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BASIS FOR ROCHE TECHNICAL IMPRACTICABILITY (TI) DETERMINATION REQUEST

AND

RESPONSE TO N.J. DEPARTMENT OF ENVIRONMENTAL PROTECTION COMMENTS

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I. INTRODUCTION

Roche implemented an Interim Remedial Measure (IRM) to reduce 1,4-dioxane (referred to as "dioxane") mass within the source area of a dioxane plume at the former Roche facility (Site) in Nutley, New Jersey. The plume emanating from this source area is referred to as the IA-1/4 Dioxane Plume. As documented in Roche's April 2019 IA-1/4 IRM Progress Report (TRC, 2019a) and Roche's December 2019 Remedial Action Workplan (RAWP; TRC, 2019b), the IRM effectively reduced dioxane concentrations in the targeted treatment zone (the "IRM Treatment Zone"). Monitoring data indicated that the remedy had become asymptotic in nearly all wells; even with several attempts to optimize remedial performance, the system was not able to further reduce concentrations in the IRM Treatment Zone.

This IA-1/4 Dioxane Plume IRM was a cutting-edge application of *in-situ* remediation for dioxane in fractured sedimentary bedrock. We are not aware of any other attempts in New Jersey (or anywhere else, for that matter) to remediate dioxane *in-situ* in a similar hydrogeologic setting. The technology and design of the IA-1/4 Dioxane Plume IRM at the Site were both innovative and based on the best available scientific research and engineering design principles.

In the December 2019 RAWP, Roche proposed to transition to Monitored Natural Attenuation (MNA) for the IA-1/4 Dioxane Plume. The December 2019 RAWP also included a request for a Technical Impracticability (TI) determination for dioxane that was deeper than the IRM Treatment Zone (*i.e.*, deeper than about 90 feet below ground surface [ft bgs], (referenced in this document as "Deep Dioxane" or "Deep Dioxane Plume") which is different than the deeper zone of the IRM Treatment Zone. On May 4, 2020, the New Jersey Department of Environmental Protection (NJDEP) sent comments to Roche, requesting additional information to support Roche's requested TI determination <u>for the Deep Dioxane Plume</u>.

This Basis for Roche's Technical Impracticability Determination (Technical Basis) presents the lines of evidence in support of Roche's request for a TI Determination for the Deep Dioxane Plume and demonstrates that the combination of dioxane's chemical characteristics and the complex Site hydrogeology create conditions such that the remediation standard is not achievable from an engineering perspective. In this Technical Basis, Roche also provides the additional information requested by the NJDEP in its specific comments. In Attachment 1, Roche cross-references the sections in this Technical Basis that provide the answers to specific NJDEP comments.

II. DESCRIPTION OF THE IA-1/4 DIOXANE PLUME IRM AT THE SITE

Roche's request for a TI Determination is based, in significant part, on its experience actually treating dioxane at the Site. During the Site-Wide Groundwater Remedial Investigation (RI), groundwater contamination was detected in several portions of the Site. Roche transitioned quickly from the RI to an aggressive groundwater remedial program, targeting several on-Site source areas where releases had generated discrete plumes. Roche designed and implemented IRMs at most of these source areas.

One of the plumes identified was the IA-1/4 Dioxane Plume, originating from the approximate boundary between Investigative Areas (IAs) 1 and 4. The horizontal extent of the IA-1/4 Dioxane Plume is shown on Figure 1. The IA-1/4 Dioxane Plume IRM was implemented in the IRM Treatment Zone vertically from the water table down to about 90 ft bgs; this vertical interval was broken down into shallow, intermediate, and deep treatment zones, as shown on Figure 2. Dioxane-impacted groundwater present at depths below 90 ft bgs, and extending to a depth of approximately 370 ft bgs, is referred to as the Deep Dioxane Plume. The IA-1/4 Dioxane Plume IRM is described below.

A. Design Challenges for Dioxane Remediation in Groundwater

Designing an IRM for dioxane at any site presents special challenges because of its physical and chemical properties. Dioxane has a low Henry's law constant, high vapor pressure, and a boiling point approximately equal to that of water, and therefore it cannot easily be stripped from water. Dioxane also has a low organic carbon partitioning coefficient, which results in low adsorption to organic carbon in the aquifer matrix or treatment media. Finally, dioxane is fully miscible in water, which can result in high dissolved phase concentrations being present in groundwater; these high concentrations produce concentration gradients that significantly enhance the diffusion of dioxane into low permeability zones within aquifers, where the dioxane becomes effectively immobile and inaccessible to treatment (this process is referred to as matrix diffusion).

Dioxane is not susceptible to air sparging/soil vapor extraction (SVE), chemical reduction (*e.g.*, zero-valent iron), or anaerobic biodegradation. Aerobic bioremediation has been documented in bench-scale and pilot studies (Adamson *et al.*, 2016), but has not been demonstrated to be effective in a full-scale application. Literature searches showed that the only viable *in-situ* treatment of dioxane in groundwater is chemical oxidation (ITRC, 2020).

