disease.

No Proven Benefits for Healthy People

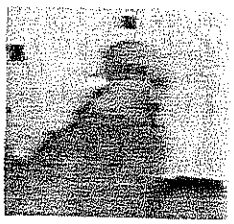
Taking preventive action, finding unsuspected disease, uncovering problems while they are treatableÑ these all sound great, almost too good to be true! In fact, at this time the Food and Drug Administration (FDA) knows of no scientific evidence demonstrating that whole-body scanning of individuals without symptoms provides more benefit than harm to people being screened. The FDA is responsible for assuring the safety and effectiveness of such medical devices, and it prohibits manufacturers of CT systems to promote their use for whole-body screening of asymptomatic people. The FDA, however, does not regulate practitioners and they may choose to use a device for any use they deem appropriate.



Compared to most other diagnostic X-ray procedures, CT scans result in relatively high radiation exposure. The risks associated with such exposure are greatly outweighed by the benefits of diagnostic and therapeutic CT. However, for whole-

body CT screening of asymptomatic people, the benefits are questionable:

- Can it effectively differentiate between healthy people and those who have a hidden disease?
- Do suspicious findings lead to additional invasive testing or treatments that produce additional risk with little benefit?
- Does a "normal" finding guarantee good health?



Many people don't realize that getting a whole body CT screening exam won't necessarily give them the "peace of mind" they are hoping for, or the information that would allow them to prevent a health problem. An abnormal finding, for example, may not be a serious one, and a normal finding may be inaccurate. CT scans, like other medical procedures, will miss some conditions, and "false" leads can prompt further, unnecessary testing.

Points to consider if you are thinking of having a whole-body screening:

- CT screening has not been demonstrated to meet generally accepted criteria for an effective screening procedure.
- Medical professional societies have not endorsed CT scanning for individuals without symptoms.
- CT screening of high-risk individuals for specific diseases such as lung cancer or colon cancer is currently being studied, but results are not yet available.
- The radiation from a CT scan may be associated with a very small increase in the possibility of developing cancer later in a person's life.
- The FDA provides additional information regarding whole-body CT screening on its Web site at: www.fda.gov/cdrh/ct/

FDA's Recommendation:

Before having a CT screening procedure, carefully investigate and

consider the potential risks and benefits and discuss them with your physician.

DHHS Publication No: (FDA) 03-0001
March 2003

Exhibit D

ACR Practice Guideline

Revised 2006 (Res. 46,17,35)*

ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF PEDIATRIC AND ADULT CHEST RADIOGRAPHY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Chest radiography is a proven and useful procedure for evaluation of the airways, lungs, pulmonary vessels, mediastinum, heart, pleura, and chest wall. The common and accepted practice consists of posteroanterior (PA) and left lateral radiographs obtained in the upright position. Under certain clinical circumstances and in certain patient populations (e.g., critically ill, postoperative, trauma, newborn), portable chest radiography may be indicated and should be performed in accordance with the ACR Practice Guideline for the Performance of Pediatric and Adult Portable (Mobile Unit) Chest Radiography.

(For pediatric considerations, see section V.D.2.)

II. GOAL

The goal of the chest radiographic examination is to help establish the presence or the absence and the etiology of disease processes that involve the thorax or to follow their course.

III. INDICATIONS AND CONTRAINDICATIONS

Indications for chest radiography include, but are not limited to:

A. Evaluation of signs and symptoms potentially related to the respiratory, cardiovascular, and upper gastrointestinal systems, and the musculoskeletal system of the thorax. The chest radiograph may also help to evaluate thoracic disease processes, including systemic and extrathoracic diseases that secondarily involve the chest. Because the lungs are a frequent site of metastases, chest radiography may be useful in staging extrathoracic as well as thoracic neoplasms.

B. Follow-up of known thoracic disease processes to assess improvement, resolution, or progression.

C. Monitoring of patients with life-support devices and patients who have undergone cardiac or thoracic surgery or other interventional procedures.

D. Compliance with government regulations that may mandate chest radiography. Examples include surveillance PA chest radiographs for active tuberculosis or occupational lung disease or exposures, or other surveillance studies required by public health law.

E. Preoperative radiographic evaluation when cardiac or respiratory symptoms are present or when there is a significant potential for thoracic pathology that may compromise the surgical result or lead to increased perioperative morbidity or mortality.

For the pregnant or potentially pregnant patient, see the ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Practice Guideline for General Radiography.

A. Physician

Additionally, physicians interpreting pediatric chest radiographs should also have had 3 months of documented formal training in pediatric radiology, including interpretation and formal reporting of pediatric chest radiographs.

Physicians whose residency or fellowship training did not include the above may still be considered qualified to interpret pediatric chest radiographs when the following are documented:

1. The physician has supervised and interpreted chest radiographs for at least 2 years.
2. An official interpretation (final report) was generated for each study.

B. Radiologic Technologist

If pediatric chest radiography is to be performed, documented training in pediatric chest radiography is required (in addition to the qualifications listed under the general radiography guideline).

V. SPECIFICATIONS OF THE EXAMINATION

A. The written or electronic request for chest radiography should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

B. A standard chest examination should include an erect PA and left lateral projection made during full inspiration. The examination may be modified by the physician or qualified technologist depending on the clinical circumstances (e.g., when young children are not yet able to stand, supine images are performed). Other positions that may be used occasionally include supine, oblique, decubitus, or lordotic. Views in expiration or with nipple markers may also be used. At times a single view, such as an anteroposterior (AP) or PA view is appropriate.

C. The chest radiograph should include both of the lung apices and costophrenic angles. The mid-thoracic vertebral bodies and the left retrocardiac pulmonary vessels should be appropriately defined. The scapulae should be positioned off of the lungs on the PA view, and the arms should be elevated for the lateral view. The vertebral column should be centered between the clavicles. The radiographic beam should be appropriately collimated to include the structures listed while limiting

exposure of the remainder of the patient and should not exceed the geometry of the image receptor.

D. Technical Factors

1. Adults: For a PA chest radiograph, the mean entrance skin exposure (ESE) should not exceed 0.3 mGy per exposure, and the exposure time should not exceed 40 msec. A high-kilovoltage technique (120 to 150 kVp) should be employed. An antiscatter technique (e.g., grid or air gap) should be used that reduces scatter at least as much as a 10:1 grid (preferably 12:1 grid). Technique charts should be posted for use by technologists in the radiographic room. An optimally exposed radiograph should display the lung parenchyma at a mid-gray level.

2. Newborns, infants, and children: In newborns and infants, a supine chest radiograph is preferred. For an AP or PA chest radiograph, the mean ESE should range from 0.05 to 0.3 mGy per exposure, respectively, for a 1-year-old to adult-sized patient using a 200-speed image receptor. The kVp should be selected to provide adequate contrast; it should range from as low as 60 for infants to as high as 150 for adult-sized patients.

   When using high-kVp techniques on larger patients, an antiscatter technique (e.g., grid or air gap) should be selected to reduce scatter equivalent to that of a 10:1 grid (preferably 12:1 grid). After establishing the correct kVp as a function of patient size, a tube current should be selected which makes the exposure time as short as feasible for fixed radiographic units, to minimize patient motion during the exposure. The selected mAs and kVp should produce an image that displays the lung parenchyma at a mid-gray level.

E. The following quality control (QC) procedures should be applied to chest radiography:

1. When the examination is completed, the images should be reviewed by qualified personnel, either a physician or a radiologic technologist.
2. Images of less than optimal diagnostic quality should be repeated as necessary. A repeat-rate program should be part of the QC process.
3. Each film or image should be permanently marked with the patient's name, identification number, right or left side, patient position, and the date and the time of the examination. Labeling the image with the patient's date of birth is strongly recommended.

VI. DOCUMENTATION AND REPORTING

New images should be compared with prior chest examinations and/or other pertinent studies that may be available.

An official interpretation (final report) of the examination should be included in the patient's medical record. Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.

VII. EQUIPMENT SPECIFICATIONS

The equipment requirements include a diagnostic radiographic unit with a rotating anode tube and tube filtration sufficient to achieve a half-value layer (HVL) greater than 3 mm of aluminum at 100 kVp. A grid should be used for adult radiography. At least a 10:1 grid (preferably 12:1 grid) with a minimum of 103 lines per inch (stationary) or 80 lines per inch (reciprocating) is recommended.

Radiographs shall be exposed only with equipment having a beam-limiting device that provides rectangular collimation.

There should be at least a 72-inch source-image distance (SID) to minimize magnification for routine upright projections. A 40-inch SID may be used when clinically necessary (e.g., supine positioning, infants and young children, immobilized patients, etc.).

The nominal source (focal spot) shall not exceed 2.0 mm; 0.6 to 1.2 mm is the recommended range.

For analog studies, intensifying screens shall be used. Any film-screen combination with a speed of at least 200 may be used.

Automatic processing is preferable with carefully controlled temperature and maintenance. A constant time and temperature shall be employed for manual processing.

Photostimulable phosphor plates or digital imaging techniques are an acceptable alternative to film-screen radiography, but require careful quality control. Since image degradation from scattered radiation is greater with photostimulable plates than with film-screen imaging, grids may be needed for radiographs of small patients.

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary

diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)."

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web page (http://www.acr.org/guidelines).

The lowest possible radiation dose consistent with acceptable diagnostic image quality should be used particularly in pediatric examinations. Radiation doses should be determined periodically based on a reasonable sample of pediatric examinations. Technical factors should be appropriate for the size and the age of the child and should be determined with consideration of parameters such as characteristics of the imaging system, organs in the radiation field, lead shielding, etc. Guidelines concerning effective pediatric technical factors are published in the radiological literature.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web page (http://www.acr.org/guidelines) by the Guidelines and Standards Committee of the Commission on General, Small, and Rural Practice.

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Suggested Reading (Additional articles that are not cited in the document but that the committee recommends for further reading on this topic)

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

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2007 (Res. 19)*

ACR PRACTICE GUIDELINE FOR PERFORMING FDG-PET/CT IN ONCOLOGY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline has been developed by the American College of Radiology (ACR) to guide interpreting physicians performing positron emission tomography/computed tomography (PET/CT) with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG) for oncologic imaging in adult and pediatric patients.

FDG-PET is a scintigraphic technique that provides three-dimensional information about the rate of glucose metabolism in the body and is a sensitive method for detecting, staging, and monitoring the effects of therapy for many malignancies. CT uses an external source of radiation to provide three-dimensional images of the density of the tissues in the body. CT images provide information about the size and shape of organs and abnormalities within the body. Combined PET/CT devices [1,2] provide both the metabolic information from FDG-PET and the anatomic information from CT in a single examination. The information obtained by PET/CT has been shown to be more accurate in evaluating patients with known or suspected malignancy than either PET or CT alone or PET and CT obtained separately but interpreted together [3-10].

FDG-PET and CT are proven diagnostic procedures. The advantages of having both PET and CT in a single device have resulted in rapid dissemination of this technology in the United States. Techniques for registration and fusion of images obtained from separate PET and CT scanners have been available for several years and have been shown to improve diagnostic accuracy [11-18]. This practice guideline, however, pertains only to combined PET/CT devices.

Several issues related to PET/CT have arisen and include equipment specifications, image acquisition protocols, supervision, interpretation, professional qualifications, and safety. A discussion of these issues by representatives of the ACR, the Society of Nuclear Medicine, and the Society of Computed Body Tomography and Magnetic Resonance is available [19,20].

II. GOAL

The goal of PET/CT imaging in oncology is to enable the interpreting physician to 1) distinguish benign from malignant disease, 2) determine the extent of disease, 3) detect residual and recurrent tumors, 4) monitor the effect of therapy, and 5) guide therapy.

III. DEFINITIONS

For the purposes of this guideline, the following definitions apply:

PET/CT fusion: The simultaneous display (superimposed or not) of registered PET and CT image sets. When superimposed, the image sets are typically displayed with the PET data color-coded onto the grayscale CT data.

PET/CT registration: The process of taking PET and CT image sets that represent the same body volume and aligning them such that there is a voxel-by-voxel match for the purpose of combined image display (fusion) or image analysis.

PET/CT scanner: A device that includes a single patient table for obtaining a CT scan or PET scan, or both. If the patient stays reasonably immobile between the scans, the PET and CT data are aligned and can be accurately fused.

IV. INDICATIONS

Indications for PET/CT include, but are not limited to, the following:

1. Evaluating an abnormality detected by another imaging method to determine the level of metabolism and the likelihood of malignancy.
2. Searching for an unknown primary tumor when metastatic disease is discovered as the first manifestation of cancer.
3. Staging patients with known malignancy.
4. Monitoring the effect of therapy on known malignancies.
5. Determining if residual abnormalities on imaging studies following treatment represent tumor or post-treatment inflammation, fibrosis, or necrosis.
6. Detecting recurrence, especially in the presence of elevated tumor markers.
7. Assisting in treatment planning.

PET/CT does not work equally well for all tumors. A continuing review of the literature is recommended to determine the most effective applications.

For the pregnant or potentially pregnant patient, see the ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with ionizing radiation.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

1. All PET/CT examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:
   a. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec; and involvement with the interpretation, reporting, and/or supervised review of 300 PET and/or PET/CT examinations in the past 36 months; 15 hours of PET and PET/CT CME (AMA category 1), at least 8 of which are PET/CT; and meets the physician training and experience requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT)[1], and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

or

[1]Should include cases that are representative of the following areas: abdomen, chest, neck, and pelvis. In meeting the requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic CT, physicians who are certified by the ABNM and have completed the ACGME approved nuclear medicine residency program, can count up to 100 hours of didactic training in CT toward satisfying the 200 hours requirement in the guideline, and 500 CT cases interpreted under the supervision of a physician qualified under the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography.

b. Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved diagnostic radiology residency program or an American Osteopathic Association (AOA) approved diagnostic radiology residency program; and involvement with the interpretation, reporting, and supervised review of 500 or more PET and/or PET/CT examinations in the past 36 months; 15 hours of PET and PET/CT CME (AMA category 1), at least 8 of which are PET/CT; and meets the physician training and experience requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT), and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

or

c. Certification in Nuclear Medicine by the ABNM or in special competence in nuclear medicine by the ABR; and involvement with the interpretation, reporting, and/or supervised review 300 PET and/or PET/CT examinations in the past 36 months; 15 hours of PET and PET/CT CME (AMA category 1), at least 8 of which are PET/CT; and meets the physician training and experience requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT), and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

or

Physicians in the certification/training categories in a, b, and c above, but without the recent PET or PET/CT involvement specified may achieve the required PET/CT training experience equivalent by completing and documenting the following:

i. Physician category a: 150 PET and/or PET/CT interpretations in a supervised situation,[2] at least 100 of which are PET/CT, and 15 hours of PET and/or PET/CT CME, at least 8 of which are PET/CT. The physician training requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals must be met.

ii. Physician category b: 200 PET and/or PET/CT interpretations in a supervised situation, at least 150 of which are PET/CT, and 25 hours of PET and/or PET/CT CME, at least 8 of which are PET/CT. The physician training requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals must be met.

iii. Physician category c: 150 PET and/or PET/CT interpretations in a supervised situation, at least 100 of which are PET/CT, and 15 hours of PET and/or PET/CT CME, at least 8 of which are PET/CT. The physician training requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals must be met.

or

d. Physicians not board certified in radiology or nuclear medicine, or not trained in a diagnostic radiology residency or nuclear medicine program who assume the responsibilities of supervising, interpreting, and reporting PET/CT examinations, should meet the following criteria: completion of an ACGME approved residency program plus 80 hours of PET and PET/CT CME, at least 40 of which are PET/CT, and supervision, interpretation, and reporting of 500 PET/CT cases in a supervised situation. In addition, these physicians must meet the training requirements in the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

[2]Acceptable ways to have PET/CT and CT case interpretations in a supervised situation include practice-based learning locally or in a visiting fellowship, learning in an interactive live case based on conference where an interpretation is rendered and then scored or critiqued, or distance learning such as over the Internet, in an interactive case-based format where an interpretation is rendered and then scored or critiqued, under the supervision or review of physicians expert in the field.

and

2. The physician shall have documented training in the physics of nuclear medicine and diagnostic radiology. Additionally, the physician must demonstrate training in the principles of radiation protection; the hazards of radiation exposure to patients, radiological personnel and the public; handling radiopharmaceuticals; and the appropriate regulatory and monitoring requirements.

and

3. The physician should be thoroughly acquainted with the many morphologic, pathologic, and physiologic radiopharmaceutical distributions with artifacts demonstrated on PET/CT. Additionally, the supervising physician should have appropriate knowledge of alternative imaging methods, including the use and indications for general radiography and specialized studies such as angiography, ultrasonography, magnetic resonance imaging (MRI), and alternative nuclear medicine studies.

and

4. The physician should be familiar with patient preparation for the examination. The physician must have training in and knowledge of the properties of radiopharmaceuticals used as well as in the recognition and treatment of adverse effects of contrast materials that may be employed.

and

5. The physician shall have the responsibility for reviewing all indications for the examination; specifying the radiopharmaceutical dose and the type, dose, and administration rate of any contrast materials employed; specifying imaging technique and protocol; treating and documenting of any adverse reactions and relevant patient counseling; interpreting images; generating official interpretations (final reports); and maintaining the quality of the images and the interpretations.

The required qualifications set forth in section V.A above will become applicable by July 1, 2009. Until then the physician should work toward achieving these requirements in a supervised situation or where expert consultation is readily available.

Maintenance of Competence

All physicians performing PET/CT examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. If competence is assured primarily based on continuing experience, a minimum of 75 examinations per year is recommended in order to maintain the physician's skills. Because a physician's practice or location may preclude this method, continued competency can also be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation.

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The ACR considers certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and is a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this standard are Diagnostic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

The medical physicist or other qualified scientist performing services in support of nuclear medicine facilities should meet all of the following criteria:

1. Advanced training directed at the specific area of responsibility (e.g., radiopharmacy, medical physics, health physics or instrumentation).
2. Licensure, if required by state regulations.
3. Documented regular participation in continuing education in the area of specific involvement to maintain competency.
4. Knowledge of radiation safety and protection and of all rules and regulations applying to the area of practice.

C. Radiologic and Nuclear Medicine Technologist

See the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

Representatives of the Society of Nuclear Medicine and the American Society of Radiologic Technologists (ASRT) met in 2002 to discuss the training of technologists for PET/CT. The recommendations from that consensus conference and the plans for training technologists for PET/CT are given in [21]. As a consequence of this conference and ensuing educational

recommendations, cross-training and continuing educational programs have been developed to educate radiologic, radiation therapy, and nuclear medicine technologists in PET/CT fusion imaging.

The Nuclear Medicine Technology Certification Board (NMTCB) has developed a PET specialty examination that is open to appropriately educated and trained, certified, or registered nuclear medicine technologists, registered radiologic technologists, CT technologists, and registered radiation therapists, as defined on the NMTCB Web site (www.nmtcb.org). The American Registry of Radiologic Technologists (ARRT) offers a CT certification examination for qualified radiologic technologists and allows certified or registered nuclear medicine technologists who have met the educational and training requirements to take this examination. Eligibility criteria are located on the ARRT Web site (www.arrt.org).

VI. SPECIFICATIONS OF THE EXAMINATION

A. The written or electronic request for an FDG-PET/CT examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006)

See the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Extracranial Head and Neck in Adults and Children, the ACR Practice Guideline for the Performance of Pediatric and Adult Thoracic Computed Tomography (CT), and the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Abdomen and Computed Tomography (CT) of the Pelvis.

Sections VI. B, C, E, F below have been copied from an article in the *Journal of Nuclear Medicine Technology*, "Procedure Guideline for Tumor Imaging with ^{18}F-FDG PET/CT 1.0," with permission from the Society of Nuclear Medicine. [22].

B. Patient Preparation

The major goals of preparation are to minimize tracer uptake in normal issues, such as the myocardium and skeletal muscle, while maintaining uptake in target tissues (neoplastic disease). The preparation should include, but not be limited to, the following:

1. Pregnancy testing when appropriate.
2. Fasting instruction and no oral or intravenous fluids containing sugar or dextrose (4 to 6 hours).
3. Serum glucose analysis immediately prior to FDG administration.
4. Hydration (a loop diuretic, without or with bladder) catheterization, may be used to reduce accumulated urinary tracer activity in the bladder.
5. Keeping the patient in a warm room 30 to 60 minutes prior to injection and until the time of FDG injection to help minimize brown fat uptake. Lorazepam or diazepam given prior to injection of FDG may reduce uptake by brown adipose tissue or skeletal muscle. Beta-blockers may also reduce uptake by brown fat.
6. Focused history regarding diabetes, recent exercise, dates of diagnosis and treatments, medications, and recent trauma or infections.

C. Radiopharmaceutical

For adults, the amount of radiopharmaceutical administered should be 370 to 740 MBq (10 to 20 mCi); and for children, 5.18 to 7.4 MBq/kg (0.14 to 0.20 mCi/kg). The radiopharmaceutical should be injected at a site contralateral to the site of concern. With PET/CT, the radiation dose to the patient is the combination of the dose from the PET radiopharmaceutical and the dose from the CT portion of the study.

