ATTACHMENT 2: SCIENTIFIC ASSUMPTIONS, FINDINGS AND CONCLUSIONS TO BE ADDRESSED BY PEER REVIEWERS

The statute mandate for external scientific peer review (Health and Safety Code Section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices.

We request that you make this determination for each of the following assumptions, finding and conclusions that constitute the scientific portion of the proposed regulatory action. An explanatory statement is provided for each issue in order to focus the review.

An important caveat should be noted for the reviewers. The vast majority of existing OWTS are conventional systems (septic tank and dispersal system).

1. **It is reasonable to use expected waste strength as a trigger for submitting a report of waste discharge (State permit application) and for determining the necessary approach to direct State regulation and oversight through waste discharge requirements.**
   These regulations establish an upper limit for wastewater organic and solids strength due to concern for the performance and operating longevity of the dispersal field. Sections 2.4, 2.6.6, and 6.1.2 of the Policy allow commercial facilities that have an OWTS with biochemical oxygen demands (BOD) less than 900 mg/L provided that those facilities also have a grease interceptor. Other commercial OWTS with wastewater having a BOD greater than 900 mg/L and/or not having a grease interceptor would have to file for a separate waste discharge permit or waiver thereof.

2. **Use of the design flow as a trigger for submitting a report of waste discharge (State permit application) and for determining the necessary approach to direct State regulation and oversight through waste discharge requirements is reasonable.**

   Experience shows that larger OWTS (greater than 3,500 gallons-per-day) are more likely to fail than smaller ones and are best limited to design flows of less than 6,000 gallons-per-day (Plews et al. 1985). The Policy Section 2.6.2 would require that OWTS owners with new or replaced OWTS notify the regional water board if the flow rate is in excess of 3,500 gallons-per-day and if the system is not specifically allowed by a local permitting agency in the local agency management plan. The Policy Sections 2.6.3, 6.1.1 and 9.4.2 would require all existing OWTS owners not covered by an existing waiver or waste discharge requirements notify the regional water board if the flow rate is in excess of 10,000 gallons-per-day. The regional water board would then determine whether it would issue specific waste discharge requirements or a waiver that may be more stringent than required by the proposed regulations to guarantee protection of water quality.

3. **A site evaluation is required in Tier 1 (Section 7 of the proposed Policy) to determine that adequate soil depth is present in the dispersal area. Soil depth would be measured vertically to the point where bedrock, hardpan, impermeable soils, or saturated soils are encountered or an adequate depth has been determined.**

   Soil is the primary media that treats wastewater from OWTS. It also serves as the receiving environment and ultimate assimilation point for the wastewater volume that is passed from the structures through the OWTS. Bedrock, hardpan, impermeable soils, and saturated soils do not provide a porous media to provide adequate treatment to safely dispose wastewater with surety of proper treatment and disposal.

4. **A site evaluation for seasonal groundwater is required in Section 7.3 using one or a combination of the following methods: direct observation of the highest extent of soil mottling observed in the examination of soil profiles, direct observation of groundwater levels during the anticipated period of high groundwater, or other methods, such as historical records, acceptable to the local agency. Where a conflict in the above methods of examination exists, the direct observation method indicating the highest level shall govern.**

   All the prescribed methods are valid methods to determine seasonal high groundwater, with the most valid method being direct observation during the time that groundwater is most likely to be expected at its seasonal high level. This is because direct observation conclusively indicates actual groundwater levels.

5. **Section 7.4 requires that percolation test results in the effluent disposal area shall not be faster than one minute per inch (1 MPI) or slower than ninety minutes per inch (90 MPI) because of problems associated with allowing OWTS on soils that exhibit faster percolation rates than 1 MPI and slower than 90 MPI. All percolation rates shall be based on actual or simulated wet weather conditions by performing the test during the wet weather period as determined by the local agency or by presoaking of percolation test holes and shall be a stabilized rate.**

   In OWTS, soils provide both treatment and disposal of the wastewater. If soils percolate the wastewater too quickly, insufficient treatment of the wastewater can occur before entering groundwater. However, if the soil percolates too slowly, the soil may not be able to accept all of the wastewater and the wastewater may subsequently surface and pose a condition of nuisance or pollution. A commonly allowed acceptance rate is between 1 and 120 MPI. As such, the allowable interval proposed in the Policy is conservative towards protection from surfacing. Presoaking the percolation test hole helps to stabilize the rate at which soils absorbs the water and helps to estimate the long-term acceptance rate.

