No. 10-17636

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

TRI-VALLEY CARES, MARYLIA KELLEY and JANIS KATE TURNER,

Plaintiffs-Appellants,

v.

UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION and LAWRENCE LIVERMORE NATIONAL LABORATORY,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANSWERING BRIEF FOR FEDERAL APPELLEES

IGNACIA S. MORENO
Assistant Attorney General

JENNIFER SCHELLER NEUMANN
BARCLAY T. SAMFORD
Attorneys, U.S. Dep't of Justice
Env't & Natural Resources Div.
999 18th Street,
South Terrace, Suite 370
Denver, CO 80202
(303) 844-1475
clay.samford@usdoj.gov

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

STATUTES:

RULES and REGULATIONS:

GLOSSARY

APA	Administrative Procedure Act
BDRP	Biological Defense Research Program
Br.	Opening Brief of Plaintiffs-Appellants Tri-Valley CARES, et al.
BRTA	Biological Risk and Threat Assessment
BSL	Biosafety Level
CDC	Centers for Disease Control and Prevention
CEQ	Counsel on Environmental Quality
DOE	Department of Energy
EA	Environmental Assessment
EIS	Environmental Impact Statement
FONSI	Finding of No Significant Impact
FREA	Final Revised Environmental Assessment
HEPA	High Efficiency Particulate Air-Purifying
IBC	Institutional Biosafety Committee
MCE	Maximum Credible Event
NEPA	National Environmental Policy Act
NIH	National Institute of Health
NNSA	National Nuclear Security Administration
NRC	National Research Council of the National Academies of Science
OIO	DOE Health, Safety and Security Office of Independent Oversight
REA	Revised Environmental Assessment
TVC	Tri-Valley CAREs

STATEMENT OF JURISDICTION

Plaintiffs-appellants Tri-Valley CAREs, Marylia Kelley, and Janis Kate Turner (collectively "TVC") brought this action in the United States District Court for the Northern District of California (Saundra Brown Armstrong, Judge) against the United States Department of Energy, National Nuclear Security Administration, and Lawrence Livermore National Laboratory (collectively "DOE"), alleging violations of the National Environmental Policy Act ("NEPA"), 42 U.S.C. §§ 4321-4370f, and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. The district court had jurisdiction under 28 U.S.C. § 1331 (federal question) and 28 U.S.C. § 1346 (federal defendant).

The district court entered an order granting summary judgment to DOE on September 30, 2010. 1ER3; SER17; 1ER4.[1] On November 18, 2010, TVC filed a timely notice of appeal. 1ER1. This Court's jurisdiction rests on 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

I. Whether DOE was arbitrary or capricious in determining that the threat of terrorist attack on DOE's Biosafety Level 3 lab at the Lawrence Livermore National Laboratory did not require preparation of an Environmental Impact Statement under NEPA.

---

[1] TVC's Excerpts of Record is cited as "ER" preceded by volume number and followed by document and page number. Appellees' Supplemental Excerpts is cited as "SER" followed by the page number.

II. Whether DOE's discussion in its Revised Environmental Assessment of a 2005 shipping incident involving anthrax and its determination not to include a discussion of a "restricted" experiment was arbitrary or capricious.

III. Whether DOE was arbitrary or capricious in determining that a 2008 Security Assessment did not constitute significant new information necessitating supplementation of the Revised Environmental Assessment.

IV. Whether the district court abused its discretion in denying TVC's motion to supplement the administrative record.

STATEMENT OF THE CASE

I. NATURE OF THE CASE

This is TVC's second challenge to DOE's compliance with NEPA in conjunction with the construction and operation of a Biosafety Level 3 facility at Lawrence Livermore National Laboratory to research ways to reduce and counter the threats posed by biological weapons. In 2002, when it first proposed the facility, DOE prepared an Environmental Assessment pursuant to NEPA that thoroughly evaluated the proposed facility's potential environmental impacts. DOE concluded that the facility would not have significant environmental impacts and issued a Finding of No Significant Impact, which under NEPA obviates the need to prepare a full Environmental Impact Statement. In TVC's first challenge, this Court generally upheld DOE's environmental analysis, but remanded the case to DOE to "consider

whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement." 1ER24:4.

On remand, DOE prepared a Revised Environmental Assessment that comprehensively considered the threat of terrorist attack. Based on that analysis, DOE issued a Finding of No Significant Impact. In this second round of litigation, TVC again challenges DOE's compliance with NEPA, asserting that the Revised Environmental Assessment does not take the requisite "hard look" at the threat of terrorist attack, and that DOE did not adequately address new information that developed during the remand. The district court rejected TVC's assertions, finding DOE had fulfilled its obligations under NEPA.

II. STATUTORY BACKGROUND

A. National Environmental Policy Act

NEPA establishes a process whereby federal agencies are to consider the environmental consequences of proposed major federal actions. Vermont Yankee Nuclear Power Corp. v. Natural Res. Def. Council, 435 U.S. 519, 558 (1978). These procedures "require that agencies take a "'hard look" at environmental consequences.'" Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 350 (1989) (quoting Kleppe v. Sierra Club, 427 U.S. 390, 410 n.21 (1976)). But NEPA's requirements are procedural, not substantive. Strycker's Bay Neighborhood Council v. Karlen, 444 U.S. 223, 227-28 (1980). So long as "the adverse environmental effects of the proposed action are adequately identified and evaluated, the agency is not

constrained by NEPA from deciding that other values outweigh the environmental costs." Robertson, 490 U.S. at 350.

NEPA requires a federal agency to prepare an Environmental Impact Statement ("EIS") before taking any major action "significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). To determine whether the impact of a proposed action will be significant enough to warrant an EIS, the agency may prepare an Environmental Assessment ("EA"). 40 C.F.R. § 1501.4(b), (c). An EA is

> [a] concise public document . . . [that b]riefly provide[s] sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact . . . [and] include[s] brief discussions of the need for the proposal, of alternatives . . . , of the environmental impacts of the proposed action and alternatives . . . .

40 C.F.R. § 1508.9. If, based on the EA, the agency concludes that the proposed action will not significantly impact the environment, then it issues a Finding of No Significant Impact ("FONSI") in lieu of an EIS. 40 C.F.R. § 1508.13; see generally Dep't of Transp. v. Public Citizen, 541 U.S. 752, 756-58 (2004). Regulations issued by the Council on Environmental Quality ("CEQ") set forth a number of factors for agencies to consider in deciding whether environmental impacts are significant and therefore necessitate an EIS. 40 C.F.R. § 1508.27.

B. Administrative Procedure Act

TVC's allegations regarding the adequacy of DOE's NEPA analysis are reviewed pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 706 et

seq. See, e.g., Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 882 (1990) (reviewing alleged NEPA violation under the APA). Under the APA, this Court may set aside DOE's evaluation of the LLNL BSL-3 facility only if it finds it was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971). A decision is arbitrary and capricious "only if the agency relied on factors Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, or offered an explanation that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." Lands Council v. McNair, 537 F.3d 981, 987 (9th Cir. 2008) (en banc) (citation and quotation marks omitted).

Although this inquiry is thorough, the standard of review is narrow and highly deferential to the agency. Overton Park, 401 U.S. at 416. A court cannot substitute its judgment for that of the agency, id. at 416, and the agency's decision "will be upheld so long as [it] do[es] not collide directly with substantive statutory commands and so long as procedural corners [have been] squarely turned," Citizens Awareness Network, Inc. v. NRC, 59 F.3d 284, 290 (1st Cir. 1995) (citation and quotation marks omitted).

Judicial review is to be "'particularly deferential'" where, as here, the agency is making "'predictive judgments about areas that are within the agency's field of

expertise.'" Lands Council v. McNair, 537 F.3d at 992 (quoting Earthlink, Inc. v. FCC, 462 F.3d 1, 12 (D.C. Cir. 2006)).

III. STATEMENT OF THE FACTS

The National Nuclear Security Administration ("NNSA") of the DOE has responsibility, among other things, for national programs aimed at reducing and countering the threats posed by biological weapons. 2ER1:5. In 2002, DOE determined that, in order to implement this mandate, it needed to expand its capabilities to research infectious agents and biotoxins associated with potential bioweapons threats. DOE found this work requires a facility classified as Biosafety Level 3 ("BSL-3"), referring to the "Biosafety in Microbiological and Biomedical Laboratories" guidelines promulgated by the Centers for Disease Control and Prevention and the National Institutes for Health (collectively, "CDC-NIH"). 2ER1:71-85. The CDC-NIH guidelines are designed to standardize procedures, safety equipment, and facility design in order to protect laboratory workers and the public. The guidelines classify laboratory operations into four levels of ascending degree of protection, from BSL-1 to BSL-4. 2ER1:71. BSL-3 laboratories work with agents that may cause diseases with serious or lethal consequences *if untreated* and that have the potential of aerosol (airborne) transmission. 2ER1:10. There are over 1,350 BSL-3 labs in the United States, including laboratories at medical and veterinary schools, and university research laboratories. Id.

A. The Original EA

The site DOE selected for the BSL-3 facility is the agency's Lawrence Livermore National Laboratory ("LLNL") near Livermore, California. LLNL was founded as a nuclear weapons design laboratory, but has since become a premier center for scientific research into a variety of fields of national importance, including energy, biomedicine, and environmental science. 2ER1:6-7.

Prior to the opening of the BSL-3 lab in January 2008, LLNL only maintained BSL-1 and BSL-2 facilities. 2ER1:5. Therefore, when research at LLNL required use of a BSL-3 laboratory, off-site private and University facilities had to be used. Id. The use of off-site facilities was problematic for DOE because chances of cross-contamination and degradation of samples is increased by excessive handling and transportation; because security at off-site facilities cannot be guaranteed; and because off-site BSL-3 laboratories are frequently committed to projects for other entities. Id.

