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UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY

ENVIR. APPEALS BOARD

IN THE MATTER OF: )  
)  
)  
E. I. du Pont de Nemours )  
and Company )  
)  
Wilmington, DE )  
)  
)  
Respondent )  
)  
)  
Washington Works Facility )  
Route 892 South DuPont Road )  
Washington, Wood County, WV )  
)

Docket No. TSCA-HQ-2004-0016  
Docket No. RCRA-HQ-2004-0016  
Docket No. TSCA-HQ-2005-5001

**CONSENT AGREEMENT AND FINAL ORDER**

1 Complainant, the United States Environmental Protection Agency ("EPA" or the  
2 "Agency") and Respondent, E.I. du Pont de Nemours and Company ("DuPont")(referred to  
3 collectively as "the parties") have agreed that settlement of this matter is in the public interest,  
4 and that execution of this Consent Agreement and Final Order, without further litigation, is the  
5 most appropriate means of resolving this matter;

6 Before the taking of any testimony, without further adjudication of any issue of fact or  
7 law, and upon consent and agreement of the Parties, it is hereby Ordered and Adjudged as  
8 follows:

1                   **I. PRELIMINARY STATEMENT**

2                   1. EPA initiated this proceeding for the assessment of civil penalties, pursuant to the  
3 Toxic Substances Control Act (“TSCA”), 15 U.S.C. §§ 2601 et seq., and the Resource  
4 Conservation and Recovery Act (“RCRA”), as amended by the Hazardous and Solid Waste  
5 Amendments of 1984 (“HSWA”), 42 U.S.C. §§ 6901 et seq., and RCRA’s implementing  
6 regulations.

7                   2. The parties are entering into this Consent Agreement to resolve the violations alleged  
8 in the First Amended Complaint, incorporated by reference in its entirety into this document, and  
9 the Second Complaint, also incorporated by reference in its entirety into this document, referred  
10 jointly in this Consent Agreement as the “Consolidated Action.” Respondent has entered into  
11 this Consent Agreement in order to resolve this matter, to avoid unnecessary business disruption,  
12 and to avoid the necessity of litigation. Nothing in this Consent Agreement should be taken as  
13 an admission of liability by Respondent or an admission as to any issue of fact or law raised by  
14 Complainant’s allegations in the Consolidated Action unless specifically stated below.

15                   3. In the Consolidated Action, Complainant alleges that on three separate occasions as  
16 described in Counts I, II and IV of the First Amended Complaint and Second Complaint,  
17 Respondent failed to comply with the requirements of TSCA §§ 8(e) and 15, 15 U.S.C.  
18 §§ 2607(e) and 2614. As stated in its Answers to the First Amended Complaint and the Second  
19 Complaint, which are incorporated in their entirety into this document, Respondent denies these  
20 allegations.

21                   4. The Complainant further alleges that, as described in Count III of the First Amended  
22 Complaint, Respondent violated RCRA § 3005(a), 42 U.S.C. § 6925(a), 40 C.F.R. § 270.30(h),

1 and West Virginia Hazardous Waste Management Rule § 33-20-11.1, and Part 1, Section I.7 of  
2 the Corrective Action portion of DuPont’s hazardous waste permit for the Washington Works  
3 Facility located in Washington, West Virginia. As stated in its Answer to the First Amended  
4 Complaint, which is incorporated by reference in its entirety into this document, Respondent  
5 denies this allegation.

6 5. This Consent Agreement and Final Order shall apply to, and be binding upon,  
7 Respondent, its officers, directors, employees, successors and assigns, including, but not limited  
8 to, subsequent purchasers.

9 6. For the purpose of this proceeding, Respondent will not contest EPA’s jurisdiction to  
10 settle this action and to enter into this Consent Agreement and Final Order.

11 7. For the purpose of this proceeding, Respondent waives any right to contest the  
12 allegations in either the Consolidated Action or this Consent Agreement and waives its right to  
13 appeal or to seek judicial review of the Final Order accompanying this Consent Agreement.

14 8. Without admitting the factual or legal allegations contained in the Consolidated  
15 Action, except as stated in Paragraphs 6 and 7, above, Respondent consents to the terms of this  
16 Consent Agreement and Final Order.

17 **II. ADDITIONAL ALLEGED VIOLATIONS RESOLVED IN THIS**  
18 **CONSENT AGREEMENT AND FINAL ORDER**  
19

20 1. The parties agree to settlement of the following alleged violations before the filing of  
21 a complaint, pursuant to TSCA § 16, 15 U.S.C. § 2615, and 40 C.F.R. § 22.13(b).

22 2. Respondent is alleged to have violated, on four separate occasions, TSCA §§ 8(e) and  
23 15, 15 U.S.C. §§ 2607(e) and 2614, as further described in Paragraphs II.3. – II.9., below.

1           3. Complainant alleges the following to form the factual basis for Count V:

2           a. Sometime in 2002, a third party performed testing that would detect levels of  
3 perfluorooctanoic acid (PFOA) in the blood serum of ten individuals living in West Virginia.  
4 Because only one of these ten individuals reportedly had ever worked at DuPont's Washington  
5 Works Plant, this exposure to PFOA is considered to be non-occupational.

6           b. At the time this community serum sampling was performed, these ten  
7 individuals reportedly drank private well water located near one or more DuPont landfills at  
8 which DuPont disposed ammonium perfluorooctanoate (APFO), also referred to by Complainant  
9 as perfluorooctanoic acid (PFOA). The ten individuals also lived in the vicinity of DuPont's  
10 Washington Works Plant in West Virginia.

11           c. DuPont represents to EPA that at no time before August 13, 2004, did DuPont,  
12 including any of its officers, employees, contractors, and/or consultants, have knowledge of the  
13 2002 blood serum sampling results for these non-occupational individuals.

14           d. On December 20, 2004, DuPont submitted to EPA the 2002 blood serum  
15 sampling results for these non-occupational individuals.

16           4. Complainant alleges that Respondent should have immediately submitted the 2002  
17 blood serum sampling results for the ten non-occupational individuals, discussed in Paragraph  
18 II.3., above, when Respondent obtained this information.

19           5. The following general factual allegations are relevant to, and incorporated in,  
20 Paragraphs II.6. – II.8., below:

1 a. In June 1991, EPA published the “TSCA Section 8(e) Reporting Guide” (1991  
2 Reporting Guide), in which EPA provided reporting guidance for determining when to report  
3 significant lethality observed in animal studies.

4 b. The 1991 Reporting Guide establishes specific numeric values that correspond  
5 to the following three toxicity categories: extremely toxic, highly toxic, and moderately toxic.

6 6. Complainant alleges the following to form the factual basis for Count VI:

7 a. On or before July 11, 1997, DuPont performed an acute inhalation toxicity  
8 study for a perfluorinated chemical substance, the identity of which has been claimed as TSCA  
9 Confidential Business Information by DuPont.

10 b. This acute inhalation toxicity study was performed on male rats which were  
11 exposed to the test substance in an aerosol form. The study results were compiled by DuPont in  
12 an internal document described as Report No. HL-1997-00599.

13 c. On or before January 17, 2002, DuPont performed an acute inhalation toxicity  
14 study on male rats using the same perfluorinated chemical substance in the same form and  
15 exposure pathway as was used in the test described in subparagraph b, above, but at different  
16 concentrations than were used in the 1997 study.

17 d. While DuPont submitted Report No. HL-1997-00599 to EPA on December 7,  
18 2004, DuPont had reported the results of the 2002 acute toxicity study to EPA on January 22,  
19 2002, which EPA designated as 8EHQ-0102-15057 in the TSCA §8(e) Docket.

20 7. Complainant alleges the following to form the factual basis for Count VII:

21 a. On or before July 11, 1997, DuPont performed an acute inhalation toxicity  
22 study on a perfluorinated chemical substance, different from the chemical substance at issue in

1 Count VI, above, the identity of which has been claimed as TSCA Confidential Business  
2 Information by DuPont.

3 b. This acute inhalation toxicity study was performed on male rats which were  
4 exposed to the test substance in an aerosol form. The study results were compiled by DuPont in  
5 an internal document described as Report No. HL-1997-00600.

6 c. DuPont submitted Report No. HL-1997-00600 to EPA on December 7, 2004.

7 8. Complainant alleges the following to form the factual basis for Count VIII:

8 a. On or before August 29, 1997, DuPont performed an acute inhalation toxicity  
9 study on a perfluorinated chemical substance, different from the chemical substance at issue in  
10 Counts VI and VII, above, the identity of which has been claimed as TSCA Confidential  
11 Business Information by DuPont.

12 b. This acute inhalation toxicity study was performed on male rats which were  
13 exposed to the test substance in an aerosol form. The study results were compiled by DuPont in  
14 an internal document described as Report No. HL-1997-00598.

15 c. DuPont submitted Report No. HL-1997-00598 to EPA on December 7, 2004.

16 9. Under the 1991 Reporting Guide, where significant lethality occurs at a dose or  
17 concentration comparable to an acute inhalation LC50 value of less than or equal to 0.5 mg/l,  
18 which EPA equates to 500 mg/m<sup>3</sup>, the test substance is considered extremely toxic and the  
19 results of the study must be immediately reported to EPA.

20 a. Complainant alleges that based upon the results of the study described in HL-  
21 1997-00599 (which has been designated in EPA's TSCA § 8(e) Docket as 8EHQ-1207-15856  
22 Supplement) discussed in Paragraph II.6., above, the test substance is extremely toxic under the

1 1991 Reporting Guide. Complainant alleges that Respondent should have immediately  
2 submitted the results of this study to EPA under TSCA § 8(e) when DuPont obtained this  
3 information.

4 b. Complainant alleges that based upon the results of the study described in HL-  
5 1997-00600 (which has been designated in EPA's TSCA § 8(e) Docket as 8EHQ-1207-15856  
6 Supplement) discussed in Paragraph II.7., above, the test substance is extremely toxic under the  
7 1991 Reporting Guide. Complainant alleges that Respondent should have immediately  
8 submitted the results of this study to EPA under TSCA § 8(e) when DuPont obtained this  
9 information.

10 c. Complainant alleges that based upon the results of the study described in HL-  
11 1997-00598 (which has been designated in EPA's TSCA § 8(e) Docket as 8EHQ-1207-15856  
12 Supplement) discussed in Paragraph II.8., above, the test substance is extremely toxic under the  
13 1991 Reporting Guide. Complainant alleges that Respondent should have immediately  
14 submitted the results of this study to EPA under TSCA § 8(e) when DuPont obtained this  
15 information.

16 10. For the purpose of this proceeding, Respondent will not contest EPA's jurisdiction to  
17 settle this action and to enter into this Consent Agreement and Final Order.

18 11. For the purpose of this proceeding, Respondent neither admits nor denies the factual  
19 allegations, and denies the legal allegations, stated in Paragraphs II.2. – II.9., above.

20 12. For the purpose of this proceeding, Respondent waives any right to contest these  
21 additional alleged violations, and waives its right to appeal or to seek judicial review of the Final  
22 Order accompanying this Consent Agreement.

1                   **III. TERMS OF SETTLEMENT**

2                   1. Pursuant to TSCA § 16 and RCRA § 3008, the nature, circumstances and extent of the  
3 alleged violations, Respondent's agreement to perform Supplemental Environmental Projects  
4 (SEPs) and other relevant factors, Respondent agrees to pay **ten million two hundred fifty**  
5 **thousand dollars (\$10,250,000)** in accordance with the terms set forth below in order to settle  
6 the allegations in the Consolidated Action and in Section II of this Consent Agreement.

7                   2. Without admitting any liability, Respondent enters into this Consent Agreement and  
8 consents for the purposes of settlement to ratification by the Environmental Appeals Board of the  
9 attached Final Order requiring the payment of the civil penalty cited in Paragraph III.1., above,  
10 and the performance of the SEPs in accordance with Section IV., below.

11                  3. Not more than thirty (30) days following the effective date of the Final Order,  
12 Respondent shall submit either a cashier's or certified check, payable to the order of the  
13 "Treasurer, United States of America," in the amount of **ten million two hundred fifty**  
14 **thousand dollars (\$ 10,250,000)**, to:

15                                   EPA-Washington  
16                                   (Hearing Clerk)  
17                                   Docket No. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016,  
18   TSCA-HQ-2005-5001  
19                                   P.O. Box 360277  
20                                   Pittsburgh, PA 15251-6277

21                  or pay **ten million two hundred fifty thousand dollars (\$10,250,000)** by wire transfer with a  
22 notation of "DuPont, Civil Penalty Docket Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016,  
23 TSCA-HQ-2005-5001" by using the following instructions:



1 Name of Beneficiary: EPA  
2 Number of Account for deposit: 68010099  
3 The Bank Holding Acct: Treas\_NYC  
4 The ABA routing Number: 021030004

5 4. Respondent shall provide, within fourteen (14) business days after making the  
6 payment required in Paragraph III.3., a copy of the check or wire transfer letter to:

7 Mr. Tony Ellis  
8 US EPA - Headquarters (2245A)  
9 Office of Civil Enforcement  
10 1200 Pennsylvania Ave. N.W.  
11 Washington, DC 20460

12 The check or wire transfer shall bear the case docket number. Interest and late charges shall be  
13 assessed as specified in Paragraph IX.2.

14 5. The amount specified in Paragraph III.3., above, represents civil penalties assessed by  
15 EPA and shall not be deductible by DuPont for purposes of Federal taxes.

16 **IV. SUPPLEMENTAL ENVIRONMENTAL PROJECTS**

17 1. Respondent shall implement the two SEPs described in detail in Appendices A and B  
18 to this Consent Agreement, which have been approved by EPA and are attached hereto and  
19 incorporated into this Consent Agreement by reference. Respondent shall implement the two  
20 SEPs in accordance with the respective provisions set forth in Appendices A and B. Appendix A  
21 is entitled Fluorotelomer-based Product Biodegradation Testing. The total cost of this SEP  
22 (referred herein as “SEP A”) is set at five million dollars (\$5,000,000). Appendix B is entitled  
23 Microscale Chemistry and Green Chemistry For Junior High Schools and High Schools in Wood

1 County, West Virginia. The total cost of this SEP (referred herein as “SEP B”) is set at one  
2 million two hundred fifty thousand dollars (\$1,250,000).

3 2. SEP Completion: Both SEPs shall be completed within the timeframes established in  
4 Appendices A and B. Therefore, SEP A is to be completed within the timeframe specified in, or  
5 extended in accordance with, Appendix A. SEP B is to be completed within the timeframe  
6 specified in, or extended in accordance with, Appendix B.

7 3. In implementing the SEPs, Respondent shall incur eligible costs of not less than, and  
8 Respondent shall not be required to incur eligible costs in excess of, the amount indicated in  
9 Paragraph IV.1., above, for each SEP. Eligible SEP costs include the costs of planning and  
10 implementing the SEPs but do not include attorneys fees, the costs of employees performing  
11 functions that are part of their regular duties, certain potential additional management costs  
12 related to implementation of SEP B, as agreed to by the parties, and costs, if any, expressly  
13 specified in the applicable Appendices A and B as not eligible.

14 4. Respondent is responsible for the satisfactory completion of the SEPs in accordance  
15 with the requirements of this Consent Agreement, its Appendices and attachments. *“Satisfactory  
16 completion” or “satisfactorily completed” means that Respondent shall expend not less than the  
17 amount indicated for that SEP in Paragraph IV.1., above, on SEP activities described in  
18 Appendix A or B respectively and performed in accordance with the applicable Appendix A or B  
19 respectively.* Although Respondent may use contractors or consultants in planning and  
20 implementing a SEP, Respondent always remains responsible for the satisfactory completion of  
21 the SEP. In performing activities under any of the SEPs, Respondent shall not be required to  
22 incur eligible costs in excess of the amount indicated for that SEP in Paragraph IV.1., above.

1           5. With regard to each of the SEPs, Respondent certifies the truth and accuracy of each  
2 of the following:

3           a.       that, as of the date of executing this Consent Agreement, all cost information  
4                   provided to EPA in connection with EPA's approval of each SEP is complete and  
5                   accurate and represents a fair estimate of the costs necessary to implement the  
6                   SEPs;

7           b.       that, as of the date of executing this Consent Agreement, Respondent is not  
8                   required to perform or develop any of the SEPs by any federal, state, international  
9                   or local law or regulation and is not required to perform or develop any of the  
10                  SEPs by agreement, grant, or as injunctive relief awarded in any other action in  
11                  any forum;

12          c.       that, as of the date of executing this Consent Agreement, each SEP is not a project  
13                   that Respondent was planning or intending to perform or implement other than in  
14                   settlement of the claims resolved in this Consent Agreement;

15          d.       that, as of the date of executing this Consent Agreement, Respondent has not  
16                   received, and is not negotiating to receive, credit for any of the SEPs in any other  
17                   enforcement action; and

18          e.       that Respondent will not receive any reimbursement for any portion of any SEP.

19          6. SEP Completion Report: Not later than sixty (60) days after the date set for  
20 completion of each SEP, or after Respondent has expended the amount indicated for that SEP in  
21 Paragraph IV.1., above, on activities under the SEP, Respondent shall submit a SEP Completion

1 Report to the person indicated in Paragraph V.1. The SEP Completion Report shall contain the  
2 following information:

- 3 a. a detailed description of the SEP as implemented;
- 4 b. a description of any problems encountered in completing the SEP and the  
5 solutions thereto;
- 6 c. an itemized list of all eligible SEP costs;
- 7 d. certification that either the SEP has been fully implemented pursuant to  
8 the provisions of this Consent Agreement and the applicable Appendix or  
9 that Respondent has expended the amount indicated for that SEP in  
10 Paragraph IV.1., above, in a good faith effort on activities under the SEP;  
11 and
- 12 e. a description of the environmental and public health benefits resulting  
13 from implementation of the SEP (with a quantification of the benefits, if  
14 feasible).

15 7. EPA may, in its sole discretion, require any information in addition to that described  
16 in the preceding Paragraph that is reasonably necessary in order to determine the adequacy of  
17 each SEP completion or eligibility of SEP costs, and Respondent shall provide such information  
18 within thirty (30) days, unless the parties agree that additional time is necessary to provide the  
19 information.

20 8. Within sixty (60) days after receiving a SEP Completion Report, or if EPA does not  
21 receive a SEP Completion Report, within sixty (60) days after the date set for completion of the  
22 SEP or after Respondent has notified EPA that it has expended the amount indicated for that SEP

1 in Paragraph IV.1., above, on activities under the SEP, EPA shall notify Respondent whether or  
2 not Respondent has satisfactorily completed that SEP. If EPA notifies Respondent that a SEP is  
3 not satisfactorily completed, Respondent shall have ten (10) business days following receipt of  
4 such notice to object to the Agency's determination. Respondent's objection must be in writing  
5 and submitted to the person in Paragraph V.1. EPA and Respondent shall have an additional  
6 thirty (30) days from the receipt by EPA of Respondent's objection to reach agreement on  
7 changes necessary to the SEP, during which period Respondent shall not be deemed to be in  
8 violation of this Consent Agreement. If the Parties cannot reach agreement on any such issue  
9 within this thirty (30) day period, EPA shall provide a written statement of its decision to  
10 Respondent, which decision shall be final. If the SEP has not been satisfactorily completed,  
11 stipulated penalties may be assessed under Section VII. of this Consent Agreement. If  
12 Respondent has satisfactorily completed all SEP activities described in the relevant Appendix  
13 but the amount expended on performance of the SEP is less than the amount indicated for that  
14 SEP in Paragraph IV.1., above, then negotiations shall occur as provided under Section VI. of  
15 this Consent Agreement.

16 9. Each submission required under this Section shall be signed by an official with  
17 knowledge of the SEP and shall bear the certification language set forth in Paragraph V.4.,  
18 below.

19 10. Any public statement, oral or written, in print, film, or other media, made by  
20 Respondent making reference to the SEPs under this Consent Agreement shall include the  
21 following language: "This project was undertaken in connection with the settlement of an

1 enforcement action taken by the U.S. Environmental Protection Agency under the Toxic  
2 Substances Control Act and the Resource Conservation and Recovery Act.”

3 **V. REPORTING REQUIREMENTS**

4 1. Respondent shall submit the following reports:

5 a. Within thirty (30) days after the end of each calendar-year quarter (*i.e.*, by April 30,  
6 July 31, October 30, and January 30) after execution of this Consent Agreement, until  
7 termination of this Consent Agreement pursuant to Paragraph IX.9., Respondent shall submit in  
8 writing to:

9 Mr. Tony Ellis  
10 US EPA - Headquarters (2245A)  
11 Office of Civil Enforcement  
12 1200 Pennsylvania Ave., N.W.  
13 Washington, DC 20460\*  
14 Phone: 202-564-4167  
15 Fax: 202-564-0035  
16 Email: [ellis.tony@epa.gov](mailto:ellis.tony@epa.gov)  
17 (*\*Note: Above is for US Postal Service,*  
18 *courier deliveries use zip code 20004.*)

19 a quarterly report for the preceding quarter that shall include a discussion of Respondent’s  
20 progress in satisfying its obligations in connection with each SEP including, at a minimum, a  
21 narrative description of activities undertaken, compliance with the schedules or milestones set  
22 forth in the applicable Appendix, and a summary of costs incurred since the previous report.

23 b. If Respondent violates, or has reason to believe that it probably will violate, any  
24 requirement of this Consent Agreement, including its Appendices, Respondent shall notify EPA  
25 of such violation and its likely duration, in writing, within ten (10) business days of the day  
26 Respondent first becomes aware of the violation, with an explanation of the violation’s likely  
27 cause and of the remedial steps taken, or to be taken, to prevent or minimize such violation. If

1 the cause of a violation cannot be fully explained at the time the report is due, Respondent shall  
2 so state in the report. Respondent shall investigate the cause of the violation and shall then  
3 submit an amendment to the report, including a full explanation of the cause of the violation,  
4 within thirty (30) days of the day Respondent becomes aware of the cause of the violation.  
5 During this thirty (30) day period Respondent shall not be deemed to be in violation of this  
6 Consent Agreement. Failure by Respondent to comply with the notice requirements of this  
7 Paragraph shall render this Paragraph void and of no effect as to the particular incident involved  
8 and constitute a waiver of the Respondent's right to request an extension of its obligation under  
9 this Consent Agreement based on such incident. Nothing in this Paragraph or the following  
10 Paragraph relieves Respondent of its obligation to provide the notice required by Paragraph IX.5.  
11 of this Consent Agreement (Force Majeure).

12 2. Whenever any violation of this Consent Agreement or any other event affecting  
13 Respondent's performance under this Consent Agreement may pose an immediate threat to the  
14 public health or welfare or the environment, Respondent shall notify EPA orally or by electronic  
15 or facsimile transmission as soon as possible, but no later than twenty-four (24) hours after  
16 Respondent first knew of, or should have known of, the violation or event. This procedure is in  
17 addition to the requirements set forth in the preceding Paragraph.

18 3. All reports and notices required under this Consent Agreement or its  
19 Appendices shall be submitted to the person designated in Paragraph V.1.a. of this Consent  
20 Agreement.

1           4. Each report submitted by Respondent under this Section, each final report as defined  
2 in the applicable SEP, and each SEP Completion Report shall be signed by an official of the  
3 submitting party and include the following certification:

4           I certify under penalty of law that I have examined and am familiar  
5 with the information submitted in this document and all attach-  
6 ments and that this document and its attachments were prepared  
7 either by me personally or under my direction or supervision in a  
8 manner designed to ensure that qualified and knowledgeable  
9 personnel properly gather and present the information contained  
10 therein. I further certify, based on my personal knowledge or on  
11 my inquiry of those individuals immediately responsible for  
12 obtaining the information, that the information is true, accurate and  
13 complete. I am aware that there are significant penalties for  
14 submitting false information, including the possibility of fines and  
15 imprisonment for knowingly and willfully submitting a materially  
16 false statement.

17 This certification requirement does not apply to emergency or similar notifications where  
18 compliance would be impractical.

19           5. Respondent agrees that EPA may at reasonable times and in a reasonable manner  
20 inspect the locations of ongoing SEP activities at facilities owned by Respondent or owned or  
21 operated by any contractor or sub-contractor of Respondent who conducts SEP activities and  
22 observe the staff performance at any such location in order to confirm that each of the SEPs is  
23 being undertaken in conformity with the representations made herein. Respondent shall cause to  
24 be included in any contract or sub-contract for the conduct of SEP activities a provision  
25 requiring access for EPA inspection in accordance herewith.

26           6. Respondent shall maintain for a period of five (5) years after termination of this  
27 Consent Agreement legible copies of documentation of the underlying research and data for any  
28 and all documents or reports submitted to EPA pursuant to this Consent Agreement or its



1 Appendices and shall provide the documentation of any such underlying research and data to  
2 EPA not more than thirty (30) days after a request for such information, unless otherwise stated  
3 in an Appendix.

4 7. The reporting requirements of this Consent Agreement do not relieve Respondent of  
5 any reporting obligations required by any federal, state, or local law, regulation, permit, or other  
6 requirement.

7 8. Any information provided pursuant to this Consent Agreement may be used by the  
8 United States in any proceeding to enforce the provisions of this Consent Agreement and as  
9 otherwise permitted by law.

10 9. All SEP Completion Reports required under Paragraph IV.6., quarterly reports  
11 required in Paragraph V.1.a., and final reports as defined in the applicable SEP, shall be provided  
12 to EPA in a version that is immediately available for public review. Confidential Business  
13 Information (CBI), if any, shall be redacted by Respondent and a statement inserted for each  
14 redacted item in the public version that Respondent declares that information CBI. A CBI  
15 version of the report will be sent simultaneously with the public version.

16 **VI. EXPENDITURES LESS THAN AGREED SEP MINIMUMS**

17 1. If all activities under a SEP are satisfactorily completed, but Respondent expends less  
18 than the total amount agreed upon for the SEP, the parties shall either:

19 a) negotiate additional SEPs or

20 b) negotiate to redirect the remaining money to a SEP already agreed to as part of this

21 Consent Agreement

22 to adjust for the balance of the unexpended funds.

1           2. If the parties cannot agree to additional SEPs and cannot agree to redirect the money  
2 to a SEP already agreed to under this Consent Agreement, then Respondent shall be considered  
3 to have not satisfactorily completed the SEP even though all work is satisfactorily performed.

4           **VII. STIPULATED PENALTIES**

5           1. If a SEP is not satisfactorily completed only because Respondent expends less than  
6 the total amount agreed upon for the SEP and the parties did not agree under Paragraph VI.2. to  
7 direct the money to an additional SEP or redirect the money to an existing SEP already agreed to  
8 under this Consent Agreement, Respondent shall pay a stipulated penalty equal to the difference  
9 between the amount of eligible SEP costs incurred by the Respondent and the applicable amount  
10 set forth in Paragraph IV.3.