6. **Section 7.5 stipulates minimum horizontal setbacks as follows:**

   a. **5 feet from parcel property lines.**

      This setback is designed to protect the septic tank and dispersal system. Surcharges due to soil loads associated with structures can damage an OWTS. The default assumption for surcharges in building codes usually establishes a zero surcharge load when the structure on the soil is two times the distance of the depth of the cut. Setting OWTS away from the property lines helps assure that surcharges on an OWTS will be minimal, if not zero, since OWTS are usually not very deep and structures often have their own setback from property lines.

   b. **100 feet from water wells and monitoring wells, unless regulatory or legitimate data requirements necessitate that monitoring wells be located closer.**

      OWTS are identified as a possible contaminating activity (PCA) for groundwater (CA DHS 1999). OWTS contamination of water supplies is known to cause diseases such as infectious hepatitis, typhoid fever, dysentery, and various gastrointestinal illnesses (US EPA 1977). It is also known that dissolved contaminant plumes from conventional OWTS can travel hundreds of feet and exceed drinking water standards (USEPA 2002). Thus, discharges from OWTS are known to impair or threaten impairment of beneficial uses of groundwater in the immediate vicinity of the discharge.

      This setback is established using a common standard of practice. Many references and technical documents prescribe 100 feet for OWTS setback from a well. While well pollution is documented to have occurred on occasion, the setback has been successful.

   c. **100 feet from any unstable land mass or any areas subject to earth slides identified by a registered engineer or registered geologist; other setback distance are allowed, if recommended by a geotechnical report prepared by a qualified professional.**

      Unstable land masses can be further destabilized by direct addition of water to the soil column. A setback of 100 feet or greater, if prescribed by a professional geologist, will assist in minimizing any further destabilization of unstable areas.

d. **100 feet from springs and flowing surface water bodies where the edge of that water body is the natural or levied bank for creeks and rivers, or may be less where site conditions prevent migration of wastewater to the water body.**

For the same reasons described in Issue 6.b. above regarding concerns for pathogens, this setback is being established because springs and flowing surface water bodies are often areas of interflow, where groundwater exits the subsurface to become surface waters. Since the intent of subsurface disposal is to treat and dispose the wastewater in the subsurface, areas of interflow pose a design threat. A setback minimizes such design failure. The Policy prescribes 100 feet because it is a standard of practice often used in design manuals and local ordinances.

e. **200 feet from vernal pools, wetlands, lakes, ponds, or other surface water bodies where the edge of that water body is the high water mark for lakes and reservoirs, and the mean high tide line for tidally influenced water bodies.**

For the same reasons described in Issue 6.b. above regarding concerns for pathogens, this setback is being established because lakes, wetlands and other placid surface water bodies are often areas of interflow, where groundwater exits the subsurface to become surface waters. Since the intent of subsurface disposal is to treat and dispose the wastewater in the subsurface, areas of interflow pose a design threat. Unlike flowing waters, these water bodies with a relatively low level of mixing, due the lack of flow, will collect interflow and retain it, creating nuisance conditions. A setback minimizes such design failure. The Policy prescribes 200 feet because it is a standard of practice often used in design manuals and local ordinances.

f. **150 feet from a public water well where the depth of the effluent dispersal system does not exceed 10 feet;**

For the same reasons described in Issue 6.b. above regarding concerns for pathogens, public water wells may have a have a greater zone of influence on the surrounding groundwater than monitoring wells, private domestic wells. Also, if the OWTS design fails, these public water wells also can affect more people and pose a risk to public health. For this reason, the Policy requires increased separation from the OWTS and public well, which is determined by multiplying the standard well separation by a factor of safety of 1.5.

g. 200 feet from a public water well where the depth of the effluent dispersal system exceeds 10 feet in depth.

