

Comments on the
DEPARTMENT OF CONSERVATION
GEOLOGIC ENERGY MANAGEMENT DIVISION
PUBLIC HEALTH RULEMAKING

*DRAFT RULE FOR PROTECTION OF COMMUNITIES AND WORKERS FROM HEALTH
AND SAFETY IMPACTS FROM OIL AND GAS PRODUCTION OPERATIONS
PRE-RULEMAKING RELEASE FOR PUBLIC REVIEW AND CONSULTATION*

Prepared for Earthjustice

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In this report, I review the California Geologic Energy Management Division's (CalGEM's) *Pre-Rulemaking Draft Rule for the Protection of Communities and Workers from the Health and Safety Impacts of Oil and Gas Operations* (Oct. 21, 2021) (hereafter "draft regulations") and the *Response to CalGEM Questions for the California Oil and Gas Public Health Rulemaking Scientific Advisory Panel*. My review focuses on evaluating these materials in the context of statistical, epidemiological, and public health practice regarding the analysis of data for drawing inferences for public health policy-making.

This report addresses: (1) feasible ways CalGEM should strengthen the engineering mitigation controls in its draft regulations to be more protective of human health and safety; (2) the Scientific Advisory Panel's findings of a causal relationship between close geographic proximity to oil and gas development and adverse public health outcomes, and the value of an epidemiological approach to support public health-based regulations; (3) the applicability of studies conducted outside California or involving different engineering practices; (4) the limits of a toxicology approach; and (5) the demands of the precautionary principle.

Background and Qualifications

My academic background is in statistics with an emphasis in medical statistics and biostatistics. I hold a German diploma in statistics with a minor in theoretical medicine and biometrics from Dortmund Technical University (2000), a Masters in Science in statistics with emphasis in biostatistics from the University of Auckland in New Zealand (2001), and a Ph.D. in applied environmental statistics and policy from the Yale School of the Environment (2007). My professional career spans 20 years in the field of sustainability, including the sustainability of the built environment, sustainable environmental design, as well as climate change and decarbonization strategies. I have worked in the United Nations Statistics Division, Environment Statistics Unit (2000-2003), the environmental think tank Ecologic Institute (2009-2014), the Natural Resources Defense Council (2014), Harvey Mudd College (2015-2019, on leave 2019-

2020), and the Nueva School (2019-2020). I am currently the Director of the Zilkha Center for Environmental Initiatives at Williams College (2021-present). Particularly relevant for the issues at hand is my work with the Natural Resources Defense Council and during my time at Harvey Mudd College on the environmental and human health risks of unconventional oil and gas development with particular focus on California.

1. CalGEM must strengthen its regulations to protect public health and safety during the full life cycle of an oil or gas well.

Oil and gas production, including both conventional and unconventional oil and gas development, is a heavy and disruptive industrial process with numerous environmental risks and impacts (Stamford and Azapagic, 2014; Epstein et al., 2002; Srebotnjak and Rotkin-Ellman, 2014). A well's life cycle begins with oil and gas exploration activities, followed by well pad development, drilling, and well completion that lead to production and ongoing idling and maintenance operations, and finally well plugging and abandonment.

The draft regulations presented by CalGEM for public comment seek to establish a strong, 3,200-foot setback distance between oil and gas production activities and infrastructure and communities in their proximity. The draft regulations address several sources of risk to public health and safety that can result from standard oil and gas industry operating practices as well as from accidental spills, well upsets, and other failures.

The proposed new and enhanced safeguards cover (i) the Leak Detection and Response Plan, (ii) Vapor Venting Prevention, (iii) Baseline Water Sampling and Testing, (iv) Sound Controls, (v) Lighting Controls, (vi) Dust Controls, (vii) Gas Sampling and Analysis, (viii) Produced Water Sampling and Analysis, (ix) Non-Emergency Spill Reporting, (x) Production Facility Secondary Containment, (xi) Wellhead Containment, (xii) Stuffing Box Containment, (xiii) Tank Construction and Leak Detection, (xiv) Tank Testing and Minimum Wall Thickness Requirements, (xv) Out-Of-Service Production Facility Requirements, (xvi) Pipeline Inspection and Testing, (xvii) Pipeline Cleanup and Abatement, (xviii) Maintenance and Monitoring of Production Facilities, Safety Systems, and Equipment, (xix) Cementing Casing, (xx) Drilling Fluid Program, and (xxi) Plugging and Abandonment.

