UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

TRI-VALLEY CARES, *et al.*,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF ENERGY, *et al.*,

Defendants.

No. C 08-01372 SBA

ORDER

[Docket No. 13]

REQUEST BEFORE THE COURT

Before the Court is Plaintiffs' Amended Motion for Preliminary Injunction (the "Motion") [Docket No. 13], Defendants' Opposition to Plaintiff's Motion for Preliminary Injunction (the "Opposition") [Docket No. 11], and Plaintiffs' Reply to Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction (the "Reply") [Docket No. 16]. This is plaintiffs' second suit under the National Environmental Policy Act of 1969 (the "NEPA"), 42 U.S.C. § 4321 *et seq.*, to prevent defendants from operating a biosafety level-3 facility at the Lawrence Livermore National Laboratory ("LLNL") in Livermore, California, on the grounds defendants have allegedly failed to comply with the NEPA.

In their Motion, plaintiffs seek a preliminary injunction on four grounds. First, they assert that defendants' Final Revised Environmental Assessment ("FREA") does not properly address the possibility of a terrorist attack, and thus defendants illegally issued a Finding of No Significant Impact ("FONSI"). Second, they assert that defendants illegally failed to prepare an Environmental Impact Statement ("EIS"). Third, they assert that defendants deliberately and illegally withheld material information from a Revised Environmental Assessment ("REA") which was circulated for public comment. And fourth, they assert that defendants illegally failed to publicly circulate their FONSI. As such, they claim that a preliminary injunction should issue, because they are likely to prevail on the merits of these claims at trial, and because the balance of hardships tips sharply in their favor.

The Court having reviewed the parties' pleadings, finds this matter appropriate for resolution without a hearing under Federal Rule of Civil Procedure 78(b). As discussed below, on their first, second, and fourth counts, plaintiffs have not stated a serious question of law, nor have they shown they would likely prevail on their merits at trial. On their third count, however, plaintiffs have shown they would likely prevail on the issue of whether defendant the United States Department of Energy (the "DOE") should have supplemented its REA with details regarding two 2005 shipping incidents and circulated this information for public comment. Nonetheless, they fail to show any irreparable injury. As such, the Court DENIES the Motion.

BACKGROUND

I. The Biosafety Level-Three Facility at Lawrence Livermore National Laboratory

On December 16, 2002, pursuant to its statutory mission to reduce the global danger from weapons of mass destruction, including biological weapons, the National Nuclear Security Administration (the "NNSA"), an agency within the DOE, authorized the construction of a "biosafety level-3"[1] ("BSL-3") laboratory at LLNL. Defs.' Ex. "1" at 4 (Final Revised Envntl. Assessment (the "FREA")). The facility was designed using CDC and NIH guidelines for the operation of BSL-3 facilities.[2] *Id.* at iii, 11, 17.

The DOE originally proposed the BSL-3 laboratory as part of the Chemical and Biological National Security Program, an initiative developed in response to the 1997 Defense Against Weapons of Mass Destruction Act, 50 U.S.C. § 2301, and designed to engage the NNSA's laboratories in improving preparedness for chemical and biological attacks. FREA at 4. Congress subsequently transferred some of the NNSA's biological security mission to the Department of Homeland Security (the "DHS"). *Id.* The DHS is authorized to access the DOE's laboratory

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[1] Guidelines issued by the Centers for Disease Control and Prevention (the "CDC") and the National Institutes for Health (the "NIH") divide lab operations into four levels, BSL-1 to BSL-4. BSL-3 laboratories work with agents which may cause diseases with serious or lethal consequences if untreated and which have the potential of aerosol (airborne) transmission. There are over 1,350 BSL-3 laboratories in the United States. FREA at 8. Common examples are hospital surgical suites, laboratories associated with medical schools, or university research laboratories. *Id.* at 6.

[2] According to the DOE, these guidelines are found in the fourth edition of *Biosafety in Microbiological and Biomedical Laboratories* ("*Biosafety*"), published by the CDC and NIH in April 1999. FREA at 6, 73.

resources in furtherance of its biological security mission, and the LLNL contemplates the majority of research conducted at the BSL-3 facility will be performed for the DHS. *Id.*

Current bioscience work at LLNL targets both the reduction of the national threat from terrorism using biological weapons and the enhancement of public health capabilities. *Id.* at 6. For example, LLNL has developed the Biological Aerosol Sentry and Information System (BASIS) to aid in the early detection and rapid response to biological attack. *Id.* Prior to opening the BSL-3 lab, LLNL only maintained microbiology laboratories equipped to operate at BSL-1 and -2. *Id.* at 7. This forced LLNL to conduct its BSL-3 research at off-site private sector and university facilities. *Id.* at 8. This was a problem because LLNL had no control over off-site security, and excessive handling and transportation increased the risk of cross-contamination and degradation. *Id.* Further, these laboratories were in high demand and frequently committed to projects for other entities. *Id.* Thus, the DOE determined that future bioscience work at LLNL required the construction of an on-site BSL-3 facility. *Id.*

After considering alternatives, *see id.* at 26-27, a prefabricated building installed next to existing BSL-2 facilities was chosen as the BSL-3 facility. *Id.* at 9. The 1,500 square-foot BSL-3 facility has three BSL-3 lab rooms, and is designed for a normal occupancy of up to six workers. *Id.* All air-handling systems were designed as required by CDC guidelines. *Id.* at 17. Thus, the facility has a High Efficiency Particulate Air-Purifying (HEPA) air filtration system, in which all laboratory room air passes through two HEPA filters in series before being vented outside. *Id.* at 13. Each filter is at least 99.97 percent efficient at removing bioagents. *Id.* at 43, 55. One room within the facility has pressurized HEPA-filtered cages to hold up to 100 rodents. *Id.* at 15-16. And, the facility operates at negative air pressure, that is, with an air pressure less than that of outside air, drawing air into the facility, in the event a breach. *Id.* at 17; Docket No. 12, Ex. "7" ¶ 6 (Decl. of Leslie A. Hofherr ("Hofherr Decl.")). In the event of main power loss, a backup power system would enable workers to safely shut down any work occurring in the BSL-3 facility. FREA at 17. In the event all power were lost, the air supply would shut down, and "zone-tight" dampeners would close, to prevent air flow within the facility. *Id.*

II. The 2002 Initial Environmental Assessment (EA)

Pursuant to the NEPA, the DOE performed an initial EA for the proposed BSL-3 laboratory. The EA considers the environmental impacts of the BSL-3 laboratory on a wide range of issues, including human health, *id.* at 40, ecological resources, *id.* at 39, transportation, *id.* at 56, waste management, *id.* at 48, geology, soils and seismology, *id.* at 49, noise, *id.* at 47, and air quality, *id.* at 46. The EA also discusses how CDC and NIH guidelines govern the facility's operations and mitigate the risk of laboratory-acquired infections and possible affects of an accidental release.

As the EA notes, the CDC and NIH have established standards for operating BSL-3 labs. *Id.* at 17-19. These require that before infectious microorganisms may be handled, a risk analysis must be prepared, and the local medical community informed of the agent, how to identify it, and treat its associated diseases. *Id.* at 18. Prior to using a CDC designated select agent,[3] the facility must register with the CDC and show it meets biosafety level requirements for working with that agent. *Id.* at 17. Only personnel registered with the CDC may handle such agents. *Id.* at 65. And, the CDC conducts periodic inspections. *Id.* at 21. For microorganisms which are not select agents, the facility would still handle them according to CDC and NIH guidelines. *Id.* at 18.

In addition, under NIH regulations, operations at the BSL-3 laboratory would be subject to the LLNL Institutional Biosafety Committee (the "IBC"), which includes staff members, health care providers, a DOE official, and at least two public members. *Id.* at 5-6. All pathogen experiments must be first reviewed and approved by the IBC. Defs.' Ex. "6" at C-8 (FREA App. "C": Public Comments on the EA ("FREA App. 'C' ")). This is designed to involve the public in approving BSL-3 research and reviewing safety and compliance protocols. *Id.* at C-11.

In considering the possibility of a laboratory-acquired infection and its risk to facility personnel and the public, the DOE drew from the experiences of three sources it considered relevant and comparative: (1) hundreds of other CDC-registered BSL-3 laboratories; (2) the U.S. Army's Biological Defense Research Program (BDRP) laboratories; and (3) LLNL's BSL-1 and -2

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[3] A "select agent" and/or toxin generally means all biological agents or toxins listed in 42 C.F.R. § 73.3 or § 73.4. 42 C.F.R. § 73.1. Subject to certain exclusions, these agents and toxins "have the potential to pose a severe threat to public health and safety, to animal health, or to animal products." *See id.* §§ 73.3, 73.4. The select agent program "implements the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002" related to working with select agents. *Id.* § 73.2.

laboratories. FREA at 40-42. With regards to the first category, the DOE found that since CDC guidelines were issued in 1974, there had been an extremely low incidence of laboratory-acquired infections in laboratories following the guidelines. *Id.* at 41. Further, it examined sources compiling data covering the early 20th Century through August 2000, and found "a noticeable lack of laboratory-acquired infection reports" from 1990 through 2000. *Id.* at 50.

With regards to the BDRP, in 1989 the Army prepared a programmatic or system-wide EIS, or PEIS, for its laboratories. *Id.* at 41. Defendants reviewed this and found the Army's BDRP laboratories had "no occurrences of overt disease in laboratory . . . in BSL-3 facilities," save for a 1980 focal infection with *F. tularensis* at a puncture wound site. *Id.* And, in 2000, a worker exposed to *Burkholderia mallei*, which causes glanders, recovered after hospitalization. *Id.* In the PEIS, the Army estimated the rate of public infection from its Army Medical Research Institute of Infectious Diseases[4] from 1970 through 1989 at less than 0.001 per 1,000,000 person-years, and the risk of death to a lab worker at 0.005 per 1,000,000 person-years. *Id.* at 41-42.

Regarding LLNL, the DOE found in the prior 20 years there had seen no unintentional releases of bioagents or infections of lab personnel or the public from its biological operations. *Id.*

In addition to considering CDC, BDRP, and LLNL experiences, the EA analyzes the potential impacts of abnormal events or accidents through a "catastrophic release scenario" (the "Release Scenario") which shows the "outside bounds" of the impact of a pathogen's accidental release.[5] *Id.* at 51. This scenario shows that in the event of a bioagent release, there would be no significant impact on public health and safety. *Id.* at 55. In light of the foregoing, the DOE issued the EA in December 2002, *id.* at ii, concluding that the proposed BSL-3 laboratory would have no significant impact on the environment. Specifically, it concluded that the "potential human health effects of the proposed BSL-3 laboratory would be the same as those demonstrated for similar CDC-registered laboratories" subject to the CDC and NIH guidelines for BSL-3 facilities. *Id.* at iv, *see id.* at 40-42. The DOE thus issued a Finding of No Significant Impact ("FONSI").

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[4] Defendants do not explain the relationship between this entity and the Army's BDRP program as a whole.

[5] This is also known as a "bounded event." *See* discussion in part IV.A.1 *infra*.

III. The Prior Litigation in 2003 and 2004

On August 26, 2003, plaintiffs[6] brought suit in this Court, under the NEPA, challenging the EA on numerous grounds, in *Tri-Valley Cares v. U.S. Department of Energy*, No. C 03-3926-SBA, 2004 WL 2043034, 2004 U.S. Dist. LEXIS 18777 (N.D. Cal. Sep 10, 2004). *See* Docket No. 1 in case 03-03926 SBA. On September 10, 2004, this Court granted summary judgment for the DOE and denied summary judgment for plaintiffs. 2004 WL 2043034 at *1, 2004 U.S. Dist. LEXIS 18777 at *3-*4. In so ruling, the Court found defendants' EA supported the issuance of a FONSI and did not require an EIS. 2004 WL 2043034 at *1, *17, 2004 U.S. Dist. LEXIS 18777 at *6, *51. On appeal, the Ninth Circuit noted the EA failed to consider the environmental impact of a terrorist attack, as required by its holding in *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Commission*, 449 F.3d 1016 (9th Cir. 2006). *Tri-Valley Cares v. Dep't of Energy*, 203 Fed.Appx. 105, 107 (9th Cir. 2006). It thus affirmed in part and reversed in part, remanding for the DOE to consider whether the threat of a terrorist act necessitated the preparation of an EIS. *Id.* at 106-07.

IV. The March 2007 Revised Environmental Assessment (REA)

Following the Ninth Circuit's decision, the DOE issued a memorandum in 2006, providing interim guidance on how to address "intentional destructive" acts in NEPA documents. *See* Pls.' Ex. "13" at 1 (the "Guidelines Memo"). The DOE prepared a draft Revised EA (the "REA") in March 2007, which considered the impacts potentially associated with terrorist attacks, which it circulated for public comment from April 11 through May 11, 2007. Docket No. 13, Ex. "4" at cover; FREA at 8.

