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A. General Philosophy

The primary goal of the Division of Drinking Water (DDW) of the State Water Resources Control Board is to assure that all Californians are, to the extent possible, provided a reliable supply of safe drinking water. In furtherance of this goal, DDW continues to subscribe to the basic principle that only the best quality sources of water reasonably available to a water utility should be used for drinking. When feasible choices are available, the sources presenting the least risk to public health should be utilized. Furthermore, these sources should be protected against contamination. Whenever possible, lower quality source waters should be used for nonconsumptive uses, such as irrigation, recreation, or industrial uses, which pose lower health risk.

The use of contaminated water as a drinking water source always poses a greater health risk and hazard to the public than the use of an uncontaminated source because of the chance that the necessary treatment may fail. Thus, the use of an extremely impaired source should be avoided where alternatives are available, unless the additional health risks, relative to the use of other available drinking water sources, are known, minimized, and considered acceptable.

Extremely impaired sources are those that contain, or are likely to contain, very high concentrations of contaminants (see Section B), multiple contaminants, or unknown contaminants (such as groundwater subject to contamination from a Superfund site).

Drinking water quality and public health protection must be given greater consideration than costs or cost savings when evaluating alternative drinking water sources or treatment processes.

DDW recognizes that there are extremely impaired sources in California that need to be remediated and for which the resulting product water represents a significant resource that should not be wasted. In some situations, it may be reasonable to consider the use of these treated extremely impaired sources for domestic use. Some communities may not have any choice, due to limitations in their water supply. In such cases, the public health principles as set forth in this process memorandum should be used to guide the evaluation. If the water is determined to be too contaminated to be reliably treated, or if the potential risk to public health is determined to be too far above acceptable levels, the extremely impaired source should not be permitted for domestic use.

This update of the 97-005 memorandum seeks to incorporate lessons learned from DDW’s review of projects over the past decade, and to provide information to staff and to water system consultants on what is necessary for a thorough review. It identifies information that is needed for review of a proposal to use an extremely impaired source, thereby minimizing missteps and repetition by project proponents/applicants, and the workload that those activities generate.
B. Purpose of Process Memo 97-005

This memorandum was originally issued in 1997 to address proposals to use water generated from large remediation projects [e.g., Superfund cleanups, that is, sites under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)], in which federal and/or state environmental agencies—not drinking water regulators—and their consultants seek to make use of the project-generated water.

In these cases, federal and state agencies as well as the “responsible parties” involved in site cleanup are focused on removal of the “contaminant mass” from soil and groundwater to prevent the spread of contamination. These entities are guided by particular federal and state statutes, such as CERCLA and the Clean Water Act, which may not fully address the requirements of DDW and its implementation of the federal and state Safe Drinking Water Acts.

The proponents/applicants of a CERCLA environmental cleanup project may focus on capture of the contaminant plume and treatment of the contaminated water for a relatively short list of identified or targeted contaminants to remove their mass from the soil or groundwater. DDW, on the other hand, is entrusted to “impose permit conditions … it deems necessary to assure a reliable and adequate supply of water at all times that is pure, wholesome, potable and does not endanger the health of consumers” (California Health and Safety Code Section 116540) and to take the health risk posed by all the contaminants into consideration. The priorities of project proponents/applicants may have a slightly different emphasis than those of DDW, or of the community that is proposed to receive this water as part of its drinking water supply. For example, high nitrates in the groundwater associated with past agricultural practices may not be a targeted contaminant to be removed for the CERCLA project. However, DDW will require the nitrate to be treated prior to use as a domestic water source and the cost of the treatment will need to be agreed upon by parties involved.

Because of the inherent risk associated with the extremely impaired source, the evaluation for its use, including examination of the sources and the levels of contamination, the acceptability and reliability of the treatment processes and the adequacy of the monitoring and maintenance program is far more detailed and deeper in scope, in comparison, than a typical drinking water source. Therefore, it is important from the outset that project proponents/applicants (which must include a water system) realize if the proposed beneficial use of the water generated by the cleanup project is for domestic water supply, it is in the project proponents’ interest to cooperate with DDW so that the evaluation will proceed in an efficient manner and a decision can be quickly reached.

The purpose of this process document is to set forth the process and principles by which DDW would evaluate the proposals, establish appropriate permit conditions, and approve the use of an extremely impaired source for direct potable use.
C. Extremely Impaired Sources

An extremely impaired source is a source that meets two or more of the following criteria:

- contains a contaminant that exceeds 10 times its MCL based on chronic health effects,
- contains a contaminant that exceeds 3 times its MCL based on acute health effects for example, nitrate or perchlorate,
- contains a contaminant that exceeds 10 times its NL, based on chronic health effects,
- contains a contaminant that exceeds 3 times its NL, based on acute health effects,
- contains one or more contaminants that meet any of the criteria of the four bullet points above and the source has not been adequately characterized by responsible parties,
- is a surface water that requires more than 4 log Giardia/5 log virus reduction,
- is a surface water source that on an annual average contains more than five percent treated wastewater, unless it is associated with an approved drinking water-related surface water augmentation project,
- is extremely threatened with contamination due to known contaminating activities within the long term, steady state capture zone of a drinking water well or within the watershed of a surface water intake,
- contains a mixture of contaminants of health concern beyond what is typically seen in terms of number and concentration of contaminants,
- is designed to intercept known contaminants of health concern.

Examples include:

- Extremely contaminated ground water
- Sewage effluent dominated surface water
- Oilfield produced water
- Water that is predominantly recycled water (unless associated with an approved drinking water-related project using groundwater replenishment or surface water augmentation); urban storm drainage; treated or untreated wastewater; or agricultural return water
- Products of toxic site cleanup programs

If the impaired source produces or would be expected to produce water that meets only one of the above criteria, it may not be considered extremely impaired. However, DDW may require the submittal of a technical document addressing the elements listed in Sections D, subsections 1, 2, 3 and 4, as presented below. This is to ensure that no uncommon contaminants are present at levels that may pose a potential health concern.
These determinations will be site specific, and DDW will set appropriate conditions within the domestic water supply permit. DDW recognizes that the circumstances surrounding each situation may be different. Project proponents/applicants who copy or use prior 97-005 evaluations when preparing their own evaluations must recognize that a prior approval of one project should not be interpreted as a precedent for another project.

