

US EPA ARCHIVE DOCUMENT

EPA PROJECT XL
FINAL PROJECT AGREEMENT

**LABORATORY-SCALE HIGH-TEMPERATURE CATALYTIC
OXIDATION PROCESS TO TREAT LOW-LEVEL MIXED WASTES**

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ORTHO-McNEIL PHARMACEUTICAL

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1. Introduction to the Agreement

1.1 Brief Description of the Project and Its Purpose

This agreement concerns a pharmaceutical research facility which the Ortho-McNeil Pharmaceutical Corporation, in conjunction with the R. W. Johnson Pharmaceutical Research Institute (hereinafter "OMP," unless otherwise specified) operates in Spring House, Pennsylvania, and is reached pursuant to the Environmental Protection Agency's (EPA's) Project XL. Project XL (eXcellence and Leadership) comprises an initiative of EPA's under which potential Project Sponsors are encouraged to propose new approaches to environmental protection that can advance our nation's environmental goals more effectively and efficiently than current regulatory and policy tools or procedures.

OMP conducts pharmaceutical research and development at its research facility in Spring House, Pennsylvania. In order to meet the Food and Drug Administration's requirements for studying the safety and efficacy of new pharmaceuticals in the human body, OMP uses drugs "labeled" (marked) with radioisotopes, which enables the drugs' bioabsorption and metabolism in the body to be tracked with precision. This project concerns the handling of small quantities of OMP laboratory sample wastes which contain tritium (^3H) and carbon-14 (^{14}C), which OMP uses as tracers in its research due to the relatively low radiotoxicity of these radioisotopes and because they naturally occur in the environment. OMP is licensed by the Nuclear Regulatory Commission (NRC) to handle radioactive materials in its laboratories. (Copy of the license is attached as Appendix J. The NRC's existing controls on OMP's operations are unaffected by this project.)

OMP's research process produces small quantities of waste solutions containing solvents and radiolabeled material. The organic component of these wastes is a "hazardous waste" regulated by EPA under the Resource Conservation and Recovery Act (RCRA), and the radioactive component of these wastes is regulated by NRC as a "low-level waste" (LLW) under the Atomic Energy Act (AEA) of 1954. This combined waste, termed "low-level mixed waste" (LLMW), is subject to regulation by both EPA and the NRC.

The quantities of LLMW generated by OMP are relatively small. Each "batch" of LLMW generated by OMP at its Spring House facility typically ranges from less than 50 milliliters to several liters in volume; yearly OMP generates less than 50 liters of LLMW in total. The amount of radioactive materials contained in this LLMW is also quite small. (As a condition of its NRC license, the NRC requires that OMP have no more than 50 curies ("Ci") of tritium; 4 Ci of carbon-14; and 5 Ci total of any other byproduct material with Atomic Nos. 3 - 83 on hand at any one time). (Further details about the nature and amount of radioactive material handled

by OMP, and the regulatory framework which governs LLMW in Pennsylvania, is presented below).

Presently, the only permitted treatment option for LLMW such as OMP's involves off-site transportation and disposal at a Treatment, Storage and Disposal facility (TSDF) licensed by the NRC and permitted under RCRA. Commercially permitted TSDFs utilize incineration to treat LLMW wastes, which destroys the RCRA "hazardous waste" component of the LLMW, or solidification and land burial. Under either disposal methodology, the radioactivity contained in LLMW is not recovered for reuse.

OMP proposes to achieve environmental performance superior to currently available practices through the use of a bench-scale high-temperature catalytic oxidation (HTCO) process which destroys the RCRA "hazardous waste" component of the LLMW and traps the remaining low-level radioactive material on-site, all within the same NRC-regulated laboratory in which the material is generated. OMP has been operating this process since 1996 as part of a treatability study approved by the Pennsylvania Department of Environmental Protection (PADEP) under its Solid Waste Management Act, 35 P.S. §§6018.101 - 6020.1304 (SWMA).

OMP is pursuing this XL Project, including the attendant stakeholder process, to assure greater regulatory certainty from EPA as well as PADEP. PADEP and EPA are in support of this XL project.

Benefits of the High-Temperature Catalytic Oxidation Process

OMP's high-temperature catalytic oxidation process appears to represent an environmentally superior way to address small quantities of LLMW in several respects. First, since waste is processed in the same secure, NRC-licensed laboratory where it is created, the risk of off-site spills, worker exposures, and releases during storage, transportation, and handling, while minimal when managed pursuant to RCRA, are further reduced. Second, the radioactive components are captured (in the form of radioactive carbon dioxide or tritiated water) rather than being lost through the incineration process (e.g., through incorporation in air pollution control media that is disposed of), and consequently providing a somewhat homogeneous and consistent waste stream that is amenable to recycling and reuse.

Additionally, OMP has shared, and commits to continuing to share, this technology freely. This technology has broad application to other research institutions, government agencies such as the National Institutes of Health (NIH), colleges and universities, and hospitals that also generate LLMW. OMP has funded the travel of

several of its scientists to conferences, educational institutions, and private facilities to facilitate the broadest possible distribution of this technology. (See Appendix I.)

Through this XL Agreement, OMP is seeking further regulatory certainty for its LLMW treatment process. Pursuant to this XL Project, OMP would continue to not be required to obtain a permit under RCRA for its LLMW catalytic oxidation process. However, OMP's LLMW would remain a RCRA solid waste, and be subject to other RCRA authorities, including EPA's authority to issue orders under Section 7003 (which addresses situations of "imminent and substantial endangerment to health or the environment").

1.2 Description of the Ortho-McNeil Facility / Community / Geographic Area

The OMP Spring House facility occupies 172 acres in Spring House, Lower Gwynned Township, Montgomery County, Pennsylvania. The main facility comprises 758,000 sq. ft. of building space. The Spring House facility also includes a man-made stormwater retention pond used for firefighting and landscaping purposes, tennis courts, a baseball field, an exercise trail and a guest house. The facility was constructed in 1980 on land previously used as farmland and is bordered by Rohm & Haas to the West, a farm to the North, and residential areas and country clubs to the South and East.

The OMP Spring House facility houses four separate operating companies: Ortho-McNeil Pharmaceutical (OMP), the R. W. Johnson Pharmaceutical Research Institute (PRI), the Janssen Research Foundation (JRF) and Advanta Corporation. OMP, PRI and JRF are divisions of Johnson & Johnson, while Advanta, a financial services company, is an unrelated company which leases space in the building. OMP is the owner and landlord of the facility and provides engineering and maintenance support for PRI and JRF. OMP also operates a small manufacturing plant that produces PANCREASE® (pancrelipase) Capsules (used for the treatment of exocrine pancreatic enzyme deficiency in patients with cystic fibrosis) and VASCOR® (bepiridil hydrochloride) Tablets (used for the treatment of chronic stable angina). Both PRI and JRF perform pharmaceutical-related research and development, including discovery and clinical and non-clinical development at the Spring House facility.

1.3 Purpose of the Agreement

This Final Project Agreement ("the Agreement") is a joint statement of the plans, intentions and commitments of EPA, PADEP, and OMP to carry out this pilot Project at OMP's Spring House facility. This Project will be part of EPA's Project

XL program to develop innovative approaches to environmental protection.

This Agreement does not create legal rights or obligations and is not an enforceable contract or a regulatory action such as a permit or a rule. (The previous statement applies to both the substantive and the procedural provisions of this Agreement.) While the Parties to the Agreement fully intend to follow these procedures, they are not legally obligated to do so. The Parties do anticipate that both EPA and PADEP will issue a site-specific rule(s) and/or permit(s) applicable to OMP's facility, through which the regulatory flexibility sought by OMP will be achieved, which will also contain conditions which OMP must meet and maintain. For more details, please refer to Section 6 – Legal Basis for the Project.

All Parties to this Agreement will strive for a high level of cooperation, communication, and coordination to assure successful, effective, and efficient implementation of the Agreement and the Project.