In order to evaluate the environmental impacts of a BSL-3 facility at LLNL and meet its obligations under NEPA, DOE prepared an EA. 2ER1. The EA comprehensively examined alternatives to the construction of an on-site BSL-3 lab and their potential environmental impacts.

In particular, the EA focused on how the BSL-3 lab's operations might affect the health of laboratory personnel and the public. The analysis drew from three relevant categories of experience: the experiences of existing CDC-monitored BSL-3 labs, the experience of the Army's Biological Defense Research Program ("BDRP")

labs, and DOE's own experience with microbiology labs. 2ER1:44-45. With respect to the first category, DOE found that labs operating pursuant to the CDC-NIH guidelines have an extremely low incidence of laboratory-acquired infections. 2ER1:44. The Army's labs have a similarly impressive safety record; the risk of public infection from Army microbiology labs between 1970 and 1989 was less than 0.001 infections per 1 million person-years, and the risk of death to a laboratory worker was 0.005 deaths per 1 million person-years. 2ER1:45. As for DOE's experience, in the past 20 years, LLNL's biological research facilities have not resulted in any infections of lab personnel or the public. Id. DOE concluded, based on the experiences of existing CDC-monitored BSL-3 labs, the Army's BSL-3 and BSL-4 labs, and LLNL's existing BSL-1 and BSL-2 biological research labs, that routine laboratory operations at the LLNL BSL-3 facility would not pose any discernible threat to human health. 2ER4:3.

In addition to evaluating normal operations, DOE considered the potential impacts of abnormal events through a "Maximum Credible Event" ("MCE"), a scenario designed to show the outside bounds of the impact of a catastrophic event that caused the accidental release of a pathogen. 2ER1:54-58. As explained more fully below, the MCE revealed that even in the extremely unlikely event of a bioagent release, there would be no significant impact on public health and safety.

Based on its consideration of all reasonably foreseeable environmental impacts, and given the proven safety record of CDC-monitored and Army BSL-3 laboratories,

the safety record of existing biological operations at LLNL, and the negligible impact of even a highly unlikely catastrophic release scenario, DOE concluded that the BSL-3 lab would not significantly impact the human environment, and on December 16, 2002, issued a FONSI approving the lab.

Construction of the BSL-3 facility was completed in 2005. The lab is a 1,500 square foot facility that contains three BSL-3 lab rooms, one of which is equipped with pressurized filtered cages to handle up to 100 rodents. 2ER1:17-19. No more than six workers normally will occupy the facility. 2ER1:13. Among the safety features of the building is a High Efficiency Particulate Air-Purifying ("HEPA") air filtration system, in which all laboratory room air passes through two state-of-the-art HEPA filters before being vented outside. 2ER1:16, 19. Each HEPA filter is a minimum of 99.97 percent efficient at removing bioagents. 2ER1:46.

Operations at the BSL-3 lab are governed by a stringent set of guidelines and regulations. 2ER1:20-22. For example, the CDC-NIH standards for BSL-3 facilities require that, before it handles infectious microorganisms, a lab must prepare a risk analysis, and inform the local medical community of the agent to be handled and the methods of identifying and controlling the diseases associated with that agent. 2ER1:21. Further, prior to using any CDC-designated select agents, the facility must register with the CDC and demonstrate that it "meets biosafety level requirements for working with the particular biological agent." 2ER1:20. The CDC regularly inspects facilities. 2ER1:24. Moreover, pursuant to NIH and DOE regulations, LLNL's

Institutional Biosafety Committee ("IBC"), which includes scientific staff members, health care providers, a DOE official, and at least two members of the public, also oversees the BSL-3 lab's operations. 2ER1:9-10. The IBC must review and approve all experiments with select agents and toxins prior to the commencement of work.[2] 2ER1:21.

B. TVC's First Lawsuit

In August 2003, TVC brought suit alleging numerous deficiencies in the EA and FONSI for the LLNL BSL-3 lab. The district court granted summary judgment to DOE and TVC appealed. SER212; 1ER1. This Court found that with the exception of the possibility of a terrorist attack, DOE took "a 'hard look' at the identified environmental concerns and that DOE's decision was fully informed and well-considered." 1ER24:4. With regard to the possibility of terrorist attack, the Court remanded the decision to DOE to "consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement." Id. This Court emphasized that there "'remain open to the agency a wide variety of actions it may take on remand and we do not prejudge those alternatives.'" Id. (quoting San Luis Obispo Mothers for Peace v. NRC, 449 F.3d 1016 (9th Cir. 2006) (brackets and ellipsis omitted).

---

[2] Select agents "have the potential to pose a severe threat to public health and safety, to animal health, or to animal products," and are therefore subject to additional requirements on their possession, use and transfer. 42 C.F.R. § 73.2.

C. The Revised EA

On remand, DOE prepared a Revised EA ("REA") to determine whether the threat of terrorist attack necessitated preparation of an EIS. The agency addressed three attack scenarios: a destructive direct attack on the facility—such as an airplane crash—that would breach facility containment; theft and release of a pathogen by a terrorist; and theft and release of a pathogen by an insider with access to the facility. 2ER1:60-67.

With regard to a pathogen release caused by a direct attack that breaches facility containment, DOE found the impacts were within the bounds disclosed by the MCE scenario and would not be significant. 2ER1:62. As to theft and release of a pathogen by a terrorist, DOE found that, in light of the hundreds of other BSL-3 facilities where comparable pathogens are available, the risk of a terrorist acquiring pathogenic material is not significantly increased by the presence of such material at LLNL. 2ER1:65-66. Finally, DOE found that the threat of an insider stealing, cultivating and successfully releasing a pathogen was not significant enough to require preparation of an EIS. 2ER1:66-67.

DOE also included in the REA new information that had developed after issuance of the original EA, including a 2005 incident involving shipment of anthrax samples from LLNL to private labs. 2ER1:59.

In April 2007, DOE released a draft REA for public comment. 2ER1:12. After evaluating public comment, DOE concluded that neither the risk of a terrorist

attack, nor the new information developed since the issuance of the original EA, showed that the BSL-3 lab would have a significant impact on the environment. On January 25, 2008, DOE released a final REA and issued a FONSI. 2ER1; 2ER4. Full operations at the facility began on January 25, 2008. 1ER19:9.

D. TVC's Challenge to the REA

On March 10, 2008, TVC filed suit challenging the adequacy of the REA and moved for a preliminary injunction to stop operations at the facility. 1ER2:3. The district court denied TVC's motion for a preliminary injunction, 1ER2:9, and the parties filed cross-motions for summary judgment. During the pendency of the parties' summary judgment motions, TVC filed a motion seeking to supplement the administrative record. 1ER2:12. On September 30, 2010, the district court granted summary judgment to DOE on TVC's NEPA claims, and denied TVC's motion to supplement the administrative record. SER1, 16-19.

SUMMARY OF ARGUMENT

On appeal, TVC raises five arguments: (1) that DOE erred in concluding the threat of terrorist attack on the BSL-3 lab did not require preparation of an EIS, Br. 35-48; (2) that DOE deprived the public of relevant information about a shipping incident involving anthrax and a "restricted" experiment, Br. 48-55; (3) that DOE should have supplemented the REA in response to a 2008 Security Assessment, Br. 55-57; (4) that DOE erred in concluding an EIS was not required, Br. 57-58; and (5) that the district court erred in denying TVC's motion to supplement the

administrative record, Br. 59-65. The district court's rejection of each of these claims was appropriate and should be affirmed on appeal.

I. DOE took a hard look at whether the threat of terrorist activity required preparation of an EIS. While TVC disputes the methodologies used and conclusions drawn by DOE, the record shows that DOE reasonably concluded that the threat of terrorist attack would not have a significant impact on the human environment.

II. The level of detail provided in the REA is sufficient to determine whether to prepare an EIS or a FONSI, and to allow the public to comment on the environmental impacts of the lab. While the TVC contends that the REA should have contained more details about the 2005 anthrax shipping incident, the discussion in the REA is consistent with the requirements of NEPA. DOE's decision not to include a discussion of the restricted experiment in the REA was also reasonable as it does not provide information relevant to the evaluation of environmental impacts in the REA.

III. After issuance of the REA for the BSL-3 lab, DOE's Health, Safety and Security Office of Independent Oversight conducted a Security Assessment at LLNL. DOE properly prepared a supplemental report to address the Security Assessment, and reached the reasonable conclusion that it did not constitute significant new information requiring supplementation of the REA

IV. TVC's undeveloped claim that the CEQ's significance factors, 40 C.F.R. § 1508.27, require preparation of an EIS for the LLNL BSL-3 should be deemed

waived. Should the Court consider the claim, the record demonstrates that the CEQ significance factors support DOE's determination that an EIS was not required.

V. The district court did not abuse its discretion by denying TVC's motion to supplement the administrative record with a report prepared two years after DOE's revised EA and FONSI were issued. TVC failed to comply with the local rules, and the proffered document did not fall within any of the limited exceptions to record review.

STANDARD OF REVIEW

This Court reviews a district court's grant of summary judgment on NEPA claims *de novo*. Northern Cheyenne Tribe v. Norton, 503 F.3d 836, 845 (9th Cir. 2007). The district court's decision to exclude extra-record evidence is reviewed for abuse of discretion. Northwest Envtl. Advocates v. Nat'l Marine Fisheries Serv., 460 F.3d 1125, 1133 (9th Cir. 2006).