D. Protocol for CT Imaging

The PET/CT examination can be performed either as a diagnostic PET/CT scan with the CT scan obtained for attenuation correction and anatomic correlation or as a diagnostic PET scan and an optimized CT scan, with or without contrast. If a diagnostic CT scan is requested, the CT protocol appropriate for the body region(s) requested should be used. If the CT scan is obtained for attenuation correction and anatomic correlation, the CT parameters should be set to minimize patient radiation dose, while still ensuring that the CT images are of sufficient quality to allow for accurate anatomic correlation of PET findings.

For the diagnostic CT scan of the abdomen and/or pelvis, an intraluminal gastrointestinal contrast agent may be administered to provide adequate visualization of the gastrointestinal tract unless medically contraindicated or unnecessary for the clinical indication. This may be a positive contrast agent such as dilute barium or Gastrografin, or a negative contrast agent such as water. Highly concentrated barium collections may result in an attenuation-correction artifact that leads to a significant overestimation of the regional FDG concentration [23]; dilute barium and oral iodinated agents cause less overestimation and do not impact image quality [23-26].

When indicated, the CT scan can be performed with intravenous contrast material using appropriate injection techniques. High intravascular concentrations of intravenous contrast agents may cause an attenuation-correction artifact on the PET image [27, 28], but the impact is limited [24,29].

PET and CT findings should be correlated with each other. Clinically important findings on the CT scan should be reported.

Breathing patterns during CT acquisition - for PET/CT the position of the diaphragm should match as closely as possible on the PET emission and the CT transmission images.

E. Protocol for PET Emission Imaging

Emission images are obtained at least 45 minutes following radiopharmaceutical injection. Emission image acquisition time varies from 2 to 5 minutes or longer per bed position for body imaging and is based on the administered activity, patient body weight, and the sensitivity of the PET tomograph (as determined largely by detector composition and acquisition method).

Semiquantitative estimation of tumor glucose metabolism using the standardized uptake value (SUV) is based on relative lesion radioactivity measured on images corrected for attenuation and normalized for the injected dose and body weight, lean body mass, or body surface area. The accuracy of SUV measurements depends on the accuracy of the calibration of the PET tomograph, among other factors. The reproducibility of SUV measurements depends on the reproducibility of clinical protocols, and is affected by dose infiltration, time of imaging after FDG administration, type of reconstruction algorithms, type of attenuation maps, size of the region of interest, changes in uptake by organs other than the tumor, methods of analysis (e.g., max, mean), etc. This measurement is performed on a static emission image typically acquired more than 45 minutes postinjection.

A change of intensity of uptake with semiquantitative measurements, expressed in absolute values and percent change, may be appropriate in some clinical scenarios. However, the technical protocol and analysis of images need to be more consistent in the two sets of images.

F. Interpretation

With an integrated PET/CT system, typically the software packages provide registered and aligned CT images; FDG-PET images and fusion images in the axial, coronal, and sagittal planes; and maximum-intensity-projection (MIP) images for review in the 3D-cine mode. FDG-PET images with and without attenuation correction should be available for review.

Normal and variable physiologic uptake of FDG can be seen to some extent in every viable tissue, including the brain, myocardium (where the uptake is significant in some patients despite prolonged fasting), breast, liver, spleen, stomach, intestines, kidneys and urine, muscle, lymphoid tissue (e.g., tonsils), bone marrow, salivary glands, thymus, uterus, ovaries, testes, and brown adipose tissue.

On whole-body scans, studies have shown that FDG-PET imaging of the brain is relatively insensitive for detecting cerebral metastases, partially related to the high physiologic FDG uptake in the gray matter.

Although the pattern of FDG uptake and specific CT findings as well as correlation with history, physical examination and other imaging modalities are usually the most helpful in differentiating benign from malignant lesions, semi-quantitative estimates (e.g., SUV) may also be of value, especially for evaluating changes with time or therapy.

Processes other than malignancies may cause false-positive and false-negative results. The following list, although not all-inclusive, includes the most commonly encountered causes:

1. False-positive findings
    a. Physiologic uptake that may lead to false-positive interpretations
        - Salivary glands and lymphoid tissue in the head and neck
        - Thyroid
        - Brown adipose tissue
        - Thymus, especially in children
        - Lactating breast
        - Areola
        - Skeletal and smooth muscle (more marked with hyperinsulinemia)
        - Gastrointestinal (e.g., esophagus, stomach, bowel)
        - Urinary tract structures (containing excreted FDG)
        - Female genital tract (e.g., uterus during menses, corpus luteum cyst)

b. Inflammatory processes
   - Postsurgical inflammation/infection/hematoma, biopsy site, amputation site
   - Postradiation (e.g., radiation pneumonitis)
   - Postchemotherapy
   - Local inflammatory disease, especially granulomatous processes (e.g., sarcoidosis, fungal and mycobacterial disease)
   - Ostomy site (e.g., trachea, colon) and drainage tubes
   - Injection site
   - Thyroiditis
   - Esophagitis, gastritis, inflammatory bowel disease
   - Acute and occasionally chronic pancreatitis
   - Acute cholangitis and cholecystitis
   - Osteomyelitis, recent fracture sites, joint prostheses
   - Lymphadenitis

c. Benign neoplasms
   - Pituitary adenoma
   - Adrenal adenoma
   - Thyroid follicular adenoma
   - Salivary glands tumors (e.g., Warthin's, pleomorphic adenoma)
   - Colonic adenomatous polyps and villous adenoma
   - Ovarian thecoma and cystadenoma
   - Giant cell tumor
   - Aneurysmal bone cyst
   - Leiomyoma

d. Hyperplasia/dysplasia
   - Graves' disease
   - Cushing's disease
   - Bone marrow hyperplasia (e.g., anemia, cytokine therapy)
   - Thymic rebound hyperplasia (after chemotherapy)
   - Fibrous dysplasia
   - Paget's disease

e. Ischemia
   - Hibernating myocardium

f. Artifacts
   - Misalignment between PET and CT data can cause attenuation correction artifacts. PET images without attenuation correction and fusion images can be used to help identify these artifacts.
   - Inaccuracies in converting from polychromatic CT energies to the 511 keV energy of annihilation radiation can cause artifacts around metal or dense barium, although these artifacts are less common with newer conversion algorithms.

g. False-negative findings
   - Small size (< 2 x resolution of the system)
   - Tumor necrosis
   - Recent chemotherapy or radiotherapy
   - Recent high-dose steroid therapy
   - Hyperglycemia and hyperinsulinemia
   - Some low-grade tumors (e.g., sarcoma, lymphoma, brain tumor)
   - Tumors with large mucinous components
   - Some hepatocellular carcinomas, especially well-differentiated tumors
   - Some genitourinary carcinomas, especially well-differentiated tumors
   - Prostate carcinoma, especially well-differentiated tumors
   - Some neuroendocrine tumors, especially well-differentiated tumors
   - Some thyroid carcinomas, especially well-differentiated tumors
   - Some bronchioloalveolar carcinomas
   - Some lobular carcinomas of the breast
   - Some skeletal metastases, especially osteoblastic or sclerotic tumors
   - Some osteosarcomas

VII. EQUIPMENT SPECIFICATIONS

See the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET/CT Imaging Equipment, the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Extracranial Head and Neck in Adults and Children, the ACR Practice Guideline for the Performance of Pediatric and Adult Thoracic Computed Tomography (CT), and the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Abdomen and Computed Tomography (CT) of the Pelvis.

A. Performance Guidelines

For patient imaging, the PET/CT scanner should meet or exceed the following specifications:

1. For the CT scanner
   a. Spiral scan time: <5 sec (<2 sec is preferable)
   b. Slice thickness and collimation: <5 mm (<2 mm is preferable)
   c. Limiting spatial resolution: >8 lp/cm for >32 cm display field of view (DFOV) and >10 lp/cm for <24 cm DFOV
2. For the PET scanner
   a. In-plane spatial resolution: <6.5 mm
   b. Axial resolution: <6.5 mm
   c. Sensitivity (3D): >4.0 cps/kBq

d. Sensitivity (2D): >1.0 cps/kBq
e. Uniformity: <5%

3. For the combined PET/CT scanner
   a. Maximum co-scan range (CT and PET): >160 cm
   b. Maximum patient weight: >350 lb
   c. Patient port diameter: >59 cm

B. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

C. A fusion workstation with the capability to display CT, PET, and fused images with different percentages of CT and PET blending should also be available.

D. PET/CT scanning done specifically for radiation therapy planning should be performed with a flat table top, immobilization devices as needed, and the use of appropriate positioning systems.

VIII. DOCUMENTATION

A. Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.

In addition, the procedure section should include the dose of radiopharmaceutical, route of administration, uptake time, field of view, patient positioning, and baseline glucose level.

The findings section should include description of location, extent, and intensity of abnormal FDG uptake in relation to normal comparable tissues and describe the relevant morphologic findings related to PET abnormalities on the CT images. An estimate of the intensity of FDG uptake can be provided with the SUV; however, the intensity of uptake may be described as mild, moderate, or intense or in relation to the background uptake in normal hepatic parenchyma (average SUV weight: 2.0 to 3.0, maximum SUV: 3.0 to 4.0). If the CT scan was requested and performed as a diagnostic examination, the CT component of the study may be reported separately, if necessary to satisfy regulatory, administrative, or reimbursement requirements. In that case, the PET/CT report can refer to the diagnostic CT scan report for findings not related to the PET/CT combined findings.

When PET/CT is performed for monitoring therapy, a comparison of extent and intensity of uptake may be summarized as metabolic progressive disease, metabolic stable disease, metabolic partial response, or metabolic complete response using published criteria for these categories [30].

IX. EQUIPMENT QUALITY CONTROL

PET performance monitoring should be in accordance with the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras and the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET/CT Imaging Equipment.

CT monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment.

The quality control (QC) procedures for PET/CT should include both the CT procedures and the PET procedures according to the ACR Technical Standards. The QC procedures for the CT should include air and water calibrations in Hounsfield units for a range of kV. The QC procedures for PET should include a calibration measurement of activity in a phantom containing a known radionuclide concentration, generally as a function of axial position within the scanner field of view. A daily check on the stability of the individual detectors should also be performed to identify detector failures and drifts.

In addition, for PET/CT, the alignment between the CT and PET scanners should be checked periodically. Such a check should determine an offset between the CT and PET scanners that is incorporated into the fused image display to ensure accurate image alignment.

X. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)."

Facilities, in consultation with the medical physicist should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

XI. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web page (http://www.acr.org/guidelines).

In all pediatric patients, the lowest exposure factors should be chosen that would produce images of diagnostic quality.

For specific issues regarding CT quality control, see the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT).

For specific issues regarding PET and PET/CT quality control, see section IX on Equipment Quality Control.

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment.

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline
2007 (Resolution 19)
Amended 2009 (Resolution 11)

Exhibit E

American College of Radiology September 2002
Statement on CT Screening Exams

amednews.c
AMERICAN MEDICAL NEWS

HEALTH

Full-body scans: Buying peace of mind

This new trend offers patients full-body CT screens to detect serious illnesses e waiting rooms full of patients with stacks of scan reports and worried looks?

By SUSAN J. LANDERS, **amednews staff. Sept. 3, 2001.**

Washington -- The newspaper and magazine ads are enticing. "A simple 15-minute exan "Why take a chance?"

Radiologists who conduct the exams, which are actually full-body computed tomograph earliest stages of several conditions in asymptomatic patients. The conditions range fron wouldn't be attracted to such a marvelous procedure that can help see into a patient's me

But at the same time, this increasingly available screening practice raises tricky issues th exam room and across the health care financing system.

"It's a great concept," said Sandra Fryhofer, MD, immediate past president of the Ameri Society of Internal Medicine. "[But] I don't think we're there yet." It reminds her of a Sta care: "Quick, painless and easy."

The latest series of CT scanners do lend a sci-fi aspect to modern medicine. The machin views of all types of tissue. Targeted CT scans are frequently used to diagnose many can pancreatic cancer. CT scans also are being used to detect early heart disease.

But many physicians take a harsher view of the growing popularity of full-body scans fo the scans subject patients to unnecessary exposure to radiation or to possibly risky follo conditions that frequently turn out to be harmless.

The critics look for the large-scale studies that demonstrate the effectiveness of the body improving patient morbidity and mortality rates. But these studies haven't been done yet

In addition, some fault the expensive screening tests for siphoning off scarce health care initial scan, which ranges from about $800 to more than $1,000, but health insurance co necessary follow-up tests.

Joel Bowers, MD, is the medical director of MillenniumScan, a facility that opened its d months ago. MillenniumScan already performs about 18 full-body scans a day.

Like most such facilities, which are springing up around the country, asymptomatic pati appointments themselves. No physician referral is needed.

In its opening months, MillenniumScan has detected early lung tumors, four brain tumo cancer and a few abdominal aortic aneurysms.

With the less-than-positive news in hand, patients are referred to their family physicians by Dr. Bowers were confirmed by additional tests.

Dr. Bowers is enthusiastic about the effectiveness of the scans. "I've seen a lot of things who has 25 years experience. "And time will tell, but I think this has a lot of potential an

Bradley Jabour, MD, a neuroradiologist and CEO of Smart Heart and Health, a preventi Calif., also supports the use of whole body scans, but with provisos. "If you ensure the a no-radiation scans, thereby providing a test that is both accurate and safe, why wouldn't lives when disease is likely to rear its ugly head?" he said.

Dr. Jabour's facility has established criteria to guide patients to the most appropriate scan certain low-risk patients, such as those younger than 40, those with no family history of

Need for follow-up

The scans do present a conundrum to the primary care physician confronted by a patient frightening news.

Dr. Fryhofer had a Medicare patient who came in with a full-body scan that showed sign a gastroenterologist gave her a clean bill of health.

Even if no other signs of illness are present, a primary care physician can't ignore the sc

"You have an obligation to follow through," Dr. Fryhofer said. "As a primary care physi sure all the i's are dotted and the t's are crossed."

Paul van Gorp, MD, a family physician in Long Prairie, Minn., said the scans might help early, and likely more curable, stage. But he sees problems.

He sees the likelihood that many of the benign conditions detected by the very sensitive use will lead to useless additional evaluations and testing that may cause the patient harm

But he agrees that the findings can't be ignored. "Now you have an objective report that obligated, because of liability issues, to chase it," Dr. van Gorp said.

Even good reports can create a false sense of security.

"There are a whole host of health risks that scans don't touch upon," Dr. van Gorp said. comprehensive health assessment that also addresses such matters as cholesterol levels, detection and such risk factors as immunizations and lifestyle issues, he noted.

But patients whose scans have not revealed any abnormality may be tempted to forgo an

Dr. Bowers argues that his facility works closely with a patient's primary care physician supplemental source of information.

Dr. Bowers also emphasizes that the body scan is a screening study and, like all such stu that will turn out to be nothing. He compares the criticisms of whole body scans to those mammography was introduced.

"There were a lot of naysayers about mammography who said, 'You're going to find all t do about it?' " Dr. Bowers said. While a significant number of breast biopsies done as a s be negative, he noted, "that does not mean that they shouldn't be done."

Studies now show that the mortality rate for breast cancer has gone down significantly, l

Dr. Bowers also said follow-up tests are not necessarily invasive. "Very often, you go fr in many cases, is either not invasive or minimally invasive," he said. For example, the n to have brain tumors was an MRI, not brain surgery.

"I don't think it is a valid argument to say that just because you're going to find many thi nonlethal, that we shouldn't do it," Dr. Bowers said. "It's up to physicians to attack what

FDA concerns

The Food and Drug Administration is keeping an eye on full-body scanning, although n made. The agency has only limited power over the use of the scanners.

"We can address improper claims being made for a particular piece of equipment," said physicist in the FDA's Center for Devices for Radiological Health. "But once a physicia lot the FDA can do about how the individual physician uses that device."

FDA concerns center on the lack of scientific data or evidence that the scans are useful. the benefit to the patient?' There are really no studies that show that they help that much.

Another problem, he added, is that many of the scans are done without the use of an inje that better accentuates the difference between normal and abnormal tissue, thus raising t scan is not the best.

Meanwhile, Robert Smith, PhD, director of the American Cancer Society's screening pr issue. "It's a waste of money and a bad idea," he said.

"As cutting edge as the technique seems, we do not know whether this test is even as go tests that have been around for a long time," he said.

While CT scans hold promise for diagnosing colorectal cancer and lung cancer and dete Smith would rather see those scans performed as stand-alone tests and then only when t person is at risk for a disease.

And Robert Stanley, MD, chair of the Dept. of Radiology at the University of Alabama- mistake for radiologists to be offering the scans to asymptomatic, healthy adults.

In April, Dr. Stanley used his bully pulpit as president of the American Roentgen Ray So take responsibility for giving sound advice and for selecting the appropriate people to sc argument that people have the right to spend their money on the costly procedure.

"But guess who starts paying for biopsies and follow-ups? It's the health insurance comp said. "Once the normal, average person is told there is a nodule in their lung that could b when they were 20 years old -- and now they're 50 -- or it could be a very early cancer -- person's response? No. 1, they'd get anxious, and No. 2, they'd want something done abo

Dr. Jabour has a different view. Using the example of mammography's effectiveness wit way, it's going to prove that when people get older, they will be more likely to have dise and, rather than waiting for the symptoms of those diseases, there will be statistics that s many lives. It's pretty much common sense."

ADDITIONAL INFORMATION:

ACR votes thumbs down

The American College of Radiology's position statement on total body CT screening:

> *"The American College of Radiology (ACR), at this time, does not i scientific evidence to justify recommending total body computed to screening for patients with no symptoms or a family history sugges.*
>
> *"To date there is no evidence that total body CT screening is cost-effective or is eff addition, the ACR is concerned that this procedure will lead to the discovery of nu ultimately affect patients' health, but will result in increased patient anxiety, unnec and treatments and wasted expense.*
>
> *"ACR will continue to monitor scientific studies concerning this procedure."*
>
> -- Sept. 2000

Scanning the promises

Excerpts from ads and Web sites promoting full body CT scans:

- People are taking more responsibility than ever for their own h is absolutely critical for good health.
- Bring a friend with you and receive $50 off both scans.
- As seen on "Oprah."

- Thirty minutes can save a life, your own.
- Enhances the annual physical into the 21st century.

Weblink

The American College of Radiology (http://www.acr.org/)

American Roentgen Ray Society (http://www.arrs.org/)

Society of Cardiovascular and Interventional Radiology (http://www.scvir.org/)

Exhibit F

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Screening in the Dark: Ethical Considerations of Providing Screening Tests to Individuals When Evidence is Insufficient to Support Screening Populations

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Johns Hopkins Bloomberg School of Public Health, and Berman Institute of Bioethics, Johns Hopkins University

Abstract

During the past decade, screening tests using computed tomography (CT) have disseminated into practice and been marketed to patients despite neither conclusive evidence nor professional agreement about their efficacy and cost-effectiveness at the population level. This phenomenon raises questions about physicians' professional roles and responsibilities within the setting of medical innovation, as well as the appropriate scope of patient autonomy and access to unproven screening technology. This article explores how physicians ought to respond when new screening examinations that lack conclusive evidence of overall population benefit emerge in the marketplace and are requested by individual patients. To this end, the article considers the nature of evidence and how it influences decision-making for screening at both the public policy and individual patient levels. We distinguish medical and ethical differences between screening recommended for a population and screening considered on an individual patient basis. Finally, we discuss specific cases to explore how evidence, patient risk factors and preferences, and physician judgment ought to balance when making individual patient screening decisions.

Keywords

computed tomography; decision-making; evidence; ethics; professionalism; screening

During the past decade, screening tests using computed tomography (CT) have disseminated into practice despite neither conclusive evidence nor professional agreement about their efficacy and cost-effectiveness at the population level (United States Preventive Services Task Force [US PSTF] 2004a; Hillman 2003a; Illes et al. 2003; Kalish et al. 2004; Lee and Brennan 2002; American College of Radiology [ACR] 2004). These screening tests often involve CT scans that aim to detect specific diseases, such as chest CT to detect lung cancer

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in smokers or CT angiography to detect cerebral aneurysms. Additionally, whole-body CT screening examinations aim to search for a wide range of possible diseases. Screening CT tests are directed at apparently healthy adults, who may have risk factors such as smoking or family history, to detect disease that has not yet produced symptoms. The hope is that by detecting such diseases at earlier stages, patient outcomes will improve and treatment will be less costly than if detected at a later stage.

The primary goal of population-based screening is to decrease disease-specific mortality (Black & Welch 1997; Kopans et al. 2003; Morrison 1992). Most CT screening tests lack sufficient evidence demonstrating reduction in population mortality and are not recommended by professional societies as population-based screening tools (Administration 2002; Council on Scientific Affairs 2003; Force 2004a; Radiology 2004). Nevertheless, many individual physicians and physician groups offer a variety of screening tests, at times marketing screening services directly to consumers (Illes et al. 2004). Indeed, patients generally seek these tests themselves and, in certain instances, obtain screening tests without a physician's referral ("patient self-referral").