These safeguards are scientifically sound based on a range of potential sources of harm to nearby communities resulting from *typical* operations, equipment emissions, accidents, and malfunctions, but CalGEM should strengthen them to reflect the reality of an oil or gas well's *full* life cycle impacts on the environment and nearby communities. A systematic mapping of each life cycle phase's activities (see Figure 1) and associated sources and pathways of potential releases of contaminants into air, water, and soil, as well as other sources of impacts such as noise and light, coupled with corresponding safety precautions would permit a systematic reduction in the likelihood and severity of harmful impacts. Such an approach would also enable CalGEM to consider cumulative risks that arise, for example, from the successive release of an air contaminant such as fine particulate matter (PM_{2.5}) from equipment and processes across multiple phases, as well as the aggregate risks from the presence of multiple emissions sources on the same or nearby well pads.

Indeed, lifecycle-based risk assessment and engineering control measures aimed at their mitigation should not be limited to wells located within the proposed setback distance, but should also apply to all wells statewide—active, permitted but not yet drilled, idle, and improperly abandoned or orphaned—in order to protect human health and the environment. Integrated into a standard code of operations, the measures would help reduce harmful emissions, prevent accidents, leaks, and spills, and provide for clear communication and response measures in case of malfunctions. At a minimum, the approach would lead to the curtailment of the dirtiest, most harmful practices at oil and gas production sites, including but not limited to the on-site use of diesel engines due to their toxic fumes (OEHHA, 2001), gas and liquids flaring due to air and noise pollution (Emam, 2016), and on-site fossil fuel power generation due to air pollution (it is noted that all three activities are also sizeable sources of greenhouse gas emissions).

