

June 13, 2007

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

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

NRC STAFF RESPONSE TO THE
LICENSING BOARD'S JUNE 6, 2007 ORDER

INTRODUCTION

On June 6, 2007, the Atomic Safety and Licensing Board ("Board") in the above-captioned proceeding issued an order presenting questions to be addressed by the NRC staff ("Staff"). The Staff's responses to the Board's questions follow.

STAFF RESPONSES

1. Reduced to its essence, the Staff's explanation in its May 21, 2007 response (at the top of p. 8) of its safety review of an irradiator application indicates that the Staff reviews the safety portion of the application to determine compliance with Volume 6 of NUREG 1556. Further, compliance with that NUREG, in turn, suffices to demonstrate compliance with the applicable provisions of 10 C.F.R. Part 36 and 10 C.F.R. Part 20 and satisfaction of 10 C.F.R. § 30.33(a)(2) in the absence of extraordinary and unique circumstances. With respect to the Pa'ina Hawaii irradiator application, has the Staff concluded that the application satisfies 10 C.F.R. § 30.33(a)(2)?

Prior to addressing the Board's specific question as to whether the Staff has determined that Pa'ina's application complies with 10 C.F.R. § 30.33(a)(2), one portion in the Board's summation of the Staff's argument on page 8 of the Staff's May 21, 2007 response requires clarification. The Board's summation states that the "Staff reviews the safety portion of the application to determine *compliance* with Volume 6 of NUREG 1556." Order at 1-2 (emphasis added). This is not entirely accurate. Applicants are not required to comply with guidance

documents.¹ Although the Staff follows all applicable guidance when reviewing applications, the standard an application must meet is compliance with the applicable regulations, not compliance with guidance. Therefore, while the Staff's review of an irradiator will be conducted pursuant to the guidance in Volume 6 of NUREG-1556, the review is conducted to determine whether the application complies with the specific requirements of 10 C.F.R. Part 36, 10 C.F.R. Part 20, and other applicable regulations. If the Staff determines that an application is consistent with applicable guidance, it will generally find that an application complies with all the requirements of all applicable regulations, and, therefore, the Staff usually will find that the application complies with 10 C.F.R. § 30.33(a)(2). In the instant case, although the Staff's safety review of Pa'ina's application has not been finalized, the Staff has found that the application is consistent with the guidance in NUREG-1556, Volume 6, and therefore, that it complies with all applicable regulations, including 10 C.F.R. § 30.33(a)(2).

- a. Did the Staff reach its safety conclusion by finding that the application met the requirements of Volume 6 of NUREG 1556 (Jan. 1999) and no extraordinary and unique circumstances existed requiring additional analysis? Stated otherwise, is it the Staff's view that compliance with Volume 6 of NUREG 1556, in and of itself and in the absence of extraordinary and unique circumstances, demonstrates compliance with 10 C.F.R. Parts 20 and 36 and all other applicable safety regulations including 10 C.F.R. § 30.33(a)(2)?

The Staff's safety conclusions are based on a determination that Pa'ina Hawaii's application is consistent with the guidance in NUREG-1556, Volume 6, and, therefore, complies with all applicable safety regulations. Although applicants are not required to comply with NRC guidance and may meet NRC regulatory requirements through alternative means,

¹ Although an application that is consistent with applicable guidance will generally be found to comply with applicable regulations, and application that is inconsistent with applicable guidance is not necessarily noncompliant with applicable regulations. *University of Missouri*, CLI-95-1, 41 NRC 71, 98 (1995).

an irradiator application that conforms to NUREG-1556 will generally be found to comply with the regulatory requirements. The Staff does not make a separate specific finding that extraordinary and unique circumstances are absent.

- b. What is the specific regulatory basis for the Staff's position that "extraordinary and unique circumstances" are a factor in determining compliance with 10 C.F.R. § 30.33(a)(2)? If no specific regulation or other authority exists, so state.

