AUTHORIZATION TO DISCHARGE UNDER THE
NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

In compliance with the provisions of the Federal Clean Water Act as amended, (33 U.S.C. §§1251 et seq.; the "CWA"), and the Massachusetts Clean Waters Act, as amended, (M.G.L. Chap. 21, §§26-53),

OPK Biotech, LLC

is authorized to discharge from a facility located at

11 Hurley Street
Cambridge, MA 02141

to the receiving water named the Charles River, a class B water, in accordance with effluent limitations, monitoring requirements, and other conditions set forth herein.

This permit shall become effective on the first day of the calendar month following sixty (60) days after the date of signature.

This permit and the authorization to discharge expire at midnight, five (5) years from the last day of the month preceding the effective date.

This permit supersedes the general permit for reverse osmosis reject water that was issued on April 4, 1995 and that expired on April 4, 2000.

This permit consists of 8 pages in Part I including effluent limitations and monitoring requirements and 25 pages in Part II, Standard Conditions.

Signed this 14th day of December, 2011

/S/SIGNATURE ON FILE

Stephen S. Perkins, Director	David Ferris, Director
Office of Ecosystem Protection	Massachusetts Wastewater Management Program
Environmental Protection Agency	Department of Environmental Protection
Region 1	Commonwealth of Massachusetts
Boston, MA	Boston, MA

PART I.A. **Effluent Limitations and Monitoring Requirements**

1. During the period beginning on the effective date and lasting through expiration, the permittee is authorized to discharge reverse osmosis (RO) reject water from outfall serial number **001**, to a storm drain which discharges to the Charles River. Such discharges shall be limited and monitored by the permittee as specified below:

EFFLUENT CHARACTERISTIC	EFFLUENT LIMITS		MONITORING REQUIREMENTS	
PARAMETER	**AVERAGE MONTHLY**	**MAXIMUM DAILY**	**MEASUREMENT FREQUENCY**	**SAMPLE[1] TYPE**
Flow[2]	45,000 GPD	50,000 GPD	Continuous	Recorder
pH Range[3]	6.5 – 9.0 s.u.		1/Week	Grab
Dissolved Oxygen[3]	Not less than 6.0 mg/l		1/Month	Grab
Total Suspended Solids	10 mg/l	15 mg/l	1/Month	Grab
Total Ammonia Nitrogen	Report mg/l	Report mg/l	1/Month	Grab
Total Residual Chlorine	Report ug/l	Report ug/l	1/Month	Grab

The discharge of wastewaters to the Charles River from any cleaning or backwashing of these RO units, any of their associated components, or any filtration devices is prohibited.

Footnotes:

1. Samples taken in compliance with the monitoring requirements specified above shall be taken at Outfall 001 (to a storm drain to the Charles River) prior to mixing with any other stream. Any change in sampling location must be reviewed and approved in writing by EPA and MassDEP. All samples shall be tested using the analytical methods found in 40 CFR §136, or alternative methods approved by EPA in accordance with the procedures in 40 CFR §136.

2. The flow shall be continuously measured and recorded using a flow meter.

3. Requirement for State Certification. For pH, the minimum and maximum values for each month shall be reported.

PART I.A. **Effluent Limitations and Monitoring Requirements**

2. During the period beginning on the effective date and lasting through expiration, the permittee is authorized to discharge reverse osmosis (RO) reject water from outfall serial number **002**, to a storm drain which discharges to the Charles River. Such discharges shall be limited and monitored by the permittee as specified below:

EFFLUENT CHARACTERISTIC	EFFLUENT LIMITS		MONITORING REQUIREMENTS	
PARAMETER	**AVERAGE MONTHLY**	**MAXIMUM DAILY**	**MEASUREMENT FREQUENCY**	**SAMPLE[1] TYPE**
Flow[2]	100 GPD	Report GPD	Continuous	Recorder
pH Range[3]	6.5 – 9.0 s.u.		1/Month	Grab
Dissolved Oxygen[3]	Not less than 6.0 mg/l		1/Month	Grab
Total Suspended Solids	10 mg/l	15 mg/l	1/Quarter	Grab
Total Ammonia Nitrogen	Report mg/l	Report mg/l	1/Quarter	Grab
Aluminum, Total	Report mg/l	Report mg/l	1/Quarter	Grab
Total Residual Chlorine	Report ug/l	Report ug/l	1/Quarter	Grab

The discharge of wastewaters to the Charles River from any cleaning or backwashing of these RO units, any of their associated components, or any filtration devices is prohibited.

Footnotes:

1. Samples taken in compliance with the monitoring requirements specified above shall be taken at Outfall 002 (to a storm drain to the Charles River) prior to mixing with any other stream. Any change in sampling location must be reviewed and approved in writing by EPA and MassDEP. All samples shall be tested using the analytical methods found in 40 CFR §136, or alternative methods approved by EPA in accordance with the procedures in 40 CFR §136.

2. The flow shall be continuously measured and recorded using a flow meter.

3. Requirement for State Certification.

Part I.A. Conditions applicable to Outfalls 001 and 002:

a. The discharge shall not cause a violation of the water quality standards of the receiving waters.

b. The effluent pH shall be in the range of 6.5 through 9.0 standard units.

c. The discharge shall not cause objectionable discoloration of the receiving waters.

d. The effluent shall contain neither a visible oil sheen, foam, nor floating solids at any time.

e. The results of sampling for any parameter above its required frequency must also be reported.

3. Toxics Control

a. The permittee shall not discharge any pollutant or combination of pollutants in toxic amounts.

b. Any toxic components of the effluent shall not result in any demonstrable harm to aquatic life or violate any state or federal water quality standard which has been or may be promulgated. Upon promulgation of any such standard, this permit may be revised or amended in accordance with such standards.

4. Numerical Effluent Limitations for Toxicants

EPA or MassDEP may use the results of the chemical analyses conducted pursuant to this permit, as well as national water quality criteria developed pursuant to Section 304(a)(1) of the Clean Water Act (CWA), state water quality criteria, and any other appropriate information or data, to develop numerical effluent limitations for any pollutants, including but not limited to those pollutants listed in Appendix D of 40 CFR Part 122.

5. All existing manufacturing, commercial, mining, and silvicultural dischargers must notify the Director as soon as they know or have reason to believe:

a. That any activity has occurred or will occur which would result in the discharge, on a routine or frequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

(1) One hundred micrograms per liter (100 ug/l);

(2) Two hundred micrograms per liter (200 ug/l) for acrolein and acrylonitrile; five hundred micrograms per liter (500 ug/l) for 2,4-dinitrophenol and for 2-methyl-4,6-dinitrophenol; and one milligram per liter (1 mg/l) for antimony;

(3) Five (5) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 C.F.R. §122.21(g)(7); or

(4) Any other notification level established by the Director in accordance with 40 C.F.R. §122.44(f).

b. That any activity has occurred or will occur which would result in the discharge, on a non-routine or infrequent basis, of any toxic pollutant which is not limited in the permit, if that discharge will exceed the highest of the following "notification levels":

(1) Five hundred micrograms per liter (500 ug/l);

(2) One milligram per liter (1 mg/l) for antimony;

(3) Ten (10) times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 C.F.R. §122.21(g)(7); or

(4) Any other notification level established by the Director in accordance with 40 C.F.R. §122.44(f).

c. That they have begun or expect to begin to use or manufacture as an intermediate or final product or byproduct any toxic pollutant which was not reported in the permit application.

6. This permit may be modified, or revoked and reissued, on the basis of new information in accordance with 40 CFR §122.62.

B. UNAUTHORIZED DISCHARGES

The permittee is authorized to discharge only in accordance with the terms and conditions of this permit and only from the outfalls listed in Parts I A.1 and I.A.2 of this permit. Discharges of wastewater from any other point sources are not authorized by this permit and shall be reported in accordance with Section D.1.e. (1) of the General Requirements (Part II) of this permit (Twenty-four hour reporting).