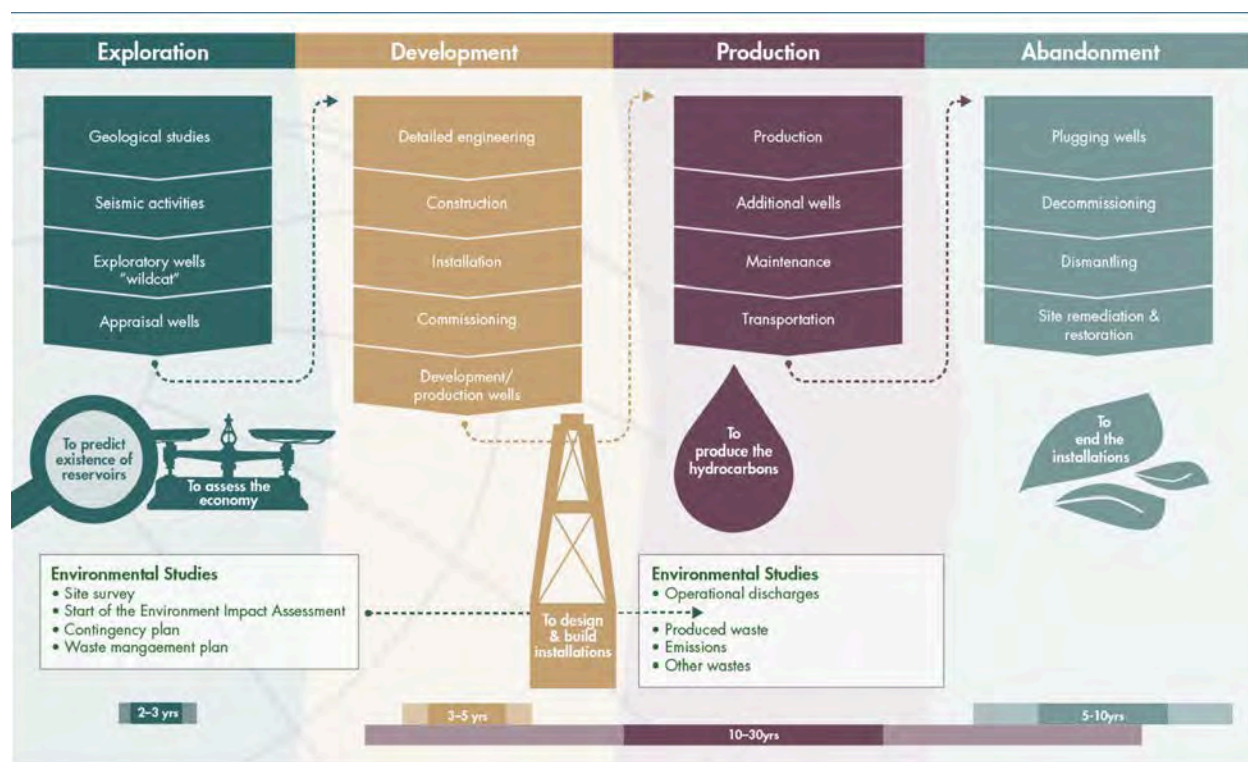


Figure 1: Overview of the life cycle stages of a generic oil or gas well. Source: John Campbell, The International Association of Oil and Gas Producers (OGP), "Activities and Risks" presentation.

Importantly, CalGEM must specify how the setback distance will be measured between oil and gas operations and sensitive receptors. In order to best address the life cycle impacts of oil and gas development activity on surrounding communities, CalGEM must employ the most health protective approach and measure the distance from the property line of sensitive receptors to the fenceline of well sites.

The following comments discuss specific measures in the draft regulations and where they should be further strengthened to protect public health and the environment.

§ 1765 Setback Exclusion Area

- § 1765(a)(2): “The production facilities are necessary for compliance with local, state, or federal requirements”

The draft regulations should state clearly the applicable laws and regulations to ensure that the scope of this paragraph is clear.

- § 1765(a)(4): “The production facility is replacing an existing facility of the same type with no resulting expansion of the geographic footprint.”

This measure is very concerning as it does not limit or prohibit new facilities that have higher production volumes, release more pollutants, or require more intense or frequent maintenance or work-over schedules. CalGEM should remove this provision.

§ 1766 Leak Detection and Response Plan

- § 1766(a): “After [EFFECTIVE DATE PLUS TWO YEARS], the operator shall suspend all production and injection operations in all areas within the setback mitigation area where a Leak Detection and Response Plan is not fully implemented.”

Here and throughout the draft regulations, the lead-times allowed for complying with the draft regulations are lengthy. For Leak Detection and Response Plan development, for example, the U.S. Environmental Protection Agency (EPA, 2014) notes that oil and gas production and refining facilities are significant sources of volatile organic compounds (VOCs) and volatile hazardous air pollutants (VHAPs) and should be subject to Leak Detection and Repair (LDAR) regulations and best practices. Providing a shorter, one (1) year lead-time for the development of an LDAR plan recognizes the importance and urgency of the issue while providing sufficient time for development.

- § 1766(b)(1): Detection Target Identification Element

This measure addresses leaks that may result in emissions leaving the oil field. It is problematic that only methane and hydrogen sulfide are identified as two target chemical constituents when oil and gas production facilities are known to release a host of other hazardous and toxic air contaminants, including toxic PM_{2.5}, carbon monoxide, nitrous oxide, ozone, and VOCs such as aromatic (cyclic and polycyclic) hydrocarbons like benzene, which are known to be persistent and mobile in the environment and widely recognized as harmful to most living organisms through carcinogenic and mutagenic effects.¹² Hydrogen sulfide (H₂S), albeit ubiquitously present at oil and gas production sites and detectable by its ‘rotten egg’ smell at concentrations as low as 0.0005 parts per million (ppm), can be a misleading

¹ See, e.g., Gonzalez, D.J.X, Francis, C.K., Shaw, G.M., Cullen, M.R., Baiocchi, M., Burke, M. (2022). Upstream oil and gas production and ambient air pollution in California. *Science of the Total Environment*, 806: 150298. <https://doi.org/10.1016/j.scitotenv.2021.150298>.

² See U.S. Dept. of Health & Human Services, Agency for Toxic Substances & Disease Registry, *Toxicological Profile for Polycyclic Aromatic Hydrocarbons* (Aug. 1995), <https://www.atsdr.cdc.gov/toxprofiles/tp69.pdf> (accessed Dec. 10, 2021).

warning indicator since its presence dulls the sense of smell and thus may be missed by human smell at higher concentrations. Continuous on-site monitoring for H₂S is necessary for this reason and due to its immediate danger to health and safety at ambient concentrations of 100 ppm. The National Institute for Occupational Safety and Health (NIOSH) set exposure limits for H₂S of 10 minutes at 10 ppm. The Occupational Safety and Health Administration (OSHA) set similar exposure limits of 10 minutes at 20 ppm.