D. Elements of an Evaluation Process for an Extremely Impaired Drinking Water Source

**IT IS IMPORTANT TO NOTE:**

- **The steps in the Evaluation Process are sequential in nature. That is, each step relies upon the findings and conclusions of the prior step.** These steps should not be done concurrently, e.g., presentation of the treatment equipment proposal and reliability sections should proceed only after the Drinking Water Source Assessment and Contaminant Assessment (SA/CA) and Raw Water Quality Characterization are made final.

- **Each step should include clear, specific detailed statements of findings, interpretations, and conclusions as they relate to the goal of each step** (not just a statement of the tasks that were performed).

1. Drinking Water Source Assessment and Contaminant Assessment

This section includes a discussion of Drinking Water Source Assessment (SA) and Contaminant Assessment (CA), plus addition information pertinent to both assessments.

a. Drinking Water Source Assessment (SA)

The purpose of the drinking water source assessment for the extremely impaired source is to determine the extent to which the aquifer or surface water is vulnerable to contaminating activities in the area. There may be additional contaminants associated with activities that contribute to the known contamination, or other contamination sources that have yet to impact the drinking water source. There may not be drinking water MCLs, advisory notification levels or monitoring requirements established for these additional contaminants, but health related information may be available through other programs. The assessment should include:

- Delineation of the source water capture zones (groundwater sources) or watershed areas (surface water sources)
  - For groundwater sources: Evaluate the hydrogeology and delineate capture zones. A description, including maps and hydrogeologic cross-sections, of the
capture zones of the proposed drinking water sources must be provided. This should include a discussion of how the capture zones were determined, assumptions and methods used, and time frames. Supplemental field work may be necessary to fill in the data gap in hydrogeological information.

- For surface water sources: Delineate watershed areas
- Identification of contaminant sources
  - Identify the origin of known contaminants already detected in the source water and predict contaminant level trends
  - Present a list which identifies all chemicals or contaminants used at or generated by facilities responsible for the known contamination
  - Identify all potential contaminant sources (including the potential contamination sources currently or historically present within the capture zones or watershed areas)
  - Present a list that identifies all other potential chemicals or contaminants that may be associated with potential contaminant sources.
  - Present maps showing the locations of known or suspected contaminating activities, including the spill or disposal sites

b. Contaminant Assessment (CA)

The purpose of the contaminant assessment is to provide a characterization of the contamination of soils and groundwater at and around the contamination and former contamination sites located within the long-term capture zone or watershed areas of the drinking water source. This means there must be a description of the history of chemical activities at the site(s), including intentional releases, spills and waste management or if applicable, remediation practices. The characterization of the known contamination in soil and water includes identification of the chemicals involved, and their concentrations in soil and water at and near the contaminated site. This can be supplemented by or presented as plume maps.

If there is an existing system of monitoring wells at the site, data from these wells should be utilized for this step. If there is an existing Remedial Investigation/Feasibility Study (RI/FS) or other environmental documentation, it should also be utilized as an informational source. However, existing cleanup projects typically focus on only a few major contaminants and additional site specific sampling and analyses will often be required to fill in any data gaps that come into play when proposing a drinking water source. This could include analysis for chemical contaminants which may not been previously tested for, or should have been tested at lower detection levels.

For example, the project proponents/applicants often have to check for low levels of less traditional drinking water contaminants including contaminants of interest to DDW, such as nitrosamines, 1,4-dioxane or site-specific contaminants, e.g. RDX, TNT or other explosives, which may have been largely ignored during the cleanup of other major “target contaminants.”
Based on site history, chemical usages, fate and transport of the contaminants in the environment, a list of additional potential source water contaminants must be prepared, and sampled for, if not previously performed. All contaminants with potential health effects must be identified and considered. Attention should be paid to the following chemicals with regard to activities or conditions that may contribute to possible presence:

- Title 22 drinking water regulated chemicals and Title 22 unregulated chemicals requiring monitoring
- Chemicals for which drinking water notification levels are established
- Chemicals listed pursuant to Safe Drinking Water and Toxic Enforcement Act of 1986, to the extent feasible
- Microbiological quality
- Priority pollutants
- Hazardous wastes and constituents mentioned in 40CFR Part 261, including Appendices VII and VIII
- Chemicals of Emerging Concern as recommended by the State Water Resources Control Board’s Science Advisory Panel in the most recent version of the “Monitoring Strategies for Chemicals of Emerging Concern (CEC) in Recycled Water” report.

Tentatively identified chemicals (TICs) and peaks signifying the presence of unidentified chemical species that show up on GC/MS scans should also be investigated to fully evaluate the water quality in the source area. If such contaminants are consistently detected, they should be included in the Raw Water Quality Characterization (RWQC). If the RWQC estimates them to be detectable at the production well(s), their treatability must be evaluated to see if they can be removed. If these contaminants cannot be destroyed or removed by the proposed treatment, the applicant will need to expend time and efforts needed to identify such compounds and then determine if they are innocuous or of health concern, or modify the proposed treatment.

Based on the information gathered in the steps above, the project proponents/applicants should present a map showing the intersection of the proposed water source capture zone with the contaminated areas and plumes. The project proponents/applicants must also identify the list of contaminants of concern and the potential contaminants of concern for the proposed drinking water sources.

The contaminant concentration ranges ascertained in the CA are used in the subsequent step of estimating the concentration of contaminants at the inlet of the proposed treatment equipment.

c. Both Assessments

The text of reports submitted by the proponent/applicant should be as quantitatively descriptive and specific as possible. Although presentation of information in graphical
or tabular forms is welcome, general or vague statements, with detailed information buried in voluminous tables or appendices is not acceptable.