ARGUMENT

I. DOE REASONABLY DETERMINED THE THREAT OF A TERRORIST ATTACK DID NOT REQUIRE PREPARATION OF AN EIS.

A. DOE properly evaluated a terrorist attack resulting in a breach of containment.

On remand, the first terrorist attack scenario considered by DOE was a bioagent release caused by a direct terrorist attack capable of breaching facility containment, such as a suicide airplane crash or delivery of an explosive device.

2ER1:62. DOE concluded, through use of a maximum credible event scenario designed to model the outermost bounds of the impacts of a reasonably foreseeable bioagent release, that any release caused by such an attack would not have significant impacts. While TVC disputes DOE's use of the maximum credible event to bound the impacts of direct terrorist attack, the record shows this methodology was reasonable and should be upheld by this Court.

In the original EA, DOE developed a maximum credible event ("MCE") to evaluate the outside bounds of the impact of the release of a pathogen caused by a catastrophic accident. 2ER1:54. In selecting an appropriate scenario, DOE considered triggering events such as earthquakes, explosions, fires and airplane crashes, but concluded that because microorganisms are generally rendered innocuous by high temperatures, fire, and sunlight, such events would reduce, rather than enhance, the consequences of a release. Id. Thus, after reviewing multiple accident scenarios, see 2ER1:86-88, DOE determined the most appropriate release scenario for its MCE was one similar to that used by the U.S. Army in conducting NEPA analyses for its own biological research labs. 2ER1:54-56.

The MCE that DOE used for the LLNL BSL-3 lab modeled a scenario in which a liter of *C. burnetii,* which causes Q-fever, is accidentally aerosolized and released within the lab, resulting in the production of almost 10 billion airborne human infective doses. 2ER1:57. The pathogen plume was then modeled as it moved through the lab and outside via the ventilation system. Id. For conservative

results, the Army assumed the lab had only one HEPA filter operating at only 95 percent effectiveness. 2ER1:88. The Army concluded the chance of public exposure to even a fraction of one infective dose was extremely remote; at a distance of only 2 meters from the building, one liter of air would contain less than 1 infective dose, and at 128 feet, one liter of air would contain less than 1/100th of an infective dose. 2ER1:57.

DOE found that the chances of exposure at LLNL were even more remote. 2ER1:57-58. The Army scenario assumes one HEPA filter that is only 95 percent effective. 2ER1:57, 88. The LLNL BSL-3 lab, however, filters all room air through two HEPA filter banks, each of which is 99.97% effective. 2ER1:58. The Army scenario also assumes a lab in close proximity to the public, but the LLNL BSL-3 is one-half mile from the nearest public area. 1ER2:58. Finally, the Army scenario assumes lower wind speeds than are prevalent at LLNL, and higher wind would decrease airborne concentrations more quickly. Id. Based on this analysis, DOE concluded that even under a highly unlikely catastrophic accident, there would be no significant impact on public health or safety.

DOE's use of this MCE bounding analysis for the impacts of abnormal catastrophic events such as earthquakes and accidental plane crashes was upheld during TVC's challenge to the original EA. SER221-222; 1ER24. That question is thus not subject to relitigation. See Fund for Animals, Inc. v. Lujan, 962 F.2d 1391, 1399 (9th Cir. 1992) ("The doctrine of collateral estoppel bars the relitigation of issues

that were resolved in a prior proceeding."). On remand, DOE determined that the MCE release scenario was also appropriate for bounding the impacts of a pathogen release resulting from a breach of facility containment caused by a direct terrorist attack—such as bombing or suicide plane crash.

Contrary to TVC's assertion, DOE's use of the accident-based MCE to bound the impacts of an intentional terrorist attack is reasonable and supported by DOE's NEPA guidance. DOE's Memorandum on the "Need to Consider Intentional Destructive Acts in NEPA Documents," explains that an accident based scenario "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 (e.g. fires, explosions, drops, punctures, aircraft crashes)." 2ER19:2. Here DOE correctly observed that the "physical initiating events or forces," of an accidental plane crash were similar to those of an intentional plane crash. The agency then reasonably concluded that since its MCE scenario was bounding of the impacts of a release caused by an accidental airplane crash, it was also bounding of the impacts of a release cause by a purposeful plane crash or other purposeful events with similar destructive forces. 2ER1:62

TVC also errs in asserting that DOE violated its guidance on consideration of intentional destructive acts by failing to "explicitly consider whether the accident scenarios are truly bounding of intentional destructive acts." Br. 39-40. Not only is the guidance document not itself legally enforceable, Western Radio Serv. v. Espy, 79

F.3d 896, 901 (9th Cir. 1996), but the REA does contain an extensive analysis of whether its MCE is truly bounding of a breach caused by a terrorist attack. DOE explains in the REA that numerous factors serve to limit the consequences of a breach event. 2ER1:62-63. First, routine lab operations are conducted within closed biosafety cabinets with their own HEPA filtration, and use only very limited quantities of biological agents—usually only enough to begin cultures in a petri dish. 2ER1:62. Material samples are typically handled in a liquid or solid medium, so that if spilled, the risk of aerosolization would be negligible. When not in use, organisms are stored in 2 milliliter ("ml") sealed plastic vials and locked in -80° C freezers in accordance with LLNL and Federal requirements. 2ER1:98. Thus, for a significant quantity of a pathogen to be released, the lab itself, the freezers, and the individual vials would all have to be breached, and frozen material would have to be converted to a dispersible form. 2ER1:96-100. Further, if the lab structure were breached and materials in a dispersible form released, the negative air pressure in the building means that air would be drawn *into* the building and through the HEPA filtration system instead of inside air escaping unfiltered. 1ER3:3. The REA also explains that the fire resulting from an airplane crash or explosive device of the magnitude necessary to breach containment would itself kill BLS-3 organisms quickly.[3] 2ER1:62. Finally, in the event that a bioagent is released, microorganisms are generally rendered innocuous by

[3] For example, anthrax spores are sterilized in 30 seconds at 200° C, while the flame temperature for gasoline in an "open pool" fire is 1,026° C. 2ER1:98.

exposure to outside conditions, in particular exposure to sunlight and dehydration. Id.

Based on these factors, DOE concluded that its accident-based MCE scenario was truly bounding of the impacts of a facility breach caused by a intentional terrorist act. Id.[4] This conclusion is reasonable and should be upheld.

Finally, TVC attempts to portray the bounding analysis as inconsistent with a discussion of "intelligent initiators" in a DOE "Emergency Management Guide." Br. 40. The cited guide, however, is not directed at NEPA compliance but instead provides "suggested nonmandatory approaches" for completing an internal DOE hazard survey process. 1ER11; SER29. Even if the Guide had any relevance to NEPA, or was legally binding, it does not undermine DOE's use of a bounding analysis. To the contrary, the Guide specifies:

> In many cases, malevolent event scenarios will produce releases and consequences similar to those that could be caused by accidental, natural phenomena, or other external initiating events. Identifying a malevolent event as a potential initiator does not necessarily mean that a separate detailed analysis of that scenario is needed.

SER30.

---

[4] DOE's use of the bounding analysis is also supported by DOE's "Guidance on Accident Analyses under NEPA," which suggests that a bounding analysis may be appropriate in circumstances –such as the instant case– where there is "analytical uncertainty," and specifically recommends use of an accident scenario to bound the impacts of a terrorist attack on the transportation of nuclear waste. SER190; SER 207.

In sum, DOE concluded that the chance of a terrorist attack resulting in a breach of facility containment and the release of a pathogen was exceedingly remote. Assuming such a breach, however, DOE concluded that the resulting release would fall within the bounds of the existing MCE scenario, and would not have a significant impact on human health or the environment. This analysis is well-reasoned and should be upheld.

B. DOE properly evaluated the theft and release of a pathogen by an outside terrorist.

The second class of terrorist act DOE considered was the theft and release of a pathogen by a terrorist. 2ER1:65. The REA explains that the types of pathogens potentially of interest to terrorists are widely available from sources other than the LLNL BSL-3 lab. Not only do hundreds of BSL-3 facilities in the United States regularly handle and store these substances, but many are available from common environmental sources. 2ER1:66.[5] Thus, a terrorist seeking such materials would be able to find them in any of hundreds of BSL-3 labs nationwide that do not have the mandated safeguards and security infrastructure of LLNL, or from unguarded natural sources.[6] 2ER1:66. Based on the wide availability of such materials, DOE concluded

---

[5] See 2ER1:65 (describing the environmental sources of the organisms that cause anthrax, Valley Fever, Hantavirus, Plague and Rabbit Fever).

[6] TVC claims to have submitted expert testimony refuting DOE's assertion that bioagents are readily available in nature. Br. 42 n.7. The cited testimony, however, is not properly before the Court. The cited declaration was submitted to the district court in support of TVC's motion for a preliminary injunction. 1ER22. TVC has

that the proposed facility at LLNL would not have a significant impact on the "avenues already available to a terrorist for obtaining pathogenic materials or measurably increase the likelihood of this type of malicious act." Id. In other words, when measured against a background in which pathogenic organisms are available in hundreds of locations, the addition of a single well-guarded facility at LLNL does not significantly alter the *status quo*. Where the proposed action does not significantly alter the *status quo*, it does not have a significant impact under NEPA. Burbank Anti-Noise Group v. Goldschmidt, 623 F.2d 115, 116 (9th Cir.1980) (holding that an EIS is not required when "the proposed federal action will effect no change in the *status quo*.").

