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COMMISSIONERS

Dale E. Klein, Chairman
Gregory B. Jaczko
Peter B. Lyons

In the Matter of	)	
	)	Docket No. 30-36974-ML
PA'INA HAWAII, LLC	)	
(Materials License Application)	)	

CLI-08-03

MEMORANDUM AND ORDER

This proceeding stems from Pa'ina Hawaii, LLC's (Pa'ina) application for a materials license to possess and use byproduct material in connection with an underwater irradiator, to be located in Honolulu, Hawaii, near the Honolulu International Airport. Recently, the Commission invited the parties to address two questions that the Atomic Safety and Licensing Board certified to the Commission.[1]

At issue is the scope of an underwater irradiator licensing proceeding, and whether it requires or otherwise properly may encompass siting-related safety contentions. Intervenor Concerned Citizens of Honolulu (Concerned Citizens) has proffered safety contentions addressing "risks asserted to be endemic" to the proposed irradiator site, including aircraft crashes, earthquakes, hurricanes, and tsunamis. Pa'ina and the NRC Staff argue that except for unusual circumstances not evident in this case,

[1] *Pa'ina Hawaii, LLC* (Materials License Application), CLI-07-26, 66 NRC ___ (slip op. Oct. 24, 2007).

site-related analyses for irradiators are unnecessary and fall beyond the scope of irradiator proceedings.

The Board's primary certified question to the Commission asks whether "in the circumstances presented, 10 C.F.R. § 30.33(a)(2)[2] requires a safety analysis of the risks asserted to be endemic (*i.e.*, aircraft crashes and natural phenomena) to the proposed irradiator site at the Honolulu International Airport?"[3] In the event the Commission were to conclude that such a siting safety analysis is not "as a matter of law, outside the scope of this proceeding," the Board also asks the Commission to address what "probability threshold" would trigger the need for such a site analysis.[4]

In this decision, the Commission concludes that contentions raising irradiator siting concerns are not barred, as a "matter of law," from irradiator proceedings. However, the regulatory history of NRC irradiator regulations indicates that the agency purposefully refrained from adopting any site selection requirements for irradiators because it concluded that irradiators are generally unlikely to pose any significant risk of offsite harm. The Part 36 rulemaking makes clear that in considering irradiator siting, the NRC expressly considered the potential risks of aircraft crashes and various natural phenomena, yet still concluded that irradiators generally can be safely located anywhere that local authorities permit industrial buildings to be constructed.[5] As NRC guidance endorsed by the Commission and reached in a rulemaking, following notice and comment, the Part 36 rulemaking conclusions are entitled to special weight, and should

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[2] Section 30.33(a)(2) states that an application will be approved if "[t]he applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property."

[3] Memorandum (Certifying Question to the Commission)(Aug. 31, 2007) at 17 (unpublished)(hereinafter Board Memorandum Certifying Question).

[4] *Id.* at 18.

[5] *See* Final Rule, Licenses and Radiation Safety Requirements for Irradiators, 58 Fed. Reg. 7715, 7725 (Feb. 9, 1993)(Final Rule).

be considered in judging whether Concerned Citizens' safety contentions calling for siting analyses present sufficient basis and are otherwise sufficiently supported.

Below we address these conclusions, as well as the Board's question on "probability threshold." Given, however, this long-pending proceeding's complex procedural history, and the number of matters still before the Board, we begin with a look at the current status of Concerned Citizens' contentions. While the Board's certified questions bear only on Concerned Citizens' *safety* contentions, for clarity, we outline both the safety and environmental contentions.

I. Background

Concerned Citizens filed a request for hearing on October 3, 2005. Because portions of the Pa'ina application addressing safety issues contained sensitive, publicly unavailable information, the Board bifurcated the contention admissibility portion of the proceeding, issuing separate decisions on the proffered environmental and safety contentions.

The Board first issued a decision on Concerned Citizens' two environmental contentions.[6] Both contentions claimed that the NRC failed to comply with the National Environmental Policy Act (NEPA) because it improperly invoked a "categorical exclusion" regulation, 10 C.F.R. § 51.22(c)(14)(vii), which permits the NRC to forego conducting an environmental review for irradiator licensing actions. By definition, the "categorical exclusion" rule applies only to classes of licensing actions that the NRC, by rule or regulation, has found "do[] not individually or cumulatively have a significant effect on the human environment."[7]

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[6] LBP-06-4, 63 NRC 99 (2006).

[7] *See* 10 C.F.R. § 51.22(a).

In its Environmental Contention 1, Concerned Citizens noted that the "categorical exclusion" provision contains an exception for "special circumstances" that could prompt the need for an environmental assessment (EA) or environmental impact statement. [8] Environmental Contention 1 argued that the NRC failed to consider and explain whether any extraordinary circumstances precluded invocation of the categorical exclusion rule. In Environmental Contention 2, Concerned Citizens went on to claim that due to the possibility of threats unique to the location or design of the proposed Pa'ina irradiator, including potential airplane crashes, tsunamis, and hurricanes, there are "special circumstances" warranting an environmental assessment or environmental impact statement. The Board admitted both contentions, although it found inadmissible portions of Contention 2 that relied on claims of potential terrorist acts or health consequences from irradiated foods.[9]

Following a Joint Stipulation between Concerned Citizens and the Staff, the two parties jointly moved to dismiss the two environmental contentions. As part of the Joint Stipulation, the Staff agreed to prepare an EA for the proposed irradiator, with Concerned Citizens retaining the right to file contentions challenging the adequacy of any NEPA document the Staff might prepare. The Board approved the agreement, and therefore dismissed the environmental contentions.[10]

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[8] *See* 10 C.F.R. § 51.22(b).

[9] LBP-06-4, 63 NRC at 107-15. Pa'ina filed an interlocutory appeal of the Board's decision admitting Environmental Contentions 1 and 2. The Commission denied the interlocutory appeal. *See* CLI-06-13, 63 NRC 508 (2006).

