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 INITIAL BRIEF IN RESPONSE TO CLI-08-04

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April 10, 2008

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INTRODUCTION

On March 27, 2008, the Commission invited the parties to brief two issues relating to the scope of the potential environmental impacts that the Nuclear Regulatory Commission (NRC) must consider in reviews under the National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321–4437 (NEPA). Those issues are: (1) whether the NRC lacks authority to reject an irradiator license for nonradiological food safety reasons and therefore need not consider food safety under NEPA, and (2) whether in light of NEPA's "rule of reason," the Food and Drug Administration's (FDA's) comprehensive review and regulation of the safety of irradiated foods, including NEPA reviews, excuse NRC from considering food safety in its own NEPA reviews. *Pa'ina Hawaii, LLC*, CLI-08-04, 67 NRC __ (slip op. at 2–3). The Staff respectfully submits that the NRC lacks the authority to reject an irradiator license for nonradiological food safety reasons and, therefore, the NRC did not have to consider hazards allegedly linked to the consumption of irradiated food in determining whether issuing Pa'ina a materials license is a major federal action requiring preparation of an environmental impact statement (EIS). The Staff further submits that NEPA's rule of reason provides an independent basis for reaching this same conclusion.

BACKGROUND

On June 27, 2005, Pa'ina applied for a license to possess byproduct material to be used at an irradiator in Honolulu, Hawaii.[1] Pa'ina plans to use its facility to irradiate fresh fruit and vegetables for shipment to the United States mainland, as well as to irradiate cosmetics and pharmaceutical products.[2] On August 2, 2005, the Staff placed notice in the Federal Register of the opportunity to request a hearing on this licensing action.[3] The Federal Register notice addressed the scope of the licensing action, explaining that the Staff's review of Pa'ina's application would focus on the safety, physical security, and emergency preparedness aspects of radioactive material to be used in the irradiator.[4] The notice explained that "other federal agencies, such as the U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA), are responsible for determining the food types and products used for human consumption that may be safely irradiated."[5] The Federal Register notice also stated that an environmental assessment (EA) for the licensing action was not required, because the action was categorically excluded from NEPA review under 10 C.F.R. § 51.22(c)(14)(vii).[6]

On October 3, 2005, Concerned Citizens of Honolulu (Intervenor) filed its hearing request, setting forth numerous safety and environmental contentions.[7] Among its

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

[2] *Id.* at 8–9.

[3] *Notice of License Request for Pa'ina Hawaii, LLC, Irradiator in Honolulu, HI and Opportunity To Request a Hearing*, 70 Fed. Reg. 44,396 (August 2, 2005).

[4] *Id.* at 44,396.

[5] *Id.*

[6] *Id.*

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

environmental contentions, the Intervenor argued 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.[8] The Board admitted this contention, along with a portion of another environmental contention in which the Intervenor argued that risks associated with aircraft crashes, tsunamis and hurricanes constitute "special circumstances."[9]

In its hearing request, the Intervenor also argued that the irradiation of papayas and mangos, two fruits Pa'ina intends to process at its facility, may cause adverse human health impacts and that these potential impacts also constitute special circumstances precluding the Staff from relying on the categorical exclusion at 10 C.F.R. § 51.22(c)(14)(vii).[10] The Board rejected this argument, finding that the Intervenor "present[ed] only speculation, not facts, to support its claim."[11] The Board noted that the Intervenor's own expert asserted no more than that health impacts associated with the consumption of irradiated food is "the subject of considerable scientific debate."[12] Further, the Board explained that, in its hearing notice, the

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[8] *Id.* at 22–24.

[9] Memorandum and Order (Ruling on Petitioner's Standing and Environmental Contentions), LBP-06-4, 63 NRC 99, 112–13 (2006). In a separate ruling, the Board admitted three safety contentions. Memorandum and Order (Ruling on Petitioner's Safety Contentions), LBP-06-12, 63 NRC 403, 415, 418, 420 (2006).

[10] Hearing Request at 22–24.

[11] *Pa'ina Hawaii, LLC,* LBP-06-04, 63 NRC at 144.

[12] *Id*.

Commission had stated that it is the responsibility of the FDA and the USDA to determine the food types used for human consumption that may be safely irradiated.[13] "In light of these factors," the Board concluded, "the Petitioner's speculative claim concerning the possible health effects of irradiating papayas and mangos does not rise to the level of special circumstances necessary to invoke the exception under 10 C.F.R. § 51.22(b) for the categorical exclusion of irradiators."[14] The Board therefore found the Intervenor's contention related to the safety of irradiated food inadmissible.