C. MONITORING AND REPORTING

1. **For a period of one year from the effective date of the permit**, the permittee may either submit monitoring data and other reports to EPA in hard copy form or report electronically using NetDMR, a web-based tool that allows permittees to electronically submit discharge monitoring reports (DMRs) and other required reports via a secure internet connection. Specific requirements regarding submittal of data and reports in hard copy form and for submittal using NetDMR are described below:

a. Submittal of Reports Using NetDMR

NetDMR is accessed from: http://www.epa.gov/netdmr. **Within one year of the effective date of this permit**, the permittee shall begin submitting DMRs and reports required under this permit electronically to EPA using NetDMR, unless the facility is able to demonstrate a reasonable basis, such as technical or administrative infeasibility, that precludes the use of NetDMR for submitting DMRs and reports ("opt-out request").

DMRs shall be submitted electronically to EPA no later than the 15th day of the month following the completed reporting period. All reports required under the permit shall be submitted to EPA as an electronic attachment to the DMR. Once a permittee begins submitting reports using NetDMR, it will no longer be required to submit hard copies of DMRs or other reports to EPA and will no longer be required to submit hard copies of DMRs to MassDEP. However, permittees shall continue to send hard copies of reports other than DMRs to MassDEP until further notice from MassDEP.

b. Submittal of NetDMR Opt-Out Requests

Opt-out requests must be submitted in writing to EPA for written approval at least sixty (60) days prior to the date a facility would be required under this permit to begin using NetDMR. This demonstration shall be valid for twelve (12) months from the date of EPA approval and shall thereupon expire. At such time, DMRs and reports shall be submitted electronically to EPA unless the permittee submits a renewed opt-out request and such request is approved by EPA. All opt-out requests should be sent to the following addresses:

Attn: NetDMR Coordinator
U.S. Environmental Protection Agency, Water Technical Unit
5 Post Office Square, Suite 100 (OES04-1)
Boston, MA 02109-3912

and

Massachusetts Department of Environmental Protection
Surface Water Discharge Permit Program
627 Main Street, 2nd Floor
Worcester, Massachusetts 01608

c. Submittal of Reports in Hard Copy Form

Monitoring results shall be summarized for each calendar month and reported on separate hard copy Discharge Monitoring Report Form(s) (DMRs) postmarked no later than the 15th day of the month following the completed reporting period. All reports required under this permit shall be submitted as an attachment to the DMRs. Signed and dated originals of the DMRs, and all other reports or notifications required herein or in Part II shall be submitted to the Director at the following address:

U.S. Environmental Protection Agency
Water Technical Unit (OES04-SMR)
5 Post Office Square - Suite 100
Boston, MA 02109-3912

Duplicate signed copies of all reports or notifications required above shall be submitted to the State at the following address:

Massachusetts Department of Environmental Protection
Bureau of Waste Prevention
Northeast Regional Office
205B Lowell Street
Wilmington, MA 01887

Duplicate signed copies of all reports or notifications required above, with the exception of DMRs, shall be submitted to the State at the following address:

Massachusetts Department of Environmental Protection
Division of Watershed Management
Surface Water Discharge Permit Program
627 Main Street, 2nd Floor
Worcester, Massachusetts 01608

Any verbal reports, if required in **Parts I** and/or **II** of this permit, shall be made to both EPA and to MassDEP.

2. The permittee shall attach a copy of the laboratory case narrative to the respective DMR Form submitted to EPA and MassDEP for each sampling event reported. The laboratory case narrative shall include a copy of the laboratory data sheets for each analyses, providing the test method, the detection limits for each analyte, and a brief discussion of whether all appropriate Quality Assurance/Quality Control (QA/QC) procedures were met and were within acceptable limits.

D. STATE PERMIT CONDITIONS

1. This authorization to discharge includes two separate and independent permit authorizations. The two permit authorizations are (i) a federal National Pollutant Discharge Elimination System permit issued by the U.S. Environmental Protection Agency (EPA) pursuant to the Federal Clean Water Act, 33 U.S.C. §§1251 et seq.; and (ii) an identical state surface water discharge permit issued by the Commissioner of MassDEP pursuant to the Massachusetts Clean Waters Act, MGL c. 21, §§ 26-53, and 314 CMR 3.00. All of the requirements contained in this authorization, as well as the standard conditions contained in 314 CMR 3.19, are hereby incorporated by reference into this state surface water discharge permit.

2. This authorization also incorporates the state water quality certification issued by MassDEP under § 401(a) of the Federal Clean Water Act, 40 CFR 124.53, MGL c. 21, § 27 and 314 CMR 3.07. All of the requirements (if any) contained in MassDEP's water quality certification for the permit are hereby incorporated by reference into this state surface water discharge permit as special conditions pursuant to 314 CMR 3.11.

3. Each agency shall have the independent right to enforce the terms and conditions of this permit. Any modification, suspension or revocation of this permit shall be effective only with respect to the agency taking such action, and shall not affect the validity or status of this permit as issued by the other agency, unless and until each agency has concurred in writing with such modification, suspension or revocation. In the event any portion of this permit is declared invalid, illegal or otherwise issued in violation of state law such permit shall remain in full force and effect under federal law as a NPDES Permit issued by the U.S. Environmental Protection Agency. In the event this permit is declared invalid, illegal or otherwise issued in violation of federal law, this permit shall remain in full force and effect under state law as a permit issued by the Commonwealth of Massachusetts.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NEW ENGLAND - REGION I
5 POST OFFICE SQUARE, SUITE 100
BOSTON, MASSACHUSETTS 02109-3912

FACT SHEET

DRAFT NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) PERMIT TO DISCHARGE TO WATERS OF THE UNITED STATES PURSUANT TO THE CLEAN WATER ACT (CWA)

NPDES PERMIT NUMBER: MA0036366

PUBLIC NOTICE START AND END DATES: October 20, 2011 – November 18, 2011

NAME AND MAILING ADDRESS OF APPLICANT:

OPK Biotech, LLC
11 Hurley Street
Cambridge, MA 02141

NAME AND ADDRESS OF FACILITY WHERE DISCHARGE OCCURS:

OPK Biotech, LLC
11 Hurley Street
Cambridge, MA 02141

RECEIVING WATER(S): Charles River
(USGS Hydrologic Code #01090001 – Charles River Basin)

RECEIVING WATER CLASSIFICATION(S): Class B - Warm water fishery, Restrictions: CSO

SIC CODE: 2834, 2836

Table of Contents

I. Proposed Action, Type of Facility and Discharge Location

OPK Biotech, LLC, the permittee, formerly the Biopure Corporation, operates a biopharmaceutical manufacturing facility in Cambridge, Massachusetts. This facility is engaged in the production of oxygen-carrying therapeutics made from bovine blood products. The permittee has applied to the U.S. Environmental Protection Agency (EPA) for reissuance of its NPDES permit to discharge reverse osmosis (RO) reject water to Outfall 001. This effluent is

routed under the permittee's property and connects to an 18" City of Cambridge storm drain line that runs underneath Second Street and discharges to the Charles River. In addition, the permittee has requested the authorization to discharge a similar RO reject water discharge through another outfall, designated Outfall 002, which also discharges to the same storm drain as Outfall 001, eventually discharging to the Charles River. The current permit ("1995 Permit") was issued on April 4, 1995, and expired five years from the effective date (April 4, 2000). EPA received a permit renewal application from the applicant dated December 28, 1999. Since the renewal application was deemed timely and complete by EPA, the permit has been administratively continued pursuant to 40 CFR § 122.6.

The 1995 permit authorized the discharge of RO reject water from Outfall 001 at up to a monthly average flow of 27,360 gallons per day (GPD) to a storm drain to the Charles River. See **Figure 1** for a map of the facility and the outfalls and **Figure 2** which shows the locations inside the facility where the outfalls are sampled.

II. Description of Treatment System and Discharges

Outfall 001 – Reverse Osmosis Reject Water

To achieve the required level of water purity for its pharmaceutical production, OPK Biotech employs a reverse osmosis (RO) system to treat the incoming municipal drinking water, which is supplied by the City of Cambridge. See **Figure 3** for a water flow schematic of this process. The output of the RO system is a purified water, which is used in pharmaceutical production, and the RO reject water, which is discharged to Outfall 001. This reject water contains the typical chemical parameters of the source water, but at higher concentrations. The permittee also generates multi-media filter backwash waters, carbon filter backwash waters, and water softener regeneration waters which are treated on site and discharged to the Massachusetts Water Resources Authority (MWRA) sanitary sewer via a separate permit.