B. Site-Specific Design Challenges that Affect Remediation Effectiveness

These remedial design challenges for dioxane are further complicated by the Site's geologic conditions. The Site is underlain by fractured sedimentary bedrock, which contains both primary (matrix) and secondary (fracture) porosity (also known as dual-porosity bedrock). Groundwater migration occurs almost solely within the secondary porosity (*i.e.*, the interconnected fractures). However, the majority of dioxane mass resides within the primary porosity, due to matrix diffusion (Parker, *et al.*, 2010). Both injection- and extraction-based remediation technologies treat contaminant mass present within the secondary porosity only and are not able to effectively treat contaminant mass present within the primary porosity.

As will be discussed in greater detail in Section III, in the case of dioxane, the only viable *in-situ* remediation technology is injection of chemical oxidants to treat the dioxane present within transmissive bedrock fractures. Therefore, the goal of the IA-1/4 Dioxane Plume IRM was to treat accessible dioxane mass within transmissive bedrock fractures. Any effort to treat dioxane at this Site by extracting it from the groundwater and treating it *ex-situ* will not, for the same reasons, be successful in reducing dioxane concentrations below a certain level. That is, pumping groundwater cannot extract dioxane from the primary porosity; in fact, such extraction is less aggressive than *in-situ* chemical oxidation (ISCO) in addressing dioxane in the primary porosity.

Significant characterization of bedrock fractures at the Site revealed that the density of fractures generally decreases with increasing depth, so the proportion of dioxane mass available for treatment decreases with increasing depth; that depth also increases the difficulty of injecting into the bedrock formation given fewer transmissive fractures at depth. The decreasing presence of fractures was confirmed by geophysical data from two monitoring well clusters in the IRM Treatment Zone (MW-2C/DW-12CR and MW391C/DW67B) and one well cluster immediately downgradient of it (MW-136C/DW-68B). As can be seen below, within and immediately downgradient of the dioxane source area, the fracture density decreases within increasing depth (over 40% reduction) significantly below mean sea level (msl).

AVERAGE NUMBER OF FRACTURES PER LINEAR FOOT OF DEPTH WITHIN THE DIOXANE SOURCE AREA

Elevation Interval (feet msl)	**Treatment Zone**	**Fracture Density MW-2C/DW-12CR**	**Fracture DensityMW-391C/DW-67B**	**Fracture DensityMW-136C/DW-68B**	**Average Fracture Density**
80’ to 50’	S2	0.40	0.60	0.37	0.46
50’ to 0’	S3	0.34	0.70	0.20	0.41
0’ to -100’	D1	0.22	0.53	0.25	0.33
-100’ to -200’	D2	0.18	0.35	0.25	0.26

msl = elevation in feet relative to mean sea level

Because the injected oxidant can only effectively treat the dioxane in the transmissive fractures, the treatment system needs to focus on areas with the largest number of those fractures, *i.e.* from zones at or about 90 ft bgs to the water table (which is about 15 to 20 ft bgs) in the source area. Furthermore, as can be seen on the fracture histograms provided on Figure 3, within the source area, the vertical distribution of fractures at elevations below msl is not evenly distributed. If deeper ozone injection were conducted, this uneven distribution of fractures would channel ozone into those few transmissive fractures present, resulting in the vast majority of the Deep Dioxane Plume receiving no treatment. Treatment of the Deep Dioxane Plume is further complicated by matrix diffusion, as discussed above.

C. Roche's IRM Design

There have been very few (if any) attempts to remediate dioxane *in-situ*, especially in fractured bedrock. The technology and design of the IRM at the Site were both innovative and based on the best available scientific research and engineering design principles.

The IA-1/4 Dioxane Plume IRM addressed an area of approximately 140,000 square feet to a depth of up to 90 ft bgs. Figure 1 depicts the lateral extent and Figure 2 shows the vertical extent of the IRM Treatment Zone. As can be seen on Figure 2, the higher concentration portion of the IA-1/4 Dioxane Plume is closer to land surface in the center of the source area, and occurs slightly deeper as it migrates downgradient, to the south. The IRM targeted an area that contained not only dioxane, but also lower concentrations of volatile organic compounds (VOCs) in certain portions of the treatment zone. The IRM was designed to address both dioxane and the VOCs.

Treatment of dioxane within the fractured bedrock of the IA-1/4 Dioxane Plume required an innovative and aggressive, *in-situ* approach. As shown on Figure 1, TRC designed a dense network of injection and In-Well Air Stripping (IWAS) wells to treat the entire targeted volume as quickly and aggressively as possible, using ozone as the oxidant. The injection wells and IWAS wells were installed at an approximate 70-foot spacing. The IWAS wells stripped the low concentrations of VOCs present in the IRM Treatment Zone and were employed to recirculate groundwater around the ozone injection wells, enhancing ozone distribution and limiting short-circuiting of the injected gas.