On March 20, 2006, the Intervenor and the Staff entered into a joint stipulation resolving all issues associated with the Intervenor's admitted environmental contentions.[15] As part of that stipulation, the Staff agreed to prepare an EA concerning Pa'ina's application. The Staff released draft and final EAs on December 21, 2006 and August 10, 2007,[16] and the Intervenor filed amended environmental contentions challenging the analysis in each document.[17] Among its amended contentions, the Intervenor argued that the EAs failed to analyze potential health risks related to the consumption of irradiated food.[18] The Intervenor's arguments on irradiated food were the same as those set forth in its initial contention—except they now challenged the

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[13] *Id.*

[14] *Id.* at 114–15.

[15] NRC Staff and Concerned Citizens of Honolulu Joint Motion to Dismiss Environmental Contentions (March 20, 2006) (ADAMS ML060820592).

[16] Draft Environmental Assessment Related to the Proposed Pa'ina Hawaii, LLC Underwater Irradiator in Honolulu, Hawaii (December 21, 2006) (ADAMS ML063470231); Final Environmental Assessment for Proposed Pa'ina Hawaii, LLC Underwater Irradiator in Honolulu, Hawaii, (August 10, 2007) (ADAMS ML071150121).

[17] Intervenor's Contentions Re: Draft Environmental Assessment and Draft Topical Report (February 9, 2007) (ADAMS ML070510116); Intervenor Concerned Citizens of Honolulu's Amended Environmental Contentions #3 through #5 (September 4, 2007) (ADAMS ML072530634).

[18] Intervenor's Amended Environmental Contentions #3 through #5 at 29–30.

Staff's EAs, rather than reliance on a categorical exclusion—and the Intervenor merely referenced its earlier supporting basis in the amended contention.[19]

On December 21, 2007, the Board ruled on the Intervenor's amended environmental contentions.[20] Among other admitted contentions, the Board admitted the fifth portion of amended environmental contention 3, which alleged that the Final EA improperly failed to consider adverse effects on human health potentially linked to the consumption of irradiated food.[21] The Board reasoned that "the use of the product of the irradiator is an inextricably intertwined connected action that may require the Staff to consider in the final EA the possible health effects of human consumption of irradiated tropical fruits."[22] The Board found that the Intervenor therefore raised an admissible contention consisting of a legal issue that can only be resolved after the contention is fully briefed.[23] The Board did not explain, however, why the Staff would have to consider in an EA the particular health effects alleged by the Intervenor—an increased cancer risk from consuming irradiated papayas and mangos—if, as the Board found previously, the Intervenor's claim rested on "only speculation, not facts"[24] and the supporting basis for the Intervenor's contention had not changed. In other words, the Board did not

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[19] *Id.* (citing "Declaration of William W. Au in Support of Petitioner's Areas of Concerns" (September 29, 2005) at ¶ 6).

[20] Memorandum and Order (Ruling on Admissibility of Intervenor's Amended Environmental Contentions) (December 21, 2007) (unpublished).

[21] *Id.* (slip op. at 20–23).

[22] *Id.* (slip op. at 22–23).

[23] *Id.* (slip op. at 23).

[24] *Pa'ina Hawaii, LLC,* LBP-06-04, 63 NRC at 144.

address how, under NEPA, the health risks alleged by the Intervenor could be considered "effects" of licensing Pa'ina's irradiator to the extent they are based on mere speculation.[25]

DISCUSSION

1. The NRC Lacks the Authority to Reject an Irradiator Application Based on Nonradiological Food Safety Impacts and, Accordingly, Does Not Need to Consider Those Impacts in Determining Whether to Prepare an Environmental Impact Statement

A federal agency can act only within the scope of its statutory authority. *See Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374, (1986) (holding that "an agency literally has no power to act . . . unless and until Congress confers power upon it"); *cf. Atlantic City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) (noting that the Federal Energy Regulatory Commission "is a creature of statute, having no constitutional or common law existence or authority, but only those authorities conferred upon it by Congress") (internal quotation marks and citation omitted). To the extent the NRC has the authority to reject an irradiator license for nonradiological food safety reasons, that authority would be granted by either NEPA or the Atomic Energy Act of 1954, 42 U.S.C. §§ 2011–2297 (AEA). As discussed next, however, neither statute confers such authority.[26]