11           2. If Respondent represents it has satisfactorily completed a SEP, but EPA notifies  
12 Respondent under Paragraph IV.8. that the SEP has not been satisfactorily completed for reasons  
13 other than, or in addition to, those set forth in Paragraph VII.1, Respondent shall pay a stipulated  
14 penalty equal to the amount of the SEP as specified in Paragraph IV.1., which penalty shall be in  
15 addition to any penalty required in Paragraph VII.1., above.

16           3. If Respondent ceases work on a SEP prior to its completion and EPA notifies  
17 Respondent under Paragraph IV.8. that the SEP has not been satisfactorily completed because  
18 the cessation is contrary to the provisions of the SEP or of this Consent Agreement, Respondent  
19 shall pay a stipulated penalty equal to the amount of the SEP as specified in Paragraph IV.1., and  
20 any penalties owing under Paragraph VII.4., below, as of the day Respondent ceased work.

1 4. If Respondent fails to comply with the terms of this Consent Agreement or its  
2 Appendices and the failure is not excused under the provisions of this Consent Agreement or its  
3 Appendices, Respondent shall pay stipulated penalties as follows:

<b>Violation</b>	<b>Stipulated Penalty</b>
4 a. Failure to pay the civil penalty specified in 5 Paragraph III.3. above. 6	\$5,000 per day
7 b. Failure to timely submit, modify, or implement, as 8 approved, reports (including SEP Completion 9 Reports), studies, analyses, protocols, or other 10 submittals required in this Consent Agreement or its 11 Appendices.	\$1,000 per day per violation during the first thirty (30) days, \$2,500 per day per violation thereafter
12 c. Any other violation of this Consent Agreement or 13 its Appendices.	\$1,000 per day per violation

14 5. All stipulated penalties shall begin to accrue on the day after the performance is due or  
15 on the day a violation occurs, whichever is applicable, and shall continue until performance is  
16 satisfactorily completed or until the violation ceases, whichever is applicable. Nothing in this  
17 Consent Agreement shall prevent the simultaneous accrual of separate stipulated penalties for  
18 separate violations of this Consent Agreement.

19 6. EPA may, in its unreviewable discretion, waive payment of any portion of stipulated  
20 penalties that may accrue under this Consent Agreement.

21 7. All stipulated penalties are due and owing, upon written demand by EPA, no later  
22 than sixty (60) days after Respondent receives such demand.

23 8. All stipulated penalties shall be paid in a manner set forth in Paragraph III.3.

24 9. In any action concerning EPA's assessment of a stipulated penalty under this Consent  
25 Agreement, EPA shall be entitled to judgment for the claimed penalty amount unless Respondent

1 demonstrates, and the court finds, that EPA acted arbitrarily or capriciously in its determining  
2 that stipulated penalties should be assessed against Respondent.

### 3 **VIII. EPA ACCEPTANCE OF SEP COMPLETION REPORT**

4 1. Within sixty (60) days after receipt of each SEP Completion Report described in  
5 Section V.1., above, EPA shall notify the Respondent, in writing, that: a) the SEP Completion  
6 Report does not comply with Paragraph IV.6. in which case Respondent shall have an  
7 opportunity in accordance with Paragraph VIII.2., unless the parties agree to additional time, for  
8 Respondent to correct the deficiencies; or b) the SEP Completion Report complies with  
9 Paragraph IV.6. and the project has been completed satisfactorily; or c) the SEP Completion  
10 Report complies with Paragraph IV.6. but the SEP has not been satisfactorily completed and  
11 stipulated penalties may be assessed. Before EPA assesses stipulated penalties, Respondent may  
12 invoke the procedure in Paragraph IV.8.

13 2. If EPA notifies Respondent that a SEP Completion Report does not comply with  
14 Paragraph IV.6 but EPA has not yet made a final determination about whether that particular  
15 SEP has been satisfactorily completed, Respondent shall have ten (10) business days following  
16 receipt of such notice to object to the Agency's determination. Respondent's objection must be  
17 in writing and submitted to the person in Paragraph V.1. EPA and Respondent shall have an  
18 additional thirty (30) days from the receipt by EPA of Respondent's objection to reach  
19 agreement on changes necessary to the SEP Completion Report. If agreement cannot be reached  
20 on any such issue within this thirty (30) day period, EPA shall provide a written statement of its  
21 decision to Respondent, which decision shall be final and binding upon Respondent.

1           3. In the event the SEP Completion Report does not comply with Paragraph IV.6. and  
2 the parties have completed the procedure in Paragraphs VIII.1. and VIII.2., EPA may assess  
3 stipulated penalties against Respondent in accordance with Paragraph VII.4.b.

4           **IX. OTHER MATTERS**

5           1. Respondent may request, and EPA may grant, an extension of time for any action  
6 required of Respondent under this Consent Agreement.

7           2. Payment Provisions: Pursuant to 31 U.S.C. § 3717, EPA is entitled to assess interest  
8 and penalties on debts owed to the United States and a charge to cover the cost of processing and  
9 handling a delinquent claim. Interest will therefore begin to accrue on a civil or stipulated  
10 penalty if it is not paid by the last date required. Interest will be assessed at the rate of the  
11 United States Treasury tax and loan rate in accordance with 4 C.F.R. § 102.13(c). A charge will  
12 be assessed to cover the costs of debt collection, including processing and handling costs and  
13 attorneys fees. In addition, a non-payment penalty charge of six (6) percent per year  
14 compounded annually will be assessed on any portion of the debt which remains delinquent  
15 more than ninety (90) days after payment is due. Any such non-payment penalty charge on the  
16 debt will accrue from the date the penalty payment becomes due and is not paid. 4 C.F.R. §§  
17 102.13(d) and (e).

18           3. Nothing in this agreement shall be construed as prohibiting, altering or in any way  
19 limiting the ability of EPA to seek any other monetary or non-monetary remedies or sanctions to  
20 which EPA is legally entitled, including but not limited to injunctive relief or an action to collect  
21 stipulated penalties, for Respondent's violation of: 1) any provision of law not resolved by the  
22 settlement of claims for civil penalties pursuant to TSCA and RCRA as alleged in the

1 Consolidated Action and the violations alleged in Section II, above, or 2) any applicable  
2 requirement under this Consent Agreement or its Appendices except that EPA will not seek to  
3 compel performance of a requirement in Appendices A or B.

4 4. This Consent Agreement and Final Order shall not relieve Respondent of its  
5 obligation to comply with all applicable provisions of federal, state or local law, nor shall it be  
6 construed to be a ruling on, or determination of, any issue related to any federal, state or local  
7 permit.

8 5. Force Majeure:

9 a. If any event occurs which causes or may cause delays in complying with this  
10 Consent Agreement or its Appendices, Respondent shall notify Complainant in writing not more  
11 than ten (10) days after the delay or Respondent's knowledge of the anticipated delay, whichever  
12 is earlier, to the person in Paragraph V.1.a., above. The notice shall describe in detail the  
13 anticipated length of the delay, the precise cause or causes of the delay, the measures taken and  
14 to be taken by Respondent to prevent or minimize the delay, and the timetable by which those  
15 measures will be implemented. The Respondent shall adopt all reasonable measures to avoid or  
16 minimize any such delay. Failure by Respondent to comply with the notice requirements of this  
17 Paragraph shall render this Paragraph void and of no effect as to the particular incident involved  
18 and constitute a waiver of the Respondent's right to request an extension of its obligation under  
19 this Consent Agreement or its Appendices based on such incident.

20 b. If the parties agree that the delay or anticipated delay in complying with this  
21 Consent Agreement or its Appendices has been or will be caused by circumstances entirely  
22 beyond the control of Respondent, the time for performance hereunder may be extended for a

1 period no longer than the delay resulting from such circumstances. In such event, the parties  
2 shall agree to such extension of time, during which period Respondent shall not be deemed to be  
3 in violation of this Consent Agreement or its Appendices.

4 c. In the event that EPA does not agree that a delay in complying with this  
5 Consent Agreement or its Appendices has been or will be caused by circumstances beyond the  
6 control of the Respondent, EPA will notify Respondent in writing of its decision and any delays  
7 in the completion of the affected SEP shall not be excused.

8 d. The burden of proving that any delay is caused by circumstances entirely  
9 beyond the control of the Respondent shall rest with the Respondent. Increased costs or  
10 expenses associated with the implementation of actions called for by this Consent Agreement  
11 shall not, in any event, be a basis for changes in this Consent Agreement or extensions of time  
12 under section (b) of this Paragraph. Delay in achievement of one interim step shall not  
13 necessarily justify or excuse delay in achievement of subsequent steps; it is Respondent's burden  
14 to establish that a delay in achievement of one interim step justifies or excuses delay in  
15 achievement of subsequent steps.

16 6. For purposes of Federal taxes, Respondent indicates that it does not intend to deduct  
17 funds expended in the performance of the SEPs from the company's income except to the extent  
18 and in the event that such costs exceed six million two hundred fifty thousand dollars,  
19 (\$6,250,000).

20 7. This Consent Agreement and Final Order constitutes a final settlement by EPA of the  
21 claims for civil penalties pursuant to TSCA and RCRA as alleged in the Consolidated Action  
22 and in Section II, above. EPA covenants not to sue Respondent in any forum for civil penalties

1 pursuant to TSCA or RCRA for any allegations in the Consolidated Action or in Section II,  
2 above. Nothing in this Consent Agreement and Final Order is intended to, nor shall be construed  
3 to operate in any way, to resolve any criminal liability of the Respondent. Except for the claims  
4 settled in this Consent Agreement and Final Order, compliance with this Consent Agreement and  
5 Final Order shall not be a defense to any actions subsequently commenced pursuant to Federal  
6 laws and regulations administered by EPA, and it is the responsibility of Respondent to comply  
7 with such laws and regulations.

8 8. Each undersigned representative of the parties to this Consent Agreement certifies  
9 that he or she is fully authorized by the party represented to enter into the terms and conditions  
10 of this Consent Agreement and to execute and legally bind that party to it.

11 9. Respondent's obligations under this Consent Agreement and its Appendices shall  
12 terminate upon Respondent:

13 a) paying the civil penalty specified in Paragraph III.3., above, and either

14 b) satisfactorily completing all SEPs and paying any stipulated penalty due under  
15 Paragraph VII.4. or,

16 c) paying stipulated penalties under Paragraphs VII.1-3.

17 Within thirty (30) days of termination of Respondent's obligations of this Consent Agreement  
18 and its Appendices in accordance with this Paragraph, the parties shall file a notice of  
19 termination thereof with the Headquarters Hearing Clerk.

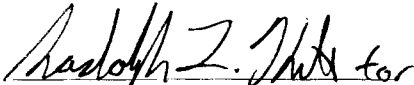
20 10. The effect of settlement described in Section IX.7., of this Consent Agreement and  
21 Final Order is conditional upon the accuracy of the Respondent's representations to EPA that  
22 EPA relied upon in settling this matter.

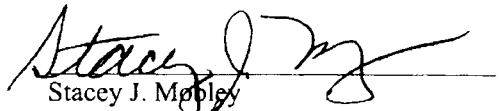


1           11. Each party shall bear its own costs and attorneys fees in connection with the action  
2 resolved by this Consent Agreement and Final Order.

3 For Complainant:

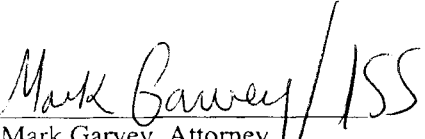
For Respondent:

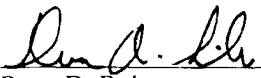
4  
5   
6 Walker B. Smith, Director  
7 Office of Civil Enforcement  
8 U.S. Environmental Protection

  
Stacey J. Mabley  
Sr. Vice President and General Counsel  
E. I. du Pont de Nemours and Company

9 Date: Nov. 23, 2005

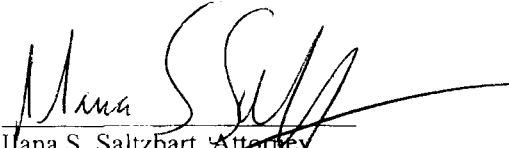
Date: 23 November 2005

10   
11 Mark Garvey, Attorney  
12 Toxics and Pesticides Enforcement Division  
13 Office of Civil Enforcement  
14 Counsel for EPA

  
Peter D. Robertson  
Duane A. Siler  
Patton Boggs L.L.P.  
Counsel for DuPont

15 Date: 11/23/05

Date: 11/23/05

16   
17 Ilana S. Saltzbar, Attorney  
18 Toxics and Pesticides Enforcement Division  
19 Office of Civil Enforcement  
20 Counsel for EPA

21 Date: 11/23/05

1 **BEFORE THE ADMINISTRATOR**  
2 **UNITED STATES**  
3 **ENVIRONMENTAL PROTECTION AGENCY**  
4

5 \_\_\_\_\_  
6 IN THE MATTER OF: )  
7 )  
8 )

9 E. I. du Pont de Nemours )  
10 and Company )

11 )  
12 Wilmington, DE )  
13 )  
14 )

15 Respondent )  
16 )

17 Washington Works Facility )  
18 Route 892 South DuPont Road )  
19 Washington, Wood County, WV )  
20 \_\_\_\_\_ )

Docket No. TSCA-HQ-2004-0016

Docket No. RCRA-HQ-2004-0016

Docket No. TSCA-HQ-2005-5001

21  
22 **FINAL ORDER**

23 Pursuant to Section 16 of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§  
24 2601 et seq., and Section 3008 of the Resource Conservation and Recovery Act ("RCRA"), as  
25 amended by the Hazardous and Solid Waste Amendments ("HSWA"), 42 U.S.C. §§ 6901 et seq.,  
26 it is hereby ORDERED THAT:

27 1. Respondent shall comply with all of the terms of the Consent Agreement, incorporated  
28 herein by reference, including the terms of the Consent Agreement relating to performance of the  
29 SEPs attached to and incorporated in the Consent Agreement;

30 2. Nothing in the Consent Agreement relieves Respondent from complying with the  
31 requirements set forth in TSCA and RCRA and the regulations thereunder;

32 3. Respondent is assessed a civil penalty in the sum of **(Ten Million Two Hundred Fifty**  
33 **Thousand Dollars (\$10,250,000)**;

34 4. Respondent shall, within thirty (30) days of the effective date of this Order, forward a  
35 certified or cashier's check, payable to the order of the "Treasurer of the United States of  
36 America", in the amount of **\$ 10,250,000** to:

37 EPA-Washington

38 (Hearing Clerk)

39 Docket No. Docket No. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016,  
40 TSCA-HQ-2005-5001

41 P.O. Box 360277

42 Pittsburgh, PA 15251-6277

1 or an electronic payment of **\$ 10,250,000** by wire transfer as instructed in this agreement.  
2 The check or wire transfer shall bear the notation “DuPont, Civil Penalty Docket Nos. TSCA-  
3 HQ-2004-0016, RCRA-HQ-2004-0016, TSCA-HQ-2005-5001.”

4 5. Failure to remit the civil penalty in Paragraph 3, above, in accordance with this Order  
5 will constitute a breach of this Order and will cause Respondent to become subject to the  
6 stipulated penalty of five thousand dollars (\$5,000) per diem immediately, plus interest as  
7 allowed by law, and without further proceedings.

8 IT IS SO ORDERED.  
9

10 Environmental Appeals Board  
11

12 Date \_\_\_\_\_  
13  
14  
15

\_\_\_\_\_  
Environmental Appeals Judge  
U.S. Environmental Protection Agency

1 APPENDIX A  
2 TO CONSENT AGREEMENT AND FINAL ORDER

3 FLUOROTELOMER-BASED PRODUCT BIODEGRADATION TESTING  
4 SUPPLEMENTAL ENVIRONMENTAL PROJECT

5 I. OVERVIEW OF FLUOROTELOMER-BASED POLYMER PRODUCT  
6 BIODEGRADATION TESTING SUPPLEMENTAL ENVIRONMENTAL PROJECT

7 A. This document, Appendix A, describes the Fluorotelomer-Based Product  
8 Biodegradation Testing Supplemental Environmental Project (“Biodegradation SEP”) that  
9 Respondent, E. I. du Pont de Nemours and Company (“DuPont”) has agreed to perform pursuant  
10 to Section III of the Consent Agreement and Final Order (“CAFO”) in TSCA-HQ-2004-0016, et  
11 al., entered into between DuPont and the United States Environmental Protection Agency  
12 (“EPA” or “Agency”) (collectively, “the parties”). This Appendix describes the SEP activities  
13 that DuPont will conduct to the extent that applicable funding allows.

14 B. In compliance with, and in addition to, the requirements of the CAFO, DuPont, shall  
15 (1) comply with the requirements of this Appendix and Attachments A-G, and (2) require any  
16 entity that DuPont contracts with to fulfill DuPont’s obligations under this SEP, to comply with  
17 the requirements of this Appendix and Attachments A-G.

18 C. ***Purpose and Background.*** The purpose of this Biodegradation SEP is to determine  
19 the degradation potential of the nine commercial fluorotelomer-based products identified in  
20 Attachment A to this Appendix (“the Fluorotelomer Products” or “Fluorotelomer Products”) as  
21 well as the degradation potential of corresponding synthesized or purified polymers equivalent to  
22 the Fluorotelomer Products with respect to the chemical composition that creates their  
23 fluorotelomer functionality (“Corresponding Polymers”). Eight of the nine Fluorotelomer

1 Products to be tested under this Biodegradation SEP are fluorotelomer-based polymers, while the  
2 ninth is a fluorotelomer-based phosphate ester. The Fluorotelomer Products are products that  
3 were sold by DuPont prior to the date DuPont signs the Consent Agreement, and that DuPont  
4 will provide as the chemical substances to be tested pursuant to this Biodegradation SEP. An  
5 understanding of the degradation potential of the Fluorotelomer Products will be developed by  
6 considering the results of both OECD Guideline 303A and semi-continuous activated sludge  
7 (SCAS) studies. Accordingly, this Biodegradation SEP is designed to: (1) provide information  
8 regarding the behavior of the Fluorotelomer Products and their Corresponding Polymers in  
9 activated sludge biological wastewater treatment systems using a simulated sewage treatment  
10 plant test (OECD Guideline 303A), and (2) provide information on the inherent biodegradation  
11 potential of the Fluorotelomer Products and their Corresponding Polymers using SCAS.

12 a. The OECD Guideline 303A study is a sewage treatment plant (“STP”)  
13 simulation in activated sludge used to generate data concerning the fate of a test substance  
14 during biological treatment, using laboratory-scale aerobic STP. Conditions are controlled to  
15 simulate the operating conditions of a wastewater treatment plant. The study is designed to  
16 determine the elimination of the test substance by aerobic microorganisms in a continuously  
17 operated test system simulating the activated sludge process. Naturally occurring carbon in the  
18 sewage feed and the test substance are the sources of carbon and energy for the microorganisms.  
19 The study investigates the distribution of the test substance and its degradation product(s)  
20 between the different phases in the test system: aqueous, biomass (activated sludge), and  
21 gaseous. The laboratory will run the test for twelve (12) weeks and will measure analytes that  
22 are indicative of degradation by determining the amount and rate of formation of observed

1 degradation product(s) in the aqueous, sludge, and gas phases. Performing OECD Guideline  
2 303A on the Fluorotelomer Products and then comparing the results to the same study performed  
3 on their Corresponding Polymers will enable a close look at the potential performance of each of  
4 the Fluorotelomer Products and their Corresponding Polymers in a sewage treatment plant  
5 simulation.

6 b. The modified SCAS test is an inherent biodegradability study in which  
7 the test substance is exposed to activated sludge microorganisms in an aerated, aqueous medium  
8 with periodic settling of the solids and renewal of the aqueous phase with fresh media and test  
9 substance. The laboratory will run the test for twelve (12) weeks and will measure analytes that  
10 are indicative of degradation by determining the amount and rate of formation of observed  
11 degradation product(s) in the aqueous, sludge, and gas phases. Performing SCAS on the  
12 Fluorotelomer Products and then comparing the results to the same study performed on their  
13 Corresponding Polymers will enable a close look at the potential aerobic biodegradation of each  
14 of the Fluorotelomer Products. The test also gives an indication of the potential for removal of  
15 the test substances via sorption to the activated sludge inoculum.

16 **D. Use and Functionality of Fluorotelomer Products.** Fluorotelomer products are used  
17 widely in a range of commercial applications, including some that are directly released into the  
18 environment, such as fire fighting foams, as well as soil, stain, and grease resistant coatings on  
19 carpets, textiles, paper, and leather. Fluorotelomer products are aqueous dispersions. They  
20 originate from fluorotelomer iodides  $[F(CF_2CF_2)_n-I]$ ; where  $n= 3,4,5$  commonly] which are  
21 commercially made by reacting pentafluoroethyl iodide with tetrafluoroethylene to create even-  
22 number-carbon polyfluoroalkyl iodides. Although the telomerization process can be used to

1 produce odd-number-carbon raw materials, those are not intentionally made or sold by DuPont.

2 Fluorotelomer iodides are functionalized to create a series of fluorotelomer raw materials  
3 [including other fluorotelomer iodides  $[F-(CF_2-CF_2)_n-CH_2-CH_2-I, n = 3,4,5 \text{ commonly}]$  and  
4 fluorotelomer alcohols  $[F-(CF_2-CF_2)_n-CH_2-CH_2-OH, n = 2,3,4,5 \text{ etc.}]$  that are then appended to  
5 an organic or inorganic moiety that contains the fluorotelomer as a functional group. As an  
6 example, fluorotelomer acrylate monomers  $[F-(CF_2-CF_2)_n-CH_2-CH_2-O-C(O)-CH=CH_2, n =$   
7  $3,4,5 \text{ commonly}]$  are copolymerized with one or more of a group of hydrocarbon monomers to  
8 create an acrylic polymer with fluorotelomer functionality. The most common fluorotelomer  
9 raw material used in DuPont's fluorotelomer products is the family of fluorotelomer alcohols.  
10 These alcohols are generally further transformed into polymeric and non-polymeric  
11 fluorotelomer-based products. This Biodegradation SEP involves the testing of polymeric and  
12 non-polymeric fluorotelomer products based on these common fluorotelomer intermediates; any  
13 reference in this Biodegradation SEP to DuPont's commercial Fluorotelomer Products and their  
14 Corresponding Polymers is a reference to both the polymeric and non-polymeric products.

15 DuPont generally manufactures product concentrates as aqueous dispersions of  
16 fluorotelomer products that are sold to industrial customers who dilute, formulate, and blend the  
17 fluorotelomer products. These customers then either apply these new formulations to finished  
18 articles or sell them to other customers who apply them to finished articles. In this way, the  
19 DuPont commercial Fluorotelomer Products being tested as part of this Biodegradation SEP are  
20 thus analogous to paint concentrates and the finished articles to a cured paint surface.  
21 Evaluations of these biodegradation studies carried out on DuPont's Fluorotelomer Products for  
22 the purpose of attempting to assess the biodegradation potential of cured fluorotelomer-based

1 polymer products would need to be carefully done given the differences between the cured and  
2 uncured fluorotelomer-based products. Substances made with fluorotelomer functionality should  
3 not be referred to as either “perfluorinated” or “fluoropolymers” as these terms describe other  
4 materials.

5 E. As part of this Biodegradation SEP, DuPont will:

6 1. Provide sufficient quantities, as described in Sections II.D-E, below, of  
7 DuPont’s nine Fluorotelomer Products, listed in Attachment A.

8 2. Prepare the following chemical substances (referred to collectively as  
9 “Corresponding Polymers”).

10 a. A purified polymer for each of the Fluorotelomer Products listed in  
11 Attachment A that has been isolated from the Fluorotelomer Product and redispersed (“Purified  
12 Fluorotelomer Product”). On or before February 1, 2006, DuPont and EPA will agree on the  
13 procedure(s) that DuPont will use to purify the Fluorotelomer Products to produce the Purified  
14 Fluorotelomer Products, taking into consideration the need to optimize various factors, including  
15 the appropriate duration of extraction and redispersion processes, the desired purity of the  
16 Purified Fluorotelomer Products, the schedule for delivery of the Purified Fluorotelomer  
17 Products to the laboratories for characterization, testing and studies, and the overall schedule for  
18 completing this Biodegradation SEP. Within seven (7) business days of producing each Purified  
19 Fluorotelomer Product, DuPont shall provide EPA with the procedure(s) used to produce such  
20 Purified Fluorotelomer Product and the purity level achieved for such Purified Fluorotelomer  
21 Product.



1                   b. A synthesized fluorotelomer product containing a purified polymer,  
2 comparable to the Fluorotelomer Product for which it corresponds, that is prepared in the  
3 laboratory using production plant raw materials (“Synthesized Fluorotelomer Product”).

4                   c. A synthesized fluorotelomer product containing a purified polymer,  
5 comparable to the Purified Fluorotelomer Product for which it corresponds, that is prepared in  
6 the laboratory using high purity raw materials (“Lab-scale Synthesized Fluorotelomer Product”).

7                   **3. *Timing of Test Substance Transfer.***

8                   a. Within thirty (30) days of entering into a contract with (1) the  
9 laboratory performing biodegradation and (2) the laboratory performing characterization,  
10 DuPont shall transfer the sufficient quantities, as described in Sections II.D-E, below, of the nine  
11 Fluorotelomer Products to such laboratories.

12                   b. Within thirty (30) days of entering into a contract with (1) the  
13 laboratory performing biodegradation and (2) the laboratory performing characterization,  
14 DuPont shall transfer the sufficient quantities, as described in Sections II.D-E of the  
15 Corresponding Polymers, identified on Attachment A for pilot testing, to such laboratories.

16                   c. DuPont shall transfer sufficient quantities, as described in Sections  
17 II.D-E, of the Corresponding Polymers that EPA selects for biodegradation studies to such  
18 laboratories to timely commence characterization and the biodegradation studies as required in  
19 each laboratory’s EPA-approved work plan.

20                   **4. *Third Party Laboratory Contract: Characterization.*** Contract with a Third  
21 Party Laboratory (“laboratory”) to characterize the Fluorotelomer Products, their Corresponding  
22 Polymers identified in Attachment A for pilot testing, and any of their Corresponding Polymers

1 selected by EPA for biodegradation studies according to Attachment B parameters to help inform  
2 the results of the biodegradation studies. The characterization of these Fluorotelomer Products  
3 and Corresponding Polymers, discussed in greater detail in Attachment B, will determine, using  
4 the most accurate instrumentation and procedures available as of the time of testing, and the best  
5 achievable precision, the amount of residual monomers and oligomers, other residuals, and the  
6 molecular weight distribution of polymeric material in the Fluorotelomer Products and  
7 Corresponding Polymers.

8 **5. *Third Party Laboratory Contract: Biodegradation.*** Contract with a Third  
9 Party Laboratory (“laboratory”) to:

10 a. Pilot test the Fluorotelomer Products and Corresponding Polymers, as  
11 identified in Attachment A, following study guidelines for OECD Guideline 303A (aerobic  
12 sewage treatment for activated sludge units) and modified semi-continuous activated sludge  
13 (SCAS).