2. Full Characterization of the Raw Water Quality

The end product of this step is to characterize the quality of the water that will be fed into the treatment system, so that the treatment system is properly designed. This should include an evaluation of all the contaminants found present in the CA as to whether they are or will eventually appear at the production/extraction wells and plant influent.

The proponent/applicant should include a clear explanation of how the characterization was performed. This can include an examination of current quality of the water at the extraction wells, if they are available for sampling, but must include an estimate or projection of concentration trends and variability that the production wells will be showing in the future. If a mathematical averaging or modeling technique is used, all assumptions must be identified and justified.

The appropriate level of monitoring and treatment to produce a safe drinking water cannot be determined unless the raw water quality is fully understood. The following categories should be evaluated to fully characterize the source water quality:

- Title 22 drinking water regulated chemicals, including lead and copper, and Title 22 unregulated chemicals for which monitoring is required
- Chemicals for which drinking water notification levels are established
- Chemicals listed pursuant to Safe Drinking Water and Toxic Enforcement Act of 1986, to the extent feasible
- Microbiological quality
- Priority pollutants
- Gross contaminant measures [total organic carbon (TOC), etc.]
- Hazardous wastes and constituents mentioned in 40CFR Part 261, including Appendices VII and VIII
- Chemicals of Emerging Concern as recommended by the State Water Resources Control Board’s Science Advisory Panel in the most recent version of the “Monitoring Strategies for Chemicals of Emerging Concern (CEC) in Recycled Water” report.
- Any additional compounds identified as contaminants of concern or the potential contaminants of concern during the CA process.

The detection of any additional contaminant identified during the raw water quality characterization tests (step 2) should require a re-assessment of the SA/CA in terms of that contaminant (step 1).

The project proponents/applicants should determine variability of contaminant concentrations with time (seasonal and long term), with pumping rate and with any other variable that may change the concentrations of contaminants reaching the treatment plant influent and explain how the design concentrations were arrived at. The project
proponents/applicants should include in this section a table of the contaminants expected in the raw water at the plant inlet and their expected range of concentrations. The table should be accompanied by a discussion of the degree of uncertainty and the safety factor commensurate with the degree of uncertainty of the concentrations.

A second table should be prepared which lists additional potential contaminants associated with the contaminating activities. These compounds could include for example, those which are associated with releases or have been consistently detected in soil or groundwater beneath or around the contamination sites, and which were not included in the first list. Generally, these would not factor into the treatment plant design, but should be checked for on an appropriate schedule in production and upstream monitoring wells.

3. Drinking Water Source Protection

If the use of an extremely impaired source is to be approved as a drinking water supply, the origin of contamination must be controlled to:

- Prevent the level of contamination from rising.
- Minimize the dependence on treatment for contaminant removal by the public drinking water system.

There must be a program in place to control the level of contamination. At a minimum, best management practices for waste handling and waste reduction should be required at the origin of the contamination. In addition, an evaluation of cleanups, mitigations and remediations within the capture zones of the proposed production well or surface water source should be performed to demonstrate that releases are not continuing.

Water systems proposing to use an extremely impaired source can take specific steps to develop a program to protect all of its drinking water sources. Such a program could include keeping informed of all environmental cleanups within the system’s jurisdiction, being aware of any new facilities handling hazardous material or hazardous wastes and ensuring, to the extent feasible, that such facilities are in compliance with current hazardous waste regulations and handling of toxic compounds so that the risk of future releases are minimized.

- The drinking water source protection program should identify specific personnel that will act as liaisons with agencies that may be involved with permits involving hazardous materials and wastes as well as remediations or cleanups undertaken by USEPA, the California Department of Toxic Substances Control (DTSC), the local Regional Water Quality Control Board, and the local health department or fire department.

- These liaisons should be aware of all such activities, and attend public meetings and hearings held by these agencies as well as to be sure to be on all project mailing
lists for notices and fact sheets published by state and federal environmental agencies.

Included in the design of the treatment facilities, a source treatment facility, usually at the origin of the contamination, low flow, hot spot type treatment is needed. The source treatment facility effluent will not be used as a domestic source. In addition, monitoring between the origin of the contamination and the drinking water source (from a monitoring well or monitoring wells) should be conducted to determine the level of contamination, to demonstrate contaminant control, and to reasonably assure that the contamination level will not increase at production/extraction wells.

4. Effective Treatment and Monitoring

a. Treatment

The 97-005 submittal must include a treatability assessment for all contaminants projected to be detectable at the production/extraction wells. DDW has encountered situations associated with Superfund cleanups that focus on MCLs only and only for a few major “target contaminants”. This is not satisfactory for an extremely impaired source. The applicant and consultant must address all contaminants of health concern and to treat down to the lowest concentration feasible. In many cases, this may turn out to be the level of non-detection (ND) or to the detection limit for purposes of reporting (DLR). Similarly, treatment for drinking water will likely require more effective and reliable contaminant removal to a lower level than is associated with site cleanup. Hence, project proponents will need to adopt a different approach for such projects, keeping in mind the intended use of water produced by the project.

With more extensive “drinking water-oriented” concerns kept in mind, the treatment process used to treat the extremely impaired source prior to direct usage in a domestic water distribution system must be commensurate with the degree of risk associated with the contaminants present. As a minimum, treatment of extremely impaired sources should include use of the best available treatment technology defined for the contaminant(s) by the US Environmental Protection Agency or DDW. Preference should be given to proven, reliable treatment technologies. Furthermore, the treatment processes must have reliability features consistent with the type and degree of contamination.

