Review of Draft Criteria - Approach

- What is in the criteria?
- What is the basis for the pathogen log reduction requirements?
- How does one judge compliance with the LRT criteria?
  - Do we need to be compliant 100% of the time? 95% of the time?
What are the criteria?

- **Virus**: 20
- **Giardia**: 14
- **Crypto**: 15

**Acceptable operation for 24 hours within 4-log buffer**

- **Virus**: 16
- **Giardia**: 10
- **Crypto**: 11

- **Discontinue delivery**
  - Within 60 minutes, notify State Board and each public water system
Derivation of LRVs
Calculating Risk

1. Exposure Assessment

- Raw wastewater
- Treatment
- Drinking water levels
- Drinking water consumption
- Exposure

2. Dose-Response

- Dose-response

There are a lot of decisions to consider when calculating risk...

What data should we use?

What about molecular data?

Should we use a point estimate or distribution?

Is treatment constant or does it vary?

How much water do people drink?

How do you account for failures?

Which D-R functions to use?
“To minimize the chance that the required log reductions necessary to meet the health objective are not consistently met, DPR projects must provide log reduction capacity in excess of the basic LRVs (redundant LRV treatment).”
Calculating the Benchmark Treatment – Virus

1. Exposure Assessment

- DDW used point estimate of highest concentration of norovirus recorded (1E9 GC/L)
- DDW assumed consumption of 2 L/day

2. Dose-Response

- DDW used the hypergeometric dose-response (Teunis et al. 2008; alpha = 0.04; beta = 0.055)
- Daily risk of 2.7x10^-7
Dose-response comparison

LRT of 16
HYP DR vs FP DR
GC:IU of 10,000:1

Dose-response comparison

LRT of 16
HYP DR vs FP DR
GC:IU of 10,000:1
Previous Recommendations from 1/13/22 Mtg

Recommendation:
- Pathogen concentrations: use DPR-2 distributions

Continue to Evaluate:
- Type of data: molecular and culture data
- GC:IU ratios: point estimates and ranges
- Dose-response: consider multiple functions
Norovirus – Range of Assumptions

- Raw WW:
  - DPR-2 Distribution: $\mu_{\text{log}} = 4.0; \sigma_{\text{log}} = 1.2$

- GC:IU
  - Option 1 = GC:IU of 1:1\(^1\)
  - Option 2 = Uniform distribution of GC:IU of 200:1 to 1:1\(^2\)
  - Option 3 = Uniform distribution of GC:IU of 1,000:1 to 1:1\(^3\)

- Dose-Response
  - Hypergeometric (conservative)
  - Fractional-Poisson

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\(^1\) Ratio of GC:IU will not be constant (Gerba and Betancourt (2019) Assessing occurrence of waterborne viruses in reuse systems)

\(^2\) Minimum ratio of 200:1 (Donia et al. (2010) Statistical correlation between enterovirus GC numbers and infectious viral particles in wastewater samples)

\(^3\) Ratios of 1:1 to 10,000:1 (and up to 100,000:1) reported in DPR-2
Norovirus Required LRTs (Hypergeometric D-R)
Norovirus Required LRTs (impact of HYP and FP)

Range of potential virus LRTs based on Norovirus: 10 to 13
Enterovirus Assumptions

- Raw WW:
  - DPR-2 Distribution\(^1\): \(\mu_{\log} = 3.2; \sigma_{\log} = 1.0\)
  - Assume 10% of total viruses were culturable\(^2\): \(\mu_{\log} = 4.2; \sigma_{\log} = 1.0\)

- D-R
  - Use Rotavirus D-R (Beta Poisson) as conservative estimate – in line with virus requirements for Surface Water Treatment Rule and California IPR regulations

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\(^1\) Second passages were completed for all flasks for both the BGM and A549 cell culture assay,

\(^2\) Safety factor of 10 is reasonable estimate (Gerba and Betancourt 2019).
Range of potential virus LRTs based on Enterovirus: 12 to 13
Enterovirus Required LRTs

Range of potential virus LRTs based on Enterovirus: 12 to 13

Upper-end of both enterovirus/rotavirus (culture) and norovirus (molecular) is 13 LRV
Failures
Failure increases risk from 4- to 6-logs

Failures assumed to be 6-log, 1x per year
Failure increases risk from 4- to 6-logs

Window of redundancy spans from 4-logs (15 min) to 6-logs (24 h).