1.4 List of Parties Who Will Sign the Agreement

The Parties to this Final Project XL Agreement are:

- 1) The United States Environmental Protection Agency
- 2) The Pennsylvania Department of Environmental Protection
- 3) Ortho-McNeil Pharmaceutical

1.5 List of Project Contacts

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2. *Detailed Description of the Project*

2.1 **Summary of the Project**

Ortho-McNeil proposes to achieve environmental performance superior to currently available practices through the use of a bench-scale high temperature catalytic oxidation (HTCO) process which destroys the RCRA “hazardous waste” component of the LLMW and traps the remaining low-level radioactive material on-site, all within the same NRC-regulated laboratory in which the material is being handled.

Following the application of the catalytic oxidation process, one of two types of treatment residue remains. When the sample had used tritium as the radioisotope tracer, the remaining low-level radioactive material is trapped in the form of low-level radioactive water utilizing cryogenic traps to condense the emissions from the process. When carbon-14 is used as the radioisotope tracer, the remaining low-level radioactive material is in the form of low-level carbon dioxide, which is passed through a 45% potassium hydroxide solution and converted to potassium carbonate solution. According to OMP, the HTCO process has proven to be extremely effective in treating a broad range of organic solvents and has routinely achieved destruction removal efficiencies (“DRE”) of 99.999 to 99.99999%. A more detailed description of the elements of the process is discussed in Section 2.2 below.

See Appendix A for a Simplified Schematic of the High Temperature Catalytic Oxidation Process.

See Appendix B for a list of hazardous organic components and the corresponding DRE achieved by the oxidation process.

2.2 **Description of the Specific Project Elements**

2.2.1 *Project Element # 1 – Generation of Low-Level Mixed Waste*

The generation of LLMW is an unavoidable result of pharmaceutical research which involves the study the safety of drug compounds in the human body, given the FDA’s requirement of the use of radioactive tracers in such research. During these studies, carbon-14- and tritium-labeled compounds are synthesized for use in the development of potential new therapeutic compounds. These syntheses generate millicurie (mCi) to Curie (Ci) quantities of LLMW test samples containing a wide variety of organic materials which are classified as “hazardous wastes” under RCRA (see Appendix F for an explanation of the units of measurement of radioactivity). These consist of contaminated aqueous mixtures and various organic solvents, intermediates, and reagents used in the synthesis and

purification of radiolabeled samples. The organic components include hydrocarbons, halocarbons, acetonitrile, alcohols, ethers, and aromatic compounds. A single preparation involves volumes ranging from less than 50 mL to several liters.

2.2.2 Project Element # 2 – High-Temperature Catalytic Oxidation

As an alternative to long-term storage of radioactive hazardous materials at its facility, or the off-site transportation and disposal of this waste at an NRC licensed, RCRA permitted TSDF, OMP has developed a bench-scale, high-temperature catalytic oxidation process to destroy the organic components of its mixed waste test samples as they are generated. In this process, the liquid LLMW is completely reacted with oxygen or air at high temperature in the presence of an oxidation catalyst. The spent test samples are passed through an electrically heated, stainless steel tube packed with a platinum catalyst. Heat is provided using a tube furnace equipped with three separately controlled heating zones. Liquid samples are blended and pumped into the heated catalyst tube using a pair of high performance liquid chromatography (HPLC) pumps. An electronic safety supervisor system monitors critical pressures and temperatures during operations and automatically turns the pumps off if an unsafe condition develops. The entire process is operated under a fume hood with continuous air monitoring (see details in Section 3.7.1.3). (A detailed description of the catalytic oxidation process is included in Appendix G.)

2.2.3 Project Element # 3 – Trapping and Recovery of Effluents

After passing through the heated zone, water and the radiolabeled reaction product, (tritiated water or carbon-14-labeled carbon dioxide, depending on the radioisotope used as the tracer) are collected, free of hazardous organic chemicals, using appropriate pressure-tight traps. For tritium-labeled test samples, a series of three dry ice-cooled traps are used. Carbon-14-labeled carbon dioxide is scrubbed through a series of four gas washing bottle traps containing a 45% solution of potassium hydroxide. The trapped samples may be passed through the process again to achieve higher destruction efficiency as necessary.

2.2.4 Project Element # 4 – Disposition of Treatment Residues

After the radiolabeled products are trapped, they can be further processed and solidified in cement and disposed off-site at the NRC-licensed low-level radioactive waste disposal facility in Barnwell, SC (as is currently done under the treatability exemption granted by PADEP). Additionally, OMP is currently working with various companies to develop and test technology to recover the radioactive

component of the trapped effluent for reuse, in lieu of disposal via solidification or incineration. This option is further discussed in Section 3.2.1 and Section 5.1 below.

3. *How the Project Will Meet the Project XL Acceptance Criteria?*

3.1 Anticipated Superior Environmental Performance

The use of OMP's high-temperature catalytic oxidation process, which treats the LLMW test samples as they are generated, potentially results in several environmentally superior benefits as compared to presently available commercial treatment and disposal alternatives involving incineration or land disposal:

- The radioactive component of OMP's LLMW is captured as a uniform, consistent waste stream and is amenable to recovery and reuse.
- Under OMP's proposal, all LLMW is handled on-site, in the NRC-regulated, controlled laboratory environment in which it is generated, thereby further reducing the potential for spills or releases during on-site and off-site handling and transportation.

3.2 Additional Non-Environmental Benefits

In addition to the anticipated elements of superior environmental performance mentioned above, the on-site treatment of LLMW utilizing high-temperature catalytic oxidation is also anticipated to result in other benefits as well. These benefits include: (1) opportunities to develop technologies to recycle/reuse tracer radionuclides and other technological advances, (2) cost savings, and (3) paperwork and labor reduction. Each of these benefits is detailed below. Additionally, the transferability of the benefits of this Project – facilitated by OMP's decision not to patent the technology and make it freely available to all interested parties – is discussed at Section 3.5 below.

3.2.1 Opportunities to Develop Radioactivity Recycling / Reuse and Other Technologies

The principal advantage of excluding from RCRA's definition of hazardous waste the small volumes of LLMW created and treated (using OMP's HTCO process) within an NRC-licensed pharmaceutical research and development laboratory, is the potential for generating a uniform, nonRCRA-hazardous waste stream of low-level radioactive waste that is amenable to recycling and reuse. This is an improvement over the alternative management (i.e., disposal) of air pollution control residues containing the radionuclides. Additionally, there has been interest

from outside parties who would like to utilize and improve on the technology developed by OMP to facilitate the recycling of radioactivity (see also Section 3.5).

- An international company is interested in recovering tritium from the radioactive water generated by the catalytic oxidation process. This process would recycle the tracer radionuclides and eliminate its release into the environment. The technology to recover and reuse tritium is currently available and there is notable interest in developing the market utilizing this approach.
- A domestic company would like to manufacture a standard bench-top system, based on OMP's unit, that could be sold off-the-shelf to research institutions enabling them to perform on-site treatment in a laboratory setting. This would produce a uniform radioactive waste stream that is receptive to recycling, the availability of which would allow for the further development of a market for tracer radionuclide recycling.
- A TSDF currently licensed by the NRC and permitted under RCRA to treat LLMW is interested in scaling-up the catalytic oxidation process to create a viable, environmentally-sound, cost-effective, commercial treatment alternative for LLMW in which radioactivity could be recovered.

3.2.2 Cost Savings

Currently, many research institutions do not undertake research which generates LLMW due to the limited disposal options and high disposal costs associated with these wastes. OMP's alternative environmental management strategy would result in a considerable cost savings opportunity for OMP, Johnson & Johnson, and other research and development (R&D) institutions which conduct this type of research. Current commercially available TSDFs charge up to \$40,000 per curie of activity to treat LLMW. Based on the survey of 100 domestic pharmaceutical companies, universities, commercial facilities and other organizations conducted by the International Isotope Society in 1996, domestic institutions generate approximately 16,000 curies of tritium and carbon-14 LLMW annually. At an average disposal cost of \$30,000 per curie (which does not include costs for waste analysis and transportation), disposal of LLMW is costing domestic companies, conservatively, up to \$480 million per year. For OMP, disposal costs would range from \$250,000 to \$300,000 per year for LLMW if OMP were unable to use its HTCO process. Company wide, Johnson & Johnson believes that these disposal costs may exceed \$1.5 million per year. These costs may be passed on to customers in higher costs for prescriptions and other pharmaceutical products.