The RO reject water effluent flow and pH are measured before they are discharged to Outfall 001. The flow meter is read on a daily basis and these flow records are kept on-site. Grab samples for TSS are taken on a monthly basis from a sample port on the discharge line prior to discharge to Outfall 001.

Since the City of Cambridge's water contains some residual chlorine, this water is dechlorinated at the site via activated carbon filtration units, since chlorine would be detrimental to the operation of RO units. There is also a multi-media filter to remove the incoming solids and a water softener to reduce hardness followed by a 10 micron pre-filter and ultraviolet disinfection prior to passing through the membrane filtration of the RO unit. As mentioned earlier, filter backwash from these units is discharged to the MWRA sanitary sewer and not allowed to be discharged to Outfall 001. A summary of recent Discharge Monitoring Reports (DMRs) from Outfall 001 data may be found in Table 1, an attachment to this fact sheet.

Outfall 002 – Reverse Osmosis Reject Water

The permittee has requested the authorization to discharge RO reject water from another RO unit that supports the research lab facilities at the site. This incoming water undergoes multi-media filtration and carbon bed filtration. Currently, the permittee discharges approximately 2000 gallons per month of this reject water to the MWRA along with other process wastewaters. The permittee is able to connect this reject water to the same storm drain line that Outfall 001 discharges to, which in turn discharges to the Charles River. As a supplement to its permit

application, the permittee sampled this smaller RO reject water stream on two separate occasions (February and April of 2011) for conventional pollutants as well as for several metals and the results are shown below:

Parameter	Result	Parameter	Result
Antimony	ND, ND	Nickel	ND, ND
Aluminum	ND, 110 ug/l	Selenium	ND, ND
Arsenic	ND, ND	Silver	ND, ND
Beryllium	ND, ND	Thallium	ND, ND
Cadmium	ND, ND	Zinc	ND, ND
Chromium	ND , ND	Ammonia	0.51 & 0.77 mg/l
Copper	ND, ND	TSS	ND, ND
Lead	ND, ND	pH	7.83 & 8.0 s.u.
Mercury	ND, ND	TRC	0.05 & 0.09 mg/l
TSS	ND, ND		

Based on these sample results, which showed mostly non-detect readings and low levels for other parameters, this permit authorizes this new discharge as well. This discharge is believed to be of similar effluent quality to the main reject water discharge at Outfall 001 and is also discharged to the same storm drain to the Charles River. However, since the incoming water to this RO system undergoes fewer filtration steps and there are detectable levels of aluminum and TRC, this draft permit has proposed effluent monitoring to better assess the characteristics of this outfall over a longer period.

Since this is a proposed new discharge, the MassDEP has conducted an antidegradation evaluation, as required by 314 CMR 4.04, as described below, and as shown in Fact Sheet Attachment A. The MassDEP's findings are included with this draft permit and conclude that the discharge will not impair any existing or designated water use or cause any significant lowering of water quality. The Permit is consistent with the antidegradation provisions of the Massachusetts Surface Water Quality Standards set forth in 314 CMR4.04.

III. Receiving Water Description

Under the state water use classification system, MassDEP has designated this segment of the Charles River, which runs from the Boston University Bridge to the New Charles River Dam in Boston (Segment MA72-38), as a Class B water (314 CMR 4.00). Class B waters are designated as a habitat for fish, other aquatic life, and wildlife and for primary and secondary contact recreation. These waters are to be suitable for public water supply following appropriate treatment, irrigation and other agricultural uses, and compatible industrial cooling and process uses. The waters shall have consistently good aesthetic value. This segment of the Charles River does not always meet the state water quality standards prescribed for Class B waters, especially after wet weather. This segment is on the MassDEP's 2008 303(d) list of impaired waters for chlorophyll-*a*, DDT, dissolved oxygen (DO) saturation, DO concentration, excess algal growth, temperature, secchi disk transparency, phosphorus (total), nutrient/eutrophication biological indicators, PCB in fish tissue, oil and grease, and taste and odor.

IV. Limitations and Conditions

The effluent limitations and all other requirements described in Part VI of this Fact Sheet may be found in the draft permit.

V. Permit Basis: Statutory and Regulatory Authority

General Requirements

The Clean Water Act (CWA) prohibits the discharge of pollutants to waters of the United States without a National Pollutant Discharge Elimination System (NPDES) permit unless such a discharge is otherwise authorized by the CWA. The NPDES permit is the mechanism used to implement technology and water quality-based effluent limitations and other requirements including monitoring and reporting. This draft NPDES permit was developed in accordance with various statutory and regulatory requirements established pursuant to the CWA and any applicable State regulations. The regulations governing the EPA NPDES permit program are generally found at 40 CFR Parts 122, 124, 125, and 136.

When developing permit limits, EPA must consider the most recent technology-based treatment and water quality-based requirements. Subpart A of 40 CFR Part 125 establishes criteria and standards for the imposition of technology-based treatment requirements in permits under Section 301(b) of the CWA, including the application of EPA-promulgated effluent limitations and case-by-case determinations of effluent limitations under Section 402(a)(1) of the CWA. EPA is required to consider technology and water quality-based requirements as well as all limitations and requirements in the existing permit when developing permit limits.

Technology-Based Requirements

Technology-based treatment requirements represent the minimum level of control that must be imposed under Sections 301(b) and 402 of the CWA (see 40 CFR §125 Subpart A) to meet best practicable control technology currently available (BPT) for conventional pollutants and some metals, best conventional control technology (BCT) for conventional pollutants, and best available technology economically achievable (BAT) for toxic and non-conventional pollutants. There are no effluent limitations guidelines which are applicable to this facility.

In general, the statutory deadline for non-POTW, technology-based effluent limitations must be complied with as expeditiously as practicable but in no case later than three years after the date such limitations are established and in no case later than March 31, 1989 (see 40 CFR §125.3(a)(2)). Compliance schedules and deadlines not in accordance with the statutory provisions of the CWA can not be authorized by a NPDES permit.

In the absence of published technology-based effluent guidelines, the permit writer is authorized under Section 402(a)(1)(B) of the CWA to establish effluent limitations on a case-by-case basis using best professional judgment (BPJ).

The effluent monitoring requirements have been established to yield data representative of the discharges under the authority of Section 308(a) of the Clean Water Act, according to regulations set forth at 40 CFR § 122.41(j), 122.44(i) and 122.48. The monitoring program in the permit specifies routine sampling and analysis which will provide continuous information on the reliability and effectiveness of the installed pollution abatement equipment. The approved analytical procedures are to be found in 40 CFR 136 unless other procedures are explicitly required in the permit.

Water Quality-Based Requirements

Water quality-based limitations are required in NPDES permits when EPA and the State determine that effluent limits more stringent than technology-based limits are necessary to maintain or achieve state or federal water quality standards (WQS). See Section 301(b)(1)(C) of the CWA.

Receiving water requirements are established according to numerical and narrative standards adopted under state law for each water quality classification. When using chemical-specific numeric criteria to develop permit limits, both the acute and chronic aquatic-life criteria, expressed in terms of maximum allowable in-stream pollutant concentration, are used. Acute aquatic-life criteria are considered applicable to daily time periods (maximum daily limit) and chronic aquatic-life criteria are considered applicable to monthly time periods (average monthly limit). Chemical-specific limits are allowed under 40 CFR § 122.44(d)(1) and are implemented under 40 CFR § 122.45(d). The Region has established, pursuant to 40 CFR 122.45(d)(2), a maximum daily limit and average monthly discharge limits for specific chemical pollutants.