In all, the full-scale injection scheme for the IA-1/4 Dioxane Plume IRM included 44 ozone sparge wells, 34 IWAS wells, and nine vapor extraction trenches (VETs). Each ozone sparge well includes an upper and lower (shallow and deeper) injection interval, for a total of 88 total sparge points in the treatment area, as follows:

- Shallow IRM Treatment Zone (15 or 20 to 40 ft bgs): Includes 16 ozone sparge wells screened across two depth intervals (25-40 ft bgs and 55-70 ft bgs) and 13 IWAS wells screened between 10 and 60 ft bgs. This shallow remedial zone corresponded to what was previously labeled Zone S1 (saturated bedrock at elevations above 80 feet msl). The upper ozone sparge intervals were positioned in the Shallow IRM Treatment Zone and the lower ozone sparge intervals were positioned in the Intermediate IRM Treatment Zone; the IWAS wells straddled both the Shallow and Intermediate Treatment Zones.

- Intermediate IRM Treatment Zone (40 to 70 ft bgs): This intermediate zone corresponded to Zone S2, from 50 to 80 feet msl. The lower ozone sparge intervals in the 16 shallow zone sparge wells described above, and the upper ozone sparge interval in the 28 deeper zone sparge wells described below, injected ozone into the Intermediate Treatment Zone. The lower portion of the shallow IWAS wells, and the upper portion of the deeper IWAS wells, straddled the Intermediate Treatment Zone.

- Deep IRM Treatment Zone (70 to 90 ft bgs): Includes 28 ozone sparge wells screened across two depth intervals (45-50 ft bgs and 75-90 ft bgs) and 21 IWAS wells screened between 30 and 80 ft bgs. This deeper zone corresponded to the upper half of Zone S3, which extended from sea level to 50 feet msl (about 70 to 120 ft bgs). The upper ozone sparge intervals were positioned in the Intermediate IRM

Treatment Zone and the lower ozone sparge intervals were positioned in the Deep IRM Treatment Zone; the IWAS wells straddled both the Intermediate and Deep Treatment Zones.

Ozone was selected as the chemical oxidant because it could be generated and distributed on-Site to allow for continuous injection and without the need for transport of high volumes of the liquid oxidant through the surrounding residential community. The volume of an alternative liquid oxidant (*e.g.*, persulfate) required for the IRM Treatment Zone was calculated to be approximately 1.4 million gallons, requiring approximately 250 6,000-gallon tanker trucks of high-strength oxidant to be routed through the residential community surrounding the Site. The ozone application presented essentially no risk to the surrounding residents. However, ozone did present potential hazards to Site workers (see below), though due to the inactive nature of the Site at that time, these hazards were manageable through careful control of injection pressures, ozone-monitoring sensors, VETs, and frequent inspection of equipment and distribution lines.

D. Target Concentrations/Rationale

In line with the NJDEP's guidance to implement IRMs to remove, contain, or stabilize source areas of groundwater contamination, the IA-1/4 Dioxane Plume IRM was designed to treat groundwater in the source area that exceeded a target concentration of 500 micrograms per liter (µg/L) both horizontally and vertically. However, due to the conservative nature of the design, the IRM actually encompassed the area and volume of affected groundwater that had dioxane concentrations above 250 µg/L.

The selected treatment goal aimed to reach an average concentration of 50 µg/L in the IRM Treatment Zone (*i.e.*, a 90% reduction). It was recognized from the outset that the limitations to remediation presented by the fractured sedimentary bedrock would inhibit the ability to achieve ozone contact with the significant portion of the dioxane mass that resided in the primary porosity and small isolated fractures. Therefore, it would never be possible to achieve average dioxane concentrations significantly less than 50 µg/L in groundwater within the more transmissive fractures because back diffusion of dioxane from the rock matrix and small isolated fractures would replenish the plume for decades to come (Adamson *et al.*, 2016; National Academies of Sciences, Engineering, and Medicine, 2015).

E. System Operation and System Performance/Effectiveness

1. Installation of the System

The treatment system was completed in June 2016 and initial operation began in late June 2016. The system operation was suspended approximately 2 weeks later due to concerns over ozone leaks in the tubing joints and rotometers (gas flow meters). The ozone distribution panels were completely replaced with upgraded tubing and meters. The deeper portion of the treatment system returned to operation in September 2016, and the entire system was operational by November 2016 and continued until October 2018, at which time the operation was focused on a few areas where concentrations remained high. This optimization effort, focusing on small portions of the entire treatment area, continued through January 2019.