3.2.3 Paperwork and Labor Reduction

Facilities subject to the RCRA permitting requirements for the on-site treatment of hazardous wastes under 40 CFR Part 270 are subject to an extensive, time-consuming, permit application process and compliance program. While appropriate to commercial facilities which are in the business of treating large quantities of wastes from many different sources, the Parties to this Agreement believe that these requirements are not necessary with respect to OMP's bench-scale HTCO process, when it is undertaken within OMP's NRC-licensed laboratory and subject to the limits and conditions described herein. Allowing the regulatory flexibility to treat small volumes of LLMW on-site without a RCRA permit under these specified conditions (see Section 4 for further details) would relieve the associated paperwork and resource burden providing additional benefits to both the sponsor and regulatory agencies.

3.3 Stakeholder Involvement and Support

OMP has mounted an extensive effort to measure and ascertain stakeholder involvement and support for this Project. OMP focused on a number of stakeholder groups, including the local community, Johnson & Johnson Spring House employees, State and Federal regulatory agencies, and local, state and national environmental groups. Support for the Project has been generally positive from all stakeholders to date. Copies of all correspondence from stakeholders and commenters, as well as summaries of public meetings, are included in the project Information Repository as set forth in Section 3.3.5.

3.3.1 Regulatory Authorities

OMP hosted a meeting on October 20, 1999 to explain its Project XL proposal to State and Federal regulatory agencies. The meeting included representatives from EPA Headquarters, EPA Region III, PADEP, NRC, the Lawrence Berkeley National Laboratory, Johnson & Johnson Worldwide Environmental Affairs, Johnson & Johnson Safety & Industrial Hygiene, the R.W. Johnson Pharmaceutical Research Institute and Ortho-McNeil Pharmaceutical. The purpose of the meeting was to familiarize the agencies with OMP's proposal including the background, benefits and requested flexibility. EPA and PADEP have continued to communicate with each other regarding this project, including how best to carry out the intentions of the Parties as expressed in this Agreement.

3.3.2 Local Community and Environmental Groups

Stakeholder involvement from the local community and local environmental groups has been cultivated in many ways during the developmental stages of the Project.

These methods include communicating through the news media, announcements at Township meetings, public meetings, and direct contact of interested parties.

The local community has been involved in the Project through a variety of methods. OMP actively participates in two community environmental groups: The Lower Gwynedd Township (LGT) Industrial Compact (Compact) and the Community Advisory Council (CAC) sponsored by Rohm & Haas Corporation. The Compact includes members of the five major industries in Lower Gwynedd Township - Ortho-McNeil, Rohm & Haas, COGNIS (formerly Henkel Corporation), Siemens-Moore Process Automation Inc. (formerly Moore Products), and Aventis Crop Sciences (formerly Rhone-Poulenc, Inc.) - the LGT Supervisors, Township Manager and Fire Marshall and two township citizens. The Compact meets quarterly and provides a regular forum for open discussions about relevant information about the use of hazardous substances within LGT and other environmentally related issues. OMP is also a regular member of the CAC which has approximately 30 community residents who meet to discuss business issues, including environmental issues, with Rohm & Haas and OMP on a quarterly basis. During the development stages, OMP has provided continuous updates on this Project to the Compact and CAC and solicited comments, and plans to continue updating the community groups during the implementation of the Project.

At a LGT supervisor meeting on February 16, 2000, OMP announced the acceptance of the Project by EPA into its Project XL Program and invited the community to attend a public meeting to be held at the OMP facility. A newspaper article announcing the public meeting was published in *The Reporter* on February 16, 2000. OMP also personally invited all the members of the LGT Compact and the CAC to attend the public meeting as well as the Executive Director of the local Wissahickon Valley Watershed Association. OMP hosted the public meeting on the Project on February 28, 2000. *The Ambler Gazette* published an article about the meeting and project on March 1, 2000 (see Appendix D for copies of the newspaper articles).

On July 18, 2000, OMP hosted a stakeholder meeting at its Spring House facility. The meeting was attended by representatives from EPA, PADEP, OMP, and Johnson & Johnson and focused specifically on addressing concerns raised by the Sierra Club, which was also represented at the meeting. The objectives of the meeting were to brief the Sierra Club representative about the EPA Project XL Program and provide the history of the OMP XL project, to discuss the catalytic oxidation treatment process with OMP scientists, to explain the regulatory oversight for OMP's XL project and to address any specific concerns raised by the Sierra Club with respect to OMP's project. The meeting also included a site tour including the radiosynthesis laboratory suite, which houses the high-temperature catalytic oxidation unit. In addition, a draft version of this FPA was reviewed by all

participants. After the meeting and a more thorough review of the draft FPA, the Sierra Club submitted extensive comments on the FPA which have been addressed in this version of the FPA. A list of stakeholders who were invited to the meeting is available in the project Information Repository (see Section 1.5) along with the agenda and the attendance sheet.

OMP will hold periodic public meetings with the local community to provide updates and information on the Project, and to address any concerns that may arise.

3.3.3 National Environmental Groups

OMP has worked with EPA and a third party consultant to notify and communicate with national environmental groups, and other interested parties about the Project. Appendix H lists all of the environmental, industry, and other groups and associations that OMP has informed about this proposed project. The Project Information Repository includes comments received (including comments on prior drafts of this FPA).

3.3.4 Other Interested Parties

The success of HTCO in the treatment of mixed wastes at OMP has generated great interest among many parties including government agencies, the National Tritium Labeling Facility, the National Institutes of Health, domestic and international pharmaceutical companies, commercial manufacturers, raw material suppliers and mixed waste treatment facilities.

3.3.5 Project Information Repository

A collection of project documents has been established in the Lower Gwynedd Township building, located at 1130 N. Bethlehem Pike, Spring House, Pennsylvania 19477. This information repository contains records of all stakeholder meetings, identification of the stakeholders, relevant materials and minutes. Those on the project mailing list, including all stakeholders, participants in the FPA development process, and any members of the general public who have expressed interest in the project, have had copies of all minutes and other materials from the meetings, including the drafts of the FPA, made available to them. The stakeholders and interested parties on the project mailing list can be found in Appendix H. EPA has established a web-site located at www.epa.gov/Projectx that also contains project documents.

3.3.6 Annual Stakeholder Meetings/Updates

Stakeholder meetings shall be held annually, on or within two months of the annual anniversary of the signing of the final FPA.

3.4 Innovative Approach and Multi-Media Pollution Prevention

OMP’s proposal – to treat small quantities of LLMW generated by R&D activities utilizing a bench-top high-temperature catalytic oxidation process to destroy the organic component of the “waste” while capturing the radioactive component in a highly controlled laboratory environment – represents an innovative, alternative approach to currently available methods for the management and treatment of LLMW. As previously discussed, the current commercially available method requires the off-site transportation and treatment of LLMW via incineration at a permitted TSD facility. OMP’s proposal would capture the radioactivity from this waste stream and allow for the potential recovery and reuse of the radioisotope tracers (see Section 3.2.1 and Section 5.1 for more details on this potential recycling alternative).

