

RAS I-52

September 15, 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. 030-36974
)	
Materials License Application)	ASLBP No. 06-843-01-ML
)	

LICENSEE PA'INA HAWAII, LLC'S REBUTTAL MEMORANDUM IN OPPOSITION
 TO INTERVENOR CONCERNED CITIZENS OF HONOLULU'S AUGUST 26, 2008
 INITIAL WRITTEN STATEMENT OF POSITION
 AND
 IN RESPONSE TO NRC STAFF'S INITIAL STATEMENT OF POSITION
AND INITIAL WRITTEN TESTIMONY

DIRECT TESTIMONY OF MICHAEL KOHN

EXHIBIT A

CERTIFICATE OF SERVICE

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OFFICE OF SECRETARY
 RULEMAKINGS AND
 ADJUDICATIONS STAFF

TEMPLATE = SECY-037

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I. INTERVENOR FAILS TO CITE OR MENTION THE CURRENT
LEADING CASE IN THE 9th CIRCUIT REGARDING JUDICIAL
REVIEW OF AGENCY ACTIONS AND DECISIONS.

Now comes Licensee PA'INA HAWAII, LLC ("Pa'ina") and
submits its rebuttal to the legal arguments made by
Intervenor CONCERNED CITIZENS OF HONOLULU ("Intervenor") in
its Initial Written Statement of Position filed herein on
August 26, 2008.

On July 2, 2008 the 9th Circuit Court of Appeals,
sitting en banc, reversed a 3-judge panel within its own
circuit. See The Lands Council v. McNair, ___ F. 3d ___,
2008 U.S. App. LEXIS 13998, 2008 WL 264001 (9th Cir. July 2,
2008) In the McNair decision, the 9th Circuit announced a
"sea change" in the manner by which it would review agency

decisions. The Court specifically held that henceforth, it would defer to agency discretion unless the agency "entirely failed to consider an important aspect of the problem," or offered an explanation "that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" 2008 U.S. App. LEXIS 13998, at 11.

Furthermore, the 9th Circuit in McNair reiterated that it should be "most deferential" where federal agencies are making predictions or forecasts within their areas of special expertise. Id., at 30.

The 9th Circuit's recent McNair decision, where a decision of a federal agency (the Forest Service) was under review, was so different from the 9th Circuit's prior decisions that it has attracted the attention of other federal courts. Thus, the New Hampshire federal district court described the significance of the 9th Circuit's decision in the following words:

"The opinion in McNair is plainly one of the most significant environmental decisions issued by the Court of Appeals for the Ninth Circuit in recent years. Among other things, it acknowledges that that court's environmental jurisprudence, as expressed in various panels over time, has embraced the notion that federal courts should engage in a far more active role in the oversight of forest management than is legally appropriate. That opinion also reaffirms the limited and highly deferential standard of

review that courts must employ when asked to review decisions rendered by the Forest Service. Additionally, it either overrules or substantially undermines several [other] prominent panel opinions" Sierra Club v. Wagner, 2008 DNH 145; 2008 U.S. Dist. LEXIS 63470, at 10 (2008)

The New Hampshire federal district court went on to emphasize that the "comprehensive forest management plan" which had been created by the Forest Service had been "well thought out" after being "publicly vetted;" consequently, that plan deserved great deference in the particular lawsuit before the New Hampshire court. Id., at 11-13.

Unfortunately, in the case at bar, Intervenor did not cite, refer to or even mention the en banc decision of the 9th Circuit in McNair. Nor did Intervenor mention the "highly deferential" standard of review affirmed, or reaffirmed, in McNair. Thus, in this case, any other standard of review proposed by Intervenor regarding review of the Staff's EA is necessarily erroneous.

In light of the rationale underlying the McNair decision, it should be emphasized that the Nuclear Regulatory Commission has also established comprehensive, detailed rules governing irradiators and the licensing of irradiators. The comprehensive and detailed rules were "publicly vetted" by means of numerous public hearings.

The Staff's EA, which was performed and created within the framework of the detailed and comprehensive NRC regulatory program, deserves "great deference" herein.

