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come into compliance with §§ 125.60 and 125.65, as determined appropriate by EPA on a case-by-case basis. Such additional time, however, shall not extend beyond August 9, 1996. This paragraph does not apply to any application that was initially tentatively approved, but as to which EPA withdrew its tentative approval or issued a tentative denial prior to February 4, 1987.

§ 125.60 Primary or equivalent treatment requirements.

(a) The applicant shall demonstrate that, at the time its modification becomes effective, it will be discharging effluent that has received at least primary or equivalent treatment.

(b) The applicant shall perform monitoring to ensure, based on the monthly average results of the monitoring, that the effluent it discharges has received primary or equivalent treatment.

(c)(1) An applicant may request that the demonstration of compliance with the requirement under paragraph (b) of this section to provide 30 percent removal of BOD be allowed on an averaging basis different from monthly (e.g., quarterly), subject to the demonstrations provided in paragraphs (c)(1)(i), (ii) and (iii) of this section. The Administrator may approve such requests if the applicant demonstrates to the Administrator's satisfaction that:

(i) The applicant's POTW is adequately designed and well operated;

(ii) The applicant will be able to meet all requirements under section 301(h) of the CWA and these subpart G regulations with the averaging basis selected; and

(iii) The applicant cannot achieve 30 percent removal on a monthly average basis because of circumstances beyond the applicant's control. Circumstances beyond the applicant's control may include seasonally dilute influent BOD concentrations due to relatively high (although nonexcessive) inflow and infiltration; relatively high soluble to insoluble BOD ratios on a fluctuating basis; or cold climates resulting in cold influent. Circumstances beyond the applicant's control shall not include less concentrated wastewater due to excessive inflow and infiltration (I&I). The determination of whether the less con-

centrated wastewater is the result of excessive I&I will be based on the definition of excessive I&I in 40 CFR 35.2005(b)(16) plus the additional criterion that inflow is nonexcessive if the total flow to the POTW (i.e., wastewater plus inflow plus infiltration) is less than 275 gallons per capita per day.

(2) In no event shall averaging on a less frequent basis than annually be allowed.

[59 FR 40658, Aug. 9, 1994, as amended at 61 FR 45833, Aug. 29, 1996]

§ 125.61 Existence of and compliance with applicable water quality standards.

(a) There must exist a water quality standard or standards applicable to the pollutant(s) for which a section 301(h) modified permit is requested, including:

(1) Water quality standards for biochemical oxygen demand or dissolved oxygen;

(2) Water quality standards for suspended solids, turbidity, light transmission, light scattering, or maintenance of the euphotic zone; and

(3) Water quality standards for pH.

(b) The applicant must: (1) Demonstrate that the modified discharge will comply with the above water quality standard(s); and

(2) Provide a determination signed by the State or interstate agency(s) authorized to provide certification under §§ 124.53 and 124.54 that the proposed modified discharge will comply with applicable provisions of State law including water quality standards. This determination shall include a discussion of the basis for the conclusion reached.

§ 125.62 Attainment or maintenance of water quality which assures protection of public water supplies; assures the protection and propagation of a balanced indigenous population of shellfish, fish, and wildlife; and allows recreational activities.

(a) *Physical characteristics of discharge.* (1) At the time the 301(h) modification becomes effective, the applicant's outfall and diffuser must be located and designed to provide adequate

initial dilution, dispersion, and transport of wastewater such that the discharge does not exceed at and beyond the zone of initial dilution:

(i) All applicable water quality standards; and

(ii) All applicable EPA water quality criteria for pollutants for which there is no applicable EPA-approved water quality standard that directly corresponds to the EPA water quality criterion for the pollutant.

(iii) For purposes of paragraph (a)(1)(ii) of this section, a State water quality standard “directly corresponds” to an EPA water quality criterion only if:

(A) The State water quality standard addresses the same pollutant as the EPA water quality criterion and

(B) The State water quality standard specifies a numeric criterion for that pollutant or State objective methodology for deriving such a numeric criterion.

(iv) The evaluation of compliance with paragraphs (a)(1) (i) and (ii) of this section shall be based upon conditions reflecting periods of maximum stratification and during other periods when discharge characteristics, water quality, biological seasons, or oceanographic conditions indicate more critical situations may exist.