In addition, release of contaminants into the ambient air and regional airshed is just one pathway by which chemicals associated with oil and gas production enter the environment, in addition to soil and water contamination and light and noise pollution. It is therefore critically important for CalGEM to require comprehensive leak detection and response programs that also ensure proper notification of communities and first responders as soon as potential leaks and other hazards are detected.

- § 1766(b)(2)(A): “If hydrogen sulfide detection is required, then the alarm trigger point for the in-field emissions detection system shall not exceed 5 parts per million of hydrogen sulfide.”

OSHA (OSHA, 2021) limits for H₂S already indicate health effects at 2-5 ppm and odor detection at even lower concentrations, thus CalGEM should set the threshold at OSHA’s lower limit of 2 ppm to ensure the most protective measure.

- § 1766(b)(2)(D): “The emissions detection system shall include an alarm system that effectively, immediately, and reliably alerts the operator when triggered. If the operator is able to demonstrate background levels of the target constituents in the area covered by the plan, then the Division may approve alarm set points higher than those prescribed in paragraphs (A) and (B) to account for those demonstrated background levels.”³

To allow for timely alert notification and ensure this measure works effectively in practice, CalGEM must require operators to have a staff member on site at all times and specify that, where this is not possible, operators must provide procedures for how the appropriate staff will be notified. The goal is to protect the health and safety of workers and communities, thus CalGEM should also already take into account prevailing background concentrations of the target contaminants in question and ensure that permissible alarm set points are fixed with respect to best available public health information, regardless of background concentrations.

- § 1766(b)(3): “The Alarm Response Protocol Element shall provide for immediate action to rapidly identify and correct the source of the emissions.”

CalGEM must define “immediate” to ensure the agency, oil and gas operators, and the public understand how alarm response protocols will function in practice and how compliance will be measured.

³ Any reference to “the Division” in the draft regulations is referring to CalGEM.

- § 1766(b)(3)(B): “In the event that the source of the emissions is not identified and the leak stopped within 48 hours, the alarm response protocol shall include a communication plan for notification of people in the community”

Allowing oil and gas operators a 48-hour window for finding the source and stopping a leak will not adequately reduce exposure risks to nearby communities. The communication protocol should instead depend on identification of the substances that are leaking and their toxicity to humans, especially sensitive receptors such as children, pregnant women, the elderly, and those with preexisting conditions. CalGEM should err on the side of caution and advise people in communities as soon as the leak is detected, i.e., within the first 2-3 hours, about the existence of the leak and subsequent updates as soon as more information becomes available, including when the leak has been stopped and exposure risk has receded to background levels.

- § 1766(b)(3)(C): “The operator’s consultation with emergency response entities shall address lower flammability limit alarm set points and protocols for response to detection of target constituents that exceed lower flammability limits.”

Methane is both flammable and a potential explosive. The limits should therefore be set low enough to avoid both hazards. For example, NIOSH has specified a maximum recommended safe methane concentration for workers during an 8-hour period of 1,000 ppm.

- § 1766(b)(3)(D): “The alarm response protocol shall provide for collection and testing of a sample of the emissions content when a continuous alarm event indicates that emissions may have traveled into the community. When developing the alarm response protocol, the operator shall consult with the local public health authority to identify appropriate sampling and testing methodologies”

The sampling and analysis should be attempted and carried out safely as soon as possible if the composition of the emissions source is not or insufficiently known. The sooner this information is available, the more likely and in a timely manner can operators prevent and mitigate potentially harmful exposures and ensure mitigation measures and communication with on-site workers, first responders, and communities.

- § 1766(b)(4)(B): “The protocol for continuing evaluation shall provide for an update to the Leak Detection and Response Plan at least once every five years to incorporate new findings.”

CalGEM should revise this language to require an update to the LDAP at least once every five years, or when substantial changes at the production site occur, whichever time period is shorter.

§ 1766.1 Vapor Venting Prevention

- § 1766.1(a)(3): “The operators shall provide the Division documentation of the results of each vapor venting prevention system inspection within 60 days of completion.”

This measure could be improved by specifying in more detail the types of information that should be provided, including date of inspection, systems inspected and their locations, volumes and types of liquids and volatile compounds that are controlled by the systems, type of problem(s) identified, if any, and corrective actions being taken. If the problem(s) could not be corrected at the time of the inspection, information should be shared with CalGEM about the timeframe within which the problem(s) will be corrected and a subsequent notice will be provided when repairs have been completed.