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[25] *See* 40 C.F.R. § 1508.8(b) (defining "indirect effects" of an agency action as effects "which are caused by the action and are later in time or farther removed in distance, *but are still reasonably foreseeable*") (emphasis added); 40 C.F.R. § 1508.7 (defining "cumulative impact" as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and *reasonably foreseeable future actions*") (emphasis added). *See also No Gwen Alliance, Inc. v. Aldridge*, 855 F.2d 1380, 1386 (9th Cir. 1988) (holding that merely speculative propositions need not be discussed in either an EA or EIS). In other words, the Board identified a general legal issue—whether in certain circumstances the Staff might have to consider health risks related to the consumption of irradiated foods—but did not explain why this issue need even be reached to the extent the Intervenor is unable to show that the adverse health impacts it alleges might be reasonably foreseeable impacts of licensing Pa'ina's irradiator.

[26] The Energy Reorganization Act of 1974 (ERA), 42 U.S.C. §§ 5801–5879, also provides the NRC with substantive authority. However, none of the ERA's provisions would appear to grant the NRC regulatory authority over nonradiological hazards involving irradiators.

A. NEPA Does Not Provide the NRC with the Authority to Reject an Irradiator Application for Nonradiological Food Safety Reasons

It is well established that NEPA does not impose substantive requirements on agency decisionmaking. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350–53 (1989). *See also Natural Resources Defense Council v. EPA*, 822 F.2d 104,129 (D.C. Cir. 1987) (explaining that "NEPA's mandate is, of course, procedural. . . . NEPA's mandate, however, stops at this requirement; NEPA does not require that certain outcomes be reached as a result of the evaluation."). The Supreme Court recently affirmed the limited nature of NEPA's mandate, holding that "NEPA imposes only procedural requirements on federal agencies with a particular focus on requiring agencies to undertake analyses of the environmental impact of their proposals and actions." *Department of Transportation v. Public Citizen*, 541 U.S. 752, 757–58 (2004). These decisions firmly establish that, while NEPA prescribes the process for agency decisionmaking, it does not prescribe substantive requirements that agencies must satisfy.

Nor does NEPA provide substantive authority upon which an agency might deny a license application based on factors otherwise outside the scope of the agency's statutory authority. *Winnebago Tribe v. Ray*, 621 F.2d 269, 272-73 (8th Cir. 1980), *cert denied*, 449 U.S. 836 (1980); *Kitchen v. FCC*, 464 F.2d 801, 802–03 (D.C. Cir. 1972). Because NEPA does not broaden an agency's existing authority, whatever action an agency chooses to take must be within its province in the first instance. *Natural Resources Defense Council*, 822 F.2d at 129. *See also Gage v. AEC*, 479 F.2d 1214, 1221 n.19 (D.C. Cir. 1973) (holding that regulating the acquisition of land for purposes of potential construction may very well have exceeded the

Atomic Energy Commission's (AEC's) organic power and that NEPA did not authorize action going beyond an agency's organic jurisdiction).[27]

The NRC's understanding of its authority to regulate nonradiological environmental impacts under NEPA changed, for a period of time, after the D.C. Circuit's 1971 decision in *Calvert Cliffs' Coordinating Comm., Inc. v. AEC*, 449 F.2d 1109, 1113 n.4 (D.C. Cir. 1971). *Calvert Cliffs* held that NEPA not only permitted, but compelled, the AEC[28] to take environmental values into account. *Id.* at 1112–1113. After *Calvert Cliffs*, the Commission no longer confined its NEPA reviews to radiological hazards. *See, e.g., Public Service Company of New Hampshire v. NRC*, 582 F.2d 77 (1st Cir. 1978) (affirming the Commission's finding that, based on authority provided by NEPA and the AEA, the NRC could regulate nonradiological environmental impacts related to utility transmission lines); *Detroit Edison v. NRC*, 630 F.2d 450, 452 (6th Cir. 1980) (same). These cases were decided before *Methow Valley* and *Natural Resources Defense Council*, however, and based on those intervening decisions, the Staff submits that NEPA does not provide the NRC with the substantive authority to deny a license or impose license conditions. Indeed, since *Methow Valley*, it does not appear that any federal court has permitted an agency to rely upon NEPA itself to deny a license or impose license conditions.

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[27] Further, regulations issued by the Council on Environmental Quality (CEQ), which has advisory responsibilities under NEPA, do not broaden an agency's substantive authority under NEPA. *See Natural Resources Defense Council,* 822 F.2d at 129 n.25 (holding that CEQ regulations could not broaden an agency's authority beyond that set forth in its organic statute).

