

**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”)

Shire Human Genetic Therapies, Inc.

is authorized to discharge from a facility located at

**Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway
Cambridge, MA 02138**

to receiving water named

**Alewife Brook
Mystic River Watershed**

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

This permit shall become effective on the first day of the calendar month immediately following 60 days after signature.

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

This permit supersedes the permit issued on March 13, 2015.

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

Signed this day of

**KENNET
MORAFF** Digitally signed by
KENNETH MORAFF
Date: 2021.01.27
15:55:07 -05'00'

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

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 Alewife Brook. The discharge shall be limited and monitored as specified below. The discharge of wastewaters from the cleaning of any RO unit components or the backwashing of any carbon or multi-media filters is prohibited.

Effluent Characteristic	Effluent Limitations		Monitoring Requirements ^{1,2,3}	
	Average Monthly	Maximum Daily	Measurement Frequency ⁴	Sample Type ⁵
Effluent Flow ⁶	20,000 GPD	30,000 GPD	Continuous	Recorder
pH ⁷	6.5 – 8.3 S.U.		1/week	Grab
Total Suspended Solids (TSS)	30 mg/L	45 mg/l	1/quarter	Grab
Dissolved Oxygen	Not less than 5.0 mg/l		1/month	Grab
Total Residual Chlorine (TRC) ⁸	0.22 mg/l	0.27 mg/l	1/month	Grab
Total Copper	52 µg/l	73 µg/l	1/quarter	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 which contains flow from both RO units, 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) and the State. The Permittee shall report the results to EPA and the State of any additional testing above that required herein, if testing is done in accordance with 40 CFR. § 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., $< 50 \mu\text{g/L}$, if the ML for a parameter is $50 \mu\text{g/L}$). 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. Sampling frequency of 1/month is defined as the sampling of one discharge event in each calendar month. Sampling frequency of 1/quarter is defined as the sampling of one discharge event in each 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 (NODI) Code (e.g., "C" for "No Discharge").
5. A grab sample is one sample taken 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 gallons per day (GPD). The total flow for each operating date shall be recorded and attached to each monthly DMR form.
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.).
8. For the purposes of this permit, TRC analysis must be completed using a test method in 40 CFR § 136 that achieves a minimum level of detection no greater than $30 \mu\text{g/L}$. The compliance level for TRC is $30 \mu\text{g/L}$.

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 ($\mu\text{g/L}$);
 - (2) 200 $\mu\text{g/L}$ for acrolein and acrylonitrile; 500 $\mu\text{g/L}$ 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 $\mu\text{g/L}$;
 - (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

There are no special conditions.

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 electronically using NetDMR no later than the 15th day of the month following the monitoring period. 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;
 - (3) Notification of proposal to add or replace chemicals and bio-remedial agents including microbes
- 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

Duplicate signed copies of all WET test reports shall be submitted to the Massachusetts Department of Environmental Protection, Division of Watershed Management, at the following address:

**Massachusetts Department of Environmental Protection
Bureau of Water Resources
Division of Watershed Management
8 New Bond Street
Worcester, Massachusetts 01606**

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 MassDEP's Emergency Response at:

888-304-1133

E. STATE 401 CERTIFICATION CONDITIONS

1. Pursuant to 314 CMR 3.11 (2)(a)6., and in accordance with MassDEP's obligation under 314 CMR 4.05(5)(e) to maintain surface waters free from pollutants in concentrations or combinations that are toxic to humans, aquatic life, or wildlife:
 - a. Within six months of the effective date of this Final Permit, the Permittee shall submit to MassDEP an evaluation of whether the facility uses any products containing any per- and polyfluoroalkyl substances (PFAS) and whether use of those products can be reduced or eliminated. The analysis shall be submitted electronically to massdep.npdes@mass.gov.
 - b. Within six months after EPA's multi-lab validated method for wastewater is made available to the public on EPA's Clean Water Act methods program website¹, or two years from the effective date of the Final Permit, whichever is earlier, the Permittee shall conduct monitoring of the effluent for PFAS compounds as detailed in the table below. If EPA has not issued a validated test method by twenty (20) months after the effective date of the Final Permit, the Permittee shall contact MassDEP (massdep.npdes@mass.gov) for guidance on an appropriate analytical method.

Effluent (Outfall 001)

Parameter	Units	Measurement Frequency ²	Sample Type
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¹ See <https://www.epa.gov/cwa-methods/other-clean-water-act-test-methods-chemical> and <https://www.epa.gov/cwa-methods>.

² Quarters are defined as January to March, April to June, July to September, and October to December. Samples shall be taken during the same month each quarter and shall be taken 3 months apart (e.g., an example sampling

Perfluorohexanesulfonic acid (PFHxS)	ng/L	Quarterly	24-hour Composite
Perfluoroheptanoic acid (PFHpA)	ng/L	Quarterly	24-hour Composite
Perfluorononanoic acid (PFNA)	ng/L	Quarterly	24-hour Composite
Perfluorooctanesulfonic acid (PFOS)	ng/L	Quarterly	24-hour Composite
Perfluorooctanoic acid (PFOA)	ng/L	Quarterly	24-hour Composite
Perfluorodecanoic acid (PFDA)	ng/L	Quarterly	24-hour Composite

Notwithstanding any other provision of the Final Permit to the contrary, monitoring results shall be reported to MassDEP electronically (massdep.npdes@mass.gov) within 30 days after they are received. Those results do not need to be reported to EPA through NetDMR.

- c. After completing one year of monitoring, if four consecutive samples are reported as non-detect for all six PFAS compounds, then the Permittee may submit a request to MassDEP to discontinue PFAS monitoring. Any such request shall be made in writing and sent to massdep.npdes@mass.gov. The Permittee shall continue such monitoring pending written approval from MassDEP to discontinue it.

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

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¹ Updated July 17, 2018 to fix typographical errors.

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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

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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

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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

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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

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- (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

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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

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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.

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- 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

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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

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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

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“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 96-483 and 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

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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

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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.

LC₅₀ means the concentration of a sample that causes mortality of 50% of the test population at a specific time of observation. The *LC₅₀* = 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

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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).

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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

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(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

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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

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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.

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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

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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

RESPONSE TO COMMENTS

NPDES Permit # MA0040321 Shire Human Genetic Therapies, Inc. Cambridge, MA

The U.S. Environmental Protection Agency's Region 1 (EPA) is issuing a Final National Pollutant Discharge Elimination System (NPDES) Permit for Shire Human Genetic Therapies, Inc. located in Cambridge, MA (the Facility). This permit is being issued under the Federal Clean Water Act (CWA), 33 U.S.C., §§ 1251 et. seq.

In accordance with the provisions of 40 CFR §124.17, this document presents EPA's responses to comments received on the Draft NPDES Permit #MA0040321 (the Draft Permit). The Response to Comments explains and supports EPA's determinations that form the basis of the Final Permit. From July 1, 2020 through July 30, 2020, EPA solicited public comments on the Draft Permit.

EPA received comments from Shire Human Genetic Therapies, Inc., dated July 28, 2020.