In an era that promotes evidence-based medicine and cost effectiveness, the marketing and diffusion of these CT screening examinations into current practice before rigorous empirical evaluation raises concern. Image-based screening tests carry important risks for patients: CT exposes patients to radiation, and high false positive rates may lead to invasive, risky, and costly follow-up procedures. Further, the detection of pseudo-disease—that is, cancers that grow so slowly that they never produce symptoms or impact a patient's health—leads to interventions and treatments that provide no medical benefit and may pose significant risk (Black and Welch 1993; Malm 1999; Welch 1996, 2001, 2004). Those supporting widely available CT screening, however, argue that the benefits of early detection outweigh these risks. Supporters also consider that patients ought to have access to new screening technology in the pursuit of preventive healthcare, either with or without a physician's referral, and should be able to decide for themselves if the benefits outweigh the risks without waiting several years for the results of rigorous efficacy studies (Brant-Zawadzki 2000, 2002a; Henschke et al. 2006; Siedt 2004).

The early diffusion of CT screening tests into practice raises questions about physicians' professional roles and responsibilities within the setting of medical innovation, as well as the appropriate scope of patient autonomy and access to unproven medical technology. The purpose of this article is to explore how physicians ought to respond when new screening examinations that lack conclusive evidence of overall population benefit emerge in the marketplace and are requested by individual patients. To this end, the article begins by considering the nature of evidence and how it influences decision-making for screening at both the public policy level and at the level of the individual physician and patient. We distinguish important medical and ethical differences between screening that is recommended for a population, and screening that may be considered on an individual-patient basis when population screening is not yet recommended. Finally, we discuss several specific cases in order to explore how evidence, patient risk factors and preferences, and physician judgment ought to balance when making individual patient screening decisions. We shall argue that under most circumstances, physicians should discourage individual patient access to screening examinations prior to conclusive evidence and professional society endorsement of population-based screening. However, there may be certain circumstances under which it could be appropriate to screen patients, provided that well-controlled observational studies have established the possibility of early detection, patients have well-defined risk factors for the screened disease, patients greatly value screening information, and physicians believe the benefits may outweigh the risks for particular patients.

While our discussion will focus on the diffusion of CT screening tests, many of the issues raised by these particular tests can be generalized to other areas of medicine where new technology is introduced and marketed to patients before conclusive evidence and professional agreement exist about its benefit to populations.

THE ROLES AND LIMITATIONS OF EVIDENCE IN GUIDING DECISION-MAKING

Traditional principles of medical ethics, including beneficence, autonomy, and justice (Beauchamp and Childress 2000), help articulate the moral force of grounding treatment decisions in evidence. Ashcroft (2004) writes that advocates of evidence-based medicine (EBM):

> can generally be characterized as having a strong ethical sense of the importance of avoiding unnecessary harms to patients and improving health care in the interests of the general good … This approach had a strong ethical imperative behind it, rooted in concern to do no harm, to do one's best for one's patient, and to do so justly by eliminating waste (131).

Physicians are entrusted with promoting the well-being of patients by recommending treatments that are on balance beneficial. Proponents of EBM assert that only well-designed clinical trials can quantify the risks and benefits of certain treatments to a level of sufficient accuracy, enabling physicians and patients to understand and choose the best course of treatment. Further, evidence regarding the outcomes of treatments applied to well-defined groups of patients can guide policy makers in their efforts to optimally allocate resources, in turn improving distributive justice in the healthcare system.

While there are strong ethical reasons to ground both health policy decisions and individual patient care decisions in evidence, great variability exists in the strength of evidence for tests and therapies in medicine. The traditional "levels of evidence" in EBM, ranging lowest to highest, include expert opinion, single case reports, uncontrolled case series, case series using historical controls, controlled observational studies, and finally randomized controlled trials (RCTs) (Cochrane.org; Meakins 2002). For screening tests, the level of evidence produced by particular study designs has important implications for screening decisions. For example, observational studies, namely case-control or cohort studies, that control for relevant variables in the screened and non-screened groups may reliably demonstrate that a screening test detects disease at an earlier stage. Importantly, however, increased detection of early-stage cancers and prolonged survival represent intermediate endpoints that may not translate into improved morbidity and mortality for the screened population.[1] Observational designs are subject to the effects of lead time, length time, and overdiagnosis biases, and cannot answer the question of whether or not screening improves overall population outcomes, such as disease-specific mortality, considered to be a more important endpoint. (Black and Welch 1997).

RCTs are considered the highest level of clinical evidence (Pocock 1983), and are of particular importance for evaluating screening tests; RCT designs avoid important biases and can provide valid information about whether improves disease-specific mortality in the screened population (Black and Welch 1997) The value of RCTs has been demonstrated via numerous examples in recent history of procedures and devices that were developed and disseminated into practice, only later to be shown in randomized clinical trials to be

[1] *Disease-specific survival* and *disease-specific mortality* are distinct ideas, measured in different ways. Survival statistics are better suited to measuring patient outcomes after treatment of known disease, whereas mortality is better suited to measuring the outcomes of population screening; unlike survival statistics, mortality measurements are resistant to the biases described previously in text.

ineffective or harmful (Cobb et al. 1959; Dimond et al. 1960; Group 1985; Mello and Brennan 2001). Unfortunately, RCTs of screening tests can require thousands of patients, years of follow-up, and high cost to complete. A recent example is the National Lung Screening Trial (NLST), sponsored by the National Cancer Institute (Bethesda, MD), to evaluate the benefit of screening smokers for lung cancer with chest CT. The NLST has enrolled 50,000 patients, will take a total of 8 years to complete, and costs approximately $200 million (Black et al. 2006; Hillman 2003b; Sunshine and Applegate 2004; Swensen et al. 2005). As such, it is not practically feasible to conduct an RCT to evaluate every new screening test.

The level of evidence for various tests or therapies influences the strength and nature of policy recommendations, including population-screening guidelines. For example, the US PSTF and the Physician's Data Query (PDQ) database program have both developed methods for evaluating the scientific evidence behind various preventive medical services, such as screening tests (Franco et al. 2002). The US PTF formulates recommendations of variable strengths depending on the grade, or quality, of evidence, and its recommendations are considered the "gold standard" for preventive services such as screening (Harris et al. 2001; Woloshin et al. 2005; Woolf et al. 1996). According to the US PSTF model, a screening test for which well-designed RCTs demonstrate population benefit, i.e., "level I evidence," may translate to a "grade A" recommendation that there is strong evidence to support screening. Similarly, a screening test for which there are well-designed observational studies, such as a non-randomized cohort or case-control studies, i.e., "level II evidence," may translate into a "grade B" or "grade I" recommendation that there is either fair or insufficient evidence, respectively, to support the test (US PST 2007a; Harris et al. 2001).

While these formalized connections between evidence and clinical guidelines/health policy exist, a subset of physicians and entrepreneurs have marketed CT screening tests directly to consumers before higher-level evidence and professional endorsement exist. This phenomenon raises deeper questions about how evidence ought to play a role in two types of decision-making regarding screening: 1) public policy decisions and practice guidelines to recommend screening for a particular population, and 2) individual decisions between a physician and patient regarding screening. To this end, we shall explore the medical and moral differences between screening activities that are recommended for specific populations, such as mammography for women older than 50 years, and those that have not been recommended for populations but are nonetheless marketed to or requested by individual patients, such as lung CT screening in smokers. The following paragraphs articulate these differences and explain why they may allow different evidence requirements.

Population-Based Screening: Epidemiological Characteristics, Ethical Foundations, Evidence Requirements

Population-based screening is a public health activity. Morrison (1992) has defined population screening as:

> a systematic testing of asymptomatic individuals for preclinical disease. The purpose is to prevent or delay the development of advanced disease in the subset of patients with preclinical disease through early detection and treatment (4).

Cole and Morrison (1980) further specified the objective of cancer screening as "to reduce morbidity and mortality from that cancer among persons screened at a reasonable cost" (1263). Most population-based screening tests possess certain defining features: a disease or risk factor to be detected, a specific population screened, a recommended time interval between screening tests, the sensitivity and specificity of the screening test, and the body of

research evidence concerning the medical benefit and cost-effectiveness of screening (Black and Welch 1997; Morrison 1992). Obuchowski and colleagues (2001) have outlined ten criteria for effective screening that can be used to evaluate the utility and appropriateness of an image-based screening test for a population (Table 1).

Population-based screening tests are typically endorsed by professional societies and governmental bodies, such as the American Cancer Society (Atlanta, GA), the American College of Radiology (Reston, VA), and the US PSTF among others, based upon evidence suggesting that the overall benefits to the target population outweigh the risks (US PSTF 2004; Hillman 2003b). Pap smears, mammograms, and colonoscopies are current examples of screening tests recommended for particular target populations. Given the great investment of public resources for promoting a population-based screening examination and its widespread impact on the public's health, the level of evidence required to support population-based screening should be high, ideally based upon RCT data.[2] Furthermore, Woolf and colleagues (1996) has noted,

> the burden of proof [to demonstrate that interventions result in more good than harm before recommending them to the public] is even more appropriate for preventive services [including screening examinations], which are offered to essentially healthy persons as something "good for them" (514).

Once a screening test is recommended, patient and professional groups advocate for insurance coverage in order to provide broader access to screening, based upon the understanding that all in the target population are entitled to the benefits of screening.

Individually-Requested Screening: Epidemiological Characteristics, Ethical Foundations, Evidence Requirements

We define "individually requested" screening tests as those which have not been recommended at the population level, but which are nonetheless sought by patients or offered by physicians on an ad-hoc basis when either party is concerned about latent disease and believes that early detection may provide life-saving benefits. Individually requested screening tests lack high-level evidence of population benefit from RCTs, and most CT screening tests fit into this category. Examples include lung screening CT in smokers, brain CT angiography (CTA) or magnetic resonance angiography (MRA) screening for cerebral aneurysms, and whole-body screening CT.

The state of evidence for individually requested screening tests varies greatly, from screening examinations with no trial data (as for whole-body screening CT) to examinations for which trials have established that screening detects disease earlier in its course but have not yet concluded that screening improves population outcomes (as for lung CT screening in smokers) (Black et al. 2006; Henschke et al. 2006). Most CT screening examinations are not considered by professional societies, governmental bodies, or insurers to have sufficient levels of evidence of population benefit to recommend population screening. In some cases, such as for cerebral aneurysm screening, professional societies are largely silent and strong guidelines do not exist. In other cases, such as for whole-body CT screening, professional societies actively discourage screening. In the case of lung cancer screening, professional guidelines state that current evidence is insufficient to recommend for or against routine lung cancer CT screening in people older 60 years who have smoked for more than 20 years (US PSTF 2006; Strauss et al. 2005).

[2] It should be noted that groups such as the US PSTF does not always require RCT-type evidence before recommending a screening test: Pap smears, for example, are supported by evidence from multiple observational studies (Woolf et al. 1996).

Despite the lack of endorsement, CT screening tests are readily available for use and direct-to-consumer marketing efforts have encouraged patients to seek screening. Under such circumstances, individual physicians and patients need to consider whether screening is appropriate. This leads to a more fundamental question about how to incorporate existing evidence—specifically, evidence at a level lower than RCT-type evidence—into individual patient care decisions. While the "evidence" of evidence-based medicine is often defined in terms of outcomes-based research on *populations*, applying EBM to *individual* cases is a complex problem. Sackett and colleagues (1996) has stated that:

> EBM is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients, taking into account individual patients' predicaments, rights, and preferences using best evidence from clinically relevant research (71).

Using this concept of EBM, Ashby and colleagues have argued that Bayesian decision-making is a useful model for incorporating evidence from clinical trials into individual patient care decisions (Ashby and Smith 2000). Bayesian models consider the best available evidence based upon population studies, as well as individual patient risk factors, characteristics, values, and the clinician's insights. This approach can be helpful for individual decision-making in light of uncertain or inconclusive evidence. Bayesian belief networks are already being developed to aid in the interpretation and management decisions for patients undergoing mammography (Burnside et al. 2000, 2006). Further, Bayesian decision-making may be particularly useful for individual screening decisions when practice guidelines conclude that there is insufficient evidence to either support or oppose a screening test for a population.

The differences between population-based screening and individually requested screening imply, in our view, that the two types of decision-making may require different levels of evidence. Promoting the good of the population is the main objective of public health policy decisions, which affect large numbers of people and require substantial investment of public resources. Decisions to recommend screening for a population, therefore, should be based upon the highest possible level of evidence of population benefit from clinical trials. Promoting the good of the individual patient is the main objective of individual patient care decisions. Decisions to recommend screening for an individual, therefore, should be based upon an individual's risk profile and preferences in addition to the best available evidence. These individually based decisions, we believe, may not require the higher levels of evidence, such as RCTs, that are desirable for population-based decisions. Rather, individual patient and physician characteristics and values may be given more weight in the decision-making process regarding individually requested screening.

The next section focuses on how physicians ought to respond to patient requests for screening examinations when the population risks and benefits are still uncertain. We examine various combinations of scientific evidence, professional guidelines, patient risk factors and preferences, and physician beliefs in order to more precisely demarcate when an individually requested screening examination is and is not appropriate. Indeed, we suggest that it may be appropriate in certain cases to allow patients access to screening even before RCT-level evidence and professional guidelines support population screening. We include a description of the particular safeguards we feel should be in place when individually requested screening is considered.

ROLES AND RESPONSIBILITIES OF PHYSICIANS REGARDING INDIVIDUALLY REQUESTED SCREENING

Given that many new screening examinations lack the level of evidence to be recommended as population-based screening tools, how should individual physicians respond when their patients express interest in obtaining such examinations? There may be a great deal of pressure from worried patients, industry, medical–legal concerns about missing latent disease, and the technological imperative in medicine to provide new tests, particularly image-based screening tests that visualize the anatomy in spectacular detail.

All physicians who consider adopting new screening technology, in our view, have a minimum set of basic responsibilities to protect the welfare of their patients. First, physicians ought to understand the epidemiological basis for evaluating and recommending screening tests for populations. This includes understanding the pitfalls of length time, lead time, and overdiagnosis biases that compromise the validity of certain study designs, as well as understanding the potential for false-positive and false-negative results and the risks, costs, and psychological stress for patients associated with follow-up tests and procedures. Second, physicians should evaluate the existing literature and consult professional society guidelines regarding screening tests that their patients may request. Such awareness of the state of evidence and professional recommendations is essential in order for physicians to better evaluate whether screening may be in their patients' best interests. This will also help them explain to patients the potential risks, benefits, and uncertainties of the screening examination.

The third basic responsibility for physicians is to advocate or, when possible, be involved in early, formal evaluation of new screening tests for which there is a poor evidence base. We believe that all physicians have a professional duty to incorporate evidence into their decision-making and the field should encourage research to formally evaluate innovative practices. While it is unlikely to be financially or practically feasible to conduct an RCT for each screening test that emerges in practice, other study designs and forms of evidence—well-controlled observational studies and computer-based decision analysis (Gazelle et al. 2005), for example—are more easily produced and may inform screening practices. When feasible, physicians should consider becoming involved in such studies that, when begun early in the application of a new screening test, can gather valuable information about the sensitivity and specificity of the test and provide the initial "proof of concept" that screening can at least detect disease early in its progression (Woolf et al. 1996).

The fourth basic responsibility for physicians is to refrain from engaging in direct-to-consumer advertising of screening services to patients before they are recommended for the population. Research suggests that people often overestimate the benefits and underestimate the risks from various cancer screening tests (Katapodi et al. 2004; Marcus 1999; Schwartz et al. 2004; Vernon 1999; Woloshin et al. 2000). Further, research on direct-to-consumer advertising of pharmaceuticals suggests that many consumers assume that all advertised drugs are safe and/or effective (Bell et al. 1999). It is possible that consumers may falsely infer that any screening examination advertised by physicians offers more benefits than risks and/or is recommended by physicians as a whole. Given the high likelihood of misleading patients, consumer advertising before screening is endorsed for a population, in our view, is unprofessional.

After fulfilling these basic responsibilities, individual physicians will still need to decide whether a new screening test is appropriate for specific patients in their care. Making the decision to screen a patient in light of inconclusive evidence of population benefit is difficult and involves weighing several different factors. We suggest physicians and patients consider

four primary factors, based on the Bayesian approach described earlier, to address these decisions: 1) the strength of evidence and nature of professional recommendations for a particular screening examination, 2) the patient's risk factors for the screened disease, 3) the patient's valuation of screening information, and 4) the clinician's own experience and intuitions. The following paragraphs explore three specific scenarios with variable evidence-based professional recommendations, using the US PSTF language and levels of evidence as a guide when possible. The US PSTF grades the strength of its evidence-based recommendations from "A" (*strongly recommends*), "B" (*recommends*), "C" (*no recommendation for or against*), "D" (*recommends against*), or "I" (*insufficient evidence to recommend for or against*) (Harris et al. 2001). We focus on screening tests with D- and I-type level recommendations, as these are the categories under which most CT screening examinations currently fall, examining how patient characteristics and values and physician preferences ought to weigh and balance at each of these levels. Importantly, we acknowledge that screening decisions will be highly context-dependent, as the nature of disease, risks inherent to the screening test, and invasiveness and costs of follow-up studies will vary greatly among screening tests. Nevertheless, we outline the important considerations for several common CT screening scenarios that physicians and patients may face.

Case 1: Professional Society Guidelines Discourage the Screening Examination. ("Class D"-Type Recommendations)

The first case we consider involves a screening examination that is explicitly discouraged by professional society guidelines, or has a "class D"-type level recommendation. Such screening examinations may have either no or low-quality evidence of benefit for populations or may have sufficiently strong evidence of patient harm. Low-quality evidence includes evidence from uncontrolled case series or poorly controlled observational studies. An example of such a situation would be a whole-body CT scan requested by an asymptomatic, healthy 55-year-old individual with no risk factors except age, who wants to gain peace of mind. There have been no clinical trials to evaluate the benefit of whole-body CT screening, and many professional societies explicitly discourage this examination (US Food and Administration [US FDA] 2002; American Medical Association [AMA] Council on Scientific Affairs 2003; US PSTF 2004a; ACR 2004).

Physicians should generally discourage individual patients from screening when there is no or poor evidence and professional society discouragement, regardless of their personal beliefs about the utility of the examination, the patients' risk profile, and patient beliefs and preferences for screening. There are several reasons for this position. First, in this case, the potential risks and benefits of screening are poorly understood, making it quite difficult for a physician to estimate whether the test will be on balance beneficial. Discouraging screening in such cases coheres with a physician's professional duties to protect patients from tests that may cause more harms than benefits, including diagnostic screening tests of great uncertainty. Further, we agree with Doukas and colleagues (1997) that, by educating their patients about the risks and benefits of the screening test, physicians may "articulate the boundaries of their own professional integrity, for patients cannot compel physicians to render services that run counter to their best professional and ethical judgment" (486).

A secondary concern in this case has to do with the judicious use of shared healthcare resources. It has been argued that a just health system should not tolerate the proliferation of expensive, unproven therapies that lead to spiraling costs and shift resources away from more urgent healthcare needs, even if the market would support this (Sox 2001). As care provided to one patient will most likely affect the care available to others, denying patient requests for screening in this case coheres with a physician's duty to act as a prudent

steward of shared healthcare resources by discouraging costly tests with poorly understood likelihood of medical benefit.

Some have argued that as long as informed consent explains the risks, benefits, and uncertainties, patients should be able to access screening services that they believe will benefit them, particularly if they are willing to assume the costs (Amis 2003; Brant-Zawadzki 2002a, 2002b). We disagree with this view, however, particularly for screening tests of class D-type level recommendation. While physicians should generally take into account patient preferences in medical decision-making, screening decisions are particularly complex and challenging. Previous research on screening with mammography, prostate-specific antigen (PSA), and colonoscopy suggests that patients generally tend to overestimate the benefits and underestimate the risks of screening tests (Schwartz et al. 2000, 2004; Silverman et al. 2001; Volk et al. 1999, 2003; Woloshin et al. 2000). Importantly, the recent increase of direct-to-consumer marketing of screening puts patients at risk of making harmful choices in the absence of adequate guidance and constraints. That is, the context has changed such that some information coming from health professionals (i.e. screening advertisements) is not based on a clear, balanced presentation of existing evidence.

Even if the individual requesting the whole-body CT had a good understanding of the uncertainties of the test and believed he would derive great psychological benefit from screening, these potential psychological benefits are inadequate, in our view, to outweigh the potential medical risks, including radiation exposure, false-positive results leading to invasive, risky, and costly follow-up procedures, false negatives, and the detection of pseudo-disease. The primary goal of medicine, including the administration of medical services, is to benefit patients' health (Beauchamp and Childress 2000; Pellegrino 2001). As such, patients should not have free access to any medical test or treatment they desire and can pay for, as they would for other types of goods and services. Indeed, constraining patient autonomy under the conditions of Case 1 is appropriate, in our view, as physicians should actively protect them from medical products of poorly quantified risks and benefits.