In the REA, in order to analyze the threat terrorist activity posed to the BSL-3 laboratory, the DOE was required to take a different approach than it did for analyzing the threat posed by accidents. FREA at 57-58. For the latter, the DOE used historical data to estimate the likelihood with which certain types of accident and catastrophic events occur, then analyzed the potential consequences. *Id.* For terrorist activity, however, not only is suitable historical data unavailable,

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[6] Not all the plaintiffs in the first suit are plaintiffs in the current suit, as those who were involved in a separate action related to the Los Alamos National Laboratory which has been resolved, have not joined the current suit. *See* Docket No. 177 in case 03-3926 at 2:18-3:5. Also, there is a new plaintiff in the current suit, Jedidjah De Vries. *Id.*

but attempting to predict or model intentional human acts is impractical if not impossible. *Id.* Instead, the DOE assumed a terrorist attack would occur, and then considered increasing levels of protective strategies, until the risk of a successful attack, as well as the attractiveness of the facility to attackers, had been reduced to an acceptable level. *Id.* at 58. Because there are an infinite number of possible attack scenarios, rather than analyze specific ones in the REA, the DOE considered three general types of threats, and their potential impacts on the environment: (1) facility damage or destruction from direct terrorist attacks that results in loss of containment; (2) the theft and subsequent release of pathogenic material by a terrorist from outside LLNL; and (3) the covert theft and subsequent release of pathogenic material by an insider with access to the facility. *Id.*

A. Direct Attack Resulting in Loss of Containment[7]

The DOE considered that a loss of containment of pathogenic materials could result if one or more persons deliberately damaged the BSL-3 facility. *Id.* at 59. Possible scenarios considered for this type of attack were a suicidal plane crash or an explosive device delivered by vehicle or on foot. *Id.* In considering the impact or consequences from a loss of containment due to such an attack, the DOE first determined the bounded or outer limits of any release and then analyzed factors which could mitigate it. *Id.* at 59-61.

1. The Accident-Based Release Scenario and its Dispersion Model

In determining the bounded or outer limits of any release due to a loss of containment caused by a terrorist attack, the DOE concluded that they would be the same as those it had determined for a release attributable to an accident or natural catastrophe. *Id.* at 59. In the initial EA, the DOE developed the Release Scenario to evaluate the "outside bounds" or the reasonably foreseeable maximum bounds of the impact of an *accident- or catastrophe-based* release of a dangerous bioagent. *Id.* at 51. In formulating the Release Scenario, the DOE considered triggering events such as an accidental spill, an earthquake, an explosion, a fire, or an accidental airplane crash. *Id.*

Although the DOE considered numerous possible scenarios for modeling an accident- or catastrophe-based release, it chose the Release Scenario as the most appropriate one, as the Army

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[7] The Court does not discuss the theft scenarios in this Order, as plaintiffs do not address them in the Motion. *See infra* note 22.

used it to conduct NEPA analyses of its own biological research labs. *Id.* at 52. According to the Army, the Release Scenario is a "maximum credible event."[8] *Id.* In the Release Scenario, a liter of *coxiella burnetii* (*C. burnetii*) is divided among six centrifuge tubes, which are placed in a centrifuge, with loose caps and/or loose O-rings. *Id.* at 54. When the centrifuge is activated, some of the tubes' contents are aerosolized, resulting in the production of almost 10 billion airborne human infective doses ("HID"s).[9] *Id. C. burnetii* was chosen as a representative of all types of BSL-3 microorganisms because it poses a high human health risk, is "highly durable, infectious, and transmissible, and has excellent environmental sustainability." *Id.* at 53.

The Army then modeled a plume of HIDs as it moved through the lab and outside via the ventilation system. *Id.* at 54. For conservative results, the Army assumed the lab had only one HEPA filter operating at only 95 percent effectiveness. *Id.* The Army concluded the chance of public exposure to an HID at a 50 percent rate of contracting the disease ("HID-50") was extremely remote: At a distance of only 7 feet from the building vent, one liter of air would contain less than 1.00 HID-50, less than 0.10 HID-50 at 53 feet, and less than 0.01 HID-50 at 125 feet. *Id.* at 54.

The DOE found the chances of exposure at the LLNL were even more remote than those modeled by the Army. *Id.* at 54-55. The Army scenario assumed one HEPA filter that was 95 percent effective. The LLNL BSL-3 lab, however, filters all room air through two HEPA filter banks, each of which is at least 99.97 percent effective. *Id.* at 55. The Army scenario also assumed a lab in close physical proximity to the public, but the LLNL BSL-3 lab is one-half mile from the nearest public area. *Id.* at 52-53. Finally, the Army assumed lower wind speeds than are prevalent at LLNL. *Id.* Higher wind speeds would decrease airborne concentrations more quickly. *Id.* Based on this analysis, the DOE concluded that even under a highly unlikely catastrophic release, there would be no significant impact on public health or safety.

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[8] A reasonably foreseeable event with a low probability of occurrence, but with high consequences.

[9] Apparently, centrifuge accidents are not purely hypothetical. FREA at 52. After needle sticks, equipment-related accidents are the second-most common route of agent exposure. *Id.*; *see also* Docket No. 13, Ex. "1" ¶ 18 at 9 para. 1 (centrifuge incident at University of Texas at Austin), ¶ 18 at 11 para. 1 (same at University of Texas at Houston) (Decl. of Edward Hammond).

2. Operational, Explosive, and Environmental Factors

In analyzing potential terrorist attacks, the DOE found several factors would severely limit the consequences of such an event. First, during routine lab operations, very limited quantities of biological agents would be in use – usually only enough to begin cultures in a petri dish – and such agents would typically be handled in a liquid or solid medium, so that if spilled, very few organisms would be released to the air. *Id.* When not in use, organisms are stored in 2 mL sealed plastic vials and locked in freezers at -80° C. FREA App. "C" at C-22. Thus, the release of a quantity of pathogen would require a breach of the lab itself, the freezers, and the individual containment vials, and the conversion of the frozen material to a dispersible form. *See id.* at C-24. Even if the structure were breached and dispersible materials released, the negative pressure in the building would draw air into it and exhaust it through the HEPA filtration system. Hofherr Decl. ¶ 6.

Second, the DOE concluded a fire resulting from an airplane crash or explosive device of the magnitude necessary to breach containment would kill BLS-3 organisms quickly.[10] FREA at 59. In addition, any force sufficient to breach all levels of containment would breach containers of disinfectant, such as bleach, which would also kill organisms. *Id.*

Finally, in the highly unlikely event a bioagent were released, microorganisms would generally be rendered innocuous by exposure to outside conditions, in particular, sunlight and dehydration. *Id.* The DOE found these factors would substantially reduce the number of microbes released as a result of a direct attack within minutes, and the impacts of a facility breach caused by a direct terrorist act, such as a plane crash, would be no greater than the impacts addressed in the accident-based Release Scenario previously analyzed in the initial EA. *Id.* at 59.

3. Inoculations and Medical Treatment

The DOE's conclusions in the REA regarding the lack of any significant impact on public health, took into account the fact that all the bioagents used in the BSL-3 facility cause diseases for which treatment or inoculation is available. *Id.* at 60. Further, LLNL has briefed local health care

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[10] For example, *Bacillus anthracis* spores are sterilized in 30 seconds at 200° C. FREA App. "C" at C-22. In comparison, the flame temperature for gasoline in a "open pool" fire is 1,026° C. *Id.*

providers, so if necessary, the consequences of any release could be mitigated by inoculation and treatment of exposed individuals. *Id.*

4. Physical and Operational Security

Finally, the DOE noted in the REA that the probability of a successful terrorist attack on the facility is mitigated by the extensive security measures in place at LLNL and the BSL-3 facility itself. *Id.* at 60-61. Unlike the majority of the 1,350 BSL-3 labs nationwide, which are mostly academic or clinical facilities, the LLNL site is protected by extensive physical security. *Id.* at 61. LLNL is surrounded by a patrolled security fence with badge-identification required for entry. *Id.* And it has its own security force, including an armed emergency response force. *Id.* In addition to LLNL security, access to the BSL-3 facility is limited to employees registered with the CDC and trained and qualified under its guidelines. *Id.* at 16, 61. Access to individual lab rooms within the building is limited to staff members approved to work during specific shifts, and all lab rooms are equipped with motion sensors. *Id.* at 61. Finally, within the lab, select agents are stored in locked freezers when not in use. *Id.*

The DOE also prepared a *Biological Risk and Threat Assessment* (BRTA) for the BSL-3 facility, which examined its potential vulnerability to terrorist attacks and recommended security countermeasures to such threats. *Id.* at 61. Based on the BRTA, the DOE also prepared the *LLNL Select Agents and Toxins Security Plan* which set out a protection program for LLNL's select agent use and storage areas. *Id.* Thus, the DOE concluded the chance of a terrorist attack resulting in a breach of facility containment and the release of a pathogen was exceedingly remote. Nevertheless, it concluded that if such a breach were to occur, the resulting release would fall within the bounds of the Release Scenario developed in the initial EA, and would not significantly impact human health or the environment.

V. October 4, 2007 Hearings before the House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations

On October 4, 2007, a House subcommittee held hearings titled "Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States," regarding the "serious risks" posed by the proliferation of BSL-3 and BSL-4 laboratories in the United States after

September 11, 2001. Docket No. 13, Ex. "9" at 1 (Opening Statement of Chairman Bart Stupak ("Chair"); Ex. "17" (Statement of Keith Rhodes, Chief Technologist Ctr. for Techn. & Eng'g Applied Research & Methods, U.S. Gov't Accountability Office ("GAO")). The subcommittee was concerned that no single government agency had responsibility for monitoring or ensuring the safety of these laboratories, nor did any agency know how many there were, what research they conducted, or how safe or secure they were. Chair at 1 para. 4; *see* GAO.

The subcommittee also examined the issue of lax oversight and under-reporting. In particular, it noted there is no federal oversight for the possession, use, or transport of dangerous pathogens like hanta virus, SARS, or dengue fever, nor were theft or accident reports required, as these are not select agents. Chair at 2 para. 2. Further, the subcommittee noted select agent accidents appeared to be under-reported, Chair at 2 para. 4, which is problematic for a system reliant on self-reporting, GAO at 3 para. 2. While the CDC testified there had been no known releases of a regulated pathogen or biological toxin from a BSL-3 or BSL-4 laboratory, Docket No. 13, Ex. "8" at 1 para. 5 (N.Y. Times article dated 10/4/2007 ("NYT")), it was concerned about unreported incidents, AP at 2 paras. 10-11.

The CDC testified that since 2003, three laboratory-acquired infections had sickened five personnel. NYT at 1 para. 6. The subcommittee chair noted that until information leaked to the public, Texas A&M University had repeatedly and intentionally failed to report select agent rule violations. Chair at 2 para. 4; NYT at 2 para. 7. This included failing to report that one researcher had been infected in 2006 and became seriously ill with *brucella*, and that blood tests of three other workers showed Q fever exposure. *Id.* The CDC closed A&M's laboratory. NYT at 2 para. 7.

The subcommittee was troubled by the fact the CDC had inspected A&M just prior to these violations becoming public, but had failed to detect any of them. Chair at 5. This led the subcommittee to question the thoroughness of CDC inspections. Chair at 2, para. 5. The GAO testified there were too many laboratories for the level of oversight provided. Docket No. 13, Ex. "11" para. 4 (L.A. Times article dated 10/5/2007 ("LAT")). The CDC's Director of the Coordinating Office for Terrorism Preparedness and Emergency Response testified, "As a young program, there is a lot we can learn and there is a lot we can do to improve our oversight." *Id.* at 1

para. 7. Although in 2001 the CDC had instituted background checks for researchers with access to select agents and begun inspecting federally financed labs once every three years, it testified it could broaden its document review and conduct more surprise inspections. *Id.* at 2 paras. 9-10. The GAO testified, however, that the FBI had become concerned with "its burgeoning workload in conducting background checks" for select agent researchers. LAT paras. 15-16. Finally, the subcommittee focused on whether BSL-3 and BSL-4 laboratories were designed and operated properly, based on an incident at the CDC's BSL-4 facility in Atlanta involving a complete loss of electrical power. Chair at 2 paras. 6-7; *see* GAO at 2 para. 3; Docket No. 13, Ex. "15" at 1 para. 8 (Assoc. Press article dated 10/2/2007).

VI. The 2008 Final Revised Environmental Assessment (FREA)

On January 25, 2008, after evaluating public comment, the DOE found no significant environmental impact would result from a terrorist attack on the BSL-3 laboratory. It thus released a Final Revised EA (the "FREA") and a FONSI on January 25, 2008. Opp'n at 5:25; *see* FREA and Defs.' Ex. "4" (U.S. DOE Revised FONSI). The FREA duplicated the REA, except for a few administrative updates, *see* FREA at 2, 4, 8-9, and three substantive updates, *see id.* at 6, 50, 56. While one of the substantive updates addresses two shipping incidents in 2005, *see id.* at 56, the other two address the 2007 subcommittee hearings.

In regards to the hearings, the DOE notes that since the EA was issued in 2002, "the CDC has investigated several laboratory incidents involving exposure of personnel to biological agents that resulted in infection." *Id.* at 50-51. The DOE discusses the four Texas A&M personnel, and notes that "in November 2004, three cases of tularemia were reported for Boston University laboratory researchers . . . ." *Id.* Further, that "[t]hese and other exposures to biological agents during laboratory incidents since 2002 resulted only in treatable illness, and are not known to have resulted in either death or secondary infections." *Id.* It thus concludes that "[t]he relatively small number of accidental exposures during this 5-year period supports NNSA's assertion that although it is possible, it is improbable laboratory staff would acquire an accidental laboratory-acquired infection during the operation of the proposed BSL-3." *Id.*

BSL-3 operations at the facility began the same day as the FREA's release.[11] *See* Defs.' Ex. "5" ¶ 3 (Decl. of Eric Gard).

VII. This Litigation

On March 10, 2008, plaintiffs filed a Complaint alleging defendants had failed to prepare an adequate EA and FONSI, failed to prepare an EIS, failed to supplement their REA, and failed to publicly circulate the FONSI. *See* Docket No. 1. On March 26, 2008, they filed their Motion seeking a preliminary injunction on the grounds they were likely to prevail on the merits of these issues, and because the balance of hardships tips sharply in their favor. Mot. at 2:3-7.