[28] The ERA established the NRC and transferred the AEC's licensing and regulatory functions to the NRC. 42 U.S.C. §§ 5841–42.

B. The Atomic Energy Act Does Not Provide the NRC with the Authority to Reject an Irradiator License for Nonradiological Reasons

The NRC derives its authority to issue licenses for nuclear materials and nuclear facilities from the AEA. The NRC's authority to license irradiators is found in Section 81 of the AEA, 42 U.S.C. § 2111, while Section 161 authorizes the Commission to "establish by rule, regulation, or order, such standards and instructions to govern the possession and use of special nuclear material, source material, and byproduct material as the Commission may deem necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property[.]" 42 U.S.C. § 2201(b). Consistent with the authority provided in sections 81 and 161, the NRC issued regulations that the Staff applied in licensing Pa'ina's irradiator. The regulations applying to irradiators specifically are contained in 10 C.F.R. Part 36, "Licenses and Radiation Safety Requirements for Irradiators."

As its title makes clear, Part 36 is concerned with radiological, rather than nonradiological, health and safety risks. That is because the NRC's authority to regulate irradiators originates from Section 81 and 161 of the AEA, which are concerned with radiological risks to health and safety. The view that Sections 81 and 161 pertain to radiological, rather than nonradiological, risks is supported by case law predating the NRC's establishment. In *New Hampshire v. AEC*, 406 F.2d 170, 175 (1st Cir. 1969), the First Circuit found that, through the AEA's provisions mandating that the AEC protect the common defense and security and the health and safety of the public, "Congress has viewed the responsibility of the Commission as being confined to scrutiny of and protection against hazards from radiation."[29] *See also Detroit*

[29] The First Circuit further explained that its understanding was bolstered by an examination of the legislative history of the 1954 AEA legislation, which revealed that Congress, "in thinking of the public's health and safety, had in mind only the special hazards of radioactivity." *New Hampshire v. AEC*, 406 F.2d 170, 174, n.4 (1st Cir. 1969), *cert. denied*, 395 U.S. 962 (1969) (citing S. Rep. No. 1699, Vol. I, Legislative History of the Atomic Energy Act of 1954, p. 751; H.R. Rep. No. 2181, *id*., p. 99, reprinted in U.S.C.C.A.N. 3458).

Edison, 630 F.2d at 451 (noting that prior to NEPA's enactment, “the Commission perceived its duties under the Atomic Energy Act primarily in terms of protecting the public from radiation hazards”); *Calvert Cliffs,* 449 F.2d at 1113 n.4 (noting that the Commission’s original understanding was that its statutory mandate for regulating licensees did not extend beyond the radiation hazards posed by its regulatory actions, because its special expertise was limited to radiological matters).

The view that the Commission has the authority to regulate only radiological hazards pertaining to irradiators is supported by the text of Section 81 and the structure of the AEA as a whole. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43, 845 (1984) (explaining that the first step in determining the meaning of a statutory provision is to consider its language and its context in the regulatory framework or statute as a whole). *See also Kokoszka v. Belford*, 417 U.S. 642, 650 (1974) (explaining that to determine Congress’s intent in enacting a statute, a court “will not look merely to a particular clause in which general words may be used, but will take in connection with it the whole statute[.]"); *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs.*, 484 U.S. 365, 371 (1988) (noting that “a provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme"). Section 81 provides that:

> No person may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, own, possess, import, or export any byproduct material, except to the extent authorized by this section, section 82 or section 84. The Commission is authorized to issue general or specific licenses to applicants seeking to use byproduct material for research or development purposes, for medical therapy, industrial uses, agricultural uses, or such other useful applications as may be developed. . . . The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.
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> . . . .

42 U.S.C. 2111(a). Nowhere does Section 81 mention nonradiological hazards. This stands in contrast to Section 84 of the AEA, "Authorities of Commission Respecting Certain Byproduct Material," which applies to uranium mill tailings and other material defined as "byproduct material" under Section 11.e.(2) of the AEA.[30] Section 84.a.(1) states, in pertinent part:

> The Commission shall insure that the management of any byproduct material, as defined in section 11e.(2), is carried out in such manner as (1) the Commission deems appropriate to protect the public health and safety and the environment from *radiological and non-radiological* hazards associated with the processing and with the possession and transfer of such material taking into account the risk to the public health, safety, and the environment, with due consideration of the economic costs and such other factors as the Commission determines to be appropriate[.]