Particularly in light of the 9th Circuit's McNair decision, all of Intervenor's remaining, purported contentions ought to be dismissed because those contentions essentially seek to micromanage the Staff's functions, and to deny any deference to that agency staff.

II. CONCLUSION.

Based upon the recent McNair decision by the 9th Circuit Court of Appeals, the proper standard of review of the Staff's Environmental Assessment (and Final Topical Report) in this case ought to be the "arbitrary and capricious" standard, with a "highly deferential" standard to be applied where the NRC Staff applied its predictive, scientific expertise, i.e., in virtually all of its review.

DATED: Honolulu, Hawaii Sept. 15, 2008.



FRED PAUL BENCO
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Pa'ina Hawaii, LLC

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
BEFORE THE SECRETARY

In the Matter of)
Pa'ina Hawaii, LLC) Docket No. 030-36974
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Materials License Application) ASLBP No. 06-843-01-ML
)

WRITTEN DIRECT TESTIMONY OF MICHAEL KOHN

Question.1: What is your name and title?

Answer.1. My name is Michael Kohn and I am the managing member of Pa'ina Hawaii, LLC. I have also owned and/or operated several other businesses involving food and food sales. I have 19 years of experience in packing, shipping and marketing Hawaii papaya and seafood around the world. I am responding to the NRC Staff's review and analysis of e-beam technology as set forth in its Final Environmental Assessment for the Pa'ina Hawaii, LLC Irradiator (transmitted August 17, 2007), and the NRC Staff's testimony transmitted to Pa'ina Hawaii, LLC on August 26, 2008.

Q.2: How and when did you become interested in irradiating produce and other products?

A.2: In the early 90's I became interested in shipping papayas to the US Mainland. However, the only USDA-approved treatment was by applying heat, which made it impossible to ship high quality, tree-ripened fruits to the Mainland, like we were then shipping to Europe. In 1996, I received a phone call from Dr. Lyle Wong of the Hawaii Department of Agriculture ("HDOA") asking me to participate in a pilot program by shipping untreated fruits to the mainland for irradiation. USDA only agreed to allow for untreated fruits to

be shipped directly to Chicago and Newark. Special trucking in sealed vehicles to the irradiation facilities added significantly to the already high cost of shipping on direct flights. Chicago, New Jersey and New York were not well-developed markets for Hawaii papayas. Still, despite the very high cost and the undeveloped markets we had no problems selling irradiated, high quality and tree-ripened papayas in those cities. The pilot program was successful, but it also highlighted the limitations which I've mentioned. In order to avoid excessively high transportation costs, as well as the needless and quality degrading time delays in shipping to the Mainland, the pilot program concluded that Hawaii agriculture needed its own irradiation capabilities to be followed by shipping to the Mainland.

Q.3: What were your first actions towards acquiring or implementing irradiation into the Hawaii food industry?

A.3: In 1996 it was apparent to me that Hawaii would need an irradiator that would be accessible to shippers and farmers from all of the islands. It needed to be cost-effective and be able to accommodate increasing export volumes to come. I learned of a company called GRAY*STAR that had designed and developed a Cesium-137 irradiator. It would have been able to treat entire pallets of product at a time. It was very easy to operate and had high throughput rates. It was, from an economic point of view, the best design of any commercial irradiator and I decided to make a downpayment on a unit. Unfortunately, the NRC did not approve the source design using Cesium-137 and GRAY*STAR subsequently halted the development of this particular irradiator. My deposit was returned. Later, I learned about the Genesis underwater cobalt-60 irradiator from GRAY*STAR.

I also contacted other irradiator vendors. Nordion was the only company that had a long track record in building industrial-sized irradiators which were capable, for example, of

sterilizing hundreds of millions of pounds of medical equipment. But their large category IV units did not fit Hawaii's more modest needs or budgets.

