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")

Genzyme Corporation

is authorized to discharge from a facility located at

Genzyme Corporation
500 Soldiers Field Road
Allston, MA 02134

to receiving water named

Charles River
Charles River Watershed

in accordance with effluent limitations, monitoring requirements and other conditions set forth herein.

This permit shall become effective on [DATE].[1]

This permit expires at midnight on the last day of the month preceding the effective date.

This permit supersedes the permit issued on March 31st, 2015.

This permit consists of this **cover page**, **Part I**, and **Part II** (NPDES Part II Standard Conditions, April 2018).

Signed this day of

_____
Ken Moraff, Director
Water Division
Environmental Protection Agency
Region 1
Boston, MA

[1] Pursuant to 40 Code of Federal Regulations (CFR) § 124.15(b)(3), if no comments requesting a change to the Draft Permit are received, the permit will become effective upon the date of signature. Procedures for appealing EPA's Final Permit decision may be found at 40 CFR. § 124.19.

PART I

A. EFFLUENT LIMITATIONS AND MONITORING REQUIREMENTS

1. During the period beginning on the effective date and lasting through the expiration date, the Permittee is authorized to discharge reverse osmosis reject water through Outfall Serial Number 001 to the Charles River. The discharge shall be limited and monitored as specified below. The discharge from the cleaning or backwashing of the RO units or any of their components is prohibited.

Effluent Characteristic	**Effluent Limitations**		**Monitoring Requirements[1,2,3]**	
	Average Monthly	**Maximum Daily**	**Measurement Frequency[4]**	**Sample Type[5]**
Effluent Flow[6]	0.066 MGD	0.12 MGD	Continuous	Recorder
Total Suspended Solids (TSS)	Report mg/L	Report mg/L	1/Quarter	Grab
pH[7]	6.5 – 9.0 S.U.		1/Week	Grab
Dissolved Oxygen	Not less than 5.0 mg/l		1/Month	Grab

Footnotes:

1. Effluent samples shall yield data representative of the discharge. A routine sampling program shall be developed in which samples are taken at a point prior to discharge to Outfall 001 and prior to mixing with any other stream. Changes in sampling location must be approved in writing by the Environmental Protection Agency Region 1 (EPA). The Permittee shall report the results to EPA of any additional testing above that required herein, if testing is done in accordance with 40 CFR Part 136.

2. In accordance with 40 CFR § 122.44(i)(1)(iv), the Permittee shall monitor according to sufficiently sensitive test procedures (i.e., methods) approved under 40 CFR. Part 136 or required under 40 CFR chapter I, subchapter N or O, for the analysis of pollutants or pollutant parameters (except WET). A method is "sufficiently sensitive" when: 1) The method minimum level (ML) is at or below the level of the effluent limitation established in the permit for the measured pollutant or pollutant parameter; or 2) The method has the lowest ML of the analytical methods approved under 40 CFR . Part 136 or required under 40 CFR chapter I, subchapter N or O for the measured pollutant or pollutant parameter. The term "minimum level" refers to either the sample concentration equivalent to the lowest calibration point in a method or a multiple of the method detection limit (MDL), whichever is higher. Minimum levels may be obtained in several ways: They may be published in a method; they may be based on the lowest acceptable calibration point used by a laboratory; or they may be calculated by multiplying the MDL in a method, or the MDL determined by a laboratory, by a factor.

3. When a parameter is not detected above the ML, the Permittee must report the data qualifier signifying less than the ML for that parameter (e.g., < 50 µg/L, if the ML for a parameter is 50 µg/L). For calculating and reporting the average monthly concentration when one or more values are not detected, assign a value of zero to all non-detects and report the average of all the results. The number of exceedances shall be enumerated for each parameter in the field provided on every Discharge Monitoring Report (DMR).

4. Measurement frequency of 1/week is defined as the sampling of one discharge event in each seven-day calendar week. Measurement frequency of 1/month is defined as the sampling of one discharge event in each calendar month. Measurement frequency of 1/quarter is defined as the sampling of one discharge event during one calendar quarter. Calendar quarters are defined as January through March, inclusive, April through June, inclusive, July through September, inclusive and October through December, inclusive. If no sample is collected during the measurement frequencies defined above, the Permittee must report an appropriate No Data Indicator Code (e.g., "C" for "No Discharge")

5. A grab sample is one sample collected over no more than a 15-minute period. A recorder takes continuous flow measurements using a totalizer or similar device, when the Facility is discharging from an outfall.

6. Effluent flow shall be reported in million gallons per day (MGD).

7. The pH shall be within the specified range at all times. The minimum and maximum pH sample measurement values for the month shall be reported in standard units (S.U.). To confirm that the available dilution is sufficient to prevent exceedance of the Massachusetts WQS, the permittee has the option to conduct a study to demonstrate that the instream pH is meeting MA WQS. The results of the study will be used to determine the pH limit in future permits.

   For pH study option, see Part I.C.1.

Part I.A. continued.

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

3. The discharge shall be free from pollutants in concentrations or combinations that, in the receiving water, settle to form objectionable deposits; float as debris, scum or other matter to form nuisances; produce objectionable odor, color, taste or turbidity; or produce undesirable or nuisance species of aquatic life.

4. The discharge shall be free from pollutants in concentrations or combinations that adversely affect the physical, chemical, or biological nature of the bottom.

5. The discharge shall not result in pollutants in concentrations or combinations in the receiving water that are toxic to humans, aquatic life or wildlife.

6. The discharge shall be free from floating, suspended and settleable solids in concentrations or combinations that would impair any use assigned to the receiving water.

7. The discharge shall be free from oil, grease and petrochemicals that produce a visible film on the surface of the water, impart an oily taste to the water or an oily or other undesirable taste to the edible portions of aquatic life, coat the banks or bottom of the water course, or are deleterious or become toxic to aquatic life.

8. All existing manufacturing, commercial, mining, and silvicultural dischargers must notify EPA as soon as they know or have reason to believe (40 CFR. § 122.42):

   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) 100 micrograms per liter (µg/L);
      (2) 200 µg/L for acrolein and acrylonitrile; 500 µg/L for 2,4-dinitrophenol and for 2-methyl-4,6-dinitrophenol; and one milligram per liter (mg/L) for antimony;
      (3) Five times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 CFR. § 122.21(g)(7); or
      (4) Any other notification level established by EPA in accordance with 40 CFR § 122.44(f) and State regulations.

   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) 500 µg/L;
      (2) One mg/L for antimony;
      (3) 10 times the maximum concentration value reported for that pollutant in the permit application in accordance with 40 CFR. § 122.21(g)(7); or
      (4) Any other notification level established by EPA in accordance with 40 CFR § 122.44(f) and State regulations.

   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.

B. UNAUTHORIZED DISCHARGES

1. This permit authorizes discharges only from the outfall listed in Part I.A.1, in accordance with the terms and conditions of this permit. Discharges of wastewater from any other point sources are not authorized by this permit and shall be reported in accordance with Part D.1.e.(1) of the Standard Conditions of this permit (24-hour reporting).

C. SPECIAL CONDITIONS

1. pH Study

In order to continue the pH limit of 6.5-9.0 in future permits, within 3 years of the effective date of the permit, the permittee shall conduct a study to demonstrate that the pH in the receiving water does not exceed the range of 6.5-8.3. At least 6 months prior to beginning to conduct the study, the permittee shall contact MassDEP (npdes@mass.gov) at MassDEP for guidance on completing the study. The completed pH study shall be submitted in accordance with Part 1.D.2. and Part 1.D. 6.

2. Discharges of Chemicals and Additives

The discharge of any chemical or additive, including chemical substitution, which was not reported in the application submitted to EPA e or provided through a subsequent written notification submitted to EPA is prohibited. Upon the effective date of this permit, chemicals and/or additives which have been disclosed to EPA may be discharged up to the frequency and level disclosed, provided that such discharge does not violate §§ 307 or 311 of the CWA or applicable State water quality standards. Discharges of a new chemical or additive are authorized under this permit 30 days following written notification to EPA unless otherwise notified by EPA. To request authorization to discharge a new chemical or additive, the Permittee must submit a written notification to EPA in accordance with Part I.D.3 of this permit. The written notification must include the following information, at a minimum:

a. The following information for each chemical and/or additive that will be discharged:

   (1) Product name, chemical formula, general description, and manufacturer of the chemical/additive;
   (2) Purpose or use of the chemical/additive;
   (3) Safety Data Sheet (SDS), Chemical Abstracts Service (CAS) Registry number, and EPA registration number, if applicable, for each chemical/additive;
   (4) The frequency (e.g., daily), magnitude (i.e., maximum application concentration), duration (e.g., hours), and method of application for the chemical/additive;
   (5) The maximum discharge concentration; and
   (6) The vendor's reported aquatic toxicity, if available (i.e., NOAEL and/or LC_{50} in percent for aquatic organism(s)).

b. Written rationale which demonstrates that the discharge of such chemicals and/or additives as proposed will not: 1) will not add any pollutants in concentrations which exceed any permit effluent limitation; and 2) will not add any pollutants that would

justify the application of permit conditions different from, or in addition to those currently in this permit.

D. REPORTING REQUIREMENTS

Unless otherwise specified in this permit, the Permittee shall submit reports, requests, and information and provide notices in the manner described in this section.

1. Submittal of DMRs Using NetDMR

   The Permittee shall continue to submit its monthly monitoring data in discharge monitoring reports (DMRs) to EPA and the State no later than the 15th day of the month following the monitoring period electronically using NetDMR. When the Permittee submits DMRs using NetDMR, it is not required to submit hard copies of DMRs to EPA or the State. NetDMR is accessible through EPA's Central Data Exchange at https://cdx.epa.gov/.

2. Submittal of Reports as NetDMR Attachments

   Unless otherwise specified in this permit, the Permittee shall electronically submit all reports to EPA as NetDMR attachments rather than as hard copies. Because the due dates for reports described in this permit may not coincide with the due date for submitting DMRs (which is no later than the 15th day of the month following the monitoring period), a report submitted electronically as a NetDMR attachment shall be considered timely if it is electronically submitted to EPA using NetDMR with the next DMR due following the particular report due date specified in this permit.

3. Submittal of Requests and Reports to EPA Water Division (WD)

   a. The following requests, reports, and information described in this permit shall be submitted to the NPDES Applications Coordinator in EPA WD:

      (1) Transfer of Permit notice;
      (2) Request for changes in sampling location; and
      (3) Request to discharge new chemicals or additives.

   b. These reports, information, and requests shall be submitted to EPA WD electronically at R1NPDESReporting@epa.gov or by hard copy mail to the following address:

U.S. Environmental Protection Agency
Water Division
NPDES Applications Coordinator
5 Post Office Square - Suite 100 (06-03)
Boston, MA 02109-3912

4. Submittal of Reports in Hard Copy Form

a. The following notifications and reports shall be signed and dated originals, submitted in hard copy, with a cover letter describing the submission:

(1) Prior to December 21, 2020, written notifications required under Part II. Starting on December 21, 2020, such notifications must be done electronically using EPA's NPDES Electronic Reporting Tool ("NeT"), or another approved EPA system, which will be accessible through EPA's Central Data Exchange at https://cdx.epa.gov/.

b. This information shall be submitted to EPA ECAD at the following address:

U.S. Environmental Protection Agency
Enforcement and Compliance Assurance Division
Water Compliance Section
5 Post Office Square, Suite 100 (04-SMR)
Boston, MA 02109-3912

5. State Reporting

Upon completion, an electronic copy of the pH Study described in Part I.C.1. shall be submitted to MassDEP electronically (npdes@mass.gov).

6. Verbal Reports and Verbal Notifications

a. Any verbal reports or verbal notifications, if required in Parts I and/or II of this permit, shall be made to both EPA and to the State. This includes verbal reports and notifications which require reporting within 24 hours (e.g., Part II.B.4.c. (2), Part II.B.5.c. (3), and Part II.D.1.e.).

b. Verbal reports and verbal notifications shall be made to EPA's Enforcement and Compliance Assurance Division at:

617-918-1510

c. Verbal reports and verbal notifications shall be made to the State's Emergency Response at:

888-304-1133

E. STATE PERMIT CONDITIONS

1. This permit is in the process of receiving water quality certification issued by the State under § 401(a) of the CWA and 40 CFR § 124.53. EPA will incorporate by reference all state water quality certification requirements (if any) into the final permit.

NPDES PART II STANDARD CONDITIONS
(April 26, 2018)[1]

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[1] Updated July 17, 2018 to fix typographical errors.

A. GENERAL REQUIREMENTS

1. Duty to Comply

The Permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the Clean Water Act (CWA or Act) and is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or denial of a permit renewal application.

a. The Permittee shall comply with effluent standards or prohibitions established under Section 307(a) of the Clean Water Act for toxic pollutants and with standards for sewage sludge use or disposal established under Section 405(d) of the CWA within the time provided in the regulations that establish these standards or prohibitions, or standards for sewage sludge use or disposal, even if the permit has not yet been modified to incorporate the requirement.

b. Penalties for Violations of Permit Conditions: The Director will adjust the civil and administrative penalties listed below in accordance with the Civil Monetary Penalty Inflation Adjustment Rule (83 Fed. Reg. 1190-1194 (January 10, 2018) and the 2015 amendments to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note. See Pub. L.114-74, Section 701 (Nov. 2, 2015)). These requirements help ensure that EPA penalties keep pace with inflation. Under the above-cited 2015 amendments to inflationary adjustment law, EPA must review its statutory civil penalties each year and adjust them as necessary.

(1) Criminal Penalties

(a) *Negligent Violations.* The CWA provides that any person who negligently violates permit conditions implementing Sections 301, 302, 306, 307, 308, 318, or 405 of the Act is subject to criminal penalties of not less than $2,500 nor more than $25,000 per day of violation, or imprisonment of not more than 1 year, or both. In the case of a second or subsequent conviction for a negligent violation, a person shall be subject to criminal penalties of not more than $50,000 per day of violation or by imprisonment of not more than 2 years, or both.

(b) *Knowing Violations.* The CWA provides that any person who knowingly violates permit conditions implementing Sections 301, 302, 306, 307, 308, 318, or 405 of the Act is subject to a fine of not less than $5,000 nor more than $50,000 per day of violation, or by imprisonment for not more than 3 years, or both. In the case of a second or subsequent conviction for a knowing violation, a person shall be subject to criminal penalties of not more than $100,000 per day of violation, or imprisonment of not more than 6 years, or both.

(c) *Knowing Endangerment.* The CWA provides that any person who knowingly violates permit conditions implementing Sections 301, 302, 303, 306, 307, 308, 318, or 405 of the Act and who knows at that time that he or she is placing another person in imminent danger of death or serious bodily injury shall upon conviction be subject to a fine of not more than $250,000 or by imprisonment of not more than 15 years, or both. In the case of a second or subsequent conviction for a knowing

endangerment violation, a person shall be subject to a fine of not more than $500,000 or by imprisonment of not more than 30 years, or both. An organization, as defined in Section 309(c)(3)(B)(iii) of the Act, shall, upon conviction of violating the imminent danger provision, be subject to a fine of not more than $1,000,000 and can be fined up to $2,000,000 for second or subsequent convictions.

(d) *False Statement.* The CWA provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than $10,000, or by imprisonment for not more than 2 years, or both. If a conviction of a person is for a violation committed after a first conviction of such person under this paragraph, punishment is a fine of not more than $20,000 per day of violation, or by imprisonment of not more than 4 years, or both. The Act further provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or non-compliance shall, upon conviction, be punished by a fine of not more than $10,000 per violation, or by imprisonment for not more than 6 months per violation, or by both.