42 U.S.C. § 2114 (emphasis added). This section unambiguously grants the Commission the authority to regulate both radiological *and* nonradiological hazards associated with 11.e.(2) byproduct material.

Interpreting Section 81 in the context of AEA Chapter 8 (Sections 81–84) as a whole, 42 U.S.C., §§ 2111–2114, makes clear that section 81 vests the Commission with the authority to regulate only radiological hazards. Had Congress intended for Section 81 to apply to nonradiological hazards, it could have included in that section language analogous to that of Section 84. Conversely, had Congress understood Section 81 to provide the Commission with the authority to regulate nonradiological hazards, the language in Section 84.a.(1) would have been unnecessary.[31] *See, e.g., Am. Nat'l Red Cross v. S.G.*, 505 U.S. 247, 263 (1992) (explaining that traditional principles of statutory construction counsel against reading

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[30] Section 84 is not relevant to Pa'ina's application because the material to be used in Pa'ina's irradiator is 11.e.(4) byproduct material, not 11.e.(2) material.

[31] Section 84 was added to the AEA pursuant to Section 205 the Uranium Mill Tailings Radiation Control Act of 1978 (UMTRCA), 42 U.S.C. § 7901–7942. Section 275 of the AEA, "Health and Environmental Standards for Uranium Mill Tailings," which was also added by UMTRCA, refers to "non-radiological hazards" as well. Section 274 of the AEA, "Cooperation with States," refers to "nonradiological hazards," but only in the context of 11.e.(2) byproduct material. The Staff has not found any other AEA section mentioning either "non-radiological" or "nonradiological" hazards.

Congressional enactments as superfluous). Congress's decision to give the Commission authority over nonradiological hazards associated with 11.e.(2) byproduct material thus demonstrates that it did not intend to confer on the Commission authority over nonradiological hazards associated with *non*-11.e.(2) material, such as that to be used at Pa'ina's irradiator. *Cf. Cal. Indep. Sys. Operator Corp. v. FERC*, 372 F.3d 395, 401 (D.C. Cir. 2004) (holding that Congress's "specific and limited enumeration of FERC's power over corporate governance in section 305 [of the Federal Power Act] is strong evidence that section 206(a) confers no such authority on FERC").

Thus, examining the text and structure of the AEA's relevant provisions leads to the conclusion that the NRC does not have the authority to deny an irradiator license for nonradiological reasons. Although the Staff believes this conclusion is clear from the text and structure of the AEA, it is further supported by the legislative history of the AEA, which shows that, in adopting the statute, Congress "had in mind only the special hazards of radioactivity." *New Hampshire*, 406 F.2d at 174 n.4. *See also Securities Indus. Assn. v. Federal Reserve Sys.*, 847 F.2d 890, 893 (D.C. Cir. 1988) (holding that a court may examine a statutory provision's contemporaneous legislative history if the provision's meaning is not clear from its text and structure). Moreover, the NRC's interpretation of the AEA's statutory provisions pertaining to irradiators, as reflected in Part 36, which applies to *radiation* hazards, is consistent with this conclusion. *See NLRB v. United Food & Commercial Workers Union, Local 23*, 484 U.S. 112, 123–24 (1987) (holding that if Congress's intent is not clear based on a review of statutory language and legislative history, a court may rely on an reasonable interpretation by the agency charged with administering the statute).

Accordingly, in the case of an irradiator application like Pa'ina's, the NRC lacks the authority to impose license conditions based solely on nonradiological impacts or—to answer the question posed by the Commission—deny a license based on those impacts.

C. Because the NRC Lacks the Authority to Deny an Irradiator Application Based on Nonradiological Food Safety Impacts, It Need Not Consider Those Impacts in Determining Whether to Prepare an Environmental Impact Statement

In *Public Citizen*, the Supreme Court held that the Federal Motor Carrier Safety Administration (FMCSA) did not need to consider the environmental effects of Mexican motor carriers entering the United States under the North American Free Trade Agreement for purposes of determining whether the agency's action—issuing application and safety-monitoring regulations for those carriers—was a "major federal action" requiring the agency to prepare an EIS.[32] 541 U.S. at 770. The Court reasoned that, "where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant 'cause' of the effect." *Id.* The "critical feature" of the case, in the Court's view, was the fact that FMCSA lacked the ability to countermand the President's lifting of a twenty-year moratorium on Mexican motor carriers entering the United States or to otherwise categorically exclude Mexican motor carriers from operating within the United States. *Id.* at 766. "FMCSA has only limited discretion regarding motor vehicle carrier registration; it must grant registration to all domestic or foreign motor carriers that are 'willing and able to comply with' the applicable safety, fitness, and financial-responsibility requirements, and FMCSA has no statutory authority to impose or enforce emissions controls or to establish environmental requirements unrelated to motor carrier safety." *Id.* at 758-59 (citation omitted). Moreover, the Court found that neither of the purposes of NEPA—informing the public and ensuring agency consideration of the environmental impacts of its actions—would be served by requiring FMCSA to consider the impacts of Mexican motor carriers. Knowledge of the