In approximately 1999 a relatively new and uncertain irradiation technology was introduced to Hawaii. At that time Titan Corporation and two Big Island entrepreneurs invited the Hawaii agriculture community for a presentation in Hilo. A company called Hawaii Pride intended to build the irradiator. I was one of many who flew to Hilo in order to attend the presentation. Titan's irradiator would operate similar to a bypass category IV irradiator. Product would be placed on small carriers through a maze of concrete walls that would allow for a continuous treatment process. The uniqueness was its power source. Instead of cobalt-60, electricity would produce a powerful e-beam. Three Titan representatives attended. Garry Loda was the chief scientist and explained the technology. He also explained that simple e-beam would not generate enough energy to penetrate papaya boxes and thus an x-ray converter would be needed. Nothing was mentioned about the great loss of electricity when E-beam was converted to X-ray. The only financial data made available at that meeting was when I had asked one of the Titan's executives how much the facility would cost. I was given a price tag of \$10 million by that executive. Further, Hawaii Pride estimated a price of 15 cents per pound to irradiate papayas.

Over the previous years I had made financial calculations and a price tag of \$10 million for the e-beam irradiator with x-ray features added seemed far too high a price, even for an optimistic estimate of the pounds of papayas to be treated.

Q.4: What followed after the meeting?

A.4: After I left the meeting in Hilo, I learned from other sources that converting E-beam to X-ray would result in some 93% energy loss, a substantial loss given that Hawaii's electricity

costs were already among the nation's very highest, since Hawaii imported carbon-based oil for electricity. I also learned that Hawaii Pride would also employ various skilled workers to maintain and operate the equipment, a substantial added cost which I hadn't even considered before. Based upon these major additional costs, building an E-beam with X-ray unit made very little economic or environmental sense to me.

Nevertheless, I admired both John Clark and Eric Weinert, who decided to move ahead and build the E-beam with X-ray facility. To achieve the needed throughput (in order to break even or make a profit) they had added a papaya processing line to allow for contract packing. John and Eric repeatedly invited the industry to make use of their facility. They also asked me how to best pack and ship papayas. I tried to help them as much as possible.

Furthermore Eric Weinert and John Clark had promised that the facility would be open to everyone in Hawaii and that was certainly also in my interest. By the summer of 2000 the facility started to operate.

Q.5: What happened after the opening of Hawaii Pride?

A.5: From the 1996 pilot program I had made many contacts throughout the US, and we started to ship papaya to the Mainland through Hawaii Pride. However, within a few months Eric Weinert visited me in Honolulu telling me that Hawaii Pride required an exclusive papaya treatment contract with me to ensure a substantially higher use of their facility. The use of the facility was not meeting its projections. It came at no surprise to me as I knew that Hawaii Pride needed far more throughput just to cover its costs and break even.

The economic situation was so grim for Hawaii Pride that in 2002 I was approached by the company asking me to invest in it. I was shown data showing how Hawaii Pride could get back to

the road of recovery. The required throughput was about as high as I had estimated in 2000. Hawaii Pride's break even point required annual throughput treatment of 16 million pounds of papayas, 5.2 million lbs of sweet potatoes / banana and some 500,000 lb of other exotic fruit. This was an incredibly and unrealistically high amount of throughput.

Q.6: What was the outcome of the investment negotiations?

A.6: I declined to invest in Hawaii Pride's E-Beam with X-ray added. My highest estimates of throughput showed production reaching 10 million pounds of papaya by the 10th year. Since I am in the produce and food business for 8-16 hours every day, and since I talked to many farmers and shippers every day, it seemed highly unlikely for Hawaii Pride to treat 16 million pounds of papaya annually, within 2 years, as Hawaii Pride's spreadsheet called for just to break even. My estimates showed reaching 10 million pounds in 10 years.

Q.7: Were there any other problems with the Hawaii E-beam with X-ray added unit?

A.7: Yes, there were. Frequent equipment failures led to the shut-down of the irradiator. Often it was just for a few days. But I recall in particular two Christmas seasons, normally the busiest and most profitable time of the year for Hawaii shippers. In both cases the X-ray unit shut down for two weeks. Needless to say, this devastated many of the farmers and shippers. Product had to be destroyed, fed to farm animals or sold well below cost on the local market. Customers were equally disappointed.