All treatment processes used must be optimized to reliably produce water that contains the lowest concentration of contaminants feasible at all times. The entire flow from the extremely impaired source needs to pass through the complete treatment process or processes unless a reasonable alternative is available. Any water from other sources that is available for blending prior to entry into the distribution system should be used to provide an additional safety factor.
Multi-barrier treatment is a set of independent treatment processes placed in series and designed and operated to reduce the levels of a contaminant. Each barrier should effectively reduce the contaminant by a significant fraction of the total required reduction. Multi-barrier treatment may be appropriate when:

- The primary treatment is not sufficiently reliable;
- The primary treatment is of uncertain effectiveness;
- There is no direct way to measure the contaminant (e.g., pathogenic microorganism);
- The health effect of the contaminant is acute; and/or
- Very large reductions in contaminant concentration are required.

In situations where there is additionally a regional or basin-wide contaminant (e.g., nitrates or TDS) that is not coming from identified contamination areas, blending with another water source not involved with the cleanup may be considered.

b. Monitoring

Monitoring associated with a proposal to use an extremely impaired source as a drinking water supply will likely require more extensive monitoring, in terms of frequency of testing as well as numbers of contaminants, than is associated with typical drinking water sources. Detection and reporting limits for all analytical chemistry work should be as low as practicable. In all cases, the effluent from the proposed treatment processes must be tested for regulated drinking water contaminants using drinking water analytical methods rather than analytical methods for hazardous waste or solid wastes. Other contaminants tested for should be reported using similar reporting limits.

Supplemental monitoring wells are typically required to provide periodic glimpses of the original contamination and to provide an early warning in case unexpectedly high concentrations or new contaminants are moving toward production/extraction well(s). The monitoring program for the production/extraction wells and up-gradient monitoring wells must be crafted to check for additional contaminants identified in the SA/CA and RWQC that potentially may migrate to the wells. In addition, the extremely impaired water source may contain a mixture of contaminants, some of which may be unidentified. TICs and unidentified contaminants must be addressed. If the source is approved by the DDW, the associated permit amendment should include a provision to update analytical methods and monitoring associated with the site to provide an appropriate level of vigilance.

The water quality surveillance plan should include specific proposed monitoring wells or monitoring locations and a proposed sampling and analysis plan. The purpose of these requirements is to provide early warning of any unexpected increases in contaminant concentrations or detections of additional contaminants, so that appropriate actions can be taken.
The submittal must also include a sampling and analysis plan for the drinking water source(s) and at appropriate locations in the treatment plant. Plant compliance should rely on drinking water analytical methods if available for the plant effluent, usually on a weekly basis. Operational monitoring of locations within the treatment train must be crafted on a case-by-case basis. All proposed monitoring plans must include the proposed analytical method and reporting limits.

If the project is permitted, the permit may contain a provision that allows for adjustment of the monitoring program based on additional information.

c. Treatment and Monitoring Program Proposal

The description of the proposed treatment and monitoring should include the following:

- Performance standards (if available, also use a field measurable indicator of treatment efficiency);
  - Identify level to assure compliance with the treatment objective
  - The treatment objective for all contaminants should be optimized to the lowest extent feasible and must assure compliance with the MCL at all times.
  - In addition to the treatment objective optimization for regulated contaminants, treatment should also be optimized to reduce the concentrations of unregulated contaminants below NLs, where NLs have been established.

Treatment at facilities treating water from an extremely impaired source containing specific contaminants for which the MCL is higher than the public health goal (PHG), should be designed and operated to meet or be as near as possible to the PHG where this can be accomplished in a cost effective manner.

- Operations plan that identifies all operational procedures, failure response triggers, and loading rates, including:
  - Process monitoring plan
  - Process optimization procedures
  - Established water quality objectives or goals
  - Level of operator qualification
  - Frequent, thorough inspections to ensure that mechanical or rotating equipment is operating as designed. Finding evidence of a mechanical problem may provide a quicker indication of a problem than waiting for analytical results.

- Reliability features
  - Response Plan for failure to meet the treatment objective
  - Alternative disposal methods
  - Shutdown triggers and restart procedures

- Compliance monitoring and reporting program
Notification plan: The water system’s emergency notification plan should be used as a starting point when addressing the notification requirement. A decision tree can also be utilized to explain how various situations will be handled.

Extremely impaired source water quality surveillance plan, which includes monitoring between the origin of the contamination and the extremely impaired source that is proposed for drinking water.

d. DDW Staff Evaluation of Treated Water Objectives or Goals

DDW seeks to minimize the potential for cumulative risks from the actual and potential contaminants in the extremely impaired source. The project proponents/applicants must set the treated water objectives or goals for the contaminants to the lowest concentrations feasible. By providing enhanced treatment, DDW believes there is a public health benefit that may accrue, in that the enhanced treatment may reduce or remove other contaminants that may be present but are unregulated and/or unknown.

This subsection describes a practical method DDW Staff may use in evaluating the treated water objectives or goals of the combined effluent of the proposed facility, to ensure the cumulative risk of multiple contaminants under normal operation has been reasonably addressed by the project proponents/applicants.

Use of MCL-Equivalents to Evaluate Treated Water Goals

To judge the appropriateness of treatment for an extremely impaired source with multiple contaminants, the following assessment could be used. The goal here is to keep the concentrations of contaminants as low as possible, evaluating them in terms of MCL-equivalents, or when MCLs are not available, surrogate values for MCL-equivalents. Each group of contaminants (acute vs chronic endpoint) should be kept separate, with a goal for each group to be below a single MCL-equivalent, as described below.

For purposes of this step an MCL-equivalent is such that, for example, two contaminants each at half its MCL is one MCL-equivalent, while four contaminants each at one-quarter of its MCL is one MCL-equivalent.

Where an MCL is not available for a contaminant, a surrogate value is used. For non-regulated contaminants with DDW Notification Levels (NLs), this surrogate value is equal to one-tenth of the contaminant’s Response Level, or 0.1 RL (Occasionally, the NL for a contaminant is higher than the health risk-based level, due to analytical limitations. Because analytical capability is one of the factors to be considered when an MCL is developed, the NL may be used as the surrogate value in the MCL-equivalent calculation when 0.1 RL is lower than the NL. Please note that DDW reviews laboratory analytical capabilities periodically, and the NLs may be lowered to values closer to the health-based advisory values based on the outcome of the review).