Although EPA's decision-making process has benefited from the comments submitted, the information and arguments presented did not raise any substantial new questions concerning the permit that warrants EPA exercising the discretion to reopen the public comment period or make changes to the Draft Permit.

A copy of the Final Permit and this response to comments document will be posted on the EPA Region 1 web site: http://www.epa.gov/region1/npdes/permits_listing_ma.html.

A copy of the Final Permit may be also obtained by writing or calling Nathan Chien, USEPA, 5 Post Office Square, Suite 100 (Mail Code: 06-1), Boston, MA 02109-3912; Telephone: (617) 918-1649; Email Chien.Nathan@epa.gov.

I. Summary of Changes to the Final Permit

Part E. of the Final Permit has been renamed to “State 401 Certification Conditions” and has been changed to incorporate all state water quality 401 Certification conditions pertaining to the monitoring requirement for per- and polyfluoroalkyl substances (PFAS).

II. Responses to Comments

Comments are reproduced below as received; they have not been edited.

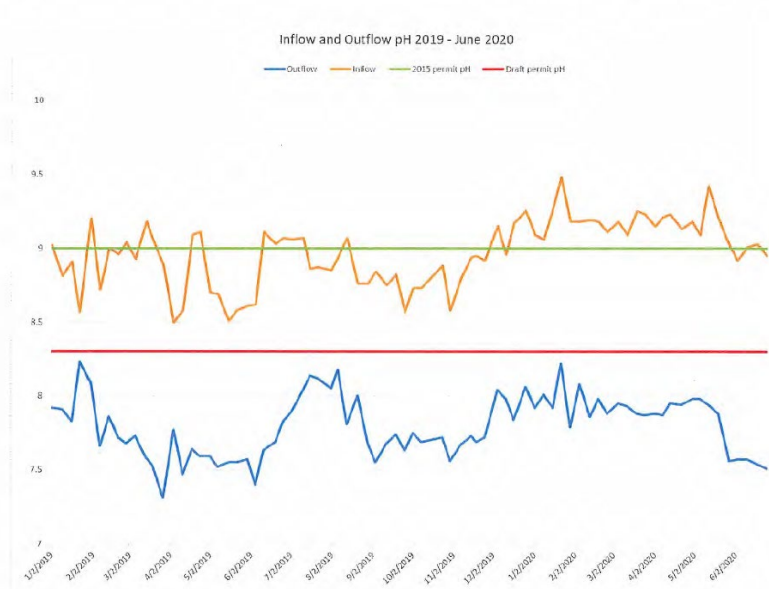
A. Comments from Shire Human Genetic Therapies, Inc., received on July 28, 2020.

Comment 1

Shire requests to maintain current pH permit limits of 6.5 – 9.0 S.U. of water discharged to the Alewife Brook instead of the range of discharge in the draft EPA NPDES permit of pH 6.3 – 8.3 S.U. Even though Shire has recently maintained a pH below the 8.3 S.U. threshold the pH of the discharge water can vary significantly as a result of the City of Cambridge inflow water.

In the water sampling data provided in Figure 1 for the period of January 2019 – June 2020 pH of incoming water from the City of Cambridge has ranged from 8.5 to 9.5 S.U. Shire has controls to lower the pH of the RO Reject discharge water but this adjustment is only proportionate to the incoming water pH levels. A pH permit limit below 9.0 S.U. would result in a continuous risk of exceedance due to the uncertainty of the City of Cambridge inflow water pH levels. As such, our request is to continue to discharge water under a pH parameter range of 6.5 – 9.0 S.U.

Figure 1 Inflow and Outflow pH 2019- June 2020. Data is derived from weekly sampling results.



Response to Comment 1

The pH limitation imposed in the Draft Permit is based on State Water Quality Standards (WQSs), specifically 314 CMR 4.05(3)(b)3., which states, “pH. Shall be in the range of 6.5 through 8.3 standard units and not more than 0.5 units outside of the natural background range. There shall be no change from natural background conditions that would impair any use assigned to this Class.” EPA has interpreted this WQS to mean that the pH of the effluent at the point of discharge must remain within this range in order to ensure that the receiving water does not become impaired for any of its designated uses. The Final Permit is being issued with state certification under CWA § 401 demonstrating that MassDEP agrees that a pH limitation of 6.5-8.3 S.U. is necessary to ensure the effluent does not impair any designated uses of the Charles River.

In limited situations and with concurrence from MassDEP, EPA has allowed for pH limitations outside the ranges defined in State WQSs on a case-by-case basis if the waterbody segment is not already impaired for pH, and it can be shown that the receiving waterbody will remain within the designated pH range 6.5-8.3 S.U., or as naturally occurs, and the discharge will not cause or contribute to any impairments in the receiving waterbody. While historical data for the Facility submitted in Discharge Monitoring Reports does indicate that pH is sometimes above the upper 8.3 S.U. WQS limitation, monitoring data over the last year has demonstrated that the Facility can meet the State WQS range even under the current conditions. For example, in the figure submitted by the Permittee, while source water pH was consistently above 8.3 S.U. (and as high as 9.5 S.U. on two occasions), the Facility’s effluent never exceeded 8.3 S.U. It is EPA’s understanding that the Facility has the technology in place to modify the pH of their effluent and pH conditioning technology is widely used at other facilities discharging Reverse Osmosis reject water in New England. Therefore, EPA has found that an alternate pH limitation is not necessary for this discharge.

The commentator’s central point is that the source water for their discharge is higher than what State standards define as natural pH conditions for the receiving waterbody. However, for NPDES permits the chemistry of the effluent discharge is the applicable permitting point of interest and not the chemistry of the effluent’s source water. While municipal drinking water is a relatively “clean” source water, it is treated with chemicals such as chlorine in concentrations greater than what would be found in natural waterbodies. In addition, the reverse osmosis process changes the relative amounts of those chemicals in reject water discharged as effluent. Given all of the above considerations, EPA maintains that the pH limitations of 6.5-8.3 S.U. are (1) a correct interpretation of State WQSs, (2) achievable by the Facility using technology currently utilized, and (3) in line with the CWA’s objective of restoring and maintaining, “the chemical, physical, and biological integrity of the Nation’s waters” through the elimination of the discharge of pollutants. The Final Permit contains no changes from the Draft Permit.

**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”)

Shire Human Genetic Therapies, Inc.

is authorized to discharge from a facility located at

**Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway
Cambridge, MA 02138**

to receiving water named

**Alewife Brook
Mystic 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 at midnight on the last day of the month preceding the effective date.

This permit supersedes the permit issued on March 13, 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**

- 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 Alewife Brook. The discharge shall be limited and monitored as specified below. The discharge of wastewaters from the cleaning of any RO unit components or the backwashing of any carbon or multi-media filters is prohibited.