A facility's design flow is used when deriving constituent limits for daily and monthly time periods as well as weekly periods where appropriate. Also, the dilution provided by the receiving water is factored into this process where appropriate. Narrative criteria from the state's water quality standards are often used to limit toxicity in discharges where (a) a specific pollutant can be identified as causing or contributing to the toxicity but the state has no numeric standard; or (b) toxicity cannot be traced to a specific pollutant.

EPA regulations require NPDES permits to contain effluent limits more stringent than technology-based limits where more stringent limits are necessary to maintain or achieve state or federal WQS. The permit must address any pollutant or pollutant parameter (conventional, non-conventional, toxic and whole effluent toxicity) that is or may be discharged at a level that causes or has "reasonable potential" to cause or contribute to an excursion above any water quality criterion. See 40 CFR Section 122.44(d)(1). An excursion occurs if the projected or actual in-stream concentration exceeds the applicable criterion. In determining reasonable potential, EPA considers (a) existing controls on point and non-point sources of pollution; (b) pollutant concentration and variability in the effluent and receiving water as determined from the permit application, monthly Discharge Monitoring Reports (DMRs), and State and Federal Water Quality Reports; (c) sensitivity of the species to toxicity testing; (d) known water quality impacts of processes on wastewater; and, where appropriate, (e) dilution of the effluent in the receiving water.

WQS consist of three parts: (a) beneficial designated uses for a water body or a segment of a water body; (b) numeric and/or narrative water quality criteria sufficient to protect the assigned designated use(s); and (c) antidegradation requirements to ensure that once a use is attained it will not be degraded. The Massachusetts Surface Water Quality Standards (MA SWQS), found at 314 CMR 4.00, include these elements. The state will limit or prohibit discharges of pollutants to surface waters to assure that surface water quality standards of the receiving waters are protected and maintained or attained. These standards also include requirements for the regulation and control of toxic constituents and require that EPA criteria, established pursuant to Section 304(a) of the CWA, shall be used unless a site-specific criterion is established. The conditions of the permit reflect the goal of the CWA and EPA to achieve and then to maintain WQS.

Antibacksliding

A permit may not be renewed, reissued or modified with less stringent limitations or conditions than those contained in the previous permit unless in compliance with the anti-backsliding

requirements of the CWA [see Sections 402(o) and 303(d)(4) of the CWA and 40 CFR §122.44(l)(1 and 2)]. EPA's antibacksliding provisions prohibit the relaxation of permit limits, standards, and conditions except under certain circumstances. Effluent limits based on BPJ, water quality, and state certification requirements must also meet the antibacksliding provisions found at Section 402(o) and 303(d)(4) of the CWA.

The regulations at 40 CFR §122.44(l)(2)(i)(B)(1) offer an exception to the antibacksliding provisions based on information that was not available at the time of permit issuance and which would have justified the application of a less stringent effluent limitation. This exception is also referred to as "new information".

Regarding pH, the upper end of the pH range has been changed from 8.3 standard units (s.u.) to 9.0 s.u. This change is based on new information that shows that the permittee's source water from the MWRA is often above 8.3 s.u. and that with the dilution available to the discharge, it would not be expected that the discharge would cause or contribute to a violation of the instream State pH range requirement of 6.5 – 8.3 s.u.

For Total Suspended Solids, since all prior monitoring has not detected TSS in the effluent, monitoring for this parameter has been changed from weekly to twice per month. This change is being allowed according to the "new information" exception.

Antidegradation

Federal regulations found at 40 CFR Section 131.12 require states to develop and adopt a statewide antidegradation policy which maintains and protects existing instream water uses and the level of water quality necessary to protect the existing uses, and maintains the quality of waters which exceed levels necessary to support propagation of fish, shellfish, and wildlife and to support recreation in and on the water. The Massachusetts Antidegradation Regulations are found at Title 314 CMR 4.04. This draft permit is being reissued with limits similar to those in the existing permit. As mentioned previously, and as shown in MassDEP's Antidegradation Review and Determination in Attachment A, the discharge will not impair any existing or designated water use or cause any significant lowering of water quality. The Permit is consistent with the antidegradation provisions of the Massachusetts Surface Water Quality Standards set forth in 314 CMR4.04.

State Certification

Under Section 401 of the CWA, EPA is required to obtain certification from the state in which the discharge is located that all water quality standards or other applicable requirements of state law, in accordance with Section 301(b)(1)(C) of the CWA, are satisfied. EPA permits are to include any conditions required in the state's certification as being necessary to ensure compliance with state water quality standards or other applicable requirements of state law. (See CWA Section 401(a) and 40 CFR §124.53(e).) Regulations governing state certification are set out at 40 CFR §124.53 and §124.55. EPA regulations pertaining to permit limits based upon water quality standards and state requirements are contained in 40 CFR §122.44(d).

VI. Explanation of Permit's Effluent Limitations

Flow

The 1995 permit established a monthly average flow limit of 27,360 GPD for Outfall 001. The facility entered an extended shutdown period from June 30, 2008 through February of 2010 during which time there was no discharge of RO reject water. Production was started up again and sampling was initiated beginning in March of 2010. The last three years of data have shown variable flows between 3325 and 18,619 as monthly averages. The permittee has requested a permitted flow increase based on its anticipated production schedule which will likely result in monthly average discharges up to 45,000 gpd and daily maximum flows up to 50,000 gpd, for Outfall 001. The permittee has estimated that it currently discharges up to 2000 gallons per month or about 67 gpd to the MWRA. Therefore, this permit has established a monthly average flow limit of 45,000 gpd and a daily maximum flow limit of 50,000 gpd for Outfall 001 and a monthly average flow limit of 100 gpd for Outfall 002 to allow for monthly variation from the permittee's estimate. The increase in flow to Outfall 001 and the new flow at Outfall 002 are subject to the findings of the MassDEP's antidegradation review, which has concluded that these discharges will not impair any existing or designated water use or cause any significant lowering of water quality.

pH

The pH range in the 1995 permit was limited to the Class B range of 6.5 to 8.3 s. u. which is the range required by state WQS found at 314 CMR 4.05. For Outfall 001, the DMRs have reported effluent pH in the range of 5.8 to 8.33 s.u. since September of 2006 with four violations of the pH range. The draft permit continues to require weekly grab samples for pH and a reporting of the monthly pH range in the DMRs.

The permittee has demonstrated that its source water is often above 8.3 s.u. and that the effluent could not always be within this permitted range without pH adjustment. EPA has determined that the upper range of the pH shall be limited at 9.0 s.u. This is the highest level allowed in EPA technology guidelines. EPA expects that the instream State WQS of 8.3 s.u. would still be met, due to the significant amount of dilution available to this discharge once it enters the Charles River. The draft permit continues to require weekly grab samples for pH and a reporting of the monthly pH range in the DMRs.

For Outfall 002, the draft permit has established a monthly monitoring requirement for pH with the same limited range of 6.5 – 9.0 s.u.

Total Suspended Solids (TSS)

Since RO systems concentrate solids in the intake water, the 1995 permit had established limits of 10 mg/l monthly average and 15 mg/l daily maximum for TSS for Outfall 001. All monitoring results since 2006 for Outfall 001 have shown TSS levels to be consistently not detected in the effluent. Therefore, the TSS limit has been maintained, but the monitoring frequency has been changed from once per week to once per month. This ongoing monitoring will assure that the filtering mechanisms that are used prior to the RO unit's filtration system are working properly and that suspended solids do not pass through to the effluent in the reject water. For Outfall 002, the draft permit has established a quarterly monitoring requirement with the same monthly average (10 mg/l) and daily maximum (15 mg/l) limits for TSS to assure that the incoming water is filtered adequately.

Dissolved Oxygen (DO)

Consistent with the Class B State WQS, there has been a minimum dissolved oxygen (DO) level of 6.0 mg/l established in the permit for both outfalls, to be monitored once per month. The 1995 permit did not have any DO requirements for Outfall 001.