15-min failure = 4-log increase in risk
24-h failure = 6-log increase in risk
Approach for Evaluating Redundancy

Add 6-log of redundancy. This will be protective.
Add 5-log of redundancy.

Will this still be protective if we have a 6-log failure?
Approach for Evaluating Redundancy

Add 5-log of redundancy. Will this still be protective if we have a 6-log failure?

To evaluate...we could look at risk if our performance band looks like this.
Evaluating Risk – Performance Assumption

- Treatment goals: 13 LRT + 5 LRT redundancy = 18
- Model includes intermediate and complete failure (undetected) scenarios
  - 18 LRT – 90% -- performance typically at design conditions (13 + 5)
  - 15 LRT – 9% -- periods with lower redundancy (13 + 2)
  - 12 LRT – 1% -- full 6-log failure occurring 1% of the time (18 – 6)
- DDW assumed one 15-min, 6-log failure occurring 1x/year
  - 1% is more conservative than DDW assumption (0.003%)
Virus Comparison – Daily Risk

12 LRT – 1%
15 LRT – 9%
18 LRT – 90%

Entero – 10% culturable
Entero – no adjustment
Virus Comparison – Daily Risk

12 LRT – 1%
15 LRT – 9%
18 LRT – 90%

Entero – 10% culturable
NoV – hypergeometric
Entero – no adjustment
NoV – fractional Poisson
Virus Comparison – Annual Risk

12 LRT – 1%
15 LRT – 9%
18 LRT – 90%

Entero – 10% culturable
Entero – no adjustment
NoV – hypergeometric
NoV – fractional Poisson
Potential Virus Requirements

- Minimum treatment for public health protection: LRT = 13
- Minimum redundancy needed to address failures: +5 logs
  - 5-log buffer protective against a conservative 6-log failure rate (1% occurrence)
  - 99% compliance with daily risk goal
  - >99% with annual risk goal (< once in 100 years)
- Proposed compliance requirements for LRTs:
  - 18 LRT – 90%
  - 15 LRT – 9%
  - **13 LRT – 1%**
What are the criteria? (5-log redundancy)

Pathogen Log Reduction Performance

Acceptable operation for 24 hours within 4-log buffer

- 20
- 14
- 15

Discontinue delivery

- 16
- 10
- 11

Within 60 minutes, notify State Board and each public water system

At or above design conditions 90% of time

- 18

Acceptable operation 9% of time

- 15

Acceptable operation 1% of time

- 13

Discontinue delivery

Within 60 minutes, notify State Board and each public water system
Approach for Evaluating Redundancy

Public Health Protection: LRT 13

Add 4-log of redundancy. Will this still be protective if we have a 6-log failure?

To evaluate...we could look at risk if our performance band looks like this →
Evaluating Risk – Performance Assumption

- Treatment goals: 13 LRT + 4 LRT redundancy = 17
- Model includes intermediate and complete failure scenarios
  - 17 LRT – 90% -- performance typically at design conditions (13 + 4)
  - 14 LRT – 9% -- periods with lower redundancy (13 + 1)
  - 11 LRT – 1% -- full 6-log failure occurring 1% of the time (17 – 6)
- DDW assumed one 15-min, 6-log failure occurring 1x/year
  - 1% is more conservative than DDW assumption (0.003%)
Virus Comparison – Daily Risk

11 LRT – 1%
14 LRT – 9%
17 LRT – 90%

Entero – 10% culturable
Entero – no adjustment
Virus Comparison – Daily Risk

11 LRT – 1%
14 LRT – 9%
17 LRT – 90%

Entero – 10% culturable
NoV – hypergeometric
Entero – no adjustment
NoV – fractional Poisson
Virus Comparison – Annual Risk

11 LRT – 1%
14 LRT – 9%
17 LRT – 90%

Entero – 10% culturable
NoV – hypergeometric
Entero – no adjustment
NoV – fractional Poisson
Potential Virus Requirements