[10] Order (Confirming Oral Ruling Granting Motion to Dismiss Contentions)(Apr. 27, 2006)(unpublished). Pa'ina appealed the Board's decision, objecting to the terms of the Joint Stipulation, particularly the Staff's agreement to prepare an EA, even though there had not yet been any litigation on the merits of the Concerned Citizens' contentions challenging the application of the "categorical exclusion" rule. The Commission denied the interlocutory appeal. *See* CLI-06-18, 64 NRC 1 (2006).

In a separate decision on Concerned Citizens' safety contentions, the Board admitted three contentions, numbered 4, 6, and 7.[11] Safety Contentions 4 and 6 asserted that Pa'ina's application failed to describe procedures for responding to accidents involving a prolonged loss of electricity and events involving natural phenomena. NRC regulations for irradiators require licensees to have "emergency or abnormal event procedures" for various events, including a prolonged loss of electricity and natural phenomena, such as an earthquake, tornado, flooding, etc.[12] Following the Board's decision, Pa'ina provided to the NRC outlined procedures for prolonged loss of power and for natural phenomena. The Board then granted a Pa'ina motion to dismiss Safety Contentions 4 and 6 as moot.[13]

Safety Contention 7

The third admitted safety contention – Safety Contention 7 – claimed that the Pa'ina application "fails completely to address the likelihood and consequences of an air crash," and that these issues needed to be addressed given the proposed irradiator's location by the Honolulu International Airport, a major airport claimed to have a relatively high rate of aircraft accidents.[14]

In January 2007, Pa'ina moved to dismiss Safety Contention 7 on the ground that it had become moot. Pa'ina argued the contention was moot because the Staff had

[11] LBP-06-12, 63 NRC 403, 412-20 (2006). Concerned Citizens originally submitted twelve safety contentions, but withdrew two prior to the Board's ruling.

[12] *See* 10 C.F.R. §§ 36.53 (b)(6) and (9).

[13] Memorandum and Order (Ruling on Admissibility of Two Amended Contentions)(June 22, 2006)(unpublished). Pa'ina submitted Amended Safety Contentions 4 and 6 challenging Pa'ina's outlined emergency procedures for prolonged loss of power and natural phenomena, but the Board found the amended contentions inadmissible under NRC contention rules. *Id.*

[14] LBP-06-12, 63 NRC at 418 (internal citation omitted). The Commission denied Pa'ina's interlocutory appeal of the Board's decision to admit Safety Contention 7. *See* CLI-06-13, 63 NRC 508 (2006).

made available -- on the NRC's Agencywide Documents Access and Management Systems (ADAMS) database -- what Pa'ina called a "Safety Topical Report," addressing the likelihood and consequences of an aircraft crash into the proposed irradiator.[15]

The Staff supported Pa'ina's motion to dismiss Safety Contention 7. The Staff explained that it issued in December 2006 a draft EA for the Pa'ina irradiator, which examined the probability and consequences of an aircraft crash. The Staff further explained that the findings in the draft EA were based upon a report prepared by the Center for Nuclear Waste Regulatory Analyses, titled "Draft Topical Report on the Effects of Potential Natural Phenomena and Aviation Accidents." The Staff's motion referred to this report in shorthand as the "Safety Topical Report." Noting that "the EA and Safety Topical Report provide the information allegedly omitted from the application," the Staff argued that Safety Contention 7 should be dismissed as moot.[16]

Because Pa'ina had not met the agency's procedural requirements for filing motions, the Board did not grant Pa'ina's motion to dismiss Safety Contention 7. But the Board went on to say that it would later, on its own motion, dismiss the contention as moot, given that the "Draft Safety Topical Report ... cures the originally alleged failure" to address aircraft crashes.[17] The Board also noted that Concerned Citizens would later be able to file amended contentions challenging the "Draft Safety Topical Report and the Draft Environmental Assessment."[18]

Notably, Safety Contention 7 remains admitted at this time. The Board has not ruled yet on whether Safety Contention 7 is moot, and recently indicated that it will defer

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[15] *See* Applicant Pa'ina Hawaii, LLC's Motion to Dismiss Safety Contention 7 (Jan. 9, 2007) at 4.

[16] NRC Staff Response to Applicant Pa'ina Hawaii, LLC's Motion to Dismiss Safety Contention #7 (Jan. 19, 2007) at 3.

[17] Order (Rejecting Motion to Dismiss)(Jan. 25, 2007) at 2.

[18] *Id.* at 4.

ruling on the contention until after the Commission's decision on the Board-certified questions.[19]

Contentions Challenging Draft Topical Report and Draft Environmental Assessment

On February 9, 2007, Concerned Citizens filed two safety contentions challenging the draft Topical Report.[20] Safety Contention 13 challenged the draft Topical Report's analysis of aircraft accident probability and consequences. Safety Contention 14 challenged the draft Topical Report's analysis of the safety risks from natural phenomena, including tsunamis, hurricanes, and earthquakes.

On the same day, Concerned Citizens also filed three environmental contentions challenging the draft EA. Environmental Contention 3 asserted that the draft EA fails to take a "hard look" at the potential environmental impacts of the proposed irradiator. More specifically, Environmental Contention 3 claimed the draft EA (1) relies on generalized statements instead of adequate analysis; (2) fails to consider numerous potential impacts and accident scenarios; (3) fails to consider potential impacts from terrorism, given a recent Ninth Circuit Court of Appeals ruling rejecting the NRC's policy of not providing NEPA analysis of potential terrorism impacts; and (4) fails to address potential impacts from irradiating food. Environmental Contention 4 claimed a failure to address alternatives. Lastly, Environmental Contention 5 claimed that the significance of potential environmental effects requires the NRC to prepare an environmental impact statement.