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The RL is the level at which DDW recommends removal from service of the source that contains the contaminant. The RL is equal to a $10^{-4}$ risk level for contaminants considered to pose a carcinogenic risk, and 10 times the NL for non-carcinogens. For non-carcinogens, the NL is the concentration considered to pose no significant health risk, taking into account the no observable adverse effect level from laboratory animal studies, appropriate uncertainty factors to scale from laboratory animal to human exposures, and other considerations used in standard human health risk assessments. Thus, the surrogate MCL values to use for chemicals with RLs correspond to $10^{-5}$ risk for carcinogens, and to the NL for non-carcinogens. For this evaluation, the NL can be considered analogous to the PHG, and the RL, analogous to 10 times the MCL, at which point sources are removed from service. In between are the MCL and its analog for this evaluation, 0.1 RL.

Applying the same principal, for non-regulated contaminants without DDW NLs, but with USEPA Health Advisory Levels, this surrogate value is equal to $10^{-5}$ cancer risk level (that is, one-tenth of the contaminant’s Health Advisory Level for a carcinogen, which is the concentration of a contaminant in water corresponding to an estimated lifetime cancer risk of 1 in 10,000, or $10^{-4}$ cancer risk level). For non-carcinogens, the Lifetime Health Advisory Level may be used as the surrogate. The Lifetime HA is the concentration of a chemical in drinking water that is not expected to cause any adverse noncarcinogenic effects for a lifetime of exposure, calculated using the oral Reference Dose and incorporating a drinking water Relative Source Contribution factor of contaminant-specific data or a default of 20 percent of total exposure from all sources.

Where NLs/RLs or USEPA Health Advisory Levels do not exist, risk assessments following standard procedures can enable the determination of the surrogate MCL-equivalent values to use for this evaluation.

If known contaminants can be reduced to an MCL-equivalent of 1 or lower or even to 0 for the mixture of contaminants, it is DDW’s belief that a prudent and practical approach has been implemented in providing extra caution for the protection of public health. This approach also helps in identifying the contaminant that contributes most to the MCL-equivalent, which may be useful in focusing additional treatment.

The assessment should include (in a table or tables):

- A list of chemicals that will be or are likely to be present in water delivered to consumers under normal operations and the maximum anticipated concentration. (NOTE: exposures from treatment failures are discussed in section 5).
- The MCL (or action level for lead and copper), 0.1 RL or similar concentration determined from an USEPA Health Advisory Level or other appropriate risk assessment for the contaminant, and its DLR.
- The maximum anticipated concentration of each contaminant
The ratio of the concentration of each contaminant to its MCL, 0.1 RL, or similar concentration determined from an USEPA Health Advisory Level or other appropriate risk assessment. Chemicals should be separated by the primary health concern, e.g., nitrate and perchlorate, which are considered to pose acute health risk; arsenic, hexavalent chromium, some organic chemicals and others, which are considered to pose chronic health risks such as the risk of cancer; and boron, fluoride, selenium, vanadium and others, which are considered to pose chronic, non-cancer health risks.

Each ratio for an individual chemical should be determined. The goal is to have the sum of the ratios equal to 0. The sum of the MCL-equivalent ratios needs to be less than or equal to 1.

For example, consider an extremely impaired source that contains perchlorate, nitrate, TCE, arsenic, hexavalent chromium, NDMA, 1,4-dioxane, PFOA and PFOS at the levels presented in Table 1. The sum of the concentration ratios of 0.7 MCL-equivalents for the acute risk contaminants, indicates that this level of treatment would be acceptable (Table 1). The sum of 1.6 MCL-equivalents for the chronic, cancer health risk contaminants exceeds the 1 MCL-equivalent treatment requirement. In this example, the source does not contain contaminants posing chronic, non-cancer risks. If it has, the MCL-equivalent should be calculated separately for the chronic, non-cancer causing contaminants as well.

Additional treatment to reduce the chemicals to non-detect levels would reduce the MCL-equivalent total for the contaminants contributing to chronic health risk (see below, and Table 2). Also, if arsenic or hexavalent chromium can be demonstrated to occur as a result of the natural background, there may be some allowance given (see below, and Table 3).
Table 1: Compare contaminants in treated water with their MCLs (or surrogate MCLs)

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Maximum Effluent Concentration</th>
<th>MCL (or surrogate MCL*)</th>
<th>Concentration/MCL</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute, Non-Cancer Endpoint</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitrate (as NO₃)</td>
<td>30,000</td>
<td>45,000</td>
<td>30,000/45,000</td>
<td>0.7</td>
</tr>
<tr>
<td>Perchlorate</td>
<td>ND</td>
<td>6</td>
<td>0/6</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL – MCL-equivalent</td>
<td></td>
<td></td>
<td></td>
<td>0.7 ≤ 1</td>
</tr>
<tr>
<td>(acute effects)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic, Cancer Endpoint</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulated Contaminants</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>TCE</td>
<td>ND</td>
<td>5</td>
<td>0/5</td>
<td>0</td>
</tr>
<tr>
<td>Arsenic</td>
<td>7</td>
<td>10</td>
<td>7/10</td>
<td>0.7</td>
</tr>
<tr>
<td>Hexavalent Chromium</td>
<td>6</td>
<td>10**</td>
<td>6/10</td>
<td>0.6</td>
</tr>
<tr>
<td>Non-Regulated Contaminants</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NDMA</td>
<td>0.01</td>
<td>0.03*</td>
<td>0.01/0.03</td>
<td>0.3</td>
</tr>
<tr>
<td>1,4-Dioxane</td>
<td>0.8***=ND</td>
<td>3.5*</td>
<td>0/3.5</td>
<td>0</td>
</tr>
<tr>
<td>PFOA</td>
<td>ND</td>
<td>0.0051*</td>
<td>0/0.0051</td>
<td>0</td>
</tr>
<tr>
<td>PFOS</td>
<td>ND</td>
<td>0.0065*</td>
<td>0/0.0065</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL – MCL-equivalent</td>
<td></td>
<td></td>
<td></td>
<td>1.6 &gt; 1</td>
</tr>
<tr>
<td>(chronic effects)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concentrations are in units of µg/L.