Effluent Characteristic	Effluent Limitations		Monitoring Requirements ^{1,2,3}	
	Average Monthly	Maximum Daily	Measurement Frequency ⁴	Sample Type ⁵
Effluent Flow ⁶	20,000 GPD	30,000 GPD	Continuous	Recorder
pH ⁷	6.5 – 8.3 S.U.		1/week	Grab
Total Suspended Solids (TSS)	30 mg/L	45 mg/l	1/quarter	Grab
Dissolved Oxygen	Not less than 5.0 mg/l		1/month	Grab
Total Residual Chlorine (TRC) ⁸	0.22 mg/l	0.27 mg/l	1/month	Grab
Total Copper	52 µg/l	73 µg/l	1/quarter	Grab

Footnotes:

- 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 which contains flow from both RO units, 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) and the State. The Permittee shall report the results to EPA and the State of any additional testing above that required herein, if testing is done in accordance with 40 CFR. § 136.
- 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., $< 50 \mu\text{g/L}$, if the ML for a parameter is $50 \mu\text{g/L}$). 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. Sampling frequency of 1/month is defined as the sampling of one discharge event in each calendar month. Sampling frequency of 1/quarter is defined as the sampling of one discharge event in each 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 (NODI) Code (e.g., "C" for "No Discharge").
5. A grab sample is one sample taken 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 gallons per day (GPD). The total flow for each operating date shall be recorded and attached to each monthly DMR form.
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.).
8. For the purposes of this permit, TRC analysis must be completed using a test method in 40 CFR § 136 that achieves a minimum level of detection no greater than $30 \mu\text{g/L}$. The compliance level for TRC is $30 \mu\text{g/L}$.

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 ($\mu\text{g/L}$);
 - (2) 200 $\mu\text{g/L}$ for acrolein and acrylonitrile; 500 $\mu\text{g/L}$ 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 $\mu\text{g/L}$;
 - (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

There are no special conditions.

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 electronically using NetDMR no later than the 15th day of the month following the monitoring period. 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;
 - (3) Notification of proposal to add or replace chemicals and bio-remedial agents including microbes
- 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

Duplicate signed copies of all WET test reports shall be submitted to the Massachusetts Department of Environmental Protection, Division of Watershed Management, at the following address:

**Massachusetts Department of Environmental Protection
Bureau of Water Resources
Division of Watershed Management
8 New Bond Street
Worcester, Massachusetts 01606**

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 MassDEP'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.

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(April 26, 2018)¹

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¹ Updated July 17, 2018 to fix typographical errors.

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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

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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

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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

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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

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- (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

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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

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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.

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- 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

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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

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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

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“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 96-483 and 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

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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

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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.

LC₅₀ means the concentration of a sample that causes mortality of 50% of the test population at a specific time of observation. The *LC₅₀* = 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

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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).

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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

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(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

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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

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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.

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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

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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: MA0040321

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

NAME AND MAILING ADDRESS OF APPLICANT:

Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway
Cambridge, MA 02138

NAME AND ADDRESS OF FACILITY WHERE DISCHARGE OCCURS:

Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway
Cambridge, MA 02138

RECEIVING WATER AND CLASSIFICATION:

Alewife Brook (MA71-04)
Mystic River Watershed
Class B (CSO)

SIC CODE: 2834 (Pharmaceutical Preparation)

**CONFIDENTIAL/DRAFT/PRE-DECISIONAL/INTER-AGENCY DELIBERATIVE
NOT FOR RELEASE**

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1.0 Proposed Action

Shire Human Genetics Therapies, Inc (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 from the Shire Human Genetics Therapies, Inc (the Facility) into Alewife Brook.

The permit currently in effect was issued on March 13, 2015 with an effective date of June 1, 2015 and expired on May 31, 2020 (the 2015 Permit). The Permittee filed an application for permit reissuance with EPA dated December 4, 2019, as required by 40 Code of Federal Regulations (CFR) § 122.6. Since the permit application was deemed timely and complete by EPA on April 14, 2020, the Facility's 2015 Permit has been administratively continued pursuant to 40 CFR § 122.6 and § 122.21(d). In lieu of a site visit, EPA and the State held a conference call with the Permittee on May 18, 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. *Arkansas v. Oklahoma*, 503 U.S. 91, 105 (1992). *See also* 40 CFR §§ 122.4(d), 122.44(d)(1), and 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 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 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.

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 established 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

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).

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 level³ (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

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).

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 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

Shire Human Genetic Therapies, Inc. operates a biopharmaceutical facility in Cambridge, Massachusetts. See Figure 1 for a site location map. The Facility is engaged in the development, commercialization and manufacturing of therapeutic proteins for gene therapy applications. The

⁴ <https://netdmr.zendesk.com/hc/en-us>

current permit, which was issued in 2015, authorized the discharge of up to a daily maximum of 30,000 gallons per day (GPD) of reverse osmosis (RO) reject water to Alewife Brook through Outfall 001. The RO reject water is routed to a storm drain connection which travels for approximately half a mile before discharging to the Wheeler Street outfall, designated as permitted Outfall 001, into Alewife Brook. A location map can be seen in Figure 1.

3.1.1 Effluent Limitation Guidelines

EPA has not promulgated technology-based effluent limitation guidelines (ELGs) for the discharge of RO reject water from Pharmaceutical Preparation (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

To achieve the required level of water purity for its pharmaceutical production, Shire employs two separate RO units to treat municipal water supplied by the City of Cambridge. The outputs of these RO units are purified water which is used in pharmaceutical production and RO reject water, which is discharged through Outfall 001. This reject water contains the typical parameters which are found in drinking water, except at higher concentrations. Flow is measured by a recorder at the outlet of each RO unit and all other parameters are sampled at the sampling port which contains the combined flow from both RO units prior to discharge to the storm drain and eventually to Alewife Brook via Outfall 001.

The water used for the RO system proceeds through a series of pretreatment steps aimed at maintaining the effective operation of the RO units. Figure 2 depicts a process flow diagram of these steps; both RO systems undergo the same pretreatment. City water entering the treatment system first passes through a multimedia filter for control of large particulate matter. Any backwash from the multi-media filters is discharged to the MWRA sanitary sewer and is prohibited from being discharged to Outfall 001. The influent then passes through one of a pair of water softeners that serves to prevent scale build up on the RO membranes. A break tank, functioning as a pressure control device, separates the rest of the treatment system from these initial steps.

Residual chlorine sourced from the Cambridge city water is detrimental to the operation of RO units and is removed through carbon filtration. A heater is used to bring the water temperature above 50 degrees fahrenheit to both improve RO membrane performance and get the water to an appropriate temperature for its use after membrane filtration. pH conditioning occurs through the addition of sulfuric acid with a target pH range of 7.0-8.0 S.U. An ultraviolet (UV) disinfectant is

set up to prevent biofouling of the RO membranes. The treated water passes through a final 5-micron filter before entering the RO membranes. The RO membranes are replaced periodically based on treatment performance. Performance is monitored by the pressure differential across the membranes. RO membranes are not cleaned on site, if that were to change the discharge of wastewaters generated from cleaning the membranes is not covered by the Draft Permit.

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 April 2015 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 Alewife Brook (Segment ID MA71-04), which is comprised of less than one (1) acre in Cambridge, Massachusetts. Alewife Brook is part of the Mystic River Watershed. Alewife Brook originates at the outlet of Lower Mystic Lake (Segment ID MA71027), and discharges to the Mystic River.