TVC maintains that DOE was required to restrict its consideration, pursuant to 40 C.F.R. § 1508.27(a), to the risk of a terrorist theft and release event "in the context of the Livermore locale." Br. 41-42. While 40 C.F.R. § 1508.27(a) indicates that site-specific actions are generally evaluated in the context of the project locale, nothing in the regulation limits DOE's discretion to determine that a different scale of analysis is appropriate for a particular impact. See Nat'l Parks & Cons. Ass'n. v. Babbitt, 241

---

not appealed the denial of its motion for a preliminary injunction, and the records on which that motion was adjudicated are not before this Court. Extra-record declaration testimony is not admissible on summary judgment absent an affirmative demonstration that it falls within an exception to the record review rules. See infra at 50. TVC made no such demonstration in the district court, and does not attempt to make one here. This extra-record document should be disregarded by the Court. TVC also includes in its Excerpts of Record two other declarations from preliminary injunction proceedings that were not admitted by the district court on summary judgment. See 1ER21, 23. They too should be disregarded by this Court.

F.3d 722, 731 (9th Cir. 2001) ("Context simply delimits the scope of the agency's action."). The case law is clear, in fact, that an "agency has the discretion to determine the physical scope used for measuring environmental impacts" so long as the scope of analysis is reasonable. Idaho Sporting Cong. v. Rittenhouse, 305 F.3d 957, 973 (9th Cir. 2002) (citing Kleppe v. Sierra Club, 427 U.S. 390, 414 (1976)). The "identification of the geographic area" within which a project's impacts on environmental resources may occur "is a task assigned to the special competency of the appropriate agencies." Kleppe, 427 U.S. at 414.

Here, DOE's determination to treat the threat of terrorist theft and subsequent release of a pathogen as a national one not limited to the Livermore area is reasonable. The record does not show any meaningful difference between the materials present at the LLNL BSL-3 lab and those present at hundreds of other BSL-3 facilities. Nor does it show any terrorist presence particular to the Livermore area that would suggest the LLNL BSL-3 lab should be considered under unique threat of attack. Nor does it show that a terrorist is more likely to release a pathogen near the location where it was stolen than to transport and release the pathogen elsewhere. And while TVC disagrees with the scope of analysis chosen by DOE, the question of whether a terrorist would prefer to attempt to steal pathogens from a heavily guarded federal facility or from any of the hundreds of relatively unguarded BSL-3 facilities nationwide, is one DOE is entitled to answer based on its own biosecurity expertise. Marsh v. Oregon Natural Res. Council, 490 U.S. 360, 377 (1989). Lands Council v.

McNair, 537 F.3d at 993 ("[O]ur law . . . requires us to defer to an agency's determination in an area involving a 'high level of technical expertise.'").[7]

DOE's determination that the impacts of the theft and release of a pathogen by an outside terrorist were best considered in a nation-wide context was a reasonable exercise of the agency's expertise, and should be upheld by this Court.

C. DOE properly evaluated the theft and release of a pathogen by an LLNL insider.

The third terrorism scenario considered by DOE was the threat of the theft and release of a pathogen by an LLNL employee. 2ER1:66. TVC faults DOE for not developing an "empirical" model of a pathogen release under this scenario, and for not discussing other "potential sabotage actions." Br. at 44-47. These criticisms fail.

While DOE did not utilize the modeling methodology preferred by TVC, the record shows that DOE took a hard look at the threat of an insider theft and complied with NEPA by providing a "convincing statement" of why that threat did not require preparation of an EIS. Ocean Advocates v. U.S. Army Corps. of Eng'rs, 402 F.3d 846, 864 (9th Cir. 2005).

---

[7] TVC's passing claim that DOE's analysis of the terrorist theft scenario is compromised by concerns about security at LLNL fails. Br. 43. The GAO report cited by TVC examines the results of a 2008 Security Assessment at LLNL. 2ER18:2. As discussed in detail below, see infra 43-46, while the Security Assessment found security concerns at LLNL, it specifically concluded the security features of the BSL-3 lab are "robust and significantly exceed the requirements" of applicable law. 2ER8:6. Nothing in the Security Assessment or the subsequent GAO Report suggests that DOE was arbitrary or capricious in evaluating whether the threat of a terrorist theft and release of a pathogen was a significant impact requiring an EIS.

As explained in the REA, DOE began its analysis by addressing the probability that an insider with access to select agents and toxins would have the motive to commit such as attack. 2ER1:68 First, individuals with access to these materials must pass through multiple screenings, including the Department of Justice Security Risk Assessment, authorization by the Department of Health and Human Services, and registration with the CDC. Id. LLNL also maintains its own "Select Agent Human Reliability Program" ("SAHRP"), which selects, trains and monitors all individuals whose work requires access to select agents. 2ER1:68. Finally, the likelihood of insider theft is lessened by the scale of operations at the facility: generally fewer than 10 individuals have access to select agents in the BSL-3 lab. Id. Given the "human reliability programs, security procedures, and management controls at the facility and the laboratory," and the small number of individuals with access to pathogens, DOE reasonably concluded that the theft of pathogenic materials by an insider from LLNL "is not expected to occur." 2ER1:69.

Assuming an insider with access to, and motive to release, a pathogen, DOE next evaluated the most reasonably foreseeable theft scenario. The REA explains that the most reasonably foreseeable scenario would be for an insider to attempt to covertly remove a small sample of a pathogen that would require additional growth and preparation prior to dispersal. 2ER1:100. This assumption is based on the fact that direct removal of a large quantity of material would be quickly noticed because material inventories are regularly audited, and because the LLNL BSL-3 lab does not

contain large amounts of "ready-to-use aerosolized pathogens," but instead stores material in frozen form in 2 ml vials. 2ER1:100. Under such circumstances, the thief would have to successfully steal, culture, produce, store, transport and disperse a pathogen all while maintaining its virulence. 2ER1:66. The REA notes that "[a]ccomplishing these requirements was difficult even for long-term and well-funded programs in the former Soviet Union and other state-run programs." 2ER1:66.[8] On the basis of the extremely low probability of an insider with a motive to release a pathogen and the extremely low likelihood that such a theft would result in significant impacts, DOE reasonably concluded that the threat of an insider theft and release did not require preparation of an EIS.[9]

---

[8] TVC's unsupported claim that the 2001 anthrax mailing attacks were perpetrated by an insider who successfully obtained a pathogen from a laboratory where he worked, does not render DOE's analysis arbitrary. Br. 45. The record makes clear that LLNL's security planning takes this possibility into account, and that LLNL has instituted human reliability programs to prevent individuals who might be security threats from gaining access to the BSL-3 lab. 2ER1:68, 99-100. There is no evidence in the record to suggest that comparable program was in place at the facility allegedly involved in the 2001 anthrax mailing attacks.

[9] The fact that DOE acknowledged that "[t]aken to extremes, one can even postulate scenarios with catastrophic implications," 2ER1:67, does not mean DOE erred in determining that the threat of an insider theft did not require preparation of an EIS. See Br. 46. DOE was obligated to, and did, disclose the most reasonably foreseeable insider theft scenario. NEPA does not require that DOE dream-up the worst-case insider theft scenario and speculate over those impacts. Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 356 (1989) (upholding CEQ's decision to remove a "worst case analysis" requirement from the NEPA regulations, and noting that by "requiring that an EIS focus on reasonably foreseeable impacts, the new regulation 'will generate information and discussion on those consequences of greatest concern to the public and of greatest relevance to the agency's decision,'

TVC faults DOE for not developing an "actual empirical" model of the impacts of release as part of its discussion of an insider theft event. Br. 44, 46. DOE is not, however, obligated to use any particular type of methodology in its evaluation. This Court directed DOE to "consider whether the threat of terrorist activity necessitates the preparation of an [EIS]," and emphasized that in considering that question, there "'remain open to the agency a wide variety of actions it may take on remand and we do not prejudge those alternatives.'" 1ER24:4 (quoting San Luis Obispo Mothers for Peace v. NRC, 449 F.3d 1016, 1035 (9th Cir. 2006) (brackets and ellipsis omitted).

DOE's determination not to develop an empirical model of a pathogen release perpetrated by an insider was reasonable, because such modeling was not necessary to the determination that an EIS was not required. The through explanation of the extremely unlikely convergence of events that would have to take place for an individual to steal and successfully release a pathogen, and of the human reliability programs, security procedures, and management controls in place to prevent such an event provide the necessary "convincing statement" of reasons as to why the threat of an insider theft and release did not require an EIS. Ocean Advocates v. U.S. Army Corps of Eng'rs, 402 F.3d at 864.

---

rather than distorting the decisionmaking process by overemphasizing highly speculative harms") (citations omitted).

This approach comports with NEPA, which recognizes that agencies have discretion to choose appropriate methodologies, as well as with this Court's remand, which explicitly emphasized DOE's discretion to determine the appropriate mode of analysis. See e.g., Lands Council v. McNair, 537 F.3d at 993 (emphasizing that courts defer to an agency's determinations in areas involving a "high level of technical expertise."); id. at 1003 ('NEPA does not require us to 'decide whether an [EIS] is based on the best scientific methodology available.'") (citations omitted).

Contrary to TVC's claim, the discussion of an insider theft event in the Army's BDRP EIS supports DOE's conclusions in the REA. Br. 45. There, the Army concluded—as does DOE here—that the "possibility of a scenario of this type occurring or resulting in significant harm are very remote." 2ER21:32. See also 2ER21:31 (finding "infinitesimally small probability" of an insider having necessary knowledge, access, and motive). The Army concluded that "even a purposeful release of material outside of a containment laboratory is unlikely to result in human or environmental exposures beyond a small and finite area, and then for only a short period of time." SER155.

TVC also faults DOE for not analyzing other attack scenarios, such as sabotage of the lab autoclaves, deliberate release of an infected animal, or deliberate self-infection. Br. 44-45. The district court correctly found that TVC had forfeited its right to pursue this claim by failing to raise it during the public comment period.