* One-tenth of the RL is used as the surrogate MCL. When the value of one-tenth of the Response Level is lower than the NL, the NL is used as the MCL surrogate.

** The MCL for hexavalent chromium of 10 µg/L was repealed in September 2017 due to a court order. DDW is in the process of adopting a new MCL.

*** Is below a level considered reliably detectable by DDW; therefore, the maximum concentration is considered ND and the ratio is set to zero.

Note: Values should include one significant figure.

**DLRs Limit the Required Levels of Treatment**

From Section 4, Part C, we know the project proponent should remove the contaminant to the level as near the PHG as possible. For nitrate in this example, the concentration is already below its PHG, so the goal of meeting the PHG is met. However, nitrate still needs to be added to the calculation as it contributes to the cumulative MCL-equivalent for acute, non-cancer risk. The DLR often limits the ability to monitor the chemical. Therefore, treatment does not need to be to the level below the DLR, unless a lower concentration can easily be attained for the contaminant.
In the above example, additional treatment to reduce the concentration of nitrate to below the DLR would reduce their contribution to 0 MCL-equivalents (see Table 2). Reducing the concentrations of arsenic, hexavalent chromium, NDMA and 1,4-dioxane to below their DLRs would be the best approach to minimize their contributions to the cumulative exposure. Note 1,4-dioxane in Table 1 is below its DLR and was removed from consideration (ratio = 0). NDMA is at its Notification Level. It contributes to the elevated MCL-equivalent. Substituting the treatment-derived ratios in Table 2 for the ratios in Table 1 shows, for example, that treatment of either arsenic or hexavalent chromium to ND, plus NDMA to ND would result in an MCL-equivalent equal to or lower than 1 (0.6, if treating arsenic and NDMA or 0.7, if treating hexavalent chromium and NDMA). Treatment of all three to ND would result in an MCL-equivalent of 0.

### Table 2: Consider reducing the contaminants in delivered water to below the DLRs

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Maximum Effluent Concentration</th>
<th>MCL (or surrogate MCL*)</th>
<th>Concentration/MCL</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute, Non-Cancer Endpoint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nitrate (as NO₃)</td>
<td>ND (&lt;2,000)</td>
<td>45,000</td>
<td>0/45,000</td>
<td>0</td>
</tr>
<tr>
<td>Perchlorate</td>
<td>ND (&lt;4)</td>
<td>6</td>
<td>0/6</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total – MCL-equivalent</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td><strong>Chronic, Cancer Endpoint</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TCE</td>
<td>ND (&lt;0.5)</td>
<td>5</td>
<td>0/5</td>
<td>0</td>
</tr>
<tr>
<td>Arsenic</td>
<td>ND (&lt;2)</td>
<td>10</td>
<td>0/10</td>
<td>0</td>
</tr>
<tr>
<td>Hexavalent Chromium</td>
<td>ND (&lt;1)</td>
<td>10**</td>
<td>0/10</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total – MCL-equivalent</td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td><strong>Non-regulated Contaminants</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NDMA</td>
<td>ND (&lt;0.005)</td>
<td>0.03*</td>
<td>0/0.03</td>
<td>0</td>
</tr>
<tr>
<td>1,4-Dioxane</td>
<td>ND (&lt;1)</td>
<td>3.5*</td>
<td>0/3.5</td>
<td>0</td>
</tr>
<tr>
<td>PFOA</td>
<td>ND (&lt;0.004)</td>
<td>0.0051*</td>
<td>0/0.0051</td>
<td>0</td>
</tr>
<tr>
<td>PFOS</td>
<td>ND (&lt;0.004)</td>
<td>0.0065*</td>
<td>0/0.0065</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Total – MCL-equivalent</td>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

Concentrations are in units of micrograms per liter (µg/L).

* One-tenth of the RL is used as surrogate for MCL. When the value of one-tenth of the RL is lower than the NL, the NL may be used as the MCL surrogate.

** The MCL for hexavalent chromium of 10 µg/L was repealed in September 2017 due to a court order. DDW is in the process of adopting a new MCL.
**Consideration of Background Credit for Naturally-Occurring Contaminants**

In some situations, background levels of contaminants present due to their natural occurrence may be taken into account, and enhanced treatment may not need to be ND. For this to occur,

- Treatment for each contaminant must be to a level below the MCL;
- While treatment below the DLR is desirable, some credit for natural arsenic or hexavalent chromium may be used, provided that the source assessment results clearly demonstrate that the arsenic and/or hexavalent chromium is present naturally and at natural concentrations, as they would be in the absence of the reason the source is extremely impaired;
- If the natural background level of the arsenic or hexavalent chromium is lower than half the MCL, that value may be used as the background credit. If the natural level is greater than half the MCL, background credit is calculated by subtracting half the MCL from the maximum concentration delivered, as shown in Table 3. (Because this is an extremely impaired source, it is prudent not to allow full credit for background levels, consistent with the goal of enhanced treatment.)
- The ratio of the concentration of each contaminant to its MCL is then calculated by subtracting the background credit from the maximum concentration of the contaminant in the delivered water, and then dividing it by the MCL.