OMP recognizes that pollution prevention is the cornerstone of a proactive waste management program. While this Project focuses specifically on the “end-of-pipe” treatment of LLMW unavoidably generated during R&D operations due to current FDA protocol, OMP has made a concerted effort at minimizing all other R&D wastes at the source (i.e. pollution prevention) through the implementation of a comprehensive Waste Minimization Program (WMP). This WMP, which was implemented in January 1998, uses a performance-based approach to encourage the implementation of new and innovative ideas to minimize all R&D wastes at their point of generation. The WMP targets hazardous and radioactive wastes as well as air emissions, wastewater discharges, and biohazardous and non-hazardous wastes. The goal of the program is to have each R&D department (13 in all) submit three waste minimization ideas per year and to implement at least one new waste minimization practice per year. The WMP has been endorsed by upper management and has been very successful. To date, 26 waste minimization practices have been implemented resulting in the following benefits:

Waste Minimization

- Hazardous Waste – reduced by 34,605 pounds
- Biohazardous Waste – reduced by 3,905 pounds
- Radioactive Waste – reduced by 275 pounds
- Non-Hazardous Waste – reduced by 93,530 pounds
- Wastewater – reduced by 700,000 gallons

Cost Savings

Disposal Costs	= \$ 42,572
Material Costs	= \$ 62,433
Labor Costs	= <u>\$ 20,200</u>

Total Savings: \$125,205
Miscellaneous Benefits –

Recycling – increased by 6,105 pounds
Labor – reduced by 2,016 man-hours

The OMP Waste Minimization Program was recognized by the Commonwealth of Pennsylvania with the Governor's Award for Environmental Excellence in 1998.

3.5 Transferability of the Approach to Other Entities or Sectors

EPA has recognized that, nationally, the capacity for the treatment and disposal of certain LLMW is not available, and that it is appropriate to provide safe and legal alternatives for the disposal of LLMW.

Ortho-McNeil has found that limited availability of mixed waste disposal facilities, high disposal costs, the lack of adequate storage facilities, and current regulatory restriction on treatment options and accumulation times have severely restricted most research activities that generate mixed wastes. This has caused a disadvantage for domestic pharmaceutical research institutions, which must utilize radioactive materials if they are to compete in the highly competitive commercial arena. High disposal costs limit research activities that generate mixed wastes and have effectively locked out small research institutions and universities from participating in this research.

The HTCO technology developed by OMP is transferable to any organization that generates or treats mixed wastes. This includes pharmaceutical companies, research institutions, and colleges and universities, among others. OMP believes that this process is an environmentally superior method for the management of LLMW, and has decided not to patent the technology and has made it available to all interested parties.

In addition, OMP has dedicated its own time and resources to help interested parties implement this technology. As of today, OMP has worked with three companies or organizations who are using this technology: 1) the Research Triangle Institute in North Carolina, 2) the Lawrence Berkeley National Laboratory in California and 3) Ontario Power Technologies, a technology company in Ontario, Canada interested in commercializing the HTCO process. The Research Triangle Institute and the Lawrence Berkeley National Lab, like OMP, are both operating bench-scale systems under a State Treatability Study exemption. Ontario Power Technologies has scaled-up the system for commercial use. OMP has hosted and provided demonstrations to almost 100 companies, organizations and individuals who have shown interest in utilizing this technology. These

outreach efforts are discussed further in Appendix G.

3.6 Feasibility of the Project

Ortho-McNeil has operated the high-temperature catalytic oxidation process since January 1996 under a Treatability Study exemption approved by the PADEP. To date, 27 test samples with a total volume of 20,404 mL and a total activity of 1,920.373 mCi have been tested for process effectiveness under the treatability study. Over 2400 hours of development and operating experience by OMP and other companies at several sites has shown that the process effectively destroys a wide variety of materials in a safe operation. During the Treatability Study, the catalytic oxidation process has been run under a wide range of operating conditions, with a multitude of organic materials, to achieve optimal efficiency. See Appendix B for a list of hazardous organic components and their corresponding destruction removal efficiencies (DRE).

OMP management fully supports this Project and will ensure that sufficient resources are allocated to implement it.

3.7 Monitoring, Reporting, Accountability, and Evaluation Methods

3.7.1 Monitoring

3.7.1.1 Organic Concentration in Effluent and Destruction Removal Efficiency

The organic concentration in the effluent from the process has been monitored utilizing gas chromatography (GC) with a detection limit of 50 ppb. GC analysis has proven that the process has been extremely effective in treating a broad range of organic solvents and has routinely achieved DRE of 99.999% to 99.99999%. OMP will continue to monitor the process to ensure that such DREs are maintained. This monitoring includes the continuous monitoring of carbon monoxide (CO) while the process is running. The oxidation process is complete when no CO is detected, indicating that organics present in the sample have been destroyed to levels less than 0.1 parts per million. GC analysis will be performed on any new organic compound not previously processed. In addition, Appendix B contains a detailed description of the experimental conditions under which the samples from the effluent stream are collected and analyzed.

3.7.1.2 Radioactivity in Effluent

Liquid scintillation analysis and radioactive mass balances have been used to measure radioactivity in the effluent from the process and has demonstrated that

the catalytic oxidation process is a closed-loop system to 99 ± 1 %.

3.7.1.3 Radioactivity in Air Emissions

OMP is licensed by the NRC to use radioactive materials in its research laboratories pursuant to a "Type A Broad Scope" license for research and development. The radioactive materials license states that "concentrations in effluent air shall be within the limits specified in 10 CFR 20." The NRC effluent limits in 10 CFR Part 20 are $2.00E-8$ uCi/mL tritium and $6.00E-8$ uCi/mL for carbon-14. The catalytic oxidation unit is housed in a laboratory fume hood within the radiosynthesis lab suite. All seven (7) fume hoods in the lab suite are connected to a dedicated stack for air emissions. No other pharmaceutical research operations, or other processes performed at the facility, are tied into this system. Air emissions monitoring for radioactivity is performed whenever the process is operating. The monitoring is performed on the consolidated, non-turbulent air stream within the ventilation system after the juncture of the seven hoods and prior to emissions into the atmosphere via the dedicated stack. During calendar year 1999, air emissions monitoring revealed an annual average effluent concentration of $3.55E-12$ uCi/mL for tritium and $3.03E-11$ uCi/mL for carbon-14. As can be seen from these results, the 1999 air concentrations were less than 0.05% of the limits specified by the NRC in 10 CFR Part 20 for allowable concentrations in effluent air. Air emission monitoring results are available in the Project Information Repository identified in Section 1.5 above.

3.7.2 Reporting

Under the treatability study exemption, OMP is required to submit annual reports to the Pennsylvania Department of Environmental Protection (PADEP). The annual report contains the information required by 25 PA Code Section 261.4(f)(9). This information is as follows:

- I] Facility Information
 - a. Company
 - b. EPA ID No.
 - c. Point of Contact

- II] Summary of Previous Year's Treatability Studies
 - a. Name, Address and EPA ID Number of Generator of Waste Samples
 - b. Types, by Process, of Treatability Studies Conducted
 - c. Names, Address and EPA ID Number of Persons for Whom Studies Have Been Conducted
 - d. Total Quantity of Waste in Storage Each Day

- e. Quantity and Types of Waste Subjected to Treatability Studies
- f. Date each Treatability Study was Conducted
- g. Final Disposition of Unused Samples/Residues from Each Treatability Study

III] Current Year's Treatability Studies Forecast

- a. Estimate of Number of Studies to be Conducted
- b. Amount of Waste Expected to be Used in Treatability Studies

See Appendix E for the Calendar Year 1999 Annual Treatability Report submitted by Ortho-McNeil to the PADEP on March 14, 2000. The annual reports from 1996 to date are available in the Project Information Repository identified in Section 1.5.

As part of this project, OMP will continue to prepare and submit reports containing this information to PADEP and EPA biannually (twice a year), beginning six months following the effective date of this FPA.

Additionally, OMP will include the following additional information in each biannual report:

- a. The calculated DRE for organic compounds in each batch, including the basis for this determination.
- b. The calculated recovery rate of the radioactivity, including the basis for this determination.