- Minimum treatment for public health protection: $LRT = 13$
- Minimum redundancy needed to address failures: $+4$ logs
  - $4$-log buffer protective against a conservative $6$-log failure rate ($1\%$ occurrence)
  - $99\%$ compliance with daily risk goal
  - $>99\%$ with annual risk goal (< once in $100$ years)
- Proposed compliance requirements for LRTs:
  - $17$ LRT – $90\%$
  - $14$ LRT – $9\%$
  - $13$ LRT – $1\%$
What are the criteria? (4-log redundancy)

**Pathogen Log Reduction Performance**

- **20**: Acceptable operation for 24 hours within 4-log buffer
- **14**: Discontinue delivery
- **15**: Within 60 minutes, notify State Board and each public water system
- **16**: Within 60 minutes, notify State Board and each public water system
- **10**: Within 60 minutes, notify State Board and each public water system
- **11**: Within 60 minutes, notify State Board and each public water system

**Pathogen Log Reduction Performance**

- **17**: At or above design conditions 90% of time
- **14**: Acceptable operation 9% of time
- **13**: Discontinue delivery
- **13**: Within 60 minutes, notify State Board and each public water system

Acceptable operation 9% of time

Discontinue delivery

Within 60 minutes, notify State Board and each public water system
Crypto
Crypto

- Raw WW:
  - DPR-2 Distribution: $\mu_{\log} = 1.7; \sigma_{\log} = 0.4$
  - DPR-2 Distribution: $\mu_{\log} = 1.9; \sigma_{\log} = 0.6$ (combined DPR-2)
- D-R
  - Beta-Poisson (Messner et al. 2016)
  - Exponential (US EPA 2005)
Crypto Required LRTs (Beta-Poisson D-R)
Crypto Required LRTs (Exponential D-R)

Range of potential Crypto LRTs: 8 to 10
Approach for Evaluating Redundancy

Add 6-log of redundancy.
This will be protective.
Add 5-log of redundancy. Will this still be protective if we have a 6-log failure?

To evaluate...we could look at risk if our performance band looks like this ➔
Evaluating Risk – Performance Assumption

- Treatment goals: $10 \text{ LRT} + 5 \text{ LRT redundancy} = 15$
- Model includes intermediate and complete failure scenarios
  - $15 \text{ LRT} – 90\%$ -- performance typically at design conditions ($10 + 5$)
  - $12 \text{ LRT} – 9\%$ -- periods with lower redundancy ($10 + 2$)
  - $9 \text{ LRT} – 1\%$ -- full 6-log failure occurring 1% of the time ($15 – 6$)
- DDW assumed one 15-min, 6-log failure occurring 1x/year
  - 1% is more conservative than DDW assumption (0.003%)
Crypto – Daily Risk with 5-log redundancy

9 LRT – 1%
12 LRT – 9%
15 LRT – 90%
9 LRT – 1%
12 LRT – 9%
15 LRT – 90%
Potential Crypto Requirements

- Minimum treatment for public health protection: LRT = 10
- Minimum redundancy needed to address failures: +5 logs
  - 5-log buffer protective against a conservative 6-log failure rate (1% occurrence)
  - 99% compliance with daily risk goal
  - >99% with annual risk goal (< once in 100 years)
- Proposed compliance requirements for LRTs:
  - 15 LRT – 90%
  - 12 LRT – 9%
  - **10 LRT – 1%**
What are the criteria? (5-log redundancy)

Pathogen Log Reduction Performance

- **Acceptable operation for 24 hours within 4-log buffer**
  - 20
  - 14
  - 15

- **Discontinue delivery**
  - 16
  - 10
  - 11

- **Within 60 minutes, notify State Board and each public water system**

Pathogen Log Reduction Performance

- At or above design conditions 90% of time
  - 18
  - 15

- **Acceptable operation 9% of time**
  - 15
  - 12

- **Acceptable operation 1% of time**
  - 13
  - 10

- **Discontinue delivery**
  - 10

- **Within 60 minutes, notify State Board and each public water system**
Approach for Evaluating Redundancy

Public Health Protection: LRT 10

Add 4-log of redundancy. Will this still be protective if we have a 6-log failure?