(2) The evaluation under paragraph (a)(1)(ii) of this section as to compliance with applicable section 304(a)(1) water quality criteria shall be based on the following:

(i) *For aquatic life criteria:* The pollutant concentrations that must not be exceeded are the numeric ambient values, if any, specified in the EPA section 304(a)(1) water quality criteria documents as the concentrations at which acute and chronic toxicity to aquatic life occurs or that are otherwise identified as the criteria to protect aquatic life.

(ii) *For human health criteria for carcinogens:* (A) For a known or suspected carcinogen, the Administrator shall determine the pollutant concentration that shall not be exceeded. To make this determination, the Administrator shall first determine a level of risk associated with the pollutant that is acceptable for purposes of this section. The Administrator shall then use the

information in the section 304(a)(1) water quality criterion document, supplemented by all other relevant information, to determine the specific pollutant concentration that corresponds to the identified risk level.

(B) For purposes of paragraph (a)(2)(ii)(A) of this section, an acceptable risk level will be a single level that has been consistently used, as determined by the Administrator, as the basis of the State’s EPA-approved water quality standards for carcinogenic pollutants. Alternatively, the Administrator may consider a State’s recommendation to use a risk level that has been otherwise adopted or formally proposed by the State. The State recommendation must demonstrate, to the satisfaction of the Administrator, that the recommended level is sufficiently protective of human health in light of the exposure and uncertainty factors associated with the estimate of the actual risk posed by the applicant’s discharge. The State must include with its demonstration a showing that the risk level selected is based on the best information available and that the State has held a public hearing to review the selection of the risk level, in accordance with provisions of State law and public participation requirements of 40 CFR part 25. If the Administrator neither determines that there is a consistently used single risk level nor accepts a risk level recommended by the State, then the Administrator shall otherwise determine an acceptable risk level based on all relevant information.

(iii) *For human health criteria for noncarcinogens:* For noncarcinogenic pollutants, the pollutant concentrations that must not be exceeded are the numeric ambient values, if any, specified in the EPA section 304(a)(1) water quality criteria documents as protective against the potential toxicity of the contaminant through ingestion of contaminated aquatic organisms.

(3) The requirements of paragraphs (a)(1) and (a)(2) of this section apply in addition to, and do not waive or substitute for, the requirements of §125.61.

(b) *Impact of discharge on public water supplies.* (1) The applicant’s modified discharge must allow for the attainment or maintenance of water quality

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which assures protection of public water supplies.

(2) The applicant's modified discharge must not:

(i) Prevent a planned or existing public water supply from being used, or from continuing to be used, as a public water supply; or

(ii) Have the effect of requiring treatment over and above that which would be necessary in the absence of such discharge in order to comply with local and EPA drinking water standards.

(c) *Biological impact of discharge.* (1) The applicant's modified discharge must allow for the attainment or maintenance of water quality which assures protection and propagation of a balanced indigenous population of shellfish, fish, and wildlife.

(2) A balanced indigenous population of shellfish, fish, and wildlife must exist:

(i) Immediately beyond the zone of initial dilution of the applicant's modified discharge; and

(ii) In all other areas beyond the zone of initial dilution where marine life is actually or potentially affected by the applicant's modified discharge.

(3) Conditions within the zone of initial dilution must not contribute to extreme adverse biological impacts, including, but not limited to, the destruction of distinctive habitats of limited distribution, the presence of disease epicenter, or the stimulation of phytoplankton blooms which have adverse effects beyond the zone of initial dilution.

(4) In addition, for modified discharges into saline estuarine water:

(i) Benthic populations within the zone of initial dilution must not differ substantially from the balanced indigenous populations which exist immediately beyond the boundary of the zone of initial dilution;

(ii) The discharge must not interfere with estuarine migratory pathways within the zone of initial dilution; and

(iii) The discharge must not result in the accumulation of toxic pollutants or pesticides at levels which exert adverse effects on the biota within the zone of initial dilution.

(d) *Impact of discharge on recreational activities.* (1) The applicant's modified discharge must allow for the attain-

ment or maintenance of water quality which allows for recreational activities beyond the zone of initial dilution, including, without limitation, swimming, diving, boating, fishing, and picnicking, and sports activities along shorelines and beaches.