[32] *Public Citizen* did not address whether, had its rulemaking been a major federal action, FMCSA would have been required to address these effects in its EIS. Although that issue appears to be within the scope of the Commission's briefing invitation, the Staff respectfully declines to address that issue because its resolution is not essential to a ruling in the present case.

environmental impacts of Mexican motor carriers would not have affected FMCSA decisionmaking because FMCSA simply lacked the power to act on such information. *Id.* at 768.

The NRC's statutory mandate, as it pertains to nonradiological impacts from irradiators, is analogous to that of FMCSA. Under Section 81 of the AEA, the NRC may deny an application seeking a materials license for industrial or agricultural uses—Pa'ina's intended uses—only where the applicant is not equipped to comply with the NRC's radiological safety requirements. As in the case of FMCSA, the NRC cannot deny a license to an applicant if the applicant is capable of complying with the agency's safety licensing requirements; the "critical feature" upon which the Court relied in *Public Citizen* is thus present here. 541 U.S. at 766. Further, although the second sentence of Section 81 states that the Commission is "authorized" to issue licenses—language that might suggest the NRC has discretion to not issue licenses—this language is qualified by Section 81's subsequent description of the circumstances under which the Commission shall deny a license application. The only ground given for denying a license under Section 81 is that the applicant is not equipped to observe the NRC's safety standards. That these standards are *radiological* safety standards has been established above. *Natural Resources Defense Council*, 822 F.2d at 129–30; *New Hampshire*, 406 F.2d at 175. Accordingly, under Section 81, the NRC may not deny an irradiator application for nonradiological reasons. The NRC lacks authority over the nonradiological impacts of irradiators to the same degree that FMCSA lacks authority over the environmental impacts of Mexican motor carriers entering the United States. Because the NRC lacks authority over these impacts, it does not need to consider them in an EA. *Public Citizen*, 541 U.S. at 770.

A number of lower court decisions have emphasized that *Public Citizen*'s holding is limited to circumstances where the agency truly has "no ability" to take actions that could lessen environmental impacts of concern to the plaintiffs. For example, courts have held that an

agency does not lack authority over environmental effects where only its own regulations prevent the agency from considering an effect, or where the agency has the discretion to not issue a rule limiting consideration of the effect. *Sierra Club v. Mainella*, 459 F. Supp. 2d 76 (D.D.C. 2006); *Center for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 508 F.3d 508, 546-547 (9th Cir. 2007); *Oregon Natural Res. Council Fund v. Brong*, 492 F.3d 1120, 1134 (9th Cir. 2007). Those cases are not relevant here, where the NRC's authority to deny an irradiator application for nonradiological reasons is limited by the AEA itself, not merely the NRC's regulations. Nor did the NRC's adoption of Part 36 represent any discretionary decision on the part of the NRC to license irradiators. Although 10 C.F.R. Part 36 sets forth irradiator licensing requirements, Part 36 merely consolidated and clarified the existing requirements for irradiator licensing and operation. *License and Radiation Safety Requirements for Irradiators*, 58 Fed. Reg. 7715, 7716 (February 9, 1993) (final rule).[33] Even without any regulatory action on the part of the NRC, an interested person could have submitted an application for an irradiator license, which the NRC would have had to consider under the criteria in Section 81 of the AEA.

Although under *Public Citizen* the NRC is not *required* to consider nonradiological impacts in an EA, agency practice has been to discuss such impacts in certain instances where the discussion would further NEPA's public information purpose.[34] For example, in the present licensing action, the Staff received a comment stating that the irradiator facility would be an

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[33] *See also* 55 Fed. Reg. 50008, 50010 (December 4, 1990) (proposed rule) (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").

[34] *See Recommendations for the Preparation of Environmental Assessments and Environmental Impact Statements (the Green Book), Second Edition* (2004) at 28 (explaining that "[b]ecause one purpose of NEPA analysis is to inform the public, consider analyzing an accident scenario in which the public has expressed a keen interest, even when the scenario is not reasonably foreseeable").

"awful sight to see."[35] It is in this context that the Staff assessed the potential visual impacts of the irradiator, which would be nonradiological impacts, explaining that because the irradiator will be enclosed in an industrial-type building of size and color similar to other buildings at the Honolulu International Airport, no visual impacts are expected.[36] On the other hand, where the alleged nonradiological impacts have been comprehensively reviewed by other agencies with relevant expertise, the NRC may decide it is more appropriate to identify and summarize the other agencies' analyses, as the Staff did here with respect to food safety.[37] The NRC is in this sense applying a variant of the "rule of reason" discussed in the next section, deciding whether and to what extent to consider nonradiological impacts in an EA based on the degree to which such information would further NEPA's public information purpose.

II. In Light of NEPA's "Rule of Reason," the Staff Does Not Need to Consider Nonradiological Food Safety Impacts in Determining Whether Licensing an Irradiator is a "Major Federal Action"

The Supreme Court in *Public Citizen* held that there was another, independent, reason why FMCSA did not need to consider the environmental effects of Mexican motor carriers in determining whether the agency's rulemaking required preparation of an EIS. The Court explained that inherent in NEPA and its implementing regulations is a "rule of reason," which ensures that agencies determine whether and to what extent to prepare an EIS based on the usefulness of any new potential information to the decisionmaking process. 541 U.S. at 767 (citing *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 375–376 (1989)).

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[35] Final EA at C-12.

[36] *Id.* at 7.

[37] *See Id.* at C-8, C-9, C-18 (citing FDA sources); 8–9, 12–15, C-13 (citing USDA or APHIS sources).

"Where the preparation of an EIS would serve 'no purpose' in light of NEPA's regulatory scheme as a whole," the Court found, "no rule of reason worthy of that title would require an agency to prepare an EIS." *Id.* at 767–68 (citing *Aberdeen & Rockfish R. Co. v. Students Challenging Regulatory Agency Procedures (SCRAP)*, 422 U.S. 289, 325 (1975); 40 C.F.R. §§ 1500.1(b)–(c) (2003)).[38]

Applying NEPA's rule of reason here, it is apparent that the NRC need not consider food safety issues unrelated to radiological safety in determining whether to prepare an EIS. Food safety is within the specific statutory mandate of the FDA and USDA, agencies with specialized expertise in assessing nonradiological food safety hazards. The FDA and USDA have regulations specifically addressing the issues raised by the Intervenor here,[39] and—as the Commission noted in its briefing invitation—in issuing its rules the FDA has in fact considered the very studies upon which the Intervenor relies.[40] The rulemaking of the FDA and USDA fully encompasses all the hazards alleged by the Intervenor; there is no radiological component to the alleged food safety hazard that might arguably fall outside the expertise of the FDA or USDA and within the province of the NRC. The NRC relied on FDA rulemaking when promulgating

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[38] Although *Public Citizen* confirmed that a rule of reason exists under NEPA, this rule had previously been applied by lower federal courts relying on 40 C.F.R. § 1500.1 to find that agencies, in their NEPA analyses, did not need to consider environmental impacts where those analyses would serve no useful purpose. *See, e.g., Idaho Conservation League v. Bennett*, 2005 U.S. Dist. LEXIS 35356, 22–23 (D. Idaho 2005) (explaining that "the purpose of an EA is not to collect massive amounts of needless detail but to provide analysis on the most significant aspects of an action in a brief and concise manner"); *Defenders of Wildlife v. Hogarth*, 330 F.3d 1358, 1373 (Fed. Cir. 2003) (holding that "NEPA's purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action"); *Valley Citizens for Safe Environment v. Aldridge*, 695 F. Supp. 605, 610-611 (D. Mass. 1988) ("NEPA documents must concentrate on the issues that are truly significant to the action in question, rather than amassing needless detail").

[39] *See* 21 C.F.R. §§ 170.21–45 (FDA); 7 C.F.R. §§ 305.31–34 (USDA).

[40] *Pa'ina Hawaii, LLC*, CLI-08-04, 67 NRC __ (slip op. at 3 n.9) (citing 70 Fed. Reg. 48,057, 48,067 (Aug. 16, 2005)).