2. System Performance and Efforts to Enhance

The average dioxane concentrations during IRM implementation in each of the vertical treatment zones and for the whole treatment volume are presented on Figure 4. Roche's implementation of the ISCO remedy, using ozone as the oxidant, reduced dioxane concentrations in the range of 1,000s of µg/L before treatment to an average of about 100 µg/L or less after treatment, but could not appreciably reduce concentrations in the range of 50 to 100 µg/L to lower concentrations. *See* Figure 51 in Appendix A[1] for dioxane concentrations after treatment n HGU 3, which is the lowest portion of the IRM Treatment Zone.

The IRM's effectiveness in destroying dioxane in groundwater diminished over the course of the 2 years of system operation, reaching an apparent asymptote in 2018. Roche made several efforts to enhance the dioxane remediation. First, the aqueous ozone radical has a relatively short half-life which was most likely further reduced by reactions with minerals in the bedrock. When Roche noted that dissolved oxygen levels were remaining near zero milligrams per liter (mg/L) in several wells in the IRM Treatment Zone, Roche targeted those wells with additional treatment through the injection of a different oxidant – activated persulfate (APS) with peroxide. Due to a longer typical half-life of persulfate, the reagent was anticipated to survive migration to the targeted wells with enough potency to affect treatment of dioxane upon contact. However, the persulfate reacted with minerals in the iron-rich bedrock matrix to a much greater extent than expected, resulting in essentially no destruction of dioxane in areas where matrix reactivity was high. A transient increase in certain metals concentrations was observed in these areas as a result of the preferential oxidation of the minerals in the bedrock. The result of this enhanced oxidation pilot test reinforced the decision that ozone sparging, even with its limitations, was the only technology to remediate dioxane in this fractured rock setting.

In an additional effort to optimize performance and treat the remaining dioxane, Roche started a program to deliver more ozone mass at higher pressures in the vicinity of wells where concentrations routinely remained above 100 µg/L. However, 2 months of this greatly increased treatment focus had no measurable effect on dioxane concentrations in the targeted wells. We believe this is due to a lack of connected fractures in these areas through which unreacted ozone could readily migrate.

After nearly 24 months of continuous operation, Roche noted asymptotic conditions in average dioxane concentrations. After the APS injection and ozone enhancement efforts were attempted and found to have limited efficacy, Roche terminated operation of the systems on January 28, 2019.

Roche conducted post-IRM groundwater monitoring on a quarterly basis throughout 2019 and early 2020 to evaluate the potential for concentration rebound within the IRM Treatment Area. The data demonstrate that dioxane concentrations have been significantly reduced throughout the IRM Treatment Area and are in steady state following completion of IRM activities, and that no significant rebound has occurred. Steady-state conditions indicate that dioxane concentrations in groundwater within the fractures are in equilibrium with dioxane concentrations in the rock matrix (primary porosity). Because of matrix diffusion, the majority of the remaining dioxane mass is present within the rock matrix where it is

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[1] The figures in Appendix A were originally included in the most recent Site-Wide Groundwater Progress Report submitted to the NJDEP (TRC, February 2020).

relatively immobile and inaccessible to injected treatment chemicals. This explains why attempts to optimize system performance were not successful.

3. Ozone Safety Issues and Corrective Steps

Ozone is known to have a corrosive effect on all of the components of the ozone generating and injection system, including the ozone generators, tubing, gaskets, valves, and rotometers. As ozone flows through the system, it will begin to react at the weak points of each one of the system components and can cause leaks over time. Further exacerbating the potential for leaks is the high pressure under which the system operated because of the depth of the injection wells and the pressure required to force the gas into the fractures of the rock (fracture entry pressure). The leaks not only create a system efficiency issue, but because ozone is a strong oxidizer, it presents a potential hazard to on-Site workers.[2]

In addition to leaks from the ozone injection system itself, ozone injected into the subsurface can be released to the atmosphere and create a health risk if any unreacted ozone can reach the shallow surface by migrating upward through vertical fractures or borehole annuli. To address this potential concern, several soil VETs were installed in the treatment area to capture potential fugitive ozone emissions. In the initial stages of operation, ozone was detected in the VETs, which prompted modifications to the components of the system.

During the operation of the IA-1/4 Dioxane Plume IRM, ozone was injected into the fractured bedrock as a gas generated on-Site having approximately 6-10% ozone. In order to inject the gas into the bedrock, the system had to generate sufficient pressure to overcome 1) the hydrostatic pressure of the overlying water above the point of injection and 2) the pressure required to force air into water-filled fracture openings (fracture entry pressure). At 150 feet below the water table, the hydrostatic pressure alone is 65 pounds per square inch (psi). Based on observations during the injections, pressure readings from some of the shallow wells could be as high as 65 psi. Since the shallow wells were approximately 20 feet (9 psi) below the water table, the fracture entry pressure at these locations would have been 56 psi. Therefore, the combined pressure that would be needed to inject ozone at 150 feet below the water table would be expected to be at least 120 psi, with the potential to be greater due to the lower fracture density observed at that depth.