Alewife Brook is classified as Class B, warm water fishery in the Massachusetts WQSs, 314 Code of Massachusetts Regulations (CMR) 4.05(3)(b). 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.”*

Alewife Brook is listed in the *Massachusetts Year 2016 Integrated List of Waters* (“303(d) List”) as a Category 5 “Waters Requiring a TMDL.”⁵ The cause of impairment listed is debris, trash, copper, dissolved oxygen, E. Coli, flocculant masses, lead, odor, oil and grease, PCBs, phosphorus, scum/foam, sediment bioassay, and transparency/clarity. A TMDL has been developed for bacteria in the Mystic Watershed⁶. To date, no other TMDLs have been developed for any of the other listed impairments. The status of each designated use is presented in Table 1.

⁵ *Massachusetts Year 2016 Integrated List of Waters*. MassDEP Division of Watershed Management Watershed Planning Program, Worcester, Massachusetts.

⁶ *Final Pathogen TMDL for the Boston Harbor, Weymouth-Weir, and Mystic Watersheds*, MassDEP Division of Watershed Management, Worcester, Massachusetts; October 2018.

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	Not Assessed

According to the *Mystic River Watershed and Coastal Drainage Area 2004-2008 Water Quality Assessment Report*,⁷ this water body segment is impaired for designated uses of aquatic life, aesthetics and primary and secondary contact recreation. The Fish Consumption Use is listed as not assessed. However, Alewife Brook is included in the Massachusetts Department of Public Health fish consumption advisory for PCBs in some species.⁸ The RO reject water discharged from the Facility is not expected to contribute to any of these impairments.

4.2 Available Dilution

To ensure that discharges do not cause or contribute to violations of WQSs under all expected conditions, QBELs are derived assuming critical conditions for the receiving water.⁹ The critical flow in rivers and streams is some measure of the low flow of that river or stream. Massachusetts WQSs require that for rivers and streams, the lowest flow condition is the lowest mean flow for seven consecutive days, recorded once in 10 years, also known as the 7-day 10-year low flow (7Q10). See 314 CMR 4.03(3)(a).

MassDEP calculated the 7Q10 for Alewife Brook using data from the United States Geological Survey's (USGS) National Water Information System database and the USGS's StreamStats Web Application¹⁰. That low flow value (Q_s) and the permitted flow limitations for the Facility (Q_d) were used to calculate dilution factors (DF) 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:

⁷ Water Quality Assessment Report. MassDEP Division of Watershed Management, Worcester, Massachusetts; March 2010, Report Number: 71-AC-2.

⁸ Freshwater Fish Consumption Advisory List. Massachusetts Department of Public Health Bureau of Environmental Health; July, 2019. <https://www.mass.gov/lists/fish-consumption-advisories>

⁹ EPA Permit Writer's Manual, Section 6.2.4

¹⁰ USGS StreamStats National Data Collection Station Report for Station 01173500: <https://streamstatsags.cr.usgs.gov/gagepages/html/01103025.htm>

$$\text{Chronic DF} = (0.344 \text{ MGD} + 0.02 \text{ MGD}) / 0.02 \text{ MGD} = 18$$

$$\text{Acute DF} = (0.344 \text{ MGD} + 0.03 \text{ MGD}) / 0.03 \text{ MGD} = 12$$

Where the Chronic DF is used to derive average monthly WQBELs and the acute DF is used to derive maximum daily WQBELs.

5.0 Proposed Effluent Limitations and Conditions

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.

5.1 Effluent Limitations and Monitoring Requirements

The State and Federal regulations and data regarding discharge characteristics were used during the effluent limitation development process. Discharge is included in Appendix A. EPA's Reasonable Potential Analysis is included in Appendix B and results are discussed in the applicable sections below.

5.1.1 Effluent Flow

From April 2015 through March 2020 daily maximum effluent flow has ranged from 4,161 gallons per day (GPD) to 20,658 GPD (Appendix A). The Facility's 2015 Permit limits the discharge to a daily maximum flow rate of 30,000 GPD and an average monthly flow rate of 20,000 GPD. The monthly average flow limitation was exceeded a single time during October 2017. The Draft Permit maintains the maximum daily and average monthly flow limitations.

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 intake 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, the effluent pH ranged from 7.29 to 8.98 S.U. (Appendix A). Since the start of 2019, effluent pH has not exceeded the 8.3 S.U. WQS. Due to this recent performance, the

ability of the Facility to condition for pH, and to ensure the effluent meets WQSs, the Draft Permit limits pH from 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 this Facility, a media filter and 5-micron pressure filter are used to remove particulate matter. The discharge created from backwashing these filters is not authorized in the Draft Permit.

The 2015 Permit imposed average monthly and maximum daily total suspended solids (TSS) limitations of 30 mg/L and 45 mg/L, respectively, monitored quarterly by grab sample. From April 2015 through March 2020, maximum daily total suspended solids (TSS) concentrations reported by the Permittee were all non-detects except for one detection at the beginning of the reporting period of 13 mg/L (Appendix A). The Draft Permit maintains the current permits TSS limits in accordance with anti-backsliding requirements found in 40 CFR § 122.44(1). These limitations were established using BPJ pursuant to CWA § 402(a)(1). The limitations were based upon the TSS concentrations estimated to be achievable by using filters to treat reverse osmosis from potable water treatment facilities. Performance data from the Facility indicate that these TBELs are routinely achievable and no material or substantial changes in operations that would affect the achievement of these limits have occurred since these limitations were imposed.

5.1.4 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 aquatic life.

From April 2015 through March 2020, DO concentrations have ranged from 6.59 to 11.96 mg/l. The 2015 Permit included a WQBEL for DO of 6.0 mg/l based on State WQS for Class B waters. However, this was an incorrect interpretation of the water quality standards – found at

314 CMR 4.05(3)(b)1. Since Alewife Brook is a Class B warm water fishery, the correct WQBEL would be a minimum DO concentration of 5.0 mg/l. 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).”

5.1.5 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. In RO systems, dechlorination is a typical pretreatment step designed to prevent membrane damage. Depending on the source water concentration, the treatment performance of the carbon filters, and the proportion of reject water to purified water generated by the RO system, chlorine can build to toxic levels in RO reject water.

The Reverse Osmosis General Permit (ROGP) – issued by EPA in 2002 – authorized the Facility’s discharge starting in 2004. The ROGP was not reissued after its expiration in 2007 and the Facility replaced their discharge coverage with an individual permit in 2009; however, permit limits from the ROGP were maintained in the 2009 Permit and the subsequent 2015 Permit. For Total Residual Chlorine (TRC), the ROGP contained TBELs implemented using BPJ under CWA § 402(a)(1)(B). These TBELs were a monthly average limit of 0.11 mg/l and a daily maximum limit of 0.2 mg/l and were based on national water quality criteria, adjusted for the Facility’s dilution¹¹. During issuance of the 2015 Permit, the TRC limits were carried forward and treated as WQBELs by adjusting the national water quality criteria by the Facility’s dilution factor.