Q.8: Were there any more contacts with Titan Corporation to sell you one of their units?

A.8: Yes, there were. I believe it was in late 2002 or early 2003. The USDA and CDFA were looking for a commercial-sized irradiator on Oahu to accommodate a planned increase in fruit fly pupae

production, i.e., the irradiation of fruit fly pupae to sterilize the pupae and make reproduction in California and elsewhere impossible. I was still looking for an appropriate irradiator. By that time, Titan had spun off their irradiation unit under the name of Surebeam.

At that time, Surebeam's Michael Gormley (the financial officer of Surebeam) estimated that a bare minimum, completed facility would cost some \$6.75 million, not including land purchase of an additional \$250,000. Later, he lowered the asking price to \$4.75 million, which was still much too high.

Q.9: Even assuming no breakdowns in operation of an e-beam irradiator with x-ray attachment, have you ever compared the e-beam irradiator with x-ray attachment over against a Genesis underwater irradiator?

A.9: Yes I have. I have used Michael Gormley's figures and compared it to the Genesis underwater irradiator. As I explained above, the initial investment is far greater for an E-beam with X-ray unit, meaning serious financial losses are sure to be suffered. I am not aware of any U.S. company now producing the E-beam irradiator of a smaller size appropriate for Hawaii. I believe a Belgian company, IBA, is selling much larger units for approximately \$10 million on up. My calculations show that profitability is reached at a throughput level of some 1.8 million pounds for the Genesis underwater unit vs well over 20 million pounds of throughput for the now-bankrupt Surebeam unit. The operational cost for the Surebeam unit is far greater. The cost of energy required to treat is greater and the per-pound cost is therefore much greater for an E-beam with X-ray added. Plus, there is now no technical support for the Surebeam E-beam with X-ray added, and no reliable replacement parts for the equipment. It is my opinion that E-beam with X-ray added is a technology whose time has never come for Hawaii's agricultural products.

Q.10: Why did you decide to select and acquire an underwater irradiator, over against e-beam or e-beam with x-ray added?

A.10: By 2005, I had decided that e-beam technology was totally and unquestionably inadequate for the uses which I intended. It could not handle the many agriculture and other products which were not uniformly thin. For products that were of moderate thickness, e-beam technology required treatment on two sides of the product, which would generally double the time and cost of treatment. Even more troubling was the unreliability of the X-ray technology, which caused and threatened to cause substantial losses to my client base. Finally, Surebeam had filed bankruptcy, suggesting that there is very little if any market or demand for relatively smaller e-beam units in the U.S. anymore. As I stated, the major producer is in Belgium, and its larger units generally cost \$10 million and up.

E-beam with x-ray added was even more undesirable because of the huge requirement for electricity required. Further, most of the energy is lost during the conversion from electron beams to photons to penetrate the product, so it was bad from an environmental point of view.

Q.11: Are you aware of any brochures or other publications which support your analysis leading up to your choice of an underwater irradiator.

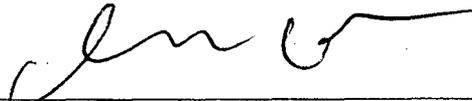
A.12: Yes, I would note that a publication of the Food Irradiation Processing Alliance refers to most of what I have mentioned above. FIPA is a trade association of the principle companies active in the food irradiation industry. They include manufacturers and users of cobalt-60, X-ray and E-beam irradiators. Their Q & A section is a relatively even-handed summary of the different irradiator technologies. (See Exhibit A attached hereto, pages 1-2 and 8-10 from a FIPA brochure)

Q.13: I have no further questions.

A.13: Thank you.

I declare under penalty of perjury that I have reviewed the foregoing Rebuttal Testimony and Declaration of Michael Kohn and know the contents to be true and correct to the best of my knowledge and belief.

DATED: Honolulu, Hawaii Sep 15, 2008.



MICHAEL KOHN

Food Irradiation

Questions and Answers



Food Irradiation Processing Alliance

Benebion. S.A.