LEGAL STANDARD

I. Preliminary Injunctions under Federal Rule of Civil Procedure 65

Federal Rule of Civil Procedure 65 permits the issuance of a preliminary injunction, the purpose of which is to preserve the relative positions of the parties until a trial on the merits can be conducted. *See E. & J. Gallo Winery v. Andina Licores S.A.*, 446 F.3d 984, 990 (9th Cir. 2006); *LGS Architects, Inc. v. Concordia Homes*, 434 F.3d 1150, 1158 (9th Cir. 2006). A party seeking a preliminary injunction must show either: (1) a combination of probable success on the merits and the possibility of irreparable injury, or (2) that serious questions are raised and the balance of hardships tips sharply in its favor. *Faith Ctr. Church Evangelistic Ministries v. Glover,* 462 F.3d 1194, 1201-02 (9th Cir. 2006), *amended and superseded on denial of reh'g by* 480 F.3d 891 (9th Cir. 2007), *cert. denied*, 128 S.Ct. 143 (2007). These two formulations represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases. *LGS Architects*, 434 F.3d at 1155; *see also Harper v. Poway Unified Sch. Dist*., 445 F.3d 1166, 1174 (9th Cir. 2006) (the greater the relative hardship to the moving party, the less probability of success must be shown to support the grant of a preliminary injunction).

Under the sliding scale theory, a party seeking an injunction "need not demonstrate that he

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[11] By stipulation, the parties agreed to a voluntary limitation on operations at the BSL-3 facility for 60 days, pending this Court's ruling on the preliminary injunction. Mot. at 10 n.1. This limitation requires: (a) no aerosol testing; (b) no rodent infection experiments; (c) no production, generation, or knowing receipt of genetically modified biological material that would require management of the facility at the BSL-3 level; and (d) the total amount of agents in the facility for which BSL-3 containment is recommended in *Biosafety* shall not exceed 100 ml. *Id.*

will succeed on the merits, but must at least show that his cause presents serious questions of law worthy of litigation." *Topanga Press, Inc. v. City of Los Angeles*, 989 F.2d 1524, 1528 (9th Cir. 1993), *cert. denied*, 511 U.S. 1030 (1994). Additionally, in cases where the public interest may be affected, the court must consider the public interest as a factor in balancing the hardships. *Harris v. Bd. of Supervisors*, 366 F.3d 754, 760 (9th Cir. 2004).

While a preliminary injunction will not be issued without security by the applicant under Federal Rule of Civil Procedure 65(c), a district court has wide discretion in setting the amount of a bond, and the bond amount may be zero if there is no evidence the party will suffer damages from the injunction. *See Conn. Gen. Life Ins. Co. v. New Images of Beverly Hills*, 321 F.3d 878, 882 (9th Cir. 2003).

II. The National Environmental Policy Act of 1969 (NEPA)

As the Supreme Court has held, the NEPA, 42 U.S.C. § 4321 *et seq.*:

> does not work by mandating that agencies achieve particular substantive environmental results. Rather, NEPA promotes its sweeping commitment to "prevent or eliminate damage to the environment and biosphere" by focusing Government and public attention on the environmental effects of proposed agency action. 42 U.S.C. § 4321. By so focusing agency attention, NEPA ensures that the agency will not act on incomplete information, only to regret its decision after it is too late to correct. *See Robertson*, 490 U.S., at 349, 109 S.Ct., at 1845. Similarly, the broad dissemination of information mandated by NEPA permits the public and other government agencies to react to the effects of a proposed action at a meaningful time.

Marsh v. Or. Natural Res. Council, 490 U.S. 360, 371 (1989).

"NEPA has twin aims. First, it places upon an agency the obligation to consider every significant aspect of the environmental impact of a proposed action. Second, it ensures that the agency will inform the public that it has indeed considered environmental concerns in its decisionmaking process." *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 97 (1983) (internal citations and quotation marks omitted).

In this regard, EISs are required by 42 U.S.C. § 4332(C), which mandates all federal

agencies:

> include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on--
>
> (i) the environmental impact of the proposed action,
>
> (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
>
> (iii) alternatives to the proposed action,
>
> (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
>
> (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

42 U.S.C. § 4332(C) (emphasis added).

In order to determine whether a major federal action will significantly affect the quality of the human environment, and require an EIS, an agency prepares an EA. 10 C.F.R. § 1021.321;[12] 40 C.F.R. § 1508.9.[13,14] If the agency determines a proposed action will not significantly affect the quality of the human environment, no EIS is required, and the agency instead issues a FONSI. 40 C.F.R. § 1508.9.

III. Judicial Review under the Administrative Procedure Act (APA)

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[12] Section 1021.321(b) of title 10 states, in part, "A DOE EA shall serve the purposes identified in 40 CFR 1508.9(a), which include providing sufficient evidence and analysis for determining whether to prepare an EIS or to issue a FONSI."

[13] Section 1508.9 of title 40 states:
"Environmental Assessment":
> (a) Means a concise public document for which a Federal agency is responsible that serves to:
>
> (1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact [FONSI].
>
> (2) Aid an agency's compliance with the Act when no environmental impact statement is necessary.
>
> (3) Facilitate preparation of a statement when one is necessary.

[14] All citations to the Code of Federal Regulations are for the 2008 edition.

Because the NEPA does not create a private right of action, Plaintiffs' challenges to DOE action is governed by the Administrative Procedure Act (the "APA"), 5 U.S.C. § 701 *et seq.* *See Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1989). The APA provides that a "person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of the relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

The APA, however, limits the scope of judicial review of agency actions. In general, a court may not set aside an agency's action unless it was "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with the law." *Id.* § 706(2)(A); *Marsh*, 490 U.S. at 378. In making this determination, a court " 'must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.' " *Marsh*, 490 U.S. at 378 (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977))). "This inquiry must 'be searching and careful,' but 'the ultimate standard of review is a narrow one.' " *Id.* In reviewing an agency's action, a court must be "highly deferential" to the agency; and, a court "may not set aside agency action as arbitrary or capricious unless there is no rational basis for the action." *Friends of the Earth v. Hintz*, 800 F.2d 822, 831 (9th Cir. 1980).

In a NEPA challenge, a court may not "substitute [its] judgment for that of the agency concerning the wisdom or prudence of a proposed action." *Laguna Greenbelt, Inc. v. U.S. Dep't of Transp.*, 42 F.3d 517, 523 (1994). Under the NEPA, an agency is not required "to elevate environmental concerns over other appropriate considerations." *Balt. Gas & Elec. Co.*, 462 U.S. at 97. An agency need only take a "hard look" at the environmental consequences before taking a major action. *Id.* And, a court's deferential "scope of review does not enable [it] to decide whether [it] would have given the same hard look and reached the same conclusion." *Kettle Range Conservation Group v. U.S. Forest Serv.*, 147 F.3d 1155, 1157 (9th Cir.1998).

Nonetheless, a court "must determine whether the agency articulated a rational connection between the facts found and the choice made." *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife Serv.*, 273 F.3d 1229, 1236 (9th Cir. 2001). Further, a court "must not 'rubber-stamp . . . administrative decisions that they deem inconsistent with a statutory mandate or that frustrate the

congressional policy underlying a statute.' " *Id.* (citing *NLRB v. Brown*, 380 U.S. 278, 291-92 (1965)).

Lastly, "an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." *Marsh*, 490 U.S. at 378; *see also Friends of Endangered Species, Inc. v. Jantzen*, 760 F.2d 976, 986 (9th Cir. 1985) ("[N]or does NEPA require us to resolve disagreements among various scientists as to methodology"); *Life of Land v. Brinegar*, 485 F.2d 460, 472 ("disagreement among experts will not serve to invalidate an EIS"); *Webb v. Gorsuch*, 699 F.2d 157, 160 (4th Cir. 1983) ("When there is conflicting expert opinion, it is for the administrative agency and not the courts to resolve the conflict.").

ANALYSIS

Plaintiffs plead four counts against defendants in their Complaint: (1) failure to prepare an adequate EA and FONSI, (2) failure to prepare an EIS, (3) failure to supplement and circulate their REA, and (4) failure to publicly circulate their FONSI. Mot. at 11:15-19.

I. Failure to prepare an adequate Environmental Assessment and Finding of No Significant Impact

Plaintiffs assert that the DOE had no authority to issue a FONSI, because the terrorism analysis in the FREA is "grossly deficient." Mot. at 12:12:23-24. They claim this is because the DOE failed to take a "hard look" at this issue, which is an abuse of discretion under the NEPA. *Id.* at 12:24-26. Plaintiffs note that, under 10 C.F.R. § 1021.322, the "DOE shall prepare a FONSI only if the related EA supports the finding that the proposed action will not have a significant effect on the human environment. If a required DOE EA does not support a FONSI, DOE shall prepare an EIS . . . ." 10 C.F.R. § 1021.322. In support of their position, plaintiffs raise a number of arguments. As discussed below, however, the Court finds that plaintiffs fail to show it was arbitrary and capricious for the DOE to issue the FREA or a FONSI, and finds that none of their arguments support their assertion that the DOE failed to take a hard look at the issue of intentional destructive acts.

A. Using an accident scenario as a bounded analysis for an intentional destructive

act.

Plaintiffs first assert that the DOE's terrorism analysis is flawed, because it is based on a bounded event, the Release Scenario, which is an *accident*, rather than an *intentional destructive act*. Mot. at 13:8-28. Specifically, plaintiffs assert that the 2006 Guidelines Memo cautions that "accident scenarios may not fully encompass potential threats posed by intentional destructive acts." *Id.* at 13:15-16. They also assert that the DOE's 2002 *Recommendations for Analyzing Accidents under the NEPA* (the "Recommendations"), *see* Pls.' Ex. "16"; Defs.' Ex. "8," require document preparers to develop realistic accident scenarios by considering a reasonable range of events, including those with a low probability of occurrence, but high consequences, and those with a high probability of occurrence, but low consequences. Mot. at 13:17-24.

In opposition, defendants note that the Guidelines Memo expressly provides that accident-based scenarios may be appropriate "for many, if not most, situations where the potential sabotage or terrorist scenarios and the accident scenarios involve similar physical initiating events or forces[,]" and encourages decision-makers to "explicitly consider whether the accident scenarios are truly bounding of intentional destructive acts." Opp'n at 12:7-12. Defendants assert that the DOE did this, and having determined the Release Scenario was the proper bounded event for the *forces and damage* generated by earthquakes, accidental plane crashes, *et seq.*, it then also determined it was the proper bounded event for intentional destructive acts, because they would generate the same *forces and damage*. *Id.* at 12:12-16.

Plaintiffs assert that the DOE should not use a "bounding" analysis, because the Recommendations warn it could "mask differences among alternatives and be less informative about the potential need for mitigation" *Id.* at 13:24-26. They argue that the Recommendations say this occurs because bounding "analyses are utilized by NEPA document preparers to compensate for analytical uncertainty by using conservative approaches that overestimate potential impacts." *Id.* at 13:26-28.

In opposition, defendants respond that the Recommendations expressly provide for bounding. Opp'n at 12:17-21. They assert that the Recommendations merely compare the merits of bounding analyses with other scenarios. *Id.* at 12:18-19. Further, they argue that the

Recommendations suggest a bounding analysis may be appropriate in circumstances–such as this case–where there is "analytical uncertainty."[15] *Id.* at 12:19-21.

Defendants also discuss Attachment 1 to the Recommendations, which addresses "intentional destructive acts," and how *accident* analyses *and bounding* may be used to analyze them. *Id.* at 21-23. In this regard, Attachment 1 advises that document preparers may compare accidents to intentional acts, if the consequences, i.e., damaging forces, are similar. *Id.* Thus, defendants note that the DOE has used bounding analysis to analyze the effects of a plane accidentally crashing into a rail cask of spent nuclear fuel, in order to also protect it against sabotage generating similar destructive forces. *Id.* at 12:17-23.

In reply, plaintiffs assert that it is "eminently reasonable to question whether the consequences [of] malicious acts deliberately designed to breach containment are truly bounded by the accidents and natural events analysis evaluated in the original EA . . . ." Reply at 8:15-17.

Having considered the parties' argument, the Court finds that plaintiffs have failed to show that the DOE acted arbitrarily or capriciously. First, unlike agency regulations issued pursuant to notice and comment rule-making, and published in the Code of Federal Regulations, internal agency guidance documents, such as the Recommendations and the Guidelines, are not legally enforceable. *W. Radio Serv. v. Espy*, 79 F.3d 896, 901-02 (9th Cir. 1996). That is, while an agency is generally bound by its "regulations," it is not generally bound by its "internal guidelines." *Id.* Thus, had the DOE failed to follow the Recommendations or the Guidelines, the Court would not have the authority to hold the DOE acted arbitrarily or capriciously.

That said, however, if the Recommendations and Guidelines had the force of law, the Court would, nevertheless, find that the DOE's actions in analyzing the potential impact of terrorist attacks, were not arbitrary or capricious. The DOE developed a bounding analysis for earthquakes and accidental plane crashes in its initial EA, then applied that analysis to intentional destructive acts in the FREA, as the DOE determined the *destructive forces* generated by the unintentional and

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[15] The Court notes the Recommendations also state these analyses could be more defensible than more realistic approaches as they are unlikely to *underestimate* potential accident consequences. Recom. at 5.

intentional incidents were similar. The DOE clearly took a "hard look" at the issue of whether and how to use bounding analyses and whether and how to use the Release Scenario to analyze the impact of potential terrorist attacks. *Balt. Gas & Elec. Co.*, 462 U.S. at 97. As such, it did not act arbitrarily or capriciously, and neither the parties nor the Court may substitute their judgment for the DOE's. *Laguna Greenbelt*, 42 F.3d 517, 523 (1994). Thus, the Court finds plaintiffs have not shown they would likely prevail on the merits of this issue, nor have they presented a serious question of law worthy of litigation in its regard. *Topanga Press*, 989 F.2d at 1528.