From April 2015 through March 2020, TRC concentrations have ranged from 0.022 mg/l to 0.12 mg/l. For the permit reissuance, EPA conducted a reasonable potential analysis to determine if the Facility’s discharge causes, or has 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). The acute and chronic EPA *National Recommended Water Quality Criteria* for TRC are as follows:

¹¹ Quality Criteria for Water (Gold Book), May 1, 1986, EPA 440/5-86-001.

Freshwater acute = 0.019 mg/l
Freshwater chronic = 0.011 mg/l

The reasonable potential analysis is contained in Appendix B.

The results of EPA's analysis indicate discharges of TRC do not have reasonable potential to cause or contribute to an excursion above water quality criteria. Given these results, no new permit limits have been added; instead, in accordance with anti-backsliding requirements, the Facility's previous permit limits have been maintained in the Draft Permit. These limits include an average monthly TRC concentration no greater than 0.22 mg/l and a maximum daily concentration no greater than 0.27 mg/l. However, the monitoring frequency has been changed from weekly to monthly to match similar NPDES permits for Facility's discharging RO reject water in Massachusetts¹².

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 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 2015 Permit contained limits (monthly average of 52 µg/l and a daily maximum of 73 µg/l) on total copper that were carried over from the ROGP and which were based on a dilution range of 10 to 100. The permittee has reported total copper values as high as 64 µg/l during the monitoring period (Appendix A). 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). The acute and chronic EPA *National Recommended Water Quality Criteria* for copper are as follows:

Copper:
Freshwater acute (Class A or B) = 8.2 µg/l
Freshwater chronic (Class A or B) = 5.8 µg/l

The reasonable potential analysis is contained in Appendix B.

¹² See NPDES Permits MA0040291 and MA0040483.

The results of EPA's analysis indicate discharges of copper do not have a reasonable potential to cause or contribute to an excursion above the chronic or acute water quality criterion. Given these results, no new permit limits have been added; instead, in accordance with anti-backsliding requirements, the Facility's previous permit limits have been maintained in the Draft Permit. These limits include an average monthly total recoverable copper concentration no greater than 52 µg/l and a maximum daily concentration no greater than 73 µg/l monitored quarterly.

5.1.7 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. The inclusion of WET requirements in the Draft Permit will assure that the Facility does not discharge combinations of pollutants into the receiving water in amounts that would be toxic to aquatic life or human health.

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 regulations at 40 CFR Part 122.44(d)(ii) state, "When determining whether a discharge causes, has the reasonable potential to cause, or contributes to an in-stream excursion above a narrative or numeric criteria within a State water quality standard, the permitting authority shall use procedures which account for existing controls on point and non-point sources of pollution...(including) the sensitivity of the species to toxicity testing..." The current permit had no WET testing requirement.

Due to the nature of the discharge, 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 Cambridge city (drinking) water for its process and treats this water for solids, bacteria, 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 source water, the treatment it undergoes prior to the RO filtration system, and the historic DMR effluent data do not indicate a reasonable potential for toxicity in this discharge.

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 Alewife Brook 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.¹³ 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 brevirostrum*) and Atlantic sturgeon (*Acipenser oxyrinchus*), have not been identified in Alewife Brook or the Mystic 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 Alewife Brook to spawn.

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.

¹³ See [for USFWS at <https://ecos.fws.gov/ipac/>] and/or [for NMFS at <https://www.greateratlantic.fisheries.noaa.gov/protected/section7/index.html>]

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). "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.

A review of the relevant essential fish habitat information provided by NOAA Fisheries¹⁴ indicates that the outfall exists within designated EFH for 4 federally managed species. The EFH species and life stages are listed in Table 2.

Table 3: EFH Species and Life Stages in the Vicinity of Shire's Outfall 001 at Latitude 42°23'24", Longitude -71°8'36"

EFH Species	Lifestage(s) Found at Location
Atlantic Surfclam	Juvenile, Adult
Scup	Juvenile
Summer Flounder	Adult
Black Sea Bass	Adult

EPA's Finding of all Potential Impacts to EFH Species

- 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 Alewife Brook or the Little River, another nearby

¹⁴ NOAA EFH Mapper available at <http://www.habitat.noaa.gov/protection/efh/efhmapper/>

surface water body, 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 0.03 MGD will be implemented year-round in order to ensure predicted mixing with the receiving water;
- Discharge limits have been proposed for flow, total suspended solids, pH, dissolved oxygen, total residual chlorine, and total copper 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.

EPA believes that the conditions and limitations contained within the Draft Permit adequately protects all aquatic life, including those species with designated EFH in the receiving water. Further mitigation is not warranted. Should adverse impacts to EFH be detected as a result of this permit action, or if new information is received that changes the basis for EPA's conclusions, NOAA Fisheries will be contacted and an EFH consultation will be re-initiated.

In addition to this Fact Sheet and the Draft Permit, information to support EPA's finding is included in a letter under separate cover that will be sent to the NOAA Fisheries Habitat Division after the public comment period has begun.

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:

Nathan Chien
EPA Region 1
5 Post Office Square, Suite 100 (06-1)
Boston, MA 02109-3912
Telephone: (617) 918-1649
Email: Chien.Nathan@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, 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 at EPA's Boston office between the hours of 9:00 a.m. and 5:00 p.m., Monday through Friday, excluding holidays, from Nathan Chien, EPA Region 1, Water Division, Industrial Permits Section, 5 Post Office Square, Suite 100, Boston, Massachusetts 02109-3912 or via email to Chien.Nathan@epa.gov.