To evaluate...we could look at risk if our performance band looks like this →
Evaluating Risk – Performance Assumption

- Treatment goals: 10 LRT + 4 LRT redundancy = 14
- Model includes intermediate and complete failure scenarios
  - 14 LRT – 90% -- performance typically at design conditions (10 + 4)
  - 11 LRT – 9% -- periods with lower redundancy (10 + 1)
  - 8 LRT – 1% -- full 6-log failure occurring 1% of the time (14 – 6)
- DDW assumed one 15-min, 6-log failure occurring 1x/year
  - 1% is more conservative than DDW assumption (0.003%)
Crypto – Daily Risk with 4-log redundancy

8 LRT – 1%
11 LRT – 9%
14 LRT – 90%
8 LRT – 1%
11 LRT – 9%
14 LRT – 90%
**Potential Crypto Requirements**

- Minimum treatment for public health protection: LRT = 10
- Minimum redundancy needed to address failures: +4 logs
  - 4-log buffer protective against a conservative 6-log failure rate (1% occurrence)
  - 99% compliance with daily risk goal
  - >99% with annual risk goal (< once in 100 years)
- Proposed compliance requirements for LRTs:
  - 14 LRT – 90%
  - 11 LRT – 9%
  - **10 LRT – 1%**
Pathogen Log Reduction Performance

At or above design conditions 90% of time

Acceptable operation 9% of time

Acceptable operation 1% of time

Discontinue delivery

Within 60 minutes, notify State Board and each public water system

Acceptable operation for 24 hours within 4-log buffer

Discontinue delivery

Within 60 minutes, notify State Board and each public water system

What are the criteria? (4-log redundancy)
Giardia Assumptions

- Raw WW:
  - DPR-2 Distribution: $\mu_{\log} = 4.0; \sigma_{\log} = 0.4$
- D-R
  - Exponential (Regli et al. 1991)
Giardia Required LRTs

Giardia LRT: 10
Add 5-log of redundancy. Will this still be protective if we have a 6-log failure?

To evaluate... we could look at risk if our performance band looks like this →

Public Health Protection: LRT 10
Evaluating Risk – Performance Assumption

- Treatment goals: 10 LRT + 5 LRT redundancy = 15
- Model includes intermediate and complete failure scenarios
  - 15 LRT – 90% -- performance typically at design conditions (10 + 5)
  - 12 LRT – 9% -- periods with lower redundancy (10 + 2)
  - 9 LRT – 1% -- full 6-log failure occurring 1% of the time (15 – 6)
- DDW assumed one 15-min, 6-log failure occurring 1x/year
  - 1% is more conservative than DDW assumption (0.003%)
Giardia – Daily Risk with 5-log redundancy

9 LRT – 1%
12 LRT – 9%
15 LRT – 90%
Giardia – Annual Risk with 5-log redundancy

9 LRT – 1%
12 LRT – 9%
15 LRT – 90%
Potential Giardia Requirements

- Minimum treatment for public health protection: LRT = 10
- Minimum redundancy needed to address failures: +5 logs
  - 5-log buffer protective against a conservative 6-log failure rate (1% occurrence)
  - 99% compliance with daily risk goal
  - >99% with annual risk goal (< once in 100 years)
- Proposed compliance requirements for LRTs:
  - 15 LRT – 90%
  - 12 LRT – 9%
  - **10 LRT – 1%**
Suggested Recommendations

- The Panel recommends a probabilistic analysis utilizing the DPR -2 dataset rather than the static maximum point estimate approach for development of the LRVs.

- While the current LRV criteria can be considered protective of public health, additional analysis is recommended to address potential overengineering treatment barriers and to conduct an intentional effort by DDW to require a reasonable number and combination of such barriers.

- The Panel probabilistic analysis identified alternative LRVs that adequately protect public health and are based on scientifically defensible assumptions.

- The Panel also suggests an alternative approach to address compliance with the LRVs that greatly simplifies the response time-based approach currently proposed.
Summary of proposed criteria with 5-log redundancy

Pathogen Log Reduction Performance

- Acceptable operation for 24 hours within 4-log buffer
  - 20
  - 14
  - 15

- Discontinue delivery
  - 16
  - Crossed out
  - 10
  - Crossed out
  - 11

Within 60 minutes, notify State Board and each public water system

Pathogen Log Reduction Performance

- At or above design conditions 90% of time
  - 18
  - 15
  - 15

- Acceptable operation 9% of time
  - 15
  - 12
  - 12

- Acceptable operation 1% of time
  - 13
  - Crossed out
  - 10
  - Crossed out
  - 10

Within 60 minutes, notify State Board and each public water system
Questions?