3.7.3 Accountability

OMP assumes all accountability for monitoring, recordkeeping, reporting and evaluating the progress of the Project. OMP will continue to monitor the process effluent streams as described in Section 3.7.1. In addition, OMP will continue to keep records and submit reports to the PADEP and EPA as discussed in Section 3.7.2.

3.7.4 Evaluation Methods

OMP will continue to monitor and evaluate the efficiency of the catalytic oxidation process as discussed in Section 3.7.1. As part of this project, OMP will submit this data, as well as other information relevant to the success of the Project, in a biannual report to EPA and PADEP.

3.8 Avoidance of Shifting Risk

The implementation of this Project will not result in a shifting of risk from one

environmental media to another. OMP will continue to comply with all applicable State and Federal requirements (other than those associated with TSDF permitting) during the implementation of the Project. These requirements include PADEP and EPA regulations concerning the management of hazardous wastes and NRC regulations for handling radioactive materials in accordance with OMP's "Type A Broad Scope" license for research and development.

OMP has reviewed Executive Order 12898 on Environmental Justice and has concluded that the Project will not result in any unjust or disproportionate environmental impacts.

4. *Regulatory framework: Background; Description of the Requested Flexibility; Anticipated Implementing Mechanism*

4.1 Background: Regulatory Status of Mixed Waste in Pennsylvania Under the AEA and RCRA

Mixed waste, including LLMW such as OMP's, comprises both radioactive and hazardous wastes, regulated under two federal statutes. In Pennsylvania, radioactive wastes are regulated by the Nuclear Regulatory Commission (NRC) under the Atomic Energy Act (AEA), 42 U.S.C. §§ 2011-2296. The AEA regulates three types of materials associated with radiation hazards: "source, special nuclear, and byproduct material." *Id.* at § 2021. Hazardous wastes are regulated by EPA and/or Pennsylvania under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901, *et seq.*, as well as by Pennsylvania under applicable state laws, including the Solid Waste Management Act (SWMA), 35 P.S. §§ 6018.101 - 6020.1304. Facilities handling mixed waste generally must comply with both AEA and RCRA statutes and regulations, whose requirements are generally consistent and compatible. However, Congress did specifically exclude "source," "special nuclear," and "byproduct material" from RCRA's definition of solid waste (and thus hazardous waste and the Subtitle C program), to avoid overlap with the AEA. See 42 U.S.C. § 6903(27). Moreover, Section 1006(a) of RCRA, 42 U.S.C. 6905(a), provides that the AEA shall take precedence in the event provisions of requirements of the two acts are found to be inconsistent. The AEA thus retains exclusive authority over radioactive waste, while RCRA regulates nonradioactive waste.

Initially it was unclear whether "byproduct material" under the AEA included the hazardous waste portion of mixed waste in which case it might be excluded from the definition of "solid waste" under 42 U.S.C. § 6903(27). In a July 3, 1986 Federal Register notice (51 FR 24504), EPA announced its determination that the hazardous waste portion of mixed waste is not byproduct material and therefore is subject to dual AEA/RCRA regulation (with which determination DOE subsequently

agreed, see 10 C.F.R. § 962.3). In this same notice EPA also announced that "States that already have authorized [RCRA] programs must revise their programs (if necessary) and must apply for authorization for hazardous components of radioactive mixed waste."

Pennsylvania received authorization to implement the RCRA base program in January 30, 1986, prior to EPA's July 3, 1986 Federal Register notice.¹ Therefore in Pennsylvania at present, mixed wastes are not considered RCRA hazardous wastes, and thus are not subject to RCRA.² Pennsylvania does exercise independent authority over mixed waste under its Solid Waste Management Act, 35 P.S. §§ 6018.101 - 6020.1304 (SWMA), and it has been under this authority that OMP has been processing its LLMW in its catalytic oxidation unit pursuant to the SWMA's provisions governing treatability studies.

This XL project was undertaken and developed by EPA, PADEP, and OMP under the assumption that Pennsylvania will receive authorization for mixed wastes prior to implementation of required regulatory flexibility (discussed further in Section 4.2).

4.2 Requested Flexibility -

4.2.1 Background and Basis for Requested Flexibility

RCRA generally requires that a facility such as OMP's obtain a RCRA permit in order to treat on-site materials designated as "hazardous wastes," subject to certain exceptions and exemptions. (See 40 C.F.R. § 270.13 and § 270.14 and applicable sections in 40 C.F.R. § 270.15 through § 270.29). Assuming OMP's LLMW is a RCRA hazardous waste, its HTCO process meets RCRA's definition of "treatment" (which typically triggers a requirement to obtain a RCRA permit)

¹ Section 3006(b) of RCRA provides that States may apply to EPA for authorization to administer and enforce a hazardous waste program pursuant to Subtitle C of RCRA. Authorized State programs are carried out in lieu of the Federal program. Pennsylvania received its initial authorization to implement provisions of RCRA effective January 30, 1986 (51 Fed. Reg. 1791, January 15, 1986).

² Pennsylvania has prepared a revised RCRA authorization package, incorporating provisions of SWMA and other Commonwealth statutes and specifically requesting authorization to regulate mixed waste, which it has submitted to EPA. As required by RCRA, the Commonwealth's Statement of its Attorney General notes that the Commonwealth adopts EPA's determination that the hazardous waste portion of mixed waste is not byproduct material and is subject to RCRA.

because the oxidation destroys the organic components of the samples.³

Notwithstanding its July 1986 **Federal Register** notice in which it announced its determination that the hazardous waste portion of mixed waste is subject to dual AEA/RCRA regulation, EPA has recognized the potential that RCRA and AEA requirements can pose unnecessarily duplicative regulatory requirements. On November 19, 1999, after reviewing comments received on a March 1, 1999 Advanced Notice of Proposed Rulemaking, EPA issued a Proposed Rule for the Storage, Treatment, Transportation, and Disposal of Mixed Waste under 40 CFR Part 266. In the proposed Rule, the EPA would allow the on-site treatment of LLMW (and on-site storage of LLMW), without a RCRA treatment permit, where the LLMW is physically or chemically treated in a tank or container in accordance with the generator's NRC license requirements. However, EPA determined that, based on information then available, certain forms of treatment would not be included within the proposed exemption. OMP's HTCO process would be included in those processes not eligible for the proposed exemption. Therefore, the November 19, 1999 proposed Rule, even if adopted, would not allow OMP to utilize the high-temperature catalytic oxidation process without a RCRA TSDF permit.

OMP does not wish to apply for a RCRA TSDF permit for its Spring House facility. OMP states that it is a healthcare company, and does not wish to be in the business of commercial hazardous waste treatment. OMP states that it does not and will not ever accept LLMW from off-site generators for treatment at its facility. In addition, OMP believes that the current regulations, which require a RCRA TSDF permit to treat hazardous wastes, generally are not necessary for the type of treatment encompassed in its HTCO processing of laboratory-scale waste at its Spring House facility.

EPA believes that, while RCRA's permit regulations would otherwise apply to OMP's HTCO process, the goals of protection of public health, welfare and the environment which are served by RCRA's TSDF permitting process are met at OMP's facility by the terms and conditions of OMP's NRC license (including, in

³ OMP did consider whether its NRC-licensed laboratory met the definition a "totally-enclosed treatment facility" as defined in 40 CFR § 260.10, in which case a TSDF permit would not be required under 40 CFR § 264.1(g)(5). OMP determined that it did not qualify for this exemption because its HTCO unit is not "directly connected to an industrial production process," as required by 40 CFR § 260.10.

Moreover, even if OMP had qualified for an exemption from the requirement that it obtain a TSDF permit under 40 CFR § 264.1(g)(5), the radioactive residues would still be subject to RCRA's "derived from" rule (see 40 CFR § 261.3(c)(2)(i)), under which any residues from the treatment of a listed hazardous waste are deemed to remain a hazardous waste. OMP anticipates that some of the LLMW it will process in its HTCO process will be listed hazardous wastes.

particular the very small quantities of LLMW involved and the controlled nature of the HTO process), particularly when combined with the other terms and conditions of the regulatory relief which EPA and PADEP intend to provide under this Agreement (e.g., requirements imposed under PADEP's treatability study). The Parties to this FPA will negotiate other specific conditions as necessary to ensure protection of human health and the environment, which will be contained in the site-specific rule needed to implement the XL project.