July 1, 2020

Date

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

Figures

Figure 1: Location Map

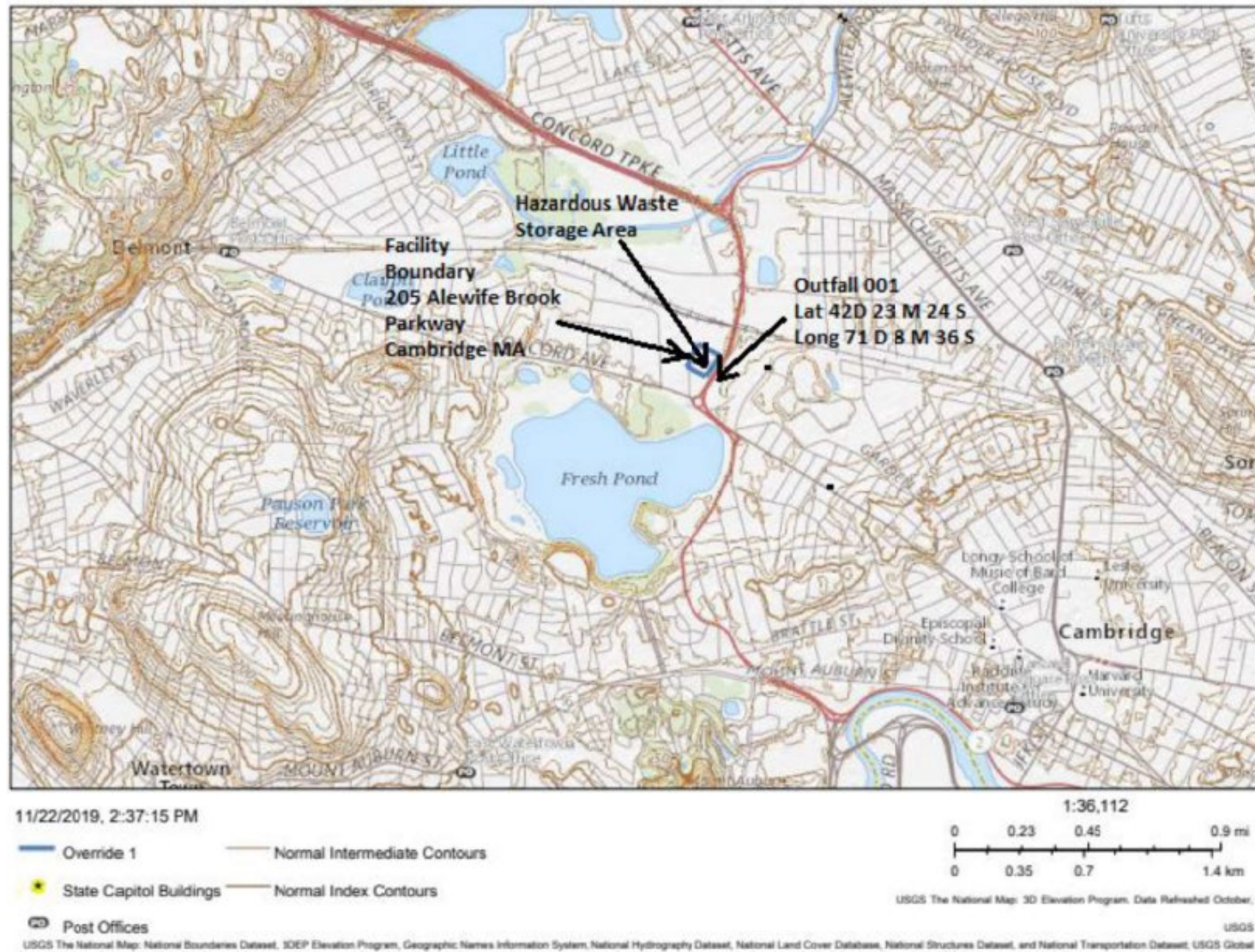
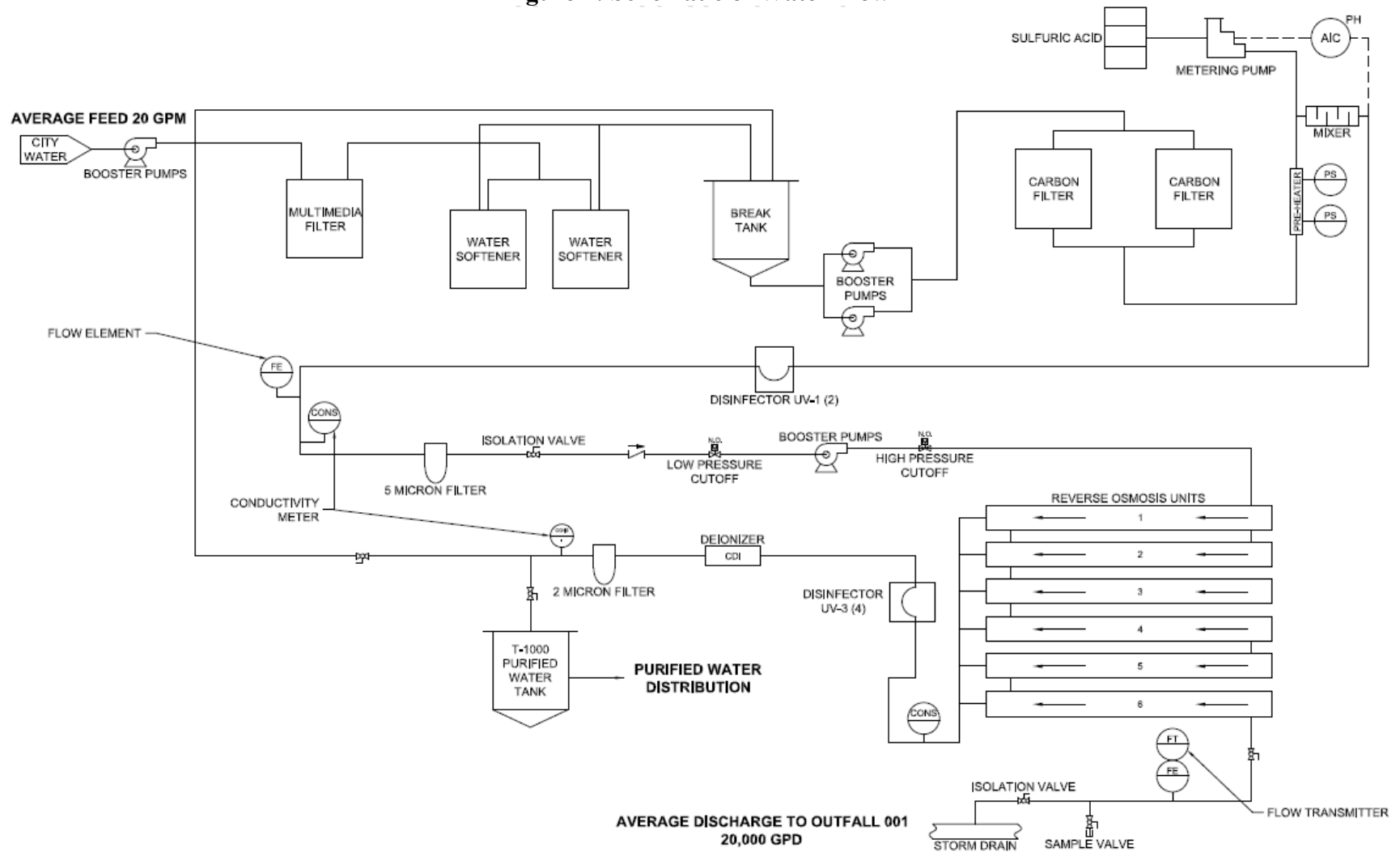


