

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of)	
)	
PA'INA HAWAII, LLC.)	Docket No. 30-36974-ML
)	
Material License Application)	ASLBP No. 06-843-01-ML

NRC STAFF'S RESPONSE TO COMMISSION'S
OCTOBER 24, 2007 MEMORANDUM AND ORDER

Michael J. Clark
Counsel for the NRC Staff

November 7, 2007

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OCTOBER 24, 2007 MEMORANDUM AND ORDER

INTRODUCTION

On October 24, 2007, the Commission issued an order inviting the parties to brief the question whether, under the circumstances presented in this case, 10 C.F.R. § 30.33(a)(2) requires a safety analysis of risks associated with aircraft crashes and natural phenomena at the irradiator site proposed by Pa'ina Hawaii, LLC. *Pa'ina Hawaii, LLC*, CLI-07-26, 65 NRC ___ (2007) (slip op. at 3). In the event it were to answer this question affirmatively, the Commission also invited the parties to address the appropriate probability threshold beyond which a site-related safety analysis would be required. *Id.* The NRC Staff herein responds to the Commission's order and respectfully submits that the Commission should answer "no" to the first question and, for that and other reasons, not reach the second question.

BACKGROUND

To fully answer all issues raised in the Commission's order, the Staff will provide detailed summaries of the procedural background of this case and the background of Part 36, which contains the NRC's regulations applying specifically to irradiators.

I. Procedural Background

On June 23, 2005, Pa'ina Hawaii, LLC (Pa'ina) filed an application for a license to possess and use byproduct material in connection with an underwater irradiator.¹ Pa'ina plans to build its irradiator at the Honolulu International Airport, in close proximity to other industrial facilities. The irradiator will contain a doubly-encapsulated cobalt-60 source secured inside a plenum that is anchored to the bottom of a pool of water 18'6" deep and approximately 81" by 95" wide.² Pa'ina plans to use its facility for the commercial irradiation of food and other products, which will be submerged in the pool and exposed to the source. As is typical of underwater irradiators, the pool water will provide the primary means of radiation shielding.³

On October 3, 2005, the Intervenor in this case, Concerned Citizens of Honolulu, filed a request for hearing in connection with Pa'ina's license application, setting forth twelve safety and two environmental contentions.⁴ The Board admitted three safety contentions but subsequently dismissed two contentions after Pa'ina submitted supplemental procedures addressing relevant issues.⁵ The remaining contention, safety contention 7, alleges Pa'ina's application is inadequate because it "fails completely to address the likelihood and consequences of an air crash" at the irradiator facility. The Staff opposed safety contention 7 because the Intervenor did not cite any specific requirement that an application include such

¹ Application for Material License for Pa'ina Hawaii, Rev. 00 (June 23, 2005) (ADAMS ML052060372).

² See Final Environmental Assessment for Proposed Pa'ina Hawaii, LLC Irradiator (August 10, 2007) (ADAMS ML071150121) at 2-3, A-3.

³ Application for Material License for Pa'ina Hawaii, Rev. 00 at 30.

⁴ Request for Hearing by Concerned Citizens of Honolulu (October 3, 2005) (ADAMS ML052970026).

⁵ *Pa'ina Hawaii, LLC*, LBP-06-12, 63 NRC 403 (2006); Memorandum and Order (Ruling on Admissibility of Two Amended Contentions) (June 22, 2006) (unpublished).

information and, for that reason, the contention presents an impermissible challenge to the NRC's regulations.⁶

The Board also admitted environmental contention 1 and a portion of environmental contention 2.⁷ In these contentions the Intervenor challenged the Staff's finding that the present licensing action is categorically excluded from review under the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. §§ 4321–4437, and alleged that the Staff must prepare an Environmental Assessment (EA) or Environmental Impact Statement (EIS). The Intervenor argued in contention 1 that the Staff improperly invoked the categorical exclusion for irradiators at 10 C.F.R. § 51.22(c)(14)(vii) by failing to provide a reasoned explanation of why risks associated with aircraft crashes, tsunamis and hurricanes at the Honolulu International Airport do not constitute "special circumstances" such that, under 10 C.F.R. § 51.22(b), the categorical exclusion does not apply. In contention 2, the Intervenor affirmatively argued that risks associated with aircraft crashes, tsunamis and hurricanes constitute "special circumstances."

On March 20, 2006, the Intervenor and the Staff entered into a joint stipulation resolving all issues associated with the Intervenor's environmental contentions 1 and 2.⁸ Pursuant to that

⁶ Staff Response to Request for Hearing by Concerned Citizens of Honolulu (October 28, 2005) (ADAMS ML053040280) at 11.

⁷ *Pa'ina Hawaii*, LLC, LBP-06-4, 63 NRC 99 (2006).

⁸ NRC Staff and Concerned Citizens of Honolulu Joint Motion to Dismiss Environmental Contentions (March 20, 2006) (ADAMS ML060820592). The Staff did not concede the admissibility of any contention, nor did the Intervenor concede that any contention was inadmissible. Rather, under the terms of the agreement, the Staff merely agreed to take certain actions in order to resolve the contentions. The Staff maintains its position that it need not make an affirmative finding there are no "special circumstances" before it can rely on a categorical exclusion in 10 C.F.R. § 51.22(c). In practice, placing the burden on the Staff to prove there are no "special circumstances" would force the Staff to conduct an EA-like analysis before it can rely on a categorical exclusion even though—as the rulemaking record to section 51.22 makes clear—the Commission adopted categorical exclusions with the express purpose of removing the need for the Staff to prepare EAs for specified licensing actions. *Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions and Related Conforming Amendments*, 49 Fed. Reg. 9352, 9365–81 (March 12, 1984).

stipulation, the Staff agreed to complete an EA concerning Pa'ina's application. The Staff also agreed that, before it issued any final finding of no significant impact (FONSI), the Staff would issue a draft FONSI for public review and comment and hold at least one public meeting in Honolulu, Hawaii. The Intervenor reserved its right pursuant to 10 C.F.R. § 2.309(c) to file additional contentions challenging the adequacy of the Staff's NEPA review after the Staff published a final FONSI. The Board approved the joint stipulation and, accordingly, dismissed environmental contentions 1 and 2.⁹