1ER3:10. The same result should apply on appeal.[10] See Dep't of Transp. v. Pub. Citizen, 541 U.S. at 764-65 (holding claims not raised to the agency during public comment period are forfeit); North Idaho Comty. Action Network v. U.S. Dept. of Transp., 545 F.3d 1147, 1156 n.2 (9th Cir. 2008) (holding that where plaintiffs' preferred "alternative was not raised and identified until . . . well after the notice and comment periods . . . closed, any objection to the failure to consider that alternative has been waived").

If this Court elects to consider TVC's belated allegations, the record shows that DOE did not err in omitting discussion of such scenarios from the REA. While it is possible to conjure limitless attack scenarios, NEPA does not obligate an agency to consider "every alternative device and thought conceivable by the mind of man." Vermont Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 551 (1978). See also San Luis Obispo Mothers for Peace v. NRC, 635 F.3d 1109, 1118 (9th Cir. 2011) (rejecting argument that NRC was required to consider "a group of credible attacks"). Here DOE developed a reasoned analysis of terrorism that covers a reasonable range of threats. TVC presents no evidence that evaluating additional scenarios would add meaningfully to the disclosure of impacts. Indeed, DOE's exclusion of autoclave damage, release of an infected animal and deliberate self-infection from the REA is

[10] TVC has not appealed from, or even acknowledged, the district court's determination that the claim was waived.

supported by the Army BDRP EIS, which identifies all three scenarios, but quickly rejects the possibility that they pose any significant environmental risk. 2ER21:28-30.

In sum, DOE took a hard look at the possibility of insider theft and provided a convincing statement of reasons that possibility did not require preparation of an EIS. The fact that DOE did not adopt TVC's preferred methodology does not render DOE's analysis arbitrary or capricious. The district court's grant of summary judgment on this issue should be affirmed.

D. DOE's evaluation of the threat of terrorist attack is supported by this Court's decision in San Luis Obispo Mothers for Peace.

In San Luis Obispo Mothers for Peace v. NRC, 449 F.3d 1016, 1035 (9th Cir. 2006)(Mothers for Peace I) this Court remanded an EA prepared by the NRC for failing to consider the possible impacts of terrorist attack. Mothers for Peace I, in turn, became the basis for this Court's remand of the EA for the BSL-3 lab. 1ER24. The terrorism analysis prepared by NRC on remand was recently reviewed and upheld by this Court, San Luis Obispo Mothers for Peace v. NRC, 635 1109 (9th Cir. 2011) ("Mothers for Peace II"), and provides persuasive support for the analysis prepared by DOE for the LLNL BSL-3 lab.

In approaching the evaluation of the threat of terrorist attacks on remand, NRC, like DOE, first considered site-specific factors which would make the probability of a successful terrorist attack very low. Compare Mothers for Peace II, 635 F.3d at 1113 (resilient design of spent fuel casks, location and low profile of

building) with 2ER1:63-64 (discussing security measures to counter direct attacks at BSL-3). Both agencies then assumed a successful attack and used a maximum reasonably foreseeable event to bound the impacts of an attack. Compare Mothers for Peace II, 635 F.3d at 1113 (projecting radiation dose released by "most severe plausible threat") with 2ER1:54-58, 62 (projecting pathogen release from "Maximum Credible Event"). Both agencies concluded the threat of terrorist attack would not have a significant impact, and complied with the terms of their remands by completing a supplemental EA rather than completing an EIS.

TVC urges that the terrorist threat analysis upheld in Mothers for Peace II is more credible than that used by DOE because NRC's selection of a plausible threat was informed by "a level of additional analysis . . . not done by DOE," and cites to NRC's consideration of a "generic analysis of plausible threat[s]" and interactions with "law enforcement and intelligence communities." Br. 33. To the contrary, DOE's threat scenario is also supported by "a level of additional analysis." Indeed, in contrast to the generic analysis used by NRC, DOE prepared a site-specific Biological Risk and Threat Assessment ("BRTA") for the LLNL BSL-3 lab. The BRTA includes "in-depth analysis" of the potential vulnerability of the facility to terrorist attacks and security countermeasures to such threats, and informs the discussion of terrorist threats presented in the REA.[11] 2ER1:64.

[11] TVC objects in passing to DOE's withholding of the BRTA, which is classified, from the administrative record. TVC made no such objection in the district

The NRC's approach to the evaluation of terrorist threats under NEPA is analogous in important respects to that conducted by DOE, and this Court's decision in Mothers for Peace II provides persuasive authority for upholding the analysis prepared by DOE in this case.

D. DOE's use of *Coxiella burnetti* as a representative pathogen was not arbitrary or capricious.

TVC claims DOE erred in not analyzing releases of "biotoxins, viruses or genetically modified organisms." Br. 47. The claim that DOE should have considered the release of other organisms was adjudicated in DOE's favor in TVC's first challenge to the BSL-3 facility, and should not be relitigated now. SER222; 1ER24. Should this Court choose to revisit this issue, the record supports DOE's use of *Coxiella burnetti* as a representative pathogen in its release scenario.

DOE explained in the REA that it used *Coxiella burnetti,* a rickettsial microorganism that causes Q fever, as a "representative of all types of BSL-1, BSL-2 and BSL-3 laboratory microorganisms (bacteria, rickettsia, viruses, fungi, parasites, and prions) because it is highly durable, infectious, and transmissible, and has excellent environmental survivability." 2ER1:56. TVC presents no evidence to suggest that DOE erred in using *Coxiella burnitti* as a representative pathogen.

---

court, and as this Court noted in Mothers for Peace II, NEPA does not obligate federal agencies to disclose classified terrorist attack scenarios. 635 F.3d at 1116-17. (citing Weinberger v. Catholic Action of Hawaii, 454 U.S. 139 (1981)).

The fact that the Army EIS cited by TVC did consider releases for three separate pathogens, does not render DOE's analysis arbitrary. Indeed, the Army found that the separate analysis of additional pathogens did not alter its conclusions. 2ER21:16 ("The three MCEs theorized in this section indicate no risk to the environment, and only an insignificant risk to the immunized work force."). DOE's use of *Coxiella burnetti* as a representative pathogen in its release scenario was not arbitrary or capricious and should be upheld.

II. THE REA PROPERLY DISCUSSES AND INFORMS THE PUBLIC OF THE INFORMATION NEEDED TO CONSIDER AND COMMENT ON THE ENVIRONMENTAL IMPACTS OF THE BSL-3 LAB.

TVC's second claim is that DOE deprived the public of information necessary to comment on the REA by not including in the REA sufficient detail about a 2005 incident involving shipments of anthrax, or a discussion of a "restricted" experiment conducted without necessary CDC-NIH approval.[12] These claims fail. First, while

[12] In the district court TVC alleged that DOE purposefully withheld this information in a bad faith effort to frustrate public comment. 1ER3:11. The district court rejected that claim, finding the "mere fact that DOE possessed certain information that was not included in the EA does not ipso facto establish bad faith." 1ER3:12. Despite an occasional statement intimating improper motive, see, e.g., Br. 23 ("DOE deceptively downplayed" the incident); id. at 26 ("hidden" information), id. at 49 n.10 (DOE "withheld" information from the Court), TVC appears to have abandoned its bad faith claim and on appeal is proceeding under the theory that the omission of information from the REA was arbitrary and capricious. Br. 31-32. We respond to TVC's arbitrary and capricious claim above. To the extent TVC continues to allege that DOE acted in bad faith, it has presented no evidence sufficient to overcome the well-established presumption that government agencies "act properly and according to law." FCC v. Schreiber, 381 U.S. 279, 296 (1965). See also Citizens

the REA does not contain all the detail demanded by TVC, it contains a discussion of the 2005 shipping incident that is more than sufficient to satisfy the public disclosure obligations of NEPA. Second, TVC's claim regarding the CDC-NIH restricted experiment is not properly before this Court. This claim was dismissed by the district court because it was not included in TVC's complaint. SER14. TVC has not appealed that decision. If this Court does consider TVC's claim, DOE's decision not to include a discussion of the restricted experiment in the REA was reasonable as it does not provide information relevant to the evaluation of environmental impacts in the REA.

The purpose of an EA under NEPA is not to amass and disclose all possible details regarding a proposal, but to create a "concise public document" that serves to "[b]riefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact." 40 C.F.R. § 1508.9. See also League of Wilderness Defenders Blue Mountains Biodiversity Project v. Allen, 615 F.3d 1122, 1136 (9th Cir. 2010) (NEPA review "must concentrate on the issues that are truly significant to the action . . ., rather than amassing needless detail.")(quoting 40 C.F.R. § 1500.1(b)); Northwest Envtl. Advocates v. Nat'l Marine Fisheries Serv., 460 F.3d 1125, 1139 (9th Cir. 2006)

---

to Preserve Overton Park v. Volpe, 401 U.S. 402, 415 (1971) (federal agencies are entitled to a "presumption of regularity"). Any claim of bad faith should therefore be rejected.

("NEPA requires not that an agency engage in the most exhaustive environmental analysis theoretically possible, but that it take a 'hard look' at relevant factors.").[13] With regard to public involvement, an EA must "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 v. U.S. Army Corps of Eng'rs, 524 F.3d 938, 953 (9th Cir. 2008).

A. DOE's discussion of a 2005 shipping incident involving anthrax in the REA was not arbitrary or capricious.

In 2005, a professor at Louisiana State University who owned a collection of anthrax samples being used for research at LLNL, contracted with a former LLNL employee ("the Visitor") to return to LLNL as a visitor to package and ship the collection to two private labs: the Midwest Research Institute ("MRI") and the American Type Culture Collection/Biodefense and Emerging Infections Research Repository ("ATCC/BEI"). 2ER12:3. In addition to being a former employee of LLNL, the Visitor had been the principal investigator of the anthrax collection at LSU. Id.