Total Residual Chlorine (TRC)

Historically, RO reject water discharges have contained low levels of TRC from municipal intake water and/or chlorine based chemicals which have been used to clean the RO units. The permittee does not perform any cleaning of the RO units on site as these units are changed out periodically by a vendor who performs cleanings off-site. The intake water for this RO system is City of Cambridge water, which contains low levels of TRC. The permittee uses carbon filter beds to treat for the incoming water TRC. Although TRC monitoring was not required in the 1995 permit, the permittee voluntarily sampled its effluent for TRC since May 2006 and every sample resulted in a non-detect value for TRC. The more recent sampling for proposed Outfall 002 showed TRC values of 0.05 and 0.09 mg/l. Since the permittee will continue to use City of Cambridge's water as the source water and to assure that the carbon filters are working properly, this permit has established a once per month TRC monitoring requirement for Outfall 001 and a quarterly monitoring requirement for Outfall 002.

Ammonia Nitrogen

When RO units are bleached or cleaned with hypochlorite or other chlorine based compounds, chloramines are created, which in turn results in the reject water containing ammonia. Therefore, Total Ammonia Nitrogen (TAN) monitoring is typically required of RO reject water permits. The permittee does not clean its RO units on site, as its vendor takes away spent RO units on a regular basis and replaces them with new cartridges. The permittee has noted that any washwaters resulting from the disinfection of storage tanks are discharged to the MWRA sewer and not to any outfalls in this permit. Although TAN monitoring was not required in the 1995 permit for Outfall 001, the permittee voluntarily sampled its effluent for TAN since May of 2006 and detected TAN in the range of ND to 3.9 mg/l. Since these recent levels of TAN are above typical background levels and may contribute to nutrient related impacts in the receiving water, a monthly monitoring requirement has been established in this draft permit. In addition, a quarterly monitoring requirement for Outfall 002 has been established.

Aluminum

In recent sampling for Outfall 001, total aluminum was not detected. As noted earlier, one of two recent sampling events detected total aluminum in proposed Outfall 002 at 110 ug/l. The chronic water quality criterion for aluminum is 87 ug/l and the acute criterion is 750 ug/l as shown in *National Recommended Water Quality Criteria: 2002* (EPA-822-R-02-047). EPA does not have adequate data with which to make a determination as to whether the aluminum in proposed Outfall 002 has a reasonable potential to violate WQS. Therefore, a quarterly total aluminum monitoring requirement has been established in the draft permit.

VII. Essential Fish Habitat Determination (EFH)

Under the 1996 Amendments (PL 104-267) to the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. § 1801 et seq. (1998)), EPA is required to consult with the National Marine Fisheries Services (NMFS) if EPA's action or proposed actions that it funds, permits, or undertakes, may adversely impact any essential fish habitat such as: waters and substrate necessary to fish for spawning, breeding, feeding, or growth to maturity (16 U.S.C. § 1802 (10)). Adversely impact means any impact which reduces the quality and/or quantity of EFH (50 C.F.R. § 600.910 (a)). Adverse effects may include direct (e.g., contamination or physical disruption), indirect (e.g., loss of prey, reduction in species' fecundity), site-specific or habitat-wide impacts, including individual, cumulative, or synergistic consequences of actions.

EFH is only designated for species for which federal fisheries management plans exist (16 U.S.C. § 1855(b) (1) (A)). EFH designations for New England were approved by the U.S. Department of Commerce on March 3, 1999. The following is a list of the EFH species and applicable lifestage(s) for the area that includes Massachusetts Bay, to which the Charles River discharges:

Species	Eggs	Larvae	Juveniles	Adults
Atlantic cod (*Gadus morhua*)	X	X	X	X
haddock (*Melanogrammus aeglefinus*)	X	X		
pollock (*Pollachius virens*)	X	X	X	X
whiting (*Merluccius bilinearis*)	X	X	X	X
Red hake (*Urophycis chuss*)	X	X	X	X
white hake (*Urophycis tenuis*)	X	X	X	X
winter flounder (*Pseudopleuronectes americanus*)	X	X	X	X
yellowtail flounder (*Pleuronectes ferruginea*)	X	X	X	X
windowpane flounder (*Scopthalmus aquosus*)	X	X	X	X
American plaice (*Hippoglossoides platessoides*)	X	X	X	X
ocean pout (*Macrozoarces americanus*)	X	X	X	X
Atlantic halibut (*Hippoglossus hippoglossus*)	X	X	X	X
Atlantic sea scallop (*Placopecten magellanicus*)	X	X	X	X
Atlantic sea herring (*Clupea harengus*)		X	X	X
long finned squid (*Loligo pealei*)	n/a	n/a	X	X
short finned squid (*Illex illecebrosus*)	n/a	n/a	X	X
Atlantic butterfish (*Peprilus triacanthus*)	X	X	X	X
Atlantic mackerel (*Scomber scombrus*)	X	X	X	X
summer flounder (*Paralicthys dentatus*)				X
scup (*Stenotomus chrysops*)	n/a	n/a	X	X

black sea bass (*Centropristus striata*)	n/a		X	X
surf clam (*Spisula solidissima*)	n/a	n/a	X	X
bluefin tuna (*Thunnus thynnus*)			X	X

A review of the 23 species in this table for the Mirant Kendall Station (MKS) draft permit (MA0004868) in 2004 revealed that the life stages of concern were present in the seawater salinity zone (salinity > 25.0 parts per thousand) or the mixing water/brackish salinity zone (0.5 < salinity < 25.0 parts per thousand) only. The MKS permit discharges just downstream OPK Biotech's outfall. No life stage was identified as inhabiting the tidal freshwater salinity zone. Although there is some seasonal salt water intrusion into the Lower Basin of the Charles River (that segment below the Boston University Bridge), the freshwater of the Charles River in the vicinity of this Facility's discharges does not experience appreciable mixing with the saline Boston Harbor water, due to the location of New Charles River Dam and Locks at the mouth of the river. This dam highly regulates the river level and flow of the Charles River, resulting in the river possessing the characteristics of the freshwater salinity zone.

Based on the available information, EPA has determined that OPK Biotech's operation, as restricted by the draft permit conditions, will not directly or indirectly cause adverse effects to EFH species or their habitat, because the draft permit contains limits that are protective of the aquatic species in the Charles River. For the RO reject water discharges, appropriate limits and monitoring requirements have been established and all cleaning wastewaters will be discharged to the MWRA's sewer system and not directly to the Charles River.

VIII. Endangered Species Act (ESA)

Section 7(a) of the Endangered Species Act of 1973, as amended (ESA) grants authority to and imposes requirements upon Federal agencies regarding endangered or threatened species of fish, wildlife, or plants ("listed species") and habitat of such species that has been designated as critical (a "critical habitat"). The ESA requires every Federal agency, in consultation with and with the assistance of the Secretary of Interior, to insure that any action it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of critical habitat. The United States Fish and Wildlife Service (USFWS) typically administer Section 7 consultations for bird, terrestrial, and freshwater aquatic species. The NMFS typically administers Section 7 consultations for marine species and anadromous fish.

EPA has reviewed the federal endangered or threatened species of fish, wildlife, and plants to see if any such listed species might potentially be impacted by the reissuance of this NPDES permit and has not found any such listed species. EPA has determined that there are no species of concern present in the vicinity of the outfall from this Facility. Therefore, EPA does not need to formally consult with NMFS or USFWS in regard to the provisions of the ESA. Further, the effluent limits established in this permit ensure the protection of aquatic life and maintenance of the receiving water as an aquatic habitat. During the public comment period, EPA has provided a copy of the Draft Permit and Fact Sheet to both NMFS and USFWS.

Other Conditions

The remaining conditions of the permit are based on the NPDES regulations, 40 CFR Parts 122 though 125, and consist primarily of management requirements common to all permits.

IX. State Certification Requirements

EPA may not issue a permit unless the State Water Pollution Control Agency with jurisdiction over the receiving waters certifies that the effluent limitations contained in the permit are stringent enough to assure that the discharge will not cause the receiving water to violate State WQS. The MassDEP has reviewed the draft permit and advised EPA that the limitations are adequate to protect water quality. EPA has requested permit certification by the State pursuant to 40 CFR 124.53 and expects that the draft permit will be certified.