14 b. Perform OECD Guideline 303A and SCAS studies on the  
15 Fluorotelomer Products and any Corresponding Polymers selected by EPA to be used in the  
16 biodegradation studies.

17 c. The laboratory will conduct these biodegradation studies on the  
18 Fluorotelomer Products and any of their Corresponding Polymers in order to investigate the  
19 degradation potential of these Fluorotelomer Products to produce perfluorooctanoic acid (PFOA)  
20 or other analytes identified in Attachment C, and to determine the potential, if any, for their  
21 Corresponding Polymers to degrade to form PFOA or other analytes identified in Attachment C.

1                   6. *Panel Administrator Contract.* Contract with an independent third party  
2 (“Panel Administrator”) to implement and administer the Peer Consultation process under this  
3 Biodegradation SEP. As discussed in greater detail in Section V, a Peer Consultation Panel will  
4 be involved in this Biodegradation SEP at specified milestones.

5                   E. *Applicability of Results.* Because this Biodegradation SEP is designed to examine (1)  
6 the inherent biodegradation potential of the Fluorotelomer Products and their Corresponding  
7 Polymers and (2) the biodegradation potential and fate of the Fluorotelomer Products and their  
8 Corresponding Polymers under aerobic sewage treatment plant simulation conditions, it does not  
9 address the biodegradation potential of the Fluorotelomer Products or their Corresponding  
10 Polymers in soil, sediments, landfills, or aquatic or marine systems, nor does it address  
11 degradation under anaerobic conditions. Additionally, using the results of this Biodegradation  
12 SEP to attempt to assess the biodegradation potential of cured polymers would need to be  
13 carefully done given the differences between cured and uncured fluorotelomer-based products.

14                   Inherent biodegradability tests are designed to assess whether a substance has any  
15 potential for biodegradation. According to OECD Guidance on the Use of the Globally  
16 Harmonized System for the Classification of Chemicals which are Hazardous for the Aquatic  
17 Environment (April 2001), a positive result in an inherent biodegradation test indicates that the  
18 test substance will not persist indefinitely in the environment; however, rapid and complete  
19 biodegradation cannot be assumed. A negative result in an inherent biodegradation test does not  
20 definitively demonstrate that a chemical will not biodegrade under any conditions, but rather that  
21 the chemical will not biodegrade under the conditions of the test. Aerobic sewage treatment  
22 simulation tests are designed to yield information on the behavior of chemicals in aerobic

1 sewage treatment plants. These tests permit the measurement of the rates of loss of the test  
2 chemical, formation and identification of degradation products, partitioning of these chemicals to  
3 sludge solids, and volatilization under conditions controlled to mimic those found in full-scale  
4 aerobic wastewater treatment systems. The results from these studies are indicative of how the  
5 test substance will behave in full-scale systems.

## 6 II. GENERAL OBLIGATIONS AND REQUIREMENTS

7       A. **Total Cost.** DuPont must spend no less than five million dollars (\$5,000,000) in  
8 eligible SEP costs in performing activities under this Biodegradation SEP, but is not required to  
9 spend more than five million dollars (\$5,000,000) in eligible SEP costs.

10       B. **SEP Completion.** DuPont shall comply with the deadlines set forth in this Appendix  
11 and will use its best efforts to satisfactorily complete this Biodegradation SEP, within the  
12 meaning of Section IV.4 of the CAFO, no later than three (3) years from the date DuPont  
13 receives the signed Final Order of the Environmental Appeals Board approving the Consent  
14 Agreement (“SEP Completion Date”). No later than sixty (60) days prior to the SEP Completion  
15 Date, if DuPont believes that it will be unable to satisfactorily complete the SEP within such  
16 three-year period, DuPont shall petition EPA to extend the SEP Completion Date based upon  
17 DuPont’s assertion of good cause to extend such date. The Office of Civil Enforcement, in  
18 consultation with the Office of Pollution Prevention and Toxics, will review DuPont’s petition  
19 and meet with DuPont to discuss its petition. The Office of Civil Enforcement, in consultation  
20 with the Office of Pollution Prevention and Toxics, shall determine whether DuPont has  
21 demonstrated that there is good cause to extend the SEP Completion Date and, if determining  
22 that DuPont has demonstrated good cause, determine how long to extend the SEP Completion

1 Date.

2           **C. *Good Laboratory Practices and Study Monitor.*** For purposes of this Biodegradation  
3 SEP, with regard to characterization and biodegradation testing and studies, DuPont and its  
4 contractors shall be subject to, and must comply with, 40 C.F.R. Part 792. Each laboratory  
5 conducting research under this Biodegradation SEP shall designate a Study Director in  
6 accordance with 40 C.F.R. § 792.33. DuPont shall designate a Study Monitor that will serve as  
7 the point of contact for EPA and the laboratories.

8           **D. *Supply of Test Substances to Laboratories.*** DuPont shall provide the laboratory that  
9 it contracts with to perform characterization and the laboratory that it contracts with to perform  
10 the biodegradation studies, sufficient quantities of the Fluorotelomer Products, identified in  
11 Attachment A, and any Corresponding Polymers, to perform all of the tests and studies discussed  
12 in this Biodegradation SEP for which such laboratory has been contracted to perform. Sufficient  
13 quantities of the Corresponding Polymers, identified in Attachment A for pilot testing, must  
14 include the quantities necessary to perform characterization, the pilot tests, and biodegradation  
15 studies, even if such Corresponding Polymers are not selected by EPA to be used in the  
16 biodegradation studies. Each Fluorotelomer Product and Purified Fluorotelomer Product that  
17 DuPont provides to the laboratory performing characterization must be from the same production  
18 batch as provided to the laboratory performing the biodegradation studies. Each Synthesized  
19 Fluorotelomer Product and Lab-scale Synthesized Fluorotelomer Product that DuPont provides  
20 to the laboratory performing characterization must be from the same laboratory batch as  
21 provided to the laboratory performing biodegradation testing.

1           E. ***Supply of Test Substances to EPA.*** EPA shall receive sufficient quantities of the  
2 Fluorotelomer Products identified in Attachment A, and Corresponding Polymers, to replicate  
3 the characterization and biodegradation studies (i.e., OECD Guideline 303A and SCAS tests  
4 (including pilots)) performed under this Biodegradation SEP. DuPont shall fulfill this obligation  
5 by providing these sufficient quantities of the Fluorotelomer Products and Corresponding  
6 Polymers to the laboratory performing characterization. In dividing the samples that it receives  
7 from DuPont for transfer to EPA, such laboratory shall not divide the quantity of each test  
8 substance that it receives from DuPont evenly but rather, shall divide each test substance in a  
9 sufficient amount for the laboratory to also perform characterization and then shall provide the  
10 larger remainder of each divided sample to EPA following the chain of custody procedures in  
11 Attachment D. DuPont and the laboratory performing characterization shall develop  
12 appropriate holding procedures for the test substances to assure the chemical integrity of such  
13 substances. These appropriate holding procedures shall be provided to EPA seven (7) days in  
14 advance of the date that the laboratory provides the divided samples to EPA.

15           F. ***Chain of Custody.*** Any instance in which, pursuant to this Biodegradation SEP,  
16 DuPont or a laboratory transfers either Fluorotelomer Products, Corresponding Polymers, or  
17 other chemicals to a laboratory or to EPA, DuPont and/or such laboratory(ies) are required to  
18 follow the chain of custody procedures in Attachment D of this Appendix.

19           G. ***EPA Review and Approval (or Acceptance) Process.*** EPA will review and either  
20 approve or, pursuant to Section II.G.3, below, accept all work plans, protocols, contracts, request  
21 for proposals/bids, confidentiality agreements, lists, material modifications, and any other  
22 submission other than a final report, progress report, preliminary report, or quarterly report,

1 relating to performance of this Biodegradation SEP.

2 1. In providing comments to DuPont regarding such documents or submissions,  
3 EPA will include justification(s) and/or rationale(s) for the comments. EPA will provide such  
4 comments to DuPont within a reasonable amount of time, commensurate with the type and  
5 nature of the document or submission being reviewed.

6 2. All of EPA's comments, including requested changes, to a document or  
7 submission enumerated above must be incorporated by DuPont, and/or its contractors, and  
8 resubmitted to EPA for approval. With regard to contracts, request for proposals/bids, and  
9 confidentiality agreements, if DuPont believes that EPA's comments do not relate to the  
10 performance of the Biodegradation SEP, DuPont shall notify EPA within seven (7) business days  
11 of DuPont's receipt of such comments. In this notification to EPA, DuPont shall explain why it  
12 believes that EPA's comments do not relate to the performance of this Biodegradation SEP and  
13 that such comments are not required to be incorporated into the document. EPA shall consider  
14 DuPont's explanation before making a final decision regarding whether such comments relate to  
15 the performance of this Biodegradation SEP; provided, however, that EPA will not unreasonably  
16 require DuPont to modify or remove from any such contract or agreement any provision that  
17 requires the contractor to indemnify DuPont for stipulated penalties that DuPont pays under  
18 Section VII.4 of the CAFO as a result of the contractor's failure to perform work in accordance  
19 with a schedule to which the contractor has agreed.

20 3. In limited circumstances, EPA may, in its discretion, after reviewing a  
21 proposed contract, proposed confidentiality agreement, or proposed protocol opt to accept such a  
22 document without formally approving it. If EPA exercises this option, EPA will notify DuPont

1 that the proposed contract or proposed confidentiality agreement has been accepted.

2 H. ***Submission Procedures and Transfer of Test Substances to EPA.*** All submissions  
3 by DuPont, a laboratory, or the Panel Administrator to EPA shall be submitted via first class  
4 mail, return receipt requested, or by commercial delivery service with documented delivery, to  
5 the person identified in Section V of the CAFO. All submissions shall be provided in electronic  
6 format on a compact disc (CD). All submissions shall be accompanied by a cover letter in  
7 hardcopy, that describes the contents of the CD, and complies with any other requirements of the  
8 CAFO. EPA will specify, in advance of the transfer of test substances addressed in Section II.E,  
9 above, where to transfer such divided samples.

10 I. ***Final Reports containing Confidential Business Information.*** All final reports  
11 provided to EPA containing Confidential Business Information (“CBI”) must also be provided to  
12 EPA in a sanitized version within thirty (30) days of submission of the CBI version. Such final  
13 reports include final laboratory reports under 40 C.F.R. Part 792, final reports of the Peer  
14 Consultation Panel, and SEP Completion Reports submitted pursuant to Section IV of the  
15 CAFO. Any claim of CBI must be substantiated pursuant to 40 C.F.R. Part 2, upon submission  
16 of the sanitized version.

17 J. ***Manner in which Testing and Studies shall be Performed.*** The characterization and  
18 biodegradation studies must be performed in the following manner and in compliance with the  
19 following Attachments, unless DuPont or its contractor requests, and EPA approves, a change, or  
20 if EPA, after consultation with DuPont, determines that a change is appropriate:

21 1. DuPont shall use one laboratory to characterize the Fluorotelomer Products, the  
22 Corresponding Polymers identified in Attachment A for pilot testing, and any Corresponding



1 Polymers that EPA selects for biodegradation studies, in accordance with Attachment B.

2 2. DuPont shall use one laboratory to perform OECD Guideline 303A and SCAS  
3 studies (referred collectively herein as the “biodegradation studies”), in accordance with  
4 Attachment C.

5 a. This laboratory shall perform the OECD Guideline 303A and SCAS  
6 studies concurrently on the Fluorotelomer Products and any Corresponding Polymers that EPA  
7 selects for biodegradation studies, following both the sequence, and grouping (to maximize  
8 laboratory efficiency, capacity allowing) provided in Attachment A.

9 b. If, based on their submissions in response to the Request for Proposals  
10 (“RFP”) and any further information that DuPont or EPA receives, none of the laboratories  
11 identified in Attachment G appears to be reasonably capable of, or if no laboratory is willing to  
12 contractually commit to, completing all of the biodegradation studies (including pilots) by no  
13 later than twenty-seven (27) months after receipt of the Fluorotelomer Products and any  
14 Corresponding Polymers (or such longer time as EPA approves), the parties agree to implement  
15 the following approach, in the following order of preference:

16 i. DuPont shall use one laboratory identified in Attachment G to  
17 perform the biodegradation studies but not the analytical component of the studies, and DuPont  
18 shall use the laboratory that DuPont contracts with to perform characterization of the  
19 Fluorotelomer Products and any Corresponding Polymers under this Biodegradation SEP, as a  
20 subcontractor for the analytical component of the biodegradation studies; or

21 ii. DuPont shall propose two laboratories identified in Attachment  
22 G to perform the biodegradation studies and shall propose how to divide the biodegradation

1 work between the two laboratories, subject to EPA approval.

2 3. Pilot Testing

3 a. The laboratory performing the biodegradation studies shall conduct one  
4 14-day pilot test for OECD Guideline 303A and one 14-day pilot test for SCAS on each of the  
5 Fluorotelomer Products that have been selected for pilot testing as identified in Attachment A,  
6 and shall conduct one 14-day pilot test for OECD Guideline 303A and one 14-day pilot test for  
7 SCAS on each of the Corresponding Polymers that have been selected for pilot testing as  
8 identified in Attachment A, to develop test data that can inform protocol decisions and to  
9 establish that these biodegradation studies can produce results that can be analyzed and  
10 quantified with regard to the biodegradation potential of the Fluorotelomer Products and any  
11 Corresponding Polymers.

12 b. EPA reserves the right, after reviewing the results of the first pilot of  
13 the Fluorotelomer Products or first pilots of its Corresponding Polymers, to specify the use of the  
14 Corresponding Polymers for the pilot tests in the remaining groups.

15 c. The Peer Consultation Panel, described in Section V, below, shall  
16 review the results of such pilots, including the pilots' protocol and design, in conjunction with  
17 the characterization data. The Panel Administrator shall develop and forward to EPA and  
18 DuPont a final Panel report providing: (1) each participating Panel member's comments and  
19 recommendations on appropriate final protocols for the laboratory to use for the biodegradation  
20 studies and (2) comments and recommendations regarding which of the Corresponding Polymers  
21 should be used in the biodegradation studies. EPA will review the Panel report and any  
22 comments that DuPont has submitted to EPA pursuant to Section II.K, below. EPA will then

1 transmit its comments and judgments to DuPont and require DuPont to direct the laboratory to  
2 develop a final protocol, within a specified timeframe, to be submitted to EPA for approval. The  
3 final protocol that the laboratory develops shall consider the Panel report and EPA's comments  
4 and judgments. The laboratory shall not commence the biodegradation studies until it has  
5 received EPA's approval of the final protocol and EPA's determination regarding which of the  
6 Corresponding Polymers shall be used in the biodegradation studies.

7 K. At any time during the performance of this Biodegradation SEP, DuPont may provide  
8 comments to EPA regarding the following technical documents: protocols, test methods,  
9 analytical methods (and any modifications of such technical documents), and the Panel report  
10 addressing the charge set forth in Section V.A.2.b. To be eligible for consideration by EPA,  
11 DuPont must submit such comments to EPA within seven (7) business days of DuPont's receipt  
12 of the technical document. EPA reserves the right to directly seek input from the appropriate  
13 laboratory regarding DuPont's comments. The extension of deadlines in Section II.L, below,  
14 does not apply to this Section II.K. A request for an extension of this deadline shall be subject to  
15 EPA's discretion, and granted for good cause shown.

1 L. Extensions of deadlines other than the SEP Completion Date

2 1. **First Extensions.** For an extension of a deadline specified in this Appendix or  
3 in a work plan or other submission implementing this Biodegradation SEP, other than the SEP  
4 Completion Date, DuPont shall be entitled to a first extension as a matter of right, provided that  
5 DuPont submits a written notice to EPA that it is exercising this provision, no later than one  
6 business day prior to the deadline.

7 a. For deadlines of thirty (30) days or less, DuPont shall automatically  
8 receive an extension equal to the number of days initially provided in this Appendix.

9 b. For deadlines greater than thirty (30) days, DuPont shall automatically  
10 receive a 30-day extension unless DuPont requests, and EPA approves, an extension greater than  
11 thirty (30) days, for good cause shown.

12 c. For deadlines that are not stated in terms of number of days after a  
13 preceding event but are stated as specific dates, DuPont shall automatically receive a 30-day  
14 extension unless DuPont requests, and EPA approves, an extension greater than thirty (30) days,  
15 for good cause shown.

16 2. **Second Extension (for Third Party Work only).** For an extension of a  
17 deadline other than the SEP Completion Date involving work that DuPont has contracted with a  
18 third party to perform, if, after exercising its right to an automatic extension provided in Section  
19 II.L.1, above, DuPont requests a second extension of the same deadline, such extension shall be  
20 granted provided that DuPont's Study Monitor sent a written notice to the third party no later  
21 than five (5) business days before the deadline, and DuPont requests an extension no later than  
22 one (1) business day prior to the deadline. In exercising this provision, DuPont shall furnish

1 EPA with the written notice that it sent to the third party.

2 a. For deadlines of thirty (30) days or less, DuPont shall receive an  
3 extension equal to the number of days initially provided in this Appendix.

4 b. For deadlines greater than thirty (30) days, DuPont shall receive a 30-  
5 day extension unless DuPont requests, and EPA approves, an extension greater than thirty (30)  
6 days, for good cause shown.

7 3. ***Additional Extensions.*** DuPont's request for an extension other than the SEP  
8 Completion Date for which there is either: (a) a second request for an extension of a deadline  
9 that does not involve work that DuPont has contracted with a third party to perform, or (b) a  
10 third request for an extension of a deadline that does involve work that DuPont has contracted  
11 with a third party to perform, or (c) subsequent requests for extensions of deadlines addressed in  
12 Sections II.L.3.a-b, such requests are subject to EPA's discretion, and granted for good cause  
13 shown. In granting a request for an extension under Section II.L.3, EPA may grant an extension  
14 of time different from the amount of time requested by DuPont.

1                   4. *Delays resulting from EPA Review.* If DuPont is delayed in performing a  
2 required action prescribed in an EPA-approved work plan and the delay is caused only because  
3 of EPA's review and approval of a submission that DuPont provided to EPA sufficiently in  
4 advance of the deadline so as to allow EPA a reasonable amount of time to review and approve  
5 the submission, commensurate with the type and nature of the submission, DuPont will be  
6 entitled to an extension to perform the required action. The extension shall be equal to the  
7 number of days of EPA's review and approval of the submission and shall be calculated from the  
8 date that EPA received such submission through the date that EPA transmitted its approval of the  
9 submission to DuPont. If, during its review and prior to its approval, EPA requests that DuPont  
10 make changes to the submission, in calculating the extension, the parties shall not include the  
11 amount of time for DuPont to make such changes and resubmit the document to EPA for  
12 approval. Such time excluded from the extension shall start from the date that EPA transmits the  
13 requested changes to DuPont through the date that EPA receives the amended submission,  
14 incorporating the requested changes. But, such time excluded from the extension shall not  
15 include time during which EPA is still reviewing a portion of the submission for which EPA has  
16 also requested changes. If an extension is granted under this provision, DuPont may still request  
17 an extension of the extended deadline under Sections II.L.1-3, above.

18                   5. To the extent that this Section II.L governs requests for extensions of deadlines  
19 under this Biodegradation SEP, it shall supersede any provisions in the CAFO concerning the  
20 extension of deadlines.

1 III. SELECTION OF THIRD PARTY LABORATORIES

2 A. *Development of Confidentiality Agreement.* Within forty-five (45) days from the  
3 date DuPont signs the Consent Agreement, DuPont shall submit to EPA the confidentiality  
4 agreement that DuPont intends to use with any laboratory. Within seven (7) business days of  
5 receipt of EPA’s approval (or acceptance) of the confidentiality agreement, DuPont must provide  
6 the laboratories listed in Attachment G with a confidentiality agreement and request that such  
7 confidentiality agreement be signed and returned by a date certain consistent with the deadlines  
8 established in this Appendix.

9 B. *Development of Request for Proposals.* By February 1, 2006, DuPont shall submit to  
10 EPA one or more draft Requests for Proposals (RFPs) to be sent to all of the laboratories  
11 identified in Attachment G to solicit proposals for (1) characterizing the Fluorotelomer Products  
12 and any Corresponding Polymers, and (2) conducting the OECD Guideline 303A and SCAS  
13 studies on the Fluorotelomer Products and any Corresponding Polymers (including pilot testing).

14 The proposed RFPs must at least include the following elements:

15 1. The laboratory’s obligation, if selected, to follow 40 C.F.R. Part 792, and  
16 prepare (or subcontract for preparation of) and comply with, a QAPP, provided in Attachment E  
17 of this Appendix.

18 2. All existing information that would be reasonably relevant to assisting the  
19 laboratory to develop a firm cost estimate, with pricing, for the work that the laboratory is  
20 solicited to perform, which must include such information as the identity, structure, and  
21 compositional analysis of the Fluorotelomer Products. The laboratory’s proposal may be based  
22 upon not-to-exceed estimates for the proposed work or any other method that provides, to the

1 extent feasible, a firm cost estimate for the work.

2 a. Laboratories receiving the RFP for characterization of the  
3 Fluorotelomer Products and Corresponding Polymers must provide cost estimates for  
4 characterizing all of the Fluorotelomer Products and their Corresponding Polymers.

5 b. Laboratories receiving the RFP for the biodegradation work must  
6 include cost estimates for conducting 14-day pilot tests for OECD Guideline 303A and 14-day  
7 pilot tests for SCAS on the Fluorotelomer Products and the Corresponding Polymers, as  
8 identified in Attachment A, and for performing OECD Guideline 303A and SCAS studies on all  
9 Fluorotelomer Products and their Corresponding Polymers.

10 3. The laboratory's cost proposal should include the identification of any  
11 analytical methods that the laboratory anticipates needing to develop in order to perform any of  
12 the required analytical work associated with the characterization or biodegradation studies  
13 required under this Biodegradation SEP.

14 4. For the laboratories receiving the RFP for the biodegradation work, DuPont  
15 shall provide the guidelines for OECD Guideline 303A and SCAS, included in Attachment C of  
16 this Appendix.

17 5. A requirement that the recipient identify in its proposal a general schedule and  
18 budget for completion of the proposed work identified in the RFP in accordance with the  
19 deadlines and criteria set forth in this Appendix.

20 6. A copy of Section II.L, above, and the terms and conditions identified in  
21 Section III.F.2, below.



1           7. Notice that failure to submit a proposal meeting all of the criteria in the RFP to  
2 DuPont within thirty (30) days of the laboratory's receipt of the RFP may render the laboratory  
3 ineligible for selection.

4           C. Within seven (7) days of receipt of the approved RFP, DuPont shall provide the EPA-  
5 approved RFPs to all laboratories listed in Attachment G that have submitted to DuPont a signed  
6 confidentiality agreement. If DuPont has not received a signed confidentiality agreement from a  
7 laboratory by the date that DuPont is required to provide the RFP, DuPont shall notify EPA why  
8 it cannot send the RFP to such laboratory. EPA reserves the right to contact such laboratory to  
9 inquire why it has not returned the confidentiality agreement and, if such laboratory agrees  
10 within seven (7) business days of contact by EPA to sign and submit the confidentiality  
11 agreement to DuPont, DuPont shall then provide the RFP to the laboratory.

12           D. **Laboratory Eligibility.** Within forty-five (45) days of EPA's approval of the RFPs,  
13 or such longer time as EPA has approved in accordance with Section III.D.2, below, DuPont  
14 must receive a firm proposal back from a laboratory receiving an RFP in order for that laboratory  
15 to be eligible to perform work under this Biodegradation SEP.

16           1. DuPont shall require the recipients to submit one duplicate copy of its proposal  
17 to EPA concurrent with its submission to DuPont.

18           2. If a laboratory that received the RFP does not submit a proposal to DuPont  
19 within thirty (30) days of receipt of the RFP, EPA reserves the right to contact such laboratory to  
20 inquire why it has not submitted a proposal to DuPont. If the laboratory indicates that it wants to  
21 submit a proposal, the laboratory must do so by a date to be specified by EPA, which shall not be  
22 longer than fourteen (14) days after contact by EPA, unless the parties agree to a longer time

1 period.

2 E. *Selection of Laboratories*. No later than fourteen (14) days after receipt of the last  
3 bid that DuPont received within the applicable period for submission under III.D, DuPont must  
4 propose to EPA the laboratory that DuPont would like to use to perform the characterization of  
5 the Fluorotelomer Products and Corresponding Polymers, and the laboratory that DuPont would  
6 like to use to perform the biodegradation studies of the Fluorotelomer Products and  
7 Corresponding Polymers.

8 1. DuPont must provide EPA with a detailed rationale describing why DuPont  
9 has selected such laboratories to perform the work and why it has not selected the other  
10 laboratories that submitted a proposal to perform such work.

11 2. DuPont shall contract with only one laboratory to perform both the modified  
12 SCAS and OECD Guideline 303A studies on the Fluorotelomer Products and Corresponding  
13 Polymers. DuPont shall contract with only one laboratory to characterize the Fluorotelomer  
14 Products and Corresponding Polymers.

15 3. If, after proposal submission, EPA rejects either the laboratory for  
16 characterization and/or the laboratory for biodegradation testing, EPA will provide DuPont with  
17 a written rationale for the rejection and require DuPont to propose a different laboratory from  
18 which DuPont has received a proposal. The parties will continue this process until EPA agrees  
19 to DuPont's laboratory selection.

20 4. If no laboratories submit proposals to DuPont, or if none of the proposals  
21 submitted is acceptable to EPA, the Directors of the Office of Civil Enforcement and the Office  
22 of Pollution Prevention and Toxics shall meet with DuPont to discuss appropriate changes that

1 can be made to this Biodegradation SEP to foster laboratory participation in the performance of  
2 this Biodegradation SEP. EPA and DuPont shall first implement the alternative approach set  
3 forth in Section II.J.2.b before EPA considers whether to expand the list of potential laboratories  
4 identified in Attachment G to include foreign laboratories. If the parties cannot agree to any  
5 such appropriate changes, or if after agreeing to such appropriate changes, no laboratories submit  
6 a proposal, this Biodegradation SEP shall be deemed to have ceased prior to its completion, in  
7 which case, DuPont shall not be subject to Section VII.3 of the CAFO but DuPont shall be  
8 subject to Section VII.1 of the CAFO, and the parties may exercise Section VI of the CAFO even  
9 though this Biodegradation SEP is not deemed satisfactorily completed.

10 F. **Laboratory Contract Requirements.** Within thirty (30) days of EPA's approval of the  
11 laboratories under Section III.E, DuPont must provide EPA with a final draft of the proposed  
12 contract that DuPont and the two laboratories have negotiated.

13 1. No contract shall be executed by DuPont and a laboratory until EPA has  
14 reviewed and either approved or accepted the contract in accordance with Section II.G.2.

15 2. The proposed contract must include the following terms and conditions in  
16 addition to the elements discussed in Section III.B, above:

17 a. The laboratory consents to inspection, for purposes of this  
18 Biodegradation SEP, at any reasonable time, as provided in 40 C.F.R. § 792.15.