To help prepare its EA, the Staff contracted with the Center for Nuclear Waste Regulatory Analysis to address risks associated with aircraft crashes and various natural phenomena. The Center prepared Draft and Final Topical Reports addressing these risks, and the Staff relied on these reports in its Draft and Final EAs. Following release of the Draft Topical Report¹⁰ and Draft EA,¹¹ the Intervenor submitted both environmental and safety contentions—environmental contentions 3 through 5 and safety contentions 13 and 14—alleging that the draft documents insufficiently analyzed risks to Pa'ina's irradiator associated with aircraft crashes and natural phenomena.¹² Then, following release of the Final Topical Report¹³ and Final EA,¹⁴

⁹ Order (Confirming Oral Ruling Granting Motion to Dismiss Contentions) (April 27, 2006) (unpublished).

¹⁰ Draft Topical Report on the Effects of Potential Natural Phenomena and Aviation Accidents at the Pa'ina Hawaii, LLC Irradiator Facility (Dec. 31, 2006) (ADAMS ML063560344).

¹¹ Draft Environmental Assessment Related to the Proposed Pa'ina Hawaii, LLC Underwater Irradiator in Honolulu, Hawaii (December 21, 2006) (ADAMS ML063470231) ("Draft EA") (December 21, 2006) (ADAMS ML063470231). On June 1, 2007, the Staff published a supplement to the Draft EA addressing the potential environmental impacts of a terrorism attack at the facility. Consideration of Attacks on the Proposed Pa'ina Hawaii, LLC Irradiator (June 1, 2006) (ADAMS ML071290585).

¹² Intervenor's Contentions Re: Draft Environmental Assessment and Draft Topical Report (February 9, 2007) (ADAMS ML070510116).

the Intervenor sought to amend its contentions, arguing that the final documents perpetuated deficiencies in the draft documents and introduced new deficiencies.¹⁵ The Board has not yet ruled on whether these contentions are admissible, either as originally submitted or as amended.

In environmental contention 3 and safety contention 13, the Intervenor challenged the Draft Topical Report's analysis of the probability and consequences of an airplane crash at the irradiator site. The Staff did not oppose two limited portions of environmental contention 3, namely those portions claiming the Staff needed to further analyze debris force from potential aviation accidents and hurricane frequency and strength. The Staff also did not oppose the portion of safety contention 13 related to crash probability, but only because it raised the very same issue set forth in one of the portions of environmental contention 3 the Staff was not opposing.¹⁶ However, the Staff opposed safety contention 13 to the extent the Intervenor argued the Staff had to analyze the safety *consequences* of an aircraft crash at the irradiator site.¹⁷ The Staff's response was consistent with its previously stated position that in the present case NRC regulations do not require a site-related analysis of safety consequences. The Staff

¹³ Final Topical Report on Aircraft Crash and Natural Phenomena Hazard at the Pa'ina Hawaii, LLC Irradiator Facility (May 1, 2007) (ADAMS ML071280833).

¹⁴ Final Environmental Assessment for Proposed Pa'ina Hawaii, LLC Underwater Irradiator in Honolulu, Hawaii, (August 10, 2007) (ADAMS ML071150121).

¹⁵ Intervenor Concerned Citizens of Honolulu's Amended Safety Contentions #13 and #14 (June 1, 2007) (ADAMS ML071620236); Intervenor Concerned Citizens of Honolulu's Amended Environmental Contentions #3 Through #5 (September 4, 2007) (ADAMS ML072530634).

¹⁶ NRC Staff Response to Intervenor Concerned Citizens of Honolulu's Contentions Re: Draft Environmental Assessment and Draft Topical Report (March 12, 2007) (ADAMS ML070730650) at 4, 10.

¹⁷ *Id.* at 4. Specifically, the Staff argued, "Because the aircraft consequence analysis at issue in amended Safety Contention #13 is not required by law or regulation, the part of amended Safety Contention #13 concerning that analysis fails to raise a genuine dispute on a material issue of law or fact and, therefore, is inadmissible."

also opposed safety contention 14, which alleged that the Staff should have addressed site-related safety risks from natural phenomena, because that contention was untimely. The Intervenor could have submitted safety contentions addressing tsunamis, hurricanes and earthquakes in its original hearing request—the Intervenor did, in fact, submit *environmental* contentions relating to tsunamis and hurricanes—but the Intervenor failed to submit safety contentions on those subjects and did not demonstrate good cause for its late filing of safety contention 14.¹⁸

On April 30, 2007, and again on June 6, 2007, the Board posed questions to the Staff regarding the Staff's interpretation of the safety requirements applicable to licensing irradiators.¹⁹ The Board also inquired as to how the Staff applied those requirements in this particular case. The Staff responded to the Board's questions in filings dated May 7, May 21 and June 13, 2007. With respect to whether its safety review of an application must address site-specific risks associated with aircraft crashes and natural phenomena, the Staff stated its position that an applicant "demonstrat[ing] compliance with applicable specific regulations, such as 10 C.F.R. Part 36 or applicable provisions in 10 C.F.R. Part 20, has, absent extraordinary and unique circumstances calling for additional analysis, demonstrated compliance with 10 C.F.R. § 30.33(a)(2)."²⁰ The Staff also explained, in response to the Board's specific question

¹⁸ *Id.* at 4–6.

¹⁹ Order (Posing Questions For The Parties) (April 30, 2007) (unpublished); Order (June 6, 2007) (unpublished).