B. Using two HEPA filters in the Release Scenario.

In attacking the DOE's terrorism analysis, plaintiffs assert that because a terrorist attack would breach the facility's walls, it is unreasonable for the DOE to base a release from such an attack on the Release Scenario, which assumes any release would pass through two 95 percent efficient HEPA filters. *Id.* at 14:1-7. In opposition, defendants assert that the facility's negative air pressure system would draw in outside air, in the event of a breach. Opp'n at 13:3-8. In reply, plaintiffs assert that terrorists could take out the power, preventing the negative pressure system from functioning. Reply at 8:19-9:4.

The Court notes that plaintiffs appear to present two separate arguments. First, they appear to argue that the DOE fails to consider that a terrorist attack could cause a "double failure" of both the HEPA filters and the negative pressure system. With regards to this argument, the Court makes two observations. First, there is no evidence that the DOE ignored the possibility of a "double failure." To the contrary, the fact that the DOE has a filter system and a negative pressure system in place, shows that they have considered the need for both systems. Further, in the event that main and backup power were lost, zone-tight dampeners would seal the air circulation system. FREA at 17. Thus, the DOE has provided a contingency for a "double failure." As such, the Court finds that the DOE considered the relevant factors involved in a possible "double failure," *Marsh*, 490 U.S. at 378, and rationally responded to this possibility, *Friends of the Earth*, 800 F.2d at 831.

Second, the Court notes that it would be difficult, if not impossible or cost-prohibitive, to render the BSL-3 facility impervious to all possible terrorist attack scenarios. The Recommendations and the Guidelines Memo only require the DOE to consider a reasonable range of

attacks, and the possible destructive forces they would generate. The DOE need not consider any "worst-case" scenarios. The decision as to where various potential attacks fall on the reasonableness spectrum is entrusted to the DOE's experts, whose reasonable opinion this Court may not reverse, even if more persuasive "what if . . ." opinions are presented to it. *Marsh*, 490 U.S. at 378. Thus, as long as the DOE took a "hard look" at possible terrorist attack scenarios, *Balt. Gas & Elec. Co.*, 462 U.S. at 97, this Court will defer to its judgment, *Laguna Greenbelt*, 42 F.3d at 523.

Plaintiffs' second apparent argument is that the DOE failed to consider how a "double failure" attributable to a terrorist attack might result in a larger release than contemplated by the Release Scenario. With regards to this argument, the Court makes two observations. First, in the initial EA, the DOE considered the dual-HEPA filtration system, the negative pressure system, and the zone-tight dampening system, in adopting the Release Scenario as a bounded event for earthquakes, accidental plane crashes, *et seq.* Docket No. 19, Ex. "1" at 12, 12 n.9, 17-18; FREA at 51-54. Thus, in the initial EA, the DOE determined that despite a possible "double failure," the forces generated by a reasonably foreseeable accident or natural occurrence would not result in a release in excess of the Release Scenario. Both this Court and the Ninth Circuit approved the initial EA. Then, in the FREA, the DOE considered the dual-HEPA filtration system, the negative pressure system, and the zone-tight dampening system, in adopting the Release Scenario as a bounded event for terrorist attacks. FREA at 13, 13 n.11, 17, 59-61. In part I.A *supra*, this Court approved this adoption as the DOE's experts rationally determined a reasonably foreseeable terrorist attack on the facility would generate the *same forces* as a reasonably foreseeable accident or natural catastrophe. Thus, in essence, this Court has also approved the DOE's determination in the FREA that despite a possible "double failure," the forces generated by a reasonably foreseeable terrorist attack would not result in a release in excess of the Release Scenario.

Second, the Court notes that plaintiffs appear to misunderstand the purpose of the Release Scenario. They appear to argue that it is a poor model for the release a terrorist attack would generate, because a terrorist would not simply load a centrifuge with loosely capped tubes. As just discussed, however, the Release Scenario is not intended to mimic any specific type of terrorist attack. Rather, it simply models the bounded conditions for a release due to a loss of containment

attributable to an accident, a natural catastrophe, or a terrorist attack.

In conclusion, the DOE took a hard look at the Release Scenario, and it did not arbitrarily utilize two 95 percent efficient HEPA filters in its analysis. *Balt. Gas & Elec. Co.*, 462 U.S. at 97. Thus, the DOE did not act arbitrarily or capriciously. *Marsh*, 490 U.S. at 378. As such, the Court finds that plaintiffs have not shown that they would likely prevail on the merits of this issue, nor have they presented a serious question of law worthy of litigation in regards to it. *Topanga Press*, 989 F.2d at 1528.

C. The Mitigators of Fire, Heat, Sunlight, Bleach, *et seq.*

In addition to challenging the DOE's use of the HEPA filters in the Release Scenario, plaintiffs assert that it was unreasonable for the DOE to assume "heat, fire, sunlight, wind, or *exploding containers of disinfectant*" would kill pathogens. *Id.* at 14:7-10 (emphasis in original). In opposition, defendants note that plaintiffs draw support for their argument from a declaration alleging that the BSL-3 facility would work with "weaponized" bioagents, which are designed for release in explosives and thus resistant to relatively high temperatures. Opp'n at 13:8-10. Defendants respond that the facility will not work with these agents. *Id.* at 13:10-11.

The Court notes that plaintiffs' declarant did *not* make a statement regarding the facility's mission, but merely said that she "heard" that "bio-weapons . . . contain an explosive mechanism to spread the pathogens. Some biological agents may die in an explosion, but some may be spread by it." Docket No. 13, Ex. "2" ¶ 39 (Decl. of Marylia Kelley ("Kelley" Decl.)). Further, the declarant's statements are clearly not premised on personal knowledge and are both speculative and inadmissible hearsay. Thus, based on the parties' arguments, the Court finds that plaintiffs have failed to show the DOE's assumption is unreasonable. Consequently, it also finds that plaintiffs are not likely to prevail on the merits of this issue, nor have they stated a serious question of law in its regard. *Topanga Press*, 989 F.2d at 1528.

D. The Release Scenario's Dispersion Model

Plaintiffs question the DOE's conclusion that "[a]dverse health effects to uninvolved workers in adjacent buildings or the public would be extremely unlikely to develop from" the Release Scenario, given LLNL employs 8,000 persons in a 1.3-square-mile or 821-acre area. Mot.

at 14:10-14. Defendants respond that this conclusion was based on the Release Scenario showing a concentration of less than 1/10th HID_{50} per liter of air, at a distance of 125 feet from release. *Id.* at 14:1-4. The only support plaintiffs provide for their argument is that in 1979 an anthrax release occurred in Sverdlovsk, in the former Soviet Union, which killed 100 people when an operator at a military microbiology facility removed a HEPA filter but did not replace it. *See* Docket No. 13, Ex. "3" ¶¶ 7-9 (Decl. of Mark Wheelis, Ph.D. ("Wheelis" Decl.)).

For three reasons the Court finds this incident does not show the DOE acted arbitrarily or capriciously in using the Release Scenario to determine adverse health effects resulting from a loss of containment. First, plaintiffs do not indicate whether the BSL-3 facility will work with similar amounts or concentrations of anthrax as involved in the Sverdlovsk release. Second, this incident was an accident, not a terrorist attack. And, this Court and the Ninth Circuit previously approved the EA with regards to its accident analysis. Finally, plaintiffs may not meet their burden merely by positing possible attack scenarios, even if this Court were to consider this incident as a possible terrorist attack scenario. Thus, the Court finds plaintiffs have failed to show the DOE arbitrarily or capriciously used the Release Scenario to determine the likelihood with which uninvolved workers in adjacent buildings or the public would develop adverse health effects due to a release. *Marsh*, 490 U.S. at 378. As such, plaintiffs are not likely to prevail on the merits of this issue, nor have they stated a serious question of law in regards to it. *Topanga Press*, 989 F.2d at 1528.

E. The Release Scenario's Dispersion Radius

Plaintiffs state that "the terrorism analysis is deficient because it fails to adequately analyze the consequences of a release of pathogenic material on Livermore Lab's employees, the over 81,000 residents of the City of Livermore, and the approximately 7 million individuals living within a 50-mile radius of LLNL." Mot. at 14:20-24. Plaintiffs assert that this is because the DOE uses the Release Scenario which unreasonably relies on any release passing through two HEPA filters and/or being mitigated by fire, heat, sunlight, or exploding disinfectant. *Id.* at 14:24-27. Further, plaintiffs assert that the DOE unreasonably fails to consider a terrorist attack which only seeks to lightly damage the BSL-3 facility, without producing a fire. *Id.* at 14:27-15:4.

Issues related to the HEPA filters and the mitigating factors have been resolved in

defendants' favor. As for plaintiffs' "light attack" theory, again, plaintiffs cannot meet their burden solely by advancing "what if . . ." scenarios. Further, defendants counter in their Opposition, that the "DOE's assumption that any direct attack severe enough to compromise these multiple layers of containment would also involve explosion and fire is a reasonable one." Opp'n at 13:21-23. Further, "[t]he question of the most likely attack scenario is a matter of expertise in which the Agency's experts are due deference." *Id.* at 13:15-17.

The Court defers to the DOE's experts, *Marsh*, 490 U.S. at 378, and finds plaintiffs have not shown that the DOE failed to take a "hard look" at any of these issues, *Balt. Gas & Elec. Co.*, 462 U.S. at 97. Thus, they have not shown they would likely prevail on the merits of any them, and they have not stated a serious question of law in regards to them. *Topanga Press*, 989 F.2d at 1528.

F. Inoculations and Medical Treatment

Plaintiffs assert that defendants unreasonably assume that "diagnostic testing and medical treatment will be immediately available to those whose health is endangered by a release of deadly bioagents." Mot. at 15:5-7. In particular, plaintiffs assert that defendants' reliance on post-release inoculations fails to consider a release involving multiple pathogens, or pathogens which are difficult to detect, do not immediately cause illness, or are genetically modified to withstand antibiotics. *Id.* at 15:7-17.

In opposition, defendants assert that the FONSI was not issued because of the availability of "immediate" medical treatment. Opp'n at 13:25-14:1. Defendants assert it was issued, in part, because according to the Release Scenario, agent concentrations drop to negligible amounts at or beyond 125 feet from the point of release. *Id.* at 14:1-4. Thus, defendants assert that although the agents used in the facility are amenable to treatment, and that local health care providers are briefed regarding such treatment, the FONSI was not issued on this basis. *Id.* at 14:4-7. As for the genetic modification argument, defendants state that "[s]uch work is closely regulated, and any experiment proposing to transfer a drug resistant trait to a microorganism requires specific approval by the NIH." *Id.* at 14:7-10.

Plaintiffs present two arguments in reply. First, they assert that "the facility is intended, in part, to perform testing and bioforensic analysis of pathogenic material released in a terrorist

attack."[16] Reply at 9:10-13. Second, they assert that the facility might "test threat bioagents 'for antibiotic susceptibility which could lead to additional deaths by not providing appropriate therapeutics.' "[17] *Id.* at 9:13-15. Plaintiffs thus assert that the DOE's medical treatment analysis was faulty, having failed to account for such agents.

Defendants respond to plaintiffs' concerns by noting that the Release Scenario's dispersion model clearly shows there is apparently little to no need for any medical treatment at or beyond 125 feet from the point of release.[18] Further, contrary to plaintiffs' allegations, defendants indicate in the EA that inoculations and medical treatment could be utilized within *hours* of release, not *immediately*. Thus, for the reasons discussed in parts I.D and I.E *supra*, addressing the Release Scenario's dispersion model, the Court finds plaintiffs have not shown they would likely prevail on the merits of this issue, nor have they stated a serious question of law in its regards, *Topanga Press*, 989 F.2d at 1528.

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[16] Plaintiffs cite to defendants' Exhibits "10" and "11" in support of this statement. Exhibit "10," however, merely indicates the facility will test agents from the DHS' BioWatch program which collects air samples from "key urban areas across the country for the purpose of detecting a potential release of a terrorist related biological agent." Docket No. 12, Ex. "10" ¶ 3 (Decl. of Jeffrey Steifel ("Steifel Decl.")). It does not discuss antibiotic resistant agents.

As for Exhibit "11," it consists of five short paragraphs of biotech defense terms which are not models of clarity. *See id.*, Ex. "11" (Decl. of Susan Elizabeth George). For example:

> [The Chemical and Biological Division ("CBD") of the Science and Technology directorate of the DHS] has an active R&D program in biological surveillance and detection which will require BSL-3 capability to better understand the potential influence of virulence, viability, and countermeasures resistance markers in the near term and those of the advanced threat in the far term. The resulting high impact markers will be developed into next generation detection systems. [LLNL] is one of three DOE national laboratories that has self identified as a CBD provider through the Under Secretary's process.

Docket No. 12, Ex. "11" ¶ 2 (Decl. of Susan Elizabeth George).