FOOD TECHnology Service Inc.

GRAY*STAR, Inc.

MDS Nordion

REVISS Services/Puridec

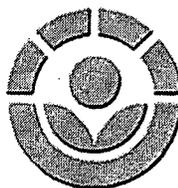
Sadex Corporation

Securefoods Inc.

Sterigenics - Food Safety

STERIS Isomedix Services, Inc.

FIPA is an affiliate of the International Irradiation Association



"Radura"

EXHIBIT A

This document has been prepared to assist food industry representatives and other interested parties in answering questions on food irradiation. It is current as of September 2006 and is updated periodically.

It was prepared by representatives of FIPA and agreed to by the total consensus of the members of FIPA. For more in depth information on these issues and/or any other questions that you might have, please contact either the individual members of FIPA or the Chairman:

*Richard Hunter
Food Technology Service, Inc.
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Phone: 863-425-0039*

The Q&A has two answers for each question:

*The "a" answer is intended to be a short, easy to understand, "sound bite".
The "b" answer provides more complete and detailed information.*

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1) Consumer Benefits

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- 1.2 Is irradiation used for non-food products?
- 1.3 Are irradiated foods being sold now?
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- 1.5 Does irradiated food cost more?
- 1.6 Are consumers buying irradiated food?
- 1.7 Who endorses the use of food irradiation?
- 1.8 Why not just cook food thoroughly to kill bacteria?
- 1.9 Does irradiated meat need to be cooked?
- 1.10 Why the emphasis on irradiating hamburger and not steak?
- 1.11 How does irradiation affect shelf-life?

2) Commercial Questions

- 2.1 What is the food irradiation process?
- 2.2 What equipment is employed to irradiate food?
- 2.3 At what step in the processing of food is irradiation used?
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- 2.5 How does irradiation fit within HACCP?
- 2.6 How much radiation is used?
- 2.7 How does the irradiation process destroy bacteria?
- 2.8 What is the cost of a typical irradiation facility?

3) Nutrition & Taste

- 3.1 Are irradiated foods still nutritious?
- 3.2 How does irradiation affect the taste of food?

a) There are several processes that are collectively referred to as “**FOOD IRRADIATION**”. Food is irradiated by placing it in, or moving it through, a field of ionizing energy consisting of electron beams or gamma rays or x-rays. Irradiation produces a wide range of beneficial effects on various foods including pathogen reduction, disinfestation of insects, growth inhibition, control of parasites and shelf-life extension.

b) There are several processes that are collectively referred to as “**FOOD IRRADIATION**”. The object of each process is to kill or impair the breeding capacity of unwanted living organisms or to effect the product morphology in a beneficial way that will extend shelf-life. Each process has an optimal dose of ionizing energy (radiation) dependent on the desired effect. The dose of radiation is measured in grays (Gy). A “gray” is a unit of energy equivalent to 1 joule per kilogram. This unit of measure is based on the metric system. Thus, 1 kilogray (kGy) is equal to 1,000 grays (Gy). All three forms of ionizing energy have the same effect, gray for gray. Some of the major processes are:

Pasteurization (Pathogen Reduction) – Irradiation is used to effectively eliminate disease causing organisms including bacteria and parasites. (e.g. Irradiating ground beef to make it safe from *E. coli* O157:H7. Irradiating live oysters to make them safe from *vibrio*.)

Sterilization – Irradiation is used at a very high dose to eliminate all organisms so that refrigeration is not required (shelf stable). (e.g. Certain foods are sterilized for NASA astronauts.)

Sanitation – Irradiation is widely used to reduce organisms for spices, herbs and other dried vegetable substances. (e.g. Irradiating spice blends that are added to meat for hot dogs and other “Ready to Eat” products that may not be cooked again.)

Shelf-life Extension – Shelf-life can be extended for certain foods using radiation by lowering the population of spoilage causing organisms, including bacteria and mold. On certain fruits and tubers, irradiation delays ripening and/or sprouting. (e.g. Irradiating berries to reduce mold. Irradiating fresh fruits to extend their market reach. Irradiating potatoes, onions and garlic to impair cell division and hence allow them to go through the “off” season without sprouting.)