4.2.2 Requested Flexibility

OMP is requesting that -

- (1) it be allowed to treat small volumes of LLMW on-site in its HTO process without a RCRA TSD permit, and
- (2) that the radioactive residue from its HTO process not be considered a hazardous waste.⁴

4.2.3 Additional Flexibility

The Parties to the Agreement do not anticipate any need to provide flexibility from any additional Federal and/or State requirements. If the parties agree that additional flexibility is necessary and appropriate, the flexibility may be added to this Project and will be subject to public notice and comment, as appropriate.

4.3 Legal Implementing Mechanisms

4.3.1 Federal

EPA believes that the most appropriate way to provide the requested regulatory flexibility is to add OMP's LLMW to the list of solid wastes which are excluded from the regulatory definition of hazardous waste under 40 CFR. § 261.4(b).⁵ 40 CFR § 261.4(b) includes a number of solid wastes which would otherwise qualify as RCRA hazardous wastes, but which EPA has determined do not require regulation

⁴ Regardless of whether OMP is required to obtain a RCRA TSD permit to process its LLMW with its HTO process, RCRA's "derived from" rule (see 40 CFR § 261.3(c)(2)(i)) provides that any residues from the treatment of a listed hazardous waste are deemed to remain a hazardous waste, subject to RCRA's manifesting requirements. OMP anticipates that some of the LLMW it will process in its HTO process will include listed hazardous wastes.

⁵ As discussed in Section 4.1 above, OMP's LLMW is not at present a RCRA hazardous waste in Pennsylvania. However, the Parties anticipate that Pennsylvania's proposed revised base RCRA authorization program, under which OMP's LLMW will become a RCRA hazardous waste, will be in place by the time necessary regulatory changes are implemented.

as such because of the limited nature of the risks they pose, or because they are adequately regulated under another environmental program. EPA expects to propose a site-specific exclusion for OMP's LLMW, subject to several conditions, such as:

- The exclusion would apply only to OMP's LLMW which is created, and processed, within its NRC-licensed Spring House laboratory, in accordance with its NRC license and its existing PADEP treatability study conditions.
- OMP would not be permitted to process more than 50 liters of LLMW per year.
- OMP must monitor the Destruction Removal Efficiency for the hazardous organic component of the LLMW
- OMP must monitor the capture efficiency for the radioactive component of the LLMW.
- OMP must report the data gathered to EPA and PADEP biannually.

Excluding OMP's LLMW from RCRA's regulatory definition of hazardous waste would have the effect of removing RCRA jurisdiction over OMP's HSCO processing of LLMW within OMP's NRC-licensed laboratory. NRC regulatory controls and oversight would continue for the low-level radioactive samples and treatment products that would remain from the process, and the residuals to be managed as a low-level radioactive waste.

4.3.2 Pennsylvania

Pennsylvania's hazardous waste regulations are structured such that the 40 CFR § 261.4 exclusions, as well as the bulk of the Title 40 federal hazardous waste regulations, are incorporated by reference into Title 25 of Pennsylvania's rules and regulations. The specific section of Pennsylvania's regulations that incorporates the 40 CFR § 261.4 exclusions is 25 Pa. Code § 261a.1. As provided for at 25 Pa. Code § 260a.3(e), the incorporation by reference includes any subsequent modifications and additions to the incorporated portions of the Code of Federal Regulations (CFR). Thus, EPA's addition of OMP's LLMW to the list of solid wastes which are excluded from the definition of hazardous wastes under 40 CFR § 261.4(b) would similarly exclude it from Pennsylvania's definition of hazardous waste, and OMP would not be required to obtain a hazardous waste permit from PADEP.

Since the OMP exclusion would be promulgated as an exclusion from

classification as hazardous waste at 40 CFR § 261.4(b), the material would still be regulated as residual waste under Title 25, Article IX of Pennsylvania's rules and regulations. PADEP anticipates granting a permit by rule under 25 Pa. Code § 270a.60, because OMP's catalytic oxidation process could be deemed to have a residual waste processing permit (captive processing facility permit-by-rule) if the conditions of 25 Pa. Code § 287.102(b) are met.

If the radioactivity-containing residuals from OMP's HTO process qualify as "residual waste" under the SWMA, PADEP anticipates issuing a permit by rule under 25 Pa. Code § 270a.60.

5.0 Discussion of Intentions and Commitments for Implementing the Project

5.1 OMP's Intentions and Commitments

5.1.1 Intentions

OMP's ultimate goal is to make high-temperature catalytic oxidation with the capture, recovery and reuse of the radionuclide tracer component the worldwide standard for the treatment of research-generated LLMW. OMP is fully committed to accomplishing this goal.

Pursuing this XL Project is the first step in achieving this objective. OMP intends to continue to study various LLMW streams to further improve the efficiency of the catalytic oxidation system and to better define the parameters and capabilities of the system.

5.1.2 Commitments

In conducting this Project, OMP commits to comply fully with all applicable laws and regulations (including, without limitation, all applicable air emission concentration limits as required under the federal Clean Air Act and as specified in OMP's NRC license, which are 2.00E-8 uCi/ml for tritium and 6.00E-8 uCi/ml for carbon-14), permit conditions, and legal implementing mechanisms and all other elements set forth in this Agreement.

Specifically, OMP commits to the following conditions and limitations on the scope of this project, and recognizes that EPA and PADEP intend to include them as enforceable conditions in the site-specific regulatory mechanism(s) which the agencies intend to use to carry out his project:

1. OMP agrees to process only LLMW generated within its NRC-licensed Spring House facility, and only up to the volume limits set forth in the

PADEP Treatability Study, i.e. 50 liters per year, to meet the reporting requirements set forth in Section 3.7.2.

2. Monitor and report, biannually, Destruction Removal Efficiencies for all organic components of the LLMW subject to treatment.
3. Monitor and report, biannually, capture efficiencies for the radioactive component of the LLMW subject to treatment.

In addition, OMP commits (but without the weight of enforceable conditions) to continue to work with other companies, other organizations, and research institutions to:

1. Develop a standard, bench-scale, off-the-shelf treatment unit, based on its HTO technology, to be made available to all companies and institutions which generate R&D quantities of LLMW.
2. Further develop the technology and market for recycling and reuse of the radioactive component of LLMW. In support of this goal, OMP will prepare (and submit to EPA for review and comment) a proposed plan summarizing how it expects to accomplish this goal.

5.2 EPA's and PADEP's Intentions and Commitments

The EPA intends to propose and issue (subject to applicable procedures and review of public comments) a site-specific rule, amending 40 CFR Part 261.4, which applies to the OMP Spring House facility. The site-specific rule will also allow for withdrawal or termination and a post-Project compliance period consistent with Sections 10 and 11 of this Agreement, and will allow for the transfer procedures included in Section 8. The standards and reporting requirements set forth in Section 3.7 will be implemented through the site-specific rule.

The Pennsylvania Department of Environmental Protection intends to propose and issue (subject to applicable procedures and review of public comments) a permit-by-rule as necessary under 25 Pa. Code § 270a.60.

5.3 Project XL Performance Targets

Ortho-McNeil intends to achieve the following performance targets during the implementation of the Project:

1. Achieve Destruction Removal Efficiencies of 99.999% or higher for all organic components of the LLMW subject to treatment.

2. Achieve capture efficiencies of 99% or greater for the radioactive component of the LLMW subject to treatment.

5.4 Proposed Schedule and Milestones

OMP will continue to operate the catalytic oxidation process under its PADEP treatability study exemption until this Final Project Agreement is signed and its terms implemented through the appropriate legal implementing mechanism(s).