[17] Plaintiffs misquote Exhibit "10." The full version of the quote defendants provide is:

> Without the addition of the LLNL BSL-3 level laboratory, there is the potential to significantly delay the scientific scrutiny of the identified agent that could impact responses and mitigation to a bioterrorism event. For example, the ability to test *for antibiotic susceptibility which could lead to additional deaths by not providing appropriate therapeutics.*

Steifel Decl. ¶ 4 (plaintiffs' quoted portion in italics).
Thus, the declaration does not discuss the BSL-3 working with resistant agents, but rather, identifying a given agent's *non-resistant properties* to provide effect antibiotic therapy.

[18] Defendants' observations regarding the close regulation regarding transferring drug resistancy are non-responsive, however.

G. The difficulty of obtaining agents from LLNL's BSL-3 facility versus natural sources or other BSL-3 facilities.

Plaintiffs assert that it is unreasonable for the DOE to assert that because its pathogens are readily available from naturally occurring sources, the BSL-3 facility is not a relatively attractive terrorist target. Mot. at 15:18-21. Characterizing this as a "bald" assertion, plaintiffs claim that the facility would be tempting to terrorists, as it could produce agents not found in nature, would have agents that could be used as bioweapons, would have agents in amounts and concentrations not found in nature, and would possess relatively virulent strains of agents, like the Vollum strain of anthrax. *Id.* at 15:21-16:4.

Defendants respond that "[a] dispute over whether a terrorist would prefer to attempt to steal from a heavily guarded federal facility or to collect samples from unguarded domestic livestock operations, is a question of expertise as to which DOE is entitled to rely on its expertise in biosecurity issues." Opp'n at 15:1-6. Further, they note that the DOE's assessment of the facility's relative un/attractiveness also turns on the fact that it is substantially more secure than hundreds of other BSL-3s located across the country.[19] *Id.* at 15:6-10.

In reply, plaintiffs essentially assert that LLNL's BSL-3 facility would not be the same as these hundreds of other BSL-3s, which would make it more attractive to terrorists. Specifically, they assert that defendants' own declaration states that as part of a national biodefense response network, the facility " 'will have confirmatory assays, approved sampling methods, and authorization to work with multiple agents of concern' to the [DHS], which 'is not the case for most BSL-3 laboratories in the country.' " Reply at 9:21-24. Further, plaintiffs allege that the facility would work with "bioagents used in terrorist attacks, which would likely be weaponized to some degree,"[20] *id.* at 10:4-6, and would store or aerosolize greater quantities of agents than other BSL-3

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[19] Defendants also claim that "[t]here is no difference in kind or concentration between the agents that may be used at the LLNL BSL-3 and those used at other BSL-3 facilities." Opp'n at 15 n.8. The cited source, however, only provides support for BSL-3 facilities in *the Bay Area*. *See id.*; Hofherr Decl. ¶ 9.

[20] The Court notes that plaintiffs' declarant states, "[a]erosolization of select agents is a form of weaponizing . . . bioagents . . . ." Wheelis Decl. ¶ 6. He does not say that all aerosolized agents are "weaponized to some degree," as plaintiffs assert. Further, the FREA states while the BSL-3 will

facilities,[21] *id.* at 10:6-8.

This Court must defer to the DOE's experts, even in the face of contrary opinions from plaintiffs' experts. *Marsh*, 490 U.S. at 378. Further, contrary to plaintiffs' claim, the FREA shows that the DOE took a hard look at the issue of collecting and capturing pathogens from natural sources. *See* FREA at 62-63; *Balt. Gas & Elec. Co.*, 462 U.S. at 97. Likewise, it carefully assessed whether its BSL-3 facility was more secure than hundreds of others throughout the country. *See* FREA at 61; *Balt. Gas & Elec. Co.*, 462 U.S. at 97. Thus, there is no legal significance to any distinctions between LLNL's BSL-3 and other BSL-3s. The Court finds that plaintiffs would not likely prevail on the merits of this issue, nor have they stated a serious question of law in its regard. *Topanga Press*, 989 F.2d at 1528.

H. The alleged failure to analyze a release which would disrupt the entire Bay Area.

Plaintiffs note that the FREA discusses the dramatic health impacts and economic disruption occasioned by the mailing of anthrax in 2001. Mot. at 16:9-11. They assert that the DOE failed to consider how a release from the BSL-3 could cause the evacuation of the LLNL, the closure of nearby Interstate 580, and "unprecedented economic disruption throughout the San Francisco Bay Area and the United States." *Id.* at 16:12-15. Defendants again point to the Release Scenario's dispersion model, which shows negligible concentrations at 125 feet. Opp'n at 14-16. The Court finds defendants' response adequate. Further, for the same reasons discussed in parts I.D and I.E *supra*, the Court finds that plaintiffs would not likely prevail on the merits of this issue, nor have they stated a serious question of law in its regard. *Topanga Press*, 989 F.2d at 1528.

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use a commonly available nebulizer for rodent challenge studies, where a rodent is "challenged" with an aerosolized agent, FREA at 45, it will not have any equipment for creating "milled" weaponized agents, nor would it be legally allowed to do so, FREA App. "C" at C-23 para 2.

[21] The Court notes that plaintiffs' expert states, in part:

> At the proposed LLNL BSL-3 facility, the quantities, concentrations, the genetic modification of and the aerosolization of biological select agents are distinctly different than at most BSL-3 facilities in hospitals, universities, and other civilian research organizations in California and the country. LLNL is a military laboratory with a major portion of its budget devoted to the design and development of nuclear weapons.

Wheelis Decl. ¶ 5.
The expert provides no support for his conclusion, nor does the first sentence draw support from the second.

I. Summary

Based on the evidence presented, the Court finds that the DOE took a hard look at the potential environmental impact of an intentional destructive act on the BSL-3 facility. Thus, plaintiffs have not shown they would likely prevail on the allegation that the DOE improperly prepared the FREA or issued the FONSI. The Court further finds that plaintiffs have failed to present any serious questions of law in regards to these two acts.[22]

II. Failure to Prepare an Environmental Impact Statement

Plaintiffs fail to show that the DOE acted arbitrarily and capriciously in failing to prepare an EIS. They contend that the DOE should have prepared an EIS under 42 U.S.C. § 4332(2)(C). Mot. at 16:23-26. This section requires an EIS for "major Federal actions significantly affecting the quality of the human environment . . . ." 42 U.S.C. § 4332(2)(C). As the Ninth Circuit has held, "[n]ot every project necessitates an EIS." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 864 (9th Cir. 2005). "Where an EIS is not categorically required, the agency must prepare an [EA] to determine whether the environmental impact is significant enough to warrant an EIS." *Id.* (citing 40 C.F.R. §§ 1501.3, 1508.9). "If the action will significantly affect the environment, an EIS must be prepared, while if the project will have only an insignificant effect, the agency issues a FONSI." *Id.* (citing 40 C.F.R. §§ 1501.3, 1501.4).

An EIS must be prepared if "substantial questions" are raised as to whether a project may cause significant degradation of some human environmental factor. *Id.* A plaintiff need not show significant effects *will* in fact occur, but need only raise substantial questions as to whether a project *may* have a significant effect. *Id.* at 864-65. The term "significantly" in § 4332(2)(C) is determined by evaluating two components: context and intensity. 40 C.F.R. § 1508.27 para. 1; *Ocean*

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[22] The analysis in part I addresses plaintiffs' arguments directed at the Release Scenario, which the DOE uses in the FREA to model a release caused by a loss of containment due to a terrorist attack. In addition to this type of threat, the DOE also considered two other threats in the FREA: (1) the theft and release of pathogenic material taken by a terrorist from outside LLNL; and (2) the theft and release of pathogenic material taken by an insider with access to the facility. FREA at 58. In their Motion, plaintiffs only address the first scenario. Defendants note this in their Opposition. Opp'n at 14:21-15:10. Plaintiffs respond in their Reply by merely repeating certain arguments they made in their Motion regarding the Release Scenario. Reply at 10:9-11:22. As the Court addressed plaintiffs' arguments regarding the Release Scenario, in part I, there is no need to revisit them in regards to the two theft scenarios.

Advocates, 402 F.3d at 865. The Court evaluates each of these components, in turn.

A. Context

"Context" refers to the setting in which a proposed action will take place. *Ocean Advocates*, 402 F.3d at 865. As 40 C.F.R. § 1508.27(a) states:

> Context. This means that the significance of an action must be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality. Significance varies with the setting of the proposed action. For instance, in the case of a site-specific action, significance would usually depend upon the effects in the locale rather than in the world as a whole. Both short- and long-term effects are relevant.

Id.

In regards to context, plaintiffs make two arguments which, neither individually nor collectively, show the BSL-3 facility would "significantly affect[] the quality of the human environment . . . ." First, plaintiffs assert that a sufficiently large release would have a human and economic impact, similar to the 2001 mailings of anthrax. Mot. at 17:18-26. Defendants rebut by correctly noting that the Release Scenario's dispersion model shows essentially no effect beyond 125 feet from the release point.[23] Opp'n at 16:5-9. The Court agrees, as this issue has been resolved in defendants' favor in parts I.D and I.E *supra*.

Second, plaintiffs assert that because the DOE determined it should prepare an EIS for a BSL-3 facility at the Los Alamos National Laboratory ("LANL") in Los Alamos, New Mexico, the DOE should prepare one for the BSL-3 facility at LLNL. Mot. at 17:27-18:7. Plaintiffs support this assertion with two points. First, they note that both LANL and LLNL are classified nuclear weapons design laboratories. *Id.* at 18:8-9. And second, they note that LANL required additional seismic analysis even though it was in a less populated area, and allegedly further than LLNL is

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[23] Defendants also assert that plaintiffs argument here is barred by res judicata. Defendants correctly note res judicata bars the relitigation of claims where there is (1) identity of claims; (2) final judgment on the merits; and (3) identity of privity of the parties. *W. Radio Serv.*, 123 F.3d at 1192; Opp'n at 15:26-16:5, 16 n.2. The Court notes, however, while the Ninth Circuit affirmed the DOE's dispersion model for accidental scenarios, plaintiffs are within their rights to challenge it anew, in regards to the issue of intentional destructive act scenarios.

from a seismic fault. *Id.* at 18:8-18. Defendants counter by noting that after the LANL facility was built, the DOE determined that its location on fill material on the sloping side of a canyon required additional seismic analysis. Opp'n at 16:14-17. Defendants thus assert that the need for an EIS at the LANL is unrelated to any such need at the LLNL. *Id.* at 16:12-13, 17-18. The Court agrees with defendants' conclusion that plaintiffs' comparative argument fails to show the DOE was arbitrary or capricious in determining not to prepare an EIS for the LLNL facility. *Marsh*, 490 U.S. at 378. Thus, on the issue of context, the Court finds that plaintiffs have neither shown they would prevail on its merits at trial, nor have they stated a serious question of law. *Topanga Press*, 989 F.2d at 1528.

B. Intensity

"Intensity" means "the severity of the impact." 40 C.F.R. § 1508.27(b); *Ocean Advocates*, 402 F.3d at 865. "In considering the severity of the potential environmental impact, a reviewing agency may consider up to ten factors that help inform the 'significance' of a project . . . ." *Ocean Advocates*, 402 F.3d at 865. "In certain cases one of these factors may be sufficient to require preparation of an EIS in appropriate circumstances." *Id.*

In their Motion, plaintiffs assert that defendants violated four intensity factors: (1) The degree to which the proposed action affects public health or safety, 40 C.F.R. § 1508.27(b)(2); (2) The degree to which the effects on the quality of the human environment are likely to be highly controversial, *id.* § 1508.27(b)(4); (3) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks, *id.* § 1508.27(b)(5); and (4) Whether the action threatens a violation of federal, state, or local law or requirements imposed for the protection of the environment, *id.* § 1508.27(b)(10). As discussed below, none of these individually or collectively show the BSL-3 facility would "significantly affect[] the quality of the human environment . . . ." The Court addresses each of them in turn.

1. The degree to which the proposed action affects public health or safety.

Plaintiffs state that "operation of the proposed BSL-3 facility at LLNL, including the inadequately studied risks of terrorist attack, accidents, earthquake, and fire, has the potential to cause significant impacts to public health and safety." Mot. at 4-6. Defendants correctly note that

this Court and the Ninth Circuit have already addressed the DOE's assessment of issues other than a terrorist attack. Opp'n at 17:4-7. They also correctly observe that in regards to terrorist attacks, the study was adequate. *Id.* at 17:7-9. The Court agrees with defendants for the reasons stated in parts I, and especially I.A, *supra*.

2. The degree to which the effects on the quality of the human environment are likely to be highly controversial.

"A proposal is highly controversial when there is 'a substantial dispute [about] the size, nature, or effect of the major Federal action rather than the existence of opposition to a use.' " *Anderson v. Evans*, 371 F.3d 475, 489 (9th Cir. 2004) (quoting *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1212 (9th Cir. 1998) (quoting *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1335 (9th Cir. 1992))). As the Ninth Circuit has observed:

> In [*Found. for N. Am. Wild Sheep v. USDA*, 681 F.2d 1172 (9th Cir. 1982)], we found a substantial dispute where the agency "received numerous responses from conservationists, biologists, and other knowledgable [sic] individuals, all highly critical of the [environmental assessment] and all disputing [its] conclusion. . . ." 681 F.2d at 1182. But in [*Friends of Endangered Species, Inc. v. Jantzen*, 760 F.2d 976 (9th Cir. 1985)], we recognized that where "virtual agreement exists among local, state, and federal government officials, private parties, and local environmentalists," the criticisms of the plaintiff and its experts are not sufficient to demonstrate the existence of a public controversy. 760 F.2d at 986-87.

Greenpeace Action, 14 F.3d at 1334 (no misspelling in *Wild Sheep*).