In an unpublished order, the Board stated that it would wait to rule on the environmental contentions until after the Staff issued its final EA, and until after the

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[19] Board Memorandum Certifying Question at 6.

[20] *See* Intervenor Concerned Citizens of Honolulu's Contentions Re: Draft Environmental Assessment and Draft Topical Report (Feb. 9, 2007).

deadline for filing any amended contentions challenging the final EA.[21] The Board also stated that it would rule separately on the proffered safety contentions challenging the draft Topical Report.

Contentions Challenging Final Topical Report and Final Environmental Assessment

The Staff made available a final Topical Report in May 2007, and issued its final Environmental Assessment in August 2007.[22] Concerned Citizens responded by filing amended safety and environmental contentions challenging the final documents.[23] The amended contentions claimed that the final EA and Topical Report repeated deficiencies of the draft documents, and contained new flawed information.

Concerned Citizens' amended safety and environmental contentions challenging the final EA and final Topical Report have the same titles, and present largely similar concerns, as the earlier contentions challenging the draft EA and draft Topical Report. Amended Safety Contentions 13 and 14 claim deficiencies in the Topical Report's analyses of potential aircraft crashes and natural phenomena. Amended Environmental Contention 3 claims that the Staff failed to take a "hard look" at potential environmental impacts.[24] Amended Environmental Contention 4 claims that additional analysis of

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[21] *See* Order (Regarding Environmental Contentions)(unpublished)(July 18, 2007).

[22] *See* Final Topical Report on the Effects of Potential Aviation Accidents and Natural Phenomena at the Proposed Pa'ina Hawaii, LLC, Irradiator Facility (May 2007)(ADAMS accession number ML071280833); Final Environmental Assessment for Proposed Pa'ina Hawaii, LLC Underwater Irradiator in Honolulu, Hawaii (Aug. 2007)(ADAMS accession number ML071150121).

[23] Intervenor Concerned Citizens of Honolulu's Amended Safety Contentions #13 and #14 (June 1, 2007); Intervenor Concerned Citizens of Honolulu's Amended Environmental Contentions # 3 through # 5 (Sept. 4, 2007).

[24] One of the numerous claims made in Environmental Contention 3 is that while the final Environmental Assessment does examine the potential for terrorist acts, the NRC did not take a sufficiently "hard look" at potential impacts from terrorism.

"alternatives" is required. And amended Environmental Contention 5 claims that the proposed irradiator's potential impacts require an environmental impacts analysis.

The Board recently admitted amended Environmental Contentions 3 and 4.[25] The Board deferred ruling on the admissibility of amended Environmental Contention 5, which asserts that the Staff is obligated to prepare an EIS for the proposed irradiator. Calling amended Contention 5 "premature," the Board stated it would first "reach[] the merits of [environmental] contentions 3 and 4," which go to the adequacy of the EA, before it could "determine[] whether an EIS is required."[26]

Additional Comment on the Topical Report

At this point, it bears noting that significant confusion apparently resulted from the Staff -- both in its draft and final environmental assessments, and its response to the Pa'ina motion to dismiss Safety Contention 7 -- having referred to the Topical Report as the "Safety Topical Report." This gave the impression that the Topical Report was a Staff *safety review* document, separate from the environmental review conducted in the EA. Significantly, however, in a May 21, 2007 response to Board questions, the Staff clarified that the purpose of the Topical Report was to support the Staff's environmental

[25] Memorandum and Order (Ruling on Admissibility of Intervenor's Amended Environmental Contentions)(Dec. 21, 2007)(Memorandum on Environmental Contentions)(slip op.). The Board initially deferred ruling on the portion of Environmental Contention 3 that challenges the Staff's analysis of potential terrorism-related impacts. The Board stated that it would wait to rule on that portion of the contention until it "ha[d] the benefit of the Commission's guidance from its treatment of [an] analogous contention in the *Diablo Canyon* proceeding." *Id.* at 20. Following issuance of the Commission's decision in the *Diablo Canyon* proceeding, the Board directed the parties in this proceeding to provide additional briefs, addressing how the Commission's decision in *Diablo Canyon* might impact the admissibility of the NEPA-based terrorism claims raised in Environmental Contention 3. *See* Order (Requiring Parties to File Responsive Pleadings)(Jan. 24, 2008)(unpublished). On March 4, 2008, the Board ruled on the admissibility of the terrorism-related challenges, admitting the claims only to the extent that they assert that the Staff failed to disclose data underlying its terrorism analysis. *See* Memorandum and Order (Ruling on Admissibility of Intervenor's Terrorism-Related Challenges)(Mar. 4, 2008)(unpublished).

[26] Memorandum on Environmental Contentions at 33-34.

review, that the report was prepared "with only the requirements of NEPA in mind," and that the Staff drew no "safety conclusions" from the report.[27]

The Staff's clarification suggests that the Topical Report should only be considered part of the Staff's environmental review, not its safety review.[28] Indeed, the Staff has suggested that, had it conducted a *safety* analysis of potential aircraft crash consequences, such an analysis "would differ" from the Topical Report's consequence analysis, "completed for the Staff's environmental review," because "there are different regulatory standards for environmental and safety reviews."[29]

Ultimately, the Staff completed a safety review of the proposed Pa'ina irradiator. In August 2007, the Staff provided a description of its safety review, and issued the irradiator license to Pa'ina.[30] Concerned Citizens sought a stay of the effectiveness of the Pa'ina irradiator license. In ruling on the stay application, the Board noted that Pa'ina has yet to enter into a final lease for the proposed site to build the irradiator. The

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[27] Board Memorandum Certifying Questions, at 6 (citing NRC Staff Response to the Licensing Board's April 30, 2007 Order (May 21, 2007) at 4 n.3).