A variation on this case includes a situation in which a physician actually believes the benefits of screening could outweigh the harms for a particular patient, despite no or low quality evidence of its benefit and professional societies discouragement. A physician may encounter particular patients with strong risk factors for disease who place great value on the knowledge derived from screening. One example could be a patient with a family history of pancreatic cancer who would like a whole-body CT screen to rule out this aggressive cancer for reassurance. The US PSTF (2004b) recommendations explicitly discourage whole-body CT screening for this purpose. Initial, small prospective studies suggest that screening patients with a strong family history can detect disease early, while the impact of screening on long-term mortality remains unknown (Canto et al. 2006). While cases like these are difficult, were commend a conservative approach that gives more weight to the low level of evidence and to professional society guidelines than to individual patient and physician preferences; clinicians should generally not provide screening examinations that have low level or no evidence and are discouraged by professional societies.

Case 2: Professional Society Guidelines are Neutral or Non-Existent

The second case we consider involves a screening examination for which professional recommendations are either neutral or non-existent. The evidence for such screening examinations may be of low quality, sparse, or in the early stages of production. One current example of this situation could include using magnetic resonance imaging (MRI) and/or MRA of the brain to screen for cerebral aneurysms in patients with a positive family history. The US PSTF does not have specific guidelines for cerebral aneurysm screening. The only

official guideline comes from the Stroke Council of the American Heart Association (Dallas, TX), stating that while current evidence argues neither for nor against population screening, clinicians may consider it for particular patients on an individualbasis. (Bederson et al. 2000). Currently, few studies have evaluated the use of MRI/MRA as screening tests, and there is no evidence that cerebral aneurysm screening benefits population morbidity or mortality (Crawley et al. 1999; The Magnetic Resonance Angiography in Relatives of Patients with Subarachnoid Hemorrhage Study Group 1999). Scenarios such as these are common, and the lack of directive guidelines implies that physicians and patients need to draw upon factors other than evidence to make decisions about screening (Woolf et al. 1996).

Similar to Case 1, physicians and patients should be aware that screening under these circumstances may expose patients to poorly quantified risks and benefits. And, although neutral professional society guidelines may appear an invitation for physicians to engage in screening as they like, there is another reason to be cautious about granting patients access to screening tests that have a poor evidence base: this may slow the progression of research that aims to better characterize the risks and benefits of the test. If physicians were to commonly grant patient requests for unproven screening test when there is no or low quality evidence and neutral guidelines, the motivation to conduct or participate in research trials to formally evaluate the test may diminish. Indeed, granting patients access to such screening tests may lead to their gradual diffusion into practice, potentially becoming understood as standard of care and further delaying our ability to characterize the risks and benefits of a screening examination. As mentioned previously, there are numerous examples of medical treatments that have diffused into practice in such a manner, only later to be proven ineffective or harmful to patients after more formal evaluation. These include internal mammary artery ligation for angina (Cobb et al. 1959; Dimond et al. 1960), internal carotid artery bypass to prevent the recurrence of stroke (Group 1985), and bone marrow transplantation for breast cancer (Mello and Brennan 2001). The delay in rigorous evaluation of these treatments caused thousands of patients to suffer harms from unnecessary and non-beneficial interventions. Thus, commonly allowing patients access to a screening test at a stage when there is no or low-quality evidence of benefit poses a threat to the research enterprise and, ultimately, to patient welfare.

The best approach, in our view, would be for physicians to discourage screening in most cases with neutral or non-existent recommendations and advocate better evaluation of screening. For patients with well-defined risk factors who would greatly value information from a particular screening examination, such as a patient with cardiovascular risk factors and first-degree relatives who have died from cerebral aneurysm rupture, physicians should consider encouraging enrollment in research trials that will bolster the evidence base for a screening test. This may constrain both patient and physician autonomy. However, in general these constraints are justified for all of the reasons given in Case 1: protecting patients from poorly quantified harms, protecting them from possible overestimated expectation of benefits, and curbing waste in the healthcare system. An additional justification is the desire to move research forward in an expedient manner so that the results can benefit individual and population-level decision-making as soon as possible, particularly when professional society guidelines are non-directive.

Case 3: Professional Society Guidelines State Evidence is Insufficient to Recommend For or Against a Screening Test ("Class I" Recommendation)

The last case we consider involves a screening examination with class I-type level recommendations. According to the US PSTF, class-I recommendations state that evidence is insufficient to recommend for or against routine population screening because evidence that the screening test is effective does not exist, is of low quality, or conflicting (US PSTF

2007b). We wish to focus on situations in which the screening test has undergone substantial evaluation and there is valid evidence from properly controlled observational studies suggesting that a screening test detects disease at earlier stages, but data from RCTs has not yet emerged to establish the benefit (or "effectiveness") for population outcomes. These cases, in our view, may be the most complex and controversial. Lung CT screening in smokers is a current example of this situation (USPSTF 2004c). There is great debate in the medical literature about whether it is appropriate to offer smokers chest CT screening, either on an individual basis or at the population level. Smoking is a well-established risk factor for lung cancer. (Samet 1993) and controlled observational trials have established that lung CT in smokers detects lung cancer at earlier stages. Several RCTs are currently underway to determine whether screening smokers will decrease lung-cancer related mortality (Gohagan et al. 2004; NLST 2007; Swensen et al. 2005; Xu et al. 2006) Those in favor of screening worry that patients are being deprived of a life-extending test while we wait for RCT-level data to arrive (Henschke et al. 2006). Others counter that there is no guarantee that early detection will lead to a reduction in population-based mortality, and the relatively great risks and costs associated with the follow-up of asymptomatic lung lesions must be balanced against higher-level proof of population benefit (Patz et al. 2001; Swensen et al. 2005).

Under such circumstances, in light of a class I-type level recommendation, we argue that it may be appropriate for physicians and patients who greatly value potential information from screening to engage in screening provided certain conditions are met. First, the patient should have well-defined risk factors for the disease to be screened. Importantly, these risk factors should be specified by either a group of clinical experts or clinical research collaborators as helpful in defining which patients are likely to benefit from screening. For example, the NLST has used pack-year smoking history and age to demarcate the high-risk population that may benefit from lung cancer screening with chest CT. In order to minimize the risks and maximize the potential benefits from individually based screening, therefore, defined risk factors for the screened disease should exist in order to place a patient within or outside of the potential target population. The second condition for screening under class I-type recommendations is that well-controlled observational trial data should have already established that a screening test increases early detection rates in the target population and that RCTs are well underway. Lung cancer screening with chest CT could meet these two conditions for certain patients.

Under these two conditions, it is reasonable to believe that the benefits of screening could outweigh the harms for an individual patient, even when clinical trials have not yet established a mortality benefit at the population level. While offering screening in this scenario may expose patients to the risks and unknowns of screening and compromise the expediency of research, these drawbacks may be attenuated in certain circumstances; specifically, if previous research and preliminary data from ongoing clinical trials point strongly toward a potential benefit and have well characterized aspects such as sensitivity and specificity of screening, concerns about exposing patients to the harms of screening without any benefit are reduced. Further, for screening tests in which RCTs are ongoing, there is less of a concern that offering patients screening outside of trials jeopardizes the research enterprise. Thus, the threats to patient welfare and research expediency in Case 3 may be at a level low enough to allow for patient and physician preferences to weigh more heavily in the decision of whether or not to screen.

As Malm (1999) has argued, while it is important to ground population-based screening recommendations in the best possible evidence rather than upon assumptions about the value of early detection, "a screening recommendation is ethically justified only if the test reasonably can be expected to be beneficial on balance to the person taking it" (33). Under the two conditions described previously, we believe that individual physicians and patients

may have adequate information to expect a screening test to be beneficial on balance. Indeed, denying all individual requests for any screening examination until the completion of RCTs is too rigid, absolute, and unrealistic a position for several reasons. First, performing RCTs for every potential screening test will never be practically feasible: the quality of evidence exists on a continuous spectrum, and thinking intelligently about where we are on that spectrum is more important than designating absolute "cutoffs" of evidence below which any screening is unacceptable. Second, it is important to allow some space for individual patient desires and physician judgment to enter the decision-making process under conditions of uncertainty. As we have noted, one option might be to encourage physicians who screen patients before RCT-level evidence is available to contribute their patients' information to a national database that would collect observational data on screening.

We consider briefly the analogy between early access to new screening tests and early access to new pharmaceuticals for severely ill patients who have exhausted standard treatment options. The conflict between conducting thorough research and accommodating individual patient access to promising, potentially life-saving therapies gained unprecedented attention in the midst of the AIDS epidemic in the late 1980s. Severely ill patients who could not gain entry to clinical trials fought for access to those unproven therapies off-label, arguing the risk-benefit analysis made sense given that they were facing certain death. This debate has evolved to the point where many pharmaceutical companies and the US FDA have provisions for granting patients with a variety of severe diseases off-label access ("compassionate use") to investigational new drugs, provided early phase clinical trials have shown promise and certain safeguards are systems are in place to track patient outcomes. (Pfizer 2008; Thompson 2000). Important lessons for screening can be drawn from the history of off-label pharmaceutical use. Yet, while similar ethical tensions arise in both settings—respecting patient autonomy, protecting against unknown risks, promoting population benefits via research—important differences between the nature of screening and treating life-threatening illness may imply a different threshold for access. Certainly, novel pharmaceuticals pose more immediate and potentially more severe harms than do diagnostic screening tests. Likewise, such interventions potentially offer more immediate benefits for severely ill patients than do screening tests for apparently healthy ones. In our view, the more urgent situation of patients without standard treatment options provides a more compelling reason to provide early access, assuming there is adequate surveillance and treatment of adverse events and outcomes, and that clinical trials are already adequately populated to produce population-level evidence.

While it may be appropriate for individual physicians to refer eager patients with defined, specific risk factors for screening in certain cases, it is important that safeguards and quality assurance mechanisms are in place to maximize the benefit of screening under these conditions. The appropriateness of screening also depends upon, we argue, the quality of the informed consent process, quality of screening equipment, and thoroughness of follow-up of screening results with patients and their physicians. Because all of these factors are provided in the controlled setting of a research trial, the option to offer eligible patients trial enrolment is even more attractive. The following paragraphs articulate why these particular features can make screening individual patients appropriate, despite lack of conclusive evidence about population benefit.

Criteria and Safeguards for Granting Patient Access to Unproven Screening Examinations, Outside the Research Context

A critical safeguard for screening patients with an unproven examination is a thorough informed consent process to ensure patients understand the potential risks, benefits, and uncertainties of the screening test. This is particularly crucial given ample evidence to

suggest that people often misperceive the goals or effects of cancer screening, are poor estimators of their personal cancer risk, and are generally enthusiastic about cancer screening (Katapodi et al. 2004; Kreuter 1999; Marcus 1999; Schwartz et al. 2004; Vernon 1999; Woloshin et al. 2000). For example, in a study of the general population's attitudes toward cancer screening, Schwartz and colleagues (2004) found that patients had a strong enthusiasm for cancer screening, both for specific cancers and whole-body screening, even despite past personal experience with false positives and unnecessary work-up. When asked about whole-body CT screening, 86% of respondents wanted a free scan. Of these, 73% would rather have a scan than $1000 and only 27% mentioned there may be a downside to a body CT scan: 14% mentioned false-positive results and 3% unnecessary work-up (Schwartz et al. 2004) Other studies reveal that people are quite tolerant of false positive screening results, have a poor understanding of pseudo-disease, overestimate the benefits from screening, and perceive screening as a primary rather than secondary prevention tool. (Aiken et al. 1995; Domenighetti et al. 2003; Schwartz et al. 2000) As Schwartz and colleagues (2004) have noted, public misperceptions about the benefits and burdens from screening, combined with a "cultural enthusiasm for screening create an environment ripe for the premature diffusion of screening technologies, placing the public at risk of overtesting and overtreatment" (71).

Given evidence that people often misestimate the risks and benefits from both proven and unproven screening examinations, the appropriateness of screening will hinge heavily upon the quality of the informed consent process. For some patients, such a process may dissuade them from screening despite their initial eagerness. For example several studies indicate that men are less likely to be interested in screening for prostate cancer with PSA testing if they are made aware of the 'pros,' 'cons,' and uncertainties during informed consent. (Flood et al. 1996; Volk et al. 1999; 2003; Wolf et al. 1996) The population benefit of routine PSA screening in men older than age 50 years has not been established, and professional society guidelines do not currently recommend routine screening (US PSTF 2002). Many have advocated that risk communication for PSA screening should aim at more neutral informed consent or shared decision-making to help ensure that patients make screening decisions that are in their best interests (Chan and Sulmasy 1998; Chan et al. 2003; Vernon 1999) After patients have an adequate understanding of the risks, benefits, and uncertainties of the screening examination, they can better decide whether such risks and unknowns are acceptable to them.

While we agree that physicians should strive to provide information about risks, benefits, and uncertainties, there will remain disputes in the field about what sort and how much information to provide patients. For example, research suggests that physicians have different notions of what patients should be told about PSA screening during informed consent. A study by Chan and colleagues (2003) revealed that, despite professional guidelines supporting informed decision making, non-urologists were more likely than urologists to rate facts reflecting uncertainty as highly important for men to know, including statements about prostate cancer risk, screening with PSA, and treatment. Individual physicians could be better guided in their approach to consent by more explicit guidelines from professional societies regarding the specific types of risks, benefits, and uncertainties that should be stressed to patients. One interesting model is provided by a recent outline of information for patients about the risks, benefits, uncertainties, and state of evidence associated with lung cancer CT screening. (Strauss et al. 2005).

Another safeguard for screening patients before population screening is recommended involves using screening equipment of adequate quality. Some have expressed concern that the use of older scanners, lack of intravenous contrast, or lack of adequate radiologist training in a particular modality or organ system compromises the sensitivity and specificity

of screening examinations, producing results that are difficult to interpret and may lead to more diagnostic testing (Berlin 2003; Fishman and Horton 2002) For screening tests that have already been validated and considered standard of care, it is likely that guidelines will already exist regarding equipment quality, technical standards, and required physician training. Radiologists reading mammograms, for example, must be certified and are required to read a minimum number of studies per year. Such technical and training guidelines will not exist for screening tests of unproven value, opening the door to variations in techniques and competency potentially harmful to test validation and patient well being. One example of this situation is provided by MRA for cerebral aneurysm detection, where there is preliminary evidence to suggest that the detection rate depends upon the quality of the equipment and the training of the radiologist in three-dimensional imaging of the cerebral vasculature (Schwab et al. 2008).

The final safeguard to providing appropriate screening is to establish routine mechanisms to ensure timely communication of the results to the primary care physician, adequate counseling of patients about the meaning of results, and timely follow-up of any positive findings. Patients should be referred for screening from their primary care physician, who has discussed their understanding of and expectations for screening. The physician's referral, combined with thorough follow-up of results, is particularly important in light of recent data from Illes and colleagues indicating great variability in the manner and extent to which results of self-referred CT screening examinations were communicated with physicians and patients (Illes et al. 2003).

CONCLUSION

Engaging in individual-based screening before population-based screening is endorsed by evidence and professional guidelines raises timeless questions about physicians' duties in the setting of innovation and the scope of patient autonomy to access new technology. We hope that the issues and cases presented here may help guide individual physicians as they consider how to respond to patient requests for new screening examinations.

To best balance the goals of consumer protection, patient autonomy, and prudent innovation, we believe it generally inappropriate for physicians and patients to engage in individually requested screening. There may be a few exceptions, however: when rigorously-designed clinical trials are underway and good evidence already exists to suggest potential population benefit from screening, when well-defined, specific patient risk factors for disease have been articulated, and when patients and clinicians both value screening information. Such screening activities should employ specific safeguards, including careful informed consent, high-quality equipment, and thorough follow-up of results. Despite these individual exceptions, referring physicians and the field as a whole should be vigilant in the appraisal of evidence, and continue to support formal evaluation of new screening examinations. This will better ensure that the best evidence is available for patients and their physicians to make good choices about screening.

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Table 1

Ten Criteria for Effective Screening

1	The disease screened has serious consequences.
2	The screening population has a high prevalence of detectable preclinical disease.
3	The screening test detects little pseudo-disease.
4	The screening test has high accuracy for detecting the detectable preclinical disease.
5	The screening test detects disease at a point in which intervention improves outcome.
6	The screening test causes little morbidity.
7	The screening test is affordable and available.
8	Treatment exists.
9	Treatment is more effective when applied before symptoms begin.
10	Treatment is not too risky or toxic.

Criteria from Obuchowski and colleagues (2001).

Exhibit G

Early Lung Cancer Program Protocol dated July 1, 2011

July 1, 2011

International Early Lung Cancer Action Program: Enrollment and Screening Protocol

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Overview

The International Early Lung Cancer Action Program (I-ELCAP) has as its broad research objective the advancement of knowledge for early diagnosis and treatment of lung cancer. Details of the specific aims and the theoretical basis for the research are given elsewhere (1-15).

The participating institutions need to commit themselves to performing baseline and at least one repeat screening (while more are desirable for precision), and follow-up of at least 10 years of all diagnosed lung cancer cases. It is critical for validity of the I-ELCAP database that each institution is committed to fully document the initial and all subsequent screenings for as long as the screenings on that person continue, and to transmit the documentation to the I-ELCAP database. It is also critical to identify and document all instances of interim diagnosis of lung cancer among the screenees, as well as reasons for instances of discontinuation of the screenings.

The treatment interventions of diagnosed cancers can be selected by each institution. However, each participating institution must be committed to document, for each diagnosed case of lung cancer, not only the timing and nature of the intervention(s) (if any) but also the prospective course in respect to manifestations of metastases.

The development of a protocol has been a concern of the ELCAP (Early Lung Cancer Action Project) Group for more than a decade (1-5), and updatings have been made in the framework of the International Conferences (4) organized by this Group and in their resultant international consortium on screening for lung cancer, I-ELCAP. The research program of I-ELCAP is guided by a common protocol (5, 6) and its approach to long-term follow-up (7, 8). The most recently updated version of the protocol is presented below – with the understanding that the pathology aspects of the screening in the I-ELCAP are guided by a separate protocol specific to its process (9, 10).

In the framework of the I-ELCAP protocol, there is opportunity for the conduct of related *ancillary studies*: various non-CT (e.g., sputum, blood, urine) tests can be deployed parallel with the low-dose CT test. This provides an opportunity for studying their relative merits for one and their value as add-ons for another. Similarly, various treatment options for early lung cancer can be studied.

Admissibility for collaboration

The admissibility criteria for an institution to collaborate in the I-ELCAP are as follows:

1. It is committed to implement the protocol's regimen of early diagnosis specified below, including at least one repeat screening.

2. It submits to the I-ELCAP database the institutional documents which approve the screening and participation in the I-ELCAP; that the institution is committed to conform to the stated requirements, and is amenable to auditing of the data for compliance with those requirements.

3. It is committed to provide the I-ELCAP database with each successive instance of baseline screening, and to fully documenting this and also all repeat screenings.

4. It is committed to identify, and to document, each instance of interim diagnosis of lung cancer, including its symptoms/signs.

5. It is committed to document the reason(s) for discontinuation of screening.

6. It is committed to document the timing and nature of the intervention(s), if any, in each instance of diagnosed lung cancer, including in interim-diagnosed cases.

7. It is committed to follow and document each diagnosed case of lung cancer, interim-diagnosed cases included, until manifestations of metastases, death (its cause), or otherwise, for at least 10 years.

8. It is committed to deploy the ELCAP web-based management system for CT screening for lung cancer, and in this framework to submit all the research data – and images as well as pathology specimens (their digital counterparts) – to the I-ELCAP database.

9. It is committed to conform to all other policies of the I-ELCAP, notably those concerned with quality assurance (below).

It deserves note that among the contributors to I-ELCAP could very well be those studies performing randomized controlled trials (RCTs) contrasting CT screening with either no screening or some other type of screening. Here the relevant contributions would derive from the CT screening arm of such a trial, provided that all of the requirements above would be satisfied.

Indications for screening

As screening is for asymptomatic persons, needed is documentation of the symptom profile, specifically current presence/absence of potential manifestations of lung cancer which include worsening cough, hoarseness, hemoptysis, and unexplained loss of weight. Symptomatic persons are ineligible for enrollment.

Indications for subject participation may vary somewhat, notably as to age and smoking history as these can be set by each participating institution, and those indications must be specified. The person must also be willing to undergo at least one repeat screening on schedule.

Regimen of screening

In this protocol, 'screening' refers to the entire process of the pursuit of early, rule-in diagnosis of lung cancer. It begins with the initial low-dose CT scan. A positive result of this test is followed by further diagnostics, possibly including biopsy and pathologic assessment of the specimen.

It is understood that there may need to be occasional exceptions to the protocol. Each site is fully responsible for performance of the CT scans and the interpretation, and workup recommendations. In those cases for which protocol recommendations are not followed, it is important to document the reasons for this and to record all results of the alternative workup.

Image production

In this regimen, the initial imaging is the same in baseline and repeat screenings. As there are a large variety of CT manufacturers and models, the following are general guidelines for the image production. Scans should be acquired on multi-detector-row scanners with 4 or more rows. Scans should be acquired so that images can be reconstructed at 1.25 mm or less. There is no specific definition of "low-dose," although historically most screening protocols have used scan parameters of

120-140 kVp and 30-100 mAs. **We suggest that scans be obtained at 120 kVp or lower and 40 mAs or lower.** Collimation and pitch also affect dose, and these should be set to allow for the lowest dose, while maintaining acceptable image quality. It may be useful to reconstruct the images using both a standard and high-resolution kernel. Scan parameters may also be adjusted to allow for higher doses on large patients. In addition, new dose reduction techniques are being made available by scan manufacturers, and these may also be used, providing that acceptable image quality is maintained.