19 b. All laboratory personnel must directly answer any questions from EPA  
20 pertaining to work the laboratory is performing under this Biodegradation SEP. Any request  
21 from EPA for written information from a laboratory pertaining to work it is performing under  
22 this Biodegradation SEP will be transmitted through DuPont's designated Study Monitor.

1 DuPont's Study Monitor shall notify the laboratory of EPA's request for such information within  
2 three (3) business days of EPA's request, and the laboratory shall provide such information to  
3 EPA and DuPont within three (3) business days of DuPont's Study Monitor's notice to the  
4 laboratory.

5 i. If, based upon oral or written information so obtained, EPA  
6 believes that a minor modification(s) to an approved or accepted test protocol or other analytical  
7 method must be made, EPA will inform DuPont of the modification and require DuPont to  
8 instruct the laboratory to implement the change immediately and continue running the test.  
9 DuPont may submit comments for EPA's consideration regarding such modification, in  
10 accordance with Section II.K, above.

11 ii. If, based upon oral or written information so obtained, EPA  
12 believes that a modification to an approved or accepted test protocol or other analytical method  
13 must be made that requires the laboratory to stop the test and start again, EPA will inform  
14 DuPont of the modification and require DuPont to instruct the laboratory to provide EPA and  
15 DuPont with all data generated up to that date and immediately terminate the test and re-run the  
16 test implementing the modification. DuPont may submit comments for EPA's consideration  
17 regarding such modification, in accordance with Section II.K, above.

18 c. EPA shall have the exclusive authority to approve all work plans,  
19 protocols, and test methods that the study sponsor would otherwise approve under 40 C.F.R. Part  
20 792 as well as any analytical methods not expressly enumerated in 40 C.F.R. Part 792, and the  
21 QAPPs. DuPont may submit comments for EPA's consideration regarding such technical  
22 documents, in accordance with Section II.K, above.

1                   d. **Material Modifications.** Any proposed material modification that a  
2 laboratory or DuPont would like to make that involves work conducted under this  
3 Biodegradation SEP must be approved by EPA prior to implementation. For purposes of this  
4 Biodegradation SEP, a material modification is an adjustment to the work conducted under this  
5 Biodegradation SEP made in the normal course of implementing such work that would result in a  
6 substantive alteration of the biodegradation studies or other activities conducted under this  
7 Biodegradation SEP.

8                   e. EPA and DuPont shall receive written notification from the laboratory  
9 no later than five (5) business days before the laboratory makes any modification that involves  
10 work previously approved by EPA under this Biodegradation SEP, except as provided in Section  
11 III.F.2.f, below. If, based upon this notification, EPA believes that such modification is material,  
12 EPA will orally notify DuPont and the laboratory immediately, and require DuPont to instruct  
13 the laboratory to submit such proposed modification to EPA for approval within the timeframe  
14 that EPA establishes in the oral notice. DuPont may submit comments for EPA's consideration  
15 regarding such modification, in accordance with Section II.K, above.

16                   f. **Emergency Modifications.** In the event of an emergency, the  
17 laboratory may make a modification that involves work previously approved by EPA under this  
18 Biodegradation SEP, to address an unforeseen circumstance or occurrence that will have an  
19 adverse affect on the test if not immediately implemented. The laboratory shall provide notice to  
20 EPA and DuPont within twenty-four (24) hours of such modification. If, based upon this  
21 modification, EPA believes that the laboratory must stop the test and start again or that the  
22 laboratory should implement an additional change, EPA will require DuPont to instruct the

1 laboratory to provide EPA and DuPont with all data generated up to that date and either  
2 immediately terminate the test and re-run the test or immediately implement the additional  
3 change. DuPont may submit comments for EPA's consideration regarding such modification or  
4 additional change, in accordance with Section II.K, above.

5 g. **Progress Reports.** Within thirty (30) days of commencing the  
6 technical work, and by the first day of each month thereafter until the laboratory submits its last  
7 final report under Section IV.C, below, the laboratory shall provide EPA and DuPont with a  
8 progress report that describes the technical work performed, a copy of the raw data generated up  
9 to that date, and costs incurred.

10 h. **Information Exchange.** When the laboratory provides any information  
11 in written form to EPA or DuPont concerning the laboratory's work under this Biodegradation  
12 SEP, the laboratory shall provide such information to the other party as soon as practicable. The  
13 laboratory is not responsible for disseminating information that it receives in written form from  
14 DuPont; DuPont shall concurrently provide the information to EPA. When the laboratory  
15 provides information in oral form to EPA or DuPont concerning the laboratory's work under this  
16 Biodegradation SEP, the laboratory shall communicate such information to the other party as  
17 soon as practicable. The laboratory is not responsible for communicating information it receives  
18 in oral form from DuPont or EPA; each party shall communicate such information to the other  
19 party. However, when the laboratory receives an oral communication from DuPont or EPA, it  
20 shall notify both parties and provide a brief written description of such oral communication. To  
21 the extent practicable, the parties shall jointly communicate orally with the laboratory in light of  
22 the laboratory's obligation to prepare a written notification to the parties when it receives an oral

1 communication, not jointly, from either party.

2 i. The laboratory shall allow Peer Consultation Panel members to visit the  
3 laboratory, as necessary, when the Peer Consultation Panel has a meeting(s) and/or deliberations  
4 relevant to the work that the laboratory is performing under this Biodegradation SEP.

5 G. **Contract Execution.** Within five (5) business days of receipt of EPA's approval (or  
6 acceptance) of the proposed contract in accordance with Section II.G.2, DuPont must sign and  
7 forward the contract to the laboratory for execution.

8 a. DuPont and the laboratory shall seek to execute the contract within thirty (30)  
9 days of receipt of EPA's approval (or acceptance) of the proposed contract. If DuPont and the  
10 laboratory have not executed the contract within thirty (30) days, DuPont must, inform EPA of  
11 the delay, explain the reason for the delay, provide a reasonable estimate as to when the contract  
12 will be executed, and exercise its right to an automatic extension in Section II.L, above. After  
13 exercising its right to an automatic extension in Section II.L, but before a second request for an  
14 extension under Section II.L, if DuPont believes that, notwithstanding its best efforts, the  
15 laboratory will not enter into the contract with DuPont, DuPont shall provide notice to EPA of  
16 the impasse. EPA reserves the right to contact such laboratory, upon receipt of such notice from  
17 DuPont, to inquire why the laboratory has not entered into the contract with DuPont. If DuPont  
18 and the laboratory have not entered into a contract within fourteen (14) days EPA's inquiry,  
19 unless DuPont and EPA agree to a longer time period, then the parties shall follow the approach  
20 set forth in Section III.H, below.

21 b. Within five (5) business days from the date that DuPont and the laboratory  
22 execute the contract, DuPont must notify EPA that it has entered into the contract with the

1 laboratory.

2 H. If no laboratory enters into a contract with DuPont, the Directors of the Office of  
3 Civil Enforcement and the Office of Pollution Prevention and Toxics shall meet with DuPont to  
4 discuss appropriate changes that can be made to this Biodegradation SEP to foster laboratory  
5 participation in the performance of this Biodegradation SEP. If the parties cannot agree to any  
6 such appropriate changes, or if after agreeing to such appropriate changes, no laboratories enter  
7 into a contract with DuPont, this Biodegradation SEP shall be deemed to have ceased prior to its  
8 completion, in which case, DuPont shall not be subject to Section VII.3 of the CAFO but DuPont  
9 shall be subject to Section VII.1 of the CAFO, and the parties may exercise Section VI of the  
10 CAFO even though this Biodegradation SEP is not deemed satisfactorily completed.

11 I. **Commencement of Work.** Within thirty (30) days from the date that DuPont and each  
12 laboratory execute the contract, the laboratory must commence the work it has agreed to perform  
13 under the contract, as described in Section IV, below.

14 IV. TESTS TO BE PERFORMED ON DUPONT'S FLUOROTELOMER PRODUCTS AND  
15 CORRESPONDING POLYMERS

16 A. Characterization of the Fluorotelomer Products and Corresponding Polymers

17 1. As provided in Section III.I, the laboratory shall commence the work identified  
18 in this Section IV.A, within thirty (30) days from the date that DuPont and the laboratory execute  
19 the contract to perform work under this Biodegradation SEP. The laboratory shall commence  
20 such work by submitting a work plan to EPA that describes the work the laboratory has been  
21 contracted to perform, addressing all requirements for such work under this Biodegradation SEP  
22 (including Attachment B), and a general schedule and budget for completion of the work.  
23 Within forty-five (45) days from the date that DuPont and the laboratory execute the contract to



1 perform work under this Biodegradation SEP, the laboratory shall submit to EPA all relevant  
2 technical documents that require EPA's approval.

3 2. Within fourteen (14) business days of EPA's approval of the work plan and all  
4 relevant technical documents, the laboratory shall begin the implementation of the EPA-  
5 approved work plan.

6 3. Within fourteen (14) business days of characterizing each Fluorotelomer  
7 Product and any Corresponding Polymers, the laboratory shall provide EPA and the Panel  
8 Administrator, a Certificate of Analysis, as provided in Attachment F, as well as the protocols  
9 and a copy of the raw data. The laboratory shall provide the QAPP to the Panel Administrator  
10 with the first Certificate of Analysis but need not provide the QAPP for the remaining eight  
11 Fluorotelomer Products and Corresponding Polymers.

12 B. Biodegradation Studies: OECD Guideline 303A and SCAS

13 1. As provided in Section III.I, the laboratory shall commence the work identified  
14 in this Section IV.B, within thirty (30) days from the date that DuPont and the laboratory execute  
15 the contract to perform such work. The laboratory shall commence such work by submitting a  
16 work plan to EPA that describes the work the laboratory has been contracted to perform,  
17 addressing all requirements for such work under this Biodegradation SEP (including Attachment  
18 C), and a general schedule and budget for completion of the work. Within ninety (90) days from  
19 the date that DuPont and the laboratory execute the contract to perform work under this  
20 Biodegradation SEP, the laboratory shall submit to EPA all relevant technical documents that  
21 require EPA's approval.

22 2. Within fourteen (14) business days of EPA's approval of the work plan and all

1 relevant technical documents, the laboratory shall begin the implementation of the EPA-  
2 approved work plan.

3 a. The laboratory shall run the SCAS test for twelve (12) weeks. The  
4 inoculum source shall be activated sludge mixed liquor from a municipal wastewater treatment  
5 plant operating in compliance with its National Pollutant Elimination Discharge System  
6 (“NPDES”) permit. Settled domestic sewage from a municipal wastewater treatment plant  
7 operating in compliance with its NPDES permit shall be used as feed. Daily samples of the  
8 aqueous phase, sludge solids, and off gas shall be collected, analyzed, and quantified for the  
9 analytes listed in Attachment C of this Biodegradation SEP. If at any time EPA determines, or if  
10 DuPont or the laboratory recommends and EPA determines, that daily sampling is not necessary,  
11 EPA will notify DuPont to instruct the laboratory of a change in the sampling schedule and  
12 establish a new timeframe for sampling. Analyses shall be conducted using the most accurate  
13 instrumentation and procedures available as of the time of testing. All analytical methods shall  
14 be approved by EPA prior to the start of the studies.

15 b. The laboratory shall run the OECD Guideline 303A test for twelve (12)  
16 weeks. The inoculum source shall be activated sludge mixed liquor from a municipal  
17 wastewater treatment plant operating in compliance with its NPDES permit. Settled domestic  
18 sewage from a municipal wastewater treatment plant operating in compliance with its NPDES  
19 permit shall be used as feed. Daily samples of the aqueous phase, sludge solids, and off gas shall  
20 be collected, analyzed, and quantified for the analytes listed in Attachment C of this  
21 Biodegradation SEP. If at any time EPA determines, or if DuPont or the laboratory recommends  
22 and EPA determines, that daily sampling is not necessary, EPA will notify DuPont to instruct the

1 laboratory of a change in the sampling schedule and establish a new timeframe for sampling.  
2 Analyses shall be conducted using the most accurate instrumentation and procedures available as  
3 of the time of testing. All analytical methods shall be approved by EPA prior to the start of the  
4 testing.

5 3. The laboratory shall conduct one 14-day pilot test for OECD Guideline 303A  
6 and one 14-day pilot test for SCAS on each of the Fluorotelomer Products that have been  
7 selected for pilot testing as identified in Attachment A, and shall conduct one 14-day pilot test  
8 for OECD Guideline 303A and one 14-day pilot test for SCAS on each of the Corresponding  
9 Polymers that have been selected for pilot testing as identified in Attachment A, to develop test  
10 data that can inform protocol decisions and to establish that these biodegradation studies can  
11 produce results that can be analyzed and quantified with regard to the biodegradation potential of  
12 the Fluorotelomer Products and Corresponding Polymers.

13 4. ***Pilot Preliminary Reports.*** No later than fourteen (14) days after the  
14 laboratory completes each pilot test, the laboratory shall provide EPA, DuPont, and the Panel  
15 Administrator with a preliminary report regarding the pilot test results. In providing the  
16 preliminary report, the laboratory shall summarize the pilot test results and provide the QAPP,  
17 the protocols, and a copy of the raw data.

18 5. Within fourteen (14) business days after EPA has approved the final design  
19 and protocols for the OECD Guideline 303A and SCAS studies, the laboratory shall begin the  
20 biodegradation studies following the sequence and groupings (capacity allowing) provided in  
21 Attachment A.

1 a. EPA reserves the right to omit any analyte identified in Attachment C  
2 for purposes of the biodegradation studies.

3 b. Upon consideration of the Panel's report addressing the charge in  
4 Section V.A.2.c, additional characterization data for any purified or synthesized Corresponding  
5 Polymers that had not been characterized prior to the Panel's report, and the amount of  
6 remaining eligible SEP dollars, EPA shall determine which of the Corresponding Polymers, if  
7 any, shall be used in the biodegradation studies.

8 **6. Study Preliminary Reports.** Within seven (7) business days of the laboratory  
9 completing the biodegradation studies on the first Fluorotelomer Product and any of its  
10 Corresponding Polymers (or first group of Fluorotelomer Products and any of their  
11 Corresponding Polymers), the laboratory shall submit a preliminary report summarizing the  
12 study results to EPA, DuPont, and the Panel Administrator for distribution to the Peer  
13 Consultation Panel.

14 a. In providing the preliminary report, the laboratory shall also provide  
15 the protocols and a copy of the raw data. The laboratory shall only provide the QAPP to the  
16 Panel Administrator with the first Fluorotelomer Product and any of its Corresponding Polymers  
17 (or first group of Fluorotelomer Products and any of their Corresponding Polymers).

18 b. As the laboratory completes biodegradation studies on each  
19 Fluorotelomer Product and Corresponding Polymers (or group of Fluorotelomer Products and  
20 Corresponding Polymers), the laboratory shall submit preliminary reports and associated  
21 information described in Section V.B.6.a, above, to EPA, DuPont, and to the Panel  
22 Administrator for distribution to the Peer Consultation Panel.

1 C. Reporting Test and Study Results

2 1. Each laboratory shall follow 40 C.F.R. Part 792, subpart J in preparing the  
3 final report for the tests that it performs.

4 2. Each laboratory must submit a final report to EPA, DuPont, and the Panel  
5 Administrator within thirty (30) days of completing all of the work identified in its contract with  
6 DuPont.

7 V. PEER CONSULTATION FOR TESTS PERFORMED ON DUPONT'S  
8 FLUOROTELOMER PRODUCTS AND CORRESPONDING POLYMERS

9 A. *Peer Consultation Panel and Charges.* As part of this Biodegradation SEP, DuPont  
10 shall contract with an independent third party to serve as a Panel Administrator to implement and  
11 administer the Peer Consultation process under this Biodegradation SEP.

12 1. The Panel Administrator shall select a Peer Consultation Panel ("Panel") that  
13 will address the charges set forth in Section V.A.2, below.

14 a. The Panel Administrator shall solicit potential Panel member  
15 nominations from the public, will allow self-nomination, and may nominate potential Panel  
16 members. The parties may submit Panel member nominations to the Panel Administrator.

17 b. After receiving Panel member nominations, the Panel Administrator  
18 shall develop a pool of potential Panel members that will be subject to comment by EPA,  
19 DuPont, and the public.

20 c. After considering all comments received regarding the Panel member  
21 pool, the Panel Administrator shall select a potential Panel and submit the potential Panel to EPA  
22 and DuPont for comment. The Panel Administrator has the exclusive authority to select the  
23 Panel. If both parties, independently, recommend to the Panel Administrator that a particular

1 potential Panel member would not be appropriate to serve on the Panel, the Panel Administrator  
2 shall remove such individual from the potential Panel and from the pool, select a new potential  
3 Panel from the pool of potential Panel members, and then submit a new potential Panel to EPA  
4 and DuPont for comment. The Panel Administrator shall follow this approach until it has  
5 selected a final Panel.

6 d. The Panel Administrator shall treat all comments received under  
7 Sections V.A.1.b and V.A.1.c as confidential.

8 2. The Panel is charged to:

9 a. Review the approved or accepted protocols that the laboratory used to  
10 characterize the Fluorotelomer Products and Corresponding Polymers for chemical  
11 characteristics, compositional analysis, oligomeric content, molecular weight distribution, and  
12 residual content as discussed in Attachment B of this Biodegradation SEP and determine:

13 i. whether the approved or accepted protocols were sufficiently  
14 robust to provide reliable characterization data, and

15 ii. whether the laboratory correctly followed the protocols.

16 b. Review the design and approved or accepted protocol that was used to  
17 run each pilot and results for each pilot to provide comments and recommendations for  
18 developing a final design and protocol for the OECD Guideline 303A and SCAS studies that will  
19 be approved by EPA prior to implementation by the laboratory.

20 c. Compare the pilot results and characterization data of each  
21 Fluorotelomer Product to the pilot results and characterization data of its Corresponding Polymer  
22 to advise EPA regarding the similarities and differences of the Corresponding Polymers as

1 compared to the Fluorotelomer Products, and which, if any, of the Corresponding Polymers  
2 should be used in the biodegradation studies.

3 i. If, based upon such comparison, the Panel can identify one  
4 Corresponding Polymer for each Fluorotelomer Product that should be used in the  
5 biodegradation studies, the Panel shall so state, and provide a detailed explanation as to why it is  
6 appropriate to use only this one Corresponding Polymer in the biodegradation studies.

7 ii. If, based upon such comparison, the Panel cannot identify one  
8 Corresponding Polymer for each Fluorotelomer Product but can identify two Corresponding  
9 Polymers for a particular Fluorotelomer Product, the Panel shall so state, and provide a detailed  
10 explanation as to why it is appropriate to use the two Corresponding Polymers in the  
11 biodegradation studies.

12 iii. If, based upon such comparison, the Panel cannot identify two  
13 Corresponding Polymers for each Fluorotelomer Product and recommends that all three  
14 Corresponding Polymers for a particular Fluorotelomer Product be used in the biodegradation  
15 studies, the Panel shall so state, and provide a detailed explanation as to why it is appropriate to  
16 use all three Corresponding Polymers in the biodegradation studies.

17 iv. If, based upon such comparison, the Panel cannot identify any  
18 Corresponding Polymers for a Fluorotelomer Product and recommends that no Corresponding  
19 Polymer be used in the biodegradation studies, the Panel shall so state, and provide a detailed  
20 explanation as to why it is not appropriate to use any Corresponding Polymers in the  
21 biodegradation studies.

1 v. The Panel shall also advise EPA as to whether the laboratory  
2 should run a 14-day pilot test for OECD Guideline 303A and SCAS on each of the  
3 Corresponding Polymers that it recommends should be used in the biodegradation studies but  
4 which were not pilot tested by the laboratory performing the biodegradation work.

5 d. Advise EPA regarding which analytes that were measured for in the  
6 pilot tests should also be measured for in the biodegradation studies.

7 e. Evaluate the results of the OECD Guideline 303A and SCAS studies  
8 performed on the fluorotelomer products and any corresponding purified fluorotelomer products,  
9 and advise EPA as to what the results mean, both for the individual substances and for the group  
10 of test substances as a whole.

11 f. Provide comment on whether 14C labeling or other methods would  
12 enhance the characterization of the test substances, measurement of the potential for  
13 biodegradation, and/or the evaluation of the biodegradation study results. If so, the Panel should  
14 describe how, and in what ways, the use of 14C-radiolabeled Lab-scale Synthesized  
15 Fluorotelomer Product would increase the usefulness of the results of the characterization and  
16 biodegradation studies.

17 3. EPA, after consultation with DuPont, may submit additional, timely charges to  
18 the Panel that relate to, and are consistent with, the purposes of this Biodegradation SEP.

19 4. The Panel Administrator may request a clarification from EPA regarding the  
20 charges set forth in Section V.A.2, above. Such request must be made in writing. The Panel  
21 Administrator will provide DuPont a copy of its written request and EPA will provide DuPont  
22 with a copy of its written response to the request, in accordance with Section V.E.8, below.



1           B. *Requirements of Panel Input.* The Panel will provide input to EPA on an advisory  
2 basis; such input will be provided by way of a summary document that reflects the individual  
3 opinions of the Panel members. The Panel Administrator may designate fewer than all members  
4 of the Panel to participate in providing advice on specific charges. Accordingly, at different  
5 times during the Peer Consultation process, the Panel may be composed of different experts  
6 appropriate to the issue(s), but shall only be composed of the experts that have been selected by  
7 the Panel Administrator to serve as members of this Peer Consultation Panel. While consensus is  
8 not required, an accurate summary of all opinions expressed by the individual members must be  
9 submitted to EPA. The Panel will not operate under a consensus-based process but rather should  
10 identify areas of agreement and disagreement, and provide supporting scientific rationale. While  
11 EPA will consider the advice and recommendations it receives from the Panel, EPA is not bound  
12 by such advice or recommendations.

13           C. Qualifications and Requirements for Panel Members

14           1. The Panel must be composed of scientific experts who, collectively, have  
15 extensive and broad experience relevant to such areas as conducting and/or assessing  
16 biodegradation testing and environmental fate of polymers, and laboratory analysis and  
17 characterization of polymers and fluorochemicals. Specific knowledge of fluorotelomer  
18 chemistry is desirable.

19           2. Panel members must have sufficient technical expertise to make meaningful  
20 contributions to science-based evaluations.

21           3. Examples of the types of expertise that will be needed include, but are not  
22 limited to, conducting biodegradation testing, environmental fate, polymer chemistry, analytical

1 chemistry under 40 C.F.R. Part 792, and/or fluorotelomer/ fluoropolymer chemistry.

2 D. General Requirements for the Peer Consultation Process

3 1. One Panel will be selected by the Panel Administrator and shall be composed  
4 of at least four (4) but no more than eight (8) members collectively meeting the qualifications  
5 stated in Section V.C.

6 2. In selecting the Panel, the Panel Administrator shall use conflict of interest  
7 guidelines approved by EPA. DuPont shall have an opportunity to review and provide  
8 comments to EPA regarding the conflict of interest guidelines.

9 3. The Panel Administrator shall submit information to Administrative Record  
10 (AR) 226 to ensure that the public has an opportunity to nominate panel members, access to the  
11 Panel's sanitized final reports, and access to all sanitized laboratory final reports. The Panel  
12 Administrator shall not disclose any information that would be Toxic Substances Control Act  
13 Confidential Business Information if submitted to EPA.

14 4. Panel meetings and deliberations will not be open to the public but will be  
15 open to DuPont and EPA employees and/or contractors with Toxic Substances Control Act  
16 Confidential Business Information clearance. Such Panel meetings and/or deliberations may  
17 also be open to other individuals or entities that EPA would like to attend, subject to  
18 confidentiality agreements, and prior approval from DuPont.

19 5. If practicable, Panel meetings and deliberations will be held at or near the  
20 facilities of the laboratory conducting work relevant to the charge or charges under consideration  
21 at such meetings and/or deliberations so that Panel members can visit the laboratory, as needed.

1                   6. EPA and DuPont may submit written comments to the Panel Administrator  
2 regarding technical documents developed by the laboratories under consideration by the Peer  
3 Consultation Panel. The Panel Administrator shall not provide such written comments to Panel  
4 members in advance of any Panel meetings or deliberations but only provide such comments to  
5 the Panel members at the time of the Panel meetings or deliberations so as not to bias the Panel  
6 members' premeeting consideration of any particular issue under consideration.

7                   E. Selection and Responsibilities of the Panel Administrator

8                   1. By February 1, 2006, the parties will agree to the Panel Administrator.

9                   2. By March 15, 2006, DuPont must provide EPA with a final draft of the  
10 proposed contract that DuPont and the Panel Administrator have negotiated. The contract shall  
11 not be executed by DuPont and the Panel Administrator until EPA has reviewed and either  
12 approved or accepted the contract. The contract shall provide for appropriate confidentiality  
13 provisions.

14                  3. Within seven (7) business days from receipt of EPA's approval (or acceptance)  
15 of the proposed contract, DuPont must sign and forward the contract to the Panel Administrator  
16 for execution.

17                  a. DuPont and the Panel Administrator shall seek to execute the contract  
18 within twenty-one (21) days of DuPont's receipt of EPA's approval (or acceptance) of the  
19 proposed contract. If DuPont and the Panel Administrator have not executed the contract within  
20 twenty-one (21) days of DuPont's receipt of EPA's approval (or acceptance) of the proposed  
21 contract in accordance with Section II.G.2, DuPont must inform EPA of the delay, explain the  
22 reason for the delay, provide a reasonable estimate as to when the contract will be executed, and

1 exercise its right to an automatic extension provided in Section II.L, above. However, if DuPont  
2 believes that, notwithstanding its best efforts, the candidate Panel Administrator will not execute  
3 the contract with DuPont, DuPont shall provide notice to EPA of the impasse. EPA reserves the  
4 right to contact such candidate Panel Administrator, upon receipt of such notice from DuPont, to  
5 inquire why it has not entered into the contract with DuPont. If DuPont and the candidate Panel  
6 Administrator have not entered into a contract within fourteen (14) days after EPA's inquiry,  
7 unless EPA and DuPont agree to a longer time period, then the parties shall follow the approach  
8 set forth in Section V.E.4, below.

9 b. Within five (5) business days from the date that DuPont and the Panel  
10 Administrator execute the contract, DuPont must notify EPA that it has entered into the contract  
11 with the Panel Administrator.

12 4. If no Panel Administrator enters into a contract with DuPont, the Directors of  
13 the Office of Civil Enforcement and the Office of Pollution Prevention and Toxics shall meet  
14 with DuPont to discuss appropriate changes that can be made to this Biodegradation SEP to  
15 foster Panel Administrator participation in the performance of this Biodegradation SEP. If the  
16 parties cannot agree to any such appropriate changes, or if after agreeing to such appropriate  
17 changes, no potential Panel Administrators enters into a contract with DuPont, this  
18 Biodegradation SEP shall be deemed to have ceased prior to its completion, in which case,  
19 DuPont shall not be subject to Section VII.3 of the CAFO but DuPont shall be subject to Section  
20 VII.1 of the CAFO, and the parties may exercise Section VI of the CAFO even though this  
21 Biodegradation SEP is not deemed satisfactorily completed.