[28] *See also* NRC Staff's Response to Commission's October 24, 2007 Memorandum and Order (Nov. 7, 2007)("Staff Response to Commission"), at 8 (Staff did not draw safety conclusions from the Topical Reports because it considers site-specific safety analyses for this licensing action to be unnecessary). If it is the case that the Staff did not rely at all on the Topical Report for its safety review, and considers the report only part of its environmental review, then it would appear inappropriate to classify as "safety" contentions those proffered contentions challenging the Topical Report. In effect, the contentions challenging the Topical Report are challenging the Staff's environmental review, not its safety review. Given the confusion over what the Topical Report represents, the so-called "safety" contentions (Contentions 13 and 14) challenging the Topical Report could, if appropriate, be added to or folded into the environmental contentions challenging the EA. The Board may wish to seek the parties' positions on this point.

[29] NRC Staff Response to the Licensing Board's June 6, 2007 Order (June 13, 2007) at 6.

[30] Pa'ina Hawaii, LLC, Safety Review (August 18, 2007)(ADAMS accession number ML072260186). The Staff explains that the document it refers to as the "Safety Review" is not a formal Safety Evaluation Report (SER), but represents a narrative description of the items considered by the Staff, as it goes down a "safety review checklist typically used ... when considering an irradiator license application." *See* NRC Staff Response to Commission at 7 n.22.

Board therefore is holding the stay application in abeyance "until the question of the Applicant's lease for the proposed irradiator is resolved." [31]

Contentions Challenging the Staff's Safety Review

Challenging the Staff's safety review, Concerned Citizens has now submitted two new safety contentions.[32] Safety Contention 15 claims that the Staff's review is deficient because it fails to examine safety risks from potential aircraft crashes, tsunamis or hurricanes. Safety Contention 16 claims that the Staff's review inadequately analyzes the safety risks from earthquakes. At the heart of the contentions is Concerned Citizens' argument that the Staff's safety review does not support a conclusion that the "proposed irradiator would 'protect health and minimize danger to life or property,' as required by 10 C.F.R. § 30.33(a)(2)."[33]

II. The Parties' Arguments on the Board's First Certified Question

In certifying questions to the Commission, the Board asks the Commission to clarify the intent of the regulations governing irradiator licensing, and specifically to resolve whether a safety "siting analysis" of risks asserted to be endemic to the proposed irradiator's site is required and litigable:

The Board's first certified question asks the following:

1. Whether, in the circumstances presented, 10 C.F.R. § 30.33(a)(2) requires a safety analysis of the risks asserted to be endemic (*i.e.* aircraft crashes and natural phenomena) to the proposed irradiator site at the Honolulu International Airport?

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[31] *See* Board Order (Temporarily Holding in Abeyance Stay Application)(Oct. 5, 2007) at 2 (unpublished). Pa'ina continues to provide monthly updates on the status of its lease negotiations.

[32] *See* Intervenor Concerned Citizens of Honolulu's Contentions Re: Final Safety Evaluation Report (Sept. 14, 2007).

[33] *See id.* at 2.

The Board's question centers on 10 C.F.R. § 30.33(a)(2), a rule stating the general requirement that an applicant's "proposed equipment and facilities [must be] adequate to protect health and minimize danger to life or property." This rule is found in 10 C.F.R. Part 30, which contains NRC rules of *general* applicability to domestic licensing of byproduct material. The NRC also has a set of regulations *specific* to irradiator licensing, codified at 10 C.F.R. Part 36. The NRC issued the Part 36 regulations to "consolidate[], clarif[y], and standardize" requirements for irradiator licensing.[34] Prior to implementing Part 36, the NRC licensed irradiators "on a case-by-case basis with relatively few specific requirements contained in formal regulations." [35] The Part 36 regulations are intended to provide a "formal, detailed, comprehensive set of regulations" for irradiator licensing.[36]

Part 36 specifies numerous design, performance, and operations requirements for both *underwater* irradiators, "in which both the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool," and *panoramic* irradiators, "in which the irradiations are done in air in areas potentially accessible to personnel." [37] Section 36.13 outlines various categories of requirements that must be satisfied for an irradiator license. In particular, section 36.13(a) states, "[t]he applicant shall satisfy the general requirements specified in § 30.33 of this chapter and the requirements contained in this part." Consequently, section 36.13 incorporates into the Part 36 irradiator regulations the

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[34] *See* Final Rule, 58 Fed. Reg. at 7716.

[35] *Id.*

[36] *Id.*

[37] 10 C.F.R. § 36.2. The Part 36 regulations apply to two kinds of panoramic irradiators: those in which the sources are stored in shields made of solid material (panoramic dry-source-storage irradiators), and those in which the sources are stored under water in a storage pool (panoramic wet-source-storage irradiators).

general requirement -- from § 30.33(a)(2) -- that a facility be "adequate to protect health and minimize danger to life or property."

Much of the dispute in this proceeding centers on the relationship between the specific design, performance, operations and other technical requirements in Part 36 and the general requirement that the facility be adequately protective. In calling for safety analyses of risks asserted to be endemic to the proposed Pa'ina irradiator facility, Concerned Citizens' safety contentions are based on § 30.33(a)(2)'s general requirement. Pa'ina and the Staff, however, argue that Concerned Citizens is improperly invoking the general requirement of § 30.33(a)(2) to seek additional safety analyses that are unnecessary and beyond the scope of this proceeding. The Staff argues, for example, that "considering the text and structure of the regulations, it is clear the Commission intended the comprehensive requirements in Part 36 to prescribe a means of complying with the general requirement in section 30.33(a)(2)."[38]

The Staff and Pa'ina further argue that the Part 36 rulemaking history shows that the NRC already generically considered the risk posed by natural events such as tornados, tidal waves, flooding, and earthquakes, and even considered the risk of an airplane crashing into an irradiator, but nevertheless concluded that irradiators can be safely located anywhere that local governments allow occupied industrial facilities. The Staff therefore claims that absent a showing that an irradiator poses a "unique threat not addressed by State or local requirements, the Commission intended for the specific design and performance requirements in Part 36 to render a site-related safety analysis unnecessary."[39]

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[38] NRC Staff's Reply to Intervenor's Opening Brief (Nov. 14, 2007) at 2 (Staff Reply). *See also* Applicant Pa'ina Hawaii, LLC's Brief in Response to Oct. 24, 2007 Memorandum and Order of NRC (Nov. 7, 2007) at 3 (Pa'ina Response).