Disinfestation – Irradiation is used to stop reproduction of both storage and quarantine insect pests. (e.g. Irradiating foreign produced mangoes to eliminate the seed weevil, which is a quarantined pest, for import to the US. Irradiating papaya to eliminate fruit flies, which are quarantined pests, for import from Hawaii or foreign countries into the US mainland.)

All three forms of irradiation are referred to as a “cold process”. Although all of the radiation energy is converted to heat during treatment, the process typically increases the product temperature by about 1 degree Celsius.

2.2 What equipment is employed to irradiate food?

a) Food is irradiated in “irradiators” that use electron beams or gamma rays or x-rays as their source of ionizing energy (radiation). Irradiators are designed to enable the irradiation of the food products to the desired dose and dose uniformity, without exposing workers or members of the public to radiation and without any effect on the environment.

b) Food is irradiated in “irradiators” that use electron beams or gamma rays or x-rays as their source of ionizing energy (radiation). All commercial irradiators have four primary components, a

source of radiation, a method of product conveyance, "shields" to prevent exposure of personnel and the environment to radiation and safety systems. Ionizing radiation is penetrating energy and thus, products are usually irradiated after they are fully packaged. Below is a description of the four types of irradiators that are commercially available or in use today for food processing. The choice of which irradiator is most cost effective for a particular product depends on the type of product, how it is packaged, the product dose, dose uniformity requirements and, most important, logistics.

Electron Beam Irradiator (employing a radiation chamber) – The source of electron beams is an "accelerator". Accelerators generate and accelerate electrons very fast towards the food product being irradiated. Because electrons have mass, they can only penetrate about 1.5 inches (3.8 cm) into a typical food product or about 3.5 inches (8.9 cm) if the food product is irradiated on both sides. Electrons also have an electric charge. This charge allows the stream of accelerated electrons to be scanned by magnets to track across the product. A commercial food electron beam irradiator, accelerates the electrons to an energy of up to 10,000,000 electron volts (10 MeV). Electron beam irradiators typically use massive concrete, steel or lead shielding. Electron Beam accelerators can be turned on and off. Safety interlocks ensure that a person cannot enter the radiation chamber where the food is being irradiated when the accelerator is "on". Product is usually passed through the scanned "beam" on roller type conveyors.

Gamma Irradiator (employing a radiation chamber) – The source of photons in a gamma irradiator is cobalt-60. Unlike electron beams that are generated on site using electric power, cobalt-60 is produced off site in nuclear reactors and transported in special shipping containers ("casks") to the site. Cobalt-60 is a solid radioactive metal that is contained in two welded encapsulations of stainless steel creating a "sealed source". The sealed source contains the "radioactive" cobalt-60, but allows the photons ("radiation") to pass through the encapsulations and ultimately into the food product. Because Cobalt-60 photons have no mass, they can penetrate more than 24 inches (60 cm) of food product if irradiated on both sides. Gamma irradiators that employ a radiation chamber typically have shields made out of massive concrete or steel. Cobalt-60 continuously emits radiation and cannot be turned "off". To allow personnel access to the chamber, the source is lowered into a storage pool of shielding water when it is not being used to irradiate product. The shielding water does not become radioactive. Safety interlocks are used to assure that a person cannot enter the chamber when the source is not in the stored position (at the bottom of the pool of water). Hanging carriers, totes and roller conveyors are typically employed to move the product through the chamber.

Gamma Irradiator (underwater) – Like the radiation chamber irradiator above, an underwater gamma irradiator uses cobalt-60. Unlike a radiation chamber irradiator, an underwater irradiator stores the cobalt-60 permanently at the bottom of a pool of water. Instead of raising the cobalt-60 into a shielded chamber, the product, placed in water free containers, is lowered to the bottom of the pool adjacent to the cobalt-60 to receive a dose of radiation. The water acts as the shield. The shielding water does not become radioactive. No above ground shielding or radiation chamber is present. There is no need for interlocks to prevent personnel from entering a radiation chamber when the cobalt-60 is present, because there is no radiation chamber. Typically, the product is loaded into water free containers and the containers are lowered/raised using a hoist mechanism.