Images should be acquired in a single breath from the lung apices through the lung bases. The use of contrast material is not involved. For the workup of lung abnormalities that have been identified, typically the same low dose parameters can be used.

Reading of images

The resulting images are read by a radiologist at the site. The reader is aware that the images derive from the initial CT for early diagnosis of lung cancer, and also is informed of whether they are from baseline or repeat screening. The reader views the images as they are displayed in a high-resolution monitor at their typical window and level settings, scrolling through the images one at a time. For the purposes of assessing the size of a nodule or that of a mediastinal abnormality, however, the following settings are used: lung window width 1500 and lung window level -650, and mediastinal window width 350 and mediastinal window level 25.

For a number of screenings, a second, 'central' reading is done for quality assurance and teaching purposes, without knowledge of the results of the first, site reading. The site radiologist receives the 'central' reading report, with discrepancies, if any, highlighted. In case of a discrepancy, the site radiologist may find it necessary to change the site report; and in this event, the updated report is also submitted to the central facility, where a record is kept. The site radiologist sends the final report to the subject and to his/her referring physician. The quality of the scan and its interpretation is solely the responsibility of the site.

In both baseline and repeat screening, the reader's first concern with the images from the first, low-dose test is to identify all *non-calcified* nodules visible in them. A nodule is manifest as a focal non-linear opacity, whether the nodule be solid, part-solid, or nonsolid (the latter two corresponding to 'ground-glass opacity'), located in the parenchyma or endobronchially. A nodule is classified as non-calcified if it fails to meet the usual criteria for benign, calcified nodules. Thus, a nodule less than 5 mm in diameter is non-calcified if all of it appears less dense than the ribs (on bone and lung windows); a nodule 5-20 mm in diameter is non-calcified if most of it is non-calcified (by that criterion) and/or the calcification does not correspond to a classical benign pattern (complete, central, lamellated, popcorn) and/or the edge is spiculated (to any extent); and a nodule over 20 mm in diameter is non-calcified if any part of it is non-calcified (by the criterion above).

The reader documents each of the nodules that even alone would have made the result positive. Specifically, as for each of these nodules, the reader documents the location, size, consistency ('solid,' 'part-solid' or 'nonsolid'), presence of calcifications, edge and presence of spiculations. A nodule is classified as part-solid if it has patches within it that completely obscure the lung parenchyma, and non-solid if none of the lung parenchyma in it is completely obscured (11). In making the distinction between part-solid and nonsolid nodule, blood vessels within the nodule, despite their appearance as solid components, are not regarded as solid components.

Nodule diameter is the average of length and width. Length is measured on a single CT image that shows the maximum length; width, defined as the longest perpendicular to the length, is measured on

the same CT image. In I-ELCAP research these measures will be replaced by computer-based assessments of volume when there is sufficient evidence of their validity.

The reader also documents other findings in the chest, including those in the mediastinum, heart, soft tissues, and bones.

Mediastinal masses can occur anywhere in the mediastinum, including in the thymus, heart, and esophagus; and a mass in the neck, such as the thyroid, may extend into the mediastinum. Such mediastinal and soft tissues masses are documented as to location and size. The reader also documents findings in the visualized upper abdomen as to location and size.

Each coronary artery is identified (main, left anterior descending, circumflex, and right). Evidence of calcification in each artery is documented as none, minimal, moderate, or severe, scored as 0, 1, 2, and 3, respectively. Minimal calcification was defined if less than 1/3 of the length of the entire artery, moderate as 1/3-2/3, and severe as more than 2/3 shows calcification. With 4 arteries thus scored, each subject received a CAC score in the range from 0 to 12.

The extent of emphysema is identified and classified as none, mild, moderate, or severe, each being scored 0 to 3, respectively. Mild emphysema is defined by having no discrete areas of decreased CT attenuation but splaying of blood vessels suggesting parenchymal expansion or having occasional discrete areas of decreased attenuation; moderate emphysema if discrete areas of decreased attentuation can be identified involving less than half of the lung parenchyma; and, severe emphysema if discrete areas of decreased attenuation can be identified involving more than half of the lung parenchyma. Each subject receives an emphysema score in the range from 0 to 3.

Screening frequency

When application of the regimen at baseline does not lead to the diagnosis of malignancy, repeat screening is scheduled for a preset time subsequent to the initial, low-dose test at baseline. Whereas the protocol calls for annual repeat screening, each institution is free to choose the timing of the repeat screening. In reality, however, practicality leads to variation in this preset interval. Such variations do not threaten the validity of the study, so long as they arise from compelling circumstantial matters (and thereby are as though randomly assigned) and these would provide an opportunity to study the implications of different intervals to repeat screening (in the regimen) as for the resultant diagnostic distribution.

If Stage I, II or IIIA lung cancer is diagnosed, screening may be continued with the original schedule after the intervention is completed.

Baseline screening

At *baseline* the result of the initial CT is positive if at least one solid nodule, part-solid nodule, or solid endobronchial nodule 5.0 mm or more in diameter is identified (11-15). When non-calcified nodules are identified but all of them are too small to imply a positive result, including a nonsolid nodule of any size, the result is semi-positive and calls for CT 12 months after the initial one at baseline. If no nodules are identified, the test is negative, a repeat CT is to be performed 12 months later.

When the result is positive, further diagnostic work-up concerns all nodules which even alone would

have made the result positive. However, the work-up is different according to the size of the largest nodule.

For solid and part-solid nodules 5 mm but less than 15 mm, there are two options. The preferred option (A) is to perform another low-dose non contrast CT 3 months later; if it shows growth at a malignant rate (see growth assessment), biopsy is recommended; if there is no growth or partial or complete resolution, the workup stops. If the nodule is solid and greater than 10 mm in diameter or the solid component of a part-solid nodule is greater than 10 mm in diameter, then another option (B) is to perform PET scan and if the result is positive, biopsy is recommended, while if negative or indeterminate a low-dose CT 3 months later is performed and acted on as specified in option A. When multiple nodules are present and occult infection or inflammation is a possibility, an added option (C) is a course of a broad-spectrum antibiotic with anaerobic coverage followed by low-dose CT 3 months later (13) and the result is acted on as specified in option A.

For solid and part-solid nodules 15 mm or larger in diameter two additional options are available. If the nodule appearance is highly suggestive of lung cancer, immediate biopsy is one option (D). As occult infection is a possibility, option (E) is a course of an antibiotic with anaerobic coverage followed by low-dose CT 1 month later (13); if the CT shows no resolution or growth at a malignant rate (see growth assessment), biopsy is recommended. If there is partial or complete resolution on CT, the workup stops.

If a solid endobronchial nodule 5.0 mm or more is identified, a low-dose non-contrast CT scan is performed within 1 month. At the time of the follow-up CT scan, the participant is asked to cough vigorously several times. If the nodule is still present, the participant is referred for pulmonary consultation, and if necessary, bronchoscopy.

For all individuals in whom the diagnostic work-up was stopped or the biopsy did not lead to a diagnosis of lung cancer, repeat CT 12 months after the initial baseline CT is to be performed.

Repeat screening

On *repeat* screenings, again, the reader's first concern with the initial CT is to identify all non-calcified nodules, but now *regardless of size*, and with special regard for the nodules(s), if any, that produced a semi-positive result on the initial CT at baseline. The focus, among these, is on those nodules that are showing *growth* since the previous screen, of overall size or the size of the solid component if previously part-solid, or appearance of a solid component if previously nonsolid. To determine whether growth has occurred, the reader compares the current images with the corresponding previous ones, displayed side-by-side.

On repeat screening, the result of the initial, low-dose CT test is positive if at least one non-calcified solid or part-solid nodule 3 mm or larger, or a solid endobronchial nodule 5.0 mm or larger in diameter with interim growth is identified, whether newly seen or seen in retrospect but not previously identified. If a new solid or part-solid nodule less than 3 mm or nonsolid nodule of any size is identified, the result is semi-positive and calls for CT 12 months later. If the test is negative, a repeat CT is to be performed 12 months later.

The documentation of the repeat-screen nodules of record -- ones that even alone would have made the test result positive -- is analogous to that at baseline, except that this documentation is supplemented by the corresponding characterization of the nodule in the previous screen. The further diagnostic workup depends on the size and consistency (solid or part-solid) of the nodule(s) of

record.

If all the non-calcified newly identified solid or part-solid nodules are more than 3.0 mm but less than 5.0 mm in diameter, low-dose non contrast CT at 6 months after the prior one is to be performed; any nodule with further growth at a malignant rate (see growth assessment) is recommended for biopsy; if growth is not at a malignant rate or no growth is seen in any of the nodules or they have completely or partially resolved the workup stops.

If at least one of the newly identified noncalcified nodules, either solid or part-solid, is 5 mm in diameter or larger, the preferred option (A) is an immediate course of a broad-spectrum antibiotic with anaerobic coverage followed by low-dose CT 1 month after the prior low-dose test. If it shows growth (see growth assessment), biopsy is recommended; if there is complete or partial resolution, the workup stops. If the nodule is unchanged, then there are two options (B) and (C). Option (B) is to perform a low-dose CT 3 months after the initial CT and if it shows growth, biopsy is recommended, otherwise the workup stops. Option (C), preferably for solid nodules 10 mm or larger and part-solid nodules whose solid component is 10 mm or larger, is to perform PET scan and if it is positive, immediate biopsy is recommended while if it is indeterminate or negative, low-dose CT 3 months after the initial CT is performed. If the nodule shows growth on this follow-up CT, biopsy is recommended, otherwise the workup stops.

If a solid endobronchial nodule 5.0 mm or more is identified, a low-dose non-contrast CT scan is performed within 1 month. At the time of the follow-up CT scan, the participant is asked to cough vigorously several times. If the nodule is still present, the participant is referred for pulmonary consultation, and if needed, bronchoscopy.

For all individuals in whom the work-up was stopped or the biopsy did not lead to a diagnosis of lung cancer, repeat CT 12 months after the prior baseline or repeat CT is to be performed.

Assessment of growth

Growth of a nodule is defined as enlargement of the entire nodule and/or of the solid component of a part-solid nodule and/or the development of a solid component in a nonsolid nodule on the follow-up CT after the initial annual repeat CT. Short-term assessment of growth, based on CT images, includes consideration of the measurement error and whether nodule volume doubling rate is consistent with malignancy. Volume doubling rates are based on measuring the change in nodule volume from two time separated scans. The time between these two scans must be sufficiently long for a significant detectable change in volume to occur.

The initial low-dose CT scan is used for the initial nodule measurement. All subsequent CTs of the nodule(s) are again performed at low-dose, ideally with the same scanning parameters that were used to acquire the initial images. The use of contrast material is not involved.

Conservative criteria for a significant percent change in the nodule diameter or growth of the solid component in part-solid nodules are: a) for nodules < 5 mm in diameter, it should be at least 50%; b) for nodules 5 - 9 mm in diameter, it should be at least 30%; c) for nodules ≥ 10 mm in diameter, it should be at least 20%. The time between the serial CT scans to observe these changes is given in the baseline and repeat screening sections of this protocol. A very rapid growth rate in the relevant time period is more suggestive of an infection than a malignancy and in this case a course of antibiotics followed by CT 1 month later is to be performed.

Computer assisted growth rate is still a topic of research, and there is variation among the different software that is currently available. These guidelines have been developed as a result of the evaluation of our in house software, and may differ from others, including those that are commercially available. With careful technical and clinical quality review as outlined below, the results of computer analysis are useful in guiding the workup. In this assessment, the screening site has access to having an analysis performed using the ELCAP web-based research tools (16-20). When using any computer assisted software, the radiologist must be satisfied with the quality of the CT images and the computer segmentation results as ultimately it is clinical judgment that determines whether growth has occurred. The computer scans and the segmentation should be inspected for image quality (e.g., motion artifacts) and for the quality of the segmentation. The radiologist should visually inspect both nodule image sets side-by-side to verify the quality of the computer segmentation for each image that contains a portion of the nodule. The segmentations should also be examined for extreme errors such as when a vessel is segmented as part of a nodule in one scan but not in the other. Scan slice thickness should not exceed one-third of the nodule size. Also, use of automated algorithms when there is variation in the scanning parameters, in particular, different collimation, should be interpreted with caution.

Communication of results

The results of the interpretation of the initial, low-dose CT scan are sent to the referring physician and the participant. Early-diagnosis regimen is described in the consent form and is to be communicated by the physician to each subject. If, however, the subject or his/her physician refuses to follow the recommended regimen, the actual work-up must be carefully documented using the web-based management system.

Biopsy

For the biopsy procedure, CT-guided percutaneous transthoracic fine-needle aspiration is preferred, as this is a 1-hour, minimally invasive, outpatient procedure performed with local anesthesia at the needle puncture site. If this is not feasible, ultrasound or other guided bronchoscopic biopsy is an option. Video-assisted thoracoscopic (VAT) biopsy can be used; however, use of this procedure requires a very strong suspicion of malignancy. It is recommended that prior to VAT, growth assessment at a malignant rate be performed as well as a PET scan when feasible. The images of the cytology and histology specimens are entered into the web-based management system.

The biopsy specimens are described and classified into standard diagnostic categories. Digital images of the cytology and histology slides are submitted for independent reading by the I-ELCAP Cytology and Pathology Panels. The diagnosis of these panels is used as the final diagnosis for study purposes, and it is documented on the study forms in the I-ELCAP database.

Classification and characterization of diagnosed cancers

A diagnosis (rule-in) of lung cancer is classified as a baseline screen-diagnosis if it results from work-up prompted by a positive result of the initial CT on baseline, regardless of when the diagnosis actually is achieved. It is classified in this way also if the result was 'semi-positive' in the sense of calling for a repeat CT 12 months later -- on the grounds that at least one non-calcified nodule was identified but none met the size criteria for a positive result. If the result of the initial CT at baseline is negative and diagnostic work-up is prompted by suspicion-raising symptoms (or an incidental

finding) before the scheduled first annual repeat screening, it is classified as an interim-diagnosis in the baseline cycle, again regardless of when the diagnosis is achieved. Analogous attributions are applied in the context of repeat-screening cycles.

Each diagnosed cancer is characterized according to indicators of how early and otherwise significant the cancer is – all of this bearing on the prognostic issues. Initially the descriptors are defined on a-priori grounds, as specified in the section below. Ultimately, once enough outcome information is available, the descriptors of prognostic relevance can be selected on the basis of the accrued data.

Principal among these descriptors/indicators is the *clinical stage* of the disease at diagnosis. Clinical Stage I, for purposes of I-ELCAP research, is defined by no manifestations of lymph node metastases in the hila, mediastinum, supraclavicular or axillary regions, nor distant metastases in adrenals, liver, spleen, bones, or soft tissues visible in the chest CT and no signs of metastases on PET scan, if performed. The presence/absence of lymph-node and distant metastases (N and M status) is assessed on the most recent CT scan at the time of diagnosis, and also from a PET scan, if available. The person is still classified as being of clinical Stage I as long as these imaging studies do not demonstrate evidence of lymph node or distant metasases (N0M0) even when there is more than 1 adenocarcinoma, all less than 30 mm in diameter (6, 21, 22). Monitoring and quality assurance is directed to this aspect of the Program.

Closely related to the clinical stage of the disease is the *size* of the tumor, notably within Stage I (23). Quality assurance in respect to this descriptor of the diagnosed malignancies is internal to the I-ELCAP database, as the study data from the images are available for central measurement. Two measurements of size can be used. One of these is the 'diameter' involved in the present regimen of early diagnosis presented above: the 'diameter' is the average of the nodule's length and width. In the analyses, however, an alternative to this may also be used: the nodule volume determined automatically using available software.

Important also is the tumor's *volume doubling rate*. This rate is critical to the early-diagnostic regimen, particularly for tumors less than 15 mm in diameter, and is also presumably quite significant prognostically. This doubling rate can also be derived centrally – and on the basis of automated volumetry (16-20).

Eminently important are the pathology data, especially for the distinction between cell types, most notably small-cell and non-small-cell types (21-25). Further differentiation of adenocarcinoma subtypes are being made (22). Other descriptors of prognostic significance may be added, if data-analysis affirms their relevance. The study data for analysis are, again, derived centrally.

It is hoped that prognostic characterization of the diagnosed cancers can also, in the not too distant future, be in part based on 'biomarkers' of the cancer's degree of aggressiveness. Pursuit of this goal is part of the research aims of I-ELCAP.

Intervention policy

When lung cancer has been diagnosed by the experimental regimen of early diagnosis, that diagnosis creates a situation not inherently one of medical research but of medical practice. The I-ELCAP protocol (of research) naturally does not dictate decisions of practice. However, since the concern in the Program is to learn from the treatment intervention practices, close documentation of the intervention(s) is required. Also important to carefully document is the occurrence of any

complications of the intervention(s), notably surgical death (within 30 days) and other serious complications.

The pathologic stage of the cancer in terms of presence/absence of lymph-node involvement and respective station (N and M status) and intrathoracic extension (M) is based on the surgical findings which are documented. Representative pathology slides are sent for review by the Pathology Panel according to the pathology protocol (10).

Embedded in the framework of the I-ELCAP, there is opportunity to study the relative merits of *alternative interventions*. With select subtypes of lung cancer diagnoses, some institutions may wish to participate in randomized controlled trials (RCTs) designed to address the relative merits of different therapeutic interventions. RCTs on prevention options are also possible, studies directed, for example, to chemoprevention of recurrence.

The choice of intervention, including the decision whether to intervene, naturally is dependent on individualized prognosis under whatever action is considered. To develop new knowledge for the individualization of prognosis, ancillary studies on the role of biomarkers are encouraged among I-ELCAP participants.

The *ELCAP* Management System

For the purposes of I-ELCAP, there is a web-based interactive system to guide the actions, and to document these actions and various findings, from the initial contact to schedule the baseline screening to the end of the follow-up of at least 10 years of a diagnosed case of lung cancer (26). The system is accessed from any computer connected to the Internet at the participating institution. It presents the context-relevant data form and thereby provides for immediate data entry, at the initial contact and at each subsequent encounter. Not only does it guide the actions in any given encounter, but it also schedules the next one. All of the information is automatically transmitted to the institution's data repository. The system monitors protocol conformity as well as completeness and consistency of the data at the time of its entry.

The system also provides for electronic transmission of CT images (using standard DICOM protocols) and digital pathology 'slides' to the institution's repository. This allows for central reading, including the automatic assessment of nodule volumes and rate of growth. At the same time, each participating institution has high-speed computer access to its own data.

The system assures confidentiality and reliability. In the transmission, secure scripts are used. Unique passwords are required for access to particular segments of the central database. Accessing the data from each institution involves built-in encryption to maintain security over the Internet (ssh2 and SSL for web access). Identification of the subject is available only to the participating institution, as only the system-assigned code-identifier is available in the I-ELCAP database.

Quality assurance

In I-ELCAP, quality assurance is a central concern. It begins with application of the criteria for data-contributing institutions' admissibility for collaboration (above), and it is served by the built-in management system described above. Additional elements are an integral part of the I-ELCAP database. These include, but are not limited to: central reading of images for teaching purposes, the training of site coordinators as to the I-ELCAP database, and monitoring of their performance – and

recommending corrective actions, as needed.

A team of professionals consisting of radiologists, pulmonologists, thoracic surgeons, oncologists, and pathologists working together and meeting regularly has proven to be the most important contribution to assurance of quality in implementing the protocol with efficiency and safety. Such a multi-disciplinary team should be formed and serve at every I-ELCAP site.

Qualifications of the radiologists in the participating institutions consist in board-certification and if possible subspecialization in chest imaging. They have continual access to the electronic teaching files imbedded in the management system and are encouraged to visit the I-ELCAP database center for training sessions provided by its chest radiologists who are highly experienced in the use of CT in the various phases and situations involved in early diagnosis of lung cancer (cf. Regimen of Early Diagnosis, above). This training is concentrated in the time before an institution begins its subject enrollment and it is also available subsequently as needed. The first 100 baseline CTs submitted by a site are also read at the I-ELCAP database. The site receives each central report together with a discrepancy report and is asked to prepare the final report using the central input. After completion of the first 100 baseline CT scans, a report of the results are sent to the site and a conference call is scheduled to discuss the results and any other questions and concerns. A similar process occurs after the next 100 and after 500 baseline CTs are completed. For the radiologists, review of I-ELCAP teaching files (electronically available by the web-based management system) and participation in the International Conferences on Screening for Lung Cancer are required.

As for the pathologists in the participating centers, information regarding the preparation and reading of cytology and histology specimens is provided by the pathology protocol (10). In addition, an outside panel of pathology experts, the Pathology Panel and Cytology Panel, review the pathology specimens (below).

Qualifications of the site pathologist consist of board-certification in pathology and, if possible, subspecialization in chest pathology. These qualifications are supplemented, as needed by on-site training at the I-ELCAP database with pathologists who are experienced in the pathology readings of specimens obtained in the context of the I-ELCAP protocol. They can also participate in the reviews that are held by the Pathology and Cytology Panels. Quality assurance is provided by comparisons of the site readings with those of the Expert Cytology Panel and Expert Pathology Panel. For the pathologists, review of I-ELCAP teaching files (electronically available by the web-based management system) and participation in the International Conferences on Screening for Lung Cancer are recommended.