(2) There must be no Federal, State, or local restrictions on recreational activities within the vicinity of the applicant's modified outfall unless such restrictions are routinely imposed around sewage outfalls. This exception shall not apply where the restriction would be lifted or modified, in whole or in part, if the applicant were discharging a secondary treatment effluent.

(e) *Additional requirements for applications based on improved or altered discharges.* An application for a section 301(h) modified permit on the basis of an improved or altered discharge must include:

(1) A demonstration that such improvements or alterations have been thoroughly planned and studied and can be completed or implemented expeditiously;

(2) Detailed analyses projecting changes in average and maximum monthly flow rates and composition of the applicant's discharge which are expected to result from proposed improvements or alterations;

(3) The assessments required by paragraphs (a) through (d) of this section based on its current discharge; and

(4) A detailed analysis of how the applicant's planned improvements or alterations will comply with the requirements of paragraphs (a) through (d) of this section.

(f) *Stressed waters.* An applicant must demonstrate compliance with paragraphs (a) through (e) of this section not only on the basis of the applicant's own modified discharge, but also taking into account the applicant's modified discharge in combination with pollutants from other sources. However, if an applicant which discharges into ocean waters believes that its failure to meet the requirements of paragraphs (a) through (e) of this section is entirely attributable to conditions resulting from human perturbations

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other than its modified discharge (including, without limitation, other municipal or industrial discharges, nonpoint source runoff, and the applicant's previous discharges), the applicant need not demonstrate compliance with those requirements if it demonstrates, to the satisfaction of the Administrator, that its modified discharge does not or will not:

- (1) Contribute to, increase, or perpetuate such stressed conditions;
- (2) Contribute to further degradation of the biota or water quality if the level of human perturbation from other sources increases; and
- (3) Retard the recovery of the biota or water quality if the level of human perturbation from other sources decreases.

§ 125.63 Establishment of a monitoring program.

(a) *General requirements.* (1) The applicant must:

(i) Have a monitoring program that is:

(A) Designed to provide data to evaluate the impact of the modified discharge on the marine biota, demonstrate compliance with applicable water quality standards or water quality criteria, as applicable, and measure toxic substances in the discharge, and

(B) Limited to include only those scientific investigations necessary to study the effects of the proposed discharge;

(ii) Describe the sampling techniques, schedules and locations (including appropriate control sites), analytical techniques, quality control and verification procedures to be used in the monitoring program;

(iii) Demonstrate that it has the resources necessary to implement the program upon issuance of the modified permit and to carry it out for the life of the modified permit; and

(iv) Determine the frequency and extent of the monitoring program taking into consideration the applicant's rate of discharge, quantities of toxic pollutants discharged, and potentially significant impacts on receiving water quality, marine biota, and designated water uses.

(2) The Administrator may require revision of the proposed monitoring

program before issuing a modified permit and during the term of any modified permit.

(b) *Biological monitoring program.* The biological monitoring program for both small and large applicants shall provide data adequate to evaluate the impact of the modified discharge on the marine biota.

(1) Biological monitoring shall include to the extent practicable:

(i) Periodic surveys of the biological communities and populations which are most likely affected by the discharge to enable comparisons with baseline conditions described in the application and verified by sampling at the control stations/reference sites during the periodic surveys;

(ii) Periodic determinations of the accumulation of toxic pollutants and pesticides in organisms and examination of adverse effects, such as disease, growth abnormalities, physiological stress, or death;

(iii) Sampling of sediments in areas of solids deposition in the vicinity of the ZID, in other areas of expected impact, and at appropriate reference sites to support the water quality and biological surveys and to measure the accumulation of toxic pollutants and pesticides; and

(iv) Where the discharge would affect commercial or recreational fisheries, periodic assessments of the conditions and productivity of fisheries.

(2) Small applicants are not subject to the requirements of paragraph (b)(1) (ii) through (iv) of this section if they discharge at depths greater than 10 meters and can demonstrate through a suspended solids deposition analysis that there will be negligible seabed accumulation in the vicinity of the modified discharge.

(3) For applicants seeking a section 301(h) modified permit based on:

(i) A current discharge, biological monitoring shall be designed to demonstrate ongoing compliance with the requirements of § 125.62(c);

(ii) An improved discharge or altered discharge other than outfall relocation, biological monitoring shall provide baseline data on the current impact of