[39] Staff Response to Commission at 13.

Concerned Citizens, on the other hand, stresses that the NRC "cannot possibly determine" that the proposed Pa'ina facility will adequately protect public health and safety, as required under § 30.33(a)(2), unless risks asserted to be endemic to the site (*i.e.*, tsunamis, hurricanes, aircraft crashes) are first analyzed.[40] Concerned Citizens argues that one cannot evaluate whether local requirements will adequately protect against "threats that are endemic to a proposed irradiator unless one first performs a thorough analysis of those threats."[41] Additionally, Concerned Citizens stresses that it "does not bear the burden of affirmatively proving that the irradiator would not be safe."[42]

As to the Part 36 rulemaking history, Concerned Citizens argues that "[e]ven if it were proper to consider the regulatory history, nothing in the Statement of Considerations suggests the Commission gave any thought to whether *underwater* irradiators of the design Pa'ina proposes would be safe from aviation accidents and natural disasters."[43] Moreover, Concerned Citizens argues that it did show that the Pa'ina irradiator's location presents "unique threats" that distinguish it from "ordinary licensing actions."[44]

III. Analysis

To address whether safety issues raising siting concerns are litigable in irradiator proceedings, we begin by looking at Part 36 and its rulemaking history. Unlike rules for various other NRC licensing actions which contain express criteria governing site

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[40] Intervenor Concerned Citizens of Honolulu's Opening Brief Re: Questions Certified by the Licensing Board on Aug. 31, 2007 (Nov. 7, 2007) at 8 (Intervenor's Opening Brief).

[41] Intervenor Concerned Citizens of Honolulu's Reply Re: Questions Certified by the Licensing Board on Aug. 31, 2007 (Nov. 14, 2007) at 8 (Intervenor's Reply).

[42] *Id.* at 8.

[43] Intervenors' Opening Brief at 9 (emphasis added).

[44] *Id.* at 8.

selection, Part 36 does not provide any siting requirements.[45] The lack of site selection criteria is intentional. The Statements of Consideration (SOC) for Part 36 indicate that in developing the Part 36 regulations, the NRC considered whether there was a need to impose limits on irradiator siting, but determined that no specific siting limitations were warranted.[46]

An entire section in the SOC is devoted to the topic of "Siting, Zoning, Land Use, and Building Code Requirements." There, the Staff explains its view that irradiators in general are unlikely to pose a significant offsite risk, and therefore can be safely located *anywhere* local governments allow industrial facilities to be built:

> The NRC believes that an irradiator meeting the requirements in the new Part 36 would present no greater hazard or nuisance to its neighbors than other industrial facilities, because there is little likelihood of such an irradiator causing radiation exposures offsite in excess of NRC's part 20 limits for unrestricted areas. All irradiator experience to date indicates that irradiators do not present a threat to people outside the facility. Therefore, the NRC believes that, in general, irradiators can be located anywhere that local governments would permit an industrial facility to be built.[47]

The SOC section on "siting" explains that while irradiators may have a large radioactive inventory, "radioactive materials in irradiators are not volatile like the noble gases and iodines produced in a reactor." [48] The section further makes clear that the NRC explicitly considered whether there should be siting requirements because of potential floods, tidal waves, or earthquakes, but concluded that "irradiators could be

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[45] *Compare, e.g.,* 10 C.F.R. Part 100, Appendix A; 10 C.F.R. §§ 72.90-102; 10 C.F.R. Part 40, Appendix A; 10 C.F.R. § 61.50.

[46] The Commission "often refer[s] to the Statement[s] of Consideration as an aid in interpreting our regulations." *Duke Energy Corp.* (Catawba Nuclear Station, Units 1 and 2), CLI-04-11, 59 NRC 203, 208 n.12 (2004). *See also Public Citizen v. Carlin*, 184 F.3d 900, 911 (D.C. Cir. 1999)("[w]e regularly rely upon the preamble in interpreting" agency rules, given that "[t]he purpose of the preamble, after all, is to explain what follows").

[47] Final Rule, 58 Fed. Reg.at 7726.

[48] *Id.* at 7725.

built in any area of the country," although irradiators built in seismic areas would need shielding walls designed to withstand an earthquake.[49]

A separate section of the SOC – indeed titled "Aircraft Crashes" -- examines "whether there should be a prohibition against locating irradiators near airports because of risk of radiation overexposures caused by an airplane crash." [50] This discussion even conservatively *assumes* the scenario of a "source ... damaged as a result of an airplane crash," but concludes nonetheless that "large quantities of radioactivity are unlikely to be spread from the immediate vicinity of the source rack because the sources are not volatile."[51] The discussion further concludes that "the radiological consequences of an airplane crash at an irradiator would not substantially increase the seriousness of the accident," and that "[t]herefore, the NRC will allow the construction of an irradiator at any location at which local authorities would allow other occupied buildings to be built." [52]

Concerned Citizens points out that the SOC's siting discussions refer at times to the adequacy of shielding walls of *panoramic* irradiators -- which can have walls consisting of six feet of reinforced concrete -- while the proposed Pa'ina irradiator's Cobalt-60 sources "would be stored in an irradiator pool with a liner consisting of 6 inches of concrete, with ¼ inch of steel on the inside and outside."[53] But the Part 36 rules clearly were developed to serve as a standardized set of rules for both panoramic *and* underwater irradiators. [54] The siting discussions in the SOC look broadly at the

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[49] *Id.* at 7726. Section 36.39(j) therefore requires panoramic irradiators built in seismic areas to have concrete shielding meeting the seismic design requirements of appropriate industry or local building codes.