The study coordinators of the participating institutions are trained by the senior supervisor of the coordinators as to the I-ELCAP database.

If issues arise that cannot be resolved by conference calls, site visits to the participating institution are made to better assess the issue. The site will be provided a reasonable period of time to accomplish any remedial actions.

Outcome determination

Every effort will be made by the I-ELCAP sites to assure complete 10-year follow-up of all diagnosed cases of lung cancer. The beginning of this is documentation of all information that serves to identify the patient over time including the Social Security number in the US (or equivalent

internationally). And where the local efforts fail, assistance in locating the person or identifying his/her death will be given, as well as in documenting whether manifestations of metastases have occurred and the cause of death.

Embedded in this protocol is the opportunity to pursue the analysis of those data in the database that provide new information related to the diagnosis and prognosis of lung cancer, according to its diagnostic distribution and treatment interventions.

Smoking cessation

Smoking cessation efforts need to be built into the program, particularly for current smokers but also for former smokers. CT screening provides "a teachable moment" for smoking cessation advice (27) and has been shown not to cause former smokers to start smoking (28). However, personalized counseling or referral to quit lines and other support groups is useful.

Workup of ancillary findings

The following recommendations for thymic masses, cardiac calcifications and emphysema may be modified as additional data accrue in I-ELCAP.

1. **Thymic masses**

Based on the frequency and natural course of thymic masses identified in baseline and annual repeat screenings for lung cancer (29), the following work-up recommendations are made: If the mass is less than 3.0 cm in diameter on baseline CT, follow-up CT one year later is recommended. If the thymic mass is greater than 3.0 cm or shows growth on the follow-up CT, then further workup according to standard practice is recommended.

2. **Cardiac calcifications**

If the cardiac calcification score is 4 or more, a referral to a cardiologist, with special focus on preventive cardiology is recommended (30, 31).

3. **Emphysema**

If emphysema is present and previously unrecognized, pulmonary function testing and consultation with a pulmonologist are recommended (32).

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Exhibit H

August 30, 2011, Memorandum Re
DuPont: CT Scans and Medicare

MEMORANDUM

TO: Edgar C. Gentle, Esq.

FROM: Diandra S. Debrosse, Esq.

DATE: August 30, 2011

RE: DuPont;CT Scans and Medicare; Our File No. 4609-1{I}

It is of no consequence for Medicare purposes whether the QSF or DuPont pays for CT Scans as it does not involve medical treatment for which billing will be sent to Medicare or Medicaid. The only issue which arises is with regard to any intermediary testing which may be required by the physician to make a determination as to whether the CT Scan is medically necessary.

The Medicare Secondary Payer Statute (the "MSP Statute") allows Medicare to recover "payments that have been made, or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance." 42 U.S.C. 1395y(b)(2)(A) (2010). The MSP Statute applies where Medicare is a secondary payer, that is to say, only liable to pay the remainder of medical bills that some other person or entity is not responsible to pay. 42 U.S.C. 1395y(b)(2)(A) (2010).

Future Medical Testing

Medicare and Medicaid is not being asked to pay for any test incidental to medical care in the Settlement's medical monitoring program. It is our understanding that all Parties are in agreement that DuPont is the primary payor with regard to medical testing.

The only potential Medicare or Medicaid issue which may arise is where a physician may

determine that additional tests (e.g., a chest x-ray) or services are necessary to determine whether he or she should recommend a CT Scan for an eligible claimant. Arguably, these tests and/or services are part of the medical monitoring program and should be covered by DuPont. In the event that DuPont were to disagree with this position, and Medicare and/or Medicaid were to cover the preliminary exam or other preliminary services necessary to make a CT Scan recommendation, there would potentially be room for Medicare or Medicaid to seek reimbursement for these services.

Payment by DuPont v. The QSF

Whether the QSF or DuPont pays for the CT Scan has no bearing on the above analysis and means nothing to Medicare or Medicaid. CMS's main focus is to ensure that they do not pay for services that should be paid by another party. In this matter, whether the QSF or DuPont pays, the main focus is to ensure that Medicare or Medicaid is not billed for any services which can be seen as part of the medical monitoring program.

As part of the guidelines, physicians should be emphatically reminded to solely bill the QSF for any testing covered under the medical monitoring program.

II. PRELIMINARY MEDICAL MONITORING IMPLEMENTATION BUDGET NOVEMBER 1, 2011 TO AUGUST 31, 2012

MEMORANDUM

TO: **Edgar C. Gentle, III, Esq.**

FROM: **Terry D. Turner, Jr., Esq.**

DATE: **August 31, 2011**

RE: **Perrine-DuPont Settlement - DuPont Objections; Our File Nos. 4609-1 {R}, {NN} and {GG-1}**

The purpose of this memorandum is provide you with my critique of the Objections of E. I. DuPont De Nemours and Company to Proposed Second Budget and Proposed Order Regarding Same (the "DuPont Objections") filed by DuPont on August 19, 2011 and attached. The following paragraph numbers correspond to the paragraph numbers contained in the DuPont Objections.

2. DuPont states that the draft Budget is not based on actual numbers or negotiated testing rates. The Claims Administrator has experience in this area to provide an educated estimate on the projected budgetary expenses, and the Third Party Administrator is well qualified to provide a projection on testing rates.

9. DuPont cites the January 18, 2011 Order concerning the setting aside of reasonable reserves to cover the estimated cost of the medical monitoring program, although this can be viewed as a separate matter from actually funding the year Budget in advance.

11. This appears to address the Bridge Funding issue, to be briefed then decided by the Court.

15. This appears to address the Bridge Funding issue, to be briefed then decided by the Court.

19. The Budget does not assume that all active claimants will come in at once during the first year, it is based on a 75% show-up rate.

20. The attached Budget summary of projected expenses shows that we estimate a total of $4,535,873.12 in Medical Monitoring Program post-implementation date expenses. Of this amount, $480,963.66 represents administrative expenses (excluding FASB 5 Contingency Reserve amounts), which is 10.60% of the projected Medical Monitoring Program post-implementation date expenses. The FASB 5 Contingency Reserve is not only for possible additional administrative expenses, but is a general contingency for any other under-projected expenses.

In our latest draft of the proposed Budget, we have segregated CT scan costs and incremental administrative costs related thereto (excluding common expenses so it is not a fully-allocated cost

projection). We also allocated an additional $52,123.77 of the administrative expenses to CT scan related administrative expenses (taking into account reasonably foreseen future litigation expenses, design costs, and extraordinary administrative costs in administering this part of the Medical Monitoring Program), so that the Medical Monitoring Settlement Fund - Post September 1, 2011 Implementation Date Expenses (Excluding CT Scan Expenses) administrative expenses would equal approximately 10.36%.

Of the total medical monitoring program post-implementation date administrative expenses totaling $480,963.66 (excluding FASB 5 expenses), (i) $249,477.63, or 10.36%, of the $2,407,835.93 post-implementation date expenses (excluding CT scan expenses) represent administrative expenses; and (ii) $231,486.03, or 10.88%, of the $2,128,037.19 post-implementation date CT scan expenses represent administrative costs.

Finally, concerning Dr. Brookshire's administrative expense estimate, it may be that Dr. Brookshire estimated a 10% administrative fee rate for the Third Party Administrator, not Claims Administrator and Claims Office costs. In fact, the Third Party Administrative costs are now at 4.15%. Dr. Brookshire also assumed that implementation of the Medical Monitoring Plan would be non-controversial, absent complications respecting the CT Scan.

In a call with the Finance Committee on August 31, 2011, a question was asked about including Guardian Ad Litem fees in the CT Scan portion of the budget. Although the Guardian Ad Litem represents children, they will ultimately become adults who are CT Scan eligible, so we believe Guardian Ad Litem participation is appropriate. We split her budgeted fees as follows: 75% for Non-CT Scan Budget and 25% for CT Scan Budget.

Should you need anything further, please let me know.

TDTjr/
Attachment

PERRINE DUPONT SETTLEMENT ADMINISTRATION BUDGET NO. 2
SEPTEMBER 1, 2011 THROUGH AUGUST 31, 2012

September 1, 2011 DRAFT

	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING*	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES)**		D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES##	TOTAL
September 2011	$644,965.13	$159,959.63	$12,592.91	+		$817,517.67
October 2011	$644,965.13	$104,834.63	$13,931.66	+		$763,731.42
November 2011	$644,965.13	$44,542.31	$130,812.41		$117,651.66	$937,971.51
December 2011	$651,051.19	$24,018.75	$283,658.33		$254,454.40	$1,213,182.67
January 2012	$650,919.94	$11,025.00	$284,198.71		$255,252.76	$1,201,396.41
February 2012	$663,126.19	$0.00	$284,052.08		$254,454.40	$1,201,632.67
March 2012	$661,944.94	$0.00	$282,700.15		$253,038.79	$1,197,683.88
April 2012	$1,207,514.44	$0.00	$283,240.53		$253,837.15	$1,744,592.12
May 2012	$1,207,514.44	$0.00	$282,700.15		$253,038.79	$1,743,253.38
June 2012	$1,207,514.44	$0.00	$282,700.15		$253,038.79	$1,743,253.38
July 2012	$1,249,514.44	$35,000.01	$137,394.61		$117,034.41	$1,538,943.47
August 2012	$1,207,514.44	$0.00	$129,854.24		$116,236.04	$1,453,604.72
TOTALS	$10,641,509.85	$379,380.33	$2,407,835.93	#	$2,128,037.19	$15,556,763.30

+ $26,524.57 in Bridge Funding with ultimate payment obligation (DuPont or original Medical Monitoring Fund deposit) to be determined by the Court.

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont (with caveat in footnote + above).

The total amount includes $41,420 in projected CTI Administrators expenses for a Central Repository for Scientific Research Concerning Test Results, with these projected expenses only being used for the purpose of collecting and maintaining the test results, and NOT to do research, which may be performed by an independent researcher. This issue was resolved by the Court on August 24, 2011, with test results to be stored for consenting claimants.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES #	Total
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 46,000.00	$ -		$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 5,000.00	$ -		$ 5,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ 10,000.00	$ -		$ 10,000.00
Previously Approved Claims Administrator Legal Fees for Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Class Member Cash	$ -	$ 25,000.00	$ -		$ 25,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 86,000.00**	**$ -**	**$ -**	**$ 200,550.00**
B. Property Program Only Expenses ***					

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00					$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00					$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -			$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ -**	**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -	$ 50,000.00	$ 11,993.25	+		$ 61,993.25
Medical Provider Medical Monitoring Expenses	$ -		$ -			$ -
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ 5,000.00	$ -			$ 5,000.00
Total Medical Monitoring Program Only Expenses	**$ -**	**$ 55,000.00**	**$ 11,993.25**	+	**$ -**	**$ 66,993.25**
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 5,000.00				$ 10,000.00
Printing Costs	$ 500.00	$ 500.00				$ 1,000.00
Web Hosting	$ 12.50	$ 12.50				$ 25.00
Claims Office Rent	$ 350.00	$ 350.00				$ 700.00 [1]
Office Cleaning	$ 12.50	$ 12.50				$ 25.00
Copy Machine Rental	$ 200.00	$ 200.00				$ 400.00
Office Insurance	$ 100.00	$ 100.00				$ 200.00
Photocopies	$ 1,250.00	$ 1,250.00				$ 2,500.00
Telecopies	$ 125.00	$ 125.00				$ 250.00
Postage	$ 250.00	$ 250.00				$ 500.00
Federal Express	$ 125.00	$ 125.00				$ 250.00
Office Supplies	$ 250.00	$ 250.00				$ 500.00
Office Equipment	$ 125.00	$ 125.00				$ 250.00
Telephone Service	$ 625.00	$ 625.00				$ 1,250.00
Westlaw Legal Research	$ 75.00	$ 75.00				$ 150.00
Vehicle Insurance and Repairs	$ 100.00	$ 100.00				$ 200.00
Claims Administrator Residence Rent	$ 300.00	$ 300.00				$ 600.00
Utilities for Claims Administrator Residence	$ 62.50	$ 62.50				$ 125.00
Airfare (6 round trips from Alabama)	$ 1,550.00	$ 1,550.00				$ 3,100.00
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 180.00				$ 360.00
Claimant File Storage Monthly Rent	$ 150.00	$ 150.00				$ 300.00

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Total Common Expenses	$ 11,342.50	$ 11,342.50	$ -		$ -	$ 22,685.00
E. FASB 5 Contingency Reserve (5% of above accounts)	$ 30,712.63	$ 7,617.13	$ 599.66	+	$ -	$ 38,929.41
TOTAL of A, B, C, D and E	$ 644,965.13	$ 159,959.63	$ 12,592.91	+	$ -	$ 817,517.66

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:50 basis between A, Property Remediation ($11,342.50) and B, Medical Monitoring (Pre-Implementation Date) ($11,342.50).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

+ After adjusting the estimated number of Medical Monitoring claimants to 3,500, the projected TPA pre-Implementation Date Medical Monitoring claimant preparation services during September and October 2011 increased from $26,524.57 to 27,300.00 (including the 5% FASB 5 Reserve). We anticipate that the FASB 5 Reserve for September and October 2011 should be sufficient to fund this additional amount of $775.43, so we have excluded this additional amount from the Budget and it will not affect the requested Bridge Funding amount.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMTATION DATE CT SCAN INCREMENTAL EXPENSES #	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 46,000.00	$ -		$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 2,500.00	$ -		$ 2,500.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ 10,000.00	$ -		$ 10,000.00
Previously Approved Claims Administrator Legal Fees for Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Class Member Cash	$ -	$ 25,000.00	$ -		$ 25,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00		$ -		$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 83,500.00**	**$ -**	**$ -**	**$ 198,050.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 *****

Property Program Soil and House Testing Payments	$ 199,860.00		$ -			$ 199,860.00	
Property Clean-up Technical Advisor	$ 25,000.00		$ -			$ 25,000.00	
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ -**	**$ 488,360.00**	
C. Medical Monitoring Program Only Expenses ****							
Third Party Administrator Fees and Expenses	$ -	$ -	$ 13,268.25	+		$ 13,268.25	2
Medical Provider Medical Monitoring Expenses	$ -		$ -			$ -	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ 5,000.00	$ -			$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ 5,000.00**	**$ 13,268.25**	+	**$ -**	**$ 18,268.25**	
D. Common Expenses Shared by Both Settlement Programs							
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 5,000.00				$ 10,000.00	
Printing costs	$ 500.00	$ 500.00				$ 1,000.00	
Web Hosting	$ 12.50	$ 12.50				$ 25.00	
Claims Office Rent	$ 350.00	$ 350.00				$ 700.00	1
Office Cleaning	$ 12.50	$ 12.50				$ 25.00	
Copy Machine Rental	$ 200.00	$ 200.00				$ 400.00	
Office Insurance	$ 100.00	$ 100.00				$ 200.00	
Photocopies	$ 1,250.00	$ 1,250.00				$ 2,500.00	
Telecopies	$ 125.00	$ 125.00				$ 250.00	
Postage	$ 250.00	$ 250.00				$ 500.00	
Federal Express	$ 125.00	$ 125.00				$ 250.00	
Office Supplies	$ 250.00	$ 250.00				$ 500.00	
Office Equipment	$ 125.00	$ 125.00				$ 250.00	
Telephone Service	$ 625.00	$ 625.00				$ 1,250.00	
Westlaw Legal Research	$ 75.00	$ 75.00				$ 150.00	
Vehicle Insurance and Repairs	$ 100.00	$ 100.00				$ 200.00	
Claims Administrator Residence Rent	$ 300.00	$ 300.00				$ 600.00	
Utilities for Claims Administrator Residence	$ 62.50	$ 62.50				$ 125.00	
Airfare (2 round trips from Alabama)	$ 1,550.00	$ 1,550.00				$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 180.00				$ 360.00	
Claimant File Storage Monthly Rent	$ 150.00	$ 150.00				$ 300.00	
Total Common Expenses	**$ 11,342.50**	**$ 11,342.50**	**$ -**		**$ -**	**$ 22,685.00**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 *****

E. FASB 5 Contingency Reserve (5% of above accounts)	$ 30,712.63	$ 4,992.13	$ 663.41	+	$ -	$ 36,368.16
TOTAL of A, B, C, D and E	$ 644,965.13	$ 104,834.63	$ 13,931.66	+	$ -	$ 763,731.41

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:50 basis between A, Property Remediation ($11,342.50) and B, Medical Monitoring (Pre-Implementation Date) ($11,342.50).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

2. An additional $1,275 in expenses were included for October 2011, January 2012, April 2010, and July 2012 for quarterly meeting attendance expenses.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court

+ After adjusting the estimated number of Medical Monitoring claimants to 3,500, the projected TPA pre-Implementation Date Medical Monitoring claimant preparation services during September and October 2011 increased from $26,524.57 to 27,300.00 (including the 5% FASB 5 Reserve). We anticipate that the FASB 5 Reserve for September and October 2011 should be sufficient to fund this additional amount of $775.43, so we have excluded this additional amount from the Budget and it will not affect the requested Bridge Funding amount.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 35,500.00	$ 4,238.31	$ 6,261.69	$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 1,250.00	$ -		$ 1,250.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -		$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00		$ -		$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 36,750.00**	**$ 8,274.79**	**$ 12,225.21**	**$ 171,800.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**	**$ -**	**$ 488,360.00**

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -		$ 5,965.31	$ 8,813.19	$ 14,778.50	
Medical Provider Medical Monitoring Expenses	$ -		$ 100,921.90	$ 89,760.80	$ 190,682.70	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 110,637.21**	**$ 99,823.99**	**$ 210,461.20**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 2,500.00	$ 2,500.00		$ 10,000.00	
Printing Costs	$ 500.00	$ 250.00	$ 250.00		$ 1,000.00	
Web Hosting	$ 12.50	$ 6.25	$ 6.25		$ 25.00	
Claims Office Rent	$ 350.00	$ 175.00	$ 175.00		$ 700.00	1
Office Cleaning	$ 12.50	$ 6.25	$ 6.25		$ 25.00	
Copy Machine Rental	$ 200.00	$ 100.00	$ 100.00		$ 400.00	
Office Insurance	$ 100.00	$ 50.00	$ 50.00		$ 200.00	
Photocopies	$ 1,250.00	$ 625.00	$ 625.00		$ 2,500.00	
Telecopies	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Postage	$ 250.00	$ 125.00	$ 125.00		$ 500.00	
Federal Express	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Office Supplies	$ 250.00	$ 125.00	$ 125.00		$ 500.00	
Office Equipment	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Telephone Service	$ 625.00	$ 312.50	$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 75.00	$ 37.50	$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 100.00	$ 50.00	$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 300.00	$ 150.00	$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 62.50	$ 31.25	$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 1,550.00	$ 775.00	$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 90.00	$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 150.00	$ 75.00	$ 75.00		$ 300.00	
Total Common Expenses	**$ 11,342.50**	**$ 5,671.25**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 30,712.63**	**$ 2,121.06**	**$ 6,229.16**	**$ 5,602.46**	**$ 44,665.31**	
TOTAL of A, B, C, D and E	**$ 644,965.13**	**$ 44,542.31**	**$ 130,812.41**	**$ 117,651.66**	**$ 937,971.51**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:25:25 basis between A, Property Remediation ($11,342.50), B, Medical Monitoring (Pre-Implemenation Date) ($5,671.25) and C, Medical Monitoring (Post Implementation) ($5,671.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,125.00	$ 22,875.00	$ 4,238.31	$ 6,261.69	$ 79,500.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,675.00**	**$ 22,875.00**	**$ 8,274.79**	**$ 12,225.21**	**$ 158,050.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**	**$ -**	**$ 488,360.00**

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 *****

C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 7,358.71	$ 10,871.79	$ 18,230.50
Medical Provider Medical Monitoring Expenses	$ -		$ 245,096.04	$ 217,990.52	$ 463,086.56
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 256,204.75**	**$ 230,112.31**	**$ 486,317.06**
D. Common Expenses Shared by Both Settlement Programs					
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00
Web Hosting	$ 18.75		$ 6.25		$ 25.00
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00
Office Cleaning	$ 18.75		$ 6.25		$ 25.00
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00
Office Insurance	$ 150.00		$ 50.00		$ 200.00
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00
Telecopies	$ 187.50		$ 62.50		$ 250.00
Postage	$ 375.00		$ 125.00		$ 500.00
Federal Express	$ 187.50		$ 62.50		$ 250.00
Office Supplies	$ 375.00		$ 125.00		$ 500.00
Office Equipment	$ 187.50		$ 62.50		$ 250.00
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,002.44**	**$ 1,143.75**	**$ 13,507.54**	**$ 12,116.88**	**$ 57,770.60**
TOTAL of A, B, C, D and E	**$ 651,051.19**	**$ 24,018.75**	**$ 283,658.33**	**$ 254,454.40**	**$ 1,213,182.66**

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 10,500.00	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 10,500.00**	**$ 8,274.79**	**$ 12,225.21**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 7,873.36	$ 11,632.14	$ 19,505.50