Figure 2: Schematic of Water Flow

Appendices

Appendix A: Discharge Monitoring Data

SHIRE Monthly Effluent Monitoring Data Outfall 001 – 1 – A							
Parameter	Flow rate	Flow rate	pH	pH	TRC	TRC	DO
	Monthly Avg	Daily Max	Minimum	Maximum	Monthly Avg	Daily Max	Minimum
Units	gal/d	gal/d	S.U.	S.U.	mg/L	mg/L	mg/L
Effluent Limit	20000	30000	6.5	9	0.22	0.27	6
Minimum	4161	8537	7.29	7.59	0.022	0.04	6.59
Maximum	20658	25990	8.23	8.98	0.12	0.17	11.96
Median	17536.5	19476	7.755	8.07	0.05	0.08	9.085
No. of Violations	1	0	0	0	0	0	0
Monitoring Period End Date							
4/30/2015	8537	8537	7.82	8.15	0.054	0.09	10.26
5/31/2015	11116	18396	7.83	8.03	0.0325	0.08	8.25
6/30/2015	8215	13000	7.81	7.94	0.0625	0.09	9.02
7/31/2015	16505	22000	7.72	8.03	0.034	0.06	8.11
8/31/2015	17472	19750	8.04	8.14	0.05	0.08	7.88
9/30/2015	18341	20470	8.05	8.15	0.038	0.06	7.07
10/31/2015	18616	22780	7.86	8.18	0.038	0.07	8.28
11/30/2015	19190	21310	7.85	8.89	0.023	0.04	9.23
12/31/2015	18293	20500	7.42	7.98	0.03	0.04	8.97
1/31/2016	17826	19550	7.83	8.01	0.055	0.07	9.37
2/29/2016	18319	20350	7.98	8.03	0.035	0.07	9.95
3/31/2016	18907	21040	7.68	8.13	0.032	0.06	10.27
4/30/2016	18607	19410	7.69	8.31	0.0225	0.04	9.83
5/31/2016	18673	19790	7.84	8.42	0.04	0.08	8.31
6/30/2016	18333	19840	8.11	8.54	0.032	0.08	8.12
7/31/2016	15027	20010	8.14	8.53	0.025	0.06	7.81
8/31/2016	17462	19780	7.9	8.97	0.068	0.09	8.07
9/30/2016	18648	19450	7.51	8.04	0.07	0.08	7.84
10/31/2016	19196	20410	7.58	8.63	0.065	0.09	8.46
11/30/2016	18725	21140	7.74	7.98	0.07	0.12	9.46
12/31/2016	17527	20490	7.69	8.24	0.12	0.17	10.38
1/31/2017	18238	20020	8.2	8.38	0.08	0.16	10.07
2/28/2017	17705	20130	7.52	7.94	0.038	0.05	9.83
3/31/2017	18136	21100	7.41	8.24	0.044	0.07	9.37

4/30/2017	17760	19390	7.72	8.05	0.022	0.05	8.91
5/31/2017	18265	21960	7.86	7.99	0.03	0.07	9.86
6/30/2017	18089	24150	7.82	8.39	0.038	0.08	8.92
7/31/2017	15897	18500	7.93	8.66	0.047	0.07	8.24
8/31/2017	16285	19880	8.23	8.51	0.05	0.08	8.04
9/30/2017	17743	19410	7.72	8.27	0.0325	0.05	8.86
10/31/2017	20658	25990	7.81	7.98	0.03	0.05	9.12
11/30/2017	18660	19930	7.94	8.31	0.046	0.1	9.29
12/31/2017	18892	20150	7.77	8.01	0.05	0.09	9.53
1/31/2018	17557	19502	7.59	8.05	0.07	0.11	10.59
2/28/2018	17546	19390	7.86	8.01	0.04	0.05	9.95
3/31/2018	17898	19771	7.69	8.13	0.034	0.05	10.34
4/30/2018	17598	19053	7.93	8.21	0.05	0.07	10.25
5/31/2018	17277	18843	7.84	8.24	0.03	0.04	9.06
6/30/2018	17669	19577	7.58	8.98	0.038	0.07	7.63
7/31/2018	17741	19778	7.32	7.86	0.0475	0.08	7.81
8/31/2018	17311	19135	7.63	7.88	0.06	0.1	7.48
9/30/2018	18031	21327	7.73	8.02	0.06	0.11	7.71
10/31/2018	16743	19195	7.56	7.86	0.12	0.15	9.13
11/30/2018	16983	18200	7.29	8.03	0.06	0.12	9.11
12/31/2018	14724	17729	7.38	8.31	0.09	0.14	9.43
1/31/2019	11497	14033	7.83	8.23	0.07	0.11	11.38
2/28/2019	11013	13989	7.66	7.86	0.07	0.13	9.72
3/31/2019	11886	14318	7.31	7.73	0.04	0.09	10.98
4/30/2019	12747	17400	7.47	7.77	0.05	0.11	8.97
5/31/2019	12388	15515	7.52	7.59	0.06	0.08	7.23
6/30/2019	11265	14063	7.4	7.83	0.08	0.09	6.92
7/31/2019	9017	12612	7.89	8.14	0.04	0.08	8.48
8/31/2019	4161	10645	7.68	8.18	0.08	0.13	6.59
9/30/2019	8505	13659	7.55	7.74	0.11	0.13	7.11
10/31/2019	13824	19105	7.56	7.75	0.06	0.12	9.04
11/30/2019	13345	18971	7.67	7.73	0.04	0.07	10.11
12/31/2019	13321	17033	7.84	8.06	0.06	0.1	11.94
1/31/2020	12761	17377	7.79	8.22	0.052	0.06	10.11
2/29/2020	13889	19390	7.86	8.08	0.09	0.15	11.96
3/31/2020	12977	18664	7.96	7.95	0.09	0.11	11.46

SHIRE
Quarterly Effluent Monitoring Data
Outfall 001 – 1 – Q

Parameter	TSS	TSS	Copper	Copper
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	Monthly Avg	Daily Max	Monthly Avg	Daily Max
Units	mg/L	mg/L	ug/L	ug/L
Effluent Limit	30	45	52	73
Minimum	No Data	No Data	2	2
Maximum	No Data	No Data	35	64
Median	No Data	No Data	Non-Detect	Non-Detect
No. of Violations	No Data	No Data	0	0
Monitoring Period End Date				
4/30/2015	13	13	2	2
5/31/2015	NODI: 9	NODI: 9	NODI: 9	NODI: 9
9/30/2015	NODI: B	NODI: B	NODI: B	NODI: B
12/31/2015	NODI: B	NODI: B	NODI: B	NODI: B
3/31/2016	NODI: B	NODI: B	NODI: B	NODI: B
6/30/2016	NODI: B	NODI: B	NODI: B	NODI: B
9/30/2016	NODI: B	NODI: B	NODI: B	NODI: B
12/31/2016	NODI: B	NODI: B	NODI: B	NODI: B
3/31/2017	NODI: B	NODI: B	NODI: B	NODI: B
6/30/2017	NODI: B	NODI: B	NODI: B	NODI: B
9/30/2017	NODI: B	NODI: B	NODI: B	NODI: B
12/31/2017	NODI: B	NODI: B	NODI: B	NODI: B
3/31/2018	NODI: B	NODI: B	2	2
6/30/2018	NODI: B	NODI: B	NODI: B	NODI: B
9/30/2018	NODI: B	NODI: B	NODI: B	NODI: B
12/31/2018	NODI: B	NODI: B	35	64
3/31/2019	NODI: B	NODI: B	5	5
6/30/2019	NODI: B	NODI: B	3	3
9/30/2019	NODI: B	NODI: B	2	2
12/31/2019	NODI: B	NODI: B	2	2
3/31/2020	NODI: B	NODI: B	3	3

Notes:

TRC = total residual chlorine

DO = dissolved oxygen

TSS = Total Suspended Solids

S.U. = standard units

gal/d = gallons per day

mg/l = milligrams per liter

ug/l = micrograms per liter

NODI: B = measured value was below the method detection limit

Red = Violation of Effluent Limitation

Appendix B: Reasonable Potential Analysis**Methodology**

A reasonable potential analysis is completed using a single set of critical conditions for flow and pollutant concentration that will ensure the protection of water quality standards. To determine the critical condition of the effluent, EPA projects an upper bound of the effluent concentration based on the observed monitoring data and a selected probability basis. EPA generally applies the quantitative approach found in Appendix E of the *Technical Support Document for Water Quality-based Toxics Control* (TSD)¹ to determine the upper bound of the effluent data. This methodology accounts for effluent variability based on the size of the dataset and the occurrence of non-detects (i.e., samples results in which a parameter is not detected above laboratory detection limits). EPA used this methodology to calculate the 95th percentile.