[50] *Id.* at 7726.

[51] *Id.*

[52] *Id.*

[53] Intervenor's Opening Brief at 2.

[54] *See* 10 C.F.R. § 36.1(b); Final Rule, 58 Fed. Reg. at 7716.

question whether siting restrictions are warranted for irradiators. They reach the *blanket* conclusion that irradiators, in general, "can be located anywhere that local governments would permit an industrial facility to be built."[55]

And notably, throughout Part 36, there are requirements that apply only to panoramic irradiators or only to underwater irradiators.[56] There are no Part 36 siting requirements for *any* kind of irradiator, underwater irradiators included, and the SOC nowhere intimates that one or another category of irradiator may present risks

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[55] Final Rule, 58 Fed. Reg. at 7726. Simply because the SOC chose to highlight the adequacy of the typically 6-feet thick concrete walls of panoramic irradiators in no way suggests that underwater irradiators would be more vulnerable to aircraft crash or weather events. As the Staff notes, there are many more requirements for panoramic irradiators than for underwater irradiators. *See* Staff Reply at 5. Accordingly, panoramic irradiators "may require special safety features to provide protection *equivalent* to that afforded sources in underwater irradiators," where the sources are attached to the bottom of a deep pool. See Staff Response to Commission at 15 (emphasis in original). For example, there are seismic-related design requirements for panoramic irradiators located in seismic zones, but no specific seismic design requirements for underwater irradiators. *See* 10 C.F.R. § 36.39(j); *see also* NUREG-1556, Vol. 6, "Consolidated Guidance About Materials Licenses, Program Specific Guidance About 10 CFR Irradiator Licenses," Final Report (Jan. 1999) at 8-24 ("[f]or underwater irradiators, no response is required from the applicant" regarding seismic-related shielding design).

Pa'ina similarly argues that the SOC, in referencing the protective nature of thick concrete walls, was emphasizing how even panoramic irradiator sources — which are exposed in air when the irradiator is in use — would be protected in the event of a natural disaster or airplane crash. Pa'ina states that the SOC is referring to panoramic wet-source-storage irradiators, which also are "pool" irradiators, but "typically [have] an *aboveground* 6' thick reinforced concrete shield whose prime purpose is to prevent radiation from escaping when the source materials are brought up out of the water to treat the fruits, vegetables or other products." See Applicant Pa'ina Hawaii, LLC's Reply to Intervenors' Opening Brief Filed Nov. 7, 2007 (Nov. 14, 2007)(Pa'ina's Reply) at 5 (emphasis in original). Pa'ina claims that the SOC was considering whether "an airplane crash or natural disaster might occur *while the radioactive sources are above water"* at the wet-source storage panoramic irradiator, while at an underwater irradiator "the source rack is *always* at the bottom of the pool both during storage and during the irradiation of the product." *Id.* (emphasis in original). The bottom of the proposed Pa'ina irradiator, for example, would have a depth of approximately 18 ½ feet below floor level. *See* Pa'ina Application for a Material License (Rev. 00, June 20, 2005) at 46; *see also* Pa'ina Hawaii, LLC, "Geotechnical Report" (Weidig Geoanalysts)(Nov. 30, 2005)(ADAMS accession number ML053460276)(Geotechnical Report) at 2.

In any event, it is clear from the Part 36 rulemaking that the NRC – in promulgating requirements for panoramic *and* underwater irradiators – considered potential safety risks related to siting, but discerned no aircraft crash or natural phenomena risk warranting *any* irradiator siting restrictions, for either underwater or panoramic irradiators.

[56] *See generally, e.g.*, 10 C.F.R. §§ 36.39, 36.41.

warranting special requirements for site selection. As the Staff states, there is "no evidence the Commission intended to exempt underwater irradiators from its conclusion that irradiators can be built in any industrial area." [57] Moreover, the aircraft crash analysis in the SOC goes beyond considering the adequacy of irradiator shielding, to conclude that even if a source were damaged, consequences would not be significantly greater than damage from the crash alone.

Therefore, the SOC clearly indicates a deliberate NRC decision to forego imposing specific siting limitations on irradiators. The SOC does hold open the possibility that the NRC may choose, in an exceptional case, to conduct a "facility siting" review, "if a unique threat is involved which may not be addressed by State and local requirements." [58] But the general expectation was that the NRC would not need to conduct a special safety review of facility siting. Instead, both the SOC and section 36.1(a) stress the responsibility of licensees to satisfy all applicable State and local "siting, zoning, land use, and building code requirements." [59]

As guidance reached in a rulemaking following notice and comment, and endorsed by the Commission, the SOC is entitled to "special weight."[60] Therefore, in judging whether contentions calling for irradiator siting analyses are adequately supported, it would be inappropriate to disregard what the NRC already has concluded about irradiator siting and the potential risks posed by aircraft crashes and various natural phenomena.

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[57] Staff Response to Commission at 16.

[58] Final Rule, 58 Fed. Reg. at 7725.

[59] *See* 10 C.F.R. § 36.1(a); *see also* Final Rule, 58 Fed. Reg. at 7725.

[60] *See, e.g., Yankee Atomic Elec. Co.* (Yankee Nuclear Power Station), CLI-05-15, 61 NRC 365, 375 n.26 (2005)(quoting *Long Island Lighting Co.* (Shoreham Nuclear Power Station, Unit 1), ALAB-900, 28 NRC 275, 290 (1988)); *see also Private Fuel Storage, L.L.C.* (Independent Spent Fuel Storage Installation), CLI-01-22, 54 NRC 255, 264 (2001); *Philadelphia Elec. Co.* (Limerick Generating Station, Units 1 and 2), ALAB-819, 22 NRC 681, 711 n.40 (1985).