The Staff's position is based on its interpretation of the Commission's regulatory regime for irradiators rather than a specific regulatory direction in a regulation or other statement of Commission position. This position is based on the Staff's interpretation of the relationship between 10 C.F.R. § 30.33(a)(2) and the more detailed requirements outlined in 10 C.F.R. Part 36, and is illustrated by the licensing guidance in NUREG-1556, Volume 6, where the focus is on meeting the specific requirements outlined in 10 C.F.R. Part 36. Although compliance with 10 C.F.R. § 30.33(a)(2) is of overarching concern in the Staff's review of irradiator license applications, the guidance that the Staff uses to evaluate these applications provides criteria and acceptable applicant responses that address only the specific, detailed requirements of 10 C.F.R. Part 36 or other applicable regulations such as 10 C.F.R. Part 20. Even where compliance with 10 C.F.R. § 30.33(a)(2) is specifically cited as a requirement, as in section 8.9.3, Shielding, no additional criteria are included for complying with section 30.33(a)(2).

In the forward to NUREG-1556, Volume 6, the Staff states that NUREG-1556 describes "methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations; techniques the staff uses in evaluating applications, including specific problems and postulated accidents; and data the NRC staff needs to review applications for licenses." NUREG-1556, Volume 6 at x. Although applicants may deviate from guidance documents, the Staff may not arbitrarily deviate from guidance it has published. NUREG-1556 does not provide any criteria for judging compliance with 10 C.F.R. § 30.33(a)(2) other than criteria

related to the general requirements of 10 C.F.R. Part 36. Thus, unless an irradiator application, or some discrete facet of an application, is so unique that it does not fit the guidance in NUREG-1556, the Staff cannot arbitrarily apply criteria for evaluating regulatory compliance in addition to those already made publicly available in NUREG-1556. In essence, although the Staff cannot arbitrarily determine that meeting the guidance in NUREG 1556 is inadequate to meet the regulations, the question of “extraordinary and unique circumstances” simply gives the Staff the ability to make an initial determination of whether the proposed facility fits within the parameters of the guidance document.

- c. Specify the portions of Volume 6 of NUREG 1556 that address the issues raised in the Intervenor’s Safety Contention #13.

Generally the portions of NUREG-1556, Volume 6 related to facility design, source robustness, and operating procedures address the issues raised in Safety Contention #13. Criteria for evaluating the portions of the application related to the issues raised in Safety Contention #13 can be found in Item 5, Item 9, and Item 10.8 of NUREG-1556, Volume 6.

- d. The Staff asserts that it has found no “extraordinary and unique circumstances calling for additional analysis,” to demonstrate compliance with 10 C.F.R. Parts 36 and 20 and 10 C.F.R. § 30.33(a)(2). How did the Staff conclude that there were no “extraordinary and unique circumstances”? Provide a full discussion of the analysis performed by the Staff to make this determination, including an explanation of why the proposed site for this irradiator does not raise the risks from aircraft crashes, tsunamis, earthquakes, and hurricanes to the level necessary to constitute “extraordinary and unique circumstances.”

The Staff’s conclusion that there is nothing “extraordinary” or “unique” about the Pa’ina Hawaii applicants was based on primarily on the collective experience and professional judgment of the members of the Staff completing the safety review of the application, as informed by the application and responses to requests for additional information, site visits to the proposed location of the irradiator in Hawaii and the facilities in Pennsylvania where the irradiator will be manufactured, and knowledge of other licensed irradiators. The Staff reviewed all available information to ensure that there is nothing about the proposed Pa’ina Hawaii

irradiator that would distinguish it from other irradiators of comparable design and source size. Of particular interest throughout the review have been the issues raised by Concerned Citizens regarding the location of the irradiator and the potential for aircraft crashes, hurricanes, tsunamis, and earthquakes. In this regard, the Staff's site visits in Honolulu have ensured the Staff that the site and design have been adequately described in the application, and the Staff has confirmed that there are currently licensed irradiators in similar localities, including several irradiators located at or near airports, irradiators located in coastal areas or other hurricane-prone regions, and irradiators located in areas of seismic activity. The Staff's review has confirmed that there is nothing about either the design or location of the proposed Pa'ina Hawaii irradiator that would distinguish it from irradiators previously licensed by the NRC. Again, this review primarily assures the Staff that they have all necessary information and that there is nothing indicating that established guidance documents are not appropriate for evaluating this facility.