For the same reasons described in Issue 6.b. above regarding concerns for pathogens, deeper disposal systems have the potential to contaminate groundwater because there is potentially less unsaturated soil below the leachfield. For this reason, the Policy requires increased separation from the OWTS and the public well which is determined by multiplying the standard well separation by a factor of safety of 2.0.

h. Where the effluent dispersal system is within 600 feet of a public water well and exceeds 20 feet in depth and the separation from the bottom of the system and ground water is less than five feet, the horizontal setback required to achieve a two-year travel time for microbiological contaminants shall be evaluated. A qualified professional shall conduct this evaluation. However in no case shall the setback be less than 200 feet.

For the same reasons described in Issue 6.b. above regarding concerns for pathogens, deeper disposal systems have the potential to contaminate groundwater because there is potentially less unsaturated soil below the leachfield. Where the OWTS exceeds 20 feet in depth and the separation from the bottom of the system and ground water is less than five feet, the OWTS begins to look more like a design for groundwater reinjection rather than an OWTS for wastewater treatment and dispersal. For this reason, simple factors of safety will not address the overall potential water quality problems and the Policy requires an evaluation by a qualified profession to ensure adequate destruction of pathogenic materials travelling in an aqueous environment.

i. Where the effluent dispersal system is within 1,200 feet from a public water systems' surface water intake and within the catchment of the drainage, the dispersal system shall be no less than 400 feet from the high water mark of the reservoir, lake or flowing water body.

For the same reasons described in Issue 6.b. above regarding concerns for pathogens, this requirement is directly related to the California Department of Public Health's Drinking Water Source Assessment Program (DWSAP). This requirement effectively requires that all OWTS must be outside the Protection Zones of surface waters used for consumption (CA DPH 1999).

j. Where the effluent dispersal system is located more than 1,200 but less than 2,500 feet from a public water systems' surface

water intake and within the catchment of the drainage, the dispersal system shall be no less than 200 feet from the high water mark of the reservoir, lake or flowing water body.

For the same reasons described in Issue 6.b. above regarding concerns for pathogens, this requirement is directly related to the California Department of Public Health's Drinking Water Source Assessment Program (DWSAP). This requirement effectively requires that all OWTS must be outside the Protection Zones of surface waters used for consumption (CA DPH 1999).

7. **Natural ground slope in all areas used for effluent disposal shall not be greater than 25 percent for Tier 1 and 30 percent for Tier 2.**

   Slopes can cause problems for the use of OWTS. If not constructed properly, dispersal systems constructed on sloping land can lead to surfacing of the water down gradient. Slopes in excess of 25% may limit the use of machinery (USEPA 1980; Crites 1998) in addition to problems related to surfacing wastewater. Tier 1 (Section 7.7) is subject to 25 percent due to less oversight in the OWTS management system. For Tier 2, where management is done under a local agency management plan, slopes are allowed (Section 9.4.4) up to 30 percent.

8. **The average density for any subdivision of property occurring after the effective date of this Policy and implemented under Tier 1 shall not exceed one single-family dwelling unit, or its equivalent, per 2.5 acres for those units that rely on OWTS (Section 7.8).**

   Accumulations of pollutants, particularly nitrogen compounds, in the groundwater are a major concern for the use of OWTS. It is OWTS density that leads to pollution due to the fact that the amount of wastewater exceeds the assimilative capacity of the groundwater (Canter and Knox 1986). Furthermore, Canter and Knox note: "Areas with more than 40 [OWTS] per square mile can be considered to have potential contamination problems." However, other researchers (Brown and Bicki 1997) have found that most of the studies that they reviewed "estimated that the minimum lot size necessary to ensure against contamination is roughly one-half to one acre." As such, an average density of one OWTS per 2.5 acres is a good step forward and between two estimations.

9. **All dispersal systems shall have at least twelve (12) inches of soil cover (Section 8.1.4).**

   Twelve inches of backfill over the dispersal system is common practice (U.S. Public Health Service 1967).

10. The minimum depth to the anticipated highest level of groundwater below the bottom of the leaching trench, and the native soil depth immediately below the leaching trench, shall not be less than prescribed in Table 1.