For example, Concerned Citizens claims that Pa'ina "must evaluate the likelihood that aviation accidents and natural disasters would occur, and the potential for such events to result in radioactive exposures above the limits established in Part 20 to protect life and property."[61] Concerned Citizens states that "[w]ithout such analysis, the NRC cannot possibly determine whether Pa'ina's 'proposed equipment and facilities are adequate to protect health and minimize danger to life or property,'" as required by 10 C.F.R. § 30.33(a)(2).[62] But as the SOC makes clear, the NRC itself *already* generically evaluated the potential for aircraft crashes and natural phenomena (tidal waves, tornadoes, flooding, earthquakes), but concluded that, as a general matter, the consequences of such events would not differ significantly because of the presence of an irradiator.[63] The NRC therefore found no health and safety basis to restrict irradiator siting, or to impose a requirement that applicants perform siting analyses.

Concerned Citizens argues that section 30.33(a)(2) is "clear in placing the burden on the applicant to demonstrate its proposed facility would be safe from *all threats*," and that because section 30.33(a)(2) is clear, it is "improper" to even consider the regulatory history of Part 36.[64] But section 30.33(a)(2) is a general and "standard requirement[] for all NRC licensees,"[65] while the SOC outlines how the NRC specifically considered, in the rulemaking for irradiator requirements, *the very kinds of "threats"* the Intervenors now raise – aircraft crash and natural phenomena. Moreover, by determining that the potential threats posed by aircraft crash and natural phenomena do

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[61] Intervenors' Opening Brief at 8.

[62] *Id.*

[63] *See, e.g.* Final Rule, 58 Fed. Reg. at 7726 ("radiological consequences of an airplane crash at an irradiator would not substantially increase the seriousness of the accident").

[64] Intervenors' Opening Brief at 9 (emphasis added).

[65] *See* Final Rule, 58 Fed. Reg. at 7717.

not warrant a siting review, the NRC likewise *already determined* that such siting analyses typically should be unnecessary for an applicant to show that its facility is "adequate[ly]," protective, as section 30.33(a)(2) requires.

We are not suggesting that contentions calling for siting reviews are inadmissible as a matter of law. The rulemaking history leaves open the possibility that there could be a need for the NRC to review facility siting "on a case by case basis, if a unique threat is involved which may not be addressed by State and local requirements."[66] As the Staff describes, "under the regulatory regime envisioned by the Commission in adopting Part 36, "there could be circumstances where "the Staff needs to conduct a site-specific analysis." [67] Therefore, a contention calling for a siting safety analysis is not barred by the Part 36 regulatory scheme.

But contentions questioning an irradiator facility's siting must be sufficiently supported, in light of the SOC's conclusions. Contentions demanding that an applicant provide detailed, comprehensive siting analyses must be based on more than generalized, conclusory claims of a potential for an aircraft crash because of a nearby airport, or generalized claims that there could be an earthquake, high winds, flooding, or similar event. To require applicants or the NRC Staff, as an initial matter, to provide

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[66] *Id.* at 7725.

[67] Staff Response to Commission at 21. The Staff requested additional information from Pa'ina "including [on] some issues relating to seismic design," even though Part 36 seismic design requirements are applicable only to panoramic irradiators and not underwater irradiators. *See* Staff Response to Commission at 18 n.32; *see also* Staff Reply at 7. The Staff acknowledges that it requested this information. The Staff stresses that its review in this case of two seismic issues, potential soil liquefaction and seismic separation, did "not elevate the issue of seismic design to a requirement in this particular case." *See* Staff Response to Commission at 18 n.32. However, the Staff's incorporation of Pa'ina's responses on the seismic issues into the Pa'ina license, included as License Condition 22, makes Pa'ina's assurances a license requirement. *See* Pa'ina Hawaii, LLC, New License (Aug. 17, 2007)(ADAMS Accession Number ML072320269) at 3, License Condition 22, referencing Pa'ina's letters received on Mar. 9, 2006; Sept. 7, 2006; and teleconference notes dated Sept. 28,2006); *see also* Pa'ina Hawaii, LLC — Deficiency Fax re: Application (Jan. 25, 2006)(ADAMS Accession Number ML060260023); Pa'ina Hawaii, LLC — Deficiency Letter, Request for Additional Information (Aug. 7, 2006)(ADAMS Accession Number ML062190173).

comprehensive, detailed studies proving that airports and potential natural phenomena do not pose a significant safety risk, would be contrary to the Part 36 rulemaking conclusions, which specifically found siting safety reviews unnecessary (even assuming such risks). Petitioners must set forth, with adequate elaboration and support, a plausible claim that a proposed facility would not be adequately protective in the event of specific phenomena.[68] The degree of support necessary for a contention will depend on how obvious a threat the asserted risk is, given the irradiator facility's design and protective features (*e.g.*, depth and dimensions, lack of volatility of sources, shielding provided by water and/or concrete, temperatures, pressure, impact, and other conditions the source assemblies have been tested to withstand, etc.). "While we do not expect a petitioner to prove its contention at the pleading stage," we expect a contention to "present a reasonable scenario" of potential consequences.[69] The "quality of the evidentiary support" at the contention filing stage, however, "need not be of the quality necessary to withstand a summary disposition motion."[70]

Our adjudicatory process exists to examine adequately supported claims of public health and safety or environmental harm. It would be an inappropriate use of adjudicatory and other NRC resources to allow petitioners to trigger time-consuming hearings or gratuitous analyses based merely on generalized, poorly supported scenarios of harm, with little or no description of how a claimed harm might actually occur. Asserted threats must be supported by asserted facts, or expert opinions, including appropriate references to the specific sources and documents on which the

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[68] *See generally* 10 C.F.R. § 2.309(f).

[69] *See Private Fuel Storage, L.L.C.* (Independent Spent Fuel Installation), CLI-04-22, 60 NRC 125, 138-39 (2004).