²⁰ NRC Staff Second Response To The Licensing Board's April 30, 2007 Order" (May 21, 2007) (ADAMS ML071420518) at 8; NRC Staff Response To The Licensing Board's June 6, 2007 Order (June 13, 2007) (ADAMS ML071650545) at 3–4.

on this point, why it concluded Pa'ina's application presents no "unique" or "extraordinary" circumstances requiring a site-related safety analysis.²¹

On August 17, 2007, the Staff issued NRC License No. 53-29296-01, authorizing Pa'ina to possess and use sealed sources in connection with its proposed underwater irradiator. The Staff also released its Safety Review (SR) for the Pa'ina irradiator.²²

On August 31, 2007, the Board certified to the Commission the question whether 10 C.F.R. § 30.33(a)(2) requires a safety analysis addressing aircraft crashes and natural phenomena at the proposed irradiator site.²³ The Board stated that it would wait to resolve the Intervenor's remaining safety contentions—contentions 7, 13 and 14—until the Commission ruled on the certified question. *Id.* at 6. Although the Board referred only to these safety contentions in its certification, the Board also has not yet ruled on environmental contentions 3 through 5.

After the Board's certification, on September 14, 2007, the Intervenor filed safety contention 15, arguing that the SR is deficient because the Staff failed to consider whether the Licensee's irradiator would be safe in the event of an aircraft crash, tsunami or hurricane; and safety contention 16, arguing that the Staff inadequately considered seismic risks.²⁴ The Staff opposed both contentions on the grounds that they challenged only the adequacy of the Staff's safety review, an issue outside the scope of this proceeding. The Staff also opposed the

²¹ Staff's Response to June 6, 2007 Order at 4–5.

²² Pa'ina Hawaii, LLC, Safety Review of the License Application (August 18, 2007) (ADAMS ML072260186). The Staff has referred to this document as a "Safety Review" because it is a narrative version of the safety review checklist typically used by the Staff when considering an irradiator license application.

²³ Memorandum (Certifying Question to the Commission) (August 31, 2007) (unpublished).

²⁴ "Intervenor Concerned Citizens of Honolulu's Contentions Re: Final Safety Evaluation Report" (September 14, 2007) (ADAMS ML072610141).

contentions because they were untimely and because they failed to identify a genuine dispute with the Staff on a material issue of law or fact.²⁵

As the Commission noted in its October 24, 2007 Memorandum and Order, the Board has expressed some frustration and confusion over responses received from the Staff. However, the Staff has consistently argued that because the Intervenor is unable to demonstrate that a site-related safety analysis is necessary in this case, the Intervenor fails to satisfy the contention requirements at 10 C.F.R. § 2.309(f)(1)(vi). The settlement agreement approved by the Board resolved environmental contentions 1 and 2—not any safety contention—and the Draft and Final Topical Reports, which were released in connection with the Draft and Final EAs, were prepared to assist the Staff in settling those environmental contentions. Although safety conclusions could arguably be drawn from the data in the Draft and Final Topical Reports, the Staff has not done so in reviewing Pa'ina's application because the general safety conclusions made by the Commission during its Part 36 rulemaking apply to Pa'ina's proposed facility and render a site-specific analysis unnecessary. The Intervenor has not identified any unique siting issue raised by Pa'ina's application that falls outside the scope of the Commission's Part 36 rulemaking, and, as explained below, a site-related safety analysis would be inconsistent with the Commission's express intent in adopting Part 36 to license irradiators under comprehensive, general safety criteria, rather than requiring case-by-case siting analyses of irradiator applications.

II. Background Pertinent to the Safety Review of Irradiator Applications

In 1993, the Commission adopted 10 C.F.R. Part 36, "Licenses and Radiation Safety Requirements for Irradiators." Although regulations in other parts of 10 C.F.R., including Parts

²⁵ NRC Staff's Response to Intervenor's Contentions on Staff's Safety Review (October 9, 2007) (ADAMS ML072830435) at 6–14.

20 and 30, contain requirements that may also apply to irradiators,²⁶ Part 36 contains the NRC's regulations applying to irradiators specifically.

The Commission's primary rulemaking documents relating to Part 36 include the Statements of Consideration (SOCs) to both the Part 36 proposed and final rules. *License and Radiation Safety Requirements for Irradiators*, 55 Fed Reg. 50008 (December 4, 1990) (proposed rule); 58 Fed. Reg. 7715 (February 9, 1993) (final rule). As made clear in the SOC to each rule, the Commission's intent in adopting Part 36 was to provide a comprehensive set of rules for irradiators. "This rule consolidates, clarifies, and standardizes the requirements for the licensing and operation of current and future irradiators." 58 Fed. Reg. at 7716. *See also* 55 Fed. Reg. at 50010 (explaining that a comprehensive rule is needed in part because, "[o]n subjects that are not covered in the regulations or [draft regulatory] guide [FC 403-4] or for which there are no criteria on what is acceptable, the applicant has no way of knowing what will be accepted"). The Commission considered whether the NRC should follow its existing practice of reviewing irradiator applications on a case-by-case basis under general criteria, but it explicitly rejected that approach: "[T]he issue is whether to license [irradiators] under a formal, detailed, comprehensive set of regulations as was proposed or whether to continue licensing on a case-by-case basis with relatively few specific requirements contained in formal regulations. The NRC's decision is to adopt a comprehensive, formal set of regulations." 58 Fed. Reg. at 7716.

In adopting the comprehensive rules in Part 36, the Commission specifically considered risks to irradiators posed by aircraft crashes and earthquakes. 58 Fed. Reg. at 7720–21, 7726–27. The Commission also considered risks posed by natural phenomena capable of causing

²⁶ Part 20 specifies "Standards for Protection Against Radiation"; Part 30 sets forth "Rules of General Applicability to Domestic Licensing of Byproduct Material."

flooding, tidal waves, and tornado-force winds. *Id.* Notwithstanding these risks, the Commission concluded that, “in general, irradiators can be located anywhere that local governments would permit an industrial facility to be built.” *Id.* at 7726. The Commission recognized that it may be appropriate for the NRC to review irradiator siting on a case-by-case basis “if a unique threat is involved which may not be addressed by State and local requirements.” *Id.* at 7725. However, the Commission otherwise intended the “comprehensive, formal set of regulations” in Part 36 to guide the Staff as it reviews irradiator applications and eliminate the need for the Staff and applicants to address facility siting on a case-by-case basis.