While the ozone injection system was operating, at pressures ranging between 25 psi and 85 psi, fugitive ozone was detected inside and outside the trailers that housed the ozone generators and booster pumps. Out of an abundance of caution for the potential health effects of breathing ozone, the system had an alarm that resulted in the immediate shutdown of the system when ozone was detected above the defined threshold. This alarm was frequently triggered due to leaks, despite ongoing maintenance and repairs. Alarms were addressed promptly, and the system operated 90% of the time during the 2-year operational period. Operating at higher pressures on a continuous basis was not practical.

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[2] Breathing ozone can cause both acute and chronic health problems. These problems can include chest pain, coughing, throat irritation, and airway inflammation. It also can reduce lung function and harm lung tissue (USEPA, 1996 and 2019).

Concerns with high pressure oxidant injection are specifically identified in design guidance for *in-situ* sparge systems which have identified that a number of systems have had failures due to high pressure, including inadvertent aquifer fracturing and annular seal failure on wells due to excessive pressure. (Wisconsin Department of Natural Resources [DNR], 2015). These concerns have been corroborated by technology vendors who have indicated that the risk of leaks and damage to fittings or couplings increases with increasing injection pressures. They noted that the more complex the sparging system (*i.e.*, more couplings and other connections), the greater the risk of leaks.

III. EVIDENCE SUPPORTING TECHNICAL IMPRACTICABILITY DETERMINATION

Given Roche's experience with the IA-1/4 Dioxane Plume IRM, the nature of the Site, and the limit of available technologies, Roche's request for a TI Determination is well founded. Roche bases its request on the lines of evidence outlined below.

1. Roche's IA-1/4 Dioxane Plume IRM Employed Cutting Edge Technology to Treat Dioxane in Fractured Sedimentary Bedrock

Roche's use of ISCO to treat dioxane in the particular setting of the Site was cutting edge. To the best of our knowledge, this IRM was the first-ever injection of ozone in fractured sedimentary bedrock to treat dioxane in New Jersey (or anywhere else).

The innovative nature of the technology implemented for the Site is further supported by the recently published Interstate Technology and Regulatory Council (ITRC) update for 1,4-dioxane treatment (ITRC, 2020). In this publication, ITRC provided an overview of 29 dioxane treatment technologies. ITRC noted that for all of these technologies, large treatment areas are challenging and/or cost-prohibitive, and heterogeneity (such as characterized by the fractured bedrock system at the Site) leads to variable effectiveness.

Of the 29 possible technologies presented, only nine are considered by ITRC to be fully demonstrated to be effective in treating dioxane. Of these, five are *ex-situ* treatment technologies that are generally not applicable to aggressive source area remediation. MNA and phytoremediation were also listed, but neither of these technologies is capable of rapidly treating a dioxane source area in fractured sedimentary bedrock.

The remaining two technologies identified by ITRC are forms of ISCO. This assessment is consistent with findings presented by Adamson *et al.* (2016), who indicated that ISCO is the only viable *in-situ* treatment option for dioxane. Roche implemented two types of ISCO technologies – ozone, which ITRC listed as an emerging technology, and APS injections, which ITRC listed as a fully demonstrated technology – as part of the large-scale IA-1/4 Dioxane Plume IRM. Of these two, Roche demonstrated that ozone injection was the only viable technology at the Site because it degraded dioxane while not reacting excessively with minerals in the bedrock, as was the case for APS. This demonstrates the cutting-edge nature of Roche's dioxane remediation program as well as Roche's conclusion that there are no other viable and effective technologies suitable for the IA-1/4 Dioxane Plume at this Site.

2. Roche Made Repeated Efforts to Optimize IRM System Performance, But Could Not Reduce Average Dioxane Concentrations Below 50-100 μg/L

The IA-1/4 Dioxane Plume IRM was a significant undertaking, and not a token effort. It encompassed a treatment area of 140,000 square feet to a depth of up to 90 ft bgs. The system included 88 individual ozone sparge points to inject ozone into the fractured sedimentary bedrock, 34 IWAS recirculation wells to enhance ozone distribution within the treatment zone, and nine VETs to capture potential fugitive ozone emissions. Ozone was injected into the subsurface nearly continuously for almost 24 months, resulting in significant dioxane concentration reductions in the source zone. When this approach proved ineffective at completely addressing some recalcitrant areas within the IRM Treatment Zone, Roche attempted to inject APS, a powerful oxidant with a longer half-life, to see if it might be more effective in reaching and reducing the dioxane residuals[3]. That effort was not successful. Roche then attempted to optimize the ozone injection system by delivering focused and enhanced ozone injections in just a few wells around these hot spots. This did not result in sustained improvement in concentration either. Despite multiple attempts to optimize the ISCO program, groundwater monitoring results demonstrated that ISCO had reached its limits and was not effective at further reducing average dioxane concentrations below the range of 50-100 µg/L, most likely because the Site's hydrogeologic setting is dominated by fractured sedimentary bedrock that is storing a residual mass of diffused and inaccessible dioxane.