- § 1766.1(c): “For operations within the setback mitigation area, required vapor venting prevention systems must be installed and operational by [EFFECTIVE DATE PLUS TWO YEARS]. For all other operations, required vapor venting prevention systems must be installed and operational by [EFFECTIVE DATE PLUS FIVE YEARS].”

As per my comment on § 1766 Leak Detection and Response Plan, subdivision (a) above, the compliance times proposed are too long compared with best practices published by EPA (EPA, 2014). A one (1) year timeframe would allow addressing important vapor venting protections in a feasible and timelier manner, and reduce risks to nearby communities. In addition, the section should address and clearly specify what operations are being referred to and clarify if operations outside of the setback mitigation area are included in these regulations.

§ 1766.2 Baseline Water Sampling and Testing

In general, § 1766.2 should specify procedures or consequences if the collected water sample(s) do not meet existing health and safety standards and regulations.

Furthermore, scientific studies and literature have identified per- and polyfluoroalkyl substances (PFAS) in association with oil and gas well drilling fluids. PFAS, also known as toxic forever-chemicals, are increasingly being detected in drinking water and any site that uses or intends to use such substances in oil and gas development processes should include them in their list of analytes in § 1766.2, subdivision (d)(3)(A) for water quality sampling and testing. While PFAS include a class of thousands of compounds, CalGEM should at least require baseline testing for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), which are on the Prop 65 list due to developmental toxicity. The California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment (OEHHA) is also in the process of setting public health goals for them.

In addition, drinking water contamination is not the only pathway and source of possible exposure for people and communities near oil and gas development sites. The paragraph should, therefore, broaden the definition of waters subject to testing to include “water that is, or may reasonably be, used for any beneficial use”, which includes uses such as livestock grazing, agriculture, fishing, and recreation near oil and gas development sites. This definition is already codified in section 3131 of the California Public Resources Code.

- § 1766.2(a): “Before commencing any work that requires a Notice of Intention under Public Resources Code section 3203, the operator shall contact property owners and tenants . . .”

This measure should specify by what communication means, e.g., postal mail or mailbox drop notices, property owners and tenants will be contacted and how non-response will be handled, i.e., how many attempts will be made to contact the property owners and tenants. CalGEM should require at least two (2) attempts.

- § 1766.2(b): “If a property owner or tenant requests sampling and testing of a water well or surface water, then drilling may not commence until a baseline water sample has been collected, provided that the owner’s or tenant’s request is delivered in writing with a record of delivery to the operator within 20 calendar days from the date notice is provided and the surface property owner makes necessary accommodations to enable the collection of a water sample within 10 days.”

This measure should address the need to make sure that the sample is actually received and analyzed by the laboratory prior to the commencement of drilling. CalGEM also should require operators to use an accredited, independent third-party laboratory, and keep the owner or tenant informed throughout the process.

§ 1766.3 Sound Controls

- § 1766.3(a)(1): “Sound levels from oil and gas production operations shall not exceed 45 decibels, as measured anywhere on the property line.”

While this measure is a good start, CalGEM should consider strengthening the noise limits in light of the nearly around-the-clock noise emanating from oil and gas sites. For example, the World Health Organization (WHO) noise guidelines recommend noise not exceeding 40 decibels (dB) for nighttime sleep (WHO, 2021). Kern County also has an absolute threshold of 65 dB. In addition to regulating nighttime noise levels, CalGEM should consider adding limits on daytime noise, especially in the vicinity of sensitive receptors such as schools and daycare facilities, hospitals, and clinics.

§ 1766.5 Dust Control

- § 1766.5(a): “Dust control measures to be employed within property boundaries shall include, but are not limited to: . . .”

CalGEM should also add the mixing of drilling muds to the list of dust control measures because of the potential for drilling mud components and additives such as barite powder and calcium carbonate to escape into the air.

§ 1766.6 Gas Sampling and Analysis

- § 1766.6(a): “Operators shall have a representative gas analysis for each field or distinct geologic area in which the operator produces gas within the setback mitigation area.”