Because Part 36 applies to three different types of irradiators—underwater irradiators; panoramic, dry-source-storage irradiators; and panoramic, wet-source-storage irradiators—there are instances where the SOC discusses a type of irradiator specifically. In the context of safety requirements, these discussions appear where the Commission identifies special safety considerations applicable to a particular type of irradiator. For example, the Commission discusses in detail the requirement in 10 C.F.R. § 36.23(a)–(h) that panoramic irradiators have access control systems to prevent workers from inadvertently entering the radiation room while the source is exposed. 58 Fed. Reg. at 7717–18. The Commission also discusses the requirement in 10 C.F.R. § 36.29(b) that underwater irradiators have radiation monitors over irradiator pools. *Id.* at 7719. In each case, the Commission addresses a type of irradiator specifically in order to point out special safety features that will ensure the irradiator meets the requirements of Parts 20, 30 and 36. Read in context, it is clear the Commission does not mention other types of irradiators in these sections because other irradiators do not require precisely the same safety features to meet regulatory requirements.

DISCUSSION

In safety contentions 7 and 13 through 16—the five safety contentions on which the Board has not yet ruled—the Intervenor argues that the Staff’s safety analysis is deficient because it fails to address risks associated with aircraft crashes, tsunamis and hurricanes, and because the Staff insufficiently analyzes risks associated with earthquakes. The Intervenor does not argue that such an analysis is required by 10 C.F.R. Part 36, but rather by 10 C.F.R. § 30.33(a)(2), which states that an application for a specific license will be approved if “[t]he applicant’s proposed equipment and facilities are adequate to protect health and minimize danger to life or property[.]” The Board, for its part, has suggested that 10 C.F.R. § 36.13(a) is also relevant to determining the scope of the Staff’s safety analysis.²⁷ Section 36.13(a) states that “[t]he applicant shall satisfy the general requirements specified in § 30.33 of this chapter and the requirements contained in this part.”

I. The Proper Relation Between Part 36 and 10. C.F.R. § 30.33.

The threshold question asked by the Commission is, in essence, how the specific regulations applying to irradiators in Part 36 relate to the general provisions of 10 C.F.R. § 30.33. In other words, to the extent an applicant shows it will comply with all specifically applicable requirements in Part 36, has the applicant also shown its “proposed equipment and facilities are adequate to protect health and minimize danger to life or property,” as required by section 30.33(a)(2)? The starting point for analyzing any issue of regulatory interpretation is the language and structure of the regulations themselves. *Yankee Atomic Energy Co.* (Yankee Nuclear Power Station), CLI-05-15, 61 NRC 365, 373 (2005); *Long Island Lighting Co.* (Shoreham Nuclear Power Station, Unit 1), ALAB-900, 28 NRC 275, 288 (1988). A regulation’s meaning cannot be derived by viewing the regulation in isolation. Rather, the Commission must

²⁷ Memorandum (Certifying Question to the Commission) at 2.

consider the NRC's entire regulatory scheme, and regulations addressing the same subject should be construed together. *Northeast Nuclear Energy Co.* (Millstone Nuclear Power Station, Unit No. 3), CLI-01-10, 53 NRC 353, 366 (2001). If the Commission is unable to reach a determination after considering the text and structure of pertinent regulations, it will then refer to the contemporaneous histories of the regulations involved. *Louisiana Energy Services, L.P.* (Claiborne Enrichment Center), CLI-97-15, 46 NRC 294, 300 (1997).

Both 10 C.F.R. § 30.33(a)(2) and § 36.13(a) leave open the possibility that there will be certain cases where an applicant who has satisfied all specifically applicable requirements in Part 36 needs to augment its safety analysis to comply with the general requirements of section 30.33. However, neither the text of Part 36 and section 30.33 nor the structure of the regulations provides unambiguous guidance for determining when such cases exist. With respect to siting, the only mention of this topic in Part 36 is in 10 C.F.R. § 36.1(a), which contains the statement, "Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities." Because the regulations are ambiguous on the relation between Part 36 and 30.33, it is appropriate to refer to the regulatory history of Part 36 for further guidance on the Commission's intent with respect to siting issues involving irradiators. *Louisiana Energy Services*, CLI-97-15, 46 NRC at 300.

The SOC to the Part 36 final rule directly answers the question of when an applicant or the Staff needs to conduct a site-related safety analysis. According to the SOC, where an applicant shows its irradiator complies with the specific requirements in Part 36, the applicant need not address natural phenomena potentially affecting the irradiator's siting unless "a unique threat is involved which may not be addressed by State and local requirements." 58 Fed. Reg. at 7725. The SOC includes this statement in its discussion of "*Siting, Zoning, Land Use, and*

Building Code Requirements,” which specifically addresses safety risks from natural phenomena such as earthquakes, flooding and tidal waves. 58 Fed. Reg. at 7725–26.

Another section of the SOC specifically discusses aircraft crashes and answers the question whether irradiators can safely be located near airports. The SOC answers this question affirmatively and effectively states that, when an irradiator will be built in an industrial area, a site-related safety analysis of aircraft crashes is *never* required: “The NRC has concluded that a prohibition against placing an irradiator where other types of occupied buildings could be placed is not justified on safety grounds. . . . Therefore, NRC will allow the construction of an irradiator at any location at which local authorities would allow other occupied buildings to be built.” 58 Fed. Reg. at 7726.

To read section 30.33(a)(2) as requiring that the applicant or the Staff consider siting on a case-by-case basis even where there is no unique threat left unaddressed by State and local requirements—or to read these sections as requiring the Staff to consider aircraft crashes where the irradiator will be built adjacent to other occupied buildings—would be inconsistent with the Commission’s unequivocal statements in the SOC. To read section 30.33(a)(2) in this manner would also frustrate the Commission’s clearly stated intent that Part 36 “standardize[] the requirements for the licensing and operation of current and future irradiators.” 58 Fed. Reg. at 7716. Reading section 30.33(a)(2) in this manner would force the Staff to follow the approach specifically rejected by the Commission in adopting Part 36, as it would require the Staff to resume its past practice of reviewing siting criteria on a case-by-case basis.