[70] *See* Final Rule, Rules of Practice for Domestic Licensing Proceedings, 54 Fed. Reg. 33,168, 33,171 (Aug.11,1989).

petitioner intends to rely.[71] Further, there must be an "*explanation* of the basis" for a contention,[72] in this case an explanation of how a significant harm may result given the design of the facility and sources. If a contention is admissible, a consideration on the merits can determine if a safety analysis is in fact warranted.

Whether Concerned Citizens' pending safety contentions go beyond generalized claims and are adequately supported is a matter for the Licensing Board to determine. The Board must also determine whether asserted claims are timely, and otherwise meet all contention requirements.[73] For instance, the Board must evaluate whether the pending safety contentions raise claims that could have been raised in Concerned Citizens' original petition for hearing. "Petitioners must raise and reasonably specify at the outset their objections" to a licensing action.[74]

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[71] 10 C.F.R. § 2.309(f)(v).

[72] *See* 10 C.F.R. § 2.309(f)(ii)(emphasis added); *see also Dominion Nuclear Connecticut, Inc.*, CLI-01-24, 54 NRC 349, 359 (2001). Section 30.33(a)(2) does not specify that an irradiator applicant must conduct a siting safety analysis of man-made or natural external events. A petitioner, therefore, cannot – without more – merely invoke this general regulation to claim that a siting analysis must be performed. Sufficient basis for the contention must be provided.

[73] We note, for example, that one of Concerned Citizens' pending safety contentions – Safety Contention 16 – claims that the Staff's Safety Review "inadequately analyzes safety risks from earthquakes." *See* Intervenor Concerned Citizens of Honolulu's Contentions Re: Final Safety Evaluation Report (Sept. 14, 2007) at 6-9. The Commission has not evaluated whether the contention meets NRC contention requirements, but we take this occasion to remind the parties that the issue in this proceeding is the adequacy of the Pa'ina application, not the adequacy of the Staff's Safety Review. *See, e.g. Curators of the University of Missouri* (Trump-S Project), CLI-95-1, 41 NRC 71, 121-22, *aff'd on motion for reconsid.*, CLI-95-8, 41 NRC 386, 403 (1995). The Staff's review of seismic design issues apparently stemmed from a geotechnical report submitted by Pa'ina. *See* Geotechnical Report (Nov. 30, 2005)(ADAMS ML053460276).

[74] *Duke Energy Corp.* (McGuire Nuclear Station, Units 1 and 2; Catawba Nuclear Station, Units 1 and 2), CLI- 03-17, 58 NRC 419, 427 (2003).

Board's Second Certified Question

Because we conclude that safety issues related to irradiator siting are not, as a matter of law, outside the scope of an irradiator proceeding, we next consider the Board's second certified question:

> What is the appropriate probability threshold (*i.e.*, probability of an event for which consequences exceed regulatory limits) beyond which a site-related safety analysis is required?

As discussed above, Concerned Citizens claims that the Staff should perform a siting analysis for the proposed Pa'ina irradiator because of "unique" threats posed by the Pa'ina irradiator's particular location – threats not commonly at issue for irradiators in general, but asserted to pose special safety risks for this one. Concerned Citizens also argues that the Commission should establish a "probability threshold" for irradiators. It further suggests that the Commission determine that, for irradiators, the probability of an event occurring for which consequences would exceed regulatory limits is 10^{-6}.[75] Concerned Citizens goes on to argue that "[w]ithout an established probability threshold, neither the Staff nor the Commission can make a rational and informed determination" whether there is anything "extraordinary and unique" about Pa'ina's proposed site.[76]

We disagree that the Staff must first establish a general "probability threshold" for irradiators to determine if there are significant safety concerns associated with the proposed Pa'ina site location. Concerned Citizens has pointed to particular site-related factors that it believes render the proposed location unsafe, such as the nearby major airport runways and the location within a tsunami evacuation zone. It is not necessary to establish a general "probability threshold" for irradiators to assess in qualitative terms the significance and plausibility of the particular asserted siting-related threats.

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[75] Intervenor's Reply at 11.

[76] *Id.* at 15.

If one or more of Concerned Citizens' safety contentions go to hearing, then the applicant must demonstrate that the proposed facility is "adequate to protect health and minimize danger to life or property." If that is not done, and ultimately there is a determination that one or more siting-related risks require additional safety analysis before the NRC can conclude that the facility meets all applicable regulatory requirements, including 10 C.F.R. § 30.33(a)(2), then the Staff would need to conduct the additional analysis (or require additional analysis by Pa'ina). This may call for a probability or consequence analysis. But we see no need at this phase of the proceeding to establish a "probability threshold" for irradiators in general or for particular events.

IV. Conclusion

To be admissible, a contention calling for an irradiator siting analysis that relies upon 10 C.F.R. § 30.33(a)(2) must conform to all the requirements of 10 C.F.R. § 2.309(f)(1), including providing sufficient basis to show that a siting analysis is necessary to determine that the facility will be "adequate to protect health and minimize danger to life or property." In evaluating whether Concerned Citizens contentions meet NRC threshold contention admissibility standards, appropriate consideration should be given to any relevant reasoning or conclusions outlined in the Part 36 SOC. Whether a siting safety analysis in fact is *required* in this case is appropriately determined by the Board, following a hearing, if safety contentions go to hearing.

IT IS SO ORDERED.

For the Commission

Annette L. Vietti-Cook
Secretary of the Commission

Dated at Rockville, Maryland,
this 17th day of March, 2008.

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
PA'INA HAWAII, LLC	)	Docket No. 30-36974-ML
	)	
	)	
(Honolulu, Hawaii Irradiator Facility)	)	

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing COMMISSION MEMORANDUM AND ORDER (CLI-08-03) have been served upon the following persons by electronic mail this date, followed by deposit of paper copies in the U.S. mail, first class, and NRC internal mail.

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Dated at Rockville, Maryland
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