Plaintiffs assert that "there are substantial disputes regarding the need for the proposed facility, the consequences of an accidental or deliberate release of pathogenic material from the facility, as well as the proposed action's compliance with the Biological Weapons Convention [the "BWC"]." Mot. at 15-18. Defendants assert that the issue of whether or not the facility's effect on the environment is controversial was resolved in their favor, in the prior litigation. Opp'n at 11-14.

Turning first to defendants' argument, the Court notes the issue of the consequences of an *accidental* release was addressed in the prior litigation. Defendants thus incorrectly assert the issue

of "consequences" was raised in the prior litigation, in regards to *deliberate releases* or *a potential terrorist attack*.

Turning to plaintiff's arguments, the Court finds no evidence in the three declarations to which they cite which supports their contention that "substantial disputes" surround the issues of the need for the facility, the consequences of a release, or BWC compliance.[24] On the issue of the "need" for the facility, however, plaintiffs have presented evidence regarding the rapid and substantial rise in the number of BSL-3 and BSL-4 facilities since 2001, which is discussed in part III.D *infra*. While this evidence reveals questions exist regarding how many such facilities are required in the Unites States, the existence of these questions does not rise to the level of a "substantial dispute" regarding the need for LLNL's BSL-3 facility. Moreover, plaintiffs fail to establish how the issues of "need" or BWC compliance are directly relevant to resolving the question of whether the DOE took a hard look at the potential impact of terrorist attacks. At best, plaintiffs have merely shown that there is opposition to the facility's operation. Thus, the Court finds that plaintiffs are not likely to prevail on the issue of controversy, nor have they stated a serious question of law regarding it. *Topanga Press*, 989 F.2d at 1528.

3. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.

An agency "must generally prepare an EIS if the environmental effects of a proposed agency action are highly uncertain." *Nat'l Parks & Conservation Ass'n v. Babbitt*, 241 F.3d 722, 731-32 (9th Cir. 2001). The mere existence of uncertainty, however, does not mandate an EIS. *Id.* at 732 n.9. An EIS "is mandated where uncertainty may be resolved by further collection of data," or "where the collection of such data may prevent 'speculation on potential . . . effects. The purpose of an EIS is to obviate the need for speculation by insuring that available data are gathered and analyzed prior to the implementation of the proposed action.' " *Id*. at 732.

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[24] Plaintiffs cite to paragraphs 4 through 21 of the Declaration of Edward Hammond, Docket No. 13, Ex. "1"; paragraphs 36 through 40 of the Kelley Declaration; and, paragraphs 7 through 24 of the Wheelis Declaration. Mot. at 20:18. Plaintiffs fail to indicate, however, which paragraphs address need, accidents, terrorism, or the BWC. On review, the Court finds few paragraphs actually address terrorist attacks. With regards to these, the Court notes that merely claiming a controversy exists does not suffice as evidence of a controversy. *See, e.g.*, Kelley Decl. ¶ 36.

Plaintiffs assert that the facility's effects on the environment are uncertain as there "is no precedent for a release of pathogenic material from such a facility in the United States." Mot. at 21:4-6. Plaintiffs also assert that this safety record is no justification for failing to consider a release, especially considering the 100 dead from the Sverdlovsk release, and that the BSL-3 will work with agents which could be used as bioweapons and will work with genetically modified agents which pose unknown risks. *Id.* at 21:11-17. Defendants assert that the safety record of American BSL-3 facilities belies plaintiffs' claims of uncertainty as to what impact they have on their surroundings. Opp'n at 16-25. Plaintiffs reply that only a "thorough" analysis of the consequence of a theft and release by a terrorist, or of a release which impacts the entire Bay Area, would resolve the uncertainty here. Reply at 13:22-14:2.

The Court finds that plaintiffs have failed to indicate how the facility's operations are "highly uncertain," as required by *National Parks*. The safety record of such facilities,[25] the FREA, the Release Scenario, and the dispersion model suggest the potential impact of the facility's operation to a reasonable certainty. As such, plaintiffs have failed to demonstrate that more data is required to prevent "speculation." Moreover, they have failed to show that they are likely to prevail on this issue or to state a serious question of law regarding it. *Topanga Press*, 989 F.2d at 1528.

4. Whether the action threatens a violation of federal, state, or local law or requirements imposed for environmental protection.

Plaintiffs assert that operation of the facility will violate the BWC, more formally known as the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, March 26, 1975, 26 U.S.T. 583. Mot. at 21:20-24. Article I states, in part:

> Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:

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[25] Plaintiffs have presented evidence, discussed in part III.D *infra*, which raises questions as to whether BSL-3 facilities have under-reported incidents occurring since 2002. Nonetheless, there is insufficient evidence before the Court for it to find the long-term safety record of these facilities suggests the potential environmental impact of the operation of LLNL's proposed BSL-3 facility is "highly uncertain," so as to require an EIS.

> (1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes . . . .

Id., art. I.

Plaintiffs assert that the facility may hold up to fifty liters of pathogenic material, used in aerosol rodent challenge studies, and its work may involve the genetic manipulation of agents and toxins, such that BWC violations could occur. Mot. at 22:1-5. Defendants assert that: (1) the facility will be operated in compliance with the BWC; (2) the Court and Ninth Circuit have already barred this issue as irrelevant in the prior litigation; and (3) as these courts previously held, this is a policy argument, beyond the bounds of NEPA, *Metro. Edison Co. v. People against Nuclear Energy*, 460 U.S. 766, 777 (1983) (NEPA is not a policy grievance process). Opp'n at 18:2-13.

Whether or not the Court barred this particular issue as irrelevant in the prior litigation, it is clear that this issue is irrelevant in this litigation, which concerns whether the DOE adequately assessed the potential environmental impact of a terrorist attack. Further, BWC compliance is an inappropriate issue for a NEPA challenge, under *Metropolitan Edison*. Moreover, plaintiffs fail to indicate how a treaty like the BWC falls under § 1508.27(b)(10), which only addresses "federal, state, or local law or requirements imposed for the protection of the environment[.]" The Court finds that plaintiffs have failed to show they are likely to prevail on this issue, or to state a serious question of law regarding it. *Topanga Press*, 989 F.2d at 1528.

C. Summary

As plaintiffs fail to demonstrate that they would likely prevail on either the context or intensity components of the "significance" concept under 42 U.S.C. § 4332(2)(C), they fail to demonstrate that they would likely prevail on their second count alleging that the BSL-3 facility requires an EIS, on the ground that it is a "major Federal action[] significantly affecting the quality of the human environment . . . ."

III. Failure to Supplement and Circulate a Revised Environmental Assessment

Plaintiffs assert that they will likely prevail on the merits of their third count, that the DOE failed to supplement the REA as required by law. More specifically, they assert that the DOE

intentionally withheld information from the draft REA regarding matters which affect the quality of the human environment in a significant manner. They assert that the public was thus denied a reasonable opportunity to have meaningful input in the decision-making process, prior to the DOE issuing the FREA. As discussed below, the Court finds that plaintiffs would likely prevail on the issue as to whether the DOE should have supplemented and circulated its REA with details of two 2005 shipping incidents.

As the Supreme Court has held, "an agency need not supplement an EIS every time new information comes to light after the EIS is finalized. To require otherwise would render agency decisionmaking intractable, always awaiting updated information only to find the new information outdated by the time a decision is made." *Marsh*, 490 U.S. at 373 (footnote omitted). "On the other hand, . . . NEPA does require that agencies take a 'hard look' at the environmental effects of their planned action, even after a proposal has received initial approval." *Id.* at 374-75. And, as the Ninth Circuit has held, "a federal agency has a continuing duty to gather and evaluate new information relevant to the environmental impact of its actions." *Warm Springs Dam Task Force v. Gribble*, 621 F.2d 1017, 1023 (9th Cir. 1980) (citing 42 U.S.C. § 4332(2)(A), (B)).

The decision whether to supplement is governed by the same standard which applies to preparing an EIS, that is: (1) whether or not there remains a "major federal action" to occur; and (2) "if the new information is sufficient to show that the remaining action will 'affec[t] the quality of the human environment' in a significant manner or to a significant extent not already considered . . . ." *Marsh*, 490 U.S. at 375 (quoting 42 U.S.C. § 4332(2)(C)). The "significance" of the information is determined by analyzing "context" and "intensity" under 40 C.F.R. § 1508.27. *Marsh*, 490 U.S. at 374 n.20; *see also* 10 C.F.R. § 1021.314(a);[26] 40 C.F.R. § 1502.9(c)(1)(ii).[27] The standard for supplementing an EA is the same as for an EIS. *Idaho Sporting Cong., Inc. v.*

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[26] This subdivision states, the "DOE shall prepare a supplemental EIS if there are substantial changes to the proposal or significant new circumstances or information relevant to environmental concerns, as discussed in 40 CFR 1502.9(c)(1)." 10 C.F.R. § 1021.314(a).

[27] This subdivision states, "(c) Agencies: [¶] (1) Shall prepare supplements to either draft or final environmental impact statements if: [¶] . . . [¶] (ii) There are significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts." 40 C.F.R. § 1502.9(c)(1)(ii).

Alexander, 222 F.3d 562, 566 n.2 (9th Cir. 2000).

"An agency, when preparing an EA, must provide the public with sufficient environmental information, considered in the totality of circumstances, to permit members of the public to weigh in with their views and thus inform the agency decision-making process." *Bering Strait Citizens for Responsible Res. Dev. v. United States*, 524 F.3d 938, 953 (9th Cir. 2008).[28] As such, "[w]e do not say that [a draft EA] is always required or that it is never required." *Id.* at 952.

A. The 2005 Anthrax Shipping Incidents

Plaintiffs would likely prevail on the issue as to whether the DOE should have supplemented the REA with information regarding two 2005 shipping incidents. In March 2007, the DOE revised its 2002 EA. *See* REA at cover. On May 11, 2007, the DOE released the REA for public comment, which considered the environmental impacts potentially associated with terrorist attacks. Regarding a 2005 shipping incident, the DOE states:

> LLNL has never had a biological-material transportation accident (PC 2002). However, in September 2005, LLNL sent shipments of vials containing select agent material to two offsite laboratories. Upon receipt, it was determined that the inner packaging of these shipments violated DOT packaging requirements and that the labels were missing important information. No illnesses or injuries occurred. The incident was examined and reviewed by the CDC and the DOT. In addition, an Incident Analysis Committee was empanelled [sic] by the LLNL to review the incident conduct to determine the root causes. During the review period, all select agent transfers were suspended at LLNL.
>
> At the end of the review, the CDC, DOT, and NNSA determined that corrective actions were implemented successfully. Subsequently, LLNL's permit to work with select agents and toxins was renewed by CDC in 2006 for 3 years and

[28] The parties cite to *Bering Strait Citizens for Responsible Res. Dev. v. United States*, 511 F.3d 1011 (9th Cir. 2008), Opp'n at 19:20-22; Reply at 14:16-21, but this was amended and superseded on denial of rehearing on April 30, 2008, 524 F.3d at 938.

transfers were allowed to resume.

Accidents due to transportation of microorganisms are not expected to increase due to the Proposed Action. The addition of milliliter-quantity samples shipped to and from the BSL-3 facility through federal or by commercial or private courier would not be expected to change the overall incidence of risk of transportation accidents. Samples could consist of cells in media contained within DOT-certified packages. The consequences of such accidents would be anticipated to be minor, based on the historical data.

REA at 57.

In the FREA, issued in or after January 2008, *see* FREA at cover, this text was substantially and significantly more detailed. In pertinent part, it states:

[A]n incident occurred in August-September 2005 in connection with a shipment of a collection of vials containing the select agent Bacillus anthracis (anthrax) to two laboratories, one located in Florida and the other in Virginia. At one lab, workers unpacking the shipment discovered that some of the vials had leaked from their primary containers into the inner packaging of the secondary container. However, the material did not escape from the secondary container into the packing material within the tertiary shipping container. Although the unpacking process was conducted in a laboratory, it was not conducted in a Biological Safety Cabinet (BSC), as required, which resulted in five workers being exposed to liquid from the packages while unpacking the secondary containers. These employees received medical treatment as a precaution and there were no adverse health effects. No liquid penetrated the outer shipping container and there was no public release.

FREA at 56.

In addition, the FREA notes:

At the second lab, discrepancies were noted between the shipping inventory and the samples in the container. As required by 42 CFR 73, the recipients of the shipments notified the Centers for Disease Control and Prevention (CDC) of these

problems. As a result, the CDC suspended all LLNL transfers of select agents. An NNSA Occurrence report was filed regarding the incident and LLNL issued a full stand-down of all select agent work.

Id.

The FREA continues:

> An analysis of the shipping incident resulted in multiple corrective actions to strengthen LLNL's packaging and transportation program for select agents and other bio-hazardous materials at LLNL. Actions taken to prevent recurrence included an expansion of the Select Agent Security Plan, additional training related to packaging and shipping regulations, clarifying roles and responsibilities, a new bio-governance model, and an improved inventory system.

Id.