5.5 Project Tracking, Reporting and Evaluation

As set forth in this Agreement, the Project is expected to achieve superior environmental performance to that which would otherwise be achieved through traditional regulatory compliance. To evaluate the performance and results of the Project, OMP must prepare biannual evaluation reports to be submitted to EPA and PADEP, which will include the annual report elements outlined in Section 3.7.2. The biannual evaluation will include a summary of the efforts made by OMP with respect to the intentions and commitments in Section 5.1 and a summary of the performance targets in Section 5.3 above.

EPA, PADEP and OMP will re-evaluate the regulatory flexibility and legal implementation mechanisms of the Project in the event that EPA or PADEP issues any proposed or new rule or regulation which has material relevance to the Project.

In addition, the Parties will evaluate the status and overall success of the Project as discussed in Section 5.7 below. OMP will prepare a draft evaluation report, which it will provide to the other stakeholders no later than ninety (90) days prior to the scheduled termination of the Project, which will include:

1. An analysis of the superior environmental performance achieved by the Project as set forth in this Agreement,
2. A comparison of the environmental benefits originally anticipated to result from OMP's commitments under the Project and the benefits actually achieved by the Project,
3. A review of any new statutory or regulatory requirements applicable to the Project,
4. An analysis as to whether the continuation of the Project is warranted based on continued or future anticipated superior environmental performance, and
5. If applicable, a proposal to continue the Project including any modifications

or enhancements to the Project to continue achieving superior environmental performance.

5.6 Periodic Review by the Parties to the Agreement

The Parties will hold periodic performance review conferences to assess their progress in implementing the Project. Unless they agree otherwise, the date for these conferences will be concurrent with annual Stakeholder Meetings. No later than thirty (30) days following a periodic performance review conference, OMP will provide a summary of the minutes of the conference to all Direct Stakeholders and to the project Information Repository. Any additional comments of participating Stakeholders will be reported to EPA.

5.7 Duration of the Project

This Agreement will remain in effect for five (5) years, unless the Project ends at an earlier date, as provided in Section 7 (Amendments or Modifications to the Agreement), or Section 8 (Transfer of Project Benefits and Responsibilities to a New Owner). The implementing mechanism(s) will contain “sunset” provisions ending authorization for the Project five (5) years after the effective date of the site-specific rule or permit. The implementing mechanism(s) will also address withdrawal or termination conditions and procedures as described in Section 10. This Project will not extend past the agreed upon date, and OMP will comply with all applicable requirements following this date, unless all parties agree to an amendment to the Project term.

6. *Legal Basis for the Project*

6.1 Authority to Enter into the Agreement

By signing this agreement, EPA, the Commonwealth of Pennsylvania, and OMP acknowledge and agree that they have the respective authorities, discretion, and resources to enter into this Agreement and to implement all applicable provisions of this Project, as described in this Agreement.

6.2 Legal Effect of the Agreement

This Agreement states the intentions of the Parties with respect to OMP’s XL Project. The Parties have stated their intentions seriously and in good faith, and expect to carry out their stated intentions.

This Agreement in itself does not create or modify legal rights or obligations, is not a contract or a regulatory action, such as a permit or a rule, and is not legally

binding or enforceable against any Party. Rather, it expresses the plans and intentions of the Parties without making those plans and intentions binding requirements. This applies to the provisions of this Agreement that concern procedural as well as substantive matters. For example, the Agreement establishes procedures that the Parties intend to follow with respect to dispute resolution and terminations (see Sections 9 and 10). However, while the Parties fully intend to adhere to these procedures, they are not legally obligated to do so.

EPA intends to propose for public comment the site-specific rule and/or permit needed to implement this Project. Any rules, permit modifications or legal mechanisms that implement this Project will be effective and enforceable as provided under applicable law.

This Agreement is not a “final agency action” by EPA, because it does not create or modify legal rights or obligations and is not legally enforceable. This Agreement itself is not subject to judicial review or enforcement. Nothing any Party does or does not do that deviates from the provisions of this Agreement, or that is alleged to deviate from the provisions, of this Agreement, can serve as the sole basis for any claim for damages, compensation or relief against any Party.

6.3 Other Laws or Regulations that may Apply

Except as provided in the legal implementing mechanism(s) for this Project, the Parties do not intend that this project will modify any other existing or future laws or regulations.

6.4 Retention of Rights to Other Legal Remedies

Except as expressly provided in the legal implementing mechanism(s) described in Section 4.2, nothing in this Agreement affects or limits OMP’s, EPA’s, the Commonwealth of Pennsylvania’s, or any other signatory’s legal rights. These rights may include legal, equitable, civil, criminal or administrative claims or other relief regarding the enforcement of present or future applicable federal and state laws, rules, regulations or permits with respect to the facility.

Although OMP does not intend to challenge agency actions implementing the Project (including any rule amendments or adoptions, permit actions, or other actions) that are consistent with this Agreement, OMP reserves any rights it may have to appeal or otherwise challenge any EPA or PADEP action to implement the Project. With regard to the legal implementing mechanism(s), nothing in this Agreement is intended to limit OMP’s right to an administrative or judicial appeal or review of the legal mechanism(s), in accordance with the applicable procedures for such review.

7. *Amendments or Modifications to the Agreement*

This Project is an experiment designed to test new approaches to environmental protection and there is a degree of uncertainty regarding the environmental benefits and costs associated with activities to be undertaken in this Project. Therefore, it may be appropriate and necessary to amend this Agreement at some point during the duration of the Project.

This Final Project Agreement may be amended by mutual agreement of all Parties at any time during the duration of the Project. The Parties recognize that amendments to this Agreement may also necessitate modification of legal implementation mechanism or may require development of new implementation mechanism(s). If the Agreement is amended, the EPA and OMP expect to work together with other regulatory bodies and stakeholders to identify and pursue any necessary modifications or additions to the implementation mechanisms in accordance with applicable procedures. If the Parties agree to make a substantial amendment to this Agreement, the general public will receive notice of the amendment and be given an opportunity to participate in the process, as appropriate.

In determining whether to amend the Agreement, the Parties will evaluate whether the proposed amendment meets Project XL acceptance criteria and any other relevant considerations agreed on by the Parties. All Parties to the Agreement will meet within ninety (90) days following submission of any amendment proposal (or within a shorter or longer period if all Parties agree) to discuss evaluation of the proposed amendment. If all Parties support the proposed amendments, the Parties will (after appropriate stakeholder involvement) amend the Agreement.

8. *Transfer of Project Benefits and Responsibilities to a New Owner*

The Parties expect the implementing mechanisms will allow for a transfer of OMP's benefits and responsibilities under the Project to any future owner or operator upon request of OMP and the new owner or operator, provided that the following conditions are met:

- A. OMP will provide written notice of any such proposed transfer to EPA and PADEP at least ninety (90) days before the effective date of the transfer. The notice is expected to include identification of the proposed new owner or operator, a description of its financial and technical capability to assume the obligations associated with the Project, and a statement of the new owner or operator's intention to take over the responsibilities in the XL Project of the existing owner or operator.

- B. Within forty-five (45) days of receipt of the written notice, the Parties expect EPA and PADEP, in consultation with all stakeholders, will determine whether: 1) the new owner or operator has demonstrated adequate capability to meet EPA's requirements for carrying out the XL Project; 2) is willing to take over the responsibilities in the XL Project of the existing owner or operator; and 3) is otherwise an appropriate Project XL partner. Other relevant factors, including the new owner or operator's record of compliance with Federal, State and local environmental requirements, may be considered as well.

It will be necessary to modify the Agreement to reflect the new owner and it may also be necessary for EPA and PADEP to amend the appropriate rules, permits, or other implementing mechanisms (subject to applicable public notice and comment) to transfer the legal rights and obligations of OMP under this Project to the proposed new owner or operator.