One sample might not be sufficient to characterize the field or geologic area’s produced gas. The key term here is “representative”. Determination of the sufficient number of gas samples that need to be taken with respect to time and spatial extent should be done with statistical

and expert input. I recommend CalGEM consult EPA guidance on collection of ambient air samples (EPA, 2016).

- 1766.6(d): “The requirements of this section do not apply to underground gas storage projects or gas storage wells.”

Underground gas storage projects and gas storage wells should not be exempted from gas sampling and analysis. The massive Aliso Canyon methane gas leak and many leaks of smaller gas volumes have demonstrated that underground gas storage facilities can and do leak gases to the surface and can also communicate with groundwater sources used for drinking water.

§ 1766.7 Produced Water Sampling and Analysis.

- § 1766.7(a): “For produced water from wells within the setback mitigation area, the operator shall provide the Division representative chemical analyses for all produced water transported away from the oilfield where it was produced.”

Produced water often changes in chemistry and/or makeup over time and a clear sampling and analysis schedule should be specified. As an oil and gas bearing reservoir is produced, the compositions typically change with time as well as laterally and vertically. It is, therefore, difficult but important to obtain a representative sample of produced water. A single sample is also too small in total mass to give a complete understanding of the composition of produced water and it is, therefore, understood that many samples need to be obtained and analyzed. The sampling sites should be selected to fit into a comprehensive network to cover an oil or gas-producing field.

§ 1766.8 Non-Emergency Spill Reporting

- § 1766.8(a): “All spills of one-half barrel or more of oil or 10 barrels or more of produced water, that occur within the setback mitigation area, shall be reported to the Division within three days.”

A volume of 10 barrels of produced water (which is equivalent to 10 standard bathtubs) is a non-negligible volume with respect to its potential to harm the environment and human health (Laffon et al., 2016; Brussaard et al., 2016). CalGEM should reduce the reporting threshold for produced water *and* flowback to 5 barrels.

§ 1773.1 Production Facility Secondary Containment

- § 1773.1(b): “Within the setback mitigation area, gravel shall not be used as the sole means of secondary containment.”

CalGEM should provide explicit examples (or an exhaustive list, if practical) on what other forms of secondary containment, such as dikes, berms, curbs, drip pans, sumps, oil retention ponds, and sorbent materials, should be used, since gravel’s high permeability might allow spilled fluids to rapidly pass through it and contaminate soils and potentially reach surface water bodies and groundwater.

- § 1773.1(e): “Operators shall inspect secondary containment for identification of any tears, cracks, or other damage on a weekly basis. All damage to secondary containment shall be repaired immediately.”

CalGEM should require operators to keep records of damage as well as the timing and extent of repairs. This information will be critical to help CalGEM identify ongoing issues with certain equipment or particular operators and determine if more systematic measures are necessary to address these issues.

§ 1773.2 Tank Construction and Leak Detection

- § 1773.2(d), (e)

CalGEM should combine these two subdivisions into a single subdivision that specifies that leak detection systems are required for all tanks that have no impermeable barrier, as all such tanks pose risks to the environment and human health via contamination of soil and groundwater resources, and that the compliance period for retrofitting be set to one (1) year for tanks within the proposed setback distance and two (2) years for tanks outside of it.

§ 1773.4 Tank Testing and Minimum Wall Thickness Requirements

- § 1773.4(f): “The Supervisor or district deputy may require that a tank that has had a leak resulting in the release of a reportable quantity be tested to verify integrity prior to being put back into service.”

CalGEM should revise the language in this measure to require testing before equipment that leaked is put back into service. There is no reason why CalGEM should allow an operator responsible for a leak in a reportable quantity to avoid such testing.

- 1773.4(g): “A tank that is not repaired within 60 days of failing an inspection or test required by this section shall be taken out of service and designated as an Out-of-Service tank. The Supervisor or district deputy may grant one extension of up to 120 days if the operator shows to the satisfaction of the Supervisor or district deputy that there is no significant threat as a result of the extension.”

CalGEM must define “significant threat” in the regulations, as it currently leaves too much room for wide interpretation. Guidance may be taken from EPA’s definition of risk and approach to risk assessment and mitigation.

§ 1774.1 Pipeline Inspection and Testing

- § 1774.1(a): “Operators shall visually inspect all aboveground pipelines for leaks and corrosion at least once a year.”

CalGEM must also add a requirement for the operator to keep records of each inspection and submit them periodically to CalGEM.