1                   5. ***Peer Consultation Process Work Plan.*** Within sixty (60) days of contract  
2 execution, the Panel Administrator must submit to EPA a proposed work plan (including all  
3 applicable attachments) that addresses the following:

4                   a. The process, schedule, and budget for implementing and administering  
5 the Peer Consultation process under this Biodegradation SEP from the date the Panel  
6 Administrator executes the contract with DuPont through the date that the Panel Administrator  
7 submits to EPA and AR226 the Panel’s final report from the last Panel meeting.

8                   b. A description of the process for nominating and selecting the Panel  
9 members, in accordance with Section V.A.1, above, and the rationale to be used in determining  
10 how many experts to empanel to address the charges.

11                  c. The schedule for the Panel to timely address the charges in Section  
12 V.A.2 to ensure the most efficient use of the Panel.

13                  i. The Panel Administrator shall communicate with the laboratory  
14 performing the biodegradation testing to determine if it would be appropriate to have the Peer  
15 Consultation Panel review the results of the first pilot test for OECD Guideline 303A and SCAS  
16 and, once the laboratory has begun the full biodegradation studies, the results of the OECD  
17 Guideline 303A and SCAS studies for the first grouping of chemical substances identified in  
18 Attachment A, i.e., the three Fluorotelomer Products identified as the A group, and any  
19 Corresponding Polymers selected for testing, or any subsequent groupings identified in  
20 Attachment A, as appropriate. The Panel Administrator may seek a recommendation from the  
21 laboratory with regard to this issue and/or the Panel Administrator may make its own  
22 determination after reviewing the data as to whether it is appropriate to convene the Peer

1 Consultation Panel to review such results or to delay the review until all pilot tests and all  
2 biodegradation studies are completed.

3 ii. Regardless of how Peer Consultation is handled with regard to  
4 reviewing the first pilot test results and biodegradation study results, all pilot tests and  
5 biodegradation studies shall be reviewed by the Peer Consultation Panel.

6 d. The proposed conflict of interest guidelines that will be used to screen  
7 potential Panel members. The Panel Administrator shall send the conflict of interest guidelines  
8 to DuPont concurrent with its submission to EPA. DuPont shall have fourteen (14) business  
9 days to provide comments to EPA regarding such conflict of interest guidelines.

10 e. The proposed contract for the Panel members, including the proposed  
11 honorarium to be paid to each Panel member.

12 f. The proposed confidentiality agreements for the Panel members.

13 g. The process that the Panel Administrator will use to draft, on behalf of  
14 the Panel, the Panel's reports. The Panel Administrator must address the following:

15 i. The process and schedule for the Panel Administrator to  
16 compile comments from the Panel; and

17 ii. The process and schedule for the Panel Administrator to submit  
18 a draft of the document to the Panel members for their review and comment before such  
19 document becomes final.

20 h. The number and timing of the Panel's meetings to address the charges  
21 identified in Section V.A.2. If the Panel Administrator would like to arrange a Panel meeting or  
22 deliberation at a laboratory located outside of North America, the Panel Administrator shall seek

1 prior approval from EPA before arranging such meeting.

2 i. A discussion of any other function(s) not expressly stated herein but  
3 that are necessary to implement and administer the Peer Consultation process under this  
4 Biodegradation SEP.

5 6. Within seven (7) days of receipt of EPA's approval of the work plan, the Panel  
6 Administrator must commence the Peer Consultation process, as described in the EPA-approved  
7 work plan.

8 7. The Panel Administrator is responsible for arranging Panel meetings and/or  
9 deliberations, and acting as facilitator during Panel meetings and/or deliberations; coordinating  
10 exchange of information to Panel members; submitting all Panel reports to EPA and DuPont,  
11 with a sanitized version concurrently submitted to AR 226; and for carrying out all other  
12 functions necessary to implement and administer the Peer Consultation process under this  
13 Biodegradation SEP.

14 8. **Information Exchange.** When the Panel Administrator provides any  
15 information in oral or written form to EPA or DuPont concerning the Peer Consultation process,  
16 the Panel Administrator shall provide such information to the other party in the same form as  
17 soon as practicable. The Panel Administrator is not responsible for sharing information it  
18 receives in oral or written form from EPA or DuPont; the party providing such information to the  
19 Panel Administrator shall concurrently provide the information in the same form to the other  
20 party. However, when the Panel Administrator receives a substantive oral or written  
21 communication from DuPont or EPA that impacts the Panel Administrator's implementation  
22 and/or administration of the Peer Consultation process, it shall notify both parties of the

1 communication and provide a brief written description of the content of the communication.

2 9. Recommendations, Advice, and Conclusions of the Panel

3 a. ***Final Panel Reports submitted to the Parties.*** Within forty-five (45)  
4 days of each Panel meeting, the Panel Administrator shall submit a final written report, on behalf  
5 of the Panel, to EPA and DuPont, that addresses the charge or charges under consideration at  
6 such meeting.

7 b. ***Final Panel Reports submitted to AR 226.*** Within thirty (30) days  
8 after the Panel Administrator has submitted a final written report to EPA and DuPont, such final  
9 written report and a sanitized version of such final written report shall be submitted to AR 226.

10 VI. Miscellaneous

11 A. Eligible SEP Costs

12 1. The cost for providing sufficient quantities, as described in Sections II.D-E,  
13 above, of the Fluorotelomer Products for characterization, biodegradation pilot tests, and  
14 biodegradation studies shall not be an eligible SEP Cost.

15 2. The cost of preparing sufficient quantities, as described in Sections II.D-E, for  
16 characterization of Corresponding Polymers identified for pilot testing in Attachment A, and up  
17 to two additional Corresponding Polymers that the Panel recommends pursuant to charge  
18 V.A.2.c, shall not be an eligible SEP Cost.

19 3. The cost of preparing sufficient quantities, as described in Sections II.D-E, for  
20 biodegradation pilot tests of the Corresponding Polymers, as identified on Attachment A, shall  
21 not be an eligible SEP cost.

22 4. The cost of preparing sufficient quantities, as described in Sections II.D-E, for



1 biodegradation studies of up to two of the Corresponding Polymers that the Panel identifies  
2 pursuant to charge V.A.2.c, shall not be an eligible SEP cost.

3 B. The title, section headings, and sub-headings used in this Appendix A are intended  
4 by the parties to assist in reading the document and have no legal meaning or effect.

5 C. Unless otherwise indicated, the word “days” as used in this Appendix refers to  
6 calendar days.

7 D. Unless otherwise provided in this Appendix or its Attachments, terms shall have the  
8 same meaning as provided in 15 U.S.C §§ 2601 et seq. and 40 C.F.R. Parts 2 and 792. Terms  
9 not defined in 15 U.S.C §§ 2601 et seq. and 40 C.F.R. Parts 2 and 792, but that are defined in  
10 this Appendix or its Attachments, shall be given the meaning as defined in this Appendix or its  
11 Attachments.

12 E. Except as otherwise provided, all communications between the parties, including  
13 DuPont’s third party contractors, shall be in writing.

## APPENDIX A – BIODEGRADATION SUPPLEMENTAL ENVIRONMENTAL PROJECT

### ATTACHMENT A

The following table (which contains Toxic Substances Control Act Confidential Business Information) identifies the sequence and grouping of: (1) biodegradation pilot tests for the nine commercial fluorotelomer-based products identified in Table 1 of this Attachment (“Fluorotelomer Products”), (2) biodegradation pilot tests for corresponding synthesized or purified polymers equivalent to the Fluorotelomer Products with respect to the chemical composition that creates their fluorotelomer functionality (“Corresponding Polymers”), (3) biodegradation studies for the Fluorotelomer Products, and (4) biodegradation studies for any Corresponding Polymers.

The first column, Pilot Test Group, identifies the order of the Fluorotelomer Products (and their Corresponding Polymers) for pilot testing and then specifies which of the Fluorotelomer Products (and their Corresponding Polymers) should be grouped together for purposes of pilot testing. In both the pilot phase and when conducting the biodegradation studies, the laboratory shall test the Fluorotelomer Products separately from the Corresponding Polymers. The laboratory shall follow the alphabetical sequence (i.e., A, B, C, D) to determine the order for the Fluorotelomer Product pilot tests. The laboratory shall follow the numerical sequence within a group (i.e., A1, A2, A3) to determine which Fluorotelomer Products (and their Corresponding Polymers) in the group should be pilot tested first.

The laboratory shall determine whether to pilot test the second or third chemical in a group (e.g., in the A group, A2 and/or A3), by using the following approach. Using the A group as an example, if the test substances in A1 (the Fluorotelomer Product and its Corresponding Polymers) can be evenly dispersed in the experimental matrix and the 8-2 FTOH and PFOA analytes are quantifiable in the test system, the laboratory shall not pilot A2 or A3, because the criteria established in A1 should be applicable to A2 and A3. However, if any of the test substances in A1 do not remain dispersed in the experimental matrix or if the 8-2 FTOH and PFOA analytes are not quantifiable in the test system, the laboratory shall make appropriate adjustments during the pilot of A1 and shall pilot A2, applying the adjustments it made during the pilot of A1 in its pilot of A2. If any of the test substances in A2 do not remain dispersed in the experimental matrix or if the 8-2 FTOH and PFOA analytes are not quantifiable in the test system, the laboratory shall make appropriate adjustments during the pilot of A2 and shall pilot A3, applying the adjustments it made during the pilot of A2 in its pilot of A3. The laboratory shall follow this pilot testing approach for groups A, B, C, and D.

The second column, Test Sequence Group, identifies the order of the Fluorotelomer Products and their Corresponding Polymers for biodegradation studies. This column identifies which Fluorotelomer Products and Corresponding Polymers can be grouped together for biodegradation studies, to maximize laboratory efficiency, capacity allowing. If the laboratory does not have the capacity to perform the biodegradation studies on multiple chemicals at one time, then the laboratory shall follow the sequence order by Group number and Substance number to establish the testing sequence for each Fluorotelomer Product and any Corresponding Polymers.

The TPL shall run the first pilot (i.e., the pilot for test substance A1) and the 8-2 Alcohol control pilot concurrently.

**Table 1 (Non-CBI)**

<b>Pilot Test Group</b>	<b>Test Sequence Order</b>	<b>Non-CBI Chemical Name</b>	<b>CAS Number</b>
Control	1	Telomer B Alcohol 1-Decanol,3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10-heptafluoro-	678-39-7
A1	Group 1 Substance 2	Polysubstituted urethane	
A2	Group 1 Substance 3	Polysubstituted urethane	
A3	Group 1 Substance 1	Fluorinated substituted urethane	
B	Group 2 Substance 1	Polysubstituted phosphate salt	
C1	Group 3 Substance 3	Polysubstituted acrylic copolymer	
C2	Group 3 Substance 2	Perfluoroalkyl acrylate copolymer latex	
C3	Group 3 Substance 1	Perfluoroalkyl acrylate copolymer latex	
D1	Group 4 Substance 1	Polysubstituted acrylic copolymer	
D2	Group 4 Substance 2	Polysubstituted methacrylic copolymer	

## APPENDIX A – BIODEGRADATION SUPPLEMENTAL ENVIRONMENTAL PROJECT

### ATTACHMENT B:

#### Characterization of Fluorotelomer Products and Corresponding Polymers

##### I. Purposes

The characterization of the nine commercial fluorotelomer-based products identified in Table 1 of Attachment A to this Appendix (“Fluorotelomer Products”) and the corresponding synthesized or purified polymers equivalent to the Fluorotelomer Products with respect to the chemical composition that creates their fluorotelomer functionality (“Corresponding Polymers”) serves the following purposes:

- A. To Address the identity, purity, quantity and composition of the Fluorotelomer Products and Corresponding Polymers.
- B. To Explain the outcome of the biodegradation studies performed on the Fluorotelomer Products and Corresponding Polymers.

##### II. Characterization Procedures

###### A. Analysis of Fluorotelomer Products and Corresponding Polymers

The laboratory performing characterization of the Fluorotelomer Products and Corresponding Polymers shall determine the molecular weight distribution of each Fluorotelomer Product and any Corresponding Polymers. The Fluorotelomer Products and Corresponding Polymers shall be dissolved in AK-225G:THF. If the laboratory determines that AK-225G:THF is not an effective solvent, the laboratory shall use another, more effective, solvent. The actual solvent that the laboratory uses shall be documented in laboratory records and the reasoning for the alternative choice provided to EPA as part of the final report. The laboratory shall determine the weight percent of undissolved solids and provide such information to EPA as part of the final report.

The laboratory shall wash or leach the Fluorotelomer Products and any Purified Fluorotelomer Products, as that term is defined in Appendix A, using a scientifically acceptable method that is approved by EPA.

The laboratory shall determine the number average molecular weight and weight average molecular weight of the dissolved Fluorotelomer Products and Corresponding Polymers by size exclusion chromatography (“SEC”) pursuant to OECD Guidelines 118 (“Determination of the Number-Average Molecular Weight and the Molecular Weight Distribution of Polymers using Gel Permeation Chromatography”) and 119 (“Determination of the Low Molecular Weight Content of a Polymer using Gel Permeation Chromatography”). The laboratory shall use Polymethyl methacrylate (PMMA) or another appropriate polymer standard. Molecular Weight

(MW) of the standards must bracket the MW of the Fluorotelomer Products and Corresponding Polymers being determined.

B. Concentration of impurities in Fluorotelomer Products and Corresponding Polymers

The laboratory shall measure the levels of impurities specified in Table 1 of this Attachment using the most accurate instrumentation and procedures as of the time of testing. Values shall be expressed in weight concentrations (mg analyte /kg polymer) and mole concentrations (mole analyte /kg polymer). The final report shall include test and reference standards, equipment, preparation of standards and samples, calibration curve with at least five standards and  $r^2 > 0.99$ , fortifications bracketing the sample concentrations, and documentation that standard recoveries of 70 to 130% were achieved.

C. Analysis of total fluorine

The laboratory shall combust reference standards and blanks using Wickbold torch method. Mineralized inorganic fluoride (F-) shall be trapped in distilled water or aqueous sodium hydroxide. Fluoride ions shall be quantitated with fluoride ion selective electrode or ion chromatography. Values shall be expressed in weight concentrations (mg /kg polymer) and mole concentrations (mole /kg polymer). Successful recovery of the reference standard is defined as 70-130%. Following successful recovery of the reference standard, the Fluorotelomer Products and Corresponding Polymers shall be combusted and total fluorine of the combusted Fluorotelomer products and Corresponding Polymers shall be quantified.

D. Weight percent of total carbon

The laboratory shall calculate the weight percent of total carbon.

E. Particle size of solid Corresponding Polymers

When a Fluorotelomer Product, as a solution, is purified to form its corresponding Purified Fluorotelomer Product, it is anticipated that the Purified Fluorotelomer Product may be in a solid form. If the Purified Fluorotelomer Product remains as a liquid, no particle size determination is possible. If the Purified Fluorotelomer Product is in a solid form, it shall be ground to a uniform particle size of  $< 250 \mu\text{m}$  under low temperature conditions using liquid nitrogen. The ground Purified Fluorotelomer Product preparation will be visually inspected for uniformity and particle size  $< 250 \mu\text{m}$ . This particle size will help ensure that the Purified Fluorotelomer Products will be uniformly suspended in aqueous test solutions. The pilot test shall determine whether the studies require addition of the test substance in solid or liquid form.

### III. Documentation

- A. The identity of each Fluorotelomer Product and any Corresponding Polymers must be documented including:
  - 1. Name of the polymeric product (including lot or batch number)
  - 2. Concentration of active ingredient
  - 3. Date of purification
  
- B. The following supporting analytical data must be documented for each Fluorotelomer Product and any Corresponding Polymers:
  - 1. Equipment and reagents used to generate data
  - 2. Test and reference substances
  - 3. Preparation of standards and samples
  - 4. Analytical equipment operating conditions
  - 5. Calibration and analysis results
  - 6. Calculations
  
- C. The following characterization data must be documented for each Fluorotelomer Product and any Corresponding Polymers, and included in the final report:
  - 1. Ppm and mole/kg of each impurity listed in Table 1, below.
  - 2. Molecular weight distribution of each Fluorotelomer Product and Corresponding Polymers including:
    - a. If >90% solubilized, include % of undissolved solids
    - b. Number average molecular weight (Mn) of the polymer fraction
    - c. Weight average molecular weight (Mw) of the polymer fraction
    - d. Weight of fluorochemical charged to polymer (as manufactured)
  - 3. Calculation of total carbon weight %
  - 4. Total organic fluorine
  - 5. Particle size inspection

Table 1  
List of Analytes

Name	CAS Number
6-2 Fluorotelomer Alcohol	647-42-7
8-2 Fluorotelomer Alcohol	678-39-7
10-2 Fluorotelomer Alcohol	865-86-1
8-2 Fluorotelomer ethene	21652-58-4
8-2 Fluorotelomer Iodide	2043-53-0
10-2 Fluorotelomer Iodide	2043-54-1
Perfluorooctyl Iodide	507-63-1
Perfluorodecyl Iodide	423-62-1
8-2 Fluorotelomer acrylate (only for polyacrylates)	27905-45-9
8-2 Fluorotelomer saturated Acid	27854-31-5
8-2-Fluorotelomer unsaturated Acid	70887-84-2
Perfluorooctanoic Acid	335-67-1
2-H Perfluorooctanoic Acid	142821-03-2
Perfluorononanoic Acid	375-95-1
Perfluorodecanoic Acid	335-76-2
Perfluoroundecanoic Acid	2058-94-8
7-3 Fluorotelomer Acid	812-70-4
7-2 Fluorotelomer iso-ethanol	24015-83-6
7-2 Fluorotelomer unsaturated Acid	755-03-3
7-3 Fluorotelomer unsaturated Amide	56017-64-2
PFOA telomer 8-2 ester Octanoic acid, pentadecafluoro-, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluorodecyl ester MW 860	NA

APPENDIX A – BIODEGRADATION SUPPLEMENTAL ENVIRONMENTAL PROJECT

**ATTACHMENT C**

List of Analytes

<b>Name</b>	<b>CAS Number</b>
6-2 Fluorotelomer Alcohol	647-42-7
8-2 Fluorotelomer Alcohol	678-39-7
10-2 Fluorotelomer Alcohol	865-86-1
8-2 Fluorotelomer ethene	21652-58-4
8-2 Fluorotelomer Iodide	2043-53-0
10-2 Fluorotelomer Iodide	2043-54-1
Perfluorooctyl Iodide	507-63-1
Perfluorodecyl Iodide	423-62-1
8-2 Fluorotelomer acrylate (only for polyacrylates)	27905-45-9
8-2 Fluorotelomer saturated Acid	27854-31-5
8-2-Fluorotelomer unsaturated Acid	70887-84-2
Perfluorooctanoic Acid	335-67-1
2-H Perfluorooctanoic Acid	142821-03-2
Perfluorononanoic Acid	375-95-1
Perfluorodecanoic Acid	335-76-2
Perfluoroundecanoic Acid	2058-94-8
7-3 Fluorotelomer Acid	812-70-4
7-2 Fluorotelomer iso-ethanol	24015-83-6
7-2 Fluorotelomer unsaturated Acid	755-03-3
7-3 Fluorotelomer unsaturated Amide	56017-64-2



<p>PFOA telomer 8-2 ester        Octanoic acid, pentadecafluoro-,        3,3,4,4,5,5,6,6,7,7,8,8,9,9,10,10,10-heptafluorodecyl        ester        MW 860</p>	<p>NA</p>
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Any other impurities that the laboratory performing the biodegradation studies detects shall be identified, and quantified, if possible.

Analysis

Analyses shall be conducted using the most accurate instrumentation and procedures as of the time of testing. It is anticipated that analytical detection limits for the analytes will be in the sub parts per billion.

All analytical data, including any estimated or laboratory qualified values that are below quantitation limits, and all raw data including, but not limited to, laboratory notebook entries, chromatographs, and mass spectra will be included in the final reports and in the monthly reports submitted under Section III.F.2.g of Appendix A.

SCAS and OECD Guideline 303A Protocols

The laboratory shall conduct biodegradation pilot tests and studies on the nine commercial fluorotelomer-based products identified in Table 1 of Attachment A to this Appendix (“Fluorotelomer Products”) and any corresponding synthesized or purified polymers equivalent to the Fluorotelomer Products with respect to the chemical composition that creates their fluorotelomer functionality (“Corresponding Polymers”) following the guidelines for SCAS and OECD Guideline 303A provided below. Since these test methods were not developed to test polymer materials, appropriate modifications to the protocols may be necessary. Accordingly, the laboratory shall develop protocols which shall be approved by EPA prior to initiation of any biodegradation studies, including pilot testing.

**OECD GUIDELINE FOR THE TESTING OF CHEMICALS**  
**Simulation Test – Aerobic Sewage Treatment**  
**303 A: Activated Sludge Units**

**OECD Guideline 303 is subject to copyright and is not included in this Attachment C to Appendix A to the Consent Agreement and Final Order, In the Matter of: E. I. du Pont de Nemours and Company, Docket Nos. TSCA-HQ-2004-0016, RCRA-HQ-2004-0016, TSCA-HQ-2005-5001.**

**To purchase a copy of OECD Guideline 303, visit: [www.oecdbookshop.org](http://www.oecdbookshop.org) (ISBN # 9264070427).**

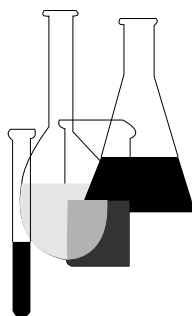
**To view a read-only copy of OECD Guideline 303, visit the EPA reading room located in EPA's Docket Center, Rm. B102–Reading Room, EPA West Building, 1301 Constitution Ave., NW, Washington, DC. Request to view OPPT-2003-0012-0169.**

**The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in the EPA Docket Center, is (202) 566–0280.**



# Fate, Transport and Transformation Test Guidelines

## OPPTS 835.5045 Modified SCAS Test for Insoluble and Volatile Chemicals



## INTRODUCTION

This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.

The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

**Final Guideline Release:** This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202-512-1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), or call 202-512-0132 for disks or paper copies. This guideline is also available electronically in ASCII and PDF (portable document format) from EPA's World Wide Web site (<http://www.epa.gov/epahome/research.htm>) under the heading "Researchers and Scientists/Test Methods and Guidelines/OPPTS Harmonized Test Guidelines."

**OPPTS 835.5045 Modified SCAS test for insoluble and volatile chemicals.**

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is 40 CFR 795.45 Inherent Biodegradability: Modified SCAS Test for chemical Substances That Are Water Soluble or Water Insoluble and Volatile..

(b) **Introductory information**—(1) **Prerequisites.** (i) Water solubility of the test chemical must be established.

(ii) The organic carbon content of the test chemical must be established.

(2) **Guidance information.** (i) Information on the relative proportions of the major components of the test chemical will be useful in interpreting the results obtained.

(ii) Information on the toxicity of the chemical may be useful to the interpretation of low results and in the selection of appropriate test concentrations.

(3) **Standard documents.** This Test Guideline has been based on the papers cited under paragraphs (e)(1) and (e)(2) of this guideline.

(c) **Method**—(1) **Introduction, purpose, scope, relevance, application and limits of test**—(i) **The method.** (A) The method is an adaptation of the Soap and Detergent Association Semi-Continuous Activated Sludge (SCAS) procedure for assessing the primary biodegradation of alkylbenzene sulphonate. The method involves exposure of the chemical to relatively high concentrations of microorganisms over a long time period (possibly several months). The viability of the microorganisms is maintained over this period by daily addition of a settled sewage feed.

(B) Since the conditions provided by the test are highly favorable to the selection and/or adaptation of microorganisms capable of degrading the test chemical, the procedure may also be used to produce microbial inocula adapted to selected chemicals for use in other tests. The test is applicable to organic chemicals that are water insoluble or water insoluble and volatile and that are not inhibitory to bacteria at the test concentration.

(ii) **Reference chemicals.** In some cases when investigating a new chemical, reference chemicals may be useful; however, specific reference chemicals cannot yet be recommended. Data on several chemicals used in interlaboratory tests are provided (see following Table 1.) primarily so

that calibration of the method may be performed from time to time and to permit comparison of results when another method is employed.

**Table 1.—Examples of Results of SCAS Test on Various Chemicals Used in the OECD/EEC Interlaboratory Test**

Test chemical	O <sub>T</sub> (mg/L)	O <sub>t</sub> - O <sub>c</sub> (mg/L)	Percent biodegradation/bioelimination
4-Acetylamino benzene sulfonate.	17.2	2.0	85
Tetrapropylene benzene sulfonate.	17.3	8.4	51.4
4-Nitrophenol .....	16.9	0.8	95.3
Diethylene glycol .....	16.5	0.2	98.8
Aniline .....	16.9	1.7	95.9
Cyclopentane tetracarboxylate ..	17.9	3.2	81.1

Duration of test is 40 days, except 120 days for cyclopentane tetracarboxylate.

(iii) **Principle of the test method.** (A) Activated sludge from a sewage treatment plant is placed in an aeration (SCAS) unit. The test chemical and settled domestic sewage are added, and the mixture is aerated for 23 hours. The aeration is then stopped, the sludge is allowed to settle, and the supernatant liquor is removed. The sludge remaining in the aeration chamber is then mixed with a further aliquot of test chemical and sewage and the cycle is repeated.

(B) This method requires use of a chemical-specific analytical technique or <sup>14</sup>C-labeled test chemical. The purpose of the method is to determine the fate of the test chemical in a conventional activated sludge treatment plant. To this end, a complete mass balance for the test chemical is established by quantifying parent chemical in settled effluent sludge solids (insoluble test chemicals whether volatile or not), effluent plus solids (insoluble test chemicals whether volatile or not), and off gases (volatile test chemicals only). The identification and quantification of degradation products in all phases are recommended, but not required.

(iv) **Quality criteria—(A) Reproducibility.** When primary biodegradation is considered, very precise data are obtained for chemicals that are extensively degraded. The results reported in the reference under paragraph (e)(1) of this guideline suggest 95-percent confidence limits of less than ±3 percent, and this includes interlaboratory tests. As would be expected, wider confidence limits are obtained for less biodegradable chemicals.

(B) **Possibility of standardization.** Since the method uses a feed of settled sewage, absolute standardization is not possible unless this feed were replaced by synthetic sewage. However, since the method is designed

to give an indication of the biodegradability potential of a chemical and is not a simulation test such standardization is unnecessary.

(C) **Possibility of automation.** Automation of this method would be possible but would be expensive. As the method is not labor intensive, the exercise would offer few advantages.