9. *Process for Resolving Disputes*

Any dispute which arises under, or with respect to, this Agreement will be subject to informal negotiations between the Parties to the Agreement. The period of informal negotiations will not exceed twenty (20) calendar days from the time the dispute is first documented, unless that period is extended by a written agreement of the Parties to the dispute. The dispute will be considered documented when one party sends a written Notice of Dispute to the other Parties.

If the Parties cannot resolve a dispute through informal negotiations, the Parties may invoke non-binding mediation by describing the dispute with a proposal for resolution in a letter to the Regional Administrator for EPA Region III. The Regional Administrator will serve as the non-binding mediator and may request an informal mediation meeting to attempt to resolve the dispute. He or she will then issue a written opinion that will be non-binding and does not constitute a final EPA action. If this effort is not successful, the Parties still have the option to terminate or withdraw from the Agreement, as set forth in Section 10 below.

10. *Withdrawal From or Termination of the Agreement*

10.1 Expectations

Although this Agreement is not legally binding and any party may withdraw from the Agreement at any time, it is the desire of the Parties that it should remain in effect through the expected duration of five (5) years, and be implemented as fully as possible unless one of the conditions below occurs:

1. Failure by any party to (a) comply with the provisions of the enforceable implementing mechanisms (i.e., conditions) for this Project, or (b) act in accordance with the provisions of this Agreement. The assessment of the failure will take nature and duration into account.
2. Failure of any party to disclose material facts during development of the Agreement.
3. Failure of the Project to provide superior environmental performance consistent with the provisions of this Agreement.
4. Enactment or promulgation of any environmental, health or safety law or regulation after execution of the Agreement, which renders the Project legally, technically or economically impracticable.
5. Decision by an agency to reject the transfer of the Project to a new owner or operator of the facility.

In addition, EPA and PADEP do not intend to withdraw from the Agreement if OMP does not act in accordance with this Agreement or its implementation mechanisms, unless the actions constitute a “substantial failure” to act consistently with intentions expressed in this Agreement and its implementing mechanisms. The decision to withdraw will, of course, take into account the failure’s nature and duration.

OMP will be given notice and a reasonable opportunity to remedy any “substantial failure” before EPA’s withdrawal. If there is a disagreement between Parties over whether a “substantial failure” exists, the Parties will use the dispute resolution mechanisms identified in Section 9 of this Agreement. The EPA and the Commonwealth of Pennsylvania retain their discretion to use existing enforcement authorities, including withdrawal or termination of this Project, as appropriate. OMP retains any existing rights or abilities to defend itself against any enforcement actions, in accordance with applicable procedures.

10.2 Procedures

The Parties agree that the following procedures will be used to withdraw from or terminate the Project before the expiration of the Project term. They also agree that the implementing mechanism(s) will provide for withdrawal or termination consistent with these procedures.

1. Any party that wants to terminate or withdraw from the Project is expected to provide written notice to the other Parties at least sixty (60) days before the withdrawal or termination.

2. If requested by any party during the sixty (60) day period noted above, the dispute resolution proceedings described in this Agreement may be initiated to resolve any dispute relating to the intended withdrawal or termination. If, following any dispute resolution or informal discussion, a party still desires to withdraw or terminate, that party will provide written notice of final withdrawal or termination to the other Parties. If any agency withdraws or terminates its participation in the Agreement, the remaining agencies will consult with OMP to determine whether the Agreement should be continued in a modified form, consistent with applicable Federal or State law, or whether it should be terminated.
3. The procedures described in this Section apply only to the decision to withdraw or terminate participation in this Agreement. Procedures to be used in modifying or rescinding any legal implementing mechanisms will be governed by the terms of those legal mechanisms and applicable law. It may be necessary to invoke the implementing mechanism's provisions that end authorization for the Project (called "sunset provisions") in the event of withdrawal or termination.

11. *Compliance After the Project is Over*

The Parties intend that there be an orderly return to compliance upon completion, withdrawal from, or termination of the Project. The following process will be used to return to compliance:

11.1 Orderly Return to Compliance with Deferred Regulations, if the Project Term is Completed and Not Extended

If, after an evaluation, the Project is terminated because the term has ended, OMP will return to compliance with all deferred requirements by the end of the Project term, unless the Project is amended or modified in accordance with Section 7 of this Agreement (Amendments or Modifications). OMP is expected to anticipate and plan for all activities to return to compliance sufficiently in advance of the end of the Project term. OMP may request a meeting with EPA and/or PADEP to discuss the timing and nature of any actions that OMP will be required to take. The Parties should meet within thirty (30) days of receipt of OMP's written request for such a discussion. During this meeting, the Parties will discuss in reasonable, good faith, which of the requirements deferred under this Project will apply after termination of the Project.

11.2 Orderly Return to Compliance with Deferred Regulations in the Event of Early Withdrawal or Termination

In the event of a withdrawal or termination not based on the end of the Project term, and where OMP has made efforts in good faith, the Parties to the Agreement will determine an interim compliance period to provide sufficient time for OMP to return to compliance with any regulations deferred under the Project. The interim compliance period will extend from the date which EPA or PADEP provides written notice of final withdrawal or termination of the Project in accordance with Section 10 of this Agreement. By the end of the interim compliance period, OMP will comply with the deferred standards set forth in 40 CFR Part 262, 264, 265 and/or 270 and the corresponding PADEP regulations under 25 PA Code as applicable. During the interim compliance period, EPA and/or PADEP may issue an order, permit, or other legally enforceable mechanism establishing a schedule for OMP to return to compliance with deferred regulations as soon as practicable. This schedule cannot extend beyond 6 months from the date of withdrawal or termination. OMP intends to be in compliance with all applicable Federal, State, and local requirements as soon as is practicable, as will be set forth in the new schedule.

12. *Effective Date and Signatories*

12.1 Effective Date

This Final Project Agreement between Ortho-McNeil Pharmaceutical, the U.S. Environmental Protection Agency and the Commonwealth of Pennsylvania Department of Environmental Protection to permit OMP to operate a high-temperature catalytic oxidation process to treat radioactive/hazardous LLMW generated by research and development activities on-site is effective after signature by the undersigned.

12.2 Signatories

The Signatories to this Agreement are as follows:

Bradley Campbell
Regional Administrator
U.S. Environmental Protection Agency – Region III

James Seif
Secretary
Pennsylvania Department of Environmental Protection

Michael R. Esposito
Lead Environmental Engineer
Ortho-McNeil Pharmaceutical - Spring House, Pennsylvania

STATEMENT OF BELIEFS

As a member of the Johnson & Johnson Family of Companies, OMP, and all of our employees, adhere to *Our Credo*, a system of values and a statement of principles and beliefs which guide our business in all that we do. *Our Credo* makes commitments to being a responsible corporate citizen to the communities in which we live and work and to the world community as well, to protecting the environment and natural resources, to developing innovative programs, and to providing high quality products and services for our patients at a reasonable cost. In pursuing this Project XL initiative, OMP believes we are upholding the Johnson & Johnson *Credo* pledge to our customers, employees, communities and stockholders.

APPENDIX A

SIMPLIFIED SCHEMATIC
HIGH-TEMPERATURE CATALYTIC OXIDATION PROCESS

APPENDIX B

LIST OF HAZARDOUS ORGANIC COMPOUNDS
AND CORRESPONDING DRE

APPENDIX C

EPA ACCEPTANCE LETTER OF OMP PROJECT XL PROPOSAL FOR FINAL
PROJECT AGREEMENT NEGOTIATIONS

APPENDIX D

NEWSPAPER ARTICLES ON THE OMP PROJECT

APPENDIX E
TREATABILITY STUDY ANNUAL REPORT

APPENDIX F

EXPLANATION OF UNITS FOR MEASUREMENT
OF RADIOACTIVITY

APPENDIX G

**DETAILED DESCRIPTION OF THE HIGH-TEMPERATURE
CATALYTIC OXIDATION PROCESS**

APPENDIX H
OUTREACH EFFORTS

APPENDIX I
TECHNOLOGY TRANSFER EFFORTS

APPENDIX J
NRC LICENSE