---

[13] See also CEQ 40 Questions, "36a. Environmental Assessments (EA). How long and detailed must an environmental assessment (EA) be? . . . Since the EA is a concise document, it should not contain long descriptions or detailed data which the agency may have gathered. Rather, it should contain a brief discussion of the need for the proposal, alternatives to the proposal, the environmental impacts of the proposed action and alternatives, and a list of agencies and persons consulted." 46 Fed. Reg. 18026, 18037 (Mar. 17, 1981).

The Visitor returned to LLNL, and on August 25, 2005, packaged and shipped to MRI 1,065 samples from the collection. This shipment arrived without incident. 2ER12:4. On September 13, 2005, the Visitor shipped 3,108 samples to ATCC/BEI. 2ER12:5. This shipment arrived intact, but ATCC/BEI noted concerns with the packaging and discrepancies between the shipment and the inventory. 2ER12:6. On September 14, 2005, the Visitor sent a second shipment of 1,025 vials to MRI. 2ER12:5. In unpacking the vials, MRI employees discovered improperly closed vials and were exposed to anthrax that had leaked into the interior packaging. 2ER12:5-6. The MRI employees reported "nothing was detected on the outside of the shipping container and therefore [the leak was] 'not a public health issue.'" 2ER12:6. The MRI employees obtained medical treatment but never became ill. 2ER12:5.

As a result of the incident, on September 22, 2005, the CDC suspended all transfers of select agents from LLNL. SER148. LLNL voluntarily suspended work with select agents pending an investigation and established an Incident Analysis Committee.[14] SER31, SER32.

In December 2005, the Incident Analysis Committee completed a comprehensive report, which—while identifying several procedural deficiencies in

[14] TVC's claim that LLNL "failed to comply" with its "stand-down order," Br. 25, is belied by the record, which makes clear that select agent work did cease under the stand-down order. SER31, SER32. The documents cited by TVC do not suggest select agent work continued, but indicate that DOE was critical of LLNL managers for not enforcing the stand-down by collecting select agent access keys. 2ER14, 15.

need of correction—traced many of the causes of the incident to the unique role of the Visitor. 2ER12. The report found that because the Visitor was both a former employee and the prior principal investigator of the collection, several LLNL employees inappropriately deferred to Visitors' experience and perceived expertise rather than following proper procedures.[15]

In response to the Incident Analysis Report, LLNL implemented numerous corrective actions, including "expansion of the Select Agent Security Plan, additional training related to packaging and shipping regulations, clarifying roles and responsibilities, a new bio-goverance model, and an improved inventory system." 2ER1:59-60. In February 2006, the DOT inspected LLNL's select agent program and concluded that the procedures were "fine," and that the incident resulted from "an unusual event." SER34. Shortly thereafter, the CDC noted with approval the changes implemented by LLNL and allowed the resumption of the transfer of select agents. SER149. On April 18, 2006, the DOE Livermore Site Office authorized resumption of select agent work at LLNL. SER35. The record shows that a

[15] See, e.g., SER61 (The LLNL Responsible Official ("RO") failed to follow proper shipment procedures and relied on the Visitor's experience, certification and knowledge of the regulations.); SER56 ("RO forgot that the Visitor was off [the CDC] permit list and also forgot to reinstate the Visitor"); and SER57("Because the Visitor had been an LLNL Employee, was the name of record on some of the documentation, and was also trained in the safety and health procedures for select agents, some of the parties assumed incorrectly that the Visitor could handle select agents without further review.").

subsequent DOT inspection of the LLNL Select Agent Program found no violations. SER89-93.

In the original EA, DOE carefully considered the impacts of shipping infectious materials to and from the BSL-3 lab. DOE found that there are approximately 800,000 daily shipments in the United States of hazardous materials, including approximately 200 tons of infectious medical waste. 2ER1:59. Despite the amount of hazardous material shipped daily, the risk of fatality from hazardous waste transportation incidents is less than .11 per million shipments, and the specific risk from infectious substance incidents is too low to be ranked. Id. DOE thus concluded that the addition of milliliter-quantity samples from LLNL to the hundreds of tons of infectious material already safely shipped throughout the United States every day, would not have a significant impact on the risk of transportation accidents. 2ER1:60. DOE's analysis of the potential impacts of transportation and shipping of infectious materials was upheld by this Court during TVC's first appeal. SER219-220; 1ER24.

In the draft REA, DOE added a brief discussion the 2005 shipping incident, but found that more detailed discussion was not warranted, because when considered against the decades-long history of safe shipments of hundreds of tons of infectious materials, "the incident and the circumstances leading up to it did not add significant information regarding potential environmental impacts relating to transportation activities associated with the operation of the BSL-3 lab or challenge the conclusions

of the document regarding transportation activities." 1ER17:2-3. The draft REA did not identify anthrax as the agent involved in the incident because the DOE Classification Guide for Chemical/Biological Defense Information directs that public documents should not link an agent which can be used for a biological weapon with a specified facility within a site. 1ER17:3

Once TVC brought its concern about the 2005 shipping incident to DOE's attention through comments on the draft REA, DOE included a more detailed discussion in the final REA with the hope of helping the public "better understand why the incident did not add significant information and did not challenge the conclusions of the document." 1ER17:4. At this point, given the widespread public knowledge that the incident involved anthrax, DOE was also able to identify anthrax in the final REA. Id.[16]

Considered "in the totality of the circumstances," DOE's discussion of the shipping incident was reasonable, and "provide[d] the public with sufficient environmental information . . . to weigh in with their views and thus inform the agency decision-making process." Bering Strait, 524 F.3d at 953. The shipping

[16] TVC emphasizes the district court's observation, in the preliminary injunction context, that information on the shipping incident was not disclosed until after the close of the public comment period and the termination of the prior litigation. Br. 54. TVC fails to note that on summary judgment, after full consideration of the record, the district court reversed this preliminary finding, and concluded that "DOE's decision regarding the handling of information regarding the shipping incident was reasonable and justified." SER16.

analysis in the REA is based on the safe history of the transportation of *thousands* of shipments annually of hundreds of *tons* of infectious materials. 2ER1:59. DOE reasonably concluded that a single transportation incident, in which nobody was injured and there was no public release, did not alter the agency's assessment of the potential impacts of the proposed facility, and that adding additional detail to the discussion of the incident would not have added signification information regarding potential environmental impacts relating to the operation of the BSL-3 lab. 1ER17:2-3.

TVC faults DOE for failing to disclose "important details" of the anthrax shipping incident, but fails to specify how the inclusion of still further detail would have altered the analysis. The mandate of federal agencies under NEPA—particularly when preparing an EA—is not to amass all possible detail, but to create a "concise public document" that serves to "[b]riefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact." 40 C.F.R. § 1508.9. While DOE's discussion of the 2005 shipping incident did not contain all of the detail desired by TVC, it was legally sufficient under NEPA and should be upheld.[17]

---

[17] TVC makes a one sentence assertion that DOE violated NEPA by beginning operations at the BSL-3 lab upon issuance of the FONSI and REA, instead of taking additional public comment. Br. 51. This claim was considered and rejected by the district court. See SER18-20. TVC's passing reference—without "specifically and distinctly" arguing its claim—is inadequate to pursue the issue on appeal. Christian Legal Soc'y v. Wu, 626 F.3d 483, 487 (9th Cir. 2010). See also id. (noting the Court

B. DOE's determination not to include a discussion of a 2005 restricted experiment in the REA was not arbitrary or capricious.

TVC alleges that DOE erred in not including in the REA a discussion of a "restricted" experiment which was conducted at LLNL without necessary CDC approval. This claim has not been properly raised on appeal, and should not be considered by this Court. Should the Court consider the claim, the record demonstrates DOE properly determined that the experiment need not be discussed in the REA.

The district court declined to consider TVC's restricted experiment claim because it was not pled in TVC's complaint. 1ER3:14. TVC did not address that dispositive ruling in its opening brief, and thus has waived its right to challenge it. See Smith v. Marsh, 194 F.3d 1045, 1052 (9th Cir.1999) ("[O]n appeal, arguments not raised by a party in its opening brief are deemed waived.").

TVC's waiver notwithstanding, the district court's ruling is correct.[18] TVC's amended complaint does not mention the restricted experiment claim, and thus failed to "give the defendant fair notice of what the plaintiff's claim is and grounds upon which it rests." Swierkiewicz v. Sorema N.A., 534 U.S. 506, 512 (2002) (citation

---

will not consider matters only "argued in passing, or that were bare assertions with no supporting argument") (quotations and citations omitted).

[18] Had TVC properly appealed the district court's ruling, this Court's review would be *de novo*. See Pickern v. Pier 1 Imports, 457 F.3d 963, 969 (9th Cir. 2006) (upholding district court's determination not to consider during summary judgment an argument plaintiff did not include in its complaint).

omitted). TVC's claim is no more appropriate on appeal than it was in the district court, and the district court's ruling should be affirmed.

If the Court chooses to consider TVC's restricted experiment claim, it is clear that DOE was not arbitrary or capricious in determining not to address the incident in the REA. As noted above, the purpose of an EA is not to catalog all events with any relationship to the project. Rather, it is to take a hard look at relevant materials and "[b]riefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact." 40 C.F.R. § 1508.9. Here, the restricted experiment incident provides no information relevant to the evaluation of environmental impacts in the REA.