As stated previously, the remedy implemented by Roche was at the cutting edge of industry practice. In a recent Fact Sheet (March 2020) entitled *Remediation and Treatment Technologies – 1,4-Dioxane,* ITRC described *in-situ* ozone treatment of dioxane as an *emergent* technology, and pointed out the positive and negative aspects of the approach. One of the drawbacks cited is "Large treatment areas are challenging and/or cost prohibitive, and heterogeneity leads to variable effectiveness". Roche implemented this innovative emergent remedial approach, because it was the only approach that could reduce dioxane concentrations, and continued its operation until the complex heterogeneity of the fractured bedrock limited its effectiveness.

3. Hydrogeologic Features Limits the Effectiveness of Treatment Preventing Further Reductions of Dioxane Concentrations Especially at Depth

Roche's inability to reduce dioxane concentrations below 50-100 µg/L in the IRM Treatment Zone is due to the constraints of the hydrogeologic setting as explained above, and those constraints would be even more challenging for efforts to address the Deep Dioxane Plume. The constraints are well-established in the peer-reviewed literature, including papers by several leading research scientists, such as Dr. John Cherry, Dr. Beth Parker, Dr. Bernie Kueper, Dr. Allen Shapiro, Dr. Charles Newell, among many others (*e.g.*, The National Academies of Sciences, Engineering, and Medicine, 2015; Day-Lewis *et al.*, 2017; Parker *et al.*, 2010; Adamson *et al.*, 2016; Lipson e*t al.*, 2005).

Day-Lewis *et al.* (2017) reports "at most 'aged' sites where contaminant releases occurred decades ago, recalcitrant contaminant mass now resides in the much lower permeability matrix blocks between fractures (immobile porosity)." The article further states "remedial technologies involving injections of fluids and amendments can be ineffective as they may only reach the mobile porosity in practical timeframes, while the immobile porosity continues to store and slowly release contaminant mass by diffusion across concentration gradients between the immobile and mobile porosity." The National Academies of Sciences, Engineering, and Medicine (2015) indicates that "treatment approaches for plumes in fractured rock conceptualized as large, diffuse, and unstructured are limited if non-existent." Adamson *et al.* (2016) states that "given these challenges, management of these secondary 1,4-dioxane sources using less-intensive methods such as natural attenuation and institutional controls may be more feasible."

[3] It was not more effective, because it was consumed by reactions with minerals in the bedrock, due to the natural oxidant demand of the iron-rich bedrock.

These challenges would be particularly acute in the Deep Dioxane Plume, which is present at elevations below sea level where the number of bedrock fractures is significantly less and the vertical distribution of those fractures is more sporadic than in shallower bedrock. If ozone injection was conducted in the Deep Dioxane Plume, this uneven distribution of fractures would channel ozone into those few transmissive fractures present, resulting in the vast majority of the Deep Dioxane Plume receiving no treatment.

Collectively, this esteemed group of research scientists agrees that active remediation at dual-porosity fractured bedrock sites yields limited benefit, as it cannot address the significant contaminant mass present within the primary porosity (matrix) of the bedrock. Therefore, Roche believes that implementation of active remedial technologies will not significantly reduce the longevity of the Deep Dioxane Plume, as the lesser degree and heterogeneous distribution of fracturing at depths below msl (about 100 to 120 ft bgs in the area of the IA-1/4 Dioxane Plume) significantly complicates distribution of remedial additives within the fracture network and would leave large blocks of dioxane-impacted rock matrix untreated.

Experience at the Site confirms this research and teaches that current concentrations of dioxane downgradient of the treatment zone and in the Deep Dioxane Plume are not amenable to treatment. Figures 52 and 53 from Appendix A[4] show the distribution of dioxane in HGUs 4 and 5, which includes the wells in the deeper zones below the IRM Treatment Zone, where the Deep Dioxane Plume resides. Nearly all of the wells in HGUs 4 and 5 showed dioxane concentrations less than 50 µg/L. Therefore, the Deep Dioxane Plume as a whole is characterized by dioxane concentrations that are too low to be effectively treated by the remedial approach employed in the IRM treatment area. In fact, the current concentrations in these wells are lower than the concentrations achieved through Roche's cutting edge treatment. Based on the performance of the IA-1/4 Dioxane Plume IRM, which reduced dioxane concentrations generally to a range of 50 to 100 µg/L, concentrations in the Deep Dioxane Plume (and at any other locations with concentrations no higher than 50 to 100 µg/L) are below the effective range of ISCO treatment at the Site.

4. Attempting to Treat the Deep Dioxane with Ozone Injection Risks Spreading the Dioxane

Any *in-situ* injection remedy has the potential to spread contamination in unanticipated directions. In a U.S. Environmental Protection Agency (USEPA) Engineering Issue Paper (Huling and Pivetz, 2007) entitled *In-Situ Chemical Oxidation*, the authors state "The injection of any oxidant solution into a source area can result in the displacement of contaminated ground water from the source area and transport into potentially uncontaminated areas."