Table 1: Tier 1 Minimum Depths to Groundwater and Minimum Soil Depth from the Bottom of the Dispersal System	
Percolation Rate	**Depth to groundwater**
Percolation Rate ≤1 MPI	Only as authorized in a Tier 2 Local Management Program
1 MPI< Percolation Rate ≤ 5 MPI	Twenty (20) feet
5 MPI< Percolation Rate ≤ 30 MPI	Eight (8) feet
30 MPI< Percolation Rate ≤ 90 MPI	Five (5) feet
Percolation Rate > 90 MPI	Only as authorized in a Tier 2 Local Management Program
MPI = minutes per inch	

The requirements for this portion of the Policy are established to ensure that wastewater discharged from OWTS has sufficient time to receive treatment prior to entering groundwater. The separation for groundwater requirements listed in Table 1 are taken from the Basin Plan from the Central Coast Regional Water Quality Control Board (Central Coast RWQCB

11. Dispersal systems shall be a leachfield, designed using not more than 4 square-feet of infiltrative area per linear foot of trench as the infiltrative surface, and with trench width no wider than 3 feet. Seepage pits and other dispersal systems may only be authorized for repairs where siting limitations require a variance. Maximum application rates shall be determined from stabilized percolation rate as provided in Table 2, or from soil texture and structure determination as provided in Table 3.

Table 2: Application rates as determined from stabilized percolation rate

Percolation Rate	Application Rate		Percolation Rate	Application Rate		Percolation Rate	Application Rate
(minutes per Inch)	(gallons per day per square foot)		(minutes per Inch)	(gallons per day per square foot)		(minutes per Inch)	(gallons per day per square foot)
<1	Requires Local Manage-ment Program		31	0.522		61	0.197
1	0.8		32	0.511		62	0.194
2	0.8		33	0.5		63	0.19
3	0.8		34	0.489		64	0.187
4	0.8		35	0.478		65	0.184
5	0.8		36	0.467		66	0.18
6	0.8		37	0.456		67	0.177
7	0.8		38	0.445		68	0.174
8	0.8		39	0.434		69	0.17
9	0.8		40	0.422		70	0.167
10	0.8		41	0.411		71	0.164
11	0.786		42	0.4		72	0.16
12	0.771		43	0.389		73	0.157
13	0.757		44	0.378		74	0.154
14	0.743		45	0.367		75	0.15
15	0.729		46	0.356		76	0.147
16	0.714		47	0.345		77	0.144
17	0.7		48	0.334		78	0.14
18	0.686		49	0.323		79	0.137
19	0.671		50	0.311		80	0.133
20	0.657		51	0.3		81	0.13
21	0.643		52	0.289		82	0.127
22	0.629		53	0.278		83	0.123
23	0.614		54	0.267		84	0.12
24	0.6		55	0.256		85	0.117
25	0.589		56	0.245		86	0.113
26	0.578		57	0.234		87	0.11
27	0.567		58	0.223		88	0.107
28	0.556		59	0.212		89	0.103
29	0.545		60	0.2		90	0.1
30	0.533					>90	Requires Local Management Program

Table 3: Design Soil Application Rates

(Source: USEPA Onsite Wastewater Treatment Systems Manual, February 2002)

Soil Texture (per the USDA soil classification system)	**Soil Structure Shape**	**Grade**	**Maximum Soil Application Rate(gallons per day per square foot)** [1]
Coarse Sand, Sand, Loamy Coarse Sand, Loamy Sand	Single grain	Structureless	0.8
Fine Sand, Very Fine Sand, Loamy Fine Sand, Loamy Very Fine Sand	Single grain	Structureless	0.4
Coarse Sandy Loam, Sandy Loam	Massive	Structureless	0.2
	Platy	Weak	0.2
		Moderate, Strong	Prohibited
	Prismatic, Blocky, Granular	Weak	0.4
		Moderate, Strong	0.6
Fine Sandy Loam, very fine Sandy Loam	Massive	Structureless	0.2
	Platy	Weak, Moderate, Strong	Prohibited
	Prismatic, Blocky, Granular	Weak	0.2
		Moderate, Strong	0.4
Loam	Massive	Structureless	0.2
	Platy	Weak, Moderate, Strong	Prohibited
	Prismatic, Blocky, Granular	Weak	0.4
		Moderate, Strong	0.6
Silt Loam	Massive	Structureless	Prohibited
	Platy	Weak, Moderate, Strong	Prohibited
	Prismatic, Blocky, Granular	Weak	0.4
		Moderate, Strong	0.6
Sandy Clay Loam, Clay Loam, Silty Clay Loam	Massive	Structureless	Prohibited
	Platy	Weak, Moderate, Strong	Prohibited
	Prismatic, Blocky, Granular	Weak	0.2
		Moderate, Strong	0.4
Sandy Clay, Clay, or Silty Clay	Massive	Structureless	Prohibited
	Platy	Weak, Moderate, Strong	Prohibited
	Prismatic, Blocky, Granular	Weak	Prohibited
		Moderate, Strong	0.2