(2) **Description of the test procedure—(i) Preparations.** (A) The aeration units are cleaned and fixed in a suitable support. The air inlet tubes are connected to the supply manifold. A small laboratory-scale air compressor is used to aerate the units, and the air is presaturated with water to reduce evaporation losses from the units.

(B) If the test chemical is volatile, exhaust gases from the aeration units should be passed through a suitable trap (such as Amberlite XAD-4, Rohm and Haas, Philadelphia, PA) to remove volatilized organics.

(C) A sample of mixed liquor from an activated sludge plant treating predominantly domestic sewage is obtained. Approximately 150 mL of the mixed liquor are required for each aeration unit.

(D) The organic carbon analyzer is calibrated using potassium hydrogen phthalate.

(E) Stock solutions of the test chemicals are prepared: The concentration normally required is 400 mg/L as organic carbon which gives a test chemical concentration of 20 mg/L carbon at the start of each aeration cycle if no biodegradation is occurring.

(F) If the test chemical is insoluble in water at 400 mg/L it may be necessary to use ultrasound dispersion to obtain a uniform stable suspension. Alternatively, test chemical may be added directly to the aeration units.

(G) The organic carbon content of the stock solutions is measured.

(ii) **Test conditions.** A high concentration of aerobic microorganisms is used, and the effective detention period is 36 hours. The carbonaceous material in the sewage feed is oxidized extensively within 8 hours of the start of each aeration cycle. Thereafter, the sludge respire endogenously for the remainder of the aeration period, during which time the only available substrate is the test chemical unless this is also readily metabolized. These features, combined with daily reinoculation of the test when domestic sewage is used as the medium, provide highly favorable conditions for both adaptation and biodegradation.

(iii) **Performance of the test.** (A) A sample of mixed liquor from a suitable activated sludge plant is obtained and aerated during transportation to the laboratory. Each aeration unit is filled with 150 mL of mixed

liquor, and aeration is started. After 23 h, aeration is stopped, and the sludge is allowed to settle for 45 min. The tap is opened, and 100 mL of the supernatant liquor is withdrawn. A sample of settled domestic sewage is obtained immediately before use, and 100 mL is added to the sludge remaining in each aeration unit. Aeration is started anew. At this stage no test chemicals are added, and the units are fed daily with domestic sewage only until a clear supernatant liquor is obtained on settling. This usually takes up to 2 weeks, by which time the dissolved organic carbon in the supernatant liquor at the end of each aeration cycle should be less than 12 mg/L.

(B) At the end of this period the individual settled sludges are mixed, and 50 mL of the resulting composite sludge is added to each unit.

(C) One hundred milliliters of settled sewage are added to the control units, and 95 mL of settled sewage plus 5 mL of the appropriate test chemical stock solution or suspension (400 mg organic carbon/L) to the test units. If test chemical is added directly to aeration units, 100 mL of settled sewage is added, as in the control units.

(D) Aeration is started again and continued for 23 h. The sludge is then allowed to settle for 45 min and the supernatant drained off and analyzed for parent chemical. Before analysis the liquors are filtered through washed 0.45  $\mu\text{m}$  membrane filters and centrifuged. Temperature of the sample must not exceed 40 °C while it is in the centrifuge.

(E) If the test chemical is insoluble or expected to sorb significantly to sludge solids, settled sludge is also collected by an appropriate means (such as centrifugation) and extracted to remove test chemical, and the extract is analyzed for parent chemical.

(F) If the test chemical is volatile, traps for removing volatile organics from exhaust gases are also extracted and the extracts analyzed for parent chemical.

(G) The fill and draw procedure under paragraphs (c)(2)(iii)(C) through (c)(2)(iii)(F) of this guideline is repeated daily throughout the test.

(H) Before settling, it may be necessary to clean the walls of the units to prevent the accumulation of solids above the level of the liquid. A separate scraper or brush is used for each unit to prevent cross contamination.

(I) The length of the test for chemicals showing little or no biodegradation is indeterminate, but experience suggests that this should be at least 12 weeks.

(d) **Data and reporting**—(1) **Treatment of the results.** (i) The concentration of parent chemical in settled effluent sludge solids (insoluble test chemicals whether volatile or not), effluent plus solids (insoluble test



chemicals whether volatile or not), and off-gases (volatile test chemicals only) is plotted versus time for the test units. As biodegradation is achieved the level of the test chemical will decrease and approach a steady state. Once the levels of the test chemical are found to be constant over three consecutive measurements, three further measurements are made.

(ii) An example of the application of specific analytical technique to the SCAS test is discussed in the reference in paragraph (e)(2) of this guideline.

(e) **References.** The following references should be consulted for additional background information on this test guideline.

(1) A Procedure and Standards for the Determination of the Biodegradability of Alkyl Benzene Sulfonate and Linear Alkylate Sulfonate. *Journal of the American Oil Chemists Society* 42:986 (1965).

(2) Games, L.M. et al. Fate and distribution of a quaternary ammonium surfactant octadecyltrimethylammonium chloride (OTAC), in wastewater treatment. *Environmental Science and Technology* 16:483–488 (1982).

## APPENDIX A – BIODEGRADATION SUPPLEMENTAL ENVIRONMENTAL PROJECT

### **ATTACHMENT D: Chain of Custody Procedures for Shipping Test Substances**

#### I. Purpose

In order to ensure accurate generation of test substances and data, DuPont and/or the laboratories used by DuPont handling test substances and conducting tests and studies must follow acceptable procedures that document and/or explain how the test substances were packed and shipped. This Attachment outlines the minimum procedures that must be followed and the documentation that must be retained for the study records when packing and shipping test substances. As used in this Attachment, test substances include, the nine commercial fluorotelomer-based products identified in Table 1 of Attachment A to this Appendix (“Fluorotelomer Products”), corresponding synthesized or purified polymers equivalent to the Fluorotelomer Products with respect to the chemical composition that creates their fluorotelomer functionality (“Corresponding Polymers”), and other chemicals.

#### II. Test Substance Identification

Before a test substance can be shipped, each test substance must have a unique identification number and this number must be entered on the chain of custody form and test substance information form. DuPont or the laboratory preparing or providing the test substance must provide the name of the test substance, the identification number and the date by which the test substance will be ready for shipment either to EPA or to another third party laboratory, whichever is applicable.

A copy of the chain of custody form must be included in the package containing the test substance to be sent to either EPA or to another third party laboratory, with the test substance information form. The identification number serves to relate the test substance with information on the activities and conditions that fully describe the origin of the test substance. Test substance identification will also include a project number in order to link the test substance with a specific study.

#### III. Packaging Test Substances

For test substances that are not regulated by DOT, place the volume of each test substance specified by the study protocol into duplicate containers appropriate for shipment. Double-bag each test substance, using zip-lock plastic bags. Complete the Identification Sheet for the study records. For test substances that are regulated by DOT, ship in separate 30 mL containers and use the numbering system as specified above. Also include on each label number X of total number Y.

#### IV. Shipping to Laboratories and to EPA

##### **A. Packing**

Each test substance should be labeled with the identification number. Fluorotelomer Products and Corresponding Polymers should not be shipped in the same package to reduce the potential for contamination. To avoid contamination, sampling equipment and

containers made from fluoropolymers should be avoided. Carefully cleaned polypropylene and polystyrene sample containers and centrifuge tubes have been satisfactorily used for the analysis of fluorinated compounds. However, all containers that come in contact with treated and untreated test substances must be confirmed to be free of PFOA. Containers that are not free of PFOA should be triple washed in high purity organic solvent, i.e., methanol, acetonitrile or isopropanol, and reconfirmed to be free of PFOA before use. The use of disposable labware is recommended, i.e., pipets.

The containers should be placed in a zip-lock plastic bag that is labeled with the test substance Identification Number and Project Number as described above. Be sure that the bag is tightly closed and puncture-free. Place the label with the identification number, project number and lot number on the outside of the inner plastic bag. Include the chain of custody form and the MSDS in the box(es) containing the test substances. Follow all appropriate shipment requirements.

#### **B. Material Safety Data Sheets**

Appropriate MSD sheets should be included. Ensure that the MSD sheet can be removed from the box without disturbing the packing contents. Place the MSD sheet in an envelope and place the envelope on top of the test substances in the box. The chain of custody form must also be placed in the box.

#### **C. Shipping Papers**

The chain of custody form serves as a packing list for the shipment and to document the contents of the shipment. It must accurately reflect the contents of the shipment. It is to be included in the package with the test substance(s).

Each chain of custody form must include the following:

- Project number
- Unique test substance number of each test substance in the shipment
- Unique shipment number
- Signature of investigator responsible for test substances and date on which the shipment left this person's custody

The packer of the shipment has the responsibility to verify that the test substance listed on the chain of custody form corresponds to the test substance actually shipped and that the test substance description on the chain of custody form is accurate. Any discrepancies must be rectified before the test substance is shipped.

The chain of custody form must be placed in the box. Place the chain of custody form in an envelope and place the envelope on top of the test substances in the box.

#### **D. Commercial Air Delivery Service**

Ship each package using a door-to-door carrier so that the package/articles will arrive during the normal 5-day workweek. Do not ship packages if the arrival date does not fall on a business work day.

**E. Airbills/Bill-of Lading**

A separate Airbill or the like is preferred for each shipment number, even if several different shipment numbers are sent at the same time. In this way, one Airbill can be associated with one shipment number. If this is not practical, at least clearly indicate on the Airbill each shipment number that was included in the shipment. A space is generally provided by the shipper for special notations.

When samples are surrendered to a carrier, documentation must be obtained from the carrier such as a copy of the Airbill or Bill-of-Lading that indicates that the chain of custody of the shipment has been transferred to the carrier. This document must bear the shipment number, the carrier's name, the date of transfer of custody, and signature of the sender. This documentation must be retained and become part of the study records.

Retain the original Airbill for the study records.

**F. Shipment Notification**

Immediately upon shipment, notify the recipient and include:

- Date of Shipment
- Carrier
- Overnight or Two-day delivery
- Date of Anticipated Arrival
- Tracking Number
- Approximate Size of Package
- Approximate Weight of Package
- Type of Test Substance



# EPA Requirements for Quality Assurance Project Plans

**EPA QA/R-5**

Quality



## FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Assurance Project Plan (QA Project Plan) as a tool for project managers and planners to document the type and quality of data needed for environmental decisions and to describe the methods for collecting and assessing those data. The development, review, approval, and implementation of the QA Project Plan is part of EPA's mandatory Quality System. The EPA Quality System requires all organizations to develop and operate management structures and processes to ensure that data used in Agency decisions are of the type and quality needed for their intended use. The QA Project Plan is an integral part of the fundamental principles and practices that form the foundation of the EPA Quality System.

This document provides the QA Project Plan requirements for organizations that conduct environmental data operations on behalf of EPA through contracts, financial assistance agreements, and interagency agreements; however, it may be used by EPA as well. It contains the same requirements as Chapter 5 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs*, which has been developed for internal use by EPA organizations. A companion document, *EPA Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 1998) provides suggestions for both EPA and non-EPA organizations on preparing, reviewing, and implementing QA Project Plans that satisfy the requirements defined in this document.

This document is one of the *EPA Quality System Series* documents which describe EPA policies and procedures for planning, implementing, and assessing the effectiveness of a quality system. Questions regarding this document or other *EPA Quality System Series* documents should be directed to:

U.S. EPA  
Quality Staff (2811R)  
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e-mail: [quality@epa.gov](mailto:quality@epa.gov)

Copies of *Quality System Series* documents may be obtained from the Quality Staff or by downloading them from the Quality Staff Home Page:

[www.epa.gov/quality](http://www.epa.gov/quality)

## **ACKNOWLEDGMENTS**

This document reflects the collaborative efforts of many quality management professionals who participate in the challenge for continual improvement in quality systems supporting environmental programs. These individuals, representing the EPA, other Federal agencies, State and local governments, and private industry, reflect a diverse and broad range of needs and experiences in environmental data collection programs. Their contributions and the comprehensive reviews during the development of this document are greatly appreciated.



# TABLE OF CONTENTS

	<u>Page</u>
<b>CHAPTER 1. INTRODUCTION</b> .....	<b>1</b>
1.1 BACKGROUND .....	1
1.2 QA PROJECT PLANS, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-1994 .....	2
1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM .....	4
1.4 INTENDED AUDIENCE .....	4
1.5 PERIOD OF APPLICABILITY .....	4
1.6 ADDITIONAL RESOURCES .....	4
1.7 SUPERSESSION .....	5
<b>CHAPTER 2. QA PROJECT PLAN REQUIREMENTS</b> .....	<b>7</b>
2.1 POLICY .....	7
2.2 PURPOSE .....	7
2.3 APPLICABILITY .....	7
2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS .....	7
2.4.1 General Content .....	7
2.4.2 Level of Detail .....	8
2.5 QA PROJECT PLAN PREPARATION AND APPROVAL .....	8
2.6 QA PROJECT PLAN IMPLEMENTATION .....	9
2.7 QA PROJECT PLAN REVISION .....	9
<b>CHAPTER 3. QA PROJECT PLAN ELEMENTS</b> .....	<b>11</b>
3.1 CONTENT REQUIREMENTS .....	11
3.2 GROUP A: PROJECT MANAGEMENT .....	12
3.2.1 A1 - Title and Approval Sheet .....	13
3.2.2 A2 - Table of Contents .....	13
3.2.3 A3 - Distribution List .....	14
3.2.4 A4 - Project/Task Organization .....	14
3.2.5 A5 - Problem Definition/Background .....	14
3.2.6 A6 - Project/Task Description .....	14
3.2.7 A7 - Quality Objectives and Criteria .....	15
3.2.8 A8 - Special Training/Certification .....	15
3.2.9 A9 - Documents and Records .....	15
3.3 GROUP B: DATA GENERATION AND ACQUISITION .....	15
3.3.1 B1- Sampling Process Design (Experimental Design) .....	16
3.3.2 B2 - Sampling Methods .....	17
3.3.3 B3 - Sample Handling and Custody .....	17
3.3.4 B4 - Analytical Methods .....	17
3.3.5 B5 - Quality Control .....	18

		<b><u>Page</u></b>
	3.3.6 B6 - Instrument/Equipment Testing, Inspection, and Maintenance . . . . .	18
	3.3.7 B7 - Instrument/Equipment Calibration and Frequency . . . . .	18
	3.3.8 B8 - Inspection/Acceptance of Supplies and Consumables . . . . .	19
	3.3.9 B9 - Non-direct Measurements . . . . .	19
	3.3.10 B10 - Data Management . . . . .	19
3.4	GROUP C: ASSESSMENT AND OVERSIGHT . . . . .	20
	3.4.1 C1 - Assessments and Response Actions . . . . .	20
	3.4.2 C2 - Reports to Management . . . . .	20
3.5	GROUP D: DATA VALIDATION AND USABILITY . . . . .	21
	3.5.1 D1 - Data Review, Verification, and Validation . . . . .	21
	3.5.2 D2 - Verification and Validation Methods . . . . .	21
	3.5.3 D3 - Reconciliation with User Requirements . . . . .	21

**REFERENCES . . . . . 23**

**APPENDIX A. CROSSWALKS AMONG QUALITY ASSURANCE DOCUMENTS . A-1**

A.1	BACKGROUND . . . . .	A-1
A.2	CROSSWALK BETWEEN EPA QA/R-5 AND QAMS-005/80 . . . . .	A-1
A.3	CROSSWALK BETWEEN THE DQO PROCESS AND THE QA PROJECT PLAN . . . . .	A-3

**APPENDIX B. TERMS AND DEFINITIONS . . . . . B-1**

**FIGURES**

		<b><u>Page</u></b>
1.	EPA Quality System Components and Tools . . . . .	3
2.	Example Document Control Format . . . . .	14

**TABLES**

		<b><u>Page</u></b>
1.	Group A: Project Management Elements . . . . .	13
2.	Group B: Data Generation and Acquisition Elements . . . . .	16
3.	Group C: Assessment and Oversight Elements . . . . .	20
4.	Group D: Data Validation and Usability Elements . . . . .	21

# CHAPTER 1

## INTRODUCTION

### 1.1 BACKGROUND

Environmental programs conducted by or funded by the U.S. Environmental Protection Agency (EPA) involve many diverse activities that address complex environmental issues. The EPA annually spends several hundred million dollars in the collection of environmental data for scientific research and regulatory decision making. In addition, non-EPA organizations may spend as much as an order of magnitude more each year to respond to Agency requirements. If decision makers (EPA and otherwise) are to have confidence in the quality of environmental data used to support their decisions, there must be a structured process for quality in place.

A structured system that describes the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications is called a quality system. All organizations conducting environmental programs funded by EPA are required to establish and implement a quality system. EPA also requires that all environmental data used in decision making be supported by an approved Quality Assurance Project Plan (QA Project Plan). This requirement is defined in EPA Order 5360.1 A2 (EPA 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, for EPA organizations. Non-EPA organizations funded by EPA are required to develop a QA Project Plan through:

- 48 CFR 46, for contractors;
- 40 CFR 30, 31, and 35 for assistance agreement recipients; and
- other mechanisms, such as consent agreements in enforcement actions.

The QA Project Plan integrates all technical and quality aspects of a project, including planning, implementation, and assessment. The purpose of the QA Project Plan is to document planning results for environmental data operations and to provide a project-specific “blueprint” for obtaining the type and quality of environmental data needed for a specific decision or use. The QA Project Plan documents how quality assurance (QA) and quality control (QC) are applied to an environmental data operation to assure that the results obtained are of the type and quality needed and expected.

The ultimate success of an environmental program or project depends on the quality of the environmental data collected and used in decision-making, and this may depend significantly on the adequacy of the QA Project Plan and its effective implementation. Stakeholders (i.e., the data users, data producers, decision makers, etc.) shall be involved in the planning process for a program or project to ensure that their needs are defined adequately and addressed. While time spent on such planning may seem unproductive and costly, the penalty for ineffective planning

includes greater cost and lost time. Therefore, EPA requires that a systematic planning process be used to plan all environmental data operations. To support this requirement, EPA has developed a process called the Data Quality Objectives (DQO) Process. The DQO Process is the Agency's preferred planning process and is described in the *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000b). The QA Project Plan documents the outputs from systematic planning.

This requirements document presents specifications and instructions for the information that must be contained in a QA Project Plan for environmental data operations funded by EPA. The document also discusses the procedures for review, approval, implementation, and revision of QA Project Plans. Users of this document should assume that all of the elements described herein are required in a QA Project Plan unless otherwise directed by EPA.

## **1.2 QA PROJECT PLANS, THE EPA QUALITY SYSTEM, AND ANSI/ASQC E4-1994**

EPA Order 5360.1 A2 and the applicable Federal regulations (defined above) establish a mandatory Quality System that applies to all EPA organizations and organizations funded by EPA. Components of the EPA Quality System are illustrated in Figure 1. Organizations must ensure that data collected for the characterization of environmental processes and conditions are of the appropriate type and quality for their intended use and that environmental technologies are designed, constructed, and operated according to defined expectations. The QA Project Plan is a key project-level component of the EPA Quality System.

EPA policy is based on the national consensus standard, ANSI/ASQC E4-1994, *Specifications and Guidelines for Environmental Data Collection and Environmental Technology Programs*. The ANSI/ASQC E4-1994 standard describes the necessary management and technical elements for developing and implementing a quality system. This standard recommends using a tiered approach to a quality system. This standard recommends first documenting each organization-wide quality system in a Quality Management Plan or Quality Manual (to address requirements of *Part A: Management Systems* of the standard) and then documenting the applicability of the quality system to technical activity-specific efforts in a QA Project Plan or similar document (to address the requirements of *Part B: Collection and Evaluation of Environmental Data* of the standard). EPA has adopted this tiered approach for its mandatory Agency-wide Quality System. This document addresses Part B requirements of the standard.

A Quality Management Plan, or equivalent Quality Manual, documents how an organization structures its quality system, defines and assigns QA and QC responsibilities, and describes the processes and procedures used to plan, implement, and assess the effectiveness of the quality system. The Quality Management Plan may be viewed as the "umbrella" document under which individual projects are conducted. EPA requirements for Quality Management Plans are defined in *EPA Requirements for Quality Management Plans (QA/R-2)* (EPA 2001). The

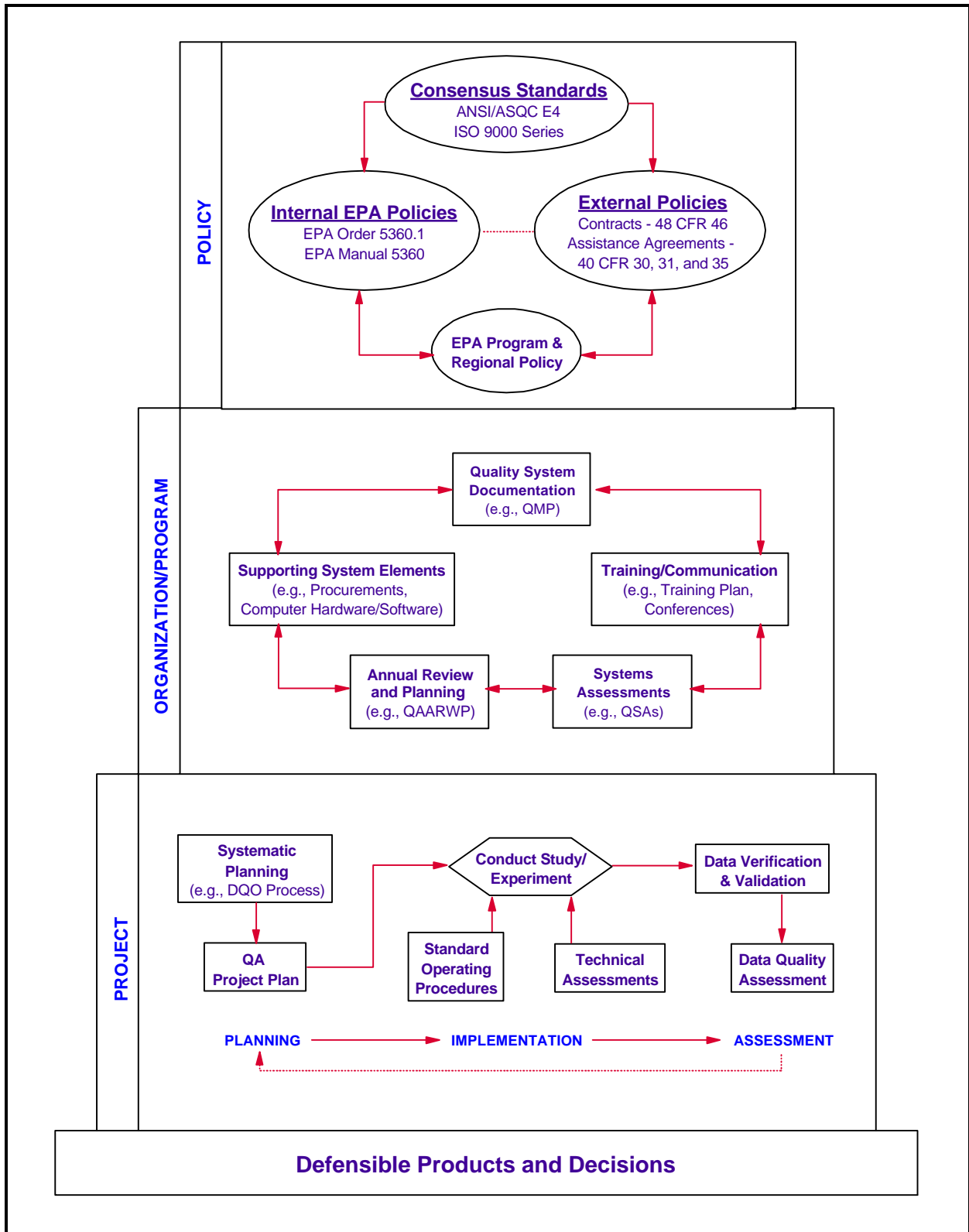


Figure 1. EPA Quality System Components and Tools

Quality Management Plan is then supported by project-specific QA Project Plans. In some cases, a QA Project Plan and a Quality Management Plan may be combined into a single document that contains both organizational and project-specific elements. The QA Manager for the EPA organization sponsoring the work has the authority to determine when a single document is applicable and will define the content requirements of such a document.

### **1.3 THE GRADED APPROACH AND THE EPA QUALITY SYSTEM**

Recognizing that a “one size fits all” approach to quality requirements will not work in organizations as diverse as EPA, implementation of the EPA Quality System is based on the principle of graded approach. Applying a graded approach means that quality systems for different organizations and programs will vary according to the specific objectives and needs of the organization. For example, the quality expectations of a fundamental research program are different from that of a regulatory compliance program because the purpose or intended use of the data is different. The specific application of the graded approach principle to QA Project Plans is described in Section 2.4.2.

### **1.4 INTENDED AUDIENCE**

This document specifies the requirements for developing QA Project Plans for organizations that conduct environmental data operations funded by EPA through contracts, financial assistance agreements, and interagency agreements. EPA organizations may also use this document to develop QA Project Plans since this document is clearer and more user-friendly than the equivalent requirements defined in Section 5.3 of EPA Order 5360 A1 (EPA 2000), *The EPA Quality Manual for Environmental Programs* (an internal policy document). However, the preparation, submission, review, and approval requirements for EPA organizations are still contained in Section 5.2 of EPA Order 5360 A1 as these represent internal EPA policy.

### **1.5 PERIOD OF APPLICABILITY**

This document shall be valid for a period of up to five years from the official date of publication. After five years, it shall either be reissued without change, revised, or withdrawn from the EPA Quality System.

### **1.6 ADDITIONAL RESOURCES**

Guidance on preparing QA Project Plans may be found in a companion document, *EPA Guidance for Quality Assurance Project Plans (QA/G-5)* (EPA 1998). This guidance discusses the application of the QA Project Plan requirements and provides examples. Other documents that provide guidance on activities critical to successful environmental data operations and complement the QA Project Plan preparation effort include:

- *Guidance for the Data Quality Objectives Process (QA/G-4)*, (EPA 2000b)
- *Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents (QA/G-6)*, (EPA 1995)
- *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, (EPA 2000a)

## **1.7 SUPERSESSION**

This document replaces QAMS-005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (EPA 1980) in its entirety.

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## **CHAPTER 2**

### **QA PROJECT PLAN REQUIREMENTS**

#### **2.1 POLICY**

All work funded by EPA that involves the acquisition of environmental data generated from direct measurement activities, collected from other sources, or compiled from computerized data bases and information systems shall be implemented in accordance with an approved QA Project Plan. The QA Project Plan will be developed using a systematic planning process based on the graded approach. No work covered by this requirement shall be implemented without an approved QA Project Plan available prior to the start of the work except under circumstances requiring immediate action to protect human health and the environment or operations conducted under police powers.

#### **2.2 PURPOSE**

The QA Project Plan documents the planning, implementation, and assessment procedures of, and how specific QA and QC activities will be applied during a particular project. The QA Project Plan demonstrates conformance to Part B requirements of ANSI/ASQC E4-1994.