According to minutes from LLNL's Institutional Biosafety Committee, back in November 2005, the CDC identified 29 transportation-related issues for resolution and gave LLNL 30 days to address them. Docket No. 13, Ex. "12." The CDC and the Department of Transportation (DOT), however, did not allow the LLNL to resume select agent transfers until February 2006. FREA at 57. In January 2007, the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS") alleged that in 2005, LLNL had violated shipping and packaging laws. *Id.* at 57. Further, the OIG alleged that LLNL violated security and access requirements by allowing an unauthorized person to package anthrax, and that LLNL's Responsible Official failed to ensure compliance with select agent shipping and packaging laws. *Id.* Allegedly, the person's authorization had lapsed, and had not been renewed. *Id.* The Regents of the University of California paid $450,000 to resolve these allegations. *Id.*

In regards to the first incident, according to a 2007 San Francisco Chronicle article, the unauthorized person, who subsequently resigned, failed to place twist-off caps on 2 vials, out of a shipment of 1,025 vials, and failed to tighten a cap on a third vial. Docket No. 13, Ex. "10" at 1. The exposed workers received Cipro. *Id.* In the second incident, which occurred the following day, a shipment of about 3,000 vials had more vials than it should have. *Id.* Apparently, lab officials

failed to inspect the shipments or verify their inventories. *Id.*

Plaintiffs note that these incidents occurred while the prior litigation was on appeal to the Ninth Circuit, which addressed, *inter alia*, whether the DOE had adequately evaluated the potential environmental impact from a transit-related release. Mot. at 24:5-10. They note that defendants never advised either this Court or the Ninth Circuit of these developments. *Id.* Moreover, despite the fact that the incidents occurred in *2005*, the DOE failed in its *2007* REA to mention anthrax was involved, that an unauthorized person had failed to cap vials, that any liquid had escaped, that workers were treated, that LLNL's shipping procedures were lacking and had been suspended, or that the OIG had levied a fine of $450,000. *Id.* at 24:10-18. Plaintiffs characterize these omissions as misleading and an attempt by the DOE to downplay the incidents. *Id.* Plaintiffs assert that these omissions directly contradict the DOE's assertions in the EA regarding its safety training and protocols, and that only CDC-registered persons had access to select agents. *Id.* at 25:12-23. They also claim that these incidents implicate not only the topics assessed by the DOE in its initial EA but also its terrorism assessment. *Id.* Lastly, they assert that the DOE's lack of candor and failure to supplement, until it issued the FREA, directly circumvented judicial review and public comment under the NEPA. *Id.* at 25:24-25:4.

Defendants make three arguments in opposition. First, they assert that, after the public comment period closed for the REA, the DOE allegedly received complaints from plaintiffs regarding the lack of detail regarding the 2005 incidents, and thus, added more detail to the FREA. Opp'n at 19:14-17. Second, they assert that they were not required to circulate or re-circulate any draft EAs under *Bering Strait*. *Id.* at 19:20-20:1. Third, they assert that the supplemental information in the FREA did not affect the environment in a significant manner or to a significant extent not already considered. *Id.* at 20:10-12.

Having considered the parties' arguments, the Court finds that plaintiffs have shown they would likely prevail on the merits of this issue. In this regard, the Court first notes that the issue as to whether or not the DOE should have supplemented the *2007* REA, with information about *2005* shipping incidents, would not be an issue at all and certainly not before this Court, had the DOE simply *placed this information in the 2007 REA*. Instead, it waited until *2008* to "supplement" the

FREA with a more detailed account. It is unclear why the DOE failed to include in the 2007 REA, in a section *specifically addressing* the potential environmental impacts of *transit-related incidents*, information *more than a year old*, about two 2005 shipping incidents.

The DOE's arguments are unpersuasive on this issue. That it "supplemented" the 2008 FREA in response to alleged complaints about the 2007 REA, does not excuse or explain its initial failure to place this information in the 2007 REA. Its contention that the information was not "significant" under the NEPA[29] is belied by the very fact the DOE felt compelled to withhold this information until *after* the close of the public comment period and until *after* the termination of the prior litigation. As the Supreme Court has stated, "NEPA has twin aims. First, it places upon an agency the obligation to consider every significant aspect of the environmental impact of a proposed action. Second, it ensures that the agency will inform the public that it has indeed considered environmental concerns in its decisionmaking process." *Balt. Gas & Elec. Co.*, 462 U.S. at 97 (internal citations and quotation marks omitted). Here, the DOE did neither, and plaintiffs have reasonably concluded the DOE may have attempted to avoid public comment on these incidents.

As a result, the DOE did not "provide the public with sufficient environmental information, considered in the totality of circumstances, to permit members of the public to weigh in with their views and thus inform the agency decision-making process." *Bering Strait*, 524 F.3d at 953. Thus, the Court finds the DOE's decision to omit this information from the 2007 REA and insulate it from public scrutiny was arbitrary and capricious. *Marsh*, 490 U.S. at 378. Plaintiffs have thus shown they would likely prevail on the merits of this issue at trial. *Topanga Press*, 989 F.2d at 1528.

B. October 2007 Newspaper Article

Plaintiffs also assert that the DOE should have supplemented with an October 2, 2007 Associated Press ("AP") article which reports that American laboratories "handling the world's deadliest germs and toxins have experienced more than 100 accidents and missing shipments since

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[29] In this regard, the DOE appears to focus too much on the outcomes of the incidents, i.e., that nobody took ill or died, rather than on the public's right and need to know in order to make informed decisions and to have meaningful input into government affairs. Further, this information is clearly significant, as it speaks to the "intensity" or severity of the BSL-3 facility's impact. See 40 C.F.R. § 1508.27(b); *Ocean Advocates*, 402 F.3d at 865.

2003, and the number is increasing steadily as more labs across the country are approved to do the work." Mot. at 26:6-10. These accidents include animal bites or scratches, skin cuts, needle sticks, unaccounted for animals,[30] broken vials, contaminated waste leaks, dropped containers, defective seals, missing or lost shipment, *et seq*. *Id.* at 26:11-13. The article states, "Thirty six (36) accidents and lost shipments were reported between January and August 2007, which is nearly double the number reported during all of 2004." *Id.* at 26:13-16. Plaintiffs assert that this information contradicts the DOE's assertions in its REA that laboratory accidents at the BSL-3 are "improbable." *Id.* at 26:17-19. They also assert that the "significant number of transportation-related incidents" reported, questions whether defendants may assert that such incidents "are not expected to increase" when the BSL-3 becomes operational. *Id.* at 26:19-22.

In turn, defendants assert that in preparing the REA, the DOE determined that "the risk of laboratory infection in the facility was no different than at other BSL-3 facilities and was not significant based on the nearly 30-year history of safe operations of BSL-3 labs in the country." Opp'n at 21:2-5. The DOE further states, "Nothing in the October 2007 article makes the DOE's conclusion–which is based on decades of experience–arbitrary or capricious. Nor does the article demonstrate a 'seriously different picture of the likely environmental harms stemming from the proposed action.' " *Id.* at 21:5-8 (quoting *Wisconsin v. Weinberger*, 745 F.2d 412, 420 (7th Cir. 1984)).

The Court agrees with defendants. The article states that while the number of labs "approved by the government to handle the deadliest substances" has nearly doubled from 2004 through 2007, the number of accidents and lost shipments has risen steadily, such that the number reported in 2007 (through August) was almost double the number reported in 2004. Docket No. 13, Ex. "15" at 1 paras. 1, 4, 6. Thus, the article suggests that there has been a roughly one-to-one correlation between the rise in the number of laboratories and incidents since 2004. The article, however, fails to indicate whether the incident rate, that is the number per laboratory, is relatively high or low.

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[30] Apparently due to cannibalism by other animals or due to an inability to identify individual small rodent bodies when numbers of them are simultaneously subject along with their loose bedding to high-temperature sterilization. Docket No. 13, Ex. "15" at 2, para. 5, at 3 paras. 5-7.

Further, it is not even clear if the article is referring only to laboratories registered to handle select agents. Thus, the article does not contradict the DOE's conclusion in its REA that laboratory accidents at the BSL-3 are "improbable." Further, because the article does not state how many accidents were transportation-related, plaintiffs' characterization of this unknown figure as "significant," is unpersuasive and fails to rebut the DOE's conclusion in its REA that the rate of such accidents is not expected to increase.[31] In short, on the issue of the rising numbers of laboratory accidents since 2002, the article provides no "significant new . . . information relevant to environmental concerns[,]" *see* 10 C.F.R. § 1021.314(a), not already covered by the DOE in the EA, REA, or FREA. Thus, the Court does not find the DOE's failure to supplement the REA on this issue was arbitrary and capricious. *Marsh*, 490 U.S. at 378. As such, plaintiffs have not shown they would likely prevail on the merits of this issue, nor have they presented a serious question of law in regards to it. *Topanga Press*, 989 F.2d at 1528.

C. October 4, 2007 Government Accounting Office Study

Plaintiffs assert that the DOE should have supplemented with information from October 4, 2007 Government Accounting Office Testimony titled *High-Containment Biosafety Laboratories*. Mot. at 27:5-28:3. The testimony was provided in October 4, 2007 hearings before the House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations, discussed in part III.D, *infra*. The testimony observes that the number of BSL-3 and BSL-4 laboratories is "proliferating" post-2001. Docket No. 13, Ex. "17" at 1 para 1. Plaintiffs assert that the DOE failed to analyze how this proliferation might obviate the need for the BSL-3 or affect the terrorism analysis ordered by the Ninth Circuit. Mot. at 27:23-26.

Defendants assert that the testimony is not new information and was considered in the EA, the REA, and the FREA, while the GAO document itself was cited in the FREA. Opp'n at 21:11-13. As such, defendants assert that plaintiffs essentially disagree with the weight defendants accorded

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[31] In their Motion, plaintiffs allege biological shipments "may" be ten times the level they were prior to when the BSL-3 became operational, citing page 21 of the FREA as their source. Mot. at 26:23-26. The Court notes, however, page 21 of the FREA discusses shipping procedures, but provides no information regarding the number of shipments to or from the LLNL or the BSL-3 at any time.

this information. *Id.* at 21:13-15. In this regard, defendants note they not only took a hard look at the need for *a* BSL-3 facility in *any* location, more importantly, they considered the need for an *on-site* BSL-3 facility, to avoid the inherently increased security risks and quality control problems associated with using an off-site facility. *Id.* at 21:17-22:5.

Defendants' argument that they cited the GAO document in the *FREA*, does not address plaintiffs' concerns regarding *circulating a supplemented REA* for public comment. Nonetheless, the Court agrees that the information contained in the GAO testimony is not significant new information relative to the REA, on the issue of whether or not LLNL "needed" a BSL-3. Although the GAO presented the information in October 2007, after the March 2007 REA was circulated, the information itself addresses an increase in the number of BSL-3 and BSL-4 laboratories in the United States since *before 2001*. *See* Docket No. 13, Ex. "17" at 1, para. 1.

Further, as defendants indicate, the increasing demand for biodefense research and laboratory facilities in the early 21st century was analyzed and presented to the public in the EA, REA, and FREA. *See, e.g.*, FREA at 4, 6-8. In this regard, while plaintiffs appear to allege the social and political forces driving an increase in the number of BSL-3 and BSL-4 laboratories in the United States should *lessen* the need for one at LLNL, they fail to refute defendants' position that these forces in fact have *created* the need for one at LLNL. Thus, because plaintiffs have failed to show the GAO "proliferation" information was "significant" new information under the NEPA, *Marsh*, 490 U.S. at 375, regarding the issue of LLNL's need for a BSL-3, the Court finds that the DOE's failure to supplement the REA with this information was not arbitrary or capricious, *id.* at 378. As such, plaintiffs have not shown they would likely prevail on the merits of this issue, nor have they presented a serious question of law in regards to it. *Topanga Press*, 989 F.2d at 1528.

D. October 4, 2007 Congressional Hearings

As already noted, On October 4, 2007, the House Committee on Energy and Commerce's Subcommittee on Oversight and Investigations held a hearing titled *Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*. Mot. at 28:6-8. Plaintiffs assert that statements made during these hearings indicate an accidental release could be "catastrophic," no one federal agency tracks the number of BLS-3 and BSL-4 laboratories, the increased number of

these facilities is questionable, and poor safety training and reporting practices pose a potential security and health threat. *Id.* at 27:8-11, 28:6-14. As such, plaintiffs assert that these hearings raised substantial questions regarding the need for LLNL's facility and its safety and security, requiring supplementation of the REA. *Id.* at 28:15-18. Defendants assert that none of this information demonstrates any of the FREA's conclusions were arbitrary or capricious nor demonstrates a 'seriously different picture of the likely environmental harms stemming from the proposed action.' " Opp'n at 22:7-12 (quoting *Weinberger*, 745 F.2d at 420).

In reply, plaintiffs note that the GAO testified there was no central government authority overseeing all BSL-3 or BSL-4 laboratories, and that the oversight provided was inadequate given the number of existing laboratories. Reply at 16:8-9. Further, they note that the CDC official in charge of overseeing these facilities testified that the CDC's oversight could be improved and it was "critically important" for the government to form a task force to oversee them. *Id.* at 16:9-14 (quoting LAT para. 8). They also note that defendants "repeatedly attempt to bolster their assertion that the proposed facility will not have a significant impact on the human environment based on the 'stringent set of guidelines and regulations' under which BSL-3 facilities must operate[.]" *Id.* at 16:14-17 (quoting Opp'n at 3:26). They thus state that "the fact that a federal official charged with ensuring such oversight admits to its inadequacies provides 'a *seriously* different picture of the environmental landscape such that another hard look is necessary.' " Reply at 16:17-20 (quoting *Weinberger*, 745 F.2d at 418 (emphasis in original)).