In 2003, researchers at LLNL began a study of *Yersina pestis* (the bacteria that causes plague) to determine which of the organism's genes cause virulence. SER23 Before commencing their studies, the researchers received approval from the Laboratory's Institutional Biosafety Committee, which is composed of approximately a dozen members, including three from the local community. Id. Part of the experiment involved creating a transient drug resistance to the antibiotic Chloramphenicol. SER24. Department of Health and Human Services and CDC-NIH regulations classify as "restricted," and require prior approval of, any experiment that deliberately transfers drug resistance to microorganisms if the acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. Id. In this case, the LLNL IBC concluded that the research

did not fall within the "restricted" experiment category because Chloramphenicol is not used in the United States or other developed nations to treat illness associated with *Yersinia pestis* due to its harmful side effects. Id.

In 2005, during a regular CDC inspection, LLNL scientists presented summaries of their work to CDC officials. Id. The CDC disagreed with LLNL's classification of the experiment because under rare circumstances Chloramphenicol is still used to treat *Yersinia pestis*. SER25. CDC directed LLNL to destroy all samples containing Chloramphenicol resistence. Id. LLNL complied, and the IBC now sends all proposed experiments that may involve the introduction of any antibiotic resistance to CDC-NIH for approval. Id. The CDC ultimately concluded no penalty was warranted. Id.

The restricted experiment incident reflects nothing more than a reasoned scientific disagreement between the CDC and LLNL's Institutional Biosafety Committee. Inclusion of a discussion of the experiment would not have materially altered the evaluation of potential environmental impacts set forth in the REA, and its exclusion from the document did not deprive the public of "sufficient environmental information . . . to weigh in with their views and thus inform the agency decision-making process." Bering Strait, 524 F.3d at 953.

The REA properly informed the public, and should be upheld.

III. DOE PROPERLY DETERMINED NOT TO SUPPLEMENT THE REA.

TVC alleges DOE violated NEPA by failing to supplement the REA to address the results of a Security Assessment conducted at LLNL by DOE's Health, Safety and Security ("HHS") Office of Independent Oversight ("OIO") in March and April 2008. The Security Assessment, which included a mock attack on the "Superblock," where special nuclear materials are stored, identified several deficiencies in performance of the protective force. SER87. In response, DOE complied with NEPA by preparing a supplement report which concluded that the Security Assessment did not constitute significant information requiring supplementation of the REA.[19] This determination should be upheld.

NEPA imposes a duty to supplement NEPA analyses in response to "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). A supplemental EIS or EA is not required "every time new information comes to light after the EIS is finalized. To require otherwise would render agency decisionmaking intractable, always awaiting updated information." Marsh, 490 U.S. at 373-74. To

[19] TVC also faults DOE for not "supplementing" the REA with information on the anthrax shipping incident and restricted experiment. Those incidents, however, occurred in 2005, well before issuance of the REA. They are thus properly addressed in TVC's allegation that the REA did not contain sufficient discussion of the incidents, see supra at 32-42, and not through a claim that DOE failed to supplement the REA with significant new information.

warrant supplementation, the new information or changed circumstances must present a "seriously different picture of the likely environmental harms stemming from the proposed project." Wisconsin v. Weinberger, 745 F.2d 412, 420 (7th Cir. 1984).

Federal agencies use a variety of "'non-NEPA' environmental evaluation procedures . . . for the purpose of determining whether new information or changed circumstances require preparation of a supplemental EA or EIS." Idaho Sporting Cong. v. Alexander, 222 F.3d 562, 566 (9th Cir. 2000). See also Marsh, 490 U.S. at 376 (holding that the question of whether new information requires a supplemental NEPA analysis "is a classic example of a factual dispute the resolution of which implicates substantial agency expertise").

In compliance with NEPA, in July 2008, DOE prepared a supplemental report to determine whether the Security Assessment constituted significant new information requiring supplementation of the REA. SER85-88. In its report, DOE carefully examined whether the deficiencies the Security Assessment identified in the performance of the LLNL protective force significantly altered the outcomes of any of the three terrorist attack scenarios developed in the REA.

With regard to scenario one—the threat of an outside terrorist attack breaching containment—the supplemental report found that the analysis in the REA "does not rely on the assumption of effective security, but instead, in evaluating environmental impacts, assumes that a terrorist attack succeeded and facility damage resulting in a

breach of containment occurs." SER86. The supplemental report concludes that "[b]ecause the effectiveness of the security force is not relied upon in reaching the conclusion that a terrorist attack resulting in a breach of containment will not result in significant impacts to the environment, the Security Report does not constitute significant new information that would require additional evaluation of Scenario I pursuant to [NEPA]." SER86.

With regard to scenario two—the covert theft and release of a pathogen by a terrorist—the supplemental report found that the REA's observation that "there are other, less secure facilities from which to obtain pathogenic materials than the LLNL BSL-3 facility remains accurate." SER88. In particular, the deficiencies with the protective force were primarily related to the Superblock and the protection of special nuclear materials. Id. With regard to the BSL-3 lab, the Security Assessment specifically noted that the security features of the BSL-3 lab are "robust and significantly exceed the requirements of [Public Law 107-188, Public Health Security and Bioterrorism Preparedness Response Act of 2002]." 2ER8:6. The supplemental report therefore concluded that with regard to scenario two, the Security Assessment "does not constitute significant new information requiring additional evaluation of this conclusion under NEPA." SER88.

Finally, with regard to scenario three—theft and release of a pathogen by an insider—the supplemental report found that the Security Assessment provided no basis to revisit the conclusions in the REA that insider theft was highly unlikely due to

the personnel security program, human reliability programs and management controls. SER88. In fact, the Security Assessment observed that LLNL's personnel security and human reliability programs were "effectively managed and meeting DOE expectations." Id. DOE concluded that the Security Assessment did not constitute significant new information requiring supplementation of the REA. SER88.[20]

Thus, DOE has considered the Security Assessment, and reached the reasoned determination that the report did not show a "seriously different picture of the likely environmental harms stemming from the proposed project" and a supplemental REA is not needed. Wisconsin v. Weinberger, 745 F.2d at 412.[21] This conclusion should be upheld on appeal.

IV. DOE PROPERLY CONCLUDED AN EIS WAS NOT REQUIRED.

TVC makes a cursory assertion that DOE was compelled, under the CEQ's significance factors, 40 C.F.R. § 1508.27, to prepare an EIS for the LLNL BSL-3. Br. 58. TVC's failure to argue this claim "specifically and distinctly" in its opening brief

---

[20] TVC also cites a 2008 GAO Report, but this Report was commissioned to review the Security Assessment and examine the factors contributing to the deficiencies found therein. 2ER18:3. It does not identify additional security concerns.

[21] Any significance the Security Assessment may have had has been overtaken by more recent events. In April 2009, the Office of Independent Oversight again conducted a security assessment, and found that "LLNL has made significant progress to address previously identified security deficiencies and to strengthen the overall effectiveness of the Lab's protection programs." SER95. Ordering preparation of a supplemental EA to address circumstances that have already been remedied would serve no purpose.

dictates that it should be deemed waived. Greenwood v. FAA, 28 F.3d 971, 977 (9th Cir. 1994). Should the Court consider this claim, the record demonstrates that DOE was not arbitrary or capricious in determining an EIS was not required for the BSL-3 lab.

CEQ regulations provide that among the factors an agency may consider when determining whether environmental impacts are significant, are: "the degree to which the proposed actions affects public health or safety[;]" "[t]he degree to which the effects on the human environment are likely to be highly controversial[;]" and "[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks." 40 C.F.R. § 1508.27(b)(2),(4),(5).

With regard to the effect on public health and safety, the record shows that DOE took a hard look, and—based on decades of safe operations of hundreds of CDC-registered BSL-3 labs, the U.S. Army's labs, and DOE's own microbiology labs—reached the reasonable conclusion that the LLNL BSL-3 facility will not significantly impact public health or safety. 2ER1:43-45. Indeed, with regard to a release caused by means other than terrorism, this Court has already upheld DOE's conclusion that such events will not have a significant impact on public health. SER212, 221-222; 1ER24. With regard to the risk of a release as a result of a terrorist act, DOE conducted a careful evaluation, and reached the reasonable conclusion that there would be no significant impact on public health. See supra at 14-29. That conclusion is well-reasoned and should be upheld.

Nor are the environmental impacts of LLNL BSL-3 sufficiently "controversial" to trigger the need to complete an EIS. An action is "controversial" if a "substantial dispute exists as to its size, nature, or effect." Cold Mountain v. Garber, 375 F.3d 884, 893 (9th Cir. 2004)(quotation and citation omitted). See, also, 40 C.F.R. § 1508.27(b)(4). Controversy does not exist simply because "some are highly agitated about, vigorously oppose, or have raised questions about the action." See Fund for Animals v. Williams, 246 F. Supp.2d 27, 45 (D.D.C. 2003). This Court has already upheld the district court's conclusion that the BSL-3 facility is not "highly controversial" as to its effects outside the context of terrorism. SER230-231; 1ER24. There is not a substantial dispute over the size, nature or effect of the project in light of the terrorism analysis. The agency took a hard look at multiple attack scenarios and conducted an analysis that comports with both common-sense and agency guidance, and reached a conclusion that is not arbitrary or capricious. See supra at 14-29.

With regard to whether the effects of the BSL-3 lab are "highly uncertain or involve unique and unknown risks," the record makes clear that the BSL-3 facility will conduct biological research that is not substantially different from the research being conducted at hundreds of other BSL-3 labs across the country. The risks of such research are well known and, as a result of regulations and procedures developed through decades of experience, are not significant. 2ER1:44-45.

DOE's determination not to prepare an EIS is not arbitrary or capricious and should be upheld by the Court.