#### **2.3 APPLICABILITY**

These requirements apply to all environmental programs funded by EPA that acquire, generate, or compile environmental data including work performed through contracts, work assignments, delivery orders, task orders, cooperative agreements, interagency agreements, State-EPA agreements, State, local and Tribal Financial Assistance/Grants, Research Grants, and in response to statutory or regulatory requirements and consent agreements. These requirements are negotiated into interagency agreements, including sub-agreements, and, in some cases, are included in enforcement settlement and consent agreements and orders. Where specific Federal regulations require the application of QA and QC activities (see Section 1.1), QA Project Plans shall be prepared, reviewed, and approved in accordance with the specifications contained in this document unless explicitly superseded by the regulation.

#### **2.4 GENERAL CONTENT AND DETAIL REQUIREMENTS**

##### **2.4.1 General Content**

The QA Project Plan must be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. Chapter 3 of this document describes specific elements to address for QA Project Plans submitted to EPA. In some cases, it may be necessary to add special requirements to the QA Project Plan. The EPA organization sponsoring the work has the authority to define any special requirements beyond

those listed in this document. If no additional requirements are specified, the QA Project Plan shall address all required elements. Each EPA organization defines their organizational-specific requirements for QA Project Plan documentation in their Quality Management Plan. All applicable elements defined by the EPA organization sponsoring the work must be addressed.

While most QA Project Plans will describe project- or task-specific activities, there may be occasions when a *generic* QA Project Plan may be more appropriate. A generic QA Project Plan addresses the general, common activities of a program that are to be conducted at multiple locations or over a long period of time; for example, it may be useful for a large monitoring program that uses the same methodology at different locations. A generic QA Project Plan describes, in a single document, the information that is not site or time-specific but applies throughout the program. Application-specific information is then added to the approved QA Project Plan as that information becomes known or completely defined. A generic QA Project Plan shall be reviewed periodically to ensure that its content continues to be valid and applicable to the program over time.

#### **2.4.2 Level of Detail**

The level of detail of the QA Project Plan should be based on a graded approach so that the level of detail in each QA Project Plan will vary according to the nature of the work being performed and the intended use of the data. As a result, an acceptable QA Project Plan for some environmental data operations may require a qualitative discussion of the experimental process and its objectives while others may require extensive documentation to adequately describe a complex environmental program.

### **2.5 QA PROJECT PLAN PREPARATION AND APPROVAL**

The QA Project Plan may be prepared by an EPA organization, a contractor, an assistance agreement holder, or another Federal agency under an interagency agreement. Except where specifically delegated in the Quality Management Plan of the EPA organization sponsoring the work, all QA Project Plans prepared by non-EPA organizations must be approved by EPA before implementation.

The QA Project Plan shall be reviewed and approved by an authorized EPA reviewer to ensure that the QA Project Plan contains the appropriate content and level of detail. The authorized reviewer, for example the EPA project manager<sup>1</sup> with the assistance and approval of the EPA QA Manager or by the EPA QA Manager alone, are defined by the EPA organization's Quality Management Plan. In some cases, the authority to review and approve QA Project Plans is delegated to another part of the EPA organization covered by the same Quality Management

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<sup>1</sup> This term refers to the EPA official responsible for the project. This individual may also be called Project Officer, Delivery Order Project Officer, Work Assignment Manager, or Principal Investigator.

Plan. In cases where the authority to review and approve QA Project Plans is delegated in writing by EPA to another organization (i.e., a Federal agency or a State under an EPA-approved Quality Management Plan when the environmental data operation itself has been delegated to that organization for implementation), it is possible that the EPA project manager and EPA QA Manager may not be involved in the review and approval steps.

## **2.6 QA PROJECT PLAN IMPLEMENTATION**

None of the environmental work addressed by the QA Project Plan shall be started until the QA Project Plan has been approved and distributed to project personnel except in situations requiring immediate action to protect human health and the environment or operations conducted under police powers. Subject to these exceptions, it is the responsibility of the organization performing the work to assure that no environmental data are generated or acquired before the QA Project Plan is approved and received by the appropriate project personnel. However, EPA may grant conditional approval to a QA Project Plan to permit some work to begin while non-critical deficiencies in the QA Project Plan are being resolved.

The organization performing the work shall ensure that the QA Project Plan is implemented as approved and that all personnel involved in the work have direct access to a current version of the QA Project Plan and all other necessary planning, implementation, and assessment documents. These personnel should understand the requirements prior to the start of data generation activities.

## **2.7 QA PROJECT PLAN REVISION**

Although the approved QA Project Plan must be implemented as prescribed; it is not inflexible. Because of the complex and diverse nature of environmental data operations, changes to original plans are often needed. When such changes occur, the approving official shall determine if the change significantly impacts the technical and quality objectives of the project. When a substantive change is warranted, the originator of the QA Project Plan shall modify the QA Project Plan to document the change and submit the revision for approval by the same authorities that performed the original review. Only after the revision has been received and approved (at least verbally with written follow-up) by project personnel, shall the change be implemented.

For programs or projects of long duration, such as multi-year monitoring programs or projects using a generic QA Project Plan, the QA Project Plans shall be reviewed at least annually by the EPA Project Manager (or authorized representative). When revisions are necessary, the QA Project Plan must be revised and resubmitted for review and approval.

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## CHAPTER 3

### QA PROJECT PLAN ELEMENTS

#### 3.1 CONTENT REQUIREMENTS

The QA Project Plan is a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. The QA Project Plan must provide sufficient detail to demonstrate that:

- the project technical and quality objectives are identified and agreed upon;
- the intended measurements, data generation, or data acquisition methods are appropriate for achieving project objectives;
- assessment procedures are sufficient for confirming that data of the type and quality needed and expected are obtained; and
- any limitations on the use of the data can be identified and documented.

Most environmental data operations require the coordinated efforts of many individuals, including managers, engineers, scientists, statisticians, and others. The QA Project Plan must integrate the contributions and requirements of everyone involved into a clear, concise statement of what is to be accomplished, how it will be done, and by whom. It must provide understandable instructions to those who must implement the QA Project Plan, such as the field sampling team, the analytical laboratory, modelers, and the data reviewers. In all aspects of the QA Project Plan, the use of national consensus standards and practices are encouraged.

In order to be effective, the QA Project Plan must specify the level or degree of QA and QC activities needed for the particular environmental data operations. Because this will vary according to the purpose and type of work being done, EPA believes that the graded approach should be used in planning the work. This means that the QA and QC activities applied to a project will be commensurate with:

- the purpose of the environmental data operation (e.g., enforcement, research and development, rulemaking),
- the type of work to be done (e.g., pollutant monitoring, site characterization, risk characterization, bench level proof of concept experiments), and
- the intended use of the results (e.g., compliance determination, selection of remedial technology, development of environmental regulation).

The QA Project Plan shall be composed of standardized, recognizable elements covering the entire project from planning, through implementation, to assessment. These elements are presented in that order and have been arranged for convenience into four general groups. The four groups of elements and their intent are summarized as follows:

- A Project Management - The elements in this group address the basic area of project management, including the project history and objectives, roles and responsibilities of the participants, etc. These elements ensure that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.
- B Data Generation and Acquisition - The elements in this group address all aspects of project design and implementation. Implementation of these elements ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and are properly documented.
- C Assessment and Oversight - The elements in this group address the activities for assessing the effectiveness of the implementation of the project and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.
- D Data Validation and Usability - The elements in this group address the QA activities that occur after the data collection or generation phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

All applicable elements, including the content and level of detail under each element, defined by the EPA organization sponsoring the work must be addressed in the QA Project Plan. If an element is not applicable, state this in the QA Project Plan. Documentation, such as an approved Work Plan, Standard Operating Procedures, etc., may be referenced in response to a particular required QA Project Plan element to reduce the size of the QA Project Plan. Current versions of all referenced documents must be attached to the QA Project Plan itself or be placed on file with the appropriate EPA office and available for routine referencing when needed. The QA Project Plan shall also address related QA planning documentation (e.g., Quality Management Plans) from suppliers of services critical to the technical and quality objectives of the project or task.

### **3.2 GROUP A: PROJECT MANAGEMENT**

The elements in this group (Table 1) address project management, including project history and objectives, roles and responsibilities of the participants, etc. These elements document

that the project has a defined goal, that the participants understand the goal and the approach to be used, and that the planning outputs have been documented.

<b>Table 1. Group A: Project Management Elements</b>	
A1	Title and Approval Sheet
A2	Table of Contents
A3	Distribution List
A4	Project/Task Organization
A5	Problem Definition/Background
A6	Project/Task Description
A7	Quality Objectives and Criteria
A8	Special Training/Certification
A9	Documents and Records

### **3.2.1 A1 - Title and Approval Sheet**

On the Title and Approval Sheet, include the title of the plan, the name of the organization(s) implementing the project, the effective date of the plan, and the names, titles, signatures, and approval dates of appropriate approving officials. Approving officials may include:

- Organization's Project Manager
- Organization's QA Manager
- EPA Project Manager
- EPA QA Manager
- Others, as needed (e.g., field operations manager, laboratory managers, State and other Federal agency officials)

### **3.2.2 A2 - Table of Contents**

Provide a table of contents for the document, including sections, figures, tables, references, and appendices. Apply a document control format (Figure 2) on each page following the Title and Approval Sheet when required by the EPA Project Manager and QA Manager.

Section No. _____
Revision No. _____
Date _____
Page ___ of ___

**Figure 2. Example Document Control Format**

### **3.2.3 A3 - Distribution List**

List the individuals and their organizations who need copies of the approved QA Project Plan and any subsequent revisions, including all persons responsible for implementation (e.g., project managers), the QA managers, and representatives of all groups involved. Paper copies need not be provided to individuals if equivalent electronic information systems can be used.

### **3.2.4 A4 - Project/Task Organization**

Identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. Include the principal data users, the decision makers, the project QA manager, and all persons responsible for implementation. The project quality assurance manager must be independent of the unit generating the data. (This does not include being independent of senior officials, such as corporate managers or agency administrators, who are nominally, but not functionally, involved in data generation, data use, or decision making.) Identify the individual responsible for maintaining the official, approved QA Project Plan.

Provide a concise organization chart showing the relationships and the lines of communication among all project participants. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended. The organization chart must also identify any subcontractor relationships relevant to environmental data operations, including laboratories providing analytical services.

### **3.2.5 A5 - Problem Definition/Background**

State the specific problem to be solved, decision to be made, or outcome to be achieved. Include sufficient background information to provide a historical, scientific, and regulatory perspective for this particular project.

### **3.2.6 A6 - Project/Task Description**

Provide a summary of all work to be performed, products to be produced, and the schedule for implementation. Provide maps or tables that show or state the geographic locations of field tasks. This discussion need not be lengthy or overly detailed, but should give an overall picture of how the project will resolve the problem or question described in A5.



### **3.2.7 A7 - Quality Objectives and Criteria**

Discuss the quality objectives for the project and the performance criteria to achieve those objectives. EPA requires the use of a systematic planning process to define these quality objectives and performance criteria.

### **3.2.8 A8 - Special Training/Certification**

Identify and describe any specialized training or certifications needed by personnel in order to successfully complete the project or task. Discuss how such training will be provided and how the necessary skills will be assured and documented.

### **3.2.9 A9 - Documents and Records**

Describe the process and responsibilities for ensuring the appropriate project personnel have the most current approved version of the QA Project Plan, including version control, updates, distribution, and disposition.

Itemize the information and records which must be included in the data report package and specify the reporting format for hard copy and any electronic forms. Records can include raw data, data from other sources such as data bases or literature, field logs, sample preparation and analysis logs, instrument printouts, model input and output files, and results of calibration and QC checks.

Identify any other records and documents applicable to the project that will be produced, such as audit reports, interim progress reports, and final reports. Specify the level of detail of the field sampling, laboratory analysis, literature or data base data collection, or modeling documents or records needed to provide a complete description of any difficulties encountered.

Specify or reference all applicable requirements for the final disposition of records and documents, including location and length of retention period.

## **3.3 GROUP B: DATA GENERATION AND ACQUISITION**

The elements in this group (Table 2) address all aspects of data generation and acquisition to ensure that appropriate methods for sampling, measurement and analysis, data collection or generation, data handling, and QC activities are employed and documented. The following QA Project Plan elements describe the requirements related to the actual methods or methodology to be used for the:

- collection, handling, and analysis of samples;

- data obtained from other sources (e.g., contained in a computer data base from previous sampling activities, compiled from surveys, taken from the literature); and
- the management (i.e., compiling, handling) of the data.

The methods described in these elements should have been summarized earlier in element A6. The purpose here is to provide detailed information on the methods. If the designated methods are well documented and are readily available to all project participants, citations are adequate; otherwise, detailed copies of the methods and/or SOPs must accompany the QA Project Plan either in the text or as attachments.

<b>Table 2. Group B: Data Generation and Acquisition Elements</b>	
B1	Sampling Process Design (Experimental Design)
B2	Sampling Methods
B3	Sample Handling and Custody
B4	Analytical Methods
B5	Quality Control
B6	Instrument/Equipment Testing, Inspection, and Maintenance
B7	Instrument/Equipment Calibration and Frequency
B8	Inspection/Acceptance of Supplies and Consumables
B9	Non-direct Measurements
B10	Data Management

### **3.3.1 B1- Sampling Process Design (Experimental Design)**

Describe the experimental data generation or data collection design for the project, including as appropriate:

- the types and numbers of samples required,
- the design of the sampling network,
- the sampling locations and frequencies,
- sample matrices,
- measurement parameters of interest, and
- the rationale for the design.

### **3.3.2 B2 - Sampling Methods**

Describe the procedures for collecting samples and identify the sampling methods and equipment, including any implementation requirements, sample preservation requirements, decontamination procedures, and materials needed for projects involving physical sampling. Where appropriate, identify sampling methods by number, date, and regulatory citation. If a method allows the user to select from various options, then the method citations should state exactly which options are being selected. Describe specific performance requirements for the method. For each sampling method, identify any support facilities needed. The discussion should also address what to do when a failure in the sampling or measurement system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented.

Describe the process for the preparation and decontamination of sampling equipment, including the disposal of decontamination by-products; the selection and preparation of sample containers, sample volumes, and preservation methods; and maximum holding times to sample extraction and/or analysis.

### **3.3.3 B3 - Sample Handling and Custody**

Describe the requirements for sample handling and custody in the field, laboratory, and transport, taking into account the nature of the samples, the maximum allowable sample holding times before extraction or analysis, and available shipping options and schedules for projects involving physical sampling. Sample handling includes packaging, shipment from the site, and storage at the laboratory. Examples of sample labels, custody forms, and sample custody logs should be included.

### **3.3.4 B4 - Analytical Methods**

Identify the analytical methods and equipment required, including sub-sampling or extraction methods, laboratory decontamination procedures and materials (such as in the case of hazardous or radioactive samples), waste disposal requirements (if any), and any specific performance requirements for the method. Where appropriate, analytical methods may be identified by number, date, and regulatory citation. Address what to do when a failure in the analytical system occurs, who is responsible for corrective action, and how the effectiveness of the corrective action shall be determined and documented. Specify the laboratory turnaround time needed, if important to the project schedule.

List any method performance standards. If a method allows the user to select from various options, then the method citations should state exactly which options are being selected. For non-standard method applications, such as for unusual sample matrices and situations, appropriate method performance study information is needed to confirm the performance of the

method for the particular matrix. If previous performance studies are not available, they must be developed during the project and included as part of the project results.

### **3.3.5 B5 - Quality Control**

Identify QC activities needed for each sampling, analysis, or measurement technique. For each required QC activity, list the associated method or procedure, acceptance criteria, and corrective action. Because standard methods are often vague or incomplete in specifying QC requirements, simply relying on the cited method to provide this information is usually insufficient. QC activities for the field and the laboratory include, but are not limited to, the use of blanks, duplicates, matrix spikes, laboratory control samples, surrogates, or second column confirmation. State the frequency of analysis for each type of QC activity, and the spike compounds sources and levels. State or reference the required control limits for each QC activity and corrective action required when control limits are exceeded and how the effectiveness of the corrective action shall be determined and documented.

Describe or reference the procedures to be used to calculate applicable statistics (e.g., precision and bias). Copies of the formulas are acceptable as long as the accompanying narrative or explanation specifies clearly how the calculations will address potentially difficult situations such as missing data values, “less than” or “greater than” values, and other common data qualifiers.

### **3.3.6 B6 - Instrument/Equipment Testing, Inspection, and Maintenance**

Describe how inspections and acceptance testing of instruments, equipment, and their components affecting quality will be performed and documented to assure their intended use as specified. Identify and discuss the procedure by which final acceptance will be performed by independent personnel (e.g., personnel other than those performing the work) and/or by the EPA project manager. Describe how deficiencies are to be resolved, when re-inspection will be performed, and how the effectiveness of the corrective action shall be determined and documented.

Describe or reference how periodic preventive and corrective maintenance of measurement or test equipment or other systems and their components affecting quality shall be performed to ensure availability and satisfactory performance of the systems. Identify the equipment and/or systems requiring periodic maintenance. Discuss how the availability of critical spare parts, identified in the operating guidance and/or design specifications of the systems, will be assured and maintained.

### **3.3.7 B7 - Instrument/Equipment Calibration and Frequency**

Identify all tools, gauges, instruments, and other sampling, measuring, and test equipment used for data generation or collection activities affecting quality that must be controlled and, at

specified periods, calibrated to maintain performance within specified limits. Describe or reference how calibration will be conducted using certified equipment and/or standards with known valid relationships to nationally recognized performance standards. If no such nationally recognized standards exist, document the basis for the calibration. Identify the certified equipment and/or standards used for calibration. Indicate how records of calibration shall be maintained and be traceable to the instrument.

### **3.3.8 B8 - Inspection/Acceptance of Supplies and Consumables**

Describe how and by whom supplies and consumables (e.g., standard materials and solutions, sample bottles, calibration gases, reagents, hoses, deionized water, potable water, electronic data storage media) shall be inspected and accepted for use in the project. State acceptance criteria for such supplies and consumables.

### **3.3.9 B9 - Non-direct Measurements**

Identify any types of data needed for project implementation or decision making that are obtained from non-measurement sources such as computer data bases, programs, literature files, and historical data bases. Describe the intended use of the data. Define the acceptance criteria for the use of such data in the project and specify any limitations on the use of the data.

### **3.3.10 B10 - Data Management**

Describe the project data management process, tracing the path of the data from their generation to their final use or storage (e.g., the field, the office, the laboratory). Describe or reference the standard record-keeping procedures, document control system, and the approach used for data storage and retrieval on electronic media. Discuss the control mechanism for detecting and correcting errors and for preventing loss of data during data reduction, data reporting, and data entry to forms, reports, and databases. Provide examples of any forms or checklists to be used.

Identify and describe all data handling equipment and procedures to process, compile, and analyze the data. This includes procedures for addressing data generated as part of the project as well as data from other sources. Include any required computer hardware and software and address any specific performance requirements for the hardware/software configuration used. Describe the procedures that will be followed to demonstrate acceptability of the hardware/software configuration required. Describe the process for assuring that applicable information resource management requirements are satisfied.

Describe the process for assuring that applicable Agency information resource management requirements (EPA Directive 2100) are satisfied (EPA QA Project Plans only). If other Agency data management requirements are applicable, such as the Chemical Abstract Service Registry Number Data Standard (EPA Order 2180.1), Data Standards for the Electronic

Transmission of Laboratory Measurement Results (EPA Order 2180.2), the Minimum Set of Data Elements for Ground-Water Quality (EPA Order 7500.1A), or new data standards as they are issued by EPA, discuss how these requirements are addressed.

### 3.4 GROUP C: ASSESSMENT AND OVERSIGHT

The elements in this group (Table 3) address the activities for assessing the effectiveness of project implementation and associated QA and QC activities. The purpose of assessment is to ensure that the QA Project Plan is implemented as prescribed.

C1	Assessments and Response Actions
C2	Reports to Management

#### 3.4.1 C1 - Assessments and Response Actions

Describe each assessment to be used in the project including the frequency and type. Assessments include, but are not limited to, surveillance, management systems reviews, readiness reviews, technical systems audits, performance evaluations, audits of data quality, and data quality assessments. Discuss the information expected and the success criteria (i.e., goals, performance objectives, acceptance criteria specifications, etc.) for each assessment proposed. List the approximate schedule of assessment activities. For any planned self-assessments (utilizing personnel from within the project groups), identify potential participants and their exact relationship within the project organization. For independent assessments, identify the organization and person(s) that shall perform the assessments if this information is available. Describe how and to whom the results of each assessment shall be reported.

Define the scope of authority of the assessors, including stop work orders, and when assessors are authorized to act.

Discuss how response actions to assessment findings, including corrective actions for deficiencies and other non-conforming conditions, are to be addressed and by whom. Include details on how the corrective actions will be verified and documented.

#### 3.4.2 C2 - Reports to Management

Identify the frequency and distribution of reports issued to inform management (EPA or otherwise) of the project status; for examples, reports on the results of performance evaluations and system audits; results of periodic data quality assessments; and significant quality assurance

problems and recommended solutions. Identify the preparer and the recipients of the reports, and any specific actions recipients are expected to take as a result of the reports.

### **3.5 GROUP D: DATA VALIDATION AND USABILITY**

The elements in this group (Table 4) address the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements determines whether or not the data conform to the specified criteria, thus satisfying the project objectives.

<b>Table 4. Group D: Data Validation and Usability Elements</b>	
D1	Data Review, Verification, and Validation
D2	Verification and Validation Methods
D3	Reconciliation with User Requirements

#### **3.5.1 D1 - Data Review, Verification, and Validation**

State the criteria used to review and validate -- that is, accept, reject, or qualify -- data, in an objective and consistent manner.

#### **3.5.2 D2 - Verification and Validation Methods**

Describe the process to be used for verifying and validating data, including the chain-of-custody for data throughout the life of the project or task. Discuss how issues shall be resolved and the authorities for resolving such issues. Describe how the results are conveyed to data users. Precisely define and interpret how validation issues differ from verification issues for this project. Provide examples of any forms or checklists to be used. Identify any project-specific calculations required.

#### **3.5.3 D3 - Reconciliation with User Requirements**

Describe how the results obtained from the project or task will be reconciled with the requirements defined by the data user or decision maker. Outline the proposed methods to analyze the data and determine possible anomalies or departures from assumptions established in the planning phase of data collection. Describe how reconciliation with user requirements will be documented, issues will be resolved, and how limitations on the use of the data will be reported to decision makers.

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## REFERENCES

- 40 CFR 30, Code of Federal Regulations, "Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations."
- 40 CFR 31, Code of Federal Regulations, "Uniform Administrative Requirements for Grants and Cooperative Agreement to State and Local Governments."
- 40 CFR 35, Code of Federal Regulations, "State and Local Assistance."
- 48 CFR 46, Code of Federal Regulations, "Federal Acquisition Regulations."
- ANSI/ASQC E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*, American National Standard, January 1995.
- EPA Directive 2100 (1998), *Information Resources Management Policy Manual*, U.S. Environmental Protection Agency, Washington, DC.
- EPA Order 2180.1 (June 1987), *Chemical Abstract Service Registry Number Data Standard*, U.S. Environmental Protection Agency, Washington, DC.
- EPA Order 2180.2 (December 1988), *Data Standards for the Electronic Transmission of Laboratory Measurement Results*, U.S. Environmental Protection Agency, Washington, DC.
- EPA Order 5360 A1 (May 2000). *EPA Quality Manual for Environmental Programs*, U.S. Environmental Protection Agency, Washington, DC.
- EPA Order 5360.1 A2 (May 2000), *Policy and Program Requirements for the Mandatory Agency-wide Quality System*, U.S. Environmental Protection Agency, Washington, DC.
- EPA Order 7500.1A (October 1992), *Minimum Set of Data Elements for Ground-Water Quality*, U.S. Environmental Protection Agency, Washington, DC.
- U.S. Environmental Protection Agency, 2001. *EPA Requirements for Quality Management Plans (QA/R-2)*, EPA/240/B-01/002, Office of Environmental Information.
- U.S. Environmental Protection Agency, 2000a. *Guidance for Data Quality Assessment: Practical Methods for Data Analysis (QA/G-9)*, EPA/600/R-96/084, Office of Environmental Information.

- U.S. Environmental Protection Agency, 2000b. *Guidance for the Data Quality Objectives Process (QA/G-4)*, EPA/600/R-96/055, Office of Environmental Information.
- U.S. Environmental Protection Agency, 1998. *Guidance for Quality Assurance Project Plans (QA/G-5)*, EPA/600/R-98/018, Office of Research and Development.
- U.S. Environmental Protection Agency, 1995. *Guidance for the Preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents (QA/G-6)*, EPA/600/R-96/027, Office of Research and Development.
- U.S. Environmental Protection Agency, 1980. *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans*, QAMS-005/80, Office of Research and Development.

## APPENDIX A

### CROSSWALKS AMONG QUALITY ASSURANCE DOCUMENTS

#### A.1 BACKGROUND

This appendix contains crosswalks between this document and other QA planning documents. The first crosswalk compares this requirements document with its predecessor document, QAMS 005/80, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans* (EPA 1980). The second crosswalk compares the elements of the QA Project Plan defined in this document with the steps defined in *Guidance for the Data Quality Objectives Process (QA/G-4)* (EPA 2000b), the Agency's preferred systematic planning process for environmental decision making. This crosswalk is provided to assist the reader in determining how the outputs from the DQO Process can be integrated into a QA Project Plan.