(2) *Civil Penalties*. The CWA provides that any person who violates a permit condition implementing Sections 301, 302, 306, 307, 308, 318, or 405 of the Act is subject to a civil penalty not to exceed the maximum amounts authorized by Section 309(d) of the Act, the 2015 amendments to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note, and 40 C.F.R. Part 19. *See* Pub. L.114-74, Section 701 (Nov. 2, 2015); 83 Fed. Reg. 1190 (January 10, 2018).

(3) *Administrative Penalties*. The CWA provides that any person who violates a permit condition implementing Sections 301, 302, 306, 307, 308, 318, or 405 of the Act is subject to an administrative penalty as follows:

(a) *Class I Penalty.* Not to exceed the maximum amounts authorized by Section 309(g)(2)(A) of the Act, the 2015 amendments to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note, and 40 C.F.R. Part 19. *See* Pub. L.114-74, Section 701 (Nov. 2, 2015); 83 Fed. Reg. 1190 (January 10, 2018).

(b) *Class II Penalty.* Not to exceed the maximum amounts authorized by Section 309(g)(2)(B) of the Act the 2015 amendments to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461 note, and 40 C.F.R. Part 19. *See* Pub. L.114-74, Section 701 (Nov. 2, 2015); 83 Fed. Reg. 1190 (January 10, 2018).

2. Permit Actions

This permit may be modified, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit

condition.

3. Duty to Provide Information

The Permittee shall furnish to the Director, within a reasonable time, any information which the Director may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The Permittee shall also furnish to the Director, upon request, copies of records required to be kept by this permit.

4. Oil and Hazardous Substance Liability

Nothing in this permit shall be construed to preclude the institution of any legal action or relieve the Permittee from responsibilities, liabilities or penalties to which the Permittee is or may be subject under Section 311 of the CWA, or Section 106 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA).

5. Property Rights

This permit does not convey any property rights of any sort, or any exclusive privilege.

6. Confidentiality of Information

a. In accordance with 40 C.F.R. Part 2, any information submitted to EPA pursuant to these regulations may be claimed as confidential by the submitter. Any such claim must be asserted at the time of submission in the manner prescribed on the application form or instructions or, in the case of other submissions, by stamping the words "confidential business information" on each page containing such information. If no claim is made at the time of submission, EPA may make the information available to the public without further notice. If a claim is asserted, the information will be treated in accordance with the procedures in 40 C.F.R. Part 2 (Public Information).

b. Claims of confidentiality for the following information will be denied:

(1) The name and address of any permit applicant or Permittee;
(2) Permit applications, permits, and effluent data.

c. Information required by NPDES application forms provided by the Director under 40 C.F.R. § 122.21 may not be claimed confidential. This includes information submitted on the forms themselves and any attachments used to supply information required by the forms.

7. Duty to Reapply

If the Permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the Permittee must apply for and obtain a new permit. The Permittee shall submit a new application at least 180 days before the expiration date of the existing permit, unless permission for a later date has been granted by the Director. (The Director shall not grant permission for applications to be submitted later than the expiration date of the existing permit.)

8. State Authorities

Nothing in Parts 122, 123, or 124 precludes more stringent State regulation of any activity

covered by the regulations in 40 C.F.R. Parts 122, 123, and 124, whether or not under an approved State program.

9. Other Laws

The issuance of a permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of State or local law or regulations.

B. OPERATION AND MAINTENANCE OF POLLUTION CONTROLS

1. Proper Operation and Maintenance

The Permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the Permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems which are installed by a Permittee only when the operation is necessary to achieve compliance with the conditions of the permit.

2. Need to Halt or Reduce Not a Defense

It shall not be a defense for a Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

3. Duty to Mitigate

The Permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.

4. Bypass

a. Definitions

(1) *Bypass* means the intentional diversion of waste streams from any portion of a treatment facility.

(2) *Severe property damage* means substantial physical damage to property, damage to the treatment facilities which causes them to become inoperable, or substantial and permanent loss of natural resources which can reasonably be expected to occur in the absence of a bypass. Severe property damage does not mean economic loss caused by delays in production.

b. *Bypass not exceeding limitations.* The Permittee may allow any bypass to occur which does not cause effluent limitations to be exceeded, but only if it also is for essential maintenance to assure efficient operation. These bypasses are not subject to the provisions of paragraphs (c) and (d) of this Section.

c. Notice

(1) *Anticipated bypass*. If the Permittee knows in advance of the need for a bypass, it shall submit prior notice, if possible at least ten days before the date of the bypass. As of December 21, 2020 all notices submitted in compliance with this Section must be submitted electronically by the Permittee to the Director or initial recipient, as defined in 40 C.F.R. § 127.2(b), in compliance with this Section and 40 C.F.R. Part 3 (including, in all cases, Subpart D to Part 3), § 122.22, and 40 C.F.R. Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, Permittees may be required to report electronically if specified by a particular permit or if required to do so by state law.

(2) *Unanticipated bypass*. The Permittee shall submit notice of an unanticipated bypass as required in paragraph D.1.e. of this part (24-hour notice). As of December 21, 2020 all notices submitted in compliance with this Section must be submitted electronically by the Permittee to the Director or initial recipient, as defined in 40 C.F.R. § 127.2(b), in compliance with this Section and 40 C.F.R. Part 3 (including, in all cases, Subpart D to Part 3), § 122.22, and 40 C.F.R. Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, Permittees may be required to report electronically if specified by a particular permit or required to do so by law.

d. *Prohibition of bypass.*

(1) Bypass is prohibited, and the Director may take enforcement action against a Permittee for bypass, unless:

(a) Bypass was unavoidable to prevent loss of life, personal injury, or severe property damage;

(b) There were no feasible alternatives to the bypass, such as the use of auxiliary treatment facilities, retention of untreated wastes, or maintenance during normal periods of equipment downtime. This condition is not satisfied if adequate back-up equipment should have been installed in the exercise of reasonable engineering judgment to prevent a bypass which occurred during normal periods of equipment downtime or preventative maintenance; and

(c) The Permittee submitted notices as required under paragraph 4.c of this Section.

(2) The Director may approve an anticipated bypass, after considering its adverse effects, if the Director determines that it will meet the three conditions listed above in paragraph 4.d of this Section.

5. Upset

a. *Definition*. *Upset* means an exceptional incident in which there is an unintentional and temporary noncompliance with technology based permit effluent limitations because of factors beyond the reasonable control of the Permittee. An upset does not include noncompliance to the extent caused by operational error, improperly designed treatment facilities, inadequate treatment facilities, lack of preventive maintenance, or careless or

improper operation.

b. *Effect of an upset.* An upset constitutes an affirmative defense to an action brought for noncompliance with such technology based permit effluent limitations if the requirements of paragraph B.5.c. of this Section are met. No determination made during administrative review of claims that noncompliance was caused by upset, and before an action for noncompliance, is final administrative action subject to judicial review.

c. *Conditions necessary for a demonstration of upset.* A Permittee who wishes to establish the affirmative defense of upset shall demonstrate, through properly signed, contemporaneous operating logs, or other relevant evidence that:

(1) An upset occurred and that the Permittee can identify the cause(s) of the upset;
(2) The permitted facility was at the time being properly operated; and
(3) The Permittee submitted notice of the upset as required in paragraph D.1.e.2.b. (24-hour notice).
(4) The Permittee complied with any remedial measures required under B.3. above.

d. *Burden of proof.* In any enforcement proceeding the Permittee seeking to establish the occurrence of an upset has the burden of proof.

C. MONITORING REQUIREMENTS

1. Monitoring and Records

a. Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.

b. Except for records of monitoring information required by this permit related to the Permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least 5 years (or longer as required by 40 C.F.R. § 503), the Permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least 3 years from the date of the sample, measurement, report or application. This period may be extended by request of the Director at any time.

c. Records of monitoring information shall include:

(1) The date, exact place, and time of sampling or measurements;
(2) The individual(s) who performed the sampling or measurements;
(3) The date(s) analyses were performed;
(4) The individual(s) who performed the analyses;
(5) The analytical techniques or methods used; and
(6) The results of such analyses.

d. Monitoring must be conducted according to test procedures approved under 40 C.F.R. § 136 unless another method is required under 40 C.F.R. Subchapters N or O.

e. The Clean Water Act provides that any person who falsifies, tampers with, or

knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than $10,000, or by imprisonment for not more than 2 years, or both. If a conviction of a person is for a violation committed after a first conviction of such person under this paragraph, punishment is a fine of not more than $20,000 per day of violation, or by imprisonment of not more than 4 years, or both.

2. Inspection and Entry

The Permittee shall allow the Director, or an authorized representative (including an authorized contractor acting as a representative of the Administrator), upon presentation of credentials and other documents as may be required by law, to:

a. Enter upon the Permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

b. Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

c. Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and

d. Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Clean Water Act, any substances or parameters at any location.

D. REPORTING REQUIREMENTS

1. Reporting Requirements

a. *Planned Changes*. The Permittee shall give notice to the Director as soon as possible of any planned physical alterations or additions to the permitted facility. Notice is required only when:

(1) The alteration or addition to a permitted facility may meet one of the criteria for determining whether a facility is a new source in 40 C.F.R. § 122.29(b); or

(2) The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants which are subject neither to effluent limitations in the permit, nor to notification requirements at 40 C.F.R. § 122.42(a)(1).

(3) The alteration or addition results in a significant change in the Permittee's sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan.

b. *Anticipated noncompliance*. The Permittee shall give advance notice to the Director of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.

c. *Transfers.* This permit is not transferable to any person except after notice to the Director. The Director may require modification or revocation and reissuance of the permit to change the name of the Permittee and incorporate such other requirements as may be necessary under the Clean Water Act. *See* 40 C.F.R. § 122.61; in some cases, modification or revocation and reissuance is mandatory.

d. *Monitoring reports*. Monitoring results shall be reported at the intervals specified elsewhere in this permit.

(1) Monitoring results must be reported on a Discharge Monitoring Report (DMR) or forms provided or specified by the Director for reporting results of monitoring of sludge use or disposal practices. As of December 21, 2016 all reports and forms submitted in compliance with this Section must be submitted electronically by the Permittee to the Director or initial recipient, as defined in 40 C.F.R. § 127.2(b), in compliance with this Section and 40 C.F.R. Part 3 (including, in all cases, Subpart D to Part 3), § 122.22, and 40 C.F.R. Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, Permittees may be required to report electronically if specified by a particular permit or if required to do so by State law.

(2) If the Permittee monitors any pollutant more frequently than required by the permit using test procedures approved under 40 C.F.R. § 136, or another method required for an industry-specific waste stream under 40 C.F.R. Subchapters N or O, the results of such monitoring shall be included in the calculation and reporting of the data submitted in the DMR or sludge reporting form specified by the Director.

(3) Calculations for all limitations which require averaging or measurements shall utilize an arithmetic mean unless otherwise specified by the Director in the permit.

e. *Twenty-four hour reporting.*

(1) The Permittee shall report any noncompliance which may endanger health or the environment. Any information shall be provided orally within 24 hours from the time the Permittee becomes aware of the circumstances. A written report shall also be provided within 5 days of the time the Permittee becomes aware of the circumstances. The written report shall contain a description of the noncompliance and its cause; the period of noncompliance, including exact dates and times, and if the noncompliance has not been corrected, the anticipated time it is expected to continue; and steps taken or planned to reduce, eliminate, and prevent reoccurrence of the noncompliance. For noncompliance events related to combined sewer overflows, sanitary sewer overflows, or bypass events, these reports must include the data described above (with the exception of time of discovery) as well as the type of event (combined sewer overflows, sanitary sewer overflows, or bypass events), type of sewer overflow structure (e.g., manhole, combined sewer overflow outfall), discharge volumes untreated by the treatment works treating domestic sewage, types of human health and environmental impacts of the sewer overflow event, and whether the noncompliance was related to wet weather. As of December 21, 2020 all

reports related to combined sewer overflows, sanitary sewer overflows, or bypass events submitted in compliance with this section must be submitted electronically by the Permittee to the Director or initial recipient, as defined in 40 C.F.R. § 127.2(b), in compliance with this Section and 40 C.F.R. Part 3 (including, in all cases Subpart D to Part 3), § 122.22, and 40 C.F.R. Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, Permittees may be required to electronically submit reports related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section by a particular permit or if required to do so by state law. The Director may also require Permittees to electronically submit reports not related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section.

(2) The following shall be included as information which must be reported within 24 hours under this paragraph.

(a) Any unanticipated bypass which exceeds any effluent limitation in the permit. *See* 40 C.F.R. § 122.41(g).
(b) Any upset which exceeds any effluent limitation in the permit.
(c) Violation of a maximum daily discharge limitation for any of the pollutants listed by the Director in the permit to be reported within 24 hours. *See* 40 C.F.R. § 122.44(g).

(3) The Director may waive the written report on a case-by-case basis for reports under paragraph D.1.e. of this Section if the oral report has been received within 24 hours.

f. *Compliance Schedules.* Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 14 days following each schedule date.

g. *Other noncompliance.* The Permittee shall report all instances of noncompliance not reported under paragraphs D.1.d., D.1.e., and D.1.f. of this Section, at the time monitoring reports are submitted. The reports shall contain the information listed in paragraph D.1.e. of this Section. For noncompliance events related to combined sewer overflows, sanitary sewer overflows, or bypass events, these reports shall contain the information described in paragraph D.1.e. and the applicable required data in Appendix A to 40 C.F.R. Part 127. As of December 21, 2020 all reports related to combined sewer overflows, sanitary sewer overflows, or bypass events submitted in compliance with this section must be submitted electronically by the Permittee to the Director or initial recipient, as defined in 40 C.F.R. § 127.2(b), in compliance with this Section and 40 C.F.R. Part 3 (including, in all cases, Subpart D to Part 3), §122.22, and 40 C.F.R. Part 127. Part 127 is not intended to undo existing requirements for electronic reporting. Prior to this date, and independent of Part 127, Permittees may be required to electronically submit reports related to combined sewer overflows, sanitary sewer overflows, or bypass events under this section by a particular permit or if required to do so by state law. The Director may also require Permittees to electronically submit reports not related to combined sewer overflows, sanitary sewer overflows, or bypass events under this Section.

h. *Other information.* Where the Permittee becomes aware that it failed to submit any

relevant facts in a permit application, or submitted incorrect information in a permit application or in any report to the Director, it shall promptly submit such facts or information.

i. *Identification of the initial recipient for NPDES electronic reporting data*. The owner, operator, or the duly authorized representative of an NPDES-regulated entity is required to electronically submit the required NPDES information (as specified in Appendix A to 40 C.F.R. Part 127) to the appropriate initial recipient, as determined by EPA, and as defined in 40 C.F.R. § 127.2(b). EPA will identify and publish the list of initial recipients on its Web site and in the FEDERAL REGISTER, by state and by NPDES data group (see 40 C.F.R. § 127.2(c) of this Chapter). EPA will update and maintain this listing.

2. Signatory Requirement

a. All applications, reports, or information submitted to the Director shall be signed and certified. *See* 40 C.F.R. §122.22.

b. The CWA provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or non-compliance shall, upon conviction, be punished by a fine of not more than $10,000 per violation, or by imprisonment for not more than 6 months per violation, or by both.

3. Availability of Reports.

Except for data determined to be confidential under paragraph A.6. above, all reports prepared in accordance with the terms of this permit shall be available for public inspection at the offices of the State water pollution control agency and the Director. As required by the CWA, effluent data shall not be considered confidential. Knowingly making any false statements on any such report may result in the imposition of criminal penalties as provided for in Section 309 of the CWA.

E. DEFINITIONS AND ABBREVIATIONS

1. General Definitions

For more definitions related to sludge use and disposal requirements, see EPA Region 1's NPDES Permit Sludge Compliance Guidance document (4 November 1999, modified to add regulatory definitions, April 2018).

Administrator means the Administrator of the United States Environmental Protection Agency, or an authorized representative.