- § 1774.1(h)(3)(i): “For pipelines that are subject to mechanical integrity testing under subdivision (f) . . . mechanical integrity testing is not required to be completed until

January 2, 2020. . . For these pipelines, mechanical integrity testing shall be scheduled, completed, and mechanical integrity test results documented per subdivision (f) prior to January 2, 2020.”

It appears CalGEM has not updated these dates to reflect the current rulemaking timeline. The agency should update these dates accordingly.

§ 1777 Maintenance and Monitoring of Production Facilities, Safety Systems, and Equipment

- § 1777(c)(1): “Facilities that are not operating properly or are leaking shall be repaired, replaced, or safely isolated within seven days of identification or in accordance with other applicable requirements, whichever is sooner.”

Depending on the severity of the malfunction, CalGEM should require immediate shutdown of operations. CalGEM should first define a severe malfunction event. For example: “an event whereby (i) the system is not usable for any purpose and/or (ii) any other subsystem in the system does not work properly for one (1) day and/or (iii) any work or service or function of the system is not running in accordance with its operating criteria as defined in the technical specifications and/or the operation and maintenance manuals.”

- § 1777(c)(2): “Fluids, including rainwater, shall be removed.”

CalGEM should update this language to require the safe removal *and* disposal of fluids, including rainwater.

§ 1722.4 Cementing Casing

- § 1722.4(d): “The Division will allow exceptions on a case-by-case basis based on a demonstration that compliance would be impracticable.”

CalGEM must remove this sentence, as case-by-case exemptions dilute the intent of this regulation and open the door to wide discretionary interpretation.

2. There is a causal relationship between proximity to oil and gas operations and adverse health and safety impacts.

The body of scientific, peer-reviewed studies examining the associations, linkages, and causal relationships between elevated health hazards and risks and proximity to oil and gas exploration, drilling, production and maintenance, and well abandonment runs into the hundreds, if not thousands of studies if broadly defined. The studies range from those examining individual wells to those examining large oil and gas fields with thousands of wellheads. They consider the full life cycle of oil and gas development and measure releases of a wide variety of compounds and chemicals into the air, soil, surface and groundwater, and address issues such as noise and light pollution. In addition to studying health risks due to exposure to harmful, hazardous and toxic compounds, studies have also looked at the psycho-social effects, crime and accident statistics, and other social and economic characteristics of wellbeing and community vitality of oil and gas development on nearby people and communities. They extend to oil and gas waste management,

oil and gas infrastructure such as collector, aggregator, and transmission pipelines, refineries, and sand/silica mining for hydraulic fracturing operations.

Collectively, these studies have identified a substantial range of harmful impacts from oil and gas development on human health, including respiratory, neurological and behavioral, teratogenic, carcinogenic, endocrine, cardiovascular, hematological, dermatological, and other organ systems. They have linked stress, loss of sleep, and community tensions to arrival of oil and gas development in and near communities that have not previously been exposed to the industry. Livestock, water contamination, impacts on lands and waters used for agriculture, recreation, fishing, and bathing have been documented as well.

Many of these studies examining the relationships between oil and gas production and health impacts on populations living in the vicinity of associated sites, facilities, and equipment have been criticized for being merely associative as opposed to causative. The use of metrics on the proximity and density of oil and gas operations, sometimes coupled with data on oil and/or gas production volumes, as proxies for potential exposure to the environmental releases of harmful chemicals and contaminants by oil and gas operation has been described as being hypothetical and lacking the robust scientific basis drawing conclusions on causal effects.

Toxicological studies, including risk assessments, have been cited by the oil and gas industry as a gold-standard for making health-based causal claims. However, toxicology has its own limitations, including small sample sizes, being constrained to laboratory experiments that at most partially replicate in-situ conditions, and the need to use animals to test for toxicity. Epidemiology, in contrast, has developed proven tools and approaches to work with available data and still arrive at scientifically sound and defensible conclusions. The nine Bradford-Hill criteria for establishing causality in epidemiological analyses discussed in the Scientific Advisory Panel's October 1, 2021 response to CalGEM, for example, is an established and robust approach to reducing the likelihood of interpreting coincidental associations as causal relationships. As the Scientific Advisory Panel experts have demonstrated in their response, evidence of health impacts of living and working in close proximity to oil and gas operations is growing and establishing that it is these operations that are the cause or contributing factor for observed negative health respiratory, cardiovascular, and perinatal outcomes.

The Panel's summary and response to questions also reflects standard scientific practice to treat statistically significant findings with caution and complete careful evaluations of the studies' design, data collection, and validation processes, statistical modeling, analysis and validation approach, while ensuring a comprehensive statement of limitations. Their extensive literature review and rigorous study selection criteria resulted in a collection of relevant, applicable, and high-quality studies, the affirmative and consistent findings of which allowed the Panel to draw the conclusions that with high levels of certainty, oil and gas development and associated exposures pose a range of minor to serious human health risks, including to fetuses, and that such risks are more likely and more consistently found in proximity to oil and gas wells, especially at distances within 1 kilometer.

3. Both conventional and unconventional oil and gas development present similar health risks.

The Scientific Advisory Panel's review of the peer-reviewed literature and those of other authors also demonstrates that conventional and unconventional oil and gas development share many of the same processes, equipment, and releases of chemicals and contaminants into the environment. Unconventional oil and gas production tends to increase these impacts (with the possible exception of the land footprint of well pads due to the possibility of long-lateral, directional drilling that allows concentrating wellheads on a smaller surface area) due to the need for more materials and chemicals, longer drilling times, more frequent work-over needs or repeated well stimulation along lateral/directional target zones, and greater waste volumes. Although California's geology is different from that of other (conventional and unconventional) oil and gas production areas, studies from other areas can be used to inform the types, sequence, and duration of processes, species of chemicals and contaminants used and potentially released, as well as exposure pathways for workers and nearby communities in the California context. As the Panel concludes, there are many environmental and health hazards and risks that are intrinsic to both conventional and unconventional oil and gas development, thus supporting the conclusions drawn by studies and health risk assessments focusing on one or the other.

4. A toxicological approach is too narrow for public health-based regulations.

Just as studies from other geographical areas may provide valid and helpful insights into the types of health and safety risks posed by oil and gas operations to workers and communities in their vicinity in California, so can epidemiological and toxicological studies support and inform the analysis of the specific causal links and pathways of how oil and gas operations impact people's health.

Toxicological analyses, however, rely on controlled experimental conditions and the ability to establish clear dose-response functions that cannot typically be created in situations involving humans in real-life situations with many uncontrollable and potentially confounding variables and serious ethical limitations. Toxicologists also often need to work with very small sample sizes due to experimental and ethical constraints on laboratory animals or human subjects. Epidemiological studies, by contrast, may involve hundreds and thousands of participants with conditions that are as controlled as possible, or at least as observed as possible, such that potentially confounding factors can be accounted for in the analysis. Thus, limiting conclusions on the health and safety of oil and gas operations strictly to controlled toxicological laboratory studies is both unrealistic and an artificially narrow view of the scientific study of human-environment interactions.

The body of epidemiological studies within the scientific literature examining the impacts from oil and gas development also continues to grow rapidly, while toxicological studies remain a smaller subset, with many studies examining toxics from transportation or other sources as opposed to those associated with oil and gas operations.

5. CalGEM must adopt public health regulations in line with the demands of the precautionary principle.

CalGEM's mission is to “. . . protect[] public health and safety and environmental quality, including reduction and mitigation of greenhouse gas emissions associated with the development of hydrocarbon and geothermal resources in a manner that meets the energy needs of the state.” (Pub. Resources Code, § 3011(a).) Such protection of public health and safety and environmental quality requires a proactive stance that should seek, as much as possible, to identify, characterize, mitigate, and eliminate threats to public health and environmental quality before they materialize.

A guiding principle for such an approach is the precautionary principle, which prescribes being cautious, deliberate, and careful in permitting, facilitating, enabling, and otherwise supporting new and existing activities, with a view toward first identifying their potential negative effects, especially on vulnerable populations. The burden of proof to demonstrate a high degree of safety in such circumstances—for example, the permitting requirements for drilling through a non-exempt groundwater aquifer—falls on the permit applicant. CalGEM's public health regulations would follow the spirit of the precautionary principle if at each step of oil and gas development, the regulations examine the potential impacts of development activity and their severity on nearby communities and the environment, and regulate the activities in order to minimize the risks of the impacts to occur—even if this results in oil and gas development effectively becoming impossible in certain locations and contexts. Putting public health and safety and environmental quality first is the basic premise underlying a precautionary approach to oil and gas regulation.

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