X. Public Comment Period, Public Hearing, and Procedures for Final Decision

All persons, including applicants, who believe any condition of the draft permit is inappropriate must raise all issues and submit all available arguments and all supporting material for their arguments in full by the close of the public comment period, to the U.S. EPA, Massachusetts Office of Ecosystem Protection (CIP), 1 Congress Street, Suite 1100, Boston, Massachusetts 02114-2023. Any person, prior to such date, may submit a request in writing for a public hearing to consider the draft permit to EPA and MassDEP. Such requests shall state the nature of the issues proposed to be raised in the hearing. A public hearing may be held after at least thirty days public notice whenever the Regional Administrator finds that response to this notice indicates significant public interest. In reaching a final decision on the draft permit the Regional Administrator will respond to all significant comments and make these responses available to the public at EPA's Boston office.

Following the close of the comment period, and after a public hearing, if such hearing is held, the Regional Administrator will issue a final permit decision and forward a copy of the final decision to the applicant and each person who has submitted written comments or requested notice. Within 30 days following the notice of the final permit decision, any interested person may submit a request for a formal hearing to reconsider or contest the final decision. Requests for formal hearings must satisfy the requirements of 40 CFR 124.74, 48 Fed. Reg. 14279-14280 (April 1, 1983).

XI. EPA and MassDEP Contacts

Additional information concerning the draft permit may be obtained between the hours of 9:00 a.m. and 5:00 p.m., Monday through Friday, excluding holidays, from the EPA and MassDEP contacts below:

George Papadopoulos, Massachusetts Office of Ecosystem Protection
5 Post Office Square, Suite 100 - Mailcode OEP 06-1
Boston, MA 02109-3912
Telephone: (617) 918-1579 FAX: (617) 918-0579

Catherine Vakalopoulos, Massachusetts Department of Environmental Protection
Division of Watershed Management, Surface Water Discharge Permit Program
1 Winter Street; Boston, Massachusetts 02108
catherine.vakalopoulos@state.ma.us
Telephone: (617) 348-4026; FAX: (617) 292-5696

September 26, 2011 Stephen S. Perkins, Director

Date

Office of Ecosystem Protection
U.S. Environmental Protection Agency

Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection
One Winter Street Boston, MA 02108 • 617-292-5500

ATTACHMENT A

ANTIDEGRADATION REVIEW AND DETERMINATION

September 23, 2011

Permittee
OPK Biotech, LLC
11 Hurley St. Cambridge, MA 02141
NPDES Permit MA0036366

Receiving Water
Charles River Basin
Segment: MA72-08
Classification: B_{CSO}, Warm Water Fishery

Introduction
OPK Biotech, LLC, formerly Biopure Corporation, operates a biopharmaceutical manufacturing facility in Cambridge, Massachusetts. This facility is involved in the production of oxygen-carrying therapeutics made from bovine blood products.

The current permit, last issued in 1995, authorized the discharge of reverse osmosis (RO) reject water from Outfall 001 at up to a monthly average flow of 27,360 gallons per day (GPD) to a storm drain to the Charles River. The effluent is routed under the permittee's property and connects to an 18" City of Cambridge storm drain line that runs underneath Second Street to the Charles River.

The permittee has requested a permitted flow increase based on its anticipated production schedule which will likely result in monthly average discharges up to 45,000 gpd and daily maximum flows up to 50,000 gpd, for the combined discharge from Outfall 001, as well as a new outfall designated as 002 which is described below. Therefore, this draft permit has established a monthly average flow limit of 45,000 gpd and a daily maximum flow limit of 50,000 gpd for Outfall 001 and an average monthly flow of 100 gpd for Outfall 002.

As noted above, the permittee has requested the authorization to discharge RO reject water from another RO unit that supports the research lab facilities at the site. This incoming water undergoes multi-media filtration and carbon bed filtration. Currently, the permittee discharges approximately 2000 gallons of this RO reject water per month to the MWRA sewer system along with other process wastewaters. The permittee is able to connect this RO reject water to the same storm drain line discharging to the Charles River as the existing permitted reject water discharge and this has been designated as Outfall 002.

NPDES Permit History

The permittee has applied to the U.S. Environmental Protection Agency (EPA) for reissuance of its NPDES permit to discharge RO reject water to the Charles River through Outfalls 001 and 002. The current permit was issued on April 4, 1995, and expired five years from the effective date (April 4, 2000). EPA received a completed permit renewal application from the applicant dated December 28, 1999. Since the renewal application was deemed timely and complete by EPA, the permit has been administratively continued pursuant to 40 CFR § 122.6.

Applicability

This discharge constitutes an increased discharge to a surface water of the Commonwealth. In accordance with the State's Antidegradation Provisions [314 CMR 4.04], the increased discharge is subject to this Antidegradation Review and Determination.

Technology Based Review

Though most NPDES permits are required to contain technology based limits, there are no technology based standards for RO reject water discharges. Instead, this permit includes effluent limitations based on best professional judgment (BPJ).

OPK Biotech requires highly purified water for the production of its therapeutics. Incoming tap water must first be pretreated to maintain operation of the reverse osmosis units. The water is dechlorinated using activated carbon filtration units, solids are removed using a multi-media filter, and a water softener is added to reduce the hardness. The water then passes through a 10 micron pre-filter and ultraviolet disinfection prior to passing through the RO unit.

Determination of Applicability of Specific Antidegradation Designations

The federal Antidegradation Policy established three tiers of protection. The first tier established a standard that is applicable to all waters, and requires that all "existing uses" of a water body and level of water quality necessary to protect those existing uses be maintained and protected (40 CFR 131.12(a)(1)). Under Massachusetts Antidegradation requirements, "in all cases existing uses and the level of water quality necessary to protect those existing uses shall be maintained and protected" (314 CMR 4.04). Existing uses are defined as, "those designated uses and any other uses that do not impair the designated uses that are actually attained in a water body on or after November 28, 1975; except that in no case shall assimilation or transport of pollutants be considered an existing use." *Massachusetts Implementation Procedures for the Antidegradation Provisions to the Massachusetts Water Quality Standards* (http://www.mass.gov/dep/water/laws/antideg.pdf) require (1) an identification of existing uses, (2) a determination of water quality impacts, and (3) comparison with criteria. Tier II protects high quality waters for their existing level of quality. Limited degradation also may be allowed by MassDEP where it determines that a new or increased discharge is insignificant or pursuant to 314 CMR 4.04(5), an authorization is granted to allow lowering of water quality.

The applicable Massachusetts Water Quality Standards identify the Lower Charles River as a Class B water that is designated to support aquatic life and recreational uses. According to the MAWQS (MassDEP 2007), these waters are designated as a habitat for fish, other aquatic life, and wildlife, and for primary and secondary contact recreation. These waters shall have consistently good aesthetic value.

This facility discharges its RO reject water to the Charles River (segment MA72-38). According to the Massachusetts Year 2008 Integrated List of waters, this segment is impaired for chlorophyll-*a*, DDT, dissolved oxygen, oxygen saturation, excess algal growth, oil and grease, Secchi disk transparency, temperature, nutrient/eutrophication biological indicators, taste and odor, total phosphorus, and PCB in fish tissue. Therefore, the discharge is subject to a Tier I review for these impairments, and a Tier II review for other pollutants that are not causing impairment to the Charles River.

Tier I Review

The Charles River is a Class B warm water fishery as listed in 314 CMR 4.06. Even with the proposed increase in discharge, the amount of nitrogen is not expected to contribute to algal blooms, organic enrichment, and low dissolved oxygen. Overall, the discharge will not impair existing water uses or result in a level of water quality less than specified for a Class B water.

Tier II Review

High quality waters are protected and maintained for their existing level of quality. Discharges are permitted to these waters only when there will be no significant lowering of water quality, or an Antidegradation Authorization is granted to allow a lowering of water quality. MassDEP may determine that a discharge is insignificant "because it does not have the potential to impair any existing or designated water use and does not have the potential to cause any significant lowering of water quality." See 314 CMR 4.04(2). Based on sampling results of the two discharges, the travel time in the storm drain, and additional dilution by storm water, the discharge will not further impair the Charles River, and is therefore deemed insignificant. In view of the high level of pretreatment and available dilution in the stormwater drain and the Charles River, this discharge is considered insignificant.

Authorizations

Under 314 CMR 4.04(4), an authorization to discharge to the waters designated for protection under 314 CMR 4.04(2) may be allowed by the MassDEP where the applicant demonstrates that:

1. *The discharge is necessary to accommodate important economic or social development in the area in which the waters are located;*

The applicant, OPK Biotech, LLC, conducts biopharmaceutical research and production at this facility.

2. *No less environmentally damaging alternative site for the activity, source for the disposal, or method of elimination of the discharge is reasonably available or feasible;*

OPK Biotech discharges RO reject water to a storm drain that discharges to the Charles River. Based on previous sampling of OPK Biotech's discharge, total residual chlorine (TRC) is present at low levels. MassDEP has determined that even with an increase in flow from OPK Biotech, due to the travel time in the storm drain during which TRC breaks down, there will not be an adverse impact to the Charles River. The addition of RO reject water from another unit also will not appear to have an adverse impact to the Charles River. Though ammonia and TRC were measured at low levels and one sample contained 110 ug/l of aluminum, other metals and TSS were not detected and only 2000 gallons will be discharged per month.

3. *To the maximum extent feasible, the discharge and activity are designed and conducted to minimize adverse impacts on water quality, including implementation of source reduction practice; and*

The design of the system includes reverse osmosis filters that are replaced on a scheduled basis. They are not cleaned on-site.

4. *The discharge will not impair existing water uses nor result in a level of water quality less that that specified for the Class.*

As described above, the effluent characteristics of the RO reject water will not impair the designated uses of the Charles River. To the maximum extent feasible, the discharge and activity are designed and conducted to minimize adverse impacts on water quality.

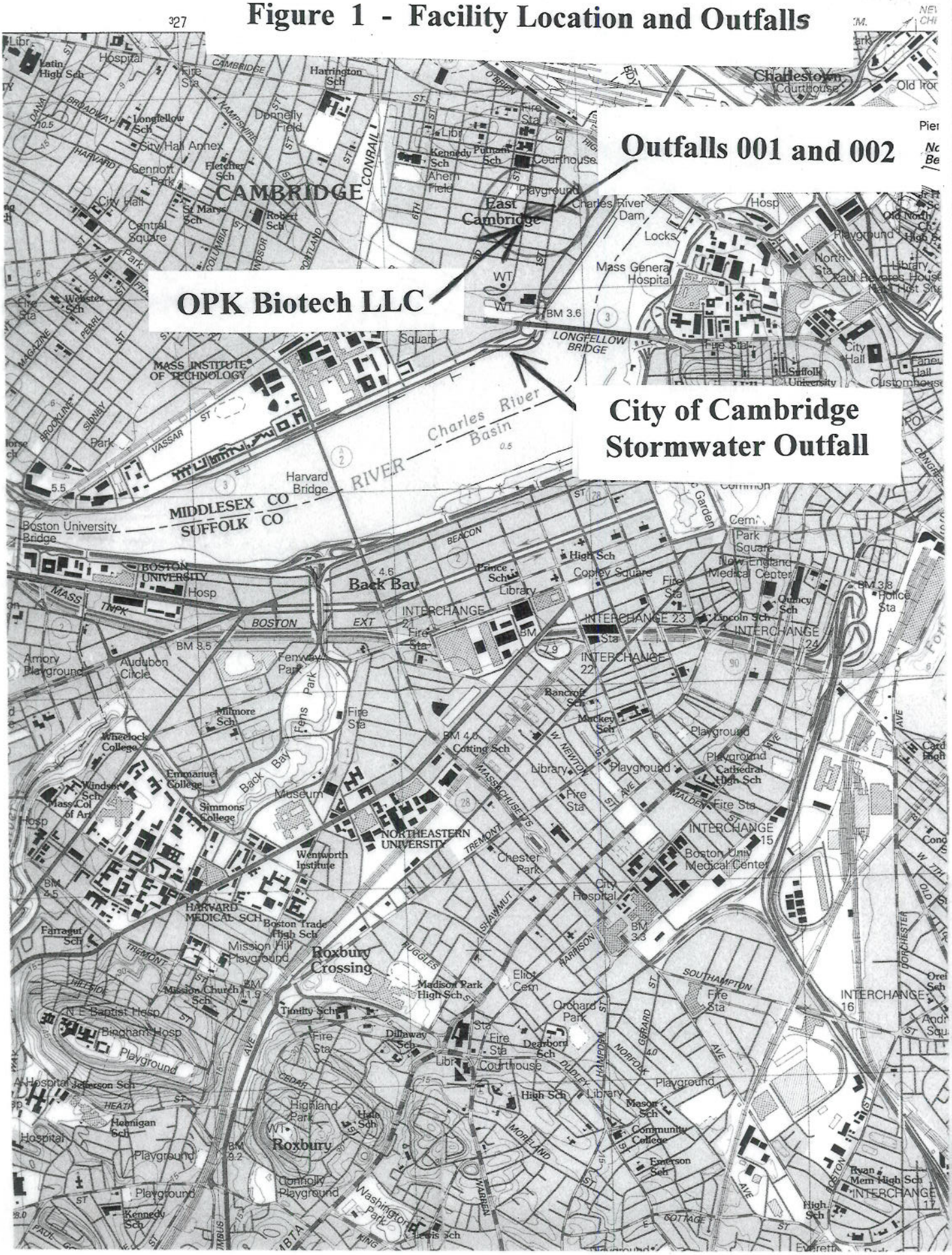
Determination

The Department has determined that the proposed discharge meets the requirements of the Antidegradation provisions of the Massachusetts Surface Water Quality Standards and complies with the policy document *Implementation Procedures for the Antidegradation Provisions of the Massachusetts Surface Water Quality Standards, 314 CMR 4.00, effective 10/21/2009.*

Signed: _____ *Date:* 9/23/11

David Ferris, Director
Massachusetts Wastewater Management Program
Department of Environmental Protection
Commonwealth of Massachusetts
Boston, MA

Figure 1 - Facility Location and Outfalls



OPK BIOTECH NPDES PERMIT REAPPLICATION

Figure 2 – Outfall Sampling Locations

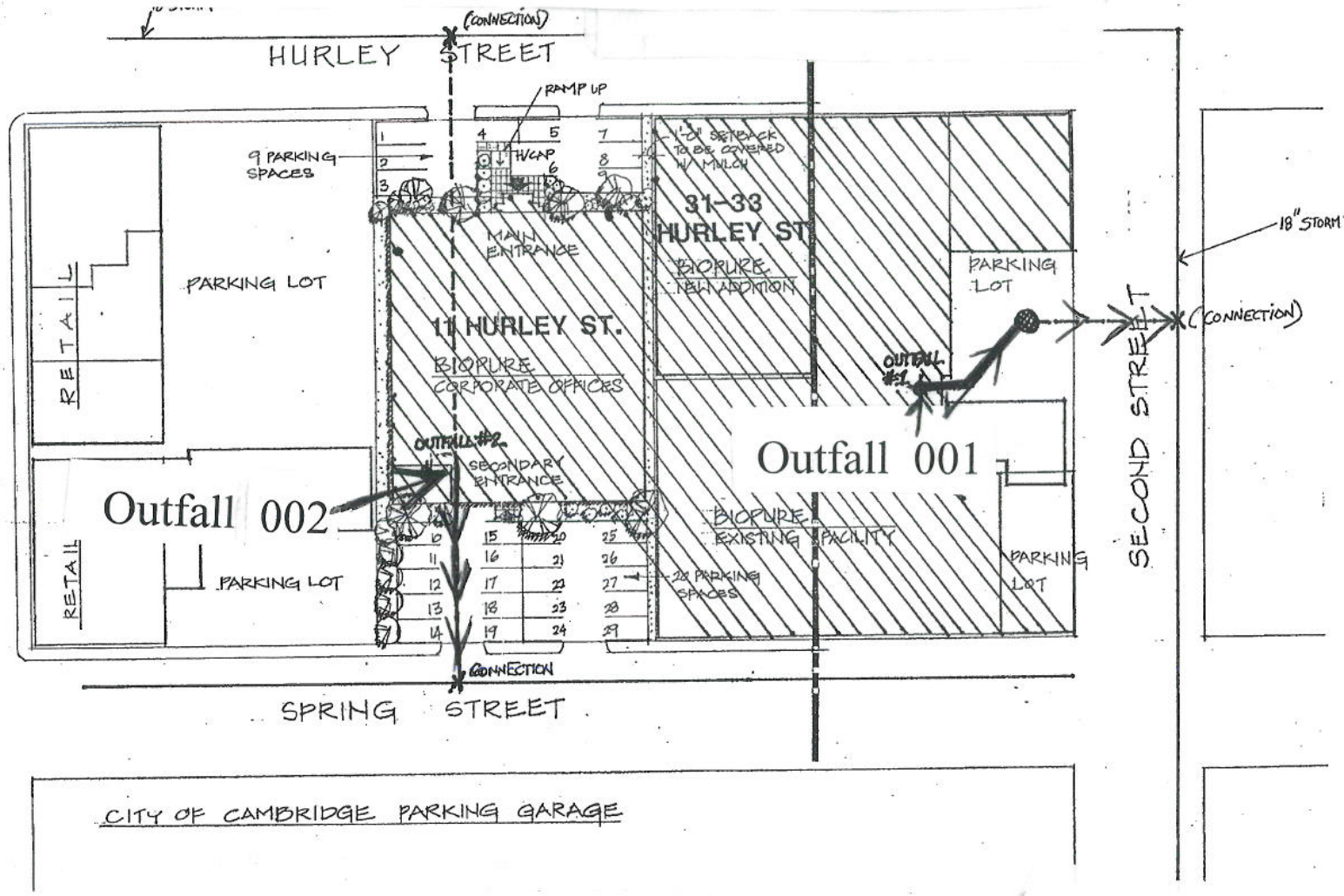
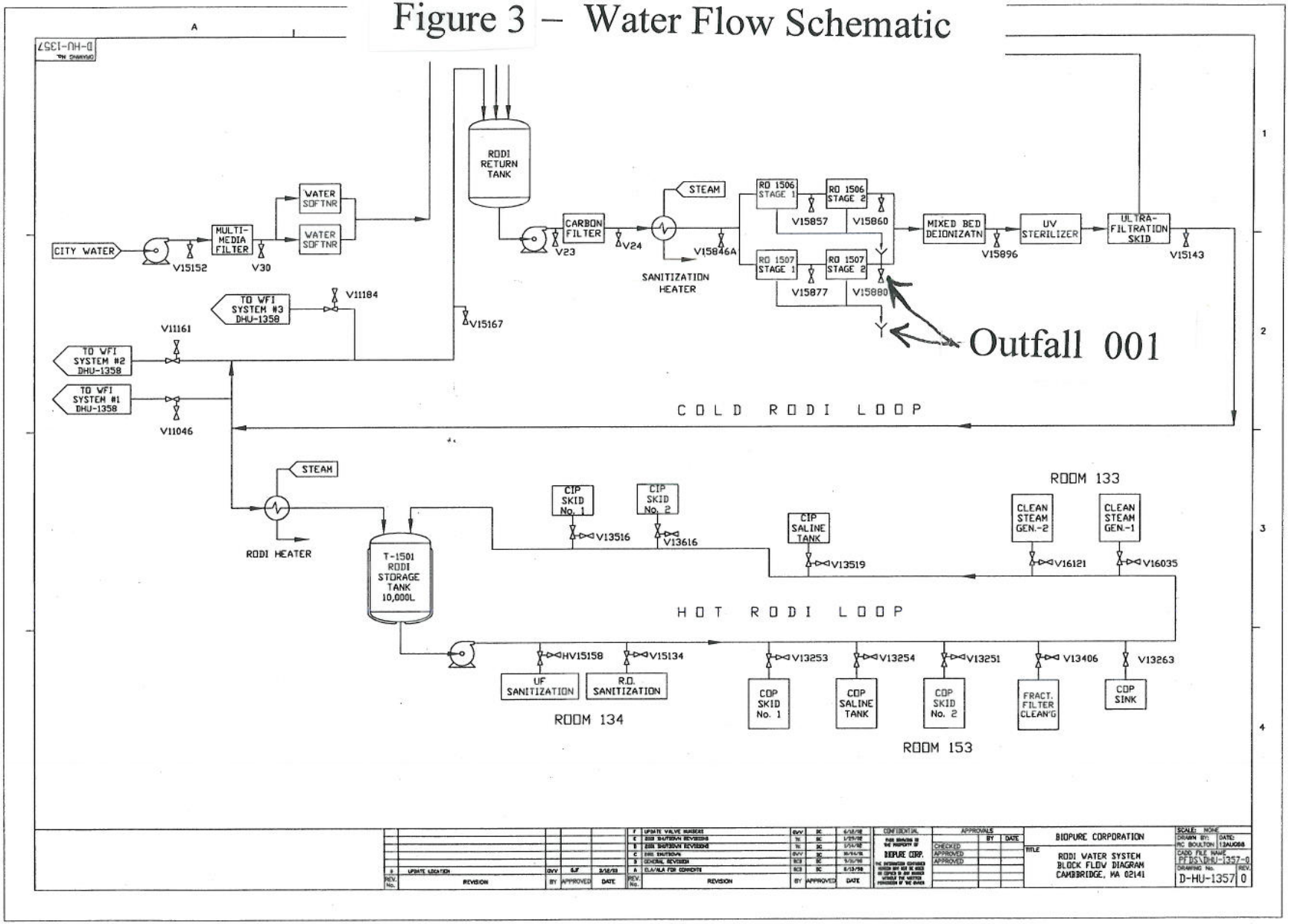


Figure 3 – Water Flow Schematic



OPK Biotech, LLC MA0036366

Response to Public Comments

In accordance with the provisions of 40 C.F.R. §124.17, this document presents EPA's response to comments received on the draft NPDES Permit, #MA0036366. This response to comments explains and supports the EPA determinations that form the basis of the final permit. From October 20, 2011 to November 18, 2011, the United States Environmental Protection Agency ("EPA") and the Massachusetts Department of Environmental Protection ("MassDEP") (together, the "Agencies") solicited public comments on a draft NPDES permit, #MA0036366, developed pursuant to a permit application from OPK Biotech, LLC ("OPK Biotech"), for the reissuance of a National Pollutant Discharge Elimination System ("NPDES") permit to discharge reverse osmosis reject water from outfall numbers 001 and 002 to a storm drain that discharges to the Charles River in Cambridge, Massachusetts.

After a review of the comments received, the Agencies have made a final decision to issue this permit authorizing these discharges. The final permit is identical to the draft permit that was available for public comment. Although there was additional information that was submitted by the permittee regarding the fact sheet, the information and arguments presented did not raise any substantial new questions concerning the permit. EPA did, however, note these clarifications to the fact sheet for the record.

Copies of the Final Permit may be obtained by writing or calling EPA's NPDES Industrial Permits Branch (OEP 06-1), Office of Ecosystem Protection, 5 Post Office Square, Suite 100, Boston, MA 02109-3912; Telephone: (617) 918-1579.

Comments submitted by Jason Cupp, OPK Biotech:

Comments 1, 2 and 3:

1. In the Fact Sheet, page 8, under Antibacksliding, the new TSS sampling rate should read "once per month" not twice.

2. In the Fact Sheet, page 4, under Outfall 001 - Reverse Osmosis Reject Water, the 10 micron pre-filter is the first thing the incoming city water hits. There is no longer a multi-media filter.

3. In the Fact Sheet, page 3, under Outfall 001 - Reverse Osmosis Reject Water, strike the reference to multi-media filter backwash waters (not applicable).

Response to Comments 1, 2, and 3:

EPA acknowledges your comments regarding clarifications to the fact sheet. Since the fact sheet cannot be changed after the public comment period, these clarifications are noted for the record.

November 28, 2011