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 245,096.04	$ 217,990.52	$ 463,086.56	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 256,719.40**	**$ 230,872.66**	**$ 487,592.06**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 30,996.19**	**$ 525.00**	**$ 13,533.27**	**$ 12,154.89**	**$ 57,209.35**	
TOTAL of A, B, C, D and E	**$ 650,919.94**	**$ 11,025.00**	**$ 284,198.71**	**$ 255,252.76**	**$ 1,201,396.41**	

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 125,050.00**	**$ -**	**$ 8,274.79**	**$ 12,225.21**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 7,358.71	$ 10,871.79	$ 18,230.50
Medical Provider Medical Monitoring Expenses	$ -		$ 245,096.04	$ 217,990.52	$ 463,086.56

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 256,204.75**	**$ 230,112.31**	**$ 486,317.06**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Claims Administrator Office Vehicle 1 Year Warranty	$ 1,125.00		$ 375.00		$ 1,500.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 18,138.75**	**$ -**	**$ 6,046.25**	**$ -**	**$ 24,185.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,577.44**	**$ -**	**$ 13,526.29**	**$ 12,116.88**	**$ 57,220.60**	
TOTAL of A, B, C, D and E	**$ 663,126.19**	**$ -**	**$ 284,052.08**	**$ 254,454.40**	**$ 1,201,632.66**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($18,138.75), B, Medical Monitoring (Pre-Implementation Date) ($1.00) and C, Medical Monitoring (Post Implementation) ($6,046.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 125,050.00**	**$ -**	**$ 8,274.79**	**$ 12,225.21**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00	$ -	$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00	$ -	$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00	$ -	$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 *****

Third Party Administrator Fees and Expenses	$ -	$ -	$ 6,446.16	$ 9,523.59	$ 15,969.75
Medical Provider Medical Monitoring Expenses	$ -	$ -	$ 245,096.04	$ 217,990.52	$ 463,086.56
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ -	$ 3,750.00	$ 1,250.00	$ 5,000.00
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 255,292.20**	**$ 228,764.11**	**$ 484,056.31**
D. Common Expenses Shared by Both Settlement Programs					
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00
Web Hosting	$ 18.75		$ 6.25		$ 25.00
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00
Office Cleaning	$ 18.75		$ 6.25		$ 25.00
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00
Office Insurance	$ 150.00		$ 50.00		$ 200.00
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00
Telecopies	$ 187.50		$ 62.50		$ 250.00
Postage	$ 375.00		$ 125.00		$ 500.00
Federal Express	$ 187.50		$ 62.50		$ 250.00
Office Supplies	$ 375.00		$ 125.00		$ 500.00
Office Equipment	$ 187.50		$ 62.50		$ 250.00
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,521.19**	**$ -**	**$ 13,461.91**	**$ 12,049.47**	**$ 57,032.57**
TOTAL of A, B, C, D and E	$ 661,944.94	$ -	$ 282,700.15	$ 253,038.79	$ 1,197,683.88

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implemenation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -		$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00		$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	$ -	**$ 8,274.79**	**$ 12,225.21**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00				$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00				$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00				$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	$ -	$ -		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 6,960.81	$ 10,283.94	$ 17,244.75

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 245,096.04	$ 217,990.52	$ 463,086.56	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 255,806.85**	**$ 229,524.46**	**$ 485,331.31**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	[1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 13,487.64**	**$ 12,087.48**	**$ 83,075.82**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 283,240.53**	**$ 253,837.15**	**$ 1,744,592.13**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	$ -	**$ 8,274.79**	**$ 12,225.21**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00				$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00				$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00				$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	$ -	$ -	$ -	**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 6,446.16	$ 9,523.59	$ 15,969.75

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 245,096.04	$ 217,990.52	$ 463,086.56	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 255,292.20**	**$ 228,764.11**	**$ 484,056.31**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 13,461.91**	**$ 12,049.47**	**$ 83,012.07**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 282,700.15**	**$ 253,038.79**	**$ 1,743,253.38**	

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 8,274.79**	**$ 12,225.21**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 6,446.16	$ 9,523.59	$ 15,969.75

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 245,096.04	$ 217,990.52	$ 463,086.56	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 255,292.20**	**$ 228,764.11**	**$ 484,056.31**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 13,461.91**	**$ 12,049.47**	**$ 83,012.07**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 282,700.15**	**$ 253,038.79**	**$ 1,743,253.38**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 8,274.79**	**$ 12,225.21**	**$ 173,000.00**
B. Property Program Only Expenses * **					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ** **					
Third Party Administrator Fees and Expenses	$ -		$ 5,567.42	$ 8,225.33	$ 13,792.75
Medical Provider Medical Monitoring Expenses	$ -		$ 100,921.89	$ 89,760.80	$ 190,682.69

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 110,239.31**	**$ 99,236.13**	**$ 209,475.44**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Audit and Income Tax Return	$ 40,000.00	$ 33,333.34	$ 6,666.66		$ 80,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	[1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 57,013.75**	**$ 33,333.34**	**$ 12,337.91**	**$ -**	**$ 102,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 59,500.69**	**$ 1,666.67**	**$ 6,542.60**	**$ 5,573.07**	**$ 73,283.02**	
TOTAL of A, B, C, D and E	**$ 1,249,514.44**	**$ 35,000.01**	**$ 137,394.61**	**$ 117,034.41**	**$ 1,538,943.46**	

[1] Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 ***

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhbit E.

***** For this month, common overhead expenses (excluding Audit and income Tax Return) are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25). Audit and Income Tax Return expenses were split as follows: (1) 50% (or $40,000) charged to the Property Remediation Fund and 50% (or $40,000) charged to the Medical Monitoring Fund; and (2) for the Medical Monitoring Fund, its portion of Audit and Income Tax Return expenses were further split, assessing Medical Monitoring (Pre-Implementation Date) with 8/12 (January 2011 through August 2011) of these expenses and dividing the remaining 4/12 (September 2011 through December 2011) equally between Medical Monitoring (Pre-Implementation Date) and Medical Monitoring (Post-Implementation).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 4,238.31	$ 6,261.69	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 4,036.48	$ 5,963.52	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 8,274.79**	**$ 12,225.21**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**	**$ -**	**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 5,052.77	$ 7,464.98	$ 12,517.75
Medical Provider Medical Monitoring Expenses	$ -		$ 100,921.89	$ 89,760.80	$ 190,682.69

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 109,724.66**	**$ 98,475.78**	**$ 208,200.44**
D. Common Expenses Shared by Both Settlement Programs					
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00
Web Hosting	$ 18.75		$ 6.25		$ 25.00
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00 [1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00
Office Insurance	$ 150.00		$ 50.00		$ 200.00
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00
Telecopies	$ 187.50		$ 62.50		$ 250.00
Postage	$ 375.00		$ 125.00		$ 500.00
Federal Express	$ 187.50		$ 62.50		$ 250.00
Office Supplies	$ 375.00		$ 125.00		$ 500.00
Office Equipment	$ 187.50		$ 62.50		$ 250.00
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 6,183.54**	**$ 5,535.05**	**$ 69,219.27**
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 129,854.24**	**$ 116,236.04**	**$ 1,453,604.71**

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

SCHEDULE OF APPENDIX AND EXHIBITS

Appendix A:	Suggested Fees Appendix
Exhibit A:	Detailed Property Program Budget Developed by Claims Administrator and Property Technical Advisor
Exhibit B:	Non-Binding Medical Monitoring Program Third Party Administration Budget Submitted to the Court on June 30, 2011*
Exhibit C:	Medical Monitoring Program Medical Providers Budget Developed by Third Party Administrator*
Exhibit D:	Claims Office Rent Adjustment Substantiation
Exhibit E:	Third Party Administrator and Medical Provider Medical Monitoring Fees and Expenses

* Assumes 3,000 Medical Monitoring claimants.

APPENDIX A

SUGGESTED FEES APPENDIX

A. Claims Office and General Case Administration Services
[September 2011 to January 2012 = 50% to A (Property Remediation Settlement Fund), 25% to B (Medical Monitoring Settlement Fund (Pre-Implementation)), and 25% to C (Medical Monitoring Settlement Fund (Post Implementation)); February 2012 to August 2012 = 75% to A (Property Remediation Settlement Fund) and 25% to C (Medical Monitoring Settlement Fund (Post Implementation))]

Legal Assistant/Receptionist at Office	
$50/h x 145	= $ 7,250
Associate Attorney	
$150/h x 110	= $16,500
Partners	
$200/h x 15	= $ 3,000
Claims Administrator	
$250/h x 25	= $ 6,250
	$33,000

B. Database Loading and Programming

1.	$ 80 (blended) /h x 625	= $50,000	[Sep '11 thru Nov '11] 50% to A (Property Remediation Settlement Fund) and 50% to B (Medical Monitoring Settlement Fund (Pre-Implementation))
2.	$ 80 (blended) /h x 468.75	= $37,500	[December 2011] 67% to A (Property Remediation Settlement Fund) and 33% to B (Medical Monitoring Settlement Fund (Pre-Implementation))
3.	$ 80 (blended) /h x 150	= $25,000	[Jan '12 to August '12] 100% to A (Property Remediation Settlement Fund)

C. Tax and Accounting Support
[September 2011 to January 2012 = 50% to A (Property Remediation Settlement Fund), 25% to B (Medical Monitoring Settlement Fund (Pre-Implementation)) and 25% to C (Medical Monitoring Settlement Fund (Post Implementation)); February 2012 to August 2012 = 75% to A and 25% to C]

$150 (blended) /h x 60 = $ 9,000

D. Property Program Soil and House Testing Class Member Checks
4,965 checks for 7 months (September 2011 to March 2012)
@ $5.00/check[1] = $24,825

E. Medical Monitoring Registered Class Member Checks
1,000 checks for September, 500 checks
For October and 250 checks for
November @ $5.00/check[1] = $8,750.00

F. Medical Monitoring Monthly Provisioning

Legal Assistant
$50/h x 7 = $ 350

Accountant
$80/h x 5 = $ 400

Associate Attorney
$150/h x 15 = $ 2,250

Partner
$200/h x 20 = $ 4,000

Claims Administrator
$250/h x 12 = $ 3,000
$10,000

[1] This amount represents the Claims Administrator's estimated costs related to the issuance of a Class Member Property Program Soil and/or House testing check and a Class Member Medical Monitoring check, which includes, but is not limited to, check stock, envelopes, preparation time, postage, and printing. Not included in this amount is the cost of issuing a Federal Form 1099-MISC if the check amount exceeds $600. The Claims Administrator will bill the actual costs; if the actual costs are less than $5 per check, the Claims Administrator will bill the lesser amount.

G. Property Program Oversight (September 2011 Through March 2012)[2]

Legal Assistant	
$50/h x 250	= $ 12,500
Construction Supervisor	
$100/h x 100	= $ 10,000
Associate Attorney	
$150/h x 200	= $ 30,000
Claims Administrator	
$250/h x 50	= $ 12,500
	$ 65,000

H. Previously Approved Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Cash (October 2011)

Issuance of 5,000 Checks @$5/check	= $25,000
Accountant/Attorney	
$125 (blended) x 100	= $ 12,500
Claims Administrator	
$250/h x 50	= $ 12,500
	$ 50,000

I. Property Program Oversight (April 2012 Through August 2012[2])

Legal Assistant	
$50/h x 370	= $ 18,500
Construction Supervisor	
$100/h x 100	= $ 10,000
Associate Attorney	
$150/h x 250	= $ 37,500
Partner	
$200/h x 100	= $ 20,000
Claims Administrator	
$250/h x 40	= $ 10,000
	$ 96,000

[2] Under the Property Program, Claimant registration is projected to be from July 2011 through October 10, 2011. Soil and house testing is projected to be from August 2011 through March 2012. Soil remediation is projected to be from April 2012 through March 2013. House remediation is projected to be from April 2013 to March 2015.

EXHIBIT A

Terry D. Turner Jr.

Subject: Perrine Zone v1A; 4609-1-dd

This budget estimate for the Zone 1A Spelter Remediation work is very preliminary. So far we have: Testing, Interior Residential Cleaning, Soil Replacement, and Remediation Project Administration.

1. Testing - 227 homes expending $5,500.00 each for testing and inconvenience has an estimated cost totaling $1,249,000.00

2. Interior Residential Cleaning – 227 homes expending 13,959.58 for Cleaning, additional sampling, and temporary relocation for an estimated cost totaling $3,169,000.00

3. Soil Replacement – Time, materials, for collection, replacement, and disposal has an estimated total cost of $7,482,000.00

4. Project Administration for Zone 1A – Including Project Management. Supervision, Record Keeping, Information Databases, Administration, Bonding and Insurances, and a contingency at an estimated total of $3,410,000.00

The total estimated cost for Zone 1A is $15,308,000.00.

Some detail breakdowns are available, but they have not yet been put into a presentable form.

How detailed do you want to tie these figures down. The Cleaning and soils work is provided by Mr. Marc Glass. The overhead figures are based on percentages, not detailed information. They include 5% Project Management, 4% Supervision, 1% Record Keeping, 1% Informational Databases, 2% Administration, 10% Bonding and Insurance, and a 3% contingency.

Bill Sublett
2853 Avenida De Soto
Navarre, Florida 32566
Phone (850) 485-2643
E-Mail: Sublett01@AOL.com

Preliminary Cost Estimation Zone 1A
Interior Residential Cleaning and Soil Replacement
Perrine Class Area

I. Zone 1A Interior Cleaning

Zone 1 Interior Clean/Home	12,559.58
Zone 1A Homes	227
	$2,851,024.66
Pre/Post (90-day) Sampling	1,200.00
	$272,400.00
2-day Relocation for Res/Pets	$200.00
	$45,400.00
Total Avg. per Home	$13,959.58
Sub-Total	$3,168,824.66

II. Zone 1A Soil Remediation

Data:

Pre-Qualification Sampling, Excavation 6-inch soil from Residential Lots, Replace, Site Restoration, Post Sample

Number Zone 1A Residential Lots	227
Avg. sq. ft. Residential Lot	9120
Avg. cu. Ft. Residential Lot (6-inch)	4560
Avg. cu. Yd. Residential Lot (6-inch deep)	168.8888889 cubic yard/residential lot
1.35 tons per cubic yard	228 tons soil to remove/replace/residential lot
Total Zone 1A Cubic yard	38,337.7778
Total Zone 1A Tons	51,756.0000 tons soil to remove/replace

Per Res. Lot Time and Material Calculation

Soil transport/disposal	$13,741.56
Soil Backfill Placement	$13,148.76
Labor/Site Restore	$4,912.80
Pre/Post (90-day) Sampling	$1,155.00
Avg. Res. Lot	$32,958.12
Sub-Total	$7,481,493.24

***Estimated Zone 1A On-Site Remediation** **$10,650,317.90**

*On-site estimates based on average per property remediation time and material estimates and are not inclusive of overall project management/supervision, recordkeeping, informational databases, or administration.

EXHIBIT B

Projection of CTI Administrators Administrative Fees for the
Perrine DuPont Medical Monitoring Program

Description of Fee Component	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Initial Set-Up Fee [1]	$ 6,500	$ 0	$ 0	$ 0	$ 0	$ 6,500
Provider Negotiations of Fees Schedules [2]	$ 0	$ 10,000	$ 0	$ 10,000	$ 0	$ 20,000
Communication Materials [3]	$ 9,450	$ 9,450	$ 9,450	$ 9,450	$ 9,450	$ 47,250
Production/Distribution of Plastic ID Cards [4]	$ 8,015	$ 801	$ 801	$ 801	$ 801	$ 11,219
Administrative Fee per Active Claimant [5]	$ 93,660	$ 92,568	$ 91,358	$ 90,030	$ 106,057	$ 473,673
Scheduling/Appointment Reminder Letters [6]	$ 9,660	$ 9,426	$ 9,193	$ 8,958	$ 8,724	$ 45,961

[1] This is in addition to the initial Provider network design expenses, which are capped at $50,000 in the Agreement. Based on Fee Pricing Schedule provided by CTI Administrators.

[2] This is in addition to the initial Provider network design expenses, which are capped at $50,000 in the Agreement. Estimated utilizing blended hourly rates for approximately 48 hours of services with an estimated three service providers from the Fee Pricing Schedule. This is based upon CTI Administrators renegotiating fees every two years.

[3] Based on 23.33% of yearly average of CTI Administrator invoices for the Tolbert Healthcare Project, which contained an average of 15,000 claimants as opposed to the 3,000 claimants in the Medical Monitoring Program. Dr. Michael Brookshire's May 23, 2007 study of costs for the Medical Monitoring Program utilized a 5% attrition rate each year for claimants, but this was offset by a projected 5% increase each year in materials cost.

[4] Based on 3,500 claimants receiving their ID cards in year one, with the Fee Pricing Schedule showing a cost of $1.85 per claimant and adding $0.44 for postage, and assuming 10% need to be replaced each year.

[5] Based on Fee Pricing Schedule per active claimant and incorporating Dr. Brookshire's 5% attrition rate each year for claimants.

[6] Based on Fee Pricing Schedule, which includes up to three letters to a claimant every other year, with one and a half letters being used for projection purposes each year. This expense also incorporates Dr. Brookshire's 5% attrition rate each year for claimants.

Projection of CTI Administrators Administrative Fees for the
Perrine DuPont Medical Monitoring Program

Central Repository for Possible Scientific Research Concerning Test Results [7]	$ 48,323	$ 38,086	$ 37,307	$ 36,509	$ 39,424	$ 199,649
Quarterly Meetings [8]	$ 5,100	$ 5,355	$ 5,623	$ 5,904	$ 6,199	$ 28,181
Consulting Services [9]	$ 14,000	$ 14,700	$ 15,435	$ 16,207	$ 17,017	$ 77,359
Totals	**$ 194,708**	**$ 180,386**	**$ 169,167**	**$ 177,859**	**$ 187,672**	**$ 909,792**

[7] These expenses would only be for the purpose of collecting and maintaining the test results, and not to do research, which may be performed by an independent researcher. Based on Fee Pricing Schedule per test per claimant. The expense also utilizes Dr. Brookshire's May 23, 2007 study to determine the approximate amount of claimants that would participate in each of five different tests each year, which include urinary, lungs, plumbism, skin and gastro intestinal.

[8] Based on a combination of the Fee Pricing Schedule and yearly average of travel costs experienced in the Tolbert Healthcare Project, with travel costs being increased by 5% each year. The Court, CTIA, and the Claims Administrator, after consulting with the Finance Committee, may review the need to have quarterly in-person meetings from time to time.

[9] These are described in Agreement Section II, I, on page 15. Based on 50% of yearly average of CTI Administrator invoices for the Tolbert Healthcare Project, which contained an average of 15,000 claimants as opposed to the 3,500 claimants in the Medical Monitoring Program. It is estimated that consulting services would still be an essential part of the Medical Monitoring Program, thus this cost was not reduced strictly in accordance with the ratio of claimants. Since this expense contains travel expenses, it was also increased by 5% each year.

EXHIBIT C

Claim Cost Recap by Recommended Tests							
Adult Uninary System Test	Adult Skin Test	Plumbism (lead poisoning) Adult Population	Plumbism (lead poisoning) Child Population	Adult GI Test	Lung System Tests Adult Males (CT Scan)	Lung System Tests Adult Females (CT Scan)	Total Claim Counts
$1,784,532	$10,796	$289,708	$84,408	$220,881	$1,423,425	$1,546,386	$5,360,137

Assumptions used in budget estimate.

The seven tests, clinical procedures, and number of tests recommended were extracted from the report, Estimate of the present value of medical monitoring costs per 1,000 persons, 2008-2046 by Michael L. Brookshire, Ph.D. dated May 23, 2007.

The cost estimates were made assuming a population of 3,000 participants.

Clinical Procedure Codes (CPT) and estimated costs were derived from the Physicians' Fee Reference PFR 2011, 28th Edition. Dr. Brookshire's report did not include CPT codes so we used our best judgment as to the procedure codes we thought to be most appropriate.

Cost for each procedure were estimated at the 75th percentile of Reasonable and Customary fees. This is a conservative estimate being approximately twice what Medicare would pay and approximately 20% higher than the 50th percentile (the median charge). Most commercial insurance plans pay Reasonable & Customary charges at the 80th percentile. There were considerable differences in our cost estimates for individual procedures when compared to the estimates presented by Dr. Brookshire.

Costs were adjusted for Geographic area. The Geographic Multiplier for the Spelter/Morgantown area is

Details of each test are shown in separate worksheets.

Estimated Costs are for payments to providers of service and do not include administration fees.