V. THE DISTRICT COURT PROPERLY DENIED TVC'S MOTION TO SUPPLEMENT THE ADMINSTRATIVE RECORD.

TVC alleges that the district court erred in denying its motion to augment the administrative record with a report by the National Research Council of the National Academies of Science ("NRC") issued two years after publication of the REA. The district court denied TVC's motion for failure to comply with the local rules, and because the report proffered by TVC did not fall with the exceptions to record review. Neither determination was an abuse of discretion.

A. The district court's denial of TVC's motion for failure to comply with the local rules was not an abuse of discretion.

Conspicuously absent from TVC's opening brief is the fact that the district court denied their motion to augment the administrative record for failure to comply with the local rules. SER20. Denial of a motion for noncompliance with the local rules is well within the district court's discretion. Grove v. Wells Fargo Fin. California, Inc., 606 F.3d 577, 582 (9th Cir. 2010). On appeal, TVC makes no effort to justify its noncompliance or to demonstrate that this is one of the "rare cases" in which the Court of Appeals should "question the [district court's] exercise of discretion in connection with the application of local rules." United States v. Warren, 601 F.2d 471, 474 (9th Cir.1979) (per curiam). This Court should affirm the district

court's denial of TVC's motion to supplement the record for failure to comply with the local rules.

B. The district court properly concluded the NRC Report did not fall within the exceptions providing for supplementation of the record.

Even if the district court's denial of TVC's motion for failure to abide by the local rules constituted an abuse of discretion, its alternative holding that the NRC report did not fall within one of the exceptions to record review was correct.

Subject only to four narrow exceptions, judicial review of an agency decision under the APA is limited to the administrative record that existed before the agency at the time the decision was made. Camp v. Pitts, 411 U.S. 138, 142 (1973) ("the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court."). A reviewing court may consider extra-record materials in APA cases only: "(1) if necessary to determine 'whether the agency has considered all relevant factors and explained its decision,' (2) 'when the agency has relied on documents not in the record,' (3) 'when supplementing the record is necessary to explain technical terms or complex subject matter,'" or (4) "'when plaintiffs make a showing of agency bad faith.'" Inland Empire Pub. Lands Council v. Glickman, 88 F.3d 697, 703-04 (9th Cir. 1996) (quoting Friends of the Payette v. Horseshoe Bend Hydroelectric Co., 988 F.2d 989, 997 (9th Cir. 1993) (per curiam) and Nat'l Audubon Soc'y v. U.S. Forest Serv., 46 F.3d 1437, 1447 n.9 (9th Cir. 1993)).

TVC claims that the NRC report falls within the exception for documents necessary to determine whether the agency has considered all relevant factors. Br. 61. The NRC report, however, was published approximately two years after DOE issued the REA and FONSI and thus DOE did not have the opportunity to consider the factors addressed in the report at the time it made its decision. This Court has firmly held that post-decision information "'may not be advanced as a new rationalization either for sustaining or attacking an agency's decision,'" because "'it inevitably leads the reviewing court to substitute its judgment for that of the agency.'" Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv., 450 F.3d 930, 943 (9th Cir. 2006) (quoting S.W. Ctr. for Biological Diversity v. U.S. Forest Serv., 100 F.3d 1443, 1450-51 (9th Cir. 1996) and Asarco, Inc. v. EPA, 616 F.2d 1153, 1160 (9th Cir. 1980)). The bar on post-decision evidence applies to the exception for extra-record documents necessary to determine whether the agency has considered all relevant factors. Id. at 943. See also S.W. Ctr. for Biological Diversity, 100 F.3d at 1450 (holding document issued after challenged decision was made was not admissible for the purpose for determining whether agency considered all relevant factors).

The district court thus properly denied TVC's motion to supplement the record.

C. Even if the NRC Report falls within a record review exception, the district court properly concluded it does not demonstrate a legal deficiency in the REA.

Finally, even if the Court determines that documents unavailable to the agency at the time the challenged decision was made may fall within an exception to record review, the district court did not abuse its discretion in finding that the NRC report does not illuminate any deficiency in the REA and that therefore supplementation of the record was inappropriate.

The NRC report examines a 2006 EIS prepared by the Army for its proposed expansion of the U.S. Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland. 1ER7:1. Among other things, the report examines the Army's MCE analysis, which is based on a modeled pathogen release from a hypothetical centrifuge accident similar to that used in the LLNL BSL-3 EA. Contrary to TVC's assertion, the NRC report did not "find that the catch-all centrifuge action was not a reasonable surrogate for an intentional act." Br. 64. Instead, NRC's criticism of the MCE scenario was that its results were not independently verifiable because the modeling data used by the Army was not transparent, and that the MCE scenario was not reasonably foreseeable because of the string of errors that would have to occur in order for there to be a release of a large volume of a pathogen. 1ER7:4. This shortcoming does not—as TVC assumes—mean that the release scenario is overly constrained, but instead that it overestimates the chance of a release. In the NRC's words: "Despite the committee's estimation that an exceptionally large aerosol release

might pose a human health risk, there are no reasonably foreseeable scenarios where such a release could occur." Id. Thus, while the NRC report does allege shortcomings in the analysis used by the Army, those shortcomings do not suggest that the Army's release scenario underestimated the results of a pathogen release. To the extent the NRC's observations are transferrable to this case, they similarly do not suggest that DOE's evaluation was understated or legally insufficient.

TVC also claims that the NRC report faulted the Army for failing to consider a variety of issues, all of which—TVC contends—are "relevant factors that were not analyzed in the Livermore Lab BSL-3 FREA." Br. 64-65. First, TVC misreads the NRC report, which is in fact listing scenarios that were addressed in the Army's EIS. See 1ER7:4.[22] Second, each of the listed issues was considered in the BSL-3 REA. See 2ER1:48 (handling of animals); 2ER1:59-60 (shipping and transportation impacts); 2ER1:66-67 (threat of an insider with malicious intent); 2ER1:52, 54 (external acts such a natural disasters); 2ER1:45-46 (risk of public infection and direct transmission from workers); and SER161-162 (cumulative effects).

VI. THE REMEDY REQUESTED BY TVC IS INAPPROPRIATE

In its request for relief, TVC requests, in part, that DOE be compelled to prepare an EIS, and that continued operations of the BSL-3 lab be enjoined. Br. 65-

[22] The sole scenario NRC faults the Army for not including is one not listed by TVC, release of an infected arthropod. 1ER7:4. The NRC goes on to note that had the Army considered such a release scenario, it would have found "significant ecological barriers that make associated relative risks small." Id.

68. If this Court finds a deficiency in the REA, TVC's requested relied is inappropriate.

With regard to TVC's suggestion that DOE should be directed to prepare an EIS, should this Court find DOE's NEPA analysis insufficient, the appropriate remedy is a remand to DOE to prepare an analysis consistent with the Court's holdings. Whether that analysis takes the form of an EIS or a supplemental EA is a choice that should be left to the agency. Ctr. for Biological Diversity v. National Highway Traffic Safety Admin., 538 F.3d 1172, 1178-79 (9th Cir. 2008) (noting "preparation of an EIS is not mandated in all cases simply because an agency has prepared a deficient EA or otherwise failed to comply with NEPA"); Metcalf v. Daley, 214 F.3d 1135, 1146 (9th Cir. 2000) (concluding that "in consideration of our limited role in this process, we have decided that it is appropriate only to require a new EA"); Jones v. Gordon, 792 F.2d 821, 829 (9th Cir. 1986) (holding that although the federal agency "has unreasonably decided not to prepare an [EIS]," the district court erred in ordering one).

Injunctive relief is an "extraordinary remedy" that does not issue automatically upon a finding of legal error. See Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982) (An injunction is an "extraordinary remedy" that "should issue only where the intervention of a court of equity is essential in order effectually to protect . . . against injuries otherwise irremediable.") (quotations omitted). See also Winter v. NRDC, 555 U.S. 7, 376 (2008) (assuming NEPA violation but nonetheless denying

injunctive relief as contrary to the public interest). Rather, a request for injunctive relief requires that plaintiffs demonstrate irreparable harm and that courts consider and balance the equities. eBay Inc. v. MercExchange, 547 U.S. 388, 391 (2006). The facts necessary to determine the propriety of injunctive relief are not before this Court, and should this Court find any error in NEPA analysis prepared by DOE, it should remand the matter to the district court to determine whether injunctive relief is warranted. See NRDC v. U.S. Forest Serv., 421 F.3d at 817 n. 29 (holding the propriety and scope of such relief raises "'intensely factual issues, and for that reason should be decided in the first instance by the district court.").

CONCLUSION

For the foregoing reasons, the judgment of the district court granting summary judgment in favor of DOE and denying TVC's motion to augment the administrative record should be affirmed.

Respectfully submitted,

IGNACIA S. MORENO
Assistant Attorney General
JENNIFER SCHELLER NEUMANN
Attorney, U.S. Dep't of Justice
Env't & Natural Resources Div.

/s/Barclay Samford
BARCLAY T. SAMFORD
Attorney, U.S. Dep't of Justice
Env't & Natural Resources Div.
999 18th Street,
South Terrace, Suite 370
Denver, CO 80202

(303) 844-1475
clay.samford@usdoj.gov

May 2011

90-1-4-12452

STATEMENT OF RELATED CASES

There are no related cases within the scope of Ninth Circuit Rule 28-2.6.

CERTIFICATION OF COMPLIANCE WITH FED. R. APP. P. 32(a)(7)

I certify that this brief complies with the type-volume limitations set forth in Federal Rule of Appellate Procedure 32(a)(7)(B). This brief contains 13,911 words.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on May 12, 2011.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/Barclay Samford
BARCLAY T. SAMFORD
Attorney, U.S. Dep't of Justice
Env't & Natural Resources Div.
999 18th Street,
South Terrace, Suite 370
Denver, CO 80202
(303) 844-1475
clay.samford@usdoj.gov