The evidence before the Court shows a rapid expansion in the numbers of BSL-3 and BSL-4 facilities in recent years, but no corresponding expansion or centralization of oversight. On the one hand, this information is within the purview of the goal of the NEPA's informed public comment-making process to enable the DOE to appropriately respond or modify proposed actions. *Bering Strait*, 524 F.3d at 953. On the other hand, however, it is unclear how or to what extent a lack of centralized oversight directly affects the CDC and NIH oversight of LLNL's BSL-3 facility. Nor is it clear how or to what extent this issue affects the DOE's historic analysis of the health impacts from operating hundreds of CDC-registered BSL-3 laboratories. *See* FREA at 40-42. Thus, the Court does not find the DOE's failure to supplement the REA on this issue was arbitrary and

capricious. *Marsh*, 490 U.S. at 378. As such, plaintiffs have not shown they would likely prevail on the merits of this issue, nor have they presented a serious question of law in regards to it. *Topanga Press*, 989 F.2d at 1528.

E. December 2005 University of Maryland Report

According to plaintiffs, in December 2005, Milton Leitenberg, Senior Research Scholar at the Center for International and Security Studies at the University of Maryland, released a report entitled *Assessing the Biological Weapons and Bioterrorism Threat*, prepared for the Strategic Studies Institute, a division of the U.S. Army War College. Mot. at 28:20-23. In his report, Leitenberg says, "the U.S. biodefense research program appears to be drifting into violation of Article 1 of the [BWC]." Id. at 28:23-25. Plaintiffs assert that Leitenberg attributes this condition to a lack of national-level oversight to ensure such compliance. *Id.* at 28:26-27. Plaintiffs assert that this raises questions as to LLNL's *capability* to comply with the BWC, especially "because determining compliance with the BWC is notoriously difficult . . . ." *Id.* at 28:27-29:3.

Defendants' assert that the 2005 report does not present "new" information, and thus plaintiffs had the burden to produce it during the 2007 comment period, if they felt it relevant. Opp'n at 22:17-23:1. They also assert that even if it were new information, it would not be "significant" under the NEPA, because under *Metropolitan Edison*, it is a policy matter beyond the NEPA's scope. *Id.* at 23:2-5.

When the DOE set out to issue the REA in 2007, it had a duty to supplement its 2002 EA, under *Marsh*, as a "major federal action" was still pending. Further, this duty did not vary depending on when new information arose during the interim. That said, the BWC issue is a policy matter beyond the scope of this NEPA proceeding. Further, plaintiffs may not assert that LLNL's capability to comply with it is questionable merely because its compliance may be difficult to monitor. The DOE is entitled to the presumption it "will act properly and according to law." *FCC v. Schreiber*, 381 U.S. 279, 296 (1965). Thus, the Court finds plaintiffs have not shown they would likely prevail on the merits of this issue, nor have they presented a serious question of law in regards to it. *Topanga Press*, 989 F.2d at 1528.

IV. Failure to Publicly Circulate the Findings of No Significant Impact

Plaintiffs' final count alleges the DOE failed to circulate its FONSI for public comment. Mot. at 29:18:-30:3. The "DOE shall issue a proposed FONSI for public review and comment before making a final determination on the FONSI if required by 40 C.F.R. § 1501.4(e)(2)." 10 C.F.R. § 1021.322. Under 40 C.F.R. § 1501.4(e)(2), "[i]n certain limited circumstances . . . the agency shall make the [FONSI] available for public review . . . for 30 days before the agency makes its final determination whether to prepare an [EIS] and before the action may begin." There are two "limited circumstances." First, "[t]he proposed action is, or is closely similar to, one which normally requires the preparation of an environmental impact statement under the procedures adopted by the agency pursuant to § 1507.3[.]" *Id.* § 1501.4(e)(2)(i). Or, "[t]he nature of the proposed action is one without precedent." *Id.* § 1501.4(e)(2)(ii). As the first circumstance is inapplicable, the parties focus on whether or not the BSL-3 facility is "without precedent."

In this regard, plaintiffs assert that the DOE's action is "without precedent" because the DOE has not previously operated a BSL-3 laboratory. For support, plaintiffs direct the Court to *Sabine River Authority v. U.S. Dep't of Interior,* 745 F.Supp. 388 (E.D. Tex. 1990). In *Sabine,* the Department of the Interior (the "DOI") proposed to accept a conservation easement on 3,800 acres of land, but the Sabine River Authority (the "SAR") wanted to build a reservoir which would flood the easement. *Id.* at 392. Under the NEPA, the DOI drafted a EA and held a public hearing. *Id.* It then issued a final EA recommending acceptance, issued a FONSI indicating there was no need for an EIS, and accepted the easement. *Id.*

The SAR, *inter alia*, asserted that the DOI should have provided a 30-day comment period after the FONSI issued. *Id.* at 401. The SAR asserted that the DOI's proposed action was "without precedent" because no other conservation easements had been acquired in the proposed reservoir area. *Id.* at 402. The court disagreed, finding under 40 C.F.R. § 1501.4(e)(2)(ii), because the DOI had accepted easements before, under circumstances posing a conflict with other users, its proposed action was not "without precedent." *Id.*

At first blush, *Sabine* appears to support plaintiffs' position, because, the DOE has not previously operated a BSL-3 facility. The First Circuit, however, has expressly interpreted the terms "without precedent," under § 1501.4(e)(2)(ii), as focusing on whether the *environmental impact* of

the action is without precedent, not whether the actor has *performed* the proposed action before. Thus, in *Alliance to Protect Nantucket Sound, Inc. v. U.S. Dep't of Army*, 398 F.3d 105 (1st Cir. 2005), the Alliance asserted that the Army was required to circulate a FONSI, under § 1501.4(e)(2)(ii), where a private entity sought a navigability permit from the Army, so it could place an offshore data tower in Nantucket Sound in the Outer Continental Shelf ("OCS"). *Id.* at 107, 114-15. The Alliance asserted that the tower was without precedent, as there had never been such a structure in the OCS. *Id.* at 115. The Army noted there was a data tower in state waters off Martha's Vineyard, and the proposed data tower was similar to other pile supported structures in Nantucket Sound. *Id.* The court found that the Army's determination that the data tower was not "without precedent" was reasonable. *Id.* As the court held:

> The CEQ regulations . . . are designed to address *environmental impact*. Based on the Corps's findings about the existence of similar pile-driven structures in Martha's Vineyard and near the shore of Nantucket Sound, we can see nothing unprecedented about the way this data tower will *impact the environment*.

Id. (emphasis added).

This Court is persuaded that the First Circuit's interpretation comports with the NEPA. Plaintiffs' interpretation would treat every proposed action as without precedent, if proposed by an actor who had not previously proposed such an action, even if the proposed action had been performed by hundreds of other actors. NEPA, however, does not focus on *who* proposes an action, but on the *environmental impact* of a proposed action. Nor is the First Circuit's interpretation inconsistent with the Eastern District of Texas' in *Sabine*. The *Sabine* court found that there were precedents for the practice of accepting easements, because the DOI had accepted them before, under like circumstances. This suggests that the environmental impacts of the practice were well established. In turn, this suggests the *Sabine* court was focused not on whether the DOE had performed the proposed action, but was focused on whether the proposed action had been performed

previously. Thus, the *Alliance* and *Sabine* holdings are consistent.[32]

Based on the foregoing, the Court finds there are in excess of 1,350 BSL-3 laboratories already in operation, LLNL's proposed BSL-3 facility is not "without precedent" under § 1501.4(e)(2)(ii), and the DOE was not required to circulate its FONSI for public comment. As such, plaintiffs have not shown they would likely prevail on the merits of this issue, nor have they presented a serious question of law in regards to it. *Topanga Press*, 989 F.2d at 1528.

V. Irreparable Injury

Plaintiffs assert the possibility of three irreparable injuries. First, they assert that because the BSL-3 facility will handle "deadly bioagents," "genetically modified organisms[,]" and bioagents "which could have offensive uses as bioweapons[,]" any release due to a terrorist attack, earthquake, operator error, *et seq.* "would pose a grave danger of irreparable health impacts to an untold number of individuals." Mot. at 31:21-32:3; *see* Reply at 17:18-18:2. Second, they assert that they have suffered a "procedural injury," because defendants failed to supplement the REA with information regarding the two 2005 shipping incidents and other developments, such as the October 2007 congressional hearings, and circulate it for public comment, which allowed defendants to act without the benefit of public comment. Mot. at 32:4-14. Third, they assert that they have suffered a "procedural injury," because defendants failed to prepare an EIS. *Id.* at 32:14-16.

Defendants counter that plaintiffs fail to show how the risks of operating the BSL-3 facility at LLNL are different than any of the other 1,350-plus facilities currently operating around the country. Opp'n at 24:3-6. They also assert that as required by law they took a hard look at the potential environmental impact of an intentional destructive act on the BSL-3 facility and properly determined that it would not have a significant impact on the environment. *Id.* at 7-10. They also note that plaintiffs' hypotheses involving a release that poses "a grave danger of irreparable health impacts to an untold number of individuals," involve chains of events and multiple contingencies far

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[32] Likewise, in *Advocates for Transportation Alternatives, Inc. v. U.S. Army Corps of Engineers*, 453 F.Supp.2d 289 (D. Mass. 2006), the court held that a proposal to restore commuter service to an unused railroad right-of-way, was not without precedent, where two other right-of-ways had already been restored. *Id.* at 311. Though the proposing actor was the same for all three right-of-ways, *id.* at 294-95, the court merely pointed to the act and not the actor, in holding that the Army did not have to publicly circulate its FONSI, *id.* at 311.

too speculative and unlikely to occur to support injunctive relief. *Id.* at 24:20 (citing *Caribbean Marine Servs. Co. v. Baldrige*, 844 F.2d 668, 675 (9th Cir. 1988)).

The Court finds that plaintiffs have failed to show the possibility of an irreparable injury. With regards to plaintiffs' first argument, the Court notes that they have presented no evidence that the facility would work with bioagents usable as bioweapons. Likewise, plaintiff's concerns regarding incidents other than terrorist attacks, such as earthquakes or operator error, have already been rejected by this Court and the Ninth Circuit.

Focusing on the remainder of plaintiffs' first argument, plaintiffs attempt to demonstrate the possibility of an irreparable injury by using the same arguments they previously raised to show that defendants in the FREA performed an inadequate analysis of the potential environmental impact of intentional destructive acts. The Court agrees with defendants, however, that it has found that defendants took a hard look at this issue and that plaintiffs have failed to state any serious questions of law in its regard. While environmental harm is generally irreparable, plaintiffs cannot demonstrate irreparable harm from the facility's operation merely by invoking this principle. *The Lands Council v. McNair*, 537 F.3d 981, 1004 (9th Cir. 2008). Nor can they meet their burden if the evidence shows an irreparable injury is unlikely or its risk of occurrence is negligible. *R.C.A.L.F. v. U.S.D.A.*, 415 F.3d 1078, 1104 (9th Cir. 2005). Attenuated, conjectural, or speculative injuries will not suffice. *Caribbean Marine Servs.*, 844 F.2d at 675. Plaintiffs attempt to meet their burden, however, by asserting that they face the possibility of irreparable injury either from: (1) a release whose effect terminates at *125 feet from the facility*, as predicted by the FREA; or (2) the *mere possibility* of a larger release. The first release is too attenuated and the second too speculative to constitute irreparable harm to plaintiffs. Thus, their first argument fails to show the possibility of an irreparable injury from the BSL-3 facility's operation.

Turning to plaintiffs' second argument, the Court notes that "[a]n agency, when preparing an EA, must provide the public with sufficient environmental information, considered in the totality of circumstances, to permit members of the public to weigh in with their views and thus inform the agency decision-making process." *Bering Strait Citizens for Responsible Res. Dev.*, 524 F.3d at 953. When government decision-makers fail to do this, there is an added risk to the environment

that they will act without the benefit of public comment regarding the likely effect of their decision upon the environment. *Sierra Club v. Marsh*, 872 F.2d 497, 500 (1st Cir. 1989). Plaintiffs claim that they were harmed by defendants' failure to supplement the REA with certain information, including details regarding the 2005 shipping incidents. The Court notes that besides this lost opportunity, there is no evidence that this deprivation substantively harmed plaintiffs. That is, they have not indicated what comments they would have provided to defendants, had this information been provided, or how their comments might have altered defendants' conclusions in the FREA. Nor have they shown that by taking corrective action in 2006, defendants have not already considered this issue. *See Warm Springs Dam Task Force*, 621 F.2d at 1023 (comments may be futile where agency has considered issue in the absence of comments). Thus, plaintiffs' second argument fails to show the possibility of an irreparable injury to them from the BSL-3 facility's operation.

Finally, with regards to plaintiffs' third argument, that they suffered a "procedural injury," by virtue of defendants' failure to prepare an EIS, given the Court's finding that plaintiffs have not shown a serious of question of law as to whether defendants should have prepared one, plaintiffs could not have been irreparably injured by defendants' failure.

VI. Plaintiffs have failed to make the required showing for a preliminary injunction.

A party seeking a preliminary injunction must show either: (1) a combination of probable success on the merits and the possibility of irreparable injury, or (2) that serious questions are raised and the balance of hardships tips sharply in its favor. *Faith Ctr. Church Evangelistic Ministries v. Glover*, 462 F.3d 1194, 1201-02 (9th Cir. 2006). With regards to their first, second, and fourth counts, plaintiffs have failed to raise any serious questions, much less demonstrate probable success on the merits. With regards to their third count, they have demonstrated a probable success on the merits as to whether defendants should have supplemented the REA with details regarding the 2005 shipping incidents and circulated this information for public comment. They have not, however, shown irreparable injury.

CONCLUSION

Accordingly, the Court DENIES the Amended Plaintiffs' Notice of Motion and Motion for Preliminary Injunction [Docket No. 13].

IT IS SO ORDERED.

February 9, 2009

Saundra Brown Armstrong
United States District Judge