Wastewater application rates are established for pathogen reduction, long-term unsaturated soil treatment of the wastewater, and to prevent surfacing of OWTS effluent in the dispersal system. The wastewater application rates contained in Tables 2 and 3 are developed from application rates specified in the Central Coast Regional Water Board's Water Quality Control Plan (Central Coast Regional Water Board 2011) and the 2002 USEPA Design Manual. The application rate associated with percolation testing has been broken down across the acceptable percolation rates by staff. However, these application rates are within the range of recommended/suggested values contained in both USEPA design manuals (USEPA 1980, USEPA 2002).

12. Dispersal systems shall not exceed a maximum depth of 10 feet as measured from the ground surface to the bottom of the trench.

This requirement is established to allow dispersal systems to target the preferential portion of the soil column, maximizing the amount of atmospheric oxygen for wastewater treatment.

13. No dispersal systems or replacement areas shall be covered by an impermeable surface, such as paving, building foundation slabs, plastic sheeting, or any other material that prevents oxygen transfer to the soil.

This requirement is established to maximize the amount of atmospheric oxygen for wastewater treatment.

14. Rock fragment content of native soil surrounding the dispersal system shall not exceed 50 percent by volume for rock fragments sized as cobbles or larger and shall be estimated using either the point-count or line-intercept methods.

Soils with a high fraction of coarse fragments (gravel, cobbles and rock) pose a problem for the treatment of the wastewater because the volume occupied by the coarse fragments is not available for providing the treatment of the wastewater (Woessner et. al. 1987, Ver Hey et. al. 1987).

15. Septic Tank Construction and Installation: All new or replaced septic tanks and new or replaced grease interceptor tanks shall comply with the standards contained in Sections K5(b), K5(c), K5(d), K5(e), K5(k), K5(m)(1), and K5(m)(3)(ii) of Appendix K, of Part 5, Title 24 of the 2007 California Code of Regulations.

These standards are industry standards found in the California Plumbing Code (CA Building Standards Commission 2011)

16. New and replaced OWTS septic tanks shall be designed to prevent solids in excess of three-sixteenths (3/16) of an inch in diameter from passing to the dispersal system. Septic tanks that use a National Sanitation Foundation/American National Standard Institute (NSF/ANSI) Standard 46 certified septic tank filter at the final point of effluent discharge from

the OWTS and prior to the dispersal system shall be deemed in compliance with this requirement.

The draft regulations require all new septic tanks to restrict solids particles in excess of 3/16 inch in diameter from passing through to the dispersal field, thereby prolonging the life of the dispersal system. This value was selected from the body of knowledge surrounding septic tank effluent filters (1/8 effluent screens).

17. The proposed regulations (Section 9.4.5) would allow design of gravel-less dispersal systems with a reduction (adjustment multiplier of 0.7) of the minimum required dispersal system area for effluent application.

It has been shown in the laboratory and in the field that gravel-less chambers function as well as conventional dispersal systems even when the system sized is reduced by as much as fifty percent in size (King, et. al. 2002). When gravel-less chambers are sized equivalently to conventional OWTS, it has been shown that the long-term acceptance rate can be 1.5 to 2 times higher than that of conventional OWTS dispersal systems (Seigrist et. al. 2004). For this reason, SWRCB staff has included a multiplier allowing the reduction of the dispersal system when chambers are used.

18. The proposed Policy identifies OWTS within 600 lateral feet of an impaired water body listed for nitrogen or for pathogens pursuant to §303(d) of the Federal Clean Water Act as contributing to the impairment of the water body when further designated by the Regional Water Board. For purposes of this Section, impairment is limited to nitrate or bacterial contamination.