Urinary System (Kidney & Bladder) Cost Estimate (Male & Female Over age 15)

Initial Population	3,000
Less % below age 15	9.30%
Participants Beginning Uninary System Tests	2,721

	% of beginning population taking test	Number of Tests			Year 1 Claim Cost	Most Likely CPT Code	75th Percentile U & R
		Year 1	Year 2	Year 3			
		2011	2013	2015			
% Completing Tests in each round		100%	85%	75%			
All Participants	100%	2,721	2,313	2,041			
Physical Exam					$282,984	99213	$104
Urinalysis (dip stick)					$68,025	81000	$25
Urine Cytology					$791,811	88112	$291
Urine Beta-2 microglobulin					$223,122	82232	$82
Venipuncture					$54,420	36415	$20
BUN					$81,630	84520	$30
Creatinine					$95,235	82565	$35
Redo	6%	163	139	122			
Urinalysis (dip stick)					$4,082	81000	$25
Urine Cytology					$47,509	88112	$291
Urine Beta-2 microglobulin					$13,387	82232	$82
Venipuncture					$3,265	36415	$20
BUN					$4,898	84520	$30
Creatinine					$5,714	82565	$35
Follow-up Examination	2%	54	46	41			
Consultations (2)					$14,258.04	99241	$131
Urinalysis (repeat)					$1,361	81000	$25
Cystoscopy with biopsy					$61,386	52204	$1,128
CT Scan of Abdomen & CT Scan of Pelvis					$40,325	71476	$741
CT Scan of Pelvis					$63,018	72192	$1,158
Follow-up Examination (second)	1%	27	23	20			
Consultations (2)					$7,129.02	99241	$131
Urinalysis (repeat)					$680	81000	$25
Cystoscopy with biopsy					$30,693	52204	$1,128
CT Scan of Abdomen & CT Scan of Pelvis					$20,163	71476	$741
Follow-up Examination (Urine-Beta-2 or BUN/Creatinine Positives)	2%	54	46	41			
Consultations with Nephrologist x 2					$14,258.04	99241	$131
Urinalysis (repeat)					$1,361	81000	$25
Veinpuncture					$1,088	36415	$20
BUN					$1,633	84520	$30
Creatinine					$1,905	82565	$35
Labwork to look for other causes of Kidney failure					$2,721	?	$50
2% of Participants Positive from BUN/Creatinine	2%	54	46	41			
Consultations with Nephrologist x 2					$14,258.04	99241	$131
Urinalysis (repeat)					$1,361	81000	$25
Veinpuncture					$1,088	36415	$20
BUN					$1,633	84520	$30
Creatinine					$1,905	82565	$35
Labwork to look for other causes of Kidney failure					$2,721	?	$50
Total Claims		3,075	2,614	2,306	$1,784,532		
		Geographic Multiplier			0.91		

Adult Skin Tests							
Adults Testing Positive to Uninary system tests	54						
	% of remaining population taking test	Number of Tests			Year 1 Claim Cost	Most Likely CPT Code	75th Percentile U & R
		Year 1	Year 3	Year 5			
		2011	2013	2015			
% Completing Tests in each round		100%	85%	75%			
Adults Testing Positive to Uninary system tests	100%	54	46	41			
Consult with Dermatologist					$7,129	99241	$131
50% Examined by Dermatologist Get Biopsy	50%	27	23	20			
Biopsy					$4,735	11100	$174
Total Claims		82	69	61	$10,796		
		Geographic Multiplier			0.91		

Plumbism (Lead Poisoning) Adults

Initial Population	3,000
Less % below age 18	12.50%
Adults Beginning Plumbism Tests	2,625

	% of remaining population taking test	Number of Tests			Year 1 Claim Cost	Most Likely CPT Code	75th Percentile U & R
		Year 1	Year 3	Year 5			
		2011	2013	2015			
% Completing Tests in each round		100%	85%	75%			
All Participants							
Whole Blood Lead	100%	2,625	2,231	1,969	$207,375	83655	$79
Plumbism Redo							
Whole Blood Lead	5%	131	112	98	$13,125		$100
Follow-up Medical							
Consultation w/ Medical Toxicologist x 4 visits	2%	53	45	39	$27,510	99241	$131
repeat Whole Blood lead					$4,148	83655	$79
Venipuncture for repeat					$1,050	36415	$20
Zinc Protoporphyrin					$4,830	84202	$92
Complete Blood Count					$2,573	85025	$49
Follow-up Neuropsychiatric							
Neuropsychiatric Evaluation	5%	131	112	98	$46,200	96118	$352
Neuropsychiatric Evaluation Retest							
Neuropsychiatric Evaluation	25%	33	28	25	$11,550	96118	$352
Total Claims		2,973	2,527	2,230	**$289,708**		
		Geographic Multiplier			0.91		

Plumbism (Lead Poisoning) Children Age 18 & Below

Initial Population	3,000
Less % above age 18	87.50%
Children Beginning Plumbism Tests	375

	% of remaining population taking test	Number of Tests			Year 1 Claim Cost	Most Likely CPT Code	75th Percentile U & R
		Year 1	Year 3	Year 5			
		2011	2013	2015			
% Completing Tests in each round		100%	85%	75%			
All Participants							
Whole Blood Lead	100%	375	319	281	$29,625	83655	$79
Plumbism Redo							
Whole Blood Lead	5%	19	16	14	$1,481	83655	$79
Follow-up Medical							
Consultation w/ Medical Toxicologist x 4 visits	10%	38	32	28	$19,650	99241	$131
repeat Whole Blood lead					$2,963	83655	$79
Venipuncture for repeat					$750	36415	$20
Zinc Protoporphyrin					$3,450	84202	$92
Complete Blood Count					$1,838	85025	$49
Follow-up Neuropsychiatric							
Neuropsychiatric Evaluation	20%	75	64	56	$26,400	96118	$352
Neuropsychiatric Evaluation Retest							
Neuropsychiatric Evaluation	25%	19	16	14	$6,600	96118	$352
Total Claims		525	446	394	**$84,408**		
		Geographic Multiplier			0.91		

Adult GI Tests

Initial Population	3,000.00
Less % below age 18	9.30%
Adults Beginning GI Tests	2,721.00

	% of remaining population taking test	Number of Tests			Year 1 Claim Cost	Most Likely CPT Code	75th Percentile U & R
		Year 1	Year 3	Year 5			
		2011	2013	2015			
% Completing Tests in each round		100%	85%	75%			
All Participants							
Stool Hemoccult	100%	2,721	2,313	2,041			
5% Participants Testing Positive					$206,796	82274	$76
Follow-up Examination	5%	136	116	102			
15% Proctologist Refferal & Reenter Screening					$10,340	82274	$76
Gastroenterologist Evaluation	15%	20	17	15			
Biopsy (upper GI)					$2,673	99241	$131
					$22,918	43239	$1,123
Total Claims		2,877	2,446	2,158	**$220,881**		
		Geographic Multiplier			0.91		

Lung System Males Age 35+ Claim Cost Estimate

Initial Population	3,000
Less % below age 35	36.00%
Less % female	51.60%
Adult Males Beginning Lung System Tests	929

??

	% of remaining population taking test	Number of Tests			Year 1 Claim Cost	Most Likely CPT Code	75th Percentile U & R
		Year 1	Year 3	Year 5			
		2011	2013	2015			
% Completing Tests in each round		100%	85%	75%			
All Participants							
CT Scan of Chest	100%	929	790	697			
40% Positives					$934,856	71250	$1,006
Repeat CT Scan of Chest	40%	372	316	279			
Consultation with Supervising Physician					$373,942	71250	$1,006
25% of Positives					$48,694	99241	$131
	25%	93	79	70			
Pulmonologist Consultation (2-3 office visits)							
50% of Pulmonologist Consults					$30,434	99241	$131
Repeat CT Scan	50%	46	39	35			
Other 50% of Pulmonologist Consults					$46,743	71250	$1,006
35% Referred to Cardiothoracic Surgeon	35%	16	14	12			
Cardiothoracic Surgeon Consult					$0		
Lung Biopsy					$2,130	99241	$131
65% Referred to Cardiothoracic Surgeon					$44,592	32095	$2,742
Pulmonologist Lung Biopsy	65%	30	26	8			
					$82,813	32095	$2,742
Total Claims		1,487	1,264	1,100	$1,423,425		
		Geographic Multiplier			0.91		

Lung System Females Age 35+ Claim Cost Estimate

Initial Population	3,000.00	
Less % below age 35	36.00%	
Less % male	48.40%	??
Adult Females Beginning Lung System Tests	991	

	% of remaining population taking test	Number of Tests			Year 1 Claim Cost	Most Likely CPT Code	75th Percentile U & R
		Year 1	Year 3	Year 5			
		2011	2013	2015			
% Completing Tests in each round		100%	85%	75%			
All Participants	100.0%	991	842	743			
Rapid Pregency Test					$31,703	81025	$32
All Participants Not Pregnant	99.5%	991	838	739			
CT Scans					$996,664	71250	$1,006
40% Positives	40.0%	396	335	296			
Repeat CT Scan					$398,666	71250	$1,006
Consultation with Supervising Physician					$51,914	99241	$131
25% of Positives	25.0%	99	84	74			
Pulmonologist Consultation (2-3 office visits)					$32,446	99241	$131
50% of Pulmonologist Consults	50.0%	50	42	37			
Repeat CT Scan					$49,833	71250	$1,006
Other 50% of Pulmonologist Consults	35.0%	17	15	13			
35% Referred to Cardiothoracic Surgeon					$0		
Cardiothoracic Surgeon Consult					$2,271	99241	$131
Lung Biopsy					$47,540	32095	$2,742
65% Referred to Cardiothoracic Surgeon	65.0%	32	27	8			
Pulmonologist Lung Biopsy					$88,288	32095	$2,742
Total Claims		1,585	1,341	1,167	$1,546,386		
		Geographic Multiplier			0.91		

EXHIBIT D

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
e 55 B ST
SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $240.29

Due Date MAY 13, 2010

Rate Code/Schedule 003/E Check Digit 0801

eport an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related stions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

u now have the option of enrolling in PowerPay, r direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863187

Present APR 22, 2010 - Actual Reading	30105
Previous MAR 18, 2010 - Estimated Reading	27531
Total KWH Used for 35 Days	2574

Allegheny Power

Balance Last Bill	347.87
Payment - MAR 25, 2010	347.87 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 2574 KWH	230.71
Environmental Control Charge	9.58
Current Charges	$240.29

TOTAL AMOUNT DUE $240.29

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	04/22/2009	03/18/2010	04/22/2010
	35	29	35
	4700	3767	2574
ng Type	Actual	Estimated	Actual
aily Usg	134	130	74
emp	45	33	50
ally Cost	$11.48	$12.00	$6.87
lthly Usg	5276	4880	4697
nth Usg	63049	58256	58130

meter reading will be estimated, see back of provide a customer reading between 16, 2010 and MAY 17, 2010.

Paid 4-26-10 CK# 3123

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
:e 55 B ST
as SPELTER WV 26438

Non-Residential

Account Number	3 10 10 454 08150 2
Amount Due	$347.33
Due Date	JUN 08, 2010

Rate Code/Schedule 003/B Check Digit 0026 Page 1 of 1

eport an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related
stions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

ur average cost per day is higher than your
evious bill. This may be due to temperature
ange, estimated reading or customer controlled
age change.

u now have the option of enrolling in PowerPay,
r direct payment plan, by signing the back of the
stub when submitting payment.

Usage Information Meter # 34853187

Present MAY 18, 2010 - Estimated Reading	33866
Previous APR 22, 2010 - Actual Reading	30105
Total KWH Used for 26 Days	3761

Allegheny Power

Balance Last Bill	240.29
Payment - APR 27, 2010	240.29 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 3761 KWH	333.34
Environmental Control Charge	13.99
Current Charges	$347.33

TOTAL AMOUNT DUE **$347.33**

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	05/18/2009	04/22/2010	05/18/2010
	26	35	26
	4069	2574	3761
ling Type	Estimated	Actual	Estimated
Daily Usg	157	74	145
Temp	58	50	57
Daily Cost	$13.42	$6.67	$13.36
Mthly Usg	5215	4897	4666
onth Usg	62422	58130	55822

meter reading is scheduled for JUN 17, 2010.

Paid 5-21-10 CK# 3140

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
ce 55 B ST
ss SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $703.68

Due Date JUL 15, 2010

Rate Code/Schedule 003/8 Check Digit 0816 Page 1 of 1

report an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related
stions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

our average cost per day is higher than your
evious bill. This may be due to temperature
ange, estimated reading or customer controlled
sage change.

ou now have the option of enrolling in PowerPay,
ir direct payment plan, by signing the back of the
ll stub when submitting payment.

Usage Information Meter # 34863187

Present JUN 22, 2010 - Actual Reading	41578
Previous MAY 18, 2010 - Estimated Reading	33866
Total KWH Used for 35 Days	7712
Allegheny Power	
Balance Last Bill	347.33
Payment - MAY 22, 2010	347.33 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 7712 KWH	674.99
Environmental Control Charge	28.69
Current Charges	$703.68

TOTAL AMOUNT DUE $703.68

Corrected Bill

Paid 6-27-10 CK # 3161

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
e	06/22/2009	05/18/2010	06/22/2010
's	35	26	35
H	6620	3761	7712
ding Type	Actual	Estimated	Actual
Daily Usg	189	145	220
Temp	66	57	68
Daily Cost	$16.08	$13.36	$20.11
Mthly Usg	5307	4666	4758
onth Usg	63685	55822	56914

t meter reading will be estimated, see back of
to provide a customer reading between
17, 2010 and JUL 18, 2010.

MonPower
A FirstEnergy Company

SPELTER VOL FIRE DEPT
ce 55 B ST
ss SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $360.42

Due Date MAY 16, 2011

Rate Code/Schedule 003/B Check Digit 0810

eport an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call
Kdays from 7:00 a.m. until 6:00 p.m.

Important Information

ou now have the option of enrolling in PowerPay,
r direct payment plan, by signing the back of the
l stub when submitting payment.

Usage Information Meter # 34863187

Present APR 18, 2011 - Estimated Reading	83798
Previous MAR 18, 2011 - Estimated Reading	79990
Total KWH Used for 31 Days	3808

Mon Power

Balance Last Bill	285.90
Payment - MAR 25, 2011	285.90 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 3808 KWH	347.36
Environmental Control Charge	13.06
Current Charges	$360.42

TOTAL AMOUNT DUE **$360.42**

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	04/22/2010	03/18/2011	04/18/2011
	35	24	31
	2574	3020	3808
ng Type	Actual	Estimated	Estimated
aily Usg	74	126	123
emp	50	41	47
aily Cost	$6.67	$11.91	$11.63
ithly Usg	4697	4392	4544
nth Usg	56130	52459	54288

neter reading will be estimated, see back of
provide a customer reading between
16, 2011 and MAY 17, 2011.

Paid 4-27-11
CK# 3347

MonPower
A FirstEnergy Company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $529.51

Due Date JUN 08, 2011

Rate Code/Schedule 003/B Check Digit 0941 Page 1 of 1

eport an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call
kdays from 7:00 a.m. until 6:00 p.m.

Important Information

ur average cost per day is higher than your
evious bill. This may be due to temperature
ange, estimated reading or customer controlled
ge change.

I now have the option of enrolling in PowerPay,
direct payment plan, by signing the back of the
stub when submitting payment.

Usage Information Meter # 34863187

Present MAY 18, 2011 - Estimated Reading	89440
Previous APR 18, 2011 - Estimated Reading	83798
Total KWH Used for 30 Days	5642

Mon Power

Balance Last Bill	360.42
Payment - APR 28, 2011	360.42 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 5642 KWH	510.16
Environmental Control Charge	19.35
Current Charges	$529.51

TOTAL AMOUNT DUE $529.51

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	05/18/2010	04/18/2011	05/18/2011
	26	31	30
	3761	3808	5642
g Type	Estimated	Estimated	Estimated
ily Usg	145	123	188
mp	57	47	58
ily Cost	$13.36	$11.63	$17.65
ily Usg	4686	4544	4636
n Usg	55822	54288	55574

eter reading is scheduled for JUN 17, 2011.

Paid 5-25-11 CK# 3364

MonPower
A FirstEnergy Company

Name	SPELTER VOL FIRE DEPT
Service Address	55 B ST SPELTER WV 26438
	Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $865.21

Due Date JUL 13, 2011

Rate Code/Schedule 003/B Check Digit 0942

To report an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

Your average cost per day is higher than your previous bill. This may be due to temperature change, estimated reading or customer controlled usage change.

You now have the option of enrolling in PowerPay, our direct payment plan, by signing the back of the bill stub when submitting payment.

Usage Information Meter # 34863187

Present JUN 22, 2011 - Actual Reading	98723
Previous MAY 18, 2011 - Estimated Reading	89440
Total KWH Used for 35 Days	9283

Mon Power

Balance Last Bill	529.51
Payment - MAY 24, 2011	529.51 C
Balance Remaining	$0.00
Current Charges:	
Base Charge for 9283 KWH	833.37
Environmental Control Charge	31.84
Current Charges	$865.21

TOTAL AMOUNT DUE $865.21

Paid 6-17-11 Chk# 3388

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
Date	06/22/2010	05/18/2011	06/22/2011
Days	35	30	35
KWH	7712	5642	9283
Reading Type	Actual	Estimated	Actual
Avg Daily Usg	220	188	265
Avg Temp	68	58	67
Avg Daily Cost	$20.11	$17.65	$24.72
Avg Mthly Usg	4758	4836	4788
12 Month Usg	56914	55574	57145

Next meter reading will be estimated, see back of bill to provide a customer reading between JUL 17, 2011 and JUL 18, 2011.

EXHIBIT E

THIRD PARTY ADMINISTRATOR AND MEDICAL PROVIDER MEDICAL MONITORING FEES AND EXPENSES

The Third Party Administrator (the "TPA") and the Medical Provider Medical Monitoring fees and expenses are based on the assumption that there will be 3,500 Medical Monitoring claimants, based on the non-binding projection provided to the Court on June 30, 2011, in Exhibit B, and taking into account the number of medical monitoring registration forms received to date. The Medical Provider Medical Monitoring fees and expenses for the Budget period were projected by the Third Party Administrator at $5,753,887 for 3,000 Medical Monitoring claimants (includes $5,360,137 in testing expenses in Exhibit C plus $393,750 in CT scan consultation expenses), but we have adjusted the testing cost projection downward from $5,360,137 to $3,354,279, as follows: (1) we adjusted upward the Third Party Administrator's Medical Provider Medical Monitoring fees and expenses to $6,253,493.17, based upon the increase in Medical Monitoring claimants to 3,500; (2) Dr. Michael L. Brookshire's Expert Report estimated that only 75% of the Medical Monitoring claimants would show up for their tests; and (3) we are estimating that of the 75% of Medical Monitoring claimants that may be eligible to have a CT scan, only 50% of those CT scans may be considered diagnostically medically necessary. Our estimate for the projected number of CT scans is predicated on Section 3(c) of the Memorandum of Understanding (the "MOU") that no routine CT scans shall be performed as part of the medical monitoring program, although the Defendant shall provide CT scans that are diagnostically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in the litigation. In accordance with Section 3 of the MOU between the Parties, the Defendant shall provide a medical monitoring program for all enrolled Plaintiffs on a pay-as-you-go basis, paying a sum certain each calendar year that reasonably secures such medical monitoring expenses for each such calendar year and, if the sum certain is not sufficient for payment of anticipated medical monitoring expenses, the Defendant shall make an additional payment to reasonably secure such medical monitoring expenses for the calendar year. It is estimated that the additional Third Party Administrator and Medical Provider fees and expense for each additional Medical Monitoring claimant over 3,500 total claimants per year would equal $1,186.35 per claimant[1].

Medical Provider Medical Monitoring Expenses: Because the TPA projects dividing the Medical Monitoring claimants into 4 groups for testing during the months of November 2011 through February 2012, we have allocated the projected Budget period Medical Provider Medical Monitoring Expenses of $3,813,654 as follows: (i) 5% of the total (or $190,682.70) allocated to November 2011 (the beginning of testing); (ii) 5% of the total (or $190,682.69) each to July 2012 and August 2012; and (iii) the remaining 85% (or $3,241,605.92) was allocated evenly among the months of December 2011 through June 2011.

The Medical Provider Medical Monitoring Expenses include estimated CT scan expenses totalling $1,335,841, and CT scan consultation expenses for 75% of the Medical Monitoring claimants (2,625) at $175 per consultation totalling $459,375. The budgeted amount for CT scan expenses is in dispute among the Parties, thus, we have separated these CT scan expenses and the

---

[1] Of this amount, $381.67 represents the additional testing cost per Medical Monitoring claimant per year related to CT scans.

related administrative expenses into a separate Budge column, column D.

Third Party Administrator Fees and Expenses: Included within Third Party Administrator Fees and Expenses are $48,323 in expenses during the Budget period for a Central Repository for Scientific Research Concerning Test Results and would only be for the purpose of collecting and maintaining the test results, and not to do research, which may be performed by an independent researcher. For the Budget period, these Central Repository expenses were allocated based upon the same method as Medical Provider Medical Monitoring Expenses, discussed above.

As for the remaining Third Party Administrator Fees and Expenses: (i) those expenses that are claimant sensitive (Communication Materials, Production/Distribution of ID Cards, and Scheduling/Appointment Reminder Letters) were allocated during the Budget year with 75% of the Budget year expense split evenly among the first 6 months, and 25% of the Budget year expenses shared evenly among the remaining six months; (ii) the Administrative Fee Per Active Claimant and Consulting Services expenses were allocated evenly each month throughout the Budget year; and (iii) the Quarterly Meetings expenses were allocated quarterly during the months of October 2011, January 2012, April 2012, and July 2012.