The SOC to the Part 36 proposed rule further supports the conclusion that, absent 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. The SOC explains that, to develop a basis for the proposed safety requirements,

the NRC comprehensively reviewed the operating experience of large irradiators. 55 Fed. Reg. at 50011. The NRC published the results of its review in NUREG-1345, "Review of Events at Large, Pool-Type Irradiators" (1989). NUREG-1345 identified forty-five events at U.S. irradiators having some actual or potential safety significance. 55 Fed. Reg. at 50012. However, only three events were related to natural phenomena or other site problems, and, of these three events, *none* had any significant radiological impact. *Id.* This operating experience provides a sound basis for the Commission's conclusion, in the final rule, that applicants and the Staff need not perform a site-related safety analysis unless there are unique circumstances unaddressed by State or local building codes.

In certifying the question to the Commission, the Board raised the Intervenor's argument that the discussion of aircraft crashes in the SOC to the final rule was intended to apply only to panoramic irradiators, not underwater irradiators:

Indeed, as the Petitioner states in its reply to the Applicant's argument, the comments relied upon by the Applicant are from the Statement of Considerations to the Part 36 rulemaking discussing panoramic irradiators in which "[t]he radioactive sources . . . would be relatively protected from damage because they are generally contained within 6-foot thick reinforced concrete walls and are encapsulated in steel." As the Petitioner also points out, the sources in the Pa'ina Hawaii irradiator "would be in a pool with a liner consisting of 6 inches of concrete, with 1/4-inch steel on the inside and outside."²⁸

This argument is without merit. In the SOC, the Commission plainly states that Part 36 applies to each of the three types of irradiators discussed therein. 58 Fed. Reg. at 7715-16. As noted above, where the Commission discusses a type of irradiator specifically in the context of safety requirements, it does so because the irradiator design requires special safety features to comply with Part 36 and section 30.33. The regulations in Part 36 reflect this approach by making clear that certain design requirements apply only to panoramic irradiators, certain

²⁸ Memorandum (Certifying Question to the Commission) at 14.

requirements apply only to underwater irradiators, and certain requirements apply to both types of irradiators. *Cf., e.g.,* 10 C.F.R. § 36.39(a), (c), (e).

Such is the case where the SOC discusses panoramic irradiators in the context of aircraft crashes. Contrary to the Intervenor's suggestion, the quoted text does not show that the Commission found six-foot thick concrete walls necessary to protect all irradiators against aircraft crashes. Rather, the Commission appears to have concluded that, because their sources are exposed to a greater extent, panoramic irradiators may require special safety features to provide protection *equivalent* to that afforded sources in underwater irradiators. Consistent with this conclusion, the regulations themselves make certain design criteria, including seismic criteria, applicable only to panoramic irradiators. 10 C.F.R. § 36.39(j). This conclusion is further supported by the plain language of the quoted text: the Commission noted that sources in panoramic irradiators are *generally* contained within six-foot thick walls, reflecting its awareness that sources might not *always* be contained within such walls. 58 Fed. Reg. at 7726. Also significant is that the Commission did not rely solely on source protection in concluding that, notwithstanding any risk from aircraft crashes, an irradiator can be built "at any location at which local authorities would allow other occupied buildings to be built." *Id.* The Commission explained that "[e]ven if a source were damaged as a result of an airplane crash, large quantities of radioactivity are unlikely to be spread from the immediate vicinity of the source rack because the sources are not volatile." *Id.*

By focusing on special risks to panoramic irradiators, the Commission's discussion of aircraft crashes mirrors its discussion of risks from tornadoes. There, the Commission likewise addressed panoramic irradiators specifically, finding—using language very similar to that used in the discussion of aircraft crashes—"that there was no need for special design requirements because the shielding by its very nature (about six feet thick reinforced concrete) is inherently

resistant to tornadoes.” 58 Fed. Reg. at 7721. The Commission did not mention underwater irradiators in its discussion of tornadoes because such references were unnecessary given that the construction and design requirements for underwater irradiators specified in Part 36 will ensure sources are adequately protected from tornadoes.²⁹ A similar analysis applies in the case of aircraft crashes, and the Staff sees no evidence the Commission intended to exempt underwater irradiators from its conclusion that irradiators can be built in any industrial area. 58 Fed. Reg. at 7726.

II. The Regulations Do Not Require that the Staff Conduct a Site-Related Safety Analysis

As explained in the plain language of the SOC to the final rule, under the regulatory regime envisioned by the Commission when adopting Part 36, the Staff needs to conduct a site-specific analysis relating to aircraft crashes and natural phenomena only if “a unique threat is involved which may not be addressed by State and local requirements.” 58 Fed. Reg. at 7725. To trigger additional analysis under section 30.33(a)(2), an intervenor would have to explain why any threat it identifies is “unique”—a very high threshold given that the SOC shows the Commission has already considered threats posed by aircraft crashes, earthquakes, tidal waves, flooding, tornado-force winds and other natural phenomena. 58 Fed. Reg. at 7725–26. The intervenor would also need to explain why the phenomena it identifies have not been adequately taken into account in State and local requirements governing the irradiator’s siting. Without addressing these fundamental underpinnings of the regulations, an Intervenor would be unable to show there is a genuine dispute as to whether the Staff needs to conduct a site-related safety analysis of an irradiator application. See 10 C.F.R. § 2.309(f)(1)(vi) (placing

²⁹ In the present case, the pool at the Licensee’s proposed irradiator will be approximately 18’6” deep, and the sealed sources will be at the bottom of the pool, covered by approximately 12 to 18 feet of water. See Final EA at 2 and A-3.

burden on petitioner to demonstrate there is a genuine dispute with the applicant on a material issue of law or fact).

The SOC to the final rule further shows that, in adopting Part 36, the Commission intended that no seismic analysis would typically be required for an underwater irradiator.³⁰ In its discussion, the Commission states that “all irradiators must have shielding walls constructed of reinforced concrete designed to meet generally accepted building code requirements for reinforced concrete.” 58 Fed. Reg. at 7720. However, “shielding walls” are characteristic of panoramic irradiators—*water* is the primary shielding medium in underwater irradiators³¹—and the Commission’s discussion therefore should not be construed as imposing any seismic requirements on underwater irradiators other than those contained in State or local building codes. This interpretation is consistent with 10 C.F.R. § 36.39, “Design Requirements,” which clearly delineates whether particular design requirements apply to pool irradiators, panoramic irradiators, or both. See, e.g., 10 C.F.R. § 36.39(a), (c), (e). The provisions setting forth seismic requirements apply only to panoramic irradiators. 10 C.F.R. § 36.39(j).

Even where a panoramic irradiator is involved, if the irradiator will be located outside seismic zones, the SOC shows the Commission did not intend for the Staff to independently perform a seismic analysis beyond determining the irradiator will meet generally accepted building code requirements. 58 Fed. Reg. at 7720, 7725–26. Further, even where a panoramic irradiator *will* be located in a seismic zone, the SOC does not indicate the Commission intended to require a site-related analysis of seismic risks unless those risks are left unaddressed by

³⁰ The exception, just mentioned, is where “a unique threat is involved which may not be addressed by State and local requirements.” 58 Fed. Reg. at 7725.

³¹ See 10 C.F.R. § 36.25, “Shielding,” at (a)–(b) (prescribing maximum dose rates outside the walls of panoramic irradiators and over pool edges at pool irradiators).

applicable building codes. “The NRC decided that *irradiators could be built in any area of the country*, but that irradiators in seismic areas (as defined in § 36.2) would need shielding walls designed to withstand an earthquake.” (Emphasis added.) 58 Fed. Reg. at 7726. The Commission further explained with respect to panoramic irradiators: “The intent of the final rule is that shield walls in seismic areas would have to retain their integrity in the event of an earthquake by requiring that they be designed to meet the seismic requirements of local building codes or other appropriate sources.” *Id.* at 7721.³²

III. Applying the Above Framework in the Context of this Case

Having set forth the overall framework the Commission developed for licensing irradiators, the Staff will now turn to that part of the Commission’s question asking whether “in the context of this case” 10 C.F.R. § 30.33(a)(2) requires a safety analysis of aircraft crashes and natural phenomena. The general requirements of section 30.33(a)(2) could logically be applied so that the Staff, applicants or intervenors might in certain circumstances address safety issues not contemplated by the specific regulations in Part 36. However, the present case does

³² In its Memorandum and Order, the Commission noted that the Staff’s SR does, in fact, discuss certain seismic issues, and the Commission invited the Staff to address the context in which it conducted a site-related review of seismic risks. *Pa’ina Hawaii, LLC*, CLI-07-26, 65 NRC __ (2007) (slip op. at 3, n. 10). The Staff included brief discussions of two seismic issues—potential soil liquefaction and seismic separation—in the SR because it had already considered those issues to some extent from a safety perspective. The Staff analyzed seismic issues in the first instance because Pa’ina’s application itself addressed those issues. In preparing its application, Pa’ina contracted with Weidig Geotechnical, which prepared a geotechnical report that was incorporated in the application. *Pa’ina Hawaii, LLC—Geotechnical Report* (November 30, 2005) (ADAMS ML053460276) The geotechnical report provided information to be used by Pa’ina’s architect and its civil engineers in designing the foundations for the building and irradiator. The Staff found it necessary to submit requests for additional information to Pa’ina in order to fully understand the analysis in the geotechnical report, including some issues relating to seismic design. Deficiency Fax re: Application Dated June 23, 2005, for a New License and Geotechnical Report Dated September 14, 2005 (January 25, 2006) (ADAMS ML060260023). The Staff considered the additional information provided by Pa’ina, found this information sufficient to answer the Staff’s questions, and arrived at the conclusions stated in the SR. While the seismic information submitted by Pa’ina was not required to comply with Part 36, the mere fact that the Staff reviewed this information to make sure it understood the contents of Pa’ina’s application does not elevate the issue of seismic design to a requirement in this particular case, nor does it establish that there are unique circumstances regarding application of the Part 36 design criteria to Pa’ina’s facility.

not present such circumstances. The Staff's questions to Pa'ina and the inclusion in the SR of some information on seismic issues demonstrates no more than that the Staff carefully reviewed Pa'ina's application and the design of the proposed facility, a necessary step in ascertaining whether there was any obvious reason to look beyond Part 36's requirements in this case. More is not needed. To require that the Staff provide some affirmative analysis to prove a negative—the absence of any unique circumstance—would turn the intent of the Part 36 rulemaking on its head by removing the very predictability that the Commission sought to bring to the irradiator licensing process by adopting the comprehensive rules in Part 36. 58 Fed. Reg. at 7716; 55 Fed. Reg. at 50010.

The Staff does not find any suggestion in the SOC that the Commission intended for applicants or the Staff to revalidate the applicability of Part 36 on a case-by-case basis.³³ Such a requirement would conflict with the Commission's goal in adopting Part 36 to "enhance the efficiency of the regulatory process governing irradiators." 58 Fed. Reg. at 7715. Another of the Commission's goals in adopting Part 36 was to clarify the requirements for the licensing of irradiators. 58 Fed. Reg. at 7715. Requiring the applicant and the Staff to disprove the existence of a unique threat to each irradiator's siting would not serve that purpose, and it could force applicants to conduct wide-ranging analyses in even ordinary licensing actions.

Requiring the applicant or the Staff to show a unique threat does not exist is also inconsistent with the careful allocation of responsibilities in the Commission's adjudicatory rules.