Applicable standards and limitations means all, State, interstate, and federal standards and limitations to which a "discharge," a "sewage sludge use or disposal practice," or a related activity is subject under the CWA, including "effluent limitations," water quality standards, standards of performance, toxic effluent standards or prohibitions, "best management practices," pretreatment standards, and "standards for sewage sludge use or disposal" under Sections 301, 302, 303, 304, 306, 307, 308, 403 and 405 of the CWA.

Application means the EPA standard national forms for applying for a permit, including any additions, revisions, or modifications to the forms; or forms approved by EPA for use in

"approved States," including any approved modifications or revisions.

Approved program or *approved State* means a State or interstate program which has been approved or authorized by EPA under Part 123.

Average monthly discharge limitation means the highest allowable average of "daily discharges" over a calendar month, calculated as the sum of all "daily discharges" measured during a calendar month divided by the number of "daily discharges" measured during that month.

Average weekly discharge limitation means the highest allowable average of "daily discharges" over a calendar week, calculated as the sum of all "daily discharges" measured during a calendar week divided by the number of "daily discharges" measured during that week.

Best Management Practices ("BMPs") means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of "waters of the United States." BMPs also include treatment requirements, operating procedures, and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw material storage.

Bypass see B.4.a.1 above.

C-NOEC or *"Chronic (Long-term Exposure Test) – No Observed Effect Concentration" means* the highest tested concentration of an effluent or a toxicant at which no adverse effects are observed on the aquatic test organisms at a specified time of observation.

Class I sludge management facility is any publicly owned treatment works (POTW), as defined in 40 C.F.R. § 501.2, required to have an approved pretreatment program under 40 C.F.R. § 403.8 (a) (including any POTW located in a State that has elected to assume local program responsibilities pursuant to 40 C.F.R. § 403.10 (e)) and any treatment works treating domestic sewage, as defined in 40 C.F.R. § 122.2, classified as a Class I sludge management facility by the EPA Regional Administrator, or, in the case of approved State programs, the Regional Administrator in conjunction with the State Director, because of the potential for its sewage sludge use or disposal practice to affect public health and the environment adversely.

Contiguous zone means the entire zone established by the United States under Article 24 of the Convention on the Territorial Sea and the Contiguous Zone.

Continuous discharge means a "discharge" which occurs without interruption throughout the operating hours of the facility, except for infrequent shutdowns for maintenance, process changes, or similar activities.

CWA means the Clean Water Act (formerly referred to as the Federal Water Pollution Control Act or Federal Water Pollution Control Act Amendments of 1972) Public Law 92-500, as amended by Public Law 95-217, Public Law 95-576, Public Law 96-483and Public Law 97-117, 33 U.S.C. 1251 *et seq*.

CWA and regulations means the Clean Water Act (CWA) and applicable regulations promulgated thereunder. In the case of an approved State program, it includes State program requirements.

Daily Discharge means the "discharge of a pollutant" measured during a calendar day or any

other 24-hour period that reasonably represents the calendar day for purposes of sampling. For pollutants with limitations expressed in units of mass, the "daily discharge" is calculated as the total mass of the pollutant discharged over the day. For pollutants with limitations expressed in other units of measurements, the "daily discharge" is calculated as the average measurement of the pollutant over the day.

Direct Discharge means the "discharge of a pollutant."

Director means the Regional Administrator or an authorized representative. In the case of a permit also issued under Massachusetts' authority, it also refers to the Director of the Division of Watershed Management, Department of Environmental Protection, Commonwealth of Massachusetts.

Discharge

(a) When used without qualification, *discharge* means the "discharge of a pollutant."

(b) As used in the definitions for "interference" and "pass through," *discharge* means the introduction of pollutants into a POTW from any non-domestic source regulated under Section 307(b), (c) or (d) of the Act.

Discharge Monitoring Report ("DMR") means the EPA uniform national form, including any subsequent additions, revisions, or modifications for the reporting of self-monitoring results by Permittees. DMRs must be used by "approved States" as well as by EPA. EPA will supply DMRs to any approved State upon request. The EPA national forms may be modified to substitute the State Agency name, address, logo, and other similar information, as appropriate, in place of EPA's.

Discharge of a pollutant means:

(a) Any addition of any "pollutant" or combination of pollutants to "waters of the United States" from any "point source," or

(b) Any addition of any pollutant or combination of pollutants to the waters of the "contiguous zone" or the ocean from any point source other than a vessel or other floating craft which is being used as a means of transportation.

This definition includes additions of pollutants into waters of the United States from: surface runoff which is collected or channeled by man; discharges through pipes, sewers, or other conveyances owned by a State, municipality, or other person which do not lead to a treatment works; and discharges through pipes, sewers, or other conveyances, leading into privately owned treatment works. This term does not include an addition of pollutants by any "indirect discharger."

Effluent limitation means any restriction imposed by the Director on quantities, discharge rates, and concentrations of "pollutants" which are "discharged" from "point sources" into "waters of the United States," the waters of the "contiguous zone," or the ocean.

Effluent limitation guidelines means a regulation published by the Administrator under section 304(b) of CWA to adopt or revise "effluent limitations."

Environmental Protection Agency ("EPA") means the United States Environmental Protection

Agency.

Grab Sample means an individual sample collected in a period of less than 15 minutes.

Hazardous substance means any substance designated under 40 C.F.R. Part 116 pursuant to Section 311 of CWA.

Incineration is the combustion of organic matter and inorganic matter in sewage sludge by high temperatures in an enclosed device.

Indirect discharger means a nondomestic discharger introducing "pollutants" to a "publicly owned treatment works."

Interference means a discharge (see definition above) which, alone or in conjunction with a discharge or discharges from other sources, both:

(a) Inhibits or disrupts the POTW, its treatment processes or operations, or its sludge processes, use or disposal; and

(b) Therefore is a cause of a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation) or of the prevention of sewage sludge use or disposal in compliance with the following statutory provisions and regulations or permits issued thereunder (or more stringent State or local regulations): Section 405 of the Clean Water Act, the Solid Waste Disposal Act (SWDA) (including title II, more commonly referred to as the Resources Conservation and Recovery Act (RCRA), and including State regulations contained in any State sludge management plan prepared pursuant to Subtitle D of the SDWA), the Clean Air Act, the Toxic Substances Control Act, and the Marine Protection, Research and Sanctuaries Act.

Landfill means an area of land or an excavation in which wastes are placed for permanent disposal, and that is not a land application unit, surface impoundment, injection well, or waste pile.

Land application is the spraying or spreading of sewage sludge onto the land surface; the injection of sewage sludge below the land surface; or the incorporation of sewage sludge into the soil so that the sewage sludge can either condition the soil or fertilize crops or vegetation grown in the soil.

Land application unit means an area where wastes are applied onto or incorporated into the soil surface (excluding manure spreading operations) for agricultural purposes or for treatment and disposal.

LC_{50} means the concentration of a sample that causes mortality of 50% of the test population at a specific time of observation. The LC_{50} = 100% is defined as a sample of undiluted effluent.

Maximum daily discharge limitation means the highest allowable "daily discharge."

Municipal solid waste landfill (MSWLF) unit means a discrete area of land or an excavation that receives household waste, and that is not a land application unit, surface impoundment, injection well, or waste pile, as those terms are defined under 40 C.F.R. § 257.2. A MSWLF unit also may receive other types of RCRA Subtitle D wastes, such as commercial solid waste, nonhazardous sludge, very small quantity generator waste and industrial solid waste. Such a landfill may be

publicly or privately owned. A MSWLF unit may be a new MSWLF unit, an existing MSWLF unit or a lateral expansion. A construction and demolition landfill that receives residential lead-based paint waste and does not receive any other household waste is not a MSWLF unit.

Municipality

(a) When used without qualification *municipality* means a city, town, borough, county, parish, district, association, or other public body created by or under State law and having jurisdiction over disposal of sewage, industrial wastes, or other wastes, or an Indian tribe or an authorized Indian tribal organization, or a designated and approved management agency under Section 208 of CWA.

(b) As related to sludge use and disposal, *municipality* means a city, town, borough, county, parish, district, association, or other public body (including an intermunicipal Agency of two or more of the foregoing entities) created by or under State law; an Indian tribe or an authorized Indian tribal organization having jurisdiction over sewage sludge management; or a designated and approved management Agency under Section 208 of the CWA, as amended. The definition includes a special district created under State law, such as a water district, sewer district, sanitary district, utility district, drainage district, or similar entity, or an integrated waste management facility as defined in Section 201 (e) of the CWA, as amended, that has as one of its principal responsibilities the treatment, transport, use or disposal of sewage sludge.

National Pollutant Discharge Elimination System means the national program for issuing, modifying, revoking and reissuing, terminating, monitoring and enforcing permits, and imposing and enforcing pretreatment requirements, under Sections 307, 402, 318, and 405 of the CWA. The term includes an "approved program."

New Discharger means any building, structure, facility, or installation:

(a) From which there is or may be a "discharge of pollutants;"

(b) That did not commence the "discharge of pollutants" at a particular "site" prior to August 13, 1979;

(c) Which is not a "new source;" and

(d) Which has never received a finally effective NPDES permit for discharges at that "site."

This definition includes an "indirect discharger" which commences discharging into "waters of the United States" after August 13, 1979. It also includes any existing mobile point source (other than an offshore or coastal oil and gas exploratory drilling rig or a coastal oil and gas exploratory drilling rig or a coastal oil and gas exploratory drilling rig or a coastal oil and gas developmental drilling rig) such as a seafood processing rig, seafood processing vessel, or aggregate plant, that begins discharging at a "site" for which it does not have a permit; and any offshore or coastal mobile oil and gas exploratory drilling rig or coastal mobile oil and gas developmental drilling rig that commences the discharge of pollutants after August 13, 1979, at a "site" under EPA's permitting jurisdiction for which it is not covered by an individual or general permit and which is located in an area determined by the Director in the issuance of a final permit to be in an area of biological concern. In determining whether an area is an area of biological concern, the Director shall consider the factors specified in 40 C.F.R. §§ 125.122 (a) (1) through (10).

An offshore or coastal mobile exploratory drilling rig or coastal mobile developmental drilling rig will be considered a "new discharger" only for the duration of its discharge in an area of biological concern.

New source means any building, structure, facility, or installation from which there is or may be a "discharge of pollutants," the construction of which commenced:

(a) After promulgation of standards of performance under Section 306 of CWA which are applicable to such source, or

(b) After proposal of standards of performance in accordance with Section 306 of CWA which are applicable to such source, but only if the standards are promulgated in accordance with Section 306 within 120 days of their proposal.

NPDES means "National Pollutant Discharge Elimination System."

Owner or operator means the owner or operator of any "facility or activity" subject to regulation under the NPDES programs.

Pass through means a Discharge (see definition above) which exits the POTW into waters of the United States in quantities or concentrations which, alone or in conjunction with a discharge or discharges from other sources, is a cause of a violation of any requirement of the POTW's NPDES permit (including an increase in the magnitude or duration of a violation).

Pathogenic organisms are disease-causing organisms. These include, but are not limited to, certain bacteria, protozoa, viruses, and viable helminth ova.

Permit means an authorization, license, or equivalent control document issued by EPA or an "approved State" to implement the requirements of Parts 122, 123, and 124. "Permit" includes an NPDES "general permit" (40 C.F.R § 122.28). "Permit" does not include any permit which has not yet been the subject of final agency action, such as a "draft permit" or "proposed permit."

Person means an individual, association, partnership, corporation, municipality, State or Federal agency, or an agent or employee thereof.

Person who prepares sewage sludge is either the person who generates sewage sludge during the treatment of domestic sewage in a treatment works or the person who derives a material from sewage sludge.

pH means the logarithm of the reciprocal of the hydrogen ion concentration measured at 25° Centigrade or measured at another temperature and then converted to an equivalent value at 25° Centigrade.

Point Source means any discernible, confined, and discrete conveyance, including but not limited to, any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, landfill leachate collection system, vessel or other floating craft from which pollutants are or may be discharged. This term does not include return flows from irrigated agriculture or agricultural storm water runoff (see 40 C.F.R. § 122.3).

Pollutant means dredged spoil, solid waste, incinerator residue, filter backwash, sewage, garbage, sewage sludge, munitions, chemical wastes, biological materials, radioactive materials

(except those regulated under the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 *et seq*.)), heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water. It does not mean:

(a) Sewage from vessels; or

(b) Water, gas, or other material which is injected into a well to facilitate production of oil or gas, or water derived in association with oil and gas production and disposed of in a well, if the well is used either to facilitate production or for disposal purposes is approved by the authority of the State in which the well is located, and if the State determines that the injection or disposal will not result in the degradation of ground or surface water resources.

Primary industry category means any industry category listed in the NRDC settlement agreement (*Natural Resources Defense Council et al. v. Train*, 8 E.R.C. 2120 (D.D.C. 1976), *modified* 12 E.R.C. 1833 (D.D.C. 1979)); also listed in Appendix A of 40 C.F.R. Part 122.

Privately owned treatment works means any device or system which is (a) used to treat wastes from any facility whose operator is not the operator of the treatment works and (b) not a "POTW."

Process wastewater means any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, byproduct, or waste product.

Publicly owned treatment works (POTW) means a treatment works as defined by Section 212 of the Act, which is owned by a State or municipality (as defined by Section 504(4) of the Act). This definition includes any devices and systems used in the storage, treatment, recycling and reclamation of municipal sewage or industrial wastes of a liquid nature. It also includes sewers, pipes and other conveyances only if they convey wastewater to a POTW Treatment Plant. The term also means the municipality as defined in Section 502(4) of the Act, which has jurisdiction over the indirect discharges to and the discharges from such a treatment works.

Regional Administrator means the Regional Administrator, EPA, Region I, Boston, Massachusetts.

Secondary industry category means any industry which is not a "primary industry category."

Septage means the liquid and solid material pumped from a septic tank, cesspool, or similar domestic sewage treatment system, or a holding tank when the system is cleaned or maintained.

Sewage Sludge means any solid, semi-solid, or liquid residue removed during the treatment of municipal waste water or domestic sewage. Sewage sludge includes, but is not limited to, solids removed during primary, secondary, or advanced waste water treatment, scum, septage, portable toilet pumpings, type III marine sanitation device pumpings (33 C.F.R. Part 159), and sewage sludge products. Sewage sludge does not include grit or screenings, or ash generated during the incineration of sewage sludge.

Sewage sludge incinerator is an enclosed device in which only sewage sludge and auxiliary fuel are fired.

Sewage sludge unit is land on which only sewage sludge is placed for final disposal. This does

not include land on which sewage sludge is either stored or treated. Land does not include waters of the United States, as defined in 40 C.F.R. § 122.2.

Sewage sludge use or disposal practice means the collection, storage, treatment, transportation, processing, monitoring, use, or disposal of sewage sludge.

Significant materials includes, but is not limited to: raw materials; fuels; materials such as solvents, detergents, and plastic pellets; finished materials such as metallic products; raw materials used in food processing or production; hazardous substance designated under Section 101(14) of CERCLA; any chemical the facility is required to report pursuant to Section 313 of title III of SARA; fertilizers; pesticides; and waste products such as ashes, slag and sludge that have the potential to be released with storm water discharges.

Significant spills includes, but is not limited to, releases of oil or hazardous substances in excess of reportable quantities under Section 311 of the CWA (see 40 C.F.R. §§ 110.10 and 117.21) or Section 102 of CERCLA (*see* 40 C.F.R. § 302.4).

Sludge-only facility means any "treatment works treating domestic sewage" whose methods of sewage sludge use or disposal are subject to regulations promulgated pursuant to section 405(d) of the CWA, and is required to obtain a permit under 40 C.F.R. § 122.1(b)(2).

State means any of the 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, the Trust Territory of the Pacific Islands, or an Indian Tribe as defined in the regulations which meets the requirements of 40 C.F.R. § 123.31.