Part 36,[41] and it is eminently reasonable for the NRC to rely on the FDA's and USDA's continuing regulatory actions to conclude that the NRC need not consider nonradiological food safety issues. Given these other agencies' comprehensive evaluations of potential nonradiological food safety hazards, it simply would not be useful for the NRC to independently analyze those hazards. The NRC's evaluation would, in other words, "serve no purpose in light of NEPA's regulatory scheme as a whole." *Public Citizen*, 541 U.S. at 767–68. Further, as the Supreme Court has emphasized, NEPA's demands must "remain manageable" if its goals are to be met; otherwise, "available resources may be spread so thin that agencies are unable adequately to pursue protection of the physical environment and natural resources." *Metropolitan Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 776 (1983). Requiring the NRC to consider nonradiological food safety hazards in its EAs would divert agency resources with no benefit to either the NRC's decisionmaking process. Accordingly, under NEPA's rule of reason, the NRC need not consider these nonradiological impacts in determining whether to prepare an EIS.

Even if the Commission were to find that NEPA's rule of reason does not exempt the NRC from considering nonradiological food safety issues in its EAs, there would still be no need to require the Staff to independently analyze those issues in the present case. That is because CEQ regulations expressly permit—and encourage—agencies to rely on existing environmental analyses prepared by other agencies. *See, e.g.*, 40 C.F.R. § 1500.4 ("Reducing paperwork"), § 1502.20 ("Tiering"), § 1502.21 ("Incorporation by Reference"). Relying on these regulations, courts have held that where another agency's environmental analysis addresses the same

[41] In its Statement of Consideration for the proposed rule, the NRC noted, "The Food and Drug Administration has approved the use of gamma irradiation for the disinfestation and preservation of foodstuffs (21 CFR 179.26). Any food may be irradiated up to 100,000 rads (1,000 grays) for the purpose of disinfestation, such as to kill insects and parasites." *Licenses and Radiation Safety Requirements for Large Irradiators*, 55 Fed. Reg. 50,008, 50,009–10 (December 4, 1990).

issues faced by an agency preparing an EA, the latter agency is not required to duplicate the work already performed. *San Francisco Baykeeper v. United States Army Corps of Eng'rs*, 219 F. Supp. 2d 1001, 1013 (D. Cal. 2002). *See also Sierra Club v. United States Army Corps of Eng'rs*, 295 F.3d 1209, 1215 (11th Cir. 2002) (holding that an agency is not required to duplicate work done by another federal agency that has jurisdiction over a project); *Piedmont Envtl. Council v. Strock*, 394 F. Supp. 2d 803, 812 (D. W. Va. 2005) (same). Here, the Staff considered both the FDA's position on the human consumption of irradiated food and three recently issued USDA rules addressing the safety of irradiated fruits and vegetables.[42] The USDA's 2006 rulemaking specifically addressed the safety of irradiation treatment for imported fruits and vegetables, including products imported to the U.S. mainland from Hawaii.[43] Further, the 2006 rulemaking was based on an EA prepared by the USDA that showed the irradiation of fruits and vegetables would have no significant impact on human health.[44] In these circumstances, the Staff's reliance on FDA and USDA regulatory actions discharged any obligation it had to consider nonradiological food safety issues in its EA for Pa'ina's irradiator.

Finally, the Staff would reiterate that, even if the NRC were required to consider certain nonradiological food safety impacts in its EAs, it would only have to consider *reasonably foreseeable* impacts, 40 C.F.R. § 1508.8(b), not the impacts alleged by the Intervenor here, which are based on "only speculation, not facts."[45]

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[42] *See* Final EA at 14–15 (citing rules issued by USDA's Animal and Plant Health Inspection Service); C-18 (FDA's position).

[43] *Treatment for Fruits and Vegetables*, 71 Fed. Reg. 4451 (February 27, 2006).

[44] *Irradiation for Phytosanitary Regulatory Treatment, Environmental Assessment* (October 1997).

[45] *Pa'ina Hawaii, LLC,* LBP-06-04, 63 NRC at 144.

CONCLUSION

The NRC lacks the authority to deny an irradiator license for nonradiological food safety reasons. Therefore, under *Public Citizen*, the Staff need not consider such issues in determining whether licensing an irradiator is a major federal action requiring preparation of an EIS. In addition, NEPA's "rule of reason" dictates that the Staff need not consider nonradiological food safety issues in an EA where those issues have been comprehensively addressed by the FDA and the USDA.

Respectfully submitted,

/RA/

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Dated at Rockville, Maryland
this 10th day of April, 2008

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

CERTIFICATE OF SERVICE

I hereby certify that copies of "NRC STAFF'S INITIAL BRIEF IN RESPONSE TO CLI-08-04" 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 10th day of April, 2008.

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