In the example shown in Table 3, the MCL-equivalent ratios for arsenic and hexavalent chromium add up to 0.4, which is lower than the combined 1.3 in Table 1, but not as low as the desired 0 in Table 2. However, if treatment to ND is too difficult to attain, and if the background levels of the naturally occurring contaminants are well characterized as required, this may be a reasonable approach to consider. If the values from Table 3 are used in Table 1, the sum of MCL-equivalents for contaminants posing chronic, cancer health risks becomes 0.7.
Table 3: Consider background levels of natural contaminants in delivered water and allow background level credit in determining MCL-Equivalents

<table>
<thead>
<tr>
<th>Contaminant</th>
<th>Maximum Effluent Concentration</th>
<th>MCL (or surrogate MCL*)</th>
<th>Background</th>
<th>Max. Concentration minus Bkgd Credit</th>
<th>Concentration/MCL</th>
<th>Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic, Cancer Endpoint</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulated Contaminants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arsenic</td>
<td>7</td>
<td>10</td>
<td>7**</td>
<td>7-5=2</td>
<td>2/10</td>
<td>0.2</td>
</tr>
<tr>
<td>Hexavalent Chromium</td>
<td>6</td>
<td>10***</td>
<td>4</td>
<td>6-4=2</td>
<td>2/10</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Hexavalent Chromium Concentrations are in units of µg/L.
* One-tenth of the RL is used as surrogate for MCL. When the value of one-tenth of the RL is lower than the NL, the NL may be used as the MCL surrogate.
** 7 µg/L is greater than half the MCL, so use 5 µg/L as background credit.
*** The MCL for hexavalent chromium of 10 µg/L was repealed in September 2017 due to a court order. DDW is in the process of adopting a new MCL.
Note: values should include one significant figure.

Table 4 below is an example of what may be included in a final report, with the background credit applied for naturally occurring contaminants.

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Max. Influent Conc.</th>
<th>DLR</th>
<th>Max. Effluent Conc.</th>
<th>MCL</th>
<th>NL</th>
<th>RL</th>
<th>Surrogate MCL***</th>
<th>Known Bkgd. ****</th>
<th>Allowable Bkgd.</th>
<th>Chronic, Cancer MCL Ratio</th>
<th>Acute MCL Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitrate</td>
<td>30,000</td>
<td>2,000</td>
<td>30,000</td>
<td>45,000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.7</td>
</tr>
<tr>
<td>Perchlorate</td>
<td>5</td>
<td>4</td>
<td>ND</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>TCE</td>
<td>15</td>
<td>0.5</td>
<td>ND</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Arsenic</td>
<td>7</td>
<td>2</td>
<td>7</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2+10 = 0.2</td>
</tr>
<tr>
<td>Cr (VI)</td>
<td>6</td>
<td>1</td>
<td>6</td>
<td>10**</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2+10 = 0.2</td>
</tr>
<tr>
<td>NDMA</td>
<td>10</td>
<td>0.005*</td>
<td>0.01</td>
<td>0.01</td>
<td>0.3</td>
<td>0.03</td>
<td></td>
<td></td>
<td></td>
<td>0.01+0.03 = 0.3</td>
<td>0</td>
</tr>
<tr>
<td>1,4-dioxane</td>
<td>3</td>
<td>1*</td>
<td>ND</td>
<td>1</td>
<td>35</td>
<td>3.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>PFOA</td>
<td>0.01</td>
<td>0.004*</td>
<td>ND</td>
<td>0.0051</td>
<td>0.01</td>
<td>0.0051</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>PFOS</td>
<td>0.01</td>
<td>0.004*</td>
<td>ND</td>
<td>0.0065</td>
<td>0.04</td>
<td>0.0065</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Sum of MCL Ratios</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.7 &lt; 1</td>
<td>0.7 &lt; 1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Concentrations are in units of µg/L.
* Because DDW does not have DLRs for unregulated chemicals, DDW established these values as the level considered reliably detectable in drinking water.
** The MCL for hexavalent chromium of 10 µg/L was repealed in September 2017 due to a court order. DDW is in the process of adopting a new MCL.
*** One-tenth of the RL is used as the surrogate MCL. When the value of one-tenth of the Response Level is lower than the NL, the NL is used as the MCL surrogate.
**** Background concentrations vary with location and must be discussed and agreed upon with the DDW.

5. Human Health Risks Associated with Failure of Proposed Treatment

Treatment technologies are not failure-proof, and insufficiently treated or untreated water may, on occasion, pass through the treatment process and into the distribution system. An assessment must be performed that includes:

- An evaluation of the risks of failure of the proposed treatment system.

The proposed treatment system must be evaluated in terms of its probability to fail, thereby exposing customers to insufficiently treated or untreated drinking water from the extremely impaired source. Likely treatment failure modes are to be evaluated.

Assumptions of the rate of failure should reflect experience and data for treatment technologies and similarly engineered projects. For proposals with multiple treatment technologies, there may be multiple failure evaluations: each may be assumed to fail individually, various combinations of technologies may be assumed to fail together, and all may be assumed to fail at the same time. For example, in prior 97-005 evaluations,

- One applicant simply assumed complete failure (as a worst case) on a conservative frequency and for a duration based on the planned operational monitoring plan and performed health risk calculations based on this;
- Another applicant performed a more involved analysis of various failure modes, including evaluating feasible failure modes followed by Event Tree Analyses. Failure modes that could affect water treatment effectiveness were carried through to the health risk calculations.

- An assessment of potential health risks associated with failure of the proposed treatment system. The health assessment must take into account:

- The duration of exposure to contaminated drinking water that would result from such a failure. The evaluation should assess the proposed frequency of monitoring and the time it takes for treatment plant operator to receive the monitoring results as it relates to protection of the public from insufficiently treated or untreated drinking water.
The human health risks associated with such exposure to insufficiently treated or untreated water over the course of that failure, considering the risks of disease from microbiological organism, and the risks of acute, chronic, non-cancer effects, and cancer risks from chemical contaminants.

Potential cumulative risks, due to multiple failures.

For chemical contaminants, the treatment failure assessment’s focus should be based on health risks associated with short-term exposures that may arise from treatment failures. Naturally occurring contaminants such as arsenic and hexavalent chromium need not be included in the treatment failure-related evaluation, provided that:

- They have been addressed in Section 4.d (DDW Staff Evaluation of Treated Water Objectives or Goals) and have been shown to be present primarily at background levels, and
- They are not included in the extremely impaired source’s chemicals requiring treatment to meet MCLs.