Store or storage of sewage sludge is the placement of sewage sludge on land on which the sewage sludge remains for two years or less. This does not include the placement of sewage sludge on land for treatment.

Storm water means storm water runoff, snow melt runoff, and surface runoff and drainage.

Storm water discharge associated with industrial activity means the discharge from any conveyance that is used for collecting and conveying storm water and that is directly related to manufacturing, processing, or raw materials storage areas at an industrial plant.

Surface disposal site is an area of land that contains one or more active sewage sludge units.

Toxic pollutant means any pollutant listed as toxic under Section 307(a)(1) or, in the case of "sludge use or disposal practices," any pollutant identified in regulations implementing Section 405(d) of the CWA.

Treatment works treating domestic sewage means a POTW or any other sewage sludge or waste water treatment devices or systems, regardless of ownership (including federal facilities), used in the storage, treatment, recycling, and reclamation of municipal or domestic sewage, including land dedicated for the disposal of sewage sludge. This definition does not include septic tanks or similar devices.

For purposes of this definition, "domestic sewage" includes waste and waste water from humans or household operations that are discharged to or otherwise enter a treatment works. In States where there is no approved State sludge management program under Section 405(f) of the CWA, the Director may designate any person subject to the standards for sewage sludge use and

disposal in 40 C.F.R. Part 503 as a "treatment works treating domestic sewage," where he or she finds that there is a potential for adverse effects on public health and the environment from poor sludge quality or poor sludge handling, use or disposal practices, or where he or she finds that such designation is necessary to ensure that such person is in compliance with 40 C.F.R. Part 503.

Upset see B.5.a. above.

Vector attraction is the characteristic of sewage sludge that attracts rodents, flies, mosquitoes, or other organisms capable of transporting infectious agents.

Waste pile or *pile* means any non-containerized accumulation of solid, non-flowing waste that is used for treatment or storage.

Waters of the United States or waters of the U.S. means:

(a) All waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide;

(b) All interstate waters, including interstate "wetlands;"

(c) All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sandflats, "wetlands", sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds the use, degradation, or destruction of which would affect or could affect interstate or foreign commerce including any such waters:

    (1) Which are or could be used by interstate or foreign travelers for recreational or other purpose;

    (2) From which fish or shellfish are or could be taken and sold in interstate or foreign commerce; or

    (3) Which are used or could be used for industrial purposes by industries in interstate commerce;

(d) All impoundments of waters otherwise defined as waters of the United States under this definition;

(e) Tributaries of waters identified in paragraphs (a) through (d) of this definition;

(f) The territorial sea; and

(g) "Wetlands" adjacent to waters (other than waters that are themselves wetlands) identified in paragraphs (a) through (f) of this definition.

Waste treatment systems, including treatment ponds or lagoons designed to meet the requirements of CWA (other than cooling ponds as defined in 40 C.F.R. § 423.11(m) which also meet the criteria of this definition) are not waters of the United States. This exclusion applies only to manmade bodies of water which neither were originally created in waters of the United States (such as disposal area in wetlands) nor resulted from the impoundment of waters of the United States. Waters of the United States do not include prior converted cropland.

Notwithstanding the determination of an area's status as prior converted cropland by any other federal agency, for the purposes of the Clean Water Act, the final authority regarding Clean Water Act jurisdiction remains with EPA.

Wetlands means those areas that are inundated or saturated by surface or groundwater at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in saturated soil conditions. Wetlands generally include swamps, marshes, bogs, and similar areas.

Whole Effluent Toxicity (WET) means the aggregate toxic effect of an effluent measured directly by a toxicity test.

*Zone of Initial Dilution (*ZID) means the region of initial mixing surrounding or adjacent to the end of the outfall pipe or diffuser ports, provided that the ZID may not be larger than allowed by mixing zone restrictions in applicable water quality standards.

2. Commonly Used Abbreviations

BOD	Five-day biochemical oxygen demand unless otherwise specified
CBOD	Carbonaceous BOD
CFS	Cubic feet per second
COD	Chemical oxygen demand
Chlorine	
Cl_2	Total residual chlorine
TRC	Total residual chlorine which is a combination of free available chlorine (FAC, see below) and combined chlorine (chloramines, etc.)
TRO	Total residual chlorine in marine waters where halogen compounds are present
FAC	Free available chlorine (aqueous molecular chlorine, hypochlorous acid, and hypochlorite ion)
Coliform	
Coliform, Fecal	Total fecal coliform bacteria
Coliform, Total	Total coliform bacteria
Cont.	Continuous recording of the parameter being monitored, i.e. flow, temperature, pH, etc.
Cu. M/day or M^3/day	Cubic meters per day
DO	Dissolved oxygen

kg/day	Kilograms per day
lbs/day	Pounds per day
mg/L	Milligram(s) per liter
mL/L	Milliliters per liter
MGD	Million gallons per day
Nitrogen	
Total N	Total nitrogen
NH_3-N	Ammonia nitrogen as nitrogen
NO_3-N	Nitrate as nitrogen
NO_2-N	Nitrite as nitrogen
NO_3-NO_2	Combined nitrate and nitrite nitrogen as nitrogen
TKN	Total Kjeldahl nitrogen as nitrogen
Oil & Grease	Freon extractable material
PCB	Polychlorinated biphenyl
Surfactant	Surface-active agent
Temp. °C	Temperature in degrees Centigrade
Temp. °F	Temperature in degrees Fahrenheit
TOC	Total organic carbon
Total P	Total phosphorus
TSS or NFR	Total suspended solids or total nonfilterable residue
Turb. or Turbidity	Turbidity measured by the Nephelometric Method (NTU)
µg/L	Microgram(s) per liter
WET	"Whole effluent toxicity"
ZID	Zone of Initial Dilution

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NEW ENGLAND - REGION 1
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: MA0040291

PUBLIC NOTICE START AND END DATES: July 1, 2020 – July 30, 2020

NAME AND MAILING ADDRESS OF APPLICANT:

Genzyme Corporation
500 Soldiers Field Road
Allston, MA 02134

NAME AND ADDRESS OF FACILITY WHERE DISCHARGE OCCURS:

Genzyme Corporation
500 Soldiers Field Road
Allston, MA 02134

RECEIVING WATER AND CLASSIFICATION:

Charles River (MA72-36)
Charles River Watershed
Class B

SIC CODE: 2834 (Pharmaceutical Preparation)

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1.0 Proposed Action

Genzyme Corporation (the "Permittee") has applied to the U.S. Environmental Protection Agency (EPA) for reissuance of a National Pollutant Discharge Elimination System (NPDES) permit to discharge reverse osmosis (RO) reject water from the Genzyme Corporation (the "Facility") into the Charles River.

The permit currently in effect was issued on March 31st, 2015 with an effective date of March 31st, 2015 and expired on February 29th, 2020 (the "2015 Permit"). The Permittee filed an application for permit reissuance with EPA dated September 23, 2019, as required by 40 Code of Federal Regulations (CFR) § 122.6. Since the permit application was deemed timely and complete by EPA on September 24, 2019, the Facility's 2015 Permit has been administratively continued pursuant to 40 CFR § 122.6 and § 122.21(d). EPA and the State conducted a site visit on February 26th, 2020.

2.0 Statutory and Regulatory Authority

Congress enacted the Federal Water Pollution Control Act, codified at 33 U.S.C. § 1251 – 1387 and commonly known as the Clean Water Act (CWA), "to restore and maintain the chemical, physical, and biological integrity of the Nation's waters." CWA § 101(a). To achieve this objective, the CWA makes it unlawful for any person to discharge any pollutant into the waters of the United States from any point source, except as authorized by specific permitting sections of the CWA, one of which is § 402. *See* CWA §§ 301(a), 402(a). Section 402(a) established one of the CWA's principal permitting programs, the NPDES Permit Program. Under this section, EPA may "issue a permit for the discharge of any pollutant or combination of pollutants" in accordance with certain conditions. CWA § 402(a). NPDES permits generally contain discharge limitations and establish related monitoring and reporting requirements. *See* CWA § 402(a)(1) and (2). The regulations governing EPA's NPDES permit program are generally found in 40 CFR §§ 122, 124, 125, and 136.

"Congress has vested in the Administrator [of EPA] broad discretion to establish conditions for NPDES permits" in order to achieve the statutory mandates of Section 301 and 402. See *Arkansas v. Oklahoma,* 503 U.S. 91, 105 (1992). *See also* 40 CFR §§ 122.4(d), 122.44(d)(1), 122.44(d)(5). CWA §§ 301 and 306 provide for two types of effluent limitations to be included in NPDES permits: "technology-based" effluent limitations (TBELs) and "water quality-based" effluent limitations (WQBELs). *See* CWA §§ 301, and 304(b); 40 CFR §§ 122, 125, and 131.

2.1 Technology-Based Requirements

Technology-based treatment requirements represent the minimum level of control that must be imposed under CWA §§ 301(b) and 402 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. *See* 40 CFR § 125 Subpart A.

Subpart A of 40 CFR Part 125 establishes criteria and standards for the imposition of technology-based treatment requirements in permits under § 301(b) of the CWA, including the application of EPA promulgated Effluent Limitation Guidelines (ELGs) and case-by-case determinations of effluent limitations under CWA § 402(a)(1). EPA promulgates New Source Performance Standards (NSPS) under CWA § 306 and 40 CFR § 401.12. *See also* 40 CFR §§ 122.2 (definition of "new source") and 122.29.

In general, ELGs for non-POTW facilities 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 cannot be authorized by a NPDES permit. In the absence of published technology-based effluent guidelines, the permit writer is authorized under CWA § 402(a)(1)(B) to establish effluent limitations on a case-by-case basis using best professional judgment (BPJ).

2.2 Water Quality-Based Requirements

The CWA and federal regulations require that effluent limitations based on water quality considerations be established for point source discharges when such limitations are necessary to meet state or federal water quality standards that are applicable to the designated receiving water. This is necessary when less stringent TBELs would interfere with the attainment or maintenance of water quality criteria in the receiving water. *See* CWA § 301(b)(1)(C) and 40 CFR §§ 122.44(d)(1),122.44(d)(5), 125.84(e) and 125.94(i).

2.2.1 Water Quality Standards

The CWA requires that each state develop water quality standards (WQSs) for all water bodies within the State. *See* CWA § 303 and 40 CFR §§ 131.10-12. Generally, WQSs consist of three parts: 1) beneficial designated use or uses for a water body or a segment of a water body; 2) numeric or narrative water quality criteria sufficient to protect the assigned designated use(s); and 3) antidegradation requirements to ensure that once a use is attained it will not be degraded and to protect high quality and National resource waters. *See* CWA § 303(c)(2)(A) and 40 CFR § 131.12. The applicable State WQSs can be found in Title 314 of the Code of Massachusetts Regulations, Chapter 4 (314 CMR 4.00).

As a matter of state law, state WQSs specify different water body classifications, each of which is associated with certain designated uses and numeric and narrative water quality criteria. When using chemical-specific numeric criteria to develop permit limitations, acute and chronic aquatic life criteria and human health criteria are used and expressed in terms of maximum allowable in-stream pollutant concentrations. In general, aquatic-life acute criteria are considered applicable to daily time periods (maximum daily limit) and aquatic-life chronic criteria are considered applicable to monthly time periods (average monthly limit). Chemical-specific human health criteria are typically based on lifetime chronic exposure and, therefore, are typically applicable to monthly average limits.

When permit effluent limitation(s) are necessary to ensure that the receiving water meets narrative water quality criteria, the permitting authority must establish effluent limits in one of the following three ways: 1) based on a "calculated numeric criterion for the pollutant which the permitting authority demonstrates will attain and maintain applicable narrative water quality criteria and fully protect the designated use," 2) based on a "case-by-case basis" using CWA § 304(a) recommended water quality criteria, supplemented as necessary by other relevant information; or, 3) in certain circumstances, based on use of an indicator parameter. *See* 40 CFR § 122.44(d)(1)(vi)(A-C).

2.2.2 Antidegradation

Federal regulations found at 40 CFR § 131.12 require states to develop and adopt a statewide antidegradation policy that maintains and protects existing in-stream water uses and the level of water quality necessary to protect these existing uses. In addition, the antidegradation policy ensures maintenance of high-quality waters which exceed levels necessary to support propagation of fish, shellfish, and wildlife and to support recreation in and on the water, unless the State finds that allowing degradation is necessary to accommodate important economic or social development in the area in which the waters are located.

Massachusetts' statewide antidegradation policy, entitled "Antidegradation Provisions," is found in the State's WQSs at 314 CMR 4.04. Massachusetts guidance for the implementation of this policy is in an associated document entitled "Implementation Procedure for the Anti-Degradation Provisions of the State Water Quality Standards," dated October 21, 2009. According to the policy, no lowering of water quality is allowed, except in accordance with the antidegradation policy, and all existing in-stream uses, and the level of water quality necessary to protect the existing uses, of a receiving water body must be maintained and protected.

This permit is being reissued with effluent limitations sufficiently stringent to satisfy the State's antidegradation requirements, including the protection of the exiting uses of the receiving water.

2.2.3 Assessment and Listing of Waters and Total Maximum Daily Loads

The objective of the CWA is to restore and maintain the chemical, physical and biological integrity of the Nation's waters. To meet this goal, the CWA requires states to develop information on the quality of their water resources and report this information to EPA, the U.S. Congress, and the public. To this end, EPA released guidance on November 19, 2001, for the preparation of an integrated "List of Waters" that could combine reporting elements of both § 305(b) and § 303(d) of the CWA. The integrated list format allows states to provide the status of all their assessed waters in one list. States choosing this option must list each water body or segment in one of the following five categories: 1) unimpaired and not threatened for all designated uses; 2) unimpaired waters for some uses and not assessed for others; 3) insufficient information to make assessments for any uses; 4) impaired or threatened for one or more uses but not requiring the calculation of a Total Maximum Daily Load (TMDL); and 5) impaired or threatened for one or more uses and requiring a TMDL.

A TMDL is a planning tool and potential starting point for restoration activities with the ultimate

goal of attaining water quality standards. A TMDL essentially provides a pollution budget designed to restore the health of an impaired water body. A TMDL typically identifies the source(s) of the pollutant from point sources and non-point sources, determines the maximum load of the pollutant that the water body can tolerate while still attaining WQSs for the designated uses, and allocates that load among the various sources, including point source discharges, subject to NPDES permits. *See* 40 CFR § 130.7.

For impaired waters where a TMDL has been developed for a particular pollutant and the TMDL includes a waste load allocation (WLA) for a NPDES permitted discharge, the effluent limitation in the permit must be "consistent with the assumptions and requirements of any available WLA". 40 CFR § 122.44(d)(1)(vii)(B).

2.2.4 Reasonable Potential

Pursuant to CWA § 301(b)(1)(C) and 40 CFR § 122.44(d)(1), NPDES permits must contain any requirements in addition to TBELs that are necessary to achieve water quality standards established under § 303 of the CWA. *See also* 33 U.S.C. § 1311(b)(1)(C). In addition, limitations "must control any pollutant or pollutant parameter (conventional, non-conventional, or toxic) which the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any water quality standard, including State narrative criteria for water quality." 40 CFR § 122.44(d)(1)(i). To determine if the discharge causes, or has the reasonable potential to cause, or contribute to an excursion above any WQS, EPA considers: 1) existing controls on point and non-point sources of pollution; 2) the variability of the pollutant or pollutant parameter in the effluent; 3) the sensitivity of the species to toxicity testing (when evaluating whole effluent toxicity); and 4) where appropriate, the dilution of the effluent by the receiving water. *See* 40 CFR § 122.44(d)(1)(ii).

If the permitting authority determines that the discharge of a pollutant will cause, has the reasonable potential to cause, or contribute to an excursion above WQSs, the permit must contain WQBELs for that pollutant. *See* 40 CFR § 122.44(d)(1)(i).