X-ray Irradiator (employing a radiation chamber) – X-rays are photons and have similar properties to gamma rays emitted by cobalt-60. X-rays are generated by using an electron beam accelerator (above) and converting the electron beam (up to 7.5 MeV) to photons by accelerating the electrons into a high density material such as tungsten, steel or tantalum. The sudden deceleration of the electrons generates x-rays and waste heat. The creating of the radiation is very similar to an electron beam irradiator

(above), including the ability to be turned on and off. The shielding and product conveyance are similar to that of a chamber type gamma irradiator (above). The safety interlocks are similar to both electron beam and chamber type gamma irradiators. The advantages of x-rays over electron beams are that they have good product penetration (over 24 inches or 60 cm of food product if irradiated on both sides). The advantages of x-rays over both types of gamma irradiators is that they do not require a shielding storage pool. However, there is a substantial loss of energy during the conversion process. Thus, it suffers a severe cost disadvantage when compared to other types of irradiators for the same product volume throughput.

2.3 At what step in the processing of food is irradiation used?

a) Products are usually irradiated after packaging to minimize the risk of recontamination. This further assures the consumer of a safer product.

b) One tremendous advantage of the irradiation process is that it can be performed on the product in its final retail package. The actual process can take place at the food processing facility, usually after packaging, or at an Irradiation Service Center. Irradiation Service Centers have been irradiating medical devices, household products, and some food products, for decades to control bacteria. In all cases, the process is conducted by qualified, licensed personnel who follow strict regulated procedures.

2.4 What other processes can control bacteria as alternatives to irradiation?

a) There is no process as flexible, as thorough, and as simple, as irradiation for reducing the microbial contamination on fresh food.

b) High Pressure processing, and other emerging technologies, are being used, but none are as universally applicable and flexible as irradiation. The use of chemicals and even extraordinary sanitary measures at the food processing site cannot guarantee food free of disease causing microorganisms. Fumigants such as propylene and ethylene oxide are often used on spices and other dry materials. Heat processing is often used, but changes the product (e.g. canned foods). Irradiation can sometimes be combined with other techniques with synergistic results.

2.5 How does irradiation fit within HACCP?

a) Irradiation, as an intervention technique, is an excellent critical control point within a HACCP system and is recognized as such by the USDA.

b) HACCP is a system that identifies the hazards associated with each food item and determines how each hazard can be reduced or eliminated at Critical Control Points (CCPs). Analysis alone cannot prevent bacterial hazards from reaching the consumer; real intervention is required that actually kills the contaminating microorganisms. Irradiation is used as a recognized kill step, or "hurdle", within HACCP plans. Irradiation is combined with other "hurdles" such as good sanitation and temperature control to maximize product safety.

2.6 How much radiation is used?

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing "LICENSEE PA'INA HAWAII, LLC'S REBUTTAL MEMORANDUM IN OPPOSITION TO INTEVENOR CONCERNED CITIZENS OF HONOLULU'S AUGUST 26, 2008 INITIAL WRITTEN STATEMENT OF POSITION AND IN RESPONSE TO NRC STAFF'S INITIAL STATEMENT OF POSITION AND INITIAL WRITTEN TESTIMONY" dated September 15, 2008 in the captioned proceeding have been served as shown below by deposit in the regular United States mail, first class, postage prepaid, this September 15, 2008. Additional service has also been made this same day by electronic mail as shown below:

Administrative Judge
Thomas S. Moore, Chair
Atomic Safety and Licensing Board
Mail Stop: T-3-F23
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
(e-mail: tsm2@nrc.gov)

Dr. Anthony J. Baratta
Administrative Judge
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Office of the Secretary
U.S. Nuclear Regulatory
Commission
ATTN:
Rulemakings and
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