³³ In its August 31, 2007 certification to the Commission, the Board stated that, if there is in fact an exception to the general rule that the Staff need not conduct a site-related safety analysis for an irradiator application, "we would expect a demonstration that it was evaluated and assessed in this proceeding." *Pa'ina Hawaii, LLC*, Memorandum (Certifying Question to Commission) at 16. The Board also stated, as a corollary, that if such an exception exists, "a necessary consequence of the exception is that an applicant must address such circumstances in its application and carry the burden that such circumstances are not present." *Id.* Based on these statements, it appears the Board would place the burden on the applicant and the Staff to affirmatively demonstrate there are no exceptional circumstances requiring a site-related safety analysis.

For example, under the general contention requirements of section 2.309(f)(1), a petitioner bears the burden of showing there is a genuine dispute on a material issue of law or fact; neither the applicant nor the Staff is required to show the *lack* of a genuine dispute. See *Changes to Adjudicatory Process, Part II*, 69 Fed. Reg. 2182, 2201–02 (January 14, 2004) (explaining Commission’s reasoning in extending to Subpart L proceedings the requirement that a petitioner proffer specific, adequately-supported contentions in order to be admitted as a party). In the context of other procedural rules referring to unique or special circumstances, the Commission has placed the burden on the petitioner to demonstrate that such circumstances are present. For example, 10 C.F.R. § 2.335, which allows a party to petition for a waiver or exemption to a Commission rule or regulation if “special circumstances” exist, unquestionably places the burden on the petitioner to make this showing. See 10 C.F.R. § 2.335(b)-(c) (requiring that a petitioner “state with particularity” in an affidavit “the special circumstances that justify the waiver or exemption”).³⁴ The “unique threat” language in the SOC for Part 36 is analogous to the “special circumstances” provision in section 2.335 in that both involve a general rule with an exception that applies only in limited circumstances. Accordingly, the petitioner seeking a hearing in an irradiator licensing proceeding should bear the burden of showing an alleged siting threat is both unique and not addressed by applicable building codes.

In the present case, the Intervenor has not remotely met its burden. In safety contentions 7 and 13 through 16, the Intervenor argues that the Staff had to consider siting because of particular threats to the Licensee’s irradiator posed by aircraft crashes, tsunamis, hurricanes

³⁴ In a contested proceeding involving an NRC Interim Policy that contained a special circumstances provision, the ALAB presumed the intervenor bore the burden of showing such circumstances existed. *Vermont Yankee Nuclear Power Corp.* (Vermont Yankee Nuclear Power Station), ALAB-876, 26 N.R.C. 277, 285 (1987). The Interim Policy at issue was “Nuclear Power Plant Accident Considerations Under the National Environmental Policy Act of 1969,” 45 Fed. Reg. 40,101 (June 13, 1980).

and earthquakes. Because the irradiator will be located at the Honolulu International Airport, in close proximity to other occupied buildings, the Intervenor's argument that the Staff had to consider aircraft crashes must fail. See 58 Fed. Reg. at 7726 (considering risks from aircraft crashes but concluding "NRC will allow the construction of an irradiator at any location at which local authorities would allow other occupied building to be built"). With respect to the natural phenomena it identifies, the Intervenor fails to even allege this case presents circumstances that would require the Staff to conduct a site-related safety analysis. As explained in the plain language of the SOC to the final rule, under the regulatory regime envisioned by the Commission in adopting Part 36, the Staff needs to conduct a site-specific analysis only if "a unique threat is involved which may not be addressed by State and local requirements." 58 Fed. Reg. at 7725. Here, the Intervenor fails to address State and local requirements that might have a bearing on the safety of the Licensee's irradiator, much less explain why those requirements fail to adequately address the threats posed by aircraft crashes and natural phenomena.³⁵

The Intervenor's argument that the Staff had to conduct a site-related seismic analysis is difficult to sustain because Pa'ina plans to build an underwater, not a panoramic, irradiator. For underwater irradiators, the Commission decided to impose neither siting nor design criteria related to potential seismic events. 10 C.F.R. § 36.39(j); 55 Fed. Reg. 7720–21, 7725–26. In any event, even in the case of a panoramic irradiator, the SOC shows that as long as the

³⁵ For example, the City and County of Honolulu recently adopted the 2003 edition of the International Building Code (IBC), which contains updated seismic requirements. CITY AND COUNTY OF HONOLULU, HAW., REV. ORDINANCES ch. 16, art. 1 (June 20, 2007), available at <http://www.honolulu.gov/refs/roh/16a1.htm>; "New Building Code Signed Into Law," <http://honoluludpp.org/WhatsNew/NewBC062007.pdf>. The Intervenor does not address the IBC's provisions, nor those of the Uniform Building Code (UBC), which previously applied in the City and County of Honolulu. The Staff's documentation, by comparison, includes references to both codes. See, e.g., Deficiency Fax re: Application Dated June 23, 2005, for a New License and Geotechnical Report Dated September 14, 2005 (January 25, 2006) (ADAMS ML060260023) (noting that the island of Oahu is located in UBC seismic zone 2A); Final EA at 10 (referring to IBC).

irradiator will be located outside seismic zones, the Commission did not intend for the Staff to perform any site-related seismic analysis beyond determining the irradiator will meet generally accepted building code requirements. 58 Fed. Reg. at 7720, 7725–26.³⁶ Moreover, even where a panoramic irradiator *will* be located in a seismic zone, the SOC does not indicate that the Commission intended to require a site-related analysis of seismic risks unless those risks are left unaddressed by applicable building codes. “The NRC decided that *irradiators could be built in any area of the country*, but that irradiators in seismic areas (as defined in § 36.2) would need shielding walls designed to withstand an earthquake.” 58 Fed. Reg. at 7726 (emphasis added.) The Commission further explained: “The intent of the final rule is that shield walls in seismic areas would have to retain their integrity in the event of an earthquake by requiring that they be designed to meet the seismic requirements of local building codes or other appropriate sources.” *Id.* at 7721.