2.2.5 State Certification

EPA may not issue a permit unless the State Water Pollution Control Agency with jurisdiction over the receiving water(s) either 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 the State WQSs, the State waives, or is deemed to have waived, its right to certify. *See* 33 U.S.C. § 1341(a)(1). Regulations governing state certification are set forth in 40 CFR § 124.53 and § 124.55. EPA has requested permit certification by the State pursuant to 40 CFR § 124.53 and expects that the Draft Permit will be certified.

If the State believes that conditions more stringent than those contained in the Draft Permit are necessary to meet the requirements of either CWA §§ 208(e), 301, 302, 303, 306 and 307, or applicable requirements of State law, the State should include such conditions in its certification and, in each case, cite the CWA or State law provisions upon which that condition is based.

Failure to provide such a citation waives the right to certify as to that condition. EPA includes properly supported State certification conditions in the NPDES permit. The only exception to this is that the permit conditions/requirements regulating sewage sludge management and implementing CWA § 405(d) are not subject to the State certification requirements. Reviews and appeals of limitations and conditions attributable to State certification shall be made through the applicable procedures of the State and may not be made through the EPA permit appeal procedures of 40 CFR Part 124.

In addition, the State should provide a statement of the extent to which any condition of the Draft Permit can be made less stringent without violating the requirements of State law. Since the State's certification is provided prior to final permit issuance, any failure by the State to provide this statement waives the State's right to certify or object to any less stringent condition.

It should be noted that under CWA § 401, EPA's duty to defer to considerations of state law is intended to prevent EPA from relaxing any requirements, limitations or conditions imposed by state law. Therefore, "[a] State may not condition or deny a certification on the grounds that State law allows a less stringent permit condition." 40 CFR § 124.55(c). In such an instance, the regulation provides that, "The Regional Administrator shall disregard any such certification conditions or denials as waivers of certification." *Id.* EPA regulations pertaining to permit limitations based upon WQSs and State requirements are contained in 40 CFR §§ 122.4(d) and 122.44(d).

2.3 Effluent Flow Requirements

Generally, EPA uses effluent flow both to determine whether an NPDES permit needs certain effluent limitations and to calculate the effluent limitations themselves. EPA practice is to use effluent flow as a reasonable and important worst-case condition in EPA's reasonable potential and WQBEL calculations to ensure compliance with WQSs under CWA § 301(b)(1)(C). Should the effluent flow exceed the flow assumed in these calculations, the in-stream dilution would be reduced, and the calculated effluent limitations might not be sufficiently protective (i.e., might not meet WQSs). Further, pollutants that do not have the reasonable potential to exceed WQSs at a lower discharge flow may have reasonable potential at a higher flow due to the decreased dilution. In order to ensure that the assumptions underlying EPA's reasonable potential analyses and permit effluent limitation derivations remain sound for the duration of the permit, EPA may ensure the validity of its "worst-case" effluent flow assumptions through imposition of permit conditions for effluent flow.[1] In this regard, the effluent flow limitation is a component of WQBELs because the WQBELs are premised on a maximum level flow. The effluent flow limit is also necessary to ensure that other pollutants remain at levels that do not have a reasonable potential to exceed WQSs.

[1] EPA's regulations regarding "reasonable potential" require EPA to consider "where appropriate, the dilution of the effluent in the receiving water," *id.* 40 CFR §122.44(d)(1)(ii). *Both* the effluent flow and receiving water flow may be considered when assessing reasonable potential. *In re Upper Blackstone Water Pollution Abatement Dist.*, 14 E.A.D. 577, 599 (EAB 2010). EPA guidance directs that this "reasonable potential" analysis be based on "worst-case" conditions. *See In re Washington Aqueduct Water Supply Sys., 11 E.A.D. 565, 584 (EAB 2004)*.

The limitation on effluent flow is within EPA's authority to condition a permit to carry out the objectives and satisfy the requirements of the CWA. *See* CWA §§ 402(a)(2) and 301(b)(1)(C); 40 CFR §§ 122.4(a) and (d); 122.43 and 122.44(d). A condition on the discharge designed to ensure the validity of EPA's WQBELs and reasonable potential calculations that account for "worst case" conditions is encompassed by the references to "condition" and "limitations" in CWA §§402 and 301 and the implementing regulations, as WQBELs are designed to assure compliance with applicable water quality regulations, including antidegradation requirements. Regulating the quantity of pollutants in the discharge through a restriction on the quantity of effluent is also consistent with the CWA.

In addition, as provided in Part II.B.1 of this permit and 40 CFR § 122.41(e), the Permittee is required to properly operate and maintain all facilities and systems of treatment and control. Improper operation and maintenance may result in non-compliance with permit effluent limitations. Consequently, the effluent flow limit is a permit condition that relates to the Permittee's duty to mitigate (*i.e.*, minimize or prevent any discharge in violation of the permit that has a reasonable likelihood of adversely affecting human health or the environment) and to properly operate and maintain the treatment works. *See* 40 CFR §§ 122.41(d), (e).

2.4 Monitoring and Reporting Requirements

2.4.1 Monitoring Requirements

Sections 308(a) and 402(a)(2) of the CWA and the implementing regulations at 40 CFR Parts 122, 124, 125, and 136 authorize EPA to include monitoring and reporting requirements in NPDES permits.

The monitoring requirements included in this permit have been establish1ed to yield data representative of the Facility's discharges in accordance with CWA §§ 308(a) and 402(a)(2), and consistent with 40 CFR §§ 122.41(j), 122.43(a), 122.44(i) and 122.48. The Draft Permit specifies routine sampling and analysis requirements to provide ongoing, representative information on the levels of regulated constituents in the discharges. The monitoring program is needed to enable EPA and the State to assess the characteristics of the Facility's effluent, whether Facility discharges are complying with permit limits, and whether different permit conditions may be necessary in the future to ensure compliance with technology-based and water quality-based standards under the CWA. EPA and/or the State may use the results of the chemical analyses conducted pursuant to this permit, as well as national water quality criteria developed pursuant to CWA § 304(a)(1), 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.

NPDES permits require that the approved analytical procedures found in 40 CFR Part 136 be used for sampling and analysis unless other procedures are explicitly specified. Permits also include requirements necessary to comply with the *National Pollutant Discharge Elimination*

System (NPDES): Use of Sufficiently Sensitive Test Methods for Permit Applications and Reporting Rule.[2] This Rule requires that where EPA-approved methods exist, NPDES applicants must use sufficiently sensitive EPA-approved analytical methods when quantifying the presence of pollutants in a discharge. Further, the permitting authority must prescribe that only sufficiently sensitive EPA-approved methods be used for analyses of pollutants or pollutant parameters under the permit. The NPDES regulations at 40 CFR § 122.21(e)(3) (completeness), 40 CFR § 122.44(i)(1)(iv) (monitoring requirements) and/or as cross referenced at 40 CFR § 136.1(c) (applicability) indicate that an EPA-approved method is sufficiently sensitive where:

- The method minimum level[3] (ML) is at or below the level of the effluent limitation established in the permit for the measured pollutant or pollutant parameter; or
- In the case of permit applications, the ML is above the applicable water quality criterion, but the amount of the pollutant or pollutant parameter in a facility's discharge is high enough that the method detects and quantifies the level of the pollutant or parameter in the discharge; or
- The method has the lowest ML of the analytical methods approved under 40 CFR Part 136 or required under 40 CFR chapter I, subchapter N or O for the measured pollutant or pollutant parameter.

2.4.2 Reporting Requirements

The Draft Permit requires the Permittee to report monitoring results obtained during each calendar month to EPA and the State electronically using NetDMR. The Permittee must submit a Discharge Monitoring Report (DMR) for each calendar month no later than the 15th day of the month following the completed reporting period.

NetDMR is a national web-based tool enabling regulated CWA permittees to submit DMRs electronically via a secure internet application to EPA through the Environmental Information Exchange Network. NetDMR has eliminated the need for participants to mail in paper forms to EPA under 40 CFR §§ 122.41 and 403.12. NetDMR is accessible through EPA's Central Data Exchange at https://cdx.epa.gov/. Further information about NetDMR can be found on the EPA NetDMR support portal webpage.[4]

With the use of NetDMR, the Permittee is no longer required to submit hard copies of DMRs and reports to EPA and the State unless otherwise specified in the Draft Permit. In most cases, reports required under the permit shall be submitted to EPA as an electronic attachment through

[2] Fed. Reg. 49,001 (Aug. 19, 2014).
[3] The term "minimum level" refers to either the sample concentration equivalent to the lowest calibration point in a method or a multiple of the method detection limit (MDL), whichever is higher. Minimum levels may be obtained in several ways: They may be published in a method; they may be based on the lowest acceptable calibration point used by a laboratory; or they may be calculated by multiplying the MDL in a method, or the MDL determined by a laboratory, by a factor. EPA is considering the following terms related to analytical method sensitivity to be synonymous: "quantitation limit," "reporting limit," "level of quantitation," and "minimum level." *See* Fed. Reg. 49,001 (Aug. 19, 2014).
[4] https://netdmr.zendesk.com/hc/en-us

NetDMR. Certain exceptions are provided in the permit such as for providing written notifications required under the Part II Standard Conditions.

2.5 Standard Conditions

The standard conditions, included as Part II of the Draft Permit, are based on applicable regulations found in the Code of Federal Regulations. *See generally* 40 CFR Part 122.

2.6 Anti-backsliding

The CWA's anti-backsliding requirements prohibit a permit from being renewed, reissued or modified to include less stringent limitations or conditions than those contained in a previous permit except in compliance with one of the specified exceptions to those requirements. *See* CWA §§ 402(o) and 303(d)(4) and 40 CFR § 122.44(l). Anti-backsliding provisions apply to effluent limits based on technology, water quality, and/or State certification requirements.

All proposed limitations in the Draft Permit are at least as stringent as limitations included in the 2015 Permit unless specific conditions exist to justify relaxation in accordance with CWA § 402(o) or § 303(d)(4). Discussion of any less stringent limitations and corresponding exceptions to anti-backsliding provisions is provided in the sections that follow.

3.0 Description of Facility and Discharge

3.1 Location and Type of Facility

The Facility is located along the western bank of the Charles River on Soldiers Field Road in Allston, Massachusetts. A location map is provided in Figure 1. The Facility is engaged in pharmaceutical production, primarily of Cerezyme®, an enzyme replacement therapy for patients with Gaucher disease. This permit authorizes the discharge of reverse osmosis (RO) reject water to the Charles River through a municipal storm drain. RO reject water is generated from the purification of incoming Massachusetts Water Resources Authority (MWRA) water for the Facility's pharmaceutical manufacturing process. A site plan is provided in Figure 2.

3.1.1 Effluent Limitation Guidelines

EPA has not promulgated technology-based effluent limitation guidelines (ELGs) for Pharmaceutical Production (SIC 2834) in 40 CFR Subchapter N Parts 405 through 471. Therefore, in accordance with CWA § 402(a)(1)(B) and 40 CFR § 125.3(c)(2), EPA may establish effluent limitations on a case-by-case basis using BPJ. The NPDES regulations in 40 CFR §125.3(c)(2) state that permits developed on a case-by-case basis under Section 402 (a)(1) of the CWA shall apply the appropriate factors listed in 40 CFR § 125.3(d) and must consider 1) the appropriate technology for the category class of point sources of which the applicant is a member, based on available information, and 2) any unique factors relating to the applicant.

3.2 Location and Type of Discharge

RO reject water is discharged to a storm drain underlying the Facility's southernmost building. The effluent is routed under the Facility and connects to the Boston Water & Sewer Commission (BWSC) storm drain system at the Massachusetts Turnpike ramp where it is directed under Cambridge Street to the BWSC storm water outfall (#SDO034) and finally to the Charles River. A site location map is provided in Figure 2.

To achieve the required level of water purity for its pharmaceutical production, the Facility employs three simultaneously operating RO units (termed "C", "D", and "E") to treat the incoming, MWRA-supplied, municipal drinking water. Before passing through the RO units, MWRA water undergoes a series of pretreatment processes that are nearly identical between the three RO treatment trains. First, the influent goes through a multimedia filtration system, trapping sediment and particulate matter. Then, the process water passes through a water softening system, removing salts that contribute to water hardness. Subsequently, the process water passes through a carbon filter and ultraviolet disinfection to remove chlorine and pathogens, respectively, from the municipal water supply. The only difference between the three systems is that treatment train E does not have an ultraviolet disinfection stage. This pretreated water is then delivered to its respective RO unit, where reject water is generated while permeate travels on for storage or use. The pretreatment system is backwashed periodically. This backwash water is sent to the MWRA sanitary sewer system and is not authorized to be discharged under this permit.

The RO units produce purified water used in production processes as well as RO reject water. This reject water contains the same chemical constituents found in the incoming municipal drinking water supply, except at higher concentrations. The RO units are taken off-line and cleaned as necessary for both routine and preventative maintenance. The RO unit filters are sent off-site for cleaning and replacement. Prior to reinstallation the RO units are triple rinsed with purified water which is discharged to the MWRA sewer. The discharge of wastewaters to the Charles River from the cleaning or backwashing of the RO units or any of their components is not authorized by the Draft Permit.

Flow is measured onsite prior to discharge to the storm sewer system and, subsequently, the Charles River. The flow meter is read daily, and records are kept on-site. Grab samples are taken on a monthly basis from a sample port on the discharge line prior to discharge to Outfall 001. If necessary, the Permittee has the capability to inject carbon dioxide for pH adjustment, prior to discharge through Outfall 001.

A quantitative description of the discharge in terms of effluent parameters, based on monitoring data submitted by the Permittee, including Discharge Monitoring Reports (DMRs), from December 2014 through March 2020 is provided in Appendix A of this Fact Sheet.

4.0 Description of Receiving Water and Dilution

4.1 Receiving Water

The Facility discharges through Outfall 001 to the Charles River (Segment ID MA72-36) in Allston, Massachusetts. The Charles River is part of the Charles River Watershed. This segment

of the Charles River is 6.1 miles long, originates at the Watertown Dam and continues to the Boston University Bridge, connecting the towns of Allston and Cambridge.

The Charles River is classified as a Class B, warm water fishery in the Massachusetts WQSs, 314 Code of Massachusetts Regulations (CMR) 4.00. Class B waters are described in the Commonwealth of Massachusetts Water Quality Standards (314 CMR 4.05(3)(b)) as follows: *"designated as a habitat for fish, other aquatic life, and wildlife, including for their reproduction, migration, growth and other critical functions, and for primary and secondary contact recreation. Where designated in 314 CMR 4.06, they shall be suitable as a source of public water supply with appropriate treatment (Treated Water Supply). Class B waters shall be suitable for irrigation and other agricultural uses and for compatible industrial cooling and process uses. These waters shall have consistently good aesthetic value."*

The Charles River is listed in the *Massachusetts Year 2016 Integrated List of Waters* ("303(d) List") as a Category 5 "Waters Requiring a TMDL.[5] The causes of impairment listed are fish passage barrier, flow regime modification, non-native aquatic plants, chlorophyll-a, DDT in fish tissue, dissolved oxygen, *E. coli*, fish bioassessments, harmful algal blooms, eutrophication biological indicators, oil and grease, PCBs, pH, phosphorus, sediment bioassay, transparency, and unspecified metals in sediments. Similarly, according to the *Charles River 2002-2006 Quality Assessment Report*,[6] this water body segment is impaired in designated uses for fish consumption, aquatic life, aesthetics, and primary and secondary contact recreation. The status of each designated use is presented in Table 1.