EPA uses the calculated upper bound of the effluent data, along with a concentration representative of the parameter in the receiving water, the critical effluent flow, and the critical upstream flow to project the downstream concentration after complete mixing using the following simple mass-balance equation:

$$Q_s C_s + Q_e C_e = Q_d C_d$$

Where:

C_d = downstream concentration

C_s = upstream concentration (median value of available ambient data)

C_e = effluent concentration (95th percentile of effluent concentrations)

Q_s = upstream flow (7Q10 flow upstream of the outfall)

Q_e = effluent flow of the Facility (permitted maximum daily flow or average monthly flow)

Q_d = downstream flow ($Q_s + Q_e$)

Solving for the receiving water concentration downstream of the discharge (C_d) yields:

$$C_d = \frac{C_s Q_s + C_e Q_e}{Q_d}$$

When the downstream concentration (C_d) exceeds the applicable criterion, there is reasonable potential for the discharge to cause, or contribute to an excursion above WQSS. *See* 40 CFR § 122.44(d). When EPA determines that a discharge causes, has the reasonable

potential to cause, or contribute to such an excursion, the permit must contain WQBELs for the parameter. The limitation is calculated by rearranging the above mass balance equation to solve for the effluent concentration (C_e) using the applicable criterion as the downstream concentration (C_d). See 40 CFR § 122.44(d)(1)(iii).

Determination of Applicable Criteria

State water quality criteria are derived from EPA's *National Recommended Water Quality Criteria: 2002*, which are incorporated into the state WQSs by reference at 315 CMR 4.05(5). Freshwater aquatic life criteria for copper are established in terms of dissolved metals and are converted to total recoverable using published conversion factors. Additionally, the criteria for copper are hardness-dependent. EPA calculated hardness-dependent chronic and acute criteria for metals detected in the effluent using the downstream hardness determined using a hardness value (135 mg/l CaCO_3) for Alewife Brook collected from a 1980 USGS publication on Water Quality in Northeastern Massachusetts¹⁵. The applicable criteria are summarized in the table below.

Summary of Applicable Criteria

Parameter	Coefficients				Applicable Criteria^{1,2,3,4}	
	ma	ba	mc	bc	Acute Criteria (CMC)	Chronic Criteria (CCC)
Units	—	—	—	—	µg/L	µg/L
Copper	0.9422	-1.7000	0.8545	-1.702	18.6	12.1
Total Residual Chlorine	—	—	—	—	19	11

¹Acute Criteria (Criterion Maximum Concentration (CMC)) = $\exp\{m_a \cdot \ln(\text{hardness}) + b_a\}$ where:

m_a = pollutant-specific coefficient

b_a = pollutant-specific coefficient

\ln = natural logarithm

h = hardness of the receiving water

²Chronic Criteria (Criterion Continuous Concentration (CCC)) = $\exp\{m_c \cdot \ln(\text{hardness}) + b_c\}$ where:

m_c = pollutant-specific coefficient

¹⁵ Delaney, David and Gay, Frederick. *Hydrology and Water Resources of the Coastal Drainage Basins of Northeastern Massachusetts, From Castle Neck River, Ipswich, to Mystic River, Boston – Plate 4*. U.S. Geological Survey. 1980. <https://pubs.usgs.gov/ha/589/plate-4.pdf>.

b_c = pollutant-specific coefficient

\ln = natural logarithm

h = hardness of the receiving water

³ For hardness-dependent criteria, see *National Recommended Water Quality Criteria, Appendix B - Parameters for Calculating Freshwater Dissolved Metals Criteria That Are Hardness-Dependent*: <http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm>

⁴ For dissolved to total recoverable metal conversion, see *Appendix A - Conversion Factors for Dissolved Metals*:

<http://water.epa.gov/scitech/swguidance/standards/criteria/current/index.cfm#appendxa>; Required by 314 CMR 4.05(5)(e).

Calculation of Reasonable Potential

EPA first calculated the upper bound of expected effluent concentrations for each parameter. EPA then used the calculated upper bound of expected effluent concentrations, the permitted effluent flow limits and the upstream 7Q10 flow to project the in-stream concentration downstream from the discharge. Since EPA lacked representative data, the upstream receiving water concentration was assumed to be negligible, i.e., equal to zero. When this resultant in-stream concentration (C_d) exceeds the applicable criterion, there is reasonable potential for the discharge to cause, or contribute to an excursion above water quality standards. The results are summarized in the table below.

Summary of Reasonable Potential Results

Pollutant	Upstream Flow MGD		Upstream Conc. (C_s) $\mu\text{g/L}$		Effluent Flow MGD		Effluent Conc. (C_e) $\mu\text{g/L}$		Downstream Conc. (C_d) $\mu\text{g/L}$		Criteria $\mu\text{g/L}$		Reasonable Potential	
	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic	Acute	Chronic
Copper	0.344		0		0.03	0.02	14.9		(1.2)	(0.8)	18.6	12.1	No	No
TRC							148.1	96.6	(11.9)	(5.3)	19	11	No	No

No parameters were found to have a reasonable potential to cause or contribute to an excursion above water quality standards.

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 (CWA), 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: **MA0040321**

PUBLIC NOTICE NUMBER: **MA-012-20**

NAME AND MAILING ADDRESS OF APPLICANT:

**Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway
Cambridge, MA 02138**

NAME AND ADDRESS OF THE FACILITY WHERE DISCHARGE OCCURS:

**Shire Human Genetic Therapies, Inc.
205 Alewife Brook Parkway
Cambridge, MA 02138**

RECEIVING WATER: **Alewife Brook (MA 93-45)
Mystic River Watershed - Class B**

The U.S. Environmental Protection Agency (EPA) has developed a draft permit for the Shire Human Genetic Therapies, Inc in Cambridge, 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:

Nathaniel Chien
U.S. Environmental Protection Agency – Region 1
5 Post Office Square, Suite 100 (06-1)
Boston, MA 02109-3912
Telephone: (617) 918-1649
Chien.Nathan@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 by appointment, 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