IV. The Commission Need Not Establish A Probability Threshold Beyond Which A Site-Related Safety Analysis Will Be Required

In its second question, the Commission invited the parties to address what probability threshold should, if reached, trigger a site-related safety analysis. As the Commission notes, it need reach this question only if it first decides that this case presents circumstances requiring a

³⁶ In its last brief filed before the Board, the Staff noted that Pa’ina’s proposed irradiator location is in a seismic zone. The Staff has determined that its prior statement was incorrect; while certain parts of Hawaii are in seismic zones, Pa’ina’s proposed site is *not* within a seismic zone. Section 36.2 defines “seismic zone” as “any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than 10 percent, as designated by the U.S. Geological Survey.” At the Honolulu International Airport, the peak acceleration in 50 years for which there is a 2 percent probability is only 0.26 times the acceleration of gravity. See Final Topical Report (May 1, 2007) (ADAMS ML071280833) at 3-2 through 3-4 (relying on USGS data). This translates into approximately a 10 percent probability that ground acceleration will exceed 0.26 times the acceleration of gravity in 250 years. See “Frequently Asked Questions (FAQ) About Return Periods,” <http://earthquake.usgs.gov/research/hazmaps/haz101/faq/parm08.php> (explaining that ground motion values representing a 2% probability of exceedance in 50 years are basically the same as those for a 10% probability in 250 years).

site-related analysis. Because the Staff believes the answer to the first question is “no,” it submits that the Commission need not consider a probability threshold here. However, to the extent the Commission considers the second question, the Staff would argue that an appropriate threshold should be based on a qualitative assessment of risks to irradiators associated with aircraft crashes and natural phenomena. The Staff is unable to identify a quantitative threshold beyond which a site-related analysis should be required.

As made clear in the SOC to the Part 36 proposed rule, there is a paucity of data on siting problems at irradiators. The SOC refers to NUREG-1345, which identifies forty-five events at large, pool-type irradiators in the United States, with a mere three of those events involving natural phenomena or other problems potentially related to siting issues. 55 Fed. Reg. at 50012. Further, none of those events had any significant safety impact or off-site consequences. *Id.* at 50013. It is the Staff’s position that, with such limited data, no meaningful probability threshold can be established related to potential siting problems at irradiators. Moreover, a review of Part 36’s regulatory history does not reveal any probability threshold analysis underlying the Commission’s adoption of the irradiator licensing rules.

In fact, in the SOCs to the final and proposed rules, the Commission itself appears to have reached this same conclusion. The approach reflected in the SOCs is that, rather than attempting to assign a probability threshold, the Commission chose to rely on the expertise of state and local governments to address potential siting concerns. The Commission repeatedly refers to local building requirements in its discussions of aircraft crashes and natural phenomena. 58 Fed. Reg. at 7720-21, 7726; 55 Fed. Reg. at 50017, 50021-22. These discussions appear to reflect the Commission’s qualitative judgment that, taking into account the specific safety features prescribed for irradiators in Part 36, it is generally appropriate to rely on local building codes to address siting concerns. This judgment is also reflected in 10 C.F.R.

§ 36.1(a), which states, “Nothing in this part relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.”

CONCLUSION

10 C.F.R. § 30.33(a)(2) does not require a safety analysis of risks associated with aircraft crashes and natural phenomena at Pa’ina’s proposed irradiator site. The Commission’s intent in adopting the comprehensive irradiator licensing rules at Part 36 was to render a site-related safety analysis unnecessary absent unique and extraordinary circumstances not present here. The Commission should direct the Board to rule on the admissibility of safety contentions 7 and 13 through 16 consistent with this interpretation.

Respectfully submitted,

/RA/

Michael J. Clark
Counsel for the NRC Staff

Dated at Rockville, Maryland
this 7th day of November, 2007

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE COMMISSION

In the Matter of)	
)	
PA'INA HAWAII, LLC)	Docket No. 30-36974
)	
Material License Application)	ASLBP No. 06-843-01

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S RESPONSE TO COMMISSION'S OCTOBER 24, 2007 MEMORANDUM AND ORDER" in the above-captioned proceedings have been Served on the following by deposit in the United States mail; through deposit in the Nuclear Regulatory Commission's internal system as indicated by an asterisk (*), and by electronic mail as indicated by a double asterisk (**) on this 7th day of November, 2007.

Administrative Judge * **
Thomas S. Moore, Chair
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
Mail Stop: T-3 F23
Washington, D.C. 20555
E-Mail: tsm2@nrc.gov

Administrative Judge * **
Paul Abramson
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
Mail Stop: T-3 F23
Washington, D.C. 20555
E-Mail: pba@nrc.gov

Office of the Secretary * **
ATTN: Rulemakings and Adjudication Staff
U.S. Nuclear Regulatory Commission
Mail Stop: O-16 G4
Washington, D.C. 20555
E-mail: HEARINGDOCKET@nrc.gov

Administrative Judge * **
Anthony J. Baratta
Atomic Safety and Licensing Board Panel
U.S. Nuclear Regulatory Commission
Mail Stop: T-3 F23
Washington, D.C. 20555
E-Mail: ajb5@nrc.gov

Office of Commission Appellate
Adjudication*
U.S. Nuclear Regulatory Commission
Mail Stop: O-16 G4
Washington, D.C. 20555

David L. Henkin, Esq.
Earthjustice
223 South King Street, Suite 400
Honolulu, HI 96813
E-mail: dhenkin@earthjustice.org

Michael Kohn, President
Pa'ina Hawaii, LLC
P.O. Box 30542
Honolulu, HI 96820

Fred Paul Benco **
The Law Offices of Fred Paul Benco
Suite 3409 Century Square
1188 Bishop Street
Honolulu, HI 96813
E-mail: fpbenco@yahoo.com

Johanna Thibault
Lauren Bregman
Law Clerks
Atomic Safety and Licensing Board Panel
Mail Stop: T-3F23
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
E-mail: JJL5@nrc.gov

/RA/

Michael J. Clark
Counsel for the NRC Staff