Table 1: Summary of Designated Uses and Listing Status

Designated Use	Status
Aquatic Life	Impaired
Aesthetics	Impaired
Primary Contact Recreation	Impaired
Secondary Contact Recreation	Impaired
Fish Consumption	Impaired

MassDEP is required under the CWA to develop a TMDL for waterbodies that are identified as impaired. A TMDL is essentially a pollution budget designed to restore the health of a waterbody. A TMDL first identifies the source(s) of the pollutant from direct and indirect discharges in order to then determine the maximum amount of pollutant (including a margin of safety) that can be discharged to a specific waterbody while maintaining water quality standards for designated uses. It then outlines a plan to meet the goal. In 2007, the MassDEP finalized the Lower Charles River Basin TMDL for Phosphorus and the Charles River Watershed Pathogen TMDL. The sources of phosphorus and pathogens are mainly from stormwater, combined sewer overflows (CSO), illicit sanitary sewage discharges, and discharges from upstream Publicly

[5] *Massachusetts Year 2016 Integrated List of Waters*. MassDEP Division of Watershed Management Watershed Planning Program, Worcester, Massachusetts;.
[6] Water Quality Assessment Report. MassDEP Division of Watershed Management, Worcester, Massachusetts; April, 2008, Report Number: 72-AC-4.

Owned Treatment Works (POTWs). This discharge is not expected to be a source of fecal coliform and total phosphorus. Therefore, no specific requirements have been included in this permit for these parameters to meet the TMDL requirements.

4.2 Available Dilution

To ensure that discharges do not cause or contribute to violations of WQSs under all expected conditions, WQBELs are derived assuming critical conditions for the receiving water.[7] The critical flow in rivers and streams is some measure of the low flow of that river or stream. Massachusetts WQSs require that in waters where flows are regulated by dams or similar structures, the lowest flow condition is the flow equaled or exceeded 99% of the time on a yearly basis, or another equivalent flow agreed upon by the State. Massachusetts has determined that the lowest flow in this case is the 7Q10 (the lowest 7-day average flow that occurs, on average, once every 10 years). *See* 314 CMR 4.03(3)(b).

Prior to permit reissuance, MassDEP calculated the 7Q10 for the Charles River using the SWToolbox software package[8]. SWToolbox allows users to compute n-day frequency analyses using the United States Geological Survey's (USGS) National Water Information System (NWIS) streamflow database[9]. MassDEP calculated the 7Q10 from a 30-year period of record (1989-2019) for the closest USGS gauging station to the Facility along the Charles River, Station No. 01104500 at Waltham. The low flow value for that gauging station is then adjusted to calculate the Facility's 7Q10 by multiplying by the ratio of the drainage area from the USGS gauging station to the drainage area of the Facility's outfall. The dilution factor (DF) was calculated using the permitted daily maximum flow (Q_d) and the critical flow in the receiving water upstream of the discharge (Q_s,) as follows:

$$DF = (Q_s + Q_d)/Q_d$$

Where:

Q_s = 7Q10 in million gallons per day (MGD)
Q_d = Discharge flow in MGD

Therefore:

DF maximum flow = (10.78 + 0.12)/0.12 = 91

From these calculations, the Facility's effluent dilution into the Charles River is 91:1.

5.0 Proposed Effluent Limitations and Conditions

[7] EPA Permit Writer's Manual, Section 6.2.4
[8] https://www.usgs.gov/software/swtoolbox-software-information
[9] https://waterdata.usgs.gov/nwis

The proposed effluent limitations and conditions derived under the CWA and State WQSs are described below. These proposed effluent limitations and conditions, the basis of which is discussed throughout this Fact Sheet, may be found in Part I of the Draft Permit.

In accordance with 40 CFR § 122.45(b)(2), EPA bases the calculation of effluent limitations upon a reasonable measure of actual production of the Facility or on flow from the Facility. EPA determined that the measure appropriate for this Facility is the maximum daily effluent flow limit, 0.12 MGD, from the 2015 Permit. The maximum daily effluent flow reflects the magnitude, frequency and duration of RO discharge during the maximum facility production. Maximum daily effluent flow is also the effluent flow value used to calculate the dilution factor for the discharge. EPA derived this measure of production from daily maximum flow values reported by the Permittee from December 2014 through March 2020 as well as the Permittee's previous maximum facility production estimates (Appendix A).

5.1 Effluent Limitations and Monitoring Requirements

The State and Federal regulations and data regarding discharge characteristics were used during the effluent limitations' development process. Discharge data is included in Appendix A and results are discussed in the applicable sections below.

5.1.1 Effluent Flow

From December 2014 through March 2020, the average monthly effluent flow ranged from 0.01 MGD to 0.07 MGD. The Facility's 2015 Permit limits the discharge to a monthly average flow rate of 0.066 MGD and a daily maximum flow of 0.12 MGD. The Facility exceeded the monthly average limit one time in March 2016. Under normal operating conditions, and as indicated by monitoring data and information provided by the Permittee, the maximum flow is typically no greater than approximately 0.09 MGD. Therefore, the Draft Permit maintains a maximum daily flow limit of 0.12 MGD and an average monthly flow limit of 0.066 MGD, as well as continuous monitoring for flow using a totalizer or similar device, when the Facility is discharging.

5.1.2 pH

The hydrogen-ion concentration in an aqueous solution is represented by the pH using a logarithmic scale of 0 to 14 standard units (S.U.). Solutions with pH 7.0 S.U. are neutral, while those with pH less than 7.0 S.U. are acidic and those with pH greater than 7.0 S.U. are basic. Discharges with pH values markedly different from the receiving water pH can have a detrimental effect on the environment. Sudden pH changes can kill aquatic life. pH can also have an indirect effect on the toxicity of other pollutants in the water.

The pH limitations stated by the Massachusetts WQS for Inland Water, Class B at 314 CMR 4.05(3)(b)3, require that the pH of the receiving water be in the range of 6.5 to 8.3 S.U. and not more than 0.5 units outside of the natural background range. The Permittee demonstrated previously that its MWRA source water is often above the effluent limit of 8.3 S.U. and was given modified pH limitations of 6.5-9.0 S.U. in earlier permits including the 2015 Permit.

During the reporting period for Outfall 001, the effluent pH was in the range of 6.5 to 9.2 S.U. with one violation of the pH limit.

Due to the significant amount of dilution available to the effluent discharge and the previous pH demonstration, EPA and MassDEP expect that the state WQS will likely be met; therefore, the Draft Permit maintains the limit of 6.5 – 9.0 S.U. from the previous permit term. However, to confirm that the available dilution is sufficient to prevent exceedance of the Massachusetts WQS, the Draft Permit includes an option to conduct a study to demonstrate that the instream pH is meeting MA WQS. The results of the study will be used to determine the pH limit in future permits. If the permittee chooses not to conduct the study, the pH limit in future permits will be aligned with the MA WQS, i.e., 6.5-8.3 S.U.

5.1.3 Solids

Solids could include inorganic (e.g., silt, sand, clay, and insoluble hydrated metal oxides) and organic matter (e.g., flocculated colloids and compounds that contribute to color). Solids can clog fish gills, resulting in an increase in susceptibility to infection or asphyxiation. Suspended solids can increase turbidity in receiving waters and reduce light penetration through the water column or settle to form bottom deposits in the receiving water. Suspended solids also provide a medium for the transport of other adsorbed pollutants, such as metals, which may accumulate in settled deposits that can have a long-term impact on the water column through cycles of re-suspension.

Due to the membrane size and treatment requirements of a typical RO treatment system, suspended solids rarely make it to the RO unit itself. Pre-treatment processes remove these solids to prevent fouling of the membrane units. In contrast, a RO membrane's effectiveness at removing dissolved solids results in RO reject waters with high total dissolved solids concentrations. At the Facility, a multimedia filter is used to remove solids prior to passing through the RO units; these filters have a range of ratings, anywhere from 0.3 to 80 microns. The discharge created from backwashing these filters is not authorized by the Draft Permit.

From November 30, 2014 through February 29, 2020, daily maximum total suspended solids (TSS) concentrations have not exceeded the minimum level (this level has not been reported by the Permittee). The Draft Permit contains requirements to report average and maximum daily values when the Facility is discharging, monitored quarterly by grab samples. These monitoring requirements have been continued from the Facility's 2015 Permit to ensure the proper operation of the filtration system and prevent the discharge of suspended solids.

5.1.4 Total Residual Chlorine

Chlorine and chlorine compounds are toxic to aquatic life. Free chlorine is directly toxic to aquatic organisms and can react with naturally occurring organic compounds in receiving waters to form toxic compounds such as trihalomethanes. Potable water sources are typically chlorinated to minimize or eliminate pathogens. 40 CFR § 141.72 stipulates that a public water system's residual disinfectant concentration in the water entering the distribution system cannot be less than 0.2 mg/L for more than four hours. From December 2014 through March 2020, daily

maximum Total Residual Chlorine (TRC) concentrations have ranged from below minimum levels to 0.44 mg/L. During this period, there were six TRC detections of: 0.11, 0.11, 0.12, 0.15, 0.16, and 0.44 mg/L. Based on these detections, EPA investigated the potential for the effluent to cause a violation of the state WQSs.

The following calculations shows what the water quality based TRC limits would be based on actual dilution of effluent from the Facility:

Water Quality Criteria[10]: Freshwater – Chronic: 0.011 mg/l; Acute: 0.019 mg/l

Dilution Adjusted Effluent Limitations[11]:

Monthly Average: 91(0.011 mg/l) = 1.00 mg/l

Daily Maximum: 91(0.019 mg/l) = 1.73 mg/l

The maximum observed TRC concentration of 0.440 mg/L is significantly below the dilution-adjusted water quality criteria. In addition, most monitoring data has resulted in no detections of TRC. Therefore, the Draft Permit does not contain an effluent limitation for TRC and due to consistent monitoring results below minimum levels, the monitoring requirement established in the 2015 Permit has been removed.

5.1.5 Total Ammonia Nitrogen

Ammonia (NH_3) is the unionized form of ammonia nitrogen. Elevated levels of ammonia can be toxic to aquatic life. Temperature and pH affect the toxicity of ammonia to aquatic life. The toxicity of ammonia increases as temperature increases and ammonia concentration and toxicity increase as pH increases. Ammonia can affect fish growth, gill condition, organ weights, and hematocrit levels, and can result in excessive plant and algal growth, which can cause eutrophication. Ammonia can also affect dissolved oxygen through nitrification, in which oxygen is consumed as ammonia is oxidized. Low oxygen levels can then, in turn, increase ammonia by inhibiting nitrification. Total ammonia-nitrogen concentrations in surface waters tends to be lower during summer than during winter due to uptake by plants and decreased ammonia solubility at higher temperatures.

Ammonia can be introduced to the RO treatment system either from the source water or from the cleaning of the RO membranes themselves. In both cases, the source water or membranes, are treated with aqueous ammonia and sodium hypochlorite to produce chloramines that act as disinfectants. In previous permits, the potential introduction of ammonia into the RO reject water treatment system led to the inclusion of Total Ammonia Nitrogen monitoring requirements to understand the extent of its presence in the effluent discharge. Currently, the Facility's RO units

[10] Quality Criteria for Water (Gold Book), May 1, 1986, EPA 440/5-86-001.
[11] Dilution factor (DF) multiplied by water quality criteria (WQC), (DF x WQC)

are taken off site for cleaning; therefore, the only potential source of ammonia in the Facility's effluent would be from the source water.

From December 2014 through March 2020, daily maximum ammonia concentrations have ranged from below minimum levels to 1.5 mg/l (Appendix A). Although this segment of the Charles River is impaired for nutrients, phosphorus is the limiting nutrient controlling aquatic plant growth and is typically the cause of eutrophication-related impairments. Generally, ammonia is not a source of impairment in the Charles River[12]. The significant dilution the Facility's effluent receives when mixed with the Charles River (91:1) relative to the maximum observed ammonia concentration (1.5 mg/l) indicates that the Facility's discharge is unlikely to cause an excursion above water quality criterion, as indicated by the following demonstration.

The water quality criteria for ammonia in freshwater are influenced by pH and temperature. Receiving water pH and temperature measurements have not been required at the Facility, therefore critical conditions for these parameters have been chosen to derive worst-case water quality criteria.

Water Quality Criteria[13]: Freshwater at pH of 8.3 and temperature of 30ºC

Chronic: 0.6 mg/l
Acute: 3.1 mg/l

Dilution Adjusted Water Quality Criteria[14]

Chronic: 91(0.6 mg/l) = 55 mg/l
Acute: 91(3.1 mg/l) = 280 mg/l

The maximum observed ammonia concentration of 1.5 mg/l is significantly below the dilution-adjusted water quality criteria. Therefore, the low ammonia concentrations present in the effluent discharge do not present a reasonable potential to contribute to nutrient impairments in the Charles River. Due to the demonstration above, no ammonia limit has been added in the Draft Permit. Given the historical low ammonia concentrations in the effluent, the reasonable potential analysis results and the fact that the Facility does not add ammonia to its discharge (cleaning waste is not authorized to be discharged), the Draft Permit has removed ammonia nitrogen monitoring requirements.

5.1.6 Total Copper

Copper is a naturally occurring constituent in the environment and generally varies in concentration according to local geology. Copper is neither created nor destroyed by biological

[12] See MassDEP's *Charles River Watershed 2002-2006 Water Quality Assessment Report* referenced above (p. 113-114) for a discussion of water quality data for this segment of the Charles River.
[13] U.S. EPA. 2013. Aquatic Life Ambient Water Quality Criteria for Ammonia - Freshwater (2013). https://www.epa.gov/sites/production/files/2015-08/documents/fact_sheet_aquatic-life-ambient-water-quality-criteria-for-ammonia-freshwater-2013.pdf
[14] DF multiplied by WQC (DF x WQC)

or chemical processes. However, it can be transformed through processes including adsorption, precipitation, co-precipitation, and complexation. Copper is an essential nutrient at low levels for humans, animals, plants and microorganisms, but toxic at higher levels. Toxicity results when copper is biologically available at toxic concentrations affecting the survival, reproduction and behavior of an organism.

The Permittee has obtained quarterly monitoring data for total recoverable copper in the discharge. For Outfall 001, from November 30, 2014 through February 29, 2020, total recoverable copper concentrations ranged from below the minimum levels to 0.705 mg/l. EPA completed an analysis to determine if these discharges cause, or have a reasonable potential to cause, or contribute to an excursion above state WQS. State WQSs contain minimum criteria applicable to all surface waters for toxic pollutants, which requires the use of EPA's *National Recommended Water Quality Criteria: 2002, EPA 822-R-02-047, November 2002* where a specific pollutant is not otherwise listed in 314 CMR 4.00. *See* 314 CMR 4.05(5)(e).

Copper is a hardness dependent metal, where metal toxicity is a function of water hardness. Hardness is defined as the amount of dissolved calcium and magnesium in a water body and levels vary across the United States.[15] An upstream facility (NPDES Permit No. MAG910748) application with measured hardness values for the Charles River, directly upstream of the Facility's Outfall 001, was used to determine hardness values for reasonable potential calculation of total recoverable copper. A receiving water hardness of 56.9 mg/L was reported in this data and used to calculate the reasonable potential of the effluent copper discharge.

The acute and chronic EPA *National Recommended Water Quality Criteria* for copper are as follows:

Copper:
Freshwater chronic (Class A or B) = 0.0058 mg/l
Freshwater acute (Class A or B) = 0.0082 mg/l

Dilution Adjusted Effluent Limitations[16]:

Monthly Average:	91 (0.0058 mg/l) = 0.528 mg/l
Daily Maximum:	91 (0.0082 mg/l) = 0.746 mg/l

The maximum observed total recoverable copper concentration of 0.705 mg/l is below the dilution-adjusted water quality criteria.[17] Therefore, the low copper concentrations present in the effluent discharge do not present a reasonable potential to contribute to copper impairments in the Charles River. Due to the demonstration above, the Draft Permit does not contain an effluent

[15] USGS. Hardness of Water. https://www.usgs.gov/special-topic/water-science-school/science/hardness-water?qt-science_center_objects=0#qt-science_center_objects
[16] Dilution factor (DF) multiplied by water quality criteria (WQC), (DF x WQC)
[17] Clarification of concentrations shown in effluent discharge DMR reports for quarterly copper monitoring were provided by the facility in a June 2, 2020 email exchange between Genzyme and EPA. The copper concentrations presented in Appendix A reflect the most accurate effluent discharge monitoring values.

limitation for total recoverable copper. The original monitoring requirement was put in place so that results could be used to make this determination, therefore, given this determination, the monitoring requirement established in the 2015 Permit has been eliminated.

5.1.7 Dissolved Oxygen

Dissolved oxygen (DO) is a measure of how much oxygen is available in a water body for biological use and is needed by aquatic organisms for survival. Rapidly moving water bodies tend to have higher concentrations of DO, but eutrophic conditions can occur when the DO level drops, and the water body becomes oxygen deficient making it unable to support more aquatic life.

The 2015 Permit included a WQBEL for DO of 6.0 mg/l based on State WQS for Class B cold waters. However, this was an incorrect application of the water quality standards – found at 314 CMR 4.05(3)(b)1. The correct WQBEL would be a minimum DO concentration of 5 mg/l since the Charles River is considered a Class B warm water. From December 2014 through March 2020 (Appendix A), DO concentrations have ranged from 5 to 17 mg/l. The dissolved oxygen levels are typical of those present in this segment of the Charles River (Segment ID MA72-36).[18] The Draft Permit has corrected the WQBEL, reducing the limit from 6.0 mg/l to 5.0 mg/l to comply with Class B Massachusetts WQS 314 CMR 4.05(3)(b)1. This change is being allowed according to the anti-backsliding regulations at 40 CFR § 122.44(l)(2)(i)(B)(2) where "The Administrator determines that technical mistakes or mistaken interpretations of law were made in issuing the permit under section 402(a)(1)(b)."

5.1.8 Whole Effluent Toxicity

CWA §§ 402(a)(2) and 308(a) provide EPA and States with the authority to require toxicity testing. Section 308 specifically describes biological monitoring methods as techniques that may be used to carry out objectives of the CWA. Whole effluent toxicity (WET) testing is conducted to ensure that the additivity, antagonism, synergism, and persistence of the pollutants in the discharge do not cause toxicity, even when the individual pollutants are present at low concentrations in the effluent.

In addition, under CWA § 301(b)(1)(C), discharges are subject to effluent limitations based on WQSs. Under CWA §§ 301, 303 and 402, EPA and the States may establish toxicity-based limitations to implement narrative water quality criteria calling for "no toxics in toxic amounts." *See also* 40 CFR § 122.44(d)(1). The Massachusetts WQSs at 314 CMR 4.05(5)(e) state, "All surface waters shall be free from pollutants in concentrations or combinations that are toxic to humans, aquatic life or wildlife." In addition, the Massachusetts WQSs at 314 CMR 4.03(2)(a) require no lethality to organisms passing through a mixing zone.

[18] Live Water Quality Data for the Lower Charles River, U.S. EPA. Oct 30, 2019. https://www.epa.gov/charlesriver/live-water-quality-data-lower-charles-river

In the Draft Permit, EPA has determined that there is not a reasonable potential for this discharge to exhibit a toxic response in the receiving water. This discharge is not believed to contain toxic substances in toxic amounts and is considered a low risk for toxicity potential. The Permittee uses MWRA drinking water for its process and treats this water for solids and chlorine prior to sending it through RO units for additional purification. Although the RO reject water that is discharged concentrates the level of pollutants in the source water, the characteristics of this drinking water, the treatment it undergoes prior to the RO filtration system, and the historical DMR effluent data for the Facility does not provide evidence that the effluent has a reasonable potential to exhibit toxicity.

5.1.9 Other Parameters Considered

Both arsenic and chloroform were reported in the Facility's 2019 application above the method detection limit. Arsenic had a concentration of 1.33 µg/L and chloroform had a concentration of 6.7 µg/L. Both arsenic and chloroform are considered toxic pollutants according to the State WQSs 314 CMR 3.17. State WQS recommend the use of EPA's *National Recommended Water Quality Criteria: 2002, EPA 822-R-02-047, November 2002* to develop minimum criteria where numeric criteria for a specific pollutant is not otherwise listed in 314 CMR 4.00. Freshwater aquatic life criteria for arsenic and human health criteria for consumption of water and organisms for chloroform are shown below:

Arsenic:	Freshwater – Chronic: 150 µg/L; Acute: 340 µg/L
Chloroform:	Consumption of Water and Organisms: 60 µg/L

For both parameters, without dilution, the applicable criteria are greater than the observed effluent concentrations. Therefore, these constituents do not have reasonable potential to cause an excursion above any water quality standards and no reporting requirements have been added to the Draft Permit.

6.0 Federal Permitting Requirements

6.1 Endangered Species Act

Section 7(a) of the Endangered Species Act of 1973, as amended (ESA), grants authority to and imposes requirements on Federal agencies regarding endangered or threatened species of fish, wildlife, or plants (listed species) and any habitat of such species that has been designated as critical under the ESA (i.e., "critical habitat").

Section 7(a)(2) of the ESA requires every Federal agency, in consultation with and with the assistance of the Secretary of Interior, to ensure 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) administers Section 7 consultations for freshwater species. The National Oceanic and Atmospheric Administration Fisheries (NOAA Fisheries) administers Section 7 consultations for marine and anadromous species.

The Federal action being considered in this case is EPA's proposed NPDES permit for the Facility's discharges of pollutants. The Draft Permit is intended to replace the 2015 Permit in governing the Facility. As the federal agency charged with authorizing the discharge from this Facility, EPA determines potential impacts to federally listed species, and initiates consultation with the Services, when required under § 7(a)(2) of the ESA.

EPA has reviewed the federal endangered or threatened species of fish, wildlife, and plants in the action area to determine if EPA's proposed NPDES permit could potentially impact any such listed species. No federally listed threatened or endangered species have been identified for the action area.[19] However, one listed endangered species, the northern long-eared bat (*Myotis septentrionalis*), was identified as "statewide". According to the USFWS, the northern long-eared bat is found in "winter – mines and caves, summer – wide variety of forested habitats." This species is not aquatic. Therefore, the proposed permit action will have no direct or indirect effect on this listed species.

The two endangered species of anadromous fish which occur in Massachusetts, shortnose sturgeon (*Acipenser brevirostrom*) and Atlantic sturgeon (*Acipenser oxyrinchus*), have not been identified in Charles River. Moreover, based on the expected normal distribution of these species, it is highly unlikely that they would be present in the vicinity of this discharge and the action area of the outfall. In addition, Atlantic sturgeon are not thought to use the Charles River to spawn. However, the Charles River drains to Boston Harbor which does hold several endangered aquatic species. The discharge dilution was determined to be large enough to discount the minimal discharge and have no effect on nearby endangered species.

EPA has structured the proposed limitations to be sufficiently stringent to assure that State WQSs will be met, including for protection of aquatic life. The effluent limitations established in this permit ensure the protection of aquatic life and maintenance of the receiving water as an aquatic habitat.

Therefore, EPA finds that adoption of the proposed permit will have no effect on any federally listed threatened or endangered species or its critical habitat, and consultation with NOAA Fisheries or USFWS under Section 7 of the ESA is not required.

6.2 Essential Fish Habitat

Under the 1996 Amendments (PL 104-267) to the Magnuson-Stevens Fishery Conservation and Management Act (*see* 16 U.S.C. § 1801 *et seq*., 1998), EPA is required to consult with the NOAA Fisheries if EPA's action or proposed actions that it funds, permits, or undertakes, "may adversely impact any essential fish habitat". 16 U.S.C. § 1855(b).

The Amendments broadly define "essential fish habitat" (EFH) as: "waters and substrate necessary to fish for spawning, breeding, feeding, or growth to maturity". 16 U.S.C. § 1802(10).

[19] See [for USFWS at https://ecos.fws.gov/ipac/] and/or [for NMFS at https://www.greateratlantic.fisheries.noaa.gov/protected/section7/index.html]

"Adverse impact" means any impact that reduces the quality and/or quantity of EFH. 50 CFR § 600.910(a). Adverse effects may include direct (e.g., contamination or physical disruption), indirect (e.g., loss of prey, reduction in species' fecundity), or site specific or habitat-wide impacts, including individual, cumulative, or synergistic consequences of actions.

EFH is only designated for fish species for which federal Fisheries Management Plans exist.[16] *See* 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.

Proposed Action and Resources: As described in Section 1.0 of this Fact Sheet, Genzyme has applied for re-issuance of the NPDES Permit for the Genzyme Manufacturing Facility. With limitations, the permit allows Genzyme to discharge RO reject water from the pharmaceutical manufacturing facility to the Charles River. EPA intends to reissue the facility's NPDES permit for the discharges described above. Thus, Genzyme will continue to discharge RO reject water from the pharmaceutical manufacturing operations to the Charles River through Outfall 001. The outfall, treatment system, and potential sources of pollution associated with the facility operations are described previously in this Fact Sheet.

EPA has determined that Charles River is covered by the EFH designation for riverine systems at Latitude 42° 21' 39" Longitude 71° 07' 02" as determined by the NOAA EFH Mapper.[20] EPA's review of available EFH information indicated that this water body and its associated discharging body of Massachusetts Bay is designated EFH.

A review of the relevant essential fish habitat information provided by NOAA Fisheries indicates that the outfall exists within designated EFH for 4 federally managed species. The EFH species and life stages are listed in Appendix B.

EPA's Opinion of all Potential Impacts and Proposed Mitigation: With the adoption of the mitigating measures contained in the Draft Permit, EPA concludes that the discharges from the permitted outfall at the Genzyme Facility will not have significant adverse effects on EFH. This conclusion is based on the following factors:

- This Draft Permit action does not constitute a new source of pollutants because it is the reissuance of an existing NPDES permit;
- The Facility withdraws no water from the Charles River, so no life stages of EFH species are subject to impingement or entrainment;
- The effluent discharged consists of *treated* city water, minimizing the likelihood of any toxic pollutants in the discharge;
- A maximum daily flow limit of 0.12 MGD will be implemented year-round in order to ensure predicted mixing with the receiving water;

[20] NOAA EFH Mapper available at http://www.habitat.noaa.gov/protection/efh/efhmapper/

- Discharge limits have been maintained for flow, pH, and dissolved oxygen in order to meet federal effluent limitations guidelines and state water quality standards;
- The Draft Permit prohibits the discharge of pollutants or combination of pollutants in toxic amounts;
- The effluent limitations and conditions in the Draft Permit were developed to be protective of all aquatic life; and
- The Draft Permit prohibits violations of the state water quality standards.

Based on the available information, EPA has determined that Genzyme'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. Any RO unit cleaning wastewaters and filtering equipment backwashes are prohibited from being discharged by this permit to the Charles River. During the public comment period, EPA has provided a copy of the Draft Permit and Fact Sheet to NMFS for consultation with NMFS under Section 305(b)(2) of the Magnuson-Stevens Act for EFH.

7.0 Public Comments, Hearing Requests, and Permit Appeals

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:

Samantha Tracy
EPA Region 1
5 Post Office Square, Suite 100 (06-1)
Boston, MA 02109-3912
Telephone: (617) 918-1621
Email: tracy.samantha@epa.gov

Prior to the close of the public comment period, any person may submit a written request to EPA for a public hearing to consider the Draft Permit. Such requests shall state the nature of the issues proposed to be raised in the hearing. A public hearing may be held if the criteria stated in 40 CFR § 124.12 are satisfied. In reaching a final decision on the Draft Permit, EPA will respond to all significant comments in a Response to Comments document attached to the Final Permit and make these responses available to the public at EPA's Boston office and on EPA's website.

Following the close of the comment period, and after any public hearings, if such hearings are held, the EPA will issue a Final Permit decision, forward a copy of the final decision to the applicant, and provide a copy or notice of availability of the final decision to each person who submitted written comments or requested notice. Within 30 days after EPA serves notice of the issuance of the Final Permit decision, an appeal of the federal NPDES permit may be commenced by filing a petition for review of the permit with the Clerk of EPA's Environmental Appeals Board in accordance with the procedures at 40 CFR § 124.19.

8.0 Administrative Record

The administrative record on which this Draft Permit is based may be accessed on EPA's website or at EPA's Boston office by appointment ., Monday through Friday, excluding holidays, from Samantha Tracy, EPA Region 1, Water Division**,** Industrial Permits Section, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109-3912 or via email to tracy.samantha@epa.gov

June 30, 2020
Date

Ken Moraff, Director
Water Division
U.S. Environmental Protection Agency

Figures

Figure 1: Location Map

Figure 2: Site Plan

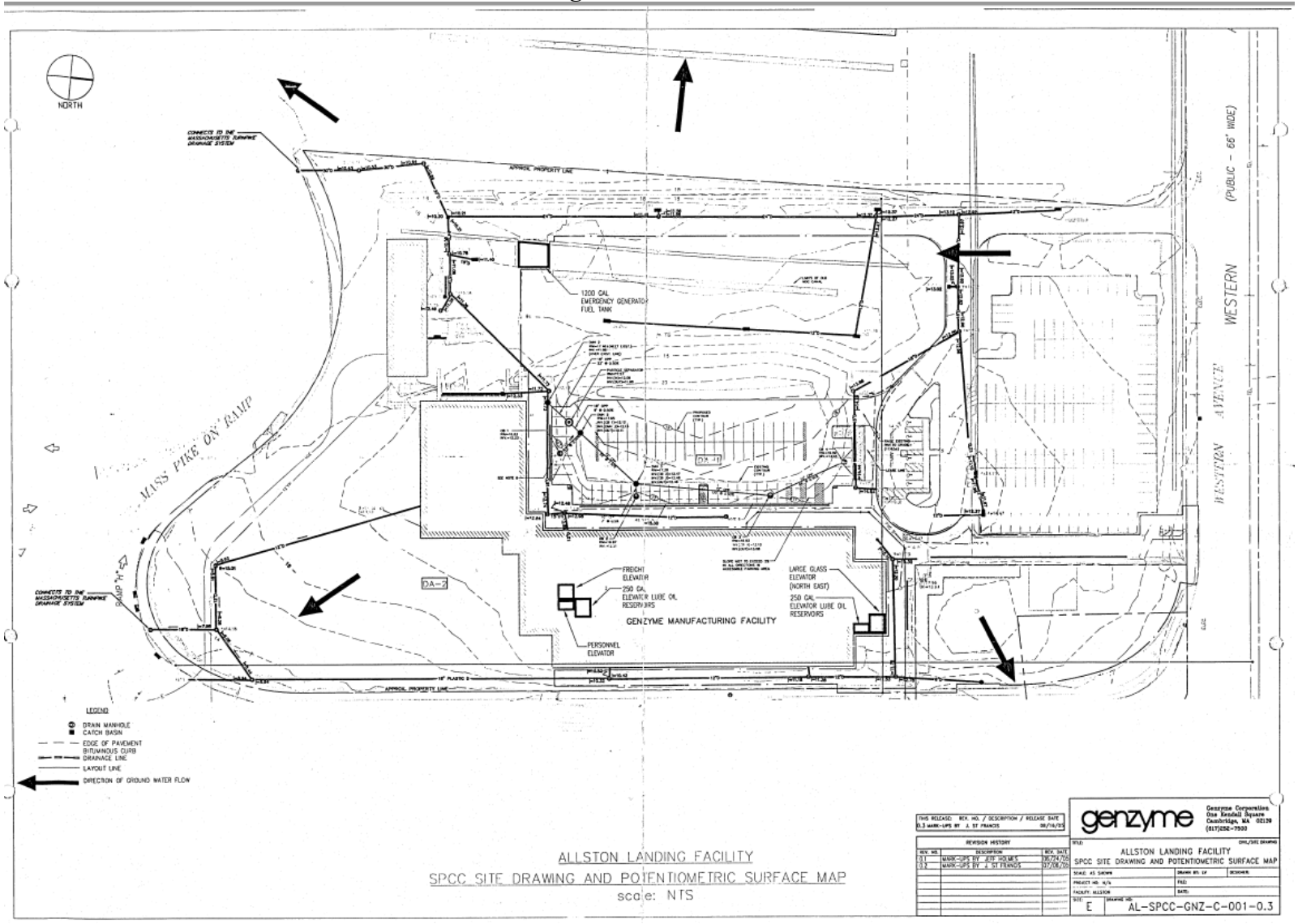
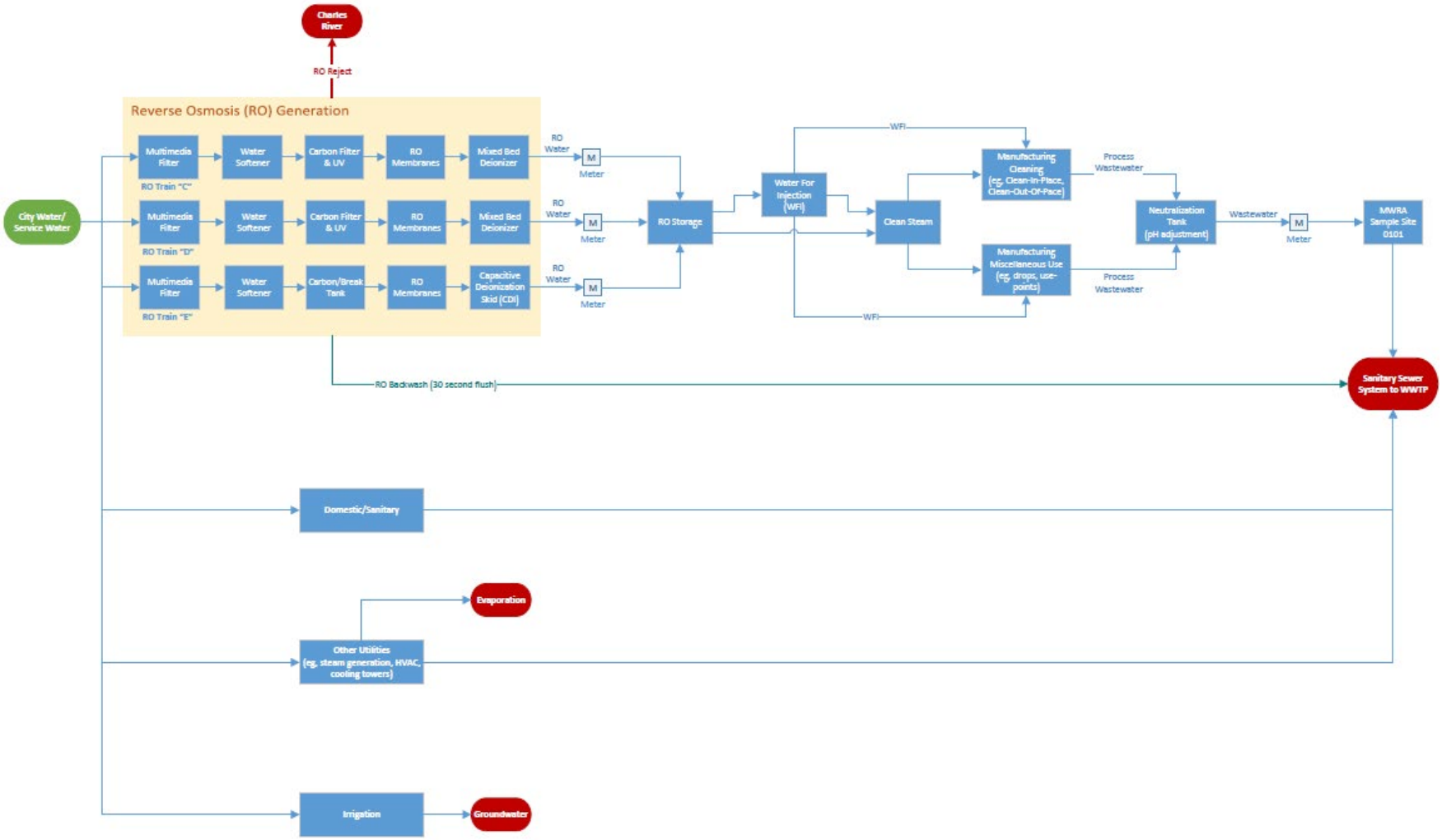


Figure 3: Schematic of Water Flow



Appendices

Appendix A: Discharge Monitoring Data

Genzyme Facility
Outfall 001 -Monthly Effluent Monitoring

Parameter	Flow	Flow	pH	pH	TRC	TRC	DO	Ammonia	Ammonia
	Monthly Avg	Daily Max	Minimum	Maximum	Monthly Avg	Daily Max	Minimum	Monthly Avg	Daily Max
Units	**gal/d**	**gal/d**	**SU**	**SU**	**ug/L**	**ug/L**	**mg/L**	**ug/L**	**ug/L**
Effluent Limit	**66000**	**120000**	**6.5**	**9**	**Report**	**Report**	**6**	**Report**	**Report**
Minimum	**10325.7**	**19973**	**6.5**	**6.74**	**0**	**0**	**5**	**0**	**0**
Maximum	**74801**	**112657.1**	**7.76**	**9.2**	**440**	**440**	**17**	**1480**	**1480**
Median	**35691**	**60705**	**7.1**	**7.9**	**0**	**0**	**12**	**756.5**	**756.5**
No. of Violations	**1**	**0**	**0**	**1**	**N/A**	**N/A**	**1**	**N/A**	**N/A**
Monitoring Period End Date									
12/31/2014	32605	63136	7.1	7.4	0	0	13	798	798
1/31/2015	52875	85053	6.6	7	120	120	10	1000	1000
2/28/2015	35417	61190	6.5	8.8	0	0	12	502	502
3/31/2015	56589	91337	6.6	7.7	150	150	12	841	841
4/30/2015	60470	87896	6.6	8.9	0	0	10	988	988
5/31/2015	61434	89841.4	6.7	7.7	0	0	14	969	969
6/30/2015	55979.5	112657.1	6.5	7.1	0	0	13	876	876
7/31/2015	38720.3	97770.8	6.8	**9.2**	0	0	13	745	745
8/31/2015	51741	72860	6.6	6.9	0	0	11	823	823
9/30/2015	57326	81687	6.6	7	0	0	12	815	815
10/31/2015	51305	79518	6.8	8.8	0	0	12	1040	1040
11/30/2015	47399.3	78396.2	7	7.9	0	0	12	1100	1100
12/31/2015	48170	60593	6.7	7.8	0	0	13	1460	1460
1/31/2016	59445	75180	7	7.5	0	0	16	907	907

2/29/2016	64353	87822	6.5	7.1	0	0	16	934	934
3/31/2016	**74801**	103531	6.6	7.6	440	440	17	1480	1480
4/30/2016	44095	69719	6.7	7.5	0	0	15	660	660
5/31/2016	34763	63211	6.52	6.74	0	0	14	1090	1090
6/30/2016	35819	86550	6.6	7	0	0	14	821	821
7/31/2016	37876	63061	6.6	7.6	0	0	14	1000	1000
8/31/2016	39277	50119	7.2	7.4	0	0	11	622	622
9/30/2016	37121	48624	7.21	7.33	0	0	16	685	685
10/31/2016	12642	68672	7.17	8.44	0	0	10	717	717
11/30/2016	42402.3	57301	7.27	7.82	0	0	11	770	770
12/31/2016	47633	63585	7.33	7.79	160	160	13	1370	1370
1/31/2017	NODI: C	NODI: C	NODI: C	NODI: C	NODI: C	NODI: C	NODI: C	NODI: C	NODI: C
2/28/2017	35741	78620	7.22	7.57	0	0	12	630	630
3/31/2017	36034	53560	7.4	8.7	0	0	14	692	692
4/30/2017	38799	54756	7.42	8.9	0	0	13	742	742
5/31/2017	51570	65305	7.5	8.4	0	0	11	552	552
6/30/2017	46776	80715	7.5	8.6	0	0	12	1160	1160
7/31/2017	32873	46828	7.2	8.1	0	0	11	787	787
8/31/2017	32873	46828	7.2	8.1	0	0	9.2	787	787
9/30/2017	35238.4	70915.6	7.52	8.1	0	0	10	1030	1030
10/31/2017	45723	66352	7.18	7.68	0	0	**5**	1160	1160
11/30/2017	40068	60592	7.2	7.8	0	0	9	89	89
12/31/2017	37656	77424	7.1	8	0	0	11	107	107
1/31/2018	37234	50045	6.9	7.9	0	0	12	85	85
2/28/2018	41672	71739	7.05	7.6	0	0	13	101	101
3/31/2018	35641	61490	7.3	7.9	0	0	15	1010	1010
4/30/2018	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2
5/31/2018	14109	30072	6.9	7.6	0	0	12	126	126
6/30/2018	18609.1	31792.3	7.24	7.63	0	0	11	940	940
7/31/2018	37234	50045	7.3	8.5	0	0	9	0	0
8/31/2018	25077	44434	6.9	7.6	0	0	8.5	95	95

9/30/2018	34712	60817	7.3	8.1	0	0	8.8	0	0
10/31/2018	21918	38524.8	6.8	7.9	0	0	7	0	0
11/30/2018	20995	40769	6.9	8.1	0	0	11	684	684
12/31/2018	19599	37627	7.1	8.1	0	0	12	87	87
1/31/2019	17977	38824	7.76	8	0	0	10	952	952
2/28/2019	17617	30745	7	8	0	0	14	986	986
3/31/2019	20658	30745	7.2	8.2	0	0	12	1010	1010
4/30/2019	16804	36505.1	7.2	8	0	0	14	1080	1080
5/31/2019	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2	NODI: 2
6/30/2019	10325.7	20721.1	6.9	7.92	0	0	12	0	0
7/31/2019	14949	34859	7.27	8.09	0	0	7.4	105	105
8/31/2019	15605.4	43536.8	7.1	8.1	0	0	11	841	841
9/30/2019	13158	19973	7.43	8.37	0	0	7.8	479	479
10/31/2019	18452.8	43462	6.73	8.52	0	0	6.2	180	180
11/30/2019	19008	63883	7.45	7.92	0	0	9.8	768	768
12/31/2019	19656	61789	7.3	8.09	0	0	11	161	161
1/31/2020	24335	43910	7.36	7.98	0	0	12	545	545
2/29/2020	20238	47950	7.48	8.1	110	110	13	190	190
3/31/2020	17625.7	33438.1	7.33	8.62	110	110	13	138	138

Genzyme Facility
Outfall 001 - Quarterly Effluent Monitoring

Parameter	TSS	TSS	Copper	Copper
	Monthly Avg	Daily Max	Monthly Avg	Daily Max
Units	mg/L	mg/L	ug/L	ug/L
Effluent Limit	Report	Report	Report	Report
Minimum	0	0	0	0
Maximum	0	0	705	705
Median	0	0	17.5	17.5
No. of Violations	N/A	N/A	N/A	N/A
Monitoring Period End Date				
11/30/2014	0	0	13	13
1/31/2015	0	0	22	22
5/31/2015	0	0	0	0
8/31/2015	0	0	14	14
11/30/2015	0	0	51	51
2/29/2016	0	0	0	0
5/31/2016	0	0	13	13
8/31/2016	0	0	0	0
11/30/2016	0	0	0	0
2/28/2017	0	0	38	38
5/31/2017	0	0	0	0
8/31/2017	0	0	27	27
11/30/2017	0	0	15	15
2/28/2018	0	0	246	246
5/31/2018	0	0	127	127
8/31/2018	0	0	705	705
11/30/2018	0	0	19	19

2/28/2019	0	0	43	43
5/31/2019	NODI: 2	NODI: 2	NODI: 2	NODI: 2
8/31/2019	0	0	23	23
11/30/2019	0	0	16	16
2/29/2020	0	0	12	12

Notes:

gal/d = gallons per day
mg/L = milligrams per liter
ug/L = micrograms per liter
SU = Standard Units
0 = parameter not detected
N/A = not applicable
NODI: C = no data indicator: no discharge
NODI: 2 = no data indicator: operation shutdown
Red text = indicates permit limit exceedance

Appendix B: Essential Fish Habitat Species

EFH Species in the vicinity of Genzyme Outfall at Latitude 42° 21' 39", Longitude 71° 07' 02"	**Lifestage(s) Found at Location**
Atlantic Surfclam	Juvenile, Adult
Scup	Juvenile
Summer Flounder	Adult
Black Sea Bass	Adult

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY – REGION 1
WATER DIVISION
5 POST OFFICE SQUARE
BOSTON, MASSACHUSETTS 02109

PUBLIC NOTICE OF A DRAFT NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) PERMIT TO DISCHARGE INTO WATERS OF THE UNITED STATES UNDER SECTIONS 301 AND 402 OF THE CLEAN WATER ACT, AS AMENDED, AND REQUEST FOR STATE CERTIFICATION UNDER SECTION 401 OF THE CLEAN WATER ACT.

PUBLIC NOTICE PERIOD: **July 1, 2020 – July 30, 2020**

PERMIT NUMBER: **MA0040291**

PUBLIC NOTICE NUMBER: **MA-014-20**

NAME AND MAILING ADDRESS OF APPLICANT:

Genzyme Corporation
500 Soldiers Field Road
Allston, MA 02134

NAME AND ADDRESS OF THE FACILITY WHERE DISCHARGE OCCURS:

Genzyme Corporation
500 Soldiers Field Road
Allston, MA 02134

RECEIVING WATER: **Charles River (MA 72-36)**
Charles River Basin - Class B

The U.S. Environmental Protection Agency (EPA) have developed a draft permit for the Genzyme Corporation in Allston, MA to discharge reverse osmosis (RO) reject water. The effluent limits and permit conditions imposed have been drafted to assure compliance with the Clean Water Act, 33 U.S.C. sections 1251 et seq., the Massachusetts Clean Waters Act, G.L. c. 21, §§ 26-53, 314 CMR 3.00, and State Surface Water Quality Standards at 314 CMR 4.00. EPA has requested that the State certify this draft permit pursuant to Section 401 of the Clean Water Act and expects that the draft permit will be certified.

INFORMATION ABOUT THE DRAFT PERMIT:

The draft permit and explanatory fact sheet may be obtained at no cost at https://www.epa.gov/npdes-permits/massachusetts-draft-individual-npdes-permits or by contacting:

Samantha Tracy
5 Post Office Square, Suite 100 (06-1)
Boston, MA 02109-3912
Telephone: (617) 918-1621
Tracy.Samantha@epa.gov

The administrative record containing all documents relating to this draft permit including all data submitted by the applicant may be inspected at the EPA Boston office mentioned above between 9:00 a.m. and 5:00 p.m., Monday through Friday, except holidays and during facility closures due to COVID-19. All data submitted by the applicant are available as part of the administrative record. Electronically available documents may be requested from the above contact.

PUBLIC COMMENT AND REQUEST FOR PUBLIC HEARING:

All persons, including applicants, who believe any condition of this draft permit is inappropriate, must raise all issues and submit all available arguments and all supporting material for their arguments in full by **July 30, 2020**, to the address or email address listed above. Any person, prior to such date, may submit a request in writing to EPA for a public hearing to consider this draft permit. 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 this draft permit, the Regional Administrator will respond to all significant comments and make the responses available to the public at EPA's Boston office.

FINAL PERMIT DECISION:

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.

KEN MORAFF, DIRECTOR
WATER DIVISION
EPA – REGION 1