#### A.2 CROSSWALK BETWEEN EPA QA/R-5 AND QAMS-005/80

QAMS-005/80 ELEMENTS		QA/R-5 ELEMENTS	
1.0	Title Page with Provision for Approval Signatures	A1	Title and Approval Sheet
2.0	Table of Contents	A2	Table of Contents
3.0	Project Description	A5	Problem Definition/Background
		A6	Project/Task Description
4.0	Project Organization and Responsibility	A3	Distribution List
		A4	Project/Task Organization
		A8	Special Training/Certification
		A9	Documents and Records
5.0	QA Objectives for Measurement Data (PARCC)	A7	Quality Objectives and Criteria
6.0	Sampling Procedures	B1	Sampling Process Design
		B2	Sampling Methods
7.0	Sample Custody	B3	Sample Handling and Custody
8.0	Calibration Procedures and Frequency	B7	Instrument/Equipment Calibration and Frequency

<b>QAMS-005/80 ELEMENTS</b>		<b>QA/R-5 ELEMENTS</b>	
9.0	Analytical Procedures	B4	Analytical Methods
10.0	Data Reduction, Validation, and Reporting	D1	Data Review, Verification, and Validation
		D2	Verification and Validation Methods
		B9	Non-direct Measurements
		B10	Data Management
11.0	Internal Quality Control Checks and Frequency	B5	Quality Control
12.0	Performance and Systems	C1	Assessments and Response Actions
13.0	Preventive Maintenance	B6	Instrument/Equipment Testing, Inspection, and Maintenance
14.0	Specific Routine Procedures Measurement Parameters Involved	D3	Reconciliation with User Requirements
15.0	Corrective Action	C1	Assessments and Response Actions
16.0	QA Reports to Management	C2	Reports to Management

### A.3 CROSSWALK BETWEEN THE DQO PROCESS AND THE QA PROJECT PLAN

Elements	Requirements	DQO Overlap
PROJECT MANAGEMENT		
A1 Title and Approval Sheet	Title and approval sheet.	N/A
A2 Table of Contents	Document control format.	N/A
A3 Distribution List	Distribution list for the QA Project Plan revisions and final guidance.	Step 1: State the Problem
A4 Project/Task Organization	Identify individuals or organizations participating in the project and discuss their roles, responsibilities and organization.	Step 1: State the Problem
A5 Problem Definition/ Background	1) State the specific problem to be solved or the decision to be made. 2) Identify the decision maker and the principal customer for the results.	Step 1: State the Problem Step 2: Identify the Decision
A6 Project/Task Description	1) Hypothesis test, 2) expected measurements, 3) ARARs or other appropriate standards, 4) assessment tools (technical audits), 5) work schedule and required reports.	Step 1: State the Problem Step 2: Identify the Decision Step 3: Identify the Inputs to the Decision Step 6: Specify Limits on Decision Errors
A7 Quality Objectives and Criteria	Decision(s), population parameter of interest, action level, summary statistics and acceptable limits on decision errors. Also, scope of the project (domain or geographical locale).	Step 4: Define the Boundaries Step 5: Develop a Decision Rule Step 6: Specify Limits on Decision Errors
A8 Special Training/ Certification	Identify special training that personnel will need.	N/A
A9 Documents and Records	Itemize the information and records that must be included in a data report package, including report format and requirements for storage, etc.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data

Elements	Requirements	DQO Overlap
<b>DATA GENERATION AND ACQUISITION</b>		
B1 Sampling Process Design (Experimental Design)	Outline the experimental design, including sampling design and rationale, sampling frequencies, matrices, and measurement parameter of interest.	Step 5: Develop a Decision Rule Step 7: Optimize the Design for Obtaining Data
B2 Sampling Methods	Sample collection method and approach.	Step 7: Optimize the Design for Obtaining Data
B3 Sample Handling and Custody	Describe the provisions for sample labeling, shipment, chain-of-custody forms, procedures for transferring and maintaining custody of samples.	N/A
B4 Analytical Methods	Identify analytical method(s) and equipment for the study, including method performance requirements.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data
B5 Quality Control	Describe quality control procedures that should be associated with each sampling and measurement technique. List required checks and corrective action procedures.	Step 3: Identify the Inputs to the Decision
B6 Instrument/Equipment Testing, Inspection, and Maintenance	Discuss how inspection and acceptance testing, including the use of QC samples, must be performed to ensure their intended use as specified by the design.	Step 3: Identify the Inputs to the Decision
B7 Instrument/Equipment Calibration and Frequency	Identify tools, gauges and instruments, and other sampling or measurement devices that need calibration. Describe how the calibration should be done.	Step 3: Identify the Inputs to the Decision
B8 Inspection/Acceptance of Supplies and Consumables	Define how and by whom the sampling supplies and other consumables will be accepted for use in the project.	N/A

<b>Elements</b>	<b>Requirements</b>	<b>DQO Overlap</b>
B9 Non-direct Measurements	Define the criteria for the use of non-measurement data, such as data that come from databases or literature.	Step 1: State the Problem Step 7: Optimize the Design for Obtaining Data
B10 Data Management	Outline the data management scheme including the path and storage of the data and the data record-keeping system. Identify all data handling equipment and procedures that will be used to process, compile, and analyze the data.	Step 3: Identify the Inputs to the Decision Step 7: Optimize the Design for Obtaining Data
<b>ASSESSMENT AND OVERSIGHT</b>		
C1 Assessments and Response Actions	Describe the assessment activities needed for this project.	Step 7: Optimize the Design for Obtaining Data
C2 Reports to Management	Identify the frequency, content, and distribution of reports issued to keep management informed.	N/A
<b>DATA VALIDATION AND USABILITY</b>		
D1 Data Review, Verification, and Validation	State the criteria used to accept or reject the data based on quality.	Step 7: Optimize the Design for Obtaining Data
D2 Verification and Validation Methods	Describe the process to be used for verifying and validating data, including the chain-of-custody for data throughout the lifetime of the project.	Step 3: Identify the Inputs to the Decision
D3 Reconciliation With User Requirements	Describe how results will be evaluated to determine if performance criteria have been satisfied.	Step 7: Optimize the Design for Obtaining Data

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## APPENDIX B

### TERMS AND DEFINITIONS

**assessment** - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

**audit (quality)** - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

**calibration** - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

**chain-of-custody** - an unbroken trail of accountability that ensures the physical security of samples, data, and records.

**contractor** - any organization or individual that contracts to furnish services or items or perform work; a supplier in a contractual situation.

**data quality assessment** - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

**data usability** - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

**design** - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

**environmental conditions** - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

**environmental data** - any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

**environmental data operations** - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

**environmental processes** - manufactured or natural processes that produce discharges to or that impact the ambient environment.

**environmental programs** - work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

**environmental technology** - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

**financial assistance** - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or items. Financial assistance mechanisms include grants, cooperative agreements, performance partnership agreements, and government interagency agreements.

**graded approach** - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results.

**independent assessment** - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

**information resources management** - the planning, budgeting, organizing, directing, training and controls associated with information. The term encompasses both information itself and related resources such as personnel, equipment, funds and technology.

**inspection** - an activity such as measuring, examining, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements in order to establish whether conformance is achieved for each characteristic.

**management system** - a structured, non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

**method** - a body of procedures and techniques for performing an activity (e.g., sampling, modeling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

**participant** - when used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.

**performance evaluation** - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

**quality** - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

**quality assurance (QA)** - an integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

**quality assurance manager** - the individual designated as the principal manager within the organization having management oversight and responsibilities for planning, documenting, coordinating, and assessing the effectiveness of the quality system for the organization.

**quality assurance project plan** - a document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

**quality control (QC)** - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

**quality management** - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, documentation, and assessment) pertaining to the quality system.

**quality management plan** - a document that describes a quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and

staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted.

**quality system** - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, documenting, and assessing work performed by the organization and for carrying out required QA and QC activities.

**readiness review** - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

**record** - a completed document that provides objective evidence of an item or process. Records may include photographs, drawings, magnetic tape, and other data recording media.

**specification** - a document stating requirements and which refers to or includes drawings or other relevant documents. Specifications should indicate the means and the criteria for determining conformance.

**supplier** - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

**surveillance (quality)** - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

**technical systems audit (TSA)** - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system.

**validation** - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

**verification** - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, verification concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

APPENDIX A – BIODEGRADATION SUPPLEMENTAL ENVIRONMENTAL PROJECT

**ATTACHMENT F:  
Test Substance Certificate of Analysis**

**DuPont Test Substance Identification:** H-XXXXX  
**Generic Name :** Fluorotelomer-based

**Test Substance Properties**

- pH
- Density ( $\text{g}\cdot\text{mL}^{-1}$ )  $\text{g}\cdot\text{mL}^{-1}$
- Weight percent solids (wt% solids) wt%
- Weight percent active ingredient (wt% a.i.) wt%
- Weight percent Fluorine (%F) %F
- Number Average Molecular Weight (Mn)
- Weight Average Molecular Weight (Mw)
- Appearance

**Test Substance Composition**

CAS# wt%

**Test Substance Trace Chemical Impurities**

Name	CAS Number	ng•mg-1 *	nmol•mg-1 *
6-2 Fluorotelomer Alcohol	647-42-7		
8-2 Fluorotelomer Alcohol	678-39-7		
10-2 Fluorotelomer Alcohol	865-86-1		
8-2 Fluorotelomer ethene	21652-58-4		
8-2 Fluorotelomer Iodide	2043-53-0		
10-2 Fluorotelomer Iodide	2043-54-1		
Perfluorooctyl Iodide	507-63-1		
Perfluorodecyl Iodide	423-62-1		
8-2 Fluorotelomer acrylate (only for polyacrylates)	27905-45-9		

8-2 Fluorotelomer saturated Acid	27854-31-5		
8-2-Fluorotelomer unsaturated Acid	70887-84-2		
Perfluorooctanoic Acid	335-67-1		
2-H Perfluorooctanoic Acid	142821-03-2		
Perfluorononanoic Acid	375-95-1		
Perfluorodecanoic Acid	335-76-2		
Perfluoroundecanoic Acid	2058-94-8		
7-3 Fluorotelomer Acid	812-70-4		
7-2 Fluorotelomer iso-ethanol	24015-83-6		
7-2 Fluorotelomer unsaturated Acid	755-03-3		
7-3 Fluorotelomer unsaturated Amide	56017-64-2		
PFOA telomer 8-2 ester Octanoic acid, pentadecafluoro-, 3,3,4,4,5,5,6,6,7,7,8,8,9,9,10, 10,10-heptafluorodecyl ester MW 860	NA		

\* based on solids content

Storage Conditions for 1 year stability (temperature and lighting conditions)

Sample Expiration Date :

Prepared By : \_\_\_\_\_ Date: \_\_\_\_\_

## APPENDIX A – BIODEGRADATION SUPPLEMENTAL ENVIRONMENTAL PROJECT

### **ATTACHMENT G: List of Laboratories for Biodegradation and Characterization**

#### Biodegradation Laboratories

Springborn Smithers Laboratories  
Massachusetts Research Center  
790 Main Street  
Wareham, MA 02571  
Phone (508) 295-2550  
Fax (508) 295-8107  
<http://www.springbornsmithers.com/simltest.html>

ABC Laboratories, Inc.  
7200 E. ABC Lane  
Columbia, Missouri 65202 USA  
(573) 443 9000 Telephone  
(573) 443 9033 Facsimile  
[http://www.abclabs.com/cd/fate/fate\\_biodeg\\_metabolism.HTM](http://www.abclabs.com/cd/fate/fate_biodeg_metabolism.HTM)

Wildlife International  
8598 Commerce Drive, Easton, MD 21601  
<http://www.wildlifeinternational.com/biodeg.htm>

#### Characterization & Analytical Support Laboratories

Exygen Research  
3058 Research Drive  
State College, PA 16801  
Toll Free : 866.533.0092  
Telephone: 814.272.1039  
Facsimile: 814.272.1019  
Email: [info@exygen.com](mailto:info@exygen.com) <<mailto:info@exygen.com>>

STL Denver  
4955 Yarrow Street  
Arvada, CO 80002  
Phone: 303-736-0100  
Fax: 303-431-7171  
<http://www.stl-inc.com/index.htm>

Quest Pharmaceutical Services  
3 Innovation Way, Suite 240  
Newark, DE 19711  
302-369-5601  
302-369-5602  
<http://www.questpharm.com/>

**APPENDIX B  
TO CONSENT AGREEMENT AND FINAL ORDER**

**MICROSCALE CHEMISTRY AND GREEN CHEMISTRY  
FOR JUNIOR HIGH SCHOOLS AND HIGH SCHOOLS IN  
WOOD COUNTY, WEST VIRGINIA:  
SUPPLEMENTAL ENVIRONMENTAL PROJECT**

**Overview**

This document describes the Micro-scale Chemistry and Green Chemistry Program that Respondent E.I. du Pont de Nemours and Company (“DuPont” or “the Company”) will implement in five junior high schools and three high schools in the public school system of Wood County, West Virginia. [Schools named in attachment 1 to this document.] The program will be implemented as a Supplemental Environmental Project (“SEP”) pursuant to Section III of the Consent Agreement and Final Order (“CAFO”). This SEP is subject to the applicable terms and conditions specified in the CAFO and to the additional specifications set forth in this Appendix. The effective date of this SEP is the same as the effective date of the CAFO.

The goals of this SEP are to (1) reduce the adverse impact to public health by minimizing the potential exposure to chemicals in schools, (2) reduce the adverse impact to the environment in and around Wood County, West Virginia by minimizing disposal of hazardous waste generated at schools and (3) enhance science safety in all of these schools (hereinafter referred to as “the SEP Goals.”

The total cost of this SEP is one million two hundred fifty thousand dollars (\$1,250,000).

DuPont plans to engage Education Planning & Oversight, Dover, Delaware, (“EPO”) to lead the design and administration of this SEP and act as project manager.

The implementation of this SEP will involve close coordination between EPO and the teachers and administrators in the participating schools. The Wood County school district may wish to modify certain aspects of this SEP in order to best accommodate local resources and objectives (if, for example, the district converts current junior high schools to grade 6-9 middle schools) but such modifications will always maintain the SEP Goals.

Consequently, EPA and DuPont recognize and agree that this SEP will be implemented flexibly although remain consistent with the SEP Goals. DuPont may request adjustments of the schedules and will inform EPA of SEP implementation in detailed progress reports. EPA and DuPont recognize that the schedules for implementation of each Program of this SEP set forth in the following work plan are good faith estimates that depend on, among other things, timely actions and responses by third parties in Wood County, WV and the participating schools, including administrators and teachers.



DuPont agrees that the cost of EPO's services in excess of \$125,000 is NOT an eligible cost of the SEP. DuPont will compensate the participating school districts and their employees for the direct expenses they incur (including costs of substitute teachers to cover instructional time during teacher training periods) as a result of participating in SEP activities, and would not otherwise incur, and that this compensation will be an allowable cost of the SEP.

It is understood that this SEP does not require DuPont to undertake any action that would render DuPont liable to any person for personal injury, property damage, economic loss or any other claim whatsoever.

### **Work Plan and Schedule**

#### **Microscale Chemistry & Green Chemistry Program in Wood County, WV**

Microscale chemistry reduces risk by reducing exposure to chemicals. Microscale involves using very small, pre-measured quantities of chemicals when conducting experiments in the 7-12 science classroom. This approach is associated with pre-packaged consumable materials for science education. The key feature of these materials is the use of nominal amounts of chemicals, often in pre-measured devices that allow a student to participate in a hands-on experiment without having large containers of excess chemicals being stored at the school.

Green Chemistry reduces risk by reducing hazard. Green chemistry involves using safer chemicals in a process that is typically used in a student laboratory course. If a chemical process employs hazardous substances – for example, a toxin or dermal irritant – there is always possible danger even if the exposure to such substances is reduced by controlling the quantity of material used. Therefore, principles of green chemistry are used to find safer reactants to produce the same results. A common type of experiment in student labs is called a “clock reaction.” In such a reaction, a sudden color change occurs when the reaction is complete. The color change allows students to measure reaction time. Instead of using formaldehyde or bisulfites in such a reaction, student labs could use ordinary household materials such as hydrogen peroxide, iodine and vitamin C tablets.

Within ninety (90) days after the effective date of this SEP, EPO will meet with administrators from Wood County school district, provide an overview of the activities to be conducted under this SEP, obtain an indication of the willingness of each to participate in the micro-scale chemistry and green chemistry program.

**Year 1: Strategic Planning:** EPO will review existing 7-12 science curricula in the school district and, in collaboration with the school district, EPO will assist in the development of a plan for implementation of instructional units, modules, and activities using pre-packaged (micro-scale and small scale) consumable materials, whether purchased from science materials vendors or refurbished through the school district's Materials Center at the 7-12 levels in that district.

EPO will complete a review of the district's 7-12 grade science curricula, including mapping district curricula to state standards. The school district will be asked to identify a Strategic Planning Leadership Team (SPLT) comprising five members representing school

administrators (principals, science specialists, school board members), 7-12 grade teachers, and may include one scientist from local industry.

SPLT will write a 5-year Strategic Plan encompassing the five elements of education enhancement: curriculum selection; teacher professional development; materials (storage, distribution, and refurbishment); assessment; and community and administrative support. Depending on availability, SPLT will either attend an NSRC (National Science Resources Center) Strategic Planning Institute or equivalent, or EPO will design a 3-4 day planning meeting during which SPLT will write a draft Strategic Plan.

EPO anticipates that these strategic planning activities will require approximately six months to complete, depending in part on how quickly SPLT does its work. EPO will prepare a report for submission to EPA at the completion of the activities but no later than 12 months from the effective date of the CAFO. This report will include a summary of costs incurred by DuPont to date, a discussion of any problems or delays encountered in the program to date, and a projection of the expenditures for the remainder of the SEP based on experience to date.

**Year 1: Curriculum Implementation:** Within 6 months (extension may be liberally granted if the timing is affected by school calendar issues) following school district review and approval of the Strategic Plan, SPLT will establish key working committees, including a Curriculum Selection Committee, a Resource Center Committee, a Professional Development Committee, and an Assessment Committee. SPLT will recruit 2 Lead Teachers from each of the 5 junior high schools (grades 7-9), 2 from each of the high schools (grades 10-12), and 4 from the 1 secondary school comprising grades 7-12 (2 from grades 7-9, 2 from grades 10-12) to implement the selected instructional units, modules, and activities using pre-packaged (micro-scale and small-scale) consumable materials.

**Curriculum Selection Committee:** EPO will conduct a Curriculum Selection workshop(s) to introduce the district to National Science Foundation-approved materials, including those approved for use at the middle school level (grades 6-8)— FOSS (Full Option Science System), STC (Science and Technology for Children), and SEPUP (The Science Education for Public Understanding Program)— and those approved for high school use in high school science classes where chemicals are used (which are set forth in Attachment 2 to this SEP). The Curriculum Selection Committee will select micro-scale chemistry materials for prospective implementation at each grade level.

**Resource Center Committee:** The Resource Center Committee will identify a location for housing science materials and will develop processes for cataloguing, distributing, and refurbishing materials. The Committee will develop a budget for ongoing operation.

**Professional Development Committee:** During Years 1 and 2, outside consultants (i.e., science specialists from other school districts and/or kit vendors or materials publishers) will provide professional development for Lead Teachers. Following the initial phase of professional development, Lead Teachers and district science specialists will staff the Professional Development Committee and design and implement district-wide professional development. The Committee will be charged with writing a plan for professional development of all teachers

of science in the district that enables them to use the materials provided under this SEP in furtherance of the SEP Goals.

EPO anticipates that these planning activities will require approximately three months to complete, depending in part on how quickly the school district approves the Strategic Plan. EPO will prepare a report for submission to EPA at the completion of these planning activities but no later than 18 months from the effective date of the CAFO. This report will include a summary of costs incurred by DuPont to date, a discussion of any problems or delays encountered in the program to date, and a projection of expenditures for the remainder of the SEP based on experience to date.

## **Year 2: Pilot Implementation Year**

During the summer prior to implementation, Lead Teachers will complete structured professional development on (a) green chemistry concepts and (b) use of one micro-scale chemistry curricular unit or module at their grade level, to be provided. School principals will be strongly urged to attend these workshops. EPO will conduct a formative evaluation of the initial professional development workshops. The Resource Center will begin operation.

At the beginning of the implementation year, Lead Teachers will pilot unit or module 1 at their respective school sites (as appropriate to curricular scope and sequence within grades 7-12). EPO will organize 2 peer observation and reflection meetings during the piloting phase. Vendor consultants will provide additional support during the pilot phase. EPO will write a summary report for the pilot. SPLT will review effectiveness of the plan.

By year-end, SPLT will be succeeded by a permanent Steering Committee charged with ongoing implementation of the intervention and with securing funding for full implementation and ongoing operation. EPO will prepare a report for submission to EPA at the completion of these activities, which will include a summary of costs incurred by DuPont to date, a discussion of any problems or delays encountered in the program to date, and a projection of expenditures for the SEP based on experience to date.

During the pilot implementation school year or the following summer, to prepare for full implementation of unit or module 1 and green chemistry principles in the following school year, Lead Teachers (with the support of outside consultants where necessary) will provide professional development on unit or module 1 and materials explaining green chemistry principles for all 7-12 teachers of science in the Wood County, WV school district. Lead Teachers will also complete 24 hours of structured professional development for unit or module 2 and will pilot unit or module 2 during the upcoming school year. The Resource Center Committee will establish procedures for materials distribution district-wide prior to the full implementation year. Assessment Committee will write a plan for teacher professional development related to formative assessment of student learning during classroom implementation. The Lead Teachers, with the Curriculum Selection Committee, will assess the results of their piloting of unit or module 1 to inform grade level-wide professional development for unit or module 1.

EPO will prepare a report for submission to EPA at the completion of these activities but not later than 3 years of the effective date of the CAFO, that will be the final SEP report for this SEP. This report shall include an accounting of all costs to DuPont for implementation of this SEP.

### **Work Plan Management**

**Contact Persons:** Within thirty (30) days of the effective date of this SEP, DuPont will identify in writing to EPA the person who will represent DuPont for purposes of communications concerning any aspect of DuPont's performance of this SEP, together with that contact person's address, telephone number, and e-mail address. EPA's contact person for this SEP is the contact point given for Reporting Requirements in the CAFO at Section V. All reports required by this SEP and all notices will be submitted to the EPA contact person at OPPTS.

**EPA Oversight of SEP Activities:** To the extent practicable, EPO will give EPA's designated contact person advance notice of meetings, training and other activities occurring under this SEP and EPA will be entitled to monitor or participate in any such meetings, training or other activities, provided that such activities do not interfere with the accomplishment of any SEP activity. EPA's right to monitor activities under this SEP does not relieve DuPont of any obligation under the SEP or the CAFO.

**Modification of Work Plan Tasks or Schedule** If it appears to DuPont at any time during the implementation of this SEP, based on EPO's reports or otherwise, that the SEP either cannot be completed in accordance with the schedule above or cannot be completed at a cost of \$1,250,000, DuPont may propose modifications of this SEP to provide for a revised timetable for the SEP activities and/or for alternative SEP activities, provided that DuPont shall not be required to spend more than \$1,250,000 in eligible costs under this SEP. Such a proposal will be in writing and will set forth the proposed modified schedule or alternative activities along with an explanation of the reasons why the original activities do not appear capable of completion within the original schedule and/or cost estimate. EPA shall consider the revised timetable or alternative SEP activities in a timely manner and must respond to DuPont's proposal in order for the proposal to be approved.

If EPA advises DuPont of such non-concurrence, the Parties will make a good-faith effort to identify alternative scheduling or alternative SEP activities. Such alternative SEP activities will conform to the SEP Goals.

## NATIONAL SCIENCE FOUNDATION-FUNDED SCIENCE INSTRUCTIONAL MATERIALS

### Middle School (Grades 6-8)

<i>Instructional Materials</i>	<i>Publisher</i>
FOSS (Full Option Science System)	Delta Education
STC (Science & Technology for Children)	Carolina Biological
SEPUP (Science Education for Public Understanding)	Lab-Aids, Inc.

### High School (Grades 9-12)

<i>Instructional Materials</i>	<i>Publisher</i>
Earth System Science in the Community (Earth Comm)	It's About Time Publishing
Active Physics	It's About Time Publishing
Chem Discovery	Kendall/Hunt Publishing Co.
Chemistry in the Community (ChemCom)	W.H. Freeman & Co.
Comprehensive Conceptual Curriculum for Physics (C <sup>3</sup> P)	University of Dallas Physics
Hands-On Physics	Concord Consortium
Introductory Physical Science (IPS)	Science Curriculum, Inc.
Minds•On Physics	Kendall/Hunt Publishing Co.
Biology: A Community Context	Glencoe/McGraw-Hill
BSCS Biology: A Human Approach	Kendall/Hunt Publishing Co.
BSCS Biology: A Molecular Approach	Glencoe/McGra-Hill
BSCS Biology: An Ecological Approach	Kendall/Hunt Publishing Co.
Insights in Biology	Kendall/Hunt Publishing Co.
Ecology: A Systems Approach	Kendall/Hunt Publishing Co.
Global Lab	Kendall/Hunt Publishing Co.
Prime Science	Kendall/Hunt Publishing Co.
Science in a Technical World	W.H. Freeman & Co.
SEPUP: Issues, Evidence & You	Lab-Aids, Inc.
SEPUP: Science & Sustainability	Lab-Aids, Inc.

### High School (Grades 9-12) [Under Development]

<i>Instructional Materials</i>	<i>Publisher</i>
Astrobiology: The Search for Life	It's About Time
BSCS Science: An Integrated Approach	[BSCS]
Exploring Earth	Houghton Mifflin Company
Foundation Science	[EDC]
Living By Chemistry	[Lawrence Hall of Science]
Science That Counts in the Workplace	Kendall/Hunt Publishing Co.
Voyages Through Time	[SETI Institute]

## Wood County (WV) Junior High and High Schools

### Junior Highs (Grades 7 - 9)

- Jackson Junior High School

Address:	1601 34 <sup>th</sup> Street Vienna, WV 26105
Phone:	304-420-9551
Fax:	304-295-9954
Principal:	Mr. Richard Summers
E-mail:	rpsummer@access.k12.wv.us
Enrollment:	587

- Blennerhassett Junior High School

Address:	Route 4, Box 475A Parkersburg, WV 26101
Phone:	304-863-3356
Fax:	304-863-3357
Principal:	Mr. Steve Angel
E-mail:	sangel@access.k12.wv.us
Enrollment:	665

- Edison Junior High School

Address:	1201 Hillcrest Street Parkersburg, WV 26101
Phone:	304-420-9525
Fax:	304-420-9527
Principal:	Ms. Jean Mewshaw
E-mail:	jmewshaw@access.k12.wv.us
Enrollment:	724

- Hamilton Junior High School

Address:	3501 Cadillac Drive Parkersburg, WV 26104
Phone:	304-420-9547
Fax:	304-420-9567
Principal:	Mr. Mike Wells
E-mail:	gwells@access.k12.wv.us
Enrollment:	640

- VanDevender Junior High School

Address:	918 31 <sup>st</sup> Street Parkersburg, WV 26104
Phone:	304-420-9645
Fax:	304-420-9647
Principal:	Mr. Steven Taylor
E-mail:	staylor@access.k12.wv.us
Enrollment:	380

## High Schools

- Parkersburg High School (Grades 10 – 12)

Address:	2101 Dudley Avenue Parkersburg, WV 26101
Phone:	304-420-9595
Fax:	304-420-9604
Principal:	Mr. Ralph Board
E-mail:	rsboard@access.k12.wv.us
Enrollment:	1,484

- Parkersburg South High School (Grades 10 – 12)

Address:	1511 Blizzard Drive Parkersburg, WV 26101
Phone:	304-420-9610
Fax:	304-420-9607
Principal:	Mr. Thomas Eschbacher
E-mail:	teschbac@access.k12.wv.us
Enrollment:	1,257

- Williamstown High School (Grades 7 – 12)

Address:	219 West 5 <sup>th</sup> Street Williamstown, WV 26187
Phone:	304-375-6151
Fax:	304-375-6194
Principal:	Mr. Jack Mental
E-mail:	jmental@access.k12.wv.us
Enrollment:	662