The potential for contaminant spread in unanticipated and unpredictable directions increases with increasing depth at the Site for several reasons. First, the decreasing fracture frequency will result in injected ozone traveling preferentially along the limited fractures, and thereby traveling less uniformly in the impacted area, and potentially pushing contaminated groundwater along preferential fractures in unpredictable directions.

[4] The figures in Appendix A were originally included in the most recent Site-Wide Groundwater Progress Report submitted to the NJDEP (TRC, February 2020).

The second reason relates to the increased pressures that would be needed to inject at greater depths. The increased pressure would exacerbate the preferential migration of injected ozone, and thereby significantly reduce effectiveness, due to the inability to distribute ozone evenly through high-concentration zones. Furthermore, injecting ozone under high pressure has the potential to create new fractures, a process referred to as hydrofracturing when done intentionally in fossil fuel exploration and some remedial approaches. The creation of new fractures would increase the spread of ozone, and possibly contaminated groundwater, in unpredictable directions. In the NJDEP's October 2017 guidance document entitled *In Situ Remediation: Design Considerations and Performance Monitoring Technical Guidance Document*; the following caution is stated: "Use of hydrofracturing is another method to increase permeability, but a thoughtful approach is needed to try to maximize fracturing in the area of contamination, without causing the spread of contamination."

Concern for displacement of impacted groundwater is further discussed by the United States Army Corps of Engineers (USACE, 2013) and Huling and Pivetz (2007); Huling and Pivetz state that "[I]njection of any oxidant solution into a source area can result in the displacement of contaminated ground water from the source area and transport into potentially uncontaminated areas...The delivery of O3(g) into the subsurface may displace volatile organics from the injection zone".

The third reason is that "gas sparging [*e.g.*, ozone sparging] in the saturated zone may displace groundwater, and entrapped gas may re-direct groundwater flow around the injection zone. The potential alteration of groundwater and contaminant transport as a result of these factors should be evaluated on a site-specific basis." (Siegrist *et al.*, 2011).

In summary, attempts to remediate the Deep Dioxane Plume are not only likely to be ineffective, but they would increase the potential for inadvertent contaminant spread.

5. Concentrated Site Development Creates Additional Challenges and Health Risks for Deep Dioxane Remediation

Roche's accelerated soil remediation and IRM groundwater remediation several years ago paved the way for the development of the Site into a medical school with ancillary research-related and other mixed uses. Four years ago, Roche sold the Site to a master developer who joined with Hackensack Meridian Health and Seton Hall University to found the Hackensack Meridian Health Medical School at the Site, whose inaugural class entered in 2018. The school is to the east of the IRM Treatment Zone. Their ancillary uses and development – some already constructed and occupied and others planned – entail densely spaced buildings and other structures directly over any hypothetical treatment area for the Deep Dioxane Plume.

More specifically, Figure 5 depicts the current and future buildings in this area of the Site. The Deep Dioxane Plume is primarily present under portions of IA-1, IA-4, IA-2, IA-9, and IA-6. Virtually all of IA-6 is covered by a recently constructed multi-story parking garage to serve the medical school students and faculty, IA-9 is largely covered by pre-existing buildings that are being repurposed for future use, and large portions of IA-1, IA-4, and IA-2 will be covered by planned buildings. The large areas that are currently or will be covered by structures would significantly inhibit the ability to install dense networks of remedial wells necessary to attempt to address the Deep Dioxane Plume (an effort that would not in any event be successful, for the reasons stated above). The remedial wells would have to be spaced closely together to effectively distribute ozone throughout the impacted area, at depths greater than what has already been treated, and the existing and planned structures would render it virtually impossible to connect these wells via a piping system to an ozone generation system in a treatment building.

Any effort to treat Deep Dioxane would also be accompanied by notable health and safety risks. Prior to the recent New Jersey stay-at-home orders, there were more than 3,200 occupants of the Site, including medical school faculty and students, university-related medical researchers, and workers for other businesses that have moved onto the Site. The projected number of occupants will grow in the near future with the opening of the Quest Diagnostics medical laboratory and the lifting of the stay-at-home orders. The center portion of IA-1/4 is an active construction area, with ongoing work on new roadways and associated utilities for the new Quest Diagnostics building and other buildings, as well as preparation for the foundations of new buildings. Roche's IA-1/4 Dioxane Plume IRM experience demonstrated that the operation of an ozone injection system at high pressures creates an increased potential for ozone leaks from above-ground equipment, and from daylighting of short-circuited ozone moving upward through preferential pathways, as discussed in Section II.E.3 above. This potential for the release of ozone from the system would be significantly higher during any effort to treat the Deep Dioxane Plume, because of even higher ozone injection pressures. Given that this is and will be an area of dense occupancy, those ozone leaks would present unacceptable health and safety risks for current workers in the area and the future occupants of these structures. These risks come with little reward, given the infeasibility of effectively treating the Deep Dioxane Plume, as outlined in Section III.3 above.

6. The Deep Dioxane Plume is Stable

Roche has recently conducted five quarterly rounds of groundwater MNA monitoring within the IA-1/4 Dioxane Plume (including in the Deep Dioxane Plume) since completion of the IRM. Figure 6 provides graphs of dioxane concentrations over time (before, during, and after the IRM) for wells within the source area, along the axis of, and along the fringes of the IA-1/4 Dioxane Plume. The overwhelming majority of these wells demonstrate that dioxane concentrations are stable; there has not been an increase in dioxane concentration ("rebound") since cessation of the IRM. Similarly, the outer margins of the dioxane impact are stable. Figure 7 shows dioxane concentrations over time in wells along the fringes of the large, commingled plume created by individual plumes of on-Site and off-Site origin.

The stable concentration trends in the IA-1/4 Dioxane Plume are consistent with the effects of matrix diffusion, which acts as a significant attenuation mechanism for dissolved-phase plume migration. The graphs on Figure 6 include data from five MNA sampling events (March, June, September, and December 2019 and March 2020) and Figure 7 includes data from a November/December 2019 Site-Wide Semi-Annual Sampling event. The most recent data packages were submitted electronically to the NJDEP and are included with this document in Appendix C. The data shows generally stable concentrations trends.

Given the stable nature of the plume, which is not expected to expand in the future, the risk profile associated with the Deep Dioxane Plume will remain effectively constant over time. In the December 2019 RAWP, Roche proposed a long-term monitoring plan that would serve to monitor and document the Deep Dioxane Plume's continued stability. And, as explained below, there are no unacceptable risks associated with groundwater impacts under or near the Site.

7. Site Contaminants Do Not Pose any Unacceptable Risks to Human or Ecological Receptors

After extensive investigations, Roche determined that there are no unacceptable risks to human or ecological receptors from the contaminated groundwater under and near the Site. That determination is based on the findings outlined in the following reports Roche submitted to assess potential risks to human and ecological receptors:

- *April 10, 2014 Ecological Evaluation and Surface Water Remedial Investigation Report* (TRC, 2014a) - approved by NJDEP on July 11, 2014;
- *April 30, 2014 Site-Wide Receptor Evaluation Update* (TRC, 2014b) - approved by NJDEP on March 17, 2015; and
- *July 2, 2018 Site-Wide Receptor Evaluation Progress Report* (TRC, 2018) - NJDEP review and approval pending.

As summarized in these reports, there is no risk from drinking impacted groundwater as all properties surrounding the Site are serviced by water utilities that obtain water from distant surface water sources. Extensive ecological and vapor intrusion investigations at the Site and surrounding properties were performed and the results of those investigations showed no unacceptable risks to human or ecological receptors from the contaminated groundwater under and near the Site. In addition, because the IA-1/4 Dioxane Plume has been demonstrated to be at equilibrium and stable, no future impacts to receptors are expected. Roche will continue to evaluate receptors as remediation of the Site progresses.

IV. CONCLUSIONS

As detailed above, there is strong technical evidence to support the TI determination requested in Roche's December 2019 RAWP for the Deep Dioxane Plume. Specifically, the combination of (1) dioxane chemical characteristics, (2) complex site hydrogeology, and (3) demonstrated technical limitations in currently available groundwater remediation methods render remediation of the Deep Dioxane Plume infeasible from an engineering perspective.

Most importantly, this TI determination is supported by direct field experience at this Site where an extensive cutting-edge IRM was conducted to actively treat dioxane in bedrock groundwater, and the resultant performance monitoring provides the basis for assessing the practical limitations in attempting to further reduce dioxane concentrations. Even after completing supplemental remedial processes to enhance treatment, post-treatment monitoring confirms that matrix diffusion is a critical limiting factor that will prevent Roche from achieving lower concentrations through active treatment. In fact, dioxane concentrations in the Deep Dioxane Plume, without treatment, are currently *lower* than the concentrations that Roche was able to achieve after treatment.

Further, as documented by ongoing Site-wide monitoring and receptor evaluation, the extensive IRM completed by Roche has ensured protection of public health, safety and the environment, and the December 2019 RAWP provides alternative measures (*i.e.*, a Classification Exception Area [CEA] and long-term monitoring) to protect receptors from potential exposures in the future. To attempt treatment of the Deep Dioxane Plume (which is in deeper bedrock groundwater), given the technical concerns identified during the implementation of the IA-1/4 Dioxane Plume IRM, would increase the potential on-Site health and safety risks, and potentially cause an otherwise stable plume to migrate, without a demonstrable reduction in dioxane concentrations present in the deep bedrock.

List of Figures:

Attachments:

Appendices:

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