- e. With regard to the Staff's safety review and any of its safety conclusions, did it rely, in whole or in part, upon the "Draft Topical Report on the Effects of Potential Aviation Accidents and Natural Phenomena at the Proposed Pa'ina Hawaii, LLC, Irradiator Facility"?

Although the members of the Staff completing the safety review are, of course, aware of the Draft Topical Report, it did not form the basis for any of the conclusions reached with regard to the safety-related review of the application.

2. In responding to the Intervenor's new contentions regarding the draft environmental assessment and draft topical report, the Staff stated it "does not contest the admissibility of the portion of Safety Contention #13 related to the probability analysis," and further that it "does not object to the admission of the portions of Contention #13 related to analysis of debris force from potential aviation accidents."

The Board is at a loss to understand how the Staff on the one hand, in its March 12 response to the contentions, concedes the admissibility of Intervenor's Safety Contention #13 and, on the other hand, in its May 21 response to our questions, insists that no safety review was performed regarding aircraft crash probabilities and consequences nor is any such review required.

- a. Explain how the Staff, consistent with its concession of admissibility of Intervenor Safety Contention #13, can now claim in its response to our original questions that the Commission's safety regulations effectively bar consideration of aircraft crashes and, therefore, do not permit establishing a threshold probability for design basis.

The Staff has conceded that the portion of Safety Contention #13 related to the calculation of the probability of an aircraft crash at the proposed facility is admissible from either a safety or an environmental standpoint for two reasons.² First, when the applicant moved to dismiss Safety Contention #7 on the basis that the Staff had performed the calculation allegedly omitted from the application, the Staff's calculation effectively became part of the application and, therefore, within the scope of the proceeding. Second, and more importantly, although the probability of an aircraft crash was calculated as part of the Staff's environmental review, had the Staff performed such a calculation during its safety review, it would have reached the same probability. Therefore, it would be illogical to deny admissibility of a contention related to the probability calculation because it was labeled a "safety" contention rather than an "environmental" contention.

In contrast, the analysis of the consequences of a potential aircraft crashes was completed specifically for the Staff's environmental review. As discussed more fully in the Staff's May 21, 2007 response, there are different regulatory standards for environmental and safety reviews, and, thus an analysis of the consequences of a potential aircraft crashes completed for the Staff's safety review would differ from the present analysis completed for the Staff's environmental review. However, the intervenors did not distinguish between safety reviews and environmental reviews and provided an identical basis for both Safety Contention #13 and the portion of Environmental Contention #3 related to the aircraft crash consequence analysis. For this reason, the Staff stated in its Contention Response that "*in the context of the*

² NRC Staff Response to Intervenor Concerned Citizens of Honolulu's Contentions Re: Draft Environmental Assessment and Draft Topical Report (March 12, 2007) ("Contention Response") at 4.

Staff's obligations under NEPA, the Staff does not object to the admission of the portions of Contention #13 related to analysis of debris force from potential aviation accidents,” and discussed the specific admissibility of the issues related to the Staff’s analysis of the consequences of aircraft crashes as part of its analysis of Environmental Contention #3. Contention Response at 4, 10 (emphasis added). Although the Staff’s response to Safety Contention #13 was admittedly unclear, it was not intended to imply that the portion of Safety Contention #13 related to the aircraft consequence analysis is admissible.

- b. If Safety Contention #13 is admissible, as conceded by the Staff, what safety issues related to aircraft crash probabilities and consequences are to be litigated in light of the Staff’s latest statement that no safety review has been performed or will be performed with respect to aircraft crash probabilities and consequences?

As stated above, the Staff concedes that the portion of the Safety Contention #13 related to the calculation of the **probability** of an aircraft crash at the proposed irradiator is admissible, and, therefore, questions regarding the accuracy or sufficiency of that calculation are litigable. The Staff maintains that there are no litigable *safety* issues with regard to the Staff’s analysis of the **consequences** of an aircraft crash at the proposed irradiator.

Respectfully submitted,

/RA by Margaret J. Bupp/

Margaret J. Bupp
Counsel for the NRC Staff

Dated at Rockville, Maryland
this 13th day of June, 2007

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NUCLEAR REGULATORY COMMISSION

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CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF RESPONSE TO THE LICENSING BOARD'S JUNE 6, 2007 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 13th day of June, 2007.

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