The assessment of potential health risks associated with failure of the proposed treatment system should include (in a table or tables):

- A list of chemicals that will be or are likely to be present in water should a treatment failure occur, and the maximum anticipated concentration (based on monitoring data, knowledge of contaminant plumes, and an appropriate safety factor).
- The MCL (or action level for lead and copper), notification level or USEPA Health Advisory Level for the contaminant.
- The appropriate value for cancer or non-cancer endpoints, based on the California Public Health Goal (PHG), or PHG-like value for the contaminant.

The assessment of health risk should utilize PHGs, which are expressed in terms of drinking water concentration, whenever they are available for a given contaminant. PHGs for carcinogens are set at the 10^{-6} lifetime cancer risk level (At that level, not more than one cancer case would be expected in a population of one million people as a result of drinking water containing that level of the contaminant daily for 70 years). PHGs for non-carcinogens are set at the no observable adverse effect level, divided by appropriate uncertainty factors, and multiplied by the relative source contribution. Each PHG document generally contains cancer (if carcinogenic) and non-cancer endpoints, and the lowest concentration is the PHG. This document should be used for each endpoint.

If PHGs are not available, PHG-like values (e.g., 10^{-6} cancer risk level) should be determined from other sources in the following order (if available):

- DDW drinking water notification levels
- Proposition 65 cancer risk values (the Proposition 65 values are 10^{-5} risks for a daily exposure. Dividing by 20 yields 10^{-6} risk for 2 liter per day ingestion)
USEPA Integrated Risk Information System (IRIS) (RfDs should be used to calculated PHG-like numbers, or for carcinogens, use IRIS $10^{-6}$ cancer risk numbers for drinking water)

USEPA Region 9 – Preliminary Remediation Goals (PRGs)

- The risk from the exposure attributable to each contaminant.
  - For carcinogen, the lifetime cancer risk from the exposure attributable to each contaminant, in units of cancer case $x 10^{-6}$.

  The cancer risk attributable to the contaminant in cancer case $x 10^{-6}$ = concentration during failure/de minimis risk concentration (e.g., PHG) x (period of exposure in days)/365 x 70 years).

  For example, an exposure to 50 ppb of a carcinogen with a 5 ppb PHG that occurs 1 day per year for 70 years would have $0.027 x 10^{-6}$ cancer risk $[(50 \text{ ppb}/5 \text{ ppb})\times(1 \text{ day/year} \times 70 \text{ years})/(365 \text{ days/year} \times 70 \text{ years})] = 50/5 \times 70 \text{ days} /25550 \text{ days} = 0.027$.

- For non-cancer hazard attributable to each contaminant, expressed as a ratio (the hazard index, HI)

  HI= the exposure in $\mu$g/L/ PHG or PHG like value in $\mu$g/L

  For example, an exposure to 60 ppb of perchlorate would produce a HI of 60 $[60 \text{ ppb perchlorate}/1 \text{ ppb (PHG)} = 60]$. 

- The sum of cancer risks and the sum of non-cancer hazards (also referred to as hazard indices HIs).
- References that indicate the origin of the PHGs, PHG-like values, and other pertinent information.

For microbiological contaminants, the risk assessment needs to consider the impact of single and multiple failures of the proposed multi-barrier treatment system, and the likelihood of exposure to virus, bacteria, or parasitic organisms, as well as the risk of infection.

An assessment should be repeated for each scenario of treatment failure unless each scenario results in the same exposures.

Risks that exceed the usual acceptable lifetime cancer risk range of $10^{-6}$ to $10^{-4}$, or that exceed a cumulative hazard index of 1 for a given organ system do not necessarily mean the project must be rejected. However, when the risks of adverse health effects, including infection risks from treatment failure are excessive, then additional treatment safeguards, additional monitoring, additional
alarms or additional maintenance inspections must be used for the protection of public health, or the proposal must be rejected.

6. Completion of the California Environmental Quality Act (CEQA) Review of the Project

CEQA review of the project must be completed before the final permit or amendment will be issued.

7. Submittal of a Permit Application

The public water system(s) that will be collecting, treating and distributing water from the extremely impaired source must submit a permit application for the use of the extremely impaired source that includes the items identified above.

A supplier of treated water to a public water system is a water wholesaler and must be permitted as a public water system, as required by the Safe Drinking Water Act. Thus, an entity focused on cleanup activities with environmental regulatory agencies must keep in mind that drinking water systems are subject to different regulatory requirements. In many cases, the requirements upon drinking water systems are more stringent that those upon cleanup projects.

8. Public Hearing

A public hearing may be held as part of the permitting process by the water system or the DDW to identify concerns of consumers who will be served water from the extremely impaired source and to assure that all parties have a chance to provide relevant information.

DDW strongly recommends that a public meeting or other form of outreach to the public occur early in the process to identify any concerns or issues the public may have with the proposed project. This may be combined with outreach activities performed by other agencies involved with a cleanup, if available.

9. DDW Evaluation

DDW staff will conduct an evaluation of the application and make recommendations.

For sources near or associated with hazardous waste sites, staff may consult with colleagues (particularly hydrogeologists and geologists) in the Regional Water Quality Control Board and or Department of Toxic Substances Control for input, since these agencies may be involved in cleanup activities, or otherwise be familiar with the project.
Requirements for DDW Approval

The following findings are required of DDW for approval to use an extremely impaired source:

- Drinking water MCLs, action levels for lead and copper, and NLs will not be exceeded if the permit is complied with, and
- The potential for human health risk is minimized by treatment, and the risk from treatment failure is minimized through good engineering practices that may involve redundancies in treatment, and efficiencies in maintenance, inspections, monitoring, and alarms.

10. Issuance or Denial of Permit

DDW either issues a permit or denies a permit for the use of the extremely impaired source. If a permit is issued, it must include all necessary treatment, compliance monitoring, operational, and reporting requirements.