The Policy establishes a capture distance (600 feet) in lieu of requiring a case-by-case determination regarding each OWTS contribution. This approach is preferred because of cost concerns regarding actual groundwater transport studies. The 600 feet distance is based on: California Department of Health Services (DHS), ***Drinking Water Source Assessment and Protection Program***. As detailed in the document (page 54), a radial distance established a microbial/direct chemical contamination zone to protect public drinking water supply wells from possible contaminating activities associated with viral, microbial and direct chemical contamination. OWTS are identified as possible contaminating activities posing “very high potential risks” (CA DHS 1999, pg 54, 92). To our knowledge the guidance was not peer reviewed.

As detailed in the document (page 54), a radial distance established a microbial/direct chemical contamination zone to protect water supply from viral, microbial and direct chemical contamination. For porous media aquifers, 600 feet was the recommended minimum distance to be sufficiently conservative for protection from microbial contaminants as well as chemical contaminants such as nitrate.

19. **Effluent from the supplemental treatment components designed to reduce nitrogen shall be certified by NSF, or other approved third party tester, to meet a 50 percent reduction in total nitrogen when comparing the 30-day average influent to the 30-day average effluent (Section 10.9).**

This standard was chosen because it provides a level of assurance to the consumer that the supplemental treatment system will meet the standards. Third party certification is designed to screen out unreliable supplemental treatment technologies. The independent third party certification protocol used by the National Sanitation Foundation (NSF) International takes components through a series of operational evaluations and stress tests using wastewater at their own NSF controlled facilities. NSF International is widely recognized (Pearson 1977), has over 30 years of experience, and has certified over 315 different OWTS products from more than 35 manufacturers.

20. **Where a drip-line dispersal system is used to enhance vegetative nitrogen uptake, the dispersal system shall have at least six (6) inches of soil cover.**

This is prescribed as part of the nitrogen removal design in Section 10.9, where such a system is used. Drip dispersal and pressure dispersal systems distribute wastewater across the dispersal field in a manner that is more uniform than conventional gravity dispersal systems (USEPA 2002). With relatively uniform distribution of the wastewater, there is a tendency to raise these systems closer to the land surface (Beggs, et. al. 2004). Drip dispersal systems are the best method to distribute the wastewater uniformly and pose less of a threat to the environment than a conventional dispersal field, due to the fact that it optimizes the retention of pollutants and allows the dispersal of the wastewater into the root dispersal field (Watson 2004). Accordingly, the Policy allows these systems to be placed less than six (6) inches from the ground surface. This is supported in literature (Crites 1998).

21. **Supplemental treatment components designed to perform disinfection shall provide sufficient pretreatment of the wastewater so that effluent from the supplemental treatment components does not exceed a 30-day average TSS of 30 mg/L and shall further achieve an effluent fecal coliform bacteria concentration less than or equal to 200 Most Probable Number (MPN) per 100 milliliters (Section 10.10).**

This standard was chosen because a it provides a level of assurance to the consumer that the supplemental treatment system will meet the standards. NSF Standard 46 certified products for disinfection meet this standard. The independent third party certification protocol used by the National Sanitation Foundation (NSF) International takes components through a series of operational evaluations and stress tests using wastewater at their own NSF controlled facilities. Third party certification is designed to screen out unreliable supplemental treatment technologies. NSF International is widely recognized (Pearson 1977.

22. **The minimum soil depth and the minimum depth to the anticipated highest level of groundwater below the bottom of the dispersal system shall not be less than three (3) feet. All dispersal systems shall have at least twelve (12) inches of soil cover.**

    This standard is required to work in conjuction to the supplemental treatment requirements specified in Section 10.10. The groundwater separation is discussed in this request above under Issue No. 10. The 12 inches of cover is discussed above in Issue No. 9.

The Big Picture

Reviewers are not limited to addressing only the specific issues presented above, and are asked to contemplate the following "big picture" questions:

1. **Are there any additional issues that are part of the scientific basis of the proposed regulations that are not described above?**

2. **Taken as a whole, is the scientific portion of the proposed regulations based upon sound scientific knowledge, methods, and practices?**

Reviewers should also note that some portions of the proposed regulations may rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statue requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

The preceding guidance will ensure that reviewer have an opportunity to comment on all aspects of the scientific basis of the proposed State Water Board action. At the same time, reviewers also should recognize that the State Water Board has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed regulations. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed.